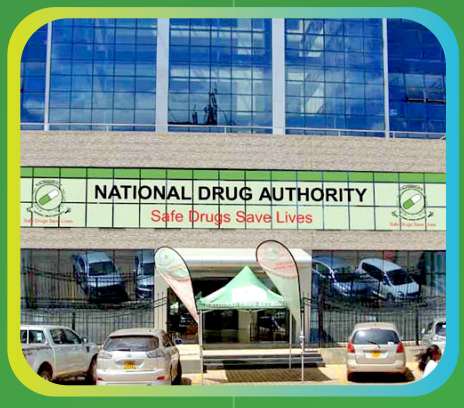
UGANDA
NATIONAL DRUG AUTHORITY
Safe Drugs Save Lives

PHARMACOVIGILANCE Bulletin

VOLUME 14, ISSUE 1, OCTOBER 2021

IN THIS ISSUE



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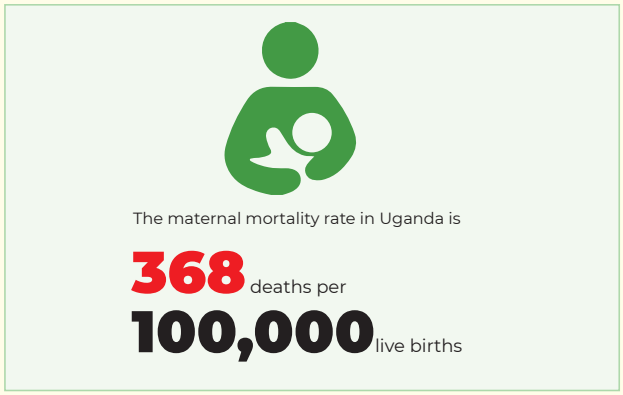
Foreword

Despite the ongoing Covid-19 challenges, Uganda observed World Patient Safety Day on 17th September 2021 together with other WHO member countries. This year's theme was "Safe maternal and newborn care" under the slogan "Act now for safe and respectful childbirth!" The maternal mortality rate in Uganda is 368 deaths per 100,000 live births and the causes are mostly preventable. We bring you highlights from the commemoration.

Medication safety is one of the ways to contribute to better outcomes for mothers and we have featured an article on Oxytocin to alert us to the risks we need to be aware of when administering this drug.



New safety concerns such as menstrual irregularities with Dolutegravir and ocular toxicities with MDR-TB drugs have been reviewed in this issue.

Between April and September 2021, NDA received 2253 reports of Adverse Events Following Immunisation with the Covid-19 vaccine and these events are characterized in this bulletin.

We have included the regular sections on foreign safety label updates and the quarterly adverse drug reaction analysis. We appreciate all of you for your continued efforts towards patient safety.

Dr. Helen Byomire Ndagije
Director Product Safety

Medication safety is one of the ways to contribute to better outcomes for mothers

Commemoration of the World patient safety day in Kamuli

Authors: Caroline Aruho, Brian Sekayombya, Denis Kibira and Helen B. Ndagije

World Patient Safety Day was established in 2019 to enhance global understanding of patient safety, increase public engagement and promote global actions to enhance patient safety and reduce patient harm. Uganda has embraced patient safety through the introduction of the 2012 Patients Charter to ensure that the rights of patients are protected as they seek health services.

This year the call to action "Act now for safe and respectful childbirth!" with the theme "Safe maternal and new-born care". The theme is based on the fact that, as much as the country has made strides in improving maternal child health indicators, there are occurrences of preventable maternal deaths, globally, 810 women die every day from preventable causes related to pregnancy and childbirth, 6700 new-borns die every day amounting to 47% of all under-5 deaths.

HEPS-Uganda in collaboration with National Drug Authority (NDA) and the Kamuli District Local Government joined the rest of the world to celebrate this year's World Patient Safety Day on 17th September 2021 at Kyemba Sande gardens. During the celebrations Sexual Reproductive Health Champions were awarded prizes for their contribution to reduction of the stock outs of essential medicines, averting early marriages, and unintended pregnancies, abortions and maternal deaths.

NDA shared on the the National perspective on patient safety, especially with regards to use of medicines, Rational use of medicines, Identification and reporting of adverse drug reactions, and drug and substance abuse. Questions on rational medicine use and medicines safety were asked and appropriate responses given.

The approaches used by HEPS – Uganda to provide information to the public through the use of VHTs, competitions, involving the young children were models that NDA could adopt to enhance provision of medicine information to the public and information on drug and substance abuse.

810
women die every day from preventable causes related to pregnancy

6700
new-borns die every day

Kamuli District Asst. Health Officer receives a plaque from NDA's Helen and district CAO.

Student essay competition winners

Commemoration of the World patient safety day at Namulonge and komamboga

Compiled by Victoria Nambasa and Regina Kamoga.

National Drug Authority in collaboration with Community Health and Information Network (CHAIN), and Uganda Alliance of Patient Organizations (UAPO) conducted pre-World Patient Safety day (WPSD) activities on 7th and 8th September 2021 at Namulonge HCIII and komamboga HCIII.The two day activity attracted seventy(70) participants who included 40 health workers (Doctors, nurses, midwives, lab technicians) ten (10) pregnant women/mothers and twenty (20) VHT's.

Issues identified and highlighted by participants during the awareness activities:

Drug stock out: Due to insufficient stock of prescribed drugs, pregnant women are forced to get the drugs from pharmacies, which could lead to change in prescription of the drug, settling for similar drugs or acquiring medicines not prescribed.

Poor quality packaging and dispensing of drugs: This causes deterioration of the drug quality and efficiency before and during the drug use. For example, the papers where medicine tablets are put are poor quality hence leading to easy contamination and erasing of the prescription when they get into contact with water or a liquid.

Limited knowledge on safe use of drugs: Health workers and VHT's lack adequate information on the various prescribed drugs. They do not know which drugs are specifically for pregnant women, new born babies and infants, quantities to prescribe hence leading to medical errors. They also lack up to date information on medication and treatment guidelines – MNCH. However, they were encouraged to seek information from the different drug information resources like the treatment guidelines, British National formulary or national medicine regulatory agency websites, which publish lists of drugs that should not be used during pregnancy.

Self-medication by pregnant women: Pregnant women are not informed about safe drugs and often self-medicate which could lead to drug misuse and wrong applications.

Use of herbal medicines recommended by nonprofessional or nonmedical personnel hence misleading them. Some herbal medicines are adulterated with products that affect pregnant women for example misoprostol, which can lead to loss of the unborn baby, incomplete abortion and many others.

Incomplete disclosure of information by the pregnant women: Lack of disclosure from the pregnant women on what drugs and herbs they have been using. They tend to withhold important information leading to wrong diagnosis and treatment hence limiting the health workers support and help.

Myths and Misconceptions: Culturally, a pregnant woman is not required to reveal her pregnancy until after a certain period. This puts pregnant women at risk as it prevents them from obtaining the necessary care, support and medication in the crucial early stages of pregnancy.

Recommendations recorded

- Increased public awareness and education on the medication Safety.
- Involving patients as active participants in pharmacovigilance and ensure that pregnant mothers share feedback on the effects of the drugs.
- Health workers getting updates regularly on safe prescription for pregnant women and children were among the recommendations made.

Group photo taken at Namulonge HCIII during the patient safety day.

MENSTRUAL CYCLE CHANGES AMONG PATIENTS ON DOLUTEGRAVIR

Authors: Authors: Eva Odongpiny, Angella Nabakooza Kigongo, Hebert Kayiga, Christine Sekaggya, Derek Sloan

DOLUPHARM is a study piloting a toll-free call intervention to improve Adverse Events Reporting. During this study, patients in one of the health facilities in Kampala and on Dolutegravir are given the NDA toll-free number to report suspected adverse events directly to the regulator. Through the study period May-Aug 2021, seven participants reported menstrual changes as presented in the table below;

Table showing menstrual cycle changes as reported by seven participants.

Table 1.Case series for patients with menstrual cycle changes

DATE OF CALL	PARTICIPANT	SOCIAL HISTORY	DRUG HISTORY	MESTRUAL CYCLE CHANGES
30/JULY/2021	MP, 22-year-old female, 66kg	No history of smoking nor alcohol intake. No children Not pregnant though no confirmatory test has been done	Initiated on ART (Tenofovir/Lamivudine/Dolutegravir 300/300/50 mg (TLD)) on January 2021. No prior history of modern contraceptive use Not received any COVID-19 vaccine	Normal menstrual cycles preceding initiation of ART that occurred at the beginning of every month. Her cycle started being irregular in May 2021, when she noticed occurrence of her menses twice. MP reported that in June 2021 she had her menses once at the end of the month lasting 4 days and, in July 2021 she didn't experience any menses.
3/AUG/2021	N.F, 35-year-old female, 62kgs	No history of smoking but on average takes 2 drinks of alcohol once every week. Has two children. Not pregnant though no confirmatory test has been done.	Initiated on ART (Tenofovir/Lamivudine/Efavirenz 300/300/600 mg (TLE)) in 2013, switched to TLD on April-2021. She has a contraceptive implant since November 2020. She received one dose of the COVID-19 vaccine in June 2021.	She experienced her menses twice in the months of; April to June, lasting 4 days each. In July she experienced her menses once.
13/AUG/2021	NA, 37-year-old female, 54kg	No history of smoking but takes one drink of alcohol occasionally. Has eight children Not pregnant though no confirmatory test has been done.	Started ART in 2019, switched to TLD in February 2021. No prior history of modern contraceptive use. Not received any dose of the COVID-19 vaccine.	Started experiencing irregular patterns after the switch to TLD. She got her menstrual periods twice in February and March 2021. Since then, she has never had her menses.
29/JULY/2021	M.D: 34-year-old female, 97kgs	She has no history of smoking, nor take alcohol. She has three children Not pregnant and did a test to confirm this.	Initiated ART (TLE) on June-2013, switched to TLD on Jan-2021. No prior history of contraceptive use. She has not received any dose of the COVID-19 vaccine.	She started having spotting since May- 2021.
9/AUG/2021	NV: 42-year-old female, 72kg	She has no history of smoking, nor take alcohol. She has no children Not pregnan,t though she has not done a confirmatory test.	Initiated on ART (stavudine/lamivudine/Nevirapine) on March/2005, transitioned to zidovudine/lamivudine/efavirenz on 20/10/2006, then TLE on September/2010, switched to TLD on December/2020. No prior history of modern contraceptive use. She has not received any dose of the COVID-19 vaccine.	She missed her menstrual periods since June 2021.

DATE OF CALL	PARTICIPANT	SOCIAL HISTORY	DRUG HISTORY	MESTRUAL CYCLE CHANGES
26/JULY/2021	L.A.N: 49-year-old female,68kg	She has no history of smoking and nor take alcohol. She has three children Not pregnant though she has not done a confirmatory test.	Initiated ART in 2006, zidovudine/lamivudine/ Nevirapine on September/2013, switched to zidovudine/lamivudine/ Lopinavir/ritonavir on August/2016, Abacavir/ lamivudine/atazanavir/ ritonavir, transitioned to TLD on March/2021. She has not received any dose of the COVID-19 vaccine.	She experiences her menses twice since April/2021.
28/JULY/2021	N.J: 44-year-old female, 65 kgs	She has no history of smoking and nor take alcohol. She has three children.	Initiated ART on March/2007 with zidovudine/lamivudine/ nevirapine, switched to tenofovir/lamivudine/ atazanavir/ritonavir, transitioned to TLD on Jan/2021. She has no prior history of modern contraceptive use. She has not received any dose of the COVID-19 vaccine.	She missed her periods since July, 2021

Discussion

Menstrual cycle changes are not among the listed side effects of dolutegravir by the manufacturer [1]. However, an increasing number of cases reporting menstrual cycle changes ensuing TLD initiation, have been observed by National Drug Authority (NDA) and recorded in the WHO vigibase global database: eight and thirty reports have been received by NDA and WHO respectively.

An article, "menstrual disorders in HIV-infected women," cited by the New York state department of health AIDS Institute [2], lists the different menstrual cycle changes and these include: amenorrhea (cessation of bleeding for >3 months), polymenorrhea (menstrual bleeding occurs <21 days after prior menses), oligomenorrhea (menstrual bleeding occurs >35 days after prior menses), menorrhagia (regular cycles with excessive flow (>80 ml) or duration (>7 days)), metrorrhagia (Irregular bleeding or bleeding between periods ("breakthrough bleeding")), menometrorrhagia (bleeding that is both heavy and irregular), post-menopausal bleeding (bleeding >1 year after cessation of menses), post-coital bleeding (Bleeding after intercourse) and mid-cycle spotting (Light bleeding around the time of ovulation).

The article further categorizes factors that may cause menstrual changes into: gynecological and non-gynecological [2]. Gynecological factors include: pregnancy, ectopic pregnancy, miscarriage, polycystic ovarian syndrome (PCOS), ovarian insufficiency - premature ovarian failure, cervical polyps, cervicitis, endometrial conditions, pelvic inflammatory disease (PID), uterine fibroids, sexually transmitted infections (STIs) and, certain cancers like endometrial, cervical, vulvar, vaginal.

Non gynecological factors include: stress, excess exercise, eating disorders, thyroid/ pituitary disease, adrenal disease, wasting, weight loss, or low body mass index. These disrupt the release of the gonadotropin-releasing hormone from the hypothalamus resulting into menstrual cycle changes [3]. Furthermore, chronic diseases like: diabetes, kidney disease, liver disease, inflammatory

bowel disease, immune suppression and certain medications like: anticoagulants, psychotropics, phenytoin, narcotic analgesics, methadone, heroin, corticosteroids, hormonal therapies, herbal supplements with estrogenic activity, protease inhibitors may also cause menstrual changes [2].

Studies carried out among HIV positive women have attributed menstrual changes to lower CD4 and HIV wasting [4]. However, all but one of these women who was initiating ART had been stable on their previous ART regimens prior to TLD transitioning.

Due to the ongoing COVID-19 vaccination and reports of menstrual changes in other settings [5], we obtained information on COVID-19 vaccination status too.

> *Studies carried out among HIV positive women have attributed menstrual changes to lower CD4 and HIV wasting*

We hypothesize that, similarly to neuropsychiatric side effects (insomnia, dizziness, nervousness, depression, headache, reduced concentration, and unexplained pain) caused by dolutegravir [6] due to its ability to cross the blood brain barrier by passive diffusion and cause neurotoxicity [7],[8],[9],[10], this same effect could affect the pulsatile secretion of the gonadotropin-releasing hormone thus disrupting the menstrual cycle. Correspondingly, not all the possible factors affecting menstrual changes were ruled out during the study, and these could be possible cofounders.

Worthy to note, dolutegravir does not induce nor inhibit the cytochrome enzymes(CYP) which are responsible for the metabolism of contraceptives[11] thus rendering no alteration of contraceptive concentration in blood [12].

Conclusion

The seven cases shared above show time plausibility with dolutegravir initiation. Since women might be uncomfortable to talk to their clinicians about menstrual changes unless prompted, we call upon health workers to ask and get more information on menstrual changes in women starting dolutegravir based regimens which can help strengthen the evidence base of this potential signal.

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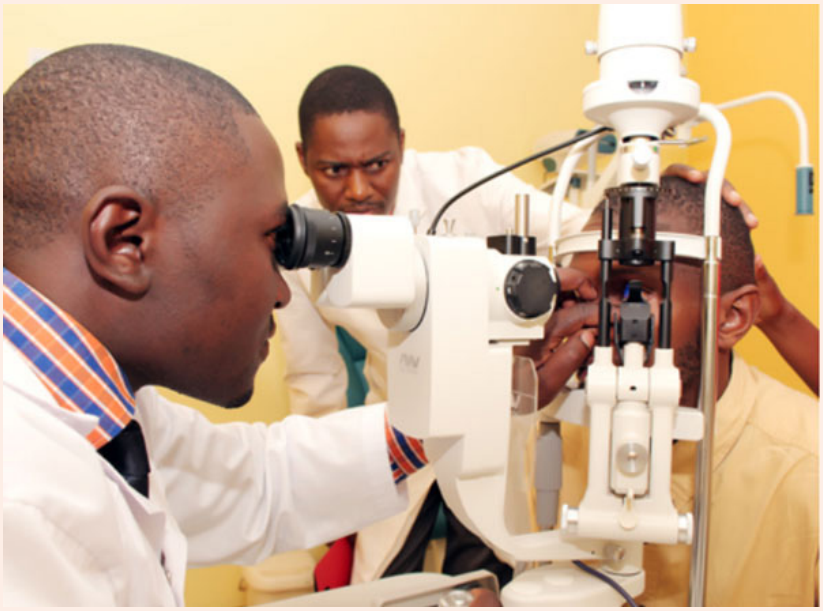
Medicine safety Updates – Local cases



Case reports: Linezolid- Eye disorders with various symptoms

Linezolid is a synthetic, antibacterial agent that belongs to a new class of antimicrobials, Theoxazolidinones. It works by killing bacteria or preventing their growth by interfering bacteria's protein synthesis. It is used for serious infections, which are difficult to treat with other antibiotics.

Linezolid can be beneficial in treatment of infections caused by gram positive bacteria which are resistant to other antibiotics, especially infections caused by multidrug resistant staphylococci or enterococci. Based on the available data from studies in patients and clinical experience of several years, linezolid represents an effective drug in the treatment of nosocomial pneumonia, community acquired pneumonia and complicated skin and soft tissue infections caused by bacteria. Linezolid has been classified as category 5 drug indicated in the management of multidrug resistant TB .

Linezolid inhibits mitochondrial protein synthesis and adverse events, such as lactic acidosis, anaemia and neuropathy (optic and peripheral), may occur because of this inhibition. These events are more common when the drug is used longer than 28 days

The National Drug Authority has received 14 individual case reports of eye disorders in patients taking Linezolid for management of MDR-TB, the youngest being a 6-year-old. Majority of patients (6) were in age group 18-44 years and 4 patients were in age group 45-64 years.

Patients presented with a wide spectrum of symptoms including blurred vision (5 patients), visual impairment (4 reports), night blindness (1), optic neuritis(1), diplopia(1), and eye pain and reddening (2). Co-reported active ingredients were Cycloserine, Clofazimine, Levofloxacin and Bedaquiline.

There are several case reports (over 800) related to visual impairment in patients taking Linezolid recorded in the global database.

Labeling and literature

The product/Linezolid Summary of Product characteristic labels optic neuropathies characterized by blurred vision, changes in visual acuity, and changes in color vision, blurred vision, or visual field defect etc. as important eye defects that occur at varying frequencies (Pfizer Ltd, 2011).

There may be an increased risk of neuropathies when linezolid is used in patients currently taking or who have recently taken antimycobacterial medications for the treatment of tuberculosis (Pfizer Ltd, 2011).

Eye disorders in Uganda are observed to be reported disproportionately frequently in association with linezolid (IC value for eye disorder is 2).

It should be noted however that all the patients who reported eye disorders were taking other concomitant drugs for MDR-TB, some of which have a predisposition to cause eye disorders as adverse events. With a disproportionate reporting of eye disorders observed, NDA continues to raise awareness that eye disorders are common with long-term use of Linezolid and concomitant ant-TB drugs.

Recommendations.

- Patients taking Linezolid should be routinely monitored for visual function. Any visual abnormality should be managed as soon as possible.
- If visual function worsens or persists, patients should be referred to a specialist/ ophthalmologist for specialized care and the anti-TB regimen may also be revisited with consultation of the TB case management team.

Considerable attention should be given to children when they are taking linezolid since they may not be able to recognize and report the events early.

References:

Pfizer Ltd. (2011, January). Zyvox 600 mg Film-Coated Tablets - Summary of Product Characteristics (SmPC) - (emc).

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MEDICINE SAFETY –Foreign reports

Diclofenac etalhyaluronate (injection) - Risk of serious shock and anaphylaxis

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) announced that the package insert for diclofenac etalhyaluronate (injection) is to be revised to include the risk of serious shock and anaphylaxis as adverse drug reactions.

Diclofenac etalhyaluronate is indicated to treat osteoarthritis in the knee and hip joints.

A total of 10 cases of serious shock or anaphylaxis have been reported in patients treated with diclofenac etalhyaluronate in Japan (from March to May in 2021). Seven of

the 10 cases were reviewed for causality and a causal relationship between the drug and event was assessed to be reasonably possible. No patient mortalities were reported and the agency advises that **sufficient preparation for emergency responses** should be ensured prior to administration. In addition, patients should be carefully monitored during drug administration.

In Uganda, Diclofenac etalhyaluronate is not a registered product. However diclofenac IM/IV is available, a few reports related to hypersensitivity reactions, presenting as angioedema, patients swelling face, and lips among others have been reported and registered in the NDA Adverse event database. Patients **should therefore be monitored for possible serious hypersensitivity reactions.**

Reference:

WHO Pharmaceuticals Newsletter No. 4, 2021 • 6(https://www.who.int/publications/i/item/who-pharmaceuticals-newsletter---n-4-2021)

COVID-19 vaccine NRVV Ad26 (JNJ 78436735) -Risk of capillary leak syndrome (CLS)

The Pharmacovigilance and risk assessment committee (PRAC) in Europe recommended that people who have previously had CLS must not be vaccinated with COVID-19 vaccine NRVV Ad26 (JNJ 78436735) (COVID-19 vaccine Janssen®) and that CLS should be added to the product information as a new adverse drug reaction.

COVID-19 vaccine NRVV Ad26 (JNJ 78436735) is indicated for preventing COVID-19 in people aged 18 years and older.

The PRAC reviewed three cases of CLS in people who have had the vaccine. Health-care professionals should be aware of the signs and symptoms of CLS and of its risk of recurrence in people who have previously been diagnosed with the condition.

Also, health-care professionals should tell people receiving the vaccine that they must seek medical attention if they experience rapid swelling of the arms and legs or sudden weight gain in the days following vaccination.

Reference: EMA, 9 July 2021

Remdesivir -Risk of sinus bradycardia

The Pharmacovigilance Risk Assessment Committee(PRAC) in Europe has recommended a change to the product information for Remdesivir (Veklury®) to include sinus bradycardia as an adverse drug reaction.

Remdesivir is indicated to treat COVID-19 in adults and adolescents with pneumonia requiring supplemental oxygen.

The PRAC reviewed available data on rare reported cases of bradycardia in patients treated with Remdesivir as well as data from clinical trials and the scientific literature.

The PRAC concluded that a causal relationship between the use of Remdesivir and the event is reasonably possible and recommended the revision of the product information.

The majority of the events of sinus bradycardia resolved a few days after the treatment with Remdesivir was discontinued.

NDA gave special import authorization of Remdesivir for use in management of covid-19 severe disease . NDA therefore **advises** healthcare workers administering this drug to monitor and report any case of sinus bradycardia,

Reference:

WHO Pharmaceuticals Newsletter No. 4, 2021 • 6(https://www.who.int/publications/i/item/who-pharmaceuticals-newsletter---n-4-2021)

Safety Updates on Covid -19 vaccines used in Uganda.

Vaccination against COVID-19 is still the most effective way to reduce deaths and severe illness from infection. In light of the COVID -19 pandemic, the NDA has approved use of various covid -19 vaccines in Uganda. There are four **COVID-19 vaccines** currently in use in Uganda i.e Covishield (Astrazeneca) Vaxzevria (AstraZeneca), Comirnaty (Pfizer) and Spikevax (Moderna) . Based on the available information, the benefit of the vaccine outweighs any safety issue identified during studies. The Authority will continue to monitor the benefit -risk profile of the vaccine as more information about COVID-19 disease and the available vaccines evolves. All import licenses are granted as provided for under the provisions of the National Drug Policy and Authority Act on emergency and extra- ordinary circumstances.

Like all medicines, COVID-19 vaccines may have some side effects (also known as Adverse Events Following Immunisation-AEFI). The majority of these side effects are mild and resolve within a few days. More side effects that are serious can occur after vaccination but are very rare. The NDA and Ministry of health closely monitors reports of suspected side effects to the COVID-19 vaccines and respond to any safety concerns.

To help us monitor the safety of the COVID-19 vaccines, we encourage everyone to report suspected side effects even if there is only a small chance that the vaccine caused them.

Update on the reported side effects

As of 30th September 2021, a total of 2253 AEFIs following administration of covid-19 vaccines have been recorded in the NDA database, contributing a 0.1% to the global reports recorded in the Vigibase. Slightly more than half (56%) being reported by male clients and most people reporting events fall in the age bracket of 18-44 years (figure 1 and 2).

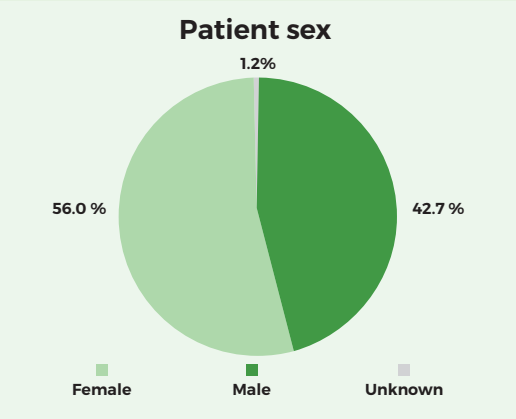

Figure 1 Gender distribution

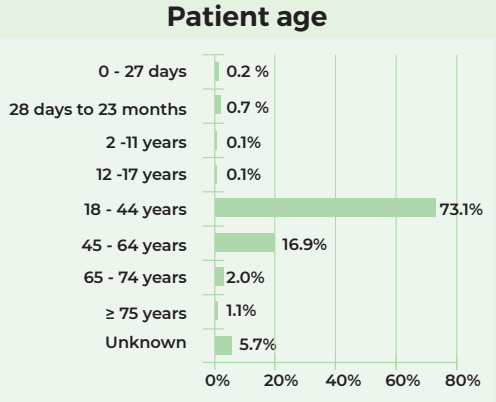

Figure 2 Age distribution

Summary of reporting reporting rates.

Table 2 AEFI reporting for covid-19 Vaccines between April-September 2021

Total AEFI reports received	**2253**
Total does administered	**2200321 as of 4th October**
Reporting rate per 1000 doses	**1.02**
Total reports for Astra Zenac(Covishield /Vaxveria)	**1962**
Total reports for CoronaVac	**29**
Total reports for Pfizer	**0**
Total reports for Moderna	**0**
Un specified brand	**262**

In general, the most frequently reported side effects suspected to be associated with the vaccines include general disorders and administration site conditions(75%)- such as pyrexia, malaise , injection site pain, sore arm,Fever , malaise , chest discomfort, chills among others and Nervous system disorders(58%)-such as headache, fatigue, monoplegia, and hypoaesthesia.(see figure 3 below. Detailed information about reactions reported and the top 30 districts from which reports were received are provided in annex 1 and 2 respectively

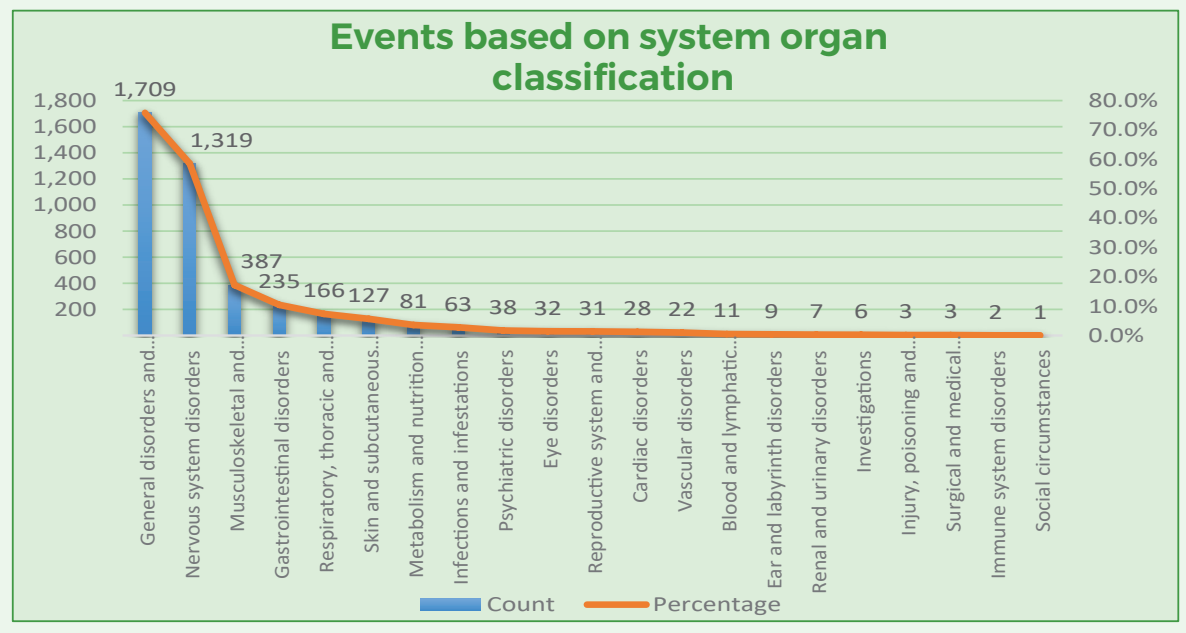

Figure 3. Events reported based on system organ classification

Severe and Serious adverse events

Overall, 181 severe adverse events were reported of which majority were causing short-term incapacitation to the recipients. **There were 51 Serious cases that were investigated and casualty assessment done by the** by the national AEFI committee. Only seven cases (presenting as conversion disorder, chest tightness, numbness, Bells'palsy, gastroenteritis, vaccine-induced anxiety) were likely related to the vaccines while the rest of the serious cases were considered coincidental events(see annex 3).

Thrombosis with thrombocytopenia syndrome (TTS) following vaccination with the AstraZeneca COVID-19 vaccine.

TTS is a rare specific syndrome that occurs when a person has blood clots (thrombosis) as well as low blood platelet counts (thrombocytopenia). Several countries have reported cases of TTS and some have assessed the cases using an internationally accepted method to rate the level of certainty of a link between the event and vaccine. The product label of Astra Zeneca has since been revised to include this very rare event. The event is reported to rarely occur usually between day 4 and 20 after vaccination. Patients have to be advised to seek immediate medical attention if, a few days after vaccination, they develop symptoms such as:

- severe or persistent headache or blurred vision
- shortness of breath, chest pain, leg swelling or persistent abdominal pain
- Unusual skin bruising and/or pinpoint round spots beyond the site of injection.

In Uganda, three (3) cases suspected to be TTS out of the 2million doses administered were investigated and they were unlikely linked to the COVID-19 vaccine because they did not meet the internationally accepted criteria for TTS. We encourage all health workers to manage clients accordingly who present with symptoms that may be suggestive of TTS and report the suspected event as we continue to monitor this event in our population

Reproductive disorders

Erectile dysfunction -Twenty one (21) cases of sexual dysfunction presenting as erectile dysfunction and loss of libido have been reported to occur following administration of to COVID -19 vaccines. Majority of the clients are between 18-44 years and majority reported to have recovered after 5-7 days. Similar reports have been reported globally (736 cases) although linkage to the vaccines has not been investigated. NDA will continue to monitor this event and will provide an update.

Bleeding disorders in women- Ten cases presenting as heavy menstruation, irregular menstruation, amenorrhea have been reported in women. Over 91 000 cases have similarly been reported globally. Linkage to the vaccines has not been confirmed but we continue to encourage you to report such occurrence as we continue to gather more information regarding the event.

Reporting platforms for AEFI following vaccination with covid 19 vaccines.

Please report all event whether minor or serious using the following platforms

Toll free: 0800 101 999

Whatsapp: 0740002070

Dial *284*99# for Covid-19(Vaccine AEFI reports only)

NDA reporting Cards

druginfo@nda.or.ug

Medsafety app

SAFETY Label Variations between 1st July 2021 and 30th September 2021

The Summary of Product Characteristics (SmPC) and product patient Information Leaflet (PIL) are the basis of information for health care professionals and patients respectively on how to use a medicine safely and effectively. They are updated regularly through the life cycle of a product as new safety or efficacy information emerges. We present below the safety label changes received in the period July to September 2021.

Generic/Brand name	Update
Nolvadex/Tamoxifen	Women should be advised not to become pregnant whilst taking Nolvadex and for nine months following the cessation of therapy due to genotoxic effects.
Covidex	Use with caution if you are pregnant or breastfeeding, suffering from heart diseases, high blood pressure or diabetes.
Anastrozole/Anastrozole 1 mg	Undesirable effects: Psychiatric disorders like depression.
Atacand Plus/ Candesartan+Hydrochlorothiazide	Special warnings and precautions for use: Acute myopia, secondary angle-closure glaucoma and choroidal effusion.
Ceftriaxone Sandoz/Ceftriaxone sodium	Special warnings and precautions for use and Undesirable effects: Encephalopathy.
Crestor/Rosuvastatin	Interactions: Newer protease inhibitors interacting with Rosuvastatin added Drug-drug interaction of Regorafenib and Darolutamide with Rosuvastatin added
Prezista/Darunavir	Therapeutic indications: Extension of indication to adolescents for use in combination with cobicistat to include adolescents aged 12 years and older weighing at least 40 kg
	Posology: Dosing updated for adolescents
Diprofos injection/Betamethasone disodium phosphate+Betamethasone diproprionate	Special warnings and precautions: Visual disturbances and anaphylactoid/anaphylaxis reactions.
Erbitux/Cetuximab	Warnings and special precautions: Interstitial lung disease with potentially fatal outcomes, cytokine release syndrome (presentation and management)

Generic/Brand name	Update
Euthyrox/Levothyroxine	Contraindications: Combination therapy of levothyroxine and an antithyroid agent for hyperthyroidism in pregnancy is contra-indicated.
	Warning: Off-label use/misuse and abuse of levothyroxine for weight loss Circulatory collapse in preterm neonates
	Interactions: Extension of drug interaction with calcium salts, additional interaction with orlistat, sevelamer, tyrosine kinase inhibitors and interaction information amended.
Afinitor/Everolimus	Adverse Drug Reaction: Lymphoedema
Amaryl-2/Glimepiride	Undesirable effects: Dysgeusia, alopecia and weight gain.
Lantus solostar/Insulin Glargine	PIL Update: Rotate injection site to prevent cutaneous amyloidosis.
Symbicort turbuhaler/ Budesonide+Formoterol	Common adverse drug reaction: Pneumonia
Zestoretic/Lisinopril	Warnings and special precautions for use: Choroidal effusion, acute myopis and angle-closure glaucoma.

Product recalls

A recall is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. The National Drug Authority recalled the products listed below and all healthcare workers, health facilities and distributors are requested to take note:

Sr. NO	PRODUCT DSCRIPTION	REASON
1	All batches of Hydrogen Peroxide 6% manufactured by smart care Ltd.	• The manufacturer is not authorised by NDA. • Several complaints regarding the quality of the product.
2	Zenvac (Bupivacaine Hydrochloride and Dextrose) Injection Batch LE20053 , Mfg date Nov. 2020 and Exp. Oct.2022 manufactured by Zen Pharma Pvt Ltd.	Reported serious adverse drug reactions related to the product.

ADR SUMMARY July –September 2021

A total of 592 adverse drug reaction reports were received and 1444 adverse event Following administration of COVID -19 vaccines. A description of COVID -19 cases is provided in section 4 already.

Clinical medical officers, followed by patients reported most as shown in figure 3, while paper based reporting, toll free line and whatsapp were used most for reporting (figure 4)

307 of the reports (51.86%) were categorised as serious with the commonest reason for the categorisation listed as life threatening. There were two deaths; one involving post-partum haemorrhage following suspected Oxytocin inefficacy and one death due to an anaphylactic reaction to Ampicillin.

Overall medicines used in management of HIV (ARVs) were reported most (86.6%; n=512), followed by Anti-TBs (8.1%; n=48) and antibiotcs(3.2%, n=19) as presented in figure 3 below.

The top reported drug (N=592) was Dolutegravir with 77.5% (n=459) reports, 42.7% (n=258) of which were cases of new onset hyperglycaemia. Isoniazid at 2.7% (n=16) was the second most reported drug, and this included 5 cases of Drug Induced Liver Injury (DILI). This was followed by Tenofovir with 2.36% (n=14) reports of Osteomalacia and Linezolid with 2.2% (n=13) reports, 3 of which were cases of visual impairment. There were 4 cases of Oxytocin inefficacy and 2 reports of itchy skin and sharp irritating nose pain with Covidex. Oxytocin inefficacy was among the serious cases and investigations are underway to establish the possible cause.

Memory loss/amnesia was among the events (8 reports) and further characterization and evaluation is being done and will be communicated.

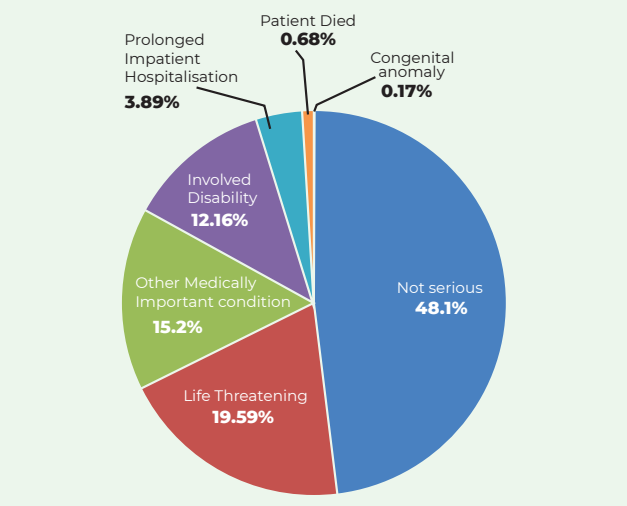

Figure 3 Proportion of reports submitted by diffrent reporter categories

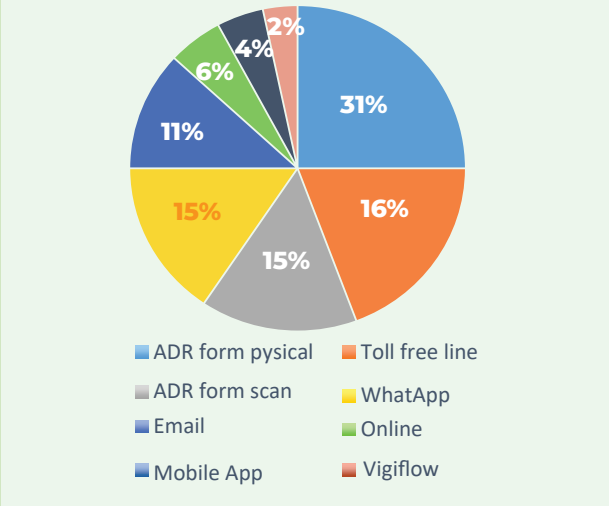

Figure 4 ADR frequency received through the different reporting platforms

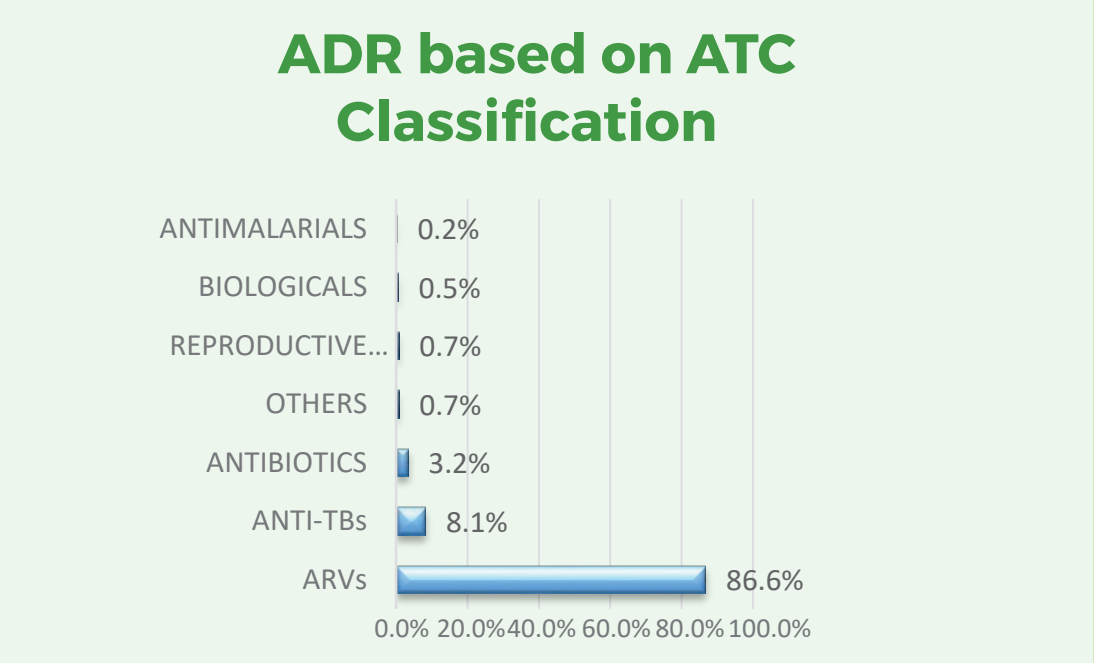

Figure 5 Proportion of ADRs bases on Anatomical Therapeutic Classification

Table 3 Top 7 Drug-Reaction Pairs

DRUG REACTION PAIR	No. of Reports
Dolutegravir	**459**
HYPERGLYCAEMIA	258
HEADACHE	25
HYPERSENSITIVITY	29
DIZZINESS	12
ARTHALGIA (JOINT PAIN)	15
INSOMNIA	15
PERIPHERAL NEUROPATHY	14
ERECTILE DYSFUNCTION	14
GENERAL BODY WEAKNESS	11
HEPATOTOXICITY	7
AMNESIA	8
NIGHT MARES	4
CHRONIC KIDNEY DAMAGE	3
PALPITATIONS	3
SKIN RASH	3
PERIPHERAL NEUROPATHY	3
IRRITATING COUGH	3
NIGHTMARES	2
ISONIAZID	**16**
DILI	5
PELLAGRA	2
PERIPHERAL NEUROPATHY	1
SKIN ITCHING	1
STEVEN JOSHSON SYNDROME	1
TDF	**14**
BONE PAIN	14
LINEZOLID	**13**
PERIPHERAL NEUROPATHY	5
VISUAL IMPAIRMENT	3
QTC PROLONGATION	1
SEVERE ANEMIA, PALPITATIONS, DIZZINESS, EASY FATIGUABILITY	1
GENTAMYCIN	**1**
CHILD STOPPED BREATHING, CYANOSIS, CHEST INDRAWING	1
SEVERE HEADACHE	1
LEVOFLOXACIN	**4**
ARTHRALGIA	2
HEADACHE, PERIPHERAL NEUROPATHIES	2
OXYTOCIN	**4**
BLEEDING (SUSPECTED DRUG INEFFICACY)	4
RHZE	**4**
JOINT PAIN	4

Performance of health facilities in reporting ADR.

Mildmay Uganda submitted the highest number of reports (n=121) followed by Kawaala hospital(n=86) and Kayunga Hospital (n=77) as shown in the table below.

Table 5 Facility performance in reporting ADRs

Facility	ADR report count
MILDMAY UGANDA	121
KAWAALA HC III	86
KAYUNGA HOSPITAL	77
MBARARA RRH	57
TASO MASAKA	34
JINJA RRH	21
LIRA RRH	19
KITEBI HC III	17
KIRUDDU NR HOSPITAL	14
TASO ENTEBBE	13
IGANGA HOSPITAL	12
MBALE RRH	12
UNKNOWN	12
MJAP MULAGO	11
SOROTI RRH	9
FORT PORTAL RRH	8
BUSOLWE HOSPITAL	6
HOIMA RRH	6
MUBENDE RRH	6
ARUA RRH	5
TASO MULAGO	5
BUNDIBUGYO HOSPITAL	4
KISWA HC III	3
KALANGALA HC IV	2
KASASA HC III	2
KAWEMPE HOME CARE	2
KISENYI HC IV	2
LUWERO HOSPITAL	2
MATANY HOSPITAL	2
MUGOYE HC III	2
MYLANLABS	2
ST FRANCIS HOSPITAL BULUUBA	2
BUSARU HC IV	1
BUSURU HC IV	1
CUF HOSPITAL NAGURU	1
KANYAMWIRIMA HC III	1
KIBOGA HOSPITAL	1
KINONI HC IV	1
LACOR HOSPITAL	1
MOROTO RRH	1
MOYO GENERAL HOSPITAL	1
MUJHU ART CLINIC	1
NYUMANZI HC II	1
RAKAI HEALTH SCIENCE PROGRAM CLINIC	1
RUGAZI HC IV	1
SSI HC III	1
ST CHARLES LWANGA HOSPITAK	1

Districts performance in ADR reporting

KYOTERA	3	1%
Buikwe	2	0%
Luweero	2	0%
Mayuge	2	0%
Napak	2	0%
Adjumani	1	0%
Gulu	1	0%
Kaabong	1	0%
Kiboga	1	0%
Moroto	1	0%
Moyo	1	0%
Rubirizi	1	0%
RWAMPARA	1	0%
Sembabule	1	0%

Annex 1 Reactions experienced and reported following covid-19 vaccination (April-September 2021)

Reactions reported/preferred terms (MedDRA)	Count	Percentage
Headache	1,078	47.8%
Pyrexia	761	33.8%
Malaise	702	31.2%
Injection site pain	397	17.6%
Dizziness	339	15.0%
Arthralgia	190	8.4%
Pain	167	7.4%
Asthenia	160	7.1%
Chills	135	6.0%
Nausea	86	3.8%
Decreased appetite	72	3.2%
Fatigue	71	3.2%
Dyspnoea	63	2.8%
Cough	62	2.8%
Chest pain	74	3.3%
Pain in extremity	60	2.7%
Myalgia	55	2.4%
Hypoesthesia	48	2.1%
Influenza	48	2.1%
Diarrhoea	47	2.1%
Vomiting	46	2.0%
Back pain	43	1.9%
Rash pruiritic	75	2.9%
Limb discomfort	37	1.6%
Injection site swelling	36	1.6%
Abdominal pain/disconfort	81	2.7 %
Hyperhidrosis	29	1.3%
Palpitations	27	1.2%
Somnolence	21	0.9%
Influenza like illness	20	0.9%
Oropharyngeal pain	18	0.8%
Thirst	16	0.7%
Insomnia	15	0.7%
Top Reported preferred terms (MedDRA)	Count	Percentage
PT: Monoplegia	12	0.5%
PT: Neck pain	12	0.5%
Vision blurred	12	0.5%
Burning sensation	10	0.4%
Nasopharyngitis	10	0.4%
Peripheral swelling	10	0.4%
Erectile dysfunction	10	0.4%
Ageusia	8	0.4%
Anosmia	8	0.4%
Hypertension/raised BP	8	0.4%
Syncope	8	0.4%
Dry throat	7	0.3%
Eye pain	7	0.3%
Loss of consciousness	7	0.3%
Lymphadenopathy	7	0.3%
Rhinorrhoea	7	0.3%
Epistaxis	6	0.3%
Haemoptysis	6	0.3%
Libido decreased/lost	9	0.4%
Nasal congestion	6	0.3%
Paraesthesia	6	0.3%
Seizure	6	0.3%
Eye pruritus	6	0.3%
Injection site mass	5	0.2%
Night sweats	5	0.2%
Sneezing	5	0.2%
Axillary pain	5	0.2%
Musculoskeletal stiffness	5	0.2%
Dyspepsia	4	0.2%
Muscular weakness	4	0.2%
Paralysis in arm	4	0.2%
Pollakiuria	4	0.2%
Restlessness	4	0.2%
Top Reported preferred terms (MedDRA)	Count	Percentage
Tinnitus	4	0.2%
Urticaria	4	0.2%
Vaginal haemorrhage	4	0.2%
Appetite disorder	4	0.2%
Aphonia	3	0.1%
Confusional state	3	0.1%
Dysmenorrhoea	3	0.1%
Dysphagia	3	0.1%
Ear pain	3	0.1%
Gait inability	3	0.1%
Haematemesis	3	0.1%
Injection site rash	3	0.1%
Muscle spasms	3	0.1%
Neuropathy peripheral	3	0.1%
Polydipsia	3	0.1%
Vaccination complication	3	0.1%
Weight decreased	3	0.1%
Wheezing	3	0.1%
Haemorrhage	3	0.1%

PT: Hot flush	3	0.1%
Vaccination site pain	3	0.1%
Acute stress disorder	2	0.1%
Top Reported preferred terms (MedDRA)	Count	Percentage
Amenorrhoea	2	0.1%
Aphthous ulcer	2	0.1%
Bone pain	2	0.1%
Breast pain	2	0.1%
PT: Dysphonia	2	0.1%
Flank pain	2	0.1%
Gait disturbance	2	0.1%
Heart rate increased	2	0.1%
Hypersensitivity	2	0.1%
Mucosal inflammation	2	0.1%
Nightmare	2	0.1%
Ocular hyperaemia	2	0.1%
Oedema peripheral	2	0.1%
Orthostatic hypotension	2	0.1%
Peptic ulcer haemorrhage	2	0.1%
Productive cough	2	0.1%
Rash papular	2	0.1%
Rhinitis	2	0.1%
Sexual dysfunction	2	0.1%
Sleep apnoea syndrome	2	0.1%
Throat irritation	2	0.1%
Thrombosis	2	0.1%
Yawning	2	0.1%
Hyposmia	2	0.1%

Annex 2 Districts from which at least 5 AEFI reports related to COVID-19 Vaccination were received(April – September 2021).

Row Labels	Count of DOR
Kampala	560
Mbarara	359
Wakiso	144
Soroti	126
Mukono	54
Jinja	50
Kasese	36
Mbale	31
Kaliro	29
Masaka	28
Kalungu	27
Luweero	26
Bushenyi	20
Ntungamo	20
Moroto	19
Kabarole	18
Ibanda	16
Isingiro	16
KYOTERA	16
Buikwe	14
Rukungiri	12
Arua	12
Sheema	10
Lira	9
Mitooma	9
Nakasongola	9
Mubende	9
Butambala	8
Sironko	8
Gulu	8
Hoima	8
Kayunga	8
Kyegegwa	8
Kiruhura	8
Oyam	7
Iganga	7
Rwampala	7
Kabale	7
Kitagendwa	7
Mityana	7
Tororo	6
Amudat	6
Kiboga	6
Mpigi	6
Amuria	6
Nakaseke	6
Nebbi	6
Manafwa	6
Bulambuli	5
NAMISINDWA	5
Luuka	5
Kaabong	5
Sembabule	5
Kamwenge	5
Masindi	5
Buvuma	5

Annex 3. Summary of serious COVID-19 AEFI investigated

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
1. Conversion disorder- as final diagnosis for event. Developed, headache, generalized body weakness, dizziness, difficulty in breathing and was hospitalized.	Hospitalization. Patient recovered	Immunization anxiety-related reaction
2. Menorrhagia as final diagnosis. 4 days after vaccination she experienced heavy PV bleeding (she evacuated heavy clots three times and changed pads about 6 times/day) associated with dizziness, headache and lower abdominal pain.	Hospitalization Patient recovered	Coincidental event
3. Chest tightness. Three hours after vaccination, she developed headache, dizziness, generalized body weakness, nausea, episodic chest tightness and cuff muscle pain. She also presented with numbness of lower limbs, which started 6 hours after vaccination.	AESI Patient recovered	**Vaccine Product related reaction** as per published literature this is because: 1, It occurred within 6hrs of vaccination 2, The vaccine is an antigen which the body could react to and the resulting inflammatory process causes pain in the chest muscles as well as other muscles in the body 3, Listed in the literature as AESI
4. Suspected pulmonary embolism 7 hours after receiving COVID- 19 vaccine, client developed chest pain, DIB, headache, easy fatigability and palpitation associated with fever.	Hospitalization Patient recovered	Immunization anxiety-related reaction
5. Epilepsy About 5 minutes after receiving the vaccine, he started feeling generalized body weakness, shortly afterwards he fell down and started convulsing, followed by loss of consciousness	Hospitalization, Patient recovered	Unclasssified pending neurologists review
6. Fatigue After 15 minutes' post vaccination, client developed nausea and generalized body weakness.	Hospital referral	Rejected as not a Serious AEFI case

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
7. Deep Vein Thrombosis (DVT). He complained of having developed a new wound over his left ankle joint five (5) days post immunization (on 17/03/2021) that progressed to become a large wound that he was admitted for. . A Doppler scan of his lower limbs was suggestive of DVT on 23/03/2021. He had not been diagnosed with DVT before	Hospital referral, AESI	**Coincidental:** Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine because: 1) Had an infected wound he was managing himself 2 months prior to vaccination; 2) Cellulitis is commonly caused by bacteria which is a common condition in the Ugandan setting; 3) Unknown antiepileptic medications that he is taking
8. Intracranial haemorrhage 42-year-old male was well till 11days post vaccination when he was found in a bath shelter unconscious having fallen, with blood-stained froth at his mouth, difficulty in breathing, and fecal incontinence.	Fatal	**Coincidental** underlying or emerging condition(s) or condition(s) caused by exposure to something other than the vaccine this is because there are several causes of Intra-cranial haemorrhage, including an accidental fall and ensuing head injury.
9.Severe occipital Headache, chest tightness About 20 minutes after immunization, client developed generalized body weakness followed by severe occipital headache, nausea, vomiting, chest tightness and shortness of breath.	Hospitalized.	**Vaccine Product related reaction** as per published literature this is because 1) Headache is one of the known AEFIs 2) Headache occurred within the 1st 24hrs. 3) Normal vital signs and clinical investigations.
10. Upper GI bleeding While at a grinding mill, he suddenly began vomiting blood, collapsed and died within a few minutes before he could be transported to a health facility	Fatal , AESI	**Coincidental.** Because 1) History of two previous upper GIT bleeding; 2) Postmortem findings revealed a duodenal ulcer; 3) was a chronic alcoholic, 4) had poor eating habits, 5) hypertension. Postmortem findings revealed advanced Pulmonary Tuberculosis, with the right lung having (cavitation, with fibrosis, caseous necrosis, granuloma formation), hilar lymphadenopathy, pleurisy and pericarditis with pericardium adherent to the chest wall.
11. Laryngopharyngitis. He developed generalized body weakness, a running nose, cough and headache associated with loss to his voice. More than a year ago, he had history of a similar illness.	Hospitalised	**Coincidental** Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine, this is because 1. He suffered a similar illness more than a year ago, the patient might have an underlying allergic airway disease 2. Laryngopharyngitis can be caused by many viruses and bacteria 3. Polypharmacy is evidenced here by use of more than two antibiotics, while increased liver enzymes might be due to intravenous Paracetamol.

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
12.Cavitary Pulmonary Tuberculosis Complained cough which got worse especially at night and it was associated with hemoptysis. It got even worse the next night when she coughed up frank blood (about 300ml), with clots (total about 1L)	Hospitalised Patient recovere d	**Coincidental** this is because 1. She had extensive lung cavitation and consolidation collapse, sufficient to cause her symptoms. 2. Tuberculosis is the commonest cause of cavitating pneumonia in our environment, and that was confirmed by gene expert in this case 3. She had radiotherapy which could have reduced her immunity hence reactivation of latent tuberculosis
13.Severe Immunization local reaction	Medically important condition	Vaccine Product related reaction
14.Confirmed covid-19 infection. One day after vaccination, she developed cough and chest pain. She was managed on Home Based Care (HBC) for 4 days, but no improvement and symptoms worsened. PCR turned out positive for COVID 19 on day 12.	Hospitalisation Patient recovered	**Coincidental**, this is because; there is an ongoing community COVID 19 infection in the country. It is not practical to identify asymptomatic clients prior to vaccination at community level. The patient developed symptoms within 24 hours of receipt of the vaccine highly suspicious that the person had pre-existing COVID-19 infection given that the minimum incubation period of COVID-19 infection is 2 days. It is still safe to vaccinate asymptomatic cases. The patient continued to improve.
15.Confirmed covid-19 infection. On admission she had low oxygen levels, she had severe Difficulty in Breathing, chest pain, cough and generalized body weakness; SPO_2 was 75% on atmospheric air and 82-92% on 3 liters of oxygen. Clinically, she had pneumonia and the facility managed pneumonia related illness.	Hospitalisation	Coincidental
16.Bleeding into breast milk About 40 minutes after the vaccination, she developed blurred vision that cleared by the evening as fever started and persisted till the next day. The axillary lymph nodes enlarged noticed bloody regurgitation of breast milk each time after feeding her baby (Day 3). She expressed breast milk and found it was blood stained (there was more blood than milk), and this is when she had the last spike of fever	Medially important condition	**Causality classification: C. Coincidental:** this is because 1. She had had cracked nipples, which had caused bleeding in the past. This patient also had painful lymphadenopathy, another known rare AEFI with Astra Zeneca vaccine against Corvid 19 *(Ref:* https://doi.org/10.1148/rycan.2021210038*, published online April 9th 2021.)* She was recovering and breast was breast feeding Except for few cases, the phenomenon of blood in breast milk is largely known to be idiopathic and self - limiting

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
17. Pulmonary Embolism	Hospitalization, AESI	**. Coincidental** Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine because: 1) There are other known causes that includes vascular malformations that might have caused blood stasis and we do not have original reports about his vasculature. 2) Doppler scan showed he had compressing lesions which could cause thrombosis. 3) He has high cholesterol hence could have other causes of thrombosis. 4) He had phlebitis reported on the Doppler scan which could cause thrombosis. **Other considerations include: A1. Vaccine product-related reaction** (As per published literature) this is because 1) It occurred 5days after vaccination, 2) The thrombosis associated with vaccine in literature goes with low platelets invariably so far., 3) Literature describes thrombosis in association with low platelets. **Comments .**There are no cases reported of thrombosis following the vaccine with normal platelets (all cases reported are associated with low platelets). The platelets were estimated on different occasions and were normal. However, we cannot exclude emerging conditions in association with the vaccine

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
18. Pulmonary Embolism	Hospitalization, AESI	Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine because: 1. The patient had normal platelets which is against the vaccine being the cause, 2. He had other features which predisposed him to thrombosis: a history of long travel, and also high BMI of 40. 3. Additionally, he was found to have a high random blood sugar, which was 10.5mmol/l (3.8-7.8). Other considerations include: A1. Vaccine product-related reaction (As per published literature) this is because 1. It is a probable AESI as per the Global Advisory Committee on vaccine safety dated April 7, 2021. It happened with in the expected 5 to 28 days following vaccination
19.Meniers disease The developed dizziness, tinnitus, easy fatigability and retrosternal pain. Just before vaccination he was well, but had history of similar illness in the past, and this was the second episode. Due to the above-mentioned complaints, he was unable to sleep for 2 days, symptoms worsened in a lying position.	Hospitalization	**. Coincidental:** this is because 1. Patient has a history of similar symptoms before vaccination 2. He has a known atopy and food allergies 3. He was on unspecified medications for asthma. If he was put of Non – steroidal - anti-inflammatory drugs, these could have caused tinnitus
20. Malaria	Medically important condition	Unclassified since she was not a serious AEFI case
21.Hypertension 5 days after receiving the vaccine), he suddenly developed chest tightness and with difficulty in breathing	Death	**Coincidental:** this is because 1. The history from the family that he was taking medication against hypertension, and had abandoned his blood pressure and heart disease medicines. He might have died of hypertensive heart disease 2. He was taking medications for hypertension for more than 10 years 3. Hypertension is common among Ugandans up to about 24% according to the NCD survey: 2014 STEPS Report

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
22. Myocardial infarction	Hospitalized. Patient recovered.	**Coincidental:** this is because: 1) She is a known diabetic for over 10 years with a diabetic foot ulcer that could be evidence of poorly controlled diabetes. 2) She has a poorly controlled diabetic; had hyperlipidemia and she was obese. 3) She had a large heart on echocardiogram, which large heart predisposes to arrhythmias that cause thrombosis. 4) She was taking oral hypoglycemic drugs **Other considerations include**: A1. Vaccine product-related reaction (As per published literature) this is because 1) It occurred 2 weeks post vaccination, 2) The vaccine can cause thrombosis which has been shown in blood vessels. However, involvement of coronary vessels in vaccine associated thrombosis has not been documented. Vaccine induced thrombosis as a possible cause of NSTEMI is less likely since vaccine induced thrombosis usually occurs in the presence of elevated D-dimer, which was not the case in this patient.
23. Respiratory failure	Death, AESI	**Coincidental** this is because: 1) There are other possible causes of respiratory failure including acute viral illnesses that can be severe in patients with chronic illnesses like him. 2) The diseased was a known Diabetic not on convectional medication, and a known HIV patient 3) He took herbs for Diabetes Mellitus **Comments by Reviewer**s: The investigations like RFT, HBA1c, were not done. Those tests might have suggested a metabolic cause of respiratory failure. His HIV status in terms of CD4 counts and Viral Loads are unknown, yet he could have stopped HIV medication just like he left taking anti-diabetic medicines. The side effects or toxic effects of the herbs the patient was taking cannot be excluded as cause or contributor to death. The postmortem report concluded that the diseased had pyelonephritis. However, the kidney sizes were normal, making kidney pathology an unlikely to be the cause of death.

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
24.Facial nerve palsy/Bells Palsy	Disabling , medically important condition	**Vaccine Product Related Reaction** this is because; 1) It occurred within two days' post vaccination 2) It is an antigen that can evoke an immunological reaction which can damage the facial nerve. 3) Cases of facial nerve paralysis have been reported in the WHO pharmacovigilance following vaccination with Corvid 19 vaccines (mRNA ones though) **Other considerations** include **Coincidental:** this is because Facial nerve palsy can occur independent of vaccinatio
25.Vertabral disc prolapse	Hospitalisation	**Causality Classification: C. Coincidental** this is because: 1) She had a history of fracture of the forearm following a fall down accident on stairs in 2018. The X-ray showed loss of lumbar lordosis is suggestive of a process that has been there for a relatively longer period than the 2 days of vaccination and vertebral disc prolapse may be inflammatory in nature given elevated D-dimers. Involvement of the spine in connective tissue disorders (Spondylitis) could be the underlying disorder to X ray changes in the spine. 2) On the other hand, the fall in 2018 in which she sustained a fracture to her arm could have also cause collateral damage to the spine. 3) Most causes of vertebral disc herniation are mechanical and these are common; 4) The age bracket favors disc prolapses.
26.Mesenteric Artery Thrombosis	Hospitalisation,	**Coincidental** this is because: 1) She has a risk factor known to be associated with mesenteric artery thrombosis which is ulcerative colitis, 2) She had repeated abdominal surgeries including intestinal obstruction and intestinal adhesions, 3) She was taking mesalamine **Other considerations include**: A1. Vaccine product-related reaction (as per published literature) this is because 1) It occurred 11 days' post vaccination, 2) A patient who presents with thrombosis and a normal platelet count post-vaccination might be in an early stage of vaccine-induced-immune-thrombotic thrombocytopenia.

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
		Comments : The platelets were normal therefore not suggestive of vaccine induced thrombocytopenia. The D-dimer were elevated. MAT was confirmed which is outside the window period of VITT. The patient's symptomatology can be explained by her primary diagnosis of ulcerative colitis. The side effects of the mesalamine are many and may be difficult to separate from some of her symptoms. Subsequently laparotomy and biopsy was done, with histology showing colonic carcinoma.
27. Gastritis A day after vaccination (she developed heaviness of left upper limb (site of injection), fever, headache, and general body numbness. These were followed by post prandial vomiting which was non projectile, non-bilious, non-bloody initially but started getting blood stained after days of continued vomiting and severe lower abdominal pain with no known relieving or aggravating factors, non-radiating and limited her routine activity	AESI	**Coincidenta**l this is because: 1) She had H pylori infection which is known to cause gastritis and there are other causes of gastritis that she could have got apart from the vaccine, 2) She was being treated with many medicines, some of which themselves could have caused gastritis, 3) She was taking azithromycin, vitamin D and vitamin C. Other considerations include: A1. Vaccine product-related reaction (As per published literature) this is because 1) The vomiting started 2 days after vaccination., 2) Astra – Zeneca Corvid 19 vaccine is known to cause some of the symptoms of gastritis, like vomiting and abdominal pain A4. Immunization anxiety-related reaction this is because 1) Vaccination usually causes anxiety. Anxiety is known to trigger stress response which involves stress hormone which could cause gastritis. Comments by Reviewers: The WBC count stated within range of normal. The prior use of a cocktail of medications against a suspected covid-19 infection compounded symptoms but also was evidence of general anxiety in the population.
28.Mesenteric Artery Thrombosis. she presented with severe abdominal pain which was worsening over time associated with abdominal fullness, nausea, loss of appetite and vomiting	Hospitalisation	Coincidental this is because: 1) she has had history of thrombosis (DVT), though this time the thrombosis is in an artery, 2) she is a known diabetic that has been poorly controlled for some time. Poor diabetic control is associated with hyperlipidaemia, which along with high blood sugar increase the chances of thrombosis Other considerations include: A1. Vaccine product-related reaction (As per published literature) this is because 1) Astra Zeneca Corvid 19 vaccine has been associated with venous thrombosis but maybe can also cause artery thrombosis Comments by Reviewers: Her platelet count was 223, 000/L which was normal. The D-dimer was elevated, 2714.85mg/ml (0-500), which may have been caused by an inflammatory process, for instance arteritis.

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
29.Gastroenteritis	Hospitalisation	Vaccine product-related reaction this is because: 1) From clinical trials phase III AstraZeneca vaccine has been documented symptoms of nausea, fever, vomiting and diarrhea, which are symptoms of Gastroenteritis (GIT), 2) It occurred within 24 hours post vaccination, 3) it is an antigen which could affect the GIT. Other considerations include: C. Coincidental this is because 1) there are many causes of diarrhea and vomiting including many viruses, bacteria protozoa and other agents, 2) Montelukust being taken for asthma can cause abdominal pain and diarrhea. Comments by Reviewers: Committee recommended that a D-dimer test should be carried out. She had other symptoms like headache, blurred vision and confusion which were still persisting at the time of assessment which need to be investigated. The tests suggested are: D-dimers, and Abdominal Doppler ultra sound scan because of previous history of a clot. This patient had symptoms commonly seen after COVID-19 vaccinations but had normal platelet counts.
30.Immunisation anxiety related reaction About five minutes after receiving the vaccine, she developed nausea and dizziness and headache; and after 30 minutes she developed difficulty in breathing, generalized body weakness and paralysis of her limbs (upper body?	Medically important event	**Immunization Anxiety Related Reaction** this is because; Anxiety is one of the known adverse effect following immunization: Immunization can result in release of stress of hormones leading to symptoms of anxiety One of the symptoms noticed by the examining physician was hyperventilation which started immediately after receiving the vaccine, consistent with immunization related anxiety. **Other considerations** .Coincidental events this is because: she was repeatedly admitted for non-organic disorder which is a suspected psychiatric illness and history of treatment (Depression), so she could have had anxiety even without vaccination.
31.Severe bronchopneumonia	Death	**Coincidenta**l events caused by exposure to something other than vaccine, this is because 1) He is a known HIV/ RVI patient for over 20 years that predisposes him to multiple chest infections, 2) Possibility of having been exposed to COVID-19 given that Uganda was experiencing a second wave of the pandemic. 3) TC, TDF/DTG - ART drugs **Other considerations** include: A1. Vaccine product-related reaction (As per published literature) this is because 1) The vaccine is known to enhance pre-existing Pneumonia, 2) Developed symptoms five days' post vaccination

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
32.Diabetes Mellitus	Hospitalization.	Coincidental or condition(s) caused by exposure to something other than vaccine because: 1) He is taking medications Dolutegriavir one of the highly active anti-retroviral drugs., 2) Diabetes mellitus can occur independent of vaccination from many other causes, 3) Known HIV patient since 2006 and Hypertensive on HAART and hypertensive medications Other considerations include: A1. Vaccine product-related reaction (As per published literature) this is because 1) There are some reported cases of exacerbation of hyperglycemia after vaccination. Pre-vaccination Random blood sugar was normal before dose 1, 2) Symptoms of Diabetes mellitus occurred within the 48hrs of vaccination)
33. Immune thrombocytopenia	Medically important event	**Coincidental**; this is because, 1) She had similar episodes of bleeding before which could have been due to low platelets or other abnormalities of the clotting system, 2) Many viral illnesses can trigger thrombocytopenia in predisposed individuals, 3) Recurrence before of mucus membrane bleeding which is a pointer to a pre-existent predisposition. **Other considerations** include: A1. Vaccine product-related reaction (As per published literature) this is because 1) It happened 6 days after vaccination and the window is 5 to 28 days, 2) The vaccine is known to cause thrombocytopenia *B1. Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event) this is because 1) The accompanying expectation of evidence of thrombosis is lacking in this case
		Comments. Extensive investigations to demonstrate immunological basis of thrombocytopenia was not done in this patient because of inaccessibility of the test. The patient was given steroids as part of management and the response to the steroids will be used as evidence of immunological basis of the thrombocytopenia. D-dimers in this case being normal makes the vaccine the less likely cause of thrombocytopenia.

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
34.Severe Pneumonia	Hospitalization. death	**Coincidental** Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine because: 1) She was found to be PCR positive for COVID 19, 2) She was an elderly person, which factor makes her prone to pneumonia caused by several causes. **Other considerations include: A1. Vaccine product-related reaction** (As per published literature) this is because 1) Very rare events occurred when the vaccine got systemic, 2) It occurred after 3 days' post receiving the vaccine **Comments by Reviewer; Pneumonia in this patient did not improve despite use of several antibiotics. She eventually turned Corvid 19 positive by PCR. Management of severe Corvid 19 disease often requires ICU setting since oxygen needs are usually higher than obtainable in ordinary ward setting.** The patient was vaccinated against COVID 19 without laboratory screening for COVID infection. Excluding the possibility of pulmonary embolism was not possible but the Chest X-ray didn't support it. The post mortem was not done. There was no CBC report (platelets count) though it was reported as normal CBC.
35.Abortion	Medically important	Coincidental because: 1) There are many causes of abortion including various virus infections in the first trimester and genetic / chromosomal abnormalities, 2) She had undiagnosed /untreated cystitis, 3) She had history of long bumpy travel and strenuous work without adequate rest including heavy object lifting for the funeral rites/ceremony. Other considerations include: A1. Vaccine product-related reaction (As per published literature) this is because 1) It is a material that can get into cells and perhaps interfere with development processes, causing foetal death and abortion, 2) It occurred 8 days after receiving the vaccine
		Comments by Reviewers: There was a fever that happened within 24hrs. of vaccination, which could have caused the intrauterine fetal death/ and abortion in 7 days. The Rhesus factor status of the mother was unknown, which could have been provided by the detailed patient clinical history. She had a bumpy journey for a whole day followed by strenuous work just before the abortion. She had untreated /undiagnosed cystitis that could have contributed to the abortion.

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
36.Optic atrophy	Disabling, AESI	Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine because: 1) There are many causes of optic atrophy, most of which were unknown (idiopathic) and others including viral infections, glaucoma, toxins, Vitamin B deficiency, ischemic injuries and radiations exposure which should be ruled out. Other considerations include: A1. Vaccine product-related reaction (As per published literature) this is because 1) The optic atrophy has been documented with other vaccines following influenza vaccine. https://www.aao.org/editors-choice/optic-neuropathy-after-influenzavaccination, 2) symptoms occurred 35 days after receiving the first vaccine. **Comments by** Reviewers: In Uganda, according to practicing Ophthalmologists, Optic atrophy background rate is high in people who report visual impairment in all age groups. There are so many other causes of blindness, but optic atrophy is common. This patient could benefit from more investigations specifically to rule out or implicate autoimmune disorders.
37. Deep Vein Thrombosis	Hopitalisation Patient was recovering	Coincidental because: 1) It can occur because of other causes like malformation of blood vessels (causing blood stasis), space occupying lesions, and vascular lesions which may cause inflammation of the veins and subsequent thrombosis. Other considerations include: A1. Vaccine product-related reaction (As per published literature) this is because 1) The thrombosis associated with vaccine in literature goes with low platelets invariably so far., 2) It occurred within 4 weeks of receiving the vaccine. Comments by Reviewers: This lady was multiparous who had 7 children delivered by traditional birth attendants and she had no medical records. Investigations of this patient didn't include pelvic and whole leg ultrasounds which would have been important. The platelets count was normal.

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
38.Nephrotic syndrome in a 16 year client	Hospitalization Patient recovered	Coincidental given that Nephrotic syndrome is a common disease in children in the Ugandan setting. Associated causes of Nephrotic syndrome in children are many in our setting: Post infectious (following both bacterial and viral infections), Malaria, Schistosomiasis, SLE & other connective tissue disorders. Symptoms occurring just a day after suggests there was an on-going process by the day the patient received the vaccine. Other considerations include: A1. Vaccine product-related reaction (As per published literature) this is because 1) There is a report of nephrotic syndrome following AstraZeneca vaccine in India. https://www.kireports.org/article/S2468-0249(21)01283-3/fulltext. This vaccine may also be an emerging or new cause of Nephrotic syndrome, as we wait for more cases to be described. India as well as Uganda are tropical, and they have higher background rate of Nephrotic syndrome. Any condition that causes fever, such as does the Astra Zeneca vaccine may cause recrudescence of Nephrotic syndrome. 2) There has also been a reported recrudescence of nephrotic syndrome in teenager with AstraZeneca vaccine. for uristic-The Johns Hopkins Hospital Point-of-Care Testing Program case 3) It has been reported between the second and 8 days.
39.Arterial Thrombosis	Hospitalization Patient recovered	C**oincidental** - It is possible that vaccination only unmasked a pre – existing narrowing of the arteries. **Other consideration**-Vaccine product-related reaction (As per published literature) this is because 1) the event was described within 30 days of receiving the vaccine, 2) There are reported case series of thrombosis following Astra Zeneca Vaccine.
40.Urticaria- The morning following vaccination, she woke up to swelling of the lips, generalized skin rash with red itchy patches, pain in the finger joints, and generalized body pain.	Disabling event/ incapacitating	coincidental - The patient had previous history of Urticaria as a reaction to ceftriaxone.The committee also to advised that the patient be cautious /refrain from the second dose until more investigations and review by an allergy specialist. Vaccine product-related reaction (As per published literature) this is because 1) There have been reported cases of Urticaria following COVID 19 vaccine. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8255352/, 2) It occurred on the next day following immunization (within 24 hours of vaccination).

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
41.Urticaria- , had no concerns immediately after until 14 days later when she developed a skin rash that was itchy in the parts of the body that sweat most. The itchy rash was associated with lip swelling and was mainly postprandial	Disabling	Coincidental .The close relationship with food /meals is very suggestive of a GIT allergen causing the urticaria or worsening the condition. The committee recommended a review by an allergen doctor to ensure that proper case management is provided. **Other considerations include:** A1. Vaccine product-related reaction (As per published literature) this is because 1) Twenty-four (24) cases have been documented elsewhere (Source: COVID-19 AstraZeneca Vaccine Analysis Print as of June 2021) 2) Symptoms occurred within 2 weeks after receiving the vaccine, 3) The vaccine contains known potential allergens including several excipients
42.Sudden death in a 68 year old male , 1 hour after vaccination.	Fatal. Event of special interest in the context of the vaccine	Coincidental-It can occur due to other causes of sudden death include heart attack, stroke etc., 2) He had history of unmanaged hypertension. He was not observed for 30 minutes' post-vaccination in which case it is not possible to exclude or incriminate anaphylaxis. **Other considerations include**: A1. Vaccine product-related reaction (As per published literature) this is because 1) There have been cases of sudden death described after COVID 19 vaccine. this happened through Anaphylaxis. Https.//www.ncbi.nlm.nih.gov/pmc Death associated with newly launched SARS COVID 19 vaccination, 2) It occurred within 1hr after vaccination
43.Death that occurred to a 24 years medical student	Fatal	Coincindental-The possible aetiological agent of death found in this patient is *Plasmodium Falciparum* malaria. It is possible to miss malaria in up to 19% of cases (false negative) that occurs because parasitized Red blood cells tend to become sticky, undergo rouleaux formation and sequester in different organs, leaving the general circulation devoid of parasitized RBC, which may explain a falsely negative blood smear. False negative Rapid Malaria tests have been documented. **In this patient** Falciparum parasites were found in the brain and hemozoin pigment was found on the liver on histopathology. Micro thrombi were found in the brain, lungs, and kidneys. Histological findings incriminate malaria as the main cause of death, however, investigations on COVID 19 indicated that she was recovering from COVID 19 infection (IGG significantly high in serum while IGM was very low). In addition, the PCR sample from the lower respiratory tract infection was positive for COVID 19. The severe and rapid respiratory failure was a sign of the COVID 19 infection. Vaccine Induced Thrombocytopenic Thrombosis **(VITT)** is unlikely in this patient because criteria are not met.

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
		Notice: In the causality assessment of this case; Experts from different background were involved including; pathologists, hematologists, NDA, MOH, WHO, invited guests and treating physicians from Mmbale Regional Referral Hospital and Kiruddu Regional Referral Hospitals.
44.Pleurisy occurring in 59 years old male	Patient recovered	**Coincidental** 1) There are several causes of pleurisy including viruses. this patient had acute respiratory tract infection which could have spread to the lung and to the pleura. There are also noninfectious causes, 2) This patient has HIV infection and could cause pleurisy. Besides the patient with HIV is prone to other opportunistic infections which could cause pleurisy, 3) HAART (TDF, CTC, DTG), Azithromycin, Warfarin, 4) He had upper respiratory tract infections **Other considerations include**: A1. Vaccine product-related reaction (As per published literature) this is because; 1) It is documented that it can cause pleurisy: a case of Interstitial lung disease has been reported following AstraZeneca vaccine. http://dx.doi.org/10.1136/thoraxjnl202176O9. 2) It occurred after 7 days' post vaccination.
45. Vaccine Induced Anxiety that occurred in a 19 years old female student at Mukono school		**Immunization anxiety-related reaction** because: 1) Anti vaccine information was circulating in the media: specifically, at that time there was a media hype about a student who has died following vaccination, 2) Vaccine induced anxiety has been found against human papilloma vaccine (HPV) Immunization stress-related responses presenting as psychogenic non-epileptic seizures following HPV vaccination in Rio Branco, Brazil https://doi.org/10.1016/j.vaccine.2020.08.044, 3) It occurred after 30 minutes of vaccination, 4) Vaccine induced is common in young adults and there have been other cases with similar events. 5) Anxiety related reactions have been documented with COVID 19 Vaccines. https://www.verywellhealth.com/vasovagal-syncope-linked-to-fainting-after-vaccination-5094157, 6) Biological processes like hormones involved in generating the pathophysiology of anxiety.

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
		Other considerations include: C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine this is because 1) She had previous history of sudden unexplained collapse. This case was part of a cluster that happened to other two students receiving the same vaccine from the same site/school, on the same day. All the students improved by the following day. Being in a large group at the time of vaccination, it is possible not to get adequate pre-vaccination counseling.
46.Vaccine Induced Anxiety that occurred in a 21 year old female student at Mukono school of health sciences	Hospitalization Patient recovered	Immunization anxiety-related reaction
47.Vaccine Induced Anxiety that occurred in a 22 years old female student at Mukono school of health sciences from Mukono District.	Hospitalization Patient recovered	Immunization anxiety-related reaction
48.Spondylosis that occurred to a 61 years old male. He developed paralysis involving the left upper limb, which started as paresthesia injected arm (left) that was associated with a dull pain radiating to the upper back. This was later followed by weakness in same (left) and paralysis of the ring and little finger of same limb.**14 days after dose** the weakness spread to the right side of the body, with both legs losing sensation but no associated pain.	Hospitalization, disabling Patient was recovering	**. Coincidental** Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine because: 1) The are many associations of spondylosis including HLA type and obesity and spectrum of rheumatic conditions, 2) Being overweight or obese can significantly contribute to symptoms associated with osteoporosis, osteoarthritis, rheumatoid arthritis, degenerative disc disease, spinal stenosis, and spondylolisthesis. https://www.spineuniverse.com/conditions/back-pain/back-pain-obesity, **Other considerations include: A1. Vaccine product-related reaction** (As per published literature) this is because 1) An increasing number of rheumatic conditions including spondylosis being documented after using COVID 19 vaccine., 2) It occurred within a plausible time window -7 days' post second dose **Comments by Reviewers:** Though MRI imaging positively diagnosis spondylosis, one would have expected a history of chronic pain and disability. This patient needed more extensive investigations particularly to exclude malignant conditions that could cause sudden onset of backbone disease and other conditions. A biopsy of spinal tissue or histology may elucidate the cause further.

Reported event	Reason for seriousness and outcome	National AEFI Committee Causality conclusion
48.Spontaneous Abortion: occurred in 40 years old female from Kampala		**Coincidental** this is because: 1) She had history of similar event in sept 2020, 2) There are several causes of abortion and it can occur irrespective of vaccination, 4) She had falling down accident post vaccination/ trauma. 5) She is also obese **Other considerations include**: A1. Vaccine product-related reaction (As per published literature) this is because 1) The vaccine is a foreign body and it can provoke, join tissue and might interfere and affect the organ development, 2) It occurred the following day post vaccination **Comments by Reviewers**: This patient was unable to afford laboratory investigations and treatment. In addition, we couldn't get the detailed clinical record of this patient. The team recommends a detailed gynecological assessment of the patient.
49.Convulsion : occurring in a 38/M sanitation worker at KCCA central division	Hospitalized Patient Recovered	**Coincidental** Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine because: 1) He is a known alcoholic, 2) There are many other causes of seizures including chronic alcoholism, viral infections and other infections, as well as idiopathic epilepsy, 3) Alcoholism, which could induce seizures,

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