



Impact of the Healthcare Professionals and Patients/Citizens Information on the Spontaneous Report of Suspected Adverse Reactions

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INTRODUCTION

The Spontaneous reporting is one of the main methods used in Pharmacovigilance to establish, in the post-marketing authorization period of a medicinal product, the safety profile of this health product, in a more complete and accurate way. (1)

The Spontaneous reporting system, despite having been established for more than five decades and enable the monitoring of all medicines marketed, throughout their entire life cycle, in large populations and with reduced costs, still has, currently, an extent that is less than desirable. (1)

One of the strategies to increase the reporting of adverse reactions is the educational approach, through the implementation of training and dissemination actions, addressed to healthcare professionals and patients/citizens. (2)

The Setúbal and Santarém Pharmacovigilance Centre (UFS) was established in January 2017 and composes, along with seven more Pharmacovigilance Regional centers, and by the Risk Management Directorate of the Drug (DGRM) coordination, the National Pharmacovigilance System in Portugal. (3)

In the last 10 years, the region under the responsibility of the new Pharmacovigilance Centre (UFS) presented an average reporting rate of 71 reports/million inhabitants/year, a value far from the national goal established by the National Competent Authority (INFARMED), of 250 reports/million inhabitants/year, which motivated a great proactivity by this organization, in order to reverse this scenario, through several measures, which included training and dissemination actions.

AIMS

The aim of the present study was to evaluate the impact of training activities for healthcare professionals and patients/citizens, conducted during the year 2017, by the UFS team in their region.

METHODS

We performed an analysis of the cases reported during the year 2017, coming from the institutions targeted by UFS training actions during the same year, comparing the periods before and after each action, and assessing the weight of this contribution regarding the total number of cases reported in the same period.

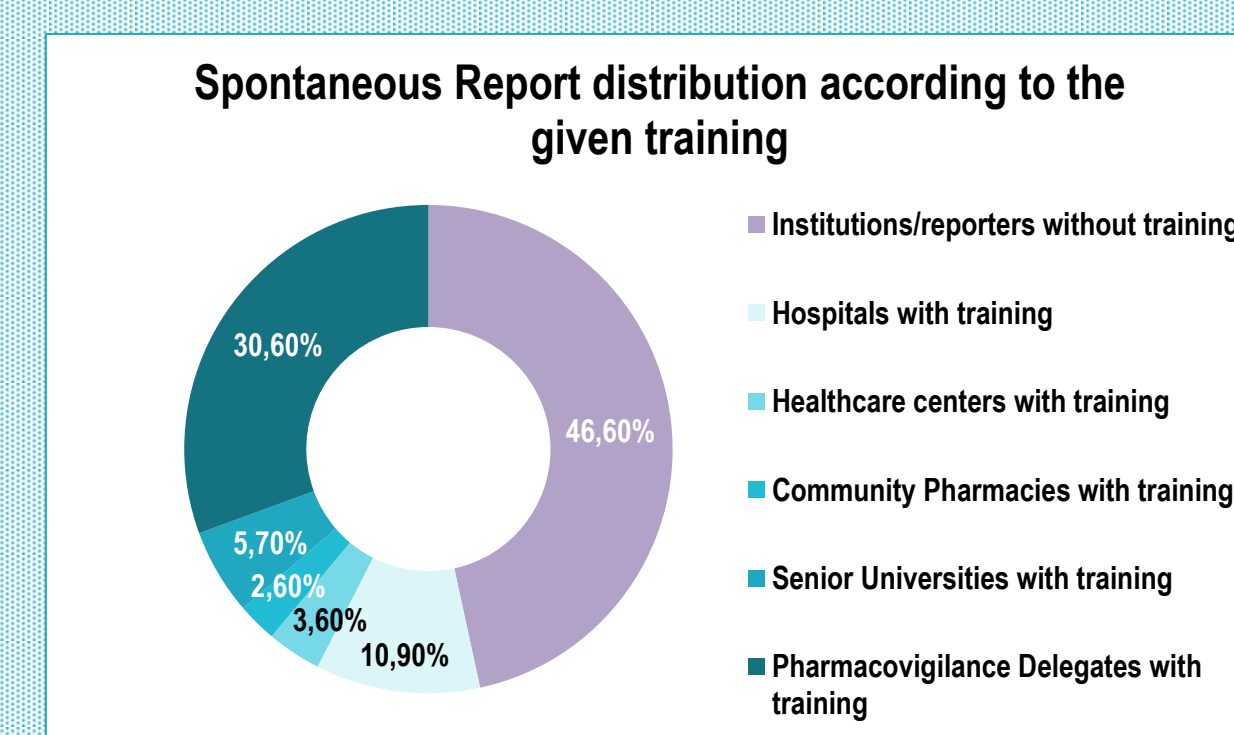
RESULTS

The 43 training/dissemination actions developed in 2017 reached 928 individuals of which, 126 were physicians, 91 nurses, 69 pharmacists and 642 were pharmacy technicians, other healthcare professionals, students or citizens. These actions were responsible for 53.4% of all reports submitted to the UFS during 2017, and contributed to the observed increase in the ratio number of reports/million inhabitants /year, from 71 to 148, in the Setúbal and Santarém region.

Training/dissemination actions 2017	
Participants Category	Number of participants involved
Physicians	126
Pharmacists	69
Nurses	91
Others	642
pharmacy technicians, other healthcare professionals, students or citizens	
Total	928

Training/dissemination actions 2017	
Institution	Actions number
Hospitals	10
Healthcare centers	6
Community Pharmacies	15
Senior Universities	5
Pharmacovigilance Delegates	2
Courses	
Health Schools	5
Total	43

Spontaneous Report distribution according to the given training	
N = 193	
Institution	Reports number post training
Hospitals	21 (10,9%)
Healthcare centers	7 (3,6%)
Community Pharmacies	5 (2,6%)
Senior Universities	11 (5,7%)
Pharmacovigilance Delegates	59 (30,6%)
Total	103 (53,4%)



DISCUSSION

Consistent with the findings of this study, educational approach had previously been recognized by other authors as an important strategy in the growth of Pharmacovigilance systems, namely, Ribeiro-Vaz et al 2016, who reported that in addition to the protocols established with Immunoallergology departments of some hospitals, the training was the only measure with significant results in the increase of the reporting rate in the Northern region of Portugal. (2)

The systematic review by Pagotto et al 2013 also indicates that the training activities were responsible for an increase in the number of reports and for the improvement of the quality of their information. (4).

CONCLUSIONS

The training sessions represent an excellent strategy for spontaneous reporting dissemination and promotion, among healthcare professionals and patients/citizens, but should not be the Pharmacovigilance System only approach to increase the spontaneous reporting rate.

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