AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

SMART SAFETY SURVEILLANCE

Spotlight

The Smart Safety Surveillance Newsletter in Africa

Edition 1

May 2021

In this edition:

Introducing the AU's Smart Safety Surveillance Programme

The African Union's Smart Safety Surveillance (AU-3S) programme was launched in early 2020, with the long-term goal of strengthening the safety surveillance of medical products across the African continent for priority health products. The programme aims to tackle continental challenges such as low adverse event reporting rates, siloed pharmacovigilance (PV) systems, and limitations in safety expertise. With COVID-19 reinforcing the need for strong African PV, AU-3S is currently supporting the safety surveillance of COVID-19 vaccines in 4 pilot countries. These countries are Ethiopia, Ghana, Nigeria, and South Africa – altogether comprising ~30% of Africa's population. The AU-3S team works closely with their National Regulatory Authorities (NRAs) and Expanded Programmes on Immunisation (EPIs). The UK's Medicines and Healthcare products Regulatory Agency (MHRA) is providing technical support in the development and delivery of the programme.

To support countries, the AU-3S team has multiple initiatives, including four main programme solutions:

- Promotion of electronic vaccine data collection to stimulate adverse event reporting by healthcare providers and the public, through the development of an AEFI form for the Med Safety App, and support to regulatory authorities and immunisation programmes to roll it out
- Establishment of an interim common African safety database known as the Data Integration and Signal Detection (DISD) system, to detect signals in combined cross-country data from the four African countries currently involved in the programme.
- Establishment a multi-country group of safety experts, known as the AU-3S Joint Signal Management Group (AU-3S JSM Group), to validate, prioritise, and assess the cross-country signal reports from the interim DISD system.
- Facilitate capability strengthening modules covering end-to-end aspects of safety surveillance, from data collection to causality assessment; these training modules are run by the MHRA.

> ***"This is the opening of a whole new chapter for pharmacovigilance in Africa"***
>
> **- Prof. Dicky Akanmori, WHO AFRO (Regional Advisor for Vaccine Regulation)**

AU-3S will expand these activities to other African countries in the future, including for other new and innovative products in the AU priority diseases areas including HIV, TB, Malaria , Ebola, and COVID-19

The programme is being funded by The Bill and Melinda Gates Foundation (BMGF) and works closely with a number of critical African and global stakeholders such as the WHO AFRO, WHO EMRO, African COVID-19 Vaccine Deployment Readiness and Execution Taskforce (ACREDT), the Africa CDC-led African Vaccine Delivery Alliance (AVDA), and the US FDA.

Launch of a vaccine-specific reporting form for the Med Safety App

The AU-3S team recently launched a vaccine-specific reporting form for the Med Safety App - a mobile application that can be used to by healthcare professionals and members of the public to report side effects from medicines and vaccines.

Why is a vaccine form required?

The existing form in the Med Safety App was designed to report adverse events from medicines but reporting adverse events from vaccines, Adverse Events Following Immunisation (AEFIs), requires different data to be entered. To enable e-reporting of vaccine data using the Med Safety App, the AU-3S team facilitated the development of a vaccine reporting form in the Med Safety App. This form uses WHO core variables for AEFI reporting, which are also the basis for the existing paper reporting forms.

What happens to the data?

When a case report is created it goes directly into the Vigilance Hub (the back-end system of the Med Safety App) and from there into the regulatory authority's database, the WHO global database VigiBase. Each data element in the form is mapped to International Council for Harmonisation compliant E2B fields (the international standard for transmitting adverse event reports), to ensure smooth automated transfer. Both regulatory authorities and immunisation programmes have access to the Vigilance Hub, enabling visibility of the case data in near real time so signals can be detected and any safety actions can be taken swiftly.

What are the benefits of the form?

- Enables the Med Safety App to be a single e-reporting tool for both vaccines and medicines
- Available for the reporting of AEFIs for all vaccines, not just COVID-19 vaccines
- Typically, AEFI reporting is done by health care professionals only, but this form allows the public to self-report AEFIs
- Standardised form enables cross country signal detection and analysis

> ***"Having a common reporting tool shared by African countries helps build confidence into our data"***
>
> **- Mimi Darko, Ghana FDA (CEO)**

What are the benefits of the Vigilance Hub?

- Improves collaboration and visibility of data between the regulatory authority & the immunisation programmes
- Enables the immunisation programmes to edit cases with updated information after follow up
- Enables the export of line lists of AEFI data

Where has this been launched?

- This form has now been launched in Ghana, Nigeria, South Africa, and Ethiopia
- Communications and training rollouts are still underway, but we are already seeing reports being created using this new AEFI form
- This AEFI reporting form can be readily made available to any other countries using the Med Safety app on request

Data is now in the AU-3S Data Integration and Signal Detection System

What is the Data Integration & Signal Detection (DISD) System?

Safety data from the four countries goes into a database to provide a larger pool of adverse events from the vaccines. This will strengthen signal detection activities, help to verify existing signals and broaden the pool of data available for evaluation.

This database, for the interim, is the MHRA Sentinel system. The data is then analysed via the Empiricia system where data mining analysis is performed on this wider data set. The DISD system is the combination of both the database and signal analysis system.

The outputs of these data mining runs will be used by the AU-3S Joint Signal Management (JSM) Group, which launched in April 2021, to investigate potential signals. The MHRA provides technical support to the AU-3S JSM Group's analysis and interpretation of the signal reports.

Why do we need it?

The AU-3S system seeks to complement the WHO/Uppsala Monitoring Centre (UMC) system by creating a platform to look at African data in the African context. It enhances the ownership of African data which will be shared with the global system run by WHO/UMC and at the same time provides an avenue for capability strengthening in safety data management for African PV systems.

The plan in the longer term is for a continental database (AfriVigilance) containing data from numerous different data sources across the end-to-end product lifecycle. The data will be readily transferable from the interim DISD system to the long-term AU-3S continental system.

What is the current status?

AEFI data from Ghana and Nigeria is now in the AU-3S DISD system. Data from South Africa and Ethiopia will follow shortly.

Data mining runs are now being performed to feed into the AU-3S Joint Signal Management Group.

> ***"We have limited capacity and capabilities to analyse the data we collect, so having access to the signal detection system is a major benefit"***
>
> **- Mafora Matlala, SAHPRA (Head of Pharmacovigilance Unit)**

The AU-3S Joint Signal Management Group has been established

Due to historically relatively low levels of adverse event reporting in African countries, AU-3S is focused on strengthening capacity for detecting and assessing safety signals that potentially would not be picked up in a single country's data. The AU-3S Joint Signal Management (JSM) Group has been set-up to validate, prioritise, and assess cross-country signals based on integrated data.

The AU-3S JSM Group does not replace the function of the national health product safety committees, but rather is designed to support and work with these national committees. It is not a decision-making body, but it will share its findings and recommendations with national committees for determining actions to be taken in country. The AU-3S JSM Group will also communicate findings to a wider AU audience through the AUDA network.

Additionally, the AU-3S JSM Group aims to:

- Promote collaboration on the topic of safety surveillance amongst African member countries
- Be a forum for technical support from reference medical products regulatory authorities to African regulatory authorities and other relevant public health programmes
- Strengthen the capabilities of AU-3S JSM Group members through engagement with experts from reference regulators and sharing of experiences and best practices across member countries

The AU-3S JSM Group's key roles are performed by a group of expert members with support from a Secretariat. Members include representatives from the AU-3S pilot countries' NRAs, EPIs, and national product safety committees and are supplemented with independent experts for key subject matter expertise. The secretariat is led by AUDA-NEPAD, with representatives from countries for capacity strengthening, and from the MHRA for technical support.

The AU-3S JSM Group has now been formed. The initial kick off meetings with both the secretariat and the AU-3S JSM Group have taken place and very positive feedback was received from both. The Terms of Reference have been agreed, and the election of the chairperson will be taking place at the next meeting in May.
The secretariat is currently in the process of analysing, validating, and prioritising the data from the first data mining run and developing the reports to take for discussion at the first AU-3S JSM Group meeting in mid-May.

> ***"The AU-3S JSM Group is an opportunity to learn from each other and to bring national data to the cross-country level for investigation. We are bringing the theory we learned into practice"***
>
> **- Mafora Matlala, SAHPRA (Head of Pharmacovigilance Unit)**

AU-3S Capability strengthening

AU-3S is facilitating capability strengthening training sessions with AU-3S's technical partner, the MHRA. These sessions aim to strengthen countries' safety surveillance capacities across a comprehensive range of topics and are recommended to anyone involved or interested in effectively monitoring the safety of medical products. These sessions aim to be general to safety surveillance and specific considerations for COVID-19 vaccines are included where relevant.

Four of the five planned training modules have been successfully completed by April 30, 2021. Each session, given in a webinar format, has seen between 100 – 250 attendees in participation, with 75% of individuals rating their experience as either very good or excellent on average across all 13 completed sessions. Once complete, a consolidated set of the training recordings, presentations, and Q&A documents will be made available for further use and distribution by all countries or organisations. Links to past trainings, which can be viewed by anyone, are included below.

> ***"Trainings were targeted at identified capability gaps and this improved the capacity of healthcare workers and staff"***
>
> **- Uchenna Elemuwa, NAFDAC (Deputy Director of PV/PMS)**

Module 1 – Data collection

1. Introduction to pharmacovigilance; Overview of spontaneous reporting schemes & promotion (Watch; Password: 2%n3C9+J)
2. ADR data and vaccine specific considerations; Tools and resources for data collection and management (Watch; Password: ap6=rWef)
3. Good practice coding (Watch; Password: *Vc2br5h)

Module 2 – Signal detection and management

1. Causality assessment (Watch; Password: ^B.2Ted&)
2. Signal detection, management, validation, and assessment (Watch; Password: Q%z1r!d#)

Module 3 – Benefit/risk assessment

1. Risk assessment (Watch; Password: $iJ30kf*)
2. Risk management plans (Watch; Password: Q=4JXzU6)
3. Periodic safety update reports (Watch; Password: &jPHK%5z)
4. Role of pharmacoepidemiology in pharmacovigilance; Epidemiology and regulatory decision making (Watch; Password: 3E%*05GY)

Module 4 – Safety communication

1. Risk communication – routine communication, crisis management, media handling, special considerations for vaccines (Watch; Password: !xSru8N5)
2. Decision making in communications (Watch; Password: 38@Dca51)

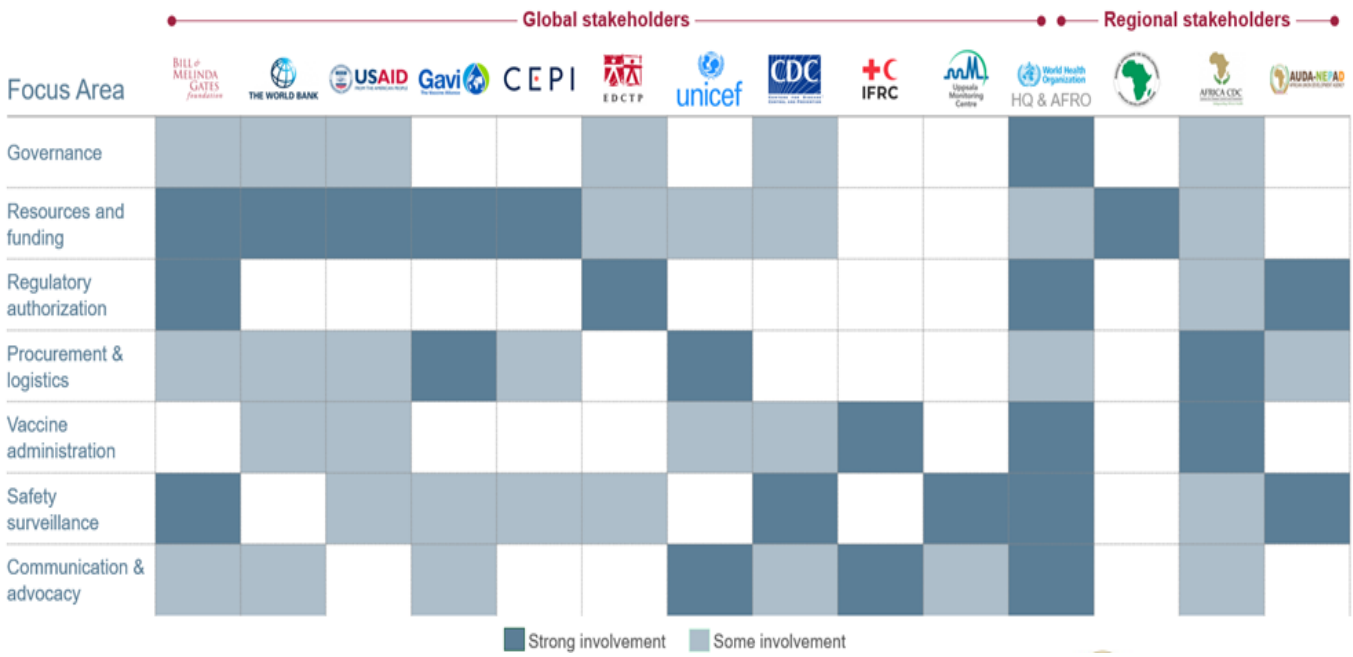
Module 5 – Pharmacovigilance expert advisory committee

(access links available June 2021)

1. National safety committees – experience from the UK
2. Joint committees

AU-3S COVID-19 initiatives mapping

AU-3S has conducted a mapping to understand the key continental and global stakeholders' major initiatives related to the COVID-19 emergency response in Africa. This information was gathered through desktop research and interviews held directly with stakeholders. The research focused on initiatives surrounding vaccine administration, safety surveillance, and communication and advocacy, as well as mapped initiatives relating to governance, funding, regulatory authorisation, and vaccine procurement and logistics.



Extract from initiatives map - accurate as at March 2021

Highlighted fields indicate focus areas along the vaccine delivery chain where a particular stakeholder has ongoing initiatives for COVID-19 vaccine delivery

The mapping found several key insights:

- Most global and regional stakeholders expanded their scope of support and launched initiatives beyond their traditional activities to support Africa in managing the COVID-19 pandemic
- There are stakeholders providing strategic and technical support across all focus areas mapped
- From mapped activities, there appears to be some overlap of initiatives; however, collaboration can avert this risk and avoid duplication
- Most stakeholders are collaborating with other organisations and ambitious multi-stakeholder initiatives have been launched (e.g. COVAX), while regional forums ensure coordination off all stakeholders have been put in place (e.g. African Vaccine Delivery Alliance)

The AU-3S team has played a key role in information sharing, transparency, and driving connection between the various safety initiatives to ensure that opportunities for collaboration in Africa and with AU-3S pilot countries are not missed.

> ***"This research is helpful for us to coordinate with other active players when planning our own COVID-19 vaccine initiatives"***
>
> **- Technical Director of global organization**

Upcoming AU-3S perspective on safety surveillance in Africa

The COVID-19 pandemic and COVID-19 vaccines rollout, by their unprecedented nature and record timelines respectively, further strengthen the importance of safety surveillance. To support stakeholders in conducting safety surveillance, the World Health Organisation has published the "COVID-19 Vaccines: Safety Surveillance Manual".

This manual is a comprehensive set of guidelines that all countries are encouraged to leverage as a core document in ensuring the successful safety surveillance of their populations during the COVID-19 vaccines rollout.

The World Health Organisation has also released a protocol for active vaccine safety surveillance titled "Cohort event monitoring (CEM) for safety signal detection after vaccination with COVID-19 vaccines" – based on the principles outlined in the above-mentioned manual.

AUDA-NEPAD will shortly release a publication that aims to provide a series of reflections to successfully implement the guidance provided in these documents, within the context of Africa. In addition, this publication will provide an overview of relevant tools, materials, and initiatives to support African countries to effectively implement safety surveillance of COVID-19 vaccines and future medical products. It will also provide relevant key learnings based on the experience of the AU-3S programme. We hope that you are looking forward to the release! The publication will be made available on the AU-3S microsite and will be distributed to the AU-3S mailing list.

Get to know the AU-3S team

Prof. Aggrey Amball

African Union Development Agency Supervisor and Advisor to AU-3S

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Mercedes Leburu

AU-3S Programme Officer: Project Management

Ladji Sidibe

AU-3S Programme Officer: IT and Website

Modupe Adeyemo

AU-3S Programme Officer: Governance & Policy

Join the AU-3S team

We currently have the following positions available:

- AU-3S Programme Officer: Policy Advisory Officer
- AU-3S Programme Officer: Health Products Safety Surveillance

If you are interested in applying for any of the above roles or have any enquiries, please email AU3S@nepad.org

Links to additional safety-related resources

Reports on the use of COVID-19 vaccines

COVID-19 vaccines are arguably the most important tool in the fight against the virus. The vaccines prevent severe cases and deaths from COVID-19 infections. However, health regulators agree that vaccines will present common mild side effects such as headache, fatigue, fever, and nausea. In rare cases, moderate to acute adverse events might occur. Bearing this in mind, it is important for governments and health authorities to inform and reassure the public on the safety and the efficacy of the vaccines.

Below are some key links to COVID-19 vaccines safety related resources:

- **CDC (USA) and FDA (USA)** - *Morbidity and Mortality Weekly Report (MMWR): Allergic reactions including anaphylaxis after receipt of the first dose of the Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020*. Accessible: Link
- **CDC (USA)** - *Local reactions, systemic reactions, adverse events, and serious adverse events: Moderna COVID-19 Vaccine*. Accessible: Link
- **CDC (USA)** - *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*. Accessible: Link
- **CDC (USA)** - *Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination*. Accessible: Link
- **MHRA (UK)** - *Coronavirus vaccine - weekly summary of Yellow Card reporting*. Includes safety considerations on the Pfizer/BioNTech and Oxford University/AstraZeneca COVID-19 vaccines. Accessible: Link
- **WHO** - *WHO statement on AstraZeneca COVID-19 vaccine safety signals*. Accessible: Link
- **African Union and Africa CDC** - *Statement to African Union Member States on the deployment of the AstraZeneca COVID-19 Vaccine to the continent and concerns about adverse event reports coming from Europe.* Accessible: Link

Active surveillance

The WHO defines active surveillance as an active system for the detection of adverse events. This is achieved by active follow-up after vaccination. The WHO further recommends that countries are to ensure that key passive surveillance objectives are met before incorporating aspects of active surveillance.

The WHO active surveillance protocol can be used to assist low- and middle-income countries monitor previously unrecognised and unsuspected adverse reactions to COVID-19 vaccines. The MHRA and FDA have provided further details on their active surveillance across key topics for COVID-19 vaccines.

Further information on these recommendations can be found in the links below:

- **WHO** - *Protocol template: Cohort Event Monitoring (CEM) for safety signal detection after vaccination with COVID-19 vaccines*. Accessible: Link
- **WHO** - *Evaluation of COVID-19 vaccine effectiveness.* Accessible: Link
- **MHRA (UK)** - *Report of the Commission on Human Medicines Expert Working Group on COVID-19 vaccine safety surveillance*. Accessible: Link
- **FDA (USA) and others** - *COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol.* Accessible: Link

Vaccine advocacy and risk communications

To build public trust in the safety of COVID-19 vaccines, governments and key stakeholders must devise a clear risk communication strategy and increase vaccine advocacy campaigns. These campaigns will be critical in vaccine acceptance, and building trust among the general population that the vaccines are safe and critical to combating the virus.

Africa CDC, working with other stakeholders including AU-3S, monitors reports of adverse events following immunization for all COVID-19 vaccines, and provides further guidance to member states.

More information on best practices can be found on the links below:

WHO AFRO and others - Overview of Africa Infodemic Response Alliance (AIRA) and an infodemic management crash course. Accessible: Link

WHO AFRO and others - Viral Facts Africa is an initiative to combat online health misinformation. The initiative is producing an array of content for easy sharing primarily on social media sites. Accessible: Press release, Website, Facebook, Instagram, Twitter

UNICEF - *Vaccine misinformation management field guide: Guidance for addressing a global infodemic and fostering demand for immunization*. Accessible: Link

IFRC - *COVID-19 Global Risk Communication and Community Engagement Strategy*. Accessible: Link

IFRC - *Community feedback package*. Tools and guidelines to listen and respond to communities in response to COVID-19. Accessible: Link

IFRC - *Africa Community Feedback Reports.* Weekly reports providing an analysis of beliefs, fears, and rumours. Accessible: Link

IFRC - *Ask Dr. Ben*. Ad-hoc factsheets where top 4-5 questions / rumours posed by communities are addressed: Link

The African Union Development Agency - NEPAD (AUDA-NEPAD) was established in 2018 as part of the global reforms geared at improving the African Union's impact and operational efficiency

The African Union's Smart Safety Surveillance (AU-3S) programme was launched in 2020, with the long-term goal of strengthening the safety surveillance of medical products across Africa

Spotlight: The Smart Safety Surveillance Newsletter in Africa is a newsletter published by AU-3S which provides an update on safety surveillance in Africa and key progress made by the AU-3S programme

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