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NARRATIVE REVIEW

# Exploratory study on analgesic pharmacovigilance actions of clinical teachers in stomatology.

# Estudio exploratorio sobre las acciones de farmacovigilancia de analgésicos de docentes clínicos en estomatología

Rosy Itzel Suazo Ramos [1] | Karla Marisol Teutli Mellado [2] | Julia Flores-Tochihuitl [2]

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**Institutional Affiliation**

[1] Benemérita Universidad Autónoma de Puebla, Facultad de Estomatología, Licenciatura en Estomatología, Puebla México.
[2] Benemérita Universidad Autónoma de Puebla, Facultad de Estomatología, Puebla México.
[3] Benemérita Universidad Autónoma de Puebla, Facultad de Estomatología, Laboratorio multidisciplinario, Puebla México.

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**Correspondence author:** Julia Flores Tochihuitl. Address: Av. Manuel Espinosa Yglesias 31 Pte. 1304, Los Volcanes, 72410 Puebla, Puebla, México. Tel (222) 229 55 00 Email: julia.flores@correo.buap.mx

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**ABSTRACT**

**Introduction:** Drugs in the family of non-steroidal anti-inflammatory analgesics (NSAIDs) can cause adverse drug reactions (ADRs) and drug-drug interactions, hence the importance for the stomatologist to know how to prescribe and use each drug rationally.
Currently, there is no information on the pharmacovigilance actions of analgesics that are the responsibility of the stomatologist, so the objective of this research was to explore the pharmacovigilance actions carried out by clinical teachers in stomatology.
**Materials and methods:** For the purposes of this study, a 23-question questionnaire derived from the Mexican Official Standard NOM-220-SSA1-2016 on pharmacovigilance actions of analgesics was constructed. Google forms were used in a self-administered manner.
**Results:** 67.56% of the participants (n=37) were female. Regarding years of experience they have a minimum of 5 years and a maximum of 42 (M=13.36, SD=8.2). Most of the teachers (64.86%) monitor the analgesics they prescribe; however, 86.66% of the participants have never detected an Adverse Drug Reaction (ADR) and 70% do not monitor the possible pharmacological interactions of the prescribed analgesics.
**Conclusion:** There is a need for updating and educational initiatives in pharmacovigilance in stomatology, monitoring analgesic prescription patterns, developing prescription guidelines to ensure that patients receive the most effective treatment for their oral pain, and structuring a protocol in accordance with current standards for the reporting of ADRs and the recording of drug interactions.

## CLINICAL RELEVANCE

Teachers in undergraduate clinics and students should carry out responsible pharmacological management as it is an important action in stomatology. This research focuses on exploring the pharmacovigilance actions carried out by teachers in a public institution in Mexico. The findings allow us to know the pharmacovigilance activities of teachers specifically in the rational use of analgesic drugs, the reporting of adverse reactions and the detection of possible drug interactions. It is necessary for teachers to use a protocol for pharmacovigilance and monitoring of analgesic prescription patterns for oral pain.

## INTRODUCTION

Oral pain is one of the main causes of visits to the stomatologist, so the pharmacological treatment commonly used for its management are those of the family of non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol because they are easily accessible and over-the-counter; they are also the most consumed worldwide and the most used for the treatment of pain in stomatology.[1] In very specific cases it is necessary to use weak opioids, which are controlled drugs that the stomatologist can prescribe for moderate or severe pain.

The prescription of drugs for analgesic purposes should be prescribed in adequate doses and with the pertinent duration to avoid non-compliance with therapeutic objectives and the appearance of adverse effects even when they are observed as a routine process for the treatment of pain.

Pharmacovigilance is the science and activities related to the detection, evaluation, understanding and prevention of adverse reactions or any other health problem related to drugs or vaccines.[2] It should be emphasized that these actions are not exclusive to physicians but to all health professionals, so it is the stomatologist's responsibility to monitor compliance and identify possible interactions with other drugs that the patient may be consuming and thus promote the rational use of analgesics through efficient prescribing. Some of the adverse events related to the consumption of NSAIDs include gastrointestinal events, or hepatic necrosis due to paracetamol overdose; or drowsiness, nausea, vomiting and possible death from respiratory arrest due to opioid overdose.[3]

The Mexican Official Standard NOM-220-SSA1-2016 determines the installation and operation of pharmacovigilance, in which criteria of efficacy, quality and safety and the benefit/risk ratio for the therapeutic use of a drug or vaccine should be considered.[4]

For these reasons, it is important that the stomatologist contributes to the rational use of drugs according to the guidelines for good prescribing, reports adverse drug reactions and detects possible drug interactions in patients. The act of medical prescription constitutes a fundamental pillar for the rationality of therapeutics and, therefore, the study of prescribing habits provides information very close to the reality of drug use.[5]

Therefore, this research aims to determine the pharmacovigilance actions of analgesics (rational use of drugs, detection of RAM and identification of drug interactions) of clinical teachers of the Faculty of Stomatology of the BUAP.

## MATERIALS AND METHODS

The research was exploratory, cross-sectional and observational. An adapted questionnaire of 23 questions was applied, which was applied in the period from January to June 2022. The population was 106 teachers from the stomatology clinics of a public university, and 34.90% participation was obtained. The selection criteria included teachers who taught undergraduate clinics at a public university, who had more than 2 years of clinical experience, and who agreed to participate in the research.

### Procedure

An initial questionnaire was developed in which the Official Mexican Standard NOM-220-SSA1-2016 on pharmacovigilance actions for analgesics and the manual entitled “WHO pharmacovigilance indicators” were taken into account; the instrument was validated by expert judgment, which were six experts in the area of pharmacology who served as judges in terms of clarity, precision, accuracy and comprehension of the instrument generated. The pertinent changes were made and it was piloted with 10 participants, questions were eliminated and finally the final questionnaire was constructed, which included 23 questions in total and was applied to the sample.

Teachers were invited to participate through the use of self-administered Google forms and others in their printed version, the link was sent via e-mail along with a letter of invitation.

**Instrument**

**Stage 1.** Design and piloting of the Pharmacovigilance (PV) knowledge assessment questionnaire.

**1.1** The VF knowledge variables of interest to be measured, their dimensions and indicators were determined. Subsequently, a set of items was developed for each variable based on: a) previous studies carried out in other countries b) a questionnaire of the Federal Commission for Protection against Health Risks (COFEPRIS) and c) questions formulated according to the applicable Mexican regulations, the guidelines for the construction of items of the National Evaluation Center for Higher Education (CENEVAL) and Bloom's taxonomy (cognitive conceptual level of knowledge) were considered and a preliminary version of the questionnaire was created.

**Stage 2.** The content validity of the questionnaire was determined using the Delphi method by submission to consensus of a multidisciplinary panel of 6 experts in the area of pharmacology.

**Analysis**

The results obtained from the questionnaires were entered into an Excel table and the data of the quantitative variables were analyzed using percentages, mean, standard deviation and corresponding graphs. The prescription of NSAIDs, paracetamol, opioids and their most frequent combinations were determined according to the treatment and therapeutic objective of the stomatologist by means of measures of central tendency. The qualitative data analysis of the open-ended questions on knowledge and the application or not of pharmacovigilance was also performed.

## RESULTS

They are presented in 2 sections: in the first one, the results concerning the teachers' profile are developed, in the second one, what refers to pharmacovigilance actions and attitudes such as knowledge of the Mexican Official Standard NOM-220-SSA1-2016 “Installation and operation of pharmacovigilance”.

**First section: Teachers' profile**

67.56 % of the participants (n=37) were female; 72.97 % of the participants have a specialty. 27.02 % are related to pediatrics and 16.21 % are related to orthodontics. 45.94 % have a master's degree and only 10.81 % of the participants (n=4/37) have a doctorate. Most of the participants have several years of experience practicing their specialty or master's degree with a minimum of 5 years and a maximum of 42 years (M=13.36, S.D.=8.2).

Regarding their experience teaching clinical subjects, 70.27 % of the participants teach undergraduate clinics, 24.32 % (n=9/37) undergraduate and postgraduate and 5.40 % only postgraduate, where Integral I, II and III clinics were the most reported. The minimum experience was 3 years and a maximum of 41 years (M=11.97, SD=9.08).

**Second section: Analgesic pharmacovigilance actions**

In relation to pharmacology and/or pharmacovigilance updating, 67.56% of the teachers have not taken any course in the last 5 years. On a scale of 1 to 5, the teachers were asked about their level of knowledge of pharmacovigilance, with 1 being very little and 5 being very good knowledge. The majority (37.83%) mentioned having a low level of knowledge, 29.72% a regular level, 13.51% a good level and only 2.7% mentioned having a very good level of knowledge and 6.21% mentioned having a very low level of knowledge. This reaffirms the need to have a protocol for teachers for pharmacovigilance in clinics.

To verify pharmacovigilance actions, the manual entitled “WHO pharmacovigilance indicators: a practical manual for the evaluation of pharmacovigilance systems” was taken into account, where the scope of pharmacovigilance is established and 90.59% identified adverse drug reactions/events.

From the official Mexican standard NOM-220-SSA1-2016, Installation and operation of pharmacovigilance, a series of guides are derived, such as the Pharmacovigilance Guide for the notification of AE (Adverse Effect), SRAM (Suspected Adverse Drug Reaction), ESAVI (Events Suspected to be Attributable to Vaccination or Immunization) or any safety problem related to the use of drugs and vaccines which is unknown by 86.48% of the teachers.

According to this standard, 64.86% of the participants keep themselves informed and updated on safety data related to vaccines and the drugs they prescribe, dispense or administer; 51.35% receive, record and notify case reports of MRSA, AMR, ESAVI and any other safety problem related to the use of vaccine drugs, also 27.2% continuously participate in pharmacovigilance dissemination and promotion activities. A small percentage do not report the self-medication habits of patients of any age range (8.10%) nor do they belong to a pharmacovigilance committee, local, national or international (10.81%).

In 16.21% of the teachers in the clinics considered that pharmacovigilance is an action proper to physicians and nurses and that prescribing an analgesic is not a major problem because possible ADRs or drug interactions are not fatal.
Almost all clinical teachers (95.59%) do not know where to find the forms for reporting ADRs in the institution.

Among the actions that teachers take upon identifying an AMR, they mentioned the following: “suspend the medication and administer antihistamines”, ‘report it’, ‘inform COFEPRIS and pharmacist’, ‘change or suspend the medication’, ‘call the physician or emergency department’. However, 33.63% reported that “they have not been presented with the case”, one teacher mentioned “not knowing what to do” and another that “there is no protocol to follow”. As we can see, there is a great need for practical application on the subject.

The teachers were asked about post-prescription analgesic monitoring actions, the answers included “patient-student and student-teacher communication”; “direct questions to the patient”, “records” “request to the students to be aware of the patients”, “no monitoring” and “evolution notes”. Regarding the detection of pharmacological interactions of the analgesics prescribed by the teachers during their working day, they reported that 86.48% have never detected one, however, 8.10% detected one interaction for every one out of ten patients attended and 5.40% reported detecting one interaction for every 21 or more patients attended. Finally, they commented that “information on a pharmacovigilance center should be provided for those who are not so closely related to the subject” and that “training for everyone would not be a bad thing”.

## ETHICAL ASPECTS

The purpose of the study was explained to the participants, who were assured that the data collected would be used only for research purposes and that the findings did not represent an evaluation of their work performance.

## DISCUSSION

The participants have an average experience of 11.9 years teaching undergraduate and postgraduate clinics at the School of Stomatology of the Public University, of which 67.56% are female. 27.02% of the participants have a specialty related to the area of pediatric dentistry. The response percentage was lower than a similar study conducted by Sudhakar et al. in 2015 [17] with a participation of (83.3%).

The reason for the lower response percentage in our research could be because when the questionnaire was applied there was still the health emergency generated by the SARS-CoV2 virus (COVID-19), which prevented access to the faculty clinics and personal approach to the teachers, so the process had to be mainly through an invitation via email. The questionnaire contains 23 questions to answer and takes approximately 20 minutes of the participants' time, which may have generated disinterest in answering it.

As reported by Sudhakar et al. in 2015, [17] there is a general belief that health professionals, especially stomatologists (dentists), have little awareness about pharmacovigilance. Little updated scientific literature is found on pharmacovigilance in stomatology which could justify the results obtained in our questionnaire regarding this topic. 67.56% of the participants have not taken a refresher course in pharmacology and/or pharmacovigilance in the last five years, which confirms the importance of updating in this area. Although the majority preferred to omit the reason, some of the participants reported that the reasons were cost, lack of time and that there are no specialized courses on these topics. This suggests proposing a refresher course because pharmacovigilance actions are also the task of stomatologists.

Jadhav et al. in 2017 [18] reported that after the invention of a drug, more information is known about its therapeutic activity, but less is known about its safety. Because of the above, they recommend conducting activities related to pharmacovigilance. 94.59% of the teachers identify at least one of the pharmacovigilance actions marked by WHO; “Identification of adverse drug reactions/events”. Most of the teachers (64.86%) monitor the analgesics they prescribe. The above is in agreement with Halling et al. in 2018 [19] who reported that, for NSAIDs, careful patient selection is essential to avoid adverse effects. Educational initiatives and international monitoring of analgesic prescribing patterns, as a database for the development of prescribing guidelines, can help ensure that patients receive the most effective treatment for their dental pain without compromising their overall health.

Pharmacovigilance in Mexico is regulated by the Mexican Official Standard NOM-220-SSA1-2016 “Installation and operation of pharmacovigilance,” at least 64.86% of the teachers selected one of the correct actions described in this standard. Jadhav et al. in 2017 [18] reported that reporting of unwanted adverse drug reactions becomes very important not only for future referrals and development of better drugs, but also to avoid unnecessary burden on the health care system and patient morbidity or mortality.

It is a reality that in the clinics of the Faculty there is no pharmacovigilance protocol with which teachers can be guided to report ADRs. This was similar to that reported by Sudhakar et al. (2015) [17] where they showed that about 51% (agree or strongly agree) of the participating dentists stated that they had no idea how to report ADRs to the relevant authorities and regarding pharmacovigilance related to their practice and only 7% have identified an ADR.

According to Seymour [29] drug-drug interactions are important and can result in morbidity and even significant mortality. Fortunately, the latter is a rare occurrence in relation to prescribing in stomatology. Stomatologists prescribe a limited range of medications and, for the most part, these are safe. However, interactions can occur so it is essential to obtain a complete drug history from patients at each visit.

The low percentage of drug interaction detection and ADR reporting is possibly related to the lack of updating and the lack of motivation to participate in this type of actions. Only two teachers suggested training and more information on pharmacovigilance and its centers in the state of Puebla.

In the scientific literature there is very little updated information on pharmacovigilance in stomatology and even less related to the use of analgesics. The present investigation contributes on these topics and allows reflection to implement ways of providing pharmacological therapies with adequate analgesics to patients attended in clinics.

The intention of detecting the areas of pharmacovigilance that should be reinforced is to contribute to a strengthened teaching staff. In addition, the reported results represent an opportunity to conduct large-scale studies of this type in order to propose to national health authorities the creation of guidelines and/or pharmacovigilance programs with a greater stomatological focus and including commonly prescribed drug groups.

It is necessary to implement updating in pharmacology and pharmacovigilance in the area of stomatology, use all nearby resources to carry out pharmacovigilance actions. It is also necessary to structure a protocol according to current standards for the reporting of AMR in the faculty clinics and for the registration of drug interactions. Also implement educational initiatives, monitoring of analgesic prescribing patterns, and development of prescribing guidelines to help ensure that patients receive the most effective treatment for their oral-facial pain.

## CONCLUSIONS

Odontalgia is the type of orofacial pain most frequently seen in clinics and it is therefore suggested that a pharmacological treatment protocol for this type of pain be implemented. Ibuprofen is the most commonly used analgesic in the clinics of the public university; it is necessary to guarantee a good prescription according to the therapeutic indications of this and other analgesics and the characteristics of the patient.

Respondents show lack of knowledge about some pharmacovigilance tasks such as the identification and reporting of ADRs, so training in this regard is suggested. There is a low percentage of detection of drug interactions, it is therefore necessary to thoroughly explore whether the cause is the low ability to identify them or that they are making a responsible prescription to prevent them.

Finally, intervention strategies are suggested, as well as educational sessions, classes, presentations and group discussions, raising awareness of the importance of reporting ADRs in daily practice; In addition, a workshop for filling out the COFEPRIS AMR notification format with the support of teaching materials such as slides, brochures, videos, among others.

## DECLARATION OF CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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