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Research Paper

Situation analysis of the pharmacovigilance system in Nepal using the indicator-based pharmacovigilance assessment tool (IPAT)

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Abstract

Objectives The aim of this study was to assess the national and regional pharmacovigilance centres in Nepal in terms of their policy frameworks, structure and functioning.

Methods A descriptive cross-sectional study was conducted during January 2021 among regional pharmacovigilance centres, and the national pharmacovigilance centre and the Ministry of Health and Population. The indicator-based pharmacovigilance assessment tool (IPAT) consisting of 43 indicators (26 core and 17 supplementary) assessing different aspects of pharmacovigilance was used.

Key findings Of a total of 14 candidates representing regional pharmacovigilance centres, 12 agreed to participate. The national pharmacovigilance centre located at the Department of Drug Administration had an acceptable level of infrastructure and manpower but poor functioning and weak collaboration with regional centres. There are no policies and procedures specifically related to pharmacovigilance and no requirement for pharmaceutical companies to report adverse drug reactions (ADRs). The national centre received only 42 ADR reports during the evaluation period. The regional centres are mostly located (10 out of 14) in the Kathmandu Valley and had qualified manpower and basic resources. There were poor process indicators suggesting problems with functioning in terms of ADR reporting, signal generation and drug safety communication.

Conclusions Underreporting of ADRs, weak processes and poor coordination among centres limit functioning of the system. Creating more awareness, involving consumers and pharmaceutical companies in the reporting process, and conducting more training programmes are needed for the proper functioning of pharmacovigilance services in Nepal.

Keywords: adverse drug reaction reporting systems; policy, pharmacovigilance; regional pharmacovigilance centre; Nepal

Introduction

Nepal is a landlocked country in South Asia situated between two giant countries, India and China, with an area of 1 47 181 square kilometres and a population of ~29 million. The country is administratively divided into 7 provinces, 77 districts and 753 local bodies.[1] Under the new federal setup, the healthcare system has a new governance structure with Ministry of Health and Population (MoHP) at the central level, Ministry of Social Development (MoSD) at the provincial level and health section or health department at the local government level.[2]

Adverse drug reactions (ADRs) are a possible threat for the people of Nepal due to many reasons including extensive use of alternative therapies, including natural health products and underdeveloped systems for detecting and reporting ADRs. The national drug regulatory authority, the Department of Drug Administration (DDA) has been involved in pharmacovigilance activity and is the National Pharmacovigilance Center. The Drugs Act 1978 was promulgated as an initial process for assuring safety, quality and efficacy of drugs in the country. Consequently, DDA was established as an executive body for drug regulation in 1979. Pharmacovigilance as a programme was initiated by the government in 2004, and DDA was designated as a National Pharmacovigilance Center in 2006. DDA was also given the responsibility for liaising with the Uppsala Monitoring Centre, Uppsala, Sweden, the World Health Organization (WHO) Collaborating Center for International Drug Monitoring. There were a few centres established as regional pharmacovigilance centres beginning from the year 2004 located at Pokhara and Kathmandu.[3, 4]

Currently, there are 15 regional pharmacovigilance centres operating in Nepal. The database for recording ADRs was started in 2004, and currently, it has only 547 documented ADRs.[5] These regional pharmacovigilance centres report ADRs to the national centre (DDA), and they mainly focus on patient safety and promoting the rational use of medicines. ADRs are reported using an online form available at the website of the national pharmacovigilance centre. The national centre also conducts training programmes as a part of capacity building for creating awareness and enhancing the capabilities of the healthcare professionals for improving pharmacovigilance activity in Nepal.[6]

Based on the WHO Minimum Requirements for a functional National Pharmacovigilance System, every centre should recruit one full-time staff with clear definition of his/her role and responsibilities.[7, 8] Additionally, there must be some basic grants and funds to operate the programme. The WHO's minimum requirements also mandate that there should be facilities for working and collaborating with the international drug monitoring programmes, and a national ADR reporting form as part of a national database for recording and forwarding the ADR reports to the WHO Program for International Drug Monitoring. There must also be a system for collating and managing the ADR reports and a national level pharmacovigilance advisory committee for the technical works associated with the reported ADRs. Finally, the minimum requirements include the creation of a clear strategy for communication of both routine activity and crisis management.

So far, there has been no systematic assessment of pharmacovigilance in the country, and it is expected that there may be challenges associated with the pharmacovigilance programme like in other developing countries[9] related to financial status, human resources and capacity building. Hence, the objectives of this study were to explore and assess the pharmacovigilance system in Nepal using the IPAT tool.

Methodology

Study design

A descriptive cross-sectional study was conducted during January 2021 among 14 respondents, 12 from regional pharmacovigilance centres (two centres did not respond and one centre was started after completion of the survey), and one each from the national pharmacovigilance centre and the Ministry of Health and Population.

Inclusion criteria

All the regional pharmacovigilance centres and the national pharmacovigilance centre.

Exclusion criteria

Hospitals other than the notified regional pharmacovigilance centres and public health programmes like Malaria, HIV AIDS, Kala-azar and Filaria. Tuberculosis programme was included as they are one of the notified regional pharmacovigilance centres. Other public health programmes except tuberculosis are not linked with the national pharmacovigilance programme till date. Pharmaceutical industries and medicine importers were also excluded.

Data collection tool

The indicator-based pharmacovigilance assessment tool (IPAT) consisting of 43 indicators (26 core and 17 supplementary) was used to assess different aspects of the national pharmacovigilance programme.[8] The IPAT cover five components of pharmacovigilance and medicine safety. These indicators were classified based on their importance for a functioning pharmacovigilance system. The indicators are of two types, core and supplementary. The vital ones are categorized as core and others are categorized as supplementary indicators. These indicators are also categorized further into three classes based on the product or results being measured as structural, process and outcome indicators. The structural indicators measure systems and physical infrastructures from the national and regional pharmacovigilance centres. The process indicators evaluate how the pharmacovigilance system works and the outcome indicators measure the results of different pharmacovigilance activity.

The tool aims to assess the pharmacovigilance systems through a set of questions targeted on structures, processes and the outcome of the pharmacovigilance systems. The areas assessed for the pharmacovigilance are:

1. Policy, law and regulation (4 indicators, 1.1–1.4)
2. Systems, structures and stakeholder coordination (15 indicators, 2.1–2.15)
3. Signal generation and data management (6 indicators, 3.1–3.6)
4. Risk assessment and evaluation (8 indicators, 4.1–4.8)
5. Risk management and communication (10 indicators, 5.1–5.10)

The first two areas are structural; the process indicators include a few in group 2 and all indicators in groups 3 and 4. The outcome indicators are in group 5.

Method of data collection

The coordinators from each regional pharmacovigilance centre were contacted through a phone call to collect data about their centre. Their feedback and suggestions regarding the data were elicited through a telephonic interview. Data from the national centre were

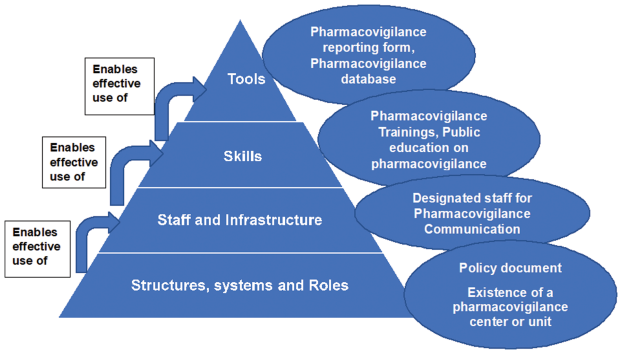

Figure 1 Current situation of capacity building for the pharmacovigilance system in Nepal.

collected by contacting the key informants managing these functions. Similarly, the data from the Ministry of Health and Population were collected by contacting the relevant personnel. Data were collected using the IPAT indicators from the Ministry of Health and Population and National pharmacovigilance centre using 26 core indicators and 17 supplementary indicators (1.1–1.4, 2.1–2.15, 3.1–3.6, 4.1–4.5, 5.1–5.7 and 5.9–5.10). Similarly, data were collected from different regional pharmacovigilance centres using 19 core indicators and 11 supplementary indicators (2.1–2.5, 2.8–2.11, 2.13, 3.3–3.6, 4.1, 4.3–4.8, 5.1, 5.3–5.10).

Scoring of the data

The scoring of the questionnaire was done as per the standard method for scoring and numerical values were used to depict evaluation findings. All the responses with numbers and percentages meeting the assessment criteria were coded as Yes and those which did not meet the specified criteria were coded as No. The response recorded as 'Yes' for a core indicator was given a value of 2, and for the supplementary indicator was given a value of 1. A No response was given a value of 0. The maximum possible score was 52 for the core indicators and 17 for the supplementary indicators. Similar type of scoring was also used in studies done in other countries.[10, 11] The assessment period was 2 years (2019 and 2020) since 2020 was affected by the COVID-19 pandemic.

Data analysis

The data from the regional and national pharmacovigilance centres were tabulated for a clear understanding of the results. The percentage score for each component was calculated and if this was more than 60% then it was concluded that the component met the specific needs. Similar scoring and presentation were used in other studies.[12, 13]

Ethics approval and consent to participate: the ethical approval for the research was obtained from the Nepal Health Research Council on 14 October 2020. The participants were informed about the purpose of the research and written consent was obtained before enrolling them. Participant anonymity was maintained throughout the research.

Results

Twelve respondents from 12 regional pharmacovigilance centres and two from national pharmacovigilance centre and the ministry of health and population were interviewed and thirteen respondents were pharmacists.

Table 1 Demographic characteristics of respondents and information about the regional pharmacovigilance centres (n = 12)

Characteristic	Number (percentage)
Age (in years) of the respondent from regional centres	
20–30	1 (8.3)
31–40	7 (58.3)
41–50	3 (25)
>50 years	1 (8.3)
Gender	
Male	11 (91.6)
Female	1 (8.3)
Education	
Bachelors	1 (8.3)
Masters	9 (75)
PhD	2 (16.6)
Location of the PV centre	
Inside Kathmandu Valley	10 (83.3)
Outside Kathmandu Valley	2 (16.6)
Qualification of the regional PV centre coordinator	
PhD in Pharmacy	2
MD Pharmacology	1
MPharm	7
PharmD	2
Others	0
Years of professional experience of the coordinator	
<5 years	3 (25)
5–10 years	6 (50)
>10 years	3 (25)
Number of beds in the attached hospital	
<500	4 (33.3)
>500	8 (66.6)
Name of the regional centres included in this study	Starting year
Institute of Medicine (IOM)	2006
Manipal College of Medical Sciences (MCOMS)	2006
KIST Medical College	2008
Civil Hospital	2011
Patan Academy of Health Sciences	2013
Norvic Hospital	2017
Nepal Medical College	2017
Kathmandu University School of Medical Sciences	2017
Nepal Cancer Hospital and Research Center	2018
Nepal Army Institute of Health Sciences	2018
College of Medical Sciences	2018
Chitwan Medical College	2019

Table 1 represents the data from the 12 regional pharmacovigilance centres. More than half (58.3%) of the centre coordinators were from the age group of 31–40 years with a dominance of male participants. Seventy-five percent of respondents were having master's level of educational qualification. More than half (58.3%) of the regional pharmacovigilance centres were established after 2016. Out of the 14 regional pharmacovigilance centres, 10 were in Kathmandu and only 4 centres were located outside the Kathmandu Valley. The newest centre (15th) added to the list is also based in the Kathmandu Valley. Maximum number of centres were attached to hospitals with more than 500 beds. Half of the regional pharmacovigilance centre coordinators were having a work experience of 5–10 years.

Assessment of pharmacovigilance system at the national pharmacovigilance centre

Eight structural indicators out of 15, 6 process indicators out of 18 and 3 outcome indicators out of 10 were fulfilled obtaining a maximum

score of 69 (Supplementary Table S1, Assessment of the national pharmacovigilance centre and ministry of health and population).

Table 2 shows the performance of national pharmacovigilance center as per the five different components for pharmacovigilance as per the IPAT tool. The national pharmacovigilance center obtained an overall score of 43.4% (30/69). Table 3 shows the policy, law and regulation present in the national pharmacovigilance center. The results show the existence of a policy document that contains essential statements on pharmacovigilance or medicine safety (stand-alone or as a part of some other policy document) but there was no specific legislation for pharmacovigilance till date.

However, there are no policies and procedures related to pharmacovigilance incorporated in the current national medicines policy.[14] The new national medicines policy with reference to pharmacovigilance is still under development. There are no legal provisions in the national medicines policy, no requirement for pharmaceutical companies to report ADRs of their marketed products and no requirement for conducting post-marketing surveillance studies (Supplementary Table S1, statements 1.3 and 1.4).

Pharmacovigilance assessment of regional centres

There were 31 indicators with 19 core indicators and 12 supplementary indicators to assess the regional pharmacovigilance centres. There were 8 structural, 14 process and 9 outcome indicators. The maximum score was 50 (Supplementary Table S2, Assessment for regional centres).

Table 4 shows the performance of regional pharmacovigilance centers. The number of ADRs reported by a particular regional centre during the study period ranged from 0 to 35. This was very low as many centres did not report ADRs. Figure 1 shows current situation of capacity building for the pharmacovigilance system. It explains how the structures, systems and roles enables the effective use of staff and infrastructure and how that enables the skills and tools to be used for strengthening the pharmacovigilance system in Nepal.

Discussion

A well-structured and managed pharmacovigilance programme can contribute immensely to patient safety. Countries have set up pharmacovigilance programmes and as of now, there are 145 full member countries and 26 associate member countries in the WHO Programme for International Drug Monitoring.[15] Indigenous pharmacovigilance is necessary for countries to generate and validate their own safety data in local populations. Nepal is still a largely import-driven pharmaceutical market with lack of post-marketing surveillance studies and high presence of counterfeit medicines in adjoining countries.[16] Hence, it is vital to have a stringent pharmacovigilance mechanism. Though Nepal joined the international pharmacovigilance programme 15 years back, so far there has been no systematic assessment of the programme. A systematic and periodic assessment of the system can help to identify lacunae and address them at an earlier stage. This study is the first one in the country to assess the national pharmacovigilance programme and provides a deeper insight into drug safety mechanisms at the national and regional levels.

Currently, there are 15 regional pharmacovigilance centres with an addition of eight centres since 2016. From a system perspective, it is important to note that most centres are in the Kathmandu Valley, where the capital is located. This holds true even for the entire healthcare system, wherein most advanced healthcare facilities are concentrated in the capital city. This finding is contrary to other countries such as India wherein the regional centres are more widely distributed.[17] More distribution of regional centres throughout the country is the need of the hour. A unique observation is that 13 regional centres are in academic hospitals which train medical students and are attached to a medical school. This is a positive trend that eventually improves the sustainability and creates expert manpower for running pharmacovigilance activity.

An overall assessment of the National Pharmacovigilance Center and Ministry of Health in this study shows the presence of 'acceptable' levels of dedicated infrastructure and manpower. However, there has been no active engagement between the national centre and key stakeholders in terms of improving the activity and reporting procedures. During the last 15 years, the country has initiated the concept of drug safety through training and educational programmes. However, there are no policies and procedures related to pharmacovigilance incorporated in the current national medicines policy.[14] The new national medicines policy with reference to pharmacovigilance is still under development.

There are no legal provisions in the national medicines policy, no requirement for pharmaceutical companies to report ADRs of their marketed products and no requirement for conducting post-marketing surveillance studies (Supplementary Table S1, statements 1.3 and 1.4). Several countries mandate pharmaceutical companies to report ADRs of their products in the country.[18] Reporting by pharmaceutical companies can complement the pharmacovigilance programme in the country in improving reporting rates and identifying certain formulation-specific ADRs.

The scores from the assessment of the national pharmacovigilance centre were 33.3% for the policy, law and regulation measures. This finding is very similar to a study done in Sierra Leone[12] and lesser than another study done in Burkina Faso.[13] For the systems, structures and stakeholder's coordination, our findings showed only 53.8% score whereas the studies from Sierra Leone and Burkina Faso were indicating a better status (scores of 96% and 68%, respectively).

The assessment of systems, structures and stakeholders showed a 'fairly good' outcome wherein 6 out of 10 core indicators related to 'structure' were fulfilled by the national centre. For the 'process', only one out of four core and one supplementary structural indicator were fulfilled. The finding clearly shows a greater lacuna in the process than structure at the national level. For the signal generation and management, results showed that only 50% of scores were achieved in contrast to the studies from Africa (100% and 60%).[12, 13]

Risk assessment and evaluation assessment obtained only 25% of maximum scores whereas, the scores for the African countries were 43% and 71%, respectively. Similarly, the scores for risk management and communication were found to be 38.4% which was lower than those reported in the African countries.[12, 13]

Table 2 Pharmacovigilance performance of national pharmacovigilance centre

Pharmacovigilance components	Score (%)	Target outcomes
Policy, law and regulation	2/6 = 33.3	Not achieved
Systems, structures and stakeholder coordination	14/26 = 53.8	Not achieved
Signal generation and data management	6/12 = 50	Not achieved
Risk assessment and evaluation	3/12 = 25	Not achieved
Risk management and communication	5/13 = 38.4	Not achieved
Overall score	30/69 = 43.4	Not achieved

Table 3 Policy, law and regulation in the national pharmacovigilance centre

Policy, law and regulation	Document availability
Existence of a policy document that contains essential statements on pharmacovigilance or medicine safety (stand-alone or as a part of some other policy document)	Available
Existence of specific legal provisions for pharmacovigilance in the national medicines' legislation or similar legislation	Not available
Legal provisions require that the marketing authorization holder mandatorily report all serious ADRs to the national drug regulatory authority	Not available
Legal provisions require the marketing authorization holder to conduct the same or similar post-marketing surveillance activities for products as required by stringent regulatory authorities	Not available

Table 4 Pharmacovigilance performance of regional pharmacovigilance centres

Regional centres	Score (%)	Target outcomes
A	16/50 = 32	Not achieved
B	12/50 = 24	Not achieved
C	14/50 = 28	Not achieved
D	16/50 = 32	Not achieved
E	15/50 = 30	Not achieved
F	30/50 = 60	Not achieved
G	20/50 = 40	Not achieved
H	18/50 = 36	Not achieved
I	15/50 = 30	Not achieved
J	27/50 = 54	Not achieved
K	21/50 = 42	Not achieved
L	12/50 = 24	Not achieved

Risk assessment and evaluation showed a poor response except for the fact that there were 43 ADR reports received during the past 2 years. This number is lower compared with the past wherein there were a greater number of ADR reports. As per the earlier reports, one of the regional centres alone received a total of 355 ADR reports during its initial 3 years and 6 months of operation.[4] This drop in the number of ADR reports could be attributed to the presence of motivated individuals at certain centres for a particular period and their departure leading to a decrease in numbers. Underreporting of ADRs is common worldwide even in countries with well-developed ADR reporting systems.[19, 20] Measures for improving ADR reporting rates are well reported in the literature[21] and appropriate methods can be chosen. Involving patients in ADR reporting can improve the reporting rates.[22] At the national level, the risk communication is poor, though the DDA publishes the Drug Bulletin of Nepal wherein the emphasis is on drug safety though the published reports are predominantly from foreign countries and there is a lack of local signals.[23]

The regional centres seem to possess a good structure but a weak process. In most cases, the centres are equipped with basic computers, drug information resources, internet etc., and manned by a well-qualified staff, in most cases, a pharmacist but unfortunately, they have poor process indicators. Very few regional centres publish a drug bulletin or newsletter, and this is often not published regularly but they do have reference resources related to drug safety available with them at the centre. The health professional curricula also do not adequately emphasize pharmacovigilance though in the past there have been a few pharmacovigilance modules conducted for medical,[24] pharmacy,[25] and nursing students.[26]

The indicators assessment showed that none of the five above-mentioned sections were fulfilled by the 12 regional centres which was very similar to the study from Sierra Leone and a bit different from the findings from Burkina Faso, where one of the public health facilities studied had scored more than 60% indicating the achievement of the target score for a good pharmacovigilance system.[12, 13]

Regional centres use either self-developed ADR reporting forms or the one developed by the DDA,[27] but most did not have a form to report medication error and drug therapy failure. There have also not been many drug utilization studies conducted by the centres recently and no synchronization with the public health programmes in the country. The ADR reporting rates were also poor with most centres reporting less than 10 ADRs in a year suggesting the need for immediate interventions. There were also poor risk management and communication in terms of providing medicine safety information to healthcare providers and no drug bulletin or newsletter was being published on drug safety-related issues. Some of these services such as publishing drug bulletin,[23] providing drug information related to patient safety were carried out by some centres earlier but have not been sustained over time. Though the hospitals had Drug and Therapeutics Committee, their involvement in pharmacovigilance was minimal. The findings show the regional centres and their attached teaching hospitals did not focus special attention on supporting the pharmacovigilance programme. Drug safety ensuring mechanisms are largely lacking or even if existing did not sustain for long. Undoubtedly one might argue that the regional centres being attached to teaching hospitals certainly have the capacity to report ADRs. All that need is the willingness and commitment from all key stakeholders. These changes can occur only if a clear road map for functional pharmacovigilance is provided by the national centre with active involvement of regional centres and their attached hospitals.

Limitations

This IPAT study was planned to be conducted over a 1-year period. Since 2020 was affected by the COVID-19 pandemic, the authors of this research collected information over 2 years (2019 and 2020). Moreover, the authors could not obtain responses from two regional pharmacovigilance centres. A new regional centre at Mediciti hospital, Kathmandu was not included in the study as it has been added recently after the completion of the data collection.

Recommendations

Based on the study findings, the authors would like to make the following recommendations: pharmacovigilance services should be promoted and feature in the medicine policy and regulatory frameworks in Nepal. The national drug regulatory authority must mandate pharmaceutical companies to monitor and report any suspected ADRs occurring within the country. Pharmacovigilance is currently restricted only to ADR reporting and there is a need to

incorporate medication errors and drug therapy failures into the system. Regional centres should be encouraged to report more ADRs and publish drug bulletins and other information sources. The national centre can use information technology to monitor and support regional centres more effectively. Strategies should be adopted to improve the pharmacovigilance-related processes. Vertical programmes like HIV, AIDS, Malaria should be incorporated within the national pharmacovigilance programme. National safety advisory committee with multi-sectoral stakeholders should be established for the smooth functioning of pharmacovigilance activity.

Conclusions

There are no policies and frameworks at the national level regarding pharmacovigilance. The absence of guidelines on risk assessment, absence of signal generation, weak data management, poor synchronization with national public health programmes and weak communication systems impact pharmacovigilance at the national level. At the level of regional centres, physical infrastructure and qualified manpower exist but weak functioning with poor data management, signal generation and communication is seen. Adequate training for health professionals regarding drug safety-related resources and task-specific initiatives both at the health ministry and national drug regulatory authority level can help improve the pharmacovigilance programme leading to better patient safety.

Supplementary Material

Supplementary data are available at *Journal of Pharmaceutical Health Services Research* online.

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Author Contributions

N.J., S.P., P.R.S., S.K.C. and P.B.K. conceived and designed the study. N.J. and S.P. finalized the methodology. S.P., S.K., P.B.K. and P.R.S. finalized the tool used. N.J., S.K. and P.B.K. collected the data. N.J. and S.P. analyzed the data. S.P., N.J. and P.R.S. drafted the manuscript. All authors were involved in editing the drafted manuscript. The final manuscript has been read and approved by all the authors.

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Conflict of Interest

None declared.

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