

Pharmacovigilance in Libya: Current Status and Future Trends

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ABSTRACT

Libya, like other countries around the world, are working to develop vigorous pharmacovigilance systems. While the majority of the developed countries have established efficient pharmacovigilance systems, Libya still lack the basic structure to create such systems. This commentary emphasizes on the necessity of establishing pharmacovigilance system and focus on its current status and future prospect in Libya.

Key words: Pharmacovigilance, Libya, Adverse drug reaction, Healthcare, Medicines.

INTRODUCTION

According to WHO, pharmacovigilance describes the sciences and activities related to the detection, assessing, understanding and prevention of Adverse Drug Reactions (ADRs) or any other drug-related events.¹ A number of adverse reactions associated to drugs encouraged the initiation of the discipline of “pharmacovigilance”. Perhaps, the disaster of Thalidomide drug in 1961 is one of the incidences when many of congenitally deformed neonates were born. This prompted WHO for effectual study of adverse reaction of drugs, which is the launching of pharmacovigilance. Subsequently, a number of adverse drug events were detected.² There were several efforts to establish such system in Libya during 2000-2010, but finally the programme launched in 2015 and is running positively and delivering noticeable results. The purpose of pharmacovigilance is the detection a potential harm, which is then explored and analyzed to reduce the possible hazard. This data is further communicated to the healthcare authorities and general public to enhance the patient care health safety.³

Necessity of Pharmacovigilance

Medicines are discovered with the purpose of saving human lives. During clinical trials of drug development, medicines are examined

for their safety profile on cautiously selected patients only. Yet, after their release in the marketplace, medicines are audited during post marketing surveillance phase which depend on spontaneous reporting of possible drug related adverse reaction. Death due to a disease is often noticeable, but death from a medicine is unacceptable. In USA, drug related adverse events are among the topmost 10 reasons of mortality⁴ and in UK, ADRs cause around 5700 deaths per year.⁵ The proportion of patient’s admission to hospitals due to ADRs in some countries is around 10 percent.²

WHO states the definition of ADRs as any drug effects, which is harmful, unintended and undesired, which occur at normal therapeutic doses.⁶ It occurs due to many reasons, such as the restraint of scope of clinical trial statistics to a specific population sample, patients may suffer co-morbidities or consuming other medicines, off-label use of drugs or distinction in the genetic makeup of individuals.⁷

WHO encourage every country to develop a nationwide pharmacovigilance center to report drugs related adverse reaction and to identify which drug are more susceptible to show ADRs. As a consequence, now

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several countries send report for such drugs to Uppsala Monitoring Centre (UMC), which further examines and distributes the required information worldwide. Currently, 136 members of developed and developing countries are full members of the WHO programme for international drug monitoring and are working with UMC in Sweden.⁸ Nevertheless, 96% of the developed countries have local pharmacovigilance systems in collaboration with UMC, whereas only 27% of the low- and middle-income countries have such developed pharmacovigilance systems.⁹ This lower number of pharmacovigilance systems in these countries is owing to absence of infrastructure and resources.¹⁰

Pharmacovigilance in Libya

Libya's population in 2015 was 6.3 million which means that the population has increased by 32.6% in the past 25 years. Primary health care is well developed and accessible all across the country. Reports revealed that there are about 7,000 doctors, 1.3 per 1,000 inhabitants. Many doctors have been trained abroad and overall Libyan doctors have good skills.¹⁰

In 2015 by the resolution number 448, the Libyan ministry of health established a drug auditing and surveillance system. However, the work on pharmacovigilance did not started until 2017, when Dr. Samir Elsaqer, the Head of National Center for Health System Development, announced the strategic plan of 2018 to be involve the funding the pharmacovigilance system in Libya.¹¹ Thereafter, under the Department of Pharmacy, equipment and medical supplies, Libyan Ministry of Health in 2015, the Libyan Pharmacovigilance Department (LPVD) was established. The LPVD serves as one of the several health ministerial divisions to regulate the safety, quality and availability of medicines in the country. The LPVD developed an agenda for post marketing surveillance of drugs with the collaboration of WHO office in Libya. WHO office in Libya also established a series of workshops and seminars for LPVC (Libyan Pharmacovigilance Committee) members in order to emphasis the need for ADRs reporting.¹² As a result of these efforts, in 2019, Libya became the associated member of UMC.¹³

LPVD has formulated strategies for pharmacovigilance events and its local medicine control unit is repeatedly issuing drug safety alerts based on the evidence received from WHO office in Libya and from the post marketing surveillance.¹⁴ In 2018, EU -funded WHO project has organized a special training named as, "Strengthening Health Information System and Medical Supply Chain Management (SHAMS)" for the LPVD officers.

Moreover, fundamental trainings and talks have also been deliberated by LPVD to train and educate healthcare experts about pharmacovigilance.¹²

To support spontaneous reporting of an ADRs, the department of pharmacy, equipment and medical supplies in Libyan ministry of health has suggested to initiate LPVD divisions in the vicinity of every 30 pharmacies to be available for patients, pharmacists and healthcare professionals to report any ADRs. By doing so, the LPVD will partly fulfilling WHO's aim of enhancing patient care and safety from medicine's use perspective and will also contribute towards the assessment of benefits, hazards and cost-effective use of medicines.¹⁵

Summary and Future Prospects

In order to boost safe use of medicines, good pharmacovigilance actions must be practiced to confirm the rational use of information for correct purpose, but challenges occur in the form of financial and legal restrictions. Libya required stakeholder engagement and efforts to evaluate severity, reason and certainty of potential ADRs. To date, there is no such data available to WHO center for drug auditing about ADRs' statistics from Libya, in this context, these efforts would also help the collection of this data.¹⁶ There is also a need to enhance the communication between Libyan pharmacovigilance centre and healthcare specialists, which can be happen by engaging several policies and strategic guidelines such as medicine alerts, letters to doctors, information sheet, media reports, patient information flyers and personal comments to the ADR reporter. In addition, the pharmacovigilance system requires a major renovate, which contains a multi stakeholders' tactics and adjustment of methods to address medicines safety issues in the Libya.

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CONFLICT OF INTEREST

The author declare that they have no competing interests.

ABBREVIATIONS

WHO: World Health Organization; **ADRs:** Adverse Drug Reactions; **UMC:** Uppsala Monitoring Centre; **LPVD:** Libyan Pharmacovigilance Department; **LPVC:** Libyan Pharmacovigilance Committee; **SHAMS:** System and Medical Supply Chain Management.

SUMMARY

Pharmacovigilance is a science dealing with assessment and finding of any potential drug-related reactions. Consequently, drug prescribing errors is considered as an efficient phenomenon for medical errors. Libya required stakeholder involvement and efforts to assess severity, cause and certainty of potential drug adverse reactions.

REFERENCES

1. WHO. Pharmacovigilance. World Health Organization. 2004. Available from: https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvig/en/.
2. Mandal S, Mandal M. Evolution of Pharmacovigilance Programme: Present status in India. *Pharma Times*. 2017;49(5):31-6.
3. Waller P, Harrison-Woolrych M. An introduction to pharmacovigilance: John Wiley and Sons. 2017.
4. Banda JM, Evans L, Vanguri RS, Tatonetti NP, Ryan PB, Shah NH. A curated and standardized adverse drug event resource to accelerate drug safety research. *Sci Data*. 2016;3:160026.
5. Pirmohamed M, *et al*. Adverse drug reactions as cause of admission to hospital: Prospective analysis of 18 820 patients. *BMJ*. 2004;329(7456):15-9.
6. WHO. Safety of medicines - a guide to detecting and Reporting Adverse Drug reaction. World Health Organization. 1972. Available from: <http://apps.who.int/medicinedocs/en/d/Jh2992e/2.html>.
7. Khamar B. Off-label use of medicines: medical research and medical practice. *Indian J Ophthalmol*. 2007;55(6):411-2.
8. Uppsala Monitoring Centre. Available from: <https://www.who-umc.org/>.
9. Hussain R, Hassali M. Current status and future prospects of pharmacovigilance in Pakistan. *J of Pharm Policy and Pract*. 2019;12(14):1-3.
10. Libya: Health. LookLex Encyclopedia. Retrieved 2011-08-31. Available from: <http://i-cias.com/e.o/libya.health.htm>.
11. Alwasat gate. Available from: <http://alwasat.ly/news/libya/222080>.
12. Libya Health Emergencies and Humanitarian update. Report from WHO 2018. Available from: <https://www.humanitarianresponse.info/>.
13. UMC. Global Pharmacovigilance. World Health Organization, Sweden. 2018. Available from: <https://www.who-umc.org/global-pharmacovigilance/members/>.
14. Libyan business news. 2019. Available from: <http://libyanbusiness.tv/>.
15. Africa-gate-news. Available from: <https://www.afrigatenews.net>.
16. WHO. WHO policy perspectives on medicines Pharmacovigilance: Ensuring the safe use of medicines. World Health Organization. 2004. Available from: <https://apps.who.int/medicinedocs/en/d/Js6164e/>.