



A RETROSPECTIVE STUDY ON DRUG UTILISATION EVALUATION FOR PREGNANCY IN A TERTIARY CARE TEACHING HOSPITAL

Tasneem A K , Karanki Srinivasu, Mohammad Nezamuddin Khan , S. P. Ahalya*

Department of Pharmacy Practice, SRM College of Pharmacy, SRM Institute of Science and Technology,
Kattankulathur, India

2408

Corresponding Author:

Ahalya S P, Assistant professor,
Department of Pharmacy Practice,
SRM College of Pharmacy,
SRM Institute of Science and Technology,
SRM Nagar, Kattankulathur, 603203.
Mobile number: 8056125149
E-mail: ahalyasp1994@gmail.com

ABSTRACT:

Background: Drug Utilization Evaluation studies are crucial to the health care system's efforts to rationalize patient care practices like prescribing, dispensing, and usage of medications. In pharmaco-epidemiological studies, DUE plays a crucial role. This study was carried out to assess the prescription and medication use patterns in expectant mothers, comprehend the significance of different classes of drugs used during pregnancy, and categorize them according to US FDA categorization. **Methodology:** 118 pregnant women's case files were obtained from the medical record department who were admitted in a time span of 3 months, and a retrospective observational study design was chosen to analyze the cases using MS Excel software. Each case file was analyzed for the demographic variables, various categories of drugs prescribed during pregnancy; co-morbidities if present, various drugs under each category; and categorization of prescribed drugs according to US FDA pregnancy category guidelines. **Result:** The study revealed that the most common co-morbidity was found to be gestational diabetes mellitus, followed by the thyroid. The most commonly prescribed drugs were vitamins and minerals (26.06%) followed by antibiotics (13.73%). Levocetirizine (35.38%) was the most commonly prescribed anti-histamine. Category B (59.77%) drugs were found to be the most widely prescribed. **Conclusion:** The present study showed that vitamins and mineral supplements were the most commonly prescribed drugs during pregnancy, while anti-pyretic drugs were used less. Use of category B drugs must be reduced, while category X drugs should be completely avoided. Along with Vitamin D, the use of folic acid should also be increased.

Keywords- drug utilization evaluation, pregnancy, vitamins, pregnancy drug categories, antibiotics

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INTRODUCTION:

According to World Health Organization (WHO), Drug Utilization Evaluation (DUE) or Drug Utilization Review is defined as "marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences".

Usage of minimum number of drugs to acquire finest possible therapeutic effect in a short period of time and at an affordable cost is known as rational drug prescribing. The DUE study's major objective is to support the rational prescribing pattern.[1] DUEs play a crucial role in pharmacoepidemiological



investigations by helping to understand how medications are used, their quality, effectiveness, and results.[2] DUE studies can be of 3 types- Retrospective, Concurrent, Prospective. Retrospective DUE involves conducting the investigation after a patient has received pharmaceutical therapy. In order to stop the recurrence of improper use or misuse of pharmaceuticals, it aids in the detection of patterns in prescription, dispensing, or administration of drugs. This serves the establishment of prospective standards and target intervention.

Pregnancy is most valuable time a woman goes through in her life. And during this phase pregnant ladies have to take a number of medications in order to stabilize their as well as fetus health. However, it is impossible to avoid drugs in early pregnancy as it may be dangerous to the mother as well as to the fetus. The primary aim throughout maternity is healthy pregnancy with physical safety and psychological fulfillment for mother and the infant. And to achieve this goal, health practitioners prescribe a number of medications. Sometimes if left unchecked some medication agent may cause congenital malformation. Such agents are known as Teratogens. These teratogens can easily pass through placental barrier and can affect the fetus. In order to prevent use of such drugs, United State Food and Drug Administration (US FDA) has laid guidelines with respect to safety of drug utilization during pregnancy according to which drugs entering market are categories as A, B, C, and D and X. So in order to prevent rationalizing drug therapy for pregnancy is very much important.[3]

Numerous studies have been organized in developing countries where prescribing practice is mostly used, to recognize the need for interventional procedures for the purpose of rational prescription throughout the pregnancy period in order to produce safe, effective and desired effects of drugs.[3,4]

In order to check the rationality of drug prescribing pattern among pregnant women visiting our tertiary care hospital, this study was conducted through retrospective analysis of data.

The study's objective was to assess the pregnant women's population at Chennai's tertiary-care teaching hospital's drug use patterns during pregnancy.

METHODOLOGY:

The purpose of the study is to assess the drug usage patterns among 25 to 35-year-old pregnant women. Retrospective observational study design was used. The procedure and paper were created using Food and Drug Administration (FDA) criteria. A teaching hospital for tertiary care hosted the research. The data was obtained from the medical records department. The study period was 3 months (October 2021-December 2021). The drug chart in the case sheet was analyzed. Out of total 153 cases we have collected 118 cases based upon the inclusion and exclusion criteria. The inclusion criteria include prescription of antenatal women between 25-35 years of age. Focuses on the drug utilization pattern of prescribed drugs. Pregnant women with co morbid condition were included in the study. The exclusion criteria includes patient who voluntarily got discharged and with an incomplete case history. 35 cases out of 153 were excluded because they didn't match the criteria for inclusion.

RESULTS:

The aim of the study was to assess the drug prescribing practises among pregnant patients in tertiary care facilities.

1. Age wise distribution:

Among 50 patients, 42.7% of study population belongs to age group of ≤ 25 years, followed by 62 patients of age group 26-35 years with observed percentage of 52.54% and finally for 6 patients of age group > 35 years with observed percentage of 5.08%. This shows that maximum pregnant women fall under the age group of 26-35 years.

2. Gravida wise distribution:



The different stages of the Gravida wise distribution was also included in the study. Among 118 patients, 36.44% of population consist of 43 patients in primi-gravida stage and 63.55% of population incorporate 75 patients in multi-gravida stage.

3. Co-Morbid wise distribution/co-morbid condition:

Among 32 patients, 37.50% of population of GDM were found to be 12 cases, 34.37% of population were found to be 11 cases of thyroid, 12.50% of population were found to be 4 cases of HTN, 9.37% of population were found to be 3 cases of thyroid along with GDM and finally 6.25% of population were found to be 2 cases of DM. Therefore most co-morbid condition were found to be GDM and less co-

morbid condition were found to be GDM along with thyroid.

4. Distribution of prescription according to FDA pregnancy risk group:

In this study, among 118 patients, for 4.9% of population 35 drugs of category-A were prescribed, for 59.77% of population 422 drugs of category-B were prescribed, for 21.38% of population 151 drugs of category-C were prescribed, for 3.25% of population 26 drugs of category-D were prescribed, for 10.19% population 72 drugs category-X were prescribed. The most prescribed drug belongs to category-B which was found to be 59.77% followed by least prescribed drug belong to category-D that was found to be 3.25%.

CATEGORY	DESCRIPTION
A	Adequate, well-controlled studies in pregnant women have not show many risk to the fetus in the first 3 months of pregnancy. There is no evidence of risk later either.
B	There have been no adequate, well-controlled studies in women but studies using animals have not shown any risk or animal studies that have found risk, this was not confirmed by adequate studies with pregnant women.
C	No adequate, well-controlled studies have been performed in pregnant women but studies in animals have shown harmful effect to the foetus, orthere have not been any studies done with either animals or women. CAUTION IS ADVISED but the benefits of this medication still may outweigh the risks.
D	Clear evidence of RISK TO HUMAN FOETUS. Benefits may still outweigh the risks if the woman has a serious condition that cannot be treated effectively by a safer drug.
X	Clear evidence that the medication CAUSES ABNORMALITIES IN THE FOETUS. Risks outweigh the benefits for women who are or may become pregnant.



S.NO	Category	No. of drugs	Percentage (%)
1.	CATEGORY A	35	4.90
2.	CATEGORY B	422	59.77
3.	CATEGORY C	151	21.38
4.	CATEGORY D	26	3.25
5.	CATEGORY X	72	10.19

TABLE 01: Distribution of prescription according to FDA pregnancy risk group

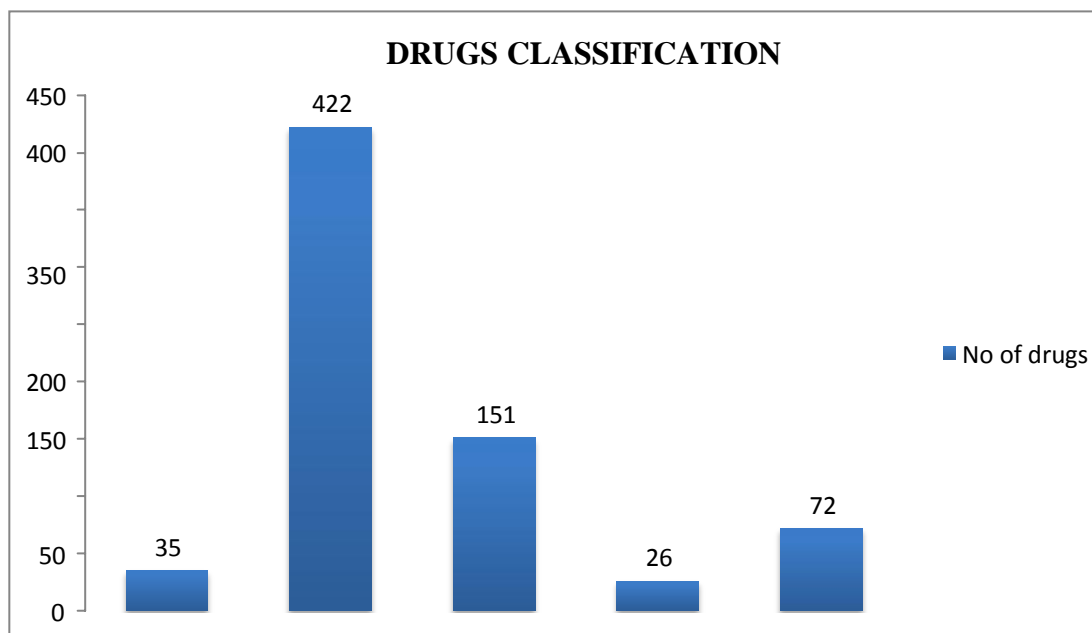


FIGURE 01: FDA drug risk category wise prescription pattern

5. Utilization pattern of Vitamins and Minerals supplements class wise distribution:

In this study, among 118 patients, the most prescribed drug under this class was for 21.73% of population 40 drugs of Vitamin D were prescribed, for 18.47% of population 34 drugs of Mecobalamin were prescribed, for

16.84% of population 31 drugs of Calcium were prescribed, for 13.58% of population 25 drugs of Vitamin B12 were prescribed, for 11.95% population drugs of Folic acid were prescribed, for 10.32% of population 19 drugs of Accucal were prescribed, for 7.06% of population 13 drugs of pyridoxine were prescribed.

S. No	Vitamins and Mineral Supplements	No. of drugs	Percentage (%)
1	VITAMIN D	40	21.73
2	MECOBALAMIN	34	18.47
3	CALCIUM	31	16.84
4	FOLICACID	22	11.95



5	VITAMIN B12	25	13.58
6	ACCUCAL	19	10.32
7	PYRIDOXINE	13	07.06

TABLE 02: Utilization pattern of Vitamins and Minerals supplements class wise distribution

6. Utilization pattern of Antibiotics:

Among 118 patients, 40 drugs of Cephotaxime is found to be the highest number of drugs prescribed to 42.55% of population, followed by 28 drugs of Ampicillin were prescribed to 29.78% of population, followed by 19 drugs of Clindamycin were prescribed to 20.21% of population, followed by 5 drugs of Nitrofurantoin were prescribe to 5.31% of population and by 2 drugs of Levofloxin is found to be the least number of drugs prescribed to 2.12% of population.

S.NO	Antibiotics	No.of drugs	Percentage (%)
1.	CEPHOTAXIME	40	42.55
2.	AMPICILLIN	28	29.78
3.	CLINDAMYCIN	19	20.21
4.	NITROFURANTOIN	05	05.31
5.	LEVOFLOXIN	02	02.12

TABLE 03: Utilization pattern of Antibiotics

7. Utilization pattern of Anti-histamine:

23 Levocetizine drugs was found to be the maximum number of drugs prescribed to 35.38% of population, followed by 16 Cetrizine drugs were prescribed to 24.61% of population, followed by 15 CPM drugs were prescribed to 25.07% of population, followed by 11 Doxylamine drugs were found to be the minimum number of drugs prescribe to 16.92% of population.

S.No	Anti-histamine	No of Prescriptions	Percentage(%)
1.	Levocetizine	23	35.38
2.	Cetrizine	16	24.61
3.	CPM	15	23.07
4.	Doxylamine	11	16.92

TABLE 04: Utilization pattern of Anti-histamine

8. Drug utilization pattern prescribed drugs:

The drug utilization pattern of prescribed drugs depicted that the maximum number of drugs prescribed were found to be 184 vitamins and mineral supplement were prescribed to 26.06% of population, 97 antibiotic drugs were prescribed to 13.06% of population, 65 Anti-Histamine drugs were prescribed to 9.20% of population, 46 NSAID drugs were prescribed to be 6.51% of

population, 42 H2 blockers were prescribed to 5.94% of population, 40 Antimalarial were prescribed to 5.66% of population, 38 CPis drugs were prescribed to 5.38% of population, 36 Anti-Arrhythmic were prescribed to 5.19% of population, 28 Anti-Emecics drugs were prescribed to 3.76% of population, 67 of other drugs were prescribed to 9.47% of population and minimal drugs were found to be 23 Antipyretics drugs were prescribed to 3.25% of population.



S.NO	Prescribed drugs	Category	No. of prescription	Percentage (%)
1	VITAMIN AND MINERAL SUPPLEMENTS	DIETARY SUPPLEMENTS	184	26.06
2	ANTI BIOTICS	CATEGORY-B	97	13.73
3	ANTI HISTAMINE	CATEGORY-C	65	9.2
4	NSAID	CATEGORY-B/D	46	6.51
5	H2 BLOCKERS	CATEGORY-B	42	5.94
6	ANTI MALARIALS	CATEGORY-B	40	5.66
7	ANTI HYPERTENSIVES	CATEGORY-C	40	5.66
8	PPI	CATEGORY-B	38	5.38
9	ANTI ARRHYTHMIC	CATEGORY-C	36	5.19
10	ANTI EMETICS	CATEGORY-A	28	3.96
11	ANTI PYRETICS	CATEGORY-B	23	3.25
12	OTHERS	-	67	9.49

TABLE 05: Drug utilization pattern prescribed drugs

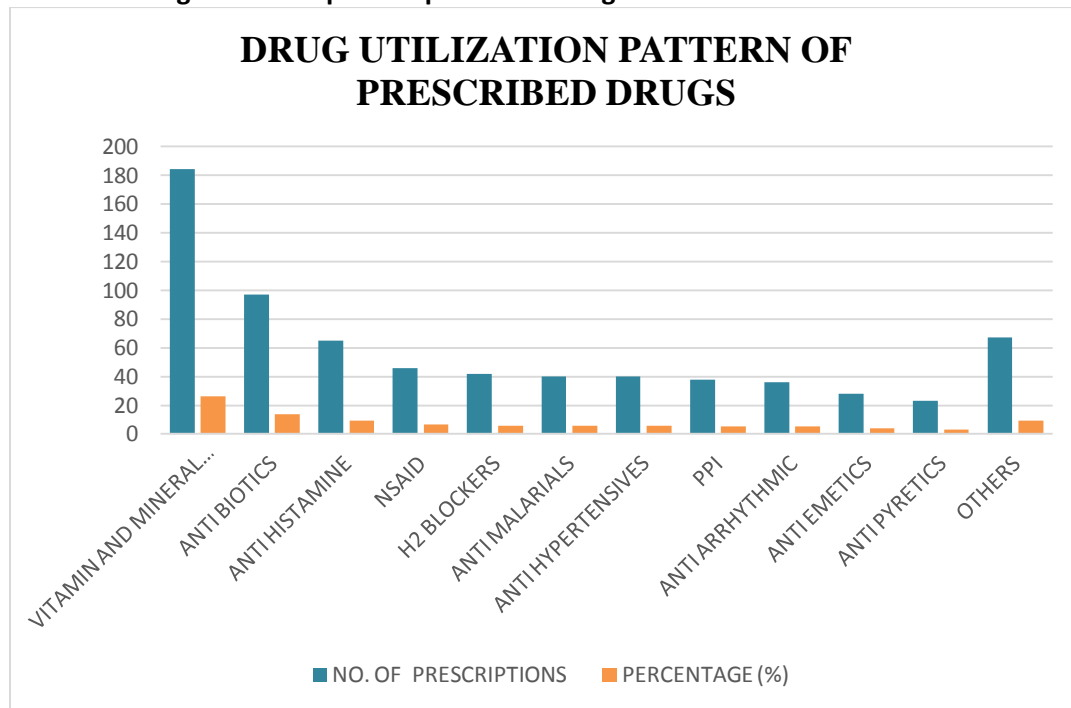


FIGURE 02: Drug utilization pattern of prescribed drugs



DISCUSSION:

The majority of pregnant women in our study (n=62, 52.54 %) were between the ages of 25 and 35, which is comparable to the results of [5] Savitha A et al, who determined that patients were between the ages of 25 and 35, which represents the normal reproductive age range.

In investigation, the largest number of cases with a co morbid condition of GDM was found to be 12 cases (37.50 %), followed by thyroid 11 cases (34.37 %), HTN 4 cases (12.50 %), thyroid & GDM 3 cases (9%), and DM 2 cases (6.23 %).

Vitamins and mineral supplements (n=184, 26.06 %) were the most commonly prescribed class of medications in our research of 118 prescriptions. It was observed that vitamin and mineral supplements were the most usually given medicine, similar to a study conducted by J.Z.Al-Hamimi et al.[6]

Vitamin and mineral supplements were found to have the highest number of medication prescribed (184 drugs, or 26.06 %), followed by antibiotics (97 drugs, or 13.06 %), and antihistamines (65 drugs, or 65 %). Anti-malarial 40 drugs (5.66 %), followed by Anti hypersensitive 40 drugs (5.66 %), followed by PPIs 38 drugs (5.38 %), followed by Anti-Arrhythmic 36 drugs (5.19 %), followed by Anti emetics 28 drugs (3.96 %), followed by Antipyretics 23 drugs (3.25 %), followed by Miscellaneous 67 drugs (9.49 %).

According to our research, the majority of prescription medications (59.77 %) fall into FDA drug risk Category B. It's similar to the research done by [5] Savitha A, et al. The maximum prescribed medicine in their study belongs into the group B.

In this study, category B received 59.77 %, followed by Category C (21.38%), Category X (10.19%), Category A (4.90%), and Category D (3.25 %).

Vitamin D 40 drugs (21.73 %), Mecobalamin 34 drugs (18.47 %), Calcium 31 drugs (16.84 %), Folic acid 22 drugs (11.95 %), Vitamin B12 25 drugs (13.58 %), Accucal 19 drugs (10.32 %), and Pyridoxine 13 drugs were found to be the most popular vitamins and mineral supplement drugs in our study (7.06 %).

Number of Antibiotic drugs prescribed were found to be Cephotaxime 40 medications (42.55 %), Ampicillin 28 drugs (29.78 %), Clindamycin 19 drugs (20.21 %), Nitrofurantoin 5 drugs (5.31 %), and Levofloxin 2 drugs (2.12 %).were determined to be the most commonly administered antibiotics in our study.[7,8]

CONCLUSION:

Prescribing for pregnancy is mostly an emotionally driven set - up without any back-up of potent empirical proof. It's absolutely essential being alert towards potential prescribing troubles. Because fetal safety is a top consideration, only approved medications that's been used for a long period of time are preferred over experimental alternatives. Medication doses at the lower end of the therapeutic window are mostly recommended in pregnancy to reduce fetal risk. Most of the women in our study were 25-35 years of age .Most of the commonly occurring co morbidity were thyroid, hypertension, diabetes mellitus. Before prescribing, counseling is necessary, and it must include aspects such as the cost and consequences of the medication, the period of pregnancy, and the existing proof in relation to the chosen treatment. Vitamins and minerals are most commonly prescribed medication.[2,6,9,10] Anti-pyretic drugs and anti-emetics were prescribed least. Most of the prescriptions consisted of generic medication. Anti-histamines, NSAIDS, proton pump inhibitors, anti-arrhythmic drugs were other prescribed drug categories. Category B drugs are mostly prescribed drugs with Category D drugs being least prescribed. The warning note-'not to be taken in pregnancy unless benefits exceed dangers' on most medication labels, provides a severe burden on the practitioner. If in doubt, one should always seek the advice of coworkers or experts in the field.[4,11-13] Since not all women can experience perfect health during their 9-month gestation,



interdisciplinary teams frequently come up with novel solutions in consultation with the potential mother. Reduced use of category B drugs and full abstinence from category X drugs were advised. The majority of the medication was from NLEM (National List of Essential Medication).

LIMITATIONS:

- The sample size was small.
- In several cases, pre - existing health conditions and medications were not disclosed, which represented a study limitation.

AUTHORS CONTRIBUTION:

The idea, planning, and implementation of the study were greatly aided by all of the writers. Tasneem and Srinivasu worked on data gathering, processing, and interpretation; Nezamuddin and Tasneem wrote the article. Ahalya SP gave the article a critical evaluation and was in charge of conceptualizing, overseeing, and finalizing the piece. The finished manuscript has been read and approved by all authors.

ABBREVIATIONS:

DUE- Drug Utilization Evaluation, US FDA- United State Food and Drug Administration, WHO- World Health Organization, GDM- Gestational Diabetes Mellitus, HTN- Hypertension, DM- Diabetes Mellitus, NSAIDs- Non Steroidal Anti Inflammatory Drugs

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CONFLICT OF INTEREST:

No authors have disclosed any conflicts of interest.

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REFERENCES:

- [1] Michelle IJ, Dhanushri E, RAJ VN, Syed MA, Priyadharshini A, Ahalya SP. A Retrospective Drug Utilization Study on Psychiatric Illness in a Tertiary Care Teaching Hospital. *J Pharm Res Int* 2021;33:148–53. <https://doi.org/10.9734/jpri/2021/v33i40b32274>.
- [2] Jayadeva BT, Panchaksharimath P. A retrospective study on drug utilization in patients with acute exacerbation of bronchial asthma in adults at a tertiary teaching hospital in Bengaluru. *Egypt J Chest Dis Tuberc* 2016;65:19–22. <https://doi.org/10.1016/j.ejcdt.2015.09.002>.
- [3] Sri Roja I, Shanmugasundaram P, Sathesh Kumar S. A retrospective study on prescribing pattern of drugs among pregnant inpatients in tertiary care hospital. *Res J Pharm Technol* 2018;11:5287–92. <https://doi.org/10.5958/0974-360X.2018.00963.0>.
- [4] Tamirci M. Evaluation of the Pregnant Women's Approaches Regarding Drug Utilization. *North Clin Istanbul* 2020;8:49–56. <https://doi.org/10.14744/nci.2020.27003>.
- [5] A. S, H. S, Gumma K. Drug pattern use during pregnancy: a prospective study at tertiary care teaching hospital. *Int J Basic Clin Pharmacol* 2016;5:192–5. <https://doi.org/10.18203/2319-2003.IJBCP20160126>.
- [6] Al-Hamimi J, Al Balushi K. Patterns of prescription drugs use among pregnant women at Sultan Qaboos University Hospital and Sultan Qaboos University Hospital Family and Community Medicine Clinic, Oman. *J Pharm Bioallied Sci* 2016;8:309–13. <https://doi.org/10.4103/0975-7406.199347>.
- [7] Malaeb DN, Fahs IM, Salameh P, Hallit S, Saad M, Bourji J, et al. Assessment of vancomycin utilization among lebanese



- hospitals. Saudi Med J 2019;40:152–7.
<https://doi.org/10.15537/smj.2019.2.23872>.
- [8] Al-Hadithi D, Al-Zakwani I, Balkhair A, Al Suleimani YM. Evaluation of the appropriateness of meropenem prescribing at a tertiary care hospital: A retrospective study in Oman. Int J Infect Dis 2020;96:180–6.
<https://doi.org/10.1016/j.ijid.2020.04.045>.
- [9] Vadhariya A, Chen H, Serna O, Zamil H, Abughosh SM. A retrospective study of drug utilization and hospital readmissions among Medicare patients with hepatic encephalopathy. Medicine (Baltimore) 2020;99:e19603.
<https://doi.org/10.1097/md.00000000000019603>.
- [10] Bedewi N, Sisay M, Edessa D. Drug utilization pattern among pregnant women attending maternal and child health clinic of tertiary hospital in eastern Ethiopia: Consideration of toxicological perspectives. BMC Res Notes 2018;11:1–7.
<https://doi.org/10.1186/s13104-018-3966-5>.
- [11] Wing DA, Simhan HN, Grobman WA, Iams JD, Caritis SN, Wapner RJ, et al. Prescription and Other Medication Use in Pregnancy 2019;131:789–98.
<https://doi.org/10.1097/AOG.0000000000002579>. Prescription.
- [12] Romero Viamonte K, Salvant Tames A, Sepúlveda Correa R, Rojo Manteca MV, Martín-Suárez A. Compliance with antibiotic prophylaxis guidelines in caesarean delivery: a retrospective, drug utilization study (indication-prescription type) at an Ecuadorian hospital. Antimicrob Resist Infect Control 2021;10:1–8.
<https://doi.org/10.1186/s13756-020-00843-1>.
- [13] Thamby SA, Juling P, Xin BTW, Jing NC. Retrospective studies on drug utilization patterns of asthmatics in a Government hospital in Kedah, Malaysia. Int Curr Pharm J 2012;1:353–60.
<https://doi.org/10.3329/icpj.v1i11.12060>.

