

# Development and Validation of a Questionnaire on Pharmacovigilance Knowledge among Health Professionals in Morocco

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## ABSTRACT

**Background:** Pharmacovigilance is one of the priority programs of the World Health Organization, with the aim of detecting the adverse effects of drugs. Morocco is one of the countries open to the world and was the first Arab and African country to participate in the international pharmacovigilance program. The purpose of this study is to develop and to validate a reliable and reasonable questionnaire, to measure knowledge and practices related to pharmacovigilance among health professionals in Morocco.

**Materials and Methods:** This is a cross-sectional study that took place between January and March 2018. The study was based on a questionnaire. Pharmacovigilance experts validated the questionnaire and the final instrument was applied to health professionals practicing in different hospitals in Morocco. The statistical validation of the questionnaire is based on the calculation of the Cronbach Coefficient Index and a factor analysis.

**Results:** The study involved 262 health professionals, including 39% of physicians, 35% of pharmacists and 26% of nurses. The average age of the participants was  $35.2 \pm 8.4$  years old. The Cronbach alpha value of the set of items was 0.7, similarly, the calculation of Cronbach's alpha showed a homogeneity of the different dimensions of the questionnaire used this for knowledge ( $\alpha = 0.6$ ) and practices related to pharmacovigilance ( $\alpha = 0.6$ ). On the knowledge side, 65% of participants correctly answered the

definition of pharmacovigilance, 81% were aware of its primary objective. We have noted that 52% of health workers, were aware of the existence of a national pharmacovigilance program in Morocco and 71% of the existence of the poison control center and pharmacovigilance of Morocco. The questionnaire has also shown that 28% of participants have reported an adverse reaction to the Poison Control and Pharmacovigilance Center of Morocco. **Conclusion:** Results showed that questionnaire is a well-structured, objective, valid and reliable in the Moroccan context, the questionnaire could be an instrument to assess knowledge and practice in Pharmacovigilance.

**Key words:** Validation, Questionnaire, Pharmacovigilance, Health Professionals, Morocco.

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## INTRODUCTION

Adverse Drug Reactions (ADRs) are a serious problem affecting public health internationally. Indeed, in 1961 following the tragedy of thalidomide, ten developed countries collaborated and joined the World Health Organization (WHO) to implement the first seed of a new science, pharmacovigilance.<sup>1</sup> According to WHO, defined pharmacovigilance as "the science and activities related to the detection, evaluation, understanding and prevention of adverse effects or any other problem related to drugs".<sup>2</sup> In 1968, a WHO international drug surveillance programme was launched the main objective of identifying pharmacovigilance signals as early as possible. The programme now contains more than 80 member countries from around the world who contribute to the writing of individual case safety reports in the WHO's global ICSR database system, VigiBase.<sup>3</sup>

At the continental level, 38 African countries are members of the international pharmacovigilance network (32 official members and 6 associate members). Despite this increase, pharmacovigilance in Africa is still considered low.<sup>4</sup> This weakness is reflected in the rate of participation in the enrichment of the UMC database. In 2012, for example, the notification rate of African countries did not exceed 1.6% of the total number of notifications received.<sup>4</sup> Morocco is one of the developed countries in the field of pharmacovigilance due to the Poison Control and pharmaco-

vigilance Center, as well as a collaborating center of WHO. However, a study conducted by the Poison Control and Pharmacovigilance Center of Morocco showed that the average number of notifications was 205 reporting per 4 months with a rate of 87 reported cases / million inhabitants / year.<sup>5</sup> This weakness of notifications could be influenced by several factors, among others the pharmacovigilance status. Indeed, so far, no national survey has been conducted to assess the knowledge and practices of health professionals regarding pharmacovigilance in Morocco. In this sense, our objective is to validate a questionnaire in pharmacovigilance, as well as to determine the state of knowledge and the practice of pharmacovigilance with health professionals in Morocco.

## MATERIALS AND METHODS

This cross-sectional study took place between January and March 2018. The population studied concerns health professionals (doctors, nurses and pharmacists) working in various public hospitals in Morocco. The literature review<sup>6-8</sup> concerning the assessment of the state of knowledge and Pharmacovigilance (PV) practices allowed us to use a scale of 25 items. The latter were submitted to the experts of the PV experts, of the professors of higher education for their scientific advice and to a linguist to judge the comprehensibility of the items because this scale will be

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intended for an Arab-French speaking population. The advice of these experts allowed us to discard 9 items. A total of 16 items were selected for the assessment of the state of knowledge and practices related to PV. They are spread over 3 dimensions

- Knowledge on pharmacovigilance (8 items)
- Practice of pharmacovigilance (6 items)
- Factors leading to the practice of pharmacovigilance (2 items)

Similarly, we conducted a self-administered questionnaire that examined the socio-demographic and professional information of the participants in this study. Thus, a survey form was distributed personally and requested to be completed outside working hours. Data confidentiality was entrusted to the respondents by the anonymity of the participant. In our study, the process of validating the scale of the assessment of the knowledge state and the practice of PV among health professionals is based on two stages. Initially, we calculated the reliability of the entire questionnaire and the three dimensions of the scale by Cronbach's alpha. Next, exploratory factor analyzes were performed. Statistical analyzes were done by the Statistical Package for the Social Sciences (SPSS, version 21). The data collected were therefore the subject of exploratory analyzes to determine the dimensionality of the scale of assessment of the knowledge state and the practice of PV among health professionals in Morocco. Principal component factor analysis (PCF) is the most efficient method for synthesizing information and uncovering the underlying structure of a concept since it is a method for analyzing multi-variate data. Which makes it possible to simultaneously explore the relationships that exist between several variables studied.<sup>9</sup> In our study we used the Kayser Meyer Olkin (KMO) test. A KMO of less than 0.5 is unacceptable, 0.5 is low, more than 0.6 is acceptable, 0.7 is average, 0.8 is meritorious and 0.9 is excellent<sup>10</sup> and Bartlett's sphericity test to assess the potential effectiveness of the PCR studied. For a factor analysis to be feasible the Bartlett test must be significant ( $p < 0.05$ ),<sup>11</sup> so we have calculated Cronbach's alpha to verify the reliability and homogeneity between the items on the scale. Measured. An alpha between 0.6 and 0.8 is acceptable for an exploratory study.<sup>12,13</sup>

## RESULTS

### Sociodemographic and professional profile of the study population

The population of our study covers 262 health professionals, including 39% of physicians, 35% of pharmacists and 26% of nurses. The average age of the participants was  $35.2 \pm 8.4$  years old. Women who participated in this study are more than men with a percentage of 69% are Health professionals working in rural areas are represented by a percentage of 21%. Participants with an average experience of  $9.1 \pm 5.5$  years, ranging from one year to 25 years of experience (Table 1).

### Validation of the questionnaire

#### a. Internal reliability of the questionnaire items

The Cronbach alpha value of the set of items was 0.7, similarly, the calculation of Cronbach's alpha showed a homogeneity of the different dimensions of the questionnaire used this for knowledge ( $\alpha = 0.6$ ) and practices related to PV ( $\alpha = 0.6$ ) (Table 2).

#### PV: Pharmacovigilance

To make a factorial analysis of the questionnaire, we took into consideration the value of the KMO index and Bartlett's sphericity test. For our study, the KMO index was  $0.6 > 0.5$ , which shows an acceptable value for doing the factor analysis, so, Bartlett's sphericity test is highly significant. (Table 3)

**Table 1: Professional and demographic parameters of our population.**

Variables	Number	Percentage
<b>Status</b>		
Physician	101	39%
Pharmacist	92	35%
Nurse	69	26%
<b>Mid exercise</b>		
Rural	55	21%
Urban	207	79%
<b>Gender</b>		
Masculine	82	31%
Feminine	180	69%

**Table 2: Cronbach alphas values of all items and dimensions of the questionnaire.**

	Cronbach's alpha	Items
Sets of items	0.7	14
Knowledge in PV	0.6	9
PV practices	0.6	5

**Table 3: The KMO index (Kaiser - Mayer - Olkin) and Bartlett Test.**

		Valeur
<b>KMO index</b>		<b>0.6</b>
<b>Bartlett's sphericity test</b>	Chi-square approx.	1181.5
	Ddl	91
	<b>Signification</b>	<b>0.00</b>

To study the factorial structure of the collected data, we opted for a Principal Component Analysis (PCA), the latter was done with varimax rotation on all the items of the questionnaire.

This analysis identified four factors that account for 60% of the total variance. The first factor consisting of three items (item 11, item 12 and item 13) explains 17.3% of the inertia, the second factor consisting of three items (item 3, item 4 and item 6) explains 16.3% of the observed variance, the third factor consisting of four items (item 5, item 7, item 8 and item 9) explains 15.3% of the total variance and the fourth factor consisting of four items (item 1, item 2, item 10, item 14) explains 11.1% of observed variance. The homogeneity of items allowed us to name the first factor "Practice of PV", the second factor "Training in PV", the third factor "Knowledge of PV at the national level" and the fourth factor "Academic knowledge of PV". The factor analysis allowed to retain a dimension for the practice (factor 1) and three dimensions for the state of knowledge in the field of PV (factor 2, factor 3 and factor 4). To test the reliability of these new dimensions of the questionnaire we determined the Cronbach's alpha, this demonstrated a very high homogeneity between the items (Table 4).

### Profile of the knowledge state and the practice of pharmacovigilance in our population.

#### a. Knowledge state in pharmacovigilance

In terms of knowledge, 65% of participants responded correctly to the definition of PV according to the World Health Organization, 81% were aware of its main objective. 39% of health professionals studied PV at the initial level and only 20% of participants attended continuing education. We have noted that 52% of health workers were aware of the existence

**Table 4: Cronbach's alpha for the new dimensions of the questionnaire.**

Dimension	Sub-dimensions	Items	Cronbach's alpha
Practice of PV		item 11, item 12 et item 13	0.72
	Training in PV	item 3, item 4 et item 6	0.71
Knowledge state of PV	Knowledge of PV at the national level	item 5, item 7, item 8 et item 9	0.69
	Academic knowledge of PV	item 1, item 2, item 10 et item 14	0.75

**Table 5: Distribution of responses for each dimension 1 item (knowledge state).**

Item	Questions	Yes n(%)	No n(%)
1	Do you know what pharmacovigilance is?	171(65%)	91(35%)
2	Do you have an idea about the objectives of pharmacovigilance?	211(81%)	51(19%)
3	Have you studied pharmacovigilance during your initial training?	102(39%)	160(61%)
4	Have you participated in ongoing training on pharmacovigilance?	52(20%)	210(80%)
5	Do you think that pharmacovigilance should be taught in detail to health professionals?	258(98%)	4(2%)
6	Where is the International Monitoring Center for Adverse Drug Reactions?	49(19%)	213(81%)
7	Do you know about the existence of a national pharmacovigilance program in your country?	135(52%)	127(48%)
8	Do you know that there is a Poison Control and Pharmacovigilance Center in Morocco?	185(71%)	77(29%)
9	Are you aware of the occurrence of an adverse drug event?	236(90%)	26(10%)

**Table 6: Responses for each item in dimension 2 (Practice of pharmacovigilance).**

Items	Questions	Yes n(%)	No n(%)
10	Have you ever received a patient with an adverse event related to drugs or other health products?	237(90%)	25(10%)
11	Have you ever reported an adverse event to the National Center / Department / Pharmacovigilance Unit?	74(28%)	187(72%)
12	Have you ever seen the adverse reaction reporting form?	65(25%)	197(75%)
13	Have you ever received training on how to report adverse drug reactions?	9(3%)	253(97%)
14	Which of the following methods is commonly used by the health professional to monitor the adverse effects of new drugs after they are introduced to the market?	9(3%)	253(97%)

of a national PV program in Morocco and 71% of the existence of the poison control and pharmacovigilance center in Morocco. Only 19% of participants knew that the International Monitoring Center for Adverse Reactions was in Sweden and 98% of participants thought that pharmacovigilance should be taught in detail to health professionals. For the concept of an adverse event, 90% of investigations were aware of the occurrence of an adverse drug event. (Table 5)

### b. Practice of pharmacovigilance

On the practical side of PV, 28% of the participants who reported an adverse reaction to the Poison Control and Pharmacovigilance Center of Morocco, as well as 24% of respondents who saw the adverse reaction reporting form. We have noted that 3% of respondents who received training on how to report adverse drug reactions and the same percentage for participants who knew about the method used to determine the relationship between drug effects and drug use (Imputability), as well as we found that 90% of the respondents had already received a patient with an adverse event related to the use of drugs or other health products. (Table 6)

## DISCUSSION

Adverse drug reactions are a real public health problem at the national and international levels. For this reason, health professionals need to be aware of PV. To our knowledge, this is the first study in Morocco with regard development and validation of a questionnaire on PV knowledge among health professionals. In our study, the response rate was very good (87.3%) and was similar to those reported in other studies from the Arabia countries.<sup>14-16</sup> On an international scale, typical participant response rates for such studies vary quite extensively, from approximately between 50 to 97%, as a function of the study population and how the questionnaire was.<sup>17,18</sup> These differences in participation rates could be due to lack of time and overwork. Participants may have felt uncomfortable responding due to their lack of knowledge of the basic concepts of PV and ADRs and therefore refused to participate.<sup>18</sup> At the level of pharmacovigilance knowledge, Results from this study show that the most of health professionals had good knowledge regarding the concept of PV and ADRs in terms of their definitions and their object if, this result is consistent with a study conducted in India and in Saudi Arabia.<sup>19,16</sup> On the other hand, a study carried out in Cameroon showed that the PV knowledge score is very low.<sup>20</sup> These differentiations in levels of knowledge about PV could be due to academic PV programs for each country. The majority (72%) of participant do know the Anti-poison and Pharmacovigilance Center of Morocco (MAPPC); however, we noted that 28% of them did not report an adverse reaction during their professional career. These results are consistent with internationally published studies also revealed a low reporting rate: Qatar (29.3%),<sup>21</sup> Istanbul (21%),<sup>22</sup> Jordan (19.5%)<sup>23</sup> and Northern China<sup>24</sup> (14.6%). A meta-analysis done in India on the knowledge and practice of PV, has shown that 28.7% (95%CI: 16.4-40.9;  $p < 0.001$ ) of them were not interested in reporting ADRs.<sup>25</sup> These low rates of adverse drug reaction reporting may be due to several factors. The main reasons for under-reporting ADRs are lack of time, lack of knowledge about reporting mechanisms, lack of awareness of the existence of the national pharmacovigilance system, belief that the ADR was already well known, doubt about the importance of ADRs. The main reasons for under-reporting ADRs are lack of time, lack of knowledge about reporting mechanisms, lack of awareness of the existence of the national pharmacovigilance system, belief that the ADR was already well known, doubt about the importance of ADRs.<sup>26</sup> According to the literature review, studies have been demonstrating the state of knowledge in pharmacovigilance has an impact on the reporting of adverse effects.<sup>27</sup>

The lack of awareness of a national ADR reporting centre or lack of knowledge of ADR reporting process has also been reported in KSA,

Kuwait, in Iran and Jordan. We have 48% in our study who were not aware that there is a national pharmacovigilance program, although the Moroccan Minister of Health asks health professionals and the pharmaceutical industry to report adverse drug-related reactions in Ministerial Circular No. 2DR / 10 of 1992 and in the text of Law 17-04 of 2005 on medicines.<sup>28</sup> In our study, the majority of participants had no knowledge of reporting procedures, similar to studies in developing and developed countries, In China, 71% of health professionals had no knowledge of reporting procedures.<sup>29</sup> In Malaysia, almost 40% of participants were not aware of the existence of a national adverse drug reaction reporting system.<sup>30</sup>

In terms of knowledge assessment and PV practice, to our knowledge, this is the first study in Arab countries with regard development and validation of a questionnaire on pharmacovigilance in the Arab context. Validation of the questionnaire was based on Churchill's paradigm.<sup>31-33</sup> In Mexico, a study conducted on the validation of the pharmacovigilance questionnaire determined a very high internal homogeneity of items with a Cronbach index of 0.7.<sup>34</sup> In our study, the internal reliability of the questionnaire was important with a Cronbach index of 0.7.

## CONCLUSION

The results show that health professionals in Morocco have a lack of knowledge about how to report adverse drug reactions. There is an urgent must carry out awareness campaigns for health professionals, in the interest of reporting adverse reactions.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## ABBREVIATIONS

**KMO index:** Kaiser - Mayer - Olkin; **PV:** Pharmacovigilance; **WHO:** World Health Organization.

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