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Ahmad Z. Al Meslamani

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EDITORIAL

Underreporting of Adverse Drug Events: a Look into the Extent, Causes, and Potential Solutions

Ahmad Z. Al Meslamani [a,b]

[a]College of Pharmacy, Al Ain University, Abu Dhabi, United Arab Emirates; [b]AAU Health and Biomedical Research Center, Al Ain University, Abu Dhabi, United Arab Emirates

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1. Introduction

Adverse drug events (ADEs) represent a global public health challenge that impacts both patients and healthcare systems alike. ADE is defined as any harm caused by medication that could potentially be prevented [1,2]. Medication errors (MEs), among the many preventable ADEs, often stem from flaws in healthcare delivery system or healthcare professionals' knowledge, workload, or competency issues; as a result, MEs can increase healthcare costs while negatively affecting patient health outcomes. Adverse drug reactions (ADRs), although unintended, may still occur even with appropriate medication usage and may have severe health implications [1,3]. Unfortunately, the methods used to assess their prevalence often understate its impact [1,2].

Underreporting of ADEs refers to the failure or incomplete reporting of incidents where patients experience harmful reactions from medications by healthcare providers, patients, or pharmaceutical companies. Examples include ADRs and MEs. Different countries, including the US, the UK, Canada, and Australia, have implemented reporting systems for medication errors and ADRs, such as FAERS in the US; Yellow Card Scheme in the UK; Canada Vigilance Program as examples of systems, which collect reports of adverse drug events from healthcare professionals and patients [4–6]. Nonetheless, underreporting is still a widespread and ongoing problem [7,8].

To maintain medication safety, specific steps must be taken; however, without first understanding its extent and root causes it would be impossible to provide advice as to their implementation. Therefore, this commentary aims to assess the current state of under reporting of adverse drug events (ADEs) and identify their underlying causes. After this analysis, potential solutions to mitigate the problem will be discussed.

2. Extent of underreporting of adverse drug events

Reporting medication errors (MEs) is a crucial responsibility of healthcare professionals, and each health system has a specific reporting process in place. Several studies have assessed the extent of underreporting of these events using different methodologies and used different denominators to calculate the rate of underreporting. This variability can limit the ability to understand the pattern of inadequate reporting of MEs. In various hospital settings in the United States [9], Turkey [10], Japan [11], Iran [12], Malaysia [13], Ethiopia [14], and Saudi Arabia [15], potential underreporting of MEs among physicians, pharmacists, and nurses have been documented. In a Korean hospital, the rates of reporting prescribing, dispensing, and administration errors were 43.7%, 57.4%, and 37.1%, respectively [16]. David Palmero et al [17], found a huge discrepancy between the frequency of MEs reported voluntarily with the number of MEs identified using a direct observation in a Swiss hospital.

Reporting systems for adverse drug reactions (ADRs) are implemented in most countries. However, the literature shows a widespread and significant underreporting of ADRS worldwide [18]. A systematic review by Hazell and Shakir analyzed 37 studies conducted in different countries and found that the rate of underreporting of ADRs exceeded 90% in many cases [7]. The authors concluded that underreporting was a global problem and that it affected all types of ADRs, including life-threatening incidents [7]. A study conducted in Sweden by Bäckström, Mjörndal, and Dahlqvist reported an underreporting rate of 84% for serious ADRs in five hospitals, indicating that the problem of underreporting persists even in countries with well-established reporting systems [19].

Overall, the global prevalence of underreporting of ADEs, is a major cause for concern. Such underreporting can lead to delays in identifying safety issues associated with drugs and cause harm to patients. Additionally, it can impede identification of flaws in the medication delivery process, posing further drug safety risks. It is worth noting that even in countries with advanced healthcare systems, the underreporting of ADEs persists, indicating that the issue is not solely related to inadequate infrastructure or resources.

3. Factors contributing to underreporting of adverse drug events (ADEs)

The main factors leading to underreporting of ADEs are summurised in Table 1. The reporting of adverse drug events (ADEs) by healthcare professionals is essential for improving patient safety and care quality. However, several factors can impact the accuracy and effectiveness of ADE reporting, which

CONTACT Ahmad Z. Al Meslamani amaslamanie1095@gmail.com AAU Health and Biomedical Research Center, Al Ain University, Abu Dhabi, United Arab Emirates

Table 1. Causes of ADEs underreporting.

	Sub-factors
1- Healthcare professionals	
Fear-based factors	Fear of retribution or punishment for reporting an error or ADE
	Fear of litigation or malpractice lawsuits
	Fear of damaging reputation or career prospects
	Fear of being perceived as incompetent or careless
Knowledge-based factors	Lack of understanding or awareness of the reporting process
	Poor knowledge about the clinical outcomes of ADEs
	Lack of knowledge about the definitions and classifications of ADEs
	Lack of knowledge about the severity of ADEs
	Lack of training or education on reporting ADEs
	Misconceptions or myths about ADE reporting (e.g. thinking that only serious events need to be reported)
System-based factors	Ineffective reporting tools (e.g. cumbersome or time-consuming forms)
	Facing difficulty in using the electronic system (e.g. technical issues)
	Insufficient feedback or follow-up on reported events
	Lack of standardized reporting criteria or definitions
Organisational-based factors	Lack of leadership support or encouragement for reporting ADEs
	Lack of resources (time, staff, funding) to support reporting efforts
	Prioritization of other performance metrics over ADE reporting
	Culture of blame or punishment rather than learning from errors
	Lack of communication or collaboration among healthcare teams
	Lack of accountability or transparency in reporting processes and outcomes
2- Patients and consumers	
Personal-based factors	Lack of motivation to report ADEs
	Fear of being labeled as a 'difficult' patient or receiving negative consequences
Information-based factors	Lack of awareness of the reporting process
	Lack of awareness of the importance of reporting ADEs
	Misunderstanding or confusion about the reporting process or criteria
	Limited health literacy or understanding of ADEs
System-based factors	Limited access to reporting mechanisms or support for reporting (e.g. language barriers, lack of internet access)
	Insufficient feedback or follow-up on reported events

can be broadly categorized into fear-based, knowledge-based, system-based, and organizational-based factors.

Fear-based factors or potential negative repercussions of reporting an error or adverse event (ADE), include potential retribution, litigation costs, reputational harm, or career prospects [12]. Fear can create an atmosphere of silence among healthcare providers, leading them to underreport adverse drug events (ADEs) with potentially negative outcomes for patients. Knowledge-based factors may impede reporting, including a lack of awareness or comprehension about how ADE reporting should occur; poor knowledge regarding clinical outcomes related to adverse drug events (ADEs); or misconceptions and myths surrounding reporting [20]. Unavailable training or education on reporting Adverse Event Disclosures can obstruct effective reporting. System-related factors involve tools and processes in place for reporting ADEs, including ineffective reporting tools or systems, difficulties using electronic systems, and lack of standard criteria/definitions [20]. Failing to provide proper feedback or follow-up can discourage healthcare professionals from reporting any adverse drug events (ADEs). Organization-related factors that hinder effective reporting include lack of leadership support, insufficient resources, prioritization of other metrics over ADE reporting and creating an atmosphere of blame or punishment. Poor collaboration or communication within healthcare teams, as well as lacking accountability or transparency regarding reporting processes and outcomes also interfere with effective reporting.

Patients and consumers often face various personal-based barriers that reduce their willingness to report ADEs [21]. One such barrier may be a lack of motivation due to thinking ADEs are common side effects from medications that should not warrant reporting; fear of labeling themselves 'difficult patients' or suffering negative consequences can also prevent people from reporting them.

On top of personal factors, patients and consumers may also be affected by information-based and system-based factors when ADEs. Limited access to reporting mechanisms/support plus inadequate feedback/follow-up after reports can contribute to underreporting by patients/consumers; language barriers/lack of internet access could contribute to underreporting by underreporting reported events [21].

ADRs can have severe ramifications on patient health and wellbeing, yet these reactions often go unreported, leaving us unaware of their true safety impact [22]. Notoriety bias may contribute to the underreporting of ADRs by healthcare professionals; healthcare workers may report more frequently those ADRs, which have already garnered media coverage, while more obscure or lesser publicized ADRs might slip under the radar and go undetected [22]. Additionally, including ADRs in an SPC can cause unwarranted assumptions that any potential reactions have already been included and thus do not require reporting [22]. Furthermore, certain ADRs such as sexual disorders can be hard for patients or healthcare providers to report due to discomfort or stigmatism. Addressing these concerns and raising awareness of their significance to improve medication safety and patient outcomes requires raising awareness. By encouraging healthcare professionals to report all ADRs, regardless of notoriety or perceived relevance, more comprehensive understanding of medication safety may be gained; eventually leading to improved patient care outcomes.

4. Expert opinion

This editorial sheds light on a global problem related to underreporting ADEs, with multiple contributing factors from different domains. Furthermore, this investigation calls attention to the need for further observational studies with real-world data to fully examine ADE underreporting; current literature predominantly relies on self-reported information while lacking investigations using root cause analysis methodologies, such as root cause analysis or comparative root cause analysis techniques for investigating its root causes, strategies must account for different domains, which contribute toward underreporting of ADEs.

For healthcare professionals and patients to report adverse drug events (ADEs), it is necessary to create, validate, and implement multifaceted strategies, which address all obstacles related to reporting ADEs. One key strategy involves creating a global consensus regarding definitions, categories, clinical significance, and communication of this knowledge to regulatory bodies and healthcare facilities across regions or healthcare facilities; this will provide a standardized, uniform method of reporting across healthcare environments.

As ADEs do not receive as much media coverage, innovative solutions must be found to increase awareness among healthcare professionals and patients of this health issue. Such approaches must take into account low learner engagement issues in educational programs; social media can serve to educate the public of its importance when reporting ADEs. Low learner engagement refers to situations in which learners do not fully immerse themselves in the learning process and do not actively take part or exhibit interest in activities related to education and training, potentially leading to decreased motivation, decreased retention of information, and ultimately poor learning results [23].

Health coaching has proven effective at motivating individuals and increasing their sense of responsibility [24], so this strategy may also serve to incentivize healthcare providers and patients to report adverse drug events effectively. A good approach for increasing reporting would include providing education on ADE recognition and reporting as well as feedback mechanisms and removing barriers such as fear or lack of time that prevent reporting errors or adverse drug events (ADEs).

Enhancing electronic reporting systems' functionality and usage are also vital in combatting the underreporting of ADEs [25]. Healthcare organizations should design user-friendly reporting systems, which offer clear instructions and are straightforward. In order to meet their mission effectively, healthcare organizations need user-friendly systems that offer guidance in an intuitive way and that make reporting effortless for anyone involved. Healthcare professionals and patients' input should be carefully taken into consideration to ensure systems fulfill their specific requirements and needs. Healthcare professionals need training and support in using reporting systems effectively, including technical assistance to promptly address technical issues that may arise, feedback, and follow-up on reported events. Healthcare organizations should ensure patient accessibility to reporting systems, particularly for those who may lack technological proficiency. Patient-friendly reporting tools such as mobile apps or web forms may help facilitate easy and timely reporting of ADEs.

Beyond traditional reporting methods, various data sources may also help collect and generate ADEs information such as social media platforms, online patient forums and electronic health records. Social media platforms like Twitter and Facebook have become popular platforms for patients to express their experiences with medication use, enabling researchers to mine this data to identify any ADEs. Online patient forums provide another source for reporting ADEs not captured through traditional reporting channels. Electronic health records (EHRs) may also help identify ADEs by providing a complete history of a patient's medical history that allows searches of specific medication-related events. Privacy concerns must be carefully taken into account when using these data sources and data mining algorithms must be carefully designed and validated to reduce false positives and maintain accuracy. While these sources remain relatively new and continue to develop, their potential lies in furthering our knowledge about ADEs and improving medication safety.

5. Conclusion

This editorial emphasizes the need for concerted efforts to address the global problem of underreporting of ADEs. Multifaceted approaches should be developed and implemented, along with root cause analysis methods used to pinpoint root causes for underreporting; such efforts will allow healthcare professionals and patients alike to report more accurately, thus contributing to patient safety improvements and healthcare outcome improvements.

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Author contribution statement

Ahmad Z. Al Meslamani conceptualized the study design, extracted data, analyzed data, and drafted the manuscript.

ORCID

Ahmad Z. Al Meslamani http://orcid.org/0000-0002-8370-9562

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