Accelerating Maternal and Newborn Survival: The AMANI study

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6) STRUCTURED ABSTRACT

Background

The AMANI (Accelerating Maternal And Newborn survival) study aims to address persistently high rates o maternal and neonatal mortality in Kenya by improving maternal and infant death auditing and response. Maternal and Perinatal Death Surveillance and Response (MPDSR) is an evidence-based practice which results in meaningful reductions in maternal and newborn deaths through health system changes and improved quality of care. The WHO-developed MPDSR guidelines were adopted by the Kenyan government as national policy nearly a decade ago. However, MPDSR is rarely conducted with fidelity.

Methods

We will conduct a cluster randomized trial across 20 health facilities to test the practice facilitation package (includes audit and feedback (AF) and enhanced mentorship (EM)) using the RE-AIM framework. In Aim 1, we assess participation in practice facilitation in intervention facilities (Reach) and evaluate the effectiveness of the AMANI intervention on maternal and perinatal mortality, adoption of MPDSR following a death, and implementation of MPDSR with partial or full fidelity (primary outcome). We will identify determinants of implementation fidelity and track adaptations to MPDSR implementation. A 24-month implementation phase will be followed by a 12-month maintenance phase, during which no external practice facilitation will occur. We will evaluate if the strategy has an impact on maintenance phase fidelity and if AF and EM activities are continually implemented in intervention facilities. For the analysis of our primary outcome, the effect of AMANI on fidelity to MPDSR will be analyzed using a Poisson regression with robust errors to determine the effect of the intervention on the proportion of MPDSR cycles conducted with full fidelity. For qualitative analyses, two primary coders will code individual interview and focus group transcripts separately in Dedoose and will conduct content analysis within a mix of deductive and inductive coding to identify key themes. In Aim 2 we will investigate the primary mechanisms through which the practice facilitation package influences MPDSR implementation fidelity. For this analysis, we will conduct a multilevel mediation analysis using a series of hierarchical linear mixed-effects models (with a random effect for facility) to estimate the influence of the implementation strategy on primary outcomes of full fidelity and adoption.

Intended Impact

By leveraging routine data sources and political support, this study has the potential to dramatically influence progress towards achieving Sustainable Development Goals 3.1 and 3.2 by improving the implementation of the WHO-endorsed MPDSR tool. Moreover, it contributes to the collaborative testing of a pragmatic strategy to enhance the adoption, integration, and sustainability of an evidence-based intervention, potentially reducing preventable deaths in high mortality settings.

7) EXECUTIVE SUMMARY

Title: Accelerating Maternal and Newborn Survival: The AMANI study

Objective: This study aims to test whether practice facilitation, including both audit and feedback and enhanced mentorship can increase adoption of maternal and perinatal death surveillance and response (MPDSR) in Kenya with fidelity and, ultimately, reduce maternal and perinatal deaths.

Aims:

Aim 1: To evaluate the AMANI practice facilitation package using the RE-AIM framework to assess the strategy's Reach, Effectiveness, Adoption, Implementation, and Maintenance.

- Aim 1a: To track the number, proportion, and representativeness of health workers who participate in each component of the practice facilitation package (ex. Participate in mentorship services) in intervention facilities (reach).
- Aim 1b: To determine the effect of the strategy package on secondary outcomes of maternal, neonatal and perinatal mortality and MPDSR technical knowledge (effectiveness).
- Aim 1c: To evaluate the number and proportion of deaths for which the MPDSR cycle is initiated and evaluate determinants of adoption (adoption).
- Aim 1d: To (i) determine the effect of the strategy package on the *primary outcome of implementation of the MPDSR process with fidelity,* (ii) identify determinants of implementation fidelity using the consolidated framework for implementation research (CFIR) within interviews and focus group discussions with health workers involved in MPDSR implementation, and (iii) track facility-specific adaptations to MPDSR implementation and identify how facilities incorporate MPDSR steps into their practice context and facility infrastructure using the Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME; implementation).
- Aim 1e: To track the proportion of facilities implementing MPDSR with fidelity and proportion of intervention facilities sustaining each component of the strategy package 6 and 12 months after withdrawing external practice facilitator support.

Aim 2: To determine the primary mechanism through which the practice facilitation package influences MPDSR implementation with fidelity.

Methods 1&2: cluster randomized trial with surveys, record abstraction, and administrative records.

1c: qualitative interviews and focus group discussions with MPDSR committee members

Population: 1&2: health facility staff (MPDSR committee members and facility administrators)

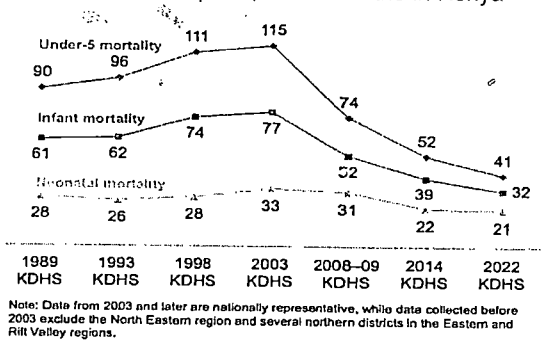
Sites: 20 health facilities in Nairobi and Western Kenya

Study Duration: 5 years

8) BACKGROUND

A1. Neonatal and maternal survival targets in Kenya are far from being met. Between 1990 and 2016, global under-5 mortality dropped by 62% compared to just 49% in neonates. As a result, newborn deaths now account for over half of under-5 mortality with 98% of these deaths occurring in low-and-middle income countries (LMICs) [1]. **Kenya ranks among the countries with the highest number of neonatal deaths (~40,000 per year) with a neonatal mortality rate of 21 deaths per 1,000 live births (Fig 1), far above the Sustainable Development Goal (SDG) 3 target of 12 per 1,000 births by 2030** [2,3]. Neonatal deaths now account for 60% of all infant deaths and 51% of under-5 deaths in the country. Progress on reducing maternal mortality is similarly slow, with an estimated maternal mortality ratio of 530 deaths per 100,000 live births [4]. Despite government efforts, including provision of free maternity services in all facilities, transformational progress is needed for Kenya to reach the SDG goal of achieving a maternal mortality ratio less than 70 per 100,000 [5].

Figure 1. Deaths per 1,000 live births in Kenya

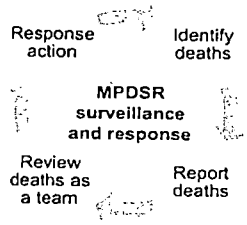


Note: Data from 2003 and later are nationally representative, while data collected before 2003 exclude the North Eastern region and several northern districts in the Eastern and Rift Valley regions.

A2. Increasing coverage of facility deliveries is not sufficient to reduce neonatal or maternal mortality. While Kenya has experienced a significant increase in health facility deliveries [6,7], there has not been a concomitant reduction in maternal and neonatal mortality or stillbirth [8]. In fact, a large prospective population-based study of 36,375 deliveries found no change in perinatal mortality despite a significant increase in facility utilization [9]. The possible explanation for the lack of mortality benefit in facilities include delays in necessary referrals, delays in providing appropriate care for complicated pregnancies and insufficient quality of newborn care in facilities. In addition, there appears to be no significant changes in causes of neonatal deaths in Kenyan MOH facilities after implementation of the free maternal health care policy [10]. Most neonatal deaths in LMICs are due to common, preventable causes such as birth asphyxia, preterm birth, neonatal infections, and congenital abnormalities [11]; half of maternal deaths and 58% of newborn deaths could be averted with delivery of improved quality care [12]. *Poor quality of care is, in part, driven by a lack of information about frequency and causes of death, cultures of blame that prohibit remedial action to address quality issues, lack of systematic tracking of responses to deaths, and inadequate allocation of material and human resources* [13].

A3. Maternal and Perinatal Death Surveillance and Response (MPDSR) processes prioritize and guide system changes needed to improve quality of care. The MPDSR is an established and evidence-based intervention for reviewing **and responding** to maternal and perinatal deaths. MPDSR involves quality improvement (QI) to assign causes of death, identify actions that may contribute to prevention of further deaths, implement identified actions, and follow-up to understand associated impact (Fig 2). The World Health Organization (WHO) released the original MDSR guidance in 2013, with the perinatal portion added in 2017, and recommends that death reviews be conducted in all hospitals globally. MPDSR has also been included in the United Nations' Global Strategy for Women's and Children's Health and the African Union Commission's action plan towards ending preventable maternal, newborn, and child mortality in Africa [14,15]. Kenya adopted MPDSR guidelines in 2016 and implementation of MPDSR is a priority of the Kenyan Ministry of Health in order to achieve National Health Policy 2013-2030 goals. Kenya has incorporated MPDSR into DHIS indicators and trained health workers on implementation of MPDSR tools [16].

Figure 2. MPDSR cycle



A4. Maternal and perinatal death audits are evidence-based and reduce preventable mortality. The Confidential Enquiry into Maternal Deaths in Kenya, a precursor to MPDSR, found that 92% of maternal deaths received sub-optimal care, significantly contributing to the deaths [17,18]. Evidence suggests that maternal and perinatal death reviews result in meaningful reductions in maternal deaths, severe acute maternal morbidity, and early neonatal mortality [19–21]. The QUARITE trial, the only LMIC study included in the Cochrane Review of

death audits for reducing maternal and perinatal mortality, was designed to empower obstetric teams to conduct maternal and perinatal death reviews and significantly reduced inpatient neonatal mortality within 24 hours of birth (adjusted OR 0.74, 95%CI 0.61-0.90) as well as inpatient maternal mortality (adjusted OR 0.85, 95%CI 0.73 -0.98) among the almost 192,000 births [21]. These improvements occur through modifiable practice changes and improved quality of care particularly in the time around labor and birth [19,22], when 50% of maternal deaths and 40% of stillbirths and neonatal deaths occur [23]. Death reviews not only have positive effects on perinatal mortality quality of care indicators, but large mortality audit programs have identified disparities in quality and equity of health services, resulting in improved health sector accountability [24]. *Thus, interventions that support MPDSR implementation in Kenya have potential to impact quality of care, assist in prioritizing very limited resources and ultimately improve morbidity and mortality outcomes for women and newborns.*

A5. Despite widespread political support, MPDSR is rarely implemented with fidelity in Kenya. Few countries, including Kenya, have robust operational MPDSR systems and most have specific weaknesses around alignment between the MPDSR and facility quality improvement (QI) processes [25]. While the maternal and perinatal death "surveillance" component of MPDSR is well established in many facilities in Kenya, there continues to be a need for more accurate and complete data, and the enactment and monitoring of the "response" components remain extremely weak [26]. In order to improve MPDSR implementation, particularly at the facility level, it is necessary to build administrator and health care worker confidence and skills, develop more explicit guidance on cause of death assignment, support robust death reviews, and strengthen alignment of MPDSR and QI efforts including strategies for developing, prioritizing and monitoring implementation of recommendations [27]. This must include supporting recommendations that are specific, measurable, achievable, relevant and time-bound [28].

Barriers to successful implementation of MPDSR include perceived "blame culture" linked to death auditing. In some contexts, providers perceive MPDSR meetings as futile, burdensome, poorly facilitated, and exacerbating of emotional fatigue and burnout [29]. They describe fearing punitive repercussions associated with death reviews, and in some settings there is evidence of false documentation, avoiding difficult cases and lack of engagement in the process [30]. Ineffective management, communication and coordination across teams also impedes the MPDSR process. However, evidence suggests that with good mentorship, a safe blame-free learning environment, and sufficient resources to support the surveillance and response process, MPDSR can be successful in its mission as well as an important educational initiative [31]. Despite significant evidence regarding both negative and positive factors influencing MPDSR utilization, to our knowledge there have not been any large interventional studies aimed at addressing determinants of MPDSR implementation.

A6. Practice facilitation is a promising implementation strategy to improve MPDSR implementation with fidelity, but evidence from the Global South is weak. A 2020 Cochrane review of death audit and review suggested that death auditing should be supported by external facilitators to provide supervision and mentorship [21]. Practice facilitation is a strategy that engages skilled external facilitators to support implementation of evidence-based guidelines through sustained QI. A systematic review found that primary care practices in high income settings were nearly three times more likely to adopt evidence-based guidelines when exposed to practice facilitation [32]. Practice facilitation also increases the likelihood of success of QI initiatives and improves quality of care metrics across diverse clinical settings [32–34]. A review of 39 systematic reviews of promising implementation strategies in low resource settings concluded that practice facilitation is an effective strategy but all available evidence was generated in high income settings; the review called for further research to determine effectiveness of practice facilitation in low-income countries [35]. *Practice facilitation that involves components of audit and feedback (AF) and enhanced mentorship (EM) may improve MPDSR implementation by supporting health workers to thoroughly engage in mortality data, normalizing challenging conversations, establishing shared accountability for responding to deaths, educating on MPDSR processes as well as QI best practices, and promoting psychological safety.* This study will advance the field of implementation science through the rigorous testing of practice facilitation in a low-resource setting.

9) LITERATURE REVIEW

B1. This proposed project will be the first to rigorously evaluate a multicomponent *implementation strategy package* specific for MPDSR and respond to lessons from Kenya's recent National Annua MPDSR Report [26]. The report, together with findings from our recent trial to reduce neonatal mortality (R01HD098105) in Kenya, provide preliminary evidence that an implementation strategy addressing in-hospital deaths and engaging health workers in participatory approaches to change the MPDSR implementation climate is needed to address low utilization of this evidence-based tool. Simultaneously, the Kenya Ministry of Health (MOH) and MPDSR partners have prioritized implementation research to support MPDSR as a crucial next step for the MPDSR process success [36].

B2. The study's practice facilitation strategy package was co-designed with the Kenya Central MOH, health facilities, and maternal/perinatal and implementation researchers. MPDSR is an evidence-based intervention that is already mandated for use within current Kenyan policy. However, many evidence-based interventions are not implemented to their full potential because they lack involvement and input from key stakeholders or evidence users. In Kenya, the MOH has reported significant gaps in MPDSR implementation, including systematic inconsistencies and inaccuracies of data reported by health facilities, limited follow-up on the implementation of QI actions identified during MPDSR meetings, and low coverage of perinatal death reviews [37]. Healthcare providers have further emphasized that inadequate MPDSR reviews are conducted due to lack of stakeholder engagement and blame culture, while poor implementation of QI actions are attributable to limited follow-up and lack of incentives [31]. In this study, implementation strategy development was informed by formative work with providers and leaders at MOH facilities to specify the strategy for the context. Such collaborative development between policymakers, implementers, and researchers increases the probability that the implementation strategy will be appropriate for the settings [38].

B3. Hybrid clinical-implementation research can accelerate progress towards identifying effective strategies to increase uptake of MPDSR with fidelity. In this study we propose a cluster-randomized hybrid type III study design, in which we are testing the effect of a practice facilitation package with primary implementation outcomes, while also observing and gathering evidence about clinical outcomes including mortality [39]. A hybrid type III design is appropriate because (a) there is evidence that maternal and perinatal death reviews can improve perinatal and maternal outcomes, (b) there is extensive evidence regarding determinants of MPDSR implementation, and (c) practice facilitation is a broadly used implementation strategy for both QI initiatives and guideline implementation that requires moderate adaptation to the Kenyan MPDSR context [40]. Importantly, because MPDSR is inconsistently implemented, it is likely that there is extensive missing data about the number of maternal and perinatal deaths. Thus, the proposed study design provides the opportunity to improve implementation of evidence-based guidelines, while also addressing data quality and completeness issues in essential mortality surveillance data, a unique benefit of hybrid type III designs.

B4. Despite being widely used, practice facilitation is an underspecified strategy that requires additional transparency and interrogation. The term practice facilitation is often an umbrella term used to refer to heterogenous sub-components, without detailed interrogation of the active components of the practice facilitation package. There has been a call to "open the black box of practice facilitation" to understand active ingredients (e.g. mechanisms of action) of the strategy(s) responsible for influencing positive changes in QI and guideline implementation [41]. This study is innovative in that mechanisms of action will be fully evaluated to understand what components of practice facilitation result in improved implementation of MPDSR with fidelity.

B5. There is a dearth of evidence about mechanisms of action in implementation science and behavioral health research, and meta reviews indicate that evidence on reporting or investigation into mechanisms is limited [42]. A 2020 systematic review identified only 46 studies with a mechanism focus across health disciplines [43]. Understanding mechanisms through which behavioral interventions lead to targeted outcomes is necessary to generalize and optimize the impact of behavior change interventions. Failing to fully understand mechanisms of an intervention may lead to a mismatch between the strategy and the barriers or determinants it is attempting to address [43]. In this study, we will evaluate the potential mechanisms of a practice facilitation package to improve MPDSR implementation, driven by the Information-Motivation-Behavior skills (IMB) model [44].

The AMANI study brings together a strong interdisciplinary team with complementary expertise in implementation science, quality improvement, maternal and perinatal health, behavior change and facility and community-based interventions to improve maternal and perinatal health. The AMANI team also has significant experience evaluating interventions to improve maternal and perinatal health including large trials within MOH facilities to increase uptake of essential maternal and neonatal interventions and care practices (Fig 3)

Figure 3. Select preliminary studies by the AMANI team

Study	CHAIN	Mama Aweza	Lishe Bora	MW NEO RCT	CHV-NEO	TEAMs Toolkit
Status	Completed project	Completed project	Data analysis underway	Data analysis complete	Currently enrolling	Currently enrolling
PIs	Singa (site PI)	Singa (site PI)	Means	Unger	Ronen	Means
Team	Means	Means, Unger, Ronen, Richardson	Singa	Kinuthia, Wamalwa, Ronen, Richardson	Means, Unger, Kinuthia	Singa
Overview	Identify causes of under five mortality, factors influencing guideline adherence, and potential solutions to overcome challenges	Develop an implementation strategy to improve malnutrition monitoring of young children, and reduce and death	Identify correlates of guideline deviation, and provider-derived solutions, including enhanced mentorship	Test a nurse-client communication strategy to reduce neonatal mortality and improve appropriate care seeking. N=5000	Test a CHV-client communication strategy to reduce neonatal mortality and improve care seeking	Test a provider-developed implementation strategy to increase guideline adherence via improve teamwork and communication
Identify causes of maternal and perinatal deaths			**Identify factors influencing adherence to evidence-based interventions to reduce deaths**		**Test strategies to reduce preventable deaths**	

C1. Our team (Means and Singa) has extensive experience evaluating factors influencing morbidity and mortality of children in Kenya, with a particular focus on factors influencing fidelity to guideline adherent care. Our team led the Kenya-site for the Childhood Acute Illness and Nutrition Network (CHAIN) (site PI: Singa) study, which led to the identification of causes of infant death in facilities and post-discharge. A secondary analysis of data (R03HD099270-01, PI: Means) identified the frequency and correlates of deviation from national pediatric guidelines and collected additional data regarding drivers of low fidelity [45]. The Lishe Bora study (MPI: Means and Singa) built upon CHAIN findings using participatory approaches (nominal group techniques [NGTs] and process mapping), and routine data abstraction from facility records to identify factors influencing fidelity. *These studies demonstrate that our team is experienced abstracting data from facility registers to understand fidelity to existing guidelines and using mixed methods to understand determinants of fidelity.*

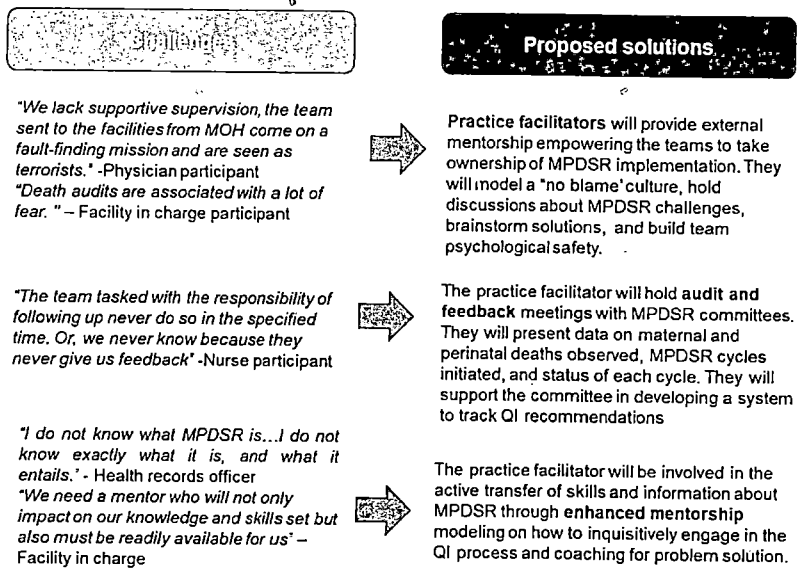
C2. Our team (Means, Kinuthia, Unger, Ronen, Singa) has extensive experience developing interventions to augment facility-based services for women, children, and adolescents in resource-limited settings. For example, the UW-KNH team developed a semi-automated interactive SMS platform, **Mobile WACh** (Mobile Solutions for Women's and Children's Health) that facilitates SMS communication between women and healthcare workers [46]. The Mobile WACh platform has been used in 8 studies in Kenya to date, several connecting women with nurses, and two (Mama Aweza and CHV-NEO) connecting women with CHVs [47–52]. These projects, in particular the Mobile WACh NEO (MWN) project (R01HD098105, N=5020) shine a light on system level challenges in preventing maternal and neonatal mortality and potential areas for improvement. **The cause of death data from MWN demonstrates that more than 67% of all deaths occurred during facility delivery and the majority were deemed preventable** [53].

C3. Our team also has extensive experience implementing audit and feedback to support neonatal mortality. Dr. Sherr led a quasi-experiment in over 150 primary care facilities in Mozambique to test an enhanced

audit and feedback strategy targeting guideline adherence for interventions that address neonatal mortality (Sherr, R01HD092449)[63]. Additionally, we have experience with iterative design of QI intervention in facilities in Western Kenya via the TEAMs Toolkit (MPI: Means and Singa), which used human centered design to engage with health workers in iterative improvements to incorporate pediatric guidelines for hospitalized children into routine care [54].

C4. The AMANI team led two co-design workshops to respond to findings from the MWN trial that most maternal and neonatal deaths were preventable and occurred in facilities. During the first workshop we presented mortality data from MWN. The goal of this meeting was to strategize collaboratively with stakeholders around institution-based approaches to prevent perinatal mortality. **County and national government partners requested that we utilize expertise from the MWN team to provide research support to accelerate MPDSR implementation** and align practice with national strategic priorities for perinatal mortality goals. As such, a second workshop was conducted to co-design implementation strategies to support MPDSR.

Figure 4. Challenges and proposed solutions by NGT participants



The second workshop used an NGT [55] and included a purposeful sample of 27 stakeholders including MOH directors, nurses, physicians, health records officers, and department heads, who participate in MPSDR implementation. Participants identified potential implementation strategies that could overcome MPDSR implementation. Ultimately the group ranked practice facilitation, as well as essential elements of practice facilitation (AF and EM), as the most potentially impactful and feasible. The AMANI intervention was designed based on these results (Fig 4).

C5. Practice facilitation is a multifaceted approach that involves skilled individuals who enable others, through a range of intervention components, to address challenges in implementation of evidence-based interventions [32,56]. Practice facilitation is a promising strategy to improve MPDSR, as the WHO MPDSR toolkit states, "Future research needs to go beyond identifying blame as a barrier to understanding how to create a culture of accountability, learning and improvement which can be achieved through strengthening leadership, improving teamwork and communication, and driving motivation while considering context" [25].

10) GUIDING FRAMEWORKS

Our proposal aims to evaluate whether practice facilitation, including both audit and feedback and enhance mentorship can increase adoption of MPDSR in Kenya with fidelity and, ultimately, reduce maternal and perinatal deaths. In the design of this study, we have drawn from several implementation science frameworks and theories to guide our outcomes definitions and data collection tools.

D1. The Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) Framework will inform the primary aim of this study. RE-AIM guides assessment of the public health impacts of complex interventions, capturing formative, process and outcome dimensions at individual, organizational and policy levels [57]. Our evaluation will provide a multi-dimensional understanding of the active ingredients that influence the impact of AMANI, and actionable information to design future expansion.

D2. We will utilize the consolidated framework for implementation research (CFIR), to characterize multi-level factors that influence implementation. The CFIR is a commonly used determinants framework that provides a menu of theory-based constructs associated with effective implementation [58].

D3. We will use the Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME) to track monthly adaptations to MPDSR implementation, and to identify how facilities incorporate MPDSR steps into their practice context over time [59]. FRAME is used to explicitly identify when and how intervention modifications occur, the impact that modifications have on intervention fidelity, and the underlying reasons for modifying the intervention.

11) RATIONALE

Improving implementation of this WHO-endorsed tool to reduce mortality will accelerate progress towards Sustainable Development Goals 3.1 and 3.2, while leveraging existing resources and political will. Findings will have pragmatic utility in Kenya and other African countries.

12) HYPOTHESIS, OBJECTIVES, & STUDY QUESTIONS:

Aim 1: To evaluate the AMANI practice facilitation package using the RE-AIM framework to assess the strategy's Reach, Effectiveness, Adoption, Implementation, and Maintenance. We will conduct a cluster randomized trial in 20 health facilities in Nairobi and Western Kenya. We will implement AMANI and evaluate implementation and clinical outcomes using the RE-AIM framework. RE-AIM guides assessment of the public health impacts of complex interventions, capturing formative, process and outcome dimensions at individual, organizational and policy levels [57].

Aim 1a) Reach: We will track the number, proportion, and representativeness of health workers who participate in each component of the practice facilitation package (ex. participate in mentorship services) in intervention facilities. Aim 1b) Effectiveness: We will determine the effect of the strategy package on secondary outcomes of maternal, neonatal and perinatal mortality, and MPDSR technical knowledge. Aim 1c) Adoption: We will evaluate the number and proportion of deaths for which the MPDSR cycle is initiated and evaluate determinants of adoption. Aim 1d) Implementation: (i) We will determine the effect of the strategy package on the *primary outcome of implementation of the MPDSR process with fidelity*, (ii) we will use the consolidated framework for implementation research (CFIR) to identify determinants of implementation fidelity through individual interviews and focus group discussions with health workers involved in MPDSR implementation, (iii) we will use the Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME) to track facility specific adaptations to MPDSR implementation, and to identify how facilities incorporate MPDSR steps into their practice context and facility infrastructure. Aim 1e) Maintenance: We will track the proportion of facilities implementing MPDSR with fidelity and proportion of intervention facilities sustaining each component of the strategy package 6 and 12 months after withdrawing external practice facilitator support.

Hypothesis: We hypothesize that the AMANI intervention will be associated with increased fidelity to all MPDSR steps (primary outcome) in intervention facilities as compared to control facilities over the 24 month implementation phase of the trial (Aim 1d). We hypothesize that the intervention will be sustained by facility staff in intervention facilities during the one year maintenance phase (Aim 1e). We also hypothesize that the proportion of MPDSR committee members who participate in practice facilitation services will increase in intervention facilities (Aim 1a), that MPDSR technical knowledge will increase in intervention facilities as compared to control facilities (Aim 1b), and that the proposition of deaths for which MPDSR is initiated will be higher in intervention facilities as compared to control facilities (Aim 1c) over the duration of the 24-month trial.

Aim 2: To determine the primary mechanism through which the practice facilitation package influences MPDSR implementation with fidelity. Drawing upon the Information-Motivation-Behavioral skills (IMB) model, we will conduct a series of mediation analyses to evaluate if AMANI engages targeted mechanisms of provider MPDSR knowledge (information), perceived social support and attitudes (motivation), and self-efficacy (behavioral skills)

and the extent to which engaged mechanisms explain the strategy's effect on MPDSR fidelity [44]. We will also evaluate changes in psychological safety and provider burnout as potential mechanisms.
Hypothesis: We hypothesize that the mechanisms that will be activated by the trial and affect fidelity to MPDSR implementation include: an increase in provider knowledge of MPDSR, an increase in provider confidence to implement MPDSR, and an increase in psychological safety (organizational climate) over the 24-month trial period.

13) STUDY DESIGN AND METHODOLOGY

13.1) STUDY AREA DESCRIPTION

AMANI will take place at 20 facilities in the Western (Kisumu, Kakamega, Homabay, Kisii, Siaya, Migori counties) and Nairobi regions of Kenya. These counties experience high rates of neonatal and maternal mortality and mortality rates in the proposed facilities are higher than the county averages. Facility inclusion criteria are: level 4 to 6 facility, conduct a minimum of 60 deliveries per month, experience an average of at least 5 perinatal mortalities in the facility per month, and have a history of conducting maternal and/or perinatal death reviews. Facilities may be a mix of both rural and urban. The proposed sites may include Kenyatta National Hospital, Pumwani Hospital, Bondo County Referral Hospital, Rachuonyo, Lumumba, Siaya County Referral Hospital, Homa Bay County Referral Hospital, Migori County Referral Hospital, Mam Lucy, JOORTH, Kisii County referral hospital, Kisumu County Hospital, Njiru Level 4 facility, Westlands sub-County Hospital, Muituini sub-County Hospital, Ahero County Hospital, Kombewa County Hospital, Ambira sub-County Hospital, Tassia Kwa Ndege Hospital, Yala sub-County Hospital,Mbagathi Hospital, Kayole 2 Hospital, and others within those counties.

13.2) INTERVENTION DESCRIPTION

The AMANI practice facilitation package includes two main components: AF and EM, both of which have amassed considerable promising evidence in high and low resource settings, including a systematic review of 140 AF trials [60–63]. The strategies are fully specified according to best practices in implementation science in Fig 5 [64]. Practice facilitators (PFs) will be clinicians (nurses, midwives, or physicians) with extensive experience implementing MPDSR and serving in leadership roles within facilities. PFs will complete further training prior to launch, including from the WHO and the Agency for Healthcare Research and Quality (AHRQ) [65,66]. Each randomized facility will be assigned to one PF, who will not have a previous history of employment at that facility.

Figure 5. Specifications of practice facilitation package components delivered in intervention facilities

Details [64]	Audit and feedback (AF)	Enhanced mentorship (EM)
Actor	External PF in years 1 and 2, no external PF in year 3	External PF in years 1 and 2, no external PF in year 3

Action	• AF meetings held with MPDSR committee members (including administrators, pediatrics, obstetrics, midwifery, and health records officers) • PFs will present data on maternal and perinatal facility deaths observed, MPDSR cycles initiated, stage of each MPDSR cycle, and proportion of MPDSR cycles (including final MPDSR step of "response"), completed with fidelity in past month • Data will be displayed in a public place using a standardized template, and updated prior to next visit • PFs will hold a discussion about challenges with MPDSR implementation and brainstorm potential solutions to overcoming challenges observed • PFs will record any noted adaptations to MPDSR implementation that providers employed over the previous month to overcome challenges	• PFs will attend MPDSR committee meetings • PFs will provide coaching on navigating data sources during committee meetings to identify all deaths • Members of the MPDSR committee will have the opportunity to meet 1:1 with PFs on a monthly basis, or as needed via WhatsApp texting or calling • PFs will provide active transferal of skills by providing information about MPDSR, providing information about how to complete QI cycles, modeling how to inquisitively engage in the QI process, and coaching for how to problem solve • PFs will record how often providers engage in mentorship services and the types of support sought • PFs will support the MPDSR committee in co-developing a system to track committee recommendations generated during QI, and subsequent decisions to adapt, adopt, or stop QI recommendations
Action target	• Provider motivation • Provider fatalism	• Provider knowledge and perceived self-efficacy • Committee processes (psychological safety)
Temporality	Active implementation (MPDSR is Kenyan policy)	Active implementation (MPDSR is Kenyan policy)
Dose	Monthly AF meetings during phase 1 (implementation period)	Monthly 1:1 mentorship meetings with PFs and ad hoc support as desired during phase 1 (implementation period)
Targeted outcomes	• Full MPDSR fidelity (primary) and partial fidelity (secondary) • Adoption (secondary) • Reduced maternal and perinatal mortality (secondary)	
Justification	PFs work with multiple facilities and provide "cross-pollination" of best practices and lessons learned.	PFs improve group processes by improving individual-level confidence and knowledge.

13.3) STUDY DESIGN

a. Overall study design: This study will utilize a cluster-randomized trial (cRCT) with a hybrid type III study design, in which we are testing the effect of a practice facilitation package with primary implementation outcomes, while also observing and gathering evidence about clinical outcomes including mortality. We will abstract one year of preceding mortality data from each facility, which will be used to inform a restricted randomization. After an initial 24-months of implementation strategy package delivery in intervention clusters, external practice facilitation support will be withdrawn and a 12-month sustained maintenance phase will help determine if a temporary and intensive period of practice facilitation can have an enduring impact on adoption and implementation of MPDSR tools with fidelity.

b. Determining baseline service readiness: We will conduct baseline service readiness assessments (SRAs) and data quality audits (DQAs) in all selected facilities to determine baseline capacity to implement MPDSR [67]. We will leverage SRA indicators, modified from the WHO Harmonized Health Facility Assessment (HHFA) service availability and readiness core/supplemental questionnaires as well as previous assessments of mortality reduction interventions implemented by our study team to include human resources, essential medicines, equipment, and infrastructure needed to implement interventions for neonatal mortality reduction [68,69]. Small stipends will be allocated to all facilities prior to randomization to address gaps apparent in SRAs, such as data stewardship, necessary equipment or material support required to implement neonatal resuscitation. DQAs will include evaluating availability and missingness of key MPDSR data in DHIS2 or other relevant data systems.

c. Establishing baseline levels of mortality: Prior to cRCT launch, we will abstract data from maternal and perinatal deaths registries in each facility for the prior 12 months. Data abstracted for each death include date of birth, date of death, location of death, sex, cause of death, and other potentially relevant and non-identifiable

data. Through baseline SRA interviews with facility leaders, we will also document if and how death auditing is currently implemented in each facility.

d. Randomization: We will conduct 1:1 restricted randomization to ensure equal allocation of facilities to each arm by number of baseline deaths (>5 or ≤5 per month), death auditing status (active or inactive), and any additional facility-level variables as needed.

13.4) AIM 1:

In Aim 1, we will implement AMANI and evaluate implementation and clinical outcomes using the RE-AIM framework. RE-AIM guides assessment of the public health impacts of complex interventions, capturing formative, process and outcome dimensions at individual, organizational and policy levels [57]. Our evaluation will provide a multi-dimensional understanding of the active ingredients that influence the impact of AMANI, and actionable information to design future expansion. The following section describes the mixed-methods approach to measure the RE-AIM domains of Reach, Effectiveness, Adoption, Implementation and Maintenance.

13.4.1) STUDY DESIGN

Mixed methods study design with mixed methods approach (qualitative interviews and focus group discussions; repeated quantitative surveys; and register abstraction)

13.4.2) STUDY POPULATIONS

Record abstraction: We will abstract data about births and deaths that occur in study facilities one year prior to study launch (~240 deaths estimated) and throughout implementation (~480 deaths estimated). We will abstract demographic information about these individuals, including contexts for the births and deaths (ex. gestational age, maternal age, etc.) and other information as needed. We will not abstract names or identifying information such as birthdate or community of origin, nor any constellation of variables that may potentially be identifiable.

Inclusion Criteria:

- Birth/death reported

Facility staff: We will invite all MPDSR committee members and facility administrators who oversee committee activities in sampled health facilities to participate in surveys and qualitative data collection. We will engage an estimated 200 MPDSR committee members (assuming approximately ~10 health workers and staff participate in each MPDSR committee) and approximately 60 facility administrators (~3 per facility).

After 24- and 36-months post-study launch, twelve facilities (three with highest fidelity to MPDSR and three with lowest fidelity to MPDSR, in each study arm) will be invited to participate in qualitative data collection. An estimated 144-204 facility staff will participate in each round of qualitative data collection.

Inclusion Criteria:

- Member of the MPDSR committee
- ≥18 years of age

13.4.3) SAMPLE SIZE DETERMINATION AND FORMULAS USED

Ten health facilities will be randomized to the intervention arm (receiving the practice facilitation package), and ten facilities will be randomized to the control arm (N=20 facilities total). With 10 sites per arm and 24 deaths per

1,000 live births per facility, we will have ≥80% power to detect an increase in fidelity from 22% to 55%, a relative change of 2.50 fold (primary outcome). And we will have ≥80% power to detect a change in adoption from 47% [70] to 70% (relative change of ~1.5 fold).

After 24 months of intervention delivery (phase 1), we will sample a minimum of three high and three low fidelity facilities from each arm, for a minimum total of 12 sampled facilities. We will conduct a minimum of two FGDs with MPDSR committee members in each facility and IDIs with a minimum of 2-3 administrators in each of the sampled facilities. With an estimated 5-7 individuals per FGD, we will engage an estimated 144-204 unique individuals in qualitative data collection. If we learn from a facility administrator that there may be tensions within an MPDSR committee, we will conduct multiple, smaller FGDs or only conduct in-depth interviews (IDIs) with MPDSR committee members at the given health facility instead. Because we aim to invite every member of MPDSR committees in selected facilities to engage in qualitative data collection via FGDs or IDIs, we expect to achieve data saturation. Qualitative data collection will be repeated after 12 months of maintenance (phase 2, 36 months after study launch) following the same facility and health worker sampling procedures to characterize adoption and fidelity during the maintenance phase after external practice facilitation has been withdrawn.

13.4.4) RECRUITMENT PROCEDURES

Following consultation with and permission from County-level Ministry of Health officials, facility administrators at all potential study facilities will be approached by the study team and invited to join the cluster randomized trial. Facility administrators will be made aware that, regardless of study arm, the study team will abstract anonymous data from facility registers, including birth and mortality registers, and MPDSR committee records. We will obtain approvals from the County-level Ministry of Health officials and facility administrators with agreement to participate in the study over the five-year project duration, including intervention periods and post-intervention periods necessary for data quality checks and for death register abstraction.

Facility administrators and healthcare workers or other staff assigned to participate in MPDSR committees in both study arms will be invited to participate in baseline (pre-intervention), midline (after 12 months), and endline surveys (after 24 months). Facility administrators and MPDSR committee members in both study arms will also be approached after 24 months of intervention delivery to participate in FGDs and/or individual interviews. For surveys and qualitative data collection, MPDSR committee members will be informed by facility administrators about the data collection activities and data collection will be planned collaboratively for days/times that pose the least disruption to routine facility operations. Thereafter, MPDSR committee members will be approached by study staff and read a recruitment script to assess interest in participating. Those who are willing will proceed to the informed consent process during which the potential participant will be provided detailed information about the study and will complete the written consent form. We will document any declines in participation.

After 24 months of intervention delivery, the study will enter a 12-month maintenance phase during which external practice facilitator support will be withdrawn from intervention facilities and we will observe if there are subsequent changes in MPDSR adoption and fidelity. We will conduct additional surveys with facility administrators and MPDSR committee members in intervention facilities only at 6- and 12-months post withdrawal to assess ongoing engagement in practice facilitation activities (audit and feedback and enhanced mentorship). In both intervention and control facilities, administrators and MPDSR committee members will participate in a final round of qualitative data collection at the end of the maintenance phase, with recruitment following the procedures described above. Facility administrators and staff assigned to participate in MPDSR committees during this time will be approached by study staff and read a recruitment script to assess interest in participating in the surveys. Those who are willing will proceed to completing the written informed consent process.

13.4.5) ENROLLMENT & STUDY PROCEDURES

Data Collection:

a. Baseline assessments: Once facility administrators have been contacted and have agreed to participate in the study, baseline service readiness and data quality assessments will be conducted at the facility using standardized questionnaires to determine baseline capacity to implement MPDSR [67]. We will leverage SRA indicators, modified from the WHO Harmonized Health Facility Assessment (HHFA) service availability and readiness core/supplemental questionnaires as well as previous assessments of mortality reduction interventions implemented by our study team to include human resources, essential medicines, equipment, and infrastructure needed to implement interventions for neonatal mortality reduction [68,69]. Small stipends will be allocated to all facilities prior to randomization to address gaps apparent in SRAs, such as data stewardship, necessary equipment or material support required to implement neonatal resuscitation. DQAs will include evaluating availability and missingness of key MPDSR data in DHIS2.

b. Register abstraction: Prior to cRCT launch, we will abstract data from maternal and perinatal deaths registries in each facility and/or DHIS2 for the prior 12 months. Data abstracted for each death include date of birth, date of death, location of death, sex, cause of death, and other relevant information as needed. During the implementation phase, we will abstract mortality data from each facility monthly and for each death we will record the following information: date and time of birth, date and time of death, type of death (antepartum stillbirth, intrapartum stillbirth, neonatal death), location of death, mother/baby transfer history, birth attendant, maternal age, maternal obstetric history, antenatal care history, HIV status, sex of baby, birthweight, gestational age, location of birth, mode of delivery (ex. vaginal, assisted, caesarean), cause of death using ICD-10/11 or ICD-PM, and other variables as needed. We will not abstract the name of the deceased, community of origin, or any names of individuals who attended to a specific death to ensure that all data abstracted from the registers are fully de-identified.

To facilitate subsequent data quality assurance of abstracted data from birth and death registers, a photo of each register will be taken, with opaque items (such as a piece of cardboard) placed on top of the patient's name, maternal date of birth, residence, and any other potentially identifying information located in the register. Data captured in the photos but not abstracted into the database will not be analyzed. Photos will be stored securely, as described in Section 16.

c. MPDSR committee meetings and practice facilitator logs: Data sources accessed include routine MPDSR committee forms, such as maternal death review (MDR) and perinatal death review (PDR) forms and practice facilitator logs. At each AF session, we will use a standardized sign-in register to document which health workers were present and their characteristics including gender, age, cadre, department, and number of years of professional experience. Facility administrators will provide monthly information regarding health workers assigned to the MPDSR committee in each facility. Practice facilitators will also document each mentorship engagement with committee members and, using a similar standardized tracking log, practice facilitators will record key demographic information of engaged staff. Practice facilitators will also record information regarding the mentorship format (individual in-person support, group in-person support, support via text, support via phone call, etc.), type of mentorship (increase knowledge of quality improvement (QI), increase technical QI skills, increase MPDSR knowledge, increase technical MPDSR skills, clinical problem solving, strategies for dealing with burnout etc.), and amount of time spent on each mentorship activity. Practice facilitators will also complete monthly surveys to document their perceptions of MPDSR processes at each facility as well as their own practice facilitation practices.

The standardized template for MPDSR implementation adaptations will include information regarding whether adaptations were planned, who participated in the decision to modify, what was modified (content, context, training/evaluation, other), the level of the modification, the context of the modification, the nature of the modification, and the reasons for the modification [59]. PFs will also record on a monthly basis any notable changes to facility context using a standardized template, including changes in leadership, facility initiatives, or other notable contextual changes.

MPDSR facility leads in intervention and control facilities will be asked to keep all MPDSR reporting forms logging MPDSR committee meeting activities. At six- and 12-months post withdrawal, study team members will collect forms and evaluate ongoing fidelity to MPDSR steps and data completeness. At six and 12 months post withdrawal, we will also conduct surveys with facility MPDSR committee members to determine if strategy package components continue to be implemented, including if (a) AF activities persist and if the AF activities have been modified, and (b) if MPDSR committee members engage regularly with the MPDSR lead in a new mentorship capacity, including frequency of 1:1 mentorship or engagement with other external MPDSR mentors (e.g., district or national-level). Data will be collected in-person using a semi-structured survey with a mix of closed-ended and open-ended questions to allow for short qualitative descriptions.

d. Staff facility surveys: We will administer a survey to MPDSR committee members in all health facilities at three time points: (1) Baseline, prior to randomization, (2) after 12 months of strategy implementation, and (3) after 24 months of strategy implementation. The survey will be administered alongside clinical vignettes (described in Aim 1b) to assess MPDSR and essential clinical technical knowledge and will include Likert-style questions related to perceptions of social support for MPDSR use (social motivation), attitude towards MPDSR (personal motivation) and perceived self-efficacy to implement each MPDSR step (behavioral skills) (Fig 6). Proposed indicators are consistent with the IMB literature, within which a core set of questions have been tailored for use across topic areas [71–74]. We will also evaluate team psychological safety and provider burnout as potential mechanisms addressed by the AMANI strategy (Fig 6) [75,76]. We will pilot test all survey questions with a minimum of ten individuals from outside of study facilities, including cognitive interviews to ensure that questions have high face validity in the Kenyan setting [77,78].

At six and 12 months post withdrawal, we will also conduct surveys with facility MPDSR committee members to determine if strategy package components continue to be implemented, including if (a) AF activities persist and if the AF activities have been modified, and (b) if MPDSR committee members engage regularly with the MPDSR lead in a new mentorship capacity, including frequency of 1:1 mentorship or engagement with other external MPDSR mentors (e.g. district or national-level). Data will be collected in-person using a semi-structured survey with a mix of closed-ended and open-ended questions to allow for short qualitative descriptions.

e. Qualitative data collection: We will conduct FGDs with MPDSR committee members in each facility and individual interviews (IDIs) with administrators in each of the sampled facilities. With 5-7 individuals per FGD, we will engage an estimated 72-108 individuals in qualitative data collection. We will utilize the consolidated framework for implementation research (CFIR), to characterize multi-level factors that influence implementation. The CFIR is a commonly used determinants framework that provides a menu of theory-based constructs associated with effective implementation [58]. A semi-structured interview guide will be used to guide FGDs and interviews, informed by a subset of CFIR constructs purposively selected by the study team based on a previous scoping review of factors influencing MPDSR uptake (Fig 8) [79]. Qualitative questions will focus factors influencing fidelity, for example: perceived acceptability of MPDSR, perceived sense of accountability, facility context and culture, experiences accessing data sources to identify deaths or evaluate progress, the perceived policy and political environment, psychological safety amongst teams, culture of blame and communication, and other questions informed by the CFIR and existing MPDSR literature [79,80]. FGDs and IDIs will be conducted in English by an experienced facilitator accompanied by a notetaker, audio-recorded, and transcribed verbatim by a transcription company.

Planned analyses: Each of the analyses for Aim 1 sub-aims are described in detail below.

1. **Aim 1a (REACH):** We will use generalized estimating equation (GEE) models with a Poisson family, robust errors, and clustering by health facility to determine if there is a significant difference in participation in strategy components (audit and feedback versus enhanced mentorship) over time. In sensitivity analysis, we will use GEE to determine if the proportion of health workers participating in each practice facilitation package component varies significantly by health worker cadre.

2. **Aim 1b (EFFECTIVENESS):**

i. *Mortality analysis:* The effect of AMANI on mortality will be analyzed using Poisson regression and robust errors, with the number of deaths during the study at each facility as the outcome and the number of deliveries at each facility as the offset. The primary exposure variable will be randomization arm. We hypothesize that AMANI will be most effective in reducing intrapartum stillbirths and neonatal deaths. This is because intrapartum stillbirths generally reflect the quality of care during labor, while antepartum stillbirths are a more useful indicator of antenatal conditions and care. Thus, in secondary analyses, models will be run separately for outcomes of maternal deaths, perinatal deaths, intrapartum stillbirths, antepartum stillbirths, and perinatal deaths.

ii. *MPDSR technical knowledge analysis:* We will assess knowledge of MPDSR and other basic essential maternal and neonatal care at birth and immediately post birth interventions (ex. administration of uterotonic drugs for a postpartum hemorrhage, immediate after birth care for infants including drying and stimulation and assessment of the baby's breathing, supporting a neonates airway) and compare changes in knowledge scores over time (baseline, after 12 months, and after 24 months). We will use a GEE model with a Poisson family, robust errors, and clustering by facility. The primary exposure variable will be randomization arm, while the outcome will be a continuous measure of knowledge scores. In sensitivity analyses, models will be run separately for MPDSR knowledge outcomes and essential maternal and perinate care knowledge outcomes.

3. **Aim 1c (ADOPTION):** We will evaluate the number and proportion of deaths for which the MPDSR cycle is initiated and evaluate determinants of adoption. We will document the number and proportion of deaths for which the first two MPDSR steps are initiated, defined as deaths identified and reported with full documentation in maternal death review (MDR) and perinatal death review (PDR) data forms within 7 days. The study team will abstract data for each maternal and perinatal death on a monthly basis from the Maternity Register (MOH 316), Maternal Baby Unity (MBU) Registry, and the Neonatal Intensive Care Registry. MDR and PDR data forms will be inspected from the same month to identify if the MPDSR process was initiated within the designated time (as described above). We will use Poisson regression with robust errors. The primary exposure variable will be randomization arm, while the outcome will be a binary outcome of adoption and the offset will be number of mortalities per facility.

   We will further evaluate adoption data to assess if mortality reports adhere to WHO guidance for perinatal mortality (ICD-PM) and assess if the documentation identifies the time of death (antepartum, intrapartum, or neonatal), follows the MPDSR-provided multilayered stepwise classification system for cause of death, and links contributing maternal conditions, if indicated. Adoption will be presented in total and stratified by maternal, neonatal and perinatal deaths, and we will use Poisson regression with robust errors to identify the effect of practice facilitation on changes in MPDSR adoption for both categories of death separately. Evidence suggests that there are a number of disincentives to reporting deaths and, thus, in subaim 1d we will use qualitative methods to understand perspectives of MPDSR committee members on factors influencing MPDSR adoption.

4. **Aim 1d (IMPLEMENTATION):**

i. *Quantitative fidelity analysis (primary study outcome):* We will determine the effect of the strategy package on the primary outcome of implementation of MPDSR with fidelity. We will measure full fidelity (primary outcome of the cRCT) as the number and proportion of deaths for which a full MPDSR cycle (six steps) are undertaken. We will also measure partial fidelity, defined as the number and proportion of MPDSR cycles for which less than six steps are implemented, and the average number of steps completed (to identify MPDSR steps posing greatest implementation challenges). The effect of AMANI on fidelity to MPDSR will be analyzed using a Poisson regression with robust errors to determine the effect of the intervention on the proportion of MPDSR cycles conducted with full fidelity. We will adjust for facility factors (e.g. patient volume and staffing levels, measured during baseline SRAs) if there appear to be meaningful differences on average between intervention and control facilities. In sensitivity analyses, we will also evaluate the influence of the intervention on fidelity score (range of 0-6), with an outcome of the number of MPDSR steps undertaken in a given facility using Poisson regression with robust errors.

ii. *Qualitative assessment of fidelity analysis:* We will use the consolidated framework for implementation research (CFIR) to identify determinants of implementation adoption and fidelity through individual interviews (IDIs) and focus group discussions (FGDs) with health workers involved in MPDSR implementation. Data will be collected in English, unless a participant expresses a desire to communicate in Swahili or another local language. Audio recordings will be transcribed verbatim and, if data were not collected in English, transcripts will be translated. Two random one-minute quality spot checks will be conducted per transcript to assess the quality of the transcription and translation. Should any errors be detected, the audio will be listened to in full and compared to the written transcript. Two primary coders will code the IDI and FGD transcripts separately in Dedoose and will conduct content analysis within a primarily deductive CFIR-based codebook to identify key themes (allowing flexibility for inductive, non-CFIR themes to emerge). After coding one transcript, coding will be compared across coders and consensus meetings will be held to finalize the codebook. Consensus meetings will be held weekly by two independent coders during coding, and a third coder will be consulted as necessary. Case memos will be written for each FGD, organized by CFIR construct and other emergent codes. Three analysts will assign strength and valence ratings for each construct using an established CFIR rating system [81]. Ratings will reflect the positive or negative influence (valence) and the strength of each construct; constructs will be coded as not enough data to assess (M), not (0), weakly (+1/-1), or strongly (+2/-2) distinguishing between low/high fidelity facilities. Findings will be used to identify determinants of adoption and fidelity and develop recommendations for MPDSR implementation, including core components of the practice facilitation strategy that can be replicated at scale.

iii. *Adaptation analysis:* We will use the Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME) to track monthly facility specific adaptations to MPDSR implementation in intervention facilities only and to identify how facilities incorporate MPDSR steps into their practice context and facility infrastructure. Of note, facilities will not be adapting the implementation strategy (AMANI practice facilitation package) and will only be adapting how the MPDSR process is integrated into facility operations. For example, an MPDSR committee may decide to modify who is responsible for reviewing data sources within a facility to identify and obtain information around maternal or perinatal deaths and the frequency in which data review occurs. The standardized adaptation tracker will include information regarding whether adaptations were planned, who participated in the decision to modify, what was modified (content, context, training/evaluation, other), the level of the modification, the context of the modification, the nature of the modification, and the reasons for the modification [59]. As an exploratory analysis, we will conduct a 24-month uncontrolled time series analysis in which we will determine if the occurrence of an adaptation influences full fidelity in intervention facilities. We will use a three-month lag, allowing us to explore if the presence of an adaptation (exogenous variable) is associated with subsequent improvements in fidelity and recognizing that there may be a lag between when an adaptation is made and when the adaptation may affect provider behaviors. We will plot the data to visualize trends, outliers, and potential patterns. We will use autoregressive integrated moving average (ARIMA) or seasonal decomposition of time series (STL) to evaluate temporal patterns and potential causal links between an adaptation and fidelity. We will conduct a series of separate sensitivity analyses to determine if different types of modifications (content, context, training/evaluation, other) are associated with relatively smaller or larger improvements in fidelity.

5. **Aim 1e (MAINTENANCE):**
   i. *Analysis of maintenance of MPDSR implementation with fidelity:* To understand if and how fidelity changes from phase 1 (intervention phase) to phase 2 (maintenance phase) we will conduct a controlled, interrupted time-series analysis that incorporates monthly facility-level estimates of fidelity, segmented into 24-months of intervention and 12-months of maintenance (when external PF support is withdrawn). This analysis will allow us to address both serial and intra-class correlation and assess temporal patterns in outcomes. The interrupted time series model will be parameterized with time as

a continuous variable indexed in months. We will test the effect size of the immediate post-intervention change in fidelity and the overall slope to determine if moving from phase 1 (interventior phase) to phase 2 (maintenance phase) had a meaningful impact on fidelity, comparing interventior and control facilities using GEE with a Poisson family, robust errors and clustering by facility.

ii. *Analysis of maintenance of the AMANI strategy package:* We will report the number and proportion of intervention arm facilities that are continuing to conduct practice facilitation activities, including sub-activities of audit and feedback and sub-activities of enhanced mentorship. We will use a Poisson regression with robust errors to determine if there is a significant difference in the prevalence ratio comparing participation in strategy components during the maintenance phase.

13.4.6 LABORATORY METHODS

Not applicable

13.4.7 DATA COLLECTION INSTRUMENTS

- Facility staff survey (baseline and months 12, 24, 30, and 36)
- MPDSR committee meeting data abstraction tool (used during all meetings in the intervention and maintenance phase)
- Maternal and neonatal death abstraction tool from DHIS2
- Maternal death review (MDR) form abstraction tool
- Perinatal death review (PDR) form abstraction tool
- Monthly MPDSR adaptation form
- Practice facilitator log of activities and services provided
- IDI/FGD discussion guides (months 24 and 36)

13.4.8 VARIABLES: Outcomes, indicators, and source documents

Primary and secondary outcomes are fully described in Figure 6. For the primary outcome (MPDSR fidelity), primary and secondary indicators are listed in Figure 7.

Figure 6. Overview of study outcomes and measures

Outcome	Aim	Level	Definition
Primary outcome			
MPDSR fidelity (implementation)	Aim 1d	Facility and arm	Number and proportion of maternal and perinatal deaths for which all six MPDSR steps are implemented in full
Secondary outcomes and measures			
Reach	Aim 1a	Facility (intervention arm)	Number, proportion, and representativeness of MPDSR committee members who participate in each component of the strategy package
Institutional Maternal Mortality Ratio (IMMR)(effectiveness)	Aim 1b	Facility and arm	Number of deaths of pregnant women within 42 days of the termination of pregnancy (from any cause related to or aggravated by the pregnancy or its management), divided by the total of deliveries in the facility over the same period of time[1]
Perinatal mortality rate (effectiveness)	Aim 1b	Facility and arm	Number of stillbirths (fetal deaths at least 28 weeks of gestation) and newborn deaths (up to and including the first seven days after birth), divided by the total births in the facility over the same time[1]
Neonatal mortality rate (effectiveness)[2]	Aim 1b	Facility and arm	Number of deaths that occur in the first 28 days of life, divided by total live births in the facility over the same period of time [1]
Adoption	Aim 1c	Facility and arm	Number and proportion of deaths for which the MPDSR cycle is initiated

Partial MPDSR fidelity (implementation)	Aim 1d	Facility and arm	Number and proportion of maternal and perinatal deaths for which less than six of the MPDSR steps are implemented, and average number of steps completed, to identify most challenging MPDSR step (Figure 9)
Adaptations (Implementation)	Aim 1d	Facility (intervention arm)	Number of modifications made per month to MPDSR implementation, including documentation of the nature of the modification, goal/rationale for modification, timing, and other features [59]
Maintenance of strategy package	Aim 1e	Facility (intervention arm)	Proportion of intervention facilities sustaining AF and/or EM 6 and 12 months after external PF support is withdrawn
Maintenance of MPDSR	Aim 1e	Facility and arm	Number and proportion of maternal and perinatal deaths for which all six MPDSR steps are implemented in full within 3 months, measured 6 and 12 months after external PF support is withdrawn
Provider technical MPDSR knowledge (Information)	Aim 1b, Aim 2	Provider, facility, and arm	Clinical vignette-based assessment of MPDSR steps, data sources, and essential knowledge
Perceived MPDSR social support (Social motivation)	Aim 2	Provider, facility, and arm	Mean response to 2 items with a five- point scale, based on IMB literature [82,83]
Attitude towards MPDSR use (Personal motivation)	Aim 2	Provider, facility, and arm	Mean response to 2 items with a five- point scale, based on motivation literature [84,85]
Perceived self-efficacy to perform MPDSR steps (Behavioral skills/fatalism)	Aim 2	Provider, facility, and arm	Mean response to 6 items with a five-point scale, based on IMB literature [71–73]
Psychological safety	Aim 2	Provider, facility, and arm	Mean response to 7 items across 3 levels of psychological safety: team leader, other team members, and team as a whole [75]
Burn out	Aim 2	Provider, facility, and arm	Mean dimension scores across 3 dimensions (emotional exhaustion, personal accomplishment and depersonalization) [76]

[1] Definition provided by MPDSR toolkit, [2] Additional sensitivity analyses conducted separately for antepartum & intrapartum stillbirths

Figure 7. Overview of primary and secondary indicators of fidelity, informed by WHO MPDSR toolkit recommendations [25]

#	Step	Primary fidelity measures[1]	Secondary indicators of fidelity
1	Death identification /notification	Maternal and perinatal death is notified through MPDSR via the case information form	• % of deaths in HMIS2 that were documented in MDR/PDR forms • % of deaths in HMIS2 documented in MDR/PDR forms within 24 hours
2	Data aggregation	Causes of death and other features of the death are documented using MDR and PDR case review forms	• % of MDR/PDR forms completed (eg. if information such as tests results are unknown, they should be marked as "unknown" and not left blank)[2] • % of MDR/PDR forms completed anonymously[2] • % of MDR/PDR forms with a cause of death using CD-10/11 or ICD-PM[2] • Causes of death documented in MDR/PDR case review forms within 7 days
3	Death review	Death review is conducted for the registered death by the MPDSR committee*	• % of deaths reviewed by the MPDSR committee • % of deaths for which modifiable factors are identified[2] by factor level • % of planned MPDSR committee meetings conducted • Average number of attendees at each MPDSR meeting • % of meetings that include all MPDSR committee members • % of meetings including all staff who helped manage the case[2]
4	Recommend solutions	At least one recommendation is generated during the death review*	• Average number of recommendations made per modifiable factor • Average number of recommendations made per death • % of recommendations with a "responsible person" & "time frame" assigned • % of meetings for which meeting minutes are finalized within 72 hours[2]
5	Implemented solutions	Recommendation(s) is implemented within 3 months	• % of recommendations that were implemented in full • % of recommendations that were partially implemented
6	Evaluate and refine activity	Implemented solution is discussed at next MPDSR meeting, with decision to repeat, stop, or refine activity	• % of facilities with evidence of data analysis to evaluate response activities • % of facilities that fully document QI activities, including decisions to adopt, adapt, or stop recommended activities and reasons for adoption or discontinuation decisions

[1] Steps needed for full fidelity. Each step contributes to overall fidelity score (0-6) [2] Key standard indicator in the MPDSR toolkit

13.4.9 TRAINING PROCEDURES

Drs. Means, Unger, and Kinuthia will oversee training of study staff on register abstraction, facility staff surveys, and training of practice facilitators. Trained study staff will work with facility staff at all facilities to ensure appropriate implementation of procedures. Dr. Means will supervise training of facilitators for the qualitative components of the study.

13.4.10 STUDY MATERIALS

- Facility Staff IDI Consent Form
- Facility Staff FGD Consent Form
- Facility Staff Survey Consent Form

13.5 AIM 2:

The IMB model identifies three core determinants of initiation and maintenance of behaviors: **Knowledge** refers to MPDSR knowledge gained from PFs. **Motivation** includes personal and social motivation to engage in MPDSR implementation with fidelity. **Behavioral skills** refer to objective and perceived skills gained by MPDSR committee members and their sense of self-efficacy in implementing MPDSR [74,82,83]. This includes elements of fatalism, meaning the degree to which providers believe that outcomes are predetermined, and they have the ability or inability to affect them. We will investigate these potential mechanisms of the AMANI implementation strategy, in addition to hypothesized mechanisms of provider burnout and team psychological safety, in order to understand why the package does or does not work in certain settings, and to inform design of a toolkit that targets activated mechanisms of action (Fig 9) [86]. There are increasing calls for trials of implementation strategies to formally explore anticipated mechanisms in order to reveal *how* they succeed or fail [87].

13.5.1 STUDY DESIGN

Analytical aim using quantitative data collected during Aim 1

13.5.2 STUDY POPULATIONS

Facility staff: We will invite all MPDSR committee members and facility administrators who oversee committee activities in sampled health facilities to participate in surveys.

Inclusion Criteria:

- Member of the MPDSR committee
- ≥18 years of age

13.5.3 SAMPLE SIZE DETERMINATION AND FORMULAS USED

Formal power analyses were not conducted for this aim, as the study was powered on Aim 1.

13.5.4 RECRUITMENT PROCEDURES

There is no unique recruitment required for this analytic aim.

13.5.5 ENROLLMENT & STUDY PROCEDURES

a. Procedures: We will administer a survey to MPDSR committee members in all health facilities at three time points: (1) Baseline, prior to randomization, (2) after 12 months of strategy implementation, and (3) after 24 months of strategy implementation. The survey will be administered alongside clinical vignettes (described in Aim 1b) to assess MPDSR and essential clinical technical knowledge and will include Likert-style questions related to perceptions of social support for MPDSR use (social motivation), attitude towards MPDSR (personal motivation) and perceived self-efficacy to implement each MPDSR step (behavioral skills) (Fig 6). Proposed indicators are consistent with the IMB literature, within which a core set of questions have been tailored for use across topic areas [71–74]. We will also evaluate team psychological safety and provider burnout as potential mechanisms addressed by the AMANI strategy (Fig 6) [75,76]. We will pilot test all survey questions with a minimum of ten individuals from outside of study facilities, including cognitive interviews to ensure that questions have high face validity in the Kenyan setting [77,78].

Planned analyses: We will report mean scores for each outcome of interest, including knowledge, motivation, behavioral skills (fatalism), provider burnout, and psychological safety. We will further conduct a multilevel mediation analysis using a series of hierarchical linear mixed-effects models (with a random effect for facility) to estimate the influence of the implementation strategy vs. control (*X*) on the outcomes of MPDSR implementation with the primary outcomes of full fidelity (*Y1*) and adoption (*Y2*). We will test the role of intervening variables (*M*), putative mediators, to quantify the proportion of the relative effect of the implementation strategy on targeted outcomes that is explained by hypothesized mechanisms. We will use a products of coefficients approach, which is believed to be a superior method relative to other mediation analysis approaches for minimizing type I error rates, maximizing statistical power, and enhancing accuracy of confidence intervals in mediation analysis [88]. We will fit the data to assess *X*'s total effect on *Y* into direct and indirect (mediated) effects by estimating the cross product of (a) the effect of *X* on *M*, and (b) the effect of *M* on *Y*, adjusted for *X* [89].We will test the mediated (indirect) effects via bootstrapping methods and the *mediation* package in R [90]. We will evaluate mediators after 12 months and, in separate models, after 24 months.

Figure 8. Criteria to establish mechanisms of strategies [27,56]

Criteria	Definition
Strong association	Association between implementation strategy and mechanism AND between mechanism and behavior
Specificity	One plausible construct accounts for change
Timeline	Causes and mediators temporally precede outcome
Gradient	Dose response relationship between mediator and outcome
Plausibility/ coherence	Logical explanation of how the mechanism operates that incorporates relevant research finding

Moderators are distinct from mediators in that they do not intervene in a causal chain but instead represent variables that change the relationship between *X* and *Y* such that the direction or magnitude of the relationship depends on the level of the moderator [88]. Through the use of multilevel mediation (moderated mediation) we will test the extent to which the relationship between the strategy, mediators, and outcomes vary across a minimum of five measurable moderating variables, including: provider cadre, years of provider experience in role, years of provider experience with MPDSR, time commitment, staff and resource availability, perception of county-level support, and other relevant variables. We will review findings within the context of the IMB and underpinning theories for other included constructs and apply five Kazdin criteria for establishing a mechanistic relationship of implementation strategies (Figure 8).

13.5.6) LABORATORY METHODS

Not applicable

13.5.7) DATA COLLECTION INSTRUMENTS

See Aim 1

13.5.8) VARIABLES: Outcomes, indicators, and source documents

See Aim 1, Figures 7 and 8

13.5.9) TRAINING PROCEDURES

See Aim 1

13.5.10) STUDY MATERIALS

See Aim 1.

14) QUALITY ASSURANCE PROCEDURES

See Aims 1 & 2

15) ETHICAL CONSIDERATIONS

15.1 ASSESSMENT OF RISKS AND BENEFITS

i) POTENTIAL RISKS

Physical: We do not anticipate any physical risks in this study.
Other risks: There may be stigma associated with the death of a mother or infant in facilities in Kenya. There may be avoidance to discuss the issue or conduct systems improvements as a result due to cultures of blame and hierarchy. An essential part of our intervention is to increase psychological safety in maternity wards to ensure that cadres of health professionals at all levels feel safe in raising and communicating concerns. We will directly measure these and similar outcomes in our study to ensure we are activating the targeted mechanisms. Additionally, breach of confidentiality and disclosure of information to persons other than the participant is a potential risk of this study. A breach of confidentiality could lead to unfair treatment by employers, and/or embarrassment or anxiety. Study staff will be trained to take all precautions to ensure confidentiality of participation and data collected and will have standardized operating procedures to follow to minimize the risks of a participant's loss of confidentially. Risk of breach of confidentiality of study data is low, as all data collected will not include names and will be located on a password protected server, and encrypted prior to upload; in addition, study staff will be trained in the importance of confidentiality during human subjects training prior to study implementation. All study participants may opt-out of any study procedure and may refuse to answer any question they are uncomfortable with.

ii) ADEQUACY OF PROTECTION AGAINST RISKS

Informed consent: Participants will provide written informed consent. See 'Human Subjects' part (c) for more information about the informed consent process.

Protections against risk: We will not be directly enrolling or sampling neonates or pregnant women. However, we will be abstracting data about births and deaths from enrolled health facilities, including the contextual information surrounding deaths such as gestational age, maternal age, and other relevant information to understand the context of the event. Abstracted de-identified patient record data and survey data will be collected and stored electronically in HIPAA-compliant, secure, password-protected encrypted REDCap databases sponsored by the UW Institute of Translational Health Sciences (ITHS). These databases will be managed by the study's data manager. All study staff will be trained on the importance of confidentiality and will receive human subjects training. In the event of an adverse event (ex. potential breach of confidentiality), participants will have an emergency contact number. We will minimize risks to privacy by collecting personally identifiable information only from participants whose contact information is required to complete study procedures. We will minimize risks to privacy by assigning subject ID numbers at the time of consent and using those ID numbers

on all data collection tools. The computer on which the participant information is stored will be password protected and only accessible to study staff. If data are breached during the study, the investigator will disclose this breach to the participant and the IRB/ERC and will seek advice from the IRB/ERC committees.

To facilitate subsequent data quality assurance of abstracted data, a photo of each register will be taken, with opaque items (such as a piece of cardboard) placed on top of the patient's name, date of birth, residence, and any other potentially identifying information located in the register. Data captured in the photos but not abstracted into the database will not be analyzed. Photos will be stored securely, as described in section 16.

iii) POTENTIAL BENEFITS OF PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

There are no direct clinical benefits to individual participants. However, health workers and facilities in the intervention arm may benefit from enhanced professional development, increased knowledge, improved teamwork, and strengthened MPDSR practices through mentorship and facilitation support. At the societal level, the study has the potential to improve the quality of maternal and newborn care by strengthening the implementation of MPDSR, leading to reductions in preventable maternal and perinatal deaths. The findings may also inform scalable, evidence-based strategies to enhance accountability and quality improvement in health systems in Kenya and similar low-resource settings.

iv) IMPORTANCE OF THE KNOWLEDGE GAINED

Knowledge gained from the study proposed in this application will include information about the MPDSR implementation process and the components of practice facilitation that facilitate full MPDSR fidelity, which may have substantial impact on maternal/neonatal mortality rates in Kenya and inform MPDSR implementation for further scale-up.

16) DATA MANAGEMENT AND STATISTICAL ANALYSIS PLANS

All study materials will be stored in a password-protected folder on a secure server maintained by the University of Washington (UW) with automated back-up at the end of each day. All datasets will be subject to data standards such as documentation of methods of collection through codebooks, standard operating procedures (SOPs) for data collection, and limitations associated with data collection. Data containing participant identifiers will not be shared, but will be preserved for six years after termination of the study, per institutional policy. Abstracted de-identified patient record data and survey data will be collected and stored electronically in HIPAA-compliant, secure, password-protected encrypted REDCap databases sponsored by the UW Institute of Translational Health Sciences (ITHS). These databases will be managed by the Principal Investigators (PIs) and study coordinator. All qualitative data collected through interviews and focus groups to address Aim 1 will be stored on a secure server. All recording devices will be wiped clean after recordings are uploaded to the secure server.

A de-identified dataset will also be created to share publicly for dissemination and publication. The final versions of any de-identified data collected and/or generated will be made publicly available within 12 months of publication. Final data gathered from this project will be archived for data sharing purposes in Dryad, NIH's recommended open-access generalist data repository. The repository software creates persistent URLs that will not change over time. Audio files and full transcripts from qualitative data collection will not be shared. Redacted transcripts to protect participant anonymity may be shared upon request.

a. Metadata, other relevant data, and associated documentation: The study protocols, sample informed consent forms, data collection instruments, data dictionaries, and codebooks will be made accessible in data repositories where data are shared. Each variable in the codebooks will include a brief description of the item, question text, variable name/label, value name/label, and codes for missing values (including unknown, not reported, not applicable, or refusal). Documentation will be provided in PDF, Word, or Excel format. Deposit of materials to Dryad requires a minimum set of descriptive information (metadata) to be provided at the point of deposit. Some

of this metadata will be automatically generated by the software used by Dryad while other pieces will be provided by the study team.

b. Related tools, software and/or code: In this study, patient record data and survey data will be accessed from REDCap databases. Data entered into REDCap will be de-identified. These data will be analyzed using R statistical software and de-identified data and analysis files developed during the study as well as quality control register photos will be stored in the UW's OneDrive, which is HIPAA-compliant and only accessible to study personnel. Transcripts and audio recordings will be stored in the UW's OneDrive. No specialized tools, software, and/or code are needed to access or manipulate shared scientific data.

c. Protections for privacy, rights, and confidentiality of human research participants: Throughout and following data collection procedures, all participant identifiers will be stored in a HIPAA-compliant, secure, password-protected encrypted REDCap database separate from the main study databases. Identifying information can only be accessed by study staff approved by the PIs. Informed consent documents completed prior to interviews and FGDs include explicit language about storage of data for use in future research and sharing of de-identified data. Participants will not be contacted or re-consented for future sharing or accessing data through repositories. Only de-identified data will be archived and available for sharing.

d. Data Monitoring: A Data and Safety Monitoring Plan (DSMP) will be drafted in accordance with the NIH policy for data safety and monitoring. The Principal Investigator (PI) will take responsibility for data safety and monitoring as part of the general oversight and scientific leadership of the study. All unanticipated problems involving risks to participants will be reported to the Kenyatta National Hospital Ethics & Research Committee (KNH ERC) and the University of Washington Institutional Review Board (UW IRB) within 48 hours of an adverse event occurrence.

In addition, an External Advisory Panel will be established at study initiation to review study progress, any scientific or policy developments that may have an impact on the study, any reported social harms or adverse events, and offer suggestions to improve study implementation and/or reporting. The panel will include experts in MPDSR and maternal and neonatal health in resource limited settings. We have been in conversation with and invited members of the WHO MPDSR Technical Working Group (Francesca Palestra and Dr. Merlin Willcox) as well as Dr. Charles Ameh from the Liverpool School of Tropical Medicine who is an expert on MPDSR in Kenya. We will also invite experts from biostatics and conduct of cluster randomized trials. The Panel will also include an ex oficio member from NICHD. The Panel will meet annually, but will receive 6-monthly written updates using a standardized template, including information about unanticipated problems or adverse events. Members on the Panel will have no conflicts of interest with the study team or institutions. The study statistician (Dr. Barbra Richardson) will oversee preparation of interim analyses and presentation to the External Advisory Panel.

17) STUDY LIMITATIONS AND HOW TO MINIMIZE THEM

Monitoring of MPDSR (eg. review of forms and mortality registers) in control facilities may in and of itself increase fidelity and associated outcomes and thus may attenuate observed effect sizes. We will investigate if behaviors may have changed in control facilities once the study was launched during planned qualitative data collection. The study may also be affected by healthcare worker strikes or staff turnover. Because we are evaluating outcomes at a facility level, as opposed to an individual level, this will not affect data collection procedures in this study. Furthermore, the intervention (practice facilitation) may help to alleviate shocks from staff turnover by providing consistent mentorship for newly appointed MPDSR committee members. We will carefully document contextual events such as strikes or major changes to staffing, in order to understand and report upon how these events may affect study outcomes.

The AMANI study also does not address implementation determinants at levels beyond the facility and factors including county-level supervision may influence provider behaviors, a potential limitation which will also be explored during qualitative research. Additionally, in this study we will not account for extra-facility deaths and, if

they are registered in the facility, they will be excluded from the analysis. This may attenuate the overall effect size in aim 1b analyses, but will improve precision around known factors contributing to deaths. Some deaths may occur amongst mothers or infants who are transferred from other facilities and brought to the facility in an advanced state, and prior efforts to improve maternal and perinatal survival in the facility may not be effective in these cases. However, mortality is a secondary outcome in this study because we expect to see an increase in recorded mortality as the intervention may improve death registration. For all of the above reasons, the study is not powered for the mortality outcome and thus mortality analyses are considered exploratory. Lastly, the relationship between adaptations and resulting changes in fidelity to MPDSR steps is complex to measure, as there may be time lags between the two. We have accounted for this in the associated time series analysis, but the approach may still fail to capture the effect of some adaptations; thus this analysis is also exploratory.

18) RESULTS DISSEMINATION

We will disseminate study findings via multiple mechanisms in the final six months of the study period. First, we will prepare study briefs for health facility and county level officials, and hold in-person dissemination meetings at each participating facility and county office. We will also present in-person or online to national-level MPDSR committees about study findings, and will offer to share final de-identified datasets in full. We will share findings with multilateral stakeholders, including the WHO, via steering and technical advisory group meetings. Sharing findings at a high level will be facilitated through intentional invitations and membership to the study's Data Safety and Monitoring Board (DSMB).

19)TIMELINE/ TIME FRAME

Activity	Year 1		Year 2		Year 3		Year 4		Year 5	
Setup & ethical review										
SRAs and DQAs										
Survey piloting and adaptation										
Surveys with indicators of knowledge, motivation, behavioral skills, psychological safety, and burnout										
PFs identified and trained										
Baseline abstraction of mortality data										
cRCT phase 1 (active practice facilitation)										
Qualitative data collection to assess drivers of adoption and fidelity										
cRCT phase 2 (maintenance)										
Maintenance surveys										
Analysis, manuscript development, and dissemination										

20) HUMAN SUBJECTS

a) Ethical Approval

We will obtain ethical approval from the University of Washington (UW) Human Subjects Division (IRB) and Kenyatta National Hospital-University of Nairobi (KNH-UoN) Ethics and Research Committee (ERC). There will be minimal risk to the participants taking part in this study. Any changes to the protocol will be submitted to the UW IRB and KNH-UoN ERC.

b) Collaborating sites

The study will be conducted in collaboration with the UW and KNH. The study will be reviewed by the KNH ERC and UW IRB and will not be started before approvals are obtained from both organizational review boards.

c) Informed Consent

Following consultation with and permission from County-level Ministry of Health officials, facility administrators at all potential study facilities will be approached by the study team and invited to join the cluster randomized trial. Facility administrators will be made aware that, regardless of study arm, the study team will abstract

anonymous data from facility registers, including birth and mortality registers, and MPDSR committee records. We will obtain approvals from the County-level Ministry of Health officials and facility administrators with agreement to participate in the study over the five-year project duration, including intervention periods and post-intervention periods necessary for data quality checks and for death register abstraction.

We will obtain written informed consent for participation in all interviews, focus groups, and surveys that occur under Aim 1. The consent will explain to each potential participant the purpose, risks and benefits of the study. Participants will be informed that they can choose to withdraw from the study at any point and for any reason. They will also be informed that participation is completely voluntary. Participants will be offered a copy of the consent form to keep. Participants who agree to participate in study activities will sign the informed consent form.

Waiver of written consent for data extraction

Register abstraction: We will abstract data from routine data sources to inform assessments of effectiveness, adoption, fidelity, and maintenance. Data sources accessed include routine MPDSR committee forms, such as maternal death review (MDR) and perinatal death review (PDR) forms. We will abstract routine birth and mortality data from the Maternity Register (MOH 316), Maternal Baby Unity (MBU) Registry and the Neonatal Intensive Care Registry. We will abstract facility records regarding maternal and perinatal deaths one year prior to study launch and throughout implementation. For each death we will record the following information: date and time of birth, date and time of death, type of death (antepartum stillbirth, intrapartum stillbirth, neonatal death), location of death, mother/baby transfer history, birth attendant, maternal age, maternal obstetric history, antenatal care history, HIV status, sex of baby, birthweight, gestational age, location of birth, mode of delivery (ex. vaginal, assisted, cesarean), cause of death using ICD-10/11 or ICD-PM, and other maternal sociodemographic information as needed. We will not abstract the name of the deceased, maternal birth dates, location/community of residence, or any names of individuals who attended to a specific death to ensure that all data abstracted from the registers are fully de-identified. We are not planning any direct contact with patients. While registers and medical records may contain personally identifiable data, study data clerks will not abstract any of these variables, nor any constellation of variables that could be personally identifiable. We are requesting a waiver of informed consent to abstract medical records from this population.

A photo of each register will be taken, with opaque items (such as a piece of cardboard) placed on top of the patient's name, date of birth, residence, and any other potentially identifying information located in the register. Data captured in the photos but not abstracted into the database will not be analyzed. Photos will be stored securely, as described in section 16.

d) Handling Adverse events

Given that the study involves minimal physical risk, adverse events are expected to be rare and primarily psychosocial in nature (e.g., emotional distress during discussions of maternal or neonatal deaths). In such cases, the study team will provide immediate support and, if needed, refer participants to available counselling or mental health services within their health facility or county health system. Any adverse events will be documented and reported according to institutional and national ethical guidelines. If an adverse event requires specialized treatment beyond the scope of the research team, the participant will be referred to appropriate clinical services outside the research team for care.

All participating facilities are established public health institutions with licensed clinical personnel and standard infrastructure to manage health needs. These facilities have access to basic emergency care, psychosocial support services, and referral mechanisms within the county health system. Should an adverse event occur, the participant will be managed at the facility level and, if needed, referred to higher-level care in accordance with Ministry of Health protocols. The research team has established communication channels with facility administrators and county health leadership to ensure timely coordination of any needed support.

21) BUDGET (total budget period 9/12/2025 to 5/31/2025)

	Particulars	BUDGET (Total) in USD
PERSONNEL		
Salaries and Wages		
	Staff salaries	600,364.00
	Staff benefits	144,545.00
TOTAL SALARIES AND WAGES		**744,909.00**
TRAVEL		
	Investigator Meeting (Local)	21,000.00
	Sub-PI travel, Fuel, tax, between sites	30,000.00
TOTAL TRAVEL COST		**51,000.00**
OTHER DIRECT COSTS		
	Service contracts	689,965.00
	Other contractual services	804,255.00
	Supplies and materials	18,400.00
TOTAL OTHER COSTS		**1,563,620.00**
TOTAL INDIRECT COSTS		**1,253,887.00**
TOTAL EXPENDITURE		**3,562,416.00**

BUDGET JUSTIFICATION

University of Washington Contractual Costs

KEY PERSONNEL

Arianna Rubin Means MPH, PhD, Principal Investigator, Dr. Means is an Assistant Professor in the Department of Global Health at the University of Washington (UW). She has an MPH in epidemiology and a PhD in implementation science and has extensive experience coordinating mixed method implementation science studies in low-and middle-income countries, including her current role as implementation science scientific lead for two large multi-country research collaborations. For this project she will oversee all study activities, including study planning, hiring and staffing, development of data collection materials and standard operating procedures, partner engagement, adherence to good clinical practice, and other scientific leadership responsibilities. We request 3 calendar months (25% FTE) in Year 1, and 2.4 calendar months (20% FTE) in Years 2-5.

Keshet Ronen, PhD, MPH, Co-Investigator, is an Assistant Professor in the Department of Global Health at the University of Washington. Dr. Ronen is principal investigator and co-investigator on a number of studies evaluating the use of mobile technology (SMS and social media) to improve mental health, maternal-child health, and HIV outcomes in adults and adolescents. She has expertise in design, implementation and evaluation of interventions to reduce neonatal mortality. She will support design of data collection instruments and analysis of fidelity data. We request 1.2 calendar months (10% FTE) in Year 1, 0.6 calendar months (5% FTE) in Years 2-4, and 1.56 calendar months (13% FTE) in Year 5.

Kenneth Sherr, Co-Investigator, is a Professor in Global Health and Adjunct Professor in Epidemiology an Industrial and Systems Engineering at the University of Washington. He is co- director of the implementatio science PhD program at the University of Washington and directs a globally recognized short course in implementation science research methods. For this study, he will provide senior supervision of adaptation o data collection instruments to the Kenyan setting, analytical decisions, and dissemination activities. We reques 0.6 calendar months (5% FTE) in Years 1-5.

Barbra Richardson, PhD, Co-Investigator, is a statistician and Research Professor in the Department o Global Health at the University of Washington and Fred Hutchinson Cancer Research Center with decades o expertise in clinical research and analyses of diverse study designs including clinical trials and longitudinal analyses. She will provide guidance on all aspects of the study analysis, including interim reporting and fina analyses. We request 0.6 calendar months (5% effort) in Years 1 and 5.

John Kinuthia MBChB, MMed, MPH, Co-Investigator, is a Kenyan obstetrician gynecologist and Head o Research at Kenyatta National Hospital, with extensive experience in maternal-child health and large implementation research projects. Dr. Kinuthia is the site Principal Investigator on this project and will lead the Kenyatta National Hospital consortium site. He will work closely with the University of Washington team and provide oversight over the implementation of all research components, including study and intervention design, preparation of data collection instruments, intervention implementation, data collection and management, statistical analyses, as well as fiscal and administrative management of the study. Dr. Kinuthia will be paid via his hourly appointment at UW. We request 1.2 calendar months (10% FTE) in Years 1-5.

Benson Singa, MBChB, MPH, Co- Investigator, is a research scientist at the Kenya Medical Research Institute (KEMRI). Dr. Singa has significant experience in leading the implementation of pediatric clinical studies, and he is a co-Principal Investigator and co-Investigator on several projects with the University of Washington/KEMRI collaboration. For this study, he will support implementation of the study intervention in facilities in Western Kenya where KEMRI has a strong scientific presence. He will also support dissemination activities and building of the final Practice Facilitation toolkit. Dr. Singa will be paid via his hourly appointment at UW. We request 0.6 calendar months (5% effort) in years 1-5.

Dalton Wamalwa, MBChB, MMed, MPH, Other Significant Contributor, is a lecturer in the Department of Pediatrics at the University of Nairobi. He participated in the International AIDS Research and Training Program at the University of Washington, where he received his MPH in Epidemiology. For this study, Dr. Wamalwa will provide senior leadership and guidance regarding perinatal death auditing, and integration of study activities into pediatric care teams. No salary support is requested from this budget.

OTHER PERSONNEL

Sean Galagan, MSPH, Senior Data Manager, is a data manager in Global WACh with experience developing automated data dashboards for tracking and reviewing data collection in clinical trials. Mr. Galagan will build automated systems to conduct monthly data quality checks of routine facility data, and will communicate with teams at Kenyatta National Hospital (KNH) regarding data quality checks and auditing. Mr. Galagan will work in collaboration with the data manager at KNH, with a focus on collaborative and bi-directional capacity building. We request 1.2 calendar months (10% FTE) for Year 1 and 1.8 calendar months (15% FTE) in Years 2-5.

Jaclyn Escudero, MPH, Research Coordinator, has extensive experience coordinating studies in Kenya, including hybrid studies incorporating both clinical and implementation outcomes. Ms. Escudero will lead drafting of all documents for ethical review boards, development of standard operating procedures, development and tracking of consent forms, development of training materials, and will work in collaborating with the study coordinator at KNH, with a focus on collaborative and bi-directional capacity building. We request 3.6 calendar months in Year 1 (25% FTE) and 2.6 calendar months (22% FTE) for Years 2-5.

Alyson Shumays, MPH, is a Manager of Program Operations in the Department of Global Health at the University of Washington. Alyson will provide coordination and administrative support in study operations at the University of Washington in Seattle. This includes study document storage and archiving, file management, coordinating travel and processing expense reimbursements, and coordinating processes/systems for communication with research teams and partners. We request 0.6 calendar months (5% FTE) in years 1-5.

Chris Kealy, BA, is the Kenya Finance Manager in the Department of Global Health at the University of Washington. She has been responsible for fiscal administration of University of Washington/Kenyan collaborative projects for ~20 years. Her activities include providing training and guidance to local administration staff in Kenya, coordination of expenditures, personnel salaries, fiscal management, establishment and management of funds at field sites, and communication with faculty in Kenya and Tanzania. The administrative and fiscal aspects of our research projects are complex and time intensive and are beyond what our central offices provide. Therefore, this effort is directly allocable to the project, is direct charged and not covered under our indirect cost recovery. We request 1.2 calendar months (10% FTE) in years 1-5.

Hayden Gaylord, Subcontract Specialist, will facilitate the implementation and manage subcontracts with KNH. He will work most closely with fiscal managers at the subaward sites and provide training and guidance. Our international subcontract interactions require time in setting up, monitoring and closing, and working with foreign institutions infrastructure. These interactions are beyond what our central offices provide and therefore this effort which is directly allocable to the project is direct charged and not covered under our indirect cost recovery. Therefore, we request 0.3 calendar months (2.5% FTE) in years 1-5.

Angela Windus, is a Budget Fiscal Analyst in the Department of Global Health at the University of Washington. She will provide purchasing, administrative and travel support throughout the study. We are requesting 0.6 calendar months of support (5% FTE) for years 1-5.

University of Washington Fringe Benefits

Funds for fringe benefits are included in the personnel budget request. These benefits include health insurance, social security & Medicare taxes, workers compensation, medical aid & industrial insurance, UWRP, state retirement, unemployment compensation, and separation leave payments for classified & professional staff and are calculated at the University of Washington's current rates.

Research faculty: 22.6%
Professional staff: 30%
Classified staff: 38.1%
Graduate student appointment: 18.2%
Hourly/Visiting scientists: 21.2%

UW-Kenya Contract Personnel

Project Coordinator, will be responsible for supervision of the field teams. She will work with the PIs and co-investigators in research planning, implementation and problem-solving. She will also be responsible for planning and facilitation of staff induction and training as well as ensuring efficient conduct of research activities to achieve study objectives and to ensure high retention rates throughout the prospective follow up phases. She will be responsible for the day-to-day follow-up with the field teams to ensure compliance with study SOPs and protocol throughout the study period. We request 7.2 calendar months (60% FTE) in Year 1 and 6 calendar months (50% FTE) in years 2-5.

Assistant Coordinator, will provide support to the Project Coordinator in overseeing the implementation of the project. She will work in collaboration with the University of Washington Research Coordinator to support the development of project materials including data collection systems, study SOPs and training materials. She will support dissemination of project information by preparing project reports on a regular basis, including financial

and technical reports to donors and all required project information to the management team and other program partners. We request 12.0 calendar months in Years 1-5.

Emmaculate Nzove, Program Manager, will be responsible for overall oversight of the administrative and fiscal management of the program. She will lead the development and continuous improvement of the necessary operational and administrative systems required to ensure successful study implementation. She will oversee the subcontract set up, monthly financial reporting, study resources management and track ethical submissions to respective review committees. She will supervise the roles of the project administrator to ensure efficiency is maintained throughout the study period. We request 1.2 calendar months (10% FTE) in years 1-5.

TBN, (1) Project Administrator, will provide daily and direct operations and research support to the project and project staff under the leadership of the program manager. He/she will assist with study staff selection and training. He/She will work closely with the program manager in development of the necessary operational and administrative systems required to ensure successful study implementation. He/She will be responsible for all day-to-day financial aspects of the study including ensuring the study staff have all the required supplies and finances to perform their duties. They will be responsible for purchasing and budget reconciliation, set up of site resources and direct human resource concerns and communications. We request 12 calendar months (100% FTE) in years 1-5.

TBN, (1) Senior data analyst, will oversee data management for this project, including quality control procedures. The data manager will be responsible for: receiving and responding to data queries and quality check reports; generating summary reports; participating in maintaining the study tracking database, preparing study forms, managing the data archives and participant files; setting up hardware, maintaining the computer system/network, performing scheduled backup for the database, and data analysis. He/She will work closely with Dr. Kinuthia as well as the University of Washington team in the development of the database, tools and training materials for the study team. We request 1.8 calendar months in Year 1 and 3.6 calendar months in Years 2-5.

TBN, (3) Data Collectors, are requested for implementation of the study protocol and conducting data collection activities. They will be responsible for abstraction of data from facility birth and mortality registers and supporting facilities in maintaining MPDSR document tracking. They will work closely with the study coordinator to ensure all SOPs, protocol guidelines, ethical considerations and Ministry of Health policies are adhered to in data collection and other study activities. We request 6.0 calendar months in Year 1 and 12.0 calendar months in Years 2-5.

TBN, (3) Practice Facilitators, will deliver the AMANI intervention in facilities randomized to the intervention, including audit and feedback activities and enhanced mentorship activities. The Practice Facilitators will participate in a number of training activities, including World Health Organization training programs on MPDSR. They will help the project team in tracking the number, proportion, and representativeness of health workers who participate in each component of the practice facilitation package in intervention facilities. We request 6.0 calendar months in Years 1 and 5, 12.0 calendar months in Years 2-4.

TBN, (1) Qualitative Evaluator, is requested to conduct individual interviews and focus group discussions with health workers involved in MPDSR reviews. The evaluator will also transcribe and analyze the data, in partnership with a coder at the University of Washington. He/She will participate in weekly meetings to provide updates to the project team during the data collection phase. We request 2.4 calendar months in Year 1, 4.80 calendar months in Years 2-4, and 7.2 calendar months in Year 5.

Fringe Benefit
Annual salary restitution calculated at 15% has been requested for all project personnel.

TRAVEL

University of Washington Travel
AMANI Protocol
v1.1
January 20, 2026

Study team travel: We request a total of $21,000 over Years 1-5 for PI and study team travel. We estimate these costs at $3,000 per trip with 2 trips each in Years 1 and 5, and 1 trip each in Years 2-4.

University of Washington Department of Global Health Recharge Center Travel

Study team ground transport: We request $6,000 per year (average of $500 per month) for a total of $30,000 for ground transport between each of the 20 study sites.

MATERIALS AND SUPPLIES

University of Washington Department of Global Health Recharge Center Supplies

Laptops: We request two study laptops for Kenya based staff to be used for data collection and analysis. We estimate the laptops to cost $2,000 each for a total request of $4,000 in Year 1.

Tablets/Phones: Nine study tablets or phones are requested for data entry and communications between the study and central team. We estimate the tablets to cost $300 each for a total request of $2,700 in Year 1.

Office Supplies: We request a total of $11,700 over Years 1-5 ($4,000 in Year 1, $3,000 in Year 2, $1,200 in Year 3, $1,000 in Year 4, and $2,500 in Year 5) for office supplies. These items will include enhancement and replacement hardware not covered by warranties, and program supplies such as magnetic tape cartridges, toner, collection tools, gloves, masks, and other costs not permissible as indirect expenses under the University of Washington's Costing Policy for Sponsored Agreements.

PUBLICATION COSTS

University of Washington

Publication Fees: We request a total of $8,300 across Years 1, and 5 for open-access publication fees. We are committed to publishing the results of our proposed work open-access to increase the accessibility of our findings in low- and middle-income countries.

CONTRACTUAL SERVICES

University of Washington Department of Global Health Recharge Center Contractual Costs

Participant fees: We request funds for light refreshments and participant reimbursements for research participants during data collection activities (ex. study meetings, focus group discussions or interviews, survey administration) which is customary practice in Kenya. This is estimated at $10 per participant per data collection engagement. We estimate a request of $2000 per year in years 1-5, for a total request of $10,000.

Translation fees: We request funds to support translation of consent forms and CRF's to local Kenyan languages. We estimate $200 per year in years 1-5, for a total request of $1,000.

OTHER DIRECT COSTS

University of Washington

Conference Fees: We request funds in Years 1 ($1,500), 2 ($1,500), 4 ($500), and 5 ($3,000) for the PI, study investigators, and staff to attend international and domestic conferences related to advancing the goals of the study and disseminating findings. The total amount requested is $6,500.

Infrastructure Capacity Building: We request $20,000 in Year 1 to support necessary improvements to infrastructure in all study facilities (N=20) prior to randomization. At baseline, we will conduct service readiness assessments (SRAs) and data quality audits (DQAs) in all facilities to determine baseline capacity to implement MPDSR. Assessments will be repeated at study endline to understand changes in readiness and data quality and will be used in the final analyses to understand factors influencing fidelity. We will leverage the existing MPDSR mapping tool, which is a checklist to identify current mortality audit and quality improvement (QI) systems in place. We will augment the mapping tool with SRA indicators, which will be modified from previous assessments of mortality reduction interventions implemented by our study team and include human resources, essential medicines, equipment, and infrastructure needed to implement interventions for maternal and perinatal mortality reduction. Small stipends will be allocated to all facilities prior to randomization to address gaps apparent in SRAs, such as gaps in data stewardship, necessary equipment or material support required to implement neonatal resuscitation, etc. These stipends are necessary for ensuring all facilities have the minimum level of material resources needed to fully engage in the AMANI practice facilitation intervention.

Annual Stakeholder Workshops: We request $7,205 per year for annual stakeholder workshops for Years 1-5 for a total cost of $36,025. These will include venue costs, participant per diems and transport costs, and light refreshments. These workshops are necessary for keeping key stakeholders informed about study progress, and building the network needed to ensure rapid uptake of study findings.

Biannual CAB Meetings: We request $2,500 each for two Community Advisory Board (CAB) meetings per year for Years 1-5 for a total cost of $12,500. These will include venue costs, participant per diems and transport costs, and light refreshments.

Meeting Fees: We request $2,000 per year for Years 1-5 for study team meetings. This includes venue costs, participant per diems and transport costs, and light refreshments, with a total cost of $10,000.

Staff Trainings: We request $2,000 per year to hold continuing medical education trainings for facility supervisors and facility staff from the study sites. We estimate these meetings will include transport reimbursement, and light refreshments for a total request of $10,000.

Communication costs: We request $3,000 per year for a total cost of $15,000 in Years 1-5. This supports maintenance of a high-speed internet connection in Nairobi for coordination and accessing online database for sample entry and management, communication with team conference lines, and long-distance charges for communication between study leadership team.

Ethics Review Committee (ERC) Fees: Submission fees for the KNH Ethics and Research Committee, which reviews and provides approval for human subjects research is budgeted at $400 in Year 1 for the initial submission, and $200 per year for submission and annual renewal. Total costs estimated at $1,200 combined in Years 1-5.

Study Office Rent: We request a total of $15,000 over Years 1-5 ($3,000 per year for Years 1-5) for maintaining the study office rent in Nairobi. We anticipate this cost will be split across projects as appropriate.

Health Insurance
We request funds to cover medical insurance costs for the study staff, a total cost of $1,867 per year for each staff working 100% FTE on this project, estimated at $13,072 per year, for a total of $65,360.

Kenyan Housing Levy: The current rate is 1.5% of base salaries and we have estimated $8,827 to cover staff salaries for Years 1-5.

National Social Security Fund (NSSF): This is a statutory 6% deduction which every employer contributes to each employee and thus we have budgeted $1,037 per year which will cover the contribution for the UW-Kenya staff in Years 1-5. The total amount requested is $5,185

ICOC (IN-COUNTRY OPERATING COSTS)

University of Washington Department of Global Health Recharge Center ICOC is requested in Years 1-5 for a total of $114,557. Field costs not accounted for through subcontracts will be managed by the University of Washington Global Assistance Program Kenya (UW-Kenya), an NGO formed in Kenya. The effort and services provided by this NGO support multiple University of Washington projects in Kenya, and represent expenses required to implement and coordinate the work in the field that are not recovered though the University's negotiated F&A rate. Utilizing the UW Kenya NGO provides a mechanism to more efficiently direct charge these allowable and necessary costs. UW Kenya service costs are allocated to grant-funded projects in direct proportion to the benefit they each receive. The rate is reviewed and approved at least annually by UW as an assurance that UW Kenya costs and UW F&A recovery are distinct and that usage of the service is shared across all users. The current rate of 10.6% of direct field costs will be assessed.

University of Washington Facilities and Administration

This project will be conducted on-campus and off-campus at the University of Washington. Facilities & Administrative Costs are calculated at the on-campus rate of **55.5%** of modified total direct costs (MTDC), and the off-campus rate of **26%** or modified total direct costs (MTDC).

22) ABBREVIATIONS AND ACRONYMS

AF	Audit and feedback
AHRQ	Agency for Healthcare Research and Quality
AMANI	Accelerating Maternal and Newborn Survival
CFIR	Consolidate Framework for Implementation Research
CHAIN	Childhood Acute Illness and Nutrition Network
CHV	Community health volunteer
cRCT	Cluster randomized clinical trial
DHIS	District Health Information System
DQA	Data quality assessment
DSMP	Data and Safety Monitoring Plan
EM	Enhanced mentorship
ERC	Ethical review committee
FGD	Focus group discussion
FRAME	Framework for Reporting Adaptations and Modifications to Evidence-based interventions
GEE	Generalized estimating equation
HHFA	Harmonized Health Facility Assessment
HIPPA	Health Insurance Portability and Accountability Act
HMIS	Health Management Information System
ICD(-PM)	International Classification of Disease (-Perinatal Mortality)
IDI	In-depth interview
IMB	Information-Motivation-Behavioral skills model

IRB	Institutional review board
ITHS	Institute of Translational Health Sciences
KNH	Kenyatta National Hospital
LMIC	Low- and middle-income country
MBU	Maternal Baby Unit
MDR	Maternal death review
Mobile WACh	Mobile Solutions for Women's and Children's Health
MOH	Ministry of Health
MPDSR	Maternal and perinatal death surveillance and resposne
MWN	Mobile WACh NEO
NGT	Nominal group technique
PDR	Perinatal death review
PF	Practice facilitator
PI	Principal investigator
QI	Quality improvement
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance Framework
SDG	Sustainable Development Goal
SRA	Service readiness assessment
UW	University of Washington
WHO	World Health Organization

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