ASSESSMENT OF RISK OF DRUG EXPOSURE IN EARLY PREGNANCY IN WOMEN IN A RURAL COMMUNITY IN MALAWI

A THESIS SUBMITTED TO THE UNIVERSITY OF MANCHESTER FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN THE FACULTY OF MEDICAL AND HUMAN SCIENCES

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SCHOOL OF NURSING, MIDWIFERY AND SOCIAL WORK
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<td>Artemisinin Combination Therapies</td>
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<tr>
<td>AIDS</td>
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<tr>
<td>AL</td>
<td>Artemether-lumefantrine</td>
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<tr>
<td>CHAM</td>
<td>Christian Health Association of Malawi</td>
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<td>DHMT</td>
<td>District Health Management Team</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>GNP</td>
<td>Gross National Product</td>
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<td>GVH</td>
<td>Group Village Headman</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>HSAs</td>
<td>Health Surveillance Assistants</td>
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<td>ITNs</td>
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<td>KCH</td>
<td>Kamuzu Central Hospital</td>
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<td>MDHS</td>
<td>Malawi Demographic and Health Survey</td>
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<td>MCH</td>
<td>Mitundu Community Hospital</td>
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<td>OTC</td>
<td>Over-the-counter</td>
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<td>SP</td>
<td>Sulphadoxine-pyrimethamine</td>
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<td>TA</td>
<td>Traditional Authority</td>
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<td>TBA</td>
<td>Traditional Birth Attendants</td>
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<td>UNDP</td>
<td>United Nations Development Programme</td>
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<td>UNFPA</td>
<td>United Nations Population Fund</td>
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<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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ABSTRACT
THE UNIVERSITY OF MANCHESTER

ABSTRACT OF THE THESIS submitted by Ezereth Susan Kabuluzi for the degree of Doctor of Philosophy entitled ‘Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi’

April 2012

Introduction: Medication use by women of childbearing age is common. During pregnancy, medications should be used cautiously because some are teratogenic and/or feto-toxic, especially during the first trimester. Few studies have assessed exposure to contraindicated medications in developing countries.

Aims and objectives: The overall aim was to assess the risk of exposure to contraindicated medicines in early pregnancy (less than 13 weeks gestation) in Malawi. Specific objectives were to (i) determine the proportion of women inadvertently prescribed contraindicated medicines in the first trimester of pregnancy in a general outpatient clinic; (ii) explore women’s beliefs, views and practices concerning medication use during pregnancy; (iii) determine the prevalence of congenital abnormalities by review of records at community and central hospital sites; (iv) to make appropriate recommendations for policy and practice in Malawi relating to medication use in pregnancy.

Methods: A mixed methods approach was used. Survey data were collected at an outpatient clinic at Mitundu Community Hospital (MCH) between 1st February 2010 and 30th July 2010 to determine the range of medicines taken by potentially pregnant women. A pregnancy test established the pregnancy rate in this group. These data were summarised using descriptive and inferential statistics, and the proportions of exposed women who were pregnant were estimated. To understand women’s beliefs, views and practices, semi-structured interviews were held with 21 pregnant women at their first visit to an antenatal clinic at MCH. The main themes were identified by Framework analysis. Retrospective data were abstracted from birth registers at MCH and Kamuzu Central Hospital (KCH) to estimate the prevalence of congenital abnormalities.

Results: Of 1103 women prescribed contraindicated medicines in the outpatient clinic, 272 were potentially pregnant. Of the 63 (23.2%) confirmed pregnant (95% CI 18.3%-28.6%), 20 knew or thought they were pregnant, 22 were not sure and 21 did not think they were pregnant. Only 153 (55.9%) were asked about pregnancy by a medical officer before prescription. 3.2% of all pregnant women (95% CI 2.5%-4.1%) attending the clinic were estimated to have been prescribed contraindicated medicines. Eight pregnant women also self-prescribed unsuitable modern medications. Women accepted as safe any medications prescribed in the clinic. They also accepted potions given by traditional birth attendants to counter witchcraft, which they believed caused pregnancy loss. They did not associate use of these medicines with congenital abnormalities, the prevalence of which (6.58/1000 births at MCH, 14.55/1000 births at KCH) was similar to international figures.

Conclusion: The study highlights areas of concern for practice, policy and research relevant to maternal health care in Malawi. Clinicians need to reduce the rate of exposure to potentially harmful medicines by paying attention to the possibility of pregnancy in women of childbearing age. There is also a need to facilitate public awareness especially among women about dangers of taking medicines.
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DEDICATION
This work is dedicated to my husband Storn, my children Tamanda and Mayamiko-Gibson.
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In 2008, she was awarded a Commonwealth Scholarship for three years to pursue a PhD course at the University of Manchester.
CHAPTER 1
INTRODUCTION AND BACKGROUND OF THE STUDY

1.1 Introduction
This chapter presents the background and aims of the study. It also describes the study context, Malawi. The structure of the thesis is also presented.

1.2 Background of the study
Medication use among women of childbearing age is common. This means that medicines could be taken by women who could be pregnant (or may become pregnant) at the time of medication use. Women may require medicines to treat pre-existing medical conditions, incidental illness or disorders which are associated with pregnancy. Early accidental medication exposure during pregnancy or intentional medication treatment of pregnant women is of concern because use of certain medicines in pregnancy can lead to congenital abnormalities in the foetus and other harmful effects. Concern about the safety of medicines prescribed to pregnant women has been increasingly evident since the thalidomide tragedy in the 1960s (Koren et al., 1998). This made the world aware of the difficulties of medication use in women. Thalidomide was used in the treatment of different disorders such as anxiety, insomnia, gastritis and tension; it was furthermore promoted as a safe anti-emetic medication during pregnancy (Miller and Strömland, 1999). The medicine was withdrawn from the market a few years after its introduction due to severe teratogenic effects including limb defects, ear malformations and/or hearing loss, ocular anomalies and other anomalies (Diggle, 2001; Miller and Strömland, 1999). The occurrence of the defects made medical professionals realise that medicines have the potential to cross the placenta and harm the developing foetus. A major function of the placenta is to enable the transfer of oxygen and nutrients from the mother to the foetus, and to eliminate metabolic waste products from the foetus (Enders and Blankenship, 1999; Ganapathy et al., 2000). Transplacental transfer involves passive transfer, active transport, facilitated diffusion, phagocytosis and pinocytosis (Syme et al., 2004). Almost all medicines taken by a woman during pregnancy have the potential to enter the foetal circulation. Most medicines cross the placenta mainly by passive diffusion (Myllynen et al., 2005; Syme et al., 2004).
1.2.1 An overview of congenital abnormalities

Congenital abnormalities can be caused by genetic, environmental and a combination of genetic and environmental factors (Beckam and Brent, 1984; De Santis et al., 2001; Kalter, 2003). It has been estimated that for all congenital abnormalities, 25% are of genetic or chromosomal origin; 10% are of known environmental origin, including medicine exposure; and 65% are of unknown aetiology (De Santis et al., 2001; Rubin, 1995). Congenital abnormalities caused by human teratogenic medicines account for approximately 1% of total congenital abnormalities.

Major congenital malformations occur in approximately 2-3% of all pregnancies, placing a considerable burden on the affected child, the family and society (Kalter, 2003). About 7% of all neonatal deaths worldwide are caused by congenital abnormalities (WHO, 2008a). Although congenital anomalies account for a smaller percentage of deaths of neonates and infants aged 1–59 months in middle-income and low-income countries than in the wealthiest countries, more than 95% of all child deaths due to congenital anomalies occur in these settings. Thus congenital anomalies affect all countries and represent a significant challenge to public health globally (WHO, 2009). However, the background prevalence rate for congenital abnormalities in the developing countries is unknown. In many developing countries, birth defects registries are absent and the health care services, from antenatal through obstetric to postnatal and adolescent health care, are challenged with fundamental gaps in the understanding, prevention and treatment of congenital anomalies (Ndibazza et al., 2011). Without comprehensive data on congenital anomalies in this region, it is difficult to evaluate possible teratogens and to institute comprehensive and effective prevention and care services.

1.2.2 Medication considerations during pregnancy

Despite the common belief that the use of medications should as much as possible be avoided in pregnancy, there are several conditions in which it is almost impossible to prevent medication use (Lyszkiewicz et al., 2001; Sachdeva et al., 2009). There might be chronic conditions which are already present before pregnancy, such as epilepsy, psychiatric disorders and HIV/AIDS, which need
continued treatment during pregnancy (McGowan and Shah, 2000; Sachdeva et al., 2009). There are also conditions which occur during pregnancy, such as nausea, diabetes mellitus and hypertension, which may also require treatment. Pregnant women may also develop acute illnesses which are short term and often self-limiting (e.g. infections) but which require treatment (Black and Hill, 2003; Niebyl, 2003). About 8% of pregnant women need permanent medication treatment due to various chronic diseases and pregnancy-induced complications (Banhidy et al., 2005). Therefore the benefit of medication therapy to the mother has to be weighed against the potential risk to the developing foetus. In addition, unnecessary use of medicines should be avoided and discouraged particularly if the medication is being used to treat symptoms that are non-life threatening or self-limited (Powrie and Kurl, 1999).

1.2.3 Prescription and non-prescription medication use

Several studies conducted in North America and Europe have found that medication use during pregnancy is common regardless of the country involved (Collaborative Group on Drug Use in Pregnancy, 1992). In contrast, very little data on use of medications in early pregnancy from developing countries are available. Given that almost 40% of pregnancies in Malawi are unintended (Malawi Demographic and Health Survey, 2010), medicines can be taken before the pregnancy is recognised by the mother, and exposure to medication may occur inadvertently in the early weeks of gestation which is the critical time of organ formation. It has been noted that the timing of exposure is crucial in relation to the development of congenital malformations (Briggs et al., 2008). The period of greatest teratogenic risk is the first trimester when organogenesis (organ formation) is taking place (Mitchell et al., 2011) although nervous system development continues throughout pregnancy and postnatally (Holmes et al., 2001; WHO, 2006). Although only a small proportion of medicines are known to be harmful to the foetus, there is still a paucity of evidence regarding foetal safety for a majority of medicines used during pregnancy (Malm et al., 2004). The lack of evidence is due to exclusion of women from clinical trials because of the risk of medication teratogenicity (Buhimschi and Weiner, 2009). The women are therefore excluded for ethical reasons.
Studies in developed countries have described a drug use prevalence of 27% to 99% in pregnancy with an average of 2.9–4.2 drugs per woman (Andrade et al., 2004; Bakker et al., 2006; Beyens et al., 2003; Garriguet, 2006; Henry and Crowther, 2000; Lacroix et al., 2000; Lagoy et al., 2005). The prevalence varies between these countries and studies due to differences in study design. The medicines which women take include both medications on prescription and over-the-counter medicines, which include vitamins and iron supplements (Donati et al., 2000; Jimenez et al., 1998; Koren et al., 1998; Schirm et al., 2004).

It is recommended that medicines should be used with caution both during pregnancy and in sexually active women of childbearing age who are not using adequate contraception (Vallance, 1996). However, despite various precautions, some accidental or unavoidable exposures to teratogens may still occur. Thus, when any woman of childbearing age is being prescribed a medication, the possibility of her being pregnant should always be considered, and should guide and inform the choice of medication. It should be possible to minimise the use of teratogenic medications during pregnancy (Andrade et al., 2006; Lee et al., 2006).

1.2.4 Use of traditional medicines

Apart from the modern medicines, the use of traditional medicines has also been reported especially from the developing world. According to the World Health Organization (WHO) (2002), traditional medicine includes diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied alone or in combination to maintain well-being, as well as to treat, diagnose or prevent illness. Traditional medicine is widely used. In Africa up to 80% of the population uses traditional medicine to meet their health care needs (WHO, 2002). In developing countries, the broad use of traditional medicine can often be attributed to its accessibility and affordability. Another reason for extensive use of traditional medicine in developing countries is that the use of traditional medicine is firmly embedded within wider belief systems (Wayland, 2004). However, the scientific effects of these medicines are unknown, especially in relation to their role in causing birth defects.
1.3 Research study context

The study was conducted in Malawi at Mitundu Community and Kamuzu Central Hospitals. A description of the hospitals is given in detail in chapter 4, Sections 4.2.1 and 4.7.1. This section will describe Malawi as a whole and delivery of health services.

1.3.1 Demographic and administrative characteristics

Malawi is a landlocked country in sub-Saharan Africa sharing boundaries with Zambia to the Northwest, Tanzania to the north and Northeast and Mozambique to the east, south and southwest. It has an area of 118,484 square kilometres of which 94,276 square kilometres is land (Malawi National Statistical Office, 2008). From north to south the country is 560 miles (896 kilometres) long and varies in width from 50 to 100 miles (80 to 160 kilometres). The country is divided into three administrative regions, namely the northern, central and southern regions (Figure 1.1). Malawi has 28 districts and each district is further divided into traditional authorities (TAs) which are ruled by chiefs. The village is the smallest administrative unit in Malawi and falls under TAs. In some villages, there are village health committees whose responsibility is to work with Health Surveillance Assistants (HSAs) on health issues at village level. HSAs are the lowest cadre employed by the Ministry of Health (MOH), are resident within communities and are attached to a health facility. The HSAs constitute a link between the community and the health facilities. A Group Village Headman (GVH) oversees several villages. There is a Village Development Committee at GVH level which is responsible for development activities. Development activities at the higher TA level are coordinated by the Area Development Committee. Politically, each district is further divided into constituencies which are represented by members of parliament and in some cases these constituencies can combine more than one TA.

Malawi has an estimated population of 13,187,632 and growing at the rate of 2.8% per annum (Malawi National Statistical Office, 2008). Approximately 86% of the population lives in the rural area. Children under five years of age constitute 17% of the population and women 15-49 years old constitute approximately 25% (Malawi National Statistical Office, 2008). The Malawi population is young, with 45% below the age of 15. Life expectancy at birth is 48.3 years for men and 51.3 years for
women. Educational attainment is higher for men than women: 20% of men have never been to school as compared to 30% of the women. The overall literacy rate is 64%. The literacy rate for women is lower at 59% compared to men at 69% (Malawi National Statistical Office, 2008). Low literacy levels especially among women and the prevailing cultural diversity have an impact on the lives of Malawians, including their health seeking behaviour and acceptance of new developments in the fields of agriculture, health and education (Malawi Ministry of Health, 2011).

1.3.2 Socioeconomic profile

The United Nations Development Programme (UNDP) Population Human Development Report 2007/2008 rates Malawi as one of the poorest countries in the world with an estimated GNP per capita of US $ 667.00 in 2005 (UNDP, 2007). More than half (52%) of the population is living in poverty (Malawi National Statistical Office, 2005) The incidence of poverty is high among the rural population with 56% classified as poor compared to 25% for urban population (Malawi National Statistical Office, 2005). Malawi’s economy is predominantly agriculture-based, depending on tobacco, tea, sugar and coffee.

1.3.3 Malawi health care system

Health care services in Malawi are provided by three main agencies. The Ministry of Health (MOH) provides about 60% of services; the Christian Health Association of Malawi (CHAM) provides 37% and the Ministry of Local Government provides 1%. There is a small private-for-profit health sector limited to the urban areas as well as health services provided by private companies, private practitioners, commercial companies, the army and the police. Basically there are three levels in the health system: a primary level comprising of health centres, health posts, dispensaries and community hospitals; a second level made up of district and CHAM hospitals; and a tertiary level consisting of the central hospitals and one private hospital with specialist services. There are five zonal health support offices in Malawi and each one has district hospitals to look after and report to the MOH.
Malawi’s health system is grossly under-resourced. Per capita expenditure is about US $12, which is inadequate for delivery of basic primary health care (Malawi Ministry of Health, 2007b). The health sector is faced with a human resource crisis especially for doctors, nurses and midwives (Kushner et al., 2004; Muula and Maseko, 2006; WHO, 2008b). The critical shortage of midwives, nurses, doctors and other health professionals has affected the ability of the health care system in Malawi to adequately address pressing health issues (Palmer, 2006). Malawi has 257 physicians which is a physician density of 0.2 per 10,000 population. The average physician density for the African region is 2 per 10,100 population (WHO, 2011). Further, there are 3,896 nurses and midwives which is a nurse/midwife density of 2.8 per 10,000 population and the average in the African region is 11 per 10,000 population (WHO, 2011). By contrast, the UK has 165,317 physicians which translates into physician density of 27.4 physicians per 10,000 population and has 621,755 nurses and midwives which is a nurse/midwife density of 103.0 per 10,000 population (WHO, 2011).

Malawi’s clinical services like those of many other African countries, rely heavily on ‘non-physician clinicians’ (Chilopora et al., 2007). Non-physician clinicians have been described as staff who are not trained as physicians but who are capable of many of the diagnostic and clinical functions of medical doctors (Mullan and Frehywot, 2008). Non-physician clinicians in Malawi are termed clinical officers and medical assistants. Clinical officers and medical assistants are trained and recruited as substitutes, or temporary cadres, until the number of medical doctors increases (Muula, 2009). Both clinical officers and medical assistants are below the level of a fully qualified medical doctor. Medical assistants receive two years of formal training, earning a Certificate in Clinical Medicine. Unlike clinical officers, medical assistants have no internship requirements and are not expected to perform surgical procedures such as caesarean deliveries (Muula, 2009).

Apart from personnel shortages in the hospitals, shortages of medicines have also been reported to be a major problem throughout Malawi (Lufesi et al., 2007). A government report indicated that key basic medicines are out-of-stock over 50% of the time (Carlson et al., 2008). The shortages are mainly as a result of low budget allocation and poor distribution from the Central or Regional Medical stores (Carlson et al., 2008).
Figure 1.1: Map of Malawi showing Lilongwe district (site for the study) and main cities.
1.4 Use of antimalarials in Malawi

In Malawi, malaria is the most common disease and a leading cause of morbidity and mortality (Malawi Ministry of Health, 2002). Malaria accounts for 40% of outpatient visits and 18% of all hospital deaths (Kabuluzi et al., 2004). Malaria transmission occurs all year round, but peaks during the rainy season. Episodes of malaria illness in the general population are estimated at 8 million per year (Malawi Ministry of Health, 2002). Most of the population therefore will seek treatment at least once a year for malaria. Children aged five years and below and pregnant women are the most affected (Heggenhougen et al., 2003). Malaria infection in children may result in anaemia, epilepsy and neurological problems (WHO, 2001b). In pregnancy, malaria increases the risk of maternal anaemia, premature births, low-weight babies and stillbirths (Desai et al., 2007; Shane, 2001; Steketee et al., 2001).

Antimalarial medication combinations that include artemisinin derivatives are now recommended by the WHO for treatment in most malaria endemic areas (WHO, 2001a). Although this recommendation includes pregnant women, there is still very little information on the safety of these medication combinations in pregnancy. Despite the wealth of research that has been conducted regarding the treatment of malaria in relation to artemisinin-based combination therapies (ACTs), at present there are no specific risk management precautions to exclude women of childbearing age from using ACTs. As such, many women may be inadvertently exposed to artemisinins early in pregnancy (Dellicour et al., 2008).

The Ministry of Health in Malawi changed its malaria policy in 2007 in response to a WHO recommendation to use artemisinin-based combination therapies for countries whose first line drugs had failed. The ministry introduced artemether-lumefantrine as the first line medication in the treatment of uncomplicated malaria, and amodiaquine-artesunate as second line with quinine for the treatment of severe malaria cases and for the management of malaria in pregnancy. Sulfadoxine-pyrimethamine (SP) is still the recommended medication for Intermittent Preventive Treatment of malaria in pregnancy (IPTp) (Malawi Ministry of Health, 2007a). However, HIV positive women do not receive IPTp with SP because they are already on a daily dose of cotrimoxazole which has the same mechanism of action as SP. Though artemether-lumefantrine is the first line of antimalarial treatment, it is contraindicated in the first
trimester of pregnancy because it is potentially teratogenic. Preclinical studies in animals have demonstrated that artemisinins can induce foetal death at high dose levels, and that at lower doses congenital abnormalities such as cardiovascular and limb deformities are sometimes produced within a very narrow dose range (Longo et al., 2006).

1.5 The role of traditional birth attendants in Malawi

Antenatal care provided by traditional birth attendants (TBAs) is a significant aspect of care delivery because it clearly relates to the beliefs and practices of pregnant women from traditional African orientation. The WHO’s definition of a TBA is ‘a person who assists the mother during childbirth and who initially acquired her skills by delivering babies herself or by working with other TBAs’. TBAs are often older women and are generally illiterate (WHO, 1992).

A trained TBA is someone who has received a short course of training through the modern health care sector to upgrade her skills. The period of actual training is normally not more than one month, although this may be spread over a long time (WHO, 1992). The United Nations Population Fund (UNFPA) has supported a TBA programme since 1970 to improve maternal and child health outcomes and as part of the Safe Motherhood Initiatives since it started in 1987. In the 1990s, UNFPA, jointly with WHO and UNICEF, issued a statement on TBAs to reflect common goals to contribute to the global effort aimed at improving reproductive health (UNFPA, 1996).

The objectives of the support to trained TBAs are to enhance the links between modern health-care services and the community; increase the number of births attended by trained attendants and improve skills, understanding and the importance of TBAs. The international conference on population and development held in 1994 in Cairo further encouraged the agenda of the Safe Motherhood Initiatives including the objective that all births should be assisted by trained persons (UNFPA, 1996).

The value of TBA training has been increasingly questioned due to poor performance (Bailey et al., 2002; Sibley and Sipe, 2006). In Malawi, it has been
observed that the country's high maternal mortality rate was partly due to a lack of skills on the part of traditional birth attendants. In particular, TBAs were not capable of quickly recognising obstetric emergency cases and were failing to provide measures to prevent transmission of HIV from mothers to their newborn children (Ngozo, 2011). As a result, the Government of Malawi took the decision to ban TBAs as health care practitioners in 2007. It was hoped that by preventing TBAs from practising, mothers would utilise the country’s medical facilities, but nearly half of all deliveries still occur outside medical facilities (FaceofMalawi, 2011). Despite the ban however, women still visited the TBAs. At the start of 2011, Malawi reversed the ban because it was also observed that maternal mortality rose after the ban because the TBAS continued to work in secret (Ngozo, 2011).
1.6 Rationale for the study

Malawi relies on drug interventions for control of malaria and other major diseases in the country. It is therefore vital to assess the potential risk of inadvertent exposure to teratogenic medications which could result in an increased risk of adverse pregnancy outcomes and/or congenital malformations. Given the widespread use of antimalarials and other prescription contraindicated medicines in pregnancy, women of childbearing age are at high risk of inadvertent exposure to teratogenic medications early in pregnancy (Dellicour et al., 2008). Women could be exposed to the medicines because they might not be aware that they are pregnant or they have not disclosed their pregnancies (Stokes et al., 2008; Ward et al., 2007; WHO, 2010). In a study set in the Gambia, it was noted that women attending general outpatient clinics were not routinely asked about pregnancy, and medications for chronic health problems were rarely reviewed or even recorded on antenatal clinic cards (Stokes et al., 2008). Nosten et al. (2007) recommend that all women of childbearing age should be asked about the possibility of pregnancy before being prescribed an antimalarial drug. Women could also be exposed to non-prescription medicines which might include traditional medicines apart from contraindicated medicines given under prescription. These medicines could also be potentially feto-toxic (Varga and Veale, 1997).

There is a paucity of information relating to the use and risks of medications during pregnancy in women in developing countries. In such countries, the combination of unregulated acquisition of medications and cultural practices result in use of medicines that may lead to exposures that potentially put the foetus at risk. This particularly applies in countries such as Malawi, where drugs are often obtained from the market or pharmacies without a prescription. The researcher was motivated to undertake a study exploring prescription practices and self-medication in women of childbearing age about which there is no information available in respect to first trimester drug exposure risk in Malawi. As far as the researcher is aware, no study has been conducted in Malawi to assess practices and potential for exposure to contraindicated medicines in women who might be pregnant.

1 The word medicine and drug shall be used interchangeably in this thesis
It is of great importance in public health to determine how women are assessed and managed to reduce inadvertent medication exposure in pregnant women by the health workers. It is also important to explore the level of awareness and knowledge about these risks by women themselves, such as general effects to the mother and foetus, and the potential risk of congenital abnormalities.

Published information on the use of medicines during pregnancy in developing countries is scarce. The research is also intended to advance current knowledge on utilisation of medicines among pregnant women and provide information and feedback to healthcare workers and women so that medicines are used safely and judiciously. The results from this study will help to inform policy and practice regarding the safe prescription of contraindicated medicines in pregnancy in women of childbearing age in Malawi.

**Motivation to conduct the study by the researcher**

This study was conceived out of my personal interest when the government of Malawi introduced a new antimalarial drug, artemether-lumefantrine. During this time, I was undertaking clinical supervision of student nurses from Kamuzu College of Nursing who were involved in the care of women of childbearing age in general in patient and outpatient settings. A proportion of women who attended these clinics were prescribed artemether-lumefantrine, this medication needs to be taken with caution in women of childbearing age. As an instructor I was required to be meticulous in teaching the nurses to be more careful whenever they came across a woman’s prescription which had artemether-lumefantrine. At the time of introduction, it was emphasised that when prescribing artemether-lumefantrine the prescriber should take account of women of childbearing age, and that pregnancy should be excluded (either through pregnancy testing or asking the women about possible pregnancy). This action was taken because artemether-lumefantrine has a teratogenic potential. In addition to artemether-lumefantrine, other medicines which have a potential harm to the foetus could also have been prescribed. I then decided to explore the extent to which women are being carefully managed by clinicians when artemether-lumefantrine and other contraindicated medicines are being prescribed.
1.7 Objectives of the study

1.7.1 Aim

The overall aim of the study was to assess the risk of exposure to contraindicated medicines in early pregnancy (less than 13 weeks gestation) among women attending the general outpatient clinic at a community hospital.

1.7.2 Specific objectives

i. To determine the proportion of women who have been inadvertently prescribed contraindicated medicines in the first trimester of pregnancy in a general outpatient clinic.

ii. To explore women's beliefs, views and practices concerning medication use during pregnancy.

iii. To determine the prevalence of congenital abnormalities through review of records at community and central hospital sites.

iv. To make appropriate recommendations for policy and practice in Malawi relating to medication use in pregnancy.
1.8 Structure of the thesis

This thesis is divided into 8 chapters. The first chapter described the background to the study about medication use in pregnancy and its consequences. A description of health care system in Malawi was made. It also included aims and objectives of the study.

Chapter two describes the literature related to human development and teratogenic potential of medicines. It also provides the literature on views, beliefs and practices concerning medication use during pregnancy. Information on congenital abnormalities is also described.

Chapter three describes in detail the methodology of the study. It also describes the theoretical framework that guided the data collection.

Chapter four provides the methods used to achieve the study objectives. The chapter gives by an account of methods of securing access to study sites and discusses ethical considerations. The chapter also describes the sampling principles and procedures, including the inclusion and exclusion criteria. This is followed by a presentation of the data generation methods of record review, survey and in-depth interviews. Lastly, data analysis and the rigour of the study are discussed.

Chapters five, six and seven report results from the quantitative and qualitative parts of the study. Chapter 5 provides background contextual data for the two main arms of the study, reporting on the prevalence of congenital abnormalities in the study location in Malawi. Chapter 6 then gives details of women of child bearing age attending a general outpatients clinic who had been prescribed contraindicated medication, reporting on their medication intake and medicines prescribed in the outpatient department, and giving estimates of the proportion of women of child bearing age and the proportion of women in the first trimester of pregnancy being prescribed contraindicated medication. Finally, Chapter 7 reports on the views, beliefs and practices about medicines in pregnancy of women attending an antenatal clinic.

Chapter eight synthesises the findings of the thesis and provides the overall discussion and conclusion for this study. It discusses the main findings of the study,
and comments on the strengths and limitations of the study. It also considers the implications for practice, policy and research. This is followed by references and appendices.

1.9 Summary

The chapter outlined the effects of certain medicines on the developing foetus and why medicines should be avoided in pregnancy. It included background information about Malawi and the current use of antimalarials. The rationale for the study was given and the study aims and objectives were elaborated. This chapter also outlined the organisation of the thesis and the content of each chapter. The next chapter gives a review of the literature on medication use and related issues such as congenital abnormalities.
CHAPTER 2
LITERATURE REVIEW

2.1 Introduction

This chapter presents a review of the literature related to the present study. The review preferentially considered studies involving the use of medicines in pregnancy in developing countries. There are limited studies involving general medication use in pregnancy from the developing countries hence most studies reviewed were from developed countries. Papers included in this review were identified by electronic searches of PubMed, MEDLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), the European Medical Data base (EMBASE), Psychological literature (PSYCINFO), the Applied Social Sciences Index and Abstracts (ASSIA), the British Nursing Index, and Midwifery Information and Resource Service (MIDIRS). Combinations of the following keywords were used: teratogenesis, congenital abnormalities or birth defects, malaria, intermittent preventive/presumptive treatment, artesiminin, over-the-counter medication, prescription medication, traditional medicine, inadvertent medication exposure, medication use in pregnancy, medication exposure in pregnancy, beliefs and perceptions.

Additional references were hand searched from relevant journals and links to related articles. A further search was done using names of authors who had published several papers relevant to this study. Studies which have been included are those with both abstract and full text. Searches were limited to publications in the English language during the period 1983 to 2011. The rationale for this was because of the growing interest in malaria research from the 80's which lead to exploration of issues of drug therapies in malaria in pregnancy. Studies which focused on drug use in pregnant women were included.

In this chapter, a description of basic concepts of teratogenic and fetotoxic potential of medicines is given. A description of congenital abnormalities and their causes is also presented. This is followed by an overview of the literature related to various studies that addressed prescription medication use during pregnancy. A review is
also included of studies of self-medication by pregnant women. Women’s beliefs, views and practices concerning medicines in pregnancy are described. A review of women’s perceptions of causes of congenital abnormalities is also presented.

2.2 Human development and teratogenesis

In order to gain an insight into how medicines affect the unborn baby, an understanding of how the foetus develops is essential. This section will describe foetal growth and how teratogens may affect foetal development.

2.2.1 Human development

Moore (1998) described human development as a continuous process that begins when an ovum from a female is fertilised by a sperm from a male. The cell which results from the union of the ovum and the sperm is called a zygote. Cell division, migration, programmed cell death; differentiation, growth and cell rearrangement transform the fertilized ovum, a highly specialized cell, a zygote into a multicellular human being. There are three main phases of the human development. These are: the preimplantation, embryonic and foetal phases (Moore, 1998). The preimplantation phase is the initial phase which begins when a sperm fertilizes the ovum. During this phase there is differentiation of cells before implantation takes place. Implantation occurs when the zygote implants itself in the uterus where the embryo develops. After the implantation, the embryonic phase follows. During the embryonic period, (from 14 to 60 days after conception), the basic phases in organogenesis (the formation of organs) take place. The most important organs are the heart, lungs, liver as well as limbs and the brain. The foetal phase is from the end of the embryonic stage to term when growth and functional maturation of the formed organs and systems occur (Moore, 1998).
2.2.2 Teratogenesis

Teratogenesis is defined as the dysgenesis or defective development of foetal organs as evidenced either structurally or functionally (Moore, 1998). Some manifestations of teratogenesis include congenital malformation, intrauterine growth restriction, carcinogenesis and foetal death. Teratogens are factors that cause birth defects (Sadler, 2006). Recognised teratogens include viruses such as rubella and cytomegalovirus; environmental factors such as hyperthermia and irradiation; chemicals such as mercury and alcohol; and therapeutic medicines such as inhibitors of the renin–angiotensin system, thalidomide, isotretinoin, warfarin, valproic acid and carbamazepine (Moore, 1998). The effect produced by a teratogenic agent depends upon the developmental stage in which the foetus is exposed to the agent, the dose of the substance and susceptibility of the foetus at the time of exposure. The timing of exposure is considered the most important determinant of teratogenesis (Moore, 1998). Dose is also a critical feature of any teratogenic exposure. Teratogenic effects occur only when the dose of an agent exceeds a certain threshold (Brent, 2004b). The higher the dose of the teratogen, the more likely it will cause a malformation.

There are four critical periods in human development (Moore, 1998). Exposure to teratogenic agents during the first 2-3 weeks after conception is generally thought to have no effect or to result in spontaneous loss. The time from conception until implantation is considered as the ‘all or none’ period, as insults to the embryo are likely to result in either death of the conceptus and miscarriage or in intact survival (Nava-Ocampo and Koren, 2007). The subsequent period of organogenesis, from 18 to 60 days after conception (about 4 to 11 weeks after the start of the last normal menstrual period) is the time of greatest sensitivity to most teratogenic exposures. Most structural congenital abnormalities are thought to be produced during this interval (Walbrandt Pigarelli and Kraus, 2008). As organogenesis ends, susceptibility to anatomic abnormalities declines. Thus foetal exposure to teratogens later in gestation usually does not produce gross structural abnormalities, although there are exceptions. Adverse exposures during the foetal period more often result in growth restriction or functional disorders of the central nervous system, kidneys or other organs (Brent, 2004b).
Fetotoxicity refers to the functional changes that can occur to the fetus as a result of medication in the second and third trimesters. These effects are more subtle and more difficult to assess and therefore there are fewer data to support or refute these types of associations. Fetotoxicity can occur anytime between the late first trimester and birth and may cause a variety of effects. Medicines usually only affect the growth and maturation of the foetus, since organogenesis is completed by the end of the embryonic period, although the development of the external genitalia continues into the second trimester and the development of the central nervous system is an ongoing process for the duration of the pregnancy and beyond.

Medicines can therefore exert potentially harmful effects on the unborn child during any stage of the pregnancy though to varying degrees (Walbrandt Pigarelli and Kraus, 2008). For most medicines, the major concern is following exposure in the first trimester of pregnancy because medicines have the greatest potential to cause malformations during the organogenesis phase. In addition, organogenesis is often complete before the woman realizes she is pregnant and many commonly prescribed medicines have teratogenic potential.

### 2.3 Congenital abnormalities

#### 2.3.1 Definition and prevalence of congenital abnormalities

Congenital anomalies are any abnormalities that are present at birth, even if they are not detected until much later (Kalter, 2003; Moore, 1998). Congenital abnormalities are divided into major and minor anomalies related to their clinical significance (Moore, 1998). Major congenital malformations are defined as physical defects causing a significant functional disturbance and requiring medical or surgical intervention (Kalter, 2003; Koren et al., 1998). A major congenital abnormality has also been defined as an abnormality of prenatal origin that, if uncorrected or uncorrectable, significantly impairs normal physical or social functioning or reduces normal life expectancy (WHO, 1999). Examples of major congenital abnormalities include heart defects, cleft lip or palate, Down’s syndrome and neural tube defects (WHO, 2009). Minor congenital anomalies are relatively mild physical divergences.
from normal, with little or no medical or cosmetic consequence (Kalter, 2003). An example of such is hypospadias that is mild and may be missed (Koren et al., 1998).

Every year more than 7.9 million children (6% of total births worldwide) are born with a serious congenital disorder due to genetic or environmental causes (WHO, 2008d). Literature indicates that congenital malformations are a major cause of infant mortality and postnatal physical defects in both developed and developing countries (Khoshnood et al., 2005; Lee et al., 2001b; Rosano et al., 2000; Schempf et al., 2007; WHO, 2008d). Congenital abnormalities are the most important causes of disability in both developed and developing countries (EUROCAT Working Group, 2002; WHO, 2003; Yoon et al., 1997).

The prevalence and types of congenital malformations differ from one country to another and even in the same country from one region to another. This depends on the definition of congenital malformations applied; method of their detection, length of time the population was under observation, ethnic and socio-economic characteristics of the population studied (AIHW NPSU: Birch et al., 2004; Christianson et al., 1981; Terry et al., 1985). Studies have reported prevalence rates ranging from 1-4% of all live born infants (Blomberg et al., 2000; De Santis et al., 2004; Kalter, 2003; Schumacher, 2004; Shi et al., 2002). In Western populations, major congenital abnormalities occur in approximately 2-3% of all pregnancies (Kalter, 2003). The birth prevalence of congenital anomalies in the developing world is underestimated by deficiencies in diagnostic capabilities and lack of reliability of medical records and health statistics, and poor follow-up for examination for anomalies in the postnatal period (Ndibazza et al., 2011; Penchaszadeh, 2002). In general, the occurrence of birth defects is probably much higher than estimated when quantifying birth defects at delivery. The congenital anomalies seen in live births are those that have survived intrauterine life (Dolk et al., 2010). Congenital anomalies are a major cause of early spontaneous abortions (Dolk et al., 2010).
2.3.2 Causes of congenital abnormalities

The majority of congenital abnormalities are of unknown origin, which makes prevention problematic. Generally congenital abnormalities of known origin are due to one of three principal causes: genetic factors, environmental factors or a combination of genetic and environmental factors (Beckam and Brent, 1984; De Santis et al., 2001; Kalter, 2003), sometimes known as complex or multifactorial causes (Czeizel, 2005). Genetic factors include chromosomal aberrations such as Down’s syndrome and Mendelian single-gene defects such as achondroplasia. Environmental factors include infectious diseases such as rubella or which cause high fever; chronic maternal diseases such as diabetes mellitus; medicinal products; alcohol; smoking and pollutants such as herbicides, pesticides and methyl mercury (Brent, 2004a; Czeizel, 2005; Schumacher, 2004). Gene-environmental interactions lead to congenital abnormalities such as isolated neural-tube defects, orofacial clefts, cardiovascular malformations, congenital pyloric stenosis, congenital dislocation of the hip, undescended testis and hypospadias (Czeizel, 2005).

Genetic or chromosomal factors account for 25% of total congenital abnormalities and environmental for 10% but 65% are of unknown origin (Czeizel, 2005; De Santis et al., 2001; Rubin, 1995; Shepard, 1995). Teratogenic medicines are thought to account for approximately 1% of total congenital abnormalities (Banhydy et al., 2005; Brent, 2004b; De Santis et al., 2004; Kalter, 2003). Though the percentage for medication-induced abnormalities is small, it is preventable, hence worth the effort of addressing the problem.

Contributory factors may also include increasing maternal age (El-Shafei et al., 1986; Hollier et al., 2000; Singh and Al-Sudani, 2000), high gravidity (El-Shafei et al., 1986), parental consanguineous marriages (Bromikera et al., 2004; El-Shafei et al., 1986; Mosayebi and Movahedian, 2007; Stoll et al., 1994) and a previous history of miscarriages and maternal hypertension. Foetal sex is also relevant as more males than females are affected. The male reproductive system is apparently much more susceptible to errors in development (Lary and Paulozzi, 2001). Abnormal levels of testosterone and other hormones produced by the male reproductive tract after testicular differentiation probably account for this difference (Lary and Paulozzi, 2001).
Prevalence studies of congenital abnormalities are useful to establish baseline rates, to document changes over time and to identify evidence to aetiology. They are also important for health services planning and evaluating antenatal screening for congenital anomalies particularly in high risk populations (Dastgiri et al., 2002). It has been observed that birth prevalence of congenital anomalies in the developing world is underestimated by deficiencies in diagnostic capabilities and lack of reliability of medical records and health statistics (Penchaszadeh, 2002). There are challenges in performing congenital abnormalities prevalence studies especially in developing countries. Sevane et al. (2012) highlight factors which complicate the assessment of drug exposure in pregnancy in developing countries. First, pregnant women are more likely to present with clinical complaints of several diseases, which are prevalent in resource-poor settings, thus requiring drug prescription. Second, recording of drug exposure during pregnancy in routine clinical records is frequently inadequate. Third, there is a lack of quality baseline data on birth outcomes within the target population to be used as a comparator in causality assessment. Finally, in most areas there are no pharmacovigilance systems in place.

2.4 Description of traditional and modern medicine

Traditional medicine (TM) refers to health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being (WHO, 2008c). In developed countries, traditional medicine is commonly referred to as Complementary and Alternative Medicine (CAM). According to the Cochrane Collaboration, complementary medicine (CM) has been broadly defined as all such practices and ideas which are outside the domain of conventional medicine in several countries and defined by its users as preventing or treating illness, or promoting health and wellbeing (Manheimer and Berman, 2008). Western medicine or biomedicine is often contrasted with the approach taken by traditional medicines practitioners. Western medicine is usually associated with diseases of the physical body only, and is based on the principles of science, technology, knowledge and clinical analysis developed in America and Western Europe (Richter, 2003).
Traditional medicine may be codified, regulated, taught openly and practised widely and systematically, and benefit from thousands of years of experience but sometimes it may be highly secretive, mystical and extremely localized, with knowledge of its practices passed on orally (WHO, 2002). The medicine may be based on salient physical symptoms or perceived supernatural forces (WHO, 2002). Traditional medicine seeks to provide a meaningful explanation for illness and to respond to the personal, family and community issues surrounding illness. According to WHO (2008), traditional medicine provides health coverage for over 80% of the world population, especially in the developing world. Traditional medicine is highly popular in many developing countries because it is firmly embedded within wider belief systems.

2.5 Prescription medication use during pregnancy

Most women use prescribed medicines during pregnancy according to studies from western countries (Andrade et al., 2004; Engeland et al., 2008; Hardy et al., 2006; Headley et al., 2004; Lacroix et al., 2009; Lee et al., 2006; Malm et al., 2003; Mitchell et al., 2011; Olesen et al., 1999; Riley et al., 2005). The prevalence of medication use during pregnancy ranges from 27% to 85% (Andrade et al., 2004; Bakker et al., 2006; Beyens et al., 2003; De Vigan et al., 1999; Egen-Lappe and Hasford, 2004; Engeland et al., 2008; Garriguet, 2006; Malm et al., 2003; Olesen et al., 1999; Refuerzo et al., 2005). These proportions increase to up to 99% when multivitamins and minerals are also taken into consideration (Egen-Lappe and Hasford, 2004; Headley et al., 2004; Lacroix et al., 2000; Refuerzo et al., 2005).

Variations in the prevalence rates in medication utilisation studies make comparison difficult because of differences in study design. For instance, some studies use interviews and questionnaires while others use prescription databases for collecting data on medication. Different prescription regulations may also account for these differences since some preparations such as iron are considered non-prescription medicines in some countries.
A study in France reported that 99% of a sample of 1000 women living in Haute-Garonne in South West France received a prescription for at least one medication during pregnancy with a mean of 13.6 medications per woman. The mean number of prescribed medicines per woman was 5.2 in the first trimester, 7.1 in the second trimester and 6.6 in the third trimester (Lacroix et al., 2000). While in Australia a survey on patterns of medication use during pregnancy showed that women used an average of 0.7 to 0.8 prescribed and 2.3 to 2.6 non-prescribed medicines (a total of 3.1 to 3.3) during the three pregnancy trimesters, compared with 1.0 prescribed and 2.2 nonprescribed medicines prior to pregnancy. Use of prescribed and non-prescribed medication was 96 to 97% across trimesters (Henry and Crowther, 2000).

In the US, Refuerzo et al. (2005) conducted a study on the frequency of prescription, OTC, and herbal use. They found that 96.9% of the women had taken at least one medication while pregnant. After excluding prenatal vitamin and iron supplements, they found 62.8% used OTC medications and 4.1% used herbal medicines.

A study in the UK by Headley et al. (2004) on the self-reported use of all types of medicinal products collected during pregnancy in a large cohort in southwest England, reported that 92.9% of pregnant women had used at least one product at some stage. After exclusion of iron, folate, vitamins, supplements, herbal and homeopathic products and skin emollients, 83% had used conventional therapeutic medications. In an Irish study including 61,252 women giving birth in Dublin from 2000 to 2007 examining medication use during early pregnancy, it was found that at least one medication was used by 23,989 (39.2%) women (Cleary et al., 2010). Over the counter (OTC) medications were reported by 11,970 (19.5%) women, illicit drugs in 545 (0.9%) and herbal medicines/supplements in 352 (0.58%) (Cleary et al., 2010).

Engeland et al. (2008) found that among more than 100,000 pregnant women in Norway in 2004–2006, approximately 57% received a prescription medication. In Italy, Gagne et al. (2008) found that among more than 30,000 deliveries, 70% of the women were prescribed at least one type of medicine during pregnancy.

Medicines taken by the women were varied. They included analgesics, vitamin/mineral supplements, antacids, antispasmodics, antiemetics, benzodiazepines and antibiotics.
To anticipate and avoid medication exposure in early pregnancy, when prescribing a medication to a young woman, clinicians should consider that she may already be or soon become pregnant (Autret-Leca et al., 2011). In order to guide health care providers in prescribing medicines to pregnant women several classification systems have been developed based on human evidence, and when unavailable, on animal data. The purpose of these classifications is to give information to health care professionals about possible or established risk or safety of using medicines during pregnancy (Alván et al., 1995; Doering et al., 2002). They also help to increase awareness among women and clinicians of adverse pregnancy outcomes associated with the use of certain medications. Thus, it should be possible to minimise the risks to the foetus by reference to these classification systems (De Santis et al., 2004; Rubin, 1998; Weiner et al., 2005). Well-recognised classification systems are those from the United States, Australia and Sweden (ADEC, 1999; Briggs et al., 2005; Sannerstedt et al., 1996). Although the systems vary, general recommendations do apply for most medicines. Table 2.1 shows the United States Food and Drug (FDA) classification system.
<table>
<thead>
<tr>
<th>Pregnancy Category</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Adequate and well-controlled human studies have failed to demonstrate a risk to the foetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters).</td>
</tr>
<tr>
<td>B</td>
<td>Animal reproduction studies have failed to demonstrate a risk to the foetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the foetus in any trimester.</td>
</tr>
<tr>
<td>C</td>
<td>Animal reproduction studies have shown an adverse effect on the foetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the medication in pregnant women despite potential risks.</td>
</tr>
<tr>
<td>D</td>
<td>There is positive evidence of human foetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the medication in pregnant women despite potential risks.</td>
</tr>
<tr>
<td>X</td>
<td>Studies in animals or humans have demonstrated foetal abnormalities and/or there is positive evidence of human foetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the medication in pregnant women clearly outweigh potential benefits.</td>
</tr>
</tbody>
</table>


Several studies have reported potentially harmful prescribing for pregnant women (Andrade et al., 2004; Andrade et al., 2006; Bakker et al., 2006; Cooper et al., 2004; Garriguet, 2006; Hardy et al., 2006; Lacroix et al., 2000; Malm et al., 2004; Olesen et al., 1999; Riley et al., 2005; Schirm et al., 2004; Wen et al., 2008). The prescription rates vary. Major differences in study design, study population, time period, medication exposure ascertainment method and medication classification systems for example some used FDA system while others used Australian or Swedish systems and this makes it difficult to reconcile rates observed in different studies.
FDA pregnancy classification categories are explained in Table 2.1. Medicines in pregnancy categories C and D may have some potential risk to the foetus but that is considered to be outweighed by the potential benefits. The FDA considered that medicines in category X should not be prescribed to pregnant women because the risks outweigh the benefits. A study conducted in Canada by Wen et al (2008) using a pharmacist database to estimate the frequency of exposure to prescription FDA category C, D, and X medicines in pregnant women showed that a total of 3604 (19.4%) of the women were found to have used FDA category C, D and X medications at least once during pregnancy. The pregnancy exposure rates were 15.8, 5.2 and 3.9%, respectively, for category C, D and X drugs, and were 11.2, 7.3 and 8.2%, respectively, in the first, second and third trimesters. The most common medicines were salbutamol, cotrimoxazole, ibuprofen, naproxen and oral contraceptives. Salbutamol and cotrimoxazole are category C medicines while ibuprofen and naproxen are category D medicines and oral contraceptives are category X medicines.

Autret-Leca et al. (2011) conducted a study in France primarily aimed at evaluating the incidence of exposure to teratogenic medicine during early pregnancy. A total of 1.1% women received at least one medication that was contraindicated during the first trimester, 9.5% received a medication that was not recommended, and 42.8% received a medication that was to be avoided.

A US retrospective study of prescriptions filled during pregnancy using data from eight health maintenance organisations, conducted between 1996 and 2000 found that 64% of pregnant women were dispensed a prescription medication during pregnancy and that 9.4% of pregnancies were exposed to medications with potential for foetal harm (Andrade, 2004). In this study, it was found that 4.8% of pregnant women received a medication from category D and 4.6% received a medication from FDA category X within the 270 days prior to delivery (Andrade et al., 2004). Overall, 3.4% of women were dispensed a category D medication and 1.1% were dispensed a category X medication after the initial prenatal care visit. The most frequently dispensed category D and X medicines included doxycycline, atenolol, secobarbital, lorazepam, clonazepam, alprazolam, propylthiouracil, temazepam, ergotamine, testosterone, flurazepam, triazolam, warfarin and simvastatin (Andrade et al., 2004). Another study in the US by Andrade et al (2006) showed that 3.3% of women
received FDA category D or X during the pregnancy period. Similarly, another US study by Riley et al. (2005) reported that 4.0% of the women were prescribed category D or X medicines. The study was aimed at evaluating the extent of prescription drug use and the use of category D or X drugs during pregnancy and examining the maternal characteristics associated with use.

Lacroix et al. (2000) examined all of the original prescriptions that were issued throughout the pregnancy of 1000 women who lived in southwest France in 1996. A total of 59% of the women had a prescription for a medication from FDA category D; 1.6% of the women received prescriptions for medicines in category X. The medicines included clomiphene, estradiol and isotretinoin.

Using the UK General Practice Research Database, Hardy et al. (2006) identified a cohort of 81,975 pregnant women and estimated the frequency and types of medications prescribed during pregnancy in the UK between 1991 and 1999. Results showed that 0.6% women were prescribed with one or more category X prescriptions in the first trimester (Hardy et al., 2006). Cleary et al. (2010) conducted a study in Ireland including 61,252 women giving birth in Dublin from 2000 to 2007 to examine medication use during early pregnancy of FDA category D and X medicines. The study revealed that 2.5% and 3.2% of women received an FDA category D medication and an FDA category X medication, respectively, during the first trimester. Asthma, depression and hypertension medications were among the most commonly reported medicines.

A study was undertaken by Bakker (2006) in the Netherlands. The aim of the study was to compare the prescription of medicines in women over a period from 2 years before until 3 months after pregnancy, regarding the type of medicines used and the foetal risk. It was a cohort study based on pharmacy records of women giving birth to a child between 1994 and 2003. The study population included 5,412 women for whom complete pharmacy records were available. About 79.1% of the women received at least one prescription during pregnancy and 2.4% of medicines belonged to the FDA category D/X. The harmful medicines prescribed in the first trimester for pregnancy related symptoms were ovulation-stimulating medicines and for chronic conditions, antiepileptics. Doxycycline was responsible for the high percentage of harmful medicines for occasional use in the first trimester. The researchers in this
study argue in favour for a cautious prescribing of medicines to healthy women in the fertile age, in which the prescription of harmful medicines should be avoided as much as possible.

Olesen et al. (1999) conducted a study in Denmark with the objective of examining medication prescription pattern in Danish women from 12 weeks prior to conception until 12 weeks post-partum. The study included 16,000 primiparous women and reported that 18.0% of women received at least one medication during pregnancy with proven or probable harmful foetal effects according to the Swedish classification. Gagne et al. (2008) conducted a study in Italy using FDA classification which showed that 2.0% of pregnant women received a medication from category D and 1.0% received a medication from category X (Gagne et al., 2008). By linking three nationwide registration databases in Finland, a study reported that 20.4% of women used at least one prescription medication during pregnancy with potential foetal risk and 3.4% used at least one clearly harmful medication (Malm et al., 2004). In a German study, 1.2% of women were administered a potentially teratogenic medication during pregnancy (Egen-Lappe and Hasford, 2004).

Kebede et al. (2009) conducted a study to assess drug use among antenatal women in Addis Ababa. A total of 1268 women were included in the study; of which 71.3% of them were prescribed at least one drug during pregnancy. It was reported that 12.4% of the pregnant women who reported illness in the 2 weeks prior to the date of the interview, self-medicated themselves with either over the counter or prescription drugs or traditional herbs. Nearly 4% of the pregnant women in this study were prescribed a category D or X medication, with 3.6% exposed to category D medications and approximately 0.2% exposed to category X medications.

The reviewed studies have shown medication use during pregnancy is prevalent and that some potentially harmful medicines are being prescribed to pregnant women. Among the most frequently used medicines identified by the different studies were: analgesics, vitamins/mineral supplements, antacids, antispasmodics, antiemetics, and antibiotics. The studies have also shown that medication use prevalence during pregnancy varies.
2.6 Self-medication

Self-medication is a major form of self-care (Drug Utilization Research Group, 1997). In most illness episodes, self-medication is the first option (Geissler et al., 2000; Hayran et al., 2000; Martins et al., 2002; Sclafer et al., 1997). Various definitions of self-medication are found in the literature. Self-medication can be defined as the use of medicines to treat self-diagnosed disorders or symptoms, or the intermittent or continued use of a prescribed medication for chronic or recurrent disease or symptoms (WHO, 2000b). While some authors define self-medication as the use of any medication not prescribed by a licensed health practitioner, others widen their definition to include any alteration to the recommended dose guidelines undertaken by the patient (Saeed, 1988) or the obtaining and consuming of medicines without the advice of a physician either for diagnosis, prescription or surveillance of treatment (Montastruc et al., 1997). Self-medication is a process by which the patient assumes a greater degree of responsibility for the management of a minor ailment, using a pharmaceutical product that is available without a prescription (Hughes et al., 2001).

Self-medication may include the use of herbs, the retention and re-use of prescription medicines or the direct purchase of prescription-only medicines without medical input (Awad et al., 2005). It involves the use of medicinal products by the consumer to treat self-recognized disorder, symptoms, recurrent disease or minor health problems (Afolabi, 2008; Awad et al., 2005; Galato et al., 2009).

Self-medication is practised by considerable proportion of the population and is affected by socio-demographic and socio-economic factors (Cocks and Dold, 2000; Lau et al., 2000; Lee et al., 2001a; Sleath et al., 2001). The practice of self-medication is common worldwide in both developed and developing countries (Figueiras et al., 2000; Fuentes Albarrán and Villa Zapata, 2008). In addition, self-medication is becoming an increasingly important component of health care in both developing and developed countries (Cocks and Dold, 2000; Deshpande and Tiwari, 1997; Drug Utilization Research Group, 1997; Gore and Madhavan, 1994; Hardon, 1987; Montastruc et al., 1997; Sleath et al., 2001). In a survey by WHO from 38 countries (25 developing and 13 developed countries), it was reported that in many parts of the world up to 80% of illness episodes are self-medicated with modern
medicines and even when formal health care channels are used, it is often the consumer not the prescriber who determines whether and how the medicines are used (WHO, 1998).

The easy availability of a wide range of medicines and in the case of developing countries, the inadequate health services result in increased proportions of medicines used for self-medication compared to prescribed medicines (Shankar et al., 2002). With the ease of access to over-the-counter (OTC) medications and alternative therapies, there has been an increase in the use of non-prescribed medications and herbal remedies in pregnancy. Studies report that 4.0% to 62.0% of pregnant women use some form of herbal and alternative therapies and between 29.0% and 93.0% use over-the-counter medication during pregnancy (Bercaw et al., 2010; Forster et al., 2006; Glover et al., 2003; Maats and Crowther, 2002; Refuerzo et al., 2005). However, inappropriate use of medicines during pregnancy may cause permanent and severe damage to the foetus (Beckam and Brent, 1984).

The following subsections will present use of herbal medicines and over-the-counter medications by pregnant women as part of self-medication practices.

### 2.6.1 Herbal medication use in pregnancy

Herbal medicine is a component of traditional medicine. Herbal medicines are defined as finished, labelled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant material, or combinations thereof, whether in the crude state or as plant preparations (WHO, 2000a). Traditional herbal medicine refers to the therapeutic values of herbal medicine beyond the medication’s active ingredients in which the herbal medicine is considered to be active only when it is imbued with an invisible life force (Hills et al., 2006). Many people in developed countries use herbal medicine as self-care because there is a wide misconception that ‘natural’ means ‘safe’ (Tiran, 2003; WHO, 2008c). They may be unaware of potential side-effects, and how and when herbal medicines can be taken safely. Herbal medicines are widely used for pregnancy-related complaints and acute illnesses. The reasons why people in developed countries are showing interest in the use of herbal medicines is that in
these countries, the safety and efficacy of some herbs is well documented (Tiran, 2003). However, in most countries, either no safety monitoring system exists or the existing safety monitoring system excludes herbal medicines (WHO, 2004). Some herbs that have been well researched are garlic, ginger, ginkgo biloba and ginseng (Tiran, 2003). Herbal supplement use in pregnancy is regarded as natural (Tsui et al., 2001). A Canadian study including 27 purposefully selected pregnant women found that the women considered herbs to be safer than pharmaceuticals because they were ‘milder’, ‘more natural’, ‘simpler, more familiar’ or ‘caused fewer side effects’ (Westfall, 2003). The general perception that these preparations are safe may lead to inappropriate use, especially during pregnancy. Studies in animal models have found some herbal medicine use in pregnancy is associated with congenital malformations (Chan et al., 2003).

Herbal medicine is the most widely used complementary and alternative medicine (CAM) during pregnancy and has been mostly studied (Allaire et al., 2000; Conover, 2003; Forster et al., 2006; Gibson et al., 2001; Hollyer et al., 2002; Pinn and Pallet, 2002). Several studies in the western countries have reported that the use of herbal medicines during pregnancy is relatively frequent (Broussard et al., 2010; Forster et al., 2006; Gibson et al., 2001; Glover et al., 2003; Hepner et al., 2002; Hollyer et al., 2002; Holst et al., 2009a; Lapi et al., 2010; Maats and Crowther, 2002; Nordeng et al., 2011; Nordeng and Havnen, 2004; Pinn and Pallet, 2002; Refuerzo et al., 2005; Tsui et al., 2001; Westfall, 2003).

The reported use of herbal remedies during pregnancy ranged from 4% to 62% in different studies (Broussard et al., 2010; Forster et al., 2006; Gibson et al., 2001; Glover et al., 2003; Hepner et al., 2002; Hollyer et al., 2002; Lapi et al., 2010; Maats and Crowther, 2002; Nordeng et al., 2011; Nordeng and Havnen, 2004; Pinn and Pallet, 2002; Refuerzo et al., 2005; Tsui et al., 2001).

A study in Norway by Nordeng and Havnen (2004) investigated 400 postpartum women who were interviewed about the use of herbal medicines within 3 days after giving birth by using a structured questionnaire. Thirty-six per cent of the pregnant women had used herbal medicines during pregnancy with an average of 1.7 products per woman. The study found that use of herbal supplements increased as pregnancy progressed. The most commonly used herbs were echinacea, iron-rich
herbs, ginger, chamomile and cranberry. Among the women having used herbal medicines in pregnancy, 39% had used herbal medicines that were considered possibly harmful or for which accurate information on safety in pregnancy was not available. Use of herbal medicines in pregnancy had often been recommended by family or friends. Another significant finding of this study was that fear of conventional medication led some women to choose herbal remedies over antibiotics to treat urinary tract infections leading to the possibility of inadequate treatment (Nordeng and Havnen, 2004).

Pinn and Pallet (2002) reported that about 12.0% of women attending an antenatal clinic in an Australian district hospital used herbal medicines. They recruited mothers who presented at the clinic for the first booking at 16 to 24 weeks of pregnancy but did not mention how they defined the herbal medicine users. The study revealed that raspberry leaf, golden seal, ginger, echinacea and St John’s wort were among commonly used herbal medicines during pregnancy. However, the researchers did not include the indication for use in their study. A survey conducted among pregnant women in the US found that 13.3% of the women surveyed reported using dietary supplements during pregnancy (Tsui et al., 2001). In this study, echinacea, pregnancy tea and ginger were the most frequently used herbs. The herbal medicines used during pregnancy in this study were in most cases considered not to be harmful. Iron-rich herbs are considered to be safe in pregnancy when used in recommended therapeutically doses (Tsui et al., 2001).

Holst et al. (2009) conducted a study in the UK on the use of herbal medicines by 578 pregnant women. Results showed that that 57.8% had used an herbal product during pregnancy. The commonly used herbal products were ginger, cranberry and raspberry leaf (Holst et al., 2009b).

Similarly, in developing countries, women also use herbal medicines in pregnancy. Varga and Veale (1997) conducted a study in South Africa on the utilisation of a specific herbal medicine isihlambezo. It was used to treat common pregnancy-related ailments such as oedema, indigestion, constipation, infection and high blood pressure. Pharmacological analysis suggested the possibility of harmful consequences of isihlambezo despite its therapeutic effect (Varga and Veale, 1997). A recent study in Nigeria by Tamuno et al. (2011) using a structured questionnaire
was conducted on 500 pregnant women attending an antenatal clinic to collect data on demographics, obstetric factors, knowledge and use of herbal medicine during pregnancy. The study showed that 31.4% of pregnant women used herbal medicines in the present pregnancy. Ginger (zingiber officinale) and garlic (allium sativa) were the most commonly used herbal medicines used by the women (Tamuno et al., 2011). A study conducted in Nigeria by Fakeye et al. (2009) reported that most women used herbal concoctions. In the study, it was found that more than two-third of respondents (67.5%) had used herbal medicines in crude forms or as pharmaceutical pre-packaged dosage forms, with 74.3% preferring self-prepared formulations. Almost 30.0 % who were using herbal medicine at the time of the study believed that the use of herbal medicines during pregnancy is safe (Fakeye et al., 2009).

There are different sources from which pregnant women get herbal medicines. Some studies report that friends or family suggest use of herbal medicines (Tsui et al., 2001). In the developing countries for example, traditional birth attendants (TBAs) are the common sources of herbal medicines (Johns and Sibeko, 2003) while in the developed countries women get herbal medicines from pharmacies or from known practitioners involved in herbal medicines. Information about source of herbal medicines was from family members and friends and others buying directly from herbal stores (Abrahams et al., 2002; Forster et al., 2006; Hollyer et al., 2002; Holst et al., 2009b; Nordeng and Havnen, 2004; Rahman et al., 2008; Tsui et al., 2001).

One of the most frequently cited reasons for using herbal medicines was a desire to avoid the side effects of conventional treatments (Palinkas et al., 2000). Although consumers often think that herbal medicine products are risk free (Eisenberg et al., 1998), the evidence available to date implies that some herbal medicinal products are associated with risks (Ernst, 2002). Women take herbal medicines to treat cold, gastrointestinal upset, abdominal pain, musculoskeletal pain, and also to combat threatened miscarriage and infection (Aviv et al., 1993; Donati et al., 2000; Henry and Crowther, 2000; Splinter et al., 1997).

The studies have shown that despite the advice that medicines should be avoided in pregnancy, women take herbal medicines because of their perception that herbal medicines are safer than prescribed medicines. Adverse events associated with
particular medicines could also influence women to opt for herbal medicines. Influence of significant others also contributes to the women taking the medicines.

2.6.2 Over-the-counter medication use during pregnancy

This section presents studies that looked at medications which women buy over the counter. The review will exclude herbal medicines because this has been discussed in Section 2.6.1.

Many people, pregnant women included, use over the counter (OTC) medicines for their self-medication. They consider OTC medications safe because they are available without a prescription. A few OTC medicines have a proven safety profile for use during pregnancy, while others have unproven safety or are known to adversely affect the foetus (Conover, 2002; Tillett et al., 2003). In addition, the safety of a certain OTC product may change depending on the gestational age of the baby. Over-the-counter medication use by pregnant women is very common as evidenced by several studies. Although, OTC medicines are meant for self-medication and are of proven efficacy and safety, their improper use due to lack of knowledge of their side effects and interactions could have serious implications, especially in children and older people and also in special physiological conditions like pregnancy and lactation (Choonara et al., 1996; Murray and Callahan, 2003). Several authors caution that the use of certain OTC medications has the potential to cause harmful effects on the foetus, particularly nonsteroidal anti-inflammatory medications and aspirin (Black and Hill, 2003; Li et al., 2003; Tillett et al., 2003).

In a large scale, retrospective study in the United States by Werler et al. (2005) non-prescription medication use was quantified for more than 10,000 pregnant women. Data were collected from two case-control studies: the Slone Epidemiology Centre Birth Defects Study and the National Birth Defects Prevention Study. They found most pregnant women had taken an OTC product, most commonly acetaminophen, pseudoephedrine, diphenhydramine and guaifenesin. By characterising medication use before and during pregnancy they discovered a trend of increased use during pregnancy compared to the three months prior. Rates of analgesic and decongestant
use were higher for white women, those with at least a high school education and women who were 20 years and older (Werler et al., 2005).

A study examining prescription, OTC and herbal medicine use in a rural, obstetric population, in West Virginia, US, found 92.6% self-medicated with at least one OTC product and 45.2% used herbal medicines (Glover et al., 2003). In addition, 20.8% took five or more OTC medications during pregnancy. They noted a trend of increased use as pregnancy progressed, especially with acetaminophen, calcium carbonate, cough drops and guaifenesin. Other common over-the-counter medications used included ibuprofen, aspirin, prenatal vitamins and non-sedating antihistamines.

Akanbi et al. (2005) in Nigeria studied self-medication pattern of antimalarial medicines. They reported that most of their participants had used chloroquine and pyrimethamine before their first antenatal visit. Since these medicines were taken before the first visit, it could be assumed that they were taken in early pregnancy during the period of organogenesis. Pyrimethamine is an antifolate with an expected teratogenic potential. In questionnaire-based descriptive study of 410 antenatal clients attending primary, secondary and tertiary centres in Ibadan, Nigeria, it was found that 19.2% of the women self-medicated. The most used medicines were hemanthinics and analgesics such as acetaminophen (Bello et al., 2011).

The next section will give a description of beliefs, views and practices related to medication use in pregnancy.
2.7 Beliefs and practices concerning medication use in pregnancy

Cultural background may have an important impact on the perception and attitudes toward taking medications (Horne et al., 2004). Traditional beliefs are transferred by word of mouth from generation to generation and adherence to them also depends on the women’s education and the amount of information given to the women (Liamputtong et al., 2005). There are different beliefs and practices about use of medicines in pregnancy. Mostly, these beliefs are influenced by the knowledge women have about the medicines. There are many beliefs and practices that govern this thinking and might have an effect on a woman's willingness to take medicines during pregnancy or vice versa (Mbonye et al., 2006). A study in Uganda showed both positive and negative perceptions with regard to the use of sulfadoxine-pyrimethamine (SP) in pregnancy. Results showed that SP was perceived to be an effective medication that cures malaria quickly. However, SP was perceived to be strong and thought to weaken pregnant women causing abortion and foetal abnormalities (Mbonye et al., 2006).

A study conducted by Holst et al. (2009) in the UK, found that women were aware of the fact that ‘herbal’ does not equal ‘safe’ but they all stated a belief in herbs being safer than pharmaceuticals. Pregnancy made some women more interested in herbs than pharmaceuticals. The most important reason for herb use was a belief in their safety relative to pharmaceutical medicines. However, in this study the women were aware that the medicines were not completely safe which was not the case in the other studies (Hollyer et al., 2002; Nordeng and Havnen, 2004; Vickers et al., 2006).

Some studies have demonstrated that women have some knowledge about which medicines are believed to be harmful and those believed to be safe during pregnancy. In studies conducted in the Gambia and Malawi, findings revealed that women were able to understand the concept that some medicines were contraindicated in early pregnancy (Brabin et al., 2009; Launiala and Honkasalo, 2007; Tolhurst et al., 2008). In the Gambian study, women named chloroquine as a Western medication to be avoided during the first trimester because it was bitter, a characteristic associated with abortifacients (Brabin et al., 2009). There was also a general agreement that one local herb cleaned the baby in utero and was safe to
take even in the first month of pregnancy, unlike another herbal remedy which could not be taken in early pregnancy but was thought to be safe later (Brabin et al., 2009). In similar findings in a study conducted in Malawi, women expressed that all bitter-tasting medicines should be avoided, because they are known to cause miscarriage. Traditional medicine, such as herbs and roots, as well as chloroquine, quinine and penicillin were classified as prohibited medication because they are bitter (Launiala and Honkasalo, 2007) but traditional medicine was sometimes used to prevent miscarriage. Another study conducted in Malawi by Tolhurst et al. (2008) found that most participants, including traditional healers, agreed that a pregnant woman should not take any bitter medicine (modern or traditional). The most common examples of bitter Western medicine included ‘capsules’ and these were mainly antibiotics and penicillin in particular and antimalarials. A similar study conducted in South Africa showed that 12.3% of women interviewed believed that traditional herbs can hurt the unborn baby (Peltzer et al., 2009).

Mubyazi et al. (2005) conducted a study in Tanzania which found that pregnant women tended to seek treatment from traditional healers and self-medication with local herbs for malaria management. Despite use of herbal medicine and self-medication, some women believed SP taken during pregnancy could cause abortion, whilst others decided to take a smaller dosage than what is recommended. In Tanzania women were also concerned about the use of SP because of fear over risk of severe skin reactions known as ‘Steven Johnson’s Syndrome’ (Mubyazi et al., 2005). Similarly, Ouma et al. (2007) in Kenya found that side effects of SP caused anxiety and fears. Overall women were generally reluctant to take the medicine during pregnancy because of concerns for potential effects on the unborn child.

Maimbolwa (2003) conducted a study in Zambia exploring childbirth practices and beliefs. The study found that TBAs were constantly consulted by pregnant women. If they were consulted, illnesses or sicknesses during pregnancies were explained by culturally accepted causes. Precautions and preventive measures were taken, as a pregnant woman and the foetus were believed to be in a physically and spiritually weak state and thus more susceptible to illnesses, sicknesses, witches and evil forces in the environment. Due to this susceptibility, in some cultures pregnancy is kept a secret until such a time that the pregnancy is visible (Maimbolwa, 2003;
Stokes et al., 2008). Thus women avoid public exposure of their pregnancy during the first months because fear of sorcery-related harm to mother or foetus (Maimbolwa, 2003). The practice of avoiding disclosure of pregnancy may inadvertently expose a woman and foetus to a potentially harmful medication if the health worker is unaware that she is pregnant.

Abrahams et al. (2002) studied indigenous healing practices and self-medication among pregnant women in Cape Town, and found that the majority of Xhosa speaking women followed indigenous health practices for both themselves and their babies because of the need to ‘strengthen’ the womb against witchcraft or sorcery, to prevent childhood illnesses, and to treat symptoms they perceive that biomedical services would not be able to treat. Self-medication with non-prescribed medicines, herbs and Dutch remedies was common among Afrikaans speaking women. Herbs and Dutch remedies were mainly used to treat indigenous illness while OTC medicines were used to treat minor ailments associated with pregnancy. Similarly, Mbonye et al. (2006) in Uganda found that most pregnant women preferred to use self-treatment with herbs, either alone or in combination with OTC medication. Only when self-treatment failed and the symptoms of the disease persisted, did pregnant women seek care from health units (Mbonye et al., 2006).

In conclusion, the above studies have found that pregnant women are aware that medicines can harm their unborn babies but most believed that some medicines during pregnancy were acceptable. The general beliefs about use of certain medicines and self-medication could predispose women to taking potentially harmful medicines. Conversely if women believe in taking traditional herbs and accessing OTC medications, they may inadvertently take medications that are potentially harmful to the foetus.
2.8 Perceptions of causes of congenital abnormalities

Studies identified in the literature on perceptions of causes of congenital abnormalities often focused on specific abnormalities such as cleft lip or club foot. Some reference will be made to these studies as the beliefs held could be applicable to other types of congenital abnormalities.

Lay theories of illness causation which could also include causes of congenital abnormalities, are universal and locate the aetiology or causation of ill health either within the individual, the natural, the social and the supernatural world (Helman, 2001). It is common to attribute congenital abnormalities to supernatural beings or maternal impressions during pregnancy.

Snow et al. (1983) described traditional health beliefs and practices among lower class Black Americans. Infants and children were viewed as innocent victims of their parents' misdeeds and parental sin was commonly blamed for deformity, seizure disorders or retardation. Conversely a study by Croot et al. (2008) of Pakistani parents living in the UK found that some parents referred to a child with a disability as a gift or blessing from God either through the pleasure they had from looking after the child, or because the child brought with them the promise of future reward and salvation (Croot et al., 2008). Similarly, in a study in an Asia American group, individuals viewed a baby with a cleft lip as a gift from God (Cheng, 1990) while another Indian population described it as God’s will (Weatherley-White et al., 2005).

Apart from describing having a baby with a congenital abnormality as a gift from God, some parents suggested that God had given them a child with a disability as a test of their abilities as parents (Croot et al., 2008). When asked how they would pass or fail the test, the responses indicated that parents felt they were being tested about how they looked after the child (Croot et al., 2008).

In some cultures, individuals may feel that a family is given a child with a disorder as a punishment from God for parental sin (Kenen, 1980; Meyerson, 1990). In a study conducted in India, participants were convinced that parents had sinned in a past life and that a child’s cleft palate was a direct punishment of this transgression (Weatherley-White et al., 2005). Nigerian mothers assumed that cleft lip was caused
by evil spirits, that the spirits were angered by the mothers staying in the sun too long (Nwanze and Sowemimo, 1987).

In a study conducted in India, participants reported supernatural causes of birth abnormalities in children such as a woman viewing an eclipse during her pregnancy (Minhas, 2007; Weatherley-White et al., 2005). Hispanic women specifically reported a lunar eclipse as a cause of cleft lip or palate (Meyerson, 1990).

Some causes of birth defects are attributed to maternal impressions, i.e. something the pregnant woman thinks or sees. For example, there is a belief that a child born with microcephaly or anencephaly is the result of his/her mother looking at a monkey during the pregnancy (Kené, 1980), or in other cases, the other animal which has been named in causing birth defects is the rabbit. Studies reveal that in some cultures there is a belief that a cleft lip is caused by looking at or eating a rabbit, hence the name hare-lip (Cheng, 1990; Toliver-Weddington, 1990). The latter belief is prevalent in Chinese cultures. In America, there was a belief that when a pregnant woman is frightened by a rabbit, this could cause cleft lip (Henderson and Primeaux, 1981).

In other studies it has been reported that some cultures believe a child will be born with a birth defect if a pregnant woman takes pity on or mocks an affected individual (Henderson and Primeaux, 1981; Meyerson, 1990; Snow, 1983; Toliver-Weddington, 1990). Thus, if a pregnant woman sees a person with a disability and laughs, God may ‘put the same thing’ on her infant to remind her to be more charitable in future. The sight of the disabled child is a constant reminder to her (and everyone else in the neighbourhood) as long as she lives (Snow, 1983).
2.9 Summary

From the reviewed literature, use of medications has undesirable effects of the foetus and should be avoided in pregnant women and by women of a childbearing age in general. The literature has shown that congenital abnormalities contribute to perinatal mortality and morbidity worldwide. A review of studies on medication use during pregnancy has shown that many women take prescription or self-medication at least in pregnancy. The literature has also shown that cultural beliefs may affect the medicines which are taken during pregnancy.

Studies in the literature have examined medication use in pregnant women mainly after pregnancy is known or outcome is known. Appendix 1 shows 22 studies that were critically appraised. This was aided by the use of the appropriate critical appraisal tool for each study design (CASP, 2007). Most of the studies were cross-sectional in design using computerised pharmacy records and interviews. The majority of studies were conducted in the developed countries such as the UK, USA and Europe, therefore the findings cannot be generalised to other settings such as the developing countries.

In Malawi, there was one study which was identified which explored women’s views about use of medicines in pregnancy. This study was conducted by Launiala et al. (2007) who examined women’s knowledge and perceptions about the use of medication in pregnancy. This study utilised focus group discussions and medication identification exercise to collect data in the community. No study about the use of medicines was found that had been conducted in the clinic setting in Malawi.

The present study is important because it will provide information about use of medicines in early pregnancy.
CHAPTER 3
METHODOLOGY

3.1 Introduction

This chapter describes the methodology chosen for the study. The chapter begins with a discussion of the concept of research paradigms and then justifies the paradigm used for this research. This is followed by a description of different research methodologies. The research design for the study is also described.

The main aim of the study was to assess the risk of medication exposure in women in early pregnancy. This study is divided into three parts relating to: (i) a review of records providing preliminary data about congenital abnormalities; (ii) medicines that were prescribed to women of childbearing age in the general outpatient department and (iii) the beliefs and views of women from the antenatal clinic concerning medication use during pregnancy. The three arms of the study are distinct but linked.

The following study questions helped to guide the choice of research methods to achieve the aim:

1. What is the prevalence of congenital abnormalities at Mitundu Community and Kamuzu Central Hospitals?
2. What proportion of women prescribed contraindicated medicines is likely to be pregnant?
3. What type of beliefs, views and practices do women have concerning medication use in pregnancy?
4. What concerns do women hold about pregnancy disclosure that could affect their medication use (or prescription)?
5. What are their perceived causes of congenital abnormalities?
3.2 Research paradigm

A paradigm can be defined as a basic set of beliefs or assumptions that guide research (Creswell, 1998). There are many different paradigms in science and they differ in terms of their underlying assumptions. Thus, in order to choose the suitable paradigm, it is necessary to understand the assumptions underpinning each paradigm. The basic philosophical assumptions are ontology, epistemology and methodology (Creswell and Plano Clark, 2007; Guba and Lincoln, 1994). Ontology refers to the nature of reality and what can be known about it. Epistemology refers to the nature of the relationship between the knower and what can be known. Methodology refers to the techniques or research methods that are used to obtain knowledge (Guba and Lincoln, 1994). The following section discusses three major paradigms namely: positivism, constructivism and pragmatism.

3.2.1 Positivist paradigm

Positivism is the oldest paradigm in the modern science. Positivists believe that universal laws and truths drive one reality. They are assumed to be objective and independent. From this viewpoint, positivists use experimental and quantitative methods to test and verify hypotheses (Guba and Lincoln, 1994). Positivists believe that knowledge is only significant if it is based on observations of external reality. Positivists aim to measure and analyse the causal relationships between variables in the process of the research inquiry (Easterby-Smith et al., 1991). The inquiry is assumed to be value free, and the investigator and the phenomenon are assumed to be independent. This approach presumes to prevent individuals’ values and biases from influencing outcomes (Guba and Lincoln, 1994). Since the present study deals with variables within the context of complex real life healthcare experiences, the use of this paradigm alone is insufficient because the complex experiences cannot be captured adequately using quantitative methods.
3.2.2 Constructivist paradigm

Constructivists believe that there are multiple, constructed realities with any context. Further they believe that the researcher is not independent from the subject of the study, but interacts with the respondents to construct the outcome (Guba and Lincoln, 1994). Therefore, the outcome of the inquiry is constructed through the joint effort of the researcher and respondents during the process. The assumptions of constructivism are subjective and the created knowledge is understood to depend on the interaction between the interviewer and the respondents (Guba and Lincoln, 1994). Constructivists use qualitative and naturalistic methods to inductively and holistically understand human experience in context-specific settings.

This paradigm on its own is also unsuitable for this research. This is due to the research aiming to determine the rate of pregnancy among women who have been prescribed medicines with a potential harm to the foetus. This is an objective process, not a subjective one, as the constructive paradigm requires.

3.2.3 Pragmatist paradigm

Pragmatist researchers consider the research question to be more important than either the methodological approach or the paradigmatic assumptions that underlie the research method (Tashakkori and Teddlie, 1998). They believe that both quantitative and qualitative methods are useful. According to Tashakkori and Teddlie (1998) decisions regarding the use of either qualitative or quantitative methods (or both) depend upon the research question. Pragmatists may be both objective and subjective in epistemological position. Pragmatists agree with positivists that there is an external reality but they deny that there is an absolute truth (Creswell, 2003; Tashakkori and Teddlie, 1998). Pragmatism does not require commitment to any one philosophical system (Creswell, 2003) and researchers are free to choose methods that best meet their needs and purposes. It provides a philosophical underpinning for mixed method studies (Tashakkori and Teddlie, 1998). Furthermore, pragmatism supports the combined use of quantitative and qualitative research methods within the same study, and rejects the forced choice between positivism and constructivism.
(Tashakkori and Teddlie, 1998). Pragmatism as a general belief system has been used to justify combining qualitative and quantitative methods in sciences (Johnson and Onwuegbuzie, 2004).

3.3 Research methodology

A research methodology is ‘a model which entails theoretical principles as well as a framework that provides guidelines about how research is done in the context of a particular paradigm’ (Sarantakos, 1994). There are three approaches that inform the gathering of data in any research, namely the quantitative approach, the qualitative approach, and mixed methods approach (Creswell and Plano Clark, 2007; Tashakkori and Teddlie, 1998).

3.3.1 Quantitative approach

A quantitative approach is defined 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 (Creswell, 1994). The main aims of the quantitative approach are to objectively measure the social world, to test hypotheses and to predict and control human behaviour. Quantitative methodology usually draws upon the positivist paradigm and facilitates the investigation of the causal relationship between variables (Morse and Field, 1996). Creswell (2008) points out that a quantitative approach is useful when attempting to test a theory or explain or identify factors that influence results.

The most common quantitative approach methods include experiments, quasi-experiments and surveys. The approach uses objective measures to assess these relationships and usually reports results numerically (Tashakkori and Teddlie 2009). The strengths of a quantitative approach is that it can produce factual, reliable outcome data that may be generalisable to some larger population (Patton, 2002). Some limitations of quantitative studies are that data collection may be time-
consuming, measurement of concepts may not be absolute, and underlying assumptions for statistical analysis are sometimes violated.

3.3.2 Qualitative approach

A qualitative approach can be defined as an inquiry process of understanding a social or human phenomenon, based on building a complex, holistic picture, formed with words, reporting detailed views of informants, and conducted in a natural setting (Creswell, 1994). Qualitative research also involves an interpretative, naturalistic approach to the world (Brewer, 2000). This means that qualitative researchers study things in their natural settings, attempting to make sense of phenomena in terms of the meanings people bring to them (Guba and Lincoln, 1994). Its main aim is to understand life and the meaning that people attach to it (Lincoln and Guba, 1985). It is appropriate when variables are unknown and the theory base is inadequate, incomplete, or simply missing due to a lack of previous research (Creswell, 1994). Qualitative methodology draws upon constructivism, the belief that reality is constructed through a combination on people’s perspectives and their social world (Silverman, 2000). The approach facilitates in-depth exploration of people’s experiences and views and is usually used when little is known of the subject in question (Morse and Field, 1996).

Main qualitative methods include individual interviews, focus groups and observation. The benefits of using qualitative approaches are that they give richness and a deeper insight into the phenomena under study (Hancock, 1998). Limitations are that there is the possible effect of the researcher’s presence on the people they are studying (Carr, 2008) thus the relationship between the researcher and participants may distort study findings; data analysis is also time consuming and consequently expensive (Hancock, 1998) and also the reliability of qualitative research is weakened by the fact that the process is under-standardised and relies on the insights and the abilities of the observer, thus making an assessment of reliability difficult (Duffy, 1985).
3.3.3 Mixed methods approach

A mixed methods approach is research where qualitative and quantitative approaches are combined. Some researchers focus on the philosophical assumptions, for example Tashakkori and Teddlie (1998). Others focus on the techniques or methods of collecting and analysing data, for example Greene, et al., (1989); Creswell, et al., (2003); Johnson and Onwuegbuzie (2004). Creswell et al. (2007) have given a broad definition focusing on the philosophical assumptions and the methods. They define this approach as a research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis of data and the mixture of qualitative and quantitative approaches in many phases in the research process. As a method, it focuses on collecting, analysing, and mixing both quantitative and qualitative data in a single study or series of studies.

There are five major purposes or rationales for conducting the mixed methods approach: (1) triangulation which is seeking convergence and corroboration of results from different methods and designs studying the same phenomenon; (2) complementarity which is seeking elaboration, enhancement, illustration and clarification of the results from one method with results from the other method; (3) initiation which is discovering paradoxes and contradictions that lead to a re-framing of the research question; (4) development which is using the findings from one method to help inform the other method; and (5) expansion which is seeking to expand the breadth and range of research by using different methods for different inquiry components (Greene et al., 1989).

The fundamental principle of the mixed methods approach is that the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone (Creswell and Plano Clark, 2007). The goal of the mixed methods approach is to draw from the strengths and to minimise the weaknesses of both qualitative and quantitative approach (Johnson and Onwuegbuzie, 2004). Another advantage is that the mixed methods approach can answer a broader and more complete range of research questions (Johnson and Onwuegbuzie, 2004). Also, applying the mixed methods approach can improve insights into an understanding of the data, which might be missed when
using a single approach. Nevertheless, conducting the mixed methods approach takes time and resources to collect and analyse both quantitative and qualitative data. It also requires that the researchers are familiar with the collection and analysing both quantitative and qualitative data (Creswell and Plano Clark, 2007). Creswell et al. (2003) identified six major types of mixed methods designs or strategies namely: sequential explanatory strategy, sequential exploratory strategy, sequential transformative strategy, concurrent triangulation strategy, concurrent nested strategy and concurrent transformative strategy. Descriptions of these strategies are outlined in Table 3.1.

Table 3.1: Table showing six major mixed methods strategies

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Data collection and analysis</th>
<th>Priority</th>
<th>Integration</th>
<th>Theoretical perspective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequential explanatory strategy</td>
<td>Quantitative data collection and analysis is conducted first, followed by qualitative data</td>
<td>Priority is given to quantitative data</td>
<td>At interpretation stage</td>
<td>May or may not have a specific theoretical perspective</td>
</tr>
<tr>
<td></td>
<td>collection and analysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sequential exploratory strategy</td>
<td>Qualitative data collection and analysis is conducted first, followed by quantitative data</td>
<td>Priority is given to qualitative data</td>
<td>At interpretation stage</td>
<td>May or may not have a specific theoretical perspective</td>
</tr>
<tr>
<td></td>
<td>collection and analysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sequential transformative strategy</td>
<td>There are two data collection phases; however, either method may be used first</td>
<td>Priority may be given to either qualitative or quantitative methods or both</td>
<td>At interpretation stage</td>
<td>Has a theoretical perspective to guide the study</td>
</tr>
<tr>
<td>Concurrent triangulation strategy</td>
<td>Both types of data are collected and analysed at the same time</td>
<td>Priority is equal between the methods</td>
<td>At interpretation stage</td>
<td>May or may not have theoretical perspective</td>
</tr>
<tr>
<td>Concurrent nested strategy</td>
<td>Both types of data are collected and analysed at the same time</td>
<td>One of the methods has a priority</td>
<td>At data analysis stage</td>
<td>May or may not have theoretical perspective</td>
</tr>
<tr>
<td>Concurrent transformative strategy</td>
<td>Both types of data are collected at the same time</td>
<td>May have equal or unequal priority</td>
<td>At data analysis or interpretation</td>
<td>Has a specific theoretical perspective</td>
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</table>
3.4 Design chosen for the study

The design adopted was a mixed method approach, combining quantitative and qualitative elements. A study design is determined by a research question (Mays and Pope, 2000). Mixed methods are chosen when a study’s question cannot be answered by using one single method (Teddlie and Tashakkor, 2009). The main question for this study was to assess the risk of medication exposure in early pregnancy. The present study adopted the mixed methods research design adopting the pragmatic paradigm. The pragmatic paradigm, which is considered to be most suitable for a mixed methods study (Morgan, 1996; Sandelowski, 2000; Tashakkori and Teddlie, 2003), was chosen to underpin this study. The research question drives the choice of methods. The rationale for a mixed method approach was that neither quantitative nor qualitative methods were sufficient by themselves to capture the trends and details of the situation, such as issues concerning women’s risks of medication exposure in pregnancy. The overall design used in the study was concurrent triangulation strategy (Creswell, 2003). Thus quantitative and qualitative data were collected and analysed at the same time. Both forms of data were given equal priority. Each data set remained separate from one another during the analysis, but the results were converged, or triangulated, during the interpretation phase of analysis to answer a research question (Creswell, 2003; Sandelowski, 2000). This strategy was selected for several reasons. First, it allows the findings to be confirmed, cross-validated, and corroborated within a single study. Second, this strategy resulted in a shorter data collection time compared to other mixed methods strategies, e.g. the sequential strategies (Creswell and Plano Clark, 2007).

This study has been approached from the pragmatic perspective where the purpose of the research has driven the choice of method rather than a particular ideological position and no attempt has been made to prioritise one particular method. Pragmatists support both objective and subjective views and do not believe that causal relationships can always be proven in real world (Tashakkori and Teddlie, 1998). The pragmatic approach is consistent with exploring complex issues, in this case medication exposure. Pragmatism was seen as supporting the underpinning principle of women’s use of medicines. It offered the flexibility to use various methodologies together to understand and incorporate the accounts of the women.
In the present study, the positivist paradigm was used in the generation of quantitative survey data to provide an objective description of the risk to which women are exposed to medicines in early pregnancy while the constructivist paradigm was used in the qualitative data generation of the study as it is best suited to the study of participants’ beliefs and views concerning medication use during pregnancy. Also, the prevalence data on congenital abnormalities required a quantitative approach. The quantitative approach provided an insight of the extent of how many women were being exposed to potentially harmful medicines in early pregnancy. The qualitative approach was used to allow for a descriptive analysis of women’s beliefs, views and practices concerning medication use during pregnancy. Qualitative methods were chosen as they have great value in sensitively exploring perceptions and practices in different cultural perspectives. A qualitative approach provided a richer understanding of women's beliefs towards medication use during pregnancy and gave insight into previously unexplored areas. The data regarding congenital abnormalities was based on a retrospective analysis of hospital records. This data contributed to the preliminary findings about the prevalence of congenital abnormalities and gave a picture of the most common abnormalities.

3.4.1 Choice of retrospective review of records

A retrospective review of records was chosen because of the time the researcher had available to execute the study. It also allowed for a choice of reviewing records over a defined time, in this study, records from 2006 to 2010 were reviewed.

3.4.2 Choice of a cross-sectional survey

There are several designs used in quantitative research namely: case-control studies, cohort studies, randomised controlled trials, secondary data analysis and surveys.

In case-control studies, cases (those with disease) are compared to appropriately selected controls (without disease) to determine whether they differ with respect to exposures. For example, the researchers look for differences between groups in
antecedent behaviours or conditions such as smoking (Polit and Beck, 2012). Another quantitative design is the cohort design. Cohort studies are also called follow-up studies in which a group of individuals (the cohort) is followed up for a period of time to see if subsets with exposure to different factors differ in terms of subsequent outcomes or risks (Polit and Beck, 2012). Randomised controlled trial (RCT) is a design where patients are assigned to different treatments. Thus, a group of patients is selected and then patients are randomly allocated to different treatments or treatment and placebo groups. Randomisation aims to ensure that patients on different treatments are comparable with respect to baseline characteristics, as well as known and unknown risk factors (Jourbert and Katzenellenbogen, 1997). Another type of study design is the secondary data analysis. Secondary analysis involves the use of existing data from a previous study to test new hypotheses or answer new questions (Polit and Beck, 2012). In some cases, a secondary analysis involves examining relationships among variables that were previously unanalysed. The other quantitative type of quantitative study is the survey design. In survey design, attributes of a large population can be identified from a small group of individuals (Babbie, 2004; Fowler, 1993). Also as many questions could be asked and it is possible to reach a large enough group within a short period of time (Fowler, 1993). Babbie (2004) identifies two basic types of surveys: cross-sectional surveys and longitudinal surveys. Cross-sectional surveys gather information of a particular population at a distinct time. Longitudinal surveys on the other hand, collect information over a period of time.

This study utilised the cross-sectional survey method to collect information concerning exposure to medications in early pregnancy. In order to estimate prevalence rates (at a fixed point in time for each participant) and collect detailed information about medication use, the best study design was a prospective survey.

3.4.3 Choice of a qualitative design

Qualitative research describes the depth, richness, and complexity inherent in the phenomena and involves putting pieces together to understanding the whole (Burns and Grove, 1999). The qualitative approach is based on the world view that there is no single reality, perceptions differ from persons and over time and what is known
has meaning only within a given context (Burns and Grove, 1999). Thus a descriptive qualitative method was used to explore and gain in-depth knowledge and understanding of beliefs, views and practices concerning medication use in pregnancy in women in Mitundu Community, Malawi (Parse, 2001; Polit and Beck, 2012).

3.5 Theoretical Framework

The next section describes the symbolic interactionism theory which is the theoretical framework that guided in the data analysis and interpretation of the qualitative study findings. Firstly, a description of the theory is given and this will be followed by a description of how the theory is applied to the study.

3.5.1 Symbolic interactionism

The theoretical framework that guided analysis and interpretation of the qualitative data is symbolic interactionism. The framework has been chosen as the most appropriate for this study because of the sociological enquiry about beliefs, views and practices related to medication use in pregnancy. Symbolic interactionism is a theory of human behaviour, primarily based on the premise that human experience is mediated by interpretation. According to this perspective, as people interact mutually and with other social objects, they attribute meaning to them and react based on these meanings, which are dynamic and change as interactions occur (Charon, 2004).

Symbolic interactionism is a sociological framework which was developed by Blumer in 1969 and consists of three main premises. The first premise is that human beings act toward things on the basis of the meanings that the things have for them. Such things include everything that the human being may note in his world. These things are not just confined to physical materials like chairs and trees, they also include everything that the human being may note in his world (Blumer, 1969). Thus, activities of others and guiding ideals are classified under things. The second premise is that the meaning of such things is derived from, or arises out of, the social
interaction that one has with one’s fellows (Blumer, 1969). Thus, meaning is not inherent to a thing or object, but it is created through interaction with other human beings.

The third premise is that these meanings are handled in, and modified through, an interpretative process used by the person in dealing with the thing he encounters (Blumer, 1969). Thus meaning is central to the foundation of symbolic interactionism. Blumer argues that too often meanings get looked over or counted as unimportant. He puts forward that in symbolic interactionism the meanings that things have for human beings are central in their own right. Blumer (1969) states, ‘to ignore the meanings of things toward which people act is seen as falsifying the behaviour under study’ (p. 3).

Symbolic interactionism sees meanings as social products, as creations that are formed in and through the defining activities of people as they interact (Blumer, 1969). Also meanings play their part in action through a process of self-interaction, which Blumer describes as communication of an individual with oneself (Blumer, 1969).

### 3.5.2 Application of the theoretical framework to the present study

As explained in the premises upon which symbolic interactionism is based, human behaviour has meaning for the self and for others. This assumption of behaviours’ significance applies both to completed and anticipated acts. The meaning of an act is at some level part of a person’s decision-making. When it comes to use of medicines in pregnancy, use can mean different things, depending on context. For example, choices among behavioural options are based on the chooser’s definition of the situation. Different definitions explain why people sometimes respond differently even to the same situational and cultural influences. One person, for example, may interpret use of traditional medicine as a potential harm to the unborn baby while another may interpret it as an important medicine which can strengthen the pregnancy.

To understand the potential for risk of exposure to harmful medicines, there must be an appreciation of the women’s beliefs, views and practices to medication use in
pregnancy and an understanding of their moral judgments. For example, without a better understanding of what women believe and practise in pregnancy in relation to medicine use, we cannot understand if use or non-use of some medicines is the result of social interactions the women have with either significant others and/or health workers. The literature has shown that women may be exposed to harmful medicines because they have not disclosed their pregnancy. Disclosure therefore could be related to social interactions women have with others and how they value or are guided by cultural norms relating to disclosure. Thus, if pregnancy is kept a secret, the women could not even disclose to the health worker that they are pregnant, a situation which could put the woman at risk of inadvertent exposure. Women’s beliefs and views towards medication use in pregnancy are created and enhanced by institutionalised social constructions that then determine whether a woman takes medicines or not. This socially constructed belief is real in its consequences and will enormously impact the ways in which women interpret the usefulness or harmfulness of medicines in pregnancy.

3.6 Ethical principles

Human rights need to be protected during research. Researchers have an ethical responsibility to protect participants’ human rights during research (Burns and Grove, 1999). During the research study the following ethical considerations were made to protect the rights of participants during the course of the research study. Details of the ethical principles followed are presented in relevant sections.

3.6.1 The principle of beneficence

This principle requires that the actions of researchers are directed at improving the wellbeing of study participants and that they should not cause harm to the participant (IJsselmuiden, 1997). Participants have the right to freedom from harm and discomfort where researchers have an obligation to avoid, prevent or minimise harm. Therefore, researchers have a duty to minimise harm and maximise benefits.
Studies that cause temporary discomfort are considered as minimal risk studies (Burns and Grove, 1999).

### 3.6.2 The principle of respect for human dignity

This principle includes the right to self-determination and the right to full disclosure. In self-determination it is argued that humans should be treated as autonomous agents who are capable of controlling their actions (IJsselmuiden, 1997; Polit and Beck, 2012). Self-determination means that prospective participants can voluntarily decide whether to take part in a study, without risk of prejudicial treatment. Participants also need to be free from coercion by the researcher especially when the researcher is in a position of authority or influence over potential participants. This right has to be respected by researchers and that the researchers have an obligation to enable the autonomy of individuals by providing information that allows individuals to make autonomous decisions (IJsselmuiden, 1997). Participants also have a right to full disclosure which involves that the researcher has fully described the nature of the study, the person’s right to refuse participation, the researcher’s responsibilities, and likely risks and benefits. Informed consent of participants is based on the right to self-determination and the right to full disclosure.

### 3.6.3 Principle of justice

The notion of justice means that people receive what is due to them (IJsselmuiden, 1997). This principle includes participants' right to fair treatment and their right to privacy.

#### 3.6.3.1 Right to fair treatment

Right to fair treatment refers to the equitable distribution of benefits and burdens of research (Polit and Beck, 2012). For instance, all who stand to benefit from the research should contribute to its risks and discomforts. For example, research that may benefit the rich and the poor should be conducted among both groups, and not
only the poor (IJsselmuiden, 1997). Thus, participant selection should be based on study requirements and not on a group’s vulnerability.

3.6.3.2 Right to privacy

Research with humans involves intrusion into person’s lives hence participants need to have a right to privacy. In this, researchers should ensure that their research is not more intrusive than it needs to be and that participant’s privacy is maintained continuously (Polit and Beck, 2012). Participants have the right to expect that their data will be kept confidentially. Anonymity exists when the subject cannot be linked to the data collected (Burns and Grove, 1999). Confidentiality is the management of the data shared by the subject (Burns and Grove, 1999).

3.7 Summary

In this chapter the study methodology was explained in relation to the study aims and the researcher’s philosophical positioning. The rationale for choosing the mixed methods design for the study was explained. The most appropriate study design for each arm of the study was chosen. A retrospective review of records was chosen because of the limited time the researcher had to conduct the study. Survey design was selected for quantitative data collection because the research question required this approach. Qualitative design was chosen because the research question about women’s beliefs, views and practices of medication use in pregnancy could adequately be addressed using this approach. A theoretical framework which guided the data collection and analysis of the qualitative data was described. In the next chapter, procedures and steps that were taken to conduct the study are detailed. This includes setting the scene and issues of access. Addressed also are the ethical processes that were undertaken both before and during the research process.
CHAPTER 4

METHODS

4.1 Introduction

This chapter describes the detailed research methods used to conduct the study. The chapter begins by describing the study set-up activities undertaken before the study started. This included selection of research sites, securing access to these sites and ethical considerations governing data collection. The research design, sample and setting, procedures for data collection, instrumentation, and methods for data analysis related to the research questions are described.

The main aim of the study was to assess medication exposure in women in early pregnancy. This chapter is divided into three parts describing the methods used to assess: (i) secondary data on congenital abnormalities from hospital records; (ii) numbers and types of contraindicated medicines that were prescribed to women of childbearing age in the general outpatient department; (iii) beliefs, views and practices of women from antenatal clinic concerning medication use during pregnancy.

4.2 Study set-up and preliminary stages

This section describes activities undertaken prior to conducting the study. Issues of selection of study sites and procedures taken to secure access to the sites will also be described.

4.2.1 Selection of study sites

Initially in January 2009, the researcher visited three institutions, namely Kawale Health Centre, Area 25 Health Centre and Mitundu Community Hospital in Malawi to finally decide which site was most suitable. Data available for 2008 showed Mitundu Community hospital served a population of 99,515, Kawale Health Centre a population of 200,000 while Area 25 Health Centre served a population of 80,002.
For numbers of women of childbearing age, Mitundu had 22,888 while Kawale and Area 25 Health Centre could not provide statistics and it was therefore difficult to estimate a potential pregnancy rate for the latter two sites. The researcher also collected statistics about patient attendance including an average attendance for women of childbearing age. Patient flow was observed as this could affect whether women who required prescriptions would have time, and be able to locate, the researcher after their outpatient visit. Organisationally, Mitundu Community Hospital seemed to offer the best chance of smooth patient flow from outpatient consultation to researcher to pharmacy. The researcher also chose Mitundu Community Hospital for the questionnaire survey because the sample size requirement could be satisfied by data collected at the outpatient clinic at this site alone. There were also practical considerations of travel distance, cost implications and time available to execute the study, and Mitundu was relatively easier to access. Qualitative interviews were also conducted at Mitundu Community Hospital which had busy antenatal clinics which would facilitate recruitment of pregnant women for the study on beliefs, views and practices related to medication use during pregnancy.

Kamuzu Central and Mitundu Community Hospitals were chosen for the review of records. Kamuzu Central Hospital, Lilongwe is the main referral hospital which receives most complicated cases from district hospitals within the central region of Malawi. It was very likely that babies born with congenital abnormalities within the district hospitals would be referred here for specialist care. The researcher consulted with a paediatrician who, nevertheless, drew attention to the difficulty of getting data because records were not properly kept. Mitundu Community Hospital was included as this was the site for the main study and kept a birth register.

4.2.2 Gaining access to the study sites

Once ethical approval was granted by ethics committees, the fieldwork in Malawi began with the researcher renewing contact with the institutions to get formal permission to conduct the studies as planned. The researcher recognised that gatekeepers hold key positions in the hierarchy of a group or institution under study and their influence can make the researcher’s life either easy or difficult (Berg, 2009). Local permission was sought from the Mitundu Community Hospital
management team through Lilongwe District Health Office (Appendix 12). Permission was sought from the Kamuzu Central Hospital Director to review records from the registers (Appendix 13). Both institutions granted the researcher permission to conduct the study (Appendix 14 & 15). At Mitundu Community Hospital arrangements were made to go to the village chiefs to explain the study. A meeting was held with 15 leaders in the catchment area of the hospital at the headquarters of the chief. This was to ensure that village heads and leaders were aware of the study and had no objections to requesting women to participate. The researcher was accompanied by a Health Surveillance Assistant from the hospital to the sensitisation meeting which provided a good forum for discussion. The leaders were given an opportunity to ask questions to try to allay any misinformation and superstition. The chiefs asked if the researcher would be issuing any new medicines to the women, and she clarified that the women would only be interviewed and were not being examined by the researcher except for urine pregnancy testing. As the researcher was a Malawian health worker who shared similar beliefs and cultural values the leaders were receptive to the study.

Another meeting was convened with all Medical Assistants and midwives at Mitundu hospital to explain the research and its procedures. This was necessary because the quantitative survey about contraindicated medicines being prescribed involved some interruption to the day to day running of the outpatient clinic. The Medical Assistants were requested to refer to the researcher any woman of childbearing age prescribed medicines with a potential for foetal harm.

Malawi has an Essential Medicines List (Malawi Ministry of Health, 2009) that outlines which medicines are to be stocked at each level of the health care system. Medicines that are categorised for central hospitals cannot be found at the district hospital and health centres. Those stipulated for district hospital use cannot be stocked at the health centre. Table 4.1 shows some commonly used medicines at a community hospital that have some pregnancy contraindications and cautionary advice. This list was provided to the researcher by the hospital pharmacy.
Table 4.1: Selection of medicines commonly prescribed in Malawi which are contraindicated during pregnancy

<table>
<thead>
<tr>
<th>Medicine</th>
<th>FDA</th>
<th>Group</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>C</td>
<td>Pain killer</td>
<td>Impaired platelet function and risk of haemorrhage; delayed onset and increased duration of labour with increased blood loss; closure of foetal ductus arteriosus in utero and possibly persistent hypertension of the newborn; kernicterus in jaundiced newborns</td>
</tr>
<tr>
<td>Artemether-lumefantrine</td>
<td>C</td>
<td>Antimalarial</td>
<td>(1)* can induce foetal resorption if given in high doses to experimental animals during a narrow time window in early gestation; cardiovascular malformations; skeletal defects including shortened and/or bent long bones and scapulae, misshapen ribs, cleft sternebrae and incompletely ossified pelvic bones</td>
</tr>
<tr>
<td>Ciproflaxin</td>
<td>C</td>
<td>Antibiotic</td>
<td>(1, 2, 3)* Avoid; arthropathy in animal studies</td>
</tr>
<tr>
<td>Cotrimoxazole</td>
<td>C</td>
<td>Antibiotic</td>
<td>(1)* Teratogenic risk; (3)* newborn blood haemolysis and methaemoglobinemia</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>D</td>
<td>Antibiotic</td>
<td>Contraindications after 15 weeks’ gestation, because of effects on teeth and bones</td>
</tr>
<tr>
<td>Gentamycin</td>
<td>C</td>
<td>Antibiotic</td>
<td>(2, 3)* Small risk of auditory or vestibular nerve damage; avoid unless essential</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>C</td>
<td>Analgesic (nonsteroidal anti-inflammatory medication)</td>
<td>(1, )* Most manufacturers advise avoid; (3) *with regular use closure of foetal ductus arteriosus in utero and possibly persistent hypertension of the newborn; delayed onset and increased duration of labour</td>
</tr>
<tr>
<td>Albendazole</td>
<td>C</td>
<td>Antihelmintic</td>
<td>Manufacturer advises toxicity in animal studies</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>B</td>
<td>Antibiotic</td>
<td>Should not be used in the first trimester. Animal experiments suggest mutagenic and carcinogenic effects, but no embryotoxic/teratogenic effects have been reported in humans</td>
</tr>
<tr>
<td>Phenobarbitone</td>
<td>D</td>
<td>Anticonvulsant</td>
<td>Interfere with folate metabolism hence causes neural tube defects</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>D</td>
<td>Antibiotic</td>
<td>(1)* Effects on skeletal development in animal studies; (2, 3)* dental discolouration; maternal hepatotoxicity with large parenteral doses</td>
</tr>
<tr>
<td>Sulfadoxine-pyrimethamine</td>
<td>C</td>
<td>Antimalarial</td>
<td>(1)* Theoretical risk of causing neural tube defects secondary to maternal folate deficiency</td>
</tr>
</tbody>
</table>

*Trimester of risk
Women were not to be referred if they were very ill and might require a hospital admission. It was indicated that the researcher might occasionally consult with the Medical Assistants if she was concerned that a change in prescription was indicated. Dispensary staff at the hospital pharmacy were asked to check for the researcher’s signature in the patient’s Health Passport (this is a patient-retained booklet in which consultation notes and treatment are written) as an indication that the patient had been referred to the researcher for screening eligibility in the study. The availability of registry data to check the number of eligible women who were given prescriptions also helped the researcher to check if patients had been missed.

Midwives were also briefed on the procedures for referring antenatal women to the researcher after their routine antenatal check-ups. They were requested to refer women at their first antenatal visit, especially those in their early pregnancy for potential participation in the qualitative interviews of views and practices concerning medication use during pregnancy.

4.2.3 Space issues

The hospital made available a private office for the duration of the study. This was in the x-ray department which was non-functional at that time. This followed initial allocation to two other rooms which had been unsatisfactory because they were too far from the outpatient clinic and would have risked loss of women if they could not locate the room. The researcher assigned one of the registry personnel to help direct the women.

4.2.4 Women’s waiting time

Women had to wait for at least three hours before being seen by a Medical Assistant. Once referred to the researcher, waiting times varied from a few minutes to one hour. To avoid women leaving, the researcher regularly reassured the women and requested them to wait for her. The women were given drinks as they waited. After administering the questionnaire, they were given petty cash equivalent to £1.00 for transport.
4.2.5 Timetabling

Mitundu Hospital did not conduct an outpatient consultation on Wednesday afternoons and had no antenatal clinic that day. As such, the researcher utilised the afternoon for reviewing records at Kamuzu Central Hospital.

It proved too difficult to conduct in-depth interviews on the same day as questionnaires as women referred for the survey constantly interrupted the interview and were kept waiting for a long time. A week was later dedicated to in-depth interviews only. More women were attending during the rainy season (February to April) but fewer women of lower parity than expected were being recruited. During the dry season, attendance declined which slowed the recruitment rate. The researcher additionally administered questionnaires on Saturday mornings when the clinic opened for a half day.

4.2.6 Ethical considerations for the study

There were a number of general ethical considerations which were identified in the design of this study. These related to issues of consent, risks to participants, confidentiality and storage of data. Ethical considerations specific to each part of the study will be presented in the appropriate chapter.

Ethical approval for the study was obtained from the University of Manchester Ethics Committee (Appendix 9). Ethical approval was also given by the Kamuzu College of Nursing Research and Publications Committee (Appendix 10) because the researcher is an employee of the University of Malawi, Kamuzu College of Nursing. Further approval was given by the Malawi College of Medicine Research and Ethics Committee before commencing the study (Appendix 11). The College of Medicine is a branch of the Malawi National Health Research Committee.
4.2.6.1 Consent

Survey and interview participants were asked to provide written consent or apply a thumb print prior to participating in the study. The option of using a thumb print was provided because the literacy levels for most Malawians are low especially among women. Participants were able to choose not to participate or withdraw any time. Participants were made aware that this would not jeopardise their treatment or care.

4.2.6.2 Risk to participants

The survey may have raised issues that could have caused distress to participants, especially the result of a pregnancy test. In the event that participants became distressed, arrangements were put in place with the hospital team to provide counselling services. This situation did not occur during the study.

4.2.6.3 Confidentiality

All the data collected were treated as confidential. No names were used on data collection tools. A master list of participants was kept separate from the research documents and these were locked away. The digital voice recorder used for the interviews and completed survey questionnaires were kept locked in a dedicated filing cabinet. Subsequent to the completion of the research report, all recordings will be erased, and notes and questionnaires destroyed.

4.3 Revisions following commencement of data collection

Data collection for the study started one month later than planned because ethical approval in Malawi was delayed. One of the supervisors, who has experience of conducting research in Africa, made a field visit during the third week of data collection from 22 to 25 February 2010. During her visit, some changes were made to the procedures. The initial proposal had assumed that, with high malaria rates, the daily referral rate of women would be too high for data collection by one researcher.
The recruitment was limited by restricting inclusion to women of lower parities. In the event, too few women were being recruited and given the time available for data collection, the sample size would not have been achievable. The lower than expected recruitment could have reflected an effect of some selection process by the Medical Assistants. To avoid under recruitment, medical assistants were asked to send all women of childbearing age who had been given prescriptions to the researcher who then decided on eligibility. Some additions were also made to the survey questionnaire, namely for women to specify what medicines they bought and why. The field visit by the supervisor was useful because as a novice researcher, the researcher was offered support in terms of logistics of running the study which needed to be adjusted according to the prevailing circumstances at the hospital.

In addition to the field visit, regular supervisory meetings were conducted via telephone and email to assess the progress of the study and to identify and address any problems experienced in the field. Initially it was thought that the supervisory contact could be conducted via Skype, but regular and consistent internet access was not achieved in Malawi.

All data collection was conducted by the researcher. She recognised the importance of lone worker safety issues while carrying out research in the field and referred to the lone worker policy of the School of Nursing, Midwifery and Social Work at the University of Manchester. Though the policy was designed for research in the UK, the guiding principles were applied and adhered to by the researcher in Malawi by confirming her whereabouts with Kamuzu College of Nursing. She also carried a mobile phone in case of any emergency. The main safety issues were related to travel as roads are poor and there is a high road accident rate.

Once at the clinic the researcher was collecting data within a busy community hospital and was in contact with the hospital management. They were aware of what the researcher was doing in their hospital as the researcher was working alongside other health workers.
4.4 Parts of the study
The study had three arms with two having quantitative approaches and one with qualitative approaches as shown in Figure 4.1

**Quantitative approach**
- Data collection
  - Retrospective record review
- Data analysis
  - Statistics
- Results
- Interpretation

**Quantitative approach**
- Data collection
  - Questionnaire survey
- Data analysis
  - Statistics
- Results

**Qualitative approach**
- Data collection
  - In-depth interviews
- Data analysis
  - Charts in Microsoft word
- Results

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**Figure 4.1: Flow diagram showing the study methods**
4.5 Quantitative Study - Retrospective review of records

This section describes methods used to undertake a retrospective review of records of hospital registers to assess the number and type of congenital abnormalities recorded.

4.5.1 The setting

This part of the study was conducted at Mitundu Community and Kamuzu Central Hospitals. Mitundu Community Hospital has been described in section 4.6.1. Kamuzu Central Hospital (KCH) is one of four referral hospitals in Malawi, serving a population of approximately 5 million people in nine districts (Figure 4.2) of the central region of Malawi. It has a bed capacity of 980. The hospital is divided into two wings. These are Bottom Hospital, which is the old hospital, and the new hospital which comprises the main wing. It serves as a teaching hospital for Kamuzu College of Nursing College of Medicine and Malawi College of Health Sciences. The hospital is almost fully dependent on government financing with a fairly small portion of their revenue generated through user fees collected at the fee paying outpatient department and the fee paying inpatient wards. KCH offers the following services: medical, surgical, obstetrics and gynaecology, paediatrics, ophthalmic, dermatology, dental and intensive care services. As a referral hospital, it receives patients from all nine districts of the region and from different strata of society. The hospital has two maternity wings, fee paying and non-fee paying, and this study was conducted in the non-fee paying wing where most of the deliveries take place. This maternity unit serves as a referral for all high risk pregnancies within Lilongwe and a number of normal obstetric cases from the local community are treated. The paediatric ward is housed within the main hospital and admits patients who come as referrals from other hospitals, referrals from the labour ward and also patients who are brought in from home by their parents or guardians. The paediatric ward has a bed capacity of 215.
4.5.2 Population

The population was records of all babies born in the public maternity ward at KCH from 1 January 2006 to 30 June 2010 and records of all babies born at MCH between January 2006 and June 2010. Apart from birth records, paediatric ward records of KCH were also included. The dates 1 January 2006 to 30 June 2010 were selected as it was anticipated that the records would still be within the hospital and reasonably accessible. After six years, records are sent to national archives for storage.

4.5.2 Data collection

4.5.2.1 Condition of records

Records at the hospitals were not stored on a computer but as paper patient files. Unfortunately these paper records were not properly kept at either hospital. For example at Mitundu Community Hospital some patient files were kept in an old container and they had gathered dust to such an extent that they could not be read and some could not be retrieved as they were physically caught in iron sheets. At Kamuzu Central Hospital patient files were misfiled and it was difficult to verify if all the records had been accessed due to the chaos in the record office. In addition some files were damaged by water which had previously flooded the records office.

Also for paediatric admission books, the researcher was informed that some books were missing from the shelves. This had the implication that the recorded abnormalities could be an underestimation of the actual figures available at the hospital. There was no system of following patients who had been referred from the maternity wing of the hospital to the paediatric ward.
4.5.2.2 **Actual data collection**

Details on congenital malformations were compiled by reviewing the delivery registers from the records department of the two hospitals. Congenital abnormality records were obtained from patient files from maternity ward registers of MCH and KCH while records for paediatric patients were only reviewed at KCH from the paediatric ward admission book.

**Maternity files:** The labour chart was the source document as no standard recording form or reporting system was followed by the medical team. Patient file notes were usually written by medical officers and nurse/midwives from the time of hospital admission until discharge. Abnormalities were recorded on the labour chart as part of the examination of the new born. There was a section to record any abnormalities observed.

**Paediatric admissions:** For the paediatric patients, admission books were reviewed to determine the number and type of admissions of congenital abnormalities recorded. To ensure that the babies referred from the labour ward were not double entered, the researcher relied on the date of transfer and checked if there was a similar admission with the same congenital abnormality and name to eliminate duplication. However, there was no duplication found, maybe due to no documentation in the labour register. Some of the cases involved children who had been discharged home, then readmitted months or years later.

The total number of births was noted as well as the total number of malformed babies so that the percentage of malformations and prevalence could be estimated. Variables extracted were: maternal age, parity, gravidity, gestation at birth, birth weight and area of residence.

Data were extracted to a proforma developed by the researcher (Appendix 2). It was initially intended to collect information on the type of abnormality, year registered, sex, gestational age, birth weight, maternal age, parity and gravidity, and place of residence. However, due to non-availability and inconsistency of records, the following variables were extracted because they were more consistent: type of abnormality, year registered, maternal age and parity, gestational age, sex and birth weight.
Any documentation which indicated there was an abnormality was noted. The type of congenital abnormalities was classified by the diagnostic standardization of congenital malformation from the *International Classification of Diseases (ICD- 10)* codes by World Health Organisation (2007). ICD-10 is a system of coding that notes various medical records including diseases, symptoms, abnormal findings and external causes of injury (WHO, 2007). However, in this study, it was not always easy to accurately assign cases to their proper categories because there was insufficient data and also the terminology used in the register was imprecise.

### 4.5.2.3 Estimation of missing numbers of deliveries

Labour ward admission records were incomplete for KCH, and the numbers of deliveries were missing for December 2008, the whole of 2009, and January and February 2010. The numbers of deliveries for these 15 months were estimated proportionately using simplifying assumptions as follows.

It was assumed that the delivery rate in December 2008 would be similar to that for the same month in the previous year adjusted for the totals for the remainder of the two years. The number of deliveries for December 2008 was estimated by multiplying the number for December 2007 by the ratio of the total for January to November 2008 to the total for January to November 2007. This estimated figure was then used to calculate the total number of deliveries for 2008.

It was assumed that the total number of deliveries in 2009 would show the same proportional change from the total in 2008 as the change in the total in 2008 compared to the total in 2007. The total number of deliveries for 2009 was estimated by multiplying the total for 2008 by the ratio of the total for 2008 to the total for 2007. The number of deliveries for each month in 2009 were similarly estimated by multiplying the number for the month in 2008 by the same ratio.

It was assumed that the delivery rate in January and February 2010 were proportionately related to the delivery rates in the same months in 2009, the proportional change being the same as the one used in the previous calculation. The number of deliveries for January and February 2010 were estimated by
multiplying the numbers for January and February 2010 by the ratio of the total for 2008 to the total for 2007.

4.5.3 Data analysis

Data were recorded and entered into SPSS Release 16.0. The data file was checked for any errors by inspecting if any frequency values for each of the variables fell outside the range of possible values. Where errors were identified, they were corrected as far as possible. Descriptive statistics are those that summarise patterns in responses of cases in a sample (De Vaus, 2002). Descriptive analysis was performed to determine prevalence of malformations and distributions maternal and neonatal characteristics. The descriptive statistics used were means and standard deviations for continuous variables. Frequencies and percentages were used to present categorical variables. According to Pallant (2005) nonparametric techniques are used when study data are measured on nominal (categorical) and ordinal (ranked) scales. This study has therefore used nonparametric techniques to test the significance of the results because most of the variables are measured on nominal (categorical) with some being measured on ordinal (ranked) scales. As a requirement for using the nonparametric techniques, the study data fulfilled the assumption of independent observations (Pallant, 2005). Each case was only counted once, it could not appear in more than one category or group, and data from one subject could not influence the data from another.

In some cases it was necessary to reduce response categories by substantive recoding for purposes of performing nonparametric tests such as Pearson’s chi-square test. The variables that were recoded were maternal age, gestational age and birth weight. Maternal age was recoded as a categorical variable which allowed the ages to be grouped together in 5 year age bands. Gestational age and birth weight were recoded as dichotomous variables.

Percentages and prevalence of occurrence of congenital abnormalities per 1000 births were calculated. The rate of congenital abnormalities was compared with chi-square tests. Pearson’s chi-square or Fisher exact tests were used to compare categorical measures depending on cell counts (Pallant, 2005). Chi-square tests for
trend were also used. If the expected cell counts were less than five in the contingency tables, Fisher’s exact test was used. All statistical testing was conducted at the significance level of 0.05.

4.6 Quantitative Study – Survey

4.6.1 The setting

The study was undertaken in Lilongwe district at Mitundu Community Hospital (MCH). Lilongwe district is in the central region of Malawi (Figure 4.2). Lilongwe covers a total land area of 6159 square kilometres representing 6.5% of Malawi’s total land area. It is the district with the largest population in the country with the city having a population of 669,021 people and the rural area 1,228,146 people in 2008 (Malawi National Statistical Office, 2008). The annual rainfall for Lilongwe ranges between 700 mm and 1000 mm with an average temperature of 25°C. The district has 65 health facilities which are run by Government, Christian Health Association of Malawi (CHAM) and Private Practitioners.

MCH is a community hospital in Lilongwe district serving a rural population of 112,399 (Lilongwe District Health Office Annual report 2010). It has a bed capacity of 54. It is located 40 kilometres away from the capital city, Lilongwe (Figure 4.2). The main economic activity in the community is agriculture involving the growing of maize, groundnuts, cassava and sweet potatoes for domestic use and to supplement household income. The main tribe is Chewa. Christianity is the predominant religion and impacts upon the local way of life and culture. Formal education levels are mostly low for adults particularly the women, reflected in the high levels of illiteracy. In the area served by the MCH, there were an estimated 25,852 women of childbearing age with 5,620 expected pregnancies and 3,445 births in the year 2010 (Lilongwe District Health Office, 2010) at the time of data collection. Services offered included: outpatient consultations, general in-patient care, family planning, antenatal, maternity, tuberculosis screening and management, HIV testing and counselling. Nutrition rehabilitation for malnourished children is also provided. The most common presenting diseases included malaria, diarrhoea, pneumonia, acute respiratory
infection, malnutrition, sexually transmitted infections, common injuries and wounds. Staffing levels during the data collection period were as follows: two clinical officers, four medical assistants, 19 nurses, one pharmacy technician, one laboratory technician and two laboratory assistants. It should be noted that the hospital was facing acute shortages of medicines during the data collection period because the central medical supplies could not supply the medicines due to financial constraints of buying the medicines. However, this is a chronic problem in the government hospitals across the country.
Figure 4.2: Map of Lilongwe district showing the study sites
4.6.2 Population
The population of interest was those women who were potentially pregnant attending the general outpatient clinic in Mitundu Community Hospital and who had been prescribed medicines that have a potential for foetal harm and were contraindicated in pregnancy.

4.6.2.1 Criteria for selection of the sample
The selection of the sample was aimed to capture all women who had the potential to be pregnant. The following inclusion and exclusion criteria were therefore applied

4.6.2.1.1 Inclusion criteria
- women of any parity who had been prescribed contraindicated medicines in pregnancy
- not on contraception
- not menstruating
- those breastfeeding a baby more than six months old

4.6.2.1.2 Exclusion criteria
- women who were on contraception
- those who were menstruating or had a recent menstruation
- those who were breastfeeding a baby less than six months old
- very ill patients

Very ill patients were excluded as it may cause distress. The severity of the illness was assessed by the Medical Assistants by observing the general condition of the woman. For instance, those women who were finding it difficult to sit up or unable to hold a conversation were excluded. Also if the woman herself told the researcher that she was not comfortable to stay on and be interviewed, she was not pressurised to stay.
Initially, there was an inclusion criterion that the woman be of parity 0-2 but as indicated above (Section 4.3) this was revised.

The researcher determined if the women met the inclusion criteria (checking the health passport for prescribed contraindicated medicines and asking the women questions about their contraception, menstruation and breastfeeding status). Once a woman was considered eligible to participate, she was invited to have the details of the study explained to her. If more than one woman was sent to the researcher, they were asked to wait until the researcher was free. Having a suitable waiting area immediately outside helped to avoid losing women. The waiting area helped reduce two sources of response bias, due to women overhearing current interviews and modifying their own responses, and women failing to wait for their interview, who may differ in some aspects from those who are interviewed.

4.6.2.2 Sample size

For calculating the required size of the sample, a prevalence rate formula was used considering the following criteria: an assumed pregnancy rate at any point in time of 22% of the total population of women of childbearing age in Malawi, a desired precision of +/-5%, a confidence level of 95%, and the average patient flow at the hospital. There were no baseline statistics from the hospital on the pregnancy rates of women among those prescribed contraindicated medicines. Consequently, the pregnancy prevalence rate in the population was used as a surrogate for the calculation. The sample size calculation itself is robust to minor changes in the chosen prevalence rate.

The initial sample size calculation was based on recruiting women of parity 0-2. Prior to the data collection period it was estimated from the hospital records that a total of 7,920 women of childbearing age would attend the outpatient clinic during the six months of the data collection period (120 days being open during the week). Of these, 1742 (22%) were likely to be of parity 0-2, and of these, 383 (22%) were likely to be pregnant. An estimated 61 women of childbearing age were likely to be seen in the outpatient clinic per day. Out of these, 13 (22%) were likely to be nulliparous up to second parity, with about 3 (22%) likely to be pregnant. The actual total number of women who attended the outpatient clinic during the recruitment period was 8970.
For the purpose of estimating the pregnancy rate amongst women given contraindicated medicines, a sample of 264 women was required to give a 95% confidence interval with at most a 5% margin of error for estimating a population percentage of 22%. This was assumed initially to be applicable to women of parity 0-2, but it also applied more appropriately when the inclusion was extended to women of all parities. The sample size was arrived at by using the sample size formula to estimate a proportion with a given margin of error (Daniel, 1983) as follows:

\[ n = \frac{Z^2pq}{d^2} \]

where

- \( n \) = sample size
- \( Z \) statistic (\( Z \)): For the level of confidence of 95%, \( Z = 1.96 \)
- \( p \) = an estimate of the proportion of people falling into the group of interest in the population (22%)
- \( q = 1 - p \)
- \( d \) = required precision or margin of error (\( d = 0.05 \))

In this study, \( p \) is 22%, which is the average number of women estimated to be pregnant at any given time

Applying the formula:

\[ n = \frac{3.84^2 \times 0.22 \times (1-0.22)}{0.05^2} = 263.6 \]

Rounding upwards, the required sample size was 264

### 4.6.2.3 Recruitment

Recruitment was conducted during both wet and dry seasons to give a representative spread of participants. The wet season data collection period was anticipated to be from January to April 2010 and the dry season from April to July 2010. Data collection commenced on 1\(^{st}\) February 2010 instead of the first week of January due to a delay in ethical approval from Malawi College of Medicine Ethics Committee.
Identification of potential participants began each morning when patients arrived at the hospital for their outpatient consultation. Consecutive sampling was employed to identify women who met the inclusion and exclusion criteria outlined in Section 4.2.2.1. Consecutive sampling was the method of choice for this objective. The process of consecutive sampling is that every person who meets the eligibility criteria is approached (Kendall, 2003). This helps minimise recruitment bias. The Medical Assistants were asked to inform any eligible patient that a research nurse/midwife was conducting a research study related to the medicine she has been given, and was asked whether she would be willing to talk to the researcher and consider joining the study. If the woman agreed, she was directed to a separate private room where the researcher was sitting.

Participants were not under any obligation to participate in the research and could withdraw at any time without penalty.

**Consent**

The researcher read the contents of the information pack (Appendix 3a & 3b) to the potential participants in the vernacular language because most women were illiterate. No participant volunteered to read the pack on their own. The information sheet included information explaining the purpose of the research, the relevance of participation and anticipated benefits to them as well as the country’s health service delivery. The participants were informed that their names would not appear on the data collection sheet and that code numbers were used to maintain anonymity and confidentiality. Participants were informed that data would not be shared with anyone to ensure confidentiality. The researcher took care not to assert any pressure on the participants to take part and it was made clear that medical treatment was not dependent on agreement to participate in the study. However, women were warned that their prescription would change if it was found that they were pregnant. Participants were also asked to consent to a pregnancy test before administration of the questionnaire; those who refused were still included because they gave consent to complete the questionnaire. Written informed consent was obtained, with either a signature or thumb print (Appendix 5a & 5b), confirming that the purpose and study procedures had been discussed and participants were given the opportunity to ask
questions. For all participants questionnaires were administered on the same day because it would have been impractical to arrange an alternative time and it was envisaged that many participants would be reluctant to spend time and money returning to the clinic. In addition, tracking participants to their homes across a large catchment area would be time-consuming and difficult for a lone researcher, especially during the rainy season where roads were impassable due to mud. None of the potential participants referred to the researcher declined to participate in the study.

4.6.3 Survey instrument development

A questionnaire (Appendix 7a) was developed using information from the literature. The questionnaire was prepared in the English language and it was then translated into Chichewa, which is the local language of the participants (Appendix 7b). The questionnaire was designed to be completed by the researcher and to gain relevant information regarding the following: participant’s age, marital status, ethnic group affiliation, education and source of income. Levels of education were categorised as (1) no education (2) primary education, (3) secondary education and (4) tertiary education. Income was categorised as (1) regular income, (2) irregular income and (3) no income. The questionnaire had questions on medications for chronic conditions, recent medications taken, reasons for medication use and source of medication. It also asked for number of births, uneventful pregnancy events, the age of the youngest child and whether the woman was breastfeeding.

4.6.4 Pilot study

The questionnaire was piloted to check if the questions were clear, to determine how long it was going to take to interview a participant, and to identify any areas that needed corrections and refinement before commencing data collection. The sequence of the questions was changed as a result of the pilot study but no wording changes were made. The questionnaire took approximately twenty minutes to complete. The pilot study was conducted in December 2009 at Mitundu Community
Hospital with five women. The data from these women were excluded from the final analysis.

4.6.5 Data collection

The questionnaire was filled out in English by the researcher though the language used with participants was Chichewa. The questionnaire was anonymised with use of a code, with no personal identifying information recorded on it. The date of interview was documented.

Several techniques were used to help the participants to recall the history of medication use, including showing samples of commonly used medicines as examples. Women were asked to name the sources from which they got their medicines. The patient handheld records were reviewed for any previous hospital consultations and to check the current diagnosis and prescription.

A pregnancy test was requested from the participants to check their pregnancy status. The test used the SD BIOLINE hCG pregnancy test strip for urine (Standard Diagnostics, 2006). This is a highly sensitive pregnancy testing kit which detects pregnancy at low levels of the pregnancy hormone (25mIU/ml) and could be administered at any time of the day. The kit is easy to use and results are read within 3 minutes. This was convenient for the participants as they did not have to wait a long time for the results to be available. Participants were assured that the urine sample was used only for the purpose of checking whether or not they were pregnant. They were also informed that a very recent pregnancy may not be detected by the test and that occasionally the test is not always accurate (i.e. all urine tests can give false negative or false positive results) so any early signs of pregnancy should not be ignored.
4.6.6 Main ethical issues

**Anticipated benefits and risks of the study to participants**

Participants were informed that for pregnant women who had been prescribed medicines with a potential harm to the foetus, appropriate action would be made to have their prescription reconsidered. It was explained that this was an important aspect of the study as Medical Assistants are normally not able to test for pregnancy and therefore cannot identify women in early pregnancy. In this event therefore, the researcher returned to the Medical Assistant to discuss the case. Medical Assistants were made aware in advance that this might occur and agreement was reached that the Medical Assistant would review the case and the prescription at short notice so that alternative medicines could be considered.

Hammersley and Atkinson (1995) note that the process of interviewing may cause anxiety. In this study, participants were interviewed about medicines which they had taken. Being interviewed might have raised concerns about using medicines when pregnant. To allay anxiety, participants were assured that the purpose of the questions was just to have an idea of what medicines pregnant women usually take. It was pointed out that some medicines may be harmful during the first trimester of pregnancy but not in the later trimesters, while other medicines may be harmful throughout pregnancy. A clarification was made that pregnant women need to take extra caution before taking any medicine so that they take only those medicines which are considered safe in pregnancy and only when it is necessary to do so. Thus, the discussion avoided giving the impression that medicines are all harmful throughout pregnancy.

Though the study did not have any known risk to health, it was anticipated that some participants might be distressed upon finding that they were pregnant or that they were not pregnant when anticipating a pregnancy. Counselling services had been arranged but were not utilised.
4.6.7 Data management

Questionnaires were assigned a code number and kept in a secure place. Consent forms were separated from the questionnaires and kept in a locked cupboard at the College of Nursing. The paperwork was carried by hand by the researcher on her return trip from Malawi. Storage is currently at the School of Nursing, Midwifery and Social Work at the University of Manchester. The records will be kept until the research has been completed and afterwards destroyed. Data are being stored on a password protected computer.

4.6.8 Data analysis

Quantitative data were entered, cleaned and managed using SPSS (SPSS for Windows Release 16, SPSS Inc., Chicago, IL, USA) by the researcher. The accuracy of data entered was checked by cross checking against ten per cent of the hard copies of the questionnaires. Any inaccuracies were checked as well by running basic procedures in SPSS. Data were analysed initially using descriptive statistics. Data were summarised using means and standard deviations for continuous variables, and frequencies and percentages for categorical variables.

The main outcome measure was the pregnancy rate among women prescribed contraindicated medication in early pregnancy. Secondary outcome measures were the percentage of women asked about the possibility of pregnancy by the health workers before being prescribed contraindicated medicines during general outpatient consultations and the percentage of women having taken a medicine with potential for foetal harm through self-medication. The proportion of women treated for different conditions during pregnancy was reported, as well as the percentage of women who did not agree to a pregnancy test. Women who did not agree to urine testing but were sure of being pregnant were retained in the study. All women who refused pregnancy testing were sure of their pregnancy status.

Characteristics of pregnant and non-pregnant women were compared. Pearson’s chi-square test was used to test the significance of the differences in percentage between the women who were pregnant and those who were not. The chi-square
test for trend was used for ordinal variables. Fisher’s exact test was used where the expected number in any cell was less than five.

4.7 Qualitative Study – In-depth interviews

This section describes the qualitative interviews which were conducted. The setting, population and all data collection procedures are described in detail.

4.7.1 The setting

Interviews took place at Mitundu Community Hospital, the same site as the questionnaire survey but with patients from a different clinic.

4.7.2 Population

The population consisted of women coming to the antenatal clinic for an initial visit in the first or second trimester of their pregnancy.

4.7.2.1 Inclusion criteria

- Women coming for an initial antenatal visit in their first or second trimester

4.7.2.2 Exclusion criteria

- Women coming for a subsequent antenatal visit

Initially, the study plan was to interview women in the first trimester but this was reconsidered during the supervisory visit after observing that the numbers of women in the first trimester were not attending as frequently as had been anticipated. The researcher therefore included women in their second trimester. The average number of women who attend the antenatal clinic at Mitundu Community Hospital is 100 per
day. The average number of women who presented at the antenatal clinic in the first trimester of pregnancy was two per week.

4.7.3 Sampling

Purposive sampling was used to recruit the sample for the qualitative component of the study. In purposive sampling, the researcher decides purposely to select the widest variety of participants, or those who are judged to be typical of the population under study, or participants who might be particularly knowledgeable about the topic (Polit and Hungler, 1999). In this study participants who were judged to be typical of the population were selected. The researcher purposively sampled women coming for their first antenatal visit, who may have recently taken medication in early pregnancy. The second antenatal visit is at about six months gestation, at which point, the woman’s health would have stabilised and she may not remember clearly what medication she was taking in early pregnancy. Twenty-one women were asked to participate. Initially a sample size of about 20 was decided upon based on the consideration that transcription of interviews and data analysis are time consuming (Ritchie et al., 2003). The actual sample size for the interviews of antenatal women was guided by the principles of data saturation. Data saturation is said to have been reached when no new information is generated from each subsequent interview (Polit and Beck, 2008).

4.7.4 The interview topic guide

An in-depth interview guide was developed by the researcher for the study (Appendices 8a & 8b), based on the main and the associated objectives. Interview guides ensure good use of limited interview time; they make interviewing multiple subjects more systematic and comprehensive and they help to keep interactions focused (Hoepfl, 1997). The interview guide comprised of open ended questions that required narratives from the participants. It was designed by the researcher to be referred to by her when interviewing the participants. The use of open-ended questions is advocated to guide interviews in qualitative research (Polit and Beck,
In the guide, prompts were used to encourage the women to talk more. In-depth semi-structured interviews were chosen as the most appropriate to access the beliefs, views and practices of study participants (Parahoo, 1997).

The guide was initially developed in English and translated into Chichewa. Items in the interview guide included those addressing women’s beliefs and views about use of medicines in pregnancy, medicines which women take in pregnancy (modern and traditional). Specifically they were asked about use of sulfadoxine-pyrimethamine (SP) for Intermittent Preventive Treatment of malaria in pregnancy (IPTp) and if they were aware of IPTp timing in terms of stages of pregnancy, pregnancy disclosure practice and perceived causes of congenital abnormalities.

4.7.4.1 Piloting the interview guide

The researcher piloted the interview with three participants. This enabled the researcher to gauge how participants responded, how long the interviews would take and how easily understood the topics were. The transcribed interviews were sent to supervisors at the University of Manchester to comment on the relevance of the discussion and to suggest ways to improve interviewing techniques or topics to be explored.

4.7.5 Recruitment of participants

Midwives working in the antenatal clinic were requested to identify women who came for an initial visit at the clinic for potential participation in the study. The procedure for obtaining consent was the same as for the survey.

4.7.6 Data collection

The interview began with a full explanation of topic areas and with permission of the women; the interviews were recorded with a digital recorder. Some quantitative demographic data were collected about the background information of the participants. This included participants’ demographic information and some obstetric
The interviews ranged in duration from 13 minutes to 31 minutes. All the recordings were given a numerical code to maintain confidentiality. Names were not used in transcriptions to maintain confidentiality. After the interviews, field notes were made about mood and behaviour of participants where necessary. At the end of the interview, participants were thanked for participating and asked if they had any comments and questions to ask on the interview process. They were once more assured of the confidential and anonymous nature of the interviews. Data were transferred from the voice recorder onto a computer. This transfer allowed for a secure password-protected electronic storage of raw data (McLellan et al., 2003).

Data saturation started to be noted in the 19th of the 21 interviews, when no new information was emerging from the interviews.

4.7.6.1 Data transcription

The interviews were transcribed verbatim (McLellan et al., 2003) into the vernacular language, Chichewa, by the researcher. The process proved to be very useful in terms of immersion with the data, allowing the researcher to become more familiar with the contents.

4.7.6.2 Data translation

The interviews were immediately translated from Chichewa into English by an independent expert in languages, and then back translated into Chichewa by another independent language expert. Back-translation is translating from the target language back to the source language and the equivalence between source and target versions can be evaluated (Brislin, 1970; Chapman and Carter, 1979). In this study, the process involved translating the interviews from English to Chichewa, the original language. To ensure conceptual and grammatical equivalence, translations were reviewed collaboratively by the researcher and the translator (both bilingual Chichewa-English speakers). Transcripts were read over again while listening to the tape to ensure accurate transcription.
4.7.6.3 **Data management**

All transcripts were assigned a code and will only be identified this way in any ensuing reports and publications. Verbatim material reported by participants was anonymised at source to ensure that they cannot be identified. Digital recordings (downloaded onto the researcher’s laptop computer) and transcripts were kept in a secure place during the study. Consent forms were separated from the transcripts and kept in a locked cupboard. The digital recorder was kept in a locked drawer in the researcher’s office at the College of Nursing and only the researcher had access to the recorder.

4.7.7 **Data analysis**

Data were analysed manually by use of a word processing program, Microsoft Word. A computer program designed for this purpose may assist analysis, or it may be done manually using highlighters or cut-and-paste technology (Webb, 1999). Nvivo software was initially planned to be used for organising the data but due to insufficient funds to buy the licence, the researcher resorted to manual analysis of the data.

The underlying principles of symbolic interactionism guided data analysis and interpretation. This theory formed an overarching framework for the qualitative analysis. The premise being that people socially construct their own world, particularly in relation to the meaning they attach to objects, events and behaviours. As such, interpretations will vary from group to group (Blumer, 1969). In these interviews the focus was on the experiences of pregnant women in Malawi. Given this context the analysis both explored, and was attentive to, expressions in the transcripts that indicated women’s own beliefs and views. The meanings attached to beliefs and views contributed to the women’s actions on the use of medicines during pregnancy. These ascribed meanings helped the researcher to interpret the data and give an account of women’s voices during interviews.
4.7.7.1 Framework analysis

Thematic framework is used to classify and organise data according to key themes, concepts and emergent categories. Framework analysis was selected as the approach to analysis because it facilitates rigorous and transparent analysis (Ritchie et al., 2003). The framework approach makes between and within subject analysis possible, enabling researchers to compare and contrast participants’ opinions and perceptions in each sub-theme, therefore illustrating the similarities and differences between them. There are five key stages in the analysis (Ritchie et al., 2003): familiarisation; identification of the thematic framework; indexing; charting; mapping and interpretation. The stages however are not necessarily a linear process.

The first stage, familiarisation, was achieved by reading and re-reading of interview transcripts. This allowed the researcher to be immersed in the data and identify recurring issues and ideas. The ideas were noted and related to the objective about beliefs, views and practices concerning medication use. A coding framework was devised based on these themes and all data were coded with this framework (Appendix 16).

Having done this, the second stage, identifying a thematic framework was completed by arranging the recurrent issues that had emerged into themes and sub-themes. Relevant quotes were also identified at this stage to illustrate the themes. Themes and sub-themes were given unique colour codes using a highlighter to identify issues arising – this process constitutes the third stage, indexing. Indexing is a stage which involves applying these codes to the transcripts to identify arising issues. The fourth stage, charting, involved creating tables of quotes and comments to compare data from across interviews. Charts were constructed for each of the main themes that emerged, with sub-theme categories placed down the columns and participants placed along the rows at the top of the charts. Charting involved indicating how many participants had made statements relating to each theme, and in which settings each theme had been identified. This procedure provides for a broad indication of the importance of themes in the whole sample. These charts were used to describe similar and divergent beliefs, views and practices, develop explanations and find associations between them. Themes were compared, contrasted and aligned following multiple shifting and re-shuffling activities. Once data were grouped into
themes and sub-themes, the immersion cycle was repeated. Where data did not support or opposed certain themes, the themes were altered or additional themes were made. Mapping and interpretation is the final stage which involved exploring patterns and key issues by making comparisons and developing explanations that were grounded in the data. Thus mapping and interpretation is the integration of the key findings into a meaningful whole.

Reliability of the data and interpretation of the findings were checked at each stage of the process by supervisors. The framework for the analysis was developed by the researcher and her supervisors who agreed to the indexing, charting and mapping of the data-set. The framework, findings and interpretation of the analysis were discussed and approved by the supervisors, who agreed that the findings reflected the data collected. Figure 4.3 shows the process of the data analysis.
Figure 4.3: Diagram showing the process of thematic data analysis
4.7.8 Rigour of the qualitative data

To ensure the study is rigorous and trustworthy (Creswell, 1998; Lincoln and Guba, 1985) audiotaped and written verbatim versions of the interviews were compared to ensure accuracy and completeness of data. An audit trail of copies of all materials used to collect and analyse the data, as well as the analytical products, was maintained.

The researcher used purposive sampling to interview women who were coming to receive antenatal care for the first time, as they were likely to have recently taken some medicines in early pregnancy. A digital voice recorder was used to ensure accuracy in reporting what was said.

Dependability was achieved by ensuring that the process of analysis was clear. Framework aided the visibility of the analysis by facilitating an audit trail, allowing the reader to follow analytical process (Ritchie et al., 2003). The process was made evident by the description of the interview guide, the development of the framework and charts and giving examples of how the data moved from raw data to themes. In this study supervisors closely monitored the data analysis.

Confirmability was achieved by supervisors checking that the data’s accuracy, relevance and meaning were in congruence with what the researcher found. Confirmability is concerned with establishing that the data represent the information participants provided, and that the interpretations of those data are not invented by the inquirer (Polit and Beck, 2012).

Transferability was achieved by providing sufficient descriptive data so that readers can evaluate the applicability of the data to other contexts. Transferability refers to the potential for extrapolation, which means the extent to which findings can be transferred to or have applicability in other settings or groups (Polit and Beck, 2012).
4.8 Summary

In this chapter the procedures and steps taken to prepare for, and conduct the research, were detailed. It has described the study setting and stated the rationale for selecting the study sites. This included the process for review of records, the survey and in-depth interviews. Review of records was conducted at Mitundu Community and Kamuzu Central Hospitals, with data analysed descriptively and inferentially using SPSS. For the survey, questionnaires were administered to women of childbearing age who had been prescribed a medication which is contraindicated in pregnancy at Mitundu Community Hospital general outpatient clinic. The data were analysed using descriptive and inferential statistics using SPSS. For the qualitative part of the study, in-depth interviews of women who came at Mitundu Community Hospital for initial antenatal visit were conducted. The qualitative data were analysed manually using framework analysis. Addressed also were the ethical processes that were undertaken both before and during the research process. A presentation of the data analysis follows in chapters five, six and seven. Chapter five will present results from review of records while chapter six will present results from the survey and chapter seven will present findings from in-depth interviews.
CHAPTER 5
RESULTS OF REVIEW OF RECORDS OF CONGENITAL ABNORMALITIES AT KAMUZU CENTRAL AND MITUNDU COMMUNITY HOSPITALS

5.1 Introduction

This chapter presents the results of record review which was done at Kamuzu Central Hospital (KCH) and Mitundu Community Hospital (MCH). Firstly, results from labour ward registers of both hospitals will be presented concurrently and secondly, results from KCH paediatric ward will be presented. The objective of the study was to collect preliminary data on prevalence of congenital abnormalities. This provided useful contextual data for the two main arms of the study, the questionnaire survey of women of child bearing age attending an outpatients clinic who had been prescribed contraindicated medication (Chapter 6) and the qualitative interviews of women attending an ante-natal clinic on their views, beliefs and practices about medicines in pregnancy of women (Chapter 7).

5.2 Labour ward records for Kamuzu Central and Mitundu Community Hospitals

There were an estimated 50257 births recorded at KCH between January 2006 and June 2010. Out of the total births, 731 cases of congenital abnormalities were recorded. There were 10643 births recorded at MCH between January 2006 and June 2010. Out of these births, 70 cases of congenital abnormalities were registered.

It has to be noted that the KCH figure is estimated because data for some months were missing. The process for estimating the number of births for the missing months has been reported in chapter 4, the methods chapter. The MCH figure is exact because the hospital had complete records for all the months.
5.2.1 Maternal and neonatal characteristics

Maternal and neonatal characteristics of the recorded congenital abnormalities for both hospitals are summarised in Table 5.1. At both hospitals, just over one third of mothers were aged 20 - 24 years. The mean age at KCH was 24.9 years (SD 6.0, median 24.0 years) and at MCH, 26.7 years (SD 6.3, median 25.0 years). At KCH there were more mothers aged <20 years (18.5%) than at MCH (7.1%). The difference between the hospitals in mean maternal age was statistically significant (t = 2.36, df = 790, p = 0.019), as was the difference in the distribution of maternal age groups ($\chi^2_{\text{TREND}} = 6.33$, df = 1, p = 0.012). The most common parity of the mothers at KCH was parity 1 (240, 32.1%) whereas MCH, the most common parities were 3 and ≥5 (19, 27.1% and 21, 30.0% respectively). The difference between the hospitals in parity was also statistically significant ($\chi^2_{\text{TREND}} = 12.23$, df = 1, p = 0.001).

In terms of neonatal characteristics, more males than females were delivered with congenital abnormalities at KCH than MCH (53.6% vs. 45.7%), but the difference was not statistically significant ($\chi^2 = 1.91$, df = 1, p = 0.167). There was a significant association between the rate of congenital abnormalities and gender (Binomial exact p = 0.006, assuming equal proportions of males and females born) at KCH where the sample size was much larger, but not at MCH (Binomial exact p = 0.631).

A high proportion of babies with congenital abnormalities were born preterm, especially at the community hospital (25.7% vs 19.3%) but the difference between the hospitals was not significant ($\chi^2 = 1.77$, df = 1, p = 0.184). Mean birth weight was 2935.4 (SD 590.3) grams for KCH and 2788.8 (SD 658.0) grams for MCH. The difference between the means just failed to be statistically significant (equal variance t = 1.95, df = 767, p = 0.052, unequal variance t = 1.78, df = 79, p = 0.079), and there was no significant difference between the hospitals in the percentage born under 2500 grams ($\chi^2 = 0.50$, df = 1, p = 0.478).
Table 5.1: Maternal and neonatal characteristics for the congenital abnormalities recorded at Kamuzu Central Hospital (KCH) and Mitundu Community Hospital (MCH), Malawi, January 2006 – June 2010

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>KCH (n=731) (%)</th>
<th>MCH (n=70) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maternal age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 20 years</td>
<td>135 (18.5)</td>
<td>5 (7.1)</td>
</tr>
<tr>
<td>20 - 24</td>
<td>256 (35.0)</td>
<td>24 (34.3)</td>
</tr>
<tr>
<td>25 - 29</td>
<td>166 (22.7)</td>
<td>16 (22.9)</td>
</tr>
<tr>
<td>30 - 34</td>
<td>102 (14.0)</td>
<td>13 (18.6)</td>
</tr>
<tr>
<td>35 - 39</td>
<td>50 (6.8)</td>
<td>8 (2.9)</td>
</tr>
<tr>
<td>40 years and above</td>
<td>15 (2.1)</td>
<td>2 (2.9)</td>
</tr>
<tr>
<td>Not recorded</td>
<td>7 (1.0)</td>
<td>2 (2.9)</td>
</tr>
<tr>
<td><strong>Parity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>240 (32.1)</td>
<td>10 (14.3)</td>
</tr>
<tr>
<td>2</td>
<td>146 (20.0)</td>
<td>11 (15.7)</td>
</tr>
<tr>
<td>3</td>
<td>122 (16.7)</td>
<td>19 (27.1)</td>
</tr>
<tr>
<td>4</td>
<td>88 (12.0)</td>
<td>8 (11.4)</td>
</tr>
<tr>
<td>≥ 5</td>
<td>130 (17.8)</td>
<td>21 (30.0)</td>
</tr>
<tr>
<td>Not recorded</td>
<td>5 (0.7)</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>392 (53.6)</td>
<td>32 (45.7)</td>
</tr>
<tr>
<td>Female</td>
<td>320 (43.8)</td>
<td>37 (52.9)</td>
</tr>
<tr>
<td>Ambiguous genitalia</td>
<td>2 (0.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Not recorded</td>
<td>17 (2.3)</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td><strong>Gestation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 37 weeks</td>
<td>586 (80.2)</td>
<td>51 (72.9)</td>
</tr>
<tr>
<td>&lt;37 weeks</td>
<td>141 (19.3)</td>
<td>18 (25.7)</td>
</tr>
<tr>
<td>Not recorded</td>
<td>4 (0.5)</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td><strong>Birth weight</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 2500 grams</td>
<td>591 (80.8)</td>
<td>56 (80.0)</td>
</tr>
<tr>
<td>&lt; 2500 grams</td>
<td>109 (14.9)</td>
<td>13 (18.6)</td>
</tr>
<tr>
<td>Not recorded</td>
<td>31 (4.2)</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alive</td>
<td>665 (91.0)</td>
<td>61 (87.1)</td>
</tr>
<tr>
<td>Dead</td>
<td>13 (1.8)</td>
<td>2 (2.9)</td>
</tr>
<tr>
<td>Still birth</td>
<td>43 (5.9)</td>
<td>7 (10.0)</td>
</tr>
<tr>
<td>Unknown/not recorded</td>
<td>10 (1.4)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>
5.2.2 Classification of congenital abnormalities

Table 5.2 shows the ICD-10 classification of the different types of congenital abnormalities. At KCH, 1.5% of babies had a congenital abnormality with a prevalence of 14.55/1000 births for all abnormalities while 0.7% of babies had a congenital abnormality with a prevalence of 6.58/1000 births for all abnormalities at MCH. Overall the prevalence of congenital abnormalities was significantly higher at KCH than MCH ($\chi^2 = 42.96$, df = 1, p = < 0.001).

The musculoskeletal system was the most affected, involving 564 out of 731 babies (77.2%) and 57 out of 70 babies (81.4%) at KCH and MCH respectively. Among this group, the most frequent abnormalities were polydactyly, talipes and umbilical hernia. A total of 425 cases of polydactyl were recorded at KCH, giving a prevalence of 8.46/1000 births while a total of 40 of polydactyl cases were recorded at MCH, giving a prevalence of 3.76/1000 births. There were 48 infants born with talipes at KCH giving a prevalence of 0.96/1000 births. MCH had 6 infants with talipes giving a prevalence rate of 0.57/1000 births. At KCH there were 42 babies with umbilical hernia giving a prevalence of 0.84/1000 births.

There were also a number of nervous system defects affecting 58 (7.9%) and 3 (4.3%) babies at KCH and MCH respectively. In this group, the common abnormalities were hydrocephalus and spina bifida. A total of 15 babies at KCH had spina bifida, giving a prevalence of 0.30/1000 births. Fourteen babies were recorded as having cleft lip and palate at KCH. The prevalence for the sample was 0.28/1000 births while one case was recorded at MCH giving a prevalence of 0.09/1000 births. Other defects were reported much less frequently.
Table 5.2: Recorded congenital abnormalities among deliveries at Kamuzu Central and Mitundu Community Hospitals, Malawi, January 2006 – June 2010

<table>
<thead>
<tr>
<th>Congenital abnormality</th>
<th>KCH (n=731) Frequency (%)</th>
<th>MCH (n=70) Frequency (%)</th>
<th>Prevalence per 1000 births KCH (n=50257)</th>
<th>Prevalence per 1000 births MCH (n=10643)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All abnormalities</td>
<td>731 (1.5)</td>
<td>70 (0.7)</td>
<td>14.55</td>
<td>6.58</td>
</tr>
<tr>
<td><strong>Musculoskeletal system</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polydactyly</td>
<td>564 (77.2)</td>
<td>57 (81.4)</td>
<td>11.22</td>
<td>5.35</td>
</tr>
<tr>
<td>Talipes</td>
<td>425 (58.1)</td>
<td>40 (57.1)</td>
<td>8.46</td>
<td>3.76</td>
</tr>
<tr>
<td>Umbilical hernia</td>
<td>42 (5.7)</td>
<td>0 (0.0)</td>
<td>0.84</td>
<td>0.00</td>
</tr>
<tr>
<td>Leg deformity</td>
<td>23 (3.1)</td>
<td>5 (7.1)</td>
<td>0.42</td>
<td>0.47</td>
</tr>
<tr>
<td>Exomphalos</td>
<td>12 (1.6)</td>
<td>2 (2.9)</td>
<td>0.24</td>
<td>0.19</td>
</tr>
<tr>
<td>Others</td>
<td>14 (1.9)</td>
<td>2 (2.9)</td>
<td>0.00</td>
<td>0.19</td>
</tr>
<tr>
<td><strong>Nervous system</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocephalus</td>
<td>28 (3.8)</td>
<td>2 (2.9)</td>
<td>0.56</td>
<td>0.19</td>
</tr>
<tr>
<td>Spina bifida/meningocele</td>
<td>15 (2.1)</td>
<td>0 (0.0)</td>
<td>0.30</td>
<td>0.00</td>
</tr>
<tr>
<td>Anencephaly</td>
<td>14 (1.9)</td>
<td>0 (0.0)</td>
<td>0.28</td>
<td>0.00</td>
</tr>
<tr>
<td>Encephalocele</td>
<td>1 (0.1)</td>
<td>0 (0.0)</td>
<td>0.02</td>
<td>0.00</td>
</tr>
<tr>
<td>Neural tube defect</td>
<td>30 (4.1)</td>
<td>0 (0.0)</td>
<td>0.60</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Genital system</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormality of penis</td>
<td>18 (2.5)</td>
<td>0 (0.0)</td>
<td>0.36</td>
<td>0.00</td>
</tr>
<tr>
<td>Undescended testicles</td>
<td>4 (0.5)</td>
<td>0 (0.0)</td>
<td>0.08</td>
<td>0.00</td>
</tr>
<tr>
<td>Hydrocele</td>
<td>2 (0.3)</td>
<td>0 (0.0)</td>
<td>0.04</td>
<td>0.00</td>
</tr>
<tr>
<td>Indeterminate sex</td>
<td>2 (0.3)</td>
<td>0 (0.0)</td>
<td>0.04</td>
<td>0.00</td>
</tr>
<tr>
<td>No urethra</td>
<td>1 (0.1)</td>
<td>0 (0.0)</td>
<td>0.02</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Eye, ear, face and neck</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal face</td>
<td>6 (0.8)</td>
<td>0 (0.0)</td>
<td>0.12</td>
<td>0.00</td>
</tr>
<tr>
<td>Eye abnormality</td>
<td>5 (0.7)</td>
<td>0 (0.0)</td>
<td>0.10</td>
<td>0.00</td>
</tr>
<tr>
<td>Low set ears</td>
<td>2 (0.3)</td>
<td>0 (0.0)</td>
<td>0.04</td>
<td>0.00</td>
</tr>
<tr>
<td>No eye ball</td>
<td>2 (0.3)</td>
<td>0 (0.0)</td>
<td>0.04</td>
<td>0.00</td>
</tr>
<tr>
<td>Others</td>
<td>4 (0.5)</td>
<td>0 (0.0)</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Cleft lip and palate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple abnormalities</td>
<td>10 (1.4)</td>
<td>2 (2.9)</td>
<td>0.20</td>
<td>0.19</td>
</tr>
<tr>
<td><strong>Digestive system</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tongue tie</td>
<td>5 (0.7)</td>
<td>1 (1.4)</td>
<td>0.10</td>
<td>0.09</td>
</tr>
<tr>
<td>Mouth deformity</td>
<td>1 (0.1)</td>
<td>0 (0.0)</td>
<td>0.02</td>
<td>0.00</td>
</tr>
<tr>
<td>Imperforate anus</td>
<td>1 (0.1)</td>
<td>0 (0.0)</td>
<td>0.02</td>
<td>0.00</td>
</tr>
</tbody>
</table>
Table 5.2: Recorded congenital abnormalities among deliveries at Kamuzu Central and Mitundu Community Hospitals, Malawi, January 2006 – June 2010 (continued)

<table>
<thead>
<tr>
<th>Congenital abnormality</th>
<th>KCH (n=731) Frequency (%)</th>
<th>MCH (n=70) Frequency (%)</th>
<th>Prevalence per 1000 births KCH (n= 50257)</th>
<th>Prevalence per 1000 births MCH (n=10643)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Down’s syndrome</em></td>
<td>6 (0.8)</td>
<td>0 (0.0)</td>
<td>0.16</td>
<td>0.00</td>
</tr>
<tr>
<td><em>Respiratory system</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal nose</td>
<td>1 (0.1)</td>
<td>1 (1.4)</td>
<td>0.02</td>
<td>0.09</td>
</tr>
<tr>
<td>Abnormal nose patency</td>
<td>1 (0.1)</td>
<td>0 (0.0)</td>
<td>0.02</td>
<td>0.00</td>
</tr>
<tr>
<td><em>Circulatory system</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart abnormality</td>
<td>1 (0.1)</td>
<td>0 (0.0)</td>
<td>0.02</td>
<td>0.00</td>
</tr>
<tr>
<td>Patent ductus arteriosus</td>
<td>1 (0.1)</td>
<td>0 (0.0)</td>
<td>0.02</td>
<td>0.00</td>
</tr>
<tr>
<td><em>Conjoined twins</em></td>
<td>1 (0.1)</td>
<td>0 (0.0)</td>
<td>0.02</td>
<td>0.00</td>
</tr>
<tr>
<td><em>Not elsewhere classified</em></td>
<td>21 (2.9)</td>
<td>4 (5.7)</td>
<td>0.42</td>
<td>0.38</td>
</tr>
<tr>
<td>Growth</td>
<td>12 (1.6)</td>
<td>2 (2.9)</td>
<td>0.24</td>
<td>0.19</td>
</tr>
<tr>
<td>Mass</td>
<td>4 (0.5)</td>
<td>0 (0.0)</td>
<td>0.08</td>
<td>0.00</td>
</tr>
<tr>
<td>False teeth</td>
<td>3 (0.4)</td>
<td>0 (0.0)</td>
<td>0.06</td>
<td>0.00</td>
</tr>
</tbody>
</table>

5.2.3 Maternal and neonatal characteristics for common congenital abnormalities

This section describes maternal and foetal characteristics for common congenital abnormalities for both KCH and MCH. The abnormalities to be described are polydactyly, talipes, umbilical hernia, hydrocephalus, spina bifida and cleft lip and palate.

5.2.3.1 Maternal characteristics for common congenital abnormalities

Table 5.3 shows the maternal characteristics and the common congenital abnormalities.

**Age**

The most common age group for mothers with babies born with polydactyly was 20-24 years (36.6%; 39.5%) at KCH and MCH respectively. Similarly the common age group for mothers with babies with talipes was 20-24 years (35.4%) at KCH while for MCH common age group was 35-39 (50.0%). The common age group for mothers with babies born with umbilical hernia was 20-24 years at both hospitals. However,
babies with hydrocephalus were commonly found in mothers in the 25-29 year age range at KCH while at MCH one mother had a baby with hydrocephalus in the age range 30-34 years and above 40 years. Spina bifida cases were found at KCH only and the most common maternal age group was 25-29 years.

Parity
The most common parity for mothers with babies born with polydactyly was para 1 (28.9%) at KCH and para 3 and 5 (28.9%) at MCH. For babies born with talipes, the most common parity for their mothers was para 1 (41.7%) at KCH and para 5 (50.0%) at MCH. The most common parity for mothers with babies born with umbilical hernia was para 3 (29.3%) at KCH and para 2 (66.7%) at MCH. Babies born with hydrocephalus were commonly delivered by mothers with parity 5 or more (32.1%) at KCH and similarly at MCH the only baby with hydrocephalus was delivered by a mother with parity 5 or more (100.0%). Spina bifida babies were most commonly found in para 3 (33.3%) mothers. Finally, cleft lip and palate babies were most commonly found in para 1 (46.2%) mothers at KCH and the only baby with cleft lip and palate at MCH was found in a mother para 3.

5.2.3.2 Neonatal characteristics for common congenital abnormalities
Table 5.3 shows the neonatal characteristics for common congenital abnormalities.

Sex
Overall there were more males than females with polydactyly at KCH. There were 233 (55.3%) males vs 188 (44.7%) females. On the contrary at MCH there were more females than males with polydactyly, 18 (46.2%) males vs 21 (53.8%) females. For talipes, overall males were slightly more affected than females with a frequency of 25 (53.2%) males and 22 (46.8%) females at KCH while at MCH there were 4 (66.7%) males and 2 (33.3%) females. The percentages for KCH and MCH were similar.

There were more females 28 (68.3%) than males 13 (31.7%) affected with umbilical hernia at KCH. Similarly at MCH more females 2 (66.7%) than males 1 (33.3%) were affected. The percentages at the hospitals are comparable. There were more males than females with hydrocephalus 15 (62.5%) and 9 (37.5%) respectively at KCH
while at MCH the two recorded cases of hydrocephalus were both females. Males were also more affected with spina bifida than females with a frequency of 9 (69.2%) and 4 (30.8%) respectively. There was no recorded case of spina bifida at MCH.

**Gestational age**
At KCH 352 (87.8%) babies with polydactyly were born at term while 49 (12.2%) babies were born preterm. Similarly at MCH, 31 (79.5%) babies were born at term and 8 (20.5%) were born preterm. Generally most babies were born at term gestation despite having a congenital abnormality. An exception was for two hydrocephalic babies who were both born preterm at MCH and also a baby with cleft lip and palate at MCH was born preterm.

**Birth weight**
The majority of babies were born with birth weight ≥ 2500 grams despite having an abnormality. The only exception was for spina bifida where there was equal frequency for babies with birth weight ≥ 2500 grams and birth weight < 2500 grams. Also the only baby with cleft lip and palate at MCH had birth weight < 2500 grams.
Table 5.3: Maternal and neonatal characteristics: distribution of common congenital abnormalities

<table>
<thead>
<tr>
<th>Congenital abnormality</th>
<th>Polydactyly</th>
<th>Talipes</th>
<th>Umbilical hernia</th>
<th>Hydrocephalus</th>
<th>Spina bifida</th>
<th>Cleft lip/palate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>KCH</td>
<td>MCH</td>
<td>KCH</td>
<td>MCH</td>
<td>KCH</td>
<td>MCH</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Freq (%)</td>
<td>Freq (%)</td>
<td>Freq (%)</td>
<td>Freq (%)</td>
<td>Freq (%)</td>
<td>Freq (%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20 years</td>
<td>80 (18.9)</td>
<td>2 (2.6)</td>
<td>10 (20.8)</td>
<td>1 (16.7)</td>
<td>7 (17.1)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>20 - 24</td>
<td>155 (36.6)</td>
<td>15 (39.5)</td>
<td>17 (35.4)</td>
<td>2 (33.3)</td>
<td>15 (36.6)</td>
<td>3 (100.0)</td>
</tr>
<tr>
<td>25 - 29</td>
<td>103 (24.3)</td>
<td>10 (26.3)</td>
<td>6 (12.5)</td>
<td>0 (0.0)</td>
<td>8 (19.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>30 - 34</td>
<td>55 (13.0)</td>
<td>9 (23.7)</td>
<td>8 (16.7)</td>
<td>0 (0.0)</td>
<td>8 (19.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>35 - 39</td>
<td>26 (6.1)</td>
<td>3 (7.9)</td>
<td>44 (12.5)</td>
<td>3 (50.0)</td>
<td>2 (4.9)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>≥40 years</td>
<td>4 (0.9)</td>
<td>0 (0.0)</td>
<td>1 (2.1)</td>
<td>0 (0.0)</td>
<td>1 (2.4)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>143 (33.8)</td>
<td>3 (7.9)</td>
<td>20 (41.7)</td>
<td>2 (33.3)</td>
<td>10 (24.4)</td>
<td>1 (33.3)</td>
</tr>
<tr>
<td>2</td>
<td>97 (22.9)</td>
<td>6 (15.8)</td>
<td>5 (10.4)</td>
<td>1 (16.7)</td>
<td>7 (17.1)</td>
<td>2 (66.7)</td>
</tr>
<tr>
<td>3</td>
<td>68 (16.1)</td>
<td>11 (28.9)</td>
<td>7 (14.6)</td>
<td>0 (0.0)</td>
<td>12 (29.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>4</td>
<td>47 (11.1)</td>
<td>7 (18.4)</td>
<td>7 (14.6)</td>
<td>0 (0.0)</td>
<td>3 (7.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>≥ 5</td>
<td>68 (16.1)</td>
<td>11 (28.9)</td>
<td>9 (18.8)</td>
<td>3 (50.0)</td>
<td>9 (22.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>233 (55.3)</td>
<td>18 (46.2)</td>
<td>25 (53.2)</td>
<td>4 (66.7)</td>
<td>13 (31.7)</td>
<td>1 (33.3)</td>
</tr>
<tr>
<td>Female</td>
<td>188 (44.7)</td>
<td>21 (53.8)</td>
<td>22 (46.8)</td>
<td>2 (33.3)</td>
<td>28 (68.3)</td>
<td>2 (66.7)</td>
</tr>
<tr>
<td>Gestation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 37 wks</td>
<td>352 (87.8)</td>
<td>31 (79.5)</td>
<td>38 (84.4)</td>
<td>4 (66.7)</td>
<td>36 (90.0)</td>
<td>3 (100.0)</td>
</tr>
<tr>
<td>&lt;37 wks</td>
<td>49 (12.2)</td>
<td>8 (20.5)</td>
<td>7 (15.6)</td>
<td>2 (33.3)</td>
<td>4 (10.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Birth weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥2500 grams</td>
<td>371 (89.4)</td>
<td>36 (92.3)</td>
<td>37 (78.7)</td>
<td>4 (66.7)</td>
<td>37 (97.4)</td>
<td>3 (100.0)</td>
</tr>
<tr>
<td>&lt;2500 grams</td>
<td>44 (10.6)</td>
<td>3 (7.7)</td>
<td>10 (21.3)</td>
<td>2 (33.3)</td>
<td>1 (2.6)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>
5.3 Kamuzu Central Hospital paediatric records

5.3.1 Paediatric patient characteristics

Patient characteristics of the recorded congenital abnormalities are summarised in Table 5.4. There were more males than females (103; 51.87% vs 96; 48.2%). Three patients did not have gender recorded. The majority 112 (55.4%) of the babies were less than 28 days old. A small percentage (5.0%) was more than one year old.

Table 5.4: Distribution of congenital abnormalities according to patient characteristics at Paediatric Ward, Kamuzu Central, Malawi, January 2006-June, 2010

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Frequency</th>
<th>Percentage (%) (n=202)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>103</td>
<td>51.8</td>
</tr>
<tr>
<td>Female</td>
<td>96</td>
<td>48.2</td>
</tr>
<tr>
<td>Not recorded</td>
<td>3</td>
<td>1.5</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 28 days</td>
<td>112</td>
<td>55.4</td>
</tr>
<tr>
<td>29 – 365 days</td>
<td>31</td>
<td>15.3</td>
</tr>
<tr>
<td>&gt; 365 days</td>
<td>10</td>
<td>5.0</td>
</tr>
<tr>
<td>Not recorded</td>
<td>49</td>
<td>24.3</td>
</tr>
</tbody>
</table>

5.3.2 Classification of congenital abnormalities

A total of 202 cases of congenital abnormalities were identified from the ward’s admission book although some books were not available for the researcher to check. As presented in Table 5.5, the most common congenital abnormalities were those involving the digestive system 56 (27.9%), nervous system 49 (24.3%) and musculoskeletal 39 (19.3%). Cleft lip and palate was found in 28 (13.9%) and genital abnormalities in 15 (7.4%) patients.
Table 5.5: Recorded congenital abnormalities among paediatric admissions January 2006 - June 2010 at Kamuzu Central Hospital - Malawi

<table>
<thead>
<tr>
<th>Congenital abnormality</th>
<th>Frequency</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Digestive system</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imperforate anus</td>
<td>41</td>
<td>20.4</td>
</tr>
<tr>
<td>Hirsprung’s disease</td>
<td>10</td>
<td>5.0</td>
</tr>
<tr>
<td>Oesophageal atresia</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td>Anal stenosis</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>Pyloric stenosis</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>Retroesophageal fistula</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Nervous system</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spina bifida</td>
<td>38</td>
<td>18.9</td>
</tr>
<tr>
<td>Hydrocephalus</td>
<td>7</td>
<td>3.5</td>
</tr>
<tr>
<td>Encephalocele</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Musculoskeletal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exomphalos</td>
<td>26</td>
<td>12.9</td>
</tr>
<tr>
<td>Gastroschisis</td>
<td>10</td>
<td>5.0</td>
</tr>
<tr>
<td>Talipes</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td>Prune belly syndrome</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Cleft lip/palate</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undescended testes</td>
<td>6</td>
<td>3.0</td>
</tr>
<tr>
<td>Abnormality of penis</td>
<td>3</td>
<td>1.5</td>
</tr>
<tr>
<td>Genital malformation</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td>Indeterminate sex</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>Female genitalia malformation</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Respiratory system</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congenital stridor</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Circulatory system</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart abnormality</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Multiple abnormality</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conjoined twins</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Not elsewhere classified</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mass</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td>Growth</td>
<td>2</td>
<td>1.0</td>
</tr>
</tbody>
</table>
5.4 Summary

This chapter has presented results of record review giving preliminary prevalence of congenital abnormalities at both Mitundu Community and Kamuzu Central Hospitals. The next chapter presents results from the survey which was undertaken at Mitundu Community Hospital.
CHAPTER 6
RESULTS OF OUTPATIENT SURVEY

6.1 Introduction

This chapter presents results of the questionnaire survey. This was a cross-sectional descriptive study of women of childbearing age attending an outpatient clinic at Mitundu Community Hospital. Specifically the study aimed to determine the proportion of women who had been inadvertently prescribed contraindicated medicines in the first trimester of pregnancy in the general outpatient clinic. Pregnancy was determined by a urine pregnancy test. As noted in chapter 4, the Methods chapter, women of reproductive age attending a general outpatient clinic between 1 February 2010 and 30 July 2010 were reviewed on their illness by a Medical Assistant. After review, the Medical Assistant requested all women of childbearing age to then proceed to the researcher for potential participation in the study.

Out of 1012 women who were referred to the researcher, 721 were excluded before interview as not being potentially pregnant. The researcher administered questionnaires to the remaining 291 women. Nineteen questionnaires were not included in the data analysis because during the interview, the women revealed information about themselves that did not meet the inclusion criteria: they were excluded on the basis that they were using contraception, had just had menstruation or were breastfeeding a baby less than six months old. The analysis included data from 272 women (Figure 6.1).
Figure 6.1: Flow diagram showing participants included in the analysis
6.2 Pregnancy status

All women were asked about the possibility of pregnancy by the researcher. Twenty-nine (10.7%) of the 272 women included in the analysis thought they were pregnant, 170 (62.5%) did not think they were pregnant and 73 (26.8%) were not sure/did not know if they were pregnant. A urine pregnancy test was offered to all women who consented to the test. Sixty (22.1%) of the 272 women tested positive and 196 (72.1%) tested negative. Thirteen (4.8%) participants did not wish to have a urine pregnancy test while three (1.1%) did not consent to the test because they were sure they were pregnant. Of the 256 women given the pregnancy test, 23.4% tested positive. Among the 26 women who thought they were pregnant and were tested (excluding the three who were sure), 19 (73.1%) were confirmed pregnant by the pregnancy test. Among 170 who did not think they were pregnant, 157 were tested; 21 (13.4%) had a positive test result (12.4% of the 170). All 73 who were not sure were tested and 22 (30.1%) had a positive test result.

In this report therefore reference will be made to 63 (23.2%) women who were judged to be in the first trimester of pregnancy. These include the 60 women who had a positive pregnancy test and the three women who did not have pregnancy test performed but were sure they were pregnant.
6.3 Characteristics of participants

Characteristics of participants will be presented as socio-demographic and reproductive characteristics.

6.3.1 Socio-demographic characteristics of participants

The socio-demographic characteristics of the participants in this study are presented in Table 6.1. Descriptive statistics were used to describe the sample characteristics and are presented as frequencies and percentages.

**Age**

Women were aged between 17 and 39 years. The largest group of participants (110, 40.4%), were in the 20 to 24 age category. The mean age of the pregnant group was 25.0 years (SD 5.2, Median 23.0) and the non-pregnant group was 25.3 years (SD 5.3, Median 24.0). There was no significant difference in age group between pregnant and non-pregnant women ($\chi^2_{\text{TREND}} = 0.03$, df = 1, $p = 0.875$).

**Tribe**

The majority of participants 233 (85.7%) were of the Chewa tribe which is the main tribe in this rural community. This was followed by Ngoni with 15 (5.5%) of the participants. The other tribes were Yao, Lomwe and Ngoni and these were least represented. There was no significant difference in tribe between pregnant and non-pregnant women (Fisher’s exact test $p = 0.419$).

**Marital status**

In terms of marital status, 221 (81.2%) were married, 30 (11.0%) never married, 8 (2.9%) were divorced, 8 (2.9%) were separated and 5 (1.8%) widowed. There was no significant association between pregnancy status and marital status (Fisher’s exact test $p = 0.166$).

**Living arrangements**

The majority 208 (76.5%) were living with their husbands, 28 (10.3%) were living with parents, 24 (8.8%) were living with their relatives 8 (2.9%) were living with in-laws in a family compound and 4 (1.5%) were living with others such as friends.
There was no significant association between pregnancy status and who the women were living with (Fisher's exact test $p = 0.090$).

**Educational level**

The majority 142 (52.2%) had received primary education but 83 (30.5%) had no form of education. Only 47 (17.3%) had been educated beyond primary level. There was no significant association between pregnancy status and educational level ($\chi^2_{\text{TREND}} = 0.84$, df = 1, $p = 0.359$).

**Income**

Income was categorized as i) regular income ii) irregular income and no income. Findings show that 15 (5.5%) participants had regular income while 109 (40.1%) had irregular income and 148 (54.4%) did not have any source of income. There was no significant association between pregnancy status and income ($\chi^2_{\text{TREND}} = 2.96$, df = 1, $p = 0.085$).

**Table 6.1: Socio-demographic characteristics of participants by pregnancy status**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (n=272) Frequency (%)</th>
<th>Non-pregnant (n=209) Frequency (%)</th>
<th>Pregnant (n=63) Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 20</td>
<td>31 (11.4)</td>
<td>26 (12.4)</td>
<td>5 (8.1)</td>
<td>0.875</td>
</tr>
<tr>
<td>20 – 24</td>
<td>110 (40.4)</td>
<td>82 (39.2)</td>
<td>28 (44.4)</td>
<td></td>
</tr>
<tr>
<td>25 – 29</td>
<td>62 (22.8)</td>
<td>48 (23.0)</td>
<td>14 (22.2)</td>
<td></td>
</tr>
<tr>
<td>30 – 34</td>
<td>49 (18.0)</td>
<td>37 (17.7)</td>
<td>12 (19.0)</td>
<td></td>
</tr>
<tr>
<td>35 – 39</td>
<td>20 (7.4)</td>
<td>16 (7.7)</td>
<td>4 (6.3)</td>
<td></td>
</tr>
<tr>
<td><strong>Tribe</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.419</td>
</tr>
<tr>
<td>Chewa</td>
<td>233 (85.7)</td>
<td>180 (86.1)</td>
<td>53 (84.1)</td>
<td></td>
</tr>
<tr>
<td>Ngoni</td>
<td>15 (5.5)</td>
<td>12 (5.7)</td>
<td>3 (4.8)</td>
<td></td>
</tr>
<tr>
<td>Yao</td>
<td>10 (3.7)</td>
<td>6 (2.9)</td>
<td>4 (6.3)</td>
<td></td>
</tr>
<tr>
<td>Lomwe</td>
<td>7 (2.6)</td>
<td>6 (2.9)</td>
<td>1 (1.6)</td>
<td></td>
</tr>
<tr>
<td>Tumbuka</td>
<td>6 (2.2)</td>
<td>5 (2.4)</td>
<td>1 (1.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.166</td>
</tr>
<tr>
<td>Married</td>
<td>221 (81.2)</td>
<td>163 (78.0)</td>
<td>58 (92.1)</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>30 (11.0)</td>
<td>26 (12.4)</td>
<td>4 (6.3)</td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>8 (2.9)</td>
<td>7 (3.3)</td>
<td>1 (1.6)</td>
<td></td>
</tr>
<tr>
<td>Separated</td>
<td>8 (2.9)</td>
<td>8 (3.8)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>5 (1.8)</td>
<td>5 (2.4)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
</tbody>
</table>
Table 6.1: Socio-demographic characteristics of participants by pregnancy status (continued)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (n=272) Frequency (%)</th>
<th>Non-pregnant (n=209) Frequency (%)</th>
<th>Pregnant (n=63) Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Living arrangements</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Husband alone</td>
<td>208 (76.5)</td>
<td>152 (72.7)</td>
<td>56 (88.9)</td>
<td>0.090</td>
</tr>
<tr>
<td>Parents</td>
<td>28 (10.3)</td>
<td>25 (12.0)</td>
<td>3 (4.8)</td>
<td></td>
</tr>
<tr>
<td>Own relatives</td>
<td>24 (8.8)</td>
<td>22 (10.5)</td>
<td>2 (3.2)</td>
<td></td>
</tr>
<tr>
<td>In-laws in family compound</td>
<td>8 (2.9)</td>
<td>7 (3.3)</td>
<td>1 (1.6)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4 (1.5)</td>
<td>3 (1.4)</td>
<td>1 (1.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Educational level</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.359</td>
</tr>
<tr>
<td>No education</td>
<td>83 (30.5)</td>
<td>65 (31.1)</td>
<td>18 (28.6)</td>
<td></td>
</tr>
<tr>
<td>Primary school</td>
<td>142 (52.2)</td>
<td>111 (53.1)</td>
<td>31 (49.2)</td>
<td></td>
</tr>
<tr>
<td>Secondary school</td>
<td>47 (17.3)</td>
<td>33 (15.8)</td>
<td>14 (22.2)</td>
<td></td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.085</td>
</tr>
<tr>
<td>Regular</td>
<td>15 (5.5)</td>
<td>12 (5.7)</td>
<td>3 (4.8)</td>
<td></td>
</tr>
<tr>
<td>Irregular</td>
<td>109 (40.1)</td>
<td>90 (42.9)</td>
<td>19 (30.6)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>148 (54.4)</td>
<td>107 (51.2)</td>
<td>41 (65.1)</td>
<td></td>
</tr>
</tbody>
</table>

6.3.2 Reproductive characteristics

All women were asked whether they had ever been pregnant. For those who had been pregnant before, they were asked about number of pregnancies and births they had experienced. They were also asked to describe the outcome of each pregnancy in terms of type of delivery, multiple deliveries and number of living children. Women were also asked if they had experienced any adverse events including miscarriages, stillbirths and ectopic pregnancies (Table 6.2).

**Gravidity**

Results indicate that there was similar representation of participants across all categories of gravidity. There was no significant association between pregnancy
status and gravidity ($\chi^2_{\text{TREND}} = 1.03$, df = 1, $p = 0.310$). Mean number of pregnancies was 2.2 (SD = 1.6, Median 2 pregnancies).

**Parity**
Overall women were evenly presented in all parity categories. There were no significant differences between pregnant and non-pregnant women ($\chi^2_{\text{TREND}} = 0.86$, df = 1, $p = 0.354$).

**Number of children**
The mean number of children was 2.0 (SD = 1.2, Median 2 children) and there was no significant association between pregnancy status and number of children ($\chi^2_{\text{TREND}} = 1.05$, df = 1, $p = 0.305$).

**Adverse pregnancy events**
Participants were asked about experiences of any eventful or adverse outcome of pregnancy. Miscarriage had been experienced by 50 (21.9%) of the participants, preterm birth by seven participants, stillbirth by four and twin pregnancy by four participants. Only one participant had experienced an ectopic pregnancy. There was no significant association between pregnancy status and the occurrence of the adverse pregnancy events taken one by one.

**Table 6.2: Reproductive characteristics of participants by pregnancy status**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total Frequency (%)</th>
<th>Non-pregnant Frequency (%)</th>
<th>Pregnant Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gravidity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>44 (16.2)</td>
<td>36 (17.1)</td>
<td>8 (12.9)</td>
<td>0.310</td>
</tr>
<tr>
<td>1</td>
<td>56 (20.6)</td>
<td>40 (19.0)</td>
<td>16 (25.8)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>63 (23.2)</td>
<td>55 (26.2)</td>
<td>8 (12.9)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>56 (20.6)</td>
<td>40 (19.0)</td>
<td>16 (25.8)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>34 (12.5)</td>
<td>25 (11.9)</td>
<td>9 (14.5)</td>
<td></td>
</tr>
<tr>
<td>≥ 5</td>
<td>19 (7.0)</td>
<td>14 (6.7)</td>
<td>5 (8.1)</td>
<td></td>
</tr>
<tr>
<td><strong>Parity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>50 (18.4)</td>
<td>41 (19.5)</td>
<td>9 (14.5)</td>
<td>0.354</td>
</tr>
<tr>
<td>1</td>
<td>59 (21.7)</td>
<td>43 (20.5)</td>
<td>16 (25.8)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>73 (26.8)</td>
<td>62 (29.5)</td>
<td>11 (17.7)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>52 (19.1)</td>
<td>34 (16.2)</td>
<td>18 (29.0)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>28 (10.3)</td>
<td>22 (10.5)</td>
<td>6 (9.7)</td>
<td></td>
</tr>
<tr>
<td>≥ 5</td>
<td>10 (3.7)</td>
<td>8 (3.8)</td>
<td>2 (3.2)</td>
<td></td>
</tr>
</tbody>
</table>
Table 6.2: Reproductive characteristics of participants by pregnancy status
(continued)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total Frequency (%)</th>
<th>Non-pregnant Frequency (%)</th>
<th>Pregnant Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of children</td>
<td>64 (23.5)</td>
<td>51 (24.3)</td>
<td>13 (21.0)</td>
<td>0.305</td>
</tr>
<tr>
<td>1</td>
<td>71 (26.1)</td>
<td>52 (24.8)</td>
<td>19 (30.8)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>67 (24.6)</td>
<td>60 (28.6)</td>
<td>7 (11.3)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>49 (18.0)</td>
<td>31 (14.8)</td>
<td>18 (29.0)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>17 (6.2)</td>
<td>14 (6.7)</td>
<td>3 (4.8)</td>
<td></td>
</tr>
<tr>
<td>≥ 5</td>
<td>4 (1.5)</td>
<td>2 (1.0)</td>
<td>2 (3.2)</td>
<td></td>
</tr>
<tr>
<td>Miscarriage*</td>
<td>n=228</td>
<td>n=174</td>
<td>n=54</td>
<td>0.725</td>
</tr>
<tr>
<td>Yes</td>
<td>50 (21.9)</td>
<td>37 (21.3)</td>
<td>13 (24.1)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>178 (78.1)</td>
<td>137 (78.7)</td>
<td>41 (75.9)</td>
<td></td>
</tr>
<tr>
<td>Stillbirth*</td>
<td>&gt;0.999</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (1.8)</td>
<td>3 (1.7)</td>
<td>1 (1.9)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>224 (98.2)</td>
<td>171 (98.2)</td>
<td>53 (98.1)</td>
<td></td>
</tr>
<tr>
<td>Preterm birth*</td>
<td>0.200</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7 (3.1)</td>
<td>7 (4.0)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>221 (96.9)</td>
<td>167 (96.0)</td>
<td>54 (100.0)</td>
<td></td>
</tr>
<tr>
<td>Twin pregnancy*</td>
<td>0.260</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (1.8)</td>
<td>2 (1.1)</td>
<td>2 (3.7)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>224 (98.2)</td>
<td>172 (98.9)</td>
<td>52 (96.3)</td>
<td></td>
</tr>
<tr>
<td>Ectopic pregnancy*</td>
<td>&gt;0.999</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (0.4)</td>
<td>1 (0.6)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>227 (99.6)</td>
<td>173 (99.4)</td>
<td>54 (100.0)</td>
<td></td>
</tr>
</tbody>
</table>

*This calculation excludes women who have never been pregnant

6.3.3 Other characteristics

Distance from participants’ homes to hospital.

The majority of the participants, 149 (54.8%), lived within 0-5 km distance. Few, 33 (12.1%), lived more than ten kilometres away from the hospital. Only 6 (2.2%) lived more than 16 kilometres from the hospital.

Contact with chemicals

Participants were asked if they had been in contact with chemicals in the last two months. Sixty-two (22.8%) reported being in contact. The commonly reported
chemical was fertilizer and was reported by 59 (21.7%) participants. Three reported having being in contact with insecticides.

*Use of tobacco and alcohol*

Two participants reported use of tobacco while six reported use of alcohol.

### 6.4 Patient information about present illness

Participants were asked about symptoms experienced during their present illness and what actions they had taken.

#### 6.4.1 Symptom categories reported by participants for the current visit

Participants reported one or more symptom categories for their present illness as shown in Table 6.3. The most frequent category was general body pains reported by 135 (49.6%). Almost as frequently reported were gastrointestinal symptoms 131 (48.2%). Within this category pregnant women were more likely to report nausea than the non-pregnant women ($\chi^2 = 7.60$, df = 1, $p = 0.006$). Similarly within the category of cardiac symptoms pregnant women were more likely to report heart palpitations than the non-pregnant women (Fishers’ exact test $p = 0.002$). Also in the respiratory symptom category, pregnant women were more likely to report colds and sneezing than the non-pregnant women (Fisher’s exact test $p = 0.012$). Lastly, pregnant women were more likely to report increased salivation than non-pregnant women in the miscellaneous symptom category (Fisher’s exact test $p = 0.012$).

Participants’ reports of having felt unwell showed wide variation. The mean number of days feeling unwell was 7.5 days (SD = 9.6, Median 4 days) and the range was 1 to 90 days. Fifty-four (19.9%) participants reported that they had the symptoms recurrently.
Table 6.3: Reported categories of current symptoms by pregnancy status

<table>
<thead>
<tr>
<th>Symptom Category</th>
<th>Total (n=272) Frequency (%)</th>
<th>Non-pregnant (n=209) Frequency (%)</th>
<th>Pregnant (n=63) Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>General body pains</td>
<td>135 (49.6)</td>
<td>99 (47.4)</td>
<td>36 (57.1)</td>
<td>0.174</td>
</tr>
<tr>
<td>General aches</td>
<td>79 (29.0)</td>
<td>58 (27.8)</td>
<td>21 (33.3)</td>
<td>0.392</td>
</tr>
<tr>
<td>Backache</td>
<td>52 (19.1)</td>
<td>36 (17.2)</td>
<td>16 (25.4)</td>
<td>0.148</td>
</tr>
<tr>
<td>Painful legs</td>
<td>12 (4.4)</td>
<td>11 (5.3)</td>
<td>1 (1.6)</td>
<td>0.306</td>
</tr>
<tr>
<td>Painful arm</td>
<td>5 (1.8)</td>
<td>5 (2.4)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Joint pains</td>
<td>2 (0.7)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Shoulder pain</td>
<td>2 (0.7)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Pins and needles in feet</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>≥2 General body pain symptoms</td>
<td>16 (5.9)</td>
<td>14 (6.7)</td>
<td>2 (3.2)</td>
<td>0.376</td>
</tr>
<tr>
<td>Gastrointestinal symptoms</td>
<td>131 (48.2)</td>
<td>96 (45.9)</td>
<td>35 (55.6)</td>
<td>0.180</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>104 (38.2)</td>
<td>80 (38.3)</td>
<td>24 (38.1)</td>
<td>0.979</td>
</tr>
<tr>
<td>Nausea</td>
<td>24 (8.8)</td>
<td>14 (6.7)</td>
<td>10 (16.1)</td>
<td>0.006</td>
</tr>
<tr>
<td>Vomiting</td>
<td>11 (4.0)</td>
<td>7 (3.3)</td>
<td>4 (6.3)</td>
<td>0.286</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>7 (2.6)</td>
<td>6 (2.9)</td>
<td>1 (1.6)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Abdominal fullness</td>
<td>3 (1.1)</td>
<td>1 (0.5)</td>
<td>2 (3.2)</td>
<td>0.135</td>
</tr>
<tr>
<td>Anal pain</td>
<td>2 (0.7)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Epigastric pain</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Unable to pass stools</td>
<td>1 (0.4)</td>
<td>0 (0.0)</td>
<td>1 (1.6)</td>
<td>0.232</td>
</tr>
<tr>
<td>Loss of appetite</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>≥2 GI symptoms</td>
<td>23 (8.5)</td>
<td>14 (6.7)</td>
<td>9 (14.3)</td>
<td>0.058</td>
</tr>
<tr>
<td>Nervous symptoms</td>
<td>94 (34.6)</td>
<td>69 (33.0)</td>
<td>25 (44.0)</td>
<td>0.329</td>
</tr>
<tr>
<td>Headache</td>
<td>82 (30.1)</td>
<td>60 (28.7)</td>
<td>22 (34.9)</td>
<td>0.346</td>
</tr>
<tr>
<td>Dizziness</td>
<td>15 (5.5)</td>
<td>12 (5.7)</td>
<td>3 (4.8)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>≥2 Nervous symptoms</td>
<td>2 (0.7)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Respiratory symptoms</td>
<td>80 (29.4)</td>
<td>63 (30.1)</td>
<td>17 (27.0)</td>
<td>0.629</td>
</tr>
<tr>
<td>Cough</td>
<td>73 (26.8)</td>
<td>58 (27.8)</td>
<td>15 (23.8)</td>
<td>0.536</td>
</tr>
<tr>
<td>Chest pain</td>
<td>18 (6.6)</td>
<td>16 (7.7)</td>
<td>2 (3.2)</td>
<td>0.261</td>
</tr>
<tr>
<td>Cold/sneezing</td>
<td>10 (3.7)</td>
<td>4 (1.9)</td>
<td>6 (9.5)</td>
<td>0.012</td>
</tr>
<tr>
<td>Breathlessness</td>
<td>5 (1.8)</td>
<td>5 (2.4)</td>
<td>0 (0.0)</td>
<td>0.593</td>
</tr>
<tr>
<td>≥2 Respiratory symptoms</td>
<td>24 (8.8)</td>
<td>18 (8.6)</td>
<td>6 (9.5)</td>
<td>0.823</td>
</tr>
</tbody>
</table>
### Table 6.3: Reported categories of current symptoms by pregnancy status

(continued)

<table>
<thead>
<tr>
<th>Symptom category</th>
<th>Total (n=272) Frequency (%)</th>
<th>Non-pregnant (n=209) Frequency (%)</th>
<th>Pregnant (n=63) Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gynaecological symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>15 (5.5)</td>
<td>13 (6.2)</td>
<td>2 (3.2)</td>
<td>0.532</td>
</tr>
<tr>
<td>Vulva sores/itching</td>
<td>8 (2.9)</td>
<td>5 (2.4)</td>
<td>3 (4.8)</td>
<td>0.392</td>
</tr>
<tr>
<td>Pain on micturition</td>
<td>5 (1.8)</td>
<td>3 (1.4)</td>
<td>2 (3.2)</td>
<td>0.328</td>
</tr>
<tr>
<td>Abnormal vaginal discharge</td>
<td>3 (1.1)</td>
<td>2 (1.0)</td>
<td>1 (1.6)</td>
<td>0.548</td>
</tr>
<tr>
<td>Painful sex</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>≥2 Gynaecology symptom</td>
<td>7 (2.6)</td>
<td>5 (2.4)</td>
<td>2 (3.2)</td>
<td>0.665</td>
</tr>
<tr>
<td>Infection related symptoms</td>
<td>22 (8.1)</td>
<td>17 (8.1)</td>
<td>5 (7.9)</td>
<td>0.960</td>
</tr>
<tr>
<td>Fever</td>
<td>9 (3.3)</td>
<td>5 (2.4)</td>
<td>4 (6.3)</td>
<td>0.219</td>
</tr>
<tr>
<td>Shivering</td>
<td>5 (1.8)</td>
<td>4 (1.9)</td>
<td>1 (1.6)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Painful swallowing</td>
<td>4 (1.5)</td>
<td>4 (1.9)</td>
<td>0 (0.0)</td>
<td>0.576</td>
</tr>
<tr>
<td>Painful ear</td>
<td>2 (0.7)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Painful breast</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Cardiac symptoms</td>
<td>19 (7.0)</td>
<td>9 (4.3)</td>
<td>10 (15.9)</td>
<td>0.004</td>
</tr>
<tr>
<td>Heart palpitations</td>
<td>18(6.6)</td>
<td>8 (3.8)</td>
<td>10 (15.9)</td>
<td>0.002</td>
</tr>
<tr>
<td>Puffiness of face</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Swelling of legs in the morning</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>≥2 Cardiac symptoms</td>
<td>2 (0.7)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Urinary symptoms</td>
<td>6 (2.2)</td>
<td>4 (1.9)</td>
<td>2 (3.2)</td>
<td>0.625</td>
</tr>
<tr>
<td>Dysuria</td>
<td>5 (1.8)</td>
<td>3 (1.4)</td>
<td>2 (3.2)</td>
<td>0.328</td>
</tr>
<tr>
<td>Blood in urine</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Miscellaneous symptoms</td>
<td>26 (9.6)</td>
<td>21 (10.0)</td>
<td>5 (7.9)</td>
<td>0.617</td>
</tr>
<tr>
<td>Nonspecific chest pain</td>
<td>16 (5.9)</td>
<td>14 (6.7)</td>
<td>2 (3.2)</td>
<td>0.376</td>
</tr>
<tr>
<td>Body rash</td>
<td>5 (1.8)</td>
<td>5 (2.4)</td>
<td>0 (0.0)</td>
<td>0.593</td>
</tr>
<tr>
<td>Increased salivation</td>
<td>3 (1.1)</td>
<td>0 (0.0)</td>
<td>3 (4.8)</td>
<td>0.012</td>
</tr>
<tr>
<td>Acne</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Swelling in the mouth</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
</tbody>
</table>
6.4.2 Actions taken by participants to alleviate their current complaint

One hundred and twenty-one (44.5%) took some medication for their current complaint. A hundred and ten (40.4%) participants took modern medicine in trying to alleviate their symptoms before coming to hospital. Nine (3.3%) took traditional medicine and two (0.7%) participants used a combination of both modern and traditional medicine. One hundred and fifty (55.1%) participants took no medication for their illness.

6.5 History of malaria and malaria medications

All women were also asked if they had recently taken medicines for malaria as this was considered to be one of the most common causes of inadvertent exposures to teratogenic medications. The survey showed that 16 (5.8%) participants had taken antimalarials such as sulfadoxine-pyrimethamine (2; 0.7%), artemether-lumefantrine (11; 4.0%) and quinine (3; 1.1%). Five participants took the medicine as self-medication and it was taken as prescribed medication by 11 women. Three out of the 16 women who took antimalarials were pregnant and one took sulfadoxine-pyrimethamine, another took quinine and the other took artemether-lumefantrine.
6.6 Chronic conditions and related medication

Some participants may have been taking medicines for chronic conditions. If available, this information was confirmed from the woman’s health passport booklet. Women were specifically asked about common conditions that frequently require recurrent treatment (Table 6.4).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Total (n=272) Frequency (%)</th>
<th>Non-pregnant (n=209) Frequency (%)</th>
<th>Pregnant (n=63) Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>8 (2.9)</td>
<td>6 (2.9)</td>
<td>2 (3.2)</td>
</tr>
<tr>
<td>Asthma</td>
<td>2 (0.7)</td>
<td>1 (0.5)</td>
<td>1 (1.6)</td>
</tr>
<tr>
<td>Anaemia</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Syphilis</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Tuberculosis*</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1 (0.4)</td>
<td>0 (0.0)</td>
<td>1 (1.6)</td>
</tr>
</tbody>
</table>

*This participant was also taking medicines for HIV hence the number of participants taking medicines for chronic conditions was 13

A total of 13 (4.8%) participants were being treated for chronic conditions. Of the 13 participants who reported having taken/taking medicines for the six conditions in Table 6.4, 8 women were taking HIV medicines (antiretroviral drugs). Seven of the eight HIV positive women were taking trimune while one was taking efavirenz. Two out of the eight HIV positive women were pregnant. One woman was taking trimune and the other was taking efavirenz. In addition to the antiretroviral drugs, the HIV positive women were also taking cotrimoxazole as a prophylactic treatment against HIV-related opportunistic infections. Out of the two women who took asthma medicine, one was pregnant. One participant reported taking ferrous sulphate for anaemia and another had taken phenobarbitone for hypertension. The participant who reported syphilis was given gentamycin, metronidazole and doxycycline. One participant had previously taken medicines for pulmonary tuberculosis.
6.7 Range of other medicines taken

Participants were asked about any other medicines taken in the last two months and reasons for ingestion. The last two months covered the period when some of the participants would have been pregnant. This enquiry excluded medicines for malaria and chronic conditions listed above. Of the 144 (52.9%) participants who reported use of medicines, 112 (77.8%) were non-pregnant and 32 (22.3%) were pregnant women (Table 6.5).

The most common class of medicines taken was analgesics, taken by 109 (74.7%), which included paracetamol, aspirin and ibuprofen. Other common types of medicines reported were antibiotics, antacids, cough remedies and traditional medicine. The medicines were either self-medicated, prescribed by medical personnel or given by traditional healers. A total of 113 (78.5%) participants out of those who used medicines in the last two months self-medicated while 28 (19.4%) had medicines prescribed for treatment. Three (2.1%) had taken both self-medicated and prescribed medicines. There was no difference in recent medication intake between pregnant and non-pregnant women ($\chi^2 = 0.85, df = 1, p = 0.357$) (Table 6.5). The mean number of medicines reported by participants was 1 (range 1 to 3). Most participants 102 (90.3%) took inappropriate dosage of the medicines, thus duration in most cases was less than required. The estimation of the appropriate duration was made with reference to Malawi Standard Treatment Guidelines.

Participants self-mediated with analgesics, antibiotics, cough remedies and antacids. Some of the medicines taken were those which would normally be obtained by prescription only. These medicines included ibuprofen (16; 14.2%), indomethacin (12; 10.6%), cotrimoxazole (14; 12.4%) and metronidazole (3; 2.7%). Out of 32 pregnant women who self-mediated, eight took non-prescribed medicines that would not be recommended at some stage of pregnancy. Seven women were in the first trimester while one was in the second trimester. Some women used traditional medicine and it was used by six non-pregnant women and four pregnant women.
Table 6.5: Medicines taken by participants in the last two months by pregnancy status

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Total (n=144) Frequency (%)</th>
<th>Non-pregnant (n=112) Frequency (%)</th>
<th>Pregnant (n=32) Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Analgesics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td>109 (75.7)</td>
<td>83 (74.1)</td>
<td>26 (81.2)</td>
<td>0.406</td>
</tr>
<tr>
<td>Aspirin</td>
<td>84 (58.3)</td>
<td>66 (58.9)</td>
<td>18 (56.2)</td>
<td>0.786</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>22 (15.3)</td>
<td>16 (14.3)</td>
<td>6 (18.8)</td>
<td>0.536</td>
</tr>
<tr>
<td>≥ 2 analgesics</td>
<td>14 (9.7)</td>
<td>12 (10.7)</td>
<td>2 (6.2)</td>
<td>0.736</td>
</tr>
<tr>
<td><strong>Other analgesic:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td>84 (58.3)</td>
<td>66 (58.9)</td>
<td>18 (56.2)</td>
<td>0.786</td>
</tr>
<tr>
<td>Aspirin</td>
<td>22 (15.3)</td>
<td>16 (14.3)</td>
<td>6 (18.8)</td>
<td>0.536</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>20 (13.9)</td>
<td>15 (13.4)</td>
<td>5 (15.6)</td>
<td>0.747</td>
</tr>
<tr>
<td>≥ 2 analgesics</td>
<td>14 (9.7)</td>
<td>12 (10.7)</td>
<td>2 (6.2)</td>
<td>0.736</td>
</tr>
<tr>
<td><strong>Antibiotics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cefuroxime</td>
<td>34 (23.6)</td>
<td>30 (26.8)</td>
<td>4 (12.5)</td>
<td>0.093</td>
</tr>
<tr>
<td>Cefaclor</td>
<td>18 (12.5)</td>
<td>16 (14.3)</td>
<td>2 (6.2)</td>
<td>0.363</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>11 (7.6)</td>
<td>9 (8.0)</td>
<td>2 (6.2)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>3 (2.1)</td>
<td>3 (2.7)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Dapsonazole</td>
<td>3 (2.1)</td>
<td>2 (1.8)</td>
<td>1 (3.1)</td>
<td>0.532</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>1 (0.7)</td>
<td>1 (0.9)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Gentamycin</td>
<td>1 (0.7)</td>
<td>1 (0.9)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Benzyl penicillin</td>
<td>1 (0.7)</td>
<td>1 (0.9)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>≥ 2 antibiotics</td>
<td>4 (2.8)</td>
<td>3 (2.7)</td>
<td>1 (3.1)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Cough remedy</td>
<td>4 (2.8)</td>
<td>3 (2.7)</td>
<td>1 (3.1)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Cough lozenges</td>
<td>2 (1.4)</td>
<td>1 (0.9)</td>
<td>1 (3.1)</td>
<td>0.396</td>
</tr>
<tr>
<td>Cough syrup</td>
<td>2 (1.4)</td>
<td>2 (1.8)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Antiparasitic</td>
<td>3 (2.1)</td>
<td>3 (2.7)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Albendazole</td>
<td>3 (2.1)</td>
<td>3 (2.7)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Other medicines</td>
<td>17 (11.8)</td>
<td>13 (11.6)</td>
<td>4 (12.5)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Magnesium trisilicate</td>
<td>12 (8.3)</td>
<td>9 (8.0)</td>
<td>3 (9.4)</td>
<td>0.729</td>
</tr>
<tr>
<td>Antiparasitic</td>
<td>3 (2.1)</td>
<td>3 (2.7)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Phenobarbitone</td>
<td>1 (0.7)</td>
<td>1 (0.9)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Traditional medicine</td>
<td>10 (6.9)</td>
<td>6 (5.4)</td>
<td>4 (12.5)</td>
<td>0.229</td>
</tr>
</tbody>
</table>
6.7.1 Reasons for taking medicines

Participants were asked why they took medicines in the last two months (Table 6.6). The most common reasons were: abdominal pains (37; 25.7%), headache (34; 23.6%), general body pains (34; 23.6%), cough (18; 12.5%), backache (11; 7.6%), chest pain (7; 4.9%) and respiratory tract infection (5; 3.5%). There were other conditions which had a low frequency, thus there was one participant in each reported condition. There was no significant difference in the reasons reported by pregnant and non-pregnant women.

Table 6.6: Reasons reported for taking medicines in the last two months by pregnancy status

<table>
<thead>
<tr>
<th>Reason for medication use</th>
<th>Total sample (n = 144) Frequency (%)</th>
<th>Non-pregnant (n = 112) Frequency (%)</th>
<th>Pregnant (n = 32) Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pains</td>
<td>37 (25.7)</td>
<td>30 (26.8)</td>
<td>7 (21.9)</td>
<td>0.575</td>
</tr>
<tr>
<td>Headache</td>
<td>34 (23.6)</td>
<td>24 (21.4)</td>
<td>10 (31.2)</td>
<td>0.249</td>
</tr>
<tr>
<td>General body pains</td>
<td>34 (23.6)</td>
<td>23 (20.5)</td>
<td>11 (34.4)</td>
<td>0.104</td>
</tr>
<tr>
<td>Cough</td>
<td>18 (12.5)</td>
<td>17 (15.2)</td>
<td>1 (3.1)</td>
<td>0.076</td>
</tr>
<tr>
<td>Backache</td>
<td>11 (7.6)</td>
<td>6 (5.4)</td>
<td>5 (15.6)</td>
<td>0.067</td>
</tr>
<tr>
<td>Chest pain</td>
<td>7 (4.9)</td>
<td>7 (6.2)</td>
<td>0 (0.0)</td>
<td>0.349</td>
</tr>
<tr>
<td>Respiratory tract infection</td>
<td>5 (3.5)</td>
<td>5 (4.5)</td>
<td>0 (0.0)</td>
<td>0.587</td>
</tr>
<tr>
<td>Fever</td>
<td>2 (1.4)</td>
<td>2 (1.8)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Tonsillitis</td>
<td>2 (1.4)</td>
<td>2 (1.8)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Peptic ulcer disease</td>
<td>2 (1.4)</td>
<td>1 (0.9)</td>
<td>1 (3.1)</td>
<td>0.396</td>
</tr>
<tr>
<td>Others*</td>
<td>10 (6.9)</td>
<td>9 (8.0)</td>
<td>1 (3.1)</td>
<td>0.459</td>
</tr>
</tbody>
</table>

Worms, dyspepsia, painful foot, diarrhoea, abnormal vaginal discharge, painful arm, pubic pain, lack of sleep, painful throat, pain in anal area.

Out of the 113 participants who self-medicated, 96 (85.5%) participants took an appropriate medicine suitable for the reported symptom. In contrast, 17 (15.0%) participants did not take appropriate medicines for the reported symptom for example taking cotrimoxazole for general body pains and quinine for abdominal pains.
6.8 Purchase of medicines for self-medication

6.8.1 Medicines purchased for self-medication

Participants were asked about purchase of medicines. Two hundred and thirty-six (86.8%) participants reported that they sometimes buy medicines. As shown in Table 6.7, 173 participants were asked about the types purchased. The medicines they purchased included analgesics (160; 92.5%), specific anti-inflammatory medicine - indomethacin (24, 13.9%), antibiotics (31; 17.9%) antacids - magnesium trisilicate (14; 8.1%) cough remedies (16; 9.2%) and antimalarials (7; 4.0%).

Table 6.7: Medicines which participants bought

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Total (n=173) Frequency (%)</th>
<th>Non-pregnant (n=133) Frequency (%)</th>
<th>Pregnant (n=40) Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesics</td>
<td>160 (92.5)</td>
<td>121 (91.0)</td>
<td>39 (95.5)</td>
<td>0.303</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>151 (87.3)</td>
<td>113 (85.0)</td>
<td>38 (95.0)</td>
<td>0.095</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>37 (21.4)</td>
<td>31 (23.3)</td>
<td>6 (15.0)</td>
<td>0.262</td>
</tr>
<tr>
<td>Aspirin</td>
<td>31 (17.9)</td>
<td>23 (17.3)</td>
<td>8 (20.0)</td>
<td>0.696</td>
</tr>
<tr>
<td>Other analgesic</td>
<td>24 (13.9)</td>
<td>17 (12.8)</td>
<td>7 (17.5)</td>
<td>0.449</td>
</tr>
<tr>
<td>:Indomethacin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibiotics</td>
<td>31 (17.9)</td>
<td>26 (19.5)</td>
<td>5 (12.5)</td>
<td>0.308</td>
</tr>
<tr>
<td>Cotrimoxazole</td>
<td>26 (15.0)</td>
<td>21 (15.8)</td>
<td>5 (12.5)</td>
<td>0.610</td>
</tr>
<tr>
<td>Penicillin V</td>
<td>3 (1.7)</td>
<td>3 (2.3)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>1 (0.6)</td>
<td>1 (0.8)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>1 (0.6)</td>
<td>1 (0.8)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>1 (0.6)</td>
<td>1 (0.8)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Cough remedy</td>
<td>16 (9.2)</td>
<td>14 (10.5)</td>
<td>2 (5.0)</td>
<td>0.368</td>
</tr>
<tr>
<td>Cough lozenges</td>
<td>15 (8.7)</td>
<td>13 (9.8)</td>
<td>2 (5.0)</td>
<td>0.525</td>
</tr>
<tr>
<td>Cough syrup</td>
<td>1 (0.6)</td>
<td>1 (0.8)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Antacids</td>
<td>14 (8.1)</td>
<td>12 (9.0)</td>
<td>2 (5.0)</td>
<td>0.526</td>
</tr>
<tr>
<td>Magnesium trisilicate)</td>
<td>14 (8.1)</td>
<td>12 (9.0)</td>
<td>2 (5.0)</td>
<td>0.526</td>
</tr>
<tr>
<td>Anti-malarials</td>
<td>7 (4.0)</td>
<td>4 (3.0)</td>
<td>3 (7.5)</td>
<td>0.202</td>
</tr>
<tr>
<td>Sulfadoxine-pyrimethamine</td>
<td>3 (1.7)</td>
<td>2 (1.5)</td>
<td>1 (2.5)</td>
<td>0.548</td>
</tr>
<tr>
<td>Artemether-lumefantrine</td>
<td>1 (0.6)</td>
<td>1 (0.8)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Quinine</td>
<td>3 (1.7)</td>
<td>1 (0.8)</td>
<td>2 (5.0)</td>
<td>0.134</td>
</tr>
</tbody>
</table>
6.8.2 Reasons for self-medication

One hundred and sixty-eight (71.2%) out of the 236 participants who bought medicines were asked about the reasons for buying the medicines. These were mainly: their illness being perceived as not being severe enough to warrant going to hospital (68; 25.0%), getting sick out of hours (46; 16.9%), long distance preventing them from going to hospital (31; 11.4%), having other commitments (9; 3.3%) and no medicines at the hospital (4; 1.5%). Some less frequently cited reasons were: for quick relief of symptoms, crowd avoidance at the hospital and having no trust in the hospital medicines.

6.8.3 Source of money for buying medicines

One hundred (42.4%) participants stated that if they bought medicines, they used their own money while 110 (46.6%) requested the money from their husbands and 20 (8.5%) from their parents. The other participants obtained money from either other family members or friends for buying medicine.

6.9 Use of folic acid

Only one participant had heard about folic acid and knew it as ‘blood boosting’ medicine. None of the women had ever purchased this product.

6.10 Storage of medicines in the home

This item was added after the study started to gain information about medicines being stored by the participants; therefore 43 (15.8%) participants were omitted from the analysis. Thirty nine (39/229; 17.0%) participants stored medicines in their own home, and these medicines included paracetamol, aspirin, ibuprofen, cotrimoxazole, metronidazole, erythromycin, magnesium triscilicate, ferrous sulphate, quinine, artemether-lumefantrine and traditional medicine. Medicines would be used for future
illness involving themselves or other family members. In some cases, participants were keeping medicines as a part of continuation of current treatment.

Out of the 39 who kept medicines in their home, 33 were asked about the source of the medicine. Most of the medicines were acquired through local shops (13/33; 39.4%) or the hospital (18/33; 54.5%).

### 6.11 Pregnancy

#### 6.11.1 Pregnancy status enquiry

All participants were asked by the researcher if the Medical Assistant had enquired about pregnancy (Table 6.8). A total of 152 (55.9%) participants, just over half of the sample, confirmed that they were asked this question. Seventeen (11.2%) out of those who were asked about pregnancy suspected they were pregnant, while 12 (10.0%) of those not asked thought they were pregnant. There was no association between a participant’s perceived pregnancy status and whether she was asked whether she was pregnant ($\chi^2 = 0.11$, df = 2, $p = 0.944$). Out of the 29 women who thought they were pregnant, 14 (48.3%) told the Medical Assistant they were pregnant; 3 (10.3%) did not disclose their pregnancy because they were not sure yet if they were really pregnant and 12 (41.4%) did not disclose because they were not asked; only 18 (62.1%) had told someone else (husband or friend) that they were pregnant.

<table>
<thead>
<tr>
<th>Participants’ perceived pregnancy status</th>
<th>Total (n=272)</th>
<th>Asked about pregnancy (n=152)</th>
<th>Not asked (n=120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thought they were pregnant</td>
<td>29 (10.7)</td>
<td>17 (11.2)</td>
<td>12 (10.0)</td>
</tr>
<tr>
<td>Did not think they were pregnant</td>
<td>170 (62.5)</td>
<td>94 (61.8)</td>
<td>76 (63.3)</td>
</tr>
<tr>
<td>Not sure about pregnancy/did not know</td>
<td>73 (26.8)</td>
<td>41 (27.0)</td>
<td>32 (26.7)</td>
</tr>
</tbody>
</table>
6.11.2 Characteristics of women who did and did not disclose their pregnancy to the clinician

There were no significant differences in age, tribe, marital status, living arrangements, educational level, gravidity and parity between the women who disclosed and those who did not disclose their pregnancy status (Table 6.9). None of the p-values were < 0.05 and this may be due to the small sample sizes in the groups.
Table 6.9: Characteristics of participants by pregnancy disclosure response

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (n=29) Frequency (%)</th>
<th>Disclosed (n=14) Frequency (%)</th>
<th>Did not disclose (n=15) Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 20</td>
<td>3 (10.3)</td>
<td>1 (7.1)</td>
<td>2 (13.3)</td>
<td>0.554</td>
</tr>
<tr>
<td>20 – 24</td>
<td>11 (37.9)</td>
<td>7 (50.0)</td>
<td>4 (26.7)</td>
<td></td>
</tr>
<tr>
<td>25 – 29</td>
<td>8 (26.70)</td>
<td>3 (21.4)</td>
<td>5 (33.3)</td>
<td></td>
</tr>
<tr>
<td>30 – 34</td>
<td>6 (20.7)</td>
<td>3 (21.4)</td>
<td>3 (20.0)</td>
<td></td>
</tr>
<tr>
<td>35 – 39</td>
<td>1 (3.4)</td>
<td>0 (0.0)</td>
<td>1 (6.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Tribe</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.732</td>
</tr>
<tr>
<td>Chewa</td>
<td>23 (79.3)</td>
<td>12 (85.7)</td>
<td>11 (73.3)</td>
<td></td>
</tr>
<tr>
<td>Ngoni</td>
<td>2 (6.9)</td>
<td>0 (0.0)</td>
<td>2 (13.3)</td>
<td></td>
</tr>
<tr>
<td>Yao</td>
<td>2 (6.9)</td>
<td>1 (7.1)</td>
<td>1 (6.7)</td>
<td></td>
</tr>
<tr>
<td>Lomwe</td>
<td>1 (3.4)</td>
<td>0 (0.0)</td>
<td>1 (6.7)</td>
<td></td>
</tr>
<tr>
<td>Tumbuka</td>
<td>1 (3.4)</td>
<td>1 (7.1)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Married</td>
<td>28 (96.6)</td>
<td>14 (100.0)</td>
<td>14 (93.3)</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>1 (3.4)</td>
<td>0 (0.00)</td>
<td>1 (6.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Living arrangements</strong></td>
<td></td>
<td></td>
<td></td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Husband</td>
<td>28 (96.60)</td>
<td>14 (100.0)</td>
<td>14 (93.3)</td>
<td></td>
</tr>
<tr>
<td>Parents</td>
<td>1 (3.4)</td>
<td>0 (0.0)</td>
<td>1 (6.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Educational level</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.144</td>
</tr>
<tr>
<td>No education</td>
<td>9 (3.1)</td>
<td>6 (42.9)</td>
<td>3 (20.0)</td>
<td></td>
</tr>
<tr>
<td>Primary school</td>
<td>16 (55.2)</td>
<td>7 (50.0)</td>
<td>9 (60.0)</td>
<td></td>
</tr>
<tr>
<td>Secondary</td>
<td>4 (13.8)</td>
<td>1 (7.1)</td>
<td>3 (20.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Gravidity</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.952</td>
</tr>
<tr>
<td>0</td>
<td>3 (10.3)</td>
<td>1 (7.1)</td>
<td>2 (13.3)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>6 (20.7)</td>
<td>4 (28.6)</td>
<td>2 (13.3)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>4 (13.8)</td>
<td>1 (7.1)</td>
<td>3 (20.0)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>7 (24.1)</td>
<td>3 (21.4)</td>
<td>4 (26.7)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>7 (24.1)</td>
<td>5 (35.7)</td>
<td>2 (13.3)</td>
<td></td>
</tr>
<tr>
<td>≥ 5</td>
<td>2 (6.9)</td>
<td>0 (0.0)</td>
<td>2 (13.3)</td>
<td></td>
</tr>
<tr>
<td><strong>Parity</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.598</td>
</tr>
<tr>
<td>0</td>
<td>4 (13.8)</td>
<td>2 (14.3)</td>
<td>2 (13.3)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>7 (24.1)</td>
<td>4 (28.6)</td>
<td>3 (20.0)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>7 (24.1)</td>
<td>2 (14.3)</td>
<td>5 (33.3)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>6 (20.7)</td>
<td>5 (35.7)</td>
<td>1 (6.7)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>4 (13.8)</td>
<td>1 (7.1)</td>
<td>3 (20.0)</td>
<td></td>
</tr>
<tr>
<td>≥ 5</td>
<td>1 (3.4)</td>
<td>0 (0.0)</td>
<td>1 (6.7)</td>
<td></td>
</tr>
</tbody>
</table>
Pregnancy test results

Table 6.10 shows a breakdown of the participants' perceived pregnancy status by the results of their pregnancy test. Although only 29 women thought they were pregnant, there were 60 positive test results, with a further three pregnancies not needed to be confirmed by a test. Of the 29 women suspecting they were pregnant, 9 (31.0%) had negative test results; among the other 243 who either did not think they were pregnant or were not sure, 43 (17.7%) had positive test results.

Table 6.10: Participants' perceived pregnancy status and pregnancy test results

<table>
<thead>
<tr>
<th>Participants' perceived pregnancy status</th>
<th>Total (n=272) Frequency (%)</th>
<th>Positive test (n=60) Frequency (%)</th>
<th>Negative test (n=196) Frequency (%)</th>
<th>Test not done (refused) (n=13) Frequency (%)</th>
<th>Test not done (pregnant) (n=3) Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thought they were pregnant</td>
<td>29 (10.7)</td>
<td>17 (28.3)</td>
<td>9 (4.6)</td>
<td>3 (100.0)</td>
<td></td>
</tr>
<tr>
<td>Did not think they were pregnant</td>
<td>170 (62.5)</td>
<td>21 (35.0)</td>
<td>136 (69.4)</td>
<td>13 (100.0)</td>
<td></td>
</tr>
<tr>
<td>Not sure/did not know</td>
<td>73 (26.8)</td>
<td>22 (36.7)</td>
<td>51 (26.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6.12 Diagnoses made at the outpatient clinic

Diagnosis refers to a specific diagnosis by the Medical Assistants in the outpatient clinic or impressions or sign of illness written down in the health passport. In most instances diagnoses were based on symptoms presented by the patients at the outpatient clinic. According to review of symptoms, there was no pattern in the complaints being given by the patients and diagnosis being made. The only diagnosis for which the Medical Assistant was able to confirm through laboratory studies was malaria though not all patients who were suspected of having malaria had microscopy performed.

Fifteen participants’ diagnoses were not recorded by the researcher at the very beginning of the survey. Table 6.11 displays the results for 256 participants. These results are listed in their order of frequency of diagnosis.

Table 6.11: Diagnoses made at the outpatient clinic by pregnancy status

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Total (n=256) Frequency (%)</th>
<th>Non-pregnant (n=195) Frequency (%)</th>
<th>Pregnant (n=61) Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All malaria cases</td>
<td>73 (28.5)</td>
<td>54 (27.7)</td>
<td>19 (31.1)</td>
<td>0.602</td>
</tr>
<tr>
<td>Clinical malaria</td>
<td>62 (24.2)</td>
<td>44 (22.6)</td>
<td>18 (29.5)</td>
<td>0.269</td>
</tr>
<tr>
<td>Test-positive malaria</td>
<td>11 (4.3)</td>
<td>10 (5.1)</td>
<td>1 (1.6)</td>
<td>0.468</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>56 (21.9)</td>
<td>47 (24.1)</td>
<td>9 (14.8)</td>
<td>0.123</td>
</tr>
<tr>
<td>Worms</td>
<td>32 (12.5)</td>
<td>19 (9.7)</td>
<td>13 (21.3)</td>
<td>0.017</td>
</tr>
<tr>
<td>Musculoskeletal pain</td>
<td>23 (9.0)</td>
<td>19 (9.7)</td>
<td>4 (6.6)</td>
<td>0.448</td>
</tr>
<tr>
<td>Peptic ulcer disease</td>
<td>18 (7.0)</td>
<td>15 (7.7)</td>
<td>3 (4.9)</td>
<td>0.576</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>9 (3.5)</td>
<td>7 (3.6)</td>
<td>2 (3.3)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>8 (3.1)</td>
<td>6 (3.1)</td>
<td>2 (3.3)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Gastroenteritis</td>
<td>6 (2.3)</td>
<td>4 (2.1)</td>
<td>2 (3.3)</td>
<td>0.631</td>
</tr>
<tr>
<td>Minor pregnancy disorders</td>
<td>6 (2.3)</td>
<td>1 (0.5)</td>
<td>5 (8.2)</td>
<td>0.003</td>
</tr>
<tr>
<td>Trichomoniasis</td>
<td>5 (2.0)</td>
<td>3 (1.5)</td>
<td>2 (3.3)</td>
<td>0.342</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>4 (1.6)</td>
<td>3 (1.5)</td>
<td>1 (1.6)</td>
<td>&gt;0.999</td>
</tr>
</tbody>
</table>
Table 6.11: Diagnoses made at the outpatient clinic by pregnancy status (continued)

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Total Frequency (%)</th>
<th>Non-pregnant Frequency (%)</th>
<th>Pregnant Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower abdominal pain</td>
<td>4 (1.6)</td>
<td>2 (1.0)</td>
<td>2 (3.3)</td>
<td>0.241</td>
</tr>
<tr>
<td>Gastritis</td>
<td>3 (1.2)</td>
<td>3 (1.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Dysmenorrhoea</td>
<td>3 (1.2)</td>
<td>3 (1.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Ear infection</td>
<td>2 (0.8)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Abnormal vaginal discharge</td>
<td>2 (0.8)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Tonsillitis</td>
<td>2 (0.8)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Urticaria</td>
<td>2 (0.8)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>2 (0.8)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Endometriosis</td>
<td>2 (0.8)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>2 (0.8)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Vaginitis</td>
<td>2 (0.8)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Amoebiasis</td>
<td>2 (0.8)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Others&lt;sup&gt;a&lt;/sup&gt;</td>
<td>18 (7.0)</td>
<td>16 (8.2)</td>
<td>2 (3.3)</td>
<td>0.258</td>
</tr>
</tbody>
</table>

<sup>a</sup>Mastitis, heartburn, asthma, acne, Pelvic Inflammatory Disease, cold, Tropical Splenomegalogy Syndrome, giardiasis, skin rash, candidiasis, maxillary abscess, peri-anal sore, cervicitis, epigastric pain, cough, migraine headache, abdominal pain, amenorrhoea, anorexia

Malaria was the most prevalent infection (73; 28.5%), diagnosed either clinically in 62 (24.1%) or microscopically in 11 (4.3%) participants. There was no significant difference between pregnant and non-pregnant women in malaria diagnosis ($\chi^2 = 0.27, \text{df} = 1, p = 0.602$). The diagnosis of minor pregnancy disorders was made in the case of one non-pregnant woman. There was a significant difference between pregnant and non-pregnant in the diagnosis of ‘worms’. Pregnant women were more likely to be diagnosed as having worms than the non-pregnant women ($\chi^2 = 5.69, \text{df} = 1, p = 0.017$).
6.13 Medicines prescribed in the outpatient department

The distribution of medicines prescribed to the women is as shown in Table 6.12.

Table 6.12: Frequency distribution of the medicines prescribed by pregnancy status

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Total (n=272)</th>
<th>Non-pregnant (n=209)</th>
<th>Pregnant (n=63)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency (%)</td>
<td>Frequency (%)</td>
<td>Frequency (%)</td>
<td></td>
</tr>
<tr>
<td>Analgesics</td>
<td>249 (91.5)</td>
<td>188 (90.0)</td>
<td>61 (96.8)</td>
<td>0.086</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>113 (41.5)</td>
<td>77 (37.1)</td>
<td>36 (57.1)</td>
<td>0.004</td>
</tr>
<tr>
<td>Aspirin</td>
<td>98 (36.0)</td>
<td>81 (38.8)</td>
<td>17 (27.0)</td>
<td>0.188</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>37 (13.6)</td>
<td>29 (13.8)</td>
<td>8 (12.7)</td>
<td>0.811</td>
</tr>
<tr>
<td>Indomethacin</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>157 (57.7)</td>
<td>128 (61.2)</td>
<td>29 (46.0)</td>
<td>0.032</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>71 (26.1)</td>
<td>55 (26.3)</td>
<td>16 (25.4)</td>
<td>0.884</td>
</tr>
<tr>
<td>Cotrimoxazole</td>
<td>64 (23.5)</td>
<td>57 (27.3)</td>
<td>7 (11.1)</td>
<td>0.008</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>25 (9.2)</td>
<td>18 (8.6)</td>
<td>7 (11.1)</td>
<td>0.547</td>
</tr>
<tr>
<td>Gentamycin</td>
<td>4 (1.5)</td>
<td>3 (1.4)</td>
<td>1 (1.6)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>4 (1.5)</td>
<td>4 (1.9)</td>
<td>0 (0.0)</td>
<td>0.576</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>2 (0.7)</td>
<td>1 (0.5)</td>
<td>1 (1.6)</td>
<td>0.410</td>
</tr>
<tr>
<td>Antimalarials</td>
<td>78 (28.7)</td>
<td>58 (27.8)</td>
<td>20 (31.7)</td>
<td>0.539</td>
</tr>
<tr>
<td>A-lumefantrine*</td>
<td>65 (23.9)</td>
<td>49 (23.4)</td>
<td>16 (25.4)</td>
<td>0.750</td>
</tr>
<tr>
<td>SP*</td>
<td>13 (4.8)</td>
<td>9 (4.3)</td>
<td>4 (6.3)</td>
<td>0.506</td>
</tr>
<tr>
<td>Others</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albenzole</td>
<td>61 (22.4)</td>
<td>45 (21.5)</td>
<td>16 (25.4)</td>
<td>0.519</td>
</tr>
<tr>
<td>Mag trisilicate*</td>
<td>13 (4.8)</td>
<td>11 (5.3)</td>
<td>2 (3.2)</td>
<td>0.739</td>
</tr>
<tr>
<td>Vitamin B complex</td>
<td>6 (2.2)</td>
<td>5 (2.4)</td>
<td>1 (1.6)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Ferrous sulphate</td>
<td>5 (1.8)</td>
<td>4 (1.9)</td>
<td>1 (1.6)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Nystatin pessaries</td>
<td>5 (1.8)</td>
<td>4 (1.9)</td>
<td>1 (1.6)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Calamine lotion</td>
<td>3 (1.1)</td>
<td>3 (1.4)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Phenobarbitone</td>
<td>3 (1.1)</td>
<td>3 (1.4)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Piriton</td>
<td>3 (1.1)</td>
<td>3 (1.4)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Pyridoxine</td>
<td>2 (0.7)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Promethazine</td>
<td>2 (0.7)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Oral rehydration</td>
<td>2 (0.7)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>salt</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Analgesics were the most frequently prescribed medicines (249; 91.5%). Those who were pregnant were more likely to be prescribed paracetamol ($\chi^2 = 8.22$, df = 1, $p = 0.004$). Antibiotics were the second most prescribed medicines (157; 57.7%). Six types of antibiotics were encountered in the study. Metronidazole (71; 26.1%) was the most frequently prescribed antibiotic. The other frequently prescribed antibiotic was cotrimoxazole (64; 25.5%). But this was more likely to be prescribed to non-pregnant rather than the pregnant women ($\chi^2 = 7.03$, df = 1, $p = 0.008$). Antimalarials were the third frequently prescribed medicines. Artemether-lumefantrine (65; 23.9%) was the most frequently prescribed antimalarial medicine. The other antimalarial which was prescribed was sulfadoxine-pyrimethamine (13; 4.8%). Albendazole (61; 22.4%) was the only antiparasitic medicine prescribed and was given with equal frequency to women in both pregnancy groups.

Other groups of medicines encountered included antacids. Prescribed antacid was magnesium trisilicate (13; 4.8%). Other medicines prescribed were vitamin B complex, ferrous sulphate, nystatin pessaries, calamine lotion, phenobarbitone, piriton, pyridoxine, promethazine, anal suppositories, amitriptyline, bisacodyl, folic acid, salbutamol and cimetidine. The median number of medications prescribed during outpatient consultations was 2 (range 1 to 4) and mean number was 2.3. A classification of medicines according to risk to the foetus by United States Food and Drug Administration (FDA) (Table 6.13) indicated that of all the medicines

### Table 6.12: Frequency distribution of the medicines prescribed by pregnancy status (continued)

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Total (n=272) Frequency (%)</th>
<th>Non-pregnant (n=209) Frequency (%)</th>
<th>Pregnant (n=63) Frequency (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Others</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anal suppositories</td>
<td>2 (0.7)</td>
<td>2 (1.0)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Amitriptyline</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Bisacodyl</td>
<td>1 (0.4)</td>
<td>0 (0.0)</td>
<td>1 (1.6)</td>
<td>0.232</td>
</tr>
<tr>
<td>Folic acid</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Salbutamol</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Cimetidine</td>
<td>1 (0.4)</td>
<td>0 (0.0)</td>
<td>1 (1.6)</td>
<td>0.232</td>
</tr>
</tbody>
</table>

*A-lumefantrine: Artemether-lumefantrine; Mag trisicilacate: Magnesium trisicilicate; SP: Sulfadoxine-Pyrimethamine*
prescribed, 6 (2.2%) participants were prescribed medicines in category A, 76 (27.9%) participants had medicines belonging to category B, 217 (79.8%) participants had medicines in category C and 28 (10.3%) participants were prescribed medicines in category D. A total of 129 (47.4%) participants were prescribed medicines which are non-classified by FDA pregnancy category. None was prescribed medicines belonging to category X.

Table 6.13: Prescribed medicines according to FDA classification

<table>
<thead>
<tr>
<th>Category</th>
<th>List of medicines</th>
<th>Total (n = 272) Frequency (%)</th>
<th>Non-pregnant (n = 209) Frequency (%)</th>
<th>Pregnant (n = 63) Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Folic acid, Pyridoxine, Nystatin pessaries</td>
<td>6 (2.2)</td>
<td>6 (2.9)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>B</td>
<td>Metronidazole, Erythromycin, Cimetidine, Bisacodyl, Piriton</td>
<td>76 (27.9)</td>
<td>59 (28.2)</td>
<td>17 (27.0)</td>
</tr>
<tr>
<td>C</td>
<td>Artemether-lumefantrine, Sulfadoxine-Pyrimethamine, Cotrimoxazole, Ciproflaxin, Albendazole, Indomethacin, Ibuprofen, Aspirin, Promethazine, Anal suppositories, Salbutamol</td>
<td>217 (79.8)</td>
<td>173 (82.8)</td>
<td>44 (69.8)</td>
</tr>
<tr>
<td>D</td>
<td>Doxycycline, Gentamycin, Phenobarbitone</td>
<td>28 (10.3)</td>
<td>21 (10.0)</td>
<td>7 (11.1)</td>
</tr>
<tr>
<td>Not classified</td>
<td>Paracetamol, Magnesium trisilicate, Calamine lotion, Oral Rehydration Salt, Vitamin B complex</td>
<td>129 (47.4)</td>
<td>93 (44.5)</td>
<td>36 (57.1)</td>
</tr>
</tbody>
</table>
6.13.1 Non-recommended medicines prescribed to pregnant women

Table 6.14 shows the list of non-recommended medicines prescribed to pregnant women during the study period. A total of 12 (30.0%) of the pregnant women who were asked about pregnancy by the Medical Assistant were prescribed albendazole, 11 (27.5%) were prescribed metronidazole, 10 (25.0%) had artemether-lumefantrine, 5 (12.5%) were prescribed cotrimoxazole, 3 (7.5%) were prescribed doxycycline, 3 (7.5%) were prescribed ibuprofen, 2 (5.0%) had sulfadoxine-pyrimethamine and 1 (2.5%) was prescribed gentamycin.

<table>
<thead>
<tr>
<th>Prescribed medicine</th>
<th>Total (n=63) Frequency (%)</th>
<th>Pregnancy ascertained in OPD (n=40) Frequency (%)</th>
<th>Pregnancy not ascertained in OPD (n=23) Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole</td>
<td>16 (25.4)</td>
<td>12 (30.0)</td>
<td>4 (17.4)</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>16 (25.4)</td>
<td>11 (27.5)</td>
<td>5 (21.7)</td>
</tr>
<tr>
<td>Artemether-lumefantrine</td>
<td>16 (25.4)</td>
<td>10 (25.0)</td>
<td>6 (26.1)</td>
</tr>
<tr>
<td>Cotrimoxazole</td>
<td>7 (11.1)</td>
<td>5 (12.5)</td>
<td>2 (8.7)</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>7 (11.1)</td>
<td>3 (7.5)</td>
<td>4 (17.4)</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>8 (12.7)</td>
<td>3 (7.5)</td>
<td>5 (21.7)</td>
</tr>
<tr>
<td>Sulfadoxine-pyrimethamine</td>
<td>4 (6.3)</td>
<td>2 (5.0)</td>
<td>2 (8.7)</td>
</tr>
<tr>
<td>Gentamycin</td>
<td>1 (1.6)</td>
<td>1 (2.5)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>
6.14 Estimation of rates of prescription of contraindicated medication and women at risk

As stated in Chapter 1, the overall aim of the study was to assess the risk of exposure to contraindicated medicines in early pregnancy among women attending a general outpatient clinic at a community hospital in Malawi. More specifically, an objective of the survey part of the study was to determine the proportion of women inadvertently prescribed contraindicated medicines in the first trimester of pregnancy in this clinic.

As described in Section 6.1, all women of childbearing age who were prescribed such medication at the clinic during the data collection period from 1 February 2010 to 30 July 2010 were referred to the researcher. The researcher screened the referrals and those considered to be potentially pregnant were asked to participate in the survey and were then interviewed. A small number of those interviewed were subsequently excluded from data analysis when it became clear during data collection that they could not be potentially pregnant. At the very start of the data collection period, a record of the number of women being referred to the researcher but not considered to be potentially pregnant was not kept; this was instituted from 25 February 2010.

Estimates of the prescription rates of contraindicated medicines in the outpatient clinics were first made based on all women referred during the period from 25 February 2010. In a sensitivity analysis for this important estimation, the process was repeated for referrals from 1 February 2010 based on estimated numbers being referred up to 25 February 2010 and compared with the initial estimates. This may have had an impact because while the researcher was familiarising herself with data collection, relatively more women were interviewed after initial screening but subsequently excluded from the survey data as not being potentially pregnant. Consequently, rates adjusted for the numbers of women estimated to have been referred to the researcher before 25 February 2010 should be more accurate.

The following calculations are based on a total of 8970 women of child-bearing age attending the outpatient clinic between 1 February 2010 and 30 July 2010.
6.14.1 Rates estimated from collected data

From records kept by the researcher, 1012 (11.3%; 95% CI 10.6% to 12.0%) women had been prescribed contraindicated medications and were referred to the researcher. This includes all women interviewed before 25 February 2010 and all women referred on and after 25 February 2010.

Out of the 1012 women prescribed contraindicated medications and referred to the researcher, 272 were considered ‘at risk’ of being pregnant after initial screening by the researcher (26.9%, 95% CI 24.2% to 29.7%). Sixty-three women were found to be pregnant, all but one in their first trimester (23.2% of the 272 ‘at risk’ participants; 95% CI 18.3% to 28.6%; 6.2% of the 1012 women of child-bearing age referred to the researcher; 95% CI 4.8% to 7.9%).

In summary, over one in nine women of childbearing age attending the outpatient clinic were given prescriptions for medicines that could harm the foetus at the most vulnerable stage of pregnancy. Over one in four such women were ‘at risk’ of being pregnant, almost one in four ‘at risk’ women were indeed pregnant, and consequently one in sixteen women of childbearing age being prescribed the medication were pregnant in their first trimester.

6.14.2 Rates adjusted for women screened out at start of data collection

The 1012 women recorded as being referred to the researcher included

- prior to 25 February 2010, 34 potentially pregnant women recruited to the survey; 13 women screened as being potentially pregnant but found not to be potentially pregnant during interview and data collection
- on and after 25 February 2010, 238 potentially pregnant women recruited to the survey; 6 women screened as being potentially pregnant but found not to be potentially pregnant during interview and data collection; 721 women referred to the researcher but screened out as not being potentially pregnant
The actual number of women being screened out before 25 February 2010 was not recorded. However, if the proportion of eligible women recruited before 25 February 2010 was the same from 25 February 2010 onwards, then

\[
\frac{34}{34 + 13 + X} = \frac{238}{238+6+721}
\]

where \(X\), the number of women being screened out before 25 February 2010, is estimated to be 91. This means that an estimated total of 1012+91 = 1103 women were referred to the researcher between 1 February 2010 and 30 July 2010. The previous estimation was repeated assuming a total of 1103 referrals to the researcher during the full data collection period.

Out of the 8970 women of child-bearing age attending the outpatients clinic, 1103 (12.3%; 95% CI 11.6% to 13.0%) women were estimated as having been prescribed contraindicated medications and referred to the researcher.

Out of the estimated 1103 women prescribed contraindicated medications and referred to the researcher, 272 were considered ‘at risk’ of being pregnant after initial screening by the researcher (24.7%, 95% CI 22.1% to 27.3%). Sixty-three women were found to be pregnant, all but one in their first trimester (23.2% of the 272 ‘at risk’ participants; 95% CI 18.3% to 28.6%; 5.7% of the estimated 1103 women of child-bearing age referred to the researcher; 95% CI 4.4% to 7.2%).

Compared with the estimates of rates based on known data, the percentage ‘at risk’ of being pregnant among those prescribed contraindicated medication fell from 26.9% to 24.7%. The percentage of pregnant women among those participating in the survey was not affected (23.2%), but the percentage pregnant among those thought to have been referred to the researcher fell from 6.2% to 5.7%.

In summary, over one in eight women of childbearing age attending the outpatient clinic were given prescriptions for medicines that could harm the foetus at the most vulnerable stage of pregnancy. Almost one in four such women were ‘at risk’ of being pregnant, almost one in four ‘at risk’ women were indeed pregnant, and consequently over one in eighteen women of child-bearing age being prescribed the medication were pregnant in their first trimester.
### 6.14.3 Prescription rates for different pregnancy rates

From the previous two subsections, around one in sixteen or one in eighteen women of childbearing age attending the outpatient clinic who were prescribed contraindicated medicine were indeed pregnant in their first trimester and putting their foetus at risk. An equally important question is the rate of being inadvertently prescribed contraindicated medicine among all pregnant women attending the clinic in their first trimester.

Of the 8970 women of childbearing age attending the clinic between 1 February 2010 and 30 July 2010, 63 were identified as being pregnant (all but one in their first trimester) and having been prescribed contraindicated medication. An unknown number in their first trimester would have attended and not been prescribed such medication, and would not have been referred to the researcher. The true first trimester pregnancy rate for women attending the outpatient clinic at the time of data collection was not known, but from hospital records, it was expected to lie between 20% and 30%. This suggests that between 1794 and 2691 women pregnant in their first trimester may have attended between 1 February 2010 and 30 July 2010. Table 6.15 shows the rates of prescription of contraindicated medicine for different values for this pregnancy rate. For example, if the true first trimester pregnancy rate was 22%, then 1973 of the 8970 women attending would have been pregnant in their first trimester, with 63/1973 or 3.2% being prescribed contraindicated medicines (95% CI 2.5% to 4.1%). For pregnancy rates between 20% and 30%, the rate of inadvertent prescription of contraindicated medicine lies between 2.3% and 3.5%.
### Table 6.15: Estimated percentage of women pregnant in first trimester prescribed contraindicated medication by pregnancy rate from 1\textsuperscript{st} February to 30 July 2010

<table>
<thead>
<tr>
<th>Estimated rate of pregnancy in first trimester</th>
<th>Number of pregnant women in first trimester attending clinic (Out of 8970)</th>
<th>Number prescribed contraindicated medication</th>
<th>Percentage prescribed contraindicated medication</th>
<th>95% CI for prescription rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>1794</td>
<td>63</td>
<td>3.5%</td>
<td>2.7% to 4.5%</td>
</tr>
<tr>
<td>21%</td>
<td>1884</td>
<td>63</td>
<td>3.3%</td>
<td>2.6% to 4.3%</td>
</tr>
<tr>
<td>22%</td>
<td>1973</td>
<td>63</td>
<td>3.2%</td>
<td>2.5% to 4.1%</td>
</tr>
<tr>
<td>23%</td>
<td>2063</td>
<td>63</td>
<td>3.1%</td>
<td>2.4% to 3.9%</td>
</tr>
<tr>
<td>24%</td>
<td>2153</td>
<td>63</td>
<td>2.9%</td>
<td>2.3% to 3.7%</td>
</tr>
<tr>
<td>25%</td>
<td>2243</td>
<td>63</td>
<td>2.8%</td>
<td>2.2% to 3.6%</td>
</tr>
<tr>
<td>26%</td>
<td>2332</td>
<td>63</td>
<td>2.7%</td>
<td>2.1% to 3.4%</td>
</tr>
<tr>
<td>27%</td>
<td>2422</td>
<td>63</td>
<td>2.6%</td>
<td>2.0% to 3.3%</td>
</tr>
<tr>
<td>28%</td>
<td>2512</td>
<td>63</td>
<td>2.5%</td>
<td>1.9% to 3.2%</td>
</tr>
<tr>
<td>29%</td>
<td>2601</td>
<td>63</td>
<td>2.4%</td>
<td>1.9% to 3.1%</td>
</tr>
<tr>
<td>30%</td>
<td>2691</td>
<td>63</td>
<td>2.3%</td>
<td>1.8% to 3.0%</td>
</tr>
</tbody>
</table>

**6.15 Summary**

Results have shown that 23.2% of the women in the sample were pregnant. Among those pregnant, some did not think that they were pregnant and yet a pregnancy test revealed positive results. Of the 63 pregnant women in the sample, a third knew or thought they were pregnant (20), a third were not sure (22) and a third did not think they were pregnant (21). For the women in the sample, all of whom had been prescribed contraindicated medication, there was no association between the woman’s self-perceived pregnancy status and whether or not she was asked whether she was pregnant. Despite the medical assistant asking about the possibility of pregnancy and a woman’s belief that she was or might be pregnant, contraindicated medicines were still being prescribed. Between 2.3% and 3.5% of all pregnant women attending the outpatient clinic during the 6 months of the survey
may have been prescribed contraindicated medicines. Assuming a first trimester pregnancy rate in the outpatient clinic of 22.0%, as indicated by past records, the most likely estimate of the percentage being prescribed contraindicated medicines is 3.2%. Given that a considerable number of women also practised self-medication, current practice may incur a significant risk to the foetus. The next chapter presents findings from the qualitative arm of the study.
CHAPTER 7
FINDINGS FROM IN-DEPTH QUALITATIVE INTERVIEWS

7.1 Introduction

This chapter presents findings from in-depth interviews conducted to explore women’s beliefs, views and practices concerning medication use during pregnancy. Demographic characteristics of the women are presented first followed by recurring themes related to beliefs and views that influence medication use during pregnancy. Medicines to which women referred could be either modern or traditional and many women used both.

The research questions which guided the qualitative data collection were:
   a. What type of beliefs, views and practices do women have concerning medication use in pregnancy?
   b. What concerns do women hold about pregnancy disclosure that could affect their medication use (or prescription)?
   c. What are their perceived causes of congenital abnormalities?

7.2 Socio-demographic characteristics

Ten of the 21 pregnant women who were interviewed at the antenatal clinic were in the age group of 25-29 years. Twelve of them had never attained formal education and all the women were married. As for the gestation of pregnancy, 11 were between 13 and 20 weeks of gestation. In terms of gravidity, seven of the women had already two or more pregnancies (Table 7.1).
<table>
<thead>
<tr>
<th>Socio-demographic characteristics</th>
<th>Frequency</th>
<th>Percentage (%) (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 20</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td>20 – 24</td>
<td>4</td>
<td>19.0</td>
</tr>
<tr>
<td>25 – 29</td>
<td>10</td>
<td>47.6</td>
</tr>
<tr>
<td>30 – 34</td>
<td>5</td>
<td>23.8</td>
</tr>
<tr>
<td>35 – 39</td>
<td>1</td>
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<tr>
<td><strong>Marital status</strong></td>
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<td>Married</td>
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<td><strong>Educational level</strong></td>
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<tr>
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<td>Primary school</td>
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<tr>
<td>Secondary school</td>
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<td>4.8</td>
</tr>
<tr>
<td><strong>Gestation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to 12 weeks</td>
<td>7</td>
<td>33.3</td>
</tr>
<tr>
<td>13-20</td>
<td>11</td>
<td>52.4</td>
</tr>
<tr>
<td>21-24</td>
<td>3</td>
<td>14.3</td>
</tr>
<tr>
<td><strong>Gravida</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>28.6</td>
</tr>
<tr>
<td>3</td>
<td>7</td>
<td>33.3</td>
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<tr>
<td>4</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td>5 and above</td>
<td>5</td>
<td>23.8</td>
</tr>
<tr>
<td><strong>Parity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td>1</td>
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<td>33.3</td>
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<td>2</td>
<td>9.5</td>
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<tr>
<td>4</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td>5 and above</td>
<td>3</td>
<td>14.3</td>
</tr>
</tbody>
</table>
7.3 Themes from the interviews

There were several interesting issues which arose from the interviews and these are presented as themes. Although these themes will be discussed separately, they are nevertheless interlinked. The themes are as follows: beliefs about modern and traditional medicines, awareness of appropriate use of medicines, choice of medication during pregnancy and perceived causes of congenital abnormalities. A summary of the themes and sub-themes emerging from the interviews is shown in Table 7.2. Selected quotes are presented to illustrate the discussions which took place during interviews.

Table 7.2: Main themes and subthemes that emerged from the data

<table>
<thead>
<tr>
<th>Main themes</th>
<th>Subthemes</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.3.1 Beliefs about traditional and modern medicine</td>
<td>7.3.1.1 Strengthening the pregnancy</td>
</tr>
<tr>
<td></td>
<td>7.3.1.2 Protection from witchcraft</td>
</tr>
<tr>
<td>7.3.2. Awareness of appropriate use of medicines</td>
<td>7.3.2.1 Lack of awareness of medication safety in early pregnancy</td>
</tr>
<tr>
<td></td>
<td>7.3.2.2 Knowledge of medicines dispensed at the antenatal clinic</td>
</tr>
<tr>
<td></td>
<td>7.3.2.3 Advice on medication use during pregnancy by health workers</td>
</tr>
<tr>
<td>7.3.3 Choice of medication during pregnancy</td>
<td>7.3.3.1 Preference for modern medicines</td>
</tr>
<tr>
<td></td>
<td>7.3.3.2 Preference for combining modern and traditional medicines</td>
</tr>
<tr>
<td>7.3.4 Perceived causes of congenital abnormalities</td>
<td>7.3.4.1 Witchcraft</td>
</tr>
<tr>
<td></td>
<td>7.3.4.2 ‘It is God’s plan’</td>
</tr>
<tr>
<td></td>
<td>7.3.4.3 Punishment</td>
</tr>
</tbody>
</table>
7.3.1 Theme 1: Beliefs about modern and traditional medicines

Women provided varied information about their beliefs and views on medication use during pregnancy. Some of the women spoke of the benefits of medicines for pregnancy. Whereas women talked about the benefits of traditional medicines in detail, for modern medicines women just stated that they helped them but without clear explanation. The traditional medicines which women were referring to were those medicines which they received from Traditional Birth Attendants (TBAs) or elderly women from their communities. The medicines were taken to ensure their wellbeing and that of their unborn children throughout the period of pregnancy. Women explained that the medicines were used for ‘strengthening the pregnancy’ and prophylactically to increase the general wellbeing of the pregnant woman. Two subthemes are inclusive to this theme namely: strengthening the pregnancy and protection from witchcraft.

7.3.1.1 Strengthening the pregnancy

This subtheme relates to the cultural belief that once someone is pregnant, she needs traditional medicine to ‘strengthen the pregnancy’. By strengthening, the women meant preventing the pregnancy from miscarriage. Traditional medicine played a very central role in the care of pregnancy because it was believed to stabilise the pregnancy during the early period. This belief was held by most of the women regardless of their age. For example:

‘I don’t know but others say that the medication prevents loss of the pregnancy’.

( Participant 2, aged 20 years)

‘During the first month when they have missed a period they wear this medicine. They call it strengthener in order to prevent a miscarriage’.

( Participant 4, aged 25 years)

There were varied forms of the medicines which women described. Some medicines were in form of roots, herbs or tree barks which were prepared as herbal concoctions taken orally in liquid form. Others were in the form of powder which was added to
porridge while some were assembled as medicated strings which were tied around the waist, as described by the following women:

‘I hear that they (pregnant women) are given herbs which they mix with porridge… Yes they put it in porridge and they say this strengthens the pregnancy’.

(Participant 6, aged 28 years)

‘They boil the roots in water and give us the liquid only’.

(Participant 3, aged 31 years)

No. It is in form of wood pieces which are fastened to a string then the string is tied around the waist’.

(Participant 4, aged 25 years)

‘Roots. They are the ones that are soaked in water and then boiled on fire…they just give us the water and the roots remain’.

(Participant 17, aged 30 years)

These therapies were repeated every week. Some herbs were taken by the women from the time they learnt of the pregnancy until they gave birth. However, some herbs were soaked and women advised to use them for several days or until bitterness was lost, at which time the remainder was discarded.

‘They tell us to stop taking the medicine when they lose their bitterness’.

(Participant 11, aged 30 years)

Some women also took roots and herbs whenever they thought it appropriate during their pregnancy.

Women explained that they performed rituals in order for the medicines to work to prevent miscarriages. These rituals were symbolic and mandated a place and direction to face when taking the medicine. The following interaction with the interviewer illustrates this point:

Participant: ‘They do stand at the doorway when taking the medicine …you face this way’(indicating)

Interviewer: ‘Outside?’
Participant: ‘Yes’
Interviewer: ‘You don’t face inside’
Participant: ‘No…They add water and one drinks the water and drops the wooden spoon down’.
(Participant 4, aged 25 years)

A similar description of the ritual was described thus:
‘Some people take the medication from a wooden spoon, after which the spoon is dropped down sliding against the chest. Thereafter, the wooden spoon is picked by a child who places it at its proper place…some take the medication while at the doorway and take the wooden spoon into the house’.
(Participant 7, aged 34 years)

However, some women did not know why the remedies had to be taken, nor did they perform rituals. Most women said they received the herbal medicines from TBAs who did not tell them the purpose of the medicine. They just took it because this is the custom as the following quotes illustrate:

Interviewer: ‘What do they say is the use of the medicine?’
Participant: ‘I will not be able to explain well because we just go and we are given the medicine’.
(Participant 3, aged 31 years)

Participant: ‘They say to clean the body’.
Interviewer: ‘Cleaning for what purpose?’
Participant: ‘I don’t know’
(Participant 11, 30 years)

Another one said that the medicine was used to induce hunger as shown in the following quote:
‘I also used to get root medicine in a mixed form…they said they were for inducing hunger’.
(Participant 21, aged 22 years)

The use of the expression of ‘inducing hunger’ could mean that the medicine was used as an anti-nausea remedy since most pregnant women have nausea in pregnancy and consequently they avoid eating food.
Even though women described medicines as having a strengthening effect, some expressed concern in case they caused miscarriage. Reference was made to both modern and traditional medicines. Some women mentioned that all bitter-tasting drugs should be avoided as they may cause miscarriage, albeit this contradicts bitter concoctions taken by women as described above. Modern medicines in capsule form were considered dangerous, with a power to cause miscarriage, as the following comments illustrate:

**Participant:** ‘When we have general body pains they tell me to go to hospital because if we take medicines from shops maybe you can cause a miscarriage’.

**Interviewer:** ‘Is there any medicine from the shops which you have heard about that can cause a miscarriage?’

**Participant:** ‘Maybe capsules’.

(Participant 4, aged 25 years)

‘When one takes capsules and other medicines the pregnancy can be miscarried’.

(Participant 9, aged 32 years)

Much of the concern over taking medicines during pregnancy was due to fears about complications and side effects for the baby. The medicine being referred to in the following excerpt is traditional medicine which is boiled and supposed to be taken while hot:

‘But if I drink hot medicine which is also bitter, will that be alright for the baby? ...the child made movements for some time and it was not good at all. I knew that it was because of the medicine and that is when I decided not to take these medicines any more’.

(Participant 10, aged 36 years)

Moreover, some women indicated that medicines, especially modern, were used for aborting an unwanted pregnancy. For example:

‘...this happened to someone in my village. She became illegally pregnant by her boyfriend and they agreed to go and buy the capsules and she drank the
capsules. She became so weak that she could not sit on a bicycle carrier. Then they used an oxcart to take her to the hospital until she aborted’.

(Participant 4, aged 25 years)

‘Sometimes one may take an overdose of medicine with the aim of aborting the pregnancy’.

(Participant 8, aged 25 years)

‘They say that as soon as one takes the medicine, the pregnancy is aborted if one wants to abort’.

(Participant 20, aged 24 years)

7.3.1.2 Protection from witchcraft

Women believed traditional medications protected them from witchcraft. There was a general belief that pregnant women were vulnerable to actions of witchcraft especially in early pregnancy. Some explained that a pregnancy disappears through witchcraft and is identified as such because there is no preceding illness, and sometimes with no bleeding. Thus most women saw witchcraft as responsible for pregnancy loss, causing a pregnancy to ‘disappear’ rather than causing a miscarriage. The following quotes illustrate the women’s belief about protection from witchcraft:

‘I just see some women carrying the medicine. The women normally say that the medicine protects the pregnancy so that it is not lost through witchcraft’.

(Participant 5, aged 18 years)

This was corroborated by another woman

‘… that is when they may decide to go for traditional medicine because you don’t know how things are in the body, yes because nowadays there is magic.'
"Others tie\(^2\) the ‘thing’ (unborn baby) that is when they take the traditional medicine, thinking that witchcraft is involved'.

( Participant 9, aged 32 years)

The following quotes illustrate how women identified a pregnancy which has been lost through witchcraft:

**Participant:** ‘When witchcraft is involved you don’t even notice how it has been lost.’

**Interviewer:** You don’t even see as if you are menstruating?

**Participant:** ‘Not at all. You just realise that the pregnancy is not there’.

( Participant 17, aged 30 years)

‘Disclosing anyhow will make some people to remove the pregnancy mysteriously’.

( Participant 18, aged 21 years)

However, it should be noted that a few women did not hold the belief that witchcraft could actually cause or account for the disappearance of a pregnancy. The following excerpts illustrate this:

‘They (women) just realise that it is lost but I don’t believe it because the one carrying the pregnancy is supposed to feel that something is happening’.

( Participant 5, aged 18 years)

‘There is not any benefit for those who hide because if they are afraid of witchcraft, time will come when witches will still know that they are pregnant… As I have already said, the most important thing is to believe in God. When one prays to God, Satan will not have any room to do harm’.

( Participant 8, aged 25 years)

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\(^2\) ‘Tie the thing’: the woman meant that magic was used to cause obstructed labour later in pregnancy which to the woman symbolized the baby had been ‘tied’. 
Failure of pregnancy in the form of miscarriage was nevertheless widely perceived to be caused by witchcraft. Consequently the state of pregnancy itself was regarded as a state of vulnerability to the actions of jealous people. Thus, a pregnancy was not revealed but was deliberately concealed. Women described how pregnancy is kept secret from other people thus:

**Interviewer:** ‘Why don’t you want to disclose?’

**Participant:** ‘To prevent jealous people from inflicting harm on me’

( Participant 2, aged 20 years)

‘We don’t do this because we are afraid of losing the pregnancy through witchcraft’.

( Participant 3, aged 31 years)

Despite keeping pregnancy a secret from other people, women indicated that they disclosed their pregnancy to the most immediate family members such as husbands or mothers and mothers-in-law. The women said that the husband was told about the pregnancy because he was the one responsible for it. Mothers or mothers-in-law were also told in order to give some advice concerning care of the pregnancy. This was expressed in the following:

‘It is only I, my husband and my parents who know about it. My parents have to know because they are the ones who can advise me on a number of issues such as how to take care of myself, like how I should dress up or how I should behave’.

( Participant 5, aged 18 years)

‘I don’t disclose. It is only my husband who knows… that is how I do it and it is the husband who reports to my parents’.

( Participant 19, aged 25 years)

Other women stated that there were not any taboos or restrictions on discussing matters related to pregnancy but that they simply found it a sense of self-discipline not to disclose their pregnancy. To these women, a woman who speaks openly
about her pregnancy was seen as undisciplined. Therefore, pregnant women do not disclose to avoid unwanted attention. The following quotes illustrate this:

‘Yes. But those who want to show off disclose their pregnancy… those who are cultured cannot disclose the pregnancy in its early stages’.

(Participant 4, aged 25 years)

‘No there are no such beliefs but it is just about personal discipline so that people should not talk about you that you just announce’.

(Participant 6, aged 28 years)

‘It is just a way of maintaining your dignity’.

(Participant 13, aged 29 years)

In summary, women were conscious of the dangers of losing a pregnancy and took various steps to avoid this. They used traditional medicines predominantly and tried to avoid arousing the jealousy of people with malicious intent by keeping their pregnancy a secret. The next theme presents women’s awareness of appropriate use of medicines.

### 7.3.2 Theme 2: Awareness of appropriate use of medicines

This theme highlights women’s awareness about use of medicines during pregnancy in general. It also explored women’s knowledge of routine medications dispensed at the antenatal clinic as prophylactic measures against malaria and anaemia. It included their awareness of the medicine names as well as the appropriate timing for taking such medicines during pregnancy. There are three subthemes under this theme. These are: lack of awareness of medication safety in early pregnancy, knowledge of medicines dispensed at the antenatal clinic and advice on medication use during pregnancy by health workers.


7.3.2.1 **Lack of awareness of medication safety in early pregnancy**

Women were asked if there were some specific stages of pregnancy when medicines should be avoided. Some women indicated that the timing of taking (i.e. the gestational age) of medicines does not matter. If someone is not feeling well she might take medicines at any stage of pregnancy as the following excerpt illustrates:

> ‘It all depends on how one feels physically. If one feels unwell even at the beginning of the pregnancy, they can take medication so that they feel better’.  
> (Participant 7, aged 34 years)

Similarly women who had used traditional medicines did not consider timing of medication to be a problem as shown in the following quote:

> ‘It depends on when you start going to the traditional birth attendant. One may start taking the medicine during the first visit to the traditional birth attendant but if you don’t go anywhere then you cannot start taking medicine’.  
> (Participant 17, aged 30 years)

However, one stated that after the third month of pregnancy a pregnant woman should avoid medicines. This is shown in the following:

> **Participant**: After the third month because that is when you are sure that you are pregnant and you are not supposed to take medicine.  
> **Interviewer**: But can you take medicine at the beginning?  
> **Participant**: Maybe you can take medicine at the beginning.  
> (Participant 22, aged 25 years)

The women were asked if they were aware of the timing of fansidar, an antimalarial medicine, which is given prophylactically during the second and third trimester of pregnancy. They replied that the doctor knew when to give it and they could not ask for it if not given:

> **Participant**: I just saw her telling me that ‘go, I will not give you fansidar  
> **Interviewer**: Were you expecting to receive?  
> **Participant**: Yes. I was expecting to get it because I have come here at the hospital.  
> (Participant 6, aged 28 years)
This woman did not understand why she was not given the medicine and no explanation was made to her by the midwife. The midwife may have forgotten or it may have been because it was too early (i.e. in the first trimester) to administer fansidar.

Women did not have accurate knowledge on the gestational stages of the developing embryo/foetus as illustrated in the following:

‘At three months the baby is not developed and we do not regard it as a baby… because at that time it is still in form of blood only’.

(Participant 22, aged 25 years)

The above statement shows that women had very little knowledge on child development in the uterus. They believe that the baby is in form of blood until 4-6 months. In addition, women referred to the unborn baby as a ‘thing’ during the discussions as the following expressions illustrate:

‘There is no any problem because one has to seek help from different places because hospitals may sometimes fail to assist when the ‘thing’ is not properly positioned while traditional birth attendants can assist’.

(Participant 7, aged 34 years)

‘Because I am suffering from malaria, my blood will also be infected with malaria the ‘thing’ can be receiving the same malaria infected blood’.

(Participant 9, aged 32 years)

Another woman had no idea about formation of the baby from the time a woman conceives as evidenced in the following:

**Interviewer:** ‘Do you know how the baby looks like from when the pregnancy starts until it grows?’

**Participant:** ‘No, we don’t know what is in the abdomen’.

(Participant 21, aged 22 years)
7.3.2.2 Knowledge of medicines dispensed at the antenatal clinic

All women reported receiving different types of medicine at their current antenatal visit and while some of the women described these drugs by name, others distinguished the different types by colour and size. Medicines that were commonly named were iron tablets, while for those who used colour as a descriptor; red pills would normally be iron tablets. Similarly with antimalarials, some referred to them by name, i.e. fansidar, whereas others used a description, for example three white tablets taken all together. Overall, most women did not know the names of the medicines. A few women knew why the medicines were given to them at the antenatal clinic but the majority reflected limited knowledge of their use.

The following statements illustrate expressions of women who knew the use of the medicine but did not know the names:

‘They just gave me the medicine and told me that it was for malaria. I don’t know if it was fansidar or panadol. They gave me three tablets which I have taken at once’.

(Participant 12, aged 26 years)

**Interviewer:** ‘What medicine have they given you?’

**Participant:** ‘Something like panadol. Yes, I just received and took the blood medicine and the other one which I have already taken – three pills.’

( Participant 15, aged 28 years)

Some women knew the names of the medicines but did not know what these medicines were used for as the following illustrate:

**Interviewer:** *Do you know what fansidar is used for?*

**Participant:** *No. I don’t know. Because it is medicine they tell us to take. They just tell us to take it. Maybe the doctors know the problem that one has.*

( Participant 6, aged 28 years)

**Interviewer:** *So what did they say is the use of fansidar?*
**Participant:** We don't know its use. We just get the medication and take it.

(Participant 7, aged 34 years)

‘I think it is fansidar because they give fansidar... they have not told me its use’.

(Participant 22, aged 25 years)

These findings suggest either that the women do not know or have only a vague idea of the purpose and names of routinely prescribed medicines. This is evident even for some women who had been pregnant several times and had been attending antenatal care.

A minority of the women however demonstrated knowledge of the medicines dispensed at the antenatal clinic. This is shown in the following:

**Interviewer:** ‘But why did you take fansidar?’

**Participant:** ‘They (midwives) told us that it protects the unborn child from malaria’.

(Participant 2, aged 20 years)

**Interviewer:** ‘What is the use of fansidar?’

**Participant:** ‘It is for malaria’.

(Participant 11, aged 30 years)

‘They (midwives) told us that a pregnant woman should be given blood medicine and fansidar at four months to prevent malaria’.

(Participant 13, aged 29 years)

Some women said they took traditional medicines only during the first pregnancy because they were given the medicines by older women. This may suggest that the elderly played a role in deciding which medicines to take, especially the younger women. As the women progressed in their childbearing experience, they became experienced and switched on to modern medicines. The following quotes illustrate this:
‘I once took the medicine during my first pregnancy. That time I had my mother. When my first baby was born she died so the second pregnancy I did not take any traditional medicine until I delivered my baby’.

( Participant 4, aged 25 years)

‘You know that when one is pregnant for the first time there are a lot of people who would want to advise you on what to do’.

( Participant 12, aged 26 years)

‘I took medicine for my first pregnancy. They told me that the medicine would help me to deliver without problems. This was traditional medicine’.

( Participant 8, aged 25 years)

7.3.2.3 Advice on medication use during pregnancy by health workers

The women were asked about the advice they were given, heard or received. It is evident that the health workers reinforced women’s beliefs that one of the main reasons for medication caution was pregnancy loss. The following quotes illustrate this:

‘Health workers advise us not to take any medication on our own to avoid losing the pregnancy- not even penicillin. They also advise us to seek medical attention at the hospital when we are feeling unwell so that we are assisted appropriately’.

( Participant 2, aged 20 years)

‘But when we come to antenatal clinic, they discourage us from taking traditional medicine’.

( Participant 8, aged 25 years)
'They tell us that when one is pregnant they should not take indocid and other dangerous medicines because they may cause the pregnancy to be miscarried'.

(Participant 17, aged 30 years)

Women also stated that they were advised not to take medicines during pregnancy due to effects of the medicines on the foetus. The effects were negative but not specified and reflected a general idea about their ‘bad influence’, for example, that ‘medicines can destroy the baby’. The following quote illustrates a general explanation about the effect of medicines on the unborn child:

**Participant:** ‘They tell us that it is dangerous to take traditional medicine when one is pregnant because this may destroy the child as one may not be sure about the medicine that she is being given.

**Interviewer:** How will the child get destroyed?

**Participant:** ‘I don’t know exactly because they don’t tell us in a straight forward way’.

(Participant 14, aged 23 years)

Several comments suggest that the health workers are respected, viewed as figures of authority, and women effectively do what health workers tell them. The ways in which the women talk about their overall acceptance of whatever medicines were given reinforces this impression and suggested that they had a lot of trust in what the midwives and other health workers were telling them and followed their advice/instructions.

Even though the health professional’s advice was against taking some medicines during pregnancy, this advice was not always accepted, especially in respect of traditional medicines as evidenced in the following quote:

‘I just know that it is good to go to both traditional birth attendants and hospital because this is what we are used to do and it is what our parents tell us to do’.

(Participant 17, aged 30 years)
7.3.3 Theme 3: Choice of medication during pregnancy

Some women reported using both traditional and modern medicine during pregnancy reflecting a dual health belief system. Women used either modern medicine or traditional medicine depending on the reason for use. If the medicine was to be used for witchcraft related issues, women used traditional medicine, and if they thought the problem was not caused by witchcraft, they used modern medicines. Traditional medicines were commonly obtained from traditional birth attendants and the older women tended to have used these more than the younger ones especially during the current pregnancy. The women stated that both health-care systems worked collectively for the benefit of both mother and baby and therefore, should be used together. The following subsections describe the health systems and medication choices.

7.3.3.1 Preference for modern medicines

Some women who indicated that they used only modern medicine had previously used traditional medicines, especially in the first pregnancy. After seeing the effects of the traditional medicines they decided not to use them again in subsequent pregnancies. The following quotes illustrate the expressions of those women who changed from using both types of medicine to using modern medicines only:

‘I don’t have any belief in them. What stopped me from believing is the taking of medicine during the first pregnancy because during the second delivery I delivered without problems yet I did not take any medicine’.
(Participant 8, aged 21 years)

‘Yes. I was not feeling well with the pregnancy and that is when I took the traditional medicine but for the rest, I take scientific medicine’.
( Participant 9, aged 32 years)

Others said they knew little about traditional medicines or did not use traditional medicines because they believed only God could protect and were opposed to traditional medicine and said the following:
‘Where I live is not far from the TBA and if I wanted I would have gone there’.  
(Participant 5, aged 18 years)

‘I just didn’t entertain the idea of using traditional medicine’.  
(Participant 12, aged 26 years)

‘Only that I am not concerned with traditional medicine’.  
(Participant 18, aged 21 years)

While some women indicated that they only took medicines which they have been given at the antenatal clinic, others said they additionally bought medicines. The medicines which women bought mostly included analgesics. This is illustrated in the following quotes:

**Interviewer:** ‘You didn’t take the medicine even during your previous pregnancy?’

**Participant:** ‘I have taken some medicine… when we have a headache we go and buy hedax. If it is malaria we go and buy panadol and we drink.’  
(Participant 4, aged 25 years)

‘And when one doesn’t have money for the injection that is when they buy the tablets at a price of say K50… about five types… one tablet for each type’.  
(Participant 6, aged 28 years)

**Interviewer:** ‘So where do you get the medication from?’

**Participant:** ‘We buy from grocery shops… in there we find quinine, panadol, aspirin and novidar and we buy from there’.  
(Participant 7, aged 34 years)
7.3.3.2 Preference for combining modern and traditional medicines

Most women stated that they used both modern and traditional health systems during pregnancy.

‘There are times when we go to traditional birth attendants and the medicine they give us is just for that time and it is not time yet to come here. When we are done with that then it is time to come here as I have come today we take our medicine from here’.

(Participant 3, aged 31 years)

The competency of health workers and better equipment were amongst the reasons to use the hospital for maternal health care needs because health staff can screen blood, do a clinical examination, especially if there are complications. This is demonstrated in the following:

‘When there is a problem one may go to a traditional birth attendant but when it fails there that is when they go to the hospital’.

(Participant 21, aged 22 years)

Another woman said the following:

‘They tell us that when traditional birth attendants have failed to deal with a situation, we should come to the hospital’.

(Participant 11, aged 30 years)

Some women still acknowledged that they would still go to the traditional birth attendants who were perceived as having special expertise in managing problems that fell outside western medicine.

If a woman believed she was experiencing a problem which modern medicine cannot deal with she would seek a traditional healer, such as a Traditional Birth Attendant because health professionals were perceived as unable to treat such problems. The following quote illustrates:

‘Because these days there is witchcraft and traditional birth attendants may help on this one while hospitals are helpful when one has a complication. That is why we go for both’.

(Participant 17, aged 30 years)
Another woman explained thus:

‘There is no problem because one has to seek help from different places because hospitals may sometimes fail to assist when the ‘thing’ (baby) is not properly positioned, while traditional birth attendants can assist. Sometimes it may also happen that traditional birth attendants may fail to assist on the same problem while hospitals can help. That is why we go to both the hospital and traditional birth attendants’.

( Participant 7, aged 34 years)

Women talked about traditional medicine being of help in normalizing a malpositioned baby. A woman shared her experience thus:

‘For the first pregnancy, I went to the traditional birth attendant and I was told that the baby was badly positioned. She gave me medication and on my follow up visit I was told that the baby was properly positioned’.

( Participant 7, aged 34 years)

And another stated

‘According to people, the goodness is that the ‘thing’ (the unborn baby) may not be properly positioned and the medicine helps to normalise the position’.

( Participant 12, aged 26 years)

The issue of proper position was not further explored by the interviewer and none spontaneously described a ‘normal position’.

In summary, women used either modern medicine or traditional medicine depending on the reason for use.
7.3.4 Theme 4: Perceived causes of congenital abnormalities

Generally many women did not know the cause of congenital abnormalities. However, some attributed them to witchcraft, ‘God’s plan’ and punishment. During the interviews, some women seemed to lack awareness of such children in the community. However, some had mentioned having delivered malformed foetuses which they described as a monster. The interviews reflected that women did not appear to know that some medicines taken during pregnancy could cause birth defects as the following quotes illustrate:

**Interviewer:** ‘Have you ever heard that the herbs may also lead to delivery of a baby with physical abnormality?’

**Participant:** ‘No. I haven’t heard about that. What I have heard is that the child can develop epilepsy or even die because of the herbs which the mother took while pregnant’.

(Participant 6, aged 28 years)

**Interviewer:** ‘Have you ever heard that taking medication may sometimes cause the unborn child to be born with a disability?’

**Participant:** ‘No. I have not heard about that’.

(Participant 7, aged 34 years)

7.3.4.1 Witchcraft

Similarly some women attributed the cause of congenital abnormality to the influence of witchcraft. The following quotes illustrate:

‘Some thought that the child was bewitched’.

(Participant 6, aged 28 years)

‘People were saying that this was due to witchcraft’.

(Participant 7, aged 34 years)

‘It may also be due to witchcraft’.

(Participant 10, aged 36 years)
7.3.4.2 ‘It is God’s plan’

Since women did not associate medication use with birth defects, they did not blame themselves for not taking care of their own health during pregnancy, or for taking non-recommended traditional and modern medicines. Instead they attributed this outcome to be due to outside forces, such as the act of God as shown in the following excerpts:

‘It is natural according to God’s plan’.
(Participant 10, aged 36 years)

‘It is the will of God’.
(Participant 16, aged 24 years)

‘Sometimes it is just natural as planned by God’.
(Participant 19, aged 25 years)

Since women attributed having a malformed baby to God, the community would not accuse the woman of questionable behaviour because they believe that no one can question the decision of God.

7.3.4.3 Punishment

That women sought to distance themselves from blame became clear from statements where they admitted that the behaviour of a pregnant woman might have led to her child being born with a disability. An abnormality was conceived as punishment for misbehaviour. Examples of such behaviours were stealing from someone’s garden which is protected by charms or laughing at a disabled person. This is illustrated in the following quotes:

‘Some people say that the parents stole something, others say the parents did their witchcraft at someone who is more powerful than them; these are the things which I have heard about’.
(Participant 4, aged 25 years)

‘They say that this happens if one laughs at disabled people’.
(Participant 19, aged 25 years)

One woman mentioned that if the pregnant woman’s husband was wearing masquerading attire\(^3\), the woman can have a baby looking like a monster. This is evident in the following:

‘But sometimes people say that if the husband takes part in a traditional dance that involves wearing of masks and masquerading as certain wild characters when the woman is pregnant, then the child may be born like one of the characters for the traditional dance’.

( Participant 19, aged 25 years)

7.4 Summary

This chapter has presented women’s beliefs, views and practices concerning medication use in pregnancy. Findings indicate that women used both modern and traditional medicines in line with their belief systems. With regard to the causes of congenital abnormalities, women did not associate this birth outcome with medication use.

The next chapter will discuss the key findings from the study. Conclusions drawn will also be presented. Strengths and limitations of the study will also be discussed. This will be followed by implications of the findings to practice, policy and future research in Malawi.

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\(^3\) This is a traditional spiritual dance where the dancers wear masks often representations of animals or reptiles. The dance is imbedded in magical activities where only those who have gone through its initiation ceremony are allowed to get close by. This is mainly male activity, and women are not allowed to see.
CHAPTER 8
DISCUSSION

8.1 Introduction

Pregnant women are advised to be cautious about taking medications during pregnancy, but few studies have investigated the use of medications by Malawian women. In this study, survey data were collected at an outpatient clinic in a Community Hospital outside Lilongwe city, to determine how many women had been prescribed medicines which would be contraindicated in pregnancy, either in the first or all trimesters. To be able to understand their beliefs, views and practices concerning medication use in pregnancy, interviews were also held with 21 pregnant women who came for their initial antenatal visit. Data were additionally collected from birth registers to estimate the prevalence of congenital abnormalities, since contraindicated medications may result in birth defects. This chapter provides a discussion of the main findings which emerged from the study, comparing the findings to existing literature. It also presents strengths and limitations of the research. Recommendations for practice, policy and future research are offered and conclusions are highlighted.

Over a period of six months, 272 women who were potentially pregnant were identified as having been prescribed medications that should be used cautiously, or not at all, during pregnancy. Pregnancy tests were carried out on most of these 272 women and 63 (23.2%) were found to be in early pregnancy. Yet only 152 (55.9%) had been asked by the prescribing Medical Assistant in the outpatient clinic whether they might be pregnant. It was estimated that 3.2% of all pregnant women attending the outpatient clinic in a six month period were being prescribed contraindicated medicines. Eight pregnant women (2.9% of the 272) in the sample were additionally exposed to contraindicated medicines within the last two months as a result of self-prescription. It is not known how many of the women who were not formally prescribed such medicines during the six months of the study were self-medicating with the medicines. In interviews, women seemed unaware that medicines given in a health facility could be dangerous if taken incorrectly. Nor did they associate these
medicines with any risk of congenital abnormalities, even though the birth registers indicated that they occurred at least as frequently as in western countries.

Based on data collected using both quantitative and qualitative approaches, several explanations for the high level of exposure can be proposed.

First, since the early pregnancy is not visible, the health worker is not immediately alerted to its presence. Early in the pregnancy it may also not be recognised by the woman herself. These pregnancies would only be detected using tests. More women would be identified as pregnant if the clinician always asked a screening question before prescribing certain medications, but this did not always occur. However this study suggests that a screening question would not be sufficient because 21 women who did not think they were pregnant, and 22 who were not sure, had pregnancy confirmed by a test. Conversely 9 who thought they were pregnant and 51 who were not sure, all had a negative test result. A pregnancy test therefore provides a much greater level of safety when prescription of a contraindicated medication is being considered. One problem would be the cost of these additional tests. A pregnancy test might also be refused by women who suspected a pregnancy but concealed it for cultural reasons.

Second, in the first trimester women are very likely to become ill, especially with malaria, when the majority of primigravidae develop parasitaemia. If symptoms are mild because of partial immunity, self-treatment with painkillers or antimalarials is often tried in the first instance and could lead to inadvertent exposure of the foetus.

Third, women were extremely concerned about pregnancy loss during the early weeks, which they attributed to witchcraft. In this culture, the appropriate response was to take traditional medications, the toxicity of which is not known.

Finally, women implicitly trusted health workers and any medicine prescribed was likely to be accepted as safe. Importantly, women lacked awareness that some medications should be treated with caution. For example they had no knowledge that folic acid should be taken to prevent congenital abnormalities.

The following sections will discuss the evidence for these four explanatory conclusions in relation to other studies in Malawi and elsewhere.
8.1.1 Unknown pregnancy status

An exposure to a contraindicated medication in early pregnancy might be accounted for by the fact that the clinician was not aware of the pregnancy due to his/her failure to ask the women about the possibility or presence of pregnancy. Since detection of a first trimester pregnancy is uncertain, it requires the clinician to take this possibility into consideration when dealing with women of childbearing age, who may not volunteer this information. A study of pregnancy disclosure in the Gambia noted that women expected health workers to realise they were pregnant and not give them medication that would harm them (Brabin et al., 2009). Women may also be unaware of the need to inform the clinician prescribing medication for them that they are pregnant.

In this study, over half (55.9%) of those who were asked about pregnancy by the clinician did in fact disclose their pregnancy status by telling the clinician that they were pregnant. There were some cases despite the clinician enquiring about pregnancy and the women suspecting pregnancy, when contraindicated medicines were still prescribed. This could be due to the lack of availability of alternative medicines at the hospital in particular, or the country as a whole. The Malawi Essential Medicines List (Malawi Ministry of Health, 2009) is very limited. Certain drugs are only available at Central and District Hospitals and a short list of drugs is supplied to Community Hospitals and Health Centres. Underlying constraints to the health system in Malawi are well known, such as insufficient stocks of essential drugs (Carlson et al., 2008). Therefore, no safer alternatives are sometimes available for the pregnant women.

Prescribing contraindicated medicines when pregnancy status is unknown could be reduced by clinicians asking the date of the last menstrual period and eliciting symptoms suggestive of pregnancy, as well as by ruling out current use of contraception. To reduce costs, clinicians could use their discretion to confirm a potential pregnancy before a contraindicated medication is prescribed. In many settings and Malawi alike, pregnancy testing is often used to rule out pregnancy prior to contraception (Stanback et al., 2002). A study in South Africa reported that patients were required to buy the pregnancy tests from local pharmacies before antenatal care could be initiated (Morroni and Moodley, 2006).
Possible reasons for clinicians’ failure to ask about pregnancy could be that they were working under pressure to review the large volume of patients who attended the outpatient clinic. Critical shortages were noted in the number of clinicians available during the study period. On average usually there was one clinician on duty per day. Thus clinicians could be very busy and unwilling to give time to further assess women for pregnancy. Malawi’s health system is experiencing a shortage of human resources (Kushner et al., 2004; Muula and Maseko, 2006; Palmer, 2006; Zijlstra and Broadhead, 2007) and this leads to a heavy workload for health workers which reduces their ability to provide quality care to the patients.

One of the contraindicated medicines which was commonly prescribed was artemether-lumefantrine (AL) and was given to 25.4% of the pregnant women. AL is the first line treatment for malaria in Malawi but is contraindicated in the first trimester. WHO treatment guidelines exclude artemisinin compounds for use in the first trimester of pregnancy unless there is no alternative or the mother’s life is at stake (WHO, 2010). However, quinine, an antimalarial, which is recommended for pregnant women in the first trimester, was not prescribed for those women (4) who thought were pregnant and pregnancy was ascertained by the Medical Assistant. Another antimalarial, SP, was prescribed to 11.1% (Table 6.14) of the pregnant women. SP was being prescribed when there were stock outs of the AL. SP is also not recommended in early pregnancy because it is a folic acid antagonistic and moreover it is no longer the first line treatment of malaria in Malawi because of its decline in efficacy (Malawi Ministry of Health, 2007a).

Albendazole, a commonly prescribed anthelmintic, was given to 16 of the pregnant women. The reason could be that some symptoms of pregnancy were presumed to be indicative of worm infestation rather than pregnancy. Worm symptoms and pregnancy symptoms overlapped and worms were twice as often diagnosed in pregnant compared to non-pregnant women (p = 0.017). This was risky for the women as the medical assistant had not ruled out a possible pregnancy. Had they been more aware, they might have considered that some symptoms were indicative of pregnancy rather than illness. Prescription of albendazole could be withheld for a few weeks and treatment given in the second trimester, providing that the clinician had weighed the benefit and risk of delayed treatment. The high prescription rate does not arise from careful assessment of worm burden but rather to a pattern of
routine treatment for common gastrointestinal problems with this medication. Albendazole has been shown to be teratogenic in rats and rabbits at high dosage. There are no reports of malformations following inadvertent exposure to high multiple doses during the first trimester of pregnancy, but given the lack clear evidence, albendazole should be avoided in the first trimester (WHO, 1996).

There was high use of antibiotics especially cotrimoxazole and metronidazole. Cotrimoxazole and metronidazole were prescribed to 6.3% and 25.4% of the pregnant women respectively (Table 6.14). Cotrimoxazole could potentially cause foetal harm. Cotrimoxazole is a folic acid antagonist that may cause neural tube defects in the babies (Hernandez-Diaz et al., 2000; Wen and Walker, 2004). Some conditions, such as colds, for which these antibiotics were prescribed, could be self-limiting. Metronidazole in this study was classified as potentially harmful in reference to Malawi Syndromic management guidelines which stipulate that metronidazole should not be used in the first trimester (Malawi Ministry of Health, 2007).

Health workers prescribe syndromically for most conditions and this is problematic because many infections present with similar symptoms. Malaria typically presents with non-specific symptoms such as headache, myalgia, fever, anorexia and malaise that are impossible to differentiate from several other febrile illnesses common in the population. This results in overdiagnosis and subsequently overuse of antimalarials (Amexo et al., 2004; Bardaji et al., 2008; Chandramohan et al., 2002; Ndyomugyenyi et al., 2007; Njama-Meya et al., 2007; Reyburn et al., 2004). Malaria accounted for 28.5% of diagnoses made to the women in the study sample. The most recent guidelines for the treatment of malaria from the World Health Organisation (WHO) recommend that, in all settings, clinical suspicion of malaria should be confirmed with a parasitological diagnosis, except in places where parasitological diagnosis is not possible (WHO, 2010). However, in most parts of Africa where malaria is endemic, parasitological diagnosis is not always possible due to lack of equipment and microscopic expertise, hence presumptive treatment continues. In some instances however the clinical symptoms have not always been predictive of positive malaria (Bardaji et al., 2008; Rogier et al., 2005). In areas where malaria is endemic such as Malawi, pregnant women, especially if they are primigravida and secundigravida, are at high risk because of lack of parity-specific immunity (Bouyou-Akotet et al., 2003;
Brabin, 1991; Brabin, 1983; McGregor, 1984; Rogerson et al., 2000; Steketee et al., 1996; Tako et al., 2005).

8.1.2 Self-medication by pregnant women

In developing countries like Malawi limited access to health care and appropriate medicines may cause women to seek for an alternative source of treatment. A total of 113 (78.5%) of the women had self-medicated in the previous two months and 8 (25.0%) of the pregnant women had self-medicated with a contraindicated medicine, possibly before the pregnancy was recognised.

The literature has shown that use of medications may relate to differences in culture and access to healthcare, which may influence the practice of self-medication (Chang and Pravin, 2003; Coffman et al., 2008; Mainous et al., 2009). Self-medication was facilitated by the availability of drug retail outlets in the community where most of the drugs were obtained. Some medicines such as non-steroidal anti-inflammatory drugs (NSAIDs) and antibiotics, which are supposed to be obtained through prescription, are readily available in Malawi and can be purchased in the local markets. It was noted that women tended to purchase medicines which they had previously received from the hospital. This suggests that they did so based on familiarity and/or successful treatment.

The main reasons for practising self-medication in this study were perceiving the illness to be mild, experiencing illness out of routine clinic hours, and the long distance to the nearest hospital, as low severity of symptoms is frequently cited as a reason for self-medication in many settings (Abula and Worku, 2001; Andualem and Gebre-Mariam, 2004; Lam et al., 1994; Omolase et al., 2007; Shankar et al., 2002). In addition, women could think themselves pregnant rather than ill. Pregnant women are known to suffer varieties of minor ailments such as back pain, headache, heartburn, nausea, and vomiting which may be treated with self-medication.

Of the women included in this study, 45.2% lived more than 5km from the hospital as presented in Section 6.3.3. In rural areas of Malawi, access to navigable roads and motor vehicles is limited and in many cases women do not have money to pay for their transport. However, there was no significant difference between those who lived
nearer and further from the hospital regarding their practice of self-medication, in contrast to other studies that have shown that distance from the health centre is a major determinant of health service utilisation (Hjortsberg and Mwikisa, 2002). A recent study in Nigeria among pregnant women found that long distance to the public health facilities was the main reasons given by women in practising self-medication. In the present study, women treated themselves for various symptoms such as headache, abdominal pains and backache. Others even diagnosed themselves as having malaria and therefore self-medicated with antimalarials. Since the practice of self-medication is high in the general population, pregnant women who have not been instructed otherwise, can be expected to do so.

Analgesics were the most commonly used class of medicines for self-medication, which is similar to findings in the literature (Arrais et al., 1997; Drug Utilization Research Group, 1997; Shankar et al., 2002) as were antibiotics (Calva, 1996; Osaka and Nanakorn, 1996). This is in contrast with European countries and North America where outpatient antibiotics are largely restricted to prescription-only use.

Four participants took antimalarials and only one of them was pregnant. This low rate of self-medication with antimalarials could due to government control of availability of artemether-lumefantrine in local shops. Women were familiar with the symptoms of malaria which would encourage self-treatment. Studies from Sudan and countries in Latin American (Awad et al., 2005; Calva, 1996; Drug Utilization Research Group, 1997) showed patients treated themselves due to familiarity with the symptoms. Twelve (10.6%) of the women who self-medicated used indomethacin and three were pregnant. Indomethacin is known to be associated with an increased risk of gastrochisis and therefore is contraindicated throughout pregnancy. Five pregnant women had used ibuprofen as self-medication. Ibuprofen is contraindicated during the first trimester of pregnancy. Ibuprofen is associated with an increased risk for gastroschisis (Tillett et al., 2003; Torfs et al., 1996). Women were not aware of these potential complications.

The high prevalence of self-medication among pregnant women needs to be addressed. A study among pregnant women in Ethiopia by Kebede et al. (2009) showed that 12.4% of the pregnant women who reported illness in the 2 weeks prior to the date of the interview, self-medicated themselves with either over the counter
or prescription medicines. Traditional herbs, paracetamol, and antacids were the commonly used medicines for self-medication by the pregnant women (Kebede et al., 2009). In Nigeria, Bello (2011) reported that 19.2% self-medicated. Medicines used were haematinsics and pain relieving pills. Neither study reported the gestational timing of intake of these medicines. Another study conducted in Nigeria showed that women self-medicated with pyrimethamine, an antifolate drug, in early pregnancy (Akanbi et al., 2005).

Some studies have shown that pregnant women self-medicate with herbal medicines (Fakeye et al., 2009; Gibson et al., 2001) and this was also confirmed in the present study. Apart from self-medication practices from which women were exposed to contraindicated medicines, cultural practices in pregnancy could also expose the women to traditional medicines which could be potentially harmful.

### 8.1.3 Cultural beliefs related to taking medications during pregnancy

Most women interviewed in this study did not rely wholly on western or traditional medicine, but used both. This was irrespective of age, parity and educational level.

This dual use could be rooted in the women’s belief systems. Blumer (1969) contends that human beings live in an environment of objects and that their activities revolve around these objects which may be physical, social or abstract. The nature of an object is affirmed by the meaning it has for the person or community and this meaning is not in the object itself but in the reaction of the people towards it. For instance, the pregnant woman has to behave in a way that is acceptable to the beliefs in the community and this may require her to use traditional medicines. Accessing a mixture of traditional and modern services during pregnancy is a common finding in the literature (Amooti-Kaguna and Nuwaha, 2000; Eugene and Lynn Clark, 2010; Rutakumwa and Krogman, 2007). The decisions of which to use depends on the perceived cause of the illness or problems. In Malawi traditional medicines were used for a variety of purposes such as to counteract witchcraft and to strengthen pregnancy.
8.1.3.1  Medicine to counteract witchcraft

Women took traditional medicines in form of herbs to prevent the pregnancy from being lost through witchcraft. Another Malawian study showed that witchcraft is used to explain occurrence of sudden deaths, severe illnesses, strange events, bad luck, and anything that interrupts the normal course of events, such as a pregnancy loss (Englund, 1996). Similar findings were reported in another study from Mangochi district, Malawi (Launiala and Honkasalo, 2007) which explored rural women’s perceptions of multiple vulnerabilities during pregnancy. Witchcraft was cited as one of the vulnerabilities responsible for pregnancy loss. Certainly, witchcraft is a narrative used to understand social events where no other explanation is available. Similar findings were reported in a study done among pregnant women in South Africa where women followed indigenous healing practices for both themselves and their babies because of the need to ‘strengthen’ the womb against sorcery and to treat symptoms they perceived biomedical services would not be able to treat (Abrahams et al., 2002). Studies in other countries reported that women used herbs to protect the pregnancy from bad omens and evil spirits (Amooti-Kaguna and Nuwaha, 2000; Henda and Peltzer, 2005; Maimbolwa, 2003). In some of these studies pregnancy is described as a state of acute vulnerability to the actions of jealous others (Abrahams et al., 2002; Chapman, 2006; Izugbara, 2000; Jewkes and Wood, 1998).

8.1.3.2  Medicine to strengthen pregnancy

Traditional medicine in this study was used to strengthen pregnancy while in other countries herbs or minerals are used as a tonic to clean the womb (Amooti-Kaguna and Nuwaha, 2000; Henda and Peltzer, 2005; Varga and Veale, 1997), to ease delivery (Henda and Peltzer, 2005), or to induce labour (Henda and Peltzer, 2005). Herbal medicines are widely administered by traditional birth attendants (Johns and Sibeko, 2003). In the present study herbs were soaked and women advised to use for several days or until taste was lost. These medicines were symbolically (ritually) taken through the instruction of the traditional birth attendants (TBAs). This sometimes involved dropping a wooden spoon which they used for taking the
medicines, a ritual intended to reinforce the power of the medicines. This was symbolising that the pregnancy has been ‘strengthened’. In Nigeria, Izugbara (2000) found that women do recognise the hazardous nature of pregnancy and childbirth. They believe that pregnancy and childbirth put women in very risky situations, and that pregnant women are particularly vulnerable to supernatural attacking by evil forces. They believed that they could be successfully protected from these supernatural powers by the great goddess of agriculture, fertility and health. Results showed that pregnant women indulge in traditional medicine to protect themselves. By taking these, women seek an implicit social and cultural endorsement of the risky nature of pregnancy and childbearing (Izugbara, 2000).

8.1.3.3 Trust in traditional birth attendants

Most women in this study had at one point used traditional medicines obtained from traditional birth attendants. The women did not seem to know what type of herbs they were given. Pregnant women never questioned the skills of the TBAs, who are considered to be very knowledgeable about herbs and their uses. The status of TBAs in the society is high in many African communities, and they are highly respected, perform important cultural rituals and provide essential social support to women during childbirth (Chipfakacha, 1997; UNFPA, 1996; WHO, 1992). Pregnant women and their families tend to rely on the opinion of the TBAs (Titaley et al., 2010) and their claimed possession of supernatural powers. For example in this study women were unclear about gestational age, and relied on the TBA, who often misinformed them by making the women believe that an early pregnancy was an advanced pregnancy and that it could ‘disappear’ without bleeding due to witchcraft. Despite a government ban of TBAs, women were still visiting them for pregnancy related issues.

A study done in Southern Malawi, Namitambo area, to investigate perceptions of preterm birth, infections in pregnancy and perinatal mortality among women drew attention to the dangers of taking traditional medicine, for which there was no standard dosage (Tolhurst et al., 2008). In the present study the women who used traditional medicines did not seem to be fearful in using them unlike another
Malawian study which reported pregnancy medicines from traditional healers were feared because of their power (Launiala and Honkasalo, 2007). Such fear could relate to concerns that the medicine might have adverse effects on the infant (Young and Ali, 2005). The contrasting findings with the two studies in Malawi could be because the study by Launiala & Honksalo was based on a focus group discussion, whereas in the present study, confidential in-depth interviews may have enabled women to confide to the researcher what they actually did in practice. Also, the differing geographical and tribal constitution of the different study sites could explain why some were liberal about use of traditional medicines and others not.

### 8.1.4 Women’s knowledge of pregnancy medicines

A study in Mozambique by Chapman (2006) found that women intentionally utilize both modern and traditional health care systems in order to optimise their care. In Malawi women did not consider the antenatal services provided at the clinic adequate to meet their spiritual and interpersonal needs during pregnancy.

Women had total trust in the health workers and rarely questioned their care. Women did not often know what medicines were being given to them at the antenatal clinic but stated that it is the ‘doctors’ who know the use of the medicine. Launiala and Honkasalo (2007) also reported that few women in their Mangochi study were able to differentiate between the common analgesic paracetamol (paracetamol) and sulfadoxine-pyrimethamine (SP). Women identified medicines by shape and colour and described them in terms of their benefits, such as ‘medicines preventing malaria’ and ‘medicines increasing blood’. Such findings seem to imply that women were not aware of the full details of what they are being given. Health workers may have failed to given an adequate explanation about the medicines and women took them without questions.

This trust in health workers was also observed in the Gambia. Women were uncertain about the medicines used for intermittent preventive treatment in pregnancy (IPTp), but they accepted the medicines as safe because health workers administered them (Brabin et al., 2009). In the present study, even though the women could not report what specific medicines were for in a strict biomedical sense, many of them had their own explanations and beliefs about the function of the
medication. For example, some of the medicines were thought to "give them more blood". Women's knowledge, as reported by this study, reveals a widespread acceptance of effects of medicines on pregnancy but only a vague knowledge of why some medicines are given, and for what reasons. The most common knowledge was of medicines increasing blood in the body. The main reasons why women do not have adequate knowledge, especially of malaria medicines, is difficult to understand because for many years there has been mass education on malaria and its prevention and treatment in Malawi, including malaria treatment for pregnant women.

Women had some understanding that certain modern medicines should be avoided during pregnancy. Some women had been told not to take bitter medicines to avoid miscarriage. Women were asked in the survey about medicines which they did not like when pregnant and most of them mentioned bitter tasting pills which cause miscarriage. Similar findings were obtained by Launiala & Honkasalo (2007). Women also mentioned that any medicines in capsule form should be avoided and their view of suitability was largely based on taste and medicinal efficacy. If women judge medicines on their taste or size, they may be vulnerable to taking harmful medicines.

8.1.5 Association of medicines with congenital abnormalities

Most women did not attribute the occurrence of birth defects to the use of medicines when asked by the interviewer if the women knew or had heard about medicines causing such problems. The finding that the baby is not perceived as a human being during the first months is a concern because this may signal that medicines can be taken safely in early pregnancy. In a study conducted in the Gambia, Islamic women also described the developing human into several stages namely: water, clot, piece of meat then human being (Brabin et al., 2009). This conceptualisation is not based on the biological facts outlined in Chapter 2 Section 2.2.1. In a culture which is embedded in traditional beliefs, it can be difficult to think of a congenital abnormality arising as a result of taking medicines. Nor has public information alerted women to these dangers. All women in this study, except one, reported no knowledge about
folic acid which is not routinely administered to women of childbearing age who intend to become pregnant or are pregnant in Malawi.

Some women expressed the view that there are no people/babies with congenital abnormalities in their community. This may reflect the relative rarity of these events or the fact that these children largely do not survive. Otherwise women attributed congenital abnormalities to witchcraft, ‘God’s plan’ and punishment.

Similar findings were found in a study exploring maternal care practices and perceptions of birth defects in Central India where respondents mentioned witchcraft as a possible cause of congenital abnormalities (Minhas, 2007). Two studies in Malawi and Uganda exploring perceptions of causation of club foot also attributed the cause of this abnormality to witchcraft (Bedford et al., 2011; Konde-Lule et al., 2005).

Others believed that a congenital abnormality is ‘God’s will’. This concurs with a study by Oginni et al. (2009) in Nigeria in which participants mentioned God’s will as the major reason for the cause of cleft lip and palate. Other findings from Nigeria, also on cleft lip, stated ‘God’s will’ as one cause (Olasoji et al., 2007). In a UK study among Pakistani and Bangladeshi parents, having a child with a disability was seen as a test or punishment from God or God’s will (Bywaters et al., 2003).

Similarly the present study found a belief that having a baby with a congenital abnormality could be a result of punishment for the wrong which the mother or father did. For instance, it was believed that if a woman was laughing at someone with a disability she would bear a child with a disability too. Studies have reported a common belief in many cultures that a child will be born with a birth defect if a pregnant woman mocks an affected individual which is like a form of punishment (Dryden, 1990; Meyerson, 1990; Snow, 1983; Toliver-Weddington, 1990). Women also reported that some congenital abnormalities are a consequence of stealing by either the father or mother. However, the wrongdoing could be traced to the mother who would be blamed for bearing a child with a congenital abnormality. Thus, most of the blame for an abnormal child seems to fall on the mother.

Some women claimed that if the husband was wearing masquerading dance kit while his wife was the pregnant, she will bear an abnormal baby looking like a
monster. Similar beliefs are reported by Kenen (1980) who states that many of the nonmedical causes of birth defects are attributed to maternal impressions, something the pregnant woman thinks or sees. For example, some believe a child born with microcephaly or anencephaly is the result of his/her mother looking at a monkey during the pregnancy (Kenen, 1980).

Women in Mitundu community do not have the appropriate knowledge of the possible causes of congenital malformations. On the other hand, by attributing congenital abnormalities to external factors like witchcraft or God's plan, people can place the blame for congenital abnormalities outside themselves. The implication is that the firmer the women hold tight to these cultural beliefs, the more likely they will take medicines which could be harmful. It has to be noted that Malawi has no Drugs in Pregnancy Registries and it is difficult to demonstrate that many of these medications actually cause harm. Even if the medicines could be proven to cause harm, the women might not accept this explanation because their belief system would not accommodate it.

The prevalence of congenital abnormalities was sought as there is no previous recorded estimate for the two hospitals. However since congenital assessment is not systematized, the rates reported here are likely to be underestimated, although it is similar to the international figures. A similar distribution is also observed in that males were more affected than females (Alshehri, 2005; Bakare et al., 2009; Golalipour et al., 2005; Lary and Paulozzi, 2001; Muga et al., 2009; Ndibazza et al., 2011; Office for National Statistics UK, 2002; Riley and Halliday, 2008; Tootoonchi, 2003). Sex differences may be due to variations in susceptibilities to teratogenic processes or in prenatal survival after teratogenesis (Tennant et al., 2011) and hormonal effects of the different sexes (Lary and Paulozzi, 2001). There was also a parity effect which showed that high parity women were more likely to have babies with congenital abnormalities. Since parity commonly goes hand in hand with maternal age, this may explain the increased incidence of congenital malformation with increased age and parity.
8.1.6 Women’s mediation of risk

In this study the risk that was identified and assessed was exposure to contraindicated medicines in early pregnancy in women. In order to understand how women and health workers were dealing with the risk of contraindicated medication exposure in pregnancy in Malawi, the sociocultural context in which this happened has to be considered. There is need to understand the women’s perception and understanding of the risk at hand.

According to Connors (1992) risk can be perceived as a hierarchical concept that was used in a study of intravenous (IV) drug users to understand their behaviour and perceived risk of contracting HIV through drug injection using shared needles. The study observed that the nature of IV drug use requires that members of this subculture take an inordinate number of other risks in order to maintain their drug use habit. These other risks included obtaining money to purchase the drugs (often through theft), purchasing the drugs illegally and finally using the drugs through sharing of needles. Interviews with the drug users showed that they did put the risk from sharing needles during drug use low in the hierarchy of the risks (Connors, 1992). Hence the researchers learnt that reducing the risk of HIV transmission in IV drug users must involve changing the way the drug IV users perceive the risk of HIV transmission in the hierarchy of the risks. The concept of risk hierarchy can also be used to understand how the women in Mitundu, Malawi, perceived and mediated the risk of taking contraindicated medicines in pregnancy.

Interviews with the women during the study showed that they were aware of possible risks which a woman might be exposed to during her pregnancy.

In Nigeria, Izugbara (2000) found that women do recognise the hazardous nature of pregnancy and childbirth. An example of the hazards which women recognised was their vulnerability to supernatural attacking by evil forces (Izugbara, 2000). One of the risks which the women in the Mitundu area were very much aware of is the risk of pregnancy loss. In most cases the women believed that the loss of pregnancy was mainly due to witchcraft. The women therefore obtained medications for what they
called ‘strengthening’ the pregnancy. They acquired the traditional medicines from traditional birth attendants. They women trusted the traditional birth attendants that they would always give them safe medicines that would not harm them. Due to their beliefs, their perception of the risk of some medicines being the causative agent of birth defects or pregnancy loss appeared to be minimal. Those women who took traditional medicines did not think that some traditional medicines would be potentially harmful in pregnancy. The women equally trusted health workers as did with the traditional birth attendants and believed that they would never give them medicines which are harmful.

The women in this study were also aware of the fact that pregnant women are more at risk of illnesses than non-pregnant women (for example malaria). Whenever the women experienced symptoms of any disease they either self medicated, obtained traditional medicines or got treatment from the health facilities. Often it was a combination of modern and traditional medicines. The women did not show much knowledge of the fact that some the medications they were taking could be contraindicated in pregnancy.

It was notable that very few women were aware of the fact that some medicines are contraindicated in pregnancy. Most of the women who were aware placed the risk of contraindicated medicines in pregnancy very low in the hierarchy of risks in pregnancy. They looked at medicines (traditional and modern medicines) as mainly being beneficial to their pregnancy.

Reduction of the risk of exposure to contraindicated drugs in pregnant women therefore needs to involve understanding of the women’s perception of the risk. This depends on the information the women have on the physiology of pregnancy. Health workers therefore need to be attentive to women’s hierarchy of perceived risks. Current policy needs to address health promotion messages to the women so that they understand the physiology of pregnancy and how medicines can be used appropriately in pregnancy. However, in this study it was found that a certain proportion of pregnant women were still getting contraindicated medicines, therefore it is important to continuously remind or retrain the health workers on how to reduce the risk even further.
8.2 Summary

In summary, although not all women acknowledged the use of traditional medicines, most were familiar with them, and expressed their positive effects on the pregnancy. Failure of pregnancy in the form of miscarriage was widely perceived to be caused by witchcraft. Consequently the state of pregnancy itself was regarded as a state of vulnerability to the actions of jealous others. Thus pregnancy is not revealed or is deliberately concealed but the most immediate family during the early stages of pregnancy. Women coming for general outpatient consultation were further exposed to harmful medications because of failure themselves to disclose pregnancy, or by inadequate procedures to rule out pregnancy before prescribing some medications. These cumulative risks result in an unacceptably high exposure rate, which this study has partly been able to quantify.
8.3 Strengths and limitations of the study

The use of a mixed methods approach provided a more comprehensive understanding of risk of medication exposure in early pregnancy in women in Mitundu Community, Malawi, because the different methods complemented each other (Creswell et al., 2003; Happ et al., 2006; O'Cathain et al., 2007). Use of the survey allowed exploration of health workers’ clinical practices. Women provided information on their self-medication practices before visiting the hospital. In-depth interviews helped the researcher to get a multiplicity of views on medication use in pregnancy (Parahoo, 1997).

In terms of the survey, the researcher was successful in gaining the support of staff of the hospital and local chiefs for the research. It took some time to set up a smooth referral system and some women were missed at the start. However after a while, the medical assistants in the outpatient clinic routinely referred women to the researcher. By checking pharmacy records, it was possible to ascertain that very few women receiving prescriptions were lost to the study. None of the women sent through to the researcher declined to participate. This could be because generally people obey authority figures, although the researcher sought to ensure that none felt coerced. Women may nevertheless have viewed the researcher as part of the hospital staff and felt reluctant to voice their true opinions.

Data were systematically collected data over 6 months, including dry and rainy seasons. This covered variations in prescription and disease pattern variations during the two seasons although due to petrol shortages and bad weather, the study started late in the rainy season which may have reduced the number of women with malaria. Following the rains attendance also falls because it is the busiest planting season, so the sample size was not maximised. Ascertaining pregnancy by urine testing increased the reliability of the estimate of inappropriate prescribing.

To further increase accuracy in women were shown samples of some commonly available medicines when asked to identify medicines they had taken.

The main drawback of the study design was that prescription practices may have changed as a result of the researcher’s presence. Therefore, these results may not give a practical picture of what clinicians do in normal practice. It can reasonably be
assumed that practice was improved by the presence of the researcher and that the proportion of inappropriate prescriptions has, in fact, been underestimated.

The congenital retrospective review of records faced significant limitations. In the hospital, some files were missing and others had been damaged by water which flooded the storage area. Also in some case notes there was no recording on the section of the baby examination after birth. Hess (2004) notes that retrospective studies rely on accuracy of written records and that important data may quite often not be available due to scanty recording. Rates of congenital abnormalities from a medical record review may be underestimated owing to the varying quality of information in the medical record entries (Roman and Tabsh, 2004). On the other hand the major obstacle facing developing countries is that of the management of health information systems (Tale and Alefaio, 2005). The challenges facing health information systems as identified by Tale and Alefaio (2005) include lack of resources, space, ad hoc approaches to records and poor archive management.

8.4 Recommendations

Based on the results of the study, recommendations have been made to help improve patient care and management. These recommendations have implications for practice, policy and future research.

8.4.1 Practice

There is a need to educate health workers regarding the potential dangers of prescribing contraindicated medications to women of childbearing age. Because the use of medications continues to increase for the management of common conditions prescribers need to evaluate patient's childbearing status. Health workers should take into account that female patients may be pregnant, thus the treatment of choice should include medications that are known to have no potential harm to the foetus. In addition, health workers should routinely enquire about pregnancy before prescribing medicines for any woman of reproductive age, including adolescent girls. In line with
this, health workers such as clinicians and midwives should know which of the medicines available to them are not safe to use in any of the three pregnancy trimesters.

Though self-medication is difficult to eliminate, interventions such as dissemination of information about problems of use of medicines by women of childbearing age through media, health education sessions, and posters can be made. Every woman should know what medications they can use, why some caution is required and what medicines should be avoided. This information may need to be linked to giving women a better understanding of how the foetus develops so that they understand the importance of caution in the first trimester.

Women also need to be educated on signs of pregnancy such as a missed period so that they are able to report this if they seek health services for their illness. This would help in the clinician’s decision on what medication to prescribe for the women.

In Malawi, songs are a popular means of disseminating health information messages and this could be utilised as an effective tool for information sharing in the community. The existing Malawi national health education band can compose songs about medicines in pregnancy.

Another form of dissemination could be in the form of posters, although these would only be suitable for those who are literate. The poster could be placed in waiting rooms/areas within the hospital displaying information about risks associated with medication use. In addition to hospitals, the posters could also be mounted in public places such as shops and markets.

Record keeping and storage need to be improved by sensitizing health workers and ward clerks that this helps in data source for future research.

Midwives, clinicians and obstetricians need to accurately record and describe the type of congenital abnormalities when they examine newborn babies. This would provide a source of data for specific abnormalities encountered in the hospitals.
8.4.2 Policy

The current policy in Malawi is that artemether-lumefantrine prescription should always exclude pregnancy, if possible through a pregnancy test. This should therefore be extended to other medications which are known to be potentially teratogenic such as cotrimoxazole. This can be done as on-the-job training within the current programs by the ministry of health. The Ministry of Health will be informed about the study findings that clinicians do not tend to ask about possibility of pregnancy. Therefore, within already existing trainings, this can be brought up during refresher trainings. This should involve clinicians, nurses and midwives.

Educational programmes and information interventions should be undertaken so that health workers can be provided with ethical training that will enable them to weigh the benefit of the medicine for the mother against the potential risk for the foetus. Therefore, intensive education regarding the dangers of using non-prescribed medicine, especially traditional medicine and over the counter medicines during pregnancy should be instituted by the Ministry of Health in Malawi.

The prescription of folic acid before pregnancy and in pregnancy is not currently routinely done in Malawi. Consequently all but one of the women had never heard about folic acid. More information is needed to find out why this intervention is not being implemented so that policy issues of administering folic acid to women of childbearing age could be considered.

8.4.3 Research

Further research should be planned to include a national cross sectional survey to determine the overall prevalence of inadvertent medication exposure in early pregnancy in Malawi. Also, further studies have to be done on self-medication by women of childbearing age at the community level.

Prescribing medication is part of a consultation process in which the health worker interacts with the woman. This current study was not able to explore what happens within these consultations to note the influence of both the health workers and the
women themselves on the outcome of this process. If funding could be secured for such a study it would help to increase our knowledge as to why certain medications were prescribed, despite being contraindicated.

Views of witchcraft are present in Mitundu community, but the full extent of its role in maternal health issues health still requires more investigation. Beliefs in witchcraft and western biomedical explanations are not mutually exclusive, and this requires further exploration.

Future studies in Malawi should attempt to ascertain prevalence rates of congenital malformations in all central hospitals. This will give an idea of an overall prevalence of the congenital abnormalities in the country as a whole and contribute to WHO work on Drugs in Pregnancy Registries information. Thought needs to be given to how to systematically assess the rate of congenital abnormalities resulting in stillbirth and neonatal deaths in village deliveries. With the ever increasing introduction of new drugs for tropical diseases and their widespread use in mass distribution disease control programmes, this is an ethical imperative.

8.5 Conclusion

This is the first study in Malawi to investigate prescription and use of contraindicated medicines among women of childbearing age. It contributes to the literature on medication use in Malawi. It also provides cultural meanings associated with taking medicines in pregnancy and perceptions of causes of congenital abnormalities. The study has provided baseline data on the prevalence of congenital malformations in one community and one major referral hospital.

Women of child bearing age were frequently prescribed contraindicated medicines in the absence of pregnancy ascertainment. The finding that 23.2% of the women were pregnant indicates the need for better practices by health workers of ensuring the safe use of medications that are considered to carry risks to the unborn baby. Medications that may adversely affect the developing foetus were prescribed for many pregnant women. However, given that most nearly half of all pregnancies are unnoticed in the early weeks, there are challenging practical difficulties in avoiding first-trimester exposures.
The data indicate that clinicians do not give sufficient attention to this issue. While under certain clinical circumstances, it is necessary to treat women of reproductive age with medications that can cause birth defects, this can often be avoided. Health care providers can help reduce the risk posed by such medications by being sensitive to the possibility of pregnancy when a contraindicated medicine is being prescribed. Clinicians must pay particular attention to medication safety during the first trimester of pregnancy, because it is during this time that organogenesis occurs and the developing embryo is at risk for teratogenesis (Powrie and Kurl, 1999). However, there are certain situations where the doctors are left with no option but to prescribe teratogenic medications when a suitable replacement is not available and/or when the benefits of the medication to the mother outweigh the possible risk to the foetus (Rohra et al., 2008). This is sometimes the case in Malawi where there is a narrow range of medicines to choose from and a high disease burden, but should be exceptional.

One of the most interesting aspects of this study was the revelation of many superstitious beliefs that govern behaviour during pregnancy. It was clear in this study that beliefs, views and practices of women concerning medication use in pregnancy illustrate reliance on superstitious or cultural beliefs to explain the causes of complications during pregnancy. Girls need to be much better educated and encouraged to ask questions so that they are less accepting of such beliefs. Most of the women interviewed expressed their lack of knowledge on medication use. It is evident that many women in this study had limited exposure to information, resulting in ignorance of medication use during pregnancy. For example timing of medicines was strongly accepted at the beginning of pregnancy. The effect of these medicines is right at the start of pregnancy when women are unlikely to know, or are unsure, about pregnancy. However, if they had some biological knowledge, they should be alert to their exposure to pregnancy. If women know that some medicines can cause problems, they would be cautious in using them. This does not happen because women have not been alerted to the dangers of medicines. They do not know what medicines they are given. They have mistaken notions about what the medicines achieve such as easy delivery and have little idea about gestational ages.
Traditional medicines were used to preserve and protect the foetus from harm. This study found that unborn babies are protected by taking herbal concoctions. The participants showed trust in the methods used by traditional birth attendants (TBAs). Therefore, the continual and extensive use of traditional medicines and combined traditional and modern medicines by pregnant women is a major problem that must be addressed through public education. This could be included as an activity in the Ministry of Health’s health promotion programme.

The figures and prevalence rates obtained for congenital abnormalities provide preliminary results and approximate estimates only, since the study was a retrospective one using hospital records, and consequently subject to biases and omissions. Knowledge of prevalence and distribution of congenital abnormalities would help as the first step in the study of the epidemiology and planning of preventive and eradication strategies.
8.6 Personal reflection

There were a number of challenges that I faced throughout the conduct of this study. I found it quite challenging to conduct in-depth interviews with women whose culture did not encourage them to express their own views and opinions. As a developing researcher I attempted to apply my qualitative interviewing skills to encourage the women talk and open up to discuss their beliefs and practices on medicines in pregnancy. My supervisors were supportive in helping me to develop my interviewing skills.

It was also challenging for a novice researcher to be able to negotiate and fit within the day-to-day running of the outpatient clinic from which participants were recruited. I learned to be flexible in order to adapt to the hospital procedures. As a lone researcher, I was given all the necessary support while away from the UK. My position during the research study would be described as both that of an insider and an outsider. I considered myself as an insider because I had prior knowledge working with outpatient patients and clinicians. I was an outsider because I did not belong to the Mitundu Community and would not know some of the common prevailing beliefs and practices about medication use during pregnancy. In addition, I was aware that my role as a researcher would be influenced by my experience with the topic of study, which would influence data collection and analysis. However, the opportunity to be able to undertake this doctoral study has equipped me with knowledge and skills which I will use as an independent researcher.
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### Appendix 1: Summary of reviewed key studies on medication use in pregnancy

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<tr>
<th>Author, country and source</th>
<th>Title</th>
<th>Objectives</th>
<th>Participants/sample</th>
<th>Method/Design</th>
<th>Key findings</th>
<th>Strengths</th>
<th>Limitations</th>
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<tbody>
<tr>
<td>Holst et al. (2009) UK</td>
<td>The use and the user of herbal remedies during pregnancy</td>
<td>To describe the use and the user of herbal remedies during pregnancy and to study the sources of information about herbs used</td>
<td>578 women; &gt; 20 weeks gestation presenting at an antenatal clinic</td>
<td>Survey Self-administered questionnaire</td>
<td>57.8% used herbal medicines, family and friends main source of information</td>
<td>Used self-administered questionnaires which is a relatively quick method of collecting information from a large group in a standardised way</td>
<td>Response rate of 55.7%; Study carried out in one hospital in one region in the United Kingdom; respondents may not be representative of pregnant women in the UK hence cannot be generalised</td>
</tr>
<tr>
<td>Engelrand (2008) Norway</td>
<td>Prescription drug use among fathers and mothers before and during pregnancy. A population-based cohort study of 106 000 pregnancies in Norway 2004–2006</td>
<td>To describe the use of prescribed drugs in both mothers and fathers before and during pregnancy in Norway</td>
<td>100,000 women</td>
<td>Prescription data base</td>
<td>During pregnancy, 57% were prescribed drugs. In the first trimester, 33% of mothers were dispensed drugs, while the figure was 29% for mothers in the last trimester. Among fathers, 25% used prescribed drugs during the 3 months prior to conception</td>
<td>This study is based on data from population-based registries covering the entire population of Norway</td>
<td>Drug use may have been overestimated because study did not know whether participants actually used the drugs or when they used them</td>
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### Appendix 1: Summary of reviewed key studies on medication use in pregnancy (continued)

<table>
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<tbody>
<tr>
<td>Stokes et al. (2008) The Gambia</td>
<td>The right to remain silent: a qualitative study of the medical and social ramifications of pregnancy disclosure for Gambian women</td>
<td>To explore factors which might inadvertently expose women to drugs which are contraindicated in pregnancy</td>
<td>Younger women; older women, adolescent girls, TBAs, men</td>
<td>4 focus group discussions with younger women of an average age of 25; 4 with older women, three with adolescent girls, 1 with TBAs, and 4 with men</td>
<td>Women acutely ill in early pregnancy hoped health workers would recognise pregnancy without explicit disclosure; Women said that they knew, and sought to avoid, some contraindicated drugs, but their knowledge was basic</td>
<td>Presented a more realistic view of pregnancy cultural issues including intake of medicines by pregnant women through focus group discussions</td>
<td>Did not assess health workers' awareness of the cautions and contraindications associated with the use of specific drugs by pregnant women</td>
</tr>
<tr>
<td>Launiala and Honkasalo (2007) Malawi</td>
<td>Ethnographic study of factors influencing compliance to intermittent preventive treatment of malaria during pregnancy among Yao women in rural Malawi</td>
<td>To examine women's knowledge and perceptions about the use of medication in pregnancy and the timing and motivation concerning use of antenatal clinic services</td>
<td>Women of the reproductive age in the community; nurses in the clinic</td>
<td>Ethnography including focus group discussions, in-depth interviews, drug identification exercises, participant observation and a 'knowledge, attitudes and practices' survey</td>
<td>Unclear messages about Intermittent preventive treatment with sulfadoxine-pyrimethamine (IPT-SP) from nurses; women's limited understanding of IPT-SP</td>
<td>Ethnographic approach allowed for discovery of insights into complex contexts influencing women's knowledge and practices about medication use in pregnancy</td>
<td>Investigating compliance from the pregnant women's perspective only without including health workers perspectives about medication use</td>
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## Appendix 1: Summary of reviewed key studies on medication use in pregnancy (continued)

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<tr>
<td>Mbonye et al. (2006) Uganda</td>
<td>Perceptions on use of sulfadoxine–pyrimethamine (SP) in pregnancy and the policy implications for malaria control in Uganda</td>
<td>To assess perceptions of SP in pregnancy</td>
<td>Pregnant women, non-pregnant women, adolescent girls and men</td>
<td>Separate Focus Group Discussions: pregnant women; non-pregnant women aged; adolescent girls; men</td>
<td>SP perceived to be an effective drug that cures malaria quickly but is also believed to be strong and weakens pregnant women; causes abortions and foetal abnormalities</td>
<td>Qualitative with use of focus group discussions</td>
<td>Study was not able to show how perceptions on SP vary with seasons of the year</td>
</tr>
<tr>
<td>Andrade et al. (2006) USA</td>
<td>Use of prescription medications with a potential for foetal harm among pregnant women</td>
<td>To estimate the prevalence of use of prescription drugs with a potential for foetal harm</td>
<td>114,165 women who delivered an infant between 1996 and 2000</td>
<td>Retrospective study using automated databases</td>
<td>1305 (1.1%) received a teratogenic drug during the 270 days before delivery</td>
<td>Use of several health plans located in different geographic regions of the United States hence study could be generalised</td>
<td>Use of medical review does not indicate if the medications were taken; reason for taking cannot be verified; study did not ascertain if the prescriber counselled the patients about potential risks</td>
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### Appendix 1: Summary of reviewed key studies on medication use in pregnancy (continued)

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<tbody>
<tr>
<td>Förster et al. (2006) Australia</td>
<td>Herbal medicine use during pregnancy in a group of Australian women</td>
<td>To measure the prevalence of herbal medicine use in a group of pregnant women attending a public tertiary maternity hospital in Melbourne, Australia</td>
<td>588 pregnant women at 36-38 weeks gestation</td>
<td>Consecutive sampling using a self-administered questionnaire</td>
<td>36% took at least one herbal supplement during current pregnancy; The most common supplements taken were raspberry leaf, ginger, and chamomile</td>
<td>Data collection method relatively quick and collected in a standarised way</td>
<td>Results could be affected by recall bias; Study did not ask if women reported their herbal supplement use to their care provider</td>
</tr>
<tr>
<td>Hardy (2006) UK</td>
<td>Safety of medications prescribed before and during early pregnancy in a cohort of 81,975 mothers from the UK General Practice Research Database (GPRD)</td>
<td>To demonstrate a linkage methodology for mother and baby automated medical records, and describe frequency, type, and pregnancy risk level of medications prescribed during pregnancy in a GPRD cohort</td>
<td>81,975 women</td>
<td>General practice research data base</td>
<td>65% of mothers had more than 1 prescription in early pregnancy; Category X medications were prescribed to 0.6% of mothers in early pregnancy</td>
<td>Linkage of maternal and baby automated medical records enables definition of cohorts with which to evaluate a wide range of outcomes following medication prescription in pregnancy</td>
<td>Use of data base does not indicate if the medications were taken</td>
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<tr>
<td>Riley (2005) USA</td>
<td>Correlates of Prescription Drug Use during Pregnancy</td>
<td>To evaluate the extent of prescription drug use and the use of category D or X drugs during pregnancy and examine the maternal characteristics associated with use</td>
<td>Cohort of pregnant women from 2001 to 2003</td>
<td>Medical record and survey data</td>
<td>1.1% of women received a category X medication anytime during pregnancy</td>
<td>1626 (99%) of the women had medical records available for review</td>
<td>Could not examine the association between exposure to any drug and clinical outcomes because of limited statistical power</td>
</tr>
<tr>
<td>Refuerzo et al. (2005) USA</td>
<td>Use of Over-the-Counter Medications and Herbal Remedies in Pregnancy</td>
<td>To determine the frequency of prescription and over-the-counter (OTC) medications, and herbal remedies used by pregnant women</td>
<td>418 postpartum women prior to hospital discharge</td>
<td>Prospective observational study Self-administered questionnaire</td>
<td>76.5% took one medication after excluding vitamins; 62.8% used OTC medications; herbs 4.1%</td>
<td>Recall in women of medicines used was aided by listing by both brand and common name of more than 120 medicines and herbs</td>
<td>Response rate not reported</td>
</tr>
<tr>
<td>Westfall (2004), Canada</td>
<td>Herbal Healing in Pregnancy: Women’s Experiences</td>
<td>To explore pregnant women’s perspectives on herbal medicine</td>
<td>27 pregnant women</td>
<td>Qualitative study, two semi-structured interviews</td>
<td>Many women considered herbs them to be safer than pharmaceutical drugs</td>
<td>Rich data obtained due to rapport between researcher and participants</td>
<td>Results cannot be generalised due to qualitative nature of the study</td>
</tr>
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<tbody>
<tr>
<td>Headley (2004) UK</td>
<td>Medication use during pregnancy: data from the Avon Longitudinal Study of Parents and Children</td>
<td>To present data on the self-reported use of all types of medicinal products collected during pregnancy in a large cohort in southwest England</td>
<td>14,119 Pregnant women with a delivery date during 1991-1992</td>
<td>Questionnaire</td>
<td>92.4% used at least one product at some stage in pregnancy</td>
<td>Reports use of medicinal product at different stages of pregnancy</td>
<td>Women could not have remembered use of some products</td>
</tr>
<tr>
<td>Nordeng and Havnen (2004) Norway</td>
<td>Use of herbal drugs in pregnancy: a survey among 400 Norwegian women</td>
<td>To investigate the use of herbal drugs by pregnant women</td>
<td>400 postpartum women (within 3 days of birth) at Ulleval University Hospital, Oslo</td>
<td>Structured questionnaire</td>
<td>36% had used herbs</td>
<td>Using both open-ended questions and listing common herbs were done to identify more accurately any use of herbal drugs in pregnancy</td>
<td>Included women with healthy children only, and this may underestimate the use of herbal drugs in pregnancy because of recall bias</td>
</tr>
</tbody>
</table>
### Appendix 1: Summary of reviewed key studies on medication use in pregnancy (continued)

<table>
<thead>
<tr>
<th>Author, country and source</th>
<th>Title</th>
<th>Objectives</th>
<th>Participants/sample</th>
<th>Method/Design</th>
<th>Key findings</th>
<th>Strengths</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andrade et al. (2004) USA</td>
<td>Prescription drug use in pregnancy</td>
<td>To provide information on the prevalence of the use of prescription drugs among pregnant women in the United States</td>
<td>152,231 women who gave birth to an infant</td>
<td>Retrospective automated databases of 8 health maintenance organisations</td>
<td>Almost one half of all pregnant women received prescription drugs from categories C, D, or X of the FDA</td>
<td>Using several sites from different geographic regions allowed for generalisation results</td>
<td>Study was not able to ascertain whether drugs that were dispensed before delivery were prescribed for use and were taken during pregnancy</td>
</tr>
<tr>
<td>Schirm et al. (2004) The Netherlands</td>
<td>Drug use by pregnant women and comparable non-pregnant women in The Netherlands with reference to the Australian classification system</td>
<td>To describe drug use in pregnancy, and compare drug use of pregnant women with non-pregnant women with respect to possible teratogenicity</td>
<td>7,500 women</td>
<td>Cross-sectional study based on Pharmacy records Data base</td>
<td>85.6% had used at least one drug during pregnancy</td>
<td>Excluding folic acid, iron and vitamins are excluded, 69.2% used at least one drug during pregnancy</td>
<td>No information could be collected about actual drug use</td>
</tr>
</tbody>
</table>
## Appendix 1: Summary of reviewed key studies on medication use in pregnancy (continued)

<table>
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<tr>
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<th>Key findings</th>
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<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egen-Lappe and Hasford (2004) Germany</td>
<td>Drug prescription in pregnancy: analysis of a large statutory sickness fund population</td>
<td>To examine the prescription of drugs in Germany prior to, during and after pregnancy</td>
<td>41,293 women from a statutory sickness fund</td>
<td>Data base</td>
<td>96.4% received at least one drug during pregnancy; Excluding vitamins, minerals, iodide and iron, 85.2% received at least one drug</td>
<td>Study included pregnant women from the whole of Germany Using prescription data has the advantage of providing a large population-based sample for analysis</td>
<td>Data on intake such as date, amount, or duration were not available. Since it is known that not all drugs prescribed are actually administered, drug use may have been over-estimated</td>
</tr>
<tr>
<td>Malm et al. (2003) Finland</td>
<td>Prescription drugs during pregnancy and lactation--a Finnish register-based study</td>
<td>To examine the use of prescription drugs in Finnish women before and during pregnancy and lactation</td>
<td>43,470 pregnant women</td>
<td>Register based pharmacy records</td>
<td>46.2% purchased at least one drug and 12.7% three or more different drugs during pregnancy</td>
<td>Study used four nation-wide registers, which enabled high coverage of drug prescription data</td>
<td>Register-based studies may be biased regarding actual drug intake</td>
</tr>
</tbody>
</table>
## Appendix 1: Summary of reviewed key studies on medication use in pregnancy (continued)

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<th>Strengths</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pinn and Pallet (2002)</td>
<td>Herbal medicine in pregnancy</td>
<td>To assess the frequency of alternative medical usage in an antenatal population</td>
<td>305 pregnant women attending antenatal clinic (16-24 weeks gestation)</td>
<td>Self-administered questionnaire</td>
<td>39% used CAM, 12% used herbs; Most commonly consumed herb was raspberry leaf</td>
<td>Asked women early on in pregnancy and would easily recall herbal use</td>
<td>Response rate not reported, indication for use of medicine not included in the study design</td>
</tr>
<tr>
<td>Maats and Crowther (2002)</td>
<td>Patterns of vitamin, mineral and herbal supplement use prior to and during pregnancy</td>
<td>To assess vitamin, mineral and herbal use pre-conceptually and in the three trimesters of pregnancy</td>
<td>211 pregnant women (&gt;26 weeks gestation)</td>
<td>Interview with structured questionnaire</td>
<td>62% of the women used both a vitamin or mineral supplement and a herbal preparation during the course of pregnancy</td>
<td>Response rate 89%, study presented a breakdown of medication use across all pregnancy trimesters</td>
<td>Exclusion of non-English speaking women to participate in the study</td>
</tr>
<tr>
<td>Gibson et al. (2001)</td>
<td>Herbal and alternative medicine use during pregnancy: a cross-sectional survey</td>
<td>To determine the frequency of use of herbal and alternative medicine by women during pregnancy</td>
<td>250 pregnant women attending antenatal clinics</td>
<td>Self-administered questionnaire</td>
<td>9.1% used herbs during pregnancy; Association between prior use of herbs and the use of herbal medicine in pregnancy</td>
<td>97% response rate</td>
<td>Participants could not get clarification on the questionnaire; there could be recall bias on use of medicine</td>
</tr>
</tbody>
</table>
## Appendix 1: Summary of reviewed key studies on medication use in pregnancy (continued)

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<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donati et al (2000)</td>
<td>Drug use in pregnancy among Italian women</td>
<td>To describe the use of drugs among Italian women during pregnancy and to compare it with other reports in Italy from the last 10 years</td>
<td>9004 women who gave birth in 1995-1996</td>
<td>Questionnaire</td>
<td>75% of the participants took at least one drug during pregnancy. Users took a median number of two drugs</td>
<td>The sample was representative of the entire region because all health districts within the region participated.</td>
<td>The sample was not representative of the entire country because only the health districts that volunteered were included. Asking mothers after delivery may have led to some underestimation of drug use due to recall bias.</td>
</tr>
<tr>
<td>Lacroix et al (2000)</td>
<td>Prescription of drugs during pregnancy in France</td>
<td>To collect information about drug prescriptions in pregnant women</td>
<td>1000 women</td>
<td>Retrospective survey of records French Health Insurance Service</td>
<td>99% of the women received a prescription for at least one drug during pregnancy. 1.6% of pregnant women received at least one category X drug during pregnancy</td>
<td>Use of retrospective survey ensured researchers to obtain reliable information on all drug prescriptions during the whole of pregnancy;</td>
<td>Study could not determine if medicines received were medicines taken</td>
</tr>
</tbody>
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Appendix 2: Congenital abnormalities data extraction proforma
Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi

<table>
<thead>
<tr>
<th>ID code</th>
<th>Congenital abnormality</th>
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<th>Year registered</th>
<th>Type of Register</th>
<th>Age of mother</th>
<th>Residence</th>
<th>Parity</th>
<th>Gestation</th>
<th>Sex</th>
<th>BW</th>
<th>Outcome</th>
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Appendix 3a : Participant Information Sheet (Outpatient)

RESEARCH TITLE: Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. I will read the information to you regarding the study. I will tell you about the purpose of the study and what will happen if you decide to take part.

What is the purpose of the study?
The purpose of the study is to help us understand which medicines women know to be safe to use when they are pregnant. We aim to interview 264 young women of childbearing age about medicines they have recently taken. This information will be used to improve the information provided by health workers to women who are, or could be, pregnant.

Why have you been chosen?
You have been chosen because you are a young woman within the childbearing age and have been prescribed medicines while attending outpatient clinic here at Mitundu Hospital. Sometimes women and health workers are unaware of a pregnancy. Some medicines are better to avoid when pregnant and we wish to check that you are taking the most suitable medicines.

Do you have to take part?
No. It is up to you to make a choice as to whether to take part in the study or not. If you choose to take part, you will be asked to give your consent by signing or thumb printing a consent form.

What will happen to you if you take part?
If you chose to participate in this study, you will be asked to answer a number of questions on medicines which you have previously taken or are taking. This will take place in a room within the hospital premises. We will also ask you about past pregnancies, and whether you are suspicious that you might be pregnant now. Your pregnancy status will be checked because sometimes it is difficult to know for sure whether you are pregnant or not. We will ask you to provide a urine sample in a container and the researcher will test to see if you are pregnant. The test is generally accurate, but please note that it might not detect a very early pregnancy so you should not ignore any other pregnancy signs. Very occasionally it may indicate you are pregnant when you are not. Based on the results of the pregnancy test, we will review the medicines given today to make sure they are suitable for anyone who is pregnant and change them if they are not. After the pregnancy test you will then be asked some further questions about yourself by the researcher. You do not have to answer any questions that you do not feel comfortable talking about and you may stop the interview at any time. The interview will last approximately forty five minutes.

If you feel upset or unwell during the interview, we will stop. If you would like to talk to someone to get advice, we will arrange for you to see one of the hospital counsellors. They are available to discuss your concerns and any other decisions you would want to make arising from the interview or a discovery of a pregnancy which you did not expect.
What are the possible benefits of taking part?
There might be some benefits of taking part in this study. If we find out that you are pregnant and that you have been given/or are taking medicines which are not supposed to be taken in pregnancy, your treatment will be changed. Even if this is not the case, your taking part should have future benefits. The results will be used to inform government programmes with a view to improving health services and ensuring that women are treated properly when they are pregnant.

What are the possible risks for you taking part?
There are no known risks associated with this study. However, if you feel uncomfortable at any time when completing the questionnaire, the interview will be stopped.

What if there is a problem?
If any time you have questions or problems related to this study, you may contact me, Mrs. Ezereth Kabuluzi (see contact number at the end). I will try to resolve the problem in the first instance. If you remain unhappy and wish to complain formally, or if the problem relates directly to me you can do this through the Principal of Kamuzu College of Nursing (see contact number at the end).

Will my taking part in the study be kept confidential?
Yes. Only the researcher (Mrs Ezereth Kabuluzi) and her supervisors will have access to the information that you have given us and all the study documents containing your information will be kept under key and lock. All your personal information will be kept confidential. Consent forms will be stored in a locked cabinet and will only be accessible to the researcher. A study number will be used on the questionnaire instead of your name and this number will only be known to the researcher. Nobody from outside will be able to link the number to your identity. Data will be put onto a computer but only the researcher will know the password to start the computer. None of the data on the computer will have your name on it.

What will happen if you do not want to carry on with the study?
You are free to withdraw at any time during the study without giving reasons. A decision to withdraw at any time, or a decision not to take part, will not affect any future treatment or care you may require.

What will happen to the results of the research study?
This study is being undertaken as a higher degree (PhD) being undertaken by myself at the University of Manchester, UK. The results will be presented in a thesis. In addition, the results may be published and presented at conferences.

Who is organizing and funding the research?
The Commonwealth Commission has paid for me to study in England. I am being supervised by Dr Linda McGowan and Dr Loretta Brabin (University of Manchester, UK).

Who has reviewed the study?
This study has been reviewed by University of Manchester Research and Ethics committee, Kamuzu College of Nursing Research and Publications committee and
College of Medicine Research and Ethics committee (Dates and reference numbers here) and has been given ethical approval to conduct the research.

Please keep this information sheet and should you wish to take part, you will also be given a copy of the consent form.

Thank you very much for taking time to read/listen to the information.

Contact details:

Lead Researcher  
Ezereth Kabuluzi  
Kamuzu College of Nursing  
Private Bag 1  
Lilongwe.  
Phone 0888 326409 Email: ezekabuluzi@kcn.unima.mw

The Principal  
Kamuzu College of Nursing  
Private Bag 1  
Lilongwe

Supervisors:

Dr. Linda McGowan  
Lecturer in Women’s Health  
School of Nursing, Midwifery and Social Work, Faculty of Medical and Human Sciences  
University of Manchester Room 6.038  
University Place, Oxford Road, Manchester, United Kingdom  
Tel: 00 44 161 306 7841 ; Email: linda.mcgowan@manchester.ac.uk

Dr. Loretta Brabin  
Reader in Women’s Health  
Academic Unit of Obstetrics & Gynaecology University of Manchester Reception, 5th Floor (Research) St. Mary's Hospital, Oxford Road, Manchester M13 9WL  
Tel: 00 44 161 276 6388; Fax: 00 44 161 276 6134  
Email: Loretta.Brabin@manchester.ac.uk
Appendix 3b: Participant Information sheet (Outpatient - Chichewa version)
Chikalata Chodziwitsa Kafukufuku

RESEARCH TITLE: Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi


Cholinga cha kafukufukuyu ndi chiyani?

Nchifukwa chiyani mwasankhidwa?
Mwasankhindwa kutenga nawo mbali pa pakafukufukuyu chifukwa ndi mu mmodzi mwa amayi a msinkhu obereka omwe akulembelani mankhwala lero m'mene munawerera kuchipatala kuno. Pali mankhwala ena amene mayi oyembekezera sayenera kumwalo. Ilfe tikuwembekezera zimwe amayi oyembekezera sayenera kumwalo. Nchifukwa chiyani?

Kodi muli oumilizidwa kutengapo mbali pakafukufukuyu?
Ayi. Inu muli ndi ufulu wakutengapo mbali kapena kukana pakafukufukuyu. Ngati mwasankha kutengapo mbali pa kafukufukuyu ndi mafunso amene simuli omwe akulemba kapena kudinda chindinda chidindo ndi chala chanu (ngati simudziwa kulemba) pa chikalata chomwe ndili nacho.

Zichitika zotani ngati mutengapo mbali?

Kodi ubwino wotengapo mbali pafukufukuyu ndi otani?

Ndi zovuta zanji zomwe mungakumane nazo potengapo mbali pafukufukuyu?
Palibe vuto iri lonse. Muli ndi utfulu kulekera panjira panjira ngakhale kafukufuku ali mkati.

Nanga ngatipali vuto panthawi ya kafukufukuyu?
Ngati muli ndi vuto kapena funso panthawi yakafukufukuyi mukhoza kufunsa a, Mrs. Ezereth Kabuluzi (Namibala yao iri pa musipa). Iwowa adzayesetsa kukuthandizani. Ngati simunakhutitsidwe ndi chithandizo chawo, awuzeni a kulu a Kamuzu College of Nursing (Namibala yao iri pamapeto a chipepepalachi).

Kodi pali chinsinsi potengapo mbali pafukufukuyu?

Chingachitike nchiyani ngati simufuna kupitiriza kafukufukuyu?
Muli ndi utfulu kusiyila panjira kutengapo mbali pafukufukuyu posapereka zifukwa. Ndpico ichi sichidzasokoneza kulandira chithandizo pachipatala pamene mukafuna chithandizo.

Kodi zotsatira za kafukufukuyu mudachita nazi chiyani?
Zotsatira za kafukufukuyi zidzapereka ku sukulu ya Manchester, ku UK. ngati mbali ya maphunziro koma zidzakikidwa m'mabuku osiyansiyana kuti anthu awerengeko. Komanso zidzaulutsidwa m’misonkhano.

Kodi wapereka ndalama za kafukufukuyu ndani?
A Commonwealth Commission ku England. Ndipo ine akundiyang’anira ndi Dr Linda McGowan ndi Dr Loretta Brabin (a ku University ya Manchester, UK).

Nanga wapereka chilolezo kuti kafukufuku achitike ndi ndani?
Kafukufukuyi wawunikidwa ndi a University ya Manchester Research ndi Ethics Committee, Kamuzu College of Nursing Research and Publications Committee ndi College of Medicine Research and Ethics Committee (Dates and reference numbers here) ndipo adavoleleza kuti palibe vuto.

Ngati mutengapo mbali sungani chikalata chodziwitsa ichi ndiponso ndikupatsani kalata ya chilolezo.

Zikomo kwambiri powerenga/ kapena kuvetsera za kafukufukuyu.
Adilesi ndi telefoni ya omwe mugawaimbile mutakhala ndi funso:

Mwini kafulufuku
Ezereth Kabuluzi
Kamuzu College of Nursing
Private Bag 1
Lilongwe.

Phone 0888 326409 Email: ezekabuluzi@kcn.unima.mw

The Principal
Kamuzu College of Nursing
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Supervisors:

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5th Floor (Research) St. Mary’s Hospital Oxford Road Manchester M13 9WL
Tel: 00 44 161 276 6388, Fax: 00 44 161 276 6134
Email: Loretta.Brabin@manchester.ac.uk
Appendix 4a: Participant Information Sheet (Antenatal)

**RESEARCH TITLE:** Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. I will read the information to you regarding the study. I will tell you about the purpose of the study and what will happen if you decide to take part.

**What is the purpose of the study?**
The purpose of the study is to help us understand which medicines women know to be safe to use when they are pregnant. We aim to interview 20 pregnant women about medicines they have recently taken. This information will be used to improve the information provided by health workers to women who are, or could be, pregnant.

**Why have you been chosen?**
You have been asked to take part because you are pregnant and you attended the clinic in the first 13 weeks of your pregnancy. Some medicines are better to avoid when pregnant and we wish to check that you are taking the most suitable medicines.

**Do you have to take part?**
No. It is up to you to make a choice as to whether to take part in the study or not. If you choose to take part, you will be asked to give your consent by signing or thumb printing a consent form.

**What will happen to you if you take part?**
If you chose to participate in this study, you will be asked to answer a number of questions on drugs which you have previously taken or are taking. You will also be asked about your views about taking medicines in pregnancy. The interview will last approximately one hour. The interviews will take place in a room within the hospital premises. With your permission, the interview will be taped so that it can later be written down accurately. You do not have to answer any questions that you do not feel comfortable talking about and you may stop the interview at any time.

If you feel upset or unwell during the interview, we will stop. If you would like to talk to someone to get advice, we will arrange for you to see one of the hospital counsellors. They are available to discuss your concerns and any other decisions you would want to make arising from the interview.

**What are the possible benefits of taking part?**
There might be some benefits of taking part in this study. If we find that you have been given/or are taking medicines which are not supposed to be taken in pregnancy, your treatment will need to be changed. Even if this is not the case, your taking part should have future benefits. The results will be used to inform government programmes with a view to improving health services and ensuring that women are treated properly when they are pregnant.

**What are the possible risks for you taking part?**
There are no known risks associated with this study. However, if you feel uncomfortable at any time during the interview or when completing the questionnaire the interview will be stopped.

**What if there is a problem?**
If any time you have questions or problems related to this study, you may contact me, Mrs. Ezereth Kabuluzi (see contact number at the end). I will try to resolve the problem in the first instance. If you remain unhappy and wish to complain formally, or if the problem relates directly to me you can do this through the Principal of Kamuzu College of Nursing (see contact number at the end).

**Will my taking part in the study be kept confidential?**
Yes. Only the researcher (Mrs Ezereth Kabuluzi) and her supervisors will have access to the information that you have given us and all the study documents containing your information will be kept under key and lock. All your personal information will be kept confidential. Consent forms will be stored in a locked cabinet and will only be accessible to the researcher. A study number will be used on the questionnaire instead of your name and this number will only be known to the researcher. Nobody from outside will be able to link the number to your identity. Data will be put onto a computer but only the researcher will know the password to start the computer. None of the data on the computer will have your name on it.

**What will happen if you do not want to carry on with the study?**
You are free to withdraw at any time during the study without giving reasons. A decision to withdraw at any time, or a decision not to take part, will not affect any future treatment or care you may require.

**What will happen to the results of the research study?**
This study is being undertaken as a higher degree (PhD) being undertaken by myself at the University of Manchester, UK. The results will be presented in a thesis. In addition, the results may be published and presented at conferences.

**Who is organizing and funding the research?**
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**Who has reviewed the study?**
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*Please keep this information sheet and should you wish to take part, you will also be given a copy of the consent form.*

*Thank you very much for taking time to read/listen to the information.*
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Oxford Road
Manchester M13 9WL
Tel: 00 44 161 276 6388, Fax: 00 44 161 276 6134 Email: Loretta.Brabin@manchester.ac.uk
Appendix 4b: Participant Information Sheet (Antenatal - Chichewa version)

Chikalata Chodziwitsa Kafukufuku

RESEARCH TITLE: Assessment of Risk of Drug Exposure in Early Pregnancy in Women in Rural and Urban Communities in Malawi


Cholinga cha kafukufukuyu ndi chiyani?

Nchifukwa chiyani mwasankhidwa?
Mwasankhidwa kutenga nawo mbali pa kafukufukuyu chifukwa ndinu mmodzi mwa amayi oyembekezera amene mwayamba sikelo miyexi titatu yooyambiriira. Pali mankhwala ena amene mayi oyembekezera sayenera kumwa. Ife tikufunitsitsa kuti tidziwe/tione kuti mumwadi mankhwala oyenera.

Kodi muli oumilizidwa kutengapo mbali pakafulufukuyu?
Ayi. Inu muli ndi ufulu wakutengapo mbali kapena kukana pakafulufukuyu. Ngati mwasankha kutengapo mbali muyera kuvomereza posainira kapena kudinda chindinda chidindo ndi chala chanu (ngati simudiwi kulemba) pa chikalata chomwe ndili nacho.

Zichitika zotani ngati mutengapo mbali?

Ngati simukepeza bwino panthawi imene tikufunsa mafunzitsa munene kuti tiime. Tili ndi aphungu a zachipatala omwe angakuthandizeni ngati mungafune chithandizo.
Kodi ubwino wotengapo mbali pakafulukuyu ndi otani?

Ndi zovuta zanji zomwe mungakumane nazo potengapo mbali pakafulukuyu?
Palibe vuto liri lonse. Mulikho zanji zomwe mungakumane nazo potengapo mbali pakafulukuyu ali mkati.

Nanga ngati pali vuto panthawi ya kafukufukuyu?
Ngati muli ndi vuto kapena funso panthawi yakafulukuyi mukhoza kufunsu a Mrs. Ezereth Kabuluzi (Nambala yao iri pa musipa). Iwowa adzayesetsa kukuthandizani. Ngati simunakhuwitisiswe ndi chithandizo chawo, awuzeni akulu a Kamuzu College of Nursing (nambala yao iri pamapeto a chipandepepalachi).

Kodi pali chinsinsi potengapo mbali pakafulukuyu?

Chingachitike nchiyani ngati simufuna kupitiriza kafukufukuyu?
Muli ndi ufulu kusiyla panjira kutengapo mbali pakafulukuyu posapereka zifukwa. Ndipo ichi sichidzasokoneza kulantira chithandizo pachilolezo pamene mukafuna chithandizo.

Kodi zotsatira za kafukufukuyu mudachita nazi chiyani?
Zotsatira za kafukufukuyi zidzaperskedwa ku sukulu ya Manchester, ku UK. ngati mbali ya maphunziro koma zidzakidwa m'mabuku osiyasize kuti anu awerengeko. Komanso zidzaulutsidwa m'misonkhano.

Kodi wapereka ndalama za kafukufukuyu ndani?
A Commonwealth Commission ku England. Ndipo ine akundiyang’anira ndi Dr Linda McGowan ndi Dr Loretta Brabin (a ku University ya Manchester, UK).

Nanga wapereka chilolezo kuti kafukufuku achitike ndi ndani?
Kafukufukuyi wawunikidwa ndi a University ya Manchester Research ndi Ethics Committee, Kamuzu College of Nursing Research and Publications Committee ndi College of Medicine Research and Ethics Committee (Dates and reference numbers here) ndipo adavoleleza kuti palibe vuto.

Ngati mutengapo mbali sungani chikalata chodziwitsa ichi ndiponso ndikupatsani kalata ya chilolezo.

Zikomo kwambiri powerenga/ kapena kuvetsera za kafukufukuyu.
Adilesi ndi telefoni ya omwe mugawaimbile mutakhala ndi funso:
Mwini kafukufuku
Ezereth Kabuluzi
Kamuzu College of Nursing
Private Bag 1
Lilongwe.
Phone 0888 326409 Email: ezekabuluzi@kcn.unima.mw

The Principal
Kamuzu College of Nursing
Private Bag 1
Lilongwe

Aphunzitsi amwini kafukufuku:
Dr Linda McGowan
Lecturer in Women’s Health
School of Nursing, Midwifery and Social Work
Faculty of Medical and Human Sciences
University of Manchester Room 6.038
University Place Oxford Road Manchester, United Kingdom.
Tel: 00 44 161 306 7841 ; Email: linda.mcgowan@manchester.ac.uk

Dr Loretta Brabin
Reader in Women’s Health
Academic Unit of Obstetrics & Gynaecology
University of Manchester Reception, 5th Floor (Research) St. Mary's Hospital
Oxford Road
Manchester M13 9WL
Tel: 00 44 161 276 6388; Fax: 00 44 161 276 6134 Email:
Loretta.Brabin@manchester.ac.uk
Appendix 5a: Consent Form for Questionnaire (Outpatient)

REC Reference Number:
Participant Identification Number for this study:
Name of Lead Researcher: Mrs Ezereth Kabuluzi

CONSENT FORM FOR QUESTIONNAIRE (out patients)

Title of Project: Assessment of Risk of Drug Exposure in Early Pregnancy in Women in Rural and Urban Communities in Malawi

Please initial box

1. I confirm that I have heard/read and understood the information for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my taking part is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights affected.

3. I understand that data collected during the study will be kept anonymous.

4. I agree to provide a urine sample for pregnancy testing if I will be requested to do so.

5. By signing this form, I agree to participate in this research study.

____________________  ____________________  _______________
Name of participant   Signature or thumb print  Date

____________________  ____________________  _______________
Researcher            Signature                Date

A copy of this form will be returned to you at the interview. A further copy will be stored in the researcher site file.

Lead Researcher: Mrs Ezereth Kabuluzi, Kamuzu College of Nursing, Private Bag 1, Lilongwe, Malawi. Tel: 265 888326 409 Email: ezekabuluzi@kcn.unima.mw
Appendix 5b: Consent Form for Questionnaire (Outpatient - Chichewa version)

REC Reference Number:
Participant Identification Number for this study:
Name of Lead Researcher: Mrs Ezereth Kabuluzi

CHIKALATA CHOPELEKA CHILOLEZO CHAKAFUKUFUKU

Title of Project: Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi

Please initial box


2. Ndamvetsa kuti ndi kutenga nWo mba pakafukufukuyu mwa kufuna kwanga ndipo ndiri ndi ufulu kusya nthawi iri yonse osanena chifukwa. Izi sizidzasokoneza kundira chithandizo chachipatala changa ndi ufuku wanga

3. Ndamvetsa kuti mayankho ndapereka pakafukufukuyu sayikapo dzina langa


4. Posayinira chikalachi ndavomera kutengapo mbali pakafukufukuyu

<table>
<thead>
<tr>
<th>Dzina la otenga mbali</th>
<th>Saini kapena chidindo</th>
<th>Tsiku</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mwini kafukufuku</td>
<td>Saini</td>
<td>Tsiku</td>
</tr>
</tbody>
</table>

Tikupatsani chikalatchi tikatha kafukufuku ndipo china chikasungidwa ndi otsogolela kafukufuku

Mwini kafukufuku: Mrs Ezereth Kabuluzi, Kamuzu College of Nursing, Private Bag 1, Lilongwe, Malawi. Tel: 265 888326 409 Email: ezechabuluzi@kcn.unima.mw
Appendix 6a: Consent Form for Interview (Antenatal)

Title of Project: Assessment of Risk of Drug Exposure in Pregnancy in Women in a Rural Community in Malawi

CONSENT FORM FOR INTERVIEW (antenatal women)

1. I confirm that I have heard/read and understood the information for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my taking part is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights affected.

3. I understand that data collected during the study will be kept anonymous.

4. I understand that the interview will be tape recorded.

5. By signing this form, I agree to participate in this research study.

-----------------------------------
Name of participant Signature or thumb print Date

-----------------------------------
Researcher Signature Date

A copy of this form will be returned to you at the interview. A further copy will be stored in the researcher site file.

Lead Researcher: Mrs Ezereth Kabuluzi, Kamuzu College of Nursing, Private Bag 1, Lilongwe, Malawi. Tel: 265 888326 409 Email: ezekabuluzi@kcn.unima.mw
Appendix 6b: Consent form for interview (Antenatal - Chichewa version)

REC Reference Number:
Participant Identification Number for this study:
Name of Lead Researcher: Mrs Ezereth Kabuluzi

CHIKALATA CHOPELEKA CHILOLEZO CHAKAFUKUFUKU (antenatal women)

Title of Project: Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi

Please initial box


2. Ndamvetsa kuti ndi kutenga nawo mbali pakafulukufukuyu mwa kufuna kwanga ndipo ndiri ndi ufulu kusiya nthawi iri yonse osanena chifukwa. Izi sizidzasokoneza kalandira chithandizo chachipepitala changa ndi ufuku wanga

3. Ndamvetsa kuti mayankho ndapereka pakafulukufukuyu sayikapo dzina langa

4. Ndamvetsa kuti zokambirana pakafulukufukuyu zijambulidwa pakawailesi

5. Posayinira chikalachi ndavomera kutengapo mbali pakafulukufukuyi

__________________________________  __________________________  __________________________
Dzina la otenga mbali                 Saini kapena chidindo      Tsiku

__________________________________  __________________________  __________________________
Mwini kafukufuku                       Saini                           Tsiku

Tikupatsani chikalatachi tikatha kafukufuku ndipo china chikasungidwa ndi otsogolela kafukufuku

Mwini kafukufuku: Mrs Ezereth Kabuluzi, Kamuzu College of Nursing, Private Bag 1, Lilongwe, Malawi. Tel: 265 888326 409 Email: ezekabuluzi@kcn.unima.mw
Appendix 7a. Questionnaire

Participant identification code: ___________________________________________________________
Date of interview: ________________________________________________________

QUESTIONNAIRE ON DRUG EXPOSURE - OUTPATIENT CLINIC

PART I – DEMOGRAPHIC DATA

Now I would like to ask you a few questions about yourself - your tribe, education attained and who you are living with

| 1. How old are you? ________________________________ years |
| 2. Which tribe do you belong to? |
| Chewa ☐ | Yao ☐ | Tumbuka ☐ |
| Lomwe ☐ | Ngoni ☐ |
| Other (please specify) ________________________________ |
| 3. What is your marital status? |
| Married ☐ | Single ☐ | Widowed ☐ |
| Divorced ☐ | Separated ☐ |
| 4. Who are you staying with? |
| Husband alone ☐ | In-laws in extended family compound ☐ |
| Own relatives ☐ |
| Other (please specify) ________________________________ |
| 5. What is the level of education that you attained? |
| No education ☐ | Primary school ☐ | Secondary school ☐ |
| Tertiary level ☐ |
| 6. Can you read to me the following sentence (show her a card where short simple sentences are written) |
| Able to read whole sentence ☐ | Able to read part of the sentence ☐ |
| Not able to read ☐ |
7. Do you have any independent income?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Other details ________________________________________________</td>
<td></td>
</tr>
</tbody>
</table>

8. What is your husband’s occupation?

<table>
<thead>
<tr>
<th>Farmer</th>
<th>Labourer</th>
<th>Teacher</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify) ______________________________________</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Do you smoke tobacco?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. Do you drink alcohol?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. Have you been in contact with any chemicals such as fertilizer, insecticides within the last 2 months?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**If Yes, note the chemical(s)________________________________________**

12. How far is your village/home from this hospital?

<table>
<thead>
<tr>
<th>0 – 5 Km</th>
<th>6 - 10 Km</th>
<th>11-15 Km</th>
<th>16 Km or more</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**PART II – CURRENT ILLNESS**

13. Why did you come to hospital today?

____________________________________________________________________
____________________________________________________________________
14. What symptoms did you have?
____________________________________________________________________
____________________________________________________________________

15. How severe were the symptoms?

- Couldn’t go to the garden (*prompt*)
- Couldn’t go to fetch water (*prompt*)
- Bearable; intermittent (*prompt*)
- Symptoms were getting worse
- Other (please specify) ________________________________________________

16. How long ago did you start to feel unwell?
____________________________________________________________________

17. Do you get the problem mentioned in Q14 regularly?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

18. Did anyone advise you to come to the hospital today?

- No, I decided myself to come
- Someone suggested that I should come (*mention*)
- Referred from health centre
- Other (please specify) ________________________________________________

19. What did you do to try and cure the illness before you came to hospital today?

- Took traditional medicine
- Took modern medicine bought from shops
- Asked friend for medicine
- Visited Health Centre
- Nothing

20. Did you visit a traditional healer?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

21. History of taking medicines for the list of conditions below

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
<th>Confirmed in Health passport/ Further details about symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<td>---------------------</td>
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<td></td>
</tr>
<tr>
<td>HIV</td>
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<tr>
<td>Syphilis</td>
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<td></td>
<td></td>
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<tr>
<td>Anaemia</td>
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<td></td>
<td></td>
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<tr>
<td>Schistomiasis</td>
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<td></td>
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<tr>
<td>UTI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>High BP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Migraine headache</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epilepsy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

22. What medicines are you/were you taking for the conditions you mentioned above?
(Women will be shown different samples of modern medicines to identify)

<table>
<thead>
<tr>
<th>Name of medicine</th>
<th>Route</th>
<th>Start date</th>
<th>Stop date</th>
<th>Reason for use</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
</tr>
</tbody>
</table>

23. Any other recent medications you are/have taking/taken (include prescription, OTC\(^4\) and traditional medicines; topical applications)

\(^4\) Over-the-counter
Name/form of medicine | Number of tablets | Start date | Stop date | Reason for use
---|---|---|---|---

24. Are you keeping any medicines at home?
   Yes ☐ No ☐

24 a. What are these?

24 b. How were they acquired?

24 c. What they might be used for again

25. Do you sometimes buy medicines?
   Yes ☐ No ☐

25a. What do you buy?

25b. Why buy from the shop, not the hospital where drugs are free?

26. Have you ever bought folic acid?
   Yes ☐ No ☐

27. Which of the following people give you money for buying medicines?
   Self ☐
   Husband ☐
   Parents ☐
   Other family members ☐
   Friends ☐
   Other (please specify)

PART IV - REPRODUCTIVE HISTORY AND VIEWS ON MEDICINES IN PREGNANCY

28. Have you ever been pregnant?
   Yes ☐ No ☐
   If never pregnant go to Q 35
29. How many pregnancies have you had? ________________________________

30. How many children do you have? ________________________________

If no children go to Q 35

31. How old is your last child? ________________________________ years

32. Are you breastfeeding the child now?
   Yes ☐  No ☐  NA ☐

33. Have you had any of the following pregnancy event(s)?

<table>
<thead>
<tr>
<th>Event</th>
<th>Yes</th>
<th>No</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miscarriage</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Still birth</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Preterm birth</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Multiple pregnancy</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

34. What do you think caused the event(s) you mentioned above?

<table>
<thead>
<tr>
<th>Event</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

35. Where did you deliver your last child?

<table>
<thead>
<tr>
<th>Location</th>
<th>☐</th>
<th>☐</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>☐</td>
<td>☐</td>
<td>TBA</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>☐</td>
<td>☐</td>
<td>NA</td>
</tr>
</tbody>
</table>

36. Where do you intend to deliver your next child?

<table>
<thead>
<tr>
<th>Location</th>
<th>☐</th>
<th>☐</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Home</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

37. Did you have a baby who was born with a physical abnormality?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
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<tbody>
<tr>
<td>☐</td>
<td>☐</td>
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</tbody>
</table>

5 Traditional Birth Attendant
(If yes, find out more e.g. type of disability, if still alive, what the child is able to do eg speak, able to feed self)

38. What do you think caused the disability?

39. Do any of your siblings, parents have a disability?
   Yes ☐ No ☐
   If yes, explore who and what type of disability

40. Does your family have a medical condition that can be passed on from one generation to the other (give example)?
   Yes ☐ No ☐

41. What medicines don't you like taking when pregnant?

42. Why don't you like taking the medicines mentioned above?

43. Are there any medicines you are allergic to?
   Yes ☐ No ☐
   If yes, what are they?

PART V - CURRENT PREGNANCY STATUS

44. When was your last menstrual period?

45. Did the doctor today ask you if you are pregnant?
   Yes ☐ No ☐

46. Do you think you are pregnant?
   Yes ☐ No ☐ Don’t know ☐

   How many weeks pregnant do you think you are? ________________ Weeks

   Go to review medicines if answer here is NO or Don’t know

47. What symptoms have made you suspect you are pregnant?
   Missed period ☐ Swollen breasts ☐
<p>| | | | |</p>
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<thead>
<tr>
<th></th>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Vomiting</td>
<td></td>
<td>Tiredness</td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

48. Did you tell the health worker that you are pregnant?

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

49. Does anyone else know that you are pregnant?

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

50. Have you started antenatal visits?

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

51. If started antenatal visits, have you taken/ been given fansidar as IPTp⁶?

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

Check health passport for assessed gestational age and number of IPTp

_________________________________________________________________
_________________________________________________________________

52. If pregnant but not attending ANC, what is the reason?

_____________________________________________________
_________________________________________________________________

Review medicines prescribed today

_________________________________________________________________
_________________________________________________________________

Ask for a pregnancy test

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td></td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Not done (pregnant)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Needs medication changed

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

**Note any additional information recorded in the health passport**

_________________________________________________________________
_________________________________________________________________

---

⁶ Intermittent Preventive treatment in pregnancy
### Appendix 7b: Questionnaire (Chichewa version)

**Participant identification code:** __________________________________________

**Date of interview:** __________________________________________

#### QUESTIONNAIRE ON DRUG EXPOSURE - OUTPATIENT CLINIC

**PART I – DEMOGRAPHIC DATA**

*Tsopano ndikufunsani za mbiri yanu*

1. Muli ndi zaka zingati? __________________________________________

2. Ndinu a mtundu wanji?

<table>
<thead>
<tr>
<th>Language</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chewa</td>
<td>☐</td>
</tr>
<tr>
<td>Yao</td>
<td>☐</td>
</tr>
<tr>
<td>Tumbuka</td>
<td>☐</td>
</tr>
<tr>
<td>Lomwe</td>
<td>☐</td>
</tr>
<tr>
<td>Ngoni</td>
<td>☐</td>
</tr>
</tbody>
</table>

Wina (fotokozani_)___________________________________________

3. Kodi muli pa banja?

<table>
<thead>
<tr>
<th>Language</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Okwatiwa</td>
<td>☐</td>
</tr>
<tr>
<td>Osakwatiwa</td>
<td>☐</td>
</tr>
<tr>
<td>Mwamuna</td>
<td>☐</td>
</tr>
<tr>
<td>adamwalira</td>
<td></td>
</tr>
</tbody>
</table>

Banja lidatha☐ Tidalekana ☐

4. Mumakhala ndi ndani?

<table>
<thead>
<tr>
<th>Language</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mwamuna wanga</td>
<td>☐</td>
</tr>
<tr>
<td>Azilamu ndi achibale</td>
<td>☐</td>
</tr>
<tr>
<td>Abale anga</td>
<td>☐</td>
</tr>
</tbody>
</table>

Zina (fotokozani)___________________________________________

5. Sukulu mudalekeza kalasi yanji?

<table>
<thead>
<tr>
<th>Level</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sindidaphunzire</td>
<td>☐</td>
</tr>
<tr>
<td>Primary school</td>
<td>☐</td>
</tr>
<tr>
<td>Secondary school</td>
<td>☐</td>
</tr>
<tr>
<td>Tertiary level</td>
<td>☐</td>
</tr>
</tbody>
</table>

6. Tawerengani chiganizo ichi (*muwoneseni mayiyu pamene palembedwa chiganizo*)

<table>
<thead>
<tr>
<th>Action</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Akutha kuwerenga chiganizo chonse</td>
<td>☐</td>
</tr>
<tr>
<td>Sanathe kuwerenga chonse</td>
<td>☐</td>
</tr>
</tbody>
</table>
7. Kodi pali chimene mumachita chomwe chimakubweretserani ndalama?

<table>
<thead>
<tr>
<th>Inde</th>
<th>Ayi</th>
</tr>
</thead>
</table>

Fotokozani ________________________________

8. Amuna anu amagwira ntchito yanji?

<table>
<thead>
<tr>
<th>Mlimi</th>
<th>Lebala</th>
<th>Mphunzitsi</th>
</tr>
</thead>
</table>

Zina (Fotokozani) ________________________________

9. Kodi mumasuta fodya?

<table>
<thead>
<tr>
<th>Inde</th>
<th>Ayi</th>
</tr>
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</table>

10. Kodi mumamwa mowa?

<table>
<thead>
<tr>
<th>Inde</th>
<th>Ayi</th>
</tr>
</thead>
</table>

11. Pamiyezi iwiri yapitayi mwagwrako mankwala ophera tizilombo kapena feteleza?

<table>
<thead>
<tr>
<th>Inde</th>
<th>Ayi</th>
</tr>
</thead>
</table>

12. Kumudzi kwanu nkotalikirana bwanji ndi chipatala chino?

<table>
<thead>
<tr>
<th>0 – 5 Km</th>
<th>6 - 10 Km</th>
<th>11 -15 Km</th>
<th>16 Km or more</th>
</tr>
</thead>
</table>

**PART II – CURRENT ILLNESS**

13. Nchifukwa chiyani munabwera kuchipatala kuno lero?

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
14. Munali ndi zizindikiro zanji?

____________________________________________________________________
____________________________________________________________________

15. Kodi zindikilo zinali zamulingo wotani
   Simkadapita kumunda (*prompt*)
   Sindimatha kukatunga madzi (*prompt*)
   Ndimamva kuwawa (*prompt*)
   Ndimalephera kupuma (*prompt*)
   Ndimona kuti zizindikiro zikufika poipa

16. Papita nthawi yayitali bwanji chiyambireni zizindikirozi?
   ___________________________ Tsiku (masiku.............)
   ___________________________ sabata ......(masabata ........)

17. Kodi mumakhala ndi vuto mwatchula pamwambali nthawi zonse?
   Inde ☐ Ayi ☐

18. Alipo anakuuzani kutu mubwere kuchipatala lero?
   Ayi, ndinaganiza ndekha kubwera ☐
   Anandiuza kuti ndibwere (tchulani) ______________________________
   Ananditumiza kuchokera ku Health Centre ☐
   Zina (Fotokozani)_________________________________________

19. Munachitapo chiyani pa vuto lanuli musanabwere kuchipatala lero?
   Ndinamwa mankhwala achikuda ☐
   Ndinakagula mankwala ku sitolo ☐
   Ndina pita kuchipatala ☐
   Ndinapempha mankwala kwa mzanga ☐

20. Kodi munapita kwa asing’anga achikuda?
   Inde ☐ Ayi ☐

**PART III – MEDICATION HISTORY**

21. Kodi mukumwa mankhwala a matenda awa?

<table>
<thead>
<tr>
<th>Nthenda</th>
<th>Inde</th>
<th>Ayi</th>
<th>Tatsimikizila mu Health passport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malungo</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Chifuwa chachikulu (TB)</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>
22. Ndi mankhwala anji omwe mukumwa pa matenda mwatchula pamwambapa?
(‘Amayi adzawonetsewa mankhwala amitundu yosiyanasiyana)

<table>
<thead>
<tr>
<th>Dzina la mankhwala</th>
<th>Kamwedwe kake/njira yomwela</th>
<th>Tsiku loyamba mankhwal a</th>
<th>Tsiku lomaliza mankhwala</th>
<th>Chifukwa chomwera mankhwala</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

23. Palinso mankhwala ena mukumwa (Achizungu, achikuda, opaka pakhungu)

<table>
<thead>
<tr>
<th>Dzina la mankhwala</th>
<th>Kamwedwe kake/njira yomwela</th>
<th>Tsiku loyamba mankhwala</th>
<th>Tsiku lomaliza mankhwala</th>
<th>Chifukwa chomwera mankhwala</th>
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<td></td>
</tr>
</tbody>
</table>
24. Kodi nthawi zina mumagula mankhwala?
   Inde [ ] Ayi [ ]

25. Kodi munagulako mankhwala otchedwa folic acid
   Inde [ ] Ayi [ ]

26. Ndi ati mwa anthu awa amakupatsani ndalama zogulira mankhwala?
   Ndekha [ ]
   Amuna anga [ ]
   Makolo anga [ ]
   Anthu ena a m’banja mwathu [ ]
   Anzanga [ ]
   Ena (Fotokozani)______________________________________________

27. Munakhalapo oyembekezera (ndi mimba)?
   Inde [ ] Ayi [ ]
   Ngati ayi pitani ku funso 35

28. Munakhalapo oyembekezera ka ngati?________________________________

29. Muli ndi ana?
   Inde [ ] Ayi [ ]
   Ngati ayi pitani ku funso 28

30. Mwana omaliza ali ndi zaka zingati?
   ______________________________________________________________

31. Kodi mukuyamwitsa mwana panopa?
   Inde [ ] Ayi [ ]

32. Kodi munakhalako ndi izi pamene munali oyembekezera?
   Vuto
   Mtnayo [ ]
   Mwana wobadwa wakufa [ ]
   Mwana wosatha masiku [ ]
   Mapasa [ ]
   Tsiku
   ______________________________

33. Kodi muganiza kuti chidapangitsa vuto liri pamwambi nchiyani?
   Vuto
   Chochitsa

PART IV - REPRODUCTIVE HISTORY AND VIEWS ON MEDICINES IN PREGNANCY

27. Munakhalapo oyembekezera (ndi mimba)?
   Inde [ ] Ayi [ ]
   Ngati ayi pitani ku funso 35

28. Munakhalapo oyembekezera ka ngati? ________________________________

29. Muli ndi ana?
   Inde [ ] Ayi [ ]
   Ngati ayi pitani ku funso 28

30. Mwana omaliza ali ndi zaka zingati?
   ______________________________________________________________

31. Kodi mukuyamwitsa mwana panopa?
   Inde [ ] Ayi [ ]

32. Kodi munakhalako ndi izi pamene munali oyembekezera?
   Vuto
   Mtnayo [ ]
   Mwana wobadwa wakufa [ ]
   Mwana wosatha masiku [ ]
   Mapasa [ ]
   Tsiku
   ______________________________

33. Kodi muganiza kuti chidapangitsa vuto liri pamwambi nchiyani?
   Vuto
   Chochitsa
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>34. Mwana omaliza munakanakachilira kuti?</td>
<td>kuchipatala</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kwazamba</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kwina(Fotokozani)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35. Mukukonza kuti mwana wanu amene mudzakhale naye mukachilire kuti?</td>
<td>Kuchipatala</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kwa a Zamba</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36. Munaberekapo mwana olumala?</td>
<td>Inde</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ayi</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Ngati inde, fufuzani zambiri monga mtundu wachilema, ngati ali moyo, ndipo amatha kuchita chain monga kuyankhula, kudya yekha)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37. Muganiza kuti chidalumalitsa mwanayu nchiyani?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38. Kodi alipo m'ale wanu kapena makolo anu amene ndi olumala?</td>
<td>Inde</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ayi</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39. Kodi kubanja kwanu kuli matenda ochokera kumakolo? (Perekani chitsanzo monga khunyu, a shuga)</td>
<td>Inde</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ayi</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40. Ndimamkhwala anji amene simufuna kumwa mukakhala ndi pakati?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>41. Nchifukwa chiyani simufuna kumwa mankhwala amenewa?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>42. Pali mankhwala amene sakuyanjani?</td>
<td>Inde</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ayi</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ngati inde ndi ati?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PART V - CURRENT PREGNANCY STATUS

43. Kodi munasamba liti komaliza?

____________________________________________________________________________________

44. Kodi lero adokortalana anakufunsani ngati muli oyembekezera?

<table>
<thead>
<tr>
<th>Inde</th>
<th>Ayi</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

45. Kodi mukuganiza kuti ndinu oyembekezera?

<table>
<thead>
<tr>
<th>Inde</th>
<th>Ayi</th>
<th>Sindikudziwa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mukuona kuti ndinu oyembekezera kwa miyezi ingati?

____________________________________________________________________________________

46. Ndi zizindikiro zanji zomwe zakupangitsani kuti muganize kuti ndinu oyembekezera?

<table>
<thead>
<tr>
<th>Sindinasambe</th>
<th>Mawere atupa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ndikusanza</th>
<th>Ndikumatopa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Zina (Fotokozani) ____________________________________________________________

47. Munawauza azachipatala kuti ndinu oyembekezera?

<table>
<thead>
<tr>
<th>Inde</th>
<th>Ayi</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

48. Alipo akudziwa kuti ndinu oyembekezera?

<table>
<thead>
<tr>
<th>Inde</th>
<th>Ayi</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

49. Munayamba sikelo ya amayi a pakati?

<table>
<thead>
<tr>
<th>inde</th>
<th>Ayi</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

50. Ngati munayamba sikelo munapatsidwa mankhwala a malungo otchedwa fansidar ndi cholinga choteteza malungo?

<table>
<thead>
<tr>
<th>Inde</th>
<th>Ayi</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Yang’ananani mu Health passport ngati anawerengera miyezi ndiponso ngati apatsidwa fansidar

____________________________________________________________________________________

51. Ngati muli oyembekezera nchifukwa chiyani simupita kusikelo?

____________________________________________________________________________________

Onani mankhwala amene apatsidwa lero

____________________________________________________________________________________

Afunika kusinthilidwa
<table>
<thead>
<tr>
<th>Funsani kuti muyese mkodzo kuti adziwe ngati ali ndi mimba</th>
</tr>
</thead>
<tbody>
<tr>
<td>Done</td>
</tr>
<tr>
<td>Not done (refused)</td>
</tr>
<tr>
<td>Not done (pregnant)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yang’anani zina zili zonse zoonjezela zomwe zalembedwa mu Health passport</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Appendix 8a: Interview guide

Participant identification code: ________________________________

Date of interview: ________________________________

Assessment of Risk of Drug Exposure in Early Pregnancy in women in a Rural Community in Malawi

INTERVIEW GUIDE

What do you think about taking medicines during pregnancy?
   Explore: the good and bad effects of medicines
   Probe if they also take medicines when not pregnant.
   Explore if some medicines are seen as bad at any time

Why do you think women may use medications in pregnancy?
   Explore: reasons such as to make baby grow, to add blood in the body, to prevent against diseases such as malaria, to hasten labour

Have you ever taken medicines in pregnancy?
   Explore: modern medicines, traditional medicines
   Explore: if the woman thinks there is a safe time in pregnancy when she can take medicine.

What were the reasons for taking the medicines?
   Explore: whether it was for prophylaxis or had health problems or for preventing pregnancy loss.

What medicines don’t you like taking when pregnant?
   Explore: modern as well as traditional medicines or combination.
   Explore: why she thinks other women would not the medicines

Why don’t you like taking the medicines mentioned above?
   Explore: about side effects previously experienced; what they heard about the effect of the medicine on pregnancy

Where did you get the medicine from?
   Explore: sources whether from the hospital or being advised by relatives, mother, husband, and significant others.
   Explore: what the views of relatives, mother and husband are about taking medicines during pregnancy.

What are your views about using fansidar in pregnancy?
   Explore: about what they know about its effects against malaria, what she thinks about its effect on the baby about herself

What are your views about using the other medicines for malaria such as artemether-lumefantrine and quinine?
   Explore: about what they know about its effect against malaria, what she thinks about its effect on the baby and herself
Appendix 8b: Interview guide (Chichewa version)

Participant identification code: ________________________________________________

Date of interview: __________________________________________________________

Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi

INTERVIEW GUIDE

Mumaona bwanji zomwa mankwala pomwe muli woyembekezera?
   Fufuzani: zabwino ndi zoyipa. Fufuzani ngati amayi amamwa mankhwala pamene Sali oyembekezera. 
   Fufuzani ngati mankhwala ena siabwino pa nthawi ina

Muganiza kuti nchifukwa chiyani amayi amamwa mankhwala pamene ali oyembekezera?
   Fufuzani: Zifukwa monga, kupangitsa mwana kuti azikula, kuonjezera magazi, kuteteza ku matenda monga malungo, kuyambitsa matenda pokachira.

Kodi mudamwako mankhwala pamene munali oyembekezera?
   Fufuzani: mankwala a chizungu, achikuda. Fufuzani ngati amayiwo amadziwa nthawi yabwino yomwera mankhwala pomwe ali oyembekezera

Ndi zifukwa ziti zomwe amamwera mankhwala?
   Fufuzani: mwina kungodziteteza, kudwala, kuopa kuti mimba ingachoke

Ndi mankhwala ati owe amayi safuna kumwa pomwe ali oyembekezera?
   Fufuzani: achizungu, achikuda onse

Nchifukwa chiani simufuna kumwa mankhwala omwe mwatchulawa?
   Fufuzani: zovuta zomwe zimawera ndi mankwala, zoipa zomwe adawma za mankhwala

Mudawatenga kuti mankhwala?
   Fufuzani: kuchipatala, kuuzidwa ndi achibale, amayi awo, amuna awo ndi anthu ena

Mumaona bwanji za kumwa fansida kwa amayi ali oyembekezera?
   Fufuzani : zovuta pa mwana, mayi ndi kuteteza ku malungo

Mmaona bwanji zogwiritsa mankhwala ena a malungo monga LA ndi kwinini pamene mayi ali oyembekezera?
   Fufuzani: zomwe amadziwa monga kudziteteza ku malungo, zovuta kwa mwana ndi mayiyo
Appendix 9: University of Manchester Ethics approval letter

Our Ref: HS/MH

Ms Ezerath Kabulozi
School of Nursing, Midwifery & Social Work
University of Manchester
Oxford Road
Manchester
M13 9PL

23 September 2009

By email and internal post.

Re: Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi
Proposal Number: 291024/NMSW

Dear Ms Kabulozi,

Thank you for the clarifications and amendments to the above study as requested by the Research Ethics Committee.

I am of the opinion that no major concerns or objections are evident of an ethical nature. Therefore on behalf of the Committee and taking Chair's Action, I am happy to grant full ethical approval.

During the progress of the study please inform the Committee of any changes or amendments that may be necessary.

On completion of the study would you please provide the Committee with a "Completion of Study Report".

In order to arrange University Insurance Cover please forward the completed Insurance Form (enclosed) along with your Research Proposal and a copy of this letter to the Purchasing Office at the address printed on the form.

Direct Contact: [Contact Information]

Howard Edlin
Tel: +44 (0)161 306 7642 Fax: 0161 306 7707
Email: Howard.Edlin@man.ac.uk

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Appendix 9: University of Manchester Ethics approval letter (continued)

Best wishes for your study,

Yours sincerely,

Howard Shilton
Chair, School Research Ethics Committee
Appendix 10: Kamuzu College of Nursing Ethics approval certificate

University of Malawi
KAMUZU COLLEGE OF NURSING
RESEARCH AND PUBLICATIONS COMMITTEE

APPROVAL CERTIFICATE

TITLE: Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi

INVESTIGATOR: Ezerezi Susan Kalulezi

DEPARTMENT/YEAR OF STUDY: PhD

REVIEW DATE: 20th October 2009

DECISION OF THE COMMITTEE: APPROVED

signature: [Signature]

DATE: 29 October 2009

DEAN, POSTGRADUATE STUDIES & RESEARCH

cc: Supervisor

DECLARATION OF INVESTIGATOR(S)

I/we fully understand the conditions under which I am/we are authorized to carry out the above mentioned research and I/we guarantee to ensure compliance with these conditions. In case of any departure from the research procedure as approved, I/we will resubmit the proposal to the committee.

DATE: 29 October 2009

signature(s): [Signature]
Appendix 11: College of Medicine Ethics approval letter

Principal
Prof. R.L. Broadhead, MBBS, FRCP, FRCPCH, DCH

College of Medicine
Private Bag 360
Chichiri
Blantyre 3
Malawi
Telephone: 677 245
877 281
Fax: 674 700
Telax: 42744

18th January 2010

Mrs E. Kabuluzi
KCN
P/Bag 1
Lilongwe

Dear Mrs Kabuluzi,

P.11/09/638 – Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi

I write to inform you that COMREC reviewed your proposal which you resubmitted for expedited review. I am pleased to inform you that your proposal was approved on 18th January 2010 after considering that you addressed all the issues which were raised in earlier reviews.

As you proceed with the implementation of your study we would like you to take note that all requirements by the college are followed as indicated on the attached page.

Yours Sincerely,

Dr. S. Kamiza
For: CHAIRMAN - COMREC

SK/kk
Appendix 12: Permission seeking letter to Lilongwe District Health Officer

Kamuzu College of Nursing
Private Bag 1
Lilongwe
Phone: 0886326409
Email: ezekakabuluzi@yahoo.com

19 January 2010

The District Health Officer
P.O. Box 1274
Lilongwe

Cc: Officer In-Charge, Mitundu Rural Hospital
    Officer In-Charge, Kawale Health Centre

Dear Sir,

REQUEST TO CONDUCT A STUDY AT MITUNDU COMMUNITY HOSPITAL AND KAWALE HEALTH CENTRE

I am a faculty member from Kamuzu College of Nursing currently studying at the University of Manchester for PhD in Nursing. As a requirement for my studies, I am supposed to submit a thesis in fulfillment of the PhD. I am therefore writing to request your permission to conduct a study at Mitundu Community Hospital and a pilot study at Kawale Health Centre. The research topic is ‘Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi’. The aim of the study is to assess the risk of exposure to contraindicated medicines in early pregnancy (less than 13 weeks gestation) among women attending clinics at a large community hospital.

Participants will be women attending outpatient clinic and antenatal women attending antenatal clinic. The proposed data collection period is from January 2010 to July 2010. The study has been reviewed and approved by the University of Manchester Research Ethics Committee, Kamuzu College of Nursing Research and Publication Committee and College of Medicine Research Ethics Committee. Please find attached the approval letters.

I offer myself to come and discuss the proposal in detail with you through an appointment. I have enclosed a summary document of the proposal. I will be grateful if you favourably consider my request.

Yours sincerely

Ezereth Kabuluzi (Mrs)
Appendix 13: Permission seeking letter to Kamuzu Central Hospital Director

Kamuzu College of Nursing
Private Bag 1
Lilongwe

Phone: 0888326409
Email: ezekeabuluzi@kcn.unima.mw

19 January 2010

The Director
Kamuzu Central Hospital
P.O. Box 149
Lilongwe

Dear Sir,

REQUEST TO CONDUCT A STUDY AT KAMUZU CENTRAL HOSPITAL

I am a faculty member at Kamuzu College of Nursing currently studying at the University of Manchester for PhD in Nursing. As a requirement for my studies, I am supposed to submit a thesis in fulfillment of the PhD. The research topic is 'Assessment of Risk of Drug Exposure in early Pregnancy in Women in a Rural Community in Malawi'. The aim of the study is to assess the risk of exposure to contraindicated medicines in early pregnancy (less than 13 weeks gestation) among women attending clinics at a large rural hospital. One of the specific objectives is to obtain preliminary data from hospital records on the frequency and type of congenital abnormalities. This is to allow future monitoring of these rates after the introduction of new drugs that carry some risks for pregnant women. I am therefore writing to request your permission to conduct review records for congenital abnormalities from Paediatric ward, Nursery and Labourward registers. The data to be included would be anonymised information recording congenital abnormalities between 2006 and 2010. No personal information will be recorded. Each record will be accorded its own identification code to maintain patient confidentiality.

The proposed data collection period is from January 2010 to July 2010.

I offer myself to come and discuss the proposal in detail with you through an appointment. I will also provide you with a summary document of the proposal. I will be grateful if you favourably consider my request.

Yours sincerely

Ezereth Kabuluzi (Mrs)
Appendix 14: Letter of permission from Lilongwe District Health Officer

To whom it may concern,

RE: PERMISSION TO CONDUCT RESEARCH IN LILONGWE DISTRICT.

Permission has been granted to the bearer of this letter,

Ezereth Susan Kabuluzi

to conduct a survey in Lilongwe District on

Assessment of Risk of Drug Exposure in Early Pregnancy in Women in a Rural Community in Malawi

Any assistance rendered would be appreciated.

Dr. L. Ndeve
DISTRICT HEALTH OFFICER

Lilongwe District Health Office
P.O. Box 1274
Lilongwe
Malawi

21st January, 2010
Appendix 15: Letter of permission from Kamuzu Central Hospital Director

Ref.No.KCH/Admi/ 21st January 2010

TO WHOM IT MAY CONCERN

RESEARCH STUDY PROPOSAL ON ASSESSMENT OF RISK OF DRUG EXPOSURE IN EARLY PREGNANCY IN WOMEN IN A RURAL COMMUNITY IN MALAWI

Reference is made to the above Research Study Proposal which has been approved by the College of Medicine Research and Ethics Committee (COMREC) P.11/09/838 as part of your fulfilment for a PhD in Nursing.

I would like to inform you that you may go a head to conduct your study here at Kamuzu Central Hospital. Please note that confidentiality of data you collect is very crucial.

Please share with the hospital a report of your final findings.

Dr. A.T. Mthambala
HOSPITAL DIRECTOR
Appendix 16: An example of analysis levels for qualitative interviews

Developing the thematic framework

A thematic framework was developed using the topics in the interview guide and common themes arising from reading and re-reading the transcripts. With constant discussions with supervisors, the framework was made up of main themes and subthemes and each was given an index number as shown in the box below.

<table>
<thead>
<tr>
<th>THEMES and SUBTHEMES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Beliefs about traditional and modern medicine</strong></td>
</tr>
<tr>
<td>1.1 Strengthening the pregnancy</td>
</tr>
<tr>
<td>1.2 Protection from witchcraft</td>
</tr>
<tr>
<td><strong>2. Awareness of appropriate use of medicines</strong></td>
</tr>
<tr>
<td>2.1 Lack of awareness of medication safety in early pregnancy</td>
</tr>
<tr>
<td>2.2 Knowledge of medicines dispensed at the antenatal clinic</td>
</tr>
<tr>
<td>2.3 Advice on medication use during pregnancy by health workers</td>
</tr>
<tr>
<td><strong>3. Choice of medication during pregnancy</strong></td>
</tr>
<tr>
<td>3.1 Preference for modern medicines</td>
</tr>
<tr>
<td>3.2 Preference for combining modern and traditional medicines</td>
</tr>
<tr>
<td><strong>4. Perceived causes of congenital abnormalities</strong></td>
</tr>
<tr>
<td>4.1 Witchcraft</td>
</tr>
<tr>
<td>4.2 ‘It is God’s plan’</td>
</tr>
<tr>
<td>4.3 Punishment</td>
</tr>
</tbody>
</table>

Indexing

All the transcripts were read in more depth and phrases marked with the relevant index number. An example of an extract from an interview with a woman talking about using traditional medicines in pregnancy demonstrates this process:

‘Moreover, I used traditional medicine just for one pregnancy. As of now I use scientific medicine’

( Participant 9)

This phrase was marked with the index number 3.1 on the framework showing statements related to subtheme of Preference for modern medicines (table above).
The charts

An example of a chart developed for the main theme *Choice of medication during pregnancy* can be seen in the table below.

<table>
<thead>
<tr>
<th>THEMES</th>
<th>Interview 6</th>
<th>Interview 7</th>
<th>Interview 8</th>
<th>Interview 9</th>
<th>Interview 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Choice of medication during pregnancy</td>
<td>'I have never been there (page 6, line 178)</td>
<td>‘I took medicine for my first pregnancy’(page 1, line 9)</td>
<td>'Moreover, I used traditional medicine just for one pregnancy. As of now I use scientific medicine' (page 2, line 45)</td>
<td>'when one is pregnant they should just go to hospital' (page 4, line 94)</td>
<td></td>
</tr>
<tr>
<td>3.1 Preference for modern medicines</td>
<td><em>Participant indicated that she has never been at a TBA</em></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2 Preference for combining modern and traditional medicines</td>
<td>'I go to traditional birth attendants when I am pregnant' (page 1, line 24)</td>
<td>'That is why we go to both the hospital and TBAs (page 14, line 434)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><em>The participant indicated that there are some issues which can be dealt with by the TBA only eg repositioning a malpositioned baby</em></td>
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<tr>
<td></td>
<td>'I was given traditional medicine after which I felt better but I continued taking the scientific medicine’ (page 3)</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td><em>Participant preference is for modern system only went to TBA during first pregnancy</em></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Summarising the data

All the indexed phrases were then summarised and placed on the relevant chart and column. The number in brackets next to the data summary was the corresponding page number in the transcript. Being able to see data from all of the interviews on the same charts facilitated the process of interpretation. Any phrases that were identified as not being represented in the subthemes were noted and retained for presentation of differing views of the women.