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## Original Research

# Assessment of prescription profile of pregnant women visiting antenatal clinics

Uchenna I. EZE, Adegbo E. EFERAKEYA, Azuka C. OPARAH, Ehijie F. ENATO.

### ABSTRACT\*

Managing medical complications in pregnancy is a challenge to clinicians.

**Objectives:** This study profiled some disease and prescription patterns for pregnant women attending antenatal clinics (ANCs) in Nigeria. A risk classification of the medicines was also determined. **Methods:** Medical case files of 1,200 pregnant women attending antenatal clinics of 3 health facilities in Benin City, Nigeria were investigated. Disease pattern was determined from their diagnoses. The prescription pattern was assessed using WHO indicators, and the United States Food and Drug Administration classification of medicines according to risk to the foetus.

**Results:** A total of 1,897 prescriptions of the 1,200 pregnant women attendees during the period under review were evaluated. Results indicated that malaria 554 (38%) was the most prevalent disease, followed by upper respiratory tract infections (URTIs, 13%) and gastrointestinal disturbances (GIT, 12%). The average number of drugs prescribed per encounter was found to be 3.0, and 2,434 (43%) of medicines were prescribed by generic name. Minerals/ Vitamins 2,396 (42%) were the most frequently prescribed medicines, and antibiotics occurred in 502 (8.8%) of the total medicines. Of all medicines prescribed, 984 (17%) were included in the foetal risk category C and 286 (5%) in category D.

**Conclusion:** The study concluded that malaria fever occurred most frequently followed by URTIs and GIT disturbances among the pregnant women. Minerals, vitamins and to a less extent anti-malarials topped the list of the prescribed medicines. The average number of medicines per encounter was much higher than WHO standards. The occurrence of contraindicated medicines was low.

**Keywords:** Teratogens. Pregnancy. Maternal Exposure. Nigeria.

### RESUMEN

Manejar las complicaciones médicas en el embarazo es un reto para los clínicos.

**Objetivos:** Este estudio delineó algunos patrones de enfermedades y prescripciones en embarazadas que visitan una clínica prenatal en Nigeria. Se determinó una clasificación de riesgo de los medicamentos.

**Métodos:** Se investigaron los historiales médicos de 1200 mujeres embarazadas que visitaron las clínicas de parto de tres centros en la ciudad de Benin, Nigeria. Los patrones de enfermedades se determinaron desde sus diagnósticos. Los patrones de prescripción se evaluaron utilizando los indicadores del a OMS y la clasificación de medicamentos de la Food and Drug Administration de Estados Unidos según el riesgo para el feto.

**Resultados:** Durante el periodo de revisión, se evaluaron 1897 prescripciones de las 1200 mujeres embarazadas que visitaron. Los resultados indicaron que la malaria con 554 (38%) fue la enfermedad más prevalente, seguida de las infecciones respiratorias altas (IRA) con 13% y enfermedades gastrointestinales (GI) con 12%. La media de medicamentos prescritos por visita fue de 3.0 y 2434 (43%) fueron prescritas en genéricos. Minerales/vitaminas, con 2396 (42%) fueron los medicamentos mas prescritos, y los antibióticos aparecieron en 502 (8.8%). De todos los medicamentos prescritos, 984 (17%) se incluían en la categoría de riesgo fetal C y 286 (5%) en la categoría D.

**Conclusión:** Este estudio concluyó que entre las mujeres embarazadas, la malaria era la enfermedad más frecuente, seguida de las IRA y las GI. Los minerales y vitaminas seguidos de los antibióticos encabezaron la lista de medicamentos prescritos. La media de medicamentos por visita fue mucho mayor que los estándares recomendados por la OMS. La aparición de medicamentos contraindicados era baja.

**Palabras clave:** Teratógenos. Embarazo. Exposición Materna. Nigeria.

## (English)

### INTRODUCTION

Pregnancy is a time of profound physiological changes in a woman's body. These unique changes challenge clinicians managing disease states during pregnancy in the selection of medications best suited to treat their patients.<sup>1</sup> Maternal drug use during pregnancy may pose a teratogenic risk to the

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foetus. However, the recommendation to avoid all drugs during early pregnancy is unrealistic and may be dangerous.<sup>2,3</sup> Pregnancy should not deter clinicians from providing their patients with appropriate management of their medical conditions, hence, prescribing in pregnancy is an unusual risk benefit situation.<sup>4,5</sup>

In 1979, the United States Food and Drug Administration (FDA) introduced a system of rating pregnancy-risk associated with pharmacological agents. This system categorised all drugs approved after 1983 into one of five pregnancy risk categories (A, B, C, D, and X). It indicates the effect of the agent on the foetus based on available animal and human data and recommends the degree of precaution that should be undertaken with each drug. However, the risk factors assigned are sometimes difficult to interpret because they may not always reflect the latest findings.<sup>6</sup>

Information on the use of drugs during pregnancy is scarce and rather anecdotal.<sup>7</sup> Despite the absence of adequate studies on the safety and effectiveness of prescription drugs for pregnant women, evidence available shows that physicians prescribe, and pregnant women take a surprisingly large number of drugs. An international investigation sponsored by WHO showed that pregnant women ingest an average of three prescription medications during pregnancy (range 1 – 15). Furthermore, 86% of the women had taken at least one prescription medication during their pregnancies.<sup>8</sup>

There have been drug use studies in Nigeria. Odusanya et al.<sup>9</sup> did a retrospective prescribing audit at primary health care facilities and reported an average of 7.27 and 4.99 number of medicines in Mushin and Ikeja Lagos Nigeria, respectively. Gharoro and Igbafe<sup>10</sup> showed that out of the 1200 pregnant women in their study, self-medication occurred in 26.8%. Folic acid was used by 76.08% of the women, antimalarials 19.45%, however studies on prescribing in pregnancy are quite few in Nigeria hence this study was done to add to the baseline of research of this sort. The objectives of this investigation were to determine the disease pattern and assess the prescription profile for pregnant women in Benin City, Nigeria. This study also assessed the types and extent of prescribing of medicines according to risk to the foetus.

## METHODS

A retrospective prescription survey was conducted among 1,200 outpatient pregnant women attending three antenatal clinics (ANCs) in Benin City, Nigeria. The investigation was performed within February to October 2000. One of the facilities was a 560-bed university teaching hospital. The other two were secondary health care facilities having 500 and 120 beds, respectively. Prescribed medicines in the hospitals are dispensed in the hospital pharmacies when available; otherwise patients are referred to the communities for refills.

Permission was sought from the authorities of the hospitals before commencement of the study. Medical case files of the pregnant women were

retrieved and reviewed, and relevant information documented in a specific data collection format designed for the study. Data were gathered on age, gravidity, medical conditions, and medicines prescribed.

A World Health Organisation's (WHO) recommended method<sup>11</sup> was used to measure some specific factors in prescribing for these women.

This method has been adopted in other studies.<sup>8,12</sup> The average number of medicines per encounter was calculated by dividing the total number of drugs by the number of encounters. Percentage encounter with generic name, percentage encounter with antibiotics, and percentage of encounter with injections were determined by dividing the number of occurrence by the total number of event, respectively, and multiplying by 100. Data on the United States Food and Drug Administration classification of medicines according to risk to the foetus were obtained based on information provided in the physician's drug handbook.<sup>13</sup>

## RESULTS

Four hundred medical case files were audited in each hospital giving a total of 1200 medical case files for the entire study. Demographics obtained showed that the average age was 25.16 (SD=3.62). Of the ANCs attendees were primigravidae 426 (35.5%), secundigravidae 260 (21.7%), and multigravidae 500 (41.6%), while in 14 cases (1.1%) the gravidity was not indicated.

Table 1 shows the pattern of medical conditions occurring among the women in the 3 health facilities. Malaria fever occurred most frequently followed by upper respiratory tract infections and gastrointestinal disturbances.

Medical condition	Frequency (%)
Malaria fever	554 (38.3)
Upper respiratory tract infection	185 (12.8)
Gastrointestinal infection	167 (11.6)
Urinary tract infection	154 (10.7)
Pains	110 (7.6)
Other infections	37 (2.6)
Premature contractions	30 (2.1)
High Blood Pressure	28 (1.9)
Nausea / Vomiting	24 (1.7)
Insomnia	21 (1.5)
Numbness of fingers	16 (1.1)
Itching	14 (1.0)
Co-morbid conditions	13 (0.9)
Mastitis	12 (0.8)
Edema	6 (0.4)
Other medical conditions.	74 (5.2)
Total	1445 (100)

A total of 1897 prescriptions were obtained from the 1200 medical case files. The average number of drugs per encounter was found to be 3.0 (range 1 – 10). Eighty-two different medicines were encountered and a total of 5708 medicines were prescribed for the entire period. Table 2 shows the WHO prescribing indicators that were evaluated.

The distribution of medicines prescribed to these pregnant women is as shown in Table 3. Minerals and vitamins were the most frequently prescribed medicines. Folic acid 671 (35.4%) was the most frequently prescribed drug in the three health facilities. Other minerals and vitamins prescribed included ferrous sulphate 645 (34%), vitamin C 152

(8.0%) and calcium lactate 19 (1.0%). Paracetamol 749 (87.9%) was the most frequently prescribed analgesic; other analgesics included methamisole 66 (7.8%), acetylsalicylic acid 27 (3.2%), piroxicam 4 (0.5%), pentazocin 2 (0.3%), dihydrocodeine 2 (0.3%), and ibuprofen 2 (0.3%).

Table 2: Prescribing indicators encountered		
Prescribing Indicator	Value obtained	Reference value <sup>11</sup>
Average number of medicines per encounter	3 (range 1 – 10)	1.6 – 1.8
Percentage of medicines prescribed by generic name	42.7	100
Percentage encounter with injectables	5.8	13.4 – 24.1
Percentage encounter with antibiotics	8.8	20 – 26.8

Antimalarials were the third most occurring medicines with an average of 640 (11.2%) for the three health facilities when compared with other groups of medicines. Chloroquine 350 (54.7%) was the most frequently prescribed antimalarial drugs for the 3 health facilities. Other antimalarials written included sulphadoxine/pyrimethamine 130 (20.3%), pyrimethamine 64 (10%), quinine 76 (11.9%), amodiaquine 48 (7.5%), proguanil 4 (0.6%), sulphamethopyrazine/pyrimethamine 2 (0.3%). Twenty different types of antibiotics were encountered in the study. Penicillins 279 (55.6%) were the most frequently used antibiotics for the antenatal clinics. Other antibacterial agents included metronidazole 59 (11.8%), macrolides 53 (10.6%), cotrimoxazole 37 (7.4%), phythylsulphathiazole 27 (5.4%) 4-quinolones 12 (2.4%), nitrofurantion 12 (2.4%), aminoglycosides (9)(1.8%), and tetracycline 1 (0.2%).

Table 3: Frequency distribution of the medicines prescribed	
Prescribed Medicines	Total (%)
Minerals /Vitamins	2396 (42.02)
Analgesics	852 (14.90)
Antimalarials	640 (11.20)
Antibiotics	502 (8.80)
Antiallergens	159 (2.80)
Antacids	108 (1.90)
Hypnotics/Sedatives	104 (1.80)
Antifungals	100 (1.75)
Expectorants	99 (1.74)
Antiemetics	58 (1.02)
Anthelmintics	52 (0.91)
Myometral Relaxants	44 (0.77)
Antihypertensives	29 (0.51)
Others	559 (9.80)

Other groups of medicines encountered included antihypertensives: methyldopa, 24 (82.8% of all antihypertensives prescribed), nifedipine 4 (13.8%) and hydrallazine 1 (3.5%), Hypnotics and sedatives encountered included diazepam 87 (83.7%), bromazepam 12 (11.5%), nitrazepam 5 (4.8%), antifungals (clotrimazole containing agents 65 (65%), tioconazole containing agents 24 (24%), nystatin containing agents 8 (8%) miconazole containing agents 3 (3%). Salbutamol 44 (0.77%) was also prescribed.

Majority of the medicines encountered were given orally 5268 (92.3%), others were by injectable route 336 (5.9%), per vaginal 99 (1.7%), instilling into the ears 2 (0.04%), eyes 1 (0.02%), anally 2(0.04%).

A classification of medicines according to risk to the foetus indicated that of all the medicines prescribed, 2743 (48.1%) were in category A, 1465 (25.7%) category B, 984 (17.2%) category C and 286 (5.0%) in category D. Table 4 shows drugs and their frequency of occurrence in this study.

Table 4: Risk classification of medicines and their frequency of occurrence (N=1200)	
A	Adequate clinical studies have shown no risk to fetus in any trimester: Folic acid (671), Vitamin C (152), Vitamin B complex (104)
B	Animal studies have not shown adverse effect on the fetus and there are inadequate clinical studies: Paracetamol (749), Amoxycillin (110), Ampicillin/Cloxacillin (115), Metronidazole (59), Erythromycin (51), Cotrimoxazole (37)
C	Animal studies have shown adverse effects, no adequate clinical studies. May be useful in pregnancy despite potential risks: Codeine (54), Salbutamol (44), Methyldopa (24)
D	There is evidence of risk to human fetus, but potential benefits may be acceptable despite potential risks: Benzodiazepines (104), Dipyrone (96), Quinine (76), Aspirin (29)
X	Animal/human studies show foetal abnormalities. Risks involved clearly outweigh benefits: (None)

## DISCUSSION

The average maternal age obtained in this study was similar to that obtained in a similar study in Nepal.<sup>7</sup> Primigravid women formed the majority of women attending the antenatal clinics. The pattern of medical conditions obtained in this study varied with those reported in Nepal study<sup>7</sup> where problem oriented drug use was mainly due to gastrointestinal tract problems (nausea and vomiting, dyspepsia), and vaginal spotting/ bleeding.

Malaria fever was the most prevalent medical condition occurring among the pregnant women in the antenatal clinics of the three health facilities. Malaria in pregnancy is a major public health problem in Nigeria, as well as other malaria endemic countries.<sup>14</sup> Previous reports indicated that pregnant women attending ANC's perceived malaria as a common health problem.<sup>15,16</sup> Malaria in pregnancy results in maternal anemia, intrauterine growth retardation, fetal low birth weight and neonatal mortality.<sup>14</sup>

The average number of drugs prescribed per encounter in the antenatal clinics differs from the standard set by WHO.<sup>11</sup> However, similar values

have been obtained in studies by Das et al.<sup>7</sup> and Krause et al.<sup>17</sup> The maximum number of drugs prescribed was 10. The high number may have resulted from prescribing routine drugs along with other medicines. The implication is that the patient may have more medicines than she can cope with in terms of cost and adherence. The high number may also increase the risk of adverse drug interactions. The total number of medicines obtained was more than that obtained by Gracia et al.<sup>18</sup> but less than that obtained by Mengue et al.<sup>19</sup> Most of the medicines were prescribed in brand names irrespective of the type, and this pattern is common in the country. The low value obtained on generic prescribing indicates that irrational prescribing occurred.

However value obtained by Das et al.<sup>7</sup> was even lower. This means that prescribers here were not complying fully with WHO recommendation that drugs should be prescribed using their international nonproprietary names. The use of brand names may lead to increased cost of drugs for these women. Factors that may be responsible for this trend include the influence of drug promotional activities, pressures of pharmaceutical detail men, lack of continuing education on the principles of rational prescribing and non-familiarity with generic names among the prescribers.

The occurrence of injectables was low in this study, which is commendable since the use of injectables may introduce a high concentration of drug to the plasma, which could lead to toxicity in the pregnant women exposed. The percentage encounter of antibiotics was lower than that prescribed by WHO and this is encouraging.

The level of antimalarial prescription was low compared to the fact that malaria is endemic in this area. Such low level was also obtained in a previous study.<sup>10</sup> This may have implication on the effectiveness malarial intervention chemoprophylaxis programme.<sup>10</sup> Prevention and treatment of malaria are essential components of

antenatal care in endemic areas, but requires special considerations during pregnancy.<sup>14</sup> Inadequate consumption of antimalarial drugs by patients may be a major contributing factor to the diminishing efficacy of the commonly available antimalarial drugs and development of drug resistant strains of the *P. falciparum* malarial parasites in our community.<sup>14</sup>

The occurrence of contraindicated medicines was low. Proper prescribing demands that such contraindications do not occur but the use of such medicines may be considered in cases where benefits outweigh the risk.<sup>20</sup> Majority of the drugs prescribed were in category A of the FDA's classification of medicines according to risk to the foetus, followed by those in category B. However drugs in C and D were also obtained. This may have been in cases where benefits outweigh the risk. Similar results have been obtained in another study.<sup>19</sup>

## CONCLUSIONS

Malaria fever occurred most frequently followed by upper respiratory tract infections and gastrointestinal disturbances among the pregnant women. Minerals, vitamins and to a less extent antimalarials topped the list of the prescribed medicines. The average number of prescriptions per encounter was much higher than WHO standard, indicating occurrence of polypharmacy. The occurrence of contraindicated medicines was desirably low.

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## CONFLICT OF INTEREST

None declared.

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