Diagnostic Errors and their Impact on Obstetric Outcomes among Post-Natal Women at Level Five Teaching and Referral Hospitals in Bungoma County, Kenya

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ABSTRACT

Diagnostic errors are a global problem. Kenya has a high annual maternal mortality prevalence ratio of 362/100,000 live births. Bungoma County has a higher prevalence of diagnostic errors of 382/100,000 live births annually which exceeds the national average. Maternal and neonatal mortality arises from morbidity caused by diagnostic errors in Bungoma County. Thus, this study investigated the relationship between diagnostic errors and obstetric outcomes among post-natal women at level five hospitals in Bungoma County. Swiss Model guided this study. The study used a cross-sectional research design which was hospital-based (Bungoma and Webuye hospitals). Systematic sampling was used to obtain 327 respondents after proportionate allocation to each hospital, and purposive sampling to select 8 healthcare 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 (0.891). Using a statistical package for social sciences version 25, descriptive and inferential statistics were run where chi-square and odds ratio were used to determine the relationship between diagnostic errors and obstetric outcomes. The findings showed that diagnostic errors on average constituted 68.7% at the antenatal care clinics. Individual diagnostic errors were delayed diagnosis (56.9%), missed diagnosis (61.2%), absent diagnosis (72.5%), wrong diagnosis (65.1%), misinterpretation of tests (75.8%) and unnecessary investigation (80.7%). The safe obstetric outcome from the diagnostic errors was 77.4% and the unsafe obstetric outcome was 22.6%. The computed Odds Ratio (OR) indicated that delayed diagnosis (OR=1.661, $p < 0.001$), missed diagnosis (OR=1.587, $p < 0.001$), absent diagnosis (OR=1.454, $p < 0.001$), wrong diagnosis (OR=1.532, $p < 0.001$), misinterpretation of tests (OR=1.425, $p < 0.001$) and unnecessary investigation (OR=1.389, $p < 0.001$) were more likely to result in a safe obstetric outcome especially when matched at the final diagnosis. The matched diagnosis was 5.625 times more likely to result in a safe obstetric outcome as compared to an unmatched diagnosis. In conclusion, diagnostic errors from the matched diagnosis were 5.625 times more likely to prevent adverse obstetric outcomes as compared to diagnostic errors from the unmatched diagnoses. This study recommends that there should be continuous monitoring and evaluation of the antenatal care units to ascertain the diagnosis and history of the pregnant women to cushion against diagnostic errors that may result in adverse obstetric outcomes.

Keywords: Antenatal Care Clinics, Diagnostic Errors, Obstetric Outcome, Pregnancy

I. INTRODUCTION

Diagnostic errors have a potential adverse obstetric outcome if not managed in time on a global level (Singh & Sittig, 2015). Misdiagnosis of pregnant women attending antenatal care clinics potentially contributes to a 2.96 times likelihood of causing an adverse obstetric outcome for women (Shimkhada *et al*., 2016). Diagnostic errors are a high priority area for the World Health Organisation with most patients globally (Singh *et al*., 2017). From previous studies, diagnostic errors arise from misdiagnosis, missed diagnosis, wrong diagnosis, delayed diagnosis, and misinterpretation of results (World Health Organisation [WHO], 2016). There is a high degree of uncertainty in diagnosis that comes from preventable harm (Boodman, 2013). Unnecessary investigations such as radiological examinations such as obstetric ultrasounds where significant diagnostic errors have led to wrong initial diagnosis (Abimanyi-Ochom *et al*., 2019). 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.

In a similar study conducted on medical students concerning diagnosis using an OSCE, the diagnostic accuracy was found to be 60% while 63% provided the correct diagnosis (Bruno *et al*., 2015). From the previous study (Cifra *et al*., 2015) 25% of diagnostic errors resulted in deaths. Diagnostic errors contribute to as many as 70% of medical errors (Royce *et al*., 2019). Delayed diagnosis as a result of overreliance on laboratory results has led to delayed treatment leading to undesired obstetric outcomes.

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 (Nathan *et al*., 2017). Major diagnostic discrepancies were fatal resulting in about 70% mortality cases 0. On average, Kenya's maternal mortality is 362 deaths per 100,000 lives that arise from diagnostic errors (0. Adverse obstetric outcomes such as anaemia, post-partum haemorrhage, baby asphyxia, premature babies, maternal deaths, neonatal deaths, stillbirths and stroke were common among pregnant women (0. About 15% of all pregnant women develop life-threatening pregnancy complications resulting from diagnostic errors 0. The 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 (0. 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 (World Health Organisation [WHO], 2018). This study helped us understand that diagnostic errors are common; however, they have not linked diagnostic errors and obstetric outcomes. Therefore, the study sought to investigate how diagnostic errors relate to obstetric outcomes.

Bungoma County recorded a maternal and neonatal mortality ratio of 382 maternal deaths per 100,000 live births (Gacheri, 2016). The Kenyan average maternal mortality ratio is 362 deaths per 100,000 live births, indicating Bungoma County statistics are quite higher than the national ratio. It is known that the collective national recommended maternal mortality ratio is 144/per 100,000 live births. However, Bungoma is essentially 2.6 times higher than the recommended national statistics. 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 relationship between diagnostic errors and obstetric outcomes at level five hospitals in Bungoma County.

1.1 Statement of the Problem

Studies have stressed the existence and the negative consequences of diagnostic errors for maternal and perinatal mortality; however, these studies do not identify a direct relationship between diagnostic errors and obstetrics outcomes (Shimkhada *et al*., 2016, Ordi *et al*., 2019). Diagnostic errors are currently common and have been given little attention in relation to medical errors. Sub-Saharan Africa has a higher burden of maternal and neonatal mortality rates. However, there is no clear relationship between diagnostic errors and 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. Therefore, this study sought to fill this gap in the extant knowledge in an effort towards identifying the direct effect of diagnostic errors on the health of mothers and their newborns. There is scanty information on the relationship between diagnostic errors and obstetric outcomes in Bungoma County. Thus, this study investigated the relationship between diagnostic errors and obstetric outcomes in level-five hospitals in Bungoma County, Kenya.

1.2 Research Objective

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

II. LITERATURE REVIEW

2.1 Theoretical Review

2.1.1 Swiss Cheese Model

The Swiss Cheese Model (SCM) has turned out to be a strong theoretical model for studying diagnostic errors in healthcare, with a special focus on obstetrics. Initially used to analyze industrial accidents the approach was found useful in analyzing medical/clinical errors when those are discussed as multiple system failures which happen in unison. Perneger *et al*. (2014) in their one-of-a-kind study on 238 adverse obstetric events, found that 84% of diagnostic errors were a result of at least three systems, which themes were staff training, communication and equipment. Altogether, Nakajima *et al*. (2019) also applied the SCM to assess maternal near-misses in Japanese hospitals to show that with the help of this model, important shortcomings in diagnosis, especially in emergency obstetric conditions, could be found.

The utility of SCM in diagnostic error literature has been supported by other methodologically drawn studies. The model was used in a quantitative and qualitative study conducted by Anderson and Davis (2018). In the study

encompassing 150 obstetrics units in the United Kingdom, the authors delineated how different holes in system defences led to diagnostic delays. Their findings revealed that diagnostic errors were most likely to occur when three specific system vulnerabilities aligned: transfer, such as shift handovers, availability of resources and lack of documentation. Martinez *et al*. (2020) replicated these findings in their study of 432 obstetric adverse events in Brazilian public hospitals using the SCM framework; they showed how the model could be used to track diagnostic failure pathways across various levels of the healthcare system. What was especially captured were long-standing and unchanging gaps regarding diagnostic safety in lower-tier healthcare facilities due to constrained resources.

Current uses of the SCM have been extended to where the developer is designing and evaluating an intervention. Recently, Thompson *et al*. (2021) used the joint model synthesizing patient-level and organizational-level data to design and conduct a multidimensional intervention in maternity units in Australia with a reduction in serious diagnostic errors of 43 per cent reporting within an 18-month intervention period. The interventions which formed their approach include the broad strengthening of the layers of defence that were identified using the SCM analysis such as improved tests and diagnostic procedures, effective communication, and staff development. Likewise, Okonkwo and Nkwo (2022) used the SCM framework to assess possible safety barriers in Nigerian tertiary hospitals in obstetrics and develop relevant safety interventions targeted directly at active and latent errors within the diagnostic process. They showed that the model may be helpful when intervention designs request an understanding of the relations between system weaknesses in the context of numerous restricted sources available.

2.2 Empirical Review

Failures in diagnosis known as diagnostic errors, include missed, wrong and delayed diagnoses of a range of disorders, significantly affect obstetrical care in all regions and Kenya in particular (WHO, 2017). These misplaced diagnoses are mainly caused by differences in the procedural flow of diagnoses, less experienced practitioners, or lack of necessary diagnostic equipment and personnel (Das, 2012; Yego *et al*., 2019). According to Yego *et al*. (2019), Bungoma County noted diagnostic mistakes at ANC visits that predispose to obstetrics complications with a 34% prevalence. Conditions associated with high-risk pregnancies are seldom diagnosed, or when diagnosed incorrectly, they inevitably result in post-partum haemorrhage, preeclampsia and other dangerous consequences in cases when they are not discovered early enough, evidencing the need for better diagnostic accuracy.

In India and the Philippines, diagnostic errors are higher when the mistake happens at an ANC visit point to attest to its significance (Chattopadhyay, 2013). Diagnostic errors in obstetrics have cognitive and system correlate triggers (Harolds, 2015). In Kenya, the absence of sophisticated diagnosis services and reliance on inadequate diagnosis procedures make this a bigger problem (Njoroge, 2012). Shimkhada *et al*. (2016) implicated false negative or false positive radiology or missed laboratory investigations result in the delay of right care and lead to more maternal and neonatal complications as well as mortality.

Harmful diagnosis results in financial, psychological, and physical difficulties for the patient since diagnostic mistakes can cause improper and excessive treatments or missed chances at early diagnosis (Abimanyi-Ochom *et al*., 2019). In Kenya, maternal mortality due to obstetric complications is one of the foremost types of disorder in particular for inpatients (Njoroge, 2012). Harolds (2015) opined that research shows that majority of the maternal deaths are preventable if the first diagnosis that a woman receives while pregnant, during labour or in the postnatal period is correct. The efficiency of such interventions is high especially at the time of the intervention because delays due to diagnostic accuracies result in complications or even deaths.

Measures put in place to reduce diagnostic errors are technological, education/training and audit checklists (WHO, 2017). That is why the introduction of diagnostic error assessments into the patient safety plan and ensuring the availability of diagnostics in areas with scarce resources are recommended (Abimanyi-Ochom *et al*., 2019; Shimkhada *et al*., 2016). That is in line with global policies seeking to improve the results of maternal and neonatal care because removing diagnostic errors will automatically decrease mortality levels among post-natal women.

III. METHODOLOGY

The study was carried out in Bungoma County, focusing on level five hospitals (Bungoma and Webuye). It has a surface area of over 3,000 km^2 with an estimated population of 1.7 million (Government of Kenya, 2019). The research design was cross-sectional. The study population was made up of women admitted in the postnatal wards with pregnancy complications; Webuye Hospital - had 5,510 admissions in maternity per year whereas Bungoma Hospital - had 6,730 admissions in maternity per year (Government of Kenya, 2014). The of 12,240 admissions in maternity per year, which formed the study. A mixed sampling method was used - systematic sampling was used to get the post-natal mothers where every k^{th} number was picked from the list of women on discharge. Before establishing the kth 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 antenatal care clinics 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). The sample size was determined using Fisher's formula (Kothari & Garg, 2016). Using proportions, Bungoma County Referral Hospital had 180 participants whereas 147 were allocated to Webuye Hospital. Healthcare providers were purposively sampled for key informant interviews in either of the hospitals depending on availability. Questionnaires and interviews were used for data collection. Data analysis was done with the aid of Statistical Package for Social Sciences (SPSS) Version 25. Reliability was determined using a split-half test and Cronbach coefficients of 0.891 were obtained. Validity was achieved by cross-checking with the supervisors. Quantitative data were presented in frequency tables and figures; inferential statistics were presented in chi-square and Odds Ratio.

Ethical consideration was sought from the approval to conduct this study from the Masinde Muliro University of Science and Technology (MMUST), the County Government of Bungoma where the study was conducted and further permission was sought from the National Commission of Science, Technology and Innovation (NACOSTI). Informed written consent was sought from the respondents before participation in the study.

IV. FINDINGS & DISCUSSION

4.1 Relationship between Diagnostic Errors as Predictors of Obstetric Outcome

Diagnostic errors among pregnant women attending antenatal care clinics were borne from delayed diagnosis (56.9%), missed diagnosis (61.2%), absent diagnosis (72.5%), wrong diagnosis (65.1%), misinterpretation of tests (75.8%) and unnecessary investigation (80.7%). Table I summarises the findings.

Table 1
Diagnostic Errors

Diagnostic errors	Frequency	Per cent
Delayed diagnosis	186	56.9%
Missed diagnosis	200	61.2%
Absent diagnosis	237	72.5%
Wrong diagnosis	213	65.1%
Misinterpretation of tests	248	75.8%
Unnecessary investigation	264	80.7%

The diagnostic errors combined constituted 68.7% of the diagnostic at the antenatal care clinics.

4.2 Obstetric Outcome

The obstetric outcome with safe results was 77.4% and the unsafe outcome was 22.6%.

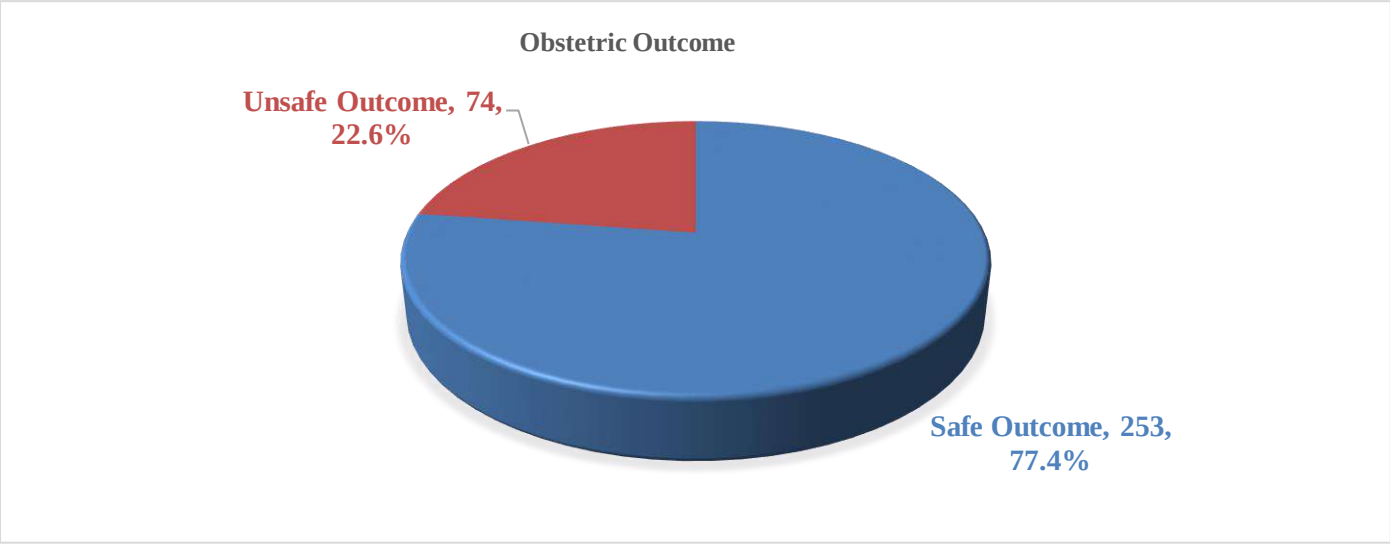

Figure 1
Obstetric Outcome from the Diagnostic Errors

4.3 Odds Ratio between Diagnostic Errors and Obstetric Outcome

Obstetric outcome was the dependent variable that was tested against diagnostic errors (delayed diagnosis, missed diagnosis, absent diagnosis, wrong diagnosis, misinterpretation of tests and unnecessary investigation) as the independent variable. The computed Odds Ratio (OR) indicated that delayed diagnosis (OR=1.661, $p < 0.001$; safe outcome), missed diagnosis (OR=1.587, $p < 0.001$; safe outcome), absent diagnosis (OR=1.454, $p < 0.001$; safe outcome), wrong diagnosis (OR=1.532, $p < 0.001$; safe outcome), misinterpretation of tests (OR=1.425, $p < 0.001$; safe outcome) and unnecessary investigation (OR=1.389, $p < 0.001$; safe outcome).

Table 2

Diagnostic Errors

Diagnostic errors		**Obstetric outcome**		**OR**	**P value**
		S	**US**		
Delayed diagnosis	US	115	26	1.661	0.000
	S	142	44		
Missed diagnosis	Unsafe	104	23	1.587	0.000
	Safe	153	47		
Absent diagnosis	Unsafe	71	19	1.454	0.000
	Safe	186	51		
Wrong diagnosis	Unsafe	94	20	1.532	0.000
	Safe	163	50		
Misinterpretation of tests	Unsafe	62	17	1.425	0.000
	Safe	195	53		
Unnecessary investigation	Unsafe	50	13	1.389	0.000
	Safe	207	57		

[OR = Odds Ratio; P = significance; S = Safe; US = Unsafe]

Furthermore, matched and unmatched diagnoses and obstetric outcomes were computed to determine the outcome of the pregnant woman at the delivery. It was revealed that obstetric outcomes predicted the matched and unmatched diagnosis. Obstetric outcome Odds Ratio (OR=5.625: 95% [3.607 - 8.772], $p < 0.001$). Thus, a matched diagnosis was 5.625 times more likely to result in a safe obstetric outcome as compared to an unmatched diagnosis.

4.4 Discussion

4.4.1 Relationship between Diagnostic Errors as Predictors of Obstetric Outcomes

Singh's theory states that diagnostic errors may result in adverse outcomes and those diagnostic errors misdirect interventions that may eventually result in an adverse pregnancy outcome **Error! Reference source not found.**). The study findings revealed that indeed there were diagnostic errors that influenced obstetric outcomes at Bungoma level five referral hospitals. The Chi-square performed showed that there was an association between diagnostic errors and pregnancy outcomes. These results showed that major diagnostic errors were associated with up to 58% adverse outcomes and these outcomes resulted in 70% mortalities 0. Furthermore, the timeliness of interventions including correct early initial diagnosis was imperative if adverse maternal outcomes were to be averted (Yego *et al*., 2019).

This study shows that unnecessary investigation, delayed diagnosis and wrong diagnosis contributed to increased diagnostic errors. This is evident that healthcare 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 making 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 a 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. Diagnostic errors have a significant bearing on the totality of patients' or clients' care (Bruno *et al*., 2015). 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 0.

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 healthcare workers whereas the study in Bungoma mainly was directed at those affected women who were pregnant. Any form of diagnostic error, 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 out at Moi Teaching and Referral Hospital 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 by Yego *et al*'s (2019). These views were reinforced by the views expressed by Harolds that misdiagnosis causes more fatalities than road traffic accidents in the United States of America (Harolds, 2015).

History taking and physical examination form the basis of the diagnostic process in a workstation. However, in this error of technology, the workstation provides the context in which the diagnostic process occurs (Word Health Organisation [WHO], 2018). This takes us to the investigation part. In this study, it was noted that unnecessary investigation and lack of interpretation were 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 of innovative equipment, instant diagnosis can be made and therefore improve initial diagnosis. Towards the same direction, Abimany-Ochom *et al* suggest that minimizing diagnostic errors in an acute setting like obstetrics requires prudent use of technology as a point of use ultrasonography (Abimanyi-Ochom *et al*., 2019).

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.

The obstetric outcome was predicted by the diagnostic errors all of the independent variables having an increasing positive association. This meant that the diagnostic errors were influencing the obstetric outcomes (safe and unsafe outcomes). The matched diagnosis was 5.625 times more likely to result in a safe obstetric outcome as compared to an unmatched diagnosis. It was important to minimise diagnostic errors from the point of the first antenatal care visit to the last antenatal care visit to inform obstetric outcomes (safe).

V. CONCLUSIONS & RECOMMENDATIONS

5.1 Conclusions

The study found that diagnostic errors influenced the obstetric outcome of pregnant women. Diagnostic errors from the matched diagnosis were 5.625 times more likely to prevent adverse obstetric outcomes as compared to diagnostic errors emanating from unmatched diagnoses. The study demonstrates that a correct diagnosis is a viable strategy for preventing unsafe obstetric outcomes.

5.2 Recommendations

There should be continuous monitoring and evaluation of the antenatal care units to ascertain the diagnosis and history of the pregnant women to cushion against diagnostic errors that may result in adverse obstetric outcomes. There should be a tradition of consulting among health practitioners on the diagnosis to get second and third opinions on a particular diagnosis to enhance accuracy and protect the health of a pregnant woman and the unborn child.

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