

## Drug utilization study in antenatal clinic of Obstetrics Gynaecology Department of a Tertiary Care Hospital attached with Medical College

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### Abstract

**Background:** The principal aim of drug utilization research is to facilitate the rational use of drugs in populations. Pregnancy is a special physiological condition. Careful consideration of the benefit to the mother and the risk to the foetus is required while prescribing drugs during pregnancy.

**Material and Methods:** Present study was Prospective, non-interventional & observational study conducted among 711 antenatal women in Obstetrics & Gynaecology Dept. during October 2014 to September 2015.

**Result:** Out of 711 antenatal women majority 328 (46.13%) were in the age group of 22 -25 years. Majority 568 (79.89%) of antenatal women were having mild anaemia while 21 (2.95%) were having moderate anaemia and majority of antenatal women were suffering from nausea and vomiting (12.37%) followed by pre- eclampsia (5.90%) and fever (3.79%). Most commonly prescribed drug was ferrous sulphate in 545 encounter followed by calcium, and vitamin B-complex same encounter 543. Total prescribed drug were 2661, from this most commonly prescribed drug class was miscellaneous about 1628 (61.18 %) drugs. Most commonly prescribed Drug in 1<sup>st</sup> trimester was folic acid 167 (97.6%) while in 2<sup>nd</sup> and 3<sup>rd</sup> trimester it was ferrous sulphate 269 (98.89%) and 265 (98.88%) respectively. Average number of drugs prescribed was 3.74. Majority 2395 (90%) of drugs prescribed by generic name. Most of the prescribed drugs were belongs to FDA category A (91.13%).

**Conclusion:** Most commonly prescribed drugs for antenatal women were ferrous sulphate, calcium, and vitamin B- complex by oral route.

**Keywords:** Drug Utilization study, Antenatal clinic

### Introduction

The rational use of drugs means that patients receive medicines appropriate for their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community. Drugs and therapeutics committees can play an important role in improving the efficiency of the pharmaceutical system, both nationally and at institutional levels. They should also perform drug utilization studies and prescription reviews.<sup>(1)</sup> The principal aim of drug utilization research is to facilitate the rational use of drugs in populations.<sup>(2)</sup>

Pregnancy is a special physiological condition. Careful consideration of the benefit to the mother and the risk to the foetus is required while prescribing drugs during pregnancy.<sup>(3)</sup> Maternal treatment with conventional doses of some medications during a susceptible period of pregnancy is known to be harmful to the developing embryo. Thalidomide and isotretinoin are the most notable examples.

### Material and Methods

Present study was Prospective, non-interventional & observational study conducted by Department of Pharmacology in association with Department of Obstetrics and Gynaecology, Shri M.P. Shah Government Medical College & Guru Gobind Singh Government Hospital, Jamnagar among 711 patients. Diagnosis and line of treatment was decided by the

Obstetrics and Gynaecologist in charge of respective UNIT. No additional drugs or investigations were advised by us during study period. The study was performed over a period of one year from October 2014 to November 2015. Data of patients matching inclusion criteria were recorded only. Data like age, sex, diagnosis, ongoing treatment were recorded from case record of patients. Informed consent of the patient was taken. Identity of patient were kept confidential. Ethical approval: The study was approved by the Institutional Ethics committee.

### Inclusion Criteria:

1. All new case of antenatal patient visiting OPD
2. Pregnant women age above 18 year, with or without co morbidities

**Exclusion Criteria:** Pregnant women diagnosed with acute and chronic medical conditions requiring hospitalization were excluded from the study.

### Result

In present study out of 711 antenatal women majority of women 328 (46.13%) were in the age group of 22 -25 years followed by almost equal 168 (23.63%) & 167 (23.48%) in 26-29 & 18-21 years age group respectively. Mean age was 22.3±3.0 years at 95% confidence limit.

In present study we found that majority 312 (43.88%) of antenatal women were in primi gravida followed by 254 (35.72%) & 145 (20.39%) in Second

gravida and multi gravida respectively. Out of 711 antenatal women 272 were in 2<sup>nd</sup> trimester which was most common followed by 268 antenatal women in 3<sup>rd</sup> trimester.

Antenatal visits are necessary for better monitoring and identify the risk factors as early as possible that may arise during antenatal period and manage them as soon as possible to avoid complications. At least 3 antenatal visits are required for better monitoring. When we classify antenatal women considering to their number of antenatal visit to antenatal clinic of Obstetrics and Gynaecology at a tertiary care hospital, we found that maximum 393 (55.27%) antenatal women had visited 3 to 5 visits.

Anaemia is the major risk factor that leads to various complications that may affect health of both mother as well as her child. When we classify their anaemia according their Hb level, we found that majority 568 (79.89%) of antenatal women were having mild anemia while 21 (2.95%) were having moderate anaemia.

In our study majority of antenatal women were suffering from nausea and vomiting (12.37%) followed by pre- eclampsia (5.90%) and fever (3.79%). (Fig. 1)

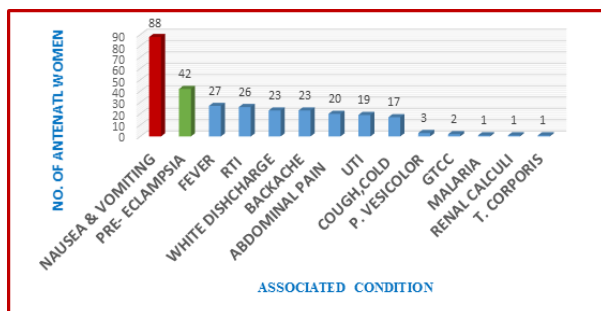


Fig. 1: Associated condition in antenatal women

RTI –Respiratory tract infection, UTI- Urinary tract infection, GTCC- Generalized tonic clonic seizure

Table 1: Utilization pattern of drugs in Antenatal clinic

Sr No.	Drug	No of Encouter	Percentage
1	Ferrous sulphate	545	76.65
2	Calcium	543	76.37
3	B complex	543	76.37
4	Vitamin -c	542	76.23
5	Folic acid	178	25.03
6	Doxynate (Doxylamine + Pyridoxine)	74	10.4
7	Paracetamol	73	10.26
8	Methyldopa	36	5.06
9	Ranitidine	25	3.51
10	Hyoscine	17	2.39
11	Cetizine	16	2.25
12	Amoxycillin	16	2.25

13	Clotrimazole	13	1.82
14	Cefixime	8	1.12
15	Nifedipine	7	0.98
16	Detromethorphan	5	0.7
17	Rabeprazole	4	0.56
18	Ciprofloxacin	3	0.42
19	Azithromycin	3	0.42
20	Diclofenac sodium	2	0.28
21	Famotidine	2	0.28
22	Metronidazole	2	0.28
23	Sod.valproate	2	0.28
24	Chloroquine	1	0.14
25	Syrup Alka	1	0.14

Table 2: WHO core Indicators

WHO prescribing indicator	Findings
Average number of drugs prescribed in antenatal clinic	3.74
Percentage of encounters prescribed by antibiotics	6.46 %
Percentage of encounters were prescribed by injection.	0.70%
No of drugs prescribed by generic name	2395(90%)
No of drugs prescribed from WHO Model list of essential medicines	2003(75.27%)

In the present study most commonly prescribed drug was ferrous sulphate in 545 encounter followed by calcium, and vitamin B-complex same encounter 543. (Table 1)

Total prescribed drug were 2661 in present study from this In this study most commonly prescribed drug class was miscellaneous about 1628 (61.18 %) drugs in which most commonly prescribed drug was calcium, Followed by Blood forming agents (27.17%) other groups prescribed were gastrointestinal drugs (4.58%), autacoids (3.41%), antimicrobial(1.72), cardiovascular system (1.61%), central nervous system, respiratory drugs (0.18%) and others (0.03%). (Fig. 2)

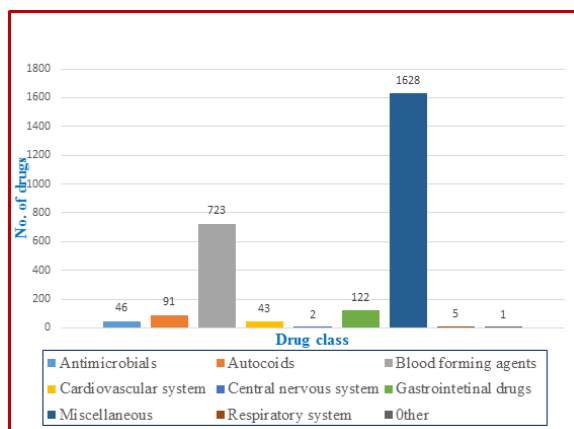


Fig. 2: Classification according to drug class

Most commonly prescribed Drug in 1<sup>st</sup> trimester was folic acid 167 (97.6%) followed by Doxynate 71 (41.5%) out of 171 women in 2<sup>nd</sup> trimester most commonly prescribed drugs were Ferrous sulphate 269 (98.89%), Vitamin-c 268 (98.52%) Calcium 267 (98.16%) B-Complex 265 (97.42%) out 272 women, and in 3<sup>rd</sup> trimester most commonly prescribed drugs were nearly same as 2<sup>nd</sup> trimester a Ferrous sulphate 265 (98.88%), Vitamin-c 264 (98.51%) Calcium 266 (99.25%) and B-Complex 267 (99.63%) out of 268. Antihypertensive agents like Nifedipine and methyldopa were prescribed in 2<sup>nd</sup> and 3<sup>rd</sup> trimester.

Total number of drugs prescribed in antenatal clinic were 2661 and Average number of drugs prescribed in antenatal clinic was 3.74 (Table 2).

Out of 711 encounters total 612 (86.07%) encounters prescribed by fixed dose combination.

Most commonly 4 drug were prescribed in 387 (54%) antenatal women followed by 5 drugs in 114 (16.03%) antenatal women. (Table 3)

**Table 3: Total number of drugs prescribed per antenatal women**

Sr. No	No. of drugs	No of patients	Percentage
1	1	75	10.54
2	2	71	9.98
3	3	22	3.09
4	4	387	54.43
5	5	114	16.03
6	6	35	4.92
7	7	6	0.84
8	8	1	0.14
Total		711	100

**Table 4: FDA category of drugs**

Sr. No	FDA Category	No. of drugs	Percentage
1	A	2425	91.13
2	B	203	7.62
3	C	30	1.12
4	D	2	0.07
5	N/A or not known	1	0.03
	Total	2661	100%

**Table 5: Anatomical classification (ATC), Prescribed Daily Dose (PDD) and Defined Daily Dose (DDD) of drugs prescribed**

Sr. No	Drug	ATC Code	PD D Mg	DD D	PDD:DD D Ratio
1	Ferrous sulphate	B03AA07	400	200	2
2	Calcium	A12AA03	500	300	1.66
3	Vitamin - c	A11GA01	400	200	2
4	Folic acid	B03BB01	5	0.4	12.5

5	Paracetamol	N02BE01	150 0	300 0	0.5
6	Methyldopa	C02AB01	750	100 0	0.75
7	Ranitidine	A02BA02	300	300	1
8	Amoxycillin	J01CA04	150 0	100 0	1.5
9	Cefixime	J01DD08	400	400	1
10	Nifedipine	C08CA05	10	30	0.33
11	Rabeprazole	A02BC04	20	20	1
12	Ciprofloxacin	J01MA02	100 0	100 0	1
13	Azithromycin	J01FA10	500	500	1
14	Sod.vaproate	N03AG01	600	150 0	0.4
15	Metronidazole	P01AB01	120 0	200 0	0.6

Most commonly prescribed route of administration was oral (99.32%) followed by topical route (0.48%).

In present study, 2395 drugs were prescribed by generic name and 266 drugs were given by brand name. So, majority of drugs (90%) were given by generic name.

In present study 2003(75.27%) drugs were prescribed from WHO Model list of essential medicines, 2015 and 2582 (97.03%) drugs were prescribed from National list of essential medicines of India, 2011.

Most of the prescribed drugs were belongs to FDA category A (91.13%) followed by category B (7.62%). (Table 4)

In present study highest ratio of PDD/DDD seen in folic acid which was 12.5, and other drug PDD/DDD ratio ranges from 2-0.33. (Table 5)

Average cost per prescription was 413.57 ₹ .

### Discussion

In present study out of 711 antenatal women majority of women 328 (46.13%) were in the age group of 22 -25 years followed by almost equal 168 (23.63%) & 167 (23.48%) in 26-29 & 18-21 years age group respectively. Mean age was 22.3 + 3.0 years at 95% confidence limit. Study conducted by Gawde SR et al in which mean age was 25 + 4.07,<sup>(4)</sup> study conducted by Das B et al in Nepal mean age was 25 year<sup>(5)</sup> and in Brazil study conducted by Fontoura A et al mean age was 24.9 years,<sup>(6)</sup> so this all are comparable. This age group /age is reproductive age of women.

In present study when we have classify antenatal women according to their gravida status, we found that majority 312 (43.88%) of antenatal women were in primi gravida followed by 254 (35.72%) & 145 (20.39%) in Second gravida and multi gravida respectively. The study conducted by Gawde SR, majority of antenatal women about 43.8% were primi gravida<sup>(4)</sup> which is comparable to our study And study done in the brazil by Fontoura A<sup>(6)</sup> about 86.98% were primi gravida, the percentage in higher than our study but majority of antenatal women were primi graviada.

In the present study out of 711 antenatal women 272 (38.26%) women had 2<sup>nd</sup> trimester which was most

common followed by 268 antenatal women in 3<sup>rd</sup> trimester. Study conducted by Etefa K et al majority of antenatal women were in 2<sup>nd</sup> trimesters (73.248 %).<sup>(7)</sup>

When we classify antenatal women considering to their number of antenatal visit to antenatal clinic of Obstetrics and Gynaecology at a tertiary care hospital, we found that maximum 393 (55.27%) antenatal women had visited 3 to 5 in antenatal clinic. This indicate better compliance of antenatal women. But there were 292 (41.07%) antenatal women those had visited antenatal clinic < 3 times, Some of them was visited the ANC clinic 1<sup>st</sup> time in first trimester, so emphasis should be given towards counselling for importance of visit during antenatal period.

Study done by Fikadu M et al Majority (80.47%) of antenatal women visited the ANC clinic 3-5 times throughout their pregnancy period.<sup>(8)</sup> Study by Sharma R et al. women visit antenatal clinic was More than 5, n=225 (55.55%) which is different from our study.<sup>(9)</sup>

When we classify their anaemia according their Hb level, we found that majority 568 (79.89%) of antenatal women were having mild anaemia while only 21 (2.95%) were having moderate anaemia. The study conducted by Gawde SR, Percentages of women having mild anaemia in 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> trimester were found to be 81%, 83% and 82% respectively, percentages of women having moderate anaemia in 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> trimester were found to be 16%, 12% and 16% respectively. Most common type of anaemia was mild anaemia.<sup>(4)</sup>

India is one of the countries with very high prevalence of anaemia in the world. Almost 58 per cent of pregnant women in India are anaemic and it is estimated that anaemia is the underlying cause for 20–40 per cent of maternal deaths in India.<sup>(10)</sup>

In our study majority of antenatal women were suffering from nausea and vomiting (12.37%) followed by Pre- eclampsia (5.90%) and fever (3.79%). Study by Das B et al in Nepal associated condition and problem oriented drug use due to nausea/vomiting (4.7%) most commonly. It is match with our study but percentage of incidence was lower than our study.<sup>(4)</sup> (Fig. 1)

In the present study most commonly prescribed drug was ferrous sulphate in 545(76.65%) encounter followed by calcium, and vitamin B-complex same encounter 543, vitamin 542 (Table 1). study done by A study done by Fontoura A in the brazil show the most common drugs prescribed was ferrous sulphate in 70.39% pregnant women. drugs.<sup>(5)</sup> A study done by Donati s on pregnancy among Italian women Ferrous sulphate (51%) and vitamins (25%) most commonly prescribed drug.<sup>(11)</sup> A study done by H. Nordeng et al, on Scandinavian women, ferrous sulphate 64.7% was most commonly prescribed drug.<sup>(12)</sup>

So, in present study most commonly prescribed drugs were ferrous sulphate, calcium, and vitamin B-complex, calcium. This all drugs are necessary during pregnancy.

As a component of prenatal care, micronutrient supplementation might reduce maternal morbidity and mortality directly by treating a pregnancy-related illness or indirectly by lowering the risk of complications at delivery. Nevertheless, the effectiveness of supplementation programs—notably of iron and folate—has tended to focus on infant outcomes, perinatal mortality, preterm delivery, and low birth weight.<sup>(13)</sup>

In the present study most commonly prescribed drug class was miscellaneous (vitamins and minerals) about 1628 (61.18%) drugs. Followed by Blood forming agents (27.17%) and antimicrobial agents (1.72%) (Fig. 2). Study done by Agarwal M et al Minerals and vitamins were the most frequently prescribed medicines (45.2%).<sup>(14)</sup> Percentage of prescription of miscellaneous drugs was lower than our study but most commonly prescribed drug group was mineral and vitamins.

Most commonly prescribed Drug in 1<sup>st</sup> trimester was folic acid 167(97.6%) followed by Doxynate 71 (41.5%), in 2<sup>nd</sup> trimester most commonly prescribed drugs were Ferrous sulphate 269 (98.89%), Vitamin-c 268 (98.52%) Calcium 267 (98.16%) B-Complex 265 (97.42%), and in 3<sup>rd</sup> trimester most commonly prescribed drugs were same as 2<sup>nd</sup> trimester a Ferrous sulphate 265 (98.88%), Vitamin-c 264 (98.51%) Calcium 266 (99.25%) and B-Complex 267 (99.63%). Antihypertensive agents like Nifedipine and methyldopa were prescribed in 2<sup>nd</sup> and 3<sup>rd</sup> trimester. Study conducted by Pinto Pereira LM in which Multivitamins, iron/folic acid and calcium were the most frequently prescribed drugs during the first, second and third trimesters (55.5%, 43.4%, 11%), (46.2%, 46.8%, 18.8%) (56.5%, 56.9%, 25.8%) of pregnancy respectively.<sup>(15)</sup> A study conducted by Joshi H et al, in the first trimester folic acid (33.4%) was most frequently prescribed followed by antiemetic drugs (14.6%), In the second trimester, iron (28.4%), calcium (28.1%) most commonly prescribed and In the third trimester, iron (29.5%) and calcium (29.5%) most commonly prescribed.<sup>(16)</sup> In our study folic acid prescribed more commonly prescribed in 1<sup>st</sup> trimester. It prevent the chance of development of neural tube defect in fetus. Prescribing frequency of iron was increased in 2<sup>nd</sup> and 3<sup>rd</sup> trimester in our study. There is increase chances of development of anaemia from the second trimester.

Total number of drugs prescribed in antenatal clinic were 2661 and Average number of drugs prescribed in antenatal clinic was 3.74 (Table 2). A study conducted by Joshi H et al average number of drugs prescribed was 3.01<sup>(16)</sup> which is comparable to our study. In foreign study done by Nordeng H in Scandinavian women average number of drugs per encounter was 2.9 and.<sup>(12)</sup> Study conducted by Eze UI in Nigeria the average number of drugs prescribes was 3. The result of this 3 study was comparable to our study.<sup>(17)</sup>

Out of 711 encounters total 86.07% encounters prescribed by fixed dose combinations. A study conducted by Harsh Joshi et al Drugs prescribed in fixed

dose combination form were 22.8%.<sup>(16)</sup> So, in our study percentage was so higher than other study may be due to majority of prescription contain Vitamin B-complex.

Out of 711 encounters total 6.46% encounters prescribed by antibiotics (Table 2). A study conducted by Harsh Joshi et al 11.17% which was nearby our study.<sup>(16)</sup>

Our study was conducted in outdoor patients (antenatal clinic) in that only 0.70% of encounters were prescribed by injection (Table 2). A study conducted by Harsh Joshi et al 2.17% of encounter prescribed by injection which was comparable to our study.<sup>(16)</sup>

Drugs used in antenatal clinic Most commonly prescribed route of administration was oral (99.32%) followed by topical route (0.48%). As our study conducted in outdoor department majority of drugs were prescribed by oral route.

In present study, 2395 drugs were prescribed by generic name and 266 drugs were given by brand name. So, majority of drugs (90%) were given by generic name (Table 2). Study done by Fikadu M et al Majority of the drugs (94.08%) were prescribed by their generic names.<sup>(8)</sup> This results comparable to our study and Study conducted by Harsh Joshi et al 21.51% drugs were prescribed by the generic name.<sup>(16)</sup> So, in our study positive result obtain from this study. A government initiative to expand the distribution of generic drugs free through primary health centres and other government healthcare centres is likely to turn state governments into the biggest bulk buyers of unbranded generic drugs.<sup>(18)</sup> So, in our study which is conducted in the government sector drug prescribed in generic name was more.

In present study 2003(75.27%) drugs were prescribed from WHO Model list of essential medicines, 2015 and 2582 (97.03%) drugs were prescribed from National list of essential medicines of India, 2011. Majority of drugs prescribed from essential medical result which was positive result.

Most of the prescribed drugs were belongs to FDA category A (91.13%) followed by category B (7.62%)(Table 4). Study done by Harsh Joshi et al majority of drugs were from category A (77.49%) followed by category B (12.64%), category C (9.15%) and category D (0.72%).<sup>(16)</sup> Percentage of this study was different in category A but most commonly prescribed drug from category A is matches with our study. In our study and in Harsh Joshi et al study prescribed drugs with category D was only 0.03% and 0.7%.

In present study highest ratio of PDD/DDD seen in folic acid 12.5. In present study conclude that folic acid, calcium, ferrous sulphate, this drugs are over utilized as their PDD/DDD ratio was 12.5, 2.2 respectively (Table 5). Ratio was higher may be due to we had calculated by its prophylactic dose and many patients were anaemic and taken therapeutic dose. Defined daily doses (DDD) are used as a standard for the measurement of drug utilisation and drug exposure in a population. The DDD

does not necessarily reflect the recommended or prescribed daily dose (PDD).<sup>(19)</sup>

Average cost per encounter in present study was 413.57 ₹ . Which was high mainly due to 4 drugs prescribed together in majority of prescription for longer period in antenatal women. The cost was calculated according to minimum price of that drug from the IDR (Indian drug Review).

## Conclusion

In the present study most commonly prescribed drug was ferrous sulphate in 545(76.65%) encounter followed by calcium, and vitamin B-complex same encounter 543, vitamin C in 542 encounter. Commonly prescribed drug group was miscellaneous which include vitamins and minerals.

Most commonly prescribed Drug in 1<sup>st</sup> trimester was folic acid and in 2<sup>nd</sup> and 3<sup>rd</sup> trimesters Ferrous sulphate Vitamin-C Calcium, B-Complex were most commonly prescribed drug.

Average number of drugs prescribed in antenatal clinic was 3.74, Most commonly 4 drug were prescribed together in 54% antenatal women followed by 5 drugs in 16.03% antenatal women which was prescribed by oral route. Majority of drugs (90%) were given by generic name. In present study 75.27% drugs were prescribed from WHO Model list of essential medicines, 2015 and 97.03% drugs were prescribed from National list of essential medicines of India, 2011. Most of the prescribed drugs were belongs to FDA category A (91.13%). The safest category during pregnancy.

This study provided a baseline data regarding the prescribing pattern of drugs used in antenatal women. Drug utilization study can help in minimizing the inherent risk in pregnant women. This study has provided a scope for further research in this area.

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