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SHORT COMMUNICATION

Pharmacovigilance in the Middle East

A Survey of 13 Arabic-Speaking Countries

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Abstract
Background The importance of countries to support their own national pharmacovigilance cannot be understated. While adverse drug reaction (ADR) data from other countries is helpful in making medication safety decisions, information may not be relevant or applicable to domestic populations.
Objective The aim of this study was to inventory national pharmacovigilance systems in place in the Middle East region.
Materials and Methods The Uppsala Monitoring Centre Assessment of Country Pharmacovigilance Situation questionnaire (February 2008) was adapted and translated into Arabic and administered to the head of the identified centres responsible for medication safety in 13 Arabic-speaking Middle Eastern countries. This survey contains domains pertaining to general programme information; overview of technology and personnel support; suspected ADR reporting and subsequent data use; and pharmacovigilance activity and advocacy.
Results Data for 11 countries were obtained: representatives from two countries did not participate (Lebanon, Syria). Six described formal national pharmacovigilance programmes (Egypt, Iraq, Jordan, Oman, Kingdom of Saudi Arabia and the United Arab Emirates), while five (Bahrain, Kuwait, Palestine, Qatar and Yemen) reported no active programme or designated centre. The majority are government funded, but staff resources are constrained, ranging from two to ten people. Sixty-seven percent of programmes facilitated submission of spontaneous ADRs to the centre by email, but none directly through a web-based platform. All used the information for drug regulatory purposes and five reported dissemination of safety information to the public.
Conclusions This is the first survey to inventory 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 programmes. Current emphasis of drug safety in the region is on detection and prevention of counterfeit products reaching the consumer. Existing mechanisms for regional collaboration should be advanced so experience from model programmes can be shared. Technology must be exploited to enhance ease of spontaneous reporting and subsequent data management.

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1 Background

Adverse drug reaction (ADR) reporting is the cornerstone of pharmacovigilance activity. Such postmarketing surveillance contributes new and often significant information regarding a medication's safety profile, particularly among broader populations than those included in clinical trials, such as children, pregnant women, the elderly and patients with multiple co-morbidities. However, it has been previously demonstrated that the majority of global information related to ADRs arises from Western nations [1]. The importance of countries to support their own national pharmacovigilance programme cannot be understated. While ADR data from other countries is helpful for local regulatory bodies to make medication safety decisions, information may not be relevant or applicable to its population. Citizens may have unique traditions and diets influencing reactions to medication. Alternative brands of

therapy may be imported or manufactured and differ in ingredients or production processes. The ADRs associated with traditional and herbal remedies also need to be monitored in each country. In some cases, adverse reactions to certain drugs may only occur in a particular ethnic group.

ADR reporting infrastructure varies throughout the world [2, 3]. Surveillance programmes within individual healthcare facilities may supplement a central national registry, which may in turn augment an international database. Most reporting systems are voluntary. Spontaneous reporting offers advantages of low expense and complexity, but time, ambiguity in ADR identification and lack of feedback are among the barriers contributing to underreporting by health professionals throughout the world [4–11]. The nature of ADR reporting systems and generated data is not currently readily available for the Middle East region.

The objective of this study was to inventory national pharmacovigilance programmes in place for Arabic-speaking countries in the Middle East.

2 Methods

The WHO Collaborating Centre for International Drug Monitoring has previously carried out a review of national pharmacovigilance systems and the Uppsala Monitoring Centre Assessment of Country Pharmacovigilance Situation questionnaire (February 2008) [25] was adapted for our study. A native Arabic speaker fluent in English translated the survey into Arabic (forward translation) and then the document was back-translated into English by a second native Arabic speaker fluent in English who was blinded to the original English version [12]. Any discrepancies were then reviewed, discussed and corrected.

Survey domains pertained to general programme information (contact information, year established); level of support (staff, technology, funding); pharmacovigilance activities; suspected ADR reporting and subsequent data use; and medication safety 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 identified head of the centres, with follow-up messages and telephone calls subsequently made as necessary. Responses to the questionnaire were received over a 6-month period. Ethics approval was obtained from the Qatar University Institutional Review Board.

3 Results

Data for 11 of 13 countries were obtained: representatives from one country did not respond within the study time period (Lebanon) and those from another country refused consent (Syria) (Table 1). Six countries possess formal national pharmacovigilance programmes (Egypt, Iraq, Jordan, Kingdom of Saudi Arabia [KSA], Oman and the United Arab Emirates [UAE]), while five (Bahrain, Kuwait, Palestine, Qatar and Yemen) reported no active programme or designated centre. With the exception of Jordan and Oman, all active programmes were formed in the past 3 years) and all are overseen by or affiliated with the government. The Egyptian Pharmacovigilance Centre receives additional operational funding from private sources. Many centres have few full-time staff members available to conduct operations: only two personnel in each of Iraq, Jordan, the UAE and Oman; but nine to ten personnel in both KSA and Egypt.

Five national centres focus their pharmacovigilance activities on receiving suspected ADR reports, while two (Jordan and Oman) are also involved in formal provision of drug information. None reported participation in poison information services, monitoring of medication errors or therapeutic ineffectiveness. A number of countries operate drug and poison information programmes that are separate from the government-based pharmacovigilance centre (Egypt, Jordan, KSA, Oman and the UAE).

It is a legal requirement for manufacturers to report suspected ADRs associated with their licensed products in all countries, except Iraq. Mandatory reporting of suspected ADRs by hospitals to national centres was also described for most countries (Iraq, Jordan, Oman and the UAE). All centres accepted reports from health professionals (physicians, pharmacists and nurses), as well as from individual patients (except Iraq), but it is not clear how the latter is promoted among the general public. While only Iraq and Oman do not facilitate suspected ADR report submission to the centre by email (fax or regular mail here is preferred), none have configured direct report through a remote-access web-based platform. Reporter access to reporting forms was principally through inclusion in hospital formulary documentation (e.g. handbook) at healthcare facilities; at pharmacies (except Egypt and Jordan); via the Internet (except Oman); or on demand from the centre itself (except Iraq and Jordan). Four countries describe this distribution as a singular standard national form (Iraq, Jordan, Oman and the UAE). The majority formally acknowledge receipt of the suspected ADR to the reporter (except Oman). The number of reports shared by these programmes in this questionnaire is given in Table 1.

In addition to suspected ADR reports of medicines, all also accepted case reports of safety issues with vaccines, herbal products (except Egypt), medical devices (except KSA and Oman) and cosmetics (except Egypt and Iraq). Three centres recorded reports using software shared by the WHO (Jordan and Iraq using Vigiflow®, and Oman using

Table 1 National pharmacovigilance programme characteristics of Arabic-speaking countries in the Middle East

Programme overview	BA	EG	IR	JO	KU	KSA	LE	OM	PA	QA	SY	UAE	YE
National pharmacovigilance programme	–	✔	✔	✔	–	✔	●	✔	–	–	●	✔	–
National pharmacovigilance programme launch—domestic (year)	–	2009	2010	2001	–	2008	●	1995	–	–	●	2008	–
WHO Programme for International Drug Monitoring member country	✔[a]	✔	✔	✔	–	✔	●	✔	–	–	●	–	–
WHO Uppsala Monitoring Centre software user (Vigiflow® or Intdis®)	–	–	V	V	–	–[b]	●	I	–	–	●	–	–
Overseen by government agency	–	✔	✔	✔	–	✔	●	✔	–	–	●	✔	–
Government-funded	–	✔[c]	✔	✔	–	✔	●	✔	–	–	●	✔	–
Full-time staff (when surveyed in 2010)	–	10	2	2	–	9	●	2	–	–	●	2	–
Pharmacovigilance combined with drug (DI) or poison information services	–	–	–	DI	–	–	●	DI	–	–	●	–	–
National suspected ADR reporting form	–	–	✔	✔	–	–	●	✔	–	–	●	✔	–
Mandatory suspected ADR reporting by hospitals	–	–	✔	✔	–	–	●	✔	–	–	●	✔	–
Accepted reports													
Traditional or herbal medicines	–	–	✔	✔	–	✔	●	✔	–	–	●	✔	–
Biologicals, including vaccines	–	✔	✔	✔	–	✔	●	✔	–	–	●	✔	–
Medical devices	–	✔	✔	✔	–	–	●	–	–	–	●	✔	–
Cosmetics	–	–	–	✔	–	✔	●	✔	–	–	●	✔	–
Reports accepted by general public (patients)	–	✔	–	✔	–	✔	●	✔	–	–	●	✔	–
Number of submitted reports in 2009	–	56[d]	–	42	–	202	●	831	–	–	●	351[e]	–
Activities to promote national reporting													
Health professional education and training (lectures or conferences)	–	✔	✔	✔	–	✔	●	✔	–	–	●	✔	–
Payment to reporters	–	–	–	–	–	–	●	–	–	–	●	–	–
Articles in professional journals or newsletters	–	✔	✔	–	–	✔	●	✔	–	–	●	✔	–
Articles or programmes in general media	–	✔	✔	–	–	✔	●	–	–	–	●	–	–
Inclusion of pharmacovigilance content in health professional schools	–	✔	–	–	–	–	●	–	–	–	●	–	–
Involvement of health professional organizations or associations	–	–	✔	✔	–	✔	●	–	–	–	●	–	–
Email/Internet	–	✔	✔	✔	–	✔	●	–	–	–	●	–	–
Paid advertisements	–	–	✔	–	–	✔	●	–	–	–	●	–	–
Continuing education units for reporters	–	–		–	–	✔	●	–	–	–	●		–
Confirmation of received report sent to reporter	–	✔	✔	✔	–	✔	●	–	–	–	●	✔	–
Reporter contacted if further information/clarification required	–	✔	✔	✔	–	✔	●	✔	–	–	●	✔	–
Use of a causality grading tool to classify reports	–	–	–	0	–	✔	●	✔	–	–	●	✔	–
Use of pharmacovigilance reports													
Drug regulatory activities in government	–	✔	✔	✔	–	✔	●	✔	–	–	●	✔	–
Shared with managers of public health programmes	–	✔	✔	–	–	–		–	–	–		✔	–
Shared with pharmaceutical manufacturers	–	✔	–	✔	–	–		–	–	–		–	–
Available to drug information/poison information centres	–	–	–	–	–	–		–	–	–		✔	–
Actively disseminated to health professionals	–	✔	✔	✔	–	✔		✔	–	–		✔	–
Advice for consumer groups or general public	–	✔	–	✔	–	✔		–	–	–		–	–
Development of national drug therapeutic guidelines	–	–	–	✔	–	✔		–	–	–		✔	–
Actions resulting from domestic pharmacovigilance activities													
Changes of drug information	–	–	✔	✔	–	✔	●	–	–	–	●	✔	–
Issue of safety warnings	–	–	✔	✔	–	✔	●	✔	–	–	●	✔	–

Table 1 continued

Programme overview	BA	EG	IR	JO	KU	KSA	LE	OM	PA	QA	SY	UAE	YE
Suspension/withdrawal of drug product	–	–	–	✔	–	✔	●	–	–	–	●	✔	–
Sharing of suspected ADR reporting information													
Newsletter or bulletins	–	✔	–	✔	–	✔	●	✔	–	–	●	✔	–
Articles in professional journals	–	–	–	✔	–	–	●	–	–	–	●	✔	–
Professional conferences	–	✔	✔	✔	–	✔	●	–	–	–	●	✔	–
Mass media to all public	–	✔	–	✔	–	✔	●	–	–	–	●	–	–
Targeted messages for consumers (e.g. in retail pharmacies)	–	✔	–	✔	–	–	●	–	–	–	●	–	–
Internet website	–	✔	✔	✔	–	✔	●	–	–	–	●	✔	–

ADR adverse drug reaction, *BA* Bahrain, *DI* drug information, *EG* Egypt, *IR* Iraq, *JO* Jordan, *KSA* Kingdom of Saudi Arabia, *KU* Kuwait, *LE* Lebanon, *OM* Oman, *PA* Palestine, *QA* Qatar, *SY* Syria, *UAE* United Arab Emirates, *YE* Yemen

✔ Indicates affirmative survey response, – indicates negative survey response, ● indicates unavailable data of non-responder, 0 indicates no response

[a] Bahrain is an associate member

[b] KSA has used Vigiflow® in the past

[c] Egypt also has private funding

[d] Year 2010

[e] These counts reflect reports of both suspected ADRs and medication errors

an older platform, Intdis®), while KSA (former Vigiflow® users) reported use of other software and Egypt reported the use of spreadsheets. National centres describing application of an assessment tool to estimate likelihood of causality between the medication and reported reaction included KSA, Oman and the UAE. All used the information for drug regulatory purposes (through their affiliation with government agencies) and communicated data with health professionals. Three (Egypt, Jordan and KSA) reported dissemination of safety information to the public through targeted messages to consumers (e.g. at retail pharmacies) and mass media vehicles to all public.

4 Discussion

While some Middle East countries have been among nations included in other prior reviews, this is the first systematic assessment of pharmacovigilance in the region specifically [3]. We found several countries currently lack coordinated national programmes, and most existing programmes are in their infancy.

Characteristics of successful reporting systems have been described and include reporting that is confidential and non-punitive; leads to timely and constructive response; expertise and resources are available for meaningful analysis; the system is capable of disseminating information on hazards and recommending change [13–15]. A number of regional models described herein possess or are developing these features. Oman's programme is the oldest with over 15 years of experience in conducting postmarketing surveillance activity, and while the centre in KSA is among the most recently formed, it is a subsection of the Saudi FDA, the largest body in the region with a formal mission that includes responsibility to ensure the safety, quality and efficacy of drugs by developing and enforcing an appropriate regulatory system. These centres can serve as important resources for neighbouring countries wishing to establish national systems, especially given devoted human resources is relatively small in most countries. An existing body, the Gulf Central Committee for Drug Registration (GCC DR), has a stated mission to unify efforts in various health initiatives, including provision of safe and effective medications with reasonable prices in Gulf states. While the level of tangible collaboration is presently low, with developing efforts concentrating on combating infiltration of counterfeit products, the GCC DR endorses establishment of national pharmacovigilance centres within individual member states and would be a logical vehicle for enhanced collaboration [16].

All responding countries with pharmacovigilance programmes in our inventory (except the UAE) are members of the WHO Programme for International Drug Monitoring and this linkage is a critical component for systematic advancement of pharmacovigilance systems worldwide and recommended for established and developing programmes alike. Indeed, while Bahrain has not yet launched a national pharmacovigilance service, it is a documented associate member of this group [17]. Nascent programmes can draw upon international partners for expertise, resources and training necessary to overcome shared barriers to drug safety monitoring in the region, such as gaps in national

drug policies, regulations for pharmaceutical industry and oversight of medical prescriptions, to name a few.

Irrespective of a sound infrastructure, any pharmacovigilance system relying on voluntary reporting is only as effective as the participation of its reporters. While the majority of responding countries indicate sharing of safety data with its country's health professionals, in one regional survey only 15% of community pharmacists in Saudi Arabia were aware of its national reporting programme [18]. Spontaneous ADR reporting initiatives need suitable and sustained promotion and can be facilitated by improved collaboration with professional organizations, including participation in educational events and scientific meetings in these Middle Eastern countries [19]. Opportunities to integrate pharmacovigilance education in the training of health professionals should also be promoted. The relatively small volume of currently documented reports received in these countries likely reflects the novelty of most of these programmes and would be expected to grow as the systems mature. Still, improved awareness must be coupled with means for minimizing barriers to spontaneous reporting. The Middle East has one of the highest uptakes of mobile technology in the world [20]. Household ownership of mobile devices in Qatar, for example, has been reported at 99% [21]. While no pharmacovigilance programme described a platform for direct web-based submission by reporters, SMS or mobile phone applications (such as that designed for the Centre for Adverse Reactions Monitoring in New Zealand) for spontaneous ADR reporting have potential as a more creative, yet practical approach to generate efficiency and further interest in reporting, especially given the parallel proliferation of handheld devices as medical tools in patient care settings [22, 23].

Limitations of our study include the timeliness and completeness of received data. Many programmes outlined plans for growth and certain responses may now be different since the original deployment of the questionnaire. If the questionnaires at some centres were delegated to other staff by the identified head of the pharmacovigilance programme, it could have affected accuracy and completeness of information provided at the time. Finally, not all countries formally participated and so the situation in the region is not fully described. External search demonstrates prior pharmacovigilance pilot activity in Lebanon as well as a Syrian Ministry of Health website with indications of a suspected ADR reporting programme [24].

5 Conclusions

This is the first inventory of pharmacovigilance specifically 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 programmes. Technology can be exploited to ease spontaneous reporting and subsequent data management. Existing mechanisms for regional collaboration should be advanced so that experience from model programmes can be shared.

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