

Carta al Editor

Educational interventions to increase pharmacovigilance in a family health unit

Intervenciones educativas para incrementar la farmacovigilancia en una unidad de salud de familia

Rita Ribeiro Barbosa

Unidade de Saúde Familiar 7 fontes, Portugal

drbrito@arsnorte.min-saude.pt

Ana Filipa Fontes

Unidade de Saúde Familiar 7 fontes, Portugal

Joana Nuno

University of Minho, Portugal

Unidade de Saúde Familiar 7 fontes, Portugal

Susana Fernandes

Unidade de Saúde Familiar 7 fontes, Portugal

Dinis Brito

Life and Health Sciences Research Institute (ICVS), Portugal

Unidade de Saúde Familiar 7 fontes, Portugal

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Mr Editor:

Adverse drug reactions (ADRs) are a relevant public health problem and a significant cause of mortality and hospitalization in developed countries, representing about 6.5 % of total hospitalizations [1]. It is estimated that most adverse reactions are detected only in the post-marketing stage, denoting the relevance of a constant drug surveillance system through pharmacovigilance activities after drugs are placed on the market. The Portuguese Pharmacovigilance System is essentially based on the unsolicited notification of suspected ADRs by health professionals to the National Authority, generating warning signs. Despite the legal imperative [2], the primary limitation to the effectiveness of this notification system is underreporting, with several studies indicating that less than 10 % of ADRs are notified to regulatory authorities [3] (Figure 1). Thus, according to data from Infarmed [4], the number of

ADR notifications received by the National Pharmacovigilance System has been increasing considerably.

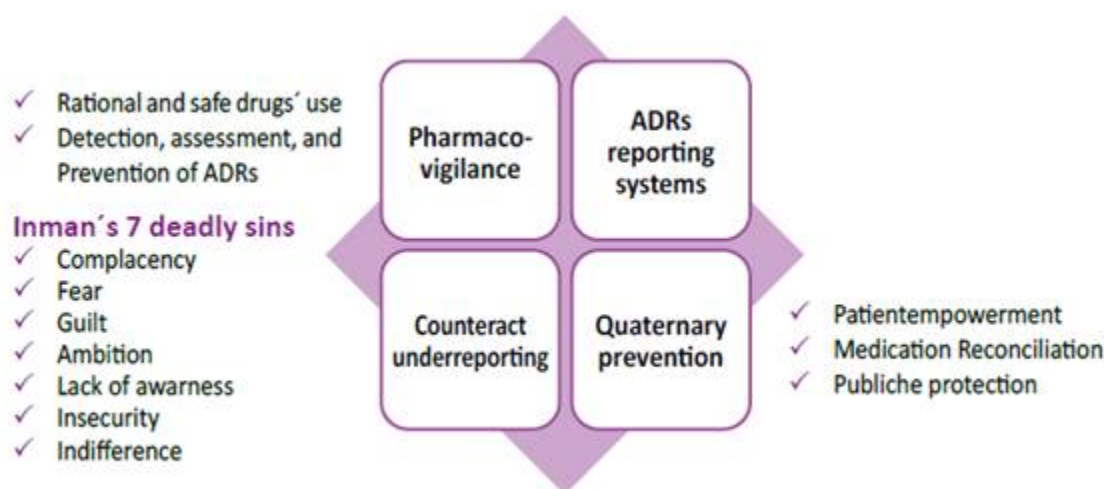


Figure 1:

Pharmacovigilance has emerged as an essential tool for quaternary prevention and has become a fundamental activity for the rational and safe use of drugs and Public Health protection. Underreporting ADRs is a very well-known phenomenon. The negative factors influencing ADR reporting are based on the “seven deadly sins”, as proposed by Inman 7.

Suspected and undescribed ADRs are the most relevant data for pharmacovigilance systems [4]. However, it is still relevant to monitor already known and documented ADRs for aspects such as possible changes in frequency, time to onset, duration, extension, and association with a specific, pharmacotherapeutic, or pathophysiological profile of the patient.

This work mainly aimed to develop pharmacovigilance strategies in the Family Heath Unit (FHU) related to the detection of adverse drug reactions. It also intended to increase basic pharmacovigilance [5], knowledge and competencies of different professionals and disseminate the online “Portal RAM” tool created by the National Authority for Medicines and Health Products I.P. in 2012 and redesigned in 2017, as the preferred tool for reporting ADRs. We assumed the goal of triplicating the number of unsolicited ADR reports for 2018 (n=4) by direct notification. The development of these competencies was promoted through a training session in April 2019, focused on the following objectives in Infarmed’s 2018 Case Report [2-4], specifically targeting data related to health professionals’ direct life notifications and related to Guimarães Pharmacovigilance Unit and the number of notifications made by the FHU in 2018. Online tool Portal RAM was presented with an interactive explanation of its operation. Brief interventions of varying length were also carried out throughout the year to clarify concerns and consolidate strategies. Twenty-three notifications were obtained,

representing an increase of more than 500 % (Table 1). The month with the highest number of reports was expectedly May, the closest to the training action. Although a dilution effect was observed over time, all months recorded notifications. Noteworthy is that nurses did not contribute to this result as doctors made all notifications.

ADRs are an increasingly important public health problem. However, underreporting is very common [6]. This study aimed to explore the effect of the sensitization program with doctors and nurses regarding the notification of ADRs. As reiterated by others, the intervention developed was effective with doctors, but not with nurses [7], which may be because the interventions were performed by doctors and, therefore, with less sensitivity to the nursing's clinical practice. It should be noted that they are also central players in pharmacovigilance activities, mainly in the identification of ADRs that remain out of the reach of other health professionals and because they are fundamental for the preservation of the health of users, in particular the most vulnerable, such as children and older adults [8].

Table 1.

Month	Direct notifications		
	Doctor	Nurse	Total
May	6	0	6
June	3	0	3
July	5	0	5
August	5	0	5
September	2	0	2
October	2	0	2

This experience encourages the need to maintain continuous intervention programs, with the involvement of nurses and other agents such as pharmacists to improve the ADR reporting rate [9]. The development of these strategies in primary health care and the consequently improved knowledge of the different drugs' safety profile ultimately ensures more robust protection of Public Health since its target population is not limited to users of functional units [10].

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Notas de autor

drbrito@arsnorte.min-saude.pt



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actamedicaperuana@cmp.org.pe

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