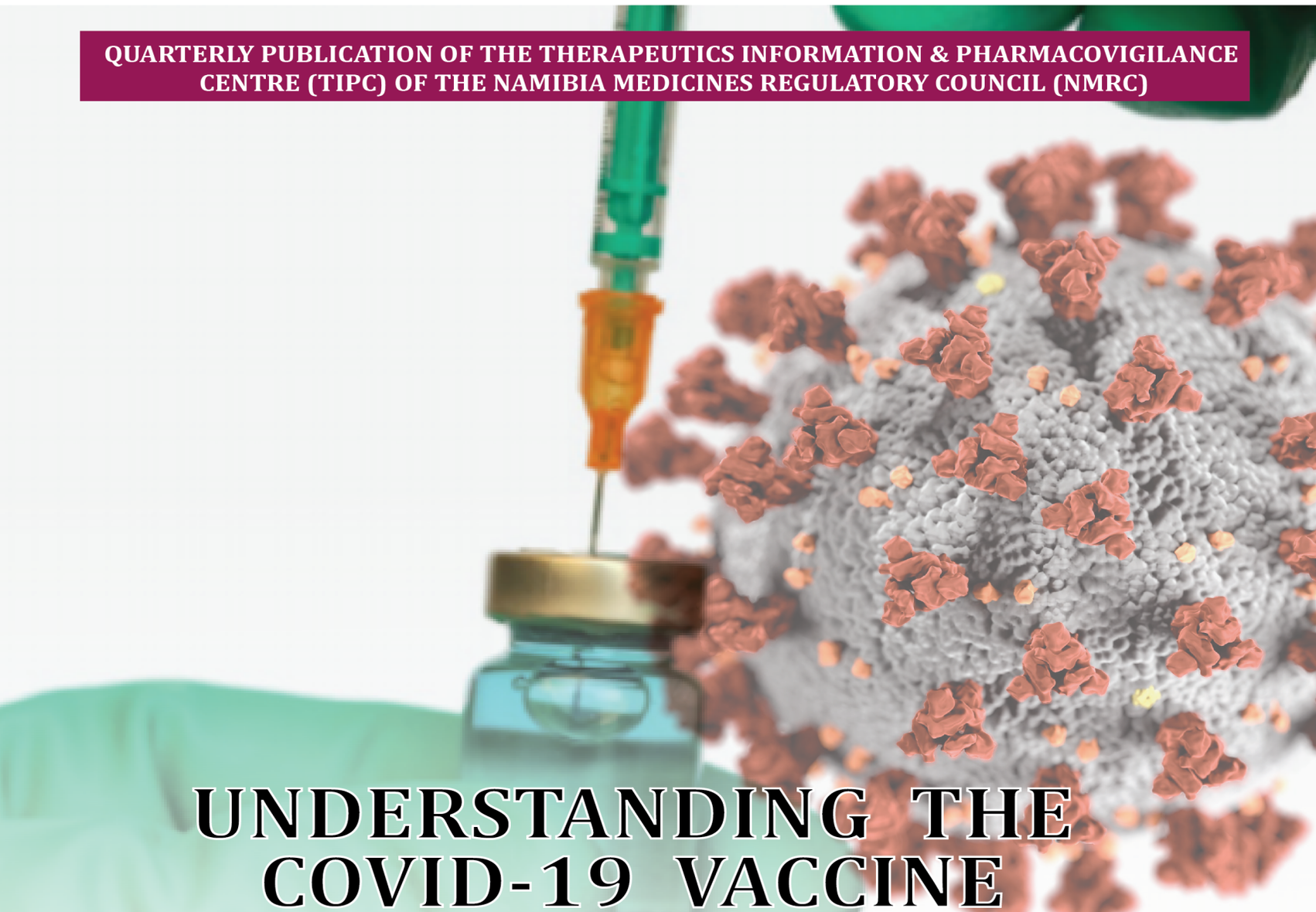
THE NAMIBIA
MEDICINES WATCH
UPDATES FOR HEALTHCARE PROVIDERS

Republic of Namibia
Ministry of Health and Social Services

QUARTERLY PUBLICATION OF THE THERAPEUTICS INFORMATION & PHARMACOVIGILANCE CENTRE (TIPC) OF THE NAMIBIA MEDICINES REGULATORY COUNCIL (NMRC)



UNDERSTANDING THE COVID-19 VACCINE SURVEILLANCE

In this issue

Volume 5, Issue1, Oct - Dec 2021

EDITORIAL POLICY

The Namibia Medicines Watch is a specialised publication that provides comparative information on medicines and communicates all local and international efforts that contribute to the availability of information to improve medicines safety and rational use. All articles published in the Namibia Medicines Watch must have relevance to the public and private health sectors of Namibia. The Namibia Medicines Watch is independent of any form of sponsorship from both local and international pharmaceutical industries. The bulletin's primary focus is to provide information that will contribute to improvement in the management and safety of patients. The editorial team and other key contributors to the publication are required to provide full disclosure of conflict of interests.

Acknowledgement

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The 4th NMRC

Anna Shimbulu / Johannes ǂGaeseb
NMRC Secretariat

The Namibia Medicines Regulatory Council is a statutory body that regulates and controls medicines and related products that are circulating on the Namibia market as defined by the *Medicines and Related Substances Control Act* (Act No. 13 of 2003). The responsibilities of the Council include registration of medicines, control of importation of medicines and monitoring their quality and safety. It has an oversight on the activities of its stewardship in developing policies, recommending laws and regulations for control of medicines and related products.

As per the Act (Act No. 13 of 2003), the council is appointed by the Minister of Health and Social Services and will have 12-member constituting of the following expertise:

- Three pharmacists
- Three medical practitioners
- One registered nurse
- Two veterinarians nominated for appointment by the Minister of Agriculture
- One legal practitioner nominated for appointment by the Minister of Justice
- One practitioner who in the opinion of the Minister has sufficient knowledge on medicines and related substances and
- One other person

The 4th Namibia Medicines Regulatory Council was appointed by the Minister of Health and Social Services, Dr Kalumbi Shangula, in January 2020 for a period of three years.

The Minister during the inaugural meeting urged the Council to be diligent, firm and yet fair in their operations that should be guided by the provisions of the Act.

The NMRC committees

The Council in turn appoints technical committees to assist it in carrying out its mandate of regulating the sale and use of medicines. The various technical and advisory committees, which have additional members outside the Council, are appointed on the basis of their relevant expertise. The following are the committees:

- Clinical Committee
- Legal and Advertising Committee
- Medicines Scheduling Committee
- Complementary Medicines Committee
- Pharmaceutical and Analytical Committee
- Veterinary Medicines Committee

As the Council conducts its meeting every three months, it has appointed an executive committee (EXCO) as provided for by the Act, which constitutes the chairperson and four other members of the Council. The EXCO may exercise powers and perform functions of the Council during periods between the Council meetings.

th NMRC

NMRC Secretariat

The Secretariat to the Council, headed by the Registrar of Medicines is the administrative and technical arm of the NMRC that handles all correspondences to and from the Council. The four technical sections that constitutes the Secretariat are the Medicines Registration; Inspections and Licensing; Quality Surveillance Laboratory (QSL) and Therapeutics Information and Pharmacovigilance Centre (TIPC).

The following are the appointed Council members

COUNCIL MEMBERS

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National training on TB/HIV medicines active surveillance

Nadine Mouton/Anna Shimbulu
NMRC Secretariat

In 2019, a Technical Working Group (TWG) was established at the national level to provide guidance and stewardship on technical aspects related to medicines safety in the management of HIV and TB. The initiative was brought forth for the intensive monitoring of new anti-TB medicines and novel regimens in the management of multidrug resistant/extensively drug resistant (MDR/XDR) TB, whose safety profiles were not well established. In addition, new medicines and optimised regimens were also introduced in the management of HIV in Namibia. The primary focus of the TWG is to oversee the monitoring of medicines safety and prevention of adverse events related to the management of HIV and TB.

In December 2019, a National Training of Trainers (ToT) on TB/HIV medicines active surveillance was conducted to introduce the concept of active drug safety monitoring and to prepare the regions for active collection and reporting of adverse reports to the Therapeutic Information and Pharmacovigilance Centre (TIPC). However, the unexpected emergence of the COVID-19 pandemic shortly after the training slowed the implementation of this activity. A refresher and implementation training was therefore necessary to ensure that this activity is aggressively reactivated.

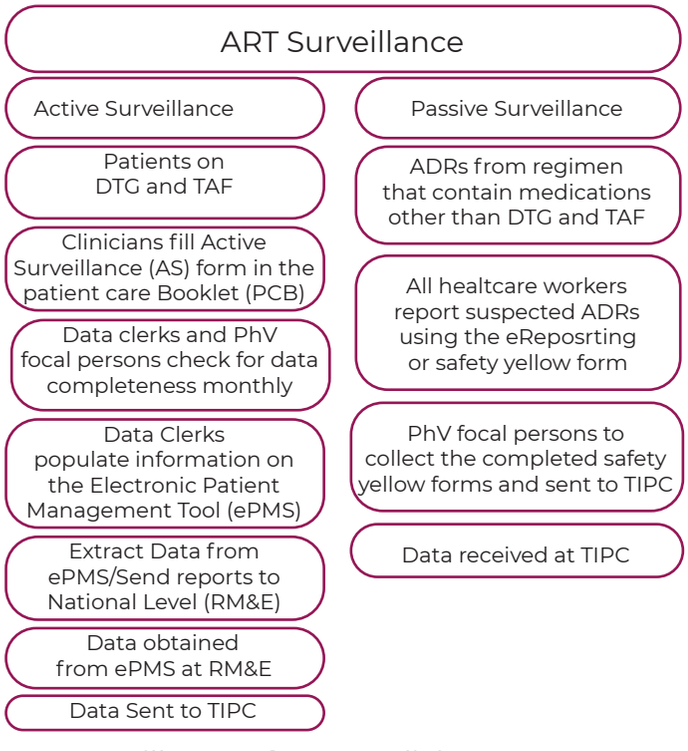
The Therapeutic Information and Pharmacovigilance Centre (TIPC), under the Namibia Medicines Regulatory Council (NMRC) in collaboration with the Directorate of Special Programs (DSP) conducted a virtual *National Training on TB/HIV Medicines Active Surveillance,*

The objectives of the training were;

- To equip participants with the basic requirements for Pharmacovigilance (PV) and TB/HIV management
- Introduce the concept of active drug safety monitoring (aDSM) for TB medicines and active surveillance for HIV medicines
- Introduce data collection tools and methods for implementing active surveillance
- Define and strengthen roles of Therapeutic Committees (TCs) in pharmacovigilance
- Capacitate individuals to train other healthcare professionals in their regions.

A total of 113 healthcare professionals from the various regions participated in the training via the Zoom platform. The training constituted a total of nine sessions with two case studies.

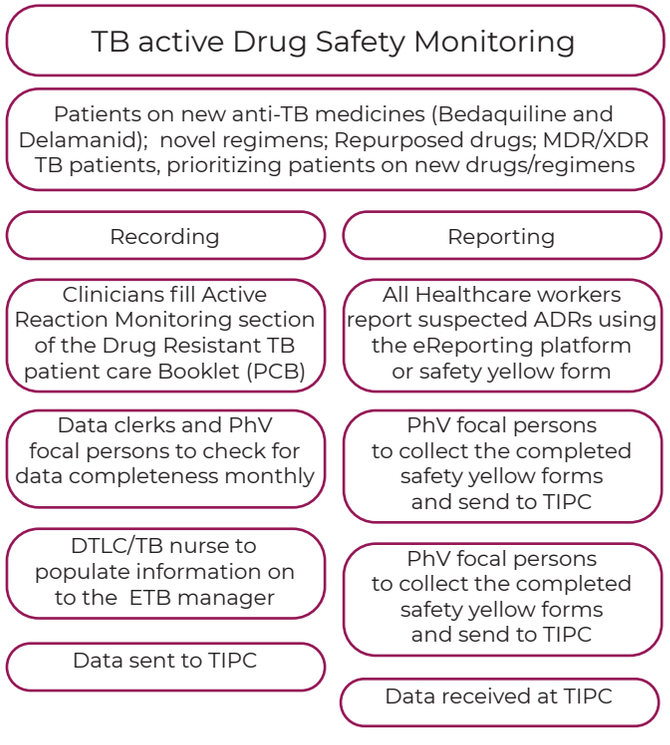
The active surveillance is expected to provide local safety data from the public healthcare sector.



A - Surveillance of HIV medicines

In light of this training, the participants are expected to put measures in place in their respective regions to ensure readiness for implementation. The TWG will provide the necessary support to the regions through assessments and communications with the focal persons.

The diagrams (A & B) below shows the algorithm of reporting and data collection for both TB and HIV medicines.



B - Surveillance of TB medicines

Dolutegravir and TAF based ART Regimens- Update on the current implementation of the Namibia ART Guidelines

Selamneh Wolkeba
Directorate of Special Programs

The management of HIV/AIDS has dramatically changed in the last few decades. This has happened mainly as the result of antiretroviral therapy (ART) which is known to improve the quality of life of people living with HIV (PLHIV) and to reduce mortality among these patients. ART encompasses using multiple antiretroviral (ARV) drugs from different classes that act on the different stages of the HIV life cycle.

For years, Namibia has been using combinations of medicines from Nucleoside Reverse Transcriptase Inhibitors (NRTIs) (e.g., abacavir, tenofovir, zidovudine), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) (e.g., efavirenz, nevirapine), and Protease Inhibitors (E.g., lopinavir, atazanavir) as first-line and/or second-line regimens in adults and children. Since 2019, dolutegravir from a new class of medicines, called Integrase Strand Transfer Inhibitor (INSTI) was the recommended medicine as part of both first and second-line regimens in the Namibian National Guidelines for Antiretroviral Therapy. In the same year, regimens containing dolutegravir 50 mg were introduced for eligible adults while children had to wait until July 2021, for the pediatric dolutegravir 10 mg formulation to become available in the market.

Studies have shown that dolutegravir has a greater genetic barrier to resistance compared to NNRTIs, which is also one of the reasons that necessitated the transition from efavirenz and nevirapine to dolutegravir based regimens. It has also demonstrated superior clinical efficacy. Paediatric dolutegravir 10 mg is a dispersible, scored tablet that is suitable for infants and children living with HIV (CLHIV) who are ≥ 4 weeks of age and weigh at least 3 kg up to less than 20 kg. This medicine has shown superior clinical efficacy and viral suppression when taken as recommended. It has also come with a simplified dosing frequency (once daily), ease of administration and free from the bitter taste that was observed with Lopinavir/ritonavir granules. As a preferred ART regimen for children, majority of children on treatment are expected to be on dolutegravir based regimen and it could be made part of second and even third line-regimen.

The 2019 National ART guidelines also introduced tenofovir alafenamide fumarate (TAF) as an alternative to tenofovir disoproxil fumarate (TDF). TAF is a prodrug of tenofovir and is a more potent medicine at a lower daily dose of 25 mg compared to TDF 300 mg. In addition to its dosing, efficacy and potency over TDF, TAF has a better safety profile on kidney function as the result of significantly

lower plasma levels of tenofovir while increasing intracellular delivery of the active moiety tenofovir-diphosphate. In addition, less bone demineralization was noted with TAF when compared to TDF. As a result, it is recommended to initiate patients on TAF-based regimens for those who are older than 50 years of age and with a history of either renal impairment or osteoporosis. Patients with a renal clearance between 30 and 59 ml/h can also benefit from TAF-based regimens.

Despite their life-saving and quality-of-life improving effects, ARVs have safety issues ranging from minor to serious adverse drug reactions (ADRs), with both short- and long-term effects. Some clinical trials and post-marketing surveillances have documented drug interactions and adverse effects against dolutegravir and TAF that include CNS-related adverse effects, weight gain, hyperglycemia, increased risk of neural tube defects, etc. Healthcare workers are advised to watch out for any possible drug interaction and adverse effects for patients on these medications and report to TIPC. In addition, MoHSS will communicate with all health facilities and healthcare workers to participate in the Active Surveillance of these new medicines in the appropriate channels.

COVID-19 Vaccine Safety

Anna Shimbulu
NMRC Secretariat

The safety monitoring of any medicinal product applies throughout its life cycle, from the pre-approval in clinical trials to the post-approval stage during clinical use.

In countries where vaccines are manufactured, the regulatory authorities oversee their development process by approving and monitoring the clinical trials, evaluating the results before licensing the vaccine for use. Strict international standards on acceptable ethical and clinical practice are considered.

Once sufficient efficacy and safety data from Clinical Trials becomes available it is compiled into a dossier that is submitted to the regulatory authorities. A benefit risk assessment is conducted, and if the safety and efficacy balance is favourable, the vaccine is approved for emergency use. This authorization is a mechanism to facilitate the availability and use of medicines including vaccines during public health emergencies, such as COVID-19 pandemic. The NMRC may authorise the use of unregistered medicinal products in emergency situations when there are no available alternatives.

At the point of marketing authorisation, the available safety data has mostly been generated from the clinical trials and little is known about clinical experience in the real world. There are limitations to clinical trials in highlighting a complete safety profile of any medicinal product. The table below shows the difference between conditions in a clinical trial and post-marketing experience:

Clinical trials	Post-marketing exposure
Smaller sample size (at least 15 000, powered for efficacy)	Much larger population (millions)
Limited duration of exposure to medicinal product or follow up	Ongoing use and longer period to observe exposure outcome
Homogenous sample population	Wider population with different characteristics
Relatively healthy participants with minimal comorbidities; mostly exclude special population	Used by people with multiple comorbidities (and concomitant medicines), includes children, pregnant woman and the elderly

In light of these limitations, rare and long-term adverse events can only be detected during post marketing exposure of the vaccines. It is for this reason that, ongoing safety monitoring is required to ensure that the benefits continues to outweigh the potential and actual risks.

Adverse events following COVID-19 vaccination

An adverse event following immunisation (AEFI) is defined as any untoward medical occurrence that follows immunisation but does not necessarily have a causal relationship with the vaccine. It may be an unfavourable symptom that a recipient complains of; an abnormal laboratory finding; sign or disease observed by a medical staff.

Minor and short-lived symptoms, such as headache, fatigue, fever and chills, muscle and joint pain as well as pain at the side of infection are expected with the COVID-19 vaccines as observed in clinical trials. These are also common with other vaccines.

Rare occurrences of severe and serious AEFIs have been detected with the global use of the COVID-19 vaccines.

Vaccine-induced immune thrombocytopenia and thrombosis (VITT), is a new syndrome that was observed in a small number of individual who received the ChAdOx1 nCoV-19 adenoviral vector vaccine (AstraZeneca, Vaxzevira™, Covishield™). Similar findings were also observed in a much smaller number of individuals who received the Ad26.COV2.S vaccine (Johnson & Johnson), another adenoviral vector vaccine [1]. The true causal relationship between VITT and the vaccines has not yet been established, but was considered plausible by the WHO. According to the European Medical Agency (EMA), the estimated incidence after vaccination with the ChAdOx1 nCoV-19 vaccines is between 1 in 125 000 and 1 in 1 million, a very rare occurrence [2]. More than 80% of the cases were females between the ages of 20 to 55 years [2].

Myocarditis and pericarditis were reported after vaccination with mRNA vaccines (Pfizer/BioNTech and Moderna). These cases are very rare, with an estimated incidence of about 4.8 cases per 1 million [3]. They were found to be generally mild and respond well to conservative treatment [4]. The cases were reported more often after the second dose and within several days after vaccination. Confirmed cases have occurred amongst people aged 30 and younger, mostly in the males. The causal relationship between the events and the vaccine is yet to be confirmed [4].

An increased risk of Guillain-Barré Syndrome (GBS) has been observed following vaccination with the adenovirus vector COVID-19 vaccines, Johnson & Johnson and Astrazeneca/Vaxzevira. By June 2021, a total of 227 cases of GBS have been reported and around 51.4 million doses of Vaxzevria have been administered in the EU/EEU [5]. In the same month, the US FDA recorded 100 cases of GBS, with approximately 12.2 million doses of the Johnson & Johnson vaccine [5]. Most people fully recover from GBS [6].

Although the available evidence suggests an association, it is insufficient to establish a causal relationship, and more rigorous studies would be required to assess the significance of these events [6], [5]. Rare cases of GBS have also been observed with other vaccines including some influenza vaccines and the shingles vaccine, Shingrix® [6].

It is noteworthy that the benefits of receiving the COVID-19 vaccines outweigh the risks of experiencing the serious AEFIs that have been observed thus far.

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3. G. A. Diaz, G. T. Parsons and S. K. Gering, "Myocarditis and Pericarditis After Vaccination for COVID-19," JAMA Network, 4 August 2021.
4. "Centers for Disease Control and Prevention," 17 August 2021. [Online]. Available: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.
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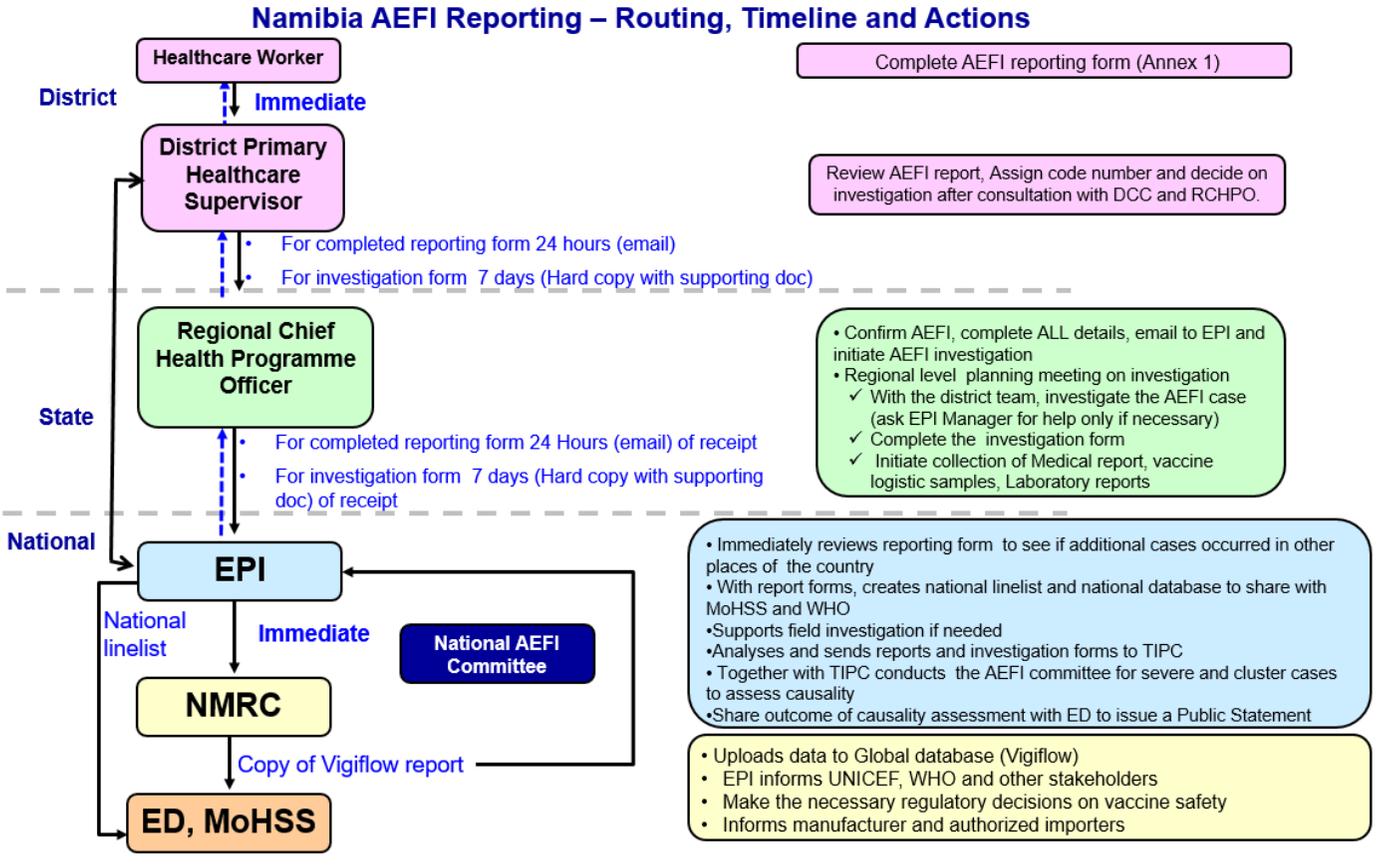
An overview of AEFI Surveillance in Namibia

Anna Shimbulu
NMRC Secretariat

The expanded program for immunisation (EPI) is a program under the Primary Health Care Directorate of the Ministry of Health and Social Services. The program is responsible for all vaccination campaigns throughout Namibia including the COVID-19 vaccination. The program ensures that the vaccines used in the country meet internationally accepted standards in terms of safety, effectiveness and quality.

The safety surveillance of all vaccines in Namibia is integrated into the vaccine delivery system. The EPI in collaboration with the NMRC oversees the reporting of adverse events following immunisation (AEFIs) throughout the country.

AEFI Reports are collected from the various health facilities country-wide. The following figure illustrates the Namibian AEFI reporting system.



The Namibian AEFI reporting system

The Namibian AEFI reporting system

The healthcare workers are responsible to identify, assess and diligently report suspected adverse events they observe or reported to them by patients or caretakers. They inform patients about any expected adverse effects known to occur with a particular vaccine and appropriately manage the AEFIs. Healthcare workers should also encourage people being vaccinated to report any adverse events they experience after vaccination.

Serious, severe or cluster AEFIs should be reported immediately and investigated to collect more information pertaining to the case. These cases are then reviewed by the interdisciplinary national AEFI committee to assess causality between the vaccine and the reported event. The causality assessment exercise helps to determine the likelihood that the event might have been caused by the vaccines received or occurred by chance.

Data collected from the surveillance system as well as the findings of the committee is ultimately shared with Namibia Medicines Regulatory Council as well as the Ministry of Health. These safety information gathered are used to make programmatic and regulatory decisions that ensure vaccines and vaccination are safe.

Statistics on the reported AEFIs with COVID-19 vaccines

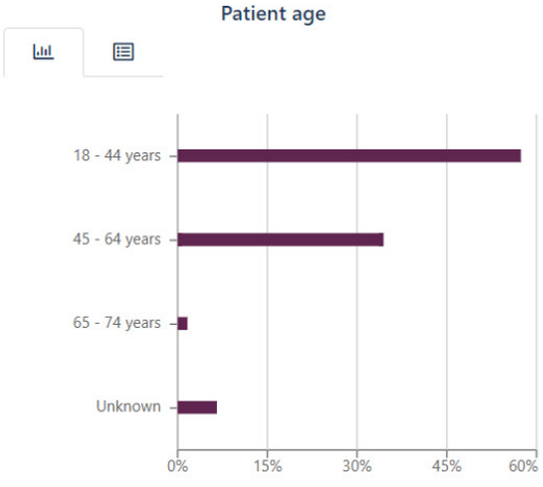


Figure 1: AEFI reports by age.

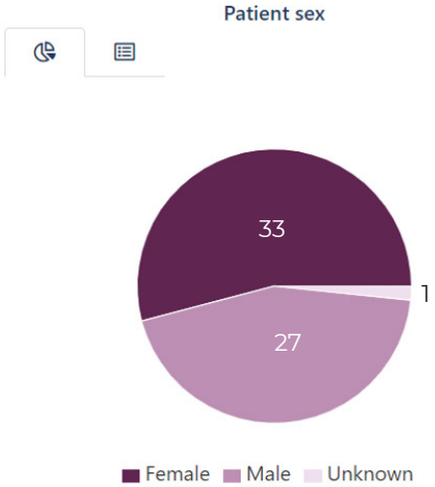


Figure 2: AEFI reports by sex.

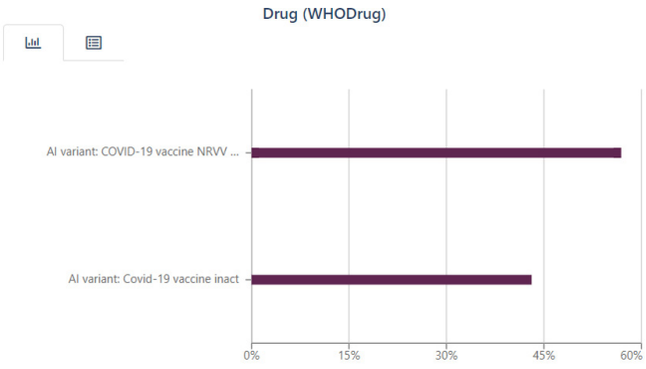


Figure 3: AEFI reports by vaccine type; AI variant: COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) = Astrazeneca / Covishield; AI variant: Covid-19 vaccine inact = Sinopharm.

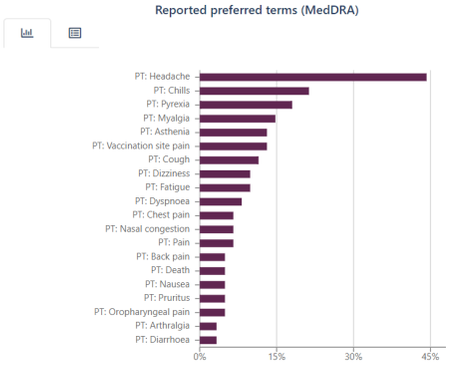


Figure 5: Percentage of AEFI reports by type of reaction.

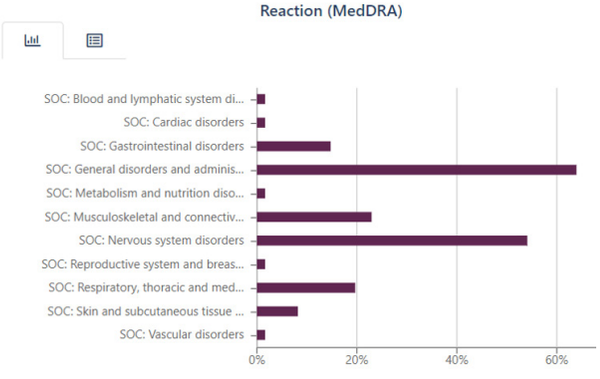


Figure 3: Percentage of AEFI reports by organ System.

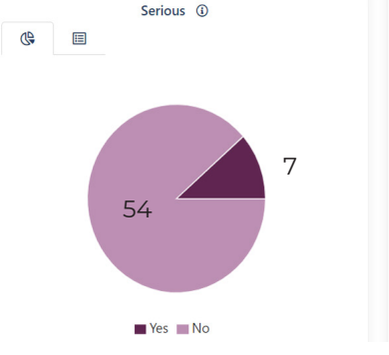


Figure 6: Indication of seriousness for the reporde AEFIs

Figure 7: Seriousness criteria of the serious AEFIs

A total of 61 AEFI reports have been received by the NMRC from the EPI so far. Majority of these were in the age group of 18-44 years (57.4%), followed by 45-64 years (34.4%), with only 1.6% in the 65-74 years, Figure 1. The females represents 54.1% (33), with the males making up 44.3% (27) of the reports, Figure 2.

Of all the AEFIs reported, 57.4% were vaccinated with AstraZeneca/Covishield vaccine, whilst 44.3% were from the Sinopharm vaccine, Figure 3.

The majority of the AEFIs were categorised as General disorders and administration site conditions (63.9%), followed by Nervous system disorders (54.1%) and Musculoskeletal and connective tissue disorders (23.0%), Figure 4. The top 5 frequently reported AEFIs by preferred terms are, Headache (44.3%), Chills (21.3%), Pyrexia (18.0%), Myalgia (14.8%) and Asthenia = Injection site pain (13.1%), Figure 5.

Seven (7) of the reported AEFIs were considered serious, of which five (5) were hospitalised and four (4) died, Figure 6&7. The serious cases are still under review by the AEFI committee to assess if there is a causal link between the vaccines and the events.

Reporting Adverse Events

1. Adverse events following use of medicinal products **other than vaccines** are reported directly to the TIPC:
   - e-Reporting - https://primaryreporting.who-umc.org/NA (link also available on the website (https://nmrc.gov.na/tipc1)

You may also scan the following QR code with your mobile phone to report

- Complete the Adverse Drug Reaction (Safety Yellow) form and send to:
  - Your local pharmacy
  - Email to info.TIPC@mhss.gov.na
  - Fax2email: 088 660 6781
  - Call TIPC @ 061 203 2406

2. Adverse Events Following Immunisation (**vaccines**) are first received by the Expanded Programme for Immunisation:

- Complete the AEFI reporting form (specific form for COVID-19 vaccines - page 25)
- Send form to Primary Healthcare Supervisors in the health facilities
- Call the national EPI focal person @ 081 669 1707

THE QUALITY SURVEILLANCE LABORATORY'S ROAD TO ISO/IEC 17025:2017 ACCREDITATION

Lavinia Mbongo / Samuel Shuuya
NMRC Secretariat

Every year, manufacturers that form part of the global pharmaceutical industry produce new pharmaceutical products to be used in various health sectors. However, it is worth noting that just because a new or existing drug was discovered and eventually approved for production, does not necessarily mean that it is 100% safe for human consumption. Pharmaceutical products are formulated with different compounds and adding too much or too little of a specific compound can lead to serious side effects, health risks and even death. It is therefore vital that these pharmaceutical products are quality assured for the end user by reputable and accredited quality control testing laboratories.

The Quality Surveillance Laboratory (QSL) is the testing arm of the Namibia Medicines Regulatory Council (NMRC), the statutory body established in terms of the Medicines and Related Substances Control Act, 2003 (Act No.13 of 2003), to regulate the use of medicines in Namibia. Since its inception in 2002, QSL has been, although commendable, carried out its testing operations without accreditation. Accreditation involves a competency assessment of the laboratory to perform its activities.

In order to conduct its testing activities with complete confidence from its customers and the general Namibian public, the laboratory must be accredited to the applicable standard (ISO/IEC 17025:2017) by an independent accreditation body. This process is now embraced by governments as a key activity in many regulated areas because of the benefits it brings to help governments meet their responsibilities and safeguard the public.

A section of the laboratory

The QSL, with the assistance of Global Fund and the Ministry of Health and Social Services has embarked on the journey towards acquiring the ISO/IEC: 17025: 2017 accreditation from SADCAS. In July 2021, Spectrum Namibia Laboratories & Consultancy was appointed as a consulting entity to assist in reviewing the QSL's Quality Management System (QMS) and address the gaps in order to position the QSL at a level where it is ready for accreditation. The review was completed in mid-July 2021, subsequently the identified gaps were addressed and the implementation of the new QMS has commenced.

Some of the laboratory personnel participating in the QMS review

With the implementation of the new QMS underway, the QSL has submitted an application to the Southern African Development Community Accreditation Services (SADCAS) in August 2021. An assessment for accreditation will then be initiated and recommendations depending on the laboratory's conformity to the requirements of the ISO/IEC 17025:2017 standard will be provided. Although accreditation is a costly process, the investment is worthwhile.

ANTIGEN TESTING FOR COVID-19

Mary Mataranyika
National Laboratory Pillar

The COVID-19 antigen test

The Coronavirus disease 2019 (COVID-19) caused by the Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) has heavily impacted global health and Namibia is no exception. Since the beginning of the pandemic, the country relied on real-time Reverse Transcription Polymerase Chain Reaction (rRt-PCR) for testing to diagnose people infected with SARS-CoV-2 [3]. The use of this Nucleic Acid Amplification Tests (NAATs) has been the gold standard to detect SARS-CoV-2 infection. The Antigen-detection diagnostic tests have been developed to directly detect the virus proteins produced by replicating viruses in respiratory secretions [1].

Although rRt-PCR is the gold standard for diagnosis, it is expensive and require, technical expertise and long result turnaround times (TATs). On the other hand, the Antigen-detection diagnostic tests have been found to be rapid, inexpensive and easy to scale-up testing capacity [4].
The rapid diagnostic tests (RDTs) can be used outside the laboratory conditions in health facilities or institutions where trained medical personnel have been certified to perform the test. The test can be performed in areas such as decentralized settings that are at or near the point of care (POC) [3].

Antigen tests are generally less sensitive than molecular tests, and their clinical performance depends on the circumstances in which they are used. It should be noted that due to the lower sensitivity, false negative antigen test results are possible and testing is most accurate when there is a high pre-test probability of SARS-CoV-2 infection (e.g. high prevalence of infection in the community, a patient whose clinical picture is consistent with COVID-19, etc.). In addition, viral carriage is highest early in infection; therefore, antigen tests are more likely to detect a true positive when used earlier.

Healthcare providers conducting antigen testing on either symptomatic or asymptomatic populations must be aware of the potential for false negative or false positive results. When the result of an antigen test does not fit the clinical circumstances of the patient, a molecular test is recommended for confirmation of the antigen test result.

The results should be interpreted with consideration of the pre-test probability of infection, including the patient's recent exposures and presence/absence of clinical signs and symptoms consistent with COVID-19. The following table should be used as guidance in interpreting results [1].

Test Result	Person Being Tested		
	Symptomatic Person	Asymptomatic person with close contact to known COVID-19 case	Asymptomatic person without close contact to known COVID-19 case
Positive	• Prompt Isolation	• Prompt Isolation	• Presumptive current infection • Prompt isolation while awaiting confirmatory PCR test result • Patients with positive confirmatory PCR test should be isolated
Negative	• No antigens were detected • Confirm negative antigen result with a PCR test • Prompt isolation while awaiting confirmatory test result	• No antigens were detected • Confirm negative antigen result with a PCR test • Prompt isolation while awaiting confirmatory test result	• No antigens were detected • No additional case follow-up necessary • Reinforce prevention measures

Take note: Close contact is defined as being within 2 meters of someone known to have COVID-19 for a total of 15 minutes or longer over a 24-hour period, or having exposure to respiratory secretions from an infected person starting from two days before the person became sick until the person was isolated.

As a result, the kits may be utilized in the following specific settings for testing [3]

- Screening of patients due for emergency surgeries and emergency need for admission to urgent care wards.
- Screening of members of the population who are closecontactsofconfirmed cases in settings of high community transmission where RT-PCR is not readily available.
- Screening of members of the community being tested due to nature of work (e.g. mineworkers, sea going workers etc.).

Ag-RDT kits must meet the minimum performance requirements of ≥80% sensitivity and ≥97% specificity compared to an approved NAAT molecular test. Ag-RDT that are not currently authorized by the Namibia Medicines Regulatory Council (NMRC) and are intended for use must undergo performance validation by any locally accredited COVID-19 testing laboratory that performs PCR tests. Reference should be made to the latest NMRC Public Notice on the Regulatory Requirements for the Sale, Distribution and Use of COVID-19 Antigen Rapid Test Kits for information on the approval and use of the kits. Any adverse event, product related issue, suspected falsified product or suspected unapproved devices should be reported to the NMRC [2].

References

1. Virginia Department of Health. (2021). Interim COVID-19 Antigen Testing Recommendations. Available: https://www.vdh.virginia.gov/coronavirus/antigen-testing-recommendations/. Last accessed 9th July 2021.
2. NMRC, Public Notice 006/2021, 23 June 2021, Ref no: 10/1
3. National Laboratory Pillar COVID-19, National Testing Strategy, November 2020 (Revised June 2021)
4. World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays: interim guidance, 11 September 2020. Geneva: World Health Organization; 2020 (WHO/2019-nCoV/Antigen Detection/2020.1). Available from: https://apps.who.int/iris/handle/10665/334253.

SUBSTANDARD AND FALSIFIED MEDICINES

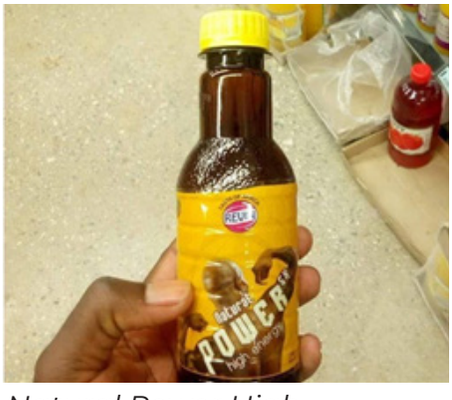
Nadine Mouton / Anna Shimbulu
NMRC Secretariat

A substandard medicine is an authorized product manufactured below quality standards or specifications. It is produced by a known manufacturer with no fraudulent intentions. Falsified medicines are intentionally and fraudulently mislabeled in a way that misrepresents their identity, composition or source, and are often produced under unregulated conditions with the actual manufacturer usually unknown. The following falsified products were found to be sold in some outlets in Namibia.

Big Booi Sex Booster for Men

This unscheduled product is marketed as herbal sex booster for men.
The manufacturer as well as the batch number were not indicated on the labelling. The NMRC's laboratory tested the product and detected the active sildenafil. This product was also reported to have been manufactured at an illegal laboratory in South Africa.

Big Booi Sex Booster for Men



Natural Power High Energy Drink sx

Natural Power High Energy Drink sx

This product is marketed as an energy drink, manufactured by Revin S.A.R.L (Zambia). It was also found to contain sildenafil. The packaging on the drink clearly states that it "increases libido" and is an "aphrodisiac". It also claims to "revitalise the body and mind". The above-mentioned products should not be sold in Namibia. Any person found in possession of these products will be prosecuted and the products confiscated.

International reports of counterfeit COVID-19 vaccines

On 16 August 2021, the WHO alerted on falsified Covishield™ COVID-19 vaccines whose authentic manufacturer is the Serum Institute of India. These vaccines were reported to be circulating in Uganda and India. The vaccine detected in Uganda had a similar batch number (B121Z040) to the genuine product, however the expiry date (10.08.2021) was falsified. The date of manufacture was not indicated on the labeling. The falsified vaccine in India came in a volume of 2ml, of which the actual manufacturer does not produce this volume. The batch number, manufacture date and expiry dates were not indicated

This vaccine has not been detected in Namibia, however vigilance is required from the pharmaceutical wholesalers/ distributors, pharmacists, healthcare workers who are vaccinating as well as the general public.

Regulatory Safety Updates

The following updates have been made to the package inserts of listed products.

Name of Product	Package Insert Safety Product
Ethambutol tablets	Contraindication Contraindicated in patients with known optic neuritis and poor vision, unless clinical judgement determines that it may be used. Interactions Avoid concurrent administration of ethambutol with aluminum hydroxide containing antacids for at least 4 hours following ethambutol administration. Side effects Thrombocytopenia, leucopenia, neutropenia, hypersensitivity, anaphylactoid reactions, hyperuricaemia, gout, pneumonitis, pulmonary infiltrates, with or without eosinophilia, anorexia, diarrhoea, hepatic reactions with hepatitis, jaundice, abnormal liver function test values, and very rarely hepatic failure, pruritus, urticarial, photosensitive lichenoid eruptions, bullous dermatitis, Stevens-Johnson syndrome, epidermal necrolysis, Interstitial nephritis, pyrexia
Pearinda Plus® (perindopril tert-butylamine salt and indapamide) tablets	Contraindication Concomitant use of fluoroquinolones with ACE inhibitors/Angiotensin Receptor Blockers such as PEARINDA PLUS is contraindicated in patients with moderate to severe renal impairment (Creatinine Clearance ≤ 30ml/min) and in elderly patients. Warnings and special precautions Concomitant use of fluoroquinolones and ACE inhibitors/Angiotensin Receptor Blockers such as PEARINDA PLUS may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and in elderly patients. Renal function should be assessed before initiating treatment, and monitored during treatment, with fluoroquinolones or ACE inhibitors/Angiotensin Receptor Blockers whether used separately and/or concomitantly. Interactions Concomitant use of fluoroquinolones and ACE inhibitors / Angiotensin receptor blockers such as PEARINDA may precipitate acute injury. The mechanism of the possible interaction between the different classes of medicines, over and above different mechanisms of kidney damage, is unknown.
Cipralex (escitalopram oxalate) tablets	Special warnings and precautions for use Haemorrhage: there have been reports of cutaneous bleeding abnormalities, such as ecchymosis and purpura, with Cipralex. SSRIs/SNRIs may increase the risk of postpartum haemorrhage. Fertility, pregnancy and lactation Observational data indicate an increased risk (less than 2-fold) of postpartum haemorrhage following SSRI/SNRI exposure within the month prior to birth. Undesirable effects Female: postpartum haemorrhage

MINISTRY OF HEALTH AND SOCIAL SERVICES

ADVERSE EVENT FOLLOWING COVID 19 IMMUNIZATION (AEFI) REPORTING FORM

Name of health facility: Name of vaccination point:	☐ Outreach ☐ Mobile ☐ Health Facility	District Region	Date patient notified AEFI to Health System: (DD/MM/YYYY) Today's date: ((DD/MM/YYYY) Reporter's full name:
Patient Full name: Physical Address of Patient:	Patient's Mobile nr:		
Sex: Male ☐ Female ☐	Birth Date: (DD/ MM/ YYYY)) Age _____Years		If female; Pregnant ☐ Lactating ☐

Name of vaccine (Generic)	Name of Manufacturer	Batch/ Lot number	Expiry date	Dose (1st, 2nd, etc.)	Dosage	Date of vaccination	Time of vaccination

Adverse Event/s (Tick all that apply)

☐ Severe local reaction	☐	>3days	Describe AEFI (Signs and symptoms) here:
☐ Seizures	☐	Febrile ☐ afebrile	
☐ Abscess			
☐ Sepsis			
☐ Toxic shock syndrome			
☐ Encephalopathy			
☐ Thrombocytopenia			
☐ Anaphylaxis			
☐ Fever≥38°C			

Others (specify here, see list of other minor AEFI's on reference page:

Adverse Event/s:

Severe	Serious	
☐ Hospitalization ☐ Life-threatening ☐ Disabling	☐ Death Date of death (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ Autopsy done: ☐ Yes ☐ No ☐ Unknown	☐ Other medically important event (Specify) below: _____ _____ _____

Outcome of event at the time of the report:

☐ Fully recovered	☐ Recovered with sequelae	☐ Fatal- unrelated to reaction	☐ fatal - reaction may be contributory	☐ Fatal - due to reaction	☐ Unknown

Past medical history (including history of similar reaction or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction) other relevant information (e.g., other cases). Use additional sheet if needed:

District level to complete

Investigation needed? ☐ Yes ☐ No	If yes, date investigation planned: DD/MM/YYYY)

National level to complete

Date report received at national level DD/MM/YYYY)	Comments

AEFI reference note			
Characteristics	□ ***Vasovagal reaction***	□ ***Immediate allergic reaction***	□ ***Vaccine side effects***
Timing after vaccination	*With 15 minutes*	*15-30 minutes of vaccination*	*1 to 3 days*
Constitutional	□*Warm* □*Cold*	□*Feeling of impending doom*	□*Fever* □*Chills* □*Fatigue*
Cutaneous	□*Pallor* □*Diaphoresis* □*Clammy skinny* □*Facial warmth*	□*Urticaria* □*Flushing* □*Angioedema*	□*Pain* □*Erythema* □*Swelling* □*Lymphadenopathy*
Neurologic	□*Dizziness* □*Lightheadedness* □*Syncope* □*Weakness* □*Change in vision* □*Change in hearing*	□*Confusion* □*Disorientation* □*Dizziness* □*Loss of consciousness* □*Weakness* □*lightheadedness*	□*Headache*
Respiratory	□*Anxiety*	□*Shortness of breath* □*Wheezing* □*Bronchospasm* □*Stridor* □*Hypoxia*	*N/A*
Cardiovascular	□*Bradycardia*	□*Hypotension* □*Tachycardia*	*N/A*
Gastrointestinal	□*Nausea* □*Vomiting*	□*Nausea* □*Vomiting* □*Abdominal cramps* □*Diarrhea*	□*Vomiting* □*Diarrhoea*
Musculoskeletal	*N/A*	*N/A*	□*Myalgia* □*Arthralgia*

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