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Knowledge and practices of pharmacists concerning off-label and on-label drug prescribing during pregnancy and breastfeeding: a study from the Kurdistan region, Iraq

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Abstract

Background: Off-label prescribing during pregnancy and breastfeeding is common due to limited approved medications, but it carries potential risks for both mother and child. Pharmacists play a key role in guiding safe drug use, yet gaps in knowledge and training may affect their ability to counsel effectively. This study was conducted to assess pharmacists' knowledge of on-label and off-label drug use during pregnancy and breastfeeding, and to evaluate their practical recommendations for managing pregnancy-related and lactation-related conditions in Duhok Governorate of Iraq.

Methods: A Cross-sectional survey using questionnaires, carried out in pharmacies across Duhok Governorate between June 2024 and September 2024. Participants from 110 pharmacies were randomly selected, 82 pharmacists agreed to participate and completed a self-administered questionnaire.

Results: Among 82 pharmacists (74.5% response rate), familiarity with off-label prescribing was highest for Metformin (75.6%) and contraceptive pills (57.3%). Common on-label drugs were correctly identified as safe, including Amoxicillin (95.1%) and Methyldopa (89.0%). Pharmacists reported moderate confidence in advising pregnant and breastfeeding women on OTC medications and supplements, though knowledge gaps persisted, particularly for less commonly prescribed drugs and supplements. Many participants also perceived pharmacy college training on pregnancy and breastfeeding care as insufficient.

Conclusion: Pharmacists demonstrate overall awareness and moderate confidence in maternal drug counseling and clinical decision-making; however, gaps in knowledge and limited formal training highlight the need for targeted education and professional development to improve safe medication use during pregnancy and lactation.

Keywords: Off-label Drugs, Pharmacist, Pregnancy, Breastfeeding, On-label drugs, Iraq

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Background

Off-label drug use refers to prescribing medications outside their regulatory approval in terms of indication, dose, route of administration, or patient population, such as children or older adults [1,2]. This practice is common worldwide and remains clinically important, particularly in areas where approved therapeutic options are limited. Recent evidence indicates substantial variability in off-label prescribing, with reported rates including 56% for gabapentinoids in Spain and approximately 21–29% of prescriptions in North America [3,4]. Off-label use is frequently observed in specialties such as oncology, Paediatrics, and obstetrics, reflecting unmet clinical needs and gaps in regulatory labeling [1,4]. However, heterogeneity in definitions and study methodologies limits the ability to generate consistent global prevalence estimates [1,5]. Medication use during pregnancy and lactation is very common, with about 90% of pregnant women using at least one medication for acute or chronic conditions, and around 40% taking supplements [6,7]. However, safety data remain limited due to the ethical restrictions on clinical trials in this population. Consequently, clinicians rely on observational studies and older FDA pregnancy risk categories, which were replaced in 2015 by the Pregnancy and Lactation Labeling Rule (PLLR), providing narrative-based safety information [8,9]. Drugs may harm the fetus through teratogenic effects or by affecting developed organs, leading to metabolic or functional disturbances. Pharmacists play a key role

in ensuring safe medication use during pregnancy as they are often the final point of contact before dispensing [10]. Off-label use may involve treating unapproved populations, indications, or dosing regimens, and is sometimes driven by cost considerations or clinical necessity [11]. Pharmacists play an essential role in ensuring safe and ethical medication use. In several countries, including the United Kingdom and Italy, pharmacists are actively involved in guiding off-label drug use, particularly in pediatrics and oncology [12,13]. Therefore, this study aims to assess the knowledge of pharmacists in Duhok Province, northern region of Iraq, regarding on-label and off-label drug use during pregnancy and lactation, as well as their clinical decision-making and recommendations for the management of common pregnancy-related and breastfeeding-related conditions.

Methods

Study design and Dataset

This was a cross-sectional questionnaire-based survey conducted in Duhok City, northern region of Iraq, between June 2024 and September 2024. The study population comprised all practicing pharmacists employed in community and hospital pharmacies in Duhok City.

Sampling Technique

A sampling frame of registered pharmacies was obtained from the Kurdistan Pharmacists Syndicate. From this list, 110 pharmacies were selected using simple random sampling, and one pharmacist from each selected pharmacy was invited to participate. All licensed practicing pharmacists working in the selected pharmacies were eligible for inclusion.

Study too and data processing

A structured questionnaire consisting of 30 questions was used, including multiple-choice and 1–5 Likert scale items. The questionnaire was divided into four sections: Section 1 collected sociodemographic and professional characteristics; Section 2 assessed knowledge of on-label drug use and over-the-counter (OTC) medications during pregnancy; Section 3 assessed knowledge of off-label drug use during pregnancy; and Section 4 evaluated pharmacists' recommended management approaches for common pregnancy and breastfeeding-related conditions. Participants selected one of three responses for each condition: refer to a physician, dispense medication, or provide advice without dispensing medicine. Face validity of the questionnaire was assessed by three experts from the College of Pharmacy, University of Duhok. A pilot study was conducted on 10 pharmacists, and necessary modifications were made to improve clarity and comprehension. Participation was voluntary, and informed consent was obtained from all participants prior to questionnaire completion. Ethical approval for the study was obtained from the relevant institutional ethics committee. Of the 110 pharmacists invited, 82 completed the questionnaire, yielding a response rate of 74.5%.

Statistical analysis

All data were entered into a database and analyzed using the Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA). Where appropriate, frequencies and percentages were used to summarize the data. For ease of interpretation, responses of "strongly agree" and "agree" were grouped as "agreed," while "strongly disagree" and "disagree" were grouped as "disagreed." The questionnaire primarily consisted of independent knowledge-based items assessing pharmacists' awareness of medication use during pregnancy and breastfeeding rather than a unidimensional scale; therefore, internal consistency reliability testing using Cronbach's alpha was not considered appropriate.

Results

Of 110 pharmacists, 82 (74.5%) agreed to participate in this study. Among the 82 pharmacists surveyed, female participants slightly outnumbered males (53.7% vs. 46.3%). The cohort was predominantly young, with nearly three-quarters aged 20–29 years (72.0%), and their mean age was 34.5 years. Most respondents held a Bachelor of Pharmacy degree (90.2%), while postgraduate qualifications were uncommon. Marital status was relatively balanced, with 52.4% unmarried and 47.6% married. Consistent with the young age distribution, 62.2% reported less than 5 years of professional experience, whereas only a small proportion had ≥10 years of experience. In terms of employment setting, the private sector represented the largest share (37.8%), followed closely by those working in both government and private sectors (36.6%). Regarding practice area, community pharmacy was the dominant field (61.0%), while 34.1% worked in hospital pharmacies and a small minority practiced in other areas (4.9%), as shown in (Table 1).

Table 1: Sociodemographic and professional characteristics of participants (N = 82)

Variable	Categories	N (%)
Gender	Male	38(46.3)
	Female	44(53.7)
Age (Years)	20–29	59(72.0)
	30–39	19(23.2)
	40–49	4(4.8)
Qualification in Pharmacy	Bachelor of Pharmacy	74(90.3)
	Master of Pharmacy	6(7.3)
	Doctor of Pharmacy	2(2.4)
Marital Status	Unmarried	43(52.4)
	Married	39(47.6)
Professional Experience (Years)	< 5	51(62.2)
	6–9	18(22.0)
	10–14	5(6.1)
	≥ 15	8(9.7)
Place of Work	Government	21(25.6)
	Private	31(37.8)
	Both	30(36.6)
Practicing Area	Hospital Pharmacy	28(34.1)
	Community Pharmacy	50(61.0)
	Others	4(4.9)

The majority of pharmacists reported familiarity with off-label prescribing (81.7%), with other sources such as professional experience or continuing education (73.2%), being the main

source of knowledge rather than formal academic training. Off-label drug use was most commonly reported in psychiatry (25.6%), pregnancy (24.4%), and pediatrics (22.0%). The leading reasons for off-label prescribing were supporting clinical trial evidence (35.4%) and physician experience (31.7%), as shown in (Table 2).

Table 2: Knowledge of the Participants about Off-label Prescribing in Different Medical Field Practices (N = 82)

Variable	Categories	N (%)
Familiar with Off-label Prescription	Yes	67(81.7)
	No	15(18.3)
Source of Knowledge	Undergraduate Study	15(18.3)
	Postgraduate Study	7(8.5)
	Other Sources	60(73.2)
Most Common Medical Fields Applying Off-Label Drugs	Psychiatry	21(25.5)
	Pregnancy	20(24.4)
	Pediatric	18(22.0)
	Cancer	18(22.0)
	Cardiac	5(6.1)
Reasons for Off-Label Drug Use	Lack of Labeled Drug	11(13.4)
	Clinical Trials Evidence	29(35.4)
	Physician Experience	26(31.7)
	Conflict of Interest	16(19.5)

Pharmacists most commonly recognized Metformin (75.6%), Aspirin (58.5%), Spironolactone (56.1%), and Contraceptive pills (57.3%) as off-label drugs used during pregnancy, all of which were statistically significant ($p < 0.05$). Awareness was lower for Enoxaparin, Tamoxifen, Vitamin D supplements, and Indomethacin, with many participants reporting “Do Not Know” or no response, indicating gaps in knowledge about off-label prescribing in pregnancy, as shown in (Table 3). Pharmacists widely recognized Amoxicillin (95.1%) and Methyldopa (89.0%) as safe for use during pregnancy, while Isotretinoin (92.7%) and Ciprofloxacin (86.6%) were predominantly considered unsafe. Awareness of safety was moderate for Azithromycin (76.8%) and Budesonide (39.0%), whereas Bactrim, Warfarin, Phenobarbital, and Lamotrigine were largely reported as unsafe or with considerable uncertainty, as shown in (Table 4). Most pharmacists reported being confident in advising pregnant (58.5%) and breastfeeding women (46.3%) and providing guidance on OTC medications for these groups (57.3% and 61.0%, respectively). The majority considered OTC drugs safe during pregnancy (73.2%) and, to a lesser extent, for breastfeeding (56.1%). Awareness of the safety of supplements was moderate, with roughly 38% for pregnancy and 43% for breastfeeding. However, a substantial proportion of pharmacists reported insufficient knowledge to solve health problems during pregnancy (26.8%) and breastfeeding (35.4%), and many felt that pharmacy college training on pregnancy and breastfeeding care was inadequate (30–36.6%), indicating persistent gaps in professional preparedness, as shown in (Table 5). The majority of the participants preferred to dispense medication for some common symptoms during pregnancy, such as Headache, sore throat and dry cough. In contrast, the majority preferred to refer those patients to their physicians for the symptoms such as Swelling of the legs, varicose veins, hemorrhoids and vaginal itching, as shown in (Figure 1).

Discussion

Safe use of medications during pregnancy and breastfeeding requires a comprehensive understanding of risk-benefit profiles for individual treatments. Pharmacists are the final and key professionals in the management of this group of patients, with the responsibility to ensure that medicines are both prescribed and dispensed appropriately. Pharmacists are the "gatekeepers," making sure that all medications, including those prescribed off-label, are prescribed and dispensed correctly. This is made possible by several legislative Acts and laws around the world that give them a say in managing the on-label and off-label use of drugs during pregnancy and in nursing mothers [14]. To our knowledge, this is the first study to be performed in the Kurdistan Region and Iraq concerning the role of pharmacists in health services provided during pregnancy and breastfeeding. The present study may provide baseline data for designing future multifaceted interventions to improve the pharmacists’ role in delivering the proper advice and resolving healthcare problems during gestation and in nursing mothers in the area. Results of this study showed that around 50% of participants were not well equipped to manage medication-related problems during pregnancy. Similar findings have been reported in recent literature, where community pharmacists demonstrated gaps in knowledge and frequently relied on referring patients to physicians when uncertain. For example, a 2024 cross-sectional study found that more than half of pharmacists contacted prescribing physicians when faced with uncertainty regarding medication safety in pregnancy, reflecting limited confidence in independent decision-making [15]. Additionally, previous research has shown that although pharmacists acknowledge their role in counseling pregnant women, their actual practice is often suboptimal, with inadequate questioning and inappropriate recommendations reported in a substantial proportion of cases [16]. A lack of education and training has consistently been identified as a key barrier to effective counselling, highlighting the need for continuous professional development and access to reliable information sources [16,17]. Efforts to improve pharmacists’ participation in managing pregnancy-related health issues have emphasized the importance of structured resources, including evidence-based guidelines and specialized information services. However, current evidence suggests that while pharmacist-led interventions have the potential to improve outcomes, further strengthening of knowledge and clinical support systems is still required [18]. To enable pharmacists to engage actively in managing health problems during pregnancy and lactation, rather than routinely referring patients to physicians, their role as essential members of the healthcare team should be strengthened. In the present study, more than half of participants reported recommending medications for common conditions such as headache, cough, fever, and upper respiratory symptoms, with fewer recommendations for gastrointestinal complaints such as indigestion, nausea, and vomiting.

Table 3: Assessment of Participants' Knowledge and Perceptions of Off-Label Prescribing Across Medical Specialties (N = 82)

Off-Label Drug Prescribed During Pregnancy	Yes	No	Do Not Know	Not Respond	P Value
Metformin	62 (75.6%)	6 (7.3%)	5 (6.1%)	9 (10.9%)	0.03
Spironolactone	46 (56.1%)	12 (14.6%)	15 (18.3%)	9 (10.9%)	
Enoxaparin	32 (39.0%)	27 (32.9%)	13 (15.9%)	10 (12.2%)	
Tamoxifen	32 (39.0%)	23 (28.0%)	18 (22.0%)	9 (11.0%)	
Vitamin D Supplements	34 (41.5%)	27 (32.9%)	13 (15.9%)	8 (9.8%)	
Aspirin	48 (58.5%)	16 (19.5%)	8 (9.8%)	10 (12.2%)	
Indomethacin	16 (19.5%)	31 (37.8%)	25 (30.5%)	10 (12.2%)	
Contraceptive pills	47 (57.3%)	15 (18.3%)	10 (12.2%)	10 (12.2%)	0.023

* Significant Difference at p<0.05

Similar findings have been reported in other studies, where pregnant women frequently presented to community pharmacies with minor ailments including headache, nausea and vomiting, indigestion, and cough, and pharmacists commonly provided pharmacological management for these conditions [19,20]. Additionally, evidence from a systematic review indicates that respiratory, gastrointestinal, and pain-related conditions are the most common minor ailments managed by community pharmacists, with analgesics and cough preparations being the most frequently recommended medications, although the appropriateness of these recommendations varies considerably [21].

Table 4: Assessment of participants' knowledge regarding the clinical use of selected medications during pregnancy (N = 82)

On-label Drugs Prescribed During Pregnancy	Response of the Participating Pharmacists		
	Safe	**Unsafe**	**Not Sure**
Amoxicillin	78 (95.1%)	4 (4.9%)	0 (0.0%)
Ciprofloxacin	8 (9.8%)	71 (86.6%)	3 (3.7%)
Azithromycin	63 (76.8%)	13 (15.9%)	6 (7.3%)
Bactrim	5 (6.1%)	59 (72.0%)	18 (22.0%)
Warfarin	5 (6.1%)	66 (80.5%)	11 (13.4%)
Phenobarbital	4 (4.9%)	64 (78.0%)	14 (17.1%)
Lamotrigine	6 (7.3%)	50 (61.0%)	26 (31.7%)
Budesonide	32 (39.0%)	30 (36.6%)	20 (24.4%)
Isotretinoin	1 (1.2%)	76 (92.7%)	5 (6.1%)
Methyldopa	73 (89.0%)	4 (4.9%)	5 (6.1%)

Furthermore, studies have shown that pregnant women often seek pharmacists' advice for symptoms such as headache, nasal congestion, and gastrointestinal discomfort, reinforcing the important frontline role of pharmacists in managing self-limiting conditions during pregnancy [22]. These large differences in pharmacists' practices between countries regarding the services recommended for the treatment of pregnancy health problems could be due to the differences in the health system, academic background of the pharmacists, patient health education and the availability of products at the local pharmacies.

Table 5: Eligibility of participants in taking care of pregnant and breastfeeding women (N = 82)

Pharmacist Opinions on Pregnancy and Breastfeeding	Response of the Participating Pharmacists		
	Disagree	**Neutral**	**Agree**
Provide Advice on OTC for Pregnant Women	8 (9.8%)	27 (32.9%)	47 (57.3%)
Provide Advice on OTC for Breastfeeding Women	9 (11.0%)	23 (28.0%)	50 (61.0%)
Should Recommend OTC for Pregnant Women	21 (25.6%)	27 (32.9%)	34 (41.5%)
Should Recommend OTC for Breastfeeding Women	18 (22.0%)	27 (32.9%)	37 (45.1%)
OTC are Safe in Pregnancy	60 (73.2%)	17 (20.7%)	5 (6.1%)
OTC are Safe for Breastfeeding	46 (56.1%)	22 (26.8%)	14 (17.1%)
Supplements are Safe During Pregnancy	23 (28.0%)	28 (34.1%)	31 (37.8%)
Supplements are Safe for Breastfeeding	16 (19.5%)	31 (37.8%)	35 (42.7%)
Confident in Advising Pregnant Women	8 (9.8%)	26 (31.7%)	48 (58.5%)
Sufficient Knowledge to Solve Health Problems During Pregnancy	24 (29.3%)	36 (43.9%)	22 (26.8%)
Confident in Advising Breastfeeding Women	12 (14.6%)	32 (39.0%)	38 (46.3%)
Sufficient Knowledge to Solve Health Problems in Breastfeeding	18 (22.0%)	35 (42.7%)	29 (35.4%)
Pharmacy College Provide Appropriate Training for Pregnancy Care	39 (47.6%)	18 (22.0%)	25 (30.5%)
Pharmacy College Provide Appropriate Training for Breastfeeding	34 (41.5%)	18 (22.0%)	30 (36.6%)

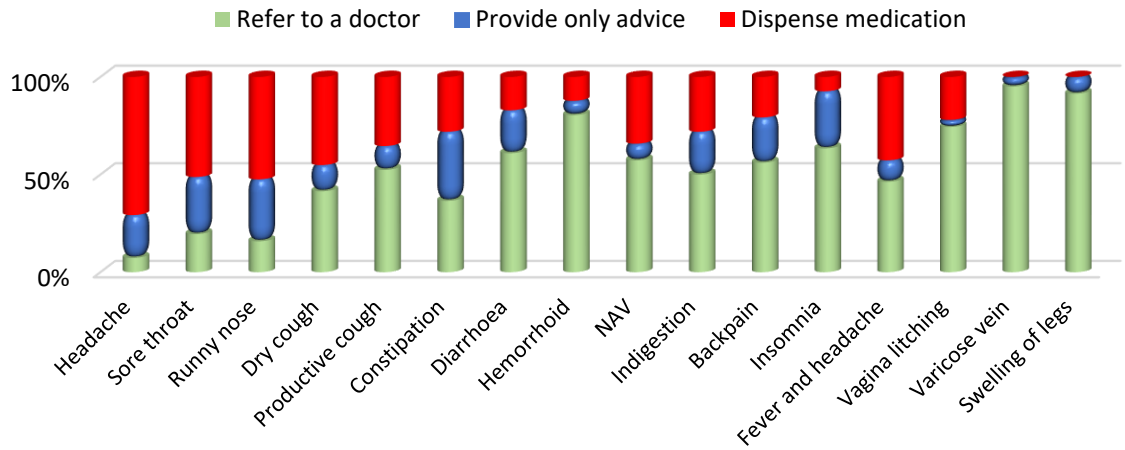

Figure.1: Response of the participants to the most common symptoms during pregnancy (n=82)

In this study, medication recommendations for the management of symptoms during pregnancy were occasionally inappropriate. This may be attributed to limited professional experience and insufficient training, as many participants reported that their undergraduate education did not adequately prepare them to manage pregnancy- and breastfeeding-related health problems. Similar findings have been reported in recent studies, where community pharmacists demonstrated gaps in knowledge and provided suboptimal counseling, often due to inadequate clinical training and limited confidence in assessing medication safety during pregnancy [15,17]. Furthermore, in the present study, most pharmacists demonstrated familiarity with off-label prescribing across various medical areas, including pregnancy and breastfeeding, indicating a generally strong awareness of this practice. This finding is consistent with international evidence, where high levels of familiarity have also been reported across different regions, including Sudan and the United States, where pharmacists show a substantial level of awareness of off-label prescribing practices [23,24]. When assessing specific knowledge of off-label medications in pregnancy, participants demonstrated higher awareness of commonly used or well-established drugs such as metformin, aspirin, and contraceptive pills. However, significant knowledge gaps were observed for medications including indomethacin, enoxaparin, and tamoxifen, indicating limited familiarity with less frequently used or more specialized therapies. This pattern is consistent with previous studies reporting better recognition of commonly prescribed medications but inadequate understanding of higher-risk or less familiar drugs requiring advanced pharmacological knowledge [15,16]. In addition, pharmacists showed strong recognition of clearly contraindicated drugs such as isotretinoin and warfarin, as well as widely accepted safe medications like amoxicillin and methyldopa. This aligns with recent evidence, including a 2024 study, demonstrating that pharmacists generally perform well in identifying drugs with well-established safety or teratogenic profiles, although knowledge remains inconsistent across different pharmacological categories [15]. Further research is needed to improve pharmacists' services for pregnant and breastfeeding women, particularly in developing countries where prescription control is limited. Strengthening undergraduate education and continuous professional development is essential to address existing knowledge gaps. Although pharmacists showed reasonable awareness of off-label prescribing and basic drug safety in pregnancy, their clinical application remains inconsistent due to reliance on non-academic sources and limited experience. Improving access to reliable, evidence-based resources is crucial to ensure safe and effective maternal counseling.

Conclusion

Although pharmacists demonstrated good awareness of off-label prescribing, their clinical preparedness to manage medication use during pregnancy and breastfeeding remains inadequate. Reliance on non-academic sources and inconsistent understanding of medications with complex safety profiles raise concerns about the reliability of clinical recommendations. These findings highlight a clear gap between theoretical awareness and practical application, emphasizing the need for strengthened pharmacy education, structured continuing professional development, and improved access to evidence-based resources to support safe and effective maternal healthcare.

Abbreviation

USA: United States of America; FDA: Food and Drug Administration; PLLR: Pregnancy and Lactation Labeling Rule; OTC: Over-the-Counter

Declaration

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Availability of data and materials

Data will be available by emailing zana.sabri@nawroz.edu.krd

Authors' contributions

Hishyar Mohammed Salih Garmavy contributed to the conception and design of the study, proposal development, and statistical analysis. Zana Sabri Qasim and Slaviya Khaleel Khalaf contributed to data collection. Darya Salih Hussein contributed to data organization and assisted in manuscript preparation. All authors contributed to drafting the manuscript and revising it critically for important intellectual content, and all authors approved the final version for publication.

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee of the College of Pharmacy, University of Duhok, Kurdistan Region of Iraq. Written informed consent was obtained from all participants prior to data collection.

Consent for publication

Not applicable

Competing interest

The author declares that he has no competing interests.

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