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Aftab Khan
Student, St. John Institute of Pharmacy and Research, Palghar, Maharashtra, India

Sejal Dsilva
Student, St. John Institute of Pharmacy and Research, Palghar, Maharashtra, India

Corresponding Author:
Aftab Khan
Student, St. John Institute of Pharmacy and Research, Palghar, Maharashtra, India

The pillars of drug safety: A comparative review

Aftab Khan and Sejal Dsilva

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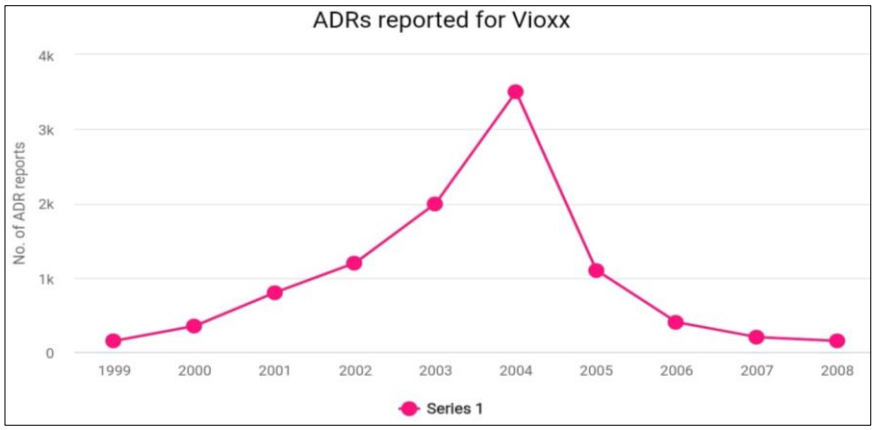
Abstract
In the entire pharmaceutical science, there are two disciplinary that guard the health of public after the drug lleaves the laboratory. these are mainly termed as the watchdogs of the pharmaceutical fields. The pharmacovigilance and pharmacoepidermology are the two vibrant fields that go in parallel path to guide the public health. This comparative study deals into the dynamic between these two fields, how the early detector of adverse effects of drugs are detected by pharmacovigilance and these signals at the population level with precision are monitered by pharmacoepidermology. These study reveals about how they form the backbone of the the drug safety.And together they act as a defense system that gives evidence based decisons. This review mostly highlights the necessity of their collaboration in ensuring a safer and smarter therapeutic future. Ultimately it highlights the absolute necessity of their collaboration that could give us a personalized care in the pharmaceutical field.

Keywords: Pharmacovigilance, drug safety, signal detection, risk management

Introduction
With the rising dependence on the drugs for managing various chronic and acute disease, the safety of drugs has become a topic of interest as it mainly depends on drug safety. The invention of any drug in the Market is a journey of have a balanced drug effects against the various risk factor. The various pre-clinicals and clinicals trials theses are often short duration and fail to detect the drugs long lasting adverse effect on the human system. These is where the two guards of the pharmaceutical industry step in mainly the-pharmacovigilance and pharmacoepidermology they play their efficient rol. These have different methodologies and operate on a different scale but ultimately they work with a common goal of safeguard the public health. Pharmacovigilance acts as a frontline warrior identifying the potential risk factor meanwhile pharmacoepidermology acts as a investigational unit. A thorough understanding of both these fields and their strength in guiding the public health is essential to enhance our ability to detect, evaluate and to understand the drug- related problems.

Historical Evolution of The Fields
Both these fields were not developed in vaccum but were mainly born from the health crises that exposed the critical gaps in the health care systems.
The most influential and the tragic event in the history of pharmacovigilance was the thalidomide disaster of the late 1950s and the early 1960s. This drug was mainly marketed as a sedative and treatment for morning sickness thalidomide was mainly responsible for severe birth defects in thousands of childrens worldwide. This tragedy sparkled worldwide leading to a immediate need for a robust international system to monitor and track the adverse effects that are faced and are caused mainly after the drug releases in the market.



Pharmacovigilance

Defination and Scope

It is defined as the science and the activities that mostly relate to the detection and assesing the adverse effects of drugs. It mainly focuses on:

- Reporting adverse drug reactions.
- Signal detection and risk managment.
- Post marketing survilance [1].
- Pharmacovigilance mostly relies on the quick reporting of the clinical observations and regulatory databases.

Pharmacoepidermology

Scope and Defination

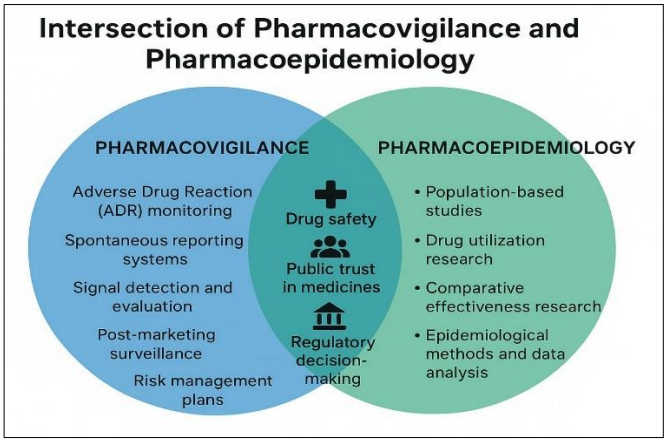
Pharmacoepidermology is a branch which mainly combines the two pharmacology and epidermology which studies the use and effects of drugs in large population. It uses the analytical methods to monitor the patterns, trends associated with the drug therapy [2].

It mainly focuses on:

- Risk benefit evaluation.
- Population level assessment.
- Drug utilization in a large population.
- Pharmacoepidermology mostly uses the cohort, case study which are supported by data from health databases, insurance records [3].

Interrelationship between the two fields

Though these fields are distinct they are complemantary to each other. Pharmacovigilance geneartes safety signals and later thses are investigated by the pharmacoepidermology through structural studies [4]. For instance a increase in the adverse drug reactions through the pharmacovigilance may lead to a need for the pharmacoepidermology study to confirm the trends. Morever the relationship is like one detects the sparks whille the other investigates the fire. This patnership of the both makes the post marketing survilance powerful and more vibrant [5].



Applications in safeguarding the public health.

In the history of these two fields the drug Vioxx commonly known as rofecoxib once was known to be a revolutionary painkiller and later it was found it causes mycocardial infraction [6]. During these times the pharmacovigilance flagged the unexpected cardiovascular side effects which was afterwards confimed by the pharmacoepidermologywhich lead to its significanly withdrawal from the market in 2004.

Global importance

Organizations such as:

- **Uppsala Monitoring Centre:** it promotes the global pharmacovigilance collaboration.
- **FDA Sentinel Initiative:** A network of pharmacoepidermology data collection.
- **EMA and CDSCO:** Both these fields are combined for the regulatory data oversight [7].

Regulatory Role

Pharmacovigilance and pharmacoepidermology are responsible for the post marketing decisions. It can mainly do vit by generating warnings, triggering the recall of drug from the market. However, the main regulatory role of pharmacoepidermology is that it quantifies risk and monitors the long term effect. It practically answers many questions which futher leads to the prescribing guidelines, drug formulatory decisions and cost effective analyses [8].

Applications of Pharmacovigilance and Pharmacoepidermology

Covid-19 Vaccine Monitoring

During the recent covid-19 pandemic the important role of the two fields came into the picture. during this pharmacovigilance correctively detected the cases of myocarditis and reported while the pharmacoepidermology monitered the rate of this incident across the population.

NSAIDS and Cardiovascular Risk-

This is the most common with people on the cardiovascular therapy. in this the pharmacovigilance confirmed that there is a acute link between the Cox -2 inhibitors with heart attacks and pharmacoepidermology continuously monitored the patient trend which further lead to reduce utility of the NSADS [9].

Future Scope for a Smarter and Safer Outcome

While witnessing the expanding role of pharmacovigilance and pharmacoepidermolgy since the times of covid. with the increasing dependence of the public on Al diagnostics, personalized medicines the need for these fields in rising. They have evolved from post marketing survilance to predictive and preventive tools. From monitoring the safety and efficacy of vaccines during the pandemics to studying their long term effects on human body and gene therapy there is a certainty of the rising role of these fields [10].

Artificial Intelligence - AI algorithms are developed to read the unstructured text in electronic health records and identify the potential ADRs earlier than ever before. Machine learning can enhance the early signal detection this can be done by

identifying the complex patterns that are invisible in the early pre-clinical trials.
Integration Of Genomics- the integration of genomics can be able to predict which patients are at a high risk for specific ADRs before they take the first dose.

Challenges Towards Pharmacovigilance and Pharmacoepidermology

Eventhough it has many pros and advances there are even several challenges faced. These two systems highly depend on public and physicians engagement. But their ill responsiveness and cause a failure to these systems.however the under developed or the developing countries lack adequate infrastructure to adopt to the system of pharmacovigilance and pharmacoepidermology. Also the limited databases and longitudinal data can lead to its failure.Pharmacovigilance and pharmacoepidermology relies on the real world data that was not collected for research purpose. This data can be incomplete and difficult to access due to privacy [11].

Conclusion

While both these fields have different methodologies and a contrasting role they promise to provide a highly essential processes. Together they form a robust and a multi-layer framework for the drug safety and the efficacy. Pharmacovigilance acts as a sensitive alarm system that alerts the medical community to potential dangers while the epidermology serves as a detector that detects the scope of the investigation. Hence the collaborative role enables the researches to generate more precise and safety data that help strength the public trust. They help fundamentally ensuring that the patient safety remains tha highest priority for the future medicines developed for the need of the various disease.

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