



KNOWLEDGE OF PRACTICING DRUG DISPENSERS ABOUT MEDICATION SAFETY DURING PREGNANCY

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ABSTRACT

Background: Drug dispensers, including pharmacists, assistant pharmacists, and professionals (Bavayashai), are crucial healthcare providers in improving medication use, particularly among pregnant women in their communities. **Objective:** This study aimed to evaluate drug dispensers' knowledge about medication safety during pregnancy. **Method:** A cross-sectional survey was carried out on practicing drug dispensers in the Dharan City of Nepal. They were asked about the safety of each medicine during pregnancy. It involved both Prescription-only medicine and Over-the-counter medications. Both descriptive and analytic statistics were utilized. **Results:** Most drug dispensers have poor knowledge of the safety of dietary supplements (Vitamin A and Caffeine) and Temazepam. While 54.2% believe alprazolam is unsafe, 15.8% assess its use based on a risk-benefit analysis. Only 15.8% know tetracycline should be used if the benefits outweigh the risks, and 43.3% deem amoxicillin safe. The majority (79.2%) recognize ethinylestradiol as unsafe for pregnant women. About 38% identify valproic acid as unsafe, and 20% assess lamotrigine based on benefit-risk. For analgesics, 55.8% know acetaminophen is safe, but there is uncertainty about aspirin and ibuprofen use during pregnancy. Few are aware that pseudoephedrine hydrochloride should be used only if the benefits outweigh the risks. Significant associations were found between dispensers' education, their practice of asking about pregnancy status, and their knowledge of medication safety during pregnancy ($P < 0.05$). **Conclusion:** Drug dispensers are the most accessible healthcare providers who can help pregnant women with their medication use. There are still gaps in knowledge where educational interventions are needed.

KEYWORDS: Teratogenic drugs, Pregnancy, Risk to fetus, Drug dispensers, Counseling.

IMPACTS ON PRACTICE

- The study highlights significant gaps in the knowledge of drug dispensers regarding medication safety during pregnancy. Implementing targeted educational interventions can enhance their understanding, thereby improving the quality of advice provided to pregnant women.
- The findings suggest the need for developing and enforcing policies that ensure drug dispensers receive continuous education and training. This will help standardize the information provided to pregnant women, potentially reducing medication-related risks during pregnancy.

INTRODUCTION

Drug therapy is frequently necessary during pregnancy to manage acute or chronic disorders such as nausea, vomiting, diabetes, asthma, and hypertension, which may require treatment for a short or extended period.^[1] Recent

research suggests a rise in drug consumption when pregnant.^[2] Approximately 90% of pregnant women are believed to utilize three or four medicines at various stages.^[3] Administering medicines during pregnancy requires utmost caution due to the potential influence on both mother and fetal health.^[4] Although many medications may be advantageous for the mother, they can potentially endanger the fetus. The task of choosing suitable drugs for pregnant women is difficult because of the distinct physiological changes that occur during pregnancy.^[5] Although there are concerns about birth defects linked with certain medications, it is neither feasible nor safe for women with continuing medical issues to eschew pharmacological treatment completely. Healthcare practitioners must meticulously assess the risk-benefit ratio while treating medical disorders in pregnant women.^[6] The risk-benefit situation needs to be carefully analyzed by health professionals in managing medical conditions in a pregnant woman.^[5] Although

there is a dearth of systematic research on the safety and effectiveness of prescription drugs for pregnant women, data indicates that a substantial quantity of prescription, over-the-counter, and herbal medications are prescribed and used by pregnant women.^[5]

Our study categorizes drug dispensers as pharmacists, assistant pharmacists, and professionals (Bavayashai). Community pharmacies play a crucial role in providing primary healthcare services in various regions across the globe, and they are frequently the initial point of contact for healthcare for people in developing nations.^[7] Effective drug utilization and control during pregnancy is vital for prenatal care, and pregnant women often seek guidance from community pharmacists.^[8] A notable study on the perception of danger linked to drugs during pregnancy discovered that the individuals most frequently sought advice from physicians, product information leaflets, and pharmacists.^[9] Nevertheless, there is a scarcity of research on the involvement of pharmacists in disseminating teratology information to pregnant women and their healthcare professionals. Pharmacists in primary care play essential functions such as addressing drug inquiries and providing guidance on adverse effects.^[10] Pharmacists have a crucial duty to address the usage of drugs during pregnancy. Pharmacists, who have the authority to distribute over-the-counter drugs, must carefully consider the advantages of treating the mother's condition in comparison to the potential hazards to the developing fetus.^[11] Carbamazepine is recognized as having teratogenic effects. However, it is essential to note that uncontrolled epileptic convulsions present a higher level of risk to the developing fetus.^[12] Pharmacists must also take into account the time of medicine administration during pregnancy.

Proper dispensing is essential for the judicious use of medication, which includes reducing the use of drugs that can cause congenital disabilities during pregnancy. Drug distributors must have current knowledge and expertise in drug dispensing for pregnant women. Erroneous perceptions of risk can result in ill-advised decisions that impact pregnancy outcomes.^[13] On the other hand, the way a woman perceives danger can affect her choice to take essential medication while pregnant. There is a widely held perception that medications are not safe to use during pregnancy. Yet, research has only identified less than 30 substances that have been proven to cause significant birth defects in people.^[14] It is crucial to minimize the use of drugs that are not necessary during pregnancy and to enhance the knowledge of healthcare practitioners and pregnant women about the potential dangers associated with medication usage.^[13] Community pharmacies serve as easily accessible hubs for acquiring prescriptions, information, and medical guidance, especially in developing nations such as Nepal, where a significant portion of the population lacks medical insurance.^[13] Drug dispensers are vital in delivering precise information and pharmaceutical

services to patients, particularly those who are pregnant. According to reports, women frequently overestimate the dangers of medications causing birth defects.^[15] Therefore, healthcare providers, especially those who dispense drugs, should rely on evidence-based information to decrease unneeded concerns and ensure the safe use of medication during pregnancy.^[9]

As far as we know, there have been no studies conducted to evaluate the level of awareness among drug dispensers in Nepal on medication safety during pregnancy. This research is necessary because drug dispensers are easily accessible to healthcare practitioners with important obligations to enhance medicine utilization, particularly among pregnant women in their localities. The objective of this study was to evaluate the knowledge of drug dispensers about medication safety during pregnancy.

METHODS

Ethics approval

Approval was obtained from the Department of Drug Administration (Ref no:328) before data collection. A written informed consent was obtained before participation in the study.

Study design

A cross-sectional survey was conducted in Dharan, Nepal, targeting all practicing drug dispensers. The study aimed to evaluate their knowledge of drug safety during pregnancy. The survey was conducted over two weeks between January and February 2018. The questionnaire used was validated for face and content by experts in clinical pharmacy and refined after a pilot study involving 15 clinical pharmacists (CPs). The reliability of the questionnaire was determined to be 0.75 using Cronbach's Alpha. Questions were derived from previously published studies by Alrabiah Z. et al., 2017.^[16]

Sampling

The study targeted all practicing drug dispensers in Dharan. According to the Department of Drug Administration, approximately 198 pharmacies were registered in Dharan, which was assumed to be equivalent to the number of drug dispensers. The pilot study indicated that 66.7% of pharmacists had good knowledge about drug safety among pregnant women. A representative sample size of 125 pharmacies was calculated using a 5% margin of error and a 95% confidence level based on a population of 198. Stratified sampling was performed based on the ward number of the pharmacies.

The sample size for an infinite population was calculated using the formula.^[17]

$$m = Z^2 \times p(1-p) / d^2 = 1.962 \times 0.67 \times (1-0.67) / 0.052 = 340$$

For a finite population ($N=198$), the sample size (n) was adjusted as follows:

$$n = m / (1 + (m-1)/N) = 340 / (1 + (340-1)/198) = 125$$

Procedure

The questionnaire consisted of two parts. The first part collected demographic data, including age, years of experience in pharmacy, country of education, educational background, practice, and whether female patients were asked about their pregnancy status. The second part assessed knowledge of drug safety during pregnancy with a list of 20 prescription and nonprescription drugs and dietary supplements commonly taken in the first trimester. Drug dispensers were asked to classify the safety of each drug during pregnancy as "safe in the first trimester," "must weigh risks and benefits for individual patients," "not safe in the first trimester," or "I don't know."

The selected medications included:

1. Drugs with known risks to the fetus: temazepam, phenobarbital, tetracycline, valproic acid, ethinylestradiol.
2. Drugs commonly used for gynecological health issues: ciprofloxacin, amoxicillin, and oral contraceptives.
3. Drugs for other health issues during pregnancy: paroxetine (depression), budesonide (asthma), lamotrigine (epilepsy and bipolar disorder).
4. Over-the-counter medications (OTC) medications commonly used during pregnancy: acetaminophen, aspirin, dextromethorphan, ibuprofen, and pseudoephedrine.

Each correct response for both prescription-only medications (POM) and OTC medications was scored as

one point, while incorrect responses and "I don't know" were scored as zero. The overall knowledge score was the sum of correct answers, with a maximum score of 20.

Data analysis

The data was entered into the SPSS version 25 for Windows for analysis. Both descriptive and analytic statistics were utilized. Results were expressed as numbers, percentages, and mean ($\pm$ SD and 95% CI) for descriptive analysis. The Mann-Whitney U test, the Kruskal-Wallis test, and the Independent t-test were used based on the nature of the data to assess intergroup differences. A P-value of less than 0.05 was considered statistically significant.

RESULTS

Out of 125 pharmacies visited, responses were obtained from 120 drug dispensers, resulting in a response rate of 96%. The demographic analysis revealed that 74.2% of respondents were male, and 25.8% were female. Most respondents (79.2%) had a health-related educational background, while 20.8% came from non-health backgrounds. The majority of participants (50%) were aged between 25-35 years, and 65.8% had 0-5 years of working experience. Regarding educational qualifications, 45% held a diploma in pharmacy, 1.7% had a bachelor's degree, and 53.3% had other academic qualifications. The sociodemographic characteristics of participants are shown in Table 1

Table 1: Sociodemographic characteristics of participants.

Characteristics	Category	Frequency	Percentage
Gender	Male	89	74.2
	Female	31	25.8
Education background	Health	95	79.2
	Non-health	25	20.8
Age group	15-24	30	25
	25-35	60	50
	36-45	26	21
	46 and above	4	3.3
Work experience (years)	0-5	79	65.8
	6-10	22	18.3
	11-20	14	11.7
	21 above	5	4.2
Education level	Diploma in pharmacy	54	45
	Bachelor's in pharmacy	2	1.7
	Others	64	53.3
Asking about pregnancy status of female patient	Always	16	13.3
	Often	34	28.3
	If she look pregnant	55	45.8
	Never	15	12.5

Most of the respondents (54.2%) believed that alprazolam is not safe, while 15.8% of respondents thought that it is used based on risk-benefit assessment. Also, most drug dispensers (43.3%) said that amoxicillin is safe, but very few drug dispensers (15.8%) knew that tetracycline should be used only if the potential benefits outweigh the risks. A

majority of drug dispensers (79.2%) knew that ethinylestradiol is unsafe to be used by pregnant. For central nervous system drugs, about 38% of drug dispensers identified valproic acid as not safe, and approximately one-fifth of drug dispensers correctly identified that lamotrigine should be used only if the

potential benefit justifies the potential risk.

Among non-prescribed analgesics, the majority of drug dispensers (55.8%) knew that acetaminophen is safe; however, they were in doubt about aspirin usage during pregnancy, while ibuprofen may be used if the potential benefit justifies the potential risk. Very few drug

dispensers knew that Pseudoephedrine Hydrochloride is used only if the potential benefit justifies the potential risk. Regarding dietary supplements, 48.4% of drug dispensers reported that Vitamin A supplements are safe. About 44% of drug dispensers knew that Temazepam was not safe for use in the first trimester. Detail information is presented in Table 2.

Table 2: Drug dispensers' response to drug safety during pregnancy.

Medication	Not safe in first trimester N (%)	Must weigh risks and benefits for individual patients N (%)	Safe in the first trimester N (%)	I don't know N (%)
Response of drug dispensers to use of prescribed medications during pregnancy (N=120)				
Alprazolam	65 (54.2)	16 (15.8)	4 (3.3)	35 (29.2)
Amoxicillin	52 (43.3)	30 (25)	32 (26.7)	6 (5)
Budesonide inhaled	46 (38.3)	23 (19.2)	24 (20)	27 (22.5)
Ciprofloxacin	75 (62.5)	24 (20)	24 (20)	9 (7.5)
Ethinylestradiol	95 (79.2)	4 (3.3)	4 (3.3)	17 (14.2)
Lamotrigine	55 (45.8)	23 (19.2)	3 (2.5)	39 (32.5)
Oral Contraceptive	85 (70.8)	3 (2.5)	7 (5.8)	25 (20.8)
Paroxetine	60 (50)	25 (20.8)	0 (0)	35 (29.2)
Carbamazepine	67 (55.8)	29 (24.2)	4 (3.3)	20 (16.7)
Tetracycline	82 (68.3)	19 (15.8)	4 (3.3)	15 (12.5)
Valproic Acid	45 (37.5)	39 (32.5)	11 (9.2)	25 (20.8)
Atorvastatin	42 (35)	43 (35.8)	25 (20.8)	10 (8.3)
Temazepam	52 (43.3)	2 (1.7)	15 (12.5)	51 (42.5)
Response of drug dispensers to use of over-the-counter (OTC) medications				
Paracetamol	19 (15.8)	27 (22.5)	67 (55.8)	7 (5.8)
Aspirin	71 (59.2)	19 (15.8)	12 (10)	18 (15)
Ibuprofen	72 (60)	11 (9.2)	30 (25)	7 (5.8)
Caffeine	67 (55.8)	15 (12.5)	15 (12.5)	23 (19.2)
Dextromethorphan	72 (60)	8 (6.7)	17 (14.2)	23 (19.2)
Pseudoephedrine Hydrochloride	72 (60)	22 (18.3)	7 (5.8)	19 (15.8)
Vitamin A	28 (23.3)	10 (8.3)	74 (61.7)	8 (6.7)

The Pearson correlation coefficient (r) between the number of working experiences in the field of drug dispensing and the total knowledge score is 0.110, indicating a very weak positive correlation. Since the p -value (P) is 0.233, which is greater than 0.05, we accept the null hypothesis (H_0). This suggests that there is no statistically significant correlation between working experience and the total knowledge score.

The mean total knowledge score of drug dispensers with a health background (13.19) is higher than those with a non-health background (10.52). The Mann-Whitney U

test results indicate a significant difference between these groups, $U=780$, $Z=-2.643$, 0.008 ($p < 0.05$).

Drug dispensers who always ask female patients about their pregnancy status have a higher mean total knowledge score (14.81) compared to those who often ask (12.03) when it appears the patient might be pregnant (13.09) or never (9.27). The Kruskal-Wallis test results indicate a significant difference among these groups, $H=17.358$, $p=0.001$ ($p < 0.05$). This information is shown in Table 3.

Table 3: Statistical Analysis of Demographic and Behavioral Factors on Knowledge Scores.

Variables	Category	Mean	Median	SD	P-value
Education background	Health	13.19	14	3.45	0.008^{U*}
	Non-health	10.52	9	4.71	
Gender	Male	12.31	13	4.07	0.171 ^U
	Female	13.55	14	3.15	
Drug Category	OTC	76.29	82	18.91	0.938 ^t
	POM	75.54	81	20.64	
Education	Diploma in Pharmacy	13.35	14	3.5	

	Bachelor in Pharmacy	10.5	10.5	0.71	0.167 ^H
	Master in pharmacy	-	-	-	
	Others	12.1	13	4.15	
Age range	15-24years	11.8	12	3.86	
	25-35Years	12.4	13	3.97	0.157 ^H
	36-45Years	14.04	14	3.28	
	46-above	13.25	14	5.19	
Experience range	0-5Years	12.10	13	3.96	
	6-10Years	13.45	14	3.38	0.203 ^H
	11-20Years	13.86	14	3.61	
	21-above	14	17	4.8	
Asking pregnancy status	Always	14.81	15.5	3.27	
	Often	12.03	12	4.02	0.001 ^{H*}
	If looks pregnant	13.29	14	3.20	
	Never	9.27	9	4.32	
^H Kruskal-Wallis. ^U Mann-Whitney U test. ^t Independent t-test					

* Shows significant at p-value 0.05.

DISCUSSION

The results of our survey of drug dispensers emphasize the lack of sufficient information about the known effects on the fetus of medications used during pregnancy and the need to make accurate and up-to-date information about these effects readily available to healthcare providers, including drug dispensers who care for pregnant women.

In this study, it was found that the availability of pharmacists in the community retail pharmacies was only 46.7 %, an indication that more than half of the drug dispensing personnel in the pharmacies were not professionally trained. The results obtained in the present study are similar to those reported by **Kamuhabwa** and his colleagues in Tanzania, in which most (61.2%) drug dispensers were not pharmacists. This might be due to weak enforcement of drug legislation in Nepal.^[18]

In general, among the specific medications asked about, a majority of respondents correctly identified medications with documented teratogenic effects^[19] (Ethinylestradiol, oral contraceptive) as being unsafe for use in the first trimester. A majority also identified medicines that are commonly used in pregnancy (amoxicillin, acetaminophen) as being safe to use in the first trimester. These results were similar to results published by **Ziyad Alrabiah et al.**^[16] However, among the remainder, opinions about safety varied more widely, perhaps reflecting the lack of definitive information available about the effects of these drugs.

Most drug dispensers have poor knowledge of the safety of dietary supplements (Vitamin A and Caffeine). This might be due to a lack of certainty about the effects of these products during pregnancy and a lack of discussion of the safety of these products during training because the **Morgan et al.** study found that residency training about the teratogenic potential of OTC drugs and dietary

supplements and herbal remedies was less than adequate. Morgan et al. study also revealed that most pregnant patients ask about the effects on the fetus of prescription medications. Still, far fewer ask about OTC medications, and fewer yet ask about alternative medications.^[20] This also may contribute to our result.

A large number of drug dispensers don't know about the safety of Temazepam. This might be due to the lack of prescribing and availability of this drug, which shows that drug dispensers rely on physicians for drug information.^[13] Less drug dispenser correctly identifies Atorvastatin as unsafe in the first trimester, which may be due to drug dispensers providing opinions and beliefs rather than evidence-based information.^[8]

There is a very weak positive association between working experience and knowledge of the safety of drugs in pregnancy, which might be due to the lack of interest in drug dispensers in counseling about the risks of medications during pregnancy^[21] and running of pharmacies for profit-driven motives by drug dispensers other than pharmacists.^[22]

This study revealed that drug dispensers have inadequate knowledge in providing information about the safety of medications used during pregnancy. It has been documented that Community pharmacies do not always offer correct advice to pregnant women.^[23] The lack of well-designed, focused didactic training and the scarce availability of continuing education programs about drug usage in pregnancy may contribute to the inadequate knowledge of drug dispensers regarding medication safety during pregnancy.

Limitations

This study has several limitations. Firstly, it was restricted to Dharan city, so the results may not represent drug dispensers in other regions of Nepal. Data

collection occurred over a specific period, capturing only the present situation and not future trends. Additionally, some drug dispensers refused to participate, and some pharmacies were closed during data collection, which may affect the representativeness of the findings. The use of a self-administered questionnaire could also introduce desirability bias. A national study is recommended to confirm these results.

CONCLUSION

Drug dispensers are the most accessible healthcare providers who can help pregnant women with their medication use. Drug dispensers should be aware of medications and dietary supplements used during pregnancy and should be familiar with the risks and benefits of the medication used and provide appropriate drug-related information to pregnant women and healthcare professionals taking care of pregnant women. Although there are some areas where drug dispensers are knowledgeable about drug safety during pregnancy, there are still gaps in knowledge where educational interventions are needed.

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