#### Impact of Educational Intervention on Maternity Nurses' Proficiency and Attitudes Toward Pharmacovigilance and Adverse Drug Reactions Reporting Safaa Abu Setta1, Amal K Khalil2, Roqaya F. Mohamed3, Asmaa Abdel Raheem Abdel Latif 4& Hanaa Elsayed Ahmed Shahin5

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### Abstract

Background: Adverse drug reactions lead to numerous fatalities, impairments, and other severe consequences. Maternity nurses administer medications, monitor positive and negative drug reactions, and are at the forefront of safety reporting. Aim: To find out the impact of an educational intervention on the maternity nurses' proficiency and attitudes towards pharmacovigilance and adverse drug reactions reporting. Design: This study employed quasi-experimental research design (pre and post-tests) with one group. Settings: The research was conducted at the Obstetrics and Gynecological Departments of University Hospital and Teaching Hospital in Shebin El-Kom, Menoufia Governorate. Sample: A purposive sample of 79 maternity nurses was selected after meeting the sample's inclusion criteria. Data collection instruments included a structured interview questionnaire, maternity nurses' practices towards adverse drug reactions reporting, and maternity nurses' attitudes towards pharmacovigilance and adverse drug reactions reporting. Results: A significant statistical variance existed in knowledge, practice, and attitudes towards pharmacovigilance and adverse drug reactions reporting among maternity nurses before and after educational intervention (p<0.001). In conclusion, the educational intervention successfully enhanced the knowledge and attitudes of maternity nurses about pharmacovigilance and adverse drug reactions reporting, leading to an improvement in their practice. Recommendations: It is important to incorporate pharmacovigilance into the nursing curriculum to familiarize nurses with this concept early in their careers, and educational initiatives on pharmacovigilance and reporting adverse drug reactions should be enhanced for maternity nurses across all healthcare facilities.

**Keywords:** Educational intervention, Maternity nurses' proficiency and attitude, Pharmacovigilance, Adverse drug reactions.

#### Introduction

Khan et al. (2020) stated that drugs

play a crucial role in treating different illnesses, but issues like adverse drug reactions (ADRs) exist. Therefore, Hu and colleagues (2022) stated that information from post-marketing studies regarding medications indicates a balance between benefits and risks identified in clinical trials. However, monitoring drugs is essential to assess safety in actual and extended circumstances. Additionally, it was mentioned that in 1968, the global individual case safety report (ICSR) database VigiBase was launched by the World Health Organization (WHO) to collect data on ADRs from over 140 countries regularly.

The first proposal for PV was introduced in France in 1974. In 2023, the World Health Organization officially defined pharmacovigilance (PV) as the study and actions concerning identification, evaluation, comprehension, and avoidance of negative effects and other medication issues. The focus in drug management has transitioned from treating diseases to overseeing drug development and clinical utilization.

Furthermore, Coleman and Pontefract

(2020) reported that an ADRs is described as "an unintended harmful response to a medication that occurs within normal usage parameters." Additionally, Guner and Ekmekcl (2019) elaborated that pharmacovigilance not only includes the surveillance of adverse reactions and monitoring of adverse events but also encompasses drug safety concerns like substance abuse, drug quality, medication errors, drug interactions, and reactions to excipients. Thus, Khan et al. (2021) stated that PV includes not just regular medications but also blood products, biological products, and vaccines. Moreover, it was mentioned that PV oversees drug safety incidences throughout the entire lifespan of the drug. In addition, ADRs can lead to severe physical injury in patients

category C have an unclear impact, while drugs in categories D and X are confirmed to be harmful. Since 1990, the Teratogen Information Service in Brazil has provided information for free.

Schuler-Faccini and colleagues (2019) stressed the importance of this knowledge for pregnant women and those planning to conceive. They identified two teratogens, misoprostol and Zika virus. In 1994, the FDA established the Office of Women's Health (OWH) to enhance safety for pregnant and breastfeeding patients and promote research. Harris et al. (2021) found that the FDA implemented a new pregnancy and lactation labeling rule in 2015, replacing letter-based categories, reflecting advances in medical care and personalized treatment.

Likewise, Byrne et al. (2020) mentioned that updated recommendations call for data from both human and animal research, encompassing details on the dangers of medication while use pregnant and breastfeeding, as well as the impacts of drugs on reproductive health. Furthermore, the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) was created by the United States Congress in 2017. The goal of this organization is to research the safety and efficacy of medications in pregnant breastfeeding women offer and and recommendations to the Health and Human Services (HHS) Secretary (Task Force on Research Specific to Pregnant and Lactating 2022). Klein et al. Women. (2022)demonstrated that aside from EudraVigilance and VigiBase, there are numerous alternative avenues available for accessing valuable drug safety data. For instance, Klein et al. gathered information on the use of s-blockers during pregnancy from Twitter and examined pregnancy outcomes related to assessing the safety of these medications.

Currently, there are no dedicated pharmacovigilance systems for pregnant women in any country. However, Placido et al. (2022) found that due to the unique features of drug use among this group and the specific concerns about drug safety during pregnancy, establishing pregnancy pharmacovigilance systems is crucial. The United Nations DoEaSA (2023) proposed that governments should establish laws and regulations to

and can result in a notable financial cost (WHO, 2023).

Furthermore, Toma et al. (2021) elaborated on the numerous obstacles that exist when it comes to ensuring the safe administration of medication to pregnant women. Additionally, they mentioned that there is also a lack of clinical trials for studying pregnant women; hence, the safety profiles of different medications in terms of pregnancy usage are still uncertain. Our objective is to offer a tool for maternity nurses to enhance drug safety in pregnant women. Due to these factors, greater focus needs to be placed on monitoring and preventing ADRs during conception and pregnancy. Park et al. (2020) found that disease treatment is crucial for the health of both mother and fetus during pregnancy, but medication safety in pregnant women affects both as well, thus emphasizing the need for risk assessment throughout a drug's life cycle.

Terracini (2021) proposed that not only the therapeutic impact of drugs on the mother should be considered, but also the influence on the growth and development of the fetus. Similarly, they determined that improper medication schedules can lead to severe and enduring negative outcomes for both the mother and the fetus. Additionally, it was mentioned that diethylstilbestrol was utilized in the treatment of pregnancy complications between the 1940s and 1960s. Furthermore, Troisi et al. (2018) discovered that women exposed to diethylstilbestrol in utero had a higher chance of experiencing infertility, negative pregnancy outcomes, vaginal and cervical clear cell adenocarcinoma. and breast cancer. Likewise, Terracini (2021) noted that the thalidomide tragedy of 1960 was a shocking event that led to the birth of tens of thousands of fetuses with seal deformities. Leandro (2020) suggested that this event serves as a reminder of issues related to drug-induced diseases and plays a crucial role in the development of PV systems.

According to the U.S. Food and Drug Administration (2008), the FDA established the pregnancy category labeling system in 1979, which is based on the reproductive toxicity of drugs. Medications are categorized into five groups: A, B, C, D, and X. Drugs in categories A and B pose no risk to the fetus; those in endorse the formation of these systems and offer channels for sharing drug safety information for healthcare institutions, pharmaceutical companies, patients, and others

to report and access vital drug information. Correspondingly, Olsson et al. (2020) documented that healthcare professionals, particularly maternity nurses, are critical components of the pharmacovigilance system. Furthermore, the Uppsala Monitoring Center (2022) discovered that inadequate reporting is attributed to health professionals' limited involvement caused by lack of understanding and unfavorable views on pharmacovigilance, such as ignorance (focusing only on significant adverse drug reaction reports) or apathy towards reporting. Therefore, Khan et al. (2022) proposed that extensive knowledge and skills in medication safety are required to effectively detect, manage, and report drug safety concerns, thus contributing to this field (WHO, 2022).

Additionally, it is essential for maternity nurses to receive proper training on the significance and procedures of reporting negative occurrences (Merriel et al., 2019). Therefore, Lie et al. (2020) suggested that having a combination of training and research abilities is necessary in this particular field. Despite there being worldwide worries regarding pharmaceutical safety, maternity nurses still do not possess sufficient knowledge and skills in pharmacovigilance and reporting adverse drug reactions (Yadav, 2020). Therefore, Paudval et al. (2020) reported that various tactics have been examined to boost ADR reporting, including the use of educational interventions (EI) for healthcare providers. Thus, this research aimed to increase understanding of drug safety concerns to enhance ADR reporting for statistical evaluations through symptom detection and health alert issuance (Faillie et al., 2016). So, the current study aimed to find out the impact of educational intervention on maternity nurses' proficiency and attitudes towards pharmacovigilance and ADR reporting.

# Significance of the study

Pharmacovigilance is increasingly crucial as global clinical trials occur, and numerous older drugs are repurposed (WHO, 2022). Khan et al. (2022) discovered that starting from the 2000s, morbidity and

mortality linked to drug use have emerged as the primary health concern globally, as well as in certain developed nations. Additionally, Coleman and Pontefract (2020) mentioned that in certain advanced nations. deaths from adverse drug reactions rank 4th and 6th in terms of all-cause mortality, making up 15-20% of healthcare costs and prompting the need for pharmacovigilance systems. Women constituted approximately 30 percent of all those who died from an overdose and of those attributed to opioids in the United States Almost 8.000 deaths in Canada in 2021 were connected to opioids, according to the WHO report from 2023. Turkey recently provided data to WHO-UMC showing that the ADRs per million population per year were 84, 94, 99, 89, 91, and 105 for the years 2017, 2018, 2019, 2020, 2021, and 2022, as reported by the

Turkish Ministry of Health in 2023. Because of the unique nature of physiological processes, pregnant and lactating women are at a higher risk of experiencing ADRs and encountering more drug safety issues (Akamine et al., 2021). According to Pillai et al. (2022), the adoption of PV is beneficial in identifying safety concerns at every stage of drug development. Due to their role as primary users of human drugs in hospitals, maternity nurses can identify any adverse effects that may arise during treatment (Liao et al., 2020). Thus, Costantine et al. (2021) discovered that participating in ADRs reporting or other patient safety efforts related to medication could safeguard patients from harm and improve favorable results. Nevertheless, successful reporting of ADRs understanding relies the on of pharmacovigilance and the ADRs reporting system, knowledge that maternity nurses currently lack (Saldanha et al., 2021). Thus, the study sought to explore how educational intervention impacts maternity nurses' skills and perspectives on reporting PV and ADRs.

#### The aim of the study

To find out the impact of educational intervention on maternity nurses' proficiency and attitudes towards pharmacovigilance and adverse drug reactions reporting.

# Research hypotheses:

H1: It is anticipated that following the educational intervention, the maternity nurses' proficiency in terms of knowledge about PV

and ADRs reporting will be better than they were previously.

H2: It is anticipated that following the educational intervention, the maternity nurses' proficiency in terms of practice of ADRs reporting will be better than they were previously.

H3: It is anticipated that following the educational intervention, the maternity nurses' attitude towards PV and ADRs reporting will be more positive than they were previously.

### **Operational definitions:**

**Educational intervention** is an organized set of learning activities designed to enable a maternity nurse to develop knowledge, practice, and attitudes relevant to PV and ADRs reporting.

**Maternity nurses' proficiency** refers to maternity nurses' knowledge and practice towards PV and ADRs reporting. It is measured using an assessment of maternity nurses' knowledge towards PV and ADRs instrument and maternity nurses' practice towards ADRs reporting instrument.

**Maternity nurses' attitudes** refer to maternity nurses' attitudes towards PV and ADRs. It is measured using maternity nurses' attitudes towards PV and ADRs instruments.

**Pharmacovigilance** involves the study and tasks performed by maternity nurses that focus on identifying, evaluating, comprehending, and averting any negative effects or issues associated with medication.

Adverse Drug Reactions reporting involves keeping track and documenting any negative or unwanted response experienced by a maternity nurse on a yellow card form as a result of using medications.

# Method

**Research Design**: The research used a quasiexperimental design involving pre-testing and post-testing with a single group.

**Research Settings:** The current research was carried out at the Obstetrics and Gynecology Department of University Hospital and Teaching Hospital in Shebin El-Koom, Menoufia Governorate.

**Sample Type:** A purposive sample of 79 maternity nurses was chosen from the study locations mentioned earlier (50 maternity nurses from the University Hospital and 29 from Shebin El-Koom Teaching Hospital)

working in inpatient departments and operating rooms.

#### Sample size calculation:

The interventional study's sample size calculation determined that 79 nurses are required. 79 nurses undergo testing before and after the educational intervention based on the higher reduction rates of poor knowledge and unawareness in nurses for reporting ADRs spontaneously. These rates are 41% and 34%, respectively, as reported by Ergün et al. (2019). This calculation ensures at least 80% power with a 95% two-sided significance level.

#### According to the formula provided below:

 $n = [(Z_{\alpha/2} + Z_{\beta})^2 \times \{(p1 \ (1-p1) + (p2 \ (1-p2))\}] / (p1 - p2)^2$ 

The required sample size in the study is determined by n, the pretest proportion is p1, the post-test proportion is p2, and the clinically significant difference between pre- and post-test is p1-p2. The value of  $Z\alpha/2$  varies depending on the level of significance, with 1.96 for 5%, while the value of Z $\beta$  depends on power, with 0.84 for 80%.

#### The participants' inclusion criteria are

- Females' maternity nurses

- Maternity nurses provide direct care to the women and have responsibility for drug administration and monitoring

#### Exclusion criteria for the participants:

- Maternity nurses are not tasked with administering and monitoring medication.

# Instruments for data collection:

Throughout the current investigation, the following instruments were used to gather the data:

**Instrument I: A structured interview questionnaire** was developed by researchers by referencing current literature to collect necessary information from study participants (Khan et al., 2022; Hussain et al., 2021; Shrestha et al., 2020; and Gidey et al., 2020). It was separated into two primary parts: **Part I: Socio-demographic characteristics**, including age, education level, work experience, work location, department, initial exposure to PV term, and where knowledge about PV and ADRs came from.

**Part II: Assessment of maternity nurses' knowledge about PV and ADRs:** It aimed to assess the level of knowledge that maternity nurses possess regarding pharmacovigilance and reporting of adverse drug reactions through

pre- and post-tests, using information from recent literatures (Chindhalore et al., 2022; Haines et al., 2020; Hadi et al., 2020) and WHO pharmacovigilance reading guidelines (WHO, 2023). It included 14 closed-ended questions, with 5 yes or no questions and 9 MCQs. These questions focused on PV and ADRs reporting, covering various topics such as awareness of PV, awareness of ADRs, knowledge of the reporting form (yellow card), recognition of the national agency of PV, familiarity with hospital PV unit or committee, precise definition of PV, correct definition of ADR, goals of PV, types of ADRs that are reported, severe ADRs, method of reporting individual ADR, reporting timeframe. responsible for ADRs reporting, and knowledge of the location of the Egyptian PV center.

# Knowledge Scoring system:

Tekel et al. (2021); Adisa and Omitogun (2019) implemented a knowledge scoring system. The literature was consulted to establish and code the 14 knowledge questions. Each knowledge question was assigned a value of one for a correct answer and zero for an incorrect answer, or if the respondent did not know the answer. All participants had a total score that ranged from 0 to 14, and it was categorized as follows:

- Good knowledge:  $\geq 75\%$  (more than 10)
- Moderate knowledge: 50-74% (7-10)
- Poor knowledge: <50% (less than 7)

Instrument II: Maternity nurses' practice towards ADRs reporting. To determine the maternity nurses' level of performance towards reporting ADRs during pre- and post-tests, researchers reviewed recent literatures (Chindhalore et al., 2022; Haines et al., 2020; Nisa et al., 2018) and WHO PV reading guidelines (WHO, 2023). Subsequently, they developed an instrument consisting of 9 questions (yes or no) related to ADRs notifications in women's clinical records, ADRs recording, submission of suspected ADRs reports, provision of ADRs reporting training, easy access to ADRs reporting forms, consultation of medicine package inserts, encouragement of women to peruse drug leaflets, counseling on drug side effects and ADRs, reporting witnessed ADRs during or after drug administration, and identification of reasons for underreporting of ADRs.

#### Practice Scoring system:

The scoring system was adopted from Tekel et al. (2021); Adisa and Omitogun (2019). According to the practice of ADRs reporting, which includes 9 questions (yes or no). A score of 1 was assigned to the answer of "yes." A score of zero (0) was assigned to responses of "no answer". A score of 7 to 9 was considered good if equal to or greater than 80%, while a score of 0 to 6 was considered poor if less than 80%.

Instrument III: Maternity nurses' attitudes towards PV and ADRs. The researchers developed this instrument after examining recent literatures (Khan et al., 2022; Shrestha et al., 2020; Gidey et al., 2020) and WHO guidelines on PV readings. It was used to evaluate the maternity nurses' attitudes towards PV and ADRs before and after the educational intervention. The 8 statements emphasized the importance of documenting ADRs for improved healthcare, making ADRs reporting mandatories for all HCPs, recognizing the vital role of trained maternity nurses in ADRs reporting, providing PV and ADRs education to all maternity nurses, stressing the need to report both serious and non-serious ADRs, highlighting the impact of ADRs reporting on patient safety, and acknowledging that ADRs can be fatal.

# Attitude Scoring system:

The maternity nurses' attitudes towards PV and ADR reporting were assessed using a 5-point Likert scale, with scores ranging from 1 to 5 (Tekel et al., 2021; Adisa and Omitogun, 2019). The nurses were requested to evaluate their level of agreement with different statements using a scale including strongly agree, agree, unknown, disagree, and strongly disagree. The total score ranged from 1 to 40 for all items and was calculated as follows: Positive attitude  $\geq 75\%$ (30 to 40), and negative attitude <75% (1 to 29). Validity:

Three professionals -- a member from the Obstetrics and Gynecology department at the Faculty of Medicine and two professors specializing in Maternal and Newborn Health Nursing at the Faculty of Nursing -- assessed the validity of the tools. They inspected the tools to verify the internal validity and accuracy of the content. They were also required to evaluate the completeness and clarity of the items. Changes and recommendations were incorporated into the tool, such as eliminating repeated questions, adding questions about PV training, and organizing questions about ADRs reporting separately from PV knowledge questions.

### Reliability:

The researchers used test-retest reliability to evaluate how consistent the instruments were internally. It was accomplished by giving the same instruments to the same subjects in comparable circumstances two times in one month apart. The knowledge questionnaire's Alpha Cronbach value was 0.797, practice' value was 0.741, and attitudes' value was 0.908. The coefficient indicates that the items seem appropriate and have an average internal consistency.

### Approval letter:

The Dean of the Nursing Faculty at Menoufia University dispatched an official letter to the relevant authorities at the study site, detailing the study's objectives. The plan to conduct the study was officially approved by the directors of the locations listed earlier.

### Ethical Considerations:

The Research and Ethics Committee of Menoufia University's Faculty of Nursing approved the study in April 2023, number (823). Additionally, ethical standards of confidentiality and informed consent were explored. It was ensured that the study did not cause any harm or pain to participants and that collected data was kept confidential and used only for the study analysis.

Before participating in the research, all nurses were given clarifications and provided with written consent. They were informed that participation in the study was voluntary, and they could withdraw at any time based on their decisions. Nurses were free to ask about any aspect of the study.

# Pilot study:

To assess the effectiveness and understandability of the tools and determine the time needed to answer the questions, 8 maternity nurses - accounting for 10% of the total - were selected for the pilot study in specified locations. To maintain the consistency of the outcomes and implement necessary modifications, they were excluded from the total sample size. The necessary changes were implemented before the actual experiment, based on the results of the initial study. At that moment, the equipment was ready to collect the necessary information for the study.

### Study Fieldwork:

The current research was executed in five phases sequentially: preparation, assessment, planning, implementation, and evaluation. During the period from early May 2023 to late August 2023, a total of four months elapsed while collecting the data.

### 1. Preparatory phase

The studv field thoroughly was reviewed. encompassing electronic dissertations, books, papers, the internet, scientific publications, and periodicals. A survey of literature in local, global, historical, and contemporary contexts was done, this was necessary to create knowledge foundation pertinent to the field of study. It also helped in the selection of an appropriate and reliable data-gathering instrument and the creation of a booklet with instructional guidance.

### 2. Assessment phase:

During the initial phase of the interview, the researchers welcomed every maternity nurse, introduced themselves, and clarified the study's objectives to secure their participation, enroll them in the study, and establish their collaboration. Additionally, the researchers informed them that participation in the study was not obligatory, and they were free to withdraw at any time. After obtaining written consent from eligible nurses, each nurse received a pre-test survey and was interviewed to collect information on their sociodemographic background and evaluate their knowledge, practice, and attitudes towards PV and reporting ADRs in maternity care. Each maternity nurse took about fifteen minutes to complete the interview, which was conducted in the maternity nurses' room in the operating room and inpatient wards.

#### 3. Planning phase:

In this phase, the researchers create the educational intervention's contents and define the study's goals and objectives. The aim of the educational program was to enhance the competence and mindset of maternity nurses regarding PV and ADRs reporting. The study aimed to improve the knowledge, practice, and attitudes of maternity nurses regarding PV and ADRs reporting. To meet the program's goals and objectives, the researchers assessed the maternity nurses' knowledge, practice, and attitudes during the assessment phase prior to the intervention sessions, and they reviewed pertinent literatures to develop and prepare the information contained in the educational booklet. The researchers also prepared different teaching aids, such as PowerPoint presentations, posters obtained from the department of drug administration, yellow cards (Arabic and English) obtained from PV center in the Menoufia University Hospital, and a guiding booklet to facilitate and illustrate teaching.

### Implementation phase:

After assessing the maternity nurses' proficiency and attitudes towards PV and ADRs reporting using pre-test question instruments, the educational sessions were conducted in the maternity nurses' room in the operating room and inpatient wards, to implement the educational intervention, which focused on information regarding PV and ADRs. Two planned sessions were provided in Arabic to the maternity nurses. The study locations were visited by the researchers three times a week for six weeks to conduct the sessions. The maternity nurses were divided into smaller groups, each consisting of 5-10 nurses. These groups were done in accordance with the nurses' free time and readiness to make it easier for them to attend the sessions. Each session took about one hour, divided between discussion on PowerPoint presentations and open discussions. Feedback was assessed at the beginning of each session to ensure nurses understood. Next, the new session's goals are presented. After every session, the researchers arranged a date for the upcoming session. The methods of instruction included lectures and group discussions.

# First Session:

The researchers provided a theoretical part through a lecture that included general knowledge regarding PV and ADRs as appropriate definition of PV, definition of ADRs, ADRs reporting form (yellow card), national agency of PV, hospital PV contact point, PV unit in the hospital, purposes of PV, types of ADRs reported, serious ADRs, reporting time, responsible person for ADRs reporting, location of Egyptian PV center., ways of reporting ADRs, and barriers to report ADRs. supported by preprepared teaching and aiding methods. The researchers gave each participant in the study the pre-planned booklet and posters to enhance their understanding of PV and ADRs reporting.

### Second session:

The researchers provided a practical part, including practical examples of how to document serious ADRs using the ADRs reporting form (yellow card) of ADRs. The researchers also distributed the reporting form (yellow card) to each participant in the study to improve their practices and attitudes towards ADRs reporting. At the end of this session, the researchers scheduled a time to interview the studied maternity nurses one month later to conduct the post-test using instruments I (Part 2), II, and III.

### 4. Evaluation phase

During this stage, the post-test was given a month after the educational intervention to evaluate how much the nurses retain the knowledge, practices, and attitudes related to PV and ADRs reporting. Furthermore, to evaluate the discrepancy between the pre and post-tests. The same instruments used in the pretest were reused in the post-test (instrument I, part 2, instrument II, and instrument III).

Statistical Analysis: Data was coded and analyzed using SPSS version 25. Descriptive statistics, including central tendency and dispersion, were used to summarize the sample characteristics. The Kolmogorov-Smirnov test was conducted to check for normality. Inferential statistics, including chi-square tests and independent t-tests, were used to evaluate the research hypotheses. The significance level was set at p < 0.05.

# **Results:**

Table 1 displays the distribution of sociodemographic characteristics among studied maternity nurses. It was revealed that 32.9% of the participants were found to be less than 30 years, and the age ranged between 24 and 54 years. Also, 51.9% of the maternity nurses in the study had obtained a bachelor's degree based on their level of education. Furthermore, 63.3% of the nurses examined were employed at a university hospital and 59.5% worked in operating rooms. Based on experience, approximately 32.9% had worked for up to 5 years, while 26.6% had over 15 years of experience. 78.5% of the nurses in the

study had no prior knowledge of pharmacovigilance, marking the first time they had encountered the concept in the survey, while 21.5% learned about it through hospital training courses.

Figure 1 displays the maternity nurses' total knowledge level about PV and ADRs both before and after the educational intervention. Before the educational intervention, 62% of the maternity nurses in the study had a limited understanding of PV and ADRs. However, following the intervention, a significant increase was seen in the number of nurses (69.6%) who had a good grasp of PV and ADRs, highlighting a notable improvement after the intervention than before.

Figure 2 displays the collective practice score of the maternity nurses towards ADRs reporting before and after the educational intervention. Before the educational intervention. 78.5% of the maternity nurses had poor reporting of ADRs. After one month, 83.5% showed good practice, with a significant improvement between preand post-intervention.

Figure 3 displays maternity nurses' barriers to ADRs reporting. It shows that the main first barrier for ADRs reporting reported by the maternity nurses was that reporting ADRs was not in their scope of practice (27.8%), followed by a lack of knowledge (20.3%), no comment (19%), ADRs was a normal side effect of the drug and relationship between drug and side effect not realized (11.4), then ADRs were not quite serios (7.6%), and finally work overload was reported by a low percentage of the nurses (2.5%).

Figure 4 displays the maternity nurses' total attitude level towards PV and ADRs both before and after the educational intervention. Prior to the educational intervention, 73.40% of the maternity nurses in the study had negative attitudes towards PV and ADRs. However, one month later, 65.80% of them exhibited positive attitudes towards PV and ADRs, showing a significant improvement between pre- and post-intervention.

Table 2 displays maternity nurses' knowledge, attitude, and practice towards PV and ADRs reporting before and after the educational intervention. It shows that there was a highly statistically significant improvement in knowledge, practice, and attitude towards PV and ADRs reporting among the studied' maternity nurses after the educational intervention than before.

Table 3 shows how nurses' sociodemographic characteristics are linked to their post-intervention knowledge scores on PV and ADRs. A significant relationship was found between education level and knowledge score, with 67.3% of maternity nurses with bachelor's degrees demonstrating good knowledge of PV and ADRs. Furthermore, a relationship exists between years of experience and knowledge scores, showing a notable discrepancy. Specifically, 34.6% of maternity nurses with over 15 years of experience demonstrated good knowledge, while 60% of those with less than 5 years of experience had poor knowledge.

Table 4 shows how the postintervention attitudes towards PV and ADRs among nurses is related to their sociodemographic characteristics. There was a clear relationship found between the educational background and attitude scores, with 71.2% of maternity nurses holding bachelor's degrees showing positive attitudes towards PV and ADRs. The years of experience were related to attitude scores, showing a significant difference. Maternity nurses with over 15 years of experience had a high percentage of positive attitudes at 36.5%, while those with less than 5 years had a high percentage of negative attitudes at 63.6%.

Figure 5 illustrates the correlation between maternity nurses' knowledge and practice scores towards ADRs reporting posteducational intervention. It indicates a strong and significant positive correlation between the knowledge and practice scores of maternity nurses (r = 0.73, P-value  $\leq 0.001$ ).

Figure 6 shows the correlation between maternity nurses' knowledge and attitudes scores towards PV and ADRs reporting following the educational program. The study revealed a strong positive correlation between maternity nurses' knowledge and attitudes, with a correlation coefficient of 0.66 and a P-value less than 0.001.

Variables	Studied maternity nurses (n=79)					
	No.	%				
Age (years):		1				
< 30	26	32.9				
30-39	23	29.1				
40-49	25	31.7				
≥50	5	6.3				
Level of education:		·				
High school	23	29.1				
Technical institute of nursing	13	16.5				
Bachelor's degree	41	51.9				
Postgraduate degree	2	2.5				
Workplace:		1				
University hospital	50	63.3				
Teaching hospital	29	36.7				
Department:						
Inpatient	32	40.5				
Surgical (operating rooms)	47	59.5				
Years of experience:		I				
≤5	26	32.9				
6-10	17	21.5				
11-15	15	19.0				
> 15	21	26.6				
Hearing about pharmacovigilance:						
Yes	17	21.5				
No	62	78.5				
Source of knowledge about						
pharmacovigilance:						
In this survey	62	78.5				
Training programs and courses	17	21.5				

# Table 1: Sociodemographic traits among maternity nurses included in the study (n=79)

Figure 1: The total knowledge level of maternity nurses about PV and ADRs before and after the educational intervention



Figure 2: Overall practice score of the maternity nurses towards ADRs reporting before and after the educational intervention





Figure 3: Maternity nurses' barriers to ADRs reporting among the maternity nurses studied (n= 79)

Figure 4: Overall attitude level of the maternity nurses towards PV and ADRs before and after the educational intervention



КАР	Time of	assessmen	t	$\chi^2$ test	P value		
	Pre-test (n=79)		Post tes	st			
			(n=79)				
	No.	%	No.	%			
Knowledge:							
High	13	16.5	55	69.6			
Moderate	17	21.5	14	17.7	52.01	< 0.001	
Low	49	62.0	10	12.7		HS	
Practice:							
Good	17	21.5	66	83.5	58.48	< 0.001	
Poor	62	78.5	13	16.5		HS	
A 44:4							
Attitude:				<i></i>		0.001	
Positive	21	26.6	52	65.8		< 0.001	
Negative	58	73.4	27	34.2	32.16	HS	
	1	1		1			

 Table 2: Maternity nurses' Knowledge, Practice, and Attitude Towards PV and ADRs before and after educational intervention.

Table 3: Relationship between nurses' sociodemographic traits and their post-intervention knowledge score on PV and ADRs. (n= 79)

Socio-Demographic		Le	vel of k	$\chi^2$	P value			
characteristics	Good		Moderate		Poor		test	
	(n=55)		(n=14)		(n=10)			
	No.	%	No.	%	No.	%		
Age(years):								
< 30	17	30.9	5	35.7	4	40.0		
30-39	14	25.5	6	42.9	3	30.0	4.22	▶ 0.05
40-49	21	38.1	2	14.3	2	20.0	ns	
$\geq$ 50	3	5.5	1	7.1	1	10.0		
<b>Educational Level:</b>								
High school	11	20.0	7	50.0	5	50.0		
Technical institute of	5	9.1	5	35.7	3	30.0		
nursing							$20.40^{*}$	$\leq 0.05$
Bachelor's degree	37	67.3	2	14.3	2	20.0		
Postgraduate degree	2	3.6	0	0.0	0	0.0		
Workplace:								
University hospital	35	63.6	9	64.3	6	60.0	0.06	> 0.05
Teaching hospital	20	36.4	5	35.7	4	40.0	ns	
Department:								
Inpatient	21	38.2	6	42.9	5	50.0	0.53	> 0.05
Surgical (operating rooms)	34	61.8	8	57.1	5	50.0	ns	
Years of experience:								
< 5	13	23.6	7	50.0	6	60.0		
5-10	10	18.2	4	28.6	3	30.0	12.70*	$\leq 0.05$
11-15	13	23.6	1	7.1	1	10.0		
> 15	19	34.6	2	14.3	0	0.0		

\* = Significant, **ns** = Not significant

Socio-Demographic		L	$\chi^2$	P value				
characteristics	Posi	itive	Moderate		Negative		test	
	(n=52)		(n=16)		(n=11)			
	No.	%	No.	%	No.	%		
Age(years):								
< 30	16	30.8	5	31.3	5	45.4		
30-39	13	25.0	6	37.5	4	36.4	4.41	> 0.05
40-49	20	38.5	4	25.0	1	9.1	ns	
$\geq$ 50	3	5.7	1	6.2	1	9.1		
Educational Level:								
High school	9	17.3	8	50.0	6	54.5		
Technical institute of	4	7.7	5	31.3	4	36.4		
nursing			3	18.7	1	9.1	22.73**	$\leq 0.001$
Bachelor's degree	37	71.2	0	0.0	0	0.0		
Postgraduate degree	2	3.8						
Workplace:								
niversity hospital	34	65.4	10	62.5	6	54.6	0.46	> 0.05
Teaching hospital	18	34.6	6	37.5	5	45.4	ns	
Department:								
Inpatient	22	42.3	5	31.3	5	45.4	0.75	>0.05
Surgical (operating rooms)							ns	
	30	57.7	11	68.7	6	54.6		
Years of experience:								
< 5	12	23.1	7	43.9	7	63.6		
5-10	10	19.2	4	25.0	3	27.3	12.39*	$\leq 0.05$
11-15	11	21.2	3	18.7	1	9.1		
> 15	19	36.5	2	12.4	0	0.0		

Table 4: Relationship between nurses' sociodemographic factors and their post-intervention attitudes towards PV and ADRs. (n= 79)

\*\*= Highly Significant, \*= Significant, **ns** = Not significant

Figure 5: Correlation between maternity nurses' knowledge and practice scores towards ADRs reporting post-educational intervention.





Figure 6: Correlation between maternity nurses' knowledge and attitudes scores towards PV and ADRs reporting following the educational program.

#### **Discussion:**

Maternity nurses are in a prime position to contribute to ADRs reporting, as they collaborate closely with women and possess extensive knowledge of health criteria, symptoms, medications, and ADRs. Maternity nurses are in a special position to track women's reactions to medications due to their role in administering drugs and documenting side effects. They frequently inform the obstetrician in charge about potential adverse drug reactions. Therefore, it is logically justified to engage maternity nurses and motivate them to participate in the ADRs reporting system (Backstrom et al., 2019).

The results of the study showed that most of the participants were under thirty years old and had one to five years of work experience. Maternity nurses' ages typically ranged between twenty-four and fifty-four years old on average. In addition, half of the maternity nurses examined had completed a bachelor's degree, and most of the nurses studied were employed in a university hospital working in operating rooms. The reason for this discovery could be that most of the maternity nurses are recent graduates from the college of nursing, all maternity nurses working in operating rooms are university graduates, and the number of supervisor nurses in the university hospital is higher than in the Shebin El-Kom teaching hospital.

This aligns with the study conducted by Hanafi et al. (2019) on the "knowledge, attitudes, and practices of nurses in Iran towards reporting ADRs." It was reported that most participants held a bachelor's degree, and their average age was thirty-one, ranging from twenty to fifty years. Similarly, Shrestha et al. (2020) conducted a study on how an educational intervention impacted PV knowledge and attitudes among health professionals in Nepal. It was noted that the majority fell within the twenty-one to thirty age range, with an average age spanning twenty to forty-six years. However, their results do not align with the present research in terms of education level, as most participants held diploma degrees.

Nevertheless, these results went against the research conducted by Guner and Ekmekci (2019). They assessed healthcare providers' knowledge of pharmacovigilance and their behavior regarding reporting adverse drug reactions, as well as the factors influencing reporting rates in Turkey. Their research discovered that most participants were between the ages of fifty and fifty-five. However, their results regarding employment history aligned with the current study, as most participants had two to five years of work experience.

The results of the recent study revealed that less than one-fourth of the nurses surveyed had learned about pharmacovigilance in hospital training courses, while over threequarters had never heard of it before this survey. The results of this study could be clarified by the fact that the training sessions were limited to mornings when nurses were busy with deliveries and surgeries. Additionally, the courses took place in closed rooms, such as operating rooms, resulting in low attendance by maternity nurses.

This discovery contradicts the study conducted by Ryamukuru et al. (2022) in Rwanda concerning the "awareness and practice of nurses and midwives in monitoring and reporting ADRs at the University Teaching Hospital of Kigali" and the study by Ergun et al. (2019) in Turkey on the "knowledge, attitude, and practice of Turkish health professionals towards PV." The studies revealed that most nurses, midwives, and health professionals who participated were familiar with PV. A substantial portion of the nurses and midwives in the research were introduced to PV during their nursing education and through interactions with healthcare professionals in classroom settings, potentially explaining the discrepancies.

The results of the study indicated a significant improvement in maternity nurses' knowledge about PV and ADRs after completing the educational program, with a highly significant difference observed between pre- and post-test levels for all knowledge items. According to researchers, these results might be explained by the fact that only one-fifth of the maternity nurses who work in operating rooms attend the training courses that are performed by the PV team in their hospital about PV and ADRs and most of the participants were the first time they heard about PV in this research. This could also be explained that post-education knowledge level could be attributed to the impact of educational sessions provided to the maternity nurses which helped them to understand PV and the reporting of ADRs.

The results were supported by studies by Shrestha et al. (2020) and Jha et al. (2019) investigating the impact of an educational intervention on healthcare professionals' perspectives on pharmacovigilance in Nepal. The study showed a notable increase in the knowledge levels of healthcare professionals following an educational program. In the same way, these results were consistent with a crosssectional study conducted by Adegbuyi et al. (2021) on the "knowledge, attitude, and behavior of healthcare professionals in primary, secondary, and tertiary healthcare centers" in Ekiti State, south-west Nigeria. They disclosed that most healthcare providers possessed a strong understanding. On the other hand, the results of a cross-sectional study conducted by Gidey et al. (2020) in Ethiopia were opposite to these findings, focusing on healthcare professionals' understanding, attitudes, and behaviors towards reporting ADRs. More than one-half of healthcare professionals were discovered to have insufficient understanding of pharmacovigilance and adverse drug reactions.

In the current study, it was discovered that more nurses examined reported being familiar with the terms PV, ADRs, and national PV agency after education compared to before. This discovery was comparable to research done in Ethiopia by Gidey et al. (2020) and Khan et al. (2023) investigation on "Healthcare Providers' understanding, views, behavior, and obstacles to Pharmacovigilance and Adverse Drug Reactions reporting". More than one-half of the participants indicated they were familiar with the terms PV and ADRs. Nevertheless, despite being aware, most participants were unfamiliar with completing the ADRs reporting form.

Furthermore, a greater number of participants correctly identified the precise definitions of PV and ADRs after receiving education compared to before. This discovery was supported by research in Ethiopia and Pakistan conducted by Khan et al. (2023) and Ali et al. (2021) on the understanding, mindset, and obstacles related to ADRs reporting among healthcare professionals in tertiary care facilities. Most participants accurately selected the meanings of PV and ADRs. On the contrary, this result differed from research done by Gidey et al. (2020) where they reported that only onequarter of the subjects accurately identified the precise explanation of PV and ADRs.

The current study discovered a significant correlation between participants' total knowledge level, their level of education, and years of experience. Maternity nurses with a bachelor's degree and more than five years of experience showed a marked improvement in their knowledge level. The results align with research conducted by Jha et al. (2019) in Nepal,

showing a notable increase in knowledge level among individuals with master's and bachelor's degrees.

The study indicated that prior to the educational intervention, over three-quarters of maternity nurses had inadequate **ADRs** reporting practices. However, after the intervention, more than four-fifths demonstrated good practice, leading to a significant improvement in their overall practice score. Additionally, this research pointed out that there was a significant statistical correlation between the educational background and years of experience of maternity nurses and their execution of monitoring and reporting ADRs. This discovery aligned with a study conducted by Li et al. (2021) regarding the "awareness and attitudes of healthcare professionals" in China. Their findings indicated a notable improvement in the practice score of healthcare professionals regarding PV after the educational intervention compared to before the intervention.

However, these results contradict the study by Shkreli et al. (2023) regarding the "knowledge, attitude, and practice towards PV and reporting of ADRs among HCPs" in Albania; as well as Ryamukuru et al. (2022) on the "awareness and practice of nurses and midwives about PV and ADRs monitoring and reporting" in Rwanda; and Khan et al. (2023) study. Based on their findings, over one-half of the respondents displayed insufficient behaviors in monitoring and reporting ADRs, resulting in an overall poor practice score for ADRs reporting. Therefore, these results indicate that it is necessary to provide training on PV, monitoring, and reporting of ADRs to all HCPs.

Moreover, the findings of the present research indicate that sixty percent of the participating maternity nurses recognize the importance of ADRs reporting. However, only one-fifth of them submitted ADRs to the PV center. A study in Nigeria by Okezie and Olufunmilayo in 2020 supported similar findings on the reporting of ADRs by doctors. It was declared that just one out of three doctors had previously documented ADRs.

Ergun et al. (2019) conducted research in Turkey, which found that only less than oneninth of doctors and one-fifth of nurses reported encountering any ADRs in their daily practice. In contrast, Belton et al. (2020) conducted research in the United Kingdom among hospital doctors and hospital pharmacists on the "attitudes of ADRs reporting", and Green et al. (2021) studied the "attitudes and knowledge to ADRs reporting". They discovered that over three-quarters had submitted an ADRs report to either the drug safety committee or a drug maker. Most hospital doctors and pharmacists in hospitals believed that reporting adverse drug reactions was a professional duty, leading to this explanation.

Before the intervention, a large number of study participants did not report any ADRs to the PV center, with over threequarters failing to report even one. The underreporting ratios are intriguing as many participants have recognized the significance and importance of spontaneous reporting of ADRs. Most nurses thought ADRs reporting is not their professional duty, which could be why this result occurred. This indicates a need for better education on the issue, which may lead to more reports.

Moreover, concerning maternity nurses' obstacles in reporting ADRs, the study found that the main reasons for under-reporting include ADRs not falling within their scope of practice, lack of knowledge, considering ADRs as normal side effects, not recognizing the connection between the drug and side effect, ADRs perceived as not serious, and a minority citing work overload. Enhanced operations of local PV facilities, teamwork among healthcare professionals, continuous educational programs, regular monitoring by local health authorities. providing motivation for healthcare providers, enforcing mandatory reporting guidelines, and utilizing automation and AI in ADRs detection and reporting are essential for enhancing the PV system in Egypt and globally.

This is in line with a study conducted by Evans et al. (2019), who analyzed attitudes towards ADRs reporting at a tertiary teaching hospital in Barcelona, Spain. Their research uncovered that the main reason for underreporting of ADRs was the clinical practitioners' incapacity to report due to their heavy workloads. Other factors contributing to the low reporting rate in that specific study comprised unfamiliarity with the spontaneous reporting system, lack of yellow cards, uncertainty regarding the assessment of adverse drug reactions, and inadequate patient privacy.

Moreover, a study conducted by Khan and colleagues (2023) in Ethiopia pinpointed various obstacles such as increased workload, the perception that individual ADRs reports are ineffectual, absence of a conducive work environment, lack of backing from healthcare authorities, and insufficient knowledge, all aimed at deterring healthcare professionals from reporting ADRs. Ali et al. (2021) conducted research in Pakistan and found that healthcare professionals face obstacles in discussing adverse drug reactions due to a lack of professional settings and incentives for reporting. In a recent systematic review conducted by Khan et al. (2022), the researchers explored healthcare professionals' understanding, opinions, behaviors. and obstacles related to reporting PV and ADRs in Turkey. They found that the primary barriers HCPs encountered when it came to PV were time constraints, uncertainty about ADRs, and not knowing where to submit reports.

The findings of the present research indicate that most maternity nurses exhibit a favorable attitude toward PV and ADRs reporting following the educational intervention. as opposed to before the education, with a substantial statistical variance between pre and post-tests results. Furthermore, their overall attitude score notably increased after the implementation of the educational intervention. Additionally, the study notes a significant statistical relationship between the educational background and vears of experience of maternity nurses and their attitudes toward reporting PV and ADRs.

Still, the results were not like those of a descriptive, cross-sectional survey carried out in Albania by Napuce and Tabaku (2019), focusing on the knowledge and practices of health professionals regarding PV. It was demonstrated that healthcare providers have a pessimistic attitude towards reporting adverse drug reactions. This is because they thought that monitoring ADRs does not pose any worry and reporting them is unnecessary. Similarly, a study conducted in Nepal by Shrestha et al. (2020) found a substantial increase in total attitude scores following an educational intervention. Hence, regular education and training are necessary to enhance nurses' attitudes and improve PV activities.

Moreover, these results align with research conducted in Nepal by Jha et al. (2019) and Shrestha et al. (2020), indicating that a larger number of participants showed cheerful outlook scores after the educational intervention, leading to a notable increase in the total attitude score. This could be because many participants believed that all ADRs are important and should be documented; a single report can have an impact, and completing the ADRs yellow form is beneficial.

Additionally, the results of the present study are in line with the research conducted by Jha et al. (2019) in Nepal, which showed a notable increase in attitudes scores among health professionals with a bachelor's degree. However, the findings diverge when it comes to years of experience, as there was a marked improvement in attitudes scores for participants with less than one year of experience.

One key discovery in the study revealed а direct correlation between knowledge, attitudes, and practices regarding reporting PV and ADRs. If maternity nurses' knowledge about PV and ADRs reporting increased, it would positively impact their attitudes and subsequently improve ADRs reporting systems. John and colleagues (2020) confirmed this discovery through their study on "Adverse Drug Reaction Reporting" in the United Arab Emirates. They stated that a direct link existed between knowledge and attitudes towards ADRs reporting, leading to enhanced ADRs reporting results.

# Conclusion:

The results of the current research suggested that most of the maternity nurses who were studied had a good knowledge of PV and ADRs, leading to positive attitudes and effective practices in monitoring and reporting ADRs. Hence, the results of this research backed the hypothesized outcomes, showing a successful enhancement and advancement in maternity nurses' skills and attitudes towards PV and ADRs reporting due to an educational intervention.

# **Recommendations:**

- Regular training programs, educational interventions, consistent monitoring, SMS alerts to HCPs (obstetricians, pharmacists, and nurses) by local healthcare authorities, interprofessional collaboration among them, and enforcement of mandatory reporting policy are essential for enhancing HCPs' understanding, behaviors, patient safety, and advancing PV efforts.

- Nursing students should learn about pharmacovigilance early in their education to familiarize themselves with the concept for their future career.

- Nursing supervisors and administrators can oversee and proactively start these programs and workshops aimed at enhancing reporting within hospitals. Consistent feedback on ADRs reports and presentations can inspire healthcare professionals to keep reporting.

- The spontaneous reporting system should be structured in the most practical and direct way to avoid incomplete reporting.

- The Ministry of Health and other related organizations should aid the pharmacovigilance contact points of local hospitals, as they play a vital role in implementing and managing the system as well as delivering the educational initiatives.

#### **Recommendations for further research:**

- Similar kinds of educational interventional studies could be conducted in other hospitals and among a larger population of healthcare professionals to explore their practice status on ADRs minimization.

- Comparable educational intervention studies could be conducted at different hospitals and with a broader group of healthcare professionals to investigate their current practices in reducing ADRs.

- Additional research to maternity nurses' knowledge about monitoring pharmacovigilance and their practice in reporting ADRs.

- More research is needed to evaluate the effects of ADE in low- and middle-income nations.

#### Limitation:

The study was limited by the small number of maternity nurses and the absence of other health professionals, such as pharmacists and obstetricians, resulting in only maternity nurses being involved in the study.

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