

Assessment of Prenatal Drug Prescription Pattern at Mbabane Government Hospital

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Abstract

Background: Pregnancy is the time of profound physiological changes in a female's body. Maternal drug use during pregnancy may pose a teratogenicity risk to the fetus. However, the fact that drugs are needed to mitigate the complications during pregnancy cannot be avoided, therefore, this study is designed to assess prenatal drug prescription pattern at Mbabane Government Hospital.

Objectives: Assess prenatal drug prescription patterns at the gynecology and maternity wards at Mbabane Government Hospital in Swaziland.

Methodology: A retrospective study was conducted at the maternity and gynecology wards at Mbabane Government Hospital from $3^{rd} - 14^{th}$ of July 2017. Data was retrieved from in-patient medical records.

Results: The study was done by enrolling 218 pregnant women. The most commonly prescribed drugs were the antimicrobial, NSAIDs, nutritional supplements, parenteral solutions and analgesics. The least prescribed were anticonvulsants. A high proportion were prescribed from US-FDA category B (42%), followed by category C (36%) and category A (9%). A small percentage of drugs (6%) were prescribed from drugs with positive evidence of risk (US-FDA category D) and (7%) were prescribed from drugs with proven fetal risk (category X).

Conclusion/ Recommendations: A considerable proportion of pregnant women were exposed to drugs, including those with positive evidence of risk and those with proven fetal risk. Healthcare providers must adopt the US-FDA risk category system when prescribing drugs to pregnant women.

Keywords: Prenatal; drug prescription pattern; US-FDA pregnancy category.

Introduction

Background

Prenatal period is associated with a range of pharmacokinetic and physiological changes which present physiological complications (Ramesh, et al, 2016).

Selection of the best medications to be used during prenatal period to manage disease states is posing challenges to the clinicians. Maternal medications can pose teratogenic risk to the fetus (Uchenna, et al, 2007). Few cases about stillbirths, premature births and babies born with deformities were reported and statistics by WHO states that in Swaziland stillbirth rate per 1,000 total births in 2009 was 18.0 and neonatal mortality rate per 1,000 births in 2013 was 29.8 (WHO, 2013).

A study from Ethiopia reported that the use of overall medications was found to be high during prenatal as well as antenatal period. 52.2% women had at least one prescription only medicines (POM) and over the counter (OTC) medications during pregnancy with the average number of 1.6 ± 0.5 POM and 1.5 ± 0.5 OTC medications respectively (Mohammed, et al, 2013).

Mohammed also mentioned that the prevalence and average number of medication used in the study is comparable with the results done in South Africa (59.3%), Egypt (86%) and Palestine (56%). In Ethiopia, higher proportion of Category-D medications was observed in the third (18.6%) and first (16.1%) trimesters as compared to the second (13.5%) trimester of pregnancy. Similarly, Category-X medications was used higher in third trimester (7.2%) and first (7.1%) trimester than second trimester (6.7%) of pregnancy (Mohammed, et al, 2013).



A study in Mumbai found the percentage that all pregnant women attending outpatient department (OPD) to receive folic acid and iron were; West-Africa (33.33%), Germany (54%), Nepal (72.8%) and Pakistan (79.4%) (Gawde, 2013). Gawde also reported that out of 760 prescriptions, only 292 prescriptions had drugs other than iron, folic acid and calcium lactate. Of 292 prescriptions only 50 prescriptions had drugs belonging to category A (17.1%), 189 (64.7%) prescriptions had category D. Majority of the drugs (apart from iron, folic acid, and calcium supplements) used during pregnancy were from category B, followed by category A and category C (Gawde, 2013).

A study in India reported that iron was prescribed only to 2.8 % women in first trimester, 39.3% women in second trimester, 50% women in third trimester where folic acid was prescribed to 74.2 %, 32.7% and 2% women in first, second and third trimester respectively (Reddy, et al, 2011).

Objectives of the study

General objectives

The aim of the study was to assess the prenatal prescription patterns and to identify commonly prescribed drugs and assess them according the US-FDA risk category system at Mbabane Government Hospital (MGH).

CLASS	DESCRIPTION
Category A	Adequate and well controlled studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy and there is no risk in later trimesters.
Category B	Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant.
Category C	Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well- controlled studies in humans, but potentially benefit may warrant use of the drug in pregnant women despite potential
Category D	There is a positive evidence of human fatal risk (birth defects, etc.), but the benefits from use in pregnant women may be acceptable despite the risk.
Category X	Studies in human beings or animals have demonstrated fetal abnormalities or there is evidence of fetal risk based on human experience, and the fetal risk of using the drug in pregnant women clearly outweighs and possible benefit.

Table 1.	US-FDA-pregnancy	category	classification	system
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Research methodology

Study area and period

The research was conducted from May up to July 2017 at maternity and gynecology wards in Mbabane Government Hospital (National referral hospital). A retrospective study was conducted at the maternity and gynecology wards in MGH from the $3^{rd} - 14^{th}$ of July 2017.

Population

The target population was all pregnant woman who attended the maternity and gynecology wards in MGH from March to June 2017 and a random sampling method was used.

Sample size: The sample size for the study was determined based on the prevalence of drug use during pregnancy. According to a study done by Hanafy et al, 2016, the prevalence prescriptions drug use during pregnancy in Egypt was 83%. By using a single proportion formula taking the prevalence of the drug use during pregnancy as 83%.

$$n = \frac{z^2 p(1-p)}{d^2}$$
$$n = \frac{1.96^2 0.83(1-0.83)}{0.05^2}$$

n = 218 sample size

N: Desirable sample size

z: z value which is the standard deviation of 1.96% at 95% confident interval.

P: Proportion of prevalence of adherence of clinicians to US-FDA pregnancy category system (83% was taken from previous studies (Hanafy et al, 2016)).

d: Margin error on p, approximately 0.05.

Result and discussions

A total of 218 pregnant women were enrolled in the study. Majority of the patients were in age group of 30-34 years (25.7%), followed by 25-29 years (25.2%), 20-24 years (21.1%),15-19 years (7.8%), 40-44 years (6.4%) and the least group was >14 years (0.9%). All the age groups have a mean of 28.64 (SD=6.941) (Table 1). A majority of the patients in the study were in first and second trimesters 87 (39.91%) while in third trimester 44(20.18%) (Figure 1).

During first trimester, the maternal disorders most frequently recorded in the patient medical files were incomplete abortion 43(19.7%), followed by ectopic pregnancy 12(5.5%), threatened abortion 8(3.7%) and antepartum hemorrhage 6(2.8%). In the second trimester incomplete abortion 32(14.7%) was the common maternal disorder, followed by pre-clampsia 18(8.3%), inevitable abortion 5(2.3%) anemia 4(1.8%) and urinary tract infection 4(1.8%). In the third trimester of gestation, pre-clampsia 24(11.0%) was the common maternal condition followed by urinary tract infection 10(4.6%), antepartum hemorrhage 3(1.4%), upper respiratory tract infection 2(0.9%) and eclampsia 1(0.5%), respectively (Figure 2).

The gynecology unit admitted the most pregnant women in first trimester (88%), followed by second trimester (86%) and (2%) in third trimester of gestation while the maternity unit admitted (45%) in third trimester, (2%) in second trimester and (0%) in first trimester of gestation.

US-FDA Pregnancy risk classification of medications

A majority of medications prescribed in pregnant women were from category B (41.8%) followed by category C (36.2%), category A (8.5%) category X (7.5%), and category D (6.0%), respectively.

A majority of category A medicines were prescribed at the first trimester (4.4%), followed by the second trimester (3.0%) and then the third trimester (1.1%). Category B had the highest medicines prescribed to pregnant women over all the other trimesters which were; the first trimester (18.1%) had more medicines, followed by the second trimester (16.8%) and the least was the third trimester (7.0). Category C; first trimester (17.6%), (14.3%) and (4.4%) respectively. A relatively high proportion of teratogenic medications from category D (3.2%) and category X (4.2%) were used highly during the first trimester. Second trimester category D and X prescription reduced to (1.0%), (2.9%) respectively and in the third trimester (1.7%), (0.4%) respectively.

Classification of medication category according to therapeutic uses

Among antimicrobials (32.6%): metronidazole (13.6%) and amoxicillin (11.6%) were frequently prescribed. Among NSAIDs (11.6%): diclofenac (9.1%) aspirin (1.9%) were frequently prescribed. Among nutritional supplements (10.0%): ferrous sulfate (3.1%), folic acid (3.0%) and multivitamins (1.7%) were frequently prescribed. Among parenteral solutions (9.6%): ringer's lactate (6.6%) and normal saline (2.6%) were commonly given to pregnant women. Among exogenous hormones (6.4%): oxytocin (6.1%) was the frequently prescribed. Among analgesics (6.1%): paracetamol (5.0%) and tramadol (1.2%) were commonly given to pregnant women.

Among antihypertensive agents (6%): methyldopa (2.5%), nifedipine (2.4%), and hydralazine (1.0%) were frequently given to pregnant women. Among gastrointestinal drugs (4.2%): hyoscinamine

(2.9%), and metoclopramide (0.8%) were frequently prescribed. Among anesthetics (2.9%): ketamine (1.8%), and propofol (0.8%) were commonly prescribed to pregnant women. Among bronchodilators (2.0%): salbutamol (2.0%) was commonly prescribed. Among the steroids (1.8%): dexamethasone (1.3%) was prescribed frequently. Among sedatives and hypnotics (1.6%): midazolam (1.6%) was prescribed frequently. Medicines that were not commonly prescribed among the total of 1190 medicines were the diuretics (0.5%), anticonvulsants (0.4%) and antihistamines (0.2%).

Number of drugs per prescription

Prescriptions with 6-10 medicines (57.8%), followed by those with 1-5 medicines (39.9%) and the least were those with 11-15 medicines (2.3%). The mean was 1.62, SD was 0.531 and the range was 2 and average was 6.5.

	Frequency	Percent	Valid Percent	Cumulative Percent
14 and below	2	.9	.9	.9
15-19	17	7.8	7.8	8.7
20-24	46	21.1	21.1	29.8
25-29	55	25.2	25.2	55.0
30-34	56	25.7	25.7	80.7
35-39	28	12.8	12.8	93.6
40-44	14	6.4	6.4	100.0
Total	218	100.0	100.0	

Table 2. Age wise distribution of prenatal women (N=218)



Figure 1. Trimester variations among pregnant women

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Figure 2. Distribution of diagnosis in the three trimesters



Figure 3. US-FDA pregnancy risk classification of medications

Table 3. Frequency distribution of FDA drug category of the drugs prescribed during prenatal admission

US-FDA	Trimester 1	Trimester 2	Trimester 3	Total
category system	No. %	No. %	No. %	No. %
А	53 4.4	36 3.0	13 1.1	102 8.5
В	215 18.1	200 16.8	83 7.0	498 41.8
С	209 17.6	170 14.3	52 4.4	431 36.2
D	38 3.2	12 1.0	20 1.7	70 6.0
Х	50 4.2	34 2.9	5 0.4	89 7.5



Figure 4. Classification of medication category according to therapeutic uses

The results of the study showed that out of 218 pregnant women 126 (57.8%) received 6-10 drugs, followed 87 (38.9%) received 1-5 drugs and the least were 5 (2.3%) who received 11-12 drugs. The average of drugs per prescription in this study was 6.5 which is much higher than WHO recommended standard which is 2.0 per prescription. The findings are almost similar with a study conducted in Saudi-Arabia which showed an average of 4.17 drugs per prescription. This is contrasted with a study conducted in Pakistan which showed an average of 1.66 drugs per prescription (Al-Humayyd et al, 2016). A study in USA showed an average of 2.2 per prescription whereas a study in Italy showed an average of 1.8 (Daw et al, 2011).

One reason for the higher number of drugs per prescription was that all of included women were inpatient and they stayed at least 4 days in the gynecology and obstetrics wards. In addition, a quarter of admitted pregnant women had at least one disease and thus this average. Despite this, keeping the mean number of drugs per prescriptions as low as possible is always preferable to reduce the risk to the fetus and the mother also.

Classification of medication categories according to pharmacological classes

Almost all pregnant women who were admitted at the gynecology and obstetrics wards were prescribed antimicrobials (32.6%) especially metronidazole (13.6%) and amoxicillin (11.6%). The next group of commonly prescribed drugs during pregnancy were the NSAIDs (11.6%) mainly diclofenac (9.1%). These two groups were followed by nutritional supplements (10.0%) (Ferrous sulphate (3.1%) and folic acid (3.0%), exogenous hormones (6.4%) (Mainly oxytocin (6.1%) analgesics (6.1%) (Especially paracetamol (5.0%). A similar study was conducted in Ethiopia reported that a majority of drug prescribed to pregnant women were the antimicrobials such as amoxicillin, metronidazole, followed by NSAIDs and nutritional supplements (Mesfin et al, 2015) and also a study conducted in France showed an increase in the prescription of antimicrobials (42%) (Daw et al, 2011).

In contrast, a study conducted in Ethiopia reported that anti-emetics and anti-infectives were the commonly prescribed drugs. This was followed by analgesics especially, paracetamol (6.5%) and NSAID (diclofenac (5.09%) (Kasaye et al, 2015) and another study in Ahmedabad reported that iron salts (78.2%), calcium (77.1%) and folic acid (46.3%) were frequently prescribed drug groups followed by uterine relaxants (24.4%), nutritional preparations (18.5%), antiemetic drugs (14.3%) and antimicrobial agents (11.9%) and others (Harsh, et al, 2012).

This variations in drug groups in prescribing during pregnancy could be due to the fact that diseases vary in different countries. Despite this variation of diseases in countries, intensive assessment of pharmacotherapy given to pregnant women should be done with respect to the US-FDA risk category, the gestational period and the risk-benefit balance of a drug before its prescription so as to prevent fetal harm.

US-FDA pregnancy risk category of medications

This study revealed that 41.8% of medication frequently prescribed during pregnancy were from category B followed by category C (36.2%), category A (8.5%), category X (7.5%) and category D (6.0%). The present findings are comparable with a study conducted in Egypt which showed that category B (41.3%) and category C 30.2% were the most prescribed, then followed by category A (12.1%), category X (0.9%) and category D (0.5%) (Hanafy et al, 2016).

This study is comparable to a study conducted in Oman which have reported that category B and category C medicines were frequently received by pregnant women, this is also similar to a study in USA which showed some pattern where category B (50.0%), followed by category C (37.8%), category A (2.4%) were frequently prescribed (Al-Hamim et al, 2016). However, this study is contrasted with studies where category A, B and C were commonly prescribed drugs. For example, a Nigerian study reported that category C and D (5.0%) (Uchenna, et al, 2007). A study by Reddy et al also contrasted the finding of the study in that he reported that a majority of drugs used, were from category A, followed by category B and category D. However, category C and X drugs constituted 2.90 % and 5.71% of drugs used during the third trimester and first trimester, respectively (Reddy, et al, 2011).

Most of public literature shows category D and X as the least prescribed drugs. However, a higher percentage of teratogenic medicines (category D 6.0% and category X 7.5%) were highlighted in the current study, which are considered contraindicated in pregnancy. This was caused by higher admissions due to women being diagnosed with an incomplete abortion, inevitable abortion and missed abortion. The Standard Treatment Guideline (STG) of Swaziland states that in either cases if the risk outweighs the benefit oxytocin (category X) must be prescribed for abortion (STG, 2012).

The current study has not deviated from the study in Ethiopia, which reported that higher proportion of Category-D medications were observed in the third (18.6%) and first (16.1%) trimesters as compared to the second (13.5%) trimester of pregnancy. Similarly, Category-X medications was used mostly in third trimester (7.2%) and first (7.1%) trimester than in the second trimester (6.7%) of pregnancy (Mohammed, et al, 2013). In the Ethiopian study it was also reported that 4% of the pregnant women were prescribed drugs form category D and X whereas a study conducted in Taiwan found that 1.1% were from category D or X drugs 0.6% (Kabede et al, 2009). It is estimated that 3.9-4.6% of the pregnant women in the USA receive category D and X drugs (Andrede et al, 2008). This variation is due to the different diseases that women presented during pregnancy.

In the current study, there was a significant decrease in prescribing of category A drugs over the three trimesters (4.4%, 3.0% and 1.1%) respectively. This is due to the fact that these are mainly vitamins and minerals and it is known that in gynecology practice the need of vitamins and minerals decreases as the pregnancy is advancing.

Trends of medication use across pregnancy trimesters

A reduction in the trend of medication use across the trimesters was demonstrated from 39.9% in first trimester and 39.9% in second trimester and 20.2% in the third trimester. This indicates that most of pregnant women participated in the study were mostly in first and second trimester and prescribers were not reluctant to prescribe medication during the first and second trimesters of pregnancy.

The current study is comparable to a study conducted in Egypt where trends of medication use decreased across the trimester; where in the first trimester was 54.0%, 35.4%, 10.6% in second and third trimester, respectively (Hanafy et al, 2016). However, the current study is contrasted with a study conducted in Ethiopia which declared an increased trend in medication use from first trimester 19.2%, to second 26.7% and third 54.0% trimesters (Mohammed et al, 2013). Mohammed suggested that the reason for the increase of use of medications across pregnancy trimesters could possibly be because the majority of pregnant women were in the third (57.2%) and second (26.3%) trimester of pregnancy, respectively (Mohammed et al, 2013).

Different medical conditions over the three trimesters

During first trimester, the maternal disorders most frequently recorded in the patient medical files were incomplete abortion 43(19.7%), followed by ectopic pregnancy 12(5.5%), threatened abortion

8(3.7%) and antepartum hemorrhage 6(2.8%). In the second trimester of gestation incomplete abortion 32(14.7%) was the common maternal disorder, followed by preeclampsia 18(8.3%), inevitable abortion 5(2.3%) anemia 4(1.8%) and urinary tract infection 4(1.8%). In the third trimester of gestation, preclampsia 24(11.0%) was the common maternal condition followed by urinary tract infection 10(4.6%), antepartum hemorrhage 3(1.4%), upper respiratory tract infection 2(0.9%) and eclampsia 1(0.5%)

Unlike other studies where nausea and vomiting were encountered in first trimester and mostly UTIs in the second trimester. For example; a study in Ahmedabad contrasted the findings in that it reported that common complaints of women coming to the hospital were abdominal pain (13.8%), vomiting (12.4%), fever (7,5%), cough (3.4%), urinary tract infections (2.7%), and discharge per virgina (2.6%) (Harsh, et al, 2012). A survey conducted in Western Nepal reported that a problem oriented drug use was due to nausea and vomiting (4.7%), dyspepsia (3.1%) and per virginal spotting/bleeding (3.4%), mainly (Sarker et al, 2013).

These study differs from mine, which presented incomplete abortion and ectopic pregnancy in the first trimester, pre-clampsia and urinary tract infections in the second trimester of pregnancy.

This could be due to that the current study included in-patients only and most of them were pregnant women admitted in the gynecology ward (79.82%) and from previous studies it had been noticed that there were little or no incidences where pregnant patient presenting nausea and vomiting were admitted in gynecology unit but only for serious medical conditions.

Conclusion and recommendations

Findings of my study showed that all admitted pregnant women were commonly prescribed category B and C medicines, followed by category A, X and D, respectively. However, approximately a quarter of pregnant women were prescribe category D and X which are thought to cause possible fetal harm. Thus, such inappropriate prescription of drugs should not be underestimated since it affect the life of both the mother and the fetus. Therefore, intensive assessment of pharmacotherapy given to pregnant women should be done with respect to the US-FDA risk category, the gestational period and the risk-benefit balance of a drug before its prescription. The prescribing trends among prescribers for pregnancy is more or less rational, but there is a lot to be improve. The lack of awareness in respect to drug prescription and use should be improved with the proper implication of information, education and communication.

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