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Pharmacovigilance and Toxicovigilance Development in Dentistry

María Renée Romero

Faculty of Dentistry, Universidad de la República, Montevideo 11400, Uruguay

Abstract: Patient safety has become a priority for the health system, including dentistry. Several studies showed that health care meant to improve people's health is an important source of disease. Good clinical practices aim to maximize effectiveness and therapeutic compliance, minimize risks and costs, respecting the patient's choice from generic drugs, also from the moment of prescribing, the supervision of drug-related events must be taken into account, not only on the patient but also in the environment. Pharmacovigilance and pharmacoecovigilance have to be conceived as a clinical practice in dentistry. There is no established culture of drug induced reaction reports by dentists in Uruguay, and awareness of environmental care is incipient. The pharmacy of faculty of dentistry, (Universidad de la República), an institutional project that has been developed since 2006, is in a transformation process. The pharmacovigilance dentistry Node is in full development. The toxicovigilance and pharmacoecovigilance activities are recent. The general aim of this project was to establish the pharmacovigilance, toxicovigilance and pharmacoecovigilance clinical practice in dentistry. The widespread use of cosmetic as toothpastes, or mouth rinses, drugs and dental materials, as well as exposure to chemical contaminants through the population's living habits and the environmental damage caused by drug wastes requires comprehensive and up-to-date information to establish rational strategies.

Key words: Dentistry, pharmacovigilance, pharmacoecovigilance, dental pharmacy, sustainability.

1. Introduction

The University of the Republic *(*Universidad de la República Oriental del Uruguay*)*, created in 1849, is the only high studies public institution in Uruguay. The faculty of dentistry (facultad de odontología) opened its doors in 1929, with four carriers: dentistry, assistants, hygienists, and dental laboratory.

In the year 2000, pharmacovigilance activities were initiated in Uruguay (Fig. 1) and some peculiarities were identified, as well as the strengths and weaknesses of drug administration to the patients who receive dental care in the clinics of the faculty.

Taking into account the impact of the damage caused by health systems, including those aimed at improving oral health, and at different levels, it is imperative to move forward in the management of drugs and dental materials, as well as in the management and analysis of their risks [1].

The drug related problems not only affect the patient, in fact, all the actors involved could be affected. The patient (the first victim) suffers directly the damage. The prescriber (second victim) suffers from the adverse effect that caused his prescription, the Institution (third victim) suffers the discredit for the damage caused by the adverse effect [2, 3] (Fig. 2).

A fourth victim could also be included in the chain of harm: the environment [4] (Fig. 3). Mismanagement of pharmaceutical waste, excessive prescribing, inadequate disposal, as well as the selection of the most polluting agents (amalgam of mercury instead of Ionomer glass cements, diclofenac and ibuprofen greater environmental pollutant potential than paracetamol or aspirin) could lead to greater environmental damage [5].

2. Pharmacovigilance in Dentistry

Dentistry is a science exposed to constant changes,

Corresponding author: María Renée Romero, DDS., professor, research fields: dentistry, clinical pharmacology, pharmacovigilance and toxicovigilance.

Fig. 1 Pharmacovigilance system in Uruguay.

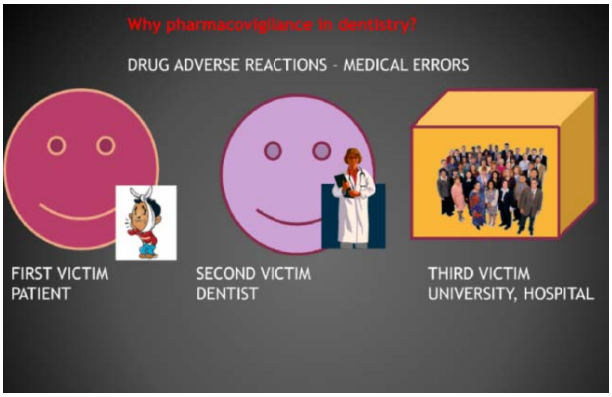


Fig. 2 Caring for the caregiver after adverse clinical effects (Scott, et al., 2016) [2].

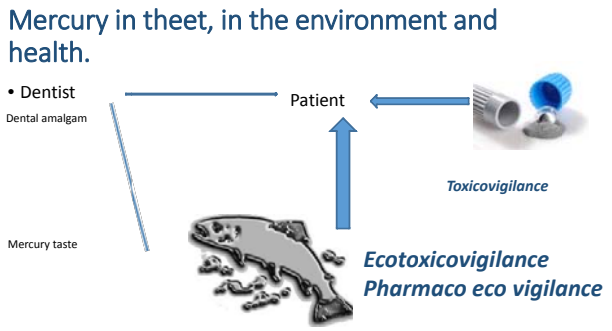


Fig. 3 Romero MR, mercury safety.

which arises from the research and production of therapeutic agents for dental use, medicines, therapeutic devices and cosmetics.

The list of medicines and dental materials is too extensive, so it is essential to provide the guidelines in the undergraduate for the selection of the most effective and safe agents.

3. Aims

The study is aimed to incorporate clinical practice of pharmacovigilance in the faculty clinics

Specifics aim:

(a) To establish pharmacovigilance into the study program.

(b) To contribute patient safety and therefore to the clinical excellence in dentistry (Fig. 4).

It is proposed to develop a culture of health [1], not only the oral health but also establish the culture of patient safety, these two cultures are closely linked to the clinical practice of pharmacovigilance, technovigilance, pharmacoecovigilance and good clinical practice of prescription.

4. Strategies

An important challenge begins from the pharmacology teaching: establish the incorporation of the pharmacovigilance in the study program.

Several strategies have been used to stimulate learning and clinical practice of pharmacovigilance, techovigilance and cosmetovigilance, establishing conditions that allow the student to live experiences to acquire new behaviours or modify existing ones, such as participation in research and extension work to apply this knowledge.

The implementation of pharmacovigilance in the dental practice is based on a situational diagnosis:

- Weaknesses of dental practice,

(1) The prescription is less frequent than the administration of medicines, local anaesthetics, antiseptics, dental materials, are administered often

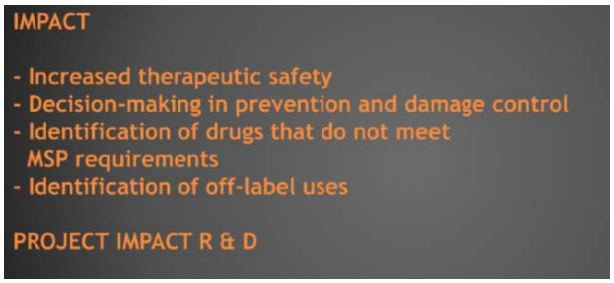


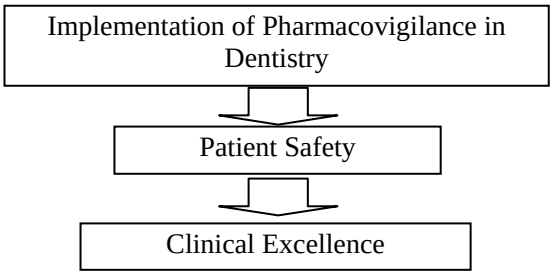
Fig. 4 Research and development project impact.

without telling the patient what is being treated or what their safety is.

(2) The "off label" use of medicines is frequent.

(3) Dental materials and therapeutic devices are not yet classified by the MSP (public health ministry) technovigilance system. The presence of so-called cosmetics but containing true drugs and toxic potential, Aluminium, is current [6, 7].

(5) The drug law in Uruguay talks about medicines and related products [8], so these last two materials and cosmetics are grouped as health technologies, included in the technovigilance [9].



- Strengths in the Faculty of Dentistry:

The development of the Institutional Pharmacy allowed ensuring the use of drugs and dental materials approved and registered by the sanitary authority, avoiding the administration of agents of uncontrolled quality, and diverse origin (Fig. 5).

The pharmaceutical stock and dental materials that manages faculty of dentistry are integrated by products that have been evaluated and selected by the teachers. With the pharmacy development, the dental materials and medicines efficiency and quality can be guaranteed.

There are differences in the concept of dental pharmacy and the communitarian pharmacy:

To contemplate the safety of drugs and dental materials, a pharmacovigilance node and technovigilance in dentistry was established, which integrates the network of nodes afferent of the national system of pharmacovigilance of the MSP, which also is afferent to the Uppsala Monitoring Centre of the WHO (world health organization).

The node operates in the pharmacy, it has a multidisciplinary team, and there they carry out internships, students from the careers of assistants and hygienists and dentistry.

The node combines teaching, research, extension and orientation activities in the attendance of adverse events attributed to drugs, dental materials and dental devices (Fig. 5). Pharmacovigilance activities are promoted from the node: clinical trials involving students, research and development (R&D) projects of good clinical practice, extension projects (understood as social use of knowledge), information with triptychs, posters in the waiting room with pharmaceutical news (Fig. 6).

5. Results

A pharmacovigilance report system has been established through the website (www.odon.edu.uy).

Pharmacovigilance is recognized as one of the research lines of the faculty, within the program of "stimulus to quality research".

In the post-graduate teaching, the thematic network of pharmacovigilance was created in conjunction with the faculties of chemistry and medicine in the interdisciplinary space of the university. Through the courses of updating and permanent education of the graduate school, actions are disseminated in pharmacovigilance throughout the country.

Table 1 Similarities and differences between dental pharmacy and conventional pharmacy.

Similarities and differences	
Dental pharmacy	Conventional pharmacy
Dispense to the dentist	Dispense to the patient
Distributes within the faculty	Is outside the clinic
Quality control	Has rules and regulations
Pharmacovigilance	Has a technical director
Institutional need	Hospital pharmacy-conventional pharmacy

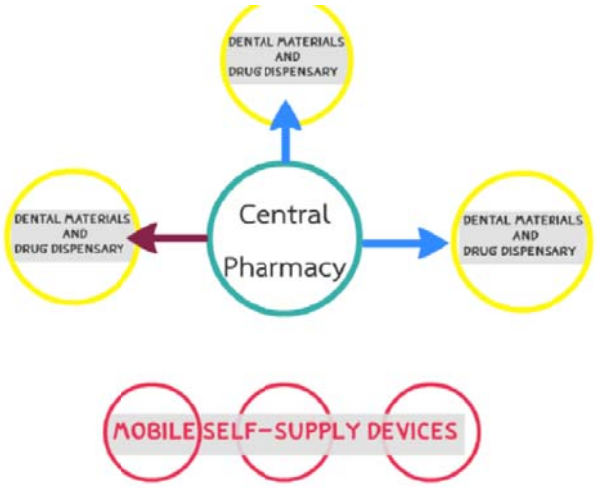


Fig. 5 Distribution of dental materials in the faculty of dentistry. The "mobile self supply devices" are in the clinical. Also the 3 drug dispensary.

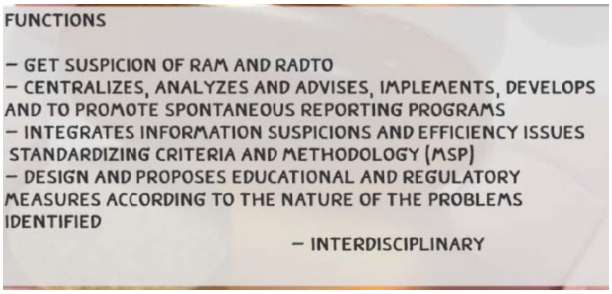


Fig. 6 Pharmacovigilance node functions.

Fig. 7 Differences of the beginning practice between pharmacovigilance and pharmacoecovigilance.

The pharmacovigilance clinical practice in dentistry contributes to the establishment of greater therapeutic safety, helps to prescribe rationally and to make adequate decisions of prevention and control considering the damages of the inadequate prescriptions, the identification of medicines that do not meet the requirements of the MSP.

A program for detecting and replacing drugs and dental materials that are not safe, or for which there is no greater scientific evidence of their efficacy and safety, such as solvents, caries detectors and caustic associations is established.

5.1 Toxicovigilance in Dentistry.

As in medicine, toxicovigilance is considered as an active process of identification and evaluation of toxicity risks that exist in a community and the evaluation, as well as the measures to be taken to reduce or eliminate them [10].

Toxicovigilance may also reveal emerging toxics that result from product reformulation, packaging change or labelling, a new drug of abuse, or environmental contamination.

It is known that the dentist is exposed and also his patients to drugs and potentially toxic substances that pollute the environment. Think of mercury, fluorine, arsenic and recently aluminium.

To optimize the quality of treatments and patient safety, we have developed a program for the identification of toxics and the supervision of drugs and dental materials. A list of effective and safe alternatives was established.

The increasing widespread use of cosmetics, mouthwashes, toothpastes, drugs and dental materials, as well as the recent knowledge of the risk of exposure to previously innocuous chemicals, require information based on scientific evidence, exhaustive and up-to-date of the efficacy and safety of some metals present in very small amounts in the tissues [7].

During their training and the practice of the profession, both the dentist and the dental laboratory are exposed to contamination by different environmental toxics and potentially harmful substances, either by contact through the skin or by inhalation.

5.2 Pharmacoecovigilance in Dentistry.

The emergence of eco-pharmacovigilance, science and activities associated with the detection, evaluation, understanding and prevention of the adverse effects of pharmaceuticals [11], 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 [12], 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 [13, 14]. 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. 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.

Ecofarmacovigilance 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 (in this case a Uruguayan law 15.443 of the MSP "products related to medicines") in the environment.

5.3 Pharmacovigilance and Pharmacoecovigilance

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.

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 (Fig. 7).

6. Conclusions

The pharmacovigilance clinical practice in dentistry contributes to the establishment of greater therapeutic safety, helps to prescribe rationally and to make adequate decisions.

The prescribing and usage of medications 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.

The faculty of dentistry is committed and conscientious to the university community with the correct procedure of elimination of pharmaceuticals, medicines and dental materials, contributing with its contribution to the creation and maintenance of sustainable cities.

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