



Quality Control and Standards of Medicinal Products: A Committed Agenda

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Authors' contributions

This work was carried out in collaboration among all authors. Author RMG conceptualised and wrote the protocol and the first draft of the manuscript. Authors CMM, JYY and LPS revised the manuscript critically and offered the final approval of the version to be published. All authors read and approved of the final manuscript.

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ABSTRACT

The use of medicinal products of various categories is burgeoning geometrically in the global landscape over the past few decades. Although Africa and Asia culturally remain the home for complementary and alternative medicines (CAM), the north with the most sophisticated allopathic medical system is making headway in CAM use. Whilst herbal medicine is generally considered "safe" because it is natural and neutral, copious evidence suggests that herbal medicine could be lethal if not used rationally. Education and training of practitioners, scientific validation, legislative regulation of herbal medicine use and open patient-practitioner communication remain the crux of the safety, quality and standardisation of medicinal products.

Keywords: Africa; allopathic medicine; herbal pharmaceuticals; indigenous knowledge; medical geography; medicinal products; over-the-counter pharmaceuticals.

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1. OPINION

The rising interest and demand globally for medicinal products, herbal health products, herbal pharmaceuticals, nutraceuticals, food supplements and herbal cosmetics over the past few decades have been documented in medical and health care literature. This is as a result of the growing recognition of these products as mainly non-toxic and having fewer side effects [1-3]. Research carried out for the UK medicines regulator, the Medicines and Health care products Regulatory Agency (MHRA), concluded that many people perceive herbal products as safe because they are natural and neutral. Indeed, anything 'natural' appears normal and safe in the eyes of the society. In Ghana, Mensah and Gyasi [4] in a study of use of herbal medicine in the management of malaria in the urban-periphery confirmed the safety of herbal medicine. This hypothesis was further validated by Willcox et al. [5] in a study conducted at the village of Missidoukou, in the Sikasso Region, Mali on *Argemone mexicana* decoction for the treatment of uncomplicated falciparum malaria amongst 80 under five years. It was observed that mild cough and diarrhoea were the commonest 'adverse events' and did not deterred patient from treatment.

Despite these arguments and the widespread demand globally, phytomedicines are not completely harmless [6]. The proliferation of herbal medicines and the treatment of plethora of diseases by a single medical preparation have created erroneous impressions in the minds of many [7]. The concept of "cure all" is employed by many traditional healers and is rooted from the vacuum between the healers and biomedical practitioners. Adewunmi and Ojewole [8] however associate this to low level of technology and acknowledgement in the practice of traditional medical profession. A number of herbal and other medicinal products are thought to be likely to cause advent events. Adulteration, inappropriate formulation, and / or lack of understanding of plant and drug interactions have led to advent reactions that are sometimes life threatening. Vickers [9] proposed that proper double-blind clinical trials are needed to determine the safety and efficacy of each plant before they are recommended for ethnopharmacological and medicinal use.

Researchers in various studies have amply shown concerns about the efficacy and safety of herbal medicines [10,11]. A number of reports

have revealed examples of incorrect use of medicinal products, including incidence of overdose, unknowing use of suspect or counterfeit herbal medicines and unintentional injuries caused by 'quack' practitioners. Herbal medicines and prescribed drugs may interact, causing toxicity to the patients. Salia [12] argues that traditional remedies can dangerously be contaminated. Herbal medicines without established efficacy may be used to replace medicines that do have corroborated efficacy. Plants have chemical defence mechanisms against predators that can be lethal to humanity. Examples of highly toxic herbs include poison hemlock and nightshade that are sourced variously in treating numerous ailments, viz. malaria. Hodges and Kam [13] observed that surgical intervention may pose pre-operative implications on patients.

Various studies are available on the safety of herbs on pregnancy. For example, Boivin and Schmidt [14] found that use of CAM is associated with a 30% lower ongoing pregnancy and life birth rate during fertility treatment. Herbal medicine use in obstetrics may adversely affect the course and outcome of pregnancy. In Ghana, a study of herbal medicine use by patients in a tertiary obstetrics and gynaecology unit of Komfo Anokye Teaching Hospital, Addo [11] confirmed that herbal medicine contributes to poor pregnancy outcome such as abortions, intrauterine growth restriction, pattern delivery and low birth weight. In consultation with physicians, usage of herbal remedies should be clarified, as some herbal preparations and remedies have the potential to cause adverse drug interactions when used in combination with various prescription and over-the-counter pharmaceuticals. Likewise, patients should inform herbalists of their consumption of orthodox prescription and other medication [15]. Against all odds, prioritising patient-healer/physician communication is therefore exigent to maintain the quality of life and wellbeing of the unsuspecting patient.

In the past few decades, there has been a new interest in the use of traditional treatments for a wide range of diseases that affect urban populations, including hypertension, diabetes, malaria, cancer and on top of these, HIV/AIDS [16]. Industrialised countries have set up research programmes to study the use of herbal medicines in treating some of these conditions. Examples include the National Centre for Complementary and Alternative Medicine

(NCCAM), now the National Center for Complementary and Integrative Health (NCCIH), established by the US government agency, and the network of the World Health Organisation (WHO) collaborating centres set up in different countries. This agency investigates CAM healing practices in the context of rigorous scientific methodology, in training CAM researchers and in disseminating authoritative information to the public and professionals. Alongside this growing interest, there have been critical concerns over the quality of medicinal products. This is largely because the increasing global demand for these products has led to large-scale manufacturing of herbal medicines. The problems associated with the logistics of large-scale production, economics and distribution have prompted policymakers to support initiatives for the development of modern standards for evaluating the quality, safety and efficacy of these medicines [17]. The challenge is to develop modern international standards for medicines and practices that have originated in varied cultural settings within parameters that can be universally understood. Altogether, concerted efforts should be marshaled to uphold the basic standards and quality control parameters according to the WHO such as quality control of crude drugs material, plant preparations and finished products; stability assessment and shelf life; safety assessment – documentation of safety based on experience or toxicological studies and the assessment of efficacy by ethnomedicinal information and biological activity evaluations.

2. CONCLUSION

The safety, efficacy and quality of medicinal products continue to vex medical geography and medical society since worldwide quality control and proper regulatory subtleties continue to remain a challenge. Regulation and legislation of herbal medicines particularly in Africa and some parts of Asia is limited despite various efforts made by regulatory authorities at different levels in different countries in developing guideline principles. Further and future advancement of CAM rest on scientific validation and technological standardisation of CAM. Education and training of those involved in the sickness episode, including traditional healers and their practices, physicians, patients and members of the community to understand and appreciate the fact that complementary and alternative health care leaves nothing to be desired when rationally applied. Understanding indigenous knowledge and practices is the forward march regarding

safety and efficacy of traditional medical therapy. Stakeholders and policymakers vis-à-vis the implementers are urged to practicalise the full incorporation of traditional systems of medicine into the mainstream health care delivery system with particular reference to the sub-Saharan African region.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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