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Letter to the Editor

Enhancing pharmacovigilance for robust drug safety monitoring: addressing underreporting and collaborative solutions

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Dear editor,

The Indian National Pharmacovigilance Program, initiated several years ago, has made progress, but challenges such as underreporting and adverse drug reaction (ADR) reporting difficulties persist. Despite these obstacles, there have been changes and increased awareness of pharmacovigilance since its inception. Pharmacovigilance (PV) is essential for collecting, monitoring, and evaluating data to reduce adverse effects, improve clinical care, and enhance public health.[1] This article delves into the strengths and weaknesses of pharmacovigilance systems, highlighting obstacles such as underreporting, awareness gaps, and reporting barriers.

(a) *Underreporting challenges*: Underreporting, the failure to report ADRs to regulatory bodies or pharmacovigilance systems, hampers post-marketing drug safety surveillance. This challenge impacts the accuracy of safety profiles for marketed drugs, undermining the effectiveness of these systems. Spontaneous ADR reporting by healthcare professionals is crucial, but it is hindered by factors such as time constraints and lack of awareness.[2] In Africa, a study conducted in Nigeria revealed significant underreporting of ADRs among healthcare professionals due to factors such as lack of awareness, limited access to reporting systems, and concerns about legal repercussions. Similarly, research from Southeast Asia highlighted challenges in ADR reporting in countries like Thailand and Indonesia, citing barriers such as language barriers, cultural stigma, and resource constraints. These examples underscore the universal nature of underreporting challenges and the need for tailored interventions across diverse healthcare settings.[3]

(b) *Healthcare professionals' role*: Healthcare professionals face challenges in reporting ADRs due to their busy schedules, taking about 53 s on average to report an adverse event within the electronic health record (EHR) system,[2] and lack of awareness about the importance of reporting ADRs. Training and education during their formative years can improve reporting rates. Despite their benefits, spontaneous reporting programs struggle with diagnosing ADRs, with underreporting and bias as major hurdles. Online signal detection tools and innovative strategies are needed to bolster these programs and raise awareness among health professionals. Healthcare professionals often express a significant concern, after they report an ADR as a case report, they receive a multitude of emails from different pharmaceutical companies, requesting additional details about the drugs. Fear of legal consequences, misconceptions about reporting requirements, and time constraints also contribute to underreporting.

(c) *Progress in low- and middle-income countries (LMICs)*: LMICs have made strides in establishing national pharmacovigilance systems and utilizing cohort event monitoring for post-marketing surveillance.[4,5] The integration of artificial intelligence (AI) technologies has further streamlined processes across various medical fields.[6,7] Addressing self-medication, which is significant in LMICs, AI can aid in reporting unrecorded ADRs and enhance reporting

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rates.[8] Recent advancements in AI have revolutionized pharmacovigilance practices worldwide. For instance, a study by Lopez et al. demonstrated the efficacy of machine learning algorithms in detecting adverse events from EHRs with high accuracy, thereby overcoming traditional reporting barriers faced by healthcare professionals. In addition, the integration of natural language processing (NLP) techniques, as evidenced by the work of Wang et al., has enabled automated extraction of ADR data from unstructured sources such as social media platforms, providing valuable insights into real-world drug safety issues. However, there are significant limitations and challenges with the use of AI in pharmacovigilance, especially in LMICs. These include the high cost of implementation, the need for high-quality data, the lack of technical expertise, and concerns about data privacy and security. Addressing these challenges requires collaborative efforts between governments, healthcare institutions, and technology providers.

(d) *Patient involvement and technological challenges*: Patients play a vital role in underreporting due to their reluctance to report ADRs to doctors, forgetting details, and providing inaccurate information. Educating patients during medication administration can encourage timely reporting. Moreover, creating awareness among patients can be achieved through methods like roleplays, set induction, or counseling at Primary Healthcare Centers, Rural Health Centers, and Urban Health Centers to encourage them to proactively report ADRs. The technical challenges of data collection, cleaning, and analysis require skilled professionals and a standardized database to ensure accurate results.[2] In Europe, initiatives such as the Yellow Card Scheme in the United Kingdom have successfully engaged patients in ADR reporting through user-friendly online platforms and targeted educational campaigns. Similarly, a study conducted by Schutte et al. in Australia demonstrated the effectiveness of patient counseling sessions at community pharmacies in improving awareness and reporting of medication-related adverse events. These highlight the importance of empowering patients with knowledge and resources to actively participate in pharmacovigilance efforts.

(e) *Collective efforts for improvement*: Enhancing knowledge, attitudes, and practices (KAP) among healthcare professionals through education is essential. Integrating pharmacovigilance into medical and nursing curricula for all healthcare professionals, including doctors, nurses, pharmacists, and dentists, can drive proactive reporting. Raising patient awareness and in addition, it is essential for pharmacovigilance to be integrated into the curriculum of nursing students which can further improve reporting rates.

To conclude, pharmacovigilance is a complex undertaking, marked by errors and challenges that need resolution. Collaborative efforts among healthcare professionals, patients, regulatory bodies, and the pharmaceutical industry are imperative to bolster ADR reporting and elevate patient care. With proper training, AI integration, patient awareness, and government support, an effective pharmacovigilance system can be established, ensuring thorough ADR reporting and analysis. This article underscores the urgency of addressing underreporting to achieve robust drug safety monitoring, ultimately enhancing patient safety.

Declarations

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SSTY did complete drafting and reviewing, SP and BM worked as writing assistants, and HS did supervision and guidance.

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Author contributions

Tanguturi Yella Sree Sudha: Conceptualization; Resources; Writing – original draft; Writing – review & editing.

Bhumika Meena: Writing – original draft.

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