

**Webinar report:**  
**South-South sharing of experiences on innovative  
approaches for strengthening drug & vaccine safety  
monitoring**

Convened by:

**Access and Delivery Partnership partners: WHO, the UNICEF/UNDP/World  
Bank/WHO Special Programme for Research and Training in Tropical Diseases  
and the WHO Regional Office for Africa**

**Webinar 1: 1 June 2022**

**Webinar 2: 8 June 2022**

## I. Index table

I. Background and objectives .....	3
II. Agenda .....	5
III. Attendees .....	7
IV. Topics .....	9
1. Innovative ways to strengthen human resources capacity in safety monitoring .....	9
1.1 Cascade training for pharmacovigilance focal points in Ghana .....	9
2. Innovative initiatives in the context of COVID-19 pandemic.....	9
2.1 Updating of pharmacovigilance (PV) tools in Senegal .....	9
2.2 Formative supervision and active pharmacovigilance at the treatment centers for COVID-19 in Senegal .....	9
2.3 Pharmacovigilance virtual trainings during COVID-19 pandemic .....	10
2.4 Weekly meetings in Togo and Niger in the framework of AEFI monitoring: experience sharing...	10
3. Future perspectives .....	10
3.1 Leveraging on disease surveillance system to strengthen pharmacovigilance in AFRO/WCA .....	10
4. Lessons learned in terms of practical experience using a digital tool for ADR and AEFI reporting.....	11
4.1 User evaluation of Med Safety App and use for AEFI reporting in Ghana .....	11
4.2 Promotion of direct reporting of individual case safety reports (ICSRs) by patients using Medsafe-360 USSD platform .....	11
4.3 Use of ODK Collect and email alerts to improve notification and data management .....	11
4.4 Cohort Event Monitoring of AEFI in persons vaccinated against COVID-19 in regions of Cameroun: an opportunity for improvement of the AEFI surveillance system .....	12
5. Innovative approaches for ADR reporting at community level .....	12
5.1 Understanding underreporting of ADR in the Philippines .....	12
5.2 Development and implementation of a patient-centered peer support intervention to promote the detection, reporting and management of ADR among PLVHI in Uganda.....	12
6. Innovative approaches to safety monitoring in the context of COVID-19 pandemic .....	13
6.1 Evaluation of the use of DHIS2 AEFI Tracker on the performance of AEFI surveillance system in Sierra Leone, April 2021- November 2021.....	13
6.2 Validation of AEFI data (Validation des données sur les manifestations post-vaccinales indésirables (MAPI)) .....	13
6.3 AEFI COVID-19 vaccine in Morocco .....	14
V. Summary .....	14
VI. Post webinar survey.....	15

## II. Background and objectives

Partners of the Access and Delivery Partnership (ADP)<sup>1</sup> (the United Nations Development Programme (UNDP) and the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)), in collaboration with the WHO Regional Office for Africa (AFRO), convened a series of virtual workshops for countries to share their experiences on innovative approaches for strengthening drug and vaccine safety monitoring, thus contributing to health system resilience.

In many disease-endemic countries, although safety monitoring systems are being strengthened, under-reporting is a persistent problem. With the introduction of new digital technologies such as the WHO-recommended MedSafety App for adverse drug reaction (ADR) reporting, countries have been conducting implementation research to best tailor the tools to their context, assessing acceptability and feasibility of digital technologies.

The recent introduction of COVID-19 vaccines worldwide and related safety concerns has further pinpointed the importance of pharmacovigilance. In 2020, countries had to strengthen their human capacity and to adapt their tools to ensure safety monitoring of the newly introduced COVID-19 vaccines.

From 2019 to 2021, TDR has supported ADP-focus countries to strengthen their safety monitoring capacity through innovative training approaches and implementation research on the use of new tools (MedSafety app, USSD coding system). To improve the scale up of these innovative interventions and reach out to non-ADP focus countries of the region, ADP partners wished to foster cooperation and technical exchanges between countries through a series of virtual webinars. These workshops are meant for national pharmacovigilance authorities from ADP-focus countries and other countries too to share their experiences and initiate inter-country dialogue that will ultimately strengthen their capacity for pharmacovigilance and drug and vaccine safety monitoring.

### Target countries and participants

- Representative of all Pharmacovigilance national authorities and involved research institutions of ADP focus countries in Africa (Ghana, Senegal, Burkina Faso, Malawi, Tanzania)
- Representatives of all Pharmacovigilance national authorities of other countries of the African region, including those of the WARN/CARN-TB involved in aDSM.
- TDR grantees involved in research projects on pharmacovigilance.

---

<sup>1</sup> The Access and Delivery Partnership (ADP)<sup>1</sup> works with low- and middle-income countries to ensure life-saving medicines and health technologies reach the people who need them. The ADP focuses on providing countries with technical skills and expertise to develop the systems and processes required to facilitate the access to and delivery of new health technologies for tuberculosis, malaria and neglected tropical diseases. The core partners include UNDP, TDR, PATH and WHO. The target countries include Ghana, Indonesia, Tanzania, Senegal, Bhutan and Burkina Faso. ADP is supported by the Government of Japan and led by the UNDP.

- Ministry of Health representative of the countries for Implementation research / operational research within the health system
- In-country technical/financial partners

These webinars were organized in collaboration with ADP partners, WHO regional officers for Drug quality/PV, and WHO PV department at HQ.

### **First webinar: Innovative capacity strengthening approaches & COVID-19 context**

The first webinar aimed at:

- Fostering exchanges between countries who implemented innovative training strategies on PV and countries who have not yet done so.
- Fostering exchanges between countries with regards to capacity strengthening activities developed specifically in the COVID-19 context.
- Providing information on best practices, training opportunities and regional support

Expected outcomes:

1. Strengthened technical and practical knowledge of PV national authorities on training strategies
2. Fostered regional and national dialogue for strengthening PV human capacity

### **Second webinar: ADR notification with digital tools & COVID-19 context**

The second webinar aimed at:

- Fostering exchanges between countries who introduced digital tools for ADR notification, especially those who piloted the introduction of the MedSafety App or USSD coding system and countries who have not yet introduced a digital tool for ADR reporting to better understand practical implementation challenges.
- Fostering exchanges between countries on how they adapted notification tools in the context of the COVID-19 pandemic.
- Providing information on best practices regarding ADR notification

Expected outcomes:

- Strengthened technical and practical knowledge of PV national authorities on methods to increase ADR reporting and challenges in implementing them
- Fostered regional and national dialogue for strengthening ADR notification

### III. Agenda

#### Agenda webinar 1 – 1 June 2022 11h00-13h30 (GMT)

Moderator: Prof Rachida Soulaymani, Rabat WHO Collaborating Centre

GMT	Topic	Speaker
11h00-11h10	<b>Innovative ways to strengthen human resources capacity in Safety monitoring</b>	
11h10-11h25	1. Cascade trainings & PV focal points in Ghana	<b>Mr George Sabblah</b> , Head of Safety Monitoring Department, FDA, Ghana
11h25-11h30	<b>Q&amp;A</b>	
	<b>Innovative initiatives in the context of COVID-19 pandemic</b>	
11h30-11h45	2. Active surveillance of ADR & on-site training during pandemic (Senegal)	Dr Aminata Diarra Lô, responsable PV, Ex Direction de la Pharmacie et du Médicament, Sénégal
11h45-12h00	3. Reporting tools adaptations (Senegal)	
12h00-12h15	4. All on-line annual PV course during pandemic (Rabat WHO CC)	Prof. Rachida Soulaymani, Directrice du CAP & PV du Maroc, WHO CC
12h15-12h30	5. Weekly review TCs with focal points (Togo)	Dr Yerima Mouhoudine, Chief of Department, PV Head Office, Togo
12h30-13h00	<b>Discussion / Q&amp;A</b>	
	<b>Future perspectives</b>	
13h00-13h30	6. Quality control and repository for all country-developed training materials <b>Discussion / Q&amp;A</b>	Edinam Agbenu, Vaccine Safety & Quality officer, WHO Afro

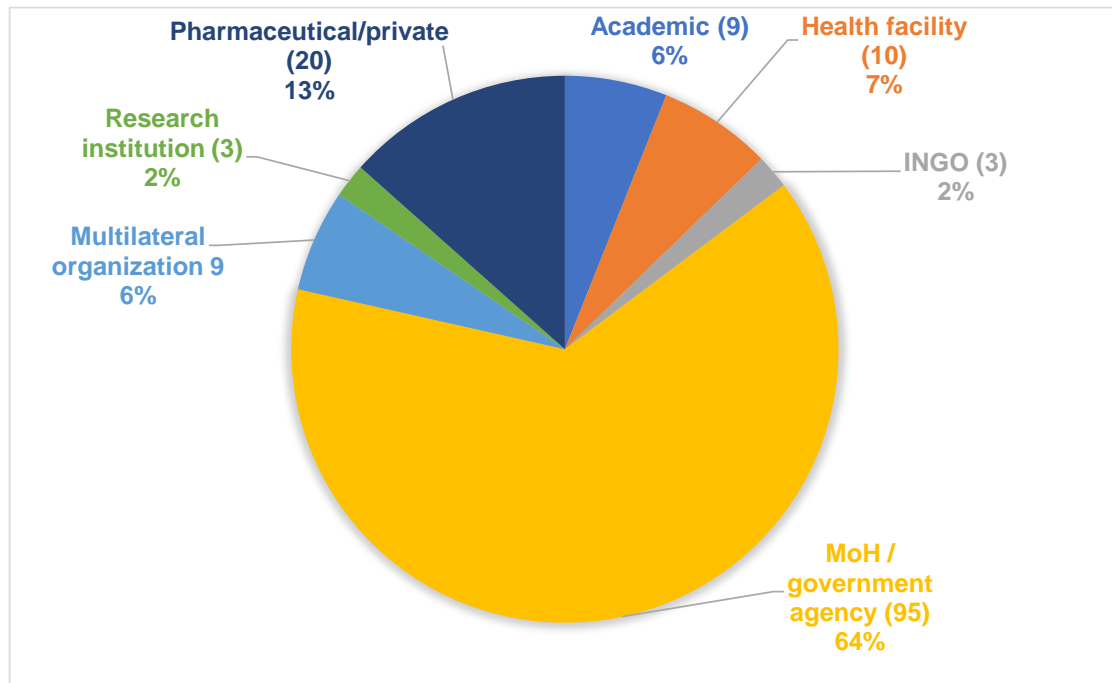
## Agenda webinar 2 – 8 June 2022 11h00-13h30 (GMT)

Moderator: **Edinam AGBENU**, Vaccine Safety and Quality Officer WHO/AFRO/UCN/VPD IST-WA CA

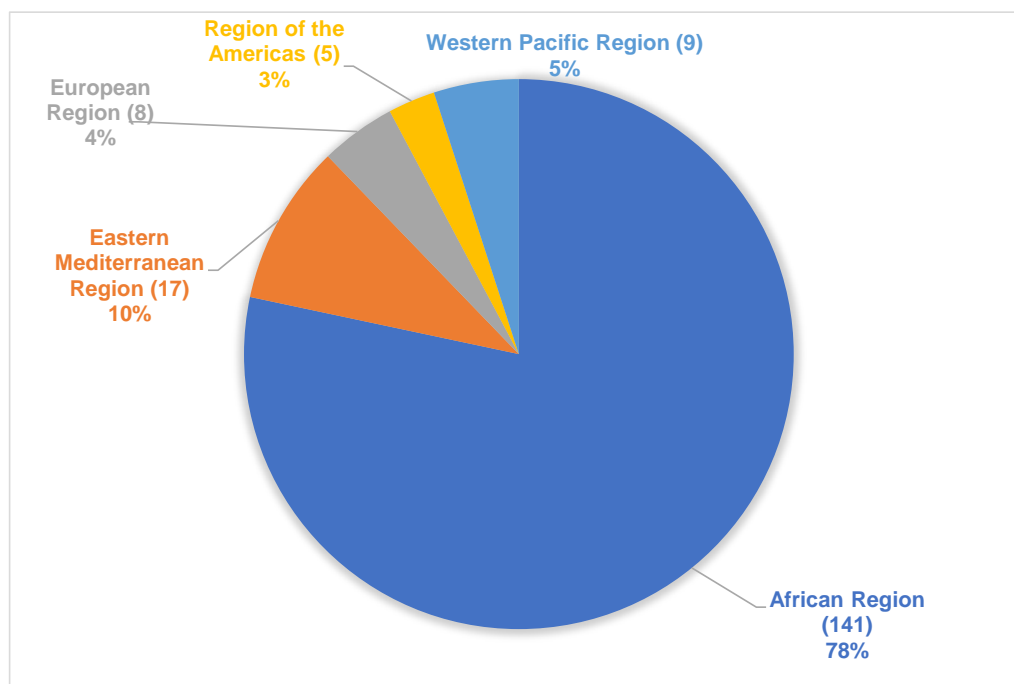
GMT	Topic	Speakers
11h00-11h05	<b>Lessons learned in terms of practical experience using a digital tool for ADR and AEFI reporting</b>	
11h05-11h15	1. User evaluation of MedSafety app and use for AEFI reporting in Ghana	<b>Irene Koramah Frempong</b> , Senior Regulatory Officer, Safety Monitoring Department, FDA, Ghana
11h15-11h25	2. Promotion and pilot introduction of USSD system for ADR reporting in Malawi	<b>Anderson Ndalama</b> , Pharmacovigilance coordinator, PMRA, Malawi
11h25-11h45	3. Use of ODK collect and mail alert for improving reporting and data utilization in Cameroun 4. Cohort Event Monitoring of AEFI in persons vaccinated with COVID-19 vaccines	<b>Dr Stéphanie Nogha</b> , Chef service des vigilances <b>Dr Annie Mengue</b> , Direction de la pharmacie, du médicament et des laboratoires, MOH, Cameroun
11h45-12h00	<b>Discussion / Q&amp;A</b>	
	<b>Innovative approaches for ADR reporting at community level</b>	
12h00-12h10	5. Understanding underreporting of ADR in the Philippines	<b>Mark Ryann Lirasan</b> , Head Pharmacovigilance Section, FDA, Philippines
12h10-12h20	6. Development and implementation of a patient-centred peer support intervention to promote the detection, reporting and management of ADR among PLHIV in Uganda	<b>Dr Ronald Kiguba</b> , Senior lecturer, Department of Pharmacology and Therapeutics, College of Health Sciences, Makerere University, Uganda
12h20-12h35	<b>Discussion / Q&amp;A</b>	
	<b>Innovative approaches to safety monitoring in the context of COVID-19 pandemic</b>	
12h35-12h45	7. Experiences for AEFI reporting using DHIS2 in Sierra Leone	<b>Dr Mutebi R. Reagan</b> , ICAP at Columbia U. (supporting Sierra Leone MOH's EPI program)
12h45-12h55	8. Validation des données sur les manifestations post-vaccinales indésirables (MAPI) au Benin	<b>Dr Jocelyne Satchivi</b> , Chef du service Vigilance, Usage Rationnel et Essais Cliniques, Agence béninoise de Régulation Pharmaceutique, Benin
12h55-13h10	<b>Discussion / Q&amp;A</b>	
13h10-13h20	9. Experience of Morocco on actions taken on AEFI cases identified, reported, investigated, and causality assessed.	<b>Dr Houda Sefiani</b> , Rabat WHO CC
13h20-13h30	<b>Discussion / Q&amp;A / Closing remarks</b>	

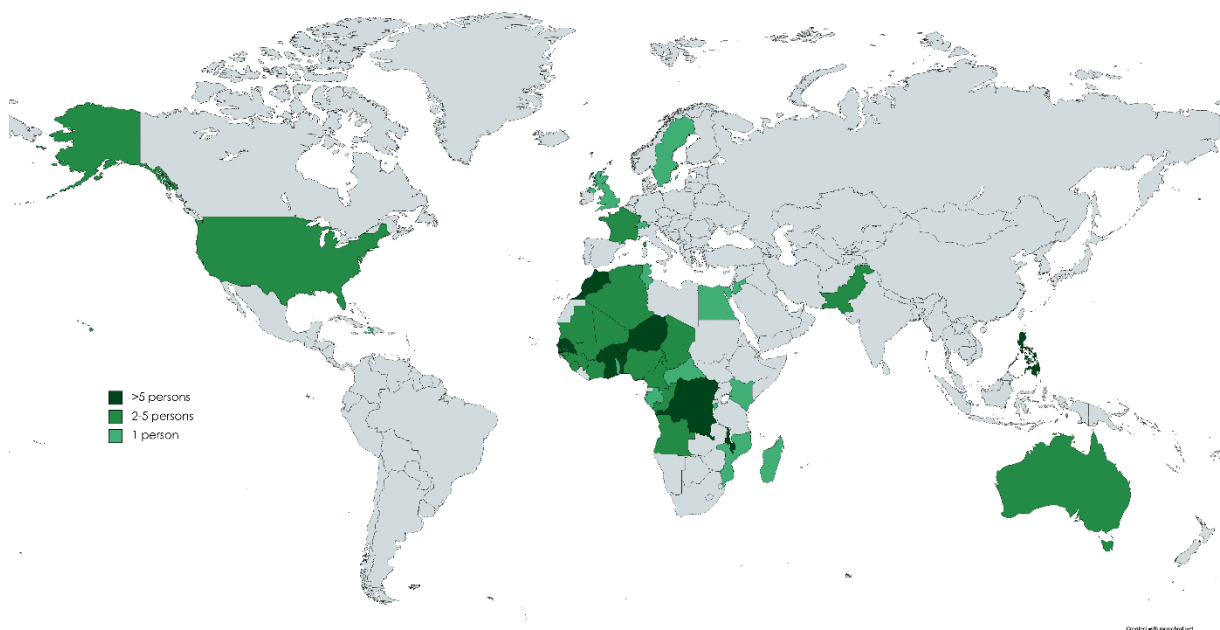
#### IV. Attendees

199 persons registered for the two webinars. 56 (44%) were of female gender out of the 126 (63%) who responded. Out of 149 persons who reported the information, a majority (64%) were representants from a Ministry of Health or a government agency. Other came from the private sector, health facilities, academic and research institutions, multilateral organizations and international governmental organizations.



Persons registered came from 45 different countries (20 did not specify their location) from all WHO regions. A large majority (78%) of registered persons came from the African region.





90 persons connected to the 2<sup>nd</sup> webinar, which includes speakers who presented their work. Attendance rate was thus 45%. Participants connected came from 36 countries. Although three quarters (77%) were from the WHO African Region, all WHO regions were represented.

60% were of feminine gender out of 73 (78%) who answered.



## V. Topics

### 1. Innovative ways to strengthen human resources capacity in safety monitoring

#### 1.1 Cascade training for pharmacovigilance focal points in Ghana

**Speaker: Mr George Sabblah, Head of Safety Monitoring Department, FDA, Ghana**

Ghana joined the WHO Programme for International Drug Monitoring in November 2001 and is the 65<sup>th</sup> member of the programme and the first country in West Africa. The FDA of Ghana serves as the National Centre for Pharmacovigilance and has the mandate to monitor the safety of health products. Safety monitoring is done in collaboration with designated healthcare workers in facilities; Institutional Contact Persons (ICPs) who report adverse reaction reports to the National Centre. In 2019, a review of National Supply Chain and Pharmacovigilance capabilities of the health system showed that Standard Operating Procedures and reporting forms for adverse reactions were not available at last-mile facilities, namely Community-Based Health Planning and Services (CHPS) zones, health centres and clinics. So, it was decided to conduct a training to decentralize pharmacovigilance to the lower levels of the health system in the country and also, to enhance safety monitoring of COVID-19 vaccines introduced in 2020. The cascade training involved a two-day training workshop held in six out of the 16 administrative regions. It relied on interactive presentations and hands-on exercises on reporting tools, pre-and post-training tests. A total of 182 healthcare professionals from lower-level healthcare facilities were trained in April 2021. Achievements included: i) improved knowledge on pharmacovigilance in all regions involved, ii) an increased MedSafety App downloads in 2021, and iii) a high ratio of one AEFI per 1 000 doses of COVID-19 vaccines administered between March 2021 and May 2022.

### 2. Innovative initiatives in the context of COVID-19 pandemic

#### 2.1 Updating of pharmacovigilance (PV) tools in Senegal

(Actualisation des outils de pharmacovigilance au Sénégal)

**Speaker: Dr Aminata Diarra Lô, responsable PV, Ex Direction de la Pharmacie et du Médicament, Sénégal**

In 2009, the national PV system of Senegal was reorganized and tools first standardized. However, peripheral health level was not involved in the process. In 2021, three workshops were organized to ensure the involvement of a large group of stakeholders in the revision and update of PV tools: notification flow, notification forms for ADR and AEFI, PV national guide, notification form of drug quality problem and Training of trainer guide.

#### 2.2 Formative supervision and active pharmacovigilance at the treatment centres for COVID-19 in Senegal

(Supervision formative et pharmacovigilance active au niveau des centres de traitement du COVID-19 du Sénégal)

**Speaker: Dr Aminata Diarra Lô, responsable PV, Ex Direction de la Pharmacie et du Médicament, Sénégal**

During the COVID-19 pandemic in 2020, temporary treatment centres for COVID-19 were set up in the country. With the objectives of documenting adverse events of drugs used for

COVID-19 and of strengthening ADR notification efforts, national PV authorities set up active PV surveillance combined with on-site formative supervisions of health workers. A specific supervision checklist was developed. ADR and causes of death were searched for using patient files in the treatment centres and recorded. One main difficulty encountered was the incompleteness of patient files which jeopardized the retrospective documentation of ADRs.

### 2.3 Pharmacovigilance virtual trainings during COVID-19 pandemic

**Speaker: Prof. Rachida Soulaymani, Directrice du CAP & PV du Maroc, WHO CC**

Since 2007, the Rabat WHO CC (RCC) has been providing pharmacovigilance training to African and EMR countries with their flagship annual course on general PV taking place in Morocco for two weeks. But with the travel restrictions due to the COVID-19 pandemic, the RCC developed a new series of on-line courses to continue reaching professionals all around the globe. Besides the course on general PV, four other courses are available on AEFI related to COVID-19 vaccines. There are also new upcoming trainings planned, one on Safety of medicinal product during pregnancy and one on Active safety surveillance. Further information on the Rabat Collaborating Center LinkedIn page and Instagram account.

### 2.4 Weekly meetings in Togo and Niger in the framework of AEFI monitoring: experience sharing

(Réunions hebdomadaires au Togo et au Niger dans le cadre de la surveillance des MAPI: partage d'expérience)

**Speaker: Dr Yerima Mouhoudine, Pharmacovigilance Officer, Direction de la Pharmacie, du Médicament et des Laboratoires, Togo**

Close monitoring of AEFI post-COVID-19 vaccination was important in the context of lack of trust in vaccines and need to take quick action. Yet, face to face meetings were limited due to COVID-19 restrictions. In both Niger and in Togo, virtual meetings to discuss AEFI were organized on a weekly basis with PV regional focal points, PV national authorities and WHO representatives. Districts used ODK to report by phone and regional focal points were equipped with computers. Lessons learned included: i) good organization and regular follow up are required for effective AEFI surveillance, ii) automatic alerts on ODK increase reactivity of surveillance system, iii) appropriate management of serious AEFI and good communication increased population's trust in the PV surveillance system and improve notification.

## 3. Future perspectives

### 3.1 Leveraging on disease surveillance system to strengthen pharmacovigilance in AFRO/WCA

**Speaker: Edinam Agbenu, Vaccine Safety & Quality officer, WHO Afro**

Demonstration of a document-sharing online platform was done. This platform allows for each country to upload documents to be shared with other countries. The tool includes a discussion forum for members to interact directly with one another.

An update was given on key indicators of AEFI post- COVID-19 vaccination for each country of the West and Central African region (reporting rate, investigation rate, etc).

#### 4. Lessons learned in terms of practical experience using a digital tool for ADR and AEFI reporting

##### 4.1 User evaluation of Med Safety App and use for AEFI reporting in Ghana

**Speaker: Irene Koramah Frempong, Senior Regulatory Officer, Safety Monitoring Department, FDA, Ghana**

Med Safety App was launched in Ghana in 2019 with a total of 11 005 downloads and 2373 ADR reports. Adverse event reports increased from 67 in 2019, 45 in 2020, to 444 in 2021 (291 from the general public and 51 from healthcare professionals). Peak downloads of the MedSafety App occurred after communication campaigns. Many activities to promote the App took place and include publication of flyers/posters, media advertisements, use of social media, sponsored entertainments and the #MedSafetyWeek. The evaluation of the app users showed high level of satisfaction in terms of ease of download. Less than half of users reported that it was easy to use and a fifth of users interviewed reported that will continue using it because it is easier than other reporting mechanisms. News items and a watch list were considered useful features of the app. Main lessons learned is that social media activities improve use of the MedSafety App which should not be advertised only as an ADR reporting tool and should focus on the benefits to the users. Internet connectivity is an issue.

##### 4.2 Promotion of direct reporting of individual case safety reports (ICSRs) by patients using Medsafe-360 USSD platform

**Speaker: Anderson Ndalama, Pharmacovigilance coordinator, PMRA, Malawi**

Malawi joined the WHO Programme for international drug monitoring in 2018. Contribution of case reports in VigiBase has been low and the low reporting rate is attributable to reliance on paper-based reporting only and low patient involvement. This is the reason for introducing the Medsafe-360 as an alternative reporting tool for direct patient reporting. This is a USSD-based platform that is free and not require a smartphone as it works without internet (sms-based). The pilot introduction showed many incomplete reports and challenges in naming medicines and side effects. National PV authorities are preparing a study to evaluate the feasibility of the Medsafe-360 as a reporting tool by patients, its acceptability and the quality of the promotional strategy and tools. The study is expected to start 2<sup>nd</sup> quarter of 2022 and finish before end of 2022.

##### 4.3 Use of ODK Collect and email alerts to improve notification and data management

(Utilisation d'ODK Collect et d l'alerte mail pour améliorer la notification et la gestion des données)

**Speaker: Dr Stéphanie Nogha, Chef service des vigilances, Direction de la pharmacie, du médicament et des laboratoires, Ministry of Health, Cameroun**

The tool ODK was introduced in 2017 in Cameroun. Prior to that year, reporting of AEFI/ ADR was rare. In 2017 there were 111 notifications. The number decreased until 2021 when notifications increased to 2204 and to 1941 in 2022. This is related to the introduction of COVID-19 vaccines and increased reporting of AEFI. ODK tool has many advantages such as its easy use, offline reporting with deferred submission in case of internet connectivity issues, data entry on a phone or tablet, transmission of GIS data, integrated dashboards and maps, Vigiflow data import, email alert for each serious ADR/AEFI reported. Main drawback is that once a report is sent, no correction can be made on the mobile phone. In addition to the ODK tool, animation of the network of focal points is key for the reporting system to function.

#### 4.4 Cohort Event Monitoring of AEFI in persons vaccinated against COVID-19 in regions of Cameroun: an opportunity for improvement of the AEFI surveillance system

(Cohort Event Monitoring des MAPI chez les personnes vaccinées contre le COVID-19 dans trois régions au Cameroun (Centre, Littoral et Nord): opportunité d'amélioration du système de surveillance des MAPI)

**Speaker: Dr Annie Mengue , Direction de la pharmacie, du médicament et des laboratoires, MOH, Cameroun**

Vaccination using different COVID-19 vaccines started in April 2021 in Cameroun. As AEFI surveillance was weak with 67 health districts not reporting AEFI, an observational study based on cohort event monitoring was set up to identify all AEFI in COVID-19 vaccinated persons during the 42-day follow up period, in three regions. ODK tool was used to collect data on recruitment and on eventual AEFI reporting. A full analysis of data will be available in July 2022.

### 5. Innovative approaches for ADR reporting at community level

#### 5.1 Understanding underreporting of ADR in the Philippines

**Speaker: Mark Ryann Lirasan, Head Pharmacovigilance Section, FDA, Philippines**

The objectives of an ongoing study in the Philippines are:

1. To assess the Knowledge attitudes and practices on ADR reporting among healthcare professionals to understand the country specific factors contributing to ADR reporting
2. To assess the effectiveness and (3) usability of the eReporting module if Vigiflow among healthcare professionals.

Both quantitative and qualitative research methods will be used and will include a knowledge, attitudes, and practices (KAP) survey using a standardized questionnaire, as well as interviews with healthcare professionals to better understand the reasons behind the trends obtained from the KAP survey. The first Philippine PV summit was organized, with more than 4000 individuals registered in the event, most of the attendees are pharmacists, followed by nurses and physicians and others. Participants were asked a series of questions on PV practices and on the use of the eReporting module. Focus group discussions are ongoing and full results of the study are expected before end of 2022.

#### 5.2 Development and implementation of a patient-centred peer support intervention to promote the detection, reporting and management of ADR among PLVHI in Uganda

**Speaker: Dr Ronal Kiguba, Senior lecturer, Department of Pharmacology and Therapeutics, College of Health Sciences, Makerere University, Uganda**

The underlying hypothesis for an ongoing study was that peer support plus mobile data transmission technologies for promoting the detection, reporting and management of ADRs in PLHIV is feasible and acceptable. Also, peer support plus mobile data transmission technologies will significantly increase the number of PV reports submitted to the national database by PLHIV during 4-months of follow-up when compared with PLHIV who do not receive peer support.

Study objectives include: i) Develop a peer support plus mobile data transmission technologies intervention, ii) Explore barriers & facilitators to peer support plus mobile technologies (MedSafety app and USSD-based system), iii) Describe the patterns of ADR-reporting by PLHIV, and iv) Estimate effect of peer support plus mobile data transmission technologies on the rate

of ADR-reporting by PLHIV. The study design is a quasi-experimental study involving 24 ART-sites matched, 12 in the intervention group with peer supporters and 12 in control group with mobile technology only (no peer support). So far, 4486 PV reports have been submitted using USSD-system and only 201 with MedSafety app. Challenges and opportunities using MedSafety app have been documented. Peer supporters are preferred to healthcare workers and USSD platform is preferred because it is easier to use than MedSafety app. Full study results will be available before end of 2022.

## 6. Innovative approaches to safety monitoring in the context of COVID-19 pandemic

### 6.1 Evaluation of the use of DHIS2 AEFI Tracker on the performance of AEFI surveillance system in Sierra Leone, April 2021- November 2021

**Speaker: Dr Mutebi R. Reagan, ICAP at Columbia U. (supporting Sierra Leone MoH's EPI program)**

The presentation gave an overview of the evaluation on the use of DHIS2 AEFI tracker in Sierra Leone following COVID-19 vaccination. This specific module of DHIS2 provides an electronic platform for the notification, reporting, investigation, and analysis of adverse events following immunization. It is modelled on the WHO reporting and investigation form for AEFI and allows the user to capture case-based data using the WHO recommended 25 core variables. The evaluation conducted to identify lessons learned from early implementation of the DHIS2 AEFI module used mixed methods. A targeted selection of preliminary results was presented in five thematic areas: 1) data quality and use, 2) system functionality, 3) infrastructure, 4) capacity building, 5) staffing and governance. Main lessons learned included i) COVID-19 vaccine AEFI data was captured in both ODK and DHIS2 (two parallel systems), thus duplicating efforts, ii) training on DHIS2 AEFI module was inadequate. As data analysis is still underway, preliminary critical areas to focus on improvements include: i) Formal comprehensive Capacity building, ii) Having more opportunities to discuss the system with more users involved in those discussions, iii) Establishing a plan for when and how to align the DHIS2 AEFI module with other systems, and iv) Discuss sustainability and ownership of the module.

### 6.2 Validation of AEFI data (Validation des données sur les manifestations post-vaccinales indésirables (MAPI))

**Speaker: Dr Jocelyne Satchivi, Chef du service Vigilance, Usage Rationnel et Essais Cliniques, Agence béninoise de Régulation Pharmaceutique, Benin**

From 2015 to 2018 there were no AEFI/ADR reported. Collaboration with Direction Nationale de Santé Publique (DNSP, agency for primary health care and public health programs) started in 2019 and led to reports being collected. The significant discrepancy in data on AEFI between the databases of DNSP et the Pharmacovigilance Unit led the health authorities of Benin to integrate PV surveillance to the National disease surveillance and response system. A coordination team was set up with members from national PV, Information & planning unit, DNSP. A data harmonization meeting has been done yearly with the participation of national, regional and district officers from stakeholders. Participants were grouped by region and there was a coordination committee with officers from national level. The tasks of the coordination team and working groups and the harmonization processes were defined. This includes

verification of completeness of reporting forms available against number expected from the weekly aggregated report, then verification against number entered in ODK collect and finally verification of the fidelity of recording in ODK collect with the paper forms. Correction followed to have a clean database suitable for analysis and each region would elaborate surveillance report which will be compiled as national safety surveillance report. So far this has been conducted yearly and help improve the pharmacovigilance data quality in Benin.

### 6.3 AEFI COVID-19 vaccine in Morocco

**Speaker: Dr Houda Sefiani, Rabat WHO CC**

Procedures for AEFI post COVID-19 vaccination in Morocco were presented. Standardized weekly reports were produced throughout the vaccination campaign ensuring the dissemination of safety surveillance information. There was a total of AEFI notifications from 28 January 2021 to 30 April 2022. Analysis of AEFI reports per region, per type of vaccine, per reporter's qualification, and per patient characteristics was performed. Analysis of types of AEFI was also done and presented.

## VI. Summary

The high registration number from a wide range of countries and regions shows the interest in pharmacovigilance and in country experience sharing.

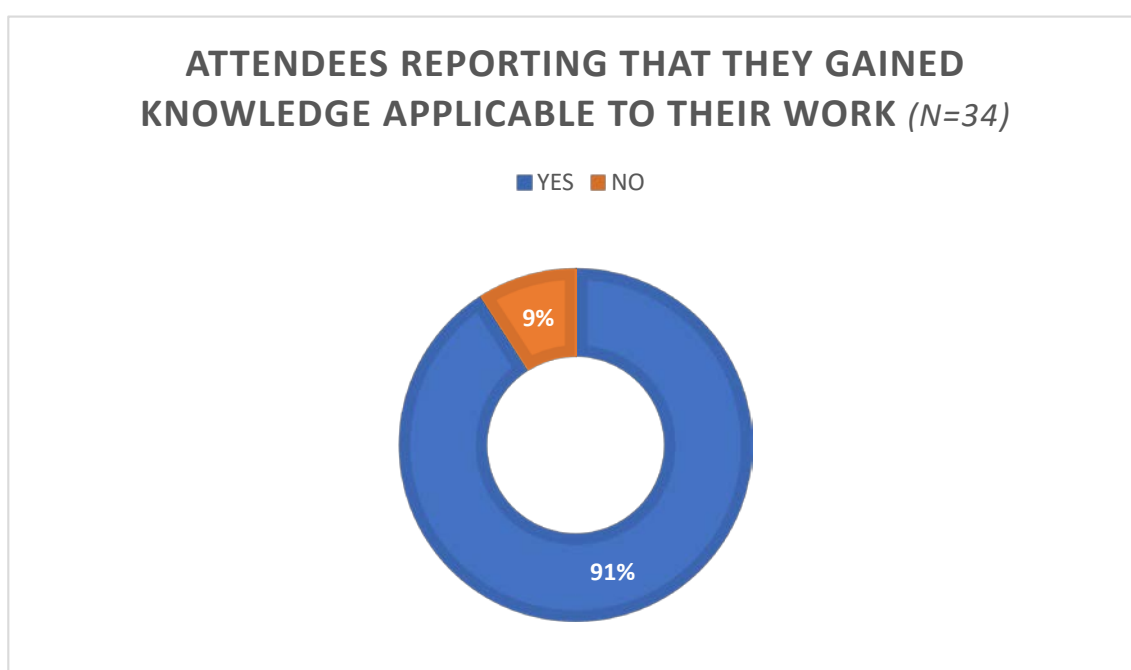
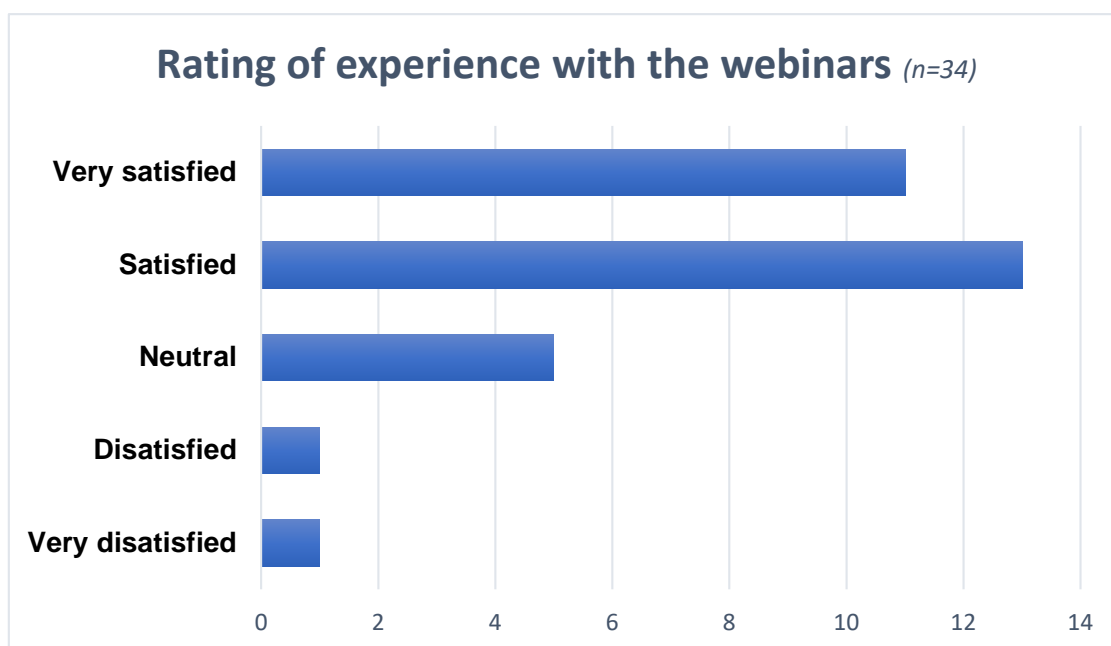
The first webinar was an opportunity for national PV authorities to present to their peers innovative training strategies. The COVID-19 pandemic was shown to be an opportunity for authorities to innovate in capacity strengthening related to PV and to strengthen AEFI surveillance and response.

The focus on digital tools for ADR and/or AEFI reporting of the second webinar was an opportunity for countries to learn about a variety of existing tools (such as the MedSafety App, ODK, USSD-based system, and DHIS2 AEFI module) as well as the value of maintaining a network of focal persons to animate the system in a public health perspective and opened the door to conducting research on practical implementation challenges related to the use of such tools in specific contexts.

Such sharing of country experiences will hopefully foster further dialogue and stimulate a stronger involvement in implementation research ultimately to strengthen PV knowledge and practices in countries where this discipline is still relatively young.

## VII. Post webinar survey

Seventeen persons filled the post-webinar survey after June 1<sup>st</sup> session and 16 filled it after June 8. Among all 34 responders, the majority were satisfied/very satisfied with the webinars and 91% of them reported that they gained knowledge applicable to their work and that they found the webinars useful for their future work. Three negative comments pointed to the poor translation French to English in the first webinar.



**ATTENDEES REPORTING THAT THEY FOUND THE  
WEBINAR HELPFUL FOR THEIR FUTURE WORK**  
(*N=34*)

■ YES ■ NO

