A qualitative exploration of the major challenges facing pharmacovigilance in Saudi Arabia

Hisham Aljadhey, PharmD, PhD, *Mansour A. Mahmoud,* B.Pharm, MSc, *Thamir M. Alshammari,* MSc, PhD, *Mohammed Al-Dhaeefi,* B.Pharm, *Hervé Le Louet,* MD, PhD, *Susana Perez-Gutthann,* MD, PhD, *Peter J. Pitts,* BA.

ABSTRACT

الأهداف: استكشاف التحديات التي تواجه التيقظ الدوائي في المملكة العربية السعودية وصياغة توصيات لتحسين التيقظ الدوائي من وجهة نظر المتخصصين في الرعاية الصحية في المملكة العربية السعودية.

الطريقة: كانت هذه الدراسة عبارة عن أربع مجموعات مناقشة جماعية مع الصيادلة والأطباء والأكاديميين الذي عقد تحت رعاية كرسي أبحاث الأمان الدوائي بجامعة الملك سعود ومركز الدواء للمصلحة العامة. ودعي ما مجموعه 29 من المتخصصين في الرعاية الصحية للمشاركة في الورشة. وكانت موضوعات محددة مسبقا للدراسة في الممارسة الحالية للتيقظ الدوائي والتحديات الرئيسية التي تواجه التيقظ الدوائي في الجهات الرقابية، والمستشفيات، والمجتمع، والأوساط الأكاديمية، وكذلك توصيات لتحسين الممارسات الدوائية.

النتائج: من المدعوين ال 29 ، 27 حضر المناقشة. من بين التحديات التي تواجه الجهات الرقابية صعوبة نماذج الإبلاغ عن الآثار الجانبية للأدوية ، وقلة من ردود الفعل حول التفاعلات المقدمة إلى الهيئة السعودية للغذاء والدواء ، عدم وجود قرارات من السلطة المحلية لسحب الأدوية ، وعدم وجود بيانات على التيقظ الدوائي. وتضمنت التحديات التي تواجه التيقظ الدوائي في المستشفيات عدم معرفة أهمية الإبلاغ عن الآثار الجانبية للأدوية ، وعبء العمل، وثقافة اللوم، وعدم وجود تعاون بين الجهات الرقابية والمستشفيات. شملت التحديات التي تواجه الصناعة الدوائية عدم وجود الكثير من مصنعي الأدوية في المملكة العربية السعودية، وعدم الاهتمام بالتيقظ الدوائي. وتضمنت التوصيات لتحسين التيقظ الدوائي الحاجة للاتصال ووجود متطلبات تنظيمية أقوى، والحاجة للبحث، والحاجة إلى نماذج الإبلاغ عن الآثار الجانبية للأدوية موحدة، والتعليم والتدريب المستمر.

الخاتمة: الدراسة قد حددت التحديات التي تواجه التيقظ الدوائي في المملكة العربية السعودية وقدمت توصيات للتغلب على هذه التحديات. هذه التوصيات قد تكون مفيدة للجهات الرقابية لتعزيز الإبلاغ التلقائي عن الآثار الجانبية للأدوية وتعزيز التيقظ الدوائي.

Objectives: To explore the challenges facing pharmacovigilance in Saudi Arabia and formulate recommendations to improve it from the perspective of healthcare professionals in Saudi Arabia.

Methods: This was a qualitative study of 4 focus group discussions with pharmacists, physicians, and academicians held under the auspices of the King Saud University School of Pharmacy and the Center for Medicine in the Public Interest, Riyadh, Saudi Arabia. A total of 29 eligible healthcare professionals were invited to participate in the discussion. The predefined themes of the study were the current practice and major challenges facing pharmacovigilance in regulatory bodies, hospitals, the community, and academia, as well as recommendations to improve pharmacovigilance practice.

Result: Of the 29 participants invited, 27 attended the discussion. Challenges facing regulatory bodies included complicated adverse drug reactions (ADR) reporting forms, lack of feedback on ADRs submitted to the Saudi Food and Drug Authority, lack of decisions from the local authority to withdraw medications, and lack of data on pharmacovigilance. The challenges to pharmacovigilance in hospitals included the lack of knowledge of the significance of ADR reporting, workload, blaming culture, and lack of collaboration between regulatory bodies and hospitals. However, challenges facing pharmaceutical industries included the lack of drug manufacturers in Saudi Arabia and lack of interest in pharmacovigilance. Recommendations to improve pharmacovigilance included the need for communication, stronger regulatory requirements, the need for research, the need for unified ADRs reporting, and continuous education and training.

Conclusion: The study has identified the challenges facing pharmacovigilance in Saudi Arabia and made certain recommendations to overcome them. These recommendations might be helpful for regulatory bodies to enhance spontaneous reporting and promote pharmacovigilance.

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From the Medication Safety Research Chair (Aljadhey, Mahmoud, Al-Dhaeefi), College of Pharmacy, King Saud University, Riyadh, University of Hail (Alshammari), College of Pharmacy, Hail, Kingdom of Saudi Arabia, Henri Mondor University Hospital (Le Louet), Paris, France, RTI Health Solutions (Perez-Gutthann), Barcelona, Spain and the Center for Medicine in the Public Interest (Pitts), New York, United States of America.

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Address correspondence and reprint request to: Dr. Hisham Aljadhey, Director of Medication Safety Research Chair, College of Pharmacy, King Saud University, Riyadh, Kingdom of Saudi Arabia. E-mail: haljadhey@ksu.edu.sa

The World Health Organization (WHO) defined pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem".[1] Pharmacovigilance has changed the scope of drug safety to encompass both pharmacological effects of medicine and the way that medicine is used in actual practice. The post-marketing assessment of the benefits and risks of medical products can be achieved through collaborative efforts from regulatory bodies, healthcare providers, and the patients.[2] Therefore, effective pharmacovigilance systems should listen to the patients and healthcare professionals, collaborate with other pharmacovigilance centers, and ensure an excellent spontaneous reporting database.[3] The thalidomide tragedy which was detected in 1961 has lead the WHO to establish a program for international drug monitoring.[1] The Saudi Food and Drug Authority (SFDA) established a national pharmacovigilance center in March 2009 under the vigilance and crisis management executive directorate.[4] Following the establishment of the Saudi national pharmacovigilance center, Saudi Arabia become a member of the WHO pharmacovigilance program.[4] This center is part of the SFDA, and it is connected with WHO Uppsala monitoring center to provide them with the local Saudi Adverse Drug Reactions (ADRs). The center accepts ADR reports from the public, healthcare professionals, and pharmaceutical industries through various means of communication; however, to date, few ADR reports have been received. In Saudi Arabia, a study showed that the national pharmacovigilance center received an approximately 439 reports (6%) in 2009; however, we should consider that this underestimate the real number of ADRs per year as not all ADRs are reported to Saudi FDA. In the period between 2009 and 2012, there were 2127 (15%) reports reported from Saudi hospitals. Of those, 1859 (12.6%) reports reported by pharmacists.[5] In addition, studies conducted in the community pharmacy settings reported that few pharmacists have ever reported ADRs.[5,6] Possible causes for under-reporting of ADRs were a lack of awareness of the method of ADR reporting, reliance on physicians to report ADRs, underestimation of ADRs' seriousness, uncertainty on the causal relationship between the ADR and the medication, and unavailability of ADR reporting forms.[6-8] With the ongoing debates on the pharmacovigilance improvement in various countries,[9] we aimed to explore the current practice of pharmacovigilance and challenges facing it from the perspective of healthcare professionals to gain an understanding and draw a road map for better pharmacovigilance practice in Saudi Arabia.

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Methods. This was a qualitative focus group discussion study held under the auspices of the King Saud University School of Pharmacy and the Centre for Medicine in the Public Interest, in May 2014. Eligible participants in the study were healthcare professionals working in regulatory bodies, hospitals, community settings, or academia. A list of 29 eligible participants with relevant experience in pharmacovigilance from Riyadh city was prepared, and all participants were invited to participate in the focus group discussion. Of these, 12 were females and 17 were males.

Participants were divided into 4 focus group discussions. Each group included people of different backgrounds. Two groups consist of female, and the other 2 groups consist of males. When possible, each group consists of at least one person from regulatory bodies, hospitals, community settings, or academia. A facilitator was assigned to each group to facilitate the discussion. In addition, one of the authors took notes during the discussion. Each focus group discussion lasted 90 minutes. Then, a plenary discussion was open for all participants, managed by a moderator. The main topics discussed were current practice and major challenges facing pharmacovigilance in regulatory bodies, hospitals, the community, and academia. Specific questions were asked to ensure that all predefined themes were covered. In addition, the moderator was allowed to ask probing questions when necessary. The discussions were conducted in the English language. Permission to conduct the study was obtained from the ethical committee of King Saud University.

The 4 focus group discussions were audio taped, transcribed verbatim and coded. Then, the transcripts and notes taken during the discussion were analyzed by one of the researcher using thematic content analysis. The final quotes under each theme were reviewed by a second researcher to ensure their reliability and trustworthiness.[10] Confidentiality and anonymity were guaranteed, and all participants were informed that no data leading to the identification of any participant would be published in any form.

Results. We invited 29 eligible participants and 27 attended the focus group discussion. The study included

16 pharmacists, 4 physicians, and seven professors; most of participants were male.

Main themes. We analyzed the focus group data using thematic content analysis. The predefined themes were challenges to pharmacovigilance and recommendations to improve it in regulatory bodies, hospitals, academia, and pharmaceutical industries. Several challenges were identified by the participants in all 4 sectors (regulatory bodies, hospitals, academia, and pharmaceutical companies). Regulatory challenges to pharmacovigilance included complicated adverse drug reactions (ADR) reporting forms, lack of feedback on ADRs submitted to the SFDA, lack of decisions from the local authority to withdraw medications, and lack of data on pharmacovigilance. Each sub-theme is discussed in detail in the following section.

Participants, especially those working in hospitals, believed that the current ADR reporting forms that have been made available from the SFDA are very complicated and need to be simplified to attract more respondents; therefore, most of the hospitals have created their own simple ADRs reporting forms. "*If you do not make the ADRs reporting forms very simple, they will not fill it. From my experience, if you put more than 3 or 4 questions nobody will respond to you*" (Physician, Focus group 1). "*Since the SFDA launched the ADR reporting forms online and during this period nobody from our hospital reported ADRs. I will tell you why: because we do not have standard policies and procedures and the SFDA form is not acceptable by all hospitals, they will not think to waste one second to fill this long form*" (Physician, Focus group 1).

Participants pointed out that there is no point in reporting ADRs to SFDA if they cannot get feedback and support from the SFDA. They hoped that the SFDA would respond to them, and perhaps help them with decisions on the reported ADRs. "*SFDA have lack of feedback! I mean we report ADRs to them, but we don't receive any feedback on the ADRs that we reported. So most of the time we make the decision by ourselves*" (Pharmacist, Focus group 1). Participants underestimated the importance of reporting ADRs to the SFDA because they believed that the SFDA does not have the necessary resources to decide on the withdrawal of a particular medication. "*If a medication has a severe ADR it is rare to see the SFDA withdrawing it from the market. The medication will be in the market as long as it is still available in Europe and the States*" (Physician, Focus group 1).

Some participants appreciated the SFDA efforts to promote pharmacovigilance among the healthcare practitioners. However, in their opinion, these efforts must be supported by data on pharmacovigilance in Saudi Arabia. The participants believed that SFDA could have a role in hospitals, perhaps by assigning representatives to follow up on ADR reporting. Also, participants believed that the lack of data on pharmacovigilance is largely due to the unrestricted access to medications from community pharmacies, because they do not know the patients, and their bio-data are not documented. "*What I see is that the regulatory bodies are doing a great job, but they are not reaching to the point because we don't see any data regarding pharmacovigilance in Saudi Arabia*" (Pharmacist, Focus group 4). "*If you ask me how many ADRs in my hospital this year I cannot give you a number because I do not have documents so the poor documentation and the culture of the people are the main issues*" (Physician, Focus group 1). "*How can we have good pharmacovigilance data when any patient can go and purchase drugs without prescription? We can have data from outpatient clinics and hospitals, but the big amount of data will be missing*" (Pharmacist, Focus group 4).

The focus group participants identified several challenges to pharmacovigilance in hospitals. These include the lack of knowledge of the significance of ADR reporting, workload, culture, and lack of collaboration between regulatory bodies and hospitals. Some participants demonstrated the lack of knowledge on the importance of ADR reporting. They believed that all ADRs are listed in the medication leaflet and there is no need to report them. However, other participants believed that they know the importance of reporting, but their staff lacks commitment to report ADRs due to their busy work environment. "*Most of the medications are imported from outside Saudi Arabia, and to be honest with you in my opinion all these medications are fully studied and fully reported. They know every thing about it so why we should write the report?*" (Physician, Focus group 1). "*In our institution, we have a system to report ADRs and medication errors. We conduct meeting every 2 months with the medical staff and after the meeting we get a good number of reports for a week or 2, but after that everybody forget about it*" (Pharmacist, Focus group 1). Although some healthcare professionals said that they get good ADR reports, they are not satisfied with the number of reports received, possibly due to the huge workload that involves patient care. "*This is a double work, and it takes a lot of time because we have to fill 2 reports, one for the hospital quality department and another one to the Saudi FDA*" (Pharmacist, Focus group 3).

Participants have blamed culture as one of the causes of ADR under-reporting. "*I think doctors do not report ADRs because they think the regulatory will say they are*

bad" (Pharmacist, Focus group 1). Most of participants raised concerns on the availability of different ADR reporting forms in hospitals and the SFDA websites. They believed that if they had to report ADRs they would choose to fill out the hospital ADRs forms. "*Every hospital has their own ADR reporting forms within the hospital, and therefore the hospital staffs do not care about the regulatory ADR reporting forms*" (Physician, Focus group 1). "*Every hospital has their own data, but they do not want to share with others, because of so many unhealthy reasons*" (Academician, Focus group 2).

The challenges to pharmacovigilance from the academic sectors included lack of education on the subject of pharmacovigilance in health sciences colleges. Participants also believed that the under-reporting of ADRs and lack of knowledge on the importance of pharmacovigilance could be due to the unavailability of the subject as part of the medical and pharmacy college students' curriculum. "*We really need intensive education for public, medical, and pharmacy students. If you ask the newly graduated students on this subject, you will find out that they are unaware of it. This subject is considered new here in Saudi Arabia*" (Academician, Focus group 1). "*I think the lack of integrating the concept of basic pharmacovigilance and patient safety is one of the main problems associated with the current challenges*" (Academician, Focus group 2).

Pharmacovigilance challenges in the pharmaceutical industries included the lack of drug manufacturers in Saudi Arabia. Almost all participants pointed out that there are few local pharmaceutical manufacturers. They believed that this is a major challenge to the future of pharmaceutical industries and to the lack of interest in pharmacovigilance. "*We have few drug manufacturers and they have a poor interest in pharmacovigilance. The reason for this is that pharmacovigilance activities will not bring financial benefit to the company so why bother and spend money and resources in it, unless there is a pressure from the regulatory bodies?*" (Academician, Focus group 2).

Participants made several recommendations to improve the current pharmacovigilance practice in Saudi Arabia. Recommendations to improve pharmacovigilance in regulatory sectors included communication, regulatory requirements to activate pharmacovigilance activities, the need for research, unified ADR forms, and need for continuous education. Participants have called on strengthening communication on pharmacovigilance through media and other resources. "*Communication with the public through media and workshops are the most important thing, and we do not have it here*" (Pharmacist, Focus group 3). "*I think the regulatory bodies, and other interested parties should identify the stakeholders and invite them to table meetings and clear to them our vision and what we are looking for and then they go back to their administration and pharmacy and hospitals*" (Pharmacist, Focus group 4). "*I recommend that The Saudi Commission for Health Care Specialties should make knowledge on pharmacovigilance as part of their requirements during Saudi Pharmaceutical Board Examinations*" (Academician, Focus group 1)

Participants believed that the SFDA should be independent in their decisions on pharmacovigilance. They suggested that the SFDA have more initiatives that support post-marketing surveillance studies. "*My dream is that the SFDA do not follow the United States FDA and do it is own research and own decision*." (Pharmacist, Focus group 1). "*We need to start extensive and structured research agenda to know where we are now and what we need to do in the future*" (Physician, Focus group 2). "*We have few published studies in medication safety in general. But, we still cannot say it is representative to our society. After all, we do not need to reinvent the wheel; we have a good structure to build on and that should be our focus*" (Academician, Focus group 2). "*We need to collect evidence through research to convince the top authorities that pharmacovigilance is a public interest*" (Pharmacist, Focus group 2).

In order to overcome the obstacles of having separate forms to report ADRs in hospitals and to the SFDA, most healthcare professionals working in the hospitals suggested a unified form that can be used by both hospitals and the SFDA. Participants pointed out that filling out both forms is time consuming and could potentially contribute to ADR under-reporting. "*Reporting ADRs to SFDA and the hospitals are a double work. We need unified ADR reporting forms that can be utilized by both the SFDA and the hospitals*" (Pharmacist, Focus group 1). Continuous education was one of the recommendations to keep the industry, the public and healthcare professionals up to date on the new drugs that are available in the market. "*Due to new generation of drugs, the regulatory bodies should conduct continuous education and update the public and healthcare professionals*" (Physician, Focus group 2) "*The Saudi FDA cannot do it alone. They need collaboration from other ministries such as the Ministry of Health*" (Academician, Focus group 2).

Most of participants believed that educating the public and all health science college students on the concept of pharmacovigilance in Saudi Arabia are very important. Therefore, they suggested that a course in pharmacovigilance be integrated in the curriculum of undergraduate students. "*Pharmacovigilance should be taught as a mandatory course in all health science college*

and not only in school of pharmacy because everybody should report ADRs" (Academician, Focus group 1).

Several initiatives were recommended by the participants including the establishment of an ADR reporting team, intensive programs on pharmacovigilance, and restricting access to prescription drugs from public pharmacies. Participants recommended having a special team with the responsibility of investigating and reporting ADRs in each hospital. "*I mean there should be a team responsible to report ADRs, if there is any problem associated with any drug they should investigate it and fills the ADR report*" (Physician, Focus group 2). Participants from academic sectors recommended an intensive program on pharmacovigilance for all health care professionals. "*An intensive training program on pharmacovigilance for physician, nurses and pharmacists are needed. Perhaps making ADR reporting as part of the internship program will enhance the interns' knowledge*" (Academician, Focus group 2). Participants pointed out the necessity to restrict community pharmacies from selling prescription drugs without a prescription. "*Even the community pharmacy need more control from the MOH and SFDA. As we heard previously in the media students can buy Lyrica® (Pregabalin) from community pharmacies during exam*" (Pharmacist, Focus group 4).

Discussion. We performed a qualitative study of healthcare professionals with diverse experiences to explore the current practice and challenges of pharmacovigilance. Challenges of pharmacovigilance related to regulatory bodies included complicated ADRs reporting forms, lack of feedback to other healthcare authorities, and the lack of data on pharmacovigilance activities. In addition, there is a lack in activating all pharmacovigilance activities by the SFDA, such as evaluating the current situation of reports and whether there is a specific signal, especially in the local reports. Risk management plans (RMPs) are not fully applied by the SFDA as there are many steps that can be taken before withdrawing a drug from the market or revoking an indication for any drug. Furthermore, the impacts of other RMPs on regulatory decisions that have proven to be effective elsewhere need to be evaluated in Saudi Arabia.

The committees that help the SFDA in their decisions should be system-based (namely, committee for cardiovascular, committee for pediatrics, and so forth), and these committees should be consulted on topics related to their specialties. From a hospital's perspective, the challenges identified to include a lack of hospital staff knowledge of the importance of ADRs reporting, a heavy workload that does not allow time for ADRs reporting, and placing blame on the culture for contributing to under-reporting. Also, there is a need to have specific units or departments responsible for monitoring the safety of medications as well as medication errors in each hospital. These departments will help to reduce the incidence of harm from medications by performing preventive measures and to act as a point of contact with the regulatory body.

Regarding the academia, challenges included the unavailability of pharmacovigilance as a subject of study in health sciences colleges. Participants suggested several recommendations including unified ADR reporting forms and the need for continuous education for healthcare practitioners to increase awareness. Pharmacovigilance educational intervention[11] and promotion of ADRs reporting by healthcare professionals[12] that have been proved to be effective in other countries should be adopted in Saudi Arabia.

One of the main reasons for ADR under-reporting in the present study was the lack of knowledge on the detection of ADRs and the lack of awareness on the ADR reporting forms. Similar findings were reported in other studies.[13-22] A heavy workload was believed to be one of the reasons for a lack of time for ADR reporting. Similarly, other studies reported the workload as one of the obstacles to spontaneous reporting of ADRs by healthcare professionals.[13,23] As reported in our study, lack of feedback from the regulatory bodies on the suspected ADRs was one of the challenges reported by a recent study.[13] Perhaps this negligence will contribute to hesitation on reporting ADRs in the future, considering that some healthcare professionals might not have enough confidence to report ADRs.[13,14]

Healthcare professionals should be trained continuously on the importance of pharmacovigilance. The involvement of patients in ADR reporting might play an important role in the improvement of pharmacovigilance.[24] However, the regulatory authority needs to make serious efforts to increase the awareness of patients and the public on ADR reporting. Health sciences colleges must incorporate pharmacovigilance courses in their curriculum to increase future healthcare providers' awareness at an early stage of their career.

In conclusion, our focus group discussion has identified the challenges facing pharmacovigilance in Saudi Arabia and formulated recommendations to improve pharmacovigilance. These recommendations might be helpful for regulatory bodies to enhance spontaneous reporting and promoting

pharmacovigilance efforts. These recommendations warrant investigation in future studies.

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