

An educational intervention on attitudes in pharmacovigilance and adverse drug reactions reports among health-care professionals: a prospective assessment

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Abstract

There are few studies on pharmacovigilance (pv) and adverse drug reactions (adr) in Mexico. The aim was to assess the effect of a pharmacovigilance training program on attitudes among healthcare professionals in a public hospital in Mexico State. This study was conducted in 100 physicians and nurses. A questionnaire was designed to assess attitudes in pv; its reliability was determined with Cronbach's alpha coefficient and criterion validity with Delphi method and applied it. Based on the needs detected, a training program was designed, applied to healthcare professionals and yet again the questionnaire was applied. In addition, adverse drug reaction reports were reviewed and compared using Wilcoxon signed-rank test. A factor analysis was performed to identify the questionnaire's main components. After the intervention, there were statistically significant differences; the number of monthly reports of suspected adr significantly increased, also improving the quality of the information collected. This study showed how an educational intervention helps increase positive abilities and attitudes about pv and adr reports among healthcare professionals.

KEY WORDS

Attitudes in pharmacovigilance, educational intervention, adverse drug reactions

Intervención educativa sobre actitudes en farmacovigilancia y reporte de reacciones adversas a medicamentos en profesionales de la salud: una evaluación prospectiva

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Resumen

Existen pocos estudios sobre farmacovigilancia (fv) y reacciones adversas a medicamentos (ram) en México. El objetivo fue evaluar el efecto de un programa de formación en fv sobre las actitudes de profesionales sanitarios de un hospital público del Estado de México. Se realizó este estudio en 100 médicos y enfermeras. Se diseñó un cuestionario de actitudes en fv; se determinó su fiabilidad con el coeficiente alfa de Cronbach y validez de criterio por método Delphi y se administró. Posteriormente, con las necesidades detectadas, se diseñó un programa de formación, se aplicó a los participantes y de nuevo se administró el cuestionario. Asimismo, se revisaron los informes de sospecha de ram y se compararon las puntuaciones mediante la prueba de rangos signados de Wilcoxon. También se realizó un análisis factorial para identificar los principales componentes de los cuestionarios. Después de la intervención, hay diferencias estadísticamente significativas y el número y calidad de informes mensuales de sospecha de ram aumentó significativamente. Finalmente, este estudio demostró cómo una intervención educativa ayudó a incrementar las actitudes positivas en fv y en el reporte de ram entre profesionales de la salud.

PALABRAS CLAVE

Actitudes en farmacovigilancia, intervención educativa, reacciones adversas a medicamentos

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Introducción

Among the objectives of pharmacotherapy, can be mentioned to prevent, palliate, control, or cure a wide range of diseases. However, because of unfortunate experiences such as the famous case of thalidomide occurred several decades ago, the need to strengthen the safety measures of medicines became a clear objective too and so Pharmacovigilance (PV) emerged as a practice aimed at safeguarding patients in the use of medicines through the detection, quantification, and evaluation of adverse drug reactions (ADR),¹ which is “any unintended harmful reaction that occurs at doses normally used in humans for prophylaxis, diagnosis, treatment or modification of a physiological function”.²

Although the formal inclusion of PV in Mexico occurred only in the last two decades with the implementation of the *Permanent Program of Pharmacovigilance* (PPFV) in 1995 and the adhesion of Mexico to the UMC in 1999, the task has been challenging. Each health institution has interpreted and adapted these general schemes to its environment.³

Most of the research of PV come mainly from Anglo-Saxon, Asian and European populations. In this regard, there are review papers that show a deficiency of knowledge in PV in some regions of the world, as well as a low dissemination of PV programs and lack of interest by those involved in the ADR detection and notification processes.⁴ In Mexico, research on PV is very scarce so work on this topic should be encouraged. The aim of this study was to evaluate the potential effect of a training program in PV on the attitudes exhibited by health professionals before and after its implementation in a public hospital in the State of Mexico.

Methods

Study Population and Settings

This research was an interventional and prospective study that took place between June 2019 and February 2020, evaluating physicians and nurses attached to a public gynecology and pediatrics hospital within the Mexico State, Mexico. To assess participants on attitudes in PV (APV) a questionnaire was designed and was applied before and after a previously designed educational intervention in the same physicians and nurses mentioned. In addition, the number and quality of reports of suspected ADR (SADR) by the health professionals working at the host hospital before and after the intervention were monitored.

Data Collection and Instrument of Evaluation

The *Questionnaire PV Attitudes* was designed considering previous studies from other countries.⁵⁻⁷ To determine the content validity of the questionnaire, the Delphi consensus method was used with a panel of 14 experts in education, FV and validation, assigned to the Universidad Autónoma del Estado de México or COFEPRIS. The panel determined by consensus that final version of questionnaire had content validity and a second version of the instrument was formulated and piloted in a sample of 20 subjects to determine its reliability by means of Cronbach's alpha coefficient and its application feasibility.

At the beginning of questionnaire, a section to collect demographic information from the participants was included. A total of 14 APV (one item for each) were measured through questionnaire, of which seven items were classified as positive within a five-point Likert scale (1: totally disagree and 5: totally agree) and seven were negative within a five-point Likert scale (1: totally agree and 5: totally disagree). Consequently, each participant could have had a maximum score of 70 points and a minimum of 14 points. The positive attitudes measured were responsibility, cooperation, interest, proactivity, altruism, willingness to learn and commitment to the patient's healthcare from pharmacotherapy. The negative attitudes were underestimation, ignorance, indifference, insecurity, fear, indisposition, and laziness.

After determining the total scores of the participants for the questionnaire, they were categorized as general negative attitude in PV (14-32 points), neutral attitude (33-51 points) and positive attitude (52-70 points) and the percentage difference before and after the educational intervention was determined.

A group compelling both physicians and nurses working at the host hospital was randomly selected for the questionnaire self-administration. One month after this first query, according to the needs detected, a targeted training program in PV was designed in four educational sessions. Some of the topics covered were essential PV definitions, classification, causality, factors that increase the risk of ADR, and PV legislation in Mexico. A sensibilization session about the importance of notifying ADRs was included. One month after the educational intervention, the instrument was administered once again to the same group of volunteers.

The SADR reports delivered within 18 months prior to the intervention and the following 6 months after training were collected and analyzed. The quality of the information contained in the SADR notifications was established according to the Mexican Official Standard NOM-220-SSA1 2016 *Installation and operation of pharmacovigilance*,⁸ which considers a SADR notification grade 3 as the best quality (complete notification) and 1 the worst (incomplete data).

Statistical analysis

The information was processed in the International Business Machines Corporation SPSS Statistics Version 22.0.0.0. The reliability by means of Cronbach's alpha coefficient was computed. The normal distribution in each item was assessed by means of the Kolmogorov-Smirnov (K-S) test corrected by the Lilliefors' significance. The effect of the educational intervention was measured by comparing the answers before and after using the Wilcoxon signed-rank test; in both cases a $p < 0.05$ value was considered significant. In addition, a factorial analysis was performed through the identified main item components in the questionnaire and afterwards the before and after educational intervention components were compared using a Mc Nemar test. Descriptive statistics like frequencies or median were also utilized. Finally, the effect in the number and quality of the SADR reports before and after the educational intervention was evaluated.

Results

Test Subject Demographics and Instrument Reliability Analysis

The Cronbach's alpha analysis on instrument was of 0.82, which is reliable. There were 39 physicians and 61 nurses that participated in the study. About more than a quarter had a specialization degree. 72 % were women, between 20 and 40 years old and having 75 % at least 5 years of caring experience.

Assessment of the Effectiveness of the Educational Intervention on PV Attitudes by means of Questionnaire PV Attitudes scores.

It was expected a decrease in scores for negative attitudes after the educational intervention, while a rise in the scores for positive attitudes after the educational intervention. In an overall analysis, significant differences were observed (applying Wilcoxon signed-rank test $p < 0.05$); positive attitudes increased as negative attitudes decreased. Results are shown in table I.

After the educational intervention, the percentage of professionals with a negative attitude remained at 2 %; however, a decrease in a neutral attitude was observed from 53 % to 26 % and positive attitude spread from 45% to 72 %, which indicates that the educational intervention generally improved attitudes in PV.

The Wilcoxon signed-rank test has demonstrated that for the case of physicians and nurses, there was a significant increase ($p < 0.05$) in positive attitudes in PV; and a remarkable decrease of negative attitudes observed in 5 of the 7 outlooks evaluated: those being insecurity, indifference, ignorance, fear, and laziness.

Likewise, physicians significantly increased ($p < 0.05$) their positive attitudes of cooperation, interest, proactivity, and willingness to learn, showing also a significant decrease in the negative attitudes underestimation and insecurity. Nurses significantly increased positive attitudes of cooperation, proactivity, and altruism.

Assessment of the Effectiveness of the Educational Intervention on Positive and Negative APV by Factor Analysis

The factorial analysis identified two components (or factors) of positive attitudes. Component one, called “PV contribution attitudes”, encompassed four attitudes: interest, cooperation, proactivity, and responsibility. Component two, called “attitudes of beneficence in PV” was made up out of three attitudes: willingness to learn, altruism and commitment to patient care.

After establishing the two components, the positive attitudes acquired before and after the educational intervention were assessed (expressed in percentages) for the total number of participants, as shown in table II. It was observed that for the categories of “totally agree” and “agree”, 89 % of the healthcare professionals acquired or reinforced attitudes of contribution to PV, compared to the value of 69% reported prior to the intervention. Similarly, 94 % of participants increased or reinforced beneficence PV attitudes in the categories of “strongly agree” or “agree” after the educational intervention, versus 77 % previously detected. Increases in both positive attitude factors were statistically significant ($p < 0.05$, with Mc Nemar test).

The seven negative attitudes were also extracted into two components. Component one, called “attitudes of disinterest in PV”, included three attitudes: indifference, underestimation and ignorance. Component two, designated “attitudes of passivity in PV”, incorporated four attitudes: laziness, indisposition, fear and insecurity. It was observed that 71% of the health professionals expressed disagreement or total disagreement towards the attitudes of disinterest in PV, compared to 57 % before the intervention. Similarly, 49 % of health professionals disagreed or strongly disagreed with the attitudes of disinterest in PV, as to 33 % prior to the intervention. However, these differences were not statistically significant ($p > 0.05$, with Mc Nemar test).

Comparison of SADR reports before and after the educational intervention

At the host hospital, within the 18 months prior to the PV educational intervention, there were reported six SADR notifications and rated as grade 1. In the six months period after the educational intervention, eight SADR notifications were registered and rated as grade 2 and four (50 %) as grade 3. This represented a six-fold increase in the number and frequency of SADR notifications imputable to the educational intervention.

Discussion

This study is relevant since it is one of the first carried out in Mexico to evaluate the impact of an educational intervention, so it can serve as a starting point to nurture the field.

The educational intervention performed between physicians and nurses was successful due to the fact that it improves their abilities in PV. Similar outcomes were observed in the increase of positive attitudes and the decrease of negative attitudes.

Table 1

Analysis of each item of PV attitudes in physicians and/or nurses by Wilcoxon test

Negative attitudes				Positive attitudes			
Attitude	Both	Physicians	Nurses	Attitude	Both	Physicians	Nurses
Total score	0.020*	0.010*	0.080	Total score	<0.001*	<0.001*	0.070
Underestimation	0.06	0.02*	0.52	Responsibility	0.02*	0.27	0.052
Insecurity	0.04*	<0.001*	0.52	Cooperation	<0.001*	<0.001*	0.14
Indifference	0.42	0.7	0.47	Interest	<0.001*	0.01*	0.07
Ignorance	<0.001*	0.21	<0.001*	Proactivity	<0.001*	0.04	0.01
Fear	<0.001*	0.08	0.04*	Altruism	<0.001*	0.15	<0.001*
Indisposition	0.09	0.52	0.1	Willingness to learn	0.03*	<0.001*	0.56
Laziness	0.02*	0.32	0.04*	Commitment to the patient's healthcare from pharmacotherapy	0.02*	0.21	0.07

*Statistical significance considering a value of $p < 0.05$.

Fuente: Elaboración propia.

Table 2

Level of positive attitudes of contribution and beneficence in PV of the study subjects before and after the intervention

Level /Group of attitudes	Percentage of subjects with attitudes in PV							
	Contribution		Beneficence		Disinterest		Passivity	
	B	A	B	A	B	A	B	A
Strongly disagree	2.0	2.0	4.0	1.0	26.0	50.0	3.0	14.0
Disagree	9.0	2.0	3.0	2.0	31.0	21.0	30.0	35.0
Neither agree nor disagree	20.0	7.0	16.0	3.0	27.0	18.0	38.0	34.0
Agree	36.0	38.0	29.0	34.0	13.0	8.0	25.0	15.0
Totally agree	33.0	51.0	48.0	60.0	3.0	3.0	4.0	2.0
Mc Nemar test p -value	0.031*		0.040*		0.119		0.175	

B: Before intervention,

A: After intervention.

Statistical significance considering p value < 0.05

Fuente: Elaboración propia.

des in PV. In both cases, these results are comparable to the findings of recent studies in other countries such as India, Saudi Arabia, and Nigeria.⁹⁻¹¹

In particular, physicians had the greatest impact on PV attitudes and abilities, while nurses appeared to show lesser improvement in both areas after the educational intervention. The overall pre-intervention questionnaire scores for nurses were higher for both abilities and positive APV and lower for negative attitudes versus their physician, so the educational intervention reassured and increased these variables to a lesser extent. The fact that nurses are in permanent and direct contact with the patients could explain why they appear more motivated than physicians regarding patients' safety.

Particularly noteworthy are the abilities of diagnosing and reporting ADR as part of the professional practice. It was observed that although many volunteers knew how to diagnose an ADR, they did not know how to notify it, how to fill in the COFEPRIS SADR Notification Form correctly, nor how to establish the causality of an ADR with the medication. The foregoing highlights the importance of spreading out the PPFV in Mexico's hospitals and training in the alternative methodologies for ADR reporting. As a matter of fact, this is a recurrent situation observed in countries where PV is an emerging field.^{6,12}

Although the numbers of notifications are still insufficient according to the total number of patients treated in the current legislation, it is outstanding such a positive impact on the number of SADR reported, as it has evidenced in other studies¹³.

In Mexico the implementation and development of PV (and other hospital pharmacy duties) as a key component of the pharmacy services arrived late and has been slowly implemented.

Conclusions

The implementation of educational interventions in PV aimed at health professionals is convenient and pertinent to improve not only attitudes in PV, but also to raise the quality and quantity of SADR notifications. Evaluations of APV among healthcare professionals support decision-making processes aimed at strengthening the state's PV system.

This study shows that the impact of this single educational intervention was significant on the rising of positive attitudes in physicians. When interventions are performed in groups highly motivated, like the nurses of this study, it is possible that the increase of positive attitudes may be moderate. These results are aligned with worldwide findings.

PV educational interventions' positive influence could be replicated in other Mexican public hospitals. It would be worth incorporating them as part of permanent education activities due to their potential benefits on improving the quality and safety of pharmacotherapy.

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Conflicto de intereses

Los autores declaran que no hay conflicto de intereses.

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