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

To the Editor

We read with great interest the article by Hisham AlJadhey et al[1] regarding the major challenges facing pharmacovigilance in the Kingdom of Saudi Arabia (KSA). We have been associated with pharmacovigilance in Nepal for many years. The first author was involved with the establishment and the operation of 2 regional pharmacovigilance centers in the country, and the second author is the chief pharmacovigilance officer at a regional center affiliated to a medical school in the country. We found many similarities and certain differences between the observed situation in KSA and the one in Nepal, a landlocked developing country in South Asia. The authors describe the respondents' perception regarding the complicated nature of the form designed by the Saudi Food and Drug Administration. In Nepal the form designed by the Department of Drug Administration (DDA), the national regulatory agency is simple and easy to use. However, many regional centers as in KSA have created their own forms based on the DDA form.

The issue of providing feedback to the doctors, nurses, and other personnel who report adverse drug reactions (ADRs) mentioned by the respondents is an important one. Health workers may be more motivated to report ADRs if they understand that reporting ADRs can improve their prescribing. A similar situation is noticed in Nepal, and all prescribers in Nepal should be informed regarding the present safety status of different marketed medicines, which would enable prescribing and dispensing decisions to be modified according to the national data.[2] Unrestricted access to medicines from community pharmacies is a big problem in Nepal as well, and patients can purchase any medicine without a prescription. Community pharmacists can play an important role in pharmacovigilance in Nepal and other developing countries, and should be trained to report ADRs.[3] The issues mentioned by respondents regarding ADR reporting in the KSA setting are of relevance to Nepal. Increased workload, which reporting ADRs would entail and heavy patient load are reasons commonly offered for reluctance to report. In Nepal, many health professionals had a wrong perception that they should be confident that a particular ADR was associated with a medicine before they could report. In educational sessions conducted for health professionals, we emphasized that many ADRs may only be possibly, or probably associated with a particular medicine, and it is not necessary to be sure and only to be suspicious while reporting ADRs. Respondents mentioned teaching health science students of pharmacovigilance as an important initiative. Like in KSA, most health science students in Nepal lack knowledge about pharmacovigilance. At KIST Medical College in Nepal, we have been conducting sessions on pharmacovigilance for medical students.[4] In many countries, patients and consumers are involved in ADR reporting. Consumer pharmacovigilance has many advantages, which have been explored in a recent article. Consumer reporting can reinforce ADR reporting systems, and partly address the problems of under-reporting.[5] Consumer reporting could be another approach, which could be tried to strengthen pharmacovigilance systems in both Nepal and Saudi Arabia. The authors must be congratulated on an important study, which highlights the challenges facing the pharmacovigilance program in KSA. Similar challenges exists in Nepal and other countries in South Asia, and a similar study conducted in Nepal may yield important and relevant results.

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Reply from the Author

We want to thank Dr. Shankar and his colleagues for their correspondence and interest in our paper published in the Saudi Medical Journal. It is interesting to have similarities in the challenges in pharmacovigilance facing 2 countries in such different parts of the world. This indicates that the issues facing pharmacovigilance are of a global nature, and needs to be addressed even in those countries who think they do not have a problem. Our study presented the opinion of participants in one qualitative study and does not represent our opinion regarding the pharmacovigilance system in KSA more broadly.

On May 2015 in Riyadh, KSA, the Medication Safety Research Chair at King Saud University and the Center for Medicine in the Public Interest sponsored

a workshop on "Pharmacovigilance in Saudi Arabia." Twenty-first century pharmacovigilance in KSA, indeed throughout the world, must be on more than just adverse drug reaction (ADR) reporting - it must be on regulatory leadership in safety, in safe use, and in achieving better and more regular positive therapeutic clinical outcomes. In addition to the size and scope of modern medicines, new expedited and conditional pathways for approval also require more robust and interactive pharmacovigilance via more regular and creative risk management plans. Risk management cannot exist without a more holistic understanding and acceptance of the responsibilities of risk.

A twenty-first century strategy for pharmacovigilance (in KSA and around the world) must also include attention to clinical outcomes, and this means a new focus on a new area - Substandard Pharmaceutical Events (SPEs). In a world where generic medicines include large molecules, critical dose drugs, and narrow therapeutic index products, pharmacovigilance programs must extend beyond the traditional World Health Organization definition. The SPEs occur when a product does not perform as expected, perhaps due to the API or excipient issues. Substandard pharmaceutical events can arise because of an issue related to therapeutic interchangeability. When it comes to the twenty-first century pharmacovigilance, we have to both broaden and narrow our views about bioequivalence to the patient level. Twenty-first century pharmacovigilance means doing what is right in addition to what has been traditionally required. Traditional risk management means finding ways to avoid risk, to mitigate it. That is important, but its tactical, and very twentieth century. In the twenty-first century, we have to invent new strategies. For pharmacovigilance to play its appropriate role in the safe use of all regulated products, and particularly of personalized medicines, collection, investigation and communication, and action on issues raised by SPEs, must be a new pillar of regulatory oversight.

Another key regulatory question is the appropriate role of regulators in coordinating input from crucial partners, such as physicians, nurses, pharmacists, disease organizations, patients, and pharmaceutical manufacturers. "Real World" event monitoring must become as specific and informing as in a clinical trial environment. To borrow a term from the nuclear disarmament discussion, 21st century pharmacovigilance must work with its various colleagues to "trust, but verify."

We are convinced that 21st century pharmacovigilance must expand its purview beyond ADRs to helping to enhance safe use and patient outcomes. Twenty-first century pharmacovigilance is 21st century healthcare leadership, and much of that leadership can come from regional regulatory leaders, such as those in KSA.

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