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Importance of Pharmacovigilance in Ayurveda

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ABSTRACT

Introduction: Ayurveda has been introduced in India around 1500 BC. Ayurvedic medicines are more accepted these days as people are looking out for the natural medications. The major function of this system is to preserve the normal wellness of people and to cure the patient. These medicines, which are generally considered as safer, are now in the aura of doubt, due to some of the recent incidences of Adverse Drug Reaction (ADR), during their usage.

Objective: Pharmacovigilance is an important step in Ayurveda to overcome and continuously monitor the ADR. Pharmacovigilance is the law and regulations for pharma industries, which deal with the detection, assessment, monitoring, understanding, prevention and reporting of adverse effects of medicines. Thus, this is the recurrent theme of ayurvedic pharmacology (dravyagunavigyan) and healing (chikitsa). The most important aim of pharmacovigilance, that is to enhance patient care and safety of the drug use, and as a result elevate rational drug use are recurring premise of ayurvedic pharmacology cology (dravyagunavigyan) and therapeutics (chikitsa).

Methods: The data was collected from different websites and databases such as PubMed, Biomedical Sciences, Science Direct, Wiley Online Library, Google Scholar, WHO, Bentham science etc. A total of 80 articles were downloaded, studied, categorized and 52 were selected to write the manuscript.

Results and Conclusion: There is requirement of an appropriate post-clinical surveillance program for ayurvedic drugs based on its quality, safety, and efficacy, for public health and disease management, which is now accessible in National Pharmacovigilance Programme for ASU (Ayurveda, Siddha, Unani) drugs, Ayurveda has explained a broad hypothesis on homeopathy medicines, in relation with its usage, causal ADR, treatment and its prevention. Spontaneous reporting of ADR related to Ayurveda plays an essential role in the identification and detection of new signals and communicating novel research questions.

1. Introduction

Ayurveda a boon for India, is a crucial part of health organization. Being a science ayurveda has an enormous history of research and advancement. From the ancient epoch to modern era, Ayurvedic science has extended its progressive hands towards research and technology, Ayurveda is usually referred as “Science of Life”. Since past thousands of years, clinical trials evidences based on safety and efficacy of ayurvedic drugs has been prioritized, to create transparency and awareness among consumers. (Patwardhan and Vaidya,; Thatte and Bhalerao, 2008) According to Price water house Coopers (PwC) and Confederation of Indian Industry (CII) report of 2017, 77 per cent of Indian families used ayurvedic formulations at this time, and this percentage in 2015 was only 69 per cent.

Ayurvedic medicines are assembling increasing worldwide attention with regard to both therapeutic actions to treat several non-infectious and chronic diseases as well as due to the risk of health hazards correlated with it (Baghel, 2010).

The international market for Ayurvedic medications is also developing. The range of the international Ayurvedic market is ordinary to approximately treble from $3.4 billion in 2015 to $9.7 billion in 2022. Associated with this escalating use of ayurvedic drugs are increasing apprehension about the safety of drugs.

There is a chief delusion amongst community and also a great numbers of doctors that Ayurvedic medication are secure and do not produce any ADR’s. Primitive text books openly state that if a medicine is taken with no information of its appropriate pharmacological action and doses, it

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would definitely work as a toxic. Although it may give the impression to be a theorized declaration, but its spirit is pulsating with the view of Pharmacovigilance (Kashinath *et al*).

The most important aim of pharmacovigilance, that is to enhance patient care and safety of the drug use, and as a result elevate rational drug use are recurringpremise of ayurvedicp'cology (dravyagunavigyan) and therapeutics (chikitsa) (Ajanal et al., 2013a). Ayurveda which is holistic system of medicine from India has elaborated the causes and methods of drug-induced consequences along with preventive measures the available data in classical texts is scattered. The compilation and analysis along with modern concept drug safety is need of the hour. Present literature review was conducted from various compendium of Ayurveda and electronic data base with search terms of 'Vyapad', 'Viruddha', 'Ahita', 'herb-herb interaction', 'idiosyncrasy', 'Prakritiviruddha' etc. The reported information was analysed for the possible correlation on concept of ADR and Pharmacovigilance of current science. Overall review demonstrated drug interaction, iatrogenic, over dose, administration of unsuitable drugs, reprehensive drug administration with respect to disease, complication from five procedural therapies (Panchakarma. Pharmacovigilance also deals with the prevention of unintended and noxious effects of medicines and other medical interventions intended for remedy and diagnosis of morbidities.

2. Need of Pharmacovigilance in Ayurvedic medications

The choice about recommendation of a medicine also relies on the yukti of the practitioners and his little estimation of theroga and rogibala, the time of taken of medicine (Kala), itslocation (desha), Satwa, Satmya, Ahara Shakti, and Vyayam Shakti. Acharya charka has consider the drug related factors such as; Prakriti, Guna, Karma, Prabhava, Desha, Rutu, Grahitam, Nihitam and Upaskrtam (Nitin L, 2012) & patient related factors such as Prakriti, Vikriti, Vaya, Bala, Satmya, Ahar Shakti, Sara, Satva, and Sanhanana (Samal, 2018).

Systematic assessment of the adverse drug reaction and adverse events from the ayurvedic medicines are more important for maintain the belief of the population on ayurvedic medicines that would be safe. If the pharmacovigilance system is systematically established in ayurveda it can force us to make more secure and system of pharmacovigilance will force us to endeavour harder to formulate more secure and genuine drugs, it can build ayurveda more realistic and faithful. A study accomplish among institutionally qualified physician in state of UP and Bihar that state that the majority of the physician is not awake about the adverse drug reaction as reported (Rastogi, 2010). In another study that similar finding also reported in Maharashtra (Thatte et al., 2008).

For traditional medicine the thought of pharmacovigilance inaugurate in Nov 2006 ("WHO | WHO traditional medicine strategy," 2005) and it controlled by the department of clinical pharmacology, TNMC and BYL Nair Ch hospital, Mumbai. On 20thand 21stNov, 2006 the clinical pharmacologist Vaidya Supriya Bhalero and Urmilla Thatte organized a workshop "pharmacovigilance of ayurvedic medicine" collaborating with WHO (Thatte and Bhalerao, 2008). In September 2008 IPGTRA recognized as National Pharmacovigilance Resource Centre for Ayurveda, Siddha and Unani Drugs (NPRC-ASU) in India (Chaudhary *et al.*, 2010).

3. Market of Ayurvedic Medicines

The ayurveda market expanded day by day, that can lead to increase the rate of ADR's by ayurvedic medicines. This increasing use of Ayurvedic medication worldwide has led to increasing concern about their safety. Lately there are a number of publications which inflate concern about the safety of Ayurvedic drugs (Kales and Saper, 2009; Parab *et al.*, 2003; Saper *et al.*). So, the pharmacovigilance system is crucial to overcome them. The recognition has of ayurveda expanded to the international market, which is manifestfrom the steady growth in ayurveda market globally in recent year. A massive part of the ayurvedic medicines worldwide used is still driven by Indian customers. Ayurvedic market of India stood at value of $4.1 billion last year, which is not accepted to jump $4.9 billion by the end of this year, but also accepted to reach $8 billion by 2022.

4. Concept of Pharmacovigilance and ADR in Ayurveda

Pharmacovigilance is the use of scientific methods to identify, track, record and analyse over time the effects of various pharmaceuticals goods in order to ensure drug quality and safety (Goyal, 2018; Sharma and Kellarai, 2014).

Adverse Drug Reactions (ADR) is termed as any noxious or unintended effects which have causal relationship with suspected drug. On the other hand, the word Pharmacovigilance does not feature in the Ayurvedic medications, other than its conception is pulsating diagonally every wording of Ayurvedic medications (Suke et al., 2015) monitoring and discovery of interactions amongst drugs and their effects in human. Pharmaceutical and biotechnological medicines are designed to cure, prevent or treat diseases; however, there are also risks particularly

adverse drug reactions (ADRs. Concept of ADR is discussed in Table 1.

4.1 Stages of Pharmacovigilance

Figure 1 ("Microsoft Word - Assessment of the Community System consultation final.doc | Enhanced Reader,".)

Concept of ADR

Concept of ADR given in Table no. 1

4.2 Sources of ADR in Ayurveda Formulations

Akala, (Improper time)
Alpamatra, (In fewer doses)
Atimatra, (In over dose)
Purana, (Very older /expired medicine)
Na Cha Bhavitam, (Inappropriate triturated)
Asamyaka Sanskrutam, (Improper purified / method).

4.2.1 Akala, (Improper time)

Here 'Kala' designate time of administration of drug and collection of the raw material for medicines. The suggestions for collection of different parts of herbal drugs at different seasons are given in ayurvedic pharmacopoeia (Ajanal *et al.*, 2015) there is a paucity of systematic documentation related to the occurrence of adverse drug reactions (ADR.

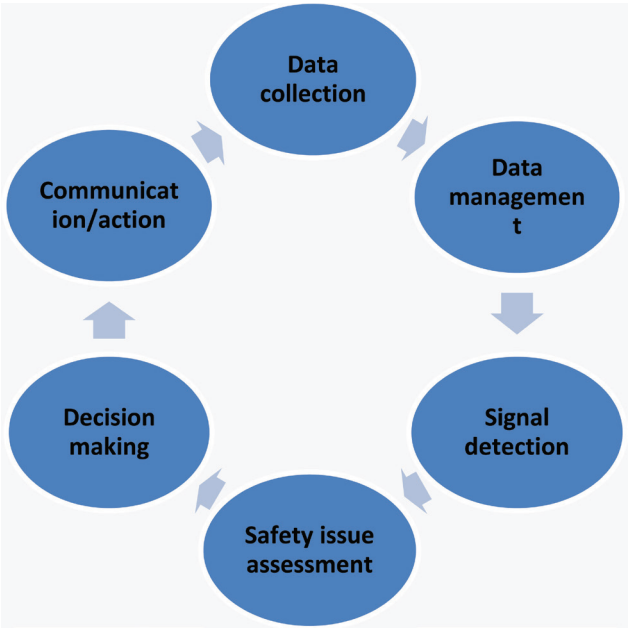

Figure 1: Stages of pharmacovigilance.

Table 1: Concept of ADR.

Concept of ADR in Ayurveda	Modern Parlance/Equivalence	Examples (Ajanal et al., 2015, 2013b)
Vaidhyakruti	Iatrogenic effect	Complication by a analyst Inappropriate assessment of patient
Viruddadrvayaprayoga	Drug interactions	Bleeding, when intake phenprocoumon along with ginger
Panchkarmavyapad	Procedural complication	Inadequate assessment of patient Defective drug administration
Ahitatamadravyas	Administration of unwholesome drug	Usage of semicarpus anacardium can lead to formation of blisters
Atimatradravyaprayoga	Drug over dose	Overdose of vatsanabha cause hypotension and bradycardia
Avastanusaradravyaprayoga	Administration of drug in distinct pathological points	Astringent are contraindicated in fever

4.2.2. Alpamatra, (In fewer doses)

Generally the Ayurvedic drugs are polyherb-mineral formulations. During the manufacturing of medicines the active ingredient are not taken in suitable quantity. The required results are not obtained and the drug may show unintended action on body. So, the quantity of active substance is very important in preparation of the medicines (Ranade and Acharya, 2015).

4.2.3. Atimatra, (In over dose)

During the manufacturing of medicines if the ingredients and active substance is not taken in the proportions as described in texts, then the formulations may act as poison. Adverse effect is also seen when taken the excess dose of medicines (Krüth *et al.*, 2004; Panda and Debnath, 2010).

4.2.4. Purana, (Very older /expired medicine)

Here "Purana" designate the time after which the any active substance or medicine lose their efficacy. According to pharmaceutical companies most of raw drugs extract loss their efficacy after 12 months. So, the raw material are used for preparation of medicine should not be older than 12 month (Krüth et al., 2004).

4.2.5. Na Cha Bhavitam, (Inappropriate triturated)

All Vishavarga and toxic metals are having narrow therapeutic index. Shodhana (purification) of these medicines decrease the therapeutic window. Major purpose of bhavanais to minimizing the adverse effect and enhance the efficacy of drugs. Hence the purification of toxic drug and trituration are not followed as given in texts, then the potency of the formulation is decrease and adverse effect may be seen (Krüth et al., 2004).

4.2.6. Asamyaka Sanskrutam, (Improper purified / method)

"Sanskar"means securing the properties of other substances within oneself. This can be done by processing with water; fire, manthan (Rubbing with other substances), desha(Influence of Geographical distribution of the drug), soucha (Maintenance of proper Hygiene, vasan (Utensils used for preparation and storage of medicines), kala (Influence of time/season) and bhavana (Trituration) etc. when these process are not performed appropriately, they lead to adverse effects (Krüth et al., 2004).

4.3. Drug Interaction in Ayurveda

Types of Drug interactions in ayurveda are given below in Table 2.

Table 2: Types of interaction in ayurveda.

Types of interaction	Example	Reference
Food – herb interaction	Payasa and menthe in combination is contraindicated Steamed grain with wine Milk with reddish	(Ajanal et al., 2013c; Sarkar *et al.*, 2013)
Herb – herb interaction	Garcinia morella with peper betal Sesamum indicum along with basella alba	(Ajanal et al., 2013c; Parasuraman *et al.*, 2014)
Animal origin drug - herb interaction	Kapotomansa with sarshapatiala Naricaletaila with pork Equal quantity of honey with grutha(ghee)	(Ajanal et al., 2013c; Kumar Shukla *et al.*, 2016)
Drug – exercise pharmacokinetic interaction	Shrama(exertion), maithuna(coitus), athapaand krodha is contraindicated while guggulu is already taken	(Ajanal *et al.*, 2013c; Rastogi, 2009)
Drug - disease interaction	Haritaki contraindicated in pregnancy, malnourished Rasayana contraindicated in alasi(lazy), vyasani(drug addicted), anatnavan(ignorance), pramadi(intoxicated)	(Ajanal et al., 2013c; orintalia and 1979, Saper *et al.*)

4.4. A lot of Challenges

Associated to assessment, detection and prevention of adverse effects that prohibit the recognition and reporting of unintended effects of ayurvedic drugs.

4.4.1. Detection of Adverse Reactions to Ayurvedic Medications

Detection of adverse effect or adverse drug reaction in ayurveda is a major challenge because people are unconcerned about the pharmacovigilance and reporting system, this can lead to lack of reporting and collection of report. In ayurveda from finding an accurate history, to analysis and to investigative the causal drugs, the way is full of obstruction, as well as:

- In the ayurvedic prospectus, the terms and concept related to adverse drug reaction monitoring is not defined that prevent correct identification of adverse drug reactions.
- Processes to study drug safety tribulations have not developed sufficiently in ayurveda.
- Although information associated to ayurvedic drugs exists in the stanzas, it is not easily affable.
- Inherent belief about the safety of ayurvedic drugs prevent the detection of signal related to adverse drug reaction and also lead to lack of reporting & collection of report relating to ayurvedic medicines.
- The causality assessment is difficult because the patients often taken the two or more medicines from different route at same time.
- Quality declaration and control in production of ayurvedic drugs is inadequate, which cause obstruction in analyzing the adverse drug reaction.
- The production and marketing of ayurvedic medicines on small scale is greater in informal sector and this

frequently makes it not possible to recognize the drugs that may be producing the adverse drug reaction (Kubde and Renuka Vihar) in brief, the Ayurvedic concepts of adverse reactions to medicines, the need for pharmacovigilance of Ayurvedic medicines, challenges in introducing pharmacovigilance in Ayurveda, and some recommendations to successfully implementing these activities. Pharmacovigilance is the science and practice related to the detection, assessment, understanding, and prevention of adverse effects of drugs or any other possible drug-related problems. The objective of the present article is to review the recent trends and challenges posed in the practice of pharmacovigilance of herbal drugs, especially in the Indian context and to shed light on the importance of pharmacovigilance practice in establishing and maintenance of rational use of these drugs. There is increasing awareness of the need to develop pharmacovigilance for herbal medicines. Applying standard pharmacovigilance techniques (WHO guidelines).

4.4.2. Assessment of Adverse Reactions to Ayurvedic Medications

Many methods and scale like Swedish method, Naranjo's scale, WHO-UMC causality assessment criteria, Dangaumou's French method, Kramer method, Drug interaction probability scale (DIPS), Australian method, Bayesian adverse reaction diagnostic instrument (BARDI) and MacBARDI spreadsheet are used for the causality assessment of an adverse event. Although many methods are existing for causality assessment of adverse event from ayurvedic medications and assign causality is possibly the greatest challenge for no. of reasons including:

- Information associated to adverse event in the ayurvedic literature is related to adverse effects is speckled and the present information related to ayurvedic drug not in electric form so , it can cause obstruction to access them. The quality of several publications doubtful because they cannot review by the journals.
- Majority of ayurvedic drugs contain multiple active substances in fixed dose. So, assessment of causality is complicated.
- Most of the case the patient can take the allopathic medicine and ayurvedic drug at same time.
- Toxicokinetic and pharmacokinetic study is very complicated and at this position the assessment of exact causality of adverse event is not easy.
- Dose related adverse event is generally not reported.
- Generally de challenge and re challenge are not performed in ayurvedic drugs, if ever is performed no intentional confirmation of adverse effect.
- The most complicated feature is lack of knowledge in performing causality assessment of ayurvedic medications (Chaudhary et al., 2014a; Kubde and Renuka Vihar) in brief, the Ayurvedic concepts of adverse reactions to medicines, the need for pharmacovigilance of Ayurvedic medicines, challenges in introducing pharmacovigilance in Ayurveda, and some recommendations to successfully implementing these activities. Pharmacovigilance is the science and practice related to the detection, assessment, understanding, and prevention of adverse effects of drugs or any other possible drug-related problems. The objective of the present article is to review the recent trends and challenges posed in the practice of pharmacovigilance of herbal drugs, especially in the Indian context and to shed light on the importance of pharmacovigilance practice in establishing and maintenance of rational use of these drugs. There is increasing awareness of the need to develop pharmacovigilance for herbal medicines. Applying standard pharmacovigilance techniques (WHO guidelines).

4.4.3. Prevention of Adverse Reactions to Ayurvedic Medication

The achievement of pharmacovigilance system is to collect, assess and understand the adverse effect to order to prevent them for public use, with the help of ayurvedic medications, the challenges comes under various levels.

- It is essential to have liaised or exchange of information between the researcher and the makers of traditional drugs, the information right now is not sufficient, between western medication and traditional Indian medication. In Indian, NPVP does not cover ayurveda medications, thus, the researchers are not aware of the need to report an adverse event.
- The information on ayurvedic drugs including unbiased, insufficient information on drug.
- People think that ayurvedic medication is safe. They are not aware about that ayurvedic medication can cause adverse events and they can take drugs for long times as they believe these medication can do no harm. Hence, they do not give the history of concomitant medications.
- Young physicians haven't yet awaked of the concept of pharmacovigilance in ayurveda because any college of graduation and post graduation teaching ayurveda still in this era does not cover the concept of pharmacovigilance.
- There is no safety data available in the pharmaceutical industry for the drugs which are in marketed phase as no industry is interested or encouraged in pharmacovigilance for ayurvedic medicine "Pharmacovigilance obligations

of Ayurveda physicians and pharma sector," (Kubde and Renuka Vihar, 2016) in brief, the Ayurvedic concepts of adverse reactions to medicines, the need for pharmacovigilance of Ayurvedic medicines, challenges in introducing pharmacovigilance in Ayurveda, and some recommendations to successfully implementing these activities. Pharmacovigilance is the science and practice related to the detection, assessment, understanding, and prevention of adverse effects of drugs or any other possible drug-related problems. The objective of the present article is to review the recent trends and challenges posed in the practice of pharmacovigilance of herbal drugs, especially in the Indian context and to shed light on the importance of pharmacovigilance practice in establishing and maintenance of rational use of these drugs. There is increasing awareness of the need to develop pharmacovigilance for herbal medicines. Applying standard pharmacovigilance techniques (WHO guidelines).

5. Demand of Pharmacovigilance in Ayurvedic Drugs

In the national pharmacovigilance centre of India, the reporting of adverse drug reaction to ayurvedic medication is negligible. The false belief that ayurvedic medication are secure and not produce any harms, be a factor to a great extent to the current state of affairs. Increasing the growth of ayurvedic drugs with artificial formulations provokes the priority of pharmacovigilance for Āyurvedic drugs. Though the regulations for production and clinical procedure of the ayurvedic drugs are stated in classics but are not being followed by health care professionals as well as industries. Pharmacovigilance system is not essential at that time for ayurvedic medicines but now the situation has been changed (Chaudhary et al., 2014b; Who). To provide a better response on herb interactions, an advanced pharmacovigilance system is needed in ayurveda. It also helps to provide systemic documentation on herb interaction to the scientific world.

5.1. Complication in Successful Employment of Pharmacovigilance in Ayurvedic Medication

- Reporting of adverse drug reactions is very minute.
- Doctors ignore the ADR's regarding to drug.
- People think that the ayurvedic drugs are always safe.
- Increasing the use of ayurvedic formulations are difficult to monitoring.
- Generally ayurvedic and allopathic medicines prescribed mutually.
- Bogus trust that no expiry date of ayurvedic medicines or drug("Misbranding of Ayurvedic pharmaceutical preparations A market survey report).
- Few medicines are prescribed in much superior dose than normal dose.
- Concepts of adverse drug reaction are not described in Ayurveda.
- Inappreciable systems of study drug safety report.
- Quality control is deprivation to produce adequate medicine("Pharmacovigilance of Ayurvedic medicines in India | Request PDF,").
- Patient compliance is poor.
- Multi ingredient composition are used in most drugs so,assessment of adverse reactions is difficult(Galib and Acharya, 2020).

6. National Centre of Pharmacovigilance for Ayurvedic Medicines

The Institute for Post Graduate Teaching and Research in Ayurveda (IPGTRA), Jamnagar conducted a two days workshop, which covers the scope, limitations, & methods of implementation of phamacovigilance system in Ayurveda. Based on the recommendation of the workshop, pharmacovigilance cell got established for Ayurvedic medicines in 2008. Even, IPGTRA recognized as National Pharmacovigilance Resource Centre for Ayurveda, Siddha and Unani Drugs (NPRC-ASU) in India (Nishteswar, 2013). The first National consultative meet of National Pharmacovigilance programme for ASU drug was organized at Department of AYUSH, Ministry of Health & FW, in New Delhi in August 2008, sponsored by WHO. Today, under the NPRC-ASU, there are 30 Peripheral Pharmacovigilance Centre (PPC) for reporting ADRs of ASU drugs. Further, these peripheral centres coordinate with Regional and Zonal Centres. Moreover, a web portal, 'ayushsuraksha.com' has been launched for online registration of ADR related to ASU drugs through an "e format"(Wal et al., 2011). A process of reporting ADR is given in Figure 2.

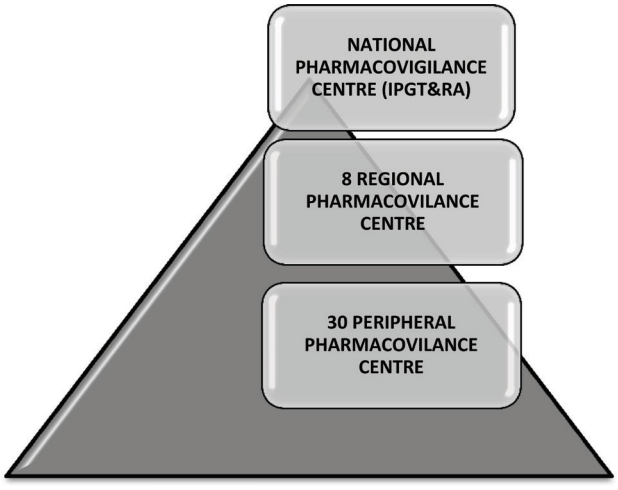

Figure 2: Reporting of ADR.

6.1. Sources of Reports

- Consumer organizations
- From clinical trials
- Health care professional
- Literature
- From consumer
- Media
- ` From UMC
- Report from pharmaceutical companies (Wal *et al.*, 2011)

6.2. Members who can Report

- Every health care professional
- Rest members of the populations
- Non- medical personnel are not favoured, they can report through general practitioner.
- Regulatory manager of pharma industry (Apte, 2016; Pirmohamed *et al.*, 1998; Rastogi *et al.*, 2007)

6.3. Minimum Criteria of Reporting

The reporting of any ADR suspected to ayurvedic formulations following minimum criteria is required-

- Patient detail (age ,sex ,weight)
- Suspected drug detail (drug name, dose, route, frequency etc.)
- Suspected ADRs detail (reaction started date, Date of recovery)
- Reporter detail (name , address, date of report)("11. What is valid ICSR? | | Pharmacovigilance," n.d.; Medicines Agency, 2017)

Follow up information is also submitted as it become available.

6.4. Centres for Reporting

Report is to be submitted in prescribe pattern. The form is to be used for reporting of ADR of ayurvedic formulation is given in figure 3

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR AYURVEDA, SIDDHA & UNANI (ASU) DRUGS.

Reporting Form for Suspected Adverse Reactions to ASU Drugs

Please note: i. All consumers / patients and reporters information will remain confidential.
ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

1. Patient / consumer identification (please complete or tick boxes below as appropriate)

Name		Patient Record Number (PRN)
Ethnicity	IPD / OPD	
Address Village / Town Post / Via District / State		Age: Sex: Male / Female Prakriti / Mizaj:

2. Description of the suspected Adverse Reactions (please complete boxes below)

Date and time of initial observation	
Description of reaction	

3. List of all ASU drugs including drugs of other systems used by the patient during the reporting period:

Medicine Name	Manufacturer Batch no.	Daily dose	Form Route of administration	Date		Reason for use
				Starting	Stopped	

4. Brief details of the suspected ASU Medicine:

a. Composition of the formulation / Part and form of the raw material used
b. Expiry date if any:
c. Remaining part of drug / Product label
d. Please tick (any one)
Ayurveda, Siddha, Unani, any other
e. Adjuvant
f. Dietary Restrictions if any
g. Whether the drug is consumed under medical supervision or used as self medication.
h. Any other relevant information.

5. Treatment provided for suspected adverse reaction

6. Out come of the suspected adverse reaction (please complete the boxes below)

Recovered:	Not recovered:	Unknown:	Fatal:	If Fatal Date of death:
Severe: Yes / No.	Reaction abated after drug stopped or dose reduced:			
	Reaction reappeared after re introduction:			
Was the patient admitted to hospital? If yes, give name and address of hospital				

Figure 3: Format for reporting ADR.
Source -http://www.ayurveduniversity.edu.in/download/ADR form.pdf

6.5. Event to report under NPP-ASU (Rastogi, 2011; Rastogi et al., 2007)

- All ADR'S suspected to ASU drugs.
- All the ASU drug interactions.
- In any severe event from the following categories-
- Hospitalization and persistence of alive hospitalization
- Result in significant or persistent disability.
- Birth defect or hereditary anomaly
- Life threatening
- Result in loss of life.

7. Physician Benefit of Pharmacovigilance in Ayurveda

The run through of Pharmacovigilance by health care professional is an understandable problem in this relation. The practicing of Pharmacovigilance benefit could be versatile and could include specific instant and distant advantages to the health care professional and his/her society. The instant benefit of routine Pharmacovigilance is the acquirer of informationabout the side effects and connection between a medicine and adverse drug reactions. The knowledge of pharmacovigilance system would indicate to improved and specific decision making with regards the treatment and patient safety. In the prolonged precede, the assembled information of adverse drug reactions can take the type of anarsenal and assist the peers, consumers and paramedics "Pharmacovigilance obligations of Ayurveda physicians and pharma sector," Sharma et al., 2017; Tiwari et al). Few ayurvedic drugs with its uses and ADR are given in Table 3.

Table 3: Ayurvedic drugs with its uses and ADR.

DRUG	USES	ADRs
CHAMOMILE	Sedative	Allergic reactions , Inhibit the action of anticoagulant
ECHINACEA	Bronchitis In clinical trials	Cause liver toxicity Toxic side effects "Pharmacovigilance obligations of Ayurveda physicians and pharma sector," n.d.)
GARLIC	Used to lower BP Used to lower cholesterol	cause inflammation of skin
FEVERFEW	migraine headache	Allergic reaction
GINSENG	Used in diabetes mellitus stimulate the adrenal gland	Cause heart disease
GINGER	Used in bowl spasm	Blood thinning properties
GINKGO BILOBA	Dementia	It have also blood thinning properties
TIRPHALA	Obesity High blood pressure Diabetes	Diarrhoea Abdominal discomfort
GUGGUL	Atherosclerosis Arthritis Acne	Stomach upset Vomiting Belching
BOSWELLIA	Rheumatoid arthritis Asthma Osteoarthritis	Stomach pain Allergic rash
GOTUKOLA	Reduce anxiety Alzheimer's disease Insomnia	Sensitivity to light Stomach upset
DEVIL'S CLAW	Arthritis Gout	Cause addictive effect

8. Pharmacovigilance Scopes in Ayurveda

The objective of pharmacovigilance in Ayurveda to enhance:

- Safety of the patient when consume Ayurvedic drugs and associated intrusion;
- Community health and maintain the wellbeing records of Ayurvedic medication.

- Evaluation of risk, advantage, harm, and efficacy ayurvedic drugs
- Promote the rational, safe, and more efficient use, and encouragement of awareness, clinical training, and education in pharmacovigilance for Ayurvedic medications and its effectual consultation to the community ("(PDF) Pharmacovigilance obligations of Ayurveda physicians and pharma sector," n.d.).

Ayurvedic drugs with its uses and ADR

Examples of ayurvedic drugs with its uses and ADRs given in Table no. 3

Conclusion

Through this we conclude that there is a requirement of appropriate post-clinical surveillance program for ayurvedic drugs based on its quality, safety, and efficacy, for public health and disease management, which is now accessible in National Pharmacovigilance Programme for ASU drugs, Ayurveda has explained a broad hypothesis on ayurvedic medicines, in relation with its usage, causal ADR, treatment and its prevention. There is also a need for extensive research to be performed for better conceptual knowledge and understanding following the standard principles associated to drug administration and wellbeing. Spontaneous reporting of ADR related to Ayurveda plays an essential role in the identification and detection of new signals and communicating novel research questions.

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Conflict of Interest

The authors would like to declare no conflict of interest regards to the study, authorship and publication of this manuscript.

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It is an original data and has neither been sent elsewhere nor published anywhere.

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References

Ajanal, M., Nayak, S., Kadam, A., Prasad, B., (2015). Pharmacovigilance study of Ayurvedic medicine in Ayurvedic Teaching Hospital: A prospective survey study. AYU (An Int. Q. J. Res. Ayurveda) *36*, 130. https://doi.org/10.4103/0974-8520.175539

Ajanal, M., Nayak, S., Prasad, B.S., Kadam, A., (2013a). Adverse drug reaction and concepts of drug safety in Ayurveda: An overview. *J. Young Pharm.* https://doi.org/10.1016/j.jyp.2013.10.001

Ajanal, M., Nayak, S., Prasad, B. S., Kadam, A., (2013b). Adverse drug reaction and concepts of drug safety in Ayurveda: An overview. *J. Young Pharm.* https://doi.org/10.1016/j.jyp.2013.10.001

Ajanal, M., Nayak, S., Prasad, B. S., Kadam, A., (2013c). Adverse drug reaction and concepts of drug safety in Ayurveda: An overview. *J. Young Pharm.* https://doi.org/10.1016/j.jyp.2013.10.001

Apte, A., (2016). Reporting of adverse events for marketed drugs: Need for strengthening safety database. *Perspect. Clin. Res. 7*, 111. https://doi.org/10.4103/2229-3485.184781

Ayurveda 2.0: Rediscovering Ancient Remedies for Modern Needs | by Dr Swati Subodh | The Startup | Medium [WWW Document], URL https://medium.com/swlh/ayurveda-2-0-rediscovering-ancient-remedies-for-modern-needs-b1a6c051eb7c (accessed 8.19.20).

Baghel, M., (2010). The national pharmacovigilance program for Ayurveda, Siddha and Unani drugs: Current status. Int. *J. Ayurveda Res. 1*, 197. https://doi.org/10.4103/0974-7788.76779

Chaudhary, A., Singh, N., Kumar, N., (2010). Pharmacovigilance: Boon for the safety and efficacy of ayuvedic formulations. *J. Ayurveda Integr. Med. 1*, 251–256. https://doi.org/10.4103/0975-9476.74427

Chaudhary, P., Lamba, N., Sharma, Y., (2014a). Pharmacovigilance and ayurveda. *J. Biol. Sci. Opin. 2*, 210–213. https://doi.org/10.7897/2321-6328.02246

Chaudhary, P., Lamba, N., Sharma, Y. K., (2014b). Pharmacovigilance and ayurveda. *J. Biol. Sci. Opin.* · 2. https://doi.org/10.7897/2321-6328.02246

Galib, Acharya, R., (2020). National Pharmacovigilance Programme for Ayurveda, Siddha and Unani Drugs. AYU (An Int. Q. J. Res. Ayurveda) *29*, 195.

Goyal, M., (2018). Pharmacovigilance: An ayurvedic viewpoint. AYU (An Int. Q. J. Res. Ayurveda) *39*, 197. https://doi.org/10.4103/ayu.ayu_82_19

Kales, S. N., Saper, R. B., (2009). Editorial ayurvedic lead poisoning: an under-recognized, international problem. *Indian J. Med. Sci.* 63. https://doi.org/10.4103/0019-5359.56108

Kashinath, S., Tasyasheetiyaadhyay, G. C., Bharati, C., (2005). undefined, n.d. Charaka Samhita of Agnivesha elaborated Vidyotini Hindi commentary.

Krüth, P., Brosi, E., Fux, R., Mörike, K., Gleiter, C. H., (2004). Ginger-Associated Overanticoagulation by Phenprocoumon. Ann. Pharmacother. *38*, 257–260. https://doi.org/10.1345/aph.1D225

Kubde, S., Renuka Vihar, M., (2016). Adverse drug reactions and pharmacovigilance of herbal medicines in India, I*nternational Journal of Green Pharmacy* (IJGP). https://doi.org/10.22377/IJGP.V10I1.610

Kubde, S., Renuka Vihar, M., Adverse drug reactions and pharmacovigilance of herbal medicines in India.

Kumar Shukla, A., Bigoniya, P., Shukla, Bigoniya, I., 2016. Herbal, Drug and Food Interaction. *Int. J. Tradi-tional Complement. Med. 1*, 33–0037.

Medicines Agency, E., 2017. Guideline on good pharmacovigilance practices (GVP) - Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2).

Microsoft Word - Assessment of the Community System consultation final.doc | Enhanced Reader [WWW Document], URL moz-extension://fc05633c-6128-4b91-aefb-7556e2703879/enhanced-reader.html?openApp&pdf=https%3A%2F%2Fec.europa.eu%2Fhealth%2Fsites%2Fhealth%2Ffiles%2Ffiles%2Fpharmacovigilance%2Fdocs%2Facs_consultation_final_en.pdf (accessed 8.19.20).

Nishteswar, K., 2013. Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar - A WHO-recognized collaborating center for traditional medicine (Ayurveda). AYU (An Int. Q. J. Res. Ayurveda) *34*, 133. https://doi.org/10.4103/0974-8520.119662

Nitin L, U. B., (2012). NEED FOR PHARMACOVIGILANCE IN ĀYURVEDA, Global Journal of Research on Medicinal Plants & Indigenous Medicine GJRMI.

Orintalia, P. S.-V. C., (1979). undefined, Dhanvantari Nighantu of Dhanvantari. 54.

Panda, A., Debnath, S., 2010. Overdose effect of aconite containing ayurvedic medicine ('Mahashankha Vati'). *Int. J. Ayurveda Res. 1*, 183. https://doi.org/10.4103/0974-7788.72493

Parab, S., Kulkarni, R., Thatte, U., (2003). Heavy metals in "herbal" medicines [3]. Indian J. Gastroenterol.

Parasuraman, S., Thing, G. S., Dhanaraj, S. A., (2014). Polyherbal formulation: Concept of ayurveda. Pharmacogn. Rev. https://doi.org/10.4103/0973-7847.134229

Patwardhan, B., Vaidya, A. D. B., Ayurveda: scientific research and publications. Curr. Sci. https://doi.org/10.2307/24111950

Pharmacovigilance of Ayurvedic medicines in India | Request PDF [WWW Document], n.d. URL https://www.researchgate.net/publication/50268272_Pharmacovigilance_of_Ayurvedic_medicines_in_India (accessed 8.20.20).

Pirmohamed, M., Breckenridge, A. M., Kitteringham, N. R., Park, K., (1998). Adverse drug reactions. BMJ *316*, 1295. https://doi.org/10.1136/bmj.316.7140.1295

Ranade, A. V., Acharya, R., (2015). Influence of time factor on phytoconstituents in certain ayurvedic medicinal plants: a comprehensive review. *J. Pharm. Sci. Innov. 4*, 235–241. https://doi.org/10.7897/2277-4572.04553

Rastogi, S., (2011). Why and how? Addressing to the two most pertinent questions about pharmacovigilance in Ayurveda. Int. J. Ayurveda Res. https://doi.org/10.4103/0974-7788.83187

Rastogi, S., (2010). Identifying attitudes about drug safety: A sample survey of ayurvedic physicians. *Int. J. Risk Saf. Med. 22*, 93–101. https://doi.org/10.3233/JRS-2010-0493

Rastogi, S., (2009. Poor quality and improper use: A review of common reasons of possible adversity in Ayurvedic practice COVID-19 and Ayurveda View project Workshop on Scientific Writing for Ayurveda Scholars View project Poor quality and improper use: A review of common reasons of possible adversity in Ayurvedic practice. *Int. J. Risk Saf. Med*. 00, 1–10. https://doi.org/10.3233/JRS-2009-0470

Rastogi, S., Rastogi, R., Singh, R. H., (2007). Adverse effects of Ayurvedic drugs: An overview of causes and possibilities in reference to a case of Vatsanabha (Aconite) overdosing.

Samal, J., (2018). Pharmacovigilance in Ayurveda – Concept and Regulations. Curr. Pharmacogenomics Person. Med. *16*, 4–8. https://doi.org/10.2174/1875692116666180419153658

Saper, R., Kales, S., Paquin, J., Jama, M. B.-, (2004). undefined, n.d. Heavy metal content of ayurvedic herbal medicine products. jamanetwork.com.

Saper, R., Kales, S., Paquin, J., Jama, M. B., (2004). undefined, Heavy metal content of ayurvedic herbal medicine products. jamanetwork.com.

Sarkar, P.K., Chaudhari, S., Chattopadhyay, A., (2013). Concept of interactions between consumable substances in Ayurveda with special reference to foods and drugs. Drug Metabol. Drug Interact. https://doi.org/10.1515/dmdi-2013-0014

Sharma, R., Hazra, J., Prajapati, P., (2017). Knowledge and awareness of pharmacovigilance among ayurveda physicians in Himachal Pradesh. *Anc. Sci. Life 36*, 234. https://doi.org/10.4103/asl.asl_41_17

Sharma, R., Kellarai, A., (2014). Pharmacovigilance and adverse drug reaction reporting perspectives among interns and postgraduates of a teaching hospital. *J. Pharmacol. Pharmacother*. https://doi.org/10.4103/0976-500X.142436

Suke, S.G., Kosta, P., Negi, H., (2015). Role of Pharmacovigilance in India: An overview. Online *J. Public Health Inform*. 7. https://doi.org/10.5210/ojphi.v7i2.5595

Thatte, U., Bhalerao, S., (2008). Pharmacovigilance of ayurvedic medicines in India. *Indian J. Pharmacol.*

Thatte, U., Pharmacology, S. B.-I. J. of, (2008). Pharmacovigilance of ayurvedic medicines in India. ncbi.nlm.nih.gov.

Tiwari, V., Tiwari, S., Rahim, A.. Need of Pharmacovigilance in Alternative Systems of Medicine, *J. Pharm. Sci. Technol. Manag*.

UMC | Uppsala Monitoring Centre [WWW Document],. URL https://www.who-umc.org/ (accessed 8.19.20).

Wal, P., Wal, A., Gupta, S., Sharma, G., Rai, A. K., (2011). Pharmacovigilance of herbal products in India. *J. Young Pharm. 3*, 256–258. https://doi.org/10.4103/0975-1483.83780

Who, n.d. Guidelines for the regulation of herbal medicines in the South-East Asia Region. https://pharmacy.utah.edu/ICBG/pdf/WebResources/TraditionalMedicines/WHO-TradMed-Safe-and-Effective.pdf

WHO | WHO traditional medicine strategy, (2005). WHO. https://apps.who.int/iris/bitstream/handle/10665/67163/WHO_EDM_TRM_2002.1.pdf;jsessionid=6FD671160190EB2AF989C18646C10640?sequence=1

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