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"A study to assess the effectiveness of nurse led education program on knowledge regarding adverse drug reaction among general population in a selected village of Rahata Taluka."

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Abstract

Background of study: Medicine are widely used to treat, prevent, and manage a broad range of health condition while therapeutic interventions are intended to promote health, they may also produce unwanted or harmful effect known as adverse Adverse drug reactions (ADRs) are unexpected and unplanned reactions to drugs, even though normal doses are being used. Adverse drug reactions (ADRs) are one of the leading causes of morbidity and mortality. It has been estimated that around 2.9-5.6% of all hospital admissions are due to ADRs and as many as 35% of hospitalized patients experience an ADR during their hospitalization. Fatal ADRs rank among the most common causes of death in the United States. The economic burden of ADRs is also considerable; for example in the United States, annual total cost of $47.4 billion for 8.7 million drug related admissions were reported. ADR spontaneous reporting systems may detect previously unrecognized adverse reactions and identify risk factors that predispose to drug toxicity and investigate causality. Spontaneous reporting of ADRs has remained the cornerstone of pharmacovigilance and is important in maintaining patient safety. However, reporting of serious ADRs rarely exceeds 10%. The initiative of an international reporting system for ADRs came in the wake of the thalidomide tragedy in the early 1960s. Voluntary ADR reporting schemes have operated since the early 1960s in many western countries, first one started in the United Kingdom in 1964. According to the World Health Organization standards, countries with the best reporting rates generate over 200 reports per 1,000,000 inhabitants per year. Therefore, in Iran with a population over 60 million, it is expected to receive at least 12000 reports per year. Unfortunately, only 2330 reports were sent to the IPC in 2006. The reporting of ADRs in hospitals is very important because severe ADRs are most likely to be seen in hospitals, ADRs can be detected early and spontaneous reports can be more accurate.

Material and Methods: A pre-experimental one-group pre-test and post-test research design was used to assess the effectiveness of a nurse-led education programme on knowledge regarding adverse drug reactions (ADRs) among the general population in a selected village of Rahata Taluka. The study sample comprised 60 participants from the general population of the selected village. A non-probability convenience sampling technique was employed for sample selection. Knowledge regarding adverse drug reactions was assessed before and after the implementation of the nurse-led education programme using a structured questionnaire. The collected data were analyzed using descriptive and inferential statistics, including mean, mean difference, paired *t*-test, and chi-square test.

Result: The demographic finding suggests that majority of general population, 23 (38.33%), belonged to the

19–38 years age group, majority gender 35 (58.33%) were female and 25 (41.66%) were male. In terms of educational qualification, the largest proportion of the general population, 22 (36.66%), had completed primary education, whereas only 3 (5%) respondents were graduates or had attained higher educational qualifications. Regarding occupation, the majority of respondents, 18 (30%), were housewives. Analysis of monthly family income showed that 24 (40%) respondents had a monthly family income of less than ₹10,000, whereas only 6 (10%) reported a monthly family income above ₹30,000. With respect to the frequency of medicine use, the majority of respondents, 49 (81.66%), reported that they frequently used medicines, while 11 (18.33%) stated that they did not use medicines frequently. Concerning experience of side effects from medicines, a substantial proportion of respondents, 42 (70%), reported having experienced side effects from medications at some point, whereas 18 (30%) had never experienced any side effect.In the pre-test level of knowledge of majority of general population 26 (43.33%) were having inadequate knowledge, 29 (48.33%) had moderately adequate knowledge, and only 5 (8.33%) had adequate knowledge. The mean pre-test score was 8.46. whereas in the post-test level of knowledge majority of general population with inadequate knowledge decreased to 8 (13.33%), while those with moderately adequate knowledge increased to 33 (55%). The number of general population with adequate knowledge increased substantially to 19 (31.66%). The mean post-test score was 13.7. The mean difference was found of pre-test score was 4.47 and post- test score was 4.64 with the standard deviation of mean difference was found out to be 5.24. The calculated 't' value was found to be 5.60 with 'p' value 0.001* which is significant concluding that the nurse led education program was found to be effective in improving level of knowledge regarding adverse drug reaction among the general population in a selected village of Rahata Taluka. There was no any significant association between post-test knowledge regarding adverse drug reactions and the selected demographic variables among the general population in a selected village of Rahata Taluka. However, a significant association was found with the participants experience of side effects from medicines.

Conclusion: The study findings have shown that the nurse led-education programme was effective to enhance level of knowledge regarding adverse drug reaction among the general population in a selected village of Rahata Taluka.

Key Words: Adverse Drug Reactions (ADRs), Nurse-Led Education Programme, Knowledge, General Population.

Chapter I
Introduction

Medicines are widely used to treat, prevent, and manage a broad range of health conditions. Although these therapeutic interventions are intended to improve health, they may also cause unwanted or harmful effects known as adverse drug reactions (ADRs). ADRs are unexpected and unintended responses to medications that occur even when drugs are administered at normal therapeutic doses. During clinical trials conducted for new drug applications, all adverse events are documented and reported regardless of their severity. After a drug is marketed, continued reporting of adverse events remains essential, and the FDA requires serious or unexpected adverse events to be reported within 15 days of their occurrence. However, limited attention has been given to the incidence of ADRs among children of all age groups. This may be due to the relatively small number of clinical trials conducted in pediatric populations because of ethical concerns, legal responsibilities, high costs, and regulatory challenges associated with drug approval. As a result, healthcare providers often rely on estimated dosing regimens, which may increase the risk of ADRs in children. [1]

Adverse drug reactions (ADRs) are harmful and unintended effects resulting from the use of medications and represent a significant cause of morbidity and mortality worldwide. Studies have estimated that approximately 2.9% to 5.6% of all hospital admissions are attributable to ADRs, while up to 35% of hospitalized patients experience at least one ADR during their hospital stay. In the United States, fatal ADRs are among the leading causes of death. In addition to their clinical impact, ADRs impose a substantial economic burden on healthcare systems. For instance, an estimated annual cost of $47.4 billion has been associated with 8.7 million drug-related hospital admissions in the United States. Spontaneous ADR reporting systems serve as a fundamental

component of post-marketing drug safety surveillance. These systems help identify previously unrecognized adverse reactions, detect risk factors associated with drug toxicity, and assess causal relationships between drugs and adverse events. Spontaneous reporting remains the cornerstone of pharmacovigilance and plays a crucial role in ensuring patient safety. Despite its importance, the reporting rate of serious ADRs is often low, rarely exceeding 10%. Consequently, under-reporting of ADRs continues to be a major challenge in pharmacovigilance programs. Nurses play a crucial role in the identification and reporting of adverse drug reactions (ADRs) and represent a valuable source of spontaneous ADR reports within hospital settings. Their knowledge, attitudes, and perceptions regarding ADR reporting can significantly influence the effectiveness of pharmacovigilance programs. Therefore, understanding the challenges faced by nurses in reporting ADRs and identifying potential solutions is essential for improving reporting practices. This survey was conducted to assess the knowledge, attitude, and practice (KAP) of nurses working in a teaching hospital in Tehran regarding Iran's national ADR reporting system. The study aimed to identify factors contributing to the under-reporting of ADRs and to determine strategies that could be implemented to enhance ADR reporting rates and strengthen patient safety. [2]

According to the World Health Organization (WHO), an adverse drug reaction (ADR) is defined as "a response to a drug that is noxious and unintended and occurs at doses normally used in humans for the prevention, diagnosis, or treatment of disease, or for the modification of physiological functions." ADRs have emerged as a significant and growing public health concern due to factors such as increasing multimorbidity, widespread polypharmacy, and the continuous introduction of new medications into the market. They are recognized as a major contributor to patient morbidity and mortality and pose substantial challenges to healthcare systems worldwide. [3]

Background of Study: Adverse drug reactions (ADRs) represent a significant global public health concern and contribute substantially to medication-related morbidity and mortality. Many ADRs result from drug effects that are not adequately recognized or monitored. Evidence from various healthcare settings indicates that ADRs account for a considerable proportion of hospital admissions, with reported rates ranging from 2.6% to 50%. Importantly, alarge number of these reactions are considered preventable, and studies suggest that as many as 80% could potentially be avoided through improved monitoring, early detection, appropriate prescribing practices, and effective management strategies. [4]

Need of Study: Different strategies have been evaluated to increase ADR notification, such as the implementation of educational interventions for health professional's purpose is to raise awareness about drug safety issues to improve ADR reporting to obtain statistical assessments by detecting signs and issuing health alerts. Therefore, the aim of this systematic review with meta-analyses was to synthesize the evidence of EI efficacy in health professionals to increase ADR reporting, attitudes, and knowledge of pharmacovigilance.[5]

Statement of Problem

"A study to assess the effectiveness of nurse led education program on knowledge regarding adverse drug reaction among general population in a selected village of Rahata Taluka."

Objective of Study:

1) To assess the existing knowledge of nurse led education program regarding adverse drug reaction among general population in selected village of Rahata Taluka.
2) To evaluate effectiveness of nurse led education program on knowledge regarding adverse drug reaction among general population in a selected village of Rahata Taluka.
3) To find out association between pre-test and post-test knowledge with selected demographic variable regarding adverse drug reaction among general population in a selected village of Rahata Taluka.

Hypothesis

H_1: There will be a significant difference between pre-test and post-test knowledge scores regarding adverse drug reactions among the general population after the nurse-led education program.

H_2: There will be a significant association between post-test knowledge scores and selected demographic

variables such as age, gender, education, occupation, and source of information.
Research methodology is a contextual framework for research, a coherent and logical scheme based on views, belief and values that guide the choices the researchers make.

Chapter II
Methodology

Research Approach: A quantitative research approach was adopted for the present study to assess the effectiveness of a nurse-led education program on knowledge regarding adverse drug reactions among the general population.
Research Design: The research design selected for the present study was a pre-experimental one-group pre-test and post-test design.
Dependent Variable: Knowledge of the general population regarding adverse drug reactions (ADRs).
Independent Variable: Nurse-led education program on adverse drug reactions (ADRs).
Extraneous variable: In current study extraneous variable used are age, gender, educational qualification, occupation, monthly family income, previous information regarding ADR.
Demographic Variables: Age, gender, educational status, occupation, monthly family income, marital status, type of family, previous knowledge regarding adverse drug reactions, source of information, and history of medication use.

Setting of the Study: The study was conducted in a selected village of Rahata Taluka, situated in the Ahilyanagar district of Maharashtra.
Population: "Population is any group of individuals that have one or more characteristics, common areas of interest to the researcher."
Target Population: The study population for the present study consisted of individuals residing in the selected village of Rahata Taluka who were aged 18 years and above, willing to participate, and available during the period of data collection.
Sample and Sample Size: Total of 60 participants were selected for the study.
Sampling technique: A non-probability convenience sampling technique was used to select the participants from the general population residing in the selected village of Rahata Taluka.
Criteria For Sample Selection
Inclusion Criteria

- General population who are:
- residents of the selected villages of Rahata Taluka
- 18 years and above age.
- willing to participate in the study.
- available during the period of data collection.

Exclusion Criteria

- General population who are:
- health professionals (e.g., doctors, nurses, pharmacists) or students of medical/nursing fields.
- physically or mentally unable to participate in the education session or complete the questionnaire.

Tools and techniques:
Section – I: Socio-Demographic Data
It consisted of demographic variables such as age, gender, educational status, occupation, marital status, previous knowledge regarding adverse drug reactions, source of information, and related background characteristics.
Section – II: Structured questionnaire – knowledge questionnaire on adverse drug reactions
Section II: A structured questionnaire consisting of knowledge-based multiple-choice questions was used as the main tool for data collection The questionnaire was designed to obtain information regarding the participants' knowledge, awareness, and perceptions related to ADRs among the general population. This tool

was used to assess knowledge regarding adverse drug reactions among the general population in a selected village of Rahata Taluka.

Plan for Data Analysis In the present study, the investigator planned to analyze the data using both descriptive and inferential statistics. The collected data were organized and tabulated using descriptive statistical measures such as frequency, percentage, mean, and standard deviation. Inferential statistical methods, including the chi-square test and paired t-test, were used to determine the association between knowledge scores and selected demographic variables, as well as to assess the effectiveness of the nurse-led education program. The analyzed data were presented in the form of tables and figures for clear interpretation and presentation of findings.

Chapter III
Result
Section -I Distribution of Socio-Demographic Variables of General Population.
Frequency and percentage wise distribution of socio-demographic characteristics

Sr.no.	Demographic variable		Frequency	Percentage %
1.	Age	>18 years	12	20
		19 years to 38 years	23	38.33
		39 years to 48 years	16	26.66
		Above 48 years	9	15
2.	gender	Male	35	58.33
		Female	25	41.66
		Transgender	0	0
3.	Educational qualification	Illiterate	13	21.66
		Primary education	22	36.66
		Secondary education	14	23.33
		Higher Secondary education	8	13.33
		Graduation and above	3	5
4.	Occupation	Housewife	18	30
		Daily wage worker	14	23.33
		Service	7	11.66
		Business	3	5
		Farmer	17	28.33
		Other	1	1.66
5.	Monthly family income in rupees	<10000	24	40
		10001 – 20000	20	33.33
		20001 – 30000	10	16.66
		>30000	6	10
6.	Do you take medicine frequently	Yes	49	81.66
		No	11	18.3
7.	Have you ever experienced side effect from medicine	Yes	42	70
		No	18	30

Section –II: Assessment of Pretest level and post-test level of knowledge regarding adverse drug reaction among the general population.

Sr. no.	Test	Mean (X)	Standard Deviation	Mean Difference
1.	Pre- test	8.46	4.47	5.24
2.	Post- test	13.7	4.64	

Frequency and percentage wise distribution of Pretest level and post-test level of knowledge regarding adverse drug reaction among the general population.

Sr. No.	LEVEL OF KNOWLEDGE	Pre- test		Post – test	
		Frequency	%	Frequency	%
1	Inadequate knowledge (1 TO 7)	26	43.33	8	13.33
2	Moderately adequate knowledge (8 TO 15)	29	48.33	33	55
3	Adequate knowledge (16 TO 23)	5	8.33	19	31.66

SECTION –III Effectiveness of nurse led education programme on knowledge regarding adverse drug reaction among general population.

Effectiveness of nurse led education programme on knowledge regarding adverse drug reaction among general population by paired 't' test.

Sr. No.	Test	Mean	Mean difference	SD	't'- test	P-Value	Level of significance
1.	Pre-test	8.47	5.24	4.47	5.60	0.001	Significant
2.	Post-test	13.7		4.6			

SECTION IV: Association between the post-test level of knowledge regarding adverse drug reaction among the general population with their selected demographic variables.

Association between the post-test level of knowledge regarding adverse drug reaction among the general population with their selected demographic variables.

predict outcome of association of post-test level of knowledge regarding adverse drug reaction among general population with their selected demographic variables. Chi square analysis was used to find out the association. The results conclude that there was no any significant association of post-test knowledge regarding adverse drug reaction among general population with selected demographic variables except have you ever experience side effect from medicine.

Chapter IV
Discussion

This chapter presents the major findings of the study and discusses them in relation to the findings of previous studies and relevant literature. The present study was conducted to evaluate the effectiveness of a nurse-led education programme on knowledge regarding adverse drug reactions (ADRs) among the general population. A pre-experimental one-group pre-test and post-test research design was adopted for the study. The samples were selected using a non-probability convenience sampling technique. A total of 60 participants from the general population residing in the selected village of Rahata Taluka were included in the study. The participants were assessed for their demographic characteristics and baseline knowledge regarding adverse drug reactions through a pre-test. Following the implementation of the nurse-led education programme, a post-test was conducted to evaluate the effectiveness of the intervention. The findings obtained from the pre-test and post-test assessments were analyzed to determine the impact of the nurse-led education programme on improving knowledge regarding adverse drug reactions among the general population of the selected village

in Rahata Taluka.

Summary:

The present study was conducted to evaluate the effectiveness of a nurse-led education programme on knowledge regarding adverse drug reactions among the general population in a selected village of Rahata Taluka. A pre-experimental one-group pre-test and post-test research design was adopted for the study. The samples were selected using a non-probability convenience sampling technique. A total of 60 participants from the general population residing in the selected village of Rahata Taluka were included in the study. Data were collected to assess the demographic characteristics of the participants and their knowledge regarding adverse drug reactions. A pre-test was conducted to determine the baseline level of knowledge, followed by the implementation of the nurse-led education programme. Subsequently, a post-test was administered to evaluate the effectiveness of the educational intervention in improving knowledge regarding adverse drug reactions among the general population.

Major findings of the study:

The majority of the general population, 23 (38.33%), belonged to the 19–38 years age group.

Regarding gender, 35 (58.33%) respondents were female, while 25 (41.67%) were male.

In terms of educational status, 22 (36.67%) general population had completed primary education, whereas only 3 (5%) were graduates or above.

With respect to occupation, 18 (30%) respondents were housewives, 17 (28.33%) were farmers and 14 (23.33%) were daily wage workers.

Regarding monthly family income, 24 (40%) general population reported an income of less than ₹10,000 per month.

A majority of the general population, 49 (81.67%), reported frequent use of medications.

The pre-test findings revealed that 26 (43.33%) general population had inadequate knowledge, 29 (48.33%) had moderately adequate knowledge, and only 5 (8.33%) had adequate knowledge regarding adverse drug reactions (ADRs).

Following the nurse-led education programme, the post-test results showed a marked improvement in knowledge levels. The proportion of respondents with inadequate knowledge decreased to 8 (13.33%), while those with moderately adequate knowledge increased to 33 (55%). The number of respondents with adequate knowledge increased considerably to 19 (31.67%).

The mean pre-test knowledge score was 8.46, which increased to 13.70 in the post-test. The calculated *t*-value was 5.60, with a *p*-value of 0.001, indicating a statistically significant improvement in knowledge following the educational intervention.

No significant association was found between post-test knowledge scores and selected demographic variables. However, a significant association was observed between post-test knowledge regarding adverse drug reactions and respondents' previous experience of medication side effects.

Conclusion:

The study was conducted to evaluate the effectiveness of a nurse-led education programme on knowledge regarding adverse drug reactions among the general population in a selected village of Rahata Taluka. The findings demonstrated that the nurse-led education programme was effective in significantly enhancing the participants' knowledge regarding adverse drug reactions, as evidenced by the improvement in post-test knowledge scores compared to pre-test scores.

Chapter V

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