



Challenges and Barriers in Patient Reporting of Adverse Effects from Over-the-Counter (OTC) Drugs: A Narrative Review

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ABSTRACT

Over-the-counter (OTC) drugs are commonly used for self-medication because of their availability and perceived safety. However, adverse drug reactions (ADRs) associated with OTC drugs are frequently underreported, posing significant risks to public health. This narrative review aims to identify the main challenges and barriers that prevent patients from reporting adverse effects of OTC drug use. Literature was retrieved from PubMed, ScienceDirect, Google Scholar, and national journals, focusing on publications from 2019 to 2024. The review reveals three major barriers: (1) limited knowledge and misconceptions about OTC drug safety, (2) socio-cultural influences such as stigma and reliance on traditional medicine, and (3) systemic obstacles including complicated reporting procedures and insufficient involvement of healthcare providers. Collectively, these barriers reduce the effectiveness of pharmacovigilance systems. This review underscores the urgent need for patient education, stronger pharmacist engagement, and the integration of digital pharmacovigilance platforms to ensure safe and responsible use of OTC drugs.



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ABSTRAK

Obat bebas (over-the-counter/OTC) banyak digunakan untuk swamedikasi karena ketersediaannya yang mudah dan persepsi aman. Namun, kejadian efek samping obat (adverse drug reactions/ADR) terkait OTC sering kali tidak dilaporkan, sehingga menimbulkan risiko serius bagi kesehatan masyarakat. Artikel tinjauan naratif ini bertujuan untuk mengidentifikasi tantangan dan hambatan utama yang menyebabkan pasien enggan melaporkan efek samping penggunaan obat OTC. Literatur diperoleh melalui PubMed, ScienceDirect, Google Scholar, dan jurnal nasional dengan fokus pada publikasi tahun 2019 hingga 2024. Hasil tinjauan menunjukkan tiga hambatan utama: (1) keterbatasan pengetahuan dan kesalahpahaman mengenai keamanan obat OTC, (2) faktor sosial-budaya seperti stigma dan ketergantungan pada pengobatan tradisional, serta (3) kendala sistemik berupa prosedur pelaporan yang rumit dan keterlibatan tenaga kesehatan yang terbatas. Hambatan-hambatan tersebut secara kolektif menurunkan efektivitas sistem farmakovigilans. Kajian ini menekankan perlunya edukasi pasien, peningkatan peran apoteker, serta integrasi platform farmakovigilans digital untuk memastikan penggunaan obat OTC yang aman dan bertanggung jawab.

Kata Kunci: Efek samping; Obat bebas; Pelaporan pasien; Farmakovigilans; Keamanan obat

1. Introduction

Over-the-counter (OTC) drugs are medications that can be purchased without a doctor's prescription and are widely used to manage minor health problems such as headaches, digestive disorders, colds, and flu [1],[2],[3]. Globally, the prevalence of OTC drug use continues to rise, supported by their affordability, convenience, and easy accessibility through pharmacies, drug stores, and even supermarkets [4],[5]. This trend highlights the increasing role of self-medication in modern healthcare.

Although OTC drugs are generally perceived as safe, they still pose potential risks. Inappropriate use, excessive consumption, or drug interactions can cause adverse drug reactions (ADRs), ranging from mild discomfort to serious health complications [6]. However, many patients underestimate these risks due to the misconception that OTC drugs are inherently safer than prescription medicines [7],[8],[9]. Such assumptions reduce awareness and contribute to low recognition of potential side effects. Such assumptions reduce awareness and contribute to low recognition of potential side effects. [10],[11],[12]. In addition, the absence of clear reporting channels and weak surveillance systems further hinder effective pharmacovigilance [13],[14],[15].

Despite the importance of adverse event reporting, there is still limited literature specifically addressing the barriers patients face in reporting adverse effects of OTC drugs. Previous studies have largely focused on usage patterns or the legal and clinical aspects of OTC use, but few have comprehensively analyzed the obstacles that prevent patients from reporting ADRs. Therefore, this narrative review aims to evaluate the major challenges encountered by patients in reporting OTC-related adverse effects and provide insights for strengthening drug safety monitoring systems.

2. Methods

Study Design

This study employed a narrative review approach, which was selected to allow a broad synthesis of evidence from empirical studies, reviews, and policy documents. Unlike systematic reviews that follow strict PRISMA protocols, the narrative design

provides flexibility to critically analyze diverse literature while still applying transparent and structured selection procedures [2],[3].

Search Strategy

The literature search was conducted across PubMed, ScienceDirect, Google Scholar, and Indonesian national journals. Search terms used in various combinations included “over-the-counter drugs,” “adverse drug reactions,” “patient reporting,” “pharmacovigilance,” and “medication safety.” To capture recent evidence, the search was limited to publications from 2019 to 2024 [9],[11].

Screening and Selection

Articles were screened in three stages (**Figure 1**). First, duplicate records were removed. Second, titles and abstracts were assessed for relevance to OTC drug safety and patient reporting of adverse events. Finally, full-text screening was applied using the following inclusion criteria: (1) focus on OTC drugs and adverse effects, (2) discussion of patient knowledge, behavior, or reporting barriers, and (3) publication in English or Indonesian with accessible full text. Exclusion criteria included studies unrelated to OTC drugs, opinion pieces without empirical evidence, and reports with insufficient methodological clarity

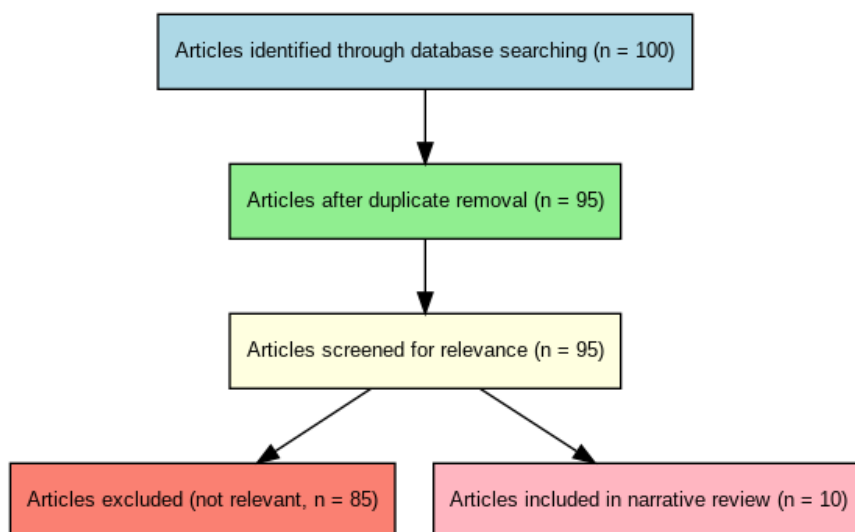


Figure 1. Flowchart of literature search and selection process

Data Analysis

Articles were screened in three stages (Figure 1). First, duplicate records were removed. Second, titles and abstracts were assessed for relevance to OTC drug safety and patient reporting of adverse events. Finally, full-text screening was applied using the following inclusion criteria: (1) focus on OTC drugs and adverse effects, (2) discussion of patient knowledge, behavior, or reporting barriers, and (3) publication in English or Indonesian with accessible full text. Exclusion criteria included studies unrelated to OTC drugs, opinion pieces without empirical evidence, and reports with insufficient methodological clarity [16].

3. Results and Discussion

Characteristics of Included Studies

A total of ten articles were included in this review. The studies were published between 2020 and 2025 and discussed a variety of challenges in reporting ADRs associated with OTC drug use. Several studies emphasized knowledge and behavioral

aspects in relation to self-medication practices [2],[3],[9], while others explored the legal and regulatory issues surrounding the circulation of medicines without prescriptions [4],[5]. Psychosocial factors, such as stigma and demographic influences, were also addressed in research focusing on patient awareness and cultural attitudes [12],[13],[14]. These findings indicate that barriers to ADR reporting are multifactorial, combining patient-level, socio-cultural, and systemic issues [15].

The details of the reviewed studies are summarized in **Table 1**, which presents the authors, reported challenges, and key findings.

Table 1. Narrative Review of Challenges in Patient Reporting of OTC Adverse Events

No.	Autor	Challenge	Summary
1.	[19]	Lack of patient knowledge	Patients believe OTC drugs are safer, so they ignore side effects and do not report them.
2.	[20]	Difficulty identifying effects	Symptoms are mistaken for other issues, delaying recognition of drug-related events.
3.	[21]	Lack of access/ time	Reporting is seen as time-consuming and difficult by busy individuals.
4.	[22]	Stigma or fear	Fear of drug withdrawal or doubts on drug efficacy discourages reporting.
5.	[23]	Not knowing how to report	Public lacks awareness of how to report adverse drug events.
6.	[24]	Brand trust	Patients trust certain brands and dismiss the possibility of side effects.
7.	[25]	Lack of awareness of interactions	15 cases linked to OTC antidepressant interactions, all involved pharmacokinetic effects but were underreported.
8.	[26]	Time constraints for pharmacists	Though pharmacists had good knowledge of NSAID risks, 46% agreed patient education was too time consuming.
9.	[27]	Socioeconomic drivers	Economic hardship, access issues, and convenience drive OTC use despite adequate knowledge.
10.	[28]	Lack of monitoring system	OTC misuse is rising, especially among youth, but underreported due to poor surveillance.

Knowledge, Awareness, and Recognition Barriers

One of the main challenges identified in this review is the lack of patient knowledge regarding the risks of OTC drug use. Many patients believe that OTC drugs are inherently safe compared to prescription medicines, which leads them to ignore possible side effects and refrain from reporting ADRs [19]. Studies in Indonesia also show that even among educated populations, such as university students, awareness about the potential harms of self-medication with OTC drugs remains limited [9]. This knowledge gap contributes significantly to underreporting.

In addition to limited knowledge, patients often face difficulties in recognizing whether their symptoms are drug-related. Mild side effects, such as nausea, fatigue, or digestive discomfort, are frequently attributed to unrelated health conditions rather than OTC use [20],[24]. As a result, many patients dismiss these reactions as insignificant and do not consider them worthy of reporting [2]. This issue is further compounded by the

perception that OTC medications are primarily designed for short-term, minor ailments, reinforcing the belief that reporting adverse effects is unnecessary.

Another barrier is the lack of awareness of proper reporting procedures. Many patients simply do not know how or where to report ADRs when they occur [23]. This uncertainty often results in inaction, even when side effects are experienced. For some individuals, reporting is also perceived as complicated and time-consuming, which discourages them from taking the necessary steps [21].

Collectively, these findings demonstrate that knowledge, awareness, and recognition barriers are critical factors that limit the effectiveness of pharmacovigilance for OTC drugs. Without sufficient awareness campaigns and structured patient education, underreporting of ADRs will persist and hinder the identification of potential safety risks.

Socio-Cultural and Systemic Barriers

Beyond individual knowledge and awareness, socio-cultural and systemic factors also play an important role in limiting the reporting of ADRs related to OTC drug use. Psychological factors such as stigma and fear have been widely reported. Some patients worry that reporting adverse events may lead to the withdrawal of a product they rely on, while others doubt the efficacy of medicines once negative reports emerge. These perceptions discourage patients from reporting, even when side effects are experienced [22].

Another cultural aspect influencing reporting is the high level of trust in specific drug brands. Patients often dismiss the possibility that the product they trust could cause side effects, resulting in reluctance to file ADR reports [24]. This “brand loyalty” represents a significant psychological barrier that cannot be overlooked.

Socioeconomic conditions further complicate the situation. In resource-limited settings, patients often prioritize affordability and convenience over safety. Studies have shown that even when individuals are aware of the risks, factors such as economic hardship, limited access to healthcare, and the practicality of self-medication drive continued OTC drug use without adequate reporting [27]. These realities indicate that knowledge alone is not sufficient to change behavior; broader socioeconomic determinants must also be considered.

From a systemic perspective, weaknesses in healthcare infrastructure and pharmacovigilance also contribute to underreporting. Pharmacists, who play a key role in patient education, frequently face time constraints that limit their ability to provide comprehensive counseling [26]. At the same time, poor monitoring systems hinder accurate documentation of misuse, particularly among adolescents, where OTC abuse such as dextromethorphan and antihistamines is increasingly reported but rarely captured in official statistics [28]. Other research further emphasizes that widespread and unregulated OTC use contributes to chronic underreporting, as patients often fail to associate symptoms with drug use [33].

Taken together, socio-cultural perceptions, economic drivers, and systemic weaknesses create a complex web of barriers that limit effective pharmacovigilance in OTC drug use. These findings underscore the importance of context-specific strategies that go beyond individual awareness, integrating cultural, social, and structural dimensions.

Implications and Limitations

The findings of this review highlight several important implications for pharmacovigilance systems and public health policies. First, the underreporting of ADRs linked to OTC drugs is not only due to patient-level knowledge gaps but also

because of unrecognized drug interactions. A retrospective review identified interactions between OTC drugs and antidepressants that went largely unnoticed, underscoring the potential risks of unmonitored self-medication [25]. This evidence suggests the need for stronger educational efforts targeted at patients undergoing chronic treatments.

Underreporting is also exacerbated by technical and systemic barriers. Studies emphasize that notification and reporting systems are often seen as complex and time-consuming, creating additional hurdles for both patients and healthcare providers [29]. Broader analyses also reveal that underreporting stems from multiple causes, including fear of consequences, lack of training, and insufficient awareness of the importance of ADR data [30]. This is consistent with findings that general public knowledge about drug purchasing and safe use especially regarding prescription-only medicines obtained without proper authorization remains limited [31]. A systematic review further confirms that underreporting by patients is widespread, shaped by factors ranging from low awareness to insufficient trust in reporting systems [32].

Pharmacists are essential actors in bridging this gap. Evidence suggests that their role in OTC selection, counseling, and education is vital in preventing misuse and improving ADR reporting [34]. Nevertheless, surveys indicate that although patients express interest in understanding side effects and contraindications, actual awareness and consultation rates remain low [35]. This highlights the need for a stronger pharmacist-patient interaction model supported by institutional and regulatory frameworks.

In addition, technology-driven approaches provide promising complementary solutions. User-friendly electronic reporting systems have been shown to reduce time burdens on patients and improve consistency in ADR reporting [36]. Advanced methods, such as the use of artificial intelligence (AI) and machine learning applied to spontaneous reporting systems, have demonstrated their ability to enhance the detection of risks associated with OTC use [37]. These innovations suggest that pharmacovigilance should evolve beyond reliance on patient initiative, incorporating proactive digital systems to ensure broader safety monitoring.

Despite these insights, this study has several limitations. As a narrative review, the article selection process was not conducted through a fully systematic protocol, increasing the possibility of selection bias. Restricting the analysis to publications between 2020 and 2025 may have excluded earlier but still relevant literature. Furthermore, all data analyzed were secondary sources, preventing direct validation of patient experiences. Finally, demographic variations were not fully considered, limiting the generalizability of the findings. Future studies should adopt empirical methods such as structured interviews, large-scale surveys, and mixed-methods approaches to validate these conclusions and develop context-sensitive interventions.

4. Conclusion

This narrative review demonstrates that patients face multifaceted barriers in reporting ADRs related to OTC medications, including limited knowledge, inaccurate risk perception, lack of awareness about reporting procedures, psychological factors such as stigma and brand trust, as well as practical obstacles like time constraints, unclear reporting channels, and limited interaction with healthcare professionals. Sociocultural and economic realities, particularly in resource-limited settings, further contribute to inappropriate use and chronic underreporting, while weaknesses in surveillance systems hinder effective monitoring, especially among vulnerable groups

such as adolescents. These findings highlight the urgent need for systemic interventions, including proactive patient education, pharmacist-led counseling, simplified reporting mechanisms, and the integration of digital pharmacovigilance tools such as AI-assisted reporting systems, in order to strengthen drug safety monitoring and reduce risks associated with OTC drug use.

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Conflict of Interest:

The authors declare no conflict of interest related to this study.

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