

Herbal Product Processing Practices of Traditional Medicine Practitioners in Kenya- Key Informant Interviews

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Abstract

Introduction: Herbalists in Kenya use self-taught processing practices which are inadequate. The objective of this study was to conduct an assessment of selected practices used by herbalists during drug processing and to identify knowledge gaps.

Method: Four long practicing traditional medicinal practitioners were identified using purposive sampling. An interview guide and field visits were used to gather data. Data analysis was done using content thematic approach.

Results: Sources of herbal knowledge were varied with the use of internet being a key finding. Regulatory compliance presented various challenges to the herbalists. The wild and cultivation of herbs were identified as key medicinal sources although the protection of biodiversity was a key concern of the herbalists. The facilities, area of practice and general hygiene were inadequate. Positive and negative practices were identified in processing of the herbal medicines.

Conclusions: Secrecy by the herbalists has resulted in limited innovation. More training of herbalists is required to improve on the quality of their drugs. It is however encouraging that they have adopted some modern methods in their practice.

Keywords: Herbalists, processing practices, herbal drugs

List of abbreviations

ERC	Ethics and Research Committee
GAPs	Good Agricultural Practices
GMPs	Good Manufacturing Practices
IPR	Intellectual Property Rights
JKUAT	Jomo Kenyatta University of Agriculture and Technology
KII	Key Informant Interviews
KNH	Kenyatta National Hospital
PPB	Pharmacy and Poisons Board
QA	Quality Assurance
TMPs	Traditional Medicine Practitioners
UoN	University of Nairobi
WHO	World Health Organization

1.0 BACKGROUND

Up to 80% of Africans visit traditional healers for their health care needs (Nelson-Harrison, et al., 2002). Traditional Medicine Practitioners (TMPs) or herbalists are seen as experts in traditional medicine. They however have no formal training in quality control and any practices are self-taught and acquired by observation. Their products have minimal quality controls and are not standardized.

All medicines including herbal drugs should be safe. Standardization prescribes a set of standards that imparts these principles and is a means for quality control (Kunle, et al., 2012). Standardization includes all

measures taken during the manufacturing process of the herbal drugs (Shinde, et al., 2009). Quality control ensures safe, consistent and predictable performance and is dependent on pre and post harvesting processes. These encompass good agricultural practices (GAPs) and good manufacturing practices (GMPs). At present, Kenya has no set standards for production of herbal medicine.

The WHO (World Health Organization) has encouraged the development of national standards and guidelines to evaluate the quality of traditional drugs. It has also emphasized on the need to develop national pharmacopoeia and monographs of medicinal plants as well as the protection of biodiversity (WHO, 2000; Shinde, et al., 2009). Recently, the Kenyan Pharmacy and Poisons Board (PPB) has encouraged herbalists to register their drugs. Information such as scientific name, the morphological part used, the geographical source and quality controls in the manufacturing process among other details are required (PPB, 2010). There is scant data on how many TMPs have complied and what benefits their disclosure has provided.

There is an urgent need in Kenya to document such intellectual information, validate and register products as well as to conserve natural resources. This is because over-exploitation of natural resources and attrition of information gurus means that this information is in danger of extinction (Muchae, 2000; Kigen, et al., 2013). To do this, ethnobotanical data, TMP processing methods and scientific information are needed to facilitate registration, value addition and standardization of products.

1.1 Statement of the problem

The use of herbal medications is extensive. In Kenya, data on processing of traditional medicine is scanty. The quality of these preparations is also wanting. Quality should be built in through GAPs and GMPs.

1.2 Study objective

To determine the type of Quality Assurance (QA) practices in processing and packaging of herbal medicines.

1.2.1 Specific objectives

- i) To determine methods of identifying plants, collecting, drying, mixing, flavoring, preserving, packaging and labeling of herbal drugs.
- ii) To identify gaps in the above practices.

1.3 Justification

This knowledge will aid in identifying gaps in practice which will be used to improve the quality and strengthen the capacity of practitioners in herbal medicine production. It will also assist in development of a curriculum in production methods of herbal medicine in Kenya. Kenya intends to set up a plant for processing herbal formulations in Nyeri Town (Njoroge, 2002). To set up this plant, there needs to be a survey on current GMPs that are already in place. This knowledge is required so as to identify knowledge and practices gaps that will aid in the design of a curriculum of herbal practitioners to promote production of quality medicines. To date, no such survey has been conducted in Kenya.

2.0 METHODOLOGY

2.1 Study design, area and study population

This was a descriptive study. The study population was TMPs (Traditional Medicine Practitioners) who had been managing patients on traditional medicines for at least five years. The study was conducted at the School of Pharmacy, University of Nairobi (UoN) and herbal clinics in Nairobi County and its environs.

2.2 Sampling Procedure

The principles of qualitative research were observed to recruit the study participants (Draper, 2004). According to the principles of qualitative research methodology, a sample size of two is adequate for an in-depth interview (Tongco, 2007). Four TMPs were selected using purposive sampling and interviewed using KII (Key Informant Interviews). Purposive sampling was used since this research aims to develop an interpretative framework of use of herbal medicines in T2DM (Pope & Mays, 1995). This sampling procedure is also considered effective when documenting secretive events and rich information sources (Zelditch, 1962; Tongco, 2007). The use of KII is an anthropological technique that uses rich information sources and has defined subjective sample selection criteria (Bernard, 2002; Tongco, 2007).

2.3 Inclusion and exclusion criteria

Traditional medicine practitioners who were 18 years and above, willing to divulge information, maintained records and who consented in writing at least 24 hours before the interview were included in the study. In addition, they should not have been involved in the practice of witchcraft and other forms of spiritual healing and had long standing associations with the UoN.

2.4 Data Collection

An interview guide was designed and used to collect information from TMPs on their methods for herbal medicine preparation and processing. Interviews were conducted in English and Kiswahili by the researcher. Consent to participate in the main study was obtained 24 hours before the interview. Each interview lasted approximately 40 minutes. If additional time was needed, a second session was booked. The interviews were audio recorded and transcribed in English within 24 hours of the interview. Audio records were destroyed by erasing. During the audio recording, notes were taken. Expressions of the interviewee were also noted.

2.5 Data Analysis

Data was analyzed using content thematic approach. The main themes were knowledge acquisition, regulatory affiliations, facilities and equipment, source of herbs, drug processing methods and perceptions of quality assurance input. Relevant verbatim quotations in the thematic areas were identified and were used to present the study findings. Practices among the TMPs were identified and compared with known information.

2.6 Ethical and Intellectual Property (IP) Considerations

Permission to carry out the study was obtained from the UoN/KNH Ethics and Research Committee of Kenyatta National Hospital (KNH) as per an approval letter (reference: KNH-ERC/A/306). This research was carried out in accordance with the basic principles defined in Guidance for Good Clinical Practice and the Principles enunciated in the Declaration of Helsinki (WHO, 2001).

Confidentiality was maintained by using pseudo names in the transcript of any herbalist, their clinics any person mentioned in the interview. Names of their formulations were also coded. In addition, all audio recordings were destroyed to conceal the identity of the person. To protect the IP rights of the herbalist, an agreement was to be signed between the herbalist, UoN, JKUAT and the investigators. In addition, the TMPs were not coerced to record the identity of the plants and the proportions used to make their herbal formulations. For those who volunteered, they were protected by concealing information in any publication. This information will be withheld from the public domain until a patent is filed.

3.0 RESULTS

3.1 Demographic Characteristics of the Traditional Medicine Practitioners

Four TMPs were interviewed. Three TMPs agreed to submit their formulations used in management of Type II Diabetes for further investigations. They also agreed to reveal individual herbs used in their formulations for analysis.

All informants were men aged 43-67 years. All were married and had acquired at least secondary school education. Two had attained college education and had formal training in a medical field. Two had full time employment in addition to being TMPs. The rest were full time TMPs who occasionally supplemented their earnings with small businesses. All four TMPs had over 15 years of experience each in the use of herbal drugs. Two practitioners were practicing in Nairobi, one in Mombasa and one in Kiambu.

3.2 Acquisition of Knowledge on Traditional Medicines

Knowledge on traditional medicine was gained via apprenticeship through family associations by inheritance, observation, and verbal instructions. Self-directed learning from books and the internet, travel, research, experimentation using trial and error and interaction with scientists also contributed to acquired knowledge. In addition, seminars and workshops on various aspects of herbal medicine were a valuable source of information. Herbalist 1 had acquired the skill of treating patients from his grandfather who himself had been a TMP. His grandfather had died before he was born but his grandmother had aided in acquisition of his skill of healing by imparting some knowledge to him.

"I was told that I had similar interests as my late grandfather. My grandmother would teach me about the herbs my grandfather used."(TMP 1)

Herbalist 2 had observed his father prepare herbal preparations for his own use and to treat fellow villagers. He had acquired interest from watching his father.

"We would collect herbs in the wild, boil and sweeten them in honey and dispense them to the sick in small gourds. This was in the late 1950s". (TMP 2)

Observation of animals also gave them an idea on helpful medicinal plants. Herbalist 2 stated that animals instinctively know which plants and minerals to consume when sick. For example, coughing goats consumed "Adams apple" and recovered. He also referred to this plant as *Solonum incanum* or 'ndongu'. All stated that they were also self taught from many years of observation, travel, trial and error.

"My interest intensified while in high school and I began field visits. I then noticed that the herbal plants throughout East Africa would keep repeating themselves in different regions and cultures. Garissa, Turkana, Pokot and Kitui in Kenya; Tanga, Moshi, Mologoro in Tanzania and Uganda used the same plants for

treatment of T2DM. This is evidence that they work because all these people cannot be wrong.”(TMP2)

Personal experiences where they themselves and close family members had been cured of various ailments strengthened their belief in herbal drugs. One TMP also stated that his treatment, of a difficult long standing respiratory condition with herbal drugs in the 1970s during formal employment had peaked his interest in herbs.

“Failure to get treatment from conventional hospitals for over four years and an ultimate cure from a herbalist then affirmed my conviction that herbs were effective. During my treatment, I recognized several herbs. I remembered what my father had taught me and my interest was awakened.” (TMP 2)

All cited the internet and books as additional sources of their knowledge. Herbalist 2 had gathered information from the internet on the use of paw paw seeds as a cause of abortion and experimented with this on his farm animals. Herbalist 1 and 2 carried written texts and publications with them which they referred to during the interviews. All noted that personal contact with various scientists at the School of Pharmacy UoN, had increased their knowledge about plant medicine. These contacts had alerted them on the importance of upgrading their skills resulting in attendance of various seminars.

Herbalist 1 also stressed that religion supported the view that herbs were recommended for treatment of many diseases. He quoted a religious verse as evidence.

“Black seeds are mentioned in religion as a cure to all diseases. During my experience, I have found this to be true.”(TMP 1)

3.3 Regulatory compliance and affiliations to professional bodies

Three TMPS were formally registered with the former Ministry of Culture and Social Services. None were registered with PPB. One was a current member of the “Herbalist Society of Kenya” and “Kiambu County Biodiversity Conservation Group”. Regardless, none of their patients ever requested to see any registration or affiliation to any professional body.

A recent announcement by the PPB that products must be registered at a cost of US\$ 500 was met with hostility. The cost was considered too prohibitive by all with one of them considering it a “poisonous board”. All were aware of Intellectual Property Rights (IPR). However, all were disillusioned with its application and thought the process was tortuous and expensive.

3.4 Sources of medicinal products

Plants, animals and minerals were cited as the source of their medicines. The following sources of plants were listed; from the wild, cultivation, importation, purchases them from other herbalists and various markets.

All the herbalists collected, formulated and dispensed their own drugs with the help of assistants trained and supervised by them. Wild source were the main supply of their herbs and included forest reserves and road reserves. Herbalist 2 and 4 cultivated some of their herbs but still considered wild sources as more diverse. All the herbalists were concerned by the loss of natural habitat from which they collect the herbs. Since the herbalists were long practicing TMPs, they noted the great decline in biodiversity over the years. Herbalist one cited saddle wood as a plant that one could no longer use due to government restrictions After a field trip to gather a rare herb, one herbalist commented;

“It is a pity that I had to travel further than usual to gather these rare herbs. A university has now been constructed in the area and they have fenced off a huge portion of land which they have burnt. The plants are difficult to get.”(TMP1)

He was also concerned about pollution at collection sites and that access to forest areas was now regulated (see plate 1).

“To enter that forest, I had to hire two forest guards to escort me to an area that I used to access freely before.”(TMP 1)



Plate 1: Polluted wild bushy area used for plant collection

Herbalist 2 was a member of Kiambu County Herbalist and Biodiversity Conservation Association. This organization advocates for replanting of various herbs for conservation purpose. A cultivated herb garden was observed at his premises. Pictures of some of the cultivated plants are shown in plate 2.



Plate 2: Cultivated herbs behind a herbal clinic

All TMPs purchased some of their herbs from markets and from other herbalists. Herbalist 1 said that he also imported herbs from other countries.

“I also get some drugs from India and Tanzania. Most of the drugs I use have been investigated and they work. I have seen this on the internet.”(TMP 1)

3.5 Facilities and Areas of Practice

Herbalist 2 and 4 had permanent clinics where they attended to their patients. The researchers visited these clinics and made observations. These facilities were comparable in design to conventional allopathic practices. Both had waiting areas, consultation rooms and drug dispensing rooms with one assistant each. Both had documentation of the professional bodies they represented at hand. Herbal drugs were displayed on shelves (plate 3). One used the facility to process and package his drugs. Herbalist 4 processed his drugs in a separate location which was not revealed. Herbalist 2 had a once weekly clinic with his patients at DoPP, UoN. Herbalist 1 and 2 were willing to travel to treat patients at their locations.



Plate 3: Stored ground herbs at herbal clinic

3.6 General Hygiene practices

Although, no physical examination of patients was observed in this study, it was observed that the herbalists did not practice hand washing before dispensing of the formulations or powders to the patients. Equipment was rinsed with water only and sometimes bar soap and water. Surfaces were cleaned only with water, no disinfectants were used.

3.7 Processing of herbs

The processing of herbal medicines consisted of the following steps; collection, drying, grinding, mixing/ formulation, flavoring, preserving, packaging and labeling.

3.7.1 Harvesting/ collection of drugs and plant identification

The TMPs were specific on the geographical locations, seasons and morphological parts collected. For example one herbalist commented;

*“The best karela (*Momordica charantia*) is from Athi River. I prefer it.” (TMP 1)*

All TMPs stated that the best season for plant collection was after the rains as most plants had sprouted, were easier to identify and quantities were abundant. Some locations were viewed as secret and were not revealed to the researcher. The TMPs used both botanical and local plant names to aid with identification. To verify the names, a botanist was engaged to confirm the identities. All TMPs herbalist were particular about the time of day that the collection of the herbs was done.

“The best time was between 11 am and 2 pm after the dew had dropped. This is because I used khaki bags for collection. This avoids wetting the bags.” (TMP 2)

The rest of the herbalists wrapped the herbs in newspaper before further processing.

Herbalist 1 used various animals for the manufacture of herbal medicines. These he collected on demand from specific suppliers. Minerals were also purchased for formulating remedies.

3.7.2 Drying of the plant materials

All herbalists preferred air drying under a shade. Plate 4 represents a drying shade. Selection of unwanted material or gabling was done manually. All TMPS cut the fresh plant parts into smaller pieces to hasten drying. All herbalists preferred to dispense dried herbs since quantities used were less. Drying also preserved the herbs. Herbalist 2 stated that fresh herbs could be used in emergencies but larger quantities were required to make the formulations.

“Drying decreases the amount of drug used. One teaspoon of dried drug is mixed with one litre water. If using oil, 3 teaspoons of the drug are dissolved in one litre.” (TMP 2)



Plate 4: A herb drying shelter

3.7.3 Size Reduction and sieving of fresh and dried material

Size reduction was done to hasten drying. Initial size reduction was done by hacking larger harder plant parts such as barks and roots with machetes which are locally known as “*pangas*”. Knives and chopping boards were used for small softer parts such as spongy leaves. Smaller plant parts such as leaves that had less moisture were dried whole. Some herbs were left intact and were ground only when a patient presented with a specific problem to avoid degradation. Further size reduction was done using a pestle and mortar (*ndii*- from the Akamba people) for dried smaller quantities. Larger quantities of dried plants were ground with commercial mills. Plates 5 and 6 present the traditional pestle and mortar used for size reduction. A picture of a commercial mill used by a herbalist is presented in plate 7.



Plates 5 and 6: Traditional tools (pestle and mortar) used to process herbal medicine



Plate 7: A modern commercial mill used by herbalists

Grinding saved them time as the ground product was stored in plastic containers for later use. Change in odor and appearance was used to determine expiry of the product. This skill to identify deterioration was gained through experience.

Sieving was done after size reduction using modern sieves. This was done to further remove unwanted large particles. A picture of the sieve is presented in plate 8.

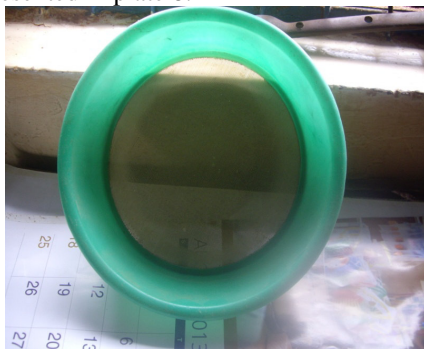


Plate 8: Sieve used to strain good materials

One herbalist preferred using a self-made grinder with “*iron teeth*” which he used on fresh plants before drying was done (plate 9).

“Grating the fresh drugs hastens drying to two weeks. After drying sieving is done.”(TMP 2)



Plate 9: Handmade drug graters

3.7.4 Formulation and mixing of herbal medicines

Mixing of various herbs into formulations by the study herbalists was considered a trade secret by all the TMPs and was observed only by trusted people. Two TMPs were reluctant to allow observers.

“I prefer to collect and mix my drugs alone. Only my daughter can observe.”(TMP 1)

One herbalist processed and formulated his drugs at a separate location from his clinic (plate 10). All others prepared the drugs at the same location where they received patients. Three TMPs dispensed their drugs as powders and one as a suspension.



Plate 10: Formulation room with equipment.

Herbalist 2 used preservatives to prevent microbial growth. His preservatives of choice were *Tamarindus indica* (tamarind) and *Eriobotrya japonica* (loquat). After dispensing his drug in tinted bottles, refrigeration was recommended.

“I used to use sodium benzoate as a preservative. I later on stopped because it was not a natural product.”(TMP 2)

Flavoring was practiced by one herbalist using *Trigonella foenum graecum* (fenugreek) and honey. Two TMPs included fenugreek for the purpose of improving patient immunity. Grains were added by another TMP who

considered them a carrier for his drug.

All formulations were dispensed orally as water decoctions. Decoctions here refer to either boiling plant powders in water or soaking them in boiling hot water for a period. Three formulations were dispensed as powders for the patients to make the decoctions on their own. One formulation was prepared and dispensed as a bottled suspension for patients. Times taken to prepare decoctions varied considerably. The amount of heat used also varied. This herbalist explained:

“I prepare my decoctions in three different ways; with water, olive oil or canola oil. Olive oil has medicinal value and it cleans the veins of cholesterol. Canola oil also has medicinal value.”

(TMP 2)

High waste and dosage inconsistencies were also noted with significant amounts of drug left over in the cooking and dispensing equipment. Ordinary cooking utensils such as aluminum cooking pans and cooking ladles were used during formulation.

3.7.5 Labeling and packing of herbal drugs

Herbalist 4 labeled his products with botanical names but it was not clear if all ingredients were revealed. Herbalist 2 used codes to label his suspension that only he could decipher. This suspension was packed in 250ml dark bottles. The remaining two TMPs provided only the packed powder in plastic bags for patient use and did not label their products.

4.0 DISCUSSION

In this study, the TMPs were found to be all men who had diverse levels of formal education. Only two had acquired medical training from recognized institutions. Two of the study TMPs cited family as a source of their traditional knowledge. This is a common way in which herbalists acquire their expertise (Gessler, et al., 1995; Birhan, et al., 2011). Zoopharmacognosy or the observation of animals to gain medicinal knowledge is in agreement with herbalists practices worldwide. (Costa-Neto, 2012). Self-directed learning and gaining knowledge from trial and error are consistent with methods in literature through which herbalists gain knowledge (Sen, et al., 2011; Asiiimwe, et al., 2014). Attendance of various seminars, reading of books and referencing of the internet were also positive skill acquisition methods. Learning from the internet by Kenyan herbalists has probably never been reported before.

There has been efforts by local universities to begin training allopathic health providers on traditional medicine. The School of Pharmacy at UoN, has introduced a degree course in complementary medicine. This will aid in increasing co-operation and understanding between the two schools of health provision. This institution also encourages research partnerships between herbalists and scientists.

In China, a credible TMP must be a member of a herbal association and be trained as a herbalist with at least four years working experience with medicinal herbs (Covington, 2001). This trend should be adapted in Kenya so that training herbalists apprenticeship under practicing qualified herbalists. This will assure that correct drug processing information is instilled in upcoming herbal practitioners. At the end of this internship, a herbalist should be certified and be subject to regular checks by a professional body to avoid quacks and unorthodox treatments.

It was also observed that patients did not bother requesting for information about the qualifications or registration of herbalists during visits. It is possible that the public are not aware of the value of this information. The public should be made aware that TMPs are regulated by official bodies and thus patients have every right to demand proper care and to report poor services, poor quality drugs as well occurrences of side effects to PPB.

There is lack of official recognition of indigenous Kenyan medicine and its practitioners. Non-inclusive regulatory mechanisms have encouraged secrecy and poor innovation. This is because the TMPs do not perceive to have fair distribution of benefits from indigenous traditional knowledge and its products. Registration policies are unpopular among TMPs. Most of them may also be unable to raise the high analysis fee required. The application for registration is US \$ 500 and renewal US \$ 300 as well as other charges (PPB, 2010). The TMPs also did not seem to have much confidence in regulation bodies with one of them referring to PPB as a “poisonous body”. Countries such as Korea and Vietnam have integrated traditional medicine into their health care system. This has included validation of traditional medicine products and introduction of GMPs (Wanakwakwa, et al., 2013). To encourage openness and increase validation of herbal use in Kenya, this should be done. The regulatory processes should be made inclusive and affordable so that they are acceptable to the TMPs. Benefit sharing has worked in India and Laos and should be applied in Kenya (Riley, 2000; Pushpangadan, 2002). However, this would also require disclosure by the herbalists. The registration of herbal products should be made easier with the fees reduced to affordable amounts.

The main source of herbs in this study was found to be wild. Wild sources are the largest suppliers of herbs, but they are threatened by over exploitation (Hamilton, 2004). It was noted that some drugs the TMPs used for this study were roots and tubers. This is known to be a great threat to conservation of plants (Asiiimwe,

et al., 2014). Two TMPs in this study were taking active steps to conserve their source of plants by cultivation. There have been similar concerns about a decline in biodiversity have been expressed by TMPs in India and Uganda (Sen, et al., 2011; Wanakwakwa, et al., 2013). A participatory rural approach has been highlighted in India to avoid loss in the traditional health care system by encouraging conservation of plants (Phondani, et al., 2014). In other counties, conservation of plants has been modernized. For example, *Piper longum* has been successfully conserved using a genetic marker technique called Random Amplification of Polymorphic DNA (RAPD) (Nikam, et al., 2012). In Asia, farming of herbs ensures a consistent product with high levels of post-harvest handling (Ten Kate & Laird, 1999)

In Kenya, large scale botanical gardens should be encouraged to aid in consistent herbal production. Education of herbalists on the importance of conservation of biodiversity should be done. Application of good agricultural practices shall ensure quality control and standardization of herbal products. Gene banks to store genetic indigenous plant material should be established to conserve biodiversity.

The need for quality control has been expressed in various traditional medicine systems and should be a key concern in the Kenyan herbal system (Sen, et al., 2011). Standard practice recommends that all ingredients and manufacturing processes be revealed for any standardization of products to occur. (Rasheed, et al., 2012). This reduces batch to batch variations (Nikam, et al., 2012). Standardization should be done from the source of origin all the way to pharmacological profiling of the finished product (Chawla, et al., 2013). However, three herbalists were not keen to reveal various information outside this study. This raises the questions on whether standardization by a body of authority would work in this country.

Collection of herbs at specific geographical locations, seasons and times is a positive practice that can reduce batch to batch variations. The optimal time of harvesting is dependent on the herb. Research should be used to guide the herbalists on the best time, stage of development and the best morphological part to collect in a specific herb. Although botanical gardens can be introduced to curb the loss of biodiversity, changing the environmental conditions under which a plant grows can also affect the quality of the herbal constituents.

During processing, the identity of the plants should be well authenticated using both macroscopic and microscopic means. This will avoid adulteration and substitution with other plants and ensure batch reproducibility. Chemical tests should be encouraged on different batches at regular intervals to confirm plant identities. Garbling to remove visible contaminants, drying under shades and size reduction to hasten drying were commendable (Kunle, et al., 2012). However, drying should take into consideration that some constituents are thermo labile. The equipment used in the above process were also mostly outdated. More modern methods of performing these tasks could be introduced.

Packaging of drugs in dark bottles is advisable for light sensitive drugs and was done by one herbalist. Labeling of products was done by two TMPs. Secrecy appeared to be maintained as codes were used by one TMP. It was also not clear if all the ingredients were declared by the TMP who labeled using botanical names or even if they were correct. It has been found that herbal remedy labels are undependable. More than 50% of the time what is listed on the bottle and what is actually in it does not tally (Kunle, et al., 2012). Instructions given on the labels were vague with no proper measures given. No warnings, duration of treatment or expiry dates were given were given. Odor and change in appearance were used to gauge expiry of products. Positive storage practices were noted such as storing ground drugs in covered clearly labeled plastic containers. Some dried herbs were kept whole until a patient presented themselves to avoid deterioration and mixing up. Dispensing in tinted bottles, advising on refrigeration after dispensing to patients and inco-operation of herbal preservatives was also recorded. Standard practices should be introduced so that the products are standardized.

All herbalists made decoctions for their patients or gave instructions to the patients on how to make them. The varied cooking times, diverse cooks (patients) and the high heat used in their preparation was thought by the researchers to produce uneven batches. No standard measures were given to the patients and none appeared to be in use by the TMPs. This was compared to the ease and convenience of tablets. The tastes and odors were also observed by the researcher to be unpalatable. Similar concerns of cumbersome preparation and bitter tastes were expressed about traditional Chinese medicine (Chun & Chesla, 2004), (Lam, 2001). There is a need to standardize the dosage forms if possible, to pre-measured patient friendly sachets that are easier to prepare for one time use. Research into improving tastes and masking odors should be done.

Hygiene is part of both GMP and GAP. The researchers noted that more could be done to encourage the practice. A study done in Kenya noted the importance of raising awareness of hand washing among herbalists (Magak & Njoroge, 2010). A study in China recorded that patients have expressed concerns about hygiene and contamination of herbal drugs (Kwan, et al., 2013) Interventions could include; wearing of clean laboratory coats, supplying a hand washing station with soap in the clinics and use of disinfectants to clean equipment and surfaces.

Protection is viewed as excluding unauthorized third party use (Downes, 1997). Others view protection as preserving traditional knowledge from negative aspects (Simpson, 1997). The herbalist in this study viewed protection of their skill as keeping it undisclosed to others. This was noted as a characteristic of Kenyan

herbalists in another study (Muchae, 2000). Without proper documentation of their trade, including information on plant species, their geographical locations and morphological parts used, there will be eventual loss of traditional knowledge. This loss is evident because younger generations are disinterested in the trade and resource areas are fast disappearing (Kigen, et al., 2013). A national pharmacopoeia should be developed with the involvement of herbalists.

Lack of disclosure by Kenyan herbalist has also hampered them from reaping larger economic gains from their skills. In this study, TMPs expressed lack of trust in the Kenyan Institutions and accused them of benefiting themselves at the cost of the herbalist. This has also encouraged secrecy among them and reduced financial gains. China earned 5 billion US \$ in 1999 from traditional medicine (Correa, 2002). In Malaysia, the per capita consumption of herbal drugs is twice that of allopathic medicines (Balasubramanian, 1997; Correa, 2002). No data on the economic importance of herbal medicines to Kenya could be found. In a study with TMPs in Kenya, they acknowledged that their information had financial value but none had entered into any future agreements (Muchae, 2000). The herbalists should be empowered with business knowledge so that the sector can be financially rewarding. In this way, the herbalists will realize the importance of imparting quality in herbal drugs. This will also aid in conservation of natural resources and encourage herbalists to register their products.

4 CONCLUSION

The regulation of Kenyan herbal medicine and its practitioners has not been viewed as beneficial by the herbalists. As a result, they have maintained high levels of secrecy which have lead to limited innovations in this field. More needs to be done to document ethnobotanical information, conserve our biodiversity and improve on the processing practices done by herbalists. However, TMPs have adopted the use of internet and some modern machines. They require training in certain selected areas of GMP and GAP.

6.0 RECOMMENDATIONS

Research and standardization of herbal drugs is required to ensure efficacy, hygiene and safety. The TMPs should be taught and encouraged to use GMP and GAP. They should be part of a benefit sharing system to discourage secrecy and encourage innovation in their trade. They should receive feedback in order to improve patient care. Education on biodiversity conservation and its implementation should be mandatory.

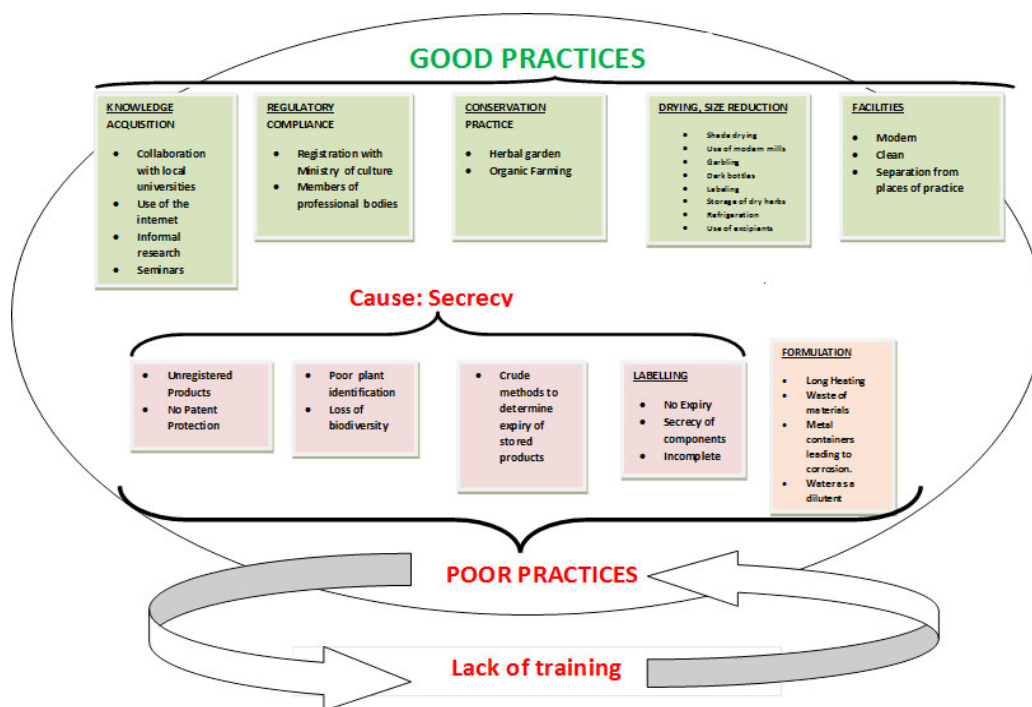


Figure 1: Summary of good and bad processing practices by TMPs in Kenya

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