Safe Drugs Save Lives

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PHARMACOVIGILANCE BULLETIN

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AEFI Report Summary 2019

Background:

Vaccines are administered as a preventive measure to large numbers of healthy individuals, particularly children and are among the safest of pharmaceuticals. Uganda National Expanded Program on Immunization (UNEPI) uses vaccines that have been proven over many years to be very safe and effective. However, no immunization can be declared to be entirely without risk and in rare instances, some people experience Adverse Events Following Immunization (AEFI).

These range from mild hypersensitivity to serious (but rare) adverse events. In addition to the vaccines themselves, the process of vaccination is a potential source of adverse events if immunization procedures and recommendations are not strictly adhered to.

Despite rare potential medical events, the benefits of immunization against diseases far outweigh the risks of adverse events following immunization. The Council for International Organizations of Medical Sciences (CIOMS) / WHO working group on vaccine pharmacovigilance (2012) defined AEFI as "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease". Vaccine pharmacovigilance is the science and activities relating to the detection, assessment, understanding and communication of adverse events following immunization and other vaccine or immunization-related issues and to the prevention of untoward effects of the vaccine or immunization.

The Ministry of Health established the National AEFI committee to assess and conduct causality assessment for all serious AEFIs. It comprises of experts from different fields of practice including pediatricians, microbiologists, physicians and pharmacists among others. The National Drug Authority (NDA) with support from UNEPI and World Health Organization (WHO) country office hosts this committee. NDA maintains a functional database as a record of all the AEFIs investigated and assessed by the committee.

Description of the AEFIs

NDA received 106 AEFIs in 2019. 10% (n = 11) were from routine immunization while 90% (n = 95) were from the mass vaccination campaign for Measles – Rubella (MR) and Polio conducted by the Ministry of Health. 69% (n = 73) of the AEFIs were not serious and most were labelled for the product. 31% (n = 33) of the AEFIs were serious in nature with 15% (n = 5) of them resulted into fatal outcomes. Among those, 2 deaths occurred among infants (28 days to 23 months) while 3 occurred among children (2 to 11 years). The notable signals registered from the mass vaccination campaign were Toxic Epidermal Necrolysis, Steven Johnson syndrome and Bullous impetigo that occurred in 6 patients following administration with MR vaccine.

A summary of all the AEFI reports received in 2019 has been detailed in Annex II (page 17) following the quarterly summary (Annex I).

Case Reports for AEFIs with Fatal Outcomes

Case I: Sudden Unexplained Death following MR and bOPV vaccination

The AEFI relates to a 22 months old female infant twin who passed on following vaccination with the Measles Rubella vaccine. The patient had no history of chronic illness or medical allergies. Following vaccination on 18th October 2019 with MR and bOPV, the child complained of severe headache around 2 am on the 19th October 2019 along with fever. The mother administered Paracetamol and LONART (Artemether/lumefantrine). The child was found lifeless the following morning. The postmortem report reviewed indicates severe anemia as the cause of death.

The MR vaccine is a live attenuated vaccine that is used to prevent both measles and rubella infection (German measles) in a single shot. The common side effects include soreness, redness, or rash at injection site, fever or swelling of the glands in the cheeks or neck. Most often, these symptoms start within 24 hours of the shot. They most often last 3 to 5 days. Serious side effects are rare and may include febrile seizures, temporary pain and stiffness in the joints (mostly in teenage or adult women), pneumonia, swelling of the brain and/or spinal cord covering, or temporary low platelet count which can cause unusual bleeding or bruising. The vaccine may also cause life-threatening infection in people with serious immune system problems.

The causality assessment carried out by the National AEFI committee classified the reaction as coincidental underlying or emerging conditions caused by exposure to something other than the vaccine. This is because the child had poor feeding habits, which could have been the cause of the anemia.

Severe anemia is not a labelled reaction for the MR vaccine however, a mild viral illness, like that caused following immunization with the vaccine, is capable of lowering mean Hemoglobin levels significantly for at least 14 days after inoculation and in individual cases up to a month. The mechanism is hypothesized to be due to changes in Iron Metabolism.

Case II: Toxic Epidermal Necrolysis following MR vaccination

A 3-year-old male child was vaccinated on the 20th October while having a cough but no other symptoms. He developed flu-like symptoms and fever 3 days after, and a measles-like rash 4 days later, when mother gave vitamin A. The next day, he was diagnosed with measles and another dose of Vitamin A was given as well as paracetamol, I.V ceftriaxone and I.V gentamycin for 2 days, then oral amoxicillin to complete 7 days of treatment. The next a day, a clinician at the same unit saw him and added prednisolone 2.5mg twice a day, diagnosing it as eczema, not measles. 12 days after the vaccination, he still had fever and was given I.V Ampiclox.

On November 2, 2019 (13 days after vaccination), the fever was so high that he had rectal paracetamol and tepid sponging through the night. On November 3, 2019, the whole back was covered with rash. The next day, he had generalized blisters and the parents had him admitted and managed on Hydrocortisone, Metronidazole and Ceftriaxone, Bisacodyl, BBC spray, wound dressing and oral morphine. He was referred to Mulago hospital on 12/11/2019, seen at Acute care unit and referred immediately to Kiruddu burns unit where he was given analgesia (paracetamol and ibuprofen), syrup Haemoforte, Vit A repeated (2 doses) and I.V hydrocortisone.

He had extensive peeling of the skin, generalized and dry, no involvement of the deeper skin layers but the eyelids were involved as well as the lips and possibly the mouth. The plan was to manage him as burns with dressing and fluid management, temperature control and basic investigations. A tentative diagnosis of Toxic epidermal necrolysis was made. Unfortunately, the child passed on the next day.

Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are severe acute skin disorders characterized by macular rashes, often with atypical target lesions, involvement of more than one mucosal site and in TEN coalescence of the rash to widespread erythema, necrosis and bullous detachment of the epidermis. The annual incidence of SJS and TEN is about one to three cases per million persons. Drugs are believed to be the cause of 80 to 90% of the cases of TEN and at least 50% of the cases of SJS (Ball et al, 2001). The remaining cases are linked to infections and a variety of other etiologies, with a small fraction without obvious triggers. Very few reports of SJS after vaccination have been published, and SJS and TEN are not usually considered among vaccine risks.

Recommendation:

Despite the plausibility of a causal relationship between vaccination and SJS and TEN, a review of AEFI reports received is reassuring in view of the small number of reports and the large number of vaccines administered in the country during the surveillance period. If vaccination causes SJS and TEN, it happens very rarely and under most circumstances is unlikely to outweigh the benefits of vaccination. Although immunization has not been evaluated as an etiology of SJS and TEN, the possible role of immunization should be considered because of the severe morbidity and mortality associated with SJS and TEN and the plausibility of this hypothesis.

Case III: Medication Error: Acute Respiratory failure following vaccination

The AEFI relates to a 2-year-old male child who died 30 minutes after vaccination with Measles Rubella Vaccine. The patient had a history of obstructed breathing while the cause of death was noted to be respiratory failure.

The vaccination centre had immunized 70 other children in the same session with no serious AEFI reported. The investigation team noted that the health worker inadvertently reconstituted the measles vaccine with a muscle relaxant Suxamethonium instead of its diluent sterile water. The reconstituted vaccine was injected to three children of whom one died while the other two developed non-fatal serious AEFIs that resolved upon treatment with hydrocortisone and Normal saline.

The investigation team noted a vial of Suxamethonium among the used vaccine vials that was similar to the diluent in appearance. The alleged wrongly reconstituted vaccine vial and used ampoule of injection succinylcholine were retrieved from the vaccination site for further investigation. Documentation of the diluent in the vaccine control book was poorly done while the cold chain storage for the vaccine was noted to have other drugs (oxytocin, and Suxamethonium)

Causality assessment done by the National AEFI committee, using the WHO algorithm, revealed a classification of A3: Immunization error-related reaction because circumstantial evidence pointed towards this possibility and that the symptoms started shortly after vaccination.

Recommendation:

Health care providers often work under intense and very high-pressured circumstances, full of distractions. It is therefore not surprising that errors do occur. They have a heavy burden of administration and require continuous multi-tasking, which results in them being more error-prone. In view of this situation, health workers should be prepared to work in these demanding work environments and avoid medication errors as much as possible. The National AEFI committee recommends that health workers ***should therefore incorporate safety assessment programs during vaccination campaigns*** as a risk minimization measure.

References

1. Ball, R., Ball, L.K., Wise, R.P., Braun, M.M., Beeler, J.A., Salive, M.E. and Vaers Working Group, 2001. Stevens-Johnson syndrome and toxic epidermal necrolysis after vaccination: reports to the vaccine adverse event reporting system. *The Pediatric infectious disease journal*, *20*(2), pp.219-223.

Case Report: Onset Diabetes with Dolutegravir in ART Naive Client

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TJB is a male 49-year-old resident of Kitooma village, Bireere subcounty, Isingiro district.

He tested HIV positive on the 8th of august 2019, and on the same day he was started on ART (**TDF/3TC/DTG**) and co-trimoxazole. Baseline weight was 43kgs, CD4 552 C/UL, HB 14.2 g/dl and Creatinine 1.22mmol/l but there was **no baseline RBS done**.

ONE month later on the 7th September 2019, he was admitted on medical emergency ward with complaints of polyuria, polydipsia and fatigue with associated weight loss. During history taking on admission, he reported a positive family history of diabetes mellitus. He was managed as a case of DKA WITH INSULIN AND IV FLUIDS and discharged on the 12th/sept/2019.

He was reviewed in the ART-clinic on 20th/September/2019 and at that time his ART regimen was changed/substituted to **TDF/3TC/EFV** and referred to the DM clinic. He attends the DM clinic and is currently on metformin tablets 500mg b.d and insulin **mixtard 30IU PB and 20IU PS.**

His last ART clinic visit was on the 16th December 2019; his weight was 50kgs (an increase of 7kgs of baseline weight) but his blood sugars have persistently remained high as illustrated in the table below.

Follow-Up Blood Sugar Monitoring

Date	Result	Type
12/09/2019	25.3 mmol/l	Random Blood Glucose
23/09/2019	21.1 mmol/l	Random Blood Glucose
26/09/2019	10.6 mmol/l	Random Blood Glucose
17/10/2019	13.2 mmol/l	Fasting Blood Glucose
14/11/2019	14.3 mmol/l	Fasting Blood Glucose
28/11/2019	13.4 mmol/l	Fasting Blood Glucose
19/12/2019	17.6 mmol/l	Fasting Blood Glucose

Recommendation:

The National Pharmacovigilance Centre has identified hyperglycaemia as a new signal to watch out for among ART experienced recipients of care who have been on older regimens for an average of over ten years. This is a unique case of rapid onset of hyperglycaemia in an ART naïve client which further highlights the importance of conducting baseline tests to screen out at-risk patients such as TJB who had a family history of diabetes.

National Drug Authority continues to encourage active safety monitoring for all patients initiated on Dolutegravir or Isoniazid preventive therapy in order to detect and manage any potential risk.

aDSM Support Supervision Report

Introduction

The Pharmacovigilance strategy for Uganda provides for active Drug Safety Monitoring (aDSM) of new drugs such as Bedaquiline and Dolutegravir among others used in public health. This is premised on the fact that such new drugs are often used in combination with existing drugs, creating a potential for previously unrecognized adverse events and drug interactions. Active monitoring of such drugs beyond spontaneous reporting is thus an important system that documents safety concerns alongside monitoring effectiveness. The National Drug Authority together with the MoH introduced Active Drug Safety Monitoring in July 2019 for Dolutegravir and Isoniazid Preventive Therapy. aDSM is being implemented in 18 sentinel sites that include all Regional Referral hospitals and ART centres of excellence with resources and capacity to monitor patients

In December 2019, support supervision for the sentinel sites was undertaken to stress active monitoring and improving quality of the reports for facilities that were reporting.

While visiting the 18 sentinel sites, other health facilities within the Regional Referral Hospitals' catchment areas were visited as well for sensitization and distribution of reporting tools. NDA visited Moroto, Soroti, Mbale, Jinja, Arua, Gulu, Lira, Mubende, Hoima, Fort Portal, Masaka, Mbarara, Kabale Regional Referral Hospitals, Iganga General Hospital and the respective HC IVs and HC IIIs in each region. IDI, MildMay and Naguru China-Uganda Friendship Hospital were also visited.

Summary of Facilities Visited.

Moroto:

1 RRH and 6 HC IIIs

No.	Health Facility
1	Moroto Prisons HC III
2.	Moroto Army Barracks HC III
3.	St Pius Kidepo HC III
4.	Nakopelimen HC III
5.	Loputuk HC III

6.	Nanduget HC III
7.	Moroto Regional Referral Hospital

Soroti:

Soroti has 2 HC IVs and 11 HC IIIs. We visited 1 RRH, 2 HC IVs and 8 HC IIIs.

No.	Health Facility
1.	Tiriri HC IV
2.	Tubur HC III
3.	Dakabela HC III
4.	Princess Diana Memorial HC IV
5.	Gweri HC III
6.	Asuret HC III
7.	Kamuda HC III
8.	Soroti HC III
9.	Western Division HC III
10.	Eastern Division HC III
11.	Soroti Regional Referral Hospital

Mbale:

1 RRH, 3 HC IVs, 7 HC III and 1 HCII

No	Health Facility
1.	Bufumbo HC IV
2.	Jewa HC III
3.	Busamaga HC III
4.	Namakwekwe HC III
5.	Nakaloke HC III
6.	Salem Kolony HC III
7.	Busiu HC IV
8.	Namatala HC IV
9.	Police HC III

10.	Sayidina Umar HC II
11.	Malukhu HC III
12.	Mbale Regional Referral Hospital

Iganga:

1 General Hospital, 1 HC IV, 8 HC III and 1 PNFP

No	Health Facility
1.	Busowoli HC III
2.	Nakalama HC III
3	Bugono HC IV
4.	Nawandala HC III
5.	Nambale HC III
6.	Namungalwe HC III
7.	Bunyiiro HC III
8.	Bulamagi HC III
9.	Iganga Municipal Council HC III
10.	Iganga Islamic Medical centre
11.	Iganga General Hospital.

Jinja:

1RRH, 5 HC IVs and 8 HC IIIs

No	Health facility
1.	Wakitaka HC III
2.	Budondo HC IV
3.	Lukolo HC III
4.	Buwenge HC IV
5.	Magamaga HC III
6.	Kakaire HC III
7.	Busedde HC III
8.	Kakira HC III

9.	Muwumba HC III
10.	Bugembe HC IV
11.	Mpumudde HC IV
12.	Walukuba HC IV
13.	Jinja Central HC III
14.	Jinja Regional Referral Hospital

From the West Nile, Northern and South Western regions, 33 health facilities and 204 professionals visited.

Arua:

No.	Health facility
1.	Arua Regional Referral Hospital
2.	Aroi HC III

Maracha:

No.	Health facility
1.	Ovujo HC III
2.	Oleba HC III
3.	Maracha District HC IV
4.	Maracha District Hospital

Gulu:

No.	Health Facility
1.	Awach HC IV
2.	Bardege HC III
3.	Gulu RRH
4.	Laroo HC IV
5.	Layibi Techo HC III

Lira:

No.	Health facility
1.	Lira Regional Referral Hospital
2.	Lira Prison HC III
3.	Ayago HC III
4.	Ogur HC III
5	Ngetta HC III
6.	Lira University Teaching Hospital
7.	Amuca SDA HC III
8.	Barapwo HC III
9.	Ober HC III
10.	PAG HC IV

Hoima:

No.	Health facility
1.	Hoima Regional Referral Hospital

Kikuube:

No.	Health Facility
1.	Kabwoya HC III
2.	Kikuube HC IV
3.	Kitoole HC II

Kabarole:

No.	Health Facility
1.	Kabalega Medical Centre
2.	Azur Christian HC
3.	Bakuku HC III
4.	Fort portal Regional Referral Hospital
5.	Holy family Virika Hospital

6.	Karambi HC III
7.	Kabarole Hospital
8.	Kigote HC III

Mubende:

No.	Health Facility
1.	Mubende Regional Referral Hospital
2.	Kasambya HC III
3.	Kibalinga HC III
4.	Nabingoola HC III
5.	Kitenga HC III
6.	Kalonga HC III

No.	Health Facility
1.	Masaka Regional Referral hospital (Uganda Cares)
2	TASO Masaka
3	TB Masaka
4	Mbarara Regional Referral hospital
5	Kabale Regional referral hospital
6	Bukulula HCIV
7	Kalungu HCIII
8	Kyanamukaka HCIV
9	Mbarara Municipal HCIV
10	Kinoni HCIV
11	Bwizibwera HCIV

Summary of Material disseminated

Material	Number
Stickers	15
ADR reporting booklets	88
Bulletins	71
aDSM booklets	15

Key findings during the support supervision

Although the sentinel sites have embraced aDSM, the actual implementation is still faced with challenges. With the exception of Mbale, Masaka and Mbarara Regional Referral Hospitals, the other sentinel sites lack supplies to perform laboratory tests especially those recommended in the aDSM protocol. National Drug Authority together with the support of the implementing partners will continue to support the sites to ensure that patients are actively monitored as provided in the guidelines. For the Health Centres visited, it was noted almost all of them had the ADR reporting tools even though the reporting rates were low.

Quarterly ADR Summary

The following is a summary of all the Adverse Drug Reaction reports received at the National Pharmacovigilance centre in the period starting 1st October 2019 to 31st December 2019.

A total of 603 ICSRs were reported in quarter two, with majority (60%) coming from central region, followed by west Nile (9%); western (8%); and Eastern (8%) regions. Kampala was the highest reporting district (37%) followed by Mbarara. Reporting by email was most used this quarter (53%), followed by the physical form (30%) with minimal reports coming through the whatsapp and online platform. Clinical officers were the highest reporting carders (34%) followed by pharmacists (12%) with patients submitting the least reports.

More than half of the reported incidents (57%) were serious, most reported as life threatening. Most reported incidents occurred in the age group of 45-64 years (34%) followed by the elderly (8%) with children (4%) and infants (1%) manifesting the least reported incidents.

Table 1 below provides the statistical description of the cases while the details are given in annex 2

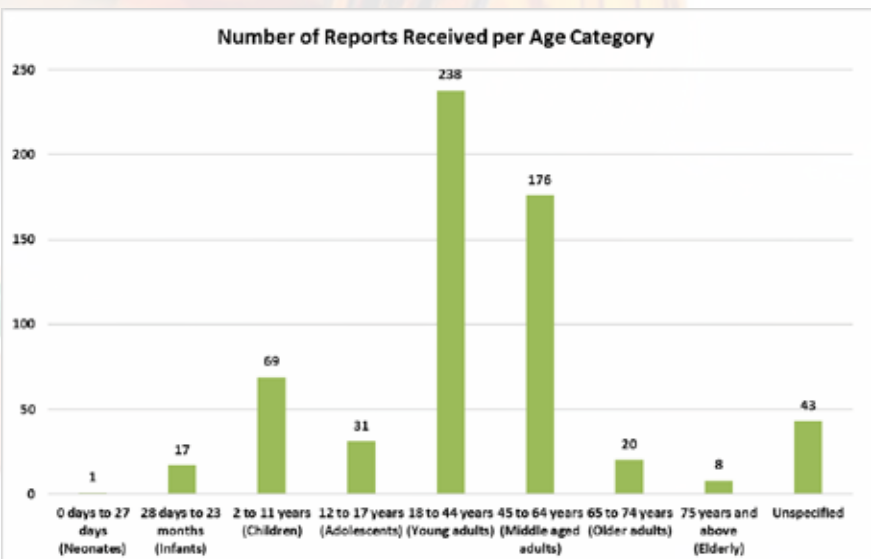
Table 2 Characteristics of ADR reports in the Uganda National Drug Authority pharmacovigilance database, distributed over three months (October to December 2019)

	Oct - Dec (N=603)
	n (%)
Mean age (± SD)	
Patient sex	
Female	380 (63.02%)
Male	217 (35.99%)
Unknown	6 (1%)
Seriousness	
Yes	309 (51.24%)
No	294 (48.76%)
Seriousness Criteria	
Death	30 (5%)
Prolonged Hospitalization	67 (11%)
Disabling	68 (11%)
Life threatening	141 (23%)
Congenital anomaly/Birth defect	3 (1%)

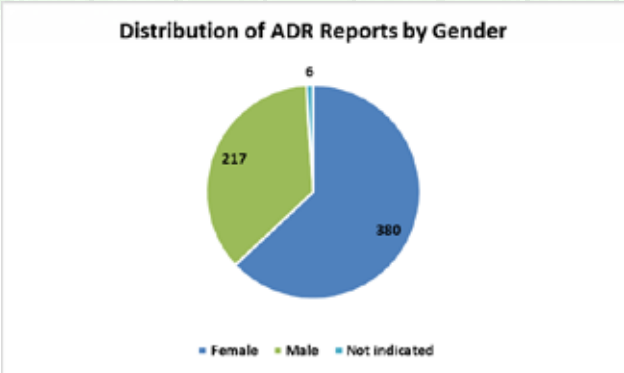
Type of reporter	
Patient	2 (0.3%)
Pharmacist	87 (14%)
Doctor	142 (22%)
Clinical Officer	205 (34%)
Nurse	74 (12%)
Patient Age groups	
0-28 days	1 (0.17%)
28 days to 23 months	17 (2.8%)
2 to 11 years	69 (11.44%)
12 to 17 years	31 (5.14%)
18 to 44 years	238 (39.47%)
45-64 years	176 (29.19%)
65 to 75 years	20 (3.32%)
Above 75 years	8 (1.3%)
Unspecified	43 (7.1%)

Age

The age categories of 18-44 years and 45 to 64 years continue to report the largest number of reactions. However, last quarter, there was an increase in the number of reactions reported in the paediatric group due to the Measles Rubella campaign.

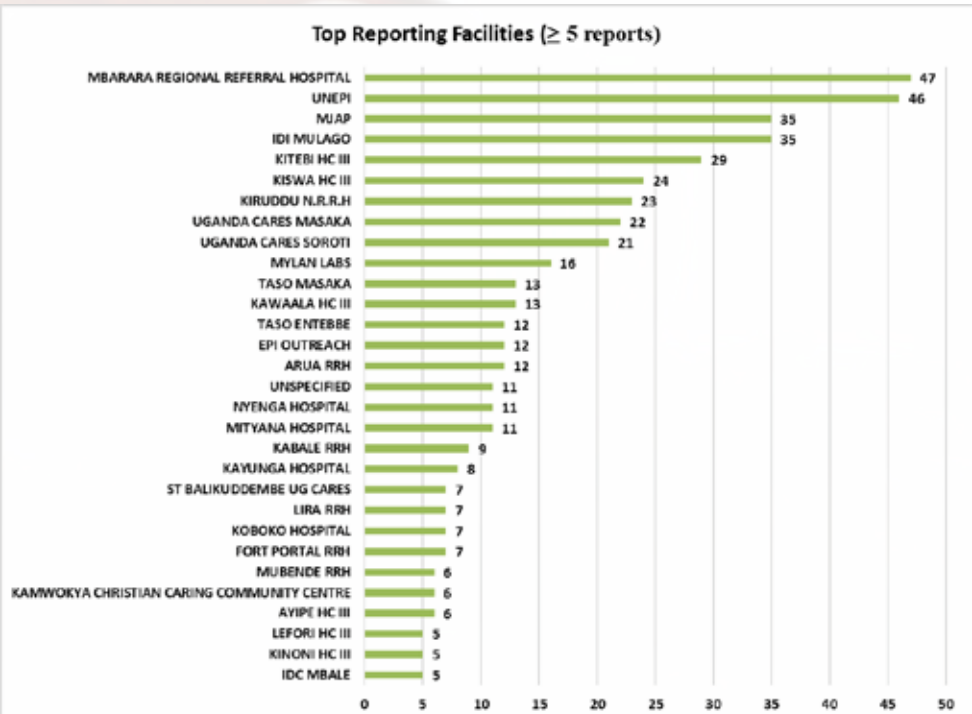


Sex



63.02% of the reports were reactions from female patients, while 35.99% were from male patients. The high proportion of reports among female patients has been theorized to be due to the differences in metabolic rates between males and females.

Health facilities/ institutions that submitted reports



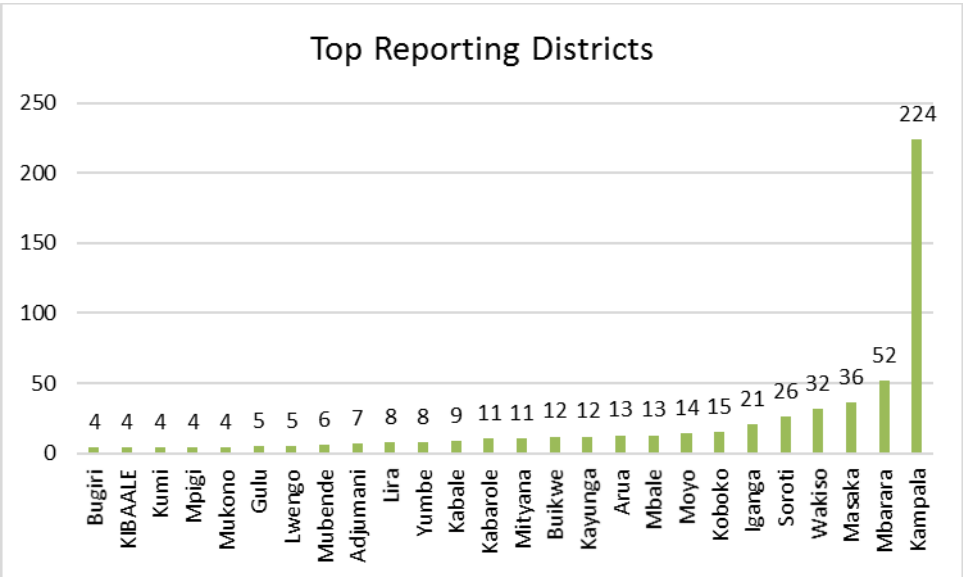
Other Facilities with less than 5 reports

Health Facility	Reports Submitted
Adjumani Hospital	4
Bugiri Hospital	4
Busiu HC IV	4
Iganga Hospital	4
Komamboga HC III	4
Kumi Hospital	4
Nsambya Home Care	4
Ayiri HC III	3
Cuf Hospital Naguru	3
Kibaale HC IV	3
Kilembe Mines Hospital	3
Kisenyi HC IV	3
Laropi HC III	3
Mulago	3
Ombachi HC III	3
Soroti Regional Referral Hospital	3
Uganda Cares Kla	3
Virika Hospital	3
Bethany Women And Family Hospital Entebbe	2
Bl HC IV	2
Bukulula HC IV	2
Butabika	2
Gulu RRH	2
Kinoni HC IV	2
Lacor Hospital	2
Lwala Hospital	2
Lwebitakuli HC III	2
Mujhu Art Clinic	2
Namatala HC IV	2
Nambale HC	2
St Stephens Hospital Mpererwe	2
Unichem Labs	2
Agago HC	1
Ahf Soroti	1
Amucu HC III	1

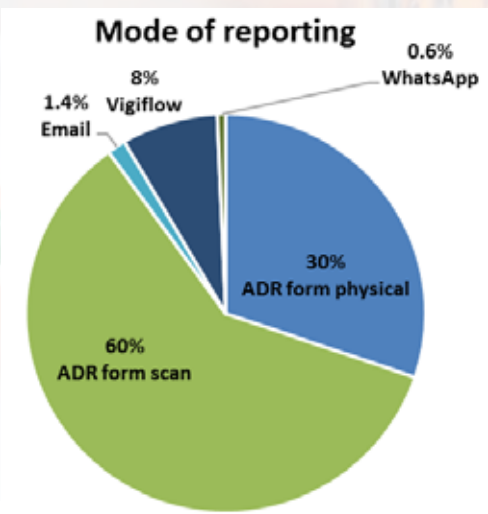
Arigle HC III	1
Ayago HC IV	1
Azur Chc	1
Budomero HC II	1
Bukoto HC II	1
Bundibugyo Hospital	1
Busesa HC IV	1
Bushenyi Medical Center	1
Busia HC IV	1
Busodwa HC III	1
Butoolo HC III	1
Bwizibwera HC	1
Devic Medical Clinic	1
Entebbe Hospital	1
Eria HC III	1
Gborokolongo HC III	1
Goboro HC II	1
GSK	1
IDI Mulago	1
IDI Mbale	1
Ikonia HC III	1
Kabarole Hospital	1
Katovu Mobile	1
Kibaale Hospital	1
Kyampisi HC III	1
LHC III	1
Luwero Hospital	1
Mbarara Municipal HC	1
Mijhu Art Clinic	1
Mildmay	1
Moyo General Hospital	1
Moyo Mission HC IV	1
Mpigi HC	1
Nalinya Ndagire HC III	1
Naproron HC IV	1
Nawampi HC II	1
Ntwentwe HC IV	1

Pfizer Global Pharmaceuticals	1
Victoria Medical Center	1
Yoyo HC III	1

Districts



Kampala submitted the highest number of reports (224) and the second highest were submitted from Mbarara District (52).

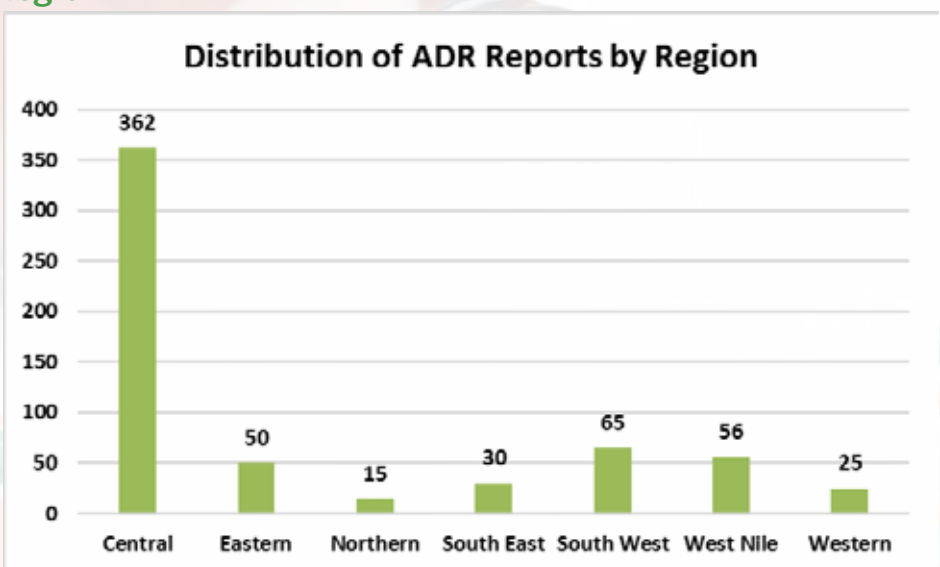


There has been increased reporting through online channels and the number of physical reports is steadily decreasing. This is a good indication that reporters are embracing digital systems of reporting which leads to quicker analysis and improved feedback.

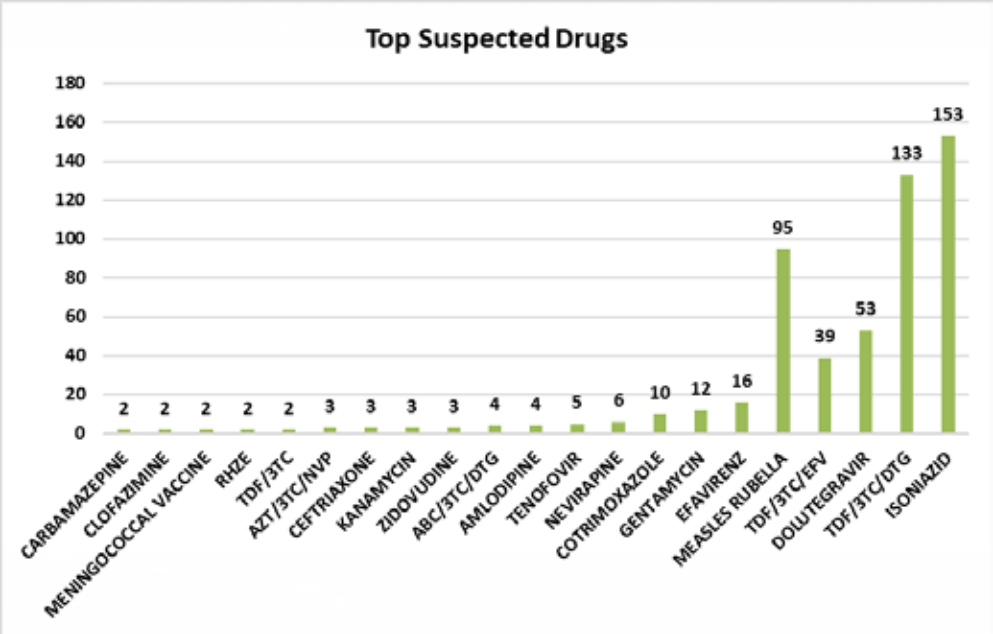
Cadres Reporting

Clinical officers are the top reporters, closely followed by doctors. Notably, two of the reports were submitted by the patients and this is expected to improve over the next year as more efforts are made towards involving patients in drug safety activities.

Region



The central region has continued to post the highest number of reports. However, in the last quarter, all NDA regions submitted reports and this is owed to the massive sensitization programmes conducted by both the NDA regional offices ad



Drug-reaction Pairs

Drug	Total Reports	Commonly Reported Reactions	Frequency
Isoniazid	**156**	**Liver injury**	**37**
		Hypersensitivity reaction	33
		Peripheral neuropathy	6
		Pellagra	3
		Blurred vision, dizziness	5
Dolutegravir	**152**	**Hyperglycaemia**	**78**
		Erectile dysfunction	4
		Headache, malaise	17
		Liver injury	7
Efavirenz	**96**	**Generalised skin rash**	**6**
		Gynaecomastia	5
		Dizziness, headache	9
		Liver injury	8
		Loss of taste	1

Measles Rubella Vaccine	**95**	**Allergic Reaction**	**28**
		Generalised Itching	12
		Headache, Body Weakness, Dizziness	6
		Fever	3
		Toxic Epidermal Necrolysis	3
Gentamycin	**12**	**Severe headache**	**8**
		Syncope	4
Cotrimoxazole	**10**	**Generalised itching**	**6**
		Swelling of lymph nodes	1
Tenofovir	**5**	**Renal toxicity**	**1**
		Osteoporosis	2
Zidovudine	**5**	**Darkening of fingernails**	**2**
		Lipodystrophy	2
Amlodipine	**4**	**Oedema**	**3**
		Amlodipine poisoning	1
Ceftriaxone	**3**	**Hypotension**	**2**
		Hives	2
Nevirapine	**3**	**Steven Johnson's Syndrome**	**1**
		Pallour, malaise, anaemia	2
Atorvastatin	**1**	Statin-induced necrotizing autoimmune myopathy, muscle weakness	1
Kanamycin	**3**	**Hearing loss**	**2**
		Wheezing	2
		Dizziness	1

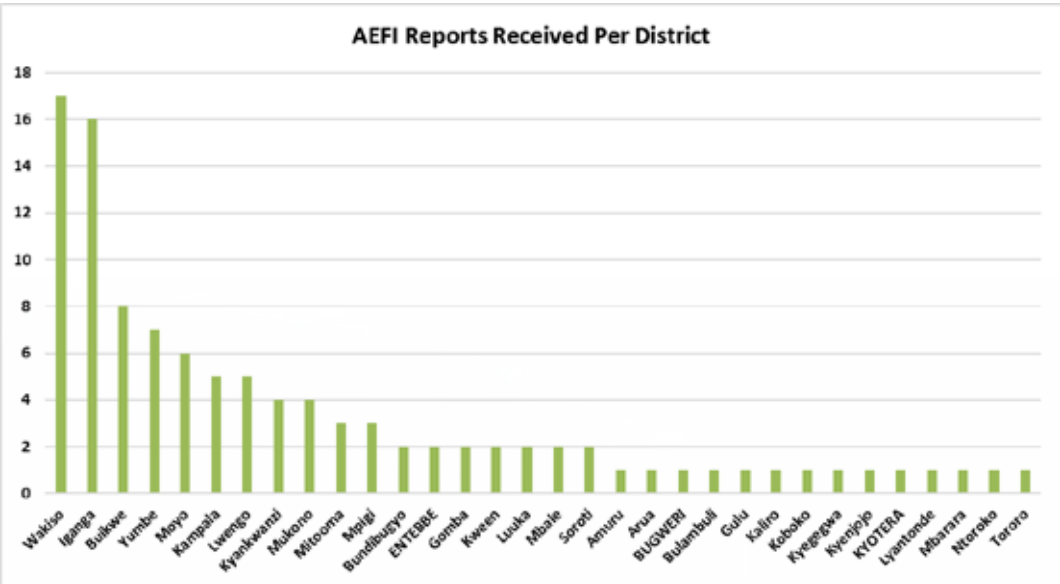
Analysis of Serious Adverse Events leading to Death

Characteristic	Frequency (%)
Sex	
Male	12 (40%)
Female	18 (60%)
Age	
0 to 27 days	
28 days to 23 months	2 (6.67%)
2 to 11 years	3 (7%)
12 to 17 years	
18 to 44 years	15 (47%)
45 to 64 years	7 (23.33%)
65 to 74 years	1 (3.3%)
75 years and above	2 (6.67%)
Suspected Drug	
Dolutegravir	10 (33.33%)
Isoniazid	10 (33.33%)
Measles Rubella	5 (16.66%)
Efavirenz	3 (10%)
Pyrazinamide	1 (3.33%)
Emitricitabin/Efavirenz/Tenofovir	1 (3.33%)
Reported reaction	
Hyperglycaemia	3 (10%) DTG
Severe Drug Induced Liver Injury	19 (63%) DTG, INH, EFV
Acute Respiratory failure	1 (3.33%) MR
Anaemia	4 (13.33%) MR, Z

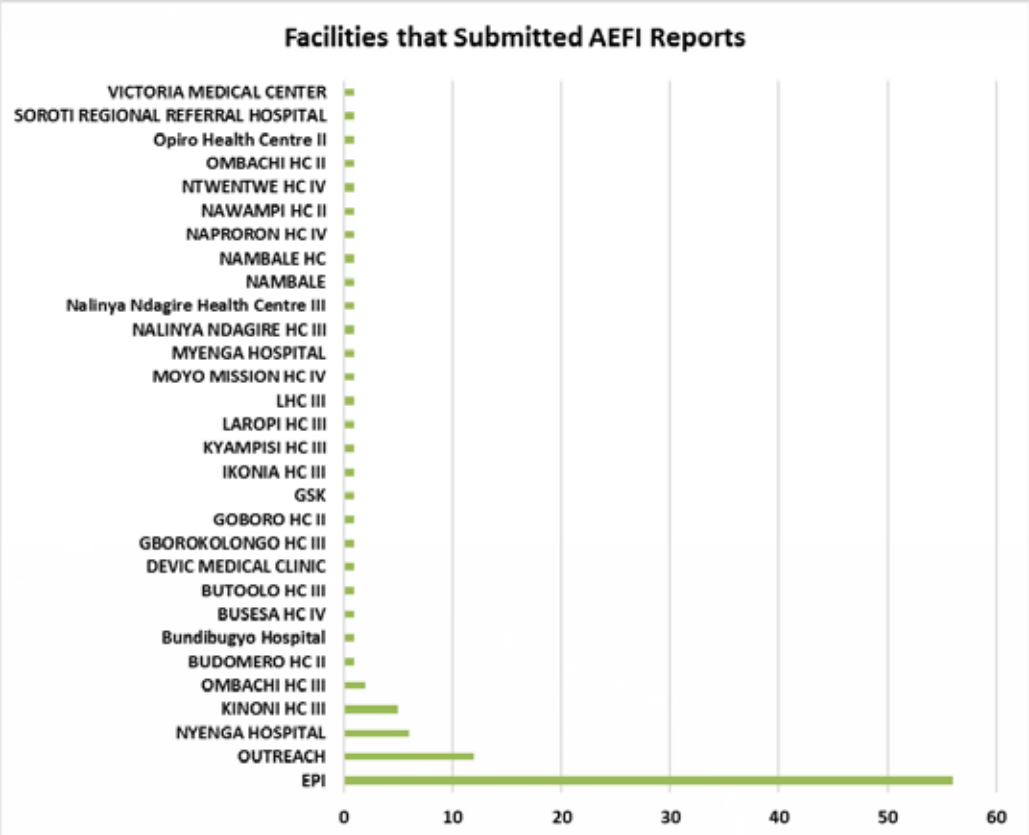
Annex II

Summary of AEFI reports submitted to the NPC in the year 2019

A total of 106 reports were received with 30% (n=33) reported to be serious. Wakiso district submitted the highest number of reports at 16% (n=17) followed by Iganga with 15% of the reports (n=16) as shown in the figure below.



Most reports were submitted directly by the EPI programme (52.9%, n=56) followed by reports collected from outreach programmes (11.3%, n=12)



Reactions in AEFI reports

Most of the AEFIs reported are labelled for the products and therefore expected following administration of the vaccine. However, some cases were reported to be serious and therefore require investigation and follow up. The Measles Rubella vaccine was the most reported product due to the mass immunization campaign that was rolled out by the Ministry of Health in October 2019. The AEFI – vaccine pairs reported are presented in the table below.

Drug AEFI Pairs	Frequency
MEASLES RUBELLA VACCINE	**84**
ALLERGIC REACTION	28
GENERALISED ITCHING	20
HEADACHE, BODY WEAKNESS, DIZZINESS	6
SKIN SWELLING	3
FEVER	3
MUMPS	3
TOXIC EPIDERMAL NECROLYSIS	3
SEVERE ANAEMIA	3
STEVEN JOHNSON SYNDROME	2
FEBRILE ILLNESS	2
INJECTION SITE ABSCESS	2
DEATH	1
MALARIA	1
VOMITING, ABDOMINAL PAIN, HIGH BODY TEMPERATURE	1
ACUTE RESPIRATORY FAILURE	1
BULLOUS IMPERTIGO	1
CELLULITIS	1
SEVERE PNUEMONIA, ANEMIA AND MALARIA	1
MEASLES RUBELLA, OPV	**4**
ALLERGIC REACTION	2
ITCHY RASH	1
SUDDEN UNEXPLAINED DEATH FOLLOWING FEVER AND HEADACHE	1
DPT+HEPB+HIB	**2**
Abscess at injection site	1
ALLERGIC REACTION	1
PNEUMOCOCCAL VACCINE	**1**
DRUG DOSE ADMINISTRATION INTERVAL TOO SHORT	1
PCV+DPT+HEP-HIB	**1**
ABSCESS	1
PCV/OPV	**1**

AFP	1
OPV, DPT, HIB,HEP,PCV	**1**
FEVER	1
DPT-HEP-HIB-BOPV-ROTAVIRUS	**1**
LOCAL SWELLING	1
DPT+HEPB+HIB1	**1**
BACTERIAL INFECTION	1
DPT+HEPB+HIB+PCV	**1**
BACTERIAL INFECTION	1
DPT,OPV,HEP,PCV,ROTA	**1**
FEVER	1
BCG vaccine	**1**
BCG ULCERATION	1
Grand Total	**106**

If you have any comments or feedback on any of the articles in this bulletin, we would be pleased to receive them at druginfo@nda.or.ug/ dps@nda.or.ug

To report Adverse Drug Reactions complete the Adverse Drug Reaction form and return it to any NDA office near you or send a direct online report at

https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationI D=UG

Fax: +256-414-655.60.80
E-mail: druginfo@nda.or.ug
Call: 0800 101 999 or whatsapp on 0791 415 555

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