

Preparation, Validation and Readability Assessment of An Educational Leaflet for Nurses on Adverse Drug Reaction Reporting

M V REKHA¹, CHRISTEENA MARIYAM THOMAS², ANSU SARAH KORUTHU³, S ASWATHY⁴ *, ATHIRA B RAJ⁵, DRISYA S NAIR⁶, ALIYA SHAHUL HAMEED⁷

¹⁻³Department of Pharmacy Practice, Mar Dioscorus College of Pharmacy, Thiruvananthapuram, Kerala.

⁴⁻⁷Final year B. Pharmacy Student of Mar Dioscorus College of Pharmacy, Thiruvananthapuram, Kerala.

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ABSTRACT

Adverse Drug Reactions are a major global health concern and a leading cause of mortality worldwide but its reporting rates remain low due to lack of awareness and lack of proper educational materials. Recognising nurses are the frontline observers of healthcare system, this study focused on the preparation, validation and readability assessment of an educational leaflet for nurses. Tertiary care hospital in Thiruvananthapuram was the study site and project involved preparation of an educational leaflet and an user-testing questionnaire validated by academic and clinical pharmacists and leaflet also satisfied BALD criteria. Readability and effectiveness was assessed by comparing pre and post test scores. Results demonstrated a statistically significant improvement in scores after the intervention, proving that the developed educational leaflet is a reliable and effective educational material on ADR reporting and ultimately strengthening pharmacovigilance and ensuring higher standards of patient safety.

Keywords: Adverse Drug Reaction; Readability; Educational leaflet; Questionnaire; Nurses; Pharmacovigilance

I. INTRODUCTION

WHO defines ADRs as "any harmful and unintended effect from a drug that occurs at an approved (recommended) dose". The Rawlins and Thompson ADR classification system sorts adverse drug responses by three characteristics - dose-dependence and predictability, time, and dose; and is comprised of the following:

- Type A ADR (Augmented) occurs at higher doses and, based on currently known pharmacology, one can predict the reaction. Type A is the most common form of ADR, and

the majority of Type A reactions will occur at the expected dose. For example, hypoglycaemia caused by insulin or bleeding associated with anti-coagulants.

- Type B ADR (Bizarre) occurs without regard to dose and is unpredictable. Type B reactions are associated with immune-mediated mechanism or idiosyncratic reactions. For example: reaction to penicillin causing anaphylaxis, and sulphonamide causing Stevens-Johnson syndrome.
- Type C ADR (Chronic) occurs due to continuous (long duration) administration of a drug. Type C reactions are related to the dose and to the length of time a subject has been on the drug, for example: long-term use of corticosteroids can cause adrenal suppression.
- Type D ADR (Delayed) occurs several months to years after a patient has received a drug. Many of these delayed ADR can be associated with the teratogenic effects of certain drugs and/or drugs that have carcinogenic effects. Examples: thalidomide and certain antineoplastic agents.
- Type E ADR (End of Use) occurs when the drug is withdrawn from a patient and may be manifested by rebound or withdrawal symptoms. Examples: Rebound hypertension due to sudden discontinuation of clonidine.
- Type F ADR (Failure of therapy) is when a patient does not get a therapeutic effect from a drug and is not expected to experience an ADR due to the drug treating a condition. A drug that has very little or no therapeutic effect could result in an ADR.

AIM

- To develop an educational leaflet for nurses on reporting of adverse drug reactions.

OBJECTIVES

Primary Objective

- To prepare an educational leaflet on reporting of adverse drug reactions (What, When, Where, Who and How to report).

Secondary Objectives

- To carry out the validation of the prepared leaflet by a panel of expert members.
- To determine the readability of the prepared leaflet.
- To prepare and validate questionnaire to assess the ADR reporting knowledge.
- To evaluate the impact of leaflet on nurses knowledge through pre and post testing.
- To strengthen Pharmacovigilance
- To ensure patient safety

II. MATERIALS AND METHODS

Materials Required:

- Data collection form
- Informed consent form
- Educational leaflet (English)
- Validated questionnaire

Data Sources:

- All the relevant and necessary data were collected by using pre -post questionnaire from the nurses.

Methodology:

- **Study Design:**
- Quasi experimental pre-test and post-test study without control group

>Study site:

Credence Hospital, Ulloor, Thiruvananthapuram

>Duration of Study:

Three months (December 2025-February 2026)

>Subjects:

Nurses currently employed at the study site

>Sample size:

The study sample consisted of 52 nurses who met the inclusion criteria and consented to participate in the study. All participants were included in the user-testing readability assessment of the educational leaflet on adverse drug reaction (ADR) reporting.

Safety considerations

○ Ethical considerations:

The study purpose was explained to all the participants, and they were enrolled only after obtaining informed consent

signed. The privacy and confidentiality of all participants will be protected. Data collection will be initiated only after obtaining permission from the concerned authority.

○ Inclusion Criteria:

Subjects of both gender, who at least have a Diploma in nursing registered under the State Nursing Council, and presently working as staff nurse at the study site in the district of Thiruvananthapuram, Kerala.

○ Exclusion Criteria:

Staff nurses who are not willing to take part in the study.

Operational Modality:

- **Development, validation and readability of the educational leaflet and user testing Questionnaire:** The User testing Questionnaire and Educational leaflet on Adverse reaction reporting for Nurses was prepared by consulting various primary, secondary and tertiary resources of information. After preparation, it was validated by an expert committee of members, consisting of academic pharmacists and clinical pharmacists. The changes suggested by the team were taken into consideration for improving the quality of the prepared leaflet. After validation total of 5 multiple choice questions prepared on the content of leaflet were finished for user testing readability assessment.
- **Data collection:** A well-designed data collection form was prepared as per the need of the study. Data including gender, age, domiciliary status, work experience (in years), and educational qualification were collected. The previously validated User testing Questionnaire and educational leaflet was administered to the subjects to get their responses recorded in it.
- **Statistical Analysis:** The study population was described using statistical analysis, which also looked at participants' knowledge of reporting adverse drug reactions (ADRs) both before and after the intervention. Based on the scoring criteria outlined in the methodology, the overall knowledge levels were further divided into good, average, and poor categories, which were then displayed as proportions. The

difference between the pre-test and post-test knowledge scores was evaluated using a paired t-test, and a p-value of less than 0.05 was used to determine statistical significance. According to the goals of the study, the results were displayed as tables and figures with the proper interpretation.

III. RESULT AND DISCUSSION

Development and Validation of Educational Leaflet

A leaflet was developed for nurses on reporting of adverse drug reactions. Information for the leaflet was gathered from a range of primary, secondary, and tertiary sources. Textbooks were consulted as tertiary references. UpToDate software served as the secondary source. Relevant research articles were utilized as primary references. The leaflet included information on the basic aspects of adverse drug reactions, including their definition, causes, types, risk groups, and other essential details. It also

explained the importance of reporting and the procedures to be followed while reporting an ADR.

The expert committee that validated the content of the leaflet, based on criteria checklist, consisted of two clinical pharmacists and three academic pharmacists. The changes suggested by the team were taken into consideration for improving the quality of the prepared leaflet. After validation, a total of 5 multiple choice questions prepared based on the content of the leaflet were finalized for user-testing readability assessment

BALD criteria

Layout and design of the Educational leaflets were assessed using BALD criteria. According to these criteria, a PIL with score greater than 20 is considered to be present with good layout as well as design characteristics. The points obtained as per the BALD criteria characteristics of the developed educational leaflet are given in Table 1.

Table 1: BALD criteria score

DESIGN CHARACTERISTICS	POINTS OBTAINED
Lines 50-89mm long	1
Separation between the lines	2
Lines unjustified	1
Serif typeface	2
Type size	3
First line indented	0
Titles lower case	1
Italics	2
Positive advice	2
Headings standout	2
Numbers all Arabic	1
Boxed text	1
Pictures	3
Number of colors	2
White space	2
Paper quality	3

As per the BALD criteria, the score obtained was 28.

Readability Assessment of Educational Leaflet

Socio-demographic details of the subjects enrolled for user-testing readability assessment

A total of 52 subjects were enrolled for the user-test in readability assessment of the prepared leaflet. The study population consisted entirely of female

participants.

Distribution of subjects based on their age

Out of the total subjects enrolled, a higher proportion belonged to the age group of less than or equal to 30 years, 28 (53.8%). The details are summarized in Table 1 and Figure 1.

Table1:Distribution of subjects based on their age

Age group (In years)	Frequency (n)	Percentage (%)
<=30years	28	53.8
>30years	24	46.2
Total	52	100

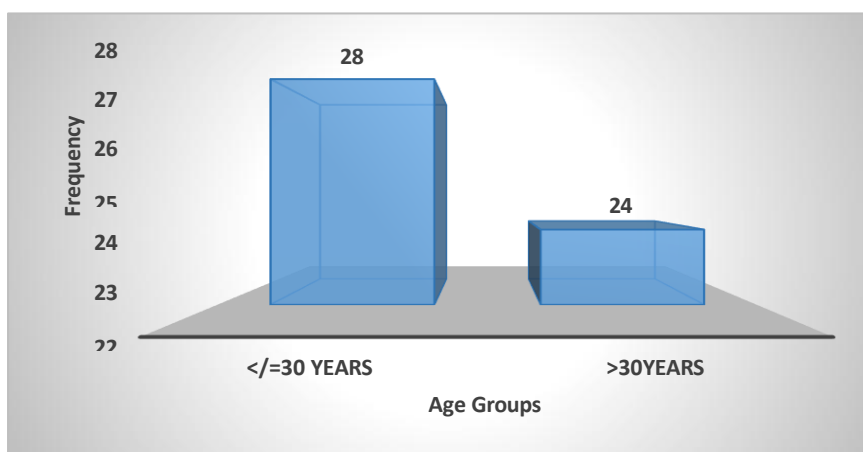


Figure1:Distributionofsubjectsbasedontheirage

Distribution of subjects based on their districts of residence

Out of the total subjects enrolled, the majority were residents of Thiruvananthapuram district, 43 (82.7%). The details are summarized in Table 2 and Figure 2.

Table2: Distribution of subjects based on their districts of residence

District of Residence	Frequency (n)	Percentage (%)
Thiruvananthapuram	43	82.7
Kollam	4	7.7
Pathanamthitta	2	3.8
Alappuzha	1	1.9
Ernakulam	2	3.8
Total	52	100

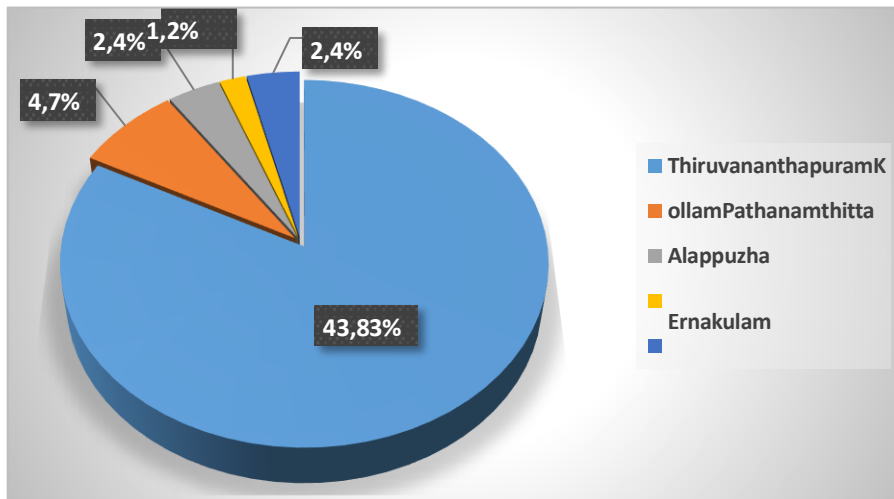


Figure2: Distribution of subjects based on their districts of residence

Distribution of subjects based on their educational qualification

Among all the subjects enrolled, 34 (65.4%) had a Bachelor's degree in Nursing as their highest educational qualification, followed by 15 (28.8%) had General Nursing and Midwifery Diploma. The details are summarised in Table 3 and Figure 3.

Table3: Distribution of subjects based on their educational qualification

Educational Qualification	Frequency (n)	Percentage (%)
Bachelor's in Nursing	34	65.4
Masters in Nursing	3	5.8
General Nursing and Midwifery Diploma	15	28.8
Total	52	100

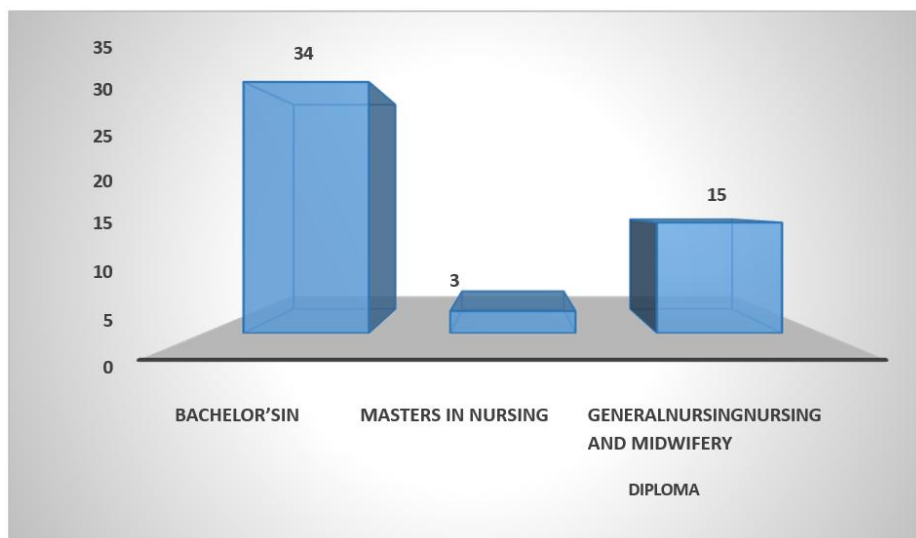


Figure3: Distribution of subjects based on their educational qualification

Distribution of subjects based on their work experience in years

Among all the subjects enrolled, a higher number had total work experience of less than or equal to 10 years, 35 (67.3%). The details are summarised in Table 4 and Figure 4.

Table4: Distribution of subjects based on their work experience in years

Work Experience(in years)	Frequency (n)	Percentage (%)
<=10years	35	67.3
>10years	17	32.7
Total	52	100

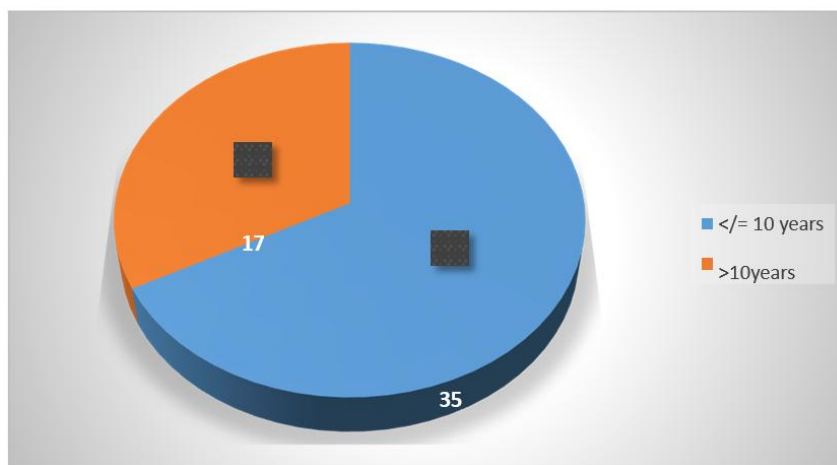


Figure4: Distribution of subjects based on their work experience in years

User-testing Readability Scores

The mean pre-test score for the leaflet was found to be 65.0 ± 23.38 . After reading the leaflet, the score significantly improved to 94.23 ± 13.33 , indicating an improvement in the nurses' level of knowledge regarding ADR

reporting. The details are summarised in Table 5.

Table 5: Mean pre test and post test scores

LeafletVersion	Pre test (Mean±SD)	Post test (Mean±SD)	t-value	p-value
English	65.0 ± 23.38	94.23 ± 13.33	-8.814	<0.001*

‘*’:Statistical significance

IV. CONCLUSION

The aim of this study is to develop an information leaflet about reporting adverse drug reactions (ADRs) to nurses, as well as establish the readability and effectiveness of this leaflet. This leaflet was developed using primary, secondary, and tertiary resources and validated by a panel of experts (clinical/educational pharmacists) to ensure content accuracy/quality. 52 nurses participated in user-testing assessments related to the leaflet's readability. The socio-demographics of study participants showed that most (69%) were 30 years of age or younger; held a Bachelor of Science in Nursing; and had worked in nursing for less than 10 years. All statistical analyses indicated a statistically significant increase in knowledge after reading the leaflet. The average pre-test score (65.0 ± 23.38) increased significantly to the average post-test score (94.23 ± 13.33), indicating that the leaflet effectively provided better knowledge of ADRs to study participants. There was also a statistically significant difference (p < 0.001) in pre-test vs. post-test scores. Therefore, this leaflet can be recognized as an effective educational resource in providing increased awareness of ADRs and improving the knowledge of nursing professionals about ADRs, which could ultimately enhance patient safety/pharmacovigilance.

REFERENCE

- [1]. Bankar M, Tewari S, Kumar S. Nursing Professionals' Awareness of Adverse Drug Reactions and Pharmacovigilance in an Institute of National Importance in India: A Cross-Sectional Study. *Cureus*. 2023;15(11)
- [2]. Kabiri N, Hajebrahimi S, Rahmani P, et al. Implementing Best Practices for Nurses in Detecting and Reporting Adverse Drug Reactions in a Tertiary Hospital in Tabriz, Iran: A Mixed-Method Study. *Health Sci Rep*. 2024;7(12)
- [3]. Ganesan S, Sandhiya S, Reddy KC, et al. The Impact of the Educational Intervention on Knowledge, Attitude, and Practice of Pharmacovigilance toward Adverse Drug Reactions Reporting among Health-care Professionals in a Tertiary Care Hospital in South India. *J Nat Sci Biol Med*. 2017;8(2):203-209.
- [4]. Hanafi S, Torkamandi H, Hayatshahi A, Gholami K, Shahmirzadi NA, Javadi MR. An educational intervention to improve nurses' knowledge, attitude, and practice toward reporting of adverse drug reactions. *Iran J Nurs Midwifery Res*. 2014;19(1):101–6.
- [5]. Abou Elmaati HMB, Mohamed EMH, Mansour HE, Tantaewy NMM, Ibrahim AA. Effect of educational intervention on nurses' knowledge, attitude and practice towards pharmacovigilance and adverse drug reaction reporting. *World J Nurs Sci*. 2016;2(3):239-49.
- [6]. Baheti TC, Malani P, Garg T, Mehani R. Assessment of knowledge, attitude and practices of adverse drug reaction reporting among nursing staff of tertiary care teaching hospital in Western rural India. *Int J Pharm Sci Res*. 2023;15(12):6022-6028.
- [7]. Mouton JP, Mehta U, Parrish AG, Wilson DPK, Stewart A, Njuguna CW, et al. Mortality from adverse drug reactions in adult medical inpatients at four hospitals in South Africa: a cross-sectional survey. *Br J Clin Pharmacol*. 2015 Oct;80(4):818-26.
- [8]. Tandon VR, Khajuria V, Mahajan A, Gillani Z, Mahajan V, Chandail V. Fatal adverse drug reactions: Experience of adverse drug reactions in a tertiary care teaching hospital of North India – A case series. *Indian J Crit Care Med*. 2014;18(5):315-318.
- [9]. Subbaiah MV, Reddy VH, Maneesha Y, Manasa P, Sreevani A, Sarala B, Reddy KN. Retrospective analysis of adverse drug reactions at South Indian tertiary care teaching hospital. *J Drug Deliv Ther*. 2022;12(2):78-82.