

Chapter 2. Defining and measuring unsafe abortion

There is substantial social and political sensitivity around the topic of induced abortion, making research, monitoring and evaluation, and advocacy on the topic challenging. In this chapter, I first provide definitions of abortion-related terms relevant to this thesis, and continue with a brief historical overview of how the current WHO definition of unsafe abortion was developed, the challenges of using this definition for measurement, and how its interpretation has evolved. I then discuss the impact of increased access to MA on quantifying the burden of unsafe abortion, describe the commonly-measured indicators of unsafe abortion in high-burden contexts, and outline the limitations of methods used to measure them. For each indicator, I explore ways of improving its measurement. Finally, I briefly explore recent research on improving the definition and measurement of unsafe abortion.

2.1 Definition of terms

An abortion is defined as the loss of pregnancy before foetal viability i.e. before a foetus becomes capable of independent extra-uterine life (22).

An induced abortion, also known as a termination of pregnancy, is an abortion initiated by deliberate action undertaken with the intent of terminating pregnancy (22).

A spontaneous abortion is one which is not induced, even if an external cause is involved such as trauma or communicable disease (22).

An unsafe abortion is defined by the WHO as *“the termination of an unintended pregnancy either by persons lacking the necessary skills or in an environment lacking the minimum medical standards or both.”* (23)

“The persons, skills and medical standards considered safe in the provision of abortion are different for medical and surgical abortion and also depend on the duration of the pregnancy. What is considered ‘safe’ should be interpreted in line with current WHO technical and policy guidance.” (24)

2.2 The evolution of the WHO definition of unsafe abortion

In the late 1980s, research into morbidity and mortality associated with abortions obtained in precarious situations focused on quantifying and reducing illegal abortions (25). This was probably due to an observed correlation between restrictive abortion laws and the large number of morbidity and mortality events in such contexts. Countries considered to have restrictive laws, also commonly described as countries where abortion is “illegal”, are those where abortion is prohibited altogether or permitted only to save a woman’s life. This description currently applies to 66 countries, the majority of which are in the global south (26). In 1997 there were 54 such countries (27).

In 1992 a WHO technical working group of experts discussed the need to focus on the safety of abortion services rather than the legality of abortion. They used the term “unsafe abortion” in their report, published in 1993, concluding that legality or illegality of services may not be the defining factor of abortion safety. They stated that the safety of abortion encompasses both *“elective induced abortions and the treatment of spontaneous or incomplete abortions”* (23). Research conducted before this consultation supported the shift from legality to safety because of the many challenges raised in identifying and quantifying illegal abortions (25). Also, even in countries with liberal abortion laws, the societal context or health system challenges may convince women to resort to unsafe abortions (28,29). The WHO working group described in greater detail the characteristics of unsafe abortions that are included in the frequently-quoted definition, such as absent or inadequate provider skills, hazardous techniques and unsanitary facilities. Since the publication of their report, the language and focus of research has firmly shifted from the legality of abortions to the concept of abortion safety (23).

2.3 Inconsistencies between the wording of the WHO definition of unsafe abortion and the way it has been used to generate estimates

Between 1992 and 2014, the definition of unsafe abortion that had emerged from the working group consultation began to be operationalized for the epidemiological measurement of unsafe abortion and its sequelae. In most countries, research

describing the burden of unsafe abortion has focused on estimating the national incidence of induced abortion (30–34) and/or the number of women hospitalized for abortion-related complications (35–38). No national studies have reported on the incidence of unsafe abortion itself. Global estimates have reported on global and regional numbers and incidence of unsafe and induced abortions, hospitalizations for abortion-related complications and the proportion of unsafe abortions out of all induced abortions (5,6,39). In the following paragraphs, I will discuss two important discrepancies between how the WHO definition is worded and how it has been practically applied to measure the global burden of unsafe abortion.

First, abortion safety has typically been conceptualized from a biomedical (clinical and public health) perspective, and the WHO definition of safety is a process-oriented one. In reality, most induced abortions in restrictive contexts are unreported or underreported in surveys and medical records (5,25,40). Hence, it is not usually feasible to verify the process (standards of clinical care) under which the majority were performed to identify what was unsafe. National and global indicators are usually generated using health facility-based outcome data on admissions for all abortion-related complications. These data are adjusted to derive indicators such as incidence of hospitalizations due to induced abortions and the incidence of induced abortions within a country. The most frequently used approach to adjust health facility data involves applying a multiplier. This is usually calculated using data from interviews aimed at understanding the process of abortion from experts who are knowledgeable about abortion in a context. They are asked a series of questions to estimate the proportion of induced abortions that result in complications but do not receive care in health facilities. However, majority of experts that have been interviewed in studies are experienced health professionals who are most likely drawing on their clinical experiences with patients to extrapolate how women are obtaining abortions(31,32,34). Hence their perspectives are more likely to be related to changing patterns in hospitalization and not on first-hand knowledge of how women procure abortions. National estimates of the incidence of induced abortions obtained after applying the multiplier to health facility data are then incorporated into global estimates of induced and unsafe abortion. Thus, in practice, data on the health

outcomes of an unsafe abortion process (morbidity and mortality) provide the basis for estimates meant to represent the process of all unsafe and all induced abortions.

Second, to arrive at the global incidence of unsafe abortions, abortions have usually been classified into safe or unsafe, largely based on the legality of abortion in a country despite the caveat provided by the technical group. In global estimates calculated since 1992 (5,16,39), all illegal abortions are assumed to be unsafe, even if in practice clinically safe technologies for abortion are readily available and performed by practitioners with relevant clinical training. This is the case, for example, in Latin America where MA has been reported to be widely available since the 1990s; or in Nigeria where, despite legal restrictions, interventions to train private sector providers in abortion care have been successful, leading to substantial uptake of these services by women and subsequent good health outcomes (41). One explanation for the assumption that all illegal abortions are unsafe is that the clandestine nature of illegal abortion is likely to be associated with reduced access to emergency care, predisposing women to greater health risk (42). It is also the case that using legality to classify contexts as safe and unsafe is easier for generating global estimates than attempting to analyse the unique situation of each country (24). Indeed a 2010 paper by WHO researchers indicates that *“operationally estimates of induced abortion are intended to capture abortions that carry greater health risks than those carried out for officially accepted reasons under the laws of the country concerned”* (43). The exception to this blanket rule in global estimates is that in countries where the laws are liberal and there is empirical evidence of both safe and unsafe abortions such as Nepal, India, Cambodia, South Africa and Ethiopia, the numbers of both types of abortions have been estimated (5).

This dichotomization of safety into two broad groups (safe and unsafe) fails to acknowledge that induced abortions occur on a multidimensional scale of resources, methods and skills (42). Whilst the legal context has a great impact on abortion provision and access within the formal healthcare system (2, 20, 21), countries differ in the de-facto application of the law. Moreover, it ignores the importance of other factors such as the enforcement of the law, social stigma associated with induced abortion, strength of the health system and quality of care provided, and status of

women. The prevalent clinical practice in each context influences the probability that induced abortion cases will develop severe complications and/or access post abortion care services. Hence, global estimates of unsafe abortion where all legal abortions are classified as safe and non-legal abortions as unsafe(22) are inaccurate as abortion practice and outcomes are not uniform in similar legal contexts.

2.4 Recent updates on how the WHO definition of unsafe abortion should be interpreted

A publication by WHO officers in 2014(24) was intended to correct the inconsistent interpretation of their definition, and to discuss how it could be operationalized for measurement. It emphasized that technical guidelines on the safe provision of abortion care are evolving and that the conceptual definition should be accompanied by this explanatory note: *“The persons, skills and medical standards considered safe in the provision of abortion are different for medical and surgical abortion and also depend on the duration of the pregnancy. What is considered “safe” should be interpreted in line with current WHO technical and policy guidance.”* Table 2-1 describes the current standards of care for safe abortions using different methods and at various gestational ages according to WHO. However, these WHO guidelines do not provide recommendations for second trimester post abortion care (PAC), and there is a lack of high quality, comparable data within published literature on this aspect of care (44).

The publication also discussed the limitations of dichotomizing safety since risk occurs across a continuum. It ultimately proposed that a multidimensional approach to assessing risk and determining the safety of induced abortion should be developed. This might include immediate determinants such as method of termination used and gestational age, and underlying social determinants such as legal context, service availability, level of stigma, women’s access to information on abortion, and women’s age and socioeconomic status. The proposed multidimensional approach to safety may expand the definition from one with a biomedical focus to one that importantly incorporates women’s views on what a safe abortion is. For example, the most critical components of a safe abortion for Kenyan women , as highlighted in a 2015 paper by Izugbara et al, could be the confidentiality offered by providers and affordability (45).

While this amendment helped to clarify how WHO envisions the interpretation of the definition of an unsafe abortion for research, it does not clearly outline how safety will be measured in light of the process versus outcome discussion. This is important in an era of increased access to MA and will be discussed in the next section. Additionally, since guidelines and their application are evolving, estimates of unsafe abortions generated during different periods of time and in different contexts may have different meaning and implications. It will be important to monitor and account for this in future estimates.

Table 2-1: Summary of WHO evidence-based standards-of-care for safe abortion care provision

Type of procedure	Gestational age	Surgical abortion	Medical abortion	Anticipated complication rates for procedures
<p>Termination of pregnancy</p>	<p>Up to 9 weeks</p>	<p>Vacuum aspiration</p>	<p>Mifepristone (200mg). After 24-48 hours, 800 mcg misoprostol buccally, sublingually or vaginally for one dose</p> <p>OR</p> <p>800ug misoprostol administered vaginally or sublingually. Up to 3 repeat doses can be administered at 3 hour intervals but no longer than 12 hours</p>	<p>a. <u>Abortion not completed (Mifepristone and Prostaglandin compared with vacuum aspiration)</u>¹</p> <p>Moderate.* RR (95% CI): 2.12 (0.37 to 12.06)</p> <p>b. <u>Blood transfusion (Vacuum aspiration compared with dilatation and curettage)</u>²</p> <p>Moderate.* RR (95% CI): 0.21 (0.01 to 4.12)</p>
	<p>9-12 weeks</p>	<p>Vacuum aspiration</p>	<p>Mifepristone (200mg). After 36-48 hours, 800 mcg misoprostol vaginally followed by 400 mcg vaginally or sublingually every 3 hours for a maximum of 5 doses of misoprostol</p> <p>OR</p>	<p>c. <u>Repeat uterine evacuation (Vacuum aspiration compared with dilatation and curettage)</u>²</p> <p>Low.* RR (95% CI): 0.67 (0.11 to 3.95)</p>

			800ug of misoprostol administered vaginally or sublingually. Up to 3 repeat doses can be administered at 3 hour intervals but no longer than 12 hours	
	Above 12-14 weeks	Dilatation and evacuation. This should be preceded by cervical preparation.	Mifepristone (200mg). After 36-48 hours, 400 mcg misoprostol orally or 800 mcg vaginally followed by 400 mcg vaginally or sublingually every 3 hours for a maximum of 5 doses of misoprostol, administered in a healthcare facility OR 400ug of misoprostol administered vaginally or sublingually repeated every 3 hours for up to 5 doses	<p>a. <u>Additional curettage required to complete evacuation (Dilatation and evacuation compared with Mifepristone and Misoprostol)</u>³</p> <p>Low.* RR (95% CI): 0.06 (0 to 1.43)</p> <p>b. <u>Bleeding requiring a transfusion (Dilatation and evacuation compared with Prostaglandin F2 alpha)</u>³</p> <p>Low.* RR (95% CI): 0.17 (0.01 to 3.6)</p>

<p>Management of incomplete abortion</p>	<p><13 weeks</p>	<p>Vacuum aspiration</p>	<p>600mcg single oral dose of Misoprostol or 400mcg single dose sublingually</p>	<p>a. <u>Death (misoprostol compared with expectant management)</u>⁴</p> <p>Very low.* RR (95% CI): 2.91 (0.12 to 70.05)</p> <p>b. <u>Death (misoprostol compared with surgery)</u>⁴</p> <p>Very low.* RR (95% CI): 1.00 (0.04 to 22.64)</p> <p>c. <u>Blood transfusion (misoprostol compared with expectant care)</u>⁴</p> <p>Very low.* RR (95% CI): 3.07 (0.13 to 74.28)</p> <p>d. <u>Blood transfusion (misoprostol compared with surgery)</u>⁴</p> <p>Very low.* RR (95% CI): 1.73 (0.19 to 16.08)</p> <p>e. <u>Need for subsequent surgical evacuation (misoprostol compared with expectant management)</u>⁴</p> <p>Low.* RR (95% CI): 0.62 (0.17 to 2.26)</p>
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Care preceding abortion	<p>All women having a surgical abortion should receive prophylactic antibiotics.</p> <p>All women should be routinely offered pain medication during medical and surgical abortions</p>
Care post abortion	<p>Contraceptive counselling and commodities should be provided to all women after abortion</p> <p>There is no medical need for a routine follow-up visit following uncomplicated surgical abortion or medical abortion using mifepristone followed by misoprostol. However, women should be advised that additional services are available to them if needed or desired.</p>

Adapted from World Health Organization. (2012). *Safe abortion: technical and policy guidance for health systems*. WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland: World Health Organization. Retrieved from http://apps.who.int/iris/bitstream/10665/70914/1/9789241548434_eng.pdf

*Grading of risk (very low, low, moderate) is according to the World Health Organization evidence GRADE criteria informing the technical guidance document (http://apps.who.int/iris/bitstream/10665/75840/1/WHO_RHR_12.10_eng.pdf?ua=1)

1. Say L et al. Medical versus surgical methods for first trimester termination of pregnancy. *Cochrane Database of Systematic Reviews*, 2005, (1):CD003037 updated 2010.
2. Kulier R et al. Surgical methods for first trimester termination of pregnancy. *Cochrane Database of Systematic Reviews*, 2001, (4):CD002900.
3. Lohr PA, Hayes JL, Gemzell-Danielsson K. Surgical versus medical methods for second trimester induced abortion. *Cochrane Database of Systematic Reviews*, 2008, (1):CD00671

2.5 Medical abortion, its impact on how women access abortions, and on the definition and measurement of unsafe abortion.

Medical abortion (MA) is the use of medication instead of surgical methods to terminate pregnancies. In the past, most unsafe abortions tended to be invasive, frequently resulting in clinically severe morbidity or death (16). These methods included the insertion of sharp objects by women, traditional practitioners, or non-qualified workers in health facilities and poorly conducted procedures with sharp equipment such as curettes by medical providers. However the use of MA, which is a much safer method for clandestine pregnancy terminations, is increasing in restrictive contexts (46). Whilst this usually heralds improved abortion outcomes for women(47), it generates more challenges for the measurement of the burden of unsafe abortions as mentioned in the introduction.

The pharmacological agents most often used for MA are misoprostol alone or in combination with mifepristone (Table 2-1). Others that can be used include approved agents like methotrexate (in combination with misoprostol), and gemeprost (in combination with mifepristone). There are also agents used to stimulate uterine contraction but with limited safety information, such as intra-amniotic hypertonic saline or hyperosmolar urea, ethacridine lactate, oxytocin and other prostaglandin analogues (48).

Misoprostol is a prostaglandin E1 analogue that was initially registered in many countries for the treatment of gastric ulcers caused by non-steroidal anti-inflammatory drugs in the late 1980s (49). Following its registration, it was realized by clinicians and pharmacists that its side effects made it highly effective for inducing abortions and in many Latin American countries it was frequently used to terminate pregnancies illegally (50,51). It is particularly appropriate for use in low- and middle-income countries, because it is inexpensive, easy to use and heat stable. Mifepristone blocks the action of progesterone on the uterus and was initially approved for use as an abortifacient in China and France in 1988 (52,53). However, it is expensive and needs to be used in combination with misoprostol to induce an abortion. Misoprostol is less effective alone

as a MA drug (73-95%) than in combination with mifepristone (94-97%)(54). In 2005, WHO included misoprostol and mifepristone in the essential drug list for the induction of labour and abortion (14). This was a step towards facilitating the registration of these drugs in low- and middle-income countries. However, as of 2015, mifepristone was only registered in 61 countries (55), and in 2012 misoprostol was registered in over 90 countries (53).

Clinically, a MA induced using optimally-prescribed misoprostol and mifepristone (Table 2-1) is not distinguishable from a spontaneous abortion (56); both are usually accompanied by uterine cramps and prolonged menstrual-like bleeding. Side effects of MA drugs include nausea, vomiting, diarrhoea, fever, incomplete abortion, haemorrhage and, very rarely, infection. If the termination fails, there is a risk of congenital abnormalities in the foetus associated with misoprostol use in early pregnancy (57,58). The absolute risk of abnormalities after misoprostol exposure is estimated to be approximately 1% (59). Evidence from studies among women and providers suggests that in restrictive contexts, the private sector and black markets play a significant role in providing women with access to MA (60–62). Within the private sector, private pharmacies and drug stores, which are often poorly regulated, are the most important sources of MA drugs for women seeking to terminate pregnancies (63).

Increasing self-use of MA is likely to *“temporarily increase and/or ultimately decrease estimates of indicators of the burden of unsafe abortion”* (64). Studies on abortion-related morbidity and mortality from Latin American countries where misoprostol has been available over the counter in pharmacies since the early 1990s suggest that, overall, increased use of MA reduces the proportion of severe abortion-related complications observed in hospital admissions. This phenomenon occurs even when the abortion is accessed illegally and/or the quality of provider information on how to take the drugs is suboptimal (50,65,66). However, the extent of MA use is unknown and attempts at clarification include interviews with women and/or providers, mystery client studies and wholesale data from the national level. It is, however, difficult to link pharmacy and mystery client interview data to individual women, which is necessary to ascertain the number of women unsafely terminating pregnancies using MA and the outcomes of such termination in restrictive contexts.

In an evolving abortion provision context, estimating the burden of unsafe medical abortions using the process-based WHO definition is even more challenging than for surgical procedures. Within the definition and its accompanying guidelines there is still a lack of clarity on the description of the appropriate provider for MA i.e. “*person lacking the necessary skills*” since women can self-administer MA drugs safely at home. In July 2015, WHO recommendations pertaining to provision of safe abortion care by different cadres included ‘women at home’ as a category of safe MA providers in the first trimester. However, the recommendation adds a proviso for this category, “*in contexts where the woman has access to appropriate information and to health services should she need or want them at any stage of the process*”(15). It is not clear what is meant by “context” in this recommendation. However, if the woman’s context is interpreted as her country of residence, as is usual in global estimates, the classification of safe MA contexts for self-administration as outlined becomes complicated. Access to appropriate information and health services is likely to differ by sociodemographic characteristics such as age, education, economic status, and place of residence. Hence, according to the WHO description, it is unlikely that many restrictive contexts would meet the criteria for women to be considered safe MA providers at the national level. This is similar to the problem of classifying induced abortions in countries as safe/unsafe on the basis of legality where laws may be theoretically similar, but the reality varies considerably and actually determines access to safe abortions.

Another challenge is that of collecting data on the safety of the MA process from women or providers. In practice, MA drugs can be procured by women from many sources (legal and illegal) who keep only limited records. Women can deny usage, and there is no readily available laboratory means of confirming use for measurement purposes. Thus, using MA, women can terminate pregnancies successfully at home, or commence the process and seek hospital admission for unsuccessful terminations or ongoing abortions whilst pretending they are spontaneous abortions (56). Since research shows that women underreport their induced abortions when asked directly (67), it is also unlikely that the process of an unsafe MA can be reliably estimated from asking women retrospective survey questions.

On the other hand, hospital studies from Latin America, where abortion laws are fairly restrictive but misoprostol has been readily available for many years, suggest that health facility outcome data remains exploitable for women who obtain unsafe MAs. These studies suggest that there are still a substantial number of admissions for abortion-related outcomes from hospital data (50,65,68,69). However, there are changes in overall patterns of admission with a reduction in the number of severe abortion-related complications admitted over time. It is important to note that whilst outcome data will be more readily available, because of the similarities in presentation, it will be more challenging to distinguish between medically induced unsafe abortions and spontaneous abortions from individual health facility records. There is therefore a need for additional research to understand how the increasing use of MA may affect patterns of hospitalization for morbidity and mortality in contexts other than Latin America. This will enable us to make the best use of readily available outcome-data to generate abortion estimates in evolving abortion contexts.

2.6 Indicators and methodological approaches frequently used to measure the burden of unsafe abortion in restrictive contexts

As a result of methodological challenges to identifying and quantifying unsafe abortion (9,42), all approaches used to estimate the burden of unsafe abortions are subject to error such as systematic misclassification (13,70). Due to the lack, or questionable quality, of data in restrictive contexts, approaches where women are not asked direct questions about their abortion experiences are most frequently employed. The most common indicators measured are:

- I. The number/rate of hospitalizations for abortion-related complications (all complications or complications due to induced abortions)
- II. The incidence rate/ratio of induced abortions.

Complications (morbidity and mortality) are outcome-based indicators, while the incidence of induced abortions conceptually incorporates process and outcomes. Whilst in reality, induced abortions consist of both safe and unsafe abortions, there has been only one national study providing estimates of the incidence of unsafe and safe abortions (Singh et al 2010)(71)(31). However, safe/unsafe is confounded with

legal/illegal abortions in this study. Usually, studies in restrictive contexts measure this indicator to describe the extent of need for abortion services within the country and to show how many women are at risk of unsafe abortions. Rates are usually presented per 1000 women of reproductive age and ratios per 100 live births.

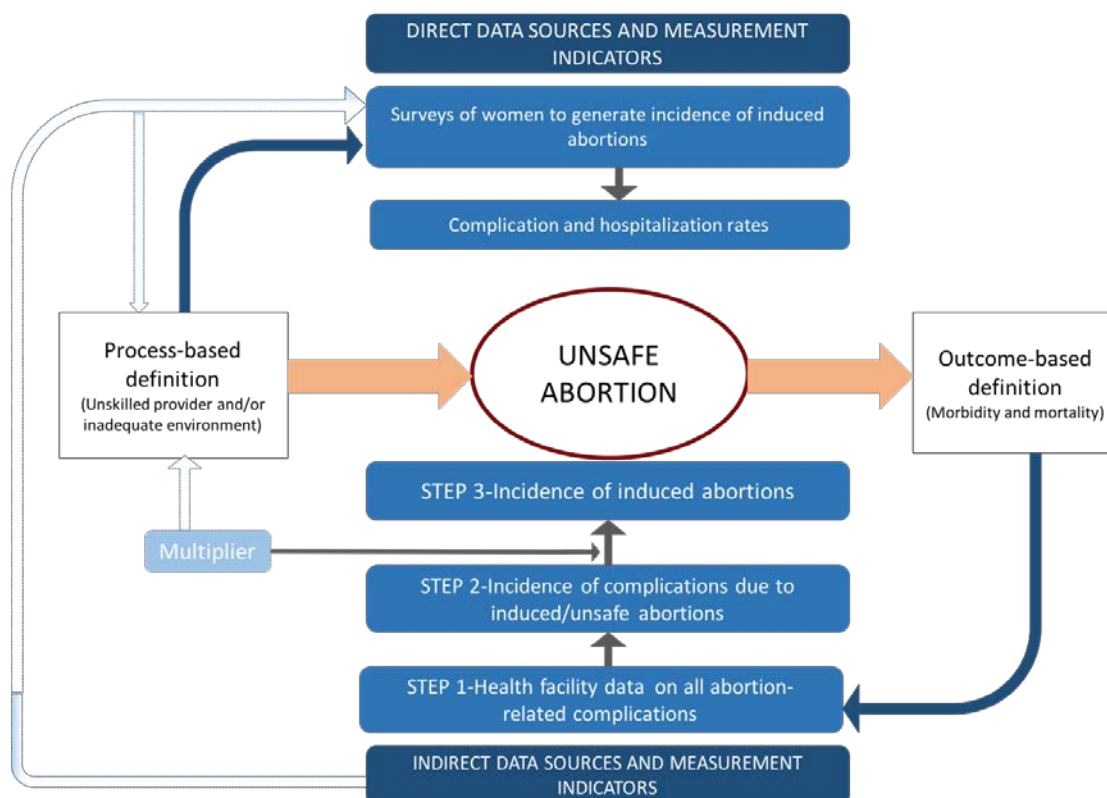
2.6.1 Data sources

The major sources of data used to estimate these indicators are registers and medical records in health facilities. Surveys among women have been conducted less frequently for reasons highlighted above. Data from health facilities include details of all admissions for abortion-related complications including morbidity and mortality due to both spontaneous and induced abortions. These data are typically adjusted to estimate the number of abortion-related complications due to induced (often assumed to be unsafely induced) abortions by estimating and subtracting the number of miscarriages. To extrapolate the number of induced abortions in the population, the estimated number of hospitalizations due to induced abortions is adjusted to account for those unsafe procedures not identified in the health facility data.

When survey data are collected, a direct approach to interviewing women about their own abortions is most often used (42). This information can be used to estimate many of the indicators of the burden of unsafe abortion that are measured using hospital data. However, survey data can also be an indirect data source when the survey methodology is used to collect data from the respondent about abortions other women have obtained.

Figure 2-1 shows how unsafe abortions can be defined based on processes or outcomes, and how these are connected to direct and indirect approaches to measurement. It highlights the two major sources of data for each approach discussed above, shows how surveys may also be an indirect approach to measurement and summarizes how the data collected are used to generate the common indicators of the burden of unsafe abortion.

Figure 2-1 Approaches to defining unsafe abortion, and the common data sources and indicators for measurement



Subsequent sections will describe the data sources and common indicator(s) at each step of “indirect data sources and measurement indicators” within. Figure 2-1 and propose measures to improve the use of data from indirect approaches to estimate indicators of the burden of unsafe abortion.

2.6.1.1 STEP 1- Health facility data on all abortion-related complications

The most common indicators derived from these data include: (i) annual number of women with abortion complications treated in health facilities and (ii) incidence rate/ratio of abortion complications in health facilities. Others include the proportion of high-severity, moderate-severity or low severity complications and case fatality rate for complications in hospital.

The major limitation of the data and these estimates is that they do not capture all the morbidity and mortality in the general population as legal, geographical and social barriers restrict women’s access to and use of healthcare for abortion-related complications (15, 16). Additionally, cases may go undetected if women are admitted

outside obstetrics/gynaecology departments; for example, in outpatient or emergency departments or in private wards, and data collection systems are not put in place to capture their details. Hence, abortion morbidity and mortality data collected on all complications within facilities and the indicators listed are often not representative of real experience in the catchment community (72). Another important factor to consider is that because the number of admissions for abortion-related complications is affected by changes in access to safe abortion methods, changes in access to and use of health facility care by women, and quality of healthcare, it can be difficult to compare this indicator over time in one context and also between different contexts.

However, data on all morbidity in health facilities still have important uses. One such use is to track changes in abortion-related outcomes after the introduction of laws, regulations or policies that affect the safety of abortion within a specific context. Routine country-level health facility data or data from high-level hospitals with large catchment populations can yield valuable historical/trend information on unsafe abortion outcomes and how they have changed with contextual events (73). Data on the number of women hospitalised for abortion-related complications are particularly easy to collect from facilities or Ministries of Health compared with hospital studies on morbidity, which require more detailed data collection from patient records or community surveys. Despite their limitations, these data can be used to investigate the immediate or long-term consequences of policy changes, which are hard to evaluate via other rigorous means such as randomized trials. A few studies exploring the association between legislative changes and changes in levels of abortion-related morbidity and mortality in hospital admissions have been conducted in Nepal (73,74), Ethiopia (75), South Africa (76,77), Dominican Republic (65), Iran (78) and Brazil (69). Only the study in Nepal used a rigorous quasi-experimental time series design to evaluate the effect of legislative change on abortion-related admissions. The others have used a before and after approach (75,77,78) or simply described numbers hospitalized over time (65,69). A before and after approach does not account for natural trends over time that may explain differences in the outcome of interest other than the policy or intervention being examined. Additionally, there may be regular fluctuations in the outcome independent of other factors due to seasonality which can

obscure the effect of an intervention/policy (79). Time-series analysis provides the opportunity to explore changes in trends for abortion-related outcomes following a defined contextual event whilst controlling for the biases encountered with statistical analyses that do not account for the nature of longitudinal data (79). Nevertheless, causal links between changes in trends and contextual changes cannot be inferred from these methods. Since greater access to safe abortion is often preceded by an event such as legal/policy change, improvement in the health systems capability, or approval of MA, the availability of hospital data on abortion-related outcomes is an opportunity to start to understand which systemic-level changes improve outcomes for women.

2.6.1.2 STEP 2- Abortion-related complications due to induced/unsafe abortions

The true cases of interest are complications due to unsafely induced abortions. Indicators that extrapolate complications due to induced abortions from primary hospitalisation data include the annual number of women with abortion complications due to induced abortions treated in health facilities and the incidence rate of induced abortion complications in health facilities. The latter indicator has also been described as the incidence rate of unsafe abortions (instead of induced)(6) on the basis that they are most likely to be the result of unsafe abortions if the woman requires hospitalisation.

Abortion-related mortality has been the adverse outcome of greatest interest for highlighting the health burden of unsafe abortions. Objectively, an abortion-related death is most likely to occur after an unsafe abortion (80,81). However, compared with abortion-related morbidity, mortality has a low incidence at sub-regional levels and within individual hospitals. Its relative rarity limits its practicality for tracking changes and the impact of interventions over time, or for understanding common deficiencies in clinical care and other determinants. Moreover, abortion deaths are reported to be the most substantially underestimated cause of maternal death (7, 17). For example, according to research using multiple bias analysis to quantify systematic error in the estimation of abortion-related mortality, deaths may be underestimated by as much as a factor of eight (82).

Research suggests that there is a substantial but poorly quantified burden of abortion morbidity for every abortion death that occurs (10,83). A 2012 systematic review by Adler et al, estimates 4195 morbidities per 100,000 live births (range 1667-10,335) in countries where abortion is considered unsafe compared with abortion-related mortality ratios of 37 and 12 per 100,000 live births in Africa and South Asia respectively (10). However, it is challenging to accurately distinguish between complications caused by induced and spontaneous abortions, which can also lead to biased estimates (67).

Methods proposed to perform this task have many limitations. The WHO Figa-Talamanca methodology, developed in 1986, attempted to classify post-abortion cases into induced (certainly induced, probably induced or possibly induced) or spontaneous cases using the clinical criteria shown in Table 2-2 (25). These criteria comprise details that should be easy to obtain from medical records.

Table 2-2 WHO Figa-Talamanca criteria used for reclassification of abortion cases

	Criteria	Certainly induced abortion	Probably induced abortion	Possibly induced abortion	Spontaneous
1	Woman’s statement that she had an induced abortion	Classify in this category if (1) OR (2) OR (3) is present	Not present	Not present	Not present
2	Health worker or relative’s statement if woman died due to abortion		Not present	Not present	Not present
3	Evidence of genital trauma or foreign body		Not present	Not present	Not present
4	Sepsis or peritonitis or admission thereafter	This criterion may be present or not present	Classify in this category if criteria (4) AND (5) are present	Classify in this category if criteria (4) OR (5) is present	Not present
5	Pregnancy unplanned (use of contraception during the cycle of conception)	This criterion may be present or not present		Classify in this category if criteria (4) OR (5) is present	Not present

Source Figa-Talamanca et al. (1986)(25).

Its limitations include poor definition of clinical criteria, unclear distinction between the real meaning of the probable and possible categories of induced abortion (42), and the use of contraceptive status before the index abortion as the sole marker of pregnancy intention. Pregnancy intention is a complex concept that cannot be solely captured by use of contraceptive at the time of conception (84,85). Contraceptive use is affected by many factors. In contexts where contraceptive prevalence is low for access or socio-cultural reasons, and unmet need is high, many women do not intend to conceive but do not use contraception. Furthermore, unplanned or unintended pregnancies can abort spontaneously (86).

A subsequent study attempting to validate the Figa-Talamanca criteria suggests that they underestimate levels of unsafe induced abortion (86). Amongst those women who had clinical evidence of having induced an abortion (N=38), only 5% declared they had induced an abortion. Additionally, amongst those women who reported having an abortion (N=27), the majority (95%) had no clinical evidence of doing so and were classified as low morbidity. This suggests that many women who had undergone induced abortions were missed using this classification. It also implies that the probably and possibly induced abortion categories are likely to underestimate women with induced abortions as the majority of women identified as having obtained an abortion had no signs of infection.

Rees et al. proposed refining the methodology by shifting away from a focus on induced abortions and classifying post-abortion cases into low, moderate and high severity complications (see Box 2-1) (87). They argued that the safety of the abortion is more important than its origin (induced versus spontaneous) because both can present with complications, and the role of an effective health system is to provide adequate care regardless of the cause. Additionally, they surmised that in restrictive contexts, estimating the burden of abortion-related morbidity and its cost to the health system, instead of focusing on its origin, is an important tool to advocate for legislative change regarding abortion. In their 1997 study in South Africa, middle and high severity categories were used as markers of unsafe abortion (87). This method is the basis of the prospective morbidity methodology (PMM) which is the most frequently used morbidity classification for abortion-related complications (31,37,38,87–89).

Box 2-1 Definition of categories for incomplete abortion hospitalization

Level of Severity	Criterion
Low (requires all criteria)	Temp. < 37.3 degrees Celsius No clinical signs of infection No system or organ failure No suspicious findings on evacuation
Moderate (requires ≥1 criterion)	Temp. 37.3–37.9 degrees Celsius Localized peritonitis (tender uterus, discharge) Offensive products of conception
High (requires ≥1 criterion)	Death Shock Evidence of foreign body/mechanical injury* Organ or system failure Temp ≥38 degrees Celsius Pulse > 119 beats/minute Generalized peritonitis
*Does not include physical evidence of misoprostol tablets.	
<i>(Source: adapted from Rees et al. (1997) (87))</i>	

More recently, Singh et al (2015) utilized a different approach to estimate the global number of hospitalizations for unsafe abortions. Applying an assumption first applied by Singh and Wulf to hospital admission data in 1991(90), they extrapolated the number of admissions due to induced abortions by estimating the number of miscarriages and subtracting them. They assumed that women having first trimester miscarriages will not usually need medical care in health facilities whilst those occurring in the second trimester (13-21 weeks) are more likely to need and seek such care. The proportion of second trimester miscarriages out of all live births was estimated using data from clinical studies whilst the proportion needing health facility care was estimated using data from interviews with in-country experts. These assumptions are now a component of the Abortion Incidence Complications Method (AICM), which is described in greater detail in Chapter 6 (section 6.3.1.1). One limitation of this approach is that the clinical studies providing data for this assumption were conducted in a high-income country in the early 1980s (91,92). This may therefore not be representative of all populations and does not account for factors like HIV or malnutrition, and diseases such as malaria in low- and middle-income countries. Additionally, there is little research on health facility care seeking patterns of women for first trimester abortions. Whilst early first trimester pregnancies, i.e. before 7

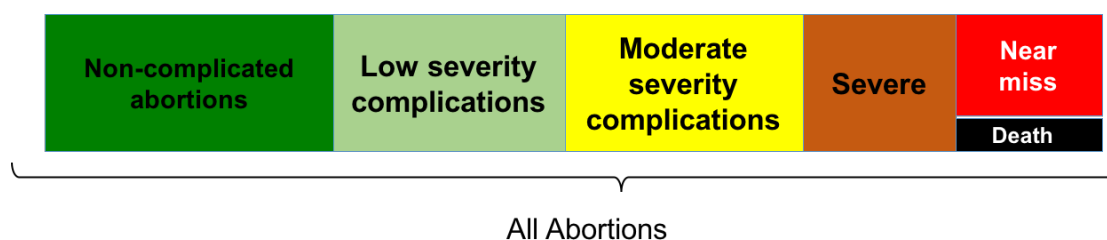
weeks, may be miscarried without knowledge of the pregnancy, those between 7 and 13 weeks may be recognized but there is little empirical research examining what women do when they miscarry at these gestations. Furthermore, the methods used to collect this information, from experts, on the proportion of women who seek care for late miscarriages are subjective.

The growing use of MA makes it more challenging to objectively identify complications of unsafe abortions using descriptive criteria such as the Figa-Talamanca or the PMM. One way to identify the most unsafe abortions using outcome data, and to improve the population representativeness of morbidity data from health facilities, is to specify a level of morbidity that can be objectively attributed to an unsafe abortion process. This can be achieved by restricting the measurement of morbidity to complications so severe that they are most likely due to an unsafe process. Such cases are likely to be found within a health facility or to be a woman who died in the community. Indeed, very severe acute abortion complications are the most objective outcomes of unsafe abortions conducted under the riskiest conditions; they are also the consequences that interventions aim to eliminate completely.

2.6.1.2.1 The case for using abortion-related near-miss as an indicator of unsafe abortion

Developments in measuring obstetric morbidity demonstrate the importance of describing and quantifying such severe acute maternal morbidity - also known as near-miss when the woman survives a near-death experience (26-29). A maternal near-miss has recently been defined by the WHO as “*A woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy*”(93). Other definitions have specified as an underlying hypothesis that near-miss cases are women who survive because of chance or good hospital care (94,95). In other words, the likelihood that these women would have survived in the community without advanced treatment is very low (10,38). Figure 2-2 describes the spectrum of abortion-related morbidity, showing how a woman can either become a near-miss or die as the worst outcomes.

Figure 2-2 The spectrum of abortion-related morbidity: from non-complicated abortions to near-miss and maternal death



Source Adapted from Say et al.(2009) (93)

Near-miss is best measured using facility data for this reason and also because self-reports of complications by women lack specificity (96,97). Severe morbidity and abortion near-misses are most likely, but not exclusively, to be the result of induced and illegal rather than spontaneous abortions (10). They occur more commonly than mortality, but not in numbers likely to overburden data capturing personnel in facilities (98). Table 2-3 outlines if and how the abortion near-miss indicator addresses the measurement issues discussed above.

Table 2-3 How my proposed unsafe abortion near-miss indicator addresses the limitations of other abortion indicators

Limitations of the indicator of unsafe abortion: admissions for abortion-related complications (all admissions or those dues to induced abortion) and abortion-related mortality*	Addressed by new definition (Yes, probably, No)	How the definition addresses the challenge
Non-representativeness of indicators	Yes	By using stringent criteria requiring hospital care to define a near-miss. Abortion near-misses are usually only identifiable at health facilities. Data available from facility records when divided by a population level denominator are more representative of the study population than other indicators currently used.
Cannot distinguish induced from spontaneous abortion.	Probably	Near-misses are more likely to be from induced than spontaneous abortions
Difficulty with tracking over time due to rarity of indicator like mortality	Probably	Research suggests that near-miss occurs in greater numbers than mortality. Thus it may be easier to compare estimates over time and to determine national trends

Not comparable in different contexts	Yes	By defining near-miss using the standardized WHO definition which has been validated in different contexts, the incidence of abortion near-miss is comparable between countries regardless of the restrictiveness of the abortion law
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**We did not compare the near-miss indicator with the incidence of induced abortions because in reality induced abortions consist of both safe and unsafe abortions. Furthermore, with the advent of misoprostol abortions are likely to be safer in restrictive contexts hence it may be less appropriate to use all induced abortions to track safety in the short to medium term.*

2.6.1.2.2 Defining and measuring abortion-near-miss

By defining near-miss complications with stringent criteria, such that almost all cases would have been seen in facilities or would have died, it is postulated that the burden measured using hospital-based data may be more representative of the general population burden (19) than the figure obtained by measuring mortality in a similar way. Thus, near-miss complications are a more accurate indicator than abortion-related mortality, which is substantially underestimated when measured using hospital data.

Near-miss events lie along the continuum of morbidity between good health and mortality. This presented challenges for researchers to reach consensus on discrete cut-off points and/or uniform case-identification criteria that capture life-threatening complications in sufficient numbers to be useful for evaluation, serve as a suitable proxy for mortality, be measured routinely, and to be comparable in different contexts(98–100).

In the early stages of applying this indicator, researchers used two approaches to measuring maternal near-miss: complication-based or organ-system dysfunction. These approaches use three types of markers: clinical, management and laboratory, each with its advantages and disadvantages, as shown in Table 2-4.

Table 2-4 Categories of indicators that have been used to measure near-miss: advantages and disadvantages

Near-miss indicator	Examples of categories under each set of indicators used	Advantages	Disadvantages
Clinical indicators related to a specific disease entity (such as Waterstone et al) (92)	<p>Severe Preeclampsia</p> <p>Eclampsia</p> <p>HELLP syndrome</p> <p>Severe haemorrhage</p> <p>Severe sepsis</p> <p>Uterine rupture</p> <p>Anaemia</p>	<p>Straightforward to interpret by a trained clinician</p> <p>Data can be obtained retrospectively from case notes or registers if they are available and reliable.</p> <p>The quality of care of a particular disease or complication can be easily assessed against corresponding clinical guidelines</p> <p>Complication rates for a particular disease can be calculated</p>	<p>Common direct causes of maternal mortality may be omitted e.g. pulmonary embolus was omitted because of the difficulty of diagnosing pulmonary emboli accurately when they are not fatal. Early pregnancy complications such as those related to ectopic pregnancies and abortions are also often omitted in maternal near-miss studies.</p> <p>Retrospectively-collected information might be problematic due to poor documentation and hence biased</p> <p>The criteria used to define morbidity often have too low a threshold of morbidity to be called maternal near-miss when compared with more recent stringent criteria.</p>
Intervention based indicators(102,103)	<p>Intensive care admission</p> <p>Emergency hysterectomy/ caesarean section</p> <p>Massive blood transfusion</p> <p>Anaesthetic accidents</p>	<p>Simple to identify the cases, usually on the basis of retrospective analysis of a hospital register</p>	<p>Allows the identification of only a fraction of all severe morbidity cases</p> <p>Variation in accessibility of the intervention, eligibility criteria for an intervention, or in the case of ICU, what constitutes an intensive care admission in different contexts makes comparability across hospitals and contexts difficult</p> <p>Biased by resources available</p>

Near-miss indicator	Examples of categories under each set of indicators used	Advantages	Disadvantages
Organ system dysfunction indicators (Mantel et al) (48)	Cardiac dysfunction Vascular dysfunction Immunological dysfunction Respiratory dysfunction Renal dysfunction Liver dysfunction Metabolic dysfunction Coagulation dysfunction Cerebral dysfunction	<p>Mimics the confidential enquiries into maternal death systems, thus the same system could be used to complement maternal death enquiries. It might allow calculation of more comparable summary measures of morbidity/mortality</p> <p>Allows for identification of critically ill women thereby establishing the pattern of diseases causing morbidity and their relative importance</p> <p>Allows for the identification of new and emerging disease priorities and study of health system response</p> <p>Variation in defining identification criteria can be avoided, particularly for similar settings, allowing the establishment of reliable summary estimates for maternal near-miss</p>	<p>Dependent on existence of a minimum level of care including functioning laboratories and basic critical care monitoring</p> <p>Retrospective identification of cases might be difficult due to inability to identify cases from registers</p> <p>May generate too small a number of cases for the purpose of evaluation (i.e. not add many cases to maternal deaths)</p>

Souza, P., Say, L., & Pattinson, R. C. (2009). *Maternal near-miss – towards a standard tool for monitoring quality of maternal health care.*, 23, 287–296. doi: 10.1016/j.bpobgyn.2009.01.007

WHO recently proposed stringent standardized criteria to identify near-miss cases, endorsed by experts through an international consultative process (93,104) (Table 2-5)

They are based on the organ-system dysfunction approach. These criteria aim to accommodate the diagnostic capacities of hospitals in different resource contexts by having three types of marker for each organ/system - clinical signs and symptoms, laboratory criteria and management-based proxies (93). The use of these criteria allows for the availability of comparable near-miss data and estimates from different contexts.

Studies in Brazil (105) and Tanzania (106) have attempted to validate these near-miss criteria. In Brazil, they were validated against the Sequential Organ Failure Assessment (SOFA) score which is used for quantifying organ dysfunction in the general population as a gold standard. In Tanzania the SOFA score was not used because of low health system capability to perform the necessary laboratory tests and because the study authors considered the near-miss criteria, derived from the SOFA score, could not be the gold standard for its validation. Instead, the WHO near-miss criteria were adapted for a low-resource setting and were validated with respect to their performance in identifying maternal deaths. To adapt the criteria, the clinical signs and symptoms were mostly used to identify cases but the cut off for blood transfusion was lowered to one unit of blood, and disease entities which were common causes of mortality in that hospital were also included. In both studies, the WHO near-miss criteria performed well against the gold standard used. However, studies comparing the performance of the WHO and previous near-miss criteria for the same population suggested that the WHO criteria omit cases of hypertensive diseases in pregnancy and severe haemorrhage (107,108). The WHO criterion for transfusions - an important marker of haemorrhage and common complication of unsafe abortions - appears too high for developing countries as most hospitals do not have good access to blood products, and it has been suggested that it be locally adapted (106,109). Additionally, the applicability of ICU admission and other laboratory criteria appears to be limited in resource-constrained contexts, leading to reduced identification of cases or underestimation of case severity (104). The use of the near-miss criteria in developing countries as it currently stands without adaptation is therefore debated (106,109).

Table 2-5 WHO maternal near-miss identification criteria

Dysfunctional system	Clinical criteria	Laboratory markers	Management-based proxies
Cardiovascular	Shock ^a Cardiac arrest	Severe hypoperfusion (lactate >5mmol/L or >45 mg/dl) Severe acidosis (pH<7.1)	Use of continuous vasoactive drugs ^h Cardiopulmonary resuscitation
Respiratory	Acute cyanosis Gasping ^b Severe tachypnea (respiratory rate >40bpm) Severe bradypnea (respiratory rate <6bpm)	Severe hypoxaemia (O2 saturation <90% for >= 60 minutes or PaO2/FiO2 <200)	Intubation and ventilation not related to anaesthesia
Renal	Oliguria ^c non responsive to fluids or diuretics	Severe acute azotemia (creatinine >= 300umol/l or 3.5mg/dl)	Dialysis for acute renal failure
Hematologic or coagulation	Failure to form clots ^d	Severe acute thrombocytopenia (<50,000 platelets/ml)	Massive transfusion of blood/red cells (>= 5 units)
Hepatic	Jaundice in the presence of preeclampsia ^e	Severe acute hyperbilirubinemia (bilirubin >100umol/l or >6.0 mg/dl)	
Neurologic	Prolonged unconsciousness ^f (lasting >12h) Stroke ^g Uncontrollable fit/ total paralysis		
Alternative severity proxy			Hysterectomy following infection or haemorrhage

Adapted from: i) Campbell, M., & Barrett, J. (n.d.). (110); and ii) Souza, P., Say, L., & Pattinson, R. C. (2009)

- a. Shock is a persistent severe hypotension, defined as a systolic blood pressure <90 mmHg for ≥60 min with a pulse rate at least 120 despite aggressive fluid replacement (>2 l).
- b. Gasping is a terminal respiratory pattern and the breath is convulsively and audibly caught.
- k. Oliguria is defined as a urinary output <30 ml/h for 4 h or <400 ml/24 h.
- l. Clotting failure can be assessed by the bedside clotting test or absence of clotting from the IV site after 7–10 min.
- m. Pre-eclampsia is defined as the presence of hypertension associated with proteinuria. Hypertension is defined as a blood pressure of at least 140 mmHg (systolic) or at least 90 mmHg (diastolic) on at least two occasions and at least 4–6 h apart after the 20th week of gestation in women known to be normotensive beforehand. Proteinuria is defined as excretion of 300 mg or more of protein every 24 h. If 24-h urine samples are not available, proteinuria is defined as a protein concentration of 300 mg/l or more (≥1+ on dipstick) in at least two random urine samples taken at least 4–6 h apart
- n. Loss of consciousness is a profound alteration of mental state that involves complete or near-complete lack of responsiveness to external stimuli. It is defined as a Coma Glasgow Scale <10 (moderate or severe coma).
- g. Stroke is a neurological deficit of cerebrovascular cause that persists beyond 24 h or is interrupted by death within 24 h.
- p. For instance, continuous use of any dose of dopamine, epinephrine or norepinephrine.

2.6.1.2.3 Limitations of using near-miss

The near-miss indicator has some limitations for estimating the burden of unsafe abortion. There is a small probability that near-miss events can occur after spontaneous abortions, or induced abortions performed optimally, leading to over-attributing near-miss cases to unsafe abortions. In Warakamin et al's 2004 study in Thailand, although 29% of induced abortions resulted in near-miss (based on Adler et al's 2012 study (10) where organ failure or dysfunction, in this case- septicaemia and uterine perforation, were used to indicate near-miss), 5% of spontaneous abortions also became near-miss complications (111). The UK confidential enquiry for 2006-2008 indicated that the mortality ratio per 100,000 maternities was 0.31 for spontaneous abortions and 0.09 for induced abortions (112). Although induced abortions are more likely to result in a near-miss than spontaneous abortions in poor resource settings, distinguishing them remains challenging and cannot be attempted using this definition.

It is also likely that as MA becomes more accessible within a country, the number of near-misses will decline over time due to the relative safety of MA compared with invasive procedures. In the long-term near-miss events will become much rarer and almost as challenging to measure as abortion-related mortality.

Nevertheless, abortion near-miss is consistent with the suggestion that severe acute complications are the most important adverse events of interest for the measurement of safety, and that they most frequently occur after induced abortions performed illegally, or under poor clinical conditions. By incorporating the concept of abortion near-miss into the classification of morbidity, my PhD research will extend the current measurement of abortion-related morbidity because: (i) it allows researchers to generate comparable measurements of unsafe abortion using abortion near-miss morbidity as an indicator in different contexts. Using the WHO standardized definitions of the indicators of abortion near-miss will facilitate objective identification of cases and reduce the variation in how severe morbidity as defined by the PMM can be interpreted across contexts; (ii) it provides an indicator of unsafe abortion representative at the population-level. This also means abortion near-miss morbidity

can be used as indicator to monitor the impact of interventions, programs and policies on the most unsafe abortions over time.

2.6.1.2.4 Integrating near-miss into the measurement of unsafe abortion

Near-miss maternal morbidity has been used successfully in obstetric care to describe the burden of maternal illness and its long-term outcomes (26, 33, 34), understand the costs of severe morbidity to households (35), assess quality of care through audits and confidential enquiries (28, 36), and examine the determinants of maternal death(37). The majority of studies describing the burden of abortion-related near-miss using the WHO near-miss criteria have been carried out in Sub-Saharan Africa. They have collected data on maternal near-misses and not specifically on abortion-related near-miss (83,113–117). They may thus miss many abortion cases as they are not focused on severe abortion-related morbidity and mortality (115).

As recommended by WHO, abortion near-miss indicators such as the near-miss incidence ratio (per 1000 live births per year), and near-miss abortion rate (per 100,000 women of reproductive age (15-49) per year)(29) can be calculated using national or regional level census information to generate comparable indicators between contexts. Since near-misses occur in greater numbers than mortality (23, 38), they may also be more satisfactory for regional comparisons of morbidity. Additionally, more information can be collected from auditing cases to evaluate the quality of maternal care provided in a facility or area. Near-miss can be used as an outcome indicator to track the impact of abortion-related interventions and policies on the most unsafe abortions in place of abortion-related mortality which is hard to capture. Furthermore, repeated estimates of the burden of near-miss can be used as an index of the safety of induced abortion services over time and access to post-abortion care at the population level. For example, a decline in the number of near-miss abortion complications over time could imply greater and timelier access to good quality services. Additionally, identifying near-miss cases provides an opportunity to understand the socioeconomic circumstances around the most unsafe abortions, possibly linked to abortion-related mortality, and to examine the effect of severe morbidity on future reproductive and health outcomes (118)

2.6.1.3 STEP 3-Incidence of induced abortion

The incidence of induced abortion, whether safe or unsafe, has most frequently been estimated using health facility data in restrictive contexts. This data is often supplemented by additional information to account for abortions not admitted in health facilities. Community-based surveys have also occasionally been used to estimate the incidence of induced abortion. This section will describe some of the most common health facility and community-based approaches that have been used.

2.6.1.3.1 Health facility-based methods

These methods rely on facility-based data collected by interviewing providers and/or from medical records (119). They are expected to estimate a minimum abortion rate, and can also be used to estimate the cost of unsafe abortion to the health system. The most frequently used method is AICM. Data on all admissions for abortion-related complications are usually adjusted for complications of spontaneous abortions as described in section 2.1.6.1.2 (120) and weighted for study design and duration of data collection (38,87). Thereafter, context-specific, locally collected multipliers are applied to adjust data to include women who did not develop complications, and/or did not seek care for them (119). (see Chapter 6, section 6.3.1.1 for further details).

The validity of multipliers to account for morbidity not identified within the facility, and extrapolate national estimates of all women undergoing induced abortion, depends on the accuracy of the research informing their assumptions (42). This is extremely important because the abortion rate/ratio estimated in any context is highly sensitive to the multiplier (67). The multiplier for the AICM is derived from numbers generated by quantitative interviews with experts within the country, which is subjective (30–32,34). Furthermore, the multiplier may be overestimated or underestimated depending on the type of expert interviewed. Health professionals have been reported to underestimate the multiplier compared with non-clinicians (e.g. people with backgrounds in research, social work, policy development and members of women's groups) when it is calculated separately for both groups. The underestimation of the multiplier by clinicians is attributed to the fact that they tend to overestimate the proportion of women who receive care for complications accompanying unsafe

abortions (120,121). In some cases where multipliers are not available for a particular country, those from a country with similar parameters are applied to the data (39,42). This is likely to introduce more bias into these national estimates as accessibility to health services may differ between countries and over time.

Another health facility based method that has provided data to estimate the prevalence of induced abortions is the prospective morbidity survey methodology. This was originally developed to classify abortion-related morbidity in hospital admissions according to severity (described in Chapter 5). The data collected using this method are combined with AICM data and the assumptions of the AICM applied to data to extrapolate overall prevalence in some countries (31,32).

2.6.1.3.2 Self-reported survey methods

Self-reported methods rely on respondents to report the occurrence of their own abortions or those of other women (122). Whilst most respondents are sampled at the community level, one self-reported method that has been tested within health facilities in Ghana (123) and Nigeria (124) is the preceding birth technique. This method was originally developed to estimate child mortality in settings where the majority of births are registered¹². In this method, women are asked about outcomes (live birth, stillbirth, miscarriage or abortion) of all prior pregnancies. Questions for this method have been asked as part of routine prenatal care amongst a convenience sample. This data source is non-representative of the population and neither African study attempted to extrapolate results to all women of reproductive age. The quality of data collected is subject to women's reports and provider attitudes (42).

Community-based data on abortion in low- and middle-income countries is particularly scarce (125). Community-based survey methods that have been applied to measure the incidence of induced abortion include those (i) using a direct approach to interviewing women; (ii) adapting direct interview methods to improve reporting, including audio computer-assisted self-interviews (ACASI) (126), the randomized-response technique (RRT) (127), the Sealed Envelope method (SEM), and the list

¹² <http://demographicestimation.iussp.org/content/childhood-mortality-estimated-health-facility-data-preceding-birth-technique>

experiment (128), or (iii) using an indirect approach such as the Anonymous Third Party Reporting method (ATPR) where women are asked about the number and characteristics of abortions amongst people in their network, or the network scale-up (NSU) approach (129). Community surveys of women can be designed to be representative of the general female population. However, they may be expensive when conducted on a large scale. Their abortion incidence results also have low validity, as induced abortions are usually underreported due to social stigma or legal repercussions (67). Furthermore there is less research into possible correction factors to adjust national survey data for underreporting (42,130) than hospital-based studies. In one study in the United States, information from ACASI was more accurate than face-to-face interviews (131). However, studies from Mexico triangulating different survey approaches to reduce underreporting suggest that in less educated and rural populations, the use of ACASI and RRT may be complex for women and yield less accurate information than face-to-face interviews (126,127). One study using the RRT in Botswana reported successful adaptation of the technique for local use (42). The few studies attempting to triangulate different survey approaches suggest that community-based methods providing privacy, or indirect approaches may be practical to circumvent the substantial underreporting of induced abortions associated with direct interview approaches in restrictive contexts (42,126).

Of the community-based methods listed above, the RRT has been used most frequently, for example in Turkey (132), Brazil, Mexico (127), and Botswana (42). This method measures the prevalence of induced abortion whilst protecting the respondent's privacy. It uses a combination of two questions (a non-sensitive question e.g. were you born in April (126), and a sensitive one about abortion) with a yes or no response, and the researchers who should know the proportion of the population who will respond 'yes' to the non-sensitive question. The respondent randomly selects one question, which is unknown to the interviewer and answers it. The prevalence of induced abortion is estimated by subtracting the expected proportion of "yes" responses to the non-sensitive question from the overall prevalence of "yes" responses (122). The proportion of the population responding "yes" to the sensitive question is also related to the probability of selecting the sensitive question (where there are two

questions, 0.5). Whilst it usually produces a higher estimate of the prevalence of induced abortion than direct questioning, it can be expensive and time consuming as it requires larger sample sizes than other indirect methods as it is based on the probability of respondents selecting the sensitive question. If the probability of selecting the sensitive question is 0.5 then the study will need twice the sample size to obtain the same power. If, in addition, the frequency of the sensitive event in the population is low, then an even larger sample size will be required. Furthermore, the accuracy of answers is affected by women's literacy, and this method produces aggregated data with no descriptive information on women (42,126,127).

The ATPR which uses an indirect interview approach was developed and conducted in Burkina Faso in 2001, and was fielded again in 2009 when it was compared with the AICM (30,119). It has also been tested in Rajasthan, India in 2004 where it underestimated abortion incidence compared with direct reports of women in a survey (122). It builds on the principle of network sampling where information is collected on the respondent's personal network (defined by the researcher) rather than their personal experience. Since it is an indirect method asking anonymously about the respondents' network, it has been used to estimate other sensitive populations such as HIV cases (130,133) and men who have sex with men (134), and may diminish the stigma associated with self-reporting an abortion. In addition to yielding estimates of the incidence of abortion, it provides individual level data on sociodemographic characteristics of women who have had an abortion and the health circumstances surrounding their abortions. It is also interesting because the data it produces can be used to calculate a multiplier to adjust health facility data, providing information to compare with other multipliers such as the AICMs. However, it is possible that with increased diffusion of MA, women are less dependent on their social networks to find methods which may cause them to confide less in their networks and result in underestimation of incidence using this method.

In restrictive contexts, it is important to estimate the incidence of induced abortions to understand the overall need for safe abortion services. It also provides a broader estimate with which we can compare estimates of hospitalizations for complications and interpret important indicators such as contraceptive prevalence rate, fertility rate

and unmet need for contraception. In addition, since there is a strong relationship between abortion laws and the risk of unsafe abortions, the incidence of induced abortion provides a valuable insight into the potential burden of unsafe abortion in these contexts. However, there is no gold standard method of evaluating estimates from the different approaches used. One approach to exploring the convergent validity of estimates and their underlying assumptions (such as the multiplier) is to triangulate estimates from different approaches (30,42). Triangulation is also important for assessing the appropriateness of different methods in different abortion contexts. Currently there is only one study in Sub-Saharan Africa (Burkina-Faso) which uses different approaches to measure the incidence of abortion in clandestine contexts and triangulates estimates and multipliers from health facility and community-based methods (30). Comparing the frequently applied AICM with the ATPR is important because, in addition to the overall estimate of induced abortion from two different data sources, it provides the opportunity to compare the multiplier which is a key component of the AICM method and to which the overall estimate is very sensitive.

2.7 Recent ideas on the definition and measurement of unsafe abortion

A recent paper by Sedgh et al describing insights from an expert group meeting discusses the challenges of outcome versus process-based definition and measurement in the changing context of MA (135). It suggests that going forward, a reasonable approach would be to classify abortion safety along a spectrum incorporating both the processes that make it unsafe and the outcomes of different degrees of unsafe processes. A 5-category spectrum using this approach was proposed with the following stages: very unsafe (not done in accordance with WHO guidelines that results in severe complications or death); unsafe (not done in accordance with WHO guidelines that results in mild or moderate complications); unsafe with low medical risk (not done in accordance with WHO guidelines with no medical risk); safe with nonmedical risk (done in accordance with WHO guidelines in contexts where abortion is illegal or stigmatized); and safe (done in accordance with WHO guidelines in contexts where abortion is legal or with little/no stigma). This approach is more comprehensive than an outcome only or process only approach because in reality, both

abortion induction processes and subsequent outcomes are important components of safety and are interlinked. More unsafe processes are more likely to result in severe outcomes and vice versa.

However, although incorporating both elements will help define abortion safety more holistically, obtaining data on a large scale to classify the safety of the process is likely to remain difficult in restrictive contexts. On the other hand, health-facility outcome data, which are often available and have been used for generating estimates could be used as a platform to explore how women obtain terminations of pregnancy and how safe these processes are.

To achieve this, one strategy might be to conduct studies within communities and different levels of health-facility among women seeking induced abortions and those admitted for abortion-related complications to document the processes preceding different outcomes. A focus on understanding the outcomes of MA obtained and used under different conditions is particularly important. Data from such studies and other data on national sales of abortion medication and community data on how women obtain abortions may facilitate the modelling of process-based estimates of unsafe abortion to compare with the estimates derived from outcomes-based method such as the AICM. This would allow the reproductive health community to refine the approaches to operationally defining and measuring the burden of unsafe abortions. Such studies could also address another potential challenge of implementing an integrated process/outcome approach to measurement: how to specify discrete cut-off points for each level of unsafe outcome that is associated with the process.

2.8 Conclusion

The issues that make induced abortion controversial and consequently unsafe in many countries have an impact not just on how unsafe abortions have been defined but also on how the definition is operationalized for measurement. The WHO definition of unsafe abortions and the newly introduced addendum linking the definition to the most current clinical guidelines highlight the importance of documenting the process under which abortions are induced. However, in practice, estimates are generated using data on outcomes. As long as induced abortion remains stigmatized, in countries

where it is restricted by law or policy, it will remain extremely challenging to capture the process of induced abortions and data on outcomes are likely to be more readily available and the use of such data is for measurement is justifiable.

Improving the measurement of the commonest indicators of unsafe abortion is necessary to understand its associated burden. With the growing use of MA, and ongoing refinements in the definition of unsafe abortion, my PhD aims to improve the way in which outcome data from health facilities is used to generate indicators that can be measured to describe and track the burden of unsafe abortion.