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## Opinion Article

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# Medication Management, Use and Safety in Non-Communicable Diseases: Any Hope for the Nigerian Patients?

## Abstract

Globally, the recognition of non-communicable diseases (NCDs) as a major cause of morbidity and mortality is increasing. The link between poor lifestyle choices such as drug use, alcohol and tobacco use, diet, lack of exercise or stress management provides a major challenge in medication use in the management of NCDs. In NCDs, the management and use of medications is associated with many challenges in the Nigerian health care system including access to medicine, infrastructural decay, quality of health professional, poor adherence to therapy, and poor knowledge of patients, among others. Despite these challenges, there is hope for Nigerian patients suffering from NCDs as the existing global approaches aimed at improving access to drugs, and medication management and use can be a live saver for them. Irrespective of poverty problems in the country, the threat from increasing prevalence of NCDs can be overcome with a combination of the efforts from government, health professionals and the individual patients. Adequate education of the patients and the public can lead to behavioral change and reduction in NCDs while at the same time improving medication use behaviours.

**Keywords:** NCDs, Drug management, Drug safety, Drug Use, Nigerian population.

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## Introduction

A non-communicable disease (NCD) is a disease which is not contagious or infectious. Examples include heart failure, hypertension, cancer, asthma, diabetes, allergies and stroke. Globally, the recognition of NCDs as major cause of morbidity and mortality is increasing. As at 1990, the leading causes of disease burden were pneumonia, diarrhoeal diseases, perinatal conditions and NCDs. By 2005, chronic

diseases—mainly cardiovascular disease, cancer, chronic respiratory diseases, and diabetes—have been estimated to cause more than 60% (35 million) of all deaths; more than 80% of these deaths occurred in low-income and middle-income countries and just less than 50% were people younger than 70 years<sup>1-3</sup>. In 2007, Abegunde et al<sup>4</sup> reported the estimates of the expected proportion of deaths from NCDs (Table 1). By 2020, it is predicted that NCDs will account for more than 70% of the global burden

**Table 1:** Projected deaths for chronic diseases for all causes in 23 selected countries for 2005, 2015 and 2030 (Percentages in parentheses)<sup>4</sup>

Deaths (all ages)	2005	2015	2030
CVD and diabetes	12.4 (33)	14.3 (35)	17.3 (36)
Cancers	4.5 (12)	5.6 (14)	7.5 (15)
Chronic respiratory	3.1 (8)	4.1 (10)	5.9 (12)
All chronic diseases	23.1 (61)	27.2 (66)	34.3 (71)

CVD=cardiovascular diseases

**Table 2:** Evolution of NCDs in developing countries (in million)<sup>3</sup>

Year	Non-communicable diseases	Communicable diseases + Maternal + Perinatal + Nutritional	Injuries	Total
1990	18.7 (47%)	16.6 (42%)	4.2 (11%)	39.5 (100%)
2000	25.0 (56%)	14.6 (33%)	5.0 (11%)	45.0 (100%)
2020	36.6 (69%)	09.0 (17%)	7.4 (14%)	53.0 (100%)

of disease, causing 70% of all deaths in developing countries, compared with less than 50% five years ago (Table 2)<sup>1-3</sup>. The implications of the increasing NCDs burden include increase in the volume of drugs requirements for NCDs, possible increase in research and development (R & D) of drugs, several fold increase in manpower requirements and increase in the need for improved manpower development.

It is known that risk factors such as a person's lifestyle, diet, exercise, alcohol and tobacco use as well as genetics or environment increase the likelihood of certain NCDs. Of these factors, 50% of all NCDs are a result of poor lifestyle choices such as drug use, alcohol and tobacco use, diet, lack of exercise or poor stress management. This provides a major challenge in medication use in the management of NCDs.

## Medication Use in Developing Countries

Many researchers have described medication use in developing countries, including Nigeria, as "irrational", and often there are documented cases of ineffective, unsuitable, suboptimal or unsafe prescribing, supply and/or consumption of pharmaceutical products. As in other developing countries, the use of medicines in Nigeria is influenced by several factors which include (1) health and drugs policy, (2) organisation and processes of healthcare provision, (3) immense differences in the availability of drugs and

services between regions (notably urban and rural areas), (4) financial constraints on the part of governments and individuals, (5) problems of access to objective product information, (6) role of the pharmaceutical industry in production and marketing, (7) prevalence of fake and counterfeit medicinal products, (8) difficulties of regulating professional practice by the Pharmacists Council of Nigeria and ensuring that only quality medicines are available to the public for use, and (9) the use of medicines in the context of local health beliefs, cultural traditions, and individuals' perspectives and preferences regarding the appropriateness of different courses of action and medication use<sup>5</sup>.

In Nigeria, the public health facilities are only one of many sources of drugs. Local pharmacies, patent medicine stores, supermarkets, chemical sellers, and drug peddlers are important suppliers of pharmaceuticals in many communities. It is estimated that more than 30% of pharmacies in Nigeria and over 50% of patent medicine stores are operating illegally. Of the registered pharmacies, less than 10% of patients enjoy the benefit of receiving adequate counseling from the pharmacists working in community pharmacies.

**Adherence to medication:** It is generally recognized that adherence to recommended medication regimens is a major problem in medication use. Adherence to (or compliance with) a medication regimen is generally defined as the extent to which patients take medications as prescribed by their health care providers. The

word “adherence” is preferred by many health care providers, because “compliance” suggests that the patient is passively following the doctor’s orders and that the treatment plan is not based on a therapeutic alliance or contract established between the patient and the physician. Rates of adherence for individual patients are usually reported as the percentage of the prescribed doses of the medication actually taken by the patient over a specified period. Adherence rates are typically higher among patients with acute conditions, as compared with those with chronic conditions as in NCDs. Even in clinical trials where adherence rates are often highest owing to the attention study patients receive and to selection of the patients, reported average adherence rates is often only 43 to 78% among patients receiving treatment for NCDs.<sup>6</sup>

There is no consensual standard for what constitutes adequate adherence. While rates greater than 80% may be considered acceptable in some disease conditions, rates greater than 95% are mandatory for adequate adherence, particularly among patients with serious conditions such as HIV/AIDS. It is acknowledged that adherence is influenced by many factors including access to care, affordability of medication, information and beliefs regarding the need for treatment, patient information and product labeling<sup>7</sup> as well as the value of trained staff to the quality of the dispensing process<sup>3</sup>. In many developing countries the more highly qualified professionals tend to be concentrated in the urban areas. Most hospital and community pharmacists spend little times (often less than 1 minute) with their patients. Boonstra *et al*<sup>3</sup> reported a mean dispensing counselling time of 25 seconds.

### Access to Medicines

One of the key building blocks of a well-functioning health system is ensuring equitable access to essential medical products, vaccines and technologies of assured quality and cost-effectiveness. However, approximately one third of the world’s population still lacks regular access to life-saving medicines<sup>8</sup>. This estimate rises to over 40% in low-income countries and over 50% in poorest countries of Asia and Africa. It is estimated that more than 90% of Nigerians

purchase medicines through out-of-pocket payments, making medicines the largest family expenditure item after food, for at least 30% of the population. Studies have also shown that availability of essential medicines is often poor in the public sector where prices are usually cheaper, forcing patients to resort to the more expensive private sector.

Medicines are often the most important cost driver of health care expenditure on hospitals and ambulatory care. Patients that have access to adequate and effective medicines at the time of need are more likely to be happy with the treatment they receive. When such medicines are unavailable or ineffective after use, patients will go elsewhere, even if they have to pay high prices to private providers, to get the care they think they need. The availability of affordable and effective medicines is, therefore, a visible indicator of the quality of health services.

Despite significant progress in increasing access to essential medicines in low and middle income countries during the past decades, many of the public health services used by the poor still lack adequate supplies of basic medicines. Drug shortages and quality problems continue to undermine the performance of health systems throughout the country. Many factors determine whether poor people can obtain affordable drugs of good quality. These includes issues related to lack of infrastructure, pricing and procurement of existing drugs, new product development, patents/intellectual property rights, manufacturing or import of drugs, macroeconomic constraints, foreign exchange fluctuations, human resources, government financing and corruption. Even when drugs are available, another major problem is affordability for well over 60% of those that require the drugs<sup>8,9</sup>.

**Pricing of drugs:** A major question is how much do Nigerians pay for drugs when compared to other countries? A recent study provides a clue that Nigerian may be paying far more than many countries for drugs. In a survey involving the use of antibiotics in Benin City, it was reported that patients pay far more than the international prices for over 87% of the 24 types of antibiotics evaluated. For the two fluoroquinolones (ciprofloxacin and ofloxacin) evaluated in the

study, Nigerians pay more than 12 times the international prices (Table 3)<sup>10</sup>.

It is known that the exclusive marketing rights obtained through intellectual property protection can restrict market competition and result in high drug prices. As a result, the World Trade Organization's (WTO) Trade-related Aspects of Intellectual Property Rights Agreement (TRIPS) requires all WTO member countries (which include Nigeria) to implement minimum standards for the protection of intellectual property<sup>8,11</sup>. Consequently, countries with pharmaceutical manufacturing capacity were permitted to enact domestic legislation allowing the production and export of generic versions of

patented drugs under compulsory licence to countries with insufficient or no manufacturing capacity. There is no evidence that Nigeria has benefited much from this for technical reasons.

## Medication Management and Safety

Medication management is an important component in palliative, symptomatic, preventive and curative treatment of NCDs. The management systems include processes used to provide medication-related therapies to patients in an organisation. These processes include proper selection and procurement, storage, ordering and transcribing, preparation and

**Table 3:** Local versus international price comparison of antibiotics utilized in four tertiary health facilities in southern Nigeria

Name of drug	Strength	International Price (US\$) <sup>1</sup>	Local Price per unit (US\$) <sup>1</sup>	MPR
Ciprofloxacin O	500 mg	0.0298	0.4237	14.32
Ofloxacin O	200 mg	0.0349	0.4237	12.14
Ceftriaxone P	1000 mg/vial	0.8821	5.9322	6.73
Ceftazidime P	1000 mg/vial	2.435	13.5593	5.57
Metronidazole O	400 mg	0.0066	0.0339	5.14
Cephalexin O	500 mg	0.085	0.4237	4.99
Flucloxacillin O	250 mg	0.0720	0.3390	4.71
Clarithromycin O	500 mg	0.2731	1.2712	4.65
Doxycycline O	100 mg	0.0174	0.0678	3.90
Amoxicillin+Clavulanic acid O	625 mg	0.2896	1.0169	3.51
Cefuroxime P	750 mg/vial	1.3376	4.6610	3.48
Tetracycline O	250 mg	0.0081	0.0254	3.14
Ampicillin+sulbactam P	1500 mg	2.3115	6.3559	2.75
Gentamicin P	40 mg/ml	0.0728	0.1695	2.33
Cefuroxime O	250 mg	0.5908	1.2712	2.15
Amoxicillin+Clavulanic acid P	1200 mg/vial	3.5532	7.6271	2.15
Ciprofloxacin P	2 mg/ml	0.0062	0.0127	1.93
Ampicillin+cloxacillin O	500 mg	0.0459	0.0678	1.48
Amoxicillin O	500 mg	0.0468	0.0678	1.45
Erythromycin O	250 mg	0.0911	0.1271	1.40
Metronidazole P	5 mg/ml	0.35	0.4237	1.21
Clindamycin O	300 mg	0.2	0.0593	0.30
Cotrimoxazole O	480 mg	0.145	0.0593	0.20
Benzylpenicillin P	600 mg/vial	0.42	0.1271	0.15

MPR (median price ratio) --- local costs of the antibiotics expressed as a ratio of the international prices; US\$1.00 = ₦118.00; O = Oral; P = Parenteral; <sup>1</sup>p<0.001 Source: Erah and Ehiaguina<sup>10</sup>

dispensing, administration and clinical monitoring of effects.

Like other Sub-Saharan Africa countries, Nigeria faces frequent stock interruptions of essential drugs for managing NCDs. Today, many NCDs including hypertension, diabetes, and cancer top the list of cause of death in many of our hospitals. Many of these cases are due to inappropriate use of drugs. Failure to take medication as prescribed significantly increases the risk that patients will experience complications resulting in injury or death, and propagate higher healthcare costs overall. In a recent study in Benin City, it was discovered that calcium channel blockers (nifedipine and amlodipine) were often prescribed for systolic heart failure for 34.3% of elderly patients but only 4.7% of them were often properly counseled leaving the rest to the consequences of adverse drug events. Even in specialist centers, many patients still receive sub-standard care and have poor access to essential medications.

Medication errors are among the most common medical errors, can occur anytime, in any step of the delivery process, and a great proportion is preventable. In Nigeria, there are no accurate data on the prevalence of medication errors or the estimated cost implications. However, in an earlier study, it was reported that adverse drug events (ADEs) and medication errors contribute to 20–72% of adverse events around the time of hospitalization and 7–12% of all permanent disabilities and deaths due to adverse events<sup>12-14</sup>. A meta-analytical report involving several studies revealed that the median preventability rate of drug-related admissions was 59%<sup>12,15</sup>. In another meta-analysis study, a median adverse drug event (ADE) preventability rate of 21% (11-38%) was reported in an ambulatory care. Cardiovascular drugs, analgesics, and hypoglycemic agents together accounted for 86.5% of preventable ADEs, and 77.2% of preventable ADEs resulted in symptoms of the central nervous system, electrolyte/renal system, and gastrointestinal tract<sup>12, 14</sup>.

Approximately 1.3 million people are injured annually in the United States following medication errors<sup>16</sup>. In a study by the FDA that evaluated reports of fatal medication errors from

1993 to 1998, the most common error involving medications was related to administration of an improper dose of medicine, accounting for 41% of fatal medication errors. Giving the wrong drug and using the wrong route of administration each accounted for 16% of the errors. Almost half of the fatal medication errors occurred in people over the age of 60. Older people may be at greatest risk for medication errors because they often take multiple prescription medications and are increasingly becoming forgetful.

#### *Medication Use in Elderly, Young and Pregnant Populations*

Medication use in elderly, infants and pregnant women is often a major challenge for the health professional. In many cases, it is the major source of unidentifiable medication-related problems in NCDs. Treatment for the elderly is frequently prescribed to relief symptoms rather than to completely control or cure a condition. The therapy of one condition can interfere with the control of another and the presence of comorbidity often complicates the assessment of drug therapy. Several factors in the elderly signal potential trouble with drug therapy. These include frailty, degree of illness, inability to look after themselves, poor appetite and nutrition, poor fluid intake, immobility, multiple illnesses, confusion and forgetfulness, and lack of supervision. The consequences of these include adherence problems, confusion over treatment, use of wrong dosage and wrong drugs, pharmacokinetic alterations, and pharmacodynamic alterations. Aging alters pharmacodynamics and pharmacokinetics, affecting the choice, dose, and frequency of many drugs. Their diminished physiologic reserves can be further depleted by effects of drugs and acute or chronic disease. In addition, pharmacotherapy may be complicated by an elderly patient's inability to purchase or obtain drugs or to comply with drug regimens.

The administration of drugs in the young is a major challenge for a number of reasons including, choosing the correct dosage form, administering correct volume and finding correct solvent for diluting or formulating preparation. For pregnant women, premature babies, and

neonates, a predominant factor is “unfinished organs” especially liver, kidneys, and CNS. All these factors affect the pharmacokinetic and pharmacodynamic behaviour of drugs in this population group. For example, infants are truly less sensitive to digoxin. Neonates have increased sensitivity to non-depolarizing neuromuscular blocking agents (d-tubocurarine). Systemic corticosteroids are particularly dangerous in children (stunted growth). Certain adverse effects of drugs are most common in the newborn period, whereas other toxic effect may continue to be important for many years of childhood. Chloramphenicol toxicity is increased in a newborn infant because of immature metabolism and enhanced bioavailability. Similarly, propylene glycol, added to many injectable drugs, including phenytoin, phenobarbital causes hyperosmolality in infants. Tetracycline are also contraindicated in pregnant women, nursing mothers, and children less than 8 years of age because they can cause dental staining and defects in enamelization of deciduous and permanent teeth as well as a decrease in bone growth. The antibiotics of the fluoroquinolone class e.g. ciprofloxacin, are not recommended for children or pregnant women, because of an association between these drugs and development of permanent lesions of the cartilage of weight bearing joints and other signs of arthropathy in immature animals of various species. Therefore, the challenge is to understand who the patient is and what medications he or she can take.

#### *Drug-Drug and Food Drug Interactions*

A **drug interaction** is a situation in which a substance affects the activity of a drug leading to either an increase or decrease in the effects of the drug, or production of an effect different from its normal effects. Typically, interaction can occur between different drugs (drug-drug interaction), foods and drugs (drug-food interactions), or drugs and herbs (drug-herb interactions). These may occur out of accidental misuse or due to lack of knowledge about the active ingredients involved in the relevant substances. Studies conducted in various countries reported rates of potential drug-drug interactions ranging from approximately 1 to 66%<sup>17</sup>. In one study, the proportion of patients with a potential drug-statin interaction (which increases the risk for developing rhabdomyolysis

was 12.1% for simvastatin, 10.0% for atorvastatin, 3.8% for fluvastatin and 0.3% for pravastatin<sup>18</sup>.

Drug-drug interactions (DDI) in patients receiving multi-drug therapy are important causes of adverse drug reactions and may lead to an increased risk of hospitalization and higher health care costs. For example, when co-administered with warfarin, NSAIDs increase gastric irritation and erosion of the protective lining of the stomach, resulting in GI bleeding. Additionally, NSAIDs decrease the cohesive properties of platelets necessary in clot formation.

In Nigeria and many other developing countries, many adverse drug reactions occurring from DDI are often ignored or considered to be part of the patients' progression of illness. Worse still, no major efforts are being made by health professionals to document such problems often due to fear of litigation.

Although many drug interactions may lead to drug-related problems, there are some advantages explored in the use of drugs. An example is the co-administration of carbidopa with levodopa (available as carbidopa/levodopa) in the management of Parkinson's disease. When given by itself, levodopa is metabolized in the peripheral tissues outside the brain, which decreases the effectiveness of the drug and increases the risk of adverse effects. However, since carbidopa inhibits the peripheral metabolism of levodopa, the co-administration of carbidopa with levodopa allows more levodopa to reach the brain un-metabolized and also reduces the risk of side effects.

### **Complementary and Alternative Medicine**

The terms *complementary* and *alternative* (CAM and TM) describe practices and products that people choose as adjuncts to or as alternatives to Western medical approaches. The use of CAM and TM is widely recognised and WHO estimates that it is used by 80% of the African population for primary health care. Although the use of herbs in traditional medical practice has been in existence for centuries, expenditure on imported herbal products into the country became popular in recent years with unguided cost implications to



the national economy. For example, many Nigerians have resorted to the use of very expensive GNLD products rather than home made products.

Many people who today choose herbal products in lieu of orthodox medications assume that because these products are natural, they must be safe, even when the evidence for this assertion is essentially anecdotal. Recent studies have shown that herbs are highly variable in quality and composition, with many marketed products containing little of the intended ingredients and containing unintended contaminants, such as heavy metals and prescription drugs.

There is remarkably little correlation between the use of traditional medicine approaches and scientific evidence that they are safe or effective. For many herbal products presently in the country, the only evidence of their safety and efficacy is embodied in folklore. Of the several herbal products manufactured in Nigeria, none has proper documentation relating to safety and efficacy based on standard scientific and clinical-based evidence. Even products that have simply been listed by NAFDAC are often paraded to have been registered by the same body.

Whatever the present situation in the country, there is no doubt that traditional medicine has a major role to play in the management of NCDs as lifestyle, diet, obesity, lack of exercise, and stress are important contributing factors in the causation of NCDs and CAM and TM approaches to these factors in particular will be increasingly important for the development of future health care strategies for the country.

### **Is there Hope for Patients with NCDs?**

Despite the several problems, some of which have been identified above, there are opportunities for correction which can easily create a favourable situation and hope for patients suffering from NCDs in the country.

First, the quality of health care professionals including pharmacists, doctors, nurses and laboratory scientists needs to be addressed while at the same time strengthening the regulation of professional practice by the professional

regulatory bodies including the Pharmacists Council of Nigeria (PCN), Medical and Dental Council of Nigeria (MDCN) and the Nursing Council of Nigeria (NCN). PCN, MDCN, and NCN should take bold steps to implement measures that will ensure that the number of professionals in training match the available human and material resources for training of their professionals. Like PCN, the MDCN and NCN should also immediately commence effective regular update lectures for their professionals. This will also require better control of prescribing and dispensing roles and handling of medications. Furthermore, both the PCN and NAFDAC must intensify efforts to destroy the thriving infrastructure of those involved in illegal distribution and sale of drugs.

Second, the government needs to quickly address professional rivalry, particularly between the pharmacists and the doctors, which limit access of the pharmacists to adequate patient information needed for effective prevention of medication-related problems and improvement of patients' drug therapy outcomes through revision of relevant legislations relating to functions and access to patients in both public and private health care facilities.

Third, advocacy programmes aimed at preventing NCDs and improving medication safety should be initiated at all levels of the health care system. There should be an effective collaboration between the Ministry of Information and Ministry of Health at Local, State and Federal levels.

Fourth, the government should make serious planned efforts to faithfully address health infrastructural decay in public health facilities across the country. This involves ensuring the availability of essential medicines, materials and supplies as well as equipment and the provision of adequate working conditions that enable them to carry out their work appropriately and effectively. No meaningful control of NCDs, for example, can be achieved in the health care system without effective diagnoses in the face of absolute or relative absence of basic diagnostic equipment and reagents.

Fifth, for effective planning, accurate epidemiological data as well as monitoring and evaluation of NCDs are needed in Nigeria health care

system. While policies by government should henceforth address allocation of reasonable funds for effective data collection, monitoring and evaluation, competitiveness and competence should dictate the allocation of even the limited research grants in the country rather than the present political and social factors.

Sixth, while adequate planning that ensures the supply of safe and cost effective medications is vital in the health care system, poor people needs to be assisted in meeting the costs of their drugs needs in order to improve their access to drugs. A Health Trust Fund similar to the Education Trust Fund is recommended as a measure that can, at least, subsidize the costs of medication for low income people suffering from NCDs. To address the high cost of drugs in Nigeria, the government must be conscious of the fact that health care products are not treated like other commodities and consumers of medicines must pay the minimal possible cost.

Seventh, WHO 12 key interventions to promote more rational drug use should be implemented with seriousness in addressing irrational use of drugs. The interventions are (1) Establishment of a multidisciplinary national body to coordinate policies on medicine use, (2) Use of clinical guidelines, (3) Development and use of national essential medicines list, (4) Establishment of drug and therapeutics committees in districts and hospitals, (5) Inclusion of problem-based pharmacotherapy training in undergraduate curricula, (6) Continuing in-service medical education as a licensure requirement, (7) Supervision, audit and feedback, (8) Use of independent information on medicines, (9) Public education about medicines, (10) Avoidance of perverse financial incentives, (11) Use of appropriate and enforced regulation, and (12) Sufficient government expenditure to ensure availability of medicines and staff<sup>19</sup>.

Eight, the five-point TB control framework called "DOTS" ("directly observed therapy, short course") provide lessons for medication use in NCD control. Human and financial resources—and therefore political commitment—are needed to develop, implement, and supervise standardized approaches to managing medication use in NCDs.

Ninth, government should increase investment in improving the quality and consistency of CAM and TM since this could reduce the cost of health care delivery, especially for NCDs where TM interventions may improve patients' sense of well-being, appetite, and energy. At the same time, in the absence of resources to extend the public health infrastructure, a network of certified CAM and TM providers could provide the infrastructure for delivering other care, such as immunizations and maternal-child health programs. The lack of product quality and consistency and the absence of compelling data on the safety and efficacy of most CAM and TM approaches present major challenges to any effort to optimize the distribution of precious health resources. These difficulties also pose opportunities for research which the government should encourage and support.

## Conclusion

The global approaches aimed at improving access to drugs, and improving medication management and use can be a life saver for NCD patients. Although poverty is a major issue in healthcare delivery in Nigeria, the threat from increasing prevalence of NCDs can be overcome with a combination of the efforts from government, health professionals and the individual patients. Knowledge is power and adequate patient education can lead to behavioral change and reduction in NCDs while at the same time improving medication use behaviours.

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