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EVALUATION OF MEDICINES PRESCRIBING PATTERN AMONG PREGNANT WOMEN AT THE PRINCESS CHRISTIAN MATERNITY HOSPITAL IN FREETOWN, SIERRA LEONE

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ABSTRACT

Background: Appropriate use of medications during pregnancy is an essential part of prenatal care, since it can affect not only the health of the pregnant woman but also that of the developing foetus. This study evaluated prescribing patterns, rational prescribing and occurrence of contraindicated medicines among pregnant women at the Princess Christian Maternity Hospital in Freetown. **Materials and Methods**: 314 antenatal prescriptions were obtained from the pharmacy of the Princess Christian Maternity Hospital and evaluated retrospectively. Prescription patterns, rational prescribing and risk to the foetus were evaluated using the WHO core prescribing indicators, index of rational drug prescribing (IRDP) and the United States Food and Drug Administration (FDA) pregnancy risk classification of medicines. **Results**: Excluding minerals and vitamins, 25 (8.0%) of pregnant women received at least one drug. The average number of drugs per encounter, percentage of drugs prescribed by generic name, percentage encounters with an antibiotic and an injection and the percentage of drugs prescribed from the NEML were 3.9, 49.5%, 53.5%, 2.2% and 99.9% respectively. The congruent indices of rational drug prescribing were 0.09. 0.50, 0.56, 4.55 and 0.99 correspondingly. Minerals and vitamins 394 (32.6%), were the most frequently prescribed medicines. Of all the medicines prescribed, 221 (43.1%) were FDA category C medicines followed by category A 125 (32.3%). **Conclusion**: The prescribing pattern was not rational as three of the prescribing indicators fell short of the WHO standard. The existence of contraindicated medicines was suitably low. Therefore, there is need to improve rational prescribing.

KEYWORDS: Medicine use, Pregnancy, Prescribed, Patterns, Sierra Leone.

INTRODUCTION

Proper use of medications during pregnancy is an essential part of prenatal care, since it can affect not only the health of the pregnant woman but also the developing foetus, which is exposed to a wide range of adverse effects.[1,2] Before the disaster caused by the use of thalidomide in the late 1950s and early 1960s, the placenta was considered a barrier capable of protecting the foetus from any pharmacological damage.[3,4]

However, it is known that most drugs, as well as various substances present in the environment have the ability to permeate the placental barrier and reach the bloodstream of the foetus, thus exposing it to pharmacological and/or teratogenic effects.[5] However, the recommendation to avoid all drugs during pregnancy is unrealistic and may be dangerous since pregnant women may encounter other diseases that can result in maternal morbidity and mortality.[6] Pregnancy should not deter clinicians from providing their patients with appropriate management of their medical conditions, however benefit-risk prescribing should be considered in such situations.[7,8]

Conventionally, women of childbearing age and pregnant women are proscribed from taking part in clinical trials especially phase 1 studies. It was not until the 1990s that the United States Food and Drug Administration (FDA) began demanding gender-specific evaluation of safety and efficacy data on all investigational new drug applications and the National Institute of Health (NIH) started requesting the addition of women in clinical research.[9]

In 1979, the FDA established a system of rating pregnancy-risk associated with pharmacological agents. This system categorised all medicines approved after 1983 into one of five pregnancy risk categories (A, B, C, D, and X). It indicates the effect of the therapeutic agent on the foetus based on existing studies in animals and humans and the level of precaution that should be undertaken with each drug. However, there may be difficulties in interpreting these risk factors because they may not always reflect the latest findings.[10]

Unnecessary and harmful drug treatment should be avoided during pregnancy. Disease requiring drug treatment must be treated adequately because if left untreated this could lead to exacerbation of the mother's illness that could not only jeopardise the mother's health but also the well-being of the foetus. A systematic review of drug utilisation studies showed a wide variation of drug use during pregnancy in developed countries, which was from 27 to 93%.[1] Medicines utilisation patterns among pregnant women in Brazil varied from 80 to 94.6%.[11-13] A study done by Eze and colleagues to assess the prescription profile for pregnant women in three health facilities in Benin, Nigeria established that minerals and vitamins were the most frequently prescribed medicines.[14]

Although several studies have been conducted in other countries especially in the developed world, no such study has been done in Sierra Leone. Therefore, this study was conducted to assess prescription patterns, rational prescribing and the occurrence of contraindicated medicines among pregnant women attending the antenatal clinic at the Out Patient Department (OPD) of the Princess Christian Maternity Hospital (PCMH) in Freetown, Sierra Leone.

METHODS

Study setting
This study was conducted at the PCMH which is an obstetrics and gynaecology referral hospital in Freetown, Western Urban district. It is also one of the teaching hospitals of the University of Sierra Leone Teaching Hospital Complex (USLTHC).

Study design and population
A retrospective cross-sectional study design was used by reviewing patient prescriptions from January 1st – March 1st, 2018. The study was conducted from January to July, 2018. The study population included pregnant women of all ages who were seen by doctors at the OPD of the PCMH and for whom medicines were prescribed. In-patients, those whose prescriptions were unavailable and outside of the study period were excluded.

Sample size determination and sampling
The sample size of 314 for the study was determined using single population proportion formula based on the prevalence of drug use during pregnancy in Ethiopia according to a study done by Kebede *et al*.[15] where the prevalence of drug use during pregnancy was 71.3%, with a 95% confidence level and 5% degree of precision used. Sample size included prescriptions for 3 months (January 1st - March 1st, 2018) that were arranged by dates and those used in this study were selected by systematic random sampling from 1200 prescriptions.

Data collection procedure
Prescriptions of the pregnant women were retrieved and information such as age, medical conditions and prescribed drugs were mined and captured in a data collection tool that was designed for the study based on the World Health Organisation/International Network of Rational use of Drugs (WHO/INRUD) prescribing indicators and the FDA classification of drug with respect to risk to the foetus.[16]

Ethical consideration
Ethics authorisation was granted by the Sierra Leone Ethics and Scientific Review Committee (SLESRC). Approval to conduct the study was also obtained from the Hospital administration. The information obtained from this study were kept confidential and used only for this research.

Data analysis
The WHO prescribing indicators such as the average number of medicines per encounter to determine the degree of polypharmacy was calculated by dividing the total number of drugs prescribed by the number of encounters. Percentage of drugs prescribed by generic name was calculated by dividing the number of drugs prescribed by generic name by the total number of drugs prescribed multiply by 100. Percentage of encounters with an antibiotic and an injection prescribed was determined by dividing the number of occurrences by the total number of events, respectively, and multiplying by 100. Percentage of drugs prescribed from the Sierra Leone National Essential Medicines List (NEML) was calculated by dividing the number of drugs doctors prescribed from the NEML by the total number of drugs prescribed expressed as percentage.

The index of polypharmacy was measured by determining the percentage of prescriptions with three or less medicines (non-polypharmacy). Generic name and essential medicines indices were determined by the drugs prescribed by generic name and from the NEML expressed in percentages respectively. The indices of rational antibiotic prescribing and safety injection were

calculated by dividing the optimal levels (30%) for antibiotic prescribing and (10%) for safety injection by the percentages of all prescriptions containing an antibiotic and an injection respectively. Each index has an optimal value of 1; the closer to 1 the calculated index is, the more rational the prescribing is. The total index of rational drug prescribing (IRDP) was obtained by adding the indices with a maximum value of 5. The IRDP is a validated method that has been used by Cole *et al.*[17] in another drug utilisation study in Sierra Leone which comprises five indices derived from the WHO core prescribing indicators for a comprehensive appraisal of medical care.

Drugs were classified according to the WHO Anatomical Therapeutic Chemical Classification System (WHO ATC) into different pharmacological groups while those with potential for foetal harm during pregnancy were assessed based on the FDA safety risk classification system using the Physicians' Desk Reference.[18,19]

All data were analyzed using Statistical Package for Social Sciences (SPSS) version 20 (IBM statistics, Armonk, NY, USA). Descriptive statistics was used to calculate frequencies and percentages and the results were presented as tables and graphs.

RESULT

Demographic characteristics of pregnant women
One hundred and fifty-one (48.0%) were within the age range of 16-25 years (Table 1).

Table 1: Age distribution of pregnant women attending antenatal clinic at PCMH.

Age of patients	Frequency	Percentage (%)
13-15 Years	18	5.7
16-25 Years	151	48.0
26-35 Years	101	32.2
36-45 Years	43	13.2
Total	**314**	**100.0**

Diseases diagnosed among pregnant women
Bacterial Vaginosis occurred most frequently among the pregnant women (Table 2).

Table 2: Profile of medical conditions among the pregnant women.

Diseases	Frequency	Percentage (%)
Bacterial vaginosis	33	21.4
Sexually transmitted infections	18	11.7
Urinary tract infections	16	10.4
Malaria	14	9.1
Pre-eclampsia	13	8.4
Common cold	11	7.1
Hyperemesis	10	6.5
Abdominal pain	9	5.8
Fever	4	2.6
Anaemia	4	2.6
*Others	22	14.3
Total	**154**	**100.0**

*Others: Headache, candidiasis, cough, generalized body pain, insomnia, trauma, fever, chest burn, anaemia, Itching, gastritis.

Common drugs prescribed to pregnant women
The distribution of medicines prescribed to these pregnant women is as shown in Table 3. Excluding minerals and vitamins, 25 (8.0%) of the pregnant women received at least one drug. Minerals and vitamins topped the list of the most frequently prescribed medicines 394 (32.6%), wherein ferrous sulphate 276 (70.1%) was the most frequently prescribed followed by multivitamins with minerals blood tonic 87 (22.1%), vitamin C 19 (4.8%) and folic acid 12 (3.0%). Paracetamol 258 (21.6%) was the most frequently prescribed analgesic followed by cocodamol 1 (0.08%). Antimalarials were the third most occurring medicines with sulphadoxine/pyrimethamine 105 (8.7%) as the most frequently prescribed antimalarial drug. Other antimalarials prescribed included artemether/lumefantrine 9 (0.8%) and quinine 1 (0.08%). Five different types of antibiotics were encountered in this study with amoxicillin 96 (8.0%) been the most frequently used antibiotics.

Table 3: Top ten drugs prescribed at the antenatal clinic.

Medicines prescribed	Frequency	Percentage (%)
Minerals and Vitamins	394	32.6
Paracetamol	258	21.4
Sulfadoxine/pyrimethamine	105	8.7
Amoxicillin	96	8.0

Metronidazole	83	6.9
Albendazole	80	6.6
Ampicillin	48	4.0
Clotrimazole	43	3.6
Antacid	19	1.6
Methyldopa	15	1.2
Others*	66	5.5
Total	**1207**	**100**

*Others: Artemether Lumefantrine, metoclopramide, diclofenac, dexamethasone, diazepam, quinine, omeprazole, tetanus vaccine, salbutamol, prednisolone, cocodamol, erythromycin, ampicillin/cloxacillin, oral rehydration salt (ORS)

At least one drug was prescribed from nine of the WHO ATC Level 1 groups in which the highest, 214 (27.4%) was from the alimentary tract and metabolism category and the lowest 6 (0.1%) from the musculo-skeletal category (Figure 1).
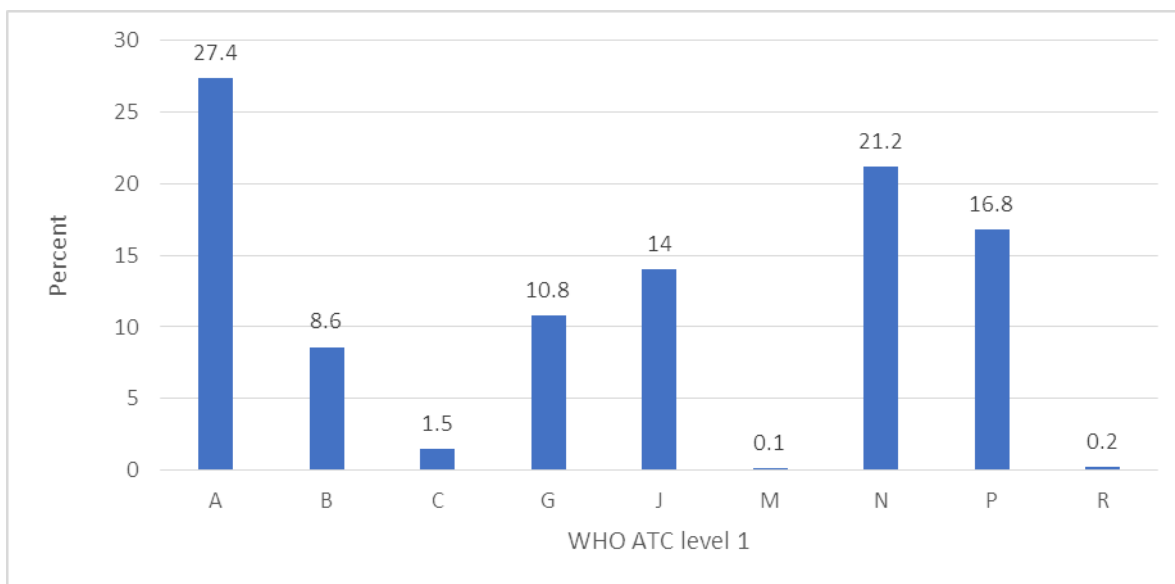

Figure 1: The percentage of medicines prescribed according to the WHO ATC Level 1 group medication categories

A-Alimentary tract and metabolism, B-Blood and blood forming, C-Cardiovascular, G-Genito-urinary system and sex hormones, J-Anti infectives for systemic use, M-Musculo-skeletal system, N-Nervous system, P-Antiparasitic products, insecticides and repellents, R-Respiratory system, S-Sensory organs, V-Various

WHO/INRUD prescribing indicators
The average number of drugs per encounter was 3.9. The percentage of drugs prescribed by generic name and from the NEML were 49.5% and 99.9% respectively. Percentage encountered with an antibiotic and an injection prescribed were 53.5% and 2.2% respectively (Table 4).

Table 4: Drug prescribing indicators at PCMH.

Drug prescribing indicators	Values obtained Average/Percentage (%)	Reference values (WHO, 1993)
Average number of drugs per encounter	3.9	1.6-1.8
Percentage of drugs prescribed by generic name	49.5%	100%
Percentage encounters with an antibiotic	53.5%	20-26.8%
Percentage encounters with an injection	2.2%	13.4-24.1%
Percentage of medicines prescribed from the NEML	99.9%	100%

NEML- National Essential Medicines List

The index of rational drug prescribing
Table 5 shows that the indices of safety injection (4.55) and polypharmacy (0.09) were the highest and lowest values correspondingly. The total IRDP was 6.69.

Table 5: Index of Rational Drug Prescribing (IRDP) indicators at PCMH.

Drug prescribing indicators	Values obtained	Optimal index
Index of polypharmacy	0.09	1
Generic name index	0.50	1
Index of rational antibiotic prescribing	0.56	1
Index of safety injection	4.55	1
Essential medicine index	0.99	1
Total IRDP indices	**6.69**	**5**

Classification of drugs according to the FDA pregnancy risk rating system

Assessment of medicines risk to the foetus according to the FDA classification revealed that 221 (43.1%) were in category C, followed by 125 (32.3%) in category A and 109 (24.3%) in category B (Figure 2).
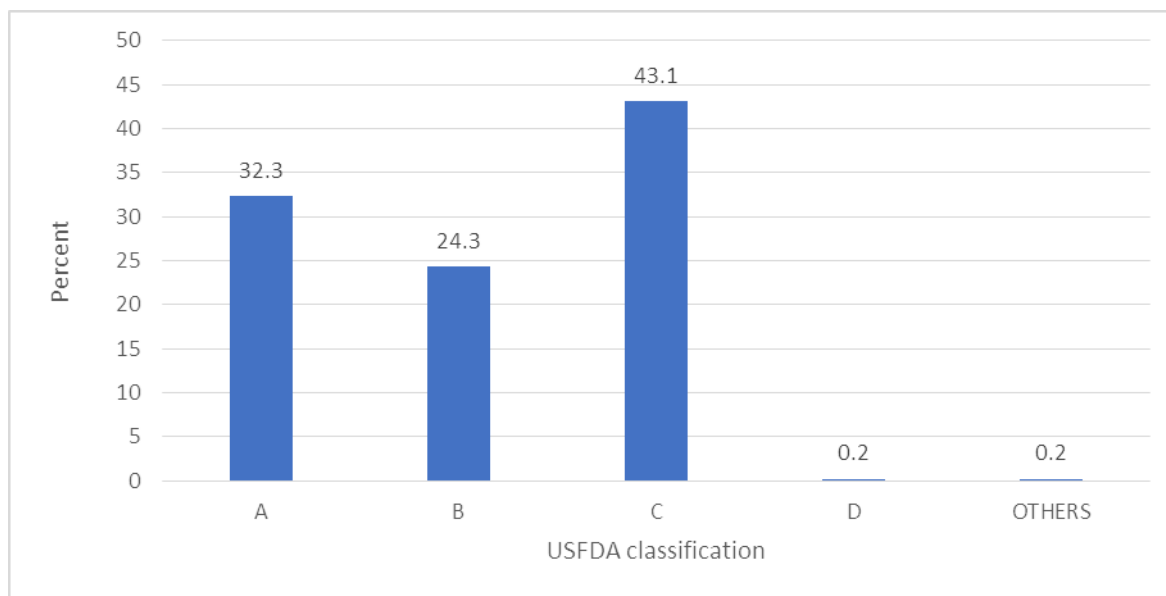

Figure 2: Risk classification of medicines and their frequency of occurrence.

A= controlled studies show no risk; B=no evidence of human risk in controlled studies; C= risk cannot be ruled out; D= positive evidence of risk; X= contraindicated in pregnancy; N=not classified by FDA

DISCUSSION

Almost half of the participants were within the maternal age range of 16-25 years and this was similar to a study that was done in Nigeria.[20] Daw *et al*.[1] conducted a systematic review of drug utilisation studies which revealed that there are wide disparities in estimates of prescription drug use in pregnancy wherein 27-93% of pregnant women took at least one drug excluding vitamins and minerals. In our study, the share of pregnant women who received at least one drug excluding minerals and vitamins was very low as compare to that done by Daw and colleagues. Yet, results of drug utilisation studies in pregnancy across high-income and the# low- and middle-income countries may differ due to differences in NEML used based on local disease epidemiology, variation in prescribing practices and medicines use, utilisation of electronic health records and type of study design employed.

The high usage of minerals and vitamins in this study is comparable with other studies done by Admasie *et al*.[21] and Belay *et al*.[22] in the Bahir Dar city and Oromia region in Ethiopia respectively. This is because many developing countries like Sierra Leone recommend micronutrient supplementation for pregnant women to prevent possible deficits, augment nutritional status and to avoid fetal health complications.[23] Analgesics were the second most prescribed drugs and paracetamol was the most frequently prescribed. This can be accounted for since paracetamol is a category A drug according to the Australian categorisation system for prescribing medicines in pregnancy and hence implies that it has been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus.[24]

The proportion of antimalarials prescribed was low taking into consideration the malaria endemicity in Sierra Leone. Such low levels were also obtained in previous studies done in Nigeria.[14,25,26] Ugwu *et al.[27]* nevertheless reported high utilisation of antimalarials. The low utilisation of sulphadoxine/pyrimethamine in

particular, may have serious implications on the success of the malarial chemoprophylaxis programme for pregnant women in Sierra Leone as the national malaria control policy requires the use of sulphadoxine/pyrimethamine as intermittent preventive therapy in pregnancy (IPTp).[28] Prevention and treatment of malaria are essential components of antenatal care in endemic countries like Sierra Leone and necessitates special considerations for pregnant women.

The occurrence of bacterial infections among the top most medical conditions obtained in this study corresponds with the fact that antibiotics were among the most prescribed drugs in which amoxicillin was the most frequently used. This may be due to the fact that amoxicillin is classified as a FDA pregnancy category B drug, which means it's considered safe to take in pregnancy. In animal studies, there were no reports of harm to developing foetuses from amoxicillin and if a woman takes it in any trimester of pregnancy, it is considered low risk.

Overall the occurrence of contraindicated medicines was low as category FDA category C drugs topped the list according to risk to the foetus, followed by categories A and B. Appropriate prescribing requires that such contraindications do not occur, but the use of such medicines may be considered in cases where benefit outweigh risk.[29]

The average number of drugs per encounter in this study was 3.90 coupled with a low index of polypharmacy of 0.09 which did not meet the WHO reference standard and thus an indication of polypharmacy. Sasidharan *et al.*[30] and Devkota *el al.*[31] reported comparable studies where the average number of drugs per encounter was 4.97 and 2.78 respectively. The high number of drugs prescribed may have resulted from prescribing routine drugs along with other medicines for actual medical conditions. The implication is that the patients may have more medicines than they can cope with in terms of adherence, cost and predisposition to adverse drug reactions.

About half of the medicines were prescribed by brand names, which corresponds with the low generic name index obtained in this study depicting irrational prescribing. Harsh *et al.*[32] and Bashrahi,[33] reported lower values in studies done in India (21.5%) and Yemen (39.3%) respectively, while Chaundhari and colleagues reported a higher value (90.0%) in a study conducted in Ethiopia.[34] This means that prescribers at the study sites are not conforming with the WHO recommendation that drugs should be prescribed using their generic names. The use of brand names when prescribing may lead to out-of-pocket expenditure and increased cost of drugs for these women. Factors that may be responsible for such include the influence of drug promotional activities, pressure by marketing representatives of pharma companies and their drug detailing activities, lack of continuing professional education on the principles of rational prescribing and non-familiarity with generic names among the prescribers.

The percentage encounter with an antibiotic was higher than the standard set by WHO coupled with a low index of rational antibiotic prescribing. Fikadu *et al.*[35] reported a similar result of 31.8% in a study conducted in Ethiopia, while contrasting results that met the WHO standard (21.6% and 12.9%) were reported by Dhar and Komaram[36] and Amorha and Okonkwo[37] respectively. This is not encouraging as irrational antibiotic prescribing can lead to development of resistant bugs and drug resistance infections which can increase the cost of healthcare and prolonged hospital stay. Antibiotic resistance can also complicate medical procedures such as organ transplant treatment of cancer patients and major surgeries.[38]

The occurrence of injectables met the WHO standard as indicated by a very high index of safety injection which is admirable since the unreasonable use of injectables may lead to a high concentration of drug in the systemic circulation, which could predispose pregnant women to toxicity. This result is comparable to an earlier conducted study by Savitha and colleagues where percentage of encounter with an injection was 1.3 %, but dissimilar to another study done by Paul and colleagues where percentage of encounter with an injection was 76.0 %.[39,40] Prescription from the NEML was almost 100% which is a strong indicator of rational prescribing.

This study provides neither information on inpatient drug prescribing nor over- the- counter use of medications. It was only limited to the prescribed drugs, from antenatal clinic prescriptions in the pharmacy. Therefore, using the existing data may underestimate the prevalence of drug use at the study site. Another limitation of this study was that it does not describe the practice of drug prescribing in other health facilities across the country. It was only limited to one maternity hospital in Freetown and hence does not assess the practice of drug use in other hospitals in rural communities, thus generalisation of the result will be impossible.

CONCLUSION

Bacterial vaginosis was the most common medical condition among the pregnant women. Minerals and vitamins supplements classified under WHO ATC level 1 were the most frequently prescribed medications. The average number of drugs per encounter, percentage of drugs prescribed by generic name and percentage encounter with an antibiotic as also depicted by their corresponding low indices of rational prescribing did not meet the WHO standard, signifying irrational prescribing at the study site. The existence of contraindicated medicines was suitably low since a high proportion of drugs were prescribed from US FDA category C followed by category A and B.

Therefore, clinicians when writing prescriptions at the antenatal clinic should use the international nonproprietary names of the drugs with lesser number of antibiotics and drugs per prescription so as to reduce the economic burden on patient, polypharmacy and antibiotic resistance. This work has provided insight and opportunity for additional studies to be done on non-prescription use of medicines in pregnant women, evaluation of drugs utilisation in an inpatient setting and assessing the relationship between drug and pregnancy risk.

ACKNOWLEDGEMENTS

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