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An Observational Study on Drug Utilization Pattern in Pregnant Women

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ABSTRACT: This Observational study evaluated drug utilization patterns among 250 pregnant women attending OPD and IPD over a period of 4 months. Drug safety was assessed using FDA pregnancy categories and PLLR(Pregnancy and lactation labelling rule) guidelines. Most participants were in the second trimester and belonged to the 28-32 years age group. Common conditions included hypothyroidism, hypertension, and diabetes. Nutritional supplements such as iron, folic acid, and calcium were commonly prescribed Most medications belonged to FDA categories A, B, and C. The study highlights safe and evidence-based prescribing practices during pregnancy.

KEYWORDS: Pregnancy, Drug Utilization Pattern, FDA Pregnancy categories, Nutritional Therapy, Hormonal Therapy, PLLR(Pregnancy and lactation labelling rule).

I. INTRODUCTION

Pregnancy is unique physiological condition associated with various anatomical, hormonal and metabolic changes that support fetal growth and maternal adaptation. During pregnancy, women are often exposed to several medication for the management of pre-existing illnesses, pregnancy related complications, and nutritional deficiencies. Drug utilisation during pregnancy requires careful considerations because certain medications may adversely affect fetal development, especially during organogenesis.[1]

Studies have shown that a large proportion of pregnant women receive one or more medication apart from routine nutritional supplements. Appropriate prescribing during pregnancy is therefore essential to ensure maternal wellbeing while minimizing fetal risk. Historical incidents such as thalidomide induced congenital malformations highlighted the importance of evaluating drug safety during pregnancy and lead to the development of the united states food and drug administration(FDA) pregnancy risk classification system.[2]

Nutritional supplementation with iron, folic acid, calcium and vitamins plays crucial role in preventing maternal anemia, neural tube defects, and other pregnancy related complications.[3]

In addition, conditions such as hypertension, gestational diabetes mellitus, hypothyroidism, infections, and hyperemesis gravidarum frequently require pharmacological intervention during pregnancy.[4]

Drug utilization studies in pregnant women help in assessing prescribing trends, rationality of therapy, and adherence to established safety guidelines such as FDA pregnancy categories and lactation labeling rule(PLLR). Such studies contribute to promoting evidence based prescribing practices and improving maternal and fetal outcomes. Therefore, the present study was undertaken to evaluate the drug utilization pattern among pregnant women attending a tertiary care hospital.

VITAMIN AND MINERAL	PREGNANCY (RDI)
Folic acid	600 microgram / day
Iron	27mg/day
Calcium	1000mg/day
Vitamin D	5 microgram / day= 200 IU
Iodine	220 microgram/day
Vitamin A	800 microgram/day
Vitamin B12	2.6 microgram/day

HORMONES IN PREGNANCY

HUMAN CHORIONIC GONADOTROPIN (HCG)	hCG is synthesized by the placenta shortly after implantation. It maintains the corpus luteum, ensuring continued production of progesterone during early pregnancy. hCG levels rise rapidly in the first trimester and are the basis for most pregnancy tests.
PROGESTERONE	Progesterone is produced by the corpus luteum; the placenta takes over production around the 10th week of pregnancy. It maintains the uterine lining for implantation, reduces uterine

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	contractions to prevent premature labor, and supports breast tissue development for lactation.
ESTROGEN	Estrogen primarily produced by the placenta during pregnancy. it stimulates uterine growth, enhances blood flow to uterine vessels, and supports fetal organ development. Estrogen also plays a role in preparing the breasts for milk production.
INSULIN	Pregnancy induces increased insulin resistance to ensure a steady supply of glucose to the fetus. To compensate, the maternal pancreas increases insulin production. If this balance is disrupted, it can lead to gestational diabetes.
OXYTOCIN	Oxytocin secreted by the posterior pituitary gland. it triggers uterine contractions during labor and promotes milk ejection during breastfeeding. Oxytocin levels rise at the onset of labor, facilitating childbirth.

FDA DRUG RISK CATEGORIES

FDA ESTABLISHED DRUG RISK CATEGORY FOR PREGNANT WOMEN [10][12]

In 1979, the FDA established five letter risk categories – A, B, C, D or X – to indicate the potential of a drug to cause birth defects if used during pregnancy

CATEGORY DESCRIPTION

Category A-Controlled studies in women fail to demonstrate a risk to the fetus in the first-trimester, there is no evidence of a risk in later trimesters and the possibilities on the fetal harm appears remote. E.g. Folic acid supplements, Prenatal vitamins, Acetaminophen (Tylenol)

Category B- Either animal reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women or animal reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester and there is no evidence of a risk in later trimesters. E.g. Ibuprofen, (Advil, Motrin), Naproxen (Aleve), Cephalexin (antibiotic)

Category C-Either studies in animals have revealed adverse effect on the fetus (teratogenic, embryological, or other) and there are no controlled studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus. E.g. Fluoxetine (Prozac, antidepressant), Metformin (Glucophage, diabetes

Category D-There is positive evidence of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life threatening situation or a serious disease for which safer drugs cannot be used or are ineffective). E.g. Isotretinoin (Accutane, acne), Lithium (mood stabilizer), Valproate (Depakote)

Category X- Studies in animals or human beings have demonstrated fetal abnormalities, or there is evidence of fetal risk based on human experience or both and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug being contraindicated in women who are or may become pregnant. E.g. Thalidomide, Misoprostol, Methotrexate (chemotherapy)

The A, B, C, D and X risk categories, in use since 1979, are replaced with narrative sections and subsections to include:

Pregnancy (includes Labor and Delivery):
- Pregnancy Exposure Registry
- Risk Summary
- Clinical Consideration
- Data

Lactation (includes Nursing Mothers)
- Risk Summary
- Clinical Considerations
- Data

Females and Males of Reproductive Potential
- Pregnancy Testing
- Contraception
- Infertility

THE PREGNANCY AND LACTATION LABELLING RULE

1: Pregnancy Sectionq

Example: Hydrocodone (Vicodin): “There are no adequate and well-controlled studies in pregnant women.”

Sertraline (Zoloft): “Pregnancy exposure registry available.”

2: Lactation Section

Example: Metformin (Glucophage): “Breastfeeding not recommended.”

Ibuprofen (Advil): “Use caution when breastfeeding.”

3: Females and Males of Reproductive Potential

Example: Fluoxetine (Prozac): “Pregnancy testing recommended before starting treatment.”

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(3) METHODOLOGY

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- STUDY SITE:

This study was conducted at Akanksha Hospital & Research Institute Anand, Gujarat.

- SOURCE OF DATA:

Patient case file, hospital records.
Related Approval:
All the clinical data of Pregnant women

- DURATION OF STUDY:

The study was conducted for the duration of 6 months after getting ethical approval from the Institutional Ethics Committee Charusat.

- STUDY DESIGN:

Observational study.

- NO. OF SAMPLES COLLECTED: 250

- MATERIALS REQUIRED:

Patient information sheet
Informed consent form
Data collection form

- STUDY CRITERIA:

Inclusion

- Pregnant women within the Age of 18-45.
- Pregnant Women who conceived Naturally and IVFs.
- All the women who are pregnant and in their 2nd and 3rd trimester.
- Pregnant women who have been prescribed or are currently taking any medication.
- Pregnant women who have provided informed consent.
- All pregnant women with or without comorbidities.

Exclusion

- Pregnant women who have not provided informed consent form.
- Pregnant women with incomplete medical records.

METHOD OF STUDY:

- This study was initiated after getting the approval from IRB & Institute Ethics Committee.
- All pregnant women who conceived naturally, within age of 18-45 years attending OPD and IPD of our study site, during the study period of 4 months were included in the study after taking informed consent.
- All the demographic and clinical information of patients were filled in predesign data collection form
- To observe drug utilization pattern in pregnant women, the FDA PREGNANCY Category and PREGNANCY & LACTATION LABELING RULE (PLLR) were used.

STATISTICAL ANALYSIS:

All the collected data were recorded into Microsoft excel After checking, and systematically analyzed to identify drug utilization patterns among pregnant women, all statistical analyses were conducted using Microsoft excel, all the quantitative data were represented in percentage (%), means and numbers.

OBSERVATIONS AND RESULTS

Variables and characteristics of participants

Variables	Characteristics	No. of patients
AGE	*18-22*	7
	23-27	66
	28-32	99
	33-37	55
	38-42	21
	43-45	2
BMI	<18	11
	18.8-24.9	80
	25-29.9	92
	30-34.9	54
	35-39.9	11
	>40	7

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2ND TRIMESTER	160	
3RD TRIMESTER	90	
PRIMIGRAVIDA	1	157
SECONDARY-GRAVIDA	2	39
MULTI-GRAVIDA	3	17
	4	8
	5	4
	6	0
	7	1
	8	0
	9	0
	10	0
	11	1

Distribution of Pregnant Women According to Age, Body Mass Index, Trimester, and Gravida

CATEGORIES	NO. OF DRUGS
A	800
B	110
C	249
D	32
X	249
Total DRUGS	1440

Presenting problems during pregnancy according to 2nd and 3rd trimester

PRESENTING PROBLEMS DURING PREGNANCY	2nd TRIMESTER	3rd TRIMESTER	No. of patients
HYPOTHYROIDISM	13	15	28
NAUSEA & VOMITING	16	9	25

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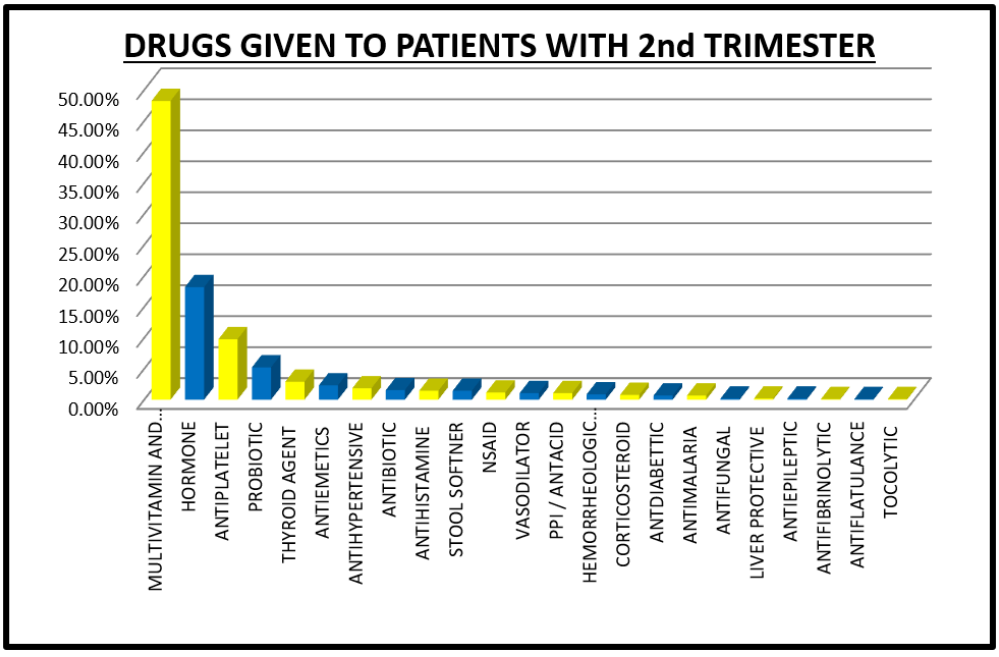
	PEDAL EDEMA	2	1	3
	PNEUMONIC INFILTRATE	1	0	1
	FEVER	9	5	14
	UTI	2	1	3
	PV SPOTTING	8	2	10
	PLACENTA PREVIA	2	1	3
	HTN	8	10	18
	HORMONAL DISORDER	1	1	2
	GESTATIONAL DIABETES	3	1	4
	MALARIA	1	1	2
	HEARTBURN	5	5	10
	CANDIDIASIS(FUNGAL INFECTION)	1	0	1
	DYSLIPIDEMIA	1	0	1
	LEAKING OF AMNIOTIC FLUID	1	0	1
	WEAKNESS\BODY ACHE	8	9	17
	ABDOMINAL PAIN	7	6	13
	EPILEPSY	0	1	1
	DIARRHEA	1	0	1
	HYPER-EMESIS GRAVIDUM	5	2	7

The table depict presenting problems during the 2nd and 3rd trimesters of pregnancy. Common issues included hyperemesis gravidarum (5 cases each trimester), nausea & vomiting (16 in 2nd, 9 in 3rd), and heartburn (5 each). Hypothyroidism (13 in 2nd, 15 in 3rd), hypertension (8 in 2nd, 10 in 3rd), and gestational diabetes were also noted. Other complaints were abdominal pain, weakness, and body aches



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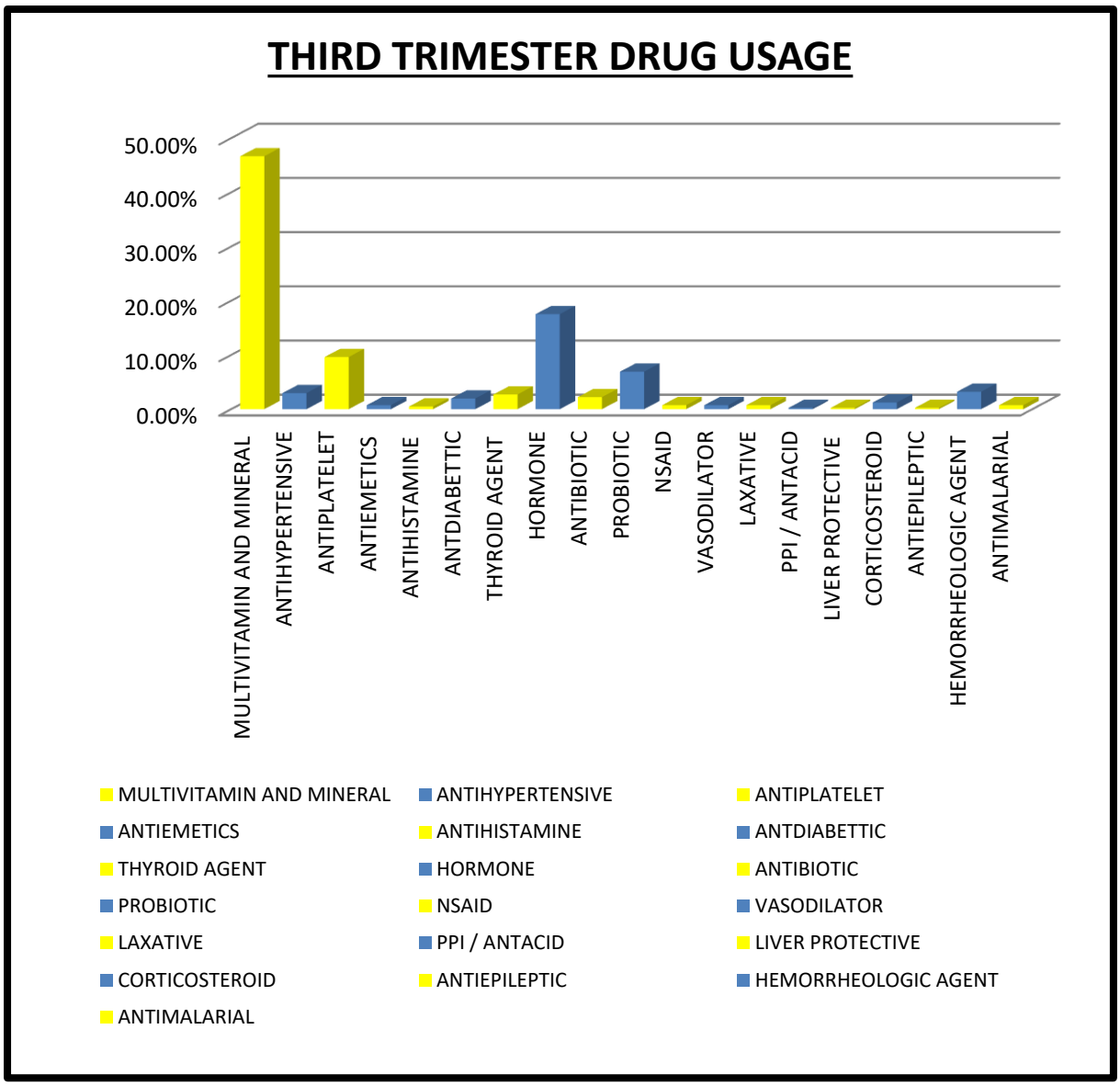
The graph shows that multivitamins and minerals (48.21%) are the most prescribed medications in the second trimester, followed by hormones (18.16%) and antiplatelets (9.75%). Other drugs like probiotics, thyroid agents, and antiemetics are used moderately, while medications such as antihypertensives, antibiotics, and NSAIDs are prescribed less frequently. Rarely used drugs (under 1%) include vasodilators, corticosteroids, antidiabetics, antifungals, and antiepileptics.



The graph shows that in the third trimester, multivitamins and minerals (46.67%) are the most prescribed drugs, followed by hormones (17.53%), antiplatelets (9.62%), and probiotics (6.92%). Other medications like antihypertensives, thyroid agents, antibiotics, antidiabetics, and NSAIDs are prescribed less frequently

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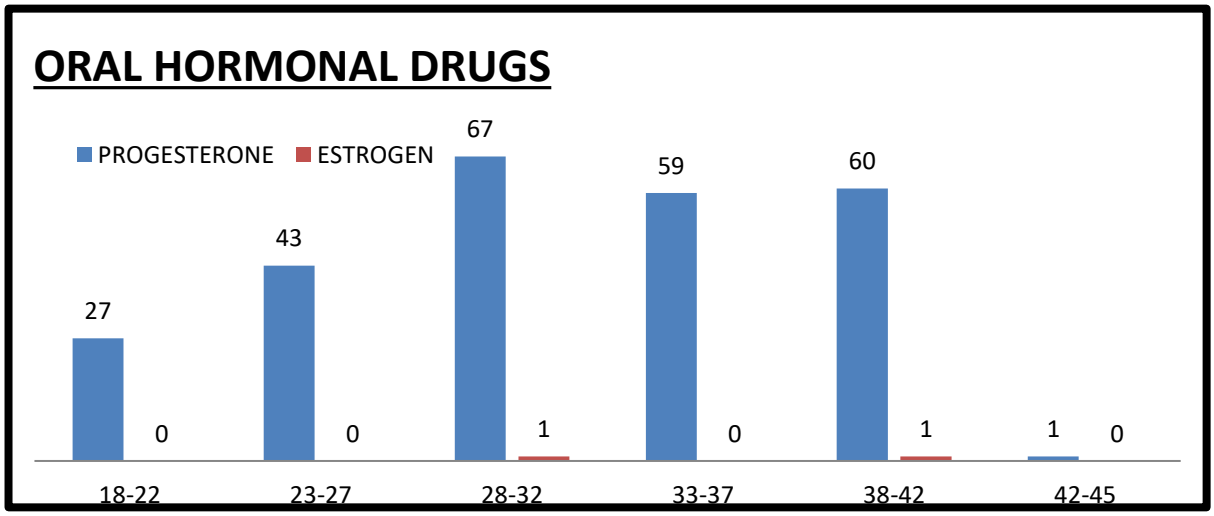
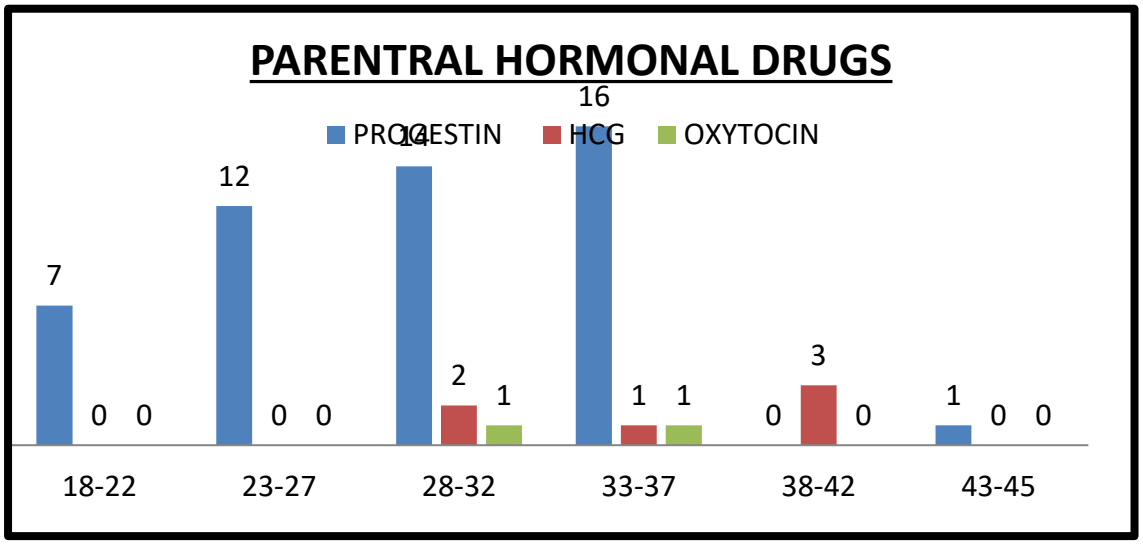


During pregnancy, oral hormonal drugs were predominantly used, with progesterone being the most common (257 instance), mainly between 28-42 weeks. Estrogen use was minimal (2 cases).



For parenteral hormonal drugs, progestin was the most frequently administered (50 cases), especially in the 28-37week period. HCG (6) and oxytocin (2) were used less frequently.

CLASSIFICATION OF DRUGS	DRUGS	NO. OF PATIENTS
ANTIHYPERTENSIVES	AMLODIPINE,VALSARTAN	3
	AMLODIPINE,BENAZEPRIL	3
	AMLODIPINE	5
	LABETALOL	18

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	NIFEDIPINE	2
ANTIDIABETICS	METFORMIN+MYO-INOSITOL	3
	GLIBENCLAMIDE,METFORMINE	5
	METFORMINE	2
	METFORMINE HCL	5
ANTIEMETICS	DOXYLAMINE SUCCINATE & PYRIDOXINE HCL	22
	ONDENSETRON	4
	TROPISETRON	1
Z IRON SUPPLYMENTS	FERROUS ASCORBATE+FPLIC ACID	70
	FERROUS ASCORBATE+FOLIC ACID+VIT B	26
	IRON+FOLIC ACID	
CALCIUM FORMULATIONS	CALCIUM+VITAMINS	118
	CALCIUM+VITAMIN D3	38
	CALCIUM	11
VITAMIN B COMPLEX		275
VITAMIN C		4
VITAMIN E		27

CONCLUSION

This observational study focused on evaluating the **drug usage patterns** among pregnant women, particularly those in their **second and third trimesters**. The primary aim was to assess **medication safety, prescribing trends**, and adherence to established guidelines, specifically the **FDA drug categories** and the **Pregnancy & Lactation Labeling Rule**.

A total number of **250 pregnant women** participated in the study, with **160 pregnant women in their second trimester** and **60 pregnant women in their third trimester**. The findings emphasize that medications prescribed during pregnancy were

largely **safe and evidence-based**, following appropriate **clinical guidelines**.

Most of the prescribed medications were categorized under **FDA drug categories A, B, and C**, including **nutritional supplements** such as **iron, folic acid, and calcium**, which are essential for maternal and fetal health. Furthermore, the study identified that **pregnancy-related conditions** such as **hypertension, gestational diabetes, and infections** were effectively managed using **appropriate medications**.

Overall, the study highlights the importance of **safe prescribing practices** in pregnancy and underscores the necessity of **following regulatory guidelines** to minimize risks to both the mother and the developing fetus. Future research should explore **long-term maternal and fetal outcomes** associated with medication use during pregnancy, further strengthening the evidence base for clinical decision-making.

Key Findings from the Study:

Safe Medication Use: Most prescribed drugs fall within FDA categories A, B, and C, ensuring minimal fetal risk while effectively managing maternal health conditions.

Nutritional Supplementation: The widespread use of iron, folic acid, and calcium supplements underscores the critical role of nutrition in pregnancy management. These supplements help prevent maternal deficiencies and promote fetal growth and development

Management of Pregnancy-Related Conditions: Common conditions such as hypertension, gestational diabetes, and infections were effectively managed using appropriate medications, ensuring both maternal well-being and fetal safety.

Adherence to Safety Guidelines: The study indicates strict adherence to prescribing regulations, minimizing the risk of teratogenic drug exposure and supporting safer pregnancy outcomes.

LIMITATIONS OF STUDY: Despite careful planning and execution, our study has certain limitations. The sample size was limited, which may affect the generalizability of the findings to a broader population. Additionally, our study was conducted over a specific time period, and therefore long-term outcomes could not be assessed. Data collection relied partly on self-reported information, which may be subject to response bias.

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CONFLICT OF INTEREST: No conflict of interest

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