Safe Drugs Save Lives

NATIONAL PHARMACOVIGILANCE CENTRE

PHARMACOVIGILANCE Bulletin

VOLUME 15, ISSUE 1, SEPTEMBER 2022

IN THIS ISSUE

COMMENT FROM SECRETARY TO THE AUTHORITY

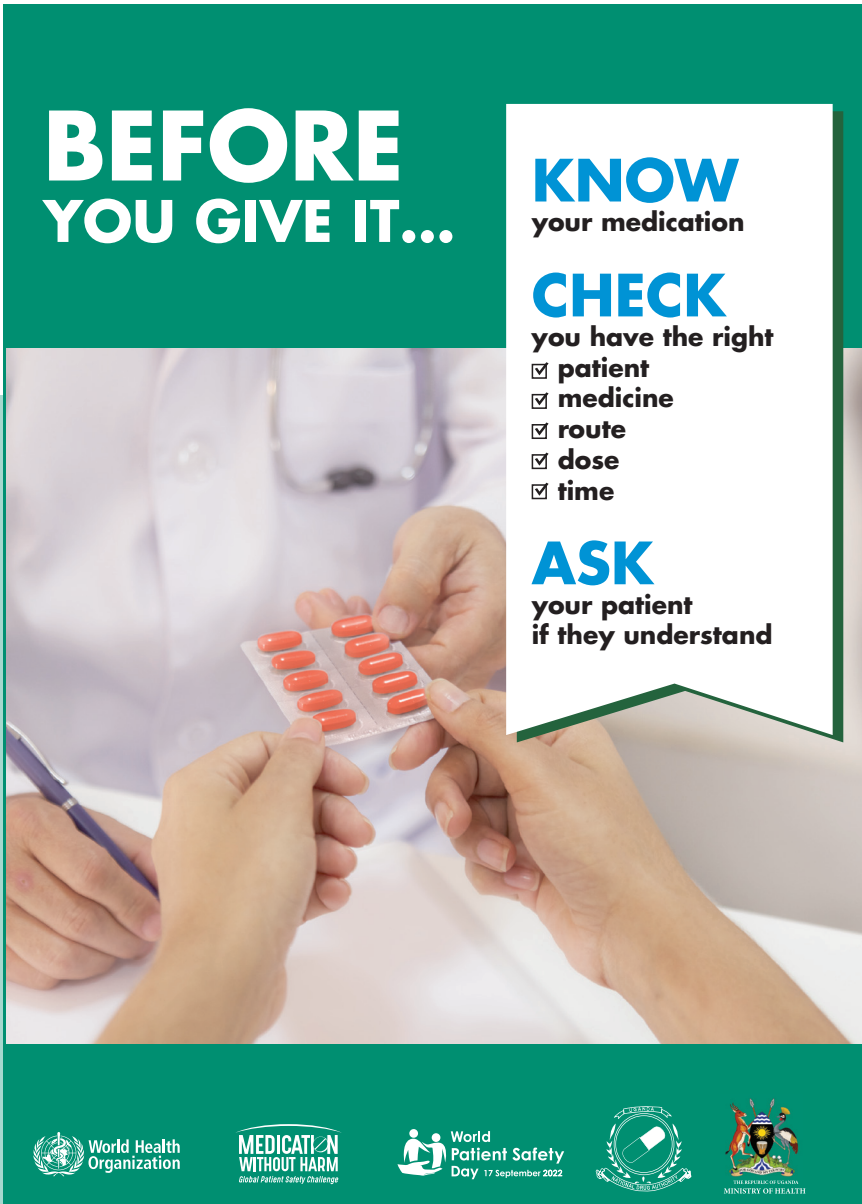
National Drug Authority is committed to strengthening stakeholder collaborations in order to enhance our regulatory mandate. We also recognize the role of the general public in monitoring and reporting on safety concerns. Therefore, this quarter we have invested efforts in conducting patient engagements as well as supporting partners who share the same vision such as the community health and information network.

We have also engaged in several media campaigns to continue to enlighten the public on our role as regulators and their role as the public. We look forward to additional activities like these as we strive towards ensuring availability of safe, efficacious and quality products on the Ugandan market.

National Drug Authority has a zero tolerance policy to substandard and falsified drug products. We shall continue to bring to book all those found in possession of such products. We advise distributors to source products from NDA authorized pharmaceutical companies as indicated in the NDA register at https://www.nda.or.ug/drug-register/.

David Nahamya

Secretary to the Authority



EDITORIAL TEAM

1. DR. HELEN BYOMIRE NDAGIJE
2. DR. DOUGLAS MWESIGWA
3. JULIUS MAYENGO
4. DAVID WALUSIMBI
5. JOANITAH ATUHAIRE
6. FRANCIS ODIPIYO

GUEST AUTHORS:

1. DR. THEREZA PILOYA-WERE
2. DR. SABRINA BAKEERA- KITAKA
3. DR. MAUREEN NAKITTO
4. DR. DEOGRATIUS MUNUBE

BEFORE YOU TAKE IT...

KNOW
your medication

CHECK
the dose and time

ASK
your health care professional

World Health Organization | MEDICATION WITHOUT HARM Global Patient Safety Challenge | World Patient Safety Day 17 September 2022

Contents

Foreword

Patient Safety remains a priority for pharmacovigilance. This quarter we have doubled our efforts in increasing awareness and visibility of patient safety activities. We collaborated with key stakeholders to mark the World Patient Safety Day on 17th September 2022.

The activities included webinars highlighting the regulator, health care provider and patient roles in ensuring safety.

As the custodian of the national ADR database, the NPC is committed to publishing emerging safety information from this data and this issue includes several safety signals identified in the reporting period.

We have also included the quarterly summary as well as safety label variations received from manufacturers, majority of which come from your tireless efforts to document and send reports of adverse drug reactions to the National Drug Authority.

We remind you to remain vigilant, especially during this time when an Ebola outbreak has been declared in the country. We wish you good health and happy reading.

Dr. Helen Byomire Ndagije, PhD

Director Product Safety

Uganda Commemorates World Patient Safety Day

National Drug Authority joined Ministry of Health and other stakeholders to mark the annual World Patient Safety Day (WPSD). WPSD is observed globally on the 17th of September every year. The objectives of WPSD are to increase public awareness and engagement, enhance global understanding, and work towards global solidarity and action by all stakeholders to improve patient safety. The theme of WPSD 2022 was "**Medication Safety". The slogan was "Medication Without Harm"**.

We all, at some point in our lives, take medications to prevent or treat illness. However, if incorrectly stored, prescribed, dispensed, administered, or monitored, medications can be dangerous. Medication errors are a leading cause of avoidable harm in health care globally. Medication safety incidents happen because of weak medication systems and human factors and can result in patient injury, disability and even death.

Together with Ministry of Health, NDA and other partners conducted a series of events including a webinar on 13th September in which the key patient safety concerns and possible solutions were discussed.

World Patients Alliance (WPA) initiated a campaign to celebrate WPSD all over the world. The WPSD webinar was held on 14th September 2022 and Dr. Helen Ndagije was one of the keynote speakers. The ministry of health also held a webinar in which Dr. Ian Mugisa presented on NDA's role in preventing harm from medication.

The activities were concluded by a main event on the 15th of September at the Ministry of Health headquarters where stakeholders reaffirmed their commitment to ensuring safety of patients. The guest of honour, state minister for health, general duties, hon. Hanifa Kawooya called on health care providers to use patient friendly language to minimize medication errors.

Figure 1 Dr. Helen Byomire Ndagije gives an interview to journalists at the main WPSD event.

Figure 2 NDA Officer Francis Odipiyo explaining to Hon. Hanifa Kawooya the role of NDA in Patient Safety

There was also a community event in which NDA partnered with the Community Health and Information network (CHAIN) and other stakeholders for a medical camp, presentations and skits aimed at increasing patient awareness of their role in safety.

Figure 3 Dispensers joined the campaign to remind patients to know, check and ask about their medication before taking it.

Community Activities:

Compiled by Regina Kamoga, ED, CHAIN.

On 23rd September, a community based safety patient event was held at Namulonge grounds. The theme was: Engaging Patient, Family and Community to Promote Medication Safety and about 1,500 people attended the event. They received knowledge about medication safety and received various free prevention and treatment services including; blood donation, COVID 19 vaccination, screening for cancer, HIV, hypertension, diabetes, malaria , eye checks, geriatric care ,mental health, sickle cell, epilepsy and medication awareness sessions , among others.

Figure 4 Blood donation drive at the event

Figure 5 Community members receiving health education while waiting to be vaccinated.

The event was organized by the Community Health And Information Network (CHAIN), National Drug Authority (NDA), Ministry of Health, Namulonge Health Center III, and the Uganda Alliance of Patients' Organization (UAPO) whose members include; CHAIN as the lead organization, Epilepsy Support Association Uganda (ESAU); National Care Centre (NACARE); Sickle Cell Association of Uganda (SAU), Uganda Women's Cancer Organisation (UWOCASO), Joyce Fertility, The Aids Support Association (TASO), Stroke Foundation Uganda (SFU), Pain Management Support Organisation, Action Group for Health, Human rights and HIV/AIDS (AGHA) and National Organization of People Living With Hepatitis.

Several partners supported the event through provision of health services, financial, technical and in-kind support. These included; Uganda Insurers Association (UIA), Kampala Pharmaceutical Industry(KPI),Wide Spectrum Enterprises (U) Limited, Medical Access Uganda Limited (MAUL), Infectious Disease Institute (IDI), Uganda Cancer Institute (UCI), Centre for Health Human Rights and Development (CEHURD), Mental Health Uganda, Mental Health Uganda, Geriatric Respite Care Foundation(GRCF-U) Rocket Health, The Academy of Health Innovation and Impact, Mengo Hospital and Kyengera Health Centre III Eye department,

Safety Signal: Early puberty among toddlers

A case study from the paediatric endocrinology clinic in Mulago Hospital

Thereza Piloya-Were[1], Sabrina Bakeera- Kitaka[1], Maureen Nakitto[2], Deogratius Munube[2],
[1]Makerere University College of Health Sciences
[2]Mulago Hospital, Kampala

Contact
Thereza Piloya-Were
Paediatric Endocrinologist/ Senior Lecturer
Department of Paediatrics and Child Health, Makerere University
Email : tpiloa@yahoo.com

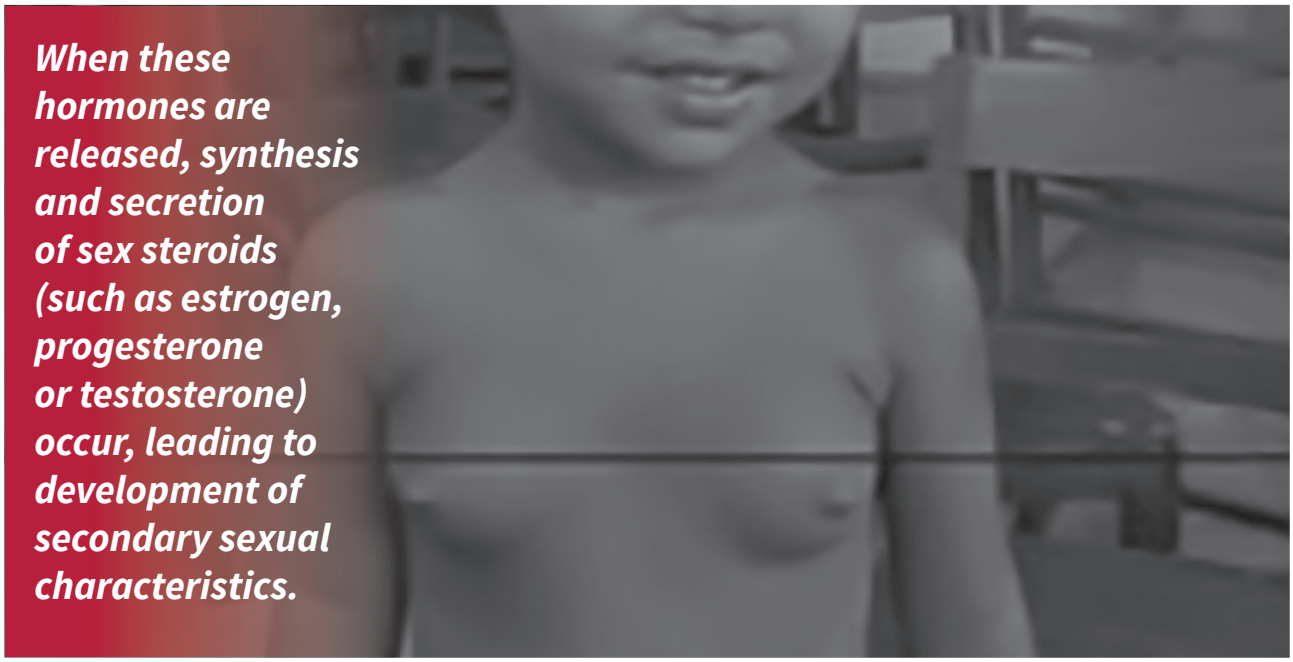
Introduction

Precocious puberty is defined as the appearance of secondary sex characteristics before age 8 years in girls (or menarche before age 9 years) and before 9 years in boys. The overall incidence of early puberty is estimated to be 1:5,000 to 1:10,000 children. The female-to-male ratio is approximately 10:1.

Normally, the brain (hypothalamus) initiates puberty by stimulating the brain to release gonadotrophin hormones called (FSH and LH), the hormones which control growth and function of the sex organs. When these hormones are released, synthesis and secretion of sex steroids (such as estrogen, progesterone or testosterone) occur, leading to development of secondary sexual characteristics. If this occurs prematurely, a child starts to develop secondary sexual characteristics and proceeds to sexual maturity at an unexpectedly early age.

Precocious puberty may be caused by premature activation of the pulse generator in the brain also known as central precocious puberty or peripheral puberty where the GnRH pulse generator is suppressed. The causes of peripheral puberty include exogenous sources of hormone ingestion like estrogen ingestion, or other preparations containing estrogens among many other causes. The risk for children to develop precocious puberty through exposure to oestrogens (or androgens) in the environment or in food is very low unless exposed to very high doses of hormones. Early Puberty may cause psychosocial disturbances but also there's accelerated bone maturations (with less time for prepubertal growth) resulting in shortening of adult stature.

We describe children who developed secondary sexual characteristics during breastfeeding when their mothers were concurrently using a specific pill for birth control described on the local market as **"CHINESE PILL."** This was mainly a self-prescribed pill or a recommendation by peers.



Results

We reviewed patient files of children with initial attendance to the Paediatric Mulago Endocrine Clinic for the period of January 2020 to August 2022 with complaints of early puberty who were age < 4 years. Fifteen patient files were extracted fulfilling the criteria. The mean age was 2.1 years (range 11 months – 4 years), 12 of the 15 (80%) were female. The commonest presentation to the clinic was breast enlargement and pubic hair development. Only 2 children reported vaginal bleeding and spotting. 6 of the 15 children reviewed had reports of their mothers using 'Chinese' pill as the current contraception method while breastfeeding, 1 boy swallowed the mother's 'Chinese' pill and developed breast and pubic hair, 1 reported being on IUD coil and 7 reported no current contraception method being used. Among the 8 who presented with early puberty and had not been exposed to Chinese pill, 6 of 8 had central precocious puberty and are undergoing treatment.

The mean age of those with exposure to Chinese pill was 1.4 years, 6 of the 7 were residing within Kampala region and only 1 was a referral from Fort Portal Regional referral hospital. Of the patients who run the hormonal tests, they all had suppressed FSH and LH (gonadotrophins) with some detectable estradiol levels. One patient had vaginal spotting. All the parents reported resolution of the symptoms of the breasts some months after cessation of the ingestion of the pill or cessation of breastfeeding although the pubic hair may stay with no new growth.

In conclusion, the 'Chinese' pill used on the market for birth control may predispose breastfeeding infants to precocious puberty due to high hormonal levels and should be kept out of reach of children.

Regulatory Communication on the Chinese Pill

National Drug Authority issued a safety alert to the public on the illegal drug and is cracking down on its illegal import and distribution.

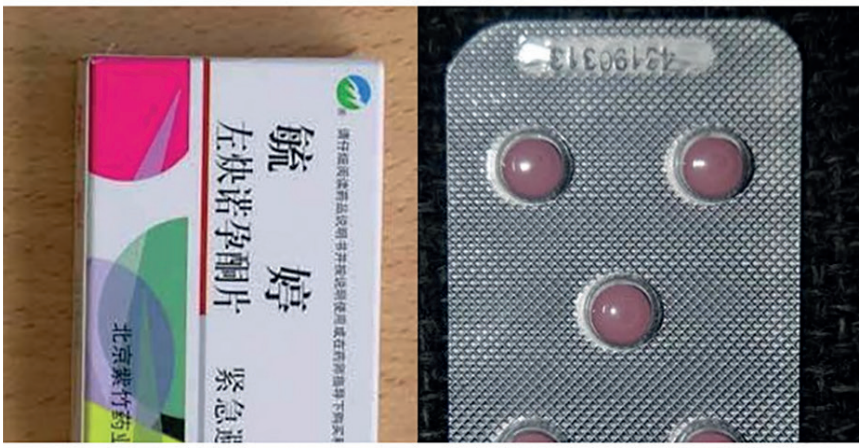
MONITOR

Search

National Education Insight World

NDA links illegal "Chinese" contraceptive pill to cancer, infertility

Friday, October 14, 2022



The Chinese Pill tablet packaging, labelling and patient information leaflet are in the Chinese language except for the claimed ngredients –Levonorgestrel and Quinestrol, according to NDA. PHOTOS/ COURTESY

By Tonny Abet

The National Drug Authority (NDA) has warned drug outlets across the country to stop stocking and sale of the unauthorised "Chinese" contraceptive pill with immediate effect.

The drug regulator said Friday that the unauthorised pill, which predisposes consumers to cancer and infertility risks, is being sold on the black market.

"The Chinese Pill tablet packaging, labelling and patient information leaflet are in the Chinese language except for the claimed ingredients –Levonorgestrel and Quinestrol," reads the notice undersigned by Dr David Nahamya, the Secretary to the

DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

1926/ID/NDA/10/2022

13th October 2022

PUBLIC NOTICE

CIRCULAR NO. 005/DIE/2022

UNAUTHORIZED CHINESE PILL TABLETS ON THE MARKET

The National Drug Authority has noted with concern the **sale of unauthorized Chinese Pill** on black market used **as a contraceptive pill**. The Chinese Pill tablet packaging, labeling and patient information leaflet are in **Chinese language** except for the claimed ingredients- **Levonorgestrol and Quinestrol**.

NDA informs the public that the Chinese Pill is NOT registered NOR authorized for sale and use in Uganda.

The pill was found to **contain high doses of the hormones above the recommended dosage** and the risks associated with use of this product include among others; prolonged bleeding, irregular menstrual periods, palpitations, possibility of developing blood clots and heart diseases, abnormally thickened endometrium, a predisposing factor for endometrial cancer and infertility.

Furthermore, when consumed, the hormones stay in the body for a long time and the **adverse effects of the pill** further **manifest in babies** that are born by **mothers**. The adverse effects include secondary sexual characteristics like premature puberty.

NDA **strongly warns** all **drug outlets or persons with immediate effect to stop stocking and sale of the Chinese Pill**. NDA post market surveillance and enforcement units are on **full alert to undertake regulatory actions** against this illegality.

NDA advises the public to stop the consumption of this product whose safety and quality cannot be guaranteed. Family planning services should be sought from qualified health professionals.

The public is expected to remain vigilant and **report any suspected substandard and falsified medical products** to NDA via **Toll free line.**

David Nahamya
SECRETARY TO THE AUTHORITY

OFFICE OF THE SECRETARY TO THE AUTHORITY

HEAD OFFICE
Plot 19 Lumumba Avenue P.O. Box 23096, Kampala, Uganda
Tel: (+256) 417 788 100, Toll Free: 0800 101 999
© 0740 002 080 (General), 0740 002 070 (Pharmacovigilance)
Website: www.nda.or.ug, Email: ndaug@nda.or.ug
Facebook: Uganda National Drug Authority
Twitter: @UNDAuthority
NATIONAL DRUG QUALITY CONTROL LABORATORY
Tel: (+256) 417 782 040 / (+256) 414 583 095

OUR MISSION

To protect and promote human and animal health through the effective regulation of drugs and healthcare products.

REGIONAL OFFICES
Central Region, Nakawa - Tel: (+256) 393 261 548
Western Nile Region, Arua - Tel: (+256) 414 671 033
South Western Region, Mbarara - Tel: (+256) 414 671 034
South Eastern Region, Jinja - Tel: (+256) 434 122 176
Eastern Region, Tororo - Tel: (+256) 392 004308
Western Region, Hoima - Tel: (+256) 465 440 688
Northen Region, Lira - Tel: (+256) 414 671 032

Fatal anemia associated with linezolid

Compiled by David Walusimbi and Francis Odipiyo

"We present 6 fatal case reports of anaemia associated with Linezolid among patients taking multidrug resistant TB treatment at 2 regional referral hospitals in Uganda."

Background

Linezolid is a synthetic oxazolidinone antimicrobial agent that is used for the treatment of diverse bacterial infections. It has been associated with the risk of myelosuppression including anemia that appears to be related to the duration of treatment. Elderly patients may be more susceptible to linezolid-induced anemia than younger patients (1,2). We present 6 fatal case reports of anaemia associated with linezolid among patients taking multidrug-resistant TB treatment at 2 regional referral hospitals in Uganda.

Case presentations

Case 1: O.A, a 46-year-old male patient weighing 43 kg, was diagnosed with rifampicin-resistant tuberculosis and admitted. He was a known HIV and tuberculosis patient on Tenofovir, Lamivudine, and Efavirenz (300/300/600 mg O.D.) for HIV and a Rifampicin-based TB regimen. The patient was anaemic (Hb 6.6g/dl), according to laboratory results. He received two units of blood transfused up to 9.2 g/dl of haemoglobin before discharge and the start of MDR-TB treatment, which included bedaquiline, linezolid (600 mg O.D), levofloxacin, clofazimine, cycloserine, and vitamin B6. The patient was readmitted after 6 months and diagnosed with linezolid-induced severe anaemia (Hb 5.6 g/dl) that led to death.

Case 2: O.Q a 60-year-old male patient presented to the hospital with symptoms of light-headedness, palpitations, fatigue, and weight loss 5 months after initiation of the MDR-TB regimen. He had no history of HIV but he was a known MDR-TB patient taking bedaquiline, linezolid, levofloxacin, clofazimine, cycloserine, and vitamin B6. Laboratory findings revealed haemoglobin levels of 6.3 g/dl, platelet count of 425 per ml,

and WBC count of 4.35 per ml. He was diagnosed with Linezolid induced anaemia, linezolid was withdrawn, and the patient was transfused with blood up to 6.3 g/dl of haemoglobin but unfortunately, he died.

Case 3: O.S an adult male patient weighing 56 kg was diagnosed with severe anaemia following initiation of MDR-TB. He was a known HIV patient taking Tenofovir, lamivudine, and Dolutegravir (300/300/50 mg O.D) for HIV and enrolled on linezolid, levofloxacin, cycloserine, and clofazimine for MDR-TB. The patient died while undergoing treatment.

Case 4: M.S is a 68 y/o male patient (with a body weight of 55Kg), who reported complaints of general body pain, lower limb weakening and loss of appetite in a period of about 2 months after he was initiated on the first line anti TB drugs (LNZ/LFX/BDQ/CYS/CFZ/Vit B6) following diagnosed with MDRTB. He is a known HIV positive (ISS) patient on HAART (TDF/3TC/DTG) as well as Hepatitis B infection. He has no history of surgery, has never smoked and stopped drinking alcohol over 3 years ago. On further examination by the clinician, he was noted to be stable but moderately wasted and with severe dehydration and a BP of 80/40mmHg. Laboratory tests done on the 5th day of admission revealed that he had Hb of 8.3g/dL, decreased levels of albumin, total proteins and sodium (figures not specified), RBS of 5.4mmol/dL, CD4 of 74cells/µL and ECG result for QTC was 402ms. He was suspected to have developed an adverse reaction (anemia) associated with Linezolid, which was hence discontinued. He was given Fefol tablets, 2g Ceftriaxone IV and 2L of Normal saline. He reportedly died.

Case 5: EC, a 31y/o female patient (weighing 37.5Kg) developed headache associated with general body weakness and poor appetite while taking the MDRTB drugs (LZD/CYS/LFX/CZ/Vit B6). She was born with a hearing defect. However, she has no history of smoking and alcohol. Only laboratory tests done were Hb (10.2g/dL) and RBS (3.1mmol/dL), other requested tests were not done. She was administered IV Normal saline, IV Dextrose 50% and Fefol tablets. Unfortunately, she died, and this was suspected to be due to an adverse reaction (drug induced anemia) associated Linezolid.

Case 6: A.J is a 44 y/o male patient with a body weight of 68Kg, known with liver cirrhosis who developed urinary retention and grossly distended abdomen. Further examination on him revealed that he had ascites, for which he was admitted and given Furosemide. While on ward, he was also discovered to have MDRTB and hence started on second line anti TB drugs (LZD/CYS/CFZ/BDQ/LFX/Vit B6). The laboratory results for tests conducted before he was initiated on the anti TB drugs were normal ALT (20.2 mmol/L), high AST (61.7mmol/L), normal Alkaline phosphatase (102.1mmol/L), low albumin (2.74g/dL), high globulin (5.16g/dL) and high BUN (24.65mg/dL). However, in the course of the treatment while still admitted, the patient died. The attending clinician suspected Linezolid to have worsened his condition.

Discussion

Drug-induced anemia has been associated with several medicines including linezolid and is a potentially life-threatening complication that requires an early diagnosis. The case reports suggest a notable concern of fatal anemia among MDR-TB patients treated with linezolid. Causality for the drug – reaction pair was assessed to be possible; supported by confirmatory laboratory tests for anemia with reasonable temporality. On the contrary, the reaction could be explained by other concomitant anti-TB medicines which are associated with Anemia (3) and the presence of HIV disease in all but one patient—which is known to affect the bone marrow and thus cause anemia (4).

All reports demonstrated a temporal relationship between the initiation of linezolid and the onset of severe anemia at about 6 months. The temporality supported the association (5) between linezolid and life-threatening anemia among patients taking Linezolid. Furthermore, we noted that the reports were among MDRTB patients taking linezolid for a relatively long period and that they were reported from 2 different regional referral hospitals in Uganda. This pattern demonstrated consistency (reproducibility) in occurrence of this adverse event that unfortunately had fatal outcomes. The structural similarity between Linezolid and chloramphenicol—an antibiotic that has been associated with aplastic anemia—at the nitro group offers credibility to the hypothesis that Linezolid is associated with anemia too (6).

Some studies have reported reversible linezolid-associated anemia, but the mechanism of association is unclear. It is thought to be caused by either a chloramphenicol-like suppression of erythropoiesis or immune-mediated thrombocytopenia (7–10). Renal insufficiency, a longer duration of linezolid therapy, and preexisting anemia are all significant risk factors for linezolid-induced myelosuppression (1).

Recommendations, Limitations and Conclusion:

Prior to starting Linezolid, patients should be screened for any risk factors listed. Importantly, those with preexisting anemia and those receiving more than 14 days of therapy should have their cell blood counts closely monitored. If significant linezolid-induced myelosuppression is suspected, the drug should be stopped immediately (2).

The absence of serum erythropoietin levels, which would have been useful in demonstrating linezolid-induced anemia due to intrinsic bone marrow failure, limited the analysis of these reports(3).

Nevertheless, Healthcare providers are advised to be cognizant of the potentially fatal linezolid associated anemia among MDRTB patients and take measures to minimize the risk.

References

1. Hanai Y, Matsuo K, Ogawa M, Higashi A, Kimura I, Hirayama S, et al. A retrospective study of the risk factors for linezolid-induced thrombocytopenia and anemia. J Infect Chemother [Internet]. 2016;22(8):536–42. Available from: https://www.sciencedirect.com/science/article/pii/S1341321X16300733
2. Electronic Medicines Compendium. Linezolid 600 mg Film-coated Tablets - Summary of Product Characteristics (SmPC) - (emc) [Internet]. 2022 [cited 2022 Sep 29]. Available from: https://www.medicines.org.uk/emc/product/9919/smpc
3. Kassa E, Enawgaw B, Gelaw A, Gelaw B. Effect of anti-tuberculosis drugs on hematological profiles of tuberculosis patients attending at University of Gondar Hospital, Northwest Ethiopia. BMC Hematol. 2016;16:1.
4. Berhane Y, Haile D, Tolessa T. Anemia in HIV/AIDS Patients on Antiretroviral Treatment at Ayder Specialized Hospital, Mekele, Ethiopia: A Case-Control Study. J Blood Med. 2020;11:379–87.
5. Parida S. Clinical causality assessment for adverse drug reactions. Indian J Anesth. 2013;57(3):325–6.
6. Lawyer MC, Lawyer EZ. Linezolid and Reversible Myelosuppression. JAMA [Internet]. 2001 Oct 24;286(16):1973–4. Available from: https://doi.org/10.1001/jama.286.16.1969
7. Bernstein WB, Trotta RF, Rector JT, Tjaden JA, Barile AJ. Mechanisms for linezolid-induced anemia and thrombocytopenia. Ann Pharmacother. 2003 Apr;37(4):517–20.
8. Waldrep TW, Skiest DJ. Linezolid-Induced anemia and thrombocytopenia. Pharmacotherapy. 2002 Jan;22(1):109–12.
9. Gerson SL, Kaplan SL, Bruss JB, Le V, Arellano FM, Hafkin B, et al. Hematologic effects of linezolid: summary of clinical experience. Antimicrob Agents Chemother. 2002 Aug;46(8):2723–6.
10. Green SL, Maddox JC, Huttenbach ED. Linezolid and reversible myelosuppression. Vol. 285, JAMA. United States; 2001. p. 1291.

Foreign Safety Signals

Source: WHO Pharmaceuticals Newsletter No. 3, 2022

Metformin: Risk of reduced vitamin B12 levels

United Kingdom. The MHRA has announced that the product information for metformin containing medicines have been updated to state that vitamin B12 deficiency is a common adverse drug reaction of metformin and may affect up to 1 in 10 people who take it.

Metformin is indicated for the treatment of type 2 diabetes mellitus and prevention of type 2 diabetes in patients with a high risk of developing it.

Vitamin B12 deficiency is a known adverse drug reaction of metformin, and the current literature has suggested that the frequency of this adverse drug reaction is higher than previously thought.

The product information has also been updated to note that the risk of this adverse reaction increases with an increase in metformin dose and treatment duration, and in patients with risk factors known to cause vitamin B12 deficiency. Health-care professionals are advised to test vitamin B12 levels in those presenting with anaemia or neuropathy, and that periodic vitamin B12 monitoring should be considered in patients with risk factors for vitamin B12 deficiency.

Reference:

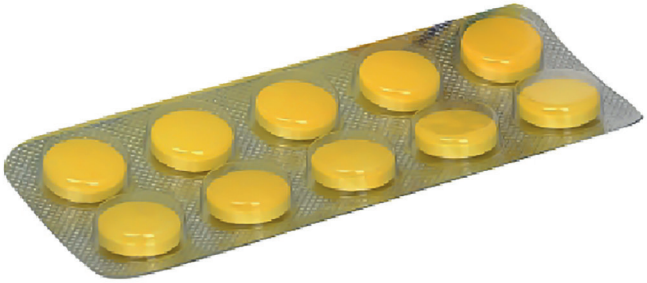
Drug Safety Update, MHRA, 20 June 2022 *(link to the source within www.gov.uk/mhra)*

Metronidazole: Risk of prolonged QT and ventricular tachycardia

Japan. The MHLW and the PMDA have announced that the product information for metronidazole containing products should be revised to include the risk of prolonged QT and ventricular tachycardia (including torsade de pointes).

Metronidazole is an antibiotic and antiprotozoal medicine. This revision applies to the oral dosage form and injections.

Cases involving prolonged QT and/or ventricular tachycardia (including torsade de pointes) reported in Japan and overseas were evaluated. In one case reported overseas, a causal relationship between the drug and event was assessed to be reasonably possible.



Reference:

Revision of Precautions, MHLW/PMDA, 14 June 2022 *(link to the source within www.pmda.go.jp/english/)*

First-generation oral sedating antihistamines: Risk of serious harm in children

Australia. The TGA has warned that first-generation oral sedating antihistamines, including those available over-the-counter (OTC), should not be used for the treatment of cough, cold and flu symptoms in children under six years and for any indication in children under two years of age.

First-generation oral sedating antihistamines include products containing diphenydramine and pheniramine. These medicines can cause children serious harm, or even death, and there is little if any evidence that they are effective in treating cough, cold and flu symptoms. Warnings on use in children have been introduced in the labelling since 2020.

Up until 24 May 2022, 226 cases reporting the use of first-generation oral sedating antihistamines in newborns, infants and children were received by TGA. The reports included a range of adverse events, including hypersensitivity reactions, vomiting, hallucination, tremor and abnormal movement. Of the 226 cases, 20 related to off-label use, misuse or overdose in children four years and under.

The TGA's independent Advisory Committee on Medicines (ACM) reinforced the importance of health professionals providing thoughtful diagnosis, advice and treatment of allergy, cold and flu symptoms in children. They also reiterated that it is inappropriate to use antihistamines for sleep and behaviour disturbance, especially in children and adolescents.

Reference:

Medicines Safety Update, TGA, 13 July 2022 *(link to the source within www.tga.gov.au)*

Dexamethasone, betamethasone: Risk of phaeochromocytoma crisis

Japan. The MHLW and the PMDA have announced that the product information for dexamethasone and betamethasone containing products should be revised to include the risk of phaeochromocytoma crisis.

Dexamethasone and betamethasone are steroids, that are available in various formulations. Products for oral use, injections and suppositories are subject to this revision.

Cases of phaeochromocytoma crisis reported with the use of dexamethasone (oral dosage form and injections) and betamethasone (injections) in Japan and overseas were evaluated. Several cases were assessed to have a possible causal relationship between the drug and event. There were no case reports of phaeochromocytoma with the use of betamethasone, but the same update to the safety information was made as a precaution.

If a marked elevation in blood pressure is observed following administration of these drugs, health-care professionals should consider the possible occurrence of phaeochromocytoma crisis and take appropriate measures.

Reference:

Revision of Precautions, MHLW/PMDA, 13 May 2022 *(link to the source within www.pmda.go.jp/english/)*

Safety Label Variations Submitted to National Drug Authority: July-September 2022

Product Name	Licence Holder	Summary of Approved Changes	Date of NDA Approval
Iopromide (Ultravist®)	Bayer East Africa Limited	SCARS added to undesirable side effects. Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP), which can be life-threatening or fatal, exfoliative dermatitis, Stevens-Johnson syndrome (SJS), have been reported with unknown frequency in association with iopromide administration. If the patient has developed a serious reaction such as SJS, TEN, AGEP or DRESS with the use of iopromide, iopromide must not be readministered in this patient at any time.	21st September 2022
Nebivolol hydrochloride (Nebilet®)	A.Menarini Manufacturing Logistics and Services	**Urticaria** has been added to the list of undesirable side effects. An additional statement that preclinical and clinical evidence in hypertensive patients has not shown that nebivolol has a detrimental effect on erectile function.	12th September 2022
Clarithromycin (Cleron 500®)	Delorbis Pharmaceuticals Limited	A warning that use of any antimicrobial therapy, such as clarithromycin, to treat H. pylori infection may select for drug-resistant organisms.	9th September 2022
Dapaglifozin (Forxiga®)	Astra Zeneca Ab-Se-151 85 Sode-talje	Update and revision of the prescribing information to include modified posology for chronic kidney disease and update to special population section to include clarification regarding renal impairment.	1st September 2022
Ceftriaxone sodium (Ceftriaxone sandoz®)	Novartis Pharma Services Inc	Update of section 4.8: Undesirable effects: Hepatitis and hepatitis cholestatic have been added as new adverse drug reactions.	31st August 2022
Dihydroartemisinin+ Piperaquine phosphate (Dpiriv®)	Royal Pharma 2011 Limited	Change of product name from Dpiriv 90/720 to Rolxin 90/720 with subsequent change in pack label and design.	3rd August 2022
Amlodipine besilate (Amlo®)	GETZ Pharma (Pvt) Limited	Change in brand name from Amlo to Lopicard 10 mg	3rd August 2022
Vitamin B1+ B2+ B6 + Niacinamide (Vitamin B Complex®)	Rene Industries Limited	Change of product name from vitamin B complex to Becoren tablets	29th July 2022
Acetyl salicylic acid (Aspirin tablets®)	Rene Industries Limited	Change of product name from Aspirin tablets to Aspiren tablets	29th July 2022

Quarterly ADR Summary

A total of 954 adverse drug reaction reports were submitted to the National Drug Authority between 1st July 2022 and 30th September 2022. 520 of these reports were AEFIs following Covid vaccination while 434 were adverse drug reactions to other drug products and vaccines. Majority (61.9%) of the reactions were reported in the 18-44 years age group. More than half (58.9%) of the reports were reported among males.

The top suspected active ingredients can be broadly grouped as antiretrovirals, anti-TBs, antipsychotics and routine vaccines.

80% of the reactions were not serious.

Variable	n (N=954)	%
Gender		
Male	564	58.9
Female	376	39.4
Unspecified	16	1.7
Age		
0-27 days (neonates)	1	0.1
28 days to 23 months (infants)	4	0.4
2-11 years (children)	75	7.9
12-17 years (adolescent)	54	5.7
18-44 years (young adults)	591	61.9
45-64 years (middle aged adults)	149	15.6
65-74 years (older adults)	20	2.1
≥75 years (elderly)	8	0.8
Unspecified	52	5.5
System Organ Classification of Reaction		
General disorders and administration site conditions	418	43.8
Nervous system disorders	223	23.4
Metabolism and nutrition disorders	91	9.5
Musculoskeletal and connective tissue disorders	88	9.2
Skin and subcutaneous tissue disorders	80	8.4
Reported suspected active ingredients		
Covid-19 vaccine	520	54.5
Dolutegravir	123	12.9
Dolutegravir; Lamivudine; Tenofovir	119	12.5
Tenofovir	43	4.5
Abacavir; Dolutegravir; Lamivudine	33	3.5
Isoniazid	19	2.0
Linezolid	17	1.8
Reported preferred terms		
Headache	169	17.7
Injection site pain	166	17.4
Pyrexia	105	11.0
Malaise	101	10.6
Asthenia	51	5.3

Dizziness	42	4.4
Hyperglycaemia	41	4.3
Athralgia	37	3.9
Pruritus	34	3.6
Seriousness		
Not serious	768	80.5
Serious	186	19.5
Seriousness criteria		
Other medically important condition	75	7.9
Disabling/incapacitating	67	7.0
Causes/prolonged hospitalization	49	5.1
Life threatening	43	4.5
Death	1	0.1
Reporter qualification		
Clinical officer	517	54.19
Doctor	131	22.05
Nurse	95	9.96
Unspecified	76	7.96
Patient	61	10.23
Pharmacist	32	3.35
Pharmacy technician	20	2.09
Top reporting facilities		
Mildmay Hospital	51	8.58
MJAP Mulago	43	4.50
Butabika National Referral Hospital	39	4.08
Jinja Regional Referral Hospital	39	4.08
Kawolo General Hospital	28	2.93
Fort Portal Regional Referral Hospital	24	2.51
Baylor	21	2.20
Lira Regional Referral Hospital	20	2.09
Mbarara Regional Referral Hospital	20	2.09
MRC/UVRI	15	1.57

Publications / Presentations

International Society of Pharmacovigilance Annual Meeting

Compiled by Douglas Mwesigwa

The ISoP 2022, 21st annual meeting (A new era of pharmacovigilance, challenges and opportunities) was held in Verona, Italy, from 20-23 September 2022 in the Polo Zanotto auditorium at the University of Verona. The meeting started on 20th September with a pre-conference programme that had 3 courses i.e. advanced signal detection, introduction to pharmacoepidemiology studies and their role in pharmacovigilance and regulatory updates across the continuum of spontaneous reporting to the risk minimization. This was followed by the conference programme on the 21st, 22nd and closed on the 23rd

On 21st September 2022, there were plenary sessions on the following topics; lessons learned from Covid-19 pandemic, traditional and innovative approaches for post marketing surveillance of covid-19 vaccines, PV of Biotechnology drugs: from advanced therapy medicine products to biosimilars, strategies to prevent medication errors: new approaches, how to communicate risk in crisis, medicines for women: global challenges and initiatives. The day was concluded with the students meet and greet within the Cloister of San Francesco and ISoP special interest groups (SIGs) meetings.

On Thursday 22nd September 2022; plenary sessions on; big data for PV – are we delivering on the promises? AI/Machine learning for drug safety signal detection in PV: where do we stand? Interaction between pharmacovigilance and clinical practice; were held, followed by the ISoP General Assembly and the Global Pharmacovigilance hot topics.

On Friday 23rd September 2022, there were plenary sessions on; training and professional framework of PV, herbal and traditional medicines PV advances, a lecture in memory of Prof. Giampaolo Velo, the Bengt Erik Wiholm Lecture and finally the closing ceremony that included poster prize awards, host presentation for ISoP 2023 and the final remarks and closure.

Achievements:

NDA presented three (p015, p119, p191) abstracts on Wednesday 21st September 2022.

Attended the different plenary sessions.

Learned about especially artificial intelligence/ machine learning in pharmacovigilance, eco pharmacovigilance, cons and pros of big data versus smart data for post marketing surveillance of vaccines or drugs.

Dr. Helen Byomire Ndagije, who is the ASOP (Africa Society of Pharmacovigilance) president raised the issues that pertain to the African chapter being equally represented into the leadership of the International society of pharmacovigilance and on the scientific advisory board.

National Drug Authority

Plot No. 19 Rumee Towers, Lumumba Avenue - Kampala, Uganda. **Toll Free:** 0800 101 999
+256 414 255 665 / 347 391 / 347 392. +256 740 002 070 ndaug@nda.or.ug
www.nda.or.ug @UNDAuthority Uganda National Drug Authority
Uganda National Drug Authority

Safe Drugs Save Lives

ISoP 2022 • 21st Annual Meeting A New Era of Pharmacovigilance: Challenges and Opportunities • 20-23 September 2022, Verona, Italy

Risk Communication: Ethionamide Induced Gynecomastia

Presentation Preference: **Oral** • Abstract Number: **ISOP22-0014**

List of Authors: **Douglas Mwesigwa**[1]
1 - National Drug Authority

Background / Introduction:

Gynaecomastia is defined as enlargement of male breasts due to enlargement of the duct tissue and periductal stroma in the male breast. It can be bilateral and symmetrical or unilateral or asymmetrical. For reasons unknown, unilateral gynaecomastia seems to be more common on the left side[1]. However for the cases in Uganda, the breast tissue swelling was bilateral. Unlike headache, dizziness, asthenia, and paraesthesia that are labelled common side effects, gynaecomastia is mentioned in the product summary characteristics of Ethionamide as a "Not Known" undesirable effect. This is because it is an ADE that was identified during post approval use of the drug.

Objective / Aim

Gynecomasting associated with the use of Ethionamide.

Methods

This is a case series presentation of retrospective data from the Uganda Pharmacovigilance database.

Results

There were 8 cases of gynaecomastia, experienced by male clients of mean age 43.63 years taking Ethionamide for treatment of multidrug resistant TB that were reported to the National Drug Authority.

ID	Age	Time to Onset	Concomitant Drugs	Action Taken	Outcome
1	45		Capreomcin Pyrazinamide Moxifloxacin Ethambutol Isoniazid, Clofazimine Pyridoxine	Dose not changed	Not recovered
2	49		Cycloserine, Pyrazinamide, Levofloxacin, Bedaquiline and Pyridoxine.	Dose not changed	Recovering
3	unk	6 months	Kanamycin, Pyrazinmide, Ethionamide, Cycloserine, Levofloxacin	Dose not changed	Not recovered
4	62		Cycloserine, Pyrazinamide, Levofloxacin and Bedaquiline	Dechallenge Rechallenge	Subsided on dose reduction
5	28		Kanamycin, Pyrazinamide, Levofloxacin, Ethionamide and Cycloserine	Unknown	Recovering
6	unk		Isoniazid, Moxifloxacin, Ethambutol and Pyridoxine	Dose not changed	Not recovered
7	44		Levofloxacin, Cycloserine and Pyrazinamide	Dose not changed	Not recovered
8	36	2 months		Unknown	Not recovered

Key: Unk = Unknown

Conclusion

Early detection of gynaecomastia and withdrawal of the medication is critical among patients using Ethionamide as the condition usually causes discomfort and embarrasement to some clients thus affecting quality of life[7]. Endocrinological and biochemical investigations including LFTs and TFTs should be carried out in order to rule out systematic causes.

References / Further Sources Of Information

1. Dixit R, George J, Sharma AK, chhabra N, Jangir SK, Mishra V, Ethionamide-induced gynecomastia. J Pharmacol Pharmacother [Internet].2012 Apr [cited 2021 Nov 3.]3(2):196. Available from:/pmc/articles/PMC3356967/
2. Banerjee SN, Ta RK, Mallick Ms, Munda MK, Ethionamide-induced gynecomastia: A rare case report . Egypt J Bronchol 2017 111 [Internet].2017 jan 24 [cited 2021 Nov 3];11(1):70-3. Available from: https://link.spriner.com/articles/10.4103/1687-8426. 198998
3. Braustein . Gynecosmastia. N Engl J Med [Internet]. 1993 Feb 18 [cited 2021 Nov 3];328(7):490-5 Available from: https://www.nejm.org/doi/abs/10.1056/NEJM199302183280708
4. Carlson H. Gynecosmastia. N Engl J med [Internet]. 1980 Oct 2 [cited 2021 Nov 3]:303(14): 795-9 Available from: https://www.nejm.org/doi/abs/10.1056/NEJM198010023031405
5. Bansal PKS and R. Gynecomastia caused by ethionamide [Internet]. [cited 2021 Nov 3] Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3480805
6. Dixit R, George J, Sharma AK, chhabra N, Jangir SK, Mishra V, Ethionamide-induced gynecomastia. J Pharmacol Pharmacother [Internet].2012 Apr [cited 2021 Nov 4.]3(2):196. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3356967/
7. Fruhstorfer BH, Malata CM. A systematic approach to the surgical treatment of gynaecomastia. Br J Plas Surg [Internet]. 2003 [cited 2021 Nov 4];56(3):237-46. Available from: https://pubmed.ncbi.nlm.nih.gov/128599919/

National Drug Authority

Plot No. 19 Rumee Towers, Lumumba Avenue - Kampala, Uganda. **Toll Free:** 0800 101 999
+256 414 255 665 / 347 391 / 347 392. +256 740 002 070 ndaug@nda.or.ug
www.nda.or.ug @UNDAuthority Uganda National Drug Authority
Uganda National Drug Authority

Safe Drugs Save Lives

ISoP 2022 • 21st Annual Meeting A New Era of Pharmacovigilance: Challenges and Opportunities • 20-23 September 2022, Verona, Italy

Pharmacovigilance in Healthcare Emergency: Lessons learned from COVID-19: Medicines

Presentation Preference: **Oral** • Abstract Number: **ISOP22-0014**

List of Authors: **Helen Byomire Ndagije**[1], **Joanitah Atuhaire**[1], **Julius Mayengo**[1], **Ismail Ntale**[1] **David Walusimbi**[1] 1 - National Drug Authority

Background / Introduction:

In Uganda, before the pandemic, reporting of Adverse Drug Reactions had been the preserve of health care professionals and they were the main beneficiaries of sensitizations and training. However, with the outbreak of the Covid pandemic, it became necessary to expand pharmacovigilance to the layperson as they were likely to receive the vaccine in a non-hospital setting, making it difficult to monitor them.

Objective / Aim

To describe the actions taken to foster pharmacovigilance during the pandemic and the lessons learned.

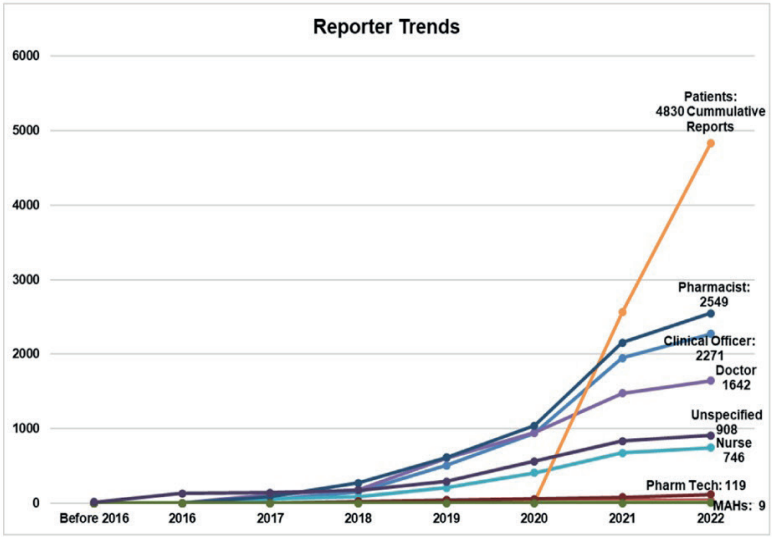
Methods

Retrospective primary data analysis of individual case safety reports submitted to the National Pharmacovigilance Centre of the Uganda National Drug Authority.

Results

Before the pandemic, annual patient report numbers were below 10. During the pandemic, the World Health Organisation supported the National Pharmacovigilance Centre to develop a patient reporting platform using the USSD code which led to a leap in report numbers to over 4000, and ultimately enabled the NPC to pass the 10,000 reports mark in VigiBase.

Trends of Reporters showing Patients Overtaking other reporter categories during the pandemic.



Conclusion

Patients had been a long-neglected reporting segment. The COVID pandemic showed that given the right tools and knowledge, they can report and provide important data components that may be missed when only health care providers report on their behalf. The Centre is now including patient engagements among the routine activities to reach out to patients.

References / Further Sources Of Information

1. Al Dweik R, Stacey D, Kohen D, Yaya S. Factors affecting patient reporting of adverse drug reactions: a systematic review. British journal of clinical pharmacology. 2017 Apr;83(4):875-83.
2. Blenkinsopp A, Wilkie P, Wang M, Routledge PA. Patient reporting of suspected adverse drug reactions: a review of published literature and international experience. British journal of clinical pharmacology. 2007 Feb;63(2):148-56.
3. Anderson C, Krska J, Murphy E, Avery A, Yellow Card Study Collaboration. The importance of direct patient reporting of suspected adverse drug reactions: a patient perspective. British journal of clinical pharmacology. 2011 Nov;72(5):806-22.
4. Jarernsiripornkul N, Krska J, Capps PA, Richards RM, Lee A. Patient reporting of potential adverse drug reactions: a methodological study. British journal of clinical pharmacology. 2002 Mar;53(3):318-25.
5. Van Grootheest K, de Jong-van den Berg L. Patients' role in reporting adverse drug reactions. Expert opinion on drug safety. 2004 Jul 1;3(4):363-8.

National Drug Authority

Plot No. 19 Rumee Towers, Lumumba Avenue - Kampala, Uganda. **Toll Free:** 0800 101 999
+256 414 255 665 / 347 391 / 347 392. +256 740 002 070 ndaug@nda.or.ug
www.nda.or.ug @UNDAuthority Uganda National Drug Authority
Uganda National Drug Authority

Safe Drugs Save Lives

ISoP 2022 • 21st Annual Meeting A New Era of Pharmacovigilance: Challenges and Opportunities • 20-23 September 2022, Verona, Italy

Litigation following Adverse Drug reactions: Impact of Regulator Involvement - A case Scenario of a Ceftriaxone Medication Error

Presentation Preference: **Oral** • Abstract Number: **ISOP22-0013**

List of Authors:

Helen Ndagije Byomire[1], Ian Mugisa[1], Joanitah Atuhaire[1], David Walusimbi[1], Ismail Ntale[1].

1 - National Drug Authority, Kampala, Uganda.

Background / Introduction:

Ceftriaxone is a commonly prescribed antibiotic in Uganda, with studies placing the prevalence of use at 50% of all antibiotic prescriptions [1]. The Summary of Product Characteristics for Ceftriaxone states that as with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been reported. However, the frequency is stated as unknown. Out of 46 reports to Ceftriaxone in the Uganda ADR database, 7 of these are of anaphylactic reactions. One of the anaphylactic reactions was fatal. A one-and-a-half-year-old male child was diagnosed with septicaemia with diarrhoea and admitted to a hospital. Day one treatment with Ceftriaxone was stopped due to a reaction of difficulty in breathing. A switch to Ciprofloxacin was made and the patient began to improve. Due to a weekend staff shift change, the change to Ciprofloxacin was not noted, resulting in re-administration of Ceftriaxone and anaphylaxis that caused the death of the patient despite all efforts to resuscitate. It is not clear in cases of injurious or fatal drug effects who should bear the liability. However, it is important to describe the role and actions of the National Regulatory Agency in such an ADR report.

Objective / Aim

To present a case study of a successful legal resolution of a fatal medication error to Ceftriaxone with the involvement of the regulator.

Methods

This is a retrospective case report. Consent was sought from the patient's family and health care provider to share the case.

Results

National Drug Authority performed a causality assessment of the serious adverse event and found that the administration of Ceftriaxone was related to the outcome of death. However, it was noted that this was a medication error with no malice aforethought and therefore the health care provider was not liable. After a review of the case a casuality assessment was performed and it was assessed to be a medication error. A sample of the medication was received for testing. A feedback report from the NDA was delivered to the clinicians which they were able to utilise in response to the legal challenge that was before them.

Conclusion

Timely and objective causality assessment from the Medicines Regulatory Agency is invaluable in providing scientific evidence that can help patients receive compensation and/or protect health care practitioners from wrongful liability for inadvertent drug effects. Health care providers hesitate to report due to fear of litigation but cases such as this one show that timely submission of quality reports is useful in establishing causality and therefore supporting compensation for the patient or protection from vicarious liability for the health care provider/manufacturer. Publication of similar cases can aid in encouraging reporting rates among patients and providers.

References / Further Sources Of Information

1. Kizito M, Lalitha R, Kajumbula H, Ssenyonga R, Muyanja D, Byakika-Kibwika P. Antibiotic Prevalence Study and Factors Influencing Prescription of WHO Watch Category Antibiotic Ceftriaxone in a Tertiary Care Private Not for Profit Hospital in Uganda. Antibiotics. 2021 Sep 26;10(10):1167.
2. Zheng ZQ, Jiang C, Yu RL, Zhou JQ, Wu ZJ, Luo JY. General characteristics, economic burden, causative drugs and medical errors associated with medical damage litigation involving severe cutaneous adverse drug reactions in China. Journal of Clinical Pharmacy and Therapeutics. 2020 Oct;45(5):1087-97.5.
3. Edersheim JG, Stern TA. Liability associated with prescribing medications. Primary care companion to the Journal of clinical psychiatry. 2009;11(3):11
4. Bhatt AD. Drug-related problems and adverse drug events: negligence, litigation and prevention. The Journal of the Association of Physicians of India. 1999 Jul;47(7):715-720. PMID: 10778594.
5. Kaufman MB, Stoukides CA, Campbell NA. Physicians' liability for adverse drug reactions. Southern Medical Journal. 1994 Aug;87(8):780-784. DOI: 10.1097/00007611-199408000-00002. PMID: 8052883.

Patient experiences of sexual dysfunction after transition to dolutegravir-based HIV treatment in mid-Western Uganda: a qualitative study

Published: 15 August 2022

Henry Zakumumpa, Ronald Kiguba, Helen Byomire Ndagije, Gilbert Ategeka, Jacquellyn Nambi Ssanyu & Freddy Eric Kitutu

BMC Infectious Diseases **volume 22**, Article number: 692 (2022)

Abstract

Background

The literature on dolutegravir (DTG)-based HIV treatment has focused on assessing therapeutic efficacy particularly with regard to viral load suppression. However, little empirical attention has been devoted to understanding the effects of DTG on quality of life, in particular sexual health and functioning in PLHIV. This study focused on understanding patient experiences of sexual dysfunction, after transition to DTG-based regimens in Rwenzori region in Mid-Western Uganda.

Methods

We adopted a qualitative exploratory research design. Between August and September 2021, we conducted sixteen in-depth interviews and six focus group discussions (48 participants) with patients reporting 'new' sexual dysfunction after transition to DTG-based regimens at seven health facilities in mid-Western Uganda. Data were analyzed by thematic approach.

Results

Decreased libido was reported in both sexes of patients within weeks of transition to DTG-based regimens. Diminished interest in sex was more frequently reported among women while men complained of a marked reduction in the frequency of sex. Women reported loss of psycho-social attraction to their long-term male partners. Erectile dysfunction was common among men in this sample of patients. Patients described their experiences of sexual dysfunction as an affront to their socially-constructed gender identities. Patients described tolerating sexual adverse drug reactions (ADRs) as a necessary tradeoff for the extension in life granted through antiretroviral therapy. A number of women reported that they had separated from their spouses as a result of perceived drug-induced sexual dysfunction. Marital strife and conflict arising from frustration with sexual-partner dysfunction was frequently reported by participants in both sexes. Several participants indicated experiencing insecurity in their heterosexual relationships due to difficulties in sexual functioning.

Conclusion

Sexual dysfunction following transition to DTG-based regimens is common in both sexes of PLHIV, who indicated that they had no prior experience of difficulties in sexual health. Our findings demonstrate that sexual ADRs negatively impact self-esteem, overall quality of life and impair gender relations. DTG-related sexual health problems merit increased attention from HIV clinicians. Further research is warranted to assess the prevalence of DTG-associated sexual dysfunction in patients in Uganda.

https://doi.org/10.1186/s12879-022-07673-z

TALK TO US

TOLL FREE **0800 101 999**

HEAD OFFICE:
Toll Free: 0800 101 999

Rumee Towers, Plot 19 Lumumba Avenue,
P. O. Box 23096, Kampala, Uganda
Tel: (+256) 417 788 100/1, 417 788 124/ 041 788 129

REGIONAL OFFICES

Central Regional Office - Kampala
Plot 1-2 Jinja Road
Premier Complex Building Nakawa
P.O. Box 40082 Kampala
Tel: +256 312 261 584

Northern Region Office-Lira
Plot 48 Ogwal, Ajungu Rd
P.O. Box 235 Lira, Tel/Fax: +256 473 420 652

South Western Region Office - Mbarara
Plot 26 Johnstone Road
Boma(after Boma Primary School)
P.O. Box 1886 Mbarara Municipality
Tel: 0485 421 088 Fax: 0485 421 220

Eastern Region Office - Tororo
Plot No: 26 Kwapa Road
P.O. Box 453, Tororo - Uganda
Tel/Fax: (+256) 454 445 195

South Eastern Region Office - Jinja
Plot 64 Gokhale Road
P.O. Box 1710 Jinja Municipality
Tel/Fax: +256 434 122 176

West Nile Regional Office - Arua
P.O Box 1034, Arua Plot.1mt
Wati Road at Anyafio, Tel: +256 372 260 087

Western Regional Office - Hoima
Muganwa Center
Plot 30 Old Tooro Road
P.O. Box 192 Hoima
Tel/Fax: +256 465 440 688

As a health professional,
I always ask my patients to report back any side effects with the medicines I give them.

Report to the NDA via;

- **Toll free: 0800101999**
- **Dial *284*99#**
- **0740002070**
- **Med Safety Mobile App**
- **druginfo@nda.or.ug**

SCAN THIS CODE FOR ONLINE REPORTING

UGANDA
NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

NATIONAL DRUG AUTHORITY