# MAGNITUDE, FACTORS ASSOCIATED WITH FAILED INDUCTION OF LABOUR THROUGH DINOPROSTONE TABS AND MATERNAL/FETAL OUTCOMES AT MUHIMBILI NATIONAL HOSPITAL 2020 TO 2022

**Yared Birage Chacha, MD**

**MMed (Obstetrics and Gynaecology) Dissertation**

**Muhimbili University of Health and Allied Sciences**

**October, 2024**

**Muhimbili University of Health and Allied Sciences**

**School of Clinical Medicine**

# MAGNITUDE, FACTORS ASSOCIATED WITH FAILED INDUCTION OF LABOUR THROUGH DINOPROSTONE TABS AND MATERNAL/FETAL OUTCOMES AT MUHIMBILI NATIONAL HOSPITAL 2020 TO 2022

**By**

**Yared Birage Chacha**

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

**Muhimbili University of Health and Allied Sciences**

**October, 2024**

## CERTIFICATION

The undersigned certifies that they have read and hereby recommends for examination of the dissertation entitled ***"Magnitude, factors associated with failed induction of labor through dinoprostone tabs and maternal/fetal outcomes at Muhimbili National Hospital 2020 to 2022"*** in partial fulfillment of the requirements for the degree of Master of Medicine in Obstetrics and Gynecology of Muhimbili University of Health and Allied Sciences.



Prof. Projestine S Muganyizi (MD, MMed, PhD)

**(Supervisor)**

**Date**: 13/11/2025

Prof. Charles Kilewo (MD, MMed, PhD)

**(Co-Supervisor)**

**Date**_____

## DECLARATION AND COPYRIGHT

I, **Yared Birage Chacha**, 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**…….

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## ACKNOWLEDMENT

Firstly, I thank the Almighty God for provision of health, life and courage to complete this study. I am sincerely grateful to my supervisors **Prof. Projestine Selestine Muganyizi** and **Prof. Charles Kilewo** for their valuable assistance and guidance throughout this research work. Their tireless advice and input since the proposal development until now is priceless and I always felt warm with you.

I am gratified to have support from my beloved family especially my wife **Neema Marwa**, My Sons Chacha Yared (David), Birage Yared (Brighton), and my daughter Debora Yared, Brothers and Sisters, My Uncle Benson and Bon for their moral support, tolerating my absence and encouraging me during ups and downs of my dissertation works. Special appreciation to my elder brother Jackson Birage for his closely supports in my career.

Finally, I am sincerely thankful to all staff members of Obstetrics and Gynaecology Departments at Muhimbili University of Health and Allied sciences, Muhimbili National Hospital and Mloganzila for their support in hypothesis formulation and the whole general idea on this proposal to commence.

Last but not the least the Government of Tanzania through the Ministry of Health for their support.

## DEDICATION

This work is dedicated to my parents**; father Birage chacha Sando** (who died 2019) and **mother Naomi Elisha Chacha** for their tender love and care throughout my life and keeping encouraging on studying more and more, to quote few words from my late father “nothing is impossible under the sun just keep on pulling “Your unending love is beyond measurable and I real appreciate

## ABSTRACT

**Background**: The methods used in induction of labour (IOL) are both pharmacological and non-pharmacological. Vaginal dinoprostone has been shown as one of the pharmacological agents that are highly effective and successful in IOL even when the cervix is unfavourable. Despite its efficacy and advantages over other methods, cases of IOL failure have been reported in the literature. However, few studies on failed induction with vaginal dinoprostone and its associated factors have been conducted; there is still a scarcity of data in this area for a better understanding in our local settings.

**Aim of the study:** The study assessed the magnitude, factors associated with failed induction of labor through dinoprostone tabs and maternal/fetal outcomes at Muhimbili National Hospital 2020 to 2022.

**Methods:** This was a hospital-based retrospective cohort study conducted at Muhimbili National Hospital (MNH). A simple random sampling method was employed to retrieve patients case files numbers from the electronic database and case notes from medical records office for induced labour from January 2020 to December, 2022 until a sample size of 517 was attained. STATA version 15.1 was used for analysis.

**Results**: A total of 517 pregnant women were enrolled in the study whereby, 69.2% (358/517) were from MNH-Upanga and 30.8% (159/517) from MNH-Mloganzila. An overall cumulative incidence of 33.1% (171/517) of failed induction of labor (FIOL) with vaginal dinoprostone was found and factors such as residence, chronic illness and pregnancy induced hypertension were independently associated with FIOL with vaginal dinoprostone ($p<0.05$). Also, non-reassurance foetal status, prolonged hospital stay and postpartum haemorrhage were reported as maternal outcomes while admission to NICU, low Apgar score and asphyxia as foetal outcomes.

**Conclusion**: The cumulative incidence of FIOL with vaginal dinoprostone among pregnant women at MNH is high and it is associated with residence, chronic illness and pregnancy induced hypertension. Exploration of these factors and preparation for alternative delivery mode prior to IOL intervention is necessary to reduce adverse pregnancy outcomes related to emergency C/S delivery.

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| ACOG | American College of obstetrics and Gynaecology |
| APGAR | Appearance, Pulse, Grimace, Activity, Respiration |
| AKI | Acute Kidney Injury |
| C/S | Caesarean Section |
| CPD | Cephalo-pelvic Disproportion |
| HIE | Hypoxic Ischemic Encephalopathy |
| FHR | Foetal Heart Rate |
| FIOL | Failed Induction Of Labour |
| GA | Gestational Age |
| IOL | Induction of Labour |
| IUFD | Intra-uterine foetal death |
| MUHAS | Muhimbili University of Health and Allied sciences |
| MNH | Muhimbili National Hospital |
| NICU | Neonatal Intensive Care Unit |
| NRFS | Non-Reassuring Foetal Status |
| $PGE_1$ | Misoprostol |
| $PGE_2$ | Prostaglandin (Dinoprostone) |
| PIH | Pregnancy Induced Hypertension |
| PROM | Pre-Labour Rupture of Membrane |
| PPH | Post-partum Haemorrhage |
| SVD | Spontaneous Vertex Delivery |
| WHO | World Health Organization |

## OPERATIONAL DEFINITIONS

**Failed Induction of Labour-In this study is defined as failure to achieve vaginal delivery within 24hours of vaginal Dinoprostone tabs 3mg use at the maximum of two doses.**

- Successful Induction of labour: Vaginal delivery following Induction of labour.
- Induction of Labour (IOL) is a procedure that artificially stimulates uterine contractions accompanied with cervical changes to achieve vaginal birth.
- Induction to delivery Interval : Time in hours between initiation of induction to vaginal delivery
- Adverse pregnancy outcome –Refers to any pregnancy events likely to occurs to both the mother and or the foetus after failed induction of labour (for example;
    - Maternal Adverse outcome - APH, Foetal distress, CS, PPH, maternal death
    - Foetal adverse outcome -Low Apgar score, Fresh still birth, Neonatal Asphyxia, NICU admission, Neonatal death,)
- Pre-term delivery to this study meant; a birth or delivery that occur before $37^{th}$ completed weeks of pregnancy
- Fresh still birth is defined as the death of foetus that occur intra-partum with fresh skin appearance;
    - Early still birth ( Foetal death occur up to 28weeks of Gestation Age)
    - Late still birth occurs between 28wks up to 36weeks of Gestation Age
    - Term still death is the death of foetus that occurs at 37 completed weeks before delivery
- Apgar score to this study meant a condition of a neonate at $1^{st}$ and $5^{th}$ minutes after delivery assessment score which used to determine the state of an infant. A=appearance (colour), P=pulse rate (Heart rate), G=grimace (Reflexes), A=activity (muscle tone) lastly is R=respiration.
    - ✓ Low score meant a score below 7 out of 10
    - ✓ Normal score meant those scored above 7 out of 10

# 1.0 INTRODUCTION

## 1.1 Background

Induction of labour is defined as the artificial stimulation of uterine contractions in order to cause foetal delivery. Induction of labour is performed with the goal of achieving vaginal delivery; it is recommended when the benefits of delivery outweigh the risks of continuing the pregnancy (1).

The most common indications for induction of labour are maternal, foetal, social, or a combination of these factors. Labour induction occurs in approximately 20% of almost all settings (2). Rates of induction of labour vary by nation; however, it is reported in the United Kingdom to be 25% in France, 15% in Norway, 22% in Canada, 30% in the United States, and 3% in Tanzania. The rate of Induction Of Labour(IOL) has increased during the last two decades in most industrialized countries (3).

Over a 15-year period, an increased rate of induction of labour for postdate pregnancies was connected with a lower still birth rate in Canada, whereas Africa had the greatest maternal mortality as well as the highest still birth and prospective death rate (1). Pregnant women with gestation Age (GA) equal to or less than 42 weeks had a higher success rate of IOL than those with GA more than 42 weeks (1).

An optimal cervical ripening agent must be effective, safe, simple to use, and agreeable to the expectant woman. The use of prostaglandins for cervical ripening during IOL was initially documented in 1960, and since then, different forms of prostaglandins has been in use with effectiveness of (PGE2) Prostaglandin $E_2$-Dinoprostone, among others it was elicited as the best PGE pharmacological agent for cervical ripening, this kind of Prostaglandin it works by opening the cervix without contraction (4,5)

Dinoprostone vaginal tabs have been declared to be superior to other prostaglandin as it works to speed dilatation of the cervix as a result it enhances the rates of successful vaginal birth within 24 hours without increasing the number of surgical deliveries. A research which was done at MNH in 2021 and published in 2024 aimed to evaluate maternal and Neonatal outcomes associated with labour Induction in tertiary Hospital resulted 61.7%

delivered vaginally and 38.3% underwent C/S with minimal maternal complication and Neonates outcomes were generally positive (5).

The vaginal route was shown to be a safe and effective method of inducing labour; nevertheless, the optimum vehicle for administering vaginal prostaglandins requires additional research (6).

Vaginal Dinoprostone has been observed to be of great use now days due to its good outcome to shorten time of labour and with few adverse events to the foetus and the mother though IOL remains a controversial concept (7). A research conducted at Muhimbili National Hospital (MNH) on health-related quality of life after IOL delivery compared PGE1 and PGE2 to see whether one had a better outcome on health-related quality of life after IOL delivery. The study revealed that women who got PGE1 scored higher on physical functioning, mental health, and bodily pain dimensions than those who received PGE2. These findings might be attributed to the PGE1 group's reduced risk of Caesarean section (C/S) and incidence of foetal poor outcomes (4). Other studies demonstrated that PGE2 is more accurate and has less side effects than PGE1 (8).

Failed induction of labour is defined as failure to initiate uterine contractions and attain cervical changes (softening, effacement and dilatation of not less than 2cm in prime and 3cm in multipara) in 24hours of vaginal Dinoprostone use at the maximum of two doses of 3mg each (2). Foetal maternal morbidity and mortality have been one of the most health problem and challenges that concern the globe for several years especially in Sub-Saharan Africa (9).

Following that, numerous techniques for serving the foetal-maternal life have been studied and implemented at multiple levels as interdisciplinary, one of which is the establishment of emergency obstetric and neonatal care job Aid Training of health staff, who would then work to assist society, particularly women and children, as well as the introduction of IOL to individuals who meet the requirements for induction into labour

A facility-based cross-sectional analysis of 379 women who had IOL surgery at Adam Hospital Medical College in Ethiopia discovered that unsuccessful IOL increased the risk of surgical delivery, Post-partum Haemorrhage (PPH), uterine hyperactivity, maternal

mortality, and new-born poor outcomes. At the worldwide level, the percentage of induction ranged from 20% to 25% in industrialized nations. According to a World Health Organization(WHO) global study conducted in Africa, the rate of IOL ranges from 1.4 % to 6.8 % (9).

Failure to induce enough uterine contractions following IOL is also related with an elevated risk of a variety of unfavourable maternal-perinatal outcomes, including unsettling foetal heart rate, postpartum haemorrhage, endometritis, stillbirth, and severe birth asphyxia. Induction of labour (IOL) is considered to increase the chance of caesarean delivery in both nulliparous and multiparous women (10). Furthermore, studies have shown that failure to induce poses a two-fold increased risk of mortality associated with C/S delivery as compared to vaginal birth (9).

Therefore, this study aimed to determine magnitude and factors associated with failed induction of labour with vaginal dinoprostone and maternal/fetal outcomes at Muhimbili National Hospital from January 2020 to December 2022.

**1.2 Literature Review**

Induction of labour occasionally fails, posing hazards to both the mother and the foetus. (11). According to the literature, when induction of labour fails, unfavourable pregnancy outcomes are more frequent (9). That is why we decided to do a study on what is the magnitude and factors associated with failed IOL through vaginal Dinoprostone and maternal/foetal outcome at MNH. Several variables are going to be discussed in details with their support from different scholars studies results, conclusions and opinions on the cause, associated factors and recommendations on how to deal with such a matter in order to avoid adverse outcome. On discussion the following variables; Magnitude of Failed IOL with vaginal dinoprostone, Factors associated with Failed IOL with vaginal dinoprostone tabs, Maternal outcomes and Foetal outcomes where more details on maternal foetal outcomes will be on the following variables ; increased caesarean section, Postpartum haemorrhage, maternal death, non-reassuring foetal status, Low APGAR score, NICU admission and neonatal death

### 1.2.1 Magnitude of FIOL with vaginal dinoprostone

Failed induction of labour is a worry for all health care workers, and determining the cause of failure is still challenging (11). Worldwide, over the previous several ten years, the incidence of IOL of pregnancy has been increased. In the developed countries, the magnitude of IOL is about 25% of all term deliveries. These magnitude is lower in developing countries; even though, in some parts, they can be as high as those observed in developed countries, For instance; a secondary analysis of World Health Organization (WHO) on the outcomes of IOL in 16 Asian and African countries, indicated the average prevalence of failed induction as 4.4% in Africa (ranged from 1.4% in Niger to 6.8% in Algeria) and 12.1% in Asia (ranged from 2.5% in Cambodia to 35.5% in Sri Lanka) (12) and was 20.5% in Adama Medical College Hospital- by Debelo et al (2022) (13). There's no single global figure that indicates the magnitude of failed induction of labour, the magnitude of failure of Induction of labour differs following induction guidelines and induction methods applied with constituency like the method used ie by Nakintu *et al* (2001) at Mulango Hospital -Uganda (14) the magnitude was very low almost to zero. Failed induction they normally end up for C/S which is among the risk to women and their baby who were not planned to deliver through C/S, this is because of its adverse outcome for both mother and foetus like long recovery period, PPH, iatrogenic injury to other organs such as bowel, bladder and adhesion as it may cause complication to future pregnancies (15) , the magnitude of failed induction of labour is of diversity due to different reasons.

### 1.2.2 Factors associated with FIOL with vaginal dinoprostone

Several studies came out with results that pointed several factors that are associated with failed induction of labour with vaginal Dinoprostone such as Gestation age (null parity), birth weight (BW) >3500 g, maternal age <30 years, methods of induction(16), non-reassuring foetal heart rate tracing, cephalopelvic disproportion (CPD), high body mass index (BMI), unfavourable cervix, and unripen cervix increase the rate of IOL (2,17). Others are PROM, Indication for IOL, Time from the start of IOL to delivery of the baby, Oligohydromnious, Congenital anomalies (Hydrocephalus, Gastroschisis) and

Chorioamnitis as has been mentioned by Mulata Desta *et al* (15) In contrast, factors like multiparty, BW <3500 g, and high Bishop score (a score of 8 or higher) increase the likelihood of success rate of IOL (18) . However, a Bishop score of 7 or lower increases the likelihood that induction will fail to result in vaginal delivery (19).In other ways the weight of the foetus was described to be independent associated with successful of IOL to some studies like in Harari Eastern Ethiopia by Beshir *et al* (2021) (20) , while in other studies like of Demssie *et al* (2022) at Adama Hospital Medical College it was reported that mothers whose foetal weight was greater than 4000gm were 4 times more likely to have failed IOL than whose foetal weight were less than 2500gm(9). Through these studies it is important to know the foetal weight before you decide to do IOL because it has effect on the outcome of the baby.

### 1.2.3 Maternal/Fetal outcome

#### 1.2.3.1 Maternal outcomes

Maternal outcomes frequently reported as a result of failed induction of labour include caesarean section due to foetal distress, excessive uterine activity which may lead to uterine rupture when induction fails, and all of these may cause PPH to the mother.

**Increased caesarean section**

Failed induction of labour using Vaginal Dinoprostone has been shown to increase at varying rates throughout countries, according to various research reports, with the greatest failure rate of 52.7% being reported in Turkey by Kulhan in 2019. The cases with failed induction and delivered through CS. Among the 52.7% CS indications were 15.2 % were related to foetal distress, 8.9 % were due to **Cephalopelvic disproportion (**CPD), and 28 % were unsuccessful inductions for unknown causes (21).

In a retrospective observation cohort research conducted in a provincial combined Hospital in Kielce, Poland from 1st February, 2018 to 31st September, 2020, the lowest failure rate was recorded to be 9.65 % (22) . In most cases, caesarean section was the direct end consequence of a failed induction, resulting in an increase in CS that was not expected.

**Post-Partum Haemorrhage**

Postpartum haemorrhage is one of the adverse pregnancy outcomes that occur as an emergency after a woman delivers and her uterus fails to contract or with some tissue remaining in the uterus after the baby is delivered or as a result of coagulopathy issues in which the blood clotting mechanism fails. Post-partum Haemorrhage was found to be one of the most detrimental to women who failed induction with vaginal Dinoprostone in various researches reports. This has been explained to be as a result of excessive uterine stimulation.

In a research conducted by Veena in Nepal from 2012 to 2013, it was reported that the rate of PPH after birth was 6%. The goal of this study was to determine the foetal maternal outcomes following IOL with Dinoprostone to pregnant women attending a teaching hospital. (23)

**Maternal Death**

According to the study done by (24), maternal mortality was 1%, indicating that women die regardless of the cause or care offered. The most common causes of maternal death are: aborted pregnancy, Obstetric haemorrhage, pregnancy-related infection, other obstetric problem (amniotic embolism, peri-partum cardiomyopathy, etc.), and unanticipated treatment difficulty and there was no obstetric problem.

**1.2.3.2 Foetal Outcomes**

Foetal outcomes evidenced in the literature include non-reassuring foetal status, low Apgar score, stillbirth, and neonatal intensive care Unit (NICU) admissions. (1,9)

**Non-Reassuring Fetal Status**

After a failed induction of labour using either technique, numerous foetal unfavourable outcomes occur, one of which is non-reassuring foetal condition, which puts a foetus in risk. A retrospective international research comprising 571 women was conducted in Spain and Italy. The study compared vaginal Dinoprostone with mechanical (balloon catheter) induction of labour, and the results were as follows. The Non Reassurance Foetal

status(NRFs) for individuals induced with vaginal dinoprostone was shown to be 25.6 % compared to those IOL with balloon catheter 17.2% and composite adverse neonatal outcome of 26.1% versus 16.7% of those IOL with balloon catheter (25)

**Low Apgar score**

When a baby is born, we expect an Apgar score of greater than 7 in the first minute and 10 in the fifth minute. This is the method used to assess the well-being of the foetus soon after delivery. Where A-appearance, P-pulse, G-grimace, A-activity, and R-respiration fail, blood supplies to the foetus in the uterus are minimized, causing the foetus to suffocate, causing the pulse rate to increase, but the appearance of the foetus changes from pink to blue, indicating low oxygen concentration in the blood, and activeness of the new born drops with poor grimace, resulting in high respiration This indicates that the infant is ill. Garang p conducted a research in Ethiopia and found low Apgar score by the rate of 10.9% of those who underwent IOL by vagina Dinoprostone (24)

**Neonatal Intensive Care Unit Admission**

Veena conducted research in Nepal from April 2012 to March 2013. The goal of this study was to determine the foetal maternal outcomes following IOL with Dinoprostone in pregnant women attending a teaching hospital in Nepal. A total of 2183 women participated in a study in which vaginal Dinoprostone was inserted in the posterior fornix of the cervix, some patients responded to a single dose while others required the second dose to deliver where 30.2 percent failed induction of labour and went for CS, admission to NICU is one of the foetal outcomes, in this study it was reported admission rate of neonate to be 13 percent reasons for these were; Apgar score is low Neonatal sepsis with early onset, perinatal asphyxia or hyaline membrane disease (23,24)

**Neonatal Death**

In terms of foetal or early neonatal problems, new-born mortality has been documented following SVD or other procedures after unsuccessful induction of labour with vaginal Dinoprostone. A research conducted in Ethiopia in 2020 found that 1.3 % of new-born deaths were caused by prenatal hypoxia, another 25 % by congenital deformity, and 50 %

by Hyaline membrane illness. There are insufficient facts on this negative, but there are also more new-born deaths that are not recorded, regardless of the cause. (24)

It has been challenging to obtain sufficient information on unfavourable pregnancy outcomes and related variables among women who failed induction with vaginal Dinoprostone, particularly in our institution and our nation in general, because this study has not been conducted in Tanzania associated with the success or failure of IOL to achieve vaginal delivery. Objective will be to determine the magnitudes and factors associated with failed IOL with vaginal Dinoprostone tabs and maternal/foetal outcomes at MNH, answers to these questions will guide the research to the expected fortune

**1.3 Problem Statement**

Recently, there has been an upward trend of IOL with vaginal Dinoprostone compared to other techniques of IOL at MNH, as indicated by statistics from the MNH birth registry from 2020 to 2022. A total of 565 pregnant women were induced in 2020, 75.4% (426/565) of these women were induced with vaginal Dinoprostone, 15.9% (90/565) with misoprostol, and 8.7% (49) with other types IOL techniques. However, 29.0% (164/565) were identified with induction failure and underwent C/S. In 2021, 396 had IOLs, with 78.3 % (310/396) with vaginal Dinoprostone, 15.4% (61/396) with Misoprostone tablets, and 6.3% (25/396) induced by other methods. Induction failure was 29.3 % (116/396). In 2022, a total of 378 pregnant women had IOL; 67.2% (254/378) with vaginal Dinoprostone, 26.5 % (100/378) with misoprostol, and 6.3 % (24/378) with other types. Induction failure was 17.5% (66/378).

At Mloganzila observational study done through birth registry and found that In 2020, 154 pregnant women had IOLs, 74.0% (114/154) with vaginal Dinoprostone, 18.2% (28/154) with Misoprostone tablets, and 7.8 % (12/154) induced by other methods. Induction failure was 28.9% (46/154). In 2021 a total of 196 pregnant women were induced, 79.6% (156/196) induced with Dinoprostone, 14.3% (28/196) with misoprostol, and 6.1% (12/196) with other types of induction of labour. But, 30.6% (60/196) were identified with induction failure and underwent C/S. In 2022 a total of 210 pregnant women were induced, 76.4% (160/210) induced with Dinoprostone, 14.6% (31/210) with misoprostol, and 9.0%

(19/196) with other types of induction of labour. But, 32.9% (69/210) were identified with induction failure and underwent C/S.

From the observational study above it show that there had been an increased IOL with vaginal Dinoprostone tabs and also increased failure rate of induction with vaginal Dinoprostone, which has resulted in an increased caesarean section rates and other complications such as ; new-born admissions to the NICU, Caesarean section the most common outcome following unsuccessful induction, may be associated with unfavourable pregnancy outcomes like PPH, extended hospital stays, and financial burden to the patient, family, and hospital. Induction of labour is linked to a number of different pregnancy complications, including maternal tiredness, maternal mortality, NRFS, poor Apgar score, NICU admission, infection-neonatal hypoxia, and neonatal death. Several global studies have focused on induction of labour with different techniques, its prevalence, foetal maternal outcome, and related variables, but less attention were paid to what factors might be associated with and the outcomes to both mother and foetus following induction failure using vaginal Dinoprostone. There's an aperture between the magnitudes and factors associated with failure of IOL under vaginal Dinoprostone tabs in relation to maternal foetal outcomes to the community who are receiving such services.

### 1.4 Conceptual Frame Work

In this conceptual framework, the dependent/outcome variable is "failed induction of labour with vaginal dinoprostone" which was categorized as yes and no after knowing the mode of delivery of mother whereby yes for failed induction of labour with vaginal dinoprostone represented mothers with caesarean section (C/S) delivery while no for failed induction of labour with vaginal dinoprostone represented mothers with spontaneous vaginal delivery (SVD). Furthermore, the independent variables were categorized into two main groups: socio-demographic factors (such as age, education level, occupation, marital status and residence) and obstetrics related factors (such as parity, gestational age, Bishop score, Patients strong contraction, postdate pregnancy, premature rapture of membrane, pregnancy induced hypertension, diabetes mellitus, antepartum haemorrhage, Oligohydromnious, Polyhydromnious and dinoprostone dose). From the framework, the arrows from the independent variables to IOL process indicate the potential influence of

the independent variables to either success IOL or failed induction of labour with vaginal dinoprostone. Intermediate variables are the Administration of Dinoprostone vaginal tabs process and timing, after the administration the patient have to stay for 8hrs then to be examined for next PV if not yet dilated she is given 4hrs which make at total of 12hrs so as to decide whether she is going for the next dose or not, the maximum dose of Dinoprostone are 2 at each 12hrs making total of 24hrs when we can diagnose failure IOL if the cervix dilatation doesn't promise SVD within 24hr.This framework visually represents the structure of the study and how various factors may affect failed induction of labour with vaginal dinoprostone. In this study these two groups of independent variables will be assessed on how they relate to the failed induction of labour with vaginal dinoprostone among pregnant women admitted at MNH.

Also, another part of this conceptual frame work represents the relationship between failed induction of labour with vaginal dinoprostone and maternal outcomes (such as prolonged hospital satay, postpartum haemorrhage, acute kidney injury, NRFTs and death) and foetal outcomes (such as admission to NICU, low Apgar score at 5 minutes, asphyxia and stillbirth). From the framework, the arrows from failed induction of labour with vaginal dinoprostone to maternal/fetal outcomes indicate the potential influence of the failed induction of labour with vaginal dinoprostone to the occurrence of maternal and foetal outcomes. Also, in this study maternal and foetal outcomes were assessed after failure of induction of labour with vaginal dinoprostone among pregnant women admitted at MNH.

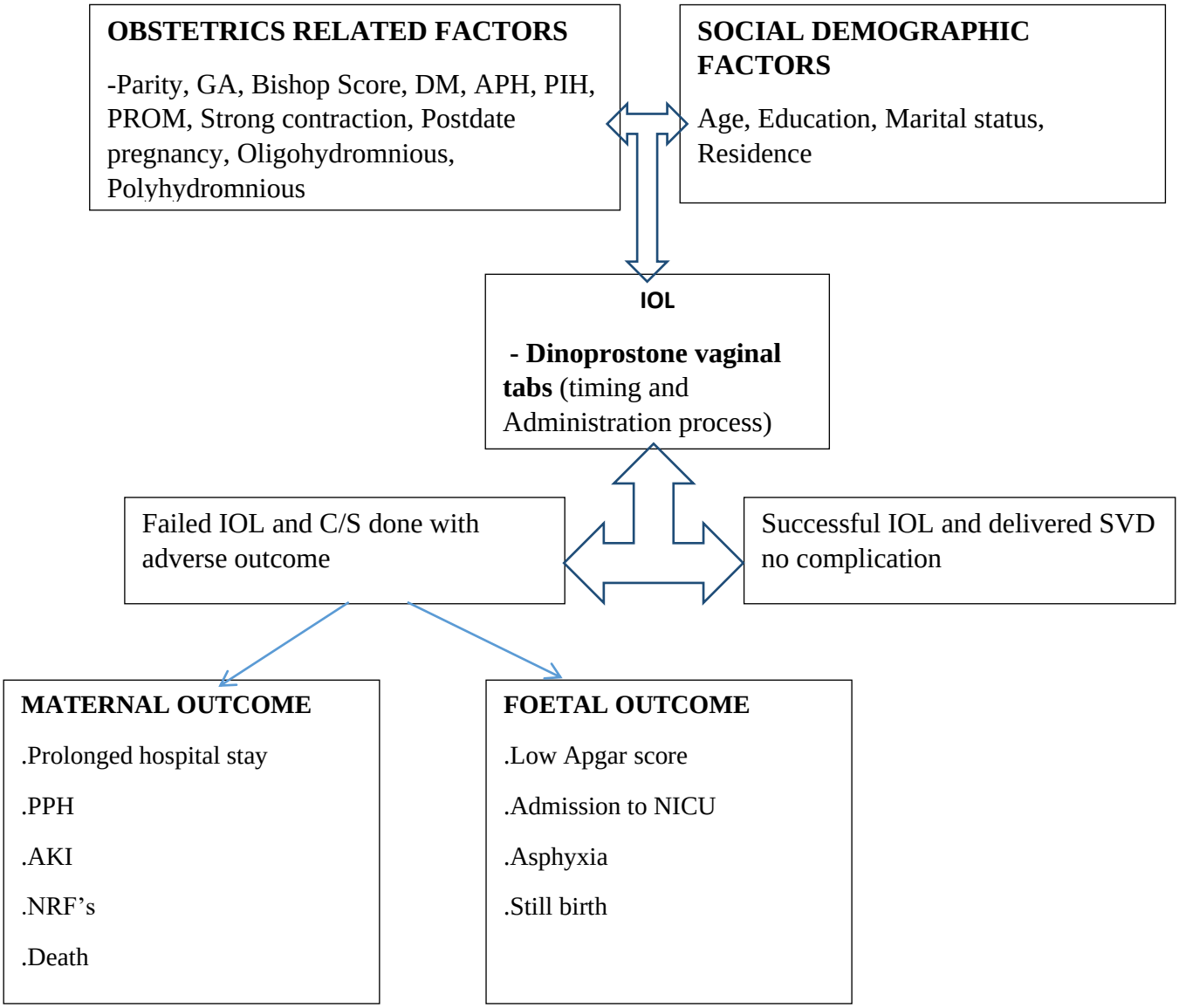



**Figure 1: Conceptual Frame Work**

## 1.5 Rationale

Following the rise of Induction of labour with vaginal Dinopstone tabs in different tertiary Hospitals MNH inclusive, with the rise of Failure rate of Induction of labour which causes the rise in caesarean section to patients who undergo IOL, scientifically if a mother delay in delivery there might be bad outcome to both foetus and mothers, this study aimed to assess the magnitude and factors associated with failed induction of labor with vaginal dinoprostone and maternal/fetal outcomes at Muhimbili National Hospital after failed induction of labour. Its result would benefit both clients and health care workers by providing information on what to do with timing, where to do corrections for better and expected outcomes for both foetuses and maternal after failed induction and unexpected caesarean section.

This study expected to show the magnitude and relationship against factors associated with failed IOL, pregnancy outcome, and then to provide a way of how to avoid or reduce the adverse pregnancy outcome prior and after failed IOL with vaginal Dinoprostone in order to add value to the society of those who receive a specific service at MNH.

The findings of this study also will spark more debate and advice on the proper procedures of IOL and how to limit time for serving lives of kids, loss of blood, time of suffering for our patients, and utterly terrible pregnancy outcomes.

## 1.6 Research Questions

### 1.6.1 Overall Research Question

What is the Magnitude and factors associated with failed induction of labour with vaginal dinoprostone and maternal/foetal outcomes at Muhimbili National Hospital from January 2020 to December 2022?

### 1.6.2 Specific Research Questions

1. What is the magnitude of failed induction of labour with vaginal dinoprostone at Muhimbili National Hospital?
2. What are the factors associated with failed induction of labour with vaginal dinoprostone at Muhimbili National Hospital?
3. What are the maternal/foetal outcomes after failure of induction of labour with vaginal dinoprostone at Muhimbili National Hospital?

## 1.7. Objectives

### 1.7.1 Broad Objective

To determine magnitude and factors associated with failed induction of labour with vaginal dinoprostone and maternal/foetal outcomes at Muhimbili National Hospital from January 2020 to December 2022.

### 1.7.2 Specific Objectives

1. To determine the magnitude of failed induction of labour with vaginal dinoprostone at Muhimbili National Hospital.
2. To determine the factors associated with failed induction of labour with vaginal dinoprostone at Muhimbili National Hospital.
3. To identify the maternal/foetal outcomes after failure of induction of labour with vaginal dinoprostone at Muhimbili National Hospital.

# 2.0 MATERIALS AND METHODS

## 2.1 Study Design

Hospitals based retrospective cohort study (26), whereby a researcher observed and retrieved information from all files of women, who underwent induction of labour by using dinoprostone from January 2020 to December, 2022**.**

## 2.2 Study Area

The study was carried out in the Dar es Salaam region. It included one tertiary hospital with two branches, MNH Upanga and Mloganzila, which are National referral Hospitals in the United Republic of Tanzania, as well as teaching hospitals for Muhimbili University of health and allied science (MUHAS) students. MNH Upanga is situated at Upanga west with a capacity of more than 1800 beds, including more than 350 beds in the maternity wing. The maternity wing has three patient blocks and a Maternity theatre.

The main block contains four wards for prenatal admission and holding post-natal patients without complications. There is also a special ward for those who require critical care services, as well as those who require particular attention (cases such as Pre-eclampsia) and a labour ward. Another maternity block has three wards: one on the first floor for mothers who delivered premature babies (for kangaroo), one on the second floor for mothers whose children are admitted to the NICU for various reasons, and one on the third floor for staff and insured patients whose children are temporarily admitted. The final ward is Executive (VIP) which is also as fast truck ward 43

Induction of labour process is initiated in the appropriate patient's ward, and when the patient is in active phase with cervix dilation greater than or equal to 4cm and acceptable effacement, she is transferred to the labour room for monitoring and delivery.

When failure of induction is diagnosed by the attending resident and Specialist on call, emergency C/S is planned, 4 theatre rooms are allocated within the Maternity block.

MNH –MLOGANZILA: This is the branch of MNH situated at Mloganzila residential area 30.4km away from MNH –Upanga via Morogoro Road, MNH Mloganzira it has a capacity of 608 beds, where 124 beds are in maternity block which has two main wards 1$^{st}$ in level 4

where all post-delivery are kept and 2nd in level 5 where all mothers waiting for Delivery are kept and all critical condition and HDU is available, labour room is found in the second floor which has a theatre with two operating rooms, this is where all C/S are done after failure of IOL. Other special patient like VIP are kept in VIP room at level 9 but are visited accordingly as routine

MNH Upanga and Mloganzila Hospitals receives referral and non-referral patients from other hospitals surrounding Dar es Salaam and far away who require specialized and non-specialized care, although these two hospitals have personnel of varying degrees. MNH Upanga has 25 Obstetrics and Gynaecology specialists, 245 nurses, 8 Medical officer (MO), 9-16 Intern doctors depending on the rotating group, and 34 Resident doctors. These staff members work in shifts, with each shift consisting of 1 specialist, 2-3 Resident/MO, 2-4 Intern Doctors, and 2-3 nurses. There are 9 Obstetric and Gynaecologist specialists, 63 Nurses, 3 MO, and 8-12 Intern Doctors in Mloganzila Hospital, depending on the rotating group. Each shift has one specialist, two resident doctors, three intern doctors, and four nurses.

Patients are treated and examined by a team of Obstetrician and Gynaecologists, Resident physicians, Medical officers, and Nurse Midwives in both hospitals. There is a major ward round that is held weekly with all obstetricians, residents, intern doctors, nurses, pharmacists, and undergraduate students. During the major ward round, patients are discussed in order of severity, beginning with those who are very serious or urgent, followed by any interested case for a student's presentation, and other patients are discussed in order of their condition.

Every day, residents and intern doctors do inter-round reviews on patients and tell the Obstetrics and Gynaecology on call on all patient well-being. Obstetrician and gynaecologist specialists decide who has criteria for induction of labour and which methods would be employed, the patient and family are told about the procedures to be used, and if they should purchase the medications to be used for induction. Bishop Score is performed prior to induction of labour by either resident or intern doctors under the guidance of a specialist. A Bishop score of 6 or above indicate that the cervix is favourable for progression into labour and that the mother could deliver vaginally.

During ward rounds, elective patients for IOL are evaluated by a team of doctors and nurses about the reasons for induction of labour, and residents administer vaginal Dinoprostone, but for emergency Induction can occur at any moment; if the ward team is still there, they normally deal with the patient; if they are not present, the on-call resident is alerted, and can then inform the specialist on call for further clarity on the protocol.

Clear information or a description regarding the patient's name, age, time of insertion, and time of next review of the patient who is induced is posted on the ward announcement board and kept in the patient's file. In the MNH procedure, IOLs with 3mg Dinoprostone are placed in the posterior fornix at 12-hour intervals; the patient required a second dosage if no cervical changes occur after the first dose of vaginal Dinoprostone. Total of two doses are expected in 24hrs. These drugs are under individual patient costs

Failure of induction of labour is diagnosed after a review with a specialist and other on-call staff, and it occurs when the patient fails to enter the active phase of labour or has no cervical changes despite the application of two doses of vaginal Dinoprostone 3mg at 12-hour intervals in a 24-hour period. Those who fail induction of labour according to procedure are delivered using other means such as C/S.

**2.3 Study Population**

The study population included all pregnant women who were induced with vaginal Dinoprostone tabs at Gestation Age of 28 weeks or above in MNH between 1st January 2020 and 31st December, 2022.

**2.4 Study Sample**

All women with GA >=28 weeks who had IOL with vaginal Dinoprostone between 1st Jan, 2020 to 31st December, 2022

**2.5 Sample Size**

The study's sample size was from women, who underwent Induction of labour with vaginal Dinoprostone from 1st January 2020 to 31st Dec, 2022.

The sample size was calculated using Leslie Kish formula 1965 as below

$N = Z^2\ p(1-p)/e^2$,

Where

"N" stands for Sample size,

"Z" stands for Z score at 95% confidence level = 1.96,

"p" for Proportion of failed induction of labour from pregnant women at a tertiary hospital in North Tanzania =26.75% (27) and

"e" for margin of error at 4%.

Thus,

$N=1.96^2$ X 26.75 (100%-26.75%)/$4^2$

N= 470

Plus 10% for missing data which was 47 (28)

Therefore the minimum required sample size was 517 dinoprostone induced pregnant women.

To allocate sample size from each study site (MNH-Upanga and Mlonganzila), the Bourley's proportional allocation formula below was used to determine how many participants were to be selected from each site.

$$n_b = \frac{n(n)}{N}$$

Where $n_b$: Bourley's proportional allocation

n: Total sample size (517)

*n*: Population allocated to respondent groups ,N: Population of the study

As previously stated Bourley's Proportional Allocation Technique was used to allocate the sample size needed from MNH-Upanga and MNH-Mloganzila (29).

Table 1: Sampling Distribution using Bourley's Proportional Allocation Technique

| **Study site** | **Population allocated to respondent groups** | **Sample Size Distribution Using Bourley's Technique** |
|---|---|---|
| MNH-Upanga | 990 | 360 |
| MNH-Mloganzila | 440 | 157 |
| **TOTAL** | **1336** | **517** |

### 2.5 Variables

#### 2.5.1 Dependent variables

IOL with vaginal dinoprostone which can be succeeded or failed

#### 2.5.2 Independent variables

Socio-demographic variables

- Age
- Education level
- Occupation
- Marital status
- Residence

Obstetrics related variables

- Parity
- Gestational age
- Bishop score
- Patients strong contraction
- Postdate pregnancy
- Premature rapture of membrane
- Pregnancy induced hypertension
- Diabetes mellitus
- Antepartum haemorrhage
- Oligohydromnious
- Polyhydromnious
- Dinoprostone dose

### 2.6 Sampling Procedure

The registry data base was used to obtain the files numbers of all women who underwent IOL using any procedure. Then, using research assistant, those who were induced with dinoprostone were distinguished from others, but also tracked down and evaluated for eligibility. Moreover, all eligible women were assigned unique number (such as 1 to 990 for MNH-Upanga and 991 to 1420 for MNH-Mloganzila). After that, by using online random number generator (https://stattrek.com/statistics/random-number-generator), assigned unique numbers were randomly selected to attain a required sample in each site (360 for MNH-Upanga and 157 for MNH-Mloganzila) so as to make a total of 517 required sample size. Finally, the patients' files were retrieved and data were collected until the required sample size was obtained.

### 2.7 Inclusion Criteria

i. Women who were induced with dinoprostone from 28 weeks of gestation onwards
ii. Women with Tanzanian nationality

### 2.8 Exclusion Criteria

-Women with missing information on mode of delivery
-Files of women with GA less than 28weeks
-Women with IUFD

### 2.9 Data Collection Procedure

Data was collected through the labour ward birth registry data base, which included identification of all patients' files numbers of those who experienced induction of labour with any method, followed by retrieval of case notes of those who were induced with vaginal dinoprostone. Registration numbers for women who underwent induction noted, and their files were traced from medical records for evaluation by a research assistant. The principal investigator reviewed patient information from the files and gathered required

data. To assure the tracking of the needed file, one research assistant was present to each studying area at both MNH Upanga and Mloganzila.

**2.10 Data Collection Tools**

The data collecting tool was adopted and customized and divided into four sections: the first for socio-demographic variables, the second for patient prior medical history and clinical features of maternal foetal, the third for Induction of labour process with mode of delivery, and the final for maternal and foetal outcomes after caesarean section. Data were retrieved from patient files and entered into the data collecting tool via questionnaires.

**2.11 Pre-testing of data collection tool**

Before the study began, the data collection tool was pre-tested at Muhimbili National Hospital. This pre-test area was chosen with consideration that the research was planned to be conducted at the same area and it would be difficult to get the ethical clearance for pre testing somewhere else different from MNH. A total number of 52 files which is 10% of all patients required for whole research, who underwent IOL with vaginal dinoprostone was involved to check whether questions set up and response are clear, appropriate, consistent, logical and well-ordered so as to create valid and reliable data. Necessary changes to the check list were made.

Pre-test of data tool were conducted for three days in a week from 800hours to 1600hours, started with introducing of research assistant to the medical record staffs and other required member of staff to make them easy access of the data from registry office. Primary researcher with research assistant gathered data and filled in the collection tool. Later, these pre test data was of important to my research plan and to assure the presence or available of the data but also was of important to create valid and reliable data which was used as a guidline to make changes in the check list (Collection tool)

**2.12 Data Analysis**

Data were entered in excel sheet and then cleaning was done to ensure quality and consistent. Data were then entered into STATA version 15.1 whereby descriptive statistics were summarized as mean and standard deviation (SD) for continuous variables and

proportions for categorical variables. Group differences for categorical and continuous variables with FIOL with vaginal dinoprostone were examined using Chi square/Fishers exact test. Then, bivariable Robust Poisson regression analysis was performed to identify factors associated with FIOL with vaginal dinoprostone among women admitted for delivery at MNH depending on the crude cumulative incidence ratio (cCIR) with 95% CI. All factors with $p<0.2$ bivariable Robust Poisson regression analysis were subjected for Multivariable Robust Poisson regression analysis to examine the associations between the outcome variable and independent variables after adjustment for other variables. Associations in the Multivariable Robust Poisson regression analysis models were presented as adjusted cumulative incidence ratios (aCIR) with 95% CI. A two-sided *p*-value less than 0.05 was considered significant (17,30,31) .

**2.13 Ethical Consideration**

Ethical clearance was obtained from Muhimbili University of Health and Allied sciences Senate Research and Publication Committee Ref. **No.DA.282/298/01.C/1508** as well as permission to conduct the study was obtained from Head of Clinical Research, Training and Consultancy Unit under the Executive Director of MNH and Head of the department of MNH Upanga (Ref no MNH/CRTCU/Perm/2024/087) and Mloganzila (Ref.: JA.294/428/01B/156). Permission was obtained from the in-charge of the wards, and medical records. Patient's consent was not requested in this study as the study did not involve the human subjects directly rather use patient documents, so waiver for consent was requested from head of research and publication, MNH (Upanga and Mloganzila) Institution Review Board. To maintain anonymity and confidentiality, patients' names and information remained highly confidential and used by the research team only, the checklist did not contain any name of the patients. All responses form for the reviewed case notes were coded and the case identification was anonym zed. The study's data will be used for academic reasons only and will be deleted five years after the results have been disseminated and published.

# 3.0 RESULTS

## 3.1 Socio-demographic and obstetric characteristics among women admitted for delivery at MNH from 1st January 2020 to 31st December, 2022 (N = 517)

A total of 517 women admitted for delivery at MNH-Upanga 69.6% (360/517) and MNH-Mloganzila 30.4% (157/517) had mean age, GA, parity and Bishop score of 30.55 ± 5.80 years, 38 ± 2 weeks, 3 ± 1 children and 7.42 ± 0.82 respectively were enrolled in the study. Of these, 52.4% (271/517) were aged above 30 years old, 53.0% (274/517) had a GA of 37 to 40 weeks, 75.0% (390/517) had a parity of greater than one and 86.3% (436/505) had Bishop score of greater or equal to seven. Majority of the enrolled women 91.9% (475/517) were from Dar es Salaam and attended secondary level of education 45.4% (225/496). Furthermore, 61.1% (312/511) of the women not employed by the government and 81.0% (419/517) were married. Majority of all recruited women 80.1% (414/517) were induced two doses of dinoprostone whereby 56.8% (284/505) of them were induced due to PIH. Only, 20.9% (108/517) of the women were in postdate pregnancy and a minimal proportion of them 3.1% (16/517) had a chromic illness commonly chronic hypetension. Moreover, 18.4% (95/5176) of the women had strong contraction and few of them 1.4% (7/517) their membrane raptured prematurely. Pregnancy induced hypertension was common to most of the recruited women 58.4% (302/517) compared to diabetes mellitus 1.7% (9/517). Additionally, Oligohydromnious and Polyhydromnious accounted 20.3% (105/517) and 10.1% (52/517) of all enrolled women respectively. Lastly, 66.9% (346/517) of the women delivered vaginally (Table 1).

**Table 2: Socio-demographic and obstetric characteristics among women admitted for delivery at MNH from 1st January 2020 to 31st December, 2022 (N = 517)**

| Variable | Frequency (n) | Proportion (%) |
|---|---|---|
| **Study site** | | |
| MNH-Upanga | 360 | 69.6 |
| MNH-Mloganzila | 157 | 30.4 |
| **Mean age = 30.55 ± 5.80 years** | | |
| Age group (years) | | |
| ≤30 | 246 | 47.6 |
| >30 | 271 | 52.4 |
| **Mean parity = 3 ± 1 children** | | |
| Parity (children) | | |
| 1 | 130 | 25.0 |
| >1 | 390 | 75.0 |
| **Mean GA at times of induction = 38 ± 2 weeks** | | |
| GA at times of induction (weeks) | | |
| <37 | 135 | 26.1 |
| 37–40 | 274 | 53.0 |
| ≥41 | 108 | 20.9 |
| **Mean Bishop score= 7.42 ± 0.82** | | |
| Bishop score | | |
| <7 | 69 | 13.7 |
| ≥7 | 436 | 86.3 |
| **Missing** | **12** | |
| **Residence** | | |
| Out of DSM | 42 | 8.1 |
| DSM | 475 | 91.9 |
| **Education level** | | |
| Primary and below | 179 | 36.1 |
| Secondary | 225 | 45.4 |
| College/University | 92 | 18.5 |
| **Missing** | **21** | |
| **Occupation** | | |
| Employed | 199 | 38.9 |
| Unemployed | 312 | 61.1 |
| **Missing** | **6** | |
| **Marital status** | | |
| Single | 90 | 17.4 |
| Married | 419 | 81.0 |
| Separated | 8 | 1.6 |

| | | |
|---|---|---|
| **Reason for induction** | | |
| Oligohydramnios | 66 | 13.1 |
| PIH | 284 | 56.8 |
| Polyhydramnios | 44 | 8.7 |
| Postdate | 108 | 21.4 |
| **Missing** | **12** | |
| **Postdate pregnancy** | | |
| No | 409 | 79.1 |
| Yes | 108 | 20.9 |
| **Chronic illness** | | |
| No | 501 | 96.9 |
| Yes | 16 | 3.1 |
| **Patient strong contraction** | | |
| No | 422 | 81.6 |
| Yes | 95 | 18.4 |
| **Premature rupture of membrane** | | |
| No | 510 | 98.7 |
| Yes | 7 | 1.4 |
| **Pregnancy induced hypertension** | | |
| No | 215 | 41.6 |
| Yes | 302 | 58.4 |
| **Diabetes Mellitus** | | |
| No | 508 | 98.3 |
| Yes | 9 | 1.7 |
| **Oligohydramnios** | | |
| No | 412 | 79.7 |
| Yes | 105 | 20.3 |
| **Polyhydramnios** | | |
| No | 465 | 89.9 |
| Yes | 52 | 10.1 |
| **Dinoprostone doses given** | | |
| One | 103 | 19.9 |
| Two | 414 | 80.1 |
| **Mode of delivery** | | |
| C/S | 171 | 33.1 |
| SVD | 346 | 66.9 |

### 3.2 Overall and cumulative incidence of FIOL with vaginal dinoprostone among women admitted for delivery at MNH from 1st January 2020 to 31st December, 2022 with participant's socio-demographic and clinical characteristics

The overall cumulative incidence of failed induction of labour with vaginal dinoprostone among pregnant women admitted at MNH from 1st January 2020 to 31st December, 2022 was found to be 33.1% (171/517) (Figure 2) whereby at Upanga was 30.3% (105/347) and Mloganzila was 38.8% (66/170) (Figure 3). The significant differences in the proportions of short FIOL with participant's socio-demographic and obstetric characteristics were observed in age, residence, reason for induction, chronic illness, pregnancy induced hypertension, diabetes mellitus and oligohydramnios ($p<0.05$). In the case of age, women with greater than 30 years were more found to have failure in vaginal dinoprostone induction 37.6% (102/2711) than those with less or equal to 30 years 28.1% (69/246) ($p=0.021$). Also, a high proportion of induction failure was seen among women residing out of DSM 73.8% (31/42) compared to those who were from DSM 29.5% (140/475) ($p<0.0001$). Furthermore, the proportion of FIOL with vaginal dinoprostone among women who were induced due to PIH 38.0% (109/287) was found to be slightly high compared to women induced due to polyhydramnios 36.4% (16/44), postdate 29.6% (32/108) and oligohydramnios 19.7% (13/66) ($p=0.028$). Additionally, women with chronic illness had greater proportion of induction failure 68.7% (11/16) when compared to those without chronic illness 31.5% (106/336) ($p=0.002$). Moreover, proportion of FIOL among women with pregnancy induced hypertension was greater 38.4% (116/302) compared to women without pregnancy induced hypertension 25.6% (55/215) ($p=0.002$). Lastly, women without oligohydramnios had a slightly high proportion 35.2% (145/412) as compared to those with Oligohydramnios 24.8% (26/105) ($p=0.002$).

On the other side, the differences of FIOL with vaginal dinoprostone observed in parity, GA, Bishop score, education level, occupation, marital status, postdate pregnancy, patient strong contraction, premature rupture of membrane, polyhydramnios and dinoprostone doses given were not significant ($p \geq 0.05$) (Table 2).

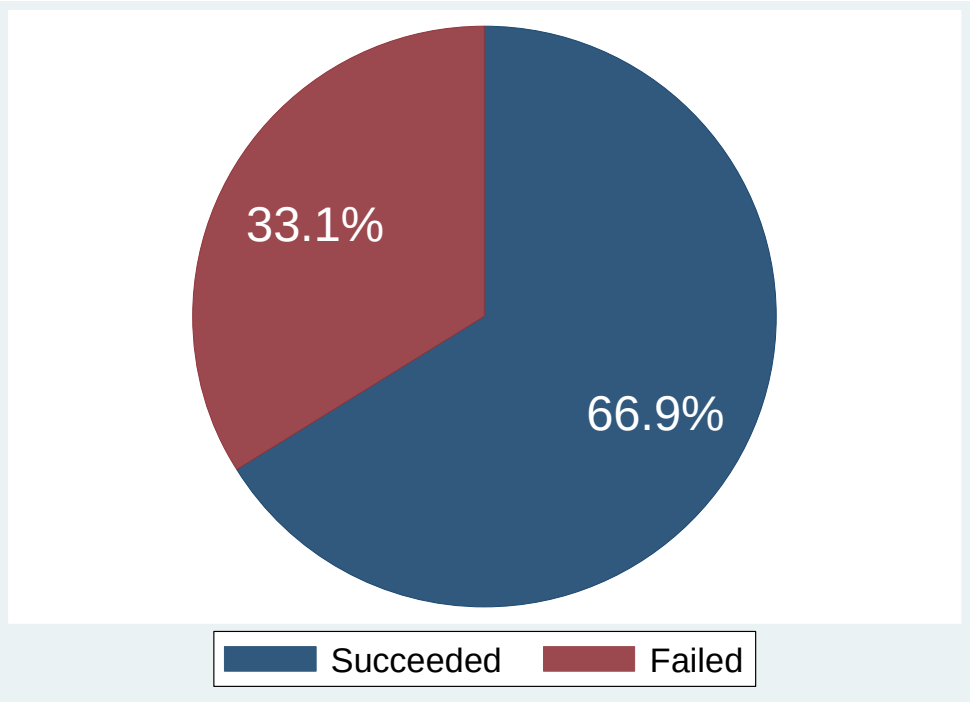



**Figure 2: Cumulative incidence of FIOL with vaginal dinoprostone among pregnant women admitted for delivery at MNH from 1st January 2020 to 31st December, 2022**

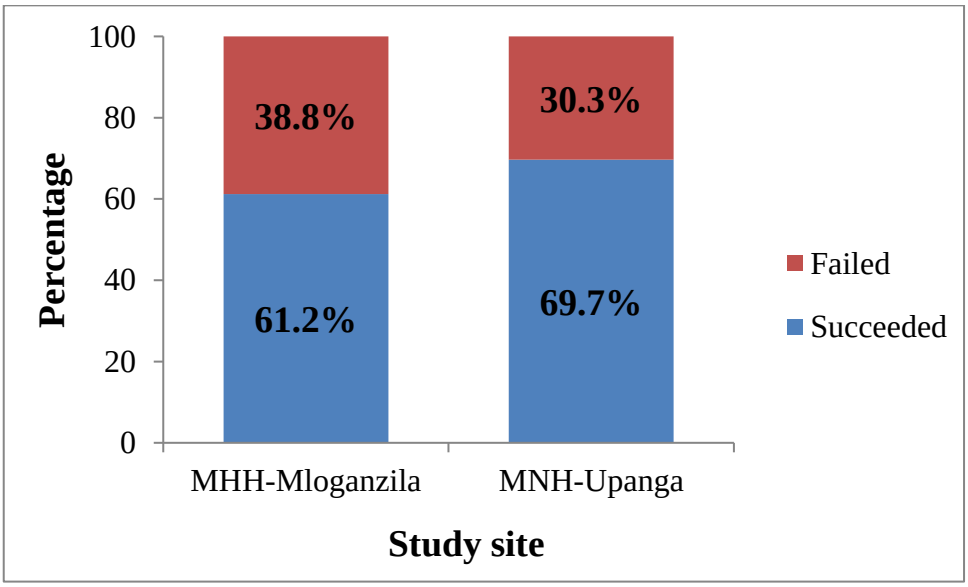



**Figure 3: Cumulative incidence of FIOL with vaginal dinoprostone among pregnant women admitted for delivery at MNH-Mloganzila and MNH-Upanga from 1st January 2020 to 31st December, 2022**

Table 3: Cumulative incidence of FIOL with vaginal dinoprostone by socio-demographic and obstetric characteristics among women admitted for delivery at MNH from 1st January 2020 to 31st December, 2022 (Chi-square and Fisher's exact test).

| **Variable** | **Total** | **IOL with vaginal dinoprostone** | | ***p*-value** |
|---|---|---|---|---|
| | | **Succeeded, n(%)** | **Failed, n(%)** | |
| **Age group (years)** | | | | **0.021** |
| ≤30 | 246 | 177 (71.9) | 69 (28.1) | |
| >30 | 271 | 169 (62.4) | 102 (37.6) | |
| **Parity (children)** | | | | 0.061 |
| 1 | 129 | 95 (73.6) | 34 (26.4) | |
| >1 | 388 | 251 (64.7) | 137 (35.3) | |
| **GA at times of induction (weeks)** | | | | 0.134 |
| <37 | 135 | 81 (60.0) | 54 (40.0) | |
| 37–40 | 274 | 189 (69.0) | 85 (31.0) | |
| ≥41 | 108 | 76 (70.4) | 32 (29.6) | |
| **Bishop score** | | | | 0.173 |
| <7 | 69 | 51 (73.9) | 18 (26.1) | |
| ≥7 | 436 | 286 (65.6) | 150 (34.4) | |
| **Residence** | | | | **<0.0001** |
| Out of DSM | 42 | 11 (26.2) | 31 (73.8) | |
| DSM | 475 | 335 (70.5) | 140 (29.5) | |
| **Education level** | | | | 0.946 |
| Primary and below | 179 | 119 (66.5) | 60 (33.5) | |
| Secondary | 225 | 151 (67.1) | 74 (32.9) | |
| College/University | 92 | 63 (68.5) | 29 (31.5) | |
| **Occupation** | | | | 0.878 |
| Employed | 199 | 132 (66.3) | 67 (33.7) | |
| Unemployed | 312 | 209 (67.0) | 103 (33.0) | |
| **Marital status** | | | | 0.184 |
| Single | 90 | 53 (68.9) | 37 (41.1) | |
| Married | 419 | 288 (68.7) | 131 (31.3) | |
| Separated | 8 | 5 (62.5) | 3 (37.5) | |
| **Reason for induction** | | | | **0.028** |
| Oligohydramnios | 66 | 53 (80.3) | 13 (19.7) | |
| PIH | 287 | 178 (62.0) | 109 (38.0) | |
| Polyhydramnios | 44 | 28 (63.6) | 16 (36.4) | |
| Postdate | 108 | 76 (70.4) | 32 (29.6) | |
| | | | | 0.392 |

| | | | | |
|---|---|---|---|---|
| **Postdate pregnancy** | | | | |
| No | 409 | 270 (66.0) | 139 (34.0) | |
| Yes | 108 | 76 (70.4) | 32 (29.6) | |
| **Chronic illness** | | | | **0.002** |
| No | 501 | 341 (68.1) | 160 (31.9) | |
| Yes | 16 | 5 (31.3) | 11 (68.7) | |
| **Patient strong contraction** | | | | 0.269 |
| No | 422 | 287 (68.0) | 135 (32.0) | |
| Yes | 95 | 59 (62.1) | 36 (37.9) | |
| **Premature rupture of membrane** | | | | 0.690 |
| No | 510 | 342 (67.1) | 168 (32.9) | |
| Yes | 7 | 4 (57.1) | 3 (42.9) | |
| **Pregnancy induced hypertension** | | | | **0.002** |
| No | 215 | 160 (74.4) | 55 (25.6) | |
| Yes | 302 | 186 (61.6) | 116 (38.4) | |
| **Oligohydramnios** | | | | **0.043** |
| No | 412 | 267 (64.8) | 145 (35.2) | |
| Yes | 105 | 79 (75.2) | 26 (24.8) | |
| **Polyhydramnios** | | | | 0.709 |
| No | 465 | 310 (66.7) | 155 (33.3) | |
| Yes | 52 | 36 (69.2) | 16 (30.8) | |
| **Dinoprostone doses given** | | | | 0.165 |
| One | 103 | 63 (61.2) | 40 (38.8) | |
| Two | 414 | 283 (68.4) | 131 (31.6) | |

### 3.3 Bivariable and Multivariable Robust Poisson's regression for the factors associated with FIOL with vaginal dinoprostone among women admitted for delivery at MNH from 1st January 2020 to 31st December, 2022 with participant's socio-demographic and clinical characteristics

Bivariable Robust Poisson's regression analysis revealed that age, residence, reason for induction, chronic illness and pregnancy induced hypertension were significantly associated with FIOL with vaginal dinoprostone among women admitted for delivery at MNH (Table 3).

On multivariable Robust Poisson's regression analysis, the factors that were independently associated with FIOL with vaginal dinoprostone among women admitted for delivery at MNH were residence, chronic illness and pregnancy induced hypertension. With regards to residence, women from outside DSM had a cumulative incidence of FIOL with vaginal

dinoprostone that was 2.21 times greater compared to those residing within DSM (aCIR=2.21, 95% CI=1.68-2.91, *p*<0.0001). Similarly, women with chronic illness had 2.20 times more cumulative incidence of FIOL with vaginal dinoprostone as compared to women without chronic illness (aCIR=2.20, 95% CI=1.34-3.62, *p*=0.002). Lastly, the cumulative incidence of FIOL with vaginal dinoprostone was 2.39 times higher among women with pregnancy induced hypertension (aCIR=2.39, 95% CI=1.59-3.60, *p*=0.002) compared to those without pregnancy induced hypertension (Table 3).

**Table 4: Bivariable and Multivariable Robust Poisson regression analysis of the factors associated with FIOL with vaginal dinoprostone among women admitted for delivery at MNH from 1st January 2020 to 31st December, 2022.**

| Variable | FIOL, n(%) | Bivariable Robust PR | | Multivariable Robust PR | |
|---|---|---|---|---|---|
| | | cCIR (95%CI) | *p*-value | aCIR (95%CI) | *p*-value |
| **Age group (years)** | | | | | |
| ≤30 | 69 (28.1) | Ref | | Ref | |
| >30 | 102 (37.6) | 1.34 (1.04-1.73) | **0.022** | 1.32 (0.94-1.85) | 0.112 |
| **Parity** | | | | | |
| 1 | 34 (26.4) | Ref | | Ref | |
| >1 | 137 (35.3) | 1.34 (0.97-1.84) | 0.072 | 1.13 (0.67-1.48) | 0.974 |
| **GA in weeks at times of induction** | | | | | |
| <37 | 54 (40.0) | 1.35 (0.94-1.93) | 0.099 | 1.12 (0.53-2.37) | 0.756 |
| 37–40 | 85 (31.0) | 1.01 (0.72-1.40) | 0.791 | 0.99 (0.49-2.03) | 0.984 |
| ≥41 | 32 (29.6) | Ref | | Ref | |
| **Bishop score** | | | | | |
| <7 | 18 (26.1) | Ref | | Ref | |
| ≥7 | 150 (34.4) | 1.32 (0.87-2.00) | 0.195 | 1.14 (0.75-1.73) | 0.538 |
| **Residence** | | | | | |
| Out of DSM | 31 (73.8) | 2.50 (1.99-3.15) | **<0.0001** | 2.21 (1.68-2.91) | **<0.0001** |
| DSM | 140 (29.5) | Ref | | Ref | |
| **Education level** | | | | | |
| Primary and below | 60 (33.5) | 1.06 (0.74-1.53) | 0.742 | | |
| Secondary | 74 (32.9) | 1.04 (0.73-1.49) | 0.815 | | |
| College/University | 29 (31.5) | Ref | | | |
| **Occupation** | | | | | |
| Employed | 67 (33.7) | 1.02 (0.79-1.31) | 0.878 | | |
| Unemployed | 103 (33.0) | Ref | | | |
| **Marital status** | | | | | |
| Single | 37 (41.1) | 1.31 (0.99-1.75) | 0.060 | 1.59 (0.97-1.47) | 0.074 |
| Married | 131 (31.3) | Ref | | Ref | |
| Separated | 3 (37.5) | 1.20 (0.48-2.97) | 0.694 | 1.14 (0.48-2.72) | 0.771 |

| | | | | | |
|---|---|---|---|---|---|
| **Reason for induction** | | | | | |
| Oligohydramnios | 13 (19.7) | Ref | | Ref | |
| PIH | 109 (38.0) | 1.93 (1.16-3.21) | **0.012** | 0.48 (0.22-1.03) | 0.059 |
| Polyhydramnios | 16 (36.4) | 1.85 (0.99-3.45) | 0.055 | 0.99 (0.44-2.25) | 0.996 |
| Postdate | 32 (29.6) | 1.50 (0.85-2.65) | 0.159 | 1 (Omitted) | |
| **Postdate pregnancy** | | | | | |
| No | 139 (34.0) | Ref | | | |
| Yes | 32 (29.6) | 0.87 (0.63-1.20) | 0.402 | | |
| **Chronic illness** | | | | | |
| No | 160 (31.9) | Ref | | Ref | |
| Yes | 11 (68.7) | 2.15 (1.51-3.07) | **<0.0001** | 2.20 (1.34-3.62) | **0.002** |
| **Patient strong contraction** | | | | | |
| No | 135 (32.0) | Ref | | Ref | |
| Yes | 36 (37.9) | 1.18 (0.88-1.59) | 0.257 | 1.24 (0.90-1.71) | 0.182 |
| **Premature rupture of membrane** | | | | | |
| No | 168 (32.9) | Ref | | | |
| Yes | 3 (42.9) | 1.30 (0.55-3.09) | 0.551 | | |
| **Pregnancy induced hypertension** | | | | | |
| No | 55 (25.6) | Ref | | Ref | |
| Yes | 116 (38.4) | 1.50 (1.15-1.97) | **0.003** | 2.39 (1.59-3.60) | **<0.0001** |
| **Oligohydramnios** | | | | | |
| No | 145 (35.2) | Ref | | Ref | |
| Yes | 26 (24.8) | 0.70 (0.49-1.01) | 0.055 | 0.73 (0.45-1.17) | 0.190 |
| **Polyhydramnios** | | | | | |
| No | 155 (33.3) | Ref | | | |
| Yes | 16 (30.8) | 0,92 (0.60-1.42) | 0.714 | | |
| **Dinoprostone doses given** | | | | | |
| One | 40 (38.8) | 1.23 (0.93-1.63) | 0.153 | 1.33 (0.94-1.88) | 0.108 |
| Two | 131 (31.6) | Ref | | Ref | |

*__cCIR__, __aCIR__ and __Ref__ represent __crude Cumulative Incidence Ratio__, __adjusted Cumulative Incidence Ratio__ and __Reference__ respectively

### 3.3 Fetal and maternal outcomes after failure of induction of labour with vaginal dinoprostone at MNH from 1st January 2020 to 31st December, 2022

The current study assessed maternal and fetal outcome after failure of induction of labour with vaginal dinoprostone.

The most common encountered maternal outcome was non-reassurance fetal status 52.6% (90/171) then followed by prolonged hospital stay 26.3% (45/171) and postpartum v haemorrhage 12.9% (22/171). There was neither acute kidney injury nor any death occurred among women (Table 4).

On the other side, most observed fetal outcome was admission to NICU 15.2% (26/171) then followed by low Apgar score 11.7% (20/171) and asphyxia 3.5% (6/171). There was nor any stillbirth seen among new-borns babies (Table 4).

Table 5: Fetal and maternal outcomes following caesarean section delivery at Muhimbili National Hospital

| OUTCOMES | Frequency (N) | Proportion (%) |
|---|---|---|
| **MATERNAL OUTCOMES** | | |
| Non re-assurance fetal status | 90 | 52.6 |
| Prolonged hospital stay | 45 | 26.3 |
| Postpartum haemorrhage | 22 | 12.9 |
| Acute kidney injury | 0 | 0 |
| Death | 0 | 0 |
| **FETAL OUTCOMES** | | |
| Admission to NICU | 26 | 15.2 |
| Low APGAR Score at 5 min | 20 | 11.7 |
| Asphyxia | 6 | 3.5 |
| Stillbirth | 0 | 0 |
| **TOTAL** | **171** | **100** |

## 4.0 DISCUSSION

The current study reported the cumulative incidence of 33.1% of FIOL with vaginal dinoprostone. The reported cumulative incidence resembles with the reported one by Demssie E. A *et al.* in Adama Hospital Ethiopia 29.6% (2022) (9), 32.4% in Lagos State teaching university Hospital-Nigeria by Abisowo O *et al.* 2017 (32). However the magnitude of cumulative incidence of failed IOL reported in this study was found higher compared to the study done by different researchers in different parts of the world like 18.1% by Khan *et al.* (2012) (33) in Karachi-Pakistan, 21.4% in Jimma University Hospital-Ethiopia by Gima W et al in 2016(18), 16% in Saudi Arabia (34), 21.3% Mulatu desta *et al.* in Arsi university Teaching Hospital- Ethiopia (2020) (15). On contrary the results of this study is encouraging as it's cumulative incidence of failed IOL comparatively lower to other studies conducted in different countries by Bello F *et al.* (2016) 36.5% in Nigeria (35), 37.5% in France by Kerbage Y *et al.* (2020) (36), 38.3% at MNH Tanzania by Shweta Jaiswa *et al.* (2024) (5), 40.3% in Addis Ababa-Ethiopia by Girma W *et al.* (2016 ) (18),42.1% by A.D *et al.* (2017) at Wolliso St. Luke Catholic Hospital- Oromia Ethipoia (37) and 50.5% at Odisha City of east India by Tripathy P *et al.* (2016) (38). The lower cumulative incidence observed in this research study may be due to the diversity of reasons but mentioning few; exclusion of women who were induced with other methods rather than Dinoprostone vaginal tabs, difference in sample size, geographical setting of the study population others may be nature of the study designs, difference in Induction protocol and data collection tool arrangement. Generally results of this study theoretically can be explained to have the cumulative incidence which is within the average comparing with various studies results attained in different parts of the world.

In this current study, the factors that were found to associate independently with FIOL with vaginal dinoprostone among pregnant women include residence, chronic illness and pregnancy induced hypertension.

The present study showed that women from outside DSM had a cumulative incidence of FIOL with vaginal dinoprostone that was 2.21 times greater compared to those residing within DSM, this resemble the result of the study done at Adama Hospital Medical College-Ethiopia by Demssie E.A *et al.* (2022) whereby the odds ratio of failed induction

among pregnant women who were residing in rural was found to be 1.77 times greater compared to urban (39). Also in 2020, Mulatu Desta *et al*, reported similar findings to this study at Arsi Zone Hospital in Ethiopia in which women living in urban were found to have low odds ratio of FIOL with dinoprostone of 0.364 as compared to women living in rural residence (15). The study done by Tadasse Tsion *et al.* in Ethiopia (2022) (40) and Tarimo C *et al*. (2020) at KCMC strongly agreed with the current study results in the residence (27). This could be because of mothers who are living at rural area facing difficulties to access Health facility timely as a result they lack proper care and early planing where to get delivery service, they also lack detection or prediction of some complication like of PIH and DM early and they may attend ANC late which subject them into possibility of having Difficult labour and failure of IOL

In the current study, mothers who had chronic illness were more likely to FIOL by 2.20 as compared to those without chronic illness. This findings relate with reported ones in Adam Hospital-Ethiopia by Demssie E A *et al* (2022) (9) . This possibly will be due to the reason that HDP increases the risk of utero placenta insufficiency as a result there's compromised function of placenta which cause failure of placenta hormone to respond to the uterotonic drugs by this way may increase likelihood of failure of IOL, and in Karachi parkistan (2012) by Khan *et al* (33) reported women who had higher weight baby with 3.5kg and above had high chance to cause Failure IOL likelihood DM do cause macrosomia and higher weight(big baby) in which DM is among of Chronic condition in pregnancy which may result in failure in IOL which was observed in our study result.

Women who had pregnancy induced hypertension had the chance of 2.39 of FIOL as compared to women without pregnancy induced hypertension. The result is similar with previous reported result by Tadesse *et a.l* (2022) from Gondar University Hospital-Ethiopia (40), who also found greater odds to pregnancy induced hypertensive women with reference to non-pregnancy induced hypertensive women. This might be resulted due to the fact that the treatment of pre-eclampsia is by a tocolytic agents like Magnesium Sulphate which may arrest the progress of labour by lowering calcium level in uterine muscle cells as a result uterine muscle relax, according to several studies MgSO4 when administered to a pregnant mother who is in labour it leads to at least 48hrs delay in the active phase of labour and hence result into failure of IOL due to the fact that IOL is

supposed to complete with expected results within 24hrs in two doses of Vaginal Dinoprostone at the intervals of 12hrs each dose(41).

On the other hand this study reported non-reassurance foetal status, prolonged hospital stay and postpartum haemorrhage as maternal outcomes and admission to NICU, low Apgar score and asphyxia as fetal outcomes following failure of IOL with vaginal dinoprostone, results of this study revealed outcomes which are in line with the results from a study done by Shweta Jaiswa *et al.* (2024) in Tanzania who reported maternal outcome such as PPH and fetal outcomes such as low apgar score at 5 minutes and admission to NICU (5) . Similary, admission to NICU, low apga score and birth asphyxia were observed by Beshir *et al* (2021) at Harari Regional State Hospital (20) . Also other studies done by Abdulkadir Y et al (2020) at Wolliso St Luke Catholic Hospital (1), Girma W et al (2016) at Jimma University Hospital Ethiopia Hospital (18), and Abisowo O *et al.* (2017) in Lagos State university Hospital (32) speculated the same maternal/fetal outcomes as per present study.

## 5.0 CONCLUSION AND RECOMMENDATION

This study aimed to determine the magnitude, factors associated with failed induction of labour using vaginal Dinoprostone tabs and maternal/foetal outcomes at MNH, the results will contributes valuable insight into practices at MNH especially on Induction of labour procedure to both patient who are principal service receiver and medical personnel as service provider. The magnitude of Failed IOL with vaginal dinoprostone among pregnant women at MNH is high and it was found to be associated with residence, chronic illness and pregnancy induced hypertension. Exploration of these factors and preparation for alternative delivery mode prior to IOL intervention is necessary to reduce adverse pregnancy outcomes related to emergency C/S delivery. The use of Dinoprostone for IOL has shown increasing trend with good expected outcome to pregnant mothers who are at term or near term by facilitating the cervix to open then labour begins, though it has been shown failing to achieve when used to premature especially those with pre eclampsia and underwent management with tocolytic agent like Magnesium sulphate. It is important to note that the study sample may not be representative of the overall population; we strongly recommend further studies with larger sample size, should be prospective so as to avoid recall bias or incomplete documentation this will provide more robust evidence on Magnitude and factors associated with failed induction of labour with vaginal dinoprostone and maternal/foetal outcomes in different population setting to confirm the results and to find out the reasons for poor outcome in pre-term pregnancy. We also advice that each case of failed induction should be managed as individual following priorities and expected outcome

## REFERENCES


1. Luke WS, Hospital C, Shewa SW, Luke WS, Hospital C, Shewa SW. Induction of Labor Prevalence and Associated Factors for Its Outcome at Induction of Labor Prevalence and Associated Factors for Its Outcome at Internal Medicine : Open Access. 2020;(January 2017).
2. Banõs N, Migliorelli F, Posadas E, Ferreri J, Palacio M. Definition of Failed Induction of Labor and Its Predictive Factors: Two Unsolved Issues of an Everyday Clinical Situation. Fetal Diagn Ther. 2015;38(3):161–9.
3. Henderson J, Redshaw M. Women ' s experience of induction of labor : a mixed methods study. 2013;92:1159–67.
4. Kagwisage J, Balandya BS, Pembe AB. Health Related Quality of Life Post Labour Induction with Misoprostol Versus. 2020;4(1):58–64.
5. Jaiswal S, Kyejo W, Kilewo C. Maternal and Neonatal Outcome in Pregnant Women Undergoing Induction of Labor at Muhimbili National Hospital, Dar Es Salaam, Tanzania. 2024;1–7. Available from: https://www.researchsquare.com/article/rs-4002773/latest%0Ahttps://www.researchsquare.com/article/rs-4002773/latest.pdf
6. Abdelaziz A, Mahmoud AA, Ellaithy MI, Abees SH. Pre-induction cervical ripening using two different dinoprostone vaginal preparations: A randomized clinical trial of tablets and slow release retrievable insert. Taiwan J Obstet Gynecol [Internet]. 2018;57(4):560–6. Available from: https://doi.org/10.1016/j.tjog.2018.06.016
7. Yosef T, Getachew D. Proportion and Outcome of Induction of Labor Among Mothers Who Delivered in Teaching Hospital, Southwest Ethiopia. Front Public Heal. 2021;9(December):1–7.
8. Tseng JY, Lin IC, Chang WH, Yeh CC, Horng HC, Wang PH. Using dinoprostone vaginal insert for induction of labor: A single institute experience. Taiwan J Obstet Gynecol [Internet]. 2020;59(5):723–7. Available from: https://doi.org/10.1016/j.tjog.2020.07.017
9. Demssie EA, Deybasso HA, Tulu TM, Abebe D, Kure MA, Teji Roba K. Failed induction of labor and associated factors in Adama Hospital Medical College, Oromia Regional State, Ethiopia. SAGE Open Med. 2022;10:205031212210810.
10. Verhoeven CJ, Uytrecht CT Van, Porath MM, Mol BWJ. Risk Factors for Cesarean

Delivery following Labor Induction in Multiparous Women. 2013;2013.

11. Mebratu A. Failed induction of labour and associated factors among women delivered in Jigjiga University Sheik Hassan Yabare Referral Hospital : a cross-sectional study. :1–16.
12. Vogel JP, Souza JP, Gülmezoglu AM. Patterns and Outcomes of Induction of Labour in Africa and Asia: A Secondary Analysis of the WHO Global Survey on Maternal and Neonatal Health. PLoS One. 2013;8(6).
13. Debelo BT, Obsi RN, Dugassa W, Negasa S. The magnitude of failed induction and associated factors among women admitted to Adama hospital medical college: A crosssectional study. PLoS One [Internet]. 2022;17(1 January):1–12. Available from: http://dx.doi.org/10.1371/journal.pone.0262256
14. Nakintu, Dr. Nuru/ Department of Obstetrics and Gyneacology, Makerere University, P. O. Box 7072 Kampala U. ORIGINAL ARTICLES A comparative study of vaginal misoprostol and intravenous oxy- tocin for induction of labour in women with intra uterine fetal death in Mulago Hospital , Uganda. Afr Health Sci. 2001;1(2):55–9.
15. Desta M, Duguma A. The magnitude of failed induction of labor and associated factors among women delivered at public hospitals of arsi zone, southeast Ethiopia, 2020: A cross-sectional study. Int J Gen Med. 2021;14(September):6021–33.
16. Giugliano E, Cagnazzo E, Milillo V, Moscarini M, Vesce F, Caserta D, et al. The risk factors for failure of labor induction: A cohort study. J Obstet Gynecol India. 2014;64(2):111–5.
17. Reichenheim M, Coutinho E. P1-498 Measures and models for causal inference in cross-sectional studies: arguments for the appropriateness of the prevalence or and related logistic regression. J Epidemiol Community Heal. 2011;65(Suppl 1):A204–5.
18. Girma W, Tseadu F, Wolde M. Outcome of Induction and Associated Factors among Term and Post-Term Mothers Managed at Jimma University Specialized Hospital: A Two Years' Retrospective Analysis. Ethiop J Health Sci. 2016;26(2):121–30.
19. CITATION 11.pdf.crdownload.
20. Beshir YM, Kure MA, Egata G, Roba KT. Outcome of induction and associated

factors among induced labours in public Hospitals of Harari Regional State, Eastern Ethiopia: A two years' retrospective analysis. PLoS One [Internet]. 2021;16(11 November):1–16. Available from: http://dx.doi.org/10.1371/journal.pone.0259723

21. Kulhan NG, Kulhan M. Labor induction in term nulliparous women with premature rupture of membranes: Oxytocin versus dinoprostone. Arch Med Sci. 2019;15(4):896–901.
22. Mlodawski J, Mlodawska M, Armanska J, Swiercz G, Gluszek S. Misoprostol vs dinoprostone vaginal insert in labour induction: comparison of obstetrical outcome. Sci Rep [Internet]. 2021;11(1):9077. Available from: https://doi.org/10.1038/s41598-021-88723-5
23. Yadav P, Shrivastava VR. Outcome of induction of labour with dinoprostone at a teaching hospital in Nepal. Int J Reprod Contraception, Obstet Gynecol. 2017;6(4):1170.
24. Lueth GD, Kebede A, Medhanyie AA. Prevalence, outcomes and associated factors of labor induction among women delivered at public hospitals of MEKELLE town-(a hospital based cross sectional study). BMC Pregnancy Childbirth. 2020;20(1):1–10.
25. Di Mascio D, Villalain C, Rizzo G, Morales-Rossello J, Sileo FG, Maruotti GM, et al. Maternal and neonatal outcomes of pregnancies complicated by late fetal growth restriction undergoing induction of labor with dinoprostone compared with cervical balloon: A retrospective, international study. Acta Obstet Gynecol Scand. 2021;100(7):1313–21.
26. Setia MS. Methodology series module 1: Cohort studies. Indian J Dermatol. 2016;61(1):21–5.
27. Tarimo CS, Mahande MJ, Obure J. Prevalence and risk factors for caesarean delivery following labor induction at a tertiary hospital in North Tanzania: A retrospective cohort study (2000-2015). BMC Pregnancy Childbirth. 2020;20(1):1–8.
28. Bujang MA. A step-by-step process on sample size determination for medical research. Malaysian J Med Sci. 2021;28(2):15–27.
29. Olonite OA. Olonite Proportional Allocation Method and the Theory of Sets: The Relevancies Within. SSRN Electronic Journal. 2022. 1–35 p.

30. Ma S. Cumulative Incidence Ratio Plots.
31. Viktorov VA, Varin AN, Grinval'd VM, Maksimov EP, Fomicheva NN, Zavalishin YK, et al. Current state and prospects for development of domestic equipment for hemodialysis with dialyzate regeneration. Biomed Eng (NY). 2003;37(1):16–21.
32. Abisowo O, Oyinyechi A, Olusegun F, Oyedokun O, Motunrayo A, Abimbola O. Feto-maternal outcome of induced versus spontaneous labour in a Nigerian Tertiary Maternity Unit. Trop J Obstet Gynaecol. 2017;34(1):21.
33. Khan NB, Ahmed I, Malik A, Sheikh L. Factors associated with failed induction of labour in a secondary care hospital. J Pak Med Assoc. 2012;62(1):6–10.
34. Al-Shaikh GK, Wahabi HA, Fayed AA, Esmaeil SA, Al-Malki GA. Factors associated with successful induction of labor. Saudi Med J. 2012 Mar;33(3):298–303.
35. Bello F, Akinyotu O. Predictors of successful induction of labour at a tertiary obstetric service in Southwest Nigeria. Trop J Obstet Gynaecol. 2016;33(2):143.
36. Kerbage Y, Senat M V., Drumez E, Subtil D, Vayssiere C, Deruelle P. Risk factors for failed induction of labor among pregnant women with Class III obesity. Acta Obstet Gynecol Scand. 2020;99(5):637–43.
37. A D, MA G, B D, Y A. Induction of Labor Prevalence and Associated Factors for Its Outcome at Wolliso St. Luke, Catholic Hospital, South West Shewa, Oromia. Intern Med Open Access. 2017;07(05).
38. Tripathy P, Pati T, Baby P, Mohapatra SK. Prevalence and predictors of failed induction. Int J Pharm Sci Rev Res. 2016;39(2):189–94.
39. Demssie EA, Deybasso HA, Tulu TM, Abebe D, Kure MA, Teji Roba K. Failed induction of labor and associated factors in Adama Hospital Medical College, Oromia Regional State, Ethiopia. SAGE Open Med. 2022;10.
40. Tadesse T, Assefa N, Roba HS, Baye Y. Failed induction of labor and associated factors among women undergoing induction at University of Gondar Specialized Hospital, Northwest Ethiopia. BMC Pregnancy Childbirth [Internet]. 2022;22(1):1–10. Available from: https://doi.org/10.1186/s12884-022-04476-7

41. Mirzamoradi M, Behnam M, Jahed T, Saleh-Gargari S, Bakhtiyari M. Does magnesium sulfate delay the active phase of labor in women with premature rupture of membranes? A randomized controlled trial. Taiwan J Obstet Gynecol [Internet]. 2014;53(3):309–12. Available from: http://dx.doi.org/10.1016/j.tjog.2013.06.014

# APPENDICES

## Appendix 1: English Version Questionnaire

### DATA COLLECTION TOOL

### MAGNITUDE AND FACTORS ASSOCIATED WITH FAILED INDUCTION OF LABOUR WITH VAGINAL DINOPROSTONE AND MATERNAL/FETAL OUTCOMES AT MUHIMBILI NATIONAL HOSPITAL FROM JANUARY 2020 TO DECEMBER 2022

**PARTICIPANT'S ID NUMBER: …….**

### A: SOCIODEMOGRAPHIC CHARACTERISTICS

1. Age ……..years
2. Parity……..
3. Gestational age:…….weeks
4. Blood pressure……mmHg
    a) SBP……. mmHg
    b) DBP…….. mmHg
5. Residence
    a) Region/City/Urban…….
    b) District/Municipal/Rural……
6. Education level attained

(a) No formal education [ ]

(b) Primary education [ ]

(c) Secondary education [ ]

(d) College/ University education [ ]

7. Occupation

(a) Employed [ ]

(b) Unemployed [ ]

8. Marital status:

   a) Single [ ]
   b) Married [ ]
   c) Widow [ ]
   d) Divorced [ ]
   e) Separated [ ]

B: CLINICAL FEATURES (MATERNAL AND FOETAL)

9. Pre- induction Bishop score of the cervix done

   a) Yes [ ]
   b) No [ ]

10. Bishop score value…….

11. The patient had any chronic illness

   a) Yes [ ]
   b) No [ ]

12. If "Yes" in question 11 mention the chronic illness……

13. Was the foetus alive on admission

a) Yes [ ]

b) No [ ]

14. Patient had strong contraction

   (a)Yes [ ]
   (b) No [ ]

15. Post term pregnancy

   (a)Yes [ ]
   (b) No [ ]

16. Premature rapture of membrane

   (a)Yes [ ]
   (b) No [ ]

17. Intra-uterine growth restriction

(a)Yes [ ]

(b) No [ ]

18. Pregnancy-induced hypertension

(a)Yes [ ]

(b) No [ ]

19. Diabetes Mellitus

(a)Yes [ ]

(b) No [ ]

20. Antepartum hemorrhage

(a)Yes [ ]

(b) No [ ]

21. Oligohydramnios

(a)Yes [ ]

(b) No [ ]

22. Polyhydramnios

(a)Yes [ ]

(b) No [ ]

C: INDUCTION OF LABOR PROCESS AND MODE OF DELIVERY

23. Reason for induction…….

24. Dinoprostone vaginal tabs 3mg used for induction

a) Yes

b) No

25. After Insertion of Dinoprostone the patient stayed on bed for 30mins

a) Yes

b) No

26. Who administered the Dinoprostone

a) Medical Doctor or Specialist

b) A nurse

27. How many doses were used

a) One [ ]

b) Two [ ]

28. Mode of delivery…

    c) SVD [ ]

    d) C/S [ ]

29. The diagnosis of Failed IOL was done by qualified Doctors

    a) Yes [ ]

    b) No [ ]

30. How many hours passed since the last dose to failed IOL diagnosis

    a) ≤8Hrs[ ]

    b) ≥8hrs [ ]

31. After how long caesarean section was performed since identification of failed IOL with Vaginal dinoprostone

    a) ≤1hr [ ]

    b) ≥2Hrs [ ]

**D: MATERNAL AND FETAL OUTCOMES AFTER CAESAREAN SECTION FOLLOWING INDUCTION FAILURE (Adverse pregnancy outcome) i e PPH, Maternal death, Hospital stay, AKI, Uterine a tony, NRFs, abnormal uterine contraction, foetal distress, low apga score, meconium stain, NICU admission, Neonatal asphyxia, HIE, abnormal cervical dilatation**

**32. MATERNAL**

| VARIABLES | RESPONSE |
|---|---|
| POST PARTUM HAEMORRHAGE | YES [ ] |
| | NO [ ] |
| MATENAL DEATH | YES [ ] |
| | NO [ ] |
| PROLONGED HOSPITALISATION | YES [ ] |
| | NO [ ] |
| ACUTE KIDNEY INJURY | YES [ ] |
| | NO [ ] |
| NON REASURANCE FETAL STATUS | YES [ ] |
| | NO [ ] |

**33. FETAL/NEONATE**

| | VARIABLES | RESPONSE |
|---|---|---|
| A | LOW APGA SCORE (BELOW 7) | YES [ ] |
| | | NO [ ] |
| B | PROLONGED HOSPITALISATION | YES [ ] |
| | | NO [ ] |
| C | NEONATAL ASPHYXIA | YES [ ] |
| | | NO [ ] |
| D | NEONATAL DEATH/IUFD | YES [ ] |
| | | NO [ ] |

**Appendix 2: 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/1508 Date: 19/01/2024

MUHAS-REC-01-2023-1508
YARED BIRAGE CHACHA
Mmed Obstetrics and Gynecology School of Medicine
MUHAS

**RE: APPROVAL FOR RENEWAL OF ETHICAL CLEARANCE.**

Reference is made to your letter dated Jan 8, 2024 concerning the request for renewal of ethical clearance.

I am pleased to inform you that the Chairman has on behalf of the Senate, approved your request of renewal of ethical clearance for the study titled **"ADVERSE PREGNANCY OUTCOME AND ITS ASSOCIATED FACTORS AMONG WOMEN WITH FAILED INDUCTION OF LABOUR WITH VAGINAL DINOPROSTONE"** as requested.

The duration of renewal of ethical clearance is one year starting from Jan 19th, 2024 to Jan 18th, 2025.

Other terms and conditions remain the same as per letter of approval of ethical clearance.

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

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

## Appendix 3: 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.141/2020 01st February 2024

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

**Re: INTRODUCTION LETTER**

We would like to inform you that the bearer of this letter is Yaredi Chache with Reg. No. HD/MUH/T.141/2020 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: "**Adverse Pregnancy Outcome and Its Associated Factors Among Women with Failed Induction of Labour with Vaginal Dinoprostone"** he is being supervised by Prof. P. Muganyizi from MUHAS and Dr. Isack Rugemalila from Mloganzila.

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.

*Ms. Victoria Mwanilwa*
**For: DIRECTOR, POSTGRADUATE STUDIES**

c.c Yaredi Chache

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 4: Permission Letter

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

**MUHIMBILI NATIONAL HOSPITAL**

*In reply please quote:*

Ref. No.: MNH/CRTCU/Perm/2024/087 Date: 19th February, 2024

Head of Department
Medical Records
**Muhimbili National Hospital**

**RE: PERMISSION TO COLLECT DATA AT MNH**

| | |
|---|---|
| Name of Student | **Yaredi Chache** |
| Title | **"Adverse Pregnancy Outcome and Its Associated Factors Among Women with Failed Induction of Labour with Vaginal Dinoprostone"** |
| Institution | Muhimbili University of Health and Allied Sciences |
| Supervisor | Prof. Muganyizi (MUHAS) |
| Co – supervisor | Dr. Matilda Ngalina (MNH) |
| Period | 16th February, 2024 to 30th March, 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. *Matilda Ngalina*** (MNH) supervisor.

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

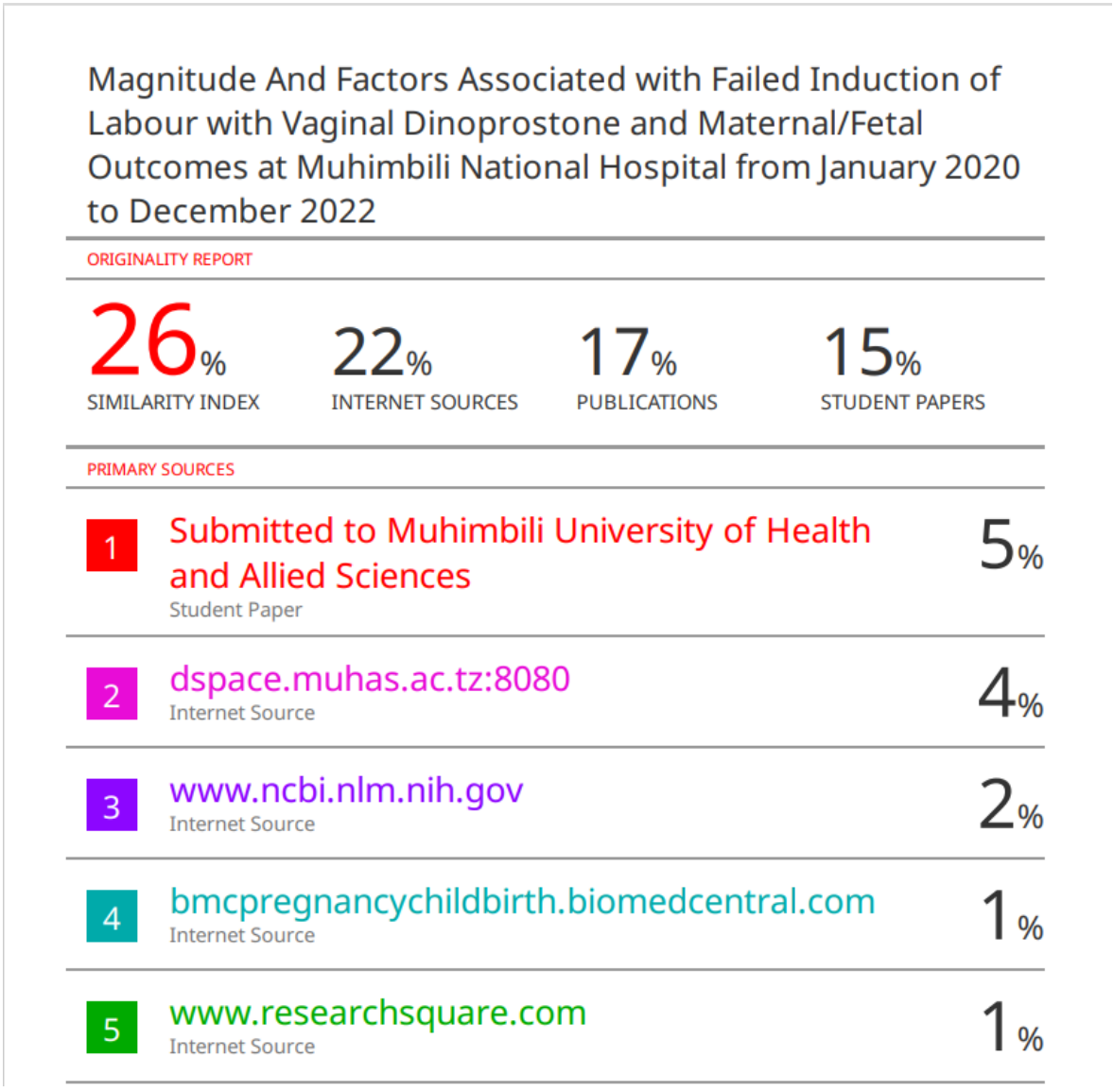
Sincerely,

**Dr. Charles K. Hallangyo**
**For: Head of Clinical Research, Training and Consultancy Unit**

c.c DICT
c.c Dr. Matilda Ngalina
c.c **Yaredi Chache**

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: Plagiarism Report**



Magnitude And Factors Associated with Failed Induction of Labour with Vaginal Dinoprostone and Maternal/Fetal Outcomes at Muhimbili National Hospital from January 2020 to December 2022

ORIGINALITY REPORT

| 26% | 22% | 17% | 15% |
|---|---|---|---|
| SIMILARITY INDEX | INTERNET SOURCES | PUBLICATIONS | STUDENT PAPERS |

PRIMARY SOURCES

| | | |
|---|---|---|
| 1 | Submitted to Muhimbili University of Health and Allied Sciences<br>Student Paper | 5% |
| 2 | dspace.muhas.ac.tz:8080<br>Internet Source | 4% |
| 3 | www.ncbi.nlm.nih.gov<br>Internet Source | 2% |
| 4 | bmcpregnancychildbirth.biomedcentral.com<br>Internet Source | 1% |
| 5 | www.researchsquare.com<br>Internet Source | 1% |