Chapter 5. Incidence of abortion-related near-miss complications in Zambia: cross-sectional study in Central, Copperbelt and Lusaka Provinces

Introduction

This chapter describes the incidence of abortion-related near-miss morbidity in three provinces in Zambia. It utilizes the concept of abortion-related near-miss to quantify and describe the burden of unsafe abortion. The paper outlines how we incorporated near-miss morbidity into the current criteria PMM used to define abortion-related morbidity from hospital data. The results of the study describe the characteristics of women hospitalized for abortion-related complications, provide abortion-related near-miss morbidity estimates for three provinces in Zambia, and discuss the challenges of utilizing the WHO near-miss criteria, without sufficient adaptation to a limited-resource context.

The methods and methodological strengths and challenges section here is more extensive than the section in the published paper due to the word count limit in peer-reviewed publications. Five tables presenting our morbidity criteria and results of the study were included in the publication and have been included in the chapter. Table 1 presents additional results on the use of contraceptives before and after admission for abortion-related complications, which were not submitted with the paper. Appendix A defining study terms and appendix B describing the pilot study which were part of the journal submission are included immediately after the manuscript. The data collection tool for this study is included in appendix 7 (within the appendices after the thesis).

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Abstract

Objectives: To describe the magnitude and severity of abortion-related complications in health facilities and calculate the incidence of abortion-related near-miss complications at the population level in three provinces in Zambia, a country where abortion is legal but stigmatized.

Study design: We conducted a cross-sectional study in 35 district, provincial, and tertiary hospitals over 5-months. All women hospitalized for abortion-related complications were eligible for inclusion. Cases of abortion-related near-miss, moderate, and low morbidity were identified using adapted WHO near-miss and the prospective morbidity methodology (PMM) criteria. Incidence was calculated by annualizing the number of near-misses and dividing by the population of women of reproductive age. We calculated the abortion-related near-miss rate, abortion-related near-miss ratio, and the hospital mortality index.

Results: Participating hospitals recorded 26,723 births during the study. Of admissions for post-abortion care, 2406 (42%) were eligible for inclusion. Near-misses constituted 16% of admitted complications and there were 14 abortion-related maternal deaths. The hospital mortality index was 3%; the abortion-related near-miss rate for the three provinces was 72 per 100,000 women, and the near-miss ratio was 450 per 100,000 live births.

Conclusions: Abortion-related near-miss and mortality are challenges for the Zambian health system. Adapted to reflect health systems capabilities, the WHO near-miss criteria can be applied to routine hospital records to obtain useful data in low-income settings. Reducing avoidable maternal mortality and morbidity due to abortion requires

efforts to de-stigmatize access to abortion provision, and expanded access to modern contraception.

Implications: The abortion-related near-miss rate is high in Zambia compared with other restrictive contexts. Our results suggest that near-miss is a promising indicator of unsafe abortion, can be measured using routine hospital data, conveniently defined using the WHO criteria and can be incorporated into the frequently utilized prospective morbidity methodology.

5.1 Introduction

Unsafe abortion is a leading and easily preventable cause of maternal mortality and morbidity (81,163). Globally, the highest regional estimate of abortion-related mortality (90 per 100,000 live births) comes from Sub-Saharan Africa, where most abortion laws are restrictive, abortion may bear greater societal stigma, poverty is common, and comprehensive abortion care services are limited (163). Unsafe abortion remains a contentious, poorly measured, and largely neglected health problem in this region.

Obtaining accurate population-representative data on unsafe abortions is more challenging in such high-burden contexts(9,42). Women having terminations of pregnancy (TOPs) are unlikely to report them in surveys and providers are unlikely to maintain accurate reports.

Hospital records on post-abortion care (PAC) admissions are the most frequently used source of data (10), but have limitations. Although national mortality may be high, numbers of deaths are often small at individual hospitals. All admissions for abortion-related morbidity in hospitals may not be representative of morbidity in the community (36,164), and it is difficult to distinguish miscarriages (spontaneous abortions) from induced abortions (terminations of pregnancy) when morbidity is of low severity, as a means of identifying unsafe TOPs (25).

The idea of near-miss morbidity aims to address some of these measurement challenges. The WHO operational definitions of maternal near-miss (93) define a level of morbidity so severe that, in women with abortion-related complications, it is most likely the result of a TOP rather than a miscarriage (89), such that survival requires hospital treatment. By extension, documented near-misses at health facilities can be assumed to represent all cases within the population (165), providing an indicator of the most severe unsafe TOPs that can be tracked over time. Since it has similar characteristics, near-miss can be used as a proxy for mortality. It occurs more frequently (115,166,167), and allows for larger samples and increased statistical power

in quantitative analyses (100). To the best of our knowledge, no studies have yet estimated the incidence of abortion-related near-miss at the population level (10).

Zambia has one of the most liberal abortion laws in Sub-Saharan Africa. Implementation is, however, impeded by a requirement for three signatories to support an elective TOP, except in an emergency. No recent studies have described the burden of TOPs or miscarriages in Zambia(143), but unsafe TOPs have been previously estimated to account for 30% of maternal deaths and 50% of gynecological admissions (17,145). Our study describes the magnitude and severity of moderate and severe complications from both miscarriage and TOP, and the incidence of abortion-related near-miss in three provinces.

5.2 Methods

5.2.1 Design, setting, and population

We conducted a cross-sectional study in Central, Copperbelt, and Lusaka Provinces. Lusaka and Copperbelt account for 69% of Zambia's total urban population (155), while Central Province is more rural. Forty-three level one (district), level two (provincial), and level three (tertiary and national) hospitals - which serve as public (N=30) or private (N=13) referral facilities and provide comprehensive care for severe complications - were eligible for inclusion and were invited to participate.

We used the Zambian Ministry of Health definition of abortion (Appendix A) (17). All women admitted with an International Classification of Diseases (ICD-10) diagnosis of incomplete, complete, missed, septic, inevitable, or spontaneous abortion, who were hospitalized for greater than 24 hours or had any complication that could potentially lead to moderate (Table A1) or near-miss morbidity, or died between 1st December 2013 and 31st April 2014, were eligible for inclusion. Each health facility was provided with two clinical algorithms containing these inclusion and exclusion criteria to display on the wall and assist data collectors with recruitment (Appendix 6).

We defined morbidity categories by adapting the prospective morbidity methodology (PMM) initially proposed by WHO to determine whether abortion complications were related to miscarriages or unsafe TOPs, adapted by South African researchers, and

subsequently used in other studies to collect data on abortion-related morbidity and management (25,37,38,87–89). We changed the morbidity categories from low, moderate, and severe (87) to low, moderate, near-miss, and suspected near-miss. We introduced anemia cut-off levels for each category using the WHO cutoffs for pregnant women (168), except in the near-miss category in which we used a level of 4g/dl. This decision was based on discussions with clinicians and experts on maternal near-miss during the design of our adapted criteria. 4g/dl is also the cut-off for severe anemia requiring urgent transfusion according to the Zambia Transfusion Service. We also revised the infection definition for the moderate category, and replaced the high-severity category with a near-miss category. We introduced anemia into our classification because hemorrhage is a major complication of unsafe abortion (169), but the PMM does not include in its categories criteria other than shock to assess severity of blood loss. Many women and hospitals are unable to objectively quantify blood loss after an abortion, but it is possible to assess the effect of blood loss by measuring haemoglobin levels in such settings. We also adapted the WHO near-miss criteria to reflect a lower middle-income country context (Table 5-1). We excluded the laboratory and management-based criteria which are rarely measured in this context as such data is rarely present in patient case files(106,114). We included as criteria anemia alone (<4g/dl), and anemia in combination with blood transfusion (4-7g/dl with any blood transfused). These criteria are important adaptations because clinical information in medical records is often incomplete in low- and middle-income countries, and parameters to identify severe bleeding objectively and classify cases as hypovolemic shock are often not readily available. We lowered the WHO near-miss threshold for a massive blood transfusion from 5 units of blood to 2 units in our adapted criteria. This is because of the scarcity of blood products in Zambia and was endorsed by our local investigator, BV. It has also been reported by maternal near-miss studies in similar settings such as Malawi(170) and Tanzania(106). Both studies suggest 2 units of blood as the optimal threshold for massive transfusion in such contexts. The suspected near-miss category was based on our experience in a pilot study in which cases were considered to be near-miss by clinicians, but the case file contained insufficient information to classify it objectively as such (Information on the pilot study

is included in Appendix B). We included the suspected near-miss cases in the near-miss category in the final analysis.

Table 5-1 Differences between WHO near-miss morbidity criteria and criteria used in the study, adapted for abortion-related complications in Zambia

NEAR-MISS SEVERITY	
WHO near-miss criteria	**Adapted near-miss criteria for study**
Clinical criteria	
Shock	Hypovolemic shock *Persistent systolic blood pressure <90 mmHg with pulse rate of at least 120 beats per minute); with or without blood hemoglobin 7-9.9 g/dl or mucocutaneous signs*
	Septic shock *Clinical diagnosis of septicaemia or one of the following: t>39C, t<36C, genital infection AND one of the following: systolic BP <90 mmHg, icterus, altered consciousness, oliguria <100ml in 4 h.*
Oliguria not responsive to fluid or diuretics	Oliguria not responsive to fluid or diuretics *Uterine output <30ml/hour for four hours or <400ml/24 hours*
Cardiac arrest	Cardiac arrest
	Generalized peritonitis, tetanus, gangrenous uterus
	Major trauma *Uterine perforation, bowel injury*
Management-based criteria	
Hysterectomy following infection or hemorrhage	Hysterectomy following infection or hemorrhage
Massive blood transfusion *(Transfusion of ≥5 units of blood)*	Massive blood transfusion *Transfusion of ≥2 units of blood*
	Haemoglobin <4 g/dl
	Hb 4.1-6.9 g/dl with >=1unit blood transfused
SUSPECTED NEAR-MISS	
Clinically suspected case of organ/systemic compromise with incomplete documentation	
Cases transfused with one unit of blood and clinical symptoms/signs of anaemia, with haemoglobin level missing from the case file, and insufficient information to objectively classify in a near-miss category	
Haemoglobin between 4 and 7g/dl with no blood transfusion given	
MODERATE SEVERITY	
Prospective morbidity methodology	Adapted study criteria
Temperature 37.3-37.9 C	Temperature >=37.3C and other signs of infection, e.g. chills and rigors, foul smelling discharge
Offensive products	Offensive products
Localised peritonitis	Localised peritonitis
	Haemoglobin 7-9.9 g/dl alone or with blood transfusion
LOW SEVERITY	

Prospective morbidity methodology	Adapted study criteria
Temperature <= 37.2 C	Temperature < 37.3C (but > 36C)
No clinical signs of infection	No clinical signs of infection
No system or organ failure	
No suspicious finding on evacuation	No suspicious findings on evacuation
	Hemorrhage not requiring any blood transfusion
	Haemoglobin 10-10.9g/dl

5.2.2 Data collection

We collected data continuously for five and a half months from 1st December 2013 to 15th May 2014. Only women admitted from the 1st December 2013 to 30th April 2014 were included in the analyses. We used a pre-tested standardized form structured to approximate patient care, in order to minimize the data collectors work and improve data quality. A one-day training was conducted with 67 data collectors (clinicians working in the wards in which eligible women were likely to be admitted) recommended by each hospital. Clinically trained study supervisors (namely OO, who is a medical doctor, and a Zambian nurse hired for the study) extracted data in three hospitals (9%) in which no in-facility data collectors were recommended. Data collectors extracted information from hospital files and did not interview women directly. They were instructed not to differentiate between complications resulting from miscarriages and TOPs. Health providers were, however, told to ask about and record reported attempts to induce abortion and to note physical evidence of attempted termination during clinical examination. Monthly supervision visits were conducted to collect completed forms and verify information from hospital files. Data collectors received a small financial incentive for participation. We collected the total numbers of women admitted for any abortion-related complication from hospital registers, regardless of complication severity and outcome, women provided with TOP, number of deliveries and total live births.

After the main study, a validation study was conducted in one tertiary hospital to verify if all cases had been included in our study. One study supervisor retrieved case files for March 2014 from the medical records department and traced women from hospital registers. Data from eligible cases were extracted retrospectively into data forms and the degree of underreporting assessed.

5.2.3 Data analysis

Data analysis was conducted in Stata 13.1, and an algorithm was used to assign morbidity level to cases using clinical signs and symptoms. We quantified the number of near-misses that would have been identified using our adapted study criteria and WHO near-miss criteria. Data from each hospital were calculated, divided by five, and multiplied by 12 to generate yearly estimates of abortion-related complications and near-misses for the 3 provinces. Data were weighted for non-response by each stratum (level of facility) in each province and for all three provinces based on the sampling fraction achieved. We derived population estimates of women of reproductive age from the Zambia 2010 census of population and housing, by assuming that women of reproductive age constituted 45.3% of all women. We used this estimate and estimates of live births from the 2013-14 Zambia Demographic and Health Survey (ZDHS) as denominators.

We calculated the overall intra-hospital abortion-related mortality ratio, intra-hospital abortion-related near-miss morbidity ratio, hospital mortality index, abortion-related near-miss morbidity rate, and abortion-related near-miss morbidity ratio for each province and for the three provinces together (terms defined in appendix A) (93,171).

5.3 Results

Of the eligible private and public facilities, 35 (81%) agreed to participate, ranging from 63% in Lusaka to 94% in Copperbelt province. Twenty-eight (93%) of public hospitals approached participated in the study, compared with seven (54%) of private hospitals. Most of the institutions that declined participation were private district-level hospitals, and most were in Lusaka province and were reluctant to provide information they considered to have legal implications. Information was recorded on 2404 cases within the study period. Data from 12 cases were excluded because gestational age was greater than 28 weeks. An additional 14 cases (11% of the total that month) were missed, but were identified in the validation study and included in the final analysis. The cases missed included 7 low-severity admissions, 5 moderate-severity admissions, and two deaths. Table 5-2 presents the complication severity of cases included and missed in the original and validation study. Other than the severity of cases, there were

no significant differences in demographic characteristics, reproductive history and hospital management of the women missed in the original study.

Table 5-2 Comparing between the level of morbidity amongst cases in the original study and the validation study

Complication severity	Women included in both the original and validation dataset	Women included in only the original dataset	Women included in only the validation dataset	Total number of women admitted in March 2014 in validation hospital	All women in study sample
Low	32 (33%)	7 (35%)	7 (50%)	49 (37%)	1405 (58%)
Moderate	20 (21%)	4 (20%)	5 (36%)	29 (22%)	595 (25%)
Near-miss	44 (46%)	8 (40%)	0	52 (40%)	392 (16%)
Death	0	1 (5%)	2 (14%)	3 (2%)	14 (1%)
Total	**96 (100%)**	**20 (100%)**	**14 (100%)**	**130 (100%)**	**2406 (100%)**

There were 26,723 births in the study period, 791 TOPs were recorded in the hospital registers, and 5771 admissions for PAC, of which we included 2406 morbidity cases (42%) after miscarriages and TOPs. Near-miss morbidity constituted 7% of PAC admissions. Amongst all the cases in our study, majority were classified as low-severity (58%), followed by moderate (25%) and near-miss (16%). We identified 14 abortion-related maternal deaths. We did not identify any near-miss cases in the validation study. A death identified in the main study was missed in the validation study, and deaths identified in the validation study had been missed in the main study. There were no differences in demographic characteristics, reproductive history, or hospital management between missed cases identified in the validation study and cases collected prospectively.

Women in our sample ranged from 12 to 49 years of age (mean 26.7), with a mean parity of 2. Altogether, 13% (95% CI 12-14) of women reported that they were using contraception at conception and most women presented in the first trimester of pregnancy (41%, 95% CI 39-43) (Table 5-3). The proportion of women reporting a termination attempt, or in whom an attempt was identified by a clinician, was 5% (95%

CI 4-6). Majority of the women in our study (94%) received antibiotics as part of their treatment whilst 50% received intravenous fluids. 61% of women included in our study were referred to the hospitals where they received care, whilst only 2% of cases were referred outwards from these hospitals for further care. Abortion-related maternal deaths were more likely to show clinical evidence of unsafe abortion (14%) than near-miss (6%), moderate-severity (7%), or low-severity cases (4%) (p=0.004). Table 5-4 shows the conditions associated with near-miss morbidity and mortality. Many near-miss cases presented with severe anemia (44%), 24% had massive blood transfusion, 27% had hypovolemic shock, and 10% had septic shock. 66% of women counselled accepted a method of contraception.

Table 5-3 Sociodemographic and reproductive characteristics of 2406 women seeking post abortion care

	Total
Age in years Mean (95% CI)	26.7 (26.4-27.9)
Number of pregnancies Mean (range)	3 (0-15)
Number of births Mean (range)	2 (0-13)
Number of pregnancy losses Mean (range)	1 (0-7)
Reported use of contraception at time of conception Proportion (95% CI)	12.8 (11.6-14.2)
Termination attempt reported or detected Proportion (95% CI)	4.8 (4.0-5.8)
Gestational age Proportion (95% CI)	
First trimester	41.0 (39.1-43.0)
Second trimester	25.1 (23.4-26.8)
28 weeks to 28weeks 6 days	0.04 (0.02-0.08)
Missing	33.5 (31.6-35.4)
Received post abortion care family planning counseling	35 (33-37)

Proportion (95%CI)	
Had PAC counseling and accepted a method of family planning Proportion (95%CI)	66 (63-70)

**These cases were analysed as eligible cases with gestational ages less than 28 weeks, based on other clinical information on procedures used to evacuate the uterus*

Table 5-4 Clinical conditions in abortion-related near-miss cases and abortion-related deaths

Causes (Not mutually exclusive)	Near-miss (n=392) n (%)	Abortion-related death (n=14) n (%)
Severe anaemia	173 (44)	4 (29)
Massive blood transfusion	94 (24)	4 (29)
Cardiac arrest	1 (<1)	6 (43)
Hypovolemic shock	104 (26)	2 (14)
Septic shock	39 (10)	7 (50)
Oliguria	1 (<1)	3 (21)
Trauma to bowel or uterus	3 (1)	0
Generalized peritonitis	0	1 (7)

Our adapted study criteria identified considerably more near-misses (392) than the WHO criteria (115). The main difference was in the massive blood transfusion category, where our definition yielded 94 cases while the WHO definition yielded five (Table 5-5). Our anemia category identified 86 near-miss cases with a diagnosis of severe or very severe anemia and no other inclusion criteria; these cases would not have been captured by the WHO criteria. Table 5-5 compares the relationship between massive blood transfusion, as defined by our study and the WHO, and anemia severity.

Table 5-5 Overlap between blood transfusion and haemoglobin levels based on WHO near-miss criteria and Zambia study adapted criteria

	Massive blood transfusion according to WHO near-miss criteria (>=5 units of blood)	Massive blood transfusion adapted for Zambia near-miss study (>=2 units of blood)
Haemoglobin level	**n (%)**	**n (%)**
Very severe anaemia (<=4g/dl)	3 (60)	21 (22)
Severe anaemia (4.1-6.9g/dl)	0 (0)	34 (36)
Moderate anaemia (7-9.9g/dl)	2 (40)	8 (8)
Missing	0 (0)	31 (33)
Total	**5 (100)**	**94(100)**

The intra-hospital abortion-related mortality ratio was 52 per 100,000 live births, the intra-hospital abortion-related near-miss morbidity ratio was 1467 per 100,000 live births, and the mortality index was 3%. We projected the annual number of near-miss complications, taking account of facility weights within each province. We estimated the annual number of near-miss cases in the three provinces in 2014 at 1022. The rate of abortion-related near-miss morbidity was 72 per 100,000 women of reproductive age, while the abortion-related near-miss ratio was 450 per 100,000 live births (Table 5-6). Lusaka province had the highest abortion-related near-miss rate at 88 per 100,000 women of reproductive age, followed by Copperbelt province at 65, and Central province at 55 (Table 5-6).

Table 5-6 Near-miss outcome indicators by province

Location	Number of women aged 15-49, 2014[1]	Number of near-miss[2] cases, 2014	Incidence of near-miss morbidity[2] per 100,000 women of reproductive age, 2014	Number of live births, 2014[1]	Incidence of near-miss morbidity[2] per 100,000 live births, 2014
Central province	329,506	182	55	65,995	280
Copperbelt province	506,280	329	65	75,747	430
Lusaka province	575,160	509	88	83,933	610
3 provinces	**1,410,945**	**1022**	**72**	**225,674**	**450**

1 Derived from Zambian 2010 Census projections using a medium level multiplier and the Zambia 2013/14 DHS for live births
2 Near-miss consists of both near-miss and suspected near-misses within the study

5.4 Discussion

Our study showed that, despite relatively liberal laws, high numbers of abortion-related near-miss morbidities and deaths occur in Zambian hospitals. There was also a high incidence of near-miss morbidity at the population level, with the most urbanized provinces having the highest tolls. Sequelae of hemorrhage were the most frequently occurring complications in near-miss cases and deaths. There were very few cases of injuries within our sample suggesting that women are utilizing less invasive means of

unsafe abortions and/or that abortion providers are perpetuating less traumatic damage to abdominopelvic organs(150). This has implications for research trying to quantify induced abortions in Zambia. Few women reported that they have induced an abortion, and with changing patterns in morbidity as procedures become safer it is increasingly difficult to objectively identify terminations of pregnancy in health facilities.

The abortion-related near-miss rate (72) and ratio (450) in our study were higher than those estimated in most studies included in a 2012 systematic review by Adler et al (range for near-miss rate 14-121, range for near-miss ratio 91-1892), while the proportion of near-miss cases amongst all abortion-related admissions (7%) was similar to their median value (6%). Near-miss occurred most frequently in urban provinces with the highest concentration of skilled providers and health facilities. This may be because, despite the availability of health facilities, urban areas have higher population densities and may have higher abortion rates amongst women who want to meet their reproductive intentions(172,173). In this scenario poor knowledge of the abortion law(21), societal stigma around unintended pregnancy(141,174) and reluctance to provide TOPs by health facilities may predispose more Zambian women to access clandestine abortions with varying levels of safety, which may increase the risk of severe complications requiring post-abortion care (141). It may also be that women from nearby provinces travel to seek care for serious complications in the large tertiary hospitals in these provinces, either because they are referred or in the hope of better or more anonymous care.

Our abortion-related near-miss ratio appears to be consistent with estimates from recent studies. The 2013-14 ZDHS estimated the national maternal mortality ratio at 398 per 100,000 live births (95% CI, 323-474) and a 2004 systematic review estimated an obstetric near-miss ratio of 380-1090 per 100,000 live births in studies using organ dysfunction criteria (98). Abortion-related near-misses constitute a proportion of all maternal near-misses and the abortion-related near-miss ratio should be higher than abortion-related mortality ratios. Similar to observations in other studies, haemorrhage accounted for the greatest proportion of near-misses and deaths (104,115,175). In comparison with a study in South Africa by Rees and colleagues, our retrospective

validation study identified fewer cases than did prospective data collection (87). To our knowledge, no other studies of abortion-related morbidity using this methodology have attempted to assess the degree of underreporting.

Only about a third of women in our study were reported to have received post abortion contraceptive counselling. However, 66% of women counselled accepted a method. This suggests that the quality of post abortion care services provided in Zambian hospitals is low as it neglects contraceptive counselling which is an integral component of PAC. PAC provides an opportunity to provide family planning to women who most likely have an unmet need for contraception, enable them avoid repeat unintended pregnancies, and reduce the future risk of maternal ill-health or death associated with another unwanted birth or unsafe abortion.

5.4.1 Strengths of this study

We think that ours is the first hospital-based study to focus on quantifying the burden of abortion-related near-miss morbidity and to use it as a measure of unsafe abortion. A large proportion of eligible hospitals participated in our study including 50% of private hospitals which have rarely been included in such studies. We extended the PMM framework by introducing a near-miss category based on standardized WHO criteria and incorporating anaemia in all the categories. Our adaptations reflect the commonest complications of unsafe abortion and apply to low-income contexts where the burden is greatest. Although seasonal variation cannot be excluded, our study was longer (5 months) than most abortion morbidity studies (2-4 weeks), presumably improving the precision of our annual estimates (87).

5.4.2 Methodological challenges

Prospective data collection was more effective in identifying near-miss cases, which were all missed in the retrospective validation study. On the other hand, neither prospective data collection nor the retrospective validation study identified all the deaths which occurred in the largest facility in this study. Identifying abortion-related deaths was particularly challenging in tertiary hospitals as hospital records were generally poor or unavailable particularly for women who died soon after admission, death certificate registers were not always available to extract data from and the cause

of death was not always recorded as abortion on the death certificate but reported by clinical staff who remembered the patient for some of the cases included. Although deaths records were also poor in provincial and district hospitals, due to the smaller patient caseload, it was easier for clinical staff to find and identify maternal death for our study. Overall, we have most likely underestimated the numbers of abortion-related deaths occurring in hospitals during the study.

It was feasible to collect information on abortion-related near-miss from routine clinical records on a large scale using the adapted WHO criteria in a resource-poor context. The quality of our data however depended on the quality of records, which varied by type and level of facility and may have been subject to error. Due to incomplete information or unavailability of blood products, 44% of near-miss cases were initially categorized as suspected near-miss. Additionally, a third of women had missing information on their gestational age. We classified them as eligible for our study based on the basis of information from data collectors and other clinical criteria e.g. most of these cases (~77%) were managed using manual vacuum aspiration which is not recommended for pregnancies over 14 weeks. The remainder were managed using medical abortion and dilatation and evacuation (some of which may have been second trimester abortions). However, it is unlikely that many of these cases are third trimester abortions as most spontaneous and induced abortions occur before 28 weeks. We are hence certain that majority of these cases were eligible for inclusion in our analysis.

This challenge of data completeness is common in low- and middle-income country hospital records(73,106). While the influence of missing data on severity classification may not be random, it is not clear how it affects the data. On one hand, more severe cases may have poorer information recorded as staff focus more on their treatment than keeping notes. On the other hand, more severe cases may have better chart information as they stay longer in hospital with more documentation by multiple clinicians(73). One study in Nepal attempted to address the data collection challenge by classifying severity based on treatment instead of clinical signs and symptoms. The ability to classify cases was improved using this approach as there was less missing data on management in the case files(73). However, unlike in this study where

administration of IV fluids and IV antibiotics appeared to be associated with severity, these interventions were provided to majority of the women in our study. Hence we cannot use them to objectively distinguish between severity levels. A treatment based index is likely to be sensitive to clinical protocols in different health facilities and contexts, hence it is less viable as a standardized measure than a clinical sign and symptom-based index.

Whilst classifying severity during the data analyses, we discovered that the categories in our study classification study are not exhaustive, with a gap between the clinical signs and symptoms of near-miss severity and moderate severity cases. For example, a woman with systolic blood pressure consistently around between 92-98mmHg who was a few points away from the cut off for hypovolemic shock (90mmHg) and had the other diagnostic symptoms (e.g. pulse rate) consistently close to the cut-off or missing from the case file was not classified in the near-miss category. If the clinician failed to recognize her as a suspected near-miss case, and there was no information to classify her as moderate severity according to the adapted criteria, we put her in the low category. However, despite the missing information clinically it is likely that such a case may have been managed as a hypovolemic shock case and would not be considered moderate morbidity. One way to deal with this is to include a severe category similar to life threatening conditions (PLTC) group in the WHO near-miss approach to classify women whose signs and symptoms fall between the moderate and near-miss categories. This category could also replace the suspected near-miss morbidity which is subjective. To improve and standardize the categorization of abortion-related morbidity expert consensus might be required on a classification system with mutually exclusive and exhaustive categories and objective criteria for each level of morbidity. There should also be a clear protocol for handling morbidity cases with missing information.

We included the clinical and management criteria which were most relevant in Zambia, and comparable to studies conducted in neighbouring countries (106,170). Similar to recent study findings in Tanzania (106,114), the WHO massive transfusion threshold (≥5 units of blood) would have excluded many eligible women in our study because many facilities did not have adequate blood banks. Using anaemia as an indicator

improved our ability to identify near-miss cases in the context of limited blood transfusion. Haemorrhage is a major complication of unsafe abortion (169), and its degree can be proxied by anaemia criteria, more readily assessed in low-income countries. Clinical information in medical records is often incomplete and parameters to identify severe bleeding objectively and classify cases as hypovolemic shock are often not readily available. Adding anaemia severity to the near-miss criteria and other morbidity categories of the PMM provides additional value in such contexts.

Setting a suitable cut-off for anaemia within the near-miss category and other morbidity levels is challenging. In this study since we analysed both near-miss and suspected near-miss cases as near-misses, we ultimately included three categories of women as near-miss anaemia cases. From table A1, the three categories were: women who survived with less than 4g/dl of haemoglobin; women with haemoglobin less than 7g/dl who any blood transfusion, and women with haemoglobin between 4 and 7g/dl regardless of whether they received blood. In summary, we included women with haemoglobin less than 7g/dl regardless of whether they received blood or not. A study in Malawi used a haemoglobin level below 6g/dl after vaginal bleeding in its near-miss criteria(109). The cut-off for severe anaemia based on the WHO categorization of anaemia severity in pregnant women is 7g/dl (168). However, this level of haemoglobin may be too high for a stringent near-miss classification in which near-misses can only survive due to hospital intervention and aimed at providing population representative estimates and for monitoring and evaluation.

Other limitations include the higher proportion of public than private hospitals that participated, which might limit generalizability. We did not collect data on all women admitted with abortion complications and, despite efforts to ensure the eligibility criteria were applied correctly, we may have missed some cases. However, we screened hospital logbooks during supervision visits to identify missed cases and relevant data were retrieved if found. Although we collected information on referral to and from facilities, we treated each entrance to a health facility as a discrete case. Only 2% of cases were referred elsewhere and it is unlikely that double-counting was substantial.

5.5 Conclusions

The frequency of abortion-related near-miss morbidity and mortality suggests that access to abortion services in Zambia remains poor despite the favourable liberal abortion law. Although collecting comprehensive and representative data on abortion-related mortality is difficult, it was feasible to identify abortion-related near-miss cases, which are a useful indicator of the most unsafe abortions and a proxy for mortality. With reasonable adaptation, the WHO criteria can be applied to routine hospital records to obtain useful data. We recommend lowering the threshold for blood transfusion, incorporating severe anaemia, and providing a standardized definition of septic shock to reflect the capabilities of health systems in low-resource contexts and to adequately capture the commonest causes of near-miss morbidity and mortality. We also recommend the development of standardized, clearly defined classification criteria to improve the classification of hospitalizations for abortion-related complications. To reduce avoidable maternal mortality and morbidity due to abortion, there is a need for concerted efforts to make women aware of the legal status of abortion and to de-stigmatize service provision and access. In addition, expanded access to modern contraceptives is essential to reduce unmet need and the occurrence of unintended pregnancies.

Details of ethics approval

The University of Zambia Biomedical Research Ethics Committee (UNZBREC) reviewed and approved the study on 3 September 2013 (protocol ID:016-04-13), the Population Council IRB on 16 January 2013 (protocol ID: 582), and the London School of Hygiene and Tropical Medicine Research Ethics Committee on 16 August 2013 (protocol ID: 6407). Ethics review authorities in two of the participating private hospitals independently reviewed and approved the study. Individual written consent was not required as no women or medical personnel were interviewed and data were extracted solely from hospital records.

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Disclosure of interests

None declared.

Contribution to authorship

VF conceived the study with input from JC and OO. OO designed the data collection tools and managed the fieldwork for the study with input from BV. OO conducted the data analysis and drafted the report, with substantial contributions from JC, BV, DO, and VF. OO, JC, BV, DO, and VF reviewed the draft manuscript for intellectual content and approved the final manuscript for publication.

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Appendix A: Definition of terms

Abortion: "Termination of pregnancy, expulsion of embryo/foetus before viability". The date of viability in Zambia is 28 weeks [20].

Maternal near-miss: A woman who nearly died, but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy (93)·(93)·

Abortion-related near-miss: A maternal near-miss case that occurs due to miscarriage or termination of pregnancy.

Maternal death: Death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes (ICD-10)(93)·

Abortion-related maternal death: Maternal death due to miscarriage or termination of pregnancy.

Live Birth (LB): Birth of an offspring who breathes or shows evidence of life [26]·

Woman of reproductive age (WRA): Woman aged 15 to 49.

Abortion-related near-miss ratio: Number of abortion-related near-miss cases per 100,000 live births. This indicator gives an estimate of the amount of care and resources that would be needed in an area or facility.

Abortion-related near-miss rate: Number of abortion-related near-miss cases per 100,000 women of reproductive age.

Intra-hospital abortion-related near-miss ratio: Number of abortion-related near-miss cases that occur in hospitals, per 100,000 live births.

Intra-hospital abortion-related mortality ratio: Number of abortion-related maternal deaths that occur in hospitals, per 100,000 live births.

Intra-hospital abortion-related mortality ratio: Number of abortion-related maternal deaths that occur in hospitals, per 100,000 live births.

Intra-hospital mortality index: Number of maternal deaths in hospitals divided by the number of women with life-threatening conditions in hospitals (i.e. maternal near-miss cases plus maternal deaths) expressed as a percentage. The higher the index, the more women with life-threatening conditions who die: an indicator of quality of care (93).

Appendix B: Description of the pilot study

The pilot was conducted by OO in October 2012. Data was extracted from 122 patient files at the largest public tertiary hospital in Zambia providing PAC and from 11 patient files at a private hospital. Thereafter OO analyzed the pilot data and amended the tool accordingly.

71% of cases were low severity, 20% moderate, 4% near-miss and 5% (N=6) suspected near-misses.

The suspected near-miss cases included:

2 women who were clinically managed as shock but had a pulse rate or blood pressure reading missing from the case files for the duration of admission. Hence we could not objectively use the study definition of shock.

4 women who were transfused with a unit of blood, had clinical signs of anaemia-pallor, cold extremities, were admitted for more than 24 hours but did not have pulse rates, blood pressures or haemoglobin measurements recorded in their case files.

After the pilot, we removed some questions which were usually unavailable in case files from the form. These included: woman's occupation, date of termination if abortion was induced, time of post abortion care procedure performed and time of discharge.

We also revised the massive blood transfusion criteria to >= 2 units of blood and introduced a suspected near-miss category to accommodate clinically severe cases with incomplete information in case-files. These included:

Cases managed as near-miss cases with organ compromise (manged as hypovolemic or septic shock, but with incomplete clinical signs in case file and perceived the clinicians in the hospital to be a near-miss)

Women who received a unit of blood with insufficient additional information (haemoglobin level, pulse rate and blood pressure) in the case file to classify them objectively as having severe anaemia or shock.

Women who fell within the criteria for severe anaemia according to the WHO (between 4-6.9g/dl) who were not transfused with blood even when it was requested by the managing clinician

These criteria were discussed with our local investigator BV who is the head of the obstetrics and Gynaecology department at the largest tertiary hospital in Zambia and has extensive experience practicing in rural areas in Zambia. They were also discussed with doctors, nurse midwives and clinical officers during the data collectors training and there is consensus that these cases count as near-misses.