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Opinion

Pharmacovigilance: Safeguarding Public Health through Drug Safety Monitoring

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INTRODUCTION

Pharmacovigilance (PV) is the science and set of activities dedicated to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems [1]. It is an essential component of public health, ensuring that the benefits of medications outweigh their risks [2]. PV spans pre-marketing clinical trials, post-marketing surveillance, and the continuous reevaluation of drug safety profiles [3]. Regulatory authorities such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and the World Health Organization (WHO) coordinate PV systems globally [4]. The increasing complexity of modern therapies, including biologics and gene therapies, makes robust PV frameworks more crucial than ever [5].

DESCRIPTION

The process of pharmacovigilance begins long before a drug reaches the market. During clinical trials, adverse events are meticulously recorded and analyzed [6]. However, because clinical trials often involve a limited and controlled population, rare or long-term adverse effects may not appear until after the drug is widely used [7]. This is where post-marketing surveillance becomes essential. Systems such as the FDA's MedWatch, the EMA's EudraVigilance, and WHO's VigiBase collect spontaneous adverse event reports from healthcare professionals, patients, and manufacturers [8].

Pharmacovigilance activities include signal detection, which involves identifying new or changing patterns in drug safety data [9]. Signals can come from spontaneous reports, observational studies, prescription data, or literature reviews [10]. Once a signal is detected, regulatory bodies may conduct further investigation, request additional studies, or issue safety alerts and product label changes [1].

DISCUSSION

Pharmacovigilance plays a critical role in identifying safety concerns early and preventing harm. One well-known example is the withdrawal of rofecoxib (Vioxx) from the market after PV data revealed an increased risk of cardiovascular events [2]. Another example is the detection of rare blood clotting disorders associated with certain COVID-19 vaccines, which led to updated prescribing guidelines and informed patient consent processes [3].

Modern PV increasingly uses real-world evidence (RWE) gathered from electronic health records (EHRs), insurance claims databases, and patient registries [4]. This approach allows researchers to study drug safety in broader and more diverse populations than those in clinical trials [5]. Artificial intelligence (AI) and machine learning tools are also being deployed for automated adverse event detection and pattern recognition [6].

Pharmacovigilance is not limited to adverse drug reactions (ADRs) but also includes medication errors—wrong dosage, incorrect administration routes, or dangerous drug–drug interactions [7]. Identifying such incidents allows healthcare providers to implement safeguards, such as computerized physician order entry (CPOE) systems with built-in alerts [8].

In low- and middle-income countries, PV faces challenges such as underreporting, lack of infrastructure, and insufficient trained personnel [9]. The WHO's Global Benchmarking Tool aims to strengthen PV systems worldwide by providing structured assessments and recommendations [10].

Public awareness is another key factor. Encouraging patients to report side effects directly can significantly improve

data collection, especially for newly marketed drugs [1]. Campaigns to promote reporting, coupled with user-friendly online tools, have increased engagement in several countries [2].

International collaboration is critical because drug safety issues often transcend national borders. The WHO Programme for International Drug Monitoring facilitates data sharing among more than 130 countries, allowing faster recognition of global safety concerns [3]. Additionally, harmonizing reporting standards through initiatives like the International Council for Harmonisation (ICH) helps ensure that data from different sources is comparable and reliable [4].

Despite advancements, underreporting remains a significant barrier to effective PV. Studies estimate that only 5–10% of serious ADRs are reported [5]. To address this, some healthcare systems have introduced mandatory reporting for certain drugs or adverse events [6]. Others have integrated PV directly into clinical workflows, so reporting becomes part of routine care [7].

CONCLUSION

Pharmacovigilance is an indispensable safeguard in modern healthcare, protecting patients from unforeseen harms and guiding the safe use of medicines. By combining real-world evidence, advanced analytics, and global collaboration, PV ensures that the benefits of pharmaceuticals are realized while minimizing risks. The future of PV will increasingly rely on proactive detection methods and active participation from all stakeholders—regulators, healthcare providers, and patients alike.

REFERENCES

1 Gilleard WL (2013). Trunk motion and gait characteristics of pregnant women when walking: Report of a longitudinal study with a control group. BMC Pregnancy and Childbirth. 13.

2 Zhang Y (2015). Characteristics of the centre of pressure progression for pregnant women during walking. Int J Biomed Eng Tech. 17: 387-397.

3 Sunaga Y (2016). Estimation of inertial parameters of the lower trunk in pregnant Japanese women: A longitudinal comparative study and application to motion analysis. Appl Ergon. 55: 173-182.

4 Bey ME (2019). Vastus Lateralis Architecture Changes During Pregnancy, A Longitudinal Study. Front Physiol. 10.

5 Ma LL, Wang YY, Yang ZH, Huang D, Weng H, et al. (2020). Methodological quality (risk of bias) assessment tools for primary and secondary medical studies: what are they and which is better? Military Medical Research. 7: 1-11.

6 Branco M (2013). Kinematic analysis of gait in the second and third trimesters of pregnancy. J Pregnancy. 2013.

7 Betsch M (2015). Spinal posture and pelvic position during pregnancy: a prospective rasterstereographic pilot study. Eur Spine J. 24: 1282-1288.

8 Branco M (2016). Kinetic Analysis of Gait in the Second and Third Trimesters of Pregnancy. J Mech Med Biol. 16: 1650055.

9 Forczek W (2019). Does the first trimester of pregnancy induce alterations in the walking pattern? PLoS ONE. 14: e0209766

10 Visser M (2005). Muscle Mass, Muscle Strength, and Muscle Fat Infiltration as Predictors of Incident Mobility Limitations in Well-Functioning Older Persons. J Gerontol A Biol Sci Med Sci. 60: 324-333.