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Physicians' Awareness and Drug Safety Monitoring for Adverse Drug Reactions Assessment in Bangladesh

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Abstract

Adverse drug reactions (ADRs) remain underreported in Bangladesh despite the country's rapidly expanding pharmaceutical sector, which limits the effectiveness of national pharmacovigilance activities. Through the identification and reporting of adverse drug reactions (ADRs), doctors play a crucial role in pharmacovigilance. However, pharmacists and other medical professionals also contribute to drug safety monitoring and the degree of awareness and participation among these professionals varies significantly, especially between urban and rural settings. This study aims to measure the awareness, attitude and practice of ADR reporting among physicians in Bangladesh, explore barriers to underreporting and investigate physicians' preferences toward a mobile system for reporting ADRs. The study also examined the physicians' opinions on fundamental ADR assessment methods, which are used to format digital reporting. A cross-sectional study was conducted across the country, among a total of 200 randomly selected physicians from all eight divisions of Bangladesh (April 2022 to March 2023). knowledge of ADR causality, severity and preventability was assessed by a structured questionnaire (Liverpool Causality Assessment Tool, Hartwig's Severity Assessment Scale and modified Schumock-Thornton preventability scale). Findings were summarized using descriptive statistics. ADR reporting awareness was considerably higher among urban physicians (71%) compared with rural practitioners. Only 28.5% of respondents had received formal training in ADR reporting. The most common barriers included heavy workload (27.58%) and insufficient clinical expertise (24.83%). Nearly half (45.5%) preferred a mobile application due to accessibility and time efficiency. Physicians also identified specific items from the Liverpool, Hartwig and Schumock-Thornton scales that should be incorporated into a user-friendly reporting app. Significant gaps persist in physicians' knowledge and reporting of ADRs in Bangladesh, particularly in rural areas. Strong support for mobile app-based reporting indicates a feasible strategy to enhance pharmacovigilance. Integrating digital tools with targeted training could substantially improve ADR reporting and medication safety nationwide.

Key words: Adverse drug reactions, pharmacovigilance, drug safety monitoring, Bangladesh healthcare system, mobile app application.

Introduction

The World Health Organization (WHO) defines an adverse drug reaction (ADR) as 'any response to a drug that is noxious and unintended, and that occurs at doses used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose (Lee, 2006). Medical and pharmaceutical sciences are being advanced and bringing life-saving treatments to the people of Bangladesh and beyond. Yet, alongside the immense benefits of modern medicine lies a quiet, persistent challenge: Adverse Drug Reactions (ADRs). To identify adverse drug reactions and ensure patient safety, pharmacovigilance is an important parameter.

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pharmacovigilance (PV), which involves identifying, assessing, understanding, and preventing adverse drug effects, depends heavily on healthcare professionals reporting suspected ADRs. Physicians, in particular, are central to this process. However, ADR reporting remains low in many low- and middle-income countries (LMICs) because of limited awareness, lack of PV training, heavy workloads, unclear reporting procedures, and minimal feedback from regulatory authorities. These challenges limit the ability of national systems to identify harmful drug reactions quickly. The ongoing advancement in medical and pharmaceutical sciences has made the availability of medicinal products in the Bangladesh Pharmaceutical market to combat and control various disease states. Irrespective of the benefits associated with the use of medicines, adverse effects associated with them have emerged as a challenge in keeping a check on Adverse Drug Reactions (ADRs). According to the World Health Organization (WHO), ADR is "A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" (Kiguba *et al.*, 2023a). To improve public health, the safe administration of medicine must be monitored through an effective reporting system. This has led to the withdrawal of many drugs in the recent past, i.e., rofecoxib, cisapride and the role of physicians is enormous in this regard (Srisuriyachanchai *et al.*, 2023)

Adverse drug events (ADEs) constitute a major public health problem. They are estimated to account for up to 5% of hospital admissions, 28% of all emergency department visits and 5% of hospital deaths. In the United States, more than 100,000 deaths are attributed annually to serious adverse drug reactions. In the UK, about 6.5% of all admissions to hospitals are due to an ADR and the overall fatality rate was 0.15%. ADR reporting does not currently appear to be considered a part of routine professional practice by healthcare professionals (Parracha *et al.*, 2023). Under-reporting of adverse drug reactions (ADRs) is very common. It has been estimated that only 6–10% of all the ADRs are reported. Surveys indicate that only one-third of Bangladeshi doctors know the official ADR reporting process (García-Abeijon *et al.*, 2023). The low awareness of the official ADR reporting process among Bangladeshi physicians is mainly due to systemic factors. Pharmacovigilance is not consistently emphasized in undergraduate or postgraduate medical training and continuing medical education on ADR reporting is limited, particularly in rural areas. In addition, reliance on paper-based reporting systems, lack of feedback from regulatory authorities, heavy patient workload and staffing shortages discourage physicians from reporting ADRs. Together, these barriers contribute to poor familiarity and low engagement with formal ADR reporting procedures.

Commonly cited barriers include lack of training, limited institutional support, unclear procedures and the belief that ADR reporting is time-consuming or difficult (Amin *et al*., 2016). At the same time, rapid growth in mobile technology offers an important opportunity. Smartphone use has increased sharply across Bangladesh, with over 70% of households owning a smartphone and more than half having regular internet access. This creates a favorable environment for digital health tools, including mobile apps for ADR reporting. To design the mobile app data, three different assessment methods are considered to formulate the standard one. There are multiple scales and tools to establish causality between a drug and a suspected ADR. Both adults and children alike are at risk for ADRs, but children are more prone to risk due to limited clinical trial data on drug safety in children. Investigators at the University of Liverpool and Alder Hey Children's Hospital pursued the question of causality analysis and developed the Liverpool Causality Assessment tool after identifying questions from the Naranjo Scale (Defer *et al.*, 2018). The algorithm classifies the suspected ADRs as definite, probable, possible or unlikely.

The causality assessment is used to establish a probable relationship between medication and ADR. The severity of ADRs can be evaluated through various available standard criteria. Most commonly

used is Hartwig's Severity Assessment scale, which focuses on objective data and clinically relevant information (Saqib *et al.*, 2018). An adverse drug event (ADE) is an adverse outcome that occurs after the use of a drug; in some case may not be linked to the use of the drug. The Schumock and Thornton criteria were developed to assess the preventability of adverse drug reactions (ADRs) (Schumock and Thornton, 1992). It has three sections, namely, definitely preventable, probably preventable and non-preventable. Section A comprises five questions, while Section B has four questions, whereas in Section C, the ADRs were non-preventable (Petrova *et al.*, 2017). Other countries have already shown that mobile apps can make ADR reporting much easier. In places like Uganda and Ghana, the Med Safety App helped doctors report more once they got some basic training (Kiguba *et al*., 2023b). According to a study conducted in the lao PDR, using a mobile app instead of paper forms resulted in faster reporting and happier customers. In addition to increasing the quantity of ADR reports, the quality of those reports also matters. These examples demonstrate that mobile reporting can function effectively, but the app must adapt to the local situation and connect accurately with the national system (Mongkhonmath *et al.*, 2024). This project aims to know the knowledge of physicians about the pharmacovigilance system in Bangladesh, to find out the cause of less adverse drug reporting from physicians, to receive opinions from physicians regarding improvement of the pharmacovigilance system and finally, to observe the efficacy of a mobile application (app) based data collection method in the promotion of adverse drug reporting (Fukushima *et al.*, 2022a). By incorporating physicians' perspectives, this study aims to support the development of an effective national ADR reporting app that can strengthen pharmacovigilance and improve medication safety across Bangladesh.

Methodology

The purpose of this cross-sectional study was to evaluate Bangladeshi doctors' knowledge and behaviors about reporting adverse drug reactions and monitoring drug safety. Understanding the current pharmacovigilance system, identifying reporting obstacles and gathering information for system improvement-particularly through data collection via mobile applications were the main goals of the study.

Study design and context: This research employed a quantitative, cross-sectional design, conducted from April 2022 to March 2023. The study spanned all eight divisions of Bangladesh.

Participants and sampling: A total of 200 physicians from diverse demographic backgrounds were randomly selected from the eight administrative divisions of Bangladesh. Participation was voluntary and informed written consent was obtained from all participants before data collection. Inclusion criteria for participation required voluntary consent and a valid Bangladesh Medical and Dental Council registration number, verifying their academic qualification as accredited by the Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh. The minimum required sample size was calculated using a single population proportion formula:

$$n = \frac{Z^2 \times p \times (1-p)}{E^2}$$

where n = desired sample size, z = standard normal deviate = 1.96 at 95% confidence interval, p = prevalence of ADR reporting (unknown) among medical practitioners living in the divisional cities of Bangladesh = 30%, and e = margin of error = 4%. The study achieved a 89% voluntary participation and response rate.

Data collection instrument: A standardized questionnaire was developed and utilized as the primary data collection instrument. The questionnaire was structured into two main sections:

Section 1 (closed questions): Focused on collecting demographic data, including the participant's sex, age, academic qualifications and professional workplace.

Section 2: Evaluated physicians' knowledge and opinions on ADR causality, severity and preventability. This section integrated three widely

recognized assessment scales: The Liverpool ADR causality assessment tool, Hartwig's Severity Assessment scale and the modified Schumock and Thornton preventability scale

Before the main study, ten experimental surveys were conducted in two different hospitals in Dhaka city to test the validity and clarity of the questionnaire. Based on participant feedback, the questions were refined, and some additional queries were incorporated to ensure comprehensibility.

Data collection procedure: Data collectors went through an intensive training program, comprising three days in the first week, followed by three hours daily for five days, to enhance their interviewing and oral communication skills. From a pool of fifteen, ten data collectors were finally selected and randomly allocated to various hospitals and clinics across the country.

We used a standardized questionnaire to interview the physicians, then went through the questions and responses (Figure 1). The standard questionnaire contained some questions related to ADR assessment (causality, severity and preventability scale). A written formal consent was obtained, and the objective of the study was informed to them by the data collectors.

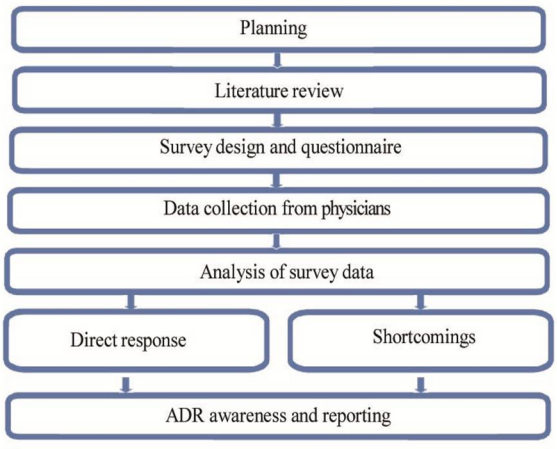

Figure 1. Flowchart of study design.

Before initiating the survey, a written informed consent form, comprising an information sheet and a consent certificate, was obtained from each participant. This informed consent form has two parts:

Part-01: Information Sheet (to share information about the study with the participant)

Part-02: Certificate of Consent (for signatures if the participant chooses to participate).

Participants were thoroughly informed about the study's background, objectives, the voluntary nature of their participation and the confidentiality and anonymity of their responses. The data collectors then administered the self-report questionnaires through direct interviews with the physicians.

Research questions: This study was based on a survey utilizing various adverse drug reaction assessment scales, including the Liverpool ADR causality assessment scale, Hartwig's Severity Assessment scale and the modified Schumock and Thornton preventability scale. A random sampling approach was used to acquire data, with the survey conducted across all eight divisions (Dhaka, Rajshahi, Chattogram, Barishal, Sylhet, Mymensingh, Khulna, and Rangpur) of Bangladesh. Two hundred physicians were selected at random from various locations to participate. The volunteers completed a developed questionnaire designed to obtain information about their awareness of drug safety and its control mechanisms. Only information from participants meeting the study's criteria was included. The research questionnaire consisted of various questions that focused on ADR identification, reporting, and drug safety monitoring. The questions were formulated according to scientifically accepted theories, taking into account the work schedules of physicians in Bangladesh and medical welfare, primarily focusing on user-friendly reporting systems for ADRs.

Data analysis: The collected survey data were analyzed using Microsoft Excel software. Descriptive statistics were employed to summarize the data, utilizing frequencies and percentages to present participants' responses. Logistic regression models were used to predict odds ratios and 95% confidence intervals were applied to quantify the association

between variables. The statistical significance level was established at P <0.05 (two-tailed).

Ethical considerations: All participants were informed about the main aims of the study. The study adhered to strict ethical guidelines to ensure the protection and well-being of all participants. These included: obtaining informed consent from all participants, ensuring their voluntary participation, respecting their privacy, upholding the anonymity and confidentiality of their responses and assessing only relevant components pertinent to the research objectives.

Result and Discussion

Sample data collection location: Data was gathered on average from eight divisions of Bangladesh, for a total of 200 samples (Figure 3). Most of the practitioners were from urban and rural levels to understand the real picture of drug safety monitoring and awareness.

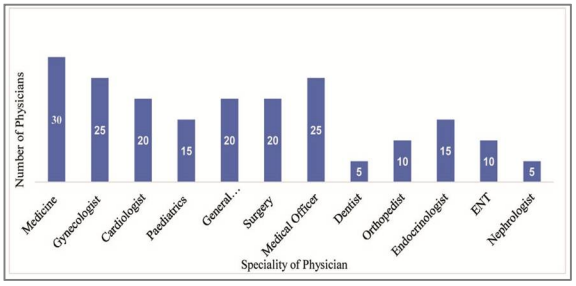

Figure 2. Distribution of the sample in accordance with the divisions.

Information about the participating physicians: Most of the participating doctors were medical specialists (Figure 2). We also found that 2.5% were dentists, and 12.5% were duty doctors, working in various hospitals and clinics, who play a crucial role in patient management.

Physicians' age range: The majority (35%) of the doctors surveyed were in the 51-60 age group, with the smallest (10%) representation from those above 70 years old (Figure 4).

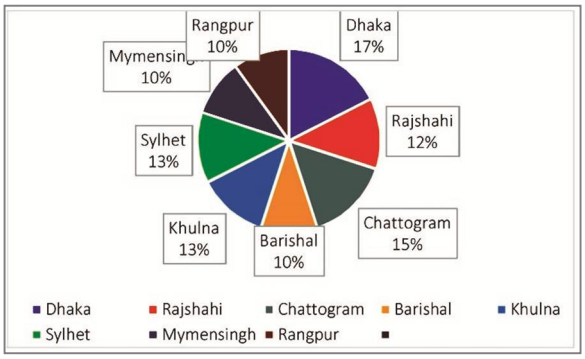

Figure 3. Distribution of samples according to their specialty.

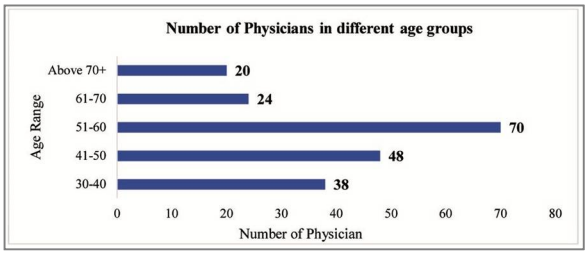

Figure 4. Distribution of the sample according to their age.

Physician's academic qualification: Doctors with the highest medical degrees were mainly found in urban areas, while those with a simple MBBS degree were more common in rural hospitals (Figure 5).

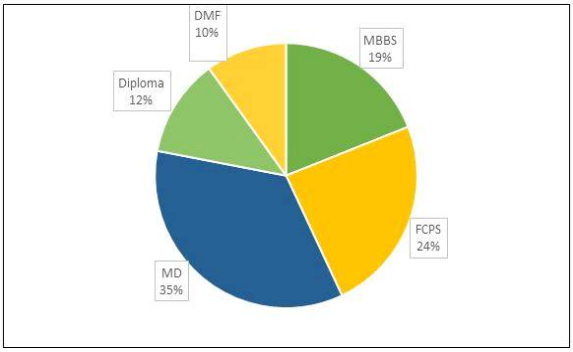

Figure 5. Distribution of samples according to their academic degree.

Physicians' awareness of adverse drug reaction reporting: Monitoring drug safety relies heavily on doctors reporting ADRs. Our survey showed that 71% of urban doctors were aware of ADR reporting formats, with only 17% unaware. A significant finding was that rural practitioners were largely unaware of ADR reporting. While our survey targeted physicians, it is important to note that other clinical

staff also show poor ADR awareness. A study showed that only 6.7% of nurses had ever reported an ADR and 93.3% had never seen the standard ADR form (Mediterranean Journal of Pharmacy and Pharmaceutical Sciences, 2025). Similarly, 78.1% of pharmacists had not seen the ADR reporting form. These data highlight a noticeable knowledge gap: nurses and pharmacists have even less exposure to pharmacovigilance procedures than physicians. Our findings -that only 28.5% of doctors had formal ADR training-likely understate the overall need for education across all cadres. This underscores the potential benefit of training programs and simplified digital tools for the broader healthcare team.

Communication tools for ADR reporting: We observed that only 28.5% of doctors had received training, participated in discussions, or attended clinical meetings about ADR reporting from relevant authorities, and 90% of these were from urban areas. Most doctors were unaware of or didn't have access to such communication from the official departments responsible for ADR reporting in Bangladesh.

Reasons for not reporting ADR events enough: Several key reasons why ADRs are underreported in Bangladesh and the busy working schedule of the physicians has the highest percentage among the 145 respondents (Table 1).

Table 1. List of reasons for under-reporting ADR events (n= 145 respondents).

Key reasons from the interview	Number of physicians	Percentage (%)
Don't know when to report	21	14.48
Think that report does not matter	19	13.10
Insufficient clinical expertise	36	24.83
Busy working schedules	40	27.58
Difficult to pinpoint the suspected drug	23	15.86

Opinions on ADR reporting systems: When asked about the most user-friendly way to report ADRs, physicians responded that the ADR reporting tools should be fast, integrated, mobile-friendly (Figure 6), automatically populated with relevant data, and provide clear feedback within the clinical workflow (Fukushima *et al.*, 2022b).

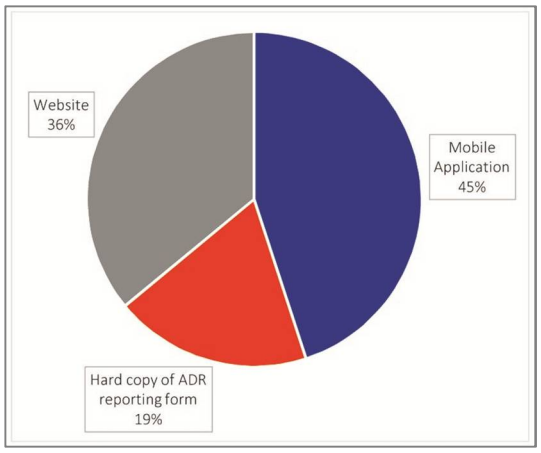

Figure 6. Opinions on ADR reporting systems.

The main reasons behind the choice of a mobile app among doctors are illustrated in figure 7.

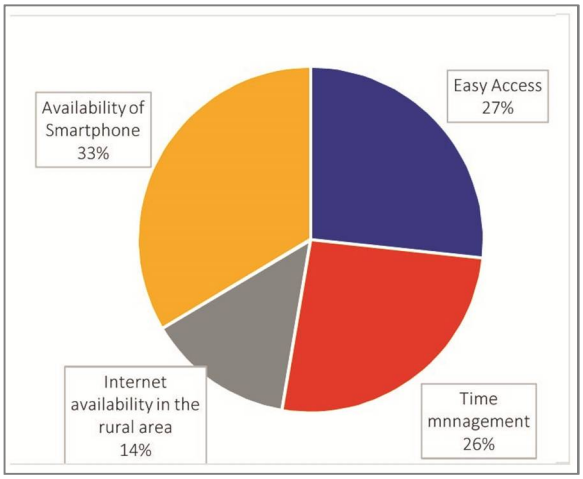

Figure 7. Purpose of mobile app for ADR reporting (n= 91respondents).

Opinions on developing a mobile App: Out of 200 participants, 170 agreed that a user-friendly mobile app would be the most convenient way to report ADRs. When asked about the goals for such an app, they highlighted the following opinions in figure 8.

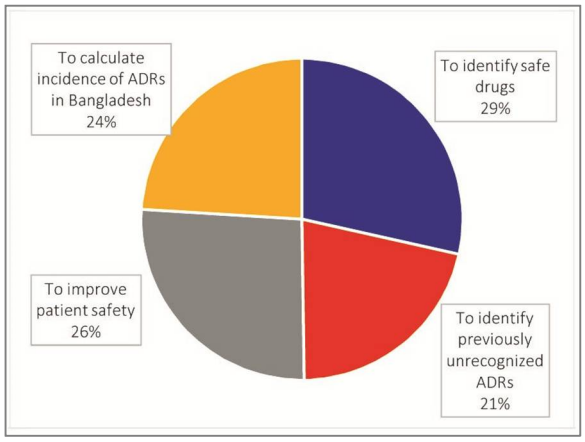

Figure 8. Participants' views on the goals of the mobile app for ADR reporting.

Opinions on the liverpool ADR causality assessment tool: Analyzing the availability of ADRs is a complex process that requires consideration of several points. Identifying ADRs and taking measures to avoid them can help us improve practice and reduce the number of patients who experience these events. Physicians discussed the Liverpool ADR Causality assessment scale. They mostly preferred the following questions from the scale for ease of reporting ADR causality (Table 2 and Table 3).

Table 2. Opinion (recommended) for the ADR Liverpool causality assessment tool.

Recommended question from Liverpool causality assessment scale	Agreed participant's number
Q1	200
Q2	190
Q3	200
Q4	170
Q8	185
Q9	200

Table 3. Opinion (not-recommended) for the ADR Liverpool causality assessment tool

Not-recommended question from Liverpool causality assessment Scale	Disagreed participant's number
Q5	170
Q6	200
Q7	109
Q10	200

Opinion for ADR severity assessment by Hartwig's scale: ADR can cause increased morbidity and mortality, so information needs to be studied about their cause and the severity of impact. From several scientific studies, we found that ADRs are underreported and therefore their importance is under-evaluated. Thus, ADRs should be more thoroughly evaluated for seriousness, causality, expectedness and severity. We discussed Hartwig's scale for measuring ADR severity (Table 4). Physicians recommended specific levels-

Table 4. Opinion (I. Recommended level and II. Not-recommended level) for ADR Severity Assessment by Hartwig's scale.

I. Recommended by participants

However, they did not recommend Level 3 and Level 6, stating these were "insignificant in the Bangladesh scenario" without further detailed explanation

Recommended level from ADR severity assessment by Hartwig's scale	Agreed participant's number
Level 1	200
Level 2	50
Level 4	160
Level 5	190
Level 7	198

II. Not recommended by participants

Not recommended level from ADR severity assessment by Hartwig's Scale	disagreed participant's number
Level 3	170
Level 6	200

Opinion for ADR preventability assessment by modified Schumock and Thornton scale: ADRs are ranked as the seventh recurrent cause of mortality because one out of every seventh inpatient experiences ADRs during their stay at the hospital (Hoggs *et al*, 2008). The Schumock and Thornton criteria were established for assessing the preventability of ADRs. The modified form of this hypothesis was widely used in major studies related to ADR (Table 5). Doctors mostly recommended the following points-

Table 5. Opinion (recommended) for the ADR preventability assessment tool.

Key criteria from the modified Schumock and Thornton preventability scale	Agreed participant's number
Definitely probable	
1	198
2	187
3	196
Probably Preventable	
7	198

Adverse drug reactions (ADRs) require our urgent attention in the case of the Bangladesh healthcare system. This study offers important insights into how adverse drug reactions (ADRs) are reported by doctors in Bangladesh, clearly showing differences in knowledge and practice between urban and rural areas. Our data indicates that a strong majority of urban physicians (71%) are familiar with the proper reporting forms, while practitioners in rural areas are largely uninformed, which reflects unequal access to information, training and institutional pharmacovigilance (PV) infrastructure across Bangladesh. Rural hospitals commonly lack ADR monitoring units, formal reporting desks and structured communication from the DGDA, which contributes to limited exposure to ADR protocols. Most doctors in the study were unaware of or didn't have access to communication, training or clinical meetings about ADR reporting from the official departments responsible for PV in Bangladesh. Only 28.5% of physicians had ever received training and 90% of those were from urban areas.

The study identified several major barriers to ADR reporting, including heavy workloads (27.58%), insufficient clinical expertise (24.83%), uncertainty about when to report (14.48%) and difficulty identifying the suspected drug (15.86%). Heavy clinical workload is a persistent obstacle in Bangladesh. Here, physician-patient ratios remain below WHO recommendations and the physician can't provide sufficient time to each patient. As they don't have sufficient time, they can't prepare documents or study or report on ADR. Insufficient clinical expertise and diagnostic uncertainty also reduce reporting. Many physicians hesitate to document an ADR unless they are fully confident of causality. These barriers can be addressed through simplified reporting processes, decision-support tools (e.g., embedded causality scales), rapid reporting pathways and institutional support systems that eliminate fear of punitive consequences.

The main reasons doctors gave for not reporting these reactions enough were things like being too busy, not having enough medical knowledge about it, or thinking their reports wouldn't make a difference. Physicians rarely receive acknowledgment or follow-up after submitting an ADR report. Research shows that healthcare professionals are more likely to report ADRs when they receive feedback, periodic bulletins, or updates on how their reports contributed to drug safety actions (García-Abeijon *et al*., 2023).

Almost 45.5% really liked the idea of using a mobile app to report these reactions, as they think it is the easiest way. They strongly agreed that an app could also help find safe drugs, catch new adverse reactions (we don't know about yet) and ensure patient safety. This means using digital tools like apps is a good and popular way to go. Doctors also gave specific ideas about what parts of different tools-like the Liverpool, Hartwig's, and Modified Schumock and Thornton scales-would be good to include. Their selections emphasize the need for a reporting tool that is structured yet simple enough to use during routine clinical practice. This gives us a

practical plan for building a useful mobile app for reporting adverse reactions in Bangladesh. So, what these results really show is that we urgently need to teach more doctors, especially in rural areas, about reporting bad drug reactions. But it also shows that doctors really want easy-to-use reporting systems, like apps, that use new technology. This can help fill the gaps in how we check drug safety and, in the end, make people in Bangladesh healthier.

Overall, the study highlights a persistent gap between awareness, attitude and practice among Bangladeshi physicians. This underscores the systemic challenges in Bangladesh's PV system, including limited training, lack of institutional support and inadequate communication from regulatory bodies. Strengthening national pharmacovigilance requires a multifaceted approach: integrating PV education into medical curricula, establishing dedicated ADR monitoring units in hospitals, simplifying the reporting pathway through mobile technology and improving regulatory communication. If they are implemented effectively, these strategies could enhance ADR reporting, improve drug safety surveillance and ultimately contribute to safer healthcare delivery across the country.

Conclusion

This research shows clear evidence that adverse drug reaction (ADR) reporting in Bangladesh is facing significant challenges, particularly due to the striking gap in awareness and practice between urban and rural medical professionals. The continued low national reporting rate, which remains far below the global average, is directly connected to practical barriers such as heavy workload and a belief that reports are ineffective. However, our study also revealed a crucial and positive path forward: the overwhelming majority of physicians view a mobile application as the most user-friendly and practical solution for reporting. Public knowledge regarding drug safety in developing countries is still unsatisfactory (International Drug Monitoring, 1972). Therefore, the necessity of pharmacovigilance has been well recognized and pharmacovigilance systems have evolved globally as a result of collaborative efforts by a handful of organizations, including health care professionals, patients, regulatory agencies, health authorities, academia, the pharmaceutical industry, the world health organization, the international conference on harmonization and others (Wysowski & Swartz, 2005). Safety information reported by physicians leads to an improved understanding of the experiences of the ADR. Moreover, as the general physicians located in countrywide should know how to report an ADR to authorities, the reporting process should be user-friendly, like through a web-based or mobile application and guide the medical practitioners through the procedure. It should be stated that ADR reporting could also assist in the reduction of medication errors. The knowledge of physicians about the pharmacovigilance system in Bangladesh is limited, and their active participation is also limited. The ICT sector has taken Bangladesh to new heights. Mobile devices have enhanced the provision of health care both for individuals and providers. Therefore, we need to ensure increased involvement of healthcare.

Thus, pharmacovigilance must immediately tackle two key areas. Firstly, we need mandatory, targeted training to fix the knowledge gap, especially for doctors in rural areas. Secondly and just as vital, is building a streamlined digital reporting system (a mobile tool) that uses the doctors' specific suggestions about causality and severity scales to be effective in Bangladesh. Successfully using this modern technology will be crucial for strengthening drug safety, getting more doctors involved and ultimately improving patient care and public health nationwide.

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