“Incorporation of sub-Saharan Maternal Near-Miss Criteria in a District Hospital in Tanzania; basis for obstetrical audit”

O.E. van der Cammen (2551260)
Master thesis Vrije Universiteit Amsterdam
Ndala Mission Hospital
Ndala, Tanzania
November 2019 – July 2020

Supervisors
Dr. S.P. Chobo, Medical doctor, Ndala Mission Hospital, Tanzania
Dr. R. Mooij, Gynaecologist, Beatrix Hospital Gorinchem, the Netherlands.
Dr. M.H. Hulsbergen, Gynaecologist, Women’s Healthcare Center Amsterdam, MScPH, the Netherlands

Content list

Abstract

Background: After introduction of the maternal near-miss (MNM) criteria by the World Health Organization (WHO), an adapted version for low-income settings (LIC) was defined, but is never validated in a district hospital in this setting. The MNM approach offers a systematic baseline assessment of maternal care and could thus be used in audit sessions. Obstetric audit is a quality improvement process in which health care is systematically reviewed according to pre-defined criteria. In audit sessions, changes in health care are developed and eventually implemented to improve quality of care.

Objective: The first aim of this study was to identify the occurrence of MNM by both the use of the WHO and the adapted sub-Saharan Africa (SSA) MNM tool. The second aim was to implement obstetric auditing of this cases to locally improve maternal health care.

Methods: This prospective cross-sectional study was done from November 4th 2019 to July 15th 2020 in Ndala Hospital, Tanzania. All pregnant women and women within 42 days after giving birth or termination of pregnancy were included when fulfilling a criterion according to either the WHO or the SSA MNM tool.

Results: The SSA MNM criteria identified 47 near-miss cases and 7 maternal deaths and the WHO criteria identified 10 near-miss cases and 5 maternal deaths. There were 948 livebirths, consequently leading to maternal near-miss ratio (MNMR) of 11 (95% CI 4 – 16) and 50 (95% CI 34-60) per 1,000 livebirths for the WHO criteria and respectively the SSA MNM criteria. The difference in these numbers seems to be primarily attributed to addition of defined severe complications in the clinical criteria and the adapted threshold for blood transfusions. Eclampsia and severe malaria form roughly half of these complications. The obstetric audits were not performed due to absence of researchers during the Covid-19 pandemic.

Conclusions: The SSA criteria are more suitable than the WHO criteria to identify patients with potentially life-threatening conditions (PLTC) in district hospitals in low-income settings. The criteria result in a mortality-index of 13.0%, and do thus not underestimate the severity of the cases, although some non-acute cases are discussable near-misses and the poor intensive care capacity in most district-size settings possibly leads to adjustment of criterion 'severe pre-eclampsia with ICU admission'. Implementation of the SSA near-miss criteria forms a strong basis for auditing. Better monitoring and documentation of patients will improve the use of the criteria and potentially the quality of audit sessions.

List of abbreviations

ANC	Antenatal clinic
ICU	Intensive care-unit
LIC	Low-income country
MD	Maternal death
MNM	Maternal near-miss
MMR	Maternal mortality ratio: incidence maternal death per 100,000 live births
MNMR	Maternal near-miss ratio: incident maternal near-miss per 1,000 livebirths
MI	Mortality index: maternal death/ maternal near-miss.
PPH	Postpartum haemorrhage
PLTC	Potentially life-threatening conditions
SSA	sub-Saharan Africa
WHO	World Health Organization
SMO	Severe maternal outcome: maternal death + maternal near-miss.

Introduction

The World Health Organization (WHO) has developed the 'Sustainable Development Goals' with goal three - ensure healthy lives and promote well-being for all at all ages- being directly health-related. Target 3.1 of this goals is to reduce the global maternal mortality ratio (MMR) to less than 70 per 100,000 live births by 2030 [1]. About 295.000 women died during and following pregnancy and delivery in 2017 globally. Over 90% of these deaths occurred in low-resource settings and most of these cases could have been prevented. In Sub-Saharan Africa (SSA), almost two-thirds (196.000) of the deaths occurred [1]. This number remains high, despite the global reduction of MMR of nearly 40% from 2000 to 2017 [1]. Most causes of maternal death in SSA are hemorrhage (24.5%), hypertension (16.0%), sepsis (10.3%), and abortion (9.6%), analyzed from 1.310.000 cases from 2003 till 2009 [2].

Maternal mortality is nevertheless still among the worst-performing health indicators in low-resource settings, since the absolute number of cases is very low (especially within single health facilities) [3]. Therefore, studying cases of women who nearly died but survived a severe complication during pregnancy, delivery, or puerperium seems to be more reliable to assess the quality of health care due to the larger numbers. These near-miss cases show many similarities in the characteristics of maternal death and are consequently providing information about challenges concerning acute complications [3]. In addition, near-misses offer lessons about the given health care by interviews with the women who survived, and even more do they show higher acceptability than auditing fatal cases, because they are perceived less threatening and challenging [4, 5]. Because of the absence of a standard definition of maternal near-miss, the WHO has initiated the process of developing this definition with identification-criteria and has tried to reach consensus by publishing the Maternal Near-Miss criteria (MNM) (Annex 1), which can be used in research and other projects to measure the incidence of maternal morbidity and mortality. The purpose of this tool is a baseline assessment and situation analysis followed by an assessment of the quality of care, eventually leading to implementation of critical interventions [3, 6]. Most important part of the baseline assessment are the near-miss criteria. MNM 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". MNM criteria are based on the assumption that all maternal deaths and near-misses involve organ dysfunction. The criteria are hence divided in clinical, laboratory-based and management-based (Annex 1) [3]. The other proportion of the baseline assessment are women with severe maternal complications (for example severe pre-eclampsia, eclampsia, sepsis, ruptured uterus, and severe postpartum hemorrhage) or women who receive critical interventions (for example blood transfusions, laparotomy, intensive care unit) [6]. Although these patients do complete the baseline assessment, they do not necessarily fulfill the MNM criteria.

Since the introduction of the WHO MNM tool, it is used in many different income settings [7, 8]. But, especially in SSA, the applicability of the tool is widely discussed and not uniformly applied [9-12]. Local implementation has been difficult, primarily because of lack of laboratory- and management-based criteria [13]. Subsequently, a consensus-based adaption has been made to enhance the applicability for the use in low-income settings, called the sub-Saharan (SSA) MNM Tool [14]. In this tool, sophisticated parameters (PaO_2/FiO_2, Bilirubin, PH, Lactate, Use of continuous vasoactive drugs and dialysis for acute renal failure) were reviewed as not applicable, while seven other clinical parameters based on obstetric diseases (Table 1) and one management parameter (laparotomy other than caesarean section) were found to be suitable for introduction in the adapted MNM tool. The SSA MNM tool is validated in hospitals in low-income setting Ethiopia and middle-income country Namibia, but is never validated in district-size hospitals in low-income settings [15, 16]. The recent research has found the tool to be a good indicator of life-threatening conditions (while the WHO MNM criteria underestimate the number of MNM). However, the SSA MNM tool has to be

validated further, especially in district hospitals in low-income settings, as well its use in audits [15-17].

In the process of the near-miss approach, audit sessions are very useful to analyze the health care situation and to assess the quality of care [6]. The WHO has therefore used the concept of criterion-based clinical audit (CBCA) in the maternal health approach [6]. CBCA is based on criteria chiefly for the management standards of patients (for example 'oxytocin for postpartum haemorrhage'). The audit is a five-step cycle involving the establishment of criteria (related to the general health care of a specific complication), measurement of current practice (by identifying cases with this subject), feedback of findings and realization of local standards, re-evaluation plus feedback and finally implementation of changes. The process of the cycle is twofold: firstly, it gives immediate feedback on achievement of a certain level of care and simultaneously it identifies credible changes needed to the improvement of care. Challenges in audit sessions are staff resistance to being evaluated, misunderstanding audit as threatening and timewasting, and insufficient organization of sessions including lack of time, difficulty of data collection and setup of audit sessions [18, 19]. These challenges can lead to negative effects on the motivation of health workers, although the last perceptions in a large public health facility in sub-Saharan Malawi were positive [20]. Moreover, the CBCA is educational and non-punitive, leading to higher acceptability in staff members. Furthermore it is locally relevant (initiated and actioned locally), not expensive and structured in the collection of information [21]. Additionally the MNM approach of the WHO serves as an accompanying assistance to clinical audit and can hence improve the organization of audit sessions. In several countries in Africa the MNM approach including clinical audit sessions was implemented. It has shown to improve the quality of health care (physical structure, equipment, staffing, training and organization of care) and to reduce maternal mortality and morbidity (incidence of uterine rupture, PPH and maternal sepsis) in low-income countries [17, 22, 23].

Tanzania is among countries with a high maternal mortality ratio (MMR). It is on the 19th place of highest MMR worldwide with 524 maternal deaths per 100,000 live births in 2017 [1, 24-27]. According to the sixth Tanzania Demographic and Health Survey in 2015-2016, 98% of women received antenatal care (ANC), although only one in four women had the first visit in the first trimester and slightly more than half of the pregnant women made more than the recommended four ANC visits. In like manner, an approximate two-thirds of the births occur in health facility assisted by skilled providers. In brief, trends in maternal health are undoubtedly improving, but many challenges are still faced [28].

The first aim of this study was to identify the occurrence of severe maternal morbidity and mortality by both the use of the WHO and the adapted SSA MNM tool for the first time in a district hospital in a low-income setting. The second aim was to implement obstetric auditing of this cases to improve maternal outcome in Ndala Hospital, Tanzania.

Methods

Study setting

This study was conducted in Ndala Mission Hospital, a district-size, private Catholic hospital in Tabora region in Tanzania. The hospital is a representation of rural hospitals in SSA, serving a catchment area of around 200,000 people. The referral infrastructure is poor with many self-referrals (patients with preference for delivery in the hospital without having a reference). The hospital has circa 2200 births annually [29]. Major and minor theater are available, intensive care unit is lacking. Primary laboratory tests can be done. Medical services are given by one doctor and four medical officers.

Study design

This is a prospective cross-sectional study. From November 4th 2019 to July 15th 2020, all pregnant women and women within 42 days after giving birth or termination of pregnancy were included when fulfilling at least one WHO or SSA MNM criterion. All maternal deaths were included in the study. Ethical approval was requested for and obtained from the ethical board of the University of Dodoma (UDOM/DRP/134/VOL IV/41).

Patient identification

The WHO and SSA criteria and their definitions are presented in Annex 1. The proposed SSA criterion 'severe pre-eclampsia with ICU (intensive care-unit) admission' was changed to 'severe pre-eclampsia', because of the absence of an ICU. Patients were screened by the screening questions on the updated SSA MNM Inclusion-Tool as shown in Annex 9. This screening included the presence of severe complications, also defined as potentially life-threatening conditions (PLTC) (1), critical interventions (2), organ dysfunction (3), or maternal death (4). If a patient fulfilled either a WHO or a MNM criterion, she was included and additional information about the case was additionally collected. The inclusion tool developed by the WHO was adjusted for this study (Annex 9). A substantial part of the adaptions was the addition of pulmonary edema, severe abortion complications, and severe malaria (part of the SSA MNM criteria) in the section with severe complications / potentially life-threatening conditions. Age, gravidity, parity and travel distance were added also added to the inclusion tool. In the process indicators methyldopa, nifedipine and hydralazine, oral and intravenous were added, since this is the locally used medical treatment in earlier studies [29]. The missing signal functions of Emergency Obstetric and Newborn Care (EmONC) were added, because it maps the availability of emergency services in health care facilities [30].

Table 1. Potentially life-threatening conditions (PLTC) or severe maternal complications

PLTC according to the WHO MNM Approach	
Severe postpartum haemorrhage	Genital bleeding after delivery, with at least one of the following: perceived abnormal bleeding (1000 ml or more) or any bleeding with hypotension or blood transfusion.
Severe pre-eclampsia	Persistent systolic blood pressure of 160 mmHg or more or a diastolic blood pressure of 110 mmHg; proteinuria of 5 g or more in 24 hours; oliguria of <400 ml in 24 hours; and HELLP syndrome or pulmonary oedema. Excludes eclampsia.
Eclampsia	Diastolic BP ≥90 mmHg or proteinuria +3 and convulsion or coma.
Sepsis or severe systemic infection	Clinical sign of infection and 3 of the following: temp >38 °C or respiratory rate of >20/min, pulse rate >90/min, WBC >12,000 (leucocytosis) or <4,000 (leukopenia).
Uterine rupture	Complete rupture of uterus during labour and/or confirmed later by laparotomy.
Additional PLTC according to the SSA MNM tool	
Pulmonary edema	Accumulation of fluids in the air spaces and parenchyma of the lungs .
Severe abortion complications	Septic in incomplete abortion, complicated Gestational Trophoblastic Disease with anemia.

Severe malaria	Severe malaria is defined as major signs of organ dysfunction and/or high-level parasitemia or cerebral malaria.

Note that all the PLTC / severe maternal complications are inclusion criteria in the SSA MNM tool except for severe postpartum haemorrhage [14]. This is only part of the baseline assessment and not a criterion on its own.

Data collection

The medical doctor (SPC) in Ndala Hospital was particularly in charge of the inclusion. Two midwives were trained to identify eligible patients and to collect data after inclusion. Other midwives and nurses were introduced to the study and stimulated to identify possible patients during their work. In the labour- and female ward, wallcharts and manuals detailing the study and the MNM criteria were available. The participating midwives and medical doctor ensured to attend the morning meeting and the obstetric and female ward, to include new patients and follow-up on the known cases. At the same time, excluded patients were double-checked at discharge to ensure that all MNM cases were included in the study. Admission- and delivery books were controlled for missed inclusions. Data of the patients were anonymously entered in the updated inclusion tool. Until discharge, extensive data were collected by checking patient files (with medical records, operative reports, details of ward round, interventions) and by questioning the patient. The inclusion tool was double-checked by SPC and confirmed by another member of the research team (OC). Patient files were verified and clinicians were asked in case of discrepancies or discussion. Two gynaecologists with several years of working experience in Ndala Hospital (MH and RM) had a final-saying in unclear cases and supervised the data collection and quality. The total number of deliveries and livebirths was gathered from the delivery book.

Data analysis

Data were collected in Microsoft Excel. The same program was used for analysis. For age, parity and gestational age, the T-test: Two-Sample Assuming Equal Variances was used. For the vital status of the infant (dead or alive) and the delivery mode (vaginal or caesarean section), the Chi-square test was used. We calculated the 95%-confidence interval for the MNMR according to confidence intervals for population proportions. Maternal Mortality Ratio (MMR: number of maternal deaths per 100,000 livebirths), Maternal Near Miss Ratio (MNMR: number of maternal near-miss per 1,000 livebirths) and mortality index (MI: maternal deaths divided by severe maternal outcome) were calculated.

Results

In the inclusion period of almost eight months, 971 women delivered from 940 singletons and 31 twins. Among the 1002 neonates, there were 948 livebirths and 54 stillbirths. The total severe maternal outcome (maternal deaths plus maternal near-miss) is 15 and 54 according to the WHO and respectively SSA MNM tool. There were 10 MNM cases identified by the WHO criteria and 47 cases by the SSA criteria. There were seven maternal deaths which were all identified with the SSA MNM tool, while the WHO criteria identified only five of the maternal deaths. The total MNM events exceeds the total number of cases, since a substantial part of the patients fulfilled more than one criterion (for example a combination of uterine rupture and hysterectomy). There were 18 MNM events identified with the criteria of the WHO and 87 with the SSA set. In table 3, the number of maternal deaths (MD), MNM cases and MNM events and the specification of the inclusions are shown.

The majority of the patients was between 20 and 35 years old. There were 14 and 5 patients in the SSA and respectively WHO group which had a caesarean section. The caesarean section rate in the

study period was 18.9% (184 caesarean sections out of 971 deliveries). The differences in the basis characteristics were not clinically significant as shown in table 2.

Table 2. Basis characteristics

		WHO (n=15)	SSA (n=54)	
Age	Average	29,67 (SD±4.0)	27,15 (SD±2.1)	p = 0.254[a]
	<20	3 (20)	13 (24)	
	20-35	9 (60)	32 (59)	
	≥36	3 (20)	9 (17)	
Parity	Average	4.50 (SD±1.58)	3.07 (SD±0.77)	p = 0.100[a]
	0	1 (7)	12 (22)	
	1-3	3 (20)	18 (33)	
	≥4	10 (67)	23 (43)	
	Unknown	1 (7)	1 (2)	
Gestational age				p = 0.319[a]
	<28	0 (0)	4 (7)	
	28-36	1 (7)	3 (6)	
	≥37	9 (60)	30 (56)	
	Unknown	5 (33)	17 (31)	
Mode of delivery				p = 0.344[b]
	Vaginal	5 (33)	27 (50)	
	Caesarean section	5 (33)	14 (26)	
	Laparotomy for ectopic pregnancy	0 (0)	1 (2)	
	Laparotomy for uterine rupture	3 (20)	5 (9)	
	Woman still pregnant	1 (7)	5 (2)	
	Unknown	1 (7)	2 (11)	
Status infant at birth				p = 0.423[c]
	Alive	7 (47)	31 (57)	
	Dead	6 (40)	16 (30)	
	unknown	2 (13)	7 (13)	

total n = Severe maternal outcome (MD + MNM), n (percentage), SD = standard deviation

[a] P-value is calculated by non-paired two tailed T-test.

[b] P-value is calculated by Chi-square test for vaginal delivery and caesarean section.

[c] P-value is calculated by Chi-square test for alive and dead.

The maternal near-miss ratio (MNMR) for the WHO criteria was 11 (95% CI 4 – 16) per 1,000 livebirths. There were 2 MNM cases for one maternal death, consequently leading to a mortality index of 33.3%. The adapted SSA criteria gave an MNMR of 50 (95% 34-60) per 1,000 livebirths and mortality index of 13.0%, specifically 6.7 MNM per one maternal death.

Table 3 provides the details of the inclusions according to the WHO and the SSA MNM criteria sets. The difference in the number of MNM cases and events between the two sets seems to be primarily attributed to the inclusions of patients with severe complications or patients receiving blood transfusions. Eclampsia and severe malaria form roughly half of these complications. There was no patient receiving more than three blood transfusions, while 19 patients received two or three. For two maternal deaths the reported data were solely sufficient to fulfill the SSA MNM criteria and the patient data were insufficient for inclusion according to the WHO criteria. The first case died of puerperal sepsis after uterine rupture and the second case died of sepsis after complicated abortion.

Hypertensive disorders and medical diseases were the three most occurring causes of severe maternal outcome (Table 3). Severe malaria occurred in 11 of 14 cases with medical diseases (*Annex 6*). 27 of the 54 MNM cases had anemia as contributory or associated condition.

Annex 7 provides the use of critical interventions. 14 of the 54 patients were diagnosed with PPH and all were given therapeutic oxytocin. The vast majority (13 patients) received blood products. Removal of retained products and hysterectomy were both carried out twice on behalf of PPH. Hysterectomy was also performed in three other cases due to uterine rupture. All the cases with eclampsia were treated with magnesium sulphate, while two-third of the severe pre-eclampsia cases received this anticonvulsant preventively. Oral antihypertensive treatment is administered to five of six patients in the last group, however no patient received intravenous treatment. There were 14 included patients undergoing a caesarean section and approximately 80% (11 women) received prophylactic antibiotic. Parenteral therapeutic antibiotics was given to five out of six patients diagnosed with sepsis.

Table 3. Maternal Near-Miss Inclusions

	WHO (n)	**SSA (n)**
Maternal deaths	5	7
Maternal near miss cases	10	47
Maternal near miss events	18	87
Clinical criteria		
Total events according to clinical criteria	**10**	**51**
Shock	7	7
Cardiac arrest	3	3
Severe pre-eclampsia	0	6
Eclampsia	0	11
Uterine rupture	0	5
Sepsis	0	6
Severe complications of abortion	0	2
Severe malaria	0	11
Laboratory-based criteria		
Total events according to laboratory-based criteria	**0**	**0**
Management-based criteria		
Total events according to management-based criteria	**8**	**36**
Hysterectomy	5	5
Use of blood products	0	19
Cardio-pulmonary resuscitation	3	3
Laparotomy other than for cesarean section	0	9

Frequency of the events exceeds the number of cases. 26 women fulfilled one criterion and 28 women fulfilled more than one criterion.

Discussion

In this study, the applicability of the WHO and the SSA MNM tool are compared in Ndala Mission Hospital. The MNM SSA tool is validated for the third time, but this is the first study to validate the tool in a district-size hospital in a low-income setting in Tanzania. To the best of our knowledge, the SSA MNM tool included all patients with potentially life-threatening conditions. This resulted in a SSA MNMR of 49.6 per 1,000 livebirths, mortality index (i.e. case fatality ratio) of 13.0% (6.7 MNM cases per one maternal death). The primary results of our study are compared to the results of the two other studies validating the SSA MNM tool in Annex 8. The SSA MNMR in our study is in between the ratios of the prospective cohort study in a tertiary referral and regional hospital in Ethiopia (80 per 1,000) [15] and the prospective cross-sectional multi-center study in a large regional, an intermediate and two district hospitals in middle-income country Namibia (34 per 1,000) [16]. The mortality index in our study is higher compared to the other studies, which could be explained by the low institutional births (approximately only half of the deliveries in Western Tanzania) and the relatively better equipped hospitals in the compared studies [28]. Another explanation could be the high

number of MNM events (about twice as much MNM events than MNM case; a substantial part of women fulfilled more than one criterion) in this study, while in Ethiopia there were 739 events in 622 cases and in Namibia 269 events in 184 cases, possibly indicating more severe cases in this study and thereby increasing the mortality index.

Details of inclusions

The difference in inclusions between the WHO and SSA MNM sets can be attributed primarily to the inclusion of patients with severe complications or patients receiving blood transfusions. Eclampsia, postpartum haemorrhage and severe malaria form a substantial part of these complications. This corresponds with a large 61-centre study in Tanzania in which postpartum haemorrhage and anemia were most commonly reported, followed by sepsis and eclampsia [12]. Other studies in Tanzania equally conclude high incidence of these underlying causes [24, 26, 31].

First of all, severe PPH is the most occurred severe complication in Ndala Mission Hospital and is still leading cause of maternal mortality in low-income settings [32]. PPH is a potentially life-threatening condition, however it is not a criterion in the WHO nor the SSA – set [14]. All patients with this diagnosis did nevertheless fulfill another criterion. Active management of third stage of labour is the main measure to prevent PPH, these days consisting of only the administration of uterotonic [33, 34]. From the included patients, 39 delivered in the hospital from whom roughly 75% received preventive oxytocin. Intravenous oxytocin is also the first treatment for PPH, and all 14 patients with this diagnosis were treated therapeutically. However no patient received any other utero-tonic drug when bleeding did not respond to oxytocin alone, despite the local guidelines [32]. The availability and the use of misoprostol and ergometrine could prevent surgical interventions and is thus an attention point [32]. Diagnosing the cause of the complication helps to customize treatment. In eight cases, the cause was not clearly documented and only defined as obstetric haemorrhage. Due to the multiple causes leading to - and the thereby dependent extensive treatment of PPH, our current data are insufficient to analyze the health care process in detail. Better situation analysis needs to be done locally to implement possible critical interventions in audit sessions. This interventions and competency-based training could improve the quality of prevention and treatment of PPH [33]. A hospital customized protocol, focusing on both diagnosis and treatment of PPH is recommended. At any rate, active monitoring of the third stage of labour with preventive oxytocin is highly recommended for every patient.

Secondly, there were 17 inclusions according to hypertensive disorders in the SSA tool. Because of absence of an intensive care-unit locally, we adjusted the criterion ‘severe pre-eclampsia with ICU admission’ to ‘severe pre-eclampsia’ to include all possible patients with PLTC (*Table 1*), although this adjustment could have resulted in a slight overestimation of the severity of the pre-eclampsia cases. The capacity of intensive care is poor in low-income countries in Africa, with an average of 0.53 ICU beds per 100,000 people and the resources in Tanzania are even below, with only 38 ICU beds distributed over national referral hospitals and presumably none in district hospitals [35, 36]. Therefore the applicability of the criterion ‘severe pre-eclampsia with ICU admission’ seems not only discussable in Ndala, but in district hospitals in low-income settings in general. The incidence of severe pre-eclampsia and eclampsia was 1.8% in this study, while this was 2.4% in 2011 and 2012 [29]. The higher occurrence of eclampsia than severe pre-eclampsia as seen in the results of this study, is previously discussed to be due to underdiagnosis of pre-eclampsia (poor measurement of blood pressure and heterogeneous clinical picture) as well as unnoticed home deliveries until development of convulsions [29]. In Ndala Mission Hospital, an appropriate protocol for pre-eclampsia and severe hypertension is available [37]. Although oral antihypertensive treatment was administered to 75% of the patients, intravenous treatment is not used at. Additionally, the stock of intravenous hydralazine is often unreliable. The same protocol describes the induction of labour in hypertensive disorders, but unfortunately this was not measured in this study. The induction of

labour and the use of antihypertensive treatment would be points to focus on, when auditing cases diagnosed with hypertensive disorders.

In the third place, severe malaria stands out in the results. In our study, 11 patients had severe malaria of whom seven were diagnosed with anemia as well. All seven patients received blood transfusions, although four patients also had postpartum haemorrhage as an indication for the transfusion. The number of cases with severe malaria has to be interpreted with caution, since the severity of the disease is in some cases discussable. For example, two cases did not report any clinical abnormality except from the positive rapid-diagnostic test. In the second study that validated the SSA criteria in Namibia, women with solely chronic anemia receiving blood transfusions and who did not fulfill any WHO criterion, were considered not to be MNM and consequently not included [16]. Although exposure of malaria during pregnancy causes maternal anemia and thus increases risk of maternal mortality and obstetric haemorrhage, we recommend a well-considered choice of the severity of malaria in further research. Malaria regarded as severe should obviously be included, but the mild or moderate form should solely be a contributory factor. In Tanzania in 2017, 88.6% of the pregnant women were tested for malaria during first ANC visit and almost 7% of these patients were tested positive [38]. To prevent malaria, the WHO recommends a dose of intermittent preventive treatment (IPT) every month starting in the second trimester [39]. In Tanzania, the coverage of IPT is increasing and it is estimated by the WHO that more than half of the pregnant women have received three doses in 2018 [40]. In coming research about MNM, it will be interesting to determine the received ITP-treatment and it is thus recommended to add to the MNM Inclusion tool.

The final parameter which stands out, is the blood transfusion. The use of five or more units of blood as part of the WHO MNM criteria is rare in low-income countries and the absence of blood transfusion is consequently associated with maternal deaths [41]. In this study specifically, the highest number of transfused blood units was three and occurred in five out of 971 patients. This explains the lowered threshold of the SSA MNM set, even though three cases with not-acute, chronic anemia where included. Similarly to the above mentioned malaria-cases and the cases in another large study [16], the inclusion of these specific cases has to be discussed, since the situation is not acute, while anemia does account for the highest percentage of indirect causes of maternal mortality in Tanzania [42].

The included patients showed differences in basis characteristics, however not being statistically significant. Firstly, the mean parity of the WHO MNM tool is 4.5 (SD±1.58) while the mean of the SSA MNM tool is 3.1 (SD±0.77). This could be explained by the high incidence of included patients with hypertensive disorders in the SSA MNM tool, since nullipara are at greater risk for developing pre-clampsia and eclampsia [43]. Further, women with their first and second pregnancies are most affected by malaria, and there was a substantial part of inclusions fulfilling the criterion ‘severe malaria’ in the SSA MNM group [44]. Secondly, there were more caesarean sections and less vaginal deliveries in the patient group included by the WHO criteria. Regarding the higher mortality index of these criteria, this could be explained by the fact that the risk of maternal death of patients undergoing a caesarean section in SSA is roughly 10 per 1,000 [45]. Thirdly, there were more stillbirths in the WHO inclusion group. In more than half of the stillbirths in low-income countries, the cause of death is unexplained or unspecified [46]. In this study, the cause of the stillbirth is not examined, but the higher incidence could be related to the higher mortality index and possibly more severe cases in the WHO group. It is recommended in SSA to improve the access to antenatal clinics in order to decrease perinatal mortality, consequently would it be interesting to add the number of ANC visits to the inclusion tool as well as the specified cause of death [47].

Lastly, five patients were clinically diagnosed with severe complications and included, while the fulfillment of the criteria remains questionable considering the objective vital signs on the inclusion papers. Three of these cases were concluded as sepsis (Table 1), when the recorded pulse rate of

these patients was in fact normal. In like manner, the two other patients with (again) normal pulse rate fulfilled the clinical criteria 'shock', because of severe hypotension. Objective normal values of vital signs evoke the discussion that patient either did not fulfill the inclusion-criteria or that these parameters were not correctly measured or documented on point of time.

Maternal deaths

There were seven maternal deaths during the study period. Three patients died because of sepsis (one related to uterine rupture and one to abortion complications) despite being treated with antibiotics. One patient was treated with two blood transfusions and therapeutic oxytocin- but died of PPH. She was diagnosed with anaemia due to severe malaria. Two of the deaths were expected to be caused by cardiac arrest as a result of postpartum pulmonary embolism. Both patients had received unsuccessful cardiopulmonary resuscitation. The last maternal death was a 37 weeks pregnant patient admitted unconsciousness with the history of pre-labour heavy vaginal bleeding at home. She died shortly after admission in spite of receiving blood transfusion. Considering the almost absence of additional examination (laboratory and radiology, as well as autopsies), the direct causes of maternal deaths were sometimes hard to determine and therefore might not be completely reliable. Two maternal deaths were incompletely identified in the admissionbook and could only be included by the SSA criteria due to the limited data.

Strengths and limitations

The main strength of the study is the first comparison of the WHO and the SSA criteria in a district-size hospital in a low-income setting. The other strengths are the structured data collection, the strongly motivated researchers locally, the intensive assistance and the created baseline for audit-sessions. The preparation of the inclusions was extended, consisting of flow-charts and manuals, and the inclusions were consequently carried out properly. All inclusions were carefully checked in almost daily video-calls and if necessary, discussed with two gynaecologists. The research created awareness of maternal morbidity and mortality among the staff members of the hospital, especially in the labour ward. This perception as well as the results offer a baseline for the set-up for audit sessions.

The study is limited in a few points. To start with, the planned audit sessions were cancelled because of the Covid-19 pandemic. The part of the team which would prepare and perform the audit sessions, could only stay in Tanzania for a few weeks. Implementation of audit sessions was therefore judged to be impossible. Furthermore, we experienced in the preparation of sessions, that effective auditing requires extended information about patients [21]. Since documentation is often poor, we recommend a prepared file to facilitate a clear view of health care and thus improve quality of auditing. The file should be comparable with the inclusion tool (Annex 9) and could be expanded with general information (clinical symptoms, examination and local critical interventions) as well as their corresponding points in time.

In the second place and as mentioned earlier, the monitoring and recordkeeping of the vital parameters was poor sometimes. Although the data were prospectively collected during patients hospital stay, intensive monitoring stays a challenge in low-resource settings [13]. These settings lack electric, self-automatic devises and often the manpower to measure the vital signs intensively. Catching abnormalities in the clinical parameters is therefore difficult. This poor assessment of clinical criteria, especially on moments where patients develop potentially life-threatening conditions, could have led to underreporting of MNM on basis of the WHO clinical criteria. The introduction of severe complications in the SSA MNM tool (such as eclampsia) is therefore a good alternative, since the complications are often clearly diagnosed and consequently documented better. Additionally, it is less dependent on a parameter which has to be checked on a certain time.

Similarly, the available laboratory tests were very limited used for inclusions conforming to the laboratory-based criteria. There was not a single inclusion made on basis of these criteria. This as well, could led to an underestimation of inclusions according to the WHO set, while most patients with organ dysfunction did fulfill the 'severe complications' - SSA criteria.

At last, this study is a single-center study with only 971 patients analyzed and a poor follow-up. The results have to be interpreted with caution when generalized with other rural hospitals. The lack of follow-up was due to practical and logistical reasons (mainly travel distance, expenses and lack of researchers and health care givers), although the purpose was a clinical and laboratory check two weeks after discharge.

Conclusion

The identification of MNM forms a well start for the implementation of audit sessions, though more detailed documentation of cases is needed for effective auditing. The SSA criteria seem to be more suitable than the WHO criteria to identify patients with potentially life-threatening conditions in district hospitals in low-income settings. The introduction of the severe complications and the lowering of the threshold of blood transfusion are proved to be appropriate adaptations. However, the inclusion of non-acute patients (in particular patients with blood transfusion for chronic anemia and patients with a discussable severity of malaria) have to be considered carefully and adjustment of the criterion 'severe pre-eclampsia with ICU admission' has to be discussed due to poor capacity of intensive care in low-income settings. Better monitoring of vital parameters is recommended despite challenges to achieve earlier diagnosis consequently improving health care.

Acknowledgement
The authors wish to gratefully thank the hospital staff, especially doctor S.P. Chobo and midwives mr. Kasitu and mr. Ndege. Their work was indispensable in the collection of data.

References

1. World Health Organization, U., United Nations Population Fund and The World Bank, *Trends in maternal mortality 2000 to 2017* 2019, World Bank: Washington D.C.
2. Say, L., et al., *Global causes of maternal death: a WHO systematic analysis.* Lancet Glob Health, 2014. **2**(6): p. e323-33.
3. Say, L., J.P. Souza, and R.C. Pattinson, *Maternal near miss--towards a standard tool for monitoring quality of maternal health care.* Best Pract Res Clin Obstet Gynaecol, 2009. **23**(3): p. 287-96.
4. Kalhan, M., et al., *Maternal Near-Miss Audit: Lessons to Be Learnt.* Int J Appl Basic Med Res, 2017. **7**(2): p. 85-87.
5. Lazzerini, M., et al., *Facilitators and barriers to the effective implementation of the individual maternal near-miss case reviews in low/middle-income countries: a systematic review of qualitative studies.* BMJ Open, 2018. **8**(6): p. e021281.
6. World Health Organization, *Evaluating the Quality of Care for Severe Pregnancy Complications: The WHO Near-Miss Approach for Maternal Health.* 2011, World Health Organisation: Geneva, Switzerland.
7. Abdollahpour, S., H. Heidarian Miri, and T. Khadivzadeh, *The global prevalence of maternal near miss: a systematic review and meta-analysis.* Health Promot Perspect, 2019. **9**(4): p. 255-262.
8. Tura, A.K., et al., *Applicability of the WHO maternal near miss tool in sub-Saharan Africa: a systematic review.* BMC Pregnancy Childbirth, 2019. **19**(1): p. 79.
9. Goldenberg, R.L., et al., *Maternal near miss in low-resource areas.* Int J Gynaecol Obstet, 2017. **138**(3): p. 347-355.
10. Witteveen, T., et al., *Validating the WHO maternal near miss tool: comparing high- and low-resource settings.* BMC Pregnancy Childbirth, 2017. **17**(1): p. 194.
11. Oppong, S.A., et al., *Incidence, causes and correlates of maternal near-miss morbidity: a multi-centre cross-sectional study.* Bjog, 2019. **126**(6): p. 755-762.
12. Pembe, A.B., et al., *Rethinking the definition of maternal near-miss in low-income countries using data from 104 health facilities in Tanzania and Uganda.* Int J Gynaecol Obstet, 2019. **147**(3): p. 389-396.
13. van den Akker, T., et al., *The WHO maternal near miss approach: consequences at Malawian District level.* PLoS One, 2013. **8**(1): p. e54805.
14. Tura, A.K., et al., *Adaptation of the WHO maternal near miss tool for use in sub-Saharan Africa: an International Delphi study.* BMC Pregnancy Childbirth, 2017. **17**(1): p. 445.
15. Tura, A.K., et al., *Severe maternal outcomes in eastern Ethiopia: Application of the adapted maternal near miss tool.* PLoS One, 2018. **13**(11): p. e0207350.
16. Heemelaar, S., et al., *Measuring maternal near-miss in a middle-income country: assessing the use of WHO and sub-Saharan Africa maternal near-miss criteria in Namibia.* Glob Health Action, 2019. **12**(1): p. 1646036.
17. Lazzerini, M., et al., *Effectiveness of the facility-based maternal near-miss case reviews in improving maternal and newborn quality of care in low-income and middle-income countries: a systematic review.* BMJ Open, 2018. **8**(4): p. e019787.
18. Muffler, N., H. Trabelssi Mel, and V. De Brouwere, *Scaling up clinical audits of obstetric cases in Morocco.* Trop Med Int Health, 2007. **12**(10): p. 1248-57.
19. Richard, F., et al., *The difficulty of questioning clinical practice: experience of facility-based case reviews in Ouagadougou, Burkina Faso.* Bjog, 2009. **116**(1): p. 38-44.
20. Bakker, W., et al., *Health workers' perceptions of obstetric critical incident audit in Thyolo District, Malawi.* Trop Med Int Health, 2011. **16**(10): p. 1243-50.
21. Graham, W.J., *Criterion-based clinical audit in obstetrics: bridging the quality gap?* Best Pract Res Clin Obstet Gynaecol, 2009. **23**(3): p. 375-88.

22. van den Akker, T., et al., *Using audits to reduce the incidence of uterine rupture in a Malawian district hospital.* Int J Gynaecol Obstet, 2009. **107**(3): p. 289-94.
23. van den Akker, T., et al., *Reduction of severe acute maternal morbidity and maternal mortality in Thyolo District, Malawi: the impact of obstetric audit.* PLoS One, 2011. **6**(6): p. e20776.
24. Litorp, H., et al., *Maternal near-miss and death and their association with caesarean section complications: a cross-sectional study at a university hospital and a regional hospital in Tanzania.* BMC Pregnancy Childbirth, 2014. **14**: p. 244.
25. Herklots, T., et al., *Validity of WHO's near-miss approach in a high maternal mortality setting.* PLoS One, 2019. **14**(5): p. e0217135.
26. Lilungulu, A., et al., *Incidence and Predictors of Maternal and Perinatal Mortality among Women with Severe Maternal Outcomes: A Tanzanian Facility-Based Survey for Improving Maternal and Newborn Care.* Obstet Gynecol Int, 2020. **2020**: p. 5390903.
27. World Health Organization, *World health statistics 2020: monitoring health for the SDGs, sustainable development goals*. 2020, World Health Organisation: Geneva, Switzerland. p. 29.
28. Ministry of Health, C.D., Gender, Elderly and Children (MoHCDGEC), [Tanzania, M.o.H.M.Z. Mainland, National Bureau of Statistics (NBS), Office of the Chief, and G.S.O.a. ICF, *2015-16 TDHS-MIS Key Findings*. 2016, MoHCDGEC, MoH, NBS, OCGS, and ICF: Rockville, Maryland, USA. p. 8.
29. Mooij, R., et al., *Characteristics and outcomes of patients with eclampsia and severe pre-eclampsia in a rural hospital in Western Tanzania: a retrospective medical record study.* BMC Pregnancy Childbirth, 2015. **15**: p. 213.
30. Bailey, P., Lobis, S., Maine, D., & Fortney, J. A., *Monitoring emergency obstetric care: A handbook. Geneva, Switzerland: World Health Organization.* 2009, Geneva, Switzerland: World Health Organization.
31. Nelissen, E.J., et al., *Maternal near miss and mortality in a rural referral hospital in northern Tanzania: a cross-sectional study.* BMC Pregnancy Childbirth, 2013. **13**: p. 141.
32. World Health Organization, *WHO recommendations for the prevention and treatment of postpartum haemorrhage*. 2012, World Health Organization: Geneva.
33. Bishanga, D.R., et al., *Improvement in the active management of the third stage of labor for the prevention of postpartum hemorrhage in Tanzania: a cross-sectional study.* BMC Pregnancy Childbirth, 2018. **18**(1): p. 223.
34. World Health Organization, *WHO Recommendations: intrapartum care for a positive childbirth experience*. 2018, World Health Organization: Geneva. p. 159-163.
35. Craig, J., E. Kalanxhi, and S. Hauck, *National estimates of critical care capacity in 54 African countries.* medRxiv, 2020: p. 2020.05.13.20100727.
36. Baker, T., et al., *Emergency and critical care services in Tanzania: a survey of ten hospitals.* BMC Health Serv Res, 2013. **13**: p. 140.
37. Odigboegwu, O., L.J. Pan, and P. Chatterjee, *Use of Antihypertensive Drugs During Preeclampsia.* Front Cardiovasc Med, 2018. **5**: p. 50.
38. Kitojo, C., et al., *Estimating malaria burden among pregnant women using data from antenatal care centres in Tanzania: a population-based study.* Lancet Glob Health, 2019. **7**(12): p. e1695-e1705.
39. World Health Organization, *WHO policy brief for the implementation of intermittent preventive treatment of malaria in pregnancy using sulfadoxine-pyrimethamine (IPTp-SP)*. 2013, World Health Organization: Geneva. p. 13.
40. World Health Organization, *World Malaria Report 2019*. 2019, World Health Organization Geneva. p. 14.
41. Bates, I., et al., *Maternal mortality in sub-Saharan Africa: the contribution of ineffective blood transfusion services.* Bjog, 2008. **115**(11): p. 1331-9.
42. Bwana, V.M., et al., *Patterns and causes of hospital maternal mortality in Tanzania: A 10-year retrospective analysis.* PLoS One, 2019. **14**(4): p. e0214807.

43. National Institute for Health and Care Excellence, *Hypertension in pregnancy: diagnosis and management (NICE Guideline 133)*. 2020, National Institute for Health and Care Excellence London. p. 7.
44. Desai, M., et al., *Epidemiology and burden of malaria in pregnancy.* Lancet Infect Dis, 2007. **7**(2): p. 93-104.
45. Sobhy, S., et al., *Maternal and perinatal mortality and complications associated with caesarean section in low-income and middle-income countries: a systematic review and meta-analysis.* Lancet, 2019. **393**(10184): p. 1973-1982.
46. Reinebrant, H.E., et al., *Making stillbirths visible: a systematic review of globally reported causes of stillbirth.* Bjog, 2018. **125**(2): p. 212-224.
47. Akombi, B.J. and A.M. Renzaho, *Perinatal Mortality in Sub-Saharan Africa: A Meta-Analysis of Demographic and Health Surveys.* Ann Glob Health, 2019. **85**(1).

Appendix

Annex 1. Inclusion criteria for Maternal Near-Miss

WHO Maternal Near-Miss criteria	Sub-Saharan Africa Near-Miss criteria
Clinical criteria	
Acute cyanosis	Acute cyanosis
Gasping[a]	Gasping[a]
Respiratory rate >40 or <6/min	Respiratory rate >40 or <6/min
Shock[b]	Shock[b]
Oliguria non responsive to fluids or diuretics[c]	Oliguria non responsive to fluids or diuretics[c]
Clotting failure[d]	Clotting failure[d]
Loss of consciousness lasting ≥12 hours[e]	Loss of consciousness lasting ≥12 hours[e]
Loss of consciousness AND absence of pulse/heart beat	Loss of consciousness AND absence of pulse/heart beat
Stroke[f]	Stroke[f]
Uncontrollable fit/total pralysis[g]	Uncontrollabel fit/total pralysis[g]
Jaundice in the presence of pre-eclampsia[h]	Jaundice in the presence of pre-eclampsia[h]
	Eclampsia[j]
	Uterine rupture[k]
	Sepsis or severe systemic infection[l]
	Pulmonary edema[m]
	Severe abortion complications[n]
	Severe malaria[o], severe pre-eclampsia with ICU admission.
Laboratory based criteria	
Oxygen saturation <90% for ≥60 minute	Oxygen saturation <90% for ≥60 minute
PaO2/FiO2 <200 mmHg	
Creatinine ≥300 mmol/l or ≥3,5 mg/dl	Creatinine ≥300 mmol/l or ≥3,5 mg/dl
Bilirubin>100 mmol/l or > 6,0 mg/dL	
pH <7.1	
Lactate >5	
Acute thrombocytopenia (<50 000 platelets)	Acute thrombocytopenia (<50 000 platelets)
Loss of consciousness AND the presence of ketoacids in urine	Loss of consciousness AND the presence of ketoacids in urine
Management based criteria	
Use of continuous vasoactive drugs[i]	
Hysterectomy following infection or haemorrhage	Hysterectomy following infection or haemorrhage
Transfusion of ≥5 units red cell transfusion	Transfusion of ≥2 units red cell transfusion
Intubation and ventilation for ≥60 minutes not related to anaesthesia	Intubation and ventilation for ≥60 minutes not related to anaesthesia
Dialysis for acute renal failure	
Cardio-pulmonary resuscitation (CPR)	Cardio-pulmonary resuscitation (CPR)
	Laparotomy other than caesarean section.

a Gasping is a terminal respiratory pattern and the breath is convulsively and audibly caught.
b Shock is a persistent severe hypotension, defined as a systolic blood pressure <90 mmHg for ≥60 minutes with a pulse rate at least 120 despite aggressive fluid replacement (>2l).
c Oliguria is defined as an urinary output <30 ml/hr for 4 hours or <400 ml/24 hr.
d Clotting failure can be assessed by the bedside clotting test or absence of clotting from the IV site after 7–10 minutes.
e Loss of consciousness is a profound alteration of mental state that involves complete or near-complete lack of responsiveness to external stimuli. It is defined as a Coma Glasgow Scale <10 (moderate or severe coma). Details on the scale on the Fig. 3.

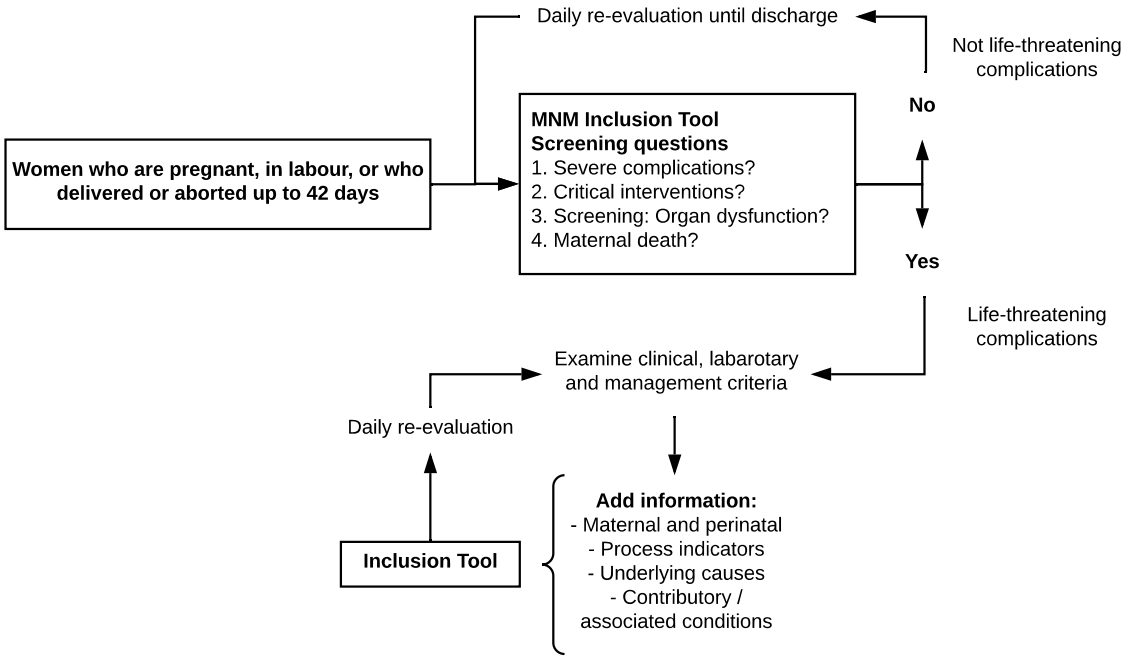
f Stroke is a neurological deficit of cerebrovascular cause that persists beyond 24 hours or is interrupted by death within 24 hours.
g Condition in which the brain is in a state of continuous seizure.
h Pre-eclampsia is defined as the presence of hypertension associated with proteinuria. Hypertension is defined as a blood pressure of at least 140 mmHg (systolic) or at least 90 mmHg (diastolic) on at least two occasions and at least 4–6 h apart after the 20th week of gestation in women known to be normotensive beforehand. Proteinuria is defined as excretion of 300 mg or more of protein every 24 h. If 24-h urine samples are not available, proteinuria is defined as a protein concentration of 300 mg/l or more (≥1þon dipstick) in at least two random urine samples taken at least 4–6 h apart.
i For instance, continuous use of any dose of dopamine, epinephrine or norepinephrine.
j Eclampsia is diastolic BP ≥90 mmHg or proteinuria +3 and convulsion or coma
k Uterine rupture is complete rupture of uterus during labour and/or confirmed later by laparotomy
l Sepsis or severe systemic infection is defined as a clinical sign of infection and 3 of the following: temp >38 0C or 20/min, pulse rate >90/min, WBC >12,000 m Pulmonary edema is accumulation of fluids in the air spaces and parenchyma of the lungs
n Severe abortion complications is defined as septic in incomplete abortion, complicated Gestational Trophoblastic Disease with anemia
o Severe malaria is defined as major signs of organ dysfunction and/or high-level parasitemia or cerebral malaria

Annex 2. Potentially life-threatening conditions or severe maternal complications

Severe postpartum haemorrhage	Genital bleeding after delivery, with at least one of the following: perceived abnormal bleeding (1000 ml or more) or any bleeding with hypotension or blood transfusion.
Severe pre-eclampsia	Persistent systolic blood pressure of 160 mmHg or more or a diastolic blood pressure of 110 mmHg; proteinuria of 5 g or more in 24 hours; oliguria of <400 ml in 24 hours; and HELLP syndrome or pulmonary oedema. Excludes eclampsia.
Eclampsia	Diastolic BP ≥90 mmHg or proteinuria +3 and convulsion or coma.
Sepsis or severe systemic infection	Clinical sign of infection and 3 of the following: temp >38 °C or respiratory rate of >20/min, pulse rate >90/min, WBC >12,000 (leucocytosis) or <4,000 (leukopenia).
Uterine rupture	Complete rupture of uterus during labour and/or confirmed later by laparotomy.
Pulmonary edema	Accumulation of fluids in the air spaces and parenchyma of the lungs .
Severe abortion complications	Septic in incomplete abortion, complicated Gestational Trophoblastic Disease with anemia.
Severe malaria	Severe malaria is defined as major signs of organ dysfunction and/or high-level parasitemia or cerebral malaria.

Note that severe postpartum haemorrhage is a PLTC, but is not a criterion in the SSA-set.

Annex 3. Wallchart for the inclusions of MNM



Annex 4 . Maternal near-miss indicators

	WHO	SSA
Livebirths	971	971
Maternal deaths (n)	5	7
Maternal near-miss (n)	10	47
Severe maternal outcome (n)	15	54
MMR (per 100,000 livebirths)*	738	738
MNMR (per 1,000 livebirths)	11 (4 – 16)	50 (34 – 60)
MNM-mortality ratio	2.0	6.7
Mortality index	33.3%	13.0%

SMO (Severe Maternal Outcome: MD + MNM), MMR (Maternal Mortality Ratio: incidence maternal death per 100,000 live births), MNMR (Maternal Near-Miss ratio: incident maternal near-miss per 1,000 livebirths), (MNM-mortality ratio: MNM : 1 MD), (Mortality Index: MD/MD+MNM) *MMR is calculated for 7 maternal deaths.

Annex 5. Severe maternal complication

Total severe maternal complications	**(n=55)**
Severe postpartum haemorrhage	14 (25.5%)
Severe pre-eclampsia	6 (10.9%)
Eclampsia	11 (20.0%)
Sepsis or severe systemic infection	6 (10.9%)
Ruptured uterus	5 (9.1%)
Pulmonary oedema	0 (0.0%)
Severe abortion complications	2 (3.6%)
Severe malaria	11 (20.0%)

Some patients had multiple severe complications while other patients had none. Overall number is total number of complications regardless of number of patients..

Annex 6. Underlying causes of SMO.

Total cases	**54**
Total causes	**63**
Pregnancy with abortive outcome	**2 (3.2%)**
Abortion	*1*
Ectopic pregnancy	*1*
Obstetric haemorrhage	**18 (28.6%)**
Uterine rupture	5
Placenta praevia	2
Abruptio placentae	1
Retained placentae	2
Other postpartum haemorrhage	8
Hypertensive disorders	**17 (27.0%)**
Severe pre-eclampsia	6
Eclampsia	11
Pregnancy-related infection	**7 (11.1%)**
Peritonitis	*1*
Chorioamnionitis	*1*
Wound-sepsis	*1*
Abortion-related sepsis	*1*
Sepsis eci	*2*
Other obstetric disease or complication	**2 (3.2%)**
Pulmonary embolism	2
Medical/Surgical/Mental disease or complication	**14 (22.2%)**
Severe malaria	11
Chronic anemia	2
Cardiac arrest	1
Unanticipated complications of management	**1 (1.6%)**
Wound-infection after C/S	1
Coincidental conditions	**1 (1.6%)**
Motorcycle accident	1
Unknown	**1 (1.6%)**

*One case could have one or two direct causes

Annex 7. Process and outcome indicators with specific conditions

Indicator	
Prevention of postpartum haemorrhage	
Women giving birth in health-care facilities (SMO cases)	39
Oxytocin use.	29
Treatment of severe postpartum haemorrhage	
Women with severe PPH	14
Oxytocin	14
Removal of retained products	2
Hysterectomy	2
Blood transfusion	13
Anticonvulsants for eclampsia	
Women with eclampsia	11
Magnesium sulfate	11
Prevention of caesarean section related infection	
Women undergoing caesarean section	14
Prophylactic antibiotic during caesarean section	11
Treatment for sepsis	
Women with sepsis	6
Parenteral therapeutic antibiotics	5
Ruptured uterus	
Women with ruptured uterus	5
Laparotomy	5

Annex 8. SSA MNM tool in other studies

	Ndala, Tanzania	**Ethiopia** [15]	**Namibia** [16]
Setting	*Low-income* District hospital	*Low-income* University (1) and regional hospital (2)	*Middle-income* National referral (1), large regional (2) and two smaller district hospitals (3,4)
Livebirths	971	7404	5772
Maternal deaths (n)	7	28	9
Maternal near-miss (n)	47	594	194
Severe maternal outcome (n)	54	622	203
MMR (per 100,000 livebirths)*	738	378	156
MNMR (per 1,000 livebirths)	50 (34 – 60)	80.2	34 (29-38)
MNM-mortality ratio	6.7	21.2	21.6
Mortality index	13.0%	4.5%	4.4%

SMO (Severe Maternal Outcome: MD + MNM), MMR (Maternal Mortality Ratio: incidence maternal death per 100,000 live births), MNMR (Maternal Near-Miss ratio: incident maternal near-miss per 1,000 livebirths), (MNM-mortality ratio: MNM : 1 MD), (Mortality Index: MD/MD+MNM) *MMR is calculated for 7 maternal deaths.

Annex 9. Maternal near-miss inclusion tool

MATERNAL NEAR-MISS INCLUSON TOOL | **Ndala Hospital Tanzania**

IDENTIFICATION

Identification code: ☐☐☐☐ I ANC Number: ☐☐☐☐☐☐☐☐☐ (or no antenatal screening ☐) I Ndala Hospital Number: ☐☐☐☐☐☐☐☐☐

Researcher: …… Date ☐☐-☐☐-☐☐

SCREENING QUESTIONS

In the questions 1 to 4, please specify

0= the condition was not present during hospital
1= the condition was present at arrival or <12 hours of hospital arrival
2= the condition developed >12 hours of hospital arrival
3= information not available/unknown or not applicable

1. **Severe complications / potentially life-threatening conditions**.

☐ A0 Severe postpartum haemorrhage
☐ A1 Severe preeclampsia
☐ A2 Eclampsia
☐ A3 Sepsis or severe systemic infection
☐ A4 Ruptured uterus
☐ A5 Pulmonary oedema
☐ A6 Severe abortion complications
☐ A7 Severe malaria

2. **Critical interventions or intensive care unit admission**

☐ B0 Use of blood products (any blood transfusion); please specify amount of units…….
☐ B1 Interventional radiology (uterine artery embolization)
☐ B2 Laparotomy (excludes caesarean section, includes hysterectomy)
☐ B3 Admission to Intensive Care Unit

3. **Organ dysfunction / life-threatening conditions**

Please see 'Flowchart for inclusion' for abnormalities in examination.

☐ **Physical examination**: respiratory rate, saturation, blood pressure, pulse rate, urine, GCS-score, temperature, ketoacids and proteins in urine and general impression of patient.
☐ **Management examination**: use of continuous vasoactive drugs, intubation and ventilation or cardio-pulmonary resuscitation.

4. **Maternal deaths**

☐ D0 Death during pregnancy or within 42 days of termination of pregnancy
☐ D1 Death after 42 days of termination of pregnancy

Please note:

- If you answered If you answered "1" or "2" to any of the questions 1 to 4, please fill in other questions.
- If you answered "0" to all of the questions 1 to 4, the woman is not eligible for this assessment. Do not answer the questions 5 to 14.
- In case of doubt on questions 1 to 4, consult the attending physician.
- In the questions 5 to 14, if information is not available, unknown or L8 Unknown not applicable, fill with "9"(s).

Maternal Near Miss

At developing SMO (time after arrival ☐☐:☐☐)

☐ C0 **Cardiovascular dysfunction**		☐ C3 **Coagulation/hematologic dysfunction**	
00 Blood pressure	☐☐☐/☐☐☐ mmHg	30 Transfusion of blood or red cells	☐☐ units
01 Pulse rate	☐☐☐ /minute	31 Thrombocytes	☐☐☐ X10^3 platelets
02 Use of continuous vasoactive drugs	Yes / No	32 Failure to form clots	Yes / No
03 Cardiac arrest	Yes / No	☐ C4 **Hepatic dysfunction**	
04 Cardio-pulmonary resuscitation	Yes / No	40 Jaundice in presence of pre-eclampsia	Yes / No
05 Lactate	☐☐ mmol/L or ☐☐ mg/dL	41 Bilirubin	☐☐☐ mmol/l or mg/dl
06 pH	☐, ☐	☐ C5 **Neurologic dysfunction**	
☐ C1 **Respiratory dysfunction**		50 Unconsciousness / coma	☐☐ hours
10 Cyanosis	Yes / No	51 Prolonged unconsciousness / coma (lasting >12 hours	Yes / No
11 Gasping	Yes / No	52 Stroke	Yes / No
12 Respiratory rate	☐☐ /min	53 Status epilepticus / uncontrollable fits or global paralysis	Yes / No
13 Saturation	☐☐☐% SaO2	54 Loss of consciousness AND absence of pulse/heartbeat	Yes / No
14 PaO2/FiO2	☐☐☐ mmHg	55 Loss of consciousness AND the presence of ketoacids in urine	Yes / No
15 Intubation and ventilation not related to anaesthesia	Yes / No	☐ C6 **Uterine dysfunction**	
☐ C2 **Renal dysfunction**		60 Infection leading to hysterectomy	Yes / No
20 Oliguria non responsive to fluids or diuretics	Yes / No	61 Haemorrhage leading to hysterectomy	Yes / No
21 Dialysis for acute renal failure	Yes / No		
22 Creatinine	☐☐☐ mmol/l or mg/dl		

MATERNAL AND PERINATAL INFORMATION

5. Date of hospital admission
E0 ☐☐-☐☐-☐☐

6. Date of delivery or uterine evacuation
E1 ☐☐-☐☐-☐☐

7. Date of hospital discharge or death
E2 ☐☐-☐☐-☐☐

8. Age
E3 ☐☐

9. Gravidity - Parity
E4 ☐☐ - ☐☐

10. Travel distance to hospital
E5 ☐☐☐ km - ☐☐☐ hours

11. Foetal presentation
E6 ☐
1= Cephalic
2= Breech
3= Transverse
4= Ectopic
5= Other

12. Final mode of delivery / end of pregnancy
E7 ☐
1= Vaginal delivery
2= Caesarean section
3= Complete abortion
4= Curettage / vacuum aspiration
5= Medical methods for uterine evacuation
6= Laparotomy for ectopic pregnancy
7= Laparotomy for ruptured uterus
8= Women discharged or died still pregnant
9= Unknown

13. Best estimate of gestation age in completed weeks (obstetric/neonatal) at:
E8 Delivery or abortion (not applicable if Q8="8") ☐☐
E9 Maternal death or hospital discharge (applicable if Q8="8") ☐☐

14. Regarding the vital status of the infant, please specify (0=alive, 1= dead)
E10 At birth ☐
E11 At hospital discharge or on the 7th day of life if still in the hospital ☐

PROCESS INDICATORS

15. About conditions at arrival in the facility and the referral process, specify (0=No, 1=Yes)
☐ F0 Delivery or abortion occurred before arrival at any health facility
☐ F1 Delivery after ☐☐:☐☐ (hours) arrival in hospital
☐ F2 Laparotomy after ☐☐:☐☐ (hours) arrival hospital
☐ F3 Woman referred from other health facility
☐ F4 Woman referred to any higher complexity hospital

16. About the use of interventions, please specify whether the woman received any of the following (0=No, 1=Yes)

Prevention of postpartum haemorrhage
☐ G0 Oxytocin

Treatment of postpartum haemorrhage
☐ H0 Oxytocin
☐ H1 Ergometrine
☐ H2 Misoprostol
☐ H3 Other uterotonics
☐ H4 Tranexamic acid
☐ H5 Removal of retained products
☐ H6 Balloon or condom tamponade
☐ H7 Artery ligation (uterine/hypogastric)
☐ H8 Hysterectomy
☐ H9 Abdominal packing
☐ H10 Blood transfusion; please specify amount of units: …..

Treatment of (pre-)eclampsia
☐ IO IV Hydralazine
☐ I1 Oral Methyldopa
☐ I2 Oral Nifedipine
☐ I3 Oral Hydralazine

Anticonvulsant
☐ J0 Magnesium sulphate
☐ J1 Other anticonvulsant

Antibiotics
☐ K0 Prophylactic antibiotic during caesarean section
☐ K1 Parenteral, therapeutic antibiotics

Fetal lung maturation
☐ L0 Corticosteroids (betamethasone or dexamethasone)

[Other Comprehensive Emergency Obstetric and Newborn Care (EmONC)]
☐ M0 Newborn resuscitation with bag and mask
☐ M1 Assisted vaginal delivery (e.g., vacuum extraction)
☐ M2 Manual vacuum aspiration of retained products of conception
☐ M3 Manual removal of placenta
☐ M4 Surgical intervention, including anesthesia (e.g., Caesarean section)

UNDERLYING CAUSES OF DEATH/NEAR MISS

17. Please specify (0=No, 1=Yes)
☐ N0 Pregnancy with abortive outcome (abortion/ectopic pregnancy)
☐ N1 Obstetric haemorrhage
☐ N2 Hypertensive disorder
☐ N3 Pregnancy-related infection
☐ N4 Other obstetric disease or complication
☐ N5 Medical/surgical/mental disease or complication
☐ N6 Unanticipated complications of management
☐ N7 Coincidental conditions
☐ N8 Unkown

CONTRIBUTORY / ASSOCIATED CONDITIONS

18. Please specify: (0= No, 1= Yes)
☐ O0 Anemia
☐ O1 HIV Infection
☐ O2 Previous caesarean section
☐ O3 Prolonged/obstructed labour
☐ O4 Other (please specify) ……..