Editorial

Pharmacovigilance: A Cornerstone for Patient Safety in the Modern Therapeutic Era

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Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.[1] In an age where new medicines are reaching the market faster than ever before—thanks to accelerated approval pathways, breakthrough therapy designations, and emergency use authorizations—ensuring their ongoing safety is of paramount importance. Now PV program plays a safeguard both patients and Health Professionals, those dealing with new as well as older drugs in the field of therapeutics.

The global pharmaceutical market was valued at over USD 1.4 trillion in 2024, with thousands of new chemical entities, biologics, and vaccines under development.[2] While innovation brings hope, it also increases the possibility of unforeseen adverse drug reactions (ADRs), which can be rare but serious, and sometimes life-threatening. PV serves as the post-marketing safety net that bridges the gap between clinical trial findings and real-world use.

Historical Evolution and Lessons to be learned

The roots of modern PV are firmly planted in tragedy. The thalidomide disaster of the late 1950s and early 1960s, which caused severe limb deformities in over 10,000 newborns worldwide, exposed the inadequacies of pre-market testing and regulatory oversight.[3] This catalyzed the establishment of formal ADR monitoring systems in many countries. Other notable incidents further reinforced the need for strong PV systems: Rofecoxib (Vioxx) withdrawal in 2004 due to increased cardiovascular risks.[4] Cisapride market suspension in 2000 after being linked to fatal cardiac arrhythmias.[5] Diethylstilbestrol (DES), used in pregnancy, later linked to cancer in the offspring decades after exposure.[6] These events demonstrate that even after rigorous pre-approval testing, long-term or rare ADRs may only emerge when drugs are used by millions over extended periods.

Global and National Pharmacovigilance Frameworks

Today, PV systems operate at national, regional, and global levels.

In the United States, the FDA's MedWatch system allows healthcare professionals and consumers to report ADRs directly. The European Medicines Agency (EMA) runs the EudraVigilance database, centralizing ADR data from EU member states.India's Pharmacovigilance Programme (PvPI) has created over 350 ADR monitoring centers since its inception in 2010.[7]

Bangladesh, through the Directorate General of Drug Administration (DGDA), has an ADR reporting system integrated with the WHO-Uppsala Monitoring Centre (UMC).[8] The WHO Programme for International Drug Monitoring, coordinated by UMC in Sweden, now includes over 170 member countries, making it the largest global PV network.[9] This facilitates the identification of rare ADRs that might only be detectable when data is pooled internationally.

Challenges in Pharmacovigilance Implementation

Despite global advances, PV systems still face substantial obstacles:

1. Under-reporting – Estimates suggest over 90% of ADRs go unreported.[10]
2. Lack of awareness – Many healthcare providers are not adequately trained in recognizing and reporting ADRs.
3. Resource constraints – In low- and middle-income countries, PV infrastructure often relies on limited funding and manpower.
4. Signal detection overload – Massive volumes of safety data can make distinguishing genuine safety signals from statistical noise difficult.[11]

Case Studies in Pharmacovigilance: Success & Failure PV has prevented many potential disasters, but failures have also occurred:

Success: Early detection of anaphylaxis risk with the monoclonal antibody omalizumab led to updated prescribing guidelines, significantly reducing patient harm.[12]

Failure: The delayed recognition of cardiovascular risk in rosiglitazone use (marketed for diabetes) resulted in thousands of avoidable heart attacks before restrictions were imposed.[13]

These examples illustrate the importance of rapid, transparent, and coordinated PV actions.

The Role of Technology in Modern PV

The digital era has transformed PV:

Big Data & AI – Algorithms analyze millions of EHR entries to detect ADR patterns earlier than traditional methods.[14] Social Media Monitoring – Patient-reported experiences on platforms like Twitter or health forums can reveal safety concerns not captured in formal reports. Mobile Apps – Many national PV programs now offer apps for easy ADR submission by both clinicians and patients. However, technological advances bring new challenges: data privacy, cyber security risks, and the need for ethical frameworks to govern the use of patient-generated data.[15]

Patient Engagement in PV

Patients are no longer passive recipients of care—they are active contributors to drug safety monitoring. Patient-reported outcomes often capture side effects that healthcare providers might miss, especially for chronic or subjective symptoms such as fatigue or mild cognitive changes. Countries like the UK have integrated direct patient reporting into their national PV systems, resulting in richer and more diverse ADR data.[16]

Future Challenges: Beyond Traditional Drugs

The scope of PV is expanding beyond conventional pharmaceuticals to include:

Biologics – Complex molecular structures with unique immunogenicity risks. Gene Therapies – Long-term and potentially irreversible effects. Digital Therapeutics – Software-driven medical interventions, raising questions about adverse "digital" events.These innovations will require PV systems to evolve with specialized monitoring strategies and international regulatory harmonization.

Recommendations for Strengthening PV

1. Integrate PV training into undergraduate and postgraduate medical, pharmacy, and nursing curricula.
2. Simplify reporting tools with mobile apps and online portals.
3. Create incentive systems to encourage ADR reporting.
4. Public awareness campaigns to empower patients as safety partners.
5. Global collaboration to share safety signals and harmonize responses.

Conclusion

Pharmacovigilance is more than a regulatory requirement—it is a shared societal responsibility. The evolving pharmaceutical landscape demands PV systems that are adaptive, transparent, and globally integrated. By combining robust regulatory oversight, technological innovation, healthcare professional engagement, and patient participation, we can ensure that medicines continue to deliver more benefits than risks. Investing in PV today will protect patient safety for decades to come.

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Prof. Dr. A. K. M. Shahidur Rahman
Joint Editor, KYAMC Journal