

Full Length Research Paper

Dynamics of herbal medicine processing and production in Benue State Nigeria

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The aim of this study was to determine the knowledge base of traditional medicine practitioners (TMPs) in Benue State in relation to current good manufacturing practice for effective quality, safety, and increased economic value. A cross-sectional study was conducted among the TMPs using questionnaire. Information such as practice area, type of herbal medicine preparations, water quality, preservatives as well as knowledge of packaging of finished herbal medicines was evaluated. Over 55% of the TMPs practice herbal medicine alone, while others combine other traditional medicine disciplines alongside herbal medicine. Majority of the TMPs produce extemporaneous products for their patient while 10% produce products for sale. A number corresponding to 18% of the TMPs use either tap or borehole water, the others use water from well, streams and rivers. The herbal medicines produced by the TMPs are largely liquids and only 47% have any knowledge of preservatives and fewer have any knowledge on packaging of herbal medicines. This study shows that the majority of the TMPs lack appropriate technical resources and knowledge for herbal medicine production. Hence, there is an urgent need for a coordinated intervention in terms of working tools and trainings.

Key words: Herbal medicine, Benue State, herbal active ingredients, formulation, conventional dosage form, water supply.

INTRODUCTION

The consumption of herbal medicines has shown phenomenal increase in recent times with global upsurge in the use of natural therapies for various healthcare needs (Ekor, 2014; Kumadoh and Ofori-Kwakye, 2017).

Herbal medicines constitute the major therapeutic element of the non-conventional healthcare of African traditional medicine. Some of the reasons adduced for the current popularity and attention to herbal medicine include:

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dependable positive impact demonstrated by herbal medicines as therapeutic tool in primary healthcare, relative low cost of therapy, easy access to herbs, herbal materials and finished herbal medicines, intimate interaction between patients and practitioners, lower relative side effect, success in the management of diseases for which conventional therapies have not done so well, acceptable elegant dosage form presentations for finished herbal medicines (Elkordy et al., 2021; Builders and Builders, 2016; Tangkiatkumjai et al., 2020). The increased demand has led to similarly increased attention currently been paid to research, production and promotion of herbal medicines in many parts of the world (Elkordy et al., 2021; Elujoba et al., 2005). In Nigeria most of herbal medicines used are not standardized and the products are mostly presented and distributed in the traditional dosage forms: namely liquid mixtures, powders, ointments and crude plant parts packed in containers. The liquid mixtures are often derived from infusions and decoctions of herbs; while the powders are pulverized plants materials (Kumadoh and Ofori-Kwakye, 2017). Tinctures are prepared by infusing the herbal materials such as barks, leaves and roots into local gins. Apart from the imported foreign brands of finished herbal medicines, only few of the finished indigenous herbal medicines are presented in appropriate dosage forms and functional packages. Many of the developed finished herbal medicine are often presented as bulk powders with dispensers, teabags, capsules, tablets, creams and ointments (Kumadoh and Ofori-Kwakye, 2017; Amrita and Arun, 2019; Poulouse, et al., 2020; Chen et al., 2020). Recently herbal medicines have been formulated using nanotechnology (Asari et al., 2012). The type of formulation and packaging presented by most of the TMPs in Nigeria may be related to the knowledge and infrastructure that are available and accessible to them. Formulating the herbal materials into conventional dosage forms will require expertise in dosage form design and preparation. An obvious knowledge in formulation techniques, quality control as well as excipients and packaging materials selection are critical for the production quality finished herbal medicines. Formulation and quality evaluation of the HM using conventional techniques are sure to enhance and optimize stability, effectiveness, acceptance and market value (Karbwang et al., 2019). Several challenges that relate to the quality and esthetic properties of herbal medicines have been ascribed to some intrinsic properties of most herbal materials, particularly herbal extracts used as the active materials (Devi et al., 2010; Karbwang et al., 2019). Some of the properties that make formulation of herbal materials into conventional dosage form challenge include: large dose volume of the active materials, poor solubility, poor absorption and poor bioavailability, instability (Enioutina et al., 2017). These challenges can be resolved during the research and development phase. Other factors that add to militate

against the quality of the finished herbal medicines in Nigeria include quality of herbs, water supply as well as the basic knowledge of processing of the herbs and herbal materials, formulation technique, preservatives and packaging. The aim of this study therefore is to determine the knowledge base of the traditional medicine practitioners in Benue State with respect to the formulation and packaging of finished herbal medicines into conventional dosage form and appropriately packaged in relation to current good manufacturing (cGMP) guidelines for effective quality and increased economic value.

MATERIALS AND METHODOLOGY

Materials

Appropriately tailored questionnaire, containing mainly questions on practice information relating to the preparation of herbal materials and finished herbal medicines by Traditional Medicine Practitioners (TMPs) in Benue State, Nigeria were prepared. A hundred and fifty questionnaires were distributed.

Methodology

A cross-sectional study was conducted across ten local government areas (LGAs) in Benue State with the aim of determining the practice patterns and the knowledge base of the TMPs in terms of dosage form formulation and packaging of herbal medicines. To do this, a hundred and fifty (150) questionnaires were administered to the TMPs from the different LGAs of the State and 98 % of the questionnaires were returned. The questionnaire evaluated questions that pertained to practice area of the TMPs, sources of their herbs and herbal materials, dosage form of the herbal medicines, methods of preparation, sources of water supply for the processing and preparation of the herbal medicines, preservatives used in herbal liquid preparations as well as packaging of the finished herbal medicines.

Statistical evaluation

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

RESULTS

Practice area of the TMPs

In evaluating the traditional medicine practice disciplines of the TMPs in Benue State, the response show that the TMPs has different areas of traditional medicine practice. The distributions of TMPs to the different traditional medicine practice disciplines in the State are presented in Figure 1. The practice areas are herbal medicine, bone setting, divination and traditional midwifery. Some TMPs practices cut across more than one practice area. Though some claim to practice only herbalism, those who are bone setters, diviners and traditional midwives or

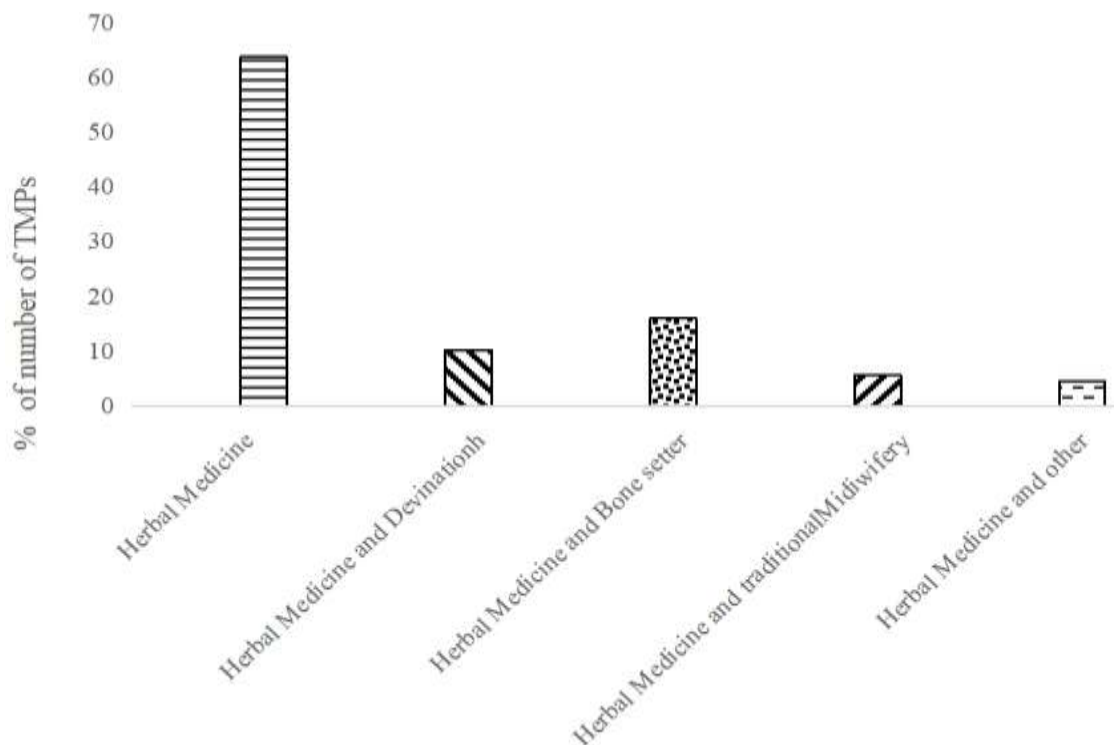


Figure 1. Traditional medicine disciplines practiced by the TMPs in Benue State.
Source: Data obtained from questionnaire and analyzed with Excel software 2016 version.

traditional birth attendants also practice herbalism as all them also agree to use herbs to prepare remedies for their patients.

Also, among the TMPs a number corresponding to 72.7 % prepare their remedies they use treating their patients themselves, while 27.2% prepare their remedies and also source remedies from other TMPs.

Type of herbal medicine preparations

A number corresponding to 63.3% of the TMP respondents produce mainly extemporaneous herbal products for use by their clients and patients in their clinic. Also, 10 % of the TMPs produce finished herbal medicine for sale and distribution while over 26 % produce for both patients use as well as for sale and distribution to the public. Thus, over 36% of the TMPs produce finished herbal medicines that are sold to the public. The results of the dosage form presentation of all the herbal medicines prepared by the respondents are presented in Figure 2. Over 68.4% of the herbal products prepared by the respondent TMPs are liquids prepared from infusions or decoctions and are packed into plastic or glass bottles. The other dominant dosage formulations that are prepared by the TMPs in Benue State are powders, ointments, pastes and cream. The creams, ointments and pastes constitute over 48% of the total

products while capsules constitute less than 3% of the dosage forms. The creams, ointment and pastes constitute medicines to be applied to the skin. No TMP produced tablets.

Water supply for the processing and preparation of finished herbal medicine

Information on the source of water supply available to the TMPs for processing and preparing their herbal medicines are presented in Figure 3. A number corresponding to 91.02 % of the respondent TMPs either use water obtained directly from the wells, from the local streams or rivers. Only 18.49% of the TMPs use either tap water or water from the borehole. Some TMPs that use borehole or tap water also use well water and water from the stream when tap or borehole water supply fails. None of the TMPs carry out any form of purification as pretreatment on the water used for the various activities during processing and preparation of the herbal medicines.

Preservatives in preparation of herbal medicines

In preparing their herbal remedies both as extemporaneous products to be consumed shortly after

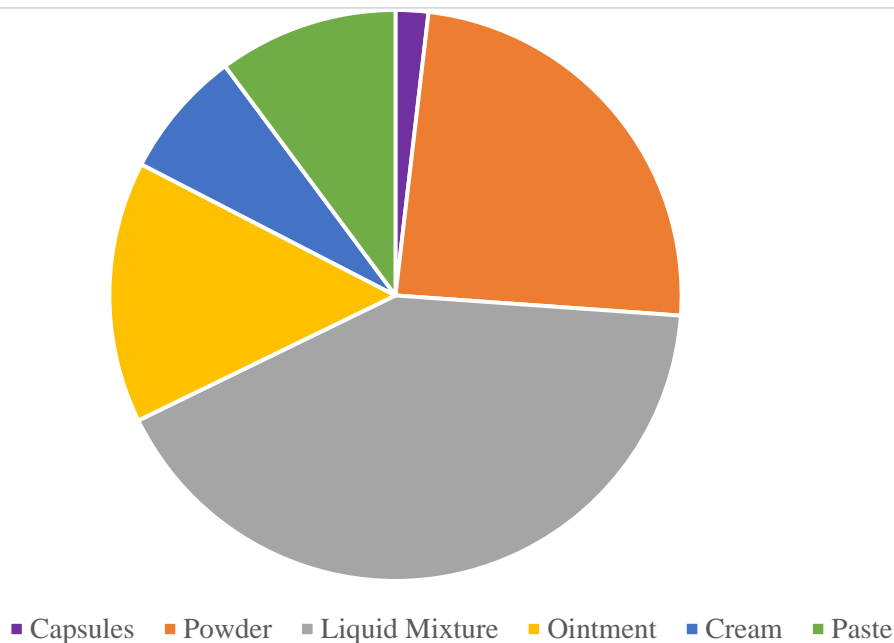


Figure 2. The dosage forms of finished herbal medicines produced and distributed by TMPs in Benue.

Source: Data obtained from questionnaire and analyzed with Excel software 2016 version.

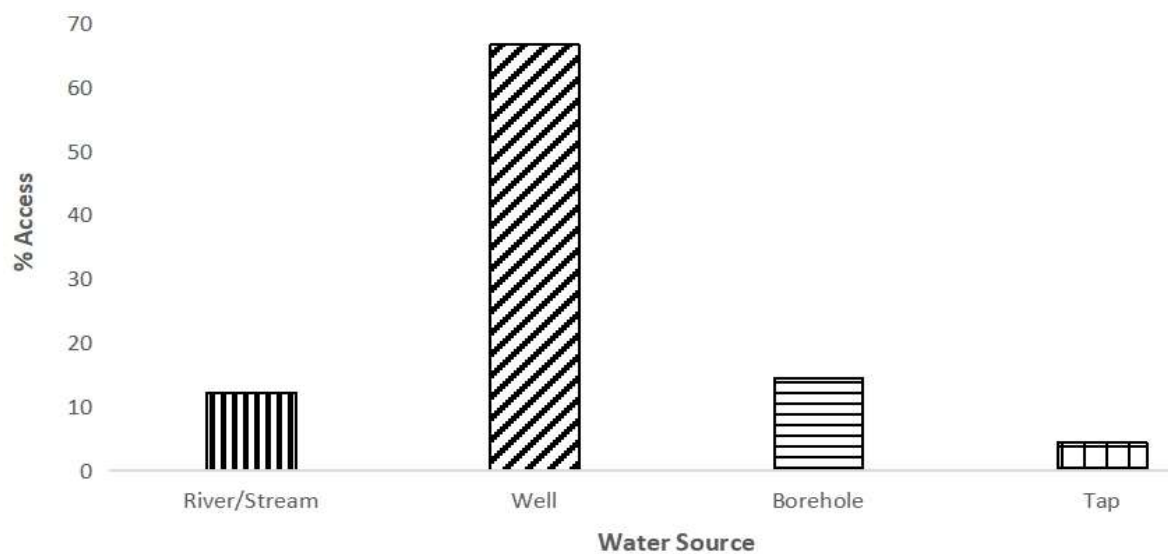


Figure 3. Sources of water supply used by the TMPs in Benue State for processing and preparing herbal medicines.

Source: Data obtained from questionnaire and analyzed with Excel software 2016 version.

preparation by patients or for distribution and sale to the public, only a number corresponding to 42.7 % of the TMPs claim to add preservatives to their products. Also, a number corresponding to 56.18% of the TMPs agree

not to add any kind of preservatives to their products. None of the TMPs has any training or any formal knowledge on current Good Manufacturing Practice (cGMP). Table 1 contains some information on the extent

Table 1. Some information on the formal trainings received by the TMPs in Benue State on aspects of herbal medicine production.

Information	Population (%)
TMPs with has knowledge/training in Good Manufacturing Practice	3.0
TMPs that add preservatives to their herbal medicines.	42.7
TMPS that have received training on prevention of spoilage of finished herbal medicine	2.0
TMPs that has training or experience on conventional dosage formulation	0
TMPs that has training on processing and preparation of herbal medicine.	2.0
TMPs that has received training on packaging	2.0
TMPs with training/ knowledge on packaging of herbal medicine	2.0

Source: Data obtained from questionnaire and presented as a percentage.

of formal trainings received by the TMPs on aspects pertaining to herbal medicine production.

Knowledge of packaging of finished herbal medicines

Some information on the basic knowledge of the TMPs in Benue State with respect to packaging of herbal medicine is presented in Table 1. A number corresponding to 72.8% of the TMPs does not know the importance of packaging in terms of the functions, criteria for selection of appropriate packaging material.

DISCUSSION

Practices area of the TMPs

Indeed, African traditional medicine is similar to the conventional healthcare system in having different areas of practice and expertise. African traditional medicine consists of a range of traditional medicine disciplines which includes both physical and spiritual dimensions. Some of the common areas of African traditional medicine practices are herbalism, bone-setting, spiritual healing (divination) and traditional midwifery (Tella, 1979). This corroborates the areas of practice of the TMPs in Benue State as presented in Figure 1. Those that practice herbalism also have disease area of specialization and expertise for which they have remedies or recipes. Most of the herbalists have expertise and remedies for more than one disease (Tugume and Nyakoojo, 2019).

Type of herbal medicine preparations

Herbal medicines are prepared into different dosage forms which are administered by different routes. The way it is traditionally prepared often reflects how it is administered. Many of the herbal medicines administered orally are often liquids which are prepared in different forms such as solutions, mixtures, and suspensions.

These liquid preparations are often prepared from infusions and decoctions as well as tinctures which are prepared by steeping the herbal materials in alcohol (Liu et al., 2017; Azwanida, 2015). These traditional methods are used by many TMPs to prepare their remedies either as extemporaneous formulations for their patients or as finished herbal medicine for sale. In commercial consideration of herbal medicines different preparations are available to suite important factors such as esthetics, safety, easy mode of administration and user acceptance (Wachtel-Galor and Benzie, 2011). Currently finished herbal medicines are commonly presented in conventional dosage forms such as tablets, capsules, teabags, creams, ointment, liquid mixtures (Kumadoh and Ofori-Kwakye, 2017). In recent times nanotechnology has also been applied in the preparation of herbal medicines (Halnor et al., 2018; Bonifácio et al., 2014). The dosage form commonly developed for an herbal recipe often depends on the knowledge, technology and resources available to the manufacturer. The dosage form presentation of the majority of the finished herbal medicine by the TMPs in Benue State is predominately liquid mixtures, simple and bulk powders (Figure 2). Such simple formulations show the level of development and technology available to the TMPs in the State. Liquid mixtures and powder formulations are prepared by simple processes using simple low cost machines. The growing demand for herbal medicine across the world has resulted in the large scale manufacture and consequent longer storage periods. The long storage period may result in stability challenges such as physical and microbial spoilage with adverse consequences on patients' safety especially when there is little consideration for cGMP as it is the case in Benue State. The evaluation of the stability of herbal medicine during the product development stage will ensure the determination of the appropriate storage conditions and the shelf-life thereby assuring the quality of the products throughout the recommended shelf life. The use of official guidelines such as WHO guidelines for stability testing of finished herbal medicines provides manufacturers, regulatory authorities and researchers with a harmonized system for stability testing.

Water supply for the processing and preparation of finished herbal medicine

Water is an important and widely used substance which is employed as a universal raw material during processing and formulation of herbal medicines. During production, water is used at various major stages such as cleaning, extraction and formulation. Thus, the water quality is a critical factor in the production safe and good quality herbal medicines. The quality of water will often depend on the source and the level of purification. Usually, the microbiological and chemical quality of water used for pharmaceutical manufacture must be controlled throughout the production, storage and distribution of the water. Water to be used for pharmaceutical manufacture should be monitored regularly for chemical, elemental and microbiological contaminants. The use of untreated water from sources such as wells, streams and rivers for processing and formulation of the herbal medicines by the TMPs in Benue State is generally unacceptable (Figure 3). This source of water is of grave poor quality due to the high level of possible contaminants resulting from human and animal fecal wastes as well as refuse and chemicals that are disposed indiscriminately into the streams and rivers. To ensure quality products the water used for processing and preparation must be of pharmaceutical quality.

Preservatives in preparation of herbal medicines

Sometimes herbal medicines are contaminated with microorganisms, hence the need for preservatives (Kosalec et al., 2009). Preservatives in herbal medicines are chemical substances used to improve the shelf life of a finished herbal medicine by protecting the product against microbial proliferation and spoilage. Countless number of microorganisms are indigenous to the soil environment where the plants are grown, poor handling conditions during harvesting and post-harvest handling and processing such as cleaning and drying are easy source of contamination. Microbial contaminations on herbal materials and finished herbal medicines often have serious consequences on both the products and the consumers. To prevent this, antimicrobial agents employed as preservatives need to be added as a component of the production formula for the finished herbal medicine (Makade et al., 2017; Zani et al., 1997). Preservatives are substances that are added to medicinal formulations to protect the product against microbial proliferation and spoilage. Dosage formulations such as liquids, creams, pastes and ointments are likely more susceptible to rapid microbial spoilage (Rahali et al., 2009; Ezeobiora et al., 2020). Also the source of water that are used for processing and preparation makes microbial contamination and spoilage eminent. Though, some of the TMPs in Benue State claim to include

preservatives in their recipes this may need to be verified. Considering the large number of the TMPs who agree not to add preservatives to their finished products or any knowledge on preservatives as presented in Table 1, calls for the urgent need for specialized training of the TMPs on various aspect of cGMP especially those that relate to herbal medicine processing, formulation, water supply and preservatives

Knowledge of packaging of finished herbal medicines

The high number of the TMPs in Benue State without appropriate knowledge on the packaging of herbal medicines (Table 1) may be as a result of absence the right information on packaging. Many of the TMPs packed their finished products in discarded bottle water containers without proper labeling. Packaging is an important factor in the stability and quality of herbal medicines (Thakur et al., 2011). The use of appropriate package is essential in holding the medicine without loss or contamination as well as maintaining the stability, efficacy and general quality of the finished herbal medicines within the pre-determined shelf life (Masand et al., 2014).

The knowledge of packaging of finished herbal medicine will direct the types of packaging components that will contain, protect and deliver a safe and effective product as well as provide appropriate information regarding especially to the product identity, storage condition and other regulatory requirement that relates to packaging. Information pertaining to the functions, types of packaging and the criteria to be considered for the selection of an appropriate package are important topics for training.

The knowledge of the TMPs on the afore mentioned topics on packaging of herbal medicines needs to be improved by targeted specialized training of the TMPs bearing in mind the over bearing importance of packaging on the overall quality of their products.

Conclusion

Benue State has a large number of TMPs who are spread all over the different local government areas. Majority of the products produced by the TMPs are extemporaneous products intended for their patients, only few of them produce finished herbal medicines for distribution and sale to the public. The TMPs generally have poor knowledge on information pertaining to conventional herbal medicine dosage formulation, water for pharmaceutical production as well as the packaging for finished herbal medicines. Hence, there is an urgent need for training of the TMPs in the State in specialized areas in cGMP so as to ensure the production of herbal medicines meet local and international quality and

regulatory requirements.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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