



REVIEW ARTICLE

Pharmacovigilance in Nepal: Present Glance and Areas to Improve.

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As the global issues ponder upon drug safety and Consumer pharmacovigilance, pharmacovigilance in Nepal started in the year 2004, however, is still in the infancy stage. In this commentary, we aimed to portray the past and present state of the PV in Nepal along with some of the international and resource-limited countries' situations along with the areas we can work on for the effective adverse event reporting, assessment, monitoring and management which leads to the drug safety and quality medicine use in some context in the resource-limited countries like Nepal.

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Introduction

Pharmacovigilance WHO defines ADR (Adverse Drug Reaction) as any response to a drug that is noxious and unintended that occurs at the dose that is used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose (World Health Organization, 2002). Statistics revealed nearly 10 billion US dollars are spent annually to address the health issues that arise from the Adverse Drug Reaction. ADRs are 4th to 6th leading cause of death and can cause short-term to long-term hospitalization ultimately increasing the mortality rates. In the context of Nepal, the ADR prevalence was found to be 0.86%, and the male-to-female ratio was found to be 0.85. Similarly, 10% of the ADR reported was found to be Severe (Alshakka et al., 2010; Worakunphanich et al., 2022). To address the ADR problem the concept of Pharmacovigilance is necessary. The history of pharmacovigilance dates back 169 years

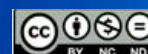
with the death of a British girl called Hannah from the chloroform used as anesthesia at that time, more noteworthy the concept of pharmacovigilance arose from the known thalidomide tragedy in the early 60's (Fornasier et al., 2018). The scientific activity of the identification, assessment, understanding, and reporting of the adverse event of the drug for the safe and effective use of the drugs keeping things in mind that no medicine is completely safe is called Pharmacovigilance. Although could be defined and explained in different ways the ultimate goal of the definition of pharmacovigilance could be the activity of assessing the medication risk for safe and effective use which aims to enhance the patient's care and safety providing reliable and balanced information for the risk-benefit management of the medicines (Pitts et al., 2016). Uppsala Monitoring Center is the international database for the storage and reporting of the Adverse Drug Reactions, also called, the WHO



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collaboration for the International Drug Monitoring. Established in the year 1978 is an independent, self-funded organization that holds the world's largest database of adverse events. It also provides training and technical support to its member countries and helps in data management by providing data management tools like Vigiflow. Further, it also publishes papers, articles, and newsletters regarding pharmacovigilance, drug safety assessment, and risk communication as well. Following are some of the Mission of the Uppsala Monitoring Centre for the rational use of the drug (Olsson S., 1998):

- Collecting and analyzing drug safety information at the international level
- Collection and maintenance of the Worldwide database of the Adverse Drug reaction.
- Disseminating the risk information.
- Training and Research

Pharmacovigilance centers are established nationwide to ensure the rational use of the drug by identifying the potential side effects and ensuring the risk-benefit ratio. They also help in the signal generation of the effect for the further evaluation and assessment of the risk possessed by the drug. Pharmacovigilance centers play the role of hawk eye for the drug information. Further safety information obtained from pharmacovigilance helps to manage drug utilization, formulation of the essential drugs program, helps in the formulation of the standard treatment guidelines as well as national and international formularies. The pharmacovigilance center plays a vital role in the clinical indicator of drug use and minimization of drug-related problems and ADR throughout the country (Jose et al., 2021).

Pharmacovigilance in Nepal

In the USA, the FDA Adverse Event Reporting system has been introduced by US FDA to support Post-marketing surveillance for medication management and adverse event reporting which allows manufacturers, consumers, and healthcare professionals to report on medication errors, adverse events if any, or the product complaints which further is available in the database as well (Sakaeda et al., 2013).

The introduction of MedWatch (Electronic Resource) which focuses on the reporting of medicine and medical devices is a voluntary reporting form designed for the public consumer and HCPs, manufacturers, importers, and store that stores medicine and medical devices. For medical devices, it is mandatory to report and abide by the law. MedWatch reporting system allows everyone to report on the ADR or any injuries caused by the medicinal product. It provides comprehensive information about the drug product, drug recalls, and Labelling changes as well (Fyfe, 2007).

Pharmacovigilance in resource-limited countries has been identified as a challenging job to do because of several indicators like lack of outcome measurement, the influence of attitude (Ignorance, leathery, fear), personal and professional factors, lack of specified manpower in the center for the reporting of the adverse events, Financial problem, lack of competent legal and policy framework (Jose & Rafeek, 2019). However, India has incorporated the concept of pharmacovigilance in its medicine policy. Overall the status of Pharmacovigilance in the resource-limited countries is not at the stage of appraisal. A review reported the lack of standardization regarding the evaluation of the pharmacovigilance System with an emphasis on the WHO core indicators (Garashi et al., 2022).

The Department of Drug Administration (DDA) is the National Pharmacovigilance Center that collects the Adverse drug reactions from its 15 regional pharmacovigilance centers and sends them forward to the International Drug Monitoring Center (Uppsala monitoring center). The adverse reactions are first reported to the regional pharmacovigilance center by the consumers, HCP, and other medical and non-medical persons, then the regional pharmacovigilance centers send the report to the national pharmacovigilance center via software Vigiflow as directed and at national center report are screened and further sent to Uppasala Monitoring Center for the assessment of the reactions(Pharmacovigilance @ [Www.Dda.Gov.Np](http://www.dda.gov.np), n.d.). The schematic diagram for the adverse reactions reporting could be outlined as:

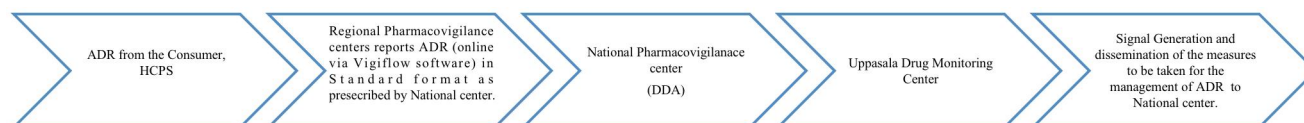


Figure 1: ADR reporting Process in Nepal

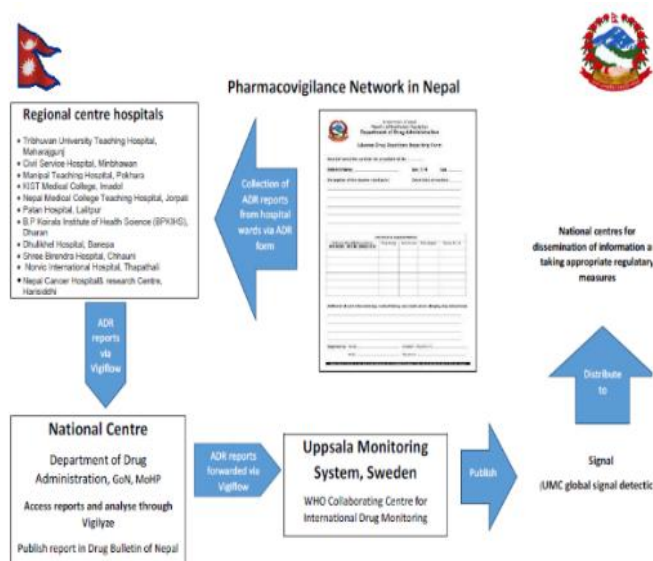


Figure 2: Schematic Diagram for the reporting of the Adverse Drug Reactions Report

Source: schematic flow process of ADR report.PNG (893×576) (dda.gov.np)

The standard format for Adverse Drug Reaction Reporting directed by the DDA contains the basic demographic information of the patient (Hospital Number, Patient name, sex, and age as well as the date of onset of the reaction), a brief description of the adverse reaction, information on the suspected medicines (Name, Brand, Generic, Batch Number, Manufacturer, Dose, Reason for the use, Date started and stoppage date of the

drug), Additional relevant information (Known drug allergies, drug interactions, medical history, and lab reports as well, finally information about the reporter which includes name and hospital of the reporter his/her involvement department (Pharmacy, Nursing, Medical), date of the reported and signature of the reporter. The standard reporting format provided by the DDA (National Pharmacovigilance Center) of Nepal is:


 Government of Nepal
 Ministry of Health
Department of Drug Administration
 Adverse Drug Reactions Reporting Form

Hospital record No. or chart No. or patient ID No. _____

Patient's Name: _____ Sex: F/ M Age _____

Description of the adverse reaction/s: _____ Onset date of reaction: _____

Information on Suspected Medicine				
Medicines (Brand & Generic Name, Manufacturer, Batch No., Dosage Form)	Daily dosage	Date started	Date stopped	Reason for use

Additional relevant information (eg. medical history, test result, known allergies, drug interactions)

Reported by: Name: _____ Hospital / Department: _____

Date: _____ Signature: _____

Please return this form to your local Drug Information Unit or Hospital Pharmacy. Thank you for taking the time to fill in this report!

Figure 3: ADR Reporting Format

Nepal became the official WHO program member in 2004 and has only reported 972 adverse reports which is too small in quantity ([Pharmacovigilance @ Wwww.Dda.Gov.Np, n.d.](#)). Though the country has 15 regional pharmacovigilance centers 12 of the centers are in the Kathmandu valley and only three are outside the valley. There are no regional centers in the Karnali and Far-west provinces of Nepal as well as the Eastern Side of the country as well. Manipal Teaching Hospital since the inception of Pharmacovigilance in Nepal has started the reporting of the ADR with the establishment of a Drug Information Center ([Shankar et al., 2007](#)). No reports have been published in any of the relevant journals, papers, or drug bulletin regarding the reporting of the ADR by the regional centers. A study conducted has reported Canada ranked first in reporting the adverse effects (348,580) while developing countries like Taiwan, Malaysia, and Thailand have reported 73,799, 99,413, 224,756 adverse effects from the year 2015 to 2019 ([Worakunphanich et al., 2022](#)). Pondering upon the data published, the National Regional Center has not done so satisfactorily in publishing the Annual reporting report of the Pharmacovigilance Centers as well as not done so well in ADR reporting as well. Besides Scarce data regarding the hospitalization of the Patient due to ADR could be found in developed countries. There may be two reasons for such scarce data either underreported or not disseminating the ADR reports by the stakeholders. Healthcare professionals possess the knowledge about pharmacovigilance and have a better attitude toward ADR reporting but due to the lack of training on the procedure of ADR reporting, the ADR is underreported or limited ([Palaian et al., 2011](#)). Pharmacovigilance in resource-limited countries is itself a challenging and not an easy task to do. Various challenges occur throughout the process. Public participation, Lack of collaboration among the practitioner and reporter, limited information about the process as well as limited manpower for the reporting of the adverse events ([Dal Pan, 2014](#); [Pitts et al., 2016](#)).

Indicator-Based Pharmacovigilance Tool (IPAT) is a performance monitoring tool for the diagnostic assessment of the Pharmacovigilance and medication safety system. The data generated by the IPAT reflects the country's existing regulatory Capabilities, System gaps, and resources available for the medication safety Programme. Hence the indicator-based tool helps the longitudinal measurement of the progress after the interventions recommended. The tool consists of 43 indicators 26 of them are core and 17 are supplementary. IPAT tools consists of the component: ([Strengthening Pharmaceutical Systems \(SPS\) Program, 2009](#))

- Policy Law regulation (4 indicators)

- System, Structures & Stakeholder coordination (15 indicators)
- Signal Generation and Data Management (6 indicators)
- Risk assessment & evaluation (8 indicators)
- Risk management and communication. (10 indicators)

A study conducted in Nepal for the analysis of the pharmacovigilance system using an indicator-based pharmacovigilance assessment tool (IPAT) showed the regional as well as national pharmacovigilance center has not achieved target outcomes in any of the indicators used in the study i.e. policy law regulations, signal generation and data management, risk assessment, and risk communication. The score obtained was only 43.4% which signifies the incompetency and failure of the structure and policy for medication safety ([Jha et al., 2021](#)) For the organization to be functionally effective in terms of the Pharmacovigilance system the average score should be more than 60% in the assessment as implied by IPAT ([Abiri & Johnson, 2019](#)). The country lacks in provision of a legal medicine policy for the pharmaceutical company to report adverse drug events. Developed countries have well-established pharmacovigilance centers and is often mandatory for pharmaceutical companies to report on the ADR of the product manufactured, however, many developing countries do not conduct Post-marketing surveillance on their citizens due to legal and ethical considerations ([Palaian, 2018](#)). Nepal's pharma market is mostly imported and enough amount of substandard drugs as well, Post marketing surveillance is still in its infancy in Nepal & the domestic companies manufacturing the medicines need not compulsory to report the ADR of the product they manufactured. ([Jha et al., 2021](#); [Palaian, 2018](#); [Palaian et al., 2010](#)) Despite of the programs conducted during the past years for the inauguration of medicine safety through training and education, the National medicine policy lacks the incorporation of the concept of Pharmacovigilance ([Jha et al., 2021](#)). The study also reported the status of the regional pharmacovigilance centers. Despite having the basic infrastructure required for the reporting the reports are failing to report the adverse drug events. Only a few of the regional centers are seen publishing drug bulletins and papers or any newsletter ([Hazell & Shakir, 2006](#); [Jha et al., 2021](#)). A study conducted in one of the regional centers of Nepal showed the highest prevalence of reporting adverse events caused by antibiotics followed by anti-hypertensive, NSAIDS, and another group of medications. The reported adverse event was maculopapular rash followed by vomiting and diarrhea. It is not that the adverse events are not being reported but is the fact that the frequency and the process of the

reporting as well as assessment of the risk and the risk communication is not well enough for medication and drug safety (Jha et al., 2012; Abiri & Johnson, 2019; Palaian, 2018; Palaian et al., 2010)

Where We Can Improve

Consumer Pharmacovigilance

Consumer Pharmacovigilance could be simply defined as the involvement of the consumer in the Pharmacovigilance program for monitoring the effects of the drugs licensed for medicinal use (European Medicines Agency, 2017). Since the safety concern always focuses on the consumers the involvement of the consumer for reporting of the adverse events previously unreported could be the new area for the upliftment of the pharmacovigilance in Nepal. The initiation of the consumer pharmacovigilance could improve the number of the signals generated and could make easily for the risk assessment and risk communication as well (Van Grootheest et al., 2003). The main limitation of consumer pharmacovigilance in resource-limited countries and under-developing countries is illiteracy and limited people involvement. Hence Stakeholders should consider this factor for the improvement of the PV (Garashi et al., 2022). Consumer pharmacovigilance is still underdeveloped in Nepal, there is no provision for the reporting of the ADR by the consumer. Since consumers are the oneself which are bearers of the ADR, the involvement of the consumer in reporting the ADR could strengthen the Pharmacovigilance system (Jha et al., 2015; Palaian, 2018; Palaian et al., 2010; Van Grootheest et al., 2003). Many underdeveloped countries are developing the self-reported form for the consumer to report the ADR they encounter, they also accept reporting from the telephones and social media as well. We being under developed country could adopt a similar procedure for reporting. Further involvement of the community pharmacy as well for the spontaneous reporting could be the area of strengthening consumer pharmacovigilance as most people are reliable to community pharmacies as their primary source of drug filling.

Political Commitment & Legal Framework

Establishing and smooth running of the PV requires political commitment and a strong legal framework. Periodic inspection of the regional PV centers, and dissemination of the annual reports of the Adverse events obtained all come under the legal framework. Drug Act of Nepal -2035 section 12 speaks about the drug being safe for public consumption however does not address the Concept of Pharmacovigilance needs to be incorporated for the assurance of the safe use of the medication (Act, 2000). Similarly, the Minimum service standard for tertiary hospitals incorporated the pharmacovigilance activities for the ADR reporting under Hospital Pharmacy Service, such policies hereafter should be implemented and inspected periodically (Index @ Dohs.Gov.Np, n.d.)

National Medicine Hence Further incorporation of the PV in the national medicine policy also comes under legal commitment as well (Jha et al., 2021; Olsson et al., 2015).

PV in Academia

Several studies conducted in Nepal showed limited knowledge about adverse drug reaction reporting among healthcare professionals, which could be due to the huge knowledge gap about the existence and process of reporting adverse drug reactions (Kc et al., 2013). Further, another study revealed the impact of educational intervention among healthcare professionals on pharmacovigilance which showed the intervention led to the improvement of the knowledge, attitude, and practice of pharmacovigilance among the HCPs (Shrestha et al., 2020). PV in academia could be the best way to improve the adverse event reporting & PV in countries like Nepal. If taught about the process of reporting and its importance at university, Academia could be the area to improve the status of Pharmacovigilance in Nepal. Incorporation of pharmacovigilance in the curriculum of the bachelor levels and master help helps the student gain in-depth knowledge about the reporting system. Practical application or training on the reporting procedure of the ADR could significantly help the pharmacovigilance system to strengthen.

Outcome measurement

Outcome measurement involves the process of measuring the effect (result) and changes in the pharmacovigilance activities. They measure the extent of the realization of the Pharmacovigilance activities for patient safety. As per the WHO Pharmacovigilance indicator following are the outcomes measurements to be addressed: (Robert & Brown, 2004)

- Percentage number of preventable ADR reported in the previous year out of total ADR reported.
- Percentage number of medicine-related Congenital malformation per 100000 births.
- Percentage number of medicines related found to be possibly associated with congenital malformations in past 5 years.
- Percentage number of substandard/ counterfeit medicines in the pharma market
- Number of patients affected due to medication error per 1000 admissions previous year.
- Average work days or school days lost due to drug-related problems.
- Cost savings attributed to pharmacovigilance activities.
- Health budget impact attributed to the pharmacovigilance activities.

- Average number of medicines per prescription
- Percentage of prescriptions with medicine exceeding manufacturer recommended dose
- Percentage of prescriptions from prescribing with medicine potential drug interaction
- Percentage of the patient receiving the information on the use of their medications and the potential ADR associated with their medicines.

PV established in resource-limited countries are young, infant, and naïve as well. Several studies conducted in developing countries showed the paucity of regulatory policy and outcome measurement has led to the underreporting of the ADR and unsuccessful decision-making for the assessment and severity of the ADR, which ultimately leads to the failure of the PV (Garashi et al., 2022; Hazell & Shakir, 2006).

For the outcome measurement WHO has developed sets of indicators that could be used to assess the status of the PV centers in the country (Robert & Brown, 2004).

Training & Research

The effective conduction of the training programme on the spontaneous reporting of the ADR could be the area to work Selection of the specified manpower for reporting and training to specific manpower can also help to increase the efficient workflow of the Pharmacovigilance.

Further allocation of funds and personnel for the reporting also could be a possible way to improve (Jha et al., 2015). Training on the software provided by the national regional center on the vigiflow should be given. Further training on procedures for the reporting of the ADR by the medical personnel should be provided. The areas of the research should be explored by the stakeholders in the management of the Pharmacovigilance system. The potential areas of the research could be attitudes of the HCP, impacts of the consumer pharmacovigilance, effectiveness of the PV systems, barriers and measures to the strength of the PV systems, decentralization of the PV centers, and so on.

Recommendation

PV is an important aspect of the assurance of drug safety in public yet the process is still in its infancy since its inception. We would like to recommend the active involvement of the stakeholders for the effective management of the ADR reporting process. Decentralization of PV centers across the country for the effective reporting of the ADR. Incorporation of the clinical pharmacist for the effective reporting and collection of the ADR in community and hospital settings as well. Mandatory establishment of PV centers with hospital beds sized more than 300, as well as allocation of governmental funds for training and research on the

PV field. Besides active surveillance is also necessary for the regional PV centers by the National PV center. The situation of the pharmacovigilance centers should be periodically measured using the WHO pharmacovigilance indicator or any other tool like Indicator the pharmacovigilance tool for the assessment of the situation. Professional collaboration among the health workers for spontaneous reporting and documentation is also needed to strengthen the status of the Pharmacovigilance centers in Nepal.

Further PV concept should also be included in the Medicine Policy. Involvement of the academia in the PV program, publishing the Reported ADR, and their assessment at annual duration could be the areas to improve the status of the PV in Nepal. Similarly, the Minimum service standard (MSS) of the hospital endorses the adverse event monitoring and Pharmacovigilance program to be conducted by the Hospital Pharmacy Department. The implication of such guidelines should be strongly endorsed by the regulatory bodies with the active involvement of the Ministry. Further decentralization of the manpower like clinical pharmacist are recommended for the active reporting and effective management of the PV centers. The stakeholders, policymakers, regulatory bodies, and concerned ministries should actively discuss the involvement of the Clinical pharmacist in the drug utilization review as provided by guidelines like MSS (Minimum Service Standard). Further, the concept of consumer pharmacovigilance which still is naïve in the context of the country should be explored along with digitalization.

Conclusion

The establishment of the PV is of utmost necessity for the reporting of drug-related ADRs and their management which ultimately helps to assure the safe use of the medications among the public. There are many areas to work on and with the help of the regulatory bodies and stakeholders, lawmakers, and policymakers, the status of the PV could easily be improved than it is at present. Making PV strong helps in the assurance of patient safety. Effective PV system leads to effective risk assessment, communication, and risk management as well which ultimately leads to patient safety.

Conflict of Interest

None

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