ASSESSMENT OF CLINICAL MANAGEMENT OF WOMEN WITH PRE-ECLAMPSIA WITH SEVERE FEATURES AND MATERNAL AND FETAL OUTCOMES AT AMANA HOSPITAL IN DAR ES SALAAM TANZANIA

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MSc. (Midwifery and Women's Health) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2024

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

SCHOOL OF NURSING

DEPARTMENT OF COMMUNITY HEALTH NURSING

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By

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A Dissertation Submitted in Partial Fulfillment of the requirements for the degree of Masters Science in Midwifery and Women's Health of the Muhimbili University of Health and Allied Sciences.

October, 2024

CERTIFICATION

The undersigned certifies that she has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled ***"ASSESSMENT OF CLINICAL MANAGEMENT OF WOMEN WITH PRE-ECLAMPSIA WITH SEVERE FEATURES AND MATERNAL AND FETAL OUTCOMES AT AMANA HOSPITAL IN DAR ES SALAAM TANZANIA"*** in (partial) fulfillment for the requirement for Masters of Science in Midwifery and Women's Health of Muhimbili University of Health and Allied Science**.**

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Date

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Mr. Alex Nyaruchary
Co-Spervisor

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Date

DECLARATION AND COPYRIGHT

I, Winfrida Makangi Kalegi declare that this dissertation is my original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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ACKNOWLEDGEMENTS

First of all, I would like to thank the Almighty God for the strength, protection, and guidance he has given me throughout the whole time of my postgraduate studies at Muhimbili University of Health and Allied Sciences.

Secondly, I would like to express my sincere gratitude to my supervisors, Dr. Agnes F. Massae Lecture at the School of Nursing at the Department of Community Health at MUHAS, and co-supervisors, Mr. Alex Nyaruchary Assistant Lecturer at the School of Nursing in the Department of Community Health at MUHAS, for the tireless support they have offered me during the whole time, from the development of the research proposal to the writing of the dissertation report.

In addition to that, I would like to thank all the lecturers from the school of nursing. I appreciate the contribution of the entire team of the Department of Community Health, together with Dr. Ali Said from the Department of Obstetrics and Gynecology (MUHAS), for his support, and my colleagues, especially Amne Saidi Baamary, for their unwavering support throughout my studies and during my research.

Also, I extend my gratitude to the medical officer in charge at Amana Regional Referral Hospital for permitting me to conduct my study in the health facilities.

Moreover, I extend my heartfelt appreciation to my beloved mother Sophia, my brother William, and my son Maxmillian, who have always been there with me; your encouragement, advice, guidance, assistance, and prayers are highly appreciated.

DEDICATION

I dedicate this work to my wonderful family members, my beloved mother Sophia Dotto Shija, my sister Esther David Kalegi, my brother William Makangi Kalegi, my lovely son Maxmillian Mathias Nkayaga; my niece Scholastica and Justina, my nephew Yohana, my sisters in law Agnes Bundala and Samaka Charles Nkayaga. You are the special gift in my life, I say thank you for being with me in all the good and hard times of my life I am also deeply grateful for the support and contributions of my late father, Makangi kalegi Seni, and my late sisters Agnes Kishimba and Flora Wande Makangi, my late brother Shija Kishimba in shaping my career development.

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ABBREVIATIONS

ACOG	American College of Obstetricians and Gynaecology
ANC	Antenatal contact
AOR	Adjusted Odd Ratio
BP	Blood Pressure
CI	Confidence Interval
COR	Crude Odd Ratio.
DBP	Diastolic blood pressure
E	Eclampsia
GA	Gestational Age
HELLP	Hemolysis Elevated Liver enzymes and Low Platelets'
ICU	Intensive Care Unit
IUFD	Intrauterine Fetal Death
LMICs	Low- and Middle- Income Countries
MCYPSCN	Maternity, Children and Young People Strategic Clinical Network
MgSO4	Magnesium Sulfate
MoH	Ministry of Health
MPE	Mild pre-eclampsia
MUHAS	Muhimbili university of health and allied Science
NICU	Neonatal Intensive Care Unit
OR	Odd Ratio
P/E	Pre-eclampsia/eclampsia
PE	Pre-eclampsia
PEWSF	Pre-eclampsia with severe features
PPH	Postpartum Hemorrhage
RRH	Regional Referral Hospital
SBP	Systolic blood pressure
SPSS	Statistical Package for Social Science
WHO	World health organization

DEFINITIONS OF KEY TERMS

Adverse maternal outcome is any complication sustained by the mother that is related to PEWSF, i.e., postpartum hemorrhage (PPH), hemolysis, elevated liver enzymes, and low platelets (HELLP) syndrome, mode of delivery, or admission to an intensive care unit (1).

Adverse fetal outcomes: newborns who develop at least one neonatal complication after birth are women with a history of preeclampsia with severe features, i.e., status of the baby as dead or alive, a low Apgar score, neonatal intensive care unit admission (NICU), stillbirth or intrauterine fetal death (IUFD), prematurity, low birth weight, and birth asphyxia of delivery, admission to intensive care unit (1).

Clinical management; are protocols which have a defined course of action to assist heath professional in decision making in patients with a specific clinical condition (21)

Pre-eclampsia with severe features (PEWSF) is when a blood pressure reading of ≥160/110 mmHg and proteinuria (≥2+ on dipstick) are present, along with accompanying severe symptoms like headache, blurred vision, epigastric pain, and reduced urine output (1, 2).

ABSTRACT

Background: Pre-eclampsia with severe features (PEWSF) is a serious complication of pregnancy have significant contribution to maternal morbidity and mortality, particularly in resource-limited settings. Despite the availability of the management guidelines, many hospitals face challenges in managing these conditions. The clinical guideline in management of PEWSF was recent introduced. The adherence to clinical guideline is critical particular to low and middle income countries due to shortage of nursing staff. However the adherence of the guideline is not well known. Understanding the current practices and adherence to clinical guidelines is crucial that may help to identify areas for improvement in the management of pre-eclampsia with severe features (PEWSF), ultimately contributing to enhanced maternal healthcare outcomes.

Adherence to clinical guidelines is critical. It might also highlight specific challenges faced in resource-limited settings, providing a clearer rationale for the study

Aim of study: To determine the association between adverse maternal and fetal outcome and clinical management of women with PEWSF at Amana Regional Referral Hospital.

Materials and Methods: Hospital-based retrospective cohort study was employed a total 200 patients' files diagnosed with PEWSF from 1st January 2023 to 31st December 2023.At Amana Regional Referral Hospital. Simple random sampling technique was utilized to select the cases; Assessment was done by extraction of information from both patients' files and Hospital electronic database. Obtained data were summarized and analyzed using Statistical Package for Social Science (SPSS) program version 27.

Results: Results: The prevalence of adherence to clinical guidelines was found to be 25 (12.5%), with adherence rates varying across different guideline components: maternal and fetal management 117 (58.5%) and monitoring maternal and fetal wellbeing and follow-up management 131 (65.5%), while a small prevalence adhered to assessment of maternal and fetal 69 (34.5%). Adverse fetal outcome: those children with gestational age ≥ 37 weeks and above had lower odds of adverse fetal outcome (95% CI: 1.469–7.741, p =.004) compared with gestational age below 37 weeks. There were high rates of fetal complications (52.5%), and prematurity (21.5%) was the most common complication identified.

Conclusion: The study highlights significant challenges in adhering to clinical guidelines for managing PEWSE, with poor adherence. Gestational age 37 and above was protective from fetal complications. There is a need to place emphasis on regular education sessions for healthcare providers on the implementation of the clinical management guidelines in the management of pre-eclampsia with severe features (PEWSF)

Key words*;* *Adherence to guideline, adverse maternal, PEWSF, clinical management*

CHAPTER ONE:

1.0 INTRODUCTION

1.1 Background

Pre-eclampsia with severe features (PEWSF) is a serious complication of pregnancy characterized by new-onset hypertension and either proteinuria or end-organ damage occurring after 20 weeks of gestation (4). Eclampsia (E) is the development of convulsions in a woman with PEWSF (3, 4). PEWSF affects 2-10% of pregnancies worldwide (5). The World Health Organization (WHO) estimates that the incidence of PEWSF is seven times higher in LMICs, affecting 2.8% of live births, compared to developed countries with an incidence of 0.4% of live births (3, 4). In sub-Saharan Africa, the reported prevalence of pre-eclampsia (PE) ranges from 1.8% to 16.7% (5, 6). In Tanzania, the incidence of PE was reported at 1.7% while that of PEWSF is about 26% (6–8).

In low-income and middle-income countries such as Tanzania, the burden of pre-eclampsia is particularly high due to limited resources and inadequate access to obstetric care. In many African countries, pre-eclampsia remains a significant public health challenge, being a leading cause of prematurity and fetal growth restriction, associated with a perinatal mortality rate five times higher than that among babies born to healthy mothers (9). Despite efforts to improve clinical outcomes, there is currently no curative treatment for pre-eclampsia except for delivery. Prompt diagnosis and appropriate clinical management are crucial for improving maternal and fetal outcomes. However, the optimal management of PEWSF can vary depending on factors like disease severity, gestational age, and resource availability.

Efforts to improve the management of PEWSF have been ongoing, with international organizations developing clinical guidelines and implementing interventions such as obstetric care services training, specialized care units, and magnesium sulfate ($MgSO_4$) for seizure prevention and blood pressure control (1,10). Despite some progress in reducing maternal deaths, PEWSF continue to pose significant risks to maternal and fetal health, especially in low-resource settings like Tanzania. This is due to the persistent challenges in translating these interventions into consistent clinical management (1, 11). Existing literature highlights the challenges in adhering to standard management

protocols for PEWSF/E in low- and middle-income countries (LMICs), including resource constraints and health system deficiencies (11,12*).* Effective utilization of clinical management guidelines during management practices of PEWSF is important to the significant impact on maternal and fetal health, particularly in regions with limited resources, such as Tanzania. While existing research has explored the association between PEWSF and adverse outcomes, a critical gap exists in our understanding of how clinical management practices at specific healthcare facilities influence these outcomes. This knowledge gap is particularly relevant in low-and-middle-income countries (LMICs) like Tanzania, where resource limitations and potential variations in practice patterns might affect patient care.

1.2 Problem statement

The magnitude of PEWSF is high in Tanzania (16%) to the global data (10-15%) (14). Clinical management of PEWSF focuses on preventing maternal morbidity through aggressive treatment of hypertensive emergencies, preventing maternal seizures in PEWSF, and reducing fetal damage. In Tanzania, the Ministry of Health (MoH) developed guidelines for the management of PEWSF and put in place all health facilities (15). The guideline was introduced in 2022 but there is limited data on the adherence of clinical guideline in management of PEWSF

Furthermore, despite the existence of these guidelines and protocols, maternal death have decreased but perinatal complications remained stable(TDHS, 2022). Therefore, it is important to check the use of that guideline if it is followed to check the outcomes associated with proper use of clinical guidelines in the management of women with PEWSF.

In addition to that, there is limited data from the Tanzanian because the guideline was recently introduced. Therefore, this study aims to assess the clinical management and association with maternal and fetal outcomes of women diagnosed with PEWSF at Amana Regional Referral Hospital.

1.3 Conceptual Framework

The conceptual framework was linked with the clinical guideline for management of PEWSF in Tanzania (15). In this conceptual framework, independent variables are: Assessment of maternal and fetal health with its components (such as history-taking, physical examination, investigations, and USS for fetal assessment).

Maternal and fetal management (such as control of seizures and seizures: the administration of magnesium sulfate protocol was crucial for controlled seizures and preventing further complications related to eclampsia, blood pressure control, and a and a delivery plan by collaboration among different healthcare professionals was emphasized to ensure comprehensive care and coordination of treatment plans)

Monitoring maternal and fetal wellbeing, follow-up, and management (such as monitoring fetal heart rate, monitoring vital signs, follow-up management, and maintaining fluid balance) were essential. They involved the insertion of an indwelling catheter for monitoring input and output and administered intravenous fluids at a controlled rate to prevent dehydration or fluid overload.

Other independent variables in this research were patient-related factors and obstetric history (such as age, gravidity, parity, and gestational age at admission).

Furthermore, the dependent variables measured were: maternal outcomes (including postpartum hemorrhage (PPH), hemolysis-elevated liver enzymes and low platelets (HELLP) syndrome), admission to the intensive care unit (ICU), and fetal outcomes (birth weight of the baby, status of the baby, i.e., died or alive, lower birth weight, premature, admission to the neonatal intensive care unit (NICU), and birth asphyxia).

From the framework, the arrows indicate the potential association or relationships between adherence to guidelines in the management of women with PEWSF and adverse maternal outcomes.

Despite the existence of such guidelines and protocols, there were persistent gaps in achieving optimal outcomes for women with PEWSF in Tanzania. Maternal and perinatal outcomes associated with the management of PEWSF included both maternal and fetal death, survival, and complications. Patients' characteristics, such as their compliance with prescribed treatments, prenatal care, and timely interventions, significantly impact the reduction of maternal and perinatal mortality rates, as well as the prevention of complications. Effective adherence can enhance overall well-being and ensure the health and safety of both mothers and infants, highlighting the critical link between patient compliance and positive clinical outcomes in cases of PEWSF (Figure 1).

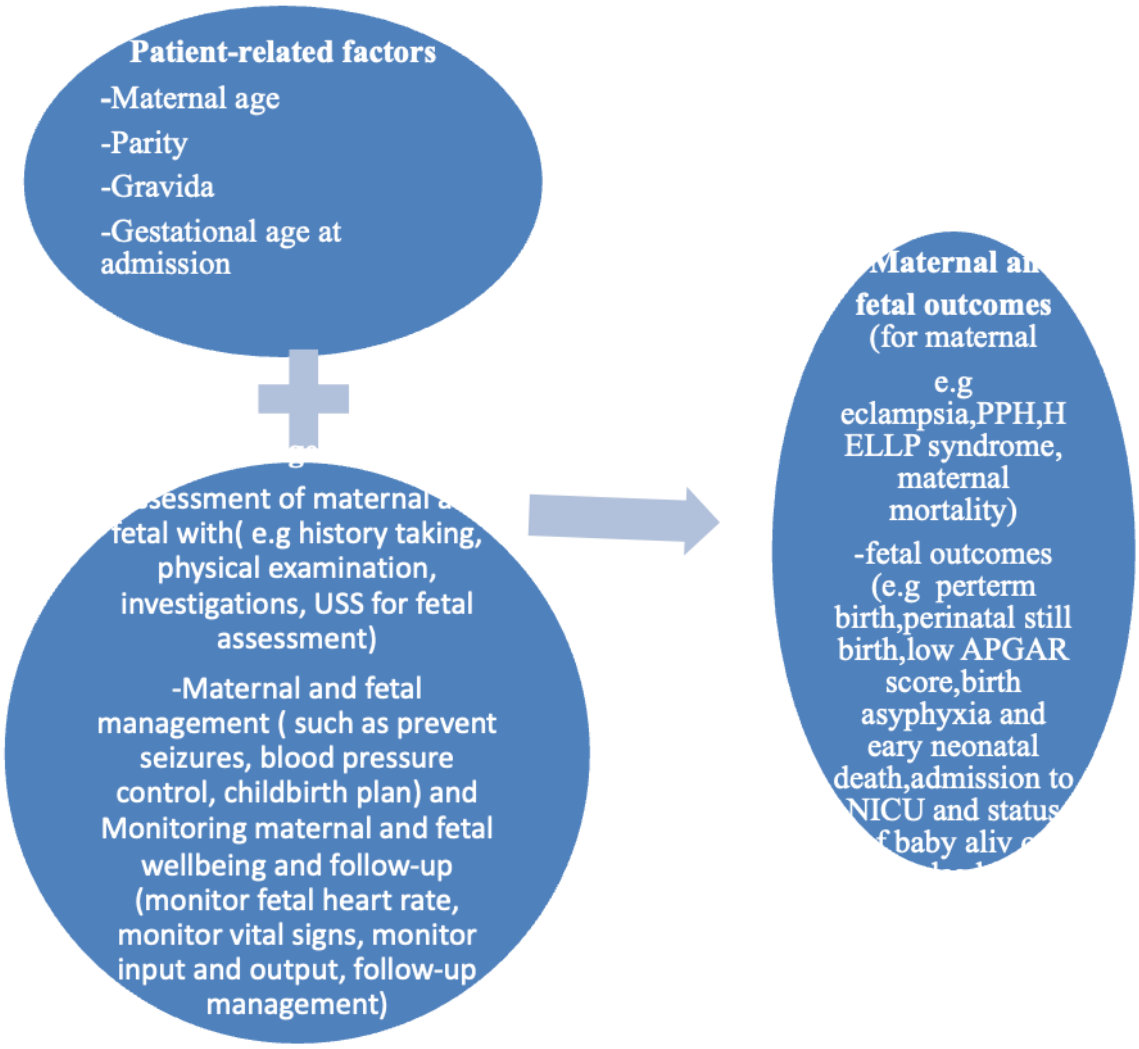


Figure 1: Conceptual framework

1.4 Rationale of the study

This study aimed to provide a thorough assessment of the management of women with PEWSF maternal and fetal outcomes at Amana Regional Referral Hospital in Dar es Salaam, Tanzania. This research can provide valuable insights into the utilization and effectiveness of current clinical management guidelines and identify areas for potential improvement to enhance outcomes for mothers and babies affected by PEWSF in Tanzania. The findings could have significant implications for improving clinical management and patient outcomes not only in this hospital but also in similar healthcare settings in our country.

1.5 Research Question

1.5.1 Main research question

What is the association between clinical management of women with PEWSF with adverse maternal and fetal outcome at Amana Regional Referral Hospital?

1.5.2 Specific research questions

i. What is the prevalence of women with PEWSF managed according to guideline at Amana Regional Referral Hospital?
ii. What is the association between adherence to guideline in the management of women with PEWSF and adverse maternal outcomes at Amana Regional Referral Hospital?
iii. What is the association between adherence to guideline in the management of women with PEWSF and adverse fetal outcomes at Amana Regional Referral Hospital?

1.6 Study Objectives

1.6.1 Broad Objective

To determine the association between clinical management of women with PEWSF with adverse maternal and fetal outcome and at Amana Regional Referral Hospital.

1.6.2 Specific objectives

i. To determine the prevalence of women with PEWSF managed according to clinical guideline at Amana Regional Referral Hospital

ii. To determine the association between adherence to clinical guideline in the management of women with PEWSF and adverse maternal outcomes at Amana Regional Referral Hospital

iii. To identify the association between adherence to clinical guideline in the management of women with PEWSF and adverse fetal outcomes at Amana Regional Referral Hospital

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Literature review search strategies

The literature search strategy for these clinical practices focused on gathering relevant studies on the management of pre-eclampsia with severe features and eclampsia globally, with a particular emphasis on high-income countries (HICs), lower- and middle-income countries (LMICs), Africa (including sub-Saharan Africa), and the local context in Tanzania. Peer-reviewed journals, databases, and publications from reputable sources were systematically explored to ensure comprehensive coverage. Searches were conducted in various databases, including PubMed, Google Scholar, and relevant medical journals, using keywords such as "Pre-eclampsia with severe features," "Eclampsia," "clinical guidelines, “facility preparedness", “adherence to guideline”, and "management practices."

2.2 PEWSF clinical management

Globally, studies highlight disparities in adherence to clinical guidelines, suggesting the need for standardized practices. In the Netherlands, a cohort study involving 222 eclamptic cases revealed sub optimal adherence to clinical guidelines, with only 10.4% receiving $MgSO_4$, and 39.6% receiving anti hypertensives in cases of elevated blood pressure. Substandard care was observed in 83% of cases (16). In Nepal, a study involving 182 cases showed better adherence, with 62.5% of severe cases receiving MgSO4 (17). Similarly, in Accra, Ghana, a cross-sectional study with 50 patients demonstrated varying adherence rates to protocols for PEWSF and eclampsia, ranging from 60% to 94% (23).

A retrospective study in Mulago Hospital, Uganda, indicated that 67% of patients received initial management by a doctor, and MgSO4 was administered to all patients (18). In Ndala Hospital, Uganda, a retrospective study involving 81 women found varied adherence to protocols, with all patients receiving MgSO4 treatment, but discrepancies in blood pressure and urine protein monitoring (19). HICs exhibit varying degrees of adherence to clinical guidelines, emphasizing the importance of consistent practices.

In a study conducted at Muhimbili National Hospital (MNH) in Tanzania, MgSO4 utilization and initiation of drug treatment for severe hypertension were 100%. However, specialist review within 2 hours of admission showed a lower adherence rate of 39%. Other aspects, such as urine testing, fluid balance monitoring, and proper partogram use, demonstrated diverse adherence rates ranging from 63% to 100% (20). LMICs in Africa exhibit diverse adherence patterns, emphasizing the need for targeted interventions to improve guideline adherence.

In a criteria-based clinical audit at Muhimbili National Hospital, Tanzania, findings mirrored those in global studies. Adherence rates for $MgSO_4$ use and blood pressure monitoring were high, but specialist reviews within 2 hours and steroid use for lung maturity were sub optimal (2 1).

This literature review provides a comprehensive overview of the global, HICs, LMICs, and local perspectives on the management of pre-eclampsia with severe features and Eclampsia, however there is limited information on clinical audit particularly at regional level hospitals in Tanzanian context.This setting the stage for the evaluation of adherence to clinical guidelines at Amana hospital which is one of the regional referral hospitals in Dar es Salaam, Tanzania.

2.3 The maternal and fetal outcome of patients admitted with PEWSF

Globally, pre-eclampsia and eclampsia contribute significantly to maternal mortality, accounting for up to 15% of maternal deaths. In developed countries, complications of pre-eclampsia are more prevalent, while in developing countries, eclampsia is a major contributor to maternal mortality (21)

. A retrospective study in Eastern India found that eclampsia constituted 43.35% of total maternal deaths, with a case fatality rate of 4.96% (22). Similarly, a study in Manipur, India, reported a maternal case fatality rate of 5.8% with pulmonary edema as a leading cause of death. Fetal outcomes included low birth weight and perinatal deaths (23). The global perspective underlines the dual impact of pre-eclampsia and eclampsia on maternal mortality in both developed and developing regions, with varying manifestations and outcomes.

In a Nigerian teaching hospital, a criteria-based audit revealed a case fatality rate of 5.8% for pre-eclampsia with severe features and eclampsia, with 13.5% perinatal deaths among multiple pregnancies (24 25). A cohort study in Zimbabwe, conducted in a lower-resource setting, reported an incidence of 1.3% for PEWSF and eclampsia, maternal mortality of 1.7%, and a significant perinatal mortality of 49.6% (26). Findings from Nigeria and Zimbabwe highlight regional variations in case fatality rates and perinatal outcomes, emphasizing the need for context-specific interventions.

In Tanzania, a descriptive cross-sectional study by Ndaboine et al. among 76 patients with PEWSF reported a case fatality rate of 7.89%, with 29 patients developing HELLP syndrome. Perinatal mortality included stillbirths, early neonatal deaths, low birth weight, and birth asphyxia (31). Similarly, a study in Dar es Salaam found a prevalence of 6% for pre-eclampsia/eclampsia, a case fatality rate of 5.1%, and 32 perinatal deaths (32). The Tanzanian context reveals unique challenges, including a notable prevalence of HELLP syndrome and a consistent pattern of perinatal deaths, emphasizing the critical importance of localized interventions.

This literature review synthesizes global, regional, and local perspectives on the management of PEWSF. The varying maternal and fetal outcomes underscore the necessity for tailored clinical guidelines and interventions in diverse healthcare settings, particularly within the context of Amana Regional Referral Hospitals in Dar es Salaam, Tanzania.

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Type of study

A retrospective cohort hospital-based study in which data were extracted from 1st January 2023 to 31st December 2023 on women managed with PEWSF**.**

3.2 Study area

The study was conducted at Amana Regional Referral Hospital (RRH), situated near the city center in Dar es Salaam, Tanzania. Amana RRH was selected as the study site due to its pivotal role in managing obstetric emergencies, particularly PEWSF. With a substantial delivery rate averaging 587 deliveries per month and approximately 7,750 deliveries annually, the hospital experiences a significant caseload. The findings can be genelizable to other hospitals because they are using the same guideline.

Averages of 48 cases of PEWSF were reported monthly, underscoring the hospital's prominence in handling these conditions. There are 84 staff in the department of obstetrics and gynecology: 14 staff in the antenatal ward with 15 beds; 14 staff in the labor ward with 12 beds; 9 staff in the postnatal ward with 34 beds; 14 post-partum staff with 40 beds; 7 staff in the ICU with 9 beds; 8 staff in the OBGY ward with 24 beds; 6 OBGY specialists, 2 midwives' specialists, and 10 doctors.

Regarding the management of patients with PEWSF, the hospital adheres **t**o the guidelines endorsed by the Tanzanian Ministry of Health (Helping Mothers Survive Pre-eclampsia and Eclampsia Provider's Guide 2022) (15). A thorough investigation into the existing protocols governing the management of these conditions at Amana RRH was conducted as part of the study. The study shed light on the standard practices employed in patient care, offering insights into the efficacy of current management strategies and identifying potential areas for improvement.

3.3 Study population

The study population consisted of all patients' files diagnosed with PEWSF. PEWSF was diagnosed by having at least four cardinal signs, which are elevated blood pressure (≥160 mmHg or diastolic pressure ≥ 110 mmHg), proteinuria ≥ +2 in the deep stick, severe headache, visual disturbance, and epigastric pain. We identified eligible participants by reviewing and searching the International Classification of Diseases code (ICD code 10) O14 in the electronic medical record and confirming the diagnosis in the file**.**

3.4 Inclusion and Exclusion Criteria

3.4.1 Inclusion criteria

All patients' files diagnosed with PEWSF managed at the Amana RRH from 1st January 2023 to 31st December 2023.

3.4.2 Exclusion criteria

All patients 'files lacking insufficient information (missing papers) to confirm PEWSF diagnosis, delivery details, or maternal and fetal outcomes and missing documentation of clinical management and patients' files with a previous history of any adverse maternal outcomes

3.5 Sample size estimation

Obtained appropriate sample size, the study utilized the Yamane (1967) sample size formula, was calculated a sample size of 200, whereby n=sample size required, N is total population (considering an estimated population of 400 cases over a 12-months period at Amana RRH) as follows:

$$n = \frac{N}{1+N(e^2)} = \frac{400}{1+400(0.05)^2} = 200$$

The chosen sample size of 200 enabled researchers to investigate deeply into the management practices and outcomes associated with PEWSF. This sample size ensures that the study has adequate power to detect significant associations and draw reliable conclusions.

3.6 Sampling method

The study was utilized simple random sampling. The sampling frame was included all patients' files diagnosed and managed with PEWSF from 1st January 2023 to 31st December 2023. A total patients files had diagnosis of PEWSF were 587. A total of 400 file met inclusion criteria. Initially, a list of selected cases with assigned patient numbers was numbered sequentially (1, 2, 3, 4) and a computerized random generator was used to select 200 cases from the available register. Subsequently, random number generator procedures were executed within the Excel sheet. The process guarantees that each case had an equal opportunity of been selected for review, thereby reduced bias and enhanced the generalizability of the study's findings**.**

3.7 Study Variables

Investigated independent variables in this research were: patients-related factors and obstetric history (such as age, gravidity, parity and gestational age at admission.

Maternal and fetal assessment (such as history taking, physical examination, laboratory investigation findings and USS for fetal assessment)

Additionally, other independent variables are maternal and fetal management,(such as administration of magnesium sulphate for management of convulsion and fetal neuro-protection, blood pressure control and delivery plan) and

Monitor maternal and fetal wellbeing and follow up management (such as monitoring vital signs, monitoring of urine output and input, monitoring fetal heart rate and follow up management).

Dependent variables measured were: Adverse maternal outcomes (includes Postpartum Hemorrhage (PPH), Hemolysis Elevated Liver Enzymes and Low Platelets (HELLP) syndrome, mode of delivery, admission to intensive care unit (ICU) and adverse fetal outcomes (birth weight of the baby, status of the baby i.e. died or alive, lower birth weight, premature, admission to neonatal intensive care unit (NICU) and birth asphyxia).

3.8 Data collection tools

The clinical management checklist was served as the primary tool for data collected as outlined in Appendix I. The clinical practice tool was exactly designed based on the clinical guidelines for the management of PEWSF in Tanzania and the criteria for clinical practices pertained to PEWSF management. It encompasses essential details such as demographic information, laboratory results, diagnosis, management procedures and

patient outcomes. It is structured into 3 main sections to ensure thorough documentation and evaluation of clinical management.

1. The first section of the checklist focused on gathering essential background information, encompassing demographic details, obstetric history, and pertinent laboratory investigation findings. The included demographic variables were: age, parity, and gestational age at admission, as well as obstetric history including previous pregnancies, medical conditions, and number of antenatal contacts. Laboratory investigation findings related to blood pressure, proteinuria, renal function tests, and any additional relevant parameters were exactly recorded in this section.
2. The second section investigated the diagnosis and initial management of PEWSF cases. It comprehensively documented presented symptoms, vital signs on admission, patient status upon arrival, and a detailed account of investigations conducted within the first 24 hours of admission. These included assessments of blood pressure, proteinuria, liver function tests, renal functions tests clotting profiles, and any imaging studies or other diagnostic procedures undertaken to confirm the diagnosis and assess disease severity.
3. The third section was dedicated to the management and monitoring of both the patient and fetal well-being throughout the course of care. It outlines the strategies employed for PEWSF management, modalities for delivery, immediate postpartum care, and ongoing monitoring and support in the postnatal period. This encompasses interventions aimed at stabilizing maternal health, ensuring optimal fetal outcomes, and addressing any potential complications raised during the perinatal period. An integral component of the data collection tool includes a dedicated section for recorded maternal and fetal outcomes. This entailed a comprehensive assessment of the clinical outcomes experienced by the mother, such as resolution of hypertension, incidence of eclamptic seizures, complications during labor and delivery, postpartum hemorrhage, and any other maternal morbidity or mortality events. Additionally, fetal outcomes were exactly documented, included measures such as gestational age at delivery, birth weight, Apgar scores, NICU admissions, perinatal mortality, and neonatal complications observed during the immediate postpartum period.

3.9 Data collection method

A checklist was used to review patients' files and electronic medical records of patients admitted from 1st January 2023 to 31st December 2023 and managed for PEWSF. This review involved both the principal investigator and research assistants (RAs) (a midwife and an obstetrician experienced in maternity care). The RAs received physical training from the principal investigator three days before the actual data collection. The training module covered the study's aim, protocol, tools, data collection procedures, and ethical considerations.

During the data collection phase, the process began with a thorough review of available documents, including patient files and electronic medical records. The RAs systematically reviewed these records and extracted the required information according to the checklist parameters. Regular communication and coordination between the researcher and RAs were maintained to address any challenges or questions that arose.

Quality assurance measures, including reviews and checks of the recorded data, were implemented to verify the accuracy and completeness of the collected data. Upon completion of the data collection phase, the research team conducted a thorough review and validation of the collected data to ensure its integrity and reliability. Any discrepancies or issues identified were promptly addressed through additional verification or clarification processes.

3.10 Validity and reliability of the study tool

The checklist items were developed based on established guidelines, including the Ministry of Health (MoH) guideline managing of PEWSF patients at a Regional hospital. Experts in obstetrics and gynecology conducted a pretesting and pilot study of the checklist to ensure validity and reliability before data were collected.

3.11 Data Management and Entry

The tool (checklist) was coded before data entry. The coded information was entered into an Excel sheet in Microsoft Excel daily. A logic check, possible ranges, and legal value set-up were done to minimize errors in the study in the study. Data was cleaned before transferring to SPSS before data analysis.

3.12 Quality Plan and Data Analysis

Statistical Package for Social Science (SPSS) program version 27 was used for analysis. Descriptive statistics related to the management of PEWSF were summarized by using frequencies and percentages. Adverse maternal and fetal outcomes and association between adherences to guidelines in the management of women with PEWSF. SubanalysisSubanalysis was utilized by identified predictors of adverse maternal outcomes.

Descriptive statistics were summarized in summarized in frequency and percent, and bivariate logistic regression was initially used to determine the association of adherence to clinical guidelines with adverse maternal or fetal outcomes.

Outcomes. Subsequently, the multivariable logistic regression model included significant variables identified in the bivariate analysis that were independent of adverse maternal and fetal outcomes and associated with adherence to guidelines in the management of women with PEWSF. . A p--value of less than 0.2 in the bivariate is significant.

A p-value of less than 0.05 was considered statistically significant. This approach aimed to identify strong associations between adherence to guidelines in the management of women with PEWSF that contributed significantly to adverse maternal and fetal outcomes.

Adherence was considered if all three components of the guideline were completed or fulfilled. The three components of the guideline were maternal and fetal assessment, maternal and fetal management, and monitoring of maternal and fetal wellbeing and follow-up. Failing to adhere to at least one of the components was considered not to comply with the guideline. Each component of the guideline also had several requirements that guided the practitioner in the management of PEWSF.

The maternal and fetal assessment had 4 requirements, maternal and fetal management had 3 requirements, and monitoring of maternal and fetal wellbeing and follow-up had 4 requirements. Also, failure to implement one of the requirements was considered not adhering to that guideline component.

Table 1: Analysis Plan

OBJECTIVE	ANALYSIS PLAN
To determine prevalence of women with PEWSF managed according to guideline at Amana RRH	Frequencies, frequency distributions Percentages
To determine the association between adherence to guideline in the management of women with PEWSF and adverse maternal outcomes at Amana RRH	Logistic regression (Bivariate and multivariable)
To determine the association between adherence to guideline in the management of women with PEWSF and adverse fetal outcomes at Amana RRH	Logistic regression (Bivariate and multivariable)

3.13 Ethical consideration

The ethical clearance was requested and obtained from MUHAS Research and Ethics review board on June 7th 2024(MUHAS-REC-06-2024-2309) approval before commencing this research. Since the data was retrieved from the patient's record, no physical contact with patients was needed therefore; no informed consent was sought from the participants. Instead, an IRB waived for informed consent was asked. Likewise, permission for conduction of the study was also obtained from Amana RRH management to access patients' files before the start of data collection activities. Confidentiality was maintained during the review of files. File numbers were not written on checklist.

3.14 Dissemination of the results

The study was part of the partial fulfillment of the Masters requirements for the degree of Masters Science in Midwifery and Women's Health at MUHAS. After successful completion and acceptance of the dissertation, it will be disseminated through department of Nursing at MUHAS. It will be submitted for publication in local and international journals.

CHAPTER THREE

4.0 RESULTS

4.1 Patient-related factors and Obstetrics History of Participants

A total of 200 files were reviewed. The age of the study participants was normally distributed, and the mean age and SD were 28.99±6.53 years. The majority were aged 25–34 years (95, 47.5%). The mean numbers of gravidity and parity were 2.64±1.67 and 1.44±1.51, respectively, with the highest percentage of women in the Multigravida sub-group being in the Multigravida sub-group being 99 (49.5%) and prime 118 (59.0%). In terms of parity, the majority had ≤ 2 (148, 74.0%). The mean gestational age was 37.39±2.82 weeks, with the majority of pregnancies at ≥ 37 weeks or more (72.5%). The mean systolic blood pressure was 167.18±8.71 mmHg, and the diastolic blood pressure was 113.23±7.58 mmHg.(Details are found in Table 1)

Table 1: Patient-related factors and Obstetrics History of Participants (n=200)

Variable	Category	Frequency	Percent (%)
Age (years)	18-24	59	29.5
	25-34	95	47.5
	≥35	46	23.0
Gravidity	Primigravida	75	37.5
	Multigravida	99	49.5
	Grand-multigravida	26	13.0
Parity	Prime Para	118	59.0%
	Parous	82	41.0
	< 28	12	6.0
Gestational age at admission(weeks)	28-36	43	21.5
	≥ 37	145	72.5

4.2 Distribution of adherence to clinical guideline in management of women with PEWSF according to major and specific categories of the guideline

The study showed overall adherence was high (65.5%) in monitoring maternal and fetal wellbeing, follow-up, and management. Majority adherence was high; all 200 (100%) adhered to vital sign recoding and monitoring fluid input and urine output in monitoring fetal heart rate at 187 (93.5%) and follow-up management at 139 (69.5%).

Additionally, in maternal and fetal management, adherence varies in specific categories of the major categories. The majority adhered to the management of magnesium sulfate (MagSO4), 173 (86.5%), and delivery planning adherence was 134 (67.0%), while 200 (100%) adhered to blood pressure control.

Other aspects of the assessment showed varying levels of overall adherence: 69(34.5%): 186 (93.0%), adhered physical examination: 141 (70.5%) adhered to history-taking; 143 (71.5%) adhered to necessary investigations; and 128 (64.0%) adhered to using ultrasound scans for fetal assessment. (Details are found in Table 2)

Table (2) Distribution of adherence to clinical guideline in management of women with PEWSF according to major and specific categories of the guideline (n=200)

Variable	Category	Sub category	Frequency (n)	Percent (%)
Assessment of maternal and fatal	History taking	Adhered	141	70.5
		Not adhered	59	29.5
	Physical examination	Adhered	186	93.0
		Not adhered	14	7.0
	Investigations	Adhered	143	71.5
		Not adhered	57	28.5
	USS for fetal assessment	Adhered	128	64.0
		Not adhered	72	36.0
Overall assessment of maternal and fetal		**Adhered**	**69**	**34.5**
		Not adhered	**131**	**65.5**

	MagSO4 management	Adhered	173	86.5
		Not adhered	27	13.5
Maternal and fatal management	Blood pressure control	Adhered	200	100
		Not adhered	0	0
	Delivery plan	Adhered	134	67.0
		Not adhered	66	33.0
Overall Maternal and fetal management		**Adhered**	**117**	**58.5**
		Not adhered	**83**	**41.5**
Monitoring maternal and fetal wellbeing and follow up	Monitor fetal heart rate	Adhered	187	93.5
		Not adhered	13	6.5
	Vital signs	Adhered	200	100
		Not adhered	0	0
	Monitoring input and output	Adhered	200	100
		Not adhered	0	0
	Follow up management	Adhered	139	69.5
		Not adhered	61	30.5
Overall monitoring maternal and fetal wellbeing and follow up		**Adhered**	**131**	**65.5**
		Not adhered	**69**	**34.5**

4.3 Adverse maternal and fetal outcomes

The study showed one patient was referred to another higher-level health facility, and there were no maternal deaths reported from PEWSF during the study period. The majority of 176 (88.0%) had no maternal complications, while 24 (12.0%) had maternal complications.

Among single, twin, or triplet pregnancies, 14 (7.0%) babies were born dead. The majority of 186 (93.0%) babies were born alive. Birth weight distribution showed 93 (46.5%) babies weighing less than 2.5 kg.

Gestational age showed 43 (21.5%) were premature births. Apgar scores for single, twin, or triplet pregnancies indicated 69 (34.2%) had low scores, and at discharge, 17 (8.5%) were dead. While the overall fetal complications were present in 105 (52.5%) (Details are found in Table 3)

Table 3: Adverse maternal and fetal outcomes (n=200)

Variable	Category	Frequency(n=200)\	Percent (%)
Maternal complications	PPH	3	1.5
	HELPs syndrome	9	4.5
	Renal failure	2	1.0
	Psychosis	1	**.5**
	Two complications (Eclampsia PPH HELLP syndrome ……)	9	4.5
Overall adverse maternal outcomes	Yes	**24**	**12.0**
	No	176	88.0
Fetal complications			
Condition of the baby at birth (single/twins pregnancy)	Alive	186	93.0
	Dead	14	7.0
Birth weight of the baby (kg)	< 2.5	93	46.5
Single/weight for twins	≥ 2.5	107	53.5
GA of the baby	Term	157	78.5
	Premature	43	21.5
Condition of baby at discharge	Alive	183	91.5
	Dead	17	8.5
Apgar Score for single /twins' baby	Good score (≥7)	131	65.8
	Low score (<7)	69	34.2
Overall adverse fetal outcomes	Yes	**105**	**52.5**
	No	95	47.5

4.4 Prevalence of women with PEWSF managed according to clinical guideline

The study showed that overall adherence to all their major categories of the guideline was 25 (12.5%). The majority adhered to maternal and fetal management 117 (58.5%) and monitoring maternal and fetal wellbeing, follow-up, and management 131 (65.5%), while a small proportion adhered to assessment of maternal and fetal health 69 (34.5%).

The adherence varied in specific categories of the major categories. When assessing maternal and fetal health, the majority adhered to physical examination, with 186 (93.0%). Other aspects of the assessment showed varying levels of adherence: 141 (70.5%) adhered to history-taking; 143 (71.5%) adhered to necessary investigations; and 128 (64.0%) adhered to using ultrasound scans for fetal assessment.

In the management of maternal and fetal management, the majority adhered to Magnesium Sulfate (MagSO4) management, 173 (86.5%), and delivery planning adherence was 134 (67.0%), while 200 (100%) adhered to blood pressure control.

Regarding the monitoring of maternal and fetal wellbeing follow-up and management, adherence was high in monitoring fetal heart rate at 187 (93.5%) and follow-up management at 139 (69.5%). Additionally, all 200 (100%) adhered to vital sign recoding and monitoring of fluid input and urine output.(Details are found in Table 4)

Table (4); Prevalence of adherence to clinical guideline in management of women with PEWSF (n-200)

Variable	Category	Sub category	Frequency (n)	Percent (%)
Overall maternal and fetal assessment	Adhered	Adhered	69	34.5
	Not adhered	Not adhered	131	65.5
Overall Maternal and fatal management	Adhered		117	58.5
	Not adhered		83	41.5
Overall monitoring maternal and fetal wellbeing and follow up and management	Adhered		131	65.5
	Not adhered		69	34.5
The overall adherence of the guideline (all 3 major categories)	Adhered		25	12.5
	Not adhered		173	87.5

4.5 The association between adherence to clinical guideline in the management of women with PEWSF and adverse maternal and fetal outcomes.

In adverse maternal and fetal outcomes, variables that showed significance were entered into the logistic regression analysis**.** Regarding adverse fetal outcome, those children with gestational age ≥ 37 weeks and above showed 0.07 times less odds of adverse fetal outcom***es*** compared with gestational age below 28 weeks.

Other variables, such as age group, gravidity, parity, gestational age, assessment of maternal and fetal management, monitoring maternal and fetal wellbeing and follow-up, and maternal and fatal management, showed no significant associations with adverse fetal outcomes.

Regarding maternal outcomes, all variables did not show a significant association with adverse maternal and fetal outcomes. (Details are found in Table 5)

Table 5: The association between adherence to clinical guideline in the management of women with PEWSF and adverse maternal outcomes (n=200)

Variable	Category	Adverse maternal outcome							
		Unadjusted				Adjusted			
		cOR	95% CI		P value	aOR	95% CI		p-values
			lower	upper			lower	upper	
Overall adherence of the guideline	Adhered	Ref							
	Not adhered	3.63	.47	28.15	.22				
Age group (years)	18-24	Ref				Ref			
	25-34	0.38	.81	19.31	.09	.1.56	.57	.357	.43
	≥35	3.49	.75	16.16	.11	..33	.06	1.19	.22
Gravidity	Primigravida	Ref				Ref			
	Multigravida	.77	.31	1.92	.57	.53	.17	.16	.27
	Grand-multigravida	.24	.03	1.89	.17	5.12	..08	.63	.76
Parity		Ref							
	Parous	0.47	0.12	1.12	0.09	.0.56	.30	1.33	.73
Gestational age at admission	< 28	Ref							
	28-36	2.14	.24	19.33	.0.50				
	≥37	1.36	.17	11.28	.77				

Table 6: The association between adherence to clinical guideline in the management of women with PEWSF and adverse fetal outcomes (n=200)

Variable	Category	Adverse fetal outcomes							
		Unadjusted				Adjusted			
		cOR	95% CI		P value	aOR	95% CI		p-value
			lower	upper			Lower	Upper	
Overall adherence of the guideline	Adhered	Ref							
	Not adhered	1.23	.53	2.84	.63				
Age group (years)	18-24	Ref				Ref			
	25-34	1.70	.88	3.28	.11	1.67	.84	3.31	.14
	≥35	1.09	.50	2.35	.833	1.10	.489	2.45	.83
Gravidity	Primigravida	Ref							
	Multigravida	1.10	.69	2.02	.76				
	Grand-multigravida	.93	.39	2.28	.86				
Parity	Prime	Ref							
	Parous	1.18	0.67	2.01	.0.57				
Gestational age at admission	< 28	Ref				Ref			
	28-36	.21	.02	1.89	.15	.22	.03	1.86	.16
	≥37	**.07**	**.01**	**.57**	**.01**	**.07**	**.01**	**.59**	**.01**

CHAPTER FOUR

5.0 DISCUSSION

5.1 Discussion.

This study assessed the clinical management of women with PEWSF and maternal and fetal outcomes at Amana RRH. The majority were aged 25–34 years. With the highest percentage of women in Multigravida. The majority of gestational age at admission was 37 weeks and above, and among them are prime Para.

The study showed that the prevalence of women with PEWSF managed according to guidelines was notably low. This is indicative of the ongoing challenges in adherence to clinical protocols in low-resource settings, despite established guidelines (5, 6). The adherence to specific components of the guidelines varied, sometimes high and sometimes low. These variations highlight the complexities and difficulties in ensuring comprehensive adherence to clinical guidelines in everyday practice.

Furthermore, some specific components of the guideline, such as adherence to blood pressure control, vital signs recording, and monitoring fluid input and urine output, were adhered to by all participants. This indicates that while some aspects of guideline adherence were well implemented, others require improvement. These discrepancies may be due to differences in training, some important information, or missed documentation for health care providers who are working in maternity department healthcare.

The study showed that children with a gestational age of 37 weeks or more were protected from adverse fetal outcomes compared to those with a gestational age below 28 weeks. This finding highlights the critical role of gestational age in determining fetal health outcomes in cases of PEWSF. Full-term pregnancies provide a more favorable environment for fetal development, thereby reducing the risk of complications associated with prematurity, such as respiratory distress syndrome, intraventricular hemorrhage, and neonatal sepsis.

The study showed no significant associations between adherence to clinical guidelines and adverse fetal outcomes. This contrasts with some existing literature that suggests a strong link between guideline adherence and improved fetal outcomes (6, 7). The lack of

significant associations in this study may be attributed to several factors, including variations in the severity of PEWSF, gestational age at presentation, and inherent challenges in resource-limited settings that may affect fetal outcomes independently of clinical management adherence.

The adverse maternal outcomes in our study were relatively good, with no maternal deaths reported and a majority of women experiencing no maternal complications. This is in contrast to the higher rates of maternal morbidity and mortality reported in broader regional studies (8, 9). The favorable outcomes observed reflects effective management practices for those aspects of care that were adhered to, particularly in the critical areas of convulsion prevention and fetal neuroprotection.

In terms of adverse fetal outcomes, the study reported significant fetal complications, such as premature births. This highlights the ongoing challenges in achieving optimal fetal outcomes in the context of PEWSF, despite adherence to some guideline components. The high rate of adverse fetal outcomes aligns with the global understanding that PEWSF is a leading cause of prematurity, particularly in low-resource settings (10)

5.2 Study limitation and mitigation

This study was limited by the availability and quality of existing medical records. Efforts was made to minimized these limitations by ensuring data collectors were well-training and by conducting precise data from reliable sources (multiple sources including clinical notes and electronic medical records) and cleaning processes.

CHAPTER FIVE

6.0 CONCLUSION AND RECCOMENDATION

6.1 Conclusion

The adherence was low, reflecting significant challenges in implementing these protocols in a low-resource setting. Adherence to guidelines did not show significant associations with maternal and fetal outcomes. The gestational age of 37 and above was protective for fetal complications.

Fetal outcomes remained concerning, with a high rate of complications and prematurity, indicating that challenges persist in achieving optimal fetal health despite adherence to some guideline components. The lack of significant associations between other factors and other components of guideline adherence and fetal outcomes reflects the complex interplay of factors affecting fetal health in low-resource environments.

6.2 Recommendations

6.2.1 To Health care system

Comprehensive Training for Healthcare Providers: Despite established guidelines, low adherence to clinical guidelines in the management of PEWSF was indicative of the ongoing challenges in adherence to clinical protocols in low-resource settings. Thus, there is a need for improving training programs, potentially increasing adherence rates.

6.2.2 To Healthcare Providers

Enhance Training and Education: The low adherence to clinical guidelines in the management of PEWSF among healthcare providers, highlights a need for improved training programs. Regular education sessions for healthcare providers working in the Maternity department unit can address knowledge gaps and emphasize the importance of comprehensive management practices, potentially increasing adherence rates.

6.2.3 To Further Research

Future qualitative studies are needed to understand the barriers to guideline adherence in management of women with PEWSF

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8.0 APPENDICES

APPENDIX I: CLINICAL MANAGEMENT CHECKLIST (ENGLISH VERSION)

Study IDN: ……. Data collection date: …….

Hospital number of the patient: …….

SECTION ONE: BACKGROUND INFORMATION

1:1:0: A: Demographic and obstetric history

1:1:1	**Age**	**……(years)**
1:1:2	**Gravid**	**…….**
1:1:3	**Parity**	**…….**
1:1:4	**Gestational age**	**…… (weeks)**
1:1:5	**Blood pressure on admission for this delivery**	**Systolic: …….** **Diastolic: …….**
1:1:6	**Number of Antenatal Visits**	…….
1:1:7	History of hypertension (Chronic/Essential)	i)Yes ii)No
1:1:8	History of Diabetes Mellitus	i)Yes ii) No
1:1:9	History of Renal disease	i)Yes ii) No
1:1:10	History of pre-eclampsia/Eclampsia in previous pregnancy	i)Yes ii) No

1.2.0 B: Laboratory investigation findings (Were the following done within 1st 24hrs?

1:2:1	**HB**	i)Yes ii)No
1:2:2	**Platelet**	i)Yes ii)No
1:2:3	**ALT**	i)Yes ii)No
1:2:4	**AST**	i)Yes ii)No
1:2:5	**Creatinine**	i)Yes ii)No
1:2:6	**Urea**	i)Yes ii)No
1:2:7	**Uric Acid**	i)Yes ii)No
1:2:8	**Blood sugar**	i)Yes ii)No
1:2:9	**Electrolytes**	i)Yes ii)No

1:2:10	**Bed side clotting time**	i)Yes ii)No
1:2:11	**MRDT/BS FOR MPS**	i)Yes ii)No
1:2:12	**USS for biophysical profile**	i)Yes ii)No

SECTION TWO: DIAGNOSIS AND MANAGEMENT

2:1:0: A: Were the following symptoms or signs recorded on admission? (Tick where appropriate)

2:1:1	Severe headache	i) Yes ii)No
2:1:2	Visual Disturbance	i) Yes ii)No
2:2:3	Epigastric pain	i) Yes ii)No
2:1:4	General oedema	i) Yes ii)No
2:1:5	Protein in urine	i) Yes ii)No
2:1:6	If Ye was it (+) (++) (+++)	

2:2:0: B: Vital signs on admission (Tick appropriate and fill values)

	Vital sign	Performed	Not Performed	**If performed, value at admission**
2:2:1	Blood pressure			
2:2:2	Pulse rate			
2:2:3	Respiratory rate			
2:2:4	Temperature			
2:2:5	Fetal Heart Rate			

2:3:1: C: Patient status at Admission

1. Conscious (Alert)
2. Semi-conscious, respond to voice
3. Semi-conscious, respond to pain stimuli
4. Un conscious (Unresponsive)

2.4.0 D: Blood pressure Control

2:4:1	Was BP recorded	i) Yes ii) No
2:4:.2	Is there any anti-hypertensive given (tablet Nifedipine, tablet Methyldopa, iv hydralazine or iv labetalol)	i) Yes ii) No
2:4:3	If yes mentions drugs	……..
2:4:4	If yes mention dose and route	……
2.4.5		

2:5:0 E: Patient's Maternal and fetal management

Management criteria/Hospital admission		
2:5:1	BP Measurement every 15-30 minute until BP less than 160/110 then 4 time / day(Target BP: 140–155 mmHg/90–100)	i)Yes ii)No
2:5:2	Dipstick Proteinuria test daily while admitted (>_300mg of protein in urine collected over 24 hours or 2+ on urine dipstick)	i)Yes ii)No
2:5:3	**Follow up investigation 3 times per week** (Complete blood count (CBC) with platelets, platelet count of less than 100,000)	i)Yes ii)No
2:5:4	(Serum creatinine Check or 2 x baseline Weekly)	i)Yes ii)No
2:5:5	(Liver enzymes Check hepatic function AST/ALT 2x normal Weekly)	)Yes ii)No
2:5:6	Fetal assessment Ultrasound every 2 weeks (Amniotic fluids volume index>5cm)	i)Yes ii) No
2:5.7	**Overall adherence (Yes=all were adhered, No= if at least 1 or more was not adhered)**	i)Yes ii) No

2:6:0: F: Pre-eclampsia with severe features management

Management criteria/prevent convulsion and for fetal neuro protection benefit)		
Initial loading dose of magnesium sulphate (**Pritchard (IV and IM)**		
2:6:1	**MGSO4 Loading dose (Pritchard)** 4 g in 20 ml (20% solution) administered iv over 5–20 minutes, followed by 5 g in 10 ml (50% solution) IM injection in each buttock	i)Yes ii) No
2:6:2	**MGSO4 Maintenance doses** 5 g in 10 ml (50% solution) IM injection every 4 hours in alternate buttocks. (if convulsions recur after 15 minutes, give 2 g [50% solution] iv over 5 minutes	i)Yes ii) No
2:6:3	Initial loading dose of magnesium sulphate (**Zuspan (IV only**) **MGSO4 Loading dose** 4 g in 20 ml (20% solution) administered iv over 5–20 minutes	i)Yes ii) No
2:6:4	**MGSO4 Maintenance doses** 1 g/ hour iv infusion	i)Yes ii) No
2.6.5	**Overall adherence (Yes=all were adhered, No= if at least 1 or more was not adhered)**	i)Yes ii) No

2:7:0: G: Monitor maternal and fetus well being

Management practices monitor for respiratory rate, reflexes and urine output hourly (mgso4, check for the 3 signs of toxicity)		
2:7:1	Respiration: ≥ 16 breaths per min	i)Yes ii) No
2:7:2	Patellar reflexes: present?	i)Yes ii) No
2:7:3	Urinary output: ≥ 30 ml per hour averaged over the last 4 hour	i)Yes ii) No
2:7:4	**If no signs of toxicity**, give 5 g MGSO4 (50% solution) + 1 ml lignocaine 2% IM every 4 hours in alternate buttock	i)Yes ii) No
2:7:5	**If yes signs of toxicity** withhold MGSO4 continue to check hourly and restart when there are no signs of toxicity	i)Yes ii) No

2:7:6	Urine output is less than 30 ml/hour:	i)Yes ii) No
2:7:7	If yes administer iv fluids lactated ringer solution or normal saline) at 1 litres in 8 hours and monitor for pulmonary edema	i)Yes ii) No
2:7:8	**If have sign of pulmonary** edema withhold iv fluids and give furosemide 40 mg IV once	i)Yes ii) No
2:7:9	**In case of respiratory arrest (**shout for help! ventilate with bag and mask, give calcium gluconate 1 g (10 ml of 10% solution) iv slowly over 3 minutes.	i)Yes ii) No
2:7:10	If the diastolic BP drops below 90 mmHg, Reduce frequency or dose of anti-hypertensive medication?	i)Yes ii) No
2:7:11	If the diastolic BP is higher than 100 mmHg, increase the dose or frequency of anti-hypertensive medication or change the anti-hypertensive medication	i)Yes ii) No
2:7:12	**Check fetal heart rate.** Daily fetal movement check and non-stress testing	i)Yes ii) No
2:7:13	Fetal growth assessment ultrasound every 2-3 weeks	i)Yes ii) No
2:7:14	Amniotic fluids volume index>5cm twice a week if birth delay	i)Yes ii) No
2:7:15	If the woman is in labor, use the patograph and check fetal heart rate every 30 minutes and her temperature every 4 hours.	i)Yes ii) No
2:7:16	Decision of senior obstetricians	
2:7:17	**Overall adherence (Yes=all were adhered, No= if at least 1 or more was not adhered)**	i)Yes ii)No

2:8:0: H: Plan for delivery

	Management practice confirm for gestational age to know when to delivery and to decide if she needs antenatal corticosteroids to help the fetus lungs maturity	
2:8:1	If fetus is viable GA is< 34 weeks, give dexamethasone 24mg IM in divided doses. give 6 mg dexamethasone IM as soon as possible, followed by another 6 mg IM 12 hours per 48 hours delivery within the next 7 days **or**	i)Yes ii)No
2:8:2	Betamethasone is also 12 mg IM as soon as possible, followed by 12 mg 12 hours later	i)Yes ii)No
2:8:3	If GA is less than 32weeks, and there is a risk of birth in the next 24	i)Yes ii)No

	hours, iv-only mgso4 (Zuspan regime) for fetal neuroprotection if iv infusion pumps or gravity drips are available.	
2:8:4	If unstabe, stable SPE ≥ 37 weeks 0 days, or any GA deliver within 24 hours	i)Yes ii)No
	Mode of delivery	
2:8:5	Vaginal birth delivery	i)Yes ii)No
2:8:6	Cesarean delivery	i)Yes ii)No
2:8:7	**Overall adherence (Yes=all were adhered, No= if at least 1 or more was not adhered)**	i)Yes ii)No

2:9:0: I: Care after delivery (postpartum)

	Management practices	
2:9:1	MGSO4 maintenance dose IM: 5 g in 10 ml (50% solution) IM injection every 4 hours in alternate buttocks was given 24 hours after birth ?or	i)Yes ii)No
2:9:2	MGSO4 maintenance dose IV (Zuspan regimen): 1 g / hour iv infusion	i)Yes ii)No
2:9:3	Vital signs monitored hourly	i)Yes ii)No
2:9:4	Urine output recorded before next dose of mgso4	i)Yes ii)No
2:9:5	Ant- hypertensive given (medication to keep diastolic BP between 90 and 100 mmHg) given?	i)Yes ii)No
2:9:6	Any signs of toxicity and document on mgso4?	i)Yes ii)No
2:9:7	**Overall adherence (Yes=all were adhered, No= if at least 1 or more was not adhered)**	i)Yes ii)No

2:10:0: J: Patient's discharge and follow up management

Management practices		
2:10:1	Investigation after birth 48/72 hour if normal don't repeat	i)Yes ii)No
2:10:2	Offer woman with a medical review with their specialist 6/8 week after birth	i)Yes ii)No
2:10:3	Aspirin 75-150mg daily for 12 week until birth for high risk (previous pre-eclampsia chronic renal disease, first pregnancy	i)Yes ii)No
2.10.4	**Overall adherence (Yes=all were adhered, No= if at least 1 or more was not adhered)**	i)Yes ii)No

SECTION THREE: PATIENT OUTCOME

3:1:0: A: Condition of the mother and fetus

3:1:1	Condition of the mother	i)Alive ii)Dead
3:1:2	Maternal complications	**1.Pph** **2.Hellp Syndrome** **3.Renal Failure** **4.Eclampsia** **5.Admission To Icu**
3:1:3	Condition of the baby	i)Alive ii)Dead
3:1:4	Birth weight of the baby	…… kg
3:1:5	Term baby	i)Yes ii)No
3:1:6	Pre mature	i)Yes ii)No
3:1:7	Apgar Score	1st min……5th min…
3:1:8	Fetal complications	**1.Birth asphyxia** **2.Admission to NICU** **3.Low birth weight** **4. Intrauterine fetal death** **5. Low Apgar score**
3:1:9	**Overall adherence (Yes=all were adhered, No= if at least 1 or more was not adhered)**	i)Yes ii)No

3:2: O: B: Discharge/death (circle appropriate)

3:2:1	Condition of mother at discharge	i) Alive ii)Dead
3:2:2	Condition of baby at discharge	i) Alive ii)Dead

3:3:0: C: Referral

3:3:1	was referral given	i) Yes ii) No
3:3:2	State of the patient	Alert, Semiconscious, Unconscious
3:3:3	Condition of the fetus	i) Alive ii)Dead

APPENDIX II: ETHICAL CLEARANCE LETTER

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATIONS

Ref. No.DA.282/298/01.C/2309 Date: 07/06/2024

MUHAS-REC-06-2024-2309
WINFRIDA MAKANGI KALEGI
SCHOOL OF NURSING
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: ASSESSMENT OF CLINICAL MANAGEMENT OF WOMEN WITH PRE-ECLAMPSIA WITH SEVERE FEATURES AND MATERNAL AND FETAL OUTCOMES AT AMANA HOSPITAL IN DAR ES SALAAM TANZANIA

Reference is made to the above heading,

I am pleased to inform you that the Chairperson has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 07/06/2024
EXPIRATION DATE OF APPROVAL: 07/06/2025

STUDY DESCRIPTION:
Purpose:
The purpose of this retrospective cohort study is to determine the association between adverse maternal and fetal outcome and clinical management of women with PEWSF at Amana Regional Referral Hospital

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2015674.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain Data Transfer Agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain Material Transfer Agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country.
8. Apply for and obtain permission to publish the results from National Institute for Medical Research. The application should be before submitting to a publisher and not concurrently through the email publications@nimr.or.tz.
9. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research, Publications & Innovations
Box 65001

Dr. Nahya Salim Masoud,
Chairperson, MUHAS Research and Ethics Committee

APPENDIX III: INTRODUCTION LETTER

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote;
Ref. No. HD/MUH/T.446/2022 10th June, 2024

The Executive Director,
Amana Regional Referral Hospital,
P.O. Box 25411,
DAR ES SALAAM

Re: INTRODUCTION LETTER WINFRIDA MAKANGI KALEGI

We would like to inform you that the bearer of this letter is **Winfrida Makangi Kalegi** with Reg. No. **HD/MUH/T.446/2022** is a student at Muhimbili University of Health and Allied Sciences (MUHAS) "pursuing **MSc. Midwifery and Women's Health.**

As part of her studies, she will be doing an elective research titled: "**Assessment of Clinical Management of Women with Pre-Eclampsia with Severe Features and Maternal and Fetal Outcomes at Amana Hospital in Dar es Salaam Tanzania".**

The research has been approved by the Chairman of University Senate.

Kindly provide her the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

c.c **Winfrida Makangi Kalegi**

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

APPENDIX IV: PERMISSION LETTER

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

AMANA REGIONAL REFERRAL HOSPITAL

Telegram "HEALTH", DODOMA
Phone No.: +255 026 – 2323267
Email: ps@afya.go.tz

REF. NO. MoHCDGEC/ARRH/R.1/VOL II/

P.O. Box 25411
DAR ES SALAAM
Phone: 022—2861903

Date: 11/06/2024

Director, Postgraduate Studies,
MUHAS,
P.O. Box 65001,
DAR ES SALAAM.

Re: PERMISSION FOR DATA COLLECTION

Refer to your letter dated 4th June, 2024 which requested us to allow **Winfrida Makangi Kalegi** to conduct research and collect data in our institution.

We are here to acknowledge your request with the following conditions, that she must submit the results of her research after completion of analysis in order the hospital to make use of data's to solve hospital problems.

Regards.

For:
MEDICAL OFFICER I/C
AMANA REGIONAL REFERAL HOSPITAL
P. O. Box 25411
DAR ES SALAAM

Dr. Rose Ntambuto
FOR: MEDICAL OFFICER INCHARGE
AMANA REGIONAL REFERRAL HOSPITAL

(All Correspondence should be directed to Medical Officer Incharge)
Email: amana@amanarrh.go.tz, Website: www.amanarrh.go.tz

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