## **CLINICAL ARTICLE**

Rethinking the definition of maternal near-miss in low-income countries using data from 104 health facilities in Tanzania and Uganda

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#### **KEYWORDS**

Near-miss; Organ dysfunction; Severe maternal morbidity; Tanzania; Uganda

#### SYNOPSIS

A near-miss definition with a lowered threshold for transfused blood units might be better for identifying maternal near-miss cases in low-resource countries.

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# **Abstract**

**Objective:** To assess the consistency of maternal near-miss incidence and mortality index between two definitions across 104 facilities in Tanzania and Uganda.

**Methods:** Based on WHO guidance, cross-sectional near-miss data were collected in Tanzania (July 2015 to October 2016) and Uganda (June 2016 to September 2017). Prepartum hemorrhage and abortion were included as additional screening events and the number of blood units transfused was recorded. Near-miss incidence and mortality index were determined by using two near-miss definitions: the WHO standard definition, and a modified definition including women receiving at least 1 unit of blood. A sensitivity analysis excluded the additional screening events.

**Results:** Near-miss incidence differed between Tanzania and Uganda (1.79 and 4.00, respectively, per 100 deliveries) when estimated by the standard definition, but was similar (5.24 and 4.94, respectively) by the modified definition. The mortality index was higher in Tanzania than in Uganda when estimated by the standard definition (8.56% vs 3.54%), but was similar by the modified definition (3.10% vs 2.89%).

**Conclusion:** The modified definition provided a more consistent estimate of near-miss incidence and mortality index. Lowering the threshold for units of blood transfusion might improve comparability between settings, but more research is needed.

## 1 INTRODUCTION

The monitoring and management of maternal complications, particularly severe complications, is a cornerstone of any quality improvement research to address the continuous high maternal and neonatal mortality in low- and middle-income countries [1]. The concept of "maternal near-miss" to define severe morbidity has evolved over the past 20 years, and the WHO defines a maternal near-miss case as "a woman who nearly died but survived a complication that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy." More specifically, near-miss is defined as any case where organ dysfunction is present, such as cardiovascular dysfunction with signs of shock or cardiac arrest, or where management criteria indicate severity, such as blood transfusion or laparotomy [2].

A systematic review in 2012 indicated a near-miss incidence of 1–15 per 100 live births in Africa based on a combination of organ dysfunction and management criteria [3]. The mortality index (i.e., case-fatality ratio) was found to range from 3% to 37% [4]. A more recent review reported a median maternal near-miss incidence of 2.4% [5], and other studies have reported low levels of near miss per 100 live births of 1.2 in Zanzibar [6], 2.5 in a rural hospital in Rwanda [7], 3.6 in district hospitals Rwanda [8], and 0.8 in Uganda [9] (Supplementary Figure S1).

Although the WHO guidance has clearly led to more harmonized reporting of near-miss cases, there has been considerable debate about the need to adapt the methodology to specific contexts. In low-income settings, reporting of signs and symptoms is not always complete; thus, management criteria might be more sensitive markers. Moreover, given that interventions such as blood transfusions are severely constrained in low-resource settings, the currently proposed cut-off of 5 units of blood might miss many severe cases [5, 10, 11].

Tanzania and Uganda have high maternal mortality ratios of, respectively, 398 and 343 deaths per 100 000 live births [2]. In both countries, most women attend prenatal care at least once, and approximately two-thirds deliver in health facilities. However, the quality

of care is low owing to insufficient health-worker training and limited or irregular availability of supplies to manage pregnancy and delivery complications [12].

To inform further methodologic development and improve maternal outcomes, the primary aim of the present study was to determine near-miss incidences and mortality indices using the WHO standard definition of near-miss and a modified definition including cases with at least 1 unit of blood transfusion. A secondary aim was to examine the relationship between the number of blood units transfused and reported organ dysfunction. The data used were primarily collected to evaluate a training intervention to reduce morbidity and mortality from postpartum hemorrhage in Tanzania and Uganda [13, 14].

#### **2 MATERIALS AND METHODS**

The present study was based on cross-sectional near-miss data prospectively collected in 23 hospitals and 38 health centers in Tanzania (July 1, 2015, to October 31, 2016) and 22 hospitals, 16 health centers (level IV), and 5 high-volume health centers (level III) in Uganda (June 1, 2016, to September 30, 2017) [12]. Ethical clearance was granted by the research and ethics committees of Muhimbili University of Health and Allied Sciences and the Commission of Science and Technology in Tanzania, and by Makerere University School of Medicine and the Uganda National Council for Science and Technology in Uganda. Both committees gave permission to compile the medical record data without seeking individual consent from the women.

In both settings, the study facilities were part of rural districts except for one larger referral hospital in Mwanza district in Tanzania. All facilities were government-owned except for 14 faith-based facilities and 1 facility managed by a non-governmental organization.

Details of the original study are presented elsewhere [12]. In brief, all women with severe complications were included in the study, as proposed by WHO guidance [2]. Data were captured by using the WHO recommended near-miss form [2] with the adaptation that abortion and prepartum hemorrhage were included as screening complications. In

addition, instead of documenting whether or not a woman received 5 units of blood, the number of transfused units was recorded.

In each facility, two staff members received a 1.5 days of initial training plus 1 day of refresher training after 5 months, on data collection for near-miss cases. Via a printed near-miss form, data were collected daily from the prenatal, delivery, postnatal, and female ward registries, patient case notes, the laboratory's blood transfusion registry, and the obituary for every woman who was pregnant or within 42 days of the end of a pregnancy. Data were uploaded bi-weekly to a password-protected secure server. Summary sheets with the number of all deliveries in the facilities and the number of near-miss cases were prepared on a monthly basis, and data were compiled over the phone and verified during supervision visits [12].

Stata version 13 (StataCorp, College Station, TX, USA) was used for data analysis. Data were presented as absolute number, number (percentage), proportion, and 95% confidence intervals (CI), with adjustment for clustering at the facility level using svyset and svy commands. The reported organ dysfunction and number of blood transfusions were cross-tabulated.

Maternal near-miss incidence, severe maternal outcome ratios (maternal near-miss cases plus maternal deaths among all deliveries), and the mortality index (deaths among cases with severe maternal outcomes; case-fatality rate) were compared between values obtained by two definitions of maternal near-miss: (1) women who had organ dysfunction, received a laparotomy for reasons other than cesarean delivery, or received at least 5 units of blood transfusion (WHO standard definition); (2) women who had organ dysfunction, received a laparotomy for reasons other than cesarean delivery, or received at least 1 unit of blood transfusion (modified definition). A sensitivity analysis was carried out excluding prepartum hemorrhage and abortion-related near-misses under the assumption that they would have been missed if they had not been included in the screen.

## 3 RESULTS

During the study period, there were 8228 and 12 843 women with complications in Tanzania and Uganda, respectively. In both countries, anemia and postpartum hemorrhage were the most commonly reported complications, followed by sepsis or severe infection, and severe abortion complications. The proportion of these complications per 100 deliveries followed a similar order (Figure 1). However, a higher percentage of abortion complication cases was reported in Uganda than in Tanzania (25.81% versus 13.38%), whereas a much higher percentage of eclampsia cases was reported in Tanzania than in Uganda (10.14% versus 3.39%) (Table 1).

The near-miss incidence per 100 deliveries was 1.79 and 4.00 in Tanzania and Uganda, respectively, using the WHO standard definition (Table 2). Excluding those cases that were probably identified by the additional screening questions on prepartum hemorrhage and abortion-related near-misses decreased the respective estimates to 1.49 and 2.94 near-misses per 100 deliveries. The near-miss incidence was more consistent between the two settings when the modified definition was used (5.24 and 4.94 per 100 deliveries in Tanzania and Uganda, respectively).

The mortality index was higher in Tanzania (8.56%) than in Uganda (3.54%) when either the WHO standard definition or the WHO definition excluding prepartum hemorrhage and abortion-related near-misses was used (8.78% and 3.62%). The mortality index was similar in Tanzania and Uganda when the modified definition was used (3.10% and 2.89%, respectively).

Estimates of near-miss incidence by the standard WHO definition and the modified definition showed major differences for all obstetric complications except ruptured uterus and ectopic pregnancy (Table 3). In Uganda, differences in near-miss incidence between the two definitions were generally smaller for all complications. In both countries, there were a large number of abortion-related near-misses and the mortality index was high (7.41% and 3.15% in Tanzania and Uganda respectively) based on the WHO standard definition.

The association between reported organ dysfunction and number of transfused blood units was assessed. In Tanzania, no organ dysfunction was documented in 50% of cases, although women were given 2–3 units of blood, suggesting the occurrence of a major complication (Figure 2). In Uganda, by contrast, organ dysfunction was reported in 50% of cases where 1 unit of blood was transfused, rising to more than 80% in cases where 3 units were given. Overall, the likelihood of reported organ dysfunction increased by 2.06 (95% CI, 1.49–2.86) for every additional unit of blood transfusion (Tanzania: odds ratio, 1.98; 95% CI, 1.42–2.76; Uganda, odds ratio, 2.23; 95% CI, 1.34–3.69).

The overall number of blood transfusions provided was similar across the two settings (Supplementary Figure S2). An average of 1.5 and 1.7 units were transfused in Tanzania and Uganda, respectively; the median (interquartile range) was 1 (1–2) in both countries. Overall, few women received more than 3 units of blood.

## **4 DISCUSSION**

The present large study of all deliveries at 104 hospitals and health centers found an overall near-miss incidence of 1.79 and 4.00 per 100 deliveries in Tanzania and Uganda. respectively, using the WHO standard definition. The incidence was higher and more consistent between the two countries (5.24 and 4.94 per 100 deliveries, respectively), using the modified definition. The near-miss mortality index was higher in Tanzania (8.56%) than in Uganda (3.54%) when the WHO standard definition was used, but similar when the modified definition was used (3.10% and 2.89%, respectively).

The present rates of near-miss using the WHO standard definition (1.79% and 4.00% in Tanzania and Uganda, respectively) compare well with other studies using the WHO standard definition [6, 7, 9]. Higher rates have been described elsewhere in sub-Saharan Africa, for example, in Mozambique where a high prevalence of HIV and a low uptake of prenatal care in the population might increase the incidence of maternal-near miss [15]. By contrast, a low incidence of only 1.58% was reported from a study in 42 tertiary facilities in Nigeria [16].

The present analysis suggests that underreporting of organ dysfunction might account for the dissimilarity between maternal near-miss incidence in the two settings aside from differences in the risk profile and quality of care provided. Clinical skills and assessments and their documentation are often neglected in low-resource settings, where there are too few maternity providers for a birthing population with a high number of complications and action is prioritized over recording [17]. In addition, major inter-assessor differences have been reported using organ dysfunction criteria, indicating that these criteria are not as clearly identifiable as hoped [18]. Even in the Netherlands, a high-resource country, severe cases were missed when organ dysfunction criteria were used [19]. Using the same definition across settings is important to increase comparability [20]; nevertheless, differences in clinical assessment and documentation might constrain comparability. Research similar to the present study on testing more pragmatic criteria is explicitly encouraged by the WHO's near-miss team [21].

The mortality index of 8.56% and 3.54% found in Tanzania and Uganda, respectively, using the WHO standard definition is at the lower range of values reported by other studies from sub-Saharan Africa. At 40.8%, one of the highest values has been reported in public tertiary hospitals in Nigeria by Oladapo et al. [16]. The present study included both primary and secondary facilities, which might partly explain the lower mortality index observed.

The present data contribute to the discussion on how many units of transfused blood should be included in the definition of near-miss events in low-resource settings — a criterion that experts in the Delphi study were unable to agree on [10]. Nelissen et al. [11, 22], as well as other researchers, have proposed that cases with at least 2 units of blood should be included [11, 22]. Massive transfusions of 5 units or more were extremely rare in the present study, reflecting the problems in blood transfusion services, as described elsewhere [23]. In both countries, a linear association was observed between the number of blood units transfused and organ dysfunction, suggesting that there is no clear optimal cut-off level.

In Uganda, where reporting of organ dysfunction was higher, more than 50% of women who received 1 unit of blood also had organ dysfunction, suggesting that blood is given mostly when the mother is in a critical state. The percentage of women with organ dysfunction increased to 80% among those receiving 4 units of blood. The reporting of concurrent organ dysfunction and blood transfusion was considerably lower in Tanzania. Although the present study cannot provide strong evidence to revise the definition, the results suggest that a threshold of 5 units of blood is likely to miss many cases. Moreover, the modified definition performed better in terms of comparability across the two settings. Lowering the threshold for blood transfusion might, however, lead to less specificity to predict severe cases of near-miss.

The present study also modified the disease conditions used to screen for near-miss and added two more conditions — severe abortion complication and prepartum hemorrhage — which are not included in the WHO standard definition [20]. There were 0.9 and 2.1 severe abortion complications per 100 deliveries in Tanzania and Uganda, respectively. These values are similar to that of 1.5 per 100 live births reported in a study from Zambia [24]. Studies that did not specifically include abortion as a screening event have reported lower rates; for example, another study in Uganda reported 39 abortion-related near-misses per 25 840 live births (0.16 per 100 deliveries) [9]. Lowering the threshold of blood transfusion also increased the identification of abortion-related near-miss cases, an observation made by a previous study in Zambia [24].

The mortality index of abortion complication was 7.41% and 3.15% in Tanzania and Uganda, respectively, using the WHO standard definition. The 7% estimate in Tanzania is close to the case-fatality rate of 8.2% reported by the WHO multi-country study [25]. The present findings suggest that severe abortion complication might be considered in future work as a screening question to identify near-miss cases [10]. The present study is also in agreement with that of Tunçalp et al. [26], who found that that anemia is a major burden. This is supported by our results in which for one-third of all screened cases, anemia was an underlying reason and in those identified as near-misses a mortality index of 8% and 6% in Tanzania and Uganda respectively, was observed. An interesting finding

of the present study was the large number of ectopic pregnancies identified; the mortality index was low in ectopic pregnancy as reported elsewhere [27].

The present study has both strengths and limitations. A large number of primary and secondary level facilities adhering to the same implementation principles were included, the standard WHO near-miss tool was used, and the study was conducted in a similar way in the two settings, Tanzania and Uganda. This improved the comparability of the results. The study also used a prospective design with continuous data collection—a design that has been proposed to lead to better identification of cases [24].

The study indicates, however, that the incidence of near-miss and the mortality index depend on the type of obstetric complication. Data collection was done by staff employed in the maternity wards, whereas other studies have used research nurses for data collection [9]. The possibility cannot be excluded that employing staff rather than using nurses might have reduced the quality of the data collection. Reporting of cases might have been biased in both directions, with both over- and underreporting of interventions and organ dysfunction.

In conclusion, the present study found that a modified definition of near-miss provided a more consistent near-miss incidence and mortality index between countries. Lowering the threshold for the number of transfused blood units might improve comparability between settings, but further studies are needed to confirm this idea. The inclusion of severe abortion complication as a screening event led to the identification of a large number of near-miss cases and might also be considered in future studies.

#### **Author contributions**

ABP and CH conceived the study. FA and ABP (Tanzania), and SA and FK (Uganda) managed the larger trial and data collection with support from CH and JLM. CH, AH, and GM performed statistical analysis. ABP drafted the manuscript. All authors contributed to revision and approved the final manuscript.

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# **Conflicts of interest**

JLM is employed by FIGO. The authors have no conflicts of interest.

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# Figure legends

Figure 1 Incidence of reported complications per 100 deliveries in Tanzania and Uganda.

**Figure 2** Organ dysfunction in cases of near-miss by type and number of blood units transfused. (A) Tanzania; (B) Uganda.

# **Supporting materials legends**

**Figure S1** Near-miss incidence and mortality index reported recent studies of near-miss in sub-Saharan Africa.

Figure S2 Number of units of blood transfused in Tanzania and Uganda.

Table 1 Frequency of reported complications by type of facility in Tanzania and Uganda a.

Screening event	Tanzania				Uganda				
Complications	23 Hospitals	38 Health	Total	Incidence	22 Hospitals	21 Health	Total	Incidence per 100 deliveries	
	(n=6970)	centers	(n=8228)	per 100	(n=9160)	centers	(n=12,843)		
		(n=1258)		deliveries		(n=3683)			
Prepartum	680 (9.76)	94 (7.47)	774 (9.41)	0.64	889 (9.71)	301 (8.17)	1190 (9.27)	0.73	
hemorrhage									
PPH	1922 (27.58)	703 (55.88)	2625 (31.90)	2.18	3583 (39.11)	1429 (38.80)	5012 (39.03)	3.06	
Severe PPH	979 (14.05)	312 (24.80)	1,291 (15.69)	1.07	1002 (10.94)	272 (7.39)	1274 (9.92)	0.78	
Severe pre-	698 (10.01)	71 (5.64)	769 (9.35)	0.64	1176 (12.84)	234 (6.35)	1410 (10.98)	0.86	
eclampsia									
Eclampsia	751 (10.77)	83 (6.60)	834 (10.14)	0.69	359 (3.92)	77 (2.09)	436 (3.39)	0.27	
Sepsis/severe	999 (14.33)	200 (15.90)	1199 (14.57)	0.99	1323 (14.44)	463 (12.57)	1786 (13.91)	1.09	
infection									
Ruptured uterus	238 (3.41)	25 (1.99)	263 (3.20)	2.04	502 (5.48)	61 (1.66)	563 (4.38)	0.34	
Severe abortion	925 (13.27)	176 (13.99)	1101 (13.38)	0.91	2109 (23.02)	1206 (32.75)	3315 (25.81)	2.03	
complication									
Main other diagnosis									
Ectopic	491 (7.04%)	8 (0.64)	499 (6.06)	0.41	418 (4.56)	44 (1.19)	462 (3.60)	0.28	
pregnancy									
Anemia	2650 (38.02)	312 (24.80)	2962 (36.00)	2.46	3432 (37.47)	654 (17.76)	4086 (31.81)	2.50	
Other <sup>b</sup>	134 (1.92)	4 (0.32)	138 (1.68)	0.11	108 (1.18)	230 (6.24)	338 (2.63)	0.21	

- <sup>a</sup> Values are given as number (percentage) unless stated otherwise. In some cases, more than one complication was reported; thus, frequencies do not sum to 100%.
- <sup>b</sup> Reported complications that were not related to any of the other complications but resulted in organ dysfunction, blood transfusion, laparotomy or maternal death.

Table 2 Key maternal outcome indicators in Tanzania and Uganda.

Indicator	Tanzania (n=120 553)	Uganda (n=163 559)
Maternal near-miss incidence,		
per 100 deliveries		
WHO standard definition	1.79	4.00
WHO standard definition b	1.49	2.94
Modified definition	5.24	4.94
Severe maternal outcome ratio,		
per 100 deliveries <sup>a</sup>		
WHO standard definition	1.96	4.14
WHO standard definition b	1.63	3.09
Modified definition	5.41	5.08
Mortality index, %		
WHO standard definition	8.56	3.54
WHO standard definition b	8.78	3.62
Modified definition	3.10	2.89

<sup>&</sup>lt;sup>a</sup> Includes 2158 and 6535 (WHO standard definition) and 6316 and 8076 (modified definition) near-misses, and 202 and 240 deaths in Tanzania and Uganda, respectively.

<sup>&</sup>lt;sup>b</sup> This definition excludes cases of prepartum hemorrhage and severe abortion-related complications, and thus 1798 and 4868 near-misses in Tanzania and Uganda (WHO standard definition).

Table 3 Mortality index by reported obstetric complications in Tanzania and Uganda

Complication	Total	Near-miss cases by complication				Mortality index (near-miss case fatality)				
	no.	WHO standard definition		Modified definition		WHO standard definition		Modified definition		
Tanzania		No.	% (95% CI)	No.	% (95% CI)	No.	% (95% CI)	No.	% (95% CI)	
Prepartum	774	163	21.06 (14.34–29.84)	535	69.12 (59.50–77.33)	18	9.94 (5.59–17.07)	18	3.25 (1.93–5.44)	
hemorrhage										
PPH	2625	652	24.84 (16.69–35.28)	1781	67.85 (57.76–76.51)	46	6.59 (4.34–9.89)	46	2.52 (1.80–3.52)	
Severe PPH	1291	415	32.15 (20.81–46.07)	931	72.11 (61.78–80.53)	29	6.53 (3.95–10.62)	29	3.02 (1.79–5.06)	
Severe pre-	769	105	13.65 (7.98–22.38)	240	31.21 (18.33–47.83)	17	13.93 (9.29–20.37)	17	6.61 (3.51–12.11)	
eclampsia										
Eclampsia	834	150	17.99 (10.24–29.66)	803	96.28 (94.09–97.68)	31	17.13 (9.18–29.70)	31	3.72 (2.32–5.91)	
Sepsis/severe	1199	250	20.85 (11.65–34.49)	1156	96.41 (94.51–97.67)	43	14.68 (7.30–27.30)	43	3.59 (2.33–5.49)	
infection										
Ruptured uterus	263	193	73.38 (60.93–82.98)	243	92.40 (86.82–95.73)	20	9.39 (5.12–16.58)	20	7.60 (4.27–13.18)	
Severe abortion	1101	200	18.17 (8.85–33.66)	870	79.02 (64.71–88.55)	16	7.41 (2.93–17.47)	16	1.81 (0.75–4.31)	
complication										
Ectopic	499	472	94.59 (87.93–97.67)	491	98.40 (96.84–99.19)	6	1.26 (0.60–2.59)	6	1.21 (0.58–2.51)	
pregnancy										
Anemia	2962	1022	34.50 (22.50–48.88)	2707	91.39 (88.09–93.84)	91	8.18 (4.91–13.32)	91	3.25 (2.38–4.43)	
Other <sup>a</sup>	138	42	30.43 (18.60–48.59)	119	86.23 (75.50–92.72)	19	31.15 (20.97–43.54)	19	13.77 (7.28–	
									24.50)	
Total	8228	2158	26.23 (18.68–35.50)	6316	76.76 (70.74–81.86)	202	8.56 (6.28–11.57)	202	3.10 (2.49–3.85)	
Jganda										

Prepartum hemorrhage	1190	572	48.07 (39.03–57.23)	707	59.41 (51.73–66.66)	21	3.54 (2.20–5.66)	21	2.88 (1.82–4.54)
PPH	5012	2678	53.43 (38.80–67.50)	3189	63.63 (49.78–75.53)	104	3.74 (2.17–6.37)	104	3.16 (1.97–5.03)
Severe PPH	1274	881	69.15 (60.70–76.49)	1040	81.63 (74.79–86.94)	69	7.26 (4.78–10.89)	69	6.22 (4.17–9.19)
Severe pre-	1410	568	40.28 (27.37–54.70)	675	47.87 (33.65–62.45)	24	4.05 (1.61–9.83)	24	3.43 (1.38-8.27)
eclampsia									
Eclampsia	436	256	58.72 (42.45–73.28)	414	94.95 (92.58–96.60)	22	7.91 (4.55–13.42)	22	5.05 (3.40-7.42)
Sepsis/severe	1786	1173	65.68 (53.72–76.26)	1718	96.19 (93.61–97.76)	68	5.48 (2.95–9.96)	68	3.81 (2.24–6.39)
infections									
Ruptured uterus	563	452	80.28 (71.85–86.66)	526	93.43 (90.66–95.42)	37	7.57 (5.30–10.69)	37	6.57 (4.58–9.34)
Severe abortion	3315	1107	33.39 (22.20–46.84)	1472	44.40 (31.02–58.65)	36	3.15 (1.28–7.53)	36	2.39 (1.07–5.24)
complication									
Ectopic	462	457	98.92 (97.90–99.45)	437	94.59 (89.57–97.27)	2	0.44 (0.13–1.44)	2	0.46 (0.14–1.49)
pregnancy									
Anemia	4086	2584	63.24 (56.11–69.83)	3398	83.16 (77.39–87.69)	157	5.73 (3.55–9.12)	157	4.42 (2.92–6.63)
Other <sup>a</sup>	338	319	94.38 (84.20–98.14)	325	96.15 (88.26–98.81)	13	3.92 (1.19–12.11)	13	3.85 (1.19–11.74)
Total	12 843	6535	50.88 (40.59–61.10)	8076	62.88 (54.35–70.69)	240	3.54 (2.08–5.97)	240	2.89 (1.82–4.54)

Abbreviations: CI, confidence interval; PPH, postpartum haemorrhage.

<sup>&</sup>lt;sup>a</sup>Other includes severe heart disease, complications of anaesthesia, malaria, HIV infection

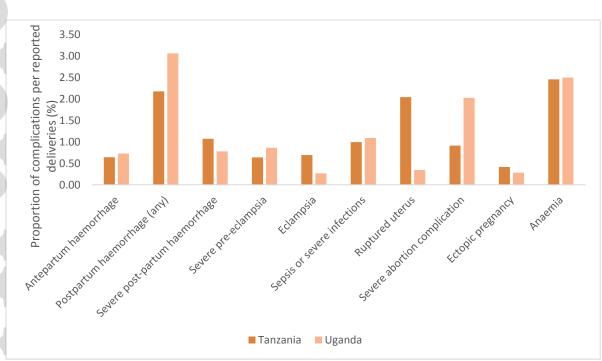
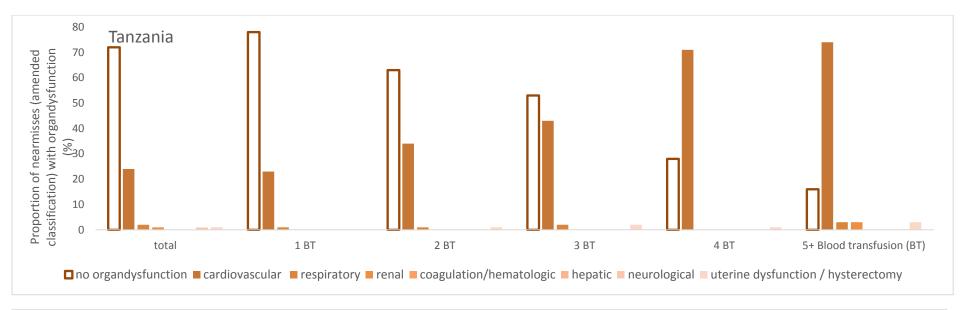


Figure 1: Incidence of reported complications per 100 deliveries in Tanzania and Uganda



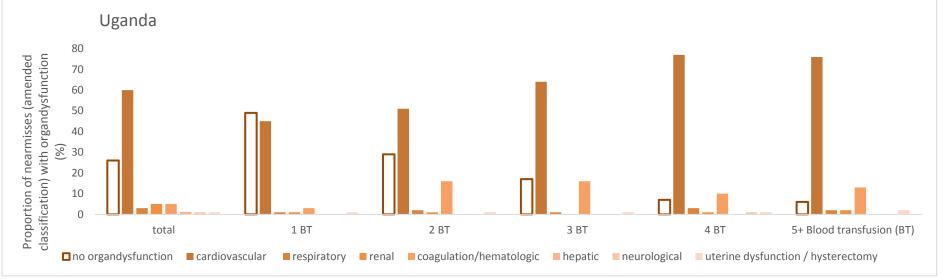


Figure 2: Organ dysfunctions in near-misses by type and number of blood bags transfused in Tanzania (A) and Uganda (B)-