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A Prospective Study to Evaluate Drug Utilization Pattern and Adverse Drug Reactions in Pregnant Females at Government Medical College in Eastern Uttar Pradesh

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ABSTRACT

Background: Drug utilization studies are important for evaluating prescribing practices and promoting rational and safe medication use during pregnancy. Physiological changes during pregnancy can alter drug pharmacokinetics and pharmacodynamics and may increase susceptibility to adverse drug reactions (ADRs). However, region-specific data on drug utilization and ADRs among pregnant women in Eastern Uttar Pradesh remain limited.
Objective: To evaluate drug utilization patterns and ADRs among pregnant women attending a tertiary care teaching hospital in Eastern Uttar Pradesh, with assessment of comorbidities, concomitant medication use, pregnancy outcomes, and medication-related clinical characteristics.
Methods: A prospective observational study was conducted from July 2022 to December 2023 in the outpatient and inpatient departments of Government Medical College, Azamgarh, Uttar Pradesh. A total of 168 pregnant women aged 18–35 years with ultrasonographically confirmed intrauterine pregnancy were enrolled consecutively after providing written informed consent. Demographic and clinical characteristics, comorbidities, prescribed medications, dosage, route, frequency, duration, concomitant medications, and treatment-related information were recorded using a structured case record form. Drug utilization was assessed using World Health Organization prescribing indicators. Participants were prospectively monitored for suspected ADRs during pregnancy and for six months postpartum. Data were analyzed descriptively using SPSS version 23.
Results: The mean age of participants was 27.30 ± 3.38 years, and the mean body weight was 59.40 ± 7.89 kg. Anaemia and hypothyroidism were among the most frequently documented comorbid conditions. Iron, folic acid, and calcium were prescribed to all participants, while their combined use constituted the most frequently observed regimen (56.5%). The mean number of drugs prescribed per prescription was 3.55 ± 1.29. Normal vaginal delivery occurred in 89.3% of participants, whereas 9.5% underwent lower-segment caesarean section and 1.2% experienced abortion. Suspected ADRs were reported in 10 participants (5.95%), with skin rash

being the most frequently observed reaction (1.8%), followed by vomiting, nausea, and injection-site redness (1.2% each).

Conclusion: Drug utilization in this cohort predominantly comprised routine antenatal supplementation and medications used according to documented clinical requirements. The observed frequency of suspected ADRs was low and the reported reactions were predominantly mild. Continued pharmacovigilance and systematic evaluation of medication safety during pregnancy are warranted.

Keywords: Drug Utilization; Pregnancy; Pregnant Women; Drug-Related Side Effects and Adverse Reactions; Pharmacovigilance; Antenatal Care.

INTRODUCTION

Pregnancy is a unique physiological state characterized by profound anatomical, hormonal, metabolic, and pharmacokinetic changes that influence maternal health and fetal development. Although pregnancy is a normal biological process, many women require pharmacological treatment for pre-existing illnesses, pregnancy-related complications, nutritional deficiencies, and acute infections. Prescribing medications during pregnancy is particularly challenging because every therapeutic decision must balance maternal benefit against potential fetal risk. Consequently, rational drug use during pregnancy remains an important component of quality maternal healthcare and requires continuous evaluation to ensure the safety of both mother and fetus. [1,2,3]

The World Health Organization (WHO) defines drug utilization research as the systematic study of the marketing, distribution, prescription, and use of medicines within a population, with particular emphasis on their medical, social, and economic implications. Drug utilization studies provide valuable information regarding prescribing practices, polypharmacy, generic prescribing, utilization of essential medicines, and adherence to standard treatment guidelines. These studies also help identify irrational prescribing patterns and contribute to improving the quality, safety, and cost-effectiveness of healthcare services. [1,4,5]

Pregnancy induces several physiological changes that significantly alter drug pharmacokinetics and pharmacodynamics. Increased plasma volume, altered plasma protein binding, enhanced renal clearance, changes in hepatic enzyme activity, and delayed gastric emptying influence drug absorption, distribution, metabolism, and elimination. Furthermore, fetal susceptibility to medications varies according to gestational age, with the first trimester representing the most critical period because organogenesis occurs during this phase. Exposure to teratogenic drugs during early pregnancy may result in congenital malformations, spontaneous abortion, fetal growth restriction, or long-term developmental abnormalities. [2,6,7]

Medication use during pregnancy is often unavoidable for the management of conditions such as iron-deficiency anaemia, urinary tract infections, gestational diabetes mellitus, hypertensive disorders, thyroid disorders, epilepsy, asthma, and nausea and vomiting of pregnancy. Iron, folic acid, and calcium supplementation constitute the cornerstone of routine antenatal care and have been consistently reported as the most frequently prescribed medications in pregnant women. However, inappropriate prescribing, unnecessary polypharmacy, empirical antibiotic use, and self-medication continue to remain important concerns, particularly in developing countries. [8,9,10,11]

Historically, the United States Food and Drug Administration (USFDA) classified drugs into pregnancy risk categories A, B, C, D, and X according to available evidence regarding fetal safety. Although this system has now been replaced by the Pregnancy and Lactation Labeling Rule (PLLR), these categories continue to be widely cited in research and clinical practice. Classification

of medications according to pregnancy safety categories assists clinicians in selecting the safest therapeutic options while minimizing fetal risk. [12,13]

Adverse drug reactions (ADRs) during pregnancy represent another major concern because physiological alterations and multiple drug exposure may increase maternal susceptibility to medication-related adverse effects. Systematic pharmacovigilance plays a pivotal role in early detection, documentation, and prevention of ADRs, thereby improving medication safety. However, ADR reporting among pregnant women remains inadequate due to under-reporting, limited awareness, and insufficient pharmacovigilance infrastructure, especially in resource-limited settings. [14,15]

India contributes substantially to the global burden of pregnancies and maternal healthcare. Drug utilization studies conducted across different regions of the country have demonstrated considerable variations in prescribing practices due to differences in disease prevalence, healthcare accessibility, socioeconomic factors, and institutional treatment protocols. Although several studies have evaluated prescription patterns among pregnant women, comprehensive prospective studies simultaneously assessing drug utilization patterns and adverse drug reactions remain limited, particularly in government healthcare institutions serving rural and semi-urban populations. [9,10,16,17,18]

Eastern Uttar Pradesh has distinct demographic and healthcare characteristics, including a predominantly rural population, nutritional deficiencies, and a high prevalence of pregnancy-related complications requiring pharmacological intervention. However, region-specific data on prescribing patterns, co-morbidities, medication safety, adverse drug reactions, and treatment costs among pregnant women are scarce. Most available studies have focused primarily on prescription patterns without integrating pharmacovigilance outcomes or evaluating WHO prescribing indicators. This lack of comprehensive local evidence represents an important research gap.

Therefore, the present prospective observational study was undertaken to evaluate drug utilization patterns and adverse drug reactions among pregnant women attending a Government Medical College in Eastern Uttar Pradesh. In addition to assessing WHO prescribing indicators, the study evaluated co-morbid conditions, concomitant drug use, ADR-related hospital admissions, duration of hospital stay, and direct treatment costs. The findings are expected to provide region-specific evidence to promote rational prescribing, strengthen pharmacovigilance activities, encourage the use of essential medicines, and improve the quality and safety of maternal healthcare.

MATERIALS AND METHODS

A prospective, observational study was conducted in collaboration between the Department of Obstetrics and Gynaecology and the Department of Pharmacology at Government Medical College (GMC), Azamgarh, Uttar Pradesh, from July 2022 to December 2023. The study was carried out in the outpatient (OPD) and inpatient (IPD) departments to evaluate drug utilization patterns, adverse drug reactions (ADRs), co-morbid conditions, concomitant drug use, frequency of ADR-related hospital admissions, duration of hospital stay, and direct treatment costs among pregnant women. The study was approved by Institutional Ethics Committee (GMCA/2021-22/IEC-002/Pharm-002).

A total of 168 pregnant women were enrolled in the study. The sample size was calculated using the standard single-population proportion formula, ($n=Z^2p(1-p)/d^2$), where ($Z = 1.96$), corresponding to a 95% confidence level; ($p = 0.875$) (87.5%) was the expected proportion of pregnant women receiving at least one medication, based on a previously published drug-utilization study [19]; and ($d = 0.05$) (5%) was the allowable absolute precision. Accordingly, the calculated sample size was (n =

$(1.96)^2 \times 0.875 \times 0.125 / (0.05)^2 = 168.07$), which was rounded to a minimum required sample size of 168 participants. The study subsequently enrolled 168 pregnant women.

Pregnant women aged 18–35 years with ultrasonographically confirmed intrauterine pregnancy who provided written informed consent were included. Women younger than 18 years or older than 35 years, those without ultrasonographic confirmation of pregnancy, critically ill patients, and those unwilling to participate were excluded.

After obtaining approval from the Institutional Ethics Committee, eligible participants were recruited consecutively. Demographic characteristics, obstetric and medical history, co-morbid conditions, prescribed medications, dosage, route, frequency, duration, concomitant medications, and direct treatment costs were documented using a structured Case Record Form (CRF). Drug utilization was evaluated using the World Health Organization (WHO) prescribing indicators.[5]

Participants were prospectively monitored throughout pregnancy for suspected ADRs, which were documented and reported to the Adverse Drug Reaction Monitoring Centre under the Pharmacovigilance Programme of India (PvPI). Medication adherence was assessed through treatment history and pill counts. Follow-up visits were scheduled every six weeks until completion of the second trimester, monthly until the eighth month, weekly until delivery, and continued for six months postpartum to detect delayed ADRs.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 23.0. Continuous variables were summarized as mean ± standard deviation (SD), whereas categorical variables were presented as frequencies and percentages. Descriptive statistical analysis was performed to characterize the demographic and clinical profiles of the participants, patterns of medication use, comorbidities, pregnancy outcomes, and reported adverse drug reactions (ADRs). The mean number of drugs prescribed per prescription and the distribution of individual medications were also summarized descriptively. As the study was designed primarily to describe drug utilization patterns and the occurrence and characteristics of ADRs, no predefined comparative hypothesis between study groups was evaluated; therefore, no inferential statistical tests were performed. Accordingly, p-values and measures of statistical significance were not applicable. All analyses were based on the 168 enrolled participants.

RESULTS

A total of 168 pregnant women were included in the study. The majority belonged to the 26–30 years age group (44.0%), followed by 21–25 years (33.3%) and 31–35 years (22.7%). The mean age was 27.30 ± 3.38 years, while the mean body weight was 59.40 ± 7.89 kg. Most participants (89.9%) had no significant past medical history, whereas 8.9% had a previous lower segment caesarean section (LSCS) and 1.2% had hypertension.

Regarding clinical diagnosis, antenatal care (ANC) without associated disease (20.8%), ANC with anaemia (20.8%), and ANC with hypothyroidism (20.8%) were the most common presentations, followed by urinary tract infection (9.5%) and vomiting (8.3%). Anaemia assessment revealed that 41.7% of women had normal haemoglobin levels, while 37.5%, 17.8%, and 3.0% had mild, moderate, and severe anaemia, respectively. Thyroid function assessment showed normal TSH levels (≤2.5 mU/L) in 53.5% of participants, while 31.0% had TSH levels of 2.51–4.5 mIU/L, 14.3% had mildly elevated levels of TSH (4.51–10.0 mIU/L), and 1.2% had markedly raised TSH levels (>10.0 mIU/L). **(Figure 1)**.

Table 1: Number of drugs

Number of Drug	Given Regimen	Frequency (n-168)	Percentage
3	Iron, Folic Acid, Calcium	95	56.5%
4	Iron, Folic Acid, Calcium, disodium hydrogen citrate	14	8.3%
	Iron, Folic Acid, Calcium, Paracetamol	13	7.7%
	Iron, Folic Acid, Calcium, Doxylamine	8	4.8%
	Iron, Folic Acid, Calcium, Lactulose	5	3.0%
	Iron, Folic Acid, Calcium, clotrimazole	3	1.8%
	Iron, Folic Acid, Calcium, Olopatadine	3	1.8%
	Iron, Folic Acid, Calcium, Iron Sucrose	2	1.2%
	Iron, Folic Acid, Calcium, Labetalol	2	1.2%
	Iron, Folic Acid, Calcium, Montelukast	2	1.2%
	Iron, Folic Acid, Calcium, ORS	2	1.2%
	Iron, Folic Acid, Calcium, Ranitidine	2	1.2%
5	Iron, Folic Acid, Calcium, Azithromycin, Paracetamol	6	3.6%
	Iron, Folic Acid, Calcium, Doxylamine, Ranitidine	4	2.4%
	Iron, Folic Acid, Calcium, Doxylamine, Clotrimazole	2	1.2%
	Iron, Folic Acid, Calcium, Doxylamine, Ondansetron	2	1.2%
	Iron, Folic Acid, Calcium, Paracetamol, Ranitidine	1	0.6%
6	Iron, Folic Acid, Calcium, Alkasol, Doxylamine, Ranitidine	2	1.2%

The average number of drugs prescribed per patient was 3.55, with a standard deviation of 1.29 drugs. This indicates that the number of drugs prescribed varies among patients, with some receiving as few as 3 drugs and others receiving up to 6 drugs per prescription.

Iron, folic acid, and calcium constituted the most frequently prescribed regimen (56.5%).

The average number of drugs prescribed per prescription was 3.55 ± 1.29, ranging from three to six medications (**Table 1**). Vaginal delivery was the predominant pregnancy outcome (89.3%), while 9.5% underwent LSCS and 1.2% experienced abortion.

Table 2: Distribution of studied patients based on pattern of drug prescribing during pregnancy

Drugs prescribed during pregnancy		Frequency (n-168)	Percentage
Supplement	Iron	168	100.0%
	Folic Acid	168	100.0%
	Calcium	168	100.0%
NSAIDs	Paracetamol	20	11.9%
Anti-emetics	Ondansetron	2	1.2%
	Doxylamine	18	10.7%
Laxative	Lactulose	5	3.0%
Allergic Conjunctivitis	Olopatadine	3	1.8%
Urine Alkalizer	Disodium hydrogen citrate	16	9.5%
PPIs and H2 blockers	Ranitidine	9	5.4%
Antibiotics/Antifungal	Azithromycin	6	3.6%
	Clotrimazole	5	3.0%
Anti – Hypertensive Agent	Labetalol	2	1.2%
Anti-allergic	Montelukast	2	1.2%

All participants received iron, folic acid, and calcium supplementation (100%). Other commonly prescribed medications included paracetamol (11.9%), doxylamine (10.7%), disodium hydrogen citrate (9.5%), ranitidine (5.4%), azithromycin (3.6%), lactulose (3.0%), clotrimazole (3.0%), ondansetron (1.2%), labetalol (1.2%), and montelukast (1.2%) (**Table 2**).

Adverse drug reactions were infrequent, with skin rash being the most common (1.8%), followed by vomiting, nausea, and injection-site redness (1.2% each), while vaginal irritation was reported in only 0.6% of

participants (**Figure 2**). Overall, the findings indicate predominantly rational prescribing practices with limited polypharmacy and a low incidence of adverse drug reactions during pregnancy.

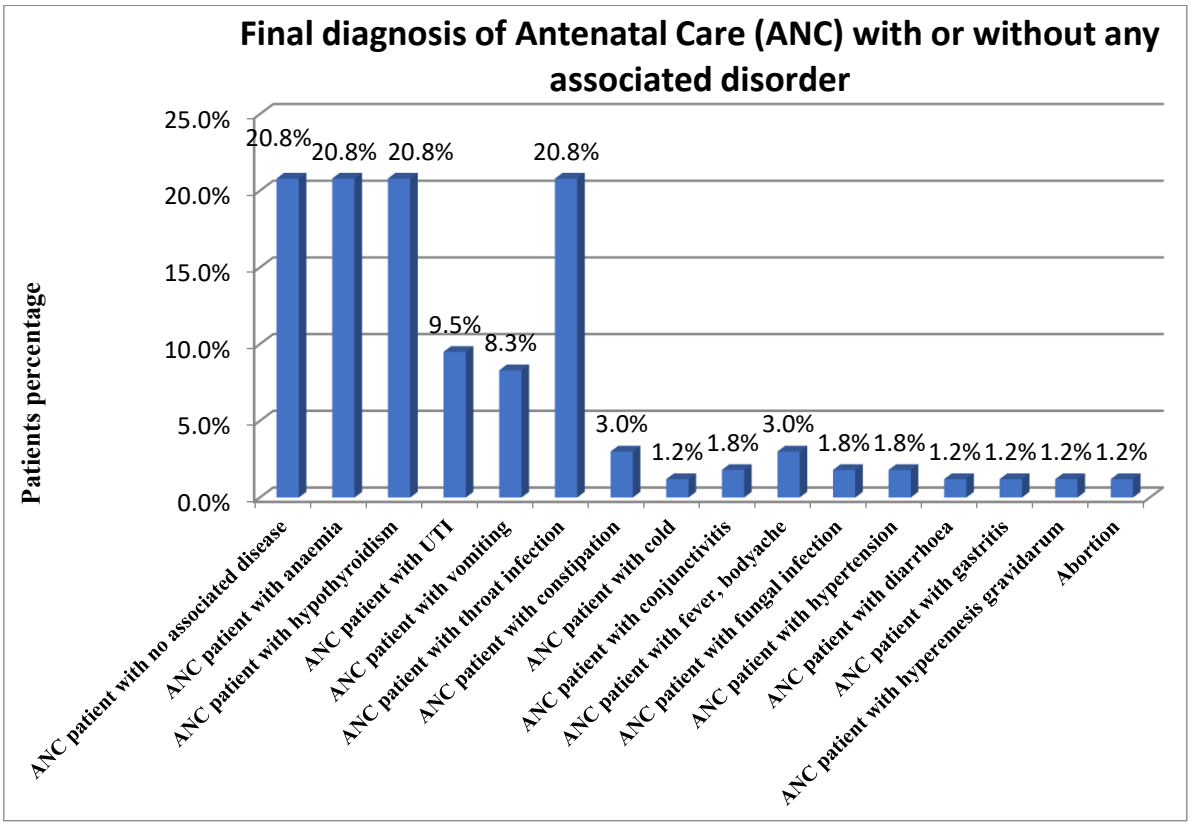

Figure 1: Final diagnosis of Antenatal Care (ANC) with or without any associated disorder

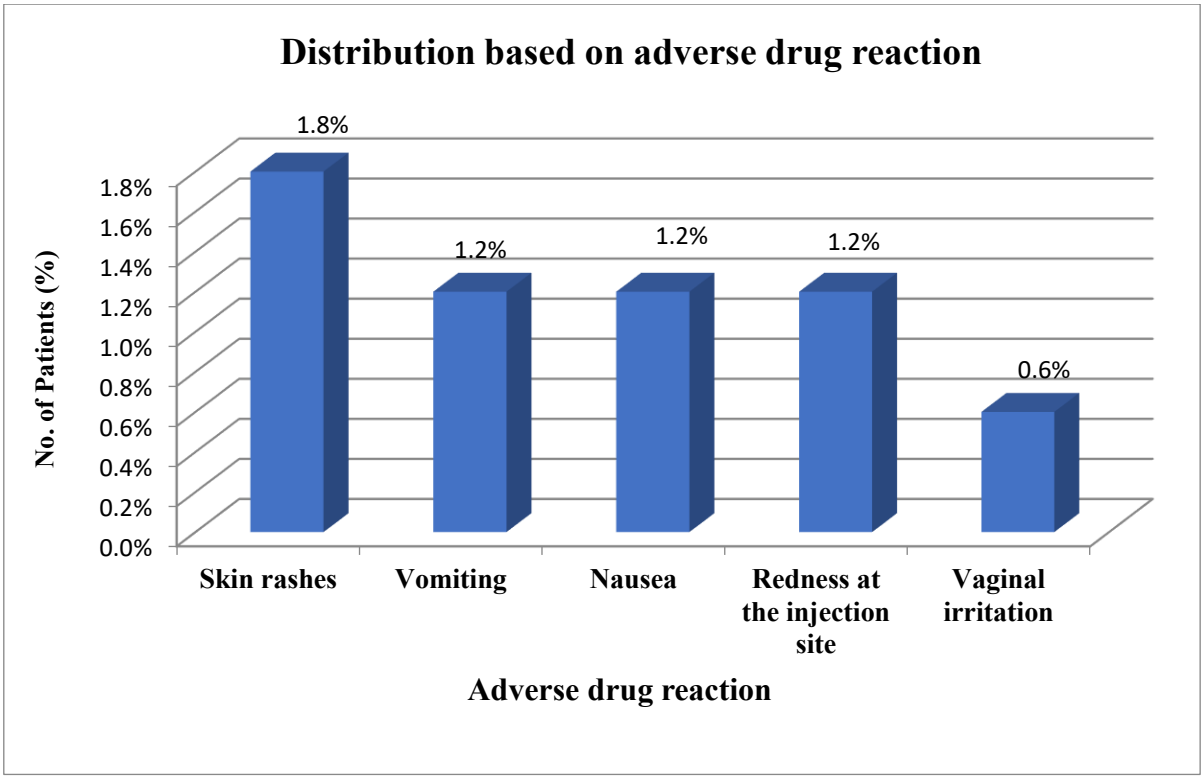

Figure 2: Distribution of studied patients based on adverse drug reaction

DISCUSSION

The present prospective observational study evaluated drug utilization patterns and adverse drug reactions among pregnant women attending a tertiary care teaching hospital in Eastern Uttar Pradesh. The majority of participants belonged to the 26–30 years age group, with a mean age of 27.30±3.38 years. These findings are comparable with those reported by Suthar et al., who observed that most pregnancies occurred in women between 20 and 30 years of age, reflecting the common reproductive age group in developing countries. [8] The absence of significant past medical illness in the majority of participants also indicates a relatively healthy antenatal population.

Anaemia and hypothyroidism were the most frequently observed co-morbid conditions in the present study. Although 41.7% of women had normal haemoglobin levels, a considerable proportion had mild or moderate anaemia, emphasizing the continued burden of nutritional deficiency during pregnancy. Similar observations have been reported in Indian studies where anaemia remains one of the commonest pregnancy-related disorders requiring pharmacological intervention. [10] Routine thyroid screening also enabled early identification and management of hypothyroidism, thereby reducing the risk of adverse maternal and fetal outcomes.

The drug utilization pattern observed in this study demonstrated good adherence to standard antenatal care practices. Iron, folic acid, and calcium supplements were prescribed to all participants, consistent with recommendations of the Government of India and findings reported by Ayesha et al., Selvaraj et al., Bedewi et al., and Fikadu et al., where these supplements constituted the most frequently prescribed medications during pregnancy. [9,10,13,14] The mean number of drugs prescribed per prescription (3.55±1.29) indicated limited polypharmacy and was lower than that reported by Amorha et al., suggesting judicious prescribing practices in the present setting. [16] Additional medications, including antiemetics, antihypertensives, antibiotics, and acid-suppressive drugs, were prescribed only when clinically indicated, reflecting individualized patient management.

The majority of pregnancies resulted in normal vaginal delivery, while only a small proportion required lower segment caesarean section. Furthermore, the incidence of adverse drug reactions was low, with skin rash, nausea, vomiting, injection-site redness, and vaginal irritation being the only reported events. These reactions were mild in nature and did not result in significant morbidity. Similar low incidences of ADRs among pregnant women have been reported by Kureshee et al and Tamirci et al., highlighting that rational prescribing coupled with active pharmacovigilance can substantially improve medication safety during pregnancy. [15,17]

The present study provides valuable region-specific data regarding prescribing trends and medication safety among pregnant women attending a government tertiary care hospital in Eastern Uttar Pradesh. However, the study was limited by its single-centre design and relatively modest sample size, which may limit the generalizability of the findings. Multicentric studies involving larger populations and assessment of fetal and neonatal outcomes would provide more comprehensive evidence regarding medication safety during pregnancy.

CONCLUSION

The present study concludes that prescribing practices among pregnant females at Government Medical College, Azamgarh, were largely rational and appropriate. Iron, folic acid, and calcium were the most commonly prescribed medications and were administered to all patients as routine antenatal supplementation. Other medicines were prescribed according to individual clinical requirements. Adverse drug reactions were observed in only 10 (5.95%) patients and were predominantly mild, with no serious ADRs reported. Overall, the medications used were generally safe and well tolerated. Continuous monitoring,

appropriate risk–benefit assessment, patient counselling, and pharmacovigilance are recommended to ensure optimal maternal and fetal safety.

Declaration by Authors

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REFERENCES

1. World Health Organization. *Introduction to Drug Utilization Research*. Geneva: WHO; 2003.
2. Stephansson O, Granath F, Svensson T, Haglund B, Ekbom A, Kieler H. Drug use during pregnancy in Sweden assessed by the Prescribed Drug Register and the Medical Birth Register. *Clin Epidemiol.* 2011; 3:43–50. doi: 10.2147/CLEP.S16305
3. Das BP, Sarkar C, Datta A, Bohra S. A study of drug use during pregnancy in a teaching hospital in western Nepal. *Pharmacoepidemiol Drug Saf.* 2003; 12(3):221-5. doi: 10.1002/pds.770.
4. Godman B, Wettermark B, Hoffmann M, Andersson K, Haycox A, Gustafsson LL. Multifaceted national and regional drug reforms and initiatives in ambulatory care in Sweden: global relevance. *Expert Rev Pharmacoecon Outcomes Res.* 2009; 9(1):65-83. doi: 10.1586/14737167.9.1.65.
5. World Health Organization. *How to Investigate Drug Use in Health Facilities: Selected Drug Use Indicators*. Geneva: World Health Organization; 1993. Report No.: WHO/DAP/93.1.
6. Briggs GG, Freeman RK, Towers CV, Forinash AB. *Drugs in Pregnancy and Lactation: A Reference Guide to Fetal and Neonatal Risk*. 11th ed. Philadelphia: Wolters Kluwer; 2017.
7. Cunningham FG, Leveno KJ, Dashe JS, Hoffman BL, Spong CY, Casey BM. *Williams Obstetrics*. 26th ed. New York: McGraw-Hill Education; 2022.
8. Suthar J, Patel R. Morbidity pattern and drug prescribing study in pregnant women of rural part of Charotar region. *Indian J Pharm Pract.* 2020;13(4):348-354. DOI: 10.5530/ijopp.13.4.59
9. Ayesha O, Ramya G. Drug utilization pattern during pregnancy in a government maternity hospital – a prospective study. *IOSR J Dent Med Sci.* 2019;18(9 Ser 11):65-77. DOI: 10.9790/0853-1809116577
10. Selvaraj N, Sekar A, Gandhi R, Jayabalan N, Ganesan S, Mohammad MA. Drug utilization pattern in pregnancy at a tertiary care hospital in Puducherry: a cross-sectional observational study. *Int J Basic Clin Pharmacol.* 2018;7(5):900-905. DOI: 10.18203/2319-2003.ijbcp20181632
11. Chaurasiya VR. The pattern of drug uses in pregnant women attending the antenatal clinic of the obstetrics and gynaecology department at a tertiary care hospital. Asian J Pharm Clin Res. 2022;15(9):149-154. doi:10.22159/ajpcr. 2022.v15i9.45028.
12. US Food and Drug Administration, HHS. Content and format of labeling for human prescription drug and biological products; requirements for pregnancy and lactation labeling. Final rule. Fed Regist. 2014;79(233):72063-72103.
13. Bedewi N, Sisay M, Edessa D. Drug utilization pattern among pregnant women attending maternal and child health clinic of a tertiary hospital in eastern Ethiopia: consideration of toxicological perspectives. *BMC Res Notes.* 2018;11(1):858. doi: 10.1186/s13104-018-3966-5
14. Fikadu M, Kebebe D, Amelo W, Gashe F. Drug utilization pattern and potential teratogenicity risk among pregnant women visiting antenatal clinic: the case of a primary hospital. *Indian J Pharm Pract.* 2015; 8(1):27-33. DOI:10.5530/ijopp.8.1.6
15. KureShee NI, Dhande PP. Awareness of mothers and doctors about drug utilization pattern for illnesses encountered during pregnancy. *J Clin Diagn Res.* 2013;7(11): 2470-2474. doi: 10.7860/JCDR/2013/6329.3582
16. Amorha KC, Okonkwo CA. Drug utilization pattern in pregnancy in a tertiary hospital in Ebonyi State, Nigeria: a five-year retrospective analysis. *Afr J Pharm Res Dev.* 2019;11(2):125-136.
17. Tamirci M, Aydin V, Soyalan M, Akici N, Goren MZ, Akici A. Evaluation of the

pregnant women's approaches regarding drug utilization. North Clin Istanb. 2020;8(1):49-56. doi: 10.14744/nci.2020.27003.
18. Emmanuel T, Nair S, Pai MV, Thunga G, Kunhikatta V. Evaluation of the drug utilization pattern among pregnant women in a tertiary care teaching hospital. Indian J Pharm Sci. 2023;85(1):119-127. doi:10.36468/pharmaceutical-sciences.1074.
19. Molla F, Assen A, Abrha S, Masresha B, Gashaw A, Wondimu A, Belete Y, Melkam W. Prescription drug use during pregnancy in Southern Tigray region, North Ethiopia. BMC Pregnancy Childbirth. 2017;17(1):170. doi: 10.1186/s12884-017-1359-8.

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