

# Strategies to Stimulate Actions for Pharmacovigilance Decentralization

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## Abstract

**Introduction:** Reporting in pharmacovigilance is an indicator for monitoring patient safety; the main limitation of this process is under-reporting.

**Objectives:** To formulate strategies to improve the attitudes and ability of health professionals and the general population, to disseminate knowledge, and to stimulate pharmacovigilance reporting of adverse drug events.

**Method:** Several strategies were implemented between 2009 and 2013 along with the creation of the Universidade Federal de Alfenas Pharmacovigilance Center (CEFAL).

**Results:** The following strategies were implemented: creation of a website, folders, and stickers; educational interventions; lectures; development of alerts and monthly bulletins; scientific research; use of social networking, and extension projects. Of the 248 adverse drug events reported, 195 were adverse drug reactions; 51 were technical defects, and 2 were medication errors. Conclusion – The decentralization of pharmacovigilance centers, such as CEFAL, is a strategy to facilitate actions in pharmacovigilance, as each center can formulate its own teaching, research, and extension strategies with the aim of promoting patient safety.

**Keywords:** Pharmacovigilance; Adverse drug reaction reporting systems; Patient safety; Health education

## Introduction

Adverse drug events (ADEs), including adverse drug reactions (ADRs), are a cause of morbidity and mortality in several countries, and represent a significant clinical issue that generates economic burden and increases the risk of patient death by almost two-fold [1-3].

The reporting of medication-related events is an indicator in the monitoring of drug and patient safety. The prevailing method is voluntary reporting the easiest and least costly but under-reporting and poor-quality reporting remain as the major limitations of this process [4-7]. It is estimated that global ADR reporting represents no more than 5-10% of the actual incidence [6].

In view of this global problem, the Brazilian Health Ministry developed initiatives through the National Health Surveillance Agency (ANVISA) to ensure the quality and effectiveness of medications and further patient safety. Thus, the implementation of the National Center for Drug Monitoring (CNMM) in 2001 has encouraged actions in pharmacovigilance (PV), and other strategies have been developed to stimulate reporting, such as the institution of the National Reporting System for Health Surveillance (NOTIVISA), the Sentinel Hospitals project, reporting pharmacies, publication of legislation, among others [8,9].

Despite those initiatives, Brazil accounted for approximately 143 reports per million populations in 2010 while the goal proposed by the World Health Organization (WHO) is 250 reports per million populations according to the Health Ministry of Portugal [10-12].

Although there are government strategies in place to prevent patient harm, a scarcity of decentralized actions was observed in PV, as well as a lack of commitment of health professionals to promoting an increase in reporting rates [11,13]. In light of this, the aim of this study was to develop strategies to encourage changes in the attitudes and abilities of health professionals, undergraduate students, and

the general population by disseminating knowledge about PV and stimulating ADE reporting.

## Method

Following the reading of articles and legislation concerning PV, it was proposed that a Pharmacovigilance Center (CEFAL) could be established at the Universidade Federal de Alfenas (UNIFAL-MG), initially as an extension project from the Dean of Extension Office, and later as an extension program [14].

## Location

The state of Minas Gerais concentrates 10% of the Brazilian population of 190,732,694 [15]. Considering the absence of a PV center in the state, CEFAL was created at the UNIFAL-MG and occupied a room at the Alfenas campus, which is used for weekly meetings to discuss PV reporting, articles, research, strategies, and goals.

## Team

The CEFAL team comprises 10 undergraduate students in different years of study in the Pharmacy program at the UNIFAL-MG School of Pharmaceutical Sciences, who are coordinated by two PhD-level professors. The team devotes an average of eight hours a week to this activity; some undergraduates are responsible for strategies while others participate in voluntary activities in general. All team members

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Received May 24, 2015; Accepted May 29, 2015; Published June 10, 2015

Citation: Abjaude SAR, Silva NRd, Marques LAM, Rascado RR (2015) Strategies to Stimulate Actions for Pharmacovigilance Decentralization 3: 165. doi:10.4172/2329-6887.1000165

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are encouraged to develop research or extension projects in the area of medication use.

## Funding

One of the undergraduates responsible for the CEFAL program has an extension scholarship granted by the UNIFAL-MG Dean of Extension Office. The CEFAL program encompasses a number of related extension projects, such as UNAFAL [16], Medication Disposal Analysis, and EDUCEFAL [17]. In addition, the undergraduate students devote part of their time to scientific research projects in the same area; therefore, some of them also receive scholarships given by other research funding agencies.

## Strategies

Specific strategies were discussed and implemented since the inception of the PV center, between 2009–2013.

## Methods for ADE detection

ADEs are identified by passive (spontaneous reporting of ADEs) or intensive (active case-finding) methods. The former can be performed by health professionals, undergraduates, and the general population through the website, telephone contact, members of the project, or the University Pharmacy. On the other hand, active case-finding is conducted by CEFAL members who monitor ADEs as part of their undergraduate research, through face-to-face interviews or by telephone.

## Preparation of the instrument

The electronic ADR, technical defect (TD), and medication error (ME) reporting forms were prepared based on the NOTIVISA forms system created by the ANVISA in 2008 to facilitate data transfer on reporting to that agency. The form is confidential and contains spaces for patient data, ADE data and medications, applicant identification, and other information.

## Data processing

The data are coded and stored in a computer in chronological order. The severity of the ADE is categorized as “serious” and “non-serious”. Serious events are those involving death, threat to life, hospitalization, or extension of hospitalization. Other events are classified as non-serious [18].

## Publicity

CEFAL is promoted by its website, social networking, folders, stickers, lectures and courses, bulletins and alerts, abstracts and posters at national and international events, publication of scientific articles, extension projects, and by the pharmacists at the University Pharmacy.

## Ethics committee

The CEFAL extension project was developed during 2009-2010 and upgraded to the CEFAL program in the following year to manage the extension projects EDUCEFAL and UNAFAL. The program was submitted to the UNIFAL-MG Research Ethics Committee and approved on May 5, 2011 under protocol No. 075/2011.

## Results

Ever since the institution of CEFAL, specific strategies (Figure 1) were established to suit the most varied types of public with the purpose of stimulating reporting and problem-solving at the local level. Before

developing any activity, the undergraduate program members received training to enable them to work with PV and its strategies.

The website is linked to UNIFAL-MG and allows the academic community to learn what the program is and how it works, access electronic reporting forms, issue alerts and bulletins, have access to links and relevant legislation, and divulge events promoting the rational use of medication. This website is publicized through folders, stickers, and social networking.

At the UNIFAL-MG School of Pharmaceutical Sciences, there is no discipline including the theme pharmacovigilance for knowledge-building. However, to further attitudes and abilities regarding PV, CEFAL promotes educational interventions every six months for the sixth- and seventh-semester students of the Pharmacy program, since those levels offer undergraduate internship at the University Pharmacy and healthcare center. The lectures are open to the general public in order to facilitate the acquisition of knowledge from the basics of PV and questions from participants.

A total of 26 alerts and 19 bulletins were published on the CEFAL website, social networks, and bulletin boards of the university in order to advance knowledge and direct reading to the vast body of information produced in this field.

In addition, to expand and further improve reporting forms, CEFAL provides electronic service to receive reports even after hours.

The members of CEFAL are encouraged to participate in scientific meetings to disseminate results of scientific research and exchange experiences with other researchers. From those collaborative efforts, manuscripts are drafted with the aim of showing the reality of the PV system and disseminating the results on a scientific basis.

In addition, the EDUCEFAL and UNAFAL extension projects provide guidance on the rational use of medications and other topics for children and older adults, who are not reached by public clinical trials on drugs and are thus more likely to experience unexpected ADRs.

Medication Disposal Analysis emerged as an outcome of undergraduate research, which verified that Alfenas lacked initiatives in medication disposal [19]. Therefore, CEFAL in partnership with a private drugstore network began to establish collection points for the medications of the University Pharmacy and at drugstores.

A study conducted by CEFAL concerning medication disposal provided the basis for the passing of a municipal law requiring Alfenas drugstores to receive excess and unused medications and provide for their disposal as required by the legislation on medications.

Voluntary reporting resulted in 87 reports of ADR, TD, and ME. Additionally, active case-finding conducted as part of three undergraduate research projects yielded 161 ADR reports (Table 1).

## Discussion

A study conducted by CEFAL showed that more than 70% of the health professionals and general population had no information on PV [11]. Moreover, the PV legislation passed in 2009 was put into question, with respondents stating that pharmaceutical companies should only give immediate priority to serious ADEs reported by health professionals, whereas non-serious ADEs should only be informed at the time of medication license renewal [11]. Hence the importance of a PV center, as these entities deal with regional problems and create strategies for immediate reporting of serious and non-serious ADEs to

Strategies	Specification
Website	Main strategy for ADE reporting, promotion, and other CEFAL program strategies.
Folder	Folders with guidance on pharmacovigilance and how to report ADE to CEFAL.
Sticker	Stickers with the logo program and website to communicate CEFAL contact information.
Educational intervention	Educational interventions of two hours' length demonstrating the types of ADE, reporting methods, and teaching how to fill in the reporting form.
Lecture	Lectures are one-hour long at the center and other educational institutions to raise awareness among undergraduates and professionals in various fields about the importance of promoting patient safety through spontaneous ADE reporting.
Alerts	Production and dissemination of a short publication to warn medication users, both prescribers and consumers, about the safety or effectiveness issue concerning the medication in question at the time.
Bulletins	Production and dissemination of a short publication related to outbreaks or disease and medication news to inform professionals and undergraduates.
Spontaneous reporting	The CEFAL reporting method can use electronic forms found on the website reporting area, by phone, or in person at the UNIFAL-MG University Pharmacy.
Active case-finding	Intensive monitoring technique of the user for a particular medication or disease for identifying possible ADE. It has been used in research undergraduates.
Feedback	Answer to the reporter with the assessment made by the team about the ADE and thanks for the reporting.
Scientific research	Production of scientific research on the subject of pharmacovigilance and rational use of medication.
Poster	Presentation of research results on a poster at events to disseminate the research line and directly promote CEFAL.
Social Networking	Use of social networking to publicize strategies (such as alerts, bulletins, promotion courses, and lectures) used by CEFAL and to encourage and inform on reporting practice.
Extension Projects	EDUCEFAL - Extension project connected to CEFAL program aimed at the inclusion of a curriculum subject about health education in elementary school in the form of weekly lectures [17]. UNAFAL - Extension project connected to the CEFAL program for the inclusion of senior adults in the digital environment along with health education issues [16]. MEDICATION DISPOSAL ANALYSIS - Extension project connected to the CEFAL program with the collaboration of a private network to ensure proper disposal of medications.

Figure 1: Specific strategies to increase the effectiveness and safety of the drug and patient safety. Alfenas, Brazil. 2009-2013.

Categories severity	of	ADR	TD	ME	TOTAL
Serious	5	0	2	7	
Non-serious	190	51	0	241	
<b>TOTAL</b>	<b>195</b>	<b>51</b>	<b>2</b>	<b>248</b>	

ADR: adverse drug reaction; TD: Technical defect and quality deviation; ME: Medication Error.

Note: The severity of the ADE is categorized as "serious" and "non-serious". Serious events are those involving death, threat to life, hospitalization, or extension of hospitalization. Other events are classified as non-serious [18].

Table 1: Frequencies of adverse drug events detected by passive and intensive methods at CEFAL, reported and classified according to the categories of severity. Alfenas, Brazil. 2009-2013.

raise reporting rates and allow timely detection of a sign [11,20].

The foundation of CEFAL in 2009 permitted the development of specific strategies to further teaching, research, and extension in order to stimulate improvements in the ability, attitudes, and knowledge of undergraduate students, health professionals, and the general public regarding PV. This initiative was primarily based on the WHO recommendations, which indicated that any health service could be an appropriate starting point to implement a PV center at a university, for instance, which could offer the benefit of administrative support and the healthcare infrastructure [21,22]. Baldoni and Pereira [13] cite CEFAL as one of the few PV reporting centers in Brazil.

The institution of PV started with the implementation of spontaneous reporting, as it is the primary strategy to maintain patient safety [23]. However, we realize the importance of having another method of stimulating reporting, since additional methods are important for monitoring qualitative data to identify specific factors and groups at increased risk, and to characterize ADR associated with medications and specific populations [4]. Thus, the methodology includes intensified reporting through scientific research.

As soon as some of the spontaneous reports of ADE were related to contraceptives, the group developed an undergraduate research study. It was found that nearly half of the female undergraduates used oral contraceptives (149/302). Half of these had insufficient knowledge about the correct use of oral contraceptives; therefore, they were more likely to suffer an adverse event [24].

The subsequent step was to seek registration through the CNMM to expedite the reporting flow and to be recognized as a center to further actions in PV. This goal was achieved in 2010 and CEFAL was made public on the official government website [25].

The CEFAL program began with the creation of its website, which contains the electronic reporting system, chosen after a review of some authors who recommend computer technology in the reporting methodology because it is easier, faster, and effective in reducing the risks and harm to patients as it contributes to increasing report rates [9,26, 27]. This is the primary means for reporting in the program, as it is more convenient to health professionals and to users, who do not need to leave their desks to report and receive a feedback.

After each reporting, program members analyze the case and send feedback to the reporter and thank him/her for the report, as this is an effective way to raise their awareness to continue ADE reporting [20].

Garcia et al. [7] hypothesized that the lack of knowledge of PV and the absence of an active PV system is a major cause of under-reporting among physicians and pharmacists. Therefore, folders and stickers were designed to promote CEFAL.

Interest in ADE reporting is generally higher in the first year of promoting the product and decreases over time [28]. However, Figueiras et al. [29] state that educational interventions with health professionals statistically increase reporting rates for 12 months. Thus, continuing education is necessary to sustain the awareness of professionals to continue notifying events. Furthermore, after the

detection of a sign, the PV systems generate quick and dynamic alerts, once more drawing attention of health care professionals, including physicians, to increasing the frequency of ADE reports associated with the medication referenced in the alert [5,28]. Bulletins are important to facilitate and provide guidance regarding the required reading for health professionals considering the substantial amount of information in the literature [30]. Thus, CEFAL publishes alerts and bulletins to raise awareness among health professionals and undergraduates to increase the reporting rates and provide continuing education on safety, quality, and effectiveness of medications.

Senior adults are the greatest users of medications, resulting in more cases of ADR-related hospitalization [31]. Considering patient safety, the UNAFAL extension project aimed at educating senior adult students on the rational use of medications and encouraging the use of computer tools for access to good health practices [16].

Children are the most accidentally intoxicated by medications [32]. Therefore, CEFAL members created EDUCEFAL extension project to stimulate change in harmful habits attitudes towards health in the school community to promote patient safety. This project includes weekly lectures in health education for elementary school [17].

After a review of undergraduate research conducted by CEFAL, it was found that only one drugstore in the city of Alfenas, Brazil had a program to dispose of medications and that most undergraduates and the population in general discarded medications in the household trash [19]. Faced with this problem, the CEFAL team implemented an extension project, "Medication Disposal Analysis" that encourages the disposal and rational use of medication by undergraduates and population at the University Pharmacy on campus.

Considering that PV is focused on patient safety and that social networks are now present in the daily life of the population, the new strategy is to use social networking to disseminate information content such as alerts, bulletins, and newsletters to educate the population on the rational use of medication to stimulate and facilitate the ADE reporting by patients. Social networking is an effective, low-cost measure to raise the rates of spontaneous reporting of ADEs [33,34].

According to Gavaza et al. [35] pharmacists' attitudes should be improved to contribute to drug safety and patient care. This should be accomplished with educational interventions. According to Ribeiro-Vaz et al. [10] this type of intervention with pharmacists tripled reporting rates significantly for four months. Thus, the educational intervention CEFAL performs twice annually to raise the awareness of undergraduate pharmacy students to increase reporting rates. There is a relationship between the increase in number of reports and the commitment to patient care according to the intensity of the educational intervention [1,9,36]. With an increase in reporting rates, it is possible to group the ADEs and quickly detect a sign and trigger an alert to prevent harm to a larger number of patients and thereby protect their safety [37].

Some studies have shown that health professionals have little knowledge of PV and do not know how to report ADEs [7,11,23,38]. The same problem is noted in the general population [11]. Considering this fact, CEFAL promotes lectures to educate both health professionals and the population with a view to fostering patient safety and medication surveillance.

The limitation of the present study was that it did not correlate the strategies with the reporting rates when several strategies were combined. The study only permitted this observation with active case-finding, for which we knew the reporting rates. Nevertheless, more

important than increasing reporting rates is to learn about PV and to improve the attitudes and abilities of health care professionals to be conveyed to undergraduates and the general population [9].

Finally, to change the culture of health professionals, it is necessary to combine strategies [39,40]. By raising awareness among undergraduate students and the general population in addition to health professionals, CEFAL demonstrates that the combination of teaching, research, and extension is a very important strategy to ensure the effectiveness, quality, and safety of the product and to promote patient care. Moreover, it is crucial that universities include the discipline of PV in the curriculum of undergraduate and graduate programs in health sciences so students become aware of the importance of a patient safety culture [20,23].

## Conclusion

Decentralization of pharmacovigilance is needed to facilitate actions. Combined strategies improve the abilities, attitudes, and knowledge of the health care professionals, undergraduates, and the general public. The results obtained by CEFAL confirm that universities can play an important role in the creation of those centers, serving as a model for other educational institutions worldwide, which could thus develop their own teaching, research, and extension strategies to promote patient safety and medication surveillance.

**Support:** Undergraduate scholarship granted by the Dean of Extension Office at the *Universidade Federal de Alfenas* - UNIFAL-MG/Brazil.

## Acknowledgments

We thank all the team at the UNIFAL-MG Pharmacovigilance Center – CEFAL for their cooperation. We are also grateful for the support of the Dean of Extension at the *Universidade Federal de Alfenas*, MG, Brazil.

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