Pharmacovigilance in the Middle East

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Background: The importance of countries to support their own national pharmacovigilance cannot be understated: citizens may have unique ethnicities, traditions, and diets influencing reaction to medication; alternate brands of therapy may be imported or manufactured and differ in ingredients or production processes; ADRs and toxicities associated with traditional and herbal remedies also need to be monitored. The objective of this study is to inventory national pharmacovigilance systems in place in the Middle East region.

Methods: The Uppsala Monitoring Center Assessment of Country Pharmacovigilance Situation (February 2008) was adapted and translated into Arabic. Survey domains pertain to general program overview; information technology support; suspected ADR reporting and subsequent data use; pharmacovigilance activity and advocacy. A comprehensive search was conducted to determine the existence of a governing body responsible for medication safety in 13 Arabic speaking Middle Eastern countries. Surveys were emailed to the head of the identified centres, with follow-up messages and telephone calls subsequently made as necessary.

Results: Data for 10 countries was obtained: representatives from two countries did not respond (Lebanon, Syria). Six described formal national pharmacovigilance programs (Egypt, Iraq, Jordan, Oman, Saudi Arabia, and the UAE), while five (Bahrain, Kuwait, Palestine, Qatar, Yemen) reported no active program or designated center. All active programs were recently formed (< 5 years). The majority (83%) are government funded and two (33%) receive suspected ADR reports and offer drug information services. Most (83%) welcomed reports from a wide variety of health professionals, as well as from the public. Sixty-seven percent facilitated submission to the centre by email, but none directly through a web-based platform. All used the information for drug regulatory purposes but only 2 (33%) reported dissemination of safety information to the public.

Conclusion: This is the first comprehensive review of the status of pharmacovigilance in the Middle East. While a number of countries participate in suspected ADR reporting activities, an estimated population of 30-50 million is without formal domestic programs. Technology must be exploited to ease spontaneous reporting and subsequent data management. Existing mechanisms for regional collaboration should be advanced so experience from model programs can be shared.