

Research Articles

Applicability and comparison of the sub-Saharan Africa and original WHO maternal near-miss criteria in a rural hospital in Western Tanzania

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Background

After the introduction of the maternal near-miss (MNM) criteria by the World Health Organization (WHO), an adapted version for low-income countries was defined but has never been validated in a rural hospital in this setting. 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 and to compare the applicability of both versions.

Methods

This cross-sectional study was done between November 2019 and July 2020 in Ndala Hospital, Tanzania. All pregnant women and women within 42 days after giving birth or termination of pregnancy were included when fulfilling at least one criterion according to either the WHO or the SSA MNM tool.

Results

The SSA MNM criteria identified 47 near-miss cases and all seven maternal deaths. The WHO criteria identified ten near-miss cases and five maternal deaths. There were 948 livebirths, consequently leading to maternal near-miss ratio (MNMR) of 50 (95% CI 34-60) and 11 (95% CI 4 – 16) per 1,000 livebirths for the SSA criteria and respectively the WHO MNM criteria. The difference in these numbers seems to be primarily attributed to the 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.

Conclusions

SSA MNM criteria are more suitable than the WHO criteria to identify patients with potentially life-threatening conditions (PLTC) in this rural hospital. The addition of clinical criteria and rejection of several unapplicable laboratory and management-based parameters in the SSA MNM tool seem appropriate adaptations for low-resource settings. However, some non-acute cases are discussable near-misses and the criterion “severe pre-eclampsia with ICU admission” seems not feasible in similar settings. Implementation of the SSA MNM 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.

Maternal mortality remains high in low-income countries, despite the global reduction of the maternal mortality ratio (MMR) of nearly 40% from 2000 to 2017. In 2017, 295.000 women died globally during and following pregnancy and delivery.¹ To improve maternal health, the World Health Organization (WHO) introduced the maternal near-miss (MNM) approach.² 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”. Near-misses show many similarities with the characteristics of maternal deaths while being higher in numbers, consequently providing information about challenges concerning acute complications.³ In addition, near-misses can offer feedback about the given health care by interviewing women who survived, and they can be incorporated into audits. Auditing of MNMs has

higher acceptability than maternal deaths and is being perceived as less threatening and challenging.^{4,5} The MNM Approach offers a baseline to assess the quality of obstetric care and includes criteria to include MNM (Table S1 in the **Online Supplementary Document**). Criteria to define MNM are divided into clinical, laboratory-based and management-based.

Since the introduction of the WHO MNM tool, it is used in different settings (low-, middle- and high-income).^{6,7} However, especially in sub-Saharan Africa (SSA), the applicability of the tool is widely discussed and not uniformly applied.^{8–11} Local implementation was difficult because of the lack of laboratory- and management-based criteria.¹² Subsequently, a consensus-based adaptation with less sophisticated parameters and with the addition of seven clinical complications based on obstetric diseases was made to enhance the applicability for the use in low-income settings, called the SSA MNM criteria.¹³ Recent research in Ethiopia and Namibia shows that the tool is a good indicator of life-threatening conditions (while the WHO set underestimated the number of MNM).^{14,15} But the SSA MNM tool needs further validation, especially in rural hospitals in low-income settings.^{14–16}

Tanzania is among countries with high maternal mortality.^{1,17–20} In 2015 and 2016, 98% of pregnant women receive antenatal care (ANC), although only one in four had the first visit in the first three months of pregnancy. Also, slightly more than half made more than four visits, while the latest recommendation of the WHO is eight visits per pregnancy.^{21,22} In rural Tanzania, roughly half of the births occur in health facilities assisted by skilled providers.²² In brief, trends in maternal health are undoubtedly improving, but many challenges are still faced.

The 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 in a rural hospital in a low-income setting which has not been studied before. The study was intended to be the baseline for the implementation of obstetric audit.

METHODS

STUDY SETTING

This study was conducted in Ndala Hospital, a rural, Faith-based hospital in Tabora region in Tanzania. This hospital has the characteristics of rural hospitals in SSA and serves a catchment area of around 200,000 people. The referral infrastructure is poor with mostly self-referrals. The hospital has circa 2200 births annually.²³ Comprehensive Emergency Obstetric and Newborn Care (CEmONC) and operative procedures are available, an intensive care unit (ICU) is lacking.²⁴ Basic laboratory tests can be done. Medical services are given by one medical doctor and four assistant medical officers.

STUDY DESIGN

This is a cross-sectional study comparing two sets of criteria. 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 obtained from the ethical board of the University of Dodoma (UDOM/DRP/134/VOL IV/41).

PATIENT IDENTIFICATION

The WHO and SSA MNM criteria and their definitions are presented in Table S1 in the Online Supplementary Document. The proposed SSA criterion “severe pre-eclampsia with ICU admission” was changed to “severe pre-eclampsia”, because of the absence of an ICU. Patients were identified by the screening questions on the updated MNM case record form.² This screening included the presence of severe complications (potentially life-threatening conditions, PLTC, see **Table 1**) (1), critical interventions (2), organ dysfunction (3), or maternal death (4). If a patient fulfilled either a WHO or an MNM criterion, she was included, and additional information about the case was collected. The adapted case record form included the addition of MNM criteria as well as age, gravidity, parity and travel distance. Also, the use of methyldopa, nifedipine and hydralazine (oral or intravenous) were added, because an earlier study identified undertreatment of hypertension as the most common form of substandard care in eclampsia patients in this hospital.²³ Lastly, the missing signal functions of Comprehensive Emergency Obstetric and Newborn Care services (CEmONC) were added because it maps the availability of emergency services in health care facilities.²⁴

DATA COLLECTION

The involved medical doctor and two trained midwives were in charge of the inclusion. Eligible patients were screened during the official morning meeting and during daily visits to the labour- and female ward. Clinicians, other midwives and nurses were introduced to the study and stimulated to identify possible inclusions by wallcharts and manuals which were provided in the wards. Excluded patients were reviewed at discharge and admission- and delivery books were controlled for patients that were missed. Data were anonymously entered in the case record form after verifying patient files and if necessary, interviewing patients. No patient consent was sought because of the observational nature of the study and the use of anonymized data. The finished forms were double-checked, and in case of discrepancies, attending clinicians were asked. Two obstetrician-gynaecologists from the Netherlands with several years of working experience in Ndala Hospital had a final say in unclear cases and supervised the data collection and quality. The total number of deliveries and livebirths was gathered from the delivery book. The aim was to follow-up the cases two weeks after discharge to update information.

DATA ANALYSIS

Data were collected and analysed using Microsoft Excel (Microsoft Inc, Seattle WA, USA). The T-test: Two-Sample Assuming Equal Variances was used for age. For the parity, gestational age, vital status of the infant and the mode of delivery, the Chi-square test was used. We calculated the

Table 1. Potentially life-threatening conditions (PLTC) or severe maternal complications according to the WHO and SSA MNM Approach

PLTC according to the WHO MNM Approach	
Severe postpartum hemorrhage	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.
Eclampsia	Diastolic BP \geq 90 mmHg or proteinuria +3 and convulsions or coma.
Sepsis or severe systemic infection	Clinical signs 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 hemorrhage.¹³ This is only part of the baseline assessment and not a criterion on its own. MNM – maternal near-miss; SSA – sub-Saharan Africa; WHO – World Health Organization.

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. The unweighted (Cohen) Kappa coefficient was used as a chance corrected standardized measure of agreement between the WHO and SSA MNM tool.

RESULTS

During the inclusion period, 971 women gave birth to 940 singletons and 31 twins. Among these 1002 neonates, 948 were born alive, and 54 were stillbirths (5.3%). The differences in the baseline characteristics were not clinically significant, as shown in [table 2](#). About 60% of the patients was between 20 and 35 years old. There were 14 patients in the WHO group and 5 in the SSA group, who had a caesarean section (CS). The CS rate in the study period was 18.9% (184/971).

The total severe maternal outcome (maternal deaths plus near-misses) was 54 and 15, according to the SSA and WHO tool, respectively. As shown in [Table 3](#), 47 MNM cases were identified by the SSA criteria and 10 cases by the WHO criteria. Seven maternal deaths were identified with the SSA tool, while the WHO tool was solely sufficient to identify five. The Cohen Kappa coefficient between the WHO and SSA MNM tool was 0.34. The total MNM events exceeds the total number of cases (87 events in 47 cases) since a sub-

stantial part of the patients fulfilled more than one criterion. There were 18 MNM events identified with the criteria of the WHO and 87 with the SSA set.

The Maternal Near-Miss Ratio (MNMR) for the WHO criteria was 11 (95% CI 4 – 16) MNM cases per 1,000 livebirths. Mortality index among the MNM was 33%, namely one maternal death compared to two MNM cases. The adapted SSA criteria gave an MNMR of 50 (95% 34-60) per 1,000 livebirths and mortality index of 13%, specifically one maternal death compared to 6.7 MNM cases.

[Table 3](#) provides the details of the cases according to the WHO and the SSA MNM criteria. The difference in the number of MNM cases and events between the two sets seemed to be primarily attributed to the inclusions of patients with severe complications or patients who received blood transfusions. Eclampsia and severe malaria formed roughly half of these complications. 27 of the 54 MNM cases suffered from anemia as a contributory or associated condition. Seven maternal deaths were identified with the SSA tool, while the WHO tool was only able to identify five. The first case which was unidentified by the WHO tool, died of puerperal sepsis after uterine rupture and the second case died of septic abortion. No patient received more than three blood transfusions, while 19 patients received two or three, from whom 13 had PPH. All patients with PPH were treated with oxytocin; two underwent a hysterectomy and two the removal of retained products. Twenty-nine of the 39 patients giving birth in the hospital received oxytocin as a prevention of PPH. Hysterectomy was also performed for all cases with uterine rupture. 75% of the patients with hypertensive disorders were administered oral antihypertensive medication, but none of them received intravenous treat-

Table 2. Sociographic and obstetric characteristics of MNM and deaths in Ndala Hospital

		WHO (n = 15)	SSA (n = 54)	
Age	Average	29,67 (SD±4.0)	27,15 (SD±2.1)	P=0.254*
	<20	3 (20)	13 (24)	
	20-35	9 (60)	32 (59)	
	≥36	3 (20)	9 (17)	
Parity				P=0.157†
	0	1 (7)	12 (22)	
	1-3	3 (20)	18 (33)	
	≥4	10 (67)	23 (43)	
	Unknown	1 (7)	1 (2)	
Gestational age				P=0.640†
	<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†
	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)	
	Undelivered	1 (7)	5 (2)	
	Unknown	1 (7)	2 (11)	
Status infant at birth				P=0.423†
	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

* P-value is calculated by non-paired two-tailed T-test.

† P-value is calculated by Chi-square test.

SSA – sub-Saharan Africa; WHO – World Health Organization.

ment. The 11 patients with eclampsia were all treated with the anticonvulsant magnesium sulphate. Five of the six septic patients received therapeutic antibiotics and 11 of the 14 patients undergoing caesarean section were administered prophylactic antibiotics.

Patients could not be followed up due to practical and logistical reasons (mainly travel distance, expenses and lack of researchers and health caregivers).

DISCUSSION

The SSA criteria were developed for sub-Saharan Africa after criticism of the applicability of the WHO MNM criteria. Approximately half of the sophisticated laboratory- and management criteria of the WHO tool were judged to be not useful in low-resource settings. These non-feasible criteria were removed, and more practical and diagnosis-based criteria were added in the adapted tool.¹³ In Ndala Hospital, the applicability of the WHO tool seems likewise discuss-

able since the laboratory-based criteria identified not a single case and only eight of the 87 MNM events were based on the original WHO management-based criteria (while those eight identified cases were also included by other SSA criteria). The SSA tool seems more appropriate than the WHO tool in this low-resource setting. To the best of our knowledge, the tool included all patients with potentially life-threatening conditions resulting in an SSA MNMR of 50 per 1,000 livebirths while the mortality index (i.e. case fatality rate) of 13.0% (6.7 MNM cases per one maternal death) does not indicate an overestimation of the included cases. This is the first study to validate the SSA tool in a rural hospital in a low-income setting although the criteria were studied before; a prospective cohort study in a tertiary referral and regional hospital in Ethiopia (MNMR 80 per 1,000)¹⁴ and a prospective multi-centre study in a large regional, an intermediate and two rural hospitals in Namibia, a middle-income country (MNMR 34 per 1,000).¹⁵ The mortality index in our study (13.0%) was higher compared to the other

Table 3. Specification of the MNM and deaths according to the WHO and SSA criteria in Ndala Hospital

	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 caesarean 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. SSA – sub-Saharan Africa; WHO – World Health Organization.

studies (approximately 4.5%), which might be explained by the low number of institutional births (about half of the deliveries in Western Tanzania) and high number of self-referrals in our study (38 of 54 patients). This suggests that most normal vaginal deliveries occur at home and patients search for health care in case of problems. Additionally, the number of MNM events (87 events in 47 cases) was higher compared to the study in Ethiopia (739 events in 622 cases) and in Namibia (269 events in 184 cases), possibly also indicating that more severe cases were included in this study and thereby increasing the mortality index.^{14,15} Lastly, most hospitals in the other studies were better equipped than Ndala Hospital, which increases the chance of better outcome.^{14,15,23}

The second aim of the study should have been the set-up of audit sessions after validating the MNM criteria. Unfortunately, this was impossible because of the Covid-19 pandemic. Audit is educational and non-punitive, which leads to higher acceptability in staff members. Furthermore, it is locally relevant, not expensive and structured in the collection of information.²⁵ Challenges in audit sessions are the resistance of staff to being evaluated, the misunderstanding that audit is threatening and timewasting, and the insufficient organization of sessions (lack of time, difficulty of data collection and setup of audit sessions).^{26,27} In several countries in Africa the MNM approach was implemented

including audits. These audits resulted in an improvement of quality of health care (physical structure, equipment, staffing, training and organization of care) and a reduction in maternal mortality and morbidity (incidence of uterine rupture, PPH and maternal sepsis) and is therefore highly recommended after performing the baseline assessment with the MNM criteria.^{16,28,29}

DETAILS OF INCLUSIONS

Eclampsia, postpartum hemorrhage and severe malaria formed a substantial part of the PLTC in this study. This corresponds with a large 61-centre study in Tanzania in which postpartum hemorrhage and anemia were most commonly reported, followed by sepsis and eclampsia.¹¹ Other studies in Tanzania reported a high incidence of the same underlying causes as well.^{17,19,30}

Severe PPH was the most frequently occurring severe complication in Ndala. In this study, the patients with PPH did fulfill a criterion in the WHO or the SSA – set. 39 of the 54 included patients gave birth in the hospital of whom roughly 75% received preventive oxytocin, which is the main measure to prevent PPH. Patients with PPH were therapeutically treated with the first-choice drug oxytocin, following the Tanzanian guidelines, but did not receive additional uterotonic drugs, despite the recommendations of

the WHO.^{31–34} The use of available misoprostol could have prevented surgical interventions when bleeding did not respond to solely oxytocin.³³ Active monitoring of the third stage of labour with preventive oxytocin as well as the use of therapeutical oxytocin and misoprostol in the treatment PPH is recommended.

Seventeen patients with hypertensive disorders were included according to the SSA MNM criteria. This study and earlier research showed that the incidence of pre-eclampsia (PE) is only half of eclampsia in Ndala, thereby possibly indicating that this minority includes the severely ill and clinical apparent patients with PE.^{23,35} In developing countries, the mortality rate of hypertensive disorders in pregnancy is high and substandard care is common unlike the care given in developed countries.^{22,23,36,37} Therefore, these patients with severe PE were judged to be MNMs and thus included in the study, although not fulfilling the original WHO nor SSA criteria because of absence of an ICU. Besides, the applicability of this criterion in further research in rural hospitals is discussable, since the ICU capacity in SSA is poor.^{38,39}

Eleven patients had severe malaria of whom seven were anemic. Although malaria and anemia in pregnancy increase the risk of maternal mortality risk, the severity of the malaria was in some cases discussable, because of poor documentation of clinical parameters.⁴⁰ In SSA, it is estimated that one-third to half of the pregnant woman are anemic and recent study in Southern-Tanzania concluded asymptomatic malaria prevalence of around one-third of the patients during first ANC visit.^{40,41} The inclusion of all pregnant women with malaria and anemia as MNMs is discussable, considering these high incidences. We recommend critical evaluation of the severity of the cases and suggest using the WHO's severity cut-off points for hemoglobin concentration.⁴²

The use of blood transfusion was another finding that stood out. The highest number of blood transfusions was three units (given in five of the 971 patients). This seems to underline the reason of the lowered threshold of the SSA MNM set, especially since the use of five or more units of blood as part of the WHO criteria is rare in low-income countries and the absence of blood transfusion is consequently associated with maternal deaths.⁴³ Although anemia does account for the highest percentage of indirect causes of maternal mortality in Tanzania, inclusion of patients with solely chronic anemia (three in this study) should be reconsidered, as is argued in the study in Namibia.^{15,44}

Basis characteristics between the two compared groups did not differ significantly. Nevertheless, three trends were observed which could mean that differences exist, although these could not be demonstrated in this small-scale study. Firstly, the mean parity of the WHO MNM group was higher than the SSA MNM group (4.50 (SD±1.58) vs 3.07 (SD±0.77) respectively, $P=0.157$). This could be explained by the high incidence of included patients with hypertensive disorders and severe malaria in the SSA MNM tool. Nulliparous women are at greater risk for developing pre-eclampsia and eclampsia, and women with their first and second pregnancies are affected most by malaria.^{45,46} Secondly, there were more stillbirths in the WHO MNM group (6/15; 40%

vs 16/54; 30%, $P=0.423$). The causes of stillbirth were not specified, like more than half of the stillbirths in low-income countries.⁴⁷ The higher maternal mortality index in the WHO MNM group might explain the higher incidence of stillbirths, because fulfilling the WHO criteria shows a higher risk for women as well as their babies. Thirdly, the assumption of more severe cases in the WHO group, might also be the explanation for the higher incidence of caesarean sections compared to vaginal births (5/15; 33% vs 14/54; 26%, $P=0.344$). The overall CS rate in this study is high (18.9%), while the WHO recommends not surpassing the 15%.⁴⁸ The rate of almost 19% in our study could be explained by the fact that half of the births in Western Tanzania are not delivered in a health facility, possibly indicating a high percentage of normal deliveries in this group whereas cases in health facilities tend to be abnormal more often with higher risk of CS.²² This corresponds with the high number of patients searching for medical help (self-referrals) among the included MNM and thus severe cases (38 of the 54 included patients). In another rural referral hospital in Tanzania, the CS rate was reported even higher in particularly low-risk patient groups with an overall rate of 35.2%.⁴⁹

The Cohen Kappa coefficient between the WHO and SSA MNM tool was 0.34 for the included MNM cases. This minimal agreement was caused by the extra cases identified by the SSA tool, as was expected. No cases were missed by the SSA tool that were identified by the original WHO tool.

MATERNAL DEATHS

Seven maternal deaths occurred during the study period. Considering the scarce additional investigations, the direct causes of maternal deaths were sometimes hard to determine and therefore not completely reliable. Two maternal deaths were incompletely identified in the admission book 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 fact that this is the first comparison of the WHO and the SSA criteria in a district-size hospital in a low-income setting. Other strengths are the structured data collection, the strongly motivated local researchers locally and the thorough assistance. The research created awareness of maternal morbidity and mortality among the staff members of the hospital. This perception, as well as the results, offer a baseline for the set-up for audit sessions.

The first limitation was the often poor monitoring and recordkeeping of the vital parameters. The data were prospectively collected, intensive monitoring was a challenge, as described in other low-resource settings.^{7–12} In this study, five patients without documented abnormal parameters were clinically diagnosed with severe complications (sepsis and shock) and were included according to SSA criteria. The introduction of complications as criteria (such as eclampsia) could be a good alternative since the diagnosis is often clear and less dependent on time-based monitoring, and consequently documented better. However, ful-

filment of criteria could remain questionable without objective parameters, and inclusions should be reviewed critically. In a similar manner, no inclusion was based on laboratory-criteria due to very limited use of laboratory tests. This and the poor documentation, could lead to an underestimation of inclusions according to the WHO set, while most patients with organ dysfunction did fulfil the “severe complications” - SSA criteria.

Secondly, this single-centre study included only 971 patients and showed poor follow-up, so the results should be interpreted with caution. A bigger sample size is needed in further research allowing more refined analysis and increasing the overall usefulness.

CONCLUSIONS

In rural hospitals, the SSA criteria are more suitable than the WHO criteria to identify patients with PLTC. The laboratory and several management criteria of the WHO tool seem not feasible for low-resource settings while the introduction of severe complications as clinical criteria and the lowering of the threshold of blood transfusion are appropriate adaptations. However, the criterion “severe pre-eclampsia with ICU admission” needs revision due to poor capacity or even the absence of intensive care. The inclusion of non-acute patients (in particular, patients with blood transfusion for chronic anemia and patients with a discussable severity of malaria) has to be considered carefully as well. The identification of MNM can be a good start for the implementation of audit sessions. Better monitoring of vital parameters and detailed documentation is needed to achieve earlier diagnoses and to effectively implement auditing.

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ETHICS APPROVAL

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AUTHORSHIP CONTRIBUTIONS

Conception and design of the study: OC, SC, RM, MH. Field work: OC, SC, JK. Data management and analysis and writing first draft: OC. Interpretation of the data and reviewing the manuscript: OC, SC, IM, RM, MH. All authors read and approved the final draft of the paper.

COMPETING INTEREST

The authors completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available upon request from the corresponding author) and declare no conflicts of interest.

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