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Research Article:

Design and Validation of a Questionnaire to Evaluate Healthcare Providers' Practices of Pharmacovigilance

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Abstract

Background: Pharmacovigilance is an important tool that ensures the safe use of medications during their entire life cycle. Healthcare providers are the main contributors to pharmacovigilance activities, and reporting adverse drug reactions is a core obligation of their clinical practice. The aim was to evaluate the validity and reliability of an adapted and translated version of the knowledge, attitude and practice (KAP) questionnaire specified on pharmacovigilance among healthcare providers. **Methods:** An observational cross-sectional survey was performed among 30 healthcare providers (n=30) to obtain their demographic data. This pilot study was conducted in Mosul city hospitals in November 2024. The other data were collected using the translated KAP questionnaire which consists of 14 questions related to knowledge, 6 questions related to attitude, 5 questions related to practice, and 1 question related to barriers to adverse drug reaction reporting. Descriptive statistics were employed. Reliability was tested using Cronbach's alpha. **Results:** Ten healthcare providers of each profession were included in the study (pharmacist, physician, nurse). The mean knowledge score was 8.03 ± 2.10 out of 14, while the mean attitude was 26.36 ± 2.25 out of 30, and the practice mean was 2.2667 ± 1.94 out of 5. The internal consistency was found to be good (Cronbach's alpha = 0.729, 0.722, and 0.722 for knowledge, attitude, and practice, respectively). Face-content validity was employed, and five specialists evaluated the validity of the questionnaire. Construct validity was also proven, where the total KAP scores were shown to be significantly higher among healthcare providers with a history of pharmacovigilance training. **Conclusion:** This study concluded that the translated KAP pharmacovigilance questionnaire is reliable and valid for evaluating the knowledge, attitude and practice among healthcare providers in Nineveh.

1. Introduction

The use of medications coveys some kind of risk. Both beneficial and harmful effects must be maintained in balance, through the entire life cycle of the medication, including the period when the medication is put to test during the pre-marketing developmental phase (1, 2). In addition, monitoring of drug safety through the post-marketing period is still required (3). The WHO defines adverse drug reactions (ADRs) as "any type of response caused by a drug, that is unintentional, noxious and takes place at the drug doses which are used for diagnosis, prophylaxis, or treatment of a disease or due to the medications for the physiological functions" (4). ADRs are the main cause of mortality and morbidity globally, and they may increase the hospitalization cost and thereby increase the cost of basic healthcare services (5).

In many instances, ADRs could be prevented from happening. This fact highlights the importance of early ADRs identification and treatment. Their preventable nature is considered the motivation for many of the currently evolving ADR reporting systems (6). The post-marketing drug surveillance system of ADRs known as pharmacovigilance (PV) is defined as "the science and the activities concerning the assessment, detection,

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understanding and the prevention of the harmful results or any adverse drug-related issues" (4).

PV plays a significant role in ADR reduction, thus development and constant improvement of this system are critical for having safe and effective clinical practice (7). Healthcare providers (HCPs), especially physicians, pharmacists and nurses are considered the major contributors to ADRs reporting. HCPs' knowledge, attitude and practice play a central role in improving patients' safety (8-12). The effectiveness of any system of pharmacovigilance depends greatly on HCPs' involvement in ADR reporting through their practice (4). HCPs are more likely to identify ADR in both community and hospital settings. Accordingly, HCPs must be alert and sensitive in detecting and resolving medication-related issues, and they should be able to educate patients on the effective use of medications (13).

The pharmacovigilance system of Iraq experiences the issue of ADR under-reporting, as in most of the pharmacovigilance systems all over the world (5, 14). One of the major drawbacks is the lack of knowledge among the HCPs (4, 13, 15). Also, the rates of ADR reporting is significantly impacted by the attitude of HCPs (16). The number of HCPs with experiences in medication surveillance is very low in both low- and middle-income countries, this is often related to the limitation in the available financial sources to support the awareness of PV (17). Numerous studies conducted among healthcare providers in different regions have highlighted a significant gap in their knowledge concerning pharmacovigilance and the reporting of ADRs. This highlights the need to understand the knowledge of HCPs about pharmacovigilance, as they are responsible for reporting ADRs during their clinical practice. Moreover, the attitudes of HCPs toward pharmacovigilance can play an important role in motivating them to report and monitor ADRs effectively (18). Although many studies that evaluate PV and ADR reporting KAP in many provinces in Iraq, have been published internationally (5, 16, 19), no such studies have been reported in Nineveh. The main objectives of this study were to develop a tool to evaluate the KAP of PV and ADRs reporting among healthcare providers, to translate the developed tool to an Arabic version, and to test the validity and reliability of this KAP questionnaire.

2. Methodology

2.1. Background

A questionnaire was developed to explore the knowledge, attitude, and practice of healthcare providers regarding pharmacovigilance and ADR reporting. The questionnaire consisted of 4 sections, comprising a total number of 26 questions. Previous studies that assessed healthcare providers KAP were reviewed for the tools used (1, 7, 12, 20-30). The study questionnaire was developed after extensive revision of the available tools to create the final version of 4 sections questionnaire. These questions were retrieved from previous studies that assessed the healthcare professionals' knowledge, attitude and practice (1, 20-26). Adjustments were made to the questions in order to make them culturally convenient, taking into account the system of pharmacovigilance in Iraq and its connection to the international pharmacovigilance system.

The distribution of the questions was as follows: 14 questions were for evaluating knowledge, 6 questions for evaluating attitude, 5 questions for evaluating practice, and one for assessing barriers. In addition, seven questions were added at the beginning of the survey for demographic data collection, which included: name, age, gender, phone number, profession (physician, pharmacist, nurse), educational level (bachelors, master, doctorate) and years of practice. After that, the questionnaire was developed in English language and translated into an Arabic version (**Figure 1**).

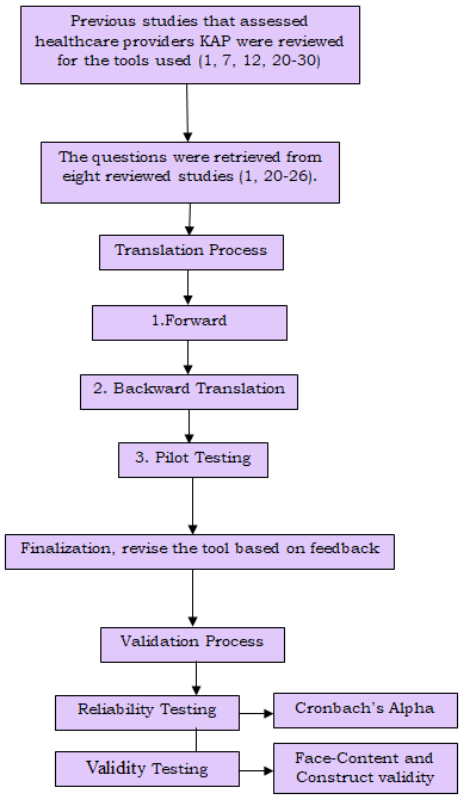

Figure 1. Flow chart of pilot study translation and validation.

2.2. Translation

The translation of the questionnaire was performed according to the guidelines recommended by Guillemin and Beaton (31). In the first step, four different translators who

their native language was Arabic, but who could speak both Arabic and English, translated the questionnaire from English to Arabic. Two of these four translators were clinical pharmacists who were aware of the aims of this questionnaire. On the other hand, the other two translators were unaware of the questionnaire's aims. After that, one of the researchers, who was Iraqi Arabian, viewed these four primary versions and compared them to the original form. After that, the first report was prepared.

Back translation was the second step of the translation process; in which, the newly developed Arabic version was translated into English. This process was performed by other four translators, who were fluent in both Arabic and English, with no medical background. The outcome of the back translation was compared to the original questionnaire form and then the second report was prepared. Discussions were held between the researchers and all the translators to ensure the precision of the questionnaire.

The final step included pilot testing of the resultant questionnaire, which was conducted through thirty healthcare providers, who completed the questionnaire and gave their comments. These HCPs will not be included in the study. Discussions were also made about the first report, the second report and the comments introduced by the HCPs and then imperative adjustments were made. The concluding version of the knowledge, attitude and practice questionnaire on ADRs reporting in Arabic, was finalized and available for the validity testing.

2.3. Data collection

This cross-sectional survey-based pilot study was conducted in Mosul city Hospitals, namely Al-Hadbaa Hospital and Ibn Al-Atheer Hospital, for 7 days period in November 2024, among HCPs. This study was carried out among thirty healthcare providers, they included ten physicians, ten pharmacists, and ten nurses. These HCPs were approached for the study and agreed to participate by giving verbal consent. Then, they were provided with a translated questionnaire related to their knowledge, attitude, and practice concerning pharmacovigilance and ADR reporting.

2.4. Validation study

The final version of the questionnaire was conferred among five specialists who are experts in the medical field. These experts concluded the face-content validity of this questionnaire. In addition, construct validity was also employed.

2.5. Statistical analysis

The collected data were tabulated by using Microsoft Excel and then they were analyzed using the Windows Statistical Package for Social Sciences (SPSS) 25. Various parameters were evaluated from the data collected from the filled questionnaire. These parameters include the frequencies and percentages of HCPs characteristics, while the mean and the standard deviation were calculated for the KAP scores. For the knowledge and practice assessment, the following scores were used: correct answer=1, wrong answer=0, I don't know=0. The attitude assessment scoring was as follows: strongly agree=5, agree=4, neither agree nor disagree=3, disagree=2, strongly disagree=1. The maximum possible score for knowledge was 14, the maximum possible score for attitude was 30, and the maximum possible score for practice was 5. Cronbach's alpha was used to assess the internal consistency, and Pearson's correlation was used to determine construct validity.

3. Results

3.1. Demographic data

A total of 30 healthcare providers' data were analyzed. Most of the participating HCPs were male (17,56.7%). The mean age was (37.8) years. The percentages of healthcare providers' profession were as follows: physician (33.3%), pharmacist (33.3%) and nurses (33.3%). Of all the HCPs, (26.7%) were doctorate holders, (6.7%) had master's degrees, and (66.7%) had bachelor's degrees. The mean years of practice was (12.8). Further details are presented in (**Table 1**).

Table 1. Demographic data of healthcare providers.

Parameters (n=30)	Mean ± SD	Frequency	%
Age	37.8 ± 13.7		
Years of Practice	12.8 ± 14.0		
Gender			
Male		17	56.7
Female		13	43.3
Profession			
Physician		10	33.3
Pharmacist		10	33.3
Nurse		10	33.3
Educational level			
Bachelors'		20	66.7
Master's		2	6.7
Doctorate		8	26.7

3.2. Face Validity

The face-content validity of the developed questionnaire was assessed through expert review to ensure its relevance in evaluating the KAP of healthcare providers. A panel of subject matter experts reviewed the questionnaire items, providing feedback on their alignment with the study objectives. Based on their recommendations, modifications were made to enhance the clarity and content coverage. After that, a small group of HCPs participated in a pilot study to assess the comprehensibility of the questionnaire.

The feedback gathered led to further adjustments. The results indicated that the questionnaire demonstrates strong face-content validity, supporting its use as a reliable tool for assessing KAP among HCPs. To determine the construct validity of the questionnaire used, a hypothesis stating that HCPs that attended training sessions or workshops of ADRs reporting demonstrate higher total KAP scores compared to those with no training history. The correlation was statistically significant (p = 0.009), and Pearson Correlation was (r = 0.469).

3.3. Reliability

The mean ± standard deviation of the KAP scores was 36.666 ± 3.817. The Cronbach's alpha coefficient for internal consistency was 0.729 for the 14 items in knowledge, 0.722 for the 6 items in attitude and for the 5 items of practice as well (**Table 2**). The item-total correlations are shown in (**Tables 3,4**, and **5**).

Table 2. Cronbach's alpha and descriptive statistics.

Scale	Cronbach's alpha	Mean	SD	No. of items
Knowledge	0.729	8.0333	2.10882	14
Attitude	0.722	26.3667	2.25118	6
Practice	0.722	2.2667	1.94641	5

Table 3. Reliability test of the 14 questions of knowledge.

Question No.	Corrected item-total correlation	Cronbach's Alpha if Item Deleted
K1	0.296	0.719
K2	0.258	0.723
K3	0.235	0.725
K4	0.389	0.709
K5	0.572	0.680
K6	0.289	0.725
K7	0.236	0.730
K8	0.516	0.692
K9	0.528	0.687
K10	0.572	0.693
K11	0.415	0.707
K12	0.212	0.735
K13	0.477	0.710
K14	-0.150	0.748

Table 4. Reliability test of the 6 questions of attitude.

Question No.	Corrected item-total correlation	Cronbach's Alpha if Item Deleted
A1	0.425	0.693
A2	0.505	0.674
A3	0.519	0.668
A4	0.604	0.632
A5	0.367	0.712
A6	0.354	0.714

Table 5. Reliability test of the 5 questions of practice.

Question No.	Corrected item-total correlation	Cronbach's Alpha if Item Deleted
P1	0.770	0.561
P2	0.654	0.596
P3	0.449	0.688
P4	0.267	0.757
P5	0.345	0.721

Discussion

This is the first study that uses a translated and validated questionnaire for evaluating the knowledge, attitude, and practice of PV and ADRs reporting among healthcare providers in Nineveh. The English KAP questions translation was performed according to the detailed procedures mentioned in the translation guidelines of Guillemin and Beaton (31). This questionnaire was created and validated, to ensure its relativity and feasibility to be used among HCPs in Nineveh.

The questionnaire is composed of 26 items (14 items for knowledge, 6 items for attitude, 5 items for practice, and one for barriers) that are appropriate for evaluating PV knowledge, attitude, and practice in other studies estimating the pharmacovigilance KAP. In comparison, the fewer questions used by other studies (24, 26), where a narrower extent was being evaluated.

Following the translation of the questionnaire, the validity of the newly translated version is still conserved. A statistically significant positive correlation (p = 0.009, r = 0.469) was found between the history of PV training and the total KAP score, indicating that PV training is positively associated with the overall KAP score. Where the total KAP scores were significantly higher among healthcare providers who had previously attended ADR reporting workshops. In addition, strong face-content validity was proven by a panel of experts. The reliability of this KAP questionnaire was studied using the internal consistency

coefficient. KAP scores showed sufficient reliability, where internal consistency exceeded 0.7. Our study among HCPs in Nineveh revealed that the 26 questions of this KAP had very good internal consistency.

The knowledge scores observed indicate moderate knowledge of HCPs. Most of the study's participants were familiar with the definitions of PV and ADRs, however only half of them were aware of the purpose of PV. While more than half of the HCPs identified the national PV center establishment, only a few identified the international ADRs monitoring center in Sweden. These results were similar to the pilot study performed in the Sultanate of Oman (32).

The mean attitude scores showed a positive attitude among the HCPs toward PV and ADRs reporting. Most of the HCPs agreed that reporting ADR is considered a necessity and a professional obligation. The majority of healthcare providers believe that pharmacovigilance and ADR reporting should be taught to healthcare workers. They also think that ADR increases the cost of healthcare. This suggests that healthcare providers recognize the importance of PV. Which is similar to the results of a study performed in Saudi Arabia (33).

The mean score of practice among healthcare providers is low. Although most healthcare providers identified ADR during their practice with patients, only some of them reported it to the National Pharmacovigilance Center. Additionally, only a few healthcare providers received training for reporting ADRs.

This study highlights a moderate level of knowledge among healthcare providers regarding pharmacovigilance and ADR reporting with gaps remaining in the understanding of PV's purpose and international monitoring systems. This may explore that there is a gap in the under graduate curriculum in the field of pharmacovigilance. Despite demonstrating a generally positive attitude toward pharmacovigilance, the actual reporting practices were found to be low, which was largely attributed to a lack of training. These results emphasize the need for targeted educational interventions and training programs to enhance both knowledge and reporting practices, ultimately strengthening pharmacovigilance systems. A study by Dina et al. (34) found that HCPs who received training on ADRs reporting showed a higher level of knowledge and positive attitudes toward PV. So, there is a concern for HCPs who did not receive an educational intervention on ADRs reporting, that their practice is most likely to show under-reporting, and demonstrate low levels of knowledge and attitude scores.

Limitations

The sample of the HCPs was smaller in this study compared to samples used in previous studies. However, this is a validation part for a questionnaire to be used in a larger work for a M.Sc. dissertation of the one-year duration of work.

Conclusions

The translated KAP questionnaire instrument showed sufficient validity and reliability. It is a feasible and reliable instrument for evaluating the knowledge, attitude, and practice of PV among HCPs.

Conflict of interest

This study is conducted as a part of the first author's master's thesis. Consequently, the authors confirm that there are no conflicts of interest.

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تطوير وتوثيق صلاحية استبيان لتقييم ممارسات مقدمي الرعاية الصحية في مجال اليقظة الدوائية

الملخص:

الخلفية: تُعدّ اليقظة الدوائية أداة مهمة تضمن الاستخدام الآمن للأدوية طوال دورة حياتها. ويُعدّ مقدمو الرعاية الصحية المساهمين الرئيسيين في أنشطة اليقظة الدوائية، حيث يُعدّ الإبلاغ عن التفاعلات الدوائية الضارة جزءًا أساسيًا من ممارستهم السريرية. هدف هذه الدراسة هو تقييم مدى صلاحية وموثوقية نسخة مترجمة ومعدلة من استبيان المعرفة، والسلوكيات، والممارسات (KAP) المتعلق باليقظة الدوائية لدى مقدمي الرعاية الصحية.

الطرق: أُجري مسح مقطعي على 30 من مقدمي الرعاية الصحية (n=30) لجمع بياناتهم الديموغرافية. وقد تم تنفيذ هذه الدراسة الاستطلاعية في مستشفيات مدينة الموصل في شهر تشرين الثاني/نوفمبر 2024. تم جمع البيانات الأخرى باستخدام النسخة المترجمة من استبيانKAP ، والذي يتكوّن من 14 سؤالًا حول المعرفة، و6 أسئلة تتعلق بالسلوكيات، و5 أسئلة عن الممارسات، وسؤال واحد عن معوقات الإبلاغ عن التفاعلات الدوائية الضارة. وقد تم استخدام الإحصاء الوصفي، وتم اختبار الموثوقية باستخدام معامل كرونباخ ألفا.

النتائج: شملَت الدراسة عشرة مشاركين من كل فئة مهنية (صيدلي، طبيب، ممرض). وكان متوسط درجات المعرفة 8.03 ± 2.10 من أصل 14، بينما بلغ متوسط المسلوك 26.36 ± 2.25 من أصل 30، ومتوسط الممارسة 2.27 ± 1.94 من أصل 5. وُجد أن الاتساق الداخلي جيد (معامل كرونباخ ألفا = 0.729 و0.722 و0.722 للمعرفة، والسلوك، والممارسات على التوالي). تم اعتماد الصلاحية الظاهرية والمحتوى من خلال تقييم خمسة مختصين لصلاحية الاستبيان. كما تم إثبات الصلاحية البنائية، حيث أظهرت النتائج أن مجموع درجات KAP كانت أعلى بشكل ملحوظ لدى مقدمي الرعاية الصحية الذين لديهم تاريخ تدريب في مجال اليقظة الدوائية.

الاستنتاج: خلصت هذه الدراسة إلى أن النسخة المترجمة من استبيان KAP المتعلق باليقظة الدوائية موثوقة وصالحة لتقييم المعرفة، والسلوكيات، والممارسات لدى مقدمي الرعاية الصحية في نينوى.

الكلمات المفتاحية مقدمو الرعاية الصحية، اليقظة الدوائية، الاستبيان، توثيق صلاحية