CRITERIA BASED AUDIT AND OUTCOMES ON THE MANAGEMENT OF ECLAMPSIA AT MUHIMBILI NATIONAL HOSPITAL; COMPARISON OF 2009 AND 2017/2018 AUDITS.

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By

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A Dissertation Submitted in Partial Fulfilment of the Requirements for the Degree of Master Medicine in Obstetrics and Gynaecology of

Muhimbili University of Health and Allied Sciences.
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CERTIFICATION.

The undersigned certifies that he has read and hereby recommends for examination of dissertation entitled ***"Criteria based audit and outcomes on the management of eclampsia at Muhimbili national hospital; comparison of 2009 and 2017/2018 audits"*** in partial fulfillment of the requirements for the degree of Master of Medicine in Obstetrics and Gynaecology of Muhimbili University of Health and Allied Sciences

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Prof. Andrea B. Pembe
(Supervisor)

_____

Date.

DECLARATION AND COPYRIGHT.

I, **Zainab Feisal,** declare that this dissertation is my original work and that has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature _____ **Date_____**

ACKNOWLEDGEMENT.

All praise to the almighty God for the blessings throughout my academic journey to-date.

Sincerest gratitude to my supervisor, Professor Andrea B. Pembe for his guidance and encouragement to aim higher and strive for excellence. His continued tireless advice and inputs from proposal development to report writing and his mentorship is priceless. Without his guidance and persistent help, this dissertation would not have been possible. God bless you.

I would to also thank the head of the department and the members of the Obstetrics and gynaecology department at MUHAS for their contributions in making this work a success. Many thanks go to Muhimbili National Hospital (MNH) for their support during data collection that made this study possible. I would also like to thank Dr. Hussein L. Kidanto for his continued support and permission to use his study done in 2009.

Finally, to my beloved husband Issak Hussein, son Muadh Issak and late daughter Aaliyah Issak, parents Mr. Feisal Khambari and Mrs. Mariam Waishoro and my siblings who were my stronghold throughout this journey. I cannot thank you enough for the continued support.

DEDICATION.

I dedicate this thesis to my beloved daughter, the late Aaliyah Issak Hussein. We started this journey together but unfortunately, you left before the end. You are deeply engraved in our hearts.

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LIST OF ABBREVIATIONS

BP	Blood Pressure.
CBA	Criteria Based Audit.
HELLP	Haemolysis, Elevated Liver enzymes, Low Platelets.
IUGR	Intra uterine Growth Retardation.
MMR	Maternal Mortality Ratio.
MNH	Muhimbili National Hospital.
RCOG	Royal College of Obstetrics and Gynaecology.
RDS	Respiratory Distress Syndrome.
SDG	Sustainable Development Goals.
TTN	Transient Tachypnea of the Newborn.
WHO	World Health Organization.

OPERATIONAL DEFINITIONS

1. **Eclampsia**: Either the manifestation of generalised tonic-clonic seizures or loss of consciousness with the existence of a sustained SBP ≥ 160 mmHg and/or DPB ≥ 110 after 20 weeks of pregnancy or documented clinical diagnosis.
2. **Clinical audit of eclampsia management**: defined as an essential quality evaluation process that aims to improve standards of care among women with eclampsia through a systematic review of local practice against explicit standards
3. **Adherence:** defined as a process whereby care provided to women with eclampsia followed the recommended standards stipulated in the Muhimbili national hospital guidelines.

ABSTRACT

Background: Globally eclampsia accounts for 10% of all maternal deaths. At Muhimbili National Hospital (MNH) eclampsia is among the three leading causes of maternal mortality. It is paramount that an audit of eclampsia is done periodically to improve on obstetric care and reduce adverse outcomes.

Objectives: To audit the adherence to the standard protocol in the management of eclampsia in women admitted at MNH and compare the adherence with the 2009 audit and obtain current outcomes.

Methodology: A descriptive cross-sectional study was conducted in the department of Obstetrics and gynaecology, MNH. Data were collected from October to November 2019. Case files of patients managed for eclampsia from January 1st 2017 to December 31st 2018 were selected to reach a total sample of 400 cases. The selected criteria were adopted from pre-existing MNH guidelines. There was a total of fourteen criteria from which the checklist was derived. Data collection was done using a structured checklist and analyzed by SPSS version 23. Calculation of proportion to the adherence to management criteria was done. The comparison between the frequency of pre-determined standards between this study and the 2009 audit by kidanto et al was carried out by using a student t-test**.** The proportion of eclamptic women who were managed as per the standard criteria was obtained by calculating the percentage of adherence for each criteria.

Results: The adherence in the management offered to eclamptic women against the standard protocol ranged between 9.5%-100% with eight out of fourteen standards scoring 90% and above. There is a statistically significant reduction in adherence to six standards out of fourteen, from the 2017/2018 in comparison to the 2009 audit of eclampsia. The case fatality rate in the current audit was 1.8% compared to 0% in the 2009 audit. There was a statistically significant improvement from 2009 audit in blood pressure monitoring, caesarean section delivery within 2hrs of decision and corticosteroid use for pregnancies less than 34weeks from (39-99.8%), (61-100%) and (24-39.9%) respectively.

Conclusion: There was a reduction in upholding of almost half of the total standard criteria over the duration of eight years from previous audit. There was a significant case fatality rate compared to no maternal deaths in the 2009 audit.

1.0 INTRODUCTION

1.1 Background.

Eclampsia is the extreme end of hypertensive disorders in pregnancy. It is a progressive disease and delivery is needed to halt the progression (1). It manifests as a new onset of generalized tonic-clonic seizures. Eclampsia may occur before twenty weeks of gestation with multiple gestations or molar pregnancies, and may additionally occur in the 6-week postpartum window (2).

Maternal mortality and morbidity from eclampsia continues to be seen around the globe (3). According to a ten-year retrospective study conducted in Tanzania, eclampsia was the leading direct cause of maternal death (4,5). At Muhimbili National Hospital (MNH), eclampsia is amongst the top three causes of maternal deaths and contributes significantly to maternal morbidities (6). The higher rate of morbidity and mortality has been attributed to the lack of efficient antenatal care, poor transport facilities, delay in effecting treatment and administrative problems (7). Maternal complications occur in 54% of eclampsia cases. They include HELLP syndrome, pulmonary oedema, cerebrovascular incidents, hepatic capsular rupture, placenta abruption, renal failure and maternal death (8).The WHO multi-country survey maternal near-miss cases were 60 times more frequent in women with eclampsia in comparison to the women without these conditions (9).

A Criteria Based Audit (CBA) is an essential tool in identifying the quality of care and management**.** Audit relies on evidence-based practices in improving patient care (10). It has been used to improve on obstetric care in both high and low-middle income countries (11). High quality obstetric care is a prerequisite for reducing maternal and perinatal outcomes (12). Audits aim to provide crucial direction for mitigation or elimination of poor health system failures (13). Recent CBAs were conducted in Ghana and Jamaica on the management of eclampsia and improvement in the quality of obstetric care by little expenditure (14).

The Sustainable Development Goal (SDG) number three seeks to ensure health and well-being for all, at every stage of life (15). The goal addresses all major health priorities including maternal and child health. Substantial global reduction of maternal mortality was achieved globally between 1990 and 2015 with a drop of 43% from 385 to 216/100,000 (16). The SDG number three's target is to reduce the global maternal mortality ratio (MMR) to less than 70 per 100,000 live births by 2030 (15).

Achievement of SDG number three is attainable in cases related to eclampsia. This is through evidence-based practice implementation at our facilities thus bridging the gap between practices against standards of management (17). Gaps have been identified in both developed as well as developing countries (18).

Bridging of these gaps and review of our criteria and modification is crucial to improve the overall outcome. Frequent audits on the management of eclampsia leads to a reduction of maternal and neonatal mortality and morbidity rate. Studies have shown groups that received management as per the pre-determined standards experienced a less significant and smaller scale of complications compared to those who haven't, hence this could be related to the services rendered and optimal compliance to the set standards identified (19).

An initial CBA of eclampsia management was initiated at MNH in 2006. Criteria were developed and on-job training was conducted on the set standards. Local practices were then evaluated against the set standards and adherence determined (20). Recommendations were then given and a re-audit was conducted in 2009. This study portrayed a significant increase in adherence to the CBA and reduction of maternal morbidity and mortality. The case fatality rate improved from 7.7% to 0% (21).

There has been an 11-year lapse in duration from the 2009 audit. This begs the question as to whether there is more improvement in adherence or a status quo. This study audits the adherence of the current practice in the management of patients with eclampsia against the set standard. It also compares the adherence of the 2009 audit against the current management standards. To depict the changes over this prolonged duration before another audit was conducted.

In 2017 a fully established maternal ICU and HDU was opened. These new facilities were fully equipped with fetal monitoring, partial pressure of oxygen monitoring and positive airway pressure ventilation. There has also been the availability of Intensivists and some trained ICU nurses. The women with eclampsia who developed kidney injury also had access to dialysis services. This brings about the curiosity as to whether there has been a change in both maternal and fetal outcomes due to these new interventions; in comparison to the 2009 audit when these facilities were unavailable.

1.2 Literature Review.

A study was conducted in the UK at the Yorkshire obstetric critical care group on the outcomes of severe pre-eclampsia and eclampsia on a total of 210,631 women between January 1999 and 31st December 2004. There was poor compliance with guidelines with no woman receiving magnesium sulphate before fits. There were thus fifty-four out of a thousand one hundred and forty-five deaths. Participants suffered from maternal morbidities with fourty nine women having ICU admissions. Twenty-five women suffered from pulmonary oedema and thirteen women suffered from temporary blindness and some areas of ischemic infarcts were visible on a CT scan (22).

Based on a study of maternal and perinatal outcomes of pre-eclampsia conducted at the Ohio state university national hospital; adherence to antepartum maternal corticosteroid administration was associated with a decreased morbidity and overall increase in survival rates of preterm infants. Similarly, adherence to protocols of antenatal magnesium sulphate administration in an analysis of six thousand infants depicted a decline of neuro-protective disorders in infants (23).

At Sultan-Abdulhalim hospital in Malaysia, an initial audit on the management of eclampsia the neonatal outcome was as follows; the prevalence of low birth weight, very low birth weight and extremely low birth weight were 28.6%, 14.3% and 9.6% respectively.

Recommendations were then given and an improvement of adherence to standards in a second audit was done. In the second audit the prevalence of low birth weight, very low birth weight and extremely low birth weight showed an overall decrease at 22.2%, 22.2% and 11.1% (24). This shows that better adherence to standards leads to an improvement of neonatal morbidity due to reduced prematurity and complications.

In the same study at sultan Abdulhalim teaching hospital on an audit of the management of eclampsia protocols were put into place in the handling of emergency cases. In the initial audit, there was a compliance of 50% while in the re-audit compliance rose to 88.9%. The consequences of implementation of these changes lead to an overall decrease in perinatal mortality rate from 0.07 per 1000 births to 0.05 per 1000 births in a re-audit. This doesn't reflect a marked improvement but shows promise of improved results with an elevation of the standards optimally (24).

Studies of a CBA in Nigeria at a tertiary teaching hospital concerning eclampsia against standards have shown that compliance with optimal standards leads to a better outcome in both the perinatal and maternal outcomes. Adherence was sub-standard for six criteria at 33.3% and very sub-standard for another seven criteria at 38.9% as a result participants presented with life-threatening complications. The case fatality rate for eclampsia was 5.8% and there were 13.5 % perinatal deaths among infants delivered. The average performance was very sub-standard at 69% in this study thus the overall outcome (25).

A CBA conducted in Ghana perceived that protocols were observed amongst the complicated and uncomplicated group of patients in severe pre-eclampsia. Those who developed imminent eclampsia, the adherence to protocol of eclampsia was at 54% amongst these participants there were two cases of perinatal mortalities. The women suffered at least one life-threatening condition as per WHO criteria (19).

Based on an audit of eclampsia conducted in Mulago hospital, Kampala and later on a re-audit was done after recommendations were given and changes implemented; in the 12% of women who were affected with eclamptic fits, 80% died during the initial audit due to sub-optimal management.

Recommendations were then given and adhered to in the re-audit and despite a similar number being affected with eclamptic fits there were no deaths (26). This emphasizes the need for protocol adherence to the overall outcome. Failure to maintain standards leads to an increase in both perinatal morbidity and outcome (27).

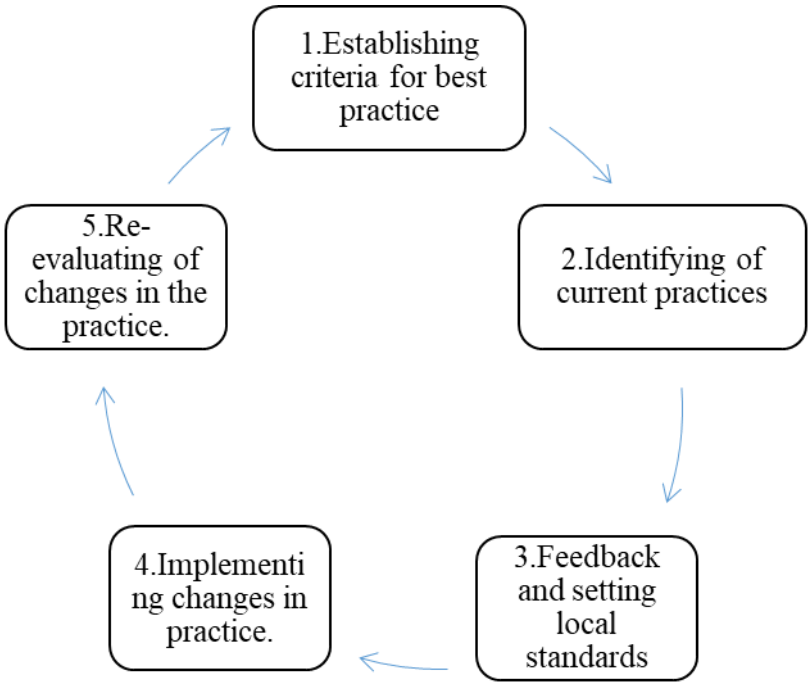
The case-fatality rate for eclampsia in women who delivered at MNH was 5.0%, compared with 16% in cases referred from other hospitals after delivery. The main cause of maternal morbidity and mortality is cerebral and pulmonary oedema. Contrary to studies from developed countries renal failure and coagulation problems were relatively rare in this study.

In an audit conducted at MNH preterm delivery and low birth weight were the major causes of neonatal death. This study showed that there were very few mothers who received corticosteroids. There were 51% of neonates affected by low birth weight due to not complying with the set standards (28). Data analysis from the initial audit was conducted and the results were presented. Gaps in the current practice were then discussed and recommendations were given and implementation was done for ten months. In the re-audit significant improvement to the criteria was visible in comparison to the initial audit. The resultant overall outcome due to improved adherence was a reduction of maternal deaths from thirty deaths to none from the initial audit to the re-audit (28).

1.3 Clinical Audit Cycle.

A clinical audit was performed during the study period. This is the systematic and critical way of analyzing the quality of medical care, including procedures used for diagnosis and treatment. There are five steps in an audit cycle in this study the cycle was not completed; the steps include**:**

Figure 1: Audit cycle.



Step 1. This was not conducted since the standards of care had already been established. A set of standards were adopted from the MNH guideline which addressed quality issues concerning the management of eclampsia. The standards were derived from criteria adopted from pre-developed literature and peer publications. These were CBA conducted by kidanto et al in 2006 and a re-audit on eclampsia conducted in 2009 at MNH. The two audit criteria and recommendations were merged to create the MNH guidelines. The checklist was developed based on the guidelines and their feasibility in this study was assessed.

Step 2: The current practice on the management of eclampsia among pregnant women admitted at MNH was then identified and compared against the set standards.

Step 3: Feedback and recommendation in regards to the research findings will be given to the obstetric department at MNH.

Step 4 and Step 5 of the audit cycle will not be completed in this study due to the time limitation. MNH will be advised to complete the cycle after the provision of recommendations. A re-audit will be recommended to assess whether changes will be implemented and later on re-evaluate for changes in practice.

1.4 Problem Statement.

Eclampsia is a major contributor to maternal and neonatal deaths in developing countries, associated with 10–15% of direct maternal deaths many of which are preventable with improved care. In the year 2006 at MNH, the case-fatality rate in eclampsia was shown to be 5.1% of all pregnant women admitted for delivery (28).

An initial audit on eclampsia was conducted in 2006 and a re-audit in 2009 at MNH. The main causes of maternal mortality in the initial audit were pulmonary oedema and cerebral haemorrhage. This are preventable conditions had the facility been well equipped thus improving maternal and neonatal outcomes as per the 2009 audit recommendations(28). There has since been a marked improvement in facilities at ward 35 at MNH with an intensive care unit established in 2017.

The 2009 audit was done 11 years ago, it raises the question of the progress that has been achieved over this duration in terms of management. This will enable us to see the impact of the time lapse on patient management. This audit will enable us to compare the current case fatality rate, improvement and deficits to the 2009 audit.

1.5 Rationale.

The audit will portray where there are improvements and deficits in the upholding of the management standards of eclampsia. This will be in comparison to the 2009 audit while focussing on low-cost interventions to remedy the deficits. The information obtained from this study will be utilized by implementers and health care providers, aiding in adherence to management standards thus impact on preventable maternal and foetal mortality and morbidity**.**

1.6 Research Questions.

1. Is there a difference in adherence in the standard protocol for management of eclampsia among women admitted in 2017/2018 and the 2009 audit?
2. What are the maternal and neonatal outcomes in women managed with eclampsia admitted at MNH?

1.7 Objectives.

1.7 Broad Objective.

To audit adherence to the standard protocol in the management of eclampsia in women admitted at MNH and compare the adherence with the 2009 audit and obtain current outcomes.

1.7.2 Specific Objectives.

1. To determine adherence to the standard protocol in the management of eclampsia in women admitted at MNH and compare to the 2009 audit.
2. To compare the adherence to standard protocol in the management of eclampsia between the current and the 2009 audit.
3. To determine the maternal and neonatal outcome among women managed with eclampsia admitted at MNH.

2.0 METHODOLOGY.

2.1 Study Design.

A descriptive cross-sectional study was adopted.

2.2 Study Duration.

The study duration was 9 months.

2.3 Study Setting.

Muhimbili National Hospital is a teaching hospital for Muhimbili University of Health and Allied Sciences, a national referral hospital and one of four large consultant hospitals in the United Republic of Tanzania. It is situated in Dar-es-Salaam, which has a population of 4,364,541 and an annual growth rate of 5.6% according to the 2012 census. The hospital serves as a referral center for the city of Dar-es-Salaam. The majority of maternity cases are referred from three municipal referral hospitals found within the city namely Amana, Temeke and Mwananyamala. It has a bed capacity of 1,500 beds. The hospital admits 1,000 to 1,200 inpatients per week.

Department of obstetrics and gynaecology is one of the largest among the clinical departments. It is composed of 2 maternity blocks. The first block has 5 obstetric wards, one labour ward (18 beds), and one ICU/HDU ward (9 beds). The second block consists of antenatal clinic and post-delivery ward for mothers who have been previously assessed and are stable. Mothers with sick neonates admitted in neonatal units, mother and neonates on Kangaroo care program are also admitted in that same block. There is an operating theatre with two rooms for Obstetrics cases and two rooms for Gynaecological cases. Approximately 9,000 deliveries are conducted every month at Maternity Block. The average number of admissions per month of obstetric cases at the maternity block is 1000 patients.

On arrival patients are admitted through labour ward. They are then directed to their respective ward, depending on the diagnosis, plan of management or delivery. There is always an available medical team on call. The team is comprised of one intern, 2 registrars/residents, one specialist and a consultant. Two shifts of nurses are always allocated, each shift lasts 12 hours. Attendance with a priority to emergency cases then stable ones is followed.

Ward 35 comprises of both I.C.U, H.D.U and pre eclampsia ward. It contains four rooms in total with two rooms allocated for patients with severe pre eclampsia and eclampsia. All patients with severe pre eclampsia and eclampsia are directly admitted at the pre eclampsia room which has a total of 12 beds. Patients with severe pre eclampsia/eclampsia are directly started on magnesium sulphate and anti-hypertensives, the baseline investigations are usually taken on admission and within twenty-four hours results are availed. These patients are closely monitored with routine checking of blood pressure, monitoring fluid input and output.

The maternity ICU was fully established in 2017, the ICU team comprises 2 intensivists, certified critical care nurses working in shifts, resident doctor and obstetrician specialist. A clear standard operating procedure (SOP) is available in the Unit containing admission criteria, management and infection control protocols.

The maternity critical care unit is divided into two areas, a 4 beds HDU with oxygen pipeline mounted on the bedside head wall, a multi-parameter monitors, with a nurse to patient ratio 1:2. The main area is the 5 bedded ICU, with a central nursing station with direct visual contact to all patients. Major types of equipments in ICU include non-invasive blood pressure, defibrillator, suction machine, oxygen pipeline and portable oxygen cylinder. Respiratory support equipment available including CPAP machine and a standard ventilator for each bed and the nurse to patient ratio.

In the 2009 audit a sample size of 88 was taken. This was due to implementation of recommendations given in the 2006 audit thus the re-audit was done over a period of 3 months. The main aim was to assess whether the recommendations provided were being adhered to by the health care providers.

2.4 Study Population.

All pregnant women admitted at MNH with a confirmed diagnosis of eclampsia

2.5 Study Sample.

All case files of women admitted at MNH due to eclampsia from January 1st, 2017 to December 31st, 2018 which were 400.

2.6 Inclusion Criteria.

- All women who were admitted with eclampsia from January 1st, 2017 to December 31st, 2018.

2.7 Exclusion Criteria.

- Women with incomplete data which included missing partograph, treatment charts and lacking pages of the history of the patient.

2.8 Sampling Technique.

Convenient sampling was done where records of all files from 1st January 2017 to 31st December 2018 of women with eclampsia were traced from the admission registry book in ward 35. A list of all patients admitted due to eclampsia was then generated from the registry. A total of 450 patients were enrolled on the list. It was then submitted to the medical record department and the patients' file names and numbers were cross-checked on the MNH electronic database. Twenty-five files were missing thus 425 files were retrieved. Seventeen files had a different diagnosis on their review, they were later on transferred out of ward 35. There were eight files with significantly incomplete data due to some missing papers containing mainly the treatment chart, partograph and some parts of the clinical notes. The files that met the inclusion criteria were 400 and were recruited**.** Data on their demographics, management, complications, interventions, investigations and outcomes were obtained through a checklist designed from pre-determined standards.

2.9 Pre-Testing Of The Checklist.

The checklist was pretested for feasibility at the same facility before the initiation of data collection.

2.10 Data Collection Tools.

Data were collected by using a checklist with standards for the management of eclampsia from the files that were identified from the ICU registry book. Information was obtained from the doctor's notes as documented in the files. Data were collected by the principle researcher from all patient files. The checklist was adopted from MNH guidelines. Collected data were categorized into 4 main sections:

A. Socio-demographics including parity, gravidity, age.
B. Components used in the management of eclamptic women at MNH (Appendix 1).
C. Maternal outcome whether complications were encountered or not.
D. Neonatal outcomes including stillbirth fresh or macerated and low Apgar or normal Apgar.

2.11 Coding Of Variables.

Each component/variable in the checklist was coded as "YES" with a score of '1' if found documented in the treatment chart and coded as "NO" with a score of '0' if not documented and not applicable was coded as '0.001'.

The codes and scores were created by the principal investigator for the effective interpretation of data. "Not applicable" data was defined as criteria that were not relevant or applicable in the management of the participant therefore their values were deducted from the total score.

A properly documented partograph was defined as the one with the following 14 components registration number, patients name and date of birth, gender, next of kin and address, uterine contractions, maternal blood pressure, moulding, cervical dilatation, foetal heart rate, respiratory and pulse rate and foetal head descent. This was adopted from an audit of partograph documentation by Markos et al (29). Patients who went for caesarean section were excluded from partograph filling and thus on the total score as they were coded as not applicable.

2.12 Validity And Reliabilty Of The Study.

The criteria had been already established from a previous CBA conducted at MNH (28). The criteria for eclampsia management were from recommendations of evidence-based criteria on the management of eclampsia. These were the Ministry of Health (MOH) guidelines, local management guidelines, the WHO manual supplemented by the WHO Reproductive Health Library CD-ROM no.8, standard textbooks, the Cochrane database and reviews in peer-reviewed journals.

In March 2006 opportunity for the authentication of adapted criteria was performed by presenting the criteria to the health care providers in a departmental meeting at MNH. The criteria were discussed and assessed on their feasibility in clinical practice based on the resources and available expertise. Fourteen standards were then developed that addressed quality issues. The department then conducted workshops to inform members on the standards.

The Principle Investigator was responsible for collecting data to maintain consistency and minimize errors. The extraction of data from the patient files or case notes was done immediately when the files were collected to avoid missing data retrieval. The record assistants were responsible for file retrieval.

2.14 Data Management And Analysis.

Using SPSS version 23, coded data were entered daily. Data cleaning was done sequentially until the completion of data entry**.** Variables were coded before analysis similar to the re-audit to enable efficient comparison between the two distribution characteristics**.** The coding was done as follows maternal age had three categories namely - 15 to 24, 25 to 34 and 35 and above. Parity status was coded into three categories, primi-parous para 1 and two and lastly para 3 and above. The mode of previous delivery was coded into vaginal delivery, caesarean delivery, assisted breech delivery and others. Gestational age was coded into 3 categories 24 to 32 weeks, 33 to 36 and 37 weeks and above.

SPSS data set for the 2009 re-audit was unavailable hence published data was used. The published data was then used to compare the distribution characteristics of the 2009 audit and the current audit by using chi-square (Appendix 3).

A total score to obtain the total adherence was then conducted for each pre-determined standard and divided by a denominator which was the sample size involved and percentages for adherence to set standards were reached. The denominator to calculate the total score thus varied based on the number of not applicable present per pre-determined standard. This gave us the proportion of adherence for each standard which were then used to compare with the individual frequencies of pre-determined standards between the 2009 audit and current audit were then conducted after obtaining their means by using t-test (Appendix 4). These data were read from the published journal by Kidanto et al 2009. The level of significance was set at <0.05. The mean adherence to the management standards of the women with eclampsia was then obtained. The total of all the percentages of criteria was obtained and divided by fourteen which was the sum of all the criteria.

Maternal outcomes were categorized into no complications, pulmonary oedema, cerebral haemorrhage, antepartum and postpartum haemorrhage, acute renal injury, aspiration pneumonia, HELLP syndrome and maternal deaths. Neonatal outcomes were grouped into an Apgar of 7 and above and below 7, stillbirth fresh and still birth macerated. After data cleaning, it was then analyzed. Descriptive statistics were used to calculate frequency and percentages of the outcomes.

There was no comparison done to the 2009 audit in terms of outcomes since the main focus of that audit was assessing adherence to implementation of recommendations offered. The current study will include pregnancy and maternal outcome to form a baseline for future audits if need be to compare.

2.15 Ethical Clearance and Considerations.

The ethical clearance was provided by Muhimbili University of Health and Allied Sciences (MUHAS) Senate Research and Publications Committee and permission to conduct the study from Muhimbili National Hospital (MNH) through Executive Director. Waiver for consent was granted from MNH since it was not required in this study. Confidentiality was assured and maintained whereby no name of the patient appeared on the checklist or analysis. Thereafter analysis of data, results and interpretation was done; it was the duty of the researcher to give feedback to the hospital about the findings and ways to improve if there is an area of improvement. The information obtained will be relayed to the obstetrics and gynaecology department as feedback. Data will then be stored for five years after which it will be destroyed.

3.0 RESULTS.

There were 450 eclamptic patients in 2017-2018 among 18,478 deliveries conducted at MNH. 400 files were obtained and all of them were evaluated.

Table 1: Demographic and obstetric characteristics of women managed with eclampsia at MNH in the 2009 and the 2017/2018 audits.

Categories	2009 audit, N=88 n (%)	2017/2018 audit, N=400 n (%)	P-value
Age groups			
15 to 24	20 (23)	218 (54.5)	<0.001
25 to 34	54 (61)	150 (37.5)	
35 and above	14 (16)	32 (8)	
Gestational age			
24 to 32	20 (24)	135 (33.8)	<0.001
33 to 36	17 (19)	144 (36)	
37 and above	50 (57)	121 (30.2)	
Type of delivery			
SVD	47 (53)	180 (45)	0.15
C/S	38 (43)	200 (50)	
ABD	2 (2.3)	3 (0.75)	
Abortions	1 (1.1)	17 (4.25)	
Parity			
0	59 (67)	255 (63.7)	0.067
1 to 2	22 (25)	76 (19)	
3 and above	7 (8)	69 (17.3)	
Maternal outcome			
Dead	0 (0)	7 (1.8)	0.24
Alive	88 (100)	393 (98.2)	

SVD –Spontaneous vertex delivery, C/S – Caesarean section, ABD – Assisted breech delivery

The comparison in frequency of age groups was statistically significant with the majority in this study being in the ages of 15 to 24. Gestational age in this study was evenly spread out at 33.8%, 36% and 30.3% while in the 2009 audit 24%, 19% and 57% respectively this was statistically significant.

Table 2: Comparison of the proportions of adherence between the 2017/2018 audit and the 2009 audit at MNH.

Standard	2009 audit n=88 (%).	2017/2018 n=400 (%).	T-test
History and documentation	87(99)	341(85.3)	< 0.001
Specialist/resident review in 1hr	87(99)	392(98)	0.53
Administration of MgSO4	88(100)	398(99.5)	0.51
Hydralazine till DBP less than 110mmhg	88(100)	185/205(90.2)	0.02
BP measurement half hourly	34(39)	399(99.8)	<0.001
Urine analysis within 2 hours of admission	87(99)	386(96.5)	0.22
Fluid balance chart 48hrs post delivery	88(100)	262(65.5)	<0.001
Respiratory rate monitoring hourly in 24hrs	88(100)	375(93.8)	0.02
Vaginal delivery within 24 hours	47/75(63)	178/180(98.9)	<0.001
Proper partograph use and documentation	68/75(91)	151/200(75.5)	<0.001
Caesarian section within 2hrs of stabilisation	23/38(61)	200/200(100)	<0.001
Baseline laboratory investigations.	76(86)	203(50.8)	<0.001
Corticosteroid use less than 34 weeks	5/ 21(24)	79/198(39.9)	0.05
Deep tendon reflex monitoring hourly/24hrs	6(6.8)	38(9.5)	0.42

*There are various denominators in some criteria due to some responses on the checklist being not applicable.

The range of adherence in terms of the management offered to eclamptic women against the standard protocol was 9.5% to 100% with eight out of fourteen standards scoring 90% and above. Though there is a reduction in the adherence to six standards; history and documentation hydralazine use till DBP less than 110mmhg, fluid balance chart 48 hours post-delivery, respiratory rate monitoring hourly in 24hrs and baseline laboratory investigations. There was an increase in adherence for blood pressure monitoring, caesarean section delivery and corticosteroid use at 99.8%, 100% and 39.9% from 39%, 61% and 24% respectively (P-value <0.000) except corticosteroid use.

Table 3: Pregnancy outcomes among women with eclampsia at MNH in 2017/2018 audit (N=400).

Pregnancy outcome	n (%)
Apgar score < 7	59 (14.8)
Apgar score 7 and above	267 (66.8)
Still birth fresh	12 (3)
Still birth macerated	31 (7.8)
Abortions	31 (7.8)

267(66.8%) neonates had an Apgar of 7 and above. There were 12 (3%) neonates who were fresh stillbirths.

Table 4*:* Maternal outcomes among women with eclampsia managed at MNH in the audit 2017/2018(N=400).

Maternal outcome	**n (%)**
Pulmonary Oedema	5 (1.3)
Cerebral haemorrhage	27 (6.7)
Sepsis	14 (3.5)
APH	5 (1.3)
PPH	31 (7.8)
Acute renal injury	14 (3.5)
Aspiration pneumonia	1 (0.3)
HELLP syndrome	21 (5.3)
Puerperal psychosis	12 (3.0)
Maternal death	7 (1.8)
No complications	295(73.8)

APH – Antepartum haemorrhage, PPH – post-partum haemorrhage, HELLP – haemolysis, elevated liver enzymes and low platelets

The case fatality rate was at 1.8%. Majority of the patients did not have complications 295(73.8%).

4.0 DISCUSSION.

The range of adherence in terms of the management offered to eclamptic women against the standard protocol was between 9.5%-100% with eight out of fourteen standards scoring 90% and above. There was an overall statistically significant reduction in adherence to six standards in comparison to the last MNH audit of eclampsia. The case fatality rate was at 1.75% from 0% in the initial re-audit which could be due to the reduction in adherence of standards. There was an improvement in adherence of the 2017/2018 audit in comparison to the 2009 audit in terms of blood pressure monitoring, caesarean section delivery within 2hrs of decision and corticosteroid use less than 34weeks at (39-99.8%), (61-98.3%) and (24-97.8%) respectively P-value 0.000. The least adherence was observed in monitoring of deep tendon reflex at 9.5% and 6% in the re-audit. Though this is low it was a statistically improved significance P-value <0.000.

This audit shows the range of 9.5-100% adherence to eclampsia management at MNH against the standards (average 75.8%) this is higher than CBA's of eclampsia in Ghana, Malawi and Nigeria where the average adherence was at 64%, 69.1% and 50% respectively (19),(30),(12). This can be explained by an audit and re-audit conducted at MNH of the management of eclampsia. There was remarkably good adherence to some protocols yet several gaps in adherence to others. The main areas of care that were sub-standard were mainly deep tendon reflex monitoring and baseline laboratory investigations. There has been an increase in adherence of blood pressure monitoring from the 2009 audit. However, there was a decrease in administration of hydralazine from the 2009 audit. Despite the existence of guidelines and protocols a gap between recommended care and clinical practice often exists, this could be due to several factors such as implementation strategies, professionals involved, nature of the guidelines, the characteristics of the patients and the environment (31). Lack of resources such as laboratory reagents and insufficient drugs is a major challenge in most low middle-income countries.

Adherence has been deemed to be low in the current audit in standards that involve patient monitoring. Respiratory rate, deep tendon reflex, fluid balance chart monitoring were adhered to by values that were lower than the 2009 audit except the deep tendon reflex

monitoring which showed slight improvement . Standards that require monitoring in other low-income countries are the least adhered to. This is visible in previous audits conducted Ghana, India and Uganda (32,19, 33). The low adherence in terms of monitoring at MNH could be due to a high influx of patients since it's a referral hospital. There has also been an increase in the population Dar-es-salaam thus despite people knowing the guidelines adherence is a challenge.

This audit depicts a case-fatality rate of eclampsia at 1.75% however, the re-audit conducted in 2009 at MNH by Kidanto et al there were no maternal deaths. The sample size in the 2009 was almost four folds lesser (21) than the current audit. This could explain the increase in the case fatality rate. In the 2009 audit, there was a significant improvement of adherence magnitude of all the set standards to the initial CBA (20)**.** In comparison to the 2009 audit done by Kidanto et al, it was noted that there was a low adherence in this study towards several guidelines. Increased numbers of patients as compared to the health care workers which could have also been worsened by urbanization. Interventions such continuous medical education, drills, training of health care workers and displaying of guidelines should be done continuously. In addition the time frame between the re-audit and this study is more than 10yrs, this therefore indicates the need for frequent re- audits so that possible gaps in management can be identified early, and the necessary changes implemented accordingly.

In this audit there were four fold less perinatal deaths unlike the 2006 CBA conducted by kidanto et al where adherence to standards was low in all the set criteria (28). In the 2009 audit there was a three times higher perinatal death than the current audit (20). There is a huge reduction in fetal deaths in this study in comparison to the 2009 audit. However, there was a small difference in fetal death in the 2009 audit. This could be explained by the fact that in eclampsia the sole purpose is to first focus on the maternal well-being rather than the neonatal outcome. The limitations in the 2009 audit could be due to lack of continuous fetal monitoring. There has since 2007 been current availability of fetal Doppler ultrasounds in ward 35. This can explain as to why there has been a significant improvement in neonatal outcomes.

5.0 STUDY LIMITATIONS AND MITIGATIONS.

Challenges faced include the fact that being a retrospective study information either in the files may lack due to missing papers from the files and some of the files were missing. Proper file arrangement and organisation and safekeeping can enable protection of file contents. This study was a cross-sectional study conducted on eclampsia management case files from one tertiary hospital, MNH. The management protocols from other referral hospitals are unknown hence affecting the outcome. The referred patients constituted for 92% of the overall case files. Feedback to the referral hospital should be relayed and harmonization of guidelines should be encouraged.

6.0 STRENGTH OF THE STUDY.

It is one of the studies that focused on assessing the management standards among women who were managed for eclampsia at MNH. The study addresses one of the main causes of morbidity and mortality in reproductive women in Tanzania. The standards were adopted from the MNH management guideline. Thus, the current practice was assessed against set standards. The outcomes were determined and are reflected by the substandard care. The major strength of this audit is that it will bring the practitioners together to discuss on the improvement of adherence to the standards and modifications where necessary. Furthermore, current identified practice will be discussed and incorporated into the guidelines to reflect on the working obstetric environment.

7.0 CONCLUSION.

There was a reduction in upholding of almost half of the total standard criteria over the duration of eight years from previous audit. There was a significant case fatality rate compared to no maternal deaths in the 2009 audit.

8.0 RECOMMENDATIONS.

In the prevention of maternal and neonatal mortality, management of eclampsia through adherence to standard protocols is a cornerstone. Increased case fatality rate and low adherence in the current audit compare to the previous re-audit underline the needs of:

- Regular provision of in-service refresher training to emphasize the practice and compliance to criteria on management.
- A routine audit should be done after every six months as recommended by kidanto et al to increase adherence to standards thus reduce maternal mortality.
- Consistent use and documentation on case notes and partograph for early and prompt actions.

- To reduce maternal and newborn mortality adherence to protocol must be emphasized among service providers.

Future research should be done to understand constraints as well as facilitators to providing standard protocols on the management of eclampsia, including health worker attitudes and behavior.

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APPENDICES.

Appendix 1: Description of the eclampsia management guidelines currently used at MNH.

All admissions are recorded in the ward 35 registry book, then the information is transferred into the electronic database of the hospital. The MNH guidelines involve that on the patient's admission at ward;

- Convulsions are managed or controlled by administering magnesium sulphate.
- Magnesium sulphate is administered at 4g stat loading dose followed by a maintenance dose of 1g/hour for 24 hours, with a recurring convulsion controlled by intravenous 2g bolus loading dose preceding a maintenance dose.
- Airways, intravenous lines and Foley's catheter should be secured.
- Hypertension with a diastolic blood pressure of more than 110mmhg should be controlled by intermittent intravenous hydralazine till diastolic is less than 110mmhg is achieved.
- Baseline laboratory investigations like liver function tests, complete blood count, urea electrolytes and creatinine, uric acid should be done within twenty four hours.
- Blood pressure and fetal heart rate should be monitored half hourly.
- After stabilization delivery plan follows subsequently with vaginal delivery within 24hours and caesarean section within two hours of the management plan.

Patients are kept under close monitoring for magnesium sulphate toxicity. The regimen is then administered until 24 hours post-delivery or after the last seizure. The stable patient is then transferred to the obstetric wards.

Appendix 2: Checklist for data collection from patient clinical notes.

AUDIT ON THE MANAGEMENT OF ECLAMPSIA AMONG WOMEN ADMITTED AT MUHIMBILI NATIONAL HOSPITAL.

CHECKLIST NO……

PATIENT REGISTRATION NO…….

A. Social demographic characteristics

1. Patient's age……
2. Date of admission…….
3. Gestational age at delivery…….
4. Parity…….
5. Marital status: -
    a) Single
    b) Married
    c) Divorced
    d) Widowed
    e) Co-habiting
    f) Other specify ……
6. Patient's mode of admission
    a. Referral from another hospital
    b. Referral from MNH clinics
7. Mental status of the patient on admission
    a. Alert/stable
    b. Confused
    c. Semi-conscious
    d. Unconscious
    e. Gasping
    f. Other specify ……

8. Duration of Eclampsia diagnosis
    a. Before delivery
    b. During delivery
    c. After delivery

Incase delivery has occurred choose the below options.

Mode of delivery: -

a) C/S
b) SVD
c) LCVE
d) ABD.

9. Number of gestations
    a) Singleton
    b) Twins
    c) triplets
    d) Other specify.
10. Management received by eclamptic women managed at MNH as documented in the clinical notes. Tick Yes/No column.

Management as per MNH protocol	**Yes**	**No**	**Not applicable**	**Not documented**
1) Complete history and documentation.				
2) Specialist review within an hour from admission.				
3) Magnesium sulphate as per regimen.				
4) Hydralazine till DBP is less than 110mmhg.				
5) BP measurement hourly.				
6) Urine analysis within 2hours of admission.				
7) Fluid balance chart 48hours post-delivery.				
8) Respiratory rate monitoring hourly in 24hours				
9) Vaginal delivery within 24 hours.				
10) Proper partogram use and documentation.				
11) Arrival of referred cases within 24hour				
12) Caesarian section within 2 hours of making decision on delivery after patient stabilisation.				
13) Baseline laboratory investigations like LFT/FBC AND U/E/C in 24hrs				
14) Corticosteroid use in gestational age of less than 34 weeks.				
15) Fetal heart rate monitoring half hourly.				
16) Delivered after completion of dexamethasone dosage				
17) Deep tendon reflex monitoring hourly for 24hours.				
18) Uric acid levels within 24 hours.				

NB:-

LFT -Liver function tests.

FBC -Full blood count.

U/E/C -Urea, electrolyte and creatinine.

11. **Outcomes for the eclamptic woman managed at MNH**

A. Maternal outcomes.

1) Pulmonary edema/respiratory failure
2) Sepsis
3) Cerebrovascular hemorrhage
4) Antepartum hemorrhage
5) Post-partum hemorrhage
6) Acute renal failure
7) Aspiration pneumonia
8) ICU admission
9) Maternal death
10) No complication.
11) Other specify ……

B. Neonatal outcomes.

1) Apgar score below 7 at 5^{th} minute
2) Apgar score of 7 and above at 5^{th} minute
3) Gestation age on delivery
4) Still birth fresh
5) Still birth macerated
6) Other specify ……

Appendix 3: Socio-demographics of published data in 2009 re-audit by kidanto et al.

Table 3 Maternal characteristics of women admitted to the eclampsia ward in the initial audit and re-audit

	Initial audit		Re-audit		p- value
	No	%	No	%	
Age (years):					
15-24	262	67	20	23	<0.001
25-34	94	24	54	61	
≥35	33	8.5	14	16	
Parity:					
0	260	67	59	67.0	<0.001
1-2	106	27	22	25	
≥3	23	5.9	7	8.0	
Gestational age (weeks):					
24-32	55	14	21	24	0.024
33-36	154	40	17	19	
≥37	178	46	50	57	
Unknown	2	0.5			
No of ANC visits:					
0	31	7.9	7	7.9	0.013
1-2	152	39	22	25	
≥3	206	53	59	67	
Mode of delivery:					
SVD	278	72	47	53	0.001
CS	76	20	38	43	
ABD	8	2	2	2.3	
others	27	6.0	1	1.1	
Maternal outcome					
Dead	30	7.7	0	0	0.001
Alive	359	92.3	88	100	

*SVD=Spontaneous vertex deliver, CS=Caesarean section, ABD=assisted breech delivery and ANC= Antenatal clinic, P-value for chi-square test of association.

Appendix 4: Published data on adherence to standard criteria by kidanto et al 2009.

Table 4 Number and percent women at the initial audit (n=389) and re-audit (n=88) that attained the standard

Standard	Initial audit		Re-audit		p-value
	No	%	No	%	
Detailed history and documentation	381	98	87	99	0.57
Management plan by senior staff	297	76	87	99	<0.001
Use of $MgSO_4$	389	100	88	100	1
Initiating drug treatment in severe hypertension	243/245	99	88/88	100	0.40
Specialist review within 2 hours of admission	99	25	34	39	0.018
BP monitored	389	100	88	100	1
Urine for albumin test	236	61	87	99	<0.001
Fluid balance chart should be maintained for 48 hours	385	99	88	100	1
Respiration rate monitored	389	100	88	100	1
Treatment with steroids for lung maturity	3/132	2.0	5/21	24	<0.001
CS within 2 hours of decision	26/78	33	23/38	61	0.005
Full blood count to all admitted patients	108	28	82	93	<0.001
Serum urea and creatinine to all patients	170	44	76	86	<0.001
Liver function test to all patients	16	4	76	86	<0.001
Delivery within 24 hours of admission	*235/343	69	*47/75	63	0.40
Deep tendon reflex assessment	2	0.5	6	6.8	<0.001
Proper use of partogram	*257/343	75	*68/75	91	0.003

*number observed per delivery.

P-value for Student's t-test of difference in prevalence between the audits.

Appendix 5: Ethical Clearance

Appendix 6: Permission to collect data at MNH