

Review Article

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Irrational use and non-prescription sale of antibiotics in Nigeria: A need for change

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Abstract

The sale of antibiotics without medical prescription has been observed in many countries. The practice is more pronounced in developing and low income countries where legislations and regulations are weak. In these countries, antibiotics are illegally purchased without medical prescriptions and very little effort has been made to tackle the situation. The role of pharmacists in contributing to healthcare remains debatable. In Nigeria, there are deficiencies in the quality of current professional practice. Community pharmacists are now seen as retailers and businessmen rather than health care providers. Nigerians are therefore left to accept the helpful and harmful practices such as self-medication with antibiotics. Self-medication with antibiotics is a universal problem and variations regarding such practices are obvious around the globe. The practice cuts across culture, gender, age, health status, social status, race and occupation. Irrational use of antibiotics increases the risk of bacterial resistance and adverse drug reactions. It has been found to produce various adverse effects in humans. It is the objective of this paper to discuss the irrational use and non-prescription sale of antibiotics in Nigeria. It will discuss the evidence, the concept of self-medication, resistance and interactions, legislation, probable solutions, changes in practice and the concept of sustainability which would help guarantee the appropriate sale and rational use of antibiotics in Nigeria.

Keywords: Pharmacy practice, Community pharmacy, Antibiotics, Prescription, Over the counter (OTC), Nigeria.

Introduction

The accidental discovery of the first antibiotic by Alexander Fleming in 1928 revolutionized the therapy of infection and reduced mortality and morbidity from microbial diseases. It became the leading weapon in the treatment of bacterial infections. The dramatic impact was attributed to lack of primary resistance among microbes and scarcity of antibiotics with a high cost which necessitated extraordinary prudence in their use. Then came a time when with progressively falling costs and increasing availability of antibiotics, the global pharmaceutical industry took advantage of the declining costs of production, expanding world markets especially in developing countries. Currently, antimicrobials are the most widely used category of drugs in the world¹ Despite the enormous gains prudent use of this class of drugs would have had on world health, the irrational use of antimicrobials has driven the relentless expansion of resistant microbes leading to a loss of efficacy of these drugs.²

The situation in developing countries is of particular concern. The use of antibiotics without medical guidance is largely facilitated by inadequate regulation of the

distribution and sale of prescription drugs.^{3,4} The situation of overuse and misuse in developing countries is particularly alarming. Higher rates of antibiotic use have been reported in several developing countries, including Pakistan, Nepal, Eritrea, Uzbekistan, Oman, Sudan, Jordan, Zimbabwe, Lebanon, Yemen, and Nigeria. The irrational use of antibiotics is not only common in developing countries, but also widespread in the developed world.¹ A study by Ronning et al which reviewed antibacterial usage in 16 European countries discovered that the use of antibiotics was higher than required and largely irrational in these countries.⁵

The sale of antibiotics without medical prescription has also been observed in many countries.⁶⁻¹⁰ The practice is more pronounced in developing and low income countries where legislations and regulations are weak.¹¹ In these countries, antibiotics are illegally purchased without medical prescriptions and very little effort has been made to tackle this public health menace. Non-prescription sale of antibiotics is a crisis that has received very minimal audience despite its long practice. It is the objective of this paper to discuss the irrational use of antibiotics and the non-prescription sale of antibiotics in Nigeria. It will discuss the evidence, the concept of self-medication, resistance and interactions, legislation, probable solutions, changes in practice and the concept of sustainability which would help guarantee the appropriate sale and rational use of antibiotics in Nigeria.

Method

In getting materials for this paper, electronic databases were searched for articles published in English between 2005 and 2011. The electronic databases searched included Pubmed central, CINAHL, Cochrane, Medline, Embase and Google scholar. Keywords used were pharmacy practice; community pharmacy; antibiotics; prescription; over the counter (OTC); Nigeria. Titles and abstracts were screened and full text papers were retrieved for studies considered relevant and for studies that contained insufficient information to allow judgment of relevance. The full text papers and papers considered relevant were assessed against the inclusion criteria. Three papers from Cochrane, four papers from Pubmed central, one paper from Embase, ten papers from Medline, two papers from Cinahl and fifteen papers from Google scholar were finally selected in writing this paper. The majority of the studies assessed over the counter sale of antibiotics in developing and middle income countries, while others assessed the

factors influencing the patterns of self-medication with antibiotics.

The Evidence

The evidence base regarding the sale of antibiotics without prescription in Nigeria is very small. Sale of antibiotics, particularly over the counter is wide spread, but very little data substantiates this claim. Despite the low evidence base regarding these claims, there have been notable consistencies between findings of different studies. A systematic review by Morgan et al of 35 community surveys from five continents revealed that non-prescription sale of antibiotics occurred worldwide and accounted for 19-100% of antimicrobial use outside of northern Europe and North America.¹² Although no detailed published data were found focusing on non-prescription sale of antibiotic in Nigeria, one paper conducted a study on the utilization of antimicrobial agents with and without prescription by out-patients in selected pharmacies in South- Eastern Nigeria.¹³ Others assessed the factors influencing self-medication in an adult Nigerian population.¹⁴

The Nigerian Pharmacy Sector

According to the Registered Council Data on Health Manpower, the number of pharmacists in the year 2001 was 9,308 of which 6,412 were registered, leaving the patient- pharmacist ratio at 10,743 to 1 based on an estimated population of 100 million in the year 2001.¹⁵ With the population estimated to increase to over 155 million, this ratio is expected to widen.¹⁶ In a statement by Mrs Gloria Abumere, the acting registrar of the Pharmacists Council of Nigeria (PCN), "there are 16,970 registered pharmacists as at 2012". This still leaves the patient-pharmacy ratio at over 10,000 to 1; a figure short of the WHO recommendation of one pharmacist to a thousand. The total number of wholesalers in the country in 2001 was 12,022 with only 6,753 registered with the Pharmacists Council of Nigeria (PCN). The PCN is a Federal Government Agency established by Decree 91 of 1992 to regulate and control the practice of pharmacy in all its aspects and ramifications.¹⁷ In the year 2001, 4,825 private pharmacies were present with only 2, 808 registered with the Pharmacists Council of Nigeria.¹⁵

Role of Pharmacists

The role of pharmacists in contributing to health care has been a focus of discussion both within and outside the profession for many years. Private pharmacies are present in many communities where they are often seen as a

convenient 'first point of call' for advice on common symptoms and other health problems.^{18,19} In some settings and for many illness episodes, local private pharmacies may constitute the only health service with which people make contact.²⁰ In Nigeria, their long opening hours substantiates their importance in various communal settings. Pharmacists have the potential to contribute to primary healthcare, however, there are deficiencies in the quality of current professional practice, of particular interest, the inappropriate sale of antibiotics.

By law in Nigeria, prescription-only medicines (POMs) which include antibiotics are not to be sold over the counter.¹⁵ Pharmacies are only licensed to dispense POMs against a valid prescription.²¹ This is however not the case in most pharmaceutical stores. Poor enforcement and lack of an efficient quality control measure by the government and regulatory bodies allow pharmacies sell POMs as over the counter drugs. In recent times, pharmacists have been viewed as retailers and businessmen rather than health care providers.^{21,22} Nigerians are therefore left to accept the helpful and harmful practices of community pharmacies which remain an unavoidable reality of the poorly managed government mandated primary healthcare delivery system.

The weakness of the primary health care system strengthens the role of community pharmacists in Nigeria. It promotes a shift from the product oriented role of community pharmacies to a patient focused practice.²³ This is confirmed in the WHO paper on Public education and rational drug use, which reports that nearly 80% of illness episodes in most developing countries are self-treated with medicines obtained from community pharmacies.²⁴ Deficiencies in the quality of professional practice by community pharmacists limit their importance despite their potential to contribute effectively to primary health care

Self-medication

The concept of self-medication encourages individuals to look after minor ailments with simple and effective remedies. This has been supported worldwide.²⁵⁻²⁷ Self-medication is believed to be a major form of self-care and people hold the view that medicines should be used in the event of any sickness or discomfort.²⁸ Self-medication has been cited as a major factor contributing to drug resistance, particularly with the use of antimicrobials. Self-medicated use of antibiotics is one of the most common ways in which antibiotics are misused.¹³ In Nigeria, antibiotics are often-times prescribed by health practitioners in the

absence of a laboratory or clinical evidence of a definite or probable bacterial infection. Reports from studies in developing countries reveal that 60 – 80% of health related problems are treated through self-medication.^{29,30}

The practice of self-medication cuts across culture, gender, age, health status, social status, race and occupation.¹⁴ In the United Kingdom, 50% of health care takes place within the realm of self-medication, however the government encourages self-reliance.^{31,32} High rate of self-medication, particularly with antibiotics is a universal problem and variations regarding such practices are obvious around the globe: Palestine (98%); Slovenia (92.3%); Croatia (88%); Malaysia (80.9%); Greece (74.6%); China (59.4%); Turkey (45.8%); USA (43%); Jordan (40.7%); Lithuania (39.9%); Ethiopia (38.5%); India (31%) and Finland (28%).³³ A study in Nigeria reports that, the prevalence of self-medication among nursing mothers stand at 47.6%.³⁴ Other studies have also confirmed the high rate of self-medication with antibiotics.^{35, 36}

In the revised version of the national drug policy paper of the Nigerian government published in 2005, self-medication was stated as essentially useful in any situation where access to health care facility is limited.³⁷ It however, reiterated that self-medication could lead to inappropriate use of drugs, delay of diagnosis and delivery of effective treatment, and could lead to drug misuse and abuse. Researchers have noted that the use of antibiotics without prescription is motivated by a complex set of factors which include unchecked sales, time constraints, cost, accessibility, shortage of doctors, influence of friends and family, education level, consumer attitudes and media campaigns.^{14, 30, 38-40}

The greatest threat self-medication with antibiotics poses is the risk of bacterial resistance and adverse drug reactions. The human malpractice has resulted in inadequate dosing and incomplete treatment course. Despite the high level of self-medication and uncontrolled sale and use of antibiotics, there has been little or no public education on the rational use of medicines.¹⁵

Antibiotic Resistance/Adverse Drug Reactions/Interactions

The irrational use of antibiotics, which is encouraged by over the counter sale of these medicines, has been found to produce various side effects in humans.¹ Obtaining antibiotics without medical prescription does not only promote antibacterial resistance, but can also promote adverse events including adverse drug effects, high cost of

treatment and complications.⁴¹ Pregnancy status is a critical situation to consider when giving medication to a child bearing woman. However, non-prescription sale of antibiotics coupled with the self-medicated treatment of various illnesses and infections of pregnant women increases the risk of complications in pregnancy. Some classes of drugs have also been reported to be avoided in pregnancy and by nursing mothers. Many antibiotics lead to adverse effects through different means: trimethoprim depresses folic acid in both microorganism and host; chloramphenicol depresses bone marrow in all recipients, use of doxycycline in pregnancy causes permanent tooth discolouration to the unborn child, and recently, flouroquinolones, another class of antibiotics, are being said to cause multiple adverse effects which may be long lasting. In addition to resistance, overuse and prolonged administration of broad spectrum antibiotics results in super infection and has been recognised to cause the death of normal intestinal and vaginal flora. The irrational use of antimicrobials is contributing to the growing resistance of treatments to the very disease that contribute most of the burden of illnesses in developing countries. The World Health Organisation states that resistance to antimicrobials is one of the world's greatest public health problems: a major cause being the irrational use of medicines.⁴²

Resistance to antimicrobials is a major concern associated with the practice. The World Health Assembly in 2005 cautioned that antimicrobial resistance was rapidly increasing with resistance up to about 70-90% of first-line antibiotics to dysentery, pneumonia, gonorrhoea and hospital infections. Memish et al in their study reported an increase in resistance to penicillin among all strains of *Streptococcus pneumoniae*.⁴³ The global antimicrobial prevalence rates vary with disease conditions. On a global scale, resistance to penicillin was estimated to be between 5% and 98% for gonorrhoea and between 12% and 55% for pneumonia and bacterial meningitis respectively.^{44, 45} For tuberculosis, 0-17% primary multidrug resistance has been established while for HIV/AIDS, 0-25% primary resistance to at least one anti-retroviral drug has been reported. Resistance of *Staphylococcus aureus* to all penicillins and cephalosporins in hospital infections has also been estimated to stand at 0-70%.^{44, 45}

Drug interaction represents a major problem with over the counter sale of antibiotics and failure of pharmacists to ask patients about accompanying medication poses significant risk to patients.

Legislation

The formal pharmaceutical retailing in most countries of the world is governed by regulations regarding ownership, staffing, medicines, prescription practices and prices.⁴⁶ In Nigeria and other low and middle income countries, enforcement of these regulations is difficult. The regulations are constrained by the limited capacity of the government and impeded by the fragmented nature of retail pharmaceutical markets.¹¹ Regulations are impeded by government's lack of enforcement staff, budget, and efficient regulatory and judicious framework.⁴⁷ The result of the widespread under-regulation in Nigeria allows for illicit sale of restricted medicines, often without prescription and by unqualified staff.^{13, 48} This is further worsened with the prevalence of fake drugs in the country which leads to unforeseen adverse effects of drugs, treatment failures, prolonged ill health and untimely death of victims.⁴⁹

The Registration and licensing of qualified pharmacists is usually the responsibility of a national or state Pharmacists' Association or Society, or a department within the Ministry of Health or government. The Pharmacy Act often stipulates the conditions and legal structures under which these bodies can operate.¹¹ The regulation of the Nigerian pharmaceutical sector is controlled by the National Agency for Food and Drug Administration and Control (NAFDAC) and the Pharmacists Council of Nigeria (PCN). NAFDAC regulates pharmaceutical products and its duties include drug registration, manufacturing, importation, promotion, marketing approval, and advertising. The PCN regulates the premises and professional practice and its duties include licensing and practice of pharmacy and pharmaceutical premises according to promulgated laws.¹⁵ An effective pharmaceutical policy is an essential piece of any country's legislation. Despite government's efforts at putting these legislations in place, the effective regulation of medicines and the practice remains a challenge for the pharmaceutical sector.¹¹

Change in Practice

The evidence which identifies that the non-prescription sale of antibiotics is inappropriate emphasizes the need for a change in practice. Changing practices over the irrational use and non-prescriptive sale of antibiotics is fundamental to public health. Changes in the behaviour of both pharmacists and pharmacy customers are likely to be required if a pharmacy is to contribute in a unique way to public health.⁵⁰ The change can be sustainable through the joint effort of the units which make up the body of such

practices: the government; the pharmacy; and the people. For the change in practice to be sustainably maintained, it is essential to understand the attitudes and belief of pharmacists and health professionals about practice, and the barriers to achieving best practice. It is also important to understand the attitudes and beliefs of the people as regards self-medication particularly with antibiotics. Community pharmacists must accept their role as health professionals and not business men, and make necessary changes in behaviour to carry out their services.

Possible solutions

In relation to self-medication with antibiotics, there is an urgent need for a global action to tackle the problem of self-medication with antimicrobial agents.¹⁴ Public awareness of the dangers associated with the practice should be raised and information should be made available on the strategies for achieving better practice. Rational use of antibiotics should be encouraged to limit the emerging antimicrobial resistance posed by indiscriminate use of antibiotics.

As regards legislations, there is a need to review and update the relevant laws. This can be done by the government in consultation with stake holders to achieve the desired objectives of the Nigerian National Drug Policy.³⁷ Government should strengthen legislation relating to essential drug policies; definition of drugs; registration of drugs; prescribing and dispensing of drugs; quality control of drugs and pharmaceutical substances; licensing of manufacturing wholesale and retail premises; licensing of qualified persons; national health insurance as it relates to drug supply to patients; offences and sanctions; administration and control of drugs; imposition of fees for services and clarification and dispensing functions. Additionally, the government should enact appropriate legislation in respect to inappropriate sale of antibiotics and designate special courts for drug related offences to enhance speedy trial of persons or corporate bodies and pharmacies apprehended for such offences.³⁷

Strategies to improve pharmacy practice with respect to sale of antibiotics should aim to increase pharmacist's knowledge and to remind pharmacists of their existing knowledge regarding antibiotics.^{51, 52} Community pharmacists should be reminded that there are policies guarding the prescription and sale of antibiotics and there are penalties for the inappropriate sale of antibiotics. They should always remember they are bound by ethics which assists in the discharge of moral and professional

obligations resting upon them to observe standards of conducts appropriate to their calling.¹⁷ Similarly, the people must accept pharmacists as provider of health services and be willing to seek advice on health issues rather than self-medicate.

Conclusion

The irrational use and non-prescription sale of antibiotics will not only promote antimicrobial resistance, but can also be linked with pronounced adverse events including drug adverse effects, high cost and complications.⁴¹ Although the practice of non-prescription sale of antibiotics is inappropriate and unethical, putting a ban on over the counter availability of antibiotics could be disastrous. For some people, there is no alternative. Restriction of some classes of antibiotics is a possibility. As practiced in the UK, where many prescription-only- medicines (POM's) have been re-classified to pharmacy-only and general sales list status, the Nigerian government can emulate this change. However, considering the Nigerian setting, there could be leakages. Changing the practice of non-prescription sale and irrational use of antibiotics requires a sustained restoration of the Nigerian Health System in a bid to make medical care available to people and promote education of the population on antibiotic use, and the rational use of medicines.

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