

Full Length Research Paper

Herbal medicine development and compliance to regulatory guidelines in Imo State Nigeria

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Herbal medicine is an important age-long resource for healthcare. The aim of this study was to determine the development of herbal medicine in relation to compliance to regulatory guidelines and product development in pursuance of the integration of herbal medicine into the healthcare system in Nigeria. Using Imo State as a case study, a cross-sectional investigation was conducted among the Traditional Medicine Practitioners (TMPs) using questionnaires. One Hundred TMPs were administered with questionnaires to determine relevant demographic details, information relating to regulatory guidelines and the quality of finished products. Ninety-eight of the questionnaires were returned completed. Of these, 72% of the TMPs were male. The dominant age of the TMPs was between 25 to 65 years. Over 80% of the TMPs were literate having a minimum of secondary school education. About 86% of the TMPs are herbal medicine practitioners. All the TMPs claimed knowledge of the existence of National Agency for Food and Drug Administration and Control (NAFDAC) as the regulatory authority for herbal medicine. Only 5% had any contact with the agency in relation to product registration, while only 1% of the products owned by the TMPs had NAFDAC registration number. Also, 97% of the TMPs produced only extemporaneous products for their patients, and only 6% have any knowledge on the formulation of some conventional dosage forms. Of the 300 herbal medicines owned by the TMPs, only 8% were presented in conventional dosage forms with appropriate packaging. The few number of herbal medicines registered with NAFDAC reflects the low level of development of herbal medicine in Nigeria. This makes the products unsafe for integration into the healthcare system at the present stage.

Key words: Traditional medicine practitioners, herbal medicine development, regulation.

INTRODUCTION

Herbal medicine (HM) is the mainstay of most traditional medicine practices of many cultures. It is also an age-

long resource for healthcare (Builders, 2019). Sometime in history HM was the only available source of therapy,

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also in recent times despite the availability and easy access to modern healthcare HM still hold a relevant position in the healthcare of people all over the world (Zamiska, 2006). In some countries herbal medicine has been integrated into the healthcare system and is used widely in therapy (Zhang et al., 2011). In Nigeria particularly, a high percentage of the population especially in remote, rural and peri-urban areas depend highly on HM for their healthcare (Oreagba et al., 2011). Despite the widespread use, inherent benefits and vast flora of medicinal plants, HM in Nigeria remain grossly underdeveloped in terms of the availability of quality finished herbal products that is adequately standardized, formulated into conventional dosage forms and duly registered. Some of the visible underlying factors that may be responsible for this under development are many and varied and may include lack of adequate information by the TMPs regarding documentation, formulation and standardization as well as scientific proof of claims, clinical trials and poor enforcement of regulatory guidelines (Abdullahi, 2011; Awodele et al., 2014). The development and regulation of herbal medicines will assure the quality of all available finished products (WHO, 2019). In countries like China and Thailand which have similar high biodiversity and a strong culture of traditional medicine as Nigeria, HM is well developed and totally integrated into their national healthcare systems (Yao et al., 2020). The integration of HM into Nigeria's healthcare system will broaden access and the availability of alternative healthcare as well as offer several economic benefits considering the nation's huge medicinal bio-flora. Despite the increasing popularity and use of HM in Nigeria, the products remain underdeveloped in terms of quality of products and compliance to regulatory guidelines. The circulation and use of such unverified herbal products is particularly dangerous and synonymous to the use of poor quality conventional medicines with similar concomitant adverse consequences. The possible development and integration of HM into the healthcare system will depend on the drive of the major stakeholder who essentially are the TMPs as far as HM practices and products are concerned. An important precursor to the integration of HM into the healthcare system is the availability of quality as well as well-regulated finished herbal products with proven safety, efficacy, stability and elegance. The aim of this study is to determine the extent of awareness of the TMPs in matters pertaining to the development of HM in Nigeria as a precursor to pursuance of HM integration into the primary healthcare system.

MATERIALS AND METHODS

One hundred copies of appropriately tailored questionnaire, consisting of two sections: A and B. Section A comprised the demographic information of the respondents depicting their gender, age, years of practice experience, education status and diseases

area of expertise. Sections B consists of questions that assess the respondents' knowledge of regulatory guidelines, dosage form and standardization of herbal medicines.

A cross-sectional study was conducted with the aim of determining the level of awareness of the TMPs in matters pertaining to the development of HM and challenges militating against the development of HM in Nigeria using Imo State as the case study. To do this questionnaire were administered to 100 TMPs from the various local government areas of Imo State. The questionnaire was designed to determine the demographic details of the TMPs, such as sex, age, type of practice, disease specialization, length of practice, type of product (extemporaneous or commercial), dosage form, knowledge of the activities of NAFDAC and the registration status of their products as well as the TMPs' perception of the likely factors militating against herbal medicine development in Nigeria using the registration with NAFDAC as a yard stick.

Statistical evaluation

Data were analyzed quantitatively using the SPSS software, results were presented as frequency and percentages.

RESULTS

Demographic details of TMPs

A total of 98 of the 100 questionnaire distributed to the TMPs were returned completed. The characteristic gender, age, education status, alternative occupation of the TMPs is presented in Table 1. Cumulatively, the majority of the TMPs were male. The broad age range of the TMPs was between 25 to 65 years and this corresponded to 89.6% of the population. The narrower age range of 25 to 45 years constituted 47% and > 45 to 65 years constituted 40%. The age range of < 25 years and > 65 years were in the minority, constituting only 4 and 1%, respectively of the entire population of the TMPs.

The education status of the TMPs is presented in Figure 1. Majority of the TMPs in Imo State as represented in this study are literate as over 73% have completed either secondary school or tertiary education. Only a few of the TMPs had no formal education. The practice characteristics of the TMPs as presented in Table 1 showed that a majority of the TMPs practice traditional herbal medicine only while others were engaged in other types of traditional medicine practices such as bone setting, traditional midwifery, divination and other combinations, these also agreed to use herbs sometimes as part of their practice. Also, apart from practicing traditional medicine, some of the TMPs were engaged in other activities as alternate sources of livelihood. Only a quarter of the population practiced traditional herbal medicine alone, while the larger number of the TMPs was also businessmen and civil servants.

Herbal recipes, products and disease specialization

All the TMPs indicated expertise and specialization on

Table 1. Some critical demographic and regulatory information.

Variable	Frequency (%)
Gender	
Male	72
Female	28
Age (Yrs)	
<25	3.1
25-45	47.9
45-65	41.7
>65	6.3
Complimentary occupations	
Business	66
Herbal medicine practice	10.1
Private organisations	8.3
Others (occupation not listed)	6.3
Duration of practice (years)	
10-May	27.8
20-Nov	30
21-30	30
>31	21.2
Type of practice	
Herbal medicine	76.6
Bone setting	12.5
Spiritual divination	2.4
Traditional midwife	6.9
Other combinations	1.5
Regulatory compliance	
TMP with knowledge of the existence of NAFDAC	100
TMP with no knowledge of the existence of NAFDAC	0
Products registered by NAFDAC	1
Products not registered by NAFDAC	99

certain disease type. The disease type of specialization by the TMPs is presented in Figure 2. Each of the TMPs treated more than one disease condition. Cumulatively, over half the population of the TMPs had recipes for treating sexually transmitted diseases and malaria, respectively while over 30% had recipes for treating diabetes, stomach ulcer, arthritis, cold and catarrh, cough, tooth ache and about 4% indicated to have remedies for treating stroke and hemorrhoids.

All the TMPs produce at least two herbal products each and claimed ownership of 300 products. Most of the TMPs produced extemporaneous products which are

prepared for treating their patients. Generally, over 65% of the herbal medicines produced by the TMPs are liquid mixtures of decoctions, 20% are powders and 5% are shredded plant materials to be prepared as will be directed by the TMP. Only about 7 and 3% of the products are presented as conventional dosage form as cream/ointment and capsules, respectively.

In respect of knowledge for preparing herbal materials into conventional dosage form only 6% responded to having knowledge on the formulation of conventional dosage such ointment, cream and capsules. None of the products were formulated as tablet.

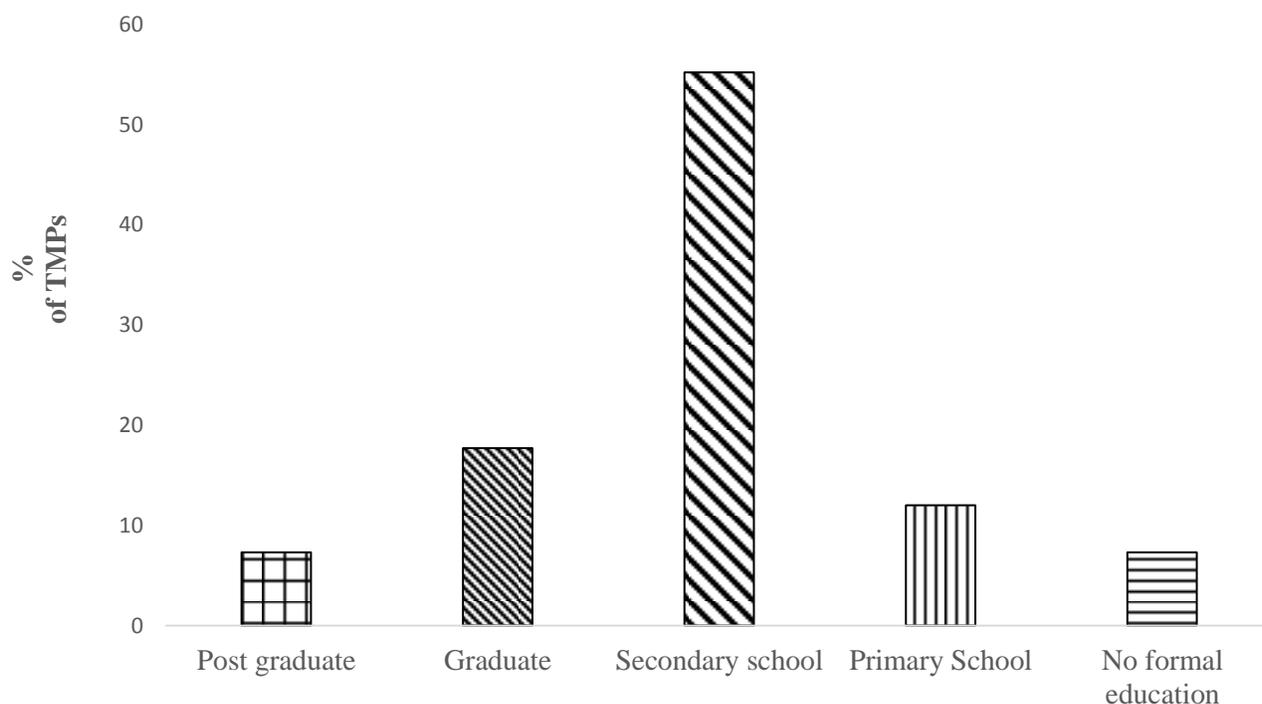


Figure 1. Education status of the TMPs in Imo State.

Regulatory and products registration issues

Some response of the respondent TMPs to questions on registration of products and regulatory matters are presented in Table 1. All the respondents claimed knowledge of the existence of NAFDAC in Nigeria. A number corresponding to 79.6% had the understanding that NAFDAC is responsible for the control of production, importation and distribution of herbal medicine in Nigeria while 20% did not know the functions of NAFDAC with respect to herbal medicine regulation. A number corresponding to 80% of the respondents understood that commercialization of herbal medicines needed to pass through the registration processes set by NAFDAC and 20% claimed to have approached NAFDAC for the registration of their products. Only 2 (0.02%) of the respondents had registered their products with NAFDAC and of the 300 products that were claimed to be produced, only 3 products (1%) were listed with NAFDAC. The listed products were all tested for efficacy, toxicity, heavy metals contents among other tests. All the respondent would wish that their products to be tested and be registered with NAFDAC. A majority of the TMPs corresponding to 64% prepared mainly extemporaneous products for their patients. Only 18% of the products were packaged, the others presented their products in makeshift containers such as used bottled water and soft drink containers. Also most of the packaged products

were of inferior quality based on the labelling and packaging requirement of NAFDAC. The majority of the respondents have never conducted any quality test on their products as only 12% agreed to have conducted some sort of quality tests on their products. The tests that had been carried out are: toxicity and microbial. Only 1% of the products corresponding to the number of the listed products had efficacy, toxicity, heavy metals studies carried out on them.

DISCUSSION

Demographic details of TMPs

The survey showed that there were higher number of men in the practice of TM in Imo State this result may be extrapolated to the general population characteristic in the country, this corroborates the result of a much wider study carried out by the Nigerian's Federal Ministry of Health in conjunction with World Health Organisation and similar surveys carried out in other African countries as well as in China and India with strong TM standing (Lambert et al., 2011; MHN-WHO, 2007). This may be attributed to the commonly used phrase Medicine man denoting traditional medicine as a profession initially practiced by the male folks (Tsai et al., 2008; Hariramamurthi et al., 2007). However, there are cultural

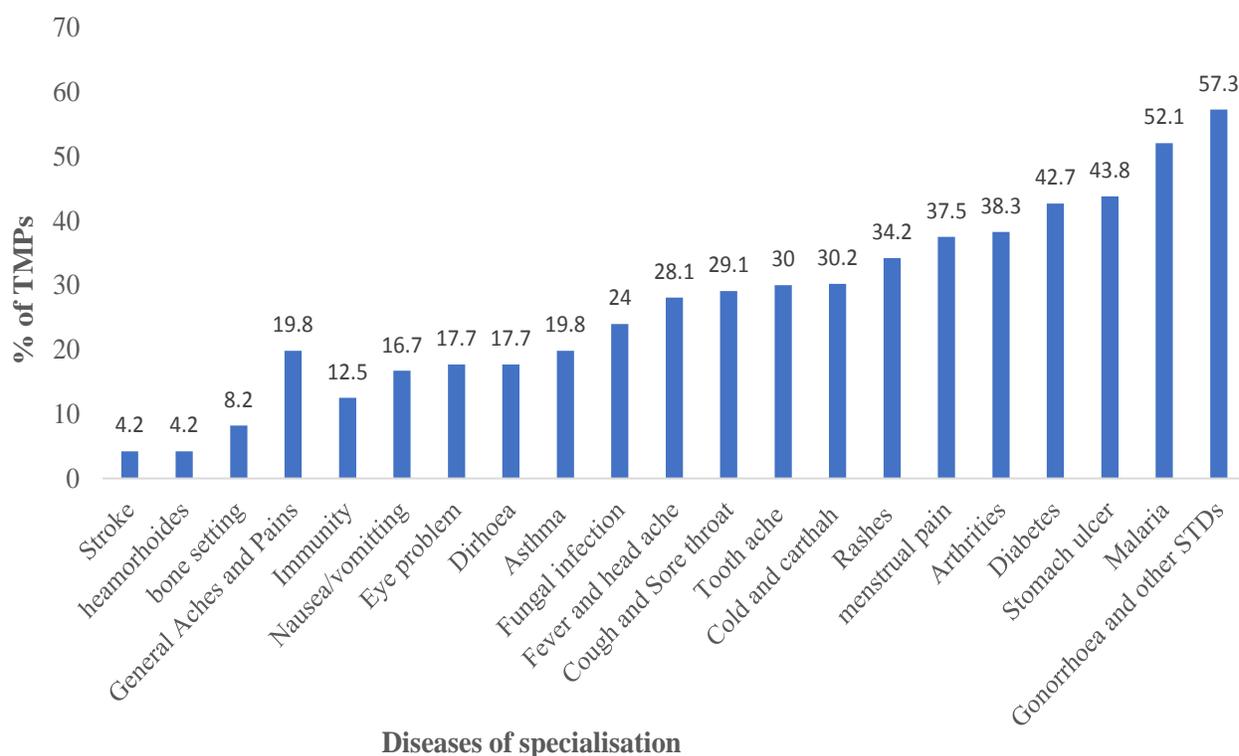


Figure 2. Profile of Herbal medicine practitioner's in Imo State diseases areas of specialisation.

variations as there are some societies where TM practice is dominated by women (Lambert et al., 2011). There are some areas of traditional healthcare that are mainly dominated by female and these include pediatric care, traditional midwifery or birth attendant and female circumcision experts (Habtom, 2008). Perhaps the current sustained lower number of females as TMPs in Nigeria may be due to the wider access and advocacy to patronize the established primary healthcare centers with the practice of conventional medicine especially in obstetrics and pediatric issues, resulting in downward trend in the requirement of services of the female TMPs. Whereas other areas of traditional medicine practice largely dominated by men especially traditional herbal medicine are increasingly gaining popularity. Hence, the dominance of the male folk in traditional herbal medicine practice may continue as the use of herbal medicine for treating various diseases is increasingly being promoted worldwide (Werner, 1980). Notwithstanding the higher ratio of men to women in the practice of traditional herbal medicine a significant number of women are also active practitioners and gender does not affect their contribution to the practice as there is no bias to the disease type they treat. Both the male and female TMPs treat both communicable and non-communicable diseases. Hence, TM is practiced by both men and women.

Table 1 shows that the age range of the TMPs is spread

within all the active adult age range. This is indeed, contrary to the generally held notion that herbalists are old people, hence the expectation that the dominant age group of the TMPs should likely be > 65 years but that was not the finding in this study (Table 1). It may be that the TMPs retire early and leave the job for their children and younger folks or that the age group (> 65 years) were not able to join the study as this survey was carried out during a training program.

Education status

The results presented in Figure 1 regarding education status again corroborates an earlier national demographic study in which a National census obtained 68% of the TMPs to have either a tertiary education and or secondary education (FMOH, 2014). The higher education level of the TMPs should be an advantage in relation to modalities of government policies, research and other development activities that will cumulate into the development and promotion of indigenous herbal medicine which is a sure way to promoting healthcare. A totally enlightened population of TMPs is sure to drive the promotion and development process of traditional herbal medicine practice (WHO, 1978). The education status of the TMPs as presented in Figure 1 is good enough to inference that

the majority of the TMPs are literate. Thus, if the TPMs are properly organized should be able to effectively direct the sustainable development of HM in Nigeria. The development of traditional HM should stay true to the vision of people's health-oriented development. In this regard emphases should be directed to ensuring that finished herbal products are safe, effective, controlled and accessible as well as imputing aesthetics by formulating them into conventional drug delivery systems such as tablets, capsules, creams, (Xiao, 2018). An important advantage of high level of literacy of the TMPs is expected to increase the potential to partner with development groups as well as a better understanding for regulatory matters, contemporary quality control and quality assurance activities relating to quality the finished herbal medicines.

Herbal recipes and disease specialization

Herbal medicines constitute the main component of traditional medicine (WHO, 2010). Nevertheless, all the TMPs whatever their area of practice use herbs as component of the tool for their practice. All the herbal medicine practitioners indicated to having a certain disease(s) of specialization. The diseases listed by the TMPs are presented in Figure 1. Some of the diseases that are treated by a majority of the TMPs include gonorrhoea and other sexually transmitted diseases, malaria, diabetes, stomach ulcer, diarrhea, arthritis, pains, menstrual problems, toothache, asthma, rashes, cough and stroke, hemorrhoid (Jahromi et al., 2021). Each of the TMPs treated more than one disease condition. A number corresponding to 57.3 and 52.1% of the TMPs indicated to have herbal recipes for treating sexually transmitted diseases and malaria respectively. Over 30% of the TMPs had recipes for treating diabetes, stomach ulcer, arthritis, cold and catarrh, cough, tooth ache and about 4% indicated to have recipes for treating stroke and hemorrhoids. The relative specialization and ability of the TMPs to treat diverse health conditions showed the level of expertise and availability of remedies for especially endemic diseases available in Imo State and Nigeria. Also, the availability of such numerous herbs and recipes for the treatment of different diseases show the availability of such wide biodiversity in herbs and herbal medicine available such that with concerted application of appropriate science and technology these can be harnessed into acceptable quality products that can translate to health and wealth sustainer.

Type of production (extemporaneous or commercial) and dosage form

Majority of the herbal medicine products were liquids formulation that is likely decoctions or infusions of multi

component recipe of herbs. Few others were powders, pastes and shredded plant materials tied together to be prepared as decoctions. In recent times herbal medicines are commonly presented in conventional dosage forms such as bulk powders, alcoholic beverages, capsules, tablets, ointments and creams (Kumadoh and Ofori-Kwakye, 2017; Builders et al., 2013). A number corresponding to 89.6% of the TMPs presented their products as liquid mixture, 39.6% as powders and 5% presented as shredded plant materials. Only 7.3 and 3.1% presented their products as cream/ointment and capsules respectively. None of the products were formulated as tablet. The result shows that the products of the TMPs are presented based on crude traditional method of preparation. Though, these dosage presentations especially the liquid based products are easy to prepare but its attendant drawbacks such as poor stability, large dose volumes, unpalatable taste and clumsy packaging of the preparations makes acceptability poor. Hence, there is a need for better product dosage form development, to formulate the recipes appropriately into stable, effective and elegant conventional dosage forms that will be generally acceptable (Kannur et al., 2018; Kumadoh and Ofori-Kwakye, 2017).

Registration status of products

Many reasons have been proposed for the contemporary upsurge in the use of herbal medicine. Some of the reasons include the application of appropriate translational research and technology, relative low cost, socio-cultural trends but a more important factor is the increased and effective regulation in many countries (Zaslowski, 2005). In countries of the world where herbal medicines are regulated, there is a requirement for registration of the products before manufacturing, importation, distribution and marketing rights are approved. The regulatory processes are not as stringent as those of the conventional medicines. In many of such countries such as Nigeria and USA, herbal medicines are generally considered as dietary supplements (Bent, 2008).

Regulation is an important aspect of development of herbal products. Effective regulation promotes confidence on products as all products are expected to undergo quality checks (WHO, 2005). Although listed HMs are not permitted to carry direct claims for diagnosis, treatment, curative or preventive indications. The status of a product been registered instils confidence of quality, safety and effectiveness on the users, it also gives producers an edge to live up to the responsibility of continuous production of the claimed quality product.

In Nigeria herbal medicine is regulated by NAFDAC and licensed as food supplement (Osuide, 2002;

NAFDAC, 2018). Considering that only about 1% of the finished HM is listed with NAFDAC, shows the poor compliance to regulation requirements. The poor regulatory compliance may be attributed—to several factors such as information gap as regards requirement for registration of herbal products, poor economic power and weak enforcement (NAFDAC, 2018). Though, there are laws relating to the regulation of all HMs produced, imported, distributed and marketed in Nigeria, the result from the study may suggest that enforcement is not be strict enough to ensure that only registered products are sold openly. The poor compliance to regulatory requirements were evident in the poor quality of products in terms of general appearance, formulation, presentation and packaging. This highlights the poor extent of herbal medicine development in Imo state and the country in general.

Conclusion

The TMPs were made up of both men and women, though, there were numerically more men than women in the practice of traditional medicine and majority of the practitioners are literate with the potential of pushing up the development and promotion of herbal medicine in Nigeria. Also, the majority of the TMPs were herbal medicine practitioners who either sell or use only herbs for treating their patients. Generally, only few of the herbal medicine produced by the TMPs in Imo State are registered by NAFDAC showing the low level of regulatory compliance. Also, the poor product presentation shows poor quality. Registration of herbal products confers confidence on users, reduce risk of substandard and fake products as well as promote economic gains and sense of responsibility on producers. This study emphatically shows the low level of development of herbal medicine and compliance to regulatory guidelines in Imo State. Considering past countrywide studies this result shows the general state of herbal medicine development in Nigeria. Hence, the need for concerted efforts to improve the TMPs' awareness and knowledge on products development and quality as well as regulatory matters.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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