Safe Motherhood

Improving maternal outcome in rural Tanzania using obstetric simulation-based training
Improving maternal outcome in rural Tanzania using obstetric simulation-based training

ACADEMISCH PROEFSCHRIFT

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TABLE OF CONTENTS

Abbreviations 7
Glossary 8
Chapter 1 Introduction 11
  1.1. Aim and scope of this thesis 12
  1.2. Background 13
  1.3. Research design 26
  1.4. Outline of this thesis 31

PART 1 - MATERNAL MORBIDITY AND MORTALITY IN A RURAL HOSPITAL IN TANZANIA

Chapter 2 Maternal near miss and mortality in a rural referral hospital in northern Tanzania: a cross-sectional study 41
  *BMC Pregnancy and Childbirth. 2013;13:141*

Chapter 3 Applicability of the WHO near miss criteria in a low-resource setting 61
  *PLoS One. 2013 Apr 16;8(4):e61248*

PART 2 - AN EDUCATIONAL INTERVENTION TO REDUCE MATERNAL MORBIDITY AND MORTALITY

Chapter 4 Helping mothers survive bleeding after birth: an evaluation of simulation-based training in a low-resource setting 81

Chapter 5 Retention of knowledge, skills, and confidence after simulation-based training in obstetric care: an educational intervention study 101
  *<under review>
### Chapter 6
The impact of simulation-based training in obstetrics on clinical behaviour and patient outcome: an educational intervention study
*under review*

### Chapter 7
General discussion and conclusion

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1. Aim and research questions</td>
<td>138</td>
</tr>
<tr>
<td>7.2. Main findings and conclusions</td>
<td>138</td>
</tr>
<tr>
<td>7.3. General conclusion</td>
<td>151</td>
</tr>
<tr>
<td>7.4. Internal validity</td>
<td>153</td>
</tr>
<tr>
<td>7.5. External validity</td>
<td>155</td>
</tr>
<tr>
<td>7.6. Future research</td>
<td>156</td>
</tr>
</tbody>
</table>

### Summary

- Muhtasari: 169
- Samenvatting: 173
- Acknowledgements/Dankwoord: 177
- Publications: 182
- Safe motherhood series: 183
ABBREVIATIONS

AAP: American academy of paediatrics
ACNM: American college of nurse-midwives
ACOG: American college of obstetricians and gynaecologists
ALSO: Advanced life support in obstetrics
AMTS: Active management of third stage of labour
ANC: Antenatal care
BMI: Body mass index
BUC: Bimanual uterine compression
CFR: Case fatality rate
CI: Confidence interval
COSTECH: Tanzania commission for science and technology
CPR: Cardiopulmonary resuscitation
FIGO: International federation of gynaecology and obstetrics
HBB: Helping babies breathe
HIV: Human immunodeficiency virus
HLH: Haydom Lutheran Hospital
HMS BAB: Helping mothers survive bleeding after birth
ICM: International confederation of midwives
ICU: Intensive care unit
IV: Intravenous
LB: Live births
MCHIP: Maternal and child health integrated programme
MD: Maternal death
MDG: Millennium development goal
MMR: Maternal mortality ratio
MN: Maternal near miss
MW: Maternity ward
NIMR: Tanzania national institute for medical research
PPH: Postpartum haemorrhage
SD: Standard deviation
SMOR: Severe maternal outcome ratio
SOFA: Sequential organ failure assessment
UNFPA: United nations population fund
VUmc: VU university medical centre
WHO: World health organization
WLTC: Women with life-threatening conditions
GLOSSARY

**Cardiac arrest**: loss of consciousness and absence of pulse or heart beat

**Case fatality rate**: the number of maternal deaths divided by the number of women with life-threatening conditions, expressed as a percentage \([\text{CFR} = \frac{\text{MD}}{(\text{MNM} + \text{MD})}]\)

**Eclampsia**: the presence of hypertension associated with proteinuria and fits. Hypertension is defined as a blood pressure \(\geq 140 \text{ mmHg (systolic)} \) or \(\geq 90 \text{ mmHg (diastolic)}\). Proteinuria is defined as excretion of \(\geq 300\text{ mg protein/24hr}\) or \(300\text{ mg protein/litre urine}\) or \(\geq 1+\) on a dipstick

**Failure to form clots**: the absence of clotting from the IV site after 7-10 minutes

**Intra hospital WLTC cases**: the number of women with life-threatening conditions (WLTC) who developed these life-threatening conditions in the hospital

**Intra hospital WLTC rate (per 1,000 live births)**: the number of women with life-threatening conditions who developed these life-threatening conditions in the hospital per 1,000 live births

**Intra hospital mortality index**: the number of maternal deaths who were not ill on arrival, divided by the number of women with life-threatening conditions who were not ill on arrival, expressed as percentage

**Live birth (LB)**: the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life. Each product of such a birth is considered live born.

**Maternal death (MD)**: the death of a woman while pregnant or within 42 days of termination of pregnancy from any cause

**Maternal mortality ratio (MMR)**: the number of maternal deaths per 100,000 live births

**Maternal near miss (MNM)**: a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy

**Maternal near miss incidence ratio**: the number of maternal near miss cases per 1,000 live births. \([\text{MNM IR} = \frac{\text{MNM}}{\text{LB}}]\)
Maternal near miss : mortality ratio: the proportion between maternal near miss cases and maternal deaths [MNM : 1 MD]

Oliguria: urinary output <30ml/hour for 4 hours or <400ml/24hr

Pre-eclampsia: the presence of hypertension associated with proteinuria. Hypertension is defined as a blood pressure ≥ 140 mmHg (systolic) or ≥ 90 mmHg (diastolic). Proteinuria is defined as excretion of ≥ 300mg protein/24hr or 300mg protein/litre urine or ≥ 1+ on a dipstick.

Proportion WLTC at arrival among all WLTC: the number of WLTC who are ill on arrival divided by the total number of WLTC

Proportion of WLTC at arrival coming from other hospitals: the number of WLTC who are ill on arrival and coming from another hospital divided by the total number of WLTC at arrival

Sepsis: a clinical sign of infection and three of the following: temperature > 38°C or < 36°C, respiration rate > 20/min, pulse rate > 90/min, white blood cell count (WBC) > 12

Severe maternal outcome (SMO): the number of maternal near misses and maternal deaths combined, also called women with life-threatening conditions [SMO = MD+MNM]

Severe Maternal Outcome Ratio (SMOR): the number of women with life-threatening conditions per 1,000 live births [SMOR = (MNM+MD)/LB]

Shock: persistent severe hypotension, defined as a systolic blood pressure < 90 mmHg for 60 min with a pulse rate of ≥ 120/min despite aggressive fluid replacement (> 2,000 ml)

Stroke: a neurological deficit of cerebrovascular cause that persists ≥24 hours, or is interrupted by death within 24 hours

Unconsciousness/coma lasting >12 hours: a profound alteration of mental state that involves complete or near-complete lack of responsiveness to external stimuli or Glasgow Coma Scale < 10

Uncontrollable fit: a condition in which the brain is in state of continuous seizure

Uterine rupture: the complete rupture of a uterus (including peritoneum) with (partial) extrusion of the fetus during labour
Women with life-threatening conditions (WLTC): the sum of maternal near miss and maternal deaths [WLTC = MNM+MD]

Women with life-threatening conditions at arrival mortality index: the maternal deaths within 24 hours after arrival divided by the number of women with life-threatening conditions who were ill on arrival, expressed as percentage. [WLTC at arrival MI = MD24/[WLTC at arrival]]
CHAPTER 1

INTRODUCTION
1.1. AIM AND SCOPE OF THIS THESIS

Recent estimates suggest that in 2013 more than 290,000 women died worldwide during pregnancy, childbirth, or within one year after termination of pregnancy (1). Most maternal deaths occurred in low-resource settings (1-4). Despite the decline in maternal mortality since 1990, it seems likely that many countries will not meet Millennium Development Goal (MDG) 5: a reduction of the maternal mortality ratio (MMR) by three quarters from 1990 to 2015 (1-5). Several issues contribute to the high MMR in low-income countries such as delay in deciding to seek care, delay in reaching an adequately functioning health facility, and delay in receiving adequate care once arrived at health facilities (6). Numerous factors cause delay in receiving adequate care at the health facility. Firstly, evidence-based interventions to manage complications during pregnancy, childbirth, and puerperium are not well implemented (7, 8). Secondly, there is a human resource crisis: less than half of the births in low-income countries are assisted by skilled providers (9). In addition to that, healthcare providers who are present have a relatively low level of knowledge and skills (10-13), and opportunities for training are lacking (10, 14). Whilst simulation-based training is known to effectively improve knowledge and skills of healthcare workers (15, 16), it is rarely implemented in low-resource settings.

In order to prevent maternal deaths in health facilities it is important to understand the scale of maternal mortality at health facilities and to identify opportunities to improve the quality of obstetric care. Whilst prevention of maternal mortality needs to be targeted at many levels, one approach that could help improving the quality of obstetric care is the introduction of in-house obstetric simulation-based training. As it is a new approach to teaching for many low-income countries it should be evaluated thoroughly and adapted accordingly before widespread dissemination.

The aim of this thesis is two-fold. The first aim is to describe the quality of obstetric care in a hospital in a low-resource setting and to identify opportunities to improve care. The second aim is to evaluate the effectiveness of low-cost low-tech obstetric simulation-based training in a low-resource setting as a way to improve quality of obstetric care.
1.2. BACKGROUND

In this section the global burden of maternal mortality and severe maternal morbidity will be addressed. The WHO near miss approach will be introduced as a new method to measure severe maternal morbidity, and the reason why mothers (nearly) die will be further explored, including the lack of in-house training opportunities for healthcare workers in low-resource settings. Next, the concept of simulation-based education is presented with an overview of its effectiveness in the field of obstetrics. It finishes with the introduction of a new low-cost low-tech obstetric simulation-based training programme for low-resource settings.

**Burden of maternal mortality**

The burden of maternal mortality is not evenly distributed throughout the world, and even within countries great disparities exist. More than 99% of all maternal deaths occur in low-income countries (Figure 1.1) (1). When comparing the MMR in the Netherlands (7 maternal deaths per 100,000 live births) with the MMR in Tanzania (390 maternal deaths per 100,000 live births) the difference between high- and low-income countries becomes clear (1).

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**Figure 1.1. Global maternal mortality ratio (maternal deaths per 100,000 live births) in 2013 (17)**
Although in recent years much progress in reducing maternal mortality has been made (1-4), it has not been sufficient for many regions to meet the target of MDG 5 (5). Part of the decline may be caused by improved methodology to estimate the MMR. Worldwide there has been an estimated annual reduction of the MMR of 1.3% since 1990, which corresponds to a total decline of 29.9% (1). Regions that have not been making progress are mainly located in sub-Saharan Africa and South Asia, of which Southern Africa has been performing worst. Their MMR has actually increased on average by 2.7% per year for the past 23 years (1). The MMR increased from an estimated 151 in 1990 to an estimated 490 in 2003. This increase can mainly be attributed to the AIDS epidemic that hit sub-Saharan Africa, and especially Southern Africa (18). Many women in the reproductive phase of their lives were infected with HIV and died due to complications of AIDS before widespread therapy was introduced. In the past ten years the MMR in Southern Africa declined again to an estimated 280 in 2013 (1). Tanzania has achieved a reduction from an estimated 498 maternal deaths per 100,000 live births in 1990 to an estimated 390 maternal deaths per 100,000 live births in 2013 (1). This corresponds to a total reduction of 25.3%, far from the 75% reduction the world committed to in MDG 5 (1).

Severe maternal morbidity
While maternal mortality on a global scale is an important problem, actual numbers of maternal deaths in individual hospitals are low. Severe maternal morbidity occurs more frequently than maternal mortality and can have a significant impact on a woman’s life. In order to study hospital-based quality of obstetric care it is important that severe maternal morbidity should be considered in addition to maternal mortality (19). Women who eventually die first go through a phase of severe maternal morbidity. Therefore, it is presumed that women who experience severe maternal morbidity share similar characteristics to women who die (20).

Two systematic reviews determining the prevalence of severe maternal morbidity showed that many studies used different identification criteria, such as disease-based, management-based, or organ system-based criteria (21, 22). Depending on the identification criteria, the prevalence of severe maternal morbidity changed. The prevalence was highest when disease-based criteria (such as eclampsia, major obstetric haemorrhage, and sepsis) were
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<table>
<thead>
<tr>
<th>Table 1.1. WHO near miss criteria (24)</th>
</tr>
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<tbody>
<tr>
<td><strong>Clinical criteria</strong></td>
</tr>
<tr>
<td>Acute cyanosis</td>
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<td>Gagping</td>
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<td>Respiratory rate &gt; 40 or &lt; 6/min</td>
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<tr>
<td>Shock</td>
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<td>Oliguria non responsive to fluids or diuretics</td>
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<td>Failure to form clots</td>
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<td>Loss of consciousness lasting &gt; 12h</td>
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<td>Cardiac arrest</td>
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<td>Stroke</td>
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<td>Uncontrollable fit/total paralysis</td>
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<td>Jaundice in the presence of pre-eclampsia</td>
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<tr>
<td><strong>Laboratory-based criteria</strong></td>
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<td>Oxygen saturation &lt; 90% for ≥ 60 minutes</td>
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<tr>
<td>PaO2/FiO2 &lt; 200 mmHg</td>
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<tr>
<td>Creatinine ≥ 300 μmol/l or ≥ 3.5 mg/dL</td>
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<tr>
<td>Bilirubin &gt; 100 μmol/l or &gt; 6.0 mg/dL</td>
</tr>
<tr>
<td>pH &lt; 7.1</td>
</tr>
<tr>
<td>Lactate &gt; 5 mEq/mL</td>
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<tr>
<td>Acute thrombocytopenia (&lt; 50,000 platelets/ml)</td>
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<tr>
<td>Loss of consciousness and ketoacids in urine</td>
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<tr>
<td><strong>Management-based criteria</strong></td>
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<tr>
<td>Use of continuous vasoactive drugs</td>
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<tr>
<td>Hysterectomy following infection or haemorrhage</td>
</tr>
<tr>
<td>Transfusion of ≥ 5 units of blood</td>
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<tr>
<td>Intubation and ventilation for ≥ 60 minutes not related to anaesthesia</td>
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<tr>
<td>Dialysis for acute renal failure</td>
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<td>Cardio-pulmonary resuscitation</td>
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See glossary for definitions

The goal of a universal definition of maternal near miss is that results can be compared across settings and over time. They should be applicable in any setting, regardless of the development status. Lastly, there should be a high threshold for the inclusion of cases in
order to reduce the burden for healthcare workers in charge of the data collection (24). The WHO near miss criteria were validated in Brazil and Canada and showed to have a high specificity and sensitivity for the identification of maternal near miss cases (20, 24, 25). However, the applicability of the WHO near miss criteria in low-resource settings is unknown.

**WHO near miss approach**

The development of the WHO near miss criteria led to the formation of the maternal near miss approach for maternal health (26). This is a guide on how to monitor, evaluate, and improve the quality of care for severe pregnancy complications based on criterion-based clinical audit (26). Audit is a proven intervention to reduce severe maternal morbidity and mortality (27-29). A criterion-based clinical audit consists of five consecutive steps that form a cycle (Figure 1.2) (7). In the first step criteria for best practice are established. For example, every woman should receive 10IU oxytocin as prophylaxis for postpartum haemorrhage (PPH) immediately after birth (30). During the second step current practice is measured. The WHO near miss approach uses the WHO near miss criteria for the identification of women with severe maternal morbidity which provides a baseline assessment of the quality of obstetric care. Thirdly, current practice is compared to ideal practice as established in the first step. The fourth step is to implement actions to achieve improvement in the quality of obstetric care. In the last step, reassessing practice perpetuates the cycle. The WHO near miss approach can be implemented in facilities to systematically assess and adjust the quality of obstetric care.

**Why do mothers (nearly) die?**

As described before, the burden of maternal mortality is considerable but does not explain why mothers (nearly) die. Delay in receiving good quality healthcare is perceived to be an important contributing factor to poor maternal outcome (31). The three delays model described by Thaddeus and Maine can be used to understand this problem (6).

Phase one concerns delay in deciding to seek care. Firstly, there may be delay in recognising danger signs of deteriorating health (32). This may occur when women do not attend antenatal care, or if they have not received health education about pregnancy during
antenatal care. Secondly, the decision to go to a health facility is made not only by the woman herself, but also often by her husband and her family. In sub-Saharan Africa, it is frequently the woman’s husband or the mother-in-law who decides where a birth takes place (33, 34). Waiting for permission to seek care may cause unnecessary delays. Thirdly, the distance a woman needs to travel to the health facility is very important in the decision to attend a health facility. The further the distance the less likely she will deliver at a health facility (33-35). Moreover, religion, level of education, previous healthcare experience, socio-economic empowerment, or a combination of these factors may influence the decision to go to a healthcare facility (33, 34, 36).

Figure 1.2. Audit cycle

Phase two concerns delay in reaching a health facility. This mainly regards infrastructure, transport, and the distribution of healthcare facilities (37). In Northern Tanzania, few basic emergency obstetric care units exist (1.6 units/500,000 people) in comparison with a relatively high availability of comprehensive emergency obstetric care units (4.6 units/500,000 people) (38). However, the distribution of health facilities throughout Northern Tanzania is uneven and shows that most facilities exist in urban areas (38).
Phase three concerns delay in receiving adequate care at the health facility. Many determinants of phase three delay are described. There may be a lack of diagnostic facilities (such as foetal monitoring and use of partograph) and/or treatment facilities (such as blood transfusion and caesarean section) (39, 40). The most important problem, however, is lack of human resources (10, 40, 41). Neonatal and maternal mortality are inversely associated with coverage of skilled birth attendance (39, 42). In Tanzania, the government spent 10% of their minimal 2012/2013 budget on health, which may explain an important part of the problem: lack of investment (43). On average there are 3.9 doctors and nurse-midwives per 10,000 Tanzanians, with three times as many healthcare workers working in facilities in urban areas than in rural ones (44). Because of lack of human resources and therefore a high workload, healthcare workers experience a disabling working environment (33, 40). They loose commitment and motivation, and this may result in poor attitudes of personnel towards patients (33, 40, 45) which influences not only current, but also future care. When patients perceive bad quality of care, it is likely that next time they will not return to the health facility (33, 34, 40, 45). Women would even bypass a nearby health facility to go to a hospital further away if the quality of care in that hospital is perceived to be better (41).

A factor that adds to the delay of receiving adequate care in health facilities is the relatively low level of knowledge and skills of healthcare workers (10-13). Audit suggests that training can improve care and reduce maternal morbidity and mortality (28, 46-48), but in-house training opportunities rarely exist (10, 14). In high-resource settings simulation-based training is increasingly used to train healthcare providers in obstetric emergency care (49-55). It can easily be adapted to pre-service and in-service settings, thereby providing a continuum of training throughout a professional career.

Simulation-based education

Historically, simulation-based training programmes have been used to prepare aviation and military personnel for work in challenging environments. In the past 20 years it has been increasingly used in medicine, especially in the fields of anaesthesia, surgery, and obstetrics (15, 49, 56, 57). One of the first doctors to recognise the need for this type of training in medicine was a pilot himself (58). In the beginning, the focus was on training individuals to become more competent in certain skills. Nowadays, the focus of simulation-based training
has shifted to training teams and communication skills. Additionally, simulation is increasingly used in assessments for medical qualifications and re-certifications (59, 60).

The four-level Kirkpatrick model is mostly used to evaluate training programmes (Figure 1.3) (61). Level 1 assesses the reaction of participants regarding the training programme. The underlying theory is that a positive reaction will facilitate learning. Reaction can be assessed using evaluation questionnaires, the results of which can be applied to improve training.

Level 2 assesses learning and refers to the knowledge and skills acquired, and attitudes developed by participants following training. This can be assessed by testing knowledge, skills, and attitudes before and after training using written tests, observed structured clinical examinations, and questionnaires. In the same way, retention of knowledge, skills, and attitudes can be tested. It is essential to know the decay of knowledge and skills after training in order to provide evidence-based guidance on timing of follow-up training. Level 3 assesses if the obtained knowledge, skills, and attitudes following training lead to improved clinical behaviour. Clinical behaviour can be assessed through structured observations or work-based assessments. Lastly, level 4 measures change in patient outcome following training. This can be assessed through structural observations or evaluating patient databases.

![Kirkpatrick model for evaluation of training programmes](image)

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**Figure 1.3. Kirkpatrick model for evaluation of training programmes**
Effectiveness of educational interventions

There is increasing evidence available about the effectiveness of obstetric simulation-based training (49-55).

**Level 1:** Research has shown that obstetric simulation-based training is acceptable and feasible in both low-income and high-income countries (49, 52, 62-69).

**Level 2:** Obstetric simulation-based training is effective in improving knowledge, skills, confidence, and teamwork of healthcare workers immediately after training (50-53, 62-67, 70-81). Only one study failed to show improvement of knowledge and confidence after training, although there may be publication bias (82). Studies regarding retention of knowledge and skills over longer periods show mixed results. Some studies demonstrate retention of knowledge up to 9-15 months after training (66, 75, 76, 81), yet another study shows deterioration of knowledge as early as two months after training (65). Two studies have evidence of retention of skills at 3-12 months after training (72, 83), while two other studies show deterioration of skills at 2-9 months after training (65, 76).

**Level 3:** Little research has been done to prove transfer of acquired knowledge and skills into clinical behaviour after obstetric simulation-based training. Sorensen et al. studied the impact of the Advanced Life Support in Obstetrics (ALSO) course in Tanzania (84, 85). They performed a prospective intervention study with observations of staff performance in labour ward before and after intervention and found no difference in the management of prolonged labour and neonatal care (84). There was however, a significant improvement in active management of third stage of labour (AMTSL) and management of PPH after training (85). Another study performed focus group discussions three and six months after obstetric emergency training to evaluate the impact of training on clinical behaviour (62). Participants reported better skills in neonatal resuscitation, use of the partograph, manual removal of the placenta, manual vacuum aspiration, AMTSL, assisted vaginal delivery, and maternal resuscitation. Sorensen et al. studied impact on clinical behaviour by evaluating questionnaires on how work routine was influenced by training (66). Participants reported that obstetric simulation-based training had a positive influence on their work. Limitations of assessing clinical behaviour by focus group discussions is that there might be peer pressure from the group on reporting performance. In addition, self-assessment, which was used in those two studies, has been shown to be unreliable (86, 87). Therefore, the results of the last two studies need to be interpreted cautiously.

**Level 4:** There is limited research showing effect of obstetric simulation-based training on patient outcome (53, 55). Most research is retrospective and reports data on neonatal outcome (53). Draycott et al. were the first to show effect on patient outcome following introduction of an emergency obstetric training course (88). They showed a significant reduction in low 5-minute Apgar scores and neonatal hypoxic-ischemic encephalopathy. On the other hand, a randomized controlled trial performed by Nielsen et al. showed no difference in adverse maternal and neonatal outcome between seven hospitals where obstetric team training based on crew resource management was introduced, and eight control hospitals without training (89). Sorensen et al. evaluated the effect of ALSO training on the incidence of PPH (85). They showed a statistically significant reduction in PPH (blood loss ≥ 500 ml) and severe PPH (blood loss ≥ 1000 ml) after training. Lastly, Phipps et al. showed a significant decrease in adverse outcome index (a composite score of clinical maternal and neonatal outcomes also used by Nielsen et al.) following the introduction of obstetric simulation-based training (90).
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**Low-cost low-tech simulation training: Helping Mother Survive Bleeding After Birth**

Few low-cost, low-tech obstetric simulation-based training programmes exist (67, 76, 91, 92), while most of maternal and neonatal mortality occurs in low-resource settings that cannot afford expensive simulators. Helping Mothers Survive is an obstetric training programme created by Jhpiego and Laerdal Global Health especially for areas with a high burden of maternal mortality (93). It is connected to Helping Babies Breathe, a low-cost low-tech neonatal resuscitation training programme (94-96). Bleeding After Birth is the first module of the Helping Mothers Survive series and addresses prevention, detection, and treatment of PPH. The training programme was reviewed and endorsed by several stakeholders such as the WHO, the United Nations Population Fund (UNFPA), the International Federation of Gynaecology and Obstetrics (FIGO), the International Confederation of Midwives (ICM), the Maternal and Child Health Integrated Program (MCHIP), the American College of Obstetricians and Gynaecologists (ACOG), the American
College of Nurse-Midwives (ACNM), and the American Academy of Paediatrics (AAP). The programme was officially released in May 2013. The training (as it was released in May 2013) consists of a full day teaching, with emphasis on simulation of scenarios relevant to basic delivery skills, active management of third stage of bleeding, and management of post partum haemorrhage. A low-cost low-tech simulator "MamaNatalie" (Laerdal Global Health) is used in the simulation scenarios (Figure 1.4).

![MamaNatalie and NeoNatalie](Photograph used with kind permission of Laerdal Global Health)

The mannequin consists of an abdomen that can be strapped around the instructor. It features a uterus that can contract and relax, a placenta that can appear complete and incomplete, and the ability to bleed up to 1,500 ml of blood. A low-cost low-tech newborn baby "NeoNatalie" (Laerdal Global Health) can be delivered by MamaNatalie and it can breathe, cry, and have cord pulsations. Several scenarios can be simulated, such as breech delivery, shoulder dystocia, assisted instrumental vaginal delivery, eclampsia, PPH, and neonatal resuscitation. Training aids include a flip chart with pictures to help the explanation...
of theoretical background and an action-plan to facilitate clinical decision-making (Figures 1.5 and 1.6). A handbook for facilitators covers a more detailed explanation of the theoretical background (97). Since the launch the teaching materials have been translated in several languages including French, Portuguese, and Swahili. Helping Mothers Survive Bleeding After Birth (HMS BAB) adopted a train-the-trainer concept in which training is cascaded down from master trainers to local facilitators to learners (98). After finishing training in a facility, the simulation mannequin and the other teaching materials are left behind to facilitate continuation of training.

In summary, although in recent years progress has been made, there is still a high burden of preventable maternal morbidity and mortality especially in sub-Saharan Africa. Many interventions to reduce the burden of disease exist, but they are not always well implemented or evaluated. One particular intervention that may help to reduce maternal morbidity and mortality is the introduction of simulation-based training. However, the acceptability and feasibility of this type of training in low-resource settings and the effect on clinical behaviour and patient outcome is largely unknown.
Figure 1.5. Example pages of flip chart Helping Mothers Survive Bleeding After Birth (97)
**Helping Mothers Survive**

**Bleeding after Birth**

**ACTION PLAN**

1. Prepare for birth
2. Birth (See HBB Action Plan for baby)
3. Give medication to expel placenta
4. Perform controlled cord traction to deliver placenta
5. Placenta out?
   - Not out: Repeat controlled cord traction
   - Out: Placenta complete?
     - Complete
       - Uterus hard?
         - Soft: Massage uterus
         - Hard: Repeat medication
       - Soft: Massage uterus
       - Hard: Press on tears
8. Bleeding normal?
   - Normal: Continue care:
     - Check tone
     - Monitor bleeding
     - Check vital signs
     - Encourage breastfeeding
   - Hard: Compress uterus
   - Soft: Keep warm

**Advanced care**

---

Figure 1.6. Action Plan Helping Mothers Survive Bleeding After Birth (97)
1.3. RESEARCH DESIGN

Aim and research questions

As mentioned before, the aim of this thesis is two-fold. The first aim is to describe the quality of obstetric care in a hospital in a low-resource setting and to identify opportunities to improve the quality of obstetric care. The second aim is to evaluate the effectiveness of low-cost low-tech obstetric simulation-based training in a low-resource setting as a way to improve quality of obstetric care.

With regard to the first aim we have addressed the following research questions (Table 1.2):

1. What is the prevalence of severe maternal morbidity and mortality in a hospital in a low-resource setting as defined by the WHO near miss approach?
2. What are the implementation levels of key evidence-based interventions in women experiencing severe maternal morbidity and mortality?
3. What is the applicability of the WHO near miss criteria in a low-resource setting?

For the second aim we have addressed the following research questions (Table 1.2):

4. Is obstetric simulation-based training acceptable and feasible in a low-resource setting (Kirkpatrick level 1)?
5. To what extent do knowledge, skills, and confidence of healthcare workers improve after obstetric simulation-based training (Kirkpatrick level 2)?
6. To what extent are knowledge, skills, and confidence of healthcare workers retained nine months after obstetric simulation-based training (Kirkpatrick level 2)?
7. To what extent does obstetric simulation-based training influence clinical behaviour and patient outcome (Kirkpatrick level 3 and 4)?

Research setting

This study was performed in Haydom Lutheran Hospital. The hospital is situated in Mbulu district of Manyara region in Tanzania. This setting in Tanzania was chosen because Tanzania is a low-income country with a high MMR. Specifically Haydom Lutheran Hospital was chosen because it has an existing research infrastructure, with an ongoing prospective observational study which used a similar research design (Helping Babies Breathe). There
was no structural in-house obstetric training programme. In addition to that the principal investigator of this study had worked for one year as medical officer in the maternity ward of Haydom Lutheran Hospital. Geographically the hospital is located on a highland plateau in Northern Tanzania, approximately 300 km southwest of the nearest city, Arusha. The area is rural and the population is predominantly poor. Three different tribes inhabit the area: the Datoga (pastoralists), the Hazabe (hunters and gatherers), and the Iraqw (agropastoralists). The Datoga and the Iraqw are the two biggest tribes. Haydom Lutheran Hospital is a 420-bed hospital owned by the Mbulu Diocese of the Evangelical Lutheran Church in Tanzania. Extrapolating from the 2002 census, the immediate catchment area is covering a population of approximately 327,000 in 2010. The hospital is the primary referral hospital for about 600,000 people, while the greater reference area covers a population of approximately 2,200,000 people (99).

The hospital provides free reproductive and child health services, basic and comprehensive emergency obstetric care, and transport by ambulance. The maternity ward is supervised by a medical officer. During the study period there were no consultants working in the hospital. Approximately 25 nurse-midwives and 16 medical attendants work in the antenatal, labour, postnatal, and gynaecology ward. Together, they take care of 60-80 in-patients daily and approximately 5,000 births annually.

Table 1.2. Overview of thesis chapters and research questions

<table>
<thead>
<tr>
<th>Research question</th>
<th>Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the prevalence of severe maternal morbidity and mortality in a rural referral hospital in Tanzania as proposed by the WHO near miss approach?</td>
<td>2</td>
</tr>
<tr>
<td>2. What are the implementation levels of key evidence-based interventions in women experiencing severe maternal morbidity and mortality?</td>
<td>3</td>
</tr>
<tr>
<td>3. What is the applicability of the WHO near miss criteria in a low-resource setting?</td>
<td>4</td>
</tr>
<tr>
<td>4. Is obstetric simulation-based training acceptable and feasible in a low-resource setting?</td>
<td>5</td>
</tr>
<tr>
<td>5. To what extent do knowledge, skills, and confidence of healthcare workers improve after simulation-based training?</td>
<td>6</td>
</tr>
<tr>
<td>6. To what extent are knowledge, skills, and confidence of healthcare workers retained nine months after simulation-based training?</td>
<td></td>
</tr>
<tr>
<td>7. To what extent does obstetric simulation-based training influence clinical behaviour and patient outcome?</td>
<td></td>
</tr>
</tbody>
</table>
Haydom Lutheran Hospital has a unique research infrastructure. To date, more than 150 articles have been published and at least 20 PhD projects have been accomplished. This has been recognised by the National Institute for Medical Research in Tanzania, who has placed a field station in Haydom. Two managers, one located in Norway and one located in Haydom, guide these research activities. An observational study (Helping Babies Breathe) started in August 2009 at Haydom Lutheran Hospital, registering antenatal and perinatal information. The studies described in this thesis could easily be incorporated into the existing research infrastructure.

Research approach and methods
To address the two aims of this thesis, two different studies were performed: 1) a cross sectional study to answer the first three research questions, and 2) an educational intervention study to address the last four research questions. Figure 1.7 depicts a timeline of the two studies that were carried out and shows which chapters were addressed. The details of the two studies are explained below and in the specific chapters.

**Educational intervention study**

- Introduction simulation-based training + before and after testing March 2012
- 9-month testing December 2012

**Cross-sectional study**

![Figure 1.7. Timeline](image-url)
Cross-sectional study

To measure the burden of maternal morbidity and mortality and to study the quality of obstetric care we performed a cross-sectional study in Haydom Lutheran Hospital. From November 2009 to November 2011 all women with severe maternal outcome (classified as maternal near miss or maternal death) who were admitted to Haydom Lutheran Hospital were included. For the identification of maternal near misses, we used the WHO near miss criteria. As not all near miss criteria were applicable, we modified the WHO near miss criteria for our setting. This entailed that one management-based criterion "admission to intensive care unit" and three disease-based criteria were added: eclampsia, sepsis, and uterine rupture. Furthermore, as Haydom Lutheran Hospital did not have a blood bank, we lowered the threshold of five units of blood to one. Data were collected with the modified WHO near miss criteria. A structured data extraction form was used to retrieve data from the medical records of all maternal near misses and maternal deaths to identify underlying causes of morbidity and mortality and interventions to correct morbidity and mortality. Data collected with this cross-sectional study were used to answer the first three research questions.

Educational intervention study

The structure of the four-level Kirkpatrick model was used to answer the research questions of the second part of this thesis. An educational intervention study was performed from May 2011 to June 2013. In March 2012 the HMS BAB training programme was introduced in Haydom Lutheran Hospital. We used a pilot version of the training programme that was launched in May 2013. The main differences were that the duration of the training was only half a day, and the teaching aids were in English. The results of the educational intervention study have been used to further improve the HMS BAB training programme. At Haydom Lutheran Hospital, four master trainers from the USA, Norway, the Netherlands, and Tanzania (all certified trainers and maternal healthcare professionals) trained a group of local facilitators. According to a train-the-trainer model, this group of local facilitators trained a multi-professional group of local clinicians, nurse-midwives, medical attendants (nurse aides without formal medical education), and ambulance drivers (without formal medical education) involved in maternity care. Immediately after training the participants evaluated the training by filling out an evaluation questionnaire (Kirkpatrick level 1). Before, immediately after, and nine months after training, the local facilitators and local learners
were tested on knowledge, skills, and confidence regarding basic delivery skills and management of PPH (Kirkpatrick level 2). Knowledge was tested using a 26-item written multiple-choice questionnaire. Skills were tested in two simulated scenarios: "basic delivery" and "management of PPH". The skills scenarios were videotaped and assessed by two independent assessors. Confidence was self-assessed using a written 5-item questionnaire. Data collected from these assessments were used to answer research questions 4, 5, and 6.

To answer the last research question, sixteen research assistants were trained to observe all hospital births from May 2011 to June 2013. According to a structured data collection form they observed basic delivery skills and management of postpartum bleeding as performed by the birth attendant (Kirkpatrick level 3). Lastly, amount of blood loss, maternal outcome, and neonatal outcome of each delivery was observed (Kirkpatrick level 4). Observations from the period before training were compared with observations from the period after training.

For more details on the sampling, data collection methods, data analysis and validity issues, I refer to Chapters 2 to 7.

Ethical approval and informed consent

Ethical approval to conduct the two studies was obtained from the Tanzanian National Institute for Medical Research (reference NIMR/HQ/R.8a/Vol.IX/1247), the Tanzania Commission for Science and Technology (reference 2013-41-ER-2011-201), and from the VU University Medical Centre, the Netherlands (reference 2011/389). Furthermore, permission to conduct the two studies was obtained from the hospital management. Data for the cross-sectional study were collected and extracted from patient records without identification of the subject. Questionnaires were filled in after discharge or death of the woman and therefore study inclusion did not have effect on the treatment. Considering these precautions, individually obtained informed consent was not required. Regarding the educational intervention study, written informed consent was obtained from each participant (facilitators and learners) before entering the study.
1.4. OUTLINE OF THIS THESIS

The first part of this thesis explores the burden of maternal morbidity and mortality in a rural hospital in Tanzania and identifies opportunities to improve the quality of care. Chapter 2 addresses research questions 1 and 2 by reporting the prevalence of severe maternal morbidity and mortality in Haydom Lutheran Hospital as defined by the WHO near miss approach. Implementation levels of key-evidence based interventions, such as oxytocin for prevention of PPH and magnesium sulphate for the treatment of eclampsia, are described. In Chapter 3, research question 3 is addressed by explaining the difficulties of applying the WHO near miss criteria in a low-resource setting and the consequences it has when they are used in different settings. Furthermore, we explore possibilities of further improving the WHO near miss criteria.

The second part of this thesis focuses on the evaluation of obstetric simulation-based training and the impact it has on the quality of obstetric care. Chapter 4 illustrates the applicability and feasibility of obstetric simulation-based training in a low-resource setting and the effect this training had on knowledge, skills, and confidence of healthcare workers. Research question 4 and 5 are addressed in this chapter. In Chapter 5, research question 6 is addressed by describing the retention of knowledge, skills, and confidence of healthcare workers nine months after training. Chapter 6 explores whether the acquired knowledge, skills, and confidence of healthcare workers is translated into improved clinical behaviour. Furthermore, we describe the effect of obstetric simulation-based training on patient outcome. Research question 7 is addressed in this chapter.

In the last part of this thesis, Chapter 7 summarises the findings from chapter 2 to 6, provides answers to research questions, addresses the limitations of the studies, and places the results of this thesis in a broader context. Furthermore, areas for further research are suggested.
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PART 1

MATERNAL MORBIDITY AND MORTALITY IN A RURAL HOSPITAL IN TANZANIA
CHAPTER 2

Maternal near miss and mortality in a rural referral hospital in northern Tanzania: a cross-sectional study

Ellen Nelissen, Estomih Mduma, Hege Ersdal, Bjørg Evjen-Olsen, Jos van Roosmalen, Jelle Stekelenburg

CHAPTER 2

Maternal near miss and mortality in a rural referral hospital in northern Tanzania: a cross-sectional study

Ellen Nelissen, Estomih Mduma, Hege Ersdal, Bjørg Evjen-Olsen, Jos van Roosmalen, Jelle Stekelenburg

ABSTRACT

Background: Maternal morbidity and mortality in sub-Saharan Africa remains high despite global efforts to reduce it. In order to lower maternal morbidity and mortality in the immediate term, reduction of delay in the provision of quality obstetric care is of prime importance. The aim of this study is to assess the occurrence of severe maternal morbidity and mortality in a rural referral hospital in Tanzania as proposed by the WHO near miss approach and to assess implementation levels of key evidence-based interventions in women experiencing severe maternal morbidity and mortality.

Methods: A prospective cross-sectional study was performed from November 2009 until November 2011 in a rural referral hospital in Tanzania. All maternal near misses and maternal deaths were included. As not all WHO near miss criteria were applicable, a modification was used to identify cases. Data were collected from medical records using a structured data extraction form. Descriptive frequencies were calculated for demographic and clinical variables, outcome indicators, underlying causes, and process indicators.

Results: In the two-year period there were 216 maternal near misses and 32 maternal deaths. The hospital-based maternal mortality ratio was 350 maternal deaths per 100,000 live births (95% CI 243-488). The maternal near miss incidence ratio was 23.6 per 1,000 live births, with an overall case fatality rate of 12.9%. Oxytocin for prevention of postpartum haemorrhage was used in 96 of 201 women and oxytocin for treatment of postpartum haemorrhage was used in 38 of 66 women. Furthermore, eclampsia was treated with magnesium sulphate in 87% of all cases. Seventy-four women underwent caesarean section, of which 25 women did not receive prophylactic antibiotics. Twenty-eight of 30 women who were admitted with sepsis received parenteral antibiotics. The majority of the cases with uterine rupture (62%) occurred in the hospital.

Conclusion: Maternal morbidity and mortality remain challenging problems in a rural referral hospital in Tanzania. Key evidence-based interventions are not implemented in women with severe maternal morbidity and mortality. Progress can be made through up scaling the use
of evidence-based interventions, such as the use of oxytocin for prevention and treatment of postpartum haemorrhage.
INTRODUCTION

Despite global efforts through the Safe Motherhood Initiative and the declaration of the Millennium Development Goals (MDG), there is only a slight decline in maternal mortality in sub-Saharan Africa (1, 2). Although Tanzania shows progress towards improving maternal health, as is shown by a 47% decline in maternal mortality ratio (MMR) between 1990 and 2010 (from an estimated MMR of 870 per 100,000 live births in 1990 to a MMR of 460 per 100,000 live births in 2010), maternal mortality remains high (3). The aim of MDG 5 is to reduce maternal mortality by 75% between 1990 and 2015 (4). Although the numbers of maternal deaths (MD) around the globe are high, absolute numbers in hospitals are low. Therefore, including cases of women who almost die, but survive pregnancy-related complications, is progressively being used to study the quality of obstetric care (5-8). These near miss cases represent most of the characteristics of maternal deaths (9). Combined, they create larger numbers and may lead to more rapid and precise reporting. Since identification criteria for near miss cases are not uniform and studies thus not comparable (6, 7), the World Health Organization (WHO) developed a new definition of maternal near miss (MNM) and identification criteria for maternal near miss cases in 2009 (10). This resulted in the “WHO near miss approach for maternal health” in 2011 (11).

Currently, in Tanzania half of the deliveries take place in health facilities and 51% of all deliveries are assisted by a skilled provider (12). Unfortunately skilled birth attendance does not necessarily equal good quality of care (13). Many evidence-based effective approaches are available to prevent and treat obstetric emergencies, but their implementation lags behind (14, 15). Human resources are scarce and policymakers encourage scaling up facility deliveries. Increased utilization of skilled birth attendants at facilities with insufficient human resources may further threaten quality of care. Negative perception of the quality of care by the community inhibits the decision to deliver in a facility (16, 17) and so a vicious circle is created. When scaling up skilled birth attendance, there is a need for a well-functioning health system with sufficient resources and a good infrastructure. Both, quantity of human resources and quality of care should be addressed (13, 18).

In order to reduce maternal mortality and severe acute maternal morbidity, it is imperative
not only to increase the numbers of skilled personnel, but also to improve access to health institutions and to reduce the delay in providing quality obstetric care within institutions. Quality of obstetric care can be measured using outcome indicators, such as case fatality rate (CFR), and process indicators, such as the use of oxytocin after delivery to prevent postpartum haemorrhage (11, 19).

This study aims to assess the occurrence of severe maternal morbidity and mortality in a referral hospital in rural Tanzania as proposed by the WHO near-miss approach and to assess implementation levels of key evidence-based interventions in women experiencing severe maternal morbidity and mortality.

METHODS
This study is part of an intervention study. Data that were collected serve as baseline for an intervention with simulation-based training in routine delivery care, prevention and treatment of postpartum haemorrhage (PPH). This was a prospective cross-sectional study, conducted from November 2009 until November 2011 in Haydom Lutheran Hospital (HLH), a referral hospital in rural Northern Tanzania. HLH is a 400-bed hospital owned by the Mbulu Diocese of the Evangelical Lutheran Church in Tanzania. The hospital provides free reproductive and child health services, comprehensive emergency obstetric care, including ambulance and radio service. Furthermore there is an Intensive Care Unit (ICU) with 24-hours medical supervision and mechanical ventilation. Annually there are around 5,000 deliveries. Extrapolating from the 2002 census, the immediate catchment area was covering a population of approximately 327,000 in 2010 (20). The greater reference area covered a population of approximately 2,200,000 people (20).

Outcome measures
The primary outcome measures were the total number of MD, MNM and live births (LB) in the hospital during the study period. Subsequently, outcome indicators were calculated such as the number of women with life-threatening conditions. As proposed by the WHO approach, overall near miss indicators were calculated such as the severe maternal outcome ratio, the maternal near miss incidence ratio, the maternal near-miss mortality ratio, and the
case fatality rate. Hospital access indicators were calculated such as the number of women with life-threatening conditions at arrival, the proportion of these women among all women with life-threatening conditions, the proportion of these women coming from other hospitals, and the women with life-threatening conditions at arrival mortality index. Lastly, intra hospital care indicators were calculated: the number of maternal near misses and deaths who developed these conditions in the hospital and the intra hospital mortality index. Implementation levels of evidence-based interventions were measured, such as use of oxytocin for prevention and treatment of PPH, use of magnesium sulphate for treatment of eclampsia, use of prophylactic antibiotics during caesarean section, use of parenteral antibiotics for treatment of sepsis, and the proportion of women with uterine rupture that occurred in the hospital.

**Inclusion criteria**

All maternal deaths and maternal near misses that were admitted to HLH were prospectively included in the study during the above-mentioned period. A maternal death is defined as: the death of a woman while pregnant or within 42 days of termination of pregnancy from any cause. A maternal near miss is defined as: a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy (10). The intention was to use the WHO near miss criteria for the identification of maternal near misses. However, not all WHO criteria were applicable, and the identification criteria were adapted to the local situation in HLH as is described elsewhere (21). Table 2.1 shows an overview of the WHO near miss criteria and the Haydom modification.

**Data collection**

Cases were identified on a daily basis by either the principal investigator (EN) or by one of the two trained research assistants (nurse-midwives). This was achieved through daily participation in the morning report and daily visits to the maternity ward, ICU and the internal medicine ward. When the inclusion criteria were met, a structured data extraction form was filled out by the principal investigator or a research assistant. Data were obtained from the patient record. The facility medical staff was questioned in case of doubt or missing information. General information and obstetric details were collected. For hospital access and intra hospital care indicators, the following information was registered: health status on
### Table 2.1. WHO near miss criteria adapted to the local context of HLH

<table>
<thead>
<tr>
<th>Clinical criteria</th>
<th>Haydom near miss criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute cyanosis</td>
<td>Acute cyanosis</td>
</tr>
<tr>
<td>Gasping</td>
<td>Gasping</td>
</tr>
<tr>
<td>Respiratory rate &gt; 40 or &lt; 6/min</td>
<td>Respiratory rate &gt; 40 or &lt; 6/min</td>
</tr>
<tr>
<td>Shock</td>
<td>Shock</td>
</tr>
<tr>
<td>Oliguria non responsive to fluids or diuretics</td>
<td>Oliguria non responsive to fluids or diuretics</td>
</tr>
<tr>
<td>Failure to form clots</td>
<td>Failure to form clots</td>
</tr>
<tr>
<td>Loss of consciousness lasting &gt; 12h</td>
<td>Loss of consciousness lasting &gt; 12h</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>Cardiac arrest</td>
</tr>
<tr>
<td>Stroke</td>
<td>Stroke</td>
</tr>
<tr>
<td>Uncontrollable fit/total paralysis</td>
<td>Uncontrollable fit/total paralysis</td>
</tr>
<tr>
<td>Jaundice in the presence of pre-eclampsia</td>
<td>Jaundice in the presence of pre-eclampsia</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Laboratory-based criteria</th>
<th>Management-based criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen saturation &lt; 90% for ≥ 60 minutes</td>
<td>Admission to intensive care unit</td>
</tr>
<tr>
<td>PaO2/FIO2 &lt; 200 mmHg</td>
<td>Hysterectomy following infection or haemorrhage</td>
</tr>
<tr>
<td>Creatinine ≥ 300μmol/l or ≥ 3.5 mg/dL</td>
<td>Transfusion of ≥ 1 unit of blood</td>
</tr>
<tr>
<td>Bilirubin &gt; 100 μmol/l or &gt; 6.0 mg/dL</td>
<td>Intubation and ventilation for ≥ 60 minutes not related to anaesthesia</td>
</tr>
<tr>
<td>pH &lt; 7.1</td>
<td>Dialysis for acute renal failure</td>
</tr>
<tr>
<td>Lactate &gt; 5 mEq/mL</td>
<td>Cardio-pulmonary resuscitation</td>
</tr>
<tr>
<td>Acute thrombocytopenia (&lt; 50,000 platelets/ml)</td>
<td></td>
</tr>
<tr>
<td>Loss of consciousness and ketoacids in urine</td>
<td></td>
</tr>
</tbody>
</table>

| Severe maternal complications | |
|-------------------------------| |
| Eclampsia | |
| Sepsis or severe systemic infection | |
| Uterine rupture | |

See glossary for definitions

arrival, maternal death within 24 hours, and referral status. For each case, one underlying cause was identified that started the cascade that led to maternal morbidity or mortality (22). For example, a primipara was admitted with obstructed labour and had a caesarean section. After caesarean section she developed sepsis. The underlying cause that started the cascade that led to maternal morbidity or mortality was obstructed labour, resulting in one diagnosis per woman (mutually exclusive, totally inclusive). For process indicators, information on preventive measures (measuring of vital signs, use of oxytocin or other uterotonics for prevention of PPH, use of prophylactic antibiotics during caesarean section) were registered, as well as the use of interventions (use of oxytocin or other uterotonics as treatment for PPH, intravenous fluid infusion, blood products, hysterectomy, magnesium...
sulphate or other anticonvulsant in case of eclampsia, parenteral therapeutic antibiotics, and laparotomy for uterine rupture).

**Quality assessment of the data**

The completed data extraction forms were checked by a second person on missing data or discrepancies. If needed, a copy of the hospital file was checked to validate the recordings. All MD cases were reviewed by a selection of the authors (EN, BEO, JVR and JS), as well as a random selection of the MNM cases and those cases, which were difficult to classify into an underlying cause. Observation bias was addressed by means of auditing all MD cases and a random sample of the MNM cases by four authors (EN, BEO, JVR, JS) until consensus was reached. All data were double entered and cross-checked in Epidata (23).

**Statistical analysis**

Data analysis consisted of frequencies of demographic and clinical variables and underlying causes. Demographic variables were cross-tabulated for maternal outcome at discharge, and compared using chi-square test for categorical variables and t-test for continuous variables. Outcome indicators were calculated using the total number of live births during the study period and the total number of MNM and MD in that same period. Descriptive frequencies were calculated for underlying causes and process indicators. All results are reported as number (n) and frequency (%). Analysis was performed using SPSS Statistics, version 20 (SPSS Inc. Chicago, Illinois).

**Ethical approval**

Ethical approval was obtained from the Tanzanian National Institute for Medical Research (NIMR) (reference NIMR/HQ/R.8a/Vol.IX/1247), the Tanzania Commission for Science and Technology (COSTECH) (reference 2012-56-NA-2011-201), and from the VU university medical centre (VUmc), the Netherlands (reference 2011/389). Data were collected and extracted from patient records without identification of the subject. Data extraction forms were filled in after discharge or death and therefore study inclusion did not have effect on the treatment. Considering these precautions, individually obtained informed consent was not required.

<table>
<thead>
<tr>
<th>Mode of delivery</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>Vaginal delivery</td>
<td>24 (75)</td>
</tr>
<tr>
<td>Caesarean section</td>
<td>15 (47)</td>
</tr>
<tr>
<td>Other</td>
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</table>

<table>
<thead>
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<th>Gestational age</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>&lt;24 weeks</td>
<td>11 (34)</td>
</tr>
<tr>
<td>≥35 years</td>
<td>100 (46)</td>
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</table>

<table>
<thead>
<tr>
<th>Previous caesarean section</th>
<th>n (%)</th>
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</thead>
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<td>22 (10)</td>
</tr>
<tr>
<td>No</td>
<td>15 (47)</td>
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<table>
<thead>
<tr>
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<th>n (%)</th>
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<tr>
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<td>46 (21)</td>
</tr>
<tr>
<td>Breech</td>
<td>1 (3)</td>
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</table>

<table>
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<th>Parity</th>
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<tbody>
<tr>
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<td>5 (na)</td>
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</table>

<table>
<thead>
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<th>Marital status</th>
<th>n (%)</th>
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<td>Married/cohabiting</td>
<td>9 (4)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (50)</td>
</tr>
</tbody>
</table>

| Age mean (SD) in years | 28.1 (6.3) |

<table>
<thead>
<tr>
<th>Tribe</th>
<th>n (%)</th>
</tr>
</thead>
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<tr>
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<td>Breech</td>
<td>1 (3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Abortion</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>22 (10)</td>
</tr>
<tr>
<td>No</td>
<td>15 (47)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>16 (50)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality assessment of the data</th>
<th>n=216</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation bias was addressed</td>
<td>17 (8)</td>
</tr>
<tr>
<td>Ethical approval was obtained</td>
<td>20 (9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statistical analysis</th>
<th>n=32</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data analysis consisted of frequencies of demographic and clinical variables and underlying causes. Demographic variables were cross-tabulated for maternal outcome at discharge, and compared using chi-square test for categorical variables and t-test for continuous variables. Outcome indicators were calculated using the total number of live births during the study period and the total number of MNM and MD in that same period. Descriptive frequencies were calculated for underlying causes and process indicators. All results are reported as number (n) and frequency (%). Analysis was performed using SPSS Statistics, version 20 (SPSS Inc. Chicago, Illinois).</td>
<td>20 (9)</td>
</tr>
</tbody>
</table>
### Table 2.2. Demographic and clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>MNM n=216</th>
<th>MD n=32</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age mean (SD) in years</td>
<td>28.1 (6.3)</td>
<td>29.4 (6.1)</td>
<td>0.266</td>
</tr>
<tr>
<td>&lt; 20 years n (%)</td>
<td>20 (9)</td>
<td>3 (9)</td>
<td></td>
</tr>
<tr>
<td>20-35 years n (%)</td>
<td>150 (69)</td>
<td>20 (63)</td>
<td></td>
</tr>
<tr>
<td>≥ 35 years n (%)</td>
<td>46 (21)</td>
<td>9 (28)</td>
<td></td>
</tr>
<tr>
<td>Marital status n (%)</td>
<td></td>
<td></td>
<td>0.341</td>
</tr>
<tr>
<td>Single/separated/divorced</td>
<td>21 (10)</td>
<td>5 (16)</td>
<td></td>
</tr>
<tr>
<td>Married/cohabiting</td>
<td>188 (87)</td>
<td>25 (78)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>7 (3)</td>
<td>2 (6)</td>
<td></td>
</tr>
<tr>
<td>Tribe (%)</td>
<td></td>
<td></td>
<td>0.477</td>
</tr>
<tr>
<td>Datoga</td>
<td>31 (14)</td>
<td>7 (22)</td>
<td></td>
</tr>
<tr>
<td>Iraqw</td>
<td>114 (53)</td>
<td>14 (44)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>61 (28)</td>
<td>9 (28)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>10 (5)</td>
<td>2 (6)</td>
<td></td>
</tr>
<tr>
<td>Parity n (%)</td>
<td></td>
<td></td>
<td>0.742</td>
</tr>
<tr>
<td>0</td>
<td>47 (22)</td>
<td>5 (16)</td>
<td></td>
</tr>
<tr>
<td>1-2</td>
<td>52 (24)</td>
<td>7 (22)</td>
<td></td>
</tr>
<tr>
<td>≥ 3</td>
<td>100 (46)</td>
<td>16 (50)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>17 (8)</td>
<td>4 (13)</td>
<td></td>
</tr>
<tr>
<td>Previous caesarean section n (%)</td>
<td></td>
<td></td>
<td>0.307</td>
</tr>
<tr>
<td>No</td>
<td>145 (67)</td>
<td>24 (75)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>41 (19)</td>
<td>3 (9)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>30 (14)</td>
<td>5 (16)</td>
<td></td>
</tr>
<tr>
<td>Gestational age n (%)</td>
<td></td>
<td></td>
<td>0.106</td>
</tr>
<tr>
<td>&lt; 24 weeks</td>
<td>40 (19)</td>
<td>7 (22)</td>
<td></td>
</tr>
<tr>
<td>24-36 weeks</td>
<td>40 (19)</td>
<td>10 (31)</td>
<td></td>
</tr>
<tr>
<td>≥ 36 weeks</td>
<td>91 (42)</td>
<td>8 (25)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>45 (21)</td>
<td>7 (22)</td>
<td></td>
</tr>
<tr>
<td>Mode of delivery n (%)</td>
<td></td>
<td></td>
<td>na</td>
</tr>
<tr>
<td>Vaginal delivery</td>
<td>80 (37)</td>
<td>15 (47)</td>
<td></td>
</tr>
<tr>
<td>Caesarean section</td>
<td>69 (32)</td>
<td>5 (16)</td>
<td></td>
</tr>
<tr>
<td>Laparotomy for uterine rupture</td>
<td>16 (7)</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Abortion/curettage</td>
<td>22 (10)</td>
<td>2 (6)</td>
<td></td>
</tr>
<tr>
<td>Laparotomy for ectopic pregnancy</td>
<td>19 (9)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Undelivered</td>
<td>9 (4)</td>
<td>9 (28)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (1)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Fetal presentation n (%)</td>
<td></td>
<td></td>
<td>na</td>
</tr>
<tr>
<td>Cephalic</td>
<td>110 (51)</td>
<td>15 (47)</td>
<td></td>
</tr>
<tr>
<td>Breech</td>
<td>10 (5)</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>9 (4)</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Abortion</td>
<td>40 (19)</td>
<td>4 (13)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>47 (22)</td>
<td>11 (34)</td>
<td></td>
</tr>
</tbody>
</table>

*na: not available, p-value could not be calculated due to too few cases.*

## RESULTS

In the two-year study period 248 women with life-threatening conditions were included at Haydom Lutheran Hospital: 216 maternal near miss cases and 32 maternal deaths. In the study period 9,471 deliveries and 9,136 live births occurred at HLH.
Demographic and clinical characteristics are shown in Table 2.2. There were no statistical differences in characteristics between the group of maternal near miss and the group of maternal deaths. The Datoga tribe, who are pastoralists, experienced relatively more deaths than near misses, but this did not reach statistical significance. Almost 20% of all near misses (n=40) and 22% of all maternal deaths (n=7) had a gestational age of less than 24 weeks on admission. For 42% of all near misses (n=91) gestational age was 36 weeks or more, compared to 25% of all maternal deaths (n=8). The most common mode of delivery was vaginal delivery: 37% MNM (n=80) and 47% MD (n=15). This was followed by caesarean section: 32% MNM (n=69) and 16% MD (n=5). There were no assisted vaginal deliveries (e.g. forceps/vacuum extraction). Almost 30% of all women who died (n=9) died undelivered.

As is shown in Table 2.3, there were 27.1 MNM and MD per 1,000 live births; this is also referred to as the severe maternal outcome ratio. For every maternal death there were 6.8 near miss cases. Hospital-based MMR was 350 per 100,000 live births (95% confidence interval (CI) 243-488), with an overall CFR of 12.9%. Nearly 70% of all women with life-threatening conditions were ill on arrival and 20.9% were referred from another hospital. Death within 24 hours occurred in 7.6% (n=13) of the women that were ill on arrival.

Table 2.3. Outcome indicators

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Near-miss indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>All live births in the hospital (n)</td>
<td>9,136</td>
</tr>
<tr>
<td><strong>Severe maternal outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>Maternal deaths (n)</td>
<td>32</td>
</tr>
<tr>
<td>Maternal near miss cases (n)</td>
<td>216</td>
</tr>
<tr>
<td>Women with life-threatening conditions (WLTC) (n)</td>
<td>248</td>
</tr>
<tr>
<td><strong>Overall near miss indicators</strong></td>
<td></td>
</tr>
<tr>
<td>Severe maternal outcome ratio (per 1,000 live births)</td>
<td>27.1</td>
</tr>
<tr>
<td>Maternal near miss incidence ratio (per 1,000 live births)</td>
<td>23.6</td>
</tr>
<tr>
<td>Maternal near miss mortality ratio</td>
<td>6.75</td>
</tr>
<tr>
<td>Case fatality rate (%)</td>
<td>12.9</td>
</tr>
<tr>
<td><strong>Hospital access indicators</strong></td>
<td></td>
</tr>
<tr>
<td>WLTC at hospital arrival (n)</td>
<td>172</td>
</tr>
<tr>
<td>Proportion WLTC at arrival among all WLTC (%)</td>
<td>69.4</td>
</tr>
<tr>
<td>Proportion of WLTC at arrival coming from other hospitals (%)</td>
<td>20.9</td>
</tr>
<tr>
<td>WLTC at arrival mortality index (%)</td>
<td>7.6</td>
</tr>
<tr>
<td><strong>Intra hospital care indicators</strong></td>
<td></td>
</tr>
<tr>
<td>Intra hospital WLTC cases (n)</td>
<td>76</td>
</tr>
<tr>
<td>Intra hospital WLTC rate (per 1,000 live births)</td>
<td>8.32</td>
</tr>
<tr>
<td>Intra hospital mortality index (%)</td>
<td>5.3</td>
</tr>
</tbody>
</table>

See glossary for definitions
Seventy-six women (30.6%) developed a life-threatening condition in the hospital, and four (5.3%) of these women died as a result of this condition.

Table 2.4 demonstrates the underlying causes for both groups (MNM and MD) and the associated CFR per underlying cause. The major cause of morbidity and mortality is postpartum haemorrhage, accounting for 27% of all underlying causes, followed by abortion related complications (17%), obstructed labour (12%), ante partum haemorrhage (11%), and hypertensive disorders (9%). Women who got severely ill from an unknown cause had the highest risk of dying with a CFR of 80%, followed by cancer (67%) and non-obstetric infectious diseases (63%).

<table>
<thead>
<tr>
<th>Direct</th>
<th>n (%)</th>
<th>CFR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indirect</td>
<td>Anaemia in pregnancy</td>
<td>19 (8)</td>
</tr>
<tr>
<td></td>
<td>Infectious disease</td>
<td>11 (4)</td>
</tr>
<tr>
<td></td>
<td>Cardiac disease</td>
<td>4 (2)</td>
</tr>
<tr>
<td></td>
<td>Cerebral disease</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Direct</td>
<td>Postpartum haemorrhage</td>
<td>67 (27)</td>
</tr>
<tr>
<td></td>
<td>Abortion related complication</td>
<td>43 (17)</td>
</tr>
<tr>
<td></td>
<td>Ante partum haemorrhage</td>
<td>26 (11)</td>
</tr>
<tr>
<td></td>
<td>Hypertensive disorders</td>
<td>21 (9)</td>
</tr>
<tr>
<td></td>
<td>Obstructed labour with uterine rupture</td>
<td>15 (6)</td>
</tr>
<tr>
<td></td>
<td>Obstructed labour without uterine rupture</td>
<td>15 (6)</td>
</tr>
<tr>
<td></td>
<td>Uterine scar rupture without obstructed labour</td>
<td>6 (2)</td>
</tr>
<tr>
<td></td>
<td>Puerperal sepsis</td>
<td>9 (4)</td>
</tr>
<tr>
<td></td>
<td>Anaesthesia related complication</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Co-incidental</td>
<td>Cancer</td>
<td>3 (1)</td>
</tr>
<tr>
<td></td>
<td>Trauma</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Unknown</td>
<td>Unknown/undetermined cause</td>
<td>5 (2)</td>
</tr>
</tbody>
</table>

See glossary for definitions

Process indicators that reflect the use of evidence-based interventions are presented in Table 2.5. Two hundred one women gave birth in the hospital, and 96 (48%) received oxytocin as part of active management of third stage of labour (AMTSL). Sixty-six women were diagnosed with severe PPH. Forty-one of these women (62%) delivered in the hospital and 25 women (38%) delivered at home or on their way to the hospital. Twenty-eight women (42%) who were diagnosed with severe PPH had received oxytocin routinely after delivery. The number of women that received oxytocin as treatment was higher: 39 (59%). Ten women received ergometrine and/or misoprostol in addition to oxytocin. Fifty-four
Table 2.5. Process indicators among women with severe maternal morbidity and mortality

<table>
<thead>
<tr>
<th>Prevention of PPH</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population: women who delivered in hospital</td>
<td>201 (100)</td>
</tr>
<tr>
<td>Oxytocin use for AMTSL</td>
<td>96 (48)</td>
</tr>
<tr>
<td>Other uterotonic use for AMTSL</td>
<td>2 (1)</td>
</tr>
<tr>
<td>All uterotonic use for AMTSL</td>
<td>96 (48)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment of PPH</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population: women with PPH</td>
<td>66 (100)</td>
</tr>
<tr>
<td>Delivery in hospital</td>
<td>41 (62)</td>
</tr>
<tr>
<td>Delivery out hospital</td>
<td>25 (38)</td>
</tr>
<tr>
<td>Oxytocin use (routine)</td>
<td>28 (42)</td>
</tr>
<tr>
<td>Other uterotonic use (routine)</td>
<td>-</td>
</tr>
<tr>
<td>All uterotonic use (routine)</td>
<td>28 (42)</td>
</tr>
<tr>
<td>Oxytocin use (treatment)</td>
<td>38 (58)</td>
</tr>
<tr>
<td>Other uterotonic use (treatment)</td>
<td>10 (15)</td>
</tr>
<tr>
<td>All uterotonic use (treatment)</td>
<td>39 (59)</td>
</tr>
<tr>
<td>IV-infusion</td>
<td>54 (82)</td>
</tr>
<tr>
<td>Blood products</td>
<td>61 (92)</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>4 (6)</td>
</tr>
<tr>
<td>CFR</td>
<td>9%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment of eclampsia</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population: women with eclampsia</td>
<td>15 (100)</td>
</tr>
<tr>
<td>Magnesium sulphate use</td>
<td>13 (87)</td>
</tr>
<tr>
<td>Other anticonvulsant use</td>
<td>10 (67)</td>
</tr>
<tr>
<td>Any anticonvulsant use</td>
<td>14 (93)</td>
</tr>
<tr>
<td>CFR</td>
<td>7%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevention of caesarean section related infection</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population: women with caesarean section</td>
<td>74 (100)</td>
</tr>
<tr>
<td>Prophylactic antibiotics</td>
<td>49 (66)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment of sepsis</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population: women with sepsis</td>
<td>30 (100)</td>
</tr>
<tr>
<td>Parenteral therapeutic antibiotics</td>
<td>28 (93)</td>
</tr>
<tr>
<td>CFR</td>
<td>27%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Uterine rupture</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population: women with uterine rupture</td>
<td>21 (100)</td>
</tr>
<tr>
<td>Occurred in hospital</td>
<td>13 (62)</td>
</tr>
<tr>
<td>Occurred out hospital</td>
<td>8 (38)</td>
</tr>
<tr>
<td>Laparotomy</td>
<td>21 (100)</td>
</tr>
<tr>
<td>CFR</td>
<td>5%</td>
</tr>
</tbody>
</table>

See glossary for definitions

women (82%) received intravenous volume replacement, whereas 61 women (92%) received blood transfusion. In four women (6%) hysterectomy was performed. Fifteen women were diagnosed with eclampsia, of which 13 women (87%) received magnesium sulphate. Ten women received diazepam, of which nine also received magnesium sulphate, indicating that 93% women received anticonvulsants. Seventy-four women underwent a caesarean section, of which 49 (66%) received prophylactic antibiotics. Twelve women (16%) developed sepsis.
after caesarean section and one woman died. Six of the women (50%) who developed sepsis received prophylactic antibiotics. Twenty-eight of the women (93%) that were diagnosed with sepsis received parenteral therapeutic antibiotics. The last process indicator regarding uterine rupture revealed that the majority of the ruptures occurred in-hospital (62%). All women underwent laparotomy, and one woman died. CFR for uterine rupture was 5%.

Of all women with life-threatening conditions, 227 women (92%) had physical examination on arrival. One hundred seventy-two women were ill on arrival and 133 (77%) had blood pressure measured, 124 (72%) had pulse rate taken and of 126 women (73%) temperature was noted. Saturation was measured in only 10 women (6%). Full blood count was taken in 155 (90%) of the women that were ill on arrival.

DISCUSSION
This article presents the results of a prospective cross-sectional study describing the quality of obstetric care in a rural referral hospital in Tanzania using the modified WHO near-miss criteria. It is one of the few studies describing maternal morbidity and mortality in Tanzania (24-28).

MMR in this hospital was 350 maternal deaths per 100,000 live births (95% CI 243-488). Country level MMR is around 460 per 100,000 live births (3, 12). Previous studies in the area revealed MMRs of 362 (95% CI 269-456) and 444 (95% CI 371-517) per 100,000 live births in 1995 and 1996 for household and antenatal clinic surveys, respectively (25). It is difficult to compare the hospital-based calculated MMR with a population-based MMR because not all women deliver nor die inside the hospital. Most likely hospital-based MMR is an overestimation because 48% of the Tanzanian women deliver at home and 85% of all maternal deaths are identified in the hospital (12, 29). Having this in mind, our estimation of MMR is relatively low compared to the national MMR, as is underlined by previous research from the area. This may be explained by the free service of the hospital for delivery care and the well-established transport services. Furthermore, although the hospital did not have medical specialists, there were frequent long-term expatriate specialists and visiting specialists from nearby referral hospitals.
A recently published systematic review was conducted that included all studies on maternal near miss from 2004 until 2010 (7). It revealed that inclusion criteria used to identify maternal near miss varied widely and therefore could not easily be compared. The findings showed MNM prevalence rates that varied from 0.04% to 14.98% depending on the different inclusion criteria that were used. These results were further sub-divided into regions and the findings from 14 studies from Africa showed that there is a near-miss prevalence rate ranging from 0.05% to 14.98%. The near-miss prevalence in HLH of 2.48% lies within the lower range of the studies from Africa that were included in this analysis. From the fourteen studies that were analyzed in the sub-group Africa, seven studies used management specific criteria (emergency hysterecmy or ICU admission) and had relatively low near-miss rates, as they did not include all near misses that were admitted to the hospital.

Although maternal mortality and morbidity ratios are relatively low compared to the rest of the country, quality of care can still be improved as is shown by the process indicators. The improvement lies in the up scaling of evidence-based interventions. As suggested by Campbell et al. “we should get on with what works” in order to reduce maternal mortality (28, 30). Implementation of evidence-based interventions such as oxytocin use immediately after delivery for prevention of postpartum haemorrhage can be improved in HLH. Only 48% of the women received routine oxytocin immediately after delivery, while WHO recommends this for all women who give birth (31). WHO also recommends the use of oxytocin for the treatment of PPH (32), however in HLH it was used in 58% of the cases with severe PPH. PPH was the leading cause of maternal morbidity and the second cause for maternal mortality in HLH with a CFR of 9%. Confronting hospital staff with these low numbers of oxytocin use reveals several possible reasons. Not recording the use of oxytocin in the hospital file is the main reason, followed by lack of protocols, shortage of staff, and high staff turnover resulting in less experienced healthcare workers. Supply of oxytocin to the ward is not considered a constraint. Although there were no official guidelines in HLH available, local policy was to give 10 IU of oxytocin immediately after birth and it was also the first drug of choice for the treatment of PPH. Use of oxytocin for prevention and treatment of PPH should be scaled up to 100% coverage.
Caesarean section seems to be one of the most important risk factors for postpartum maternal infection (33, 34). Prophylactic antibiotics reduces endometritis and decreases wound infections (35). At HLH it was used only in 66% of all women who underwent caesarean section. Twelve women (16%) developed sepsis after caesarean section and one woman died. Of the women who developed sepsis, six women (50%) received prophylactic antibiotics. Sepsis accounted for 4% of all maternal morbidities in HLH and the number of women with sepsis after caesarean section may be reduced by this simple precaution. Prophylactic use of antibiotics during caesarean section should be scaled up to 100%.

Use of magnesium sulphate in case of severe pre-eclampsia is recommended as it reduces the risk of eclampsia with 50% and might reduce maternal mortality (36, 37). Eclampsia is not very common at HLH regarding the incidence of 1.6% per 1,000 deliveries, but it does account for 6% of all women with life-threatening conditions. Case fatality rate for eclampsia was 7%. Nearly 90% of all eclamptic women received magnesium sulphate. Hypertensive disorders are typically detected during antenatal care (ANC). ANC coverage in Tanzania is relatively good: 96% of the pregnant women visit the ANC clinic once and 43% visit the ANC clinic four times or more. Most women visit the antenatal clinic 2-3 times. In Manyara region 68.2% of the women have blood pressure measured during ANC visits (12). ANC visits are a good opportunity to detect hypertensive disorders, and blood pressure should be measured on every occasion.

The majority of uterine ruptures occurred in-hospital, which reflects serious substandard care. Obstructed labour was prevalent in 12% of all maternal morbidities and mortalities. Uterine rupture is one of the medical emergencies with high maternal and perinatal mortality as is reflected by the maternal CFR of 5% (38, 39). Other hospital-based studies from low-income countries have reported case fatality rates ranging from 1 to 13% (40). Audit can be used to reduce the incidence of uterine rupture as is shown in Malawi (41). Some of the recommendations that were implemented in Malawi after several audit sessions were training of healthcare workers in order to reduce delay in diagnosing obstructed labour and delay in treatment and implementation of local guidelines for augmentation of labour. Increased supervision should lead to improved documentation and labour management.
There were several limitations to this study. First, it is a single-centre and hospital-based study and therefore findings may not reflect the situation in other settings or the population in general. Second, information is gathered from hospital files, therefore data quality depends on the quality of record keeping. We have tried to remedy this by means of conducting prospective data-collection. Third, for the collection of maternal near miss cases we have used modified WHO near miss criteria, as the original WHO near miss criteria were not applicable in the local context. This has to be taken into account when interpreting the results from this study, as there have been more near miss cases collected with the modified criteria, then would have been with the original criteria (21).

CONCLUSION

The present study shows that, although the hospital-based maternal mortality ratio is quite low compared to the country-level maternal mortality ratio, maternal morbidity and mortality remain challenging problems in a rural referral hospital in Tanzania. The WHO near miss criteria used for identification of near miss cases could not all be applied in this low-resource setting. Therefore the inclusion criteria were modified for use in Haydom. Results show that there is a gap between actual and optimal use of evidence-based interventions in women experiencing severe maternal morbidity and mortality. Improvement in the quality of obstetric care can be made through up scaling the use of evidence-based interventions.
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REFERENCES

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35. Smaill FM, Gyte GM. Antibiotic prophylaxis versus no prophylaxis for preventing...
CHAPTER 3
Applicability of the WHO near miss criteria in a low-resource setting
Ellen Nelissen, Estomih Mduma, Jacqueline Broerse, Hege Ersdal, Bjørg Evjen-Olsen, Jos van Roosmalen, Jelle Stekelenburg
CHAPTER 3

Applicability of the WHO near miss criteria in a low-resource setting

Ellen Nelissen, Estomih Mduma, Jacqueline Broerse, Hege Ersdal, Bjørg Evjen-Olsen, Jos van Roosmalen, Jelle Stekelenburg

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ABSTRACT

Background: Maternal near misses are increasingly used to study quality of obstetric care. Inclusion criteria for the identification of near misses are diverse and studies not comparable. The World Health Organization (WHO) developed universal near miss inclusion criteria in 2009 and these criteria have been validated in Brazil and Canada.

Objectives: To validate and refine the WHO near miss criteria in a low-resource setting.

Methods: A prospective cross-sectional study was performed in a rural referral hospital in Tanzania. From November 2009 until November 2011, all cases of maternal death and maternal near miss were included. For identification of maternal near misses, a local modification of the WHO near miss criteria was used, because most laboratory-based and some management-based criteria could not be applied in this setting. Disease-based criteria were added as they reflect severe maternal morbidity. In the absence of a gold standard for identification of maternal near miss, the clinical WHO criteria were validated for identification of maternal death.

Results: 32 maternal deaths and 216 maternal near misses were identified using the locally adapted near miss criteria; case fatality rate (CFR) was 12.9%. WHO near miss criteria identified only 60 maternal near misses (CFR 34.8%). All clinical criteria, 25% of the laboratory-based criteria and 50% of the management-based criteria could be applied. The threshold of five units of blood for identification of maternal near miss led to underreporting of maternal near miss cases. Clinical criteria showed specificity of 99.5% (95% confidence interval (CI): 99.4%-99.7%) and sensitivity of 100% (95% CI: 91.1%-100%). Some inclusion criteria did not contribute to the identification of cases and therefore may be eligible for removal.

Conclusion: The applicability of the WHO near miss criteria depends on the local context, e.g. level of healthcare. The clinical criteria showed good validity. Lowering the threshold for blood transfusion from five to two units in settings without blood bank and addition of disease-based criteria in low-resource settings is recommended.
INTRODUCTION

In 2011, 273,465 (uncertainty interval 256,332-291,693) women died worldwide during pregnancy, childbirth or within 42 days after childbirth (1). The majority of these women die in low-income countries, and sub-Saharan Africa carries the highest burden, with a maternal mortality ratio (MMR) ranging between 169/100,000 live births in Southern sub-Saharan Africa and 478/100,000 live births in West sub-Saharan Africa (1).

Worldwide the numbers of maternal deaths are high, but at hospital level numbers become scarce. It is important to understand the process of care that the patient has undergone in order to improve the quality of care. In this context, near miss events of women who almost died, but survived pregnancy related complications, are increasingly used in order to evaluate the functioning of the health system (2, 3). Near miss cases represent most of the characteristics of maternal deaths, but occur more often (4, 5). In addition, auditing near miss cases may be less threatening for the involved healthcare workers, because the cases can also be seen as ‘great saves’.

Identification criteria for maternal near misses or severe acute maternal morbidity were mainly divided into three areas: disease-based, management-based and organ-dysfunction-based criteria (6). However, since inclusion criteria are not uniform (2, 3, 7) and studies not comparable, the World Health Organization (WHO) developed a new definition of maternal near miss (MNM) and formulated identification criteria for maternal near miss cases in 2009 (8). A maternal near miss is defined by WHO as a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy (8). The inclusion criteria for a maternal near miss are categorised in three areas: clinical criteria, laboratory-based criteria and management-based criteria. The goal is that these identification criteria may be used in any setting, regardless of the development status. They should be comparable across settings and over time, and there should be a high threshold for identification of cases in order not to overload the health system with extra work (8). The development of the near miss criteria resulted in 2011 in the WHO near miss approach (9). This is a guideline for evaluating the quality of care for severe pregnancy complications, based on the concept of criterion-based clinical audit (10).
The WHO laboratory-based and management-based criteria were validated in Brazil and Canada (8, 11, 12). The results of the pre-validation showed that the WHO near miss criteria could identify all cases of maternal death and almost all cases who experienced organ failure (11).

The aims of this study were 1) to validate the WHO near miss criteria, especially the clinical criteria, in a low-resource setting, and 2) to further refine the WHO near miss criteria. This article reports on the experience of applying the WHO near miss criteria prospectively in a low-resource setting where the burden of maternal mortality and morbidity is high.

METHODS

A prospective cross-sectional study was conducted from November 2009 until November 2011 at Haydom Lutheran Hospital (HLH), a 400-bed referral hospital in Northern Tanzania. The hospital is located in an isolated, rural area, 300 km southwest from the nearest city, Arusha. Extrapolating from the 2002 census, the immediate catchment area covered a population of 327,000 in 2010. The greater reference area covered a population of approximately 2,200,000 (13). The hospital provides free reproductive and child health services, and comprehensive emergency obstetric care, including ambulance and radio service. Furthermore there is an Intensive Care Unit (ICU) with 24-hours medical supervision and facilities for mechanical ventilation.

**Inclusion criteria**

All maternal deaths and maternal near misses that were admitted to HLH were prospectively included in the study during the above-mentioned period. In this study, a maternal death (MD) is defined as the death of a woman while pregnant or within 42 days of termination of pregnancy, from any cause. For the identification of maternal near misses, we intended to use the WHO near miss criteria, but not all WHO criteria were applicable in this low-resource setting. Therefore, a local modification of the criteria for use in Haydom was made (Table 3.1). The definitions used for the Haydom near miss clinical criteria were the same as the definitions used for the WHO near miss clinical criteria. All clinical criteria could be applied in HLH. In the group of laboratory-based criteria, only oxygen saturation and measurement of
Table 3.1. WHO near miss criteria adapted to the local context of HLH

<table>
<thead>
<tr>
<th>WHO near miss criteria (8)</th>
<th>Haydom near miss criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical criteria</strong></td>
<td></td>
</tr>
<tr>
<td>Acute cyanosis</td>
<td>Acute cyanosis</td>
</tr>
<tr>
<td>Gasping</td>
<td>Gasping</td>
</tr>
<tr>
<td>Respiratory rate &gt; 40 or &lt; 6/min</td>
<td>Respiratory rate &gt; 40 or &lt; 6/min</td>
</tr>
<tr>
<td>Shock</td>
<td>Shock</td>
</tr>
<tr>
<td>Oliguria non responsive to fluids or diuretics</td>
<td>Oliguria non responsive to fluids or diuretics</td>
</tr>
<tr>
<td>Failure to form clots</td>
<td>Failure to form clots</td>
</tr>
<tr>
<td>Loss of consciousness lasting &gt; 12h</td>
<td>Loss of consciousness lasting &gt; 12h</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>Cardiac arrest</td>
</tr>
<tr>
<td>Stroke</td>
<td>Stroke</td>
</tr>
<tr>
<td>Uncontrollable fit/total paralysis</td>
<td>Uncontrollable fit/total paralysis</td>
</tr>
<tr>
<td>Jaundice in the presence of pre-eclampsia</td>
<td>Jaundice in the presence of pre-eclampsia</td>
</tr>
<tr>
<td><strong>Laboratory-based criteria</strong></td>
<td></td>
</tr>
<tr>
<td>Oxygen saturation &lt; 90% for ≥ 60 minutes</td>
<td>Oxygen saturation &lt; 90% for ≥ 60 minutes</td>
</tr>
<tr>
<td>PaO2/FiO2 &lt; 200 mmHg</td>
<td></td>
</tr>
<tr>
<td>Creatinine ≥ 300 µmol/L or ≥ 3.5 mg/dL</td>
<td></td>
</tr>
<tr>
<td>Bilirubin &gt; 100 µmol/L or &gt; 6.0 mg/dL</td>
<td></td>
</tr>
<tr>
<td>pH &lt; 7.1</td>
<td></td>
</tr>
<tr>
<td>Lactate &gt; 5 mEq/mL</td>
<td></td>
</tr>
<tr>
<td>Acute thrombocytopenia (&lt; 50,000 platelets/ml)</td>
<td>Acute thrombocytopenia (&lt; 50,000 platelets/ml)</td>
</tr>
<tr>
<td>Loss of consciousness and ketoacids in urine</td>
<td></td>
</tr>
<tr>
<td><strong>Management-based criteria</strong></td>
<td></td>
</tr>
<tr>
<td>Use of continuous vasoactive drugs</td>
<td>Admission to intensive care unit</td>
</tr>
<tr>
<td>Hysterectomy following infection or haemorrhage</td>
<td>Hysterectomy following infection or haemorrhage</td>
</tr>
<tr>
<td>Transfusion of ≥ 5 units of blood</td>
<td>Transfusion of ≥ 1 unit of blood</td>
</tr>
<tr>
<td>Intubation and ventilation for ≥ 60 minutes not</td>
<td>Intubation and ventilation for ≥ 60 minutes not</td>
</tr>
<tr>
<td>related to anaesthesia</td>
<td>related to anaesthesia</td>
</tr>
<tr>
<td>Dialysis for acute renal failure</td>
<td></td>
</tr>
<tr>
<td>Cardio-pulmonary resuscitation</td>
<td>Cardio-pulmonary resuscitation</td>
</tr>
<tr>
<td><strong>Severe maternal complications</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Eclampsia</td>
</tr>
<tr>
<td></td>
<td>Sepsis or severe systemic infection</td>
</tr>
<tr>
<td></td>
<td>Uterine rupture</td>
</tr>
</tbody>
</table>

See glossary for definitions

platelets could be used. The other six laboratory-based criteria, PaO2, creatinine, bilirubin, pH, lactate, and ketoacids in the urine were not available in the laboratory and could therefore not be measured. These were removed from the list of inclusion criteria. In the category management-based criteria, three out of six criteria could be used in HLH (intubation and ventilation, cardio-pulmonary resuscitation (CPR) and hysterectomy). The three management-based criteria that could not be used were use of continuous vasoactive drugs (not available), renal dialysis (not available), and transfusion of five or more units of blood. The threshold for transfusion of five units of blood or more was reduced to at least one unit of blood, as blood is very scarce in this setting and there is no functioning blood bank. Women in need of blood are dependent on family members who serve as blood donors. As a result, transfusion of even one unit of blood may be a true indicator of severe
maternal morbidity in HLH. For the same reason, admission to ICU was added to the management-based criteria. Women who require intensive care suffer from illnesses, which may be classified as severe maternal morbidity in the context of HLH. Uterine rupture, eclampsia and sepsis are common causes of maternal mortality (14). Therefore, the authors unanimously decided to add the diagnoses of uterine rupture, eclampsia and sepsis to the inclusion criteria, as they reflect severe maternal complications and were not covered by the WHO inclusion criteria for near miss. We decided to not include severe postpartum haemorrhage as a separate disease-based criterion, as it was already captured by the inclusion criteria “shock” and “use of blood products”. Data were collected with the local “Haydom near miss criteria”. Afterwards, the WHO near miss criteria were applied to the Haydom data set and compared with the Haydom near miss criteria.

Data collection and quality assessment
Cases were identified on a daily basis by either the first author (EN) or by one of the two trained research assistants (nurse-midwives). This was achieved through daily participation in the morning report and daily visits to the maternity ward, ICU and the internal medicine ward. When the inclusion criteria were met, a structured questionnaire was filled out after discharge or death of the woman. Data were obtained from hospital files. The completed questionnaires were checked by a second person on missing data or discrepancies. If needed, a copy of the hospital file was checked to validate the recordings. Variables that were collected for this study were information on presence of an inclusion criterion and final outcome (MNM or MD). Furthermore, measurements to identify clinical and laboratory-based criteria were noted (physical examination, vital signs, urinary output, oxygen saturation and full blood count). All data were double entered and cross-checked in Epidata (15).

Validation
Previous validation of the WHO near miss criteria was done with the Sequential Organ Failure Assessment (SOFA) score as gold standard for the definition of MNM (11). Six variables were used to determine the SOFA score: measurement of PaO2 or FiO2, platelet count, measurement of bilirubin, hypotension (and the use of continuous vasoactive drugs), the Glasgow Coma Score, and measurement of creatinine or urinary output (16). In this low-
resource setting we were able to collect only three of the six variables that were used to determine the SOFA score (platelet count, the Glasgow Coma Score, urinary output). Therefore the SOFA score could not be used as gold standard. In addition, it is questionable to use the SOFA score for validation because the WHO criteria were derived from it. Instead, we validated the clinical WHO near miss criteria for the identification of maternal deaths, as maternal deaths should be comparable to maternal near misses, except for the vital status (5).

Refining the near miss criteria
In order to refine the WHO near miss criteria, and thereby improve the applicability in practice, we performed a stepwise elimination process, to determine which criteria were most important. The inclusion criteria were ranked from most to least frequently used. Subsequently, the most frequently used inclusion criterion was excluded, and all cases with this inclusion criterion were (temporarily) removed from the database. Thereafter, frequencies of inclusion criteria were calculated again for the remaining cases and a new ranking was created. This stepwise elimination process helped us to rank the inclusion criteria according to importance (frequency of use).

Statistical analysis
Data analysis consisted of frequencies of the use of inclusion criteria, the presence of physical examination and measurement of vital signs, urinary output, oxygen saturation and full blood count. Validity of the (clinical) WHO near miss criteria and Haydom near miss criteria was assessed by calculating sensitivity, specificity, positive predictive value and negative predictive value against outcome (maternal death), among all women who delivered during the study period. All results are reported as number (n) and frequency (%). Analysis was performed using SPSS Statistics, version 20 (SPSS Inc. Chicago, Illinois).

Ethical clearance
The study was performed in full accordance with the guidelines for medical research of the Helsinki declaration of 1975, as revised in 2008. Ethical approval was obtained from the Tanzanian National Institute for Medical Research (NIMR) (reference NIMR/HQ/R.8a/Vol.IX/1247), the Tanzania Commission for Science and Technology.
(COSTECH) (reference 2012-56-NA-2011-201), and from the VU university medical centre (VUmc), the Netherlands (reference 2011/389). As stated by the VU university medical centre, the study does not fall within the scope of the Medical Research Involving Human Subjects Act, and formal approval was not needed. Data were collected and extracted from patient records without any identification of the subject. Questionnaires were filled in after discharge or death and therefore study inclusion did not have effect on the treatment. Considering this approach and the statement of the VUmc, individually obtained informed consent was not required.

RESULTS

According to the local Haydom near miss criteria, 248 women with life-threatening conditions were included in the two-year study period: 216 MNM and 32 MD. When the WHO near miss criteria were applied to this dataset, 92 women with life-threatening conditions remained, of which 60 MNM and 32 MD (Table 3.2). In the two-year study period 9,471 deliveries and 9,136 live births occurred at HLH, resulting in a severe maternal outcome ratio of 27.1 per 1,000 live births. Case fatality rate (CFR) for cases identified with the Haydom near miss criteria was 12.9%, whereas CFR for cases identified with the WHO criteria was 34.8%.

The difference in the number of near misses can be attributed largely to the different threshold for the transfusion of blood. For the Haydom criteria one unit was chosen, as compared to five units for the WHO criteria. Of 248 women that were included with the Haydom near miss criteria, 184 women received one unit of blood or more, compared to 58 of the 92 women selected with the WHO criteria. Two of the 58 cases had transfusion of five units or more. Figure 3.1 shows the number of blood products given, and whether there were other inclusion criteria or not. One hundred eight women received one unit of blood. Of these women, 77 women did not have another inclusion criterion. Fifty-four women received two units of blood, of which 22 women did not have another inclusion criterion. Increasing the threshold to five units of blood led to the inclusion of two cases only. Excluding the 77 women who received only one unit of blood, would lead to a rise in CFR from 12.9% to 22.6% (32/171). Other differences in the number of near misses could be
attributed to the inclusion of all cases with eclampsia, sepsis, uterine rupture and admission to ICU (Table 3.2). Women with these conditions were treated appropriately and did not reach a stage of (multiple) organ failure.

Table 3.2. Use of near miss inclusion criteria

<table>
<thead>
<tr>
<th>Illustration</th>
<th>Haydom (n=248)</th>
<th>WHO (n=92)</th>
<th>Excluded (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MNM</td>
<td>216</td>
<td>60</td>
<td>156</td>
</tr>
<tr>
<td>MD</td>
<td>32</td>
<td>32</td>
<td>0</td>
</tr>
</tbody>
</table>

**Clinical criteria**

- Acute cyanosis: 5 (5) / 5 (5)/ 5 (5)
- Gasping: 15 (15) / 15 (15) / 0 (0)
- Respiratory rate >40 or <6/min: 10 (10) / 10 (10) / 0 (0)
- Shock: 51 (51) / 51 (51) / 0 (0)
- Oliguria non responsive to fluids or diuretics: 4 (4) / 4 (4) / 0 (0)
- Failure to form clots: 3 (3) / 3 (3) / 0 (0)
- Loss of consciousness lasting >12h: 16 (16) / 16 (16) / 0 (0)
- Cardiac arrest: 26 (26) / 26 (26) / 0 (0)
- Stroke: 4 (4) / 4 (4) / 0 (0)
- Uncontrollable fit/total paralysis: 3 (3) / 3 (3) / 0 (0)
- Jaundice in the presence of pre-eclampsia: 3 (3) / 3 (3) / 0 (0)

**Laboratory based criteria**

- Oxygen saturation <90% for ≥60 minutes: 17 (17) / 17 (17) / 0 (0)
- Acute thrombocytopenia: 12 (12) / 12 (12) / 0 (0)

**Management based criteria**

- Admission to intensive care unit: 91 (63) / 63 (28)
- Hysterectomy following infection or haemorrhage: 16 (16) / 0 (0)
- Use of blood products: 184 (58) / 126 (0)
- Intubation and ventilation for ≥ 60 minutes not related to anaesthesia: 15 (15) / 0 (0)
- Cardio-pulmonary resuscitation: 19 (19) / 0 (0)

**Severe maternal complications**

- Eclampsia: 15 (5) / 10 (10)
- Sepsis: 30 (20) / 10 (10)
- Uterine rupture: 20 (13) / 7 (7)

Women can have more than one inclusion criterion.

Measurements to identify clinical and laboratory-based criteria were insufficient: 91.5% (n=227) of 248 women with life-threatening conditions had physical examination on arrival. Blood pressure was measured in 74% (n=183); pulse rate was noted in 68% (n=169) and temperature in 65% (n=161). Urinary output was measured in 10% (n=25) of all cases. Oxygen saturation on admission was only noted in 4.8% (n=10) of all women with life-threatening conditions. Full blood count (including platelet count) was taken in 90.1% (n=155) of 172 women that were ill on arrival.
The clinical WHO near miss criteria were validated for identifying maternal deaths (Table 3.3). Sensitivity was 100% (95%CI: 91.1%-100%), specificity was 99.5% (95%CI: 99.4%-99.7%), positive predictive value was 41.6% (95%CI: 31.1%-52.8%) and negative predictive value was 100% (95%CI: 100%-100%), among all women who delivered during the study period. In addition, all WHO near miss criteria that could be applied in this setting were validated and show similar sensitivity (100%, 95%CI: 91.1%-100%) and specificity (99.4%, 95%CI: 99.2%-99.5%). The positive predictive value of all criteria combined is lower than the clinical criteria alone (34.8%, 95%CI: 25.6%-44.9%), and the negative predictive value is equal (100%, 95%CI: 100%-100%). Lastly, the Haydom near miss criteria were validated. Sensitivity is 100% (95%CI: 91.1%-100%), specificity is 97.7% (95%CI: 97.4%-98.0%), positive predictive value is 12.9% (95%CI: 9.2%-17.5%) and negative predictive value is 100% (95%CI: 99.9%-100%). If the threshold for blood transfusion would be raised to two units of blood or more, sensitivity would remain at 100% (95%CI: 91.1%-100%), specificity would increase slightly (98.5%, 95%CI: 98.3%-98.8%), positive predictive value would increase to 18.7% (95%CI: 13.4%-25.1%), and negative predictive value would remain at 100% (95%CI: 100%-100%).

Table 3.4 presents the contribution per WHO inclusion criterion using a stepwise elimination process, as described in the methods section. The inclusion criterion that was used most frequently was shock. Ninety-two MNM and MD were included with the WHO criteria, of which 51 cases had shock as inclusion criterion. After excluding all women with shock, 41 MNM and MD remained. Frequencies of the remaining inclusion criteria were calculated and
Table 3.3. Validity of the WHO and Haydom near miss criteria among all women

<table>
<thead>
<tr>
<th>Maternal Outcome = Death</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHO clinical criteria</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>32</td>
<td>45</td>
<td>77</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>9,394</td>
<td>9,394</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>9,439</td>
<td>9,471</td>
</tr>
<tr>
<td><strong>WHO near miss criteria</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>32</td>
<td>60</td>
<td>92</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>9,379</td>
<td>9,379</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>9,439</td>
<td>9,471</td>
</tr>
<tr>
<td><strong>Haydom near miss criteria</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>32</td>
<td>216</td>
<td>248</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>9,223</td>
<td>9,223</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>9,439</td>
<td>9,471</td>
</tr>
</tbody>
</table>

Validity WHO clinical criteria: Sensitivity: 100%; 95%CI [91.1%-100%], Specificity: 99.5%; 95%CI [99.4%-99.7%], Positive predictive value: 41.6%; 95%CI [31.1%-52.8%], Negative predictive value: 100%; 95%CI [100%-100%]

Validity WHO near miss criteria: Sensitivity: 100%; 95%CI [91.1%-100%], Specificity: 99.4%; 95%CI [99.2%-99.5%], Positive predictive value: 34.8%; 95%CI [25.6%-44.9%], Negative predictive value: 100%; 95%CI [100%-100%]

Validity Haydom near miss criteria: Sensitivity: 100%; 95%CI [91.1%-100%], Specificity: 97.7%; 95%CI [97.4%-98.0%] Positive predictive value: 12.9%; 95%CI [9.2%-17.5%], Negative predictive value: 100%; 95%CI [99.9%-100%]
now “loss of consciousness lasting > 12h” was most frequently used (n=13). This stepwise elimination process was continued until all inclusion criteria were excluded actively or eliminated passively. The inclusion criteria that led independently to the identification of MNM and MD cases were shock (n=51), loss of consciousness lasting > 12h (n=13), cardiac arrest (n=8), hysterectomy (n=8), acute thrombocytopenia (n=4), intubation and ventilation for ≥ 60 minutes not related to anaesthesia (n=2), oxygen saturation < 90% for ≥ 60 minutes (n=1), respiratory rate > 40 or < 6/min (n=1), oliguria non responsive to fluids or diuretics (n=1), failure to form clots (n=1), jaundice in the presence of pre-eclampsia (n=1) and transfusion of five units of blood or more (n=1). Inclusion criteria that did not have an independent contribution to identification of cases (but only in combination with other inclusion criteria) were: CPR, gasping, stroke, uncontrollable fit and acute cyanosis. When this stepwise elimination process was repeated for the Haydom near miss criteria, the most frequently used inclusion criteria were: use of blood products (n=184), admission to ICU (n=41), sepsis (n=7), eclampsia (n=6), and uterine rupture (n=5). The following criteria were not used: CPR, oxygen saturation < 90% for ≥ 60 min, loss of consciousness lasting > 12h, gasping, intubation and ventilation for ≥ 60 min not related to anaesthesia, acute thrombocytopenia, respiratory rate > 40 or < 6/min, stroke, jaundice in the presence of pre-eclampsia, failure to form clots, uncontrollable fit and acute cyanosis.

**DISCUSSION**

In this paper we report on the applicability and validation of the WHO near miss criteria in a 2-year prospective cross-sectional study in the low-resource setting of a rural referral hospital in Tanzania. The results show that all clinical criteria could be used in this setting. Experience at HLH, however, indicates that it is not easy to recognise clinical criteria. In maternity ward ten nurse-midwives are available each day, divided over three shifts, to take care of 60 in-patients and an average of 15 deliveries per day. Nurse-midwives are the sentinel persons that should identify clinical signs of deterioration of a patient. With this shortage of healthcare personnel, clinical signs of deterioration may go unnoticed and this could lead to underreporting of maternal near misses.
Table 3.4. Stepwise elimination process of the WHO near miss criteria n (%)  

<table>
<thead>
<tr>
<th></th>
<th>STEP 1</th>
<th>STEP 2</th>
<th>STEP 3</th>
<th>STEP 4</th>
<th>STEP 5</th>
<th>STEP 6</th>
<th>STEP 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>MNM + MD</td>
<td>n=41</td>
<td>n=28</td>
<td>n=20</td>
<td>n=12</td>
<td>n=8</td>
<td>n=6</td>
<td>n=0</td>
</tr>
<tr>
<td>Shock</td>
<td>EXCL</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>31 (55.4)</td>
<td>9 (22.0)</td>
<td>8 (28.6)</td>
<td>EXCL</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cardio-pulmonary resuscitation (CPR)</td>
<td>19 (20.7)</td>
<td>7 (17.1)</td>
<td>6 (21.4)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Oxygen saturation &lt; 90% for ≥ 60 min</td>
<td>17 (18.5)</td>
<td>8 (19.5)</td>
<td>5 (17.9)</td>
<td>2 (10.0)</td>
<td>1 (8.3)</td>
<td>1 (12.5)</td>
<td>1 (16.7)</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>16 (17.4)</td>
<td>8 (19.5)</td>
<td>8 (28.6)</td>
<td>8 (40.0)</td>
<td>EXCL</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Loss of consciousness lasting &gt;12h</td>
<td>16 (17.4)</td>
<td>13</td>
<td>EXCL</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gasping</td>
<td>15 (16.3)</td>
<td>5 (12.2)</td>
<td>4 (14.3)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Intubation and ventilation for ≥ 60 minutes not related to anaesthesia</td>
<td>15 (16.3)</td>
<td>6 (14.6)</td>
<td>5 (17.9)</td>
<td>2 (10.0)</td>
<td>2 (16.7)</td>
<td>2 (25.0)</td>
<td>EXCL</td>
</tr>
<tr>
<td>Acute thrombocytopenia</td>
<td>12 (13.0)</td>
<td>5 (12.2)</td>
<td>4 (14.3)</td>
<td>4 (20.0)</td>
<td>4 (33.3)</td>
<td>EXCL</td>
<td>-</td>
</tr>
<tr>
<td>Respiratory rate &gt; 40 or &lt; 6/min</td>
<td>10 (10.9)</td>
<td>7 (17.0)</td>
<td>5 (17.9)</td>
<td>3 (15.0)</td>
<td>3 (25.0)</td>
<td>1 (12.5)</td>
<td>1 (16.7)</td>
</tr>
<tr>
<td>Oliguria non responsive to fluids or diuretics</td>
<td>4 (4.3)</td>
<td>3 (7.3)</td>
<td>1 (3.6)</td>
<td>1 (5.0)</td>
<td>1 (8.3)</td>
<td>1 (12.5)</td>
<td>1 (16.7)</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (4.3)</td>
<td>3 (7.3)</td>
<td>1 (3.6)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Failure to form clots</td>
<td>1 (3.3)</td>
<td>1 (2.4)</td>
<td>1 (3.6)</td>
<td>1 (5.0)</td>
<td>1 (8.3)</td>
<td>1 (12.5)</td>
<td>1 (16.7)</td>
</tr>
<tr>
<td>Jaundice in the presence of pre-eclampsia</td>
<td>1 (3.3)</td>
<td>2 (4.9)</td>
<td>1 (3.6)</td>
<td>1 (5.0)</td>
<td>1 (8.3)</td>
<td>1 (12.5)</td>
<td>1 (16.7)</td>
</tr>
<tr>
<td>Uncontrollable fit/total paralysis</td>
<td>1 (3.3)</td>
<td>3 (7.3)</td>
<td>1 (3.6)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Transfusion of blood ≥ 5 units</td>
<td>1 (4.3)</td>
<td>1 (2.4)</td>
<td>1 (3.6)</td>
<td>1 (5.0)</td>
<td>1 (8.3)</td>
<td>1 (12.5)</td>
<td>1 (16.7)</td>
</tr>
<tr>
<td>Acute cyanosis</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

EXCL: Excluded. Bold: Criteria that have an independent contribution to inclusion of cases. Step 2: Two inclusion criteria have n=8. Cardiac arrest is excluded because it was the second most frequent used inclusion criterion from start. Step 7: Six cases are left with six corresponding, independently used inclusion criteria (oxygen saturation, respiratory rate > 40 or < 6/min, oliguria non responsive to fluids or diuretics, failure to form clots, jaundice in the presence of pre-eclampsia and transfusion of blood ≥ 5 units). They are excluded simultaneously for space reasons.

Only 25% of all laboratory-based criteria could be used in HLH. Oxygen saturation measurement in our setting is only available in the ICU, and thus has only been measured in 4.8% of all cases. Although the laboratory-based criteria could be used in settings in Brazil (11, 12, 17), the use of these criteria may not be feasible in many health institutions in low-income countries due to the unavailability of sophisticated laboratory measurements. Therefore, most studies in sub-Saharan Africa used disease-based or management-based criteria that do not require a sophisticated laboratory (7, 18, 19), except for one study conducted in South Africa that used organ-dysfunction based criteria (20).
The three management-based criteria that could be used at Haydom were easy to identify and therefore used as an inclusion criterion. Because HLH does not have a well-stocked blood bank, the transfusion of five or more units of blood was considered very unlikely and occurred in only two cases. One woman received one unit of allogeneic blood and five units of auto-transfusion, following ruptured ectopic pregnancy. The other woman was diagnosed with molar pregnancy and received two units of blood in another hospital, before being referred to HLH where she received another three units of blood. Figure 3.1 shows that for HLH the optimal threshold may be set at two units of blood or more. When the threshold was set at two units, 77 women that only had one blood transfusion as inclusion criterion would not have been included. Women in this group were mainly diagnosed with abortion-related complications, antepartum haemorrhage, anaemia in pregnancy and postpartum haemorrhage, and were not considered critically ill. Despite the scarcity of blood, some women received one unit of blood transfusion without a proper indication. There were no maternal deaths in this group of 77 women.

Few studies used the WHO near miss criteria for retrospective identification of near misses (11, 12, 17, 21). Morse et al. showed how the number of near misses altered when different inclusion criteria were used in a regional referral hospital in Brazil (17): using disease-based criteria they included 87 MNM, using organ-dysfunction-based criteria they included 14 MNM and using the WHO near miss criteria only 10 MNM were left. Like in our study, using the WHO near miss criteria resulted in a very high threshold for identification of cases. In two other settings in Brazil the WHO near miss criteria were validated (11, 12). Cecatti et al. used the SOFA score as gold standard for the identification of near misses (16). Souza et al. validated the WHO near miss criteria for identifying maternal deaths. The results of both validation studies are similar to ours. In a recent study in Malawi, like in our study, the application of organ-dysfunction-based criteria underestimated severe maternal morbidity, because of absence of disease-based criteria in the WHO near miss approach (21).

In our study several inclusion criteria were detected, which did not identify near miss cases independently. These criteria are eligible for removal from the WHO near miss criteria. This will refine the WHO near miss approach and improve its applicability. This is in concordance with Morse et al., who found that only 12 out of 25 WHO near miss criteria contributed to
the identification of near misses (17). Criteria that were not used resemble criteria that were not used in our study (acute cyanosis, gasping, uncontrollable fit and CPR).

All studies showed that the applicability of the WHO near miss criteria depends on the local context and the local availability of resources, e.g. level of healthcare. Therefore we suggest different criteria that account for different levels of healthcare. For example, in a district hospital in a low-resource setting, sophisticated laboratory-based criteria are better not used. Even then local adaptation might be needed, as in our setting an advanced laboratory allowed platelet count, which is not necessary the case in other district hospitals. Most studies in low-resource settings used disease-based criteria, like eclampsia, sepsis and uterine rupture, to identify near miss cases. Excluding these cases leads to underestimation of maternal near miss cases and therefore we recommend these criteria to be added to the WHO near miss approach, despite the fact that definitions of disease-based criteria may vary among settings.

A limitation of our study is that data collection was only done in wards where pregnant women were mostly admitted. It might be possible that we missed cases that were admitted to other wards. However, HLH policy is that all pregnant women are admitted to maternity ward, and therefore the number of cases that might have been missed will be negligible.

Poor documentation has negative impact on the identification of inclusion criteria. Human resource shortage and low educational levels of staff may affect the quality of documentation and therefore may negatively interfere with case identification and data collection. We realise that our study is a hospital-based study. Many women who suffer from severe maternal morbidity in the district do not reach the hospital.

**CONCLUSION**

To our knowledge, this is the first study in which the WHO near miss criteria were used and validated prospectively in a rural referral hospital in a low-resource setting. The applicability of the WHO near miss criteria depends on the local context. In our setting, clinical criteria could be applied and show good sensitivity and specificity. However, sophisticated
laboratory and some management-based criteria could not be used. We would recommend lowering the threshold for blood transfusion from five to two units in settings where there is no blood bank. Furthermore, in low-resource settings disease-based criteria should be added to the WHO near miss criteria as they reflect severe maternal morbidity. Future research should focus on validation of the WHO near miss criteria across multiple low-income countries (22), and clinical criteria should be specifically validated for the identification of near misses.
Applicability of the WHO near miss criteria | 77

REFERENCES

PART 2

AN EDUCATIONAL INTERVENTION TO REDUCE MATERNAL MORBIDITY AND MORTALITY
CHAPTER 4

Helping mothers survive bleeding after birth: an evaluation of simulation-based training in a low-resource setting

Ellen Nelissen, Hege Ersdal, Doris Østergaard, Estomih Mduma, Jacqueline Broerse, Bjørg Evjen-Olsen, Jos van Roosmalen, Jelle Stekelenburg

CHAPTER 4

Helping mothers survive bleeding after birth: an evaluation of simulation-based training in a low-resource setting

Ellen Nelissen, Hege Ersdal, Doris Østergaard, Estomih Mduma, Jacqueline Broerse, Bjørg Evjen-Olsen, Jos van Roosmalen, Jelle Stekelenburg

ABSTRACT

Objective: To evaluate “Helping Mothers Survive Bleeding After Birth” (HMS BAB) simulation-based training in a low-resource setting.

Design: Educational intervention study.

Setting: Rural referral hospital in Northern Tanzania.


Methods: In March 2012, healthcare workers were trained in HMS BAB, a half-day simulation-based training, using a train-the-trainer model. The training focused on basic delivery care, active management of third stage of labour, and treatment of postpartum haemorrhage (PPH), including bimanual uterine compression.

Main outcome measures: Evaluation questionnaires provided information on course perception. Knowledge, skills, and confidence of facilitators and learners were tested before and after training.

Results: Four master trainers trained eight local facilitators, who subsequently trained 89 learners. After training, all facilitators passed the knowledge test, but pass rates for the skills test were low (29% pass rate for basic delivery and 0% pass rate for management of PPH). Evaluation revealed that HMS BAB training was considered acceptable and feasible, although more time should be allocated for training, and teaching materials should be translated into the local language. Knowledge, skills, and confidence of learners increased significantly immediately after training. However, overall pass rates for skills tests of learners after training were low (3% pass rate for basic delivery and management of PPH).
Conclusions: HMS BAB training has potential to contribute to education of healthcare providers. We recommend a full day training and validation of the facilitators to improve the training.
INTRODUCTION

Haemorrhage is the leading cause of maternal mortality in Africa (33.9%, 95% confidence interval (CI): 13.3-43.6%) and Asia (30.8%, 95%CI: 5.9-48.5%) and should be targeted to reduce the number of maternal deaths (1). Audit suggests that better management of postpartum haemorrhage (PPH) through training can improve care and reduce maternal mortality (2-5). Simulation-based education is increasingly used to train healthcare providers in obstetrical emergencies (6-11). It is suitable for both pre- and in-service settings, thereby providing a continuum of training throughout a professional career.

In order to improve quality of care during the day of birth, Jhpiego and Laerdal Global Health developed the simulation-based training “Helping Mothers Survive” (12). The training materials were reviewed by external stakeholders from different international organizations. HMS targets healthcare providers in countries with a high burden of maternal mortality. The first module “Bleeding After Birth” focuses on basic delivery care, active management of third stage of labour (AMTSL), and treatment of PPH (12). The training is designed for all levels of healthcare providers. It is compatible with Helping Babies Breathe (HBB), a simulation-based training that teaches routine newborn care and resuscitation (13).

The aim of this study was to evaluate Helping Mothers Survive Bleeding After Birth (HMS BAB) training by addressing the following research questions: 1) To what extent is HMS BAB training acceptable and feasible in a low-resource setting? 2) To what extent do knowledge, skills, and confidence of healthcare providers change after HMS BAB training?

METHODS

An educational intervention study was carried out in March 2012 at Haydom Lutheran Hospital, a rural referral hospital in Northern Tanzania. Annually, approximately 5,000 women give birth in the hospital. Ethical approval was obtained from the Tanzanian National Institute for Medical Research (reference NIMR/HQ/R.8a/Vol.IX/1247), the Tanzania Commission for Science and Technology (reference 2012-56-NA-2011-201), and from the VU University Medical Centre, the Netherlands (reference 2011/389). Permission to conduct the
study was obtained from the hospital management. Written informed consent was obtained from each participant before entering the study.

HMS makes use of a train the trainer model in which training is cascaded down from master trainers to local facilitators to learners (14). In this study, master trainers were certified trainers and healthcare professionals (three nurse midwives and one medical doctor) from the United States, Norway, The Netherlands, and Tanzania. They trained local facilitators in a one to one ratio. The hospital management selected local facilitators based on clinical and teaching experience. Training started with an introduction regarding the development and aim of the HMS BAB training (one hour). This was followed by three hours of theory regarding basic delivery care, active management of third stage of labour, and treatment of PPH, using training materials such as the “Action Plan” (wall poster to aid decision making), a “Training Flip Book” (graphic display used during training), and a “Facilitation Guide” (in English) (15). In the second half of the day MamaNatalie (Laerdal Global Health, Stavanger, Norway), a low-cost, low-tech birthing simulator was introduced. The different components of active management of third stage of labour and treatment of PPH were addressed by using the mannequin. Each facilitator took part in scenario training and received feedback from the master trainer.

Subsequently, local facilitators trained local learners in a half-day session under supervision of master trainers. In total there were six training sessions, divided over three days. Clinicians, nurse-midwives, medical attendants (nurse aids without formal medical education), and ambulance drivers (without formal medical education) involved in maternity care (including nurse-midwives from the intensive care unit and operating theatre) were selected by the hospital management to attend training. Training took place in a communal room in the hospital and started with a simulated scenario of a birth complicated by PPH and maternal death with a facilitator taking on the role of a patient actor. An introduction of the course by one of the master trainers followed and subsequently the learners were allocated to the four available facilitators. Training was conducted in small groups and the groups contained healthcare providers of different cadres (maximum six learners per facilitator). It started with 1.5 hour of theory using the HMS BAB training materials, and was followed by
1.5 hour of skills and scenario training with the birthing simulator. Each learner took part in one scenario and received feedback from the facilitator.

**Evaluation and assessment**

The intervention was assessed according to level 1 and 2 of the Kirkpatrick model, a method commonly used for evaluation of training programs (Figure 4.1) (16). To assess course perception (level 1), both facilitators and learners were requested to fill out an evaluation questionnaire immediately after training to record their opinion about the feasibility and acceptability of HMS BAB training. A 5-point Likert scale was used (ranging from 1= strongly disagree to 5= strongly agree). In addition, suggestions to improve training could be made in an open remark. A draft evaluation questionnaire had previously been reviewed and approved by maternal health experts in a group meeting.

![Kirkpatrick model for evaluation of training programmes](image)

**Figure 4.1.** Kirkpatrick model for evaluation of training programmes

Level 2 of the Kirkpatrick model relates to knowledge, skills, and attitudes acquired due to training. Knowledge was assessed by means of a written 26-item knowledge test that was administered immediately before and after training. It consisted of 14 multiple-choice questions and 12 yes/no questions. The criterion-referenced pass score was ≥ 70% correct answers. The knowledge test was developed and validated by Jhpiego. First, competences required for PPH prevention and management were selected and linked to a measurable...
item. Subsequently, 34 maternal health experts validated the content of the knowledge test by 1) setting a criterion-referenced pass score using the Angoff procedure, 2) providing suggestions for improving the wording of the questions, and 3) answering each question to the best of their ability. One hundred percent of all experts who were asked to complete the test passed the test, thereby ensuring construct validity. Differential item function was addressed after finishing this study. The results from the validation of the HMS BAB training in three countries were similar, showing no evidence of bias.

Figure 4.2. Flow chart of facilitators and learners

- Due to logistic reasons, only healthcare providers working in labour ward, ambulance drivers, and facilitators were enrolled for skills assessment
- Three learners arrived too late at the training venue and therefore missed test before training, but completed test after training
- One facilitator was not available for follow up due to clinical duty
- Eleven learners were not available for follow up due to leave, illness, and clinical duty
- One learner refused to complete the knowledge test because the allowance was too low, one learner forgot to complete the knowledge test
Due to logistic reasons, only healthcare providers working in labour ward, ambulance drivers, and facilitators were enrolled for skills assessment (Figure 4.2). They were tested in the week before training, and again in the week after training. Performance was assessed in two simulated scenarios using the birthing simulator: “basic delivery” and “management of PPH due to uterine atony”. The second scenario was further divided into “management of PPH” and “performance of bimanual uterine compression”.

A draft checklist based on literature and clinical experience was created, and six maternal health experts reviewed the draft checklist (17, 18). The checklist was pilot tested on dummy videos of simulated scenarios of basic delivery and management of PPH and few adjustments were made. Two scoring categories were created: done and not done. Eventually, 16 items for uncomplicated delivery and 18 items for management of PPH were selected for the checklist. Finally, essential items were identified that needed to be done in order to pass the test (five items for basic delivery, and eight items for management of PPH). The six maternal health experts reviewed and approved the final version of the checklist.

Before starting the skills test, MamaNatalie was introduced to the facilitators and learners to familiarise them with the mannequin. Furthermore, the concept of simulation was explained, along with a description of what was to be expected from the healthcare worker. A scenario description was given prior to the start of each scenario.

The skills test was videotaped and subsequently assessed by two independent assessors (both residents in obstetrics and gynaecology in the Netherlands). The assessors were blinded for the time of testing (pre- or post-intervention). Both assessors individually evaluated five dummy videos of basic delivery and management of PPH. The inter-rater agreement of dummy testing was greater than 80%. Subsequently, the first assessment of the videos of the skills test followed. Overall inter-rater agreement was 90%, and the inter-rater agreement per item on the checklist ranged from 61.1% to 100%. The Kappa (K) measure of agreement ranged between $K=0.37$ and $K=1.00$ for the pre-test and $K=0.14$ and $K=1.00$ for the post-test assessment. During a second assessment the two assessors assembled, watched the videos together, and discussed items that were scored differently. Final scores were unanimously agreed upon.
Attitude was addressed by assessing confidence of facilitators and learners in their ability to perform AMTSL, manage PPH, determine completeness of the placenta, perform bimanual uterine compression, and access advanced care. Confidence was appraised using a questionnaire, which was filled in by all facilitators and learners immediately before and after training. Five answers were possible ranging from 1= I cannot perform this skill to 5= extremely confident. This questionnaire also contained questions about their characteristics. Prior to the study, all evaluation and assessment tools were tested locally and adjusted accordingly as needed. All assessment materials were available in two languages: English and Kiswahili.

Statistical analysis
We performed a power calculation based on consensus of the authors, as there was no pilot data or literature on the effect of simulation-based training on knowledge and skills of healthcare workers in low-resource settings. To show an improvement of knowledge of healthcare providers from 50% sufficient knowledge before training to 80% after training with 80% power and a confidence interval of 95%, a sample of 40 healthcare providers was needed before intervention and the same number after intervention. Data were double entered and checked in EpiData (The EpiData Association, Odense, Denmark), and analyzed using IBM SPSS Statistics, version 20 (IBM, Armonk, NY, USA). Descriptive statistics were calculated for participant characteristics, training evaluation, confidence, knowledge, and skills. Results are reported as number (n), percentage (%), mean, and standard deviation (SD). Results before and after training results were compared using matched cohorts only. Paired-samples t-tests (two-tailed) were conducted to evaluate the impact of the intervention on the mean score of knowledge and skills. In order to assess the inter-rater reliability we calculated the percentage of agreement between the two assessors and Kappa measure of agreement for each item on the checklists. Wilcoxon signed rank test was used to compare the level of confidence before and after training.

RESULTS
Four master trainers trained eight local facilitators. The group of facilitators consisted of one medical attendant, four nurse-midwives (of which two tutors in the midwifery school), and
three clinicians. The majority of facilitators (63%) were active birth attendants at the time of training. Seven out of eight (88%) facilitators received pre-service training in AMTSL, and 75% received training in management of PPH. Only three out of eight (38%) facilitators had received in-service training in AMTSL and management of PPH throughout their professional career (Table 4.1). Eight facilitators completed the knowledge and skills test and confidence questionnaire before training and seven facilitators completed the knowledge and skills test and confidence questionnaire after training. Mean scores of the knowledge test improved, and after training 100% of the facilitators passed the knowledge test (Table 4.2). Although mean scores of the scenarios "basic delivery" and "bimanual uterine compression" improved, only two out of seven (28.6%) passed the skills test for basic delivery and none passed the skills test for management of PPH (Table 4.3). Confidence of facilitators improved significantly after training (data not shown).

Table 4.1. Participant characteristics

<table>
<thead>
<tr>
<th>Qualification</th>
<th>Facilitators (n=8)</th>
<th>Learners (n=89)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulance driver</td>
<td>0%</td>
<td>7%</td>
</tr>
<tr>
<td>Medical attendant</td>
<td>13%</td>
<td>15%</td>
</tr>
<tr>
<td>Nurse-Midwife</td>
<td>50%</td>
<td>67%</td>
</tr>
<tr>
<td>Clinician</td>
<td>38%</td>
<td>11%</td>
</tr>
<tr>
<td>Active birth attendant</td>
<td>63%</td>
<td>46%</td>
</tr>
<tr>
<td>Pre-service training AMSTL</td>
<td>88%</td>
<td>69%</td>
</tr>
<tr>
<td>Missing</td>
<td>13%</td>
<td>6%</td>
</tr>
<tr>
<td>Pre-service training management of PPH</td>
<td>75%</td>
<td>73%</td>
</tr>
<tr>
<td>Missing</td>
<td>25%</td>
<td>5%</td>
</tr>
<tr>
<td>In-service training AMSTL</td>
<td>38%</td>
<td>30%</td>
</tr>
<tr>
<td>Missing</td>
<td>25%</td>
<td>8%</td>
</tr>
<tr>
<td>In-service training management of PPH</td>
<td>38%</td>
<td>18%</td>
</tr>
<tr>
<td>Missing</td>
<td>25%</td>
<td>10%</td>
</tr>
<tr>
<td>Attended HBB training</td>
<td>38%</td>
<td>48%</td>
</tr>
<tr>
<td>Missing</td>
<td>25%</td>
<td>6%</td>
</tr>
</tbody>
</table>

See glossary for definitions

Local facilitators trained 89 learners according to the train-the-trainer model (Figure 4.2). The number of learners per facilitator ranged from three to six. The group of learners included six ambulance drivers, 13 medical attendants, 60 nurse-midwives, and ten clinicians. Half of the learners (46%) were active birth attendants at the time of training. Thirty percent of all learners had received in-service training of AMTSL, and 18% had received training on management of PPH during their career to date (Table 4.1).
Table 4.4 shows the results of the written evaluation of the HMS BAB training. Eighty-one learners and seven facilitators filled in the evaluation questionnaire. There was no difference between the two groups; therefore the results are shown together. Both facilitators and learners indicated that there was too little time allocated for theory and practice during training. Instead of a half-day course, a full-day training was suggested. Although teaching materials were well accepted, facilitators stated in an open remark that they should be translated into the local language. Furthermore, both facilitators and learners indicated that training could be done with different cadres training together.

Table 4.2. Theoretical knowledge of facilitators and learners before and after training

<table>
<thead>
<tr>
<th></th>
<th>Facilitators</th>
<th>Learners</th>
<th>Nurses</th>
<th>Medical attendants</th>
<th>Ambulance drivers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before training</td>
<td>n=7</td>
<td>84</td>
<td>59</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>mean %</td>
<td>83</td>
<td>74</td>
<td>82</td>
<td>63</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>2.6</td>
<td>2.6</td>
<td>2.4</td>
<td>2.2</td>
</tr>
<tr>
<td></td>
<td>pass %a</td>
<td>71</td>
<td>63</td>
<td>89</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>After training</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>mean %</td>
<td>92</td>
<td>80</td>
<td>93</td>
<td>81</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>2.3</td>
<td>3.0</td>
<td>1.9</td>
<td>2.7</td>
</tr>
<tr>
<td></td>
<td>pass %a</td>
<td>100</td>
<td>75</td>
<td>100</td>
<td>81</td>
</tr>
<tr>
<td></td>
<td>p-valueb</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facilitators</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learners</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinicians</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical attendants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ambulance drivers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Criterion referenced pass score is ≥ 70% correct answers

* paired-samples t-test (two-tailed) comparing mean scores

Table 4.3. Simulated practical skills of facilitators and learners before and after training

<table>
<thead>
<tr>
<th></th>
<th>Facilitators (n=7)</th>
<th>Learners (n=29)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before training</td>
<td>After training</td>
<td></td>
</tr>
<tr>
<td>mean % SD pass %</td>
<td>mean % SD pass %</td>
<td>p-valuea</td>
</tr>
<tr>
<td>Basic delivery</td>
<td>66 1.4 28.6</td>
<td>71 1.8 28.6</td>
</tr>
<tr>
<td>Management of PPH</td>
<td>73 1.4 28.6</td>
<td>67 1.2 0</td>
</tr>
<tr>
<td>Bimanual uterine compression</td>
<td>38 2.0 not rated</td>
<td>72 0.5 not rated</td>
</tr>
<tr>
<td>Basic delivery</td>
<td>43 3.7 0</td>
<td>51 3.1 3.4</td>
</tr>
<tr>
<td>Management of PPH</td>
<td>38 3.4 6.9</td>
<td>51 2.5 3.4</td>
</tr>
<tr>
<td>Bimanual uterine compression</td>
<td>18 1.3 not rated</td>
<td>43 0.5 not rated</td>
</tr>
</tbody>
</table>

* paired-samples t-test (two-tailed) comparing mean scores

In total 84 learners completed the 26-item knowledge test before and after training (Table 4.2). Mean scores increased significantly from 74% to 80%, and pass rates increased accordingly from 63% to 75%. Clinicians and nurses had higher mean scores and pass rates compared to medical attendants and ambulance drivers.

Twenty-nine learners completed the skills test before and after training (Table 4.3). Learners significantly improved their skills in all three scenarios, as is shown by the increase in mean
score. However, pass rates were very low. Pass rates for basic delivery increased from 0% to 3.4% and pass rates for management of PPH decreased from 6.9% to 3.4%.

Table 4.4. Evaluation of Helping Mothers Survive Bleeding After Birth by facilitators and learners (% (n=88)

<table>
<thead>
<tr>
<th></th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>The time allotted for this training was enough to learn how to</td>
<td>11.4</td>
<td>4.5</td>
<td>10.2</td>
<td>42.0</td>
<td>31.8</td>
<td>0</td>
</tr>
<tr>
<td>prevent, identify, and manage bleeding after birth</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There was enough time for theory during the training</td>
<td>7.9</td>
<td>13.6</td>
<td>2.3</td>
<td>45.5</td>
<td>28.4</td>
<td>2.3</td>
</tr>
<tr>
<td>There was enough time to practice with the simulator</td>
<td>4.5</td>
<td>11.4</td>
<td>11.4</td>
<td>30.7</td>
<td>39.8</td>
<td>2.3</td>
</tr>
<tr>
<td>(MamaNatalie) during the training</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The mix of teaching, discussion and practice</td>
<td>5.7</td>
<td>4.5</td>
<td>3.4</td>
<td>31.8</td>
<td>53.4</td>
<td>1.1</td>
</tr>
<tr>
<td>was appropriate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I understood the concepts of the graphics in the Flipbook</td>
<td>6.8</td>
<td>1.1</td>
<td>3.4</td>
<td>39.8</td>
<td>45.5</td>
<td>3.4</td>
</tr>
<tr>
<td>regardless of my ability to read English</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Flipbook helps me to learn how to manage bleeding after</td>
<td>6.8</td>
<td>0</td>
<td>2.3</td>
<td>39.8</td>
<td>51.1</td>
<td>0</td>
</tr>
<tr>
<td>birth</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The materials in the Facilitation Guide are easy to understand</td>
<td>5.7</td>
<td>1.1</td>
<td>7.9</td>
<td>40.9</td>
<td>39.8</td>
<td>4.5</td>
</tr>
<tr>
<td>The Facilitation Guide helps me to learn how to</td>
<td>7.9</td>
<td>2.3</td>
<td>3.4</td>
<td>31.8</td>
<td>54.5</td>
<td>3.4</td>
</tr>
<tr>
<td>manage bleeding after birth</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I can use the Action Plan to help me prevent and manage</td>
<td>8.0</td>
<td>2.3</td>
<td>3.4</td>
<td>45.5</td>
<td>39.8</td>
<td>1.1</td>
</tr>
<tr>
<td>bleeding after birth regardless of my ability to read English</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Action Plan helps me to learn how to manage bleeding after</td>
<td>4.5</td>
<td>3.4</td>
<td>6.8</td>
<td>36.4</td>
<td>48.9</td>
<td>0</td>
</tr>
<tr>
<td>birth</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The simulator (MamaNatalie) is a good tool to teach this</td>
<td>5.7</td>
<td>2.3</td>
<td>1.1</td>
<td>37.5</td>
<td>50.0</td>
<td>3.4</td>
</tr>
<tr>
<td>information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program materials (Flipbook, Facilitation Guide,</td>
<td>6.8</td>
<td>4.5</td>
<td>11.4</td>
<td>42.0</td>
<td>31.8</td>
<td>3.4</td>
</tr>
<tr>
<td>Action Plan, MamaNatalie) are acceptable in English</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program materials (Flipbook, Facilitation Guide, Action</td>
<td>6.8</td>
<td>6.8</td>
<td>9.1</td>
<td>36.3</td>
<td>37.5</td>
<td>3.4</td>
</tr>
<tr>
<td>Plan, MamaNatalie) are culturally appropriate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The training can be accomplished with the resources</td>
<td>8.0</td>
<td>1.1</td>
<td>5.7</td>
<td>50.0</td>
<td>29.5</td>
<td>5.7</td>
</tr>
<tr>
<td>currently available in Haydom</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The training is practical and fits the current situation of</td>
<td>4.5</td>
<td>1.1</td>
<td>4.5</td>
<td>39.8</td>
<td>45.5</td>
<td>4.5</td>
</tr>
<tr>
<td>maternal healthcare</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The training complements the current</td>
<td>5.7</td>
<td>0</td>
<td>0</td>
<td>34.1</td>
<td>55.7</td>
<td>4.5</td>
</tr>
<tr>
<td>emergency obstetric care training</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The training is appropriate for the current scope of practice</td>
<td>6.8</td>
<td>1.1</td>
<td>4.5</td>
<td>44.3</td>
<td>38.6</td>
<td>4.5</td>
</tr>
<tr>
<td>for birth attendants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There were enough facilitators for the number of learners</td>
<td>3.4</td>
<td>4.5</td>
<td>6.8</td>
<td>33.0</td>
<td>47.7</td>
<td>4.5</td>
</tr>
<tr>
<td>I liked that there were different provider types</td>
<td>4.5</td>
<td>3.4</td>
<td>3.4</td>
<td>37.5</td>
<td>44.3</td>
<td>6.8</td>
</tr>
<tr>
<td>training together</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The training will contribute to reducing</td>
<td>8.0</td>
<td>0</td>
<td>2.3</td>
<td>26.1</td>
<td>60.2</td>
<td>3.4</td>
</tr>
<tr>
<td>maternal mortality related to PPH</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The training will equip birth attendants with appropriate</td>
<td>4.5</td>
<td>0</td>
<td>3.4</td>
<td>38.6</td>
<td>50.0</td>
<td>3.4</td>
</tr>
<tr>
<td>knowledge, attitude and skills of managing PPH</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would like to do training with the simulator</td>
<td>6.8</td>
<td>2.3</td>
<td>1.1</td>
<td>38.6</td>
<td>50.0</td>
<td>1.1</td>
</tr>
<tr>
<td>(MamaNatalie) in the future</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would recommend the training to another birth attendant</td>
<td>5.7</td>
<td>1.1</td>
<td>1.1</td>
<td>37.5</td>
<td>52.3</td>
<td>2.3</td>
</tr>
</tbody>
</table>

DISCUSSION!
Confidence of learners regarding AMTSL, management of PPH, determination of completeness of the placenta, performance of bimanual uterine compression, and ability to access advanced care increased significantly after training (Figure 4.3).

**Figure 4.3. Distribution of confidence of learners in performing procedures before and after training (n=89)**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Pre</th>
<th>Post</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMTSL(^{a})</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PPH(^{b})</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placenta(^{c})</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUC(^{d})</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advanced care(^{e})</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^{a}\) Active management of third stage of labour, \(p=0.001\)
\(^{b}\) Postpartum haemorrhage, \(p=0.001\)
\(^{c}\) Determine completeness of placenta, \(p=0.001\)
\(^{d}\) Bimanual uterine compression, \(p=0.001\)
\(^{e}\) Ability to access advanced care, \(p=0.007\)

**DISCUSSION**

HMS BAB simulation-based training was considered acceptable and feasible in this low-resource setting. There is a clear need for in-service training as is shown by the low coverage of in-service training received by the facilitators and learners. Knowledge, skills, and confidence of learners improved significantly after training. These findings are consistent with other studies evaluating simulation-based training in obstetric care (19-25). However, pass rates of the skills test in our study were low. Singhal et al. present similar results after HBB simulation-based training in neonatal resuscitation (24). In spite of the fact that pass rates for skills testing were low after HBB simulation-based training, perinatal outcome improved after HBB training in India and Tanzania (26, 27). Other studies show an increase in mean score of skills after training compared to before training, but they do not use a global (pass/fail) rating (19, 23, 25, 28).
We do not know the reason for the low pass rate of the skills test, compared to the high pass rate of the knowledge test, but several factors could be of importance: the educational system of Tanzania, the level of competence of learners before the intervention, the length of the training, the familiarity with the simulator, the level of competence of facilitators, the ability of the skills checklist to measure effect, and the effectiveness of HMS BAB for skills training. Firstly, the philosophy of the educational system of Tanzania differs considerably from the philosophy of facilitation (29). In the educational system of Tanzania, teaching is directed one-way, and there is little interaction between teachers and students, whereas facilitation requires action and reaction from learners. More time may be needed to adapt to this new way of learning. Secondly, most clinicians and nurse-midwives received pre-service training of AMTSL and management of PPH, but medical attendants and ambulance drivers had not received any schooling before entering their job. Also, in-service coverage of training in AMTSL and management of PPH was poor. Thirdly, in the evaluation both facilitators and learners stated that there was too little time allocated for theory and practice during the training. Facilitators had a full day to master skills and taught on two occasions or more; learners had only half-day to learn basic delivery care and management of PPH. The low pass rate of the skills test may indicate that time for practical training was too short to master the required skills. Furthermore, most of the facilitators and learners did not have any previous exposure to simulation-based training even though the simulator was introduced to them. Time to become familiar with the tool may have been too short. Moreover, facilitators may not have been competent enough to teach learners. Selection of facilitators should take place after participation in training. Facilitators should receive more training and mentoring before becoming a facilitator. In addition to that, knowledge and skills testing of facilitators was done after they had finished teaching learners. Future facilitators should pass both knowledge test and skills test before becoming a facilitator, as is the case in similar courses (Advanced Life Support in Obstetrics and Managing Obstetric Emergencies and Trauma). Another contributing factor could be that the global (pass/fail) rating was invalid. The $K$ for rating basic delivery ranged between 0.53 and 0.73, indicating moderate to substantial inter-rater agreement (30). For rating management PPH, $K$ ranged from 0.22 to 0.37, indicating fair inter-rater agreement. Lastly, HMS BAB training may have been ineffective for skills training in itself, or as a result of above mentioned items.
Self-assessment alone is an inadequate measure for performance assessment (31, 32). This is reinforced by our research in which a significant increase in confidence of facilitators and learners after training, did not match the results from the skills testing (facilitators did not improve their skills as measured during the skills assessment after training, and the pass rate for skills test ranged from 0-29%). Therefore, performance should not be appraised by self-assessment alone, but also by peer-assessment such as validated knowledge and skills tests. Moreover, Kirkpatrick level 1 and 2 do not necessary relate to Kirkpatrick level 3 and 4. In a sister study at the same hospital in Tanzania, an intervention with neonatal resuscitation training was evaluated according to the four levels of Kirkpatrick (33). It showed that increased levels of knowledge and skills did not translate in change of behaviour in labour ward or improved patient outcome. Similar findings are reported by Siassakos et al. who did not find a relationship between knowledge, skills and attitude of individuals and team performance, suggesting that team working may have an important effect on the way individuals apply their knowledge and skills (34, 35). Future research should therefore also focus on the clinically relevant third and fourth level of the Kirkpatrick model. Furthermore, retention of knowledge and skills after simulation-based training, and the frequency and implementation of retraining should be addressed.

A limitation to our study was that many facilitators and learners did not have previous exposure to simulation-based training. Although we tried to reduce confounding by introducing the mannequin and explaining the concept of simulation to every healthcare worker before skills testing, this may have influenced results of the skills test. Second, assessment of the skills test was challenged because assessors did not speak Kiswahili, or only very moderately. This did not hinder most observations, as it concerned physical action. Most terms that were used were universal such as “oxytocin”, “10 IU” and “antibiotics”. Third, the group of facilitators was small (n=8), however, results were presented in order to show capability of the facilitators. Furthermore, we have analyzed many different variables (knowledge, skills, and confidence). It is possible that one of the results is significant by random chance alone; this is also referred to as multiple testing. Therefore it is important to focus on the overall trend of the results, without too much attention to p-values alone. Lastly, evaluation was done in writing, with only the opportunity to enclose open remarks at the end of the evaluation. Semi-structured interviews or focus group discussions may have
revealed more details about acceptability and feasibility of the training.

CONCLUSION

There is a clear need for in-service training in this low-resource setting. HMS BAB training was considered feasible and acceptable and significantly improved learners’ knowledge, skills, and confidence. However, pass rates for skills tests of both facilitators and learners were low. There is a gap between performance in knowledge and skills, which indicates the need for more practical training such as simulation-based training. To improve training, we would recommend that HMS BAB training would take a full day, instead of a half-day, and that teaching materials are translated into the local language. Eligible facilitators must pass both knowledge test and skills test before becoming a facilitator. Monitoring and evaluation with validated tests is recommended, and should be part of training. According to our results, global (pass/fail) rating may not be appropriate for skills tests as it showed moderate inter-rater agreement. If these issues are addressed, HMS BAB simulation-based training has great potential to help increase the number of skilled birth attendants regarding basic delivery, prevention of PPH, and management of PPH.
REFERENCES


CHAPTER 5

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Under review
CHAPTER 5

Retention of knowledge, skills, and confidence after simulation-based training in obstetric care: an educational intervention study

Ellen Nelissen, Hege Ersdal, Estomih Mduma, Jacqueline Broerse, Bjørg Evjen-Olsen, Jos van Roosmalen, Jelle Stekelenburg

Under review
ABSTRACT

Background: Retention studies of simulation-based education reveal mixed results. It is important to know the decay of knowledge, skills, and confidence over time to provide evidence-based guidance on timing of follow-up training. The aim of this study was to measure the level of knowledge, skills and confidence before, immediately after, and nine months after simulation-based training in obstetric care in order to understand the impact of training on these components.

Methods: An educational intervention study was carried out in 2012 at a rural referral hospital in Northern Tanzania. Thirty-eight healthcare workers of different cadres were trained. Knowledge, skills, and confidence were tested before, immediately after, and nine months after training. Knowledge was tested by completing a written 26-item multiple-choice questionnaire. Skills were tested in two simulated scenarios "basic delivery" and "management of postpartum haemorrhage". Confidence in active management of third stage of labour, management of postpartum haemorrhage, determine completeness of the placenta, bimanual uterine compression, and accessing advanced care was self-assessed using a written 5-item questionnaire.

Results: Mean knowledge scores increased immediately after training from 70% to 77%, but decreased to pre-training levels at nine-month follow-up (72%). The mean score in basic delivery skills increased after training from 43% to 51%, and was 49% after nine months. Mean scores of management of postpartum haemorrhage increased from 39% to 51% and were sustained at 50% at nine months. Confidence increased immediately after training, and was largely retained at nine-month follow-up.

Conclusion: Training resulted in an immediate increase in knowledge and confidence; while knowledge decayed after nine months, confidence was retained. This discrepancy may put patient safety at risk when an individual’s confidence outweighs their knowledge. It may indicate that confidence is a reflection of experience rather than knowledge, as skills were also retained after nine months. The difference between retention of knowledge and skills questions whether formal knowledge assessment through multiple-choice questionnaires
ABSTRACT

Background: Retention studies of simulation-based education reveal mixed results. It is important to know the decay of knowledge, skills, and confidence over time to provide evidence-based guidance on timing of follow-up training. The aim of this study was to measure the level of knowledge, skills, and confidence before, immediately after, and nine months after simulation-based training in obstetric care in order to understand the impact of training on these components.

Methods: An educational intervention study was carried out in 2012 at a rural referral hospital in Northern Tanzania. Thirty-eight healthcare workers of different cadres were trained. Knowledge, skills, and confidence were tested before, immediately after, and nine months after training. Knowledge was tested by completing a written 269-item multiple-choice questionnaire. Skills were tested in two simulated scenarios "basic delivery" and "management of postpartum haemorrhage". Confidence in active management of third stage of labour, management of postpartum haemorrhage, determine completeness of the placenta, bimanual uterine compression, and accessing advanced care was self-assessed using a written 59-item questionnaire.

Results: Mean knowledge scores increased immediately after training from 70% to 77%, but decreased to pre-training levels at nine-month follow-up (72%). The mean score in basic delivery skills increased after training from 43% to 51%, and was 49% after nine months. Mean scores of management of postpartum haemorrhage increased from 39% to 51% and were sustained at 50% at nine months. Confidence increased immediately after training, and was largely retained at nine-month follow-up.

Conclusion: Training resulted in an immediate increase in knowledge and confidence; while knowledge decayed after nine months, confidence was retained. This discrepancy may put patient safety at risk when an individual's confidence outweighs their knowledge. It may indicate that confidence is a reflection of experience rather than knowledge, as skills were also retained after nine months. The difference between retention of knowledge and skills questions whether formal knowledge assessment through multiple-choice questionnaires captures the expertise that is gained through simulation-based training. Therefore, future evaluation of training programmes should include evaluation of clinical behaviour and patient outcome. Plenary mandatory biannual training would be recommended for continuation of training in this low-resource setting.
INTRODUCTION

Helping Mothers Survive Bleeding After Birth is a new training package for healthcare workers in settings with a high burden of maternal mortality, developed by Jhpiego and Laerdal Global Health. It uses simulation-based education to train healthcare workers of different cadres in basic delivery skills (including active management of third stage of labour) and treatment of postpartum haemorrhage (1, 2). The training programme was introduced in a rural referral hospital in Northern Tanzania in March 2012. Knowledge, skills, and confidence of learners significantly increased immediately after training (3). This is consistent with systematic reviews showing that simulation-based education results in an immediate and significant increase in knowledge and skills of participants (4, 5).

Previous studies measuring retention of knowledge and skills after simulation-based education reveal mixed results (4, 6-11). Most retention studies of simulation-based education are performed in resuscitation training (4, 6). Few studies are performed evaluating obstetric emergency training, and even fewer are performed in low-resource settings (7-11). It is important to know the decay of knowledge, skills, and confidence over time in order to provide evidence-based guidance on timing of follow-up training.

In two systematic reviews regarding retention of resuscitation training, there is a tendency towards decay of knowledge and skills that may start three months after training, with simulated skills performance deteriorating faster than knowledge (4, 6). Most studies evaluating obstetric emergency training did not show a deterioration of knowledge and skills at six to fifteen months after training (8-11), but one study showed that decay of knowledge and skills started as early as two months after training (7). The studies described above are heterogeneous because they evaluated diverse training programmes with varying length of time (one day up to five days), in different settings (low resource vs. high resource), targeted at varying healthcare providers (from medical students to frontline healthcare workers and healthcare professionals working in obstetrics). Helping Mothers Survive Bleeding After Birth training targets educated and non-educated personnel working in low-resource settings.
The aim of this study was to measure the level of knowledge, skills, and confidence before, after, and nine months after Helping Mothers Survive Bleeding After Birth simulation-based training to understand the impact of training on these components.

METHODS

An educational intervention study with pre-, post-, and nine-month follow-up assessments was performed from March to December 2012. The Helping Mothers Survive Bleeding After Birth simulation-based training programme was introduced in a rural referral hospital in Northern Tanzania in March 2012. A cross-sectional study that took place in this hospital from November 2009 until November 2011 showed that the maternal mortality ratio was 350 maternal deaths per 100,000 live births (95% confidence interval: 243-488) (12). Postpartum haemorrhage accounted for 27% of all maternal morbidity and mortality, and the case fatality rate of post partum haemorrhage was 9% (12). The hospital has 420 beds and provides free reproductive services and comprehensive emergency obstetric care. The annual number of births at the hospital is approximately 4,700 (13).

Helping Mothers Survive Bleeding After Birth uses a train-the-trainer model in which training is cascaded down from master trainers to local facilitators to learners (14). Four master trainers trained eight local facilitators in a one to one ratio. Training of local facilitators lasted a full day and consisted of a half-day theory and a half-day skills and scenario training session regarding active management of third stage of labour and treatment of PPH. Subsequently, these eight facilitators trained 89 local learners in a half-day session under supervision of master trainers. The number of learners per facilitator ranged from three to six. Clinicians, nurse-midwives, medical attendants (nurse aides without formal medical education), and ambulance drivers (without formal medical education) involved in maternity care (including nurse-midwives from the intensive care unit and operating theatre) were selected by the hospital management to attend training. Due to logistical reasons, only learners working on labour ward, ambulance drivers, and facilitators were enrolled for testing, thus rendering 38 out of the original 89 learners eligible for analysis. Validation of local facilitators by means of knowledge and skills testing was done after teaching learners. Further details of the training are described elsewhere (3).
The study design was based on the four levels of Kirkpatrick's model for evaluation of training programmes (15). In this paper we report on Kirkpatrick level 2 (learning) for which we have measured changes in knowledge, skills, and confidence due to training. The tools used to assess knowledge, skills, and confidence have been described in detail previously (3). In brief, knowledge, skills, and confidence were tested on three occasions: immediately before training, immediately after training, and nine months after training. Knowledge about basic delivery skills, active management of third stage of labour, and management of postpartum haemorrhage was tested using a written 26-item multiple-choice questionnaire. The test was developed and validated by Jhpiego (3). Skills performance was assessed in two simulated scenarios using a low-cost, low-tech birthing simulator (MamaNatalie, Laerdal Global Health): "basic delivery" and "management of postpartum haemorrhage". A checklist for the assessment of skills performance was developed and validated by the authors (3). Each participant's skills test was videotaped and subsequently assessed by two independent assessors who were blinded for the time of testing. Confidence of learners to perform active management of third stage of labour, manage postpartum haemorrhage, determine completeness of the placenta, perform bimanual uterine compression, and access advanced care was self-assessed using a questionnaire. Five answers were possible ranging from 1=I cannot perform this skill to 5=extremely confident. At the nine month assessment all facilitators and learners were interviewed about the number of deliveries performed since initial training, as well as the number of bimanual uterine compressions performed, the number of times MamaNatalie was used for practise, and the participation in any other practise or training regarding basic delivery and treatment of postpartum haemorrhage. All assessment materials were available in two languages: English and Kiswahili.

Statistical analysis

Data was double entered in EpiData (The EpiData Association, Odense, Denmark), and analysed using IBM SPSS Statistics, version 20 (IBM, Armonk, NY, USA). Descriptive statistics were calculated for participant characteristics, exposure to clinical work and training during the follow-up time, knowledge, skills, and confidence. Results are reported as number (n), percentage (%), mean, standard deviation (SD), and range. Statistical analyses of the changes from pre-training assessment to nine-month follow-up and from post-training to nine-month
follow-up included McNemar's test for categorical values, and paired samples t-test for continuous values.

*Ethical approval and informed consent*

Ethical approval was obtained from the Tanzanian National Institute for Medical Research (reference NIMR/HQ/R.8a/Vol.IX/1247), the Tanzania Commission for Science and Technology (reference 2013-41-ER-2011-201), and from the VU University Medical Centre, the Netherlands (reference 2011/389). Permission to conduct the study was obtained from the hospital management. Informed consent was obtained from each participant before entering the study.

**RESULTS**

Thirty-eight learners completed the training and were also eligible for follow-up (see Figure 5.1). Of the 38 learners, 35 (92%) completed the knowledge test, 32 (84%) completed the skills test, and 35 (92%) completed the confidence questionnaire before training. Three learners did not complete the knowledge test and confidence questionnaire before intervention, but did complete these after intervention and at nine-month follow-up. Immediately after training, thirty-six (95%) learners completed the knowledge test, 29 (76%) completed the skills test, and 38 (100%) completed the confidence questionnaire. Follow-up of learners at nine months was available for 31 (82%) learners who completed the knowledge test, 23 (61%) who completed the skills test, and 31 (82%) who completed the confidence questionnaire.

The group of learners (n=38) consisted of six ambulance drivers (16%), 13 medical attendants (34%), 14 nurse-midwives (37%), and five clinicians (13%) (see Table 5.1). Seventy-four percent were active birth attendants at the time of training. The learners who completed the nine-month assessment assisted in this time period on average 118 births (range 0-840) and performed on average 1.3 bimanual uterine compressions (range 0-10). In nine months, one person used the birthing simulator for practise three times, and one person participated in a training organised by the Tanzanian Ministry of Health regarding management of obstetric emergencies.
Figure 5.1. Flow diagram of learners
* Three learners did not complete the knowledge test pre-intervention, but did complete the knowledge test post-intervention and at 9-month follow-up ** Three learners did not complete the confidence questionnaire pre-intervention, but did complete the confidence questionnaire post-intervention and at 9-month follow-up *** One learner did not complete the knowledge test post-intervention, but did complete the knowledge test pre-intervention and at 9-month follow-up **** One learner did not complete the skills test post-intervention, but did complete the skills test pre-intervention and at 9-month follow-up

Table 5.1. Learner characteristics and clinical activity during 9-month follow-up (n=38)

<table>
<thead>
<tr>
<th>Qualification</th>
<th>Ambulance driver n (%)</th>
<th>Medical attendant n (%)</th>
<th>Nurse-Midwife n (%)</th>
<th>Clinician n (%)</th>
<th>Active birth attendant at time of training, n (%)</th>
<th>Conducted deliveries, mean (range)</th>
<th>Conducted bimanual uterine compression, mean (range)</th>
<th>Times practised with MamaNatalie, mean (range)</th>
<th>Other practise/training, mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible: 38 (100%)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Twenty-eight learners completed the knowledge test before training and at nine-month follow-up and 30 learners completed the knowledge test immediately after training and at nine-month follow-up. Knowledge was not retained at nine-month follow-up and decreased to pre-training level (see Table 5.2). The results were further analysed for personnel with (clinicians and nurses) and without (medical attendants and ambulance drivers) formal education. A similar trend of knowledge decay was seen at nine months. Personnel with formal education achieved higher mean scores and therefore higher pass rates.

Table 5.2. Retention of knowledge among learners

<table>
<thead>
<tr>
<th></th>
<th>Before training</th>
<th>After training</th>
<th>9 months after training</th>
<th>pre vs. 9-month post vs. 9-month p-value p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All learners</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>70 (12)</td>
<td>77 (12)</td>
<td>72 (14)</td>
<td>0.386</td>
</tr>
<tr>
<td>Pass rate n (%)</td>
<td>16 (46)</td>
<td>26 (72)</td>
<td>15 (48)</td>
<td>1.0</td>
</tr>
<tr>
<td>Formally educated personnel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>79 (8)</td>
<td>86 (8)</td>
<td>83 (11)</td>
<td>0.646</td>
</tr>
<tr>
<td>Pass rate n (%)</td>
<td>15 (88)</td>
<td>17 (94)</td>
<td>12 (92)</td>
<td>na</td>
</tr>
<tr>
<td>Not formally educated personnel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>62 (8)</td>
<td>69 (11)</td>
<td>63 (9)</td>
<td>0.477</td>
</tr>
<tr>
<td>Pass rate n (%)</td>
<td>1 (6)</td>
<td>9 (50)</td>
<td>3 (17)</td>
<td>0.625</td>
</tr>
</tbody>
</table>

na: not available, p-value could not be calculated

Twenty-three learners completed the skills test before training and at nine-month follow-up. Twenty-two learners completed the skills test immediately after training and at nine-month follow-up. Compared to pre training level, learners significantly retained skills in the simulated scenario of management of postpartum haemorrhage and bimanual uterine compression at nine-month follow-up (see Table 5.3). Skills in the simulated scenario of basic delivery increased from a mean score of 43% before training to 51% immediately after training. At nine months this decreased to 49% (not statistically significant). Personnel with formal education did not retain basic delivery skills that were gained immediately after training. Further analysis showed this was attributed to the performance of clinicians in basic delivery skills (mean score (SD) before: 56% (27), after: 46% (19), and at nine months after training: 42% (13)). Formally educated personnel showed that their skills in management of PPH and bimanual uterine compression increased after training and were maintained at nine
months. Personnel without formal education retained all skills at nine months compared to before training (statistically significant). Personnel with formal education achieved higher mean scores. However, medical attendants and ambulance drivers showed a greater improvement in skills gained and retained compared to baseline. Overall pass rates of all learners were low.

Table 5.3. Retention of skills among learners

<table>
<thead>
<tr>
<th></th>
<th>Before training</th>
<th>After training</th>
<th>9 months after training</th>
<th>pre vs. 9-month p-value</th>
<th>post vs. 9-month p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All learners</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Basic delivery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>43 (22)</td>
<td>51 (19)</td>
<td>49 (19)</td>
<td>0.165</td>
<td>0.062</td>
</tr>
<tr>
<td>Pass rate n (%)</td>
<td>0 (0)</td>
<td>1 (3)</td>
<td>1 (4)</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td><strong>Management of PPH</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>39 (27)</td>
<td>51 (21)</td>
<td>50 (24)</td>
<td>0.003</td>
<td>0.724</td>
</tr>
<tr>
<td>Pass rate n (%)</td>
<td>2 (6)</td>
<td>1 (3)</td>
<td>2 (9)</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Bimanual uterine compression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>19 (20)</td>
<td>43 (25)</td>
<td>48 (25)</td>
<td>0.000</td>
<td>0.178</td>
</tr>
<tr>
<td><strong>Formally educated personnel</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Basic delivery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>57 (16)</td>
<td>61 (13)</td>
<td>55 (16)</td>
<td>0.723</td>
<td>0.221</td>
</tr>
<tr>
<td>Pass rate n (%)</td>
<td>0 (0)</td>
<td>1 (8)</td>
<td>0 (0)</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td><strong>Management of PPH</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>61 (16)</td>
<td>67 (9)</td>
<td>71 (14)</td>
<td>0.154</td>
<td>0.281</td>
</tr>
<tr>
<td>Pass rate n (%)</td>
<td>2 (13)</td>
<td>1 (8)</td>
<td>2 (20)</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Bimanual uterine compression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>33 (18)</td>
<td>53 (16)</td>
<td>55 (21)</td>
<td>0.017</td>
<td>0.212</td>
</tr>
<tr>
<td><strong>Not formally educated personnel</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Basic delivery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>29 (19)</td>
<td>43 (21)</td>
<td>44 (21)</td>
<td>0.026</td>
<td>0.188</td>
</tr>
<tr>
<td>Pass rate n (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (8)</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td><strong>Management of PPH</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>17 (15)</td>
<td>39 (19)</td>
<td>33 (16)</td>
<td>0.005</td>
<td>0.148</td>
</tr>
<tr>
<td>Pass rate n (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td><strong>Bimanual uterine compression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean score % (SD)</td>
<td>4 (8)</td>
<td>35 (28)</td>
<td>42 (28)</td>
<td>0.001</td>
<td>0.445</td>
</tr>
</tbody>
</table>

na: not available, p-value could not be calculated

Figure 5.2 shows the distribution of confidence among 38 learners before training, after training, and at nine-month follow-up. Confidence in managing postpartum haemorrhage, bimanual uterine compression, and accessing advanced care remained significantly elevated at nine-month follow-up, compared to pre training levels (p=0.029, p=0.008, and p=0.029)
respectively) and compared to post-test levels (p=0.131, p=0.081, and p=0.539 respectively). Confidence in performing active management of third stage of labour and determining the completeness of the placenta was not retained at nine-month and returned to pre training levels (p=0.282 and p=0.294 respectively when comparing pre-test to nine-month follow-up, and p=0.052 and p=0.027 respectively when comparing post-test to nine-month follow-up).

**Figure 5.2. Distribution of confidence of learners pre training, immediately post training, and at 9-month follow-up**
Placenta: determine completeness of placenta
Advanced care: access advanced care

**DISCUSSION**

Our findings show that knowledge increased immediately after training, but decreased to pre-training levels when followed up at nine months. Skills performance increased after training, and was retained after nine months. Confidence increased immediately after training, and in three out of five areas (management of postpartum haemorrhage, bimanual uterine compression, and accessing advanced care) confidence was retained at nine-month follow-up.

One limitation of this study is the before and after design; there was no control group and no randomisation. Factors other than time may have influenced the effect of training on retention of knowledge, skills, and confidence. The study was carried out in one hospital setting, which makes external validation difficult. We plan to remedy this limitation by evaluating all four levels of the Kirkpatrick model for the same training intervention. When results of each level reinforce each other, it is more likely that the improved performance of
healthcare workers is the effect of training and not just by chance alone. Another consideration for the interpretation of this study is that on all three testing occasions similar knowledge questionnaires and simulated scenarios were used. Participants may have learned from retaking the same test, and this may have resulted in a potentially larger learning effect. As this reflects the training as it is currently given, and the effect applies to all participants, we considered this limitation as minor.

Our results show that skills were largely retained over nine months despite knowledge scores declining. The type of training, which focused mainly on skills, may explain this. Furthermore, after training most learners were exposed to practical rather than theoretical repetition of what they had learned. Other retention studies reveal mixed results. Crofts et al. demonstrated that midwives and doctors in the UK did not show deterioration of performance at six and twelve months after training in management of shoulder dystocia (9). The same group of doctors and midwives also retained their knowledge regarding obstetric emergencies six months and twelve months after training (10). Homaifar et al. showed that a majority of medical students maintained knowledge, and to a lesser extent skills, nine months after a 2-day emergency obstetric training course in Rwanda (8).

This observation leads to the question whether formal knowledge tests capture the expertise that is gained through experiential knowledge. We have used multiple-choice questions to measure knowledge. One may argue that only factual knowledge can be tested this way, and that applied knowledge is not captured in multiple-choice questions (16). Miller's pyramid of competence shows that the base of the pyramid consists of "knows" or factual knowledge. A level above is "shows how", which places knowledge in the clinical context. At the top of the pyramid are "shows how" and "does", which relate to performance assessment in vitro and in vivo, respectively (17). It may be that after nine months only applied knowledge is retained, and factual knowledge declines. It may be that "shows how" and "does" is more a reflection of behaviour, rather than cognition. This may also explain why learning to ride a bike is a skill that does not decay once you have learned it. On the contrary it is relatively easy to forget a learned second language. The former would be an example of behaviour, while the latter would be an example of cognition.
Skills in management of postpartum haemorrhage and bimanual uterine compression were better retained than basic delivery skills. The rationale could be that everyday tasks (e.g. basic delivery) are engrained into someone's behaviour and therefore may be more difficult to change than less common tasks (e.g. management of postpartum haemorrhage, bimanual uterine compression) (18, 19). Bimanual uterine compression was a new skill for most healthcare workers, therefore not influenced by former experience, and was better retained after training. Furthermore, the number of steps needed to remember could have influenced retention. The more steps that need to be remembered, the easier it is to forget. In general, people can remember up to nine steps (20). In our study, basic delivery consisted of 16 steps, management of postpartum haemorrhage consisted of 12 steps, and bimanual uterine compression consisted of six steps. The lesson that can be learned here is that algorithms, such as the action plan used in the Helping Mothers Survive Bleeding After Birth training programme (2), should be as brief as possible.

There was a difference in the acquisition and retention of skills between educated and non-educated personnel. Medical attendants and ambulance drivers who had never received any formal medical education showed a greater improvement of skills immediately after training compared to clinicians and nurses. This is a typical example of a learning curve which shows an initial steep rise that will eventually flatten out. Moreover, non-educated personnel showed better retention of skills nine months after training relative to the retention of skills of educated personnel nine months after training. It may be that the initial improvement was large enough to sustain over time. Moreover, personnel without education will not have had much other practical experience (or "noise") and may therefore have showed less decay of skills. Lastly, the training may have had a bigger impact on them. Participating in this multi-professional training recognised them as part of the team and may have enhanced their motivation to engage in the training programme and learn as a result of it.

Considerable concern has arisen about self-assessment as a method of evaluating personal performance. There is a poor relationship between self-assessment and external assessment of healthcare workers (21, 22). Our data show an increase in knowledge and confidence immediately after training, with confidence being retained over time while knowledge declines. The discrepancy between our knowledge and confidence assessment may indicate
that either of these assessments is not a valid reflection of the healthcare workers' competence. It may be that factual knowledge assessment is a better measurement than confidence for assessing competence (23). This would imply that patient safety is in danger when a healthcare workers’ confidence outweighs their actual ability (24). When there is a discrepancy between confidence and knowledge, the healthcare worker may lack the knowledge to make correct decisions regarding a patient, as well as the insight needed to seek help from others. On the other hand the discrepancy between retention of knowledge and confidence may suggest that confidence is a reflection of experience rather than factual knowledge as assessed by the multiple-choice questionnaire (25). This is reinforced by our findings that simulated skills performance mirrors self-assessed confidence, and by previous research in this area (26). We do not know which of the two theories is more likely. An evaluation of level 3 and 4 of the Kirkpatrick model (clinical behaviour and patient outcome) could shed more light on this issue.

There is no clear evidence yet about the most effective way to continue training (27). Simulation-based training can be organised in dedicated training sessions outside office hours or low-dose high-frequency training sessions inside office hours. Low-dose high-frequency cardiopulmonary resuscitation training has shown to improve skill retention among paediatric providers (28). As this low-resource setting is relatively new to in-house training, it may be best to start with plenary mandatory training outside office hours. Some characteristics of the Helping Mothers Survive Bleeding After Birth curriculum may facilitate performance in plenary teaching sessions: the algorithm for basic delivery and management of postpartum haemorrhage is extensive and may need to be supervised by facilitators in order to perform correctly. Furthermore, at least two people are needed to practice. Lastly, it may take some instruction and practice on how to operate the mannequin; this could be reinforced during the plenary training sessions. Plenary training sessions could change the mindset of people that training is part of their job. Later, low-dose high-frequency training sessions could be introduced. As knowledge declined after nine months, but skills and confidence were largely retained, biannual training would suit best for this type of simulation-based training in a low-resource setting.
CONCLUSION

In conclusion, a half-day simulation-based training course resulted in an immediate increase in knowledge and confidence; while knowledge decayed after nine months, confidence was retained. The discrepancy between knowledge and confidence retention may put patient safety at risk when an individual’s confidence outweighs their knowledge. It may indicate that confidence is a reflection of experience rather than knowledge, as skills were also retained after nine months. The difference between retention of knowledge and skills questions whether formal knowledge assessment through multiple-choice questionnaires captures the expertise that is gained through simulation-based training. Therefore, future evaluation of training programmes should include evaluation of clinical behaviour and patient outcome. Plenary mandatory biannual training would be recommended for continuation of training in this low-resource setting.
REFERENCES


Retrieval of knowledge and skills | 117
CHAPTER 6

The impact of obstetric simulation-based training on clinical behaviour and patient outcome

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Under review
CHAPTER 6

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*Under review*
ABSTRACT

Importance: Postpartum haemorrhage is a major cause of maternal mortality. Prevention and adequate treatment are therefore important. However, most births in low-resource settings are not attended by skilled providers, and knowledge and skills of healthcare workers are low. Simulation-based training effectively improves knowledge and skills, but the effectiveness of training on clinical behaviour and patient outcome is not yet fully understood.

Objective: To assess the effect of obstetric simulation-based training on incidence of postpartum haemorrhage and clinical performance of basic delivery skills and management of postpartum haemorrhage.

Design, setting, and participants: We conducted an educational intervention study in a rural referral hospital in Tanzania. Sixteen trained research assistants observed all hospital-based deliveries from May 2011 to June 2013. In March 2012 we introduced "Helping Mothers Survive Bleeding After Birth", a half-day obstetric simulation-based training regarding basic delivery care, active management of third stage of labour, and management of postpartum haemorrhage. Observations before and after training were compared.

Main outcomes and measures: Primary outcome measure was incidence of postpartum haemorrhage. Secondary outcome measures were use and timing of administration of uterotonic drugs, removal of the placenta by controlled cord traction, uterine massage, examination of the placenta, and management of postpartum haemorrhage in women with 500ml blood loss or more. Maternal and neonatal mortality were recorded.

Results: 3,622 deliveries before and 5,824 deliveries after intervention were included. The incidence of postpartum haemorrhage (500-1,000ml) significantly reduced from 2.1% to 1.3% after training. The proportion of women that received oxytocin (87.8%), removal of the placenta by controlled cord traction (96.5%), and uterine massage after delivery (93.0%) significantly increased after training (91.7%, 98.8%, 99.0% respectively). The proportion of women who received oxytocin as part of management of postpartum haemorrhage...
increased significantly (before training 43.0%, after training 61.2%). Other skills in management of postpartum haemorrhage improved (uterine massage, examination of birth canal, bimanual uterine compression), but this was not statistically significant.

Conclusions and relevance: The introduction of an obstetric simulation-based training course was associated with a 38% reduction in incidence of moderate postpartum haemorrhage up to 1,000 ml and improved clinical performance of basic delivery skills and management of postpartum haemorrhage.
INTRODUCTION

Postpartum haemorrhage is a major cause of maternal mortality (1). The prevalence of postpartum haemorrhage ranges from 11% to 26% for blood loss more than 500 ml, and from 2 to 5% for blood loss more than 1,000 ml (2, 3). More than 55% of pregnant women in Africa suffer from anaemia in pregnancy (4), and therefore do not have much reserve when postpartum haemorrhage occurs. Prevention and prompt, adequate treatment of postpartum haemorrhage is therefore important. However, most births in sub-Saharan Africa are not attended by skilled providers (5). In Tanzania only 51% of all deliveries are assisted by a skilled provider (6). In addition, knowledge and skills of providers are low (5, 7-9) and in-house training facilities to keep knowledge and skills of healthcare workers up to date rarely exist (5, 10, 11). Therefore, Jhpiego and Laerdal Global Health developed Helping Mothers Survive Bleeding After Birth, a simulation-based training package targeted at healthcare workers in areas with a high burden of maternal morbidity and mortality (12). The simulation-based training package focuses on basic delivery care, active management of third stage of labour, and treatment of postpartum haemorrhage (13). Simulation-based education, and Helping Mothers Survive Bleeding After Birth in specific, has been shown to effectively increase knowledge, skills, and confidence of healthcare workers (10, 14-16) and may help to reduce maternal morbidity and mortality caused by postpartum haemorrhage.

The four-level Kirkpatrick model is often used to evaluate training programmes (17). Level one measures reaction, which can be assessed by an evaluation questionnaire that is handed out to participants after attending a training session. Level two measures change in knowledge, skills, and attitude of participants who attended training. This is also referred to as competency-based assessment, and measures what healthcare workers can do in controlled representations of professional practice (18). Level three assesses if the acquired knowledge, skills, and attitude are applied at work (clinical behaviour). This is also referred to as performance-based assessment, and measures what healthcare workers do in their professional practice (18). Lastly, level four measures change in patient outcome due to training. Most publications regarding evaluation of training programmes concern the first two levels of the Kirkpatrick model (15, 19-21). Whereas improvement in clinical performance of healthcare workers and patient outcome is the ultimate goal, research in
this area has been mainly retrospective and limited to neonatal outcome (22-28). So far, there is little evidence to suggest that training in emergency obstetric care improves maternal outcome (27). The aim of this study was to assess the effect of obstetric simulation-based training on the clinical performance of basic delivery skills and management of postpartum haemorrhage (Kirkpatrick level 3) and incidence of postpartum haemorrhage (Kirkpatrick level 4).

**METHODS**

*Study design and setting*

We conducted an educational intervention study at Haydom Lutheran Hospital, a rural referral hospital in Northern Tanzania. The hospital has 420 beds and provides free reproductive services including comprehensive emergency obstetric care. Extrapolating from the 2002 census, the immediate catchment area of the hospital is covering a population of approximately 350,000 in 2012, while the greater reference area covers a population of approximately 2,357,000 (29). The annual number of births at the hospital is approximately 5,000.

*Intervention*

The educational intervention took place in March 2012. Data were prospectively collected from the 25th of May 2011 to the 25th of June 2013. A multi-professional group of clinicians, nurse-midwives, medical attendants (nurse aides without formal medical education), and ambulance drivers (without formal education) attended a half-day training course "Helping Mothers Survive Bleeding After Birth". The training consisted of a mix of theory and hands-on practice using a low-cost low-tech simulator (MamaNatalie, Laerdal Global Health) regarding basic delivery skills, active management of third stage of labour, and management of postpartum haemorrhage. Further details of the intervention are described elsewhere (10).

*Data measurement*

Sixteen research assistants were trained by the principal investigator to structurally observe all deliveries beyond a gestational age of 28 weeks that were taking place in the hospital. To
ensure inter-rater reliability, the research assistants were retrained by the principal investigator every three months. Subsequently, their observation skills were assessed in simulated scenarios and on labour ward. Any apparent deviations in observations were discussed and corrected immediately. The observations took place in a structured manner according to a validated data collection form with accompanying standard operating procedures. According to the data collection form, the following background information was recorded of each delivery: antenatal care attendance, gestational age at delivery, mode of delivery, birth weight, and training attendance. Furthermore, the primary outcome measure was recorded: incidence of postpartum haemorrhage. Blood loss was measured as usual in Haydom Lutheran Hospital and included visual estimation, measurement using scales, or a mix of both. The method of measuring blood loss was recorded. Postpartum haemorrhage was defined as blood loss of 500 ml or more. Severe postpartum haemorrhage was defined as blood loss of 1,000 ml or more. Secondary outcome measures included: use of uterotonic drugs after delivery (categorised as: oxytocin 10 IU, oxytocin 5 IU, none, and other uterotonics such as misoprostol or other dosages of oxytocin), timing of administration of uterotonic drugs, removal of the placenta by controlled cord traction, uterine massage, and examination of the placenta. In cases complicated by postpartum haemorrhage its management was observed: use of uterotonic drugs in addition to those given routinely after delivery (categorised as: oxytocin 10 IU, ergometrine 0.2 mg, none, and other uterotonics such as misoprostol or other dosages of oxytocin), uterine massage, examination of perineum, vagina, and/or episiotomy, bimanual uterine compression, hysterectomy, and units of blood received within 24 hours. Lastly, maternal and neonatal outcome at 24 hours were recorded. A research supervisor reviewed the completed data collection forms regularly. In case of missing information or discrepancies, the data collection form was immediately returned to the research assistant for amendment.

**Sample size calculation**

In peer-reviewed articles, incidence rates of postpartum haemorrhage range between 2 and 26%, depending on the definition of postpartum haemorrhage (2, 3, 30, 31). Based on these data, we hypothesised an incidence of postpartum haemorrhage of 10%. To show a 25% decrease in the incidence of postpartum haemorrhage with 80% power and a confidence
interval of 95%, a sample of 2010 deliveries before, and the same amount of deliveries after intervention was needed.

Statistical analysis
Data were entered twice by two different data clerks and crosschecked in EpiData (The EpiData Association, Odense, Denmark). We used IBM SPSS Statistics (version 20) for data-analysis (IBM, Armonk, NY, USA). In order to assess the effect of the intervention, the study period was divided in two: 25th May 2011 to 6th March 2012 (before training) and 13th March 2012 to 25th June 2013 (after training). The training course took place from the 7th of March 2012 to the 12th of March 2012 and this period was excluded from the analysis. Observations before and after training were compared. Descriptive statistics were calculated for the background characteristics of women who delivered during the study period, the clinical performance of healthcare workers attending deliveries (basic delivery skills and management of postpartum haemorrhage), and patient outcome. Results are reported in numbers (n) and proportions (%) for categorical variables, and mean and standard deviation (SD) for continuous variables. The chi-square test was used for comparison of categorical variables. If numbers were smaller than five the fisher exact test was used. The independent samples t-test (2-sided) was used to compare continuous variables. The relationship between the amount of blood loss after delivery and caesarean section, breech delivery, birth weight, and gestational age during the pre-intervention period and post-intervention period was analyzed with linear regression models.

Ethical approval and informed consent
Ethical approval was obtained from the Tanzanian National Institute for Medical Research (reference NIMR/HQ/R.8a/Vol.IX/1247), the Tanzania Commission for Science and Technology (reference 2013-41-ER-2011-201), and from the VU University Medical Centre, the Netherlands (reference 2011/389). Permission to conduct the study was obtained from the hospital management.
RESULTS

There were 9,446 deliveries observed during the study period from May 2011 to June 2013, 3,622 deliveries before and 5,824 deliveries after intervention. Ten clinicians were working at the hospital and eight of them attended training (80%). Of the 25 nurse-midwives working in labour ward, 15 attended training (60%), and 14 out of 19 medical attendants attended training (74%). Six out of ten ambulance drivers were trained (60%).

Table 6.1 summarises the baseline characteristics. More than 97% of the women attended antenatal care. This remained constant throughout the entire study period. Women giving birth after training had a higher mean gestational age (36.4 weeks) compared to women giving birth before training (36.2 weeks) (p=<.001). The majority of babies were delivered vaginally (before training 82.4%, after training 81.0%). After training more caesarean sections were done (16.1%) compared to before training (13.5%) (p=<.001). Babies born before training had a higher mean birth weight (3,107 gram) compared to babies born after training (3,074 gram) (p=0.001).

Table 6.1. Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Before training (n=3,622)</th>
<th>After training (n=5,824)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antenatal care attendance, n (%)</td>
<td>3,530 (97.5)</td>
<td>5,684 (97.6)</td>
<td>0.46</td>
</tr>
<tr>
<td>Gestational age, mean (SD), weeks</td>
<td>36.2 (1.1)</td>
<td>36.4 (1.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mode of delivery, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal delivery</td>
<td>2,984 (82.4)</td>
<td>4,717 (81.0)</td>
<td>0.07</td>
</tr>
<tr>
<td>Breech delivery</td>
<td>66 (1.8)</td>
<td>51 (0.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Assisted vaginal delivery</td>
<td>26 (0.7)</td>
<td>25 (0.4)</td>
<td>0.06</td>
</tr>
<tr>
<td>Caesarean section</td>
<td>488 (13.5)</td>
<td>940 (16.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Missing</td>
<td>58 (1.6)</td>
<td>91 (1.6)</td>
<td></td>
</tr>
<tr>
<td>Birth weight, mean (SD), gram</td>
<td>3,107 (474)</td>
<td>3,074 (473)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Table 6.2 shows the clinical performance of basic delivery skills before and after training. The proportion of women receiving 10 IU of oxytocin after training (91.7%) was significantly higher compared to before training (87.8%). There was no difference in the proportion of women that did not receive uterotonic drugs after delivery (before training 3.0%, after training 2.9%). After training, a significantly greater proportion of women received the uterotonic drugs within one minute after birth (before training 40.4%, after training 44.3%). Removal of the placenta by controlled cord traction and subsequent uterine massage were
more frequently performed after training (98.8% and 99.0% respectively) compared to before training (96.5% and 93.0% respectively). There was no difference in the proportion of women that had their placenta examined for completeness after delivery (before training 36.9%, after training 37.0%).

Table 6.2. Basic delivery skills

<table>
<thead>
<tr>
<th>Basic delivery skill</th>
<th>Before training, n (%)</th>
<th>After training, n (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterotonic drugs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxytocin, 10 IU</td>
<td>3,180 (87.8)</td>
<td>5,338 (91.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Oxytocin, 5 IU</td>
<td>69 (1.9)</td>
<td>138 (2.4)</td>
<td>0.14</td>
</tr>
<tr>
<td>None</td>
<td>108 (3.0)</td>
<td>170 (2.9)</td>
<td>0.83</td>
</tr>
<tr>
<td>Other</td>
<td>247 (6.8)</td>
<td>178 (3.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Missing</td>
<td>18 (0.5)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Uterotonic drugs administered within one minute after birth</td>
<td>1,465 (40.4)</td>
<td>2,578 (44.3)</td>
<td>0.001</td>
</tr>
<tr>
<td>Missing</td>
<td>139 (3.8)</td>
<td>176 (3.0)</td>
<td></td>
</tr>
<tr>
<td>Removal of placenta by controlled cord traction</td>
<td>3,494 (96.5)</td>
<td>5,757 (98.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Missing</td>
<td>2 (0.1)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Uterine massage</td>
<td>3,367 (93.0)</td>
<td>5,767 (99.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Missing</td>
<td>4 (0.1)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Examination of placenta</td>
<td>1,338 (36.9)</td>
<td>2,157 (37.0)</td>
<td>0.96</td>
</tr>
<tr>
<td>Missing</td>
<td>4 (0.1)</td>
<td>0 (0)</td>
<td></td>
</tr>
</tbody>
</table>

Table 6.3 shows the management of postpartum haemorrhage before and after training. In the entire study period, 196 women (2.1%) experienced postpartum haemorrhage. The proportion of women with postpartum haemorrhage receiving 10 IU of oxytocin as part of management of postpartum haemorrhage significantly increased from 43.0% before training to 61.2% after training. The proportion of women with postpartum haemorrhage that did not receive any uterotonic drugs increased from 1.1% before training to 3.9% after training, but this was not statistically significant. After training, more women received uterine massage (before 80.6%, after 90.3%), examination of perineum, vagina, and/or episiotomy (before 51.6%, after 64.1%), and bimanual uterine compression (before training 11.8%, after training 19.4%) as part of the management of postpartum haemorrhage. However, these changes were not statistically significant. The proportion of women having a hysterectomy after postpartum haemorrhage remained constant at around 3%. The number of blood units given within 24 hours to women experiencing postpartum haemorrhage increased slightly from an average of 0.4 units before training to an average of 0.7 units after training.
Table 6.4 shows patient outcome before and after training. After training there was a significant reduction in the incidence of postpartum haemorrhage (500-1,000 ml) from 2.1% to 1.3%. No difference was seen in the group with blood loss more than 1,000 ml (before training 0.4%, after training 0.4%). In most cases blood loss was estimated visually (before training 89.3%, after training 90.8%). Linear regression analysis showed that the variables breech delivery, birth weight, and gestational age did not influence blood loss after delivery. However, when corrected for the increased number of caesarean sections, the difference in blood loss before and after delivery further increased. The proportion of women admitted to the maternity ward and discharged within 24 hours after delivery significantly decreased from 35.2% before training to 27.4% after training. The number of women admitted to the intensive care unit and the number of women who died within 24 hours after delivery did not change (respectively 16 (0.4%) and 1 (0%) before training, and 27 (0.5%) and 2 (0%) after training). The majority of infants had a normal neonatal outcome at 24 hours (before training 94.5%, after training 94.3%). The proportion of infants with any kind of difficulties increased significantly from 0.3% before to 1.0% after training. The proportion of fresh stillbirths declined slightly (before training 1.6%, after training 1.2%), and the proportion of
neonatal deaths remained constant throughout the study period (before training 0.8%, after training 0.9%).

Table 6.4. Outcome

<table>
<thead>
<tr>
<th>Blood loss, n (%)</th>
<th>Before training (n=3,622)</th>
<th>After training (n=5,824)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 500 ml</td>
<td>3,529 (97.4%)</td>
<td>5,721 (98.2%)</td>
<td>0.008</td>
</tr>
<tr>
<td>500-1,000 ml</td>
<td>77 (2.1%)</td>
<td>78 (1.3%)</td>
<td>0.003</td>
</tr>
<tr>
<td>≥ 1,000 ml</td>
<td>16 (0.4%)</td>
<td>25 (0.4%)</td>
<td>0.93</td>
</tr>
</tbody>
</table>

Method of estimating blood loss, n (%)

<table>
<thead>
<tr>
<th>Method of estimating blood loss</th>
<th>Before training (n=3,622)</th>
<th>After training (n=5,824)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual</td>
<td>3,236 (89.3%)</td>
<td>5,286 (90.8%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Measured</td>
<td>165 (4.6%)</td>
<td>122 (2.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Both</td>
<td>221 (6.1%)</td>
<td>416 (7.1%)</td>
<td>0.05</td>
</tr>
<tr>
<td>Maternal outcome after 24 hours, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admitted to MW, discharged &lt; 24hrs</td>
<td>1,274 (35.2%)</td>
<td>1,594 (27.4%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Admitted to MW, discharged &gt; 24hrs</td>
<td>2,331 (64.4%)</td>
<td>4,201 (72.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Admitted to ICU &lt; 24hrs</td>
<td>16 (0.4%)</td>
<td>27 (0.5%)</td>
<td>0.88</td>
</tr>
<tr>
<td>Death &lt; 24hrs per 100,000 live births</td>
<td>28</td>
<td>36</td>
<td>0.86</td>
</tr>
<tr>
<td>Neonatal outcome after 24 hours, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>3,423 (94.5%)</td>
<td>5,494 (94.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Any kind of difficulties</td>
<td>11 (0.3%)</td>
<td>58 (1.0%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Died after birth</td>
<td>29 (0.8%)</td>
<td>50 (0.9%)</td>
<td>0.84</td>
</tr>
<tr>
<td>Stillbirth (fresh)</td>
<td>58 (1.6%)</td>
<td>68 (1.2%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Stillbirth (macerated)</td>
<td>43 (1.2%)</td>
<td>72 (1.2%)</td>
<td>0.84</td>
</tr>
<tr>
<td>Missing</td>
<td>58 (1.6%)</td>
<td>82 (1.4%)</td>
<td></td>
</tr>
</tbody>
</table>

DISCUSSION

Our study showed a relative reduction of 38% in the incidence of postpartum haemorrhage up to 1,000 ml following the introduction of the Helping Mothers Survive Bleeding After Birth training programme (Kirkpatrick level 4). This was associated with an improvement in clinical performance of basic delivery skills and management of postpartum haemorrhage (Kirkpatrick level 3). The latter was not statistically significant except for an increase in the use of oxytocin for treatment of postpartum haemorrhage. These results are very relevant considering the high prevalence of anaemia in pregnancy in this population and the fact that most of these settings do not have blood banks (32).

The overall incidence of postpartum haemorrhage was almost 8% lower than expected. Sheldon et al. describe a similar finding in the WHO Multicountry Survey on Maternal and Newborn Health (33). The measured incidence is most likely to be an underestimation of the
actual incidence because in the majority of women blood loss was estimated visually. It is known that subjective measurement of blood loss leads to lower estimates of the incidence of postpartum haemorrhage (3, 34, 35). Furthermore, in our cohort the proportion of women with postpartum haemorrhage receiving bimanual uterine compression and hysterectomy was relatively high, indicating severe bleeding. This finding is confirmed by other research.(33) To objectively measure blood loss, we explored the use of point-of-care Hb measurements before and after delivery and the use of blood collection bags. However, this did not fit our research budget and the idea met resistance from nurse midwives who already experienced a high workload. The likely underestimation of blood loss influences the study power. In the group of women with more than 500 ml blood loss after delivery, an improvement in management of postpartum haemorrhage was observed. However, because of the lower than expected incidence of postpartum haemorrhage, our sample size was too small to show a statistically significant difference.

In addition to that, an increase of caesarean sections was observed after training. We do not know the reason for this increase, but we know caesarean sections are associated with an increased amount of blood loss after delivery compared to vaginal deliveries (36). When correcting for the increase in caesarean sections there is a further decline in the amount of blood loss after the intervention.

An interesting finding is that the performance-based assessment (Kirkpatrick level 3) did not reflect the competency-based assessment (Kirkpatrick level 2) that was performed earlier (10, 37). Whereas there was an improvement after training in basic delivery skills as observed in labour ward, this was not reflected by the results of the simulated skills test at nine months. Clinicians and nurse-midwives, who perform most deliveries, showed a significant gain in simulated basic delivery skills immediately after training, which declined to pre-training levels at nine months (37). It shows that there may be an inconsistency between competence (as assessed in simulated scenarios) and performance (as observed in clinical practice). Similar findings are shown in other studies (38-40). This can have implications for other settings as well, such as assessments for medical qualification and revalidation of fitness to practice. Competence as assessed by multiple choice questions and simulated skills tests may not reflect actual clinical performance. Therefore, assessments of medical
professionals in training programmes, during medical qualification, and revalidation of fitness to practice should include a combination of different methods, including observation of actual clinical performance. For the evaluation of training programmes this means that all four levels of the Kirkpatrick model should be assessed.

There were some limitations to our study. Firstly, the improvement seen after the introduction of the training course may be caused by other changes in the healthcare system. Therefore we have evaluated the Helping Mothers Survive Bleeding After Birth training programme on all four levels of the Kirkpatrick model. When results of each level reinforce each other, it is more likely that the improved performance of healthcare workers is the effect of training. Previously, we have shown that training was considered acceptable and feasible (level 1) (10). Knowledge, skills, and confidence of healthcare workers who attended the training programme increased immediately after training (level 2) (10). After nine months, the level of knowledge decreased to pre-training levels, and skills and confidence were partly retained (37). Because there is improvement across all levels of the Kirkpatrick model, we consider it very likely that the reduction in incidence of postpartum haemorrhage and improvement in clinical performance was due to the training course. Secondly, it was not feasible to power our study to investigate the effect of training on maternal mortality. Based on a cross-sectional study that took place in Haydom Lutheran Hospital from 2009 to 2011 (32), we would expect approximately 32 maternal deaths and maternal near misses related to postpartum haemorrhage (prevalence 0.64%). A sample of approximately 70,000 deliveries would be needed to show a reduction of 25% in postpartum haemorrhage related maternal mortality and severe maternal morbidity. Lastly, the presence of research assistants may have influenced the performance of healthcare workers being observed (Hawthorne effect). We expect this effect to be minimal as the research assistants had been present in labour ward for more than two years, collecting data by observing deliveries for other studies (41, 42), and were considered part of the team working in labour ward.
CONCLUSION

A half-day obstetric simulation-based training "Helping Mothers Survive Bleeding After Birth" was associated with a relative reduction of 38% in the incidence of postpartum haemorrhage (500-1,000 ml). Clinical performance of basic delivery skills and treatment of postpartum haemorrhage with oxytocin increased significantly after training. Other skills in management of postpartum haemorrhage (uterine massage, examination of birth canal, and bimanual uterine compression) improved after training, but this was not statistically significant. Comparing the results of Kirkpatrick level 3 (clinical performance) to previously published results of Kirkpatrick level 2 (retention of competence) showed differences. This may have implications for the assessment of healthcare professionals on other occasions such as medical qualification and revalidation. It is important that future evaluation of training programmes takes place at all four levels of the Kirkpatrick model.
CONCLUSION

A half-day obstetric simulation-based training “Helping Mothers Survive Bleeding after Birth” was associated with a relative reduction of 38% in the incidence of postpartum haemorrhage (500-1,000 ml). Clinical performance of basic delivery skills and treatment of postpartum haemorrhage with oxytocin increased significantly after training. Other skills in management of postpartum haemorrhage (uterine massage, examination of birth canal, and bimanual uterine compression) improved after training, but this was not statistically significant. Comparing the results of Kirkpatrick level 3 (clinical performance) to previously published results of Kirkpatrick level 2 (retention of competence) showed differences. This may have implications for the assessment of healthcare professionals on other occasions such as medical qualification and revalidation. It is important that future evaluation of training programmes takes place at all four levels of the Kirkpatrick model.

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CHAPTER 7

GENERAL DISCUSSION AND CONCLUSION
7.1. AIM AND RESEARCH QUESTIONS

The first part of this thesis described the quality of obstetric care in a rural referral hospital in Tanzania and identified ways to improve care. The second part of this thesis determined the efficacy of low-cost low-tech obstetric simulation-based training in a low-resource setting as a way to improve quality of obstetric care. Therefore the research questions depicted in Table 7.1 were addressed. The main findings will be summarized and discussed here according to each research question. In the general conclusion the results will be placed in a broader context. Furthermore, the internal and external validity of the study will be addressed and areas for future research will be identified.

Table 7.1. Overview of thesis chapters and research questions

<table>
<thead>
<tr>
<th>Research question</th>
<th>Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the prevalence of severe maternal morbidity and mortality in a rural referral hospital in Tanzania as proposed by the WHO near miss approach?</td>
<td>2</td>
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<tr>
<td>2. What are the implementation levels of key evidence-based interventions in women experiencing severe maternal morbidity and mortality?</td>
<td>3</td>
</tr>
<tr>
<td>3. What is the applicability of the WHO near miss criteria in a low-resource setting?</td>
<td>4</td>
</tr>
<tr>
<td>4. Is obstetric simulation-based training acceptable and feasible in a low-resource setting?</td>
<td>5</td>
</tr>
<tr>
<td>5. To what extent do knowledge, skills, and confidence of healthcare workers improve after simulation-based training?</td>
<td>6</td>
</tr>
<tr>
<td>6. To what extent are knowledge, skills, and confidence of healthcare workers retained nine months after simulation-based training?</td>
<td>4, 6</td>
</tr>
<tr>
<td>7. To what extent does obstetric simulation-based training influence clinical behaviour and patient outcome?</td>
<td>6</td>
</tr>
</tbody>
</table>

7.2. MAIN FINDINGS AND CONCLUSIONS

1. What is the prevalence of severe maternal morbidity and mortality in a rural referral hospital in Tanzania as defined by the WHO near miss approach?

Severe maternal morbidity and mortality is a significant burden in low-resource settings, especially in sub-Saharan Africa. The cross-sectional study in Haydom Lutheran Hospital showed that the maternal mortality ratio (MMR) was 350 maternal deaths per 100,000 live births (95% confidence interval 243-488). The prevalence of severe maternal morbidity was
23.6 women per 1,000 live births. For every maternal death there were nearly seven women with severe maternal morbidity. Most maternal deaths and maternal near misses could be attributed to direct causes such as postpartum haemorrhage (PPH) (27%), abortion related complications (17%), obstructed labour (12%), antepartum haemorrhage (11%), hypertensive disorders (9%), and puerperal sepsis (4%). In 15% of all women an indirect cause was identified of which anaemia in pregnancy accounted for 8%.

The MMR resulting from this study was comparable with previous research done in this area of Tanzania: 362 (95% CI 269-456) and 444 (95% CI 371-517) maternal deaths per 100,000 live births for household and antenatal clinic surveys respectively (1), and the country estimate (390-460 maternal deaths per 100,000 live births) (2-4). It has to be taken into account that estimations of maternal mortality are very uncertain because of the different ways used to measure and define maternal mortality (5). Two-thirds of countries (including Tanzania) do not have routine vital registration and certification of the underlying cause of death and are unable to reliably measure maternal mortality (6). Other methods such as health facility statistics, demographic health surveys, surveillance, and country census are relied upon, but they all have different flaws (6). In addition, the findings are hospital-based and may therefore not be generalized to the general population. Approximately 48% of all Tanzanian women give birth at home, and 85% of all maternal deaths are established in the hospital (4, 7). Although not all maternal deaths and maternal near misses that occurred in the entire population may have been captured, it is likely that the concentration of maternal deaths and near misses is higher in the hospital than in the general population. The above has to be taken into account when comparing different MMRs.

The near miss approach was used by the World Health Organization (WHO) to perform a large cross-sectional study in 357 facilities in 29 countries around the world (8). They included 314,623 women of whom 23,015 women (7.3%) had severe pregnancy complications, and 3,024 women (1.0%) developed a severe maternal outcome. The prevalence of severe maternal morbidity was somewhat higher in the WHO multicountry survey (8.3 maternal near misses/1,000 live births) compared to Haydom Lutheran Hospital (6.6 maternal near misses/1,000 live births). In the WHO multicountry survey 808 women with severe maternal outcome (26.7%) experienced postpartum haemorrhage and 784
women (25.9%) had (pre-)eclampsia. Abortion-related complications made up 15.4% and antepartum haemorrhage 12.4% (8).

PPH is recognized to be the leading cause of maternal death in the world. In Africa, an estimated 34% of all maternal deaths could be attributed to bleeding after birth (9). The prevalence of PPH worldwide is increasing. Two systematic reviews covering periods from 1997-2006 and 2003-2009 showed that the overall prevalence increased from an estimated 6% to an estimated 11% (blood loss ≥ 500 ml) (10, 11). The prevalence of severe post partum haemorrhage (blood loss ≥ 1,000 ml) increased from an estimated 1.9% to 2.8% (10, 11). Other research performed in high-resource settings confirmed an increase in prevalence as well (12). Increasing maternal age at birth, body mass index (BMI), caesarean section rates, induction of labour, and multiple pregnancy rates were suggested to be determinants of this increasing prevalence of PPH (12).

2. What are the implementation levels of key evidence-based interventions in women experiencing severe maternal morbidity and mortality?

Many evidence-based interventions to treat obstetric emergencies exist (for example the administration of oxytocin immediately after birth for prevention of PPH), but they are not well implemented (13, 14). Results from the cross-sectional study show varying implementation levels of six key evidence-based interventions in Haydom Lutheran Hospital. Only 48% of women received oxytocin as prophylaxis for PPH and 59% of women with PPH received oxytocin as treatment. Women who had caesarean sections received prophylactic antibiotics in 66% of all cases. Women with eclampsia received magnesium sulphate in 87% of all cases, 93% of women with sepsis received parenteral therapeutic antibiotics, and all women with uterine rupture had a laparotomy. In comparison with Haydom, the WHO multicountry survey showed higher implementation levels of prophylactic (overall 90.1%) and therapeutic oxytocin (overall 85.9%) regardless of the country's MMR (8). Coverage of prophylactic antibiotics for caesarean section ranged from 35.7% in countries with a low MMR to 82.5% in countries with a very high MMR, averaging overall on 87.3% (8). Implementation levels of magnesium sulphate for treatment of eclampsia (overall 85.7%)

140 | Chapter 7
were similar to our study. Coverage of parenteral antibiotics for sepsis was varying (62.2% to 89.3%), but was slightly lower overall (78.5%) compared to Haydom (8).

The implementation levels of evidence-based interventions alone cannot explain why mothers (nearly) die. In order to improve maternal health, changes should take place in the community as well and include educational and socio-economic empowerment of women (15). Almost half of pregnant women in low-resource settings suffer from anaemia in pregnancy which makes them more vulnerable to the consequences of blood loss (16). Among women with severe maternal outcome in Haydom Lutheran Hospital the prevalence of anaemia (Hb <10.5 g/dL) in pregnancy was 76.4%. Anaemia is caused by poor nutrition, infectious diseases, and genetic disorders (17). The underlying problem is much larger, however, and includes access to diverse and fortified food sources, access to adequate interventions such as deworming and iron supplementation, adequate knowledge and education about anaemia, and access to clean water and sanitation (17). This, in turn, is influenced by the level of education, socio-economic status, cultural norms, and individual behaviour (17). A low level of education was also associated with severe maternal outcomes in pregnant women (18).

A systematic review regarding delay in receiving adequate care in the facility showed that the main contributors to phase 3 delay were inadequate training opportunities (86%), inadequate drugs supply (65%), lack of personnel (60%), lack of equipment (51%), and staff motivation issues (44%) (19). In Haydom Lutheran Hospital healthcare workers experienced lack of pre-service and in-service training opportunities as well (20). In addition, there is a lack of qualified staff which may affect the monitoring of critically ill patients and reduce the chance of detecting a deteriorating patient. Results from the cross-sectional study showed that monitoring of vital signs is lacking. Of all women that were ill on arrival, only 77% had blood pressure measured, 72% had pulse rate taken, and in 73% temperature was recorded. Physical examination was performed in 92% of all women arriving in the hospital (21).

Moreover, delay in receiving adequate treatment significantly contributed to the development of severe maternal morbidity and mortality in a multicentre cross-sectional study in Brazil (22). Women with potentially life-threatening conditions experienced delay in
52%, while maternal near misses and maternal deaths experienced delay in respectively 68% and 84% of women. Results from the educational intervention study in Chapter 6 confirmed this as well. Although 88% of all women received prophylactic oxytocin, only 40% received these drugs on time within one minute after birth.

Concluding, in many areas in Haydom Lutheran Hospital the need for improvement in quality of care is obvious. The lack of staff and staff motivation are important issues to address. Implementation of treatment interventions can be improved, as well as the speed with which they are performed. However, before a patient can receive treatment there has to be adequate monitoring and detection of patients who require treatment. The different areas need to glue together to create a better functioning comprehensive health system. The challenge of reducing maternal morbidity and mortality lies not only in improving the overall quality of obstetric care in the hospital, but also in improving access to education and socio-economic empowerment of women. Within the hospital system, most improvements can realistically be achieved in this environment.

3. What is the applicability of the WHO near miss criteria in a low-resource setting?

One of the aims of the cross-sectional study was to validate the WHO near miss criteria in a low-resource setting. The criteria had only been validated in Brazil and Canada (23-25), while the purpose of the near miss criteria was that they should be used in any setting regardless of the development status (24). Most severe maternal morbidity occurs in low-resource settings; therefore it is important that the WHO near miss criteria are applicable in these areas. Results from the cross-sectional study showed that all clinical criteria could be applied in Haydom Lutheran Hospital. The clinical near miss criteria showed to be reliable in identifying maternal deaths (the closest to a near miss); sensitivity was 100%, and specificity was 99.5%. However, only 25% of laboratory-based and 50% of management-based criteria could be used in this setting. Other authors confirmed poor applicability of the WHO near miss criteria in low-resource settings (26-28).

The consequence of applying the WHO near miss criteria in low-resource settings is that severe maternal morbidity will be under-reported. In Haydom, the WHO near miss criteria
were modified to better fit the local context and to capture all severe maternal morbidity. Disease-based criteria such as uterine rupture, eclampsia, and sepsis were added because they were frequent causes of maternal mortality (29). As Haydom Lutheran Hospital did not have a blood bank it was considered very unlikely that a woman would receive five units of blood. Therefore, the threshold of five units of blood was lowered to one. Admission to the intensive care unit was added because it reflected severe maternal morbidity in Haydom Lutheran Hospital. Data were collected with the modified criteria and included 248 women with severe maternal outcome: 216 maternal near misses and 32 maternal deaths. When the WHO near miss criteria were strictly applied, there were only 92 women with severe maternal outcome left: 60 maternal near misses and 32 maternal deaths. Because of the low availability of advanced laboratory tests and sophisticated management options in settings such as Haydom, a proportion of the women with severe maternal morbidity was missed. This will cause serious under-reporting of near miss cases compared to settings that can apply all criteria.

Another effect of the application of the WHO near miss criteria in low-resource settings is that the case fatality rate (CFR) in low-resource settings will be much higher than the case-fatality rate in high-resource settings. The CFR for cases identified with the WHO near miss criteria was significantly higher (34.8%) compared to the CFR for women identified with the modified criteria (12.9%) (30). More than 70% of the women that would have been a near miss with the modified criteria were not a near miss according to the WHO criteria. A number of additional women were included using the modified criteria; those who received one blood transfusion or more (n=126), were admitted to the intensive care unit (n=28), experienced eclampsia (n=10), sepsis (n=10), or uterine rupture (n=7). In the group of women that received one blood transfusion or more, 108 women received only one unit of blood and within this group 77 women did not have another inclusion criterion. Comparing CFRs of the WHO multicountry survey and the cross-sectional study in Haydom highlights the discrepancy between CFRs even more: 16.1% in the multicountry survey versus 34.8% in Haydom (8). These findings were confirmed by a study performed in Malawi (26).

In conclusion, the applicability of the WHO near miss criteria depends on the local context and local availability of resources. In our setting not all WHO near miss criteria could be
applied, this was particularly true for the laboratory-based criteria. The consequence is that there will be an underestimation of maternal near miss cases in settings without laboratory and management facilities. The ratio of maternal deaths and maternal near miss cases will differ across settings, causing the CFR in low-resource settings to be much higher. This has to be taken into consideration when interpreting and comparing studies making use of the WHO near miss approach.

4. *Is obstetric simulation-based training acceptable and feasible in a low-resource setting?*

Simulation-based training has not often been used in low-resource settings to train healthcare workers and it differs considerably from the traditional way of teaching. Evaluation of the Helping Mothers Survive Bleeding After Birth (HMS BAB) training programme revealed that the majority of the participants (74%) considered the training programme culturally appropriate, and thought training could be accomplished with the resources currently available at Haydom Lutheran Hospital (80%). Most participants (83%) regarded the training appropriate for the current scope of practice for birth attendants. The teaching materials (flipbook, facilitation guide, action plan, and simulator) were well accepted. However, facilitators stated that the teaching materials should be translated in the local language.

In addition, a clear need for in-house training was identified. Only 30% of all participants had received in-house training regarding active management of third stage of labour (AMTSL) at some stage in their postgraduate career. A mere 18% received in-house training on management of PPH. Moreover, only 69% of healthcare workers received pre-service training in AMTSL and 73% received pre-service training in management of PPH. The shortage of in-house training in low-resource settings is also recognized by other authors (31, 32). New evidence from research is continuously emerging and therefore best practices are changing. Continued medical education is important to keep healthcare workers up to date. After the initial training the majority (89%) of participants in Haydom Lutheran Hospital were willing to participate again in the future. Results from focus group discussions among midwives in Ghana have shown that in-service training was often regarded to be ineffective because the content did not address the scope of maternal health and was often out of date.
The midwives mentioned an unclear selection process for participation in in-service training (32). These lessons highlight that training should be accessible to all healthcare workers and that the training programme contains an up-to-date curriculum that fits the current scope of practice.

5. To what extent do knowledge, skills, and confidence of healthcare workers improve after obstetric simulation-based training?

Knowledge, skills, and confidence of healthcare workers improved significantly following obstetric simulation-based training. Knowledge scores of participants improved from a mean score of 74% before training to 80% after training. Pass rates improved accordingly from 63% before training to 75% after training. Clinicians and nurses who had received a formal medical education performed better than medical attendants and ambulance drivers, who had no formal medical education. Mean scores of simulated skills in basic delivery and management of PPH improved after training, however pass scores were low (both 3%). Confidence improved in all five areas: AMTSL, management of PPH, determine completeness of placenta, performance of bimanual uterine compression, and ability to access advanced care.

Although participants improved knowledge, skills, and confidence following training, there was a discrepancy between the pass score of the knowledge test (75%) and the pass score of the skills test (3%). Comparing these results to a study validating the HMS BAB programme in India, Malawi, and Zanzibar revealed that our pass score was considerably lower than theirs, which ranged from 83%-89% (33). Three variables may have contributed to this discrepancy: the skills test, the training programme, and the participants.

The global (pass/fail) rating of the skills test may have been invalid. In order to pass the skills test in the study by Evans et al. a certain percentage (ranging from 64% to 75%) of all items on the skills checklist needed to be performed (33). In contrast, passing of our skills test was based on performing all key components on the checklist of basic delivery and management of PPH. In our study two maternal health experts independently rated the videos that contained the skills tests, whereas in the study of Evans et al. the assessment was performed
directly by one assessor. The inter-rater agreement of the two maternal health experts ranged from a Kappa of 0.53 to 0.73 for basic delivery (moderate to substantial agreement) and 0.22 to 0.37 for management of PPH (fair agreement). The difference can be attributed to the number of items that make up the global rating which was considerably higher for management of PPH. The level of inter-rater agreement has to be taken in consideration when interpreting the results.

Another reason for the low pass rate of the skills test may be that the training was not good enough to improve skills. Firstly, the philosophy of the educational system of Tanzania differs considerably from the philosophy of simulation training, facilitation, and debriefing. More time may be needed to adapt to a new way of teaching to be able to effectively transfer skills. Secondly, participants stated in the evaluation that the length of the training course was too short, and that they would prefer a full day of training. Jhpiego incorporated this feedback in the Helping Mothers Survive training programme that was launched in May 2013. Thirdly, the facilitators may not have been competent enough to teach. Skills testing of facilitators was carried out after they had finished teaching learners. Although all facilitators passed the knowledge test, only 29% passed the basic delivery skills test and none passed the management of PPH skills test. It is of utmost importance that facilitators are competent before teaching other people. Future facilitators should participate in the training first and pass both knowledge and skills test, before being selected to become a facilitator. Lastly, the teaching materials were only available in English at the time of training. Facilitators stated that the teaching materials should be translated into the local language. Jhpiego has incorporated this advice, and the teaching materials are now available in English, Kiswahili, French, and Portuguese (34).

Finally, the low level of skills of participants may have contributed to the low pass rate. The participants consisted of a multi-professional group of healthcare workers of which 22% had no medical background.

In summary, knowledge, skills, and confidence increased significantly after obstetric simulation-based training. However, pass rates of the skills test were low. Jhpiego has incorporated the suggested improvements (full day training, translation of teaching
Results from our study and previous studies have shown that obstetric simulation-based training improves knowledge, skills, attitudes, and teamwork of participants (20, 33, 35-51). However, studies addressing retention of knowledge and skills show mixed results (41, 42, 47, 52, 53). It is important to know the retention of knowledge and skills for timing of follow-up training. Therefore we repeated the knowledge questionnaire, simulated skills test, and confidence questionnaire nine months after initial training. After a significant increase immediately after training, knowledge levels declined to pre-training levels at 9-month follow-up. Skills were mostly retained nine months after training. Confidence was retained in three out of five areas: management of PPH, bimanual uterine compression, and accessing advanced care.

According to the above results, it is clear that one training session is not enough to keep knowledge, skills, and confidence up to date. We would advice training to take place at least twice yearly. Others have advocated low-dose high-frequency continuation of training: "booster" sessions that take place often (high-frequency) but do not take long (low-dose). (33). It is known that this type of training increases retention of skills of healthcare providers and may even reduce patient mortality (54-56). But the implementation of low-dose high-frequency training proved to be difficult for the HMS BAB training programme in Haydom Lutheran Hospital. During the nine-month follow-up period, learners were encouraged to continue with low-dose high-frequency training. Training materials were placed on the labour ward and in the nursing school. After finishing initial training, the facilitators discussed how to continue low-dose high-frequency training. The facilitators decided that each of them would be responsible for a group of learners, thereby taking the lead in establishing low-dose high-frequency continuation of training for this specific group. The aim was to perform one scenario per person per week. However, in the nine months following initial training only one person practised three times. Feedback that was received from
healthcare workers in Haydom Lutheran Hospital identified several barriers to continuation of training: no time to practise, no space to practise, unaware of the location of the mannequin, two people were needed to practise, lack of personnel, lack of motivation, not important, no allowance available, and not interested. We observed a lack of support to implement continuation of training from the management at maternity ward and hospital level. Most of this may be attributed to a lack of communication between the different levels. This was emphasised by one of the facilitators who was not sure if she was allowed to practise with the mannequin during work time. Solutions suggested by the facilitators included practising in plenum twice a year, putting reminders in the ward for low-dose high-frequency continuation of training, and allocating time for training by the hospital management. One of the facilitators, who worked as a teacher in the nursing school, practised three times with nursing students in a pre-service setting. According to this facilitator, the implementation in pre-service setting was easier as students were motivated and time was already allocated in the curriculum.

The success of implementation depends on the intervention (simulation-based training), the inner (labour ward) and outer setting (hospital), the individuals involved, and the process by which implementation is accomplished (57).

The simulation-based training needs to be well-structured and relevant to clinical practice (58). According to the evaluation that was done immediately after training, the training programme was well accepted and considered relevant by learners and facilitators (20). Furthermore, a non-threatening environment supports sustainability of training (58). We did not evaluate if the learning environment was experienced as threatening, but evaluation showed that learners enjoyed training with other members of staff (20).

The labour ward needs strong and engaged leadership to ensure compliance with implementation of training (58). This could have been improved in our study. Because of lack of personnel, staff perceived their workload as very high. The head of the maternity ward did not have time to be engaged in teaching at the time of training. Therefore other senior personnel were selected to become facilitators, but when implementing low-dose high-
frequency training the facilitators experienced lack of support from the head of the maternity ward.

The hospital management may need more preparation in order to successfully implement local retraining. There is no culture of practical in-house training in this hospital as shown by the low percentage of healthcare workers that received in-service education (20). Clear institutional-level commitment appears to be associated with sustaining training programmes (58). In this study only local facilitators were involved in the implementation of continuation of training. Implementation could be improved by more involvement of the management of the maternity ward and the hospital. Together, they need to create an environment that allows and encourages people to train. Another perceived barrier was the lack of time to practise. This is a difficult issue to solve, as human resources in low-resource settings are scarce. The hospital management should make training a mandatory part of the job. This could be achieved by providing job descriptions that include structured training. The head of the maternity ward should then schedule time for training.

In summary, one training session is not enough to maintain knowledge, skills, and confidence nine months after initial training. Continuation of training is crucial but needs a tailored implementation process that should take place before training is introduced. It should take into account adaptation of the training programme to the local context, commitment and strong leadership in the labour ward and hospital management, and good and continuous communication between individuals at all levels.

7. To what extent does obstetric simulation-based training influence clinical behaviour and patient outcome?

We have shown that knowledge, skills, and confidence increased significantly immediately after obstetric simulation-based training and were partly retained up to nine months (20, 59). What we do not know is whether these newly acquired assets will be incorporated into clinical behaviour and lead to improved patient outcome. Therefore, trained research assistants observed healthcare workers performing deliveries before and after training, and recorded blood loss after delivery. These observations show that the incidence of PPH (500-
1,000 ml) significantly reduced from 2.1% before training to 1.3% after training. Basic delivery skills of healthcare workers significantly improved. The proportion of women that received oxytocin, removal of the placenta by controlled cord traction, and uterine massage significantly increased after training. Management of PPH improved; there was a significant increase in the proportion of women that received therapeutic oxytocin. Uterine massage, examination of the birth canal, and bimanual uterine compression following PPH improved after training, but this was not statistically significant.

The results of this study are very relevant for a population in which 76% of women suffer from anaemia in pregnancy. In addition, in many low-resource settings such as Haydom Lutheran Hospital there is no blood bank and women depend on their relatives for blood for transfusion. A reduction in blood loss of 500-1,000 ml was assumed to be possible due to improvement in the basic steps of management of postpartum haemorrhage such as giving oxytocin, removing the placenta by controlled cord traction, and performing uterine massage. The mannequin that was used in the HMS BAB training programme has features that very realistically simulate these basic steps: a placenta that can be removed by controlled cord traction, a uterus that can contract and relax, and the ability of the mannequin to bleed up to 1,500 ml. These features may have helped the learning of these skills. In women with severe blood loss after birth (> 1,000 ml) the basic steps may not have been sufficient enough to control bleeding caused by uterine atony, and certainly not for other causes of postpartum haemorrhage.

A Cochrane review showed that the administration of oxytocin as part of AMTSL was associated with a significant reduction in PPH (>500 ml) compared to placebo alone (60). In two randomised controlled trials the added effect of controlled cord traction in AMTSL was questioned compared to the administration of oxytocin alone (61, 62). Among women without oxytocin prophylaxis, removal of placenta by controlled cord traction significantly reduced the incidence of PPH by 50% compared to expectant management (63). A Chinese randomised trial evaluated the added effect of 30 minutes of continuous uterine massage after delivery of the placenta compared oxytocin 10 IU IM alone and found no added effect (64), however the study population that was chosen for this study was questioned (65).
In conclusion, the introduction of the HMS BAB training programme was associated with a relative reduction of 38% in the incidence of postpartum haemorrhage up to 1,000 ml. This was accompanied by improved clinical performance of basic delivery skills and management of postpartum haemorrhage. It appears from randomised trials that administration of oxytocin is the most effective component of active management in reducing blood loss postpartum. Training should continue to focus on the provision of oxytocin after birth, controlled cord traction and uterine massage. These last two components may have an added effect in the absence of oxytocin and may be needed as part of managing postpartum haemorrhage.

7.3. GENERAL CONCLUSION

This thesis provided an overview of the burden of severe maternal morbidity and mortality in a hospital in rural Tanzania and identified ways to improve the quality of obstetric care, including the introduction of obstetric simulation-based training. The hospital-based maternal morbidity and mortality in rural Northern Tanzania was high. Several areas that could improve care have been highlighted and include the up scaling of timely prevention and treatment interventions for postpartum haemorrhage, eclampsia, and sepsis. It is imperative that the lack of human resources is addressed as it affects monitoring of patients and initiating treatment in a deteriorating patient. The areas mentioned above should become integrated into one well-functioning comprehensive care system. Adopting obstetric simulation-based training could fill the lack of pre-service and in-service training that was identified. It proved to be an acceptable and effective way to improve knowledge, skills, and confidence of healthcare workers that translated in improved clinical performance and maternal outcome.

*Importance of doing research in low-resource settings*

There are many challenges of undertaking research in a low-resource setting that is struggling to achieve good quality healthcare. Most important in doing research in such settings (and in any setting), is that regular healthcare may never be compromised in order to accomplish the best possible research and that it should benefit from the results of research. The research performed should be meaningful for the setting. Ideally, research
questions should be derived from these settings to create demand driven and action oriented quests. This implies that each setting has different demands and different problems. Whilst the principal investigator was working at the maternity ward of Haydom Lutheran Hospital, she launched a cross-sectional study to systematically describe the current quality of care, identify ways to improve care, and to determine further areas for research (21). When research questions are meaningful for the local context, the implementation of recommendations that follow from these research questions may be easier. A good example of this is the development of the WHO near miss criteria (24). In itself a great aim, but clearly something that was not developed by people from low-resource settings, because when implementing the WHO near miss criteria in Haydom Lutheran Hospital, many criteria were not applicable (30).

One of the challenges of doing research in low-resource settings is that healthcare providers work in an environment experiencing a major lack of personnel and should not be burdened with research tasks that consume precious time otherwise spent with patients. In Haydom Lutheran Hospital this problem was solved with the employment of recently graduated pupils from the local secondary school. There is a high level of unemployment in the area among graduates. The former students were structurally trained to do research tasks, such as observing healthcare workers in labour ward, or entering data into an electronic database. Observing the research assistants in the labour ward showed they had a sufficient understanding to be able to reliably observe births. In this way sound and objective observation of births was achieved without burdening the existing healthcare workers. Most important for the research assistants themselves was that they had a respectable job, providing both an income and valuable work experience. Several research assistants have now progressed to further studies.

It is important that research is performed in low-resource settings, because the context in which evidence is produced determines the applicability of the evidence. A good example of this is the consequence of the Term Breech Trial which showed that a planned caesarean section for breech led to reduced adverse perinatal outcome (66). This resulted in an increase in caesarean sections for breech worldwide. Unintended consequences of caesarean sections such as major blood loss and sepsis at short term, and abnormal
placentation with its complications in subsequent pregnancies, lead to worse outcomes in low-resource settings (67). The advantages of delivering a breech by caesarean section have to be balanced against the disadvantages which is different for each setting (68).

Lastly, there is significant scope for improving practice and patient outcome in low-resource settings. The clinical impact of performing research in such settings is therefore much larger. For example, training in a hospital in the UK lead to a reduction in low 5-minute Apgar scores and hypoxic-ischaemic encephalopathy, but due to the low prevalence of neonatal mortality a reduction in mortality was not seen (69). In contrast, the introduction of neonatal resuscitation training (Helping Babies Breathe) in Haydom Lutheran Hospital resulted in a 40% reduction in early neonatal mortality (56).

7.4. INTERNAL VALIDITY

All data that was produced in this study went through a systematic, rigorous quality control. First, a research supervisor checked the data collection forms on missing data or other inconsistencies. If there was any problem detected, the item on the data collection form was marked and the form was send back to the research assistant for adjustment. After this was completed, two different research assistants independently entered the data into an electronic database. The two databases were subsequently compared and any discrepancy was corrected against the original form. The electronic database was sent to the principal investigator and data was checked again on quality and consistency, and corrected against the original data collection form or hospital file if needed.

Cross sectional study

There is a certain degree of selection bias in the cross-sectional study, as we only included maternal deaths and maternal near misses that were admitted to the hospital. It is likely that the concentration of maternal deaths and near misses is higher in the hospital than in the general population, but to which extent is uncertain.

Information was gathered from hospital files, the data quality therefore relies on the quality of record keeping. It is known that there is a lot of missing data in hospital files (70, 71). To
reduce information bias, data collection occurred prospectively. In case of missing information, either the woman (in case of maternal near miss), or the healthcare worker in charge of the woman, was in most cases able to recall the missing information.

**Educational intervention study**

Confidence was self-assessed in five areas: performance of AMTSL, management of PPH, determining completeness of the placenta, performance of bimanual uterine compression, and accessing advanced care. Self-assessment alone is an inadequate form of evaluation (72, 73). It is therefore important that appraisal does not solely rely on self-assessment. As participants were assessed on all four levels of the Kirkpatrick model, overall results will provide a reliable evaluation of the effectiveness of the training programme.

Two external assessors, both maternal health experts, independently scored the performance of participants by watching videotapes of the simulated skills scenarios. To minimize bias, the external assessors were blinded for timing of testing (before training, immediately after training, or nine months after training), and as they were external, they did not know the participants. The first assessment of the video’s showed an overall inter-rater agreement of 90%, while the inter-rater agreement per item ranged from 61.1% to 100%. The Kappa measure of agreement was determined per item on the checklist and it ranged between 0.14 and 1.00.

As all deliveries from a gestational age of 28 weeks have been included in the prospective educational intervention study, we are confident that all hospital births have been observed and no selection bias within the hospital has occurred. However, women who delivered at home were not included in the study and may systematically differ. Births were observed to evaluate the effect of training; therefore this selection bias was acceptable and did not affect the results.

The presence of research assistants during the data collection may have resulted in change of performance of the observed subjects, the so-called Hawthorne effect. As the research assistants had been present in the labour ward for two years before the data-collection for this study started, we hypothesise that the effect on this particular intervention will be
minimal. Research assistants were considered part of the team working in labour ward and were for example helping to clean the delivery rooms if there were no births to observe.

To enhance inter-rater reliability of the research assistants, they were trained by the principal investigator prior to the start of the data collection and every three months thereafter. The birthing simulator was used to go through each of the steps that they needed to observe and correct and incorrect versions of performing AMTSL and management of PPH were shown. This information was also written down in standard operating procedures that not only contained text, but also many pictures. It was mandatory for the research assistants to read the standard operating procedures. After finishing training, the research assistants were tested in one or two simulated scenarios. Whilst the principal investigator simulated a birth, the research assistants were encouraged to observe or ask any information needed to complete the observation checklist. After completing the checklist, a debriefing followed and any discrepancies were addressed, until all research assistants agreed and understood the checklist. Their observation skills were further assessed in labour ward. Any inconsistency in observations was discussed and adjusted immediately.

7.5. EXTERNAL VALIDITY

The results of the two studies are based on one hospital alone and may not be generalizable to other hospitals, the general population, or across countries. Haydom Lutheran Hospital has a unique research infrastructure and has received long-standing aid from the Norwegian embassy which may make it incomparable to other sites. However, the prevalence of severe maternal morbidity and mortality is similar to other research in Tanzania and the underlying causes are comparable. Results can be used to compare over time, but when comparing across settings the above needs to be considered.

Due to the before after design of the educational intervention no causal relations between training and the improvement of clinical behaviour and patient outcome can be proven. However, the positive effect of training was shown on all four levels of the Kirkpatrick model.
which makes it more likely that training indeed contributed to improved clinical behaviour and patient outcome.

Choosing appropriate statistics and large enough sample sizes based on sample size calculations eliminated random error.

7.6. FUTURE RESEARCH

Future research should focus on the following areas:

1. Implementation of simulation-based training
2. Continuation of simulation-based training
3. Cost-effectiveness of simulation-based training
4. Simulation-based training to improve attitude of personnel toward patients
5. Using the maternal near miss approach to evaluate simulation-based training

**Implementation**

Good implementation of an intervention is as important as the effectiveness of an intervention. When an effective intervention is not well implemented, its impact will be reduced. The process of implementation is context specific and should take place before a new intervention is introduced. It needs to take into account the intervention itself (simulation-based training), the inner setting (the labour ward), the outer setting (the hospital), and the individuals that make up both settings (57). Prerequisites for success will be institutional-level commitment and strong leadership to create a culture in which training is a routine part of work, a well-designed curriculum with appropriate simulators that is relevant for local clinical practice, and a non-threatening training environment (58). Research is needed to explore barriers and facilitators to the implementation of simulation-based training and to provide answers to why some hospitals manage to implement training (69) and some do not (74). Qualitative research using focus group discussions to understand participants’ perspectives and semi-structured interviews to get more detailed information could address these issues. Participants should not only include healthcare workers, but also the managers of the ward where the intervention is going to be introduced, and the hospital management.
Continuation of training

There is no clear evidence about the most effective way to continue training (58). It can be organised in sessions that take place once or twice a year or as low-dose high-frequency sessions. In a setting where human resources are lacking it may be preferable to continue with low-dose high frequency training, however this needs to be well implemented and coordinated. Another question that needs to be answered is how often training should take place (once a day, once a week, once a month, every six months, or every year), and what the dose should be (one item in a scenario such as controlled cord traction, or bimanual uterine compression, or a full scenario such as PPH due to uterine atony). Healthcare workers themselves seem to prefer organised sessions twice a year (20). Either way, one training session is not enough to maintain knowledge, skills and confidence (59) and continuation of training should be provided.

Cost-effectiveness

One of the incentives to introduce obstetric simulation-based training for hospitals in the UK was to reduce the costs from medico-legal claims for negligent harm in obstetrics (69). In low-resource settings there are very few medico-legal claims. However, if simulation-based training is proven to reduce the costs of healthcare, this could be an extra incentive for the hospital management to introduce and sustain simulation-based training.

Attitude

Poor attitude of personnel towards patients is thought to be an important contributor to maternal mortality (75-78). While the underlying problem of lack of accountability calls for a health systems solution (75), poor attitude of staff could be addressed during simulation-based training. In simulation healthcare workers can be given the opportunity to be both patient and healthcare worker. Role-plays can be used to discuss the issue of poor attitude in subsequent debriefing.

Maternal near miss approach and simulation-based training

Effect of simulation-based training on level 4 of the Kirkpatrick model could be measured using maternal near misses and maternal deaths. It was our intention to report on prevalence of severe maternal outcome after introduction of training, however, data
collection is labour intensive and in 2013 not all maternal near misses and maternal deaths were collected. Future research should ensure there is at least one person continuously dedicated to data collection.
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SUMMARY!
Maternal morbidity and mortality in low-resource settings remain high, despite global efforts to reduce it. Delay in deciding to seek care, reaching an adequately functioning health facility, and receiving adequate care once arrived at health facilities are the most important contributing factors. Although many areas will need improvement in order to substantially reduce maternal morbidity and mortality, this thesis focuses on hospital-based interventions.

In the first part of this thesis, the quality of obstetric care in a rural hospital in Tanzania is described using the WHO near miss approach and areas for improvement of care are highlighted (chapter 2). In the second part of this thesis, low-cost low-tech obstetric simulation-based training in preventing and managing postpartum haemorrhage is evaluated as an intervention to improve obstetric care in a low-resource setting (chapter 4).

Chapter 2 reports on the poor applicability of the WHO near miss criteria in a low-resource setting. The near miss criteria were created in order to uniformly identify severe maternal morbidity. They exist of a subset of clinical criteria, laboratory-based criteria, and management-based criteria. In Haydom Lutheran Hospital, all clinical criteria could be applied, but only 25% of the laboratory-based criteria and 50% of the management-based criteria could be used. As a result, severe maternal morbidity in settings that cannot apply all criteria...

SUMMARY

Maternal morbidity and mortality in low-resource settings remain high, despite global efforts to reduce it. Delay in deciding to seek care, reaching an adequately functioning health facility, and receiving adequate care once arrived at health facilities are the most important contributing factors. Although many areas will need improvement in order to substantially reduce maternal morbidity and mortality, this thesis focuses on hospital-based interventions.

In the first part of this thesis the quality of obstetric care in a rural hospital in Tanzania is described using the WHO near miss approach and areas for improvement of care are highlighted (chapter 2-3). In the second part of this thesis low-cost low-tech obstetric simulation-based training in preventing and managing postpartum haemorrhage is evaluated as intervention to improve obstetric care in a low-resource setting (chapter 4-6).

In chapter 2 the WHO near miss approach was used to measure the prevalence of severe maternal morbidity and mortality in Haydom Lutheran Hospital in Tanzania. From November 2009 to November 2011 a cross-sectional study was performed. It showed a hospital-based maternal mortality ratio of 350 maternal deaths per 100,000 live births. The prevalence of severe maternal morbidity was 23.6 women per 1,000 live births. For every maternal death there were nearly seven women with severe maternal morbidity. The three commonest causes of maternal morbidity and mortality were postpartum haemorrhage, abortion related complications, and obstructed labour. Opportunities to improve care were identified and included up scaling timely prevention and treatment interventions for postpartum haemorrhage, eclampsia, and sepsis.

Chapter 3 reports on the poor applicability of the WHO near miss criteria in a low-resource setting. The near miss criteria were created in order to uniformly identify severe maternal morbidity. They exist of a subset of clinical criteria, laboratory-based criteria, and management-based criteria. In Haydom Lutheran Hospital all clinical criteria could be applied, but only 25% of the laboratory-based criteria and 50% of the management-based criteria could be used. As a result, severe maternal morbidity in settings that cannot apply all
criteria will be lower and case fatality rates will be higher when compared to settings than can apply all criteria.

In March 2012 the low-cost low-tech obstetric simulation-based training programme "Helping Mothers Survive Bleeding After Birth" was introduced in Haydom Lutheran Hospital. The training programme was delivered by local facilitators and covered a half-day training regarding basic delivery care, active management of third stage of labour, and treatment of postpartum haemorrhage. The training programme was evaluated according to the four-level Kirkpatrick model, which is commonly used for assessing training programmes. **Chapter 4** covers the evaluation of "Helping Mothers Survive Bleeding After Birth" regarding Kirkpatrick level 1 and 2. It shows that the training programme is acceptable and feasible in a low-resource setting. Knowledge, skills, and confidence of participants increased after training, however pass rates for skills test were generally low. In addition, a clear need for in-house training was identified.

Retention of knowledge, skills, and confidence was tested nine months after initial training. **Chapter 5** shows that knowledge decayed to pre-training levels, and skills and confidence were largely retained. Based on the above results we would recommend training at least twice per year.

In **chapter 6** the training programme was evaluated at Kirkpatrick level 3 and 4 by means of an educational intervention study. From May 2011 to June 2013 research assistants observed all deliveries in Haydom Lutheran Hospital. The incidence of postpartum haemorrhage (500-1,000ml) significantly reduced from 2.1% before training to 1.3% after training and clinical performance of basic delivery skills and management of postpartum haemorrhage improved after the introduction of the training programme.

Concluding, we have identified several areas for improvement which may benefit the quality of obstetric care in Haydom Lutheran Hospital. These areas should become integrated and form one well-functioning comprehensive care system. The WHO near miss criteria were difficult to apply in this low-resource setting. The obstetric simulation-based training programme "Helping Mothers Survive Bleeding After Birth" could address the lack of in-
house training that was identified. Evaluation of this training programme on all four levels of
the Kirkpatrick model indicates that this could be an effective way to educate health care
workers in low-resource settings.
MUHTASARI


Katika sehemu ya kwanza ya tasnifu hii ubora wa huduma ya wazazi inaelezwa kwa kutumia vigezo vya shirika la afya duniani (WHO) vya hali ya hatari ya kifo aliyoipitia mama wakati wa ujauzito, uzazi na siku 42 baada ya kujifungua (near miss) na maeneo ya kuboreshwa yameainishwa (aya ya 2-3). Katika sehemu ya pili ya tasnifu hii mafunzo mfanano (simulation) ya gharama na teknolojia rahisi katika kuzuia na kutibu utokwaji mwingi wa damu yalitumika kutathmini namna ya kuboresha hudum a ya wajawazito katika mazingira yenye rasilimali chache (aya ya 4-6).

Katika aya ya 2 tumetumia vigezo vya shirika la afya duniani (WHO) vya kupima hali ya hatari ya kifo aliyovuka mama wakati wa ujauzito, uzazi na siku 42 baada ya kujifungua (near miss) kupima ukubwa wa magonjwa na vifo vya akina mama wajawazito katika hospitali ya Kiluteri ya Haydom n chini Tanzania. Katika kipindi cha mwezi wa kumi na moja 2009 na mwezi wa kumi na moja 2011 utafiti wa muda mfupi ulifanyika. Ulionesha uwiano wa vifo vya wajawazito ili kuwa vifo 350 kwa kila vizazi 100,000 hai kulingana na taarifa ya hospitali. Kiwango cha kuugua sana kwa wajawazito ilikuwa wa mama 23.6 kwa kila wamama 1,000 waliozaa hai. Kwa kila kifo cha mzazi kulikuwa na karibu na kina mama saba wenye matatizo makubwa ya ugonjwa. Matatizo makubwa matatu ya nayosababisha akina mama kuugua na kufa ni utokwaji mwingi wa damu baada ya kujifungua, matatizo yanayohusiana na utokwaji wa mimba, na uchungu pingamizi (mtoto kushindwa kupita kwenye njia yauzazi). Fursa ya namna ya kuboresha huduma imeelezwa na inajumuisha kuongeza matumizi, kuzuia kwa wakati na kusaidia kimatibabu utokwaji mwingi wa damu, kifafa cha mimba na maambukizi baada ya kujifungua.
MUHTASARI

Magonjwa na vifo vya wajawazito katika mazingira yenye rasilimali chache hubakia vingi, licha ya juhudi kubwa ya kidunia kuvipunguza. Kuchelewa kutafuta msaada, kufikia kitu kinachofanya kazi ikamilifu, na kupata huduma iliyo kamili mara unapofika kwenye vitu vya kutolea huduma za afya ni sababu kubwa sana zinazochangia tatizo hili. Japo sehemu nyingi zitahitaji maboresho ili kuvipunguza magonjwa na vifo vya wajawazito kwa kiasi kikubwa, tasnifu hii inazingatia namna ambavyo ambavyo hospitali inavyoweza kuitatua.

Katika sehemu ya kwanza ya tasnifu hii ubora wa huduma ya wazazi inaelezwa kwa kutumia vigezo vya shirika la afya duniani (WHO) vya halaki ya hatari ya kifo aliyoipitia mama wakati wa ujuzito, uzazi na siku 42 baada ya kujifunguza (near miss) na maeneo ya kuboreshwa yameainishwa (aya ya 2-3). Katika sehemu ya pili ya tasnifu hii mafunzo mfanano (simulation) ya gharama na teknolojia rahisi katika hospitali inavyoweza kuitatua magonjwa na vifo vya akina mama wajawazito kwa kutumia vigezo vya shirika la afya duniani (WHO) vya kupima hali ya hatari ya kifo aliyoipitia mama wakati wa ujuzito, uzazi na siku 42 baada ya kujifunguza (near miss) kupima ukubwa wa magonjwa na vifo vya akina mama wajawazito katika hospitali ya Kiluteri ya Haydom nchini Tanzania. Katika kipindi cha mwezi wa kumi na moja 2009 na mwezi wa kumi na moja 2011 utafiti ulifanyika. Ulionesha uwiano wa vifo vya wajawazito ili kuwa vifo 350 kwa kila vizazi 100,000 hai kulingana na taarifa ya hospitali. Kiwango cha kuugua sana kwa wajawazito ilikuwa wa hospitali 23.6 kwa kila vizazi 1,000 waliazoa hai. Kwa kila kilo cho mzazi kulikuwa na karibu na kina mama saba wenye matatizo makubwa ya ugonjwa. Matatizo makubwa matatu ya nayosababisha akina mama kuuga na kufa ni utokwaji mwingi wa damu baada ya kujifunguza, matatizo yanayohusiana na utokwaji wa mimba, na uchungu pingamizi (mtoto kushindwa kupita kwenye njia yauzazi). Fursa ya namna ya kuboresha huduma imeelezwa na inajumuisha kuongeza matumizi, kuzuu a kwa wakati na kusaidia kimatibabu utokwaji mwingi wa damu, kifafa cha mimba na maambukizi baada ya kujifunguza.
Aya ya 3 inataarifu juu ya matumizi hafifu vya vigezo vyenyewe hatari vya vifo aliyoivuka mama wakati wa ujauzito, uzazi na siku 42 baada ya kujifungua vya shirika la afya duniani (WHO near miss criteria) katika mazingira yenye rasilimali kidogo. Vigezo hivi vimeetengenezwa ili kuwa na sare ya namna ya kutambua magonjwa makali ya wajawazito. Vinakuwepo kama sehemu ya vigezo vya kitabibu, vigezo kulingana na maabara, na vigezo kulingana na matibabu. Katika Hospitali ya Haydom vigezo vyote vya kitabibu viliweza ku tumika, lakini asilimia 25 tu ya vigezo kutokana na maabara na asilimia 50 ya vigezo kulingana na matibabu yalitumika. Kwa sababu hiyo basi, magonjwa makali ya wajawazito katika mazingira hivi vinakukaa sehemu ya viegezo vya kitabibu, viegezo kulingana na maabara, na viegezo kulingana na matibabu iliyovuka mama wakati wa ujauzito, uzazi na siku 42 baada a ya kujifungua vya shirika la a fya duniani (WHO near miss criteria) katika mazingira yenye rasilimali kidogo. Viegezo hivi vimetengenezwa ili kuwa na sare ya namna ya kutambua magonjwa makali ya wajawazito. Vinakuwepo kama sehemu ya vigezo vya kitabibu, vigezo kulingana na maabara, na vigezo kulingana na matibabu. Katika Hospitali ya Haydom vigezo vyote vya kitabibu viliweza ku tumika, lakini asilimia 25 tu ya vigezo kutokana na maabara na asilimia 50 ya vigezo kulingana na matibabu yalitumika. Kwa sababu hiyo basi, magonjwa makali ya wajawazito katika mazingira hivi vinakukaa sehemu ya viegezo vya kitabibu, viegezo kulingana na maabara, na viegezo kulingana na matibabu iliyovuka mama wakati wa ujauzito, uzazi na siku 42 baada a ya kujifungua (near miss).


Uhifadhi wa maarifa, ujuzi, na kujiamini kulipimwa tena miezi tisa baada ya mafunzo ya awali. Aya ya 5 inaonesha kuwa baada ya miezi tisa maarifa yalipungua kama ilivyokuwa kabla ya mafunzo, na ujuzi na kujiamini kwa kiasi kikubwa kulibaki. Kulingana na matokeo hapa juu tunashauri mafunzo yawe yanafanyika angalau mara mbili kwa mwaka.

Katika aya ya 6 programu ya mafunzo ilitahminiwa katika hatua ya 3 na ya 4 ya Kirkpatrick kwa kutumia utafiti wa kufanya mafunzo. Kuwa mwezi wa tano 2011 mpaka mwezi wa sita.
2013 mtafari msaidizi alifuatilia vizazi vyote katika hospitali ya Haydom. Matukio ya utokwaji mwingi wa damu (ml 500-1,000) ulionekana kupungua kwa kiasi kikubwa kutoka 2.1% kabla ya mafunzo mpaka 1.3% baada ya mafunzo na uwezo wa utendaji wa kitabibu wa ujuzi wa msingi wa uzalishaji na matibabu ya utokwaji mwingi wa damu baada ya kujifungua uliboreka baada ya kuanzisha programu ya mafunzo.

Kwa kuhitimisha, tumeonesha maeneo mengi yakubeshwa ambayo yanaweza kunufaisha ubora wa huduma ya uzazi katika Hospitali ya Kiluteri ya Haydom. Maeneo haya yanapawa kuunganishwa na kufanya eneo mmoja la kutoa mfumo wa huduma wa pamoja. Mfumo wa WHO wa viegezo vya halita ya hatari ya kifo aliyoivuka mama wakati wa uja uzito, uzazi na siku 42 baada ya kujifungua (near miss) ulikuwa vigumu kuutumia katika mazingira haya yenye rasilimali chache. Mafunzo ya programu ya uzazi wa “Kuwasaidia Wamama Wazazi Kuishi – Utokwaji wa Damu Baada ya kujifungua” wa kutumia mfanano unaweza kutatua tatizo la mafunzo ya kiidarayaliyooneshwa. Tathmini ya programu hii ya mafunzo kwa hatua zote nne za moduli za Kirkpatrick umeonesha kuwa hii inaweza kuwa namna sahihi zaidi ya kuelimisha wafanyakazi wa huduma za afya katika mazingira yenye rasilimali ndogo.

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Maternale morbiditeit en mortaliteit in ontwikkelingslanden blijft hoog, ondanks wereldwijde initiatieven om deze te reduceren. Belangrijke factoren die hieraan bijdragen zijn: vertraging bij het nemen van de beslissing om hulp te zoeken, vertraging in het bereiken van een gezondheidsinstelling en vertraging bij het krijgen van de juiste zorg eenmaal in het ziekenhuis aangekomen. Op vele gebieden zal er verbetering moeten komen om maternale morbiditeit en mortaliteit te reduceren. Dit proefschrift richt echter op de maatregelen die ziekenhuizen in ontwikkelingslanden kunnen nemen om de kwaliteit van verloskundige zorg te verbeteren.

In het eerste deel van dit proefschrift wordt de kwaliteit van verloskundige zorg in een afgelegen ziekenhuis in Tanzania beschreven met behulp van de "WHO near miss approach" en worden verschillende gebieden aangewezen waar verbetering van zorg mogelijk is (hoofdstuk 293). In het tweede deel van dit proefschrift wordt "low cost low tech" simulatie training in de verloskunde geëvalueerd als interventie om de kwaliteit van verloskundige zorg te verbeteren (hoofdstuk 496).

In hoofdstuk 2 wordt de "WHO near miss approach" gebruikt om de prevalentie van ernstige maternale morbiditeit en mortaliteit te meten in Haydom Lutheran Hospital in Tanzania. Van November 2009 tot November 2011 werd een crosssectioneel onderzoek verricht. Daaruit bleek dat in die periode het maternale sterftecijfer in het ziekenhuis 350 gevallen van moedersterfte per 100.000 levendgeborenen was. De prevalentie van ernstige maternale morbiditeit was 23.6 per 1.000 levendgeborenen. Voor elk geval van moedersterfte waren er zeven vrouwen die bijna stierven, de zogenaamde "near misses". De drie meest voorkomende oorzaken van ernstige maternale morbiditeit en mortaliteit waren hemorrhagia postpartum, abortus gerelateerde complicaties en niet vorderende baring. Mogelijkheden om de kwaliteit van zorg te verbeteren behelsden het verhogen van interventies ten gunste van de preventie en behandeling van hemorrhagia postpartum, eclampsie en sepsis.
SAMENVATTING

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In het eerste deel van dit proefschrift wordt de kwaliteit van verloskundige zorg in een afgelegen ziekenhuis in Tanzania beschreven met behulp van de "WHO near miss approach" en worden verschillende gebieden aangewezen waar verbetering van zorg mogelijk is (hoofdstuk 2-3). In het tweede deel van dit proefschrift wordt "low-cost low-tech" simulatie training in de verloskunde geëvalueerd als interventie om de kwaliteit van verloskundige zorg te verbeteren (hoofdstuk 4-6).

In hoofdstuk 2 wordt de "WHO near miss approach" gebruikt om de prevalentie van ernstige maternale morbiditeit en mortaliteit te meten in Haydom Lutheran Hospital in Tanzania. Van November 2009 tot November 2011 werd een cross-sectioneel onderzoek verricht. Daaruit bleek dat in die periode het maternale sterftecijfer in het ziekenhuis 350 gevallen van moedersterfte per 100.000 levendgeborenen was. De prevalentie van ernstige maternale morbiditeit was 23.6 per 1.000 levendgeborenen. Voor elk geval van moedersterfte waren er zeven vrouwen die bijna stierven, de zogenaamde "near misses". De drie meest voorkomende oorzaken van ernstige maternale morbiditeit en mortaliteit waren hemorrhagia postpartum, abortus gerelateerde complicaties en niet vorderende baring. Mogelijkheden om de kwaliteit van zorg te verbeteren behelsden het verhogen van interventies ten gunste van de preventie en behandeling van hemorrhagia postpartum, eclampsie en sepsis.
Hoofdstuk 3 beschrijft de slechte toepassbaarheid van de WHO near miss criteria in een ontwikkelingsland. De criteria zijn ontwikkeld om uniform ernstige maternale morbiditeit te definiëren en bestaan uit klinische criteria, laboratorium criteria, en behandel criteria. In Haydom Lutheran Hospital waren alle klinische criteria toepasbaar. Echter, slechts 25% van de laboratorium criteria en 50% van de behandel criteria konden worden gebruikt. Het gevolg hiervan is dat ernstige maternale morbiditeit ondergerapporteerd zal worden in instellingen die niet alle criteria kunnen gebruiken. Daarnaast zal de "case fatality rate" in deze context relatief hoog zijn wanneer deze vergeleken wordt met instellingen waar wel alle criteria toepasbaar zijn.

In Maart 2012 werd de "low-cost low-tech" verloskundige simulatie training "Helping Mothers Survive Bleeding After Birth" in Haydom Lutheran Hospital geïntroduceerd. De training werd gegeven door lokale trainers en bestond uit een halve dag simulatie onderwijs in basale verloskundige zorg, actieve begeleiding van het derde stadium van de baring, en behandeling van hemorrhagia postpartum. De evaluatie van deze training aangaande Kirkpatrick level 1 en 2 wordt beschreven in hoofdstuk 4. De resultaten van de evaluatie laten zien dat "Helping Mothers Survive Bleeding After Birth" acceptabel en haalbaar is in een ziekenhuis in een ontwikkelingsland. Kennis, vaardigheden, en zelfvertrouwen van deelnemers stegen significant na de training, alhoewel het slagingspercentage na vaardigheidstesten over het algemeen laag was.

Kennis, vaardigheden, en zelfvertrouwen werden negen maanden na de initiële training nogmaals getest. Hoofdstuk 5 laat zien dat na negen maanden het niveau van kennis daalde naar het niveau van vóór de training. Vaardigheden en zelfvertrouwen daarentegen bleven grotendeels behouden. Op basis van bovenstaande resultaten raden we aan de training twee keer per jaar te herhalen.

In hoofdstuk 6 wordt de training geëvalueerd op level 3 en 4 van het Kirkpatrick model door middel van een educatieve interventie studie. Van Mei 2011 tot Juni 2013 werden alle bevallingen in Haydom Lutheran Hospital geobserveerd door onderzoeksassistenten. Deze observaties lieten zien dat de incidentie van hemorrhagia postpartum (500-1,000ml) significant daalde van 2.1% voor training naar 1.3% na training. De klinische prestaties in
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Kortom, we hebben verschillende gebieden voor verbetering in Haydom Lutheran Hospital kunnen aanwijzen die de kwaliteit van verloskundig zorg ten goede zou moeten komen. Deze gebieden moeten worden geïntegreerd in een soepel functionerend, volwassen, zorgsysteem. De near miss criteria die gebruikt waren om maternale morbiditeit en mortaliteit te meten waren moeilijk toepasbaar in een ontwikkelingsland. De simulatie training "Helping Mothers Survive Bleeding After Birth" kan worden gebruikt om het tekort aan lokale training aan te vullen. Evaluatie van deze simulatie training op alle vier niveaus van het Kirkpatrick model laat zien dat dit een effectieve manier van het bijscholen van gezondheidsmedewerkers in ontwikkelingslanden zou kunnen zijn.
WHilst working as a medical officer on a maternity ward in a rural hospital in Northern Tanzania, I noticed many differences with my previous workplace on a maternity ward in a rural hospital in the Netherlands. I was particularly struck by the number of women that died during pregnancy or just after childbirth. What I had never before experienced in the Netherlands, became an unwanted regular experience in Tanzania. It inspired me to start investigating why these women die, and what we could do to prevent them from dying.

After almost four years of research I realise that in the process of answering a few questions, many more have been raised. I have come to the conclusion that there is no magic cure to solve this problem. Luckily, the things that need to change to improve the system are not rocket science and they are within reach. I would like to thank the following people who helped me to achieve this PhD.

Jos, ik heb je leren kennen toen ik nog medisch student was en coschappen ging doen in Tanzania. Sindsdien zijn we in contact gebleven en toen ik jaren later als tropenarts in Tanzania aan het werk was, was het een logische keuze om jou te vragen mij te begeleiden met het opzetten van onderzoek in Haydom. Ik heb veel van je geleerd in de afgelopen jaren. Je kritische blik en kennis van obstetrie en gynaecologie in de context van ontwikkelingslanden zoals Tanzania is van onschatbare waarde. Je lokale betrokkenheid, niet alleen in Haydom, maar op zoveel plekken in Tanzania, is indrukwekkend en een voorbeeld voor velen.

Jelle, wij delen veel meer dan alleen onderzoek doen. Al hebben we dan nog niet samen op de racefiets gezeten, een stukje hardlopen rond Mount Haydom, of een goed gesprek bij het kampvuur was een welkome afwisseling van de ups en downs die onderzoek doen met zich meebringt. Ik heb de afgelopen jaren je vermogen tot reflectie bewonderd, niet alleen wat betreft het onderzoek, maar ook persoonlijk. Bedankt voor je begeleiding in zijn vele vormen (woensdagmiddag skype sessies, logeren bij je familie in Mûnein, jaarlijks op locatie in Haydom, en hopelijk nog een keer in Bristol).
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Work hard, play hard is mijn motto. Dat laatste zou niet mogelijk zijn geweest zonder goede vrienden. Lieve Amanda, Barbara, Floor, en Sanne jullie zijn belangrijke steunpilaren in mijn leven. Bedankt voor jullie vriendschap! Dames 2001, ook al zien we elkaar niet meer dagelijks, toch is het heerlijk om af en toe bij elkaar te zijn en verder te kletsen waar we waren gebleven. Dear Helen, Lindsay, Finn and Phoebe thank you so much for making me feel at home in Bristol.

Lieve Familie Schadenberg, jullie zijn met velen en jullie zijn allemaal verschillend en uniek. Samen zijn jullie een prachtige familie en ik vind het heerlijk om er deel van uit te mogen maken. Bedankt voor al jullie steun in goede en slechte tijden en ik hoop jullie vaak te blijven zien aan deze kant van de plas.

Lieve Noud, broertje van me. Fijn dat je het samen met Robert zo goed hebt in jullie nieuwe stekkie. Heerlijk om dit moment ook met jullie te kunnen delen.

Lieve papa en mama, bedankt voor al jullie steun, niet alleen tijdens dit project, maar ook tijdens al mijn andere avonturen. Al wilden jullie mij op mijn 18de liever niet naar de andere kant van de wereld laten gaan, toch hebben jullie vertrouwen in mij gehad om me in Barcelona te laten studeren. Daar werd een fundament gelegd voor mijn interesse in andere culturen. En het mooie is, dat jullie me overal zijn op komen zoeken. Dank voor de vrijheid die ik van jullie heb gekregen om me te kunnen ontplooien tot wie ik nu ben.

Lieve Alvin, samen hebben we al vele ups en downs doorstaan. Ik kan me geen betere “other half” verzinnen dan jij. Bij jou voel ik me thuis, waar ter wereld dat ook mag zijn. Samen zijn we één. I love you :)
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SAFE MOTHERHOOD SERIES

1. The role of oral (methyl)ergometrine in the prevention of postpartum haemorrhage. Akosua de Groot, Radboud Universiteit Nijmegen, 1995
4. Confidential enquiries into maternal deaths in Surinam. Ashok Mungra, Universiteit Leiden, 1999
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