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Research Article

# Utilization of Antibiotics Among Pregnant Women in two Hospitals in Southeast Nigeria: A Pharmacoepidemiological Survey

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## Abstract

**Background:** Pregnancy is a very critical stage in a woman's life, and the use of drug especially antibiotics calls for concern. The drug utilization among this class of patients has been largely described as inappropriate which results from irrational prescribing, dispensing and administration of medications.

**Objective:** This study assessed antibiotics utilization among pregnant women in the two hospitals.

**Methods:** The study was a retrospective, cross sectional survey. It was carried out in Anambra State; Nnamdi Azikiwe University Teaching Hospital Nnewi and General Hospital Onitsha, southeast Nigeria. The study group involved pregnant mothers undergoing ante-natal care in the tertiary health care facilities. All patients' folders that met the inclusion criteria were assessed. Data included basic demographic details, number of drugs per prescription and antibiotics, relevant medical history, co-morbidities and common ailment, educational status, pre-conception and current substance use status and other factors associated with medications and supplements use during pregnancy. Data was analyzed using Statistical Package for Social Sciences version 22 and descriptive statistics.

**Results:** The finding showed that average age of pregnant women in General hospital, Onitsha is 39 years old, this value accounted for 27.44% of pregnant women in that hospital as against the average age of pregnant women in NAUTH, which is 13 years on the average, and accounted for 30.69% of pregnant women. In Onitsha general hospital, Ciprofloxacin had the highest prescription of 76 (25.3%) followed by Erythromycin (65, 21.7%), Levofloxacin, 35 (11.7%), amoxicillin, 33 (11.0%), and others. In Nnamdi Azikiwe University Teaching Hospital (NAUTH), Ampicillin/Cloxacillin was the most prescribed drug, 16 (53.4%). Most of antibiotics were prescribed twice daily (194, 64.7%) in general hospital, Onitsha. A total of 60 (20.0%) prescription had thrice daily medications, 34 (11.3) once daily and 12 (4.0%) four times daily. In NAUTH, 17 (56.7%) and 13 (43.3%) prescriptions were given twice and thrice daily. No prescription contained once or four times daily medication. There was no drug therapy problem recorded in both hospitals.

**Conclusion**: The antibiotics prescribed for pregnant women felled within the WHO risk category A and B with rare cases of prescription occurring in category D. The most frequently prescribed antibiotic was the fluoroquinolone class.

***Keywords:*** *Drug Utilization; Pregnant Women; Underlying Disease; Rational Drug Use; Health Facilities*

## Background

There has been a sturdy increase in global antibiotic prescription and consumption [1]. There is a dire need to regulate use of antibiotics [2]. There is high maternal mortality and morbidity in sub-Saharan Africa traceable to complications arising from microbial infections [3]. To manage the complications associated with pregnancy and motherhood, many medicines are employed. Antibiotics remain important in pregnancy and may be second to only iron and food supplement [4].

Lack of antibiotic stewardship has been a leading cause of antibiotic resistance in clinical practice today [5]. Neonatal Health and Birth outcome is highly dependent on maternal health, nutrition and socioeconomic factors. The use and choice of antibiotic during pregnancy depends primarily on maternal factors such as health, nutrition, mode of delivery and socioeconomic factors. These maternal factors influence the indicators used to estimate birth outcomes and neonatal health such as birth weight, Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) scores, and incidences of birth defects. Pharmacoepidemiology explores the dynamics in medication use in relation to diseases [6]. It is therefore of paramount importance to assess the drug utilization pattern in pregnancy in resource limited setting to know the extent to which good prescribing practices in these 'special population' are been adhered to.

Antibiotics have been identified as the most commonly used and misused of all drugs; for instance, about 85% of prescriptions issued by general practitioners are antibiotics [7]. The inevitable consequences of the widespread use of antimicrobial agents have been the emergence of antibiotic resistant pathogens [8]. Obstetrics and gynaecological conditions require that all medications be prescribed with specific caution. The physiological state of pregnancy has an effect on the pharmacokinetics of drugs administered, with attendant risk of teratogenicity and other physiological and anatomical effects on the developing foetus. The use of drugs in pregnancy is an issue of great concern to the patients and prescribers alike. The Thalidomide incidence of the 1960's and the teratogenic effects that was discovered related to Diethylstilbestrol in 1971 are a few instance of the dangers which prescription drugs may pose to pregnant patients [9,10]. Pregnancy is associated with changes in the physiological, psychological and psychosocial aspects of a woman's life. Categorization of drugs by Food and Drug Administration (FDA) according to their pregnancy risk should be taken into consideration before a drug is prescribed for pregnant women.

### FDA classification of drug safety in pregnancy

- Category A: No adverse effects in human pregnancies. Safety established using well controlled human studies.
- Category B: Presumed safety in human pregnancies. Limited human studies/no adverse effects in animal studies.
- Category C: Uncertain safety: Limited human studies/adverse effects in animal studies.
- Category D: Adverse effects in pregnancies. Benefits may outweigh associated risks.
- Category X: Adverse effects in pregnancies. Risks outweigh possible benefit.

### Anti-Microbials: D and X FDA drug categories

- Category D: Aminoglycosides: Gentamycin, Streptomycin, Tobramycin, Tetracyclines, Doxycycline, Minocycline, Tetracycline, Voriconazole, Chloramphenicol, Antimycotics (Amphotericin B, 5-flucytosine, Griseofulvin).
- Category X: Quinine, Thalidomide, Ribavirin, Miltefosine, oral contraceptives, statins.

This study assessed the pattern of drug utilization among pregnant women in two hospitals in southeast Nigeria.

## Methods

### Study area and setting

Anambra is a state in the South-Eastern Nigeria. The state capital is Awka. She shares boundary with Imo state in the south, Enugu in the North-East and Delta state in the west. It lies within the tropical rain forest belt of Nigeria. The people are known for business prowess, farming, trade and commerce. She has one federal hospital and State hospitals and numerous other health care facilities.

### Study design

This study was an institution-based retrospective, cross sectional survey. It was carried out in Nnamdi Azikiwe University Teaching Hospital Nnewi and General Hospital Onitsha, southeast Nigeria.

### Data collection tool and procedure

A structured check list was prepared based on the objective of the study to extract data from patients' prescriptions and folders.

### Study population

The study group involved were pregnant mothers undergoing antenatal care in the tertiary health care facilities. Their prescriptions and medical record for the period under review was utilized retrospectively for this study.

### Sample size determination

Sample size was calculated based on Yamanes study that [Yamane (1967:886)] provided simplified formula to calculate sample sizes.

### Sampling techniques

All patients' folders that met the inclusion criteria were retrospectively assessed. It included basic demographic details, number of drugs written in each order sheet, prescriptions and antibiotics, relevant medical history, co-morbidities and common ailment, educational status, pre-conception and current substance use status and other factors associated with medications and supplements use during pregnancy.

### Study duration

The study lasted from February to September 2018.

### Inclusion criteria:

I. Medical records of pregnant women undergoing ante-natal care in the hospitals
II. Eligible and complete prescriptions of pregnant women who attended antenatal clinic in the hospitals

### Exclusion criteria:

I. Folders of pregnant women with incomplete data
II. Non eligible and incomplete prescriptions of pregnant women outside the period under review.

### Ethical consideration

The Institutional Research Ethics Committee approval was obtained prior to initiation of the study from the NAUTH Research and Ethics Committee. Patients' confidentiality was observed by eliminating their names from the prescriptions to uphold confidentiality. The Ethical Approval Reference Number was: NAUTH/CS/66/VOL. 11/009/2018/007.

### Method of data analysis

The data was checked for completeness and consistency. It was analyzed and as presented as descriptive statistics of mean, frequency and percentages using Statistical Package for Social Sciences (version. 20.0 for Windows, Inc., Chicago, IL, USA). Narrative tables were used to summarize the findings.

## Results and Discussion

### Underlying disease and the rationality for antibiotics usage in pregnancy

Frequent use of antibiotics like amoxicillin, penicillin and erythromycin was outstanding in the study. Published studies carried out on pregnant women in India suggested that urinary tract infections (UTI) were predominantly the mostly diagnosed condition among pregnant women in the facilities followed by respiratory tract infection. The study suggested that urinary tract infections (UTI) popularly called bladder infections are common within the 6 to 24 week of pregnancy [11]. This is associated with changes in the urinary tract and blockade of drainage of the bladder due to resting of the uterus on the bladder and giving rise to infections [11,12]. It can lead to preterm labour and low birth weight among other presentations in the pregnant mother. Amoxicillin, penicillin and erythromycin have been considered safe for pregnant mothers. Antibiotic prophylaxis have been recommended for recurrent UTI in pregnancy [13-15]. A good knowledge of the respiratory changes that occur during pregnancy is essential in therapy of respiratory conditions during pregnancy

[16,17]. Dyspnea may be common due to increase in tidal volume. However, tachypnea can be seen as abnormal since respiratory rates predominantly remain unaltered during pregnancies that are normal [18-20].

### Status of antibiotic therapy and comparisons

The result in table 1 above showed that average age of pregnant women in General Hospital Onitsha was 39 years. This value accounted for 27.44% of pregnant women in that hospital as against the average age of pregnant women in NAUTH, which is 13 years and accounted for 30.69% of pregnant women. This implied that there were more under aged pregnant women in NAUTH than General hospital, Onitsha despite having similar standard of healthcare and being in the same state and geopolitical zone. However, this may be associated with disparity in funding and level of care. NAUTH is a tertiary teaching hospital funded by the Federal Government and has wider area of coverage and greater manpower while General Hospital Onitsha is a secondary facility with lesser funding and area of coverage. The outcome of this study as shown above is not in line with the findings of a study on drug utilization pattern in pregnancy in a tertiary hospital in Sokoto, northwest Nigeria and India where they found out that the majority of the pregnant women studied were above this age [21-23]. The highest antibiotic prescriptions were carried out between May 2018 - August, 2018 (142, 47.3%), the period associated with high rain fall distribution with high possibility of bacterial and protozoal infections, and from January 2017 - December 2018, the period of hot weather characterized by dust, dryness and high incidence of respiratory tracts infection. In General Hospital Onitsha, Ciprofloxacin had the highest prescription of 82 (27.3%), followed by erythromycin, 71 (23.7%), amoxicillin, 47 (15.7%), levofloxacin, 45 (15.0%) and others. The outcome above is in line with another study on the use of antibiotics among pregnant women in a Nigerian Tertiary Health Care Facility carried out at Uyo south- south Nigeria where fluoroquinolones were mostly prescribed [24].

| Period | General hospital Onitsha N = 39 n (%) | NAUTH N = 13 n (%) |
|---|---|---|
| Mean age: n ± SD | 27.44 ± 6.12 | 30.69 ± 5.19 |
| January 2017 - June, 2017 | 8.0 (2.7) | - |
| July 2017 - December, 2017 | 14 .0 (4.7) | - |
| January 2018 - April, 2018 | 135.0 (45.0) | 9 .0(30.0) |
| May 2018 - August, 2018 | 142.0 (47.3) | 21.0 (70.0) |
| September 2018 - December, 2018 | 1.0 (0.3) | - |

***Table 1:*** *Period of prescription and distribution of antibiotics prescribed to pregnant women in two hospitals. N: Number of Prescriptions Assessed; n: Number of Prescriptions with Antibiotics.*

Another study on Drug Utilization Pattern in Pregnancy in a Tertiary Hospital in Sokoto, North West Nigeria, Amoxicillin was the most prescribed antibiotic as against the previous study at Uyo Nigeria [21]. In General Hospital Onitsha, there were some antibiotics that fell into the WHO pregnancy Category D, which were prescribed. Drugs in this category have adverse effects in pregnancy but risks outweigh possible benefits. Among the drugs in this category prescribed in this hospital are Gentamicin which belongs to the antibiotic class of Aminoglycosides and Doxycycline which is a tetracycline. This is similar to a study in Ethiopia where 16.8% and 7.1% of medications were prescribed from category D and X.

In NAUTH between January 2017, Amoxicillin plus Clavulanic acid was the most prescribed antibiotic, 11 (36.7%) followed by Ampiclox, 5 (16.7), erythromycin, Ciprofloxacin and Amoxicillin (Table 2). The outcome of this findings in NAUTH is in line with the findings of Drug Utilization Pattern in Pregnancy in a Tertiary Hospital in Sokoto, North West Nigeria, where Amoxicillin was the most prescribed antibiotic [21]. From table 3 above, most of antibiotics were prescribed twice daily (64.7%) to pregnant women in general hospital, Onitsha. A total of 60 (20.0%) prescription were given thrice daily, 34 (11.3) once daily and 12 (4.0%) four times daily. In NAUTH, 17 (56.7%) and 13 (43.3%) prescriptions were given twice and thrice daily, while no prescription was given once or four times daily. Physiological alterations which occur during pregnancy affect and influence drug behavior like bioavailability [25-27]. This underscores the need for rational dosing modification and the need for individualized patient therapy in pregnancy [25,28].

| Hospital | S/No | Anti-biotic | Frequency of prescription n (%) | | | Total prescription |
|---|---|---|---|---|---|---|
| | | | 1st | 2nd | 3rd | n (%) |
| General hospital Onitsha. N= 300 | 1 | Erythromycin | 65.0 (21.7) | 5 .0 (1.7) | 1 .0 (0.3) | 71.0 (23.7) |
| | 2 | Ceftriaxone | 9 .0 (3.0) | 1 .0 (0.3) | 2.0 (0.7) | 12.0 (4) |
| | 3 | Amoxicillin+ Clavulanic acid | 17 .0 (5.7) | 2.0 (0.7) | 1.0 (0.3) | 20.0 (6.7) |
| | 4 | Clarithromycin | 7 .0 (2.3) | 2.0 (0.7) | 1.0 (0.3) | 10.0 (3.3) |
| | 5 | Metronidazole | 15 .0 (5.0) | 25 .0 (8.3) | 4 .0 (1.3) | 44.0 (14.6) |
| | 6 | Doxycycline | 2 .0 (0.7) | 2 .0 (0.7) | 1 .0 (0.3) | 5 .0 (1.7) |
| | 7 | Ciprofloxacin | 76 .0 (25.3) | 6 .0 (2.0) | - | 82 .0 (27.3) |
| | 8 | Amoxicillin | 33 .0 (11.0) | 14 .0 (4.7) | - | 47 .0 (15.7) |
| | 9 | Ampiclox | 9 .0 (3.0) | 1 .0 (0.3) | - | 10 .0 (3.3) |
| | 10 | Ofloxacin | 9 .0 (3.0) | 4 .0 (1.3) | - | 13 .0 (4.3) |
| | 11 | Cefixime | 2 .0 (0.7) | 2.0 (0.7) | - | 4.0 (1.4) |
| | 12 | Sulphadoxine/trimetoprine | 1 .0 (0.3) | - | - | 1 .0 (0.3) |
| | 13 | Levofloxacin | 35 .0 (11.7) | 10 .0 (3.3) | - | 45.0 (15.0) |
| | 14 | Azithromycin | 2 .0 (0.7) | - | - | 2 .0 (0.7) |
| | 15 | Gentamycin | 2 .0 (0.7) | 1 .0 (0.3) | - | 3 .0 (1.0) |
| | 16 | Doxycycline | 11 .0 (3.7) | 3.0 (1.0) | - | 14 .0 (4.7) |
| | 17 | Ampicillin | 2 .0 (0.7) | - | - | 2 .0 (0.7) |
| | 18 | Cefuroxime | 3 .0 (1.0) | - | - | 3 .0 (1.0) |
| NAUTH N= 30 | 1 | Erythromycin | 4.0 (13.3) | | - | 4 .0 (13.3) |
| | 2 | Ceftriaxone | - | - | - | |
| | 3 | Amoxicillin+Clavulanic acid | 11 .0 (36.7) | - | - | 11 .0 (36.7) |
| | 4 | Clarithromycin | - | - | - | |
| | 5 | Metronidazole | - | 2.0 (6.7) | - | 2.0 (6.7) |
| | 6 | Doxycycline | - | - | - | |
| | 7 | Ciprofloxacin | 4.0 (13.3) | - | - | 4.0 (13.3) |
| | 8 | Amoxicillin | 4.0 (13.3) | - | - | 4 .0 (13.3) |
| | 9 | Ampiclox | 5.0 (16.7) | - | - | 5 .0 (16.7) |
| | 10 | Ofloxacin | - | - | - | |
| | 11 | Cefixime | - | - | - | |
| | 12 | Sulphadoxine/trimethoprim | - | - | - | |
| | 13 | Levofloxacin | 2 .0 (6.7) | - | - | 2 .0 (6.7) |
| | 14 | Azithromycin | - | - | - | |
| | 15 | Gentamycin | - | - | - | |
| | 16 | Doxycycline | - | - | - | |
| | 17 | Ampicillin | - | - | - | |
| | 18 | Cefuroxime | - | - | - | |

***Table 2:*** *Types frequency and number of antibiotics prescribed to pregnant women in the hospitals.*

| Variables | Category | GH Onitsha n (%) | NAUTH n (%) |
|---|---|---|---|
| Dosage frequency per day | Once | 34 .0 (11.3) | - |
| | Twice | 194 .0 (64.7) | 17 .0 (56.7) |
| | Thrice | 60 .0 (20.0) | 13 .0 (43.3) |
| | Four times | 12 .0 (4.0) | - |
| Dosage form | Tablet | 283.0 (94.3) | 28 .0 (93.3) |
| | Injection | 9 .0 (3.0) | - |
| | Capsule | 8 .0 (2.7) | 2 .0 (6.7) |

***Table 3:*** *Dosage frequency per day and dosage form of antibiotics prescribed to pregnant women in two hospitals.*

### Treatment durations with antibiotics in pregnant women

The duration of treatment in most of the prescriptions as shown in table 4, 108 (36.0%), 86 (28.7%) lasted for 7 and 10 days respectively, while only 1 (0.3%) prescription lasted for one day in Onitsha general hospital. In NAUTH, duration of treatment of most prescriptions 17 (56.7) lasted for 7 days, followed by 5 days, 6 (20.0). No prescription was given for 1, 3, 6 and 21day (s) duration. The duration of antibiotics treatment from the prescriptions in General hospital, Onitsha and NAUTH is seven (7) days. This is in line with antibiotics resistance stewardship, where minimum of five days and maximum of seven days duration is recommended to avoid resistance that could result from incomplete treatment. From (Table 6 and 7) above, a total of 214 (71.3%) prescribed antibiotics in Onitsha general hospital were in 500 mg dosage form, followed by 625 mg, 15 (5.0%). The least dosage form was 80 mg (1, 0.3%). Similarly, in NAUTH, 500 mg dosage form was mostly prescribed, 20 (66.7%) followed by 625 mg dosage form, 10 (33.3%). Majority of drugs prescribed during pregnancy were antibiotics [29]. Increased use of antibiotic in pregnancy has been associated with asthma in the developmental years e.g. during early childhood [30,31]. Duration of therapy depends primarily on the nature of organisms involved, severity, presentation, trimester of pregnancy, and bioavailability of therapeutic agents involved. Duration of therapy is based on evidence-based medicine information or expert's opinion [32-40].

| Duration of treatment (days) | General Hospital Onitsha | NAUTH |
|---|---|---|
| 1 | 13.0 (4.3) | - |
| 3 | 10 .0 (3.3) | - |
| 5 | 44 .0 (14.7) | 6 .0 (20.0) |
| 6 | 1.0 (0.3) | - |
| 7 | 108 .0 (36.0) | 17 .0 (56.7) |
| 10 | 86 .0 (28.7) | 4 .0 (13.3) |
| 14 | 36.0 (12.0) | 3 .0 (10.0) |
| 21 | 2 .0 (0.7) | - |

***Table 4:*** *Duration of treatment with antibiotics prescribed to pregnant women in two hospitals.*

| Variables | Hospital | Category | Frequency (%) |
|---|---|---|---|
| DPTs, (Drug therapy problem) | General Hospital Onitsha | No | 300.0 (100.0) |
| | | Yes | 0 .0 (0.00) |
| | NAUTH | No | 30 .0 (100.0) |
| | | Yes | 0 .0 (0.0) |
| Generic prescription | General Hospital Onitsha | No | 63 .0 (22.3) |
| | | Yes | 233 .0 (77.7) |
| | NAUTH | No | 12 .0 (40.0) |
| | | Yes | 18 .0 (60.0) |
| Number of antibiotics | General Hospital Onitsha | One | 3 .0 (1.0) |
| | | Two | 67 .0 (22.3) |
| | | Three | 11.0 (3.7) |
| | NAUTH | One | - |
| | | Two | 2.0 (6.7) |
| | | Three | - |
| Class of antibiotics | General Hospital Onitsha | Class 1 | 3.0 (0.9) |
| | | Class 2 | 78.0 (26.0) |
| | | Class 3 | 10.0 (3.3) |
| | NAUTH | Class 1 | - |
| | | Class 2 | 2.0 (6.7) |
| | | Class 3 | - |
| | | No answer | - |

***Table 5:*** *Drug Therapy Problems, generic prescription, number and class of antibiotics prescribed to pregnant women in the hospitals.Values in bracket indicate response based on sample size (n) expressed in percentage.*

| Dosage | General Hospital Onitsha | NAUTH |
|---|---|---|
| | n (%) | n (%) |
| 80 mg | 1.0 (0.3) | |
| 100 mg | 20.0 (6.7) | |
| 200 mg | 9.0 (3.0) | |
| 400 mg | 13.0 (4.3) | |
| 500 mg | 214.0 (71.3) | 20.0 (66.7) |
| 625 mg | 15.0 (5.0) | 625 mg |
| 750 mg | 9.0 (3.0) | |
| 1g | 17.0 (5.7) | |
| 2g | 2.0 (0.7) | |

***Table 6:*** *Dosage of antibiotic medications prescribed.*

| General hospital Onitsha | | NAUTH | |
|---|---|---|---|
| S/No | Antibiotics | n (%) | n (%) |
| 1 | Macrolides | 83.0 (26.7) | 4.0 (13.3) |
| 2 | Cephalosporins | 19.0 (6.4) | - |
| 3 | Tetracyclines | 5.0 (1.7) | - |
| 4 | Fluoroquinolones | 140.0 (46.6) | 4.0 (13.3) |
| 5 | Aminopenicillins | 79.0 (26.4) | 9.0 (30.0) |
| 6 | Aminoglycosides | 3.0 (1.0) | - |
| 7 | Sulphonamides | 1.0 (0.3) | - |
| 8 | Metronidazole | 44.0 (14.6) | 2.0 (6.7) |

***Table 7:*** *Category of antibiotics prescribed to pregnant women in the two hospitals.*

### Level of antibiotics adherence to the FDA classification of drug safety in pregnancy in the two hospitals

In Onitsha General Hospital, fluoroquinolones had the highest frequency of prescription, followed by the macrolides, and aminopenicillins. The least prescribed category of antibiotic was sulphonamide. In NAUTH, aminopenicillins had the highest prescription, 9 (30.0%) followed by fluoroquinolones. The above findings was in line with the FDA classification of drug safety in pregnancy. It supported the outcome of another study on the use of antibiotics among pregnant women carried out in Uyo south- south Nigeria [24]. In another study in Sokoto, North West Nigeria, by Abubakar., *et al*. 2013, Amoxicillin was the most prescribed antibiotic as against the previous study [21].

## Conclusion

This study suggested that the antibiotics prescribed for the pregnant women fell under the FDA risk category A - C with rare cases of prescription occurring in category D. The most frequently prescribed antibiotic is fluoroquinolones in General Hospital Onitsha and Aminopenicillins in NAUTH. UTIs and RTIs were the predominant classes of infection in the population. Fluoroquinolones class were the mostly prescribed antibiotics. Dosing frequencies and durations relied on evidence-based medicine and clinician's discretion. Aminopenicillins and macrolides were the most prescribes antibiotics.

## Conflict of Interest

The authors have non to declare.

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