AN ASSESSMENT OF AFRICAN TRADITIONAL MEDICINES IN PREGNANCY AND ON BIRTH OUTCOMES; PHARMACISTS' PERCEPTIONS OF COMPLEMENTARY MEDICINES IN PREGNANCY

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ABSTRACT

Introduction: Increasing numbers of medicines are being used by pregnant South African women in the public sector during pregnancy, for the treatment of different biomedical and supernatural disease states and conditions. The motivation for the research is to support the development of more local pregnancy registries in order to strengthen evidence for the safety and efficacy of medicines used in pregnancy.

Methodology: A mixed methods approach was used. Women in their ninth month of pregnancy in a public sector setting, and four community pharmacists were identified. The women who met the inclusion criteria were recruited. One in-depth semi-structured interview was conducted with each woman before giving birth and data on their pregnancy outcomes were collected after labour. Coincidentally, the mother of one of the participants was found to be a traditional healer. She was also interviewed on the topic. A structured questionnaire was administered to the pharmacists.

Results: Ten pregnant women between the ages of 19 to 39 who had used or were using a traditional medicine during the pregnancy were recruited. All the participants had had at least one antenatal check up during their pregnancy with one having attended five times. No abnormal results were reported from any of the check ups or tests done during the visits. All of them had been to school and had at least Standard 8/Grade 10 education. Ten babies were seen between one and four days postpartum and no birth defects were obvious or were reported for any of them. The traditional healer did not provide additional information to what the women had said and confirmed that some of the practices the women reported were known to her as traditional medicine practices. All four pharmacists indicated that they considered complementary and alternative medicines (CAMs) to be “somewhat effective” and sold them at their pharmacies although none of them were aware of whether or not they were registered with the MCC. None of the pharmacists appeared to have an in-depth knowledge of traditional, complementary and alternative medicines (TCAMs). All four pharmacists said that it is important to have a basic understanding of TCAMs before using them, although they did not agree on the reasons for this. All of them felt that pharmacists have a professional responsibility to

provide information on TCAMs (especially herbal preparations) and two felt that providing this information is part of a medical doctors' responsibility.

Discussion: No harm from taking TCAMs could be shown. However herbal medicines have numerous ingredients some of which are unknown and taking these medicines is risky. The pharmacists in this sample were unsure whether they were accessing unreliable CAM information. Reliable sources of information and reference materials on CAMs to assist pharmacists and other healthcare professionals are needed.

Conclusion: The apparent widespread use of TCAM in pregnancy indicates a need for documentation about its efficacy and safety. The establishing of TCAM pregnancy registries should seriously be considered. Due to the increase in CAM use, CAM education during pharmacists' training as well as continuing professional development (CPD) in CAM for pharmacists in practice should be encouraged.

This thesis is dedicated to the following:

In loving memory to my late mother, Primrose Mupfumira

To my father, Taurai Mupfumira

To my siblings, Gloria Mupfumira and Tendai Mupfumira

Thank u for all the love, support and for shaping my future.

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RESEARCH OUTPUTS

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ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
APGAR	Appearance, Pulse, Grimace, Activity, Respiration
ARV	Antiretroviral
CAM	Complementary and Alternative Medicine
CHC	Community Health Centres
GMP	Good Manufacturing Practice
GPP	Good Pharmacy Practice
HC	Head Circumference
HBM	Health Belief Model
HIV	Human Immunodeficiency Virus
MCC	Medicines Control Council (of South Africa)
NVD	Normal Vaginal Delivery
OTC	Over the counter
PHC	Public Health Care
TCAM	Traditional, Complementary and Alternative Medicine
TM	Traditional Medicine
WHO	World Health Organization

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CHAPTER ONE

INTRODUCTION

[Note: References are listed according to the National Library of Medicine's "Citing Medicine" format]

1.1 Background to research

The motivation for the research is to add support to the development of local pregnancy registries in order to strengthen evidence for safety and efficacy of medicines used during pregnancy. Women may be taking medicines during pregnancy or may become pregnant while under treatment. Certain medicines are being used during pregnancy for the treatment of different disease states e.g. epilepsy and HIV and AIDS.[1] Petropoulou *et al.* (2006) stated that more than 2-million HIV infected women across the world became pregnant each year especially in developing countries. They further indicated that more than 3.2-million children and adolescents infected with HIV had acquired it through intrapartum and perinatal transmission and most of them lived in Sub-Saharan Africa.[2] Antiretroviral therapy is prescribed in pregnancy to help reduce the risk of perinatal transmission of HIV.[3]

Epilepsy is the second most common neurological disorder and most women that have it require ongoing anti-epileptic drug therapy during pregnancy to avoid the effects of the seizures on the unborn child as well as themselves.[4-6]

The use of herbal remedies is becoming increasingly popular worldwide, and in 1995 Brandt and Muller estimated that approximately 80% of the South African population had used a traditional remedy at some stage in their life.[7] A survey done in 2003 showed that a substantial number of South African women sought treatment from traditional healers for a variety of complications and disorders associated with the female reproductive system including pregnancy related conditions.[8] There are limiting factors to interpreting published observations of pregnant women exposed to medicines and these include small sample sizes as well as differing study designs.[9, 10]

Some of the reasons why implementation of pregnancy registries is important are so that teratogenic medicines can be identified and avoided in pregnant women and women of child bearing age in the event they fall pregnant. The rationale for pregnancy registries is to detect the teratogenic effects of medicines used in pregnancy as there is often insufficient data recording the foetal effects of medicines.[3, 11-15] A study carried out in South Africa in 2006 highlighted the need for active pregnancy surveillance during pregnancy of the use of antiretroviral (ARV) medicines as well as an urgent need to monitor neonates exposed to ARV therapy.[16]

Establishing pregnancy registries forms an important component of pharmacovigilance.

1.2 Field of research

The study investigated the use of Traditional, Complementary and Alternative medicines (TCAMs) by pregnant women in Grahamstown, Eastern Cape, South Africa, and the outcomes of their pregnancies. In addition the knowledge and attitudes of community pharmacists on the use of these medicines in pregnancy was investigated.

1.3 Aims and objectives of this study

The aims and objectives of this study were:

- To determine some of the reasons why a sample of pregnant women in Grahamstown chose to use traditional, complementary and alternative medicines
- To document whether any adverse events following the use of these medicines had occurred in the women during or after the pregnancy
- To document whether any adverse events following the use of these medicines had occurred in the babies during the pregnancy, labour, birth or postpartum
- To assess the knowledge and attitudes of community pharmacists about the use of TCAMs and/or complementary and alternative medicines (CAMs) during pregnancy

1.4 Significance of the study

This research question has not been extensively studied in an African context and only a few studies have focused on pregnancy outcomes. It is hoped that the information obtained by the end of the research might provide a basis for further research.

1.5 Definition of key terms

Due to various interpretations of terms it is necessary to explain and clarify the terms in the context in which they are used in this study.

The term **Traditional medicine** includes herbal medicines, animal parts and or minerals.[a] The terms **Complementary medicine** and **Alternative medicine** are used to refer to any therapy that is not conventional and is used to treat health conditions singly or in conjunction with conventional medicine. The term **herbal therapies/remedies** includes herbs, herbal preparations and materials and finished herbal products that contain parts of plants or any other plant materials or combination as active ingredients.[17] The terms **modern, conventional** and **western medicines** are used interchangeably when referring to prescribed and non-prescribed medicines that are produced chemically by synthesis to treat health conditions. The terms **therapies/remedies** and **medicines** are used interchangeably when referring to medicines and compounds used by the people who took part in the study. The person who conducted this study is referred to as the **investigator/researcher**. The terms **participants** and **individuals** are used interchangeably to refer to the people who consented to take part in the study.

1.6 Overview of chapters

The following chapter, (Chapter 2) is a review of literature related to the research topic. Literature on pregnancy registries, pregnancy, prescribing during pregnancy, as well as accessibility of antenatal facilities by women in South Africa is reviewed. It also describes the uses, problems associated with and regulatory issues of TCAMs in South Africa.

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[a] This definition does not include the use of human tissue. This is considered to be unacceptable by ethical traditional health practitioners.

Chapter 3 describes the setting in which the study was conducted, methodologies used in undertaking the study. It provides details of ethical considerations, sampling, a description of how the data was collected and data analysis conducted.

Chapter 4 presents the qualitative and quantitative results obtained. These are discussed in Chapter 5.

Chapter 6 contains the conclusions and recommendations and includes some reflections about the study.

CHAPTER TWO

LITERATURE REVIEW

2.1 Pregnancy registries

2.1.1 Introduction

Pregnancy registries are based on entirely observational data but the knowledge gained may be used to improve the accuracy of the risk benefit assessment of a medicine and counselling of women with the same exposure[12-15, 18-22] but cannot be generalised to exposed pregnant women.

2.1.2 Types of registry[b]

a) Population based registry: According to the WHO[c], a population based registry '*records data relating to all births[d] to mothers resident within a defined area, irrespective of where the birth takes place'*.[23]

b) Hospital based registry: The WHO also states that: '*…a hospital based registry records defects in babies born irrespective of where the mother lives…'*. This type of registry can establish the foetal risk of major malformations of a commonly used medicine.[23]

c) Pharmaceutical company based registry: A pharmaceutical based registry records data on pregnancy outcomes related to a sponsor's own products and is often driven by national or international drug licensing agencies. [24, 25] In South Africa the "drug licensing" agency is the Medicines Control Council (MCC), which does not use the terminology of "licensing" drugs but "registering" medicines.[e]

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[b] This does not include registries not related to pregnancy – e.g. the South African National Cancer Registry

[c] World Health Organization

[d] Births include live births, stillbirths and terminated pregnancies due to prenatally diagnosed birth defects.

[e] Medicines and Related Substances Act, 1965 (Act 101 of 1965).

d) Independent academic based registry: These are organised by independent research groups. [24]

2.1.3 Characteristics of pregnancy registries

The main rationale for having pregnancy registries is to detect teratogenic effects of medicines used in pregnancy.[3, 11-15] Determination of teratogenicity relies mostly on animal studies, pregnancy outcomes and post marketing surveillance as pregnant women are usually excluded from human clinical trials. This does not provide concrete information regarding risks in humans as some medicines that have teratogenic effects on animals may not necessarily have the same teratogenic effects in humans[26] and some that have no teratogenic effects in animals may be teratogenic in humans. Some authors suggest that the inclusion of pregnant women in trials would be ideal as there will be accumulation of important data as there is insufficient information to conclude that some medicines are not teratogenic[26,27] but because of ethical issues this cannot be defended. Data collected on teratogenicity in one geographical area may not hold true for other areas. Since the available information is limited and there are large numbers of child bearing women there is a need to collect local data for relevant regions.[f][26]

Awareness of different methods used for data collection in existing pregnancy registries is important as this may influence the outcome of the results the interpretation of the data.[24]

2.2 Pregnancy

2.2.1 Introduction

An individual woman's experience of pregnancy is not just a medical occurrence but one that also reflects her cultural values, family beliefs as well as her own beliefs.[28] Socially, pregnancy is one of the most normal physiological processes and individually it has many different perceptions.[29] However, for women experiencing uncomfortable symptoms during their pregnancy being pregnant has its own stresses.[29, 30] A

[f] The terms 'area' and 'region' are used interchangeably when referring to a geographical space.

woman's perception of her pregnancy could have an impact on her personal health and well being, her feelings towards her baby as well as her thoughts about giving birth.[31]

2.2.2 Maternal health

In 2008 the WHO estimated that every year more than 133 million babies were born worldwide and 90% of these births were from low and middle income countries. They also stated that annually, 3 million babies were stillborn and the causes of their deaths were mainly due to complications during pregnancy and during labour.[32] These complications included obstructed labour, haemorrhage, eclampsia (seizures caused by hypertensive disorders in pregnancy), infection and miscarriage. Complications may also develop because the pregnancy itself aggravated an existing disease in the woman.[33] Poor maternal health and diseases that have not been adequately treated before or during pregnancy also contribute to the complications during pregnancy as well as low birth weight of the baby and pre term births.[32]

In 2011, the Minister of Health of South Africa stated that the high maternal and child mortality rate was one of the four "pandemics" South Africa was going through and that the rates were unacceptably high.[34]

Uncomfortable symptoms experienced during pregnancy often begin at the early stages of pregnancy and may disappear by the fourth or fifth month of pregnancy. However, due to individual variation some women may feel "sick" during the entire pregnancy. Experiencing these symptoms may impact on the psychological and physical health of the pregnant woman as well as foetal outcomes.[35] The most common uncomfortable symptoms experienced during pregnancy are nausea and vomiting.[g] Other pregnancy symptoms women may experience include back pain, leg cramps, and leg oedema.[36]

Some women have realised that during pregnancy and delivery, a range of problems could be encountered and in an attempt to prevent these from happening may seek treatment from the onset of pregnancy.[37]

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[g] The infamous thalidomide disaster was associated with a remedy for nausea and vomiting.

2.2.3 Antenatal care in South Africa

2.2.3.1 Introduction

The South African Demographic Health Survey reported that antenatal care attendance in South Africa had remained over 90% since 1998 and deliveries by skilled health workers had increased from 84% in 1998 to 92% in 2003. Although they stated that attendance was high, they also highlighted that the quality of services was not optimum and further assessment and improvement was needed.[38]

Maternal and child health has been a priority for the South African government since 1994. Increased numbers of primary health care clinics have been constructed and the user fees for maternal and child services at the primary health care and district hospital levels were abolished.[39, 40]

General utilisation of these services was found to be good in South Africa with 84% of women giving birth in a health facility; 17% of these were at clinics, 42% at district hospitals and 11% at tertiary hospitals.[39, 41] However the 2010 annual report for the Eastern Cape Department of Health, states that annual coverage for antenatal care before 20 weeks was still unsatisfactory.[42]

2.2.3.2 Health systems for maternal and neonatal health

Four levels of care within the South African health care system have been established for maternal, neonatal and child health; these being community level services, primary level services, district hospital level and regional hospital level services (See Figure 2.1).[39, 43]

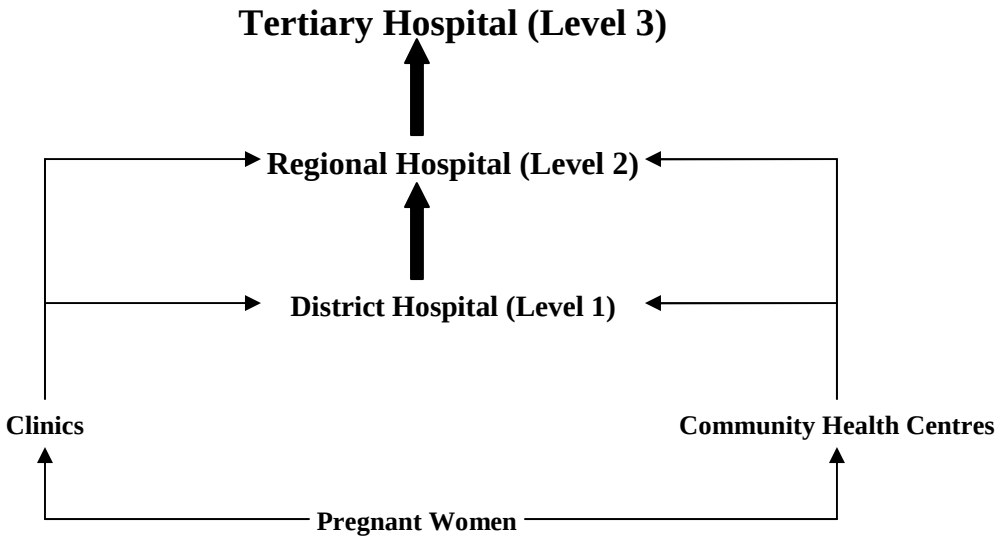

Figure 2.1: Levels of public health maternity care in South Africa[44, 45]

Community level services are provided by Community Health Centres (CHCs) and clinics. Level 1 services are provided by district hospitals, level 2 services are provided by regional hospitals which also provide some level 1 services to health centres and clinics nearby. Level 3 services comprise of specialised equipment/services to aid in the management of critically sick obstetric patients. Patients should be attended to at the lowest appropriate level of care and be referred to a higher level only when clinically indicated. This helps for optimum consumption of human and financial resources in the public sector.[44]

The comprehensive public health care for clinics requires the provision to pregnant women of antenatal care at least once a week. Ideally clinics should provide this service daily for accessibility.[46] Women are advised to have at least three or more antenatal visits before the delivery of their babies.[46, 47] This helps monitor both the mother and the developing foetus and to treat diagnosed conditions as well as refer cases with complications.[46]

Community health centres and clinics form the first ports of entry in the primary health system including maternity health care.[44, 45] Normal[h] pregnancies should be managed at these levels and only pregnancies at a high risk of complications and those that require obstetric intervention should be managed at higher levels of health care facilities. Upward referral takes place from the lower level to a higher level (See Figure 2.2). Maternity cases can be referred from Community Health Centres and clinics directly to Level 2 in some cases.[43]

(Appendix A includes a detailed description of the maternity facilities in the public sector in South Africa.)

[h] Normal pregnancies refers to pregnancies with no complications

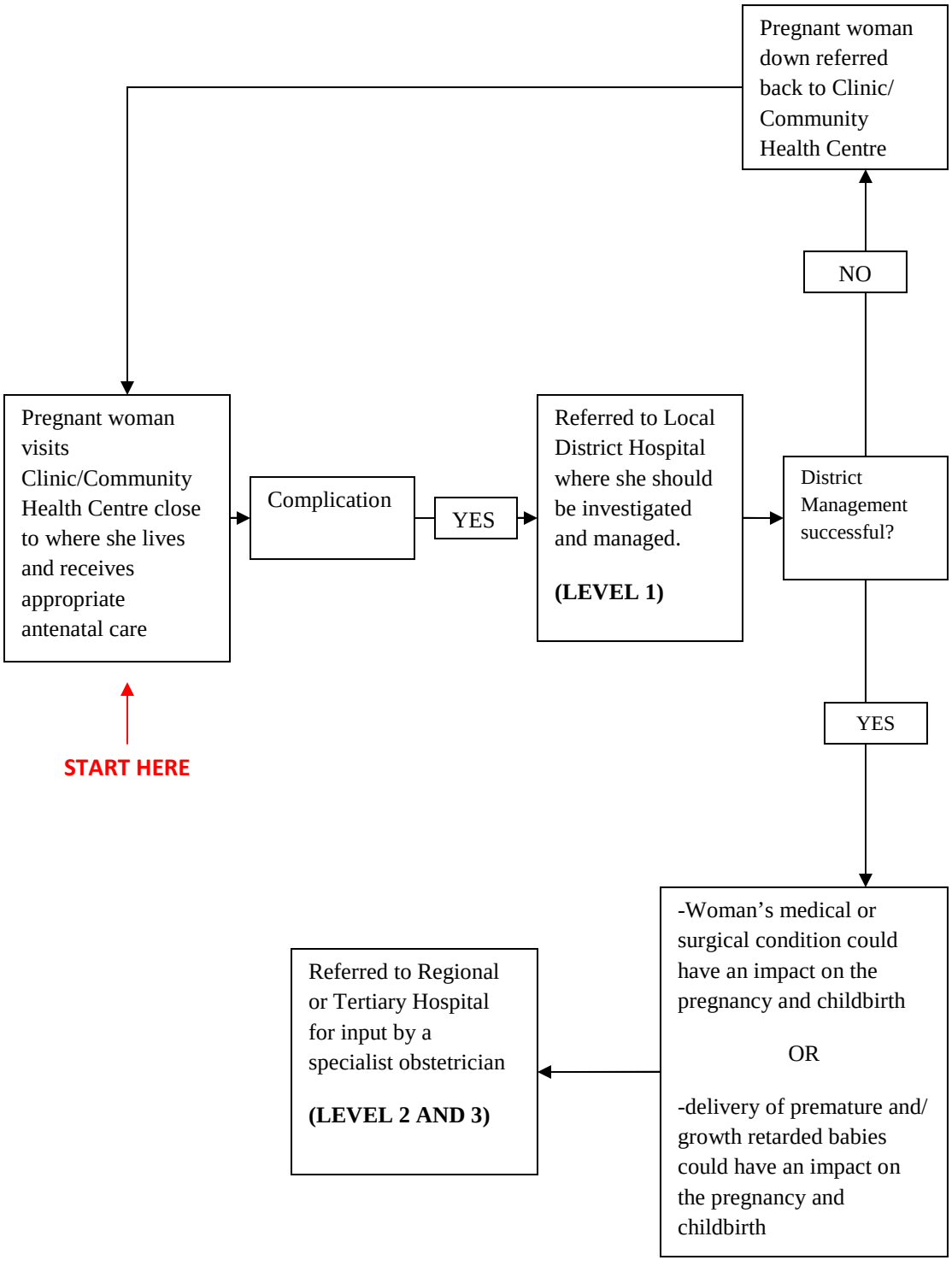

Figure 2.2: Referral system for public health maternity care in South Africa[44]

2.2.4 Coverage and quality of care

At all levels of the health system, South Africa has health service packages throughout the life cycle for mothers, babies and children[48, 49] and antenatal clinics are widely distributed with some standing alone and some within hospitals.[43] Regardless of this, the quality of care is still not up to standard.

The 2003 South African Demographic Health Survey (SADHS) indicated that the 92% of the women that delivered with the assistance of skilled health workers attended at least one antenatal visit and this percentage was a slight decrease from the utilisation observed in the 1998 SADHS which was over 90% (section 2.2.3.1).[38] The poor quality of services could have contributed to this decrease as it was one of the factors that made some pregnant women continue to self medicate and seek help from traditional healers.[49]

2.2.5 Maternity case record

In 1999, The Department of Health in South Africa noticed that different antenatal facilities used different case records within one province and this led to the development of a standardised maternity case record. The rationale was for it to provide uniform and comprehensive records to overcome the problem of the gaps noticed in the existing maternal documents. It was also to prevent the delay of intervention/action when a woman is in labour. Enquiries into maternal deaths in South Africa revealed such problems as non-utilisation of the partogram[i] and incomplete assessment of the patient – among others by medical personnel. It was also noticed that in some places the partogram was not part of the maternity case record and this resulted in the loss of useful information.[50]

The maternity case record is for use by patients in labour as well as for all pregnant women requiring general admission. The case record is kept at the antenatal facilities and a discharge summary is provided after the delivery to the woman on discharge. Each

[i] A graphic representation of the process of labour. It facilitates demonstration of problems that have/are likely to occur which may go unnoticed in written notes.

person making entries in the case record is expected to write their names in full together with their signatures after each entry.[50]

2.2.6 Prescribing during pregnancy

Careful attention must be paid to the potentially harmful effects of any medicine that is prescribed for a pregnant mother[51] the concern is due to known and unknown effects of the medication on the foetus.[52] The risk of harm caused by medicines exists throughout the entire pregnancy and is not just limited to the first trimester.[51, 53, 54] The pharmacological action as well as the pharmacokinetics of medicines is influenced by the physiological changes occurring in the woman's body during the course of the pregnancy.[51-53, 55-57] These changes include:

> i) increased plasma volume in the later stage of pregnancy resulting in a greater volume of distribution of a number of medicines; ii) changes in the binding of medicines due to alterations in plasma protein; iii) changes in elimination and hepatic metabolism and iv) increased renal elimination as well as effects on the rate and extent of absorption of the medicine due to alterations in gastrointestinal function.[51-57]

Prescribing in pregnancy is currently based on experience and treatments that have shown no sign of causing problems over a long period.[58] Therefore potential risk to the foetus should always be weighed against the advantages that the therapy may have for both the mother and baby.[51, 53, 57, 58] This is also why pregnant women should be discouraged from self medication.[51]

2.2.8 Teratogenicity

2.2.8.1 Introduction

Teratology is the study of production of defects or the abnormal development of the foetus.[52] For an agent to be classified as a human teratogen, it requires:

- Consistent and statistically significant findings by two or more epidemiologic studies of high quality that associate the exposure with the pattern of foetal malformations

- Documented exposure in perinatal development
- Rare environmental exposure associated with a rare defect[52, 59]

As proof that the agent is a teratogen, the agent may show teratogenicity in experimental animals, experimental proof that the agent is a teratogen in its unaltered state and the agent should have an association that is biologically credible.[52, 59, 60]

2.2.8.2 Severity of teratogenic effects

The severity of teratogenic effects of a medicine or any component of the medicine on the developing foetus is believed to be dependent on gestational age at the time of exposure. Possible effects include:

i) miscarriage; ii) congenital malformations; iii) biochemical disturbances and iv) psychomotor, intellectual and behavioural abnormalities.[51]

The severity of these effects may also be influenced by:

i) the dose and duration of therapy; ii) the stage of the pregnancy at which the therapy is taken and iii) the degree of the transfer of the medicine across the placenta.[51, 58]

The highest frequency of morphological defects occurs with exposure between the fourth and fourteenth week of foetal life as it is the period of organogenesis i.e. formation of body organs.[51, 58]

Due to the thalidomide catastrophe in the 1960s as well as limited data on safe use of medicines in pregnancy, pregnant women may be hesitant to take pharmacological medicines as there is a perceived risk to the foetus.[61-63] and may be more inclined to using TCAMs.

2.3 Traditional, Complementary and Alternative Medicines (TCAMs)

2.3.1 Introduction

According to the World Health Organization, traditional medicines (TMs) or complementary and alternative medicines (CAMs) include diverse health practices, approaches, knowledge and beliefs about incorporating plant, animal and / or mineral based medicines, spiritual therapies, manual techniques and exercises applied singly or in combination to maintain well being as well as to treat, diagnose or prevent illness.[17]

The terms “complementary” and “alternative” are used to refer to a broad set of healthcare practices that are not integrated into a country’s dominant healthcare system or that are not a part of the country’s own tradition.[17]

Herbal medicines are of three types, based on the nature of the active metabolites. The first category includes those used in their crude form, the second category those whose active constituents are isolated after processing the plant extracts and the third category is made up of herbal substances for which data on acute and chronic toxicity studies in animals are available.[64]

2.3.2 TCAM accessibility

South Africa’s healthcare system consists of a large under-resourced public sector which offers free primary healthcare to the majority of the population. A significantly smaller and better resourced private sector for those who can afford it exists in parallel with this and in addition a very large traditional health sector exists which is utilised by both public and private sector consumers.[65]

In the early 1990s it was estimated that over 200 000 traditional healers[66, 67] and diviners practised in South Africa in comparison to the 30 000 ‘modern’ doctors at the time. Towards the end of the 1990s round about the year 2000, the estimated number increased to 350 000.[66] In 1997, Mander estimated that 27 million South Africans used

traditional medicines which are generally available at *"amayeza"*[j] and *"muthi"* stores.[68]

Today herbal remedies are also distributed and processed by commercial firms and this commercialisation of medicines has increased their availability and accessibility outside the domain of professional practitioners.[69]

In Africa many people use TCAMs to help meet their primary health care needs and because the therapy is said to be easily accessible.[17, 70] It is also said to be the only affordable source of healthcare in some countries especially for the world's poorest patients.[70] In 2004, the then Minister of Health of South Africa stated that traditional healthcare providers were the first to be consulted by patients in up to 80% of cases especially in the rural areas.[67]

The concurrent use of allopathic (sic) and alternative methods has become popular in many western countries as this is perceived as a more 'holistic' approach to healing.[71]

2.3.3 General TCAM use

The use of TCAMs is rapidly growing in economic importance.[17, 72] The use of herbal products in pregnancy has been studied to different extents in different countries; showing a wide range in its frequency due to cultural and regional differences.[73-76] As in South Africa, in many developing countries including some African countries the use of TCAM includes up to 80% of the population.[17, 77-79]

In Asia and Latin America people continue to use traditional medicines as a result of cultural beliefs and historical circumstances.[17] In China it counts for 30-50% of their healthcare[17, 79] and China has the most documentation worldwide concerning herbal plants.[79] In Zambia, Mali, Nigeria and Ghana high fever resulting from malaria is treated with herbal medicines at home as the 1st line of treatment for 60% of the children.

[j] Translated from the isiXhosa language, "amayeza" means medicines (comprising medicines for physical illness and culturally related afflictions). The Zulu equivalent of "amayeza" is "muthi".

The WHO also estimated that traditional birth attendants assist in the majority of births in several African countries.[17]

A systematic review has shown that most people that use TCAMs do so for chronic and minor self limiting conditions. It is also common practice in cancer, HIV and AIDS patients.[80] Motivation for CAM use in older as well as younger people includes: improving quality of life, preventing illness, controlling chronic conditions, boosting the immune system as well as dealing with side effects of some conventional medicines.[81]

In various South African societies, the use of traditional medicines is deeply woven into the cultural and spiritual beliefs.[71]

TCAM users do not necessarily disregard the effectiveness and use of modern medicine but instead may find TCAM therapies more congruent with their own values and beliefs. Usually they do not discuss this with their doctors.[82, 83] However there are concerns about the safety of TCAMs treatment.[84] There may be undetected benefits and risks for patients on TCAM therapies e.g. interactions with other medicines that are administered concurrently with TCAMs or adverse effects due to the actual TCAM treatment.[82, 84-87]

Women make up the largest proportion of healthcare consumers[76, 82, 88] and are the primary users of medicines.[82, 83, 89] They may also use Complementary or Traditional medicines with insufficient information about the remedies.[82] Women continue using such therapies during pregnancy[90, 91] and lactation despite lack of evidence for safety.[91, 92] Well controlled randomised clinical trials have revealed that the use of herbal products are not necessarily free of undesirable side effects.[64, 83]

2.3.4 Regulatory issues of TCAMs

2.3.4.1 Introduction

The issues regarding the safety of herbal products are confounded by an unregulated growing market where there is a lack of effective quality control.[64, 71] Quality control of herbal medicines has an impact on their safety and efficacy.[71] The main aspect found in many regulatory systems with respect to TCAM is the lack of strict guidelines

on their assessment of efficacy and safety, safety monitoring and knowledge on the actual TCAMs.[71] Although some TCAMs may have product licences,[k] it does not mean that they have undergone stringent testing required to obtain full marketing authorisation but instead have relied on evidence from long standing use.[93]

2.3.4.2 Regulatory situation of TCAMs in South Africa

In South Africa, the Health Act of 1974 banned traditional healers and legislation such as the Medicines and Regulated Substances Control Act (Act 101 of 1965) set regulations for African traditional medicines which were not enforced.[71, 94] TMs in South Africa have been categorised separately from CAMs to enable their development.[95, 96]

After the Apartheid era, the South African Government recognised the relevance and importance of traditional healers within the healthcare system.[95] South Africa's national drug policy (NDP) was first published in 1996 and has not subsequently been revised. The national programme on TCAMs was issued in 2002.[97] In 2001, the Medicines Control Council of South Africa (MCC) established an expert committee for African TMs to address issues of their registration, regulation and control.[95, 97]. In 2003, the Minister of Health approved the establishment of a virtual reference centre for TMs and it was called it National Reference Centre for African Traditional Medicines (NRCATM) and is a collaborative effort between the Medical Research Council in South Africa (MRC), the Department of Health, Council for Scientific Industrial Research (CSIR) as well as traditional practitioners themselves.[67, 95]

The Traditional Health Practitioners Act (Act 22 of 2007) provides a regulatory framework to ensure the efficacy, safety and quality of the services traditional healers provide as well as their registration and training.[98] However it has not yet been fully implemented.

Despite this there is still a lack of strict regulations and guidelines with respect to TCAMs – particularly herbal remedies as documented by Steinman and Jobson. They

[k] In South Africa, medicines are "registered"

also document the failure of those regulatory bodies[1] of South Africa that should be protecting the public from possible consequences including unnecessary deaths.[99]

2.4 TCAM use by pregnant women

2.4.1 Introduction

The use of medicines in pregnancy has been monitored since the catastrophe with thalidomide in the 1960s.[63, 83, 100, 101] Herbal medicines have been used during pregnancy and many users take for granted that being of plant origin; they are harmless.[63, 75, 100, 102] The inclusion of herbal medicines within the definition of CAM may also give the impression that they can be used without precaution.[100] Some plants may well be beneficial, but some are highly poisonous and many others have toxic constituents.[92, 100, 103, 104]

A study in Taiwan shows that the use of traditional medicines or CAMs by pregnant women is gaining in popularity.[105] Other studies in Taiwan have shown that pregnant women with high maternal age, high education level and a positive knowledge and attitude towards traditional medicines or CAM are more likely to use them.[105] In a number of sub-Saharan countries in Africa, namely Nigeria, Ghana, Tanzania, Sierra Leone and Zimbabwe; some information regarding herbal remedies used during pregnancy has been documented.[76, 86] However, in South Africa few studies have focused on pregnancy and medicine related problems, especially where TCAMs have been used.[79, 103, 106]

In Argentina, the reproductive health of women – particularly the practices and care during conception and pregnancy is an important issue for rural maternal-baby health programmes and policies.[107] In order to achieve successful maternal baby health strategies, the women's treatment seeking behaviour and choice, traditional knowledge, beliefs and practices relating to their reproductive health are explored.[107, 108]

[1] Regulatory bodies include the Medicines Control Council (MCC), the South African Pharmacy Council (SAPC), the Public Protector and the Advertising Standards Authority of South Africa (ASA).

2.4.2 Condition related factors

Many pregnant women initiate the use of herbal products and alternative therapies without the guidance or advice of a healthcare professional.[83, 92, 103, 109]

African views of health and absence of illness reflect a belief in spiritual care, social care, community care, self-care and medical care as well as the past and the present.[110] Steenkamp [8] and Chalmers [108] state that traditional remedies are elements of the spiritual life and culture of the African people. Ngubane also highlights that in African culture, infants are considered to be particularly susceptible to harm from evil spirits. Ngubane also states how certain medicines are taken as a protective measure against bewitching or to avoid repetition of illness or misfortune as well as to ensure infants' survival.[111]

In Southern Africa, illness may be attributed to displeasure of the ancestors.[110, 112, 113] Chalmers states that supernatural forces in different forms e.g. witches and wizards are also believed to cause illness. The ancestors are said to not only cause illness but prevent it as well. She further states that in order for the ancestors to prevent illness, they must be acknowledged and shown respect through certain rituals.[110]

In Africa, both western medicine and spiritual appeasement are regarded as valuable in prevention and management of illness. Since it is believed that infants are susceptible to harm from evil spirits, acknowledgment of pregnancy is denied for as long as possible by a woman as far as disclosing it to others.[110] Women are also hesitant to disclose early pregnancy in many traditional societies as a fear of witchcraft is common and they believe that the knowledge of their conception could be used by others to harm their unborn babies.[110, 114]

Behavioural taboos, dietary limitations and the use of herbal medications have been traditionally imposed to prevent pregnancy complications as well as complications during labour.[110]

Peltzer *et.al.*[87] spoke to traditional herbalists who revealed that pregnant women consulted them during their pregnancies for the following:

- lack of foetal movement
- being past the due date of delivery
- problems with foetal position and false labour
- morning sickness, abdominal pain , constipation, heartburn
- *umoya omdaka* also referred to as the uterus being “full of wind” or “dirty”
- sexually transmitted infections (STIs)
- high blood pressure

There are traditional herbal remedies used and given to pregnant women. Treatment in the early stages of pregnancy is believed to prevent miscarriage and to ensure proper growth of the foetus and stability of the woman’s health.[29, 92] Treatment at the later stages of pregnancy serves to ensure safe delivery with no complications after delivery.[29]

In Nigeria, women take native herbs and gin during pregnancy to ensure proper bleeding after the birth of the baby that also allows the proper cleansing of the womb.[29] The treatment is administered in various forms, such as burnt herbs that are blown into the pregnant woman’s cervix by their female relatives or taken orally on a monthly basis to prevent haemorrhage, obstructed labour or retention of the placenta.[29]

A qualitative study carried out in Cape Town found that the majority of their isiXhosa-speaking participants follow indigenous health practices for both themselves and their babies because of the perceived need to “strengthen” the womb against witchcraft and to prevent childhood illnesses. They also followed indigenous practices to treat symptoms that the biosciences cannot treat. In pregnancy, herbs and minerals are often used as a tonic to clean the womb, to ease delivery, to induce labour, and to protect the child from evil and have a healthy child, as well as for pain, sickness or discomfort.[106] This is said to give the pregnant women a sense of security.[106, 115]

South African women use traditional herbal remedies as antenatal medicines or to induce labour/expel the placenta/prevent post-partum haemorrhage.[115] The most common herbal remedies used are known as "*imbelikisane*"[m], "*inembe*" or "*isihlambezo*[n]" and their herbal ingredients vary. A few of these plants used in these remedies have been examined for pharmacological activity. Both Zulu and Xhosa women take 'isihlambezo' orally during the last trimester of pregnancy to ensure healthy foetal growth and the dose is increased towards the end of the pregnancy to ensure an easy and rapid delivery.[115].

In former Transkei, a decoction of the roots of *Agapanthus africanus* and *typha sp* is taken from the third trimester to ensure an easy childbirth, to ensure that the child does not develop bowel trouble; and also to ensure that the placenta will be delivered without difficulty. Mpondo women drink this from the fourth or fifth month of pregnancy while the Xhosa[o] take it in the last two months of pregnancy for the same reasons stated above. [115]

2.4.3 Perceived benefits and risks of taking TCAMs during pregnancy

Remedies taken by pregnant women or women wanting to become pregnant have unknown consequences on foetal growth and development and this raises concerns.[63, 76, 82, 92, 104] A review by Ernst concludes that herbal products have been associated with risks to pregnant women and their babies and that few trials have been performed to document the potential benefits of herbal products for pregnant women.[116] Few studies have addressed the use of TCAM during pregnancy and even fewer have looked at pregnancy and foetal outcomes particularly in Africa.[91, 115] Risk factors of herbal medicines used in pregnancy have been found to be diverse.[63, 92, 93]

In a study done at King Edward VIII Hospital in Durban, it was shown that taking of certain traditional herbal medicines during pregnancy seemed to be associated with foetal

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[m] This is described below in 2.4.4.2.a

[n] This is described below in 2.4.4.2.c

[o] The Mpondo (or Amampondo) and Xhosa are subgroups of the Xhosa speaking people. (Xhosa speaking people are divided into sub-groups one of the sub-groups being Xhosa as well). In this document, Xhosa refers to the sub-group and not the Xhosa speaking group as a whole.

distress which was indicated by meconium in the amniotic fluid and meconium staining of the placenta. Increased caesarean section rates in the group of women that had used traditional herbal medication appeared to be associated.[117]

Meconium is a dark sticky material normally present in the intestine of a foetus at birth and is passed after birth. Its passing before birth (into the amniotic fluid) can be a sign that the foetus is not well or is becoming excessively fatigued (foetal distress).[118]

The presence of meconium discharge is of clinical importance because its presence has been associated with foetal distress and poor neonatal outcome.[99, 119] Meconium discharge and foetal distress are not always linked and it may occur in the absence of distress, particularly in post term pregnancies.[118, 119] Its presence in amniotic fluid has been associated with increased neonatal morbidity and mortality, including brain damage. Documenting the presence of meconium in the amniotic fluid or staining of the placenta is therefore important.[119]

Depending on how long the meconium has been present in the amniotic fluid, it can stain the placenta, giving it a yellow to green colour. A normal placenta has a red-grey or pink colour.

Benirschke *et al.* state that *"ideally, all placentas would have an examination by a knowledgeable pathologist, but this is unlikely to happen routinely. Those that are studied, must be adequately sampled for histology"*.[118]

2.4.4 Some TCAMs used during pregnancy

Many plant species are used to treat more than one gynaecological complaint and those remedies that are used during pregnancy must be safe.[8, 120] The remedies must not increase the risk of spontaneous abortion, birth defects or any other adverse effects.[121]

2.4.4.1 Herbal medicines used in developed countries for pregnancy related conditions

The most common herbal remedies used during pregnancy are Ginger (*Zingiber officinale*), Raspberry Leaf (*Rubus idaeus*), Chamomile (*Matricaria chamomilla*) and Peppermint (*Mentha pipereta*).[63, 83, 103, 123] Other remedies used that are mentioned

in this section include St John's Wort, Blue Cohosh, Nettle, Black Cohosh, Castor Oil and Evening Primrose.

a) Ginger (*Zingiber officinale*): Ginger is a spice obtained from dried rhizomes of *Zingiber officinale.*[124] Ginger has been studied in the context of pregnancy in a clinical setting[37, 63] although the studies involved small sample sizes.[63] Ginger is commonly used to treat morning sickness in pregnancy at a dose not exceeding 1g per day. [36, 63, 79, 121, 125, 126-129] It is said to have been used for thousands of years in Asian and Chinese medicine.[37]

Apparently ginger acts directly on the gastrointestinal tract by increasing the tone and peristalsis in the gastrointestinal tract through anticholinergic and antiserotonin actions.[63, 121]

In some literature ginger is contra-indicated for use by pregnant women because of this although there is no evidence that it acts as an abortifacient, despite suggestions that this may be an effect in high doses.[63, 121, 126]

Women suffering from vomiting and nausea may find it difficult to swallow ginger in its capsule form and therefore may take it as a tea.[73-75, 83, 127]

b) Peppermint (*Mentha pipereta*): The leaves of this herb are used.[83] Peppermint still has not been clinically tested for vomiting and nausea induced by pregnancy.[37, 108] Peppermint has been used for many years [26] for the treatment of nausea and vomiting in pregnant people.[37, 63, 75, 130]

c) Raspberry leaf (*Rubus idaeus*): The leaves of this plant are used to formulate remedies for use in pregnancy.[83, 131] Raspberry leaf is taken in the form of a tea and serves to strengthen the uterus.[59, 93, 121, 132, 133] It is also sometimes taken in tablet or tincture form.[81] It is said to be only safe to use in the last trimester of pregnancy.[63, 132, 133] It is believed to also prevent miscarriage as well as to aid in labour by making it easier.[63, 83, 108, 127, 133] It is also believed to decrease nausea in pregnancy.[108]

Its mode of action is unclear.[127] Human data show it to have either spasmodic or stimulatory effects on the uterus and this could be dose dependent.[75, 84, 127, 130]

d) Chamomile (*Matricaria chamomilla*): For chamomile, the leaves are used and it is taken in the form of a tea[83] to aid in treating nausea.[102]

e) St. John's wort (*Hypericum perforatum*): St. John's Wort is an herbal remedy that is used to treat mild to moderate depression, a condition common in women in their child-bearing age.[74-76, 91, 124, 127] Exposure to St. John's Wort into pregnancy is high due to the significant proportion of unplanned pregnancies.[91] It is used during pregnancy as an antidepressant and like all other medicines should be avoided during the 1st trimester although its contraindication during pregnancy has not yet been evaluated extensively.[124, 132]. St John's Wort has several interactions with conventional medicines including some protease inhibitors used as part of antiretroviral therapy.[134-137]

f) Blue Cohosh (*Caolophyllum thalictroides*): Blue cohosh has been used to induce labour in pregnancy.[108, 127, 132, 138] However, some of its constituents are teratogenic and its use in pregnancy in not recommended.[131, 139, 140]

Its mode of action involves the induction of labour contractions.[127]

g) Nettle: When nettle is used during pregnancy, it is believed to decrease the risk of excess bleeding during child birth and in the prevention of anaemia.[132] Nettle is often used outside of pregnancy.

h) Black Cohosh (*Cimicifuga racemosa*): Black cohosh is believed to promote labour[108, 139] but there are reports of idiosyncratic liver failure leading to death and/or requiring liver transplant. [141]

i) Castor Oil (*Ricinus communis*): Castor oil is used in pregnancy to induce labour[127, 139] and to help initiate cervical ripening.[131] It is given orally as a 60ml dose hourly and up to five doses are given.[139]

In pregnancy, it is said to induce labour by increasing prostaglandin production. The prostaglandins produced result in stimulation of uterine activity.[142]

j) Evening Primrose Oil (*Oenothera biennis*): Evening Primrose oil is extracted from the seed of the plant and is used during pregnancy as a source of essential fatty acids. It is also believed to stimulate cervical ripening.[127, 139] Its safety and efficacy in human pregnancy has not been documented.[139]

2.4.4.2 Some TCAMs used in South Africa for pregnancy related conditions

In 1992, a review by Veale *et.al* revealed that 57 plant species were used during pregnancy and childbirth by South African women.[120] In this section *Isihlambezo, Imbelikesane, umchamo wemfene, Agapanthus africanus* and *Typha sp* are reviewed.

a) *Isihlambezo*: Little is documented about it and its use.[143] This is a tonic drunk daily from mid pregnancy until and including delivery; it is also prescribed as a vaginal douche during pregnancy.[100, 138] It refers to a mixture of herbal mixtures taken by Zulu and Xhosa women.[86, 120, 139, 143] It is made up of many different components/plants and they may be regional and individual variation with regard to its ingredients.[86, 120]

Rhoicissus tridentata subsp *cuneifolia,* which is in the Vitaceae family, is one of the most frequently used species in *isihlambezo.*[143]

b) *Agapanthus africanus* and *typha sp:* A decoction of the root of *Agapanthus africanus* and *typha sp* is taken from the third trimester to ensure an easy childbirth, to ensure that the child does not develop bowel trouble and also to ensure that the placenta will be delivered without difficulty.[144]

c) *Imbelikisane*: Imbelikisane is usually given to women in the last month of pregnancy to ease labour.[106]

d) "*umchamo wemfene*": It is taken by pregnant women to induce labour as well as a problem free delivery.[145]

2.5 Some international use of recorded CAMs use during pregnancy

Table B.9. (Appendix B) is a summary of CAMs that are used in pregnancy internationally and it also gives reasons why they should be used with caution and Table

B.10 (Appendix B) is a summary of CAMs used internationally during pregnancy and why they should be completely avoided.

2.6 TCAM training and education

2.6.1 Introduction

Many conventional health practitioners discourage the use of herbal medicines especially in pregnancy due to their lack of knowledge or documented data. [147]

2.6.2 Globally

In China, TM institutions and colleges have been established and the education is integrated with every medical school containing a traditional medicine department and vice versa.[79]

In Indonesia, more than 350 monographs for herbal medicines have been produced and application of good manufacturing practice (GMP) standards has been implemented since 1991.[79]

In India, traditional medicine systems are recognised by the government of India through organs of state such as the Central Council of Homeopathy and the Central Council of Indian Medicine. These institutions prescribe the minimum standards of education in TM and advise government in matters relating to qualifications in TM, maintenance of Indian medicine registers, professional conduct standards as well as development of code of ethics for TM practitioners. The Department of Indian Systems of Medicine and Homeopathy is primarily responsible for TM education among other things.[79]

Developed countries such as Canada, France, Germany and England have regulatory systems that acknowledge the benefits of herbal medicine. In Germany, as part of their standard training, pharmacists and physicians are educated about the safety and efficacy of herbal medicines and the physicians even prescribe herbs to some of their patients.[132]

2.6.3 Training and education in South Africa

2.6.3.1 Introduction

In South Africa, there are some herbalism schools but they are either not accredited or recognised. Currently there is no formal training in TMs (for example incorporating registered traditional health practitioners as teachers) at any of the South African training institutions although some attempts have been made by some institutions to collaborate with traditional health practitioners for the development of a suitable curriculum.[95]

The Department of Education together with tertiary academic institutions can set up training programmes in TM. Some universities have tried to collaborate with traditional health practitioners to develop courses in this field but due to a lack of coordination and funding a lot of the projects have been discontinued.[95]

2.6.3.2 Training and education in pharmacy institutions

There is no in-depth training in TMs in most South African Pharmacy schools. Herbal medicinal products can be purchased from community pharmacies without any interaction between the patient/customer and the pharmacist/assistant occurring. If consultation does occur, the pharmacist/assistant may not have sufficient knowledge to feel confident about being able to provide advice/information on herbal medicinal products.[95]

It is necessary for pharmacists to be aware of the drug interactions, side effects, possible uses, contraindications as well as the dosing of herbal medicines especially because of their increasing use.[147, 148]

2.7 Conclusion

The literature related to the topic of this research reveals various factors that influence pregnant women's health behaviour and also highlights the knowledge gap that exists with respect to CAMs and pharmacists. It provides a basis for understanding and exploring the factors that apply to this setting.

CHAPTER THREE

METHODOLOGY

3.0 Introduction

In this chapter, the reasons for adopting a mixed methods methodology and how qualitative and quantitative concepts were integrated in understanding the issues being researched are explained and justified.

3.1 Setting in which the study took place

This study was carried out in Grahamstown in the Eastern Cape province of South Africa. The province is one of the most disadvantaged of the nine provinces in South Africa.[149] It includes the former Transkei and Ciskei apartheid homelands.[149, 150] In 2004 it was estimated to have a population of 6.4 million.[151] Figure 3.1 is a map showing the nine provinces of South Africa and indicating the location of the Eastern Cape Province, where the study was carried out.

Figure 3.1: Nine provinces of South Africa[152]

The Eastern Cape is divided into six regions – Cacadu being the one in which Grahamstown is situated. Cacadu is in the western side of the Eastern Cape and incorporates Grahamstown, Alicedale and Riebeek East.[149] Grahamstown is in the Makana Municipality. Figure 3.2 shows these areas.

Figure 3.2: Cacadu[153]

3.1.1 Practices in Grahamstown

The following information was used in designing the study was obtained in informal talks with a few women who lived in the township and who used the public sector facilities in Grahamstown. They were seen at the site where potential participants were to be recruited.

3.1.2 Beliefs and behaviour

Behavioural taboos and dietary limitations are often imposed[110] on pregnant women to prevent complications during pregnancy. According to the women, in Xhosa culture a pregnant woman is not allowed to eat eggs and should only eat freshly prepared food e.g. they are not allowed to eat any leftover food from the previous day as they say it is not good for the baby. They are also not allowed to walk outside in the early hours of the

morning as they believe that as ‘evil spirits’ come out at night, and are still about in the early hours – and pregnant women are vulnerable to the “evil spirits” latching onto them. Therefore if a woman is pregnant she can only walk outside later when other people that are not pregnant have walked on the streets and the “evil spirits” have disappeared.

Cultural beliefs and practices are important to most of the people staying in the township although they do not disregard western/modern medicine practices. Many of them make use of both.[110] A woman’s antenatal record from the antenatal facility she attended is required when she presents at the District Hospital during labour. Therefore some of the women will go for at least one check up so that they have the antenatal record; but will not necessarily go for the ideal number of antenatal checkups at the clinics especially if they have no complications with their pregnancies.

Many of the women visit traditional health practitioners when there is a problem during the pregnancy. If there are no complications, it seems they are less likely to do so. Some of the problems they encounter and consult the practitioners for are believed to be caused by evil spirits. It is believed that if the woman goes into labour without having fixed this problem, either she, the baby or both will not make it. The women then visit traditional practitioners to be “cleansed” of the evil. Different traditional health practitioners will use different remedies/medicines to “cleanse” the women in whichever way the healers see appropriate. Some will give the women something to “rub” on the skin, or something to “drink” and some will give both to achieve the cleansing. The practitioners do not usually tell the women the composition of the mixtures, and the women tend to just use it as directed.

3.1.3 Statement of the problem

In Grahamstown, a few cases were encountered in which it was considered by healthcare staff that the use of traditional medicines during pregnancy was associated with meconium staining of the placenta.

Informal talks with a doctor and midwives working at the maternity ward in the public sector division of Settler’s Hospital in Grahamstown helped in the development of the research instruments.

They indicated that they had encountered and recorded several cases in which it was believed that adverse pregnancy outcomes had occurred following the use of traditional medicines during pregnancy. The midwives believed that cases in which meconium has been passed before birth or during labour or where there is meconium staining of the placenta indicated that the women may have taken traditional/herbal medicines during the pregnancy.

The midwives also stated that some of the women that gave birth using their facilities and who admitted to taking traditional medicines commonly drank a mixture called "*umchamo wemfene*"[p]. The midwives stated that the intensity of the effects of the mixture seemed to be determined by the amount that these women had ingested i.e. that it was dose dependent and led to e.g. "violent" labour, foetal distress and in some cases the neonate being unwell.

The midwives reported that most of the women that took traditional medicines during their pregnancy either do not reveal this or deny it. They therefore cannot reliably document the use of traditional medicines and this is of concern to the doctors and nurses because:

- Most of the women do not know the potential effects of the traditional medicines and mixtures they are given but continue to use them regardless
- Some of the traditional medicines that they take could be adulterated with harmful components which cause adverse effects (i.e. it's not the actual herbal ingredients causing the untoward effects)
- Since they deny it and do not know or say exactly what they are taking, the use of TMs cannot be further investigated on a larger scale

3.2 Methodology

Creswell and Plano Clark [154] define "methodology" as a framework that relates to the entire process of research; and they define "methods" as techniques of data collection and

[p] Literally translated to mean "baboon's urine", it is used as a remedy given to pregnant women

analysis e.g. standardised quantitative instruments and qualitative theme analysis of text data. They also use the term “research design” to refer to the plan of action that links the philosophical assumptions of the research to specific methods. The mixed methods approach is an example of a research design.

This research has adopted these elements of Creswell and Plano Clark’s interpretation and definitions.

3.3 Sampling

3.3.1 Sampling Procedure

The sampling frame for this study was pregnant women presenting at antenatal clinic sections of Joza Clinic (a primary health care clinic) and Settler’s Day Hospital. To answer a research question a researcher decides which research sites and which people best provide information, determine the numbers of participants that will be needed to provide appropriate data and puts a sampling procedure in place.[154, 155] Sampling is the process of selecting the source of observations.[156, 157]

In mixed methods research, the researcher must make sampling scheme and sample size considerations for both the qualitative and quantitative phases in determining the study design.[157, 158]

This study sought to determine why some pregnant women in Grahamstown chose to take TCAMs during the course of their pregnancy as well as to document whether any adverse pregnancy outcomes occurred following the use of these medicines. Purposive sampling was therefore used to select the pregnant women.

Purposive sampling is a non-probability sampling technique in which the researcher intentionally selects participants who have experience in the concept being explored[154], in this case pregnant women who have taken any TCAMs at any stage of their pregnancy.

Babbie *et al.* [156] define purposive sampling as studying a small subset of a larger population in which many members are easily identifiable but interviewing all of them would be impossible.

The researcher identified a small number of pregnant women who would provide in-depth information about their individual beliefs, knowledge and perceptions – as is done in qualitative research.[154]

To select community pharmacists in Grahamstown, convenience sampling was used. This was to obtain perspectives on these pharmacists' attitudes, beliefs and perceptions about the study question. Convenience sampling is defined by Collins *et al.*[157] as choosing individuals who are conveniently available and willing to participate in a study. Four community pharmacists were enrolled into the study.

3.3.2 Inclusion criteria

Eligibility of prospective participants for the study was determined using the following criteria:

1. Pregnant women in the last month of pregnancy

- who had had a normal uncomplicated pregnancy to the date of recruitment
- who had taken traditional or complementary medicines at any stage of pregnancy prior to the date of recruitment or
- who were currently taking traditional or complementary medicines
- who were able to provide informed consent and communicate in English
- who were legally adults (18 years of age and above)

2. Pharmacists

- Practising in a privately owned community pharmacy in Grahamstown

3.3.3 Exclusion criteria

Individuals were excluded for the following reasons:

- Not meeting the inclusion criterion

3.4 Different worldviews

Creswell and Plano Clark[154] state that paradigms also known as worldviews are a way of life deeply rooted by our culture, personal experiences and history and these may change and be shaped by new experiences and thoughts.

Morgan[159] states that paradigms are:

- Model examples which rely on specific exemplars of best or typical solutions to problems
- Shared beliefs in a research field
- Epistemological stances - which Creswell and Plano Clark further expand to say that they take stances on how we gain knowledge (epistemology), the process of research (methodology), the role values play in research (axiology) and representation of different versions of the nature of reality (ontology)[154, 159]
- Worldviews - Creswell and Plano Clark categorise worldviews into four:

    i) Post positivism (quantitative approach); ii) constructivism (qualitative approach); iii) advocacy and participatory (more qualitative than quantitative) and iv) pragmatism (associated with mixed methods research)

Paradigms aid in understanding phenomena in human and social science.[160] Two widely discussed paradigms are qualitative and quantitative paradigms.[156, 160]

Qualitative study is defined by Creswell[160] as:

> …an inquiry process of understanding a social or human problem, based on building a complex, holistic picture, formed with words, reporting detailed views of informants and conducted in a natural setting. (emphasis added)

The goal is to describe and understand rather than to explain human behaviour[156] and it is different to quantitative research in that it tends to focus on the research process more than the research outcome.[156, 161] Qualitative studies use, amongst others, semi-

structured interviews, the use of personal documents to build a story (e.g. medical records) and qualitative analytical methods (e.g. thematic analysis).[156]

With thematic analysis categories of information emerge from the informants leading to patterns or theories that help explain a phenomenon.[160] The investigator may report his/her values as well as the value nature of the information gathered from the field[160] and the investigator is considered the primary instrument.[156, 161] Qualitative techniques may provide deeper insights, explanations and ideas with respect to the research topic being explored[161] than can be found with quantitative methods alone.

Teddlie and Tashakkori also state that qualitative research is exploratory and involves theory generation.[162]

Quantitative study on the other hand is defined by Creswell [160] as:

> …an inquiry into a social or human problem, based on testing a theory composed of variables, measured with numbers and analysed with statistical procedures in order to determine whether the predictive generalisations of the theory hold true. (emphasis added)

In this kind of study investigators' values are kept out of the study and 'facts' are reported from the evidence gathered in the study.[160] In quantitative research concepts, the variables and hypothesis are chosen before the study and remain fixed throughout.[160, 163] The aim is to develop generalisations that contribute to the theory and enable one to better predict, explain and understand some phenomenon.[160]

Pragmatism (associated with mixed methods research) has multiple aspects and is orientated to practice and 'what works'. Its focus is on the research outcome of the research question asked rather than the methods and the problem under study is informed by multiple methods of data collection.[154]

Tashakkori and Teddlie suggest that pragmatism is one of the paradigms that provides a foundation for mixed methods research and most of the authors cited in their handbook mention it.[164]

3.4.1 Choice of study method

To answer my research questions, a mixed methods approach was used. It is said that this approach can provide greater understanding of a health issue than one research approach on its own.[166-169] Using the mixed methods approach may gather qualitative and quantitative data separately or simultaneously.[170, 171]

Wheeldon [170] notes that:

Justification for using [mixed methods] includes the consistency of findings obtained through different instruments being tested . . . [which] binds and clarifies the results of one method with another and shows how the results from one method shape subsequent methods or research decisions.

He also notes that researchers have usefully shown how to better explain quantitative findings using qualitative data and that additional approaches are needed to meaningfully embed and bring to light qualitative data within quantitative designs.

3.4.1 Triangulation Design: Convergence Model

A triangulation (convergence) mixed methods design was adopted for this research.[154] (see Figure 3.3) Different but complementary data were collected on the same topic.[154] Qualitative and quantitative data were collected simultaneously to incorporate the strengths of both, and to validate the results.[154, 165, 170]

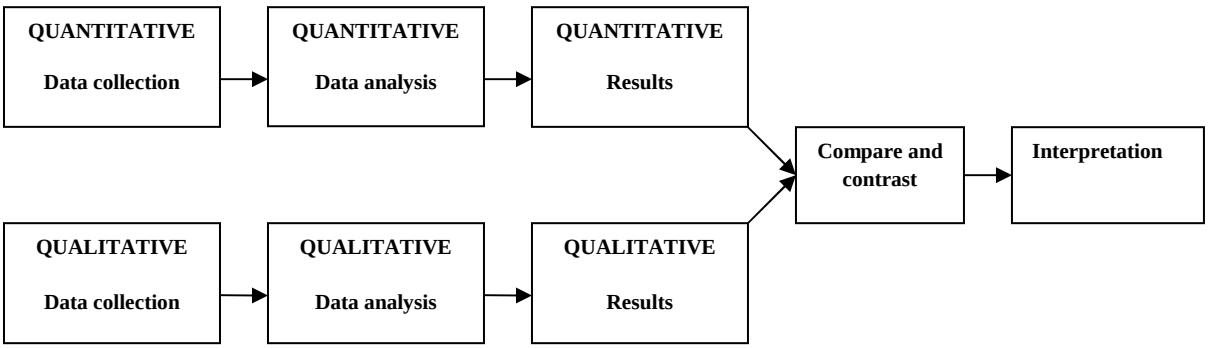

Figure 3.3: Triangulation Design - Convergence Model[154]

In this study, the quantitative component was submerged within a predominantly qualitative study design.[154] To assess knowledge of community pharmacists in Grahamstown about the use of TCAM during pregnancy, the quantitative instruments used were close-ended questions contained in a structured questionnaire in which the respondents i.e. the pharmacists were asked to select an answer from a list[156] (questionnaire attached in Appendix H). To measure the frequency of adverse events associated with the use of TCAMs in the women or their pregnancy outcomes, the quantitative instrument was a pregnancy outcomes data sheet (attached in Appendix J).

The community pharmacists' perceptions, attitudes and knowledge on TCAMs use during pregnancy was assessed using open-ended questions within the structured questionnaire mentioned above. This enabled the pharmacists to provide their own comments about the questions. In determining why the participants chose to use TCAMs, semi-structured interviews enabled the participants to describe and explain their experiences in their own words. Document analysis of the participants' medical records provided qualitative data on possible contributions to the participants' pregnancy outcomes.

Figure 3.4 provides an outline of the research design in this study.

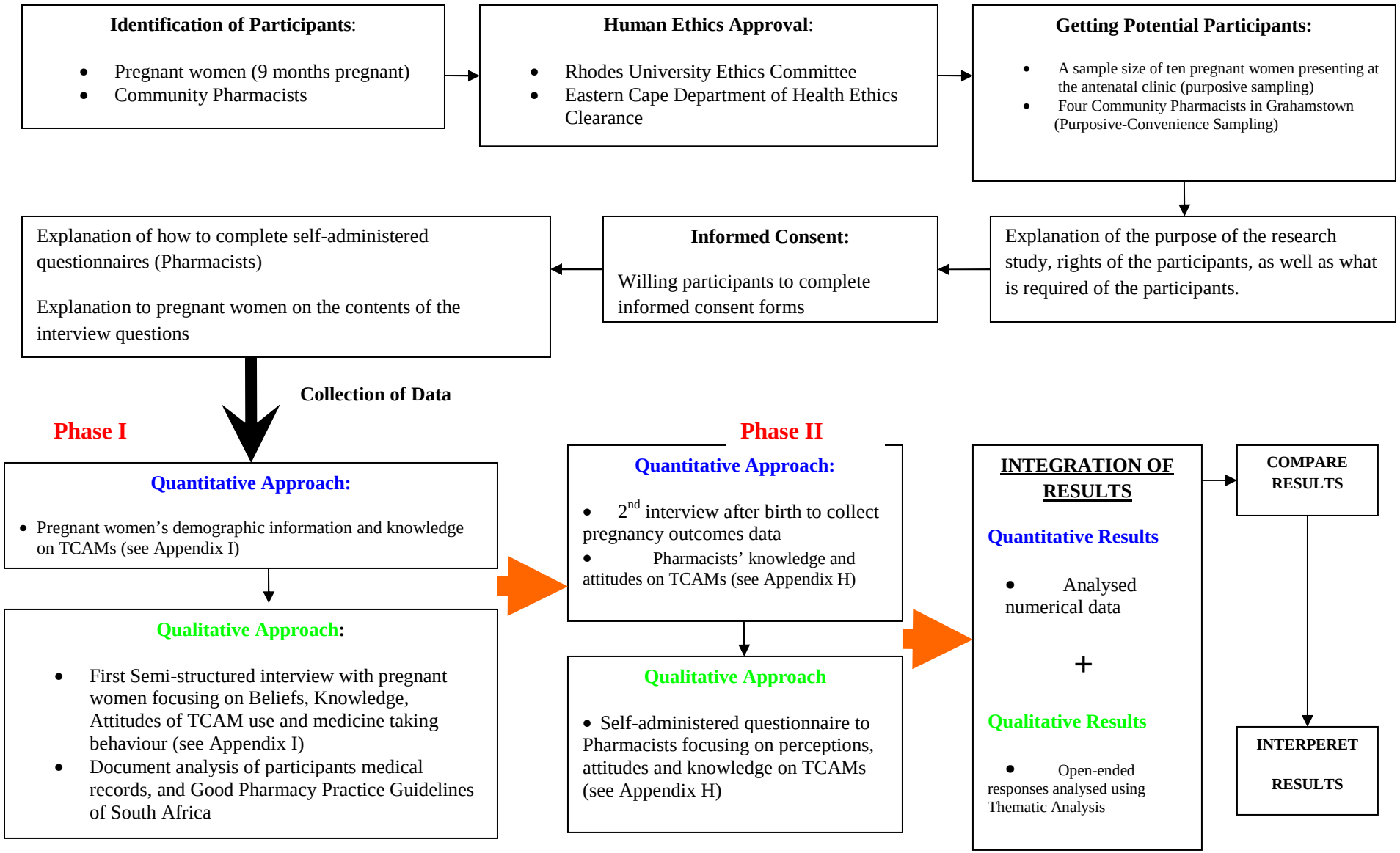

Figure 3.4: Study Design

3.5 Ethics

3.5.1 Approval

Researchers require permission to collect data from individuals and sites. Creswell and Plano Clark [154] state that permission can be granted from:

> i) the participants or people providing the data and their representatives; ii) campus institutional review boards and iii) individuals who are in charge of sites

Prior to commencing the study, ethics clearance was granted by the Rhodes University's Faculty of Pharmacy's Ethics Committee and by the Eastern Cape Department of Health (Appendices C and D) This was to ensure that the rights of the individuals and institutions participating in the study were considered as well as to assess the potential harm and risk the research may have had, prior to commencing it.[154]

The letters requesting permission were presented to the persons in charge of the hospital and primary health care clinics respectively. This was to obtain their authorisation to carry out the recruitment on their premises as well as to be allowed to look at the participants' medical records (in addition to the participants' individual consents). This process also enabled staff at the antenatal facilities to be made aware of the researcher's legitimacy and acceptance of her visits to the clinics.

3.5.2 Confidentiality

To protect the participants' rights to confidentiality, it is essential to ensure that their identities are not made public.[156] In this study, participants were assigned code numbers at enrolment and these codes were used to identify the participants throughout the study.

Written information was made available in English to all participants. The researcher ensured that information and data were stored in a secure manner[172] in the researcher's personal computer which was password protected. The confidential information was not accessible to anyone else.

3.5.3 Non-maleficence

Beaucamp and Childress state that “non-maleficence” is restricted to the non infliction of harm.[173] This study did not cause any of the participants any harm as far as is known.

3.5.4 Informed consent

A key element of an ethically conducted research study is the informed consent process.[163, 174, 175] Participants may say that they were not aware of certain components of the study including being a participant even after having signed the informed consent. Shafiq and Malhotra[174] state that this could happen because:

> i) either the investigator failed to communicate the information properly to the participant or ii) made no attempt to communicate

To avoid this, prior to obtaining written consent, all participants were made aware that as participation was voluntary they had the right to withdraw from the study at any point without having to give reasons. They were also made aware of the confidentiality and anonymity of all their personal information.[172] Particular attention was paid to ensuring no language misunderstandings occurred.

3.6 Data Collection Instruments

3.6.1 Patient Demographics

Participant’s demographic data were collected. The data included employment details, education level, participant’s age as well as the estimated date of delivery.

3.6.2 Semi-structured Interviews

One on one face-to-face interviews with the participants were conducted. These interviews enabled the researcher to clarify the participants’ answers as well as probe for more detailed information on their experiences of taking TCAMs during pregnancy. The interviews also enabled the researcher to collect in-depth data on the pregnant women’s behaviour, knowledge, beliefs and attitudes with respect to TCAMs and pregnancy.

The interviews were audio taped and transcribed.

3.6.3 Structured instruments

A follow up interview was carried out to collect quantitative data on the pregnancy outcomes (mothers and babies).

A questionnaire was designed for community pharmacists containing both closed and open ended questions (Appendix H). To avoid being ambiguous and to be precise, it contained short questions. This was also because community pharmacists' are busy professionals and they may not easily have time available for an interview. The questionnaire was divided into three main categories namely, general, knowledge and attitudes. Each close-ended question had the option for the pharmacists to further expand as to why they chose the answer from the close-ended question in their own words. To assess their knowledge and obtain general TCAM data they had to choose whether they thought a given set of statements was correct, incorrect or they did not know and with some they just had to choose a yes or a no response. To assess their attitudes on TCAM use, each item was rated on a 5-part Likert scale of 1= strongly disagree, 2= disagree, 3= neutral, 4= agree and 5= strongly agree.

3.6.4 Document analysis

Most patients that use public health sector facilities in South Africa are provided with a booklet that contains their detailed medical history records. This booklet is called a *health passport.* Pregnant women using public sector antenatal clinics have all their antenatal visits, scans, tests and results, as well as pregnancy progress update reports documented on separate forms. This information is presented at the facility when she goes into labour.

In this study the health passport and antenatal records were used to collect data on the medicines the participants took during the course of their current pregnancies; it was also used to verify some of the data that was collected during the interviews as well as supplement data from the in-depth interviews.

Document analysis of the Good Pharmacy Practice (GPP) Guidelines of South Africa was done in the context of complementary medicines and pregnancy.

3.6.5 Piloting the data collection tools

3.6.5.1 Introduction

Pretesting or piloting non-validated data collecting tools is essential when conducting research[156] to ensure that the participants would interpret and understood the questions as intended by the researcher. It also helped prevent asking questions that were intrusive or sensitive to the participants in an offensive way.

Piloting the tools enabled the investigator to identify problems such as comprehension of the interview questions, gauging/timing the length of the interviews as well as sequencing the collection of data.

3.6.5.2 Semi – structured interview

Pre-testing the semi-structured interview (See Appendix I) for the pregnant women was carried out with two women. One woman was in the last trimester of her pregnancy (9 months) and the other had given birth two weeks prior to the interview. Both women had taken traditional medicines during their pregnancies and the pregnant woman was still using them.

Following the interviews, the women were asked how they experienced the interview process and questions; and were also asked how the questions could be improved. The researcher made minor changes on the phrasing of some of the questions after feedback from the informants as well as the researchers' identification of questions that needed to be reconstructed.

3.6.5.3 Questionnaire for community pharmacists

Pre-testing was done with four colleagues who have Bachelor of Pharmacy degrees to clarify the content and to revise it where necessary. After they completed the questionnaire they were asked how the questionnaire could be improved.

From the pre-testing phase, it became apparent that some of the questions were unclear and some repetitive. For one of the questions, too many choices were available for the pharmacists to choose from which would have made analysis of the data more difficult. The researcher therefore changed it to only one choice. Questions like "Do you think

CAM treatment is effective?" were changed to "How effective do you think CAM treatment is?" to avoid giving yes/no answers and responses like "very effective/not at all effective/somewhat effective" were incorporated.

For questions on herbal medicines the researcher had to change the question to state that it was with reference to "medicinal formulations" to prevent the informants from thinking it was about the plants. Minor changes were also made on the wording of some questions.

3.7 The role of the researcher

The researcher plays a fundamental role in the success of a study.[154] The carrying out and planning of this study was principally the researcher's responsibility. The researcher ensured that the participants met the inclusion/exclusion criterion adequately and only the researcher herself had access to the maternity case record books of the pregnant women. The researcher also ensured that the ethical aspects were adhered to; and was responsible for data analysis and the writing up of the final report. (See the end of Chapter Six for the researcher's reflections).

3.8 Data collection

Bless *et al.* state that data consist of measurements collected as a result of a research study.[177] Its collection is used to obtain the information needed to address a research question.[178, 179, 180]

3.8.1 Pregnant participants

The researcher attended antenatal clinic on the days when visits from pregnant women in their last trimester were expected. The researcher identified and verbally invited women who met the inclusion criteria into the study to participate. A total of 85 pregnant women were approached and ten women met the inclusion criteria. A summary of the sampling is shown in Figure 3.5.

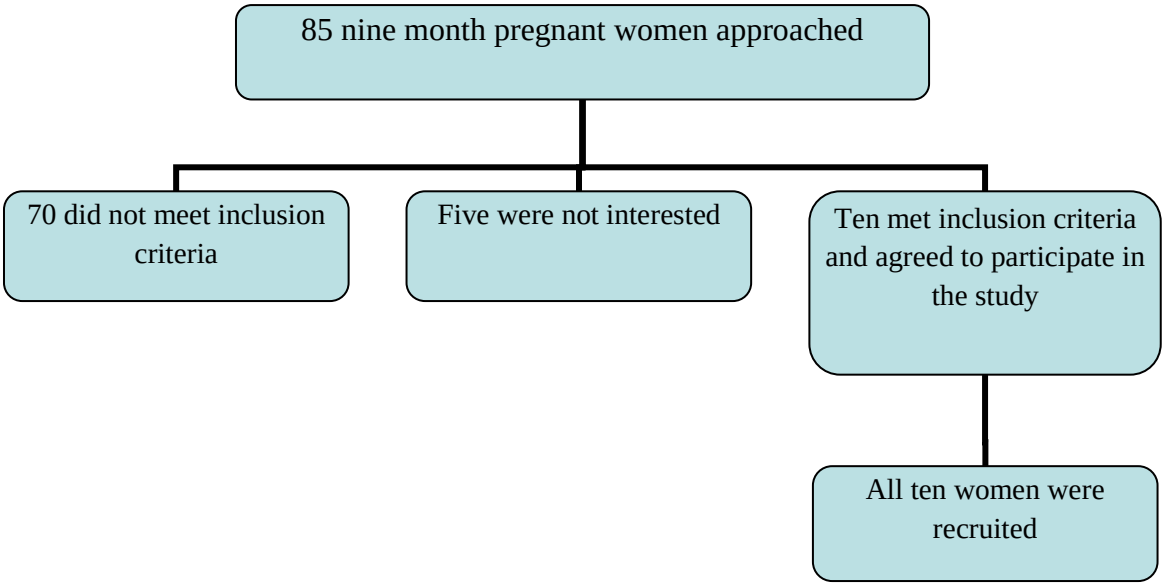

Figure 3.5: Summary of sampling of pregnant participants

The ten participants were then given information about the purposes and procedures of the study in the form of a Participant Information leaflet (Appendix E) and arrangements for the interviews were made.

The researcher initially suggested interviewing the participants at their homes, but none of the participants accepted this offer. One on one face-to-face interviews were conducted with the participants at venues of the participants' choice. Venues that ensured privacy, were easily accessible, convenient and did not incur out of pocket expenses for the participants were chosen. The interviews took approximately 15-20 minutes to complete. At the end of the interview, the women were asked to send the researcher a free cell phone "call me back" / "please call me" once they were in labour. (All the participants owned cell phones.)

Coincidentally, the mother of one of the participants was found to be a traditional healer. She was also interviewed and served as a key informant. (Appendix G includes her informed consent form and information leaflet.) The Faculty of Pharmacy ethics committee was informed of this development.

The second interviews were held after the birth of the baby within three days, in hospital. This also ensured easy access to their Maternal Case Record books which were kept in

the storage facility at the ends of their beds. Data on the outcome of the pregnancy (the baby) and the mother's health were collected from the medical records and Maternal Case Record book. The researcher was given a special dispensation by the persons in charge of the maternity wards to visit the women in the maternity wards "out of visiting and ward round hours".

The researcher collected only the data that were relevant to the study, and recorded the delivery methods, APGAR scores, assessment of the newborn, placenta details and any birth defects (Appendix J).

3.8.2 Community pharmacists

The researcher visited the four community pharmacies in Grahamstown and asked potential participants to take part in the study. The researcher provided verbal information about the research and what would be requested of the participants. The potential participants were given a chance to ask questions and to fully clarify what the research involved. The information provided was complete and accurate as far as possible. Those that agreed to participate were given the research details in a written format (Appendix E)

After obtaining informed consent from the pharmacists the researcher made appointments with them to complete the questionnaire. This was planned to be at the pharmacists' convenience while the investigator waited. In two instances, the pharmacists were not able to fill in the questionnaire at the time of the appointments due to an unexpected high influx of patients. They completed the questionnaire later that day, and the researcher collected them the following day.

3.9 Data analysis

3.9.1 Qualitative data analysis

All the interviews with the pregnant women were audio taped and transcribed. After all the questionnaires were completed and collected, the interview transcripts, interview notes and pharmacists responses to the questionnaires were analysed for themes.

Thematic analysis is defined by Braun and Clarke [181] as:

> …a method of identifying, analysing and reporting patterns/themes within data

The steps taken were:

Phase 1: Familiarisation with the data. The data were transcribed from the audio taped interviews. This helped the researcher in becoming familiar with the data. The transcripts were then checked back against the original audio recordings for accuracy and to make corrections if any. The interview transcripts as well as the pharmacists' responses were then read individually and re-read and initial ideas were noted.

Phase 2: Generating initial codes. Codes identify features of the data that appear interesting or important to the person analysing it. Coding involves analysing text for as many potential patterns and meanings or themes as possible[181] and assigning symbols to the data to meaningfully describe the phenomena.[182] The researcher coded the data manually by highlighting potential patterns using different colours on the transcripts (inductive coding).

Codes were put into a code book for consistency. During the process, some quotes were coded repeatedly, uncoded or sometimes coded once, changed, and combined.

Phase 3: Searching for themes. Braun and Clarke [181] state that:

> …a theme captures something interesting about the data in relation to the research question and represents some level of potential response or meaning within the data set.

The codes generated were sorted into potential themes and all the relevant coded data within the identified themes were pooled. According to Braun and Clarke, at this stage nothing should be excluded without looking at all the extracts (quotes in this case) in detail, as it is uncertain whether the themes hold as they are or whether some will need to be combined, refined and separated or discarded.[181]

Phase 4: Reviewing themes. At this stage, themes were reviewed and refined. The coded quotes and the entire data were checked to ensure the themes held.

Phase 5: Defining and naming themes. Generation of clear definitions and names for each theme which identified the specific details of each theme; and the overall story the analysis revealed[181] was performed. For each individual theme, a detailed analysis was undertaken and written out. It was ensured that the names of themes were an accurate reflection of the entire data set (i.e. that no data were omitted).

Phase 6: Writing the final account. The quantitative measures were combined with the qualitative interpretations. Vivid examples of quotes which captured the essence of the points demonstrated were used. The quotes were embedded within an analytic narrative to provide a rich description of the research findings.

3.9.2 Quantitative data analysis

Due to the small sample size and the aim of the study, the data collected were not suitable for analysis using complex statistical analysis methods. The participants' demographic data and their pregnancy outcomes data were entered into a Microsoft Office Excel 2003® worksheet for collation.

3.10 Validation

Validity serves a purpose of assessing the quality of data and the results in a research study.[156, 160, 163, 175, 183] It is not restricted to quantitative measures. In quantitative research the importance of validity has been accepted for a long time and has been well documented.[183] In the qualitative paradigm the main focus is for the researcher to understand human behaviour.[156]

Determination of the following are considered as scientific evidence of a study:

> i) the accuracy of the event/ account; ii) the possibilities of replicating the study and iii) the generalizability of the study.[160]

Polit *et al.*[184] define generalisability as:

> …an act of reasoning that involves drawing broad conclusions from particular instances – i.e. making an inference about the unobserved based on the observed.

To assess validity of quantitative research, the terms **internal validity** (accuracy of information and whether it matches reality, **external validity** (the generalisability of a study) and **reliability** (whether a technique applied to the study can be replicated using the same instruments) are used.[156, 160]

In qualitative research, where the researcher is the primary instrument in interpretation[178], bias must be carefully monitored as interpretation of phenomena is subjective. Lincoln and Guba came up with labels that are more suitable for qualitative research to overcome the validity issue. These are **credibility** (replaced the quantitative concept of internal validity), **transferability** (replaced quantitative concept of external validity), **dependability and conformability** (replaced quantitative concept of objectivity and reliability). The four criteria increase the quality of qualitative research.[185]

The criteria for assessing validity in this study are shown in the following headings.

3.10.1 Credibility/Internal validity

Credibility refers to the truth of how informants know and experience the phenomenon.[185, 186] According to Field and Morse,[187] a researcher should display credibility of the findings. Durrheim and Wessenaar[188] state that a credible interpretive account should be “convincing and reliable”. To decrease the prejudice intrinsic in using single data sources and methods, multiple data sources and methods were used in this study. The researcher also produced alternate interpretations from the codes generated in the analysis of findings.

Other accounts that did not fit into pre-determined themes were considered and integrated into the overall interpretation of the study where relevant. The researcher also took cognisance of factors which could have given an “opposite/opposing” interpretation of the data.

3.10.2 External validity/Transferability

Burns and Grove[189] state that external validity deals with the capacity to generalise findings of the study to other members of the population than the sample. Due to the

small sample size of this study as well as the sampling technique of the participants used, the study is not generalisable.

Transferability is the extent to which the qualitative findings could be extrapolated to other settings/contexts different from the one the original study was undertaken.[185] No claims for the transferability of the findings can be made as the sampling was purposeful, the data specific to the informants, the study setting circumscribed and the research context limited.

3.10.3 Reliability/Dependability

Burns and Grove [189] state that reliability is an extent to which an instrument consistently measures a concept. It is also said to be the ability to replicate the study.[182, 190] Accurate and careful phrasing of each question was carried out to prevent leading questions. This helped ensure the dependability of the instruments. The instruments used in this study could well be used in another study if appropriately contextualised.

3.10.4 Conformability

It is essential for a researcher to reflect on personal biases, assumptions, values and judgements as these may unintentionally influence data collection, procedures and interpretation of the findings. Research findings must primarily reveal the views of the study participants and not those of the researcher using this methodology.[160] In this study, the researcher shares such motivations and preconceptions (Chapter 6) that may have influenced the research process.[191]

CHAPTER FOUR

RESULTS

4.0 Introduction

Themes related to the beliefs, attitudes, behaviour and knowledge on TCAMs use by the pregnant women as well as those related to knowledge and attitudes of community pharmacists on the use of these medicines in pregnancy are presented. The women's pregnancy outcomes are included.

4.1 Interviewing the participants

Eight of the ten participants chose to be interviewed at the clinics in a separate semi-private space and two participants chose to be interviewed at the researcher's office.

4.1.1 Demographic characteristics of the participants

The women's ages ranged from 19 to 39 years. Six participants were from Joza Clinic and four from Settlers Day Hospital. All of them had been to school and had at least a Standard 8/Grade 10 formal education. Seven participants were unemployed and three were employed full-time. Those that were unemployed had some form of income in the form of grants, pensions and/or salaries of their parents/relatives. All the participants had had at least one antenatal check during their pregnancy with one participant having attended five times. No abnormal results were recorded for any of the check-ups or tests done.

Table 4.1 summarises each participant's demographic characteristics.

Table 4.1: Summary of pregnant participants' demographic characteristics

Respondent Number	Description
01	25 years old and has gone for 3 antenatal visits at Settlers Day Hospital during her pregnancy (one every three months). The nurses at the clinic advised her to do so. She is not employed, but her mother is employed and receives a monthly salary. She has a national diploma and is waiting to start her internship.
02	33 years old and went for one antenatal visit at Settlers Day Hospital during her pregnancy. Her mother advised her to do so. She is employed full-time and earns a monthly salary. Her education level is Grade 11 and she did training in the security sector.
03	19 years old and went for five antenatal visits at Joza Clinic during her pregnancy. Her mother advised her to do so. She is unemployed but her mother receives a monthly salary. Her education level is Grade11.
04	29 years old and went for two antenatal visits at Joza Clinic during her pregnancy. The nurses advised her to do so as that is where she discovered that she was pregnant. She is unemployed but her father receives a monthly salary. Her education level is Grade 10.
05	39 years old and went for two antenatal visits at Joza Clinic during her pregnancy. It was her decision to go for the check ups. She is unemployed and the income coming into the household is in the form of a monthly grant. Her education level is Grade 11.
06	37 years old and went for four antenatal visits at Joza Clinic during her pregnancy. She was advised by the nurses to do so. She is employed full-time and her education level is Grade 10.

07	25 years old and went for one antenatal visit during the ninth month of her pregnancy at Settlers Day Hospital. It was her decision to go for the check-up. She is unemployed and the income coming into the household is in the form of a monthly pension from her mother. Her education level is Grade 11.
08	23 years old and went for four antenatal visits at Joza Clinic during her pregnancy. It was her decision to go for the check-ups. She is employed full-time and has a Diploma in Social Development.
09	20 years old and went for one antenatal visit at Settlers Day Hospital during her pregnancy. She was advised by a nurse to go for the check-up. She is unemployed and the income coming into the household is a monthly salary from her father. Her education level is Grade 10.
10	34 years old and went for one antenatal visit at Joza Clinic during her pregnancy. Her mother advised her to go for the check-up. She is unemployed and the household income is from her mother's monthly pension. Her education level is Grade 10.

4.1.2 Attitudes and knowledge

The following themes were identified:

1. Positive attitudes towards modern healthcare
2. Knowledge and lack of knowledge of the safety of conventional medicines on the mother and the unborn baby
3. Lack of knowledge and knowledge of the safety of TCAMs on the mother and the unborn baby.
4. Culture/tradition

4.1.2.1 Positive attitudes towards modern healthcare

When the participants were asked where pregnant women that had fallen ill were supposed to seek assistance, six of the participants said the women should first go to the clinic and two said the doctor. One participant said the woman should first go to the elders and the other participant said she did not know.

Some of the participants described that they felt that doctors and the clinic staff were helpful and had solutions to the various problems the women could encounter. As some of the participants put it:

> …the clinic is good…they give you everything and proper and detailed information that you need to know… (01)
>
> …at the clinic they can get treatment that can help… (03)
>
> …sometimes the woman may feel abnormal pains and at the clinic they can help… (04)
>
> …they should go to the doctors because they are the ones that can help… (05)

Participants 06, 08 and 10 said that the doctors and clinics had adequate facilities to assist pregnant women as they could check the pregnancy including through the use of scans, detect the exact problem and find a solution for it. Therefore they said pregnant women should go to them for assistance in the event that they fall ill.

> …the doctors are the ones that can check the pregnancy… (06)
>
> …there at the clinic they test you and they will tell you what the problem is using their machines… (08)
>
> …at the clinic they check… (10)

4.1.2.2 Knowledge and lack of knowledge on safety of conventional medicines on the mother and the unborn baby

Participant 07 explained that women should go to the clinic when they fall ill because the medication issued there is not harmful. She stated:

> …it is better to go to the clinic because pills are better than traditional medicines and will not affect the child in the womb… (07)

Participant 09, who said a woman, should go to the elders, stated:

> …the elders are experienced and know which medicines to give to prevent dangers… (09)

For the knowledge component of the semi-structured interviews, eight participants "agreed" with the statement that modern medicine could not hurt the unborn baby if it is taken during pregnancy. Most said it was because modern medicines had been tested and that the doctors and nurses knew this, therefore would not issue medicines that would harm the unborn baby. One participant did not know whether or not modern medicines could not hurt the unborn baby. Some of their responses were as follows:

> …they are given by the nurses at the clinic and they know what exactly they are doing… (01)

> …because the medicine is coming from the labs it will not hurt the baby… (02)

> …I do not know because I did not use them… (03)

> …it will not happen because the doctors know what they are giving… (05)

> …if modern medicines are taken for a short while of about three to four days they are okay and will not hurt the baby… (06)

> …modern medicines are number one; they will not hurt the baby because they are from the clinics and doctors… (07)

> …they will not hurt the child because they have been tested by the doctors… (08)

> …the medicines are from the clinic so they are okay for the child… (10)

Participant 01 expanded on her response and said:

> …even the medicines sold at the pharmacies are not harmful to me so I can take them during pregnancy because they have been studied… (01)

Participant 04 said that modern medicines would not hurt the unborn baby because the doctors or nurses would provide pregnant women with medicines that were suitable for them.

> …the nurses and doctors know what medicines one is allergic to sometimes therefore will give something the woman is not allergic to and it will not hurt the baby… (04)

Participant 09 disagreed with the statement and said that modern medicines could hurt the unborn baby.

> …if they give you the wrong medication it can hurt the child… (09)

4.1.2.3 Knowledge and lack of knowledge on safety of TCAMs on the mother and the unborn baby

Concerning their knowledge of the safety of traditional medicines in pregnancy, the participants were asked to "agree" or "disagree" with a list of statements and to give reasons or comment on their choices.

Six participants said that ALL herbal/traditional/natural medicines were safe to use in pregnancy. Participant 03 said that because herbal remedies prevented women from being barren she regarded them as safe since they made women more fertile. She further said that the remedies would not hurt the unborn baby as the baby would still be alive even after the use of these remedies. Participants 05 and 08 said they were safe because they had not experienced any bad/adverse effects after they had used traditional remedies. They also shared the same views when it came to the effects of traditional remedies on the foetus and said that the remedies would not hurt the unborn baby.

Participant 09 stated that because some of the remedies are also used on the actual infants after birth, they were safe to use in pregnancy and they would not hurt the unborn baby. Participant 04 also said that traditional remedies would not hurt the foetus and put it as:

> …before they give you the traditional remedies they will ask how old the pregnancy is, because if they don't ask it may hurt the baby…so because they ask it is safe as they will give you the right medicine for the age of the pregnancy as there are different medicines for the different stages of pregnancy… (04)

Four participants said that ALL herbal/traditional/natural medicines were not safe to use in pregnancy. From the four, two participants had the same views on its effects on the foetus:

> …these traditional medicines can cause trouble if they are used at the same time with medicines from the clinic… (01)

> …for some people, they might hurt them... (02)

> …they are not right…they can do wrong things to the baby… (06)

> …sometimes they can be a danger because they can kill the mother of the baby if they are overdosed…they can also kill the baby if they are overdosed… (07)

Although some of the participants said that traditional remedies were not safe they still used them for their pregnancies.

Three of the participants said that it was necessary for a pregnant woman or anyone using TCAMs to tell a healthcare professional that they are using the medicines for safety reasons. They said:

> …these traditional medicines can be harmful with time… (01)

> …only when there is a problem it is necessary to tell them so that they know just in case it is the traditional medicines causing the problem… (09)

> …the nurses and doctors will help… (10)

Three participants "disagreed" with the statement that implied that traditional/natural/herbal medicines were more helpful than those from the clinic/hospital.

They said it was due to the unknown safety profiles of the traditional remedies. Participants 01 and 07 put it as:

> …they are not good because they can cause trouble especially when one is taking medicines from the clinic as well… (01)

> …sometimes they can be a danger as they can be stronger than those at the clinic… (07)

Participant 07 went on to further explain her reasons and said that when the traditional remedies become too potent it can be harmful to the unborn baby as well as the mother and cause complications which she did not specify.

4.1.2.4 Tradition/Culture

One participant said that it was necessary for a pregnant woman or anyone using TCAMs to tell a healthcare professional that they are using the medicines as it was part of their culture. As participant 04 put it:

> …they should know because it is our tradition and they should know that sometimes we have to protect ourselves from thing their medicines cannot protect us from… (04)

Seven of the participants said it was not necessary for anybody including pregnant women taking TCAMs to tell nurses, doctors or pharmacists that they are using them. Nine of the participants said that coming out in the open to the healthcare professionals about the use of traditional remedies by any individual would result in them being treated rudely. Three of the participants said it was necessary for anybody including pregnant women to tell a healthcare professional that they are using TCAMs.

The participants said that people should not admit to using traditional/herbal/natural medicines to a healthcare professional as the healthcare professionals “did not like it”. The participants also gave the same reasons for why they said people would be treated rudely if they admitted to the healthcare professionals. Most of them gave the following responses:

> …the doctors don’t want us to use these medicines… (02)
>
> …they don’t want us to take any other treatment… (03)
>
> …they don’t want us to use these other medicines… (05)
>
> …they don’t like the traditional medicines… (06)
>
> …we were told by the nurses that they are wrong these Xhosa medicines… (07)
>
> …they don’t want us to take them and they said something called ‘*umchamo wemfene*’ kills the child that is why they don’t want us to take them… (08)

Five participants said that traditional/natural/herbal medicines are more helpful than those from the clinic or hospital. One participant said she did not know which medicines were more helpful and the other said herbal and medicines from the clinic were equally helpful. From the five participants that said traditional/natural/herbal medicines were more helpful, some said that sometimes medicines from the clinics did not help and when they used traditional medicines they would work.

> …we have faith in traditional medicines unlike doctors when it comes to things like protecting the baby from bad things… (06)
>
> …I was taking pills from the clinic for the whole of my pregnancy and they didn’t help because my first baby wasn’t coming out, but when I took natural medicines it worked after I had taken it for one day, these things work… (08)
>
> …sometimes the medicines from the clinic don’t help and natural medicines help… (09)

4.1.3 Beliefs and behaviour

Only three participants, 01, 02 and 03 said that they knew of someone that had gone to a traditional healer/sangoma during their pregnancy and they said it did help the individuals. Participant 08 said she knew of someone who was given traditional/herbal medicines by their family and said it was effective. The rest of the participants said they

did not know of anyone that had gone to a sangoma/traditional healer during their pregnancy and also did not know of anyone that had been given traditional medicines by their family. The participants mentioned different reasons why the individuals they knew of had used traditional remedies. These included checking that the baby was fine, protecting the baby from evil spirits and bad luck, preventing caesarean births, as well as inducing labour.

The traditional healer interviewed did not provide additional information to what the women had said but confirmed that some of the practices the women reported were known to her as traditional medicine practices. This could be regarded as an unplanned form of triangulation validating the women's responses

From the beliefs and behaviour component of the interview, the following themes were identified:

1. Traditional medicine taking behaviour in pregnancy
2. Conventional medicine taking behaviour in pregnancy
3. Pregnancy outcomes

4.1.3.1 Traditional medicine taking behaviour in pregnancy

Medicines for protection from evil spirits were the most popular among the participants with six of the women having used remedies for this. They took them at gestation stages ranging from two to nine months. The participants stated it was important for them to protect their babies and the key informant (traditional healer) added to this by saying:

> …a lot of the women fear for their children's well being as there are things like for example "traps" that are placed on paths or roads that people walk on to bewitch them. When people walk on them, they can be affected and the bad spirits will catch onto them, some of the "traps" are put there on purpose and a pregnant woman and her baby can even be affected, even by a trap that is not meant for her when they walk on these paths. That is why they have to protect themselves… (Key informant)

Protection was not limited to the unborn baby but was also to protect the mother from susceptibility to evil spirits. As some put it:

> …I used the traditional medicines to shield me and the baby from witchcraft and evil spirits… (08)

> …I had *Amagada*[q] *emfene* i.e. *umchamo wemfene*[r] (baboons' urine pellets) which were black pellets I would mix for myself and drink. I also had *Isiwasho* which I got already mixed and I would also drink it then I rubbed *Amafuta enjayolwandle*[c] mixed with herbs to protect me and the baby from bad spirits… (04)

> …it was a solid mass I had to grind then boil for about ten minutes and drink it, it was called *Ncumbu*... (07)

Participant 03 also had pieces of string tied around her wrist and abdomen called "*intambo*[s]" which the respondent said was to protect her from "*umeqo*[t]". The key informant mentioned that *intambo* was made up of pieces of string which a healer twists and smears with medicine and it is given to a woman to wear around her waist until the baby is born and it serves to protect the woman and the baby from "bad things".

One participant said she used *isiwasho* to "cleanse" her pregnancy in addition to protecting the baby from evil spirits. The key informant stated that cleaning the body internally using medicines was a common practice from her experiences and some pregnant women did so too.

> …I don't know what was inside it but they also prayed for it and I drank it to cleanse my pregnancy as well as to avoid problems with the baby… (05)

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[q] Xhosa term meaning "pellets"

[r] Literally translated to mean "baboon's urine"

[s] A material which a healer twists and smears with medicine and it is worn around a persons' waist.

[t] Term directly translated to mean "jumping over dirty things" i.e. pollution.

Three of the participants used medicines to assist with labour as described below.

The purpose of *isiwasho* for participant 03 was to help reduce blood loss during labour and she took this from her second trimester until the last trimester.

> …I don't know what was put in the *isiwasho* I drank; it was given to me already mixed so that I could drink it so that I don't bleed a lot when I give birth … (03)

To reduce labour pain participant 06 drank a mixture with unknown contents. She said she was given it by a prophet at the estimated time of expected labour in the last month of her pregnancy (9 months).

Participant 08 took castor oil to induce her labour as she was past her due date for the birth. She said:

> …the baby was not coming out as nine months was about to finish so I was desperate and I told the elders who then told me to drink caster oil to help the baby to come out. I only drank it once and after a few hours a jelly came out of where the baby is and that is how I am in hospital now… (08)

Three participants used traditional remedies to help with the growth of the baby and they took the remedies ranging from two months to nine months of the pregnancy. Participant 01 did not know what was contained in what she took to help with the growth of her baby and participant 09 mixed the three items listed Table 4.2 into one mixture which she drank only once during her pregnancy when she was three months pregnant. Participant 03 used the same remedy referred to in section 4.1.3.1 to help with the growth of her baby.

> …I took it every day so that the baby would grow in my tummy… (01)

> …I drank it every day so that my baby grows… (03)

> …I drank it once only when I was three months pregnant, it was a once off dose and I didn't have to take it again and it was to help the baby grow… (09)

Table 4.2 is a summary of the traditional/herbal remedies the participants used during their pregnancies. It also shows the dosage frequencies, routes of administration, the stages of pregnancy at which the remedies were used and the methods of delivery of their babies.

Table 4.2: Remedies used by pregnant participants and methods of delivery

Respondent Number	Remedy used	Duration used (in pregnancy)	Indication(s)	Dosage/ Frequency	Route of Administration	Method of Delivery
01	Unknown	2-9	Growth of the baby	Once daily	Oral	NVD
02	Unknown	5-7	Protection of the baby	Half a cup twice a day	Oral	NVD
03	*Isiwasho*[a]	3.5-9	Growth of the baby + reduced bleeding during birth	One glass daily	Oral / enema	NVD
04	*Amagada emfene*[b]	4-9	Protection of the mother and the baby	One cup 3 times daily	Oral	Caesarean
	Isiwasho	4-9	Protection of the mother and the baby	One cup 3 times daily	Oral	
	Amafuta enjayolwandla[c]	4-9	Protection of the mother and the baby	Once daily	Topical	
05	*Isiwasho*	2-9	Cleansing the pregnancy and protection of the baby	One cup 3-4 times daily	Oral	NVD
06	Unknown	9	Reduction of labour pains	Once before labour	Oral	Caesarean
07	*Ncumbu*[d]	2-9	Protection of the mother and the baby	One cup 3 times daily	Oral	Caesarean
08	*Amanzi enjolwane*[e]	5-9	Protection of the mother and the baby	One cup daily	Oral	Caesarean
	Ivimbela[f]	5-9	Protection of the mother and the baby	One cup daily	Topical	
	Castor oil	9	Induction of labour	One 50ml bottle	Oral	
09	*Isiwasho, Versterk Druppels*[g,] *Milk Stout*[h] and *Rooipoeier*[i]	3	Growth of the baby	One 50ml bottle	Oral	Caesarean
10	Unknown	4-9	Protection of the mother and the baby	One cup daily	Oral	NVD

NVD: Normal Vaginal Delivery; a: water that has been prayed for and sometimes various salts added to it, can be used for purging[192]; b: Xhosa term for 'solid masses of baboon's urine'; c: literally 'fat of the sea dog' smeared topically to prevent entry of evil spirits[69]; d: Xhosa Traditional remedy; e: Xhosa traditional remedy containing various ingredients mixed with water; f : a brightly coloured substance resembling petroleum jelly warding off evil spirits[69]; g: Cape Dutch remedy, h: a sweet stout (beer) made with lactulose; i: literally 'red powder' (Afrikaans)

When participants were asked if they would inform a nurse, doctor or pharmacist that they were using traditional/herbal medicines, nine of the participants said they would not inform them with only one saying that she would. This is despite three participants indicating that anybody taking TCAMs must tell a healthcare professional if they are using the traditional/herbal medicines (section 4.1.2.4). They gave the same reasons stated above with participant 06 adding to what she had said previously by saying:

> …I will not tell them [health professionals] because they do not like them [traditional medicines] and I was scared I was going to get into trouble with the nurses if I tell them… (06)

The participants obtained their remedies from different sources as shown in Table 4.3.

Table 4.3: Participants' sources of TCAMs used

Respondent Number	Source where remedy was obtained
01	Elders at home
02	Diviner
03	'*Mcuba'* in a nearby neighbourhood
04	Herbalist and Church
05	Prophet
06	Prophet
07	Herbalist
08	*Amayeza* Store
09	Mother
10	Sangoma

The traditional healer highlighted that some of the remedies might contain the same ingredients but have different names depending on the source of the remedies. Some

remedies could have the same names but their ingredients might vary depending on the source e.g. *isiwasho.*

4.1.3.2 Conventional medicines taking behaviour in pregnancy

All the participants said they did not take any modern or conventional medicines during the course of their pregnancies and their health passports had no record of them using any conventional medicines during their pregnancy. They all said that they were only taking supplements such as:

- Calcium Gluconate
- Vitamin B Complex
- Iron Tablets (Ferrous Sulphate)
- Folic Acid

They were told to take these throughout their pregnancies by the nurses.

4.1.3.3 Pregnancy outcomes

All participants gave birth to live infants with five giving birth by normal vaginal delivery (NVD) and five having caesarean sections done. Ten babies were seen between one and four days postpartum. No birth defects were obvious or reported for any of them. No resuscitation was needed for any of the live infants after birth. The details of the participants' pregnancy outcomes are described below.

a) APGAR rating

The APGAR is done by a midwife, nurse or doctor and it determines how well the baby tolerated the birthing process.[193-195] It examines the baby's:

- Heart rate
- Breathing effort
- Muscle tone

- Response to stimulation (Reflexes) and
- Skin colour

Depending on the observations, each of the above categories is scored with 0, 1 or 2. Any total score less than eight means that the infant needs assistance and any score below five indicates that the infant needs urgent assistance. A score above eight indicates that the baby is in good condition.[193] The babies in this study all had a score of eight or above at both one and five minutes indicating that the babies were in good condition.

b) Birth weight

Babies born weighing less than 2.5 kg regardless of gestational age are considered low birth weight.[197] Three participants 04, 06 and 07 had babies that were low birth weight and they all had caesarean sections. The babies weighed 2.18 kg, 1.71 kg and 1.82 kg respectively.

Babies born weighing more than 4 kg are considered to be high birth weight.[197, 198] One participant (08) had a baby that weighed 4.4 kg.

The other participants had babies between 2.5 kg-4 kg.

c) Gestational age

Nine participants gave birth between the 36^{th} and 37^{th} weeks of pregnancy and participant 08 gave birth when she was 39 weeks pregnant.

d) Physical assessment of newborn

The physical assessment of the babies was done by the nurse, midwife or doctor. The following were assessed: heart rate, respiratory rate, breath sounds, abdomen, skin, cry, umbilicus, legs, feet, toes, arms, fingers, mouth, palate, tongue, muscle tone, genitalia, eyes, and reflexes. If meconium has not been passed within 24 hours, the baby is checked for a patent anal sphincter.

Each category was scored either “well” or “sick” depending on the findings. All the babies scored “well” in all categories.

e) Placenta

All the participants had normal placentas which were complete. Only participant 04 had her abruption of the placenta which is further discussed in a section yet to come in this chapter.

f) Anaesthesia

Anaesthesia was only administered to participants that had caesarean births. Participants 04, 06 and 08 were administered general anaesthetics while participants 09 and 07 had spinal blocks.

g) Complications

The five participants that had normal vaginal deliveries had no complications. The other five had complications during labour resulting in caesarean sections. The details of the complications are indicated below.

i) Caesarean deliveries

None of the participants' caesarean deliveries were planned but were due to complications and Table 4.4 shows the indications for the caesarean deliveries.

Table 4.4: Indications for Caesarean Deliveries

Respondent Code	Indication(s) for Caesarean Section
04	Abruption of the placenta
06	Prolonged labour, no foetal distress
07	Health of the mother at risk; hypertension
08	Failed induction of labour and foetal distress; hypertension
09	Prolonged first stage of labour, no foetal distress

Participant 04 had to have an emergency caesarean birth due to an abruption of the placenta during labour. This occurs when the placenta separates from the wall of the uterus, usually because of bleeding.

Participant 06 and 09 both had prolonged first stage of labour resulting in their becoming exhausted.

The health of participant 07 was at risk as she had elevated blood pressure.

Labour was induced in participant 08 on arrival at the hospital as she had an elevated blood pressure. She was given the following medication:

- Adalat XL® (Nifedipine) 25 mg eight hourly
- Misoprostol (analogue of prostaglandin E_1) immediate dose into the vagina to induce labour; when this failed it was given orally dissolved in water. She was given 20 ml of suspension every 3 hours then 40 ml every 2 hours then 60 ml immediately after the previous administered doses failed to induce labour
- Pethidine was given together with the last dose of the Misoprostol suspension

After the last medication was given, the baby went into foetal distress and an emergency caesarean section was done.

ii) Meconium Staining

Two of the participants' amniotic fluid was meconium stained and these two participants had caesarean sections. Participant 08 had grade 3 meconium staining and participant 09 grade 1 staining. Neither of these participants had meconium staining of the placenta.

Table 4.5 shows a summary of all the participants' pregnancy outcomes.

Table 4.5: Pregnancy outcomes

Code	Method of Delivery	APGAR Score		ASSESSMENT OF NEWBORN				PHYSICAL ASSESSMENT		PLACENTA				ANAESTHESIA		M.[1] Staining		B.[2] Defects	
		1 min	5 min	Weight/g	Length/cm	HC[3]	Resuscitation	Well	Sick	Normal	Abnormal	Complete	Incomplete	Y	N	Y	N	Y	N
01	NVD*	8	9	3180	55	32	None	√	-	√	-	√	-	-	√	-	√	-	√
02	NVD	8	9	3040	48	36	None	√	-	√	-	√	-	-	√	-	√	-	√
03	NVD	8	9	3480	56	34	None	√	-	√	-	√	-	-	√	-	√	-	√
04	Cesarean	8	9	2180	46	30	None	√	-		Abruption	√	-	√	-	-	√	-	√
05	NVD	9	10	3060	52	35	None	√	-	√	-	√	-	-	√	-	√	-	√
06	Cesarean	8	10	1710	41	31	None	√	-	√	-	√	-	√	-	-	√	-	√
07	Cesarean	9	10	1820	41	30	None	√	-	√	-	√	-	√	-	-	√	-	√
08	Cesarean	8	9	4400	54	35	None	√	-	√	-	√	-	√	-	√	-	-	√
09	Cesarean	8	9	3210	50	33	None	√	-	√	-	√	-	√	-	√	-	-	√
10	NVD	9	10	2861	49	33	None	√	-	√	-	√	-	-	√	-	√	-	√

1. Meconium Staining of amniotic fluid, 2. Birth Defects, 3. Head Circumference, *Normal Vaginal Delivery

4.2 Community Pharmacists

4.2.1 Introduction

CAMs were available for sale in all four pharmacies. The pharmacists select the CAMs they sell by the choice (demand) of their patients as well as the manufacturers' promotion of products. The pharmacists also reported some public sector patients purchasing medications. The pharmacists learnt about herbal medicines from TCAM literature, sales promotion, and the internet. The terms 'P1, P2, P3 and P4' are used to differentiate the pharmacists' responses. Some of the results were similar to those of Brijlal *et al*. [199] who found that the knowledge of their respondents about the awareness of mechanisms of action, contra-indications and adverse effects of herbal medicines was inadequate.

4.2.2 General

One of the three pharmacists said they had received CAMs training in university. All four pharmacists indicated that they considered CAMs to be "somewhat effective" and did sell them. Not one of them was aware of whether or not the CAMs were registered with the MCC. Three routinely ask female patients whether they are pregnant or not before they purchase any OTC medicines and one will sometimes ask depending on the pressure at work. None of the pharmacists appeared to have an in-depth knowledge of TCAMs. All four pharmacists said that it is important to have a basic understanding of TCAMs before using them, although they did not agree on the reasons for this. Three indicated that they "agreed" it is important for patients to consult a healthcare professional before using TCAMs, but one felt that a patient should first have obtained sufficient information from sources such as the internet. All of them felt that pharmacists have a professional responsibility to provide information on TCAMs (especially herbal preparations) and two felt that it is part of a medical doctors' responsibility. Table 4.6 shows the quantitative responses to some of the questions.

The following themes were identified from analysis of the "general" open-ended responses in the questionnaires:

1. Lack of evidence of the efficacy and safety of CAMs

2. Acceptance of CAMs by pharmacists

For the "knowledge and attitudes" component of the questionnaire, the following themes were identified:

1. Safety concern of CAMs in pregnancy
2. Interest in and need for CAMs training due to growing market
3. Accountability/responsibility of healthcare professionals and patients
4. Positive business benefits to pharmacies.

Table 4.6: Background data

Parameter	(n)
Were you trained in the use of CAMs?	
Yes	1
No	3
How effective do you think CAM treatment is?	
Not at all effective	-
Somewhat effective	4
Very effective	-
Do you give patients buying CAMs information on its use and	
Yes	1
No	3
Are the CAMs you sell registered with the MCC?	
Yes	-
No	1
I don't know	3
Do you support the use of CAMs by the public?	
Yes	1
No	-
Neutral	3
Do you support the use of CAMs by pregnant women?	
Yes	1
No	2
Neutral	1
Ask whether females could be pregnant before they purchase	
Yes	3
No	-
Sometimes	1

4.2.2.1 Lack of evidence on the efficacy and safety of CAMs

In supporting the use of CAMs by the public, three pharmacists were neutral although two did not support CAM use during pregnancy. One was neutral on CAM use during pregnancy (see Table 4.6)

The pharmacists said that there is lack of documented evidence with respect to the effectiveness of CAMs and because of that they would not recommend the use of the products during pregnancy.

> …the most crucial information is, do not use during pregnancy…I do not support its use during pregnancy because CAMs contain more than one active ingredient which do not have proven clinical information in pregnancy… (P1)

> …there is no scientific data available; it is not as great or comprehensive and thorough as is with that of convectional medicines… (P2)

> …In community pharmacy we hardly ever get feedback on any medication… (P3)

Three pharmacists said they did not give patients buying CAMs information on its use and effectiveness.

> … There are not enough studies that can convince us that CAMs are effective… (P1)

> …I cannot and do not inform patients on the efficacy… (P3)

> …not usually… (P4)

One pharmacist pointed out that with some CAMs there are unknown risks when they are used.

> …in certain disease states the use of CAMs could be dangerous if used alone or without proper treatment… I have no idea of side effects on the mother or foetus… (P4)

4.2.2.2 Acceptance of CAMs by the pharmacists

One pharmacist supported the use of CAMs by both the public and by pregnant women. Pharmacists that were neutral had some positive input on CAMs use.

> …CAM is effective if it is used correctly for the particular ailment… (P1)

> …I support the use of CAMs because of our modern lifestyles and the food we eat is of poor quality, the life we live is very stressful physically and mentally and CAMs return what has been lost because of this modification…I support their use in pregnancy especially the vitamins and minerals, diet is compromised and the developing foetus needs the supplementation to reduce a clinical deficiency and increase the chances of a healthy birth… (P2)

Three pharmacists said that ginger was effective in treating nausea and vomiting in pregnancy with one not giving reasons for their response and one pharmacist said they did not know (see Table 4.7).

> …ginger or ginger products are essential in treating nausea and vomiting i.e. ginger biscuits… (P1)

> …ginger tea is very helpful, only fresh ginger should be used… (P4)

One pharmacist said they would support the general use of CAMs by the public only if there is evidence that they actually work.

> …I will support the use of CAMs only if they can be regulated and registered by the MCC…

4.2.3 Knowledge and attitudes

Table 4.7 shows results of the 6-item knowledge test which was part of the questionnaire administered to the Pharmacists.

Table 4.7: Pharmacists' knowledge about TCAMs

Statement (correct answer?)	Correct	Incorrect	I don't know
Herbal medicines are natural and therefore mostly safe and without serious side effects. (incorrect)	-	4	-
St Johns wort (medicinal formulation) is a natural herbal therapy. (correct)	4	-	-
St Johns wort is effective in treating mild to moderate depression in pregnancy. (correct)	-	1	3
An adverse drug effect of St. John's wort is photodermatitis. (correct)	2	-	2
Ginger (medicinal formulation) is effective in treating nausea and vomiting in pregnant women. (correct)	3	-	1
Feverfew (medicinal formulation) is safe for use in pregnant women. (incorrect)	-	3	1

None of the pharmacists appeared to have an in-depth knowledge of the CAMs asked about, and most did not say much or anything in the open-ended section of the responses.

Table 4.8 shows the pharmacists attitudes towards CAMs.

Table 4.8: Pharmacists attitudes towards CAMs

Statement	Responses[a] (n)				
	1	**2**	**3**	**4**	**5**
It is important for patients to have a basic understanding of TCAMs before using them.	-	-	-	4	-
Pharmacists' training should place greater emphasis on education in CAM therapies.	-	-	-	2	2
Providing information about herbal medicine is not part of a Pharmacist's professional responsibility.	-	4	-	-	-
Providing information about herbal medicine is part of a medical doctor's professional responsibility.	1	1	-	2	-
It is essential for patients to consult a registered healthcare professional before using TCAM therapies?	-	-	1	3	-
Continuing education on TCAMs should be mandatory for Pharmacists.	-	1	1	2	-
Providing TCAMs to patients is more of a business decision than a healthcare decision.	1	-	3	-	-

[a] Scale of 1-5 (1= strongly disagree, 2= disagree, 3= neutral, 4= agree, 5= strongly agree)

4.2.3.1 Pharmacist's safety concern of CAMs in pregnancy

The pharmacists did express views on the safety of CAMs.

> …herbal medicines have a lot of active ingredients which do not have proven clinical information therefore they are not safe until proven such…there are herbal medicines that have been proven to be safe and effective but problem are with stabilisers, dosage forms etc… (P1)

> …some are dangerous… (P2)

> …I think most things have side-effects associated with them…and feverfew is not safe to use in pregnancy because it may cause the uterus to contract… (P3)

> …I have seen bad side-effects… (P4)

One expressed the importance for patients to consult a healthcare professional before using CAM therapies for safety precautions.

> …it is important for a patient to consult a healthcare professional before using CAMs to check whether these items are safe or not… (P1)

One said that CAM education should be done at pharmacy schools for safety precautions.

> …it is important especially in terms of drug interactions…I have heard briefly of cases of admissions in hospital… (P3)

All the pharmacists believed that it is important for patients to have a basic understanding of TCAMs before using them (score 4) but did not agree on the reasons for this. One of the reasons was:

> …clients must understand what they are using to know its possible advantages and disadvantages… (P1)

When it came to the use of CAMs during pregnancy they had different views on the uses of Feverfew and St Johns wort.

> …use in pregnancy is not recommended….not safe until proven such… (P1)

…very subjective…view point not based on scientific observation… (P2)

…pregnant women should not take Feverfew… (P3)

…not tested…would not give to a pregnant woman… (P4)

Some of the pharmacists did not know the use of the CAMs that were asked about.

…I don't know about St Johns wort treating depression… (P1)

…I don't know what category St Johns wort falls into… (P3)

4.2.3.2 Interest in and need for CAM training due to growing market

The pharmacists indicated that because of the growing market of CAMs there were various reasons why they are important.

…the market is growing; more people are using them... (P1)

Two pharmacists "strongly agreed" (score 5) that emphasis on CAMs education during pharmacists' training must be done (see Table 4.8) and credited this to an increase in usage. One 'agreed' (score 4) and did not give reasons.

…research has shown that more people are using CAM than conventional medicines therefore a pharmacist as a custodian of medicine should have background information on CAM… (P1)

…the market for CAMs is increasing therefore uses, side-effects and drug/food interactions of the CAMs play a role in pharmacotherapy… (P3)

Two "agreed" (score 4) that continuing education should be mandatory for pharmacists (see Table 4.8) but their reasons differed with P2 saying it should be because of its increased usage.

…CAM is a growing part of every pharmacy and we are already involved in it and it has to be part of us to provide a decent service and be educated on it… (P2)

One pharmacist was “neutral” about continuing education being mandatory for pharmacists but said that they should increase their knowledge on CAMs.

> …pharmacists in community and hospital are advised to do continued professional development in CAMs so as to increase their knowledge… (P1)

One pharmacist “disagreed” on greater emphasis on education in CAM therapies during pharmacists’ training saying they just need basic knowledge.

> …some emphasis yes but not great emphasis as it can be taught outside of the academic environment and there are more fundamental things that can be dealt with in the academic environment… (P2)

4.2.3.3 Accountability/Responsibility of healthcare professionals and patients

Three “agreed” (score 4) that it is important for patients to consult a healthcare professional before using CAMs. All felt that a Pharmacist has a professional responsibility to provide information on herbal medicines (score 2),

> …if one is supplying herbal medicines to a client then that client deserves to get information with respect to the medicine… (P1)

> …it is part of our responsibility but not to provide the claims of the manufacturer, we should just assist on its appropriateness… (P2)

> …we stock them therefore it should be our responsibility to know about them… (P3)

Two felt that it is a medical doctors’ responsibility (score 4) with only one giving reasons.

> …yes, they should advise the patient with respect to herbal medicines as there are ailments that herbal medicine can cause or treat… (P1)

The other two felt that it was not a medical doctors’ responsibility (Scores 1 and 2) and justified this by saying

> …there are herbal practitioners for that as well as pharmacists and their assistants to do so, doctors should focus more on primary, secondary and tertiary healthcare as they need more attention and there are more pressing issues they can deal with instead… (P2)
>
> …they are not trained… (P4)

One pharmacist was "neutral" about patients consulting a healthcare professional before using CAMs and said it was the patients' responsibility to look it up.

> ….there is a wealth of information available in the media that the patients access or can assess before they purchase these products… (P2)

4.2.3.4 Positive business benefits to pharmacists

Three pharmacists were "neutral" (score 3) that providing TCAMs to patients was more of a business decision than a healthcare decision and one "strongly disagreed" (score 1). Two did not comment and the other two said,

> …both sides of the coin are true, some sell for business and some sell for their holistic approach in improving both ways for clients, so I say both… (P2)
>
> …Professionalism is still important that is why I strongly disagree… (P4)

4.3 Good pharmacy practice guidelines in South Africa in with respect to CAMs

The good pharmacy practice guidelines of South Africa state that the minimum professional standards for services provided in a pharmacy with regards to the provision of complementary medicines[200] should be as follows:

a) Where complementary medicines are offered for sale, staff involved must be trained in the use thereof.

b) The pharmacy must stock only those complementary medicines which are judged by the pharmacist to be effective and appropriate for the treatment of the stated conditions.

c) The client must be given appropriate information about the use and effectiveness of complementary medicine sold to them.

d) The client must be informed of possible adverse reactions and drug/drug and drug/food interactions.

e) Medicines acquired and sold must comply with MCC requirements.

Guidance: Information about complementary medicines must be suitable for the needs of specific groups of clients and must not make claims which in the pharmacist's judgement, are misleading or speculative.

CHAPTER FIVE

DISCUSSION

5.0 Introduction

The mixed methods approach enabled the investigator to obtain quantitative measures of pregnancy outcomes of the participants and the knowledge of community pharmacists about the use of TCAMs during pregnancy while the qualitative interpretations allowed greater insight into the reasons why the women chose to use TCAMs; and to highlight the attitudes of community pharmacists.

5.1 Recruiting pregnant participants

Indigenous traditional practices are seldom spoken about freely as people often do not feel comfortable talking about personal practices of that nature with strangers, especially regarding their pregnancies. This is possibly why from the 85 pregnant women the researcher approached, only ten indicated that they were using traditional medicines. It is also possible that because recruitment took place in the clinic, some women did not want to risk being seen or heard talking by the healthcare professionals there about their practices.

None of the participants wanted to be interviewed at their homes possibly because they stayed with other family members and did not want to be heard or seen discussing their personal practices with the researcher, and possibly also did not want their participation in the study to be known about by others. It is also possible that they were uncomfortable with having someone they were not familiar with in their homes or that this could even in some way have had an adverse effect on the pregnancy in terms of traditional beliefs.

5.1.1 Demographic characteristics of the participants

The participants' levels of education and employment status did not visibly differentiate their behaviour in antenatal care. It is standard practice that when a woman goes for an antenatal check up she is given a date on which to come back for a follow up examination. On average a pregnant woman should have at least three antenatal check-ups. Apart from possible logistical issues such as lack of transport, some of the

participants may not have gone for more check-ups because they felt they were in good health and it was not necessary. If so, this thinking would be similar to findings from a study done in Cape Town, South Africa.[201] The Health Belief Model (see Appendix K) states that the greater the perceived risk, the greater the likelihood of engaging in behaviour that will decrease the risk[202-204]. If the participants thought their pregnancies were not at risk, they may not have gone for antenatal check-ups. The participants that did attend might also in terms of the Health Belief Model have thought that their pregnancies were at higher risk, leading to more check-ups. Unfortunately these questions were not asked and the inferences are speculative.

The maternal mortality rate (mothers who die of pregnancy related causes) in South Africa has increased over the last few years in spite of the availability of maternity care. The Minister of Health of South Africa stated in May 2011 that the high maternal mortality rate in South Africa was attributed to HIV/AIDS.[34] This means that South Africa will probably not meet its millennium development goals (MDGs) target for reducing maternal mortality by 2015. The Minister also stated that one in every three women presenting at antenatal clinics was HIV positive. This highlights the importance of women going for antenatal check-ups early during their pregnancies so that early interventions to reduce maternal and infant mortality rates can be successfully implemented.

5.1.2 Attitudes and knowledge

5.1.2.1 Positive attitudes towards modern health care

Despite positive attitudes towards and access to Western antenatal care, indigenous practices / traditional medicines use were incorporated by these women, and were seen as an important or even primary component of women's pregnancy related practices. Traditional medicines were used in addition to conventional health practices and not as a substitute for them. It is interesting to note that four women used traditional medicines despite stating that they were harmful or potentially harmful in pregnancy. It would seem that factors not revealed in this study may have played a part in this.

5.1.2.2 Knowledge and lack of knowledge on safety of conventional medicines on the mother and the unborn baby

Nearly all the women believed that modern medicines (conventional medicines) cannot hurt the unborn baby. They were aware that the medicines had been tested and had proven clinical efficacy and safety but they were not aware of the fact that most of them have not been tested for safety in pregnancy so they (reasonably) assumed that they were also safe to use in pregnancy. Participant 01 indicated that because some conventional medicines were available to the public at pharmacies without having to consult a doctor, they must be safe to use with no harmful or adverse effects. This could be a commonly held point of view. Only one participant in this study said that modern medicine could hurt the unborn child if the "wrong" medication was administered. The level of trust in pharmacies is gratifying – but it is not necessarily matched by the required responsibilities of the regulatory authorities (MCC); and it would seem that many pharmacists do not adhere to Good Pharmacy Practice as far as CAMs are concerned.

Women should have the freedom to ask prescribers and dispensers of medicines about the safety of medicines in pregnancy especially when they want to become pregnant, suspect they may be pregnant, or are already pregnant. This general "rule" should also apply to traditional / herbal medicines. Women should be aware that the same applies to self medication (over the counter) remedies.

5.1.2.3 Knowledge and lack of knowledge on safety of TCAMs on the mother and the unborn baby

Similar to findings by Peltzer *et al*.[87], six participants in this study did not believe that traditional medicines could hurt the unborn baby. Banda *et al*.[205] found in their sample of women from Lusaka, that 61% believed that traditional medicines would not hurt the unborn baby. In this study, the other four participants believed that traditional/herbal medicines could hurt the baby but did not know exactly how the medicines could hurt it. Although they considered that these remedies had the potential to harm the baby they still used them. This could be considered an example of cognitive dissonance.[206] Possibly the belief that taking of these remedies would actually serve its purpose overruled the thought that they may be harmful. It could be argued however that because of what is

sometimes referred to as an “holistic” approach to well-being, they wanted to cure themselves of or prevent health conditions that they knew conventional medicines could not address. The health belief model might depict this as a perceived risk of being vulnerable to possible supernatural influences (which would then be a perceived threat) resulting in the use of the traditional remedies to reduce their susceptibility to the illnesses (perceived benefits). It is also possible that because many traditional healers are “in touch with” the ancestors and directing the healers – that the ancestors would not want to harm “their family”. Participant 06 mentioned that some traditional medicines could be very potent and could be dangerous for the mother and the baby if ‘overdosed’. This could be indicative of an underlying belief that as long as the remedy is not overdosed it will not be harmful. The problem with this is how one can know what a “dose” is (apart from following the instructions of the traditional healer who dispensed the medicine). Especially if it is not known what the ingredients of a remedy are.

5.1.3 Beliefs and behaviour

5.1.3.1 Traditional medicines taking behaviour in pregnancy

In this study the use of traditional/herbal remedies was more common after the first three months of pregnancy. Many women do not disclose being pregnant during the first few months for fear of endangering the baby. The variation in remedies and their ingredients could be partially explained by the varied sources from which the participants obtained their remedies. Traditional sources were used alone or in combination with faith healing or even “Dutch remedies” in one case.

5.1.3.2 Initiating traditional medicines in pregnancy

None of the participants used any remedies in the first month of pregnancy possibly because a lot of pregnancies are unplanned and most women usually only discover /confirm that they are pregnant after the first few weeks.[31, 207, 208] Most women suspect that they are pregnant when they first miss their menstrual period and some may wait until two or three missed periods before concluding that they are in fact pregnant.[201, 208]

Similar to Abrahams *et al.*[201], the main reasons for the use of traditional / herbal medicines by the participants in this study was not because conventional medicine could not help, but against "supernatural" illnesses and for "protection" of the pregnancy.[69, 106, 111, 209] Abrahams *et al*.[106] found that the majority of Xhosa speaking women in Cape Town followed indigenous healing practices for both themselves and their babies because of the perceived need to 'strengthen' the womb against witchcraft.

The participants who said traditional medicines were more helpful than those from the clinic implied that traditional medicines were more helpful in shielding them from evil spirits and witchcraft as that cannot be achieved with conventional medicines.

Three constructs of the Health Belief Model- perceived susceptibility, perceived benefits and perceived barriers (see Appendix K) – may explain the decision making processes that informed traditional / herbal medicine use among the study participants. A pregnant woman might believe that during the period of her pregnancy, she is vulnerable / susceptible to health related problems. Healthier behaviours are adopted when people believe that the new behaviour will decrease their chances of getting a certain condition[202, 203] e.g. if a pregnant woman believes that a certain diet or using certain traditional / herbal medication will help decrease the chances of encountering any health related problem during the pregnancy and will help protect the baby, it will be easier to adopt that habit. The four major constructs are tailored by other variables such as education level, culture, past experience as well as motivation and other variables which influence individual perceptions.[202] If any of the new habits (e.g. the use of herbal / traditional medicines) did not cause harm to other people or family members that adopted them, the behaviour may be perceived to be safe and possibly effective. The model also suggests that behaviour is influenced by events, people or things that move people to change their behaviour i.e. cues to action[202] e.g. recovery from an illness or death due to certain actions, can determine whether a person will repeat the same actions or not.

Interventions that address traditional practices among pregnant women should, in addition to highlighting the potential effects associated with medicines taking during pregnancy, attempt to address some of the barriers that hinder them from making

informed decisions about traditional practices in pregnancy. Figure K.1 in Appendix K is a representation of the Health Belief Model.

The use of traditional medicines to help with the growth of the baby varied. They ranged from a mixture of traditional medicines, faith healing and “Dutch” medicines. Although the participants using TMs for this purpose, delivered normal birth weight infants, this cannot be directly associated with the remedies as there are many other factors that can contribute to a good pregnancy outcome. However the mothers themselves may well have associated the good outcomes with the taking of the remedies. This would in all likelihood reinforce the belief in and continued use of the medicines.

Chalmers [110] states that some women are afraid that expressing pain during labour would result in the attending nurses mocking or becoming angry with them. Or they may fear being laughed at by other women if they cried out. In addition the reason given by some women for not expressing the pain they feel during labour is that they felt it was culturally desirable for a woman to not make a noise. Many consider it acceptable to cry for help only when the baby is being born and not during the early stages of labour. Any of the above beliefs could possibly have been the reason participant 06 took a remedy to reduce labour pain. However these statements by Chalmers were not tested in the participants in this study.

Participant 08 took castor oil to help induce her labour as she stated that she was desperate for her baby to come out because she was past her expected date of delivery. This is also recorded by Peltzer *et al*.[87] as one of the problems pregnant women visit indigenous healers for. In some African cultures, a woman not giving birth at the expected time means that something is wrong or that someone is trying to prevent the baby from coming out by using *muti* on the individual. Castor oil or ricinoleic acid is a known irritant cathartic. It has been used to induce labour and help initiate cervical ripening but this use is controversial and conflicting findings have been made.[131, 139] Participant 08 believes that the castor oil did work as a “jelly like substance” came out after she drank it, and she had to go to the hospital to give birth. This jelly like substance may have been the “show” or mucous plug which comes loose when the cervix starts to dilate.[210] A full-term pregnancy is normally considered to be 40 weeks in duration,

although this may vary between 37 and 42 weeks. This time period should not be the primary measure for inducing labour, but induction should be based on the maturity of the foetus to cope with the outside life. Even with advanced technology, prediction of a birth date is not an exact science and society's expectations of an exact due date may be unrealistic. It is important for women to understand that in most cases the foetus is best kept in the uterus until it is ready to make an appearance so that being "overdue" is not viewed as abnormal.

This may be difficult to achieve especially since an individual's culture and beliefs influences their behaviour. It is difficult to shift individual's practices and beliefs away from their beliefs and practices and it is entirely up to the individual to decide what they believe in, how they want to express those beliefs and what practices they will undertake.

Many women are reluctant to discuss their use of traditional/herbal remedies with their doctors or nurses since it is assumed this would be considered unacceptable by the healthcare professionals. In this study, nine of the ten women said they would not tell a nurse, doctor or pharmacist about having used traditional medicines, even if they had used it, as they thought that telling them would have an adverse effect on the care given to them by the healthcare professionals. These are similar to findings in the study by Peltzer *et al*.[87]. Banda *et al*.[205] also found that among their sample, 64% said they would not tell an obstetric provider if they had visited a traditional healer and 54% believed that admitting to have visited a traditional healer would result in worse medical care.

This rather shocking finding confirmed by others can destroy the very fabric of a trusting relationship between patients / clients and healthcare professionals. The implications of the failure of early detection of pregnancy-related problems or medicines-related problems could be serious for both the mother and the infant.

Healthcare provision for pregnant women is shared among indigenous healers, pregnant women and western medicine and the role of traditional health practices and self-medication is ignored by some western medical practitioners unless the outcome is harmful.[106] Their reported "rudeness" to patients and often contemptuous disregard for

traditional healers and their practices could possibly be one of the reasons why the women will not tell nurses or doctors about their traditional health practices. They may have heard of such instances or have in the past experienced being belittled or made to feel at fault by healthcare professionals for doing something incorrectly. Healthcare professionals' attitudes towards patients may come across as judgemental especially when they do not share the same beliefs and values as the patients they are dealing with. The study participants could have experienced or witnessed this in the past resulting in them admitting to being unwilling to disclose their traditional/herbal medicine practices. They may fear being judged or blamed for any bad outcome that may be identified by the doctors or nurses during their check-ups. Great care was taken and efforts made to ensure that the relationship between the researcher and the participants in this study was one of respect and non-judgmentalism. The fact that information of this nature was willingly shared with the researcher seems to confirm that this was successful.

5.1.3.3 Conventional medicines taking behaviour in pregnancy

In pregnancy a woman's daily intake requirements for certain nutrients increases; especially for folic acid (folate), calcium and iron as they are vital for proper foetal growth and development as well as the mother's well being while pregnant. However these substances can be harmful if they are taken in excess.[211-213] All the participants were provided with these supplements in the correct doses by the healthcare professionals they consulted.

None of the participants needed to take 'modern' medicines during their pregnancy for any acute or chronic related conditions. None of them spontaneously mentioned self medicating for minor conditions such as headaches, and all participants appeared to be in excellent overall health.

5.1.3.4 Pregnancy Outcomes

A number of factors could be associated with the low birth weights in three of the babies. The health status of the mother influences the growth and development of the baby during pregnancy [214, 215], although this seems to have not played a role in these pregnancies. If a mother is too young and of poor health or undernourished, it increases

the chances of a low birth weight infant and pregnancy or labour complications. Again none of these were factors in these cases. Substance abuse e.g. smoking and alcohol consumed in pregnancy may contribute to low birth weight of an infant.[216] There was no evidence of substance abuse in these mothers. Other causes of low birth weight include premature birth, multiple births, decreased blood flow to the baby due to a problem with the placenta resulting in a decrease in oxygen and nutrient supply to the baby.[214-217] This is referred to as intrauterine growth retardation. None of the participants had a premature birth or multiple births. Johns and Sibeko [92] state that no published data support a direct effect of any herbal medicine on birth weight either positively or negatively. To reduce deaths and illness of infants, prevention of low birth weight has been identified as one of the main gaps to be addressed. In order to do this, improved access to antenatal care, health promotion for pregnant women and adequate nutrition during the antenatal period should be prioritised.[216] It is not possible to reach any conclusions about the causes of the three low birth weight babies in this small study. One of these three mothers (04) was using three different traditional medicines *amagada emfene and isiwasho* orally, and *amafuta enjayolwandla* topically. Her baby weighed 2.18 kg which was the highest of the low birth weight babies. If the mother had not had to have an emergency caesarean section, this baby may have developed further provided there were no other complications. The caesarean section was performed due to an "abruptio placenta". This is when the placenta detaches from the wall of the uterus either partially or totally [218, 219] usually because of bleeding between the uterus wall and the placenta. It is a very serious condition as it may result in "disseminated intravascular coagulopathy" (DIC) which can be fatal.[220] The unborn baby is starved of oxygen and nutrients and can die.[218, 219] In most cases the cause is unknown but it can be caused by abdominal trauma, advanced maternal age, substance abuse or a history of placental abruption in other pregnancies.[218] In this case the cause was unknown. If any of the traditional medicines had had an anticoagulant effect, it is possible that this could have been associated with the abruption of the placenta.

Caesarean Deliveries

Half the sample underwent caesarean sections. Some indications for caesarean section births, apart from placental abruption include foetal distress, prolonged labour and when the health of the mother or the baby is at risk. Other indications include multiple births, preterm births and birth defects.[221] Participant 07 had hypertension and this could well have been pregnancy induced hypertension (previously commonly referred to as pre-eclamptic toxaemia or PET) especially as this was her first pregnancy. The management of choice for pregnancy induced hypertension if the foetus is viable is to immediately end the pregnancy, and caesarean section is the most effective means of ending the pregnancy where the facilities are available. The possible consequences of untreated pregnancy induced hypertension are eclampsia (seizures) and death. Clearly the mother's health (and therefore the baby's health) was at risk. Foetal distress was observed with participant 08s baby. The mother had hypertension and in addition to the traditional medicines she took, she was administered additional medications in the hospital ward to induce her labour as well as to stabilise her blood pressure. She also had a "big baby".

Although this sample is not representative of any population, half the sample had caesarean section births, and the caesarean section rate has increased over the last few years internationally and in South Africa.[221] In this sample none of the participants was due to have an elective caesarean section. It is possible that some doctors perform caesarean section births for convenience even when a vaginal delivery is feasible.

Meconium Staining

Mabinda *et al*.[117] suggest that the use of herbal medication in pregnancy may lead to foetal distress. They showed an association between herbal medicines use, meconium stained liquor and high caesarean rates in their study group. The foetal distress experienced by participant 08's infant may have been associated with being a big baby (4.4 kg) leading to cephalo-pelvic disproportion. It was probably not associated with the mother's ingestion of traditional/herbal medicines. High birth weight babies may however be associated with diabetes in the mother, which may include gestational diabetes.[222] The cause of meconium staining in participant 09 is most likely related to

the prolonged labour and not herbal medicines. It is not clear what the cause of the prolonged labour was. The reasons for meconium-stained liquor being possibly associated with herbal ingestion are not known[117] and further investigation into this possible relationship is required. All the other participants' babies passed meconium only after birth even though all the participants had taken some form of herbal/traditional medicines during their pregnancies.

Overall pregnancy outcomes

All the babies delivered were in good health and no records of defects were found. Most of the mothers did well after delivery of their babies except for participant 07 who was kept under observation and kept on a drip as she was weak. The reasons for this are unknown although she herself spontaneously suggested that it was due to the herbal remedies that she had been taking during her pregnancy. However as the study was about the use of traditional medicines in pregnancy, this could well have been a spurious association simply as a result of her being a participant in the study.

In this study, no harm from taking TCAMs could be shown. However herbal medicines have numerous ingredients many of which are unknown and taking these medicines can be considered risky. If women feel the need to use these medicines for 'non-medical' (or supernatural) purposes, it may be less of a risk to the foetus and the mother herself if topical remedies were used where large molecules are not absorbed, rather than oral remedies containing unknown substances. The cultural aspects relating to beliefs about cleansing, protection of the foetus, strengthening of the uterus and growth of the baby need to be addressed by mainly cultural means, but if medications are deemed necessary, then the least harmful medications should be used. Often however, it may be the combination of rituals, supernatural communication, prayer and medications that fulfil the cultural requirements rather than just traditional medicines alone.

5.1.3.5 Limitations of this component of the study

Several limitations to this study exist despite efforts made to minimise them. The limitations included:

- The findings of this study cannot be generalised due to the small sample size and non-random sampling.
- An open-ended interviewing technique may have provided more detailed data.
- Qualitative findings are inherently subject to different interpretations, though the researcher attempted to ensure consistency in the analysis of the data to contribute to the credibility and validity of the findings
- The participants may have wanted to please the researcher and provided answers they thought she would want to hear.

5.2 Community pharmacists

5.2.1 General

Pharmacists and other healthcare professionals are expected to protect the public by evaluating the effectiveness and safety evidence for CAM therapies and sharing this information with the public.[105] The pharmacists highlighted the issue of there being insufficient dependable sources of information on CAMs that they could access. They obtained their information on CAM therapies from sales promoters, literature and the internet. Although the internet may contain a wealth of medical information to help pharmacists keep up to date, it is essential for pharmacists to be aware that some of the information may be inaccurate or biased.[223, 224] Inaccuracy and bias also applies to the information from sales promoters and manufacturers' CAM literature which is aimed at promoting particular products. The pharmacists in this sample were unsure whether they were accessing unreliable information. Reliable sources of information and reference materials on CAM to assist pharmacists and other healthcare professionals is needed.[102, 147, 225-227] One of the pharmacists interviewed surprisingly said that it was the patient's responsibility to look up information on CAM therapies. Apart from denying the pharmacist's responsibility and the requirements of Good Pharmacy

Practice[u], not all patients have access to CAMs information. Patients may be obtaining misleading or inaccurate health information, acting on it and potentially endangering their well-being. Healthcare professionals including pharmacists should be well informed on CAM therapies and have reliable sources of CAM information which they can immediately access at their practice sites. The South African Pharmacy Council's (SAPC) GPP standards (clause 1.2.11.5(a)) requires that every pharmacist selling CAMs *must* have a comprehensive textbook on complementary medicine available as a reference. Not one of the pharmacists interviewed (and by implication not one of the four pharmacies in Grahamstown included in the study) had such a textbook "available for consultation".

Regarding the responses to how effective the pharmacists thought CAM treatment is, "somewhat effective" was selected by all the participants. This rather ambivalent response seems to indicate that the pharmacists were not prepared to take a definitive stance about the effectiveness of CAMs.

The minimum good pharmacy practice standards (in South Africa) for the provision of complementary medicine require that the staff involved in the sale of these products be trained in their use and only stock those complementary medicines judged by the pharmacist to be effective and appropriate for the treatment of stated conditions. The pharmacists in this study were unaware of the effectiveness and appropriateness of CAMs therefore it raises concerns as to how they select which ones to sell at their pharmacies as they cannot only base it on what the patients ask for. Therefore with respect to GPP in terms of complementary medicines, minimum standards for their provision are still not being fully met by the pharmacists in this study and this could well be the case with other pharmacists in other parts of South Africa.

None of the pharmacists said that they did not support the use of CAMs by the public. This is not surprising since all the pharmacies were selling CAMs. The fact that some

[u] The commitment of the pharmacy profession (in South Africa) is to promote excellence in practice for the benefit of those they serve (http://www.sapc.za.org/G_PublicationsD.asp)

people use CAMs because they think they maintain their general well-being and are thought by some people to have a preventative role would contribute to their supporting the use of CAMs by the public. Although some healthcare professionals agree that CAMs can play an important part in healthcare promotion, there is very little evidence for this and similar findings are reported in other studies.[228-232] When it comes to medicines (including traditional medicines and CAMs), the standard "caveat emptor" (let the buyer beware) must more responsibly become 'caveat vendor' (let the seller beware or "be aware").

Many pharmacists know that most CAM products have not been tested in pregnancy and their safety profiles are unknown.[225] It can be considered that selling CAMs to a pregnant woman, knowing that there are no safety data, is unethical. The South African Pharmacy Council's (SAPC) Good Pharmacy Practice (GPP) Guidelines make no specific mention of community pharmacists routinely checking whether or not women are pregnant, could be pregnant or are planning to become pregnant before dispensing or selling any medicines including CAMs. The only mention in this regard is related to the administration of immunisation agents. [GPP 2010, clause 2.14.2(h)(iii) page 133] This is a serious anomaly in the GPP guidelines as it should be a routine concern in dispensing or selling of medicines to every woman of child-bearing age.

Healthcare providers and CAM consumers should be aware that scientific research to date is limited and scientific assessment is fundamental to enable an informed choice to be made among treatments. This has important public health implications. However, because of the limited patentability of vitamins, herbs and other natural products, industry-sponsored research remains inadequate and alternative funding sources must bridge the gap in ensuring research is conducted. In the meantime sellers and dispensers of CAMs find themselves in a quandary. The justification for selling products of unknown quality, safety and efficacy because consumers 'want them' is inadequate. At present it is only the pharmacist's conscience which is the determining factor.

5.2.2 Knowledge and attitudes

One of the minimum standards for the provision of complementary medicines in the South Africa's Good Pharmacy Practice Guidelines requires that CAMs acquired and sold at a pharmacy must comply with Medicines Control Council (MCC) requirements. Although practicing pharmacists are required to follow the rules in the GPP manual and support its implementation, none of the pharmacist said they knew if the CAMs they sold were registered with the MCC. This is another surprising finding, but may be partly explained by the uncertainty created by the MCC since the 2002 complementary medicines call up. The fact that the pharmacists continued to sell them although they were not sure of their registration status and safety profiles gives the impression that the pharmacists in this study did not view the CAMs they sold as a potential threat to the safety of its consumers.

P2's statement "…I support the use of CAMs because of our modern lifestyles and the food we eat is of poor quality, the life we live is very stressful physically and mentally and CAMs return what has been lost because of this modification…" was rather strange coming from a pharmacist who should know better and who also mentioned that there is not enough evidence on the effectiveness of CAM therapies. There is no evidence that the food we eat is of such poor quality and that we need anything to "improve" it, except better food. There is also no evidence that CAMs can "return" anything of what has "been lost" or that the substances in CAMs are more effectively absorbed and utilised by the body than if they were contained in foods.

The pharmacists answered more questions about the uses of herbal medications correctly than about their adverse effects and cautions. This finding is similar to the results from other studies.[232, 233] Several side effects and drug-herb interactions have been documented, and pharmacists should be informed and knowledgeable about the risks of these. They should also be knowledgeable about the risks and benefits of CAMs in pregnancy as it is part of a pharmacist's responsibility to safeguard public health and to improve the well being of patients. The participating pharmacists also agreed on this responsibility.

Although most of the pharmacists felt that they had a greater responsibility to provide information on CAM therapies compared to medical doctors, three of the pharmacists felt that they had been insufficiently educated about herbal products and other types of alternative medicines during their training at their universities. This is similar to observations in other studies.[85, 105]

The pharmacists felt that continuous professional development with respect to CAM therapies might assist in providing comprehensive patient counselling and information. A requirement in the GPP guidelines however is that any pharmacist (and their staff) selling complementary medicines must be trained in them. Provision of information to patients about CAMs must not include claims which are misleading or speculative. Clearly none of the pharmacists in this small sample met these standards. It should be noted that the 2008 version of GPP standards contains exactly the same requirements. The only reference to traditional medicines in the SAPC's GPP standards appears in clause 2.25.1(h)(i) where it is stated that as part of a patient's information / database, a complete medicine history including "all prescription medicines, non-prescription medicines, medication obtained from friends and family members, use of home remedies or *traditional* medicine, vitamins, natural and homeopathic remedies."

Olatunde *et al*., highlighted an ethical predicament of the pharmacists selling natural health products even when they do not have enough knowledge to answer questions on their safety and efficacy.[234]

Three of the pharmacists remained neutral when they were asked whether selling CAMs was more of a business decision than a healthcare decision with two of them not commenting on their choice. This "non" response may have been so that it does not reflect negatively on their profession, and they probably saw it best not to comment. P2's response that some pharmacists do sell CAMs purely for business was similar to the findings by Olatunde *et al*.[234] that suggested that pharmacists generated income from consumer demand for natural products. Pharmacist P4 however strongly disagreed with the statement that selling CAMs was more of a business decision than a healthcare decision. The reason given for this response that "professionalism (of the pharmacist) is

still important" seems to contradict this pharmacist's behaviour whose response when asked about providing "patients" with information on the use and effectiveness of CAMs, was "not usually".

5.2.3 Limitations of community pharmacists' phase of the study

Limitations to this part of the study include:

- A non-validated instrument (questionnaire) was used as the researcher was not aware of any validated instruments that could have been used. This is a limitation of many survey instruments as only a few survey tools have been validated.[154] This issue is compounded in South Africa where instruments are often not validated for comprehension rather than just language (i.e. accurate translation) of the research population (although all the pharmacists interviewed were English speaking).

- The results are not generalisable to any other pharmacists since the convenience sample measured only four community pharmacists working in Grahamstown.

- The possibility that incorrect interpretations of the answers were made.

CHAPTER SIX

CONCLUSIONS, RECOMMENDATIONS AND REFLECTIONS

6.0 Conclusion

The widespread use of TCAM in pregnancy indicates the need for documentation about their efficacy, safety and the need to establish TCAM pregnancy registries. Bridging the gap between the women's perceived needs and those of the care providers is a challenge. Traditional practices are likely to remain part of the women's practices particularly as these are influenced by cultural beliefs and values. There was no evidence of adverse effects experienced by the women and those of their babies due to ingestion of traditional / herbal medicines. However this does not mean that all such preparations are safe. People using them should be carefully monitored especially when they are pregnant. Healthcare providers should question pregnant women in a manner that is non judgemental about the use of TCAMs and not ridicule them for using it. They should try to incorporate an understanding of the women's beliefs and practices into the western healthcare system for the benefit of the women and their babies. This might allow women to be more comfortable and more open to freely letting healthcare professionals know which TCAMs they are using and what they are for. Creating a platform for the documentation of their risks and benefits might then be possible. This may help the providers become better equipped to advise pregnant women about which TCAMs to avoid and which ones they can continue taking if they wish to do so. People should be careful of the herbal / traditional remedies that they take and also be cautious of the sources of their remedies as some sources may be counterfeit and adulterate their remedies with substances that could continue to be harmful to people ingesting them.

Pharmacists feel and accept that it is part of their professional responsibility to counsel patients on CAMs as well as to educate them and provide information on it. Due to the increase in CAMs use, CAMs education during pharmacists' training as well as continued professional development education programmes in CAMs for practising pharmacist should be encouraged. They need to know what the CAMs are used for, claims, adverse effects, efficacy, benefits and risks – especially in pregnancy. This will make it possible for pharmacists to be more confident when counselling patients with

respect to CAMs. Evidence of the effectiveness of CAM therapies should be documented in order to have reliable CAM sources and CAM products should be properly registered and regulated. The good pharmacy practice guidelines in South Africa should be revised with regard to pharmacists checking whether or not women are pregnant or planning to become pregnant before providing them with CAMs.

6.1 Recommendations

6.1.1 Recommendations for healthcare service delivery and policy makers

- Serious consideration must be given to setting up TCAMs pregnancy registers.
- Healthcare professionals should constantly educate and remind women visiting their facilities and those in their surrounding areas of the importance of attending antenatal care rendered by trained health personnel. This could be done by conducting discussions with the patients at the clinics and hospitals as they wait in waiting areas to be attended to as well as by using written information in the form of educational posters and patient information leaflets as done with other conditions like TB, cholera etc.
- The trend for pregnant women to seek help only when they think there is a problem should be overturned. Healthcare professionals should make them aware of the long-term benefits of routine check-ups as some complications can be prevented or lessened before they are severe. At the same time healthcare professionals must not turn pregnancy into a disease.
- Healthcare professionals should make pregnant women aware of the teratogenic effects of some medications as well as encourage them to avoid self medicating during pregnancy
- Pharmacists can raise awareness on various medications including CAMs through patient education programmes. This will help make those that are not aware that they can consult a pharmacist about their health matters that they can do so.

- There is a need to strengthen pharmacists' CAM knowledge due to the increased usage of CAMs by the public, the availability of CAMs at pharmacies and the potential interactions they could have with conventional medicines as well as potential benefits and teratogenicity in pregnancy. The pharmacist's role in the use of CAMs (and all medicines) in pregnancy or women wanting to become pregnant, should be more explicit in the Good Pharmacy Practice guidelines.

- Ensure copies are made of information from patient folders before these are sent back to storage as it is very difficult to find them for future reference after they have been returned.

- Continued professional education on CAMs should be mandatory for pharmacists in South Africa as it is one of the requirements in the Good Pharmacy Practice Guidelines of South Africa that pharmacists should be knowledgeable on their efficacy, appropriateness and possible adverse reactions due to drug-drug/food-drug interactions.

- Traditional health practitioners and western healthcare professionals should set up mechanisms to communicate with each other and address the issue of pregnancy and share information on the various methods of treating pregnant women's health conditions. (Traditional health practitioners could share information about the protective or cleansing rituals and medicines, and the rationale for their use.)

6.1.2 Recommendations for Future Studies

The findings from this study can be used to guide future research in similar fields as follows:

- Determining strategies to encourage more pharmacists to recognise and accept their responsibility in ensuring the safe use of CAMs

- Determining the contents of remedies taken by pregnant women. This will help determine which constituents of the remedies are safe or harmful and which are effective or ineffective

6.3 Researchers Reflections on the Research Process

In this section, I use the first person as it is a reflection of my experiences of the research course.

Choosing the research topic was challenging and I had to do a lot of background reading and consulting with my supervisor on the relevance of CAMs use during pregnancy in South Africa. After going through a lot of literature on the topic and the current affairs in the country, I was satisfied with its relevance to South Africa. I had never been exposed to nor done any qualitative research prior to this study and that was a challenge. It was not an easy challenge but I was determined to learn and apply it to my research study. Writing the research proposal gave me the opportunity to clarify my ideas and research methodology in order to achieve the research objectives.

After being granted ethics approval I recruited the study participants and I found it challenging recruiting the pregnant participants. Although I approached a lot of pregnant women, it took about six months to recruit a total of ten participants for this phase of the study.

Many of them did not fit the inclusion criteria and some just did not want to take part or hear about the study at all. I also realised that approaching the women in English intimidated them or made them uncomfortable. I was then informed that they considered it disrespectful for African people to approach them in English especially if they are younger. Since I can speak and understand basic Xhosa I would approach the women and greet them in Xhosa and it made a significant difference to how they responded and they were more willing to listen to what I had to say. Some of those that did not meet the inclusion criteria even discussed what they knew with regard to traditional medicines they know of that people used in pregnancy. Before getting into the details of my study, I let them know that Xhosa was not my first language and that all communication with respect to the study would be done in English and they seemed to not have a problem with this. I had to constantly remind them that I was not a person of authority and that I was a student doing research. I also had to reassure them that I was not going to discuss anything we spoke about with anyone. I did not ask for their real names as well which

made them comfortable too. This helped the participants open up and engage in more detailed conversation with me.

An interesting observation I made was that as I was recruiting the participants, the moment the other women saw other women opening up and talking to me, they also warmed up and spoke to me and vice versa.

The decision not to pay the participants was decided together with my supervisor. I did not want to promote inducement to participate in the study and preferred that they participate because of their own willingness. To those that agreed to participate in the study, I made sure that they did not incur out of pocket expenses due to participation and if they needed to communicate with me they would send a free "please call me" and I would phone them back. I did not want the participants to be inconvenienced in any way because of participating in this study which might result in them withdrawing from the study. Obtaining informed consent from the all the participants was not difficult.

Recruiting the pharmacists was without any problems but getting them to actually complete the questionnaires in time was difficult as they were constantly busy and I did not want to disrupt them while they were busy with patients. I had to handle each case differently when it came to the pharmacists completing the questionnaires.

Initially I found conducting the interviews challenging but after a couple of interviews I found it less challenging. What made it challenging was that regardless of the participants being able to communicate in English, some of the things they spoke about e.g. terminologies for remedies, sources of remedies and some supernatural illnesses had to be expressed in Xhosa or Afrikaans therefore I would have to probe to try and get them to describe in detail what they were saying and confirm it with published literature and the key informant.

Self administered questionnaires were deemed easy to fill in by the pharmacists, the only obstacle they highlighted was making the time to fill them in as fully as possible due to their busy schedules.

I found the overall research process challenging but it was interesting, exciting and a huge learning experience at the same time. Practical challenges had me decrease the initial number of pregnant participants from fifteen to ten due to the difficulty in finding willing participants that fitted the inclusion criteria. I had to familiarise myself with a lot of medical terms that I came across in the participants' medical records. In many ways the entire research process made me grow personally, as well as with regard to how to conduct research and the skills I have gained from it.

In closing: After listening to what the participants had to say during the interviews, I now have a better understanding of peoples' health decision making processes and how their cultures can have a huge influence on these. I now understand why they carry out certain practices when they are pregnant and understand their importance to them. The study also increased my awareness of how people will do everything possible to make sure that they do not have any complications in their pregnancies culturally, spiritually and medically. When it comes to interacting with patients or people that are seeking medical assistance, I learnt the importance of putting myself at their level as it helps them open up and feel free to say what they want. It is unnecessary to make it obvious that one is in authority as it tends to intimidate them resulting in the patients not receiving optimum care or a researcher obtaining only minimum information.

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APPENDICES

APPENDIX A

Maternity Facilities in the Public Sector in South Africa

1. Clinics

Here, patients have access to all components of health including promotion, prevention and management with referral to minor problems and ailments. The facilities available include [47]:

- antenatal care
- post natal checks
- syphilis screening
- breast feeding advice
- care for normal newborns

2. Community Health Centres

These provide complete obstetrics services for low risk mothers and their newborns with appropriate referral. The facilities available include [47]:

- antenatal care
- treatment of common problems during pregnancy
- post natal checks
- care for both normal and sick newborns
- emergency management of neonatal complications

3. District Hospital (Level 1)

These provide 24-hour services including obstetric services for high-risk pregnancies and deliveries. The facilities available for mothers and newborns at this level of care include [47]:

- caesarean section
- treatment of medical problems during pregnancy
- foetal monitoring
- resuscitation area
- management of minor problems
- promotion of breast feeding

- routine neonatal care
- emergency care of small/sick newborns
- immunisation and follow up care

4. Regional Hospital (Level 2)

These provide secondary care and co-ordinate delivery of care with other levels in the district and province. The facilities available for mothers and newborns at this level of care include [47]:

- antenatal, delivery and post partum services
- intensive care labour ward
- resuscitation area
- special nursery
- low care nursery

5. Tertiary Hospital (Level 3)

These provide tertiary care in a given province as well as nearby provinces which have no tertiary care facility.[47] The facilities available at this level for mothers and newborns include [47]:

- antenatal wards
- admission wards
- labour wards with monitoring equipment
- post natal ward
- intensive care
- resuscitation area
- special care nursery
- observation nursery
- parent room

APPENDIX B

Table B.9: Herbs used in Pregnancy and reasons why they should be used with caution

Herb	Reason for caution
Alder buckthorn (Rhamnus frangula)	Strongly purgative should not be taken in high doses or for long periods.
Angelica (Angelica archangelica)	A uterine stimulant in high doses, but quite safe as a culinary herb.
Anise and aniseed oil (Pimpinella anisum)	A uterine stimulant in high doses, but quite safe as a culinary herb; avoid using the oil entirely.
Bitter orange (Citrus aurantiam)	A uterine stimulant in high doses, but quite safe as a culinary herb or in moderate use.
Caraway (Carum carvi)	A uterine stimulant in high doses, but quite safe as a culinary herb.
Cascara sagrada (Rhamnus purshiana)	Strongly purgative so should not be taken in high doses or for long periods.
Celery seed and oil (Apium graveolens)	A uterine stimulant in high doses, but quite safe as a culinary herb.
Chamomile oil	The oil is a potent uterine stimulant to be avoided, but the dried or fresh herb is safe in moderation.
Chili (Capsicum spp)	Avoid high doses as they may lead to heartburn; can flavour breast milk when breast-feeding. Moderate culinary use is fine.
Cinnamon (Cinnamomum zeylanicum)	A uterine stimulant in high doses, but quite safe as a culinary herb; avoid the essential oil completely.
Cowslip (Primula veris)	Strongly purgative and a uterine stimulant in high doses.
Elder bark	Strongly purgative so should not be taken in high doses or for long periods.
Fennel and fennel oil	A uterine stimulant in high doses, but quite safe as a culinary herb; avoid using the oil entirely.
Fenugreek (Trigonella foenum-graecum)	A uterine stimulant in high doses, but quite safe as a culinary herb or during labour.
Garlic (Allium sativa)	Avoid high doses as they may lead to heartburn; can flavour breast milk when breastfeeding. Moderate culinary use is fine.
Gotu kola (Centella asiatica)	Possible uterine stimulant should be used in moderation for occasional teas only.
Jasmine oil	A uterine stimulant best reserved for childbirth to ease labour.
Korean ginseng (Panax ginseng)	Clinical reports suggest that high doses in pregnancy can lead to androgynous babies (caused by overstimulation of male sex hormones); use for short periods only.
Lavender (Lavendula argustifolia)	A uterine stimulant in high doses, but quite safe as a culinary herb or for moderate use.
Licorice (Glycyrrhiza glabra)	High doses can exacerbate high blood pressure; safe in moderation.
Lovage (Levisticum officinale)	A uterine stimulant traditionally used in slow and difficult labour; safe as a culinary herb.
Marjoram and marjoram oil (Origanum vulgare)	A uterine stimulant in high doses, but quite safe as a culinary herb; avoid using the oil entirely.
Motherwort (Leonurus cardiaca)	A uterine stimulant in high doses; best limited to the final weeks and during labour.

Myrrh (Commiphora molmol)	A uterine stimulant that may lead to premature contractions; avoid high doses.
Nutmeg and Nutmeg Oil	Inhibits prostaglandin production and contains hallucinogens that may affect the foetus; once erroneously regarded as an abortifacient. Safe in normal culinary use.
Oregano (Origanum X marjoricum; O. onites)	A uterine stimulant in high doses, but quite safe as a culinary herb; avoid using the oil entirely.
Parsley (Petroselinum crispum)	Uterine stimulant that may also irritate the foetus in high doses; safe in normal culinary use.
Passion flower (Passiflora incarnata)	A uterine stimulant in high doses; safe for moderate use.
Peppermint oil	A uterine stimulant; avoid the oil entirely, although low doses of the dried herb can be used.
Raspberry leaf (Rubus idaeus)	A uterine stimulant in high doses; best limited to the final six to eight weeks and during labour.
Rhubarb root (Rheum palmatum)	Strongly purgative so should not be taken in high doses or for long periods.
Rosemary and rosemary oil	A uterine stimulant in high doses; safe in moderation and normal culinary use. Avoid using the oil entirely.
Saffron (Crocus sativa)	A uterine stimulant in high doses; safe in normal culinary use.
Sage and sage oil	A uterine and hormonal stimulant in high doses, but quite safe as a culinary herb; avoid using the oil entirely.
Senna (Senna alexandrina)	Strongly purgative so should not be taken in high doses or for long periods.
Tea, black (Camellia sinensis)	Limit to two cups a day, as excess can lead to palpitations and increased heart rate.
Thyme oil (Thymus vulgaris)	Some reports claim that it acts as a uterine stimulant, though the research is disputed; the herb is quite safe in cooking.
Vervain (Verbene officinalis)	A uterine stimulant in high doses; best limited to the final weeks and during labour.
White horehound (Marrubium vulgare)	Reputed uterine stimulant; safe in moderation in cough drops.
Wood betony (Stachys officinalis)	A uterine stimulant in high doses; best limited to the final weeks and during labour.
Yarrow (Achillea millefolium)	A uterine stimulant in high doses; best limited to the final weeks and during labour.

Sources: Reference [146]

Table B.10: Herbs used in pregnancy and reasons why they should be completely avoided

Herb	Reason to avoid
Aloe Vera	The leaves are strongly purgative and should not be taken internally.
Arbor vitae (Thuja occidentalis)	A uterine and menstrual stimulant that could damage the foetus.
Autumn crocus (Colichicum autumnale)	Can affect cell division and lead to birth defects.
Barberry (Berberis vulgaris)	Contains high levels of berberine, known to stimulate uterine contractions.
Basil oil	A uterine stimulant; use only during labour.
Beth root (Trillium erectum)	A uterine stimulant; use only during labour.
Black cohosh (Cimicifuga racemosus)	May lead to premature contractions; avoid unless under professional guidance. Safe to use during childbirth.
Bloodroot (Sanguinaria canadensis)	A uterine stimulant that in quite small doses also causes vomiting.
Blue cohosh (Caulophyllum thalictroides)	A uterine stimulant to avoid unless under professional guidance. Safe to use during childbirth.
Broom (Cytisus scoparius)	Causes uterine contractions so should be avoided during pregnancy; in parts of Europe it is given after the birth to prevent blood loss.
Bugleweed (Lycopus virginicus)	Interferes with hormone production in the pituitary gland, so best avoided.
Clove oil	A uterine stimulant used only during labour.
Comfrey (Symphytum officinale)	Contains toxic chemicals that will cross the placenta; do not take internally.
Cotton root (Gossypium herbaceum)	Uterine stimulant traditionally given to encourage contractions during a difficult labour, but rarely used medicinally today.
Devil's claw (Harpagophytum procumbens)	Uterine stimulant, oxytocic.
Dong quai (Angelica polymorpha var. sinensis)	Uterine and menstrual stimulant, best avoided during pregnancy; ideal after childbirth.
False unicorn root (Chamaelirium luteum)	A hormonal stimulant to avoid unless under professional guidance.
Feverfew (Tanacetum parthenium)	Uterine stimulant; may cause premature contractions.
Golden seal (Hydrastis canadensis)	Uterine stimulant; may lead to premature contractions but safe during childbirth.
Greater celandine (Chelidonium majus)	Uterine stimulant; may cause premature contractions.
Juniper and juniper oil (Juniperus communis)	A uterine stimulant; use only during labour.
Lady's mantle (Alchemilla xanthoclora)	A uterine stimulant; use only in labour.
Liferoot (Senecio aureus)	A uterine stimulant containing toxic chemicals that will cross the placenta.
Mistletoe (Viscum album)	A uterine stimulant containing toxic chemicals that may cross the placenta.
Mugwort (Artemesia vulgaris)	A uterine stimulant that may also cause birth defects; avoid unless under

	professional guidance. Also avoid when breastfeeding.
American pennyroyal (Hedeoma pulegioides)	Reputed uterine stimulant to be avoided during pregnancy.
European pennyroyal (Mentha pulegium)	A uterine stimulant that may also cause birth defects; avoid unless under professional guidance. Also avoid when breastfeeding.
Peruvian bark (Cinchona officinalis)	Toxic; excess may cause blindness and coma. Used to treat malaria and given during pregnancy only to malaria sufferers under professional guidance.
Pokeroot (Phytolacca decandra)	May cause birth defects.
Pseudoginseng (Panax notoginseng)	May cause birth defects.
Pulsatilla (Anemone pulsatilla)	Menstrual stimulant best avoided during pregnancy; limited use during lactation.
Rue (Ruta graveolens)	Uterine and menstrual stimulant; may cause premature contractions.
Sassafras (Sassafras albidum)	A uterine stimulant that may also cause birth defects.
Shepherd's purse (Capsella bursa-pastoris)	A uterine stimulant; use only during labour.
Southernwood (Artemisia abrotanum)	A uterine stimulant that may also cause birth defects; avoid unless under professional guidance. Also avoid when breastfeeding.
Squill (Urginea maritima)	A uterine stimulant that may also cause birth defects.
Tansy (Tanacetum vulgare)	A uterine stimulant that may also cause birth defects.
Wild yam (Diascorea villosa)	A uterine stimulant to avoid unless under professional guidance; safe during labour.
Wormwood (Artemisia absinthum)	A uterine stimulant that may also cause birth defects; avoid unless under professional guidance. Also avoid when breastfeeding.

Sources: Reference [146]

APPENDIX C: RHODES UNIVERSITY ETHICS CLEARANCE

RHODES UNIVERSITY
Grahamstown • 6140 • South Africa

FACULTY OF PHARMACY
Tel: 046 603 8381 • Fax: 046 636 1205
P O Box 94, Grahamstown, 6140
e-mail: dean.pharmacy@ru.ac.za

19 November 2010

Dear Rudo Mupfumira

RE: ethical approval by the Faculty of Pharmacy's Ethics Committee

I am pleased to inform you that the Faculty of Pharmacy's Ethics Committee has approved your application for ethical approval for your research entitled:

Presumptive effects on the mother and on the baby of Traditional, Complementary and Alternative medicines taken during pregnancy; knowledge and attitudes of community pharmacists on the use of these medicines in pregnancy

Sincerely

C. Oltmann

Carmen Oltmann, PhD

Chairperson of the Faculty of Pharmacy's Ethics Committee

APPENDIX D: EASTERN CAPE DEPARTMENT OF HEALTH ETHICS CLEARANCE

Eastern Cape Department of Health

Enquiries:	Zonwabele Merile	Tel No:	040 608 0830
Date:	17th December 2010	Fax No:	043 642 1409
e-mail address:	zonwabele.merile@impilo.ecprov.gov.za		

Dear Ms R Mupfumira

Re: Presumptive effect on the mother and on the baby of Traditional, Complementary and Alternative medicines taken during pregnancy, knowledge and attitudes of community pharmacists on the use of these medicines in pregnancy

The Department of Health would like to inform you that your application for conducting a research on the abovementioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

DEPUTY DIRECTOR: EPIDEMIOLOGICAL RESEARCH & SURVEILLANCE MANAGEMENT

APPENDIX E

Pregnant Participants' Information Leaflet

Title: Presumptive effects on the mother and on the baby of Traditional, Complementary and Alternative medicines taken during pregnancy; knowledge and attitudes of community pharmacists on the use of these medicines in pregnancy

Principal Investigator: Miss R. Mupfumira

Supervisor: Dr M.R. Jobson

Introduction

My name is Rudo Mupfumira. I am a Masters student from the Faculty of Pharmacy at Rhodes University. I am asking you to please take part in my research study which involves finding out the effects that the use of Traditional and/or Complementary and Alternative Medicines during pregnancy may or may not have on yourself and/or the baby. This consent form gives you information about my research. Once you have read and understood the contents please ask me any questions before you agree to participate in this study. If you agree to participate I will then ask you to sign this form. After signing this form, you will keep this form and I will keep a copy.

The purpose of the study (why?)

The purpose of the study is to find the reasons why pregnant women choose to use complementary or traditional medicines and to document whether any adverse events following the use of the medicines has occurred in the women or were associated with adverse pregnancy outcomes. Your contribution could be helpful to you and to other pregnant women as well as your baby and their babies.

I am looking for pregnant women in the last month of pregnancy:

- who have taken complementary or traditional medicines at any stage of pregnancy or
- who are taking complementary or traditional medicines at present
- who have normal uncomplicated pregnancy
- who are above 18years of age
- who are able to provide informed consent and communicate and understand English

What you will need to do if you agree

I will ask to come to your home so that I can ask you questions about the medicines you took or are taking during your pregnancy. I will also ask you to show me these medicines and ask you to tell me how you take them and what you take them for. I will also ask to see any medical records you keep. After your baby is born I will visit you again to ask about your baby and see any medicines you are giving it, and ask to see its health card.

Privacy

All the information I find out from you will be kept private i.e. I will not tell anyone what you show or tell me.

Your rights

You have the right to leave the study at anytime. If you do decide to do so please tell me.

Compensation

You will not be paid any money to participate in this study.

No out of pocket expenses will be paid back to you unless this has been discussed with and agreed to by the principal investigator. The principal investigator will first obtain clearance from the supervisor before committing to any payments.

In the event that you want to contact me, the principal investigator, you can send a free “call me back” to me and I will phone you back.

If you have decided to take part in this study please sign the consent form. Thank you for taking your time to read through this.

Questions

If you have any queries or concerns about this or about the study at any stage, my supervisors’ details are as follows:

Prof M.R. Jobson

Faculty of Pharmacy, Rhodes University

Tel: 046 603 8070

Fax: 046 636 1201

Email: R.Jobson@ru.ac.za

Consent Form

I, Rudo Mupfumira confirm that this information will remain confidential (private).

Signature: _____

Date: _____

I, _____ would like to participate in the study. I give you permission to come to my home and see the medicines that I have taken or am taking during my pregnancy. I also give you permission to access my baby's information after it is born.

I understand that all the information I will give you will be kept private.

Signing this document indicates that I have read and understood the research and that I also know that I may withdraw from this study at anytime without any consequences to me.

Signature: _____

Witness: _____

Date: _____

APPENDIX F

Consent Form for Pharmacists

Title: Presumptive effects on the mother and on the baby of Traditional, Complementary and Alternative medicines taken during pregnancy; knowledge and attitudes of community pharmacists on the use of these medicines in pregnancy

Principal Investigator: Miss R. Mupfumira

Supervisor: Dr M.R. Jobson

Introduction

My name is Rudo Mupfumira. I am a Masters student from the Faculty of Pharmacy at Rhodes University. I am asking you to please take part in my research study which involves finding out the possible effects that the use of Traditional and/or Complementary and Alternative Medicines during pregnancy may have on the mother and on the baby; and the knowledge and attitudes of community pharmacists on their use. This consent form gives you information about my research. Once you have read and understood please ask me any questions before you agree to participate in this study. If you agree to participate I will ask you to sign this form. After signing this form, you may keep the form and I will keep a copy.

The purpose of the study (why?)

The purpose of the study is to find some of the reasons pregnant women choose to use traditional, complementary and alternative medicines and to document whether the possibility of any adverse events which may be associated with the use of the medicines has occurred in the women or were associated with adverse pregnancy outcomes. It is also to determine some of the knowledge and attitudes of community pharmacists on the use of these medicines, including their use in pregnancy.

Only community pharmacists working in Grahamstown will participate in the study.

What I will ask you to do

I will make an appointment with you and will ask you to fill in a short questionnaire on traditional, complementary and alternative medicines. The questionnaire will be short and I will wait while you complete it. It should not take too much of your time. After you complete the questionnaire I will then take it with me.

Privacy

All this will be kept confidential. Only the Principal Investigator will know your name and it will not be linked to the questionnaire nor will it appear in the write up of the study or any subsequent publications. No identifying description of the pharmacy you work in will be included.

Your rights

You have the right to withdraw from the study at anytime without giving reasons. If you do decide to do so please tell me, and I will remove your information from the study data.

Compensation

You will not be paid to participate in this study.

If you have decided to participate please sign this form. Thank you for taking your time to read through this.

Questions

If you have any queries or concerns about the study at any stage, my supervisors' details are as follows:

Prof M.R. Jobson

Faculty of Pharmacy, Rhodes University

Tel: 046 603 8070

Fax: 046 636 1205

Email: R.Jobson@ru.ac.za

Consent

I, _____ agree to participate in the study: 'Presumptive effects on the mother and on the baby of Traditional, Complementary and Alternative medicines taken during pregnancy; knowledge and attitudes of community pharmacists on the use of these medicines in pregnancy'. I give you permission to make an appointment and wait for me to fill in the questionnaire.

I understand that all the information I will give you will be kept confidential.

Signing this document indicates that I have read and understood the research and that I also know that I may withdraw from this study at anytime without any consequences to me.

Signature: _____

Witness: _____

Date: _____

I, Rudo Mupfumira confirm that this information will remain confidential (private).

Signature: _____

Date: _____

APPENDIX G

Key Informants' Information Leaflet

Title: Presumptive effects on the mother and on the baby of Traditional, Complementary and Alternative medicines taken during pregnancy; knowledge and attitudes of community pharmacists on the use of these medicines in pregnancy

Principal Investigator: Miss R. Mupfumira

Supervisor: Dr M.R. Jobson

Introduction

My name is Rudo Mupfumira. I am a Masters student from the Faculty of Pharmacy at Rhodes University. I am asking you to please take part in my research study which involves finding out the effects that the use of Traditional and/or Complementary and Alternative Medicines during pregnancy may or may not have on yourself and/or the baby. This consent form gives you information about my research. Once you have read and understood the contents please ask me any questions before you agree to participate in this study. If you agree to participate I will then ask you to sign this form. After signing this form, you will keep this form and I will keep a copy.

The purpose of the study (why?)

The purpose of the study is to find the reasons why pregnant women choose to use complementary or traditional medicines and to document whether any adverse events following the use of the medicines has occurred in the women or were associated with adverse pregnancy outcomes. As the key informant, you will be asked to describe your experiences and knowledge as well as your perceptions relating to the above topic based on your experience in living and working with women that have taken Traditional, Complementary and Alternative medicines during their pregnancy.

What you will need to do if you agree

You will be asked to complete an interview. The interview will be audio taped and transcribed by the researcher for data analysis. The interview will be conducted at a setting mutually agreed by you and the researcher.

Privacy

All the information I find out from you will be kept private i.e. I will not tell anyone what you show or tell me.

Your rights

You have the right to leave the study at anytime. If you do decide to do so please tell me.

Compensation

You will not be paid any money to participate in this study.

No out of pocket expenses will be paid back to you unless this has been discussed with and agreed to by the principal investigator. The principal investigator will first obtain clearance from the supervisor before committing to any payments.

In the event that you want to contact me, the principal investigator, you can send a free “call me back” to me and I will phone you back.

If you have decided to take part in this study please sign the consent form. Thank you for taking your time to read through this.

Questions

If you have any queries or concerns about this or about the study at any stage, my supervisors’ details are as follows:

Prof M.R. Jobson

Faculty of Pharmacy, Rhodes University

Tel: 046 603 8070

Fax: 046 636 1201

Email: R.Jobson@ru.ac.za

Consent Form

I, Rudo Mupfumira confirm that this information will remain confidential (private).

Signature: _____

Date: _____

I, _____ would like to participate in the study. I give you permission to come to conduct the interview with me at a mutually agreed setting.

I understand that all the information I will give you will be kept private.

Signing this document indicates that I have read and understood the research and that I also know that I may withdraw from this study at anytime without any consequences to me.

Signature: _____

Witness: _____

Date: _____

APPENDIX H

Community Pharmacists' Questionnaire

Title: Presumptive effects on the mother and on the baby of Traditional, Complementary and Alternative medicines taken during pregnancy; knowledge and attitudes of community pharmacists on the use of these medicines in pregnancy

Thank you for taking your time to read through and complete this questionnaire.

Definitions:

CAM- Complementary and Alternative Medicines

MCC- Medicines Control Council

TCAM- Traditional or CAM

Traditional Medicines- medicines supplied by traditional healers

1. SECTION 1
(*Circle responses where applicable*):

1.1. Approximately how many patients from the public sector are you aware of, who purchase medicines from this pharmacy in a week?
_____

1.2. Where do you obtain **most** of your information about CAMs and Traditional medicines?
(*circlethe applicable word/phrase i.e. choose only one*):
Media Friends/Family Internet TCAM Literature Sales Promoters Doctors

Books Pharmacists Journals

Other (specify):_____

1.3. I have noticed that you sell CAMs over the counter in your pharmacy. How do you select which CAMs to sell at your pharmacy?
_____
_____
_____
_____

1.4. Were you trained in the use of CAMs? Y/N

1.5. If you answered yes to 1.4., when did you undergo training and who conducted it?
_____
_____
_____

1.6. How effective do you think CAM treatment is?

Not at all effective	Somewhat effective	Very effective

Comment:
_____
_____

_____
_____

1.7. Do you give patients buying CAMs information on its use and effectiveness? Y/N

Comment:

_____
_____
_____
_____

1.8. Are the CAMs you sell registered with the MCC? Y/N/I don't know

1.9. Do you support the use of CAMs by the public? Y/N/Neutral

Comment:

_____
_____
_____
_____

1.10. Do you support the use of CAMs by pregnant women? Y/N/Neutral

Comment:

_____
_____
_____
_____

1.11. For female patients buying medicines, do you ask whether they are, or could be pregnant before the medication is purchased? Y/N

Comment:

_____
_____
_____
_____

2. SECTION 2

Please indicate whether the statements below are correct/ incorrect, by circling the appropriate answer in the boxes below, giving your reasons for each where applicable.

2.1. Herbal medicines are natural and therefore mostly safe and without serious side effects.

Correct	Incorrect	"I don't know"
1	2	3

Reasons:

_____
_____
_____

2.2. St Johns Wort (medicinal formulation) is a natural herbal therapy.

Correct	Incorrect	"I don't know"
1	2	3

Reasons:
_____
_____
_____

2.3. St Johns Wort is effective in treating mild to moderate depression in pregnancy.

Correct	Incorrect	"I don't know"
1	2	3

Reasons:
_____
_____
_____

2.4. An adverse drug effect of St. John's Wort is photodermatitis.

Correct	Incorrect	"I don't know"
1	2	3

Reasons:
_____
_____
_____

2.5. Ginger (medicinal formulation) is effective in treating nausea and vomiting in pregnant women.

Correct	Incorrect	"I don't know"
1	2	3

Reasons:
_____
_____
_____

2.6. Feverfew (medicinal formulation) is safe for use in pregnant women.

Correct	Incorrect	"I don't know"
1	2	3

Reasons:

_____
_____
_____

3. SECTION 3

To what extent do you agree with the following statements? Indicate your responses on a scale of 1 (strongly disagree) to 5 (strongly agree), make an 'X" in the appropriate box, giving your reasons for each.

3.1. It is important for patients to have a basic understanding of TCAMs before using them.

Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

Reasons:

_____
_____
_____

3.2. Pharmacists' training should place greater emphasis on education in CAM therapies.

Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

Reasons:

_____
_____
_____

3.3. Providing information about herbal medicine is not part of a Pharmacist's professional responsibility.

Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

Reasons:

_____
_____
_____

3.4. Providing information about herbal medicine is part of a medical doctor's professional responsibility.

Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

Reasons:

_____
_____
_____

3.5. It is essential for patients to consult a registered healthcare professional before using TCAM therapies?

Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

Reasons:

_____
_____
_____

3.6. Continuing education on TCAMs should be mandatory for Pharmacists.

Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

Reasons:

_____
_____
_____

3.7. Providing TCAMs to patients is more of a business decision than a healthcare decision.

Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

Reasons:

_____
_____
_____

Thank you for your time, participation and contribution to this study.

APPENDIX I

Pregnant Participant's Interview

- Confirm the identity/code number of the participant
- Good morning/afternoon, thank you for allowing me to interview you. As I told you when we first met, I am Rudo Mupfumira, a Masters student at Rhodes University from the Pharmacy Faculty.
- (*re-explain the purpose of my research as well as the contents of the consent form with the participant*)
- Ask for health passport at the end of the interview

Date patient first seen during this pregnancy: _____

1. PATIENT DEMOGRAPHICS

1.1.Respondent Number: ☐

1.2. Months/weeks of pregnancy: _____

1.3. Estimated date of delivery: _____

1.4. Patient Age: _____

1.5a. Have you ever gone to the clinic/doctor to get this pregnancy checked by the nurses/doctor (antenatal visits)? Y/N

1.5b. If yes, how many times? _____

1.5c. Who told you to go for these check ups?

_____
_____
_____
_____

1.6a. Was there any abnormal result from any of the tests done at these check ups? Y/N

1.6b. If yes, please give details_____

2. EMPLOYMENT DETAILS

2.1. Are you employed? /Do you work? Y/N **(If yes skip 2.2a and b)**

2.2a. If no, is there some form of family income coming in? Y/N

2.2b. If yes, what type of income do you get? **Salary/Pension/Grant/Other**

3. EDUCATION DETAILS

3.1. What grade or standard did you finish at school? _____

3.2. What other education do you have if any other, please specify

_____

4. BELIEFS AND ATTITUDES

4.1a. Pregnant women may fall sick. Where do you think a sick pregnant woman should go to seek help on their sickness?

_____
_____
_____
_____

4.1b. Why do you think this?

_____
_____
_____

4.2. Do you think it is necessary for anybody taking traditional/herbal medicines to tell the nurses, doctors or pharmacists that they are taking these medicines? Y/N

4.3a. Do you think it is necessary for a pregnant woman who is taking traditional/herbal medicines to tell the nurses, doctors or pharmacists that they are taking these medicines? Y/N

4.3b. Why do you think this? (With respect to a pregnant woman)

_____
_____

4.4a. When people tell nurses, doctors or pharmacists that they are taking traditional/ herbal medicines, do you think they get treated rudely/without respect? Y/N

4.4b. Why do you think this?

_____
_____
_____

5. BEHAVIOUR

5.1a. Do you know of anyone who has gone to see a traditional healer/sangoma during their pregnancy? Y/N

5.1b. What for?

_____
_____

5.1c. Did it help? /Did it do any damage (if it did not help)?

_____
_____
_____

5.2a. Do you know of anyone who was given traditional/herbal medicines during their pregnancy by their family? Y/N

5.2b. What for? _____

5.2c. Did it help? / Did it do any damage (if it did not help)?

_____
_____
_____

5.3a. Herbs/Traditional and Natural medicines have been used for years, long before we were even born. They are still being used in this day and age. Have you ever used any of them during this pregnancy? Y/N

5.3b. If yes: Can you explain why you used them? If no: Can you explain why you did not use them?

_____
_____
_____

5.3c. Where did you get them? _____

5.3d. How many months of your pregnancy was this? _____

5.3e. Are you still taking them? Y/N

5.3f. How much did/do you use? _____

5.3g. How often do you use them?

_____
_____
_____

5.4a. Would you tell a nurse, doctor or pharmacist that you are taking herbal medicines, if you are? Y/N

5.4b. Reasons

_____
_____
_____

5.5a. Are you currently /have you taken any modern medicine during your pregnancy? Y/N

5.5b. List them and what are/were they for? (*At this point check medical records if available)*

Name of medicine	Indication	Stage of pregnancy

6. KNOWLEDGE

Do you agree or disagree with the following statements? Giving reasons for each:

6.1a. Traditional/herbal/natural medicines are more helpful than those from the clinic/hospital.

YES	NO	THE SAME	I DON'T KNOW

6.1b. Reasons

_____

_____

6.2a. ALL Traditional/herbal/natural medicines are safe to use during pregnancy.

YES	NO	I DON'T KNOW

6.2b. Reasons

_____

_____

6.3a. Traditional/herbal/natural medicines cannot hurt the unborn baby.

YES	NO	I DON'T KNOW

6.3b. Reasons

_____

_____

6.4a. Modern medicine cannot hurt the unborn baby.

YES	NO	I DON'T KNOW

6.4b. Reasons

_____

_____

Thank you for your time; this is the end of the first interview. I will see you again after you give birth for the second interview. Could you or someone else SMS or send me a "Please call me" on the day the baby is born. All the best for the last few weeks of your pregnancy, please keep well. Thank you once again.

APPENDIX J

Pregnancy Outcomes Data Sheet

Patient Code Number: _____

Outcome:	Live Infant	Abortion Spontaneous	Abortion Induced	Fresh Stillbirth	Mascerated Stillbirth
Method of delivery:					
Complications:					

APGAR ASSESSMENT

APGAR	**0**	**1**	**2**	**1min**	**5min**
Heart Rate	Absent	<100 beats /min	>100 beats/min		
Respiration	Absent	Weak cry, slow and irregular Respiration <20 min	Good cry		
Muscle tone	Limp	Some flexion of extremities	Active motion, good flexion of extremities		
Response to stimulation	No response	Grimace	Cry, cough, sneeze or urinate		
Colour	Blue or pale	Body pink, extremities blue	Completely pink		
			APGAR Score		

ANAESTHESIA

General	Regional	Epidural	Spinal	Saddle	Combination	Local	Perineal	Pudendal
Details:								

ASSESSMENT OF NEWBORN

D.O.B:		
Gestational Age (weeks):		
Resuscitation:	None required	Required
Details:		
Weight (g):		
Length (cm):		
Head Circumference (cm):		

PHYSICAL ASSESSMENT

General	Well	Sick		General	Well	Sick
Heart rate	120-160/min	<120/min	>160/min	**Legs**	Normal	Less than normal
Respiratory rate	40-60/min	Fast>60/min	Slow<40/min	**Feet**	Normal	Clubbed
Breath sounds	Quiet	Grunting	Noisy	**Toes**	Normal	Abnormal
Abdomen	Normal	Distended	Hepatomegaly	**Arms**	Normal	Not moving
	Scaphoid	Splenomegaly				Fracture
Skin	Intact	Jaundice	Rash	**Fingers**	Normal	Abnormal
		Bruising	Purpura	**Mouth**	Normal	Cleft
Cry	Normal	Hoarse	Absent	**Palate**	Normal	Cleft
		High-pitched		**Tongue**	Normal	Large
Umbilicus	Normal	Moist	Mec.Stained			Protruding
		Red	Bleeding	**Muscle tone**	Normal	Hypertonic
						Hypotonic
				Meconium	Passed	Not passed
				Eyes	Normal	Abnormal
				Reflexes	Normal	Abnormal

PLACENTA

Placenta	Normal	Abnormal	Complete	Incomplete	Meconium Staining Present	Y	N
Details:							

Birth defects detected: Y/N

If yes, list:

_____
_____
_____

End of data collecting sheet

APPENDIX K

The Health Belief Model (HBM)

Introduction

The Health Belief Model is a psychological theoretical model that attempts to describe and predict human health behaviour. [202-203] It is commonly used in health education and health promotion.[202]

Constructs of the HBM

The main constructs of the HBM:

i) perceived seriousness; ii) perceived susceptibility; iii) perceived benefits and iv) perceived barriers can be used individually or in combination to describe human health behaviour.[202]

The model has been expanded by the addition of three more constructs namely:

v) cues to action; vi) motivating factors and vii) self-efficacy.[202, 203]

Table K.1 shows the Health Belief Model Constructs Chart.

Table K.1: Health Belief Model Constructs [202-204]

Construct	Description
Perceived Susceptibility	An individual's opinion of the chances of getting a condition.
Perceived Severity	An individual's judgement of how serious a condition is and its consequences.
Perceived Benefits	An individual's conclusion as to whether the new behaviour is better than what he/she is already doing.
Perceived Barriers	An individual's opinion as to what will prevent him/her from adopting the new behaviour.
Modifying Variables	An individual's personal factors that affect whether or not the new behaviour is adopted.
Cues to Action	Factors that will activate the individual's way to do something.
Self-Efficacy	Confidence/ Personal belief in ones own ability to do something.

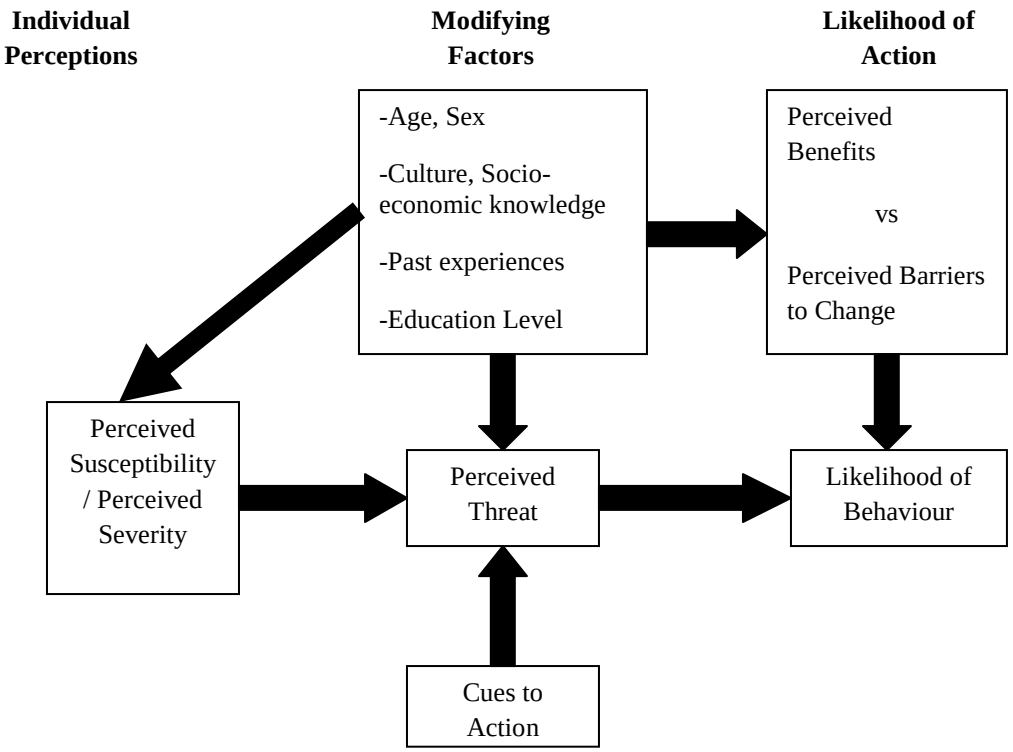

Figure K.1: The Health Belief Model [202, 203]