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# A Review on Pharmacovigilance: methods, recent developments, future perspectives and software.

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## Abstract

Pharmacovigilance begins from clinical phase and go on throughout the product life-cycle of the drug. Pharmacovigilance focuses at assessment, detection and prevention of any possible drug related problems and adverse effects, particularly acute adverse effects and chronic adverse effects of drugs, biological products, herbalism and traditional medicines. In recent years, pharmacovigilance has evolved with increasing importance to better clinical practice and public health science. The various methods used in pharmacovigilance are active surveillance, passive surveillance, stimulated reporting, targeted clinical investigation, comparative observational studies, descriptive studies. In order to keep up the demands and maintenance of patient's health the new developments in pharmacovigilance is essential. For the future guidance there are three publications in pharmacovigilance-Erice Declaration on transparency, Erice Manifesto for global reform of the safety of medicines in patient care, By Waller and Evans. To convince the patient about the safe use of the drug the pharmacovigilance in future must be able to recognize the safe problems without investing much time. And also, pharmacovigilance methods can also be used to identify that which patients can develop ADRs and how they can develop ADR and for this the most important factor will be the use of the patients as a source of information in the field of pharmacovigilance. Software are mostly used for the reporting purpose and managements of ADRs. The most commonly used software's are the following- Oracle Argus Safety, ArisG, Oracle adverse event reporting, PvNET, repClinical.

Keywords- Pharmacovigilance, Active surveillance, adverse effects, reporting.

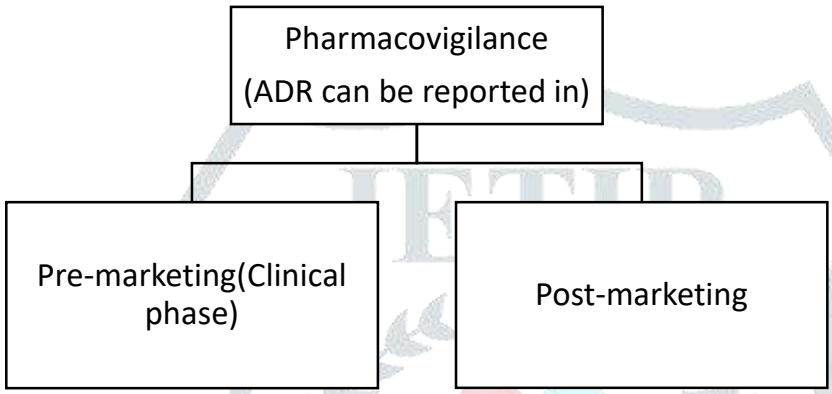
## Introduction

Pharmacovigilance focuses at assessment, detection and prevention of any possible drug related problems and adverse effects, particularly acute adverse effects and chronic adverse effects of drugs, biological products, herbalism and traditional medicines. It plays an important role in decision-making in pharmacotherapeutics. (3)(9)

It promotes safe and rational use of drugs by:

- Enhancing the timely detection of previously unknown ADRs and drug interactions.
- Detecting risk factors that develop ADRs.
- Assessment of quantitative aspects of benefit/risk analysis.
- Circulating information to improve the prescription and regulation of drug. (4)

Pharmacovigilance begins from clinical phase and go on throughout the product life-cycle of the drug. (9)

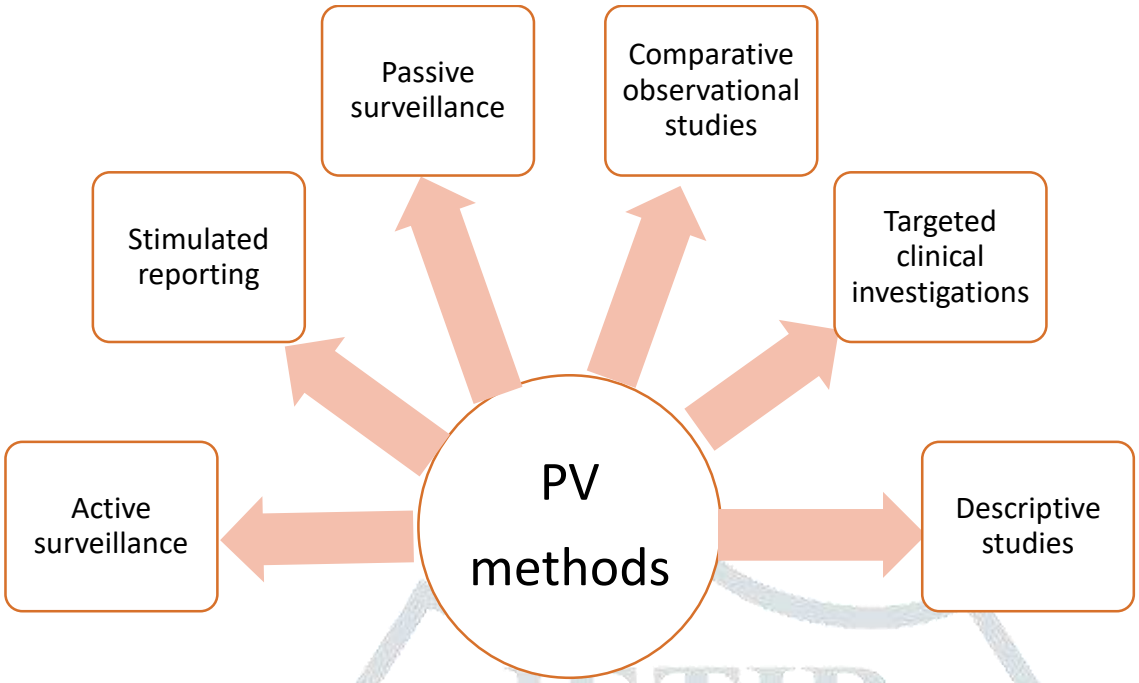



In recent years, pharmacovigilance has evolved with increasing importance to better clinical practice and public health science. But now a days, lots of challenges are faced in the field of pharmacovigilance to establish a better healthcare system in this world.

Following are the major challenges faced in the pharmacovigilance:

- Web-based sales and information
- Globalization
- Broader safety concerns
- Assessment of established products
- Economic growth in public health vs pharmaceutical industry
- Perceptions to benefit and risk. (10)

Methods of pharmacovigilance




Passive surveillance - This method of pharmacovigilance is a type of spontaneous reporting system, in this method healthcare professionals are responsible for the detection and to take the initial step to report an ADR. (11) The method of reporting is most common and its establishment is considered as:

- Effortless
- Cheapest among all the methods.

But this spontaneous method has very low reporting rate as compared with other methods. By using National ADR reporting forms, spontaneous reporting can be performed in districts where active surveillance cannot be done due to insufficiency of funds and low manpower. (12)

Active surveillance- Active measures are taken to identify the adverse events. (13) This method of pharmacovigilance depends on patient's follow up after their treatment. The adverse drug reactions can be detected by:

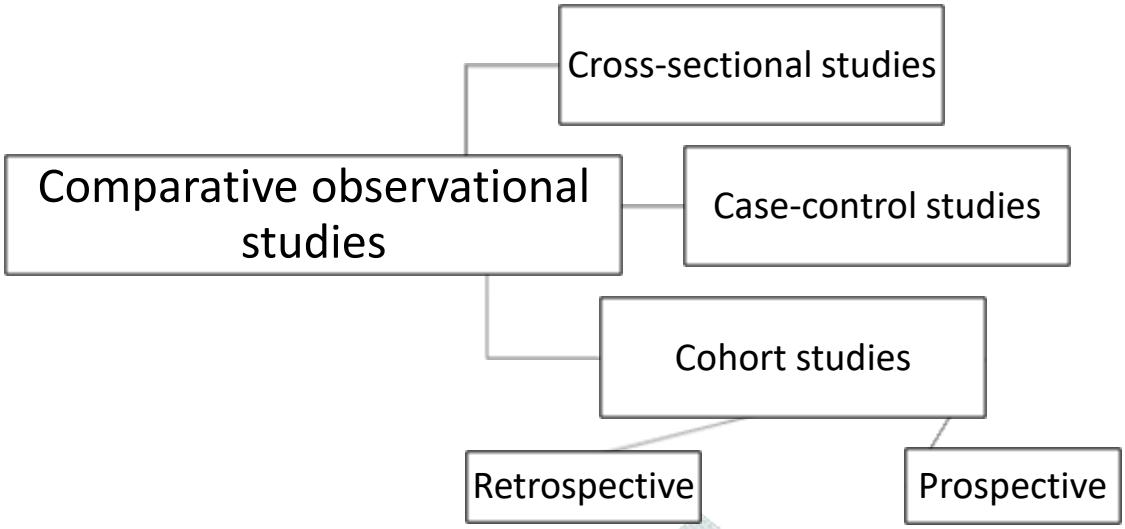
- Directly asking to the patients
- Screening of the records of patients. (12)

A comprehensive data can be feasible on individual AE reports. (13)

Stimulated reporting- According to this method health professionals encourages the reporting of the new products. Method of reporting includes:

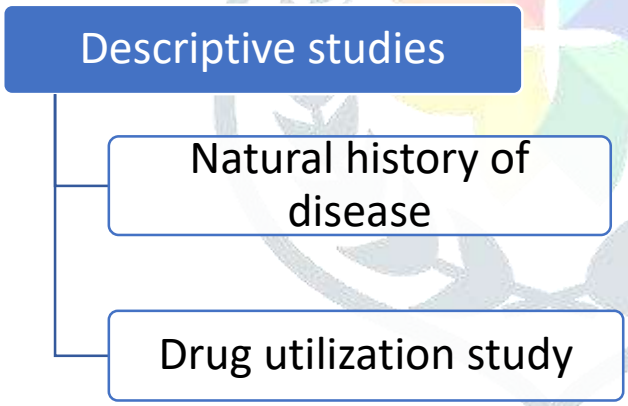
- Online reporting of adverse events
- Systematic stimulation of adverse events.

Comparative observational studies- These studies are mainly used to confirm the signals from case series or spontaneous reports. It is a traditional method for the evaluation of adverse drug events. (15)




Targeted clinical investigations- Pharmacokinetic and pharmacodynamic studies are conducted. Whenever, in pre-approval clinical trials risk factors are identified the further trials are to evaluate the mechanism of action of ADRs. (14)

Descriptive studies- In a particular population, prevalence of the use of drugs were established, which is used to acquire the background rate of outcome events. (13)




## Recent developments in the field of pharmacovigilance

In order to keep up the demands and maintenance of patient's health the new developments in pharmacovigilance is essential. For the future guidance there are three publications in pharmacovigilance.

The three publications consist of;

1. Erice Declaration on transparency: Includes following statements-
    - To provide service to the health of the public information on drug safety is necessary.
    - Providing information to the maximum amount of public and health care providers about the appropriate and safe use of the drugs or additional safety information.

- To understand the risks and benefits each and every evidence should be available and must be assessed properly.
- To ensure that the information about the safety of all the drugs should be available which is collected, then evaluated every country must have a system with independent expertise. (4)
- There should be new developments in drug safety monitoring so that the problems are identified efficiently and accurately and the solutions to the problems are communicated properly.

2. Erice Manifesto for global reform of the safety of medicines in patient care: Includes the following statements-
   • There should be active participation of the public as well as the patients in the debate of involvement of benefits and risks associated with the medicines and in decision making about their own treatment. (7)
   • For the information about the safety and effectiveness of medicines there must be new ways developed for the collection, analysis and communication of the information, an open discussion must be conducted and concluding with a decision.
   • The way in which the methods of pharmacovigilance must be improved should be learned along with the professional, official and public collaboration.
   • Based on the demonstrable benefits of pharmacovigilance to public, the support amongst politicians, officials, scientists, clinicians, patients and the general public is required. (16)
3. By Waller and Evans: Includes-
   They presented their view on way of conduct of pharmacovigilance in the future. The key values for pharmacovigilance are
   - Excellence (defined as the best possible result)
   - The scientific method
   - Transparency.

   In the paper five elements are there that are considered as essential for achieving excellence. Three of them are:

   - Process-oriented best evidence,
   - Robust scientific decision-making and
   - Effective tools to deliver protection of public health. (1)

## Future perspectives

To establish pharmacovigilance as a science, it is very important to develop new methods that can be used to make the current system stronger.

As we all know that pharmacovigilance is all about

- Detection of new ADRs
- To take regulatory actions that is needed to protect health of public by
  - Change in the summary of product characteristics (SPCs) or
  - Drug withdrawn from market. (2)

For the generation of information that can help in the decision-making process by healthcare professional about the use of the drug an emphasis has been put on this, and the communication of this information is the most important aim of pharmacovigilance. (1)

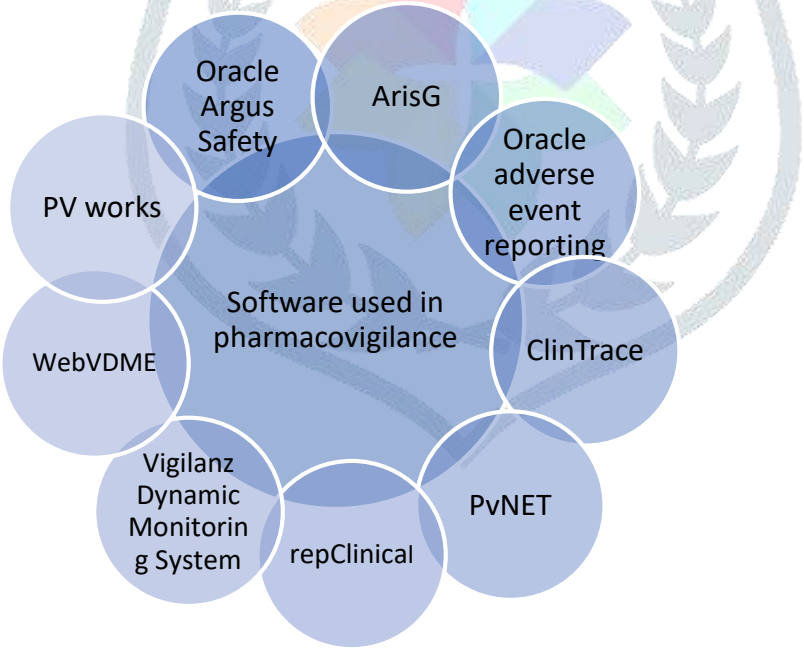
Active surveillance is used to gather information about the drugs safety for use at early stage of drug development, while gathering information in active surveillance post-marketing phase it is to be kept in mind about the collection of information within time. Spontaneous reporting was useful in generation of signals, but very low number of reports are available regarding this type of reporting. Therefore, identification of risk factors becomes low leads to difficulty in detection of ADR. (16)

For the occurrence of certain ADRs pharmacogenetics identifies individual risk factors. Now a days, it has been observed that there is a gradual change in the role of the patient. (17)

Previously, the patients were not highly aware and their participation was also very low, but a patient at present day is highly aware and informed about the disease and actively participate in treatment. In some of the countries patients has option of reporting ADRs, this development in patient will continue in future also works as a good source of information.

The Pharmacovigilance was introduced in the year 1960s, ever since field of pharmacovigilance has made an incredible journey. (15) In order to meet the requirements in the future the pharmacovigilance systems have faced a major change. The innovation needed in this field is contributed by the intensive monitoring discipline. To convince the patient about the safe use of the drug the pharmacovigilance in future must be able to recognize the safe problems without investing much time. And also pharmacovigilance methods can also be used to identify that which patients can develop ADRs and how they can develop ADR and for this the most important factor will be the use of the patients as a source of information in the field of pharmacovigilance. (1)

Software used in the field of pharmacovigilance




Software are mostly used for the reporting purpose and managements of ADRs. The most commonly used software's are the following:

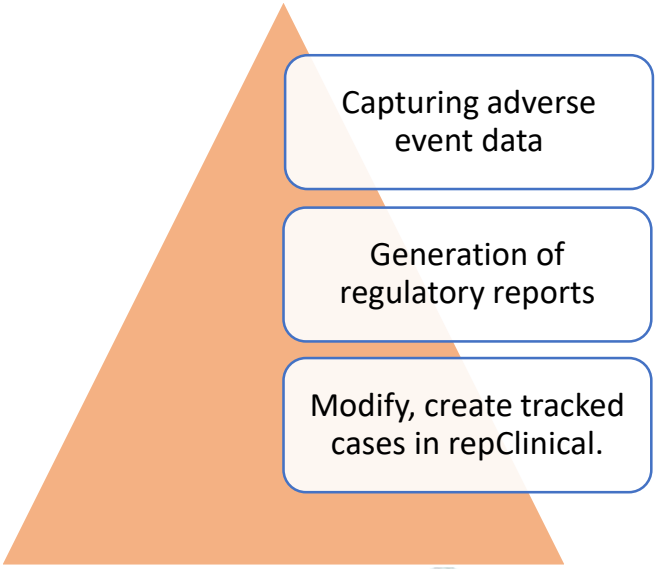
1. Oracle Argus Safety- It is a comprehensive platform mainly used to fulfill the requirements of pharmacovigilance. Now a days, pharmacovigilance is facing the problems of increase in volume of cases, complex business, to analyze safety data, disparate data sources. Therefore, it is designed to manage the needs.
   Following are the benefits of Argus safety are;
   - (18)


2. ArisG- Most commonly used software by the pharmaceutical companies, the functionality that is required to manage the adverse event reporting are provided by this software.
   ArisG uses configurable workflow and advanced automation features for the management of adverse drug reaction. A core component is formed by ArisG, this core component is of risk management system this leads to easy monitoring of the products and identify the risk factors actively by the companies.

3. Oracle adverse event reporting- This software is easy to use formed by professionals; Oracle AERS is responsible for the:


4. PvNET- It is one of the most important software that is used in adverse drug event reporting and ADR data management in pharmacovigilance as well as generation and analysis of various regulatory reports.
   PvNET helps in the integration of the safety information which ultimately helps in the decision-making process critically by the users of the software. Additional features can be added in it by add-on-modules. (18)

5. repClinical- One of the most secure web- based service, this software is mainly responsible for the management of the activities of the pharmacovigilance in a cost- effective way in timely manner. It works in very simple and effective manner (18)




## References


1. Prof. dr. A.C. van Grootheest Prof. dr. J.J. de Gier, Web-based Intensive Monitoring a patient- based pharmacovigilance tool, Optima Grafische Communicatie, Rotterdam, ISBN: 978-90-367-5516-0.
2. Helene The ophile, Manon Andre, Ghada Miremont-Salame, Yannick Arimone, Bernard Begaud, Drug Saf DOI 10.1007/s40264-013-0083-1.
3. Ronald H.B Meyboom, Antoine C.G Egberts, Frank W.J Gribnau, Yechiel A. Hekster, Drug safety 1999 Dec 21(6) 429-447, 0114-5916/99/0012-0429/S09.50/0.
4. JE Campbell, M Gossell-Williams, MG Lee, West Indian Med J 2014; 63 (7): 771, DOI: 10.7727/wimj.2013.251.
5. Manfred Hauben, Xiaofeng Zhou, Drug Safety 2003; 26 (3): 159-186 0114-5916/03/0003-0159/$30.00/0.
6. Lihite RJ and Lahkar M (2015) An update on the Pharmacovigilance Programme of India. Front. Pharmacol. 6:194. doi: 10.3389/fphar.2015.00194.
7. Jean-Louis Montastruca, Agnès Sommeta, Isabelle Lacroixa, Pascale Oliviera, Geneviève Durrieua, Christine Damase-Michela, Maryse Lapeyre-Mestrea, Haleh Bagheria, Joint Bone Spine 73 (2006) 629–632.
8. Gloria Shalviri, Kazem Mohammad, Reza Majdzadeh, Kheirollah Gholami, pharmacoepidemiology and drug safety 2007; 16: 1136–1140.
9. WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000-2003. WHO/EDM/2000.1
10. G Jeetu and G Anusha, Pharmacovigilance: A Worldwide Master Key for Drug Safety Monitoring, DOI: 10.4103/0975-1483.66802.
11. Peter R. Arlett, Xavier Kurz, Drug Discovery Today: Technologies, Innovative methods in drug regulatory sciences Vol. 8, No. 1 2011, DOI: 10.1016/j.ddtec.2011.03.003.
12. Mudasir Maqbool, Mohmad Amin Dar, Shafiqa Rasool, Ahsan Ullaha Bhat, Mohammad Ishaq Geer, Journal of Drug Delivery & Therapeutics, 2019; 9(2-s):543-548.
13. Ronald H. B. Meyboom, Klin Farmakol Farm 2011; 25(3): 102–111.
14. Kumar Sumit, Baldi Ashish, Journal of Drug Delivery & Therapeutics; 2013, 3(4), 237, ISSN: 2250-1177 http://jddtonline.info.
15. Dr. Alka Sawarkar, Dr. RK Sharma, Dr. Vidhi Gautam, Dr. K Shramankar and Dr. Neelam Dinodia, The Pharma Innovation Journal 2019; 8(8): 84-92, ISSN (E): 2277- 7695.

16. Agrawal P. Drug discovery development: An insight into pharmacovigilance. Journal of Pharmacovigilance. 2014; 2:120-122.
17. Vijay K. Challenges and Future Consideration for Pharmacovigilance. Journal of Pharmacovigilance. 2013; 1:102-105.
18. Software used in pharmacovigilance by clinskill, Argys safety, pharmacovigilance 2019.