

Adverse Effects of Medicines Is the Omani population safe?

Muna Al-Saadoon

الآثار السلبية للأدوية
هل الشعب العماني آمن؟

منى السعدون

IN THE CURRENT ISSUE OF SQUMJ, JOSE *et al.* reported that approximately 46% of the participants in their study (n = 618) held the erroneous notion that adverse effects occurred only when medications were consumed in high doses.¹ Approximately 60% of their cohort endorsed the view that medicines prescribed by doctors are completely safe. Another most disheartening finding from the study was that the Omani public appeared to hold the view that traditional medicines and over-the-counter medications were free of any side-effects.¹ In a nutshell, these findings could be extrapolated to indicate that the general public harbours sub-optimal knowledge, belief and behaviour on issues pertinent to the usage of medicine.

Patient safety is an essential principle of healthcare. Each phase of healthcare provision has the potential to trigger an error. This means that problems can occur in the practice, products, procedures or systems of healthcare provision which, in turn, could culminate in adverse events for the patients, including an adverse reaction to drugs. This reaction is defined by the World Health Organization (WHO) as “a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function”.² Although other terminologies have been used to describe unwanted effects of drugs, such as ‘toxic effect’ or ‘side-effect’, the term ‘adverse effect’ is currently the most preferred.³ Pharmacovigilance is “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem”.²

The importance of patient safety with regards to drug use has been translated into many policies and actions by the WHO, such as the initiation of the Quality Assurance and Safety of Medicines (QSM)

team to address worldwide drug safety and drug utilisation. The QSM team function to encourage member states to participate in the WHO International Drug Monitoring Programme.² A second important milestone is the work of the WHO Collaborating Centre for International Drug Monitoring, located in Uppsala, Sweden, which maintains a database for reports of suspected adverse drug reactions from the member states.⁴ These initiatives strive to promote pharmacovigilance at national levels with the objectives of improving patient care and safety with regards to the use of medications. This aim is actioned by supporting public health programmes through “providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines”.⁴

The above-mentioned international and local level initiatives have the potential to safeguard the use of medications and indeed are vital for consumer safety and protection. However, Jose *et al.*'s study suggests some significant gaps in the Omani public's awareness regarding the use of medication that need to be addressed. Their study clearly indicates that the public harbour a view that runs counter to international best practice.¹ Therefore, concerted efforts are needed to increase public knowledge in alignment with the international best practice as stipulated by the WHO. Jose *et al.*'s study found that the Omani public believe that drug side-effects occur only with high doses, implying that the public would take the liberty to titrate dosage if deemed ‘high’.¹ Conversely, it is also possible that a perceived ‘low’ dosage would be deemed ‘safe’. Such erroneous views could be a recipe for hindering compliance with treatment and observation for possible side-effects.

The WHO reported a “50% phenomenon”, indicating that half of patients do not follow treatment recommendations.⁵ Indeed, according to the National

Institute for Health and Clinical Excellence, both high and low dosages are detrimental to health.⁶ In a systematic review, van Gaalen *et al.* suggested that a failure to abide by the required dosage tends to put the patient at higher risk of an adverse drug reaction.⁷ According to the UK-based company, Patient Connect Service Limited, patients who take preventative medicines, such as those prescribed for an asymptomatic condition, are likely to fall prey to poor compliance as the preventative nature of the medication means they “do not feel immediately threatened.”⁸ If the patient has no overt symptoms, the chance of poor compliance increases or the concept of a ‘drug holiday’ comes to the forefront.

In addition to the issue of an adverse drug reaction, Jose *et al.*'s study indicated that the majority of the public in Oman deemed traditional medicines to cause few or no adverse reactions. Most disheartening was that, in another study, such a view was also endorsed by medical students in Oman.⁹ This means that sub-optimal knowledge not only exists among the general public, but also among those who are going to be the vanguard of health in the country—medical students. A major source of confusion is that traditional medicines are often parcelled as ‘food supplements’ which can evoke the ‘romance of a herbal elixir’. Although there are studies that have reported the therapeutic effects of some herbal medications,¹⁰ other studies have revealed that traditional medicinal products contain banned pesticides, microbial contaminants, heavy metals, chemical toxins or orthodox drugs.¹¹ In fact, the medical literature is rife with documentation on the toxic effects stemming from traditional medicine.^{12,13} There is a wide misconception that herbal medicines are derived from natural sources and are therefore non-toxic and safe. On this ground, there is a significant disjunction between what medical science has revealed about herbal medicine and public perception.

There are a number of implicit implications behind the prevailing romance with herbal medicine, including potential delays in medical intervention and the abandonment of biomedical treatment. It has been found that a tendency to use both treatment modalities simultaneously has the potential to compromise the efficiency of medical treatment.¹⁴ In Oman, traditional medicines are reportedly often consumed concurrently with prescription medication from a medical doctor.^{15,16} Such ‘cocktails’ have the potential to do more harm than good. For this matter WHO recommends that all member states should:

A) Establish, strengthen and implement an effective regulation of providers of herbal medicines in respect of their qualifications. B) Establish, strengthen and effectively enforce regulations on herbal medicines.

*C) Strengthen capacity-building efforts for providers, manufactures and regulators of herbal medicines in order to improve their capacity and expertise regarding assurance of safety and quality of herbal medicines. D) Include safety monitoring of herbal medicines in pharmacovigilance systems and promote the awareness of consumers/patients on safety aspects of herbal medicines. E) Provide technical support to Member States in the implementation in particular regarding the safety of herbal medicines and of traditional and complementary medicine practices.*¹⁷

Due to the rise of chronic and lifestyle diseases in Oman,¹² emerging medical conditions require a more novel approach than the existing ‘cure-oriented’ healthcare system.^{18,19} By virtue of the chronic nature of a lifestyle disease, and as these diseases are often being impervious to available biomedical care, those afflicted by these diseases may be more inclined to utilise both allopathic medicine and alternative medicine. Such ‘dual loyalty’ likely stems from emerging health education where patients are encouraged to work with their own doctor.²⁰ With this emerging trend, a concerted effort is needed to impart to both the public and medical experts alike the pros and cons of both healthcare systems. Health education in Oman appears to represent a middle way between these two contesting parties. In the midst of such a predicament, perhaps we should take note of the words of T. S. Eliot: “we shall not cease from exploration, and the end of all our exploring will be to arrive where we started and know the place for the first time.”²¹

References

1. Jose J, Jimmy B, Al-Mamari MNS, Al-Hadrami TSN, Al-Zadjali HM. Knowledge, beliefs and behaviours regarding the adverse effects of medicines in an Omani population. *Sultan Qaboos Univ Med J* 2015; 15:234–40.
2. World Health Organization. International drug monitoring: The role of national centers. Report of a WHO meeting. *World Health Organ Tech Rep Ser* 1972; 498:1–25.
3. Edwards IR, Aronson JK. Adverse drug reactions: Definitions, diagnosis, and management. *The Lancet* 2000; 356:1255–1299. doi: 10.1016/S0140-6736(00)02799-9.
4. World Health Organization. Essential Medicines and Health Products: Pharmacovigilance. From: www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/ Accessed: Feb 2015.
5. World Health Organization. Adherence to Long-term Therapies: Evidence for action. From: www.who.int/chp/knowledge/publications/adherence_introduction.pdf Accessed: Feb 2015.
6. National Institute for Health and Clinical Excellence. Medicines Adherence: Involving patients in decisions about prescribed medicines and supporting adherence. From: www.nice.org.uk/guidance/cg76/resources/guidance-medicines-adherence-pdf Accessed: Feb 2015.

7. van Gaalen J, Kerstens FG, Maas RP, Härmark L, van de Warrenburg BP. Drug-induced cerebellar ataxia: A systematic review. *CNS Drugs* 2014; 28:1139–53. doi: 10.1007/s40263-014-0200-4.
8. Patient Connect UK. From: www.patientconnect.co.uk/ Accessed: Feb 2015.
9. Al-Saadoon M, Al-Jashemi RM, Al-Farsi AM, Al-Suleimani SH, Al-Khayari HY. Medical student attitude toward traditional, complementary and alternative medicine: Cross-sectional study. *J Ethnobiol Trad Med* 2014; 122:900–905.
10. Eldeen IM, Elgorashi EE, van Staden J. Antibacterial, anti-inflammatory, anti-cholinesterase and mutagenic effects of extracts obtained from some trees used in South African traditional medicine. *J Ethnopharmacol* 2005; 102:457–64. doi: 10.1016/j.jep.2005.08.049.
11. Chan K. Some aspects of toxic contaminants in herbal medicines. *Chemosphere* 2003; 52:1361–71. doi: 10.1016/S0045-6535(03)00471-5.
12. Al-Lawati J, Morsi M, Al-Riyami A, Mabry R, El-Sayed M, El-Aty MA, et al. Trends in the risk for cardiovascular disease among adults with diabetes in Oman. *Sultan Qaboos Univ Med J* 2015; 15:e39–45.
13. Worthing MA, Sutherland HH, al-Riyami K. New information on the composition of bint al Dhahab, a mixed lead monoxide used as a traditional medicine in Oman and the United Arab Emirates. *J Trop Pediatr* 1995; 41:246–7. doi: 10.1093/tropej/41.4.246.
14. Al Asmi A, Al Maniri A, Al-Farsi YM, Burke DT, Al Asfoor FM, Al Busaidi I, et al. Types and sociodemographic correlates of complementary and alternative medicine (CAM) use among people with epilepsy in Oman. *Epilepsy Behav* 2013; 29:361–6. doi: 10.1016/j.yebeh.2013.07.022.
15. Al-Kindi RM, Al-Mushrafi M, Al-Rabaani M, Al-Zakwani I. Complementary and alternative medicine use among adults with diabetes in Muscat region, Oman. *Sultan Qaboos Univ Med J* 2011; 11:62–8.
16. Al-Lamki L. Complementary and alternative medicine: Where do we stand in the 21st century? *Sultan Qaboos Univ Med J* 2011; 11:161–4.
17. World Health Organization. Regulatory Harmonization: 16th International Conference of Drug Regulatory Authorities (ICDRA). From: www.who.int/medicines/publications/druginformation/WHO_DI_28-3_RegulatoryHarmonization.pdf Accessed: Feb 2015.
18. Al-Sinawi H, Al-Alawi M, Al-Lawati R, Al-Harrasi A, Al-Shafae M, Al-Adawi S. Emerging burden of frail young and elderly persons in Oman: For whom the bell tolls? *Sultan Qaboos Univ Med J* 2012; 12:169–76.
19. Al-Adawi S. Emergence of diseases of affluence in Oman: Where do they feature in the health research agenda? *Sultan Qaboos Univ Med J* 2006; 6:3–9.
20. Al-Adawi S, Al-Salmy H, Martin RG, Al-Naamani A, Prabhakar S, Deleu D, et al. Patient's perspective on epilepsy: Self-knowledge among Omanis. *Seizure* 2003; 12:11–8. doi: 10.1016/S1059131102001504.
21. Eliot TS. *Four Quartets*. New York, USA: Harcourt, 1943.