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Current challenges in reporting and documentation of adverse drug reactions in homoeopathy Pharmacovigilance practice: A review

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Abstract
Pharmacovigilance deals with detection, assessment, understanding and prevention of adverse drug reactions. Though the homoeopathic treatment deemed to be safest, few adverse reactions were reported which are basically, due to use of medicines without the prescription, guidance or without supervision of a qualified physician. Homoeopathy, regarded as the second largest system of treatment, is catching on popularity and extensively practiced all over the world. ADRs are poorly reported and documented in homoeopathy when compared to conventional system of medicine. It may be either because of carelessness on the part of doctor or non-development of ADR at all. Through this review an effort has been done to find out possible challenges and solutions in reporting and documentation of ADRs in Homoeopathy practice.

Methods: An intense literature study has been done on the concerned websites, databases, related journals, about implementation of pharmacovigilance in Homoeopathy. Available Publications till May 2022 along with literatures of Homoeopathy were analysed.

Results: Challenges in reporting and documentation of ADRs from confounding illness, counterfeit drugs, Web – based medications, self-medication, clinical trials were identified along with lack of awareness among Health care professionals in pharmacovigilance practice was noticed which include how to report, where to report, how to fill the form, how to identify ADRs and importance of ADRs reporting and documentation etc. Possible Solutions like conducting regular CME programmes for Health care professionals which will help them in pharmacovigilance practice and providing proper incentives or awards by government which will encourage them in ADRs reporting and documentation.

Keywords: Pharmacovigilance, homoeopathy, adverse drug reaction, aggravation

1. Introduction
Pharmacovigilance is defined by WHO as "the science and activities related to the identification, assessment, understanding and prevention of adverse medicine effects or any other possible medicine-related problems" [1]. Adverse drug reaction is a response which is noxious and unintended, and which occurs at doses typically used in patients for the preventive, diagnosis, or as a choice remedy for a complaint, or for the change of physiological function [2].

There's a wrong notion that homoeopathic drugs are fully safe. Though the homoeopathic medical practice is supposed to be safest, many adverse events were reported which are principally, due to the non-judicial use, or use without the tradition, guidance or without supervision of a good medical practitioner etc. The Department of Ayush has started a new Central scheme to encourage pharmacovigilance practice in Ayurveda, Siddha, Unani and Homoeopathy. The High ideal of the scheme is to evolve the culture of identifying adverse effects and take over safety monitoring of Ayurveda, Siddha, Unani and Homoeopathy medicines and supervision of deceptive proclamations appearing in the print and electronic media.

Despite of all the efforts by pharmacovigilance centres, reporting and documenting of ADR in homoeopathy is negligible in comparison to conventional system. The motive of this article is to explore various difficulties and challenges in dealing with adverse drug reactions (ADRs) in homoeopathy, their recognition, and reporting by Health care workers, including doctors, pharmacists, nurses and other health professionals and to provide possible solutions to the challenges identified.

Methods

An intense literature search was conducted using various publications, print journals, compendia, bibliographic databases like PubMed, google scholar, google search engines to collect all relevant articles, reports, homoeopathic archived texts, literatures, web pages etc. focusing on the scope of pharmacovigilance in Homoeopathy. Based on the available information and the present scenario, suggestions regarding how to overcome challenges and difficulties in dealing with adverse drug reactions (ADRs) in homoeopathy, their recognition, and reporting was deduced.

Discussion

Pharmacovigilance

Pharmacovigilance is the science and activities related to the spotting, evaluating, comprehension and forestalling of adverse drug effects or any other possible drug-related issues. The specific aims of pharmacovigilance are (a) to ameliorate patient suffering and safety in relation to the use of drugs, (b) identify problems related to the use of drugs and communicate the findings in a timely manner, (c) contribute to the assessment of benefit, harm, effectiveness and threat of drugs, leading to the prevention of adverse effects and maximization of benefit [1].

Adverse Drug Reaction (ADR)

Adverse drug reaction is a response which is noxious and unintended, and which occurs at doses typically used in humans for the preventive, or medicine for a unhealthy condition, or for the change of physiological function [2].

Aggravations in Homoeopathy

Aggravation is the increased intensity of the symptoms or worsening of the symptoms or condition after the administration of medicine.

Homoeopathic aggravation: Hahnemann defined Homoeopathic aggravation as the so-called homoeopathic aggravation, or rather the primary action of the homoeopathic medicine that tend to increase somewhat the symptoms of the original disease, for the first or few hours, which is definitely true for diseases of a more acute character and of recent origin." [3].

Medicinal aggravation: It denotes the appearance of new symptoms of the medicine administered to the patient

Disease aggravation: It denotes the appearance of new symptoms belonging to the sphere of disease due to its natural tendency to progress [4].

Adverse drug reaction (ADR) in homoeopathy

ADR is mainly caused by the large doses of prescribed drug. This was understood by Hahnemann in his early practice life. "Before 1801 Hahnemann used massive doses of drugs which caused unwanted aggravations and secondary effects of drugs. Due this reason he started administering small to smallest possible doses by repeated dilution of the medicine with strokes and named this process as "Potentization" [5].

"For this reason, a medicine, even though it may be homeopathically suited to the case of individual, does damage in every dose that's too large, the larger the dose the larger the deterioration, and in strong doses the high is its homoeopathic nature the more suffering of the individual it results and the higher the power of the medicine is selected much further injury occurs than any inversely large dose of a drug that's un homoeopathic, and in no respect acclimated to the morbid state(allopathic) [3].

A cross sectional study was done among Norwegian homeopath cases, where the cases were asked to register any responses after fourteen days of administration of homoeopathic drug. An aggregate of 26 of the cases reported worsening of symptoms. One third was classified as adverse events. Half of these were graded as minor and the other half as moderate according to the Common language Criteria for Adverse Events. Two thirds were classified as homeopathic aggravations [6].

A systematic review of published case reports and case series was done to know the adverse effects of Homoeopathy. The end of this methodical review was to critically estimate the substantiation regarding the adverse effects (AEs) of homeopathy. Out 38 primary reports, 30 pertained to direct adverse reactions of homeopathic remedies [7].

A prospective study regarding adverse drug reactions related to homeopathic drugs was done considering on the reports collected by a homeopathic physician. Out of 335 homeopathic successive follow- up visits, nine adverse responses were reported. This study concluded that Adverse events to homeopathic medicines are present and are distinguishable from homeopathic aggravations, but are rare and not severe [8].

Difference between aggravation and ADR

Adverse drug reaction is a response which is harmful and accidental, which occurs at doses normally used in humans for the prevention, diagnosis, or treatment of disease, or for the modification of physiological function [2], which is not expected and not known earlier. But Aggravation by homoeopathic medicine is either known or expected.

Pharmacovigilance in homoeopathy

The Department of Ayush has started a new Central scheme to encourage pharmacovigilance practice in Ayurveda, Siddha, Unani and Homoeopathy. It's the branch dealing with adverse drug reactions (ADRs), their recognition, and reporting. The common myth about herbal drugs is that these drugs are completely safe and can thus be administered by the individual on his/ her own, without a doctor's guidance. This belief has led to large- scale self-administration of medicines by people, frequently leading to disappointing end- results or unwanted after drug effects [6].

Homoeopathy and its position in world

The main principle of homeopathy, a unique scientific system of drug established by Samuel Hahnemann two hundred years ago, is that of 'Similia' (similarity), which means 'let likes be cured by likes. In other words, when a substance is able of causing a series of symptoms in a healthy individual, low doses of the same substance can treat these symptoms under certain circumstances ('similia similibus curentur') [3].

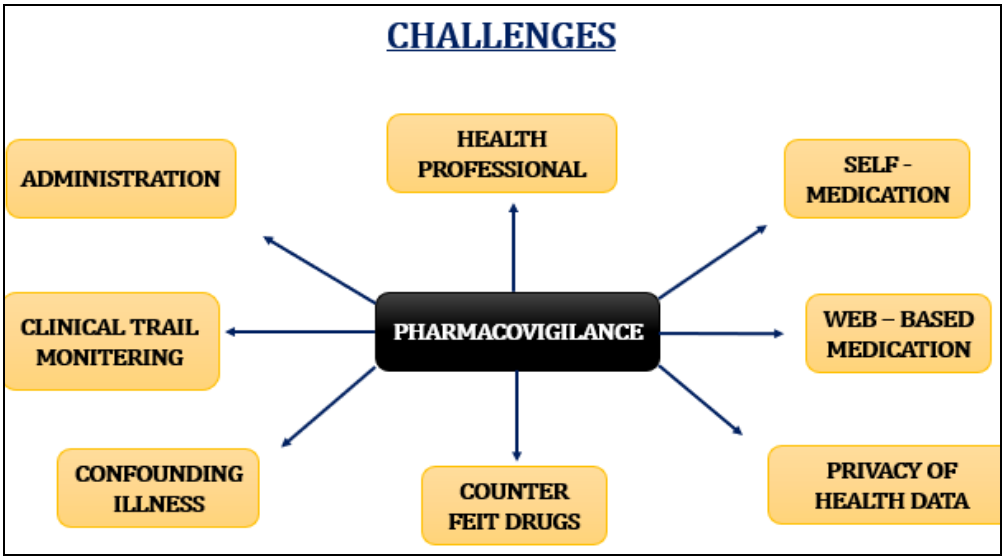
Since its inception number of practitioners and users has gradually increased and currently it is used by over 200 million people on a regular basis in the world [4]. In the World Health Organization survey regarding alternative drug that published in 2001, revealed that homeopathy is legalized in 43 countries (Asia 7, Africa 7, America 9,

Australia 2 and Europe 20) [9]. A recent study of IMRB conducted across the major areas of India reveals that 59% of the population has shifted from allopathy treatment to homeopathic treatment. Europe is the second largest player in the homeopathic market, with 29% of the population trusting the medical system [10].

In view of the above circumstances the proper implementation of pharmacovigilance in Homoeopathy will increase and ensure the safety of the drugs which is very essential for its sustained all-round growth all over the world.

Current challenges in reporting and documentation of adverse drug reactions in homoeopathy

Currently ADR is poorly reported and documented in homoeopathy. It may be either because of carelessness on part of physician or non-development of ADR at all [11].



Administration

Unfortunately, Pharmacovigilance is one activity where there are hardly any rewards or incentives from administrative authorities. Lack of motivation to report ADRs has been observed in many physicians. This leads to many ADRs getting unreported at clinical level.

Health professionals

The term ‘‘Healthcare professional’’ includes physician, pharmacists, nurses and others. Lack of Continuing Medical Education programme (CME) in pharmacovigilance for Health professionals lead to under reporting of adverse drug reactions. Reasons for not reporting adverse reactions include a) Health care professionals not sure whether it is an ADR. b) Not knowing where to and whom to report. c). Difficulty in finding the report form d) Facing difficulties to fill the report form e) Busy schedule of health care professionals and not having time to report etc.

Self-Medication

Influenced by the advertisements of the drug companies available in pamphlets patients take drugs over the counter (OTC) prescribed by pharmacist. This leads to unknown potential adverse effects which usually goes unreported.

Web-Based medication

Web based information related to drugs and diseases without authenticity leads to uncontrolled sale of medicines with questionable safety, efficacy and quality which in turn may lead to many unknown adverse effects which goes unnoticed.

Privacy of health data

A recurring theme which has achieved considerable prominence and importance, even beyond pharmacovigilance, is the privacy and confidentiality of personal data of the patient. To safe guard the personal sensitive health data of the patient sometimes physicians do not document the ADRs which in turn goes unreported.

Counter Feit drugs

Counterfeit drugs are a worldwide concern causing underreported problems. It is difficult to distinguish the actual ADRs caused by drug from the ADRs caused by its counterfeit drug. This leads to reporting ADRs of a drug which may not belong to the original drug which are intended to be according to physician.

Confounding illness

Incurable diseases with more advanced pathology like malignancy etc. may need administration of multiple drugs. In this type of conditions, the ADRs which occur are mostly due to interaction between different drugs administered, sometimes does a problem in identifying the offending drugs.

Clinical trial Monitoring

India is becoming center for clinical trial in the 21st century. In most of the clinical trials, adverse drug reactions that happen due to the test drugs goes unreported. ADRs in clinical trial are not informed to the regulatory authority due to personal interest or for the fear of litigation.

Probable solutions to overcome challenges identified in reporting and documentation of adverse drug reactions in homoeopathy

It is estimated that ADRs are the sixth leading cause of death worldwide [12].

It is necessary to improve the ADRs reporting culture of Homoeopaths. As Pharmacovigilance in homoeopathy will

not only safeguard the consumers but also can benefit the system immensely by establishing a database which would support the safety of Homoeopathic drugs which in turn can increase credibility of homoeopathy among the scientific community and lead to the increase of market value of homoeopathy.

The following solutions can help to overcome the Challenges in reporting ADRs:

- Government provides the major source of fund to run the Pharmacovigilance programme at all levels. Government should start an initiative of giving rewards or incentives along with proper appreciation and recognition for the Homoeopathic Physicians reporting ADRs with proper documentation. This initiative will encourage and motivate physicians in reporting and documentation of ADRs at clinical level.
- ADRs after proper verification can enrich our Materia medica as ADR may give new indication for that particular homoeopathic medicine. These types of advantages can be explained through Conducting regular Continuing Medical Education programme (CME) about pharmacovigilance for Health professionals and encourage them about ADRs reporting and documentation.
- Spreading awareness in public domains about the harmful effects of self-medication and web-based medication on health by conducting Health camps, TV ads etc. and guiding them to visit physician immediately when ADRs developed.
- Health information, when it is more sensitive which applies to adverse reaction reports, that directly identifies the patient or the reporter with name, address, national health number with some legal systems, determination of such individual's identity must be protected. Although current practices throughout the pharmaceutical industry and by regulatory authorities reflect a commitment to protection of personal data, new laws require some changes in personal-data handling practices.
- Stronger state licensure supervision of drug suppliers would be helpful in restricting the manufacture and supply. Trafficking in counterfeits can show extremely profitable results.
- Single remedy constitutional treatment should be followed as a primary option for confounding illness which allows physician to identify and record the ADRs easily of a particular single drug without any confusion which is not possible in case of multiple drugs are prescribed.
- To avoid burden of bureaucratic procedures most of the times ADRs in clinical trial are not informed to the regulatory authority. Explaining about the protocols and simple procedures of reporting and documentation of ADRs and its implications in terms of public health will help in increase in ADRs reporting.

Conclusion

Healthcare systems depend mostly on the identification and reporting of ADRs to find out new drug reactions, record the rate at which they are reported, analyse the possible factors that may increase risk to patients and provide information to health care professionals with a view to prevent future ADRs to occur. Monitoring drug safety is a shared responsibility of all the health professionals and the focus must always be on the collection, reporting, interpretation of ADRs. Keeping in view of the increased use of Homoeopathy, the reporting culture of homoeopaths must be improved by overcoming all the challenges. This will make the system more scientifically validated and safe for consumption.

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