



Clinical audit of drug prescriptions in Nigeria: An urgent and lifesaving need

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Abstract: A prescription is a legal document that should be carefully prepared. One of the duties of care which a doctor owes a patient is to write a drug prescription clearly, and failure to do so is negligence. One primary cause of medication error is lack of regular drug auditing and provision of necessary feedback after the process. In Nigeria, only a few studies have been done to audit prescriptions in some hospitals. There is a need to develop a standard prescription policy for use in hospitals in Nigeria that will help in reducing medication errors.

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Introduction

A prescription is an instruction from a prescriber to a dispenser (1). The writing of a prescription is an art as well as science (2). A prescription is a legal document that should be carefully prepared (3). Good drug prescription is essential in the management of patients. Bad prescription leads to ineffective and unsafe treatment. It can prolong illness and results in harm-causing to the patients (1).

A prescription should have at least the following: Name, address, telephone of prescriber, date the drug was prescribed, generic name and strength of the drug, dosage form, total amount, label that contains the instructions and warnings about the drug, name, address, age of patient, and signature or initials of prescriber, according to the World Health Organisation (1). One of the duties of care that a doctor owes a patient is to write a drug prescription clearly, and failure to do so is negligence (1). One primary cause of medication error is lack of regular drug auditing and

provision of necessary feedback after the process (4).

In Bangladesh, Sultana *et al.* (5) identified unclear writing in 3.58% of the drug prescribed and in 28.5% of the prescriptions, the dose strength of the drug prescribed was not written. In Nigeria, some studies have been done to identify drug prescriptions in some hospitals; Fadare *et al.* (6) in a retrospective analysis over a 5-month period identified omission of patient's age, hospital number and doctor's name in 30.1%, 20.3% and 2.5% of the prescriptions, respectively. Oshikoya and Ojo (7) assessed the medication errors in the outpatient unit of the Paediatrics Department of Lagos State University Teaching Hospital, Ikeja over a decade ago and errors such as omission of the duration for antibiotics use and analgesic use was seen in 1.5% and 2% of the prescriptions reviewed respectively.

Also, there are various laws relating to drug use in Nigeria (8), but there has been none on the prescription of drugs. Inappropriate prescribing is known to be a significant problem in healthcare all over the world (9). Writing a

prescription is indeed a vital part of the rational therapeutics, since a poorly written prescription can make a clinical consultation a waste of time, and cost human lives (10).

Why clinical audit?

Clinical audit is defined as a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and implementation of change (11). It is a way to find out if health care is being provided in line with standards and it allows care providers and patients to know where a service is doing well and where there is a need for improvements. The aim is to highlight the discrepancies between actual practice and standard to identify the changes needed to improve the quality of care provided to the patient (11). A well-conducted clinical audit process will achieve the following: increase the culture of clinicians; solve a problem; reduce the variability of professional conduct; and reduce the gap between theoretical standards and real life (12). The audit was first used by Florence Nightingale in 1854 to prevent post-surgical mortality (11). Since then clinical audit has been used to monitor and improve the quality of healthcare worldwide. Prescription audit is an educational activity that if regularly done can aid in improvement of prescribing quality and thus enable the patient to receive high standard and best quality care.

Laws relating to drugs in Nigeria

There is currently no Law in Nigeria which regulates the prescription of drugs, also, Nigeria as a country does not have a strict liability regime—the Laws relating to drugs in Nigeria deals with the regulation and control of the manufacturing, sale, and distribution of drugs (8).

The Poisons and Pharmacy Act, Cap 366 of 1990 is one of such Law. It regulates the compounding, sale, distribution, supply and dispensing of drugs and provides different levels of control for different categories of drugs and poisons (8).

The Food and Drugs Act Cap 150 of 1990 is another Law which regulates drugs in Nigeria (13). It prohibits the sale of certain foods, drugs cosmetics and devices as treatment for certain diseases. The Act prohibits the importation, exportation, distribution and sale of specified drugs. It prohibits the sale and distribution of food and drugs that are unfit for human consumption or poisonous to human body or has substances that can

damage the human body. It also prohibits practices such as misleading packaging, labeling, and advertising, as well as manufacturing food and drugs in unsanitary conditions. It conveys the power to appoint inspecting officers and food and drug analysts. The act makes provision in relation to drugs that contain substances harmful to the body but does not have any provision in relation to direct compensation to the victims of such harmful drugs. It has provisions in relations to forfeiture of such defective and harmful drugs and also provision for payment of fines and imposition of jail terms (13).

The Counterfeit and Fake Drugs (miscellaneous provisions) Act, Cap 73 of 1990 also regulates drug in Nigeria (14). It prohibits the production, importation, manufacture, sale and distribution of any counterfeit, adulterated banned or fake drugs. It also prohibits persons to sell any drug in an open market without permission from the proper authority. Similarly, the counterfeit (14).

The Pharmacists Council of Nigeria, Decree 91 of 1992 which repealed the Pharmacists Act of 1964 also regulates Drugs in Nigeria. This decree established the Pharmacists Council of Nigeria (15). The Pharmacist Council of Nigeria has the responsibility of determining the standard of knowledge and skill required of persons seeking to become registered members of the pharmacy profession (15). This council establishes and maintain a register of persons qualified to practice as members of the Pharmacy profession. It also reviews the code of conduct, regulate and control the practice of the Pharmacy profession, set up investigation panel and disciplines erring pharmacists as appropriate (15).

The National Agency for Food and Drug administration and control Decree No. 15 of 1993 (16). This is the decree establishing the National Agency for Food and Drug Administration and control (NAFDAC) (16). The NAFDAC Act appears to make provisions forbidding the importation, sale and distribution of harmful drugs, food, cosmetics and medical devices for human consumption, conduct tests and ensure compliance with standard specifications designated and approved by the council for the effective control of the quality of food, drugs, etc., as well as their raw materials and production, including processes in factories and other establishments. It also investigates the premises used for production and raw materials for food, drugs, etc. and establish relevant quality assurance systems, including certification of the production sites and regulated products. It also undertakes inspection of food, drugs etc. compile standard specifications and regulations and guidelines for the production, importation,

exportation, sale and distribution and registration of food, drugs, etc. (16).

The Drugs and related products (registration) Decree No. 19 of 1993 (17), makes provisions for the prohibition of the manufacture, importation, exportation, advertisement, sale or distribution of drugs, drug products, cosmetics or medical devices unless it has been registered in accordance with the provisions of the decree (17). It also stipulates the procedure for applying for registration of a drug product, conditions under which information supplied by an applicant is disclosed, and provisions for the suspension or cancellation of certificates of registration and clinical trials. Penalties for contravention of provisions of this decree are also stipulated therein (17).

The Standard Organization of Nigeria Act is another Law related to Pharmaceutical products in Nigeria (18). It has the responsibility of evaluation of quality assurance activities, including certification of systems, products and laboratories throughout Nigeria (18). It is also expected to establish an Import and Export Product Surveillance, Certification and Conformity Assessment Scheme to ensure that all products imported and exported are up to the expected standards, establish a mandatory conformity assessment programme for locally manufactured products in Nigeria (18). They also undertake registration of all manufactured products distributed, marketed and consumed throughout Nigeria, carry out training and undertake the accreditation of training institutions and organisations for purposes of international standards such as ITU, IEC, ISO, OIML, or Codex, standards or system certification throughout Nigeria (18).

In addition, they establish a Register for National standards, Standard Marks, Certification Systems and Licenses into which all matters relating to standards referred to under this Act are entered (18). The standard Organization of Nigeria also carry out investigations into the

production premises and raw materials and establish relevant quality assurance systems, including certification of the production sites for regulated products; and administer and enforce the provisions of the Act. The standard Organisation of Nigeria has the power to impose fees, fines or penalties on a person who contravenes any Import or Export Surveillance, Certification or Conformity Assessment Scheme (18).

Rational use of drugs in Nigeria

Rational use of drug is a term used to denote that patients

receive drugs according to their clinical needs, for an adequate period, at the right dose and the lowest cost to them and their community (19).

Most of the previous reports in Nigeria were on the rational use of drugs. Irrational use of drugs has been documented to be a global problem (20). The World Health Organisation estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards (20).

Examples of irrational use of medicines include many poly-pharmacy; inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections; over-use of injections when oral formulations would be more appropriate; failure to prescribe in accordance with clinical guidelines; inappropriate self-medication, often of prescription-only medicines; non-adherence to dosing regimes (19).

The World Health Organisation advocates 12 key interventions to promote more rational use, these are:

- (I) Establishment of a multidisciplinary national body to coordinate policies on medicine use;
- (II) Use of clinical guidelines;
- (III) Development and use of national essential medicines list;
- (IV) Establishment of drug and therapeutics committees in districts and hospitals;
- (V) Inclusion of problem-based pharmacotherapy training in undergraduate curricula;
- (VI) Continuing in-service medical education as a licensure requirement;
- (VII) Supervision, audit and feedback;
- (VIII) Use of independent information on medicines;
- (IX) Public education about medicines;
- (X) Avoidance of perverse financial incentives;
- (XI) Use of appropriate and enforced regulation;
- (XII) Sufficient government expenditure to ensure availability of medicines and staff (19).

Standards and guidelines for prescription of medicines

The allied medical personnel such as nurses, dentists, or a pharmacist can also prescribe drugs (1). Similarly, a dispenser could be a pharmacy technician, nurse or other health personnel. Prescription medication is a pharmaceutical drug that legally requires a medical

prescription to be dispensed (1). In contrast, over-the-counter drugs may be obtained without a prescription. Different countries have different definitions of the constituents of a prescription medicine. It is important to mention that there is a potential for abuse and misuse of prescription medication and thus it is important to distinguish both categories.

Regulations exist in different countries that control and monitor standards for prescription of medications. There is no global standard for prescription and who is entitled to write it. A standard which has been adopted and adapted by various countries and jurisdiction is the sentinel report by WHO at the end of the 20th century. The characteristics of a good prescription are clarity, and that it is written legibly and indicates what should be given. The following paragraphs will describe the minimum requirements of a standard prescription according to the review by WHO (1).

The name and contact address of the prescriber should be legibly written. This is important, since the dispenser may need to contact the prescriber for enquires. Following that, the date of the prescription should be written. This is because in some countries, pharmacists are prohibited from dispensing medications of prescription older than three to six months. The name and strength of the drug are indicated. As much as possible generic names of drugs are indicated. However, in exceptional circumstances, the trade name may be used. Precise strengths of drugs are written using universally acceptable symbols and abbreviations. The prescriber is obliged to write legibly. Additionally, the dosage, total amount of the medications, how often the dose should be taken, specific information and warnings including the duration of treatment should be communicated on the prescription. Furthermore, the patient's name, address and age (for children and elderly) should be indicated on it. This is important to distinguish patients and avoid mistakes. Lastly, the prescriber's initials and signature should be appended to the form. The question then is what guidelines do medical practitioners in Nigeria follow in writing out a prescription? Does it meet up to the minimum standard of the WHO (1)?

The legal obligation to write clearly

A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription (21).

Doctors are legally obliged to write clearly, as emphasized in the UK Court of Appeal ruling in the following case. A doctor had written a prescription for Amoxil tablets (amoxicillin). The pharmacist misread this and dispensed Daonil (glibenclamide) instead. The patient was not a diabetic and suffered permanent brain damage as a result of taking the drug. The court indicated that a doctor owed a duty of care to a patient to write a prescription clearly and with sufficient legibility to allow for possible mistakes by a busy pharmacist. The court concluded that the word Amoxil on the prescription could have been read as Daonil. It found that the doctor had been in breach of his duty to write clearly and had been negligent. The court concluded that the doctor's negligence had contributed to the negligence of the pharmacist, although the greater proportion of the responsibility (75%) lay with the pharmacist (21).

On appeal the doctor argued that the word on the prescription standing on its own could reasonably have been read incorrectly but that various other aspects of the prescription should have alerted the pharmacist. The strength prescribed was appropriate for Amoxil but not for Daonil; the prescription was for Amoxil to be taken three times a day while Daonil was usually taken once a day; the prescription was for only seven days' treatment, which was unlikely for Daonil; and finally, all prescriptions of drugs for diabetes were free under the National Health Service but the patient did not claim free treatment for the drug. All of these factors should have raised doubts in the mind of the pharmacist and as a result he should have contacted the doctor (1).

Therefore, the chain of causation from the doctor's bad handwriting to the eventual injury was This argument was rejected in the Court of Appeal. The implications of this ruling are that doctors are under a legal duty of care to write clearly, that is with sufficient legibility to allow for mistakes by others. When illegible handwriting results in a breach of that duty, causing personal injury, then the courts will be prepared to punish the careless by awarding sufficient damages. Liability does not end when the prescription leaves the doctor's consulting room. It may also be a cause of the negligence of others (1). A prescription is an order that must be written down before a drug can be dispensed (22,23). A Prescription is a written order by the prescriber to the dispenser on how the drug should be dispensed (22,23). It serves as a means of communication among the prescriber, dispenser and drug consumer pertaining to treatment. That is why doctors are legally obliged to write prescription clearly. However, most of the time

prescriptions are found to be unclear (24).

In 2016, Legese (24) at Jimma University, carried out a survey to study the factors that affect proper prescription writing in Jimma University specialized hospital. The study involved 100 physicians and 50 pharmacist using a convenience sampling technique, questionnaire and document analysis were used. Most of the physicians had knowledge on the importance of clear prescription writing and they positively perceived that sloppy prescription writing had negative impact on both pharmacists and patients, but the magnitude of writing clear prescription was low because 54.8% of the sample prescriptions were proved to be illegible. Moreover, 70% of the pharmacists also reported that physicians write clear prescription only some times. The major factors that affect the proper prescription writing, according to the physicians, are shortage of time (69%), difficulty of some medicine names to spell (80%) and lack of feedback from pharmacists (52%) on their (physicians') unclear prescription writing. The author (24) recommended, that the university collaborate with the hospital administrative bodies, ministry of health and other concerned bodies to make the physicians responsible and work cooperatively with pharmacists to alleviate the problem because illegible prescription may pose a medical threat to the treatment of a patient.

Based on the premise that it is generally accepted that doctors have illegible handwriting (25). A norm in which the writer knows what is written, but other parties often have problems reading and interpreting. In some instances, the writer may not even know what was written (25). Brits *et al.* (26) in 2016 set out to determine if illegible doctors' handwriting and other factors that can lead to dispensing errors occur on prescriptions at National District Hospital, Bloemfontein. It involved two parts; in part one the prescriptions of 20 doctors were read by five doctors, nurses and pharmacists to detect who could read it most accurately. In part two, these doctors were asked to write a prescription with an IntelliPen. There were 300 measurements altogether, 88% of the doctors read the prescriptions correctly, compared with 82% of the nurses and 75% of the pharmacists. A potential fatal error was lorazepam injection 4 mg, which was read as 40 mg (lethal dose) by 20% of healthcare workers (HCWs). With the IntelliPen only 39% of the prescriptions were readable. Only 65% of prescribers could be identified from their handwriting or the name stamp used. The authors (26) observed that pharmacists read the prescriptions worst and they were the people who must dispense the prescriptions. Some of the

reading mistakes were critical and could be lethal. Many of the prescriptions did not meet the legal requirement for prescriptions.

Global burden of prescription errors

Prescription errors are significant problems with medication errors (27,28). They affect patients' safety and quality of healthcare. Prescription errors occur when there is a significant unintentional reduction in the probability of treatment being timely and efficient or increase the risk of harm when compared with generally accepted practice (29).

Worldwide, it is asserted that over half of all medicines are prescribed, dispensed or sold inappropriately; and that half of all patients fail to take their medicine correctly (30). Medicines are used when patients receive the appropriate medicines, in doses that meet their requirements, for an adequate period and at the lowest cost to them. Irrational use occurs when one or more of these conditions are met (30).

The prevalence of prescription errors varies worldwide based on the reference parameters used. It accounts for an estimated 70% of medication errors that could potentially result in adverse effects (27,28). A meta-analysis published in 2009 revealed that the range of errors committed by junior doctors, responsible for most prescription errors, was between 2 to 514 per 1,000 prescriptions (31).

More recent studies have reported values ranging from 5% to 81% (32,33). In England, the estimated incidence of prescribing error is 500,000 per year (34). Most of the errors have been attributable to man-made factors such as fatigue, entering wrong patient information and selecting wrong options (7). The significant categories of prescribing errors are wrong patient entries; wrong drug; wrong dose, strength, frequency; wrong drug formulation and wrong quantity (7).

Prescription errors in Nigeria

In 2008, Akoria and Isah (10) in Benin (Nigeria) studied how far prescriptions met accepted standards and concluded that most prescriptions lacked the required details and were not legible. Similarly, Erhun and his co-authors (8) at the Obafemi Awolowo Teaching Hospital, Ile-Ife, South-western Nigeria in the following year examined the degree of deviation of prescriptions written by practitioners in two centres (the teaching hospital and the Health centre) from both the World Health Organization standard and the institution specifications and found that the prescriptions

written by the health centre complied better. The legal implication of non-compliance with the World Health Organization Standard in prescription writing was after that discussed (8). Ajemigbitse and his co-authors in 2013 (34) set out to identify and determine factors responsible for errors in drug prescribing and how to prevent the errors. Slip inattention, individual, team, environment and task factors were some of the factors identified. Junior doctors were affected by the prescription habits of the senior doctors. Other factors identified included inadequate training/experience, the absence of reference materials and absence of self-awareness of errors. Training and enforcement of good practice in prescribing were recommended (34).

In 2016, Ajemigbitse, Omole and Erhun (35) in their report of the assessment of the impact of providing feedback and educational intervention on prescribing error types and rates in routine practice concluded that interventions led to modest changes in prescription written and recommended that regular feedback and continuing prescriber education will sustain error reduction in prescription writing. Accurate medication prescription is essential to avoid errors and ensure best possible outcomes in healthcare.

Oshikoya and Colleagues (7) investigated medication errors at the Paediatric outpatient department of Lagos State University Teaching Hospital and reported various forms of errors. In that study, common errors identified include short medication dosing duration, the omission of age dosage and duration of drug use, improper dosing and prescription of drugs that could adversely interact. The authors did not compare the prescription with the standard of WHO and compare how it deviates from it. Furthermore, only prescriptions from paediatrics outpatient unit were analysed. A snapshot of a review of prescriptions from all units within the hospital will provide a more reliable result devoid of bias.

Gaps in prior research

All the above reports assessed the quality of prescriptions written at the various centres and factors responsible for errors in prescription writing including the need for continuous educational intervention to prevent dangers associated with errors in prescription writing. To the best of this researcher's knowledge and after a careful literature search, no study has assessed prescription writing among healthcare practitioners in Lagos, Nigeria and Africa against the background of standard WHO prototype and

has described the deviation from the norm. Hence the need for a regular clinical to assess the quality of prescriptions written at the various health institutions in Nigeria using the World Health Organization guide to right prescription as a standard.

Conclusions

The literature indicated that prescription errors constitute a significant problem among medication errors with different prevalence worldwide and of different forms. Auditing of prescription is a way of avoiding prescription error.

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Footnote

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