

**FACTORS CONTRIBUTING TO ADVERSE OUTCOMES OF PRE-ECLAMPSIA
AMONG PREGNANT WOMEN ATTENDING ANTENATAL CLINICS IN KIBERA
SLUMS, NAIROBI**

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NOVEMBER, 2012.

DECLARATION

This dissertation is my original work and has not been submitted either wholly or in part to this university or any other institution for the award of any degree or diploma.

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DEDICATION

To my family and friends, who have been there for me at all times.

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May God bless you All.

ABBREVIATIONS AND ACRONYMS

ACOG	American College of Obstetrics and Gynecology
ANC	Ante-Natal Care
APHRC	African Population and Health Research Center
BP	Blood Pressure
CI	Confidence Interval
DMOH	District Medical Officer of Health
FANC	Focused Ante-Natal Care
FP	Family Planning
GBD	Gestation By Dates
HIV/AIDS	Human Immune-deficiency Virus/Acquired Immune Deficiency Syndrome
ICD	International Classification of Diseases
IPT	Intermittent Preventive Therapy for malaria
IQR	Inter-quotient Ratio
KEPH	Kenya Essential Package for Health
KDHS	Kenya Demographic and Health Survey
KNH	Kenyatta National Hospital
LLITN's	Long Lasting Insecticide Treated Nets
MGD's	Millennium Development Goals
MMR	Maternal Mortality Ratio
MOH	Ministry of Health
MOPHS	Ministry of Public Health and Sanitation

MOMS	Ministry of Medical Services
NHSSP II	Second National Health Sector Strategic Plan
OR	Odds Ratio
PET	Pre-eclampsia Toxemia
PMTCT	Prevention of Mother to Child Transmission
PNC	Post Natal Care
RH	Reproductive Health
SPSS	Statistical Package for Social Sciences
TB	Tuberculosis
TBA	Traditional Birth Attendant
TT	Tetanus Toxoid
UN	United Nations
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USA	United States of America
WHO	World Health Organization

DEFINITION OF OPERATIONAL TERMS

- **MDG:** is a blueprint agreed upon by world leaders in the year 2000, committing their nations to a new global partnership to reduce extreme poverty and setting out a series of time-bound targets - with a deadline of 2015.
- **ANC:** is a component of maternal health program where pregnant women get comprehensive and personalized care regarding their pregnancy in order to achieve optimal outcomes for both mother and baby.
- **MMR:** Maternal mortality ratio is the number of women who die as a result of child bearing during pregnancy, or within 42 days of delivery or termination of pregnancy in one year, per 100,000 live births.
- **Maternal health:** refers to the health of women during pregnancy, childbirth and the postpartum period.
- **Maternal mortality:** Maternal mortality is the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes (WHO, 1992).
- **Pre-eclampsia:** a condition specific to pregnancy, arising after 20 weeks of gestation, characterized by hypertension and proteinuria. Oedema may also be present (ACOG, 2001).
- **Eclampsia:** is pre eclampsia complicated by convulsions in the absence of other medical conditions predisposing to convulsions (ACOG, 2001).
- **Skilled birth attendants:** is an accredited health professional – such as a midwife, doctor or nurse – who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth and the immediate postnatal

period, and in the identification, management and referral of complications in women and newborns (WHO, 2004).

- **Traditional birth attendants:** are providers that are not formally trained to handle pregnancy and child birth (WHO, 2005).
- **Hypertension:** is blood pressure of 140/90 mmHg or more on two occasions six hours apart or a diastolic pressure of 110 or more on a single occasion (Palmer et al, 1999).
- **Proteinuria:** is defined as protein concentration of 0.3 g/l or more in at least two random urine specimens collected six hours apart or urine dipstick finding of trace or 1+ or more proteins (ACOG, 2001).

ABSTRACT

Kenya, like other developing countries, has a high maternal mortality ratio. Currently maternal deaths are estimated to be 488 per 100,000 live births. Maternal mortality ratio (MMR) in slums is higher than the national average and the major direct causes are hemorrhage, sepsis and hypertensive diseases. Pre eclampsia is the main cause of hypertensive disease in pregnancy, associated with maternal mortality. The aim of the study was to determine the factors that contribute to the adverse outcomes of pre-eclampsia among pregnant women attending ANC in Kibera slums, Nairobi, as strategy to reduce the adverse outcomes in pregnancy including maternal mortality.

The study design was cross sectional. Pregnant women of gestational age 20 weeks and above in selected health facilities in Kibera slums were approached to form the study population. Women meeting eligibility criteria were interviewed until a sample size of 229 was achieved. Primary data was collected using pre-coded, structured questionnaire targeting pregnant women attending ante natal clinic (ANC) in health facilities in Kibera. Secondary data was collected by retrieving information from the ANC cards

Two hundred and twenty nine (229) respondents were interviewed, out of whom 14 were diagnosed with pre-eclampsia. The age of respondents ranged from 14-44 years with a median of 24 year, with 41.5% being in 2nd trimester while 58.5% in 3rd trimester. Less than 2% of respondents had no formal education, 52% primary education, 39.3% secondary education and 7% tertiary education. Income levels varied with 58.1% earning less than Ksh. 2500 per month, 17.9% earning between Ksh 2501-5000, 10.5% earning between Ksh. 5001-7500, 6.1% earning a

monthly average of Ksh. 7501- 10000 and 7.4% earning more than Ksh. 10000 per month. The prevalence of pre-eclampsia was found to be 6.1% while the prevalence of known risk factors were; pre-existing diabetes mellitus (1.3%), young maternal age (22.3%), primigravidae (25.8%), previous history of pre-eclampsia (6.1%), family history of pre-eclampsia, multiple pregnancy (4.8%) and pre-existing hypertension (6.6%). Referral of diagnosed patients was found to be 7.1%. Awareness of symptoms was found to be low with 37.1% of respondents identifying severe headache, 28.8% identifying blurred vision, 31.0% identifying facial edema and 33.2% identifying edema of the hands as some of the symptoms of pre-eclampsia. Nearly all the respondents (98.7%) who were aware of symptoms would visit health facility if they noticed symptoms of pre-eclampsia or had any obstetric emergencies. In terms of preparedness to handle emergencies, 73% of respondents had set aside some emergency funds, 52.7% had identified means of transport, 66.4% had identified a companion and 72.9% had identified a decision maker.

In conclusion, the prevalence of Pre-eclampsia among pregnant women attending ANC clinics in Kibera slums was found to be on the higher side of rates recorded in African settings (range of 1.8% to 7%). The most and least prevalent risk factors were primigravidae (25.8%) and diabetes mellitus (1.3%) respectively. Awareness of symptoms was low for severe headache (37.1%), blurred vision (28.8%), facial edema (31.0%) and edema of the hands (33.2%). Screening of pregnant women for known risk factors coupled with health education on symptoms of the disease and preparedness for obstetric emergencies that might occur during the pregnancy are recommended.

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CHAPTER 1: INTRODUCTION

1.1: Background to the Study

Preeclampsia is a pregnancy-related hypertensive disorder occurring usually after 20 weeks of gestation. If left untreated, it progresses to eclampsia (Medicine for Africa, 2008). Preeclampsia and eclampsia are not distinct disorders but the manifestation of the spectrum of clinical symptoms of the same condition. The mildest disorder in this continuum is pregnancy-induced hypertension. In pre-eclampsia, hypertension and proteinuria are present, and when convulsions occur in addition to these signs, the condition is referred to as eclampsia (AbouZhar, 2003). Preeclampsia has remained a significant public health threat in both developed and developing countries contributing to maternal and perinatal morbidity and mortality globally (AbouZhar, 2003). Pre-eclampsia is a frequent disorder with a reported incidence of 2-8% among pregnancies (Lopez-Jaramillo et al, 2002). However geographic, social, economic and racial differences are thought to be responsible for incidence rates up to 3 times higher in some populations (Lopez-Jaramillo et al, 2002). The prevalence of preeclampsia in developing countries ranges from 1.8% to 16.7% (Kayode and Olusimbo, 2011).

Although numerous clinical and biochemical tests have been proposed for prediction or early detection of preeclampsia, most remain unrealistic for general use in most developing countries. At present, there is not a single reliable and cost-effective screening test for preeclampsia which can be recommended for use in most developing countries (Wagner, 2004).

The WHO focused antenatal care strategy recommends screening for pre-eclampsia during the third antenatal visit at 32 weeks (WHO, 1994). In developing countries, strategies for risk

assessment should still be based on obstetric and medical history and clinical examination of women. Pregnant women should be assessed at their first antenatal clinic for risk factors of pre-eclampsia, but screening should be done at every subsequent visit. These risk factors include primigravida, maternal age (below 20 and over 35 years), multiple pregnancy, family history of pre eclampsia or eclampsia, history of pre eclampsia/eclampsia in a previous pregnancy, hydatidiform mole, renal disease, obesity, diabetes mellitus, change of male partner and women with chronic hypertension (Kirsten and Deborah, 2005). It is, however, important to note that the presence of these factors is not a guarantee to developing pre-eclampsia in the course of that pregnancy. Screening for pre-eclampsia using maternal history alone is accurate in detecting only 45.3% of cases (Papageorghiou, 2005).

Pre-eclampsia/eclampsia probably accounts for more than 50 000 maternal deaths worldwide each year. Most of these deaths are seen in developing countries, including Africa (WHO, 2005). Delays in seeking health care in African societies contribute to the high burden of maternal mortality. Delayed responses at the household level to obstetric emergencies often arise as a result of inadequate information on when to seek help and sometimes on where to seek help (Wasim et al., 2004; Akinola et al., 2008; Brunson, 2010). Lack of access to quality care has also been identified to an obstacle to reducing maternal mortality in low-income countries (Richard et al, 2010). These are due to many factors including the location, distance, and lack of transport to health facilities. Delays within the health facilities have also been shown to prevent women from receiving the care they need before, during, and after childbirth. For instance, in many countries where the health insurance scheme is still in the teething stage, getting care in emergencies may be impossible for the poor or insured (Onwujekwe and Uzochukwu, 2005).

In Kenya, standard protocols for management of pre-eclampsia (MOMS and MOPHS, 2009) are as follows: Mild pre-eclampsia should be managed as outpatient with weekly monitoring of blood pressure, body weight, proteinuria, fetal heart rate and uterine size. Patients should further be advised on bed rest at home. This can be augmented by use of phenobarbitone. Patients should be informed to report to a hospital if features suggesting severity set in or there's reduction or change in fetal movements. All patients with mild pre-eclampsia managed as outpatients should be admitted to hospital at 38 weeks gestation for delivery. Patients with severe pre-eclampsia should be admitted to hospital and the following instituted; absolute bed rest, four hourly blood pressure monitoring, daily urinalysis for proteinuria, weekly blood urea and electrolytes and hemoglobin. Drugs therapy is indicated, with phenobarbitone and methyldopa being the pharmacological agents advocated. If these measures fail to work, immediate delivery is recommended.

One of the most important preventive measurements is routine prenatal care for the pregnant woman throughout her pregnancy as this will assure early diagnosis and allow aggressive management as soon as possible. Patient education is another important aspect of preventing pre-eclampsia and other pregnancy-related diseases and problems. Healthcare education regarding the physiological changes and challenges throughout a pregnancy increases the woman's awareness of arising problems at an early point in time, thus, allowing for quick and effective medical intervention and increases the chance of therapeutic success considerably (Medicine for Africa, 2008).

Thus, the aim this study could be used to improve on the outcomes of pre-eclampsia by raising the quality of ante-natal care offered to pregnant women in the slums especially by imparting knowledge about this condition so that they can recognize important symptoms and take appropriate and timely actions. This would in turn help prevent or reduce maternal mortality attributed to pre-eclampsia.

1.2: Statement of the Problem

Pre-eclampsia is an important public health problem in the slums of Nairobi due to the magnitude of maternal deaths from eclampsia, which is a complication of pre-eclampsia. A study done by Ziraba et al (2009) to determine the causes of maternal mortality in the slums of Nairobi using two sources of data, verbal autopsy data and from the medical records of health care facilities, found that the leading causes of direct maternal deaths were abortion complications, ante partum and postpartum hemorrhage, postpartum sepsis, eclampsia, and ruptured uterus. The difference was the order of magnitude of the burden that each cause contributed. From the verbal autopsy data, abortion complications were the leading cause of maternal death (31%) while eclampsia contributed 12% of maternal deaths. From the medical records results, eclampsia (24%) was the leading cause of maternal mortality (Ziraba et al, 2009). This study sought to determine the factors that contributed to the adverse outcomes of pre-eclampsia, which include eclampsia, pregnancy losses and maternal mortality both at the national and at the global levels.

1.3: Conceptual frame work

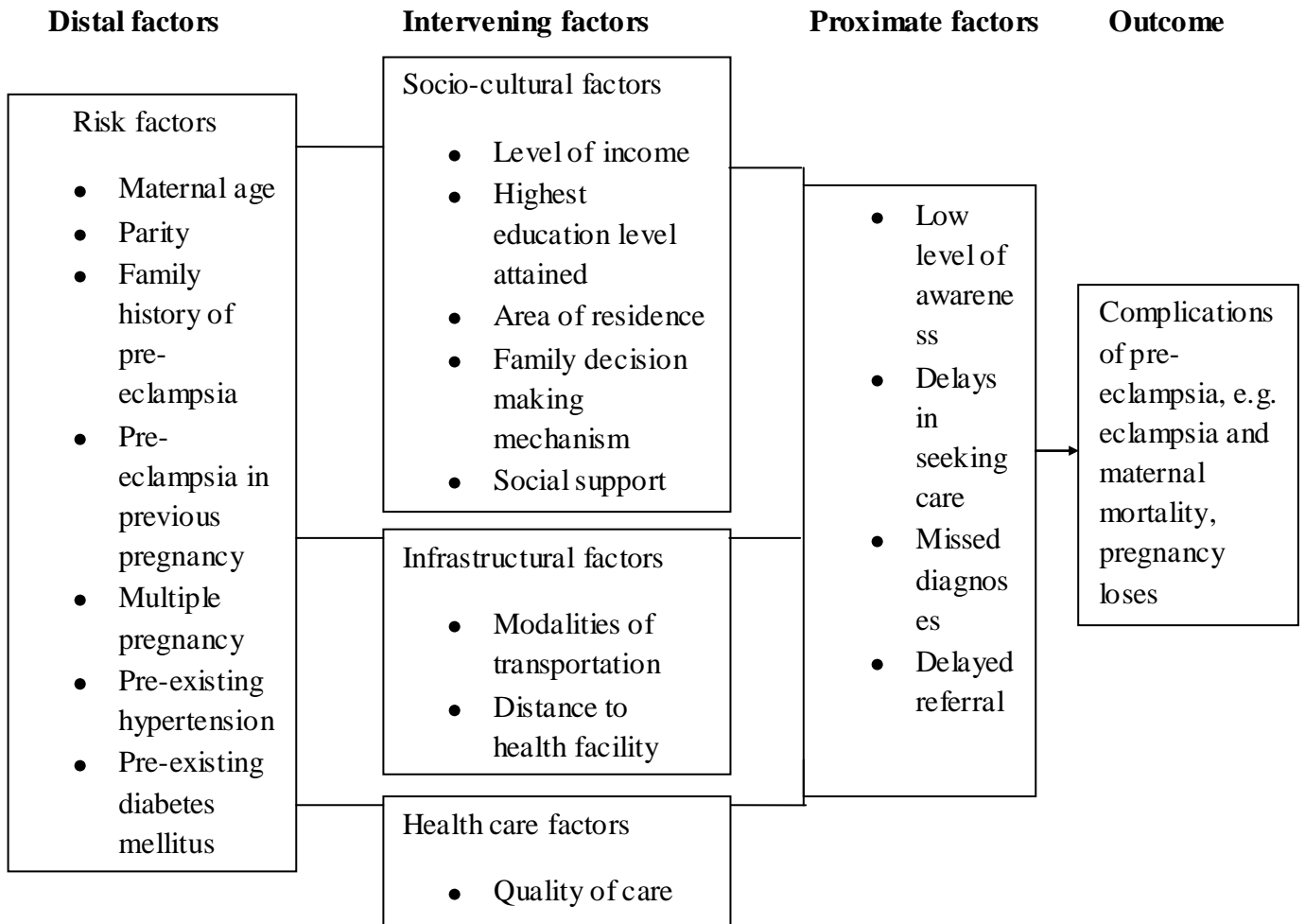


Figure 1: Conceptual framework depicting the factors that contribute to adverse outcomes of pre-eclampsia

The outcomes of pre-eclampsia are influenced by several factors. Proximate factors, also called personal factors directly impact on the outcome while distal factors, also known as risk factors influence the chance of developing pre-eclampsia during the pregnancy. These risk factors are amenable to interventions that are outside the scope of this study. The study looked at the intervening and proximate factors that contributed to adverse outcomes of pre-eclampsia.

1.4: Broad and Specific Objective of the Study

1.4.1: Broad objective

To determine the factors that contributed to the adverse outcomes of Pre-eclampsia among pregnant women attending ANC clinic in Kibera slums, Nairobi.

1.4.2: Specific objectives

1. To describe the socio-demographic characteristics of participants;
2. To determine the prevalence of pre-eclampsia among pregnant women attending ANC in Kibera slums, Nairobi;
3. To determine the prevalence of the known risk factors of pre-eclampsia among pregnant women attending ANC in Kibera slums, Nairobi;
4. To determine the prevalence of proximate factors that contributed to the adverse outcomes of pre-eclampsia among pregnant women attending ANC in Kibera slums, Nairobi.

1.5: Research Questions

1. What were the socio-demographic characteristics of study participants?
2. What was the prevalence of pre-eclampsia among pregnant women attending ANC in Kibera slums, Nairobi
3. What were the prevalence rates of known risk factors of pre-eclampsia among pregnant women attending ANC in Kibera slums, Nairobi?

4. What were the prevalence rates of proximate factors that contributed to the adverse outcomes of pre-eclampsia among pregnant women attending ANC in Kibera slums, Nairobi?

1.6: Significance of the Study

Eclampsia, which is a complication of pre- eclampsia, accounts for between 12-24% of maternal deaths in the slums of Nairobi (Ziraba et al, 2009). However, the factors associated with pre-eclampsia in Kibera slums were not known. This study sought to determine the intervening and proximate factors that are amenable to primary interventions and generate knowledge that could potentially influence the strategies to reduce adverse outcomes of pre-eclampsia (e.g. eclampsia which could cause maternal death) among pregnant women attending ANC in the slums of Nairobi.

CHAPTER 2: LITERATURE REVIEW

2.1 Burden of pre-eclampsia

Pre-eclampsia is a frequent disorder with a reported incidence of 2-8% among pregnancies. However geographic, social, economic and racial differences are thought to be responsible for incidence rates up to 3 times higher in some populations (Lopez-Jaramillo et al, 2002). The prevalence of preeclampsia in African countries ranges from 1.8% to 16.7% (Kayode and Olusimbo, 2011). In some countries such as Colombia, it is the main cause of maternal mortality. Up to 42% of maternal deaths are attributed to this disorder in Colombia (Lopez-Jaramillo et al, 2002). Pre-eclampsia/eclampsia probably accounts for more than 50 000 maternal deaths worldwide each year (WHO, 2005).

2.2 Screening for pre-eclampsia

The WHO focused antenatal care strategy recommends screening for pre-eclampsia during the third antenatal visit at 32 weeks (WHO, 1994). In developing countries, strategies for risk assessment should still be based on obstetric and medical history and clinical examination of women. Pregnant women should be assessed at their first antenatal clinic for risk factors of pre-eclampsia, but screening should be done at every subsequent visit. These risk factors include primigravida, maternal age (below 20 and over 35 years), multiple pregnancy, family history of pre eclampsia or eclampsia, history of pre eclampsia/eclampsia in a previous pregnancy, hydatidiform mole, renal disease, obesity, diabetes mellitus, change of male partner and women with chronic hypertension (Kirsten and Deborah, 2005). It is, however, important to note that the presence of these factors is not a guarantee to developing pre-eclampsia in the course of that pregnancy. Screening for pre-eclampsia using maternal history alone is accurate in detecting

only 45.3% of cases (Papageorghiou, 2005). Routine screening for pre-eclampsia based on measurement of blood pressure among all pregnant women should be practiced as recommended by the world health organization (WHO, 2003). The preferred way to measure blood pressure is by using a mercury sphygmomanometer (WHO, 1988). Urinalysis for protein should also be routinely done at every antenatal visit for pregnant women in as a complement to routine blood pressure measurement. Just as there is no cure for preeclampsia, there are no tests that can predict it.

2.3 Factors that influence the outcome of pre-eclampsia

To tackle pre-eclampsia effectively in any population, functional health systems are imperative and so is access to health care. However, in the vast majority of developing countries particularly in Africa, health care access is limited due to a number of factors resulting in three levels of delay:

Delayed responses at the household level to obstetric emergencies often arise as a result of inadequate information on when to seek help and sometimes on where to seek help (Wasim et al., 2004; Akinola et al., 2008; Brunson, 2010). This is often worsened by lack of decision-making power among pregnant women especially in Africa, poverty, and the rising cost of health care (Begum et al 2004, Bracken, 2010). The consideration of user fees and the resultant catastrophic expenditure often result in fatal delays in care seeking (Richard et al, 2010). Some socio-demographic (e.g., level of education and marital status) and cultural underpinnings of maternal health-seeking behavior have also been documented (Olusanya, 2010).

Lack of access to quality care has also been identified to an obstacle to reducing maternal mortality in low-income countries (Richard et al, 2010). These are due to many factors including the location, distance, and lack of transport to health facilities. Further, referral delays arising from the trajectory of visits to other orthodox and alternative medical practitioners have been documented to account for 46.4% of all cases of eclampsia (Onah, 2005).

Delays within the health facilities have also been shown to prevent women from receiving the care they need before, during, and after childbirth. For instance, in many countries where the health insurance scheme is still in the teething stage, getting care in emergencies may be impossible for the poor or insured (Onwujekwe and Uzochukwu, 2005). The attitudes of health service providers and perceived poor quality of care are also identified barriers (Dolea and AbouZahr, 2000; Ige and Nwachukwu, 2010).

Social factors such as religion, socio-economic status, level of education and housing have been recognized as influencing up to 27% of maternal deaths (Qiu et al, 2010). So, raising awareness of the need for women to reach emergency care without delay when complications arise during delivery is particularly critical. This is to ensure quick and effective medical intervention and to increase the chance of therapeutic success (Begum, 2004). Since many women deliver alone or with a relative (National Population Commission, 2009), community members must also be trained to recognize danger signs and develop plans for emergencies, including transport to hospitals or health centre. Prompt health seeking behavior is essential because studies have shown that reduction of the risk of death becomes more difficult when complications have developed (Begum, 2004).

Accessibility and preparedness of health facilities to handle eclampsia is essential in reducing the risk of maternal deaths. However, the slums of Nairobi have few public health facilities, with healthcare provision being provided by largely unregulated private for profit health facilities. Only 14% of these health facilities are equipped to handle eclampsia (Ziraba et al, 2009).

2.4 Pre-eclampsia and Maternal Mortality

In the slums of Nairobi, 12-24% of maternal deaths can be attributed to eclampsia (Ziraba et al, 2009). Globally, eclampsia accounts for 12% of maternal deaths (WHO, 2005). Most maternal deaths seem to occur between the third trimester and the first week after the end of pregnancy (Campbell et al, 1996). A large proportion of all maternal deaths occur in health facilities mainly due to three scenarios, namely: women who arrive in a moribund state too late to benefit from emergency care, women who arrive with complications who could have been saved if they had received timely and effective interventions, and women admitted for normal delivery who subsequently develop serious complications (Mswia et al, 2003). The scenarios in which women arrive in a moribund state may give insights into problems like referral chain between facilities, barriers in the community to accessing care, which might be physical, cultural, financial, lack of information, or lack of awareness of danger signs (McCarthy et al, 1992). A woman's lifetime risk of maternal death is 1 in 7300 in developed countries versus 1 in 75 in developing countries (WHO, 2007).

2.5 Potential impact of the study on Prevention of Pre-eclampsia in the slums of Nairobi

One of the most important preventive measures is routine prenatal care for the pregnant woman throughout her pregnancy as this will assure early diagnosis and allow aggressive management

as soon as possible. Patient education is another important aspect of preventing pre-eclampsia and other pregnancy-related diseases and problems. Healthcare education regarding the physiological changes and challenges throughout a pregnancy increases the woman's awareness of arising problems at an early point in time, thus, allowing for quick and effective medical intervention and increases the chance of therapeutic success considerably (Medicine for Africa, 2008). Inability to recognize danger signs and to act on them is a contributor to the high maternal rates in the slums of Nairobi (APHRC, 2009).

The knowledge generated from this study could be used to improve on the outcomes of pre-eclampsia among pregnant women attending ANC in Kibera slums, Nairobi. This can be achieved by improving the quality of ante-natal care offered to pregnant women in the slums especially by imparting knowledge about this condition so that they can recognize important symptoms and take appropriate and timely actions. This would help prevent or reduce complications of pre-eclampsia.

CHAPTER 3: METHODOLOGY AND MATERIALS

3.1 Study Design

The design employed for this study was a descriptive, cross sectional survey.

3.2 Variables

Dependent variable: Pre eclampsia

Independent variables: Maternal age, gestational age, parity, personal history of pre eclampsia, family history of pre eclampsia, pre existing hypertension or diabetes, multiple gestation, income levels and education levels.

3.3 Study area

The study was carried out in four health facilities within/around Kibera slums namely Langata, Woodley, Kibera and AMREF health centers.

Kibera is located in southwest Nairobi, roughly 5 kilometers from the city centre. It's approximately 2 square kilometers. The 2009 Kenya Population and Housing Census reported Kibera's population as 170,070. Much of its southern border is bounded by the Nairobi River and the Nairobi Dam, an artificial lake that provides drinking water to the residents of the city. Kibera is divided into 13 villages, including Kianda, Soweto, Gatwekera, Kisumu Ndogo, Lindi, Laini Saba, Siranga/Undugu, Makina and Mashimoni.

Kibera was selected for the study because of its dense population, the higher than national average maternal mortality ratio and the diverse ethnic and socio-cultural composition. Also, the longevity of residents of Kibera is unique, exhibiting two patterns: the group of permanent residents of the slum who have lived there for many years, and are unlikely to relocate and the group in transition, those who will eventually move out of Kibera slum to other areas of the city. Notably, several health facilities of different levels by service delivery (i.e. dispensaries, health centers, district hospital and even a national referral facility) are located either within or around Kibera slums, and provide services to Kibera residents. This makes it relatively easy for pregnant women in Kibera to access various levels of care during their antenatal period. It also provides variety of health facilities that can effectively handle different health needs during the pregnancy.

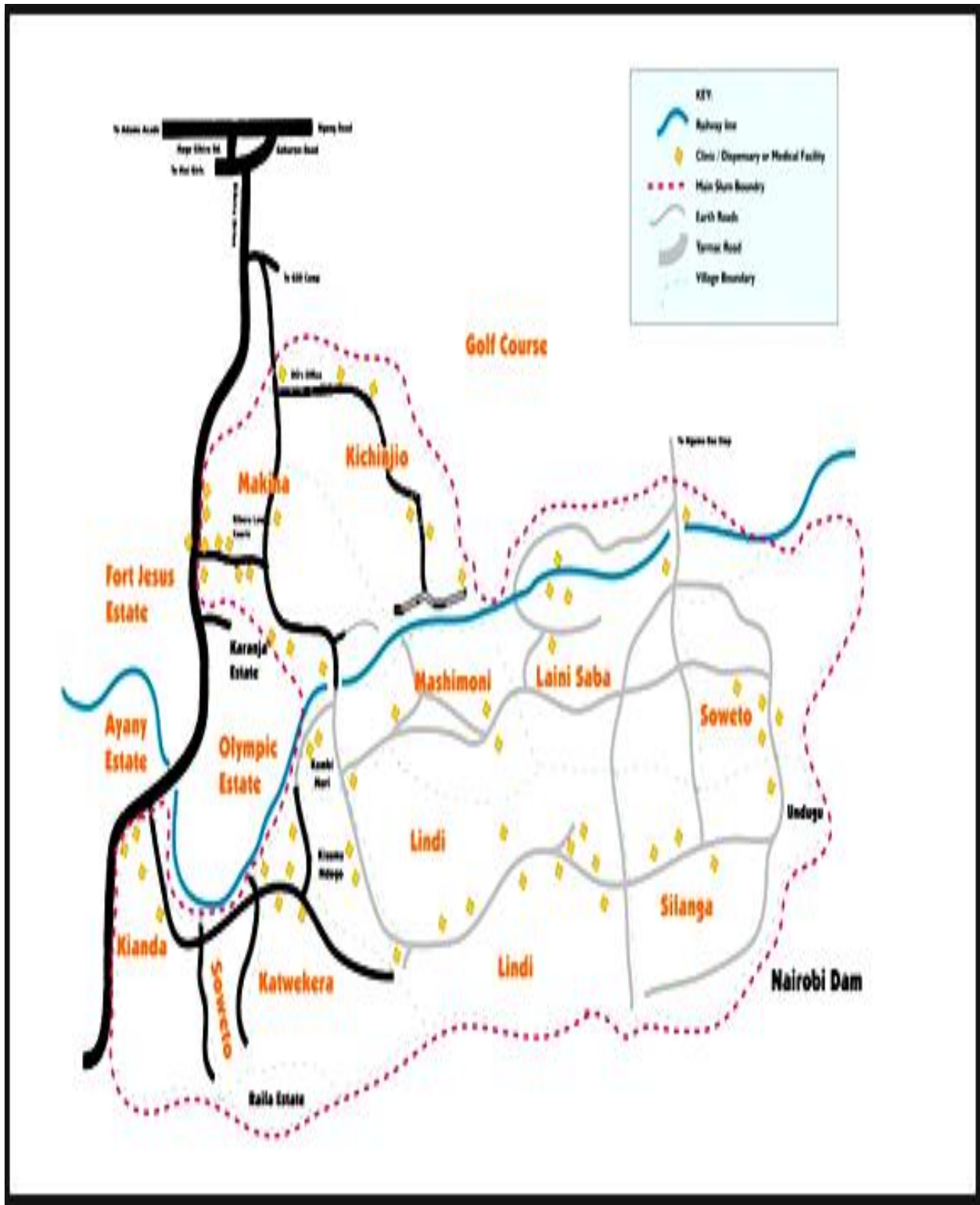


Figure 2: Map of Kibera slums

3.4 Target population

The target population was all pregnant women at risk of developing pre-eclampsia/eclampsia (gestation 20 weeks and above) residing in slums.

3.5 Study population

The study population was all the pregnant women attending ANC at Langata, Woodley, Kibera and AMREF health centers located within or around Kibera slums in Nairobi. Pregnant women eligible for inclusion are those who had attained gestational age of 20 weeks and above.

3.6 Sample size

Sample size was determined using the following formula for proportions

$$n = \frac{Z^2 [P (1-P)]}{d^2} \quad (\text{Mugenda and Mugenda, 1999})$$

- n, the required sample size;
- z, critical value associated with significance level of 95%, is 1.96;
- p, the estimated proportion of pregnant women with pre-eclampsia is 16.7% (Kayode and Olusimbo, 2011);
- d, the margin of error accepted for this study was 5%.
- The required sample size was, using the above information, 214 pregnant women. A further 22 participants (10% of the calculated sample size) were to be interviewed to cater for non-response rate, making a total of 236 participants.

3.7 Sample Selection

The sampling of the study sites was purposive. The list of all the health facilities operating in Kibera was obtained from the medical officer of health, Langata district. The health facilities are classified as public or private/non-governmental organization run. Four health facilities were selected. There are three public health centers offering ante-natal services to Kibera residents (Langata, Kibera and Woodley). All the three public health centers were selected. One non-governmental organization run health facility was selected to complete the list. This was informed by the fact that more than two thirds of pregnant women in Nairobi are likely to seek ante-natal services in a public health facility (KDHS, 2008-09).

The sampling of the pregnant women was convenient. Each pregnant woman attending ANC in these four facilities was approached after they had been reviewed by the clinicians. Those who were 20 weeks (or more) gestation by dates as indicated in the ANC cards were requested to form the sample. The research assistants then gave the consent information form to them to read. Those who accepted to participate in the study signed the consent form and were interviewed using the structured questionnaire. All those who met the inclusion criteria were interviewed as they came to the selected clinics until the sample size of 229 was achieved. Seven pregnant women declined to give consent and were thus not interviewed. On completion of the questionnaire, the interviewer wrote the questionnaire identification number at the back of the ANC card to avoid double recruitment of the same participant into the study.

3.8 Inclusion criteria

- Pregnant women above 20 weeks gestation, and consenting took part in the study.

3.9 Exclusion criteria

- Pregnant women below 20 weeks gestation at the time of interview.
- Pregnant women above 20 weeks gestation with severe pre-eclampsia.
- Pregnant women above 20 weeks gestation experiencing convulsions (eclampsia).
- Pregnant women above 20 weeks gestation who declined to participate in the study.
- Pregnant women who were minors and were not accompanied by a guardian to give consent on their behalf.

3.10 Instruments of data collection

Data were collected using pre-coded, structured questionnaire.

3.11 Data Collection Techniques

Primary data were collected using pre-coded, structured questionnaire. The questionnaire was administered trained interviewers. Secondary data was collected by retrieving information from the ANC cards.

3.12 Minimization of Errors and Biases

1. Pilot study - This was done at the ANC clinic at Mbagathi district hospital. The feedback from this exercise was used to refine the questionnaire so that it was be able to collect the intended information;
2. The study assistants were trained on the administration of the questionnaire, to minimize interviewer bias.

3.13 Data Processing and Analysis

Raw data were entered into SPSS version 17 for data management. Filled questionnaires were checked for completeness before data was entered into SPSS. Data cleaning was done by identifying outliers by running frequencies. Graphs and tables were used to summarize data. Univariate analysis was used to generate prevalence rates

3.14 Ethical Considerations

This study proposal was submitted to the KNH/UoN ethics and research committee which reviewed and approved it. The study posed minimal/no harm to participants and they were free not to participate in the study if they so wished. The participants were explicitly informed on the purpose of the study, who are involved, and the benefits of the study. Participants did not receive any form of financial or material inducement. Confidentiality of subjects was upheld. All participants who were interviewed gave informed consent. Permission was obtained from the medical officer of health, city council of Nairobi to conduct the study in health facilities under their management. Further clearances were obtained from the provincial directors of public health and sanitation and medical services, as well as the medical officers of health Langata and Dagoreti districts.

3.15 Limitations of the Study

1. The health facilities used for this study were purposively selected, with all the three public health facilities being included and one private health facility. This was informed by the finding in KDHS 2008/9 that more than two thirds of pregnant women in Nairobi

were likely to go for ANC services in public health facilities. The findings, therefore, may not be generalizable to all the pregnant women in Kibera slums.

2. The study did not employ a probabilistic method of recruiting participants into the study as all the women meeting eligibility criteria were recruited into the study thereby introducing selection bias.
3. Diagnosis of pre-eclampsia was based on high blood pressure from one reading. At least two blood pressure readings taken not less than 6 hours apart should be the ideal before a patient is declared to have high blood pressure. It's possible that this led to over-estimation of hypertensives, and hence over-estimate prevalence of pre-eclampsia
4. The study relied on urinalysis tests done by the health facilities. However, some participants who had high blood pressures had missing results for urinalysis and therefore could not be classified as having pre-eclampsia or not. This could have led to under-estimation of prevalence of pre-eclampsia

CHAPTER 4: RESULTS

The study was carried out over a three week period between 21st May and 7th June, 2012 in four health facilities within/around Kibera slums namely Langata, Woodley, Kibera and AMREF health centers. Five trained study assistants helped with data collection, with 2 study assistants being stationed in Langata health center and one study assistant in each of the remaining three health centers. Two hundred and thirty six (236) participants were approached to form the sample; however 229 participants consented to take part in the study while 7 declined to participate. Out of the 229 participants who formed the sample, 118 were recruited at Langata health center, 41 at Woodley health center, 20 at Kibera health center while 50 were recruited at AMREF health center. The number of participants recruited in each health facility was based on the workload of the month of April, 2012. The recruited participants came from all the 13 villages of Kibera. Data was collected using interviewer administered questionnaire. Women who were at least 20 weeks pregnant were enrolled into the study.

4.1 Socio-demographic Characteristics of the participants

The ages of respondents ranged from 13 years to 42 years with a median of 24 years (Figure 3). About 42% of the participants were in the 2nd trimester while 58% were in the 3rd trimester. More than half of the respondents (53.7%) had attained up to primary level of education. Only about 7% of respondents had attained tertiary education. Economically, 58.1% of respondents lived below the poverty line of 1 dollar a day (UN, 2000). Fifty nine (59) respondents (25.8%) were primigravidae, 95 respondents (41.5%) were para two, 42 respondents (18.3%) were para three,

22 respondents (9.6%) were para four while 11 respondents (4.8%) were grand multiparous (Table 2).

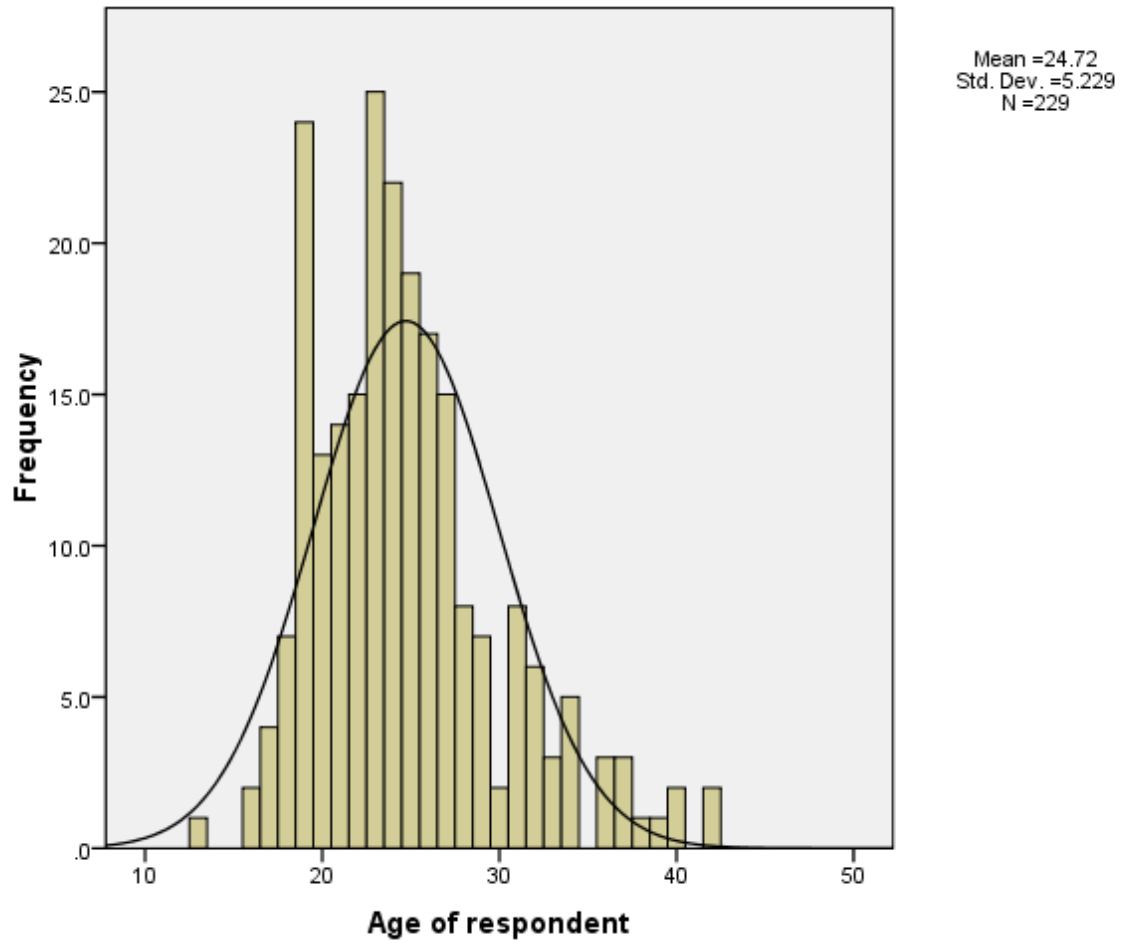


Figure 3: Age distribution of respondents (n=229)

Table 1: Distribution of the participants by Socio-demographic characteristics (n=229).

Socio-demographic Characteristics		Frequency (n=229)	Percentage
Gestational age	2 st trimester	95	41.5
	3 rd trimester	134	58.5
Level of education	None	4	1.7
	Primary	119	52.0
	Secondary	90	39.3
	Tertiary	16	7.0
Level of income per month in Kenya shillings	2500 and below	133	58.1
	2501-5000	41	17.9
	5001-7500	24	10.5
	7501-10000	14	6.1
	10,000 and more	17	7.4
Total number of pregnancies, including the current one.	One	59	25.8
	Two	95	41.5
	Three	42	18.3
	Four	22	9.6
	five and over	11	4.8

4.2 Prevalence of the Pre-eclampsia among the study participants

The variable pre-eclampsia was computed at the analysis stage by cross-tabulating high blood pressure and proteinuria. Thus, the prevalence of pre eclampsia in Kibera slums was found to be 6.1 per cent. Fourteen (14) of the two hundred and twenty nine participants interviewed were found to suffer from pre-eclampsia. However, this figure could be higher than this given that 7 participants (3.1%) had a high blood pressure but did not have a urinalysis for proteinuria done to classify them as having pre eclampsia or not. Generally, it was noted that 48.5% (111) of

participants did not have a urinalysis done but all the participants had blood pressure taken during the ANC visit.

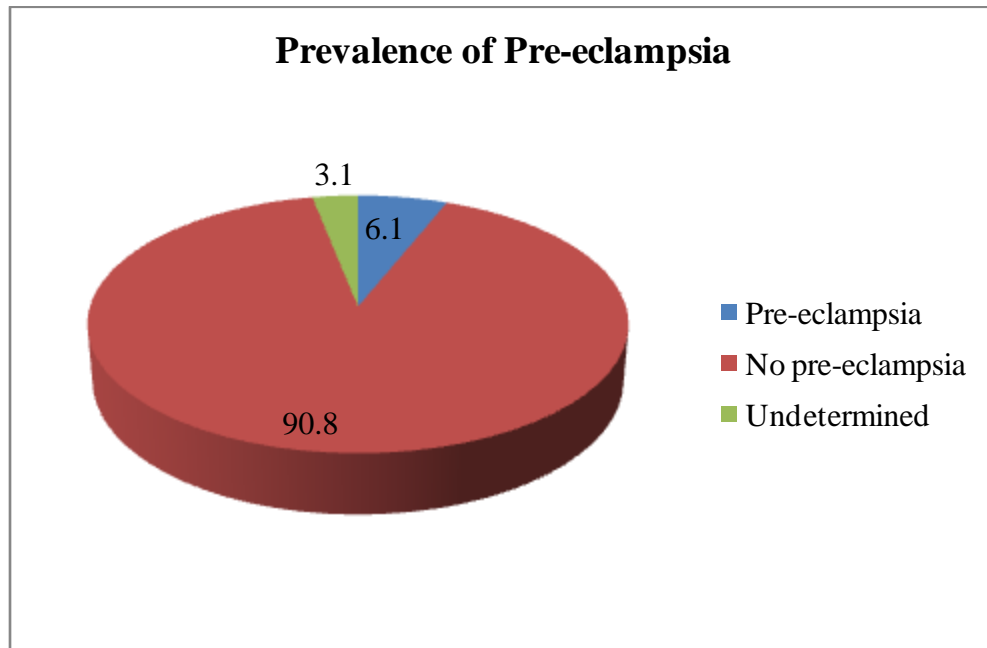


Figure 4: Prevalence of pre-eclampsia (n=229)

4.3 Prevalence of known risk factors of pre-eclampsia among pregnant women attending ANC in Kibera sums

Several risk factors have been associated with pre-eclampsia. This study sought to screen participant for the following known risk factors: young maternal age, parity, history of pre-eclampsia in previous pregnancies, family history of pre-eclampsia, multiple gestation, pre-existing hypertension as well as pre-existing diabetes mellitus. Table 2 below gives the prevalence of the selected risk factors among participants

Table 2: Prevalence of risk factors among participants (n=229)

Risk factors	Frequency	Prevalence
Young maternal age (20 years and younger)	51	22.3%
Primigravidae	59	25.8%
Previously history of pre-eclampsia	14	6.1%
Family history of pre-eclampsia	31	13.5%
Multiple pregnancy	11	4.8%
Pre-existing hypertension	15	6.6%
Pre-existing diabetes	3	1.3%

4.4 Proximate factors that contribute to adverse outcomes of pre-eclampsia among pregnant women attending ANC in Kibera slums

4.4.1 Proportion of Pre-eclamptic patients appropriately referred

Of the fourteen participants that were classified as suffering from pre-eclampsia, one (7.1%) was appropriately referred to a health facility for the management of the condition.

Table 3: Proportion of pre-eclamptic patients referred (n=229)

	Pre-eclampsia		Percentage
	Yes	No	
Referred	1	13	7.1

4.4.2 Level of awareness of symptoms of pre-eclampsia among the pregnant women attending ANC clinics in Kibera slums

Table 4: Distribution of awareness of symptoms of pre-eclampsia (n=229)

Awareness of symptoms	Yes	No
Severe headache	37.1% (n=85)	62.9% (n=144)
Blurred vision	28.8% (n=66)	71.2% (n=163)
Edema of the face	31.0% (n=71)	69.0% (n=158)
Edema of the hands	33.2% (n=76)	66.8% (n=153)

About 37% (n=85) of the participants were aware that severe headache was a symptom of pre-eclampsia while 28.8% (n=66) were aware that blurred vision was indeed a symptom of pre-

eclampsia. Further, 31.0% (n=71) identified edema of the face while 33.2% (n=76) identified edema of hands as possible symptoms of pre-eclampsia.

4.4.3 Actions taken by participants when symptoms of pre-eclampsia occurred

About 99% (n=226) would visit a health facility if they noticed any symptoms of pre eclampsia. Further, 66.4% (n=150) of these would reach a health facility within thirty minutes of starting the journey, while 28.3% (n=64) would take between thirty minutes and one hour and 5.3% (n=12) would take one hour or more to reach the health facility.

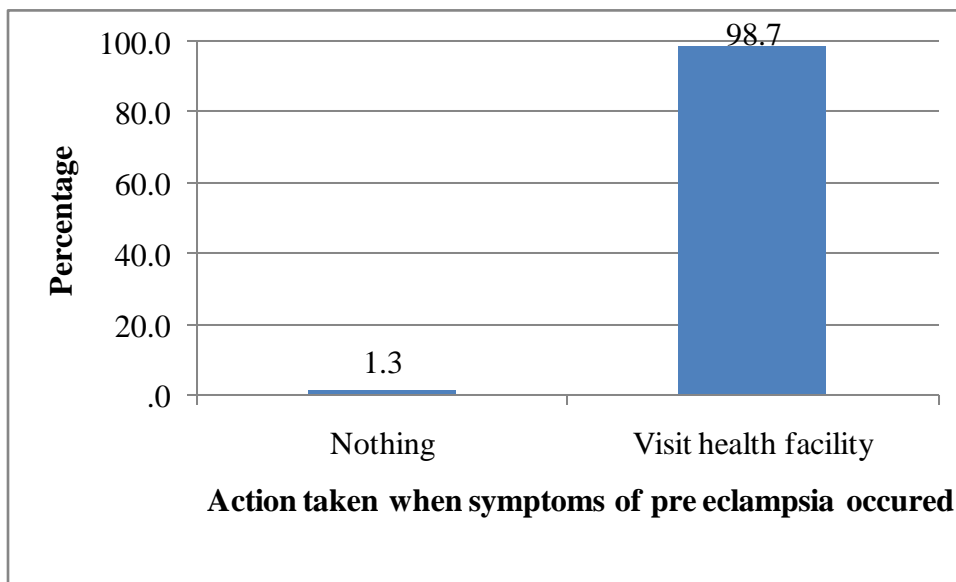


Figure 5: Actions taken by participants if symptoms of pre-eclampsia occurred in current pregnancy (n=229).

4.4.4 Preparedness of participants to deal with pre-eclampsia related emergencies

Further, the study revealed that 72.1% (n=165) of the participants had set aside some emergency funds as part of preparedness to deal with possible visit to health facility, 52.0% (n=119) had identified a means of transport, 65.5% (n=150) had identified a helper/companion while 78.2% (n=179) had identified a decision maker should there be need.

Table 5: Distribution of preparedness to deal with pre-eclampsia related emergencies among the participants (n=229).

Preparedness	n	Percentage (%)
Set aside emergency funds	165	72.1
Identified means of transport	119	52.0
Identified a helper/companion	150	65.5
Identified a decision maker	179	78.2

CHAPTER 5: DISCUSSION

The prevalence of pre-eclampsia among pregnant women attending ANC in Kibera slums was found to be 6.1%. However, some 3.1% of participants who had high blood pressures did not have corresponding urinalysis for proteinuria done to help in classifying them as having pre-eclampsia or not. Therefore, it's possible that the prevalence of pre-eclampsia in Kibera slums could be higher than that found in this study. There is paucity of data on the prevalence of pre-eclampsia in Kenya generally and Kibera slums specifically, for comparison. However, some studies done in different settings have been discussed here. Regionally, a study conducted in Addis Ababa, an urban setting in Ethiopia revealed a prevalence of 5.3% (Teklu and Gaym, 2006). Another study done in a town in Zanzibar found a prevalence rate of 9% (Tufton and Patel, 2010).

In Africa, prevalence of pre-eclampsia varies from region to region with countries such as South Africa, Egypt, Tanzania, and Ethiopia having rates ranging from 1.8% to 7.1% (Kayode and Olusimbo, 2011). In Lagos, Nigeria, prevalence of preeclampsia is 7.6% (Anorlu et al, 2005) while some urban regions in Nigeria have recorded rates as high as 16.7% (Kayode and Olusimbo, 2011). Worldwide, it's estimated that the prevalence of pre-eclampsia is a 2-8% among pregnancies (Lopez-Jaramillo et al, 2002). It worth noting, however, that the prevalence of 6.1% found in this study is on the higher side of these ranges.

The prevalence of known risk factors of pre-eclampsia in this study ranged from 1.3% for pre-existing diabetes mellitus to 25.8% for primigravidae. While these rates are low, it's still

important to look out for them so that close monitoring and follow-up of cases can be done. This will in turn ensure timely diagnosis and management. It is recommended that pregnant women should be assessed at their first antenatal clinic for risk factors of pre-eclampsia, but screening (detection of pre-eclampsia) should be done at every subsequent visit (WHO, 1994). Several risk factors are associated with the disease. These include primigravida, maternal age (below 20 and over 35 years), multiple pregnancy, family history of pre eclampsia or eclampsia, history of pre eclampsia/eclampsia in a previous pregnancy, hydatidiform mole, renal disease, obesity, diabetes mellitus, change of male partner and women with chronic hypertension (Kirsten and Deborah, 2005). It is, however, important to note that the presence of these factors is not a guarantee to developing pre-eclampsia in the course of that pregnancy. Screening for pre-eclampsia using maternal history alone is accurate in detecting only 45.3% of cases (Papageorghiou, 2005). In developing countries, strategies for risk assessment should still be based on obstetric and medical history and clinical examination of women (WHO, 1994).

Making the diagnosis of pre eclampsia is just one aspect of management of the condition. Prompt referral, treatment and follow-up of patients make the other aspects. Referral of diagnosed cases is important because health centers and dispensaries, which primarily offer ANC services, as well as other promotive and preventive health services, are managed by nurses and clinical officers (MOH, 2005). These cadres of health professionals may not have the knowledge and skills to handle obstetric complications like pre eclampsia making the need for prompt referral (to facilities where patients can get the services of a doctor) of patients diagnosed to have pre eclampsia before complications set in. Referral of 7.1% (n=1) of pregnant women diagnosed to have pre eclampsia leaves a large proportion of women requiring referral and management at risk

of developing complications of the disease. A study in Enugu state, South Eastern Nigeria, reveals that 46.4% (n=66) of maternal deaths in that state are as a result of delays in referral of patients diagnosed to have pre eclampsia/eclampsia (Onah et al, 2005). Another study done at a tertiary care hospital in Peshawar, Pakistan, revealed that 60% (n=43) of pregnant women who developed eclampsia in that health facility were as a result of some delays in seeking medical help by the pregnant women (Shaheen et al, 2003). Timely referral is therefore important in prevention of complications of pre-eclampsia.

Awareness of symptoms of pre-eclampsia was found to be low ranging between 37.1% for severe headache and 28.8% for blurring of vision. Awareness of symptoms is necessary if the pregnant women are going to be able to notice them and subsequently seek appropriate medical attention promptly. This is important because delays in seeking care lead to development of complications like eclampsia, which could in turn result in maternal deaths. In Kenya, less than half of women are aware of danger signs of pregnancy (KDHS, 2008/9). It's possible that this low level of awareness may be contributing to the high maternal deaths noted in the slums of Nairobi.

A study in Peshawar, Pakistan revealed that 60% (n=43) of patients in that study developed eclampsia as a result of delay in seeking care in part due to inability to recognize the symptoms of pre-eclampsia (Shaheen et al, 2003). These complications can be avoided if the women were able to recognize the symptoms and seek care early, given that nearly 99% of participants in this study indicated that they would care from health facilities if they noticed symptoms of pre-eclampsia.

This study also sought to describe the measures taken by participants if symptoms of pre-eclampsia, or indeed other obstetric emergencies occurred in the current pregnancy. Two hundred and twenty six respondents (98.7%) said they would immediately visit a health facility in case of an obstetric emergency. It's encouraging to note that almost all participants would visit a health facility, compared to the case of Bangladesh, where a study on determinants of the use of maternal health services showed that only 42.6% of patients who suffered fits/convulsions during pregnancy sought care from qualified medical personnel, while more than 73% of women who had edema did not seek any form of care (Nitai et al, 2003). A study in Nigeria assessing utilization of health services showed that 42.9% of pregnant mothers did not use health facilities in emergency situations (Moore et al, 2011). Further to assessing what actions participants would take, the study sought to find out how long it would take participants to reach a health facility in case a decision was made to visit one. Two hundred and fourteen respondents (94.7%) would be able to reach health facilities with one hour, one hundred and fifty (66.4%) being able to reach the health facilities within thirty minutes. This shows that women in Kibera slums have no problem with physical access to health facilities as they would reach the said facilities in a fairly short period of time compared to Nigeria, where 68.7% of pregnant women cited long distance to health facilities as an obstacle to utilization of health services (Moore et al, 2011).

The study also sought to establish the social factors that would hinder accessing care. In this regard, it was established that more than half of respondents were prepared for obstetric emergencies by setting aside some money for emergencies, identifying a helper to escort them to health facilities, identifying means of transport and even identifying a decision maker. In a

Nigerian study, costs of health care, lack of transport to health facilities as well as cost of transport were cited by a majority of participants as obstacles to utilization of health care (Moore et al, 2011). Such social factors are important in maternal safety because on average 26.8% of maternal deaths are influenced by these factors (Wasim et al., 2004; Akinola et al., 2008; Brunson, 2010). However, it would be desirable for all pregnant women to be adequately prepared for obstetric emergencies to reduce preventable maternal deaths due to social factors.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The prevalence of Pre-eclampsia among pregnant women attending ANC clinics in Kibera slums was found to be on the higher side of rates recorded in African settings (range of 1.8% to 7%) yet prevalence of known risk factors of pre-eclampsia among respondents was low. The proximate factors that contributed to the adverse outcomes of pre-eclampsia included missed diagnosis for respondents who had high blood pressure but no corresponding urinalysis for proteinuria to help classify them, very low rate of referral of diagnosed cases, lack of awareness of pre-eclampsia and its symptoms and lack of preparedness of some respondents to handle any possible complications in the course of the pregnancy. However, majority of participants were likely to seek care in health facilities.

6.2 Recommendations

1. All pregnant women attending ante natal clinic should receive information (i.e. through health talks, leaflets, etc) on symptoms of pre-eclampsia to enable them detect and take timely and appropriate actions when these are noticed. Further, all ANC clients should be educated on the need to have adequate preparations for any obstetric complications that may set in the course of the pregnancy. These preparations include setting aside some emergency funds, organizing transport, etc.
2. All pregnant women of gestation age 20 weeks should be screened for pre-eclampsia by checking blood pressure and testing urine for proteinuria. These

should be done at every subsequent ante-natal visit since pre-eclampsia can set in at any stage of the pregnancy.

3. All pregnant women should be assessed for known risk factors of pre-eclampsia at the first ante-natal visit. Patients with risk factors should then be closely followed up for development of pre-eclampsia even though the mere presence of these factors is not a guarantee to developing pre-eclampsia in the course of that pregnancy.
4. All pre-eclamptic patients should be referred to centers that have the expertise to handle them.
5. All the staff providing services at ante-natal care clinics should be sensitized on the risks pregnant women would suffer if not referred promptly.
6. Implementation research should be carried out sensitize ANC health workers on screening for pre-eclampsia and its risk factors, prompt referral and management of cases.

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APPENDICES

Informed Consent

Consent Explanation Form for Exit Interviews (using Questionnaires)

Dear Participant,

Introduction

My name is Dr Abuya Norbert Otieno, a post graduate student pursuing a Master of Public Health (MPH) degree at the School of Public Health, University of Nairobi. As one of the requirements for completion of this course, I am required to carry out a study in Kibera Slums, Nairobi.

Aim

The purpose of my study is to establish the prevalence and risk factors of pre-eclampsia among pregnant women attending Antenatal clinic in Kibera slums, Nairobi.

Procedure

Your selection to participate in this study is by chance and I wish to request you to kindly allow the interviewer to take some of your time to ask you some questions. If you agree to participate in the study, the interviewer will ask you some questions and record your answers in the questionnaire. The questions will address the factors about prevalence and risk factors of pre-eclampsia. Some of the questions may be personal. However, you are totally free not to answer any question that you are not comfortable with.

Risks

There are no risks to you or your unborn child in participating in this study. You will be simply requested to answer the questions as they are asked, and you are not obliged to answer a question if you do not feel like.

Benefits

There may be no direct benefit to you and your unborn child from this study. However, it is expected that the findings of this study will be used to come up with better plans and

interventions to reduce the suffering and deaths of pregnant women and their unborn children caused by pre-eclampsia and eclampsia in Kibera slums, and other slums around the country.

Confidentiality/Privacy

The information you give for this study will be treated with utmost confidentiality during the study and thereafter. Your name will not be recorded anywhere on the questionnaire. None of the information you give will be linked to you and it will only be used for the intended purpose.

Right to Refuse or Withdraw

Your participation in this study is voluntary. You are free to decline to participate in this study or withdraw during the process of interviewing. You are free not to answer any questions that you are not comfortable with during the interview. Refusing to participate or withdrawing from the study will not be used in any way to deny you your rights to health care or any of your other constitutional rights.

Persons to contact

In case of any complaints on any aspect of this study, kindly contact:

- 1) Dr Abuya Norbert Otieno – P.O BOX 416-00511, Ongata Rongai. Tel. 0722609587.
- 2) The Chairperson, KNH/UON-ERC P.O BOX 20723, NBI. Tel 0202726300-9 ext 44102.

Informed Consent Form

I,, after the explanation given to me regarding the study, have understood the nature, aim, risks and benefits of this study and I hereby consent/do not consent to take part in this study.

Name of respondentSignature.....

Name of interviewer.....Signature.....

Date.....

Questionnaire

Questionnaire id no

Date/...../..... (Day/Month/Year)

Health facility.....

Name of interviewer.....

1. Personal information

a. Date of birth/..... /.....

b. Place of residence (Village).....

c. Level of education (Tick one)

None primary secondary
tertiary

d. Level of income per month in Kenya shillings(Tick one)

2500 and below 2501-5000
5001-7500
7501-10000 10,000 and more

2. Clinical information (please tick appropriate response, unless indicated otherwise)

a. Total number of pregnancies, including this one.

One two three four
five and over

b. Gestation in weeks (Enter number of weeks)

c. Systolic BPmmHg

Diastolic BPmmHg (Enter readings)

d. Proteinuria nil + ++

+ + + urinalysis not done

e. Oedema absent present not indicated

f. Is this pregnancy diagnosed or suspected to be multiple?

YES NO DON'T KNOW

g. Has the health worker talked to you about your BP today?

YES NO

h. How many ANC visits have you attended this current pregnancy?

One two to three four and above

i. Have you been referred to a higher level facility because of your BP?

YES NO

3. Awareness information (Tick the appropriate response)

a. Have you heard of high blood pressure? YES NO

b. Have you heard of high blood pressure in pregnancy? YES NO

c. Are you aware that such high blood pressure in pregnancy can be complicated by getting convulsions/fits? YES NO

d. If yes to any of the above, where did you get that information from? If no to all go to question 3 (e)

Community members radio TV

Healthcare worker

e. What are some of the danger signs in this pregnancy that may make you visit a health facility? (Tick as appropriate).

Vaginal bleeding

Foetus not kicking

Convulsions

Fever

Other (Enter response)

f. Are you aware that any of the following symptoms could suggest high blood pressure in pregnancy?

(i) Severe headache YES NO

(ii) Inability to see clearly (blurred vision) YES NO

(iii) Swelling of the face YES NO

(iv) Swelling of the hands YES NO

g. What actions will you take if you notice these or any other unusual symptom during this pregnancy? (If the answer is nothing proceed to question 4)

Nothing Visit health facility Visit TBA

h. Approximately, how far from your house will you be able to get this help?

30 minutes or less 30 mins-1 hr more than 1 hr

i. How prepared are you to reach the health facility in case of an emergency?

(i) Set aside emergency funds? YES NO

(ii) Identified means of transport? YES NO

- (iii) Identified a helper/companion? YES NO
- (iv) Identified a decision maker? YES NO

4. Information on risk factors (Tick the appropriate response)

a. Do you suffer any of these illnesses?

- (i) High blood pressure YES NO DON'T KNOW
- (ii) High blood sugar YES NO DON'T KNOW
- (iii) Have you suffered high blood pressure in previous pregnancy?
 YES NO

b. Has anyone in your family suffered any of these illnesses?

- (i) High blood pressure in pregnancy? YES NO
- (ii) Convulsions/fits during pregnancy? YES NO

5. Are you satisfied with the ANC services you received here today?

YES NO

6. What improvements or changes would you like to see in order to serve you better?

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.....

.....

.....

END, THANK YOU FOR YOUR TIME



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KNH/UON-ERC
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Link: www.uonbi.ac.ke/activities/KNHUoN



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P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/82

19th April 2012

Dr. Abuya Norbert Otieno
School of Public Health
College of Health Sciences
University of Nairobi

Dear Dr. Otieno

RESEARCH PROPOSAL: "PREVALENCE AND RISK FACTORS OF PRE-ECLAMPSIA AMONG PREGNANT WOMEN ATTENDING ANTENATAL CLINIC IN KIBERA SLUMS, NAIROBI" (P42/02/2012)

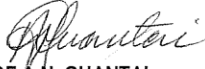
This is to inform you that the KNH/UoN-Ethics & Research Committee (ERC) has reviewed and **approved** your above revised research proposal. The approval periods are 19th April 2012 to 18th April 2013.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN -ERC website www.uonbi.ac.ke/activities/KNHUoN

Yours sincerely



PROF A.N. GUANTAI
SECRETARY, KNH/UON-ERC

- c.c. The Deputy Director CS, KNH
The Principal, College of Health Sciences, UON
The Director, School of Public Health, UON
The HOD, Records, KNH
Supervisors: Dr. Tom Olewe, Dr. Richard Ayah