

COMMENTARY

Steering medicines towards patient safety: Challenges and possible solutions

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Abstract

Medicines provide therapeutic benefits but also cause harm due to inappropriate use and adverse drug reactions (ADRs). ADRs may cause serious health consequences, imposing a significant burden on healthcare systems. Ensuring patient safety by minimising risk requires optimal ADR monitoring, transparency, accountability, and adherence to ethical principles throughout the stages of drug research and development, the approval process, and use in the real world. The current systems for assessing and assuring medicine safety have certain weaknesses and challenges, thereby increasing the risk that ADRs go unrecognised. This commentary, therefore, delves into the issues surrounding medicine safety, the risks entailed, challenges in detecting ADRs and potential solutions to address these issues. It is hoped that this piece will help stakeholders, including regulatory agencies, improve accountable systems, enhance patient safety, and foster public trust in medicines, thereby improving both individual and public health.

Keywords: Pharmacovigilance, ADR, benefit versus harm, medication errors, AI in healthcare

Introduction

Medicines have both beneficial and harmful effects. These may vary based on the medicine or individual. Clinicians should, therefore, weigh therapeutic benefit versus harm while prescribing. Appropriate medicine use involves informing patients about medicines in prescriptions, weighing risk versus benefit, and involving patients in the decision-making process. Each process has ethical implications, involving autonomy (patient information and decision making), justice (ensuring adequate representation of diverse groups, access, availability, and affordability), beneficence (ensuring maximum therapeutic benefit) and non-maleficence (implementing measures to prevent adverse drug reactions).

An adverse drug reaction (ADR) is a “noxious and unintended response to a medicine administered at doses normally used for diagnosis, prevention, or treatment of diseases” [1]. Serious ADRs may be life-threatening, lead to hospital admission, prolong hospital stay, cause disability or teratogenicity, or result in death. The economic burden due to ADRs was approximately \$6.7 billion per year in the UK [2]. Estimates of preventable medication-related harm amount to 5% of the population [3].

Historically, the thalidomide disaster raised a global alarm regarding consequences of undetected ADRs and the need to test medicines systematically and thoroughly for potential harm [4]. This systematic monitoring is done through pharmacovigilance. The World Health Organization (WHO) defines pharmacovigilance as the “science and activities relating to the detection, assessment, understanding and prevention of adverse drug effects or any other drug-related problem”. The WHO Programme for International Drug Monitoring (PIDM) created in 1968 facilitated the collection of evidence of patient harm from multiple sources [5,6]. This international collaboration enabled data sharing across countries. Since 1978, the Uppsala Monitoring Centre (UMC) has served as the WHO Collaborating Centre for PIDM.

Pharmacovigilance systems and national regulatory frameworks have contributed to multiple drug withdrawals, label changes and warnings regarding ADR. However, certain inherent weaknesses and practical challenges have impeded the setting up of a more robust pharmacovigilance system especially in low- and middle-income country (LMIC) settings. ADRs, therefore, continue to contribute to significant patient harm and economic consequences. Strengthening the pharmacovigilance system and preventing harm is therefore paramount both for individuals and society. This commentary, therefore, reflects on the gaps and challenges in the pharmacovigilance system, and possible solutions to prevent patient harm and maximise the therapeutic benefit of medicines.

Challenges in assessing medicine safety before approval

Prior to regulatory approval, medicines undergo testing both during preclinical research and clinical research (trials) for various parameters including harm. However, clinical trials are designed to assess efficacy and not “powered” to evaluate anticipated harm to the participant. This methodological weakness in the evaluation of a medicine's benefit-to-risk ratio fundamentally undermines the principle of non-maleficence [7]. Besides this, other factors influence the rate and detection of new ADR. Internal factors include challenges in protocol design, execution, and statistical analysis. External factors include trialling in a monitored and controlled environment, lack of diversity of trial participants (undermining justice), relatively short periods of medicine exposure and follow-up (months to couple of years), non-

critical peer review or failure to identify statistical weaknesses in analysis, and publication bias (undermining adherence to integrity) [8,9,10,11].

In the real world, factors such as the medicine profile and frequency of ADRs occurring, cultural and behavioural factors, patient status (age, sex, ethnicity, nutritional status, hepatic/renal function, co-morbidities), comedications, patient awareness and knowledge, and health system factors all influence the chance of experiencing and reporting ADRs. The real world is therefore very different from the clinical research world, which is much more homogenised. The weaknesses in the clinical trial design and system therefore may lead to ADRs being missed in the product label. The potential harm from these medicines post-approval may vary depending on ADR frequency, severity, and seriousness. In addition, rare ADRs (occurring in 1-10,000 people or more) and cumulative ADRs (those that appear on long-term use) may be completely missed during a clinical trial due to small sample size and short term exposure [12]. All the above complex and interlinked factors undermine the principle of non-maleficence.

Challenges in assessing medicine safety after approval

The journey of a medicine in the real world starts after regulatory approval and entry into the market. Safety is then primarily assessed through Phase 4 studies, post-marketing surveillance (PMS) and pharmacovigilance programmes. Real world usage is complex. Detecting new ADRs (those not detected in clinical trials) and attributing them to a particular medicine is a multistep process, necessitating collaborative efforts by regulatory authorities, market authorisation holders (MAH), academic institutions and hospitals, healthcare professionals (HCPs), and patients themselves, indicating shared accountability and ethical responsibility.

Though clinical research and feedback from experts contribute to detecting ADR post-approval, individual case safety reports (ICSRs) form the cornerstone of reporting suspected ADRs. Multiple good quality ICSRs contribute to "signal generation," the process of identifying potential new ADRs. Signals then undergo validation, confirmation, analysis, and assessment [13]. Despite these processes aiming for ADR detection, pharmacovigilance systems continue to suffer in the real world due to a host of factors mentioned below.

Underreporting, representativeness and funding

Regulation laxity, health system factors, and healthcare facility challenges contribute to underreporting of ADRs [14]. In LMICs, stark differences exist in reporting practices between urban and rural areas, healthcare levels (primary or secondary) and public versus private facilities that undermines the principle of justice. A lack of adequate reporting in diverse age and ethnic groups could further diminish identification of ADRs unique to these sub-groups. Insufficient funding is also a critical barrier to comprehensive

pharmacovigilance. While some LMICs have dedicated budgets, others follow a tiered approach prioritising tertiary over other healthcare levels. When funding is from external donors, sustainability of the pharmacovigilance programme is a concern [15].

Barriers to reporting by health care professionals (HCP)

In many LMICs, healthcare professionals (HCPs) are not obligated to report ADRs and maybe inadequately trained in causality assessment of ADRs. HCPs often perceive many ADR to be too insignificant to report, not serious or even attributable to disease symptoms. HCPs may also be hesitant to report ADRs due to fear of professional scrutiny [16]. ADR reporting in outpatient clinics is difficult due to workload and time pressure. For inpatients, filling a follow-up report is challenging, particularly due to quick discharge of patients. Incomplete or invalid reports may not be included for signal detection [14,17]. Importantly, the lack of direct feedback to those reporting an ADR is a disincentive. All these barriers contribute to underreporting. The hospital hierarchical system and inadequate training in ADR reporting and causality assessment may also affect the contribution from different HCPs (doctors, nurses, pharmacists). These challenges undermine the principle of shared accountability.

Inequities in patient reporting

The extent to which patients report ADR varies vastly among countries. Patient reporting is higher in high-income countries (HICs) compared to LMICs [18]. In LMICs, patients may not be aware of the need to report or the means of reporting (through apps, help line numbers etc) [19,20,21]. Furthermore, they may have difficulty recalling the timeline of events leading to an ADR. Language barriers also contribute. Incomplete reports result in poor data quality and consequently weaknesses in signal generation.

Complexity of global data integration

ADR data are generated from varied sources, including clinical trials, submitted safety documents, literature review, pharmacovigilance systems, etc. The challenge is to integrate and analyse this data in a holistic fashion. Specific barriers to integration include diverse labelling structures and heterogeneous software systems available in varying formats, complicating the analytical process and differentiation of "signal" from "noise". Even after signal identification, a proper communication mechanism to HCPs and patients about newly identified ADR poses a challenge undermining the autonomy of these stakeholders.

Inaccessible controlled access data repositories (CADR)

CADR data contain information on patients taking medicines for specific diseases such as mental disorders, Alzheimer's disease, and substance abuse. This controlled access data, driven by privacy concerns, results in lack of transparency or disproportionate data sharing [22].

Medication errors

Many HCPs are unaware that medication errors (errors while prescribing, dispensing, administering medicines) leading to ADRs should also be reported through the pharmacovigilance system. Even if aware, some are reluctant to report due to fear of scrutiny, punishment, or even legal reprisal. Hence, ADRs due to such errors remain grossly under-reported. These gaps in data on burden and consequences of such ADRs undermine principles of justice.

Inadequate collaboration and transparency between multiple stakeholders

A strong pharmacovigilance system requires collaboration between multiple stakeholders (HCPs, patients, regulatory authorities, academic entities, public and private organisations, civil society, and the pharmaceutical industry). Unfortunately, collaboration and coordination are poor in many countries. Accountability lies with these stakeholders and healthcare policy makers to ensure conducive systems for prompt reporting of suspected ADR.

Contextual and behavioural practices increasing ADR risk

Many factors could indirectly contribute to increased risk of ADR in LMICs. These include – inadequate access to healthcare facilities, gender differences, over the counter medication, self-medication, polypharmacy, incentives for over-prescribing medications, non-adherence to standard treatment guidelines, promotion strategies by industry, information overload, falsified and substandard medicine and availability of irrational fixed drug combinations in the market [23,24]. Many of these risks could be averted by providing Universal Health Care (UHC) thereby promoting the principles of fairness, justice and human rights.

As compared to older medicines, many of the newer classes may have less ADR due to improved technological processes. However, these new medicines are often more expensive leading to continued usage of older medicines with more ADRs, especially among the poor. High prices of new medicines unless covered by public authorities/governments, may also result in inequitable distribution of medicine among different socio-economic strata. This approach to pricing violates distributive justice [25,26]. Besides cost, access to these new medicines is also a challenge [26]. It often takes several years for these new medicines to become available in LMICs, raising concerns about global health justice and equity [26].

Vulnerable groups

In addition to the above challenges, neonates, children, the elderly, and those with mental illness and dementia are more vulnerable to ADRs. This is due to various factors including polypharmacy, off label use, inaccurate dosing in neonates and children, age related altered kinetics and dynamics etc. The risk of experiencing ADR also depends on ethnicity,

genetic makeup and other related factors. Genetic variability has been linked to increased predominance of ADRs in specific ethnic groups with certain medicines such as carbamazepine, abacavir etc. External factors such as nutritional status, smoking, alcoholism and concomitant medication may influence as well.

Inequities also arise with respect to the speed and completeness of withdrawal from the market once significant or serious harm from an ADR is confirmed. Some countries continue to use harmful medicines for various reasons. As per one study, the median interval between the first reported ADR and the year of medicine withdrawal was 6 years [Interquartile range (IQR): 1-15 years] [27]. Signal generation has led to many countries withdrawing medicines, but not all [27].

Potential solutions towards strengthening medicine safety

Pharmacovigilance

To ensure optimal pharmacovigilance and thereby minimise risk to patients, a multipronged strategy is critical. As with any public health problem, strengthening and investing in a strong healthcare system is foundational. To improve ADR reporting, conducting a thorough root cause analysis of existing gaps and challenges in the pharmacovigilance system is vital to facilitate the design of context-specific interventions. Strengthening regulatory implementation in countries with a poor record is also needed. In addition to the need for dedicated funding in pharmacovigilance, additional incentives for reporting ADR to healthcare centres may be needed. Building capacity among HCPs through targeted educational interventions, including training of trainers workshops, blended learning programmes and e-learning courses have been beneficial in improving knowledge and ADR reporting rates. Fostering a positive work place culture and collaboration among HCPs, seamless reporting systems, removing barriers to reporting, and adopting checkpoints to reduce medication errors are other effective measures [28].

Novel technological methods could be adopted to encourage more ADR reporting by HCPs and patients. These must be culturally acceptable and adapted to local contexts. With the advent of smartphones, a gamification application similar to fitness apps could be created with features like gaining points and badges for each ADR reported. For seamless reporting, quality response (QR) codes linked to user-friendly ADR forms can be made available and strategically placed in public places for reporting ADRs. To strengthen and validate the report, options for uploading photographic evidence of dermatological reactions could be included (without revealing patient identity), for final verification by a dermatologist. Furthermore, for the visually challenged and elderly, voice-enabled assistant platforms (Siri, Alexa) can be utilised to increase active ADR reporting.

Often, clinical trials exclude vulnerable groups (unless the medicine is exclusively meant for them). However, once the drug is approved, clinicians tend to use these medicines in vulnerable groups also. After regulatory approval, therefore, use of these medicines in vulnerable groups ideally require proactive monitoring and supervision mechanisms.

Clinical research

Early detection of ADR could be improved at the preclinical stage of drug development by utilising data resources such as extensive multi-omics datasets, pharmacokinetic and pharmacodynamic (PK-PD) data (data on chemical properties, targets, mechanisms of action). Additionally, to predict medicine safety profile, bioinformatic databases such as Bio2RDF, which links chemical structures to biological data, DrugBank101 offering drug targets, ChEMBL, providing binding affinity data, Side Effect Resource (SIDER) detailing side effect profiles, could be used [29,30,31]. In addition, adopting newer methodologies for conducting clinical trials, including adaptive trial design and decentralised trial design, will enhance the robustness of ADR data and potentially provide real-world evidence (RWE). This would assist in transforming a reactive medicine safety assessment approach into a proactive and predictive system. During phase 4 and PMS of new medicines, key stakeholders (regulators, sponsors, and HCPs) should transparently share ADR data. This can be facilitated through interoperability between various regulatory agencies' databases.

Integration of big data with Artificial Intelligence (AI)

Big data is available from a diverse array of longitudinal healthcare resources, including patient registries, electronic health records, insurance claims databases, and genomic datasets. Additionally, vast amounts of critical safety insights are available in extensive national and global pharmacovigilance databases, toxicology databases and poison centre records [32]. Having systems in place to analyse and integrate these data for prompt detection of ADR is vital.

AI-powered chatbots on pharmaceutical websites, applications and patient social media posts provide crucial real-time safety discussions on new medicines. Additionally, continuous physiological health data from wearable health devices data (eg, fitness trackers, smartwatches, pressure sensors, implants, rings with biosensors, continuous glucose monitoring devices, etc) provide valuable real-time safety information [32]. Leveraging AI on the above collective repository of real-world data can, if appropriately used, generate critical real-world evidence to ensure the safety of patients living in a real-world setting. Ethical risks such as confidentiality and privacy however need to be safeguarded through appropriate measures.

Natural language processing (NLP) can mine clinical notes, scientific literature, and regulatory information, providing crucial information on potentially serious ADR. Using machine learning methods, phenotypical manifestations reported in

ICSR can be used to estimate the likely proportion of patients with a genotype associated with drug toxicity [33]. Deep learning enables the integration of multiple variables such as comorbidities, polypharmacy, and genomic profiles. Large Language Models, such as the Generative Pre-trained Transformer (GPT) model, can be utilised for patient safety analysis [33]. Additionally, if made accessible, analysing CADR data within the AI realm can provide vital untapped safety data on this subpopulation.

Conclusion

Medicines used for therapeutic benefit may cause harm through ADRs. Despite efforts towards an optimal medicine safety assessment system, challenges exist leading to ADRs not being detected pre- and post- regulatory approval. Factors both inherent and external to clinical trials if addressed can facilitate a more robust safety profile for new medicines entering the market. Additionally, the current pharmacovigilance system in the real world needs to be predictive rather than just reactive. System-level, institutional, HCP, and patient factors, coupled with gross underreporting and inadequate representation of different healthcare setups, are often reasons for delayed identification of ADRs. Inculcating a safety culture and being sensitive to ethical implications would address many of these issues.

There is a lot of work to be done, but concurrently, the number of new medicines is increasing, thereby increasing the risk and harm to patients using these medicines. Accelerating efforts towards strengthening pharmacovigilance by leveraging advanced technologies would be essential. Integrating AI into advanced big data analytics is one such example for determining trends and patterns of potential ADRs. Active and transparent data sharing with pharmacovigilance authorities is also critical across all phases of drug development. In addition, mechanisms and systems should be in place to integrate different ICSRs for signal detection and strengthen analytical systems to validate signals. If these strategies are implemented effectively, risks from medicines could be minimised, thereby going a long way to reinforcing the basic tenets of autonomy, benefit, non-maleficence, and justice into medicine safety and public health at large.

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