CLINICAL AUDIT FOR THE MANAGEMENT AND OUTCOME OF PRETERM PRE-LABOUR RUPTURE OF MEMBRANES AT MUHIMBILI NATIONAL HOSPITAL

Evance Polin Molinga, MD

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Department of Obstetrics and Gynaecology

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By

Evance Polin Molinga

A Dissertation Submitted in Partial Fulfillment of the Requirement for the Degree of Master of Medicine in Obstetrics and Gynaecology of the

Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation titled “Clinical audit of the management and outcome of preterm prelabour rupture of membranes at Muhimbili National Hospital”, in 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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Dr. Fadhlun M Alwy Al-beity

(Supervisor)

Date: _____

_____

Dr. Belinda Balandya

(Co-Supervisor)

Date: _____

DECLARATION AND COPYRIGHT

I, Evance Polin Molinga, declare that this dissertation is my own 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.

Signature_____ Date_____

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DEDICATION

This work is dedicated to my mother Theresia J. Lasway and my beloved children Bryson, Brianna, Brandon, and Becket for their tolerance and patience during my absence at home related to this dissertation and generally to the whole program of three years.

ABSTRACT

Background: Preterm pre-labour rupture of membranes (PPROM) is among the leading causes of preterm birth which can lead to high perinatal morbidity and mortality along with maternal morbidity. Several guidelines on timely and appropriate management of PPROM are in place but are not always followed.

Aim: The study aimed to conduct a clinical audit for the management and outcome of women with PPROM at Muhimbili National Hospital (MNH).

Methodology: A clinical audit of women admitted with PPROM between January and December 2022 was conducted. Their records were reviewed to extract data on clinical management and these were abstracted into a structured checklist. The abstracted data was compared with the standard MNH PPROM management guidelines. Data was checked, entered, cleaned, and analyzed using SPPS version 23. Findings were presented using percentages to measure adherence and descriptive tables to show maternal and immediate fetal outcomes.

Result: The mean gestational age at PPROM onset was 31.78±2.30 weeks. Most women with PPROM were correctly diagnosed through history (100%) and sterile speculum examination (95.8%) with 97.1% receiving corticosteroids and only 31.6% receiving the recommended prophylactic antibiotics. Caesarean delivery was achieved in 83.1% where 76% of the neonates were admitted to the neonatal intensive care unit, 89.6% had Apgar score of ≥ 7 at 5 minutes, and 91% had low birth weight. Chorioamnionitis and abruption placenta occurred in 8.4% and 4.2% of the women.

Conclusion: Seven in ten women with PPROM received standard treatment. Antibiotic use was common but not guided by standard guidelines or lab investigations. Evidence-based interventions were not routinely performed, potentially impacting outcomes. The existing guideline needs to be reviewed to improve the management and outcome of women with PPROM.

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LIST OF ABBREVIATIONS.

ACOG	American College of Obstetricians and Gynecologists.
ACS	Antenatal Corticosteroids.
APH	Antepartum hemorrhage.
CRP	C - reactive protein.
FBP	Full blood picture.
GA	Gestation Age.
HVS	High Vaginal Swab.
IVH	Intraventricular Hemorrhage.
MNH	Muhimbili National Hospital.
MUHAS	Muhimbili University of Health and Allied Science.
NEC	Necrotizing enterocolitis.
NICU	Neonatal Intensive Care Unity.
PROM	Premature Rupture of Membrane.
PPROM	Preterm Pre-labour Rupture of Membrane.
RDS	Respiratory Distress Syndrome.
WHO	World Health Organization.

DEFINITIONS OF TERMS

Term	Definition
Clinical audit	A quality improvement process aimed at improving patient care and outcomes through systematic review and implementation of changes in care against defined criteria
Criteria	Factor or variable that allows achievement of standards and assessment of whether those standards have been reached. (Royal College of Nursing, 1990)
Preterm Pre-labour Rupture of Membranes	Is the spontaneous membrane rupture after fetal viability (28 weeks of gestation) but before 37 completed weeks and before labour onset.
Early preterm PROM	Is when the membrane rupture occurs at 28+0 weeks to 33+6 weeks of gestation
Late preterm PROM	Is when membranes rupture from 34+0 weeks to 36+6 weeks of gestation.
Conservative management	Management of patients to prolong gestation.
Latency	The duration from membrane rupture to spontaneous delivery, labour induction at 34+0 weeks or indicated delivery because of fetal or maternal indications.

1.0 INTRODUCTION

1.1 Background

Preterm Pre-labour Rupture of Membranes (PPROM) is the spontaneous membrane rupture after fetal viability (28 weeks of gestation) but before 37 completed weeks and before labour onset (1,2). Around 3% of pregnancies globally are complicated by PPROM, which accounts for 33% of all preterm deliveries (3). Fifteen million babies are born before term every year and Sub-Sahara Africa and South Asia account for over 60% of all preterm births (4–6). In Tanzania, a report by United State Agency for International Development shows 236,000 babies are born preterm each year (7). Early preterm and late preterm births are distinguished by gestation of 28+0 to 33+6 weeks and 34+0 to 36+6 weeks, respectively (5,8).

Preterm babies are at higher risk of permanent and lifelong disability and diminished quality of life (9) The most common cause of neonatal death and the second most common cause of death in children under the age of five are prematurity-related complications, such as respiratory distress syndrome (RDS) and intraventricular hemorrhage (IVH) (10,11). Preterm birth is therefore considered of central significance for attaining the United Nation' Sustainable development goal 3.2, with the goal of ending all preventable childhood deaths before the age of five years worldwide (12). The World Health Organization (WHO) priority setting exercise identified preterm birth among the top ten research priorities in 2025 (10).

The diagnosis of PPROM is mainly clinical and requires a thorough history, physical examination, and selected laboratory and imaging studies (13). Pregnant women normally report unexpected gush of fluid per vaginal with continuity leakage (13,14). It is of importance to ascertain the gestation age as it will direct the subsequent management. A sterile speculum examination is performed to evaluate the cervical dilation and effacement as well as to authenticate the diagnosis by direct visualization of leakage from the external cervical os and to exclude cord prolapse (13). During speculum examination, swabs from the cervix and vagina are taken for culture to exclude the possibility of infection as women harboring infection in these areas are seven times more likely to have PPROM (14). Digital pelvic examination is avoided as it has been indicated to reduce the latency and increase the risk of infection (13,14).

PPROM has various causes but intrauterine infection, oxidative stress-induced damage, and premature cellular senescence are presumed to be the major causes (2). The increase in intrauterine oxidative stress in response to various risk factors leads to telomere degradation and peroxidation of component of the cells and organelles resulting in aging and inflammation related to aging processes. This sterile inflammation results in membrane malfunction, loss, or reduction in microbial defense capacity, which causes infection inflammation, and membrane rupture (15). Several risk factors have been identified to be responsible for PPROM (14). These factors can be grouped as maternal, uteroplacental, or fetal in origin. Maternal factors include PPROM from a previous pregnancy, Antepartum hemorrhage (APH), smoking, low body mass index, anemia, illicit drug use (cocaine), copper and vitamin C deficiencies, diminished socioeconomic status, collagen vascular disorder, and direct abdominal trauma (2,16). Uteroplacental factors include uterine anomalies, placenta abruption, intraamniotic infection, short cervix, and uterine over distention (polyhydramnios, multiple pregnancies). Fetal factors include multiple pregnancies which are complicated with PPROM in up to 10% (1).

The management of PPROM is the most challenging issue in maternal fetal medicine. The contention issues are, accurate diagnosis in problematic cases, conservative against intervention management, use of tocolytics, duration and timing of administration of antibiotic prophylaxis and antenatal corticosteroids (ACS), methods of detecting maternal/fetal infection, and timing of delivery (1,14). Pregnancy complicated by PPROM is managed based on several factors including GA, infection (maternal or fetal), labour pain, fetal wellbeing, the anticipation of the maturity of the fetal lung, cervical status, and the availability of suitable neonatal care (2,14).
There are three categories for managing PPROM: 34–36 weeks, 32–34 weeks, and 28–32 weeks of GA, see Table 1. For late preterm PPROM, delivery is considered since lung maturity has been attained and there is no benefit in conservative management as it may increase the risk of infection for both mother and the fetus (14). In the absence of complications, women with PPROM at 28-34 weeks are managed conservatively with administration of ACS when lung maturity is not ascertained and antibiotics prophyxis is mandatory to prevent development of ascending infection (14). When used in PPROM, antibiotics have been associated with diminished chorioamnionitis, infants born within 2 and 7 days of diagnosis, neonatal infections,

treatment with surfactant, oxygen supplementation, and abnormal brain scans at discharge (17). Magnesium sulfate is given to pregnant women with PPROM complications at or before 32 weeks of pregnancy for neuroprotection in addition to the aforementioned therapies (18–20). Vigilant infection monitoring is also essential, as is fetal monitoring via ultrasound and cardiotocography (CTG). Additionally, conservative management may be linked to a higher risk of ascending infection and umbilical cord compression (21) hence it should be weighed against the risk of a quick delivery. Steroids for lung maturation, magnesium sulfate for neuroprotection, and antibiotics for women receiving conservative therapy all significantly lower perinatal morbidity and mortality associated with preterm birth. (1,3,13,17,22). Prematurity is the most feared concern during PPROM management due to preterm birth (1,16).

Table 1: Summary of the management of PPROM according to the GA.

GA (weeks)	**Plan of Management**
28^{+0}-31^{+6}	Conservative management in the absence of complications, ACS, magnesium sulfate for neuroprotection and tocolytics where appropriate, prophylactic antibiotics.
32^{+0}-33^{+6}	Conservative management in the absence of complications, ACS, tocolytics where appropriate, and prophylactic antibiotics.
34^{+0}-36^{+6}	Active delivery and prophylactic antibiotics.

Clinical audits are being utilized more frequently to evaluate and enhance the standard of obstetric treatment in low and middle-income countries, including preterm birth due to PPROM (23,24). In the clinical audit, clinical practice is compared to specified criteria-based agreed standards of care. The criteria in the clinical audit are less intimidating to workers because they have been approved by those who are responsible for the care of the patients. Clinical audit appears to be feasible in evaluating and measuring clinical practice and is continually used in hospitals to improve the work done/service provided.

1.2. Problem Statement.

Women with PPROM are at a higher risk for premature delivery and preterm birth related complications (13). PPROM is the most common single cause of preterm birth, causing perinatal mortality, acute respiratory distress syndrome (ARDS), necrotizing enterocolitis (NEC), increased neonatal intensive care unit (NICU) admission (16), and long-term disability in babies' particularly cerebral palsy (25). For women, it causes preterm labour, abruption placenta, coagulopathy, prolonged hospital stays with financial and social consequences, sepsis, and caesarian birth (26).

The proportion of PPROM at MNH has not yet been documented. However, based on routinely collected medical data out of 4755 deliveries that occurred in 2022, 127 pregnancies were complicated with PPORM (MNH registry). Despite guidelines for the management of PPROM and preterm birth, morbidity and mortality remain high, with 8% of preterm births at MNH due to PPROM. This study aims to evaluate the conformity of current practice at MNH to recommended PPROM management guidelines. By identifying areas of deviation from the best practice, this research will provide valuable insights to inform targeted interventions and, in theory, reduce PPROM associated morbidity and mortality.

1.3. The audit cycle.

This study was conducted using the audit cycle i.e., a quality improvement process to improve patient care and outcomes through systematic review and implementation of changes in care against defined criteria

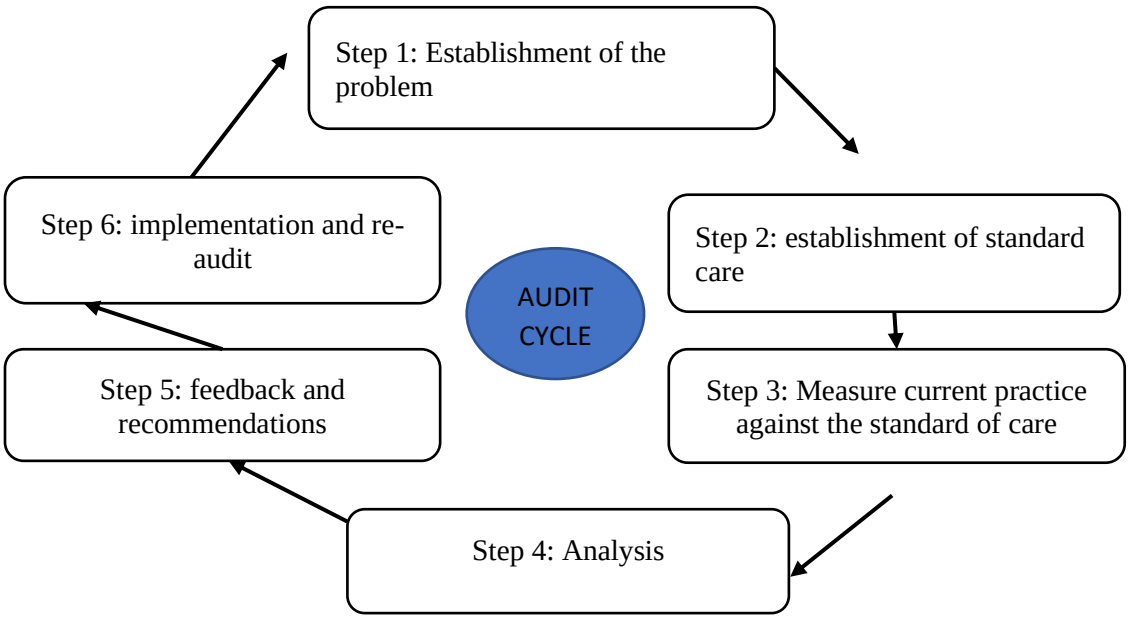


Figure 1: Audit cycle for the management and outcome of preterm premature rupture of the membranes.

Step 1

Problem establishment.

PPROM contributes about 10% of all preterm birthes at MNH. Large number of perinatal deaths are due to prematurity complications. Substandard management cause adverse outcomes for both mothers and their neonates raising the need to study the conformity to standards in the management of pregnancies complicated with PPROM.

Step 2

Establishment of standard care criteria for the management of PPROM. The criteria for management of PPROM was adapted from the MNH treatment guidelines and presented and discussed with obstetricians and gynecologist from the MNH and MUHAS Obstetrics and Gynecology department. The agreed criteria were used to measure the practice in the management and outcome of PPROM.

Step 3

The practice in the management of women with PPROM was measured. A stractured checklist comprising of maternal demographics, immediate fetal and maternal outcome, and criteria for the management of PPROM was used.

Step 4

Data collection and analysis was performed by the researcher using the SPSS version 23 from International Business Machines (IBM).

Step 5

Feedback and recommendations was provided to staffs working in the department of obstetrics and gynecology.

Step 6

This step was not conducted due to limited time and nature of the study design.

1.4. Rationale

PPROM is a leading cause of preterm birth and prolonged maternal hospitalization both antenatal and postnatal as they care for their preterm babies. Different studies have been performed on PROM with no specification on PPROM which rank high among the leading cause of preterm birth and hence prematurity. The study findings will serve as baseline data for future use in terms of follow-up and progress in the management of PPROM at MNH. It will also stir up the need for guideline update and reveal areas of practice that needs training and continuous medical education (CMEs) among practitioners. In addition, findings will provide evidence for

the need of uniterupted supplies necessary for quality and care in the management of women with PPROM.

1.5. Research Question.

1. What is the conformity of recommended clinical practices in the management of PPROM at MNH?
2. What are the immediate neonatal outcomes among women with PPROM delivering at MNH?
3. What are the maternal outcomes among women with PPROM admitted at MNH?

1.6. Objectives.

1.6.1. broad objective.

To conduct a clinical audit of recommended clinical practice in the management of PPROM at MNH.

1.6.2. Specific objectives.

I. To audit the clinical practice using the standard management guideline of PPROM at MNH.

II. To determine the immediate neonatal outcome among women PPROM delivering at MNH.

III. To determine the maternal outcome among women with PPROM admitted at MNH.

2.0 LITERATURE REVIEW

PPROM poses a dilemma for healthcare providers who must determine optimal timing of interventions by balancing premature birth against the risk of infection and on the other hand the risk of intrauterine fetal death (27). Regardless of the management provided to women with PPROM, nearly half of them give birth within a week and are inherently at risk of premature birth (28). Preterm birth is a substantial global health agenda with significant effects to the newborn, and the community in general. It affects nearly 15 million babies annually and it is the main cause of death in under-fives and remains a prominent problem in obstetric clinical practice (2,4). More than 80% of all preterm babies are born in South Asia and sub-Saharan countries (29). Despite the global burden of morbidity and mortality associated with preterm birth, few studies have evaluated the quality of intervention and management in pregnancies complicated with PPROM.

The management of PPROM is affected by gestation age and the presence of complications such as abnormal fetal testing, abruption placenta, clinical infection, and preterm labour (1,3,30). To properly evaluate, counsel, and treat patients with PROM, it is crucial to accurately determine gestational age and have a thorough understanding of maternal, fetal, and neonatal risks. The diagnosis of PPROM is normally reached based on clinical suspicion from patient history and simple testing with up to 90% accuracy (3,14,31). A sterile speculum assessment should usually ensue to confirm that the membranes have ruptured by looking for amniotic fluid accumulating in the posterior fornix or clear fluid from the cervical canal. During speculum examination, an effort is made to exclude the presence of cord prolapse as it may be among the complications of PPROM.

Different investigations (laboratory and imaging studies) are employed to support the diagnosis and help in establishing the cause of PPROM. Laboratory investigations include high vagina swab (HVS) obtained during sterile speculum examination for culture and sensitivity, full blood count (FBC), C-reactive protein (CRP), and urinalysis (30,32). An obstetric Ultrasound is routinely performed to these women to evaluate fetal well-being, amount of liquor, and gestation age. Digital vaginal examination should not be done unless the expectant mother present with

symptoms and signs of active labour or when delivery appears to be imminent because it has been demonstrated to shorten the latency period and increase infections in both the mother and the fetus (33,34).

The care and intervention provided to women with PPROM varies and is dependent on GA at the time of onset. Given that PPROM occurring between 34+0 and 36+6 weeks after GA has reached lung maturity, early delivery is the best course of action (33). However, some guidelines advocate administration of ACS when it has not been given before while others presume lung maturation and recommend delivery without ACS (2,35). Conservative management is recommended for GA between 32+0 and 33+6 after exclusion of maternal infections, the woman and fetus are stable, and lung maturity has not yet been established. ACS, antibiotic prophylaxis, as well as magnesium sulfate for neuroprotection, are given for improvement of the preterm birth outcome (3,22,35,36). Following the use of antibiotics in PPROM patients, there is a drop in incidence of both maternal and fetal infection and an increase in latency until birth (37). In Tanzania, however, magnesium sulfate is given to women with GA of <32 weeks. For GA between 28+0 and 31+6, conservative management is strongly advised unless there are contraindications. Similarly, women are provided with ACS for fetal lung maturity, magnesium sulfate for neuroprotection and prophylactic antibiotics. The controversy with ACS use is the need of a repeated course when delivery does not occur within two weeks of presentation (3,19,32,35). Utilization of tocolytics does not directly affect perinatal mortality but is linked to a longer latency and fewer births between 48 hours and 7 days. However, the main purpose of tocolysis in PPROM is to holdback delivery allowing administration of ACS (3).

The single-most feared neonatal outcome of PPROM is prematurity and its associated complications, RDS being the commonest complication (16). Other complication of prematurity includes neonatal infection, low birth weight and long hospital stay. Residual oligohydramnios has been shown to have a direct impact on neonatal survival rate and increase risk of developing RDS (38). Oligohydramnios may also affect the latency duration and timing of delivery.

PPROM has long been associated with increased maternal morbidity (34). Maternal outcomes include infection i.e., chorioamnionitis, endometritis, and septicemia, with endometritis being more common in caesarian delivery than vaginal delivery (28). Maternal infection can be a cause or a consequence of PPROM. The frequency of infection is higher with lesser GA at PPROM and longer latency period (38). Ascending infection from the lower genital tract is considered the commonest route where microorganism colonize the cervix, decidual and the fetal membrane.

Different studies have been conducted to evaluate the effectiveness of clinical audits in improvement of obstetric care. Research to evaluate the efficacy of clinical audits in obstetric care found a moderate improvement in treatment from the perspectives of medical personnel and patients (39). The treatment of obstetric disorders including obstetric hemorrhage, eclampsia, obstructed labour, genital tract infection, and uterine rupture has significantly improved, according to clinical audit study done in a Federal Medical Center in South West Nigeria (23). The application of clinical audit was concluded to be practicable and acceptable for upgrading obstetric care and it is recommended in health institutions in developing countries. Among other parameters that were measured, the use of clinical audit in the management of obstructed labour resulted in measurable improvements in the use of intravenous fluid and IV antibiotics (24). In a clinical audit study of the management and outcome of PPROM at Aminu Kano Teaching Hospital in Nigeria's Department of Obstetrics reported a prolongation in the latency and a reduction in maternal and neonatal morbidity and mortality after they were given antibiotic therapy (40). This research study is intended to unveil evidence-based practice and adherence to guidelines in the management and outcomes of women with PPROM at MNH.

3.0 MATERIALS AND METHODS

3.1 Study design

A hospital based retrospective cross sectional audit study was employed to 95 women whose pregnancies were complicated with PPROM. Comparison on the clinical practice was done against a set of criteria in the management of women with a diagnosis of PPROM admitted at Muhimbili National Hospital from a period of January to December 2022.

3.2 Study population.

All women admitted with a diagnosis PPROM between January and December 2022 at MNH.

3.3 Study area

This study was carried out at MNH, which serves as a teaching hospital for Muhimbili University of Health and Allied Sciences (MUHAS). The hospital is situated in Ilala district and accepts referrals from all over the country, mainly from the Regional Referral Hospitals in Dar es Salaam. Among other reasons, women are referred for preterm birth and care for the preterm/premature infant.

On arrival at the maternity unit, pregnant women are triaged at the Emergency Maternity Unit and those with established labour are directed to the labour ward. At the Emergence Maternity Unit, the resident/registrar clerk the patient and performs a general and systemic examination. When necessary, the specialist on call will be informed for decision-making. For patients with history suggestive of PPROM, a sterile speculum examination is done for confirmation of the diagnosis. Blood work up and an obstetric ultrasound are then ordered and the patient is admitted to respective admitting ward.

For women with GA <34 weeks conservative management is preferred while those with >34 weeks delivery is conducted with consideration of other obstetric conditions. One consultant, one specialist, two residents are on call every day. In the ward patient are reviewed on daily ward round and managed accordingly to rule out development of infection i.e., chorioamnionitis and compromise to the fetus. If labour starts the doctor on call is called to review the patient and

decision for mode of delivery is reached with regard to obstetric indication. Women who are expected to deliver vaginally are transferred to the labour ward while those with indication for abdominal delivery are prepared promptly from the ward and the theatre is informed for such procedure.

Maternity unit has direct linkage with the neonatal unit. When delivery of preterm baby is expected, whether in labour ward or theatre, the neonatal intensive care unit doctor is informed to provide immediate care to the premature baby. Preterm babies are then admitted to NICU for further management and care as they arise because of their increased risk of complication as compared to term babies.

3.4. Study sample.

All files of women admitted with a diagnosis of PPROM at MNH from January to December 2022.

3.5. Sampling and recruitment.

A convenient sampling method was used to select filles of all women with a diagnosis of PPROM from maternity ward admission records obtained from nurse in charges of respective wards from January to December 2022. The list was submitted to MNH maternity record department where record personnel assisted in the retrieval of patient's files. Exclusion criteria were applied after reviewing each file and finally, eligible files of women with PPROM were recruited to retrieve information.

3.6. Inclusion and exclusion criteria.

3.6.1. Inclusion criteria.

All files of pregnant women with PPROM admitted at MNH from January to December 2022.

3.6.2. Exclusion criteria.

Pregnant women with additional complication at admission, including APH, Intrauterine fetal death, preeclampsia with severe features/eclampsia, GA<28 weeks.

3.7. Research assistants.

Two intern doctors were trained to ensure confidentiality, and alongside the principal investigator, they assisted in extraction of information from medical files into a checklist. A record personnel assisted in obtaining files from the maternity record department.

3.8. Criteria for the management of PPROM.

According to MNH treatment guideline, patient with PPROM should be managed under the following criterion (32).

1. Diagnosis of PPROM is reached based on history of spontaneous rupture of membranes.
2. A sterile speculum examination is carried out to directly observe any amniotic fluid leaks from the cervical canal or amniotic fluid accumulating in the posterior fornix, and to rule out cord prolapse.
3. Digital vaginal examination avoided (unless imminent delivery is anticipated).
4. Remove cervical cerclage, if any.
5. Full blood count.
6. C - reactive protein (CRP).
7. High Vaginal Swab for microbiological examination.
8. Urine for routine analysis.
9. Ultrasound for fetal wellbeing.
10. Late preterm PROM (34-36 weeks of gestational age)- actively delivered.
11. Early Preterm PROM (<34 weeks of gestational age), conservative management should be used when there is no fetal or maternal need for immediate delivery.
12. ACS: A course of dexamethasone intramuscular injection, 6 mg every 12 hours for 48 hours.
13. Administration of tocolytics I/V Magnesium Sulphate/oral Nifedipine.
14. Antibiotic administered preferably Ampicillin IV 1g every 6 hourly for 48 hours; then continue with Erythromycin 500mg 8hourly or azithromycin 50mg od for 5-7 days.
15. Magnesium Sulphate for neuroprotection in women with GA <32 weeks.

16. Women observed for signs and symptoms of chorioamnionitis (foul smelling discharge, body temperature, pulse rate and abdominal tenderness) and FHR.
17. Conservative management is abandoned if the patient has:
    a) Chorioamnionitis
    b) Non reassuring fetal status
    c) Abruption placenta.
    d) Established labour
    e) Severe oligohydramnios

3.9. Data collection procedure.

A structured checklist was used to gather data, including all study variables. Files of women with diagnosis of PPROM were read repeatedly and thoroughly to make sure all-important information are captured correctly. The structured checklist consisted of three parts. Maternal demographic and obstetrics characteristics which included age, admission status, level of education, occupation, method used to calculate gestation age and GA on admission, gravidity and parity, antenatal care (ANC) status, labour pain, mode of delivery, time in hours between PPROM to admission, nature of onset of labour pain and duration from admission to delivery. Second part included maternal and neonatal outcome in relation to PPROM management as cord prolapse, placenta abruption, severe oligohydramnios, documented chorioamnionitis, sepsis, number of babies, APGAR score, birth weight and admission to NICU. Third part constituted of the criteria for the management of PPROM as adopted from the MNH obstetrics and gynecology treatment guidelines. The records of these files were analyzed to evaluate adherence to standards in the management of PPROM during hospital stay as well as immediate neonatal and maternal condition in relation to the PPROM. The checklist used for data collection for each file was coded with numbers. Check list was revised for completeness after data collection on weekly basis.

3.10. Data management and analysis.

Data entry was preceded by checking for completeness, then analysis which was performed using statistical software SPSS version 23. Data from each checklist was entered into a prepared dataset. GA at admission and delivery was grouped as 28 to < 32 weeks, 32 to <34 weeks, and 34 to <37 weeks. Maternal age was categorized as <20years, 20-24years, 25-29years, 30-34 years, 35-39years and ≥40years. Gravidity was categorized as primigravida, gravida 2-4, and grand multiparous while parity was categorized as primipara, para 2-4, and grandmaltigravida. Time from PPROM to admission was analyzed as ≤24 hours and >24 hours respectively, while latency period and time from admission to delivery were both analyzed as within or above seven days. Women were analyzed booked or un-booked based on attendance, to ANC. Birth weight was analyzed as <1000gm, 1000-<1500g, 1500-2500gm, and ≥2500 for ELBW, VLBW, LBW and normal birth weight respectively. Labour onset was analyzed as spontaneous or induced/indicated in onset and mode of delivery as vaginal or caesarian section. Each criterion was coded as 'Yes', 'No' and NA for adherence, nonadherence and not applicabe to intervention respectively. The percentage of adherence to management was calculated for each predetermined standard by taking the total score attained divided by sample size involved in the respective standard. Thus, the denominator differed between different criterion as management of PPROM differs concerning GA at time of presentation. Fetal outcome was analyzed among 89 women who delivered and APGAR score of <7, ≥7 or still birth fresh (SBF), and whether or not admitted. Maternal outcome was analyzed as no complication, chorioamnionitis, abruption placenta, cord prolapse, postpartum hemorrhage puerperal sepsis and severe oligohydramnios respectively as documented in files. Frequencies and proportions were used to summarize the descriptive statistics. Conformity to management was analysed for all 95 files, while maternal outcome was done to 89 women who delivered at MNH. Neonatal outcome was analysed to obtain APGAR score at fifth minute, birth weight and NICU admission.

3.11. Ethical clearance.

Ethical clearance was obtained from the Senate Research and Publication committee of MUHAS. The authorization to do the study was granted by the Teaching, Research and Consultancy Unit under Executive Director and head of department of MNH. Waiver for consent was granted from the head of research and publication Muhimbili National Hospital since the study involved no human subject but rather patient files. Patients' names and information were completely kept private and were only used by the study team to guarantee anonymity and confidentiality. Neither patient names nor file numbers were included on the checklist.

4.0. RESULTS

A total of 4497 deliveries were recorded during the study period. There were 95 files of women with a diagnosis of PPROM giving a proportion of 2.1%. Ninety-five women met the criteria and were retrieved from the medical records department and were analyzed.

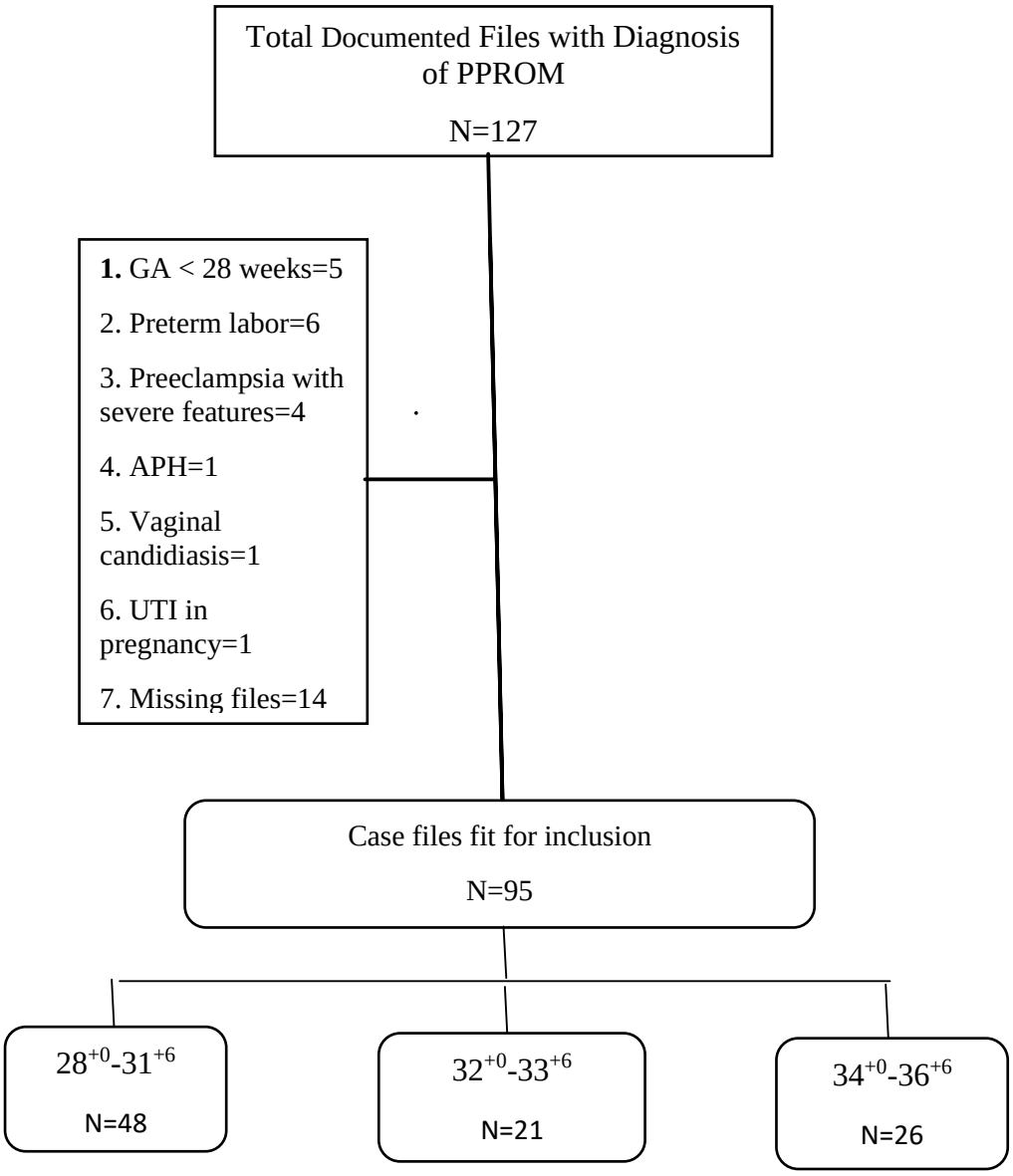


Figure 2: Flow diagram of the included and excluded audit population

Majority (68.4%) of the women with PPROM were aged between 20-34 years with mean age of 28.08±6.503 years. Most patients 81(85.3%), were admitted as referrals from other hospitals. Education level and occupation status were not documented in 87(91.6%) and 82(86.3%) respectively.

The mean gestational age on admission was 31.78±2.30 weeks and ranged from 28 weeks to 36 weeks plus 6 days. Approximately 50% of neonates were born between 28-32 weeks of gestation. Seventy-six women (80%) had their GA estimated using the Naegeles rule while 16(16.8%) and 3(3.2%) were estimated using ultrasound and extrapolation respectively. Ninety-eight percent of the women had booked and attended ANC services with 50(52.6%) presented within 24 hours of onset of PPROM (Table 2).

Table 2: Maternal characteristics of patients with PPROM (N=95)

Variables	Frequency	Percentage
Age (Years)		
<20	11	11.6
20-24	25	26.3
25-29	21	22.1
30-34	19	20.0
35-39	15	15.8
≥40	4	4.2
Education		
Primary education	1	1.1
Secondary education	7	7.4
Not documented	87	91.6
Patient admission status		
Referral from another hospital	81	85.3
From antenatal clinic	5	5.3
Self-referral	9	9.5
Employment status		
Employed	9	9.5
Unemployed	4	4.2
Not documented	82	86.3
Gestational age on admission (weeks)		
28^{+0}-31^{+6}	48	50.5
32^{+0}-33^{+6}	21	22.1
34^{+0}-36^{+6}	26	27.4
Gestational age at delivery (weeks)		
28^{+0}-31^{+6}	32	36
32^{+0}-33^{+6}	22	24.7
34^{+0}-36^{+6}	35	39.3
Method used for GA calculation on admission		
Naegeles rule (LNMP)	76	80
Obstetric USS	16	16.8
Extrapolation From USS and booking GA	3	3.2
Gravidity.		
Primigravida.	24	25.3
1-4	58	61.1
Grand Maltigravida.	13	13.7
Parity		
Nulliparity	37	38.9
1-4	58	61.1
ANC status		
Booked	94	98.9
Unbooked	1	1.1
Time of presentation to admission		
Within 24 hours	50	52.6
Above 24 hours	45	47.4

More than two-third (68.4%) of women in the study lies between the age 20-34 years with education and employment status not document in most women, 91.6% and 86.3% respectively. Almost two-third of women were maltigravida (1-4) and one in two women presenting within 24 hours of symptoms presentation.

Table 3: Maternal management outcomes of patients with PPROM (N=89)

Variables	Frequency	Percentage
Mode of delivery		
Vaginal delivery	15	16.9
Cesarean section	74	83.1
Latency period (days).		
Mean ($\bar{x}$)	7.7(7.67)	
Latency ≤7 days	54	60.7
Latency > 7 days	35	39.3
Duration from admission to delivery (Days).		
Mean ($\bar{x}$)	5.2(6.34)	
Delivery within 7 days of admission	65	73
Delivery above 7 days of admission	24	27

Most women (83.1%) delivered through cesarian section with a mean latency of 7.7 days and two-third delivering within seven days of symptom presentation.

Table 4: Frequency and percentage of adherence to MNH PPROM management standards.

Criteria	Frequency (% Achieved) Yes.	No.	ALL
The diagnosis of spontaneous rupture of membranes by maternal history	95(100)	0(0)	95
A sterile speculum examination is carried out to directly observe any amniotic fluid leaks from the cervical canal or amniotic fluid accumulating in the posterior fornix, and to rule out cord prolapse.	91(95.8)	4(4.2)	95
Digital vaginal examination avoided (unless imminent delivery is anticipated).	95(100)	0(0)	95
Remove cervical cerclage, if any	1(50)	1(50)	2
Full blood count.	95(100)	0(0)	95
C-Reactive Protein (CRP).	53(55.8)	42(44.2)	95
High Vaginal Swab for microbiological examination.	1(1.1)	94(98.9)	95
Urine for routine analysis.	67(70.5)	28(29.5)	95
Ultrasound for fetal wellbeing.	89(93.7)	6(6.3)	95
Late preterm PROM (34-36 weeks of gestational age)- actively delivered.	26(100)	0(0)	26
Early Preterm PROM (<34 weeks of gestational age), conservative management should be used when there is no fetal or maternal need for immediate delivery.	69(100)	0(0)	69
ACS: A course of dexamethasone intramuscular injection, 6 mg every 12 hours for 48 hours.	67(97.1)	2(2.9)	69
Administration of tocolytics I/V Magnesium Sulphate/oral Nifedipine.	0(0)	0(0)	

Antibiotic administered preferably Ampicillin IV 1g every 6 hourly for 48 hours; then continue with Erythromycin 500mg 8hourly or azithromycin 500mg od for 5-7 days.	30(31.6)	65(68.4)	95
• Azithromycin alone	34(35.8)		95
• Ampiclox+Azithromycin	15(15.8)		95
• Ceftriaxone+Metronidazole	13(13.7)		95
• Erythromycin	2(2.1)		95
• Ampicillin+Cloxacillin	1(1.1)		95
Magnesium Sulphate for neuroprotection in women with GA <32 weeks.	4(8.3)	44(91.7)	48
Women were observed for signs and symptoms of chorioamnionitis (foul smelling discharge, body temperature, pulse rate, and abdominal tenderness) and FHR.	89(100)	0(0)	89
Conservative management is abandoned	62(89.9)	7(10.1)	69
Chorioamnionitis	5(8.0)		62
Non-reassuring fetal status	24(38.7)		62
Abruption of the placenta.	4(6.5)		62
Established labour	16(25.8)		62
Severe oligohydramnios	29(46.8)		62

Generally, the average percentage of adherence to the standard is 70.8%

FBC is the most performed investigation and was done in all 95 patients. Cervical cerclage was not removed in one (50%) of the two women who had cerclage in-situ. Almost all women, (98.9%) had not performed HVS for microbiological examination, while approximately one-third (29.5%) of women had not performed routine urine analysis. Although all patients received an antibiotic, more than two-thirds (68.4%) of women had not received standard prophylactic antibiotics as the institution guidelines recommended. All women were observed for signs and symptoms of chorioamnionitis with conservative management abandoned in 62(89.9%) due to different reasons, the leading one being severe oligohydramnios (46.8%). There is no

documentation of the administration of intravenous magnesium sulfate or oral nifedipine as tocolytic agents in all women. (Table 4).

Table 5: Immediate neonatal and maternal outcome of women with PPROM (N=89)

Maternal outcome	**Frequency.**	**Percentage.**
No complication	75	78.9
Postpartum hemorrhage	1	1.1
Chorioamnionitis	8	8.4
Puerperal sepsis	1	1.1
Abruption placenta	4	4.2
Discharged before delivery	6	6.3
Neonatal outcome		
Singleton	81	91
Twins	8	9
Alive at birth*	96	99
Stillbirth*	1	1
APGAR Score AT 5^{TH} Minutes**		
APGAR ≥7	86	89.6
APGAR <7	10	10.4
Birth weight N=97		
<1000g	4	4.1
1000-1500g	29	29.9
1500-2500g	55	56.7
≥2500g	9	9.3
NICU ADMISSION**		
Yes.	73	76
No.	23	24

NB: *Total number of neonates equate 97 including 81 and 8 from singleton and twin pregnancies respectively **N=96 total neonates excluding one stillbirth.

Seventy-five women (84.3%) had no complication with chorioamnionitis occurring in 8(9.0%). Most babies (89.6%) had a good APGAR score at 5^{th} minutes despite having low birth weight in 90.7% of neonate with three-quarter being admitted NICU.

5.0 DISCUSSION

The study aimed to conduct a clinical audit for the management and outcomes of women admitted with PPROM at MNH. The majority of women were referred for preterm PROM, with a mean gestation age of 31 weeks. About a third of the women were at gestation age between 28 and 31+6 weeks at admission. Three-quarters of the women delivered within the first seven days of admission. Components of care that were well done included history taking, not doing a digital vagina examination, antenatal corticosteroids and active delivery of late PPROM. Some components of PPROM care were done in a substandard including the use of tocolytics, recommended antibiotics, infection screening and the use of MGSO4 for neuroprotection.

Management of all patients was conducted based on their documented GA, with conservative measures applied to women with a GA of less than 34 weeks and active delivery for those with a GA above 34 weeks. This is in line with MNH and other guidelines as delivery before 34 weeks of GA is associated with serious complications and less chance of survival particularly respiratory distress syndrome due to their lung immaturity (22). Despite one third delivering occurring before a GA of 32 weeks, only a few 8.3% received magnesium sulfate for neuroprotection. This is less compared to study at Aminu Kano Teaching Hospital 85.7%. There was minimal documentation of women social demographic information of Education level and employment status which has been shown to affect occurrence of PPROM.

The findings of this audit indicated that the diagnosis of PPROM was successfully established through patient history and sterile speculum examination. These findings are similar to those obtained from the audit at Aminu Kano Teaching Hospital (40). In line with the guideline set forth by the ACOG, digital vaginal examination was avoided in all women (100%) as it has been shown to shorten the latency period (41). An ultrasound scan was performed on 93.7% of women, primarily to ascertain the GA, AFI, and fetal presentation. In addition, ultrasound is important for estimation of fetal weight, presentation, and number of fetus as they direct the decision-making in the management process of women with PPROM. Sterile speculum examination is also important to exclude cord prolapse which may complicate the condition and alter the course of the management.

The ACS administered was dexamethasone 12mg 12 hourly for 2 days where 67(97.1%) of women with GA <34 weeks which is similar to a study by Ahmed M. Fahmy and colleagues at Sohag University where ACS was given to 97.26% (41). Fourteen women (17.2%) of those given ACS had a GA of ≥34 weeks which is contrary to institutional guidelines but in line with the international board ACOG which recommends administration at ≥34 weeks with risk of delivery provided not received a course of ACS before.

The recommended prophylactic antibiotic, ampicillin 1gm every 6 hours for 48 hours followed by Erythromycin 500mg for 5-7days was prescribed only to 31.6% of women with 50% of the remaining women receiving either oral azithromycin or ampicillin+cloxacillin alone (31). The variation in the prescription of prophylactic antibiotics observed may be linked to a lack of constant availability of recommended drugs and working in silo. Antenatal magnesium sulfate for neuroprotection was administered only in 8.3% of women. This is lesser compared to other studies which showed achievement of 85.7% and 95% of eligible women respectively (20,40). This study does not provide any documentation regarding the use of tocolytics, unlike other studies that have reported an 8.3% usage rate among women with PPROM (40). This may be attributed to the ongoing debate and lack of adequate evidence suggesting that the use of tocolysis in cases of PPROM leads to enhanced obstetric or neonatal outcomes.

Majority of neonates (89.6%) had APGAR score of ≥7, 90.7% having low birth weight and two-third being admitted NICU. The good APGAR score could be explained by the large number of women receiving ACS for the prevention of RDS for the neonate. Higher admission to NICU following PPROM is likely due to the low birth weight because of premature delivery.

Our study reported that 15% of women admitted with PPROM developed complications, and half of them developed chorioamnitis. A study in Nigeria reported a similar complication rate. We observed that infection screening was sub-optimally done in our setting, as most women had a baseline FBP. At the same time, very few were screened for urine infection, HVS, or C-reactive protein as a marker of infection. These tests could have shaped antibiotic choices and reduced the risk of chorioamnitis. Although women were given antibiotics, the choice of antibiotic was not based on the test or standard regime.

The majority of women, (83.1%) were delivered by CS which is higher compared to other studies where CS were 43%, 32%, and 53% respectively (26,40,42). This is likely due to good clinical monitoring and observation with the detection of abnormal fetal heart rate and severe oligohydramnios in 85% of women whose conservative management were abandoned. The mean value of the latency period was 7.72 ± 7.67 (1-48) which is shorter compared to 20.1 ± 13.73 days and ranged (1 – 60) observed in a study conducted at Sohag University by Ahmed M. Fahmy and colleagues (41). This could be explained by the large number of women with severe oligohydramnios 46.8% which has been shown to shorten the latency period (40). The latency period was inversely proportional to GA similar to a study by S Sultana and colleagues at Ziauddin University and Hospital (26).

6.0 LIMITATION OF THE STUDY, CONCLUSION AND RECOMMENDATIONS

6.1 Limitation of the Study.

During the stage of data collection and analysis, several limitations were encountered including missing files and poor documentation particularly of patient level of education and occupation. The study was also limited to immediate neonatal outcomes thus neonatal outcome after NICU admission were not assessed. There was also scarcity of audit studies in the management of PPROM. It being a clinical audit, the result are limited to the process of management at MNH and hence the result cannot be generalized to other hospitals. The re-audit step of the audit cycle could not be accomplished because of the limited time of study duration study and GA relied on documented GA, NO assessment of neonates after delivery to ascertain GA.

6.2 Conclusion and Recommendations

Seven out of ten women with PPROM received the standard treatment. Antibiotic use was common, however was not guided by the standard guideline or laboratory investigations. Several evidence-based interventions were not routinely done (example magnesium sulfate administration for neuroprotection) and could have impacted outcomes. There is a need for standardization among HCWs on the practice in the management of PPROM. Further studies in the management and outcome of neonates born from pregnancies complicated with PPROM are needed as well as re-audit after implementation to complete the audit cycle.

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APPENDICES

Appendix 1: Ethical Clearances

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/1963 Date: 31/10/2023

MUHAS-REC-10-2023-1963
EVANCE POLIN MOLINGA
COLLEGE OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: CRITERIA-BASED AUDIT IN THE MANAGEMENT AND OUTCOME OF PRETERM PRELABOUR RUPTURE OF MEMBRANES AT MUHIMBILI NATIONAL HOSPITAL

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: 31/10/2023
EXPIRATION DATE OF APPROVAL: 31/10/2024

STUDY DESCRIPTION:
Purpose:

The purpose of this Retrospective cross-sectional study is to establish baseline data that will be a starting point to improve the level of care given to pregnant women with PPROM.

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-%2014801.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. 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)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. 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. Kasusu Nyamuryekung'e

Ag. Chairperson, MUHAS Research and Ethics Committee

Appendix 2: 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.118/2021

20th November, 2023

The Executive Director,
Muhimbili National Hospital.
P.O. Box 65000,
DAR ES SALAAM

Re: INTRODUCTION LETTER

We would like to inform you that the bearer of this letter is Evance Polin Molinga with Reg. No. HD/MUH/T.118/2021 is a student at Muhimbili University of Health and Allied Sciences (MUHAS) "pursuing MMed. Obstetrics/Gynaecology.

As part of his studies, he will be doing an elective research titled: **"Criteria-Based Audit in the Management and Outcome of Preterm Prelabour Rupture of Membranes at Muhimbili National Hospital."** He is being supervised by Dr. Belinda Stella Balandya from MUHAS and Fadhilun Al-Beity from MNH.

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

Kindly provide him the necessary assistance to facilitate the conduct of his research.

We thank you for your cooperation.

Mr. Sebe Mohamed
For: DIRECTOR, POSTGRADUATE STUDIES

c.c Evance Polin Molinga

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 3: Permission Letter

THE UNITED REPUBLIC OF TANZANI

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/562 Date: 23rd November, 2023

Head of Department

Medical Records

Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH

Name of Student	**Evance Polin Molinga**
Title	**"Criteria-Based Audit in the Management and outcome of Preterm of Prelabour Ruptrure of Membranes at Muhimbili National Hospital".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Belinda stella Balandya (MUHAS)
Co-supervisor	Dr. Fadhilun Al-Beity (MNH)
Period	23rd November, 2023 to 23rd February, 2024

Approval has been granted to the above principal investigators to collect data at MNH. Dissemination of study findings at MNH shall be overseen by Dr. **Fadhilun Al-beity** (MNH) supervisor.

Kindly ensure the named principal investigator abide to the ethical principles and other conditions of the research approval.

HEAD, TEACHING, RESEARCH & CONSULTANCY UNIT
P. O. Box 65000
DAR-ES-SALAAM
MUHIMBILI NATIONAL HOSPITAL

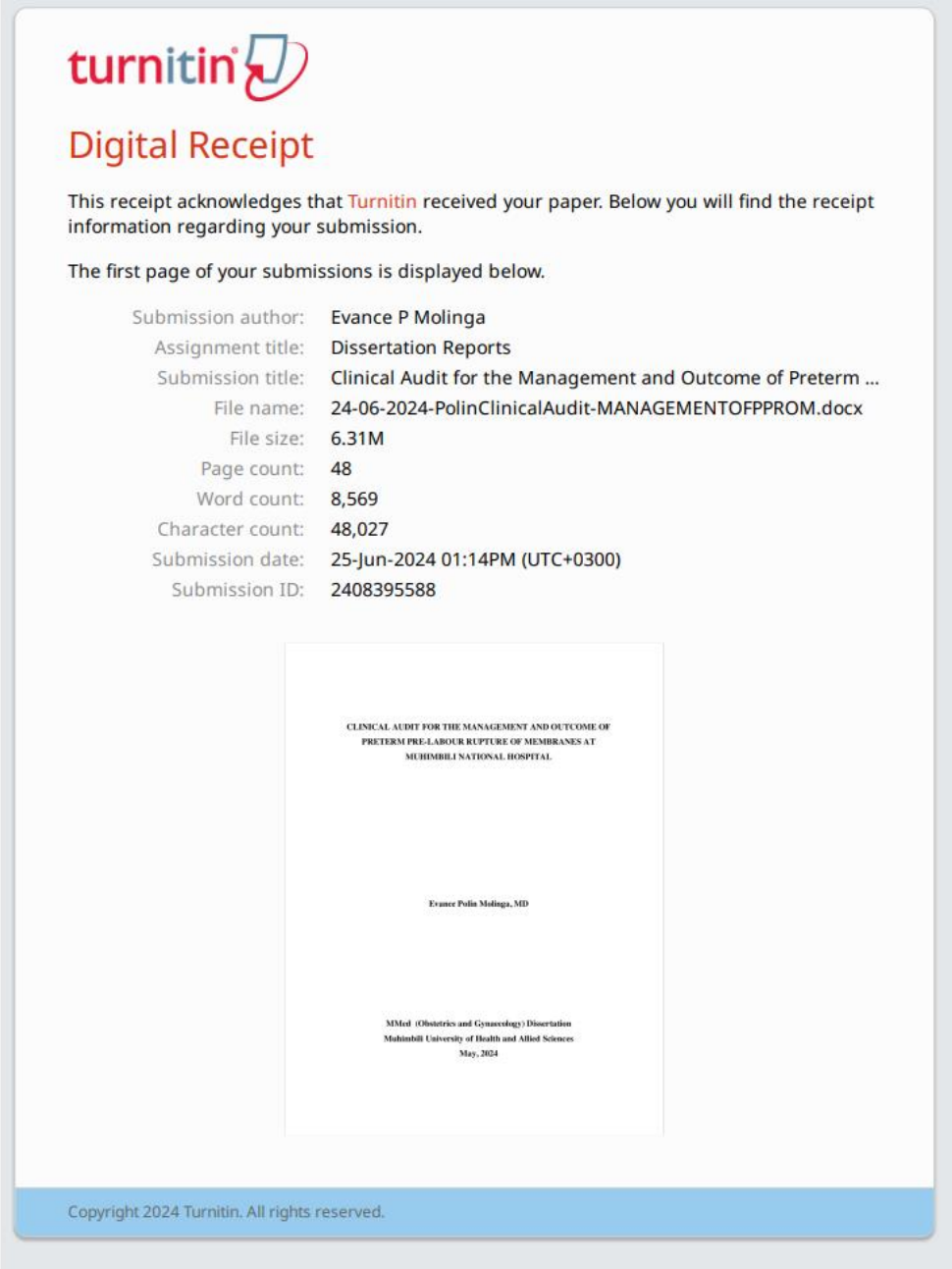
Sincerely,

Dr. Charles Pallangyo
For: Head of Clinical Research, Training and Consultancy Unit

c.c DICT
c.c Dr. Fadhilun Al-Beity
c.c Evance P. Molinga

Upanga West, Kalenga Street, Plot No. 10480/3, P.O. BOX 65000, Dar es Salaam, Tanzania.
Telephone: +255-22-2151367-9, Telephone: +255-22-2151351-2
Email: info@mnh.or.tz, Website: www.mnh.or.tz

Appendix 4: Turnitin Receipty



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Submission title:	Clinical Audit for the Management and Outcome of Preterm ...
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File size:	6.31M
Page count:	48
Word count:	8,569
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Submission date:	25-Jun-2024 01:14PM (UTC+0300)
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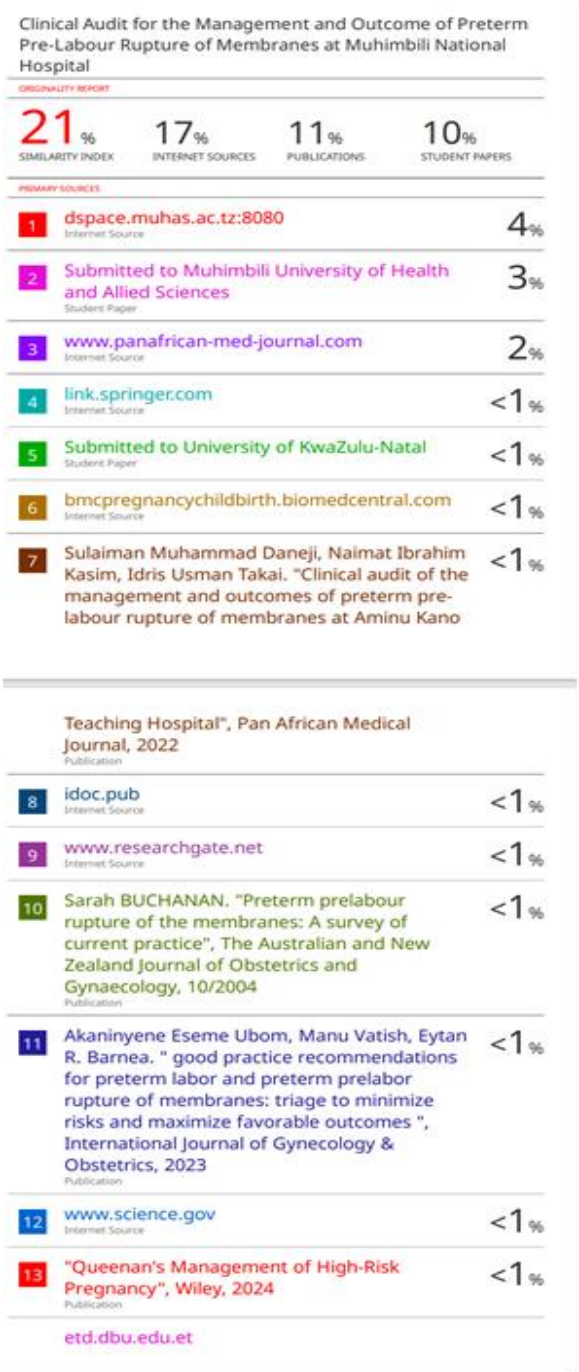
CLINICAL AUDIT FOR THE MANAGEMENT AND OUTCOME OF PRETERM PRE-LABOUR RUPTURE OF MEMBRANES AT MUHIMBILI NATIONAL HOSPITAL

Evance Polin Molinga, MD

MMed (Obstetrics and Gynaecology) Dissertation
Muhimbili University of Health and Allied Sciences
May, 2024

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Appendix 5: Plagiarsm Report



Clinical Audit for the Management and Outcome of Preterm Pre-Labour Rupture of Membranes at Muhimbili National Hospital

ORIGINALITY REPORT

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SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

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