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Original Research Article

# A cross-sectional study on rational use and prescribing pattern of drugs used in pregnant women with comorbidity in a tertiary care hospital, Bengaluru (Bangalore), Karnataka, India

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## Abstract

**Background:** Prescription data offer valuable insights into trends in drug utilization, therapeutic decision-making, and the use of generic medicines. Rational drug use entails selecting appropriate medications with the correct dosage and administration. Pregnant women with comorbid conditions present a unique challenge, as inappropriate prescriptions can have adverse outcomes for both mother and fetus.

**Objective:** This study aimed to evaluate prescribing patterns, assess rational drug use, and identify inappropriate medication use and drug interactions in this population.

**Materials and Method:** A cross-sectional study was conducted on 362 pregnant inpatients at the obstetrics and gynecology department of a tertiary care hospital in Bengaluru. Data were collected using a customized form, capturing patient demographics, clinical details, and prescription information. Drug interactions were analyzed using Lexicomp software, and Microsoft Excel was utilized for statistical analysis.

**Results:** Among 362 patients, anemia was the most prevalent comorbidity (41.43%). The majority of drugs prescribed were Category B (71.92%). Drug interactions were noted in 145 patients, with Tramadol and Metoclopramide accounting for the highest incidence (34.40%). Most interactions (59.17%) were of moderate severity, with pharmacodynamic mechanisms being predominant (86%). The WHO core prescribing indicators revealed an average of 9.31 drugs per prescription and an average antibiotic use of 26.62 per 100 encounters. Injections were administered to 88.39% of patients. Of the 3,373 drugs prescribed, 47.19% were generics, and 60.83% were listed on the Essential Drug List (EDL).

**Conclusion:** The findings indicate significant deviations from rational prescribing standards, including high polypharmacy rates and suboptimal use of generics and EDL drugs. The frequent occurrence of moderate pharmacodynamic drug interactions further highlights the need for enhanced prescribing vigilance. Strengthening adherence to WHO guidelines and ensuring the availability of EDL medications are crucial steps toward improving maternal healthcare outcomes.

**Keywords:** Prescribing pattern, Rational drug use, Pregnancy, Comorbidity, Drug interaction, WHO indicator

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## 1. Introduction

Since the discovery of diethylstilbestrol's teratogenic effects in 1971 and the prevalence of thalidomide in the 1960s, medication usage during pregnancy has been a serious problem.[1]

Pregnant women may have underlying conditions like epilepsy, diabetes, or asthma that would need continuous pharmaceutical treatment, making the usage of medications during pregnancy unavoidable even though it is concerning. Pregnant women may experience heartburn, increasing headaches, gestational hypertension, and other pregnancy-related health problems that can be treated with medicine. Medication use among pregnant women is restricted to a small number of medications with well-established safety profiles due to ethical considerations.[2,3,4]

The FDA risk category states that medications in category "A" are safe, whereas medications in classes "B" and "C" have either no evidence of harmful effects on human fetuses or positive results from animal research. Drugs classified as "D" or "X" have a known risk of fetal abnormalities; "X"

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is completely forbidden, while "D" can be used in specific circumstances where the disease poses a higher risk to the mother and baby, such as epilepsy.[5,6]

One percent of birth abnormalities are caused by unreasonable drug use, while there are other causes as well. Unreasonable drug usage during pregnancy can result in birth malformations, pregnancy termination, and potential lifelong problems. The term "rational use" refers to the appropriate dosage for the appropriate indication at a fair cost.[7]

At a conference in Nairobi in 1985, the WHO developed a crucial technique for researching the use of pharmaceuticals in healthcare facilities. To identify, assess, and promote the responsible use of pharmaceuticals in developing countries, the World Health Organization developed important drug use indicators. Drug use is primarily measured by the WHO using variables related to prescriptions, patient care, and health facilities. The percentage of prescriptions with generic names, the percentage of prescriptions containing antibiotics, the percentage of prescriptions given by injection, the percentage of prescriptions from formularies or the list of essential medications, and the average number of prescriptions written per encounter are all examples of prescribing, which is one of the main indicators of medication use.[8,9]

## 2. Materials and Methods

### *2.1. Study design and objectives*

This cross-sectional prospective study analysed patient records, including case sheets, medication records, counselling notes, history interviews, and drug interaction data. The study aimed to examine prescribing patterns and the rational use of medications in pregnant women with coexisting conditions, identify risk factors associated with inappropriate prescribing, and assess the prevalence of harmful drug prescriptions and drug interactions.

### *2.2. Study setting*

The study was conducted at Sapthagiri Institute of Medical Sciences and Research Centre a tertiary care hospital, in Bengaluru. Data was collected from the inpatient obstetrics and gynaecology department and general medicine, including patient profiles and Prescriptions, and recorded in a self-designed data collection form. The study focused on pregnant women with comorbidities who were receiving medication and had available prescription records. Ethical approval was obtained, and confidentiality was strictly maintained.

**Selection of Study Participants**

Inclusion criteria were Pregnant women admitted to the general medicine and obstetrics and gynaecology (OBG) departments with comorbidities, regardless of the trimester. Women aged 18 years and older who provided informed consent. Exclusion criteria were Women who had participated in a similar study within the last year to avoid potential bias. Pregnant women with severe mental health conditions that impair their ability to provide informed consent. Patients with incomplete medical records, missing key information, or illegible records make it difficult to assess prescribing patterns accurately women who declined to participate.

### *2.3. Data analysis*

All pregnant patient's data from the last six months was looked over and uploaded into Microsoft Excel. The collected data were compiled and analysed to determine frequencies and percentages at both aggregate and facility levels. Interviews and observational data were also recorded and processed using Excel.

### *2.4. Ethical considerations*

The study involved non-public patient data and required ethical clearance. Interviews with healthcare providers and observations of pregnant women were conducted only after obtaining written informed consent from all participants. Throughout the study, full adherence to patient confidentiality and data protection was maintained.

## 3. Results

The dataset provides an age distribution of the 362 pregnant women included in the study. The majority belonged to the 23 to 27 years age group, comprising 39.50% of participants, 43 to 47 years age group was the least represented, at 1.38%. 56.35% had a history of medication use. 134 (37.01%) were primigravida, and 228 (62.93%) were gravida. A total of 3,373 drugs were prescribed. The most frequently used category was Category B, accounting for 2,426 (71.92%) of all prescriptions, while Category X drugs were the least prescribed 2 (0.05%). **(Table 1)**

**Table 1:** a) The initial characteristics of the study participants who are pregnant b) The initial characteristics of the study variable related to prescribed drug categories according to the FDA.

| Variables | Group | Frequency | Percentage (%) |
|---|---|---|---|
| a) Age | 18 – 22 | 59 | 16.29 |
| | 23 – 27 | 143 | 39.50 |
| | 28 – 32 | 114 | 31.49 |
| | 33 – 37 | 33 | 9.11 |
| | 38 – 42 | 8 | 2.20 |
| | 43 – 47 | 5 | 1.385 |
| Past Medication History | Pregnant women with a medication history | 204 | 56.35 |
| | Pregnant women without a medication history | 158 | 43.65 |
| Gravida and Primigravida | Gravida | 228 | 62.93 |
| | Primigravida | 134 | 37.01 |
| b) Category of Drug | Category A | 200 | 5.92 |
| | Category B | 2426 | 71.92 |
| | Category C | 727 | 21.55 |
| | Category D | 18 | 0.53 |
| | Category X | 2 | 0.05 |

### *3.1. Comorbidity*

This study analysed comorbidities in 362 pregnant women, identifying anemia as the most prevalent condition, affecting 152 women (41.43%), followed by hypothyroidism which was observed in **(Figure 1)**.

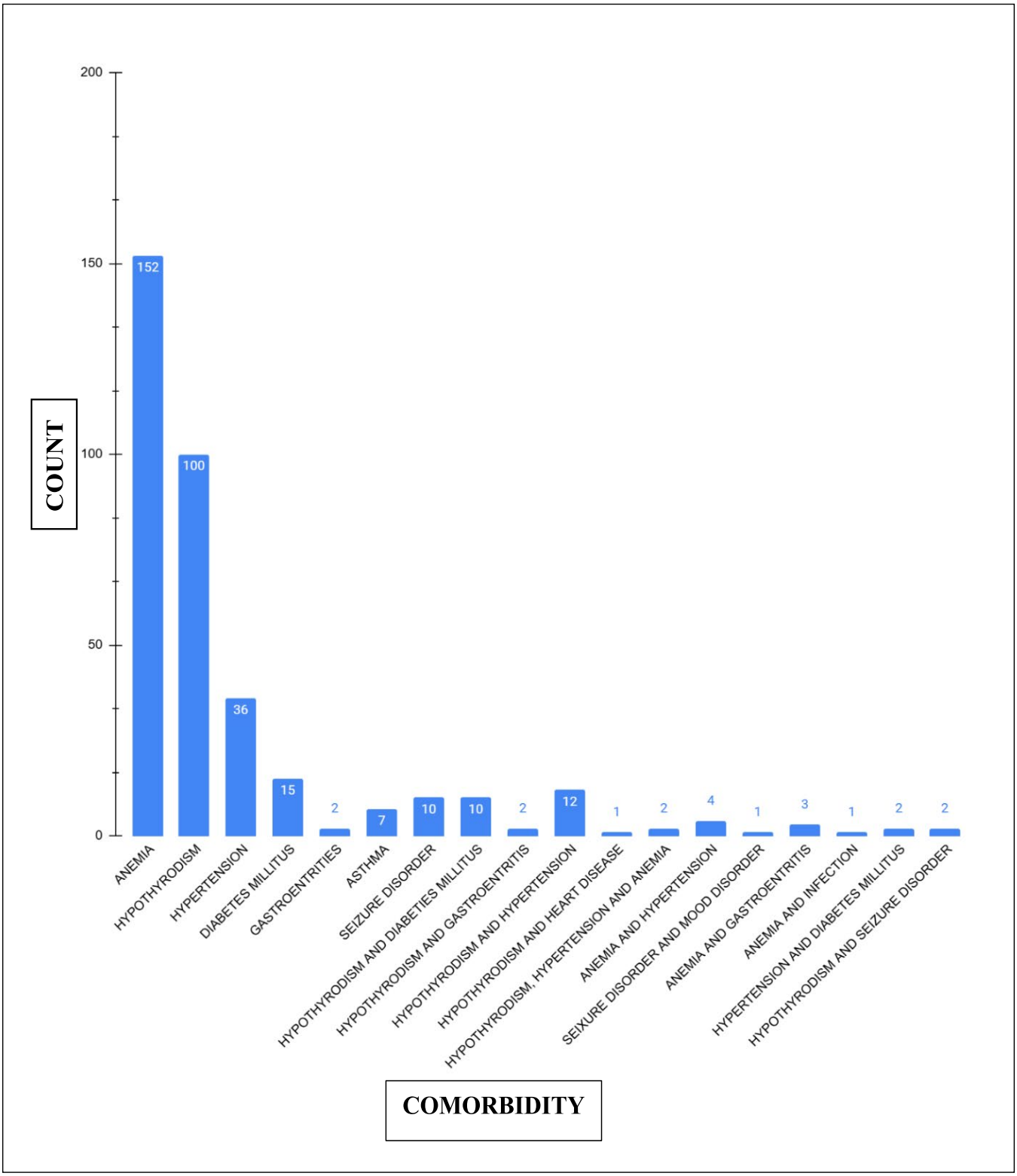


**Figure 1:** Comorbidity found in pregnant women

### *3.2. Treatment*

This study analysed data on frequently prescribed medications for 362 patients, documenting a total of 3,373 prescriptions. The most prescribed medications included Injection Metronidazole (500 mg), 334 prescriptions (9.90%) Pantoprazole, 325 prescriptions (9.63%). Other medications accounted for 814 prescriptions (24.13%). **(Table 2)**

**Table 2:** Treatment chart

| Sl. No | Most used drugs | Count | Percentage |
|---|---|---|---|
| 1 | Tablet Orofer Xt 200 Mg | 75 | 2.22% |
| 2 | Capsule A - Z Women 30 Mg | 58 | 1.71% |
| 3 | Tablet Vitamin C 500 Mg | 143 | 4.23% |
| 4 | Tablet Meftal Spas | 2 | 0.05% |
| 5 | Tablet Calcium 500 Mg | 72 | 2.13% |
| 6 | Tablet Pan 40 Mg | 260 | 7.70% |
| 7 | Injection Ceftriaxone 1 Gm | 250 | 7.41% |
| 8 | Injection Paracetamol 1 Gm | 185 | 5.48% |
| 9 | Injection Pantoprazole 40 Mg | 325 | 9.63% |
| 10 | Injection Metronidazole 500 Mg | 334 | 9.90% |
| 11 | Injection Pause 10 Mg | 42 | 1.24% |
| 12 | Injection Metoclopramide 10 Mg | 47 | 1.39% |
| 13 | Tablet Tolpa D | 216 | 6.40% |
| 14 | Injection Tramadol 50 Mg | 118 | 3.49% |
| 15 | Tablet Iron 500 Mg | 50 | 1.48% |
| 16 | Jonac Supp | 82 | 2.43% |
| 17 | Injection Perinorm 10 Mg | 100 | 2.96% |
| 18 | Tablet Cefixime 200 Mg | 200 | 5.92% |
| 19 | Other Drug | 814 | 24.13% |
| | Total | 3373 | 100% |

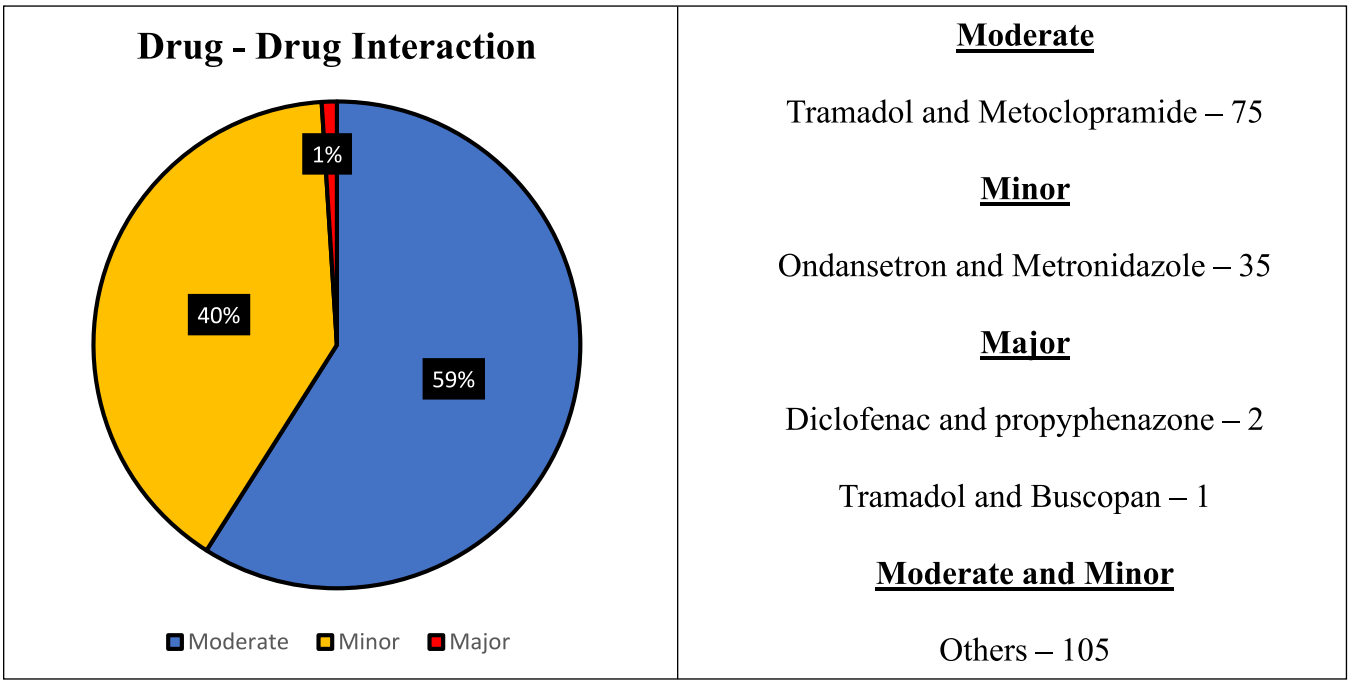


**Figure 2:** Drug–Drug interaction

### *3.3. Drug-Drug interaction*

Out of the 362 data points, 145 involved drug-drug interactions, resulting in a total of 218 interactions. The most frequent interactions included Tramadol and Metoclopramide 34.40%, classified as moderate, Ondansetron and Metronidazole 16.05%, classified as minor. Major interactions identified were Diclofenac and Propyphenazone 1.37%, also Tramadol and Buscopan 0.45% which was observed in **(Figure 2)**.

Among 362 prescriptions, 145 drug-drug interactions were found according to the degree of severity, moderate was 59.17%, minor was 39.44% and major was 1.37% and of which 101 cases had just 1 interaction, 3 cases had four interactions. The highest type of interaction was found to be pharmacodynamics interaction which was 86% followed by pharmacokinetics interaction which was 14%. Out of 30 pharmacokinetics interaction absorption was 47% and excretion was 53%. Out of 188 pharmacodynamics interaction synergism was 70%, antagonism 29%, and additive was 1%. **(Table 3)**

**Table 3:** The initial characteristics of the study variable pattern to drug-drug interactions resulting from prescribed medication.

| Variables | Group | Frequency | Percentage (%) |
|---|---|---|---|
| Severity | Major | 3 | 1.37 |
| | Moderate | 129 | 59.17 |
| | Minor | 86 | 39.44 |
| Number of DDIs | One | 101 | 69.66 |
| | Two | 26 | 17.93 |
| | Three | 11 | 7.59 |
| | Four | 3 | 2.07 |
| | Five | 4 | 2.76 |
| Type of Interaction | Pharmacokinetic Interaction | 30 | 14 |
| | Pharmacodynamics Interaction | 188 | 86 |
| Pharmacokinetic Interaction | Absorption | 14 | 47 |
| | Excretion | 16 | 53 |
| Pharmacodynamic Interaction | Synergism | 131 | 70 |
| | Antagonism | 55 | 29 |
| | Additive | 2 | 1 |

### *3.4. WHO indicator*

The study analysed 362 prescriptions, according to WHO core indicator the average number of drugs per prescription was 9.31. It was noticed that 60.83% and 47.19% of all medicines were chosen from the essential medicines list and generics respectively. Antibiotics accounted for 26.62% of all prescribed drugs and injectable dosage forms for 88.39%. **(Table 4)**.

**Table 4:** WHO indicator

| Who Core Indicator | Percentage of prescriptions (%) |
|---|---|
| Average number of drugs per prescription | 9.31 |
| Percent of drugs prescribed from EDL | 60.83 |
| Percent of drugs prescribed by generic names | 47.19 |
| Percent of antibiotics per prescription | 26.62 |
| Percent of prescriptions with at least one injection | 88.39 |

## 4. Discussion

Pregnancy can exacerbate or initiate chronic health conditions that require medical attention. The use of medications in pregnant women is particularly concerning due to altered pharmacokinetics and the potential effects on the fetus. Given the limited research on this population, observational studies are crucial to evaluate prescription patterns. The age distribution of a sample of 362 pregnant women was displayed in the data. Age groups 23 to 27 and 28 to 32 accounted for 39.50% and 31.49% of all patients, respectively. The age group of 18 to 22 years old and the age group of 33 to 37 years old make up 16.29% and 9.11% of all women respectively. While the age group of 38 to 42 years old accounts for 2.20% of all pregnant women. Pregnancies among women aged 43 to 47 account for 1.38% of all pregnancies. In conclusion, the population of pregnant women is spread throughout the age ranges, with the age group of 23 to 27 years old having the highest concentration. The study conducted by Mette Østergaard Thunbo et al showed a similar result in their study with 34.8%.[10]

Our data show that comorbidity with medication history is more common among patients, roughly 56.35%, while patients without medication history make up the other 43.65%. Mohamed A. Baraka et al did a study where they found 42.4% have a medication history and 56.9% do not have a medication history.[11]

Out of the total study subjects 228 [62.93%] subjects were found to be pregnant more than one time also known as Gravida and 137 [37.01%] subjects were first time pregnant known as Primigravida. Similar findings were found in a study by Niguse Meles Alema et al, which showed that 53.4% of gravida and 46.6% of primigravida.[6]

The study shows many drugs taken by pregnant women were from FDA pregnancy category B [71.92%]. Second and third most used medications are those in categories C and A, with 727 (21.55%) and 200 (5.92%), respectively. The least utilized medications are in categories D and X, with a total of 18 (0.53%) and 2(0.05%), almost like a study done by Mohamed A. Baraka et al where the category B and category C drugs used were 66.4% and 32.6% respectively[5,11]

Anaemia and Hypothyroidism (Thyronorm, levothyroxine drugs used) are the most prevalent co-morbidities identified in women, accounting for 152 (41.43%) and 100 (27.62%) respectively. According to our data, pregnant women suffer from a variety of comorbidities including Hypertension (labetalol , Telmisartan, Cilnidipine drugs used) 36 (9.94%), Diabetes Mellitus (Metformin drug used) 15 (4.14%), Seizure disorder 10 (2.76%), Asthma (Montelukast, Duolin, Budecort drugs used) 7 (1.93%), Gastroenteritis 2 (0.55%). Siang Ing Lee et al done a study were depression and anxiety (2.2% and 2.7), asthma 3.2%.[12,13]

The total number of most prescribed drugs used in 362 patients was 3373, with the most used drugs being Injection Metronidazole 334 (9.90%), Injection Pantoprazole 325 (9.63%), Tablet Pan 260 (7.70%), Injection Ceftriaxone 1 gm (7.41%), Tablet Tolpa D (6.40%), Tablet Cefixime 200 mg (5.92%), and Injection Paracetamol 1 gm (5.48%). Tablet Vitamin C 500 mg (4.23%), Injection Tramadol 50 mg (3.49%), Injection Perinorm 10 mg (2.96%), Jonac Supp (2.43%), Tablet Orofer-xt 200 mg (2.22%), Capsule A - Z women 30 mg (1.71%), Tablet Calcium 500 mg (2.13%), Tablet Iron 500 mg (1.48%), Injection Metoclopramide 10 mg (1.39%), Injection Pause 10 mg (1.24%), and Tablet Meftal Spas (0.05%). Other drugs used to sum up to 814 of the total drugs (24.13%). Mohamed A. Baraka et al, beta lactam 44.6% followed by azoles 30.2 % was most prescribed antibiotic.[14]

Among 362 data collected 145 cases consist of drug-drug interaction. A total of 218 drug-drug interactions were found, among them the highest interactions found were Tramadol and Metoclopramide (34.40%) which is a moderate interaction. The second highest interaction was Ondansetron and Metronidazole (16.05%) which is a minor interaction. Two more significant medication interactions were discovered: Tramadol and Buscopan (0.45%) and Diclofenac and Propyphenazone (1.37%). A comparable study by Gracia Santos-Díaz et al. found that the moderate, medium, and major factors were Tramadol and Trazodone 3.8% and Levothyroxine and Omeprazole 10.7%. Ferrous Sulphate and Omeprazole 1.3%[15,16]

A drug interaction occurred in 145 out of the 362 prescriptions. Major (1.37%), Minor (39.44%), and Moderate (59.17%) interactions accounted for the highest percentage. Muhammad Fawad Rasool et al study reveals that moderate (46.61%), mild (30.89%), and major (18.16%) were comparable. According to the data, pharmacodynamic interactions are the highest at 92% and pharmacokinetic interactions are 8%. Out of 200 pharmacodynamic interactions, 60% consist of Synergism, 18.50% consist of Antagonism and 21.50% consist of Additive interactions. There are some examples for pharmacodynamic interaction, Labetalol and Diclofenac, Tramadol and Metoclopramide, Ondansetron and Metronidazole etc. In pharmacokinetic interaction, absorption was 47% and excretion was 53, there are some examples for pharmacokinetic interactions, Metformin and Diclofenac, Doxycycline and Pantoprazole, Amikacin and Ceftriaxone etc.[17,18]

A total of 101 cases (69.66%) had only one interaction, 26 cases (17.93%) had two, 11 cases (7.59%) had three, 3 cases (2.07%) had four, and 4 cases (2.76%) had five. Similar findings were found in a study by Muhammad Fawad Rasool et al, which found that 220 (65.28%) prescriptions had one interaction, 164 (74.55%) had two interactions, and 56 (25.45%) had three or more interactions.[17]

According to WHO core indicator the average number of medicines per prescription was 9.31, out of 3373 medications 2052 [60.83%] of the medications were used from essential drug list. percentage of generic drugs used in this study was 1592 [47.19%] compared to the brand drug which is 1781 [52.80%], percentage of antibiotics per prescription was 26.62%, percentage of prescription with at least one injection was 88.39%. P. Galappatthy et al, done a similar study which found out Overall, the average number of medicines per encounter was 3.1 Medicines prescribed from EML 23.8%, Medicines prescribed in generic name 35.5% Encounters with an antibiotic 23.8%, Encounters with an injection 1.2%.[19,20,21]

## 5. Conclusion

This study highlights significant challenges in achieving rational drug use in pregnant women with comorbidities at a tertiary care hospital. High rates of polypharmacy, low use of generic drugs, and widespread injectable administration suggest a deviation from WHO-recommended prescribing practices. The predominance of pharmacodynamic drug interactions — particularly involving tramadol and metoclopramide — underscores the need for heightened vigilance and prescriber education.

These findings emphasize the urgent necessity for institutional measures to promote adherence to WHO core prescribing indicators, prioritize prescribing from the Essential Drug List (EDL), and enhance the availability of safe, cost-effective medications. Regular auditing, pharmacist collaboration, and continuing medical education can contribute to more rational and safe prescribing practices in antenatal care.

Future research should evaluate the long-term maternal and fetal outcomes associated with current prescribing trends and assess the impact of targeted interventions on improving rational drug use in pregnancy.

Implementing rational prescribing strategies may play a critical role in reducing adverse pregnancy outcomes and improving maternal health in low-resource settings.

## 6. Limitations

This study has several limitations. First, as a single-center study conducted in a tertiary care hospital, the findings may not be generalizable to other healthcare settings, such as primary or community hospitals. Second, the sample size was modest, which may limit the detection of less common prescribing patterns or rare drug interactions. Third, the cross-sectional design allowed only a snapshot of prescribing

practices; it did not enable evaluation of changes over time or the establishment of causality between prescribing behavior and clinical outcomes. Additionally, reliance on recorded prescription data introduces the possibility of documentation errors or omissions. Finally, because maternal and fetal outcomes were not assessed, we could not determine the clinical impact of irrational prescribing or drug interactions.

Future studies should include larger, multicenter populations, incorporate longitudinal follow-up, and evaluate the effect of prescribing practices on maternal and neonatal health outcomes.

## 7. Future Directions

Future research should include multicentre and larger-scale studies to validate these findings across diverse healthcare settings. Studies incorporating longitudinal follow-up are needed to assess the direct impact of prescribing practices on maternal and neonatal health outcomes. Additionally, interventional research should focus on evaluating the effectiveness of prescriber education, the implementation of evidence-based prescribing guidelines, and the impact of pharmacist-supported drug therapy reviews. Investigating cost-effectiveness and patient satisfaction with rational versus irrational drug use would also provide valuable insights. Addressing these areas will contribute to the development of safer, more effective prescribing practices for pregnant women with comorbidities.

## 8. Ethics Approval

The ethical clearance letter number: *SIMS & RC/EC-10/RR-06/2024-25* dated 25/07/2024 was obtained from the institution.

## 9. Author Contributions

All authors contributed to the conception and design of the study. Ritwam Mukhopadhyay and Animesh Das handled material preparation, data collection, and analysis. Aleena Shine and Abhishek U.N. drafted the initial manuscript. All authors reviewed and approved the final version.

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## 11. Conflict of Interest

The authors declare that there are no conflicts of interest related to this study.

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## 13. Availability of Data and Material

Not applicable.

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