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Research Article

Awareness Survey on Pharmacovigilance: Design of an Online Program for Argentinean Health Care Professionals

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Abstract

Introduction: Argentinean National Regulatory Health Authority became official member of the WHO Program for International Drug Monitoring in 1994. However, the number of Adverse Drugs Reactions (ADRs) reported is still very low. Programs in Healthcare Professionals (HCP) in other countries showed that after surveys the knowledge and awareness about pharmacovigilance reporting improved, and the number of reports increase (1 to 4).

Aim: The aim of this study is to investigate the level of knowledge about pharmacovigilance and the activity of reporting an adverse event among local HCP, including dentists. At the same time, the survey will be used as an awareness tool. We hereby report on the study design.

Methods: A cross-sectional survey is being planned, using a validated self-administered questionnaire. The questionnaires will be distributed to ~18,000 HCP from an own database, including general practitioners, pharmacists and dentists. The survey consists of questions related to adverse drug reactions and the reporting behavior of health care professionals in ordinary practice. Questions were chosen based on daily practice situations and relaxed responses. The survey form will be distributed by on-line responsive tool. The collected data will be then analyzed descriptively and results will be presented as mean and ranges, and % of total answers. The survey will have two sections, first one collecting the number of respondents, and the second one clustering the answered questions.

Results: A form with a set of 15 questions and their correspondent multiple choice options for answering was designed. Basically, question focus on daily practice load, reporting situations, reporting behaviors, and to whom the ADRs are usually reported were chosen for this survey. The on-line form allows easy answering, estimated in 3 to 5 minutes. After reporting opinions, the participants will receive a feedback about their reporting role in practice. These materials will be exposed to allow discussions. Early example of results will be included upon availability.

Conclusions: The selected set of questions to be employed in a survey provides a simple way of increasing the awareness of health professional on their reporting role of ADRs. Besides, once analyzed it will allow to measure the awareness status of a given population, in this case health professionals living in Argentina.

Introduction

Argentinean National Regulatory Health Authority became official member of the WHO Program for International Drug Monitoring in 1994. However, the number of Adverse Drugs Reactions (ADRs) reported is still very low. Programs in Healthcare Professionals (HCP) in other countries showed that after surveys the knowledge and awareness about pharmacovigilance reporting improved, and the number of reports increase.

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An adverse drug reaction is the response to medicinal product administered to a patient which is suffering a specific illness. ADR rank as fourth to sixth most common cause of death, and result in 12% of hospital admissions in develop countries. More than 100,000 people died every day as a consequence of ADRs and more than 2 million experience serious after-effects [1].

The detection of serious and unknown ADRs provides new information about the safety profile of marketed drugs [2].

Surveys of HCP in countries similar to Bhutan have indicated that adequate knowledge of both ADRs and ADR reporting is likely to increase the number of ADR reports submitted [3-7].

Safety surveillance in the premarket clinical trial process is designed to identify common Adverse Reaction (ADRs) occurring in study populations. Typical clinical development programs include sample sizes between a few hundred to several thousand study patients in total; allowing for identification of AEs occurring between approximately 3% (i.e., 3/100) down to 0.3% (i.e., 3/1,000) by the Rule of Three [8].

Argentina, with a population estimated in 40,117,096 (INDEC -

National Institute of Statistics and Census, October 27th, 2010) [9] is located in mostly in the southern half of South America. Sharing the bulk of the Southern Cone with its neighbor Chile to the west, the country is also bordered by Bolivia and Paraguay to the north, Brazil to the northeast, Uruguay and the South Atlantic Ocean to the east, and the Drake Passage to the south.

The regulation of medicinal products was implemented in 1964 with the "Medicinal law #16,463" [10], the Regimen of Good Clinical Practice for Clinical Pharmacology Studies was approved in 05/11/2010 [11] and finally the Good Pharmacovigilance Practices that appear in the Annex I of the present Provision, which will be of obligatory compliance for the holders of authorization of registration and commercialization of medicinal specialties Approved in 01/23/13 [12].

The National Agency for Drugs, Food and Medical Technology (ANMAT) is a decentralized organism of the National Public Administration created in August of 1992, by decree 1,490/92. Collaborate in the protection of human health, ensuring that medicines, food and medical devices available to citizens are effective (meeting their therapeutic, nutritional or diagnostic objectives), safety (high benefit / risk ratio) and quality (responsive to the needs and expectations of the population). To this end, it is responsible for carrying out the processes of authorization, registration, regulation, surveillance and control of the products of its competence throughout the national territory. The ANMAT depends technically and scientifically on the rules and directives given to it by the Secretariat for Policies, Regulations and Institutes of the Ministry of Health, with a regime of economic and financial self-sufficiency. In 2011, it was distinguished as the "Regional Reference Drug Regulatory Authority" by the Pan American Health Organization (PAHO) [13].

ANMAT collects and assess information from ADRs and communicates this information to the WHO Collaborating Centre for International Drug Monitoring at the Uppsala Monitoring Centre (WHO-UMC).

Argentina became a member of the WHO Program for International Drug Monitoring in 1994. In 2016, the national pharmacovigilance system received a total number of 10,597 validated initial reports though the electronic tool [14]. The present number of reports in Argentina is low, in this regards the effectiveness and success of a pharmacovigilance system in a country depends of the participation of practitioners and population. It´s necessary increase the good knowledge of ADR detecting and reporting in the health care professionals and population in order to improve the local safety information.

Methods

Study design

A structure online questionnaire consisting in 15 questions was administered to physicians, dentists and community pharmacists. The core task was a survey on a questionnaire regarding the basic concepts of pharmacovigilance. In the survey, the respondents had to choose between at least four options to determine the answer of the question. The survey was essentially the same for physicians, dentist and pharmacists.

The complete questionnaire comprised geolocation, number of patients treated per month, the proportion of patients receiving a prescription per month, the time used for pharmacovigilance purposes, the fact of mentioning a possible adverse event may affect adherence to treatment, the historical background of pharmacovigilance, proportion of patients to whom the adverse event is mentioned, etc.

The survey form was distributed by online validated responsive tool (Survey Monkey®). The collected data was analyzed descriptively and the results were presented as percentage of total answers. The survey had two sections, first one collected the number of respondents, and the second one clustered the answered questions. The statistical analysis included chi-square and z-tests.

Participants

Physicians, dentist and pharmacists were recruited from a pharmaceutical company data base which includes around 18.000 health care professionals. The usual response rate in this network "click through rate" (CTR) is 4% receiving in our survey more than 12%. Email invitation included the URL of the online questionnaire and a reminder was sent after 2weeks.

Questionnaire task

On line's survey with discrete-choice experiments are increasingly used in healthcare to quantify respondent´s preferences.

The survey had two sections, first one collected the number of respondents, and the second one clustered the answered questions. The statistical analysis included chi square and z tests.

Sample size

The aim of this study was to generate awareness on pharmacovigilance using a survey shared with different health care professionals with the idea to receive the perception and knowledge about this discipline.

From 18,000 professionals, a total of 713 medical doctors, 468 dentists, and 114 pharmacists, responded the survey. See Figure 1 for flowchart respondents. The online questionnaire was completed by 1,295 represented by: 713 medical doctors, 468 dentists, and 114 pharmacists.

Data collection tools and method

A structured, validated and reliability questionnaire was used as a data collection tool. This survey was send by email including a previous invitation to participate providing information about the aim of the survey and the rights of participants to withdraw. A reminder was sent to the participants 15 days later. The questionnaire consisted of two sections- A and B. Section A designed to obtain experience of usual clinical practice, while section B consisted of 10 multiple-choice questions investigating participants awareness of pharmacovigilance topics, level of knowledge of ADRs and ADR´s reporting. Questions 1 to 5 aimed to determine information related usual clinical practice, questions 6 to 9 aimed to determine the level of knowledge of ADR, and questions 10 to 15 aimed to determine the level of knowledge of ADR´s reporting. The questionnaire was send by email (Table 1).

Questionnaire development

The questionnaire was tested for content validity by consensus of a panel of experts related to different areas of medicine including cardiology, immunology, pediatric and psychiatry. Objectivity testing was done by distributing the questionnaire to colleagues. The comments and suggestions received were incorporated into the final version (Figure 2).

Statistical analysis

Table 1: Knowledge of ADRs among healthcare professionals.

Questions	Physician	Dentist	Pharmacist	p-value
How many patients do you attend at your consultation per month?				
0-50	46.0%	52.8%	1.2%	
51-100	47.6%	51.0%	1.4%	
101-200	58.9%	38.5%	2.5%	<0.05
+ of 200	62.1%	15.6%	22.3%	
Do not know, no answer	41.2%	29.4%	29.4%	
To what proportion of patients do you prescribe / dispense at least one drug?				
To nobody	33.3%	22.2%	44.4%	
Less than half	22.0%	73.1%	4.9%	
More than half	76.2%	16.1%	7.6%	<0.05
To all	78.7%	2.3%	19.0%	
Do not know, no answer	27.3%	45.5%	27.3%	
Do you consider that during your consultation or patient care you have sufficient time to tell you about the precautions, warnings and adverse reactions of the medicines you prescribe or dispensed?				
Yes	55.0%	37.7%	7.2%	
No	55.7%	31.1%	13.2%	<0.05
Do not know, no answer	48.3%	41.4%	10.3%	
Do you consider that mentioning an adverse event to the patient can affect your adherence to the treatment?				
Yes	59.0%	30.2%	10.9%	
No	52.6%	41.6%	5.8%	<0.05
Do not know, no answer	24.0%	66.0%	10.0%	
To what proportion of patients do you consider that you mention the precautions, warnings and adverse reactions described in the package leaflet during your care?				
To nobody	27.0%	68.3%	4.8%	
Less than half	44.3%	39.1%	16.6%	
More than half	66.9%	26.0%	7.1%	<0.05
To all	61.3%	36.0%	2.7%	
Do not know, no answer	23.8%	66.7%	9.5%	
What proportion of patients do you estimate to report adverse events?				
Any	12.7%	69.8%	17.5%	
Very few	52.4%	38.5%	9.1%	
Many	85.3%	11.7%	3.0%	<0.05
Everybody	61.5%	38.5%	0.0%	
Do not know, no answer	32.4%	47.1%	20.6%	
At what time do you think you should report a serious adverse event (death, life threatening, congenital abnormality, requiring or prolonging hospitalization, major medical event) to whom it may concern?				
In 24 hours	54.1%	37.0%	8.9%	
In 7 days	94	19	12	<0.05
In 15 days	40.0%	40.0%	20.0%	
Do not know, no answer	45.1%	47.9%	6.9%	
Do you know where to report an adverse event, if one is present?				
Yes	56.5%	31.3%	12.1%	
Do not	53.0%	41.8%	5.2%	<0.05
Do not know, no answer	58.4%	33.8%	7.8%	
Do you consider a severe adverse event to be serious?				
Do not	58.3%	33.3%	8.3%	
Yes	53.1%	37.9%	9.0%	<0.05
Not necessarily	64.5%	27.5%	8.1%	
Do not know, no answer	60.0%	40.0%	0.0%	
Do you report adverse events to a colleague responsible for the area or service in your workplace?				
Never	49.4%	42.9%	7.8%	
Only in severe or atypical cases	58.0%	33.0%	9.0%	
Only when you have restlessness or doubt about an event	51.1%	39.2%	9.7%	<0.05
Always	59.1%	33.2%	7.8%	
Do not know, no answer	36.0%	53.3%	10.7%	
Do you report adverse events to the regulatory authority?				
Never	48.6%	44.3%	7.0%	
Only in severe or atypical cases	61.3%	28.3%	10.4%	<0.05
Always	57.3%	29.1%	13.7%	
Do not know, no answer	49.4%	45.9%	4.7%	
Do you consider that adverse events described in the prospectus are reportable?				
Do not	60.4%	28.6%	11.0%	
Yes	51.6%	40.2%	8.2%	<0.05
Other (please specify)	55.7%	37.2%	7.1%	
Does it communicate adverse events to the laboratory responsible for manufacturing?				
Never	48.7%	44.0%	7.2%	
Only in severe or atypical cases	64.0%	26.1%	9.8%	<0.05
Always	61.9%	26.5%	11.5%	
Do not know, no answer	35.3%	55.9%	8.8%	
Do you communicate when efficacy is not the expected?				
Never	49.5%	42.2%	8.4%	
Only in legal or atypical cases	60.2%	29.8%	10.0%	<0.05
Always	62.0%	30.7%	7.3%	
Do not know, no answer	44.4%	47.2%	8.3%	
Do you report when a pregnant woman is exposed to some medicines?				
Never	51.2%	39.4%	9.4%	
Only in judicial or atypical cases	58.8%	33.1%	8.1%	<0.05
Always	65.5%	29.4%	5.0%	
Do not know, no answer	57.9%	32.1%	10.1%	

The statistical analysis included chi square and z tests. The questionnaire included 15 multiple-choice questions assessing the level of ADRs and ADRS reporting. For each answer, there was between 3 to 5 options.

Results

Respondents

Respondent an invitation was sent to 18,000 health care professionals including physicians, dentists and pharmacists during May 2017. The questionnaire was completed by 1,295 health care professionals.

Overall, the respondents consisted of 53, 74% HCPs; 49, 75% dentists and 70, 37% were pharmacists. Did not mention sex neither age. Among these respondents 713 were medical doctors, 468 were dentists, and 114 were pharmacists. Characteristic of the respondents are shown in Figure 3.

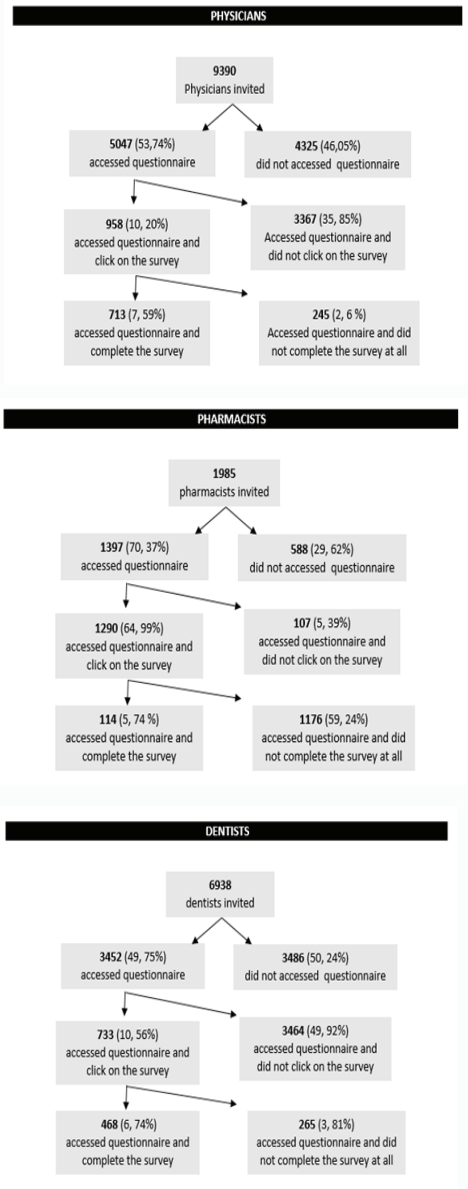

Figure 1: Flowchart respondents.

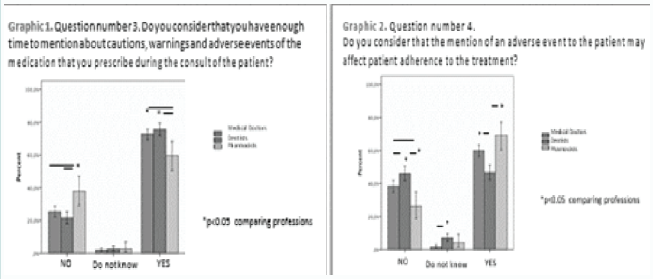

Figure 2: Questionnaire development.

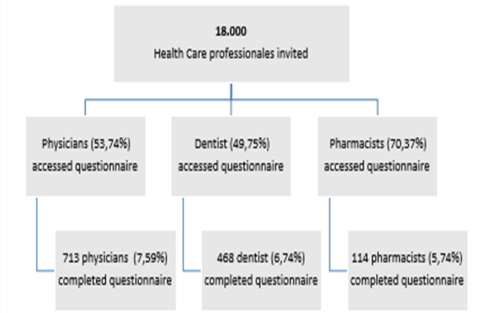

Figure 3: Characteristic of respondents.

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