Fifth
Global Vaccine Safety Initiative Meeting

Secretariat Report

Addis Ababa, Ethiopia
26-27 October 2016
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<td>Complex Regional Pain Syndrome</td>
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<td>Health Management Information System</td>
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<td>Institutional Development Plan</td>
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<td>Infant Mortality Rate</td>
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<td>Institute of Medicine</td>
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INTRODUCTION

The fifth meeting of the Global Vaccine Safety Initiative (GVSI), the WHO strategy to optimize the safety of vaccines in all countries through effective use of pharmacovigilance principles and methods, took place in Addis Ababa, Ethiopia from 26 to 27 October 2016, hosted by the African Union Commission (AUC). This general meeting guides the Global Vaccine Safety Initiative, which is the implementation mechanism for the Global Vaccine Safety Blueprint.

During the two days, immunization programme managers and national regulatory authorities pharmacovigilance staff from more than thirty countries gathered with representatives from UN agencies, academic institutions, pharmaceutical companies umbrella organizations, partner and funding agencies. Participants reported on initiatives relevant to the Blueprint objectives, shared experiences to strengthen vaccine pharmacovigilance, and identified needs and opportunities for further development.

Meeting Objectives:

The overall objective of the meeting was for Member States and partners to interact and exchange information on progress with implementation of national and global vaccine pharmacovigilance activities, share new ideas, innovations, explore new frontiers in vaccine safety, build partnerships and collaborations and define plans for further development.

Specific objectives were to:

- Review progress in implementation of GVSI.
- Address new challenges and opportunities in vaccine safety.
- Facilitate further partnerships and inter-sectorial collaborations.
- Explore safety issues of current interest.
- Identify means to promote regulatory harmonization initiatives for pharmacovigilance of vaccines.

This report summarizes the key points of discussion and outcomes of the meeting.
DAY 1-MEETING CHAIRS:  
Amb Olawale I. Maiyegun & Dr P. Tanui

Opening remarks

The Honorable Ambassador Olawale I. Maiyegun, Director for Social affairs, African Union Commission, opened the meeting and welcomed the participants to the African Union headquarters. Vaccine pharmacovigilance is of increasing importance in the African Region as a result of clinical development of new vaccines as well as the introduction of several new vaccines into many national immunization programmes. Monitoring of adverse events following immunization and active surveillance will help generate evidence to communicate effectively about the safety of vaccines and to strengthen confidence in immunization. Building on the momentum generated by the Ministerial Conference on Immunization which took place from 24 to 26 February 2016 and recognizing progress made in the regional medicines regulatory harmonization initiative (AMRH) under the New Partnership for Africa’s Development (NEPAD) and the African Union Commission (AUC), as well as the implementation of activities towards operationalization of the African Medicines Agency (AMA), WHO and AUC have agreed to jointly organize the fifth annual GVSI meeting in Addis Ababa, Ethiopia, from 26 to 27 October 2016. It is hoped that the collaboration with the African Union would bring the political and advocacy dimensions to create more awareness of the importance of vaccine pharmacovigilance in African countries.

On behalf of the WHO Representative in Ethiopia and WHO senior management, Dr P. Mainuka acknowledged the great privilege for WHO to host the fifth Global Vaccine Safety Initiative meeting in Africa particularly at the headquarters of the African Union Commission. Disease control through immunization is one of the most powerful public health interventions that has led to important reduction in mortality of young children and is now expanding its reach to all segments of the life cycle. As more vaccines become available and the disease they prevent are becoming less visible, attention to the risk benefit balance is becoming increasingly important. In recent years, implementation of the global vaccine Safety Blueprint has led to improved capacity to handle safety concerns, use adverse events monitoring as a quality control mechanism and better communicate about the value of vaccines, including explaining how immunization hazards are being managed. GVSI stakeholders were welcomed and invited to proceed with the meeting to further inform how best to implement vaccine vigilance strategies.

Following the opening statement, Dr Clive Ondari, Safety and Vigilance (SAV) Coordinator in WHO Geneva, officially launched the Adverse Event following Immunization (AEFI) causality assessment software, a newly developed IT tool to support countries in assessing and classifying in a scientific and systematic manner the cause of an AEFI. This tool is expected to give greater credibility to assessors and spokespersons when they have to inform the findings to the media and the public, and ultimately help parents and care providers to better appreciate the real cause of adverse events following immunization (AEFI) and hence maintain confidence into the immunization programme.
The Global Vaccine Safety Initiative: Review of achievements - Pr A. Dodoo

Summary

In 2011, WHO and a group of partners developed a strategic document on vaccine safety called the Global Vaccine Safety Blueprint. The Blueprint proposes a strategic plan for building and supporting a systemic approach to vaccine pharmacovigilance in all low- and middle-income countries. To implement the Blueprint strategy, the Global Vaccine Safety Initiative (GVSI) was established and focuses on building minimal national capacity for vaccine safety in the world’s poorest countries, on building enhanced capacity in countries producing vaccines and introducing new vaccines, through the coordinated efforts of major stakeholders. Since its launch in 2012, significant progress has been made. The latest developments were discussed.

Main discussion points

- For optimal vaccine safety monitoring and meaningful analysis of Adverse Event Following Immunization (AEFI) data, systematic and standard collection of critical parameters is essential. A limited number (22) of variables, called AEFI core variables are required for this purpose. These core variables were reviewed by the Global Advisory Committee on Vaccine Safety (GACVS) in December 2015 and 3 more were included - currently there are 25 core variables.

- To facilitate AEFI data reporting and management, International Vaccine Institute (IVI) developed the Vaccine Adverse Events Information Management System (VAEIMS), on the basis of WHO core variables for AEFI surveillance. VAEIMS is being used successfully in Sri Lanka and Iran. GVSI is now planning to utilize the experiences from the District Health Information System (DHIS) 2 platform, to develop a reporting system modelled on the VAEIMS – Beta version. This is planned to be piloted in one country and integrated with the country’s own existing health management information system (HMIS).

- An information technology (IT) bridging solution to enable non coded AEFI data transfer from national AEFI database to the WHO global database Vigibase coded in E2B has been developed by IVI and successfully tested in Chile. It opens the path to support countries in sharing their data with the global pharmacovigilance community with customised IT solution.

- WHO has developed an AEFI field investigation simulation training, during which course participants are exposed to an artificially created vaccine safety crisis environment, and learn how to investigate an AEFI and manage the communication response. The course has been successfully conducted in some countries in the African and Eastern Mediterranean regions.

- Extensive guidance documents and resources are currently available for building capacity both on vaccine safety communication and vaccine pharmacovigilance. GVSI has initiated a collaborative effort, led by WHO and UNICEF, to harmonize into a structured stepwise approach those communication resources integrating AEFI surveillance and vaccine safety communication. A technical working group of 12 experts has been established and four regional workshops are scheduled to pilot the concept. Ultimately, vaccine safety communication resources will be organised into a structured library so that it will become easily available, accessible and adaptable to local contexts.

- The Vaccine Safety Net was established by the World Health Organization in 2003 to facilitate access of public health authorities, health professionals and the public to reliable information on vaccine safety. Its initiation was the result of the increasing number and effectiveness of websites providing unbalanced, misleading and alarming vaccine safety information and the subsequent requests of governments, key non-governmental organizations and the United Nations Children’s Fund (UNICEF) for a mechanism facilitating the identification of and access to reliable sources of information on the web.

- The Global Advisory Committee on Vaccine Safety (GACVS) played a key role in the early stages of the Project, by defining criteria for good information practices regarding credibility, content, accessibility and design for websites containing information on vaccine safety. Candidate sites are evaluated for their adherence to these criteria. There are a total of 46 websites in 12 languages complying with the mandatory criteria that are currently listed on the WHO website; 13 will be accredited in 2016. New candidate websites are currently under evaluation and will further improve accessibility to reliable information on vaccine safety in Arabic, Japanese and Portuguese.
The GVSI has been instrumental in establishing a new working group with the Council for International Organizations of Medical Sciences (CIOMS), that developed a guidance document for Active Vaccine Safety Surveillance (AVSS) that offers a practical step-by-step approach and a graphic algorithm to support decision-makers in determining the best course of action to monitor the safety of vaccines. The concept was piloted during a workshop conducted in China, during which plans were developed to assess the background rate of intussusception (IS) and the risk of IS following rotavirus vaccines. Current data suggests a background rate that varies between 15-30 cases per 100,000 infants in South-East Asian countries like India, to 100-150 cases in some western Pacific countries like Australia. The vaccine-attributable risk is estimated to 2-4/100,000 first dose of rotavirus vaccine. Given population differences in risk of intussusception, it is important that rotavirus vaccine introduction in different parts of the world is accompanied by active intussusception surveillance studies together with rotaviral disease surveillance so that the benefits and risks can be ascertained with relevant evidence.

Following a number of deaths after pentavalent vaccination, which had been reported in the press and exploited by the anti-vaccine lobby in India, a study supported by the GVSI has been conducted by the Indian authorities through the INCLEN Trust International. The study aimed to generate evidence on the association between routine pentavalent and OPV immunization and all-cause deaths and hospitalizations in two districts in South India. This study helps to better characterize factors associated with untoward events temporally related with vaccination early in life and provides a robust empirical basis to illustrate the coincidental occurrence of serious AEFI and quantify the frequency with which those events can be expected.

In an effort to enhance the capacity for vaccine safety assessment beyond basic pharmacovigilance in LMICs, the GVSI tested the development of a global network of hospital-based sentinel sites for vaccine safety signal verification and hypothesis testing in LMICs, the Global Vaccine Safety Multi Country Collaboration (GVS-MCC) network. A demonstration project assessed the feasibility, quality and potential for sustainability of a multi-country collaboration for the evaluation of rare vaccine adverse events. This project inspired India to set up a national multicentre active AEFI sentinel surveillance project, involving 20 tertiary care hospitals across India, to collect systematic data on known AEFI and assess potential signals.

The availability of a new vaccine against malaria (RTS,S), and its planned pilot implementation projects, require a collaborative effort to closely monitor the vaccine safety while building capacity, and the GVSI will play a key role in this regard.

The GVSI is maintaining a roster of experts distributed across the WHO region to assist and support vaccine safety capacity building in countries.

Conclusions
The GVSI has made tremendous progress over the last four years, rapidly expanding its reach and bringing on board more and more partners, raising awareness around the importance of efficient vaccine safety monitoring and supporting countries in developing their system. To support the increased activities related to its expansion, it is envisaged to develop a Global vaccine safety observatory to display and measure progress over time. Vaccine safety communication will remain on the top of the agenda, and activities will be initiated to assess the current status and needs in terms of policy for vaccine injury compensation.
Summary

In 1998, the Pharmacovigilance Commission of Cameroon was created within the National Drug Commission. In 2007 the first steps were taken in establishing a system. From 2009, increased AEFI monitoring was initiated during Immunization activities. Cameroon became full member of the WHO Programme for International Drug Monitoring in 2010. In 2013 a Vigilance Service centre was created in the NRA that functions as National Pharmacovigilance Center. The activities conducted include, elaboration of documents concerning the vaccine, summarizing key information on the vaccine, updating of AEFI guidelines, training of staff, communication for advocacy and sensitization, evaluation post introduction, research.

AEFI surveillance activities included passive surveillance during routine intervention and notification/reporting through monthly reports; stimulated passive through a network of focal persons, additional trainings and data collection activities, phone calls for complementary information. Active surveillance was initiated through targets specific AEFIs (serious, signals) and by review of hospital ledgers every 45 days and investigation of serious cases.

For the integration of pharmacovigilance by public health programmes, in 2015 AEFI National Experts Committee was established, and in 2016 the Pharmacovigilance normative documents were validated. A Parliamentary Act organizing Pharmacovigilance system was introduced; guidelines were developed on Pharmacovigilance good practices, harmonised notification form for all health products inclusive of vaccines, investigation form for serious cases, clusters and signals of AEFI. Standard operating procedures (SOPs) for reporting, data management, and investigation and causality assessment were introduced in the country.

Currently the National AEFI surveillance manual is being validated, AEFI/ADR surveillance based on disease surveillance network has broadened their TORs and SOPs and toolkit are planned to be disseminated at all levels.

Discussion

• GSPI participants enquired about the challenges for the implementation, coordination with stakeholders and the specific activities that contributed to the success. In Cameroon, the key stakeholders were involved in intensive planning for 2 years, prioritising the activities including development of procedures and documentation, and health care workers (HCW) training to use the documents. There is still under reporting. There were focal persons to identify and report AEFI.

• The development of integrated training curricula of personnel was helpful. Their performance has improved recently. The optimal use of information in Vigiflow is a challenge because the Internet connection is poor. They are not able to work with the software and many are untrained on notification and investigation processes that are available. AEFI field investigation is done for severe cases.

Conclusion:

The success of the Cameroon system is attributed to improvements to the system by implementing the strengthening activities, greater collaboration between stakeholders, maintaining national Pharmacovigilance data base including AEFI and emphasis on advocacy for resource mobilization within national budget and with partners.
Summary

Dengue remains the leading vector-borne infectious disease in the Philippines, causing morbidity and mortality to people of all ages, all year round. Since 2010, there has been an increasing trend of reported suspect Dengue cases and deaths. In 2015 alone, a total of 200,415 suspect cases were reported nationwide. That is 64% higher than the reported cases in 2014. The age group mostly affected are children 5-14 years old.

In the country’s continued pursuit to introduce ways in the prevention and control of dengue in the country, the Philippines granted marketing approval to Sanofi Pasteur’s Dengue Vaccine – Dengvaxia, the 1st Dengue vaccine registered in Asia. In 2016, amidst several opportunities and challenges, the Philippines embarked on a Dengue Vaccine School-Based Immunization strategy, targeting all Grade 4 pupils (SY 2015-2016), aged 9 years and older enrolled in public elementary schools. These children are to receive 3-doses of the tetravalent Dengue Vaccine at 6 months interval.

For vaccine safety monitoring, the Philippines has an AEFI Surveillance System well established at the national and sub-national level that has been functioning since 2008. Also an AEFI Referral network was recently put in place to help the health offices at all levels in the referral of AEFI cases for immediate attention. The country also has an active National AEFI Committee, composed of experts from different fields of paediatrics, vaccinology and infectious diseases, which reviews serious AEFI cases, provides causality assessment and gives recommendations for programme improvement.

To prepare for the monitoring of this new vaccine introduction, several steps such as a baseline school survey which aims to establish a baseline on the common illnesses experienced by Grade 4 students prior to vaccine introduction, development of a guidelines for health facilities in the referral and management of serious AEFIs, trainings for AEFI surveillance were taken. Focus of the training was on the process/flow of AEFIs reporting. Uniquely the participants included school teachers so that they may be able to detect and report AEFIs. The Health Emergency management Bureau of the department of health (DOH) was also trained for reporting AEFIs. This ensured that a 24/7 hotline was available to the community to report AEFIs.

For the monitoring of AEFI, the case definitions were adopted from the WHO Immunization Safety Surveillance Manual. All AEFIs, minor and serious, were to be reported. An AEFI case may be immediately detected by the school nurse, the teacher, or a member of the vaccination team from the health center. These reports are then forwarded to the next higher level Epidemiology and Surveillance Unit (ESU) – Municipal ESU (MESU) or City ESU (CESU), then to the Provincial ESU (PESU), then to the Regional ESU (RESU) and to the Epidemiology Bureau at the DOH Central Office. Data are processed here, analysed and are then forwarded/shared to the DOH Executive Committee, Philippines FDA as the National Regulatory Authority, EPI programme, National AEFI Committee, Regional Director and other partners.

In the country’s already established surveillance system, AEFI belongs to the cluster of events, diseases and illnesses that are to be reported within 24 hours. The country’s integrated surveillance system has established surveillance units in hospitals and clinics. Hospitals and clinics who may have admitted AEFI cases can also simultaneously report the case to the next higher level.

Epidemiology Bureau has established a Central Command Post, where notification and database of AEFI reports were received and monitored daily. The office is equipped with computers, internet, telephone, a tally board and maps of the regions implementing the programme. This command post daily produced Dengue Vaccine Status Report to be circulated to stakeholders.

When triggers for an AEFI investigation is met, a composite investigating team goes on field to gather information about the case, monitor cold chain and immunization practice and gather other pertinent data needed for the causality assessment of the serious AEFI cases. The team is composed of representatives from the epidemiology and surveillance unit, EPI programme manager, FDA and health promotion officers, from the national and/or local levels. The National AEFI Committee was convened as needed to present issues and concerns, and to provide causality assessment to each reported serious AEFIs. Such meetings were conducted in April, June and July to review serious AEFI cases.

The success of the safety surveillance of dengue vaccine in the Philippines relied on the following enabling factors: a) commitment from the staff of the Department of Health and local government b) support from partners (Department of Education, FDA, medical societies) c) dedicated active disease surveillance officers at all levels.

Few challenges were faced included late reporting of AEFIs and consolidated list of vaccinated children needed for further data analysis. Those challenges were addressed through attendance to the weekly Dengue Vaccine Technical Working Group (TWG) meeting, where the regional directors and program managers are also members, regular follow-ups and feedbacks being made with the reporting regions.
Discussion

- The GVSI participants enquired about the preparatory activities before the introduction, communications for the increased AEFI detected, the experience of using school teachers, use of modern technology, difference between community based reporting and hospital based reporting, the difference in the campaign and routine surveillance and the challenges in the AEFI committee covering the whole country.

- Baseline survey was done before introducing the vaccine. The Philippines conducted a 5 year school health record review in selected schools and looked at the most common illnesses found e.g. fever, cough, cold and stomach ailments in the targeted age group. This helped to define the background rates of minor AEFI reporting. School teachers were involved in education and they notified absences and sickness. Active surveillance was done and the number of cases reported increased 3 folds. The use of cell phones and internet helped quick communication. Active follow up by the health workers and school teachers was important.

- For routine immunization, passive AEFI surveillance is done by trained surveillance officers who fill up case report forms and they electronically transmit this information. The national AEFI committee does the same work for AEFIs after routine immunization as well. Seven regional AEFI committees out of 17 regions have been established; the others send it to national committees. EPI meetings with the Immunization Technical Advisory Group (ITAG) were helpful in making decisions.

Conclusion

Around 70% of dengue fever cases occur in Asia, with the Philippines reporting 200,000 cases. On the 4th April 2016, the Philippines launched the Dengue vaccine. The historic drug took 20 years and $1.8 billion to be developed. The Philippines’ Department of Health launched a school-based immunization programme in highly affected areas, making it the first country where the vaccine is commercially available. The success of the new vaccine introduction and the confirmation of its safety profile with a good AEFI surveillance system will build confidence in the vaccine so it can be used for their vulnerable populations.

Falsified vaccines: The emerging threat

Introduction

Falsified vaccines like falsified drugs are emerging as an important public health concern. Counterfeiting vaccines is an extraordinary crime considering that their usage is directly related to the safety of human beings. Counterfeit vaccines have been reported earlier from several countries in Asia and Africa. This year Bangladesh and Indonesia reported cases of falsified vaccines. Experience on how these cases were handled was discussed.

The Bangladesh experience - Mr A. Hossein

- Early this year, the Pasteur Institute of Dakar informed WHO Country Office Bangladesh of a confirmed case of falsified yellow fever vaccine that has been procured for the Bangladesh army. In the past, the Pasteur Institute of Dakar, Senegal supplied AMARIL® (yellow fever vaccine) via a third party (Shinko Traders) to the Bangladesh army. But this year another procurer (HN Surgical Mart) supplied the same product with the same batch number but different expiry date. Shinko Traders contacted the Pasteur Institute for clarifications on this issue. Upon verification it was clear that the product was counterfeit. The relevant stakeholders were informed and WHO Bangladesh recommended to MOHFW for urgent action on this matter and destruction of the remaining ampoules as per established guidelines. Enquiries revealed that HN Surgical Mart was nonexistent in the address given. A team of inspectors of DGDA visited the store of army medical service (DGDP) and ensured that no vaccine of this lot was used or distributed. Samples were collected and sent to Pasteur institute for testing. After which the counterfeit vaccines will be destroyed.

- In response to the event, Bangladesh has decided to train focal persons from all the regulatory and supply chain for identifying the Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC), to create a network of focal points for the exchange of information and consultation, and to ensure the punishment of the Institutions/persons involved with falsification.

- The GVSI participants enquired about the drug and vaccine registration and distribution process in Bangladesh. For registration of vaccine in Bangladesh, 97% is obtained through the local manufacturer. Only 3% imported and they have strong registration system. However, the regulatory mechanism for monitoring AEFI is still under development. Supply chain monitoring is difficult because of the population.
Summary:

• In June 2016, after months of investigation Police had found and revealed a counterfeit vaccine manufacturer in South of Tangerang and the police had seized the suspects who were nurses. This caused a major media outcry and the country president intervened, initiated an enquiry and a Task Force was formed.

• The National Authority of Drug and Food Control (NADFC) coordinated with the Police and taskforce to identify the counterfeited vaccines with the assistance of the MoH that identified the affected Health Care Facilities (HCF).

• The Task Force had successfully identified the affected HCFs (Hospitals, Clinics), and then identified the affected babies/children that had been immunized with the counterfeited vaccines. Children were examined to verify whether there were AEFIs due to fake vaccines.

• The follow up actions included re-vaccination of all affected babies/children, using vaccines that were supplied by Government, involvement of Pediatric Associations, provide parents with education and information, instruct all HCFs to do procurement/purchasing through one gate only, and procedures for qualifying the supplier must put in place, tighten the control of waste/trash management in HCFs, revision of Regulations regarding HCFs and medicine management (including: One gate purchasing, qualifying of supplier), strengthen the authority power and also the organization capacity of NADFC, conduct and intensify the control on Production Facilities, distribution Facilities for Vaccines both public and private, especially in distribution part, conduct and intensify the control on HCFs process in purchase or procure the vaccines, and its storage, apply anti-counterfeit seal for vaccines bottles/vials, put barcode on the label of vaccines, synergy with all key institution and stakeholder both central and lower level to follow up NADFC sanction recommendation for any HCFs if they are found any inconsistent with the regulation, diversion, encourage the Manufacturer/Distributor to proactively in combat illegal and counterfeit products, police is persecuting the offenders.

Discussion

• GSVI participants enquired about the development of systems that prevent rather than identify and respond to falsified vaccines. They mentioned that the legal framework is not good enough as in many cases the fines are not adequate and the legal enforcement part is poor. Vaccine supply from Government is less likely to be counterfeit compared to the vaccine used in the private sector. They also enquired about the post marketing surveillance available for WHO to prevent counterfeit vaccines and commented on the need for the integration between different stakeholders.

• In Indonesia, there is a system that is used to detect falsified drugs; this is functional in community pharmacies and other places. In this instance, falsified vaccines were found in the health care facilities and the regulators are not authorized to inspect inside the health facilities. Police have the authority to respond not the health department. Therefore this caused the late detection. The country plans to reframe the rules through a MoU with Police. All vaccines are currently registered and suppliers in private sector registered and procured through one gate policy.

• For effective surveillance of SSFFC products, WHO recommends that countries develop systems to register and monitor products to prevent such events and facilitate early detection.

Conclusion

Tackling counterfeit medicines requires a multi-disciplinary approach such as Regulatory system and legislative framework strengthening, data collection and policy research, and raising awareness. Cooperation amongst all stakeholders across the pharmaceutical supply chain (public and private organizations, national regulatory and enforcement agencies, health professionals, patients, research-based and generic pharmaceutical manufacturers, drug distributors, wholesalers and retailers) is therefore critical.
Enhanced AEFI surveillance: Special studies on vaccine safety

Serious AEFI during pentavalent series in South India - Dr M. K. Das

Introduction
Since the inclusion of the Pentavalent vaccine in the National Immunization programme of Asian countries several infant deaths have been reported that caused concern about a possible role of the vaccine. Detailed investigations and causality assessments revealed that the vaccine was not responsible for the reported deaths. WHO also conducted a rigorous investigation in these countries and the Global advisory Committee on Vaccine Safety (GACVS) found no direct link between the vaccine and the AEFIs in any of the reported cases (WHO 2013). In other countries in the world (non-Asian regions), the vaccine has been used for the last 20 years with no significant safety concerns identified.

In India also, subsequent to introduction of the Pentavalent vaccine, some health professionals and professional groups raised questions about the vaccine’s relevance and raised suspicion about a possible relationship between vaccination, serious adverse events following immunization (AEFI) and sudden unexpected deaths. A study was conducted to determine the potential association of all cause death and hospitalization with routine UIP vaccinations administered to a cohort of infants in Kerala and Tamil Nadu states of India.

Summary
The study goal was to generate evidence on the association between routine pentavalent (DwPT-HBV-Hib) and OPV immunization and all cause deaths and hospitalizations in infants in Kollam district in Kerala state and Coimbatore District in Tamil Nadu State of India.

It was a prospective dynamic cohort study where the exposure factor was vaccination with pentavalent and OPV and the outcomes were the identification of serious adverse events due to any cause including deaths and hospitalization. Cohorts were assembled at the time of first dose and followed till 4 weeks after last dose of Pentavalent and Polio vaccines. Four Risk periods after a dose of vaccine was identified, R1: First week (High risk); R2: Second week (Intermediate risk); R3: Third week (Intermediate risk) and R4: Fourth week (Lowest risk).

The primary objective was to compare the all cause death and hospitalization rate 0-7 days (R1) and 22-28 (R4) days after vaccination; and the secondary objectives were to compare the all cause death and hospitalization rate between 8-14 days (R2) and 22-28 (R4) days after vaccination and to compare the all cause death and hospitalization rate between 15-21 (R3) days and > 22 days (R4) after vaccination until the next dose, 24 weeks of age or death, whichever occurs first.

To ensure quality, software based procedures such as skip logic, logic checks, reminder system and a GPS location and interview time to track interviewers were adopted, and photos of important documents were captured. This ensured real time and remote monitoring of activities.

34,914 Infants were registered in total. They received pentavalent 1 dose at the public facilities, 30,688 were finally recruited into the study after the exclusion criteria. 19 children died after the first dose, 10 after the second and 3 after the 3rd dose of pentavalent vaccine. 29,728 children were followed up for 4 weeks.

AEFI causality assessment of the deaths was done by the National AEFI Causality Assessment Committee. 27 deaths had established causes, and classified coincidental to vaccine administration. 5 deaths were unclassifiable due to inadequate information.

The causes of hospitalizations were determined in the 588 infants that were admitted, acute respiratory illness was the main cause (71.6%) followed by diarrhea 7.3%. Congenital malformation, febrile illness, Urinary tract disease, CNS disease, sepsis, febrile seizures, and intussusception accounted for the other known reasons. 4.8% of children were hospitalized for other reasons.

In conclusion, there were no safety concerns: the incidence of death and hospitalization were similar in week one, two, three and four after any of the three doses of pentavalent and OPV.
Discussion

- GVSI participants enquired about the analysis between first and third dose of vaccines, background death rate, laboratory investigations, inclusion and exclusion criteria, and healthy vaccine recipient effect and district selection.
- There were no significant differences in death incidence rates and incidence rate ratios adjusted for sex, standard of living, seasonality, age at the start of the risk period and study site, between risk periods R1-R4 for each of the three doses. The background death rate was not different from that observed in the study. Lab investigations were performed as per the advice from the treating doctors. The study participants included all subjects that received vaccine from public health system and excluded that living out of the study area. The 2 states had mature immunization programmes and had introduced pentavalent vaccines for 2 years. Low infant mortality rate (IMR) districts were selected to reduce noise. The healthy vaccine effect was considered during the analysis.

Conclusions

This study demonstrated the country capacity to conduct well designed and quality studies to better characterize factors associated with untoward events temporally related with vaccination. It also provided supporting evidence to the statements made by the GACVS regarding the safety of the pentavalent vaccine. The study results will reassure the public and lay to rest the apprehensions of Sudden Infant Death Syndrome (SIDS) and other causes of post pentavalent vaccination deaths that were attributed as vaccine related by anti-vaccine lobbies.

The Global Vaccine safety – Multi-country collaboration (MCC) for enhanced vaccine safety: experience from Chile - Mrs A. Saldaña

Introduction

The need for large sample sizes to investigate hypotheses related to possible rare vaccine-related reactions call for a multi-country collaborative approach. In this context, the GVSI, through its WHO secretariat, proposed to key countries and institutions to take part in the Multi Country Collaboration (MCC), a global network of hospital-based sentinel sites for vaccine safety signal verification and hypothesis testing.

Within the MCC, WHO and the participating institutions jointly strengthened the development of existing active surveillance of hospital-based AEFI epidemiological monitoring in different regions of the world. Ultimately, sentinel sites are expected to provide independent and timely risk-benefit information on vaccine safety issues that have the potential to affect national immunization programmes, market availability and indications of new and existing vaccines.

Summary

The GVS multi-country collaboration (MCC) network involved 25 hospitals in 16 countries from all regions. They include, Argentina (6 sites), Chile (4 sites), Peru, Uruguay, Costa Rica, Honduras, Colombia, Albania, Australia (2 sites), China, India, Iran (2 sites), Singapore, South Africa, Spain and Uganda. To assess the feasibility, quality and potential for sustainability of such network, a proof of concept study was conducted. Two known vaccine associations were assessed, namely the risk of hospitalization for aseptic meningitis (negative association) and the risk of hospitalization for ITP following measles containing vaccine (MCV). The study was done using a common protocol and case report forms, common training tools and using a central data repository with state of the art protection of patient information. Key steps involved site capacity assessments, agreements and ethical clearance, site training on protocol and data collection, data quality check and data analysis.

The pooling of data helped to identify 86 cases of aseptic meningitis of which 68 received MCV1 and 199 cases of ITP of which 127 received MCV1. Valid data were generated and the associations by strain were confirmed, proving the concept of a successful global collaboration.

In Chile, the strengths of the system included assigning a unique National Identifier (RUN) within the first week of life to > 98% of citizens, mandatory notification of hospital discharges (RUN; CIE-10) and an online National Immunization Registry, facilitating data collection. The difficulties encountered in running the study was the segmentation and quality of available medical care records, manpower and infrastructure challenges for the investigation of cases outside of the sentinel hospitals.

However, participation of Chile to the project provided opportunities for a first collaborative project between NRA/EPI/Healthcare professionals, the strengthening of safety capacities in active surveillance and methods and the recognition of the NRA as the official agency in charge of pharmacovigilance.
The challenges include the frequent turnover of staff and technical authorities and even though the NRA has the legal mandate and expertise for the investigation and analysis of AEFI, the coordination with the health care network is still incipient.

Conclusion

The study proved the concept and impact of a successful global collaboration. In Chile, it contributed to building national capacities in the area of vaccine safety in active surveillance and methods. The study also identified areas of improvement in the AEFI surveillance system, to further implement similar studies. It was also acknowledged that given the rarity of serious events, global collaboration is essential for such projects to gather meaningful information to draw conclusions.
Summary:

80 million doses of Gardasil® 4, 10 million doses of Gardasil® 9 and 720,000 doses of Cervarix® have been distributed so far in the United States. Safety data are available from several sources: the vaccine adverse events reporting system (VAERS), the vaccine safety datalink (VSD), the clinical immunization safety assessment project (CISA) and the post-licensure rapid immunization safety monitoring (PRISM). General safety studies from VAERS have provided findings consistent pre-licensure data.

Main discussion points:

• In two large health plans, Gardasil® was associated with syncope and skin infections.
• In VSD with more than 600,000 vaccinated individuals, only a non-significantly elevated risk of venous thromboembolism was identified. Those findings were replicated in Denmark and Sweden. It is important to note in particular that no associations with auto-immune and neurological disorders and HPV vaccine use could be identified through those well powered cohort analyses. No excess mortality and no concerns among vaccinated pregnant women have been identified either. The Institute of Medicine (IOM) review found rare association with anaphylaxis and consistent risk of syncope only. In VSD, studies of Gardasil 9 are under way as this is a newer product.
• Multiple controversies continue to affect the acceptability of HPV vaccines. Individual case reports of primary ovarian insufficiency, CRPS, POTS have led to media concerns. None of those are substantiated by robust epidemiological studies. CISA is currently assessing the impact of oral water hydration to prevent syncope.
• In response to questions from the audience, the presenter indicated that there is demonstrated impact of HPV vaccine on disease incidence, as a substantial decrease in precancerous lesions disease has been documented in countries that use HPV for several years. The nature of POTS, a neurological condition that affects the cardiovascular system is different from syncope which is a more generic condition. The product shelf life is established by manufacturers based on a stability studies. A vaccine with a longer shelf life should not be less effective.

Conclusion:

A large body of published data confirms the safety of HPV vaccines. Safety monitoring continues even though HPV vaccines are among the most studied for safety.

Contra-indications to vaccination - Pr J. Buttery

Summary

Contra-indications are conditions that increase chances of serious adverse reactions (vaccine should not be administered) whilst precautions would allow using the vaccine under certain circumstances. There are different views in permanent contraindications but only few are broadly recognized. They include severe allergic reactions to a vaccine component, severe combined immune deficiency (SCID), history of intussusception for rotavirus vaccines, and the use of live vaccines in persons with significant immune deficiency. During the presentation different types of immune deficiencies (congenital and acquired) were discussed.
Main discussion points:

- In day to day usage of vaccines, many conditions such as mild acute illness, allergies, low birth weight or encephalopathy are misperceived as contra-indications. However, these are not contra-indications and vaccines should be administered.

- Some vaccines, because of historical controversies have been associated with more precautions, such as hepatitis B or HPV. For rotavirus vaccines, immune deficiency is rarely a true contra-indication (except SCID). Acute gastro-enteritis can lead to lower immune reaction. Other vaccines (DTP, Hib, OPV, MMR and PCV) were also reviewed individually. The risk of encephalopathy was also addressed specifically. Sodium channel mutation (Dravet syndrome) lead to seizures and developmental regression that can be precipitated by vaccines but would occur to individuals regardless of vaccination.

- In response to questions from the audience, the age at vaccination is important in predicting vaccine effectiveness; stronger responses are seen before 15 years than after. Congenital heart diseases (CHD) are an indication rather than contraindication to vaccination but not always diagnosed by the time of the first doses. One precaution could be to conduct vaccination in health care setting when CHD has been recognized. Down syndrome is not a contra-indication to vaccination. Most immune deficiencies are not diagnosed by the time of the first vaccinations although failure to thrive should lead to clinical suspicion.

Conclusion:

There are many more situations when it is safe to immunize. True contra-indications are extremely rare.

Zika virus vaccine update - Mrs P. Bravo

During the September 2016 PAHO Council, an update on Zika virus vaccine has been provided. The current epidemic is decreasing in the Americas. The US NIH is developing a Zika virus vaccine, currently in phase 2, with phase 3 plans under way (PAHO region).
SESSION 3: Breakout sessions

Vaccine Pharmacovigilance Activities in the WHO Western Pacific Region

Drs Ananda Amarasinghe and Jinho Shin from WHO WPRO moderated the session. The key participants were representatives from Cambodia, China, Lao PDR, Papua New Guinea, and the Philippines. In addition, the International Vaccine Institute, Myanmar and industry representatives attended the session.

The specific objectives of the session were to: a) provide regional overview on vaccine safety and regulatory systems strengthening; b) update on PV needs assessments from vaccine-producing, self-procuring, and un-procuring countries; c) identify new challenges and opportunities in vaccine safety surveillance and response; and d) prioritize regional and country activities.

The WHO Western Pacific Region comprises a total of 30 Member States. According to WHO-UNICEF Joint Reporting Form data, there are 5 producing countries (Australia, China, Japan, Republic of Korea, and Viet Nam), 5 self-procuring countries (Brunei Darussalam, Malaysia, New Zealand, the Philippines and Singapore), and 17 UN-procuring countries in ways of obtaining vaccines for use in National Immunization Programme (NIP) in the Western Pacific Region. Up to now, 7 countries meet WHO criteria for functional NRA for vaccine in which vaccine pharmacovigilance function is included as essential.

Countries in WPR largely rely on spontaneous (passive) surveillance. The surveillance of AEFI is a part of pharmacovigilance (PV) regulatory requirement and vaccine non-producing countries largely rely on it. In general, active surveillance is limited in the region, mostly to vaccine producing countries. Introduction of new vaccines has created a demand for active surveillance, such as dengue vaccine introduction in Philippines. According to JRF, 13 countries had reported AEFI cases, and 10 countries indicated that the country had 10 or more cases reported per 100,000 surviving infants, meeting the Global Vaccine Action Plan (GVAP) indicator for minimal capacity for vaccine safety. AEFI committees are not established or none-functional in many lower middle income countries which procure NIP vaccines through UNICEF.

The WHO Regional Office’s support for vaccine and immunization safety strengthening is mainly focused on 3 areas: a) capacity building on PV/AEFI surveillance and response by providing AEFI training workshops for national and subnational EPI, NRA and other immunization stakeholders; b) ensuring vaccine safety through strengthening regulatory capacity: (i) NRA assessment and (ii) development and implementation support on institutional development plan (IDP); and c) ensuring vaccine security through strengthening effective vaccine management (EVM) by the support for conducting EVM assessment, and implementing. In 2016, the Regional Office published the third edition of guidelines for immunization programme managers on surveillance of AEFI and a vaccine safety communication guide for immunization programme managers and national regulatory authorities. The Office also supported many LMICs with electronic reporting data sheet template including the 25 core variables for AEFI reporting. The purpose of this simple tool is to encourage AEFI reporting and data analysis at different administrative level in resource limited countries in the region.

The session went through country presentations on PV needs assessment. China, as vaccine-producing, the Philippines as self-procuring and Lao PDR as UN-procuring provided presentations. Cambodia and Papua New Guinea also reported to the session with priority areas in need of support.

CHINA

Challenges

• Increased demand for ensuring safety with new vaccines; particularly need for active surveillance.
• Ensuring sufficient resources to the country increasing need, when comparing to the world highest population (birth cohort is 20 million).
• Increased workload at CFDA & CDC; growing vaccine production capacity, the large number of vaccine doses used and assuring the quality and safety of different types of vaccines use in the country.

Opportunities

• High level political commitments.
• Well established, fully functioning vaccine PV system supported by CFDA and CDC.
• Expanding training opportunities at national and subnational levels, supported by partners (e.g.; WHO, Academia).
PHILIPPINES

Challenges
- AEFI under-reporting; delayed reporting.
- Limited capacity for data analysis and timely Investigation of AEFI.
- Limited human resources on vaccine PV at both national and sub national levels.
- Communication gaps.

Opportunities
- PV activities are supported by DoH administrative orders, giving opportunity to reduce administrative barriers implementing PV activities.
- Availability of revised guidelines on AEFI surveillance can be used both in training and implementing the PV activities.
- Existing practice on data sharing between FDA and AEFI surveillance by the Philippines Integrated Disease Surveillance and Response.
- Availability of AEFI expert committees at both national and regional levels.

LAO PDR

Challenges
- AEFI under-reporting, delayed, only focusing on serious AEFIs – lack of skilled & trained personnel.
- Lack of timely investigation.
- Lack of vaccine safety data-sharing between NRA and EPI.
- Data analysis is limited at national level.
- AEFI committees not in operation.
- Communication gaps.

Opportunities
- AEFI system in place and national guidelines are available; this will provide opportunity to strengthen vaccine PV in the country.
- With wider training opportunities AEFI can be improved.

CAMBODIA – PRIORITY AREAS FOR PV SUPPORT
- Requested WHO to support IDP updated in 2015-2016.
- Developing AEFI guidelines for private suppliers & service providers.
- Reporting template (electronic database).

PAPUA NEW GUINEA - PRIORITY AREAS FOR PV SUPPORT
- Sensitizing HCWs with AEFI at national and sub-national level.
- Support to expand existing web-based DHIS & M-supply system into AEFI system.
- Support to ADR-PV & AEFI system strengthening.
The Regional Office’s country support plan for 2017-2018 was developed based on needs identified during the session.

- Regional workshop on vaccine safety communication for national officials (NIP, NRA, communication officer), 21-23 March 2017, Manila, the Philippines.
- Vigilance system data update through NRA assessments using Harmonized Global Benchmarking Tool (release 2016) targeting Cambodia, Lao PDR, PNG, the Philippines, Malaysia, Hong Kong, Republic of Korea, Viet Nam.
- Data reporting (VAEIMS) and analysis support targeting the Philippines, Mongolia, Papua New Guinea, Lao PDR, and Cambodia.
- Various activities to support implementing institutional development plan of priority countries.

Vaccine Pharmacovigilance Activities in the WHO African Region

The session was moderated by Dr Dicky Akanmori, IVD/FRH AFRO and Dr Mumba Mutale IST-ESA/AFRO. Participants included representatives from the National Regulatory Authorities (NRAs) and Immunization Programmes (EPI), were from Cameroun, Chad, Democratic Republic of the Congo, Ethiopia, Kenya, Liberia, Mozambique, Nigeria, Sierra Leone. Among them were Directors of National Immunization Programmes and heads of NRAs. Also present was a manufacturer, key partner in regulatory systems strengthening, the ADB and CDC.

All the countries of the region, except Senegal, are non-vaccine producing and most are GAVI-eligible and relying on prequalified vaccines supplied by UNICEF. Immunization coverage varies significantly across the region, some countries (13) attaining at least 90% coverage nationally. Apart from DTP-HiB-HepB, countries have introduced PCV, Measles-Rubella, rotavirus vaccines, HPV and are on the verge of piloting a malaria vaccine, RTS,S/AS01.

Introduction and objectives

The specific objectives of the session were to review the status of implementation of national plans for vaccine safety and pharmacovigilance in the countries of the region, identify major gaps in implementation and issues, discuss and identify the way forward to further strengthen systems and improve reporting of AEFIs in the WHO/UNICEF JRF, while handling communications around vaccines safety expertly to enhance immunization and to improve coverage.

An overview was presented highlighting the relatively low reporting of AEFIs in the region and summarizing the support of WHO and partners to develop and implement key activities in vaccine safety and pharmacovigilance initiated in 2014.

Panel Discussions

Panel members from Cameroun, the Democratic Republic of the Congo, Ethiopia and Kenya, presented their achievements and challenges, each followed by discussions. Contributions were also made by the rest of the countries present. The general discussions followed the presentations and addressed the meeting objectives.

Achievements in the implementation of national plans for vaccine safety and pharmacovigilance.

The participants understood the need for multi-stakeholders planning consistent with regional priorities.

AEFI guidelines have been developed or are in various stages of development in several countries.

Trainings: National level AEFI trainings have taken place in many countries, while sub-national training is planned or in progress e.g. Ethiopia.

AEFI Committees: these have been formed in most countries or initiatives have been taken to do so.
Challenges

- Weak detection and underreporting of AEFI in routine immunization.
- Collaboration between EPI and NRA is still sub-optimal.
- Clarity in roles and responsibilities between NRAs and EPI in some countries.
- Harmonization of tools for data collection.
- Sharing of data among stakeholders (including academic institutions).
- Lack of adequate trained human resources and funding.
- Inability to use electronic systems for AEFI reporting, especially linkage with UMC.

Discussions and way forward

- Need to address health worker attitude to encourage reporting of AEFIs.
- General communication and advocacy to improve safety culture in populations.
- Involve policy makers including parliamentarians to secure additional resources in the face of other competing priorities.
- Example of strategies used to brief policy makers and politicians in Liberia on the importance of vaccines and safety.
- WHO to support in creating better understanding between NRAs and the EPI.

This was summed up as follows:

- “Surveillance Officers have capacity but not oriented on AEFI. NRA have expertise but not field level presence. EPI are custodians of vaccine & immunization but untrained HCWs”.
- Use of the National Technical Advisory Group (NITAG), where they are functional to advocate for resources for safety and pharmacovigilance as part of new vaccine introductions.
- Explore the GAVI HSS funds & Joint Appraisal mechanism to put AEFI monitoring firmly on national agenda.
- Build sustainability into funding.

Action Points

- Clarity of roles and responsibilities of NRA and EPI with enhanced collaboration needs to be identified in countries.
- WHO and partners to support:
  - countries to finalize and disseminate normative documents and guidelines
  - capacity building from national to field level
  - establishment of National AEFI Committees in countries which lack them.
  - countries to build the capacity for risk communication
- Countries to actively involve health professional associations (pediatrics, nurses etc.).
- Countries should include vaccine safety in GAVI- HSS.
- WHO and the WHO Collaborating Centre should support countries to use electronic reporting platforms.

Conclusion

The WHO AFRO has 47 Member States, therefore the nine countries which participated in this satellite, may not have adequately represented the diverse capacity levels of vaccine safety and pharmacovigilance systems prevailing in the region. All the same the session highlighted bottlenecks in implementing vaccine pharmacovigilance across the region. Inputs received will serve as a basis for planning any support to the region by WHO and partners.
Opportunities and challenges for a Global Vaccine Safety observatory

Progress in implanting the Blueprint strategies observed in all WHO regions. As interest in vaccine pharmacovigilance is increasing, the demand for better exchange of experiences is increasing. At the same time, additional funding into vaccine pharmacovigilance requires greater accountability. Initial approaches from the GVS Initiative to monitor progress have faced limitation in encompassing the broadest stakeholder group possible. As GVSI matures, there is a need for an external independent observatory that provides stakeholders with easy access and can be dedicated to furthering communication among stakeholders. The proposed observatory would also provide regular analysis of data available through various multilateral networks in order to improve metrics used for systems development.

The meeting emphasized the importance of furthering and establishing the proposed vaccine safety observatory. A concept note will be shared with the main stakeholders of the GVSI in order to accelerate establishment of this needed resource.
DAY 2-MEETING CHAIR: Pr A. Dodoo

SESSION 4: Regional medicines regulatory harmonization initiatives

Summary

In many low- and middle-income countries, essential medicines are not always readily available and accessible. WHO estimates that one third of the world’s population does not have access to essential medicines (and more than half in some areas). One of the reasons of limited access is the insufficient regulatory capacity and lack of harmonized technical requirements for medicines regulation. Poor uptake of new and existing health solutions costs millions of lives across low-income countries. Lack of essential medicines contributes to disparities in health and life-expectancy between low-income and high-income countries. The need for regulatory cooperation and convergence has long been recognized. The following three topics were presented and discussed:

• Global developments in the regulatory harmonization for medical products regulation- Dr C. Ondari
• African Medicines Regulatory Harmonization Initiative (AMRH)- Dr P. Tanui
• The World Bank: Strengthening Vaccine Regulation and Safety- Dr A. Muhairwe

Main discussion points

• “Regulatory convergence” represents a process whereby the regulatory requirements and approaches across countries and regions become aligned over time as the same harmonized technical guidance documents, standards and scientific principles are adopted and similar regulatory practices and procedures are introduced. Regulatory convergence in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities. Several projects are ongoing in different region of the world in this regard.

• Since the establishment of the Association of South East Asian Nations (ASEAN) Pharmaceutical Product Working Group (PPWG) in 1999, several common technical requirements were developed and adopted by member countries. WHO is Supporting the Implementation of ASEAN Harmonized Requirements for drug registration (SIAHR) project aiming to analyze country specific requirements and identified gaps in the implementation of ACTD & ACTR by individual agency based on the ASEAN technical guidelines related to technical aspects of product registration; to identify strengthening needs and propose corrective measures to ensure homogeneous interpretation and implementation of the relevant guidelines.

• The African Medicines Regulatory Harmonization (AMRH) initiative under the New Partnership for Africa's Development (NEPAD), is a partnership initiative formalized in 2009 and launched in the East African Community countries in 2012 (Tanzania, Uganda, Kenya, Burundi, Rwanda). This partnership includes African countries (regulatory authorities) and regional blocs, NEPAD, AUC, PAP, WHO, Gates Foundation, DFID, PEPFAR/USG, GAVI, World Bank, and aims to improve the fragmented regulatory system for product registration in Africa by changing from a country-focused approach to a collaborative regional and simplified one. It adopts a stepwise approach, starting by harmonizing and streamlining technical requirements for product registration, leading to increased and timely product access.

• African Heads of State and Government as well as the World Health Organization (WHO) Regional Committee for Africa made a decision for the establishment of the African medicines regulatory agency. Subsequently, the AU Executive Council endorsed the roadmap for the establishment of the African Medicines Agency (AMA) based on the recommendation of the first African Ministers of Health meeting jointly convened by the African Union Commission (AUC) and the WHO. In line with the Ministerial commitment, the AUC and WHO established a Task Team to facilitate the establishment of the AMA. The AUC, the WHO and NEPAD Planning and Coordinating Agency serve as a joint secretariat for the Task Team. Legal and institutional framework and AMA business plan are now drafted. The AMA is planned to be launched in 2018.
The World Bank established a Multi Donor Trust Fund in 2011 to support global medicines regulatory harmonization (MRH). Significant results have been achieved in medicines registration among the East African Community (EAC) Partner States, comprising an agreed common technical document for registration of medicines implemented by EAC Partner States, an Integrated Information Management System established and linked in all EAC Partner States and EAC Secretariat, regulatory capacity building programmes institutionalized in existing institutions, Guidelines on regulation of vaccines have been completed and are waiting for EAC approval process, Regional Pharmaceutical policy and legal framework for mutual recognition and information sharing have been completed and submitted to EAC for validation, joint assessments of dossiers and inspections for current Good Manufacturing Practices (GMP) have started.

In the second phase of the EAC MRH, the Bank allocated $0.5 Million to EAC, from the Multi Donor Trust Fund, for the assessment of the PV situation in the EAC as well as development of a strategy and a plan to implement the strategy.

Under the MRH, a meeting of EAC NMRA PV has just concluded in Zanzibar to prepare: i) Guidelines for harmonization of PV in the EAC Partner States, ii) Plan for setting minimum requirements for harmonized minimum PV systems and electronic system reporting; iii) draft key PV operational SOPs, and iv) plan of activities for the Technical Working Group and the joint activities. The World Bank also supports medicines regulatory harmonization in other regional economic communities.

On question pertaining to the funding mechanism to support the development of regulatory agency, Dr A. Muhairwe from the World Bank explained that Country assistance strategy, a 3 year country plan is discussed between the World Bank and the Ministry of Finance, and encourage dialogue within countries to prioritize the development of medicines regulatory agencies capacities.

**Conclusion**

Making medicines is no longer a “local” business and the era of locally operating regulators is coming to an end. The future of medicines regulation lies in convergence/harmonization, collaboration and networking. Regulators are starting to function cohesively and gradually becoming a functional network rather than individual players, and individual players focusing on where they can give the best added value. Important to note that there is no good regulation without Good Governance (accountability, transparency, fair and equal treatment of all regulated parties etc.), and that capacity building is not a panacea without clear strategy and vision, and needs much better prioritization, coordination and collaboration using adding value principles.

Regulatory capacity building, promotion of collaboration, convergence and harmonization will continue to be one of the WHO priorities.
SESSION 5: Vaccine safety communication

Summary

Communication about vaccine safety is more than crisis management. There is a need for education of the population of the benefits of vaccination while also sharing the risks, if any. This needs to be done in a way that it does not impact vaccine acceptance. Appropriate skills, trainings and well researched messages, most appropriate to the target audience, are needed to communicate the element of uncertainty. All countries need to develop locally-relevant communication strategies for rapid response to public concerns, including those relating to AEFI. Whether a public concern reveals an underlying problem, or is shown to be unfounded, if the concern persists it should be addressed through dialogue with the communities concerned. In this context, the following three topics were presented and discussed:

- Addressing vaccine hesitancy – The “State of Vaccine Confidence 2016: Global insights through a 67-country survey”- Dr E. Karafillakis
- Addressing reluctance in AEFI reporting through vaccine safety communication - Dr A. Amarasinghe
- Managing safety crisis: the Namibian experience- Mr N. Shapumba
- Risk communication for Adverse Event Following Immunization, the UNICEF strategy - Dr N. Yusuf

Main discussion points:

- Vaccine hesitancy is becoming a global threat to immunization programmes. The results of a global study that surveyed 65,819 individuals across 67 countries, investigating confidence in vaccine safety and effectiveness, as well as perceptions of vaccine importance and compatibility with religious beliefs were presented. The analysis, published in EBioMedicine, was conducted in collaboration with Imperial College London and the National University of Singapore, and the data was collected by WIN/Gallup International Association.

- Overall sentiment towards vaccination is positive across all 67 countries, however there is wide variation between countries and across world regions. Confidence in vaccine safety is less positive, particularly in the European region, which has seven of the ten least confident countries, with 41% of respondents in France and 36% of respondents in Bosnia & Herzegovina reporting that they disagree that vaccines are safe, followed by Russia (28%) and Mongolia (27%), with Greece, Japan and Ukraine not far behind (25%). This is compared to a global average of 12%.

- Although in certain countries particular religious groups were more vaccine-skeptical than other groups, no one religion was globally predictive of negative attitudes. This indicates that the effect of faith on vaccine attitudes is dependent on local context, and that these attitudes are not necessarily driven by religious doctrine in itself, but mediated by political, socio-cultural and other factors.

- There a shift away from access to safety as main barrier to vaccination. This is particularly true in countries where access is no more a problem. Access in LMIC remains a major issue.

- The difference between vaccine hesitancy and vaccine resistance was discussed. Acknowledged as complex, the official definition that was agreed by SAGE is vaccine hesitancy that refers to a continuum. Vaccine hesitancy is between the vaccine confidence and the vaccine refusal. There are different scenarios that qualify for vaccine hesitancy: it includes issues of confidence, issues of compliance and convenience.

- Clarification was requested on the differences between mass fainting and mass hysteria. According to the Vaccine Confidence Project team, there is no such term as ‘mass hysteria’. The project has been looking at those events: school based immunization, the behavior and response of teenage girls and the various terms that need to be defined.

- A different perspective to vaccine safety communication was the presentation on the vaccine safety communication toolkit and how proper communication messaging and strategies can improve AEFI reporting, critical to monitoring vaccine safety and timely addressing vaccine safety concerns.

- Namibia presented a concrete example of what a country faces when it comes to addressing vaccine safety concerns, why timely managing the communication around a vaccine safety crisis is crucial to avoid loss of confidence among the public.
• Namibia learnt from its recent vaccine safety crisis the importance of involving all stakeholders (e.g. medical associations, education department, media etc.) prior any campaign, supplementary immunisation activities or new vaccine introduction; public education on what to expect, especially minor side effects and how to manage them; importance of prior sensitization on AEFI monitoring, treatment and communication, and identification of low performing regions in terms of AEFI reporting for appropriate capacity building.

• UNICEF presented the AEFI risk communication strategy by introducing two tools in development; a working paper around “building trust and responding to adverse events following immunization in South Asia: using strategic communication”, and an e-learning course on AEFI communication.

• The need to have media communication strategies for mass campaign and during new vaccines introduction was agreed. It was also acknowledged the importance of having different strategies throughout the lifecycle of a product: before the vaccine becomes available, once the vaccine is being deployed, through mass campaign but also when it is routinely available. Vaccine access and vaccine acceptance are both an issue in some countries and pharmacovigilance is all about anticipating those concerns.

• Audience was interested to learn about the socio cultural factors that may affect risk communication. The lessons learnt in Sierra Leone during the Ebola crisis, where people were told about the absence of cure for Ebola disease resulted in refusals to seek treatment at health center when they were sick were discussed. This demonstrated the difficulties of developing efficient communication messages.

Conclusion

Communicating vaccine-related information to the public cannot simply be a government instructing individuals on what they should do. Rather, it must involve an open line of communication among communities, health care workers and decision-makers about the benefits and potential risks of specific vaccines and vaccine related policies. Countries must have communication strategies that involve providing appropriate and reliable information in a prompt, ongoing manner and ensuring that information is tailored to each audience; this must include an effective crisis-communication plan for handling AEFI and other vaccine-related issues requiring rapid response.
SESSION 6: New vaccine safety tools

Electronic AEFI monitoring system: Addressing challenges in Chile

- The system and challenges- Mrs A. Saldaña
- The “Bridging Solution”-Mrs Deok Ryun Kim

Summary

The Vaccine Adverse Events Information Management System (VAEIMS) is a computer software program with conceptualized by WHO and developed by IVI in order to:

- Process Adverse Events Following Immunization (AEFI) data reported by the local level of the health care system.
- Transfer the data efficiently and effectively into a central database.
- Process AEFI data further to facilitate the conversion of the raw data and analyze the data for useful information.
- VAEIMS has been developed for countries to rapidly adapt it to their local context with minimum alternations or modifications.

After the successful development and deployment of VAEIMS Beta version in Sri Lanka and Iran, WHO has been discussing with IVI about the development of a “Bridging solution” for existing national AEFI databases in member countries to the Global database i.e. Vigibase.

- Tailor-make a bridge to be suitable to extract specific data (core variables) from the data output each country (usually – but not always - in excel format).
- Need to convert the nationally extracted data to make it E2B compatible.
- Connect the E2B output thus generated into Vigibase.

Chile was the first country to develop and deploy the (VAEIMS) bridging software. This was achieved in 4 steps.

1. Diagnosis: to determine if Chilean data base of AEFI is able to collect the 25 core variables recommended by GAVCS - the database lacked 6 variables; and, if the database allows the transfer of the ICSR under E2b standards - some of the core variables were non transferable.
2. Harmonization: Chile worked in database harmonization - between the field AEFI reports and the electronic AEFI report system.
3. Coordination with UMC-PAHO-IVI: This was achieved through maintain good communication by teleconferences, e-mails and face to face meetings.
4. Tests of compatibility UMC: Since the 10 August 2016, Chile sent tests of AEFI reports in E2b format to UMC; After 3 tests, on 12 August 2016, the “technical aspect” (encoding and structure) of the E2B XML-file was positive.

Some of the key lessons learned included:

- Understanding the importance of having a harmonized data base.
- It’s important to send reports with the largest amount of information possible.
- It’s important to keep an eye to ensure the continuity of projects.
- The communication and involvement of all actors is relevant.
- Writing minutes with the agreements of meetings helps in understanding the different points of view that result from different cultural interpretations.
Discussion

• The GVSI participants were keen on knowing the collaboration between the NRA and EPI for the use of the bridging solution, the level in which data is entered in the system i.e. field or higher level, the role of the bridging software for AEFI investigation, the challenges faced and the costs involved.

• The participants were informed that in Chile, even though the AEFI data is received by the EPI, it is not analyzed. This is sent to the NRA who analyse and provides feedback. This is done harmoniously. This also ensures that common vocabulary such as MEDRA is used all over the country. The HCW enter data directly to the main data base or this is appended through email. The NRA provides the EPI updates on the 25 core variables which are sent to the UMC as per the legal requirements of Chile. VAEIMS - Bridge is not a replacement of VigiFlow, it is a bridging tool to transfer the data in E2B format to UMC. The costs for the bridging solution is not estimated currently, but this is likely to vary based on the country database formats. The bridging solution is very helpful as in PAHO, the NRA of countries send only ADR info and not AEFI info to the WHO global database Vigibase. This will change if the bridging solution is available.

Conclusion:

The success of the Chilean Bridge of the AEFI data to the WHO global database Vigibase in the E2B format is the first success in Latin America and could be extended to other countries. This is an example of speedy decision-making to face unexpected challenges, through good communication and discussion between country PV team, IVI, and UMC. It was suggested to publish this achievement so that it can be used as a reference.

AEFI causality assessment software

Introduction and live demo

In 2012, WHO developed a methodology for causality assessment of Adverse Events Following Immunization (AEFI). The new method proposed by WHO uses a 4-stage process and allows the National Committees to review AEFI cases and guide the assessors on their causality. The methodology has been published in the WHO Global Manual for causality assessment of AEFI. http://www.who.int/vaccine_safety/publications/aefi_manual.pdf . In the current version, the tool in the manual for causality assessment is a paper form that should be used by assessor for classification of each AEFI. Given the complexity of the assessment process, high global internet, tablet and smartphone penetration, the WHO has developed an electronic software application version of the tool which will be an incentive by national (and subnational) AEFI committees of Member States to use the revised methodology. The software solution will also a useful tool for research purposes.

Currently the software application is available on the internet at http://gvsi-aefi-tools.org/. It is free to be downloaded and used offline on a personal computer android tablet or iPad to support Adverse Events Following Immunization (AEFI) causality assessment according to WHO AEFI causality assessment methodology.

Using a simulated case, the software was demonstrated to the GVSI participants. They were taken through a step by step assessment process that demonstrated that:

• The user interface is identical to the WHO AEFI causality assessment worksheet.
• It lists the basic documents that are available at the time of causality assessment and also alerts the assessor on the missing documents.
• Outlines the 4 steps outlined in the worksheet and guide the assessor in each step.
• Incorporates a built in alert system guiding the assessor to the missing or incorrect information entered.
• In the final step (Step 4), the software indicates the trends and advises the assessor to select the outcomes manually to appropriate final classification.
• Indicates the name of the person(s) who have done the assessment.
• There is built in provision to e mail and/ or share the data to a wider audience in the online web portal.
Discussion

The participants were very motivated about using the software as it follows a logical process and they indicated that the software was very useful and would minimize errors in assessments. One important suggestion to incorporate is the ability to permit the assessor to make additional recommendations in addition to the standard built-in recommendations that are available in the software.

MEETING CONCLUSIONS

The Global Vaccine Safety Initiative aims at implementing the Vaccine Safety Blueprint’s vision of effective vaccine pharmacovigilance systems established in all countries. In other words, everyone everywhere should receive vaccinations with a proper safety monitoring system in place. During two days, the presentations, discussions and deliberations by the Member States and partners demonstrated that there has been significant progress and commitment towards achieving the Blueprint goals. Many countries in Asia, Middle East and Latin America now possess minimal capacity for vaccine safety and at least 30 African countries are implementing work plans against that objective. The availability of new vaccine products usher in exciting opportunities for conducting enhanced vaccine safety projects in several countries. The active participation and involvement of diverse stakeholders is evident by the increasing attendance in the annual GVSI meeting. The enthusiasm and involvement of the GVSI network of partners, the vibrant discussions and expertise that was manifest during the meeting indicated that the efforts undertaken are bearing fruit to meet all the initiative’s goals by 2020. The GVSI endorsement of the Global Vaccine Safety Observatory, a dedicated resource that is needed at this moment of expansion to provide global vaccine pharmacovigilance stakeholders proper recognition for their contributions towards Blueprint objectives, will facilitate future support and progress monitoring over time.
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ANNEX II: Agenda

Meeting Objectives:
The overall objective of the meeting is for Member States and partners to interact and exchange information on progress with implementation of national and global vaccine pharmacovigilance activities, share new ideas, innovations, explore new frontiers in vaccine safety, build partnerships and collaborations and define plans for further development.

Specific objectives are to:

• Review progress in implementation of GVSI.
• Address new challenges and opportunities in vaccine safety.
• Facilitate further partnerships and inter-sectorial collaborations.
• Explore safety issues of current interest.
• Identify means to promote regulatory harmonization initiatives for pharmacovigilance of vaccines.

Expected Outcomes:

• Successful approaches to monitor adverse events following immunization identified.
• Specific strategies and recommendations developed for enhanced GVSI operations for vaccine safety monitoring according to local priorities.
• Collaborative mechanisms and partnerships within the GVSI and with regional regulatory harmonization initiatives established and strengthened.
## DAY 1 - WEDNESDAY 26 OCTOBER 2016

**CHAIR: Amb. Olawale I. Maiyegun**

### INTRODUCTORY SESSION

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Opening ceremony</td>
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<tr>
<td>09:15</td>
<td>Welcome remarks</td>
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<tr>
<td>09:45</td>
<td>Meeting objectives and expected outcomes</td>
<td>AUC/WHO</td>
</tr>
<tr>
<td>10:45</td>
<td>The Global Vaccine Safety Initiative: review of achievements</td>
<td>A. Dodoo</td>
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<tr>
<td>10:15</td>
<td>Coffee break</td>
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### SESSION 1: LESSONS LEARNT FROM COUNTRY EXPERIENCES

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>10:45</td>
<td>Unique Experiences</td>
<td>Moderator</td>
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<tr>
<td>10:50</td>
<td>• Cameroon – from vaccine safety activities to vaccine PV system development</td>
<td>N. Yusuf</td>
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<td>10:55</td>
<td>• Philippines – Introduction of the Dengue Vaccine</td>
<td>A. Tchiengang</td>
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<tr>
<td>11:30</td>
<td>Falsified vaccines: the emerging threat</td>
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<tr>
<td>11:45</td>
<td>• The Bangladesh Experience</td>
<td>A. Hossain</td>
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<tr>
<td>12:00</td>
<td>• The Indonesia Experience</td>
<td>S. Asfijah Abdoellah</td>
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<tr>
<td>12:15</td>
<td>Lunch break</td>
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### CHAIR: P. TANUI

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>13:30</td>
<td>Enhanced AEFI Surveillance: special studies on vaccine safety</td>
<td>M.K. Das</td>
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<tr>
<td>13:45</td>
<td>• Serious AEFI during pentavalent series in South India</td>
<td>A. Saldaña</td>
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<tr>
<td>14:00</td>
<td>• The Global Vaccine safety – Multi-country collaboration for enhanced vaccine safety: experience from Chile</td>
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### SESSION 2: SAFETY ISSUES OF CURRENT INTEREST

<table>
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<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
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</thead>
<tbody>
<tr>
<td>14:30</td>
<td>HPV vaccines safety update</td>
<td>T. Shimabukuro</td>
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<tr>
<td>14:45</td>
<td>• Contra-indications to vaccination</td>
<td>J. Buttery</td>
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<tr>
<td>15:00</td>
<td>Coffee break</td>
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</tr>
<tr>
<td>Time</td>
<td>Session Description</td>
<td>Facilitator(s)</td>
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| 16:00 – 17:30| AFRO panel discussions: challenges in moving from stand-alone activities to effective pharmacovigilance systems, acknowledged in all immunization interventions and integrated in the health system:  
• Communication among stakeholders  
• Adequacy and availability of resources | D. Akanmori                     |
|              | Breakout session on Pharmacovigilance activities in Western Pacific Region           |                                 |
|              | Participating countries: Cambodia, China, Lao PDR, Philippine, PNG, Viet Nam        |                                 |
|              | • Introduction-Objectives (5 min)                                                  | A. Amarasinghe/                 |
|              | • Producing country: functional NRA with WHO prequalified vaccines (10 min)         | J. Shin China                  |
|              | • UN procured country (10 min)                                                     | Lao PDR                        |
|              | • Self-procuring country (10 min)                                                  | Philippines                    |
|              | • Producing country: functional NRA without WHO prequalified vaccines (10 min)      | Viet Nam                       |
|              | • Reviewing GVSI indicators and map out work plan and WPRO support for year 2017-2018 (45 min) | All                            |
|              | Breakout session on opportunities and challenges for a Global Vaccine Safety observatory | Moderator A. Dodoo             |
|              | • Introduction (5 min)                                                             | P. Zuber                       |
|              | • Observatory concept (10 min)                                                     | SPG member                     |
|              | • Discuss how to display GVSI-related activities (25 min)                          |                                 |
|              | • Discuss how to monitor progress at country level (25 min)                        |                                 |
|              | • Discuss hosting arrangements for an observatory (25 min)                         |                                 |
### DAY 2 – THURSDAY 27 OCTOBER 2016
**CHAIR: A. Dodoo**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>9:00 – 9:45</td>
<td>Debriefing from breakout sessions</td>
<td>Group rapporteurs</td>
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#### SESSION 4: REGIONAL MEDICINES REGULATORY HARMONIZATION INITIATIVES

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<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>9:45 – 10:15</td>
<td>Global developments in the regulatory harmonization for medical products regulation</td>
<td>C. Ondari</td>
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<tr>
<td>10:15 – 10:45</td>
<td>Coffee break</td>
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#### SESSION 5: VACCINE SAFETY COMMUNICATION

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
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</thead>
<tbody>
<tr>
<td>11:30 – 12:30</td>
<td>Improving vaccine safety communication:</td>
<td>Moderator: P. Bravo E. Karafillakis A. Amarasinghe</td>
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<td>• Addressing vaccine hesitancy – The “State of Vaccine Confidence 2016: Global insights through a 67-country survey”</td>
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<td></td>
<td>• Addressing reluctance in AEFI reporting through vaccine safety communication</td>
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<tr>
<td>12:30 – 14:00</td>
<td>Lunch break</td>
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<tr>
<td>14:00 – 15:00</td>
<td>Improving vaccine safety communication (continuing):</td>
<td>N. Shapumba N. Yusuf</td>
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<td>• Managing safety crisis: the Namibian experience</td>
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<td></td>
<td>• UNICEF : Risk communication for Adverse Event Following Immunisation</td>
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#### SESSION 6: NEW VACCINE SAFETY TOOLS

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:00 – 15:30</td>
<td>Electronic AEFI monitoring system: Addressing challenges in Chile</td>
<td>A Saldaña Deok Ryun Kim</td>
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<tr>
<td></td>
<td>• The system and challenges</td>
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<td></td>
<td>• The “Bridging Solution”</td>
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<tr>
<td>15:30 – 16:00</td>
<td>Coffee break</td>
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<tr>
<td>16:00 – 17:00</td>
<td>AEFI causality assessment software Introduction and live demo</td>
<td>M. Balakrishnan</td>
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<tr>
<td>17:00 – 17:15</td>
<td>Concluding remarks</td>
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</table>