

**PHARMACOVIGILANCE: APPLICATION AND CHALLENGES FOR  
ODONTOSTOMATOLOGY HEALTH PRACTICE IN CAMEROON**

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**ABSTRACT**

Drugs play a significant role in human wellbeing, through treatment, prevention and diagnosis of various diseases of public health interest. The safety, efficacy, quality of the drugs, vaccines or medical administration and their rationale use constitute the main focus of the populations' use of drugs in prevention, treatment of their diseases and the prescription of these pharmaceutical products. The effective regulation of drugs is necessary to guarantee the safety, efficacy, quality, accurate use and good communication of the available drug information to the public. Pharmacovigilance is a vital instrument in public health care that supports the identification, assessment, monitoring and discovery of new chemical entities or new molecules for the benefit of the patients population. Pharmacovigilance serves for the detection and management of potential drug-drug interactions when the use of drugs with other drugs causes adverse drug reaction (Food-drug or herbal-drug interactions) which can cause harm to humans. Dental practitioners are involved in the use of different drug for oral health management. There is the need for the Dentist to be aware of adverse drug effects and potential drug interactions with other xenobiotics exposed to their patients. Dental pharmacovigilance is still a new discipline for dentist involved in treating oral diseases, like parodontal and cariogenic pathologies. This write is an overview of the importance of pharmacovigilance in the Odontostomatology health practice with the focus of Cameroon.

**KEYWORDS:** Adverse drug reaction, dentist, medicine, oral diseases, pharmacovigilance, side effects, Cameroon.

**INTRODUCTION**

The World Health Organization (WHO) defines Pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem.<sup>[1]</sup> Pharmacovigilance is an important and essential part of clinical dental field<sup>[2]</sup>, and it give emphasis on adverse drug reactions which are defined as any reaction to a drug which is harmful and unintended, including lack of efficacy used for the prophylaxis, analysis or therapy of illness or for the modification of physiological function.<sup>[2]</sup>

With an increase in the number of newer high-profile drug withdrawals, the pharmaceutical industry and regulatory agencies have raised the standards of pharmacovigilance. Early detection of signals from both

clinical drug trials and post marketing surveillance reporting have now been adapted by all leading pharmaceutical companies, in order to identify the risks associated with the medicinal product and effectively manage the risks by applying strong risk management plans throughout the lifecycle of the drug.<sup>[4]</sup> Signal detection and risk management of drug has added a new extent to the field of pharmacovigilance and with the evolving drug actions in dental field, it requires ongoing refinement in process to increase its applicability and value to public health.<sup>[5]</sup>

**History of Dental Pharmacovigilance**

Pharmacovigilance has been in existence about 170 years ago, when a young girl (Hannah Greener) from the North of England died after receiving chloroform anesthetic. As a result of other deaths and questions raised by the

clinicians and the public about the safety of anesthesia, a commission was established to take a note on this problem. The commission exhorted English doctors, including the doctor in colonies, to report deaths caused by the anesthesia, later results were published.<sup>[6-9]</sup>

The US Federal Food and Drug Act were formed on June 30, 1906, and it established that drugs must be pure and free of any contamination. Furthermore, in 1911, this organization forbade false therapeutic indications of drugs. Later in USA (1962), the amendment, requiring safety and efficacy data of drugs before premarketing submission, was approved while in 1964, the “Yellow card” (YC) was structured in the UK, which was a specific form to compile a spontaneous report of drug toxicity.<sup>[10,11]</sup>

Meanwhile many studies of observed adverse drug reactions were conducted between 1968 and 1982. In 1992, the European Society of Pharmacovigilance (ESoP) was funded, turned into the International Society of Pharmacovigilance (IsoP) with the aim to promote Pharmacovigilance, and enhance all aspects of the safe and proper use of medicines.<sup>[9,12]</sup> In 1995, the European Medicines Agency (EMA) was formed.<sup>[13]</sup> In 2001, EudraVigilance was created to be the official European database for managing and analyzing information on suspected adverse reactions to medicines which have been authorized for the market or being studied in European clinical trials.<sup>[14]</sup>

### Onset of Pharmacovigilance

Pharmacovigilance begins at clinical trials and continues all long the product life. It can be broadly divided into before-marketing (premarketing) and after-marketing phases (postmarketing).<sup>[15]</sup> The phase 1 of the clinical trial begins by collecting the information pertaining to the safety of the drug before the drug is approved. Studies will continue even after the release of the drug into the market. Postmarketing surveillance is now rendered mandatory by various drug regularity agencies around the world.<sup>[16-18]</sup>

Pharmacovigilance also deals with the following: Issues related to substandard medicines; Errors in medication, Lack of efficient reports, Inappropriate prescription of medications when it is not indicated, Reports of cases for poisoning, both acute and chronic, Cases of mortality due to drug use, Misuse and abuse of medicines, Adverse interactions with chemicals, food, and other medicines.<sup>[19]</sup>

Since 2009, the African Medicines Regulatory Harmonization (AMRH) initiative has served as a foundation for the establishment of the African Medicine Agency (AMA) (Kiguba et al 2023). The AMRH initiative was established to strengthen medicines regulation in Africa by promoting the effectiveness, efficiency, transparency and collaboration of regulatory mechanisms in these settings. In 2009, Ghana began to

host the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, which aimed to promote the uptake of pharmacovigilance by Ministries of Health and other stakeholders across Africa.<sup>40</sup> This had major impact on the development of pharmacovigilance in Africa. Training was provided in English by people with a local perspective, but it excluded Francophone countries in Africa. In 2011, Morocco became the WHO Collaborating Centre for strengthening pharmacovigilance capacity in the Eastern Mediterranean, Francophone and Arab states. This has enabled numerous patient safety-related research and training activities including the pharmacovigilance of medication errors, herbal medicines and vaccines.<sup>[1]</sup>

In Africa, 54 of the 55 countries have National Medicines Regulatory Authorities (NMRAs) or administrative units that perform all or some NMRA functions, albeit with differing levels of growth, expertise and maturity; 87% of the NMRAs lack functional pharmacovigilance systems. None of the African NMRAs are at WHO Global Benchmarking Tool maturity level 4. In SSA, only Ghana and Tanzania have NMRAs at maturity level 3, which depicts stable and well-functioning systems.

In 2016, the African Union (AU) Model Law on Medical Products Regulation, hereafter AU Model Law, was endorsed by the AU Heads of State and Government to promote medicines regulatory harmonization and collaboration in Africa. The AU Model Law is a legislative framework with 1 of its 5 key tenets being to harmonize the requirements and processes for ensuring safe medicines in Africa. The AU Model Law was developed and promoted through the AMRH initiative by the New Partnership for Africa's Development (NEPAD), which evolved into the African Union Development Agency NEPAD.

In 2019, the AU Assembly adopted the AMA treaty, which each Member State should sign and then enact a corresponding national law to implement this treaty. Rwanda was the first AU Member State to sign the treaty in 2019 and it has subsequently been signed by 16 other Member States. 38 However, only five Member States have enacted a law to implement the AMA treaty. In July 2021, the AMA was established after ratification by the minimum required number of AU Member States.

A specific challenge in LMIC is that in most countries there is little or no budgetary support for pharmacovigilance activities by national governments; there exists heavy reliance on donor funding.<sup>[3,5]</sup> The political will is necessary to enable establishment of sustainable budgets to recruit full-time pharmacovigilance staff, conduct routine pharmacovigilance trainings and develop national pharmacovigilance policies.<sup>[5,6]</sup> India demonstrated how initial pharmacovigilance initiatives failed until the national government established infrastructure for the

national pharmacovigilance system and recruited full-time pharmacovigilance staff.<sup>5</sup> In East Africa, Kenya, Tanzania and Uganda have designated budgets for pharmacovigilance activities that should be enhanced to implement national pharmacovigilance guidelines and regulations more effectively and impactfully.<sup>[7,12]</sup> Pharmacovigilance activities generate little or no income for NMRAs, which limits investment in pharmacovigilance analysis, feedback and expansion in

LMIC.<sup>[4]</sup> Introducing the European Union's pharmacovigilance fees approach, although attractive, could dampen the growth of pharmacovigilance systems in LMIC.<sup>[4,7]</sup> However, change has been proven possible: Lesotho and Namibia are excellent examples of African countries with national governments that fully fund their NMRAs.<sup>[3]</sup> The key timelines of relevance to the development of pharmacovigilance systems in LMIC is illustrated in Figure 1.

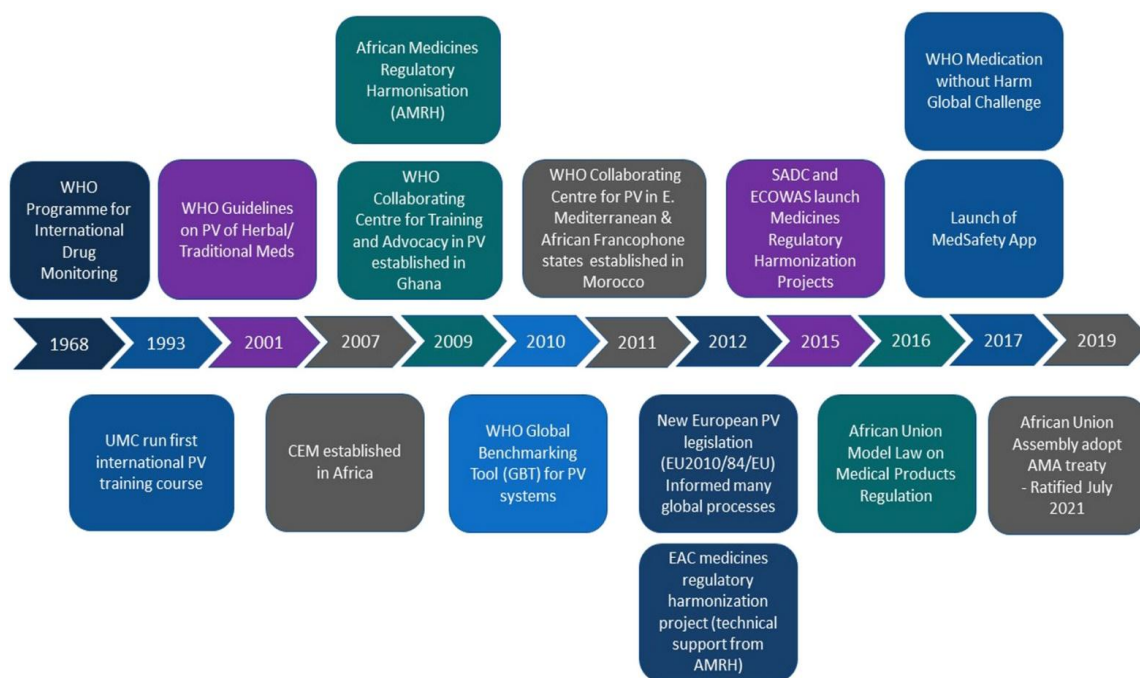


Figure 1: Key milestone in the development of Pharmacovigilance in Africa.<sup>[1]</sup>

### Pharmacovigilance reporting: Sources of data and methods of reporting

Data on drug safety can be harnessed using several methods, as show in Figure 2. Historically, most LMIC data are erived from spontaneous reports. By 2018, SSA

and Arab countries had each contributed fewer than 1 % of pharmacovigilance reports in VigiBase, indicating the importance of more proactive approaches including cohort event monitoring (CEM) and targeted spontaneous reporting (TSR).<sup>[10]</sup>

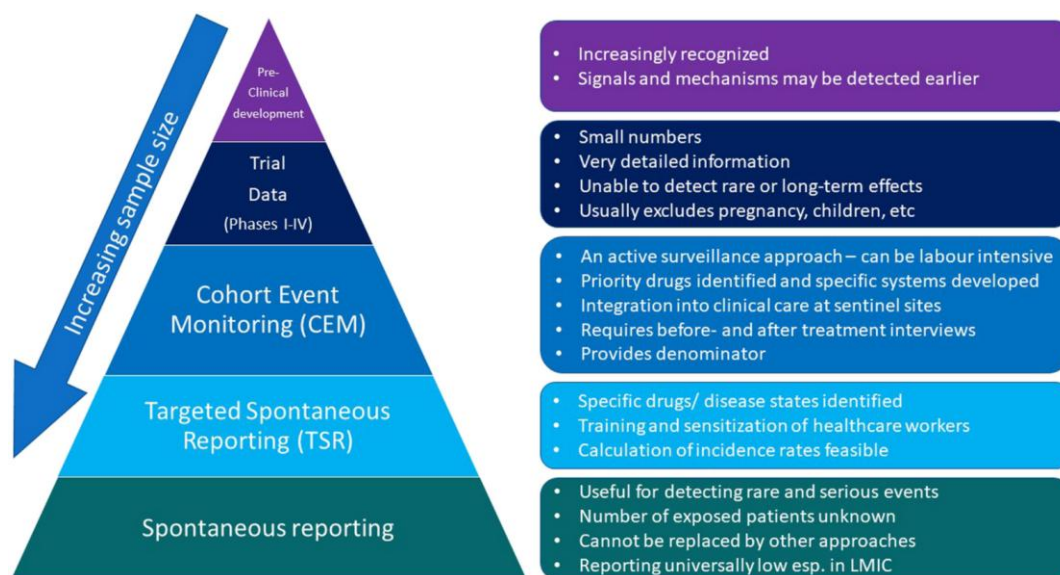


Figure 2: Pharmacovigilance reporting system.<sup>[3]</sup>

### The aims of Pharmacovigilance in Dental care

It aims to improvise the care given for the patients and their safety in relation to medicines and paramedical intervention in dental practices, improvement in safety of public health in relation to the drugs used by the public. PHV assesses the harm, risks, effectiveness, and benefits

of the drugs and evaluating their safety, rational, and more effective use.<sup>[20,21]</sup> It improves the knowledge, promote education, understanding, clinical training, and its communication to the public in pharmacovigilance.<sup>[6,22]</sup> An adverse drug reactions in the oral cavity is illustrated in Figure 3.

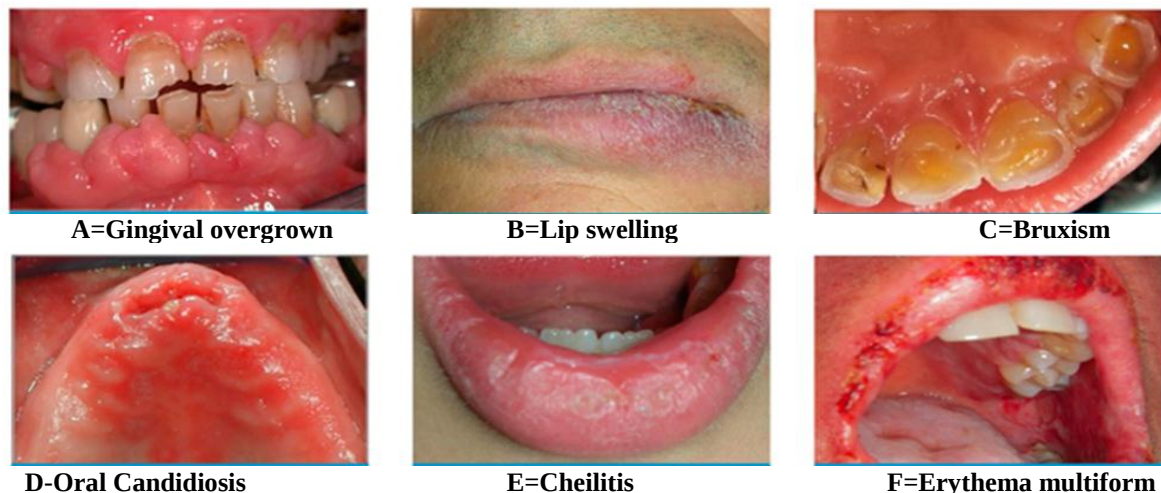


Figure 3: An illustration of the adverse drug reactions in the oral cavity.<sup>[1]</sup>

**Oro-dental pharmacovigilance:** The main changes in the new pharmacovigilance legislation involves; Modification of the definition of adverse drug reactions (ADR). Greater involvement of patients and citizens in Pharmacovigilance activities; Strengthening of the Eudravigilance database containing reports of suspected reactions reported by all EU.<sup>[23-25]</sup> Member States have increasing transparency and timeliness of important information on pharmacovigilance problems; Obligation of additional monitoring for the products contained in the specific list kept by the European Medicines Agency.<sup>[7,26]</sup> The possibility to impose further safety and efficacy studies on the certificates of marketing authorization at the time of granting the trust; Establishment within the European Medicines Agency of the Pharmacovigilance Risk Assessment Committee (PRAC). The new legislation set-up measures to facilitate the performance of PV, called the Good Pharmacovigilance Practices (GVP).<sup>[11,27]</sup> Drugs related to adverse reactions in the oral cavity is listed in table 1.

Table 1: Drugs related to adverse reactions in the oral cavity.<sup>[2]</sup>

|                         |
|-------------------------|
| Ace-inhibitors          |
| Allopurinol             |
| Local Analgesics        |
| Anorectics              |
| Anxiolytics             |
| Antibiotics             |
| Antiarrhythmics         |
| Anticholinergics        |
| Anticholinesterases     |
| Anticonvulsants         |
| Antiasmatic B2-agonists |
| Trichloroacetic acid    |

### The guideline on Good Pharmacovigilance Practices

The guideline is divided into two categories: modules covering major Pharmacovigilance processes and product- or population-specific considerations<sup>[28]</sup>, and second category were available for vaccines and biological medicinal products.<sup>[29]</sup> In November 2017, the new Eudra Vigilance format was launched; in particular, the marketing authorizations will have extended access to the EudraVigilance database to support the fulfillment of their Pharmacovigilance obligations.<sup>[11,30]</sup>

### History of Pharmacovigilance in Dental Practice in Cameroon

Pharmacovigilance in Cameroon started from 1986 when there was the advocacy for the Ministry of Public health to explore developing platform for health research ethics for the regulation of studies in humans. A formal Adverse Drug Reactions monitoring system in collaboration with the the Ministry of Public Health was initiated.<sup>[2,5,31]</sup>

### Pharmacovigilance in dentistry

Dentist's advice a wide range of drugs in their routine clinical practice for treatment of various oral conditions; mainly include antibiotics, analgesics, anti-inflammatory, and antipyretics.<sup>[17,31]</sup> Safe use of Drug in dentistry is an important aspect in patients life.<sup>[18,32]</sup> In the year 2005, report of bisphosphonate-associated osteo necrosis of the jaws made adverse drug reaction and dental pharmacovigilance is important to notice and take action by Food and Drug Administration<sup>[19,33,34]</sup> Certain drugs have the ability to cause adverse oral reactions; a list of drugs that mainly cause various adverse oral cavity reactions, enabling dentists to be observant in reporting any side effects is mentioned in Table-2. In day to day

practice usually dentists in Cameroon need to be familiar with adverse drug reactions caused by drugs that they prescribe for treatment of mucosal conditions, still

dentists also need to be aware of the other drugs that can cause oral reactions that require dental involvement.<sup>[35,36]</sup>

**Table 2: Common adverse effects of the drugs used for conditions in the oral cavity region.<sup>[10]</sup>**

|                                     |                                                                                                                                      |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Oral mucosal pigmentation           | Arsenic, bismuth, busulphan, carbamazepine, chloroquine, cyclophosphamide, gold, iron, methyldopa, oral contraceptives, zidovudine   |
| Oral ulceration                     | Alendronate, allopurinol, captopril, diclofenac, gold, indomethacin, losartan, naproxen, olanzapine, phenytoin, sulindac, vancomycin |
| Orofacial pain                      | Biperidin, griseofulvin, lithium, penicillins, vitamin A                                                                             |
| Paresthesia                         | Amitryptiline, hydralazine, interferon alpha, isoniazid, mefloquine, nitrofurantoin, phenytoin, streptomycin, vincristine            |
| Pemphigoid-like Reaction            | Amoxicillin, clonidine, furosemide, ibuprofen, isoniazid, penicillin, salicylic acid, sulphonamides                                  |
| Salivary gland pain and/or swelling | Clonidine, insulin, methyldopa, naproxen, phenytoin                                                                                  |
| Tooth discoloration                 | ACE inhibitors, doxycycline, penicillins, zopiclone                                                                                  |

The wider range of therapeutic options from different group of drugs makes dental practitioners to provide therapeutic interventions that previously were not possible. Dentists are responsible for understanding the common advantages and adverse effects of available drug choices and must self report any unexpected side effects from those drug treatments. Drug safety depends mainly on the monitoring of medicines once they have been marketed and prescribed.<sup>[37]</sup>

In order to make drugs more safe and effective in dental procedures, it is important to advise a culture of safe drug usage and immediate reporting to avoid major drug disasters.<sup>[22, 38]</sup> Post marketing adverse drug reactions reporting is important because tests in animals are insufficient to predict human safety, because clinical trials use a selective and limited number of patients for a short duration with different conditions than those involved in clinical dental practice.<sup>[5,23,39]</sup> Information about rare but serious adverse reactions, chronic toxicity of drugs, use of certain drugs in special groups such as children, pregnant women, or the elderly, or drug interactions often is incomplete or not reported. Clinical trials may be a better method to check drug's efficacy than its safety during day to day clinical usage. Lack of knowledge and less interest of dentist may be the reason for a lack of vigilance in slow reporting of adverse drug reaction.<sup>[24,40]</sup>

### **The basic components of pharmacovigilance process in dentistry**

The basic component of the pharmacovigilance process in dentistry starts with adverse-event data generation from patients. Data collected through various methods from patients should be evaluated by manufactures for seriousness, expectedness, and causality.<sup>[9,25,41]</sup> Manufacturers are also required to maintain a database of all reports of adverse events regardless of their seriousness, expectedness, or causality.<sup>[26,42]</sup> A strong regulatory framework with dental organizational support is important for introducing and implementing a robust

pharmacovigilance program at a national level. Schools of Dentistry in Cameroon needs to collaborate and integrate organizational approaches to patient safety through the initiation of a coordinated medical safety team mostly at an institutional level.<sup>[11,26]</sup> A drug safety team can be an autonomous body that reports directly to the institution's scientific committee of IRB or dentistry board or it can be a subcommittee of a larger group, such as a patient safety committee or a pharmacy and therapeutic committee.<sup>[28,43]</sup>

### **Dentistry need for Pharmacovigilance training**

Dentists need to be trained in pharmacovigilance programs. The mutual exchange of information regarding adverse drug reactions between the dentist, clinical pharmacist, pathologist, or microbiologist is crucial. Collaboration with clinical pharmacologists and clinical pharmacists can very important in the medication safety team, as professionals from a pharmacology/ pharmacy background have a focused knowledge with regard to drug therapy.<sup>[44]</sup> By being part of a medication safety team, dental specialists can play an important role in promoting a culture of safe drug usage via adverse drug reaction reporting in order to establish a causal relationship between a drug and an adverse drug reaction, education through seminars/ workshops for drug safety, and surveillance.<sup>[29-31,45]</sup>

### **Dentist and Adverse Drug Reaction**

Adverse drug reaction may be difficult to recognize, as they can act via the same physiological and pathological pathways as other diseases. When evaluating a possible drug-related adverse drug reaction, confirm that the drug and the prescribed dosage are correct.<sup>[32,46]</sup> The onset of an adverse drug reaction should be verified; it should manifest only after the drug is administered. The amount of time that elapses between the administration of the drug and the onset of the reaction must be established. After discontinuing the drug or reducing the dose, evaluate the suspected adverse drug reaction and monitor the patient's status.<sup>[33,47]</sup> It is advisable to restart the drug

treatment and monitor the recurrence of any adverse events; alternative conditions other than the drug that may have caused the reaction should also be analyzed. Using relevant evidence-based data mining information and dental experience, may determine whether there are any conclusive reports that match or mirror this patient's reaction. National pharmacovigilance centers and drug information centers are important resources for obtaining information on adverse drug reactions in Cameroon. However, the pharmacovigilance data collection channel is still at its infancy for dental adverse drug reaction monitoring.<sup>[35]</sup>

For new drugs, all suspected reactions including minor ones must be reported. For established or well-known drugs, all serious or unusual adverse drug reactions should be reported. In addition, a report should be filed whenever there is a given reaction with increased frequency, when suspected adverse drug reactions are associated with drug withdrawal, when adverse drug reactions result from an overdose or error in administering medication, when a lack of efficacy or suspected pharmaceutical defects (such as contamination during formulation and use of additives/ preservatives) are observed, and when there is a suspected adverse drug reactions in special fields of interest such as drug abuse and drug use during pregnancy and lactation.<sup>[30,36,48]</sup> The proper evaluation/ decision must be made while establishing a causal relation between a drug and an adverse drug reaction. Medication safety data can be aggregated and analyzed using tools that measure how

changes in drug prescription trends and safety measures have modified the medication use process and affected the potential for patient harm. Adverse Drug Reaction Reporting is the most commonly associated with Pharmacovigilance and consumes a considerable amount of resources of government agencies or drug regulatory authorities or drug safety departments in pharmaceutical organizations. Adverse drug reaction reporting should be done within seven days and it includes the receipt, triage, data maintaining, evaluation, distribution, reporting of AE data.<sup>[37,49]</sup> The foundation of adverse drug reactions reports may include solicited reports from patient support programs, reports from clinical or post-marketing studies, spontaneous reports from healthcare professionals or patients or other intermediaries, reports from literature sources, reporting is a regulatory requirement in most countries, reports from the media including social media and websites and reports reported to drug regulatory authorities themselves. For pharmaceutical companies adverse drug reaction reporting also provides data that play an important in assessing the risk-benefit profile of a given drug.<sup>[50]</sup>

Globally, data collected and evaluated for health regions are forwarded to WHO-Uppsala Monitoring Committee (UMC).<sup>[51]</sup> It is the most important duty of any pharmacovigilance centre to report all suspected adverse events of the drug if found. The most important ADRs and the type of ADRs that should be reported are summarized in table 3.

**Table 3: Details required for reporting ADR events.**<sup>[15]</sup>

| Important points in ADR reporting | Required Information                                                                                                                                                                                                                         | Others                                                             |
|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| What should be reported           | Adverse reactions of the drug, suspected drug's details, patient's information                                                                                                                                                               | Medications overdose, pharmaceutical defect, drug interactions     |
| Who can report                    | Medical practitioners, dental practitioners or any health care professionals, doctors, nurses, pharmacists, health care assistants, pharmaceutical technicians, pharmaceutical assistants, clinical officers and other health care providers | Manufacturers, all government and private hospital's health center |
| When ADR can be reported          | Any adverse reactions if noticed should be reported as soon as possible                                                                                                                                                                      | -                                                                  |
| How to report                     | Through completely filled yellow card form                                                                                                                                                                                                   | -                                                                  |
| Where ADR can be reported         | Fully filled completely ADR form should be submitted to pharmacovigilance center                                                                                                                                                             | -                                                                  |

The WHO has highlighted severe deficiencies in the culture of reporting adverse drug reaction. The method of generating a signal from adverse drug reaction is useful only if the signal is taken seriously and the action taken is immediate and addresses the level of concern. The drawback of pharmacovigilance today remains that drug companies continue to invest large sums of money in promotional launches instead of committing a portion of

their funds to propagating training and awareness programs that would promote early reporting of adverse drug reaction.<sup>[32,52]</sup> Increasing and updating the awareness of pharmacovigilance in dental therapeutics requires proactive participation among health care professionals in general and especially among dentists. The adverse drug effect on oral cavity is also elaborated in table 4.

**Table 4: Adverse drug effect on oral cavity.**<sup>[26]</sup>

| Adverse effect on oral cavity | Name of the drug                                                                                                                                                                                                     |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Altered taste                 | Acarbose, allopurinol, atorvastatin, azathioprine, cholestyramine, clarithromycin, enalapril, ethambutol, griseofulvin, imipenem, lithium, phenytoin, ramipril, rivastigmine, selegiline, tetracyclines, venlafaxine |
| Angioedema                    | ACE inhibitors, aspirin, captoril, cephalosporins, clonidine, indomethacin, penicillamine, quinine, streptomycin                                                                                                     |
| Cheilitis                     | Atorvastatin, busulphan, gold, indinavir, isoniazid, lithium, methyl dopa, selegiline, streptomycin, tetracyclines, vitamin A                                                                                        |
| Erythema Multiforme           | Allopurinol, amlodipine, carbamazepine, co-trimoxazole, ethambutol, fluconazole, furosemide, minoxidil, phenytoin, rifampicin, tetracyclines, valproate, vancomycin                                                  |
| Gingival swelling             | Amlodipine, cyclosporine, diltiazem, oral contraceptives, phenytoin, Valproate                                                                                                                                       |
| Hypersalivation               | Amiodarone, clonazepam, gentamicin, haloperidol, lamotrigine, nifedipine, pentoxifylline, risperidone, venlafaxine, zaleplon                                                                                         |
| Oral candidiasis              | Corticosteroids, broad spectrum antimicrobials, immunosuppressives                                                                                                                                                   |
| Adverse effect on oral cavity | Name of the drug                                                                                                                                                                                                     |
| Altered taste                 | Acarbose, allopurinol, atorvastatin, azathioprine, cholestyramine, clarithromycin, enalapril, ethambutol, griseofulvin, imipenem, lithium, phenytoin, ramipril, rivastigmine, selegiline, tetracyclines, venlafaxine |
| Angioedema                    | ACE inhibitors, aspirin, captoril, cephalosporins, clonidine, indomethacin, penicillamine, quinine, streptomycin                                                                                                     |
| Cheilitis                     | Atorvastatin, busulphan, gold, indinavir, isoniazid, lithium, methyl dopa, selegiline, streptomycin, tetracyclines, vitamin A                                                                                        |
| Erythema Multiforme           | Allopurinol, amlodipine, carbamazepine, co-trimoxazole, ethambutol, fluconazole, furosemide, minoxidil, phenytoin, rifampicin, tetracyclines, valproate, vancomycin                                                  |
| Gingival swelling             | Amlodipine, cyclosporine, diltiazem, oral contraceptives, phenytoin, Valproate                                                                                                                                       |
| Hypersalivation               | Amiodarone, clonazepam, gentamicin, haloperidol, lamotrigine, nifedipine, pentoxifylline, risperidone, venlafaxine, zaleplon                                                                                         |
| Oral candidiasis              | Corticosteroids, broad spectrum antimicrobials, immunosuppressives                                                                                                                                                   |

### Global Perspective of Pharmacovigilance and ADR Reporting

Pharmacovigilance guidelines are not uniform across the world and show considerable variation from country to country. Reporting guidelines are based on requirements that are specific for a nation and have evolved to form a system addressing the needs of that nation. The main aim of the reporting system is to monitor the harmful effects of the drugs, which helps in improving the health of the patients.<sup>[52-54]</sup> A program under the WHO termed International Drug Monitoring was initiated in 1978, with only 10 countries participating in it. It has now grown by leaps and bounds at the global level, with the active participation of 120 countries. Following WHO's suggestions in January 2010 and also considering review of the Advisory Committee regarding Safety of Medical Product (ACSoMP) in April 2010, the National Pharmacovigilance System has adopted specific functions. These functions are as follows:

- Promotion of pharmacovigilance in a country has to be implemented by collecting the ADR reports along with substandard drugs and reports of medical errors
- The information should be collected from existing ADRs of the country and also cohorts that monitor internationally in defined patients or populations.

This information has to be collaborated and harmonized for further considerations.

- Drug safety indications pertaining to unknown and poorly characterized adverse events and other events that occur due to combination of drugs have to be identified.
- The assessment of risk of ADR and outlining its management is to be undertaken.
- The recognition of the quality of the medicine and endorsing it, also to identify the resulting ADRs that may occur due to the drug. T
- He team should also take responsibility for the effective communication on drug safety and also dispel the rumors of the toxicity of medicines and vaccines.
- The information from pharmacovigilance has to be applied appropriately as it benefits individual patients, national medicine policies, public health programs, and treatment guidelines.
- The development and maintenance of information related to drug utilization has to be undertaken.
- The issues regarding unregulated prescribing of medicines and their dispensing are to be identified.<sup>[56]</sup>

### Pharmacovigilance structure in Cameroon

A nationwide pharmacovigilance program to protect the health of the patients was initiated by the WHO in collaboration with the MoH under the coordination of DPML. As a part of this program, the safety of drugs is assured under Directorate of Pharmacy medicine and Laboratories of Health Services, Government of Cameroon. Suggestions put forth by the WHO in the document titled "Safety Monitoring of Medicinal Products: Guidelines for Setting up and Running a Pharmacovigilance Center" were implemented. The Cameroon Pharmacovigilance subcommission, and the National drug commission have appointed members. National Coordinating Center (NCC) synchronizes the program under supervision of a steering committee. The National Pharmacovigilance Program was officially inaugurated on 23 November 2003 in Cameroon.<sup>[58]</sup>

### Broad Objectives of the Program

- To develop the culture of reporting and notification of unfavorable events
- To establish a robust and broader ADR monitoring system in Cameroon.

### The National Pharmacovigilance Center performs the following activities

- To ascertain the harmful drug reactions of the medicines that should be identified beforehand or to indicate certain commonly occurring reactions
- To always maintain a record of the periodic safety update reports (PSURs) provided by the pharmaceutical companies
- To exchange information on the drug safety and to establish contacts with the international organizations and agencies of pharmacovigilance
- To promulgate safety regulations outlining the actions to be taken, if necessary, to improve the safe use of the drug
- To disseminate the information on the adverse effects of drugs through bulletins, alerts, news, and seminars.

### Challenges of Dental Pharmacovigilance in Cameroon

The information available on the Internet regarding the free availability of drugs may not be entirely reliable. Such information regarding the safety, quality, and efficacy of drugs that are unregistered, prescription drugs, traditional or herbal drugs, and highly controlled substances, may be questionable.<sup>[59]</sup>

- Complications from overdose, interactions, irrational drug use, traditional or herbal medications, polypharmacy, drug abuse, and illegal sale of medications due to the self-medication practice based on the knowledge attained from the Internet, medication error, and also lack of the efficiency of medications all come under the purview of pharmacovigilance

- Imperfections and conflicts in the pharmaceutical industry while dealing with the public's health and their safety in the drug use.
- The generic sector has not fully recognized that it is their responsibility to monitor the safety of the released drug throughout the world
- Understandings of the harm, benefits, and the extent of the acceptable risk regarding the medicines have become less meaningful in the current era of information. In developed and developing countries, the drug-induced diseases have recently been given importance due to their increasing morbidity and mortality due to ADRs.<sup>[60]</sup>

While major advancements in the discipline of pharmacovigilance have taken place in the West, not much has been achieved in India. However, with more clinical trials and clinical research activity being conducted in India, India's pharmaceutical industry is now the third largest in the world in terms of volume, 14th in terms of value and now emerging as an important clinical trial hub in the world still there is a massive need to understand and implement pharmacovigilance. Developments in dental pharmacotherapeutics require dentists to constantly update their knowledge of new drugs, drug safety, and therapeutic trends.<sup>[61]</sup> Dentists must acknowledge the reporting benefits the practice of adverse drug reaction in dentistry as a whole. Early and more proper documentation of adverse drug reaction will directly influence the speed with which problematic drugs can be withdrawn from the market, directly affecting the lives of patients and more safety will be achieved by the dental fraternity as well.

### Pharmacoecovigilance and Toxicovigilance Development in dentistry

The emergence of eco-pharmacovigilance, science and activities associated with the detection, evaluation, understanding and prevention of the adverse effects of pharmaceuticals<sup>[11,62]</sup>, including dental materials, on the environment, makes it necessary to incorporate it (ecopharmacovigilance) into the daily routine of the Institution. The role of pharmacovigilance in health care has its counterpart in the environment. Following Daughton's proposal<sup>[12,63]</sup>, the classic concept of pharmacovigilance may also cover problems related to drugs in the environment, so the term pharmacoecovigilance would unify the need to detect, evaluate, understand and prevent the adverse effects of pharmaceuticals in the human and ecological health.<sup>[13,14]</sup>

The aim of the node is to ensure the responsible management of biological, pharmaceutical and other waste, to raise awareness among the community, to achieve a sustainable capacity to reduce the impact on the environment and to have the active participation of students, teachers and non-teaching staff and the patients. The general objective is to set pharmacoecovigilance in the faculty of dentistry, as a common practice. The specific objectives are as follows: to contribute to the generation of a sustainable faculty, to raise awareness of

the university community with the preservation of the environment, to promote the classification of common residues and of the dental area, RRR (reduce, recycle and reuse) the wastes of the faculty.<sup>[64-68]</sup> The methodology is to be used complied with art. 2 of the University of Republic organic law, and integrates the university goals for its development. The processing of medicines will be carried out within the scope of the institutional pharmacy, then follow the course defined by the ministry of public health and the faculty for contaminated and contaminated waste. The evaluation of the the project will be carried out through surveys and interviews with patients and the university community in general. The dissemination of information will be done through triptychs, posters and website of the faculty.<sup>[69-70]</sup> Ecopharmacovigilance has an environmental and public health approach. It can be defined as the science and activities related to the detection, evaluation, understanding and prevention of the adverse effects of drugs. Space and time in pharmacoecovigilance. The process of detecting adverse drug reactions begins once the drug has been placed in the market (pharmacovigilance), whereas eco-pharmacovigilance practice must begin at the time of the new drug synthesis and continue until its elimination or disposal.<sup>[33,71]</sup> It is important to emphasize that pharmacovigilance is applied from phase IV of the clinical trial, i.e. when the drug is marketed, and pharmacovigilance must be practiced from the moment of the synthesis of drugs, cosmetics, and dental materials

## CONCLUSIONS

The pharmacovigilance in dentistry contributes to the establishment of greater therapeutic safety, helps to prescribe rationally and to make adequate decisions. The prescribing and usage of drugs for dentist could damage health and environmental as a medical care. Focused on good dental practices, treating humans and the environment as a single, integral patient, the incidence of drug related problems and environmental damage could be reduced.

It can be concluded that pharmacovigilance continues to play a crucial role in meeting the challenges posed by the ever-increasing range and potency of medicines, all of which carry an inevitable and sometimes unpredictable potential for harm. Although health professionals report that paying attention to ADRs and timely reporting is very important, underreporting of ADRs is still a substantial problem. Undergraduate training in pharmacovigilance and awareness about risks associated with medicine use may be either deficient or unsatisfactory to prepare the prospective doctors for the job of ADR monitoring and reporting in their future career.

While prescribing medications in clinical practice, usually a trade-off between potential benefits and harms has to be taken into consideration. The harm that could be caused by medicines can be minimized by improving

quality, safety, and efficacy of the medicines and of course rational use. Expectations and concerns of the patient should be taken into consideration when any therapeutic decisions are made. Risks in drug use need to be anticipated and managed effectively. There is a definite need to improve communication between health professionals and the public and educate health professionals to understand the effectiveness or risk of medicines that they prescribe. Pharmacovigilance has definite public health implications as the frequency of ADRs being reported is increasing. It is essential to foster a sense of trust among patients in the medicines they use, which would eventually pave the way for enhanced confidence in the healthcare delivery system.

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## COMPETING INTERESTS

Authors have declared that no competing interests exist.

## AUTHORS CONTRIBUTION

AMA, EAT CNF conceived the study, wrote the manuscript; DMG, BAN, LBF, data mining, data analysis. All the authors read and approved manuscript for publication.

## CONSENT AND ETHICAL APPROVAL

Not applicable.

## DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

## COMPETING INTERESTS DISCLAIMER

Authors have declared that they have no known competing financial interests OR non-financial interests OR personal relationships that could have appeared to influence the work reported in this paper.

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