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Editorial

Adverse Drug Event Reporting: Awareness Is Not Enough

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Most drugs are used in a larger and more heterogenous population after they are brought to market than initially was evaluated in preapproval trials. Postmarketing pharmacovigilance provides data that enhance the rational and safe use of medications. In particular, the safety profile of drugs is dynamic; new information is continually assessed regarding use and outcomes. Among postmarketing surveillance methods, national voluntary reporting systems are an important conduit for the collection of information about specific adverse events involving medications. In the United States, the Food and Drug Administration's (FDA) MedWatch program collects voluntary reports from health care professionals and consumers about adverse drug reactions and errors related to drugs, biologics, nutritionals, and devices.[1] Data regarding voluntary reports on adverse events associated with vaccines are collected via the Vaccine Adverse Event Reporting System (VAERS), a program co-sponsored by the FDA and the Centers for Disease Control and Prevention (CDC).[2] Information about medication and vaccine errors are also collected via other voluntary programs founded by the Institute of Safe Medication Practices: Medication Errors Reporting (ISMP MERP) and National Vaccine Reporting Program (ISMP VERP).[3] All programs allow for individuals to confidentially report an incident, for the analyses of data to identify potential trends and problems, and for the provision of information to the global health community for optimizing patient safety.

Because these national reporting programs depend upon voluntary participation, they are limited by under-reporting and a variance in the quality of the reports received. In addition, inference regarding incidence data is limited by the lack of denominator information on overall use. Despite these limitations, MedWatch, VAERS, and ISMP programs positively impact patient care by promoting safe health care practices. The continued participation of health care professionals in the voluntary reporting of adverse events associated with medications and devices is essential in the promotion of patient safety. Because of the nature of the pharmacy profession and its involvement in patient care regarding medications, pharmacists play an important role in adverse drug reaction (ADR) reporting. Participation first requires knowledge and awareness of such programs. Recent studies that evaluated the knowledge and attitudes of US pharmacists regarding ADR show that, despite favorable attitudes toward reporting, many pharmacists have never reported an adverse drug event to the MedWatch program or admit to having inadequate knowledge regarding reporting mechanisms.[4-6] The United States is not alone in this; several international studies have documented a lack of pharmacist awareness of or experience with ADR reporting, which is a deterrent to participation in similar national programs.[7-10]

Because of this low incidence of pharmacist participation, it is essential for pharmacy school curricula to include information about adverse drug reaction and medication error reporting. Students need to gain awareness, experience, and confidence in recognizing adverse drug reactions and knowing which reactions necessitate a report to a facility or national monitoring event program. Surveys about current curricula reveal that pharmacy students' awareness with ADR and MERP programs is improving, but they do not know how to report and do not have experience with actual reporting of serious events.[11-13] International reports indicate that pharmacy curricula in other countries have the same shortcomings.[14-16] Knowledge is not enough. Awareness is not enough. Experience with assessment of adverse reactions and reporting of appropriate reactions is necessary. Faculty, instructors, and preceptors are encouraged to include ADR assessment and reporting experiences in the didactic and experiential curricula. The FDA

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has released a new MedWatch training program, MedWatch *Learn*,[17] that is directed at teaching health professionals, students, and patients how to complete the online FDA forms necessary to report various types of problems (eg, adverse drug reaction, product problem, medication error). Each form is accompanied by a case scenario that requires assessment of patient variables to complete the process. The user may prompt for helpful tips that aid in the completion of the form and define and explain the importance of the specific parameter for reporting purposes. Feedback via an answer key is provided for each case. This model is a useful approach for improving familiarity with reporting mechanisms. A similar model is used for patient reporting.

Increasing health professional and student participation in national medication reporting programs remains an important goal in promoting safe health care practices. Opportunities for improvement in pharmacy curricula and practice sites toward interactive experiences with reporting programs should be continually evaluated.

REFERENCES

1. US Food and Drug Adminstration. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. http://www.fda.gov/Safety/MedWatch/default.htm. Accessed December 22, 2013.

2. Vaccine Adverse Event Reporting System. https://vaers.hhs.gov/index. Accessed December 22, 2013.

3. National Medication Error Reporting System. https://www.ismp.org/orderforms/reporterrortoismp.asp. Accessed December 22, 2013.

4. Gavaza P, Brown CM, Lawson KA, Rascati KL, Steinhardt M, Wilson JP. Pharmacist reporting of serious adverse drug events to the Food and Drug Administration. *J Am Pharm Assoc*. 2012;52(5):e109-12.

5. Gavaza P, Brown CM, Lawson KA, Rascati KL, Wilson JP, Steinhardt M. Texas pharmacists' knowledge of reporting serious adverse drug events to the Food and Drug Administration. *J Am Pharm Assoc*. 2011;51(3):397-403.

6. Gavaza P, Brown CM, Lawson KA, Rascati KL, Wilson JP, Steinhardt M. Influence of attitudes on pharmacists' intention to report serious adverse drug events to the Food and Drug Administration. *Br J Clin Pharmacol*. 2011;72(1):143-152.

7. Prakasam A, Nidamanuri A, Kumar S. Knowledge, perception and practice of pharmacovigilance among community pharmacists in South India. *Pharm Pract (Granada)*. 2012;10(4):222-226.

8. Ahmad A, Patel I, Balkrishnan R, Mohanta GP, Manna PK. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study. *Perspect Clin Res*. 2013;4(4):204-210.

9. Santosh KC, Tragulpiankit P, Edwards IR, Gorsanan S. Knowledge about adverse drug reactions reporting among healthcare professionals in Nepal. *Int J Risk Saf Med*. 2013;25(1):1-16.

10. Pérez García M, Figueras A. The lack of knowledge about the voluntary reporting system of adverse drug reactions as a major cause of underreporting: Direct survey among health professionals. *Pharmacoepidemiol Drug Saf*. 2011;20(12):1295-1302.

11. Gavaza P, Bui B. Pharmacy students' attitudes toward reporting serious adverse drug events. A*m J Pharm Educ*. 2012;76(10):194.

12. Sears EL, Generali JA. Adverse drug reaction and medication error reporting by pharmacy students. *Ann Pharmacother*. 2005;39(3):452-459.

13. Kalari S, Dormarunno M, Zvenigorodsky O, Mohan A. Pharmacy student perceptions of adverse event reporting. *Am J Pharm Educ*. 2011;75(7):131.

14. Smith MP, Webley SD. Pharmacovigilance teaching in UK undergraduate pharmacy programmes. *Pharmacoepidemiol Drug Saf*. 2013;22(3):223-228.

15. Elkalmi RM, Hassali MA, Ibrahim MI, Widodo RT, Efan QM, Hadi MA. Pharmacy students' knowledge and perceptions about pharmacovigilance in Malaysian public universities. *Am J Pharm Educ*. 2011;75(5):96.

16. Cox AR, Marriott JF, Wilson KA, Ferner RE. Adverse drug reaction teaching in UK undergraduate medical and pharmacy programmes. *J Clin Pharm Ther*. 2004;29(1):31-35.

17. US Food and Drug Administration. MedWatch*Learn*. http://www.accessdata.fda.gov/scripts/MedWatchLearn/. Accessed December 22, 2013. ■