ANALYSIS OF TOXIC METALS AND HEALTH RISK ASSESSMENT OF SOME SELECTED HERBAL MEDICINAL PRODUCTS SOLD IN ILORIN METROPOLIS

BY

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CERTIFICATION

This is to certify that this project work was carried out by **BABA-AGBALA SALIMAT DA MILOLA** with Matric Number: **ND/23/SLT/PT/0028** in the Department of Science Laboratory Technology (SLT), Institute of Applied Science (IAS) Kwara State Polytechnic Ilorin

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DEDICATION

This project is dedicated Almighty God, who has seen me through it all. Also, to my lovel y parents and to my lovely brothers for their love and support, am very grateful for everyt hing.

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Abstract

The use of herbal medicines has increased in recent years and has gained much attentio n in the health sectors, scientific community and the public alike. The safety and quality of these products become questionable even when the efficacy and potency may be gua ranteed. In this study the presence of heavy metals in herbal preparations was determine d. Ten different herbal preparations were purchased from different parts of Ilorin. Sample s were prepared from these preparations and analyzed for the presence of Cadmium (C d), Iron (Fe) and Lead (Pb) using Atomic Absorption Spectrophotometer. Their concentrat ions were compared with WHO permissible limits. The concentration of heavy metals (P b, Fe, Cu, Cr and Cd) in the samples were compared with permissible limit of 10 mg/L, 0. 3 mg/L and 0.1 mg/L, 2mg/L and 40mg/L for Pb, Cd, Fe, Cr and Cu respectively. The con centration of lead in herbal samples ranged from 0.010±0.027 and 0.320±0.035mg/L, T he highest and the lowest concentrations were found in H3 and H4 samples which were used by traditional healers to treat hypertension and sexual impotency. The concentratio n of Cadmium in herbal samples ranged from 0.000±0.000 and 0.250±0.065mg/L. It is i mportant to note that seven (7) samples from the herbal preparations analyzed containe d iron in concentrations significantly (P=0.01) higher than the 0.1 mg/L permissible limit recommended by WHO. In this study, the concentration of chromium was found in the ra

nge of 0.180±0.062 and 0.860±0.027mg/L. The highest amount was reported in the H10 sample while the lowest amount was reported in the H8 sample. The concentration rang e of copper in tested samples was 0.370±0.006 and 0.010±0.013 mg/L as shown in Tabl e 1. The maximum concentration was reported in the H3 sample while the minimum am ount was reported in the H4 sample preparation. This result revealed that the concentrati on of copper in all traditional herbal products was found below the WHO permissible limi t (40 mg/L).The results obtained from this study showed that Iron was present in all the samples with some concentrations significantly higher than the WHO permissible limit. L ead, copper and cadmium were present in some of the samples with concentrations belo w the WHO permissible limit.

CHAPTER ONE

Background

The use of homeopathic and herbal medicines has increased in recent years (Chikezie et al, 2015). This has probably arisen as a result of a number of factors including; disillusio nment with conventional drugs, growing confidence in complementary medicine, and a b elief that the products are safe, often on the grounds that 'natural' equates to safe (Enuh *et al.,* 2012). Herbal medicine and traditional treatment are the main source of health car e and sometimes the only source of care for millions of people in developing countries (WHO, 2013). A survey carried out in Lagos, Nigeria also reported that majority of the res pondents use herbal medicines (WHO 2013; Oreagba *et al.,* 2011). However, the challeng

es associated with the use of these medicinal plants and herbal products obtained from them include safety and quality even when efficacy and potency are ascertained. The pr esence of heavy metals in the body can be detrimental to health particularly at concentra tions above tolerance level. Most are considered toxic to living organism due to their acc umulative tendency in tissues resulting in various disorders (Bakare-Odunola and Musta pha, 2014). It has been reported that the presence of heavy metals in either orthodox or herbal drugs often compound the original ailments for which they were administered wit h resultant increased morbidity for the patient (Topliss *et al.,* 2002). There are various so urces of contamination that renders the safety and quality of medicine questionable and notable amongst them is that from heavy metals. Contamination of traditional medicine s by heavy metals is of major concern because of the toxicity, persistence and bio-accu mulative nature of these metals (Osegbe and Amaku, 1985). Examples of heavy metals i nclude Arsenic (As), Lead (Pb), Mercury (Hg), Copper (Cu), Iron (Fe), Cadmium (Cd) and Z inc (Zn).

Three main sources have been proposed to be responsible for heavy metal contaminatio n of medicinal herbal products (Saeed *et al.,* 2010), viz; contamination during the proces s of cultivating the medicinal plant itself (Sharma and Dubey, 2005 Tong *et al.,* 2000), un intentional cross contamination during processing, (Chan, 2003) and the deliberate addi tion of heavy metals as therapeutic agents (Mohammad *et al.,* 2012; Ernst, 2002). The W HO has formulated guidelines for quality assurance and control of herbal medicine but most traditional practitioners lack this information (WHO, 2007). This sometimes results in medicinal plants and products derived from them being contaminated with various ty

pes and concentration of heavy metals. Some reported works established the fact that th ere are both heavy metal pollution of the environment and contamination of herbal prod ucts in Nigeria and the world at large (Nweke and Sanders, 2009). In a study conducted i n Nigeria to determine the cadmium (Cd) concentrations of herbal drugs used as antimal arial and that of chloroquine syrup, it was revealed that Cadmium was detected in 100 % of the herbal products and 75 % of the chloroquine syrups (Mohammad *et al.,* 2012). Th e concentration of Cd in all the herbal products exceeded the WHO limit, while the conce ntration in all the chloroquine syrups were within the British Pharmacopeia (BP) 2002 lim it. Another study reported the concentration of Fe ranged from 65.68-1652.89 µg/g in dif ferent products of herbal medicine purchased from various places in Karachi city of Paki stan (Tong *et al.,* 2000). A lot of cases of poisoning from heavy metal such as cadmiu m, lead, iron, mercury and manganese remain underreported while some are undocumen ted due to poor record keeping in the developing nations (Sharma and Dubey, 2005). The refore, the need for more studies investigating the safety and quality of the herbal produ cts becomes imperative.

This research focused on various herbal bitters acclaimed to be used for a variety of hea lth conditions within Ilorin Metropolis of Nigeria. The safety and quality of different man ufacturing batches of herbal preparations, in terms of their level of contamination by hea vy metals were ascertained. The heavy metals selected for this study include four biologi cally non-essential elements: Lead (Pb), Cadmium (Cd), Copper (Cu), Chromium (Cr) and one biologically essential element: Iron (Fe) which are some of the heavy metals implicat ed to be toxic in human.

1.2 Statement of the problem

The use of herbal medicines has increased in recent years and has gained much attentio n in the health sectors, scientific community and the public alike. The safety and quality of these products become questionable even when the efficacy and potency may be gua ranteed.

1.3 Aims and Objectives of the study

The aim of the study is to determine the presence of heavy metals in herbal preparation obtained from hawkers within Ilorin metropolis.

The specific objectives are

1. To determine the presence of lead, iron, copper, cadmium, and chromium in he rbal preparation consume within Ilorin metropolis.
2. To compare the concentration of the heavy metals present in the preparation c onsume within Ilorin metropolis with WHO permissible concentration.

1.4 Research Questions

1. Does heavy metals present in herbal preparation?
2. What are the regulatory standard requirements of the heavy metals concentrat ion?
3. Is herbal preparation contaminated?

1.5 Significance of the Study

The presence of heavy metals in the body can be detrimental to health particularly at co ncentrations above tolerance level. Most are considered toxic to living organism due to t heir accumulative tendency in tissues resulting in various disorders (Bakare-Odunola and Mustapha, 2014). It has been reported that the presence of heavy metals in either orthod ox or herbal drugs often compound the original ailments for which they were administere d with resultant increased morbidity for the patient (Topliss *et al.,* 2002). There are variou s sources of contamination that renders the safety and quality of medicine questionable and notable amongst them is that from heavy metals.

1.6 Scope of the study

This research focused on various herbal preparations acclaimed to be used for a variety of health conditions within Ilorin Metropolis of Nigeria. The safety and quality of differen t herbal preparations, in terms of their level of contamination by heavy metals were ascer tained. The heavy metals selected for this study include four biologically non-essential el ements: Lead (Pb), Cadmium (Cd), Copper (Cu), Chromium (Cr) and one biologically esse ntial element: Iron (Fe) which are some of the heavy metals implicated to be toxic in hum an.

1.7 Operational Definition of Terms

Herbal medicine: this is the use of plants to treat disease and enhance general health an d wellbeing. Herbs can interact with other pharmaceutical medications and should be ta

ken with care.

Herbal preparations: Preparations obtained by subjecting herbal substances to treatme nts such as extraction, distillation, expression, fractionation, purification, concentration o r fermentation. These include comminuted or powdered herbal substances, tinctures, extr acts, essential oils, expressed juices and processed exudates.

Heavy metals: refers to any metallic chemical element that has a relatively high density and is toxic or poisonous at low concentrations. Examples of heavy metals include merc ury (Hg), cadmium (Cd), arsenic (As), chromium (Cr), thallium (Tl), and lead (Pb).

Quality control is a term used to describe all measures designed to ensure the output of uniform batches of drugs that conform to established specifications of identity, strength, purity, and other characteristics.

Quality assurance: is a wide range of concept that individually or collectively influences the quality of a product. It also includes sum of the organized arrangement with the obje ctive that medicinal products are of required quality for their intended use. It is a totality of arrangement deliberately designed and intended to ensure that products will be consis tent with the quality appropriated for their use.

Good Manufacturing Practice: commonly referred to as GMP, is the part of quality assur ance, which ensures that products are consistently produced and controlled to the qualit y standards appropriate to their intended use as required by the marketing authorization.

Tablet: A solid unit dosage form of medication with suitable excipientspowder

Active pharmaceutical ingredients (APIs): are the active components in a pharmaceutic

al drug that produce the required effect on the body to treat a condition. APIs are produc ed by processing chemical compounds. In a biologic drug, the active ingredient is known as a bulk process intermediate (BPI).

CHAPTER TWO

Introduction

Traditional or folk medicine comprises practices, approaches, knowledge and beliefs not

based on scientific evidence that are applied to treat, diagnose and prevent illness within a society. It is defined by a culture's knowledge and values and thus is context-specific, a s are social constructions and negotiations of risk. When modern societies adopt such lo ng-standing health practices outside of their traditional context, these practices become "complementary, non-conventional or alternative medicine" (Crellin, 2001). The extent to which the traditional use of an herb ensures that a corresponding herbal drug is safe, ho wever, is a debachart matter. A new draft regulation published by the Brazilian National Health Surveillance Agency (Anvisa) brought this controversial topic to the center stage. The proposed regulation, which has recently undergone a public consultation for reviews and comments, defines two categories of herbal drugs for registration: "phytotherapeutic medicines" and "traditional phytotherapeutic products" (TPTP) (Anvisa, 2013). A product fits into the latter category if a long-standing (traditional) use is identified that has not b een proven unsafe and is recognized in the literature or demonstrated by ethnopharmaco logical and/or ethno-botanical studies. Once the traditional use is recognized, safety and efficacy data from pre-clinical and/or clinical studies are no longer essential requirement s to obtain approval for commercialization.

The proposed new rules for herbal medicine registration in Brazil are, to some extent, sim ilar to the regulation released by the European Parliament in 2004. According to EC Direc tive 2004/24, herbal medicines with traditional use that are acceptably safe, albeit not h aving a recognized level of efficacy, can be classified as "traditional herbal medicines pr oducts" (THMP), as detailed by Calapai (2008), Quintus and Schweim (2012) and Silano et al. (2004). In order for a medicinal product,or its corresponding products (*i.e.*, products

having the same active ingredients, the same or similar intended purpose, equivalent stre ngth and posology and the same or similar route of administration), to be classified as T HMP, it must have been in medicinal use for a period of at least 30 years, of which more t han 15 years must relate to the European Union. Herbal drugs in the THMP category und ergo a simplified registration procedure. Aspiring herbal products are required to demons trate the traditional use of the herb, but this requirement is lifted if the product complies with the European positive list established by the Committee on Herbal Medicinal Produc ts (HPMC) (Knöss and Chinou, 2012). Herbal monographs prepared by HPMC are not bin ding, and member state agencies may not agree with every single aspect of the monogra ph. For instance, applicants that refer to a HPMC monograph may be required to provide additional points on safety (*e.g.*, on genotoxicity).Drug safety and efficacy In reference t o medications, safety is the likelihood of not causing harm under the proposed condition s of use, while efficacy is the capacity to induce a clinical benefit. Both safety and effica cy depend on the drug's therapeutic indication; in principle, a substance has no clinical u sefulness if it is "safe" but lacks efficacy or if it is active on a relevant therapeutic target but its use is unsafe (Bian *et al.,* 2006). Although these are recognized as equally essent ial attributes of any medicine, safety has taken precedence over proof of efficacy in drug regulation history.

In the US, for instance, the Federal Food Drug and Cosmetic Act of 1938 required that saf ety of new drugs had to be proven by pre-marketing testing, whereas similar requirement s to demonstrate drug efficacy were introduced only 25 years later by the Kefauver-Harri

s Amendments of 1962. The idea that safety should come first in therapeutic interventio ns is conveyed by the famous Latin expression "*primum non nocere*" ("first, not do har m"), the origin of which is uncertain (Smith, 2005). Similarly, the classical version of the Hippocratic Oath that physicians take upon entering medical practice contains a promis e that expresses a similar idea (doctors are required to "keep [patients] from harm").

Tradition and safety of herbal medicines

Many supporters of herbal medicines argue that products with a long history of popular use are generally safe when used properly at common therapeutic doses (Fong, 2002). A crucial question underlying this statement is the extent to which the absence of evidence of toxicity could be taken as evidence of the absence of toxicity or safety of herbal medi cines. Whether the absence of records of adverse effects is an indication of lack of toxici ty depends on the type of toxic effect and the likelihood of observing such an adverse ou tcome under the conditions prevailing in the traditional usage (Hao *et al.,* 2013). Acute sy mptoms and short term toxic effects, such as gastro-intestinal disturbances and dermat ological effects, are likely to be recognized and associated to herbal medicine. Therefore, the absence of such observations provides some evidence of safety in these particular e ndpoints. Long-term adverse outcomes, such as cancer, liver and kidney damage, reprod uctive dysfunctions, birth defects and several morbidities that are more difficult to detec t, however, are unlikely to be associated with the popular use of a medicine, unless an ad equately designed epidemiology study (preferably, a prospective cohort study) is underta ken (Halicioglu *et al.,* 2011). Thus, the absence of evidence of these adverse effects withi

n the context of traditional usage of herbal medicines is not evidence of the absence of potential to cause them. As far as drugs are concerned, safety is assumed only when the null hypothesis (absence of toxicity) has not been disproved after being challenged by pr operly designed and comprehensive set of pre-clinical and clinical studies, that had enou gh statistical power to reject it if it were false (Gurley *et al.,* 2005).

Carcinogenic effects of traditional herbal medicines

During R&D of conventional drugs, carcinogenic potential is assessed through a battery of *in vitro* and *in vivo* short-term genotoxicity tests, and long-term rodent carcinogenicity assays. Carcinogenicity tests in rats and mice are the longest and most costly non-clinic al safety studies commonly required for a new drug marketing approval. A waiver of lon g-term carcinogenicity studies for marketing approval can be obtained if results of short- term genotoxicity tests are negative and the drug is intended to be used continuously for less than three months, or intermittently for less than six months. Long-term carcinogeni city studies have seldom been performed with herbal products, and the data of their gen otoxic potential are scant as well (Teschke, 2010). Owing to their limited duration, clinica l trials do not shed light on the carcinogenic potential of drugs. In principle, evidence on t he carcinogenicity of traditional herbal medicines could be obtained from observational epidemiological studies. Nonetheless, epidemiological studies have rarely been undertak en to address this question.

Liver toxicity associated with herbal medicines Severity of drug-induced liver toxicity (DIL I) ranges from mild dysfunction leading to raised serum levels of alanine aminotransfera

se (ALT) unaccompanied by increases in bilirubin levels and clinical symptoms reversible upon treatment discontinuation, to jaundice and overt hepatic failure that could culminate in liver transplantation or death. DILI can be broadly divided into two types: liver toxicity that depends on the dose and can be predicted by pre-clinical and clinical studies; and idiosyncratic DILI that is a rare, but severe form of liver damage that occurs only in susceptible individuals (presumably involving immuno-allergic mechanisms) and cannot be predicted by pre-marketing safety studies. Similar to conventional drugs, herbal medicines are capable of causing both predicchart and idiosyncratic DILI (Teschke *et al.,* 2012).

It should be noted that the degree of evidence for establishing a causal link between intake of a medicinal herb and liver impairment is variable, as it is for conventional drugs. In addition to the difficulties and limitations of pharmacovigilance, the vigilance related to herbal products faces additional problems, such as: self-medication, products that contain a diverse number of different plants, use in combination with classical pharmaceutical agents, the widespread belief that natural products are intrinsically safe so that patients often forget to disclose this information to their physicians, and poor quality issues, including misidentification of the plants, selection of the wrong part of the plant, adulteration, mislabeling, inadequate storage conditions, and contamination by fungi, pesticides, metals and other potential toxins (Larrey and Faure, 2011; Shaw *et al.,* 2012). The fact that several hepatotoxic plants and their constituents have a long-standing use in folk medicine is also consistent with the notion that traditional use on its own does not guarantee the safety of a phytopharmaceutical.

Kinetic interactions of herbal medicines with conventional medicines

Herbal medicines are often used concomitantly with conventional drugs, making potenti al pharmacokinetic interactions a cause for concern. Herbal drug co-administration with medicines of narrow therapeutic indices (*e.g.*, digoxin, warfarin) raises even deeper safet y concerns (Silano *et al.,* 2004). Common herbal medicines known to interact with conve ntional drugs include St. John's wort (*Hypericum perforatum* L.), ginkgo (*Ginkgo biloba* L.), ginger (*Zingiber officinale* Rosc.), ginseng (*Panax ginseng* C.A. Meyer) and garlic (*Alli um sativum* L.). St. John's wort, an herbal antidepressant, is possibly the most notorious example. It is a potent inhibitor of CYP3A4, and when co-administered with drugs metab olized by this enzyme, it decreases their clearance and increases their plasma concentrat ions (AUC). Because St. John's wort also induces the expression of CYP3A4 and the tran smembrane transporter protein PgP (P-glycoprotein) in the liver and intestines, previous and repeated administrations have opposite effects; enhancement of clearance and decr ease in AUC. The kinetic and clinical effects of a number of drugs that are substrates for CYP3A4 are altered by St. John's wort, and these drugs include cyclosporine, midazolam, oxycodone, methadone, imatinib, finasteride, bupropion, tracolimus, digoxin, atorvastin, and verapamil, among others (Leach and Moore, 2012).

Factors Responsible for Increased Patronage and Self Medication with Herbal Medicin e

Essentially, herbal remedies consist of portions of plants or unpurified plant extracts con taining several constituents which are often generally believed to work together synergist

ically. The recent resurgence of public interest in herbal remedies has been attributed to s everal factors some of which include (i) various claims on the efficacy or effectiveness o f plant medicines, (ii) preference of consumers for natural therapies and a greater interes t in alternative medicines, (iii) erroneous belief that herbal products are superior to manu factured products, (iv) dissatisfaction with the results from orthodox pharmaceuticals an d the belief that herbal medicines might be effective in the treatment of certain diseases where conventional therapies and medicines have proven to be ineffective or inadequate, (v) high cost and side effects of most modern drugs, (vi) improvements in the quality, eff icacy, and safety of herbal medicines with the development of science and technology, (v ii) patients' belief that their physicians have not properly identified the problem; hence th e feeling that herbal remedies are another option, and (viii) a movement toward self-medi cation (Bandaranayake, 2006).

The increasing utilization of herbs for self-medication by patients or individuals is also a ttributed to a number of other reasons such as (i) patients being uncomfortable about di scussing their medical problems and fear lack of confidentiality in handling their health i nformation, (ii) fear of possible misdiagnosis and wrong treatment by patients with non-specific symptoms or general malaise, and (iii) lack of time to see a physician; this is us ually a reason where prior visit did not yield any positive experience (Studdert *et al.,* 199 8). Furthermore, patients' freedom of choice of a practitioner is also encouraging their uti lization of alternative treatments and herbal remedies, although many select herbal medi cines from a deductive approach based on anecdotal information, that is, "it worked for my friend or relative" (Parle and Bansal, 2006). So also, because of the influence of religi

on and greater level of spiritual consciousness, many individuals tend to be increasingly disposed to accepting therapeutic value of a treatment based on faith or intuition rather than scientific reasoning (Astin, 1998; Zeil, 1999). Herbal medicines, therefore, become particularly alluring when the body's natural capacity for self-repair, given appropriate conditions, is emphasized (Parle and Bansal, 2006).

Influence of Regulatory Policies on Safety of Herbal Medicines

It has been observed that most of the problems associated with the use of traditional and herbal medicines arise mainly from the classification of many of these products as foods or dietary supplements in some countries. As such, evidence of quality, efficacy, and safety of these herbal medicines is not required before marketing. In the same vein, quality tests and production standards tend to be less rigorous or controlled and in some cases, traditional health practitioners may not be certified or licensed. The safety of traditional and herbal medicines has therefore become a major concern to both national health authorities and the general public (Kasilo and Trapsida, 2011).

Until 2011, there were three possible regulatory routes by which an herbal product could reach a consumer in the UK. The unlicensed herbal remedy is the commonest route which does not have to meet specific standards of safety and quality neither is it required to be accompanied by safety information for the consumer (Raynor *et al.,* 2011). Recently, the European Union (EU) implemented a directive after a 7-year transition period to harmonize the regulation of traditional herbal medicine products across the EU and establish a simplified licensing system in order to help the public make informed choices about the us

e of herbal products. This requires that all manufactured herbal products either gain a pr oduct license of the type needed to manufacture "conventional" products or become regi stered as a "traditional herbal medicinal product" (Routledge, 2008; Raynor *et al.,* 2011).

Toxicity and Adverse Health Effects of Some Common Herbal Medicines

In most countries, herbal medicines and related products are introduced into the market without any mandatory safety or toxicological evaluation. Many of these countries also l ack effective machinery to regulate manufacturing practices and quality standards. The se herbal products are continuously made available to consumers without prescription in most cases and the potential hazards in an inferior product are hardly recognized (Band aranayake, 2006). The general perception that herbal remedies or drugs are very safe an d devoid of adverse effects is not only untrue, but also misleading. Herbs have been sho wn to be capable of producing a wide range of undesirable or adverse reactions some of which are capable of causing serious injuries, life-threatening conditions, and even deat h. Numerous and irrefutable cases of poisoning have been reported in the literature (Van herweghem and Degaute, 1998; Cosyns *et al.,* 1999; Ernst, 2002). The toxicity evaluation of the polyherbal formula, Yoyo "Cleanser" Bitters®, conducted recently in our laboratory (Ekor *et al.,* 2010), was prompted by an unpublished case report of a young male adult w ho had been on self-medication with this herbal product and was subsequently admitted to the hospital on account of liver failure. Yoyo "Cleanser" Bitters® is one of the herbal re medies that is widely advertised in the various Nigerian media and as such has gained s o much public acceptance over time and continues to enjoy increased patronage among