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# Effects of Helping Mothers Survive Bleeding After Birth in-service training of maternity staff: A Cluster-Randomized trial and mixed-method evaluation

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# Effects of Helping Mothers Survive Bleeding After Birth in-service training of maternity staff: A Cluster-Randomized trial and mixed-method evaluation

### THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

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#### **ABSTRACT**

**Background:** Postpartum Haemorrhage (PPH) causes a significant amount of morbidity and mortality among mothers giving birth in sub-Saharan Africa, Tanzania included. One root cause is the insufficient health worker skills to address postpartum haemorrhage. To combat this in-service training using competency-based simulation is proposed.

**Aim**: To assess the effectiveness of the Helping Mothers Survive Bleeding After Birth (HMS BAB) in-service training of maternity staff on PPH related health outcomes, and health workers' skills. The thesis also assessed health workers' perceptions of the training and facility preparedness to support care of women with PPH in Tanzania.

**Methods:** Study I was conceptualised as a cluster-randomized trial. Interrupted time-series analysis was used to compare the following PPH related health outcomes i) PPH near miss and ii) PPH case fatality between 10 intervention and 10 comparison clusters. Study II was a before-after study of health workers (n=636), and assessed skills change immediately and ten months after the training, as well as the association between health workers' characteristics and skill change. Study III was a qualitative study using seven Focus Group Discussions (FGD) of health workers to explore their perceptions of the training implementation. A deductive theory-driven analysis informed by integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework was used. Study IV explored health workers (FGDs, n=7) and health managers (In-depth interviews, n=12) perceptions of health facility preparedness to support care given to women with PPH. The data was analysed using thematic analysis.

Results: There was a significant decline of severe PPH cases in intervention clusters compared to the comparison clusters observed immediately after the intervention. This was sustained in the post-intervention period (Study I). A small reduction in PPH case fatality was observed in intervention clusters during the post-intervention period. Health workers' skills were significantly improved immediately after the training with a small decline at tenmonths follow up (Study II). In Study III health workers reported positive perceptions of the training: the content, the training technique, use of simulated scenarios and peer practice facilitators enhanced learning. Challenges to successful training were related to organization of the training and allocating time for weekly skill practices. In Study IV health workers reported poor facility preparedness with inconsistencies and insufficiencies of resources, including few and overwhelmed maternity staff. This constrained their ability to use the new skills and to provide quality PPH-care. Additional challenges on human interactions such as communication, collaborations and leadership were highlighted.

**Conclusion**: The HMS BAB one-day training followed by eight weekly drills was effective in reducing PPH morbidities and mortality and improved health workers skills. Implementational challenges included i) organizational aspects of in-facility training, and ii) protected time for health workers to engage in weekly drills. Health providers voiced their

struggle to put their new knowledge into practice highlighting insufficiencies in health facility readiness, such as lack of drugs and blood products.

**Key words**: Helping Mothers Survive Bleeding After Birth, Competency-based training, Infacility training, Postpartum haemorrhage Near miss, Health workers' perceptions, Health facility readiness, Cluster Randomized trial

#### LIST OF SCIENTIFIC PAPERS

- I. Alwy Al-beity F, Pembe A, Hirose A, et al. Effect of the competency-based Helping Mothers Survive Bleeding after Birth (HMS BAB) training on maternal morbidity: a cluster-randomised trial in 20 districts in Tanzania. BMJ Global Health 2019;4(2):e001214. doi: 10.1136/bmjgh-2018-001214
- II. **Alwy Al-beity F**, Pembe AB, Marrone G, et al. Predictors of change of health workers' knowledge and skills after the Helping Mothers Survive Bleeding after Birth (HMS BAB) in-facility training in Tanzania. PLOS ONE 2020;15(5):e0232983. doi: 10.1371/journal.pone.0232983
- III. **Alwy Al-beity F**, Pembe AB, Kakoko D, Baker U, Hanson C. Health workers' experiences of implementation of Helping Mothers Survive Bleeding After Birth training in Tanzania: a process evaluation using Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework. *Manuscript*
- IV. **Alwy Al-beity F**, Pembe AB, Kwezi HA, et al. "We do what we can do to save a woman" health workers' perceptions of health facility readiness for management of postpartum haemorrhage. Global Health Action 2020;13(1):1707403. doi: 10.1080/16549716.2019.1707403

The publications and manuscripts will be referred to in the text as Study I-IV.

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#### LIST OF ABBREVIATIONS

AGOTA Association of Gynaecologists and Obstetricians of Tanzania FIGO International Federation of Gynaecologists and Obstetricians

HBB Helping Babies Breathe

HMS BAB Helping Mothers Survive Bleeding After Birth ICM International Confederation of Midwifery

LMIC Low and Middle-income countries MDG Millennium Development Goals

MMR Maternal Mortality Ratio

Ministry of Health, Community Development, Gender, Elderly and

MoHCDGEC Children

OSCE Objective Structured Clinical Examination

PPH Postpartum Haemorrhage

QoC Quality of Care

SARA Service Assessment Readiness Assessment

SBA Skilled Birth Attendant

SDG Sustainable Development Goals

SIDA Swedish International Development Agency

TAMA Tanzania Midwifery Association

WHO World Health Organization

#### **OPERATIONAL DEFINITIONS**

Cluster A participant group as a unit for interventional research. In this

study synonymous to a district and represented by district hospital

and 2-3 large health centers with >3000 deliveries in a year.

Competency- A training approach that focus on teaching concrete skills, where

based training learners acquire competency on that specific skill.

Context Synonymous to the environment, refer to the organizational

structure as well as norms and practices.

Degree of fit Refers to whether a new intervention/training introduced match

with the existing knowledge and practices.

Delivery caseload Number of deliveries a health worker personally assisted in the last

one-month.

Facilitation A process of enabling others to make or do something with ease.

Facilitator A person who facilitates the uptake of an intervention.

Health facility A physical structure where health services are provides for this

study includes hospitals and health centers.

Health facility 
This refers to the capacity of a health facility to provide care. In

readiness case of PPH-care, these include the availability of medical

supplies, drugs and blood, equipment's, trained health workers, protocols for management, transport for referral and the referral

process.

Health workers Professions trained to provide health services.

Implementation The process of making something active or effective

In-facility training Refers to training done in the clinical set-up; where the

participating health workers practice, sometimes referred to as "on-

site" training.

Intervention A set of action done to make a specific change.

Low-dose high A training technique used where a set of skills are trained in a short

frequency time, but enforced with repetitive frequency over a longer time

Maternal death Refers to death of a woman due to a complication that occurred

during pregnancy, childbirth or within 42 days of termination of

pregnancy, caused by, exacerbated or worsened by the pregnancy, irrespective of site and duration of pregnancy but not due to

accidental or incidental causes

Near miss Refers to a woman who nearly died but survived a complication

that occurred during pregnancy, childbirth, or within 42 days of

termination of pregnancy

On-job training Synonymous to in-service training, continuous medical education

of health workers who are already working to improve their skills.

Peer practice
A health worker coached with specific skill sets to lead her/his colleague do weekly practice sessions or drills as part of on-job training.

PPH case-fatality
Is a proportion of women who died of postpartum haemorrhage among all women who suffered from postpartum haemorrhage.

Simulation
Use of imitation for learning purpose, it can be role plays or service of simulators

Skill practices or
Training sessions were health workers organizes and train on a

drills

s or Training sessions were health workers organizes and train on a specific skill for a short time but regularly. A simulated scenario is used to get health workers to practice, sometimes referred to "low dose high frequency" training strategy.

#### 1. BACKGROUND

#### 1.1 MATERNAL MORTALITY

#### 1.1.1 The burden of maternal mortality

In 2017, approximately 295,000 (uncertainty interval 279,000-340,000) women died in pregnancy and childbirth [1]. The average global maternal mortality ratio (MMR) is 211 (uncertainty interval 100-243) per 100,000 livebirths and the lifetime risk of dying a maternal death in a 15-year-old girl is 1 in 190 [1, 2]. The burden of maternal mortality disproportionately affects women living in the least developed countries. Sub-Saharan Africa reports two-thirds of global maternal deaths (196,000), an MMR of 542 per 100,000 livebirths and a lifetime risk of maternal death of 1 in 37 [1, 2].

#### 1.1.2 Causes and timing of maternal mortality

Approximately 80% of all maternal deaths are caused by five direct preventable obstetric complications: obstetric haemorrhage, hypertensive disorders of pregnancy, sepsis, complications of abortion and obstructed labour [3-6]. Indirect causes of maternal deaths include pre-existing medical conditions, infection, anaemia and other conditions that are exacerbated by pregnancy. A quarter of all maternal deaths occur during the intrapartum and immediate postpartum period (within 24 hours) and over half of deaths occur during the postpartum period, which are often related to intrapartum complications [3, 6-8].

#### 1.1.3 Obstetric and postpartum haemorrhage

Obstetric haemorrhage is the leading cause of maternal mortality globally, contributing to a quarter of all maternal deaths [3, 4, 9]. A large discrepancy surrounding the burden of maternal deaths due to haemorrhage exists, with 99% of maternal deaths caused by haemorrhage occurring in low and middle-income countries (LMIC). Furthermore, approximately 48.5% of all global maternal deaths caused by haemorrhage occur in sub-Saharan African countries [3-6] with the majority of these cases occurring in the immediate postpartum period [10, 11].

Postpartum haemorrhage (PPH) is defined as bleeding from the genital tract in excess of 500 ml following vaginal birth [9, 12, 13]. This complication occurs in 6-10% of births and can be severe in 2-3% of births with a blood loss ≥ 1000 ml. Women with PPH suffer from rapid blood loss that may progress to organ dysfunction. Primary PPH occurs within the first 24 hours following birth and secondary PPH can occur at any time between 24 hours and six weeks postpartum. In most instances, PPH mostly occurs within 30 minutes after birth and in 50-80% of cases is caused by uterine atony − the inability of uterus to contract [12, 14]. Other causes of PPH are retained placenta tissue, genital tract trauma and coagulopathy [12, 14]. One case of PPH may be attributable to more than one cause.

Risk factors for PPH include prolonged labour, prolonged use of uterotonic drugs (as in prolonged induction or augmentation of labour), overdistended uterus (multiple pregnancy, polyhydramnios), sepsis, abnormal placentation, prior caesarean section scar, and delivery by caesarean section[12, 14, 15] However, the majority of women who develop PPH have no identifiable risk factors.

#### 1.1.4 Prevention, detection and management of postpartum haemorrhage

Six out of ten cases of PPH can be prevented by performing an evidence-based intervention: the Active Management of Third Stage of Labour (AMTSL) [12, 16-18]. The World Health Organization and maternal professional bodies recommend that AMTSL is performed at every delivery [12, 16, 17, 19] The choice of uterotonic varies, oxytocin is the first choice followed by followed by heat-stable carbetocin, misoprostol and ergometrine [19, 20]. The AMTSL involves administering a uterotonic drug, delayed cord clamping (within 1-3 minutes of birth), controlled cord traction to deliver the placenta and uterine massage. Compared to expectant management of the third stage of labour, AMTSL significantly reduces blood loss and the subsequent need for blood transfusion regardless of maternal risk group [12, 16].

In addition to prevention, health workers need to be able to identify excessive bleeding and the cause of bleeding. This is a challenging area compounded by a lack of uniform and standard methods for measurement of blood loss. Methods used to measure blood loss range from an eastern Africa traditional cloth: *khanga* (*two soaked khangas represent slightly more than 500 ml of blood loss*) [21] to collector bag [22] and weighted drapes [23], and estimation of haematocrit level. Visual estimation of blood loss, which is commonly used in LMICs, is inaccurate when compared to other measurements such as blood bags and drapes, and leads to highly underestimated blood loss measurements, even after provider training [22-25]. In addition to measuring volume loss, researchers highlight the importance of assessing the rate of blood loss as well as the clinical condition of patients, including a measure of shock [25-27]. Once a woman develops PPH, management includes resuscitating the haemodynamic instability and managing the specific cause of bleeding [14, 28] either medically (oxytocic drugs, tranexamic acid) [12, 17, 19, 29-31] or by surgical intervention (intrauterine balloon tamponade, laparotomy for B-lynch sutures, internal iliac artery ligation or hysterectomy) when necessary [14, 32, 33].

#### 1.2 STRATEGIES TO END PREVENTABLE MATERNAL DEATHS

The last three decades have seen an increasing global and country commitment to end preventable maternal deaths. The Safe Motherhood Initiative conceived in the mid-1990s first aimed to make home births safer and to improve access to emergency obstetric care [34, 35]. With the Millennium Development Goals (MDGs), the Skilled Birth Attendant (SBA) strategy was coined and became a main target within the MDG framework. This strategy aimed to reduce maternal mortality by increasing the proportion of births attended by an SBA.

Following the end of the MDG era, the global community extended its commitment through The Sustainable Development Goals (SDGs). Launched in January 2016, the SDGs have reconfirmed the importance of reducing morbidity and mortality in childbirth. SDG 3.1 calls for accelerated action to end all preventable maternal deaths and achieve a global MMR of 70 maternal deaths per 100,000 live births, or less, by 2030 [36]. Achieving this goal will require countries to reduce their MMR by at least 7.5% each year between 2016 and 2030 underscoring the importance of maternal and newborn health in achieving a better and more sustainable future for all.

Skilled health personnel, as referenced by SDG indicator 3.1.2, are "competent maternal and newborn health (MNH) professionals educated, trained and regulated to national and international standards. They are competent to provide quality and patient-centered quality care, facilitate physiological processes during labour and delivery and be able to identify, manage and refer women and/or newborns with complications", as defined by the World Health Organization (WHO), the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF), the International Confederation of Midwives (ICM), the International Council of Nurses (ICN), the International Federation of Gynaecology and Obstetrics (FIGO) and the International Paediatric Association (IPA) [37].

# 1.3 WHY DO WOMEN CONTINUE TO DIE DURING CHILDBIRTH AND IN HEALTH FACILITIES?

While birth with an SBA and in-facility deliveries have progressively increased following the inception of the MDGs, many LMICs have yet to reduce the maternal mortality [38]. The increased number of women accessing care increases the demands placed on health systems and health facilities, most of which are already overwhelmed [39, 40]. In addition, there is no uniformity in care provision in these facilities. In many instances, health facilities lack human resources and the required medical supplies to provide care when complications occur. Furthermore, linkages to higher level facilities through emergency transport are limited due to poor road infrastructure and unavailability of transport [40-42].

Despite the proportion of births being attended by an SBA being an important process indicator for maternal health globally, there are many inconsistencies between countries in what cadres are included in this definition [43, 44]. Differing cadre definitions, competencies and education processes for skilled birth attendants between countries has implications for quality of care, and can result in women not receiving life-saving interventions when required, despite statistics showing that they have delivered in the presence of an SBA [43-47].

Evidence suggests that most countries with high maternal morbidities and mortalities have substandard care [10, 40, 42, 48]. Significant shortages of competent health workers, who are unevenly distributed in these areas, contributes to this [7, 10, 49, 50]. Furthermore, health

workers who have received sub-standard training, feel unsupported, unmotivated, and overwhelmed by the increased workload brought about by increasing rates of in-facility deliveries, may also compound the problem [49, 51-54]. In some areas, health workers fear for their safety and work in fear of being punished or facing litigation in cases of poor maternal outcomes. Non-supporting policies or non-alignment of policy and guidelines at national, regional, and local levels also results in inconsistencies and poor day to day operation of services within the facilities [55].

Shortages and stock-outs of medical supplies, essential medications and challenges in blood transfusion contribute further to poor and sub-standard care. Long, unclear and demanding procurement processes affect provision of care [10, 51, 53, 54, 56]. Oxytocin, the standard uterotonic used for AMTSL and in the management of PPH, demands a cold chain, and poor handling of this drug may affect quality of the active ingredients [57, 58]. Misoprostol, a heat stable alternative, is not widely available as it can be used to induce abortion and therefore is not acceptable or trusted in many settings. Blood transfusion availability is also of concern. Lack of blood and long waiting times to receive blood and blood products are common [48, 59, 60].

Furthermore, there are several challenges in referral and transfer of patients to a higher-level facility: unpassable roads, unavailable transport and long travel times all contribute to delays in women receiving appropriate care [48, 59, 61, 62]. Other challenges include system failures, poor coordination, lack of a multi-disciplinary approach in managing PPH and overwhelmed staff [63, 64]. Unclear referral guidelines further contribute to women with complications often being referred multiple times [65, 66]. Such challenges are more prominent in LMICs, especially in sub-Saharan Africa where health-systems are weak [5, 39, 48, 59, 60].

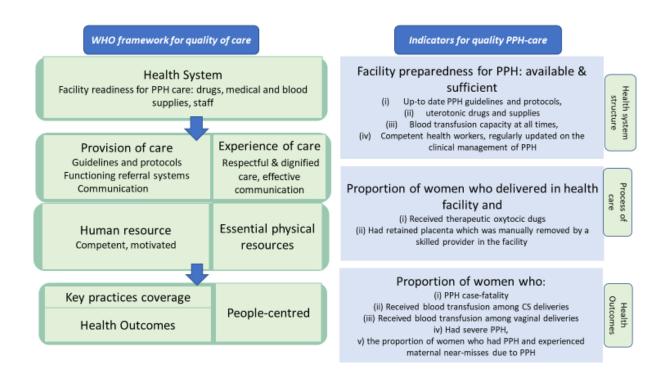
#### 1.4 QUALITY OF CARE FOR PPH

Quality of care (QoC) is a multifaceted concept with care providers, managers and recipients of care holding different views as to what constitutes QoC. In 1988, Donabedian described QoC as more than simply health care providers' performance. He noted that QoC is influenced by existing healthcare structures, patients' health-seeking behaviours, and linkages that allow optimum care to be given, all of which have an impact on health outcomes [67]. Additional dimensions have since been added to this original structure which describe in more detail the pathway including specific aspects of maternal care such as referral and communication with input, processes and outcome frameworks being used to better describe QoC [67-70].

The WHO defines quality of care as "the extent to which healthcare services provided to individuals and patient populations improve desired health outcomes" and incorporates elements of safety, efficiency, timeliness, patient-centeredness and equity [70, 71]. The framework aligns with the framework of the WHO health-system building blocks (service delivery; health workforce; information, medical products, vaccines and technologies;

financing, and governance) which is used to assess provision as well as experiences of care [72].

The time around childbirth is when more maternal deaths occur and hence is a crucial period to intervene. To reflect the importance of this period, the WHO has a set of standards for QoC related to the labour, childbirth and early postpartum period [71]. These standards are a guide to ensure women and their newborns receive evidence-based care, have access to competent health workers, and in the case where high-level care is required, then timely and effective referral is given [71]. Statement 1.3 is specific for PPH-care and states that all women with PPH should receive effective and prompt interventions according to WHO guidelines. Included in this framework are a set of indicators that measures input, process and outcome of PPH-care as depicted in **Fig 1** 



**Fig 1: The WHO framework for quality of care and quality standards for PPH-care** *Modified from [70, 71]* 

#### 1.5 MATERNAL NEAR MISS AS A MEASURE OF QOC

Maternal health has relied on mortality measures for several decades [35]. measure of maternal health outcomes as morbidities occur more frequently than maternal death [73, 74]. Women with maternal morbidity share many circumstantial and pathological factors with those who died. The quality of care they received is suggested to be the key difference which made them survive [74, 75].

A woman who experiences severe morbidity as a result of pregnancy and childbirth is classified as "Maternal near miss". The WHO defines this as 'a woman who nearly died but has survived a life-threatening complication during pregnancy, childbirth or within 42 days of termination of pregnancy' [73, 74, 76, 77]. Using this definition, the WHO have developed a tool that has become an important QoC audit tool for within and between health facilities over time and measures maternal near misses as the incidence per 1000 live-births [73, 77].

The WHO near miss definition and tool has been modified to allow for country and resource context [76, 78-85]. For example, one criterion to qualify a woman as a near miss is receiving a massive blood transfusion (≥ 5 units of blood), a scenario rarely seen in countries with weak blood transfusion services. In a country where blood availability is limited, this criterion may not be met due to poor availability, hence need for modification [84, 86]. Furthermore, reducing the threshold for blood transfusion captures more cases and may improve comparability between settings [87].

#### 1.6 INTERVENTIONS TO IMPROVE QUALITY OF CARE FOR PPH

A variety of interventions to improve QoC through supporting the implementation of evidence-based practices have been implemented and evaluated during the past two decades. These include training, supervision, audit and feedback, quality improvement and other group-solving approaches [88-90]. To maximize the effectiveness of these interventions, it is important to understand *what and why do some interventions work, and others do not*. Several frameworks have been suggested to assess acceptability, adoption, appropriateness and feasibility of the intervention [91-95]. Theory-driven evaluation, [96] and testing the causal pathway supports the understanding of effective implementation.

#### 1.7 CAPACITY BUILDING TO IMPROVE PPH

Continued medical education of existing health workers through in-service or on-the-job training is a well-established means of capacity building [97]. The content, training strategy and duration of training differ according to topic and learning needs. In sub-Saharan African countries, such training interventions were introduced in early 2000s, traditionally these are usually long (one to three weeks), centrally organized workshops, with few participants. Moreover, the costs of these trainings prohibit wider implementation, consequently there was no cascade effect to a higher proportion of national health workers. As a result, clinical

outcomes, especially in intrapartum obstetric care, have not sufficiently improved in the years after in-service training [98, 99]. These failures may also be associated with low quality trainings, educational inefficiencies and weak health-systems in LMICs [100, 101].

Over the years many innovative training approaches have been used with different attributes. In-service training that uses a "train the trainer" approach and uses short repeated sessions or skill drills has been reported to have a positive behavioural change effect. Other strategies including the use of job-aids, interactive and reflective learning, cultural sensitivity and elements of nurse empowerment have also been reported to lead to good learning outcomes [90, 102, 103]. There is however lack of robust experimental studies that give strong evidence on the effects of such training on nursing practices and clinical outcomes. A recent review produced as part of the commission of High-quality health systems in the SDG era suggested some evidence of the effect of training on health workers practices, with much higher effects when combined with group-solving strategies [101, 104].

Evaluations of different training methods in healthcare support competency-based training; greater improvements are seen in knowledge and skills gained as compared to class-based training alone [105, 106]. Competency-based training has an emphasis on learning skills, where defined units of learning are identified to allow learners to work on one competency at a time, enabling them to accomplish a larger learning goal. Competency-based training is often supported by simulation or use of scenario imitation to enhance gain [99, 106-110]. Simulation training provides a safe learning environment and reduces fear of complications as there is an absence of a real patient [111, 112].

Competency-based training using simulation and frequently repeated training sessions (practice skill drills also called "low dose high frequency") are shown to improve provider skills in maternal and neonatal care [90, 99, 105, 113-116]. Few studies however report on effect of such trainings on positive patient outcomes in maternal health [117-119].

Of recent, a novel training approach that is competency-based, uses simulation, and is performed in-facility where all maternity staff are trained together; the "Helping Mothers Survive Bleeding After Birth (HMS BAB)" has been implemented in several LMICs following successful implementation of a sister training Helping Babies Breathe. The HMS BAB training module was developed in 2013 by Laerdal Global Health and Jhpiego. This basic training focuses on assisting a routine birth, and the prevention, detection and early management of PPH. The training uses a Mama Natalie simulator, a low fidelity, low cost simulator [120, 121]. Training is delivered in a one-day session, to all available maternity staff and their alternates through a mix of short theory sessions and hands-on sessions. Furthermore, the training employs a low dose high frequency technique where health workers can participate in short practice drills on a weekly basis for 6-8 weeks following the initial training. These sessions follow a specific pre-prepared scenario and are facilitated by two health workers called "peer

practice facilitators", who have been trained and coached to lead their peers during these weekly sessions.

Studies in Tanzania, Rwanda, India, Malawi and Uganda have shown that the HMS BAB training is well received, and is effective in increasing the knowledge and skills of health workers [122-124]. The learned skills were retained for up to two years following the initial training. Nelissen et al reported improved basic delivery skills, and PPH management and a reduced incidence of PPH from 2.1% to 1.3% was reported in one study [119]. Another study reported on reduced need for blood transfusion as a proxy to less PPH cases [125]. Following this training, health workers reported an improved confidence in managing PPH, and perceived better learning experiences by use of practical sessions using realistic scenarios, team training and reflective learning [126]. Several quantitative assessments have also reported that health workers perceive to have improved confidence in managing PPH following the training [90, 100, 103, 122].

Since the introduction of the HMS BAB basic, an updated module of the training "Helping Mothers Survive Bleeding After Birth- Complete" was introduced in 2017 that addresses advance skill needs and additional quality improvements [127].

#### 1.8 EVALUATIONS OF TRAINING INTERVENTIONS

Most commonly training interventions are evaluated in regard to their effect of change of health providers practices and outcomes [101, 103]. An alternative framework to evaluate training interventions has been put forward by Kirkpatrick proposing effectiveness of a training as a continuum of learning explained in four levels: how did the participants feel about the training (Level 1-Reaction), to what extent did participants acquire intended knowledge and skills (Level 2-Learning), did the training bring practice change (Level 3-Behaviour change) and were there change in outcomes (Level -4- Results) [128]. This framework has been used widely in assessing the effectiveness of training interventions [103, 129, 130]. Belfield et al. [131] report on how educational interventions should be evaluated for their effectiveness and explored the use of five levels of effectiveness: outcomes, behaviour, learning, reaction and participation. Other authors expanded the Kirkpatrick's model to include additional components such as attitude/perception of change and change in organizational practice [132]

#### 2. THESIS RATIONALE

The Helping Mothers Survive Bleeding After Birth training has been implemented in several LMICs as a capacity building intervention. Earlier evaluations of the training using the Kirkpatrick's framework level 1-3 [128], have reported on improved learning among health workers and some effects on clinical practices [119, 122, 124, 133, 134]. These studies, however, had small sample sizes, were observational designs and were from single sites. Furthermore, the evidence is missing as to whether the improved learning observed, resulted in better practices and ultimately better health outcomes. Hence there is a need for the HMS BAB training to be more thoroughly evaluated.

With increasing literature on the effect of the training on confidence, knowledge and skills, but with a less obvious impact on clinical outcomes, the studies within this thesis were conducted to address this gap. In addition, factors affecting the implementation of such interventions, including acceptability, barriers and facilitators of the training intervention, different component of the intervention, health workers, context and intervention facilitation were explored.

Healthcare workers are the most essential resource for health care provision and are the active drivers of change in healthcare performance and health outcomes [135]. They have a central role in the uptake and ultimately contribute to the success or failure of any intervention. This thesis explored health workers' understanding and perspectives of the HMS BAB training, and its implementation processes. Understanding the barriers and facilitators to the HMS BAB training, will support improved planning for future interventions as well as the scale up of the present intervention for larger success.

All the prior evaluations of HMS BAB training have been evaluated as a single intervention, possibly because of the evaluation designs used or resource available. While assessing the effectiveness of the training, it is also important to understand and document the existing health facility readiness to PPH-care and contextualize what can be accomplished from such a single intervention

#### 3. AIM AND OBJECTIVE OF THESIS

#### 3.1 AIM

The overall aim of the thesis was to assess the effectiveness of a one-day competency-based in-service training followed by eight weekly practices of maternity staff on PPH-related maternal morbidities and mortality as well as health workers' competencies to manage PPH. In addition, the thesis aimed to explore health workers' perceptions of the training implementation as well as their perceptions of facility preparedness to support learned skills in the prevention and care of women with PPH in Tanzania.

#### 3.2 OBJECTIVES

- 1. To assess the effect of the HMS BAB training of maternity staff on reducing PPH related maternal morbidities and mortality in Tanzania.
- 2. To assess the effect of the HMS BAB training on health workers' knowledge, skills and retention of knowledge and skills at 10-month after initial training.
- 3. To explore health workers' perceptions of the implementation processes of the HMS BAB training intervention.
- 4. To explore health workers' experiences of health facility readiness that can affect prevention and care of women with PPH after the HMS BAB training.

#### 4. THESIS FRAMEWORK

The conceptual framework for this thesis (**Fig 2**) links the Kirkpatrick model of training evaluation, that has been used extensively in the past, [128, 136] and the quality of care framework [70]. The Kirkpatrick's model has been criticized to be too simple, assumes each higher level provides more effective information on the training and does not consider that organizational, individual, and training design and delivery factors that interacts with training affect the effectiveness [136, 137]. The WHO QoC Framework [70] alongside the WHO Health Systems Framework [72] and the WHO Standards for Improving Maternal and Newborn Care in Health Facilities[71] were used to assess available structural and processes support for the trained health workers to use the training and achieve desired outcomes. The framework specifies the key structural readiness aspect of drugs and supplies including blood transfusion, a functional referral system as well as the governance, information (health facility information systems) and financing. The "Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS)" framework[138, 139] was used to determine the implementation process of HMS BAB intervention.

Study III, the assessment of the appropriatness and the fit of the HMS BAB training is linked to the organizational characteristics, how health workers are abled and delivery of the intervention to facilitate or hinder its uptake. Study IV assesses the readiness of the facilities, and thus to which extent the training is effective within the common shortages in supplies. The assessment of the direct impact on leaning (Study II) links to the component of human resources, aiming to build their capacity and motivate them. Finally, study I looks at the changes in practices and the impacts of the training.

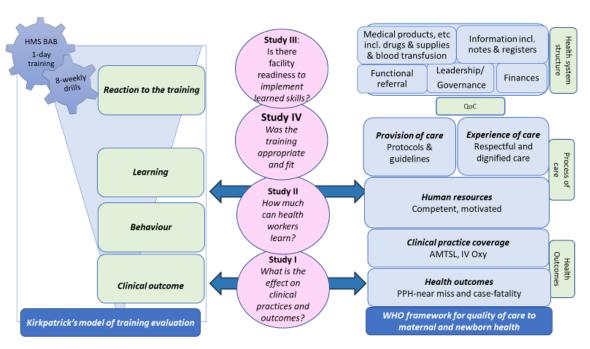


Fig 2. Thesis framework linking Kirkpatrick's training evaluation levels and components of QoC for maternal and newborn health.

## 5. MATERIALS AND METHODS

#### 5.1 OVERVIEW

This PhD study used both qualitative and quantitative methods. An overview of the different methods employed is presented in **Table 1.** 

Table 1. An overview of methods used in this PhD study

			<i>_</i>	
Study	Research question	Design	Participants and setting	Main Analysis
I	How effective is the <i>HMS BAB</i> training in reducing PPH-related maternal morbidities and mortality in Tanzania?	Cluster Randomized Trial using 20 clusters	20 clusters in Tanzania Health workers in intervention clusters (n=331) All in-facility deliveries (n=120,533)	Intention to treat analysis. Comparison of pre- and post- intervention between intervention and comparison clusters
II	What is the effect of the <i>HMS BAB</i> training intervention on health workers' knowledge, skills and retention? What are predictors of knowledge and skill change?	Before-after study without comparison group	All health workers in the HMS BAB study (n=636)  A sub-set of health workers in the intervention clusters followed up at 10-month (n=303)	Immediate and 10-month change of knowledge and skill scores Linear regression of health workers characteristics and score change
III	What are health workers' perceptions of the <i>HMS BAB</i> training intervention?	Qualitative process evaluation study	7 FGD with 42 health workers from intervention districts	Qualitative deductive theory driven analysis using the i-PARIHS framework
IV	What are health workers' experiences of health facility readiness for PPH-care	Qualitative	7 FGD and 12 indepth interviews	Qualitative content analysis

HMS-BAB: Helping Mothers Survive Bleeding After Birth

FGD: Focus Group Discussion

#### 5.2 STUDY SETTING

#### 5.2.1 Tanzania: health statistics and health policy

Tanzania has one of the fast-growing populations in the world, estimated to be 58.6 million people in 2020. The high growth rate contributed by high total fertility rate and high unmet need of family planning [140, 141]. Overall, the country' healthcare and maternal health indicators are poor (**Table 2**).

Table 2. Current health statistics for Tanzania

Indicator	Year		Reference
Population size	2020	58.5 million	[141]
Life expectancy at birth	2020	63.9 years	[141]
Proportion living in urban setting	2020	35.2% of total population	[141]
Current health expenditure per capita	2017	\$97	[141]
Total Fertility Rate [15-49 years]	2020	4.59 children born/woman	[141]
Doctors /10,000 people population	2014	0.4	[142]
Nursing cadres /10,000 people	2014	4.1	[142]
population			
Predominant midwifery provider		Nurse-midwife	[143]
Hospital beds / 10,000 people	2010	7.0	[141]
population			
Maternal mortality ratio per 100,000	2015	542 (399-712)	[1]
live births			
Neonatal mortality rate per 1,000 live	2018	21.1	[144]
births			
Stillbirth rate per 1,000 total births	2019	40.5[uncertainty interval 32.1-	[145]
		51,2]	
% of births in health facilities	2016	62.6%	[140]
Lifetime risk of maternal death	2015	1 in 36	[140]

Tanzania is committed to improving maternal and newborn health, with policy supporting increased access to quality reproductive health services and reduction in maternal and infant mortality. This is reflected in several planning and policy documents including: National Strategy for Growth and Poverty Reduction (NSGRP/MKUKUTA), and the Health Sector Strategic Plan IV 2016-2020 (HSSP IV) [146-148]. By policy, maternal and child health services are free, however out of pocket expenditures are reported [149].

Health care services are overseen by two ministries: the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) which is responsible for policies

and technical guidelines, and overseeing maternal, reproductive, child health service delivery, and the President's Office and Regional Administration and Local Governments (PORALG) oversees Regional and District Hospitals, health centers and dispensaries [146].

#### 5.2.2 The district health system

The Tanzanian health-system is decentralized to the district level [146, 148, 150]. All maternal and newborn care is coordinated by the Council Health Management Team (CHMT), governed by local government authorities. The CHMT works directly with health facilities to support their procurement, recruitment and planning needs [146]. More recently further decentralization to health facilities through the Direct Health Facility Financing (DHFF) has led to 70% of Health Basket Fund resources being channeled straight to health facilities and not via the district.

A typical district healthcare system has a pyramidal structure with one district hospital complemented by 4-6 health-centers and a large network of dispensaries. Both health centers and hospitals offer delivery and inpatient care, with hospitals offering more specialized services.

#### 5.2.3 Human resources

There are 5.5 doctors, nurses and midwives per 10,000 of the population in Tanzania, which is below the WHO minimum threshold of 23 per 10,000 population [143, 151, 152]. Furthermore, the distribution of health workers is skewed towards urban areas [147, 153]. Maternity wards are staffed by medical doctors, assistant medical officers, clinical officers, nurse-midwives and medical assistants [55, 154]. Task shifting is common in the maternity wards where assistant medical officers, a cadre of 'non-physician clinician', provide specialized care including obstetric operative care [155, 156]. The nurse-midwives cadre includes registered nurse-midwives with diploma, advanced diploma and degree or enrolled nurse midwives with certificates [157].

#### 5.2.4 Access and coverage of healthcare services

Socio-economic factors such as rural/urban, education and income significantly affect the provision of health care within the country [140, 158-160]. Over 70% of the population live within 5km of a dispensary; however, the majority of women bypass the nearest health facility to attend the next level facility where the quality of care is perceived to be better [158, 159]. Complicated cases are referred to higher-level facilities; nevertheless, the functionality of this referral system has many constraints [65]. Even within the health facilities, emergency obstetric and neonatal care services are not consistently implemented due to health system challenges [51, 53, 54, 154, 161-164].

#### 5.2.5 The HMS BAB studies setting

Studies I and II were part of the HMS BAB cluster-randomized trial in Tanzania which was implemented from November 2014 to January 2017 [165]. The HMS BAB cluster-randomized trial aimed to evaluate the effect of the training on PPH-related maternal morbidities and mortality with additional aims of improving the in-facility learning environment, translate routine data use to improve quality and to capture contextual factors that influence the training intervention. Study II was modified to include determinants of health workers' learning and retention. The two additional qualitative studies (Studies III and IV) were added to the trial with support from Swedish International Development Agency (SIDA) and were nested in the same setting.

The trial was implemented in four regions: Mwanza, Simiyu, Lindi and Mtwara (**Fig 3**). These regions were selected in collaboration with the MOHCDGEC as areas with high PPH burden and few interventions that were on-going. There were 24 administrative districts from these regions, four of which were excluded: two had no district hospital or other high-case load hospital or health center and two were physically remote which would have affected the opportunity to perform regular supervision. Therefore, the trial was implemented in 20 districts (clusters), all were mainly rural districts with the exceptional of the regional capitals. Within the 20 districts (clusters), 61 health facilities were included: 84% were government owned. **Table 3** compares maternal health indicators in the four study regions

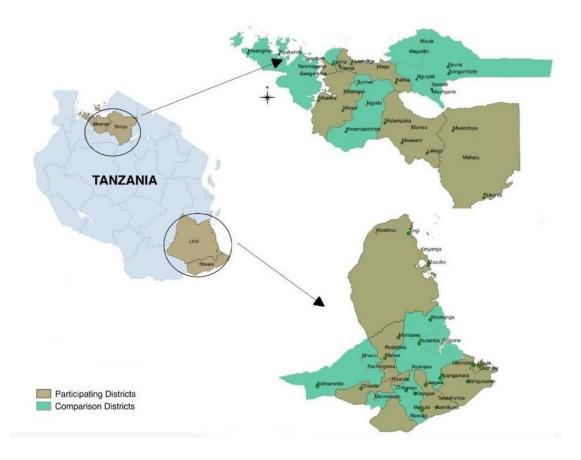


Fig 3. Map of Tanzania showing the study regions and interventional and comparison clusters

Table 3.Maternal health Indicators for the four regions included in the studies

Indicator	National	Mwanza	Simiyu	Lindi	Mtwara	Reference
Population per region (nearest millions 2017)	58.5	3.2	1.7	0.9	1.4	[166]
Proportion of mothers attending at least four Antenatal Care visits (%) (2015-16)	43.0	42.1	37.9	53.3	52.0	[140]
Proportion of in-facility delivery (%)(2015-16)	60.1	44.6	45.9	80.0	82.0	[140]
Proportion with skilled birth attendance (%)(2015-16)	63.5	47.0	49.1	80.0	85.0	[140]
Proportion of CS birth /all deliveries (%)(2015-16)	6.0	3.0	0.3	7.2	7.6	
Proportion of women with Postnatal check-up within 2 days (%)(2015-16)	31.8	20.0	11.4	44.0	53.1	[140]
Institutional maternal deaths per 100,000 live births (2014)	127	126	272	177	306	[163]
Proportion of MMR caused by PPH (%) (2014)	25.0	20.5	24.4	14.9	27.0	[163]
Case fatality for PPH (%) (2014)	2.5	2.8	1.4	4.0	4.8	[163]

#### 5.2.6 The HMS BAB intervention and Implementation

The Helping Mothers Survive Bleeding After Birth is a competency-based training that takes place in-facility (on-site). The curriculum consists of basic delivery care, AMTSL, estimation of blood loss, and initiating a cascade of actions for PPH early management: therapeutic oxytocin, uterine massage and referral to higher level. A birthing simulator (Mama Natalie) is used to support the training process (<a href="https://www.laerdal.com/products/simulation-training/obstetrics-paediatrics/mamanatalie/">https://www.laerdal.com/products/simulation-training/obstetrics-paediatrics/mamanatalie/</a>)[120].

The "low dose high frequency" training technique was used, which allowed an initial one-day training of all maternity health workers to be supplemented by eight weekly sessions. These weekly sessions were supported by a pair of "peer facility facilitators" and involved practice scenario-based drills that build on learned competencies.

The intervention was implemented in a stepwise manner. First, master trainers from Jhpiego, the pioneers of the training, trained *district-trainers*. Twelve HMS district-trainers participated in this central training. Secondly, the HMS district-trainers, in-pairs, travelled to the

intervention clusters accompanied by Jhpiego master-trainers. Each pair conducted in-facility training in the intervention facilities under the supervision of the Jhpiego master-trainers for the first training. Each pair spent one-and-a-half days per facility conducting the training. Day one was spent on the general HMS BAB training given to all health workers and day two was spent coaching two local health workers to become facility *peer facility facilitators*. A set of criteria for *peer facility facilitators* was used to select health workers who excelled in the skills training, were willing to lead others, and had good communication skills. They were coached for a half-day and were expected to organize and facilitate weekly drills lasting 30-40 minutes among their peers. Each pair of *peer facility facilitators* were given a Mama Natalie kit, training materials (flip chart, posters, provider's guide) and logbooks that had PPH case-scenarios to be practiced for 8 weeks. The *peer facility facilitators* received support from HMS district trainers through calls and supervision visits performed in the first two to three weeks.

All 31-health facilities in the ten intervention districts (clusters) were trained between January and February 2016. Health facilities in the comparison districts received the same training at the end of the main trial (January 2017). The same HMS district trainers conducted training in the intervention and comparison clusters. They received a refresher course prior to conducting this training. The HMS district trainers were all practicing medical doctors and midwives employed in the districts or had teaching positions.

#### 5.3 STUDY DESIGNS, PARTICIPANTS, DATA COLLECTION AND ANALYSIS

Studies I and II were quantitative designs: cluster randomized trial [Study I] and before-after [Study II]. Studies III and IV were qualitative designs using in-depth interviews [Study IV] and Focus Group Discussions (FGDs).

# 5.3.1. Cluster Randomized Trial to evaluate effect of HMS BAB training [Study I]

Study Design: A cluster-randomized trial design including 20 districts was used to assess the effect of the HMS BAB training intervention on PPH-related maternal morbidities and mortality in Tanzania [165]. The study design is illustrated in **Fig 4**. A cluster was an administrative district and comprised of a district hospital and 2-3 larger health centers, with a combined delivery load of ≥ 3000 per year and performing basic emergency obstetric care. The trial was registered in Pan African Clinical Trials Registry, PACTR201604001582128 on 12 April 2016 and a detailed Trial protocol is attached as **Appendix 1** [165].

At the end of baseline data collection, clusters were matched in pairs. Matching criteria were urban/rural cluster, geographical area and a balance in the outcome measurement 'PPH-related near miss cases among women who suffered PPH' available from the baseline data collection. Half the clusters were randomized to receive the intervention and the other half to be in comparison study arm. Blinding was not possible for this intervention as the intervention was on the health facility level. Contamination was a threat in two ways (i) other ongoing quality

improvements in the districts and (ii) movements of health workers and patients in between districts. Such events were documented and there were no significant other trainings taking place, or movements of workers between districts.

**Participants:** The main participants were all women who gave birth in the selected facilities during the baseline and end-line data collection periods and all health workers in the maternity wards.

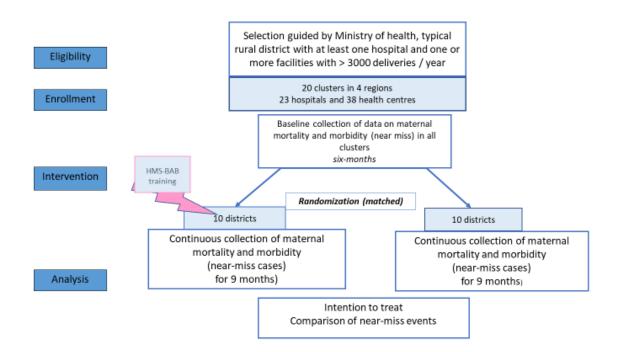


Fig 4. Evaluation design for the cluster-randomized trial

Modified from the Protocol paper: Hanson C, Pembe AB, Alwy F, Atuhairwe S, Leshabari S, Morris J, et al. Evaluating the effect of the Helping Mothers Survive Bleeding after Birth (HMS BAB) training in Tanzania and Uganda: study protocol for a randomised controlled trial. Trials. 2017;18(1):307. Attached as Appendix 1 [165]

*Outcomes and sample size:* Three primary and eight secondary outcomes were used to evaluate the changes in PPH-related morbidities, mortality and health worker's practices (**Table 4**). PPH-related maternal morbidities were defined using WHO near-miss [73]. We also assessed health-facility readiness and health workers' knowledge and skills.

The formula proposed by Hayes and Moulton for matched clusters [167] was used to estimate number of clusters needed at 80% power, 5% error and assuming an inter-cluster coefficient of 0.15, and 3000 deliveries per cluster assuming a 2% prevalence of PPH near miss as established from studies in LMIC [168-170]. The assumption was to get an effect size of 25% extrapolated from estimates of effect of consistent use of AMTSL on PPH [16] and reduced

neonatal mortality following similar newborn resuscitation training [171]. We estimated at least ten clusters were needed per study arm to achieve the desired effect of the intervention.

Table 4. Primary and secondary study outcome

Primary indicator		
Severe maternal morbidity	All cause near miss	Near miss cases among all women who delivered in the facility
·	PPH near miss	PPH near miss cases among all women who delivered in the facility
	PPH near miss among PPH cases	PPH near miss cases among women who suffered PPH during health facility delivery
Secondary indicator		
Maternal Mortality	PPH case fatality	Deaths among PPH near miss cases
Intervention	Preventive interventions	Proportion of women who received AMTSL of total women with PPH
	Management	Proportion of women who were transfused, received intravenous oxytocin, had balloon tamponade or laparotomy for hysterectomy among those who suffered PPH
Health workers	Knowledge and skills	Proportion of health care providers passing the knowledge test assessing preventive and emergency PPH-care Clinical skills score summing routine care including AMTSL, retained placenta and severe PPH
Health facility	Health facility preparedness	Proportion of facilities with PPH protocols, PPH emergency trays available at day of visit Proportion of facilities with at least a team of two midwives and one clinician at day of visit Proportion of facilities with oxytocin and supplies in delivery room at day of visit Stock-outs of oxytocin

Modified from the Protocol paper:Hanson C, Pembe AB, Alwy F, Atuhairwe S, Leshabari S, Morris J, et al. Evaluating the effect of the Helping Mothers Survive Bleeding after Birth (HMS BAB) training in Tanzania and Uganda: study protocol for a randomised controlled trial. Trials. 2017;18(1):307, Attached as Appendix 1 [165].

**Data collection:** Data collection was operationalized as three main datasets (1) a health facility assessment (2) near miss data from all women delivering in the included facilities and facing complications and (3) an aggregated number of women who delivered in-facility.

1) Health facility assessments focused on PPH-care, and was informed by the WHO SARA tool [172] and other facility assessments implemented in Tanzania and elsewhere [150, 173]. Health facility's readiness components that include the supply and availability of drugs in the facility and in the labour ward, availability of standard

PPH protocols in the labour ward, access to blood for transfusion and transport for referral, number of skilled staff were documented. Several of the questions were restricted to the day of visit to be able to assess the availability of drugs and supplies. Four graduate nurse and medical doctors implemented the assessment. They visited each facility for 1-2 days and completed the facility readiness checklist after physically verifying the availability of drugs and supplies. Two health facility assessments were performed: one at baseline (May 2015) and one at post-intervention period (October 2016). There was a plan to document availability of oxytocic drugs on a bi-weekly basis using the Open Data Kit (ODK) tool. However, this was difficult to implement, and several data points were missed.

- 2) Primary and secondary outcomes were documeted using the WHO near miss definition and tool [73]. The tool identified severe morbidities by the (i) life-threatening condition, (ii) laboratory criteria of organ dysfunction, and (iii) having received life-saving intervention such as laparotomy, blood transfusion and Intencive Care Unit (ICU) admission. The tool was modified to include parity, age, and birth outcomes and abortion complications attached as **Appendix 2**.
- 3) In addition to near miss data, data collectors reported on routine data (from delivery ward registries) including total deliveries, livebirths, stillbirths and number of caesarean and vagina births through monthly calls. This information was checked for accuracy and completion during facility supervision visits.

Two maternity staff per facility were trained to be data collectors. The training was performed over an initial two days in April 2015 and focused on the identification of near miss cases and maternal deaths, as well as manual and electronic data entry and upload. In December 2015, all data collectors received a refresher training that additionally emphasized on reporting maternal deaths. This training guided data collectors to look at death registries and identify deaths of women of child-bearing age to ensure all maternal deaths were included. For each identified near miss case, abstracted data was extracted and manually first noted down in a paper form tool. Cases were identified and enrolled from all potential wards: from the maternity ward to the female wards and the surgical/medical ward. Morning report sessions provided a starting point for collecting information on serious cases and the follow up performed.

Abstracted data was later transferred electronically in an ODK open software programmed application and uploaded after every two weeks. The uploaded data was de-identified and secured in a password protected server. Data collectors were supported through on-site supervision, regular calls and through a regional WhatsApp group that provided quick access and technical support when needed. There were a few instances where new data collectors had to be trained to replace those who had been redeployed away from the maternity ward. Some facilities needed more support. Data collectors were given a small monthly allowance in the hospitals. For health centres we expected less than five cases per month and data collectors

were reimbursed per case that was reported. Data collection started in March 2015, however, the first two months of data collection was incomplete during the start-up phase. Thus, baseline data collection ran from June 2015 until February 2016.

Data Analysis: Analysis was based on the "intention to treat" method. The analysis used the clusters (districts) as statistical units and assessed the prevalence and the trends of the indicators over the baseline and the post-intervention period. STATA software version 15 was used for all the analysis. Variables obtained from individual health facility assessments were collapsed to reflect cluster estimates and were presented as medians with interquartile range (IQR) for numerical variables, and proportions with 95% confidence interval (CI) for categorical variables. Mann-Whitney non-parametric test and  $\chi 2$  test were used to compare the two trial groups at baseline and post-intervention periods. Significant levels were set at p-value < 0.05.

All the uploaded near miss data were checked on paper and electronically for inconsistencies and unreasonable values. Near miss data from individual facilities were collapsed to create cluster level estimates which were the main basis for analysis. All in-delivery numbers reported per facility were collapsed per clusters per month and used as denominators for primary and secondary indicators. The indicators (**Table 4**) were created as ratios as defined, e.g. number of near miss in a cluster and a respective month divided by the number of deliveries in the respective district and month. For the indicator PPH near miss among women with PPH infacility deliveries we defined this indicator as a woman who had PPH of blood loss >500 ml, had a laparotomy and hysterectomy and/or received a blood transfusion. The organ dysfunction criteria included cardiovascular, respiratory, renal, hematologic, neurological and uterine dysfunction.

Interrupted time series analysis [174] was used to compare monthly prevalence of the indicators as well as the trends of the indicators at baseline period, immediately after the intervention (short term) and also over the post-intervention period (long-term) between the intervention and comparison clusters. Significant levels were set at p-value < 0.05.

# 5.3.2 Predictors and retention of knowledge and skill gain following HMS BAB training intervention [Study II]

**Study Design:** The study used a before-after design without a comparison group using data from the main HMS BAB trial.

Outcomes of interest: This study aimed to assess predictors of change in knowledge and skills, among health workers immediately after the HMS BAB training and at 10-month follow up. The hypothesis was that health workers' characteristics including years of professional experience, level of professional training and prior in-service PPH or AMTSL training would influence the learning and retention of new knowledge and skills.

**Participants:** Secondary data analysis of all health workers trained during the trial was conducted. This included 636 health workers who were trained in two periods: 337 health workers who were trained in January 2016 as part of the HMS BAB intervention clusters and 299 health workers in comparison clusters trained at the end of HMS BAB trial in January 2017. A sub-set of health workers (those training in January 2016) were re-assessed in November 2016, 10 months after the initial training to assess retention of learned knowledge and skills.

Data collection: Three paper-based tools were used (i) a self-administered questionnaire on individual health worker characteristics such as cadre, education, years of experience, number of deliveries assisted in the last month etc. (ii) a self-administered knowledge questionnaire on PPH causes and management with 15 multiple choice and True/False questions; (iii) Objective Structured Clinical Examinations (OSCEs) checklists to assess simulated skills on routine delivery and AMTSL performance, management of uterine atony and management of retained placenta tissue [122, 124]. All tools were developed and validated by Jhpiego [120, 124]. The self-administered questionnaires were in Kiswahili language. The HMS district trainers [124] assessed health workers before and immediately-after the training. As explained above, a subset of health workers were reassessed 10 months after the training.

*Data analysis:* From the 636 health workers, 30 dropped out before completing the post-training knowledge assessment. The analysis therefore included 606 knowledges scores and 592 aggregate skill scores that had both pre and immediately post-training score. Of those who were followed up at 10-month, 193 paired knowledge scores and 192 paired aggregate simulated skill scores were analyzed. A paired t-test was used to compare individual health workers' knowledge and skill scores immediately and at ten-month after training to allow for an assessment of changes in scores. Linear regression analysis was used to assess the predictors of change of knowledge and skill immediately after the training and at 10-month follow-up.

# 5.3.3. Qualitative studies of Intervention implementation [Study III] and health facility readiness for PPH-care [Study IV]

Studies III and IV data collection was performed between March and May 2017 at the end of the HMS BAB cluster trial. Both studies used FGD with health workers which were done together. Study IV also used in-depth interview from health managers.

**Design:** Study III was an interpretive descriptive qualitative process evaluation on barriers and facilitators of the HMS BAB training intervention using the integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) [138] framework. Study IV was qualitative study on health workers' and managers' experiences of health facility preparedness for PPH-care.

Study sample and participants: Four out of ten HMS BAB intervention districts were purposively selected with a balance between the two major geographical areas in Tanzania. As each cluster consisted of two facility levels: a district hospital level and two to three facilities at health center level, one focus group discussion (FGD) was conducted for each level per district. Overall, seven FGDs took place. All FGD consisted of five to seven health workers as summarized in **Table 5**. One FGD had 13 participants, however, due to emergencies, four left mid-way through the discussion. Two FGDs had less than the recommended number (six) of participants, however they fulfilled other criteria for FGDs [175].

Of the FGDs participants 88% (45/51) were female and 12% were male (6/51). The median age for the female participants was 36 years [range of 23-57] and male participants was 31 years [range 25-39]. Median experience was 3 years for both female and male, with a range of 0-30 years for female health workers and 1-5 years for male health workers. Median age of interview participants was 41 years [range 27-54], and median experience was 8 years [range 1-18].

Table 5: The FGDs composition of health worker profession qualification and gender

FGD	Profession	Females	Males
1	NM 9, MA 1, MCHA 1	11	2
2	Clinician 1, NM 4	5	0
3	NM 5	5	0
4	NM 7	6	1
5	NM 5, MA 2	7	0
6	MD 1, Clinician 1, MA 5	6	1
7	MD 1, NM 5, MA 1	5	2

MD: Medical doctor, NM: Nurse-midwife, MA: medical attendant, MCHA: Maternal and Child Health Aider, Clinicians: Assistant Medical Officers (AMO) and Clinical Officers

**Data collection**: All participants for the two studies were selected through labour ward matrons and medical officer -in-charge a day prior to the activity. For FGDs with participants from more than one facility, those from the second facility were asked to join the first facility. Those who did so were reimbursed their transport fare. Permission to conduct the FGDs in the facilities was requested from the facility-in-charge. On the day of the FGD, participants were informed about the study aims and asked to consent. Written consent was obtained from all participants. Participants were asked to respect the confidentiality of other group members.

In addition to the FGDs, twelve in-depth interviews with key informants were done for Study IV. Key informants were health managers and administrators at the health facilities who had insight into the overall district health system. Key informants included medical officers-incharge of facilities, regional and district reproductive and child health coordinators and regional

and district medical officers, they were individuals with insights into the overall health system [176]. Participants for the IDIs were identified and consented to the study.

The FGDs used a pre-prepared topic guide discussion tool. The tool had two parts. The first part (**Appendix 3a**) addressed facility preparedness (Study IV) and the second part of the tool (**Appendix 3b**) explored training content, as well as what was good about the training, what could be changed for Study III. An interview guide was used for Study IV [**Appendix 4**].

The interviews took place at a time and place convenient for the participant and privacy was observed during the interview. All FGDs were conducted in respective health facilities in the afternoon hours. On average the FGD lasted 80-110 minutes and interviews lasted 40-50 minutes. The FGDs and interviews were facilitated by the thesis author and two research assistants who had social science degrees and were experienced in qualitative studies in maternal and child health. All FGDs and interviews we conducted in the local language, Kiswahili and were audio recorded, then transcribed verbatim and translated to English with appropriate quality checks performed. Audio tapes and transcripts were stored with the main researcher (thesis author) and the electronic data stored in a secure server at the researcher's local institute.

*Analysis:* All translated transcripts were entered in an analysis software program *MAXDAQ* 2018 for analysis. All transcripts were read and re-read by the PhD student, as she familiarized herself with the text. Analysis for the two studies followed different approaches. Analysis of Study III was done before Study III.

### Study III Analysis:

Transcripts for Study III were analyzed using deductive content analysis [177] guided by the i-PARIHS framework [138, 139]. The thesis author applied the four i-PARIHS framework constructs to the health workers perceptions of the training process. The "innovation" construct was the HMS BAB training; "facilitation" construct was the training technique (on the initial day training and the weekly practice drills); "recipients" were the health workers and the "context" was the overall organization structure that supports the intervention.

A structured analysis matrix was developed by the thesis author and shared with other researchers for their inputs. Paragraphs were fitted into the structured matrix that consisted of the main i-PARIHS constructs, and its categories or characteristics of the constructs [138]. Data was then condensed into meaning units, coded and later grouped in sub-categories. Some of the sub-categories were reflected in more than one construct and not all were present in all constructs.

### Study IV Analysis:

Transcripts from FGDs and interviews were analyzed using thematic content analysis [178]. The thesis author read the transcripts several times to understand the material and coded the

first few transcripts. Coding was performed inductively [179], with labels that matched closely to the transcript text. These initial transcripts were re-read and re-coded by a qualitative supervisor. Both authors then discussed and agreed on the codes. Similar codes were grouped into main categories and sub-categories and later into themes which were developed both inductively and deductively [178] referring to health facility readiness definition [71, 172].

### **6 ETHICAL CONSIDERATION**

The studies were reviewed and cleared by the Muhimbili University of Health and Allied Science Senate, Research and Publications committee. The initial permit 2014-10-06/AEC/Vol IX/14 of 2014 was renewed in 2015 (2015-11-18/AEC/Vol X/71) and 2016 (2016-12-14/AEC/Vol XII/03). Local stakeholders at the regional and district levels were informed of the projects. Permission to conduct the research activities was also obtained from the District Medical Officers and facility administrators, who acted as gatekeepers of the districts.

#### 6.2 ETHICAL CONCERNS FOR CLUSTER TRIAL

The study design and the intervention were justified in view that the intervention is implemented in many countries while evidence of its effects is largely missing, thus equipoise was given. The HMS BAB training intervention was perceived to be beneficial for health workers' knowledge and skills regarding the management of PPH. Although less effective than individual randomized trials, a cluster design was used because the intervention needed to be administered at the facility level. All participating districts benefitted with the training, in the comparison facilities health workers received the HMS BAB training intervention at the end of the trial.

There are several ethical issues with cluster-randomized trials that were considered. First, the units of randomization, intervention and data collection are different. We randomized districts and administered an intervention to health workers and observed patients' outcomes. This brings challenges in the consenting process: who are the participants, how, by whom and when is the right time to obtain informed consent [180-182]. Written informed consent was sought and obtained from the "primary participants"; the health workers after clusters were randomized. The consent forms provided information, assessed comprehension and highlighted voluntary participation and were written in the local language. The outcome data: maternal near miss and facility delivery data were collected from maternity ward registers and case notes and are secondary data. We therefore did not need to obtain consent from women for several reasons. Firstly, there was no direct contact with women, data collected from medical registries and case files did not collect any identifiable data. Secondly, it would have been a difficult task to obtain consent for all near miss women. Finally, challenges arise when consenting women during intrapartum care and issues arise as to whether women who had complications should provide consent prior to receiving an intervention [183].

All maternal near miss data was entered in paper forms and later entered electronically and sent to a secure password protected computer. Only one person had the passcode, the local data manager, who cleaned and prepared the data for analysis.

### 6.3 ETHICAL CONCERNS FOR BEFORE-AFTER STUDY

The process of obtaining informed consent of health workers for the before-after study was the same as described for the cluster trial. Health workers were informed of the potential benefits and risks of the intervention. Furthermore, they were informed that their training scores would not be shared with facility administrators or supervisors. Health workers were also informed about the voluntary nature of their participation and that there would be follow up. Few health workers left the training intervention in between sessions, and few also refused to be followed up. We believe this was due to conflicting duties rather than simply discontinuing participation. One of the intervention components was to participate in the weekly drill sessions. Some health workers expressed that they could not participate in these sessions due to conflicting clinical duties. Expecting health workers to participate in drills sessions during busy times could be viewed as an ethical dilemma. To overcome this, we explained to health workers that in such instances they were the best judge on appropriate times for drills sessions.

#### 6.4 ETHICAL CONCERNS FOR QUALITATIVE STUDIES

Informed consent procedures were followed during the key informant interviews and during the FGDs. All participants were contacted one or two days prior to the date of the activity and provided with information about the purpose and nature of the studies, voluntary participation, and their right to withdraw from the study at any time without consequence.

Key informant interviews took place at a time and place convenient for the participant. The FGDs were conducted in the facilities to accommodate staff numbers and shifts. All FGDs were conducted during afternoon shifts, where one member of staff was able to stay on the labour ward to care for patients. We tried to minimize disruptions to routine care during the qualitative data collection. Nevertheless, some interruptions occurred, and occasionally, a few participants had to leave to provide emergency care to patients.

Immediately prior to the interviews and FGDs, information on the study purpose and voluntary participation was repeated. Consent for audio recording was obtained and it was explained that the tapes would be listened to in a private space, transcribed and translated. Participants were also made aware that only the core research team would have access to the raw identifiable data and that this would be locked and stored securely. Finally, participants were informed that data would be analyzed and published in a manner that maintained their anonymity.

As the FGDs were comprised of members from the same health care facility or near-by heath care facilities, most participants knew each other and felt free to discuss their work environment. Regardless, we discussed confidentially issues with the group and asked them to agree to maintain the confidentiality of the group. The interviews and FGDs provided an opportunity for health workers to share their experiences, and many participants commented that the opportunity to express their opinions was appreciate.

### PROJECT COLLABORATION

The HMS BAB study started in 2014 as a collaboration project between international and local professional associations: International Federation of Gynaecologists and Obstetrician (FIGO), International Confederation of Midwives (ICM), The Association of Gynaecologists and Obstetricians of Tanzania (AGOTA) and the Tanzania Midwifery Association (TAMA). The aims were to collaborate in research, whilst improving the working relationship between midwives and doctors and building local capacity in research by creating PhD and master's positions within the project. The HMS BAB study in Tanzania was part of a two-country trial [165]. This thesis presents results from Tanzania while results from Uganda are published elsewhere [184]

I was recruited to manage the project from AGOTA. My key role was to build a research team for the project, obtain ethical clearance and collaborate with the Ministry of Health, local regulatory bodies and other stakeholders in the area to conduct the research while reporting to the collaborators and funders. I worked closely with Claudia Hanson the project Principle Investigator, Prof Andrea B. Pembe, Hilda Kwezi and the late Dr Sebalda Leshabari.

My role was to operationalize the research, prepare data collection tools, recruit and train data collectors and supervise data collection and analysis and project activities including finances. With Kizito Shirima, we managed the data upload, and followed up data collectors to ensure submission and complete data. I provided feedback during the study and disseminated data at the end of the study at district, regional and Ministry level.

I started with enthusiasm and soon realized the challenges of working in remote rural facilities, from getting there during periods of bad weather, to internet connectivity issues, to data collectors being transferred away from the study facilities. I could not imagine that obtaining "number of deliveries per month" in a facility is a difficult task. However, I learned that this alone may take several days. There were many lessons learnt during the project including WhatsApp regional messaging groups used to support data collectors. I spent a significant amount of time in the districts, rarely at one place for more than a week, because the study covered a relatively large area. I experienced the difficulties in the transport between one place to another. Through this I have learnt the resilience of rural and district health workers and the personal and professional choices they make on a day to day basis. I have grown to respect them enormously.

In 2016, I enrolled in the PhD program at Karolinska Institutet, funded by SIDA-MUHAS 2015/2016 collaboration under Reproductive and Child Health cluster. I modified Study II, and designed Studies III and IV to complement the main trial. Although the aim was to enroll more students in the project, this was not realized due to different timelines that lead to several missed opportunities. This project however is a very good example of collaboration, each bringing their unique perspective and experiences to the wider group.

### 8 RESULTS

### **8.1 OVERVIEW**

A summary of main results is presented in **Table 6**. Studies I & II were performed in all districts and Studies III & IV were performed in four out of the ten intervention clusters.

Table 6: Overview of thesis findings in relation to the study objectives

Study	Objective	Major findings
I	To assess the effect of the HMS BAB training of maternity staff on reducing PPH -related maternal morbidities and mortality in Tanzania.	The training reduced in-facility PPH-related morbidity (PPH near miss) and PPH case fatality.  The effects were observed immediately after the training and throughout the post-intervention period (9-month).
П	<ol> <li>To assess knowledge and skill changes immediately after the HMS BAB training and at 10-month follow-up</li> <li>To assess association of health workers characterics and change on knowledge and skills</li> </ol>	Knowledge on PPH was already high before the training. Simulated skills on PPH was low. All health workers demonstrated an increase in PPH-knowledge and simulated skills scores immediately after the training which was significantly associated with their profession level. Experience, delivery case load or level of facility where health worker practiced had no effect on immediate change of score. All professions showed skill decline at 10-month follow-up.
III	To explore health workers' perceptions of the implementation process of HMS BAB intervention	The intervention components met health workers training needs and was clear and practical. Having local peer practice facilitators enhanced learning however time, personnel and organizational constraints were found to hinder regular practices and sustainability.
IV	To explore health workers' perceptions of the health facility readiness to provide PPH-care	Provision of PPH-care was negatively affected by poor facility preparedness experienced as inconsistent access to drugs, unreliable blood transfusion availability, unclear referral system and few, unsupported and overwhelmed health workers.

# 8.2 REDUCED PREVALENCE AND TRENDS OF SEVERE PPH MORBIDITIES AND MORTALITY

Study I included the main effect evaluation of the cluster-randomized trial. All randomized districts and facilities completed the trial.

The matched clusters (districts) comprising the intervention and comparison groups were comparable in terms of health facility infrastructure and health facility readiness (Study I). No significant difference was observed in the median number of clinicians (29 vs 22 in intervention and comparison districts, p-value= 0.38) and nurse-midwives (72 vs 62 in intervention and comparison districts, p-value= 0.29). There were no differences in health facility readiness and availability of protocols for PPH management, referral or availability of blood transfusion services.

During the intervention period (January 2016), 331 health workers were trained. They showed an average knowledge increase of 13% (95% CI 10-16). The simulated skill change observed was higher than knowledge gain, at 49% increase in AMTSL (95% CI 41-57), a 42% increase in the recognition of retained placenta (95% CI 32-50) and a 42%-increase (95% CI 39-45) in management of severe PPH.

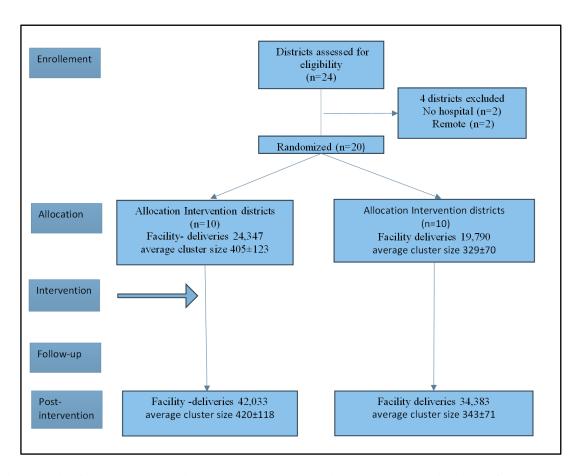


Fig 5: Trial flow chart showing enrolment, allocation and randomization of clusters and patient flow in two study arms.

Data analysis included 24,347 and 19,790 deliveries at baseline and 42,033 and 34,383 during end line data collection, in the intervention and comparison clusters respectively (**Fig 5**). Of the 120,533 women who delivered in study facilities, 6,503 met the definition of being a near miss and 202 were maternal deaths. For the primary indicators, there was no significant difference in the prevalence of all-cause near misses and PPH near misses among all women who delivered in a facility (**Table 7**).

The indicator of PPH near miss cases among women with PPH who delivered in facility, showed a significant decrease in intervention clusters from 81.8% (95% CI 73.4-90.2) to 70.1% (95% CI 60.2-80.0) compared to from 68.3% (95% CI 55.4-81.2) to 71.6% (95% CI 54.1-89.1) with p<0.01 in the comparison clusters. This effect was sustained in the post-intervention period in the intervention clusters (difference-in-differences of slopes -5.3, 95% CI: -7.8; -2.7, p<0.001) as seen in **Fig 6**. PPH case-fatality showed a downward trend from baseline that was statistically significant in the intervention clusters compared to the comparison clusters (difference-in-differences of slopes -54.0, 95% CI: -6.5; -1.5, p<0.01).

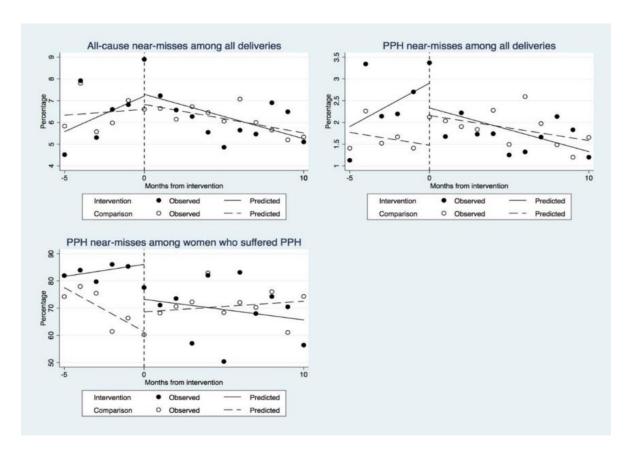


Fig 6: Prevalence and trends of primary indicators in intervention and comparison clusters at baseline and post-intervention

Reprinted with permission from: Alwy Al-beity F, Pembe A, Hirose A, Morris J, Leshabari S, Marrone G, et al. Effect of the competency-based training; Helping Mothers Survive Bleeding after Birth (HMS BAB) training on maternal morbidity: a cluster-randomised trial in 20 districts in Tanzania. BMJ Global Health. 2019;4(2):e001214

A higher proportion of women with PPH received intravenous oxytocin in intervention clusters compared to those in comparison clusters (p-value 0.004). There was a decrease in the proportion of women who received blood transfusion from 71.6% (95% CI 58.2-85.0) to 63.4% (95% CI 59.1-74.2) in the intervention clusters compared to from 65.6% (95% CI 51.2-80.0) to 67.8% (95% CI 50.0-85.5) in the comparison clusters. This difference was statistically significant (p <0.001). Most women however received a median of 1-2 units of blood only.

The main treatment modalities were intravenous oxytocin, manual removal of placenta, blood transfusion, and laparotomy for hysterectomy. Very few women with PPH received the oxytocic drug misoprostol. Other management modalities such as tranexamic acid, intrauterine balloon tamponade, abdominal packing or artery ligation were rarely used (**Fig 7**).

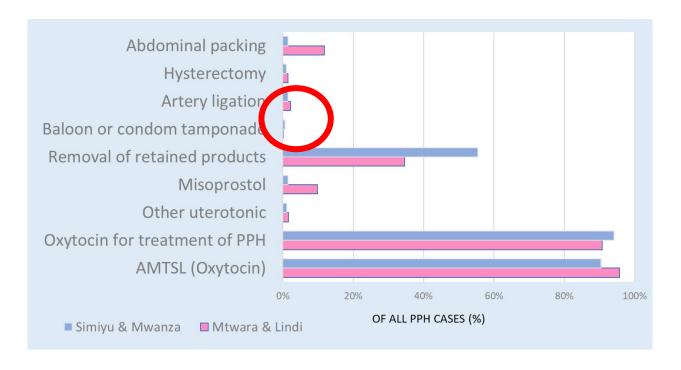


Fig 7. Intervention offered to women with PPH throughout study period

Table 7: Effects of the HMS BAB training on primary and secondary indicators using interrupted time series analysis

Outcome	Baseline indicator estimate (comparison) N / % (95% CI)	Baseline trend (comparison)	Short term effect difference between intervention and comparison district	Long term effect difference between intervention and comparison district
Primary Indicators		Estimate (95% CI)		
All-cause near misses among all women who delivered in a	1,059	0.1 (-0.3; 0.4)	-1.5 (-2.4; 2.1)	-0.3 (-1.0; 0.3)
facility	6.3% (4.5-8.2%)			
PPH near misses among all women who delivered in a facility	278 1.7% (1.1%-2.3%)	-0.1 (-0.2; 0.1)	-1.3 (-2.4; -0.11) *	-0.3 (-0.7; 0.1)
PPH near misses among women who suffered PPH during health facility delivery	278 70.1% (60.2-80.0%)	-3.2 (-5.1; -1.3)	-20.1 (-33.1; -7.0) *	-5.3 (-7.8; -2.7) ***
Secondary indicators				
PPH cases of all deliveries	411 2.5% (1.7-3.3%)	0.0 (-0.2; 0.2)	-0.8 (-2.6; 1.0)	-0.3 (-0.8; 0.2)
Deaths / case fatality in PPH near miss cases	8 3.4% (0.4-6.4%)	-2.0 (-3.1; -1.0) **	-9.3 (-21.0; 2.4)	-4-0 (-6.5; -1.5) **
AMTSL	334 81.5% (66.3-96.7%)	1.2 (-0.2; 2.6)	-3.5 (-14.1; 7.1)	2.0 (-0.9; 4.9)
Women treated with IV oxytocin	380 92.4% (88.6-96.2%)	4.8 (1.2; 8.3) *	2.7 (-10.7; 16.1)	5.2 (1.4; 8.9) **
Women with Hb <70 g/l before discharge	58 18.4% (0.2-34.5%)	0.2 (-0.8; 1.3)	1.4 (-10.6; 7.8)	-0.8 (-2.7; 1.1)
Women receiving BT	257 63.4% (51.9-74.9%)	-2.5 (-6.1; 0.9)	-22.1(-42.2; -2.1) *	-8.0 (-12.6; -3.4) **
Removal of residuals of placenta	154 35.5% (20.2-50.8%)	1.2 (-0.9; 3.3)	8.9 (-8.9; 26.7)	-1.8 (-5.9; 2.3)
Women treated with hysterectomy	18 5.4% (0-11%)	3.2 (1.6; 4.7) ***	17.2 (11.2; 23.1)	3.3 (1.6; 5.0)

significance level at \* at <0.05, \*\* at <0.001 and \*\*\*< 0.0001 Reprinted with permission from: Alwy Al-beity F, Pembe A, Hirose A, Morris J, Leshabari S, Marrone G, et al. Effect of the competency-based training; Helping Mothers Survive Bleeding after Birth (HMS BAB) training on maternal morbidity: a cluster-randomised trial in 20 districts in Tanzania. BMJ Global Health. 2019;4(2):e00121

### 8.3 KNOWLEDGE AND SKILLS AFTER THE HMS BAB TRAINING

The combined data set of health workers from both the intervention and the comparison clusters was used to assess gain in knowledge and skills following HMS BAB training. In January 2016, 337 health workers were trained, and 299 health workers were trained in January 2017. The 10-month assessment in a subset of health workers was performed only to those trained in January 2016 for operational reasons. The study assessed whether health worker characteristics predict knowledge and skills gains and retention of knowledge and skills following the HMS BAB training.

Table 8. HMS BAB trained health workers by professional characteristics (n=636).

Health worker characteristic	Medical Doctors	Other Clinicians	Nurse- midwives	Auxiliary staff	Missing	All
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Profession	13 (2.0)	56 (8.8)	435 (68.4)	128 (20.1)	4 (0.6)	636 (100)
Number of						
deliveries assisted						
in the last month						
≤5 del/month *	10 (77.0)	43 (76.8)	193 (44.4)	86 (67.2)	2 (50.0)	334 (52.6)
6-15 del/month	2 (15.4)	9 (16.1)	167 (38.4)	35 (27.3)	2 (50.0)	215 (33.7)
≥16 del/month	1 (7.7)	4 (7.1)	75 (17.2)	7 (5.4)	0	87 (13.7)
Median number of	3	2	7	4		5
deliveries [IQR]	[0-5]	[0-5]	[3-13]	[2-8]		[2-10]
Years of professional						
experience						
< 2 years	5 (38.5)	9 (16.1)	111 (25.5)	42 (32.8)	2 (50.0)	169 (26.6)
2-4 years	6 (38.5)	13 (23.1)	150 (34.5)	29 (22.7)	1 (25.0)	198 (31.1)
5-7 years	0	5 (8.9)	53 (12.2)	13 (10.2)	0	71 (11.2)
≥8 years	2 (15.4)	21 (37.5)	97 (22.3)	37 (28.9)	0	157 (24.7)
Missing	1 (7.7)	8 (14.3)	24 (5.5)	7 (5.5)	1 (25.0)	41 (6.5)
Median years of	2	5	3	3		3
professional experience [IQR]	[0-3.5]	[2-14]	[1-7]	[1-10]		[1-8]

Of those with  $\leq 5$  deliveries in the last one-month, 126 did not assist in-any delivery and 108 assisted between one and five deliveries.

Reprinted and modified from Alwy Al-beity F, Pembe AB, Marrone G, Baker U, Hanson C. Predictors of change of health workers' knowledge and skills after the Helping Mothers Survive Bleeding after Birth (HMS BAB) in-facility training in Tanzania. PLOS ONE. 2020;15(5):e0232983.

**Table 8** shows distribution of health workers characteristics in the health facilities. Majority of the staff were nurse-midwives (68%), medical doctors were 2%, clinicians were 8.8% and auxiliary staff (medical attendants) were 20%. Overall knowledge scores were high before the training, with a mean score of 74.2% (95% CI 72.8-75.5%). This increased to 89.2% (95% CI 87.5, 90.9) immediately-after the training and 85.4% (95% CI 83.5-87.3%) at the 10-month follow-up. Highly trained professions had higher pre-training knowledge scores and subsequent immediately-after training score.

On the contrary, pre-training skill scores were very low among all professions. The pre-training mean skill score increased from 38.3% (95% CI 36.8, 39.6) to 85.4% (95% CI 84.3, 86.5) immediately post-training. Knowledge and skill score increases were statistically significant across all profession's qualifications (p-value <0.001). When adjusted for pre-training score and using nurse-midwives as referral category: the immediately-after training scores were reduced by 7.6%, 3.4% and 2.7% in auxiliary staff, medical doctors and other clinicians respectively. This decrease was statistically significant in auxillary staff only (p-value <0.000) but not in medical doctors and other clinicians (p-value >0.05)

There was no statistically significant association between number of deliveries assisted in the last one-month, years of professional experience and facility level with change in knowledge and skill scores immediately-after the training. When adjusted for pre-training score however, health workers assisting 6-15 deliveries in the past one month gained 2.4% more (95% CI 0.4, 4.5, p-value 0.021) compared to those who assisted less than five deliveries.

There was a skill decline of -4.0% (95% CI -6.8, -1.2, p-value <0.001) for all professions at the 10-month follow-up. Auxilliary staff had highest skill decline from 76.6% (95% CI 73.9, 79.3) to 63.8% (95% CI 54.7, 72.9, p-value < 0.000) among all health workers. There were too few medical doctors and clinicians to have significant results. Health workers who assisted more than 6 deliveries were observed to have less skill decline compared to those who assisted less than or equal to five deliveries in the previous month. This finding was statistically significant (p-value=0.001 and 0.043 respectively) but may not be clinically significant as it is too small. Distribution of knowledge and skills scores at the different times per profession are shown in **Fig 8a** and **8b**.

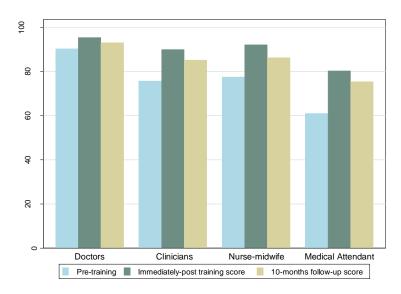


Fig 8a. Knowledge score pre-, immediately post- and 10-month after training

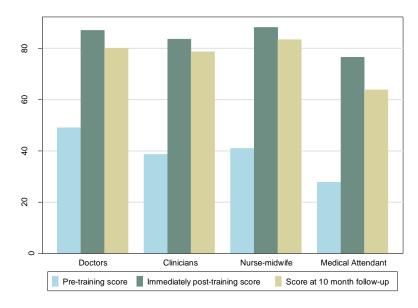


Fig 8b. Aggregate skill score pre-, immediately post- and at 10-month after training

## 8.4 HEALTH WORKERS' PERCEPTIONS OF THE IMPLEMENTATION PROCESS OF HMS BAB TRAINING

Study III explored health workers' perceptions of the training implementation process: what was good and worked and what were the barriers to implementation that could also explain the modest results seen in the main trial (Study I).

Health workers perceived that HMS BAB as a "training intervention" was unique, fit their needs, and allowed better acquisition of much needed skills in PPH prevention and management. Health workers perceived that training of all health workers in the maternity wards, irrespective of cadre, was advantageous: more staff are trained, less staff travel to out-of-facility training and reduce absenteeism and including auxiliary staff helped

Most health workers perceived to have become more knowledgeable believing to have increased competency and confidence after receiving the HMS BAB training.

"What made me really happy... was delivery of the placenta... frankly we were doing it very different ...but after getting this training, nowadays we deliver the placenta in a more skilled way." [FGD 6]

Other health workers perceived that in-facility training interfered with clinical duties in busy health facilities, causing poor concentration and less effective learning as they or their colleagues were interrupted during the training. Some health workers preferred to have the training outside of their facilities, as they felt this enabled them to concentrate more fully on the training. Some health workers preferred to have the training outside of their facilities, as they felt this enabled them to concentrate more fully on the training.

"As we were being trained other health workers had trouble with patients...they were getting complaints ...patients will knock on the door and say some bad words.... that destroys the trainer and trainees' moods..." FGD 2

The training itself was quite motivating to staff, especially as the auxiliary staff were included. Health workers valued that all facility staff were trained jointly and that the training provided space and time to reflect and discuss on the scenarios which in turn facilitated supportive learning.

Health workers expressed that to participate fully, they need to be motivated, have time and resources to practice, and be supported by their leaders to learn. Health workers are used to receiving per-diems whenever they attend a training, and the HMS BAB did not provide such monetary incentives. Some health workers expressed a preference for monetary incentives, while others believed acquiring competencies led to better job-satisfaction and was therefore a better motivator. Furthermore, busy maternity wards and staff shortages often made it difficult for health workers to meet and practice on weekly basis. Most facilities however reported regular meetings which were an opportunity for training and supporting each other.

The HMS BAB used HMS district trainers who trained local *peer practice facilitators*, who, in turn, led their colleagues in practice drills. This together with the use of simulators and practical sessions enhanced learning and skill acquisition. Some *peer practice facilitators* had challenges in manipulating the simulator and needed support. Other researchers reported a locally available facilitator or mentor enhanced uptake of an intervention [185-187].

Several organizations "contextual" factors interfered with implementation, such as poor planning. Despite facilities being informed of the training a week prior to the day of training, many health workers became aware of the training on the actual training day. Another important factor that interfered with implementation was movements of health workers

between and within facilities; sometimes key staff such as the trained peer practice facilitators were transferred out of the department, which caused disruptions to the weekly practice drills.

"What happened was one of the two peer practice facilitators had a transfer to another facility. The second person went to school. When both left, they had not trained anyone or handed over the Mama Natalie Simulator. It was only locked in the closet for sometimes and they (district trainers) came to re-train again." FGD 5

#### 8.5 OVERCOMING CHALLENGES

An overview of themes and categories representing health workers' experiences when caring for women with PPH within their health facilities are shown in **Table 10** below.

Table 10: Themes and categories.

Theme	Category
1. Inconsistent availability of	Drugs and supplies for PPH management not
resources limiting provision of	always available
care	
	Availability of blood fluctuates
	Unclear and unreliable referral system
	F 1 (11 1/1 1
	Few and unsupported health workers
2 Managament of managament	Woman with DDII are prioritized
2.Management of women with	women with PPH are prioritized
PPH is prioritized	Supportive leadership is helpful
	Supportive leadership is helpful

Modified from Alwy Al-beity F, Pembe AB, Kwezi HA, Massawe SN, Hanson C, Baker U. "We do what we can do to save a woman" health workers' perceptions of health facility readiness for management of postpartum haemorrhage. Global Health Action. 2020;13(1):1707403

### Theme 1. Inconsistent availability of resources limiting provision of care

Health workers described how inconsistencies in drugs and medical supplies hinder the provision of prompt care to women with PPH despite having acquired the skills from training. Health workers described instances of oxytocin stock-outs for up to four days, in other settings alternative oxytocic drugs such as Misoprostol were reported to be almost non-existent. Furthermore, there were shortages of basic equipment such as light sources, speculums and suture trays for use in the labour ward.

Additionally, health workers described difficulties in providing blood transfusion to women with severe PPH when needed due to the fluctuating availability of blood. Sometimes a woman is referred to another facility for blood transfusion, or relatives are requested to donate or look for known blood donors who may demand to be paid for the donation. While health workers

describe frequent shortages in blood supplies, some of the managers had a more optimistic view of improvements following a shift in policy that mandated districts to organize blood transfusion there.

"I can't say we have reached a place where we can be content with blood supply.... not yet ... You may find the lab doesn't have specific blood groups, it become a problem. This is, however, a different situation from what we had last year. Nowadays we have 10 to 15 units available for emergency at the laboratory. When a specific group is needed, then we communicate with regional blood bank to get some in our stock. It has not happened that we do not have blood at all." [Manager-IDI 6].

When a woman needs to be referred, the referral system is often unclear and difficult, with lack of communication, absence of functional emergency vehicle and accompanying health worker. Sometimes relatives hire private transport or pay for fuel, both of which delay care. Furthermore, there are lack of clear protocols as to who organizes transport and referrals. Often very sick women are transferred to a higher facility without prior communication creating friction between the two levels. Sometimes health workers at lower facilities hesitate to refer women to higher level as to avoid such situations.

Health workers' experiences were of being few with multiple responsibilities. Some described working in the delivery ward whilst also providing care of postnatal women (both vaginal and caesarean birth) as well as neonates. Most facilities have one or two midwives or nurse-midwives and auxiliary staff (medial assistants), who take on some of delivery work. In such situations both health workers and managers narrated that they cannot follow the required standard, because there is too much to do and little time, which ultimately affects the quality of care provided.

Some health managers had opposing experiences to those of health workers. For instance, health workers frequently complained of having a high number of patients such that they are unable to regularly assess and care for all, sometimes missing early PPH until it is severe. On the other hand, health managers, whilst agreeing that there are staff shortages, also reported that there are many instances when there are enough workers and yet some tasks are not performed.

### Theme 2. Women with PPH are prioritized

Health workers know PPH is a life-threatening emergency and they strive to be prepared and work together to save women with PPH despite the constraints. Examples include extending work hours to help manage a PPH case, using personal resources like mobile phones to call for help or organize blood donors for emergency transfusion.

"PPH is an emergency case...sometimes it happens when you least expect it. We prepare emergency trays like for PPH and preeclampsia with supplies like oxytocin, RL in facilities... when you are done using the tray on a patient you see you replace other things (supplies) on that emergency tray and prepare it for next case" [FGD 2]

Having a supportive immediate leader was perceived as motivating and helped health workers to manage the stressful situations in the maternity ward. Lack of supportive leadership affected their work and the care they give to women.

### 9 DISCUSSION

This thesis evaluated the effect of a capacity-building intervention; the *Helping Mothers Survive Bleeding After Birth* training on reducing PPH-related morbidities and mortality in a LMIC, while exploring the effects of contextual and implementation factors on outcomes. Following the four level Kirkpatrick framework for training evaluation we see i) positive perceptions of the training, ii) improved knowledge and skills, iii) better preventive and management practices of women with PPH and iv) reduced severe PPH morbidity and mortality. The effect on better practices and better maternal outcomes are small but encouraging.

### 9.1 THE TRAINING LEADS TO IMPROVED CLINICAL PRACTICE AND CLINICAL OUTCOMES

The analysis of the cluster-randomized trial shows a reduction in the number of women with PPH near miss among women with PPH in the intervention but not the comparison districts. A small reduction on PPH case fatality was observed in intervention clusters only. A higher proportion of women with PPH received intravenous oxytocin and less women were transfused in intervention clusters compared to comparison clusters.

The results imply that health workers recognize severe bleeding and early detection and management of PPH as crucial to prevent further decline, as has been reported in other studies [119, 125, 126]. The sister HMS BAB trial in Uganda also indicated that PPH near misses reduced in intervention districts compared to comparison districts after the training intervention [184]. In contrast to Tanzania, there was no reduction in mortality, perhaps due to the limited interventions available to women with severe PPH.

Other competency-based simulation training in maternal and neonatal health have reported improved clinical outcomes [116, 123, 171, 188-190] while others have reported that whilst knowledge and skills are improved, further research is needed on clinical outcomes [191, 192].

# 9.2 THE TRAINING LEADS TO BETTER KNOWLEDGE AND SKILLS THAT ARE RETAINED OVER 10-MONTH

Health workers' improved knowledge and skills following the training was not associated with level of experience, delivery caseload or place of work (facility level). Knowledge on AMTSL and some other aspects of PPH prevention and treatment was already high prior to the training, perhaps due to several other capacity building programs that had taken place in the country [124, 193] as well as pre-service education. There were major deficiencies in skills observed prior to the training. While this study cannot provide a definite answer, the low level of skills could be because of a true low skills level but also methodological constraints, e.g. providers are not used to OSCE assessment. Assessments carried out however, indicate that health

workers have low skill levels [50, 122, 194] which have also been documented also in reviews [45, 103].

Furthermore, auxiliary staff, although not formally accepted as skilled childbirth care providers, but sometimes charged with the responsibility of providing childbirth services, benefitted well from the training. They also showed higher skill decline than skilled health workers. This group accounted for approximately 19% of the health workers in the facilities we studied (**Table 9**). Although it is not advocated that unskilled workers conduct deliveries, there is clear documentation that in the context of shortages and unavailability of skilled attendants, auxiliary staff, most of whom are the medical attendants do perform deliveries [51, 140, 154]. Studies show that this cadre when mentored and given training; can perform deliveries where skilled providers are not available [195]. They can be supported to increase knowledge and skills in preventing and managing PPH [124].

Skill decline was observed at 10-months follow up; despite a decline, skills levels at 10-month were still above pre-training levels. Decline was higher in those less clinically active in assisting deliveries and in auxiliary staff. Similar findings are also reported by others [46, 103, 187, 196-199]. The decline observed was small and may not be significant at practice level. It is encouraging that almost a year after the training, health workers maintained learned skills to a large extent. This could be an effect of repeated simulated tests, but also the effect of frequent practice drills. Other factors associated with less decline of skills are refresher training [103, 187, 196, 199] and local mentoring programs.

The increased knowledge and skills, that were, on the whole, maintained in the intervention arms, were instrumental in the results that are reported in the main trial: less severe PPH, and more intravenous oxytocin used for the management of PPH. Even for the less obvious and non-significant results, such as fewer incidents of retained placenta, could be extrapolated from the skills gained during the training.

### 9.3 SUCCESS AND BARRIERS TO HMS BAB TRAINING INTERVENTION IMPLEMENTATION

There are few studies reporting on the implementation of simulation and competency-based training despite the importance in understanding the results of such trainings [200].

Health workers had positive perceptions on the HMS BAB training as an innovation. Health workers viewed the training as well-designed and having a good degree of fit with what they had learned before. The health workers perceived that the training raised their clinical standards and resulted in better maternal outcomes. Being trained together in-facility was advantageous in enabling staff to improve their multidisciplinary team working. Similar positive perceptions

were described by other health workers in Tanzania and Uganda following HMS BAB training [126, 185].

Conducting the training intervention in-facility was perceived as both a barrier and a facilitator to its implementation. In-facility delivery of the intervention made it possible for more staff to be trained and trained staff of different cadre as a team therefore enhanced multidisciplinary team working. Other health workers perceived that in-facility training were not ideal due to interruptions and dilemma of leaving patient care. Some health workers reported a preference for out-of-facility training as it is typically accompanied by incentives including interactions with staff from other facilities. In high income countries, one study reported no difference in the effectiveness of training whether performed as in-facility or out-of-facility [201]. This however need to be explored further in LMIC where getting health workers to a simulation laboratory or to a central training maybe a challenge and result in reducing the already few staff from their facilities. In-facility training however has been shown to improve additional aspects of maternity work such as communication and team work [103, 201]. There is a consensus that in-facility training needs better planning from the point of intervention conceptualization, to implementation and afterwards and further, to ensure that the training is more effective and acceptable [100].

Health workers can support or resist an intervention. In this case, health workers were motivated to participate in the training and the weekly skill drills to improve their skills. There were barriers that hindered health workers to participate fully, such as being too few during a shift. Additionally, having multiple tasks meant they could not allocate time to train or practice. Weekly practice drills therefore need to be planned and have allocated time so that staff can practice in a relaxed environment. When health workers are busy and overwhelmed they are unlikely to allocate time to train [191, 202, 203], therefore facility leaders need to provide support and time to allow health workers to learn.

Several health workers believed they should receive a reimbursement for the training and for the weekly drills, especially the peer practice facilitators who took their time to organize and lead the session. Giving money to training participants may increase participation, however, is unsustainable when the external support or researchers leave.

The local peer practice facilitator had an important facilitation role after the initial one-day training. They were responsible to organize and lead the weekly drills sessions that enhanced skills. The peer practice facilitators were local, accessible, flexible to plan and conduct weekly sessions. However, they felt a need for more training and support and were affected with staff movement and lack of monetary incentives. Choosing a facilitator with both clinical skills, commitment, as well as good interpersonal relationships, enhances the effectiveness and implementation of training initiatives [204].

There were several contextual barriers to the implementation of the HMS BAB training: movement of peer practice coordinators and staff turn-over, poor supervision and management, and shortages of drugs and supplies reported in Study I and IV. Blacklock et al. reported that when planning an intervention that aims to increase health workers' performance, contextual factors are a key consideration [205, 206]. A skilled health worker cannot perform without the supplies and support needed [203, 207].

The i-PARIHS framework was applied during the analysis to understand the implementation process, what has worked and why it has worked [200, 204, 208]. all the four constructs of i-PARIH framework are important in the success of an intervention such as HMS BAB training.

### 9.4 POOR HEALTH FACILITY READINESS FOR PPH-CARE

The HMS BAB is a single component intervention provided within the existing Tanzanian health system. The Tanzanian health system faces insufficiencies in all aspects of health facility readiness for PPH-care. Shortages of drugs, medical supplies and equipment, poor quality drugs, and lack of clear user-friendly protocols in accessible places are some of challenges that have been identified [51, 53, 56, 164, 207, 209]. Health workers are continuously faced with the need to save women during PPH emergencies whilst not having the needed supplies and drugs to do so. For example, we found only 22% of health facilities had an appropriate light source and speculum for assessing cause of bleeding, an important step for PPH management. Bintabara et al (2019) reported a slightly lower level than ours on a sample of facilities throughout Tanzania. Oxytocin availability was at 90%. Of note, in their study, however, many health centers did not stock the second and third line uterotonic drugs[164].

In the main trial [Study I]; a lower proportion of women with PPH received blood transfusion in intervention clusters. The study hypothesis was that the training resulted in health workers having improved skill that translated into better management to PPH, and hence the reduced need for blood transfusion. On average women received a median of 1-2 units of blood, which indicates its very restrictive use. In Study IV, health workers lamented on constraints faced due to fluctuating levels of blood supplies. Reviews in sub-Saharan African countries report the dire deficits of blood contribute to approximately 26% of PPH mortality and severe morbidities [48, 210, 211]. Lack of voluntary donors; high prevalence of infections such as syphilis, Human Immune-deficiency virus (HIV), Hepatitis B and C and lack of screening facilities at district level are underlying causes of the challenges faced by transfusion services [151, 211-213].

When referral was needed for more advanced care, the referral process was often unclear and stressful. We documented a lack of communication between facilities, a lack of appropriate health workers to accompany the patient during transfer, transporting the patient and lengthy travel as challenges faced when making referrals. These are common occurrences in the country and in other LMICs, where delays in appropriate and timely care are observed [64-66,

207, 214]. Sometimes health workers at the receiving facilities are irritated and argue with the referring facility. One can understand that they may also feel stressed as they face similar challenges to those found in lower facilities. Furthermore, only negative feedback is given. No feedback is given to the referring facilities on what happened to the woman they referred. Health workers described shortages in the number and skill levels of available maternity staff. Consequently, health workers feel overworked and overwhelmed by multiple tasks. As a result, they reported sometimes overlooking best practices to keep pace with work. There are many instances that the health workers described where they did not to use their knowledge and skills as desired as they needed to save time and survive the day. Similar challenges are reported in the country and in other LMICs where severe nurse-midwife shortages exist [45, 49, 143, 207, 215, 216].

Despite these challenges, health workers described several positive points which reflected that they work hard to find context specific solutions for the problems they face. For example, preparing emergency trays using their own funds, which are later reimbursed by women or families, mobilizing oxytocin from neighboring facilities with good stock and allocating a specific person to deal with transport during referrals.

The FGDs and interviews brought opposing views on some topics including i) workload and being overworked, ii) the acceptable or desirable number of personnel per shift and iii) rotation of staff. Some health managers were empathic to the health workers' situation while others perceived that there were adequate numbers of staff at the district level but agreed that health worker skills are not at the required level.

#### 9.5 METHODOLOGICAL CONSIDERATION

### 9.5.1 Measurement and magnitude of PPH maternal morbidity and mortality

The overall prevalence of PPH was found to be 2.5%. This level is lower than the 6-10% level documented in other studies, but perhaps reflects the methodology used in this study to measure blood loss. Studies that rely on clinical estimation of blood loss as well as use of *khanga* underestimate blood loss [23, 25, 217]. A very similar low PPH prevalence was recorded by Nelissen et al in Northern Tanzania, as well as in other studies [119, 184]. The low level of PPH may also be the result of AMTSL which was found to be consistently implemented.

To obtain the primary and secondary outcome indicators the WHO near miss tool was used [73]. The tool was modified slightly to suit study setting. It should be noted that any case where a woman received blood transfusion qualified to be a PPH-near miss due to resource challenges in the district. Such local adaptations have been made in Tanzania and in other LMICs [78, 79, 84]. The finding of near miss prevalence in this study was in line with other estimates reported for African countries [218-221]. A sister publication from the same HMS BAB trial, that combined Tanzania and Uganda data, reported near miss comparing different criteria and found

that compared to the standard WHO near miss definition, the locally adapted criteria resulted in higher but a more comparable incidence [87]. The overall PPH near miss incidence in this study was also within the range reported in other studies [75, 80]. PPH near miss contributed to approximately a third of all near miss and PPH case-fatality was also very high, similar to other study findings [75, 168, 222].

### 9.5.2 Assessment of change and predictors of health workers' knowledge and skills

To assess the determinants of changes in skills and competences[Study II], we used several health worker characteristics for which no internationally defined cut-offs are established; monthly caseload/number of deliveries and years of work experience. However, we took previous research into consideration [103, 196].

### 9.5.3 Pragmatic nature of the trial

The HMS BAB trial was implemented in a pragmatic way: Study I evaluated effectiveness of an intervention in typical clinical set-up. Pragmatic trials result in better applicability of results and generalizability than explanatory designs which test efficacy and are more controlled [223, 224]. Trials rarely have an explanatory or pragmatic design only, and usually there is a spectrum of dimensions that are considered using the Pragmatic–Explanatory Continuum Indicator Summary 2 (PRECIS-2) Tool [225, 226]. Typical districts in the country were enrolled and introduced an intervention to health workers in their own setting with no additional resources.

Another feature of pragmatism within the conduct of the trial was the use of data collectors from within the facility. The costs of the trial would have doubled if one would have employed external data collectors. External data collectors would have reduced any information bias introduced through the fact that the data collectors knew which facility received the intervention (although it would not have been easy to blind even to external data collectors). Most importantly, we cannot exclude that the training itself influenced the data collection. However, any external data collectors would have relied on what had been documented in case notes and the clinical estimation of PPH. Thus, while the costs of the trial would have doubled, it would not have been possible to exclude information bias.

After the training there was no other high-level involvement of support or coaching from the trainers. Instead, support was only provided by a facility mentor (peer practice facilitator). While such an approach clearly increases operational and financial sustainability, it also may reduce the effect of the training.

### 9.5.4 Fidelity of the HMS BAB training intervention

The HMS BAB training intervention was designed and conducted in a standard way for all participating clusters. It was a challenge to get all health workers to participate and be trained given the workload in the facilities and shortages of staff. A few health workers left the training to attend other duties. Similar challenges in allowing staff to be trained during work hours and on-site have been reported in other LMICs [191].

Apart for the initial one-day training, facilities continued to have weekly practice drills under their local peer practice facilitators. There was flexibility in the organization of the weekly practice drills. To ensure that these drills were performed, each facility documented the sessions in a logbook, indicating the number of staff who took part and the frequency of weekly drills. Three quarters of facilities completed the weekly drill sessions within the required time, while other facilities took longer. It is, however, difficult to ask health workers to take time during a busy workday and practice consistently on a weekly basis. Only those committed will do so and sustaining this in the long term may not be possible. Some authors have reported that not allocating specific time to skill drills, and having few spaced out drills can explain the lack of clinical outcomes in some settings [202, 227].

### 9.5.5 Validity

All the studies were performed in typical rural districts with patients and caregivers who are the usual users of the health system hence results are generalizable to the country setting. Including districts from two different geographic regions of the country increased generalizability. The setting and the pragmatic implementation of the trial in "real life" further maximizes generalizability [224, 226].

The Cluster-randomized design of Study I offered the possibility to estimate the effect of training adjusting for other secular improvements or change. This increased the validity of our results. Blinding was not possible due to the nature of the intervention. To reduce bias, the districts were matched using near miss events reported at baseline before randomization was performed.

There were observed changes in facility readiness such as increased PPH protocols between comparison and intervention clusters at baseline and the post intervention period, however the changes were in both groups. Blood availability improved slightly during the post intervention period in both trial arms [Study I]. Changes in service provision are typically seen in settings where there is a need for fast development and a major need to improve services. Moreover, there were other national efforts being implemented while this study took place. For example, the operational implementation of blood transfusion services changed during the conduct of the study from the zonal to the district level [228].

Health facility data and near miss data are not generally accepted as reliable estimates, although this paradigm is challenged [229]. To review the reliability of the reported near miss data we requested an independent review which was carried out in July 2016. The report indicated high correlation of near miss cases being reported by data collectors and facility records and information recorded in case file. We standardized the training of data collectors and HMS district trainers and conducted refresher training to maintain standards.

For Study II, use of same tools during the three-point assessment might have introduced bias. Other authors have used similar tools in before and after designs in the past with similar results. Having a comparison group would have improved the design or the study. We could only follow up one subset of health workers, which could have introduced bias as those who were reassessed had better scores. However, a sub-analysis to compare scores of those followed up and those who were not available for follow up showed no difference.

### 9.5.6 Trustworthiness in qualitative studies

Trustworthiness, or rigor, refers to how true the results of a study are, and how they can be judged in relation to the methods and processes used to generate them [230, 231]. Terms used while assessing trustworthiness in qualitative research are transferability, dependability and credibility.

Transferability refers to the extent to which study findings from the selected participants can be transferred to other settings [230, 232]. Studies III and IV were performed in four purposefully selected clusters out of the ten intervention clusters, each region was included. Participating health workers and managers had knowledge and experience of the intervention and of the facility readiness in their daily life. The settings reflected typical rural districts although there were some differences in interactions and other organizational aspects. The participants for FGDs were selected to ensure variability in the data, however this was not always possible in facilities with few staff. Hence, we think study findings may be transferred to the regions and country given the similar health system in the country. The findings from Study IV of inconsistent availability of supplies for care, health worker shortages have been reported from other quantitative and qualitative studies all over the country [51, 53, 163, 207]. Findings from Study III can be used as lessons to reflect on when planning for intervention in similar areas.

Credibility refers to how accurately the findings reflect the participants' perception and experiences [231]. Studies III and IV enabled participants to share their experiences of their working environment as well as of the intervention implementation. Study IV explored the experiences of managers and health workers. Using these two groups enhanced data richness and allowed for different realities to be considered. The two groups were separated so health workers could speak freely about their work environment without fear of being reprimanded later. Health managers were also able to speak on their perceptions weighing aspects of

interactions and behaviour. Findings from the FGDs and interviews were triangulated and compared to quantitative studies, and it was found that findings matched to a large extent. The number of FGDs and interviews required was determined before they took place, however during the process of analysis data saturation was reached during data collection.

Reflexivity is an important part of qualitative research where the researcher's experiences may influence research questions, data collection as well as analysis. The PhD student is an obstetrician gynaecologist and is active in clinical practice. She led the HMS BAB trial implementation in the country and provided insights on some quantitative findings, which in turn, inspired questions on health facility preparedness and on implementation. The PhD student facilitated some of the FGDs and conducted interviews with help from two researcher assistants. This was taken positively by the health workers who felt free to discuss their experiences and make recommendations for change. Having one of the HMS BAB researchers facilitate the FGDs could be seen to introduce bias into the discussion, as participants may have felt obliged to provide socially acceptable answers. However, this was not observed in the study. The PhD student visited the facilities many times and met with the health workers, managers and data collectors during supervision and training visits. This helped in having a good rapport and facilitated organization of the FGDs.

### 10 CONCLUSION

- The HMS BAB one-day competency-based training with weekly drills led by peer practice facilitators is effective in reducing PPH- related morbidities and mortality outcomes immediately after the training, and the effect is sustained over time. [Study I]
- Health workers acquired knowledge and skills, with a small but significant decline after 10-months. Few health worker characteristics such as profession, years of experience and delivery load were associated with decline of skills. [Study II]
- The training was well perceived by health workers. Implementation challenges
  included organization of the training and weekly practices in an environment where
  overwhelming clinical duties exist. The local peer facilitators enhanced learning but felt
  they needed more support. Organizational factors like staff movements, were also seen
  as barriers to regular practice. [Study III]
- Inconsistencies in all components of health facility readiness affect provision of quality care to women with PPH. These inconsistencies extend beyond the availability of drugs, equipment and human resources, to include leadership, communication skills, and referral processes. [Study IV]

### 11. IMPLICATION FOR PRACTICE

One recommendation is to upgrade the content of the training to include additional life-saving skills such as use of an intrauterine balloon catheter and use of tranexamic acid; this has already been incorporated in the HMS BAB-Complete module[127]. In addition, future training should consider all other components of health systems for a greater impact.

### **Implication for future research**

Recognize context including health systems and human interaction in the design of interventions to support and improve health workers' practices in LMIC

- To better characterise the limitations of equipment and supplies, referral and human interaction and its effect on health workers practices
- To design and evaluate intervention packages that more strongly adress health system constraints as well as the shortcomings in human interactions such as leadership and teamwork

Evaluate further how best to support and improve health workers' practices in LMIC

- To evaluate the HMS BAB and other training interventions using theory driven process evaluation to better understand facilitators and barriers of intervention outcomes.
- To determine the cost effectiveness of in-facility training interventions

### Implication for clinical practice

- Include regular on-site training including drills.
- Revise schedules and rotations in a way that allows for protected time for all health workers to participate in such training and practice drills.
- Integrate approaches beyond training, such as quality improvement or other groupsolving approaches to address problems in team work and readiness to manage complications.
- Outline local standard operation procedures, protocols or checklists for PPH management, referral and communication.
- In the COVID-19 era, encourage use of online training materials accessible to health workers.

### **Implication for Policy**

- Increase the number of health workers to appropriate levels.
- Include mechanisms of continious education and quality improvement into human resource management.
- Improve availability of equipment, supplies and other consumables to levels that allow health workers to implement evidence-based practices

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# 14. APPENDICES

### 14.1 APPENDIX 2. NEAR MISS QUESTIONAIRRE

Module 1 "Daily Birth Reco	rding" (all birth in delivery ward)
Facility code	
Mode of delivery	LCVE/SVD/CS/Breech/Other
Any induction /augmentation	on of labour? Yes/No
Parity	
Gestational age in weeks	
Number of babies	Singleton/Twins/Triplets
Report the babies outcome	(if twins or triplets the outcome of the first twin)
Babies outcome?	SBM SBF Alive
Oxytocin given?	Yes/No
Estimate the blood loss in te	erms of kangas soaked:
No of Kangas soaked	
Any complication recorded?	? Yes/No
Module 2 (Screening questi	ions)
Q: Facility code	
Age	
Parity	
Gravidity	
Place of living: District	
Ward	
Village	
Screening questions	
<del>-</del>	question (1-4) below, please answer 1) if the condition was present at arrival or within
12 hours,	was not present during the stay
	entially life-threatening conditions
A 0 Any postpartu	
A 1 Severe preecla	ımpsia
A 2 Severe eclamp	
A 3 Sepsis or sever	
· ·	on complications
	rtum haemorrhage
2. Critical interventions or inte	ensive care unit admissions
B 1 use of blood p	roducts (includes any blood transfusion) How many:
B 3 Laparotomy	
3. Organ dysfunction /life thre	_
	llar disfunction cardio-pulmonary resuscitation, severe acidosis- ph<7.1)
C 1 Respiratory	
	vanosis, gasping, severe tachypnoea -respiratory rate >40bpm,
	ypoxemia (O2 saturation < 90% for > 1 hour)
C 2 Renal dysfu	nction not responsive to fluids or diuretics, creatinine >300umol/ml or 3,5mg/dl)

C 3	Coagulation / hematologic dysfunction  (failure to form clots, massive transfusion of blood cells, or									
	severe acute thrombocytopenia					or				
C 4	Hepatic dysfunction									
	(Jaundice in the presence of pre-eclampsia,									
C 5	severe acute hyperbilirubinemia - >100umol/L or > 6mg/dL)									
	Neurologic dysfunction  (prolonged unconsciousness / co	ma (la	sting	>12 ł	nours).	strok	e. sta	itus ei	oilenticus /	
	(prolonged unconsciousness / coma (lasting >12 hours), stroke, status epilepticus / uncontrolled fits, total paralysis)									
C 6	Uterine disfunction /hysterectomy	~ + o h	· ·ctor	0.et 0.n	a\					
4. DAntownal dans	(haemorrhage or infection leadin	ig to n	yster	ecton	пу)					
4. Maternal dea	1	ancv o	r with	ain 42	) days a	ofter t	armii	nation	of pregna	ncv
	D 0 Deaths during pregnancy or within 42 days after termination of pregnancy D 1 Death after 42 days of termination of pregnancy									
Ple	ase note:					,				
	f you answered "1, 2" or "3" to any of t	he qu	estio	ns 1 to	o 4, go	to qu	estio	ns 5		
	f you answered "0" to all the question	s 1 to	4, the	won	nen is r	not eli	gible,	, do n	ot answer a	any other
•	estions (5-14)						,	c		
	n case you doubt on questions 1 to 4, In the question 5-14, if information is I					-				۵"
	erinatal Information	iot av	allabi	e, um	KIIOWII	01 110	r app	nicabi	C IIII WILII .	9
		d	d	m	m	20	у	у		
5. Date of hospit	tal/facility admission					20				
6. Date of delivery or uterine evacuation						20				
7. Date of hospit	tal discharge or deaths					20				
7 b: If women ha	d haemorrhage or blood transfusion p	lease	also	entre	the Hb	at di	schar	ge (g/	dl)	
8. Please specify	y the final mode of delivery / end of p	regna	ncy							E 3
1 =	-0 1			-	LCVE	_ 4				
2 = 3 =		Caesarean section 6= Laparotomy for ectopic pregnancy Complete abortion 7= Laparotomy for ruptured uterus								
4 =				8=	-			-	died still p	regnant
					9=		now		·	J
Module 3 "Near										
9. Please check i	n the records the best estimate of ge		_	-	-		veeks	(obs		onatal) at:
	Delivery or abortion (r	-	-			-		-	E 4	
	Maternal deaths or hospital dis	charge	e (app	olicab	le if Q 8	8="8")	)		E 5	
10. Please indica	ate the vital status of the infant (if twi	ns, ind	dicate	outo	ome o	f first	twin	) ; O=	Alive 1 = De	ead
				1=						
at birth		E 6	fr	esh /	macer	ated s	stillbi	rth/no	ot recorded	<u> </u>
after 24 hours	to disabellar and an 74h day of life	E 7				J				
· ·	ty discharge or 7th day of life	E 8				1 = 0				
Please give the b	oirth weigh birthweight					E 9				
Please try to che	eck all forms to get the following infor	matio	n on	nroce	ess indi	icator	·c			
<del>-</del>	ate whether any of the following appl			-				arrival	in the faci	lity/ referral
process,	ate whether any or the following appr	103 00	icci ii	B t.	ic com	uitioii	Julu		iii tiic iaci	iity, reierrai
specify: 0 = no; 1	L = yes									
F 0 Delivery or abortion occurred before arrival at facility										
F 1	F 1 Delivery within 3 hours of arrival in the health facility									
	F 2 Laparotomy within 3 hours of hospital arrival or in another hospital									
F 3	Women referred from other healt	h facil	ity							

	F 4	Women referred to any highe	r-level facili	ty		
		Name of referral facility				
12. Please i	ndicate	whether any of the below mer	ntioned inte	erventio	ns ha	ve been carried out (specify 0=no; 1=yes))
Preventi	on of po	ostpartum haemorrhage				
					Oth	er
	G 0	Oxytocin		G 1	ute	rotonic
Treatme	1	stpartum haemorrhage			_	
	H 0	Oxytocin		H 5		noval of retained products
	H 1	Other uterotonics		H 6		oon or condom tamponade
	H 2	Misoprostol		H 7		ery litigation (uterine/hypogastric)
				H 8	-	terectomy
				H 9	Abo	dominal packing
Anticonv	<u>ulsants</u>			=		
	10	Magnesium sulphate		11	Ot	her convulsant
Antihype	ertensiv	es				
	12	Hydralazine		13	Alc	domet
Antibioti		,				
	10	Prophylactic antibiotics durin	ng caesarear	n section		
	J 1	Parental, therapeutic antibio	_			
Fetal lun	g matur	ration				
	ΚO	Corticosteroids (betamethase	one or dexa	methaso	ne)	
	_					
Please spec	ify any	underlying causes of deaths / N	Near Miss	please sp	ecify	y 0= No; 1 = yes
	LO	Pregnancy with abortive outco	ome (aborti	on/ector	oic pr	regnancy)
		0 ,	, Ī	,	L	<i>C</i> ,,
	L1	Obstetric haemorrhage			5	Medical/surgical/mental disease and complications
	1				L	
	L 2	Hypertensive disorders			6	Unanticipated complications of management
					L	
	L3	Pregnancy-related infections			7	Coincidental condition
					L	
	L 4	Other obstetric diseases/ com	plications [		8	Unknown
Dlease snec	ify any	other known contributory / ass	sociated co	nditions	nlası	se specify 0- No: 1 - yes
riease spec	MO	Anaemia	sociated coi	iluitions	picas	se specify 0- No, 1 - yes
	M 1	HIV infection				
	M 2	Previous caesarean section				
	M 3	Prolonged/obstructed labour				
	1		nlease er	ocifi.		
	M 4	Other condition	please spe	-		
	M 5	Other condition	please spe	ecify		

# 14.2 APPENDIX 3. FOCUS GROUP DISCUSSION TOPIC GUIDE [HEALTH WORKERS]

Part 1: Focus Group Discussion Topic Guide [Health workers] on PPH-care

We know that PPH can happen at any time, requiring prompt action from health-providers, supplies and medication and resource mobilizations. I will like you to remember the last case of postpartum haemorrhage managed in your facility.

- 1. Could you share your experience in managing this case?
- 2. Can we talk about medical supplies and drugs needed for PPH What is your experience in getting them when needed?
- 3. What has been the experiences when you have needed blood and blood products in an emergency situation like PPH.
- 4. Perhaps most of us have at one time referred a woman with postpartum haemorrhage to a higher-level facility.
- 5. Can you talk a bit about the way you interact with facility administrators?
- 6. We learned that rotation of staff is at times a problem. What has been your experience on staff rotation?

#### Part 2: Health providers experiences on HMS BAB in-facility training

We conducted an intervention in form of a training "HMS BAB competency and simulation based in-facility training". The aim was to assess impact on severe PPH related near miss. You or staffs in your facility were involved in this training either in Jan 2016.I will like to take the next hour to discuss few things on the training

- 1. From your point of view, What was good about the training
- 2. What was not so good and what should be changed
- 3. Some of you had an opportunity to be clinical mentors, or participated in the weekly sessions. In your opinion how will you describe the sessions and why
- **4.** What will be your recommendation on the rolling out of such training in the country, will it be helpful or not, why do you think so

#### 14.3 APPENDIX 4. IN-DEPTH INTERVIEW GUIDE FOR HEALTH MANAGERS

- 1. In your opinion, why is postpartum haemorrhage still a problem in the area?
- 2. We stress that we need providers with skills and knowledge for emergency obstetric conditions including PPH. To this the ministry and stakeholders have and are training a lot. In your opinion have these trainings helped in terms of better care? Why? How? Do you have a record of those trained? How are they accountable?
- 3. We saw that there is staff rotation between different sections, what has been your experience as an administrator?
- 4. Some providers have reported high burn out working in the labour ward and stress due to high load and high blame area, have you come across such issues? What have you done?
- 5. Can we discuss the challenges of blood availability and use in your district?
- 6. I will also like to know a little bit more on timely availability of drugs and medical supplies including oxytocin and misoprostol.

## 14.4 APPENDIX 1 HMS BAB TRIAL PROTOCOL PAPER