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Scope of Pharmacovigilance for Ayurvedic Drugs in Nepal: A Review

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ABSTRACT:

Ayurveda along with complementary and alternative medicine (CAM) systems have their own principles, have their own pharmacopeia, but are practiced as over the counter drugs without an authentic prescription. Government of Nepal nominated Department of Drug Administration (DDA) in October 2004 as the focal point (National Pharmacovigilance Centre) to liaison with WHO collaborating centre for International Drug Monitoring (IDM), Sweden and started collecting adverse drug reactions (Nepal became a WHO program member in July 2006). Nepal joined the international pharmacovigilance program as a full member in 2007. This study is to reflect the present status of pharmacovigilance in Nepal and put light on scope of pharmacovigilance on drugs of Ayurveda and other complementary alternative systems in Nepal. For which review and analysis of concerned published literatures in print form and in online database. At present; 12 regional pharmacovigilance centers are there in Nepal. Currently, the clear pattern and scope of adverse drug reactions (ADRs) in Nepal remains unexplored. For Ayurveda drugs the concept of pharmacovigilance is not yet formally introduced in Nepal. No policy has been formulated for the same. The conventional belief that Ayurveda drugs have no ADRs should be transformed.

Keywords: Adverse drug reactions (ADRs), Pharmacovigilance, Department of Drug Administration (DDA), International Drug Monitoring (IDM)

INTRODUCTION

Ayurveda along with complementary and alternative medicine (CAM) systems have their own principles, have their own pharmacopeia, but are practiced in many countries as over the counter drugs without an authentic prescription. With increased use of herbal and CAM drugs in the present time, the main issue being raised about the drugs of Ayurveda and drugs of other CAM is regarding the safety aspect of the drug. For which so

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many reports are being published and also they are misinterpreted because of that a negative impact is being generated on these systems of medicine[1.] In context of Ayurveda and CAM drugs, with increased use of drugs of these systems, the scope for adulteration, preparation of counterfeit drugs and development of formulations which do not have conceptual basis in CAM system has increased. Further cultivation of medicinal plants with laboratory generated species is being attempted on the basis of chemical composition and is likely to be used in increased manner for commercial purpose. These changes may have profound impact on safety and efficacy of CAM drugs. Hence need of pharmacovigilance is expected. Adverse drug reactions have become a dominant health related problems in developing countries like Nepal. The main objective of pharmacovigilance is the assessment of benefit-risk profile of drug for better efficacy and safety in patients. Voluntary recording of adverse drug reactions (ADRs) is a chief component of pharmacovigilance[2.] Thalidomide drug, which was manufactured and sold between 1950s in Germany brought congenital malformations ADR as phocomelia in 6000-12000 newborns and hence got withdrawn from the market on 25th November 1961[3.]After thalidomide disaster the compilation of records on all types of injurious drug reactions started in organized form. In 20th World Health Assembly in 1971, authority of the World Health Organization (WHO) established International Drug Monitoring Program (IDMP). The recent international system of pharmacovigilance is depending on the paper disclosed in 1972 and appropriately the national pharmacovigilance centers were settled in participation with the WHO. Detailed efforts of drug safety monitoring in India started in 1997, in partnership with WHO Uppasala Monitoring Center, Sweden[4.]

According to WHO, Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems[5]. Pharmacovigilance plays an important role in rational use of medicines by providing information about adverse drug reactions (ADRs) in the general population[6].

In the year 2004, pharmacovigilance activities were initiated in Nepal and the country became a full member of the international pharmacovigilance program in 2007. The Department of Drug Administration (DDA), the national drug regulatory authority of Nepal acts as the national centre for ADR monitoring. Hospitals in Nepal were directed to report ADRs to the regional pharmacovigilance centers from where reports are sent to the national pharmacovigilance centre for its analysis. Further those reports are sent to the Uppsala Monitoring Centre (UMC) of Sweden, the World Health Organization (WHO) collaborating centre for international drug monitoring for publication and distribution[7]. Despite being crucial, the system of pharmacovigilance and voluntary reporting of ADRs has not been fully established in Nepal, with high under-reporting of such events[8].Nepal is a developing country and has several problems related to medicinal use. The majority of drugs used are manufactured in foreign countries and the safety profile of the excipients, diluents, binders, stabilizers and other additives used to prepare medicines is not validated with the genetic make-up of the Nepalese population which might be a predisposing factor for ADRs[9]. Clinical trials of new medication often do not cover the safety issues of the drug, for which post-marketing surveillance of drugs becomes crucial[10].

In Nepal, there is no strict law necessitating drug manufacturers to submit safety data from the Nepalese population prior to approval of the medicines. Hence, it is very necessary to monitor adverse effects of the medicines available in the market as the information collected during the pre-marketing and post marketing phase is inevitably incomplete with regard to possible ADRs[11].

METHOD

A search was conducted in concerned published literatures in print form and in online database for Pharmacovigilance in Nepal; ADRs for Ayurvedic drugs, pharmacovigilance for Ayurvedic drugs and data of work done on above issues was explored

RESULTS

The word ADR may not be found in Ayurvedic literature but the concepts and safety issues are vibrant throughout texts of Ayurveda. Ayurveda literatures has given utmost importance to safety and benefit of patient in every step of treatment which includes selection of raw drugs, collection, different processing techniques, and their proper administration in appropriately diagnosed patient. Overall, different causes of adverse drug reaction mentioned in Ayurveda can be grouped under follow

headings[12.]

1. Drug interaction (*Virudda-dravya-prayoga)*
2. Iatrogenic (*Vaidhya-kruti*)
3. Over dose (*Atimatra-dravya-prayoga*)
4. Administration of unwholesome drugs (*Ahitatam-dravyas)*
5. Administration of medicine in diverse pathological stages (*Avastha-anusara-dravya-prayoga*)
6. Therapeutic procedural complications (*Panchakarma-vyapad*)
7. Improper use of *Ras-aushadi* (Medicines of mineral origin)

The comparative contributing factors for ADR in Ayurveda and modern medicine are presented in table 1[13](Table 1 in Annex II).

Pharmacovigilance operational is discussed in flowchart and network in Nepal[14] (Flowchart in Annex I).

Table 2 represents Steps of ADRs reporting practice and analysis in Nepal[15] (Table 1 in Annex III).

These regional pharmacovigilance centers operate under DDA (DDA being the National centre for ADR monitoring). The regional centers reports ADRs to the National center (DDA) via 'Vigiflow' (an online software program) which are then forwarded to the Uppsala Monitoring Center (UMC) by the National Centre. The national database maintains only about 547 ADR reports so far since it started from 2004[16].

Table 3 describes List of 12 regional pharmacovigilance centers in Nepal are[17] (Table 1 in Annex IV).

On the 7th of July 2019, Nepal Cancer Hospital and Research Center (NCHRC), a tertiary cancer care hospital located at Province No.3, Nepal conducted a workshop on adverse drug reaction reporting, pharmacovigilance and its implementation in a cancer hospital. One of its sessions primarily focused on the concept of CAM, their practice and focused on certain herbs, the advantages of which are scientifically proven. Speakers highlighted the various CAM components such as dietary supplements, manipulative practices, mind-body systems, energy medicine, and ancient medical systems such as Ayurveda. Speaker explained the uses of CAM, the benefits of certain practices and integration of CAM into conventional treatment plans along with the beneficial and adverse effects of herbal supplements[18].

DISCUSSION

Under a national and total 12 regional pharmacovigilance centers in Nepal, no institution of Ayurveda of Nepal is included in it[19]. Neighboring country India, the broader land of Ayurveda has formulated several policies and doing a lot of pharmacovigilance activities for Ayurveda, Siddha and Unani (ASU) drugs[20], where Nepal has not started it yet for the same. In India national pharmacovigilance program under the control of central drug standardization control organization started since 2003. WHO emphasized need of pharmacovigilance in CAM and published guidelines on safety monitoring of herbal medicine in pharmacovigilance system in 2004. After that several amendments in drug and cosmetic act 1940 have been made to apply pharmacovigilance in CAM drugs. At present 42 ASU institutions are serving as peripheral pharmacovigilance centers in India.

So, existing national pharmacovigilance program policy should be revised and Ayurveda along with others complementary medicine system of Nepal has to be considered in it. Initially, for each system of CAM at least one national centre and some regional centers of pharmacovigilance (of CAM institutions) under it should be established as soon as possible. To develop the culture of reporting ADRs in Ayurveda system of medicine and to involve healthcare professionals and professional associations in the drug monitoring and information dissemination processes, teachers, physicians and pharmacists of Ayurveda system should be sensitized on the concept of pharmacovigilance. CME programs on pharmacovigilance should be initiated across the country[21].

Accessibility of resource centers and materials regarding Ayurveda drugs ADRs reporting, collection and collation should be made available to all stakeholders in digital and online mode.

Ayurveda has very elaborate explanation about ADR and ways to prevent it. Peer reviewed textual knowledge is necessary to minimize the occurrence of ADRs in practice. Extensive researches are needed to understand the reasoning and concept behind the classical principles in regard to the drug administration and safety of drugs, which they can help to explore new paradigm related with

pharmacokinetics, pharmacodynamics and pharmacogenomics. Systematic, spontaneous and sensible reporting of ADR related to Ayurvedic treatments plays an important role in providing signals and formulating new research orientations[22].

CONCLUSION

Ayurveda along with complementary and alternative (CAM) systems of medicines have their own principles, have their own pharmacopeia, but are practiced in many countries as over the counter drugs without an authentic prescription. The conventional belief that Ayurveda drugs have no ADRs should be transformed. Ayurveda drugs should also be analyzed on benefit-risk calculation. Responsible bodies under Nepal government should take no time to revise the national pharmacovigilance program and introduce Ayurveda and other CAM into it. Ayurvedic institutions and manpower should also be included as responsible means of reporting and analysis of ADRs of Ayurvedic drugs.

The risk of use of Ayurvedic medicine can be considerably reduced by use of good quality medications and following various guidelines and instructions mentioned in Ayurveda classics related to administration of drugs. To achieve this it is very important to understand and study the principles of drug safety mentioned along with modern pharmacovigilance in Ayurveda.

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REFERENCES

1. Ajanal, M., Nayak, S., Prasad, B. S., & Kadam, A. Adverse drug reaction and concepts of drug safety in Ayurveda: An overview. *Journal of young pharmacists: JYP*, *5*(4), 116–120. https://doi.org/10.1016/j.jyp.2013.10.001
2. Mishra P, Upadhyay P, Rawat R, Ashraf D T, Dev K, Chauhan N, A Review on Pharmacovigilance Process In India, Asian Journal of Pharmaceutical Research and Development. 2020; 8(3):190-195. DOI: http://dx.doi.org/10.22270/ajprd.v8i3.735
3. Mishra P, Upadhyay P, Rawat R, Ashraf D T, Dev K, Chauhan N, A Review on Pharmacovigilance Process In India, Asian Journal of Pharmaceutical Research and Development. 2020; 8(3):190-195. DOI: http://dx.doi.org/10.22270/ajprd.v8i3.735
4. Mishra P, Upadhyay P, Rawat R, Ashraf D T, Dev K, Chauhan N, A Review on Pharmacovigilance Process In India, Asian Journal of Pharmaceutical Research and Development. 2020; 8(3):190-195. DOI: http://dx.doi.org/10.22270/ajprd.v8i3.735
5. The importance of pharmacovigilance: Safety monitoring of medicinal products. [Internet]. Geneva: World Health Organization: 2002. Available at http://www.who.int/medicinedocs/collect/medicinedocs/pdf/s4893e/s4893e.pdf (Accessed 1/12/2021)
6. Jha N, Shankar PR, Bajracharya O, Gurung SB, Singh KK. Adverse drug reaction reporting in a pharmacovigilance centre of Nepal. AMJ 2012, 5, 5, 268-271. http//dx.doi.org/10.4066/AMJ.2012.1142
7. Jha N, Shankar PR, Bajracharya O, Gurung SB, Singh KK. Adverse drug reaction reporting in a pharmacovigilance centre of Nepal. AMJ 2012, 5, 5, 268-271. http//dx.doi.org/10.4066/AMJ.2012.1142
8. Jha N, Shankar PR, Bajracharya O, Gurung SB, Singh KK. Adverse drug reaction reporting in a pharmacovigilance centre of Nepal. AMJ 2012, 5, 5, 268-271. http//dx.doi.org/10.4066/AMJ.2012.1142
9. Jha N, Shankar PR, Bajracharya O, Gurung SB, Singh KK. Adverse drug reaction reporting in a pharmacovigilance centre of Nepal. AMJ 2012, 5, 5, 268-271. http//dx.doi.org/10.4066/AMJ.2012.1142
10. Olsson S. The role of the WHO programme on International Drug Monitoring in coordinating worldwide drug safety efforts. Drug Saf**.** 1998;19(1):1–10. doi:10.2165/00002018-199819010-00001
11. Santosh KC, Tragulpiankit P, Gorsanan S, Edwards IR. Attitudes among healthcare professionals to the reporting of adverse drug reactions in Nepal. BMC PharmacolToxicol. 2013; 14:16. doi:10.1186/2050-6511-14-16

12. Ajanal, M., Nayak, S., Prasad, B. S., & Kadam, A. Adverse drug reaction and concepts of drug safety in Ayurveda: An overview. *Journal of young pharmacists: JYP*, *5*(4), 116–120. https://doi.org/10.1016/j.jyp.2013.10.001
13. Ajanal, M., Nayak, S., Prasad, B. S., & Kadam, A. Adverse drug reaction and concepts of drug safety in Ayurveda: An overview. *Journal of young pharmacists: JYP*, *5*(4), 116–120. https://doi.org/10.1016/j.jyp.2013.10.001
14. https://www.dda.gov.np/content/pharmacovigilance
15. Jha N, Shankar PR, Bajracharya O, Gurung SB, Singh KK. Adverse drug reaction reporting in a pharmacovigilance centre of Nepal. AMJ 2012, 5, 5, 268-271. http//dx.doi.org/10.4066/AMJ.2012.1142
16. https://www.dda.gov.np/content/pharmacovigilance
17. https://www.dda.gov.np/content/pharmacovigilance
18. Shrestha S, Shrestha R, Abidi A, Upadhyay A, Khanal T, Adhikari B, Ghimire BR. Workshop on Adverse Drug Reaction Reporting, Pharmacovigilance and Its Implementation in Cancer Hospital in Nepal: An Event Report. *Adv Med Educ Pract*. 2020;11:9-14 https://doi.org/10.2147/AMEP.S225208
19. https://www.dda.gov.np/content/pharmacovigilance
20. Mishra P, Upadhyay P, Rawat R, Ashraf D T, Dev K, Chauhan N, A Review on Pharmacovigilance Process In India, Asian Journal of Pharmaceutical Research and Development. 2020; 8(3):190-195. DOI: http://dx.doi.org/10.22270/ajprd.v8i3.735
21. Baghel M. The National Pharmacovigilance Program for Ayurveda, Siddha and Unani Drugs: Current status. *International journal of Ayurveda research*, 2010.*1*(4), 197–198. https://doi.org/10.4103/0974-7788.76779
22. Baghel M. The National Pharmacovigilance Program for Ayurveda, Siddha and Unani Drugs: Current status. *International journal of Ayurveda research*, 2010 *1*(4), 197–198. https://doi.org/10.4103/0974-7788.76779

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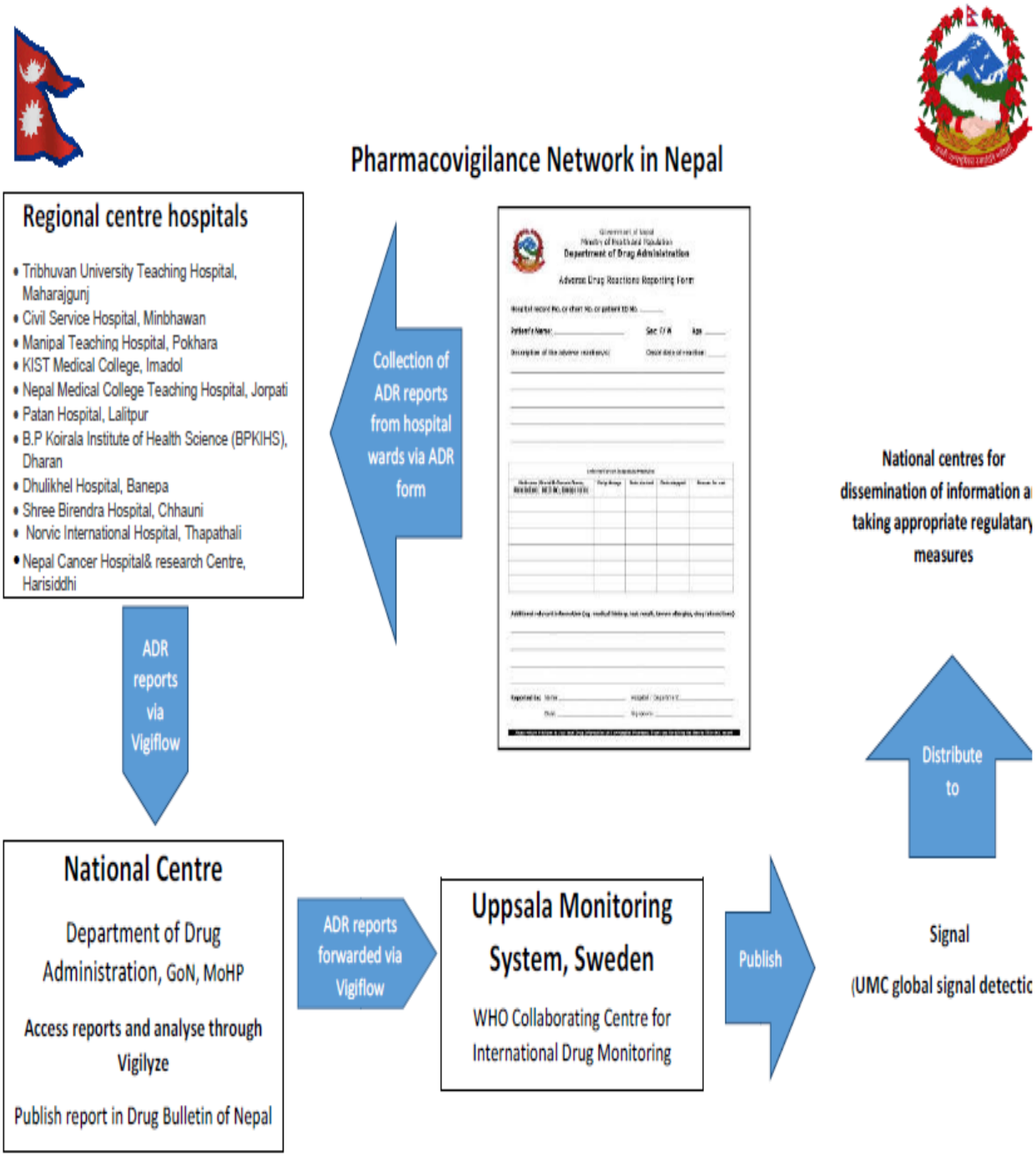
Annex I

Pharmacovigilance operational flowchart and network of centers in Nepal



Annex II

Table 1

S.N.	Character	Modern medicine	Ayurveda medicine
1.	Adverse drug reaction	Unintended drug response which is not documented during various phases of clinical trial	Intended drug response, the possible ways and mechanism of event has already been documented in various texts of Ayurveda
2.	Causes of ADR	Drug excessive effects, interaction, drug intolerance, idiosyncrasy and drug allergy	Drug interaction, iatrogenic, over dose, unwholesome drugs, drug pharmacokinetic interaction, procedural complications and GMP concern
3.	Concept of Prakriti (Constitution)	Not described	Has potential role in causing ADR
4.	Alteration of drug action due to exercise or mental status	No theoretical explanation available	Alteration of drug action can be seen due to physical or mental activities
5.	Description of wholesome and unwholesome drugs	Not described	Described
6.	Improper usage of therapeutic instruments	Not known to cause ADR	Known to cause failure of therapy
7.	GMP guidelines	Only pertaining to manufacturing of quality drugs	Violation of any specified measures can lead to diseases
8.	Relevance of diet restriction during drug administration	Generally not applicable	Reliant factor for therapeutic success
9.	Violation of therapeutic restrictions	Not related with ADR	Has potential role in causing ADR
10.	Over dose	Not included in WHO definition of ADR	Important factor to cause ADR
11.	Seasonal variation of drug action	Not described	Variation is known to cause alteration of drug action, therefore need be assessed before prescribing drug

Annex III

Table 2 Steps of ADRs reporting practice and analysis in Nepal[15]

S.N.	Steps	Software program used in Nepal
1.	Reporting of cases from different health centers on prescribed Performa	Vigiflow
2.	Collection, collation Analysis of the reported cases at National Pharmacovigilance centre	Vigilyze/VigBase
3.	Publication & distribution of the analyzed cases	Vigiflow

Annex IV

Table 3 describes List of 12 regional pharmacovigilance centers in Nepal are[17]:

S.N.	Name of regional centre	Province	Address
1	Tribhuvan University Teaching Hospital	Province 03	Maharajgunj, Kathmandu
2	Civil Service Hospital	Province 03	Minbhawan, Kathmandu,
3	Manipal Medical College and Teaching Hospital	Province 04	Pokhara, Kaski,
4	KIST Medical College and Teaching Hospital	Province 03	Imadol, Lalitpur,
5	Nepal Medical College Teaching Hospital	Province 03	Jorpati, Kathmandu,
6	Patan Hospital	Province 03	Patan, Lalitpur
7	B.P Koirala Institute of Health Science	Province 01	Dharan, Sunsari,
8	Dhulikhel Hospital	Province 03	Banepa, Kavre
9	Shree Birendra Hospital	Province 03	Chhauni, Kathmandu
10	Norvic International Hospital	Province 03	Thapathali, Kathmandu
11	Nepal Cancer Hospital and Research Center	Province 03	Harisiddhi, Lalitpur
12	College of Medical Sciences and Teaching Hospital	Province 03	Bharatpur, Chitwan