Spontaneous reporting of adverse drug reactions: nurses' perception

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Abstract. Introduction: Spontaneous reporting of adverse drug reactions is the basis of pharmacovigilance, the main objective of which is to ensure the safe use of drugs, particularly cytotoxics, through continuous monitoring of adverse events caused by them. The aims of this study were to investigate the perception of nurses towards pharmacovigilance, and identify reasons for under-reporting of adverse reactions to cytotoxic drugs in Morocco. Methods: Individual semi-structured interviews were conducted with 10 nurses in charge of administering cytotoxics drugs in the Pediatric Hemato-Oncology Department of the Children's Hospital in Rabat in 2019. The interviews were recorded, then transcribed and analyzed. Results: From this study, positive attitudes towards the reporting of adverse drug reactions by nurses were shown. Nevertheless, an insufficient level of knowledge of pharmacovigilance by the participants was showed. Lack of training was the main cause of this lack of knowledge. Conclusion: This study showed a positive perception of nurses towards pharmacovigilance and ADR reporting despite insufficient knowledge. The integration of pharmacovigilance modules in the training curriculum of nurses will help to improve ADR reporting.

Keywords: Adverse drug reactions; Spontaneous reporting; Pharmacovigilance; Nurses

Introduction

Pharmacovigilance plays a significant role in ensuring patient security and risk management in the use of medicines [1]. As defined by WHO, the pharmacovigilance is "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine/vaccine related problem" [2]. Adverse drug reactions (ADRs) are a serious public health challenge, given the large number of comorbidities, polypharmacy and the increasing number of new drugs on the market [3, 4]. It has been reported that 5-10% of hospital admissions were due to adverse drug events [5]. Also, ADRs, increase the length of hospitalization by 9% and costs by 20% [6]. In the United States of America, adverse drug reactions (ADRs) were the fifth leading cause of mortality [6]. In Morocco, a multicenter study showed an incidence of 11.5% of adverse drug reactions in surgical intensive care units [7]. Although pharmacovigilance is based on spontaneous reporting of adverse drug reactions (ADRs) by health professionals and patients, many studies have shown that ADRs are largely under-reported [8-11]. Therefore, an evolution of pharmacovigilance is necessary for a safe clinical practice, especially in oncology, given the toxicity of cytotoxic drugs [12].

In Morocco, the national pharmacovigilance system was implemented in 1989, by the creation of the national center of pharmacovigilance. In 1992, this center was the first African and Arab center to become a member of the WHO collaborating center for adverse drug reactions monitoring. In addition to the national pharmacovigilance center, the national pharmacovigilance system is composed of regional pharmacovigilance centers, technical committee of pharmacovigilance and national commission of pharmacovigilance. The main objective of this system is to promote the reporting of adverse reactions [13]. Despite efforts made, a study investigating the perception of health professionals towards pharmacovigilance in Morocco showed a negative perception [14]. Another prospective analytical study conducted in Casablanca showed that only 11.5% of participants had ever reported an adverse drug reaction, indicating the need for more efforts to encourage health professionals to be more involved in the reporting process [15].

Nurses could play a very important role in reporting adverse drug events, especially for fragile patients as in the case of children, as they often administer medications to patients and stay close by to monitor them [16-18].
In Hemato-Oncology Department of Children's Hospital in Rabat, the administration of cytotoxics is carried out by nurses. The aim of this study was to investigate the perception of nurses towards pharmacovigilance, and identify reasons for under-reporting of adverse reactions to cytotoxic drugs in Morocco.

Methods

This is a qualitative study through semi-structured interviews, conducted face-to-face with nurses responsible for the administration of cytotoxics and who have worked at least one year in the Pediatric Hemato-Oncology Department in Children's Hospital in Rabat, Morocco, in 2019.
The discussion with the interviewers was taken based on two main themes:

i) Pharmacovigilance: Definition of pharmacovigilance, knowledge of the organization of the national pharmacovigilance system and training about pharmacovigilance;
ii) ADRs: Definition of ADRs, ADR reporting form, knowledge and attitude towards ADE reporting, professional responsibility, factors affecting ADE reporting and training about ADE reporting. During the discussion, we made sure to allow participants to express other ideas related to the theme discussed.

Each interview lasted approximately 30 minutes and was conducted in a time that was appropriate for the interviewees.
Data saturation was achieved at the tenth interview.
During the discussion, detailed notes were recorded. Then, the collected data were transcribed and analyzed.

Results

During the period of study, 10 nurses were interviewed. seven of them were female. The mean age of participants was 34.76 years. The mean professional experience was 8.32 years. The majority (80%) had less than 10 years of professional practice.

Themes:

i) Pharmacovigilance: nurses participating in this study were asked to define the term of pharmacovigilance. All participants knew the term, but none of them knew the exact definition of pharmacovigilance. They have defined pharmacovigilance using their own words. Here are two of definitions given: "pharmacovigilance protects patients from adverse drug reactions", "pharmacovigilance assesses the safety and security of medicines". All participants had a positive perception of the term. They all stated that pharmacovigilance protects patients from adverse drug reactions. Regarding the national pharmacovigilance system, 7/10 of the participants knew about the existence of Pharmacovigilance Centers in Morocco, and 3/10 were not aware of the presence of these centers. 4/10 of the participants knew the exact location of the Moroccan Poison Control Center in Rabat. But no one knew the role or the purpose of this center. Also, none of the participants had ever contacted the center to report an adverse reaction to a cytotoxic drug. Regarding training about pharmacovigilance, they all affirmed they have not received any courses during their academic training.

ii) ADE reporting: All participants reported having experienced adverse events with cytotoxic drugs. 4/10 stated that the occurrence of these effects was rare, while 6/10 stated that the frequency of these effects was very rare. All participants affirmed that after administering cytotoxics, monitoring of patients is essential. In the occurrence of an adverse event, they immediately inform the treating physician. Regarding their part of the responsibility for reporting adverse events, all participants agreed that adverse events should be reported, but their responsibility consists of monitoring patients and contacting doctors in case of any adverse events: "I should administer the cytotoxics correctly and monitor the patients after administration, if a patient has an adverse reaction, I contact the doctor". All participants declared they had never seen a notification form and were not even aware of its existence. When we asked participants why reporting adverse drug reactions was not their professional responsibility, they all replied that they had never been asked to do so. Also, during their academic training, they did not receive training on reporting adverse drug reactions. One of the participants' comments was "I don't know how to do it and I have never been asked to do it". During the discussion, interviewees were asked about their attitudes towards reporting after training and workshops on reporting adverse events, 7/10 were ready to report these events. "of course, if I am trained and I know how to do it I will do it". 3/10 were did not agree to report because it will be an additional workload for them "with all the work I have to do, the notification will be an additional overwork".

Discussion

To our knowledge, there is relatively little data on nurses' perception of pharmacovigilance in Morocco. The results of this study showed a positive perception but significant insufficiency of pharmacovigilance knowledge among the participating nurses. Similar results were found in the literature. Many studies found a lack of pharmacovigilance knowledge among nurses [19-22]. An Indian study showed that more than half of health professionals are not aware of the national program of pharmacovigilance [23]. A recent systematic review including twenty-three studies about nurses' knowledge, attitudes and practices towards pharmacovigilance concluded that nurses' attitudes were better than their

knowledge and practices in pharmacovigilance [24]. In addition to lack of knowledge, nurses participating in this study believe that notification is not part of their responsibility. A Jordanian study showed that 68.7% of health professionals believe that doctors and hospital pharmacists are the responsible in reporting ADRs [25]. A Turkish study found that the majority of health professionals stated that reporting ADRs is the responsibility of physicians [26].

Lack of training and theoretical/practical courses during the training was the main factor of underreporting in this study. Knowledge has been reported to positively influence the reporting of ADRs [27]. A Moroccan single-center study concluded that pharmacy students' knowledge was improved after training sessions in pharmacovigilance [28]. A cross-sectional study in Canada showed that improving academic training in pharmacovigilance will increase the reporting rate of adverse drug events [29]. A Jordanian team found a significant improvement in the knowledge and perception of health professionals regarding pharmacovigilance after educational workshops [25]. This is why, it is necessary to integrate pharmacovigilance modules into the university training for future nurses in Morocco. Also, additional training and workshops for nurses already working is recommended in order to improve their knowledge of pharmacovigilance and involve them more in the reporting of adverse reactions. Certainly, training in pharmacovigilance will encourage more health professionals to report ADRs, but our study found that even after a training session, almost one third of participants would not be ready to report, and felt that reporting constitutes an additional workload. This result is consistent with a Quebec study which found workload to be the main barrier to reporting [29]. In addition of lack of knowledge and overwork, other reasons for underreporting have been found previously, including fear of sanction and lack of time [30].

Conclusion

ADR reporting remains the only way to monitor drug safety and improve patient security. This study showed a positive perception of nurses towards pharmacovigilance and ADR reporting despite insufficient knowledge. The integration of pharmacovigilance modules in the university training of nurses will help to improve ADR reporting in Morocco.

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