

Pharmacovigilance in Medical Writing-Arm for Patient Care



“Dying from a disease is unavoidable; dying from a medicine is unacceptable.” Lipakhin V Geneva 2005.

With indebted blessings of the Almighty God, I would like to inform our readers that our journal IJDMS has successfully completed its one year. On the occasion of our journal's Anniversary, I take this opportunity to express my profound gratitude to our managing editors, all of the Editorial board members, reviewers, readers and most importantly our publisher Renu Publishers for their constant support and untiring efforts in this endeavour of ours. I wish the journal reaches new heights.

Adverse drug reactions cause a significant amount of mortality and morbidity worldwide. The domain of pharmacovigilance made an enormous impact since it was recognized after the thalidomide disaster in the early 1960s, which resulted in foetal abnormalities. It was followed by the withdrawal of rofecoxib that renewed the interest in drug safety mechanisms. Pharmacovigilance, according to World Health Organization 2002, is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.”^[1] It plays a significant role in assuring that patients receive safe drugs. The objective of pharmacovigilance is to ensure patient care and safety related to medication. Lately, this field of drug safety has received a lot of recognition.

Pharmacovigilance is, in essence, the steps and procedure of monitoring the everyday use of essential medicines to identify and diagnosed previously unrecognized adverse drug reactions (ADRs), thereby assessing their risk/benefit balance in order to determine what action, if any, is necessary to improve their safe use. As a discipline, pharmacovigilance impacts on many specialist areas such as pharmacoepidemiology, medical practice, public health, but is most intimately linked to clinical research, development and drug licensing.

Primary scope and objectives are:

- Safety, benefits, and risk of medicine

- It should improve patient care and safety in relation to use of medicines
- It should concentrate and improves public health and safety
- Communicate and analysis should be done at risk, benefits, harm for increase benefits to patient care
- Should encourage the safety and cost effective in use of medicines
- Should promote understanding, education, and clinical training to remove awareness in respect to patient care
- Safety monitoring of medicinal products
- Guidelines should be setup for proper running of pharmacovigilance.

As per the International Conference on Harmonization Efficacy Guidelines ICHE2E pharmacovigilance methods include: passive surveillance, stimulated reporting, observational studies, targeted clinical investigations, and hypothesis generating methods. In the early 1990s, the PHARMO system of record linkage was developed in Netherlands. Earlier, pharmacovigilance was more concerned with finding new ADRs, but Waller and Evans suggested that pharmacovigilance should be less concentrated on determining harm and concentrate more on extending knowledge of safety. Pharmacovigilance program was launched in 2010 in India, to ensure the benefits of the medicines to cut down the unwanted risks involved. Therefore, early detection of signals from clinical trials and post-marketing surveillance have now been detected by major pharma companies with the aim to identify the major risks and effectively manage the risk by applying risk management plans.

Minimum requirements in pharmacovigilance documentation are:

- Should be described in a generic model document
- Adverse reaction should be properly described
- Team should be interdisciplinary for preparation, review and analysis
- License renewal should be properly checked
- Identification of new safety drugs and concerns

- An identifiable patient and name of suspected product

Future prospects should be applied:

- Should be active pharmacovigilance center worldwide
- Person should be expertise in art of monitoring and analysis
- Centers should be a set up after approval of regulatory authorities
- Should be easy to establish and cheapest to run
- Instant reporting should be done for adverse event or reaction
- Instant measurement of the outcome of response and action should be taken.

In the end, I would like to conclude by stating that the shear motive of this editorial is to make our readers aware regarding the importance of drug safety in our lives. The pharmacovigilance of tomorrow should be raised to a level such that the new safety issues are identified without delay and should be able to tell which patients are at a risk of developing ADRs.

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