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Risk factors for maternal mortality during labour induction in an urban Kenyan tertiary hospital: A case-cohort study

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Abstract

Introduction: Maternal and Perinatal Death Surveillance and Response (MPDSR) aims to reduce maternal and perinatal mortality through ongoing monitoring and retrospective data analysis. The Kiambu County Referral Hospital (KCRH) MPDSR committee observed an increase in maternal mortality with the use of misoprostol for labour induction. An administrative decision was implemented in June 2019 to replace misoprostol with dinoprostone for labour induction. Here, we sought to investigate the factors associated with maternal mortality and the role of induction agents, as well as the effectiveness of the MPDSR at KCRH.

Methods: We analysed all the 58 maternal mortality cases that occurred during the 36-month study period between January 2018 and December 2020 against a random sub-cohort of 232 controls. Multiple logistic regression, adjusted for intensified MPDSR activities and labour induction agents, was employed to identify factors affecting maternal mortality.

Results: In multivariable analysis, postpartum haemorrhage (PPH) was strongly associated with higher odds of maternal death (aOR: 14.4; 95%CI: 2.72–75.8; p = 0.002), while gestational age ≥38 weeks was associated with significantly lower odds (aOR: 0.16; 95%CI: 0.05–0.54; p = 0.003). Use of misoprostol for induction was associated with a four-fold higher odds of maternal death compared to dinoprostone (aOR: 4.95; 95% CI: 0.56–43.8; p = 0.15), although this difference was not statistically significant. Unemployment, single marital status, eclampsia, gestational hypertension, vaginal delivery, and maternal pyrexia were associated with either higher or lower odds of maternal death, but none of these associations was statistically significant. Intensified MPDSR activities were not associated with a significant change in maternal death risk (aOR: 1.07; 95% CI: 0.32–3.55; p > 0.9).

Conclusions: Although enhancing MPDSR activities did not reduce maternal mortality, inducing labour with misoprostol showed higher odds of maternal mortality compared to dinoprostone, though this association did not reach statistical significance. Our findings raise a safety concern consistent with the initial safety concern that motivated this study, and further post-marketing surveillance of labour induction methods is required to establish whether this reflects a true causal relationship. This work also underscores the urgent need to strengthen prevention and management of PPH in resource-limited settings while also ensuring careful evaluation of induction agents.

Keywords: MPDSR, Maternal Mortality, Labour Induction, Misoprostol, Dinoprostone

Citation

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Introduction

Maternal mortality is a tragic and devastating loss of life. It is defined as the death of a woman while pregnant or during the puerperium, regardless of the duration or location of the pregnancy [1]. It includes death from any cause connected to or worsened by the pregnancy or its management, but excludes death from unintentional or incidental causes, and it is the primary cause of mortality among reproductive-age women [2].

Maternal mortality remains a major global public health concern. In 2020 alone, 287,000 mothers died during childbirth worldwide [3] and nearly all countries with very high (555 – 999/100,000) to extremely high (>1000/100,000 live births) maternal mortality ratios (MMR) are located in Sub-Saharan Africa [4]. In addition, 69% of global maternal deaths in 2020 occurred in Sub-Saharan Africa [3,5], and to achieve the SDG target by 2030 the MMR needs to be reduced by at least 20.3% each year from 2020 [5]. In this regard, progress has been made [5]. Kenya, for instance, reduced its MMR by 50% between 2000 and 2020. However, despite this progress, Kenya still exceeds the global rate and falls short of the 2030 target of 140/100,000 [6,7].

Inducing labour is a therapeutic option when the risks of continuing the pregnancy outweigh prompt delivery [8]. This is commonly achieved through the use of pharmacological agents, such as prostaglandin analogues like misoprostol and dinoprostone [9]. While both are equally effective [10], our contextual use of misoprostol for this purpose is considered 'off-label' since the 250mcg tablets (the dose indicated for treating peptic ulcers) are used for labour induction after splitting the tablet into 8 sections, in place of the 25mcg tablets for labour induction [11]. When used this way, the dose may vary considerably and may raise the risk of obstetric complications like uterine rupture, placental abruption, and the need for caesarean delivery [8].

Global evidence has highlighted both the effectiveness and safety considerations of misoprostol. Cochrane reviews have shown that low-dose oral misoprostol is effective for labour induction compared with other prostaglandins, but emphasized the need for careful dosing protocols to minimize complications [12–14]. This reinforces the concerns that off-label tablet splitting in our setting may contribute to imprecise dosing and increased risk.

Maternal mortality is influenced by various factors, including medical errors and the quality of healthcare services [15,16]. A thorough and continual analysis is essential to identify and address the most significant and preventable contributors to maternal mortalities [16]. The International Federation of Gynaecologists and Obstetricians (FIGO) endorses Maternal and Perinatal Death Surveillance and Response (MPDSR) as a quality improvement approach for improving maternal and neonatal outcomes, especially the prevention of future maternal deaths [17–19].

In Kenya, the Ministry of Health formally institutionalized MPDSR through the 2016 national guidelines, framing it as a key accountability and quality-improvement mechanism [18,20]. A facility MPDSR committee was established at Kiambu County Referral Hospital (KCRH) in June 2019 to address worsening maternal mortality outcomes. The off-label use of Misoprostol for labour induction was implicated in some of the maternal deaths, which led to the committee replacing misoprostol with dinoprostone using a best clinical practice circular [21]. To investigate the basis of this decision, we examined the determinants of unfavourable labour and delivery outcomes from January 2018 to December 2020 using a retrospective cohort study [21].

In the aforementioned study, we retrospectively examined the files of 411 patients, of whom 14 resulted in maternal mortalities. We found that the use of misoprostol was associated with an increased risk of mortality, consistent with the observations of the MPDSR committee. However, our ability to study the causes and risk factors of maternal death was limited by the small number of deaths sampled. To address this limitation, we devised a case-cohort study in which all deaths during the study period are examined. Therefore, the primary objective of this study is to investigate the association between maternal mortality and the choice of induction agent following the MPDSR practice change from misoprostol to dinoprostone.

Methods

Study design and site

This was a case-cohort study design using secondary patient data from January 2018 to December 2020 at KCRH. The study site has been previously described [21]. Per the Kenya Essential Package for Health, the Kiambu County Referral Hospital is a Level 5 public sector facility. While KCRH has a catchment population of 101,596 [of which 23,805 (27.86%) are women of reproductive age], its proximity to Nairobi County City, Kenya, grants it an even larger catchment, which contributes to the approximately 800 monthly births it records.

Relevant local context

During the period of the study, the Kenya Medical Supplies Agency (KEMSA) provided pharmaceutical products and supplies to public-sector health facilities. KEMSA provides misoprostol 200 mcg tablets for off-label use in labour induction. This is problematic because the induction dose is 25 mcg, which necessitates fracturing the tablet 8 times, while it is only scored once, as previously described [21]. In addition, the global standard for the induction of labour is dinoprostone, but misoprostol is preferred due to

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its low cost and stability at room temperature [9]. The latter is also covered by Linda Mama (a government maternity health programme), while dinoprostone is not.

Sample size determination

We determined the total number of fatalities (n = 58) that occurred during the study period, including those selected for the retrospective cohort study. The Fleiss formula with continuity corrections for small samples was used to calculate the total sample size required. This calculation was conducted using the online OpenEpi tool, an open-source website provided by the Centre for Disease Control [22]. Using this tool, a total sample size of 290 (58 cases and 232 controls) had 80% power to detect an extreme odds ratio (OR) of 0.38 with the observed proportion of 42% induction among those who did not die (controls), given a ratio of 4 controls to each case.

Sampling procedure

All the maternal mortalities that occurred during the study period were included in this study (n = 58). Sampling was carried out using the previously collected data to match the cases, and the controls were recruited from all non-deceased patients recruited for the retrospective cohort study (n = 397) [21]. We assigned a random number to each of the 397 controls, sorted them in ascending order, and chose the first 232. Thus, the controls were selected via simple random sampling.

Data collection and handling

For this study, patient files were used to collect secondary data on the 58 women who died during childbirth between January 2019 and December 2020. All the records, existing in hard copy files bound and stored in a physical archive, were identified by study clerks, and this was the only additional data collected for this study. The controls were sampled from the data collected during our previous work [21]. Patient files were used to collect secondary data using a pre-designed e-tool. This data was collected retrospectively from the 24th of May 2022 to the 26th of May 2022. We also abstracted aggregate data on total deliveries and maternal death audit forms completed and uploaded onto the Kenya Health Information System (KHIS), and this was abstracted on the 24th of May 2022.

Data analysis

Cross-tabulation was used to summarise patient characteristics against the induction of labour. Pearson's Chi-square of independence and Fisher's exact test were used to test the relationship between patient characteristics and induction of labour. For the study period, we identified three outcomes of interest: maternal mortality, uterine rupture, and neonatal mortality. We ran 12 explanatory variables against each outcome and tabulated unadjusted and adjusted point estimates and their 95 percent confidence intervals. The explanatory variables were chosen based on their relationship to the exposure and outcomes as well as their clinical relevance. We calculated the odds ratio of each outcome by fitting a Bayesian Poisson Generalised linear model to the data. The Bayesian model accounts for predictor multicollinearity by selecting and clustering predictors at the same time. To assess the goodness of fit of our Bayesian GLM, we used the Akaike Information Criterion (AIC). We selected the model with the lowest AIC score that still retained clinically relevant predictors. Therefore, we compared the AIC values of different Bayesian GLM configurations to identify the model that best captures the underlying patterns in the data while avoiding overfitting. The analyses were carried out using the R statistical software v.4.0.3 (R Foundation for Statistical Computing, Vienna, Austria).

Ethical considerations

Ethics approval was obtained from the Institutional Scientific and Ethics Review Committee of the University of Eastern Africa, Baraton. The ethics approval for the retrospective cohort study is UEAB/REC/09/05/21. The ethics approval for this case-cohort study is UEAB/ISERC/27/05/2022. Because this study collected secondary data retrospectively, there was no direct interaction with patients at any point during the study, and no identifying or contact information was collected or stored during data collection. In addition, family consent was not required as the study used retrospective, de-identified records.

Results

During Jan 2018 – Dec 2020, a total of 29,125 live births and 58 maternal deaths occurred at KCRH, giving a facility maternal mortality ratio of 190 per 100,000 live births for the 3 years under study. All (100%) of the maternal mortalities were audited; however, only 2 (3.4%) were uploaded onto the KHIS in accordance with national MPDSR protocols.

Participant characteristics

Table 1 shows the characteristics of all patients: the cases and controls. The majority of patients (94%, n = 289) were between the ages of 18 and 40, and slightly more than two-thirds (65%, n = 167) were unemployed. Half of the patients (50%, n = 128) had completed secondary level education. Nearly all (93%, n = 213) were married, but the proportion of singlehood was double in the cases (11%, n = 11) compared to controls (6.5%, n = 12). Almost half of the participants were nulliparous (46%, n = 133), and more than half of the cases were preterm (58%, n = 18). The majority of the controls (82%, n = 182) had a gestational age of more than 38 weeks compared to 42% (n = 13) of cases. Nearly twice as many cases (44%, n = 14) as controls (23%, n = 53) were delivered through Caesarean section (CS).

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Table 1. Patient characteristics and maternal outcomes

Characteristic	n	Alive (n = 232)	Died (n = 58)	p-value
Labour induction	288	135 (47%)	124 (54%)	<0.001
Age (years)	289			0.78
18–40		272 (94%)	219 (94%)	53 (93%)
<18		11 (3.8%)	8 (3.4%)	3 (5.3%)
>40		6 (2.1%)	5 (2.2%)	1 (1.8%)
Occupation	257			0.62
Employed		90 (35%)	76 (36%)	14 (32%)
Unemployed		167 (65%)	137 (64%)	30 (68%)
Education	256			0.32
Primary		75 (29%)	59 (27%)	16 (39%)
Secondary		128 (50%)	110 (51%)	18 (44%)
Tertiary		53 (21%)	46 (21%)	7 (17%)
Marital status	230			0.33
Married		213 (93%)	174 (94%)	39 (89%)
Single		17 (7.4%)	12 (6.5%)	5 (11%)
Parity	288			0.019
0		133 (46%)	114 (49%)	19 (34%)
1–2		114 (40%)	91 (39%)	23 (41%)
>2		41 (14%)	27 (12%)	14 (25%)
Gestation (weeks)	253			<0.001
28–37		58 (23%)	40 (18%)	18 (58%)
≥38		195 (77%)	182 (82%)	13 (42%)
Induction agent	289			<0.001
Dinoprostone		63 (22%)	61 (26%)	2 (3.4%)
Misoprostol		70 (24%)	61 (26%)	9 (16%)
None		156 (54%)	109 (47%)	47 (81%)
Mode of delivery	264			0.011
CS		67 (25%)	53 (23%)	14 (44%)
SVD		197 (75%)	179 (77%)	18 (56%)
Newborn Outcome	286			<0.001
Alive		241 (84%)	220 (96%)	21 (37%)
Died		45 (16%)	9 (3.9%)	36 (63%)
Composite outcome	259			<0.001
Favourable		137 (53%)	137 (61%)	0 (0%)
Unfavourable		122 (47%)	86 (39%)	36 (100%)
Study period	289			0.38
Jan 2018 – Jun 2019		110 (38%)	85 (37%)	25 (43%)
Jul 2019 – Dec 2020		179 (62%)	146 (63%)	33 (57%)

n (%); CS, Caesarean section; SVD, Spontaneous vaginal delivery; Pearson's Chi-squared test; Fisher's exact test.

Risk of maternal death during childbirth

Table 2 presents a summary of our findings from both univariate and multivariable logistic regression analyses. Two factors were significantly associated with maternal death. Postpartum haemorrhage (PPH) was strongly associated with an increased risk of maternal mortality (aOR= 14.4, 95%CI: 2.72–75.8, p = 0.002). Conversely, having a gestational age of 38 weeks or more was significantly associated with a reduced risk of maternal mortality compared to those with a gestational age between 28-37 weeks (aOR: 0.16, 95%CI: 0.05–0.54, p = 0.003).

Other variables showed increased or reduced odds of maternal mortality, but these associations were not statistically significant, as their confidence intervals

Table 2. Summary of the results of the univariate and multivariable logistic regression on the risk of Maternal Death during childbirth

Characteristic	n	Univariate			Multivariable		
		OR	95% CI	p-value	OR	95% CI	p-value
Labour induction	288						
No		Ref	Ref		Ref	Ref	
Yes		0.20	0.09 – 0.39	<0.001	0.36	0.02 – 8.05	0.5
Age (years)	289						
18–40		Ref	Ref		Ref	Ref	
<18		1.55	0.33 – 5.56	0.5	0.42	0.02 – 11.1	0.6
>40		0.83	0.04 – 5.27	0.9	0.48	0.02 – 14.3	0.7
Occupation	257						
Employed		Ref	Ref		Ref	Ref	
Unemployed		1.19	0.60 – 2.44	0.6	1.43	0.42 – 4.93	0.6
Education level	256						
Primary		Ref	Ref		Ref	Ref	
Secondary		0.60	0.29 – 1.28	0.2	1.03	0.27 – 3.98	>0.9
Tertiary		0.56	0.20 – 1.43	0.2	0.59	0.11 – 3.15	0.5
Marital status	230						
Married		Ref	Ref		Ref	Ref	
Single		1.86	0.56 – 5.33	0.3	2.76	0.56 – 13.5	0.2
Parity	288						
0		Ref	Ref		Ref	Ref	
1–2		1.52	0.78 – 2.98	0.2	1.20	0.34 – 4.20	0.8
>2		3.11	1.37 – 6.98	0.006	1.58	0.25 – 10.0	0.6
Gestation (weeks)	253						
28–37		Ref	Ref		Ref	Ref	
≥38		0.16	0.07 – 0.35	<0.001	0.16	0.05 – 0.54	0.003
Gestational hypertensive disorder	290	0.00		>0.9	0.06	0.00 – 2.32	0.13
Preeclampsia and eclampsia	290	1.73	0.53 – 4.88	0.3	2.53	0.22 – 29.0	0.5
Maternal pyrexia	252						
No		Ref	Ref		Ref	Ref	
Yes		0.00		>0.9	0.57	0.02 – 20.3	0.8
Post-partum haemorrhage	263						
No		Ref	Ref		Ref	Ref	
Yes		7.11	3.03 – 16.6	<0.001	14.4	2.72 – 75.8	0.002
Induction agent	289						
Dinoprostone		Ref	Ref		Ref	Ref	
Misoprostol		4.50	1.10 – 30.3	0.061	4.95	0.56 – 43.8	0.15
None		13.2	3.88 – 82.2	<0.001	2.32	0.10 – 54.0	0.6
Mode of delivery	264						
CS		Ref	Ref		Ref	Ref	
SVD		0.38	0.18 – 0.83	0.013	0.31	0.09 – 1.08	0.064
Study Period	289						
Jan 2018 – Jun 2019		Ref	Ref		Ref	Ref	
Jul 2019 – Dec 2020		0.77	0.43 – 1.39	0.4	1.07	0.32 – 3.55	>0.9

OR = Odds Ratio; CI = Confidence Interval; Ref denotes reference group; CS = Caesarean section; SVD = Spontaneous vaginal delivery.

included 1. For example, mothers who underwent labour induction had a lower likelihood of maternal mortality compared to those who did not (aOR: 0.36, 95%CI: 0.02–8.05, p = 0.5). Similarly, mothers under 18 years (aOR: 0.42, 95%CI: 0.02–11.1, p = 0.6) and those over 40 years (aOR: 0.48, 95%CI: 0.02–14.3, p = 0.7) had reduced odds compared to mothers aged 18–40. Being unemployed was associated with higher odds of maternal mortality (aOR: 1.43, 95%CI: 0.42–4.93, p = 0.6), while mothers with tertiary education had lower odds compared to those

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with only primary education (aOR: 0.59, 95%CI: 0.11–3.15, p = 0.5).

Single mothers exhibited higher odds of maternal mortality compared to married mothers (aOR: 2.76, 95%CI: 0.56–13.5, p = 0.2), and those with more than two children also had greater odds compared to those with none (aOR: 1.58, 95%CI: 0.25–10.0, p = 0.6), though neither was statistically significant. Similarly, mothers induced with misoprostol had higher odds of mortality compared to those induced with dinoprostone (aOR: 4.95, 95%CI: 0.56–43.8, p = 0.15), although this result was also not statistically significant.

Several other factors showed non-significant associations: mothers with gestational hypertension (aOR: 0.06, 95% CI: 0.00–2.32, p = 0.13), maternal pyrexia (aOR: 0.57, 95%CI: 0.02–20.3, p = 0.8), and those delivering via SVD (aOR: 0.31, 95%CI: 0.09–1.08, p = 0.064) appeared to have reduced odds of mortality. Mothers with preeclampsia, on the other hand, had higher odds of mortality compared to those without (aOR: 2.53, 95% CI: 0.22–29.0, p = 0.5).

During the study period from July 2019 to December 2020, when MPDSR activities were intensified, there was a modest increase in the odds of maternal death compared to the earlier period (aOR: 1.07, 95%CI: 0.32–3.55, p > 0.9), though this difference was not statistically significant.

Discussion

Our study identified several key factors that were associated with or influenced maternal mortality at KCRH during the study period. With regard to our primary objective, we found that induction of labour was not associated with a change in the odds of maternal mortality. However, we observed that misoprostol use for labour induction was associated with a four-fold increase in the odds of maternal mortality compared to dinoprostone (AOR: 4.95; 95% CI: 0.56–43.8; p = 0.15). This result did not reach statistical significance, and the wide confidence interval reflects considerable uncertainty.

The intent behind our primary objective was to build upon the conclusions of a previous retrospective cohort study on the outcomes of labour management at KCRH, which implicated the contextual use of misoprostol as a labour induction agent increased the risk of maternal mortality [21]. Given the challenges of accurate dosing with fractured tablets and the possible risk of complications [12], this finding underscores the need for more rigorous post-marketing monitoring and further large-scale studies to clarify the safety of misoprostol in similar settings. Furthermore, although this finding does not establish a definitive and causal link between misoprostol use and maternal mortality, it aligns with the MPDSR committee's concerns about the off-label use of misoprostol in our facility.

Aggregate and programmatic data show that the facility MMR of 190/100,000 is significantly lower than the national MMR, but still falls short of the target of 140/100,000 that the country aims to achieve by 2030 to meet its Sustainable Development Goals [6,7]. While we anticipated that the period following enhanced MPDSR activities would be associated with a decline in maternal mortality, we observed an insignificant increase in maternal mortality at the facility. Furthermore, MPDSR audits and uploading of audit documents onto KHIS were not completed for 96.6% of the maternal deaths. This indicates that enhanced activities still fell far short of the national target of auditing and reporting all maternal deaths [18].

This finding reflects a deviation from national MPDSR reporting standards [23]; and challenges and practices contributing to these low audit numbers have previously been described by Smith et al [18]. This underreporting undermines accountability and raises important ethical concerns for maternal health policy in resource-limited settings. The finding of a low audit rate for maternal fatalities and a facility MMR of 190/100,000 compares unfavourably with findings from a study in the same region that found 64% of all deaths were audited and a facility MMR of 124/100,000 [24]. This could be attributed to the expanded catchment area and referral status of KCRH. The low audit rate, on the other hand, could also be due to the widespread t underreporting associated with KHIS [25].

We found a strong association between postpartum haemorrhage (PPH) and maternal death (aOR: 14.4; 95% CI: 2.72–75.8; p = 0.002). This association is consistent with global evidence showing PPH as the leading direct cause of maternal mortality, particularly in sub-Saharan Africa [23]. In resource-limited contexts, PPH remains a critical target for intervention where access to blood transfusion, uterotonics, and surgical interventions is often constrained. These results highlight the urgent need to strengthen preventive strategies such as active management of the third stage of labour, ensure reliable availability of uterotonics (including oxytocin and tranexamic acid), and improve referral and emergency preparedness systems. Continuous provider training in PPH recognition and management is also essential to reducing preventable deaths.

This study has confirmed the important risk factors for death during childbirth at KCRH. Several sociodemographic and economic factors were identified as contributing to an increased risk of maternal mortality, including maternal unemployment and single status. When it came to medical and obstetric factors, higher parity was associated with an elevated risk of maternal mortality. Our finding that advanced maternal age was not associated with an increased risk of maternal mortality is in contrast to the findings that extremes of maternal age pose a risk for

adverse obstetrical and perinatal outcomes [26–29]. This can be attributed to the young population served by the facility (94% were aged 18 – 40 years) and the generally reported higher-than-average contraceptive rate in its catchment population [30].

Conversely, protective factors encompassed both young maternal age (below 18) and advanced maternal age (above 40), as well as mothers with a tertiary education. Although unadjusted estimates indicated a higher risk of death for mothers younger than 18 years and a lower risk of death for mothers older than 40 years, we found no association between the age of mothers and the risk of dying during childbirth after adjusting for other risk factors. In addition, the very few women of advanced maternal age who present to this tertiary care facility are typically classified as high-risk and are therefore subject to closer surveillance, with any complications anticipated and managed promptly. Other protective factors emerged, including a gestational age exceeding 38 weeks, the presence of gestational hypertension, maternal pyrexia, and the mode of delivery being spontaneous vaginal delivery.

Even though our findings on maternal mortality risk factors are comparable to those in neighbouring countries and other regions with similar socioeconomic conditions to Kenya [16,27–29,31], there are a multitude of risk factors that have been investigated and applied differently in those countries and regions. Other studies conducted in Kenya, where maternal mortality differs significantly across its various demographic regions, report similar risk factors [24,32,33]. Similar to our findings, a meta-analysis of 6 cohort studies demonstrated that elective induction of labour at 39 weeks, compared with expectant management beyond that gestational age, was associated with a significantly lower risk of caesarean delivery and mortality, as we found in our study [34].

The study team was concerned about why misoprostol was associated with increased mortality when used for induction. The absence of a suitable recommended delivery form of 25 mcg and repeated dosing to achieve a favourable cervix for delivery may contribute to refractory uterine atony leading to postpartum that is also resistant to the uterotonic use of misoprostol [35,36]. Similarly, the lack of availability of an appropriate dosage formulation and difficulty in titration of the large formulation tablets can lead to uterine hyperstimulation [37], resulting in uterine rupture and the risk of death. Even though misoprostol is non-inferior to other methods of induction, safety owing to uterine hyperstimulation, uterine rupture and caesarean section remain reasonable concerns for which there is conflicting evidence. However, these concerns can be addressed by the use of titrated oral low-dose misoprostol that has a low rate of caesarean sections [14]. In our retrospective study, we observed that dinoprostone use was associated with increased uterine rupture but not death [38].

Our study was designed to address a safety concern regarding the use of misoprostol at KCRH; however, it is important to interpret the findings within the context of the study's methodological limitations. A larger sample size would have improved the precision of our estimates; however, the lead-up and follow-up period following the clinical decision limited the number of eligible cases. Even though the mortality files are stored separately, the accessibility of physical files from physical archives could have affected the selection of study participants, particularly controls. And although this was an evaluation of a quality improvement intervention, the availability of pharmacological variables such as dose, dosage frequency, and mode of administration would have facilitated a detailed sub-analysis of the induction agents.

Lastly, our study focused solely on the aspect of receiving appropriate treatment within a tertiary facility as it pertains to maternal mortality and therefore, examining the known delays in seeking care associated with obstetric morbidity and mortality was beyond the scope of this study [39]. However, our study's strength lies partially in the fact that this work reiterates our previous findings, even using a different study design [21], and we included every single maternal death that occurred during the study period as cases.

Conclusions

This study reinforces the understanding that maternal mortality is multifactorial and requires continuous surveillance, review, and response. We found that safety concerns raised by healthcare workers can prompt major clinical decisions, as illustrated by the shift in induction practices at KCRH. Our findings highlight potential risks associated with this contextualized use of misoprostol and reaffirm postpartum haemorrhage as a leading contributor to maternal mortality. Beyond clinical priorities, the study underscores the importance of addressing off-label induction practices and gaps in maternal death reporting as systemic patient safety and accountability issues.

What is already known about this topic

- Maternal mortality remains a leading cause of death among women of reproductive age in Sub-Saharan Africa.
- Labour induction is a common obstetric intervention, most often using agents such as misoprostol or dinoprostone.
- Maternal and Perinatal Death Surveillance and Response (MPDSR) is globally endorsed, including by FIGO, to identify and prevent maternal deaths.
- Prior research at our facility implicated labour induction agent misoprostol in maternal deaths, though this was based on a smaller retrospective sample, which only contained 14 maternal deaths.

What This Study Adds

- This study analyzes all 58 maternal deaths between Jan 2018 to Dec 2020, offering stronger empirical support for the MPDSR committee's decision.
- Findings demonstrate how MPDSR processes can guide clinical policy in resource-limited settings, while highlighting the importance of evidence-based decision-making.
- Results emphasize the need for the Ministry of Health to supply obstetric drugs in appropriate formulations, or for facilities to adopt gold-standard agents like dinoprostone to reduce preventable risks.
- This study reinforces that maternal mortality is multifactorial, requiring continuous evaluation of both clinical practices and pharmacological interventions in obstetric care.

Conflict of Interest

The authors have no conflicting interests to declare.

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Authors' contributions

MN and MMK led Conceptualization, with MN also responsible for Data Curation, Formal Analysis, Methodology, and drafting the original manuscript. MMK additionally contributed to Investigation, Methodology, and writing. RA, MM, PN, and MMa contributed to Conceptualization and Methodology, with RA also involved in critical review. PN supported Investigation. PKJ handled Data Curation and Formal Analysis, co-led drafting, and participated in review. TNK and RG assisted with Data Curation and Methodology. AOO contributed to manuscript review and editing. All authors meet the ICMJE authorship criteria.

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