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ANALYZING BARRIERS OF SPONTANEOUS ADVERSE DRUG REACTION TO REPORTING AMONG HEALTHCARE PROFESSIONALS

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ABSTRACT

Adverse drug responses (ADRs), often known as medication-related adverse events, are negative outcomes brought on by drugs. The World Health Organization (WHO) defines adverse drug reactions (ADRs) as "a response to a medication that is noxious and unintended used in man to treat." ADRs may be caused by an unanticipated mistake such an allergic response or an avoidable pharmaceutical error that results in a side effect from the delivery of medicine. ADRs can significantly hinder patients' quality of life and put more strain on the healthcare system. ADRs are one of the leading causes of morbidity and death worldwide, and they will remain a major public health concern due to the growing complexity of medications used to treat a variety of illnesses in an aging population. Adverse drug events sometimes have complicated, multiple causes. Adverse responses fall into three categories: allergic, idiosyncratic, and dose/drug related. Drug-related and dose-related adverse drug responses are mostly foreseeable, though occasionally inevitable, and are linked to the medication's dosage. The patient's susceptibility to the medicine and the combinations of medications utilized have a significant impact. Although it is somewhat prevalent, it usually does not result in serious ADR. An allergic drug response occurs when a patient experiences an inappropriate reaction to a medicine, which is typically preventable with a skin test beforehand or by efficient consultation and communication between patients and primary care institutions. The intensity of an idiosyncratic adverse medication reaction is frequently highly unexpected and is not well understood. The knowledge and attitudes of health professionals are the primary variables linked to underreporting of adverse drug reactions (ADRs), according to a large percentage of research that our group conducted in a systematic review. Here is the study that is conducted by our group that includes all the factors leading to adverse drug reactions to reporting among healthcare professionals

KEYWORDS: PV(Pharmacovigilance), Underrepoting, Adverse Drug Reaction (ADR), Patient Safety, adverse events, Primary care, general practice, home healthcare.

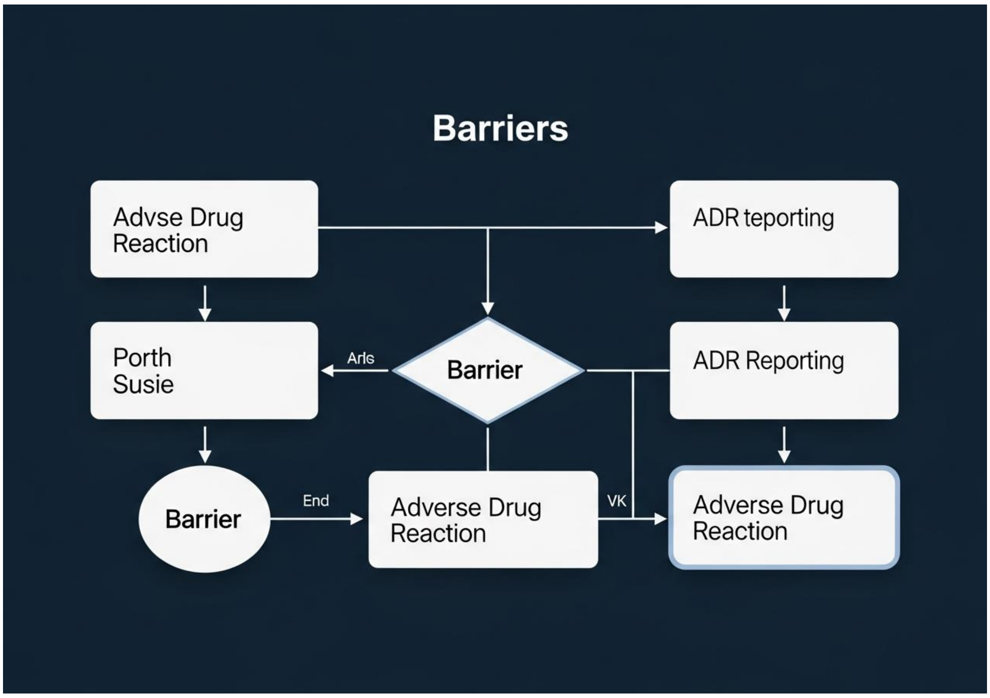
INTRODUCTION

ADRs have grown to be a serious issue for people who take several drugs, including the elderly. Up to 75% of all elderly care residents had medication inconsistencies following their transfer from a hospital to a primary care environment, according to a research. In general practice, prescription mistakes are linked to the majority of adverse drug occurrences. A major retrospective case review research found that the frequency of medication mistakes in general practice was 5% in England. The use of automated prescribing systems has increased the risk of pharmaceutical errors in the healthcare system, which can result in moderate or severe adverse drug reactions. Off-label use of rare drugs by patients and children is another factor contributing to adverse effects. The practice of providing drugs to unapproved indications by agencies like the Food and Drug Administration in the US or the Therapeutic Goods Administration in Australia is known as off-label prescription. Because there is insufficient evidence to justify the use of medications in unapproved conditions, medication errors or dose errors may occur in these situations. In addition to extending hospital stays and having a significant financial impact, adverse drug reactions (ADRs) account for 10% of outpatient visits and 3.5–10% of hospital admissions. They are also the fifth most common cause of mortality for hospitalized patients. One of the greatest ways to produce signals on unforeseen occurrences and uncommon adverse drug reactions is for health professionals to spontaneously report suspected adverse drug reactions (ADRs). This enables for ongoing assessment of the medicine's benefit-risk ratio. There is currently little information and proof about the epidemiology of ADRs. There are no systematic reviews, meta-analyses, or scoping studies that offer a thorough summary of the many kinds of adverse events in primary care, according to a preliminary search of the literature (e.g., The Cochrane Library, JBI Database of Systematic Reviews and Implementation Reports, Ovid MEDLINE). The majority of the studies that were available were modest and sometimes limited to single units. Alternatively, the majority of recent evaluations concentrated on drug management, the frequency of medication mistakes, and particular treatments to lower medication errors. Since approximately 6–10% of all ADRs are recorded, underreporting is a significant drawback of spontaneous notification systems. On the one hand, this substantial underreporting rate makes it impossible to quantify ADRs in order to determine their impact in terms of occurrence and danger; on the other hand, it delays the activation of warning signals, which has consequences for public health. Many more patients may be impacted by these delays in decisions to limit or stop using a medication. The knowledge and attitudes of health professionals are the primary variables linked to underreporting of adverse drug reactions (ADRs), according to a large percentage of research that our group conducted in a systematic review. In order to lower the risk of adverse drug events in primary care, this study aimed to address the types of adverse drug reactions (ADRs), the major medication classes linked to the responses, the causes of ADRs, their prevalence, and the implications of suffering ADRs. Clinicians will be better informed about adverse events and the class of medications that are linked to them as a result. Patient safety may be enhanced by focused educational initiatives that close these gaps. Researchers, medical professionals, and policymakers will find this scoping review helpful in developing treatments to lower adverse drug reactions in primary care today.

DATA EXTRACTION AND METHOD

The research protocol for this systematic review was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (registry number CRD42021227944), and it was carried out in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020, 27-item checklist guideline. Finding studies published between 1990 and 2018 was the goal of the search technique. In this review, a three-step search approach was applied. After doing a preliminary, restricted search of Ovid MEDLINE, the JBI Database of Systematic Reviews and Implementation Reports, and the Cochrane Central Register of Controlled Trials, the article's title, abstract, and index keywords were analyzed. Using all of the detected keywords and index phrases, a second search was conducted across all databases that were included. On March 18, 2026, the databases Ovid MEDLINE, Embase, CINAHL Plus, Cochrane Central Register of Controlled Trials, PsycINFO, and Scopus were searched. Every database used the same search approach, which is displayed in Appendix I. The Agency for Health Care Research and Quality and

Patient Safety Net Bibliography and the National Patient Safety Foundation Bibliography were also examined. Since documenting medication responses was not common before to 1990, studies published between 1990 to October 16, 2024 were included. We looked for more research in the reference lists of all the papers and publications that were found.



Barriers to patient ADR reporting

These are the barriers reporting to ADR:

1. Poor Awareness
2. Confusion as to who reports ADRs, and to whom
3. Difficulties with ADR reporting procedure and forms
4. ADR resolved
5. Lack of feedback of previous ADRs submitted
6. Mailing cost
7. Previous bad experiences

1. Poor Awareness

Poor public knowledge of ADR reporting procedures was mentioned in 14 of the 15 qualitative and quantitative investigations. The existence of a national regulating body was unknown to many individuals. 75% (range 44.1–93.8%) of participants in seven quantitative research were unaware that ADR reporting mechanisms were available. Illiteracy or lack of knowledge about medical facilities provided by hospitals and other medication centers is also a reason for it.

2. Confusion as to who reports ADRs, and to whom

Confusion among patients that who reports ADR and to whom they should report is also a major barrier behind the patient ADR reporting .For example, in America, some participants take it as their duty to report the ADR While patients in other nations identified HCPs as being primarily responsible for reporting ADRs, some participants believed it was their responsibility to do so.

3. Difficulties with ADR reporting procedures and forms

Procedure and reporting form issues were found in four quantitative and qualitative investigations. In Saudi Arabia, 80% of respondents cited challenges, compared to 15.9% in the UK. For instance, participants in the UK study reported that: (i) telephone reporting was restricted to working hours, which was inconvenient and time-consuming; (ii) paper forms were lengthy, tedious, awkwardly constructed, inconsistent with online forms, and only available in English; and (iii) technical issues with online reporting frequently led to information loss.

4. Anticipating ADRs to resolve

According to five qualitative investigations, patients did not see the value in reporting adverse drug reactions (ADRs) and thought they would go away after stopping or finishing their therapy.

5. Lack of feedback on previously submitted ADRs

Patients' complaints about the lack of feedback on filed ADR reports were documented in two studies. In a UK research, for instance, 32% of participants anticipated receiving response from the ADR report, and 1.9% thought that not receiving comprehensive comment would deter them from filing an ADR complaint in the future. The Netherlands, where the health authority offers tailored response on each ADR complaint filed, did not report this issue.

6. Mailing costs

Patients' low socioeconomic position was shown to be a deterrent to reporting adverse drug reactions (ADRs) in two studies carried out in Uganda and Nepal because they could not afford to mail their reports.

10. Prior negative experience

Previous bad experiences were identified as a barrier in one Ugandan research. Patients were afraid that their HCPs would disapprove of them if they reported ADRs.

Motives for patients to report ADRs

1. Preventing similar ADRs in others

According to seven out of ten studies, patients wished to help identify better therapies and save others from experiencing similar issues.

2. Improving Drug Safety

In five trials, patients thought that reporting adverse drug reactions (ADRs) may increase medication safety. For instance, patients in the Netherlands expressly said that they would be prepared to devote time to reporting adverse drug reactions in order to improve medication safety.

3. Considering the seriousness of the ADRs

According to three quantitative and two qualitative investigations, the primary reason why patients reported an adverse drug reaction (ADR) was because they thought it was significant. For instance, in two polls conducted in the UK, the majority of participants (62% and 86%, respectively) stated that only significant adverse drug reactions (ADRs) that necessitated hospital admission or had an impact on day-to-day living should be reported. In a similar vein, participants in Portugal agreed or strongly agreed that reporting ADRs was mostly motivated by severity.

4. Desiring personal feedback

Four qualitative and one quantitative study examined patients' need for individualized input. Participants sought confirmation that the report had been received, to learn more about the ADRs, and to locate others who had similar experiences.

5. Raising awareness of specific ADRs

Patients in three quantitative surveys stated that the only approach to raise knowledge of ADRs was to notify regulators, pharmaceutical companies, healthcare professionals, and the general public.

6. Improving HCP practices

Patients expressed the opinion that HCPs should be informed about ADRs in two quantitative research and one qualitative study. They felt that reporting ADRs would inform HCPs about unknown ADRs, and that this would improve their knowledge and practices.

6. Responding to HCPs not reporting patients' ADRs

According to two research, people were encouraged to report adverse drug reactions (ADRs) on their own when healthcare professionals failed to do so. Patients underlined that their concerns had not been taken seriously by HCPs who were consulted regarding the ADRs. Some patients in the UK were inspired to self-report by this. Because HCPs have limited time and might not be able to offer precise data, some patients were motivated to report because they did not believe that HCPs would correctly record their ADRs.

Limitations and strengths

The inability to obtain three full-text papers to assess their eligibility for inclusion was one of the review's limitations. Although there was no list of authors, the names of these papers suggested that they comprised patient reports of adverse drug reactions. Our systematic review effectively consolidated the many types of data found, even though the authors of the included studies employed a range of metrics to identify variables impacting patient ADR reporting. Our systematic review fulfilled nine out of eleven criteria when its methodological quality was evaluated using the AMSTAR tool. One of the two missing elements was not applicable as a meta-analysis that included the results of relevant studies and did not account for publication bias was not carried out.

CONCLUSION

Twenty-one studies found a number of obstacles and factors that affect patients' reporting of adverse drug reactions. The primary obstacle to patients reporting adverse drug reactions (ADRs) was low patient awareness of the reporting methods that were available, which was in line with research done with healthcare professionals. Patients reported adverse drug reactions (ADRs) primarily out of selflessness to spare others from experiencing the same side effect. Increasing patient acquaintance with the available ADR reporting methods, encouraging patients to report, giving clear instructions on how to use the reporting system, and offering feedback are all ways to actively encourage patient reporting of ADRs. It may be possible to enhance spontaneous patient ADR reporting by implementing techniques that are based on these characteristics.

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