



**USE OF NATIONAL GUIDELINES IN MANAGEMENT OF SEVERE PRE-  
ECLAMPSIA/ECLAMPSIA AT GARISSA PROVINCIAL GENERAL  
HOSPITAL**

**A COHORT STUDY**

A RESEARCH DISSERTATION SUBMITTED FOR MASTER OF MEDICINE IN  
OBSTETRICS AND GYNAECOLOGY

**PRINCIPAL INVESTIGATOR**

*Dr. John Omweri Omboga, M.B.Ch.B,*

*Post graduate student, department of Obstetrics and Gynecology, School of Medicine, College of  
Health Sciences, University of Nairobi.*

*Reg.no. H58/63998/2010*

## **SUPERVISORS**

1. Prof. James N. Kiarie, *M.B.Ch.B, (M.Med.Obs/Gyn), M.P.H*

Associate Professor, Department of Obstetrics and Gynecology, School of Medicine, College of Health Sciences, University of Nairobi and

Consultant Obstetrician and Gynecologist, Kenyatta National Hospital.

2. Dr. Weston Khisa, *M.B.Ch.B, M.Med. (Obs/Gyn).*

Honorary lecturer, consultant, department of reproductive health and VVF project manager, Kenyatta National Hospital

## TABLE OF CONTENTS

SUPERVISORS.....	ii
CERTIFICATE OF SUPERVISION.....	vi
PRINCIPAL RESEARCHER.....	vi
DECLARATION.....	vii
DEDICATION.....	viii
ACKNOWLEDGEMENT.....	ix
LIST OF ABBREVIATIONS.....	x
LIST OF FIGURES.....	xii
LIST OF TABLES.....	xiii
ABSTRACT.....	xiv
CHAPTER ONE.....	1
INTRODUCTION.....	1
BROAD OBJECTIVE.....	2
SPECIFIC OBJECTIVES.....	2
CHAPTER TWO.....	3
LITERATURE REVIEW.....	3
<i>EPIDEMIOLOGY</i> .....	3
<i>PATHOGENESIS</i> .....	5
<i>DIFFERENTIAL DIAGNOSIS</i> .....	6
<i>GUIDELINES</i> .....	12
CONCEPTUAL FRAMEWORK.....	22
CHAPTER THREE.....	24
METHODOLOGY.....	24
STUDY AREA.....	24
STUDY DESIGN.....	24
STUDY POPULATION.....	25
Inclusion criteria.....	25
Exclusion criteria.....	25
SAMPLE SIZE DETERMINATION.....	25
STUDY PROCEDURES.....	26

STUDY INSTRUMENT.....	26
DATA COLLECTION.....	26
QUALITY CONTROL .....	27
DATA ENTRY, CLEANING AND ANALYSIS .....	27
ETHICAL CONSIDERATIONS.....	28
CHAPTER FOUR.....	29
RESULTS.....	29
Clinical data on eclampsia and preeclampsia management .....	30
Management of severe preeclampsia .....	30
Guideline adherence and newborn outcomes .....	31
Identification of signs for severe preeclampsia/eclampsia by health workers .....	37
Organ risk during eclampsia.....	38
Pharmacologic management of eclampsia and preeclampsia .....	40
Guideline adherence.....	40
Availability of guidelines as perceived by health workers .....	41
Drug inventory record.....	43
STUDY LIMITATIONS.....	44
CHAPTER FIVE .....	45
DISCUSSIONS.....	45
CHAPTER SIX.....	48
CONCLUSION AND RECOMMENDATIONS .....	48
RECOMMENDATIONS .....	48
REFERENCES .....	49
APPENDICES .....	52
APPENDIX 1: INFORMED CONSENT.....	52
APPENDIX 2: CONSENT FORM.....	54
APPENDIX 3: QUESTIONNAIRE .....	55
<i>For healthcare workers</i> .....	55
APPENDIX 4: DATA ABSTRACTION TOOL FOR MANAGEMENT OF SEVERE PRE-ECLAMPSIA/ECLAMPSIA .....	58
APPENDIX 5: .....	60

NATIONAL GUIDELINES FOR QUALITY OBSTETRICS AND PERINATAL CARE .....	60
APPENDIX 6: DRUG INVENTORY RECORD.....	67

## **CERTIFICATE OF SUPERVISION**

This is to certify that this Thesis was developed under my guidance.

1. Prof. James N. Kiarie, *M.B.Ch.B*, M.Med. (*Obs/Gyn*), *M.P.H*;

Associate Professor, Department of Obstetrics and Gynecology,

School of Medicine, College of Health Sciences, University of Nairobi and

Consultant obstetrician and gynecologist, Kenyatta National hospital.

Signature.....Date.....

2. Dr. Weston Khisa, *M.B.Ch.B*, M.Med (*Obs/Gyn*);

Honorary lecturer, consultant, department of reproductive health and VVF project manager,  
Kenyatta National Hospital.

Signature.....Date.....

## **PRINCIPAL RESEARCHER**

Dr. John O. Omboga, *M.B.Ch.B*,

Post graduate student, Department of Obstetrics and Gynecology, School of Medicine, College  
of Health Sciences, University Of Nairobi.

Reg.No.H58/63998/2010

Signature.....Date.....

## **DECLARATION**

I, Dr. John O. Omboga, the principal researcher declare that this is my original work and that this dissertation has never been presented to any university for award of a degree.

## **DEDICATION**

This book is dedicated to my daughter Krister, son Kyle and dear wife Melody for their unconditional love and support.

To my late parents for their sincere sacrifice and continued support to ensure that I got the best education.



## ACKNOWLEDGEMENT

I am grateful to GOD for giving me the opportunity to do this postgraduate program. I thank the Government of Kenya through the Ministry Of Health for sponsorship in this training.

I give my sincere thanks to my supervisors Prof. James Kiarie and Dr. Weston Khisa for providing me with invaluable mentorship and guidance in developing and writing this dissertation.

My gratitude goes to **PRIME-K** for funding this study.

“The funding is from the Linked-Strengthening Maternal, Newborn and Child Health (MNCH) Research Training in Kenya. The grant is linked to partnership of innovative Medical Education in Kenya (PRIME-K). The project was supported by Award Number 5R24TW008907 from the US National institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the US National Institutes of Health”.

I thank the Medical superintended of Garissa Provincial General Hospital, Dr. Amos Ayunga and the consultant obstetrician and gynecologist Dr. Musalia who helped me collect data and Mr. Philip Ayieko, the biostatistician, who carried out the data analysis.

I would like to thank all the consultants and senior registrars in the department of Obstetrics and Gynecology, University Of Nairobi and Kenyatta National Hospital for their invaluable guidance during training. To my fellow students, thank you for the advice and support you accorded me.

A special thank you to Neema Hospital, Mbagathi District Hospital and Mama Lucy Hospital for allowing me to rotate in their institutions during my elective term from February 2012 to January 2013.

Last but not least, I thank my dear wife, Melody and children Krister and Kyle for encouraging me and tolerating my absence from home during this training.

## LIST OF ABBREVIATIONS

ACOG .....	American College of Obstetricians and Gynecologists
ALT.....	Alanine aminotransferase
ACE.....	Angiotensin Converting Enzyme
AST.....	Aspartate aminotransferase
AFI.....	Amniotic Fluid Index
ARM.....	Artificial Rapture of Membranes
BP .....	Blood Pressure
BPP .....	Biophysical Profiles
CCF .....	Congestive Cardiac Failure
C/S.....	Caesarean Section
CTG .....	Cardio Tocograph
EBM.....	Evidence-Based Medicine
FBC.....	Full Blood Count
GDP.....	Gross Domestic Product
GP .....	General Practitioner
GPGH .....	Garissa Provincial General Hospital
HELLP.....	Hemolysis Elevated Liver enzymes, Low Platelets
ICU .....	Intensive Care Unit
I.M .....	Intramuscular
I.V .....	Intravenous

IOL .....Induction of Labor

IUGR .....Intra Uterine Growth Restriction

KDHS.....Kenya Demographic Health Survey

KNH .....Kenyatta National Hospital

LFTs .....Liver Function Tests

MgSO<sub>4</sub> .....Magnesium sulphate

MOH-.....Ministry of Health

NST .....Non-Stress Test

RCOG .....Royal College of Obstetricians and Gynecologists

RI .....Resistance Index

RFTs .....Renal Function Tests

WHO .....World Health Organization

IFN-γ.....Interferon gamma

PIGF.....Platelet Inhibitory Growth Factor

sEng.....Soluble Endoglin

Th1.....T helper 1 cells

VEGF.....Vasculoendothelial Growth Factor

## LIST OF FIGURES

<i>Figure 1: Number of guideline recommended tasks performed for eclampsia patients admitted at Garissa PGH.....</i>	<i>32</i>
<i>Figure 2: Number of guideline treatment tasks completed versus development of complications</i>	<i>33</i>
<i>Figure 3: Health worker recognition of alerts for severe pre-eclampsia at Garissa PGH .....</i>	<i>38</i>
<i>Figure 4: Drugs identified for management of eclampsia and preeclampsia by health workers at Garissa PGH .....</i>	<i>40</i>
<i>Figure 5: Health worker awareness of guideline availability in GPGH.....</i>	<i>41</i>
<i>Figure 6: health workers' reported barriers to utilization of MoH guidelines.....</i>	<i>42</i>

## LIST OF TABLES

<b>Table 1:</b> Patient characteristics .....	29
<b>Table 2:</b> Basic characteristics of health workers providing maternity care at Garissa PGH...	30
<b>Table 3:</b> Performance of guideline recommended management practices for eclampsia and preeclampsia at Garissa PGH.....	31
<b>Table 4:</b> Use of guidelines, mode of delivery and neonatal apgar scores at 5 min. ....	32
<b>Table 5:</b> Newborn outcomes and guidelines.....	34
<b>Table 6:</b> Documented management of eclampsia.....	35
<b>Table 7:</b> Health worker assessment of knowledge and treatment of preeclampsia/eclampsia .....	36
<b>Table 8:</b> Body organs identified as at risk during eclampsia by health workers at Garissa PGH .....	38
<b>Table 9:</b> Assessment of guideline use.....	39
<b>Table 10:</b> Drug inventory record.....	43

## ABSTRACT

**Background:** Research shows that there is an improved outcome when standardized guidelines are used in the management of mothers with severe preeclampsia/eclampsia<sup>1,2</sup>.

Unavailability and non-use of these guidelines could contribute to deaths and poor outcomes reported in many District and Provincial Hospitals in Kenya. Lack of resources for guideline implementation and lack of continuous knowledge appraisal for healthcare workers regarding the current recommendations in the management of severe preeclampsia/eclampsia could be contributing to non-use of guidelines.

According to Kenya Demographic Health Survey (KDHS) 2008/9, maternal mortality rate is higher in Garissa Provincial General Hospital (GPGH) standing at 1000-1300 per 100,000 live births, compared to the national average of 488 per 100,000 live births.

The World Health Organization (WHO) has made progress in formulating evidence based policies. The Kenyan ministry of health guidelines for management of severe pre-eclampsia/eclampsia uses WHO guidelines as the reference with modification to fit in with the local situations. The WHO has shown and recommended the use of magnesium sulphate ( $MgO_4$ ) in the management of severe pre-eclampsia/eclampsia as it improves maternal outcome and minimizes morbidities and mortalities. Despite this policy recommendation and the eclampsia trial which showed efficacy of  $MgSO_4$  for management of severe preeclampsia/eclampsia having been published over ten years ago and despite it being a drug of choice in WHO policy, this is not widely practiced in most hospitals in Kenya. Garissa Provincial General Hospital (GPGH) is a case in point. So, clearly, shifting policy is one thing and changing behavior among health workers is another.

This study helped to identify the barriers health care workers faced in application of guidelines and helped fill the gaps between policy and practice.

**Objective:** To assess barriers to using severe preeclampsia/eclampsia guidelines at Garissa PGH.

**Design:** A cohort study where antenatal, intrapartum and postpartum treatment given to women with severe pre-eclampsia/eclampsia were analyzed. An interviewer administered questionnaire

was used to assess health workers' knowledge, attitude and practices. A drug inventory chart was used to assess drug stocking in the hospital. Women were classified into those in whose management guidelines were adhered to and those where they were not. Their subsequent outcomes were documented. The target population was antenatal women visiting Garissa PGH and a sample size of 81 cases was used to estimate the proportion in whom guidelines were followed with a 10% precision. Recruitment was done by convenient sampling. Women were included if they developed severe pre-eclampsia/eclampsia from the 20<sup>th</sup> week of gestation or in the puerperium. Data was analyzed using SPSS 16.

**Outcome measures:** maternal morbidity was assessed based on postnatal hospital stay, occurrence of eclampsia in a patient with severe pre-eclampsia, presence of organ damage and maternal death.

Fetal outcome was assessed based on the need for admission to nursery, Apgar score at 5 minutes, birth weight and gestational age at which pregnancy was terminated.

**Setting:** Garissa Provincial General Hospital.

**Materials and methods:** data abstraction tool used to determine whether treatment given to women with preeclampsia/eclampsia was according to guideline recommendations. An interviewer administered questionnaire was used to assess knowledge, attitude and practices of healthcare workers.

**Ethical considerations:** permission to carry out this research was sought from the Kenyatta National Hospital (KNH)/UoN ethics and research committee (*appendix 7*). Permission was obtained from the medical superintendent at Garissa PGH.

Health workers in this study were required to give a written informed consent (*appendix 2*) prior to their participation. The information gathered from research participants was treated confidentially.

**Results:** The study showed that more nurses (61.19%) and clinical officers (23.43%) were the majority of healthcare professionals handling women with severe preeclampsia/eclampsia than trained doctors (15.38%). It also showed that doctors were generally aware of guideline recommendations than were nurses and clinical officers (p value=1.000). Though a majority of

health care workers alluded to the existence of guidelines in the Hospital, medical records of patients managed with severe preeclampsia/eclampsia examined were short of the guideline recommendations.

Although most of healthcare workers were in agreement that guidelines for management of severe preeclampsia/eclampsia existed, they were rarely followed, if at all and thus the high mortality and morbidity noted can be attributed to this.

**Conclusion:** guidelines for management of severe preeclampsia/eclampsia were available in Garissa PGH but management of women with these conditions did not always adhere to guideline recommendations. Most of the staff managing these women had little or no knowledge on what to do hence the high mortality and morbidity reported.

**Recommendations:** There is need to consider continuing medical education for nurses, clinical officers and medical officers to shore up their knowledge on management of women with severe preeclampsia/eclampsia as per the guideline recommendations. The relevant authorities charged to ensure that quality healthcare is offered should intensify supervision to ensure the recommended management is practiced. Prospective and cohort studies will be needed to validate the findings and confirm whether our findings are due to failures in recording tasks that are actually performed or whether some tasks that are recorded are actually not performed.



# **CHAPTER ONE**

## **INTRODUCTION**

Severe preeclampsia/eclampsia remains one of the leading causes of maternal mortality and morbidity and poor neonatal outcomes worldwide, affecting 5-9% of all pregnancies. The WHO has developed evidence-based guidelines that recommend a raft of measures to reduce problems associated with this condition. One of them is the landmark preeclampsia/eclampsia trial which showed that MgSO<sub>4</sub> significantly improves outcome. The Kenyan MOH borrows heavily from the WHO guidelines for management of preeclampsia/eclampsia. These guidelines are compiled in a booklet called '*National Guidelines for quality obstetrics and perinatal care, 2012*' (appendix 5). However, in many Kenyan Hospitals, mortality and morbidity from this condition still remains high. This study set out to use Garissa PGH to assess and document availability and use of these proven guidelines in such settings.

## **STATEMENT OF THE PROBLEM**

Are guidelines for preeclampsia/eclampsia management existent in GPGH; are they referred to by healthcare workers and what are the consequences of use and/or non-use in Garissa PGH.

## **RESEARCH QUESTION**

Are guidelines for management of severe preeclampsia/eclampsia used by healthcare workers in Garissa PGH and is failure to use guidelines associated with poor maternal and neonatal outcomes?

## **NULL HYPOTHESIS (HO)**

Among women with severe preeclampsia/eclampsia, pregnancy outcomes are not different in those where evidence based guidelines are used from those in whom these guidelines are not used.

## **ALTERNATIVE HYPOTHESIS (H1)**

Use of evidence based guidelines in the management of women with severe pre-eclampsia/eclampsia is associated with improved maternal and neonatal outcomes as compared to non-use of these guidelines.

## **BROAD OBJECTIVE**

To assess the barriers that healthcare workers faced in guideline use in the management of severe pre-eclampsia/eclampsia in Garissa PGH and to document the outcomes in terms of maternal and neonatal morbidities and mortalities due to non adherence to guidelines.

## **SPECIFIC OBJECTIVES**

1. To describe current practices in peri-natal healthcare for women with severe pre-eclampsia/eclampsia in Garissa PGH and determine whether they were aligned with MOH guideline recommendations.
2. To determine barriers to the utilization of MOH guidelines in management of severe preeclampsia/eclampsia.
3. To assess knowledge, attitude and practices of different cadres of healthcare professionals in the management of severe pre-eclampsia/eclampsia

## **CHAPTER TWO**

### **LITERATURE REVIEW**

Pre-eclampsia is a multisystem disorder unique to pregnancy, which is usually associated with raised blood pressure and with or without significant proteinuria. It can present before 20 weeks gestation. Worldwide it affects 5-9% of all pregnancies<sup>5</sup>.

Eclampsia is when one or more generalized seizures occurs in association with the syndrome of preeclampsia.

#### ***EPIDEMIOLOGY***

Pre-eclampsia affects 5-9% of all pregnancies worldwide<sup>7</sup>, with onset of symptoms in the second or third trimester, most commonly after the 32<sup>nd</sup> week. Some women will experience pre-eclampsia as early as late first trimester or early second trimester, though this is rare. It is much more common in women who are pregnant for the first time<sup>8</sup>, and its frequency drops significantly in subsequent pregnancies.

Pre-eclampsia is also more common in women who have preexisting hypertension, diabetes, autoimmune disease such as lupus, various inherited thrombophilias such as factor V Leiden, renal disease, women with a family history of pre-eclampsia, obese women and women with multiple gestation. The single most significant risk for developing pre-eclampsia is having had pre-eclampsia in a previous pregnancy.

Pre-eclampsia may also occur in the immediate postpartum period, the most common period being 24-48 hours postpartum and careful attention should be given to pre-eclampsia signs and symptoms within the period.

#### ***CAUSES***

Pre-eclampsia is thought in many cases to be caused by shallowly implanted placenta which become hypoxic leading to an immune reaction characterized by secretion of up regulated inflammatory mediators from the placenta and acting on the vascular endothelium. The shallow implantation is thought to stem from the maternal immune systems' response to the placenta. This theory emphasizes the role of maternal immune system and refers to evidence suggesting a lack of established immunological tolerance in pregnancy resulting in an immune reaction

against paternal antigens from the fetus and its placenta<sup>12</sup>. In some cases of pre-eclampsia it is thought the mother lacks the receptors for the proteins the placenta is using to down regulate the maternal immune systems' response to it<sup>13</sup>. This view is also consistent with evidence showing many miscarriages to be an immunological disorder where the mother's immune system unleashes a destructive attack on tissues of the developing child<sup>14</sup>.

Studies have shown that the initiating event in preeclampsia is reduced uteroplacental perfusion as a result of abnormal cytotrophoblast invasion of spiral arterioles. Placental ischemia is thought to lead to widespread activation/dysfunction of the maternal vascular endothelium that results in enhanced formation of endothelin and thromboxane, increased vascular sensitivity to angiotensin II, and decreased formation of vasodilators such as nitric oxide (NO) and prostacyclin. These endothelial abnormalities, in turn, cause hypertension by impairing renal-pressure natriuresis and increasing total peripheral resistance<sup>34</sup>.

In many cases of the pre-eclampsia syndrome, however, the maternal response to the placenta appears to have allowed for normal implantation. It is possible that women with higher baseline levels of inflammation stemming from underlying conditions such as chronic hypertension or autoimmune disease may have less tolerance for the inflammatory burden of pregnancy. Severe pre-eclampsia can progress to fulminant pre-eclampsia with headaches, visual disturbance and epigastric pain, and further to *Hemolysis, Elevated Liver Enzymes and Low Platelets (HELLP)* syndrome and eclampsia. Placental abruption is associated with hypertensive pregnancies. These are life threatening conditions both for the developing fetus and its mother. Many theories have attempted to explain why pre-eclampsia arises, and have linked the syndrome to the presence of the following:

- Endothelial cell injury
- Immune rejection of the placenta
- Compromised placental perfusion
- Altered vascular reactivity
- Imbalance between prostacyclin and thromboxane
- Decreased glomerular filtration rate with retention of salt and water
- Decreased intravascular volume
- Increased central nervous system irritability
- Disseminated intravascular coagulation

- Uterine muscle stretch(ischemia)
- Dietary factors including vitamin deficiency
- Hughes syndrome
- Genetic factor<sup>15</sup>
- Air pollution<sup>16</sup>
- Obesity<sup>17</sup>
- Unfamiliar sperm theory<sup>18</sup>

Thyroid dysfunction: subclinical hypothyroidism in early pregnancy compared with normal thyroid function has been extruded to increase the risk of pre-eclampsia with odds ratio of 1.7<sup>19</sup>

The current understanding of the syndrome is a two stage process, with highly variable first stage which predisposes the placenta to hypoxia followed by release of soluble factors which are in many of the other observed phenomena. Many of the older theories can be subsumed under this umbrella, as the soluble factors like *sFlt-1*, a *vascular endothelial growth factor* and soluble endoglin (*sEng*) have been shown to cause, for, example endothelial cell injury, altered vascular reactivity, the classic lesion of glomerular endotheliosis, decreased intravascular volume, inflammation, etc.

### ***PATHOGENESIS***

The pathogenesis and mechanism of pre-eclampsia remain uncertain despite much research work. Some studies support notions of inadequate blood supply to the placenta making it release particular hormones or chemical agents that in mothers predisposed to the condition, leads to damage of the endothelium, alterations in metabolism, inflammation and other possible factors<sup>6</sup>.

Abnormalities in maternal immune system and insufficiency of gestational immune tolerance seem to play major roles in pre-eclampsia. One of the main differences found in pre-eclampsia is a shift towards T-helper 1(Th1) response and the production of IFN- $\gamma$ . The origin of IFN- $\gamma$  is not clearly identified and it could be the natural killer cells of the uterus, the placental dendritic cells modulating the response of T helper cells, alteration in the synthesis of or response to regulatory molecules, or changes in the function of regulatory T cells in pregnancy<sup>20</sup>. Aberrant immune responses promoting pre-eclampsia may also be due to an altered fetal allorecognition or to inflammatory triggers<sup>20</sup>. It has been documented that fetal cells such as fetal erythroblasts as well as cell-free fetal deoxyribonucleic acid (DNA) are increased in the maternal circulation in women who develop pre-eclampsia. These findings have given rise to the hypothesis that pre-eclampsia is a disease process by which a placental lesion such as hypoxia allows increased fetal

material into maternal circulation that leads to an immune response and endothelial damage ultimately resulting in pre-eclampsia/eclampsia.

Some studies suggest that hypoxia resulting from hypoperfusion up regulates sFlt-1, a VEGF and PlGF antagonist leading to damaged maternal endothelium and restriction of placental growth<sup>21</sup>. In addition, endoglin, a TGF-beta antagonist, is elevated in pregnant women who develop pre-eclampsia<sup>22</sup>. Soluble endoglin is likely up regulated by the placenta in response to upregulation of cell surface endoglin produced by the maternal immune system; although there is also the potential that sEng is produced by the maternal endothelium.

Levels of both sFlt-1 and sEng increase as severity of disease increases, with levels of sEng surpassing levels of sFlt-1 in HELLP syndrome cases. Recent data indicate that Gaddasa stress signaling regulates elevated sFlt-1 expression in pre-eclampsia<sup>23</sup>.

Both sFlt-1 and sEng are elevated in all pregnant women to some extent, supporting the idea that hypertensive disease in pregnancy is a normal pregnancy adaptation gone awry. Its natural killer cells are intimately in placentation and as placentation involves a degree of maternal immune tolerance for a foreign placenta which requires maternal resources for its support, it is not surprising that the maternal immune system might respond more negatively to the arrival of some placenta under certain circumstances such as a placenta which is more invasive than normal. Initial maternal rejection of the placental cytotrophoblasts may be the cause of the inadequately remodeled spiral arteries in those cases of pre-eclampsia associated with shallow implantation, leading to downstream hypoxia and the appearance of maternal symptoms in response to up regulated sFlt-1 and sEng.

### ***DIFFERENTIAL DIAGNOSIS***

Pre-eclampsia can mimic and be confused with many other diseases including chronic hypertension, chronic renal disease, primary seizure disorders, gallbladder and pancreatic disease, immune or thrombotic thrombocytopenic purpura, antiphospholipid syndrome and hemolytic uremic syndrome. It must always be considered a possibility in any pregnant woman beyond 20 weeks of gestation with elevated blood pressure and proteinuria in urine dipstick.

In clinical practice, taking of maternal BP is paramount. The woman should be resting and sitting at an angle greater than 45 degrees with her feet supported. The BP cuff should be of appropriate

size and should be placed at a level of the heart. Standard cuff for <33cm circumference. Large cuff (15x33cm bladder) for larger arms. Inflate cuff to 20-30mmHg above palpated systolic pressure. Deflate slowly. Read and record BP to nearest 2mmHg. Systolic BP is the first sound heard (korotkoff phase 1). Korotkoff phase 5 sound (sound disappearance) is the appropriate measurement of diastolic BP. Where this does not occur, korotkoff sound 4(muffling) is acceptable. Multiple readings should be taken over several hours to confirm the diagnosis of preeclampsia due to natural variation. BP readings must be manually recorded during the titration (of antihypertensive medicine) phase.

Complications associated with severe pre-eclampsia in the mother include placental abruption, disseminated intravascular coagulopathy, HELLP syndrome, pulmonary edema, acute renal failure, acute fatty liver of pregnancy, liver rupture, intracerebral hemorrhage and eclampsia.

Fetal complications include fetal growth restriction and in utero fetal death. Neonatal complications include those associated with preterm birth, hypoxic and neurologic injury and perinatal death.

In diagnosis, severe pre-eclampsia is defined as systolic BP 160-170mmhg and/or diastolic BP 110mmhg or higher measured on at least two occasions over several hours, combined with proteinuria >300mg total protein in a 24hr urine collection, or ratio of protein to creatinine >30mg/mmol, or usually accompanied by other hematological, neurological, hepatic or renal derangements. Additional symptoms of pre-eclampsia include onset of edema of face, head or feet, headache or visual disturbance or both, epigastric pain or vomiting or both and reduced fetal movements.

Signs of severe pre-eclampsia include increased signs of clonus, pitting edema, papilloedema, liver tenderness.

Biochemical changes include serum creatinine >0.09 units and or oliguria, raised transaminases (ALT or AST rising to above 70i.u/l), platelets less than  $100 \times 10^9$ , DIC, hemolysis and raised serum uric acid levels.

In-patient care should be provided for women with severe pre-eclampsia. Women with mild pre-eclampsia, pre-existing or pregnancy induced hypertension, monitoring may be undertaken on an outpatient basis.

Management of severe pre-eclampsia requires a multidisciplinary approach involving an obstetrician, midwife, anesthetist, physician, hematologist and a pediatrician. Blood should be sent to the laboratory for grouping and cross match, FBC, U/E/C, LFTS and coagulation profile. Patients may continue to take oral antenatal medicine, usually methyldopa if BP >140/90mmHg.

For BP >170/110 mmHg, prompt treatment is required. Prophylaxis with MgSO<sub>4</sub> should be implemented where there are premonitory signs of eclampsia (increased reflexes associated with clonus and or severe headache), visual changes or following diagnosis of severe pre-eclampsia (diastolic BP >110mmHg, proteinuria >300mg/24hr, abnormal LFTS, thrombocytopenia).

MgSO<sub>4</sub> is commenced and continued as a maintenance infusion. Serum MgSO<sub>4</sub> concentrations should be checked every 6 hrs in the ante partum and intrapartum phase to achieve a therapeutic range of 1.7-3.5 mmol/l. Reflexes and signs of clonus should be assessed at 2 hrly intervals. BP must stabilize following administration of MgSO<sub>4</sub> before considering other anti hypertensive agents. The goal is to maintain a diastolic BP of 90-100mmHg.

Hydralazine is the drug of choice for women with asthma or CCF. Accurate assessment of fluid in-put/output is essential. Iatrogenic fluid overload is a main cause of maternal death in the pre-eclampsia/eclampsia sequelae.

Protein excretion should be monitored by a full analysis of urine 4 hourly. Establish an indwelling urinary catheter for urine output measurement hourly. A urine output of less than 30mls/hr is considered inadequate during MgSO<sub>4</sub> administration. Management of oliguria during MgSO<sub>4</sub> administration should be multidisciplinary. Consider giving Hartman's 250mls stat. if no improvement, consider repeating bolus infusion. Persistent oliguria may be an indication for diuretic use following obstetric/anesthetic consultation.

Ongoing monitoring and observation include ½ hourly BP, pulse, respiratory rate taking, 1hr patella reflexes, 1hourly urine output measurement + 4 hourly testing of urinary protein, 2hourly temperature chart, continuous electronic fetal monitoring(ante partum and intrapartum) of fetus



from 26wks until clinical review, discussion by medical staff. Between 24-26wks gestation, individualized management in regard to fetal monitoring will be considered. During labor, an epidural may be considered for pain management as it has additional benefit of lowering the women's BP in the absence of contraindications and platelets must be more than  $100 \times 10^9/l$ .

Fetal monitoring involves continuous electronic fetal monitoring in labor (IUGR fetus will have less tolerance of labor than well-grown fetus). Continuous electronic fetal monitoring during administration of  $MgSO_4$  is recommended.

Delivery is indicated in the setting of the following: severe pre-eclampsia/eclampsia (once stable), uncontrollable BP despite treatment, deterioration in LFT and RFT, progressive decrease in platelets, neurological symptoms/eclampsia, abruption and non reassuring fetal status (NRFS). A fetus of gestation age greater than 37weeks should be delivered without further delay. An attempt may be made to defer delivery at very early gestation around limits of viability for steroid administration.

Mode of delivery will depend on maternal and fetal factors (gestation, presentation). If induction of labor (IOL) is undertaken with oxytocin (syntocinon)/ARM, an oxytocin (syntocinon) infusion must be delivered in a concentrated dose via a syringe driver pump. Operative birth is not routinely required for the 2<sup>nd</sup> stage but may be necessary if the BP is poorly controlled, woman has symptoms of severe cerebral irritability, or progress is inadequate. 3<sup>rd</sup> stage should be actively managed with 10 i.u oxytocin bolus i.v. Do not give ergometrine or syntometrine. This is because ergometrine has been shown to constrict coronary arteries and other peripheral blood vessels raising blood pressure to dangerous levels. This is especially fatal for women with already elevated blood pressures.<sup>32</sup>

In postpartum, most women show signs of recovery within the first 24hours of delivery, however a minority remain unstable or deteriorate after birth. Eclampsia may occur after birth; therefore close monitoring should continue until BP is stable-diuresis has occurred and urine output normalized and FBC, LFTS, RFT, serum uric acid levels are stable/normalized /improving.  $MgSO_4$  can be continued until 24 hours after delivery or after the last eclamptic fit. Postpartum

MgSO<sub>4</sub> levels may be adequately clinically assessed (reflexes, respiratory rate) unless there is renal impairment/oliguria when serum levels should be performed 6 hourly. Continue to check hourly patellar reflexes until infusion has ceased.

Indications for inpatients admission include BP >150/100 mmHg on 2 occasions, maternal symptoms and concern for fetal wellbeing. Inpatient surveillance include 4 hourly BP chart, daily urinalysis, FBC, U/E/C, uric acid, LFTS (alternate days), AFI, Doppler on admission and repeated as indicated by fetal condition, CTG 2-3 times per week, BPP weekly as required. Antihypertensive therapy if BP > 160/100 mmHg (maintain BP at 130-140/80-90mmHg).

Medications of choice are labetalol (caution in asthmatics), methyldopa and nifedipine. There is insufficient evidence to recommend one antihypertensive over the other. Drug of choice will therefore depend on the clinician's experience and familiarity with a particular drug and on what is known about its side effect profile for the woman and her baby.

There should be proper postnatal follow up for women who have had pre-eclampsia/eclampsia. Persistent high BP after 6 weeks postpartum should warrant proper physician review for other causes of hypertension and treatment administered accordingly.

### ***PREDICTING PREECLAMPSIA***

In November 2011, doctors working at the Mayo clinic announced that a new test had been discovered which involves checking patients' urine for specific cells called podocytes. Out of the 300 women tested, all women who went on to have pre-eclampsia were found to have podocytes in their urine, whilst none of the women who had a normal pregnancy; or who suffered from pregnancy induced hypertension tested positive for podocytes. Doctors said that this test appears to be extremely accurate and should become a recognized medical test soon. Podocyturia, the appearance of kidney podocyte cells in urine, appears to be an early and specific predictor of pre-eclampsia. Podocyturia results when epithelial podocyte cells from within the glomerulus detach and are shed in the urine. In this study, urine was collected from pregnant women, and cells in urine were cultured overnight and then prepared and stained for podocin, a specific protein to podocytes. The researchers followed 300 women with singleton pregnancies and successful deliveries from their first prenatal visits to delivery. Urine specimen for podocyte analysis was collected at midterm (gestational weeks 25-28) and just before delivery.

They found out that all the women who went on to have pre-eclampsia/eclampsia had podocyturia in their urine before any of the classical symptoms of these syndromes developed; While those who had uncomplicated deliveries or just pregnancy induced hypertension did not have podocytes in their urine.

The researchers therefore suggested that this test can help physicians identify women at risk of developing pre-eclampsia in their pregnancy, and it will give us the opportunity to implement early treatment of severe high blood pressure, which may improve maternal and fetal outcomes.

Since severe pre-eclampsia/eclampsia is a disease that if not well treated has deleterious effects to the mother and her unborn child, several investigators have devoted valuable time and money to find ways of preventing it. For instance, the British National Institute for health and clinical excellence (NICE) has recommended women at increased risk of developing pre-eclampsia should consider taking low dose aspirin at 75mg tablet daily from 12 weeks gestation of pregnancy until birth. This has been shown to reduce the risk of developing pre-eclampsia and delivering a low birth weight child. The NICE has also recommended that calcium supplements during pregnancy are a safe way of reducing the risk of pre-eclampsia in women at increased risk. The benefit of calcium supplements translate to less likelihood of death or serious problems due to pre-eclampsia/eclampsia. Babies are also less likely to be born preterm. However, these are research recommendations from some researchers and other researchers have failed to show a direct benefit of calcium supplementations and outcomes in women with pre-eclampsia. For instance, a Cochrane data base of systematic reviews (2002) (1):CD001059,<sup>33</sup> showed that calcium supplementation had minimal effect on the development of preeclampsia. Therefore, there still exists a large knowledge gap on what can be done to prevent pre-eclampsia. As such, aspirin and calcium do not seem to be standard routine guideline recommendations for the pregnant woman but should be individualized as per clinician's judgment.

In order to optimize good neonatal outcome the ACOG recommends weekly NST and /or BPP, twice weekly testing if oligohydramnios or fetal growth restriction is suspected, and ultrasound examination every three weeks. ACOG also recommends daily assessment of fetal movements.

ACOG does not recommend routine cesarean section (C/S) as a preferred mode of delivery for severe pre-eclampsia/eclampsia. Vaginal delivery at term is cited as the best mode of delivery

and C/S should be individualized. For the management and prevention of eclampsia, ACOG recommends use of MgSO<sub>4</sub>, which should be given intravenously or intramuscularly to control convulsions and prevent recurrence. 4g-6g loading dose diluted in 100ml of fluid is given i.v for 15-20 minutes then a continuous i.v infusion is administered at a rate of 1-2g/hr. A one American research showed that antioxidant therapy (vit.C 1000mg/day, vit.E 400mg/day) may have promise in preventing pre-eclampsia/eclampsia. Improved prenatal care, including early detection of signs and symptoms of pre-eclampsia and prophylactic use of MgSO<sub>4</sub> generally leads to a reduction in the incidence of eclampsia<sup>5</sup>.

### ***GUIDELINES***

The government of Kenya through the Ministry of Health has formulated the following guidelines to be used by healthcare workers when managing women with severe preeclampsia and eclampsia (*appendix 5*). These guidelines were developed and rolled out in 2012. The participants were drawn from various organizations including nongovernmental organizations and training institutions. Among them included the Dr. Njoroge Waithaka, Dr. Guyo Jaldesa and Prof. Z. Qureshi (KOGS/UoN).

### **Diagnosis of preeclampsia/eclampsia**

History- many cases are detected through routine prenatal screening.

- CNS
  - Headache
  - Visual disturbances- blurred vision, scintillating scotomata
  - Altered mental status
  - Cortical or retinal blindness
- Dyspnoea
- Edema-this exists in many pregnant women but sudden increase in edema or facial edema is more concerning for preeclampsia
- Epigastric or right upper quadrant (RUQ) abdominal pain: hepatic involvement occurs in 10% of women with severe preeclampsia
- Weakness or malaise

## **Physical examination**

Findings on physical examination may include the following:

- Increased BP compared with the patient's baseline or > 140/90 mmHg
- Altered mental status
- Decreased vision or scotomas
- Papilloedema
- Epigastric or RUQ abdominal pain
- Sudden increase in edema or facial edema
- Hyperreflexia or clonus: although deep tendon reflexes are more useful in assessing magnesium toxicity, the presence of clonus may indicate an increased risk of convulsions
- seizures
- Focal neurologic deficit

## **Investigations:**

### **Laboratory studies**

- CBC count and peripheral smear
  - Microangiopathic hemolytic anemia
  - Thrombocytopenia <100,000
  - Hemoconcentration may occur in severe preeclampsia
  - Schistocytes on peripheral smear
- Liver function tests: transaminase levels are elevated from hepatocellular injury and in HELLP syndrome
- Serum creatinine levels elevated due to decreased intravascular volume and decreased glomerular filtrate rate (GFR)
- Urinalysis: more than 300mg or +1 proteinuria in a 24 hour urine sample
- Abnormal coagulation profile: PT and aPTT are elevated
- Disseminated intravascular coagulopathy testing will show fibrin split products and decreased fibrinogen levels
- Hyperuricemia

## **Ultrasonography:**

This is used to assess the status of the fetus as well as to evaluate for growth restriction (typically asymmetrical IUGR). Aside from transabdominal ultrasonography, umbilical artery Doppler ultrasonography should be performed to assess blood flow

## **Management of patients with preeclampsia/eclampsia**

### **Control BP**

- Goal is to prevent cerebrovascular and cardiac complications while maintaining uteroplacental blood flow
- Control of mildly elevated BP does not appear to improve perinatal morbidity and mortality and , in fact, it may reduce birth weight
- Antihypertensive treatment is indicated for BP >160/105 mmHg. Goal is to maintain diastolic BP 90-100mmHg and systolic BP 140-155 mmHg
- First-line medications are labetalol given orally or I.V, nifedipine given orally or I.V, or hydralazine I.V. (*Atenolol, ACE inhibitors, ARBs, and diuretics should be avoided*)

### **Control of seizures**

- Follow basic principle airway, breathing and circulation (ABC)
- Treat active seizure with intravenous magnesium sulphate as a first-line agent
- Prophylactic treatment with magnesium sulphate is indicated for all patients with severe preeclampsia
- Magnesium levels, respiratory rate, reflexes and urine output must be monitored to detect magnesium toxicity. Magnesium sulphate is mostly excreted in urine and therefore urine output needs to be closely monitored. If urine output falls below 20mls/hr, the magnesium infusion should be stopped
- For seizure refractory to magnesium sulphate, benzodiazepines and /or phenytoin should be considered

## **Fluid management**

- These patients are intravascularly volume depleted with high peripheral vascular resistance. **Diuretics should be avoided**
- Aggressive volume resuscitation may lead to pulmonary edema, which occurs mostly 48-72 hours postpartum, probably due to mobilization of extravascular fluid
- Total fluids should be limited to 80mls/hr or 1ml/kg/hr
- Careful measurement of fluid input and output especially in the immediate postpartum period is advisable
- If fluids are required, preferably use Ringers Lactate or Normal saline

## **Delivery**

- Patients with mild preeclampsia are induced after 37 weeks gestation. Give steroids prior to this
- Induction of labor should be considered in patients with severe preeclampsia after 34 weeks gestation
- Eclampsia is common after delivery up to 6 weeks

## **Medication**

### **Magnesium sulphate:**

Antagonizes calcium channels of smooth muscle. Administer IV/IM for seizure prophylaxis in preeclampsia. Use IV for quicker onset of action in eclampsia

### **Schedule**

### **Loading**

20% solution or 4g IV over 5 minutes

Follow promptly with 10g of 50% solution, 5g in each buttock as deep IM injection with 1ml of 2% lignocaine in the same syringe

If convulsions occur after 15 minutes, give 2g magnesium sulphate (50% solution) IV over 5 minutes

### **Maintenance dose**

Give magnesium sulphate (50%) solution + 1ml lignocaine 2% IM every 4 hours into alternate buttocks. Continue treatment for 24 hrs after delivery or the last convulsion, whichever occurs last. If 50% solution is not available, give 1 g of 20% solution IV every hour by continuous infusion.

### **Before repeat administration, ensure that:**

Respiratory rate is at least 16 per minute

Patellar reflexes are present

Urinary output is at least 30mls/hr over preceding 4 hours

If the above are absent, withhold or delay drug

### **Keep antidote ready:**

In case of respiratory arrest, assist ventilation with mask and bag, intubate. Give 1g (10mls) of calcium gluconate IV slowly until respiration begins

### **Phenytoin**

Cardiac monitoring required because of associated bradycardia and hypotension. It is given as 10mg/kg loading dose infused IV no faster than 50mg/min, followed by a maintenance dose started 2 hrs later at 5mg/kg

### **In absence of magnesium sulphate, diazepam is used following the regime below:**

#### **Intravenous**

#### **Loading**

20mg IV slowly over 2 minutes



If convulsions occur, repeat loading dose

### **Maintenance dose**

Diazepam 40mg in 500ml IV fluids titrated to keep the woman sedated but can be aroused

Do not give more than 100mg in 24 hours

### **Rectal administration**

Give diazepam rectally when IV access is not possible. The loading dose is 20mg in 10 mls syringe. If convulsions are not controlled within 10 minutes, administer an additional 10mg per hour or more, depending on the size of the woman and her clinical response

### **Hydralazine (Apresoline)**

First line therapy against preeclamptic hypertension. It is given 5mg IV slowly over 10minutes. Repeat 5mg q20min to a maximum of 20mg

### **Labetalol**

Recommended 2<sup>nd</sup> line therapy. It's onset of action is more rapid than hydralazine. It's given at 20mg bolus; subsequently give doses of 40mg followed by 80mg IV at 10-20 min intervals to achieve BP control to a maximum of 300mg. it may also be administered by continuous infusion at 1mg/kg/hr

### **Nifedipine**

Given at 10mg orally. May be repeated after 30minutes as needed

### **Definitive management**

#### **Severe pre-eclampsia....diastolic BP>110mmhg**

- Admit in labor ward in a quiet room
- Administer parenteral antihypertensive (hydralazine 5mg iv slowly initially then 5-10mg I.V 20-30minutes PRN) or sublingual nifedipine until BP is reasonably controlled
- Monitor vital signs every 15-30 minutes

- Consider timing and mode of delivery
- Start MgSO<sub>4</sub> regime and deliver within 24 hours
- Fluid regime management (input/output)
- Do blood chemistry-LFTS, U/E/C, FBC
- If at health center, refer to a comprehensive centre accompanied by a trained nurse

### **Management of eclampsia**

- Maintain open airway
- Control fits
- Control BP and monitor quarter hourly
- Maintain fluid balance

### **Management of the fitting patient**

- Patient should be put in semi prone position so that mucus and saliva can flow out
- Tight fitting dresses around the neck should be loosened or removed
- Clean mouth and nostrils gently and remove secretions
- No attempt should be made to insert any instrument into the mouth
- Give oxygen if available continuously during fit and for 5 minutes after each fit
- Fitting should be allowed to complete its course without physically attempting to hold the patient down
- Privacy and dignity of patient must be observed –pull screens around her
- Administer magnesium sulphate as per regime to control fits.

The confidential enquiries into maternal deaths in The United Kingdom revealed substantial reduction of deaths due to preeclampsia/eclampsia from 11.9/ million to 7/million when standardized guidelines are used. Of these deaths, nine women died from cerebral causes with substandard care in 50% of cases. Therefore, there is room for improvement. In particular control of hypertension and fluid management were highlighted. The Yorkshire series had no deaths in over 1000 cases of severe preeclampsia and eclampsia and supports the view that a standardized care package for preeclampsia over delivery with proven interventions may reduce the rate of eclampsia.

The Royal College of Obstetricians and Gynecologists in collaboration with the world health organization, setting standards to improve women's health; Guideline No. 10(A)<sup>25</sup> recommends the following:

The RCOG recommends senior obstetric and anesthetic staff and experienced midwives to be involved in the assessment and management of women with severe preeclampsia and eclampsia. It also recommends BP to be checked every 15 minutes until the woman is stabilized and then every 30 minute in the initial phase of assessment. The BP should then be checked 4 hourly if a conservative management plan is envisaged and the woman is stable and asymptomatic. Further, the woman requires FBC, LFTs and RFTs done. These should be repeated at least daily when the results are normal but more often if the clinical condition changes or if there are abnormalities. Clotting studies are not required if platelet count is  $100 \times 10^6/L$ . A close fluid balance with charting of input and output is essential. A catheter with an hourly urometer is advisable in the acute situation, especially in the immediate post-partum period. An AST or ALT level above 70 i.u/l is seen as significant and a level above 150 i.u/l is associated with increased morbidity to the mother.

The RCOG recommends that the fetus should be assessed in acute setting by CTG. This gives information about fetal wellbeing at that time but does not give any predictive information. Women in labor with severe preeclampsia should have continuous electronic fetal monitoring. If conservative management is planned, then further assessment of the fetus with ultrasound measurements of fetal size, umbilical artery Doppler and liquor volume should be undertaken. Then serial assessment will allow timing of delivery to be optimized.

For control of BP, RCOG recommends starting antihypertensive treatment in women with BP > 160/110mmHg. In women with other markers of potentially severe disease, treatment can be considered at lower degrees of hypertension. Labetalol, given orally or I.V, Nifedipine given orally or I.V hydralazine can be used for the acute management of severe hypertension. In moderate hypertension, treatment may assist prolongation of the pregnancy. Nifedipine should be given orally and not sublingually. Labetalol should be avoided in women with known asthma.

Methyldopa is good for long-term preeclampsia treatment. Atenolol is associated with IUGR and should not be used. ACE inhibitors and angiotensin receptor blocking agents are contraindicated

because of unacceptable fetal renal system adverse effects. Diuretics should only be used if there is pulmonary edema.

Prophylactic MgSO<sub>4</sub> should be considered for women with preeclampsia for whom there is concern about the risk of eclampsia. This is usually in the context of severe preeclampsia once a delivery decision has been made and in the immediate post-partum period. In women with less severe disease the decision is less clear and will depend on individual case assessment. MgSO<sub>4</sub> should be continued for 24 hours following delivery or 24 hours after the last seizure. When magnesium sulfate is given, regular assessment of the urine output, maternal reflexes, respiratory rate and oxygen saturation is important. Seizures should be controlled following the basic principles of airway, breathing and circulation. Magnesium sulfate is the therapy of choice. A loading dose of 4g should be given by infusion pump over 5-10 minutes followed by a further infusion of 1g/hr maintained for 24 hours after the last seizure. Recurrent seizures should be treated with either a further bolus of 2g magnesium sulfate or an increase in the infusion rate to 1.5 or 2.0g /hr. Once stabilized, plans can then be made to deliver the woman but there is no particular hurry and a delay of several hours to make sure the correct care is in hand, is acceptable assuming that there is no acute fetal concern such as fetal bradycardia. The woman's condition always comes first. Magnesium sulfate is the therapy of choice and diazepam and phenytoin should no longer be used as first line drugs. Urine output should be closely monitored and if it becomes reduced below 20 mls/hr, the magnesium sulfate infusion should be halted. Further, if there is loss of deep tendon reflexes or respiratory depression, magnesium sulfate should be halted. Calcium gluconate 1g [10mls] over 10 minutes can be given if there is concern over respiratory depression. If seizures are not controlled, magnesium sulfate can be given a further 2g/hr. If this does not prevent the seizures, alternative agents such as diazepam or thiopental may be used, but only as single doses since prolonged use is associated with an increase in maternal death. If convulsions persist, intubation is likely to be necessary to protect the airway and maintain oxygenation. Transfer to ICU with intermittent positive pressure ventilation is appropriate in these circumstances.

Fluid restriction is advisable to reduce the risk of fluid overload in the intra-partum and post-partum periods. In usual circumstances, total fluids should be limited to 80mls/hr or 1ml/kg/hr. This should be maintained until there is post-partum diuresis. The decision to deliver should be

made once the woman is stable and with appropriate senior personnel present. If the fetus is less than 34 weeks of gestation and delivery can be deferred, corticosteroids should be given although after 24 hours the benefits of conservative management should be reassessed.

Conservative management at very early gestations may improve the post-natal outcome but must be carefully balanced with maternal wellbeing. The mode of delivery should be determined after considering the presentation of the fetus and fetal condition, together with the likelihood of success of induction of labor after assessment of the cervix. The 3rd stage should be managed with 5 units I.M syntocinon or 5 units infusion syntocinon slowly. Ergometrine or syntometrine should not be given as these can further increase BP.

Vaginal delivery is generally preferable but if gestation is below 32 weeks, C/S is more likely as the success of induction is reduced. Women should then have a careful review before discharge from hospital. Antihypertensive medication should be continued after delivery as dictated by the BP. Women with persisting hypertension and proteinuria at 6 weeks may have renal disease and should be considered for further evaluation.

Clinicians should be aware that up to 44% of eclampsia occurs post-partum, especially at term, so women with signs or symptoms of preeclampsia should be carefully assessed. Steroids are used in HELLP syndrome for rapid resolution of biochemical and hematological abnormalities. An assessment of BP and proteinuria by GP at 6 weeks post-partum is recommended. If hypertension and proteinuria persists then further investigation is recommended<sup>25</sup>.

The Royal Cornwall Hospital NHS Trust clinical Guidelines for the management of a woman with eclampsia and/ or severe preeclampsia recommends that for the control of BP, nifedipine 5mg orally stat then repeat at 20 minute intervals until BP is controlled to a maximum of 4 doses. mgso4 for the control of fits is given loading dose of 8mls (4g) of mgso4 (50%) diluted with 12 mls of N/S (0.9%) =total 20mls given I.V over 20 minutes using syringe driver at rate of 60 mls/hr. Maintenance dose 1g/hr-20 mls MgSO<sub>4</sub> (10gms) diluted with 30 mls of N/S (0.9%) =total 50mls given I.V using a syringe driver at a rate of 5mls/hr. In recurrent seizures while on MgSO<sub>4</sub>, give a further bolus of 4mls MgSO<sub>4</sub> (2g) diluted with 6mls of N/S (0.9%) given over five minutes.

If platelet count is less than  $50 \times 10^9$ , a platelet transfusion should be considered and if for C/S, this should be in consultation with the consultant hematologist.

## **RATIONALE**

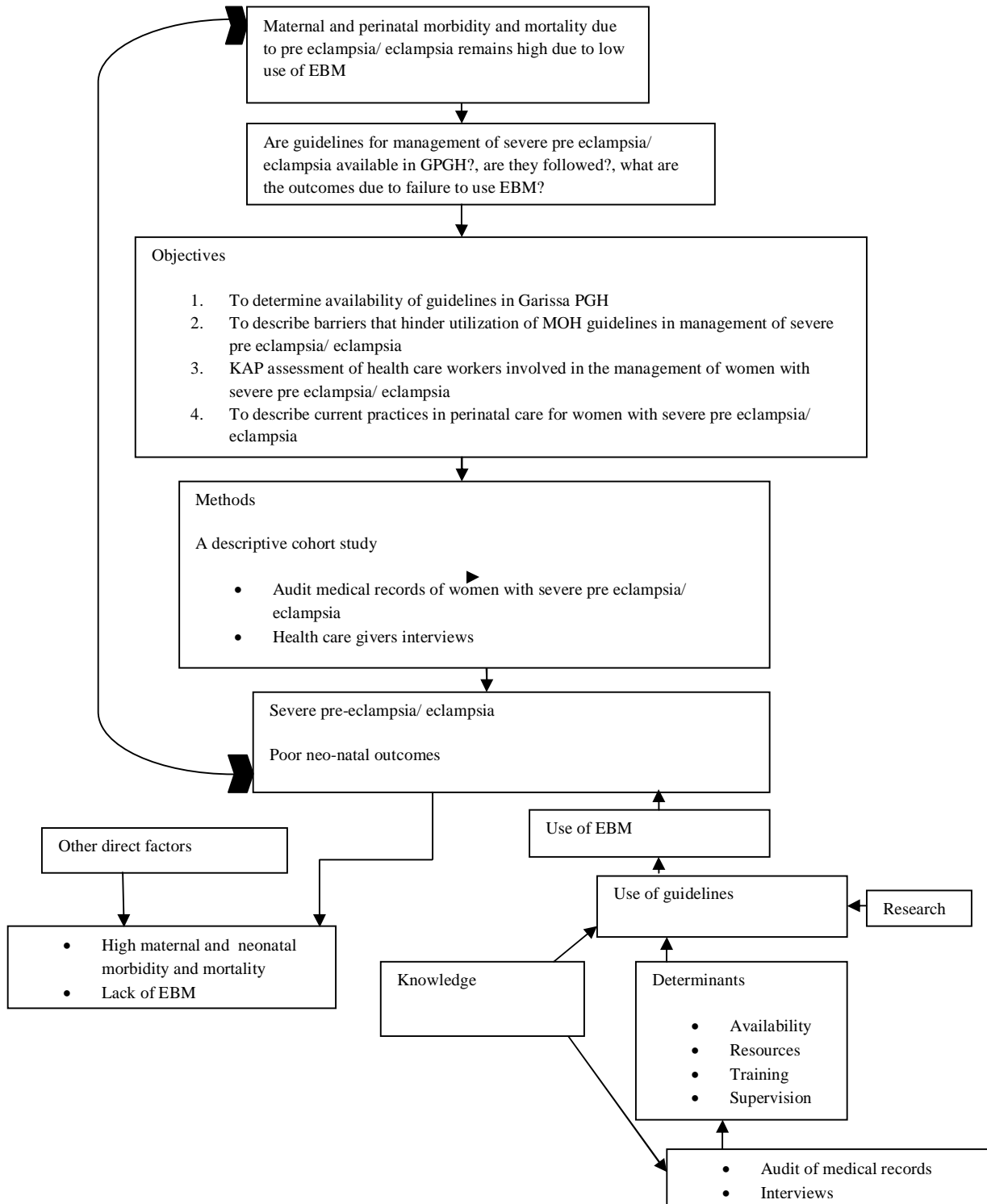
The burden of mortality and morbidity related to pregnancy and childbirth remains concentrated in developing countries. The world health statistics indicate that the majority of the deaths are occurring in Africa, more specifically sub-Saharan Africa. Poorly equipped rural health facilities that lack basic essential equipment, drugs and are understaffed make the few available health workers to be overworked and therefore compromise on the quality of healthcare given. This leads to continued reliance of the institutional norms of managing patients rather than practice evidence based medicine. A cohort study under the context was the most appropriate to assess the actual practice given to patients while minimizing potential biases. Guidelines have a unique role to simplify and standardize care.

## **CONCEPTUAL FRAMEWORK**

The management of pre-eclampsia is influenced by many factors including disease severity, gestational age, and fetal condition. Optimal management requires an appreciation of the complexity of the disease process and familiarity with its manifestation in multiple organ systems. Maternal and fetal risks and benefits must be assessed thoroughly. As evidence based medicine has shown, use of standardized guidelines has led to a significant decline in maternal and neonatal morbidities and mortalities:-prior to adoption of these guidelines, hypertensive disorders of pregnancy (read pre-eclampsia/eclampsia) were the number one cause of maternal mortalities in developed and developing world.

Individualized treatment plans should be formulated and discussed with the patient, and she should be encouraged to participate in major decisions regarding her care. In atypical cases, alternative diagnoses must be considered.

**DIAGRAMATIC REPRESENTATION OF THE CONCEPTUAL FRAMEWORK**



## **CHAPTER THREE**

### **METHODOLOGY**

#### **STUDY AREA**

Garissa PGH is the main referral hospital for North-Eastern counties of Wajir, Mandera and neighboring counties of Isiolo, Kitui in Eastern and Tana River to the coast. It is also a main referral facility for parts of Somalia. North Eastern counties have a population of 2,345,000(70% are nomads) that is dispersed in a vast region within an area of 126,000km<sup>2</sup>. This constitutes about 20% of the total land in Kenya.

It has an in-patient capacity of 248 beds distributed as paediatrics-54, surgery-67, obstetrics and gynaecology-42, and medicine 85. The average bed occupancy is 90% per year.

The obstetric and gynecological services offered by GPGH include antenatal clinics, special high risk obstetric clinics, labor ward, theatre services for emergency and elective caesarean sections and postnatal and gynecological lie in wards. On average, GPGH attends to about 480 women annually. At the time of study, there was one consultant obstetrician and gynecologist, six medical officers, ten clinical officers and forty eight nurses. The burden of preeclampsia/eclampsia is higher in GPGH than the national average standing at 1000-1300/100000; national average being 488/100000.

#### **STUDY DESIGN**

A retrospective cohort study was used in which medical records of Women with severe pre-eclampsia/eclampsia seen in the maternity ward, postnatal ward and those attending antenatal clinics were analyzed for the care given and pregnancy outcomes were documented.

A cross sectional survey of healthcare workers who were involved in the management of women with severe preeclampsia/eclampsia at the time of the study was done to assess their knowledge, attitude and practice using an interviewer administered questionnaire.

The information gathered from medical records was carefully analyzed against the MoH standard guideline recommendations to ascertain whether management was in accordance to the recommendations. The healthcare workers' knowledge, attitude and practices with regard to management of women with severe preeclampsia/eclampsia was marched against guideline



recommendations and inconsistencies discovered were compared with the shortfalls depicted from medical records.

A drug inventory chart was used to assess the hospital's essential drug stocking status.

## **STUDY POPULATION**

The study population was of medical records of women with severe pre-eclampsia/eclampsia seen in maternity and postnatal wards of Garissa PGH as well as those who attended ante-natal clinic and health care workers who attended to the women with these conditions.

### **Inclusion criteria**

- Women with severe pre-eclampsia/eclampsia admitted to GPGH at gestation >20 weeks and <6 weeks postpartum.
- Documented maternal and fetal outcome in study station.
- All healthcare workers involved in the management of women with severe pre-eclampsia/eclampsia.

### **Exclusion criteria**

- Patients received on referral after delivery.
- Health workers providing only supportive services such as physiotherapy, nutrition and counseling.

## **SAMPLE SIZE DETERMINATION**

### ***Women treated for severe preeclampsia/eclampsia***

Fisher's formula for estimating means and proportions was used to determine the sample size.

$$n = z^2 (p (1-p)) / e^2$$

Where;

n=sample size

p=percentage of pregnant women with severe pre-eclampsia/eclampsia attending or admitted to Garissa PGH managed according to MoH guidelines.

z=0.96 z value at 95% confidence

e=margin of error

Substituting a P-value of 0.05 with a precision of 10%, this gives a sample size of 81.

### ***Healthcare workers who managed women with severe preeclampsia/eclampsia***

All healthcare workers involved in the management of women with severe preeclampsia/eclampsia in the study period were interviewed. These included a consultant obstetrician and gynecologist, medical officers, clinical officers and nurses.

### **STUDY PROCEDURES**

Study participants were identified as follows: From registers at the MCH and labor ward, we identified all women seen with severe preeclampsia/eclampsia during the period. Files of all patients admitted or seen in ante natal clinic with severe preeclampsia/eclampsia were extracted. Review of medical records for the period June 2011 to June 2012 identified participants meeting inclusion/exclusion criteria. A data abstraction tool was used to document the quality of management given. The healthcare workers involved in management of women with severe preeclampsia/eclampsia were interviewed after giving a written consent. Interviews and completion of questionnaires by healthcare workers was done confidentially.

### **STUDY INSTRUMENT**

The data abstraction tool used on medical records documented information on proper diagnosis, laboratory & imaging studies, medical management, mode of delivery and postnatal follow-up. The healthcare worker questionnaire was an interviewer administered with both open-ended and closed-ended questions.

### **DATA COLLECTION**

Data was collected at Garissa PGH by the principal investigator and trained assistants using the study instruments. From medical records of women seen in Garissa PGH with severe preeclampsia/eclampsia, we extracted files meeting the inclusion/exclusion criteria. We then used coded data abstraction tool in which we documented the actual treatment administered as it was recorded. We identified health workers who worked in labor ward, antenatal and postnatal clinics and postnatal wards for interview. We explained the purpose of the study to them and had them sign informed consent. We then gave them coded questionnaires which they filled and returned to us. We went to the pharmacy section and carried out a drug stock of the essential drugs for preeclampsia/eclampsia management from June 2011 to June 2012. We collected data for two months.

## **QUALITY CONTROL**

The questionnaire was piloted by administering it to at least 10 healthcare workers in Kenyatta National Hospital. The piloting was done by the principal investigator and a trained research assistant for standardization. The questionnaires were analyzed and flaws in the design of the questionnaire were corrected. In order to avoid double recruitment, the participants' file numbers were entered in a register upon recruitment for serialization. This register was counter checked on a regular basis for any double entries and if any were discovered, one of the questionnaires was withdrawn and discarded and the serialization rectified before recruitment continued.

## **DATA ENTRY, CLEANING AND ANALYSIS**

Data collected was entered into an SPSS version 15.0 database by the principal investigator. Each record was assigned a unique identifier and names were dropped so as to maintain participants' confidentiality. Quality of data was assessed by conducting consistency checks. Data was stored in a password protected computer.

All continuous data had their measures of central tendency determined and presented as means together with their standard deviations. All data that was not Normally distributed was presented in frequency tables, bar and pie charts. Comparisons of continuous variables were done using the student t-test for Normally distributed variables and the Mann-Whitney test was applied for skewed continuous variables.

All categorical data was presented in frequency tables and graphs where applicable. Associations between these categorical variables were tested using the Pearson's Chi-square or the Fisher's exact test. A p-value of less than 0.05 was considered statistically significant.

Patient characteristics such as age, level of education, employment, marital status, and religion were summarized in a table.

Health professionals' characteristics such as age, years of service, number using guidelines and number not using was summarized in a table.

## **ETHICAL CONSIDERATIONS**

Approval was sought from KNH/UoN Ethics and Research Committee. Informed consent was obtained from all study participants. Records were coded and patients'/clinicians' names were not used. Information collected remained confidential and was used for purposes of the study only. No incentives were given to study participants.

## **LIMITATIONS**

Not all files reviewed had adequate documentation as per the National guidelines.

## CHAPTER FOUR

### RESULTS

A total of 67 health workers at Garissa PGH involved in management of maternity patients were interviewed. Data were extracted from medical notes of 45 maternity patients seen at the hospital with a diagnosis of either severe pre-eclampsia or eclampsia.

**Table 1:** Patient characteristics

	Frequency	Percent
<b>Age in years</b>		
15-25	17	37.8
26-35	10	22.2
>36	18	40
<b>Religion</b>		
Christian	21	46.7
Muslim	24	53.3
<b>Marital status</b>		
Married	39	86.7
Single	6	13.3
<b>Employment status</b>		
Employed	5	11.1
Self-employed	40	88.9
<b>Level of education</b>		
Primary	28	62.2
Secondary	11	24.4
Tertiary	6	13.3

About 60% of the patients seen were below 35 years old while 40% were above 35 years. About equal numbers were either Muslims or Christians. Majority (86.7%) of the patients were married. Only 11.1% of the patients were gainfully employed.

## Health workers interviews

### Health worker characteristics

**Table 2:** Basic characteristics of health workers providing maternity care at Garissa PGH

	Frequency(n = 67)	Percent
<b>Gender</b>		
Male	26	38.8
Female	41	61.2
<b>Age in years</b>		
19-24 years	32	48.5
25-34 years	27	40.9
35 years and above	7	10.6
<b>Level of training</b>		
Consultant Obs/Gyn	1	1.5
Medical officer	6	9.2
Clinical officer	10	15.4
Nursing officer	48	73.9

The mean age of the health workers was 26.9 years ( $\pm 6.9$ ). The age range was 29 years (19 to 48 years). Thirty-two (48.5%) health workers were between the ages of 19 and 24 years (Table 2). There were 41 (61.2%) female health workers in the study. Most of the health workers providing maternity care were either Nursing Officers, 48(73.9%) or Clinical Officers, 10 (15.4%).

### Clinical data on eclampsia and preeclampsia management

A total of 45 medical records of patients admitted to Garissa Provincial Hospital with severe preeclampsia were obtained. [*For the study period, 36 cases sampled had elevated blood pressure and proteinuria in urine and were diagnosed as preeclampsia. However, these represented mild forms of the condition and therefore, as such, were not considered in the study*]. Five (11.1%) out of these 45 patients developed eclampsia and were also managed for eclampsia.

### Management of severe preeclampsia

The mean treatment duration was 3.6 days (SD = 1.6), range 1 to 9 days. Over one-half of all severe preeclampsia patients were on treatment for durations of 3 to 4 days.

Guideline recommended management practices were performed for most of the patients' records reviewed in this study. Importantly, the basic management namely admission to a quiet room and vital sign monitoring was adhered to for all the patients (Table 3). However, drug administration practices did not consistently adhere to MoH guideline recommendations.

**Table 3:** Performance of guideline recommended management practices for eclampsia and preeclampsia at Garissa PGH

<b>Guideline recommendation</b>	<b>Number managed as per recommendation</b>	<b>Percent</b>
Admitted in quiet room	45	100
Given IV hydralazine 5mg slowly or sublingual adalat	15	37.5
Vital signs monitored every 15-30 minutes	45	100
Mgso <sub>4</sub> started and delivered within 24 hours	18	40.9
Blood work up	24	54.6

#### **Guideline adherence and newborn outcomes**

Most patients had at least three out of the five guideline recommended tasks presented in table 3 above documented to have been done within their clinical records (Figure 1).

## Guideline tasks performed

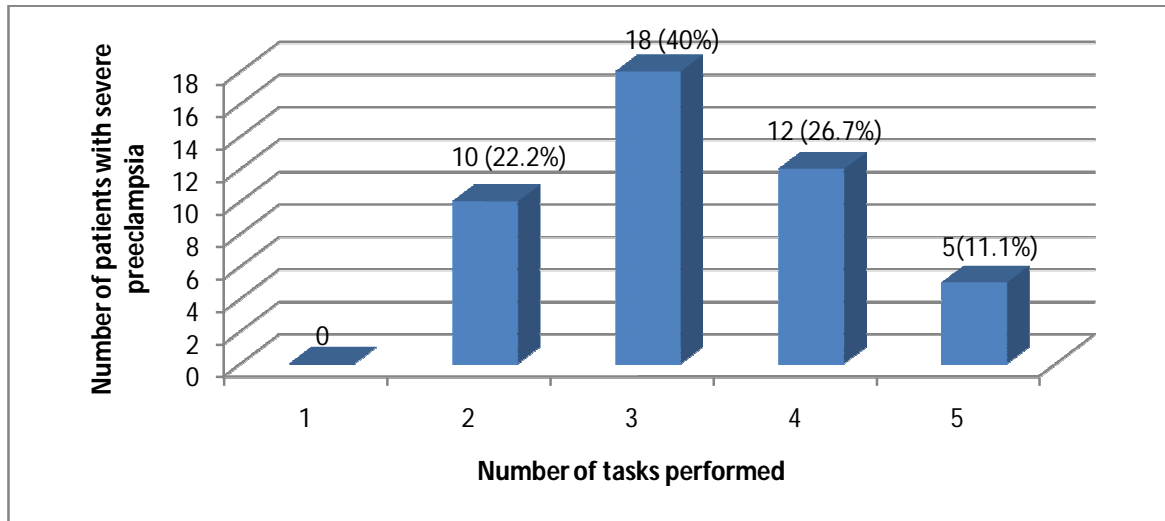


Figure 1: Number of guideline recommended tasks performed for eclampsia patients admitted at Garissa PGH

- Ten patients had two out of the five guideline recommended tasks performed.
- Eighteen patients had three tasks out of the five guideline recommended tasks performed.
- Twelve patients had four and five patients had five out of the five guideline recommended tasks performed.

**Table 4:** Use of guidelines, mode of delivery and neonatal outcomes

Guidelines	Some aspects followed		Not followed	
Apgar score at 5 min.	Alive	Died	Alive	Died
Vaginal, n=28	18	2	3	5
Cesarean section, n=17	6	4	1	6

The table above shows proportion of women in whom some aspects of guidelines were followed and those where these were not followed, their mode of delivery and the neonatal outcome at 5 minutes. In total, 30 women had some aspects of guidelines followed and 24 neonates survived at 5 minutes with only 6 dying. In those where minimal or no aspects of guidelines were followed, [n=15], only 4 neonates survived at 5 minutes with 11 mortalities.



## Guideline treatment tasks completed versus development of complications

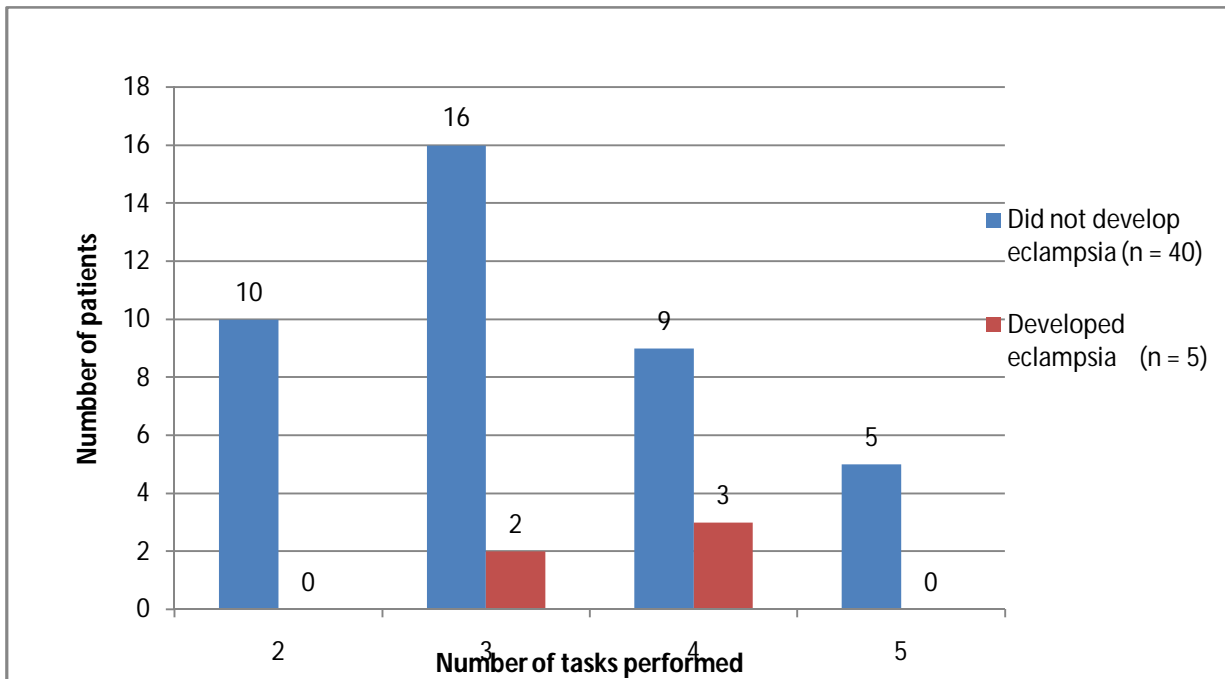


Figure 2: Number of guideline treatment tasks completed versus development of complications

Five patients developed eclampsia, 2 within the first two days and 3 on either the third or fourth day of treatment. The level of adherence to the guideline treatment task did not show a significant association with development of eclampsia ( $p = 0.28$ ).

The remaining 40 mothers with preeclampsia were all judged to be clinically stable. The most common mode of delivery was spontaneous vertex delivery 29(72.5%) and emergency C/S was conducted in 11 (27.5%) cases. The pregnancy outcomes are shown in Table 5 below, 30% had good outcomes and 10% of the infants had died

**Table 5:** Newborn outcomes and guidelines

Women with eclampsia/severe preeclampsia	Neonatal outcome				P value
	Died (n = 7)		Alive (n = 38)		
	<i>Guidelines used(%)</i>	<i>Guidelines not used(%)</i>	<i>Guidelines used(%)</i>	<i>Guidelines not used(%)</i>	
Admitted in quiet room	100	0.00	100	0.00	NA
Given IV hydralazine 5mg slowly/ sublingual adalat	14.29	85.71	36.84	63.16	0.25
Vital signs monitored every 15-30 minutes	100	0.00	100	0.00	NA
Mgso <sub>4</sub> started and delivered within 24 hours	57.14	42.86	36.84	63.16	0.42
Blood work up	57.14	42.86	52.63	47.37	0.99

Table 5 above shows the outcomes of newborn delivered by mothers who were managed according to guidelines compared to those whose management did not adhere to guideline recommendations. All 45 (100%) patients were admitted and nursed in a quiet room and had vital signs taken every 15 to 30 minutes. One (14.29%) of the seven mothers whose newborn died received IV hydralazine or sublingual adalat compared to 14 (36.84%) out of the 38 mothers whose newborns were born alive and survived up to discharge. MgSO<sub>4</sub> administration (p = 0.42) and maternal blood workup (p = 0.99) did not show statistically significant associations with newborn outcome.

## Management of eclampsia

**Table 6 :** Documented management of eclampsia

<b>Task performed</b>	<b>N = 5</b>	<b>Percent</b>	<b>Guideline recommendations</b>
Airway maintained open	0	0	Maintain open air way
Fits controlled	3	60	Control fits
Blood pressure controlled and monitored quarter hourly	3	60	Control blood pressure and monitor quarter hourly
Fluid balance maintained	2	40	Start I.V line but restrict fluid intake to avoid pulmonary and cerebral edema
<b>Treatment duration for eclampsia</b>			Catheterise and closely monitor fluid intake and urine output
2 days	2	40	
3 days	2	40	
4 days	1	20	
<b>Delivery management and outcome</b>			
Normal SVD	5	100	
Neonatal death/ still birth	3	60	
Maternal outcome			
<i>Dead</i>	1	20	
<i>Alive</i>	4	80	

In general documentation of the management tasks for eclampsia was poor. Out of the five patients with eclampsia none had documentation of support to maintain airway patency. Control of blood pressure and convulsion was not documented in two of the five patients and details of fluid maintenance were documented for two patients only. Treatment duration for eclampsia ranged from 2 to 4 days. All the five deliveries were conducted through SVD resulting in 3 fetal or neonatal deaths and one maternal death.

**Table 7:** Health worker assessment of knowledge and treatment of preeclampsia/eclampsia

<b>Recognition of preeclampsia and type of training</b>	<b>Doctors (n = 7)</b>		<b>Clinical officers (n=10)</b>		<b>Nurses (n=48)</b>		<b>P value</b>
	n/N	%	n/N	%	n/N	%	
High blood pressure > 160/110	7/7	100.0	10/10	100.0	43/48	89.6	0.764
Generalized edema	6/7	85.7	8/10	80.0	38/48	79.2	1.000
Proteinuria in urine sample	6/7	85.7	10/10	100.0	35/48	72.9	0.116
Headache	7/7	100.0	7/10	70.0	24/48	50.0	0.024
Urinary frequency	0/7	0.0	2/10	20.0	6/48	12.5	0.684
Other	3/7	42.9	2/10	20.0	9/48	18.8	0.369
<b>Organs at risk</b>							
Brain	7/7	100.0	9/10	90.0	30/48	62.5	0.051
Kidney	7/7	100.0	9/10	90.0	44/48	91.7	1.000
Stomach	0/7	0.0	1/10	10.0	3/48	6.25	0.713
Liver	6/7	85.7	8/10	80.0	14/48	29.2	<0.001
Blood	4/7	57.1	5/10	50.0	15/48	31.3	0.247
Other	0/7	0.0	1/10	10.0	0/48	0.0	0.262
<b>Fetal assessment for possible compromise</b>							
Weekly NST	3/7	42.9	5/10	50.0	21/48	43.8	0.92
Two weekly BPP	6/7	85.7	2/10	20.0	14/48	29.2	0.009
Amniocentesis	2/7	28.6	4/10	40.0	20/48	41.7	0.915
Urine dip stick analysis	2/7	28.6	4/10	40.0	15/48	31.3	0.906
Emergency C/S	0/7	0.0	5/10	50.0	10/48	20.8	0.044
Other	0/7	0.0	2/10	20.0	0/48	0.0	0.032

The recognition of headache as an alert sign for pre-eclampsia or eclampsia differed by type of health worker training with clinicians being more likely to be aware of this sign compared to nurses ( $p = 0.024$ ). All seven (100%) doctors and eight (80%) clinical officers- were aware of this sign compared to 50% of nurses.

Recognition of the remaining signs of impending preeclampsia or eclampsia including high blood pressure ( $p = 0.764$ ), edema ( $p = 1.000$ ) and proteinuria ( $p = 0.116$ ) did not show statistically significant associations with type of training.

Recognition of risk to the remaining organs was not significantly associated with the type of training of the health workers.

All the 67 (100%) health workers recognized that unborn fetuses of mothers with preeclampsia or eclampsia were at risk. Only doctors (85.7%) were able to correctly identify two weekly BBP as method of fetal surveillance ( $p = 0.009$ ). Less than 50% of doctors correctly identified weekly NST as a method of fetal surveillance compared to 50 % of clinical officers, and only 43.8 % of the nurses,  $p = 0.92$  (Table 7). On the other end, a few doctors, nurses and clinical officers erroneously identified amniocentesis, urine dipstick analysis and emergency C/S as ways of fetal surveillance.

#### **Identification of signs for severe preeclampsia/eclampsia by health workers**

The common physical presentations of eclampsia outlined in the MoH Guidelines were well known by most of the health workers (Figure 3). At least 90% of health workers reported that blood pressure measurements greater than 160/100 mmHg was a major criteria for alerting caregivers about the possibility of pre-eclampsia/ eclampsia. Generalized edema and proteinuria in urine were also well recognized signs of pre-eclampsia and eclampsia. However, headaches were recognized as a sign of pre-eclampsia or eclampsia by only 59.7% of health workers.

### Health worker recognition of alerts for severe pre-eclampsia at Garissa PGH

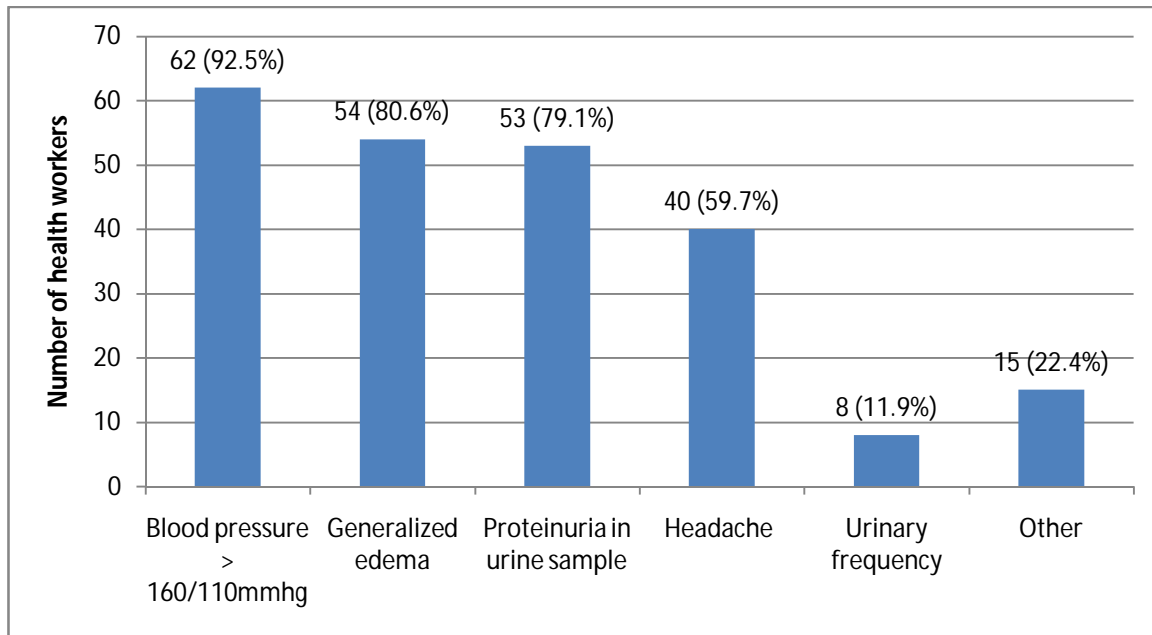


Figure 3: Health worker recognition of alerts for severe pre-eclampsia at Garissa PGH

In addition staff commonly mentioned other alerts of eclampsia or pre-eclampsia (Figure 3) including convulsions or fits (n = 5), and blurred vision (n = 2).

### Organ risk during eclampsia

Table 8: Body organs identified as at risk during eclampsia by health workers at Garissa PGH

	Frequency (n = 67)	Percent
Brain	47	70.15
Kidney	62	92.54
Stomach	4	5.97
Liver	30	44.78
Blood	25	37.31
Other	1	1.49

Only 11 health workers (16.4%) correctly identified all the three organs –brain, liver and kidney- at risk during preeclampsia or eclampsia. The percentage of health workers correctly identifying the individual body organs at risk during eclampsia or preeclampsia varied from 44.78% for liver, to 70.15% for brain and 92.54% for kidneys (Table 8).

A statistically significant association was noted between type of health worker training and the recognition of at risk organs ( $p < 0.001$ ) Nurses (29.2%) were less likely to recognize the risk posed to the liver by preeclampsia or eclampsia compared to the doctors or clinical officers, 85.7% and 80% respectively (Table 8).

**Table 9: Assessment of guideline use**

<b>Intervention for preeclampsia/eclampsia</b>	<b>Frequency (n = 67)</b>	<b>Percent</b>	<b>Guideline Recommendations</b>
Induced	53	79.1	Vaginal delivery. C/S for standard indications
All for emergency C/S	21	31.3	
Catheterized for input-output monitoring	54	80.6	Closely monitor fluid intake and urine output
Blood for U/E/C, FHG and LFTS monitoring	42	62.7	Blood chemistry alternate days
Given magnesium sulphate infusion	53	79.1	Start MgSO <sub>4</sub> regime
Other	3	4.5	
<b>Benefits of guidelines</b>			
Reduces maternal morbidities and mortalities	59	88.1	
Improves neonatal outcome	43	64.2	
Leads to unnecessary extra costs to the woman and her relatives	17	25.4	
Saves time	23	34.3	
Enables early detection of complications and therefore timely intervention	48	71.6	
Other	1	1.5	

The majority of health workers correctly understood the preferred management for women with severe pre-eclampsia/eclampsia. Only 31.3% of the healthcare workers erroneously indicated ‘all for emergency C/S’ as a preferred management option (Table 9).

Generally, majority of the healthcare workers were in agreement that the benefits of use of guidelines in the management of severe pre-eclampsia/eclampsia far outweigh the perceived disadvantages.

### Pharmacologic management of eclampsia and preeclampsia

The majority of healthcare workers correctly identified methyl-dopa, nifedipine and magnesium sulphate as drugs commonly used in managing severe pre-eclampsia/eclampsia (Figure 4). Labetalol, a less frequently used drug for management of severe PET/eclampsia, was correctly identified by 16.4 % of health workers.

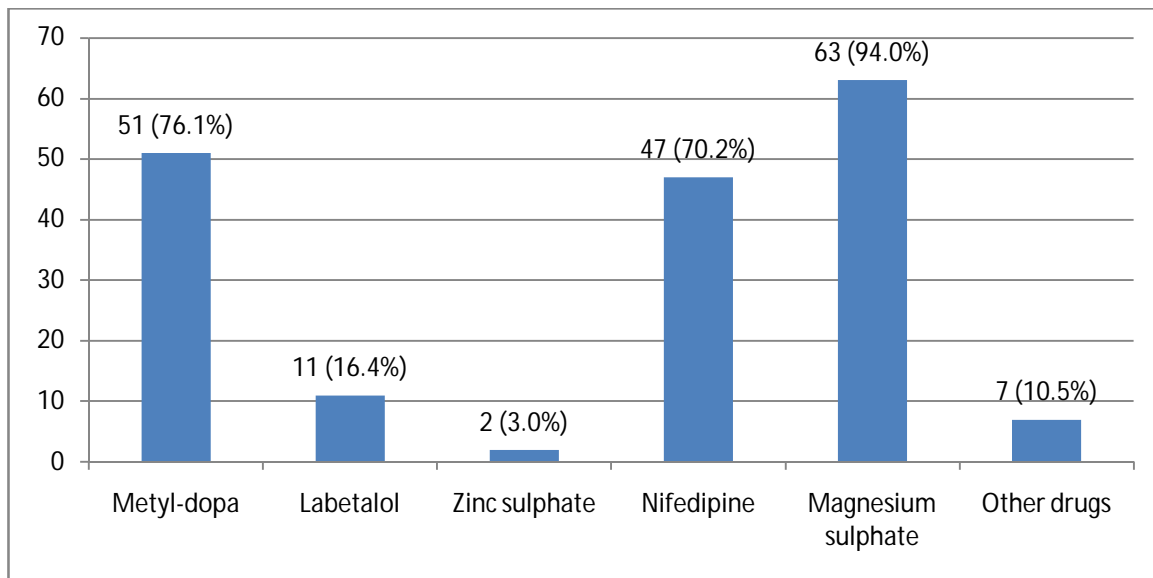


Figure 4: Drugs identified for management of eclampsia and preeclampsia by health workers at Garissa PGH

### Guideline adherence

Based on health worker self report, guidelines were mostly used when managing eclampsia and severe pre-eclampsia at Garissa PGH. Among the 67 participants, only one clinical officer and five nurses reported that guidelines were not followed in the institution when managing eclampsia or severe pre-eclampsia ( $p = 1.00$ ).



### Availability of guidelines as perceived by health workers

All doctors and clinical officers were aware of the existence of standardized guidelines for management of severe preeclampsia and eclampsia. Among the nurses, four (8.0%) nurses reported that they were unaware about the availability of these guidelines. The level of guideline availability awareness for the different health worker cadres is shown in figure 5 and reported availability did not differ significantly when it was compared among doctors (100%), clinical officers (100%) and nurses (91.7%),  $p$ -value = 0.997.

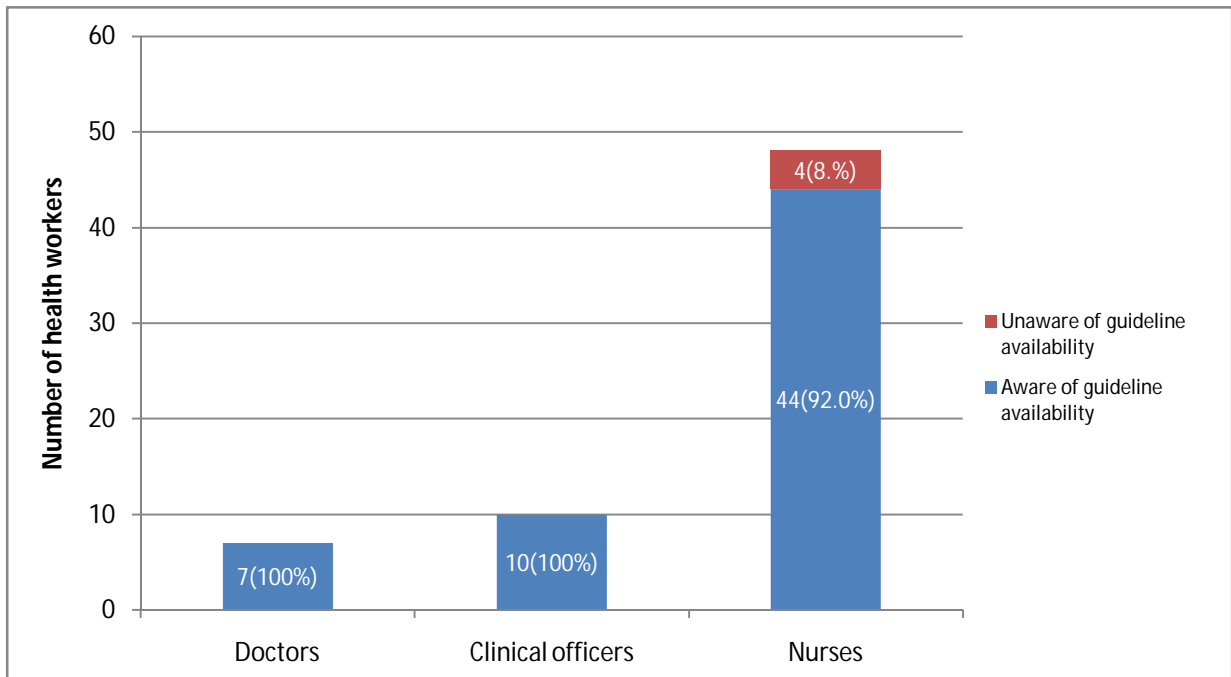
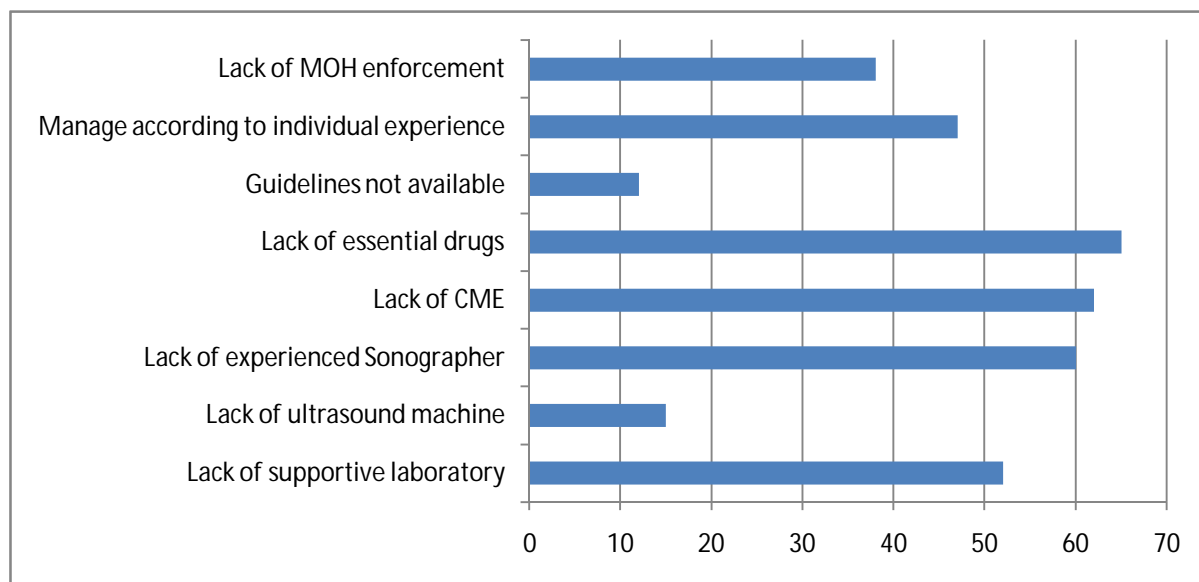


Figure 5: Health worker awareness of guideline availability in GPGH

## Barriers to Utilization of MOH Guidelines for Management of Severe preeclampsia/eclampsia at Garissa GPH



*Figure 6: health workers' reported barriers to utilization of MoH guidelines*

Health workers reported the main impediments to utilization of MoH guidelines as: lack of essential drugs (97.0%), lack of continuous knowledge appraisal (92.5%), lack of an experienced sonographer (89.6%) lack of a supportive laboratory (77.6%). Other reported hindrances include lack of supervision (56.7%), management based on individual experience (71.6%), lack of ultrasound machine (22.4%) and unavailability of guidelines (17.9%).

## Drug inventory record

**Table 10:** Drug inventory record

Drug	Stock in	Stock out/cleared	Remarks
Magnesium sulphate	-23/5/11-received 100 doses -3/3/2012-received 150 doses	All doses cleared on 20/11/11 All doses cleared on 2/6/2012	November 20 <sup>th</sup> , 2011 to march 2012-The hospital was without MgSO <sub>4</sub>
Methyl-Dopa	-10/7/2011-received 2 cartons -5/1/12-received 3 cartons -6/4/2012-received 3 cartons	Cleared December 2011 Cleared April 2012	Stock fairly well maintained
Nifedipine	-15/9/11-received 2 cartons -7/5/12-received 2 cartons	Cleared in April 2012	Stock fairly well maintained
Hydralazine	-13/5/2012-received 3 cartons -2/4/12- received 3 cartons	Cleared February 2012	Hospital was without this drug for 2 months

A drug inventory conducted in the hospital pharmacy section showed that essential drugs for management of severe preeclampsia/eclampsia were not in a constant supply. For instance, magnesium sulphate was stocked in low quantities and there was a long out of stock period before new stock was brought in. Similarly, inventory for nifedipine and hydralazine showed that there was a considerable out of stock interval before new stock was replenished.

## **STUDY LIMITATIONS**

We were only able to extract 45 files of women managed for severe preeclampsia/eclampsia out of our sample size of 81 covering the study period. Medical records of bad outcomes may have been kept away from us and therefore their data not reflected in this study and reducing our sample size. A number of medical records were mild forms of preeclampsia which we did not consider in our study. We did the study at the time when insecurity in Garissa was at its highest, hence did not get adequate time to trace all the medical records of women seen with severe preeclampsia/eclampsia thus further reducing our sample size.

Since there was no direct observation, some healthcare workers may have reported practices that were different from what they actually do e.g. reporting adherence to guidelines yet data extracted from medical records showed they were rarely, if ever used.

## **CHAPTER FIVE**

### **DISCUSSIONS**

The objective of this study was to find out if the MOH approved guidelines for management of severe preeclampsia/eclampsia existed in GPGH and if they were followed by healthcare workers while managing women with these life threatening conditions. The study also sought to establish whether healthcare workers had a general understanding of how women with these conditions should be managed. The main findings of the study are that: - The impact of severe preeclampsia was not fully understood by healthcare workers; Knowledge of effect of severe preeclampsia varied by type of health worker training; Knowledge of guideline recommendation varied by type of health worker training; Adherence to guideline was high and non adherence was associated with increased adverse effects. Although knowledge of guidelines was high, some aspects were lower for nurses and clinical officers. However, adherence to guidelines was poor except for two aspects and this non-adherence was associated with poor pregnancy outcomes.

From our study, we established that most of the healthcare givers were nurses and clinical officers. These cadres of health professionals are mostly inexperienced and could be contributing to the high morbidity and mortality rate. This is in contrast to the Royal College of Obstetricians' recommendation that women with severe preeclampsia/eclampsia be handled by obstetricians, obstetric registrars and experienced midwives<sup>25</sup>. In a study by Ahmad Reda and his colleagues titled '*updating Nurses' knowledge about preeclampsia patients' 2008*', the researchers concluded that experience is an important source of knowledge but education is a neglected area that impact on how nurses update their knowledge. They recommended that an ongoing education should be adopted to improve the quality of nursing care for preeclampsia patients<sup>27</sup>.

All healthcare workers were aware of the availability of guidelines except 4(8.0%) nurses. Most reported that guidelines were followed in management of women with severe preeclampsia/eclampsia but data extracted from medical records did not show that these guidelines were followed. Further, awareness of the preferred drug management for severe preeclampsia/eclampsia was generally high but the actual practice did not always adhere to guideline recommendations. This could mean that there is inadequate or no supervision, healthcare giver practice based on their individual experience or there is a chronic shortage of the essential drugs and equipment necessary to offer proper care. In a study by USAID and SPS

(*strengthening pharmaceutical systems in Kenya*), 2012, it was revealed that severe preeclampsia/eclampsia is one of the leading maternal mortality in Kenya, contributing to about 19%. It established that information on the availability and management of preeclampsia/eclampsia (especially MgSO<sub>4</sub>) is limited hence the high mortality due to these conditions. The study also established that there were guideline inconsistencies in the management of severe preeclampsia/eclampsia in majority of Kenyan health institutions both public and faith-based. It also showed significant discrepancies between inventory records and physical stock. For example, 78 facilities had inventory records of availability of MgSO<sub>4</sub> but only 36 facilities had records matching stock. In 65% of the time MgSO<sub>4</sub> was unavailable in 84% of the facilities observed. It also showed that MOH staff had limited or no knowledge of and access of the essential guideline drugs<sup>26</sup>. In a study by Abdalah K Ziraba and colleagues, March 2009, titled '*the state of emergency obstetric care services in Nairobi informal settlements and environs: Results from a maternity health facility survey*' showed that many health facilities do not meet a criteria for comprehensive emergency obstetric care, while the rest provided less than basic care. Lack of obstetric skills, equipment and supplies were cited as hampering facilities from providing lifesaving emergency obstetric care. They concluded that specific areas that require attention include supervision, regulation of maternity facilities and ensuring that basic equipment, supplies and trained personnel are available in order to handle obstetric complications in both public and private facilities<sup>28</sup>. This is in agreement with our study findings that Garissa PGH lacks basic equipment and has inconsistent essential drugs stocking.

In our study, we established that signs of preeclampsia such as elevated BP, and proteinuria were well identified by majority of healthcare workers. Headache which is a sign of severe preeclampsia/eclampsia was not well identified (40.7%). A small number of health workers, 5 (7.5%) and 2(3.0%), identified convulsions and blurred vision as signs. Doctors (100%) and clinical officers (70%) were able to recognize signs of impending eclampsia as compared to nurses (50%)  $p=0.024$ . only 11(16.4%) of health workers were able to identify all the body organs at risk during severe preeclampsia/eclampsia. Type of training had positive correlation with identification of organs at risk, more in doctors than other cadres,  $p<0.001$ . All health workers reported that the fetus is at risk but most did not know how to assess for the risks. Only 85.7% of doctors had some idea on one or two assessment methods. Understanding of the preferred management steps was high (60%), but these were not reflected in the medical records.

In cases where guideline recommended steps were followed, neonatal outcomes were good compared to cases where these were not followed. These observations mean that majority of Kenyan healthcare workers are ill equipped with the necessary knowledge and skills to combat the syndrome of preeclampsia/eclampsia. In a study by Frank Kagema(2010) and colleagues titled '*quality of care for prevention and management of common maternal and newborn complications: Findings from a national health facility survey in Kenya- Are services provided according to international standards*', they found that the quality of much of the maternal and newborn care provided was below the internationally accepted standards. Guidelines were lacking for the provision of evidence-based practices. The study also showed that although most of the health providers correctly diagnosed severe preeclampsia (83%) and knew appropriate initial management (77%); only about 1/3 knew the correct treatment for convulsions and the ongoing management steps<sup>29</sup>. In another study by Josephine Kibaru(2009) and colleagues titled '*influence of provider training on quality of emergency obstetric care in Kenya*', they found out that less than 20% of maternal health workers had received training in focused antenatal and postnatal care and few (18%) had training on lifesaving skills<sup>30</sup>. So clearly, there is need for health workers' capacity building if women with the syndrome of preeclampsia/eclampsia are to be given the treatment they deserve.

Severe preeclampsia/eclampsia poses a significant and fatal risk to the unborn fetus if it is not well monitored and timely intervention administered. From the study findings, nearly all healthcare workers admitted that the unborn child to a mother with severe preeclampsia/eclampsia is at significant risk. However, doctors were able to identify the various modes of surveillance and fetal assessment compared to few clinical officers and even fewer nurses. In their study titled '*Biophysical profile scores and resistance indices of the umbilical artery as seen in patients with pregnancy-induced hypertension at Kenyatta National Hospital and Marter Hospital, Nairobi*<sup>24</sup>',2006; Nguku SW, Wanyoike-Gichuhi and S Aywak AA showed that RI of umbilical artery was positively related to the duration of illness. RI is an earlier indicator of fetal compromise before any fetal distress becomes apparent. Thus, regular obstetric ultrasound fetal surveillance in severe preeclampsia/eclampsia is important for fetal well being.

## **CHAPTER SIX**

### **CONCLUSION AND RECOMMENDATIONS**

1. MOH guidelines for management of severe preeclampsia/eclampsia do exist in GPGH.
2. Majority of healthcare workers at GPGH were aware of the existence of MOH guidelines.
3. Doctors and some clinical officers, in some instances, were the health workers who frequently referred to guidelines in management of women with severe preeclampsia/eclampsia at GPGH.
4. The type of training (doctor, clinical officer or nurse) had a big impact in the assessment, diagnosis and overall management of women with severe preeclampsia/eclampsia.

### **RECOMMENDATIONS**

1. Given the low application of guidelines and the poor understanding of the recognizable signs, risks and management of severe preeclampsia among nurses and these form the bulky of health workers giving care to women with severe preeclampsia/eclampsia, there is a need to consider continuing medical education such as seminars, grand rounds and case discussions in the nursing group to shore up their skills. It is important that such trainings should be extended to clinical officers and medical officers to improve further on their professional understanding.
2. There is need for increased health sector funding by the government to address chronic essential drug and equipment shortages.
3. The relevant authorities charged with ensuring that quality healthcare is offered should intensify supervision to ensure the recommended management is practiced.
4. Further studies will need to be done in order to evaluate the use of guidelines countrywide.
5. Rolling out of guidelines to all health facilities to improve standards and optimize care of women with severe preeclampsia/eclampsia.



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## APPENDICES

### APPENDIX 1: INFORMED CONSENT

I am Doctor John Omboga, a postgraduate student registered for masters in medicine-M.med obstetrics and gynecology in the University of Nairobi. I am carrying out a study as part of the requirement for M.med qualification. My objectives are to determine the availability of National guidelines and their application in the management of severe pre-eclampsia/eclampsia in GPGH.

Study approval has been given by the Kenyatta National Hospital/University Of Nairobi ethics committee {KNH/UON-ERC}. The committee can be contacted through;

Prof. A. N. Guantai,

Secretary, KNH/UON-ERC,

P.o box 20723,

Nairobi.

E-mail:uonknh-erc@uonbi.ac.ke

My supervisors, both of whom are based at the department of obstetrics and gynecology at the University of Nairobi are:

1. Prof. James N. Kiarie
2. Dr. Weston khisa

I am requesting your participation in this study as a health worker working at GPGH. I would like to bring to your attention the following ethical considerations which will guide your participation.

1. Participation in this study is purely voluntary.
2. You may withdraw from the study at any time and there are no consequences for your decision to withdraw.
3. After you read through the explanations, please feel free to ask any questions that will allow you to understand the nature of the study.

4. Any information you provide including details on your demographic characteristics will be treated as confidential.
5. The study protocol has been reviewed by the ethics committee. The protocol can be accessible to you should you choose to know the details.

I will be available to answer any questions that will help you understand the nature of the study. If you wish to seek any clarification, kindly contact me on **0720258887**.

**PROCEDURE:** A questionnaire will be provided. It should take approximately 10-15 minutes to complete. I will be available to guide you through the questions.

**BENEFITS:** There are no direct personal benefits for participating in this study.

It is expected that study findings will help improve the management of women with severe pre-eclampsia/eclampsia in GPGH.

**APPENDIX 2: CONSENT FORM**

*I, the undersigned, do hereby consent to participate in this study whose nature, purpose and objectives have been fully explained to me. I am aware that participation is voluntary and that there are no consequences to withdrawal from the study. I have been informed that all data provided will be used for the purposes of study only.*

Signed.....date.....

*I,.....declare that I have adequately explained to participant the purpose of the of the study, procedures, risks and benefits. I have given the participant time to ask questions and seek clarification regarding the study.*

Signed.....date.....

### APPENDIX 3: QUESTIONNAIRE

#### *For healthcare workers*

##### *Demographic data.*

- Indicate your gender.....M/F
- Indicate your age.....
- Indicate your type of training.....consultant/medical officer/clinical officer/nursing officer

For each question, there are numbered possible responses. Please indicate **T** for true or **F** for false against each of the responses. A space is provided for your other possible response not covered in the numbered options.

1. What are the main physical findings that alert you about the possibility of developing severe pre-eclampsia/eclampsia?
  - a) High blood pressure above 160/110mmhg
  - b) Generalized edema
  - c) Proteinuria in urine sample
  - d) Headache
  - e) Urinary frequency
  - f) Other.....
2. Which organ systems are mainly affected by severe pre-eclampsia/eclampsia?
  - a) Brain
  - b) Kidney
  - c) Stomach
  - d) Liver
  - e) Blood
  - f) Other.....
3. In your opinion, is the unborn fetus to a mother suffering from severe pre-eclampsia/eclampsia at any risk?
  - a) Yes
  - b) No

- c) Other.....
4. If your response to question 3 is yes, how can the fetus be assessed for any possible signs of compromise?
- a) Weekly NST
  - b) Two weekly BPP
  - c) Amniocentesis
  - d) Urine dipstick analysis
  - e) Emergency C/S
  - f) Other.....
5. Are you aware of the existence of standardized guidelines for management severe pre-eclampsia/eclampsia?
- a) Yes
  - b) No
  - c) Other.....
6. In your institution, are these guidelines followed when managing severe pre-eclampsia/eclampsia? If not, which alternative is used?
- a) Yes
  - b) No
  - Other.....
7. If your answer to question 5 is yes, list the drugs that are essential for management of severe pre-eclampsia/eclampsia.
- a) Methyldopa
  - b) Labetalol
  - c) Zinc sulphate
  - d) Nifedipine
  - e) Magnesium sulphate
  - f) Other.....
8. In your opinion, what are the advantages and disadvantages of strict use of guidelines in management of severe pre-eclampsia/eclampsia?
- a) Reduces maternal morbidities and mortalities
  - b) Improves neonatal outcome



- c) Leads to unnecessary extra costs to the woman and her relatives
  - d) Saves time
  - e) Enables early detection of complications and therefore timely intervention
  - f) Other.....
9. In your institution, how are pregnant women with severe pre-eclampsia/eclampsia managed?
- a) Induced
  - b) All for emergency C/S
  - c) Catheterized for input-output monitoring
  - d) Blood for U/E/C, FHG and LFTS monitoring
  - e) Given magnesium sulphate infusion
  - f) Other.....
10. Would you recommend the use of guidelines for management of severe pre-eclampsia/eclampsia?
- a) Yes
  - b) No
  - c) Other.....
11. In your opinion, what are the factors that hinder optimal utilization of MOH guidelines for management of severe preeclampsia/eclampsia in Garisa PGH?
- .....
- .....
- .....
- .....
- .....
- .....
- .....
- .....
- .....
- .....

**APPENDIX 4: DATA ABSTRACTION TOOL FOR MANAGEMENT OF SEVERE PRE-ECLAMPSIA/ECLAMPSIA**

**Hospital no.....serial no.....**

***Mild pre-eclampsia...BP 140/90mmhg***

- a) Admitted  
Not admitted
- b) Oral aldomet 250mg given to maintain diastolic BP at 90-100mmhg.....  
Not given.....
- c) Maternal and fetal condition monitored weekly.....  
Not monitored.....
- d) Advised to take diet rich in proteins, fiber and vitamins and low in carbohydrate and salt.....  
Not advised.....
- e) Duration of treatment.....
- f) Complications.....  
.....
- g) Mode of delivery.....
- h) Pregnancy outcome.....
- i) Condition ..... of  
mother.....baby.....
- j) Apgar score at 5 minutes.....

***Severe pre-eclampsia.....Diastolic BP >110mmhg***

- a) Admitted in quiet room.....  
Not admitted.....
- b) Given IV hydralazine 5mg slowly or sublingual adalat.....  
Not given.....
- c) Vital signs monitored every 15-30 minutes.....  
Not monitored.....
- d) Mgso<sub>4</sub> started and delivered within 24 hours.....  
Not started.....
- e) Bloodworkup...U/E/C, LFTS, FHG done.....

- Not done.....
- f) Duration of treatment.....
- g) Complications.....
- h) Mode of delivery.....
- i) Pregnancy outcome.....
- j) Condition of mother.....baby.....
- k) Apgar score at 5 minutes.....

***Management of eclampsia***

- a) Airway maintained open.....  
Not maintained.....
- b) Fits controlled.....  
Not controlled.....
- c) Blood pressure controlled and monitored quarter hourly.....  
Not controlled and not monitored.....
- d) Fluid balance maintained.....  
Not maintained.....
- e) Duration of treatment.....
- f) Complications.....
- g) Mode of delivery.....
- h) Pregnancy outcome.....
- i) Condition of mother.....baby.....
- j) Apgar score at 5 minutes.....

**APPENDIX 5:  
REPUBLIC OF KENYA, MINISTRY OF HEALTH**

**NATIONAL GUIDELINES FOR QUALITY OBSTETRICS AND PERINATAL CARE  
*For Health Service Providers in Kenya***

***FOURTH EDITION.....November 2012.***

**PRE-ECLAMPSIA AND ECLAMPSIA**

**Diagnosis of preeclampsia/eclampsia**

History- many cases are detected through routine prenatal screening.

- CNS
  - Headache
  - Visual disturbances- blurred vision, scintillating scotomata
  - Altered mental status
  - Cortical or retinal blindness
- Dyspnoea
- Edema-this exists in many pregnant women but sudden increase in edema or facial edema is more concerning for preeclampsia
- Epigastric or right upper quadrant (RUQ) abdominal pain: hepatic involvement occurs in 10% of women with severe preeclampsia
- Weakness or malaise

**Physical examination**

Findings on physical examination may include the following:

- Increased BP compared with the patient's baseline or > 140/90 mmHg
- Altered mental status
- Decreased vision or scotomas
- Papilloedema
- Epigastric or RUQ abdominal pain
- Sudden increase in edema or facial edema

- Hyperreflexia or clonus: although deep tendon reflexes are more useful in assessing magnesium toxicity, the presence of clonus may indicate an increased risk of convulsions
- seizures
- Focal neurologic deficit

### **Investigations:**

#### **Laboratory studies**

- CBC count and peripheral smear
  - Microangiopathic hemolytic anemia
  - Thrombocytopenia <100,000
  - Hemoconcentration may occur in severe preeclampsia
  - Schistocytes on peripheral smear
- Liver function tests: transaminase levels are elevated from hepatocellular injury and in HELLP syndrome
- Serum creatinine levels elevated due to decreased intravascular volume and decreased glomerular filtrate rate (GFR)
- Urinalysis: more than 300mg or +1 proteinuria in a 24 hour urine sample
- Abnormal coagulation profile: PT and aPTT are elevated
- Disseminated intravascular coagulopathy testing will show fibrin split products and decreased fibrinogen levels
- Hyperuricemia

#### **Ultrasonography:**

This is used to assess the status of the fetus as well as to evaluate for growth restriction (typically asymmetrical IUGR). Aside from transabdominal ultrasonography, umbilical artery Doppler ultrasonography should be performed to assess blood flow

## Management of patients with preeclampsia/eclampsia

### Control BP

- Goal is to prevent cerebrovascular and cardiac complications while maintaining uteroplacental blood flow
- Control of mildly elevated BP does not appear to improve perinatal morbidity and mortality and , in fact, it may reduce birth weight
- Antihypertensive treatment is indicated for BP >160/105 mmHg. Goal is to maintain diastolic BP 90-100mmHg and systolic BP 140-155 mmHg
- First-line medications are labetalol given orally or I.V, nifedipine given orally or I.V, or hydralazine I.V. (*Atenolol, ACE inhibitors, ARBs, and diuretics should be avoided*)

### Control of seizures

- Follow basic principle airway, breathing and circulation (ABC)
- Treat active seizure with intravenous magnesium sulphate as a first-line agent
- Prophylactic treatment with magnesium sulphate is indicated for all patients with severe preeclampsia
- Magnesium levels, respiratory rate, reflexes and urine output must be monitored to detect magnesium toxicity. Magnesium sulphate is mostly excreted in urine and therefore urine output needs to be closely monitored. If urine output falls below 20mls/hr, the magnesium infusion should be stopped
- For seizure refractory to magnesium sulphate, benzodiazepines and /or phenytoin should be considered

### Fluid management

- These patients are intravascularly volume depleted with high peripheral vascular resistance. **Diuretics should be avoided**
- Aggressive volume resuscitation may lead to pulmonary edema, which occurs mostly 48-72 hours postpartum, probably due to mobilization of extravascular fluid
- Total fluids should be limited to 80mls/hr or 1ml/kg/hr

- Careful measurement of fluid input and output especially in the immediate postpartum period is advisable
- If fluids are required, preferably use Ringers Lactate or Normal saline

### **Delivery**

- Patients with mild preeclampsia are induced after 37 weeks gestation. Give steroids prior to this
- Induction of labor should be considered in patients with severe preeclampsia after 34 weeks gestation
- Eclampsia is common after delivery up to 6 weeks

### **Medication**

#### **Magnesium sulphate:**

Antagonizes calcium channels of smooth muscle. Administer IV/IM for seizure prophylaxis in preeclampsia. Use IV for quicker onset of action in eclampsia

#### **Schedule**

#### **Loading**

20% solution or 4g IV over 5 minutes

Follow promptly with 10g of 50% solution, 5g in each buttock as deep IM injection with 1ml of 2% lignocaine in the same syringe

If convulsions occur after 15 minutes, give 2g magnesium sulphate (50% solution) IV over 5 minutes

#### **Maintenance dose**

Give magnesium sulphate (50%) solution + 1ml lignocaine 2% IM every 4 hours into alternate buttocks. Continue treatment for 24 hrs after delivery or the last convulsion, whichever occurs last. If 50% solution is not available, give 1 g of 20% solution IV every hour by continuous infusion.

**Before repeat administration, ensure that:**

Respiratory rate is at least 16 per minute

Patellar reflexes are present

Urinary output is at least 30mls/hr over preceding 4 hours

If the above are absent, withhold or delay drug

**Keep antidote ready:**

In case of respiratory arrest, assist ventilation with mask and bag, intubate. Give 1g (10mls) of calcium gluconate IV slowly until respiration begins

**Phenytoin**

Cardiac monitoring required because of associated bradycardia and hypotension. It is given as 10mg/kg loading dose infused IV no faster than 50mg/min, followed by a maintenance dose started 2 hrs later at 5mg/kg

**In absence of magnesium sulphate, diazepam is used following the regime below:**

**Intravenous**

**Loading**

20mg IV slowly over 2 minutes

If convulsions occur, repeat loading dose

**Maintenance dose**

Diazepam 40mg in 500ml IV fluids titrated to keep the woman sedated but can be aroused

Do not give more than 100mg in 24 hours



### **Rectal administration**

Give diazepam rectally when IV access is not possible. The loading dose is 20mg in 10 mls syringe. If convulsions are not controlled within 10 minutes, administer an additional 10mg per hour or more, depending on the size of the woman and her clinical response

### **Hydralazine (Apresoline)**

First line therapy against preeclamptic hypertension. It is given 5mg IV slowly over 10minutes. Repeat 5mg q20min to a maximum of 20mg

### **Labetalol**

Recommended 2<sup>nd</sup> line therapy. It's onset of action is more rapid than hydralazine. It's given at 20mg bolus; subsequently give doses of 40mg followed by 80mg IV at 10-20 min intervals to achieve BP control to a maximum of 300mg. it may also be administered by continuous infusion at 1mg/kg/hr

### **Nifedipine**

Given at 10mg orally. May be repeated after 30minutes as needed

### **Management of patients with pre-eclampsia**

#### **Mild pre-eclampsia...BP 140/90mmhg**

- Establish if mother can rest at home
- Advice patient and relatives on importance of bed rest
- Give oral antihypertensive (aldomet 250mg tds) to maintain diastolic BP at 90-100mmhg
- Monitor maternal and fetal condition weekly
- Admit if coming too far away from hospital-advice on the worsening signs of the conditions and should report if any be present
- Advice mother to take diet rich in proteins, fiber, vitamins and low in carbohydrate and salt
- If no improvement, refer to hospital if at health center

### **Severe pre-eclampsia....diastolic BP>110mmhg**

- Admit in labor ward in a quiet room
- Administer parenteral antihypertensive (hydralazine 5mg iv slowly) or sublingual nifedipine
- Monitor vital signs every 15-30 minutes
- Consider timing and mode of delivery
- Start MgSO<sub>4</sub> regime and deliver within 24 hours
- Fluid regime management (input/output)
- Do blood chemistry-LFTS, U/E/C, FBC
- If at health center, refer to a comprehensive centre accompanied by a trained nurse

### **Management of eclampsia**

- Maintain open airway
- Control fits
- Control BP and monitor quarter hourly
- Maintain fluid balance

### **Management of the fitting patient**

- Patient should be put in semi prone position so that mucus and saliva can flow out
- Tight fitting dresses around the neck should be loosened or removed
- Clean mouth and nostrils gently and remove secretions
- No attempt should be made to insert any instrument into the mouth
- Give oxygen if available continuously during fit and for 5 minutes after each fit
- Fitting should be allowed to complete its course without physically attempting to hold the patient down
- Privacy and dignity of patient must be observed –pull screens around her
- Administer magnesium sulphate as per regime to control fits

## APPENDIX 6: DRUG INVENTORY RECORD

<b>Drug</b>	<b>Stock in/replenished</b>	<b>Stock out/cleared</b>	<b>Remarks</b>
Magnesium Sulphate			
Methyl-Dopa			
Nifedipine			
Hydralazine			