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# Knowledge-Based Integration of Zimbabwean Traditional Medicines into the National Healthcare System: A Case Study of Prostate Cancer.

By

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"Submitted in partial fulfilment of the requirements for the degree of M.Sc. in Pharmacy Administration and Policy Regulation."

December 2017

Harare, Zimbabwe

## DECLARATION

I declare that this thesis that I now submit for assessment on the programme of study leading to the degree Master of Science in Pharmacy Administration and Policy Regulation has not been submitted for the purpose of a degree at this or any other higher education institution. It is entirely my own work and has not been taken from the work of others save to the extent that such work has been cited and acknowledged within the text of this work. I agree to deposit this thesis in Healthcare-learning's institutional repository and the University of Western Cape's library or allow these institutions to do so on my behalf, subject to the British and South African Copyright Legislation and the University of Western Cape's conditions of use and acknowledgement.

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# ABSTRACT

This study sought to identify the bottlenecks in the promotion of Zimbabwean Traditional Medicines (ZTMs) towards improving the national healthcare delivery system. The indigenous medicines lost value and recognition to the Conventional Western Medicines introduced by the British colonialist since 1871 and is still dominating the national healthcare delivery system. There are growing challenges to ensure accessibility of affordable drugs especially for primary healthcare. The World Health Organization (WHO) and United Nations (UN) is in support of re-engaging indigenous medical interventions to achieve the Millennium development goals. Indigenous Traditional Medicine Knowledge-Based Systems (ITMKS) form the basis of the main source of health care for about 80% of the population in the developing countries. The implementation of the Zimbabwe Traditional Medicines Policy (ZTMP) has been at a stand-still since inception in 2007.

The research used mixed methods involving qualitative and quantitative approaches. Data was collected through desk and field research. Questionnaires and focus group discussions were used to record perceptions and attitudes of key informants. The stakeholders included Traditional Health Practitioners (THPs), Medical Doctors, Pharmacists, Medical Research Council of Zimbabwe (MRCZ) staff, Medicines Control Authority of Zimbabwe (MCAZ), Traditional Medical Practitioner's Council (TMPC), Zimbabwe National Traditional Healers Association (Zinatha), Ministry of Health and Childcare, WHO, Higher Education Institutions (UZ School of Pharmacy staff and students), Christian Groups, NGOs and Prostate Cancer Patients in Harare CBD. The stakeholders sampling framework was obtained from the list of registered practitioners. The stakeholder mapping involved selection of 5 key informants from each focus group obtained through random selection. The Snowball sampling technique was used to follow the closest 5 key informants in each focus group.

The key findings established that 80% of respondents agreed to the integration of ZTM. The major bottlenecks were lack of modern dosage forms and standardization to determine quality, safety and efficacy of the ZTM.

The study suggests that in order to fast track the integration process, a bottom up implementation strategy providing ZTM advocacy, capacity building in the institutionalization and training of ZTMPs, pharmacists and CMP need to be engaged for a favorable and quick buy-in. The study also recommends further analysis of the Indigenous Knowledge Systems (IKS) areas of specialization in pharmaceutical practice in order to improve treatment outcomes.

# ACKNOWLEDGEMENT

The success and final outcome of this project required a lot of guidance and assistance from many people and I am extremely privileged to have got this all along the completion of my project. All that I have done is only due to such supervision and assistance and I would not forget to thank them.

I respect and thank Elias Mazhindu for encouraging me to undertake this study and for all his support and guidance towards the timely conclusion of my research project. I am extremely thankful to him for providing me his support and guidance although he was also busy with his PhD studies at the University of South Africa.

I owe my deep gratitude to my project supervisor Dr Samuel Egieyeh, for the key inspiration in the field of indigenous knowledge systems that enhanced my passion in this research and in turn took keen interest on my project work and guided me all along, till the completion of my project work by providing all the necessary information for developing a good research.



I heartily thank my wife Elizabeth and children Abson, Britson and Angelbright who missed me due to the pressures of my studies.

I am thankful to and fortunate enough to get constant encouragement, support and guidance from my thesis coordinator, Mr Rafik Bapoo of the School of Pharmacy who helped me complete my thesis. I also extend my sincere gratitude to all staff in the School of Pharmacy for their timely support.

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# LIST OF ABBREVIATIONS

AHFoZ – Association of Healthcare Funders of Zimbabwe

CM – Conventional Medicine

CMP – Conventional Medicine Practitioner

HPA – Health Professions Authority

HPLC – High Performance Liquid Chromatography

IPRs – Intellectual Property Rights

IKS – Indigenous Knowledge Systems

ITMKS – Indigenous Traditional Medicine Knowledge Systems

MCAZ – Medicines Control Authority of Zimbabwe

MRCZ – Medical Research Council of Zimbabwe

NAC – National Aids Council

NDRA – National Drug Regulatory Authority

TM – Traditional Medicine

TMP – Traditional Medicine Practitioner

TMPC – Traditional Medicine Practitioner Council

WHO – World Health Organization

Zinatha – Zimbabwe National Traditional Healers Association

ZTM – Zimbabwean Traditional Medicine

# CHAPTER 1

# INTRODUCTION

## 1.0 Introduction

This section outline the background, the rationale, aim and specific objectives of this study.

## 1.1 Background to the Study

The Zimbabwe Traditional Medicine (ZTM) Policy was formulated in 2007 to improve accessibility of quality, safe and effective medicines to vulnerable communities in both rural and urban parts of the developing country. The traditional medicines (TM) have always been the only form of treatment used by the indigenous Zimbabweans since time immemorial, before Western colonization which brought about the conventional medicine (CM). The CM was imposed on the indigenous people and became the prioritized first line treatment methods in both primary and specialized healthcare, (Zhang, 2002). There has been an over-reliance on these CM for prevention and treatment of all diseases until recently when there was an emergence of new diseases that defile current CM (Waite, 2000). The CM that have been available in the official national healthcare system since colonization of Zimbabwe by the British, are no longer affordable to the majority of citizens (Cavender, 1988). The innovator, new drug molecules take 2-3 decades before they can be accessed in developing countries (Stevens, Huys 2017). Also according to Stevens and Huys 2017, the patented drug cost is beyond reach in the developing countries that are first affected by these epidemics such as the Zika virus, Ebola and other outbreaks. Peculiarly to Zimbabwe are outbreaks of diseases such as typhoid, cholera, dysentery and malaria that are

fueled by the declining economic situation (Senait Kebede et al. 2010). In a recent survey , it was estimated that the cost of bringing up a new drug onto market is close to $3 billion and requires over 10 years for development (Mullin, 2014). This cost is made up of $1.4 billion for pre-clinical studies, $1.2 billion for clinical studies and $312 million spent on post-approval development.

In contrast to the high drug development costs for CM, indigenous TM can be used naturally from the bush guided by traditional herbalists and spirit mediums (Shoko, 2017). The indigenous-based knowledge used in TM may serve the same purpose as preclinical and part of the clinical studies. This folklore knowledge can be gathered from Traditional Medical Practitioners (TMP) and documented into an indigenous knowledge dossier for use as reference and guidance in developing new safe and effective disease interventions. In addition, the cost of post-approval marketing and pharmacovigilance studies may be eliminated as the safety of TM has been established over centuries of folklore medical practice. Thus there is an opportunity to save the cost of drug development by the use of indigenous knowledge of TM as a lead to new sources of drugs.

## 1.2 Statement of the Problem



TM still plays a major role in providing basic health care to communities in Zimbabwe. As highlighted by Alfred Maroyi (2011), TM remains a convenient and easily accessible source of treatment in primary health care in Zimbabwean communities (Shoko, 2017). A report compiled by the Zimbabwe National Cancer Registry (ZNCR) showing the latest 2012 statistics for prostate cancer incidences and mortality reported the continued dominance of prostate cancer as the most frequently occurring cancer in Zimbabwean men with the incidence rate having increased by 2.7 percent from 15,4 percent in 2011 to 18,1 percent. The mortality rate from the latest reports was 9 percent. Prostate cancer trends from 2005 to 2012 showed an increase from 237 in 2005 to 454 in 2012 nationwide. The age distribution of men with prostate cancer was from 40 to 65 with over 350 cases of men above 65 recorded. Experience has shown that it is just the tip of the iceberg as many cancers have not been captured by the routine National Health

Information System because the patients do not present themselves for treatment in the mainstream health system and some deaths are not registered.

The rural communities have a long history of using traditional plants for medicinal purposes and hence the low cases of prostate cancer then. Despite the growing recognition of TM in Zimbabwe, this rich knowledge of indigenous peoples has not been sufficiently utilized for the future benefits. A study conducted by Hostettmann et al (2000) showed that the knowledge about the use of medicinal plants is readily available, but lacks further investigation for registration and market approval. This poses the risk of losing the indigenous knowledge of the TM. Therefore, there is a need to move towards registration of TM and indeed incorporate them into the healthcare delivery system.

The problem statement is that, in light of the widespread use of TM worldwide, high treatment success rate, minimum side effects and accessibility at affordable costs in poor developing countries, why has it taken Zimbabwean regulatory authorities more than a decade to implement the process of integration of TM into the healthcare delivery systems.



## 1.3 Purpose of study

The purpose of the study is to establish the bottlenecks in the implementation of the process of integration of TM in the healthcare delivery systems in Zimbabwean so that the Zimbabwean community can access safe, effective and affordable TM at all health institutions. This should complement and improve the overall disease prevention and treatment outcome in line with the WHO guidelines for ensuring total health coverage.

## 1.4 Research Objectives

The Main Objectives was to:

- Establish why the Zimbabwean Traditional Medicines Policy (ZTMP) established in 2007 has not been significantly implemented to allow integration of the TM into the mainstream healthcare delivery system.

Given the two decades of stalemate in the policy implementation that would have resulted in ZTM integration, an evaluation of progress and achievements in Policy Objectives would have necessary, hence the specific objectives were;

- To assess whether the policy minimum requirements for registration of ZTM and the practice are attainable.
- To determine the challenges of establishing accurate ZTM (Zimbabwe Traditional Medicines) information to produce the national pharmacopeia and compendium.
- To assess whether the use of indigenous knowledge information can be used as equivalent evidence to support the quality, safety and efficacy of ZTM sufficient for the integration.
- To determine the level of education and training required for the immediate integration of the ZTM practitioners in to the healthcare system.
- To come up with recommendations on the integration of ZTM into the national healthcare system.

## 1.5 Research questions

- Are the minimum requirements for registration of TM and practice attainable?
- What are the challenges of establishing accurate ZTM information to produce the national pharmacopeia and compendium?
- How can the use of indigenous knowledge information be used as equivalent evidence to support the quality, safety and efficacy of ZTM?
- What is the level of education and training required for the immediate integration of the ZTM practitioners in to the healthcare system?
- What recommendations for the integration of ZTM into the national healthcare system can be given?

## 1.6 Assumptions

The study had the following assumptions;

- The study participants would give accurate information on the use of ZTM and the nature of their practice.
- That the minimum requirements for registration of TM and the practice exist.
- There is recorded information on the quality, safety and efficacy of ZTM to use as evidence to support the integration process.
- That practitioners in traditional medicine have received some training to assist in the integration of ZTM.
- The study results and recommendations will help practitioners in the integration of ZTM policy practices.
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## 1.7 Delimitations



The researcher confined the scope of study within the resources and time capacity to complete the exercise and come up with valid, reliable, unbiased and discriminatory data from a representative sample of respondents. The questionnaire design and survey administration was done with due diligence and maximum attention to detail to reduce errors and keep within study area. The following delimitations were maintained over the study period;

- The time period stretched from the establishment of the ZTM policy in 2007 until November 2017 when the field study was finalized.
- The geographical scope was limited to Harare, the capital city of Zimbabwe. The assumption is that all patients from all corners of the country suffering from all kinds of serious or terminal illnesses converge in Harare where there is easy accessibility to the best healthcare facility and practitioners in both traditional and conventional interventions.
- The respondents to the study included the following groups of stakeholders and key informants;

- Zimbabwe Traditional Medicine Practitioners (ZTMPs)/Herbalists, TM Market Vendors.
- Medical Doctors, Pharmacists, Nurses, Laboratory Technologist.
- MRCZ, MCAZ, TMPC/Zinatha.
- Ministry of Health and Childcare (MoHCC) TM Department Staff, WHO TM Officers.
- Higher Education Institutions (UZ School of Pharmacy staff and students), Harare Institute of Technology Pharmacy Department Staff and Students researching on TM.
- Christian Groups, NGOs, Public.
- Prostate Cancer Patients.

➢ The literature to support the study was obtained with following variables within the factors affecting the integration process of ZTM into the national healthcare system;

- Zimbabwean traditional medicines.
- National healthcare policy.
- Indigenous knowledge-based integration.
- Mainstream healthcare system.
- Prostate cancer.
- Minimum requirements of ZTM and practice registration.
- ZTM pharmacopeia and compendium.
- Evidence-based decision.
- Level of education and training in ZTM.
- Recommendations on the integration of ZTM into the national healthcare system.



## 1.8 Limitations of study

The barriers likely to be faced by the researcher are as follows;

➢ Bias as a result of fear of victimization on the part of the target groups such as the MoHCC - TM department staff responsible for implementing the integration

process, trying to save their jobs in case they are responsible for the failed or delayed ZTM policy implementation. This can be circumvented by engaging staff not directly in decision making positions or accountable for policy implementation department.

- The other limitation is on accessing trade secrets of the TMPs as they have always protected their valuable IKS through passing on to the next family generation. This will simply be resolved by signing confidentiality and non-disclosure agreements. In some instances it would be appropriate to use deceptive methods by pretending as a client until a conducive opportunity arises to open up as a researcher. Also the idea of promising the benefits of IPRs, royalties, community benefit schemes and incentives upon market approval of the products can also facilitate disclosure of TM information.
- The lack of trust and confidence emanating from historical theft of ITMKS by previous researchers in the pretext academic information was overcome through letters of introduction from the MoHCC permanent secretary and the chairman of the TMPC.
- The researcher is going to make use of pre-registration pharmacists that he is supervising to interview clients and other target groups where there are high chances of biased responses.



## 1.9 Significance of study

The research findings and recommendations are going to benefit the following people and organisations;

**Body of Knowledge**

- Assist the MoHCC/WHO in reviewing the ZTM policy prior to implementation.
- Expose bottlenecks and provide solutions in the stakeholder's participation to achieve goals of ZTM integration.

- Set tone for further stakeholder consultations to improve the pace of ZTM recognition and integration.

**National Healthcare System**

- The research seeks to bring together collaboration and interdisciplinary benefits through the direct integration of ZTM to the CM to provide the complementary and synergistic effects that will improve treatment outcome.
- The research will stimulate interest in new drug development using leads from ITMKS embedded within our resourceful communities, add value through documenting the quality, safety and efficacy for global market approval and earn the nation the much needed foreign currency.
- Stimulate further ZTM research in collaboration with the international community resulting in community ownership trusts, IP rights, Royalties for ZTMPs, create employment and infrastructure development for the nation.

**The Researcher**

- The researcher as a Healthcare Consultant and business entrepreneur expects to develop better knowledge and understand about the regulation, institutionalization and market approval of TM for further consultancy work with the TMPs on the registration of their products and practice in Zimbabwe and abroad.
- The researcher is the Founder of The Zimbabwe Traditional Medicines Research Foundation (ZTMRF), hence the research skills and results will add into the ITMK sought by the organization and form the basis for further research and training of research.

## 1.10 Definitions of key terms

- Traditional Medicine (TM) is the sum 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.

- Complementary and Alternative Medicine (CAM) is the popular term for health and wellness therapies that have typically not been part of conventional Western medicine. Complementary means treatments that are used along with conventional medicine.
- Conventional Medicine (CM) is a system in which medical doctors and other healthcare professionals (such as nurses, pharmacists, and therapists) treat symptoms and diseases using drugs, radiation, or surgery. Also called allopathic medicine, biomedicine, mainstream medicine, orthodox medicine and Western medicine.
- Direct integration of TM into the mainstream healthcare system involves combined administration of both TM and CM to the same patient for the prevention or treatment of diseases and symptoms.
- Parallel integration of TM into the mainstream healthcare system involves use of each treatment method at different times for the prevention or treatment of diseases and symptoms.
- Indigenous knowledge systems, is used to describe the knowledge systems developed by a community as opposed to the scientific knowledge that is to as 'modern' knowledge. It has value not only for the culture in which it evolves, but also for scientists and planners striving to improve conditions in rural localities. Incorporating indigenous knowledge into healthcare policies can lead to the development of effective integration strategies that are cost-effective, participatory and sustainable.
- Health policy refers to any decisions or plan of actions that are implemented in order to achieve specific health care goals within a society. An explicit health policy can achieve a vision for the future which in turn helps to establish targets and points of reference for the short and medium term. It outlines priorities and the expected roles of different groups and it builds consensus and informs people.

- Health promotion is the process of enabling people to increase control over their health and its determinants, and thereby improve their health. The primary means of health promotion occur through developing healthy public policy that addresses the prerequisites of health such as income, housing, food security, employment, and quality working conditions.
- Epistemology is the nature of human knowledge and understanding that can possibly be acquired through different types of inquiry and alternative methods of investigation.
- Ontology is a branch of philosophy concerned with articulating the nature and structure of the world.

# CHAPTER TWO

# LITERATURE REVIEW

## 2.0 Introduction

Out of the Zimbabwe population of about 15 million people, 88% of men above 40 years are predisposed to prostate cancer (Kadzatsa and Chokunonga 2016). Prostate-specific antigen (PSA) is offered at a few provincial hospitals, private surgeries and laboratories (Zimstat, 2016). Mudzingwa (News 24 Zimbabwe, 23 May 2016), a herbal practitioner operating 12 Wellbeing herbal clinics in Zimbabwe reported 60% herbal medicine success rate as evidenced by his patient record review in the past 5 years of practice. At the global level, literature review shows 2-5% long-term success rate for conventional therapy Goldberg, (2010). The prostate cancer treatment success rate of 60%, established by Mudzingwa 2016 using ZTM is quite significant compared to the 2% obtained from CM. This provides justification for the urgent need of further investigations to enable the immediate integration of ZTM and improve total health coverage. Thus the ZTM policy sounds defective from the delayed integration of potential treatments for major killer diseases in developing countries. There is need for an integrative policy to support training of Traditional Health Practitioners (THP) and Conventional Medical Practitioners (CMP) to promote collaboration and patient referrals. The integration policy should facilitate cultivation, processing and development of quality and safe dosage forms for marketing within Zimbabwe's retail pharmacies and other licensed medical institutions.

The WHO Traditional Medicine (TM) strategy 2002-2005 was the first initiative to start the integration of TM into the national health care system by assisting Member States with information to develop their own national policies on traditional medicine (Zhang, 2002). This also contributed to the establishment of the ZTMC in 2007 that has been idle since then whilst other countries such as South Africa, China and India have made significant progress in ensuring accessibility of locally approved TM in both urban and

rural areas. The WHO Traditional Medicine Strategy 2014-2023 aims to establish the national standards for the universal health coverage by integrating TM services appropriately into health service delivery and self-health care.

The research seeks to investigate why the integration of the ZTM is still in its infancy, more than a decade after the establishment of the TM policy by the Ministry of Health and Child Care. It is prudent to investigate the challenges and opportunities associated with the ZTM integration policy amid numerous claims from TMPs and patients who have been successfully treated and confirmed through laboratory PSA tests that the phase 4 metastatic prostate cancer has been reduced to undetectable levels within 3 months on a 3-4 regimen course. This research is going to identify the bottlenecks in implementing the integration strategy of the TM into the current national essential drugs list that guide prioritization of recommended first-line drugs of choice by prescribers. The study is going to investigate the conventional and traditional treatment methods currently being used for prostate cancer as an example to assess the possibility of integrating the treatment options. A research survey and subsequent stakeholder validation conference will be conducted to find the challenges and opportunities in the integration process. The stakeholder's conference together with focus group discussions, key informants suggestions will make up the recommendations to the policy implementation and subsequent integration of ZTM. There is need for the stakeholders' buy-in for a smooth and successful integration process.



Information such as found in a research by Galena and Vaghefi, (2008) on the use of mushrooms in the prevention and treatment of cancer is very motivating and encouraging. They gathered and recorded statistics revealing that Cancer has become a worldwide health issue. The World Cancer Report states that the global cancer rate may increase by 50% to 15 million new cases by 2020. Treatments for cancer so far include surgery, chemotherapy, radiation therapy and some alternative treatments such as medicinal mushrooms. While chemotherapy and radiation have toxic effects on the body and compromise the immune system, medicinal mushrooms have shown promising results without the immune-compromising and toxic effects.

## 2.1 The Global use of Traditional Medicine for Prostate Cancer

The global experience with the management of prostate cancer using herbal medicines has been dominated by China and India. China has made important strides towards formulating TM in clinical treatment of prostate cancer treatment. Chinese herbal extracts have been proved to inhibit the development of prostate cancer through various mechanisms that include, inducing apoptosis, inhibiting cell proliferation and suppressing the migration of invasive human prostate cancer cells (Xueni et al 2018). Xueni et al (2018) established that the Chinese medicines with anti-prostate cancer activity are polyphenols, alkaloids, and terpenoids. The extracts of G. lucidum, Litchi, S. lappa and T. wilfordii have been proved active in the androgen-independent prostate cancer cells, and S. barbata suppressed androgen-dependent prostate cancer cells growth. Also, the extracts of S. baicalensis and W. chinensis inhibit both androgen-dependent and androgen-independent prostate cancer cells. In addition, extracts such as Guttiferone F, Honokiol, Quercetin, Triptolide, Baicalin, Gypensapogenin H, Curcumin, and dihydroisotanshinone I, inhibit both androgen-dependent and androgen-independent prostate cancer cells.



According to Richard Komakech (2017) over 60% of currently used anticancer agents are estimated to be from natural sources. The most commonly known potential anti-prostate cancer plant is Prunus africana (African cherry) which belongs to the plant family Rosaceae found in sub-Saharan Africa. The use of P. africana has been patented in France for prostate cancer treatment. Also the bark extract of P. africana has for many years been used for the treatment of benign prostatic hyperplasia (BPH). The effectiveness of the bark extract of P. africana in BPH treatment is a result of the synergistic effects of pentacyclic triterpenoids, ferulic esters of long-chain fatty alcohols, and phytosterols contained in P. africana bark. The phytosterols (including β-Sitosterol) and pentacyclic triterpenoids (including ursolic acids) also have anti-inflammatory effects on the prostate. The phytochemicals found in P. africana that have potential in prostate cancer chemoprevention and chemotherapy-both in vitro and in vivo provide leads to new block buster drugs in prostate cancer.

The TMPs in Ghana have been noted to play a very important role in health delivery in the rural areas where there is less access to conventional health facilities with 70 –80% of Ghanaians using traditional medicines, Kyei et al (2017). Kyei et al (2017) also noted that some Ghanaians believe that not all diseases are curable using conventional western medicines. To this extend, the TM in Ghana has been incorporated into the main stream medical services resulting in more patients accepting TM treatments for prostate conditions. TMs also referred to as phytotherapeutic agents have been noted to have attracted tremendous attention in Ghana for the treatment of prostate cancer because they are thought to be safer, more cost-effective and have fewer side effects than conventional alternatives. The main reason for increased use on Ghanian TM has been attributed to advanced analysis, quality control and clinical research to support the value of herbal medicine in the treatment and prevention of diseases. Also Kyei et al (2017) established that 75% of the Ghanian population depend on traditional herbal medicine for their healthcare.

Ghana has established a Center for Research in Plant Medicine (now Center for Plant Medicine Research CPMR) in 1975 to identify and characterize Ghanaian herbs with medicinal properties to support their use in a more scientific and evidence-based manner. There is tremendous biodiversity in Ghana associated with plant medicine that range from individual use, home-made product, to family-size and large scale production where the products are distributed and sold in Chemical and Pharmacy shops in the country. Ghana has established a dual system of medical practice that recognizes both traditional and conventional medical practices in law and promotes their coexistence, hence the inclusion of some traditional medicinal products in Ghana's essential drug list.

Ghana has instituted the model of integrating traditional herbal practice into the mainstream health system since 2010 based on WHO recommendations and in line with country-specific studies and observations. The Ministry of Health/ Ghana Health Service (MOH /GHS) initiated the policy on institutionalizing herbal medicine services on pilot bases. Graduate traditional herbal practitioners from the tertiary institutions are allowed to practice side by side with their orthodox practitioners with the added

advantage of each being able to make referral (either way) for further management as found appropriate. In line with these initiatives, including the certification of some TM by the Ghana Foods and Drugs Authority, it was observed that the acceptability of the integration of the herbal and conventional systems was 94.4% among core hospital staff. This level of acceptability has increased confidence in herbal medicines, reduced pressure on conventional care/ practice and ensuring the use of only herbal medicines approved by the regulatory body (Food and Drugs Authority). Some clinical staff are concerned that the move will lead to endorsement of 'quack' herbal practitioners at the expense of promoting evidence-based medicine.

## 2.1 The minimum requirements for the registration of ZTM products and the practice

Zimbabwe classifies ZTM under Alternative or Complementary Medicines and is currently holding consultative meetings to determine the regulation, which has been seriously disputed by TMPs at one of the meeting held on 22 January 2016 at the Rainbow Towers Hotel. According to Nyazema (2013), a Zimbabwean Professor in Conventional Medicines but has special interest in TM research, the following constitutes the requirements for registration of traditional herbal medicinal product in line with WHO guidelines:



- Assessment of Safety should cover all checks and controls on the toxic properties of ZTM. The ITMKS in the community that the treatment intervention has been traditionally used without any adverse effects demonstrates that the practice is safe unless new evidence is found that can lead to revising the risk-benefit status.
- Accessible literature must be reviewed with references to the first articles and monographs. Long-term use requires post-market pharmacovigilance and authorities should record reported side effects to enable the change of use.
- The dosage specification must be documented to indicate the safety margin. Any potential for abuse, abuse or addiction must be documented.

- The pharmaceutical quality assessment of the TM must be completed according to the pharmacopoeia monograph and Good Manufacturing Practice (GMP) guidelines.
- The raw plant material should be identified according to the botanical guidelines, including the family, the species and the authority to guarantee the identification of the plant. Demonstrate which part of the plant used and identify the chemical characteristics of the active ingredients. This should be followed by attaching a batch number to the product label.
- The method of extraction and processing of plant materials must be documented. This includes processes such HPLC by fractionation, purification or concentration. The production method must be described in detail according to GMP.
- The manufacturing procedure and formula for mixing excipients to produce the finished product should be illustrated in detail. The finished product should conform to the requirements and specifications for the respective dosage form.
- The stability of the finished product in the final marketing container should be examined under the prescribed storage conditions to establish the shelf life.
- The level of efficacy should be assessed covering a review of the relevant literature. Also current research information should be considered.
- The pharmacological and clinical activity of the active ingredients and their therapeutic effects should be determined and recorded.
- The research data proving the indications for the specific TM or active ingredients should be recorded together with the reported individual experiences from physicians, THP and patient testimonials.
- Herbal combined products with many active ingredients should be indicated as separate between old and new mixed products.
- Promotion and advertisements for the health professionals and the public should be in line with the approved package information.
- The product labels and package inserts must be justifiable for the purchaser or patient so convey appropriate product information to the consumer. The package information should include the product name, list of active ingredients and their

respective quantities, dosage form and indications. The dosages suitable for the young and the elderly, the method of administration, period of use, the main adverse effects, information on over-dosage, contraindications, warnings, precautions and herbal-drug interactions, use during pregnancy and lactation, expiry date, batch number, holder of the market-approval (WHO, 1991) (MCAZ Draft, 2015).

The challenges in the regulation of TM result from the different methods of classification of herbal medicines from one country to another. The same TM can be used as food, dietary supplement or herbal medicine in different countries. The prerequisites and techniques for research and evaluation of the safety and efficacy of herbal medicines are more complicated than those for CM. A single TM contain various ingredients and a mixed herbal product has even more active constituents. The time and resources to isolate every ingredient would be much higher than the CM and such analysis would not have any advantages over CM. The quality of TM raw material sources determines the safety and efficacy of herbal medicines which in turn relates to the intrinsic (genetic) factors and extrinsic factors (environmental conditions, cultivation and harvesting, harvesting in the field and post-collection, transport and archiving) Kasilo and Trapsid (2010).



## 2.2 The Challenges of Establishing the ZTM Pharmacopeia and Compendium.

The responsibility of creating the ZTM pharmacopoeia lies in the MoHCC TM Department. The ministry has set up an inter-ministerial Committee on ZTM development that is responsible for the institutionalization of medicinal herbs. The standardization of ZTM involves laboratory analysis of the chemical constituents and determining the qualitative and quantitative standards for determining the quality, efficiency, safety and reproducibility (Ndoro, 2017).

The Inter-ministerial Committee on ZTM has no resources for the collaboration of complementary activities between MoHCC technocrats and other organizations in the field of higher and tertiary education, science and innovation, the development of

agriculture, automation and water systems, the environment, water and air, industry and commerce. These ministries are critical in the overall development of good quality and effective ZTM. The Committee should incentivize and encourage financial support of herbal business, improve awareness of herbal companies, enforce GMP in order to satisfy international standards. There is also need to develop human resources for the potential industry, set up commercial cultivation of raw materials and improve cooperation between research institutes such as colleges and NGOs with the ultimate goal of expanding the level of R & D and the exchange of innovation. The foundation of the Research Institute of Natural Medicine will be in charge of investigating the scientific evidence supporting the medicinal value of ZTM and developing the products.

As indicated by Sakki and Kasilo (2010), the integrated health system includes the pooling together of traditional and orthodox therapeutic systems. The ZTM is driven under a lot of secrecy, myths and mystical powers. The ZTM practice is embedded in a strong belief of ancestral spirits. The diagnosis and efficacy of traditional remedies is associated with the influence of the ancestors. Some of the ideas in ZTM are difficult to clarify in scientific terms. Scientific research of medicinal plants must expose the traditional myths by engaging the conventional scientific principles in plants. The scientific competence of ZTM can lead to the standardization and quality control of products to ensure their safety. It is after these assessments that they can be approved for use in basic health care and be part of the national pharmacopoeia. Such research activities could also lead to the development of new drugs (Farnsworth, 1988).

The ZTM Policy needs to be reviewed to allow engaging appropriate specialized organizations to participate and collaborate in research applied directly to indigenous populations. This allows the indigenous people of Zimbabwe to have ownership of their cultural knowledge, clinical data and information to support market approval and integration of the cultural inheritance. It is unfortunate that the first foreign collaborators that were engaged in local indigenous research did not share results of the ITMK to their local partners (Varmus, Satcher 1997) and (Abbott, 2014). They lost trust and confidence with the indigenous population and hence the demand by the TMPs to exercise their rights to ensure control of all aspects of research. The indigenous

populations want to be involved in decisions regarding ownership and access to the data. They also want to be custodians of the research data which can be used to build up the national Pharmacopoeia.

## 2.3 ITMKS as Equivalent Evidence for ZTM Market Approval.

According to Zhang et al (2016), WHO has observed that the practices of TM differ from region to region due to cultural, historical, personal attitudes and the indigenous philosophical concepts associated with the ancestral practice. This differs with CM that is based on scientific evidence. The principle of TM relies on historical ITMK that includes experience passed on from generation to generation as equal evidence for the safety and efficacy. The WHO recommends that additional scientific evidence be researched in support of ITMK in support of the safety and efficacy for global market approval. Lack of research data is due to the national health care policies discriminating TM and hence the lagging behind of research methodologies for evaluating the complex TM compounds. The TM research is interdisciplinary in the fact that it relies on a holistic approach which cannot be evaluated using the conventional efficacy assessment measures.



The other difference between the main stream science and traditional knowledge systems is in the format of presentation. The elicit format of the scientific knowledge consist of formal language in the form of grammatical statements, mathematical expressions and specifications Sackey and Kasilo (2010). The scientific knowledge can be transmitted between individuals and is currently the dominant method of knowledge transfer. The ITMK format is tacit and is found in the experiences and beliefs of the community, their perspectives and values of the indigenous people and lacks formal language. The fact that TM have been used successful since time immemorial contradicts with the WHO need for scientific clinical data for market approval. TM and the practice has been field-tested for centuries and a lot of empirical knowledge has accumulated in local communities and has been maintained and transmitted orally from generation to generation by THPs and traditional community leaders. Traditional knowledge is a good example of community-based research. The weakness of TM are

as a result of its reliance and dependence on demographic stability and morality. The community is a source of strength for ITMKS in terms of the discovery process and knowledge production.

Traditional knowledge is vital in the commercialization of natural products. It can be shared to commercial interests through databases, academic publications or field collection. Traditional knowledge is being lost through modernization and the ongoing globalization processes. Additionally the ITMK is less transferable than conventional science due to its holistic socio-cultural and spiritual dimensions. The integration of TM into modern medical practices must ensure sufficient quality, safety and efficacy at a local scale whilst collecting further information for global approval in the long-run. Quality should be built in over the development process because it affects the efficacy and safety of the herbal products (Fong, 2002).

There is not much research on traditional herbal medicines in Zimbabwe mainly because of the inferiority complex and lack of resources and knowledge of the approach that will satisfy the market. There are various expectations from different stakeholder groups such as the rural based citizens who are comfortable consulting ZTMPs in the cultural mode and believe in the old age dosage forms. The urban and Christian communities prefer consulting conventional medical practitioners such as herbalists, pharmacists, doctors and nurses based in the official registered mainstream healthcare system. They also prefer modern dosage forms free of Spiritism and marks such as lacerations that will reveal mode of treatment which is against their beliefs.

Research and development in TM stretch from phytochemical analysis, standardization and quality control of herbs and dosage forms design to preclinical and clinical trials. These investigations on standardization and formulation are pre-requisites for commercialization of herbal products. The research and development is expensive such that manufacturers of TM are largely small scale and lack the desired expertise and resources. Current research on ZTM is therefore mainly academic driven focusing mainly on the field of interest of the researcher. There is more interest from social science research, evidence that the field is multi-disciplinary and requires collaboration between various faculties to derive optimum value to improve healthcare systems

(Maroyi 2013, Magaisa 2004, Choguye 2016, Moyo 2016, and Nyawo 2016). Some of the orthodox related research done on TM include the co-administration of African potato with lopinavir/ritonavir and the Moringa oleifera to investigate the pharmacokinetic drug interactions (Monera-Penduka et al 2017).

## 2.4 Level of Education and Training in ZTMP.

According to Ndoro (2017) and Waite (2000), TM is the first line of treatment for many diseases in Zimbabwe. Some critical cases require modern medical and surgical interventions and other procedures to save lives. Both types of medical intervention make healthcare more effective in the country. Thus collaboration between the practitioners of the two health systems is crucial as each has its own advantages and disadvantages. Conventional Healthcare Practitioners (CHPs) can work together with Traditional Healthcare Practitioners (THPs) to further study, research and develop ZTMs that show potential as life-saving medicines. THPs can draw upon various areas of biomedical procedures like understanding universal procedures for sterilization and hygiene, as well as having a more in depth knowledge of certain disease processes. Conventional biomedicine focuses on pathology and physiology in a scientific step by step procedure. On the other hand, Traditional Medicine looks at the bigger picture of the spirit, soul and body in a holistic manner.



The method of treatment recognizes the local customs and traditions of the people as well as the entrenched value systems. Learning from each other's knowledge and experience will enhance the knowledge of the practitioners for the benefit of the patients. Furthermore, both THPs and CHPs can collaborate to educate their respective communities on how to improve prevention measures. This can include education on reducing different forms of contamination, maintaining proper hygiene, how to reduce the spread of communicable diseases, how to treat diarrhea with oral rehydration therapy, and how to notice early warning signs of malaria in children and get the proper medical attention (WHO 2012).

According to Abdullahi (2011) some Universities in West African States such as Democratic Republic of Congo, South Africa and Tanzania have included TM in the

curricula for pharmacy and medical students. The Kwame Nkrumah University of Science and Technology in Kumasi, Ghana established a degree in Herbal Medicine since 2001 and had trained over 80 medical herbalists by December 2011. This practice increase the acceptance of TM amongst the younger generation. Most THPs lack formal school education that provides confidence and enables the THPs to realize their positions on various local, national and international subjects pertaining to their profession more clearly. Knowledge will also promote their capacity to collaborate with CHPs and biomedical scientists more effectively. Knowledge will also promote proper recording of their clinical observations. Furthermore, such education will further empower the THPs to apply new knowledge and skills acquired during training sessions and conferences. Training of both THPs and CHPs in each other's systems of expertise to understand and accept each other's' practices and limitations will enhance their knowledge and foster collaboration. The following issues can promote education, training and referrals among THPs as well as between THPs and CHPs:

- Identification of best practices in the field of collaboration between THPs and CHPs.
- Availability of appropriate referral forms and patients' forms which are easy to use and have some guidelines.
- Supporting the training of THPs on basic biomedical patient management techniques.
- Inclusion of Traditional Medicine and its importance in standard biomedical training curricula.

## 2.5 The Prevalence of Prostate Cancer

Lifestyle habits can also reduce the incidences of some diseases such as prostate cancer by eating fruits and herbs that counter abnormal growth of prostate cells and avoid processed and contaminated foods exposing to cancer.

The occurrence of prostate cancer in Zimbabwean black men is increasing and the rate is now several times higher in recent years than it was 20 years ago as reported by the Zimbabwe Cancer Registrar (Chokunonga, 2016). Mr Chokunonga spoke the same with

other oncologists at a professional workshop that the increase in prostate cancer new cases in the country is a reflection of deteriorating social and lifestyle changes besides the HIV-AIDS pandemic. The risk of prostate cancer among black Zimbabwean men increased to 6.4 percent annually above all cancers men. The prostate cancer statistics could be higher if there was a national screening program. The Prostate-Specific Antigen (PSA) testing is available at a few public hospitals and at all private laboratories. Most patients present with advanced disease because of our low PSA screening rates.

The report by (Mandivheyi, 2017) shows that most men over the age of 35 in Zimbabwe rarely carry out health checks. Most often they look for an examination only when they experience severe urinary tract pain or blockage. Lifestyle that includes refined foods, exposure to radioactive material in microwave cooking and genetically modified foods poses some risk to the prostate gland. The western diet characterized by high levels of calcium intake is associated with advanced prostate disease. Eating fish can reduce mortality from the prostate, though it does not seem to influence the incidences. There is also low incidences with a vegetarian diet. Nutrition and diet rich in lycopene contained in cooked tomatoes and other natural red product, the selenium contained in Brazil nuts, cruciferous vegetables, soy and various vegetables are associated with a lower risk of prostate disease.



The National Cancer Registry of Zimbabwe (ZNCR) report published in 2012 show that prostate cancer mortality is dominating other cancers in Zimbabwean men with occurrence rate increasing by 3% from 15.4% in 2011 to 18.1%. The mortality rate of the last reports was 9%. Models of prostate cancer from 2005 to 2012 showed an expansion from 237 in 2005 to 454 in 2012 across the country. The age distribution of men with enlarged prostate ranged from 40 to 65, with over 350 cases of men over age 65 recorded.

## 2.6 Recommendations for the Integration of ZTM into the National Healthcare System.

The integration of the ZTM should be guided by the WHO vision for member states to ensure that all people have access to promotive, preventive, curative and rehabilitative health services of sufficient quality to be effective while also ensuring that they do not suffer financial hardship when paying for these services.

The following needs to be established in planning for the integration process;

- Securing qualified TMPs is the major positive contribution to universal health coverage.
- Ensuring that ZTM is covered by public and private medical insurance companies for national health insurance reimbursement.
- Ensure ZTM regulation and registration are affordable and easily established.
- Training more medical doctors in the TM practice, a concept that can increase trust and confidence in ZTM and provide need for reimbursement of TM.

The Japanese have successfully managed the integration process such that by year 2000, 84% of the conventional physicians used kampo in daily practice. The registered medical doctors prescribing kampo medicines only was 295 049. There was 276 517 registered pharmacists dispensing kampo medicines only. Also 92 421 acupuncturists, 90 664 moxacauterists, 104 663 massage practitioners and 50 428 judo therapists practiced kampoo. By April 2000, the National Health Insurance Reimbursement List included 147 prescription kampo products and 192 herbal medicines were used in prescription kampo products. Acupuncture, moxibustion, Japanese traditional massage and judo therapy were partially covered by private health insurance.

The Traditional Chinese Medicine (TCM) and Conventional Medicine are practiced alongside each other at various levels of the health-care service, public and private insurance cover both practices. When integrating TCM into the health care system, the process and steps taken vary from country to country according to the following criteria:

- The survey of TM use which includes the benefits and risks in the context of local history and culture and promoting an appreciation of the role and potential of TM.
- Analysis of the national health resources such as finance and human resources for health.

- Strengthening the establishment of relevant policy and regulations for TM products, practices and practitioners.
- Promoting access to health and integration of TM into the national health care system through reimbursement facilities, referral and collaborative pathways.

A knowledge-based policy is the key to integrate ZTM into national healthcare systems. The ITM Research should be prioritized and supported in order to generate the knowledge. Whilst there is much to be learnt from controlled clinical trials, other evaluation methods such as the ITMK are also affordable and practical in developing economies. These include outcome and effectiveness studies, as well as comparative effectiveness research, patterns of use and other qualitative methods obtained through cheaper survey methods. This provides an opportunity to experience the "real world experiments" using different research designs and methods that are valuable and applicable to prevailing economies. This provides the importance of engaging various kinds of contributing research methods and designs in the effort to build a broad evidence base to inform national policy and decision-making.

It is also vital to obtain stakeholder confidence and buy-in through seeking technical guidance on research and evaluation of ZTM safety, quality and efficacy. This can be achieved through stakeholders' seminars and workshops on the integration of ZTM into the primary healthcare system. The national capacity building seminars and workshops on safety monitoring of herbal medicines, regulations on ZTM practice, developing national policy and programs for ZTM, regulations for herbal medicines and provision of guidelines or minimum requirements for basic training of TM providers. There is also need to arrange global meetings on the provision of technical support to promote safe and effective use of ZTM in primary health care. This should also include the provision of cooperation channels between national health authorities, guidance on self-care, information for the public in primary health care and at community level, provision for research databases and information sharing on regulatory issues.

## 2.7 Chapter Summary

It appears Zimbabwe is lagging behind in the research on and transformation of TM to achieve the safety, quality and efficacy expected by the national and regional authorities in order to be approved for market registration prior to integration into the national healthcare delivery system. The integration of ZTM can help to improve accessibility of primary healthcare through available indigenous medicines as opposed to the expensive CM that take more the two decades to reach developing countries. Trained TMPs with appropriate cultural knowledge can work together with CHPs to promote the integration process in a bottom up approach.

Outside the Zimbabwean situation are regional and international clinical research and implementation into the healthcare system. The model of integrating traditional herbal practice in Ghana, is a success story that the ZTM policy can be implemented to alleviate suffering from diseases like cancer, diabetes, hypertension and other chronic diseases. The scientific assessment of TM through to clinical trials carried out in China and India also provides a platform for the potential implementation of the ZTM policy in line with the MCAZ requirements.

# CHAPTER 3

# METHODOLOGY

## 3.0 Introduction

This chapter shows the research methodology used in the survey. The chapter analyzes research design, research philosophy, research approach, research strategy, data collection tool, sampling, data review, validity and ethical issues that have driven the research.



## 3.1 Research Design

This refers to the plan of action responsible for the execution of the field research activities that was used by the researcher in data collection, preparation and processing the data from the investigation. The research design can be defined as the overall plan on what needs to be done to create solutions to the research question. The present research sought to uncover problems that have slowed down the integration of the Zimbabwe Traditional Medicines (ZTM) into the national healthcare system. This was achieved through a survey using two types of questionnaires targeting the prostate cancer patients and other ZTM stakeholders. The survey questionnaires captured the research participants' historical characteristics and also evaluated their knowledge on prostate cancer signs and symptoms, screening and diagnostic methods, drugs and/or traditional medicine used and the quality of life obtained after the treatments.

To accommodate for alternative opinions on qualitative and quantitative research, the research used triangulation techniques. Du Plooy (1995) defines triangulation as an effort to incorporate different sources of data in the same research task to improve reliability of the results and to adjust the restrictions of each method. The two methods of data collection, the questionnaire and the interview, complement each other resulting in improved validity and reliability (Mohammad, 2013).

The study was carried out as a baseline survey of the ZTM policy and the implementation process in order to answer the question of why the integration of ZTM into mainstream healthcare delivery has not taken off. The prostate cancer patients and the respective stakeholder's of the ZTM were engaged as research participants with respect to the World Medical Association (WMA) Declaration of Helsinki for the ethical principles for medical research involving human subjects (WMA 18th General Assembly, 1964, WMA, 2017). Thus the approach used was strictly in the interest of the prostate cancer patients and the stakeholder participants. The survey strategy draws subjects from a study population to make up a study sample, which was then extrapolated to cover the population (Wilson, 2006).

## 3.2 Data Collection



### 3.2.1 Study Population

The study population examined were ZTM stakeholders and professionals including Traditional Health Practitioners / herbalists, doctors, pharmacists, medical staff from the (Medical Research Council of Zimbabwe / Medicines Control Authority of Zimbabwe / Complementary Medicines Practitioners Department / Zimbabwe National Traditional Healers Association), Ministry of Health and Child Care, WHO, University of Zimbabwe School of Medicine), Harare Botanical Gardens, other interested parties (Christian groups, NGOs and the public), ZTM Provider (CBD, Mbare Musika and Magaba) and other prostate cancer care providers.

### 3.2.2 Study Sample

Saunders et al. (2004) define a study sample as a component of a complete set of the population reflected on measurable demand. Malhotra and Peterson (2006)

characterized the study sample as a population subset comprising special components representative to support the research. The large size of target population would take ages to study and at the same time require considerable resources before there is conclusive information that the results will achieve the intended benefits. Thus, the researcher studied a small number of cases of elements within the population to represent the population and to reach conclusions about the population with minimum resources.

In all, seven prostate cancer patients (men above forty years)and thirty-three key informants selected from THP / herbalists, TM Sellers (Mbare Musika and CBD Street), medical doctors, pharmacy professionals (6 pharmacy technicians / 5 graduate retail pharmacists , 3 specialized in TM and 2 post-graduate academics), medical regulatory authorities (MRCZ, MCAZ, TMPC, ZINATHA), Zimbabwe National Herbarium (Botanical Garden), Ministry of health and childcare, WHO, University of Zimbabwe School of Pharmacy, Christian groups, NGOs and the public interested in the integration of ZTM with mainstream healthcare delivery were used in the study.

### 3.2.3 Sampling Procedure

A convenient non-randomized snowball sampling procedure was used in this study. Non-random sampling is a sampling system in which samples are assembled in a procedure that does not give each person in the population same likelihood of choice (Ginsberg, 2012).Snowball sampling is a non-random technique used to find research subjects by asking the first participant to provide the clues to the next possible participant and the chain goes on until the final participant is established (Vogt, 1999). This strategy enabled us to find participants within secretive populations like the TMPs and their prostate cancer patients who are socially stigmatized as uncivilized populations. Although it violates the principles of systematic sampling, the use of snowball strategies provides a means of accessing vulnerable groups easily at minimum cost.

Although snowball sampling procedure did not yield a large study sample, however, we were able to reach the people who rely heavily on ZTM and ZTMPs who are publicly regarded as primitive and uncivilized. Another justification for the sampling procedure

used is that there has not been much research done in the field of ZTM hence it would need more than 2 years to complete the study compared to the 6 months that are allowed by this MSc mini-thesis program. In addition, the study was personally funded therefore there was insufficient funding to complete the study of the large population. A case study was more appropriate as a pilot study to assess the level of the integration challenges and opportunities provided by the integration of ZTM with the mainstream healthcare delivery system.

### 3.2.4 Data sources

The data sources for the research were derived from both secondary and primary data to support the reasons for the delayed integration of ZTM into the mainstream healthcare system and provide the options to fast track the implementation of the integration strategy.

#### 3.2.4.1 Secondary data

This refers to the research information obtained for a different reason that is outside the initially intended purpose. The use of secondary data was supported in light of the fact that it allowed the examination of past models and gave the research the initial phase in data collection. Furthermore, secondary data is supported as it provides data that cannot be obtained through interviews and surveys. The secondary data were collected from newspapers, journal publications, reports from the Ministry of Health and the google search.



#### 3.2.4.2 Primary Data

This refers to the research information produced and obtained for the specific use of the research purposes. Van Der Walt et al. (1996) also confirmed that the raw primary data is obtained from the first sources of origination prior to collection and analysis for the specific work that needs to be done. It immediately separates unwanted material leaving only the necessary research information (Cohen, 1998). Primary data is also supported in the research because it involved real people. The primary data were collected through surveys and key informant interviews that allowed collection of large volumes of data with minimal spending plan and within a short time period.

### 3.2.5 Research data collection Instruments/tools

Research data collection tools or survey instruments are devices for gathering information for research. Hair et al. (2002) described a survey instrument in terms of the supply of queries and measurable scales with the intention of creating research original information in line with the objectives of the research.

#### 3.2.5.1 Interview Administered Questionnaire

The tool used to gather raw data directly from key informants was an organized interviewer-administered questionnaire (survey instrument) (Appendix 1). Frey and Oish (1995) described an interview as an intentional discussion in which one individual (interrogator) performs consultations and another responds (respondent). Verge (1996: 154) also characterized it as a direct encounter between the researcher and the participant for the purpose of collecting data. Interviews were used for prostate cancer patients and stakeholders/key informants because the researcher realized that the information he wanted from them was sensitive and thus needed rapport for them to divulge the information in depth.



## 3.3 Data analysis and presentation

Bell (2005), established that the data examination and data organization is required to create knowledge. The researcher used display tables to summarize information and to help enable easy referencing. This was to enable the reader to decipher and easily interpret the information in the study. Detailed discussions would follow the tables to clarify the responses and relate to literature. The researcher used both the closed and open ended questions in the analysis to lead to conclusions, recommendations and decision-making.

## 3.4 The Validity and Reliability of Research Data

The basis for the scientific data validity and reliability is on whether the information is substantial and solid. The reliability aspect emanates from the consistency of the research information in various investigations Bryman (2008). Validity is a pointer or set of markers to calibrate a set of information such that it can be tested for fitness with already confirmed idea (Bryman, 2008). The researcher has guaranteed the validity of currents research information through reference to the literature provided in the journals on similar research objectives such as the WHO publications. In addition, the researcher has guaranteed its validity by asking straight and exact unmistakable questions. A contemplated pilot was carried out before the examination, taking into account the ultimate goal of change and remedy to requests for information with the aim of reorganizing the search requests of the members under investigation. The researcher has applied the triangulation method to ensure validity of the research results. Thus comparing information collected directly from prostate cancer patients through questionnaires against interviewing key informants to verify if the challenges to ZTM integration are the same from different angles of information sources and collection methods.

## 3.5 Ethical Considerations



The research was in line with ethical guidelines in that participation was voluntary, confidential and respondents had the right to withdraw. An informed consent explaining the purpose of the study was given to respondents before issuing questionnaires. A letter of introduction from the Western Cape University, the School of Pharmacy and from the MoHCC was attached to the questionnaire explaining purpose of research in order to give assurance to the respondents that their answers would be treated in strict confidence and for academic purpose only.

The application to conduct research was submitted to three regulatory bodies involved in clinical research, the MCAZ, MRCZ and the MHPC. MCAZ is the national drug regulatory (NDRA) authority which approves and monitors all clinical trials in Zimbabwe in terms of Part III of the Medicines and Allied Substances Control Act [Chapter 15:03].

Also submitted the research proposal for ethical review by the ethics committee of the MRCZ as required by the regulations.

A letter of introduction was secured from the MoHCC that represents all medical practitioner associations such as the Retail Pharmacists Association, Zinatha, Zima and ZTMPC. An ethical clearance letter was obtained from MRCZ. A sample of THP was randomly picked from their register at Zinatha with the help of the register who knew their specialization.

The researcher also used the covert method to approach the practitioners so that they do not change behavior and conceal certain information. The Letters of Introduction and ethical review were presented to the THP for signing the consent after explaining that the information was for academic purposes only, will not be used for any other purpose, will remain confidential and their identity will not be disclosed. The principles of the Declaration of Helsinki were considered in the research design, emphasizing the benefits to subjects/patients, ensuring strict quality control of the whole process of clinical surveys and ensuring that the rights of subjects/patients are protected.

## 3.6 Chapter Summary



This chapter focused on the appropriate research methodology and research design that were used in this study. The chapter also provided an investigation into the strategies used to collect primary and secondary data, trying to meet the needs of the research question. Data was captured as interviewer notes on paper forms, questionnaire response papers, and video recording. The data was then coded and entered by category using Microsoft Excel. Data was then analyzed using SPSS 20 software with the help of a statistician. Descriptive statistics such as mean, frequency, coefficient of variation, variances, tables, percentage and graphs were used for data description. The ZTM stakeholders' response, 92.5% corresponded to 37 answered and returned questionnaires out of the expected 40 issued out in the field work. Also, the prostate cancer patients' response rate of 70% corresponds to 7 answered and returned questionnaires out of the expected 10 issued out during the field study. The snowball technique proved very successful as anticipated otherwise the randomization was not

going to achieve such high responses with 2 weeks of field study. The current secrecy in the practice due to the stigma brought about by colonization with the TMP looked down as practice for the poor and uncivilized people believing in the evil spirits and the dark world, did not allow disclosure of TMPs premises and contacts. We had to pretend as prospective patients, paid the required fees to get chance to talk to practitioners, otherwise they would prioritize patients who are at the core of their business and attend to researchers on their free time.

# CHAPTER 4

# RESULTS AND DISCUSSION



## 4.0 Introduction

The chapter sought to provide a discussion and analysis of the results collected from questionnaires that were successfully completed by prostate cancer patients as well as the stakeholders in the treatment of prostate cancer, THP / herbalists, TM Sellers (Mbare Musika and CBD Street), doctors, pharmacists, medical regulatory authorities (MRCZ, MCAZ, TMPC, ZINATHA), Zimbabwe National Herbarium (Botanical Garden), Ministry of health and childcare, WHO, University of Zimbabwe School of Pharmacy, Christian groups, NGOs and the public.

## 4.1 Demographic characteristics of the respondents

This section shall discuss and analyze the respondents' demographic characteristics.

### 4.1.1 Nature of the respondents

This section highlights the type of respondents who participated in this study and the results are illustrated in Fig 4.1 below.

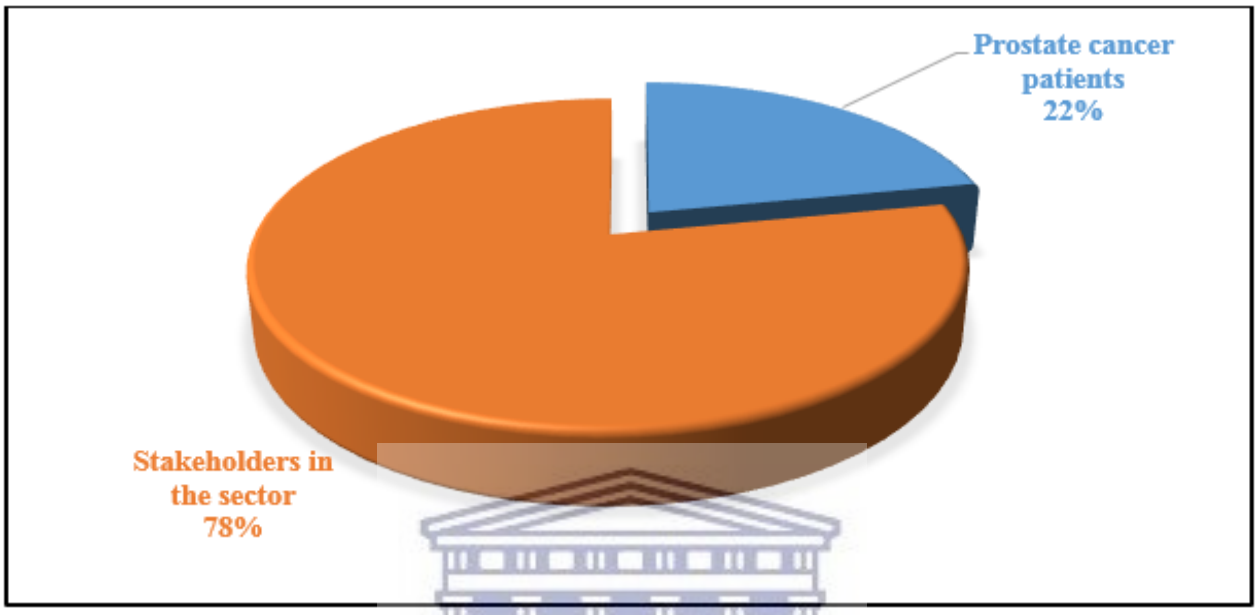


**Figure 4.1 Nature of Respondents (Total number of respondents, n = XX)**

Figure 4.1 above shows that 78% of the respondents were stakeholders who held various occupations and positions in the sector that caters for prostate cancer patients for instance medical doctors, pharmacists, traditional medicine practitioners, government workers and NGO workers while 22% of the respondents were prostate cancer patients. The representation of all the necessary stakeholders in the sector means that their different views were beneficial to this study.

### 4.1.2 Stakeholders' occupations

The section below highlights the various occupations of the stakeholders who participated in this study and these results are illustrated in Fig. 4.2 below

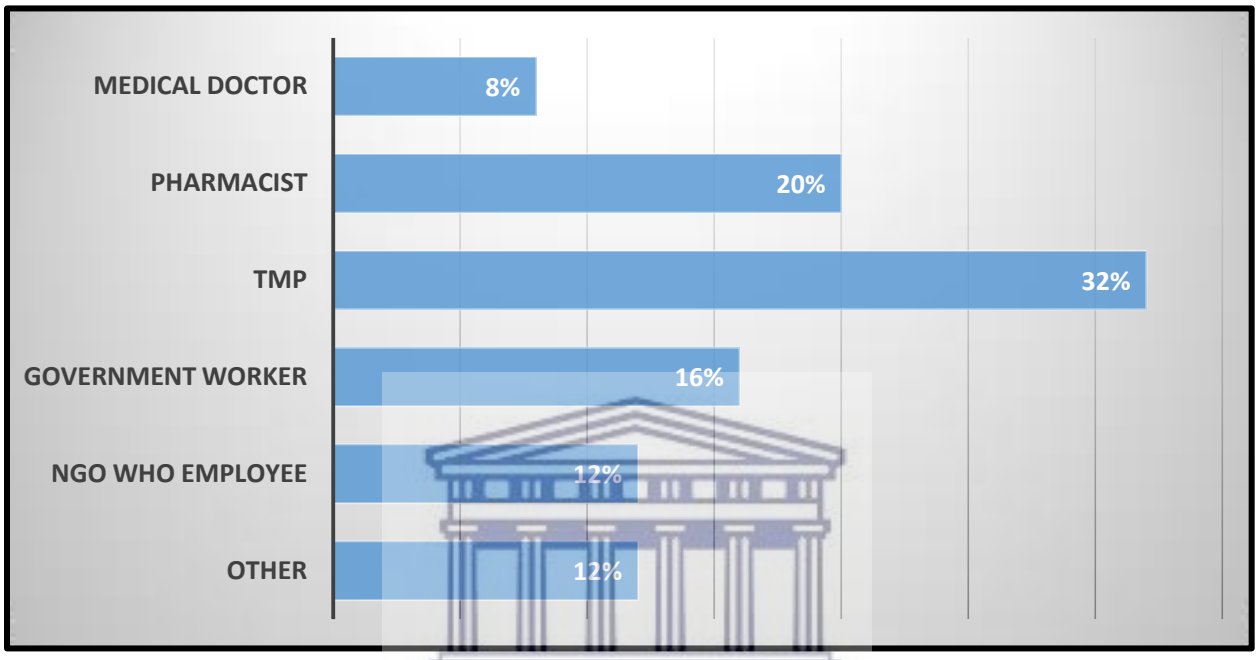


**Figure 4.2. The occupation of the stakeholders interviewed**



The figure above shows that the majority of stakeholders who participated in this study were Traditional Medicines Practitioners (TMPs) made up of 32%; followed by pharmacists (20%); then government workers (in the medicine regulation department) who constituted 16% whilst NGO employees and other stakeholders like students and pensioners were 12% whereas 8% of the respondents in this study were medical doctors. Although Traditional Medicines Practitioners were the predominant respondents in this study there was still sufficient representation of the other stakeholders that provided diverse views that was beneficial to the study.

### 4.1.3 Age

This section highlights the age of respondents who participated in this study and the results are illustrated in figure 4.3 below.

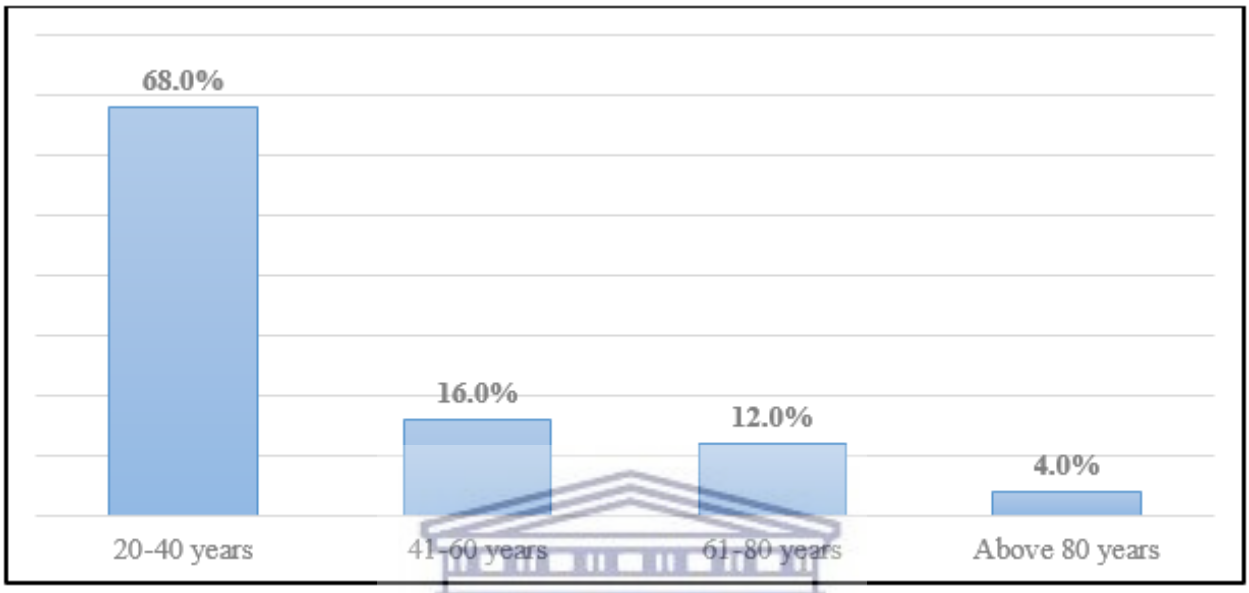


**Figure 4.3. The age of the respondents in this study.**

The figure above shows that the majority of the respondents (68%) were less than 40 years old, with 16% being 41 to 60 years whilst 12% were 61 to 80 years and those above 80 years constituted 4% of the respondents. From the result, the age distribution of the respondents reflected a young population.

### 4.1.4 Respondents' highest level of education

An analysis and discussion of the highest level of education of the stakeholders who participated in this study is shown in the section below and the findings are illustrated in Fig 4.4 below.

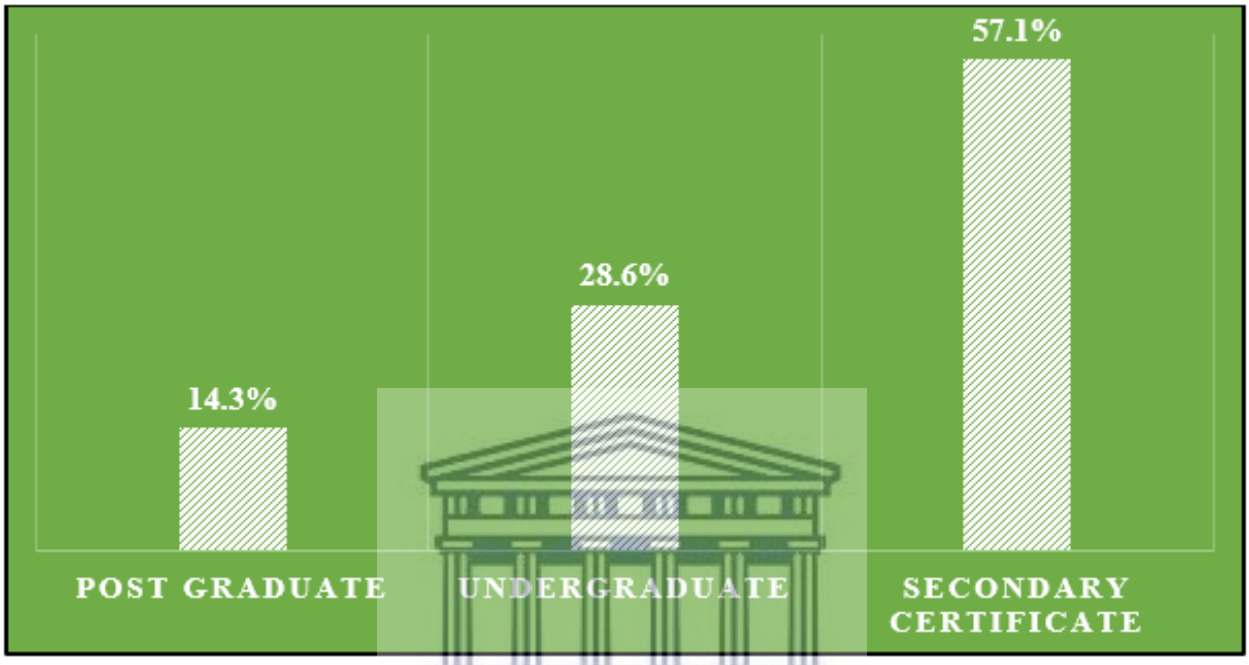


**Figure 4.4. Level of education of the respondents in this study.**



It was observed that the sample was highly educated. The majority of the respondents, 57.1%, had completed secondary school education whereas 28.6% had completed their undergraduate degrees and 14.3% of the respondents had post graduate degrees. Hence, it is expected that majority of the respondents understood the aim of this study and thus provided responses which were beneficial to the execution of this research.

## 4.2 The first choice of treatment for prostate cancer

This section shall discuss and analyze the prostate cancer patients' first choice treatment option as well as its relationship to the patient's religion. The results are shown in figure 4.5 and figure 4.6 below:

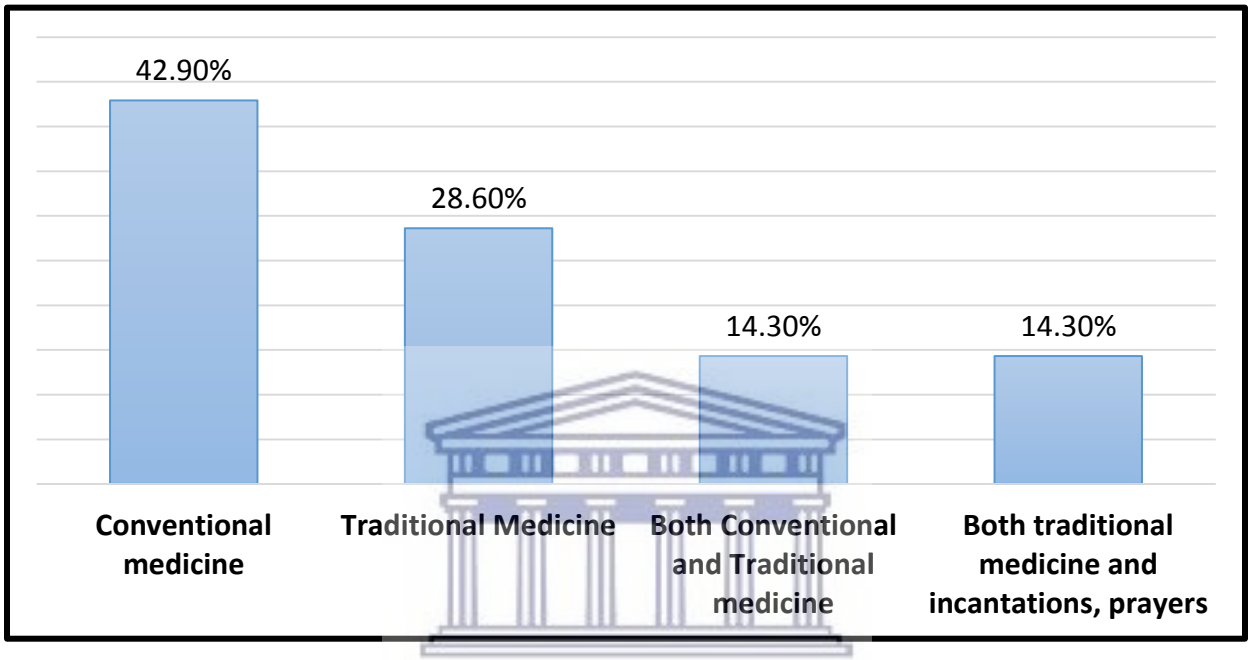


**Figure 4.5. The first choice of treatment for prostate cancer**

Figure 4.5 shows that the overall first choice for the treatment was conventional medicine as concurred by the majority of the prostate cancer patients (42.9%). The figure above also shows that 28.6% of the respondents preferred traditional medicine as their first choice of treatment. The combination of conventional medicine and traditional medicine and the combination of traditional medicine, incantation and prayers was preferred by 14.3% of the sample studied.

Overall, this result indicate that a larger percentage of the respondents in this study recognize the role and potential of traditional medicine in the treatment of such a dire condition as prostate cancer. The result is in congruence with that reported by World Health Organization by Silas et al (2015) regarding the high patronage of traditional medicine practitioners (TMP). This underscores the need to regulate the practices of the

TMP and the need for the vision for the integration of TMP with current conventional medicine practices.

### 4.2.1 First choice treatment option according to Religion.

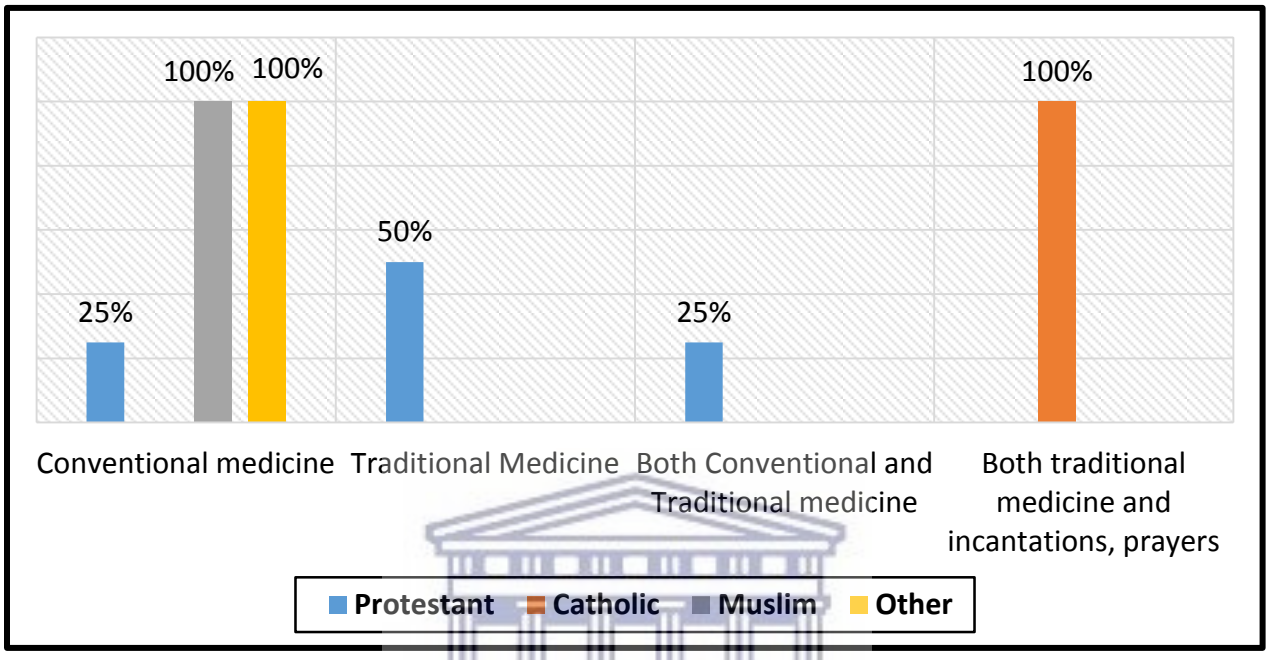


**Figure 4.6 First choice treatment option according to Religion.**

The researcher also notes that a significant proportion of religious people visit TMPs as their first port of call when they get ill. Figure 4.6 above shows that the first port of call against religion revealed that protestant communities, 50% indicated that their first port of call was the TMPs, whilst 25% stated that theirs was conventional medicine and a further 25% state that their first port of call was both modern and traditional medicine. In the case of respondents who were catholic they also stated that their first port of call was both modern and traditional medicine whilst respondents who were Muslim and those who stated that believed in other religions preferred conventional medicine as their first port of call. This is unbelievable from the outward speculation but the truth is Christians are born and bred in the culture of Indigenous Traditional medicine Knowledge Systems (ITMKS) that boosted their body strength against diseases and as a result did not suffer much diseases until recently when they got exposed to modern lifestyles full of refined foods, GMOs and industrial contamination of the environment. This entails that there is more trust, confidence, accessibility and affordability in ITMKS than the modern conventional treatments especially in the field of cancer where there

has been numerous negative occurrences such as side effects and insignificant patient recovery.

## 4.3 Type of training obtained in TM

The section below shall discuss and analyze the type of training obtained in TM by the stakeholders who participated in this study. The results are shown in figure 4.7 below:

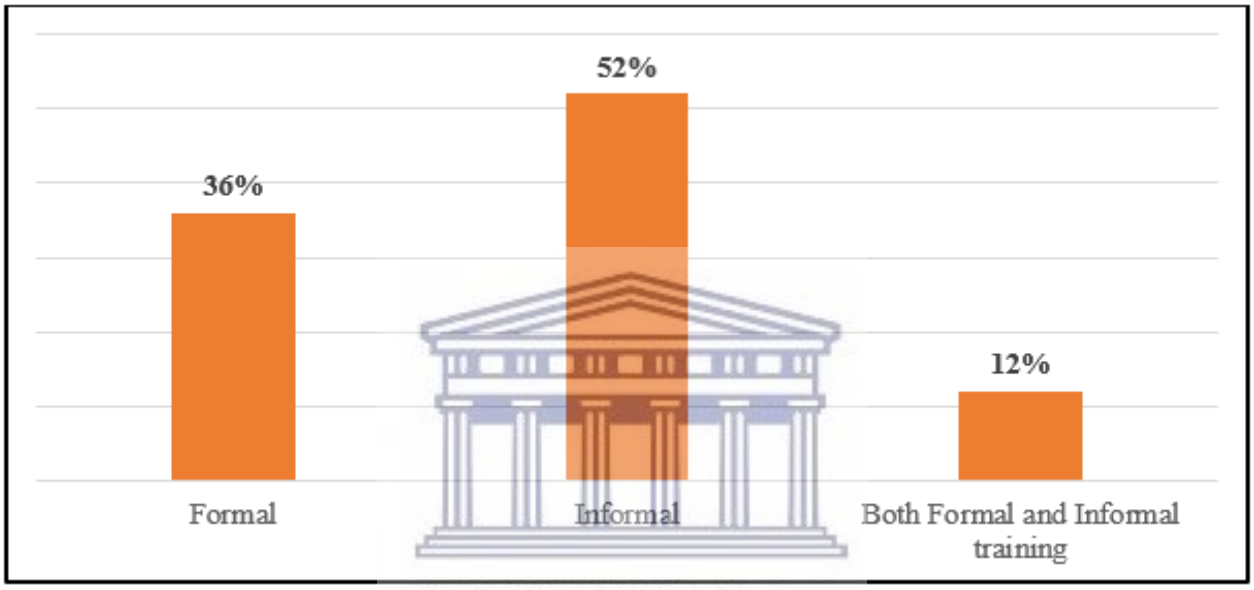




**Figure 4.7 Type of training obtained in TM**

According to the figure 4.7 above 52% of the respondents obtained informal training in TM whilst 36% obtained formal training in TM and only 12% of the respondents obtained both formal and informal training in TM. These results entail that the majority of stakeholders who assist prostate cancer patients obtained informal training in TM.

The results and conclusion of a study by Habtom 2018, reveals that training is an essential factor determining the rate of a successful traditional medicine integration process in a community monopolized with conventional medicine practice. The study showed that about 57% of Modern Medical Practitioners (MMPs) such as physicians, pharmacists, nurses and health technicians supported the idea of combined therapy (traditional and modern) for certain types of diseases, and 53% agreed to collaborate with traditional medical practitioners in research and in the treatment of certain diseases

in which the traditional medical system is claimed to be effective. The need for both MMPs and Traditional Medical Practitioners (TMPS) to be trained on combined therapy for better treatment outcomes under TM/CM integration cannot be over emphasized. The combined training will lead to an efficient and successful collaboration under different socio-cultural dimensions of health.

The results in Figure 4.7 above with 36% formal training in TM is positive enough towards training in combined therapy. The 52% under informal training needs to be quickly transformed into the formal system as it is under risk of extinction over generational changes as modern generations are more into CM than TM as observed in Figure 4.6 above. The 12% with both formal and informal training lies our hope for successful integration through modern practices of combined therapy as there is the goodwill to establish positive relationships and collaborations between both practitioners.

Also the researcher agrees with Habtom under the conclusion that there is need for proper documentation and scientific research for TM to be integrated into the national health care service. Hence there is a need for extensive training in the identification, documentation and registration of diseases that can be effectively cured by TM, as well as training of TMPs in the diagnosis, preparation and dosage control of traditional preparations and practices.



## 4.4 Will the integration of ZTM into the national health system improve total health coverage?

The section below sought to know if the integration of ZTM into the national health system could improve total health coverage. Respondents rated how strongly they agree or disagree with the above statement that integration of ZTM into the national health system will improve total health coverage. According to this study's Likert scale rating Strongly Disagree was rated as 1; Disagree was rated as 2; Indifferent had a 3 rating; Agree was rated as 4 whilst Strongly Agree had a rating of 5. The results are illustrated in the figure 4.8 below:

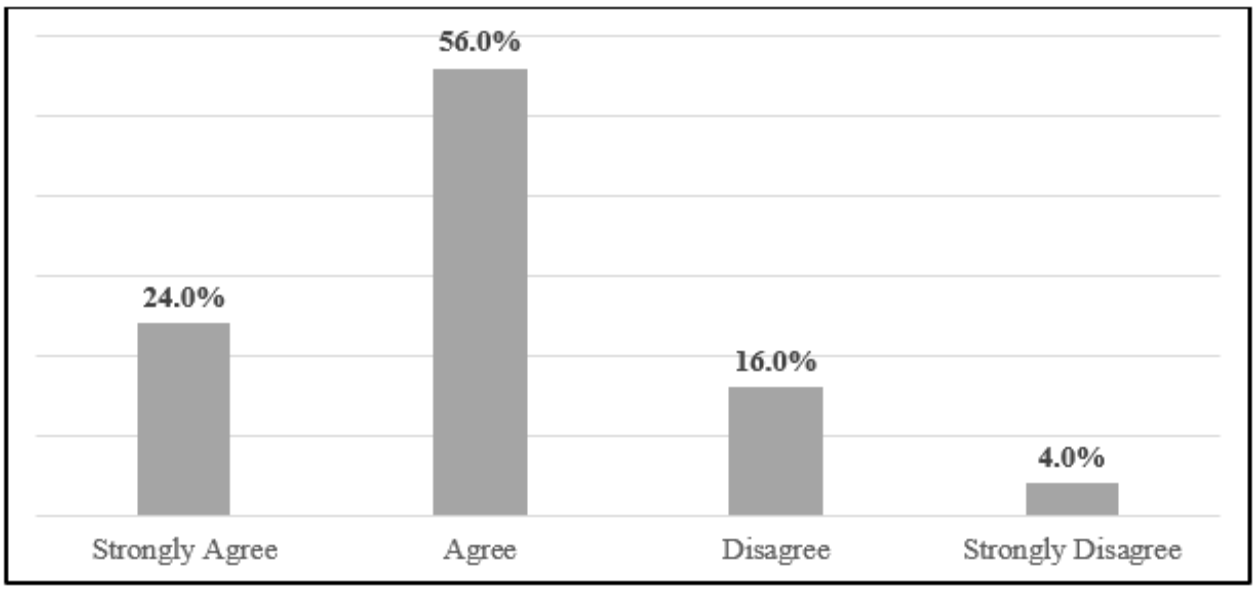


**Figure 4.8 Integration of ZTM into the national health system will improve total health coverage**

According to figure 4.8 above 56% of the respondents agree that integration of ZTM into the national health system will improve total health coverage, and an additional 24% strongly agree with the above statement whilst 16% disagree and a further 4% strongly disagree that the integration of ZTM into the national health system will improve total health coverage. According to the results shown above the majority of the respondents are in agreement that the integration of ZTM into the national health system will improve total health coverage. This entails that the majority of the stakeholders who assist prostate cancer patients as well as the cancer patients were in agreement that there is a need for the integration of ZTM into the national health system so as to improve total health coverage for prostate cancer patients. The 4% that strongly did not agree with the integration of ZTM gave their reasons as fear of toxicity caused by lack of dosage forms and undocumented safety data that has resulted in some incidences of kidney failure. The sour taste, storage conditions and Spiritism associated with the ZTM also contributed to 20% responses against such integration.

## 4.5 The reasons for the delayed integration of ZTM into the national healthcare system.

This section sought to establish which factors are strongly responsible for the delayed integration of ZTM into the national healthcare system. Respondents rated how strongly they agree or disagree with the reasons proposed in the questionnaire using a Likert scale whereby Strongly Disagree (SD) was rated as 1; Disagree (D) was rated as 2; Indifferent (I) had a 3 rating; Agree (A) was rated as 4 whilst Strongly Agree (SA) had a rating of 5. The results are illustrated in the figure 4.9 and table 4.1 below in the form of descriptive statistics per each statement together with their standard deviations.

**Table 4.1 Reasons for the delayed integration of ZTM into the national healthcare system**

| | SD | D | I | A | SA |
|---|---|---|---|---|---|
| Lack of standardization to determine quality of ZTM. | | 12.2% | 20.6% | 52.5% | 14.7% |
| Lack of scientific evidence on safety, toxicity and efficacy through clinical and non-clinical trials. | 20.6% | 55.4% | 3.4% | 20.6% | |
| Lack of modern dosage forms. | | 9.3% | | 12.2% | 78.5% |
| Associated with Spiritism in a country with more than 75% Christians | | 20.6% | 51.6% | 27.8% | |



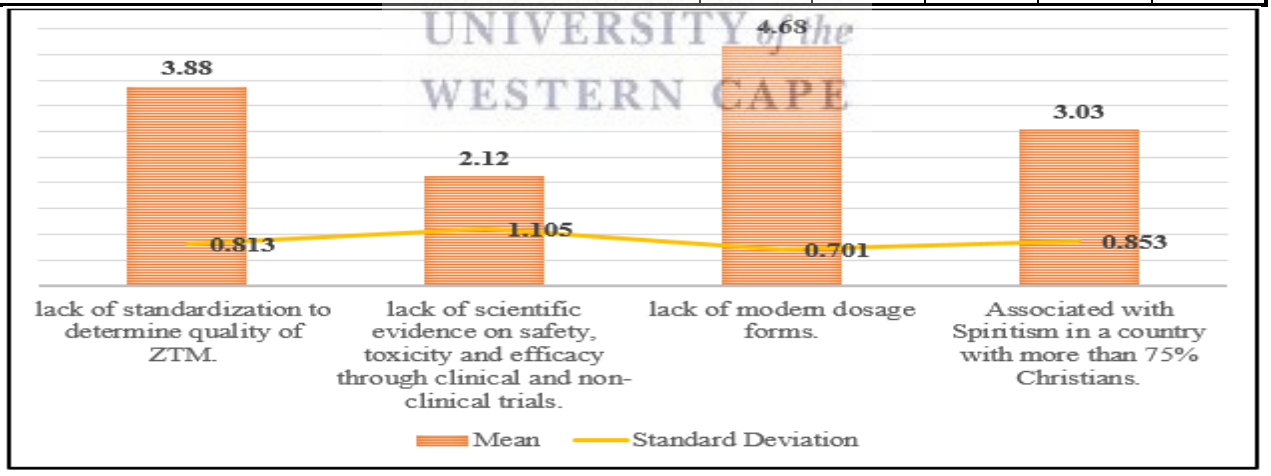


**Figure 4.9 Reasons for the delayed integration of ZTM into the national healthcare system**

Figure 4.9 above shows that the standard deviation values for all the statements above were less than the statements' mean values which reflects a small coefficient of

variation in the results. The figure above also shows that the statement with the highest mean was the lack of modern dosage forms (4.68), followed by lack of standardization to determine quality of ZTM (3.88) and followed by the association with Spiritism in a country with more than 75% Christians had a mean value of 3.03. The statement with the least mean was the lack of scientific evidence on safety, toxicity and efficacy through clinical and non-clinical trials (2.12). Therefore, these results entail that the majority of respondents strongly agree that the lack of modern dosage forms is one of the major reasons for the delayed integration of ZTM into the national healthcare system; followed by lack of standardization to determine quality of ZTM. To a lesser extent respondents believe that ZTM associated with Spiritism in a country with more than 75% Christians as well as lack of scientific evidence on safety, toxicity and efficacy through clinical and non-clinical trials best describe the reason for the delayed integration of ZTM into the national healthcare system.

## 4.6 Minimum requirements for registration of TM and the practice

This section sought to establish which of the following minimum requirements for registration of TM and the practice are attainable. Respondents rated how strongly they agree or disagree with the statements in the form of Likert scale whereby Strongly Disagree (SD) was rated as 1; Disagree (D) was rated as 2; Indifferent (I) had a 3 rating; Agree (A) was rated as 4 whilst Strongly Agree (SA) had a rating of 5. The results are illustrated in the figure 4.10 and table 4.2 below in the form of descriptive statistics per each statement together with their standard deviations.

**Table 4.2 Ease of attaining the minimum requirements for registration of TM and the practice**

| | SD | D | I | A | SA |
|---|---|---|---|---|---|
| Long-term records of ITMK use without evidence of risk. | | | 10.6% | 18.6% | 70.8% |
| Standardization for quality, safety and efficacy information. | | 2.8% | 10.6% | 71.9% | 14.7% |
| Potential for misuse, abuse or dependence. | 18.4% | 56.2% | 13.2% | 12.2% | |
| Finished Product manufacturing procedure and formula, including the amount of excipients | 66.4% | 18.6% | 2.8% | 12.2% | |

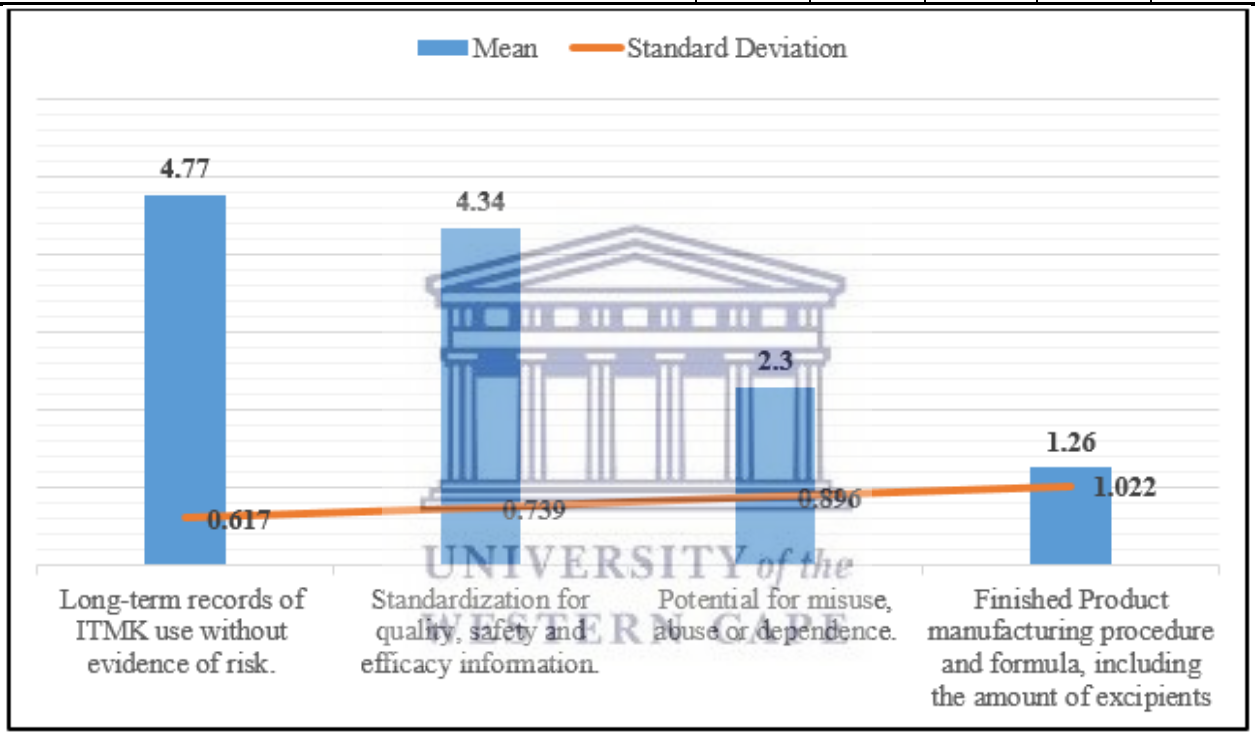



**Figure 4.10 Ease of attaining the minimum requirements for registration of TM and the practice**

The figure 4.10 above shows that the standard deviation values for all the statements above were less than the statements' mean values which reflects a small coefficient of variation in the results. According to the figure above the statement with the highest mean was long-term records of ITMK use without evidence of risk (4.77), followed by standardization for quality, safety and efficacy information (4.34) and then potential for misuse, abuse or dependence had a mean value of 2.3. The statement with the least mean was finished product manufacturing formula as well as procedure which also

include excipients (1.26). Consequently, these results entail that the main minimum requirement for registration of TM and the practice which was easily attainable was the long-term records of ITMK use without evidence of risk and standardization for quality, safety and efficacy information. However, the low mean values which were less than 2.5 could entail that potential for misuse, abuse or dependence and finished product manufacturing formula as well as procedure which also include excipients were minimum requirements for registration of TM and the practice which respondents believe were unattainable. This is particularly true to developing countries like Zimbabwe due to lack of resources and technology to carry out analytical and separation techniques such as high performance liquid chromatography (HPLC), Semi-Preparative LC, YMC glass columns, Flash Chromatography and the required accessories and solvents.

## 4.7 Challenges that affect the establishment of the national pharmacopeia and compendium with accurate ZTM information

This section sought to establish which of the following challenges the respondents thought affect the establishment of the national pharmacopeia and compendium with accurate ZTM information. Respondents rated how strongly they agree or disagree with the effect of each challenge in the form of Likert scale whereby Strongly Disagree (SD) was rated as 1; Disagree (D) was rated as 2; Indifferent (I) had a 3 rating; Agree (A) was rated as 4 whilst Strongly Agree (SA) had a rating of 5. The results are illustrated in the figure 4.11 and table 4.3 below in the form of descriptive statistics per each statement together with their standard deviations.

**Table 4.3 Challenges that affect the establishment of the national pharmacopeia and compendium with accurate ZTM information**

| | SD | D | I | A | SA |
|---|---|---|---|---|---|
| Non-disclosure of ITMK by ZTMP | | 4.7% | | 68.5% | 27.8% |
| Nature of compound ingredients that are expensive to analyze. | | | 10.6% | 62.6% | 27.8% |
| Need for complicated technology to process TM. | | 14.2% | 4.7% | 60.5% | 20.6% |
| Lack of global or regional harmonization of TM to share cost and ideas. | 2.8% | 27.8% | 57.2% | 12.2% | |

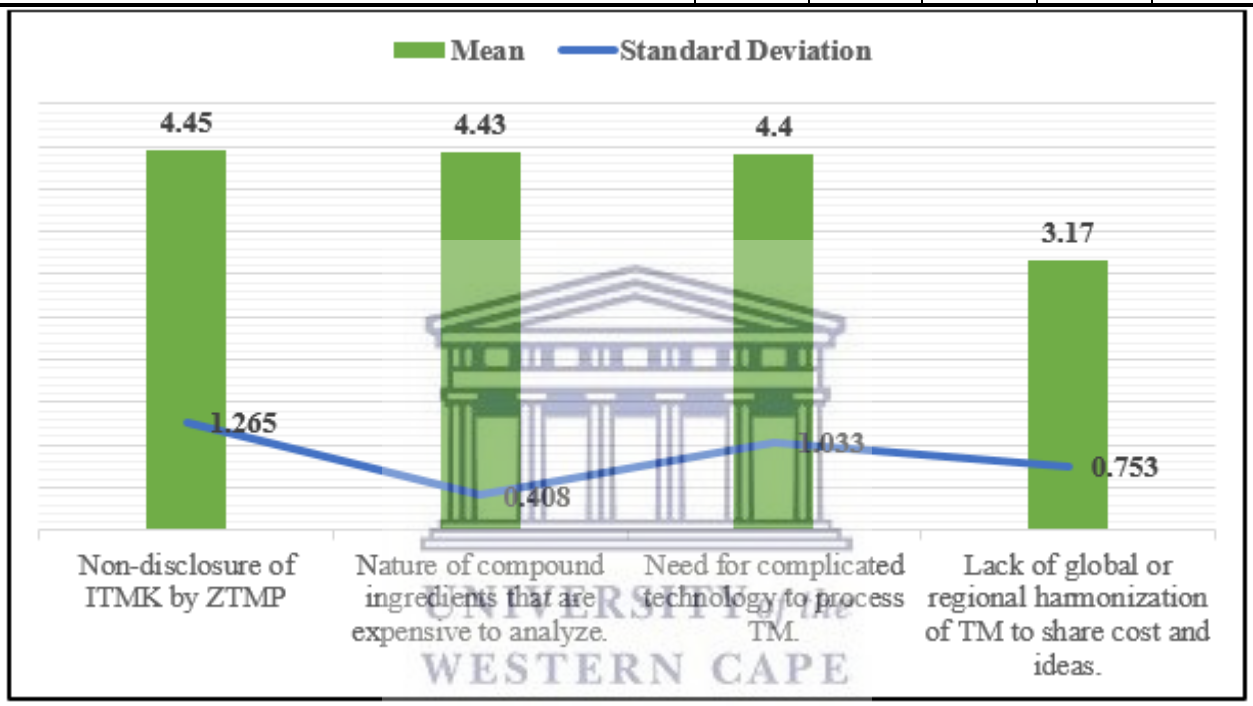


**Figure 4.11 Challenges that affect the establishment of the national pharmacopeia and compendium with accurate ZTM information**

Figure 4.11 above shows that the standard deviation values for all the statements above were less than the statements' mean values which reflects a small coefficient of variation in the results. The figure above also shows that the statement with the highest mean was the non-disclosure of ITMK by ZTMP (4.45), followed by nature of compound ingredients that are expensive to analyze (4.43) and then need for complicated technology to process TM had a mean value of 4.40. The statement with the least mean was the lack of global or regional harmonization of TM to share cost and ideas (3.17). As a result, this could mean that the majority of respondents strongly believe that the main challenge that affects the establishment of the national pharmacopeia and

compendium with accurate ZTM information was the non-disclosure of ITMK by ZTMP, followed by the nature of compound ingredients that are expensive to analyze and then the need for complicated technology to process TM. The challenge with the least effect was the lack of global or regional harmonization of TM to share cost and ideas.

## 4.8 Can indigenous knowledge information be used same as equivalent evidence to support the quality, safety and efficacy of ZTM sufficient for the integration?

This section sought to establish whether indigenous knowledge information could be used equivalent evidence similarly to scientific evidence to support the quality, safety and efficacy of ZTM sufficient for the integration. Respondents rated how strongly they agree or disagree with the statements in the form of Likert scale whereby Strongly Disagree (SD) was rated as 1; Disagree (D) was rated as 2; Indifferent (I) had a 3 rating; Agree (A) was rated as 4 whilst Strongly Agree (SA) had a rating of 5. The results are illustrated in the figure 4.12 and table 4.4 below in the form of descriptive statistics per each statement together with their standard deviations.

**Table 4.4 Can indigenous knowledge information be used same as equivalent evidence to support the quality, safety and efficacy of ZTM sufficient for the integration?**

| | SD | D | I | A | SA |
|---|---|---|---|---|---|
| Use ITMKS on its own in place of scientific evidence. | | 2.8% | | 27.8% | 69.4% |
| Use Scientific non-clinical and clinical evidence. | 14.7% | 20.6% | 46.1% | 18.6% | |
| Use both ITMKS and clinical evidence to determine quality, safety and efficacy of ZTM. | | 27.8% | 44.4% | 27.8% | |
| ITMKS can only be used as complementary or alternative evidence to scientific evidence. | 14.7% | 27.8% | 42.8% | 14.7% | |

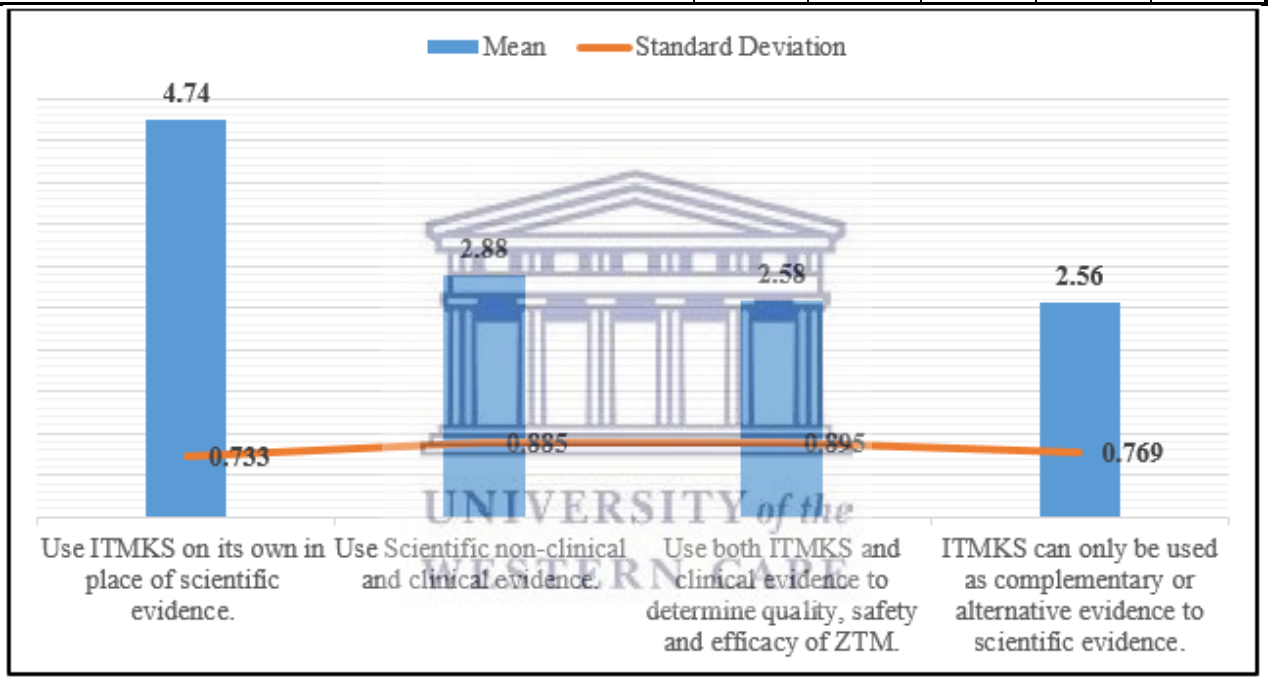


**Figure 4.12 Can indigenous knowledge information be used same as equivalent evidence to support the quality, safety and efficacy of ZTM sufficient for the integration?**

According to figure 4.12 above the standard deviation values for all the statements above were less than the statements' mean values which reflects a small coefficient of variation in the results. Furthermore, the figure above also shows that the statement with the highest mean was the use of ITMKS on its own in place of scientific evidence (4.74), followed by use of scientific (non-clinical and clinical) evidence (2.88) and the use of both ITMKS and scientific evidence to determine quality, safety and efficacy of

ZTM had a mean value of 2.58. The statement with the least mean was the use of ITMKS only as complementary or alternative evidence to scientific evidence (2.56). Consequently, these results entail that according to the stakeholder's perception, the ITMKS can be used on its' own in the same way as equivalent to scientific evidence to support the quality, safety and efficacy of ZTM, sufficient enough for the integration of ZTM. On the other hand, respondents were not as eager with the use of scientific non-clinical and clinical evidence; use of both ITMKS and clinical evidence to determine quality, safety and efficacy of ZTM and least of all the ITMKS can only be used as complementary or alternative evidence to scientific evidence.

## 4.9 What level of the Medical Practitioner's education and training could be set as the minimum requirement for the immediate integration of the ZTM?

This section sought to establish what level of the Medical Practitioner's education and training respondents believed could be set as the minimum requirement for the immediate integration of the ZTM. Respondents rated how strongly they agree or disagree with the minimum levels of education and training in the form of Likert scale whereby Strongly Disagree (SD) was rated as 1; Disagree (D) was rated as 2; Indifferent (I) had a 3 rating; Agree (A) was rated as 4 whilst Strongly Agree (SA) had a rating of 5. The results are illustrated in the figure 4.13 and table 4.5 below in the form of descriptive statistics per each statement together with their standard deviations.

**Table 4.5 Minimum levels of education and training for the immediate integration of the ZTM**

| | SD | D | I | A | SA |
|---|---|---|---|---|---|
| Certificate in ZTM and Conventional Medicines. | | 9.4% | | 62.8% | 27.8% |
| Diploma in ZTM and Conventional Medicines. | | 16.8% | | 26.8% | 56.4% |
| University degree in ZTM and Conventional Medicines. | 4.7% | 27.8% | 46.9% | 20.6% | |
| Should continue to run parallel as separate medical interventions. | | 31.2% | 50.2% | 18.6% | |

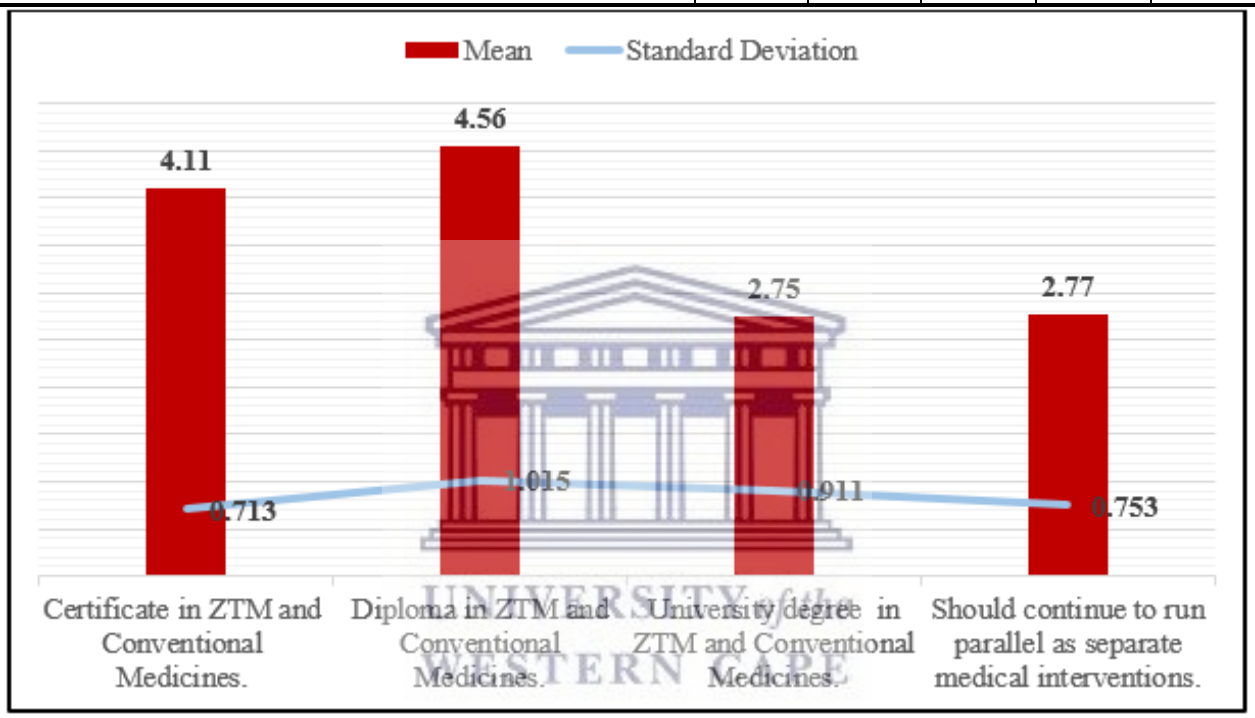


**Figure 4.13 Minimum levels of education and training for the immediate integration of the ZTM**

Figure 4.13 above shows that the standard deviation values for all the statements above were less than the statements' mean values which reflects a small coefficient of variation in the results. The figure above also shows that the minimum levels of education and training for the immediate integration of the ZTM that respondents rated the highest was diploma in ZTM and Conventional medicines (4.56), followed by certificate in ZTM and Conventional medicines (4.11) and then should continue to run parallel as separate medical interventions had a mean value of 2.77. The minimum levels of education and training with the least mean were the University degree in ZTM

and Conventional medicines (2.75). Consequently, this could mean that the majority of respondents strongly believe that the minimum level of education and training for the immediate integration of the ZTM was diploma in ZTM and Conventional medicines, followed by certificate in ZTM and Conventional medicines and then others felt the two should continue to run parallel as separate medical interventions whilst the need for a University degree in ZTM and Conventional medicines was the least rated minimum level of education and training for the immediate integration of the ZTM. This is because most Zimbabweans are literate such that even now there is already some level of communication between the TM and CM practitioners and integration mainly through referrals especially in rural communities where there is no accessibility of modern therapies or they are not affordable.

## 4.10 Recommendations for the immediate implementation considering the need to improve total health coverage

This section sought to establish which of the following recommendations for the immediate implementation considering the need to improve total health coverage. Respondents rated how strongly they agree or disagree with the effect of each recommendation in the form of Likert scale whereby Strongly Disagree (SD) was rated as 1; Disagree (D) was rated as 2; Indifferent (I) had a 3 rating; Agree (A) was rated as 4 whilst Strongly Agree (SA) had a rating of 5. The results are illustrated in the figure 4.14 and table 4.6 below in the form of descriptive statistics per each statement together with their standard deviations.

**Table 4.6 Recommendations for implementation to improve total health coverage**

| | SD | D | I | A | SA |
|---|---|---|---|---|---|
| Leave at current status quo, ZTM complementing CM. | 14.7% | 74.7% | | 10.6% | |
| Immediate integration with whatever information is available. | 18.6% | 76.7% | | 4.7% | |
| Record enough ITMK to support quality, safety and efficacy. | | 10.6% | | 70.8% | 18.6% |
| Wait for scientific clinical trials evidence to support quality, safety and efficacy. | | 27.8% | 56.8% | 15.4% | |

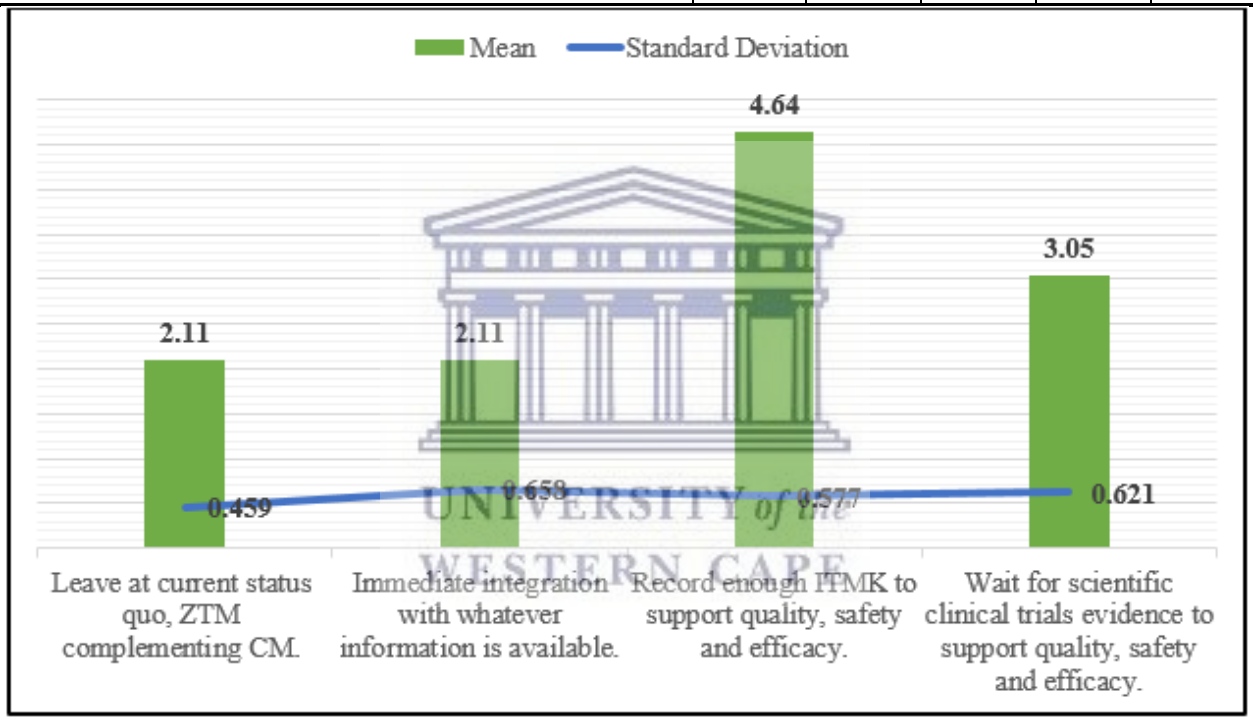


**Figure 4.14 Recommendations for implementation to improve total health coverage**

Figure 4.14 above shows that the standard deviation values for all the statements above were less than the statements' mean values which reflects a small coefficient of variation in the results. The figure above also shows that the recommendations with the highest mean was to record enough ITMK to support quality, safety and efficacy (4.64), followed by waiting for scientific clinical trials evidence to support quality, safety and efficacy (3.05) and then leave at current status quo, ZTM complementing CM as well as immediate integration with whatever information is available both had a mean value of

2.11. As a result, this could mean that the main recommendations for the immediate implementation considering the need to improve total health coverage were recording enough ITMK to support quality, safety and efficacy as well as waiting for scientific clinical trials evidence to support quality, safety and efficacy. On the other hand, the majority of respondents did not favor the following recommendations namely: leaving at current status quo, ZTM complementing CM as well as immediate integration with whatever information is available.

## 4.11 Level of ZTM/CM Integration in the Medical Practice

Appendix 4 is an anecdote extracted from a book written by a registered TMP, qualified Pharmaceutical Technician, who has two decades of experience in CM practice before venturing into ZTM. He currently operates a TM clinic that provides a significant level of integration as evidenced by the inclusive prescription for his prostate cancer patients.

The qualitative information obtained in the study has been summarised in Appendix 4 as anecdotal (or narrative) evidence. The quantitative or statistical evidence already discussed combined with the anecdotal evidence was presented to show the demand of integration in order to improve treatment outcomes by TM practitioners outside the official healthcare system.



Other forms of integration observed and recorded during focus group discussions emanated from patients who visited both TMPs and CMPs without the knowledge of each practitioner and used both treatments at the same time, or first tried CM and due to side effects or treatment failure opted to try CMP. Figure 4.6 shows that 25% of the respondents' first choice treatment option was both ZTM and modern conventional practice. Modern medicine was highly prescribed because the diagnosis was done at conventional practices which immediately prescribed CM treatment. Half the patients who opted for TM treatment were either familiar with TM or were wary of the unaffordable costs, the unbearable side effects and very poor treatment outcomes.

The low level of integration evident outside the regulated healthcare system calls for the enhanced ZTM advocacy, capacity building in training and institutionalization of the

ZTMP and speeding up of the regulation process in order to improve accessibility and treatment outcomes of the integrated healthcare system.

## 4.12 Chapter Summary

This chapter focused on the analysis of respondent's demographics, their perceptions and attitudes towards the integration of ZTM and the ultimate impact on the total health coverage. The preference treatment options were regrouped according to religion. The minimum training required for medical practitioner's to qualify in prescribing and dispensing ZTM and contribute to the integration process. The chapter also analyzed the use on ITMKS as equivalent evidence comparable to the scientific evidence to be used similarly in determining safety, quality and efficacy of ZTM prior to integration. The challenges affecting the establishment of a national database of all ZTM leading to the national Pharmacopeia and Compendium were also analyzed including the reasons for the delayed integration of the ZTM into the official distribution and treatment pathways.

# CHAPTER 5

# CONCUSIONS AND RECOMMENDATIONS

## 5.0 Introduction

In the same way as eluded by Mahomoodally (2013), this paper examined the traditional medical system in the international health delivery context as the original dominant healthcare system in Africa prior to the period of colonialism. Western religion and education together with the globalization phenomenon have distorted the nature and perception of TM in Africa. Traditional healers have provided accurate and successful leads to scientific breakthrough in conventional medicine without being recognized because of the background of the ITMKS which did not record the evidence and provide IPRs. The ITMKS can provide important links between disease and behavior as well as effective treatment not found in the Western medicine. The African leaders should develop serious attention to global trends in TM and use the ITMK to produce new innovation in the healthcare system that can bring FDI and development to respective countries. This requires that both traditional and modern doctors acknowledge their areas of strengths and weaknesses in order to complement and synergize each other's expertise. The ZTM implementation strategy should ensure mechanisms to eliminate the quacks and charlatans in the ZTMP.

## 5.1 The Influence of Religion on the Preferred Treatment Options

The study concluded that religious communities constituted more than 75% of the Zimbabwean population. Thus they must be consulted and involved in the integration process to ensure buy-in and optimum participation and support during the integration

process. The cultural beliefs contribute more in the building up of confidence, trust and belief in the quality, safety and efficacy of ZTM. In this case those who have been brought up in the culture of TM do not require further assurance through the scientific evidence.

The baseline survey also showcased that the majority of ZTM are administered in powder form through the mouth as boiled solutions of the powder. Three (3) of the six (6) respondents (50.0%) reported that they had taken oral powdered treatments for prostate cancer. There is low uptake of lacerations due to lack of modern hygiene precautions to avoid hiv/aids transmission through unsterile and multiple use of the razor blade during lacerations. The taste of ZTM is sour in most cases but this is actually favorable in the old age groups as it is associated with high efficacy. Only in the modern generation and children is the sour taste unpalatable and reduces the uptake of the medicine which was part of the reasons for delayed integration.

The baseline survey also found out that prostate cancer related services are not readily available in both rural and urban arrears and the available hospitals are not fully capacitated to offer comprehensive cancer services. Nearly half of respondents (42.9%) stay close to clinics which neither has both the conventional or traditional medicine services. About 28.6% rely on the TMP for prostate cancer treatment whilst the other (28.6%) has access to modern conventional treatments. Also the study revealed that the 42.9% relies on bicycles and scotch-carts as mode of transport which is difficult to access the prostate cancer service providers.

Respondents (42.9%) reported that they have training in drug development against (52%) that has training in ITMKS. This was followed by a (56%) response that the direct integration of ZTM will improve the national health coverage. This means collaboration between the training in drug development and ITMKS can bring about a unique type of innovation in new drugs that can cure the indigenous five killer diseases such as cancer, HIV/AIDS, diabetes, malaria and hypertension. The Cancer Association of Zimbabwe (2010) highlighted that the unavailability of cancer services was the main challenge while the high cost of services is a barrier in accessing cancer related services.

The sample was also noted to be highly educated. This confirms the high literacy level in Zimbabwe which is an added advantage to facilitate training and education between TMP and CMP which should meet the prerequisites for smooth integration.

## 5.2 Quality, Safety and Efficacy of ZTM

The results show that the majority of respondents strongly agree on the fact that the lack of modern dosage forms is one of the major reasons for the delayed integration of ZTM into the national healthcare system, followed by lack of standardization to determine quality of ZTM. To a lesser extent respondents believe that ZTM associated with Spiritism in a country with more than 75% Christians as well as lack of scientific evidence on safety, toxicity and efficacy through clinical and non-clinical trials best describe the reason for the delayed integration of ZTM into the national healthcare system.

Consequently, these results entail that the minimum requirements which could be set for registration of ZTM include the availability of long-term records for the use of ITMK without any serious evidence of risk should be satisfactory to give enough confidence for integration. The standardization of ZTM for quality, safety and efficacy information can also be determined from the folklore use records. However, the low mean values which were less than 2.5 could entail that potential for misuse, abuse or dependence and finished product manufacturing procedure and formula of excipients are part of the minimum requirements for registration of TM and the practice which respondents believe are unattainable. This is particularly true to developing countries like Zimbabwe due to lack of resources and technology to carry out analytical and separation techniques such as high performance liquid chromatography (HPLC), Semi-Preparative LC, YMC glass columns, Flash Chromatography and the required accessories and solvents.

## 5.3 Recommendations for the Integration of ZTM into the Mainstream Healthcare System

The results and consequent conclusions of this can be summed up to the main recommendations for the immediate integration considering the need to improve total health coverage, points to the recording of ITMK to support quality, safety and efficacy whilst waiting for scientific clinical trials and post-marketing pharmacovigilance evidence to support the ITMKS. On the other hand, majority of respondents did not favor the following recommendations namely: leaving at current status quo, ZTM complementing CM as well as immediate integration with whatever information is available.

According to Sackey and Kasilo (2010), the ITMKS provide excellent examples of community-based research. The community is a source of strength for traditional knowledge in terms of the discovery process and knowledge production. There are obstacles in providing IP protection same as identification of ownership as the knowledge has been in existence for centuries without being recorded but informally passed from generation to generation through training and spirit mediums.

## 5.4 Future research and perspectives

The research showed that there is increasing interest and a marked potential in the integration of TM into the healthcare system as revealed by all the stakeholders interviewed in Harare. The majority of the stakeholders who assist prostate cancer patients observed that the integration of ZTM would improve the present total health coverage. The recording of appropriate ITMKS to support quality, safety and efficacy whilst waiting for scientific clinical trials evidence is enough for immediate integration. Thus the further areas of study include collecting and recording the ITMKS in order to establish the national pharmacopeia and compendium. Another area of further research relates to the establishment of modern dosage forms in order to facilitate the efficient integration of ZTM into the national healthcare system.

The research also revealed that unlike the western conventional medical system, the ZTM system fields of specialization have been subdued by the economic crises and associated challenges of venturing into the green-fields of medicine in Zimbabwe. During focus group discussions with key stakeholders and TMPs, it was evident that every TMP claimed to be a jack of all trades and as such could treat any diseases. The

study suggests further enquiry into the areas of specialization in order to substantiate the TMP claims through in-depth patient management observations and physical checks of the ZTMs used. This will provide evidence-based systematic referral system that can be effective and produce better treatment outcomes which can be implemented in the treatment of complicated diseases such as HIV/AIDS, cancer and diabetes.

## 5.13 Conclusion

The results show that the ZTM policy has been properly crafted with appropriate structures in the MoHCC and incorporated in the regulatory authorities such as the MCAZ. The top down approach, evidenced by 36% formal training found in MoHCC, regulatory authorities and higher learning institutions, has been the major impediment to the ZTM integration into the national healthcare system due to lack of buy-in by the ZTMPs, patients and other stakeholders at the bottom of the pyramid. The 52% informally trained ZTMPs means the IKS passed on from past generation to the next is still dominating and hence the high levels of stigma and discrimination associated with the traditional medicine practice. This is further supported by the reasons for delayed integration such as lack of modern dosage forms (4.68) and standardization to determine quality of ZTM (3.88).



There is need for a bottom-up approach to dispel the stigma associated with the use of ZTM by Christian communities through transformation of the traditional medicines into modern dosage forms with proven evidence of safety, quality and efficacy. Emphasis should be put on training ZTMPs in modern health practices, TM advocacy in churches, schools and community gatherings to ensure benefits in the regulated use of ZTM are recognized. A bottom-up capacity building strategy needs to be crafted and built into the ZTM implementation plan. This will require individuals and organizations to obtain appropriate skills, knowledge, tools, equipment and other resources needed for the coexistence and collaboration between CM and ZTM practices to improve treatment outcomes.

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# APPENDICES

## 1. Ethical Approval

UNIVERSITY of the WESTERN CAPE

OFFICE OF THE DIRECTOR: RESEARCH
RESEARCH AND INNOVATION DIVISION

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21 May 2018

Dr S Egieyeh
School of Pharmacy
**Faculty of Natural Science**

**Ethics Reference Number:** BM18/1/16

**Project Title:** Knowledge-based integration of Zimbabwean Traditional Medicines into the National Health care System: A case study of prostate cancer.

**Approval Period:** 21 May 2018 – 21 May 2019

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

**Please remember to submit a progress report in good time for annual renewal.**

The Committee must be informed of any serious adverse event and/or termination of the study.



*Ms Patricia Josias*
*Research Ethics Committee Officer*
*University of the Western Cape*

***PROVISIONAL REC NUMBER -130416-050***

## 2. Questionnaire 1

UNIVERSITY of the
WESTERN CAPE

***Knowledge-Based Integration of Zimbabwean Traditional Medicines into the National Healthcare System: A Case Study of Prostate Cancer.***

**Questionnaire for Patients treated for Prostate Cancer.**

*My name is Brighton Itayi Chawatama, a M.Sc. Pharmacy Administration and Policy Regulation student with the School of Pharmacy, University of Western Cape. My research work is looking into challenges and opportunities in the integration of ZTM into the mainstream healthcare system since the establishment of the TM Policy in 2007. Your observations and any information you may consider useful for the study will be greatly appreciated for use in this study purposes only. Please feel free to withdraw from this exercise if and as you may so wish.*



## Socio-economic and Demographic variables of the household

1. Occupation of the household head:

| | | | | | |
|---|---|---|---|---|---|
| a. Unemployed | b. Farmer or Craftsman | c. Trader | d. Government worker | e. NGO worker | f. Housewife |

Other/Explain
_____

2. Are you on medical aid? YES OR NO

Level of education?

| | | | | |
|---|---|---|---|---|
| a. Post Grad | b. Masters | c. Undergrad | d. Secondary | e. Primary |

Other/Explain
_____

3. What is the nearest health facility accessible?

| | | | | |
|---|---|---|---|---|
| a. TMP | b. Village Health Worker | c. Clinic | d. Hospital | e. Mobile Clinic |



Other/Explain
_____

4. Means of transport to the nearest health center:

| | | | | |
|---|---|---|---|---|
| a. Only bicycle or animal drawn cart | b. Walking or push cart | c. Public transport | d. Hired car or ambulance | e. Own private car |

5. Does the household have any communication equipment? Yes or No

**Patient's Suburb:** _____

**Ethnic group**: _____

**Religion:** _____

P = Protestant (Adventist, Anglican, Baptist, Calvinist (Reformed), Lutheran, Methodist and Pentecostal)

C = Catholic

M = Muslim

T = Traditional religion

O = other (specify) _____

6. Is there someone in the village who can provide modern medicines?

| | | | | |
|---|---|---|---|---|
| a. Village health worker | b. Drug shop | a. Private clinic | b. Government Hospital Dispensary | c. Private Retail Pharmacy |

7. How did you discover that you have prostate cancer? TICK THE APPROPRIATE

| | | | |
|---|---|---|---|
| a. Doctor's visits | b. TM visits | c. Traditional Knowledge of Symptoms | d. Parents |

8. Did you get counselling about prostate cancer and an option to choose form of treatment?



| | | | |
|---|---|---|---|
| YES | | NO | |

9. If yes, what was your first choice treatment option and why?

| | | | |
|---|---|---|---|
| a. Modern medicine | b. Traditional/Herbal Medicine | c. Massages | d. Incantations, prayers |

Reason(s) for option indicated above_____
_____

10. Who gave the first treatment?

| | | | |
|---|---|---|---|
| a. Self-medication | b. Traditional healer | c. Health Centre | d. Parents/Village Health Worker |

11. What is the name of the treatment or components of the treatment, or can we examine the details of the treatment supplied and used? (Several answers are possible if there was more than one remedy or component)

Component 1: _____

Component 2: _____

Component 3: _____

*(Later by the enumerator: find the corresponding botanical names and enter them below. If possible, obtain samples of the plants for botanical identification):*

Component 1: _____

Component 2: _____

Component 3: _____



12. What dosage form was the TM treatment?

| | | | | |
|---|---|---|---|---|
| a. decoction – boiling herbs. | b. infusion | c. maceration – razor cut. | d. powder | e. ointment |

13. How did you take the TM treatment?

| | | | |
|---|---|---|---|
| a. By Mouth | b. Bathing | c. Inhalation | d. Massage |

Other/Specify:

_____

14. What was the taste of the TM and would you recommend someone to opt for the same compared to modern treatment methods?

| | | | |
|---|---|---|---|
| a. Unpalatable | b. Painful Surgery | c. Unbearable side effects | d. Others |

| | | | |
|---|---|---|---|
| RECOMMEND | | NOT RECOMMENT | |

15. If modern medicines, which?

| | | | |
|---|---|---|---|
| a. Chemotherapy | b. Radiation therapy | c. Surgical techniques | d. Others |

Others Explain: _____

16. If the patient was admitted to a health center, for how many days?

…… days



17. What was the taste of the modern medicine and would you recommend someone to opt for the same compared to TM treatment methods?

| | | | |
|---|---|---|---|
| a. Unpalatable | b. Painful Surgery | c. Unbearable side effects | d. Others |

| | | | |
|---|---|---|---|
| RECOMMEND | | NOT RECOMMENT | |

18. What happened to the patient after the treatment (TM or Modern medicine)?

| | | | |
|---|---|---|---|
| a. cured | b. Cured with TM | c. improved | d. no improvement or relapse |

Describe the episode _____

19. If the patient was not cured, did you try a second treatment?

| | | | |
|---|---|---|---|
| YES | | NO | |

If yes, continue below. If no, skip to Q20.

19.1 After how many days? _____

19.2 Which second treatment did you try (several responses possible)?

| | | | | |
|---|---|---|---|---|
| a. Modern medicine | b. Traditional/Herbal Medicine | c. Massages | d. Incantations, prayers | e. Sacrifices |

Others explain _____

19.3 Who gave this second treatment?

| | | | |
|---|---|---|---|
| a. Self-medication | b. Traditional healer | c. Health Centre | d. Parents/Village Health Worker |

19.4 If it was a traditional medicine, what was its name? (Several answers are possible if there was more than one remedy or component)

Component 1: _____

Component 2: _____

Component 3: _____

(Later: find the corresponding botanical names and enter them below. If possible, obtain samples of the plants for botanical identification):

Component 1: _____

Component 2: _____

Component 3: _____

19.5 What dosage form was the second treatment?

| | | | | |
|---|---|---|---|---|
| a. decoction | b. infusion | c. maceration | d. powder | e. ointment |

19.6 How was the TM administered?

| | | | |
|---|---|---|---|
| a. By Mouth and bathing | b. Laceration | c. Fumigating | d. Massage |

Other/Specify:
_____

19.7 If modern medicines was used, which one?

| | | | |
|---|---|---|---|
| a. Chemotherapy | b. Radiotherapy | c. Surgical techniques | d. Others |

Other/specify:
_____

19.8 If the patient was admitted to a health center, for how many days? ……..Days

20. What happened to the patient after this treatment?

| | | | |
|---|---|---|---|
| a. cured | b. cured with TM | c. improved | d. no improvement or relapse |

Describe the episode/worsened_____

21. Total duration of the illness: _____days

22. How much did the treatments cost?

Traditional Medicine Treatment: US$_____

Modern Medicine Treatment: US$_____

23. Did you disclose information about your prostate cancer to members of your family or community?

| | | | |
|---|---|---|---|
| YES | | NO | |

If yes, where did they direct you for treatment?

_____

24. Does everyone in the community take screening or prevention measures for prostate cancer after the age of 40 years?

| | | | |
|---|---|---|---|
| a. Always | b. Sometimes | c. If they afford | d. Never |



25. Reasons for the delayed integration of ZTM into the national healthcare system.

Kindly rate how strongly you agree or disagree with the statements below on whether the integration of ZTM into the national health system will improve total health coverage. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| a. Lack of standardization to determine quality of ZTM. | | | | | |
| b. Lack of scientific evidence on safety, toxicity and efficacy through clinical and non-clinical trials. | | | | | |
| c. Lack of modern dosage forms. | | | | | |
| d. Associated with Spiritism in a country with more than 75% Christians. | | | | | |

26. Attainability of the minimum requirements for registration of TM and the practice.

Kindly rate how strongly you agree or disagree with the statements below on the reasons for the delayed integration of ZTM into the national healthcare system. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| a. Long-term records of ITMK use without evidence of risk. | | | | | |
| b. Standardization for quality, safety and efficacy information. | | | | | |
| c. Potential for misuse, abuse or dependence. | | | | | |
| d. Finished Product manufacturing procedure and formula, including the amount of excipients | | | | | |

27. Challenges affecting the establishment of the national pharmacopeia and compendium with accurate ZTM information.

Kindly rate how strongly you agree or disagree with the statements below on the challenges affecting the establishment of the national pharmacopeia and compendium with accurate ZTM information. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| a. Non-disclosure of ITMK by ZTMP | | | | | |
| b. Nature of compound ingredients that are expensive to analyze. | | | | | |
| c. Need for complicated technology to process TM. | | | | | |
| d. Lack of global or regional harmonization of TM to share cost and ideas. | | | | | |



28. Can the use of indigenous knowledge information, be used same as equivalent evidence to support the quality, safety and efficacy of ZTM sufficient for the integration.

Kindly rate how strongly you agree or disagree with the statements below on whether the use of indigenous knowledge information, can be used same as equivalent evidence to support the quality, safety and efficacy of ZTM sufficient for the integration. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| a. Use ITMKS on its own in place of scientific evidence. | | | | | |
| b. Use Scientific non-clinical and clinical evidence. | | | | | |
| c. Use both ITMKS and clinical evidence to determine quality, safety and efficacy of ZTM. | | | | | |
| d. ITMKS can only be used as complementary or alternative evidence to scientific evidence. | | | | | |

29. The level of education and training that could be set as the minimum requirement for the immediate integration of the ZTM

Kindly rate how strongly you agree or disagree with the statements below on level of education and training that could be set as the minimum requirement for the immediate integration of the ZTM. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| a. Certificate in ZTM and Conventional Medicines. | | | | | |
| b. Diploma in ZTM and Conventional Medicines. | | | | | |
| c. University degree in ZTM and Conventional Medicines. | | | | | |
| d. Should continue to run parallel as separate medical interventions. | | | | | |

30. Recommendations for the immediate implementation considering the need to improve total health coverage.

Kindly rate how strongly you agree or disagree with the statements below on level of education and training that could be set as the minimum requirement for the immediate integration of the ZTM. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| a. Leave at current status quo, ZTM complementing CM. | | | | | |
| b. Immediate integration with whatever information is available. | | | | | |
| c. Record enough ITMK to support quality, safety and efficacy. | | | | | |
| d. Wait for scientific clinical trials evidence to support quality, safety and efficacy. | | | | | |

**Name of the interviewer:** _____

***Thank you for taking your time in completing this questionnaire.***

## 3. Questionnaire 2


**Knowledge-Based Integration of Zimbabwean Traditional Medicines (ZTM) into the National Healthcare System: A Case Study of Prostate Cancer.**

**Key Informants Questionnaire: ZTM Stakeholders and Practitioners that include THP/Herbalists, Medical Doctors, Pharmacists, MRCZ, MCAZ, PCZ, HPA, TMPC/Zinatha, Ministry of Health and Childcare, WHO, Higher Education Institutions (UZ School of Pharmacy, staff and students), Christian Groups, NGOs and Cancer Association of Zimbabwe, Prostate Cancer Patients, Public and TM Street Vendors.**



*My name is Brighton Itayi Chawatama, a M.Sc. Pharmacy Administration and Policy Regulation student with the School of Pharmacy, University of Western Cape. My research work is looking into challenges and opportunities in the integration of ZTM into the mainstream healthcare system since the establishment of the TM Policy in 2007. Your observations and any information you may consider useful for the study will be greatly appreciated for use in this study purposes only. Please feel free to withdraw from this exercise if and as you may so wish.*

The research seek to establish the efficient and safe ways of integrating ZTM into the national healthcare system. The problem is that there are herbal clinics in Zimbabwe treating prostate cancer that has been condemned as un-curable at government and private Hospitals. These herbal treatments are not recognized in the mainstream essential medicines list of Zimbabwe, neither are they registered with the Medicines

Control Authority of Zimbabwe (MCAZ). There is need put together Indigenous knowledge-based evidence to prove quality, safety and efficacy standards that enable registration of the products and practice with national regulatory authorities.

## Socio-economic and Demographic variables of the stakeholder

1. Area of residence:

| | | | |
|---|---|---|---|
| High Density Suburb | Low Density Suburb | Peri-Urban | Farm |

2. Occupation of the stakeholder:

| | | | | | |
|---|---|---|---|---|---|
| a. Medical Doctor | b. Pharmacist | c. TMP | d. Government worker | e. NGO WHO Employee | f. Street Vendor |

Other/Explain

_____



3. Level of education?

| | | | | |
|---|---|---|---|---|
| a. Post Grad | b. Masters | c. Undergrad | d. Secondary | e. Primary |

Other/Explain

_____

4. Age group

| | | | | |
|---|---|---|---|---|
| Below 20 years | 20 – 40 years | 41 – 60 years | 61 – 80 years | Above 80 years |

5. Knowledge of drug development:

| | | | | |
|---|---|---|---|---|
| Below 20% | 20 – 40% | 41 – 60 % | 61 – 80% | 81 – 100% |

6. What type of training have you obtained in TM?

| | | | |
|---|---|---|---|
| Formal | | Informal | |

## Stakeholder Indigenous Traditional Medicine Knowledge Feedback

7. To what extend do you agree/disagree that integration of Zimbabwean Traditional Medicine into the national healthcare system will improve total health coverage.

| | | | |
|---|---|---|---|
| a. Strongly Agree >75% | b. Agree 75 – 51% | c. Disagree 50 – 25% | d. Strongly Disagree<25% |

8. According to your experience and knowledge what is the approximate current level of use of TM in rural areas Zimbabwe?

| | | | |
|---|---|---|---|
| a. Strongly Agree >75% | b. Agree 75 – 51% | c. Disagree 50 – 25% | d. Strongly Disagree <25% |



9. How do you rate the level of use of TM in urban areas of Zimbabwe?

| | | | |
|---|---|---|---|
| a. Strongly Agree >75% | b. Agree 75 – 51% | c. Disagree 50 – 25% | d. Strongly Disagree <25% |

10. Do you think the direct integration of TM into the mainstream healthcare system will significantly improve treatment outcomes, the prevention or treatment of diseases and symptoms? TICK THE APPLICABLE

| | | | |
|---|---|---|---|
| YES | | NO | |

Give reason/s……
……

11. Do you agree that parallel integration of TM will improve treatment outcome of prostate cancer?

| | | | |
|---|---|---|---|
| a. Strongly Agree >75% | b. Agree 75 – 51% | c. Disagree 50 – 25% | d. Strongly Disagree <25% |

Give reason/s……
……

12. According to your experience and knowledge in the use of ZTM, what do you recommend Direct of Parallel integration to avert drug-herb interactions and obtain optimum treatment outcome.

| | | | |
|---|---|---|---|
| Direct Integration | | Parallel Integration | |

13. Which of the following integration methods of ZTM based on the extensive knowledge from folklore use/evidence for safety, quality and efficacy would you recommend?

| | | | |
|---|---|---|---|
| a. Immediate Integration | b. Integrate Using Knowledge-based Evidence (KBE) | c. Integrate Using Scientific Evidence | d. Maintain Status Quo |



14. Why do you think people are using TM?

| | | | |
|---|---|---|---|
| a. Affordability | b. Accessibility | c. Trust/Confidence | d. Uncivilized |

Other……
……..

15. Under what circumstances are people using TM?

| | | | |
|---|---|---|---|
| a. Remote Areas | b. Trust | c. Traditional Beliefs | d. Failed Conventional Medicines |

Other/explain……
……

16. What are the benefits for those using TM?

| | | | |
|---|---|---|---|
| a. Affordable | b. Highly Accessible | c. Minimal Side Effects | d. Spiritual Satisfaction |

Other/Explain……
……

17. Who is delivering TM?

| | | | |
|---|---|---|---|
| a. TMP/Herbalist | b. Parents | c. Village Elder | d. Medical Doctor/Pharmacist |

Other/Explain……
……

18. What are their qualifications?

| | | | | |
|---|---|---|---|---|
| a. Experience | b. Diploma TM | c. Pharm Hons | d. Doctor | e. TM/Herbalist |

Other/Explain……
……..



**TMK DISCLOSURE ISSUES**

19. Do you think TMP will be willing to disclose information about their practice/invention?

| | | | |
|---|---|---|---|
| YES | | NO | |

Give reason/s……
…….

20.What do you think are the implications if they are protected under Confidentiality, Intellectual Property Rights(IPRs) offer to convey legal ownership over the TMP such as patents, trademarks, copyrights, geographical indications, protection for plant varieties and trade secrets.

Explain……
……..

21. What modalities can be put in place for royalties, compensation and practice?

| | | | |
|---|---|---|---|
| a. Restructuring of mainstream healthcare system to include TMP | b. Government Policy, ZTM treated as state assets | c. Community Share Trust | d. NGO Assisted payment of royalties |

Others……
……..

**FINANCIAL RESOURCES TO PROMOTE ZTM INTEGRATION**

22. To what extend do you agree that the Zimbabwean government can provide enough national health resources for the clinical tests ZTM.

| | | | | |
|---|---|---|---|---|
| Less than 20% | 20 – 40% | 41 – 60 % | 61 – 80 % | 81 – 100 % |

Explain.....……
……



23. Do you think integration of ZTM through documentation of **TMK** (Traditional Medicines Knowledge) will assist researchers in finding new uses for traditional medicines or to develop new drugs from medicinal plants?

| | | | |
|---|---|---|---|
| YES | | NO | |

Give reason/s……
……

24. Do you think medical insurance reimbursement of TM practice and products will promote national health coverage.

| | | | |
|---|---|---|---|
| YES | | NO | |

Give reason/s……
……

## REGULATION AND INSTITUTIONALIZATION OF ZTM

25. At what stage do you suggest ZTM can be integrated? TICK APPLICABLE

1) Full dossier with product-specific safety and efficacy data
2) Well-established use with sufficient safety and efficacy data, OR
3) Traditional use with sufficient safety data and plausible efficacy (simplified registration procedure).

26. Reasons for the delayed integration of ZTM into the national healthcare system.

Kindly rate how strongly you agree or disagree with the statements below on whether the integration of ZTM into the national health system will improve total health coverage. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| a. Lack of standardization to determine quality of ZTM. | | | | | |
| b. Lack of scientific evidence on safety, toxicity and efficacy through clinical and non-clinical trials. | | | | | |
| c. Lack of modern dosage forms. | | | | | |
| d. Associated with Spiritism in a country with more than 75% Christians. | | | | | |



27. Attainability of the minimum requirements for registration of TM and the practice.

Kindly rate how strongly you agree or disagree with the statements below on the reasons for the delayed integration of ZTM into the national healthcare system. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| a. Long-term records of ITMK use without evidence of risk. | | | | | |
| b. Standardization for quality, safety and efficacy information. | | | | | |
| c. Potential for misuse, abuse or dependence. | | | | | |
| d. Finished Product manufacturing procedure and formula, including the amount of excipients | | | | | |

28. Challenges affecting the establishment of the national pharmacopeia and compendium with accurate ZTM information.

Kindly rate how strongly you agree or disagree with the statements below on the challenges affecting the establishment of the national pharmacopeia and compendium

with accurate ZTM information. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| a. Non-disclosure of ITMK by ZTMP | | | | | |
| b. Nature of compound ingredients that are expensive to analyze. | | | | | |
| c. Need for complicated technology to process TM. | | | | | |
| d. Lack of global or regional harmonization of TM to share cost and ideas | | | | | |

29. Can the use of indigenous knowledge information, be used same as equivalent evidence to support the quality, safety and efficacy of ZTM sufficient for the integration.

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| | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| a. Use ITMKS on its own in place of scientific evidence. | | | | | |
| b. Use Scientific non-clinical and clinical evidence. | | | | | |
| c. Use both ITMKS and clinical evidence to determine quality, safety and efficacy of ZTM. | | | | | |
| d. ITMKS can only be used as complementary or alternative evidence to scientific evidence. | | | | | |



30. The level of education and training that could be set as the minimum requirement for the immediate integration of the ZTM

Kindly rate how strongly you agree or disagree with the statements below on level of education and training that could be set as the minimum requirement for the immediate integration of the ZTM. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| a. Certificate in ZTM and Conventional Medicines. | | | | | |
| b. Diploma in ZTM and Conventional Medicines. | | | | | |
| c. University degree in ZTM and Conventional Medicines. | | | | | |
| d. Should continue to run parallel as separate medical interventions. | | | | | |

31. Recommendations for the immediate implementation considering the need to improve total health coverage.

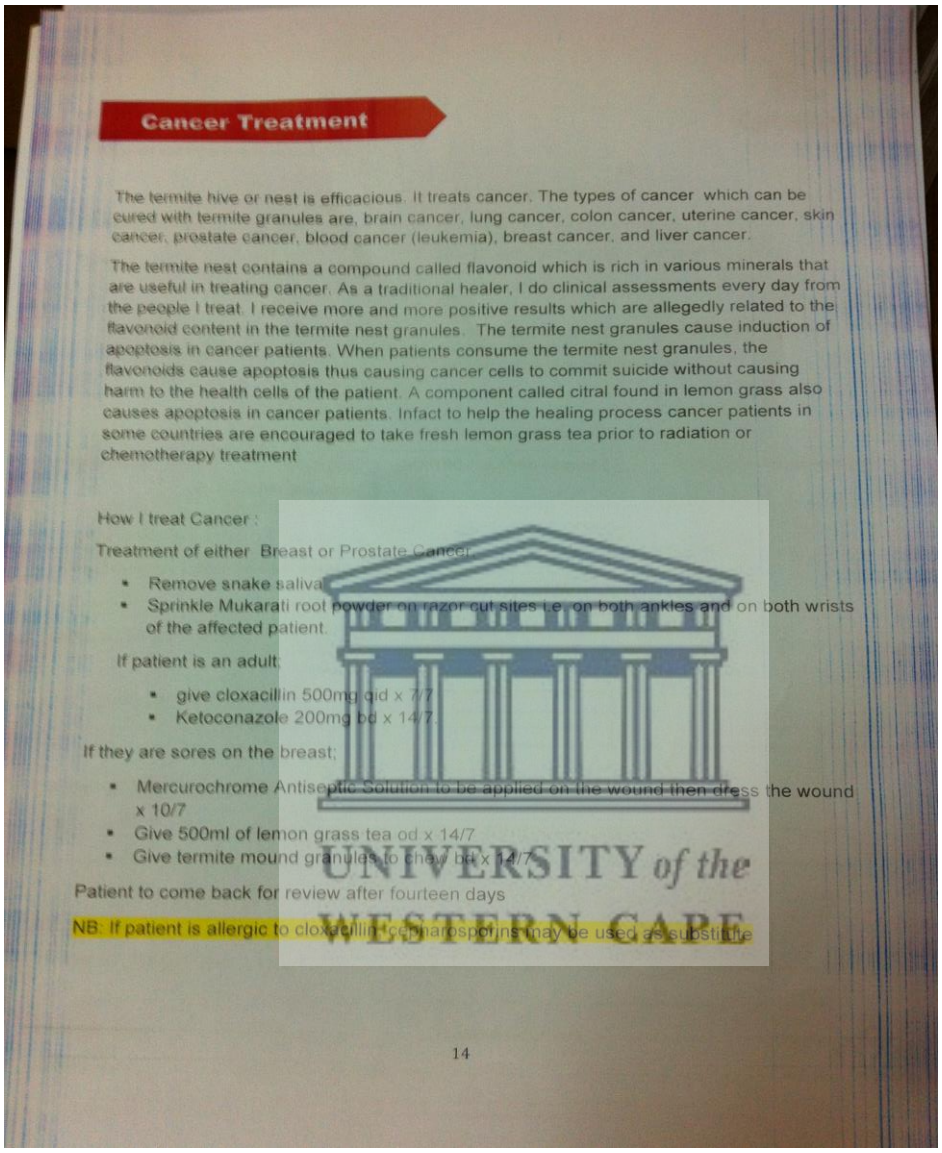
Kindly rate how strongly you agree or disagree with the statements below on level of education and training that could be set as the minimum requirement for the immediate integration of the ZTM. The ratings are in the form of a 5-point Likert scale whereby **1** represents **strongly disagree**; **2** represents **disagree**; **3** represents **indifferent**; **4** represents **agree** and **5** represents **strongly agree**.

| | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| a. Leave at current status quo, ZTM complementing CM. | | | | | |
| b. Immediate integration with whatever information is available. | | | | | |
| c. Record enough ITMK to support quality, safety and efficacy. | | | | | |
| d. Wait for scientific clinical trials evidence to support quality, safety and efficacy. | | | | | |

32. Please feel free to add any information that you consider helpful for this study.

.....
.....
.....
.....
.....
.....
.....
.....
.....

***Thank you for taking your time in completing this questionnaire.***



## Cancer Treatment

The termite hive or nest is efficacious. It treats cancer. The types of cancer which can be cured with termite granules are, brain cancer, lung cancer, colon cancer, uterine cancer, skin cancer, prostate cancer, blood cancer (leukemia), breast cancer, and liver cancer.

The termite nest contains a compound called flavonoid which is rich in various minerals that are useful in treating cancer. As a traditional healer, I do clinical assessments every day from the people I treat. I receive more and more positive results which are allegedly related to the flavonoid content in the termite nest granules. The termite nest granules cause induction of apoptosis in cancer patients. When patients consume the termite nest granules, the flavonoids cause apoptosis thus causing cancer cells to commit suicide without causing harm to the health cells of the patient. A component called citral found in lemon grass also causes apoptosis in cancer patients. Infact to help the healing process cancer patients in some countries are encouraged to take fresh lemon grass tea prior to radiation or chemotherapy treatment

How I treat Cancer :

Treatment of either Breast or Prostate Cancer;

- Remove snake saliva
- Sprinkle Mukarati root powder on razor cut sites i.e. on both ankles and on both wrists of the affected patient.

If patient is an adult;

- give cloxacillin 500mg qid x 7/7
- Ketoconazole 200mg bd x 14/7.

If they are sores on the breast;

- Mercurochrome Antiseptic Solution to be applied on the wound then dress the wound x 10/7
- Give 500ml of lemon grass tea od x 14/7
- Give termite mound granules to chew bd x 14/7

Patient to come back for review after fourteen days

NB: If patient is allergic to cloxacillin cephalosporins may be used as substitute



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**4. Anecdote: Cancer Treatment Guidelines ZTM & CM Integration by Benyamin Charles Nyaude 2018**

## 5. Student Registration Confirmation

UNIVERSITY of the
WESTERN CAPE

School of PHARMACY
FACULTY OF NATURAL SCIENCES
Private Bag X17 Bellville 7535
Telephone +27 21 9592190
Fax +27 21 9593407

28th August 2017

**TO WHOM IT MAY CONCERN**

**Dear Sir/Madam**

Mr Brighton Chawatama (student number 3782942) is registered at our institution for the MSc Pharmacy Administration and Policy Regulation degree. Part of the requirements for this degree is to complete a research project supervised by of one of our staff members.

Dr Samuel Egieyeh a lecturer in pharmacology at our school has agreed to serve as supervisor for this project. His role for this thesis is to provide online guidance on the subject matter under investigation. He will be assisted by the undersigned Mr Rafik A Bapoo as co-supervisor. I am a retired pharmaceutics lecturer and coordinator of this post-graduate programme. My responsibility is to provide administrative and academic support to complete the project timeously.

I confirm that the title of the project is: Knowledge-Based Integration of Zimbabwean Traditional Medicines into the National Healthcare System: A Case Study of Prostate Cancer.



Yours faithfully

---

Rafik A Bapoo



## 6. Medical Research Council of Zimbabwe Ethical Approval

Telephone: 791792/791193
Telefax. (263) - 4 - 790715
E-mail: mrcz@mrcz.o.s.zw
Website: http://www.mrcz.org.zw

Medical Research Council of Zimbabwe
Josiah Tungogara / Mazoe Street
P. O. Box CY 573
Causeway
Harare

APPROVAL

REF: MRCZ/B/1369 27 October 2017

**Brighton Itayi Chawatama**
Bright Pharmaceuticals
Shop 5, Stand 13415
Cnr Coppe/Kelvin North
Graniteside
**Harare**

**RE:- Knowledge-based Integration of Zimbabwean Traditional Medicines into the National Healthcare System: A Case Study of Prostate Cancer.**

Thank you for the application for review of Research Activity that you submitted to the Medical Research Council of Zimbabwe (MRCZ). Please be advised that the Medical Research Council of Zimbabwe has **reviewed** and **approved** your application to conduct the above titled study.

This approval is based on the review and approval of the following documents that were submitted to MRCZ for review:-

a) Protocol
b) Informed Consent Form
c) Data collection tools

- **APPROVAL NUMBER** : MRCZ/B/1369
  This number should be used on all correspondence, consent forms and documents as appropriate.
- **TYPE OF MEETING** : **Full Board**
- **EFFECTIVE APPROVAL DATE** : 27 October 2017
- **EXPIRATION DATE** : 26 October 2018

After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ Offices should be submitted three months before the expiration date for continuing review.

- **SERIOUS ADVERSE EVENT REPORTING:** All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ Offices or website.
- **MODIFICATIONS:** Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ Offices is required before implementing any changes in the Protocol (including changes in the consent documents).
- **TERMINATION OF STUDY:** On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ Offices or website.
- **QUESTIONS:** Please contact the MRCZ on Telephone No. (04) 791792, 791193 or by e-mail on mrcz@mrcz.org.zw

**Other**

- Please be reminded to send hard copies of your research results for our records as well as for Health Research Database.
- You're also encouraged to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study.



Yours Faithfully

.....

**MRCZ SECRETARIAT**
**FOR CHAIRPERSON**
**MEDICAL RESEARCH COUNCIL OF ZIMBABWE**

MEDICAL RESEARCH COUNCIL OF ZIMBABWE
2017 -10- 27
APPROVED
P.O. BOX CY 573 CAUSEWAY HARARE

PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH

## 7. Ministry of Health and Child Care: Approved Letter of Introduction to Carry out Research within medical stakeholders

Plot 7502
Epworth Light Industrial Park
Off Chiremba Road
Epworth, Harare

09 June 2017

The Permanent Secretary
Ministry of Health and Child Care
1122 Causeway, Harare

Dear Sir / Madam

**RE: LETTER OF INTRODUCTION TO CARRY OUT RESEARCH IN THE MoHCC**

Find attached documents as request for my authorization to carry out research in the MoHCC and affiliate organizations.

The key informants targeted by my research are:

- Medical Doctors, Pharmacists
- MRCZ staff, MCAZ regulatory officers, PCZ and HPA practice control committee.
- TMPC/Zinatha practice committee, THP/Herbalists, TM Street Vendors.
- Ministry of Health and Childcare TM Officers, WHO TM Department
- Higher Education Institutions (UZ School of Pharmacy, staff and students)
- Christian Groups, NGOs
- Prostate Cancer Patients, Public and

I also request to start from your office as soon as possible. My field work has been delayed by late ethics approval, I therefore kindly request your assistance so that I can finish my field work in a week.

Yours Faithfully

**Brighton Ifayi Chawatama**

***Pharmaceutical Consultant***