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How traditional healers diagnose and treat diabetes mellitus in the Pretoria Mamelodi area and how do these purported medications comply with complementary and alternative medicine regulations

by

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SUMMARY

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Keywords: Traditional healers, Diabetes Mellitus, South African Health Products Regulatory Authority, Medicines Control Council, complementary and alternative medicines, complementary medicines, traditional medicines.

ABSTRACT

Introduction

Medicine regulation and control is not an option but a necessity for national health programmes. In South Africa, a new amended regulation required a review of complementary and alternative medicine (CAMs) call-up for registration in November 2013, this impacted traditional healers (THs)' compliance with the regulatory authorities' on the good manufacturing practice. In return, affected the public's access to CAMs. Regarding THs patients, cases of diabetes mellitus will be investigated.

This investigation embraces methods, in the Mamelodi area of Pretoria, TH use to diagnose metabolic disorder diabetes mellitus and identify the purported medication prescribed. The study assesses what these purported medications comprise of as well as the purported medication labels for compliance with complementary and alternative

medicine regulation. It is essential to understand the functioning of the newly amended regulations of the South African Health Products Regulatory Authority (SAHPRA). Regulations surrounding the registration and post-marketing control of complementary and alternative medicines are crucial. This study's findings will be available to assist the SAHPRA to improve regulating complementary and alternatives medicines.

The study will help create awareness among traditional healers concerning new regulations, requirements, and procedures for supplying complementary and alternatives medicine to their patients.

Methods

The study comprises a survey with administered questionnaires, distributed amongst 75 THs to gain knowledge on how they diagnose diabetes mellitus in their patients and establishing Complementary and Alternative Medicines used in treating this condition. The study also includes visits, with a non-structured survey, focussing on traditional health shops and pharmacies in the Mamelodi area; to identify and assess those with diabetes mellitus and complementary and alternative medicines compliance with the South African Health Products Regulatory Authority (previous Medicines Control Council(MCC)) regulations.

Results and Discussion

According to the questionnaires, traditional healers do not use any medical materials or laboratory tests to diagnose patients. They make use of skeletal bones and prayers, sometimes followed by physicians' medical reports along with traditional healer's assessment questions. They have an understanding regarding safety, quality control, and pharmacovigilance.

Traditional healer's self-provided treatment list for diabetes mellitus displays 20 different active ingredients in various CAM therapies. The most common treatment is

plant/ herbal-based called *Muti*. Records show the most prevalent is the Oz (1 ounce/28.35 g) mixture (Oz First flush, Oz lily herbs, Oz flower of Ypres, Oz mulch root and Oz Makasan) followed by Mukwere kwere *Euclea undulata)*, Bitter leave plants, known as Uhlunguhlungu *(Brachylaena elliptica)* and other *(Brachylaena ilicifolia)*, Ndoleh *(Vernonia amygdalina)*, Bitter bossie *(Vernonia oligocephala)* all along with herbs, such as Escobilla (*Schkuhria pinnata).* The overall purported medications do not comply with SAHPRA regulation.

Pharmacies provided CAMs that are used by traditional healers only as complementary medicines. Most of them had a disclaimer on the label when not evaluated by the MCC/SAHPRA. Only two medicines were recorded as being registered by the MCC/SAHPRA known as 'Manna blood sugar support' and 'Super Moringa'.

Conclusion

The diagnosis of diabetes by THs in the Mamelodi area is mostly by divination. THs know the importance of drug monitoring with regards to safety, efficacy, and effectiveness of the medication. They are still complaining of not being understood but rather dictated to by the health regulatory bodies in terms of regulation. Although their purported medication seems successful according to themselves and their patients' feedback. Further investigation is demanded regarding glycaemic control of the 1 ounce (Oz) mixture to identify active ingredient molecules for potential drug discovery and development.

This project impacts the South African Health Products Regulatory Authority and traditional healers. The project increases the public's knowledge and signifies an advantage regarding the safety and trust of complementary and alternative medication.

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DECLARATION

I declare that this dissertation/thesis, which I hereby submit for the MSc degree of Pharmacology at the University of Pretoria, is my own work and has not previously been submitted by me for a degree at this or any other tertiary institution.

ETHICS STATEMENT

The author, whose name appears on the title page of this dissertation/thesis, has obtained, for the research described in this work, the applicable research ethics approval.

The author declares that s/he has observed the ethical standards required in terms of the University of Pretoria's Code of Ethics for Researchers and the Policy guidelines for responsible research.

Signature

ONDO Z.G

NOVEMBER 2018

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ABBREVIATIONS

ADR	Adverse Drug Reactions
AHPCSA	Allied Health Professions Council of South Africa
AIDS	Acquired Immune Deficiency Syndrome
ALA	Alpha lipoic acid
ATMs	African Traditional Medicines
CMs	Complementary Medicines
CAM	Complementary and Alternative Medicine
CTD	Common Technical Document
DM	Diabetes Mellitus
DoH	Department of Health

DURU	Drug Utilisation Research Unit
FBG	Fasting Blood Glucose
FDA	Food and Drug Administration
GMP	Good Manufacturing Practise
GTT	Glucose Tolerance Test
HIV	Human Immunodeficiency Virus
IVD	In Vitro Diagnostics
MCC	Medicine Control Council
NIH	National Institute of Health
OTC	Over the counter
PI	Package Insert
PIL	Patient Information Leaflet
SAHPRA	South African Health Products Regulatory Authority
SANAS	South African National Accreditation System
TH	Traditional healers
THO	Traditional Health Organisation
TM	Traditional Medicine
US	United States
WHO	World Health Organisation

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1. CHAPTER 1: DEFINING THE RESEARCH PROBLEM

The Department of Health (DoH), South Africa, encounters challenges regulating Complementary and Alternative Medicine (CAM). New amended regulations requested a call-up of all CAMs for registration(s) in November 2013 along with Amended act of August 2017. This impacted South African traditional healers' purported medications compliance with regulatory authorities in terms of the current good manufacturing practice and the public access to these medications for diabetes mellitus patients.

2. CHAPTER 2: LITERATURE OVERVIEW AND MOTIVATION

2.1 Introduction

CAM is widely used by patients to treat and prevent certain diseases, providing emotional and physical support.[1] The National Centre for Complementary and Alternative Medicine (NCCAM) defines CAM as a *"group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine."* [2] A complementary medicine is an adjunct to conventional therapy; alternative medicine is a replacement (instead of) conventional or allopathic medicine.[1, 2]

In the past 20 years, the increase in availability and ease of access to allopathic, conventional, or Western medicine through public health and private medical practices, led to an increased quality of life. Despite this tendency, numerous factors led to the widespread and increased appeal of CAM globally; over 80% of individuals in developing nations use CAM. One-third of the global population, with 50% in the impoverished parts of Asia and Africa do not have regular access to essential drugs.[3] In some regions of the world such as in China, CAM is more accessible and more affordable than essential drugs or allopathic medicine.[3] A large proportion of individuals choose some practices and products, believing their safety and efficacy is modest, compared to those in the aggregate.[3,4]

Patients report that traditional healers' fees may be negotiable as the method of payment is flexible (on credit or in exchange for labour); it may be contingent on outcome. This availability of outcome-contingent contracts, favours CAM to Western medicine.[5]

CAM and Traditional Medicine (TM) vary widely between countries. The World Health Organisation (WHO) published and summarised numerous surveys on their uses. TM is the sole source of health care available in developing countries, but only some privileged individuals have access to more modern medicine. In affluent countries, individuals select CAM approaches according to their cultures and beliefs.[3, 5, 6]

The WHO developed a strategy for TM and CAM, aiming to assist countries in developing national policies with evaluations and regulations. This was established to create stronger evidence, based on the safety, efficacy and quality of TM and CAM products and practices. This ensures availability and affordability of TM and CAM, including essential herbal medicine, whilst promoting the comprehensive use of TM and CAM by providers and consumers.[4]

Using CAM and TM is prevalent amongst patients, suffering from chronic, painful, debilitating or terminal conditions. The use in conditions, such as in human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS) and cancer is far higher than other conditions, ranging from 50% to 90% of cases.[6] Patients use CAM often with the assistance and guidance of THs in certain conditions, such as mental illness and impotence. Patients perceive it as requiring greater involvement for the extended family and kinship group.[5] The availability of financial support for treatments of these disorders is greater than for other illnesses, such as malaria or diarrhoea, when individuals seek conventional treatment. [5, 7]

Numerous CAM practices are not scientifically validated by medical authorities and are inadequately accepted. These practices include, Homoeopathic medicine, Western herbals, traditional Chinese medicine, Ayurvedic medicine, Unani tibb and

aroma therapeutic medicine.[8] The National Institute of Health (NIH), America, grouped them into five overlapping domains[8, 9]:

- *Biologically based practices:* These use a vast array of vitamins and mineral supplements, natural products, herbals, and unconventional diets.

- *Manipulative and body-based approaches:* These kinds of approaches appear throughout history and comprise: chiropractic massage ointments and osteopathic medicine.

- *Mind-body medicine:* Can include an array of approaches, incorporating mind and body behaviour in the sense of spiritual, meditative, and relaxation techniques (such as yoga).

- *Alternative medical systems:* The practice of acupuncture (asserts vital energy flow can be restored by placing needles at critical body points).

- *Energy medicine:* This approach uses therapies involving energy, such as biofield- or bio-electromagnetic-based interventions (Reiki therapy).

In South Africa, there is a statutory body, The Allied Health Professions Councils of South Africa (AHPCSA), established in terms of the Allied Health Professions Act, 63 of 1982 (the Act) in order to control all allied health professions which includes; Ayurveda, Chinese medicine, Acupuncture, Chiropractic, Homeopathy, Naturopathy, Osteopathy, Phytotherapy, Therapeutic aromatherapy, Therapeutic massage therapy, Therapeutic reflexology, and also Unani-Tibb.[10]

2.2 Safety aspect of complementary and alternatives medicine

The effects caused by the biodiversity of CAM and TM, indicate a major concern.[3,5] Over-harvesting of endangered species and the possible extinction of medicinal plants is a concern, not only in South Africa, but globally. Concerns remain for government authorities. These concerns include, poaching of American ginseng and black rhinoceros horn.[5]

Another issue that should be reviewed, is the quality control of materials used by THs. The control of ingredients and manufacturing procedures do not always meet the standards and requirements for their intended use. Manufacturing should be done according to Good Manufacturing Practise (GMP). Most herbal products vary between sources and batches, concerning their pureness of the component ingredients, respective amounts, and being adulterated by the presence of contaminants.[5]

Complications resulting in the incorrect use of traditional therapies, also indicate a pressing issue. The herb, Ma Huang (Ephedra), is traditionally used in China to treat short-term respiratory congestion. In the United States, the herb served as a dietary aid; long-term use led to several deaths, heart attacks and strokes.[11] In another instance in Belgium, the incorrect use of CAM, resulted in (at least) 70 patients requiring renal transplants or dialysis for interstitial fibrosis of the kidney, after consuming the wrong herb from the *Aristolochiaceae* family as a dietary aid.[7,11]

2.3 Regulations of complementary and alternatives medicine

Regulation and control of medicine is not an option but an imperative for national health programmes. CAM regulations should assist in minimising the risks of unproven medical claims with the misuse of certain traditional therapies. In South Africa, the regulations surrounding CAM and TM, significantly progressed into the legislative framework for health practitioners. Amendments to the Medicine and Related Substances Act, 1965 (Act No. 101 of 1965), as outlined by the DoH and old Medicine Control Council (MCC), set new boundaries for CAM marketing and sales in South

Africa.[12]

The legislation, published into law on 15 November 2013, calls for certain standards to be met, using a phased-in approach for implementation. These standards, amongst others, include changes to label information on packages (by 15 February 2014) and registration of certain product groups with the old MCC (several dates and call-ups).[12] These standards relate to products falling within the CAM definition, as outlined by the DoH and old MCC.[13,14]

Most complementary medicine needs to be manufactured in an MCC-approved pharmaceutical plant. All complementary medicine importers, retailers, wholesalers, and marketers are required to obtain a licence to import and sell these products. Thousands of products are available in South Africa; these can be categorised as complementary medicine.[12] The legislative requirements for these practices of medicine fall within the definition of complementary medicine and should comply with the published legislation of 2013 and 2017. [14, 15,16] The CAM legislation also indicate an on-pack labelling requirement, differing from previous standards. Thus, the medication container should include the following:

A disclaimer on the label (until it is evaluated) to the effect of: "*This medicine has not been evaluated by the SAHPRA. This medicine is not intended to diagnose, treat, cure or prevent any disease*". Label information must also be supplied in a second language.[16]

- A Package Insert (PI) providing information about the drug intended to use.
- A Patient Information Leaflet (PIL) with the following detailed information:
    - The category of medicine.
    - Its pharmacological classification.
    - Its discipline.

Brands and manufacturers should note the proof of their products' medical claims, divided into low-risk and a high-risk claim.[16,17]

The former MCC did not hold the statutory power to enforce the Medicine Act or the 'call-up for registration' of all CAMs. The authority resided only with the DoH,[13] however it was replaced by a new regulatory authority in 2016, entitled, the South African Health Products Regulatory Authority (SAHPRA), representing an upgraded version of the MCC who now has the power to enforce the Medicines Act as envisaged. It is described as similar in model to the US Food and Drug Administration (FDA). It is more independent than the MCC, falling outside of the DoH and funded only partly by the government.

The 2008 amendment also provided SAHPRA with the final authority to approve new products, medical devices or in-vitro diagnostics (IVDs), requiring the approval of the Minister of Health, resulting in significant time delays. This constraint placed the old MCC susceptible to political interference.[17]

2.4 Powers and functions of the South African Health Products Regulatory Authority (SAHPRA)

SAHPRA, like the MCC, is an organ of state, making decisions and performing through its board of directors. It provides the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicine, scheduled substances, clinical trials and medical devices, IVDs and related matters in the public's interest.[12,18] SAHPRA's powers and duties include the following:

Concerning the registration of medical products, SAHPRA[18]:

- Determines medicine, medical devices or IVDs subject to registration.

- Grants, issues or rejects, applications for certificates of registration.
- Imposes conditions on certificates of registration.
- Publishes the separate registers for medicine, medical devices and IVDs on its website.
- Authorises any individual to sell a specified quantity of any product, medical device or an unregistered IVD.

Concerning packaging, SAHPRA approves container or package labels and authorises any deviations from the requirements.

Concerning licencing, SAHPRA holds the authority to grant and renew licences to manufacture or act as a wholesaler or distributor of any medicine, scheduled substance, medical device or an IVD. SAHPRA holds a broad mandate in the public interest.[16,18]

According to Dr. Joey Gouws [14], the registrar of the former MCC, in the legislative update and status of SAHPRA, guidance to meet regulators' expectations and regulations to control CAM, should occur from 2014 to 2019. [12,14] SAHPRA should implement the updated and extended legal regimes, regulating all medicine, medical devices, IVDs, complementary medicine, cosmetics, and foodstuffs.

2.4.1 SAHPRA New Regulations

Further, SAHPRA's mandate has expanded to include the regulation and control of radiation, emitting devices, and radioactive nucleotides into the scope of authorities appearing in the Medicines Act and Hazardous Substances Act, 1973(Act No. 15 of 1973). Another regulation (40) on Implementation of good vigilance practise standards and quality management system for vigilance activities; the regulation of biological products biosimilars, and medical devices *ad hoc* inspections to comply with the South African National Accreditation System (SANAS) and other conformity assessment body with standards i.e. ISO13485.[10,18]

- **Implementation of regulatory draft framework for complementary medicines**

What are Complementary medicines?

According to the SAHPRA, complementary medicines (CMs) are non- indigenous disciplines. The terms 'complementary medicines' or 'alternative medicine' are used interchangeably with traditional medicines in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system. (Integrative medicines).[12]

SAHPRA general regulations regarding the Medicines Act published on August 2017 is to allow an amendment to the CMs definition identifying 'health supplements' as an additional group of products falling within 'CMs definition', see Graph 1 below. These products will be reviewed over time and regulatory oversight regarding these types of medicines will be established. This new regulation along with current legislation, published into law on 15 November 2013, require all companies selling CMs to register with the regulatory body following the phase-in approach as per the call-up time line stipulated. According to the roadmap, all CMs must be submitted by 15 May 2019.[10,12]

There is a need to strengthen the understanding and culture regarding regulation

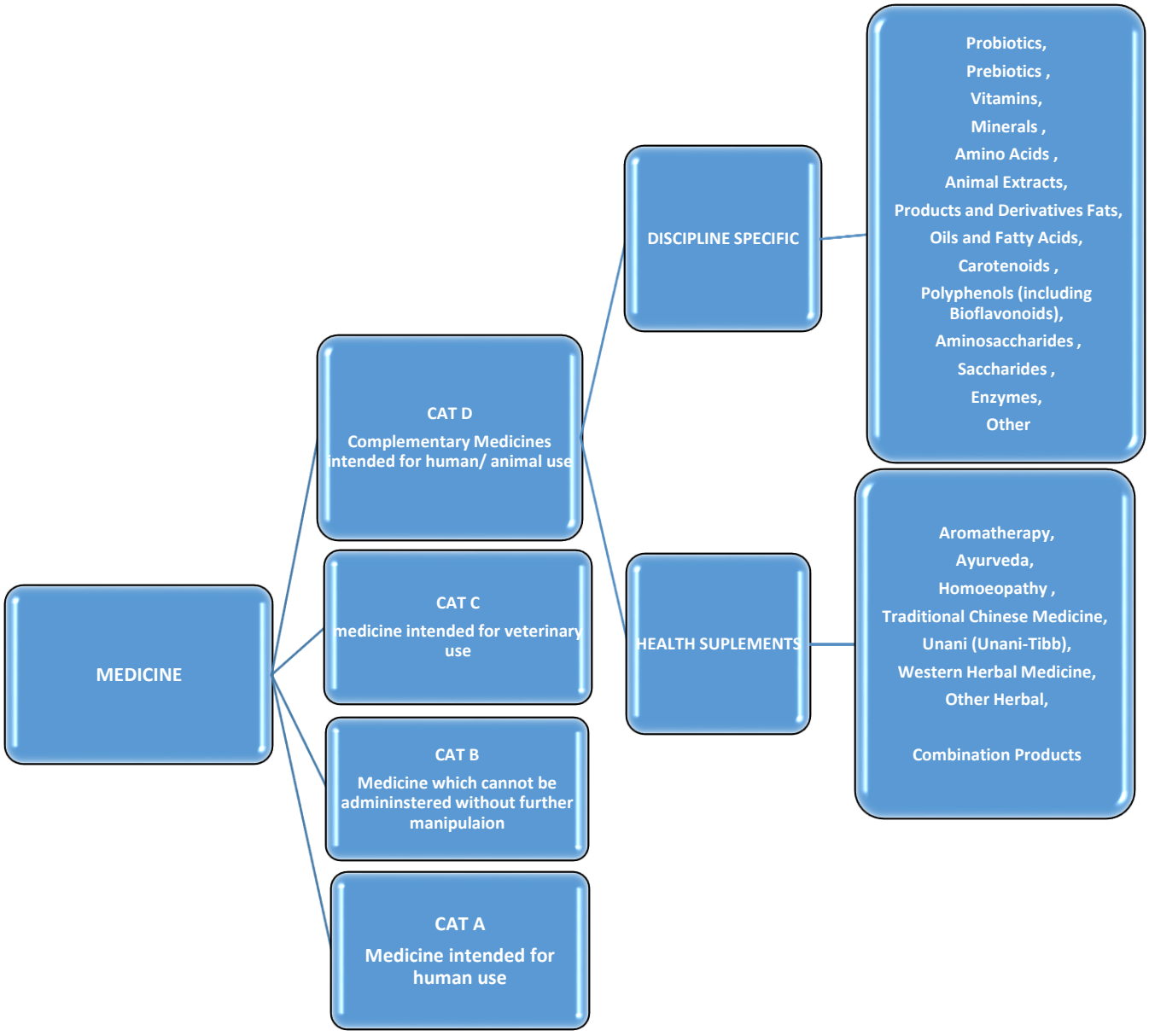
within the CM industry, since it is a previously unregulated industry. A forum under the industry task group (ITG) has been set up to engage the industry on dossier compilation and related regulatory requirements.

- **Implementation of regulation draft framework regarding African traditional medicines**

Traditional medicine or African traditional medicines (TM) is the sum or total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.[10]

SAHPRA also organised a working group to investigate regulation concerning African traditional medicines (ATMs) product for bulk sale. (i.e. not ATMs combined by an individual healer prescribed for a specific patient). This followed recommendations for CMs committee to council provision for regulations of ATMs. Draft level framework is still ongoing and includes dialogue with the African National Healer's association.[10]

GRAPH 1. Categorisation of medicines[10]



- **Health supplements or vitamins**

The categorization of medicines of SAHPRA, displays health supplements under category D. They are any substance, extract or mixture of substances as determined by the authority, sold in dosage forms or purported for use in restoring, correcting or modifying any physical or mental state by complementary health, supplementing the diet or nutritional effect. These exclude injectable preparations, medications or substances as schedule 1 or higher in the Act.[10]

In SAHPRA, vitamins fall under the 'discipline specific' subcategory of Category D CMs. They are organic molecules that are essential nutrients and cannot be synthetized in the organism. Therefore, vitamins must be obtained through a diet.[10,19]

The CAM regulations have to overcome many obstacles, the ethical considerations also appear to be causing challenges,[15] such as the principle of non-maleficence guiding individuals to 'no harm' when their actions can affect others; the principle of beneficence directing individuals to convey goods to others, whenever possible; the principle of respect of personal autonomy, requiring individuals to respect the choice and actions of others when acting voluntary, adequately understanding the information available and justice principles. This requires a fair distribution of resources or opportunities to access resources and fair compensation for harm and wrongdoing. THs express certain concerns, such as formulating the common technical document (CTD) dossiers needed for evaluation and registration of CAM therapies, concerning the active ingredients.[15]

The licencing of manufacturers, suppliers or wholesalers and the registration of each proposed site or facility involved in the production, are also alluded to. Inspection of these facilities would be difficult even if it were at a lower standard or expectation than

required for allopathic medicine.[18] The CAM industry claims that it could destroy the industry innovation and expansion and might have negative ramifications on the economy and employment market.[15, 22]

2.5 Traditional healers and training

In South Africa, THs are known as, amongst others, *inyangas* (herbalist), I*sangomas* (diviners), and *witch-doctors,* forming a crucial part in providing health care to most South Africans.[5] *Isangomas* are spiritual healers with the majority being women. They ask individuals and family many questions and may also throw bones, shells or other objects for diagnosis. The way they connect with the ancestors is to throw the bones. i.e each bone has a meaning, representing a patient's life. *Inyangas* means trees in Zulu, are healers that make medicine from herbs, roots and bark. Ground up rocks, animal horns and bones can also be used to make their medicines. After patients are diagnosed, *inyangas* go to the bushes to find specific plants necessary for healing (herbs and roots called *Muti*). These medications can be bought in markets as well as directly from *inyangas*.[5,21,23] THs of South Africa are deeply involved in the cultural and spiritual life, especially in the rural areas, consulting up to 80% of the population.[5, 23] THs believe that they are called by ancestors. Regulating THs is under the auspices of the Health Service Professions Act of 1982, as amended. Qualified THs are registered with the Traditional Healers' Organisation and are provided with a certificate of competence, stating that they are qualified healers. They are recognised as South Africa health practitioners under the Traditional Health Practitioners Act of 2007.

These qualifications are valid in Africa, Asia, Latin America, Europe, and Australia.[5] An inconvenient situation found in countries, such as South Africa, is the uncertainty that THs hold a degree, diploma, or certificate, demonstrating sufficient proficiency in traditional healing as the knowledge they gained, was passed from generation to generation. Countries, such as Argentina, Bolivia, France and China differ on the uncertainty. Those holding a degree are more regulated and trained in the CAM domain.[5, 6]

It is also well known that THs and TMs are marginalised. Their value to communities is underestimated. The entire population does not use conventional medicine; a need emerges for urgent investment and support of THs and TMs. Such investment should not only be implemented by government, but also by civil society and the private sector.[2]

Some THs and users of TMs agree that a need exists to regulate the system and to initiate traditional healer associations' nationally.[24] The Traditional Health Organisation (THO) ensures that all its members endorse human rights principles and frameworks in their dealings within the profession. The THO comprises 200 traditional health practitioner organisations or associations in South Africa.[5, 25] Depending on the strength and registration criteria, some range from 10 to 1000 members.

2.6 Diabetes Mellitus and Complementary and Alternative Medicine

DM is a chronic disease affecting glucose metabolism that could lead to serious health concerns such as reduction in physical activity and sleep disturbances with many chronic complications, including blindness, heart disease, and renal failure if not managed appropriately. DM is considered to be a metabolic disorder that mainly occurs due to defects in either insulin secretion, insulin action, or both. It is associated with abnormal elevated levels of glucose in the blood. Normally, the pancreas produces insulin and it is responsible for lowering the blood glucose concentration. [26, 27] Insulin resistance play a major pathophysiological role in type 2 diabetes ad it is highly associated with major health problems including obesity, hypertension, coronary artery diseases, dyslipidaemias and cluster of metabolic and cardiovascular abnormalities defining he metabolic syndrome.[28] The absence or insufficient production, of or resistance to the action of insulin, causes DM.

Three types of diabetes are differentiated: Type 1, Type 2 and gestational diabetes.[27] Patients with Type 1 diabetes produce little or no insulin and are referred to as insulin-dependent. Patients with Type 2 diabetes do not respond normally to insulin due to

insulin resistance and are referred to as non-insulin-dependent diabetes. Approximately 90% to 95% of patients with diabetes are diagnosed with Type 2 diabetes whereas only 5% are diagnosed with Type 1 diabetes. Type 1 diabetes is usually diagnosed in childhood and requires insulin treatment. Type 2 diabetes is mostly diagnosed in adults aged between 45 and 64. Gestational diabetes affects only pregnant women and usually disappears after they give birth.[27, 29, 30]

Physicians would use the following laboratory tests to aid in diagnosing diabetes mellitus[27-31]:

- **Random glucose test**: blood glucose levels determined from a non-fasting subject; a glucose level of 200mg/dl (11.1mmol/l) or higher will suggest diabetes
- **Fasting blood sugar (FBS):** blood glucose levels determined after 8 hours of fasting; a fasting blood glucose level from 70 to 100 mg/dL (3.9 to 5.5 mmol/l) is considered normal. 100 to 125 mg/dL (5.6 to 6,9 mmol/L) is considered as prediabetes
- **Glucose tolerance test (GTT):** measures the body response to a glucose challenge. The patient is asked to fast for 10-12 hours and then receives a 75g glucose containing drink and plasma glucose levels measured base-line, time 0, time 2 hours post glucose drink and so on. For 1-hour GTT, glucose level below 180mg/ dL (10 mmol/l) is considered normal; for 2 hours, glucose level below 140 mg/ dL (7.8 mmol/l) is normal and between 140 mg/ dL and 200mg/ dL (11.1mmol/l) indicate impaired glucose tolerance. Above 200mg/ dL at 2 hours confirm a diagnosis of diabetes.
- **Postprandial glucose**: test blood glucose levels determined 2 hours after eating. Glucose level under 140 mg/ dL (7.8 mmol/l) and pre-prandial plasma glucose between 90-130mg/dL (5-7.2mmol/l) is normal. Higher values indicate diabetes.

Glycated haemoglobin (HbA1C) is another test that assists in assessing the patients long-term (3 months) glycaemic control; it indicates the average amount of red blood cells that are glycated for the past three months. HbA1C comprises of haemoglobin A1C, a protein within red blood cells and which transports oxygen throughout the body that joins with glucose becoming ‘glycated’. For persons without diabetes, normal range for glycation is between 4% and 5.6%. Meaning 4%-5.6% of RBCs are glycated. If the HbA1C is between 5.7% and 6.4% it will be considered as prediabetes. Whereas HbA1C higher than 6.5%, indicates the individual has diabetes. For people with diabetes this is important as the higher HbA1c level, the greater the risk of developing diabetes and related complications. Also, it gives a perspective on the glycaemic control of such patient and their compliance to taking treatment and adhering to counselling.

- **Measurement of insulin sensitivity/resistance**

Insulin resistance is a troublesome which commonly aggravates the metabolic system. Many methods and indices are available for the estimation of insulin resistance. It is essential to test and validate its reliability before Insulin resistance can be used as an investigation in patients. The ‘hyperinsulinemic euglycemic clamp’ and the ‘intravenous glucose tolerance test’ are currently used as a referencing standard. Some simple methods from which indices can be derived have been validated. These include homeostasis model assessment (HOMA), and quantitative sensitivity check index (QUICKI). For clinical uses, HOMA-insulin resistance, QUICKI and Matsuda are suitable while HES, Belfiore, Cederholm, Avignon and Stumvoll indexes are suitable for research purposes. The review guideline tables below give great incite to clinicians before performing the studies.[28]

Table 1. Guidelines for insulin sensitivity/resistance for clinical purpose[28]

Method	Formula	Normal level	Advantage	Disadvantage	Correlation coefficients with HEC
HOMA-IR	$(I_0 \times G_0)/22.5$	<2.5	Simple, minimally invasive, predicts fasting steady-state G and I levels	Insulin sensitivity in subjects treated with insulin needs further validation	Normal glucose tolerance (0.65; $P<0.0001$), impaired glucose tolerance (0.56; $P<0.0001$) and with type 2diabetes (0.51; $P<0.0001$)
QUICKI	$1/\left[\log(I\mu U/mL) + \log(G\,mg/dl)\right]$	0.382±0.007 for nonobese, 0.331±0.010 for obese and 0.304±0.007 for diabetic individuals	Consistent, precise index of insulin sensitivity, minimally invasive	Normal range to be established for each laboratory due to significant inter laboratory variations in insulin assay	Correlation coefficient 0.78; $P<2 \times 10^{-12}$
Matsuda index	$10{,}000/\sqrt{(\text{fasting G} \times \text{fasting I})(\text{mean G} \times \text{mean I})}$	<4.3 predict IR	Represents both hepatic and peripheral tissue sensitivity to insulin	Its correlation is very weak in diabetic patients	0.73 ($P<0.0001$) in subjects with normal glucose tolerance, 0.66 ($P<0.0001$) in subjects with impaired glucose tolerance, and 0.60 ($P<0.0005$) in nondiabetic subjects, and in subjects with type 2 diabetes mellitus the correlation proved to be weaker 0.54 ($P<0.0001$)

HEC: Hyperinsulinemic euglycemic clamp, HOMA-IR: Homeostasis model assessment-insulin resistance, QUICKI: Quantitative insulin sensitivity check index

Table 2. Guidelines for insulin sensitivity/resistance for research purpose[28]

Method	Formula	Normal level	Advantage	Disadvantage	Correlation coefficients with HEC
Hyperinsulinemic euglycemic glucose clamp	$ISI_{HEC}=MCR/I_{mean}$ $MCR=M_{mean}/(G_{mean}\times 0.18)$	Clamp performed at 80 mU/m² min, a cutoff of 5.3 mg/kg FFM+ 17.7 z min (98% prediction probability) for IR	Direct measure of insulin under steady-state conditions	Laborious, involves intra venous infusion of insulin, frequent blood sampling	Gold standard method for quantifying insulin sensitivity
McAuley index	$e(2{,}63-0{,}28 \ln(I_0)-0{,}31 \ln(TAG_0)$	<5.8	The combination of fasting insulin (mIU/l) and triglycerides (TAG, mmol/l) showed the best pre-diction of IR	Robust method, suitable for epidemiological studies	≤0.63 in diabetic patients
Belfiore index	$2/ISI_{Belfiore}=\frac{G_s}{G_N}\times\frac{I_s}{I_N}+1$	Values above 1.27 indicate pathological IR	Showed normal value for basal glucose and insulin concentrations and for mean nor-mal value for glucose and insulin areas during OGTT	Multiple blood sampling	0.65; $P<0.01$ in subjects with normal glucose tolerance, 0.54; $P<0.01$ in subjects with impaired glucose tolerance, and 0.48; $P<0.01$ in subjects with diabetes type 2
Avignon index	$Sib = 10^8/\left(\frac{I_0\,(mU/l)\times G_0}{(mmol/l)\times VD}\right)$ $Si2h = 10^8/\left(\frac{I_{120}\,(mU/l)\times G_{120}}{(mmol/l)\times VD}\right)$	-	Determines glucose tolerance and insulin sensitivity in single test	Its correlation is very weak in diabetic patients	Normal glucose tolerance (0.89; $P\leq0.0001$), with impaired glucose tolerance (0.96; $P\leq0.0001$), and in patients with diabetes mellitus type 2 (0.69-0.83; $P\leq0.05$)
Stumvoll index	$0.156-0.0000459\times I_{120}\,(pmol/L)$ $-0.00032\times I_0\,(pmol/L)$ $-0.0054\times G_{120}\,(mmol/L)$	-	Utilizes demographic data like age, sex and BMI along with plasma glucose and insulin to predict insulin sensitivity	Very robust and weekly correlate in diabetic patients	Correlation coefficients with HEC were in the range between 0.62 and 0.79 ($P<0.001$)
Gutt index	$75{,}000+(G_0-G_{120})\ (mg/dl)$ $\times 0.19\times BW/120\times G_{mean}$ $(0,\ 120)\ (mmol/L)\times Log$ $\left[I_{mean}\,(0,\ 120)\right]\ (mU/L)$	<45 predict IR	Good to predict onset of type 2 diabetes	Suitable for epidemiological studies	Correlation coefficients with HEC 0.63; $P<0.001$

BW: Body weight, HEC: Hyperinsulinemic euglycemic clamp, BMI: Basal metabolic rate, OGTT: Oral glucose tolerance test, TAG: Triglycerides, IR: Insulin resistance, FEM: Fat-free mass, ISI: Insulin sensitivity index, MCR: Metabolic clearance rate. HEC – I_{mean}: Average steady state plasma insulin response (μIU/ml), M_{mean}: Metabolized glucose expressed as average steady state glucose infusion rate per kg of BW (mg/kg/min), G_{mean}: Average steady state blood glucose concentration (mmol/l), 0.18: Conversion factor to transform blood glucose concentration from mmol/l into mg/ml. HOMA-IR – I_0: Fasting insulin (mIU/l), G_0: Fasting glucose (mmol/l) concentration. QUICKI – I_0: Fasting insulin (mIU/l), G_0: Fasting glucose (mmol/l) concentration. McAuley index – I_0: Fasting insulin (mIU/l), TAG: Fasting triglyceride concentration. Matsuda index – I_0: Fasting plasma insulin concentration (mIU/l), G_0: Fasting plasma glucose concentration (mg/dl), G_{mean}: Mean plasma glucose concentration during OGTT (mg/dl), I_{mean}: Mean plasma insulin concentration during OGTT (mU/l), 10,000: Simplifying constant to get numbers from 0 to 12. Belfiore index – G_s, G_N: Plasma glucose concentrations expressed as fasting values or as areas obtained during a standard OGTT at 0 and 2 h (0–2h areas are equal to $G_{s,N}=G_0+G_{120}$) or at 0, 1 and 2 h (0-2h areas are equal to $G_{s,N}$). Avignon index: I and G represent the plasma concentrations of insulin (mIU/l) and glucose (mmol/l) respectively, VD is the glucose distribution volume calculated using a mono compartmental model: VD= 150 ml/kg of BW. Stumvoll index: Fasting insulin (mIU/l), G_0: Fasting glucose (mmol/l) concentration. Gutt index – I_0: Fasting plasma insulin concentration (mIU/l), G_0: Fasting plasma glucose concentration (mg/dl), G_{mean}: Mean plasma glucose concentration during OGTT (mg/dl), I_{mean}: Mean plasma insulin concentration during OGTT (mU/l)

- **Complementary medicines for diabetes mellitus**

Plant/herbs and dietary supplements are globally some of the most used CAM therapies for diabetes patients. Researchers studied different CAMs, used by patients to treat diabetes. Although some of these therapies are found to be effective in patients, some have not, and may even be dangerous. Researchers need to evaluate GMP of these therapies. This would assist patients to manage diabetes or lower the risk of developing DM.[31]

Plant based vs herbal medicines

It is very important to differentiate between the plant based and herbal based medicines.

Plants are a general group of living organisms belonging to the plant kingdom that lack the power of movement and can produce its own food. The lifespan depends on the group of plant but can grow both on earth and water. They are divided into two major groups based on reproductive (flowering and non-flowering plants). They are commonly used for leisure activities, aesthetic value and building and medical purposes.[32,33]

An herb is a type of soft plant with no little or no linin. It has herbaceous habits (herb, shrub, tree, climber and liana) that can have a much shorter lifespan and are divided into three categories depending on time of flowering (annuals, perennials and biennials). They are commonly used for cooking, beauty treatments, and aromatic and medical purposes.[33,34]

Medicinal plants can be considered as herbal plants but not all herbal plants can be considered medicinal plants. A list of plant/herbs followed by dietary supplements for the treatment of DM is summarised below; and will specify that which is used in the Republic of South Africa.

Botanical/plant products[7, 26,32]**:**

- *Allium sativum* (garlic) lowers total cholesterol levels and blood sugar levels.
- *Aloe vera* orally taken, assists to lower the fasting blood sugar.
- *Coccinia indica (ivy gourd)*. *Ayurveda* increases insulin mimetic.
- *Gymnema sylvestre (gymnema)* indicates blood sugar-lowering effects.
- *Momordica charantia* (bitter melon) may reduce blood glucose by decreasing hepatic glucose production, increasing hepatic glycogen synthesis and insulin mimetic activity.
- *Opuntia streptacantha* (prickly pear cactus, nopal) are used for glucose control.
- Panex ginseng, *P. quiquefolius* (ginseng*)* glucose-lowering effects in fasting and post-prandial (after meal) blood glucose levels and in HbA1C, using the root of this herb.
- *Trigonella foenum graecum* (fenugreek*)* decreases carbohydrate absorption and increases insulin secretion. [7, 26]

Plants with *in vivo* antidiabetic activities[26]**:**

These plants are mostly used for their antidiabetic properties.

- *Vernonia amygdalina Del. (Asteraceae)* the leaves may be consumed either as a vegetable or aqueous extract as tonics for the treatment of various illnesses
- *Hypoxis hemerocallidea Fisch. (Hypoxidaceae)*
- *Catharanthus roseus (L) G. Don (Apocynaceae)* lower blood glucose levels.
- *Leonotis leonurus L. (Lamiaceae)*
- Catha edulis Forrsk. Ex Endl. (Celastraceae).
- *Momordica foetida Schumach. (Cucurbitaceae)*. With antilipogenic activities.

- *Sclerocarya birrea (A. rich.) (Anacardiaceae)* improves glucose tolerance, reno- and cardio-protective effects in diabetics.
- *Psidium guajava Linn. (Myrtaceae)* exhibits significant hypoglycaemic activities.
- *Sutherlandia frutescens Linn. (Fabacea*e) with anti-inflammatoryproperties

Dietary supplements including[26]:

- Alpha lipoic acid (ALA). Improves insulin sensitivity, reduces nerve damage related to diabetes (diabetic neuropathy); improves the body's ability to use insulin
- Chromium. Facilitates glucose metabolism. Chromium is needed to create a glucose tolerance factor, assisting insulin; improving its action, improved HbA1C (A1C) levels.
- Magnesium. It is essential for the body's ability to process glucose. Magnesium deficiency may increase the risk of developing diabetes.
- Vanadium. Normalises blood glucose levels in animals with Type 1 and Type 2 diabetes.
- Omega-3 fatty acids. Decrease insulin resistance.

Complementary and Alternative supplements[26]:

- Vitamin D and calcium combined lower the risk of developing Type 2 diabetes.
- Natto roots.
- Momordica balsamina.
- Caju bark.
- Artemisia.
- Afra Tincture.

Regulations surrounding the registration and pharmacovigilance of CAM, need a solution. This will assist the SAHPRA in controlling the registration of these substances.

3. CHAPTER 3: AIM AND OBJECTIVES

3.1 Study aim

This study aimed to investigate how Traditional healers diagnose and treat DM and whether DM CAM therapies comply with the regulations as envisaged by SAHPRA.

3.2 Study objectives

The study objectives aimed to:

- Provide an overview and perspective on the diagnosis of diabetes by THs in the Mamelodi area, Pretoria.
- Provide a list of CAM therapies used in the treatment of diabetes by THs in the Mamelodi area in Pretoria.
- Provide a list of CAMs, used to treat DM, provided by pharmacies in the Mamelodi area, Pretoria.
- Analyse how these purported treatments comply with the SAHPRA regulations.

4. CHAPTER 4: METHODS

4.1 Study design

The study was quantitative, exploring descriptive study design, based on investigating CAM therapies amongst diabetic patients in Mamelodi area of Pretoria. Questionnaires were distributed amongst THs to establish how they diagnose diabetes and how their CAM is sourced and prescribed to their patients. Their knowledge on safety, quality control and post-marketing surveillance was considered. Pharmacies and health shops were also assessed using a non-structured survey to identify CAM therapies on their shelves, comparing them to THs therapies and their compliance with SAHPRA regulations.

4.2 Study setting, population and sampling

Mamelodi area, part of the city of Tshwane metropolitan municipality, is a township northeast of Pretoria, Gauteng South Africa with first language being Sotho and Zulu.[35] The informed consent was elaborated on, explaining the questionnaires, which was then distributed amongst THs. These were available in three languages; English, Zulu and Northern Sotho/Sepedi. It was administered and supervised with the guidance of THs and other volunteers, skilled in these languages. Questionnaires required five minutes for completion. Compensation was not offered, as participation was voluntary.

After receiving ethical approval from the Ethics Committee in the Faculty of Health sciences, permission from the Mamelodi-Ring leader of THs were sought, to meet with CAM practitioners. During the investigation, 78 THs were approached in the Mamelodi area in Pretoria. Workshops were organised at the Stanza Bopape Clinic. 2 THs who were competent (i.e. with adequate language and skills knowledge to translate the questionnaires as required) and consented to assist with the study.

Selected health shops, pharmacies and other targeted sites, as suggested by the TH-Ring leader of Mamelodi area Pretoria, were visited to discern whether they stock TMs, and then proceeded in identifying those used to treat DM. This was non-probability or

convenience sampling. The questionnaires were distributed among THs who attended the workshop. There was no complete list of THs of Mamelodi. No representation to or by the pharmacist or retailer was indicated; the retailers were not recognised as respondents in the protocol. A data overview was formed, based on the knowledge obtained. This information was collated in a structured manner, ensuring that useful descriptive data was gathered. It was further assessed for compliance (or the extent thereof), according to the requirements of CAM regulations. The research targeted 10 sites.

4.3 Measurements and data collection

This investigation aimed to identify the type of assessment tools used by THs to DM. Their knowledge on CAMs safety, quality control and pharmacovigilance, was also investigated to determining their compliance with the new SAHPRA regulations.

The estimated time line for the project was 1 month. Permission was required from the participants who completed the questionnaires. They were informed that the information would only be used for research purposes; their details remain anonymous. The research team was available to address any questions they might have had concerning the questionnaire to enhance reliability of questionnaires. The rationale for using this was because of the possibility of some participant not being literate with English and facilitate respondents' comprehension of questions. The participants' completed designed questionnaires based on the literature review. The questionnaires were both open-ended and close ended questions. They were compiled, discussed and implemented with researcher's supervisor and a statistician. There was no major problem occurring during completion and collection of questionnaires.

4.4 Variables

In the questionnaires addressed to THs, possible variables might be found on the

various CAM names and plants/herbs. The Mamelodi greater area TH Ring Leader agreed to assist in interpreting and providing perspective in using various names for the same types of ingredients. The assessment instrument and methods that they use to treat their patients could be the same, as the THs originate from the same area, with a similar education level and beliefs. Questionnaires validation was compromised because of non-random or convenient sample (THs that happened to come during the workshops were not all the THs from Mamelodi, no census or list of Mamelodi THs). The THs introduced bias, as the possibility exists that they might not have been truthful with their responses in the questionnaires. Information obtained from pharmacies shelves regarding CAMs labelling was reliable, based on discretion of the research. Bias may still occur as they might not have been all possible CAMs stocks on the market at the moment of the investigation. The non-validated questionnaires scale was measured to check internal consistency on the nature and purpose of the study.

4.5 Data management and statistical analysis

All questionnaires were perused for completeness and all the data was recorded on a Microsoft Excel spread sheet which were used for data analysis. These questionnaires were more of a data collection sheet. The statistical analysis was descriptive. The percentage were mostly used to describe and summarize the data. Responses to the closed ended questions were summarised through frequency counts and percentage calculations. Data were summarised in visual figures in an easily understandable presentation. The statistician performed all descriptive quantitative analysis. The consistency of questionnaire was tested using Cronbach's alpha test. The Alfa score was a negative value of 1.467 as indeed most of the items in the questionnaires were not correlated with one another. The research data and documents are stored for a minimum period of 15 years from the commencement of this study, at the following address: Basic Medical Sciences Building, 6th floor, 9 Bophelo Road, Prinshof Campus, Pretoria, 0001. Results were submitted for peer review and publication.

5. CHAPTER 5: ETHICAL AND LEGAL CONSIDERATIONS

Ethical approval was obtained from the Research Ethics Committee of the Faculty of Health Sciences at the University of Pretoria. The information obtained, was anonymously reported, in such a manner that no person was identified. Participation in this study was voluntary. Participants could refuse to participate or withdraw at any time without providing a reason.

A standard consent form, modified according to the objectives of this study, was distributed to each participant in their choice of language. Participants were not reimbursed for their efforts. This study was the first of its kind, by the Department of Pharmacology, contributing to drug regulatory affairs and registration of medication at the SAHPRA.

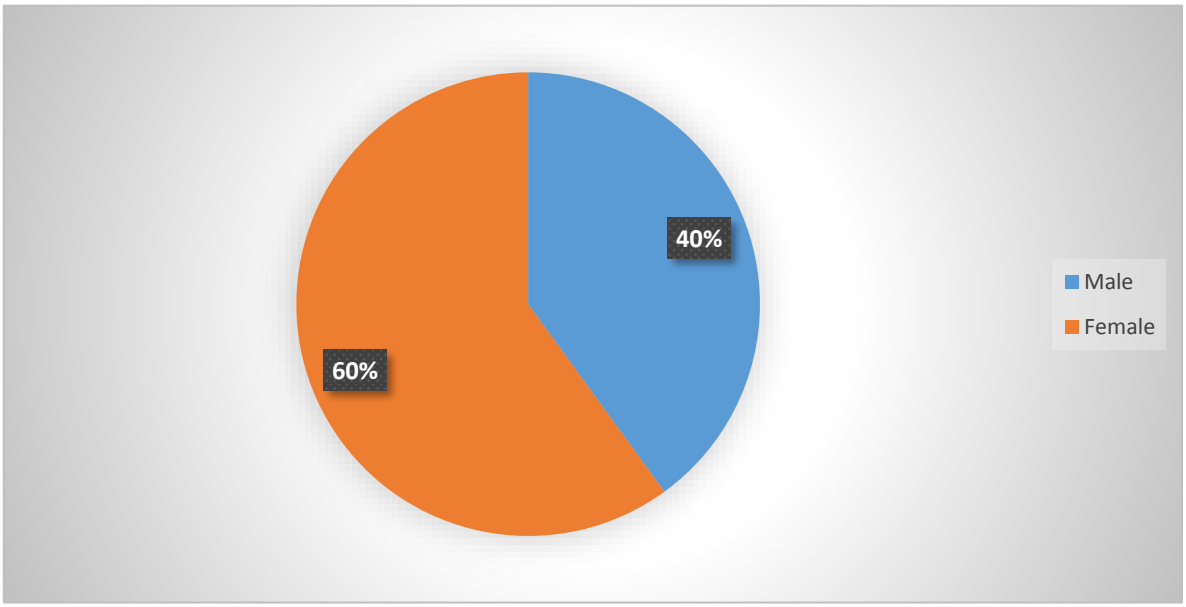
6. CHAPTER 6: RESULTS

The THs' questionnaires from the Mamelodi area is presented according to category which are as follows: THs demographic data, THs qualifications, THs experience, THs source of complementary and alternative medicines, percentage of THs who had patients with diabetes mellitus, the detail of purported treatment used by THs, THs feedback obtained from patients, the treatment efficacy assessment by THs, the THs complementary and alternative medicine regulatory analysis followed by the list of vitamins and supplements obtained from THs, referral treatment of DM, and those provided over the counter (OTC) medications in health shops (Table 6.1 and 6.2).

6.1 Traditional healer demographic data

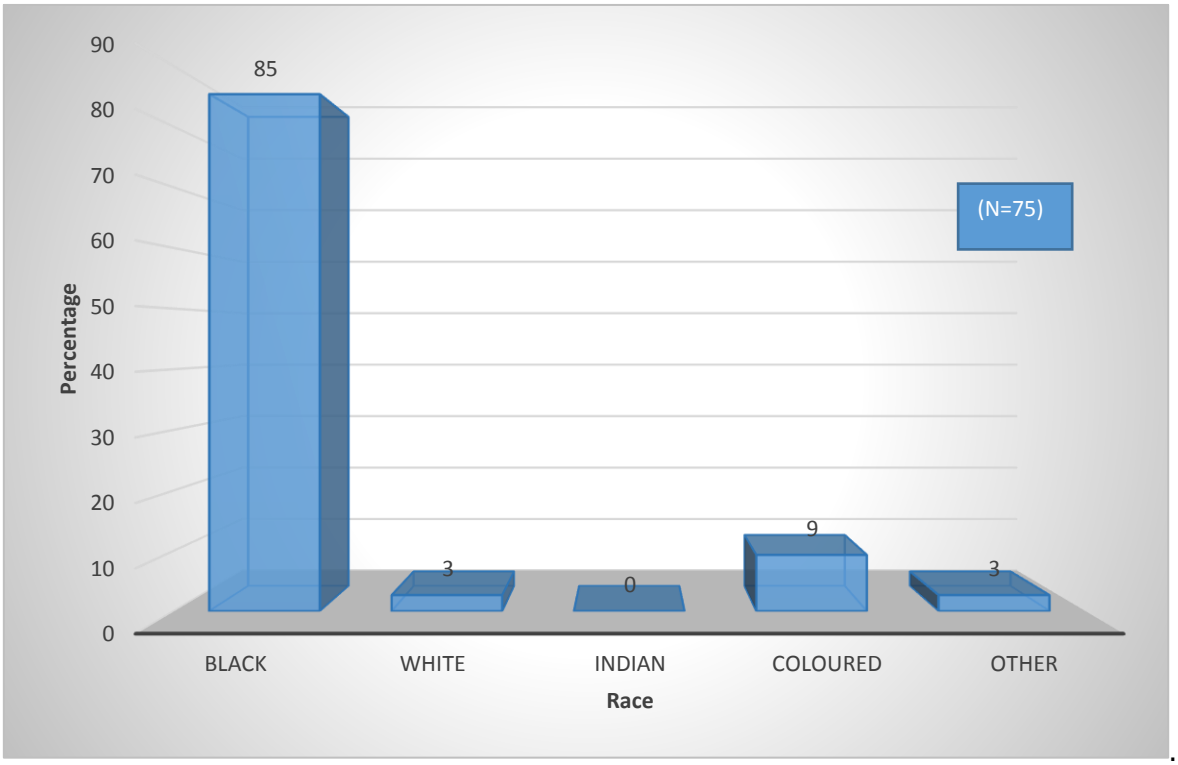
According to the 75 questionnaires administered to the TH's, 60 %(45) were females being the majority of TH's, and 40 %(30) were males (Fig 6.1.1). The female was found to have influence of practise in traditional medicine.

Figure 6.1.1: Gender of traditional healers



The race of THs that were interviewed can be divided as follows: 64 (85%) of the traditional healers were from the black population, this was also based on calculations, the modal age of TH whole group, 2 (3%) of them were whites, 7(9%) coloured and no one from the Indian population. Two (3%) of the THs indicated 'Other' as a race category (Fig 6.1.2)

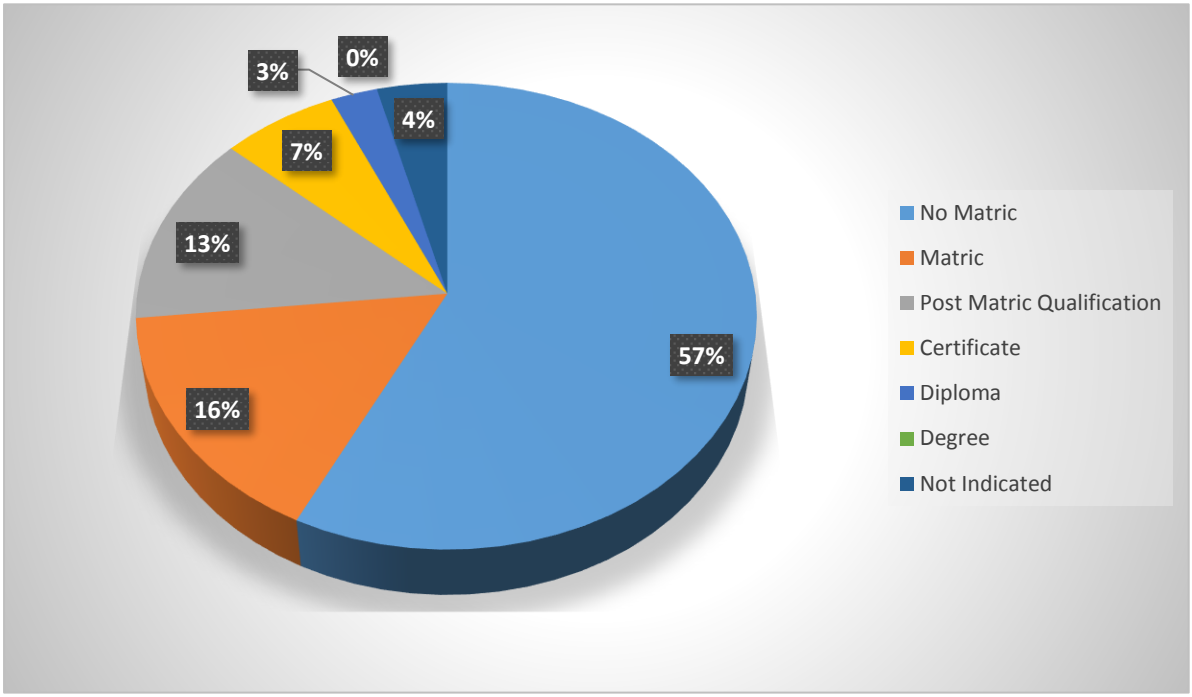
Figure 6.1.2: Race of traditional healers



6.2 Traditional healers' qualifications

Qualifications ranged from 'not indicated' to 'university degrees'. Only 2 (3%) of the Traditional Healers were recorded holding an academic degree and 3 (4%) Traditional Healers did not indicate any level of education. There were 5 (7%), Traditional Healers with a certificate, 10(13%) Traditional healers holding a post matric qualification (those are qualifications other than a certificate, degree or diploma). 43 (57%) of Traditional healers had no matric. Lastly 12 (16%) Traditional healers had a matric certificate (Fig 6.2.1). On analysis of level education, this was found to have a significant influence on CAMS practice.

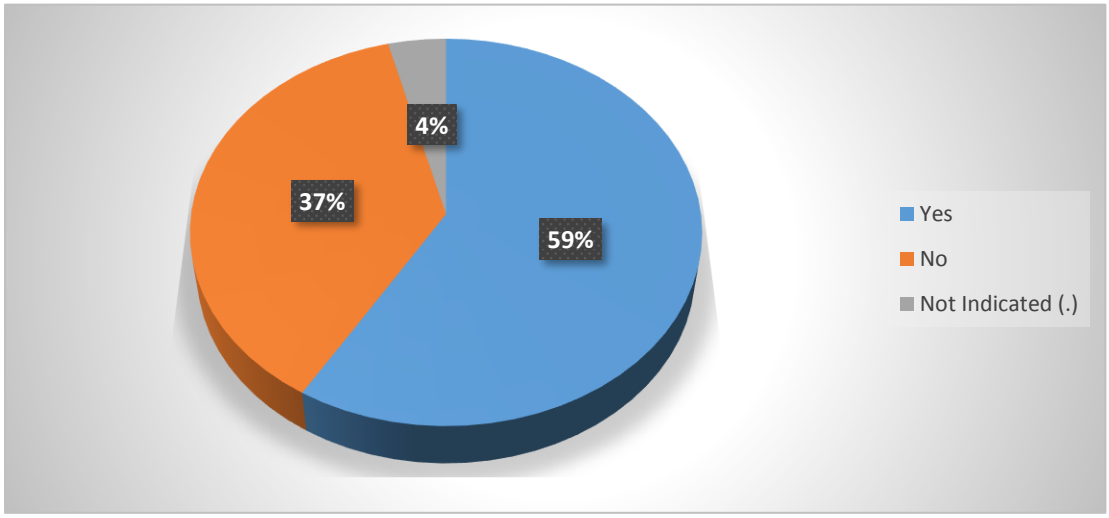
Figure 6.2.1: Traditional healers' education level



Courses relating to diabetes for Traditional healing ranged from formal to informal. 3 (4%) traditional healers did not indicate a response on the course attended to treat diabetes. 28 (37%) traditional healers did not attend any formal course on how to manage diabetes mellitus.

The remaining of 44(59%) traditional healers indicated they attended formal courses on how to treat patients; these were non-specific formal courses; it is suspected that they were rather trained by elders this then being considered as 'formal' (Fig 6.2.2).

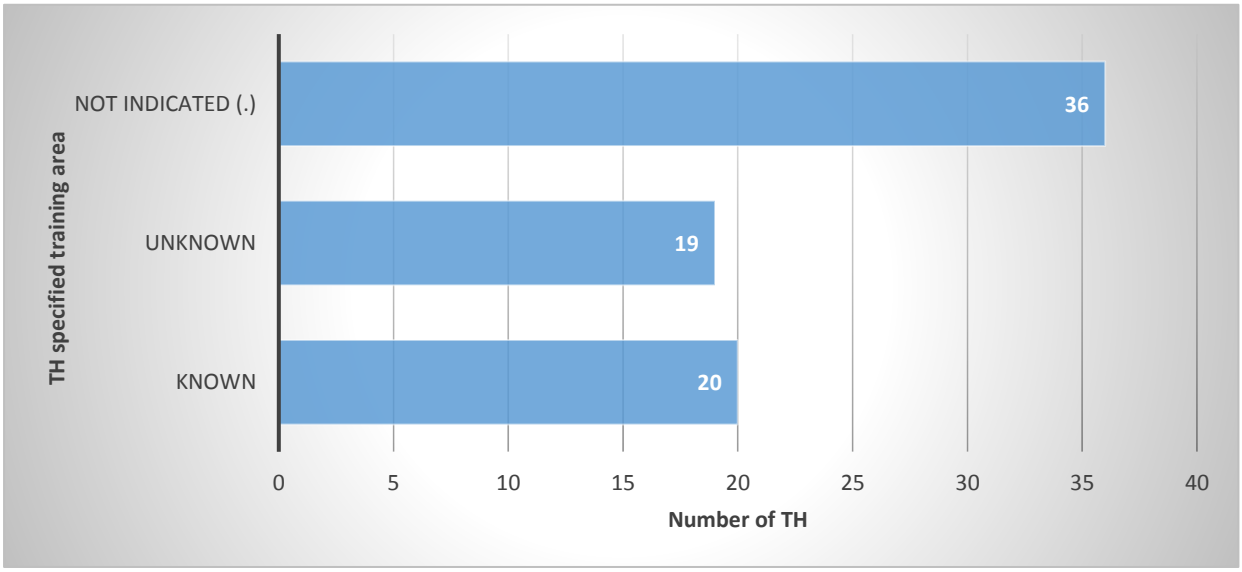
Figure 6.2.2: Indication of Traditional Healers who had attended courses related to DM



Areas where formal training for TH's are available were varied. 19 (25%) traditional healers did not mention the specific institution or area. 20 (27%) traditional healers specified the training course area, which included Mamelodi extension 5, Pelindaba, Atteridgeville, Giyani, Hammanskraal and Bela-Bela. The remaining 36 (45%) traditional healers again did not indicate any response.

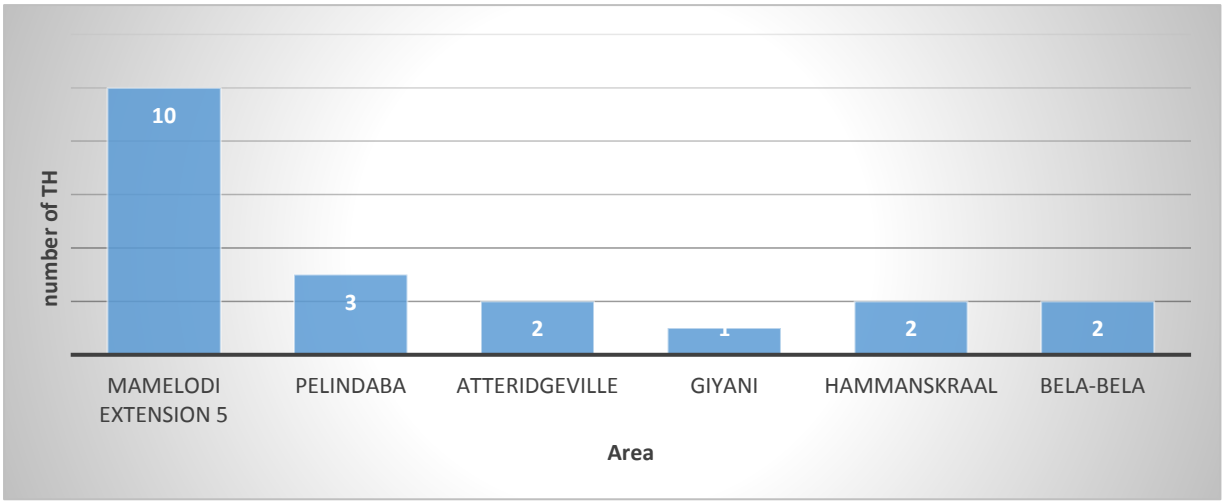
In the entire questionnaire, there were only 4 traditional healers who held a ‘Gauteng traditional and Faith medical practitioner’s certificate’ (Fig 6.2.3)

Figure 6.2.3: TH specified training area*



* Area: Training courses were attended in various parts of Pretoria and Limpopo, such as Mamelodi Extension 5, Pelindaba, Atteridgeville, Giyani, Hammanskraal and Bela-Bela. (Fig 6.2.4)

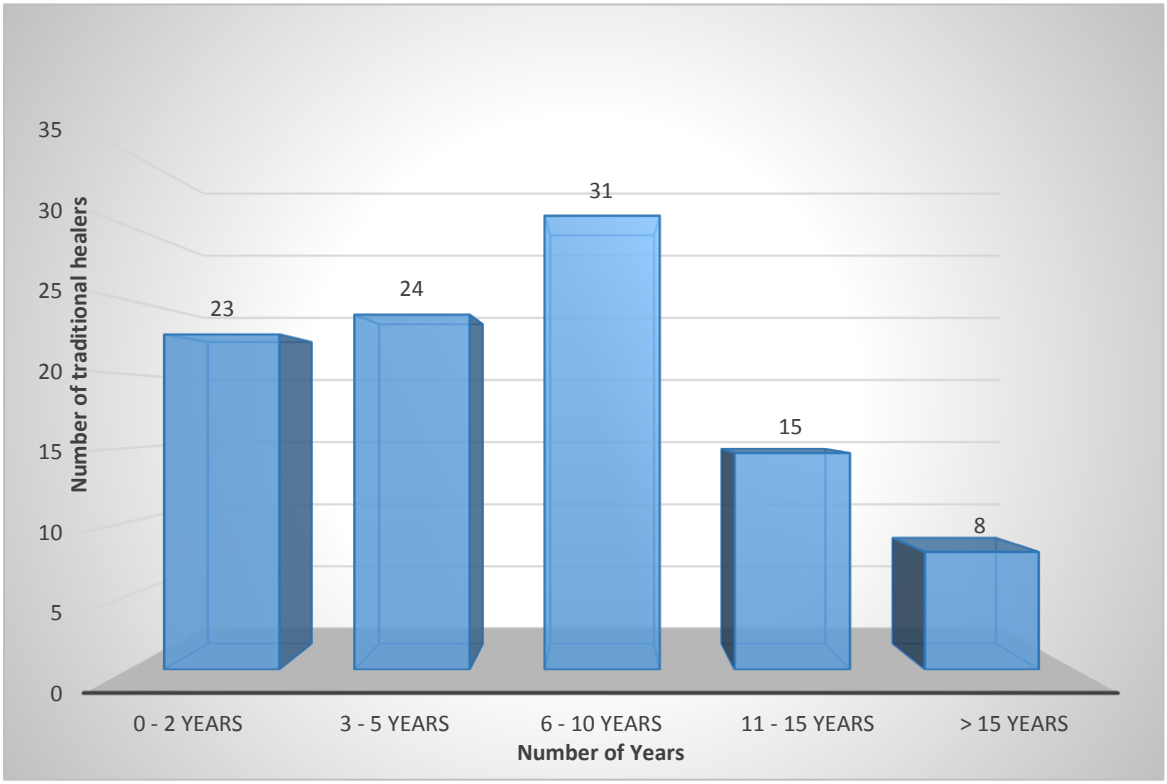
Figure 6.2.4: Known training course area



6.3 Traditional healer's experience

An important aspect was the experience healers had attained. There were 6 (8%) traditional healers who had indicated over 15 years of practice; 11 (15%) traditional healers indicated 11-15 years of practice; 17 (23%) traditional healers indicated 0-2 years of practice; 18(24%) traditional healers indicated 3-5 years of practice; 23 (31%), traditional healers indicated 6-10 years of practice which makes up the largest portion of TH recorded in TH practice; (Fig 6.3.1).

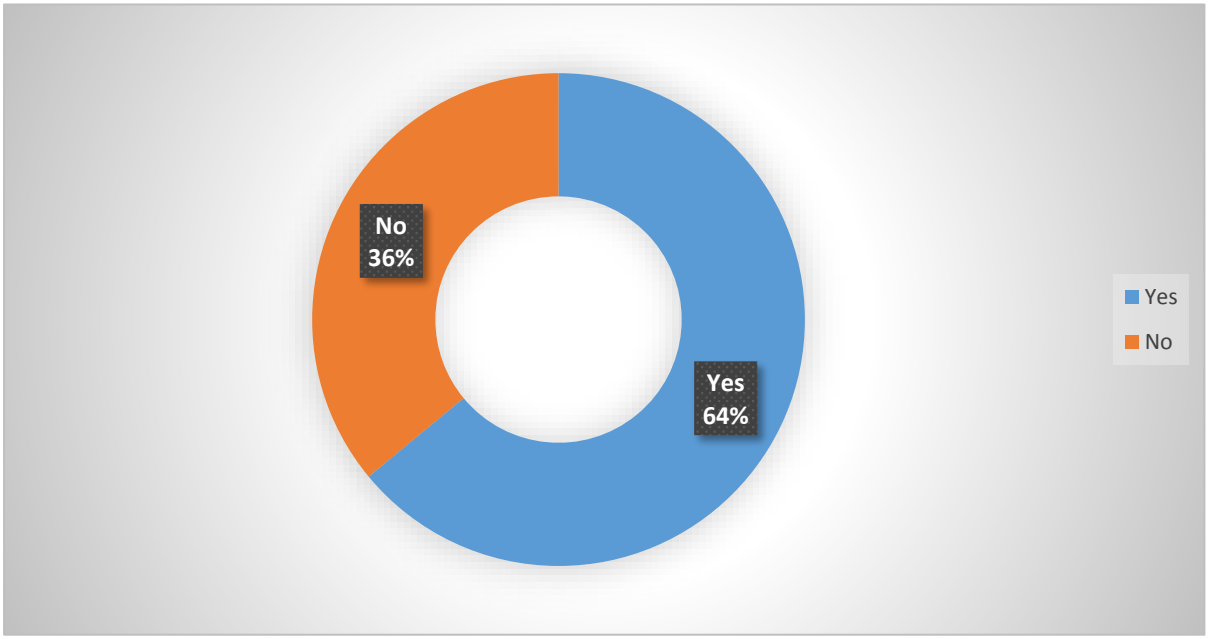
Figure 6.3.1: Traditional healers and number of years practising



6.4 Traditional healer's source of Complementary and Alternative Medicine

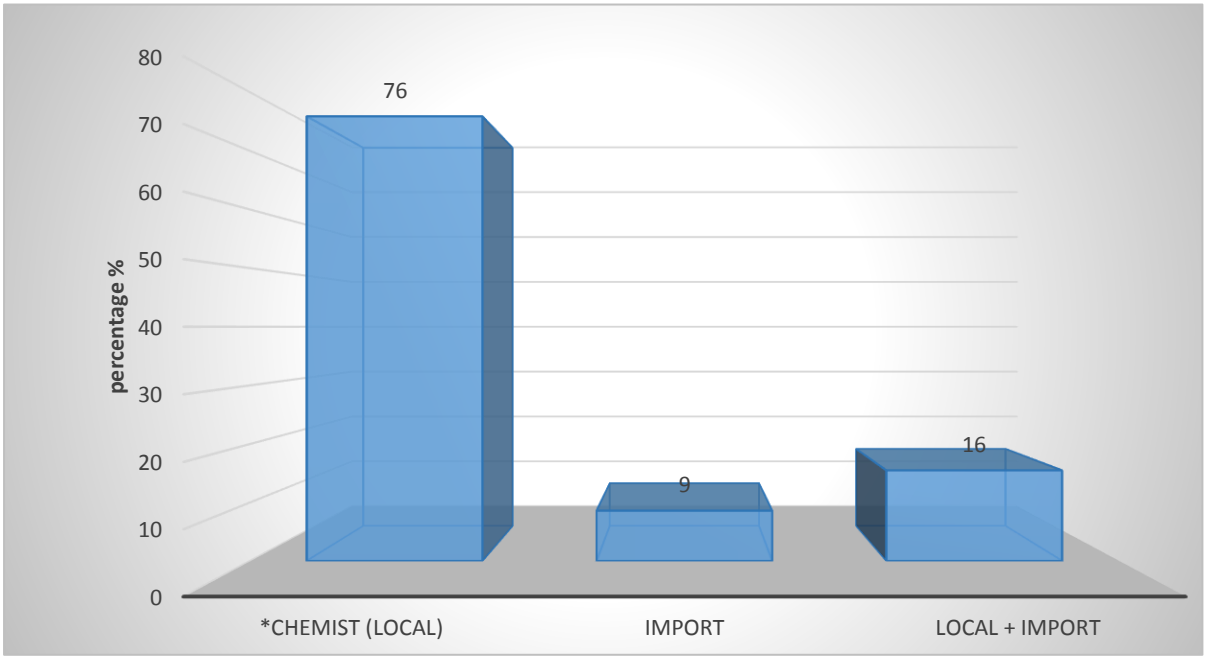
Traditional healer's self-prepared medication is known as *Muti*. Regarding the self-manufacturing of diabetes mellitus' medication's active ingredients, 48(64%) indicated preparing their own *Muti* while 27 (36%) traditional healers did not manufacture their own medications' active ingredients. (Fig 6.4.1).

Figure 6.4.1: Percentage of Traditional healers' who self-manufactured active ingredients



5(9%) traditional healers reported importing their CAMS. 9 (16%) traditional healers sourced their CAMS both locally and abroad. 44 (76%) traditional healers being the majority reported sourcing their CAMS from the bushes or local pharmacies. See (Fig 6.4.2) below.

Figure 6.4.2: Traditional healers' source of Complementary and Alternative Medicine

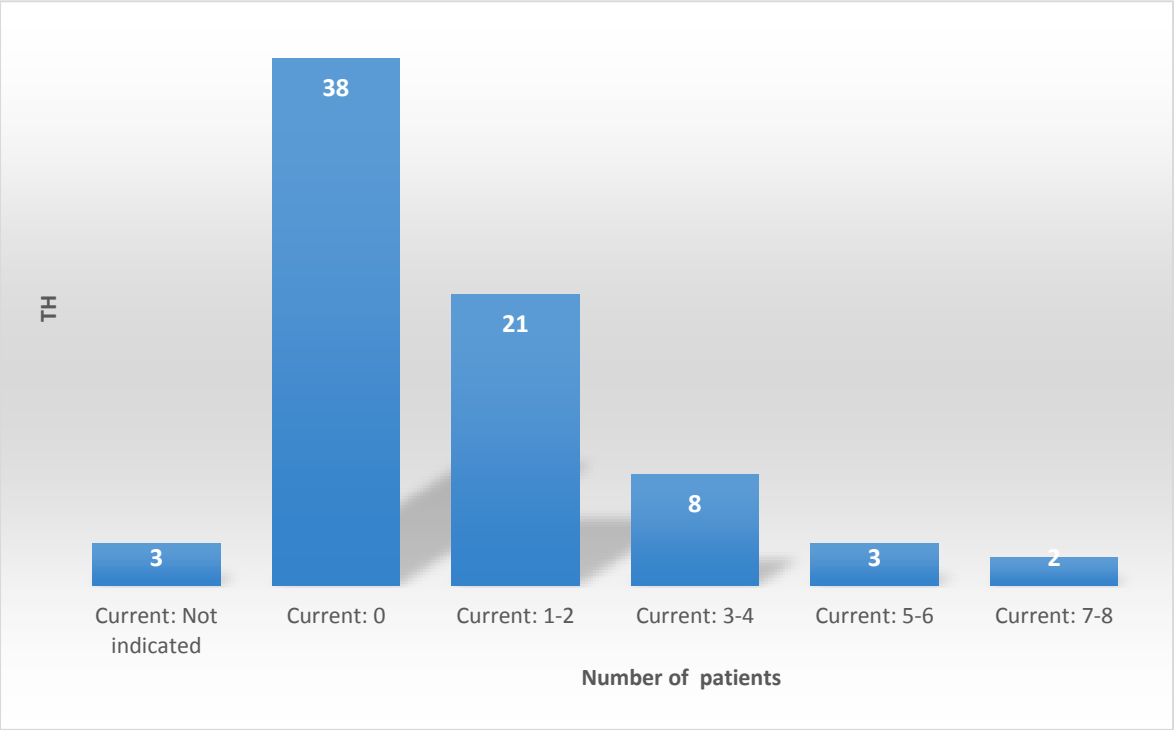


*chemist is the pharmacist

6.5 Percentage of Traditional healers who had patients with Diabetes mellitus

In this survey, 38 traditional healers had no patients (0%) suffering from DM. Then 2(3%) of the traditional healers had indicated to have 7-8 patients. 3 (4%) traditional healers did not indicate the number of patients with DM, whereas another group of 3 (4%) traditional healers indicated to have 5-6 patients. 8 (11%) traditional healers indicated to have 3-4 patients. A group of 21(28%) traditional healers indicated to have 1-2 patients (Fig 6.5.1 below).

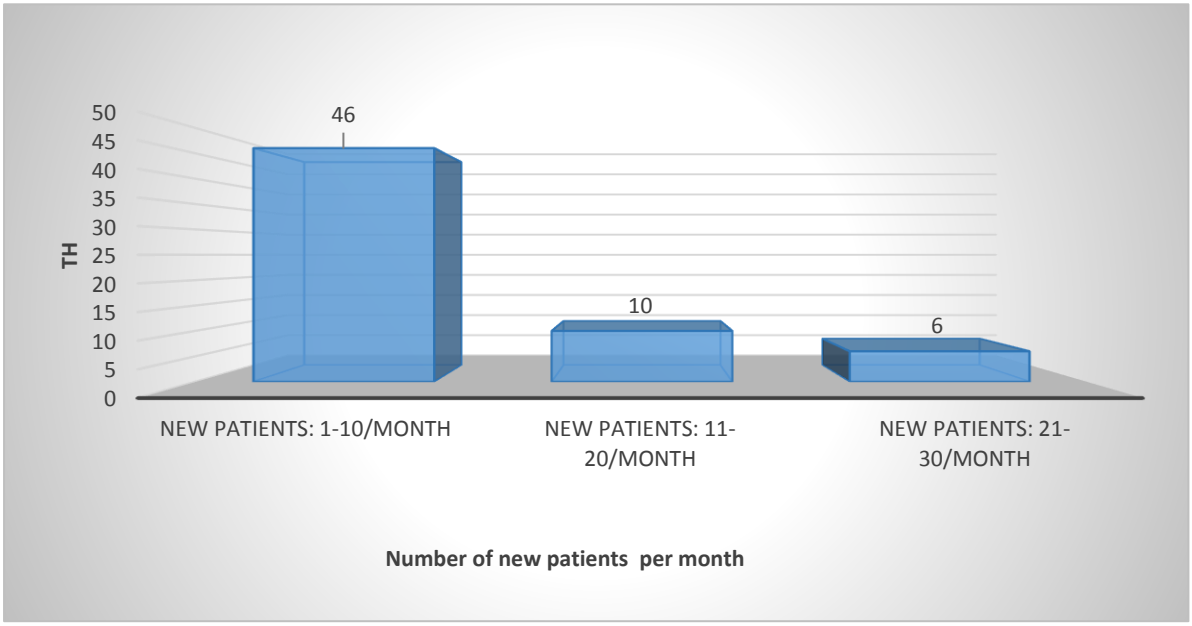
Figure 6.5.1: Diabetes mellitus patients treated by traditional healers



Regarding their number of new diabetic patients per month, the records indicated as follows:

6 (10%) traditional healers indicated to have 21-30 new patients per month. 10 (16 %) traditional healers indicated having 11-20 new patients per month. 46 (74%) traditional healers had, 1-10 new patients suffering from diabetes recorded per month. see (Fig 6.5.2) below.

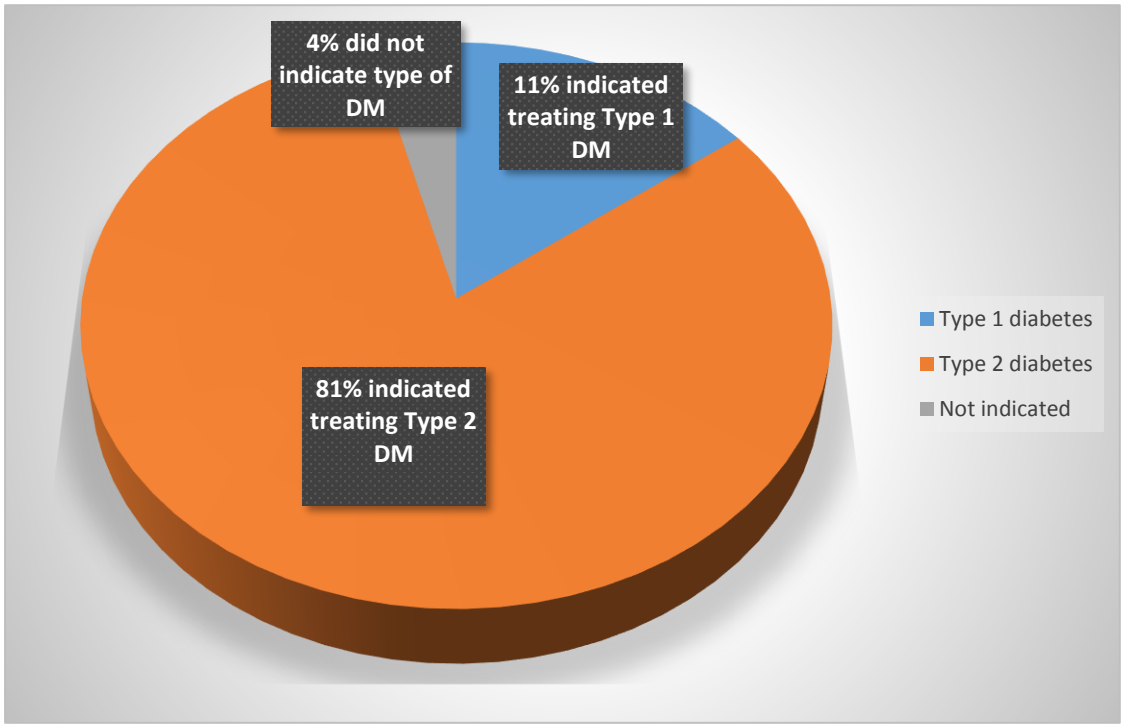
Figure 6.5.2: Traditional healer patients per month



The results of the type of diabetes mellitus treated by traditional healers is as follows:

3 (4%) did not indicate the type of diabetes they were able to treat. 11 (15%), indicating to treat type 1 diabetes; 61 (81%) being the majority number, indicated treating type 2 diabetes. (Fig 6.5.3)

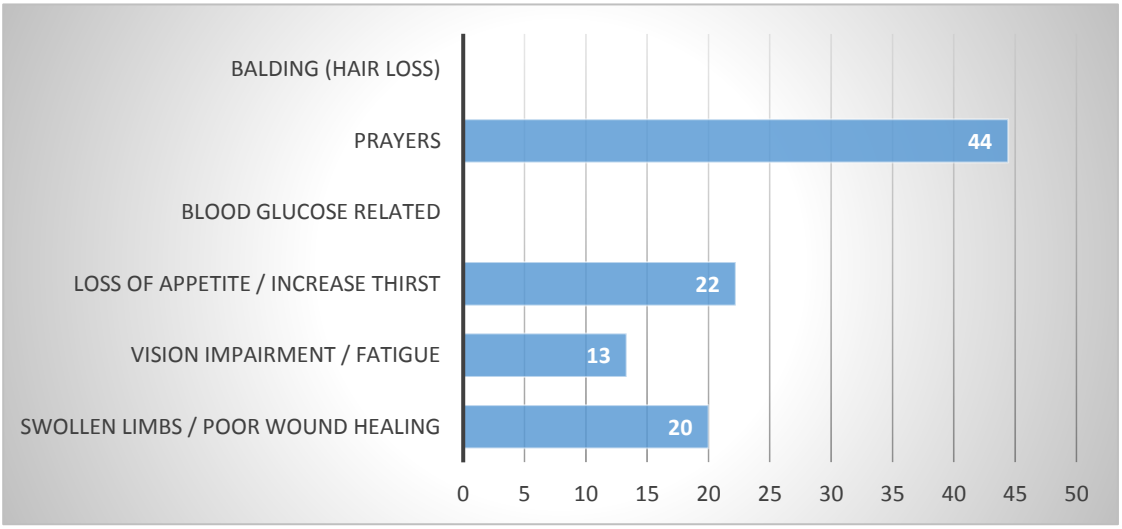
Figure 6.5.3: Percentage of type of diabetics seen by traditional healers



Concerning the diagnosis and type of tools used, only 6 (13%) traditional healers, diagnosed their patients using signs or symptoms such as fatigue and vision impairment. 9 (20%) traditional healers, diagnosed their patients according to physical signs or symptoms such as the appearance of swollen limbs or poor wound healing; 10 (22%) traditional healers, diagnosed patients using loss of appetite or increase of thirst as a sign or symptom. 20 (44%) traditional healers, made use of prayers for diagnosis also accompanied by skeletal one and shells.

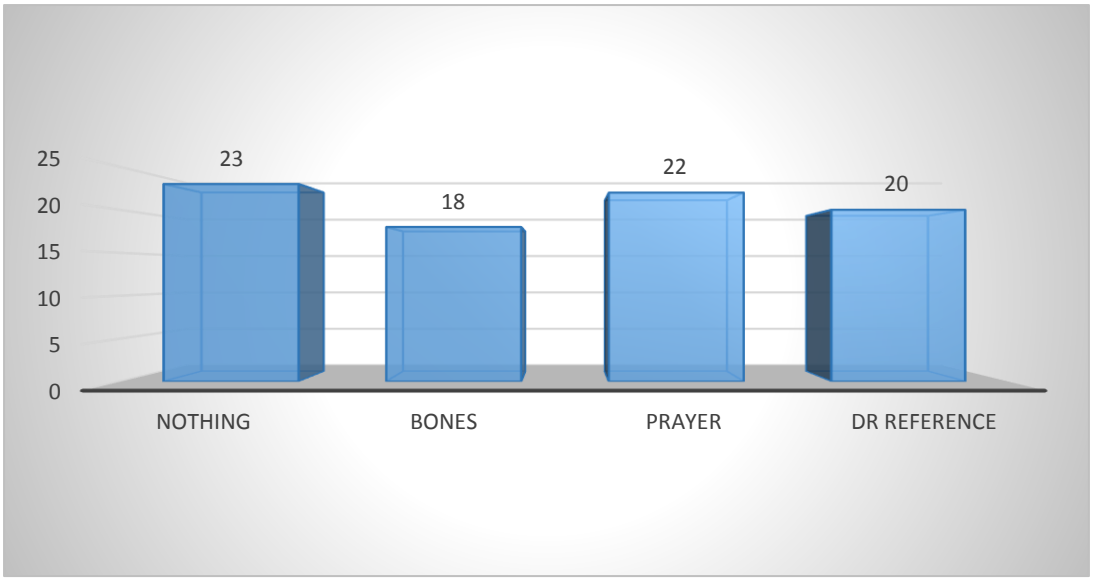
None of the TH used a blood glucose related examination for diagnosis of DM. In addition, no diagnostic criteria such as balding (hair loss) was recorded. (Fig 6.5.4)

Figure 6.5.4: THs diagnostic and assessment methods



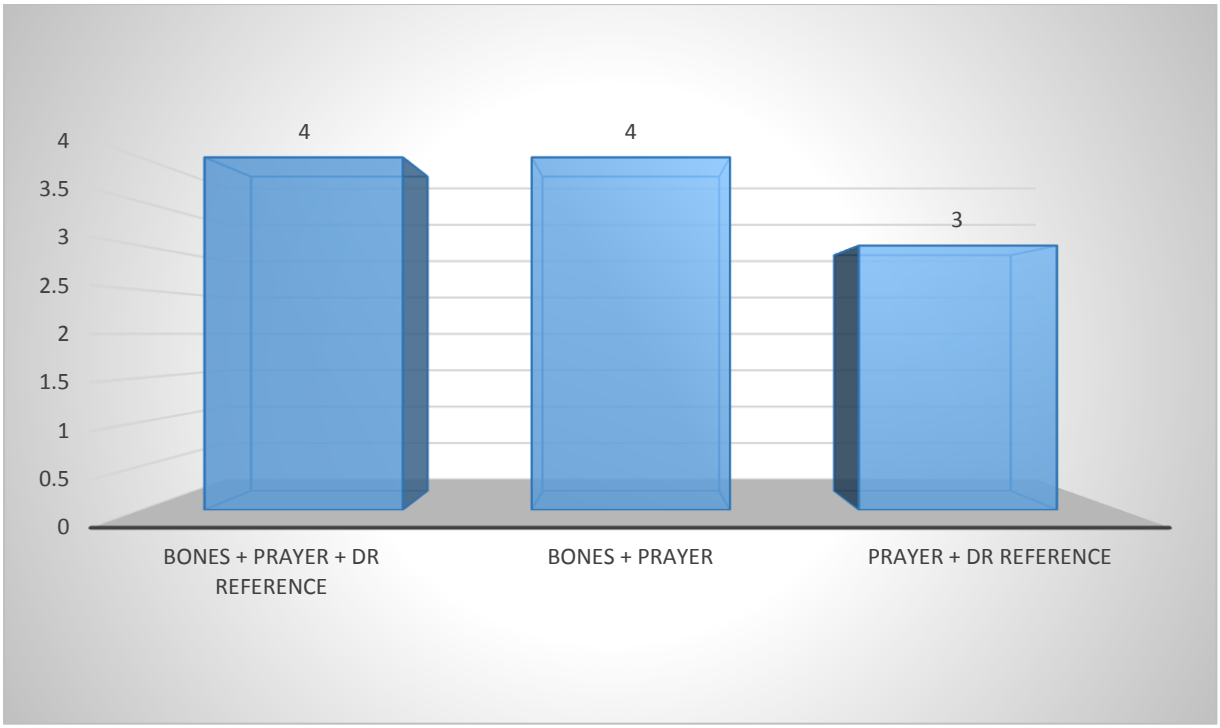
Regarding the assessment tools used by the traditional healers, results are as follows: 18 (22%) were recorded using skeletal bones and shells to assess what the problem was with their patients; 20 (24%) were making use of a physicians medical report brought by their patients as a necessary tool to assist in treatment. 22 (27%) were making use of prayers for diagnosis of DM. 23 (28%) said to use no assessment tools for treatment of DM. (Fig 6.5.5)

Figure 6.5.5: Assessment tools (1) used by traditional healers to confirm diabetes mellitus



It was found that 4 traditional healers indicated the use of skeletal bones, prayers and a physicians' medical report all at the same time. Another group of 4 traditional healers indicated the use of both bones and prayers. Lastly, 3 traditional healers indicted the use of prayers and a doctors' note at the same time for assessment. (Fig 6.5.6)

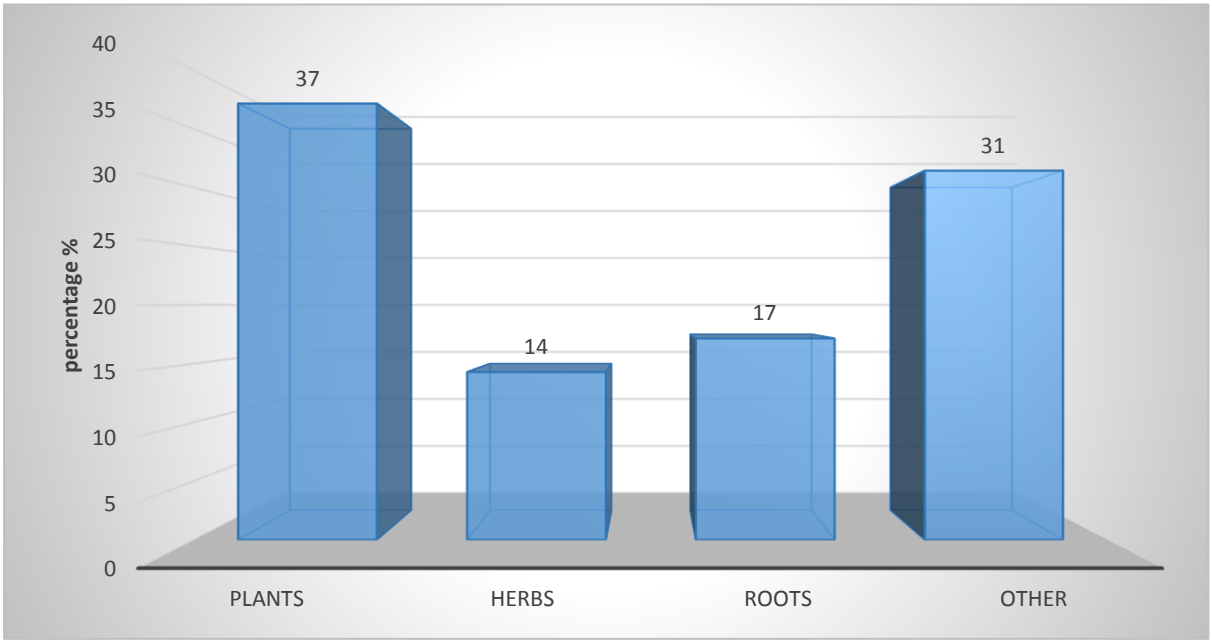
Figure 6.5.6: Assessment tools (2) used by traditional healers to confirm diabetes mellitus



6.6 Details of purported treatment (Complementary and Alternative Medicine) used by traditional healers

With regards to medication prescribed for type 1 diabetes, 5 (14%) traditional healers used herbs as treatment for type 1 diabetes; 6 (17%) traditional healers used root of barks as treatment for type 1 diabetes; 11 (31%) traditional healers used other treatments not mentioned for type 1 diabetes and lastly 13 (37%) traditional healers being the majority number used plants as treatment for type 1 diabetes. (Fig 6.6.1)

Figure 6.6.1: Treatment prescribed for Type 1 diabetes mellitus



With regards to THs prescriptions for type 2 diabetes, 9 (10%) traditional healers used herbs; 18 (20%) used roots; 27 (30%) used other treatment recipe not mentioned. 36 (40%) being the majority of traditional healers, again used plants as purported treatment for type 2 diabetes. (Fig 6.6.2)

Figure 6.6.2: Treatment prescribed for Type 2 diabetes mellitus

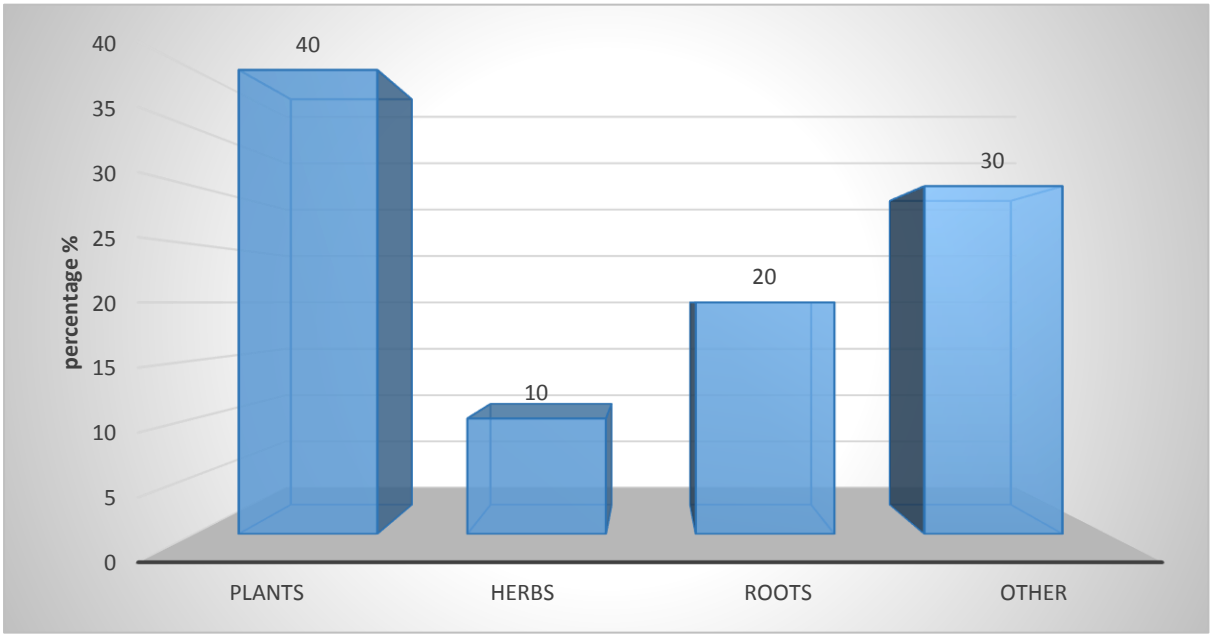


Table 6.1: Purported medication identified and used by traditional healers in the Mamelodi area

There were 20 treatments for DM identified in the Mamelodi area mostly for type 2 DM. The ringleader of THs in the Mamelodi area provided similar descriptions and names thus making it possible to associate the product name with the TH's name. Furthermore, an ethnobotanist from the University of Johannesburg assisted in identifying botanical names of the plant products.

Among the list illustrated as in table 6.1 below, 13 traditional healers recorded using mostly vitamins and minerals; these were taken in combination with other compounds such as the 1 ounce (Oz) mixture (composed of Oz First flush, Oz lily herbs, Oz flower of Ypres, OZ mulch root and OZ Makasan). The OZ mixture is to be added in boiled 2 table spoons (28.3 grams) Glauber's salts with 25ml of water. This was taken primarily along with other treatments e.g. mulch roots. The TH Indicated that their remedy had a better effect on patients when combined. Further analysis revealed these TH were from the new generation. The "Elder" THs only made use of plants, trees and bark roots known for their natural antioxidants and effective herbal medicines: bitter leaf, Mukwere Kwere and Mokgalo mixed with viscum plants. Other reported treatments included: bitter bossie, Garlic, ndoleh, cinnamon, Coast silver oak leaf, bitter aloe, broad leaf bulbine, escobilla herbs, and Amangwe bark. None of them complied with current GMP.

	Description of medication by TH	Purported medication/ plant botanical names	Plant part used	Number of TH's that used this treatment
1	Garlic plant and clove	*Allium sativum*	Clove and leaf	4
2	Bitter aloe, long trunk and red flowers. It is collected from the field	*Aloe ferox* Mill. (Asphodelaceae)	Leaf	2

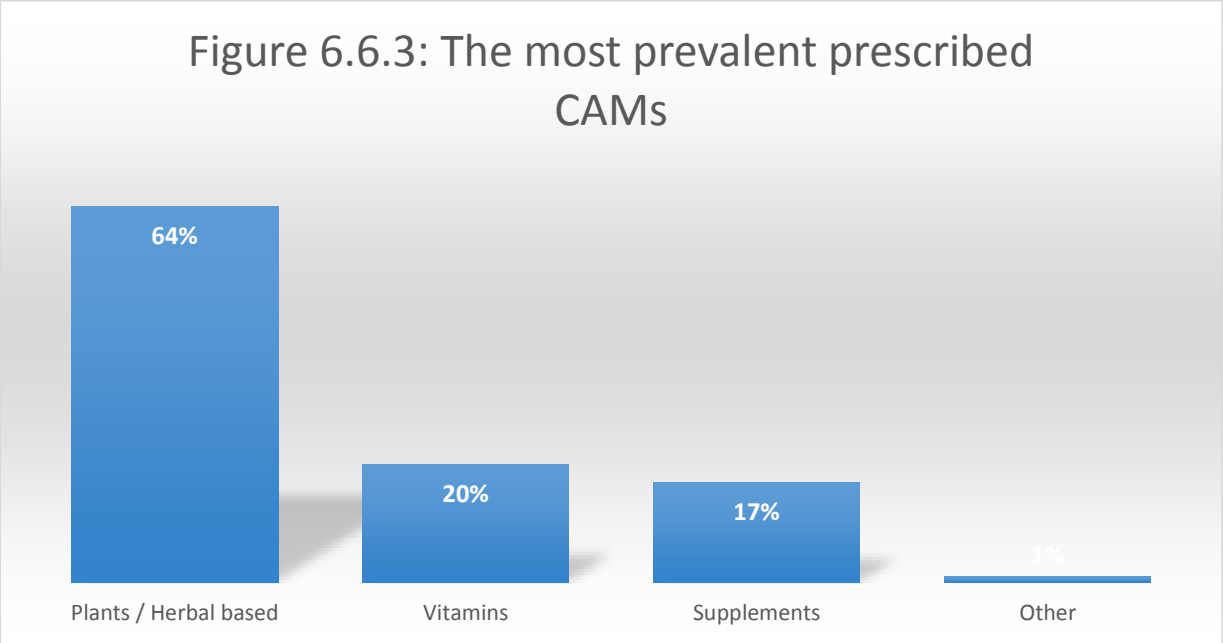
3	Bitter leaf called Uhlunguhlungu. It can be collected from the field	*Brachylaena Elliptica* (Asteraceae)	Leaf	2
4	A small bitter leaf type tree with a yellow flower and with hair, collected from the field	*Brachylaena Ilicifolia* (Asteraceae)	Leaf	1
5	Known as Coast silver oak leaf	*Brachylaena discolour* (Asteraceae)	Leaf	2
6	Thick leaf that looks like little aloe with bright red stolon inside. Called Broad leaved bulbine (matshetshafike)	*Bulbine latifolia* (Asphodel- aceae)	Leaf	2
7	Tree bark of Cinnamon, (cinnamon powder)	*Cinnamonum verum*	Root	1
8	Grey bark root from small tree 5cm by the field (ingoavouma)	*Elaeodendron transvaalense*	Root	3
9	(Mokwere kwere root) bark plant	*Euclea undulata* (Ebenaceae)	Root	7
10	Oz First flush herbs from shops	First flush (Darjeeling tea)	Herbs	8
11	Moringa leaves imported	*Moringa oleifera*	Leaf	1
12	Oz lily herbs and seeds from the shops	*Nymphaea nouchali* (Nymphaeaceae)	Herb and seeds	8
13	Oz flower of Ypres from shops	*Papaver rhoeas* (Papaveraceae)	Flower	8
14	Guava leaf, mulch roots collected from the field	*Psidium guajava* (Myrtaceae)	Leaf and root	2

15	Escobilla, herbs with yellow flowers	*Schkuhria pinnata* (Asteraceae)	Herb	2
16	(Amangwe) bark from a plant collected from the field	*Terminalia Sericea* (Combretaceae)	Leaf	2
17	Bitterleaf, or Ndoleh bought from shops/ imported	Vernonia species; *vernonia amygdalina*	Leaf	7
18	Bitter bossie herbs	*Vernonia Oligocephala* (Asteraceae);	Leaf	6
19	Vitamins from any pharmacy	Vitamins and supplements		13
20	Mokgalo mixed with viscum plants Umlahlankosi Root and leaves	*Ziziphus Mucronata*	Whole plant	6

In discerning the most prevalent prescribed CAMs, it was found that certain traditional healers chose more than 1 answer as an option for their mostly prescribed DM treatment. e.g. plants / herbal based + vitamins.

1(1%) traditional healer used “other” CAMs as treatment of both type 1 and type 2; 17 (17%) used supplements as treatment for both type 1 and type 2 DM; 20 (20%) traditional healers used vitamins as treatment of both type 1 and type 2 DM; According to the results, 64 (63%) traditional healers used plants / herbal based this is also seen on Fig 6.6.1 and 6.6.2 above, being the most popular CAMS recorded as treatment for DM of both type 1 and type 2. (Fig 6.6.3)

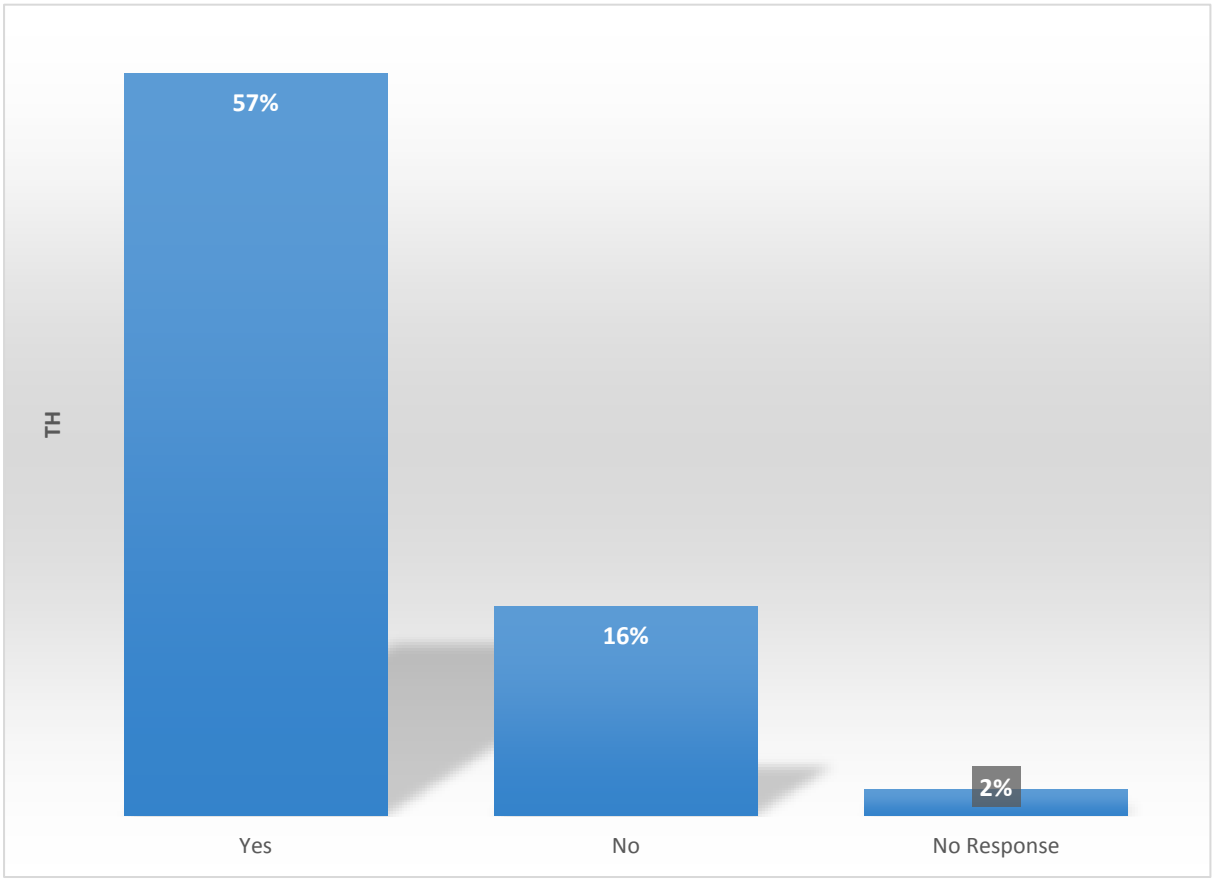
Figure 6.6.3: The most prevalent prescribed CAMs



6.7 Traditional healers' treatment feedback obtained from patients

After the prescribed treatment was taken by the patients, 2 (3%) traditional healers did not give any response regarding their patient's feedback. 16 (31%) traditional healers mentioned not receiving any patient feedback. Lastly, 57 (76%) traditional healers, comprising the majority number, mentioned to have received feedback from their patients. (Fig 6.7.1)

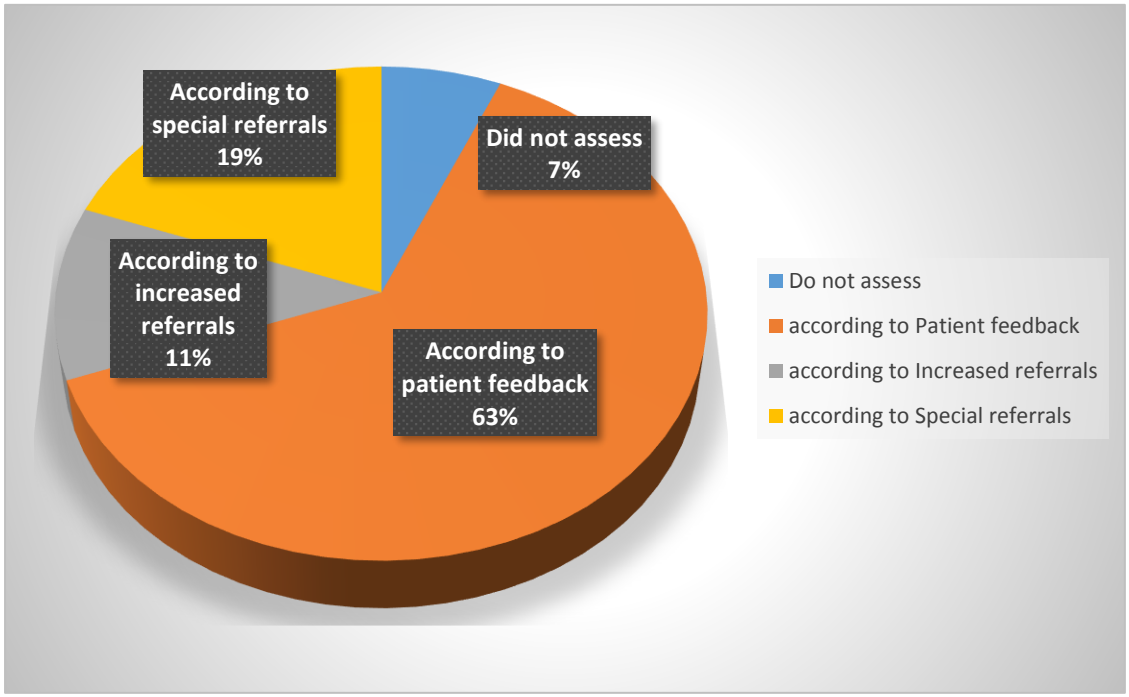
Figure 6.7.1: Traditional healers' treatment feedback received from patients



6.8 Treatment efficacy assessment by traditional healers

Another important aspect was the treatment efficacy of traditional healer's treatment. In total, of 62 traditional healers, 58 assessed the efficacy of their DM treatment. It was recorded that 4 (6%) did not assess the efficacy of DM treatment. 7 (11%) did assess the DM treatment efficacy based on an increased referral of their new patients; 12 (19%) assessed the DM treatment efficacy via special referrals (interesting this was seen as a sign of successful treatment). 39 (63%), which is the majority, assessed the efficacy based on their patient feedback. (Fig 6.8.1)

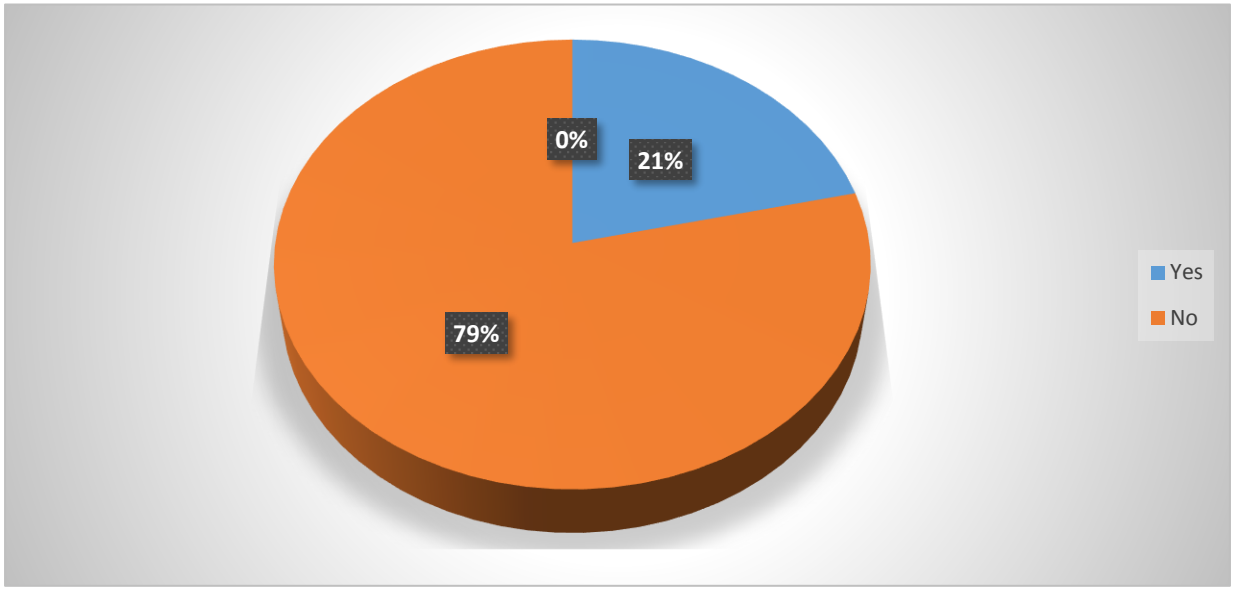
Figure 6.8.1: Diabetes mellitus treatment efficacy assessed by traditional healers



6.9 Complementary and alternative medicine regulations analysis

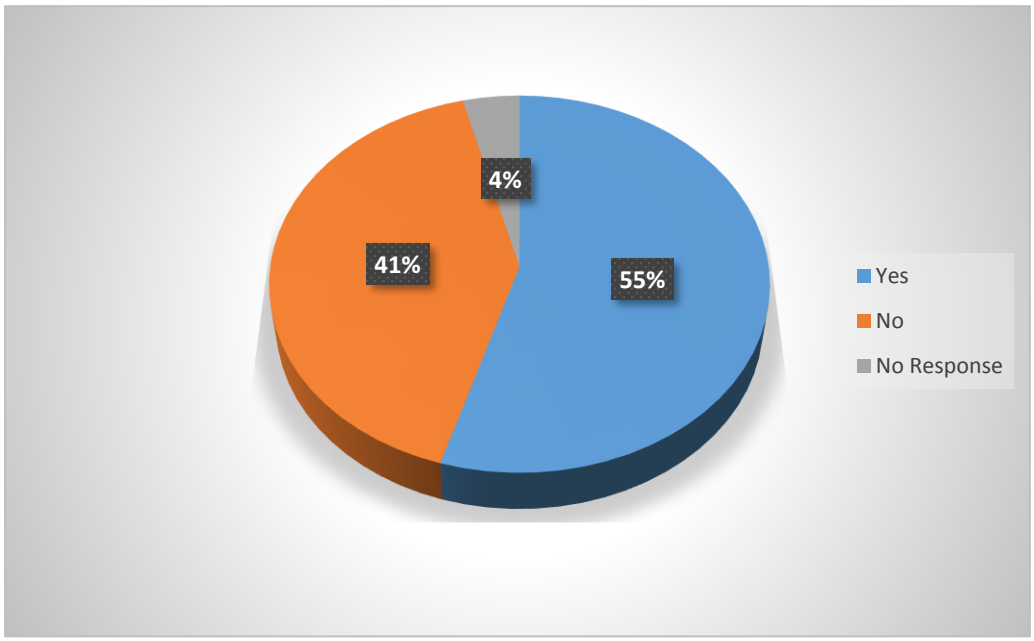
Regarding the compliance to the 2016 regulations, 16 (21%) said to have registered their CAMS with the SAHPRA. The majority, 59 (79%) reported not registering their CAMS with the SAHPRA. (Fig 6.9.1)

Figure 6.9.1: Traditional healers who indicated their treatments/medicine to be registered with the SAHPRA.



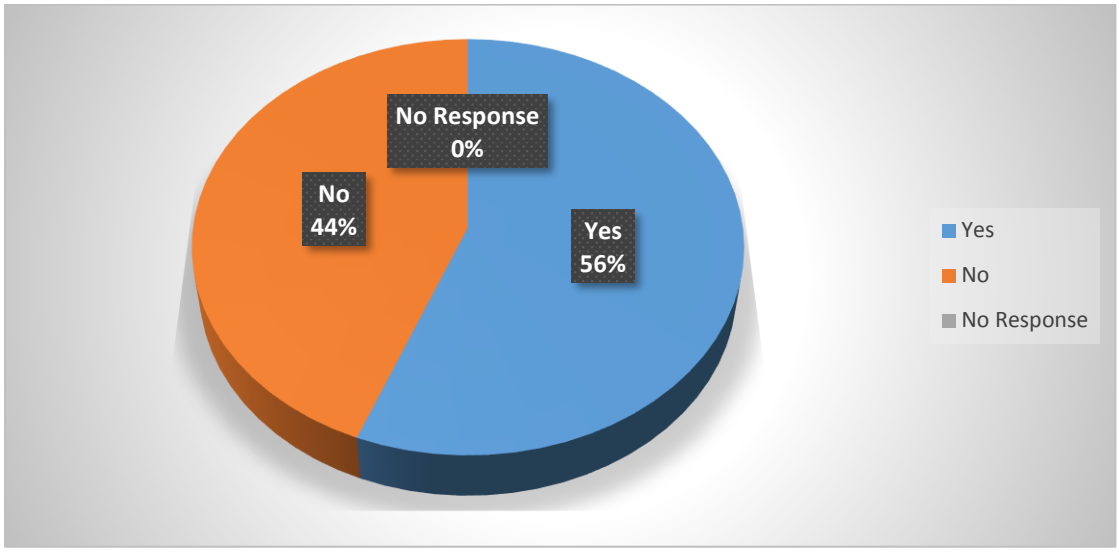
Also, 3 (4%) traditional healers, did not respond to the question on whether they were aware of the new regulations. 31 (41%) said they are not aware of the SAHPRA regulation of CAMS; 41 (55%) comprising the majority indicated to be aware of the SAHPRA regulation. (Fig 6.9.2)

Figure 6.9.2: Traditional healers' awareness of compliance with the SAHPRA CAMs regulations



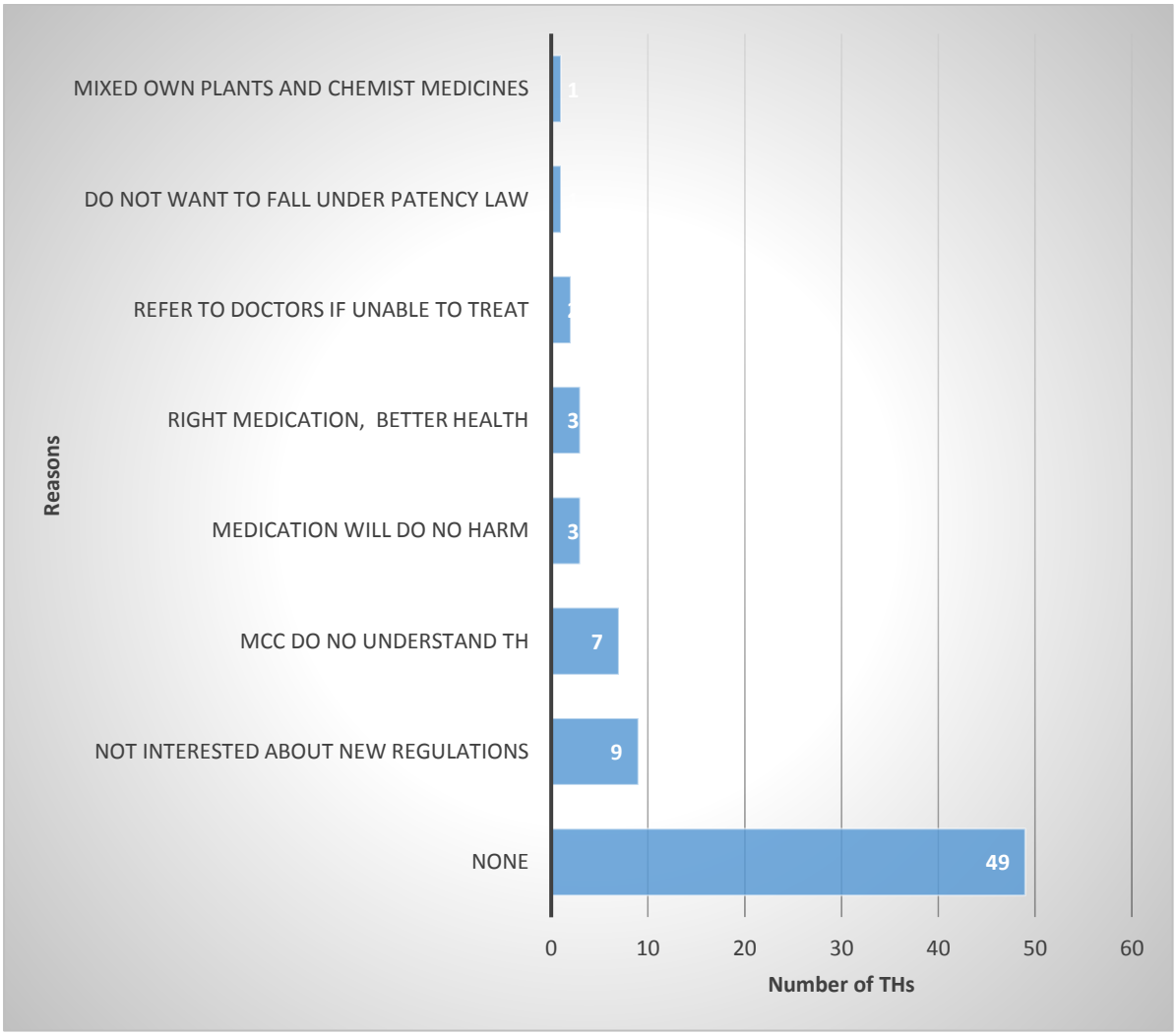
33 (44%) traditional healers did not comply with the SAHPRA regarding new regulation for CAMS; 42 (56%) traditional healers indicated compliance with the SAHPRA new regulation regarding CAMS. In the questionnaires, the (41(55%) in figure 6.9.2) number who said not to be aware of the regulation currently indicated their compliance to the SAHPRA new regulation of CAMs (hence being ironic). (Fig 6.9.3)

Figure 6.9.3: Traditional healers' compliance with the Medicine Control Council's new regulations regarding Complementary and Alternative Medicine registration



Regarding reason(s) for non-compliance, 1 (1%) traditional healer, said he did not comply as he did not want his medications to fall under patency law. Another 1(1%), said to mix his own natural plants and chemist medicines and so did not need any compliance or 2(3%), said they referred patients to doctors when they are unable to treat. 3(4%) said that they were administering the right medications, that was meant for better health of their patients. Another 3(4%), said that medication will cause harm to their patients because they knew what they were doing. 7 (9%) said that the SAHPRA did not understand their practise. 9 (12%) said to not be interested in the new regulation. 49 (65%) comprising the majority just did not give any comment. (Fig 6.9.4)

Figure 6.9.4: Reasons why traditional healers do not want to comply with the new regulations of the SAHPRA



6.10 List of Complementary and Alternative Medicine found over-the-counter (OTC)

There were 13 vitamins and supplements as referenced by the traditional healers that were available at pharmacies in the vicinity. Those pharmacies were: Tshepong pharmacy, Mamelodi pharmacy, Mahube valley pharmacies, Dichem and Clicks in Mamelodi Crossing. Inside of the pharmacies, different CAMs were found and used for chronic and lifestyle diseases and other medical conditions of which patients could seek for complementary and/or alternative treatments. Most of the CAMs manufacturers knew about the SAHPRA legislation of 2013 as they adhered to medicine label requirements: A disclaimer on the label (until it is evaluated) to the effect of: "*This medicine has not been evaluated by the SAHPRA. This medicine is not intended to diagnose, treat, cure or prevent any disease*".

One of the medicine recorded as being registered by the SAHPRA was known as 'Manna blood sugar support'. This supplement is made from a unique blend of flour from pods of Prosopis tree which grow in the harsh, arid Northern Cape Province. It is the only 100% natural organic product for blood sugar control with no side effect.

Another OTC CAMs that appears to show an inclination towards SAHPRA regulations is Insumax. It used as a multivitamin. It is known as a nutritional supplement containing nutrients supporting normal glucose metabolism. It is used in conditions that are linked to or exacerbated by insulin resistance. Each pack contains inositol, folate (as 5-MTHF), co-enzyme Q10, amino acids and antioxidants. But the CAM has not been yet been registered with SAHPRA. The rest of vitamins and supplements had the old disclaimer "*This medicine has not been evaluated by the Medicine Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease*".

Table 6.2: OTC Vitamin and supplements from traditional healers, available in Pharmacies

Product Name	Active Ingredient	Type	Manufacturer Knowledge About SAHPRA	CAM Registered
Cinnachrome	Cinnamon Chromium, Niacin	Supplement	Yes	No
Glucostop		Vitamin and Minerals	Yes	No
Dia-Bion	Antioxidant, vitamins and Minerals	Supplement	Yes	No
Blood Sugar Support	Prosopis Juliflora Var Glanolilosa	Supplement	Yes	Yes
Recharge Diabetic Care	Cinnamon, Periploka, Quassa, Amana, Oats	Supplement	No	No
Diabetic Vitamin Complex		Vitamins		No
Super Moringa	Moringa Leaf	Treatment	Yes	Yes
Morcus Spirulina	Spirulina Pacifica			
Insumax	Multivitamins	supplement	Yes	No
Chromium Select	Vit B6, Chromium, Magnesium, Manganese		Yes	No
Probetix	Pinosundia, Alpha Lipoic Acid		No	No
Brogen Cinatrol	Cinnamon Extract Chromium Alpha Lipoic Aid		Yes	No
Zychrome Tony Perguson	Zychrome Advanced Chromium Supplement	Supplement	No	No

7. CHAPTER 7: DISCUSSION

The DoH, South Africa was and still is confronted with challenges concerning the regulation of CAMs. In December 2015 the Medicine and Related Substances Amendment Act 14 of 2015 was passed into law, referred to as the 2015 amendment. Neither the amendment of 2015 nor the 2008 amendment *(medicine related substances amendment Act 72 of 2008)* were operative. The new authority, SAHPRA, took control of the purpose of the MCC in this regard in 2016 to implement the updated and extended regime.[36]

In other countries, such as in the African region, the development of national policies and regulation, especially for herbal medicine, is more limited, whereby most of them have not established herbal medicine regulations (Angola, Central African Republic and Gabon)[27]. South Africa, conversely, holds a national registration system, which also indicates a national post-marketing surveillance system for herbal medicine in development. Herbal medicine is sold in pharmacies as non-scheduled OTC medicine. They are also sold in special health/herbal medicine shops, and by licensed practitioners, without restriction (the WHO resource on the National Policy on TM and Regulation of Herbal Medicine (Report of a WHO Global Survey)). [37]

This study was based on purported medications used by THs in the Mamelodi area, Pretoria, as treatment for DM. The investigation involved two parts: firstly, to assess THs methods for diagnosing DM and secondly, assess THs knowledge regarding compliance of these medications with the new SAHPRA regulations. THs were approached with questionnaires to evaluate their DM diagnoses, sourcing or manufacturing their prescribed CAM and assessing their knowledge on CAM regulations. Pharmacies were visited and assessed, using a non-structured survey to identify CAM therapies sold as purported medication for DM.

7.1 Traditional healer demographic data

In the research study, THs attended to the questionnaires as follows; 100 THs were targeted; 75 questionnaires were fully answered with 3 uncompleted questionnaires. It was found that, 60% of THs in Mamelodi were females, and that most of THs were from the Black population (85%) (Figure. 6.1 2). It is known that both men and women can become THs in South Africa.[23] It is significant that most of the THs were females indicating perhaps the general trend, worldwide, that women should enjoy equal opportunities and status as men do for all professions.

7.2 Traditional healers' qualifications

THs held inadequate educational levels; more than 50% of THs did not hold a matric certificate (Figure 6.2.1); 59% on the other hand had attended a training course in various areas in Pretoria. These included Mamelodi Extension 5, Pelindaba, Atteridgeville, Giyani, Hammanskraal and Bela-Bela. The THs did not mention the specific institution in their questionnaire. 4 THs held a 'Gauteng traditional and faith medical practitioner's certificate'. The remaining (37%) said they did not follow any course as they indicated that their elders had trained them. These traditional healer trainers (traditional tutors) are well known in the Republic of South Africa. To become a TH diviner or herbalist, a minimum standard for training student category is 12 months. To qualify for registration for certification entitling the holder thereof to registration in term of the traditional health practitioner act the applicant needs to be minimum18-years of age.[24] The trend is recognized that THs bodies are trying to formalize THs training and congruency bringing it in-line with the SAHPRA philosophy of formalizing this profession and its recognition. Recently, 39 THs in Mamelodi were granted licences to heal by the THO after amending five-day workshop to teach them about the behaviour of TH, roles, in the community, how to work with the police, councillors and refers their patients to clinic for further attention.[38]

In comparison with other countries such as China, TH follow university courses between 2 to 5 years depending on the TH specialisation. They offer undergraduate,

masters and doctorate degrees.[3]

7.3 Traditional healer's experience

The results indicated that 31 THs, the majority, had 6-10 years of experience in practice (Figure 6.3.1). Only 8% of THs had over 15 years of practical experience; the more years you spend in the practise; the more experience you gained as a trainee. A trainee trains formally under another a TH who acts as a tutor for a period of a few months to years. [21,24]

7.4 Traditional healer's source of Complementary and Alternative Medicine

African traditional medicine makes extensive use of botanical products, but medicine prescribed by *Inyanga* may also include other formulations which has a zoological or mineral composition.[23] 48 THs (64%) extracted their own active ingredients, collected from bush meadows (see figure 6.4.1 and content on table 6.1). The remainder of the ingredients were obtained from supplier pharmacies, when they needed vitamins and supplements e.g. bitter leaf powder such as Moringa to add to the remedies.

In pharmacies, health - and traditional shops, a variety of CAMs were identified that are used for chronic or lifestyle diseases and other medical conditions, where patients seek a complementary and alternative treatment. OTC CAMs, used by THs to treat DM are displayed in Table 6.2. Roughly 75% of CAMs were bought from THs local suppliers (Figure 6.4.2), but when collected from pharmacies, it involved supplements (vitamins and minerals). THs then used the CAMs, to add value to their purported treatment, using 'traditional biologically based practices'. China herbal medicines long ago has integrated into primary health care, everything that would be used are regulated with their health care system.[3]

7.5 Aspects relating to Traditional healer's DM patient numbers

As it is known, DM is a chronic disease prevalent with morbidity and mortality associated with complications of persistent hyperglycaemia. Poorly controlled diabetes gets challenged with chronic complications that may include blindness, heart disease, and renal failure. It can also include reduction in physical activity, sleep disturbances and other complications. This metabolic disorder occurs due to the defects in either the insulin secretion, insulin action, or both. [39]

According to the findings, 21 (28%) THs treated DM, ranging from one to two patients per month. Only 2 (3%) THs had up to 7 patients per month (see Figure 6.5.1). The patients in the Mamelodi area mostly suffered from Type 2 DM (81%) (Figure 6.5.3). Some of THs treating Type 1 DM, were the eldest in the healing practice with over 15 years' experience. It appears that DM patients perhaps forms the minority of their patients. This is serious but useful knowledge as this will aid in gaining perspective from the THs point of view and capabilities in managing DM patients and allow Regulatory bodies to engage in defining their scope of practice. This is important as DM is a serious disease and if not recognized and managed properly will lead to serious disabling consequences and early death.

7.5.1 Overview and perspective on the diagnosis of DM by the THs

THs with over 15 years' experience did not diagnose diabetes with any medical tests or materials. They mostly used prayers and spiritual beliefs (44%) (Figure 6.5.4). They believe in contact with the spirits to diagnose whether the individual is sick. A leading TH in Mamelodi confirmed this statement. THs are known to "*go beyond just treating the disease*". Primarily, they '*connect*' collectively and individually.[40] This is well observed in the diagnosis of diseases in certain African traditional religions. The diagnosis is said to be done in two parts, firstly by a medical doctor and secondly to assess the 'divination' of the spiritual or mystical cause of said disease. During divination the TH generally consults the spiritual world to find out the cause of the disease or consult any violation of an established order from the side of the sick

person. This will finally lead or guide to them to the healing practise.[39,40]

The remaining THs made use of assessment questions as for sign and/or symptoms. They established vision impairment or fatigue (13% of TH) and checked for poor wound healing or swollen limbs (20% of THs). They established if patients lose their appetite or had any increasing thirst (22% of TH). These actions in combination with divination, physicians' medical report, in conjunction with details from the patient's assessment questions (44%) THs) provided the necessary treatments.

In summary, the type of assessment instruments used to diagnose DM, consisted mostly of skeletal bones and prayers, followed by the few who had access to physicians' medical report (Figure 6.5.5 and 6.5.6). THs did not have any material for medical diagnosis or physical examinations. They also did not assess the patient's family history. They did not offer tests, such as blood glucose analysis (0% observed from Figure 6.5.4). One concern is the fact that some THs had access to medical reports of their patients. Furthermore, a medical background is needed to interpret these reports and perhaps laboratory results to allow effective integration of those data into the management of the THs DM patient. Surely the average THs does not have this platform if their academic qualifications as above is considered. The knowledge on how to read and interpret physician's reports should verified.

7.6 Overview of purported treatment used by traditional healers

The most common herbal active ingredients used today in treating DM are flavonoids, tannins, phenolic, and alkaloids. The existence of these compounds implies the importance of the anti-diabetic properties of these plants. For example, tannin (bitter tasting organic substance found if some galls, bark and other plant tissues) improves the function of pancreatic beta-cells and increases insulin secretion. Quercetin (plant pigment flavonoids) is an antioxidant that acts in multiple mechanisms related to the removal of oxygen radicals, to prevent lipid peroxidation and metal ion chelation. In fact, the mechanisms of actions of plants used for hypoglycaemic purposes include:

increasing of insulin secretion, increasing of glucoses absorption by muscle and fat tissues, prevention of glucose absorption from the intestine, and prevention of glucose production from liver cells. These factors are mostly responsible for the reduction or elimination of diabetes complications.[39, 41]

The list of CAMs therapy or purported medication largely used by THs to treat DM in this study, can be seen in Table 6.1. The treatment prescribed for DM Type 1 or 2 were mostly plant-based, followed by herbs, supplements, vitamins and roots (Figure 6.6.1 and 6.6.2). Treatments mostly used, are the OZ mixture (see treatment details in table 6.1 description). These TH treatments from records and analysis were from the new generation of THs with less than five years' experience. The most popular CAM prescribed was noted to be plant/ herbal-based (Figure 6.6.3).

According to the findings, along with the clarification assistance from the TH ringleader, the eldest THs mostly used '*MUTI'* bark root from trees, called Mukwere kwere *(Euclea undulata)*, followed by bitter leave plants, known as Uhlunguhlungu *(Brachylaena elliptica)* and other bitter leaf *(Brachylaena ilicifolia*), Ndoleh *(Vernonia amygdalina)*, and Bitter bossie *(Vernonia oligocephala)* all along with herbs, such as Escobilla (*Schkuhria pinnata),* as purported treatment. The plants leaf extracts are simmered; the patients then drink the extract liquid, believing that the bitter taste of the leaves helps to clean the blood.[42] This is believed to reduce high glucose concentrations in the patient's bloodstream. Deutschländer, and co-workers found that mukwere kwere lowered the FBG levels, all confirmed in their vitro screening results.[43] This plant was used in treating DM by THs and herbalists in southern Africa. This should further be tested for hypoglycaemic activity to agree with their beliefs.[42,43]

In recent years researchers have focused on medical plants derived from natural products due to wide range of pharmacological significance. Researchers Odeyemi and Bradley showed that the plant family, Asteraceae (mostly bitter leaves for insulin release and repair of pancreatic beta cells, inhibiting carbohydrate digesting enzymes and oxidative stress), is highly reported in studies of medical plants used for traditional

management of diabetes in the Eastern Cape of South Africa. In this study, 25 family of plants were reported with only 3 A*lliaceae* (in which we find *allium stativum*/garlic) evaluated in *in vivo* studies.[44] Garlic cloves were also recorded to be used by 4 THs, its constituents mainly being sulfur-containing compounds (e.g. diallyl trisulfide, ajoene, s-allyl cysteine sulfoxide). Garlic oil lowered FBG, serum fructosamine, serum triglyceride levels. Garlic improved glycemic control through increased insulin secretion and enhanced insulin sensitivity in a 4-week double blind placebo-controlled study in 60 patients with type 2 diabetes. A daily oral feeding of garlic extracts at 100mg/kg increased plasma insulin levels with significant decreases in plasma glucose levels.[45]

One Aloaceae (*aloe ferox mill*) was also reported in the Odeyemi and Bradley study, which again was identified to have been used by 2 THs. (See table 1). Five *in vitro* plants studies of *Asphodelaceae*(in which *bulbine latifolia* also found in table 1) were identified. *Ebenaceae* and *myrticeae (*again *Euclea undalata* and *guava leaf* respectively) were found in their research study and also listed as THs treatment for DM.

From table 1, the treatment prescribed for DM is mostly plant-based, followed by herbs. This is in agreement with work done by Rutebemberwa *et a*l. who also found that herbs being reported as one of the main remedies used for treatments of patients with DM in Zimbabwe, Nigeria, Vietnam, Oman, India and China.[46] However it is clear that, should these medications be subjected to clinical evidence based medicine evaluation it cannot at this stage considered to be clinically useful in terms of the treatment of DM. Another study by Lynyera *et al*, reported that many patients were using TM to treat DM and individuals with diabetes reported seeking healthcare from traditional healers, elders, family, friends and herbal vendors. Several plants included *Moringa oleifera* and*Aloe vera*.[47] The reason for seeking alternative methods was now due to management of the diabetes. Alternative treatment such as garlic was again found. [48]

7.7 Traditional healers' treatment feedback obtained from patients

The lack of post-marketing data is also a concern for CAM regulations. Ideally, details on the patients using CAM treatment, should be provided and categorised, enabling instituted procedures concerning pharmacovigilance. The THs prescribing CAMs should keep a designated CAM (registered for this purpose) register and active patient monitoring should be instituted and through these adverse reactions recording can be kept current.[13] SAHPRA should inspect the information in accordance with reporting Adverse Drug Reactions (ADR) guidelines in South Africa.

After the treatment is completed by patients, for post-marketing surveillance, it is important to monitor the procedure regarding the safety, efficacy and effectiveness of any given medication. This would allow the detection, prevention and assessment of any advert reaction or drug-related problem- known as Pharmacovigilance-. However, implementing such a process, poses a challenge as only a few CAMs are registered and inspection of THs registers in rural areas could present a real logistical challenge to the SAHPRA.

In this study, 31% of THs reportednot to have received any feedback from their patients after the treatment (see figure 6.7.1).

Most of THs (76%) reported always receiving feedback as they use it as a reference to verify the effectiveness of their purported CAM as for example if the patients showed no signs of toxicity or unresponsiveness to the treatment.

7.8 Treatment efficacy assessment by traditional healers

To assess the efficacy of their purported treatment: it was recorded that 63% THs have indeed used feedback coming from their patients (Figure 6.8.1); 11% of THs reported to have an increase in their patients' referrals, meaning they had new patients coming in and that was probably as a referral made by one of their acquaintances. For those 11% of THs, Increased referrals meant good efficacy of DM treatment. Thus, the assessment efficacy of THs' purported treatment was mostly successful as 19% of patients coming to see THs for treatment were from the special referrals of their previous patients. Some THs indicated noticing that the patients' symptoms reduced when visiting again. Sometimes after the treatment is completed, THs patients are sent to obtain a new physician clinical report on blood glucose levels to confirm the efficacy of their purported treatment. Only 7% of THs did not assess the efficacy of their treatment.

According to the findings, if it is compared to the THs purported way of treatments to that offered in hospital, it appears as if the Mamelodi TH's treatments are more successful. However, this is based on subjective assessments and cannot be interpreted in such a manner. It appears that THs monitored their patients. Their purported medications can take up to months to show therapeutic effects but generally, there is no dietary, restriction, being herbal, as compared to taking allopathic medicines. When it comes to treating diabetes in a hospital, the patients complained finding it difficult getting access. It should be kept in mind that this is also the same situation seen in Uganda whereby antidiabetic medications are found to be out of stock, or patients who are redirected to other pharmacies.[46] On the other hand traditional healers' medications, is in good supply, in a large quantity, their CAMs and other medications available when consulting patients. Because diabetes is a chronic illness and the number of patients is on the rise, its effect on the individual's financial situation and household should not be underestimated, thus it will make hospital treatment as much as successful as TH's. There should be allopathic medicines with

more facilities available, when patients require these.[46,49] No other studies were found that compared the similarities and differences in this topic in other Western countries.

7.9 Awareness of Complementary and alternative medicine SAHPRA regulations

Regarding the analysis on how these purported treatments comply with the 2016 regulations, only one of their prescribed over-the-counter (OTC) CAMs was registered with the SAHPRA, known as *'Manna Blood Sugar Support'* (Table 6.2 above), made from a unique blend of flour from pods of the Prosopis tree and which grow in the harsh, arid Northern Cape province; a few of the TH's were aware of SAHPRAs' new regulations(The 'Insumax' CAM recorded to be aware of the regulations, falls under the vitamins and supplements indication) The rest of CAMs that were recorded to be self-manufactured by THs, did not present full compliance with SAHPRA(not yet registered); 41 (55%) of THs stated awareness of the new regulations, whilst 33 (44%) of their CAM, whether OTC CAM or self-manufactured did not follow the new regulations.

42 (56%) THs were noted to comply with the SAHPRA s' new regulations, 16 (21%) TH were CAM registered (see figure 6.9.1 and 6.9.3), which could not even be identified; 31(41%) TH was recorded to not be aware of the regulations (Figure 6.9.2). The (41%) of THs indicating "not to be aware of the new regulations" is possibly because they refused to acknowledge the new regulation; perhaps it infringes on their autonomy.12% were not interested in the new regulations, whereas 9% acknowledged that the SAHPRA did not understand their healer practise to take decisions on regulations of CAMs thus enabling them to collaborate. It is important to note that, from the packaging and labelling requirement investigated for OTC CAM treatment of DM found in the pharmacies and health shops, most of the CAM displayed the disclaimer on the label: "*This medicine has not been evaluated by the Medicine Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease*".

This indicates the manufacturer's non-compliance to the new regulations.

7.10 Complementary and Alternative Medicine found Over-the-Counter (OTC)

More than 50% of these OTCs were not registered or evaluated by the SAHPRA. The following requirement lacked, as requested by the SAHPRA: label information supplied in a second language, a package insert (PI), a patient information leaflet (PIL) with the following information: the category of medicine, its pharmacological classification and its discipline and most importantly registration of the CAMs. The CAMs found on the pharmacy shelves, were mostly vitamins and minerals (listed in Table 6.2) above, along with some powder extracted from the Moringa tree (also SAHPRA registered), cinnamon powder and chromium. It is well known that the *Moringa olifiera* has ethanoic leaf extracts significantly known to lower the level of FBC[50] in the human body. Chromium is well known to assist insulin, improving its action and thus HbA1C levels by controlling patient glucose and compliance over a period of months. Cinnamon is also known to reduce fasting and postprandial plasma glucose and as well as HbA1c. Its active components being cinnanldehyde and raphthalenemethylester derivative lowered haemoglobin A1C by 0.83% compared with usual care alone in lowering HbA1C by 0.37% in a randomized controlled trial study of type 2 diabetes patients. Its works by promoting insulin release, enhancing insulin sensitivity, and increasing glucose disposal.[51] These CAMs were the most frequently prescribed OTC vitamins or supplements to DM patients.

It is believed that there are more than 200,000 THs in South Africa, but only 25 State doctors and 92 private doctors per 100,000 people.[25,40] This would suggest that THs are more accessible and perhaps more utilized by a larger proportion of patients in South Africa; as a result, they spend more time with their patients. Also, medical doctors limit the duration of appointments. Economic and time considerations in modern medical healthcare delivery, limit doctors' capacity to address the spiritual and emotional needs of their patients. They frequently refer patients to a specialist for further assessment. [40,

[49] These aspects appear to be part of the reasons why patients prefer to consult with THs.

Support for TH are lacking in various African governments compared to Europe and Asia. In countries such as China, traditional health training is mandatory for at least one year, prior to becoming a medical doctor.[36] Such a requirement could be introduced in South Africa to ensure that medical doctors achieve an understanding of the methods used in TM. It will also benefit successful collaboration between the practices. Medical doctors can gain knowledge from THs, specifically in considering patients' emotional and spiritual needs.[36, 40] The findings of TH support for this research are similar compared to other countries such as China. It was found that central African region with more limited development of national policies and regulation as compared to Europe and Asia. All the THs use all form of herbal plants, spiritual or holistic method to heal their patients whereas medical doctors use chemistry lab test medications.[36,40, 45] The parameter of healing is not explainable within a scientifically-known methodology[21] therefore, the criteria on diagnostic tool investigation is dismissed as the investigator was not a qualified scientific 'diviner' researchers.

8. CHAPER 8: CONCLUSION

In this research, most THs did not have materials to diagnose diabetes or manage diabetes mellitus. They used skeletal bones with shell parts and practiced spiritual beliefs. The way THs diagnosed diabetes and the materials that they used differed from Western medical doctors, causing the researcher to dismiss further investigation on diagnosis. This is problematic to the DoH and SAHPRA. Failure to follow regulations can cause harm to their patients. This is a reason indicated by the South African DoH as to why challenges are still being faced concerning regulating CAM. THs again refuse to comply with new regulation because they reported that, when they are compared to medical doctors' practices, they differ throughout, although their intensions are the same. The outcomes are different when treating the patient. According to Laura Eggertson "TM is a system of medicine in the same way that Western medicine is a system; the same way naturopathic medicine is a system". [49]

With regards to the current GMP regulations, some CAMs manufacturers are aware of the SAHPRA regulation; only 2 OTC CAMs registered with the SAHPRA. 44% of THs do not want to comply. They want to be self-regulated. The system is going to swallow us, we are in trouble' said THs in the Soweto live news.[52]

Government needs to improve traditional healing services, increase financial, technical and infrastructural support and provide THs with various training workshops to improve their practices and enrich their knowledge on manufacturing. For good pharmacovigilance and avoiding toxicity, they need to improve safety, efficacy and quality of TMs. This would in-turn lead to an increase in development of TM. This is crucial, as THs have more influence and are more accessible than Western medical doctors. [40, 53]

A way to integrate THs into the mainstream healthcare system, is to avail THs in hospitals and primary or community healthcare centres. This may lead patients to

become more comfortable and accustomed to the environment.[54] The cooperation of medical doctors and THs can assist in decreasing the conflicts and misunderstandings amongst the two different paradigms of medical fields (conventional medicine paradigm treating disease with drugs and surgery and TM paradigm supporting health using natural medicine and lifestyle changes).[55] The employment laws of South Africa should also provide better cover with certificates issued, signed and registered with a professional council. Lastly a much-improved communications network and platform between the various agencies and TH's must be established to effect better knowledge of expectations regarding TH's methods of diagnosing DM in patients and regulatory aspects regarding CAMs.

Limitations

An important limitation of the study was the language barrier; as a non-South African citizen with no knowledge of Zulu and Sepedi, it was difficult to convince TH's to consent to participate in the study. The TH ringleader of Mamelodi along with Stanza Bopape 2 clinic volunteers understanding the importance this study, the current THs issue with CAMs regulations and compliance with government laws assisted throughout the study but still most of the THs did not trust the investigator. Working along with South African students in this field would probably bring more attention and control from the THs with a larger number of trustful participants. Non-validated questionnaires made it difficult to complete statistical analysis as many questions were not correlated. There were restrictions on selected pharmacies as they probably did not keep the stock of all possible CAMs available on the market. There was no census available on THs in Mamelodi, this limited the assessment of questionnaire although an attendance list was signed off by some THs along with their contact numbers. Biased answers to the questions on the diagnostic material could not be controlled as the parameter of divination method is not explained by science, thus considered to be disqualified by the researcher. Further analysis is needed by a competent researcher with traditional medicine qualifications.

9. CHAPTER 9: FUTURE STUDY OBJECTIVES

A future objective of the study is to instigate the glycaemic control of listed CAMs to identify active ingredients for potential drug discovery and development for diabetes. The study also envisages researching platforms that will encourage interaction between THs and their regulatory body and with that of SAHPRA. A qualified traditional medicine/divination researcher needs to investigate and analyse parameters of diviner diagnostic material to exclude counterfeit THs, promoting the health sector's awareness in terms of trust in CM and TM.

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11. ANNEXURES

11.1 ANNEXURE 1

PARTICIPANT'S INFORMATION LEAFLET & INFORMED CONSENT FOR ANONYMOUS QUESTIONNAIRES

Zaina Gabrielle Ondo

Student Number; 14181101

Department of Pharmacology

University of Pretoria

'How Traditional Healers Diagnose and Treat Diabetes Mellitus in the Pretoria Mamelodi Area and how do these Purported Medications Comply with Complementary and Alternative Medicine Regulations'

Dear Participant,

I am a MSC student in the Department of Pharmacology at the University of Pretoria. You are invited to volunteer to participate in our research project on the Analysis of the current regulatory status and use of Complementary and Alternative Medicines (CAMs) used to treat Diabetes Mellitus.

This letter provides information to help you decide if you would like to take part in this study. Before you agree you should fully understand what is involved. If you do not understand the information or have any other questions, do not hesitate to ask us. You should not agree to take part unless you are completely happy about what is expected of you.

The purpose of this study is to highlight CAMs therapies that are effective in treating diabetic patients. We also aim to provide a framework to advise patients on useful CAMs as well as assist the Medicines Control Council in the regulation and post-marketing control of CAMs used to treat diabetes.

We would like you to complete this questionnaire which may take about 5 minutes of your time. This informed consent will be elaborated along with the questionnaires which will be available in 3 languages English, Zulu and Sepedi and/or will be translated when necessary by assisting volunteers. We will collect the questionnaire from you at a convenient time, or you may email, fax or post the completed document to the addresses listed above. Please do not write your name (or your companies' name) on the questionnaire, as to ensure confidentiality. All returned questionnaires will be safely and securely stored as stipulated in the approved research protocol. A copy of the protocol will be made available should you so request.

The Research Ethics Committee of the University of Pretoria, Faculty of Health Sciences, and telephone numbers 012 356 3084 granted written approvals for this study. The study protocol number is **221/2017.**Your participation in this study is **voluntary**. You can refuse to participate or stop at any time without giving any reason. As you **do not write your name** on the questionnaire, you give us the information anonymously. Once you have returned the questionnaire, you cannot recall your consent. We will not be able to trace your information. Therefore, you will also not be identified as a participant in any publication that comes from this study. No compensation will be provided for participation for that aid as it is voluntary.

Note: The implication of completing the questionnaire is that informed consent has been obtained from you. Thus, any information derived from your form (which will be completely anonymous) may be used for e.g. publication, by the researchers.

We sincerely appreciate your help.

Yours truly,

Zaina Gabrielle Ondo,

Tel: 0721987106

11.2 ANNEXURE 2

TRADITIONAL / HEALER / PRACTITIONER'S QUESTIONNAIRE

1. What is your gender?

Male	
Female	

2. What is your race?

Black	White	Indian	Coloured	Other

3. What is your Education level?

No matric	
Matric certificate	
Post-matric qualification:	
Certificate in:	
Diploma in:	
University Degree in:	

4. Have you attended any courses in how to consult with patients?

_____

5. Please specify

_____

6. For how long have you been in the practice?

0-2 years	3-5 years	6-10 years	11-15 years	>15 years

7. Where do you source your Complementary and Alternative Medicines' active ingredients?

Self-manufactured	
Local suppliers	
International importation (Please specify):	
Both importation and local suppliers	

8. Approximately how many patients are you treating for Diabetes?

Currently:	
New patients:	
1-10 per month	
11-20 per month	
21-30 per month	

9. What type of Diabetes are your patients mostly suffering from?

Type 1	
Type 2	

10. How do you diagnose diabetes?

_____

_____

11. What type of assessment tools do you use?

_____

_____

12. What treatment do you prescribe for:

a. Type 1 Diabetes :

Treatment 1	
Treatment 2	
Treatment 3	
Treatment 4	

b. Type II Diabetes :

Treatment 1	
Treatment 2	
Treatment 3	
Treatment 4	

13. After your treatment is prescribed and administered do you receive feedback from your patients?

Yes	No

14. How do you assess the efficacy of your treatment:

_____

_____

15. What is the most popular CAMS you prescribe to your patients?

Plants/herbal based	

Vitamins	
Supplements	
Other (specify):	

16. Are your CAMS registered with the MCC?

Yes	No

17. If not are you aware of the MCC's CAMS regulations?

Yes	No

18. Do your CAMS products follow the Medicine Control Council's new regulation procedures regarding registration?

Yes	No

20. Comments:

_____

_____

11.3 ANNEXURE 3

SPREAD SHEET ADDRESSED TO THE HEALTH SHOPS OR PHARMACIES

	1	2	3	4	5	6	7	8	9
Product name(s)									
Active ingredient(s)									
follow SAHPRA regulations									
CAMs registered?									

Stanza Bopape 2 Clinic
Ext 8 Hector Peterson Street
Mamelodi East

25905
Gauteng

TO THE FACULTY OF HEALTH SCIENCES

MSC AND MMED ETHICS COMMITTEE OF THE UNIVERSITY OF PRETORIA

I had the opportunity to meet with ONDO Zaina Gabrielle, your Msc student in Pharmacology. She told me about her project recently titled '**Analysis of the current regulatory status and use of Complementary and Alternative Medicines used to treat Diabetes Mellitus'.** Since she needs to get in contact with some traditional healers that I provided her with who cannot speak English very well but only Zulu and Sepedi, I volunteered to assist her with the necessary translation of the questionnaire during her entire investigation.

If you have any queries, I can be reached at the number below.

I look forward to meet her soon after her ethics approval.

Sincerely,

Maria Mokebe

Leader of traditional healer

063 784 2835

M. Mokebe

Stanza Bopape 2 Clinic
Ext 8 Hector Peterson Street
Mamelodi East

25905
Gauteng

TO THE FACULTY OF HEALTH SCIENCES

MSC AND MMED ETHICS COMMITTEE OF THE UNIVERSITY OF PRETORIA

I had the opportunity to meet with ONDO Zaina Gabrielle, your Msc student in Pharmacology. She told me about her project recently titled '**Analysis of the current regulatory status and use of Complementary and Alternative Medicines used to treat Diabetes Mellitus'.** Since she needs to get in contact with some traditional healers that I provided her with who cannot speak English very well but only Zulu and Sepedi, I volunteered to assist her with the necessary translation of the questionnaire during her entire investigation.

If you have any queries, I can be reached at the number below.

I look forward to meet her soon after her ethics approval.

Sincerely,

Monica Mambo
0727833625 | 0724659509.