ADHERENCE TO MINISTRY OF HEALTH GUIDELINES IN MANAGEMENT OF SEVERE PREECLAMPSIA AT PUMWANI MATERNITY HOSPITAL, NAIROBI, KENYA.

A RESEARCH DISSERATION SUBMITTED FOR THE MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY

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DECLARATION AND APPROVAL FROM SUPERVISORS

I, Dr Muchiri W. Dorcus, the principal researcher declare that this is my original work and that this dissertation has never been presented at any university for the award of a degree.

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DEDICATION

This book is dedicated to my parents and siblings for their unconditional support.

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LIST OF ABBREVIATIONS

ACE-I -ANGIOTENSIN CONVERTING ENZYME INHIBITORS

ARBs -ANGIOTENSIN RECEPTOR BLOCKERS

CDC -CENTRE FOR DISEASE CONTROL

ICD -INTERNATIONAL CODE OF DISEASES

ICU - INTENSIVE CARE UNIT

KDHS -KENYA DEMOGRAPHIC HEALTH SURVEY

MDG -MILLENEUM DEVELOPMENT GOALS

MOH -MINISTRY OF HEALTH

KNH - KENYATTA NATIONAL HOSPITAL

MOH - MINISTRY OF HEALTH

NICE -NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

PI -PRINCIPAL INVESTIGATOR

PMH - PUMWANI MATERNITY HOSPITAL

RCOG -ROYAL COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS (UK)

SIRCLE -HEALTH SERVICES IMPLEMENTATION RESEARCH AND CLINICAL EXCELLENCE COLLABORATION

SPSS -STATISTICAL PACKAGE FOR SOCIAL SCIENCES

UON - UNIVERSITY OF NAIROBI

UNICEF -UNITED NATIONS CHILDREN FUND

UNFPA -UNITED NATIONS POPULATION FUND

WHO - WORLD HEALTH ORGANISATION

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ABSTRACT

Background

Preeclampsia and eclampsia are important reproductive health concerns being the second cause of maternal morbidity and mortality in Kenya. For this reason, the Ministry of Health in Kenya developed and implemented guidelines in order to prevent adverse outcomes and to standardise the care across all health care workers who manage women with these conditions.
Despite these efforts, the mortality and morbidity related to preeclampsia and eclampsia has not changed. This brings to question whether the guidelines are understood and utilised in accordance with the stipulation.

Objective

To determine the level of adherence to Kenya Ministry of Health guidelines in management of severe preeclampsia and eclampsia at Pumwani Maternity Hospital.

Design

This was a cross sectional study in which records of patients managed for severe pre eclampsia and eclampsia at Pumwani maternity hospital between 2010 and 2013 were reviewed.

Methodology and Setting

A retrospective analysis of recorded information was done using a template from the Ministry Of Health, Kenya guidelines on the management of severe pre eclampsia and eclampsia. The study site was Pumwani Maternity Hospital, Nairobi. A sample size of 262 was calculated for this study. The data was collected electronically by the principal investigator and trained research assistants using a data abstraction tool that had been created from existing MOH guidelines. SPSS statistical package version 21 was used to analyse the data based on the specific objectives.

Ethical consideration

Permission to carry out this research was sought from the Kenyatta National Hospital (KNH)/UON ethics and research committee and Pumwani Maternity Hospital.

Results

A total of 263 records were analysed. These were presented in tables and diagrams. The overall adherence to guidelines was 31.4%. History taking and examination was at 67.8%, investigations 13.9%, fetomaternal monitoring 26.1%, use of recommended guidelines 29.5% and post partum interventions 20%.

Conclusions

The study showed a situation of clinical practice in discordance with the prescribed standards. The adherence to guidelines was poor leading to poor assessment of patients.

Recommendations

There is overall need for regular clinical audits at the facility, dissemination of appropriate knowledge on management of severe preeclampsia and eclampsia, improvement of documentation and provision of appropriate medications if these are not available.

CHAPTER ONE

INTRODUCTION

Evidence based medicine is defined as the conscientious and explicit use of medical evidence to make decisions for patient management (1). The science of evidence based medicine has been taken up by the World Health Organisation (WHO) which in itself defines guidelines as systematically developed evidence base statements which assist providers, recipients and other stake holders to make informed decisions about appropriate health interventions. The WHO has outlined the manner in which guidelines are formulated, how they are distributed and how they should be evaluated for impact and the same has been done by the National Institute for health and care excellence (NICE) (2),(3). The development of good guidelines however does not necessarily ensure their use in clinical practise (4).

Maternal morbidity and mortality remains a big concern in the world today despite many efforts to lower it. The latest data showed Kenya's maternal mortality to be at 488 per 100,000 live births(5). Most of the causes of maternal morbidity and mortality ratio are largely preventable with severe preeclampsia and eclampsia falling into this category. Severe pre eclampsia and eclampsia is an important cause of maternal mortality in the world (6). The disease falls under hypertensive disorders of pregnancy and account a significant proportion of maternal morbidity and mortality. WHO documents 99% of maternal deaths occur in developing countries (7).When not effectively managed, preeclampsia/eclampsia is responsible for damage to multiple body organs ranging from renal and liver failure, micro vascular damage, brain, hematologic derangements and death. Guideline adherence is an area that is gaining momentum in the medical practise to evaluate how set standards are put into effect. In an evaluation in South Africa an attempt is made to assess the use of research to inform public policy making. In this

document the authors note that the use of evidence is on the rise but has not been well evaluated in translation into policy(8).

STATEMENT OF THE PROBLEM

Despite the development of standard guidelines for the management of preeclampsia and eclampsia, the morbidity and mortality from preeclampsia and eclampsia has not changed significantly even with the recognition of these as important causes of concern, some studies have attributed the lack of facilities and poor training of health care workers in management of severe preeclampsia as contributor to maternal death. There is no good evidence to show whether the Ministry of Health (MOH) guidelines are in use and whether there have been audits to see whether their effect translates to in clinical outcomes in Kenya. More specifically there are no published studies yet looking at the utilization of the preeclampsia and eclampsia guidelines in Kenya. Pirckle et al in their paper noted that here have been few studies looking at obstetrics use of guidelines and the method in which these studies have been done has been evaluated and conclusions made on the use of clinical audits. They also reported the process in measurement of quality of care is the most difficult to measure but may be the best indicator of whether medicine is properly practised(9).

CHAPTER TWO

LITERATURE REVIEW

There are currently in the world several guidelines available for use in the management of preeclampsia and eclampsia. In the Kenyan setting, these have largely been drawn from the WHO guidelines. Clinical guidelines are recommendations on appropriate treatment and care of patients and they help health care workers in decision making based on the best available evidence for the disease conditions. They should not replace the knowledge or skill of the health care workers. A survey of Canadian practitioners established that despite recommendations published by the Canadian Hypertension Society, Clinicians had not been audited to check whether or not they were using the guidelines yet standardisation of care is associated with a reduction of adverse health outcomes across medical disciplines (10). Active guideline implementation including local audits and staff education has been shown to significantly improve maternal outcomes in preeclampsia and eclampsia(11–13). Foy in his time series analysis however concluded that the passive dissemination of guidelines failed to influence adverse outcomes both maternal and perinatal(14) A Cochrane review in 2006 showed that though variable, the auditing and feedback can improve professional practice (15)

Health facilities seem not to lay emphasis in audits of these guidelines or facilitate for refreshing of their use in facilities. The guidelines currently in use by the Ministry of Health in Kenya are a revision done in 2009 following the original that were published in 2002. They are done in 3 levels to outline the levels of care offered in Kenya as community hospitals, level 2-3 hospitals (primary hospitals) and level 4-6 (tertiary hospitals). The guidelines on preeclampsia and eclampsia are part of a large volume that includes guidelines of other medical conditions. The guidelines on management of preeclampsia and eclampsia are found on chapter 58 of the third volume(16).

From this document was drawn a more specific document titled National Guidelines for Quality Obstetrics and Perinatal care. The guidelines have been revised and reviewed by authors who contributed from their areas of speciality and these authors have been drawn from all levels of health care. In this regard the review of the guidelines for preeclampsia and eclampsia was done by senior obstetricians and gynaecologists from the Ministry of Health, the Ministry of Public health and professors from the University of Nairobi. The guidelines lay emphasis on the identification and diagnosis of preeclampsia and eclampsia, the general management of the disorders and the definitive management with highlights on the use of antihypertensive medications and the use of magnesium sulphate. The guidelines mention the mode of delivery is to be based on vaginal examination findings.

Maternal health is defined as the health of women during pregnancy, childbirth and the post-partum period. Maternal health directly impacts on maternal morbidity and mortality as evidenced by the huge campaigns by the World Health organisation to enhancing health by reduction of maternal mortality. Maternal mortality is defined in ICD tenth edition as the death of a woman while pregnant or within 42 days of termination of a pregnancy, irrespective of the duration and site of pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes(17). According to a WHO worksheet,800 women die every day from preventable causes related to pregnancy and 99% of these deaths were occurring in developing countries(7). Since 1990, the mortality rate worldwide has dropped from 47% but the maternal mortality ratio has only been dropping by 3.1% which is far from the 5.5% required to achieve the Millennium Development Goals (MDG) by 2015(7).

Nationally, maternal mortality has remained a challenge over the last two decades. Currently the maternal mortality stands at 488 deaths per 100,000 live births. Maternal mortality can be attributed to direct and indirect causes. Direct causes include maternal haemorrhage, sepsis, preeclampsia and eclampsia, obstructed labour and abortion. Severe preeclampsia accounts for a significant proportion of maternal morbidity and mortality(18). When not effectively managed, preeclampsia and eclampsia is responsible for damage to multiple body organs ranging from renal and liver failure, micro vascular damage, brain, hematologic derangements and death (19). Preeclampsia definition has been revised in 2013 according to the American College of Obstetricians and gynaecologists as the new onset of hypertension and either proteinuria or end organ dysfunction after 20 weeks of gestation on a previously normotensive woman. Severe hypertension and end organ damage are considered as severe spectrum of disease(20).

There are several known strategies available to reduce the negative impact of pre eclampsia worldwide and even closer locally and these include informed and timely ability to identify and diagnose pre eclampsia and eclampsia. Strategies also include swift investigations of clients to establish effect of the disorder on both mother and baby, proper administration of drugs ranging from antihypertensives to magnesium sulphate. The strategies are also aimed at timely delivery by either caesarean or vaginal delivery depending on vaginal examination findings. The strategies have over time helped lay guidelines for prevention and treatment of this disease entity. Locally, there are few available publications outlining the burden of disease in Kenya. In one unpublished hospital survey at a national referral centre in Kenya, the maternal morbidity from pre eclampsia and eclampsia is high with 4.5% patients being admitted to intensive care unit following complications of the disease. At Pumwani Maternity hospital where this study was based, there were no figures noting the disease burden for pre eclampsia and eclampsia. There

was also no system in place to capture this data. Most maternal deaths are preventable when there is access to adequate reproductive health services, equipment, supplies and skilled healthcare workers. Locally the Government of Kenya through the Ministry of Public Health and Sanitation and Medical Services in the year 2009 revised an earlier edition of a manual, Clinical management and Referral Guidelines Volume III that was initially published in 2002.(21) This manual outlines standard expected management of various conditions in medicine. The core aspects of the guideline related to management of severe preeclampsia and eclampsia are outlined in section 58.9 where it defines pre eclampsia and eclampsia, its causes, diagnosis, emergency preparedness and management. This was published in 2010 and is disseminated to district and provincial hospitals. From this guideline, there have been other documents drawn up the latest being National Guidelines for Quality Obstetrics and Perinatal care that is more specific for maternal and child health. In summary, both documents define pre eclampsia as onset of hypertension with either proteinuria with or without oedema at a gestation of 20 weeks or more. Eclampsia is here defined as presence of fits in a patient with pre eclampsia. It recommends baseline investigations such as haemoglobin levels, urinalysis, clotting studies where available, obstetric ultrasonography for fetal assessment. For general management optimal time of delivery is to be considered, continuous assessment of maternal and fetal status, antihypertensive drugs and bed rest are to be considered. Specific management is dependent on severity of the disorder. A summary of this guideline is done on this document and scanned copies of the full document attached as Appendix 2.

Following this review, evidence suggests the availability and implementation of guidelines go a long way to the improvement of health care in the management of hypertensive disease of

pregnancy. The Ministry of Health in Kenya has developed guidelines for the purpose of standardising and improving care of preeclampsia and eclampsia whose impact on outcomes has not been tested. There was a need to evaluate whether the current national guidelines are available and how well they are adhered to. There was also a need to outline what outcomes are related to the utilization of guidelines at this facility in relation to mothers and neonates. Currently there have been few papers looking at the utilization of guidelines in Kenya most of which are in HIV and a few in paediatrics(22,23). There has only been one unpublished paper specifically addressing preeclampsia(24).

THE KENYA MINISTRY OF HEALTH GUIDELINES (2002)

The Government of Kenya through the Ministry of Health formulated the following guidelines to be used by health care workers at facilities that receive and manage women with severe pre eclampsia and eclampsia. The latest of these guidelines were rolled out in 2012. The guidelines lay emphasis on diagnosis, treatment and follow-up of these patients.

A) Diagnosis of pre eclampsia and eclampsia

1. History mainly through routine prenatal screening. The history is taken in regard to all body systems.

Central nervous system would include questions on headaches, blurring vision, Visual disturbances or altered mental status.

Respiratory system would include difficulty in breathing and dyspnoea

Oedema which even though is quite common on women would be ominous if of sudden increase associated with facial oedema

Epigastric or right upper quadrant pain due to involvement of the liver which can be a symptom in up to 16% of women with severe pre eclampsia.

B) Physical examination

They may include:

- Elevated blood pressures in comparison to the patients' baseline during the antenatal period or level 140/90 mmhg and above, absolute level of > 100 diastolic for severe pre eclampsia.
- Altered mental status.
- Decreased vision or scotomas.
- Epigastric tenderness/ right upper quadrant tenderness.
- Papilloedema.
- Facial or lower leg oedema.
- Seizures- these may occur regardless of severity of hypertension and may be difficult to interpret, usually tonic clonic and resemble grand mal seizures of epilepsy, they may occur in rapid sequence as in status epilepticus and end in death, they may be followed by a coma lasting minutes to hours and 25% of fits may occur after delivery of the baby.
- Focal neurologic deficit.

C) Investigations

Laboratory studies to include

- Urinalysis with quantification of proteinuria more than 300 mg or +1 proteinuria for pre eclampsia, protein 2+ for severe pre eclampsia
- Complete blood count (CBC) and peripheral smear features to look for are microangiopathic haemolytic anaemia, Thrombocytopenia, hemoconcentration, schistocytes on peripheral smears

- Liver function tests (LFT): elevation of liver enzymes following hepatocellular injury and in haemolysis elevated liver enzymes and low platelets (HELLP) syndrome.
- Renal Functions tests (UECR): elevations of the components of urea and creatinine specifically denoting renal dysfunction.
- Coagulation profile: elevations in prothrombin times and activated PTT.
- Fibrin degradation products, decrease in fibrinogen levels.
- Uric acid levels: An elevation in this is one of the earliest laboratory manifestations. It has low sensitivity 0-55%, but high specificity 77-95%.

Ultrasonography

This is used for assessment of foetal well being to evaluate growth restriction typically asymmetric IUGR. The guidelines recommend aside from growth, umbilical artery Doppler studies should be performed.

E) Management of patients with pre eclampsia/eclampsia

General principles

i) Control of blood pressure

The goal is to lower BP to prevent cerebrovascular and cardiac complications while maintaining uteroplacental flow. Antihypertensive treatment is indicated for diastolic pressures above 105 mmhg and systolic above 160mmhg. The goal is to maintain BP diastolic between 90-100mmhg and systolic 140-155mmhg. First line medications as quoted in the guidelines are Labetalol, given IV or orally, Hydralazine IV. The guideline recommends avoidance of atenolol,

Angiotensin converting enzyme inhibitors (ACE-I), Angiotensin receptor blockers (ARBs) and diuretics.

ii) Control of seizures

The basic principles of airway, breathing and circulation should always be followed. Active seizures are to be treated with intravenous magnesium sulphate as the first line agent. Prophylactic treatment with magnesium sulphate is indicated for all patients with severe preeclampsia. Magnesium sulphate levels, respiratory rate, reflexes and urine output must be monitored to detect toxicity. Infusion of magnesium sulphate should be stopped if output falls below 20mL/h. Staff should be aware of the risk of seizures following delivery the risk being highest within first 48 hours but can occur anytime up to 4 weeks after delivery. Benzodiazepines and/or phenytoin may be considered for seizures refractory to magnesium sulphate

iii) Fluid management

Despite the peripheral oedema seen in preeclampsia, diuretics should be avoided as the patients have intravascular volume depletion with high peripheral resistance. Aggressive volume resuscitation may lead to pulmonary oedema and this occurs 48-72 hours postpartum. Volume expansion has no benefit to these patients and should therefore be restricted to 80mL/H or 1mL/kg/hr. This means that all patients with preeclampsia and eclampsia require input output charting. If fluids are required use Ringer's lactate or normal saline. Avoid the use of dextrose or dextrose saline infusions.

iv) Delivery

This is the definitive management. Induction of labour is to be done for preeclampsia after 37 weeks. Prior to this, the immature foetus is subjected to corticosteroids in preparation for early delivery. In severe pre eclampsia, which was the focus of this study, induction should be considered after 34 weeks and in these cases the severity of disease must be weighed against the risk of prematurity. Should be as soon as patient is stabilised in the room, preferably within 6-8 hours from first convulsion or within 12 hours of admission. Delivery should occur regardless of the gestational age. Eclampsia is not an indication for Caesarean section (CS)

Mode of delivery

Vaginal delivery is recommended: if cervix is soft and favourable, if there is no absolute indication for CS and if safe anaesthesia is not available or the fetuse is dead or too premature for survival. Unfavourable cervix should be ripened with prostaglandins or Foleys catheter.

C/S should be performed if vaginal delivery is not anticipated within 8 hours for eclampsia or 24 hours for severe pre eclampsia, if there are foetal heart rate abnormalities or if the cervix is unfavourable and the foetus is alive.

Postnatal care

Anticonvulsants therapy should continue for 24 hours after delivery or the last convulsion, whichever occurs last.

Antihypertensives for as long as BP is above 110mmhg.

Input output charting.

Watch out carefully for the development of pulmonary oedema.

Consider referral in women with oliguria, coagulation failure, and persistent coma more than 24 hours after delivery.

v) Magnesium sulphate

The guidelines recommend the prescription as a loading dose of 20% solution, 4 grams IV over 5 minutes, follow this promptly with 10 grams of 50% solution, 5 gram in each buttock as deep IM with 1 ml of 2% lignocaine in the same syringe via aseptic technique. If convulsions occur after 15 minutes, give 2 grams 50% solution IV over 5 minutes

Maintenance dose: 5 grams 50% solution+1ml lignocaine 2% IM every 4 hours into alternate buttocks. Continue treatment for 24 hours after delivery or the last convulsion whichever occurs last. If 50% solution is not available, then 1gram of 20% solution given IV every hour via continuous infusion.

Patient should be examined before repeat administration for Respiratory rate at least 16 breaths/min, patellar reflexes should be present and urinary output at least 30 ml per hour preceding 4 hours. In case this is note the administration of magnesium sulphate should be stopped. Antidote should be ready and administered if there is respiratory arrest. Give calcium gluconate 1gm (10ml of 10% solution IV slowly until respiration resumes). Patient should be intubated.

vi) Phenytoin

Can be used but facility must be able to monitor cardiac activity because it can cause bradycardia and hypotension. Given as 10mg/kg loading dose infused IV no faster than 50mh/min, followed by maintenance dose started 2 hours later at 5mg/kg.

vii) Diazepam

The guidelines do allow for the use of diazepam in the absence of Magnesium sulphate, as IV and rectal where IV access is not possible. The loading dose at 20mg IV slowly over 2 minutes

and maintenance 40mg in 500 ml of fluid titrated to keep the patient sedated but arousable. Rectal administration is by use of syringe.

Definitive management

For purposes of this study emphasis was laid on severe pre eclampsia and eclampsia

- Admit the patient
- Nurse in a quiet semi dark room
- Monitor vital every 15-30 minutes
- Start MgSO4 regime
- Consider timing and mode of delivery
- Closely monitor input output of urine
- Do blood chemistry
- If blood pressure is 110 mmhg start antihypertensive
- If no improvement refer to comprehensive centre accompanied by trained nurse
- Eclampsia
- Call for help
- Maintain open airway
- Control fits
- Control blood pressure with quarter hourly monitoring
- Start IV but restrict fluid intake
- Catheterise and monitor input output

INTERNATIONAL SCOPE

The international bodies also go a long way to ensure they too have their own guidelines in relation to management of severe pre eclampsia. Notably the United Kingdom through their body of Royal College of Obstetricians (RCOG) and the American College of Obstetricians and Gynaecologists (ACOG) describe how the conditions should be managed. The guidelines go into much depth as compared to our National Guidelines(20),(25).

The Royal College in collaboration with the World Health Organisation recommends in the National Institute for Health and Care Excellence (NICE) guideline, the following: 1.Senior obstetricians and anaesthetic staff and experienced midwives should be involved in the assessment and management of women with severe pre eclampsia. Blood pressure should be charted every 15 minutes until the woman is stabilised then every half hour in the initial phase of assessment. If conservative management is envisaged, the blood pressure should be taken every 4 hours. The woman requires investigations frequently to assess end organ damage, their recommendation being complete blood counts, liver and renal functions. These should be repeated daily if normal and more frequently if conditions change clinically. Clotting studies are not necessary if platelet count is more than $100*10^6$ /L. Close fluid balance with input output chart is essential. Catheters are advised only for acute situations and especially immediate post partum. An AST/ ALT level above70 i.u/l is classified as significant and above150 i.u/l is associated with increased morbidity to the mother.

Fetal assessment recommendation is by CTG. Women in labour should be on continuous monitoring. If conservative approach is undertaken, assessments of fetuse are by Doppler studies and fetal weight assessments weekly.

Blood pressure control should be initiated as soon as BP goes above 160/110 mmhg with Labetalol as first line, Hydralazine and Nifedipine in acute management.ACE and ARBs are contraindicated in these patients due to adverse fetal renal effects.

Following a randomised controlled trial (Magpie Trial) the use of magnesium sulphate was cemented and the RCOG proceeded to emphasise its use in severe preeclampsia. The use of this drug is in the context of a decision to deliver. Caution should be taken to monitor renal functions and reflexes in these patients. Seizures should be controlled following the basic principles of airway management, breathing and circulation. A loading dose of four grams in an infusion pump running over 5-10 minutes is recommended followed by a gram an hour maintenance for 24 hours after the last seizure. Recurrent seizures should be treated with a further 2 grams bolus. Diazepam and phenytoin are no longer used as first line agents. Magnesium sulphate should be stopped if renal output is less than 20 mls/hr. Toxicity is countered by use of calcium gluconate. Persistent convulsions call for intubation of the patient to protect their airways. Fluid restriction is done to 80mls/hour or 1ml/kg/hr.

Vaginal delivery is preferred especially if fetuse is less than less than 32 weeks as the success of induction is reduced. Post partum monitoring is key. Eclampsia is common even during the post partum period.

CONCEPTUAL FRAMEWORK

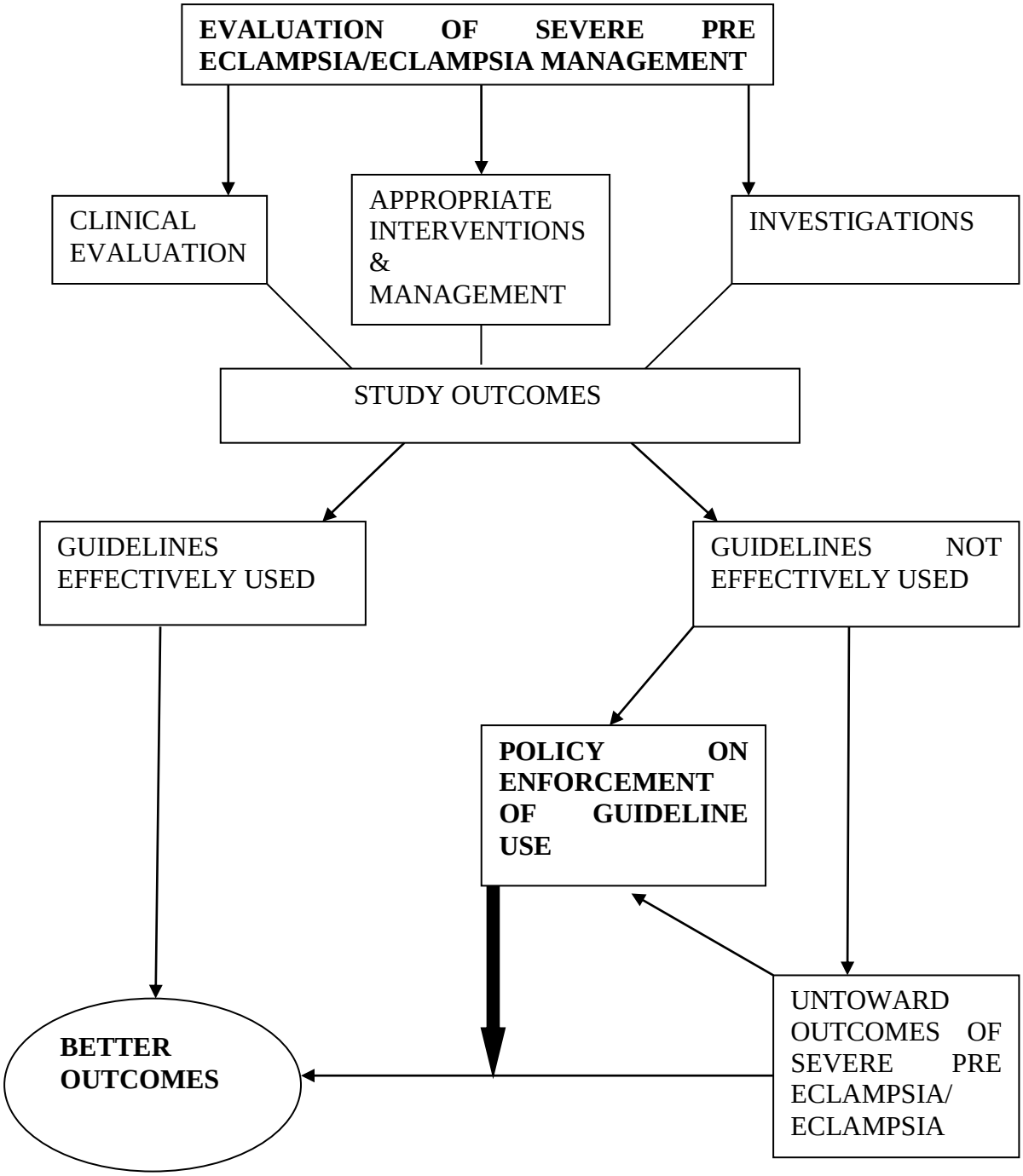
A: Narrative

There is well documented evidence for the effect on outcomes where guidelines are available for use for the management of clinical conditions. This requires the ability of clinicians and a unit handling patients with pre eclampsia and eclampsia to be able to make prompt diagnosis of the disorders. The evidence supports the proper diagnosis and documentation for this process and forms the basis of the guidelines available for use.

However, the level of adherence to these guidelines use is questioned even in their presence at many health facilities. Where present the guidelines have not been audited for their appropriate usage. This then impacts the outcome at our health facilities. It is assumed that once the guidelines are in place, the regular training of health care workers on their appropriate use should positively impact outcomes and reverse the negative trend of pre eclampsia and eclampsia.

The study went to establish how well the MOH guidelines on the management of severe preeclampsia and eclampsia are being utilized to impact clinical outcomes at a busy maternity hospital in Nairobi, Kenya. Following this, recommendations have been made toward the dissemination of information on the guidelines, the enforcement of the use of guidelines and training of health care workers on the guideline use.

B. Schematic. Author Dr Muchiri



JUSTIFICATION

Guidelines are published with an aim of improving quality of care. Despite the input on the development of guidelines in terms of money, time and man power, the impact of their roll out to improve decision making by health care workers and the intended improvement on outcomes has not been evaluated. The study sought to evaluate adherence to the Kenya Ministry of health guidelines on the management of severe preeclampsia and eclampsia. The study had to be carried out retrospectively because a prospective analysis would have influenced the health care workers in their management of severe preeclampsia and eclampsia.

RESEARCH QUESTION

What is the level of adherence to MOH guidelines in the management of severe preeclampsia and eclampsia in Pumwani Maternity Hospital?

MAIN OBJECTIVE

To determine the level of adherence to MOH guidelines in the management of severe preeclampsia and eclampsia in Pumwani Maternity Hospital

SPECIFIC OBJECTIVES

1. To outline the quality of clinical evaluation of patients managed at Pumwani Maternity hospital presenting with severe preeclampsia.
2. To establish the types of investigations carried out on the patients managed at Pumwani Maternity Hospital for severe preeclampsia and identify if these are in tandem with the MOH guidelines.
3. To assess the appropriateness of management for patients with severe preeclampsia and eclampsia based on the MOH guidelines.

CHAPTER THREE

METHODS

STUDY DESIGN

A cross sectional study, in which a data abstraction tool based on the available national guidelines on the management protocol for pre eclampsia and eclampsia was used , to assess the level of adherence to the guidelines in clinical settings from the patients past records. The data looked at specific management following the diagnosis of severe preeclampsia or eclampsia.

STUDY SITE AND SETTING

The study site was Pumwani Maternity Hospital which is a major referral hospital in Eastern Nairobi and serves as a referral for maternity cases for all Nairobi City Council clinics. It has an in- patient bed capacity of 200 and 150 baby cots. The hospital provides prenatal and antenatal services. In addition there are two functional theatres for caesarean sections fully dedicated to maternity. One is for elective but may be used for emergencies. The maternity staffs include four consultant obstetrician/gynaecologists, one Paediatrician and two hundred nurses, fifteen medical officers who work on rotation. Pumwani Hospital has no intensive care unit facility. The facility has a lab equipped to carry out investigations required for most patients with severe preeclampsia. In the study period, January 2010 to December 2013, a total of 50,851 deliveries were performed. This number included both spontaneous vaginal deliveries and caesarean sections and excluded mothers who delivered out of hospital either due to delays before arrival or births after referrals. Of note is that the hospital did not have summarised records of specific disease conditions. The study was conducted at the records office at Pumwani Maternity hospital.

STUDY POPULATION

Medical records were obtained for files of clients who had been admitted with a clinical diagnosis of preeclampsia and eclampsia between the months of January 2010 to December 2013. The files were reviewed with inclusion and exclusion criteria for diagnosis and time of admission to time of discharge or death

Inclusion criteria

1. Records of women with severe preeclampsia and eclampsia admitted to Pumwani Maternity Hospital at gestation more than 20 weeks and less than 6 weeks post partum.
2. Documented diagnosis in the records at onset of management.

Exclusion criteria

1. Files in whom the diagnosis was not clear even though the clinical entity appeared to match severe preeclampsia and eclampsia.
2. Records of patients received and referred without being managed at Pumwani Maternity hospital.

SAMPLE SIZE CALCULATION

Done using the modified Karl Fisher's formula for calculating sample size based on precision around a proportion. This type of study has not been published in Kenya and the sample size calculation was based on one study done at Garissa District Hospital that is unpublished.

$$N=\frac{Z^2 p (1-P)}{d^2}$$

Where

N=estimated sample size

Z= standard normal deviate for 95% confidence interval (1.96)

P =estimated prevalence of adherence to guidelines (0.361 from Garissa study)

d= degree of precision (5%)

Desired level of statistical significance (1.96) represents the desired power typically 0.84 for 80% power.

Prevalence of guideline use in an unpublished study at Garissa Provincial Hospital estimated at 36.1%

$$N= \frac{1.96^2\ 0.36(1-0.36)}{0.05^2}$$

To correct for finite population

$$Nf= \frac{n}{1+n/N}$$

Where N is total finite population,

N =sample size without finite population

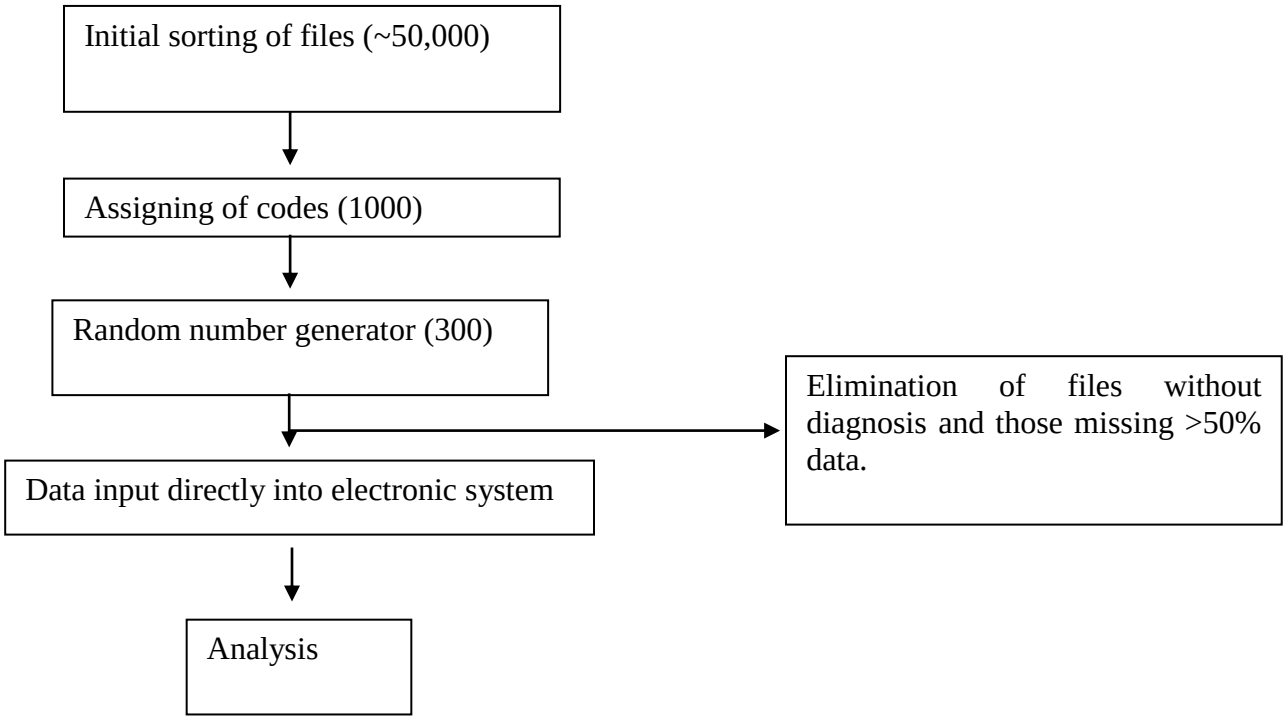
Sample size 262

$$Nf= \frac{359}{1+ \frac{359}{1000}}$$

SAMPLING PROCEDURE.

Following approval from The Ethics committee and permission from Pumwani Maternity Hospital, the principal investigator together with two trained research assistants physically went through files in the store to identify those that appeared to fit the bill of severe preeclampsia and eclampsia based on elevated blood pressures. Following this, records that had the diagnosis of severe preeclampsia and eclampsia were picked out serially .This was done because there was no specific recording or filing system for the diagnosis of severe preeclampsia and eclampsia. Three hundred files were arranged for each of the different years. Each of the files was assigned a code from 1-900. These were then fed into a random number generator on Excel software. Simple random sampling was then done to attain a total one hundred files per year. Of these twenty were excluded on the basis of lacking a documented diagnosis.

FLOW CHART DIAGRAM ON FILE RETRIEVAL



DATA COLLECTION AND MANAGEMENT:

The Investigator trained two research assistants on the use of an electronic database that was directly used for the collection of the data from patients' records. The electronic database had previously been created against the questionnaire that had been created from the Ministry of Health, Kenya guidelines on the management of severe pre eclampsia and eclampsia. Some details were predesigned from the guideline where it was not clear what to assess for such as fetal IUGR that had not been quantified in the guideline was defined as the mention of fetal biometry such as head circumference, abdominal circumference, femur length and specific weight. The principal investigator had tested the system prior to its use on the data collection. The data was collected electronically direct into a database created on MS Access on a laptop and was verified before being fed into SPSS version 21 for analysis.

Data cleaning

Upon collection, data was verified and entered into the statistical software on the same day in a coded form by the principal investigator and saved, awaiting analysis. In case of missing data, the principal investigator conducted a follow up to try and collect the missing data from patients' medical records. Files missing more than half the data required for analysis were removed. Every precaution was taken to respect the privacy of the patients whose data was collected and analyzed in this study. Patient files had no identity by name on the questionnaire but by a code number. After analysis, the data was stored in soft copy by the principal investigator and remained so for a period of one year. There were no hard copies stored by the principal investigator.

Data analysis

Basic socio demographic characteristics and patient presentation and clinical management were evaluated. Analysis was performed using the statistical software with the help of the statistician who has been involved from the initial development of the proposal. Analysis was done as per the objectives of the study, which were, evaluating the level of adherence to guidelines for management of severe preeclampsia and eclampsia. The proportions for different parameters laid out as per the National guidelines were evaluated to determine the levels of adherence for each record assessed. All data presented was as N, %, and mean, +/- standard deviation unless otherwise specified. The mean level of adherence was calculated from an average of all the variables that had been assessed in regard to the guideline.

QUALITY CONTROL

The questionnaire was pretested with 30 initially as the research assistants were being trained two weeks prior to the collection of data. Adjustments to the questions were done prior to the official data collection. All data was counter checked daily before input was made to the statistical package. The electronic collection ensured that every question was answered prior to the next being undertaken.

ETHICAL CONSIDERATION

Approval was sought from KNH/UoN Ethics and Research Committee before data collection commenced. Approval was also obtained from the Nairobi City Council, Pumwani Maternity Hospital Management Board through the medical Superintendant. Confidentiality of information obtained from the patients' records was upheld with the no use of names. There were no incentives given to the facility for this study.

LIMITATIONS

Since the study was retrospective in nature, some data was missing. Files missing more than 50 percent of the data were excluded.

The study was crossectional and therefore was not suited to discussion of outcomes and time sequence events.

The study did not look at the institutional ability to effectively manage the conditions as per the guidelines.

CHAPTER FOUR

RESULTS

A total of 263 records were reviewed for this study and data was extracted for the assessment of adherence to Kenya Ministry of Health guidelines. This data constitutes the results of this study.

Table 1: Frequency distribution of recorded general characteristics of study patients

Characteristic	N= 263	%
Age group		
15- 19	18	6.8
20-24	85	32.3
25-29	78	29.7
30-35	60	22.8
35-39	18	6.8
>40	4	1.5
Parity		
0	119	43.3
1	72	27.3
2	42	15.9
3	18	6.8
>4	12	4.6

Table 1 shows that the most frequent age group of patients with severe preeclampsia and eclampsia was 20-29 years (62%) with the modal age group being 20-24 years (32.3%) with a mean age of 26 years (SEM 0.33 and SD 5.3) and 6.8% of the study population constituted teenagers. Primigravidae constituted 43.3% while those with one previous delivery constituted 27.3%. Mean and median parity was 2+0.

Table 2: Adequacy of documentation of clinical evaluation of patients

Aspect of evaluation	*N-263*
Symptoms recorded	**n (%)**
Lower abdominal pains	100 (38)
Headache	78 (29.7)
Oedema	39 (14.8)
Epigastric pains	29 (11.0)
Convulsions	23 (8.7)
Reduced fetal movements	13 (4.9)
Physical Examination	
Pulse rate	9 (3.4)
Blood pressure	262 (99)
Fundal Height	252 (95.8)
Vaginal Examination	144 (54.8)

Table 2 shows the commonest symptom recorded were abdominal pains (38%), followed by headaches (29.7%), oedema (14.8%) and epigastric pains in only 11%. Physical examination scored high on blood pressure and fundal height examination with 99% and 95.8% of the parameters recorded respectively but poorly on vaginal examination at only 54.8% and 3.4% on pulse rate.

Table 3: Adequacy of documentation of investigations requested and results recorded

Investigations	*Investigations requested N-263 n (%)*	*Results recorded N=263 n (%)*
Hematologic		
CBC	140 (53.2)	34 (12.9)
Peripheral smear	0 (0)	0 (0)
Liver		
LFTs	133 (50.5)	20 (7.6)
Coagulation profile	0 (0)	0 (0)
Renal		
UECR	143 (54.3)	20 (7.6)
Uric acid	0 (0)	0 (0)
Urinalysis	162 (61.5)	98 (37.2)
Fetal well being	135 (51.3)	135 (51.3)
Evaluation for IUGR		16 (6.1)
Doppler Studies		1 (0.38)
Biophysical profile		29 (11)

Table 3 shows, among the patients admitted with severe preeclampsia and eclampsia, requests for investigations were recorded between 50 percent and 61.5 percent for complete blood count, liver function tests and renal function tests. Results received and recorded however were between 7.6 percent and 37.2 percent only. Ultrasonographic evaluation of the fetuse was requested and recorded for only 51.3 percent of which all results were received and recorded. Even though 100% of the Ultrasonographic results were present, they lacked important information with a paltry 0.38% for Doppler studies, 6.1% for intrauterine growth restriction evaluation and 11% for biophysical profiles. Uric acid and peripheral smears as in this table were not requested.

Table 4: Availability of results of investigations requested

Investigations	*Requested N*	*Actual results recorded No (%)*
Hematologic		
CBC	140 (53.2)	34 (24)
Peripheral smear	0 (0)	0 (0)
Liver		
LFTs	133 (50.5)	20 (15)
Coagulation profile	0 (0)	0 (0)
Renal		
UECR	143 (54.3)	20 (15)
Uric acid	0 (0)	0 (0)
Urinalysis	162 (61.5)	98 (60.4)
Fetal well being	135 (51.3)	135 (100)
Evaluation for IUGR		16 (11.8)
Doppler studies		1 (0.7)
Biophysical profile		29 (21)

Table 4 shows among the tests requested for, results did not always reflect in the files of the patients. Results made were between 50.5% and 61.5 % but return of the results was noted between 15percent for renal function and 60.4% for urinalysis.

Table 5: Adequacy of Feto-maternal monitoring of vital signs in 24 hours

Parameters	*No of records*	*No. of counts in 24hrs. per record*
Maternal pulse rate >1 (N=263)	2 (0.76)	3
Fetal heart rate& maternal BP	168 (74)	<5
	56 (24)	5-10
	3 (1.3)	>10

Table 5 shows that out of the total 9 out of 263 records in which maternal pulse had been recorded, 7 had pulse rate recorded only once in 24 hours while in 2 records the documentation was done only 3 times in 24 hours for each record. Foetal heart rate and maternal blood pressure were documented in less than 5 times, 5 to 10times and more than 10 times in 1.3 percent to 74 percent of the 227 records that had that information.

Table 6: Adequacy of management for patients with severe preeclampsia and eclampsia compared to Kenya Ministry of Health guidelines

Time of intervention	*Aspect of management (N-263)*	*n (%)*
Pre delivery	**Timing of decision**	
	Timing of delivery documented	78 (29.6)
	Medications	
	IV Magnesium sulphate Loading dose	147 (55.9)
	IV Magnesium Sulphate Maintenance	136 (51.7)
	IV Labetalol	0 (0)
	IV Hydralazine	5 (1.9)
	Oral Nifedipine	164 (62.4)
	Oral Phenobarbitone*	104 (39.5)
	Oral Methyldopa*	231 (87.8)
Post delivery		
	Time of delivery documented	208 (79)
	Blood pressure Monitoring	189 (70.7)
	Seizure prophylaxis	11 (4.1)
	Input output charting	13 (4.9)
	Auscultation for pulmonary Oedema	1 (0.4)

**Not in guidelines*

Table 6 shows the decision on timing of delivery was documented in 78% of the records. The use of magnesium sulphate was recorded in only 55.9% for loading doses and 51.7 % for maintenance dose. Administration of magnesium sulphate was all intravenous. Hydralazine was used in 1.9% of patients while Labetalol was never used. Phenobarbitone and oral methyldopa was used and documented in 39.5% and 87.8% of the records. At the same time, the actual time of delivery was documented in 79% of records. Post delivery blood pressure monitoring, seizure prophylaxis, input output monitoring and auscultation for pulmonary oedema were documented in only 0.4 to 71 percent of the records.

Table 7: Documentation of acute management of patients with convulsions

Parameters	**N=23**	**%**
Airway management	13	56.5
Bp restoration	3	13.0
Control of convulsions	2	8.6

Table 7 shows the level of compliance of management of patient in accordance to the guidelines in airway was documented as managed in only 56.5% of the 23 patients who convulsed. Blood

pressure restoration and control of convulsions was documented in only 13.0% and 8.6% respectively

Table 8: Overall adherence to MOH guidelines at Pumwani Maternity Hospital for management of severe preeclampsia and eclampsia

Parameters assessed	*Level of implementation (%)*
History and physical examination	67.8
Investigations	13.9
Fetomaternal monitoring	26.1
Use of recommended medications	29.5
Post partum Interventions	20
Mean adherence level	31.4

Table 8 shows overall performance at Pumwani Maternity hospital against the recommended MOH guidelines. The facility scored highest on history taking and examination findings (67.8). the lowest score was in investigations (13.9%) and post partum management of patients with severe preeclampsia and eclampsia (20%). The mean level of adherence was 31.4%.

CHAPTER FIVE

DISCUSSION AND CONCLUSION

The objective of this study was to find out the level of adherence to the Kenya Ministry of Health guidelines in the management of severe preeclampsia and eclampsia at Pumwani Maternity hospital. The main finding of this study was that the compliance to the guidelines was poor even though some aspects of the guideline were better followed than others. This was similar to findings from one unpublished study conducted by Omboga at Garissa Provincial hospital in 2012(24) We speculate that there may be barriers to this, maybe the lack of the guidelines on the ground or the passive dissemination of these guidelines once they are circulated with little training and little assessment of their use after dissemination.

This study found that a low parity was still significant observation at 43% of total patients presenting with severe preeclampsia and eclampsia and this has been echoed by Gold et al (26)Primiparity in a systematic review for antenatal booking of preeclamptic mothers by Kirsten et al was noted to triple the risk for development of severe preeclampsia and eclampsia. The same paper noted the incidence of hypertensive diseases incidence increased progressively to the fifth decade which was a contrast in our study which noted an increase to the third decade up to 30% before a decline to 6.8% in the fourth decade.

The use of magnesium sulphate as a major drug in severe preeclampsia and eclampsia was comparable to the study done in Garissa. Overall, the use of magnesium sulphate was at fifty percent in this study while Omboga noted 40% use. The health services implementation research and clinical excellence collaboration *(SIRCLE)*(27) conducted a survey in 22 level 4 and 5 health facilities in Kenya in 2012 and they assessed several management points for different medical conditions at these facilities. The charting of blood pressure in preeclampsia was comparable in

the report at 90% as we found in our study at 99% but that of other vital signs such as pulse rate was significantly different. The SIRCLE report noted a higher percentage of charting at 81% compared to 3.4% on pulse rate in our study. Fetal surveillance was slightly lower in the SIRCLE report at 76% compared to 86% in our study. The SIRCLE survey however did not go into detail on the depth of fetal surveillance as in this study where specific details on ultrasonographic evaluation of the fetuse were assessed. In their report they observed an overall sixty five percent use of magnesium sulphate which was higher than the finding in our study.

On the use of magnesium sulphate this study found an overall usage of 55% which was lower than the 65% usage in the SIRCLE report. Benefits of use of magnesium sulphate are well documented from the Magpie trial conducted in 2002 showed the benefit on the prophylaxis and treatment of seizures in severe preeclampsia and eclampsia(28). The use of magnesium sulphate is low in some countries classified as low resource setting as was noted in a WHO published paper on a study conducted in Mexico and Thailand which noted a low usage of 0.8-8.5% (29). In a paper published in the United Kingdom in 2010 where it is classified a high resource setting, the use of magnesium sulphate at 17% overall and Chapell et al commented on the lack of concrete documentation on when to use magnesium sulphate in the RCOG guidelines as a possible contributor between the years 2003-2005(30).Our study therefore showed a much higher usage of magensium sulphate compared to other countries in the world.

Our findings on the use of antihypertensives and the types were comparable to a study in India,(31)that noted 71% use of calcium channel blockers in their population study. The Indian study showed the use of sympatholytics (alphamethlydopa) to be at 18% compared to my study

at 87%. The same study showed the use of Labetalol was at 3% compared to my study at 0% usage.

Investigations done for patients presenting with severe preeclampsia and eclampsia were noted to be largely consistent with the guideline recommendations with up to 54 % for urea, creatinine, electrolytes, complete blood counts and haemogram but the study noted that some of the recommended investigations were missing from the patients files with none for peripheral smears, coagulation profiles and uric acid. We postulate that either these are not available at the health facility or that the health care workers were not aware of their significance and use. Pumwani hospital showed a fifty percent request made for investigations but those results that were actually reported and recorded were low and this compared with the findings of the SIRCLE report. The SIRCLE report did not assess urinalysis but our study showed a 61.5% request rate for this. We found no studies that looked specifically at these parameters to compare with our data.

The use of doppler studies in management of severe preeclampsia is well documented and the role well outlined. This was poorly done at Pumwani maternity in only 0.7% where ultrasonography was requested, we postulated that not every client had time to have a scan done but where it was done, the documentation for key features was missing with only 11 percent documentation for growth restriction assessment and 21 percent on assessment for biophysical profiles. There were no studies available as of my knowledge for comparisons on this.

The guidelines made recommendations of at least ninety six counts of fetomaternal monitoring and our evaluation at Pumwani fell short of that recommendation. Most of the patients had less than 5 counts of the monitoring done. There have been no studies going into the depth of this recommendation that we could find.

CONCLUSION

On the whole, the study depicts a situation of a clinical practice which is in discordance with the prescribed standards. The adherence to guidelines is low leading to poor assessment of patients with severe preeclampsia and eclampsia leading to poor pregnancy outcomes. The clinical evaluation was inadequate, the objective investigations were rarely requested and the recording of results was poor. Pre delivery decision making and post partum management of severe preeclampsia and eclampsia was inadequate.

CHAPTER SIX

RECOMMENDATIONS

1. The guidelines must be actively presented and enforced in Kenyan hospitals. Service providers must be educated on the guideline, its recommendation on clinical evaluation and general management of patients with severe preeclampsia and eclampsia. The appropriate recommended investigations must be done for these patients.
2. Clinical surveillance needs to be enhanced in accordance with the guidelines. The guidelines should unreservedly be availed to team leaders and workers in the labour ward.
3. Documentation must be emphasised and the hospital needs to establish proper health information systems and record keeping for patients managed with acute illnesses such as in this case severe preeclampsia and eclampsia.
4. Further regular audits of this nature need to be performed for ascertaining the use of these guidelines and these should be conducted against a background of the hospital capacity and need to further evaluate the reasons and gaps causing this poor level of adherence to the National guidelines.

TIMELINES

ACTIVITY	dec'13	May' 14	June' 14	July.' 14	Aug' 14	Sept' 14	Oct' 14
PROPOSAL DEVELOPMENT	✓						
PROPOSAL PRESENTATION	✓						
SUBMISSION TO ETHICS BOARD		✓	✓				
DATA COLLECTION					✓	✓	
DATA ANALYSIS AND REPORT WRITING						✓	
SUBMISSION OF FINAL REPORT AND ORAL DEFENCE						✓	✓

BUDGET

DR DORCUS MUCHIRI				
BUDGET FOR DECENTRALISED RESEARCH APPLICATION BUDGET				
ITEM	**QUANTITY**	**UNIT PRICE**	**TOTAL (KSH)**	**TOTAL USD**
SUPPLIES				
Biro Pens	2	20.00	40.00	0.50
Pencils	2	10.00	20.00	0.25
Box file	2	150.00	300.00	3.75
Spring files	1	100.00	100.00	1.25
Pencils sharpener	1	50.00	50.00	0.63
White out pen	1	150.00	150.00	1.88
Folder	1	50.00	50.00	0.63
Staple	1	500.00	500.00	6.25
Paper Punch	1	600.00	600.00	7.50
Staple Remover	1	250.00	250.00	3.13
Note book	2	100.00	200.00	2.50
TOTAL SUPPLIES		**1,980.00**	**2,260.00**	**26.5**
OTHERS				
Printing and Photocopying/binding	1	20,000.00	20,000.00	250.00
Final dissertation booklet	1	6,000.00	6,000.00	75.00
Ethics committee, book	1	2,000.00	2,000.00	25.00
A poster	1	6,000.00	6,000.00	75.00
TOTAL OTHER		**34,000.00**	**34,000.00**	**400.00**

Communication	**1**	**5,000.00**	**5,000.00**	**62.50**
Data statistician	**1**	**25,000.00**	**25,000.00**	**294.00**
Research assistant	**2**	**1500**	**45000**	**529**
TOTAL PERSONNEL		**31500.00**	**75000.00**	**885.5**
TOTAL EXPENSES		**67,480.00**	**111,260.00**	**1,311.5**

2 research assistant for 30 working days at a rate of 1500kshs per day to assist with data collection

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APPENDICES

APPENDIX 1: QUESTIONNAIRE

DATA EXTRACTION SHEET ON ASSESSMENT OF GUIDELINE ADHERENCE IN MANAGING SEVERE PRE ECLAMPSIA AND ECLAMPSIA.

Serial number ☐☐☐☐

Admission Date (dd/mm/yy) ☐☐☐☐☐☐

Discharge/death date ☐☐☐☐☐☐

Age ☐☐

Parity ☐

Gravidity ☐

Time of admission ☐☐☐☐

Diagnosis given on Record: (severe preeclampsia, impending eclampsia, Hellp syndrome, eclampsia)

1. Admission documentation –are the following documented (Tick appropriately)
   a. Presenting complaint Empty 1. 2.
   b. Pulse Rate Empty Actu
   c. Blood Pressure Empty Actual BP ...../.....mmHg
   d. Convulsions Empty Yes No
   e. Others (Specify) _____

3. Was urinalysis performed to determine proteinuria yes No (tick)

If yes what was result
   a. Nil ☐
   b. Proteinuria + ☐
   c. Proteinuria ++ ☐
   d. Proteinuria +++ ☐

4. Examination findings recorded

Fundal Height Actual--------- in weeks

Vaginal examination findings: stated as either Bishop's score or favourable/unfavourable

5. Baseline Investigations

	Tick	Values
Full haemogram	☐	Hb..... WBC..... Plts.....
Bedside clotting	☐	...../sec
Urea,creatinine, electrolytes	☐	Urea.....mmol/l Creat.....*u*/l
Liver function tests	☐	ALP.....ALT..... AST.....Bilirubin....
Grouping & crossmatch	☐	
Uric acid	☐	

6. Administration of Magnesium sulphate yes ☐ no ☐ tick appropriately
If yes: dose and frequency. and route. Leave. Space I.M Mgso4 5gram in each buttock

Loading dose ☐ Route IM ☐ ☐
Maintenance dose ☐ Route IM I☐ Frequency ☐
Antihypertensive drugs used yes No
If yes state specific drugs:.....

7. Feto- maternal monitoring done (Tick if done at admission)

	Tick		No. Of counts done in 24 hrs(to show at least ½ hourly)
Maternal pulse rate	☐	...../min	.....
Maternal blood pressure	☐	...../.....mmHg	.....
Foetal heart rate	☐	...../min	.....
Input /output chart	☐	input...../output.....	.....

8. Obstetrics ultrasound scan done Yes No
If yes,

	Reported (tick)	Actual figure (where present)
Biometrics reported (IUGR)	yes ☐ no ☐	
Umbilical artery resistive index reported	yes ☐ no ☐	
Biophysical score	yes ☐ no ☐	

9. Basic management of the patient with seizures outlined (tick appropriately)

a. Airway management yes ☐ o ☐
b. BP/PR restored yes ☐ o ☐
c. control of convulsions yes ☐ o ☐

10. Time of decision to deliver: Empty ..... Hrs
11. Time of delivery Empty ..... Hrs

12. Was the decision to deliver made at time of admission? Yes ☐ N☐ ☐

13. Mode of delivery:

a. Vaginal
b. Caesarean section

14. If Vaginal, was the labour?

a. Spontaneous ☐
b. Induction ☐

15. If induction time of starting Induction Empty .....Hrs

16. If Caesarean section was done, was the basis for this documented? Yes ☐ ☐

If yes, tick reason.

a. Malpresentation ☐
b. Poor Maternal condition ☐
c. Poor Bishop score ☐
d. Lack of Magnesium Sulphate ☐
e. Non Reassuring Fetal status ☐
f. Others (specify) _____

17. Postpartum interventions

a. BP control yes ☐ no ☐
b. Seizure prophylaxis with MgSO4 yes ☐o ☐
c. End organ damage surveillance Input output charting yes ☐ ☐
Auscultation for pulmonary oedema yes ☐o ☐
Coma management. Yes ☐ ☐

18. If there was end organ damage, was there follow-up on the recovery of systems

a. Haematological(HELLP) yes ☐ no ☐
b. Hepatocellular yes ☐ no ☐
c. Renal yes ☐ no ☐
d. Pulmonary yes ☐ no ☐
e. CNS yes ☐ no ☐

19. Pregnancy Outcomes in each case stated at the end of patient management.
a. Stillbirth ☐

b. Term live birth ☐ APGAR .....1...../5...../10
c. Preterm birth ☐ APGAR .....1...../5...../10
d. Referral for ICU care ☐
e. Referral for Dialysis ☐
f. Baby admission to NBU ☐
g. Referral of Baby ICU ☐
h. Referral of mother for any other complications ☐ pecify _____
i. Maternal Death ☐

APPENDIX 2: REPUBLIC OF KENYA MINISTRY OF HEALTH

NATIONAL GUIDELINES FOR QUALITY OBSTETRICS AND PERINATAL CARE

Scanned excerpt from MOH Kenya Clinical Guidelines VOL III

Pre- Eclampsia and Eclampsia

Outline

1. Introduction and Definition pre-eclampsia and eclampsia
2. Risk factors for pre-eclampsia and eclampsia
3. Classification of pre-eclampsia /Eclampsia
4. Diagnosis pre-eclampsia /Eclampsia
5. Management of pre-eclampsia and eclampsia

Introduction / Epidemiology

Preeclampsia is a disorder of widespread vascular endothelial malfunction and vasospasm that occurs after 20 weeks' gestation and can present as late as 4-6 weeks postpartum. It is clinically defined by hypertension and proteinuria, with or without pathologic oedema.

Preeclampsia is part of a spectrum of hypertensive disorders that complicate pregnancy. These include chronic hypertension, preeclampsia superimposed on chronic hypertension, gestational hypertension, preeclampsia, and eclampsia. Although each of these disorders can appear in isolation, they are thought of as progressive manifestations of a single process and are believed to share a common aetiology.

The global incidence of preeclampsia has been estimated at 5-14% of all pregnancies. In developing countries, hypertensive disorders were the second most common obstetrical cause of stillbirths and early neonatal deaths, Preeclampsia is the third leading pregnancy-related cause of death, after haemorrhage and sepsis. Preeclampsia is the cause in an estimated 790 maternal deaths per 100,000 live births accounting for 23.6%.

Race: The frequency of mortality differs among race and ethnicity, with black women having a worse mortality rate than white women.

Age: Preeclampsia occurs more frequently in women at the extremes of reproductive age.

- Younger women (<20 y) have a slightly increased risk. Primigravid patients in particular seem to be predisposed.
- Older women (>35 y) have a markedly increased risk.

Genetics have long been understood to play an important role, and the risk of preeclampsia is positively correlated between close relatives; a recent study showed that 20-40% of daughters and 11-37% of sisters of preeclamptic women also develop preeclampsia. Twin studies have also shown a high correlation, approaching 40%.

Definitions:

Consensus is lacking among the various national and international organizations about the values that define the disorder, but a reasonable limit in a woman who was normotensive prior to 20 weeks' gestation is a systolic blood pressure (BP) greater than 140 mm Hg and a diastolic BP greater than 90 mm Hg on 2 successive measurements 4-6 hours apart.

Preeclampsia in a patient with pre-existing essential hypertension is diagnosed if systolic BP has increased by 30 mm Hg or if diastolic BP has increased by 15 mm Hg.

Proteinuria is defined as 300 mg or more of protein in a 24-hour urine sample. Although more convenient, a urine dipstick value of 1+ or more (30 mg/dL) is not reliable.

Risk factors for pre-eclampsia and eclampsia

- Pregnancy-associated risk factors
  - Chromosomal abnormalities
  - Hydatidiform mole
  - Multiple pregnancy: Incidence is increased in twin gestations but is unaffected by their zygosity.
  - Oocyte donation or donor insemination
  - Urinary tract infection
- Maternal-specific risk factors
  - Extremes of age (maternal age <20 and>35 yrs)
  - Black race: (In the United States, the incidence of preeclampsia is 1.8% among white women and 3% in African Americans).
  - Family history of preeclampsia
  - Nulliparity (more common in primigravidae)
  - Preeclampsia in a previous pregnancy
  - Change of male partner
  - Diabetes
  - Obesity: Body weight is strongly correlated with progressively increased risk, ranging from 4.3% for women with a BMI <20 kg/m to 13.3% in those with a BMI >35 kg/m.
  - Chronic hypertension
  - Renal disease
  - Collagen vascular disease
  - Antiphospholipid syndrome
  - Periodontal disease
  - Vitamin D deficiency: One literature review suggests that maternal vitamin D deficiency may increase the risk of preeclampsia and foetal grown restriction.

Essential for diagnosis of Pre-Eclampsia:

Hypertension: Hypertension is blood pressure (BP) of 140/90 mmHg or more on two occasions six hours apart OR A diastolic blood pressure of 110 mmHg or more on a single occasion ***Proteinuria:*** Is a protein concentration of 0.3 g/l or more in at least two random urine specimens collected six hours apart OR Urine dipstick finding of ***'trace', '1+',*** or more proteins Normally protein is not supposed to be present in urine.
Oedema: Gradual or sudden swelling of the face, hands and legs.

Eclampsia:

It is characterized by convulsions -fits (in the absence of other medical conditions predisposing to convulsions) in a woman with pre-eclampsia.

Impending Eclampsia:

Impending eclampsia means that eclamptic fits are likely to occur very soon, usually in a woman with severe pre-eclampsia. Symptoms and Signs of impending eclampsia include:

- Severe headache
- Drowsiness
- Mental confusion
- Visual disturbance (e.g. blurred vision, flashes of flight)
- Epigastric pain
- Nausea / vomiting
- A sharp rise in blood pressure
- Decreased urinary output
- Increased proteinuria
- Hyper-reflexia

Classification of pre-eclampsia/ eclampsia

Pre-eclampsia is classified as mild, and severe. The clinical picture of the different stages is shown in the table below:

Table showing Classification and Clinical picture of Pre-eclampsia and Eclampsia

Finding	Mild Pre-eclampsia	Severe Pre-eclampsia	Eclampsia
Diastolic blood pressure	absolute level is > 90 but <100	absolute level is >100	As in severe pre-eclampsia plus fits
Proteinuria Generalized oedema including face and hands	Trace or 1+ Absent	2+ or greater Persistently present	
Headache	Absent	Present	
Visual disturbance	Absent	Present	
Upper abdominal pain	Absent	Present	
Oliguria	Absent	Present	
Diminished foetal movement	Absent	Present	

Characteristics of Eclamptic fits:

- Convulsions may occur regardless of the severity of hypertension, are difficult to predict and typically occur in the absence of hyper-reflexia, headache or visual changes.
- Convulsions are tonic-clonic and resemble grand-mal seizures of epilepsy
- Seizures may recur in rapid sequence as in status epilepticus, and end in death.
- Convulsion may be followed by coma that lasts minutes or hours, depending on the frequency of seizures.
- 25% of eclamptic fits occur after delivery of the baby.

Stages of eclamptic fit

An eclamptic fit is similar to an epileptic fit, and has the following stages:

A) Premonitory stage

This lasts 10-20 seconds, during which:

- The eyes roll or stare
- The face and hand muscle may twitch
- There is a loss of consciousness

B) *Tonic stage*

This stage lasts 10-20 seconds, during which:

- The muscles go stiff or rigid
- The colour of the skin becomes blue or dusky (cyanosis)
- The back may be arched
- The teeth are clenched
- The eyes bulge

Remember that the onset of pre-eclampsia and eclampsia can be very sudden and without warning

C) *Clonic Stage*

This stage lasts 1- 2 minutes and is marked by:

- Violet contraction and relaxation of the muscles occur
- Increased saliva causes "foaming" at the mouth
- Deep noisy breathing
- Inhalation of mucous or saliva
- The face looks congested (filled with blood) and swollen
- Tongue is bitten by violent action of the jaws

D) *Coma stage*

This may last minutes or hours. During this time

- There is a deep state of unconsciousness
- Breathing is noisy and rapid
- Cyanosis fades, but the face remains congested and swollen
- Further fits may occur before the woman regains consciousness

Differential diagnosis of Eclampsia

Eclampsia must be differentiated from other conditions that may be associated with convulsions and coma, e.g. epilepsy, cerebral malaria, meningitis, head injury, cerebrovascular accident, intoxication (alcohol, drugs, and poisons), drug withdrawal, metabolic disorders, water intoxication, , encephalitis, hypertensive encephalopathy, hysteria.

Diagnosis of Preeclampsia /Eclampsia

History:

Mild-to-moderate preeclampsia may be asymptomatic. Many cases are detected through routine prenatal screening.

Patients with severe preeclampsia display end-organ effects and may complain of the following:

- CNS
  - Headache
  - Visual disturbances - Blurred, scintillating scotomata
  - Altered mental status

    - Blindness - May be cortical or retinal
- Dyspnoea
- Oedema: This exists in many pregnant women but sudden increase in oedema or facial oedema 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 greater than 140/90 mm Hg
- Altered mental status
- Decreased vision or scotomas
- Papilloedema
- Epigastric or RUQ abdominal tenderness
- Peripheral oedema: Oedema can be normal in pregnancy; however, a sudden increase in oedema or swelling of the face is more suggestive of preeclampsia and should be promptly investigated.
- 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 haemolytic anaemia (HELLP)
    - 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 level: Levels are elevated due to decreased intravascular volume and decreased glomerular filtration rate (GFR).
- Urinalysis - Proteinuria is one of the diagnostic criteria for preeclampsia.
    - Significant proteinuria defining preeclampsia is 300 mg or more of protein in a 24-hour urine sample.
    - Proteinuria suggestive of preeclampsia is greater than or equal to 1+ protein on urine dipstick or 300 mg/L or more on urine dipstick.
- Abnormal coagulation profile: PT and aPTT are elevated.
- Disseminated intravascular coagulopathy testing will show fibrin split products and decreased fibrinogen levels.
- Uric acid
    - Hyperuricemia is one of the earliest laboratory manifestations of preeclampsia. It has a low sensitivity, ranging from 0-55%, but a relatively high specificity, ranging from 77-95%.

This is used to assess the status of the foetus 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 pre-eclampsia /eclampsia.

General principles:

BP control

- The goal is to lower BP to prevent cerebrovascular and cardiac complications while maintaining uteroplacental blood flow.
- Control of mildly increased BP does not appear to improve perinatal morbidity or mortality, and, in fact, it may reduce birth weight.
- Antihypertensive treatment is indicated for diastolic blood pressure above 105 mm Hg and systolic pressure above 160 mm Hg, though patients with chronic hypertension may tolerate higher values.
- Patients with severe preeclampsia who have BP below 160/105 mm Hg may benefit from antihypertensives because of the possibility of unpredictable acceleration of the disease and sudden increases in hypertension.
- The goal is to maintain diastolic blood pressure between 90 and 100 mm Hg and systolic pressure between 140 and 155 mm Hg.
- First-line medications are labetalol, given orally or IV; nifedipine, given orally or IV; or hydralazine IV. (*Atenolol, ACE inhibitors, ARBs, and diuretics should be avoided*).

Control of seizures

- The basic principles of airway, breathing, circulation (the ABCs) should always be followed as a general principle of seizure management.
- Active seizures should be treated 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 the urine, and therefore urine output needs to be closely monitored. If urine output falls below 20 mL/h, the magnesium infusion should be stopped.
- Be aware of the risk of seizures following delivery — up to 44% of eclampsia cases have been reported to occur postnatally. This risk is especially elevated 48 hours postpartum, but it can occur at any time up to 4 weeks after delivery.
- For seizure refractory to magnesium sulphate therapy, benzodiazepines and/or phenytoin may be considered.

Fluid management

- Despite the peripheral oedema, patients with preeclampsia are intravascularly volume depleted with high peripheral vascular resistance. **Diuretics should be avoided.**
- Aggressive volume resuscitation may lead to pulmonary oedema, which is a common cause of maternal morbidity and mortality. Pulmonary oedema occurs most frequently 48-72 hours postpartum, probably due to mobilization of extravascular fluid.
- Because volume expansion has no demonstrated benefit, patients should be fluid restricted when possible, at least until the period of postpartum diuresis. Total fluids should generally be limited to 80 mL/h or 1 mL/kg/h.
- Careful measurement of fluid input and output is advisable, particularly in the immediate postpartum period. Many patients will have a brief (up to 6 h) period of oliguria following delivery; this should be anticipated and not overcorrected.
- If fluids are required, preferably use Ringer's Lactate or Normal saline at a rate of 80 mls/ hr or 1ml/kg/hr. Avoid using Dextrose or Dextrose- Saline infusion

Delivery

- Delivery is the definitive treatment for antepartum preeclampsia.
- Patients with mild preeclampsia are often induced after 37 weeks' gestation. Prior to this, the immature foetus is treated with expectant management with corticosteroids to accelerate lung maturity in preparation for early delivery.
- In patients with severe preeclampsia, induction of delivery should be considered after 34 weeks' gestation. In these cases, the severity of disease must be weighed against the risks of prematurity.
- Eclampsia is common after delivery and has occurred up to 6 weeks after delivery. Patients at risk for eclampsia should be carefully monitored postpartum. Additionally, patients with preeclampsia successfully treated with delivery may present with recurrent preeclampsia up to 4 weeks postpartum.

Medication

Magnesium sulphate is the first-line treatment of prevention of primary and recurrent eclamptic seizures.

For eclamptic seizures refractory to magnesium sulphate, Diazepam and phenytoin may be used as second-line agents.

In the setting of severe hypertension (systolic BP, >160 mm Hg; diastolic BP, >110 mm Hg), antihypertensive treatment is recommended. Antihypertensive treatment decreases the incidence of cerebrovascular problems but does not alter the progression of preeclampsia.

Anticonvulsants:

Magnesium sulphate:

This works by antagonizing calcium channels of smooth muscle. Administer IV/IM for seizure prophylaxis in preeclampsia. Use IV for quicker onset of action in true eclampsia. The table below illustrates the dosage and administration schedule.

Magnesium sulphate schedules for severe pre-eclampsia and eclampsia

Loading Dose

Magnesium sulphate 20% Solution, 4g IV over 5 minutes
Follow promptly with 10g of 50% magnesium sulphate solution, 5g in each buttock as deep IM injection with 1mL of 2% lignocaine in the same syringe
Ensure that aseptic technique is practiced when giving magnesium sulphate deep IM injection. Warn the woman that a feeling of warmth will be felt when magnesium sulphate is given.
If convulsions occur after 15 minutes, give 2g magnesium sulphate (50% solution) IV over 5 minutes

Maintenance Dose

Give 5g magnesium sulphate (50% solution) + 1 mL lignocaine 2% IM every 4 hours into alternate buttocks. Continue treatment with magnesium sulphate for 24 hours after delivery or the last convulsion, whichever occurs last.
If 50% solution is not available, give 1g of 20% magnesium sulphate solution IV every hour by continuous infusion
CLOSELY MONITOR THE WOMAN FOR SIGNS OF TOXICITY

Before repeat administration, ensure that:
Respiratory rate is at least 16 per minute
Patellar reflexes are present
Urinary output is at least 30 ml per hour over preceding four hours

WITHHOLD OR DELAY DRUG IF:
Respiratory rate falls below 16 per minute
Patellar reflexes are absent
Urinary output falls below 30ml per hour over the preceding 4 hours
Keep antidote ready:
In case of respiratory arrest:
Assist ventilation (mask and bag, anaesthesia apparatus, intubation)
Give Calcium gluconate 1g (10mL of 10% solution) IV slowly until calcium gluconate begins to antagonise the effects of magnesium sulphate and respiration begins

Phenytoin:

Phenytoin has been used successfully in eclamptic seizures, but cardiac monitoring is required due to associated bradycardia and hypotension.
Central anticonvulsant effect of phenytoin is by stabilizing neuronal activity by decreasing the ion flux across depolarizing membranes.
Some benefits to using phenytoin are that:

- It can be continued orally for several days until the risk of eclamptic seizures has subsided,
- It has established therapeutic levels that are easily tested,
- It has no known neonatal adverse effects are associated with short-term usage.

Dosage:

10 mg/kg loading dose infused IV no faster than 50 mg/min, followed by maintenance dose started 2 hrs later at 5 mg/kg

Diazepam schedules for severe pre-eclampsia and eclampsia

Intravenous administration:

Loading dose

- Diazepam 20mg IV slowly over 2 minutes
- If **convulsions recur**, repeat loading dose

Maintenance dose

- Diazepam 40mg in 500ml IV fluids (normal saline or Ringer's Lactate) titrated to keep the woman sedated but can be aroused
- Maternal respiratory depression may occur when dose exceeds 30mgs in 1 hour
- Assist ventilation (mask and bag, anaesthesia apparatus, intubation), if necessary
- 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 10ml syringe. Remove the needle, lubricate the barrel and insert the syringe into the rectum to half its length. Discharge the contents and leave the syringe in place, holding the buttocks together for 10 minutes to prevent expulsion of the drug. Alternatively, the drug may be instilled into the rectum through a catheter.
- **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.

Antihypertensives

These agents are used to decrease systemic resistance and to help reverse uteroplacental insufficiency.

Hydralazine (Apresoline)

This is the first-line therapy against preeclamptic hypertension. It decreases systemic resistance through direct vasodilatation of arterioles, resulting in reflex tachycardia. Reflex tachycardia and resultant increased cardiac output helps reverse uteroplacental insufficiency, a key concern when treating hypertension in a patient with preeclampsia. Adverse effects to the foetus are uncommon.

Dosage

Give 5mg IV slowly over 10 mins if BP > or =160/110mm Hg; repeat 5 mg q20min to maximum of 20 mg

Labetalol

This is the recommended second-line therapy that produces vasodilatation and decreases in systemic vascular resistance. It has alpha-1 and beta-antagonist effects and beta2-agonist effects. The onset of action is more rapid than hydralazine and it results in less overshoot hypotension. Dosage and duration of labetalol is more variable. Adverse effects to foetus are uncommon.

Dosage

Give 20mg bolus, subsequently give doses of 40mg followed by 80mg IV at 10- 20 min intervals to achieve BP control to a maximum of 300 mg. Labetolol may also be administered by continuous IV infusion at 1mg /kg/hr

Nifedipine

It relaxes coronary smooth muscle and produces coronary vasodilatation, which, in turn, improves myocardial oxygen delivery. Sublingual administration is generally safe, despite theoretical concerns.

Dosage

Initial dosage is 10 mg orally of BP > or = 160/110 mm hg. One may repeat after 30 minutes as needed

Definitive Management

a) Mild Pre-eclampsia e.g. with BP 140/90

- Establish if the mother can rest at home
- Advise patient and relatives on importance of bed rest
- Give oral antihypertensives (alpha methyl dope 250mg three times daily) Maintain diastolic BP at 90-100 mmHg
- Monitor maternal and foetal condition weekly
- Admit if coming too far away from hospital,
- Advise on worsening signs of the condition, and the need to report if any signs of severe pre-eclampsia are present
- Advise mother to take a diet, which is rich in protein, fibre and vitamins but low in carbohydrate and salt
- If the mother shows no improvement and facilities /skills to manage severe eclampsia are lacking, refer to higher level

c) Severe Pre-eclampsia e.g. BP diastolic > 100 mmHg

- Admit patient
- Nurse in a quiet semi dark room
- Monitor vital signs every 15- 30 minutes
- Start MgSO4 regime
- Consider timing and mode of delivery
- Closely monitor fluid intake and urine output
- Do blood chemistry (liver enzymes and creatinine)
- If the diastolic blood pressure is 110 mm Hg or more, start antihypertensive drugs, e.g. Hydralazine 5 mg IV slowly every 5 minutes until blood pressure is lowered. Repeat hourly as needed or give hydralazine 12.5mg IM every 2 hours as needed
- If hydralazine is not available, give Labetolol or nifedipine
- If no improvement, refer to comprehensive centre accompanied by trained nurse

Management* of *eclampsia:

- Call for help
- Maintain open airway
- Control fits
- Control the blood pressure and monitor quarter hourly
- Start IV line but restrict fluid intake to avoid pulmonary and cerebral oedema. Maximum of 30 drops per minute.
- Catheterise, and closely monitor fluid intake and urine output

Management of fitting patient:

- Patient should be put in semi prone position so that mucous and saliva can drain out
- Tight fitting dresses around the neck should be loosened or removed
- No attempt should be made to insert any instrument into the mouth
- Administer magnesium sulphate (or diazepam) as per regime to control fits
- Aspirate secretions from the mouth and nostrils as necessary
- Give Oxygen continuously during fit and for 5 minutes after each fit (if available)
- Fitting should be allowed to complete its course without restraining the patient
- Privacy and dignity of patient must be observed - pull screens around her

DELIVERY: **Delivery is the only cure for pre-eclampsia and eclampsia**

- Delivery should take place as soon as the woman's condition has been stabilized, preferably within 6-8 hours from first convulsion; or within 12 hours of admission
- Delaying delivery to increase foetal maturity will risk the lives of both the woman and the foetus.
- Delivery should occur regardless of the gestational age, but **Eclampsia alone is not an indication for C/section**. Get skilled anaesthetic help early; this will also aid the management of hypertensive crises and fits.

Mode of delivery

Vaginal delivery is recommended:

- If the **cervix is favourable** (soft, dilated, effaced), rupture the membranes and induce labour using oxytocin
- If there is no absolute indication for Caesarean section
- If **safe anaesthesia is not available for C/section** or if the **foetus is dead or too premature for survival**:

If the cervix is unfavourable (firm, thick, closed), ripen the cervix using prostaglandins or a Foley catheter

Caesarean section should be done:

- If **vaginal delivery is not anticipated** within 8 hours (for eclampsia) or 24 hours (for severe pre-eclampsia), deliver by C/section
- If there are **foetal heart rate abnormalities** (< 100 or > 180 beats / minute)
- If the **cervix is unfavourable** (firm, thick, closed) and the **foetus is alive**,

Postnatal care:

- Continue anticonvulsive therapy for 24 hours after delivery or last convulsion, whichever occurs last.
- Continue antihypertensive therapy as long as the diastolic pressure is 110 mmHg or more.
- Continue to monitor urine output. If urine output is less than 500 ml in 24 hours, limit the amount of fluid intake to 500 mls per 24 hour + an amount equal to the amount of urine passed
- Watch carefully for the development of pulmonary oedema, which often occurs after delivery.
- Life threatening complications can still occur after delivery. Monitor carefully until the patient is clearly recovering.
- Consider referral of women who have:
  - Oliguria (less than 500 ml urine output in 24 hours) that persists for 48 hours after delivery

(HELLP) syndrome)

- Persistent coma lasting more than 24 hours after convulsion.

Complications

Complications of preeclampsia /eclampsia may include the following:

- Abruptio placentae with disseminated intravascular coagulopathy
- Renal insufficiency or failure
- Haemolysis, elevated liver enzyme levels, and low platelet count (or HELLP syndrome)
- Cerebral haemorrhage
- Maternal death and/or foetal demise

Prognosis

- Early detection and frequent obstetric assessment and prompt management markedly improves prognosis.
- Women at risk of preeclampsia must have pre conception care and attend ANC early and regularly
- A history of preeclampsia increases a woman's subsequent risk of vascular disease, including hypertension, thrombosis, ischemic heart disease, myocardial infarction, and stroke.

APPENDIX 3: LETTER OF REQUEST

ADHERENCE TO MINISTRY OF HEALTH GUIDELINES IN MANAGEMENT OF SEVERE PREECLAMPSIA AT PUMWANI MATERNITY HOSPITAL, NAIROBI.

Preeclampsia and eclampsia constitute important reproductive health concerns being the second cause of maternal morbidity and mortality in Kenya. For this reason, the Ministry of Health in Kenya endeavoured to have guidelines in order to eliminate adverse outcomes and to standardize the care across all health care workers who manage clients with these conditions.
Despite this, the mortality and morbidity related to preeclampsia and eclampsia has not changed which brings to question whether the guidelines are understood and utilised in accordance with the stipulation necessitating this study to evaluate these guidelines.
Objectives of the study will be: To determine the level of adherence to Kenya Ministry of Health guidelines in management of severe Preeclampsia and eclampsia at Pumwani Maternity Hospital.
Specific Objectives include

1. To outline the quality of clinical evaluation of patients managed at Pumwani Maternity hospital presenting with severe pre eclampsia.
2. To establish the types of investigations carried out on the patients managed at Pumwani Maternity for severe preeclampsia and eclampsia and identify if these are in tandem with the MOH guidelines.
3. To assess the appropriateness of interventions for patients managed with severe pre eclampsia at Pumwani Maternity Hospital.

The study will help the hospital to identify to what level the guidelines from the Ministry of Health are being utilized in the management of severe pre-eclampsia and eclampsia. This will open avenues for changes in order to better utilize the available guidelines. This study will help Pumwani Maternity Hospital identify areas that may need evaluation in order to manage patients with severe pre eclampsia. The study will also open up more areas of research on implementation science to identify any barriers and opportunities to health care management in matters regarding severe pre-eclampsia and eclampsia.

There will be no direct risks to human beings in this study because it will be a retrospective study. That said the information obtained from the records at Pumwani will be treated with utmost confidentiality. Any adverse outcomes noted will be reported to both KNH/UON ERC and Pumwani Maternity Hospital
There will be no compensation offered to the hospital for this study
The study will be carried out based on agreement from the Pumwani Maternity hospital and the PRIME-K. No physical specimens will be obtained from the hospital. The expected time of the study is between the years 2014-2015
Principal investigator will be DR MUCHIRI W.DORCUS, REGISTRAR OBS GYN. Contact TEL NO: 0720996444. Permission will be sought from KNH/UON/ERC. The Chairperson, KNH-ERB Prof. A. N. Guantai can be contacted through Telephone number +254-020-2726300 Ext 44355

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06 SEP 2014

Ref: KNH-ERC/A/299 Link:www.uonbi.ac.ke/activities/KNHUoN

8th September 2014

Dr.Dorcus Wamaitha Muchiri
Dept.of Obs/Gynae
School of Medicine
University of Nairobi

Dear Dr. Muchiri

RESEARCH PROPOSAL: ADHERENCE TO MINISTRY OF HEALTH GUIDELINES IN MANAGEMENT OF SEVERE PREECLAMPSIA AT PUMWANI MATERNITY HOSPITAL, NAIROBI, KENYA (P345/06/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 8th September 2014 to 7th September 2015.

This approval is subject to compliance with the following requirements:

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

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

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P. O. Box 30075 - 00100
Nairobi
Kenya

COUNTY HEALTH SERVICES:
PUMWANI MATERNITY HOSPITAL

PMH/DMOH/75/0530/2014

11TH SEPTEMBER 2014

TO:
Dr. Dorcus Wamaitha Muchiri
Dept. Of Obs/Gynae
School Of Medicine
University of Nairobi

RE: APPROVAL OF RESEARCH PROPOSAL

This is to inform you that that the research entitled "**Adherence to Ministry of Health Guidelines in Management of Severe Preeclampsia at Pumwani Maternity Hospital**" has been approved.

You are hereby allowed to collect data. We look forward to receiving a summary of the research findings upon completion of the study.

Yours sincerely,

DR. L.O. KUMBA
MEDICAL SUPERINTENDENT