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Implementing Best Practices for Nurses in Detecting and Reporting Adverse Drug Reactions in a Tertiary Hospital in Tabriz, Iran: A Mixed-Method Study

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ABSTRACT

Background and Aims: According to the World Health Organization (WHO), an Adverse Drug Reaction (ADR) is defined as "a response to a drug 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." The aim of this research was to evaluate the current practice and implement the best practices for detecting and reporting ADR in a tertiary hospital in Tabriz, Iran.

Methods: We used a mixed-methods sequential explanatory design in the current study. The research was conceptually informed by the Joanna Briggs Institute model of Evidence-Based Healthcare (JBI EBHC). A three-phase implementation process, outlined by this model, was used in this study. The first and third phases comprised the quantitaive phase of the study, in which we evaluated the current practice and conducted a final evaluation to measure changes in compliance with the best practice. The qualitative phase, the second phase of the JBI EBHC model, was conducted to identify barriers and develop implementation strategies. There were seven evidence-based audit criteria for evaluating the practice, with a sample size of 23 nurses for the quantitative phase and 10 participants for the qualitative phase.

Results: The quantitative findings revealed an improvement in compliance rates for all criteria following the follow-up audit. From the qualitative analysis, four themes of barriers were identified: time and workload, lack of a proper reporting system for ADR, lack of belief and readiness for change among nurses, and lack of awareness about the importance of documenting ADR.

Conclusion: The results of this implementation study demonstrated enhanced ADR reporting. It can be inferred that implementing educational strategies, such as holding conferences, informal meetings, workshops, and educational pamphlets, can facilitate the implementation of evidence into practice.

Implications for Nurses: Findings will help nurses across sectors of primary, secondary, and tertiary care use the implemented strategies to improve the quality of care and reduce ADR.

1 | Introduction

An adverse drug reaction (ADR) is one of the leading causes of numerous worldwide deaths. According to the definition of the World Health Organization (WHO), ADR is "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" [1]. ADRs are mainly classified into two groups type A and type B even though other types of ADRs are possible. Predictable reactions with high morbidity and low mortality are classified as type A and not predictable and novel reactions with low morbidity and high mortality are called type B [2].

Reporting ADR is critical due to being a life-threatening condition. For well-established drugs, only serious adverse reactions should be reported; however, for new drugs, all ADRs including minor ones must be reported [3]. Pharmacovigilance refers to ADR reporting, defined by the WHO as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems" [1]. Pharmacovigilance systems have been shown to be effective in assessing, monitoring and preventing ADRs, allowing alerts to be generated to identify new adverse reaction [4, 5].

All healthcare professionals must be aware of monitoring and reporting of ADRs, nevertheless, nurses should additionally play a proactive role in reporting adverse events. Nurses are key healthcare professionals in any health system and due to their close contact with patients to observe a patient's response regarding the drug therapy, have the privilege of detecting and reporting ADRs [6]. The majority of healthcare professionals have insufficient awareness and lack of knowledge and training about ADRs reporting. Several factors including inadequate information available from the patient, unawareness of the existence of the ADRs reporting systems, thinking of unimportance of reporting ADR, lack of motivation/feedback, and lack of time for reporting ADR were found to discourage nurses and other healthcare professionals from reporting ADRs [5, 7]. Regarding the critical role of nurses in ADR detection and reporting, sufficient attention should be paid to in-service training and education for nurses to ensure that this competence can be addressed [7].

Implementation Science is an emerging field of research that mainly focuses on planning, influencing and evaluating the adoption of evidence-based practices. Adopting evidence-based practices can improve the quality and effectiveness of the provided services in addition to reducing errors and mistakes [8]. The definition of implementation science based on the Journal of *Implementation Science* is "...the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practice into routine practice and, hence, to improve the quality and effectiveness of health services" [9]. There are evidence-based practice models for guiding change in healthcare organizations, one of them is the knowledge translation model using Evidence Summaries, a rigorous systematic review process of multiple studies to formulate a statement of evidence [10, 11].

Considering the critical issues regarding ADR reporting of nurses and lack of implementation studies in this field, the current study aimed to (1) determine current compliance of best practice recommendations for detection and reporting of ADR using an Evidence Summary [12] in a tertiary hospital in Tabriz, Iran; (2) identify barriers and implement strategies to improve areas of noncompliance; and (3) evaluate changes in compliance with the evidence-based practice recommendations using the same Evidence Summary following the implementation of strategies to address identified barriers.

2 | Research Methodology

2.1 | Research Design

This research was based on mixed-methods sequential explanatory design [13]. We decided on performing a mixed-method design to evaluate the current practice and identify barriers and implement strategies related to detection and reporting of ADRs using the advantage of both quantitative and qualitative research.

2.2 | Study Frameworks

The quantitative part of the research was conceptually informed by the Joanna Briggs Institute model of Evidence-Based Healthcare (JBI EBHC); in particular the conceptualization of evidence implementation as inclusive of context analysis, implementation and evaluation of outcomes based on evidence-based quality indicators [14]. Based on this model, within the three-phase implementation process, we used audit and feedback in a pre and posttest design to measure baseline compliance and a final evaluation to measure changes in compliance to evaluate and describe our implementation effects. The qualitative phase of the research was conducted to identify barriers and develop implementation strategies responsive to gaps in compliance.

The project used *JBI Practical Application of Clinical Evidence System (PACES), Getting Research into Practice (GRiP)* audit and feedback tool. The three phases of implementation process in the current study include:

1. Establishing a team for the project and undertaking a baseline audit based on the criteria informed by the Evidence Summary (quantitative).
2. Reflecting on the results of the baseline audit, identifying barriers based on the framework by Geerligs' work [15] and designing and implementing strategies to address noncompliance found in the baseline audit, informed by the GRiP framework (qualitative).
3. Conducting a follow-up audit to assess the outcomes of the interventions implemented to improve practice and to identify future practice issues to be addressed in subsequent audits based on the criteria informed by the same Evidence Summary (quantitative).

The quantitative part of the research (phases 1 and 3) was the main research, conducted through a questionnaire from 23 nurses at the baseline audit (phase 1) and 23 nurses at the

follow-up audit (phase 3). The qualitative phase of the research (phase 2) examined one health executive, seven nurses' and two patients' perceptions and viewpoints of barriers to the non-compliance of the Evidence Summary as well as the strategies for implementing the best practice.

2.3 | Setting

This mixed-method implementation project was undertaken in an internal medicine ward of a tertiary hospital in Tabriz, Iran. The reason for selecting this setting was the amount of adverse drug reactions that occurred and were reported in this ward. Also, the context was ready for change and all 23 nurses of the ward (out of 281 nurses in the hospital) agreed to participate in such an evidence implementation project. Furthermore, the recent local surveys in the internal medicine ward have shown that compliance with the standards regarding ADR reporting was poor and this implementation project was developed to implement all ADR reporting standards in the ward. As it is common for implementation studies, small sample size is used to better apply the changes.

2.4 | Data Collection–Quantitative Part of the Study

A quantitative questionnaire, which is called audit criteria, was developed from an Evidence Summary published by Magtoto L [12] and consisted of socio-demographic details and seven yes/no questions, including the following items:

1. A full medical history, including drug allergies and previous adverse drug reactions, was obtained at admission for each patient and was documented in the medical record.
2. Concerning adverse drug reactions, the following information was documented: drug names, signs, symptoms, severity, time to onset of the reaction and the date when the reaction occurred.
3. The patient's drug allergy status was checked before prescribing, dispensing or administering any other drugs.
4. Multifaceted strategies were used to promote and increase reporting of adverse drug reactions.
5. Healthcare professionals received training on the reporting requirements for adverse drug reactions.
6. The reporting system was easily accessible. Electronic reporting tools and reporting forms were readily available.
7. Adverse drug reactions were reported accurately in a timely manner.

2.5 | Participants and Recruitment

Twenty-three nurses were involved in the quantitative part of research (phases 1 and 3).

In the qualitative part of the research, we performed purposive sampling. One health executive, seven nurses, and two patients agreed to participate in two focus group discussions (FGDs). Nurses were the same in three phases. Each FGD lasted 45–65 min. Patients participated in the FGDs if they had experienced an adverse drug reaction from a nurse in this hospital. Also, they were involved if they had information to disseminate.

2.6 | Research Process

The quantitative part of the research consisted of phases 1 and 3. Phase 2 of the study was conducted using qualitative research.

Phase 1: Stakeholder engagement and baseline audit

The audit team included a lecturer who presented the results of each phase to the whole stakeholders and audit team, one physician and two nurses who were the coordinators in the ward, a doctorate holder in health policy who designed the project and managed the audit team in all phases, a quality assurance specialist at the hospital for implementing the strategies in phase 2 and a group of researchers for collecting and analyzing the data. The baseline audit was carried out in August 2022 with the aim of determining current ADR reporting practice in the internal medicine ward based on the seven audit criteria. The number of yes/no answers for each question (criterion) among all the 23 nurses who answered was summed up and their percentages were calculated. The project team summarized areas of excellent (over 75%), moderate (50%–75%), and low (less than 50%) performance, based on a previously published study [16].

Phase 2: Qualitative FGDs to identify barriers and design and implement strategies (GRiP)

Development of the FGDs' guides was based on the audit results from phase 1. Baseline audit results were analyzed to identify gaps between the current practice and the best practice recommendations (Evidence Summary). The FGD guide consisted of open-ended questions designed to explore the participant's perspectives and involvement with the audit process and barriers and facilitators to implementation of strategies for ADR reporting. We used the JBI GRiP framework to recognize barriers in practice and suggest changing strategies for improvement. Also, the required resources for the implementation of strategies were discussed in FGDs. FGDs were conducted by a female PhD researcher and were digitally recorded and transcribed verbatim. Field notes were taken during and following the FGDs, captured researcher insights. The process of qualitative data collection and analysis occurred iteratively.

Phase 3: Follow-up audit post-implementation of change strategy

After the implementation of strategies from FGDs, a follow-up audit was carried out in January 2023 using the same approaches as the baseline audit to evaluate changes in nurses' compliance with the same evidence-based audit criteria. The follow-up audit included all 23 nurses, a similar number involved in the baseline audit. The results of the follow-up audit and all details about the process were disseminated back to the stakeholders through four to five sessions, held 15 days apart.

Table 1 indicates the phases of the research. The changes in compliance were measured by descriptive statistics embedded in JBI-PACES in the form of percentage changes from the baseline.

2.7 | Data Analysis

In the quantitative phase, data on changes in compliance with the best practice were measured using descriptive statistics embedded in the JBI-PACES in the form of percentage changes from baseline.

For the qualitative phase of the study, transcripts and researcher notes were assigned unique identifiers and imported into MAXQDA (version 10) to support the organization and coding of the data. Deductive content analysis was used to analyze data. Codes elicited from FGDs were categorized into barriers and strategies to best practice implementation, based on the framework captured from Geerligs' work [15], in which staff-reported barriers and facilitators to implementation processes are categorized into three main domains of system, staff, and intervention. Each domain is associated with clear sub-domains.

3 | Ethical Considerations

This project was approved by the ethics committee of Tabriz University of Medical Sciences (approval code: IR.TBZME-D.REC.1401.299). We obtained signed informed consent from the participants. All participants were free to leave the research at any time. Participants' quotes were fully anonymized by removing their information.

4 | Results

Phase 1: Baseline audit (quantitative phase)

The graphical presentation of the data was assisted by JBI PACES (version 220) (Joanna Briggs Institute, Adelaide, Australia), as can be seen in Figure 1. It shows the baseline audit results for the seven audit criteria that measured detection and reporting of ADRs among nurses in a tertiary hospital. The compliance rates for Criterion 1 (obtaining full medical history at admission) and Criterion 2 (documentation of the following information for adverse drug reactions) were 70% and 39%, respectively. When it comes to Criterion 3 (initial checking of patient's drug allergy status) and Criterion 4 (using multifaceted strategies to promote ADR reporting), the compliance rates were 70% and 48%, respectively. Finally, the compliance rates for Criterion 5 (training of healthcare professionals), Criterion 6 (accessibility of reporting system) and Criterion 7 (accuracy in ADR reporting) were 61%, 70% and 87%, respectively.

Phase 2: Identifying barriers and designing and implementing strategies (GRiP) (qualitative phase)

Four themes of barriers to compliance with the best practice were identified and strategies to overcome these barriers (as summarized in Table 2) were formulated and then implemented.

TABLE 1 | Phases of the mixed-methods research.

Phase	Aim	Tools	Analysis	Outcomes and findings
Phase 1 (quantitative)	Evaluate the current practice by nurses regarding detecting and reporting ADRs	A seven-item questionnaire (audit criteria) with yes/no answers	Descriptive statistics	Frequencies of "yes" answers and percentages of each criterion
Phase 2 (qualitative)	Identifying barriers to noncompliance areas and identify and implement strategies to overcome these barriers	Two FGDs with topic guide consisted of open-ended questions	Deductive content analysis	Main themes of barriers and strategies
Phase 3 (quantitative)	Evaluate changes in nurses' compliance with best practice after implementing strategies	The same seven-item questionnaire (audit criteria) with yes/no answers used in phase 1	Descriptive statistics	Frequencies of 'yes' answers and percentages of each criterion

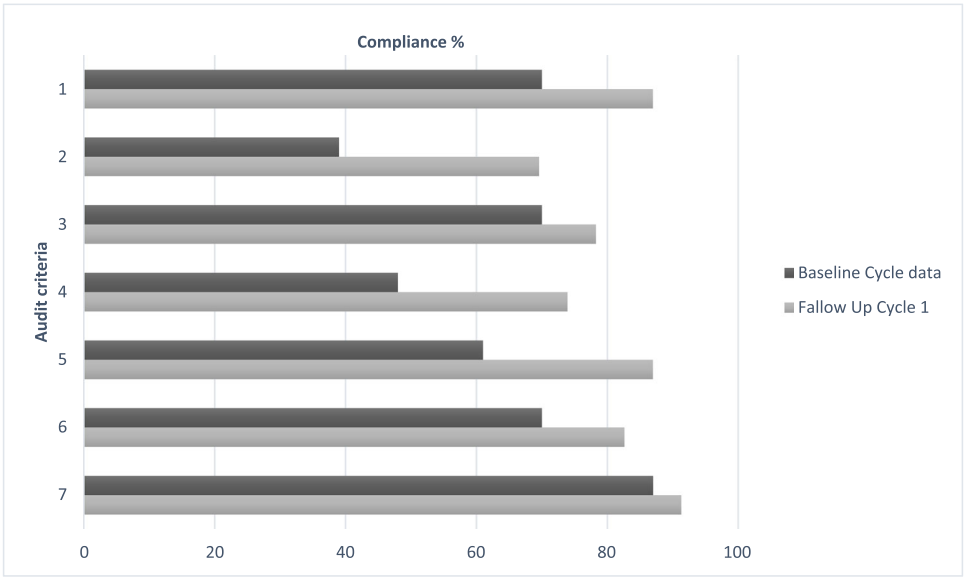

FIGURE 1 | Compliance with the best practice of adverse drug reaction in follow-up audit compared to baseline audit. A full medical history, including drug allergies and previous adverse drug reactions, is obtained at admission and documented in the medical record. (23 of 23 samples taken). For adverse drug reactions, the following information is documented: drug name; signs, symptoms, severity, and time to onset of the reaction; and the date when the reaction occurred. (23 of 23 samples taken). A patient's drug allergy status is checked with them before prescribing, dispensing, or administering any drug. (23 of 23 samples taken). Multifaceted strategies are used to promote and increase reporting of adverse drug reactions. (23 of 23 samples taken). Healthcare professionals have received training on the reporting requirements for adverse drug reactions. (23 of 23 samples taken). The reporting system is easily accessible e.g. via electronic reporting tools, availability of reporting forms. (23 of 23 samples taken). Adverse drug reactions are reported accurately in a timely manner. (23 of 23 samples taken).

Theme 1: Time and workload

The first barrier was a system-related barrier, which is based on the Geerligs' framework [15] directly related to environmental context. Almost all participants identified time and workload as key challenges to implementing ADRs. Since this implementation project was conducted during the COVID-19 pandemic in Iran, nurses were highly busy, and consequently, they had no time for ADR reporting at the hospital. One of the participants added in this regard,

> *"Manpower is low, we don't have time, and we have a lot of work. We have transfered all of these to top managers of the hospital several times whenever we get a chance. But nothing has gotten better, it is getting worse. Too many patients. This is really the main obstacle" (P5).*

Strategies to overcome this barrier included hiring additional staff, transfer of work between shift-working staff, development of a reassessment policy and procedure by the nursing office, continuous assessment and control by head nurses and the modification of procedures. Based on the GRiP framework, reassessment tools, more staff and reassessment policies and procedures were required to implement the recognized strategies in the ward. The outcome was timely ADR documentation by nurses.

Theme 2: Lack of a proper reporting system for ADR

The second system-level barrier belongs to lack of ADR reporting facilities and strategies in the studied wards. e.g., an electronic ADR reporting system was not available at the hospital. One of the participants declared,

> *"The first problem is that we do not know how to report ADR. For any reason. The next and more important problem is that we don't know where and how to report this error. We don't even know if there is a system within the hospital?" (P2)*

For this barrier, we attempted to develop new strategies for ADR reporting. Guidelines, meetings and new instructions were required for this reason. The outcome was clarifying the methods and procedures for ADR reporting.

Theme 3: Lack of belief and readiness for change among nurses

While system-related barriers focused on the overall structure of the organization, staff-related barriers mostly focused on the individual, and beliefs of those staff directly involved with carrying out the intervention. In this study, most of the nurses were not always responsive to new ways of reporting ADRs. In their belief, adopting to the changes required were difficult for them. As one of the participants mentioned regarding this issue,

> *"We are used to doing everything quickly. Because we always ran out of time, there were many patients, we don't have enough beds and we have to do the patients' works as soon as possible. We have a specific routine that we stick to and it is difficult for us to change it. Maybe there are error reporting systems and they give us training classes many times, but we can't include them in our current performance." (P7)*

TABLE 2 | Themes and getting research into practice matrix.

Domain	Theme (Barrier)	Strategy	Resources	Outcomes
System-level barriers	Time and workload	• Hiring additional staff, • Transfer of work between shift-working staff, • Development of Reassessment Policy & Procedure by the • nursing office • continuous assessment and control by head nurses • Modification of procedures	• Extra staff • Reassessment Tools • reassessment policy & procedure	On-time ADR documenting By nurses
	Lack of a proper reporting system for ADR	• Developing new strategies for ADR reporting	• Guidelines • Meetings • New instructions	Clarifying methods and procedures for ADR reporting
Staff-related barriers	Lack of belief and readiness for change among nurses	• Meetings about change leadership • Shared decision-making • Giving a sense of ownership	• Meetings	Optimal implementation of ADR reporting strategies
	Lack of awareness about the importance of ADR documenting	• Educational sessions	• Educational videos and pamphlet • Meeting room • Slides • Printed materials	Doing of ADR documenting routinely

To combat this barrier, we held three meetings for nurses, only talked about change leadership and resistance to change. In these meetings, we tried to have the full participation of all nurses so that they could determine the causes of resistance and solutions for that. Shared decision-making and giving a sense of ownership in the implementation process were other strategies we implemented for this barrier. The outcome was optimal implementation of ADR reporting strategies.

Theme 4: Lack of awareness about the importance of ADR documenting

This theme was classified under the category of 'understanding and awareness' of the adopted framework. This category included staff knowledge of the aims and process, misinterpretation of the intentions, and confusion or disregard of intervention processes. Most of the nurses in the current study were not aware of the importance of ADR, electronic reporting systems and the impact of ADR reporting on patient's outcomes. One of the participants told us,

> *"Actually, we did not know why we should report a medication error. They didn't tell us somewhere, in the university or the workplace." (P6)*

This barrier was addressed via educational meeting for authorities. We held weekly training rounds in the ward with stakeholders. The resources included face-to-face training, educational videos and pamphlets, meeting rooms, slides and printed materials. The outcome was routine ADR documentation by nurses.

Phase 3: Follow-up audit (quantitative phase)

Figure 1 presents the follow-up audit results, in comparison with the baseline results. After the implementation of strategies, the compliance rate for all criteria improved. More specifically, criteria 1 and 5 reached to 87%, criterion 2 achieved 70%, criterion 3 achieved 78%, criterion 4 achieved 74%, criterion 6 achieved 83% and criterion 7 reached 91% in the follow-up cycle.

5 | Discussion

In the current best practice implementation project, we aimed to evaluate the current practice and identify barriers and implement strategies related to improving detection and reporting of ADR at a tertiary hospital in Tabriz, Iran. Results of the current study showed that following three phases of baseline audit, identifying barriers and implementing strategies, and follow-up audit cycle, compliance with the best practice in detection and reporting of ADRs was improved in all the criteria.

The baseline audit in this study showed that documentation of ADRs was weak. Compliance of the two criteria related to ADR documentation was 69% and 39% at the baseline, which were improved to 86% and 69% at the follow-up audit. The reason for the noncompliance with the best practice might be nurses' lack of justification for doing ADRs, lack of time and knowledge about the importance of documenting patients' medical history and drug allergies. Results of a study showed that 41% of patients had a discrepancy between their self-report of allergy and the electronic medical record. Also, only 18% of patients had complete documentation about their drug reactions [17]. Results of another study indicated that serious ADRs were poorly documented in medical records at the baseline, which were significantly improved after interventions were implemented by ward pharmacists. The intervention they used was an intensive education program [18]. Giardina and colleagues found in their study that lack of clinical monitors during weekends was the main reason for not recording ADRs [19]. Under-reporting of ADR has been found to be mainly due to a lack of knowledge about how to use ADR reporting systems, conflicts of interest or simply professionals may have no time for reporting. Providing economic incentives to physicians and increasing educational activities have shown to improve ADR reporting among healthcare professionals [20]. Educational programs have been shown to improve the ADR reporting rate from 28.1% to 39.6% in another similar study [21].

The baseline audit in the current study indicated that checking patient's drug allergy status was compliant with the best practices (69.57%). This was then improved to 78.26% in the follow-up audit. In Taiwan, health smart cards were used to check and record a history of drug allergies [22]. In their systematic review, Legat and his colleagues also found that decision support systems were effective in recording patient's drug allergies [23]. In the current study, educational pamphlets as well as face-to-face meetings about the importance of checking and recording patient's drug allergies were helpful. Likewise, Blumenthal and his colleagues in their study found that educational programs and antibiotic prescribing guidelines were effective interventions in improving drug allergy check [24].

At the baseline audit of the current study, training of healthcare professionals about the ADR reporting was 60% compliant with the best practice. After implementing the strategies, however, it was improved to 86.96%. The reason for being less compliant at the baseline can be ascribed to the fact that professionals might have received no robust education or have simply forgotten their past relevant learning. As an effective intervention, we gave educational pamphlets to all nurses in the study. Results of a similar study indicated that an educational intervention has significantly improved knowledge and awareness of pharmacovigilance and ADR reporting among medical students [25]. Educational interventions have found to improve ADR reporting in many countries [26–28].

Availability of ADR reporting forms and tools was found to be 69.57% compliant with the best practice at the baseline audit, which was improved to 82.61% after implementing the strategies. At times, healthcare professionals are not aware of the existing ADR reporting forms. A systematic review showed that nonavailability of ADR reporting forms as well as other reasons were the main cause of poor ADR reporting in Ethiopia. Also, knowledge concerning the availability of ADR reporting forms was 40.68% among health care professionals [29]. Similarly in another study, 14.7% of health care professionals were not aware of the ADR reporting forms in the wards and 77.6% of health care professionals declared that there were not any ADR reporting forms at their hospitals [30]. Countries have different online ADR reporting forms. For example, while the yellow

card forms are used in the UK, India uses ADR reporting red forms and VigiFlow, and the USA employs online reporting system [31].

Timely and accurate reporting of ADR was in good compliance with the best practice in the baseline and follow-up audits (86.96% and 91.30%). The use of electronic ADR reporting systems in Uganda has shown to promote timely reporting of ADR, which enhances confidence in decisions about the safety of medicines [32]. The results of a study in China indicated that an intelligent ADR reporting system not only improved the quality of reporting and ensured the accuracy of ADR reporting but also made the process less time-consuming [33].

6 | Conclusion

A best practice implementation project was conducted to evaluate ADR reporting at a tertiary hospital in Tabriz, Iran. The results of the project indicated an improvement in ADR reporting after implementing strategies, which mostly included educational interventions. It can be concluded that training nurses through traditional face-to-face methods, sharing educational pamphlets, conducting workshops and conferences can facilitate the implementation of evidence into practice. Further follow-up audits are required to monitor changes and to implement other interventions as needed. The results of this project provided positive direction for implementing evidence-based approaches to this issue in other organizations.

Author Contributions

Neda Kabiri: conceptualization, writing–original draft. **Sakineh Hajebrahimi:** project administration, writing–review and editing. **Parvin Rahmani:** investigation, resources. **Fatemeh Molaei Tavani:** investigation, resources. **Seied Hadi Saghaleini:** writing–review and editing. **Saiedeh Razi Soofiyani:** formal analysis, writing–review and editing. **Amin Talebpour:** formal analysis, investigation, methodology, writing–original draft.

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Disclosure

The lead author Neda Kabiri had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis. Amin Talebpour, the corresponding author, affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Ethics Statement

This project was approved by the ethics committee of Tabriz University of Medical Sciences (approval code: IR.TBZMED.REC.1401.299).

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Data is available from the corresponding author, when requested.

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