A synthesis of clinical and health system bottlenecks to implementing new WHO postpartum hemorrhage recommendations: Secondary data analysis of the Kenya Confidential Enquiry into Maternal Deaths 2014–2017

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Abstract
Objective: To describe maternal deaths from postpartum hemorrhage (PPH) in Kenya by secondary analysis of the Kenya Confidential Enquiry into Maternal Deaths (CEMD) database and clinical audit of a sample of those deaths, and to identify the perceived challenges to implementing country-specific PPH guidelines.

Methods: A retrospective descriptive study using the Kenyan CEMD database and anonymized maternal death records from 2014–2017. Eight standards from the Kenya National Guidelines for Quality Obstetric and Perinatal Care were selected to perform clinical audit. The process of supporting eight Sub-Saharan African countries to develop country-specific PPH guidelines was described and perceived challenges implementing these were identified.

Results: In total, 725 women died from PPH. Most women attended at least one antenatal care visit (67.2%) and most did not receive iron and folate supplementation (35.7%). Only 39.0% of women received prophylactic uterotonics in the third stage of labor. Factors significantly associated with receiving prophylactic uterotonics were place of delivery ($\chi^2 = 43.666$, df = 4; $P < 0.001$), being reviewed by a medical doctor ($\chi^2 = 16.905$, df = 1; $P < 0.001$), and being reviewed by a specialist ($\chi^2 = 49.244$, df = 1; $P < 0.001$). Only three of eight standards had a greater percentage of met cases in comparison to unmet cases. Key concerns about implementation of the new WHO PPH guidance included use of misoprostol by unskilled health personnel, availability of misoprostol and tranexamic acid (TXA) at primary healthcare level, lack of availability of heat-stable carbetocin (HSC) due to cost, lack of awareness and education about HSC and TXA, and lack of systems to ensure quality oxytocin is available at point of care.

Conclusion: There is a need for improved quality of care for women to minimize the risk of mortality from PPH, by implementing updated clinical guidelines combined with focused health system interventions.
INTRODUCTION

An unacceptably high number of women die during pregnancy and childbirth. It has been estimated that 295,000 (279,000–340,000) maternal deaths occurred globally in 2017. Most of these deaths (86% or 254,000) occurred in Sub-Saharan Africa (SSA) and Southern Asia (SA). Sixty-three percent of all maternal deaths globally are due to direct causes, with almost half (27.1%) due to hemorrhage. Hemorrhage is the primary underlying cause of 24.5% and 30.3% of maternal deaths in SSA and SA, respectively. Sixty-two percent of all deaths due to hemorrhage globally occur in the postpartum period (62% in SSA and 86% in SA). Most maternal deaths due to postpartum hemorrhage (PPH) could be avoided by the use of prophylactic uterotonics during the third stage of labour.

The Sustainable Development Goal (SDG) 3.1 target of a global maternal mortality ratio (MMR) of less than 70/100,000 live births by 2030 (211/100,000 in 2017) can only be achieved by taking practical steps to scale up the implementation of evidence-based interventions to prevent and treat PPH. Additionally, understanding the context-specific factors that contribute to morbidity and mortality is critical to making improvements in the quality of care required to reduce the risk of maternal deaths. Maternal death review (MDR) and Confidential Enquiry into Maternal Deaths (CEMD) can be used to achieve these goals. Clinical guidelines and protocols are developed to standardize the care provided for specific medical conditions. Clinical audits can be performed as part of quality improvement to measure adherence to these standards of care in clinical guidelines, to guide corrective action for improvements in the quality of care.

1.1 Getting policy into practice for prevention and treatment of PPH in low-resource countries

The International Federation of Gynecology and Obstetrics (FIGO) “Improving access to essential medicines to reduce PPH morbidity and mortality” recommendations on the use of tranexamic acid (TXA) for the treatment of PPH and recommendations on the use of uterotonics for the prevention of PPH in 2017 and 2018, respectively. Following the WOMAN trial and the publication of the WHO Essential Medicines List (EML) to include TXA and heat-stable carbetocin (HSC), several countries in Africa and Asia have been supported to update their national EMLs with both medications. For these recommendations to have a positive impact on PPH prevention and treatment, a system-wide approach is needed.

Box 1 Country engagement to develop context-specific PPH guidance

The FIGO/ICM generic PPH protocol and clinical pathway included key definitions, early identification of risk, estimation of blood loss, choice of uterotonics, prevention and treatment at various levels of care, effective multidisciplinary teamwork, communication, and referral, which can inform a systematic approach to developing policy for PPH management in health facilities.

FIGO and ICM were supported by national obstetrics and gynecology societies and midwives’ associations to engage with ministries of health and establish PPH Expert Working Groups (EWGs) in each country. The focal persons from each professional society/association met virtually every 1–2 weeks with the international coordination team to plan for in-country activities. Two virtual/hybrid, multistakeholder workshops with the identified PPH EWG were facilitated. The objective of the first workshop was to raise awareness of the WHO PPH recommendations, discuss, and appraise current national PPH guidelines and protocols, and develop a plan to adapt the FIGO generic PPH protocol and clinical pathway to meet the needs of the country. Digital feedback forms were developed, and comments were collected during and two weeks following the workshop. These comments included suggestions to contextualize the FIGO/ICM generic PCP, and the perceived challenges with the implementation of the WHO PPH recommendations.

FIGO incorporated the comments/recommendations into the generic PCP and returned the document to the PPH EWG for review and validation with the ministry of health taking the lead.

The objectives of the second workshop were to present the country-adapted and validated PPH protocol/guidelines, discuss use and dissemination, and to agree on the content and format of job aids that could support maternity care providers better to implement the national validated PPH protocol/guidelines. The international team encouraged national government health promotion departments and graphic designers to be involved in the design of the job aids. Feedback was obtained from the PPH EWG following the same process as the first workshop. FIGO and ICM further supported their member societies/associations to disseminate the job aids.
and mortality (IAP) project (2021–2022) supported eight SSA countries to update their EML in line with WHO PPH recommendations for the use of uterotonics including TXA and HSC. Under the IAP, FIGO—in partnership with the International Confederation of Midwives (ICM)—developed a generic PPH care pathway (PCP) incorporating the WHO PPH guidance. Subsequently, IAP partnered with national member societies and associations to update their protocols/guidelines for PPH prevention and treatment, and developed and disseminated job aids for health facility-based maternal care providers. A description of engagement key stakeholders under the IAP is given in Box 1.

In this paper we use a case study to provide a justification for the approach used in the FIGO IAP project. In the case study, we present a secondary analysis of a dataset from the Kenya CEMD to describe maternal deaths from obstetric hemorrhage, factors associated with these deaths, and assess adherence to national standards for PPH management. Additionally, we discuss the opportunities for the FIGO IAP and the perceived challenges implementing updated PPH clinical guidelines in the eight SSA countries.

2 MATERIALS AND METHODS

Maternal death review is an in-depth investigation of the causes of and circumstances surrounding maternal deaths occurring at health facilities or in the community. Maternal death surveillance and response (MDSR) was introduced by WHO in 2013, building on the experiences of MDR and to address its weaknesses (identification, reporting, reviewing, and acting on all maternal deaths). MDSR is a form of continuous surveillance that links the health information system and the quality improvement process from local to national levels, which includes the routine identification, notification, quantification, and determination of causes and avoidability of all maternal deaths, as well the use of this information to respond with actions that will prevent future deaths. There are other approaches of learning from maternal deaths to improve quality of care, including CEMD and clinical audits or standard-based audits. CEMD is a systematic multidisciplinary anonymous investigation of all or a representative sample of maternal deaths occurring at an area, region (state), or entire country. It identifies the numbers, causes, and avoidable or remediable factors associated with these deaths. Clinical audits have been described as a quality improvement process that seek to improve patient care and outcomes by the systematic review of care against explicit criteria and the implementation of change. An example of explicit criteria for providing evidence-based care are clinical guidelines. Guidelines and clinical care pathways are essential to ensure that good quality of care is available to end preventable maternal mortality and morbidity.

We conducted a secondary analysis of maternal deaths due to obstetric hemorrhage that occurred in Kenyan health facilities and were included in the Kenya CEMD from 2014–2017, and performed a standard-based audit on a sample these maternal deaths due to PPH.

2.1 Kenya CEMD

Multidisciplinary teams of assessors blinded to the identities of women who died (name and location of health facilities and those of the health workers involved in their care) conducted the confidential enquiry. The teams used a standardized electronic form to extract and deliberate on information from the medical records of women who died and arrived at conclusions about the underlying cause of death, factors associated with the death, and the quality of care provided. The CEMD were conducted retrospectively. A detailed description of the Kenya CEMD process has been described in detail elsewhere.

Kenya is a low/middle-income country located in East Africa with a population of approximately 53.7 million; made up of eight regions and 47 counties, the country covers an area of 580,367 km². The Kenya CEMD data included all maternal deaths reported through the District Health Information System (DHIS2). Medical records for each death were collected from county/secondary referral hospitals (57%), national teaching and referral hospitals (19.6%), sub-county hospitals (16.0%), private hospitals (5.3%), and faith-based hospitals (1.5%), spanning all regions of Kenya.

2.1.1 Procedures for secondary analysis

The study population comprised women of reproductive age (15–49 years) who died during or after pregnancy and delivery due to obstetric hemorrhage. Thirty-two percent (n = 728) of all maternal deaths (n = 2292) included in the CEMD due to PPH were included in the analysis.

To assess compliance with Kenyan clinical guidelines for the management of obstetric hemorrhage, we conducted a standard-based audit of a sample of all cases randomly selected from the database. A sample of 21.0% of the final study dataset (n = 152) was calculated using G*Power version 3.1.9.7 software. G*Power software was chosen because it provides improved effect size calculations and is easy to use.

Data for analysis were from the CEMD datasets for the years 2014–2017 and the corresponding medical case notes. Separate databases for CEMD 2014, 2015, 2016, and 2017 were merged and cleaned. Missing data for variables of interest were identified in scanned anonymized case notes and the original data were left unaltered to reduce errors. To ensure internal validity, data were quality checked for duplicates and missing data by triangulating with case notes and the MDSR data dictionary. Furthermore, to ensure all data were reliable and linked to the correct identification number, a random sample of 10% of the final study sample (n = 73) was collected and data were compared with the case notes and initial datasets. The sample was selected using an online random number generator.

The variables of interest were sociodemographic (county, age, educational status, marital status), pregnancy factors (parity, gravidity, type of pregnancy), clinical factors (antenatal care attendance,
total number of antenatal care visits, hemoglobin status, iron supplementation, malaria status, mode of birth, active bleeding on admission, units of blood received during last admission, volume of intravenous fluids received in the 48-hour period before death, prophylactic uterotonic received), organizational factors (place of death, facility level, highest cadre of skilled health personnel involved in management, review by medical doctor, interval between admission and review by medical doctor, review by obstetrician, interval between admission and review by obstetrician, ICU care received, referral status, and total number of referrals) (Figure 1 and supporting information Table 1).

Standards for the management of PPH were selected from the Kenya National Guidelines for Quality Obstetric and Perinatal Care. The standards assessed are presented in Box 2. Clinical care case notes were used to gather information on management of obstetric hemorrhage in the sample of cases. A table was created to show whether each standard was met or not met.

2.1.2 Analysis

Analysis was carried out using SPSS version 25 (IBM Corp, Armonk, USA). Frequency tables were created for variables and χ² test was used to investigate any association between various sociodemographic, pregnancy, clinical, and organizational factors, and the likelihood of receiving prophylactic uterotonic or intensive care (Figure 1). The proportion of cases that met each standard was determined and presented.

2.1.3 Ethical considerations

This was a secondary data analysis using anonymized datasets and care records. Approval for the CEMD and analysis was granted by the Kenya Ministry of Health and the Liverpool School of Tropical Medicine. To maintain ethical standards throughout this study the following measures were taken: (1) to maintain privacy, the datasets were password protected to ensure that only the research team could access them; (2) datasets were only viewed on project password-protected computers; (3) information pertaining to the data was not disclosed outside the research team; and (4) all datasets were kept for no longer than was required by the research team to ensure they were secure and there was no accidental data loss. As the data were already anonymized and tagged with a unique identification number, confidentiality was maintained.

3 Results

Three duplicated entries were identified in the dataset, therefore 725 women who died from obstetric hemorrhage in the KCEMD data for 2014–2017 were included in the analysis.

Most of the maternal deaths reported were from the Rift valley, Western, and Coast regions and most maternal deaths were reported from Kilifi County (n = 63, 8.7%). The mean age of the women who died was 28.8 ± 6.7 years. The youngest mother was aged 13 years while the oldest was 51 years. In addition, most women who died from obstetric hemorrhage had a primary level of education (n = 208, 28.7%) and were married (n = 357, 49.2%) (supporting information Table 1).

Most women who died of obstetric hemorrhage were multiparous (n = 456, 62.8%), with 24.7% (n = 179) grand multiparous (≥5). Most pregnancies were singleton (n = 659, 90.9%). Most women had received antenatal care before their death (n = 487, 67.2%) with only 56 women not receiving any antenatal care (n = 56, 7.7%); however, there was no record of attendance for 182 (25.1%) women. Most women had between one and three antenatal care visits (n = 300, 41.4%) with only 83 women having received four visits (11.4%) and 81 women receiving 5–8 visits (11.2%) before their death. There was no record of hemoglobin status in the antenatal care records of 74.8% (n = 542) of the women who died. Most (34%, n = 62) with
hemoglobin status recorded were between 10.0 g/dL and 11.9 g/dL. A record of iron and folic acid prescription was identified in less than 20% of the women. Overall, records for key antenatal interventions were poor. Most of the women had a cesarean delivery (43.4%, n = 315) and 40.4% (n = 293) had a vaginal birth. Active bleeding was documented in admission in only 14.8% (n = 107) of cases; 49.1% (n = 356) of women did not present with bleeding on admission and less than 20% had a prolonged labor (supporting information Table 2).

Most women were referred from another facility (n = 372, 51.3%) while 228 women were not referred (31.4%). There was no record of referral for 125 women. Most women were referred once before their death (n = 334, 46.1%), while 38 (5.2%) women were referred twice. Most women who died of obstetric hemorrhage gave birth in a county/secondary referral hospital (n = 285, 39.3%). Sub-county hospitals were the second most common place for delivery (n = 157, 21.7%), followed by national teaching/referral hospitals (n = 43, 5.9%). Most women who died were reviewed by a medical doctor (n = 480, 66.2%). The most frequent highest cadre of skilled healthcare professional involved in the care of women who died were medical officers (n = 277, 38.2%) followed by obstetricians (n = 185, 25.5%). The mean time between admission and being seen by a medical doctor was 82.9 ± 141.1 minutes. The shortest interval between admission and review by a medical doctor was 1 minute (1 case) and the longest interval was 14.5 hours (1 case). Most women were reviewed by a medical doctor after admission within 30 minutes (n = 112, 15.4%). Most women received prophylactic uterotonics (n = 283, 39.0%) before their death and there was no record of administration of prophylactic uterotonics in 61.0% (n = 442) of cases. There was poor documentation of resuscitative efforts; for example, administration of intravenous fluids was only documented in 41.7% (n = 302) of the maternal deaths. About 15% (n = 105) had ICU management. About 64% (n = 460) of women who died from obstetric hemorrhage were transfused with two or more units of blood (supporting information Table 3).

There was a significant association between receiving uterotonics and some sociodemographic and clinical variables, such as place of birth ($\chi^2 = 43.666$ [df = 4]; $P < 0.001$) and being seen by a medical doctor ($\chi^2 = 16.905$ [df = 1]; $P < 0.001$) or obstetrician ($\chi^2 = 49.244$ [df = 1]; $P < 0.001$) (Table 1).

Overall, out of the eight identified standards included in the clinical audit, standards were met for at least 50% of all women who died for the first three standards audited: assessing every woman bleeding in pregnancy within 30 minutes, administration of intravenous fluids, and administration of blood transfusion when indicated. The least met standard was active involvement of a senior medical professional in management of the patient (Table 2, Figure 2).

The key perceived challenges regarding implementation of the new WHO PPH guidance collected during and after the multistakeholder IAP workshops included concerns about the use of misoprostol by unskilled health personnel, availability of misoprostol and TXA at primary healthcare level, lack of availability of HSC due to cost, lack of awareness and education about HSC and TXA, and lack of systems to ensure quality oxytocin is available at point of care.

### 4 DISCUSSION

We analyzed a large dataset from the Kenya CEMD (2014–2017) to assess the need for improved availability of evidence-based PPH guidelines and training. We also assessed a sample of the maternal deaths for compliance of care according to the Kenya National Guidelines for Quality Obstetric and Perinatal Care.

The factors associated with PPH reported in this study were similar to other studies.\textsuperscript{17-19} Healthcare workers should be aware of risk factors for obstetric hemorrhage such as grand multiparity, moderate to severe anemia, previous history of PPH, cesarean delivery, prolonged labor, and non-administration of quality uterotonics. However, women without these factors can still be at risk of PPH; therefore, vigilance and preparedness to prevent and treat PPH using evidence-based interventions is vital.

Forty-three percent of the women in our study who died underwent cesarean delivery. Increased risk of poor outcomes from obstetric hemorrhage in women following cesarean delivery has been reported in several studies, including a systematic review.\textsuperscript{17,20-23} In contrast, a retrospective study in Denmark reported that planned cesarean delivery was associated with a reduced risk of severe PPH (OR 0.82; 95% CI, 0.73–0.92) compared with vaginal delivery; however, this study was conducted in a well-resourced setting and included planned cesarean delivery. Although we did not disaggregate by type of cesarean in the present study, most of the cesarean deliveries performed in the Kenya CEMD database are likely to be emergency.

The highest cadre of medical staff that attended to women who died were medical officers (52% of cases). We also reported a significant association between patients seen by a medical doctor or specialist with the likelihood of receiving prophylactic oxytocin—findings that are consistent with other literature. A retrospective descriptive study in Bangladesh reported 2.72 times the odds (95% CI, 2.15–3.24) of receiving interventions for the prevention of PPH when a trained professional was present compared with women who were unattended. Care provider knowledge and attitudes toward use of prophylactic uterotonics have been associated with the likelihood of administration of these life-saving medications.\textsuperscript{24,25}

The three most common causes of maternal deaths in the first and second Kenya CEMD reports were obstetric hemorrhage, hypertensive disorders of pregnancy, and non-obstetric complications. However, there was an increase in the proportion of maternal deaths due to hypertensive disorders of pregnancy (17.9%, n = 239 in 2015/2016 vs 15.3%, n = 74 in 2014) and non-obstetric complications (22.2%, n = 296 in 2015/2016 vs 19.8%, n = 96 in 2014). There was a reduction in the proportion of deaths due to obstetric hemorrhage in 2015/2016 (35.5%, n = 473) compared with 2014 (39.7%, n = 192). The most frequent factors reported in both CEMD reports associated with maternal deaths were health worker-related...
factors. These included delays in starting treatment (33%, n = 160 in 2014 vs 41.3%, n = 549 in 2015/2016), inadequate monitoring (27%, n = 131 in 2014 vs 30.9%, n = 411 in 2015/2016), and inadequate clinical skills (28%, n = 136 in 2014 vs 29.1%, n = 387 in 2015/2016).

The proportion of women who received suboptimal care in which a different management approach might have resulted in a different outcome increased from 81.4% (n = 394) in 2014 to 98.1% (n = 1310) in 2015/2016. The findings of the clinical audits conducted in this study also suggest suboptimal care in the management of obstetric hemorrhage.

To improve the quality of care provided to women who develop obstetric hemorrhage, training of skilled health professionals in the implementation of WHO evidence-based recommendations is essential. The FIGO IAP project has set up a pathway to achieve this. The results of this secondary analysis and the clinical audit suggest that the FIGO IAP project is timely and should be scaled up to accelerate the achievement of the ambitious SDG 3 maternal health target.

**Key concerns about the implementation of the new WHO PPH guidance collected during and after the IAP workshops included concerns about the use of misoprostol by unskilled health personnel, availability of misoprostol and TXA at primary healthcare level, lack of availability of HSC due to cost, lack of awareness and education about HSC and TXA, and lack of systems to ensure quality oxytocin is available at point of care. These issues must be addressed for maximum impact of the new WHO PPH recommendations.**

| Variable                  | Categories                      | Received prophylactic uterotonic (n = 283) No. (%) | No record of prophylactic uterotonic (n = 472) No. (%) | χ² | df | P value |
|---------------------------|---------------------------------|---------------------------------------------------|------------------------------------------------------|----|----|---------|
| Age, y                    | 10–19 (n = 63)                  | 48 (76.2)                                         | 15 (23.8)                                            | 18.678 | 4 | 0.971   |
|                           | 20–29 (n = 301)                 | 95 (31.6)                                         | 206 (68.4)                                           |       |    |         |
|                           | 30–39 (n = 300)                 | 112 (37.3)                                        | 188 (62.7)                                           |       |    |         |
|                           | 40–49 (n = 44)                  | 27 (61.3)                                         | 17 (38.7)                                            |       |    |         |
| Region                    | Central (n = 44)                | 14 (31.8)                                         | 30 (68.2)                                            | 6.307  | 7 | 0.613   |
|                           | Coast (n = 120)                 | 40 (33.3)                                         | 80 (66.7)                                            |       |    |         |
|                           | Eastern (n = 68)                | 27 (39.7)                                         | 41 (60.3)                                            |       |    |         |
|                           | Nairobi (n = 36)                | 6 (16.7)                                          | 30 (83.3)                                            |       |    |         |
|                           | Northeastern (n = 25)           | 2 (8%)                                            | 23 (92)                                              |       |    |         |
|                           | Nyanza (n = 124)                | 58 (46.8)                                         | 66 (53.2)                                            |       |    |         |
|                           | Rift Valley (n = 183)           | 62 (33.9)                                         | 121 (66.1)                                           |       |    |         |
|                           | Western (n = 125)               | 74 (59.2)                                         | 51 (40.8)                                            |       |    |         |
| Type of pregnancy         | Singleton (n = 659)             | 263 (39.9)                                        | 396 (60.1)                                           | 2.595  | 1 | 0.273   |
|                           | Multiple (n = 23)               | 20 (87)                                           | 3 (13)                                               |       |    |         |
| Place of birth            | County/secondary referral hospital (n = 285) | 208 (73)                                        | 77 (27)                                              | 43.666 | 4 | 0.001   |
|                           | Health center (n = 36)          | 3 (8.3)                                           | 33 (91.7)                                            |       |    |         |
|                           | National teaching/referral hospital (n = 43) | 18 (41.9)                                  | 25 (58.1)                                            |       |    |         |
|                           | Private health facility (n = 28) | 2 (7.1)                                           | 26 (92.9)                                            |       |    |         |
|                           | Sub-county hospital (n = 157)   | 50 (31.8)                                         | 107 (68.2)                                           |       |    |         |
| Was patient seen by a medical doctor? | Yes (n = 480)                 | 153 (31.9)                                        | 327 (68.1)                                           | 16.905 | 1 | 0.001   |
|                           | No (n = 164)                    | 25 (15.2)                                         | 139 (84.8)                                           |       |    |         |
| Was patient seen by a specialist? | Yes (n = 153)                 | 112 (73.2)                                        | 41 (26.8)                                            | 49.244 | 1 | 0.001   |
|                           | No (n = 426)                    | 171 (40.1)                                        | 255 (59.9)                                           |       |    |         |
| Mode of birth             | Normal vaginal birth (n = 293)  | 42 (14.3)                                         | 251 (85.7)                                           | 5.707  | 2 | 0.058   |
|                           | Assisted vaginal birth (n = 7)  | 3 (42.9)                                          | 4 (57.1)                                              |       |    |         |
|                           | Cesarean delivery (n = 315)     | 60 (19)                                           | 255 (81)                                             |       |    |         |
| Units of blood received at last admission | 1 unit (n = 141)             | 15 (10.6)                                         | 126 (89.4)                                           | 8.191  | 2 | 0.017   |
|                           | 2 units (n = 189)               | 34 (18)                                           | 155 (82)                                             |       |    |         |
|                           | 3 or more units (n = 271)       | 55 (20.3)                                         | 216 (79.7)                                           |       |    |         |
guidance, and that a detailed plan for dissemination of the national document was developed. These were all achieved despite the challenges presented by the COVID-19 pandemic restrictions.

A limitation of a descriptive study that should be considered is that statistical tests cannot be used to analyze results. In addition, causal relationships between factors and maternal deaths cannot be made through preliminary measures of association, but hypotheses can be made creating avenues for future research. Another potential limitation to secondary data analysis is the lack of control of the quality of data available. However, the database was based on data extracted from multiple patient records and analyzed by multidisciplinary teams of maternal health experts who had support in cleaning the database prior to quantitative analysis. The quality and completeness of the database is also limited by the quality of the primary data sources. While clinical audits are a powerful tool for quality improvement, they are limited by the quality of data available. Possible reasons for poor quality data may be perceived fear of blame and shame associated with maternal death reviews and clinical audits, inadequate number of staff, and associated high workload. We used the $\chi^2$ test to find out whether there were significant associations between the various sociodemographic, pregnancy, clinical, and organizational factors, and the likelihood of receiving prophylactic uterotonics or ICU care exists. While this has the advantage of exploring associations between variables and is appropriate for this type of dataset, it is not able to test the strength of associations.

The standards used for the clinical audit did not include TXA because there was no standard of care detailed in the Kenya National Guideline for Quality Obstetric and Perinatal Care that was in use when these maternal deaths occurred. However, the updated national guideline published in 2022 has detailed guidance for the use of TXA. The results from the clinical audit could have been more powerful if all cases of obstetric hemorrhage, irrespective of outcome, were included; this will be an opportunity to compare the odds of a maternal death when standards are met. However, restricted funding limited the collection of data required to do this. A system of electronic medical records may mitigate the problems with data quality (for example missing data), reduce the cost associated with data collection and improve efficiency of reviews and analysis. Several innovations have been reported in the literature to improve the quality of care for women and their newborns. Some notable innovations are the use of templates to improve clinical information in paper charts, use

### TABLE 2  Clinical audit results (n = 152)

| Standard | Categories | Frequency (n) | (%) |
|----------|------------|--------------|-----|
| 1. Assess every woman bleeding in pregnancy within 30 minutes | Assessed within 30 minutes | 73 | (48.0) |
| | Not assessed within 30 minutes | 59 | (38.8) |
| | Not recorded | 20 | (13.2) |
| 2. Initial treatment with administration of IV fluids | IV fluids administered | 95 | (62.5) |
| | IV fluids not administered | 32 | (21.1) |
| | Not recorded | 25 | (16.4) |
| 3. Blood transfusion if IV fluids not enough to stabilize vital signs | Blood transfusion received | 81 | (53.3) |
| | Blood transfusion not received | 44 | (28.9) |
| | Not recorded | 27 | (17.8) |
| 4. A senior medical professional was actively involved in management of patient | Involvement of specialist in clinical management of patient | 26 | (17.1) |
| | No involvement of specialist in clinical management of patient | 109 | (71.7) |
| | Not recorded | 17 | (11.2) |
| 5. Uterotonics | Uterotonic drug administered in third stage of labor | 59 | (38.8) |
| | Uterotonic drug not administered in third stage of labor | 72 | (47.4) |
| | Not recorded | 21 | (13.8) |
| 6. IV oxytocin | IV oxytocin used as first-line medication to treat PPH | 39 | (25.7) |
| | IV oxytocin not used as first-line medication to treat PPH | 70 | (46.0) |
| | Not recorded | 43 | (28.3) |
| 7. If IV oxytocin unavailable or bleeding is unresponsive, use IV ergometrine, oxytocin-ergometrine fixed dose or misoprostol | IV Ergometrine, Oxytocin-Ergometrine fixed dose or Misoprostol was used where IV Oxytocin unavailable | 35 | (23.0) |
| | IV ergometrine, oxytocin-ergometrine fixed dose or misoprostol was not used where IV oxytocin unavailable | 65 | (42.8) |
| | Not recorded | 52 | (34.2) |
| 8. Prompt referral (within 30–60 minutes of decision) to higher facility level of care if indicated | Yes | 58 | (38.2) |
| | No | 70 | (46.0) |
| | Not recorded | 24 | (15.8) |
of simple software to convert paper charts to digital format to enable continuous quality improvement cycles, and the use of drones to significantly reduce delays in the supply of blood.31

In conclusion, the results from the present study show that there is a need for improved quality of care for women to minimize the risk of mortality from PPH. With up-to-date clinical guidelines combined with focused health system interventions (procurement and supply of quality uterotonics etc), it is anticipated that the IAP project will contribute to the reduction of PPH morbidity and mortality. The design of the IAP meetings and workshops ensured engagement and ownership of key maternal health stakeholders involved with policy development, education, and clinical practice. Other countries can also adapt the generic PPH protocol and clinical care pathway and develop relevant job aids using a similar multidisciplinary approach led by professional societies and associations.

Clinical audits and CEMD are important quality of care tools for maternal and neonatal health, although quality of medical records and cost of data collection may be limiting factors. Electronic medical records are a feasible mechanism to mitigate these challenges.

AUTHOR CONTRIBUTIONS
Concept: CA. Data collection/extraction: PG, RM, FD. Data analysis and interpretation: RM, CA, FD. Drafting the article: CA, RM, PG, FW. Critical revision of the article: CA, RM, PG, FW, HA. Final approval of the version submitted: CA, RM, PG, FW, HA.

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CONFLICT OF INTEREST
CA provides technical support to the FIGO IAP project. All other authors have no conflicts to declare.

FIGURE 2   Number of cases of maternal death from PPH with met and unmet standards of care (n = 152).

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REFERENCES
1. World Health Organization. Trends in maternal mortality 2000 to 2017: estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division: executive summary. WHO; 2019.
2. Say L, Chou D, Gemmill A, et al. Global causes of maternal death: a WHO systematic analysis. Lancet Glob Health. 2014;2(6):e323-e333.
3. World Health Organization. WHO recommendations: Uterotonics for the prevention of postpartum haemorrhage. WHO; 2018.
4. World Health Organization. Strategies toward ending preventable maternal mortality (EPMM). WHO; 2015.
5. World Health Organization. WHO Recommendation on Tranexamic Acid for the Treatment of Postpartum Haemorrhage. WHO; 2017.
6. World Health Organization. Reviewing maternal deaths and complications to make pregnancy safer. WHO; 2004.
7. Lewis G. Beyond the Numbers: reviewing maternal deaths and complications to make pregnancy safer. Br Med Bull. 2003;67(1):27-37.
8. Smith H, Ameh C, Godia P, et al. Implementing Maternal Death Surveillance and Response in Kenya: Incremental Progress and Lessons Learned. Glob Heal Sci Pract. 2017;5(3):345-354.
9. Muthigani W, Ameh CA, Godia, M P, Mgambar E, Maua JM, Okoro D, et al. Saving Mothers Lives 2017. First Confidential Report into Maternal Deaths in Kenya 2017. https://familyhealth.go.ke/wp-content/uploads/2018/02/CEMD-Main-Report-Sept-3-FINAL-Full-Report.pdf. Accessed March 15, 2022.
10. United Nations, Department of Economic and Social Affairs. World Population Prospects 2019, Volume I: Comprehensive Tables UN; 2019.
11. National Bureau of Statistics-Kenya, ICF International. 2014 Kenya Demographic and Health Survey: Key Findings. KNBS and ICF International; 2015.
12. Erdfelder E, Faul F, Buchner A, Lang AG. Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. Behav Res Methods 2009;41(4):1149–60.
13. Blaxter L, Hughes C, Tight M. How to research. 4th ed. McGraw-Hill/Open University Press; 2010.
14. Ministry of Public Health and Sanitation and Ministry of Medical Services Kenya. National Guidelines for Quality Obstetrics and Gynaecology Obstetrics.
Perinatal Care. Ministry of Health Kenya; 2015. http://guidelines.health.go.ke:8000/media/National_Guidelines_for_Quality_Obstetrics_and_Perinatal_Care.pdf. Accessed March 15, 2022.

16. Panter AT, Sterba SK, Cooper H, Dent A. Handbook of Ethics in Quantitative Methodology. Routledge; 2011.

17. Heitkamp A, Aronson SL, Van Den Akker T, et al. Major obstetric haemorrhage in Metro East, Cape Town, South Africa: A population-based cohort study using the maternal near-miss approach. BMC Pregnancy Childbirth. 2020;20(1):1-8.

18. Lao TT, Sahota DS, Cheng YKY, Law LW, Leung TY. Advanced maternal age and postpartum hemorrhage - risk factor or red herring? J Matern Fetal Neonatal Med. 2014;27(3):243-246.

19. Ononge S, Mirembe F, Wandabwa J, Campbell OMR. Incidence and risk factors for postpartum hemorrhage in Uganda. Reprod Health. 2016;13(1):1-7.

20. Xu C, Zhong W, Fu Q, et al. Differential effects of different delivery methods on progression to severe postpartum hemorrhage between Chinese nulliparous and multiparous women: a retrospective cohort study. BMC Pregnancy Childbirth. 2020;20(1):660.

21. Sobhy S, Arroyo-Manzano D, Murugesu N, et al. Maternal and perinatal mortality and complications associated with caesarean section in low-income and middle-income countries: a systematic review and meta-analysis. Lancet. 2019;393(10184):1973-1982.

22. Ngwenya S. Postpartum hemorrhage: incidence, risk factors, and outcomes in a low-resource setting. Int J Womens Health. 2016;8:647-650.

23. Dindi NP, Godia P, Allott H, Ameh C. Risk factors for maternal mortality among women who had a caesarean section delivery in Kenya: A case-control study. East Afr Med J. 2021;97(8):2961-2974.

24. Bazirete O, Nzirirambaho M, Umubeyi A, Uwimana MC, Evans M. Influencing factors for prevention of postpartum hemorrhage and early detection of childbearing women at risk in Northern Province of Rwanda: beneficiary and health worker perspectives. BMC Pregnancy Childbirth. 2020;20(1):1-14.

25. Natarajan A, Ahn R, Nelson BD, et al. Use of prophylactic uterotonic during the third stage of labor: A survey of provider practices in community health facilities in Sierra Leone. BMC Pregnancy Childbirth. 2016;16(1):1-7.

26. Aggarwal R, Ranganathan P. Study designs: Part 2 - Descriptive studies. Perspect Clin Res. 2019;10(1):34-36.

27. Smith H, Ameh C, Roos N, Mathai M, van den Broek N. Implementing maternal death surveillance and response: A review of lessons from country case studies. BMC Pregnancy Childbirth. 2017;17(1):233.

28. Mchugh ML. The Chi-square test of independence Lessons in biostatistics. Biochem Med. 2013;23(2):143-152.

29. Engmann CM, Khan S, Moyer CA, Coffey PS, Bhutta ZA. Transformative Innovations in Reproductive, Maternal, Newborn, and Child Health over the Next 20Years. PLoS Med. 2016;13(3):e1001969.

30. Lunze K, Higgins-Steele A, Simen-Kapeu A, Vesel L, Kim J, Dickson K. Innovative approaches for improving maternal and newborn health - A landscape analysis. BMC Pregnancy Childbirth. 2015;15:337.

31. Nisingizwe P, Law MR, Ndishimye P, et al. Effect of unmanned aerial vehicle (drone) delivery on blood product delivery time and wast- age in Rwanda: a retrospective, cross-sectional study and time se- ries analysis. Lancet Glob Health. 2022;10(4):e564-e569.

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