

Similarities and differences between WHO criteria and two other approaches for maternal near miss diagnosis

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Abstract

OBJECTIVES To evaluate the similarities, differences and diagnostic aspects between World Health Organization (WHO) criteria and two other maternal near miss (MNM) diagnostic tools.

METHODS A cross-sectional study was conducted from June 2011 to May 2012 in two reference maternity hospitals in Aracaju, Brazil. Prospective case identification and data collection were performed and patients were classified as an MNM case according to WHO, Waterstone and literature-based criteria. The diagnostic properties and concordance of literature-based and Waterstone criteria were calculated using WHO criteria as standard.

RESULTS Of a total of 20 435 patients, 19 239 women did not have potentially life-threatening conditions, there were 17 maternal deaths, and 77 MNM cases based on the WHO criteria. Waterstone and literature-based criteria identified 404 and 959 MNM cases, respectively, most of them related to hypertensive disorders and haemorrhage. The sensitivity, specificity and accuracy in diagnosing MNM cases using Waterstone and literature-based criteria were above 90%, but Waterstone sensitivity was 48.1%. The similarities between the Waterstone and literature-based criteria were very weak compared to WHO criteria, with a positive percentage concordance below 9%.

CONCLUSIONS Although using WHO guidelines to detect MNM cases can be difficult when implemented in low-resource settings, the results from this study reinforce the importance of this tool in detecting the truly severe cases. Waterstone and literature-based criteria are not suitable for identifying indubitable MNM. However, they remain useful as a preliminary step to select potentially severe cases, mainly those related to hypertension and haemorrhage.

keywords maternal near miss, maternal health, maternal severe cases, severe maternal morbidity

Introduction

In 2000, WHO defined eight millennium goals to be achieved by 2015, including global maternal health improvement (5th goal). To reach this goal, two priorities were suggested: reduce maternal mortality by 75% and achieve universal access to reproductive health care [1].

In 2013, approximately 290 000 maternal deaths occurred globally. The majority of these cases occurred in low- and middle-income countries, where the maternal mortality ratio (MMR) can be 14 times greater than in high-income countries [2]. Despite significant advances, there is still a need to improve the availability and quality of analysis with regard to maternal health in order to reduce maternal mortality.

MNM cases account for most of the characteristics of maternal death (MD), they occur at least three times

more frequently, and MNM occurs immediately before MD [3]. In 2009, after years without consensus with regard to the definition and criteria for MNM, the WHO defined it in an attempt to promote and standardise the concept of the condition [4]. A patient is considered to have experienced MNM when she nearly died, but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy.

Previously, Waterstone criteria considered clinical data and obstetric syndromes that could be measured routinely. The listed criteria were as follows: severe pre-eclampsia, eclampsia, HELLP syndrome, severe sepsis and uterine rupture [5]. Reichenheim *et al.*, through a systematic review of the most commonly used literature criteria, compiled a list of 13 literature-based criteria that are easy to apply and effective in searching for MNM cases [6]. Both classifications are useful in low- and middle-income settings.

Despite the current recommendations for the use of WHO criteria [4, 7], some authors state that this is not feasible for low-resource settings where the application of laboratory-based and management-based criteria is limited [8–11]. In a previous study, we presented the prevalence of potentially life-threatening conditions and maternal near miss; in this study, we evaluated the similarities and differences between Waterstone, literature-based and WHO criteria for MNM, using the latter as the reference criteria.

Methods

A cross-sectional study was performed to identify MNM situations in women during pregnancy, childbirth or post-partum up to 42 days in two reference maternity hospitals in Sergipe State, north-east Brazil, between June 2011 and May 2012.

The two maternity hospitals are the main public reference hospitals for Sergipe State: Nossa Senhora de Lourdes Maternity and Santa Isabel Hospital. The former performs approximately 400 deliveries per month and is responsible for the high-risk deliveries. The latter is responsible for 950 deliveries per month and covers low and medium obstetric risk patients; it is the only one equipped with an obstetric intensive care unit (ICU).

Every 48 h, an obstetrician specialising in maternal morbidity performed an active search in the two hospitals to identify potentially life-threatening conditions as a starting point (Table 1) [4]. Using this information, we would then identify all significant morbidity they could have for the three classification methods (Figure 1). This comprised a medical visit with patients every 48 h in all sectors including admission, pre- and post-labouring wards, ICU, surgical theatres and delivery rooms. Extra checks were performed with regard to the medical records (in case of doubt or to confirm some MNM laboratory parameters) and in the blood bank register book. These extra checks were systemic during the study period. Each sector of the hospitals had a map of patients including the diagnostic that was updated every day, so all patients interned were monitored in case they developed a potential MNM situation.

After this, four trained medical students classified patients as a MNM case or not according to three different diagnostic approaches: WHO, Waterstone and literature-based (Table 2). Another researcher resolved disagreements. Patients who were admitted twice were included in the study only once, and cases culminating in death were excluded. All listed situations by the two other approaches are included in the potentially life-

Table 1 Potentially life-threatening conditions

Haemorrhagic disorders
Abruptio placentae
Accreta/increta/percreta placenta
Ectopic pregnancy
Post-partum haemorrhage
Ruptured uterus
Other systemic disorders
Endometritis
Pulmonary oedema
Respiratory failure
Seizures
Sepsis
Shock
Thrombocytopenia <100.000
Thyroid crisis
Hypertensive disorders
Severe pre-eclampsia
Eclampsia
Severe hypertension
Hypertensive encephalopathy
HELLP syndrome
Severe management indicators
Blood transfusion
Central venous access
Hysterectomy
ICU admission
Prolonged hospital stay (>7 post-partum days)
Non-anaesthetic intubation
Return to operating room
Surgical intervention

threatening conditions or as a MNM case, so no case was missed, and the woman was classified in one way or another.

Methods are described in detail in a previous study of prevalence using the same population [11]. Both Waterstone and literature-based criteria were chosen from the literature because they were better for recognising a case as an MNM case (based on clinical parameters), an important characteristic for low-resource income settings.

Data analysis

Categorical variables were described using frequencies and percentages. Using the WHO criteria as a reference standard, the diagnostic properties of the Waterstone and literature-based criteria were calculated using binomial exact methods. The MNM incidence ratio (MNM-IR) was calculated as the number of MNM/1000 live births (LB) for the three different approaches [4].

The agreement between the three instruments was also calculated using the positive percentage concordance,

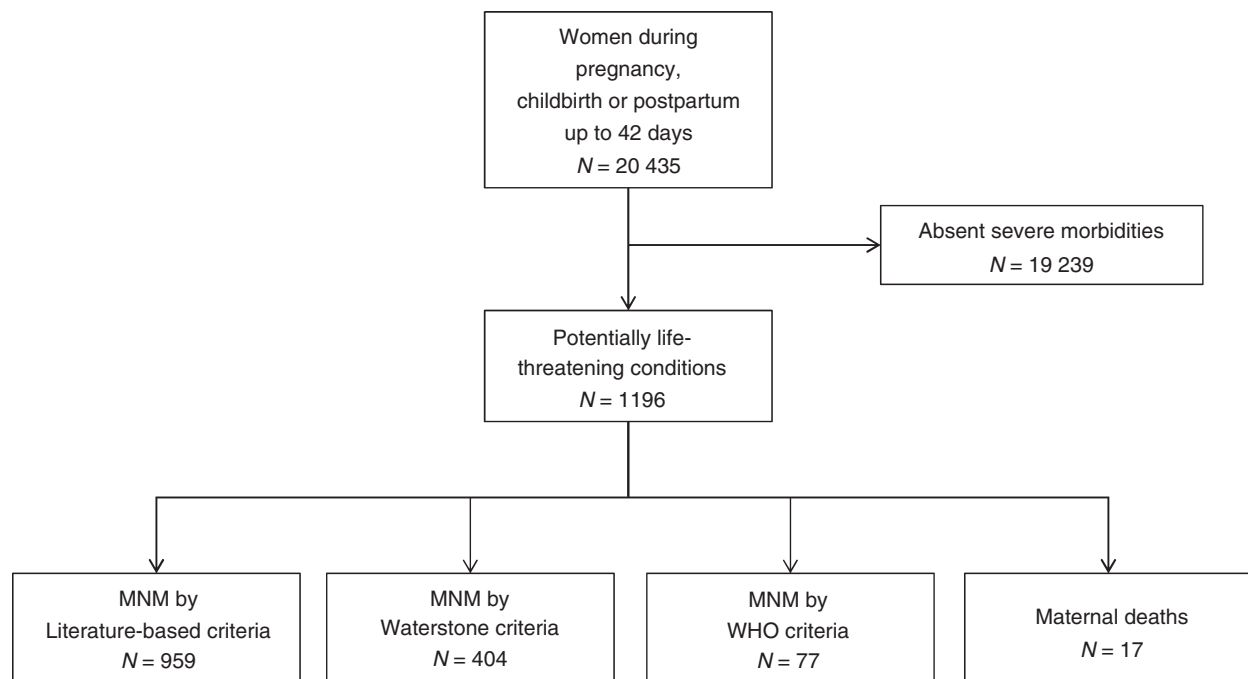


Figure 1 Method of screening of patients with maternal near miss for the three diagnostic approaches in the two selected maternities.

which is adopted for studies with a low prevalence of variables, such as MNM [12]. The Kappa test was applied to evaluate the concordance results. Kappa values and interpretations in this study were as follows: <0 (no agreement), from 0 to 0.19 (very weak agreement), from 0.20 to 0.39 (weak agreement), from 0.40 to 0.59 (moderate agreement), 0.60 to 0.79 (substantial agreement) and 0.8–1.0 (excellent agreement) [13].

The significance level used for all analyses was 5% ($P < 0.05$). The analyses were performed using SPSS software version 20.0 (IBM Corporation, Armonk, New York, USA) and Epi Info 7 (CDC, Atlanta, GA, USA). This study was reviewed according to the STARD statement [14].

Ethics

The study was approved by the Human Research Ethics Committee of the Federal University of Sergipe. The investigation was conducted according to the Declaration of Helsinki. We reviewed the charts to detect potentially life-threatening conditions and, for these women, written informed consent was obtained. For a previous study on prevalence of MNM in this population, a questionnaire was performed and occasionally this information can be valuable when classifying a patient as MNM.

Results

During the study period, a total of 20 435 patients were admitted. Of those, 1196 presented potentially life-threatening conditions, including 17 maternal deaths. A total of 964 cases were classified as presenting with an MNM situation according to at least one of the three MNM diagnostic groups. The WHO criteria classified 77 cases of MNM, and the Waterstone criteria and the literature-based criteria detected 404 and 959 cases, respectively. A total of 19 239 women of all those admitted did not present with potentially life-threatening conditions.

The Venn diagram in Figure 2 represents the relationship between the three MNM diagnostic approaches. From the 77 MNM cases identified by WHO criteria, 72 were also detected by the literature-based criteria and 37 by the Waterstone criteria. Four patients (5.2%) were detected exclusively by WHO criteria and they were eligible according to four different components.

Among the 959 cases identified by the literature-based criteria, we detected the following eligible criteria: 596 (54.8%) for severe hypertension, 308 (28.3%) for blood transfusion, 82 (7.5%) for ICU admission, 56 (5.1%) for eclampsia, 19 (1.7%) for emergent hysterectomy, 8 (0.7%) for obstetrical haemorrhage, 5 (0.5%) for oliguria, 4 (0.4%) for anaesthetic accidents or complications, 3 (0.3%) for cardiac arrest, 2 (0.2%) for pulmonary

Table 2 The WHO, Waterstone and literature-based maternal near miss criteria

WHO criteria*	Literature-based criteria†	Waterstone criteria‡
Clinical criteria	Severe hypertension	Severe pre-eclampsia
Acute cyanosis	Eclampsia	Eclampsia
Gasping	Cardiac arrest	HELLP syndrome
Respiratory rate >40 or <6/min	Pulmonary oedema	Severe bleeding
Shock	Obstetrical haemorrhage	Severe sepsis
Oliguria non-responsive to fluids or diuretics	Uterine rupture	Ruptured uterus
Clotting failure	Admission to intensive care unit	
Loss of consciousness lasting ≥12 h	Emergent hysterectomy	
Loss of consciousness and absence of pulse/heart beat	Blood transfusion	
Stroke	Anaesthetic accidents or complications	
Uncontrollable fit/total paralysis	Urea >15 mmol/l or creatinine >400 mmol/l	
Jaundice in the presence of pre-eclampsia	Oliguria (<400 ml/24 h)	
Laboratory-based criteria	Coma	
Oxygen saturation <90% for ≥60 min		
pH <7.1		
PaO ₂ /FiO ₂ < 200 mmHg		
Lactate >5		
Creatinine ≥300 µmol/l or ≥3.5 mg/dl		
Acute thrombocytopenia (<50 000 platelets)		
Bilirubin >100 µmol/l or >6 mg/dl		
Loss of consciousness AND the presence of glucose and ketoacids in urine		
Management-based criteria		
Use of continuous vasoactive drugs		
Intubation and ventilation for ≥60 min not related to anaesthesia		
Hysterectomy following infection or haemorrhage		
Dialysis for acute renal failure		
Transfusion of ≥5 units red cell transfusion		
Cardiopulmonary resuscitation (CPR)		

*Say *et al.*, 2009.†Reichenheim *et al.*, 2009.‡Waterstone *et al.*, 2001.

oedema, 2 (0.2%) by urea >15 µmol or creatinina >40 µmol, 2 (0.2%) for uterine rupture and 1 (0.1%) for coma.

Waterstone criteria identified 404 MNM cases: 308 (71.6%) for severe pre-eclampsia, 56 (13%) for eclampsia, 34 (7.9%) for HELLP syndrome, 26 (6%) for severe haemorrhage, 4 (0.9%) for severe sepsis and 2 (0.5%) for uterine rupture.

Based on the 16 243 live births in the studied maternity hospitals, the MNM-IR for the WHO criteria was 4.7 cases/1000 LB, for the Waterstone criteria was 24.8/1000 LB and for the literature-based criteria 59/1000 LB. The sensitivity, specificity, positive predictive and negative predictive value to diagnose MNM cases using the Waterstone and literature-based criteria are shown in Table 2.

Analysis of the similarities between WHO and Waterstone criteria showed a positive percentage concordance

of 8.3% (37/444), which was considered very weak ($\kappa = 0.15$, $P = 0.04$). Moreover, the similarities between the WHO and literature-based criteria demonstrated a positive percentage concordance of 7.4% (72/964), which was also considered very weak ($\kappa = 0.13$, $P = 0.03$; Table 3).

Discussion

The WHO highlights the need for change to achieve the goal of reducing maternal and neonatal morbidity and mortality [2, 9]. The study of MNM cases has proven effective in understanding the reasons underlying female deaths in childbirth [2]. We believe that all medical services need to improve the quality of maternal care worldwide, particularly in the low-/middle-income countries, and MNM cases may be a powerful way to recognise their own deficiencies. From there, changes may be

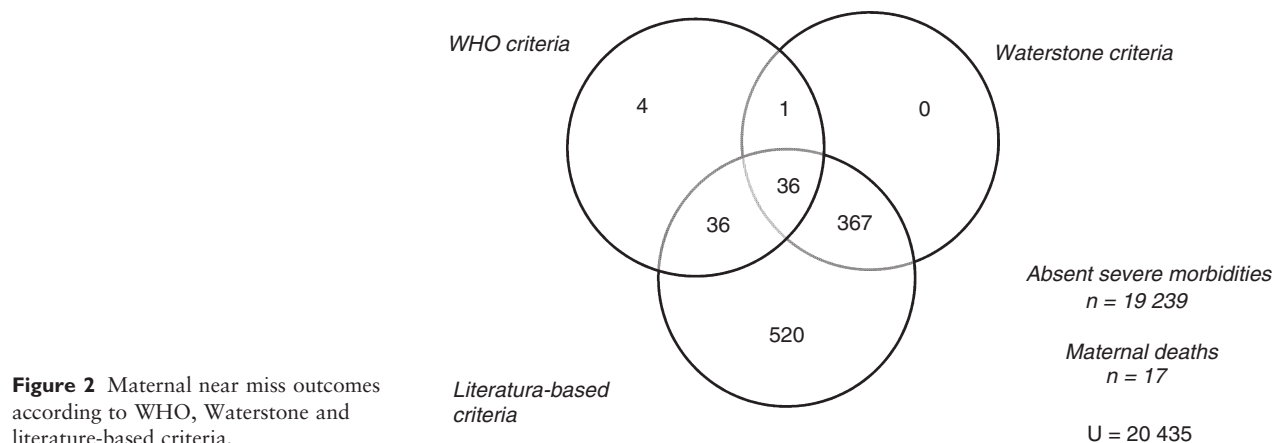


Table 3 Diagnostic properties of Waterstone and literature-based approaches for maternal near miss^{a,†}

	Waterstone % (CI 95%)	Literature-based % (CI 95%)
Sensitivity	48.05 (36.52–59.74)	93.51 (85.49–97.86)
Specificity	97.73 (97.49–97.95)	94.5 (94.15–94.86)
Positive predictive value	9.16 (6.53–12.40)	7.51 (5.92–9.36)
Negative predictive value	99.75 (99.66–99.82)	99.97 (99.92–99.99)

^aWHO MNM diagnostic approach was used as a standard reference.

[†]In brackets: CI 95%: confidence interval 95%.

proposed and comparisons were made between different health services (using the same set of criteria).

The prevalence of MNM varies widely and depends on the diagnostic approach used [3, 15, 16]. This study demonstrated this variation using three different diagnostic tools: both the literature-based criteria and the Waterstone criteria detected more cases of MNM than the reference criteria (WHO), finding twelve times and five times more cases, respectively.

The literature-based and Waterstone criteria tended to detect more cases with less severity, while the WHO criteria tended to detect the more severe cases and those cases immediately prior to death. This might be explained by the fact that the literature-based approach has weak and wide-ranging eligibility criteria. It allows women with both mild hypertension and those who received only one blood bag to be classified as MNM cases. Delivery is a condition that causes considerable blood loss even in regular situations, and the literature-based classification defines neither the level of hypertension nor the number of blood bags transfused. The Waterstone criteria also

detected all women with pre-eclampsia as MNM cases, whereas the WHO criteria only include these patients in the presence of jaundice. In general, the WHO criteria focus on severe cases and eliminate situations with borderline severity. Hypertension in pregnancy and severe haemorrhage are manageable risk factors associated with maternal morbidities, as demonstrated by many authors [3, 5, 17–19]. The detection of those morbidities may still be useful in some scenarios.

The low PPV obtained in this study reinforces the hypothesis that the literature-based or Waterstone criteria are inadequate for detecting severe cases of MNM. If the objective is to detect potentially life-threatening conditions in low-resource settings, then these two classification tools may be acceptable as they are easy to use. The low positive percentage agreement associated with a low Kappa for both literature-based and Waterstone diagnostic tools is explained by the great number of cases that the two methods identify. This weak agreement re-emphasises the need for all maternal care services to adopt the WHO approach as the standard method to classify a patient as an MNM case [4, 7, 20]. This measure will help to avoid cases of maternal death that occur every day in the poorest regions of the world.

Diagnostic techniques with high sensitivity and specificity would be ideal complements to the WHO criteria. The literature-based criteria showed high sensitivity and specificity and, despite having heterogeneous and not well-defined criteria, served as background for selection of severe maternal cases. The Waterstone criteria showed low sensitivity suggesting that, when used in association with WHO criteria, it should be adapted to avoid losing real cases of MNM.

The main limitation of the study was the difficulty in classifying patients as MNM cases using the WHO criteria. This is a limited classification for low-resource

settings. This occurred due to structural deficiencies in the health service, in particular the absence of an ICU in the high-risk maternity hospital, the lack of some therapeutic resources and laboratory parameters and the loss of information due to incomplete medical records.

Finally, it is urgent and necessary that low- and middle-income countries implement a risk evaluation system such as the WHO classification. To understand the risk factors for maternal deaths and to improve the obstetric care, it is necessary to consider the different needs of each health service. It is important to point out that this is a complex classification to apply in places that have problems with primary care, and we believe that some adjustments are necessary in order to make the tool efficient. One example is the proposed adjustment to the new WHO/MNM guidelines for quality of care for severe pregnancy complications published in 2011: this recommended a broader set of criteria, including use of blood products, severe pre-eclampsia and others [21]. We think that the literature-based and the Waterstone approaches could still be useful in certain scenarios where hypertensive disorders and severe haemorrhage are prevalent and related to maternal deaths for the simplicity of classification. Prospectively, as the WHO is the currently adopted classification system for MNM, a simplified form must be designed to reach the goal: find cases where they occur most frequently in order to save lives.

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