

**DIAGNOSTIC ERRORS AS PREDICTORS OF OBSTETRIC OUTCOMES
AMONG POSTNATAL WOMEN AT LEVEL FIVE HOSPITALS, BUNGOMA
COUNTY**

David Nandebe Wafula

A thesis submitted to the school of Public Health Biomedical Sciences and Technology
in partial fulfilment of the requirements of the award of Masters of Science in Public
Health degree of Masinde Muliro University of Science and Technology.

December, 2021

DECLARATION

Declaration by Candidate

This thesis is my original work prepared with no other than the indicated sources and support and has not been presented elsewhere for a degree or any other award.

Signature:.....

Date:.....

Wafula Nandebe David

HPH/G/1-56211/2016

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance of Masinde Muliro University of Science and Technology a thesis entitled; **“Diagnostic Errors as Predictors of Obstetric Outcomes among Postnatal women at level five hospitals, Bungoma County”**.

Signature:.....

Date.....

Dr. Benard Wesonga

School of Medicine

Masinde Muliro University of Science and Technology

Signature:

Date:

Dr. Maximilla Wanzala

School of Public Health, Biomedical Sciences and Technology

Department of Public Health

COPYRIGHT

This thesis is copyright materials protected under the Berne Convention, the Copyright Act 1999 and other international and national enactments on that behalf, on intellectual property. It may not be reproduced by any means in full or part except for short extracts in fair dealing so for research or private study, critical scholarly review or discourse with acknowledgement, with the written permission of the Director – Postgraduate Studies on behalf of both the author and Masinde Muliro University of Science and Technology.

DEDICATION

This thesis is dedicated to the late Ekhabi Lunyolo and Jesse Nandebe.

From making the diagnosis more grievous than endurance, the good Lord deliver us.

ACKNOWLEDGEMENTS

I acknowledge the almighty God who has been my pillar throughout the study period. I owe gratitude to all the women who were my respondents during the study. I thank the key informants who participated in this study. I applaud the research assistants in Bungoma and Webuye Hospitals; Inviolata Makhanu, Fatuma, Pamela Pwaipwai and Leonard Lusenaka who tirelessly worked hard during COVID 19 pandemic but ensured the study ran smoothly. I thank my supervisors Dr. Benard Wesonga and Dr. Maximilla Wanzala for their relentless support and commitment towards making sure I finish the work on time through their diligence supervision. The guidance of Dr. Nathan Shaviya as my correction supervisor is worth mentioning. I wish to salute all the staff of the following hospitals for their support, Bungoma hospital, Webuye Hospital and Kimilili Sub County Hospital and also wish to appreciate my family and classmates for their encouragement and support.

Wafula, N. D

ABSTRACT

Diagnosis is an important part of medical consultation that determines if the patient has a medical anomaly. However, the diagnosis might fail to produce the right results (diagnostic errors) hence leading to wrong intervention. Diagnostic errors are common and are a global problem, which has been understudied. In the Philippines, diagnostic errors were three times most likely to make pregnant women develop obstetric complications. Kenya as one of the global countries, has a high annual maternal mortality prevalence ratio of 362/100,000 live births, with Bungoma County exceeding the national maternal mortality prevalence ratio of 382/100,000 live births annually. Maternal mortality more often than not, a factor that arises from morbidity is fuelled by diagnostic errors that required determination of its consequences on obstetric outcomes in Bungoma County. Thus, this study investigated the diagnostic errors as predictors of obstetric outcomes among post-natal women at level five hospitals in Bungoma County. The study employed a cross-sectional research design which was hospital-based (Bungoma and Webuye hospitals). Systematic sampling was used to obtain 384 respondents after proportionate allocation to each hospital, and purposive sampling to select 8 health care workers as key informants. Data was collected using a structured questionnaire and an interview guide. The pre-test was done with validity established through crosschecking and reliability calculated using the Cronbach method (0.89). Using a statistical package for social sciences version 25, descriptive and inferential statistics was run where chi-square and odds ratio was used to determine the influence between variables, significance and prediction. The study revealed a prevalence rate of 30.4% with delayed diagnosis accounting for 43.1%, missed 38.8%, absent diagnosis 27.5%, the wrong diagnosis 34.9%, misinterpretation of results 24.1, unmatched 26.3% and unnecessary investigation 9.3%. Variation between initial diagnosis and the final diagnosis was 20.8% while diagnostic errors were significant predictors of obstetric outcomes among post-natal mothers at level five Hospitals in Bungoma County with a p-value of 0.045 at a significance of 5% ($P=0.045 < 0.05$). Demographic characteristics showed no relationship with obstetric outcomes ($P=0.54 > 0.05$). Matched diagnostic had no variations ($N=327$, $M=1.00$, $SD=0.000$); while unmatched diagnostic had variations ($N=327$, $M=1.82$, $SD=.384$). There was a relationship between diagnostic errors and obstetric outcome ($\chi^2 (1) = 251.86$, $p < .001$). An association between diagnostic error with unsafe obstetric outcomes was significant at the odds ratio of 2.03 (OR 2.03, 95% CI 1.31–2.16). The study demonstrates that a correct diagnosis is a viable strategy in preventing unsafe obstetric outcomes and by extension minimizing morbidity and mortality among pregnant women. The study conclusions are that; the prevalence of diagnostic errors is 30% and a variation between initial diagnosis and final diagnosis does exist and affects pregnancy outcome. Diagnostic errors are predictors of obstetric outcome, thus this study recommends building capacity for diagnosis among medical health care workers and precise point of use diagnostic tools were recommended.

TABLE OF CONTENTS

DECLARATION	ii
CERTIFICATION	ii
COPYRIGHT	iii
DEDICATION	iv
ACKNOWLEDGEMENTS	v
ABSTRACT	vi
LIST OF TABLES	x
LIST OF FIGURES	xi
ABBREVIATIONS AND ACRONYMS	xii
OPERATIONALIZATION OF TERMS	xiv
CHAPTER ONE: INTRODUCTION	1
1.1 Overview.....	1
1.2 Background information of the study	1
1.3 Statement of the problem.....	3
1.4 Research Objectives.....	4
1.4.1 Broad objective	4
1.4.2 Specific objectives	4
1.5 Research Questions.....	5
1.6 Justification of the Study	5
1.7 Significance of the study.....	6
1.8 Scope of the study.....	7
1.8.1 Limitations of the study	7
1.8.2 Assumptions of the study.....	7
1.9 Theoretical Models	8
1.9.1 Postulated theoretical Frameworks	8
1.9.2 Theoretical framework on the diagnostic process	9
1.10 Conceptual Framework for the study.....	10
CHAPTER TWO: LITERATURE REVIEW	12
2.1 Overview.....	12
2.2 Prevalence of diagnostic errors in obstetrics	12
2.2.1. Prevalence of misdiagnosis.....	14
2.3 Variations between Initial diagnosis and discharge diagnosis.....	16

2.3.1 Magnitude of disparities in diagnosis	19
2.3.2 Standard and actual diagnostic practices during FANC visits.....	20
2.3.3 Minimizing diagnostic errors.....	22
2.4 Relationship between diagnostic errors and Obstetric Outcomes	23
2.5 Research Gap	26
CHAPTER THREE: RESEARCH METHODOLOGY	28
3.1 Overview.....	28
3.2 Study area	28
3.2 Research Design	29
3.3 Study population.....	29
3.3.1 Inclusion criteria	29
3.3.2 Exclusion criteria	30
3.4 Study variables.....	30
3.5 Sampling design.....	30
3.6 Sample size determination	31
3.7 Data and information collection	32
3.7.2 Data collection instruments	32
3.7.3 Reliability.....	33
3.7.4 Validity	34
3.8 Pre-test	34
3.9 Data analysis	34
3.10 Ethical considerations	35
CHAPTER FOUR: RESULTS	37
4.1 Overview.....	37
4.2 Socio-demographic Characteristics	37
4.3 Antenatal care services	38
4.3.1 Handling of women during ANC attendance	38
4.3.2 Reception of information during antenatal care visit.....	39
4.4 Prevalence of diagnostic errors as predictors of obstetric outcomes	40
4.5 Variations between initial diagnosis and final diagnosis at level five hospitals....	43
4.7 Relationship between diagnostic errors as predictors of obstetric outcome	45
CHAPTER FIVE: DISCUSSION.....	47
5.1 Prevalence of diagnostic errors among post-natal mothers	47

5.2 The variations between initial diagnosis and final diagnosis	50
5.3 Relationship between diagnostic errors as predictors of obstetric outcomes	53
CHAPTER SIX: CONCLUSION AND RECOMMENDATION.....	56
6.1 Conclusions.....	56
6.2 Recommendations.....	56
6.3 Suggested study	57
REFERENCES.....	58
APPENDICES	63
Appendix I: Consent Form	63
Appendix II: Structured Questionnaire for post-natal mothers	64
Appendix III: Key Informant Interview schedule.....	67
Appendix IV: Ethical research approval documents	68
Appendix V: Map of Bungoma County.....	72

LIST OF TABLES

Table 3.1: Sample frame	32
Table 3.2: Reliability Statistics for Independent Variables	33
Table 3.3: Summary of statistical techniques	35
Table 4.1: Socio-demographic characteristics	38
Table 4.2: Response on antenatal care attendance	39
Table 4.3: Response on whether the respondents received sufficient information during ANC visit.....	40
Table 4.4: Diagnostic errors as predictors of obstetric outcomes at antenatal care	41
Table 4.5: Prevalence of Diagnostic errors against obstetric outcomes	42
Table 4.6: Matched and unmatched diagnosis as predictors of obstetric outcomes	43
Table 4.7: Variations of matched and unmatched diagnosis predicting the obstetric outcome.....	44
Table 4.8: Order of importance of the diagnostic errors predicting the obstetric outcome.....	45
Table 4.9: Diagnostic Errors * Obstetric outcome Chi-Square	46
Table 4.10: Predictors of obstetric outcomes.....	46

LIST OF FIGURES

Figure 1.1: Relationships between diagnostic errors and patient outcomes.....	9
Figure 1.2: Singh and Sittig's diagnostic error framework.....	10
Figure 1.3 Self-constructed conceptual framework.....	11

ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immune-Deficiency Syndrome
ANC	Antenatal Care
APH	Antepartum haemorrhage
CIC	Constitution Implementation Committee
CO	Clinical Officer
CPD	Cephalo-Pelvic Disproportion
DHIS	District Health Information System
EmONC	Emergency Obstetric and Neonatal Care
FANC	Focused Antenatal Care
FDG	Focus Group Discussion
HIV	Human Immune Virus
ICD 10	International classification of disease 10
IREC	Institutional Review and Ethics Committee
KDHS	Kenya Demographic Health Survey
MOH	Ministry of Health
NCPD	National Council for Population and Development
NACOSTI	National Council of Science, Technology and Innovation
OPD	Out Patient Department
OSCE	Objective Structured Clinical Examination
PPH	Post- Partum Haemorrhage
RH	Reproductive Health
Rx	Treatment
SSA	Sub-Saharan Africa

UN	United Nations
UNDP	United Nations Development
UNFPA	United Nations Population Fund
USA	United States of America
WHO	World Health Organization

OPERATIONALIZATION OF TERMS

Correct diagnosis - The diagnosis that will match initial diagnosis and discharge diagnosis that reflects the true status of disease of the patient (matched diagnosis) presumptive (safe diagnostic management)

Diagnosis- Identification of a problem (medical condition) that a client or patient presents with using ICD-10 standard

Diagnostic error is similar to misdiagnosis: is an incorrect diagnosis (wrong initial diagnosis) or misinterpretation after history, physical exam and investigation and it may be incorrect, missed or delayed or completely absent

Discharge diagnosis- is also called the final diagnosis. It is a problem identified made that reflects the true disease status of the patient. Sometimes discharge diagnosis is also called confirmatory. This diagnosis is usually ascertained with the help of investigations, or second opinion or through post mortem diagnosis (final diagnosis).

Incorrect diagnosis- It is a problem identified that does not reflect the true picture at the time of making it. After matching the initial diagnosis and discharge diagnosis, the diagnosis that does not match shall be deemed incorrect (mismatched diagnosis) unsafe diagnostic practice management

Initial diagnosis- is also called provisional or presumed diagnosis. It is a problem identified based on history, and clinical examination.

Investigations- as part of the management process is either imaging or laboratory analysis of the patient or patient's specimen in order to help reveal the problem the patient has.

Management- in this context, management is the attention given to mothers from conception to 6 weeks after delivery after identifying or her problem that is aimed at alleviating the suffering. This includes history, physical examination, investigations, treatment, counselling, follow up, referral and informing the patient.

Matched diagnosis- concurrence of initial (provisional) and final diagnosis (no diagnostic error)

Maternal morbidity: any pregnant mother, since conception in whom immediate survival is threatened and who survives by chance or because of hospital care she receives, could be informed of a complication, for example, anaemia, neonatal death, premature births

Maternal Mortality: Death of a mother due to pregnancy or pregnancy-related conditions

Obstetric outcome: pregnancy outcome,

Post-natal mothers: 6 weeks' post-delivery mothers

Problem: is a condition whether physical, mental, spiritual or social that affects an individual's health

Safe outcomes (positive): results from treatment and investigations that are due to the correct initial diagnosis or matched initial diagnosis and final diagnosis (no complication)

Standard diagnostic practice: is the standard procedure of identifying a problem of a client or patient as prescribed by MOH in the standard operating procedure manual.

Treatment: (intervention) is a service given to a patient that can be both pharmaceutical and non-pharmaceutical in order to alleviate the problem (condition) after identification

Unmatched diagnosis- non-concurrence between initial and final diagnosis (diagnostic error)

Unsafe outcome: (negative) also called adverse outcomes result from treatment and investigations that are due to incorrect (a mismatched initial and final diagnosis that may be prolonged hospital stay, unnecessary investigations, wrong and or delayed referral, complications, and mortality, reduced morale, and morbidity

Variations- inconsistencies between initial diagnosis and final (discharge diagnosis) differences between initial and final diagnosis (mismatched diagnosis)

CHAPTER ONE

INTRODUCTION

1.1 Overview

This chapter presents the background of the study from the global, regional and local perspectives on diagnostic errors and obstetric outcomes. It also states the statement of the problem as per the research gaps identified, the research objectives, research hypothesis, justification and significance of the study and the scope of the study.

1.2 Background information of the study

Diagnostic errors majorly contribute to adverse health outcomes to patients, yet they remain a growing challenge globally (Singh & Sittig, 2015). In the Philippines, misdiagnosis among obstetric providers is 2.96 times more likely to cause an adverse obstetric outcome for women with missed complications (Shimkhada *et al.*, 2016). This made diagnostic errors a high priority area for the World Health Organisation with most patients globally, highly likely to experience diagnostic errors in their lifetime yet more focus has been on medical errors (Singh *et al.*, 2017). It is known that the diagnostic error occurs from a misdiagnosis, missed diagnosis, wrong diagnosis, delayed diagnosis, and misinterpretation of results (Grabber, 2018). Therefore, Fernholm *et al.*, (2019) agree that there is a high degree of uncertainty of diagnosis that comes from preventable harms. Lacson *et al.* (2020) opined that unscheduled and unnecessary radiological examinations such as obstetric ultrasounds were significant diagnostic errors that usually result from a wrong initial diagnosis. These previous studies have shown that diagnosis is important but failed to explain the relationship between diagnostic errors and obstetric outcomes (safe and unsafe), which this study investigated.

Africa and Asia combined contribute to about 67% of the global maternal deaths, providing the bulk of countries with a high maternal mortality rate (Boodman, 2013). The adverse obstetric outcome could have been averted with the training of the local health service providers in ultrasound diagnosis from the primary health care centres (Greenwold *et al.* (2014). Instead, according to Nathan *et al.* (2017), the sub-Saharan Africa region accounts for two-thirds of maternal and neonatal deaths arising from antepartum haemorrhage, obstructed labour and pre-eclampsia causing increased maternal morbidity and mortality. Therefore, these previous studies have shown that there is a higher burden of maternal mortality rate; however, they have not provided the connection between diagnostic errors and adverse obstetric outcomes. This study thus sought to establish the connection.

In Kenya, the average maternal mortality is at 362 deaths per 100,000 lives, due to diagnostic errors (NCPD & UNFPA, 2015). Furthermore, it was reported that adverse obstetric outcomes were anaemia, post-partum haemorrhage, baby asphyxia, premature babies, maternal deaths, neonatal deaths, stillbirths and stroke among others which if diagnosed early were preventable (NCPD, 2015). According to the Kenyan Ministry of Health report, 15% of all pregnant women develop life-threatening pregnancy complications resulting from diagnostic errors (Mohr, 2017). These diagnostic errors mask the magnitude of complications. It is known that for every one maternal fatality, one hundred maternal morbidities are arising from obstetric complications (Mohr, 2017). Moreover, the World Bank reported that most of the deaths occur within the first 24 hours before and after delivery; being the most critical time (WHO, 2018). This study helped us understand that diagnostic errors are common; however, they have not clearly linked diagnostic errors with adverse obstetric outcomes and therefore the study sought to investigate how diagnostic errors influenced obstetric outcomes.

Bungoma County still records a maternal mortality ratio of 382 maternal deaths per 100,000 live births (Gacheri, 2016) yet currently, the Kenyan average maternal mortality ratio is 362 deaths per 100,000 live births. Could diagnostic errors be contributing to a sustained maternal ratio of 362 per 100,000? It is known that the collective national recommended maternal mortality ratio is 144/100,000 live births. These previous studies have shown that the maternal mortality ratio is still high; however, they are not clear whether it is promoted by diagnostic errors among pregnant women who receive obstetric services. It was against this backdrop that the study was executed to investigate the diagnostic errors as predictors of obstetric outcomes at level five hospitals in Bungoma County.

1.3 Statement of the problem

Previous studies have shown that proper diagnosis is an important determinant of a healthy obstetric outcome particularly the initial diagnosis. However, diagnostic errors have become rampant globally, which has been given little attention compared to medical errors. In sub-Saharan Africa, it was established that there was a higher burden of maternal mortality rate; however, there is no clear connection between diagnostic errors and adverse obstetric outcomes. In Kenya, it is documented that the maternal mortality ratio stands at 362 deaths per 100,000 live births. This is against the recommended national average maternal mortality ratio of 144 deaths per 100,000 live births. Bungoma County has a higher maternal mortality ratio of 382 deaths per 100,000 live births. This is even higher than the national average. Currently, there is no clear knowledge on the increased prevalence of maternal mortality among pregnant women in relation to diagnostic errors. Moreover, it is not clearly known whether diagnostic errors contribute to adverse obstetric outcomes among pregnant women at level five

teaching and referral hospitals in Bungoma County. Nor is there any literature quantifying the prevalence of diagnostic errors in Bungoma County referral Hospitals

The missing information on diagnostic errors makes it impossible to determine whether they predicted adverse obstetric outcomes. Providing information on the current diagnostic errors in relation to obstetric outcomes will help for the future projection of maternal and neonatal morbidity and mortality at level five teaching and referral hospitals in Bungoma County. This study was important as it helped to identify the increased prevalence of diagnostic errors and variations between initial and final diagnosis promoting safe obstetric outcomes. The purpose of this study was to investigate the influence of diagnostic errors as predictors of obstetric outcomes among post-natal women at level five hospitals in Bungoma County, Kenya.

1.4 Research Objectives

1.4.1 Broad objective

To investigate the diagnostic errors as predictors of obstetric outcomes among post-natal mothers at level five Hospitals in Bungoma County

1.4.2 Specific objectives

The specific objectives of the study were;

1. To establish the prevalence of diagnostic errors as predictors of obstetric outcomes among post-natal women at level five teaching and referral hospitals in Bungoma County.
2. To determine the variations between initial and final diagnosis as a predictor of obstetric outcomes among post-natal women at level five teaching and referral hospitals in Bungoma County.

3. To investigate the relationship between diagnostic errors and obstetric outcomes among post-natal women at level five teaching and referral hospitals in Bungoma County.

1.5 Research Questions

1. What is the prevalence of diagnostic errors among post-natal women in Bungoma County Teaching and Referral Hospitals?
2. Is there any variation between initial diagnosis and final diagnosis among post-natal women in Bungoma County Teaching and Referral Hospitals?
3. How are diagnostic errors related to adverse obstetric outcomes among post-natal women at level five Hospitals in Bungoma County?

1.6 Justification of the Study

Globally maternal mortality rate is of great concern. This is essential especially in developing countries that have an enormous burden of lowering maternal mortality rate as regards sustainable development Goal number 3 (SGD3). This maternal mortality rate arises from morbidity, complications occurring during and immediately after pregnancy. World health organization (2018) reports indicate that, for every one death or mortality, 100 women develop morbidities. If morbidity can be checked, then mortality may drop and therefore subsequent promotion of SGD3 is achieved. To counter morbidity, early diagnosis is of the essence in order for the intervention to be complete. So diagnostic errors could be contributing to maternal mortality both directly or indirectly yet literature is scanty and association appears not well documented

Timely and accurate diagnosis is paramount if the maternal mortality rate has to be checked. Whereas reproductive health care is expensive both for the patient and health care providers in Kenya, there are scanty resources. By having misdiagnosis, it puts

strain on their scanty resources lowering cost-effectiveness and cost-utility for the service provider and the patient whenever there is a waste. Generated information may provide ways in which this type of wastage may be reduced as per the policy on maternal death rate reduction as reported by the Ministry of Health (2017).

Avoiding excessive investigation and unnecessary treatment may improve the outcomes as envisaged by (Douglas, 2009). The correct initial diagnosis reduces the potential harm to patients and cost since standard investigations and management seek to exclude all physical illnesses that are costly, unhelpful, and risky with side effects and does not give patients lasting solutions. A system of feedback mechanisms may also help improve and sharpen the insights of clinicians involved in health care delivery as proposed by (Prakash, 2011).

1.7 Significance of the study

The study was significant since initial diagnosis ultimately determines the course of management to be taken. Delayed initial diagnosis may also be a factor in the over-reliance of diagnosis on investigations that were unavailable, expensive or traumatizing to the patient. Therefore, a close examination of the health systems and medical accounts may provide a method of appraising the quality of health care provision and identify the flaws in the diagnosis which will enhance accurate and timely diagnosis. Timely diagnosis improves the health service to mothers. It also provides a prudent look at the health care diagnostic failures, with the intent of providing feedback to clinicians about the diagnostic process performance for improvement.

A gap exists in terms of the number of cases that are affected with variations in the diagnosis especially in emergency obstetric care and their eventual outcomes yet this is necessary for audit purposes and reflection. Similarly, the trends in misdiagnosis may

help in identifying factors attributed to it and explore ways of minimizing it as some of the diagnostic errors can be minimized once understood. Measurement of misdiagnosis in the hospital set up can be used as opportunities to learn how to improve health care work system and diagnostic process in Bungoma County as suggested by Klein (2011, 2014)

1.8 Scope of the study

The geographic scope of the study was limited to referral hospitals in Bungoma County. The Referral Hospitals are Bungoma and Webuye. The two hospitals manage all complicated cases and most obstetric or reproductive health mothers are referred to these hospitals. These hospitals also have a complete set of specialists to handle complications associated with obstetrics. The focus was on reproductive health mothers who were admitted and given service by the health care workers in primary health care facilities and in the hospitals during admission.

1.8.1 Limitations of the study

The main limitation of the study was recall bias that comes about in the recollection of patients going through the diagnostic process and the care given to them. However, this was surmounted by checking the files and antenatal booklet of the respondent. Emotional factors arising from hormonal fluctuations may play a role, especially during an interview.

1.8.2 Assumptions of the study

The study makes the following assumptions:

- i. diagnostic errors have an impact on obstetric outcomes
- ii. There can be variations between initial and final diagnosis and any form of diagnostic error gives a negative obstetric outcome or adverse outcomes to

a pregnant mother either in terms of unsafe outcome or by chance safe outcome.

- iii. The sample was assumed to be representative of the Bungoma county population due to probabilistic sampling that shall be applied and the two hospitals are referral hospitals for Bungoma County and serve every corner of the county

1.9 Theoretical Models

1.9.1 Postulated theoretical Frameworks

The conceptual framework was informed by the following theories and models; Singh's (2014) theory states that missed delayed, wrong diagnosis and diagnostic process failures may result in adverse outcomes.

A: represents a patient who had a missed, delayed or wrong or incorrect diagnosis and therefore a diagnostic process failure with (negative) adverse obstetric outcome;

B: Represents a patient who gets (negative) adverse management outcome due to failure of the diagnostic process through radiological or laboratory investigations;

C: represents a patient who was given an adverse management outcome due to missed, delayed or incorrect initial diagnosis-diagnostic error (Schiff and Leape, 2012). The framework demonstrates that missed diagnosis may be due to system failure and due to cognitive factors, which eventually leads to harm from delayed or wrong treatment or test. This scenario also applies to delayed or wrong diagnoses. There may be a change in preventable variability in the diagnosis that may arise from missed, wrong or delayed diagnosis that may lead to preventable diagnostic error and ultimately improve the outcomes from being unsafe to safe (Toker, 2014). The figures help to explain the

relationship between the variables in the study and come up with a conceptual framework of which outlines the independent, dependent and intervening variables as

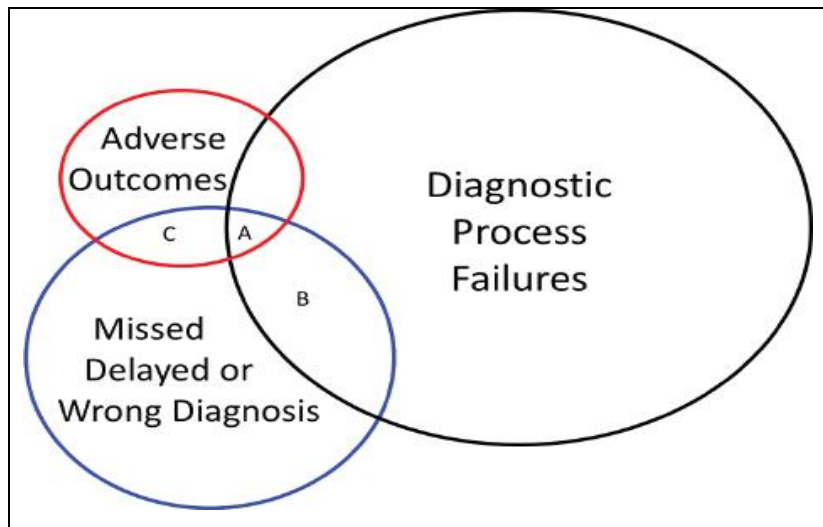


Figure 1.1: Relationships between diagnostic errors and patient outcomes.

Source: Singh 2014 © Joint Commission Resources

1.9.2 Theoretical framework on the diagnostic process

The postulated diagnostic process involves 4 main subsections. The first section highlights the patient encounter with the initial diagnostic assessment. Secondly, there is diagnostic test performance and interpretation. Thirdly there is follow up and tracking of the diagnostic information and finally, there is a subspecialty, consultation and referral issue to complete the diagnostic management process. This is followed by safe management of the patient and finally giving a safe outcome. Any failure in this cycle or this process results in a diagnostic error and the diagnostic failure results in the diagnostic error which is likely to affect the intervention that may eventually lead to an unsafe obstetric outcome.

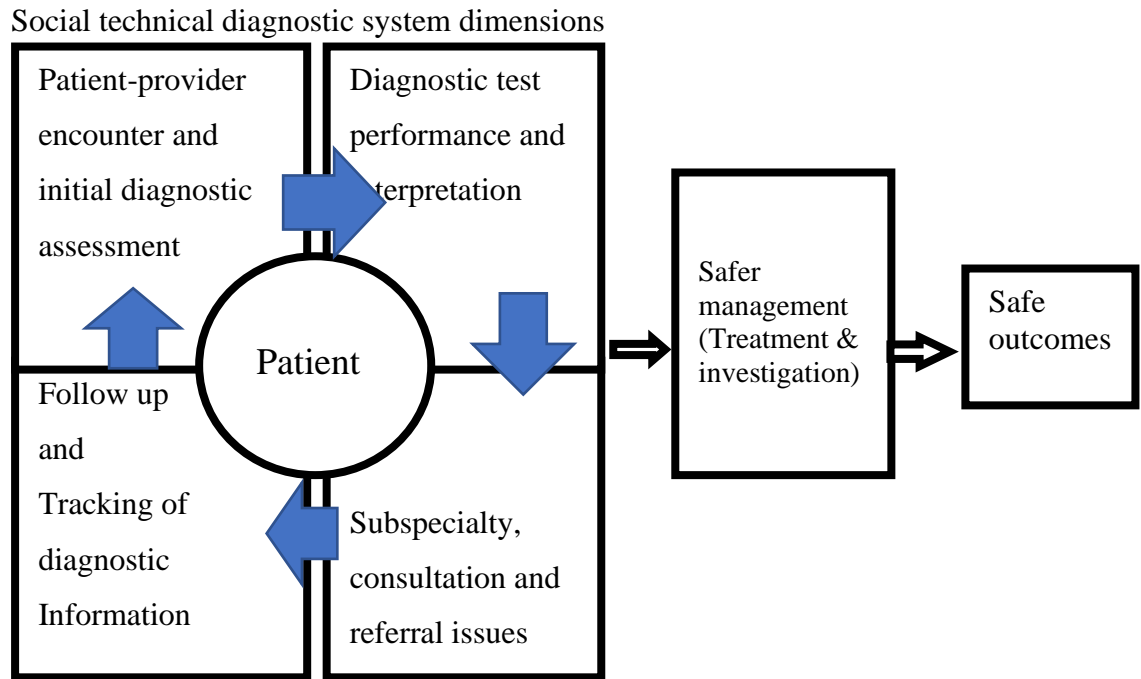


Figure 1.2: Singh and Sittig's diagnostic error framework.

Source: Reproduced from *BMJ Quality and Safety*, Singh and Sittig, (2015)

1.10 Conceptual Framework for the study

Based on the foregoing theories and models, a conceptual framework was constructed to guide the study. The independent variable was diagnostic errors (missed, delayed, wrong, absent diagnosis unmatched) and the dependent variable is adverse obstetric outcomes (obstetric complications and neonatal complications) The diagnostic error model adopted from Singh and Sittigs’ model (2015) sought to show that during the consultation of the client or patient, the diagnostic process of consultation, investigation, interpretation, referral and tracking follow up and counselling is essential. Any failure in this process -diagnosis may result in a diagnostic error that will influence the intervention (treatment) which eventually results in an adverse (unsafe) obstetric outcome. However, the unsafe obstetric outcome more often than not shall

result in increased morbidity and mortality. In the event that there is no diagnostic error, then intervention shall be timely and correct which eventually result in a safe obstetric outcome and therefore minimize maternal morbidity and mortality. In the same vein, investigations taken and interpretation of the same, correct referral and availability of the investigative facilities may have an impact on the diagnosis and finally on the outcomes. Other factors that may result in diagnostic errors include atypical history, handling of women at ANC and information provided to women at ANC.

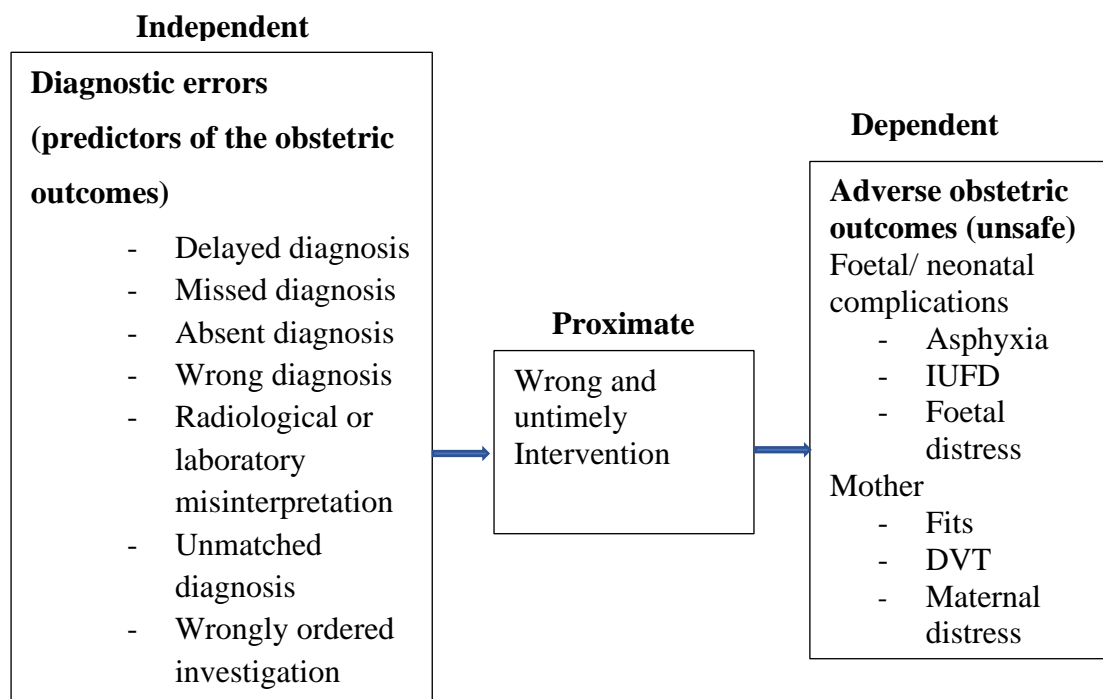


Figure 1.3 Self-constructed conceptual framework

Source: Author

CHAPTER TWO

LITERATURE REVIEW

2.1 Overview

This chapter presents the literature review of similar studies from a global perspective, regional perspective and local perspective. It focuses on the prevalence of diagnostic errors, variation of initial and final diagnosis and the relationship between diagnostic errors and adverse obstetric outcomes among women in Bungoma County Teaching and Referral Hospitals.

2.2 Prevalence of diagnostic errors in obstetrics

Diagnostic errors have a high potential of resulting in unhealthy obstetric outcomes (Prakash, 2011). These diagnostic errors have presented a blind spot in the delivery of quality health care globally as alluded to by Boodman (2013). Diagnostic errors, also called misdiagnoses are inaccurate, missed or delayed diagnosis (Liberian & Newman-Toker, 2018). To some extent, the diagnostic error may also occur as a failure in the interpretation of the results following an investigation which could be radiological or laboratory. Diagnostic errors persist throughout all settings of care and continue to harm an unacceptable number of patients and come in relation to variability in the initial and final diagnosis. These errors lead to delays in treatment, inappropriate or unnecessary treatment. This may in turn lead to physical, psychological and financial consequences that affect not only the patient but even the nation at large. Diagnostic mistakes are typically not reported and therefore not learned from.

About one billion radiologic examinations are being executed globally per year, such as ultrasounds where results were interpreted by radiologists and health care workers. The interpretations that were prone to missed or delayed diagnoses often led to patient

harm and missed opportunities for treatment (Bruno, Walker & Abujudeh, 2015). Researches indicate that diagnostic errors have received comparatively less attention yet diagnostic errors were common (Royce, Hayes & Schwartzstein, 2019). In reference to Leonard Berlin writing of 1995, which stipulated that lawsuit in Cook County, Illinois, USA - radiology-related malpractice - arose inexorably, with the majority of suits for missed diagnosis, and was no reason to believe that this pattern had since changed (Brady, 2017). The World Health Organization (WHO) has prioritised minimisation of diagnostic errors to promote patient safety in primary care, which has become a high-priority problem (Singh, Schiff, Graber, Onakpoya & Thompson, 2017). It is well known to medical practitioners that medical errors create a grave medical challenge that interferes with patients' safety (Rodziewicz & Hipskind, 2018) According to Liberman (2018), 12 million people are misdiagnosed yearly in the United States with an estimated 98,000 dying due to combined hospital mistakes. This represents a significant number in health and requires that attention be drawn to the fact that correct initial diagnosis and correct management may improve quality health care.

In Kenya, Oketch (2017) and Mutuna (2017) argued that the wrong diagnosis is a silent killer and that many patients may have died after receiving the wrong treatment from the wrong initial diagnosis. He avers that a large number of patients referred to a specialist are a result of misdiagnosis-diagnostic errors occasioned by inexperience as well as lack of specialists and equipment. Oketch (2017), further alludes to the fact that in one month a record 30 cases of misdiagnosis were recorded involving simple cases of pneumonia and malaria leading to diagnostic errors. These views are shared with Mutuna (2017). Can it, therefore, be argued that the same diagnostic errors could be happening in obstetric care? Most maternal deaths result from one or more direct causes—that is, the result directly from complications of pregnancy. The leading direct

causes of maternal deaths in Kenya are three, haemorrhage (severe bleeding), obstructed labour, and eclampsia (hypertension) which account for the vast majority of deaths though no direct evidence has been linked to diagnostic errors as probable attributions (Yego *et al.*, 2019). However, logically thinking, if the above conditions are not recognized early in terms of diagnosis, they may result in unsafe outcomes. Failure to carry out appropriate investigation has been found to carry 58 % of errors in the emergency department like in cases of obstetric emergencies as reported by Das (2012).

According to Graham (2015), diagnostic errors emanating from the misinterpretation in radiology results accounts for 49%, (Graham, 2015). Therefore, there is a highly probable cause of diagnostic errors acting as predictors of adverse obstetric outcomes. (Balogh, 2015) findings generate a significant prevalence rate that can affect the subsequent management process of patients or clients. The diagnostic error consequently affects the quality of service to the patient in terms of wrong treatment that will be given and therefore resulting in either increased cost of unnecessary drugs, social and mental repercussions notwithstanding.

2.2.1. Prevalence of misdiagnosis

A study on 'Inadequacies of Physical Examination as a Cause of Medical Errors and Adverse Events:

A Collection of Vignettes' by Verghese, Charlton, Kassirer, Ramsey and Ioannidis (2015) found out that:

... Of the 208 reported vignettes that met inclusion criteria, the oversight was caused by a failure to perform the physical examination in 63%; 14% reported that the correct physical examination sign was elicited but misinterpreted, whereas 11% reported that the relevant sign was missed

or not sought. The consequence of the physical examination inadequacy included missed or delayed diagnosis in 76% of cases, incorrect diagnosis in 27%, unnecessary treatment in 18%, no or delayed treatment in 42%, the unnecessary diagnostic cost in 25%, unnecessary exposure to radiation or contrast in 17%, and complications caused by treatments in 4%.

Globally, it is well known that cognitive bias is increasingly recognised as an important source of diagnostic error, yet not well understood (D O’Sullivan & Schofield, 2018).

In a study carried out in the Philippines using simulations, Shimkhada *et al.* (2016) found that the overall prevalence of misdiagnosis was 29.8 % and 25% for cephalo-pelvic disproportion (CPD), 33% for post-partum haemorrhage (PPH), and 31% for pre-eclampsia. These results translated into the likelihood of the clients developing complications with an odds ratio of 2.96. In this study in Bungoma County, the findings of prevalence ratio were at approximately 34% and that providers who misdiagnosed or made diagnostic errors during the ANC visits were significantly more likely (OR 2.03, 95% CI 1.31–2.16) to have patients with a complication compared with providers who did not misdiagnose. High-risk pregnancies, as expected, had an association (OR 2.34, 95% CI 0.99–1.62) with the presence of unsafe outcomes. This gives a significant number of patients that can eventually affect the morbidity and mortality of pregnant mothers. In the Philippines, the research design was a simulated survey on workers, where health care workers were exposed to simulated clinical scenarios and asked to make the diagnosis and diagnostic errors measured.

Yego *et al.* (2013), indicated in a study carried out between 2004 and 2011 that, the overall maternal mortality ratio was 426 per 100,000 live births and the early neonatal mortality rate (<7 days) was 68 per 1000 live births. The Hospital record audit showed that half (51%) of the neonatal mortalities were for young mothers (15–24 years) and 64% of maternal deaths were in women between 25 and 45 years. This study helps to

illustrate the magnitude of prevalence of morbidity and by extension of mortality of the neonates and mothers that diagnostic factors could be contributing to its increase.

2.3 Variations between Initial diagnosis and discharge diagnosis

Diagnosis is meant to provide a reliable clinical condition of the client and initial diagnosis also called provisional diagnosis, the first considered diagnosis which sets in motion the first phase of management, while the final diagnosis (confirmatory diagnosis) reveals concurrent problems after history taking, physical examination, and investigations or counter consultation (Das, 2012). It was further revealed by Das (2012) that analysis of the diagnosis between initial and final was presumed to have matched whereas deviation of the final diagnosis from initial diagnosis was presumed to have the unmatched diagnosis and therefore a variation. This represented a diagnostic error. Variations in diagnostic errors are attributed to most misinterpretation of the results, most laboratory and radiological results (Bruno, Walker & Abujudeh, 2015). According to Jutel, (2009), diagnosis is both a process and a classification scheme or a pre-existing set of categories agreed upon by the medical profession to designate a specific condition. When a diagnosis is accurate and made in a timely manner, then the patient has a chance of positive health outcome as this will result in the correct clinical decision making of the patients' problem. Once the patient comes to the health facility for health care the process of information gathering, integration, interpretation and determination of the working diagnosis ensue. This working diagnosis is also called provisional or initial diagnosis. This involves hypothesis generation which leads to a list of one potential diagnosis or a list of potential diagnoses.

According to Jutel, (2009), diagnosis is both a process and a classification scheme or a pre-existing set of categories agreed upon by the medical profession to designate a

specific condition. Health care facilities lack the tools and strategies for measuring diagnostic safety and most have not integrated diagnostic error into their existing patient safety programs (Singh & Sittig, 2015). Unsafe health care has been recognized as a global challenge and much has been done to understand the causes, consequences and potential solutions to this problem (the WHO, 2016). The standard used for diagnosis is the international classification of disease (ICD10) a criterion for disease classification (Cao & Morley, 2016). Diagnostic errors arise from both cognitive biases and knowledge deficit on a particular medical problem (Norman, *et al.*, 2017). When a diagnosis is accurate and made in a timely manner, then the patient has a chance of positive health outcome as this will result in the correct clinical decision making of the patients' problem as observed by Abimanyi-Ochom (2019) and goes on to state that once the patient comes to the health facility for health care the process of information gathering, integration, interpretation and determination of the working diagnosis ensues. This working diagnosis is also called provisional or initial diagnosis. This involves hypothesis generation which leads to a list of one potential diagnosis or a list of potential diagnoses. Reflection of initial diagnosis before making the final diagnosis was an important exercise by medical practitioners in Switzerland as it increased correct final diagnosis averting and or minimizing diagnostic errors (Mamede *et al.*, 2020).

Nathan *et al.* (2017) aver that patients expect health care providers to be competent to diagnose, plan manage, carry out practical procedures and they expect them to behave in a reasonable way demonstrating a caring and humanistic attitude while doing so. The government, the media and the public have become concerned about the quality of clinical care and have focused their attention on the way the health professionals demonstrate clinical competence. Furthermore, around the world, there is pressure to

increase accountability and to formalize the maintenance of standards as well as setting standards for the practice

Typically, clinicians consider more than one diagnostic hypothesis or possibility as an explanation of the patients' symptoms and shall refine the list as further information is obtained in the diagnosis process. Carayon (2014) asserts that the workstation provides the context in which the diagnostic process occurs. This work station includes the diagnostic machines and the personnel. The work station also entails diagnostic team members and task technologies and tools, organizational factors, the physical environment and the external environment. These factors influence both initial and final diagnosis. An exemplification of how individual factors influence initial diagnosis is provided by Croskery and Musson, (2009) as intelligence and knowledge, age affect, personality, physical state, gender and experience.

Hoffman (2009) argues that expert clinician collects a wide range of cues than their novice counterparts during their clinical decision making. This suggests that variability in initial diagnosis may be linked to the attending clinicians' characteristics. These characteristics may vary from cadre to cadre. As for the case in Kenya, various cadres attend to reproductive cases. The cadres of attendees range from nursing officers, clinical officers, medical officers and consultants. A report by Kajiliwa and Muthoni (2017) tries to blame cases of misdiagnosis on a particular cadre without evidence of the same.

Patient management depends on the initial diagnosis which is the first presumptive diagnosis that acts as the basis for the next course of action. However, whenever there is any diagnostic error, the whole process of management becomes compromised. Diagnostic errors being a grey area therefore may require an inquiry into the effect it

has on obstetric outcomes which appears to be missing in Kenya and particularly in Bungoma County.

2.3.1 Magnitude of disparities in diagnosis

In America, reports indicate misdiagnosis as a significant problem nearing and surpassing mortalities from road traffic accidents and therefore a significant problem. (Harolds, 2015) Misdiagnosis is a serious quality of care shortcomings with worrisome though poorly understood results. For example, in the U.S.A 5% of the adults are misdiagnosed in outpatient, while 50% of those misdiagnosed could end up with unsafe outcomes (Liberman, 2018). In China, it is reported that misdiagnosis was at 74% in rural areas and in India, there are very low rates of diagnosis regardless of whether it is correct or not with only 33% articulating a diagnosis

In clinical practice, achieving a low degree of variability between initial diagnosis and discharge diagnosis is essential though this degree is not well established. Making accurate diagnosis helps in the subsequent decision making especially in reproductive health where time is of the essence. Chattopadhyay (2013) observed that a high degree of diagnostic accuracy not only have clinical, financial and legal implications but also provides a means of communication between the patient and the clinician. According to Kamau and Kajiliwa (2017), a total of 936 cases of misdiagnosis have been lodged in courts for legal redress since 1997. These cases included reproductive case misdiagnosis. Mothers have lost their lives through misdiagnosis and others suffered irreversible complications. Initial diagnosis is the first considered diagnosis that informs the initiation of the first phase of management of the patient while the discharge diagnosis involves chronological analysis through investigative and interpretational

confirmatory diagnosis. Initial diagnosis, therefore, is an important step in the subsequent actions that are to be taken by the clinician in the clinical care

Results from similar research on the variability in both private and government teaching hospitals showed that disparities between initial diagnosis and discharge diagnosis stood at 57 %. It was also revealed that the practice gap was evident in the reproductive health department which is an essential department (Kar, 2010). Unlike this study, in Kenya, this should not be an issue as most health providers have practised for long before the deployment to this vital department. However, it remains to be seen especially the disparities in diagnosis between initial and final. Further still, despite an impressive evolution in diagnostic technology, the disparity between clinical diagnosis and autopsy is not declining (Vougiouklakis, 2011). This reinforces the fact that there may be little or no improvement in the variations between initial diagnosis and final or discharge diagnosis. These variations if too common could be affecting the management of obstetric clients that puts them in a vulnerable position as they may be exposed to increased morbidity since the treatment will be compromised. This represents another gap that this study filled.

2.3.2 Standard and actual diagnostic practices during FANC visits

The antenatal period of pregnancy presents an essential opportunity to health workers for reaching pregnant mothers or accessing pregnant mothers with a number of interventions that may be vital to their health, with the safe outcome (Abebe, 2017). The purpose of FANC is to optimize maternal and foetal health, provide maternal and foetal screening, make medical and social interventions were necessary as indicated and improve the outcomes of the pregnancy thereby preparing them to become mothers.

Despite ANC being a success story in Africa as observed by World Health Organization [WHO], 2012), the maternal mortality rate is still high not only in third world countries but also in Kenya. Almost all maternal mortality (99%) occurring in developing countries are due to morbidities arising during the antenatal, intrapartum and immediate postnatal period (Sophie, 2010). Of these mortalities, more than half of them occur in sub-Saharan Africa and one third occur in South Asia. The cause of these mortalities is preventable through focused antenatal care (FANC) in pregnancy, skilled care during childbirth, and care and support postnatally (WHO, 2014). However, in many African countries, the coverage of FANC is increasing, but the cover alone does not provide information on the quality of care, and poor quality in FANC clinics, correlated with poor service utilization. This is often related to an insufficient number of skilled providers (particularly in rural and remote areas), lack of standards of care and protocols, few supplies and drugs, and poor attitudes of health providers. According to Eeuwijk (2017), the majority of maternal deaths could be avoided if women had access to quality medical care during pregnancy, childbirth, and postpartum. Even though One woman in every three (32 %) made four or more antenatal visits during the course of pregnancy there is a growing consensus that access to FANC alone is insufficient to alter the present maternal health profile and that the quality of FANC services may be a key determinant of maternal and perinatal outcomes particularly with better diagnostic management practices (Sophie, 2010).

One of the priorities of the ministry of health in Kenya is to provide medical care and counselling services during pregnancy and delivery that improve the survival of both the mother and child. A majority of women in Kenya receive antenatal care from medical professionals while a small fraction receives from traditional birth attendants and the rest don't receive any care. According to Abebe (2017), qualifications of health

care providers, frequency of FANC visits, contents of services received and the kind of information given to women during their FANC, drive the quality of antenatal care. Pregnancy complications are indeed an important cause of maternal morbidity and mortality. Therefore, with the correct diagnosis from the initial contact with the mother will help avert a condition that will otherwise result in a severe complication or mortality. Maternal deaths can be avoided with access to quality health care with correct early diagnosis or early referral during pregnancy (FANC), delivery and postnatal.

Antenatal care of quality can assist determine gestational age, identifying high-risk pregnancies, detecting and monitoring pregnancy-related diseases and promoting mothers' awareness. FANC also plays an important role in the prevention of mother to child transmission of HIV and other Trans-placental diseases, reducing maternal and neonatal deaths (Vogel, 2013). Misdiagnosis in some of our health care facilities has been identified as a lack of appropriate instruments, routine laboratory tests, lack of ultrasound, therefore, hindering early diagnosis as shown by Shimkhada *et al.* (2016). Time is an important factor in the practice of obstetrics and therefore early detection and referral are essential. Whenever any of these diagnostic errors occur shall invariably lead to undesired outcomes which could have been prevented. The study sought to identify any variations that could be there right from the beginning and therefore recommend areas of emphasis in order to improve services from the primary source.

2.3.3 Minimizing diagnostic errors

The first report summary findings on maternal death audits in Kenya WHO, 2017 attributed over 75% of deaths to health care workers and diagnostic errors made by health care workers being one of them. Abimanyi-Ochom *et al* (2019) suggested some ways of minimizing diagnostic errors or misdiagnosis in acute care settings like

obstetric care and listed them as, prudent use of technology, additional clients review and error documentation in order of preferences. The study tends to agree with this suggestion; however, specific technology should be accessible, affordable and mainstreamed in rural areas so that it is widely distributed to reach more clients. These suggestions are also indicators that probably it's rather difficult to eliminate diagnostic errors completely from clinical practice

2.4 Relationship between diagnostic errors and Obstetric Outcomes

Vougiouklakis (2011) found out that the studies that involved autopsy with a focus on clinical diagnosis and the clinical autopsy showed 18.4% disagreement whereas 18.4% had agreement while 11.6% had a partial agreement and 43.3% had no provisional or initial diagnosis. In India, Chattopadhyaya (2013) while conducting a study at Kar Medical College for over a period of one month where matching was done between initial diagnosis and final diagnosis, results revealed that 43.3% had accurate initial diagnosis where the association was found to be significant. The clinical examination had 55.4 % sensitivity whereas investigative diagnosis was at 44.5% (Chattopadhyaya, 2013). In a similar study conducted on medical students concerning diagnosis using an OSCE, the diagnostic accuracy was found to be 60% while 63% provided correct diagnosis (Tsukamoto, 2012). The PICU mortality and morbidity conference (Cifra *et al.*, 2015) reported that:

... Out of 20 total diagnostic errors identified, 35% were discovered at autopsy while 55% were reported primarily through the morbidity and mortality conference. Forty per cent of errors did not cause actual patient harm, but 25% were severe enough to have potentially contributed to the death. There were slightly more system-related factors (40%) solely contributing to diagnostic errors compared with cognitive factors (20%); however, 35% had both system and cognitive factors playing a role.

Saposnik, Redelmeier, Ruff and Tobler (2016) conducted a retrospective study and found out that most healthcare providers made 36.5% to 77% case scenarios of diagnostic errors that arose from overconfidence, had lower tolerance to risk, and was promoted by the anchoring effect, and information and availability biases. Moreover, Saposnik *et al.* (2016) noted that five out of seven (71.4%) studies showed an association between cognitive biases and therapeutic or management errors. Diagnostic errors contributed to as many as 70% of medical errors (Royce, Hayes & Schwartzstein, 2019).

The above studies clearly imply that some clinicians appear not to make a diagnosis during clerkship of clients or patients and therefore rely heavily on laboratory results which may not necessarily be available early enough for the next action. Lack of early availability of results delays action or treatment of such clients leading to undesired obstetric outcomes. These undesired outcomes are primarily due to failure to make a correct initial diagnosis. In this study, the circumstances are different in terms of the research approach. Whereas the research was retrospective in the case of Chattopadhyaya (2013), a cross-section analytical design shall be used and respondents instead of vignettes as in the case of Tsukamoto (2012). The setting shall be Bungoma County and therefore shall compare the findings in Kenya with those found in India. Diagnostic errors have a significant bearing on the totality of a patient's care and impact negatively on the quality of health care of patients (Harolds, 2015). A clinical-pathological discrepancies study in Mozambique according to Ordi *et al.* (2019) posited those major diagnostic discrepancies were detected 58% of cases were results of infection that were fatal hence resulting in about 70% of the patients to mortality. The impact of misdiagnosis ranges from physical, psychological, spiritual and social trauma that has devastating effects on the patients sometimes for life. (Gatonye, 2017)

illustrates a delayed diagnosis for a cancer patient to have both physical and psychological traumata while Kabale and Kamau (2017), demonstrate the psychosocial and physical trauma that a patient had to undergo due to misdiagnosis with HIV. The outcomes that arise from an emergency obstetric misdiagnosis therefore can be more devastating since it requires emergency care.

The study, therefore, sought to look at the degree to which health services for individuals and populations have the likelihood of getting desired health outcomes which is the ultimate goal in health service. The outcomes are consistent with current professional knowledge. Six aims of quality health care are all linked to diagnosis and any form of diagnostic error will vary these outcomes. They include safe healthcare-free of injuries from the care, effective health care- providing services based on scientific knowledge to all, patient centred-responsive to needs, values and preferences, efficient-avoiding waste in terms of equipment, supplies and human resource, and equitable- services that do not vary in terms of gender, ethnic or race. A planned action failure is called a misdiagnosis or diagnostic error. Misdiagnosis, as represented by missed, delayed, wrong or no diagnosis, leads to a threat in providing quality care as they result in health care errors. There are four main types of errors in health care management that are recognized. They are diagnostic, treatment, preventive and others. Misdiagnosis is a diagnostic error that results in an adverse patient outcome (Harolds, 2015)

In Kenya, complications arising from pregnancy and puerperium are leading causes of inpatient morbidity and mortality in females according to Njoroge (2012). Direct causes of maternal mortality result from obstetric complications of pregnancy, labour and puerperium including interventions or any after-effects of these events. The delay in

receiving adequate and or correct emergence care from the initial misdiagnosis of a pregnant mother contributes to the underlying causes of maternal mortality and morbidity. Timeliness of interventions including correct early initial diagnosis is imperative if adverse maternal outcomes are to be averted. Chattopadhyaya (2013) acknowledges that a high degree of diagnostic accuracy with less variability between initial diagnosis and final diagnosis (discharge diagnosis) is important in the practice of not only medicine but more importantly obstetric care. The initial diagnostic accuracy has various serious clinical, financial and legal implications.

2.5 Research Gap

Diagnostic errors lead to delays in treatment, inappropriate or unnecessary treatment. This may in turn lead to physical, psychological and financial consequences that affect not only the patient but even the nation at large. Researches indicate that diagnostic errors have received comparatively less attention), yet diagnostic error may be common. The study sought to investigate the prevalence of diagnostic errors and how they influence obstetric outcomes.

Reducing Maternal mortality in Kenya is the greatest challenge of the counties where health is a devolved function and where the maternal deaths are above the national average as with the case of Bungoma that has a maternal mortality rate of 362 deaths per 100,000 live births. However, the causes of this maternal mortality are due to conditions in pregnancy, which if identified early (diagnosis) may be treated and help avert unsafe outcomes. The study sought to investigate if there were any diagnostic errors during FANC through to delivery that may have contributed to certain outcomes by looking at the initial diagnosis and final diagnosis. Inconsistencies between the initial diagnosis and final or discharge diagnosis form diagnostic errors or misdiagnosis

that has an influence on treatment and investigations of the client as intervening factors and compare with the outcomes and determine the associations between diagnostic errors and maternal outcomes. Thirdly there is follow up and tracking of the diagnostic information and finally, there is a subspecialty, consultation and referral issue to complete the diagnostic management process. This is followed by safe management of the patient and finally giving a safe outcome. Any failure in this cycle or in this process results in a diagnostic error.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Overview

This chapter presents the description of the study area, research design, the study population, variables of the study, sampling techniques, sample size determination, data collection, data analysis and ethical consideration.

3.2 Study area

The study was carried out in Bungoma County which is the fourth most populous county after Nairobi, Kiambu, Nakuru and Kakamega. The study used two-level five teaching and referral hospitals in Bungoma County (Bungoma and Webuye). The County borders Uganda and serves a number of patients from our neighbouring country Uganda. Bungoma County covers a surface area of just Over 3,000 km² with an estimated population of 1.7 million. The population aged below 15 years make up 46 per cent of the entire population. Among its numerous structures built for health service delivery, there are 10 Hospitals, 16 Health Centres and 88 functional Dispensaries (CIC, 2015). Bungoma County has nine sub-counties namely; Kanduyi (Bungoma South), Bumula, Sirisia, (Bungoma West) Mt Elgon, Kimilili, Webuye West, Webuye East, Tongaren (North Bungoma) and Kabuchai (Bungoma Central). Bungoma County is thought to be a rural county which may be impacting negatively in terms of specialists who are responsible for making the diagnoses (WHO, 2010). The County still records a maternal mortality ratio of 382 maternal deaths per 100,000 live births (Gacheri, 2016). This is beyond the national average of 362 deaths per 100,000 live births.

3.2 Research Design

The study adopted a cross-sectional research design. A cross-sectional design usually minimizes the bias and therefore improves Reliability. According to Sharma, (2014), a good research design minimizes bias and maximizes reliability. Regarding data to be collected in this study, it was a preferred design for the study. A cross-sectional research design is essential when collecting different data from one respondent in that it enhances flexibility and agility. Besides, the information is collected from one point in time and takes a fairly short time of period to collect data needed for the study.

3.3 Study population

According to the District health information system [DHIS], (2017), the number of admissions of obstetric cases in the nine sub-counties was as follows, Webuye hospital had 5,510 admissions in maternity per year whereas Bungoma referral hospital had 6,730 admissions in maternity per year making a total of 12,240 admissions in maternity per year. This is the number of mothers expected in post-natal wards after delivery every year translating into 1000 post-natal mothers in the post- natal ward every month. The study targeted all women admitted to post-natal wards due to pregnancy complications. These women in post-natal wards had delivered from the facility and had pregnancy or pregnancy-related complications.

3.3.1 Inclusion criteria

All mothers admitted in post-natal wards due to pregnancy were enrolled based on the sampling criteria. All post-natal women were eligible and all those who consented were included in the study. Health care providers to women during pregnancy, delivery and post-delivery were included in the study too. Only women living in Bungoma County were included in the study.

3.3.2 Exclusion criteria

Those who refused to consent and were underage were not included in the study and respondents were not admitted to maternity. Health workers in other departments were excluded.

3.4 Study variables

3.4.1 Dependent variables

Dependent variables were obstetric outcomes (pregnancy outcomes).

3.4.2 Independent variables

Independent variables are grouped as diagnostic errors which included, delayed diagnosis, missed diagnosis, absent diagnosis, misinterpretation of results both radiological and laboratory, wrong diagnosis and unnecessary laboratory or radiological investigations.

3.5 Sampling design

3.5.1 Sampling procedure

A mixed sampling method was used. Systematic random sampling was used to get the post-natal mothers in this study where every k^{th} number was picked from the list of women on discharge. Before establishing the k^{th} value, the starting value was randomly selected in excel using the random function. The post-natal mothers provided their records for verification through content analysis during the interview. Purposive sampling was used to pick the health workers who worked in ANC and maternity units who had vast experience with the areas of concern as key informant interviewees (consultant obstetrician gynaecologist, medical officers, reproductive health clinical officers and nurses working in maternity). Moreover, the two referral hospitals were

also sampled purposively because of the high volume of women seeking ANC and birthing services and they are the main referral hospitals.

3.6 Sample size determination

The sample size was determined using Fisher's formula (Kothari, 2016)

$$n = \frac{z^2 p q}{d^2}$$

Where:

n = the desired sample size (when the target population is greater than 10,000)

z = standard normal deviation set at 1.96 which corresponds to 95% confidence interval

p = proportion of the target population estimated to have a characteristic that is being measured (at 50%) to maximize sample size. (Post-natal mothers)

$$q = 1 - p (1 - 0.5) = 0.5$$

d = degree of accuracy desired set at 0.05

Therefore,

$$n = \frac{1.96^2 \times 0.5 \times 0.5}{0.05^2} = 384 \text{ respondents}$$

Using proportions, Bungoma County Referral Hospital had 211 participants whereas 173 were allocated to Webuye Hospital. Health care providers were purposively sampled for key informant interviews in either of the hospitals that depended on availability. They included a consultant obstetrician, a medical officer working in maternity, reproductive health clinical officer and a Nurse working in maternity with 4 in each hospital totalling to 8. Table 3.1 presents the sample frame.

Table 3.1: Sample frame

Sub-county	Bungoma	Webuye
Kanduyi	183	13
Bumula	35	10
Sirisia	59	18
Mt Elgon	120	98
Kimili	111	76
Webuye West	70	147
Webuye East	27	118
Tongaren	33	32
Kabuchai	35	29
Total	211	173

Data of women presented in frequencies

3.7 Data and information collection

3.7.1 Procedure

The interview was conducted with key informants using a key informant interview schedule. The key informants included consultant obstetricians, reproductive health clinical officers, medical officers working in maternity and a nurse providing services to mothers in Maternity. A schedule for key informant interviews was prepared to specifically target the professionals as observed by Kothari, (2018).

3.7.2 Data collection instruments

The study employed two data collection instruments. A structured questionnaire was used to collect data from women. The questionnaire response rate was 85.2% (327). Obstetric outcomes information was extracted from the individual woman's, ANC booklet and files through content analysis and the women's account during their pregnancy period

The questionnaire was used to collect quantitative data on the diagnostic errors as predictors of obstetric outcome in Bungoma County. The questionnaire had both open-ended and closed-ended questions which were divided into three parts: socio-

demographic, the prevalence of diagnostic errors, variation of diagnostic errors and relationship between diagnostic errors and obstetric outcome. The questionnaire return rate was 85.2% (327/384).

An observation checklist was designed to capture MCH booklet information on the variation of initial diagnosis and final diagnosis and obstetric outcome.

Qualitative data was collected using key informant interview guides. Pre-tested interviews were facilitated by the principal investigator and trained research assistants who were well versed in knowledge in antenatal care clinics and maternity operations. The interview guide was composed of open-ended questions; this gave the researcher a detailed understanding of issues under study and information that could not be directly observed. In-depth interviews were conducted on eight health care workers four from each facility sampled for the study.

3.7.3 Reliability

Kothari (2016) defines reliability as a measure of the degree to which a research instrument yields consistent results or data after repeated tests when administered a number of times. In this study, the main instrument of the measure was a questionnaire that was administered to the mothers. The reliability was determined by correlating odd and even scores obtained from the data collected. Therefore split-half test was performed and obtained the Cronbach coefficients of 0.891. Note that a Cronbach reliability coefficient of 0.70 or higher was considered "acceptable" and in this study, it was found to be 0.891 as shown in Table 3.2

Table 3.2: Reliability Statistics for Independent Variables

Cronbach's Alpha	N of Items
0.891	30

3.7.4 Validity

According to Bolarinwa (2015), Validity is the accuracy and meaningfulness of inferences, which are based on the research results. An instrument is valid if it measures what it claims to measure. Validity has to do with how much accuracy the data obtained in the study represents the variables of the study. It is largely determined by the presence or absence of systematic error in data. Content validity is a measure of the degree to which data collected using a particular instrument represents a specific domain of indicator or content of a particular concept. For a data collection instrument to be considered valid, the content selected and included must be relevant to the need or gap established. The researcher used content validity by piloting so as to ascertain whether the tools measured what was stated in the objectives. This was done through cross-checking with the supervisors.

3.8 Pre-test

A pre-test of the items was done in Kimilili Sub County Hospital to test the validity and reliability of the questionnaire. The residents of Kimilili have the same characteristics as those of the actual sample which the researcher planned to use in the study. A total of 30 women in postnatal wards and 2 key informants were engaged in the pre-test. The responses from the exercise were used to help the researcher in identifying some of the shortcomings that would have been experienced during the actual data collection exercise. Kimilili is in Bungoma County and provides services to both urban and rural dwellers.

3.9 Data analysis

Both quantitative and qualitative approaches were used. Raw data collected from the questionnaires were coded by assigning numerical values to each response and

entering it into a codebook. Thereafter the numerical numbers representing responses from the questionnaires was transferred to a code sheet so as to obtain quantitative results from the closed-ended questionnaires. The Statistical Package for social sciences (SPSS) version 25 was used to run descriptive statistics to produce frequency distribution, and percentages. The researcher also formulated categories of responses for all open-ended questionnaires and interviews so as to obtain quantitative data. Inferential statistics, Chi-square and odds ratio was used to determine the influence between variables, their significance and prediction. All *p*-values were considered statistically significant when they were less than or equal to 0.05 (≤ 0.05). Qualitative data collected from key informant interviews [(KII) was analyzed by thematic content analysis. A summary of statistical techniques is as shown in Table 3.3 below

Table 3.3: Summary of statistical techniques

Specific objective	Statistics	Statistical tool
Objective 1 To establish the prevalence of diagnostic errors among post-natal mothers in Bungoma County	Descriptive (Frequencies and percentages) Qualitative- Verbatim	SPSS v25
Objective 2 To Determine the variations between initial diagnosis and final diagnosis among post-natal mothers in Bungoma County	Descriptive (Frequencies and percentages, Mean; Standard deviation) Qualitative- Verbatim	SPSS v25
Objective3 to Determine the relationship between diagnostic errors and obstetric outcomes among post-natal mothers in Bungoma County	Inferential (Chi-Square, Odds Ratio) Qualitative- Verbatim	SPSS v25

3.10 Ethical considerations

The research ethical clearance was sought from Masinde Muliro University of Science and Technology [MMUST] Institutional Ethical Review Committee [IERC] and a

research permit from the National Council of Science, Technology and Innovation [NACOSTI]. The researcher further sought permission from MOH before carrying out the study. Prior to data collection, letters were written to the hospital Medical Superintendent of Bungoma County Referral Hospital and Webuye County Hospital to seek permission to conduct the study.

Participants were briefed on the nature of the study before the commencement of the interviews. All participants were asked for consent before participating in this study. A thumb print was accepted for those who cannot read and write. Participants in the study were informed that participation was voluntary and that no penalties were involved for those who declined to participate. In this study, there was no physical harm; however, the investigator was sensitive to psychological consequences. The researcher was sensitive to participants' emotions when probing questions that may psychologically harm them. Further, the researcher ensured the will of the subjects was respected especially for those who wanted to discontinue at any level of the study and those who chose to remain silent.

Participants of the study were informed of benefits including; the study being used in policymaking and coming up with better interventions that were to reduce diagnostic errors during pregnancy hence improving maternal outcomes. Participants in KIIs benefit was that their ideas and suggestions were to be implemented in future by the MOH Bungoma County, hospitals and the Community. There was minimal risk to the individuals participating in this study. The primary risk of this study was, therefore, the loss of confidentiality of information. This was mitigated by using numbers on each questionnaire and the KII guide not using participants' names.

CHAPTER FOUR

RESULTS

4.1 Overview

The chapter presents the research findings of this study. Descriptive statistical analysis includes; frequencies, means, standard deviations and percentages. The chapter also presents the descriptive and inferential statistical analysis of the study, and from which inferences were drawn.

4.2 Socio-demographic Characteristics

The study investigated the socio-demographic characteristics of the participants as a baseline for this study. It was important in this study to determine the participant's social characteristics. Therefore, age, parity, marital status, education level religion and income were investigated. Education level sought to understand the participant competence and ability to answer the questions. Age was categorised into two, i.e., youthful women and above youthful women. This sought to set the baseline where women beyond 35 years are more prone to complications arising from pregnancy as compared to women above 18 years and less than 35 years. According to the findings presented in Table 4.2, 78.6% of the participants were below 35 years, 65.7% had delivered at least twice, 83.8% were married, 90.2% had at least gone through primary school (formal education) and 71.3% were Christians (27.5% Muslims while 1.2% other religions).

Table 4.1: Socio-demographic characteristics

Socio-demography		Frequency	Percentage
Age			
	< 35	257	78.60%
	> 35	70	21.40%
Parity			
	First delivery	112	34.30%
	Second delivery	215	65.70%
Marital Status			
	Married	274	83.80%
	Not married	53	16.20%
Education Level			
	Primary	41	12.4%
	Secondary	176	53.7%
	Tertiary	79	24.1%
	None	32	9.80%
Religion			
	Christian	233	71.3%
	Muslim	90	27.5%
	Others	4	1.2%
Income			
	Formal	72	23%
	Informal	170	51.9%
	Others	85	25.9%

Results were presented in proportions (%); n=327

Source (Researcher, 2020)

4.3 Antenatal care services

4.3.1 Handling of women during ANC attendance

The study sought to investigate whether the respondents were handled well during their ANC attendance and the summary is as shown in Table 4.3. From the study findings, 173(52.9%) and 159(48.6%) of the respondents strongly agreed that they were treated politely and spend enough time during their antenatal care attendance respectively. 46.8% of the respondents agreed that they were examined during their antenatal care visits while 45.0% of the respondents agreed that they were informed of their progress. This showed that the expectant mothers were given attention during their antenatal care

visits. Skilled care during pregnancy and birth are encouraged to reduce avoidable maternal and newborn morbidities and mortalities. To achieve this, expectant mothers should take the lead in decisions about their health care utilization.

Table 4.2: Response on antenatal care attendance

	Strongly agree (%)	Agree (%)	Disagree (%)	Strongly disagree (%)	Not sure (%)
Treated you politely	173(52.9)	113(34.6)	35(10.7)	5(1.5)	1(.3)
Spend enough time	159(48.6)	105(32.1)	58(17.7)	3(.9)	2(.6)
Told you of progress	141(43.1)	147(45.0)	36(11.0)	2(.6)	1(.3)
Examined	152(46.5)	153(46.8)	19(5.8)	2(.6)	1(.3)
Informed the findings	154(47.1)	137(41.9)	33(10.1)	2(.6)	1(.3)

Source (Researcher, 2020)

4.3.2 Reception of information during antenatal care visit

On investigating whether the expectant mothers received sufficient information during their antenatal care visit, 82.3% of the respondents agreed that they were informed of their physical health during their pregnancy; 74.9% of the respondents accepted that they were given sufficient information on their possible mood changes during their pregnancy. With reference to baby's development, 77.4% of the respondents agreed that they were given sufficient information on how their babies' were developing and 81.7% of the respondents agreed that they were informed on what to expect during their birth. With a mean of 1.29, 70.9% of the respondents agreed that they were informed

on a post-natal period (e.g., breastfeeding, nutrition, and care for the child). The summary of the findings is as shown in Table 4.3.

Table 4.3: Response on whether the respondents received sufficient information during ANC visit

		Frequency	Per cent	Mean	SD
Your physical health during the pregnancy	Yes	269	82.3	1.18	.383
	No	58	17.7		
Possible mood changes during the pregnancy	Yes	245	74.9	1.25	.434
	No	82	25.1		
How the baby was developing	Yes	253	77.4	1.23	.419
	No	74	22.6		
What you could expect regarding the birth	Yes	267	81.7	1.18	.388
	No	60	18.3		
Post-natal period (e.g., breastfeeding, nutrition, care for the child)	Yes	232	70.9	1.29	.455
	No	95	29.1		

Source (Researcher, 2020)

4.4 Prevalence of diagnostic errors as predictors of obstetric outcomes

The researcher established the prevalence of diagnostic errors as predictors of obstetric outcomes. This was achieved through investigating the prevalence of diagnostic errors at antenatal care clinics, which potentially established the prevalence of diagnostic errors against obstetric outcomes.

4.4.1 Prevalence of diagnostic errors at antenatal care

The study sought to investigate the prevalence of diagnostic errors as predictors of obstetric outcomes. To investigate this prevalence, diagnostic error attributes on whether they were exhibited during the ANC visits was done. Therefore, it was established that the majority of diagnostic errors were caused by delayed diagnosis 141 (43.1%) with other diagnostic errors being missed diagnosis 127 (38.8%), absent

diagnosis 88 (26.9%), wrong diagnosis 111 (33.9%), misinterpretation of tests 79 (24.2%), unmatched diagnosis 86 (26.3) and unnecessary investigation 63 (19.3).

Table 4.4: Diagnostic errors as predictors of obstetric outcomes at antenatal care

Predictor of outcome	Frequency	Per cent
Delayed diagnosis	141	43.1
Missed diagnosis	127	38.8
Absent diagnosis	88	26.9
Wrong diagnosis	111	33.9
Misinterpretation of tests	79	24.2
Unmatched diagnosis	86	26.3
Unnecessary investigation	63	19.3

Results were presented in proportions (%); n=327

Source: Researcher (2020)

The researcher calculated the prevalence of the diagnostic errors, which was found to be 30.4%. The researcher calculated the mean of the individual diagnostic errors from Table 4.4. This, therefore, meant that in a hundred women seeking obstetric services 30 women experienced a diagnostic error.

4.4.2 Prevalence of diagnostic errors against obstetric outcomes

Tables 4.5 showed that delayed diagnosis contributed to 43.1% unsafe obstetric outcomes, missed diagnosis contributed to 38.8% unsafe obstetric outcomes, absent diagnosis contributed to 27.5% unsafe obstetric outcomes, the wrong diagnosis contributed to 34.9% unsafe obstetric outcomes, misinterpretation contributed to 24.2% unsafe obstetric outcomes, unmatched diagnosis contributed to 26.3% unsafe obstetric outcomes and unnecessary investigation contributed to 19.3% unsafe obstetric outcomes.

Table 4.5: Prevalence of Diagnostic errors against obstetric outcomes

Diagnostic Errors and Obstetric Outcome	Frequency	Percentage
Delayed diagnosis		
Unsafe Obstetric outcome	141	43.1
Safe Obstetric outcome	186	56.9
Missed diagnosis		
Unsafe Obstetric outcome	127	38.8
Safe Obstetric outcome	200	61.2
Absent diagnosis		
Unsafe Obstetric outcome	90	27.5
Safe Obstetric outcome	237	72.5
Wrong diagnosis		
Unsafe Obstetric outcome	114	34.9
Safe Obstetric outcome	213	65.1
Misinterpretation of tests		
Unsafe Obstetric outcome	79	24.2
Safe Obstetric outcome	248	75.8
Unmatched diagnosis		
Unsafe Obstetric outcome	86	26.3
Safe Obstetric outcome	241	73.7
Unnecessary investigation		
Unsafe Obstetric outcome	63	19.3
Safe Obstetric outcome	264	80.7

[Safe outcome = pregnancy had no complication; unsafe outcome = pregnancy had complications.]; the results were presented in proportion (%); n=327

Source: Researcher (2020)

Key informant findings corroborated this study where key informant three stated that:

... The solution to reducing diagnostic errors lies in CMEs and well-equipped diagnostic hospitals.

Key informant five stated that:

... Use of protocols, good mentorship, feedback on diagnostic errors committed, emphasis on history and proper physical examination may help in minimizing diagnostic errors.

Key informant seven stated that:

... Some facilities do not have the equipment to monitor pregnancy and some clients cannot afford investigations ordered.

4.5 Variations between initial diagnosis and final diagnosis at level five hospitals

The researcher determined the variation between the initial diagnosis and the final diagnosis. This was an essential predictor of obstetric outcomes. To determine this, the researcher conducted a content analysis of the sampled women personal medical records to ascertain whether the initial diagnosis and final diagnosis matched or did not match. From each, the researcher was also interested in the obstetric outcome from both the matched and the unmatched initial diagnosis and final diagnosis. From the 327 investigated cases, it was determined that matched diagnosis was 72.4% (237). However, the unmatched diagnosis was 27.6% (90). It was further determined that, out of 72.4% of the matched diagnosis, 70.6% (231) had a safe obstetric outcome while 1.8% (6) had an unsafe obstetric outcome. The unmatched diagnosis, on the other hand, had 6.8% (22) safe obstetric outcomes while 20.8% (68) had the unsafe obstetric outcome. The results are presented in Table 4.6

Table 4.6: Matched and unmatched diagnosis as predictors of obstetric outcomes

MCH Booklet diagnosis content analysis	Obstetric Outcome		
	Safe Outcome	Unsafe Outcome	Total
Matched diagnosis	231 (70.6%)	6 (1.8%)	237 (72.4%)
Unmatched diagnosis	22 (6.8%)	68 (20.8%)	90 (27.6%)
Total	253 (77.4%)	74 (22.6%)	327 (100%)

[MCH = Mother and Child Health Booklet, Matched diagnosis = initial and final diagnosis was correctly done; Unmatched = either initial diagnosis or final diagnosis was incorrectly done; n=327]

Source: Researcher (2020)

From the key informant interviews, these findings were corroborated by the key informant, where one stated that:

... The extent of diagnostic errors seems to be on the increase and is generally associated with the present training of health care providers, lack of basic diagnostic equipment for most health facilities during focused antenatal care such as ultrasound.

Key informant two stated that:

... Any single diagnostic error exposes a pregnant woman and her baby to a high risk of complication and possible death.

Key informant five stated that:

... Correct diagnosis improves the pregnancy outcome, lowers the cost. Initial diagnosis and final diagnosis are up to almost 10% due to poor history taking and irrelevant investigations.

Key informant six added by stating that:

... With diagnostic error, a client is given a wrong intervention leading to an effect on the pregnancy. A common misdiagnosis occurs in pre-eclampsia where it is confused for hypertension.

The researcher further calculated the variation of the initial diagnosis and final diagnosis using the matched diagnosis and the unmatched diagnosis. The matched diagnosis was coded 1 and the unmatched diagnosis was coded 2. According to Table 4.7, the matched diagnosis ($N=327$, $M=1.00$, $SD=.000$) had no variation between initial diagnosis and final diagnoses. However, the unmatched diagnosis ($N=327$, $M=1.82$, $SD=0.384$) revealed that there was a variation in diagnosis.

Table 4.7: Variations of matched and unmatched diagnosis predicting the obstetric outcome

Variations	Mean	Std. Deviation
Matched	1.00	0.000
Unmatched	1.82	0.384
Total	1.23	0.419

[Matched diagnosis=initial and the final diagnosis was in agreement; unmatched diagnosis=initial diagnosis was not in agreement with a final diagnosis]

Source: Researcher (2020)

4.7 Relationship between diagnostic errors as predictors of obstetric outcome

The researcher analysed the order of the importance of the diagnostic errors predicting obstetric outcomes (safe and unsafe). The order of importance comprised delayed diagnosis, missed diagnosis, absent diagnosis, wrong diagnosis, and misinterpretation of diagnosis, unmatched diagnosis and unnecessary investigation. The order of importance was used to determine the strength of each diagnostic error predicting obstetric outcome. Table 4.8 illustrated the findings ranked them from the least to the most predictors of obstetric outcome among pregnant women in Bungoma County.

Table 4.8: Order of importance of the diagnostic errors predicting the obstetric outcome

Diagnostic Errors	Order of Importance
Absent diagnosis	0.0200
Misinterpretation of tests	0.0683
Missed diagnosis	0.0950
Wrong diagnosis	0.1334
Delayed diagnosis	0.2373
Unnecessary investigation	0.4460

Results were presented in a ratio; n=327

The researcher was keen to evaluate whether the diagnostic errors – matched and unmatched diagnosis - were significant predictors of adverse obstetric outcomes. Therefore, the Chi-square test of independence was computed at the 0.05 significance level. The results in Table 4.9 showed that diagnostic errors (matched and unmatched diagnosis) were predictors of adverse obstetric errors ($\chi^2 (1) = 251.86^a, p < 0.001$).

Table 4.9: Diagnostic Errors * Obstetric outcome Chi-Square

Diagnostic Errors	Obstetric outcome		Statistics
	Safe	Unsafe	
Matched	231	6	$\chi^2 (1) = 251.86^a, p = .000$
Unmatched	22	68	
Total	253	74	

[a = 0 cells (0.0%) have expected count less than 5. The minimum expected count is 20.37; Matched diagnosis = initial and final diagnosis were agreeing; Unmatched = either initial diagnosis or final diagnosis or both were not agreeing; Safe outcome = pregnancy had no complication; unsafe outcome = pregnancy had complications; n=327]

Source: Researcher (2020)

Therefore, the researcher further performed bivariate analysis to establish whether there was an association between diagnostic errors (matched and unmatched diagnosis) and obstetric outcomes (safe and unsafe) among post-natal women in Bungoma County. Unsafe outcomes were determined by the presence of complications in the patient record. The study found that providers who misdiagnosed or made diagnostic errors during the ANC visits, OPD and admission were 2.03 times more likely to have patients with a complication compared with providers who did not misdiagnose (OR 2.03, 95% CI 1.31–2.16). The results are presented in Table 4.10.

Table 4.10: Predictors of obstetric outcomes

Diagnostic Errors	Obstetric outcome		Odds ratio (95% CI)	p-value
	Safe	Unsafe		
Matched	231	6	2.03 (1.31, 2.16)	0.046
Unmatched	22	68		
Total	253	74		

CHAPTER FIVE

DISCUSSION

5.1 Prevalence of diagnostic errors among post-natal mothers

This study employed the Postulated Theoretical Framework (Singh, 2014) that envisaged understanding the variables that contributed to increased diagnostic errors which were predictors of obstetric outcomes in health facilities in Bungoma County. According to KDHS (2014), the maternal mortality ratio was 382/100,000 live births annually. This number was above Kenya's average annual maternal mortality ratio of 362/100,000. The researcher investigated the variables that were contributing towards increased diagnostic errors in Bungoma, which were: delayed diagnosis, missed diagnosis, absent diagnosis, the wrong diagnosis, misinterpretation, unmatched diagnosis and unnecessary investigation.

It was established that delayed diagnosis contributed 43.1% to unsafe obstetric outcomes and 56.9% to a safe obstetric outcome. The delayed diagnosis among the diagnostic errors was established as the main predictor of unsafe obstetric outcomes among pregnant women in Bungoma County. This finding is consistent with the findings of Bernnett and Kaimenyi (2017) that opined that delayed referral was the main contributing factor to increased morbidity in pregnant women in Bungoma County. The research findings of the delayed diagnostic error being a common variable are suggestive of the delay being associated with difficulty in making a diagnosis or wrong diagnosis and sometimes unnecessary investigations. Further, still, this phenomenon may have contributed to by inability to identify the initial diagnosis and, therefore, inappropriate referral decision making.

Prompt diagnosis of a condition is at the epicentre of reproductive health. Failure to promptly diagnose a condition that might develop into an adverse condition predisposes the pregnant women towards a negative and riskier obstetric outcome that might also be fatal. This study found out that most pregnant women who developed adverse conditions during pregnancy and even fatalities among them were contributed by delayed diagnosis.

Missed diagnosis contributed 38.8% to an unsafe obstetric outcome and 61.2% to a safe obstetric outcome. Missed diagnosis misleads a clinician from the next step of the diagnostic process. In the event of an absent diagnosis, the problem is even worse because it raises dilemmas in the management of the patient. This is worse in cases of obstetric emergencies. The researcher posited that missed diagnosis contributed to an increased maternal mortality ratio of 382/100,000 in Bungoma County. Besides, absent diagnosis contributed 27.5% to unsafe obstetric outcomes, with about 72.5% safe obstetric outcomes. This finding compared to the findings in rural China and India where the absent diagnosis was up to above 70 % (Das, 2018) reveals a relatively better diagnosis in Kenya. However, it is still possible to minimize the diagnostic errors and improve pregnant women's outcomes. Hidden conditions give a false negative medical diagnosis which contributes towards wrong medical conclusions. At Bungoma County, it was established that it contributed to about a quarter of the unsafe obstetric outcomes in Bungoma County. This also meant that there was no retesting of these false-negative to try to manage the prevailing conditions that might be accessed from the pregnant woman's medical records and home history.

It was also established that the wrong diagnosis contributed 34.9% to unsafe obstetric outcomes and 65.1% to the safe obstetric outcome. The wrong diagnosis has adverse

obstetric outcomes in most cases. With the wrong diagnosis, wrong intervention might be applied and fatalities therein. Based on the maternal mortality ratio of 382/100,000 live births in Bungoma, the wrong diagnosis will continue to increase affecting Kenya's target on the national maternal mortality ratio of 147/100,000 (KDHS, 2014). The increased prevalence of maternal mortality ratio in Bungoma County could be the product of the wrong diagnosis which was noted by Oketch (2017) that the wrong diagnosis was the silent killer and might have claimed the lives of many pregnant women after wrong treatment. The findings on the wrong diagnosis were in support of Liberman (2018) where it was stated that 12 million people in the USA were misdiagnosed annually. Misinterpretation of diagnostic data contributed 24.2% to unsafe obstetric outcomes and 75.8% to the safe obstetric outcome. Lack of specialised treatment at the ANC and maternity is catastrophic to pregnant women. Also, inadequate experience in reproductive health providers working with pregnant women contributes to misinterpretation of the diagnostic data at ANC and maternity. According to Graham (2015), diagnostic errors in many instances were caused by failures in the interpretation of the findings mostly radiological and laboratory information. WHO (2016) posited that it was important to address morbidity and mortality among pregnant women and their foetuses/babies?

The unmatched diagnosis among the pregnant women contributed 26.3% to unsafe obstetric outcomes and 63.7% to the safe obstetric outcome. This was attributed to either wrong initial or wrong final diagnosis or both were wrongly done after the researcher reviewed the medical records of the participants (MCH Booklet and medical notes). The unmatched cases emanated from the unprofessionalism of the healthcare workers at the ANC and maternity. This was an unfortunate occurrence considering the global campaigns on the promotion of safe motherhood outcomes. It was established

that unnecessary investigation of the pregnancy progress contributed 19.3% to unsafe obstetric outcomes and 80.7% to the safe obstetric outcome. This led to interference with the pregnancy and created new potential adverse conditions among pregnant women.

The unmatched diagnosis is attributed to either wrong initial or wrong final diagnosis or both were wrongly done. It is clearly known that the unmatched diagnosis has a higher probability of leading to unsafe complications in birthing even death. There is a global campaign on the promotion of safe motherhood outcomes; however, diagnostic errors are persisting especially in sub-Saharan Africa. While most pregnancies and births are uneventful, all pregnancies are at risk. Failure to properly diagnose a condition contributed to errors in emergency departments that rippled to obstetric emergencies. Diagnostic errors receive comparatively less attention and yet they are common globally (Nathan *et al.*, 2017). Pregnancy is double-edged – joyful anticipatory time and on the flip side grave concern and anxious time. It can be concluded from the WHO (2018) stating that around 15% of all pregnant women globally develop a potentially life-threatening complication that calls for skilled care, some requiring a major obstetrician intervention to survive. This is exactly a concern in Bungoma County, where about 30 women in 100 women have a potential of diagnostic errors; which this study found leading to high risk to the obstetric outcome.

5.2 The variations between initial diagnosis and final diagnosis

The investigation on the variation between initial and final diagnosis among post-natal women in Bungoma County teaching and referral hospital showed that the matched diagnosis did not vary. The variation from the unmatched diagnosis indicated that the initial and final diagnosis was not agreeable. Therefore, the unmatched diagnosis was

highly varied which increased the risk of unsafe obstetric outcomes among pregnant women. It was a known fact that the way pregnant women are handled at the antenatal care clinic and maternity was important in this study of diagnostic errors as a predictor of the obstetric outcome.

This study established that pregnant women were being handled well at the facility, where the healthcare workers at antenatal care shared antenatal information concerning the pregnancy progress, which was important for birth preparedness. But, still, maternal mortality was 382 deaths per 100,000 live births. What made it a continuous problem in health facilities in Bungoma County? It was determined that most facilities were ill-equipped to effectively diagnose from the first time of consultation where the initial diagnosis was essential in planning for the next course of action. The protocols for diagnosis and subsequent treatment of a pregnancy-related condition were poor thus promoting increased diagnostic errors. The results from the study showed that initial diagnosis and final diagnosis had a standard deviation of 0.387 whereas with this variation when projected to pregnancy outcomes there were 20.4 % unsafe pregnancy outcomes resulting from these diagnostic errors. This finding tends to emphasize and support the findings of Kar, (2010) that showed that disparities between initial diagnosis and final diagnosis stood at 57%. Kar, (2010) further alluded to the gap being present in the obstetric care department dealing a significant effect to not only pregnant women but also on neonates.

In clinical practice, achieving a low degree of variability between initial diagnosis and discharge diagnosis is essential. Making accurate diagnoses helps in subsequent decision making especially in reproductive health where time is of essence (Chattopadhyay, 2013). The results of the study showed that initial diagnosis had a

significant variation to the final diagnosis which tends to agree with a study in India that gave 18.4% prevalence disagreement on clinical autopsy (Vougiouklakis, 2011), while Kar (2010) research finding gave a variation to the tune of 57%. This finding, therefore, showed that the discrepancies between initial diagnosis and final diagnosis eventually affected the management of the patient and subsequent outcomes. It was, therefore, pertinent that an initial diagnosis was correct for effective, quality and timely intervention.

A Kenyan retrospective study by Yego, *et al.* (2013), stated that complications arising from pregnancy and puerperium have been leading to increased morbidity and mortality in females and neonates. Direct causes of maternal mortality result from obstetric complications of pregnancy, labour and puerperium including interventions or any after-effects of these events. The delay in receiving adequate and or correct emergency care from the initial misdiagnosis of a pregnant woman contributes to the underlying causes of maternal mortality and morbidity. Timeliness of interventions including correct early initial diagnosis is imperative if adverse maternal outcomes are to be averted. In reference to the USA, Liberman (2018) opined that about five per cent of the adult population were misdiagnosed while they sought outpatient, services.

Abebe, (2017) avers that the purpose of focused antenatal care (FANC) is to optimize maternal and foetal health, provide maternal and foetal screening (initial diagnosis), make medical and social interventions where necessary and ultimately improve the outcomes of the pregnancy. However, the study reveals that there was nobody to interpret the results at 7% during FANC visits and &7.3 % at OPD. The study also revealed that diagnostic errors generally ranged from 7.0% to 18.7% cumulatively. FANC visits alone without an initial diagnosis that matches with discharge diagnosis is

insufficient to alter maternal outcomes. It was therefore noted that without incorporating good diagnostic management practices, FANC visits alone may not yield safe pregnancy outcomes. This study is also collaborated by a study of gap analysis between initial diagnosis and final diagnosis by Vougioklakis (2011) where the study compared clinical diagnosis and autopsy findings. In this study, it was noted that there were incidences where the initial diagnosis was missing in 43% of the cases. High prevalence rates observed in the study seem to suggest corresponding unsafe outcomes and a subsequent increase in maternal morbidity and mortality.

5.3 Relationship between diagnostic errors as predictors of obstetric outcomes

Singh's theory (2014) states that diagnostic errors may result in adverse outcomes and that diagnostic errors misdirect interventions that may eventually result in an adverse pregnancy outcome. The study finding revealed that indeed there were diagnostic errors that influenced obstetric outcomes at Bungoma level five referral hospitals. Chi-square performed showed that there was an association between diagnostic errors and pregnancy outcomes. These results are consistent with a study done by Ordi *et al* (2019) in Mozambique, where major diagnostic errors were associated with up to 58% adverse outcomes and these outcomes resulted in 70% mortalities. These findings are further reinforced by Chattopadhyaya, (2013) who acknowledges that timeliness of interventions including correct early initial diagnosis was imperative if adverse maternal outcomes were to be averted.

This study shows that unnecessary investigation, delayed diagnosis and wrong diagnosis contributed to increased diagnostic errors. This was evident that health care providers tend to pay little attention to patients' conditions and order unnecessary investigations(Shimkhada *et al*,2016) Furthermore, some health practitioners waste a

lot of time to make a diagnosis especially during the first antenatal care visit, which may magnify the underlying condition hence leading to the wrong diagnosis. It was also established that diagnostic errors were a statistically significant predictor of unsafe obstetric outcomes. However, with matched diagnosis, the chances of unsafe obstetric outcomes are very negligible. Health practitioners need to endeavour to mitigate diagnostic errors in order to promote safe obstetric outcomes. According to Harolds (2015), diagnostic errors have a significant bearing on the totality of patients or clients care. Diagnostic errors impact negatively the quality of health care of the patient or client. The impact can be in the form of physical, spiritual, psychological, and social trauma. Complications arising from pregnancy and puerperium are the leading causes of morbidity and mortality in women and the timeliness of interventions during diagnosis is pertinent for the subsequent reduction in mortalities (MOH, 2017).

To examine the relationship between diagnostic errors and obstetric outcomes, logistic regression was done and it was found that diagnostic errors predicted obstetric outcomes with diagnostic errors having 2.03 more likely to result in an adverse obstetric outcome. This finding tended to agree with a study done in the Philippines where the Odds ratio was 2.96. However, the study in the Philippines was a simulation and was mainly centred on the health care workers whereas the study in Bungoma mainly was directed at those affected women who were pregnant. Any form of diagnostic errors, therefore, that can be minimized may help in reducing the probability of an adverse outcome and promoting safe pregnancy outcomes. To illustrate the magnitude of the adverse effects of diagnostic errors, a study was carried at Moi Teaching and Referral Hospital by Yego et al 2013 and the hospital record audit showed that 51% of the neonatal mortalities occurred and 64% of maternal deaths did occur and this shows the morbidities and mortalities that occurred during and at birth which may have been

influenced by diagnostic errors. These views were reinforced by the views expressed by Harolds, (2015) that misdiagnosis causes more fatalities than road traffic accidents in the United States of America

History taking and physical examination form the basis of the diagnostic process in a workstation. However, in this error of technology, Carayon (2014), asserts that the workstation provides the context in which the diagnostic process occurs. And this takes us to the investigation part. In this study, it was noted that unnecessary investigation and lack of interpretation was an issue that contributed to the diagnostic error and therefore influenced the pregnancy outcomes. It's worth noting that in some instances backed by the key informant interview, it has been suggested that with some point of use innovative equipment, instant diagnosis can be made and therefore improve initial diagnosis. Towards the same direction, Abimany-Ochom et al (2019) suggests that minimizing diagnostic errors in an acute setting like obstetrics require prudent use of technology as a point of use ultrasonography

Direct causes of maternal mortality result from obstetric or pregnancy complications as opined by Njoroge(2012). the complications are conditions which if diagnosed early the correct interventions were undertaken. Early diagnosis especially initial diagnosis is therefore essential in minimizing diagnostic errors that are important in promoting pregnancy outcomes, whereas delayed, missed, absent, the wrong diagnosis with unnecessary investigations and wrong interpretations do influence pregnancy outcomes adversely

CHAPTER SIX

CONCLUSION AND RECOMMENDATION

6.1 Conclusions

This study found out that about 30 women in 100 women who sought services at the antenatal care clinic experienced a diagnostic error. The diagnostic errors originated from delayed diagnosis, missed diagnosis, absent diagnosis, wrong diagnosis, misinterpretation of the test, and unnecessary investigations.

The unmatched diagnosis (variation between the initial and the final diagnosis) contributed to the high burden of the unsafe obstetric outcome. The matched diagnosis (agreeable initial and final diagnosis) had no variation. The variation between the initial diagnosis and the final diagnosis was a statistically significant predictor of obstetric outcome. The unnecessary investigation, delayed diagnosis and wrong diagnosis contributed to increased diagnostic errors among the pregnant women in Bungoma County.

The study found that indeed diagnostic errors had an influence on the obstetric outcome and significantly resulted in adverse pregnancy outcomes. Diagnostic errors predicted an adverse pregnancy outcome at 2.03 times more likely than without a diagnostic error.

The study demonstrates that a correct diagnosis is a viable strategy in preventing unsafe obstetric outcomes.

6.2 Recommendations

The study recommended the following;

The ministry of health (MOH) together with county governments consider providing in-service training to the health practitioners (undergo mandatory updates especially in

emergency obstetric and neonatal care) to promote and improve their diagnostic skills in order to reduce the prevalence of diagnostic errors. Moreover, the purpose is to expand diagnostic capacity including laboratory services and point of use tests in dispensaries, health centres, sub-county hospitals and county hospitals.

MOH and the County Government of Bungoma to consider the introduction of precise and simple diagnostic technology equipment such as handheld ultrasound for obstetric use including training of health workers in their application.

There should be rapid and multiple consultations among health care workers during health care provision to pregnant mothers to improve the accuracy of the diagnosis.

6.3 Suggested study

A study is suggested to focus on determining the common sites where diagnostic errors occur and policy influence on diagnostic processes.

REFERENCES

- Abebe, S. (2017) Quality of antenatal care service in public health facilities of Chencha district, gamogofa zone, southern Ethiopia. *MOJ Women's Health*. 2017; 4(3):57–64. DOI: 10.15406/mojwh.2017.04.00086
- Abimanyi-Ochom, J., Mudiyansele, S. B., Catchpool, M., Firipis, M., Dona, S. W. A., & Watts, J. J. (2019). Strategies to reduce diagnostic errors: a systematic review. *BMC medical informatics and decision making*, 19(1), 1-14.
- Balogh, E.P., Miller, B. T. & Ball, J. R. (2015). *Improving Diagnosis in Health Care*. Committee On Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine;
- Barnett, S & Kaimenyi, P (2017). PDR dashboard, Bungoma County 2016. MANI project, Options Consultancy Services Ltd.
- Brady, A. P. (2017). Error and discrepancy in radiology: inevitable or avoidable? *Insights into imaging*, 8(1), 171-182.
- Bruno, M. A., Walker, E. A., & Abujudeh, H. H. (2015). Understanding and confronting our mistakes: the epidemiology of error in radiology and strategies for error reduction. *Radiographics*, 35(6), 1668-1676.
- Cao, L., & Morley, J. E. (2016). Sarcopenia is recognized as an independent condition by an international classification of disease, tenth revision, clinical modification (ICD-10-CM) code. *Journal of the American Medical Directors Association*, 17(8), 675-677.
- Carayon, P., Schoofs H., Karsh, B. T., Gurses, A. P., Alvarado, C. J. Smith, M., and Cheti P. (2018) *ex-worker accuses hospital of misdiagnosis after going blind and deaf*, the star newspaper of 3rd January 2018 accessed at <https://www.the-star.co.ke>
- Cifra, C. L., Jones, K. L., Ascenzi, J. A., Bhalala, U. S., Bembea, M. M., Newman-Toker, D. E., ... & Miller, M. R. (2015). Diagnostic errors in a PICU: insights from the morbidity and mortality conference. *Pediatric Critical Care Medicine* | Society of Critical Care Medicine, 16(5), 468-476.
- D O'Sullivan, E., & Schofield, S. (2018). Cognitive bias in clinical medicine. *Journal of the Royal College of Physicians of Edinburgh*, 48(3), 225-231.
- Das, J., Holla, A., Das, V., Mohanan M., Tabak D., Chan B. (2012). In urban and rural India, a standardized patient study showed low levels of provider training and huge quality gaps. *Health Aff (Millwood)* 2012; 31:2774–84. [PMC free article] [PubMed]
- Douglas, C. Nicol, F. & Robertson, C. (eds) (2013) *Macleod's clinical examination* (13th ed). Churchill Livingstone –Elsevier

- Eeuwijk M. and Angehrn T (2017) *Swiss Tropical and Public Health Institute/Swiss TPH* Basel
- Harolds, J. A. (2015). Quality and Safety in Health Care, Part V: Introduction to: Crossing the Quality Chasm. *Clinical nuclear medicine*, 40(12), 959-961.
- Gacheri, A.(2016). *Tackling high maternal deaths in Kenya*, parliament of Kenya. Policy brief
- Gatonye | Published Tue, April 11th 2017 at 00:00, Updated April 11th 2017 at 09:09
<https://www.standardmedia.co.ke/health/article/2001235855/thousands-of-kenyans-wrongly-diagnosed-treated-for-brucellosis>
- Grabber L.M., (2018), Diagnostic errors, Agency for health care research; advancing excellence in health care.
- Graham, W. Bell, J. S, Bullough C.H.W. (2015). *Can skilled attendances at delivery reduce maternal mortality in developing countries?*
- Hoffman, K. A., L. M. Aitken, and C. Duffield. 2009. *A comparison of novice and expert nurses' cue collection during clinical decision-making: Verbal protocol analysis*. *International Journal of Nursing Studies* 46(10):1335–1344.
- Jutel, A. (2009). *Sociology of diagnosis: A preliminary review*. *Sociology of Health and Illness*
- Kabale, M. (2017) *why you should not trust every laboratory test result*. Standard newspaper <https://www.standardmedia.co.ke/health/article/2001235855/thousands-of-kenyans-wrongly-diagnosed-treated-for-brucellosis>
- Kajiliwa, M (2018), why cases of misdiagnosis are on the rise. The standard newspaper
- Kajiliwa, M. and Kamau, G (2017) *Kenyans pay dearly for medical laxity*. Standard Newspaper
- Kar, R.G (2010) *gap analysis between initial diagnosis and final diagnosis*
- Kenya Demographic and Health Survey (KDHS 2014) Kenya, Ministry of Health. New Era and ORC Macro, Calverton, MD, USA; 2006.
- Klein G. (2011) *What physicians can learn from firefighters*; Paper presented at the 4th International Diagnostic Error Conference, October 23-26, 2011; Chicago, IL. 2011. Published 2014
- Klein G. (2014) *What physicians can learn from firefighters*; Paper presented at the 4th International Diagnostic Error Conference, October 23-26, 2011; Chicago, IL. 2011. Published 2014

- Kothari and Garg (2016) *Research methodology* (third edition) new age international publishers, New Delhi ISBN:978-81-224-3623-5
- Liberman, A. L., & Newman-Toker, D. E. (2018). Symptom-Disease Pair Analysis of Diagnostic Error (SPADE): a conceptual framework and methodological approach for unearthing misdiagnosis-related harms using big data. *BMJ quality & safety*, 27(7), 557-566.
- Mamede, S., Hautz, W. E., Berendonk, C., Hautz, S. C., Sauter, T. C., Rotgans, J., ... & Schmidt, H. G. (2020). Think twice: effects on diagnostic accuracy of returning to the case to reflect upon the initial diagnosis. *Academic medicine*, 95(8), 1223-1229.
- Boodman, S. G (2013). Misdiagnosis is more common than drug errors or wrong-site surgery. *Natural health* accessed at <http://www.washingtonpost.com/national/health-scie...>
- Ministry of Health (2007): *National Reproductive Health Policy*; Enhancing Reproductive Health Status for all Kenyans. MOH/ DRH.
- Ministry of Health (2017), [Kenya]. *Saving Mothers lives*. First confidential report into maternal deaths in Kenya.
- Ministry of Health [Kenya]. (2017). *Bungoma county referral strategy and investment plan 2016/17-2020/21*. Nairobi: MoH
- Ministry of Health/ DRH (2012): Revised Kenya Partograph
- Muthoni and Kajiliwa (2017). Counties blamed for rise of quacks. Standard Newspaper
- National Council for Population and Development (NCPD) and UNFPA (2013) Kenya Country Office, *Kenya Population Situation Analysis* (Nairobi: NCPD. and UNFPA, 2013).
- Njoroge, E. W. (2012). The maternal and foetal outcomes among women with obstetric emergencies referred to the Kenyatta National Hospital, Nairobi, Kenya (Doctoral dissertation, University of Nairobi, Kenya).
- Norman, G. R., Monteiro, S. D., Sherbino, J., Ilgen, J. S., Schmidt, H. G., & Mamede, S. (2017). The causes of errors in clinical reasoning: cognitive biases, knowledge deficits, and dual process thinking. *Academic Medicine*, 92(1), 23-30.
- Oketch, A (2017). *Doctors cite wrong diagnosis as silent killer in Kenya*, National News. Daily Nation of Thursday 29th 2017
- Ordi, J., Castillo, P., Garcia-Basteiro, A. L., Moraleda, C., Fernandes, F., Quintó, L., ... & Menéndez, C. (2019). Clinico-pathological discrepancies in the diagnosis

- of causes of death in adults in Mozambique: a retrospective observational study. *PLoS one*, 14(9), e0220657.
- Prakash A (2011) *medical audit (second edition)*, Jaypee brother's medical publishers. New Delhi ISBN978-93-5025-354-0
- Rettner, R. (2014). The truth about “10,000 Steps a Day.” *Live Science*, 7.
- Rodziewicz, T. L., & Hipskind, J. E. (2018). *Medical error prevention*.
- Royce, C. S., Hayes, M. M., & Schwartzstein, R. M. (2019). Teaching critical thinking: a case for instruction in cognitive biases to reduce diagnostic errors and improve patient safety. *Academic Medicine*, 94(2), 187-194.
- Saposnik, G., Redelmeier, D., Ruff, C. C., & Tobler, P. N. (2016). Cognitive biases associated with medical decisions: a systematic review. *BMC medical informatics and decision making*, 16(1), 1-14.
- Schiff G., D, Leape LL. (2012) Commentary: How can we make diagnosis safer? *Academic Medicine*. 2012;87(2):135–138. [[PubMed](#)]
- Sharma S. (2004) *Reproductive Rights of Kenyan Women: Current status and future directions*. *Nairobi Univ Med J* 2004; 2:52-4.
- Shimkhada, R., Solon, O., Tamondong-Lachica, D., & Peabody, J. W. (2016). Misdiagnosis of obstetrical cases and the clinical and cost consequences to patients: a cross-sectional study of urban providers in the Philippines. *Global health action*, 9(1), 32672.
- Nathan, R. O., Swanson, J. O., Swanson, D. L., McClure, E. M., Bolamba, V. L., Lokangaka, A., ... & Goldenberg, R. L. (2017). Evaluation of focused obstetric ultrasound examinations by health care personnel in the Democratic Republic of Congo, Guatemala, Kenya, Pakistan, and Zambia. *Current problems in diagnostic radiology*, 46(3), 210-215.
- Singh H, Meyer AN, Thomas EJ (2014) The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations.
- Singh H. Editorial: (2014). Helping health care organizations to define diagnostic errors as missed opportunities in diagnosis. *Joint Commission Journal on Quality & Patient Safety*. ;40(3):99–101. [[PubMed](#)]
- Singh, H., & Sittig, D. F. (2015). Advancing the science of measurement of diagnostic errors in healthcare: The Safer Dx framework. *BMJ quality & safety*, 24(2), 103-110.
- Singh, H., Schiff, G. D., Graber, M. L., Onakpoya, I., & Thompson, M. J. (2017). The global burden of diagnostic errors in primary care. *BMJ quality & safety*, 26(6), 484-494.

- Sittig DF and Singh H, (2014) Advancing the science of measurement of diagnostic errors in healthcare
- Sophie G, Ingrid M, Le Q, et al. (2010). Maternal health care professionals' perspectives on the provision and use of antenatal and delivery care. *BMC Public Health*. 2010;10(608):1471–2458
- The National Academies of Sciences, Engineering, and Medicine; Washington (DC): National Academies Press (US); 2015 Dec 29
- The National Academy of Sciences. (2015) Report of the Assessment of Bungoma County Health Facilities
- The Safer Diagnostic framework. *BMJ Quality and Safety*. 2015;24(2):103–110. [PMC free article]
- Verghese, A., Charlton, B., Kassirer, J. P., Ramsey, M., & Ioannidis, J. P. (2015). Inadequacies of physical examination as a cause of medical errors and adverse events: a collection of vignettes. *The American journal of medicine*, 128(12), 1322-1324.
- Vogel JP, Habib NA, Souza JP, et al (2013) Antenatal care packages with reduced visits and perinatal mortality: a secondary analysis of the WHO antenatal care trial. *Reprod Health*. 2013; 10:19
- Vougiouklakis, T., Fragkouli, K., Mitselou, A., & Boumba, V. (2011). A comparison of the provisional clinical diagnosis of death with autopsy findings. *Rom J Leg Med*, 19(3), 177-182.
- WHO (2015) Making pregnancy safer: the critical role of the skilled attendant. A joint statement by WHO, ICM and FIGO. Department of Reproductive Health and Research. WHO, Geneva. 2004
- WHO (World Health Organization) (2010). *International classification of diseases (ICD)*. Geneva: World Health Organization
- WHO, (2018) *Maternal mortality, sustainable development goals and global strategy for Women, children and adolescents' Health?*
- World Health Organization (WHO)b (2016) *maternal mortality*. [Updated November 2015]. Available from: <http://www.who.int/mediacentre/factsheets/fs348/en/> [cited 15 March 2016]
- World health organization; (2012) *Health services coverage statistics: antenatal care Coverage (percentage)*. Switzerland
- Yego, F., Williams, J. S., Byles, J., Nyongesa, P., Aruasa, W., & D'Este, C. (2013). A retrospective analysis of maternal and neonatal mortality at a teaching and referral hospital in Kenya. *Reproductive health*, 10(1), 1-8.

APPENDICES

Appendix I: Consent Form

I am Wafula Nandebe David, a Clinical Officer, lecturer and a researcher, currently studying Master of Science in Public Health at Masinde Muliro University of Science and Technology. I invite you to participate in the study “Diagnostic Errors as Predictors of Obstetric Outcomes among Post-Natal Mothers in Bungoma County”.

The purpose of the study

Purpose of the study is to determine diagnostic errors as predictors of obstetric outcomes among post-natal mothers in Bungoma County, so as to inform policy on ways of improving maternal outcomes during pregnancy.

How about the procedure

You will be required to answer questions voluntarily after giving consent. You will not be victimized if you decline to respond to the questions or if you decide to discontinue at any stage of the study. During discussion, recording of information will be done using an audio recording device which will help to retrieve the information later. Also photos of the sessions will be taken after you giving consent.

What are the benefits of the study?

The study will help in understanding the origin of diagnostic errors how, often do they occur and how to mitigate them during pregnancy and childbirth. The results will help inform policy on the strategies on how to reduce diagnostic errors during pregnancy in-order to improve maternal outcomes.

What are the risks of the Study?

The process of the study especially during data collection may bring about psychological stress upon recalling a sad moment especially those who lost a baby or pregnancy which otherwise would be avoided.

Confidentiality

The information about what I observe or you provide during the study will be kept confidential. Only the Principal Investigator and the interviewers will have access to the information. The information will be kept under key and lock by the Principal Investigator during the course of study.

Contact information of the principal investigator

Name: Wafula Nandebe David

Mobile no. 0727086632

Email Address: nandedavid@yahoo.com

Contacts of Co- investigators

Dr. Benard Wesonga

0722584572

OR

Dr. Maximilla Wanzala

0722468936

Participant’s Signature..... Date

Investigator’s Signature..... Date

Appendix II: Structured Questionnaire for post-natal mothers

Health facility code (if relevant)	Date (dd/mm/yy)	Interview number	To be completed by the interviewer

1. Introduction

Read the informed consent form to the respondent(s) and ask them to sign it.

1. Particulars (demographic characteristics)

1.1. Age /year of birth (tick appropriately)

<input type="checkbox"/> < 35yrs	<input type="checkbox"/> >35yrs
----------------------------------	---------------------------------

1.2 parity (tick as necessary)

<input type="checkbox"/> First delivery	<input type="checkbox"/> 2 and more
-----------------------------------------	-------------------------------------

1.3. Marital status Yes () No ()

1.4. Education yes () No ()

1.5 date of admission-----

1.6 date of discharge-----

1.7 Education Level

- Primary ()
- Secondary ()
- Tertiary ()
- None ()

1.8 Religion

- Christian ()
- Muslim ()
- Others ()

1.9 Income

- Formal ()
- Informal ()
- Others ()

2. handling of pregnant mothers at FANC attendance, peri-diagnostic factors and prevalence's of diagnostic errors

2.6. Did you receive sufficient information about the following during ANC visit?

- 2.6.1 Your physical health during the pregnancy Yes () No ()
- 2.6.2 Possible mood changes during the pregnancy yes () No()
- 2.6.3 How the baby was developing yes () No()
- 2.6.4 What you could expect regarding the birth yes() No()
- 2.6.5 Post-natal period (e.g. breastfeeding, nutrition, care for the child yes () No ()

- 2.7 Were you examined Yes () No ()
 If yes Were you told the findings Yes () No ()
- 2.8 If yes what were the findings
 Specify-----
- 2.9 Were you investigated Yes () No ()
 If yes, which investigation?-----
 What was the result ?-----

3. variations between unmatched and matched diagnosis, based on initial and final diagnosis matching in relation to obstetric outcomes

- 3.1 What made you to be admitted?-----
- 3.2 how long did you stay-----
- 3.3 Did your practitioner tell you the condition? Yes ()No ()
- 3.4 In case there was a problem, was it similar to what you were told during ANC visits? Yes ()No ()
- 3.5 mode of delivery (complicated) (normal)
- If complicated was it planned? (yes) (No)
- 3.6 birth

<input type="checkbox"/>	Single baby
<input type="checkbox"/>	Multiple
<input type="checkbox"/>	Other (specify)-----

- 3.7 outcome of the pregnancy
- | | |
|--------------------------|--------------------------------|
| <input type="checkbox"/> | Alive |
| <input type="checkbox"/> | Any complication to child |
| <input type="checkbox"/> | Any complication to the mother |
| <input type="checkbox"/> | Referral |

3.7 If complications arose what do you attribute these complications to?

3.8 The interviewer asks for the ANC booklet and any discharge notes and fills the table below based on the finding in the ANC and booklet (variations between initial diagnosis and final diagnosis and obstetric outcomes as observed)

3.8 <i>Serial no</i>	<i>age</i>	<i>parity</i>	<i>schedule</i>	<i>Initial dx</i>	<i>Final dx</i>	<i>Matched</i>	<i>Unmatched</i>	<i>No of investigations</i>	<i>Duration of stay</i>	<i>Treatment/given timely/not timely</i>	<i>Safety</i>	<i>Unsuccessful outcomes</i>

4. variations between unmatched and matched diagnosis, based on initial and final diagnosis matching in relation to obstetric outcomes

4. Attributions of diagnostic errors to obstetric outcomes at ANC, OPD and on admission

	Agree	Disagree
4.8.1 Lack of diagnosis at ANC		
4.8.2 Delayed diagnosis at OPD		
4.8.3 Lack of diagnosis on admission		
4.8.4 Delay in investigations		
4.8.5 wrong interpretations of tests		
4.8.6 Nobody to interpret tests		

4.9 if complications what type of complications did you get-----

4.10 what was done about this complication

4.11 Do you feel the delivery has been costly? Yes () No ()

4.13 Overall rating, do you believe the obstetric outcome is related to the following care		
Predictor of outcome	Agree	Disagree
Delayed diagnosis		
Missed diagnosis		
Absent diagnosis		
Wrong diagnosis		
Misinterpretation of tests		
Unmatched diagnosis		
unnecessary investigation		

Thank you

Appendix III: Key Informant Interview schedule

Interview schedule guide questions

1. In your own opinion describe the importance of making a correct diagnosis as early as possible in a pregnant mother right from pregnancy through to 6 weeks after delivery
2. Do you believe there are diagnostic errors (missed) observed during your practice in terms of missed, wrong, delayed or absent diagnosis in obstetric care and if yes how often do you see these errors
3. How do diagnostic errors affect management of the obstetric client and obstetric outcomes from the time these errors are made at different stages to the outcomes
4. How best do you think we can deal with these diagnostic errors in obstetrics so that we prevent them as much as possible or minimize them from happening both in this hospital and nationally?
5. How do you view the effects of diagnostic errors to the mothers, workers, hospitals and health services generally?

Probes

Importance of correct initial diagnosis

Does initial diagnosis vary from final diagnosis by any chance?

How often does it vary?

What is the reason of variation?

What are some of the diagnostic errors commonly seen?

Are diagnostic errors increasing or reducing?

How does diagnostic error affect the plan of management?

What are some of the unsafe outcomes?

What are some of the safe outcomes?






How can we prevent these diagnostic errors?

Do you believe feedback is essential in prevention of diagnostic errors?

Any resources affected by diagnostic errors

Thank you!

Appendix IV: Ethical research approval documents

 REPUBLIC OF KENYA	 NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION
Ref No: 609283	Date of Issue: 23/March/2020
RESEARCH LICENSE	
	
This is to Certify that Mr. DAVID NANDEBE WAPULA of Masinde Muliro University of Science and Technology, has been licensed to conduct research in Bungoma on the topic: DIAGNOSTIC ERRORS AS PREDICTORS OF OBSTETRIC OUTCOMES AMONG POST-NATAL MOTHERS IN BUNGOMA COUNTY for the period ending : 23/March/2021.	
License No: NACOSTUP20/4392	
609283 Applicant Identification Number	 Director General NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION
	Verification QR Code
	
NOTE: This is a computer generated license. To verify the authenticity of this document, scan the QR Code using QR scanner application.	

WAFULA NANDEBE DAVID
MASINDE MULRO UNIVERSITY OF KENYA

THE COUNTY DIRECTOR OF HEALTH
BUNGOMA COUNTY

20/04/2020

Dear sir/Madam

Re: Letter of approval for conducting research in Bungoma County

I wish to request for a letter of approval to conduct research in Bungoma County. The research is entitled *diagnostic errors as predictors of obstetric outcomes among post natal mothers in Bungoma County*. Research shall be conducted in Bungoma and Webuye county hospitals and Kimilili sub county hospitals. All ethical issues shall be observed during the study. Research license and ethical review approval letters are hereby attached



Wafula N David



REPUBLIC OF KENYA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
State Department of Basic Education and Early Learning- Bungoma County

When Replying please quote
e-mail: bungomacde@gmail.com

Ref No: BCE/DE/19/VOL.III/97

County Director of Education
P.O. Box 1620-50200
BUNGOMA

Date: 20th April, 2020

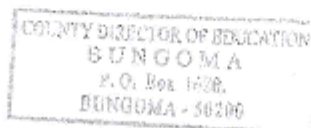
TO WHOM IT MAY CONCERN

**RE: AUTHORITY TO CARRY OUT RESEARCH – WAFULA NANDEBE DAVID –
NACOSTI/P/20/4392**

The bearer of this letter Mr.Wafula Nandebe David of Masinde Muliro University of Science and Technology has been authorized to carry out research on *"Diagnostic Errors as Predictors of obstetric outcomes among postnatal mothers in Bungoma county, Kenya"* for a period ending *August, 2020*.

Kindly accord him the necessary assistance

CHRISTINE OWINO
For: COUNTY DIRECTOR OF EDUCATION
BUNGOMA COUNTY



REPUBLIC OF KENYA



COUNTY GOVERNMENT OF
BUNGOMA
MINISTRY OF HEALTH
OFFICE OF THE COUNTY DIRECTOR



Telegrams: "MEDICAL", BUNGOMA
Telephone: (055) 30230 Fax: (055) 30650
E-mail: dncakatw@yahoo.com
When replying please quote

COUNTY DIRECTOR OF HEALTH
BUNGOMA COUNTY
P. O. BOX 18-50200
BUNGOMA

Ref: CG/BGM/CDH/RESRC/VOL.1

DATE: 21ST APRIL, 2020

WAFULA NANDEBE DAVID
MASINDE MULIRO UNIVERSITY OF KENYA



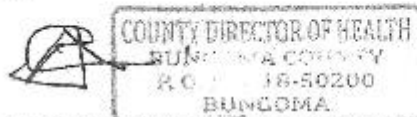
Permission
Checked
25.6.2020

RE: PERMISSION TO CONDUCT RESEARCH IN BUNGOMA COUNTY

Following your application for authority to conduct research entitled "**diagnostic errors as predictors of obstetric outcomes among post natal mothers in Bungoma County**", I am pleased to inform you that you have been authorized to undertake the survey in Bungoma and Webuye County Hospitals and Kimilili Sub County Hospitals for the period ending 23rd March, 2021.

Kindly note that, as an applicant who has been licensed under the Science, Technology and Innovation Act, 2013 to conduct research in Kenya, you shall deposit a **copy** of the final research report to the County Director of Health. The soft copy of the same should be submitted through the online Research Information system.

Thank you.



DR. JOHNSTON ARATU
COUNTY DIRECTOR OF HEALTH
BUNGOMA COUNTY

Appendix V: Map of Bungoma County

