Predicting and Preventing Stillbirths in Zimbabwe: Protocol for a Cross-Sectional Study

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2. Background

2.1 Introduction

The World Health Organization (WHO) defines stillbirth as a baby born dead at 28 weeks gestation or more, with a birthweight of ≥1000 g, or a body length of ≥35 cm (Frøen et al 2011). Annually, it is estimated there are at least 2.6 million stillbirths worldwide; 98% occur in low and middle income countries (LMICs) (Lawn et al 2011) of which a vast majority are preventable (Bhutta et al 2014). In order to make any real advances in stillbirth prevention it is crucial we understand the causes and contributory factors (Aminu et al 2014). Collecting information on where, when and why these deaths occur as well as understanding the underlying contributing causes and avoidable factors is crucial in stillbirth prevention (Frøen et al 2016). In the regions with the highest mortality burden, Zimbabwe being one, information regarding the predictors of stillbirths is poorly understood (Lawn et al 2016). For many cases of stillbirth the cause of death is never established (McClure et al 2006, Baqui et al 2011, Edmond et al 2008), either being not recorded accurately or not recorded at all (Aminu et al 2014).

Globally reported causes of stillbirth have been the focus of two recent systematic reviews of reports covering the period from 2000 to 2016 (Aminu et al 2014; Reinebrant et al 2018).
Aminu et al (2014) in their systematic review of studies reporting causes and factors associated with stillbirth in LMICs included a total of 142 studies. Factors reported to be associated with stillbirth included poverty and lack of education, maternal age (>35 years or <20 years); parity (1, ≥5), lack of antenatal care, prematurity, low birth weight and previous stillbirth. The most frequently reported cause of stillbirth were attributed to maternal factors (8-50%) including syphilis, positive HIV status with low CD4 count, malaria and diabetes. Congenital anomalies (2.1–33.3%), placental cause (7.4-42%), asphyxia and birth trauma (3.1 – 25%), umbilical problems (2.9-33.3%) and amniotic and uterine factors (6.5–10.7%) were reported as fetal related causes. Of note from this review is that seven different classification systems were identified in the individual studies but applied in only 22% of studies (that could have used a classification system), consequentially a high percentage of stillbirths remain 'unclassified'.

The more recent review (Reinebrant et al 2018) provided pooled estimates of causes for stillbirth by income setting; low, middle and high income countries. Eighty-five reports from 50 countries (489 089 stillbirths), including 28 reports (13 197 stillbirths) from LIC setting were

included. The most frequent categories in the LIC setting were unexplained (41.0%), infection 15.8%, other unspecified condition (13.8%), hypoxia peripartum death (11.6%), antepartum haemorrhage (9.3%), all other causes (8.5%).

There are however, limitations to both reviews; neither review included data specific to Zimbabwe also there was wide variation in what investigations of the mother and baby were undertaken to identify the cause of stillbirth. Further limitations related mostly to the information available from the reports being inconsistent and often of poor quality, making it difficult to get a clear picture about the causes of stillbirth.

2.2 Justification for conducting a cross-sectional study in Zimbabwe

Few studies in Zimbabwe have focused on identifying causes and associated risk factors specific to the Zimbabwean context, moreover national estimates for Zimbabwe normally provided through surveys and censuses, are known to be imprecise (Munjanja 2007).

The Ministry of Health and Child Welfare therefore conducted a maternal and perinatal mortality study in 2007, to establish precisely the national estimates for indicators relating to mothers and newborns, including data specific to stillbirth occurrence and cause (Munjanja 2007). Over the 12 month study period there were 781 stillbirths identified (rate of 17/1000 total births). The cause of the death was known in 756 cases. Unexplained intrauterine death (29.3%), preterm birth (21.7%) and intrapartum asphyxia and birth trauma (33.0%) were the leading causes of stillbirth, accounting for 84%.

Using data abstracted from hospital records collected over a 12 month period (Oct 1997-Sept 1998) in Harare Feresu and colleagues assessed socio demographic and obstetric risk factors for stillbirth (Feresu et al 2004; 2005; 2010). The annual stillbirth rate was 61 per 1000 live births. Women >35 years had a 49% increased risk of stillbirth (RR 1.49, 95% CI 1.22-1.82). Rural women had a 24% increased risk compared with women who resided in urban areas (RR 1.24, 95% CI 1.06-1.46). Not attending antenatal care was associated with increased risk (RR 2.54, 95% CI 2.21-2.92), as was preterm birth (RR 2.43, 95% CI 2.26-2.61), and low birthweight births (RR 2.16, 95% CI 2.02-2.31).

A case control study in the district of Mashonaland East Province of Zimbabwe by Tachiweyika et al (2011) including 92 cases and 185 controls covering a 12 month period (August 2008 – July 2009) identified determinants of perinatal mortality. Associations with mortality include labour complications, belonging to apostolic sect, having a home birth, maternal HIV infection, low birthweight and antenatal care. However, due to the study not distinguishing between stillbirth and early neonatal death we are unable to associate specific risk factors with outcome of stillbirth.

On the basis of a more recent retrospective small cohort study carried out at Mpilo Central Hospital, Bulawayo we begin to understand the impact leadership and accountability can have on full term intrapartum stillbirths (Ngwenya 2017). The study documents a reduction in stillbirths following simple measures including redeploying experienced midwives back to labour ward, registrars on resident on-call and a second theatre brought back into function.

Whilst the previous studies have provided information that is vital in planning services where resources and provision of health care is limited, data on stillbirth prediction remains lacking. There still remains little evidence from large observational studies that can provide the distribution of stillbirth deaths within the antenatal and intrapartum period in order to help identify the quality of antenatal and obstetric care available to the pregnant woman and prioritise appropriate intervention strategies. To our knowledge this is the first cross-sectional study conducted in Zimbabwe designed to determine the main risk factors associated with stillbirth.

2.3 Aim of Study

(i) To determine the main risk factors associated with stillbirth
(ii) Assess the feasibility of collecting a range of data to inform an intervention to reduce stillbirth rates and subsequent clinical trial.

2.4 Objectives of the Study

(i)

- To increase understanding of the risk factors associated with stillbirth

- To encourage routine identification and surveillance of stillbirths
- To identify what information / data is readily available on outcomes on women
- To determine the quality and reliability of data on important outcomes (i.e. identify gaps in the trail of data for one woman passing though antenatal care to time of birth)

(ii)

- To use the study findings to support the design of relevant interventions in stillbirth prevention for further investigation in Zimbabwe and other similar settings
- To determine what resources/personnel will be required to collect data in the trial
- To strengthen the capacity amongst health professionals to carry out observational studies

3. Research Design

3.1 Methods

This is a cross-sectional hospital-based study designed in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (von Elm E et al 2007).

3.2 Setting

The cross-sectional study will be carried out in Zimbabwe with the support of the Lugina Africa Midwives' Research Network (LAMRN). According to UNICEF the stillbirth rate for Zimbabwe is unacceptably high at 21.0 per 1000 total births respectively (UNICEF 2015), compared with the UK rate of 2.9 per 1000 (Flenady 2011).

The study will take place in a health facility in the metropolitan province of Bulawayo in Zimbabwe. MPilo Central Hospital is the largest hospital in Bulawayo, and second largest in Zimbabwe after Parirenyatwa Hospital in Harare. Mpilo is a public hospital and referral centre for the Matabeleland North, Matabeleland South and Midlands provinces of Zimbabwe. Births per year exceed 9,000.

The hospital is a teaching hospital for obstetric care providers and centres for research and specialised care. The site was chosen because it is a referral centres for a large urban / rural population and experiences a high rate of stillbirth.

3.3 Study procedures

3.3.1 Sampling strategy

All women who have delivered their baby during the study period will be eligible for inclusion.

3.3.2 Inclusion criteria

- Women (irrespective of age) who have delivered their baby whether live born or stillborn at the study site.
- Women irrespective of antenatal care booking status (booked at study site / booked elsewhere / unbooked) will be eligible for inclusion.

3.3.3 Estimated stillbirth rate at Mpilo

From data collected during January to April 2017 and October 2017 to January 2018, there were 5993 births at Mpilo Central Hospital, Bulawayo including 196 stillbirths. The average per month was 750 births of which 25 were stillbirths (stillbirth rate 33.3 per 1000).

3.3.4 Sample size calculation

The sample size calculation is based using binary multivariable logistic regression for the main analysis to identify factors having an impact on stillbirth when adjusted for each other. For reliable estimation, at least 10 participants are required for each explanatory variable for each outcome category (Peduzzi et al, 1996). Assuming a stillbirth rate of 33.3 per 1000, the number of participants required to fit a model with a given number of risk factor variables is as follows (months of data collected on consecutive births assume about 25 stillbirths per month):

- 6 explanatory variables – at least 1802 participants, including about 60 stillbirths (data on about 2.4 months of consecutive births)
- 7 explanatory variables – at least 2103 participants, including about 70 stillbirths (about 2.8 months)

- 8 explanatory variables – at least 2403 participants, including about 80 stillbirths (about 3.2 months)
- 9 explanatory variables – at least 2703 participants, including about 90 stillbirths (about 3.6 months)
- 10 explanatory variables – at least 3004 participants, including about 100 stillbirths (about 4 months)

3.3.5 Data collection processes

Data will be collected prospectively by reviewing finished episode health records for each woman delivering at the study site on or after a given start date. For example labour and birth registers, patient files/records, antenatal clinic/ward registers, postnatal registers, emergency or operating theatre records and discharge logs.

Data will include demographic/social status details, information regarding pregnancy progress and care, labour and birth, details of the death (if baby stillborn) and critical delays and modifiable factors.

The development of the study Case Report Form (CRF) was largely informed by the WHO Making Every Baby Count Stillbirth and Neonatal Death Case Review form (WHO 2016a) (See appendix 1). The option of both paper-based CRFs and an electronic system (REDCap) will be available. REDCap (Research Electronic Data Capture) is a secure web application used to build and manage the on-line Case Report Form (https://www.project-redcap.org/). The University of Manchester is a member of the REDCap Consortium. The electronic system will be more efficient, removing the need to enter large amounts of paper-based data onto computer. The electronic system also provides data management facilities, and any paper-based data will be entered onto the electronic system.

The use of REDCap will minimises the likelihood that a data set will identify individuals, as this is a highly controlled secure environment. Essential personal identifiable data is data that allows the Zimbabwe study team RAs (GD and SM) to identify the participants should they need to refer back to the original source of data (ie casenotes) for further information or for verification. Personal identifiable data would be caserecord number of patient. The data will be considered as linked anonymised ie the study team at the University of Manchester will

not be able to identify the participant using the data they receive via REDCap. It is acknowledged the data will contain information that allows the suppliers of the data (Zimbabwe Study Team) to identify the participants. This is important as it may be necessary to refer back to the original case records for further information, or for verification.

Two trained Research Assistants (midwives from the Lugina Africa Midwives' Research Network (LAMRN)) will be responsible for collating the routinely collected clinical and administrative hospital data. No intervention other than collecting anonymised data through access to hospital records at the end of the pregnancy will be performed. Data collected will be retrospective, relating to deliveries prior to the study period. On the basis of 12 CRFs being completed each working day, it is envisaged data entry is expected to take 9 months; this will capture data on 1802 newly delivered women.

3.3.6 Data storage

The study will follow a specific data protection management plan. All the information (electronic / hard copies) will be stored securely at the participating hospitals either in a locked cupboard or on a password protected database on a hospital computer. Data will be destroyed 10 years after the last publication of the study in line with recommended good practice guidelines for clinical research.

The data (CRF electronic system REDCap) is stored within The University of Manchester on an internal private network. Access to the database machine is strictly controlled. Anyone connecting must have an account on the machine and must be connected to the University of Manchester's network. Both RAs (GD and SM) have been provided with an account. Access to the web application is by password. Only named members of the research team will have access to this database. Data will be uploaded directly onto the web application using a University of Manchester encrypted laptop by study team members based in Zimbabwe. It will not be necessary to have any paper recordings of data.

The installation of Redcap is local to The University of Manchester. It consists of 2 components - the external website and a backend database. These are hosted on separate machines at the University of Manchester. The web page interface is accessible to the outside world but the actual database where the data is stored is on an internal private network hosted at the

University of Manchester, and therefore NIHR approval is not required. Access to the database machine is strictly controlled - a user must have an account on the machine and can only access it whilst on campus. The University has had both machines pen-tested (penetration tested) twice by an external company as well as by The University of Manchester's IT Services Security team in order to determine that it is indeed a secure web application.

3.3.7 Data analysis

The overall goal is to identify problems in the system that may have contributed to stillbirths, especially those that could have been prevented or avoided. Key information such as cause of death, geographic location, booking status, maternal age, parity, and gestational age, previous history of stillbirth, HIV status and known maternal risk factors from all Case Report Forms will be entered into the IBM SPSS Statistics Version 23 statistical package for quantitative analysis.

The analysis will focus on presenting the results in a readily accessible form so that factors can be identified to suggest which babies may be at higher risk of stillbirth. From the collected data and the numbers of births during the study period, stillbirth rates and percentages of fresh stillbirths (stillbirths occurring during labour) will be estimated with 95% confidence intervals for each group of interest and overall. Confidence intervals will be estimated using Wilson's method (Newcombe 2013).

The quantitative data will be analysed descriptively using frequency counts, percentages, means and standard deviations to summarise the data numerically and bar charts and histograms to summarise the data graphically. Stillbirths and other data will be compared between groups based on booking (booked at Mpilo, booked elsewhere in Bulawayo, booked outside Bulawayo and not booked), age group (under 18, 18-35, over 35), parity (primiparous, multiparous) and previous history of stillbirth. Data will be compared by group using appropriate statistical tests and, given the expected large sample size, effect sizes. Pearson's chi-square test will be used to compare categorical variables by group, with Cramér's V as an effect size. Skewed variables will be compared by group using the Mann-Whitney U test (2 groups) or the Kruskal-Wallis test (>2 groups), with the probability of superiority PS as a

pairwise effect size. Normally distributed variables will be compared by group using independent-samples t-test (2 groups) or one-way analysis of variance (>2 groups), with Cohen's d and eta^2 as respective effect sizes.

Factors that are theoretically expected to be predictive of stillbirth will be included in binary multivariable logistic regression models to assess the relationship when adjusted for other variables. The number of variables included will be carefully considered based on the final sample size, following the recommendation of Peduzzi et al (1996) for at least 10 participants per variable per outcome category to give good estimation of model parameters. Expected factors will include source of booking (booked at Mpilo/booked elsewhere/not booked), age group (<18, 18-35, >35) previous history of stillbirth, residential area (urban/rural), attending antenatal care (yes/no), preterm birth (no/yes), low birthweight birth (no/yes), labour complications (no/yes) and maternal HIV infection (no/yes). The results of a main predictive model will be reported using adjusted odds ratios with 95% confidence intervals. The final results will be assessed for clinical and practical relevance.

4. Definitions of stillbirth

4.1 Definition

WHO recommend the threshold of 28 completed weeks for mortality audits in LMIC settings (Cousens et al 2011, Lawn et al 2011).

- Antepartum stillbirth: Before the onset of labour
- Intrapartum stillbirth: After the onset of labour and before birth
- Fresh stillbirth: Death occurring during labour
- Macerated stillbirth: Death during the antenatal period (before labour commences)

4.2 Classification of stillbirth

In response to the need to better understand why stillbirths and neonatal deaths occur and what can be done to prevent them, the World Health Organization, has developed the following document: *The WHO Application of ICD-10 to deaths during perinatal period (ICD-PM)* (WHO 2016b) (Appendix x). The CD-PM is a globally applicable system for classifying perinatal mortality. The system brings together stillbirths and neonatal deaths to contributing

maternal conditions. This combined approach (mother-baby dyad) allows clinicians to classify perinatal deaths in a consistent way and compare data across different settings; the aim to focus attention on the areas where interventions are needed to improve outcomes for mothers and babies.

5. Study time period

Administrative and logistical arrangements have been made to start the study in August 2018 and collect data for a period of 9 months.

6. Monitoring of study progress

A start up meeting was held in Tanzania in October 2017 to confirm practical arrangements for the study for example roles and responsibilities of study group, required sample, choice of study sites, and local research governance approvals requirements. Subsequently, monthly review meetings will be held with the Zimbabwe and UK research team via telephone or video conference. All aspects of the conduct of the study including, research governance, setting, stakeholder membership and monitoring of data collection, progress in data analysis will be reviewed regularly; these will be formerly reported every quarter. Tracking progress will be assigned to the Research Assistants. Additional meetings will be scheduled as needs arise.

7. Patient and Public Involvement (PPI) group

Communication and capacity will be enhanced by early involvement of community representatives / establishment of a PP group. The International Stillbirth Alliance has an established PPI stream, and will support the capacity development of the in-country PPI group. A regular Monitoring and Evaluation strategy focusing on activities and outputs to demonstrate PPI progress and impact will be implemented. In addition, one of the aims of the study is to use the findings to support the design of relevant interventions in stillbirth prevention for further investigation in Zimbabwe and other similar settings. Ensuring the presence of the PPI group at study review meetings will help ensure the appropriateness and community participation in the future developed interventions. It is planned that the

presence of the PPI group will positively impact interventions both in the community and at health-care facilities through creative solutions.

8. Ethical Issues

8.1 Approvals

Ethical approval will be sought from the Research and Ethics Committee at Mpilo Central Hospital in addition to administrative approval to carry out the study. Ethical approval will also be gained from The University of Manchester.

8.2 Informed consent

Informed consent will not be required as all data obtained will be anonymised at the point of collection.

9. Dissemination / Reporting of study findings:

Stakeholders and PPI groups at all levels who can drive change, such as community leaders, civil society and organisations, radio stations, local newspapers and parent groups (particularly around the first delay in seeking care), Ministry of Health, Professional organisations, academic institutions, parent groups will be involved in the processes of dissemination. Recommendations of the study will be disseminated in a way that communicates information effectively, sensitively and via a medium that is accessible to all community members / PPI groups in order to enhance relationships and building capacity for positive change within the community.

Final interpretation of the findings of the study will be shared with the wider project management team, including a Learning and Sharing Event across all LAMRN countries. Additionally, abstracts will be submitted for international conference presentations including LAMRN conference, GLOW meetings and International Stillbirth Association. The findings will be written up and submitted to a peer reviewed journal for publication.

10. Funding

This study is funded by NIHR Global Health Research Programme, UK.

11. Study outcomes and implications for practice

The use of the study findings to improve health outcomes is central. A systematic analysis of mortality trends and events leading to stillbirths can help identify system breakdowns and provide information on local solutions to address deficiencies in service delivery. In addition, the study will assess the feasibility of collecting a range of data to inform an intervention and subsequent clinical trial.

12. References

Aminu M, Unkels R, Mdegela M, Utz B, Adaji S, van den Broek N. Causes of and factors associated with stillbirth in low- and middle-income countries: a systematic literature review. BJOG 2014; 121 (Suppl. 4): 141–153.

Baqui A, Choi Y, Williams E, Arifeen S, Mannan I, Darmstadt G, et al. Levels, timing, and etiology of stillbirths in Sylhet district of Bangladesh. BMC Pregnancy Childbirth 2011;11:25.

Bhutta ZA, Das JK, Bahl R, Lawn JE, Salam RA, Paul VK et al Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost? Lancet 2014; 384(9940):347–70

Cousens, S., Blencowe, H., Stanton, C., Chou, D., Ahmed, S., et al. (2011). National, regional, and worldwide estimates of stillbirth rates in 2009 with trends since 1995: a systematic analysis. The Lancet, 377(9774), 1319-1330

Edmond KM, Quigley MA, Zandoh C, Danso S, Hurt C, Agyei SO, et al. Aetiology of stillbirths and neonatal deaths in rural Ghana: implications for health programming in developing countries.Paediatr Perinat Epidemiol 2008;22:430–7.

Feresu SA, Harlow SD, Welch K, Gillespie BW. Incidence of and socio-demographic risk factors for stillbirth, preterm birth and low birthweight among Zimbabwean women. Paediatr Perinat Epidemiol. 2004 Mar;18(2):154-63.

Feresu SA, Harlow SD, Welch K, Gillespie BW. Incidence of stillbirth and perinatal mortality and their associated factors among women delivering at Harare Maternity Hospital, Zimbabwe: a cross-sectional retrospective analysis. BMC Pregnancy Childbirth. 2005 May 5;5(1):9.

Feresu SA. Annual distribution of births and deaths outcomes at Harare Maternity Hospital, Zimbabwe. Cent Afr J Med. 2010 May-Aug;56(5-8):30-41.

Flenady, V., et al. (2011) Major risk factors for stillbirth in high-income countries: a systematic review and meta-analysis. The Lancet 377(9774): 1331-1340.

Frøen JF, Cacciatore J, McClure EM, Kuti O, Jokhio AH, Islam M, et al. Stillbirths: why they matter. Lancet 2011;377:1353–66

Frøen JF et al Stillbirths: progress and unfinished business, In The Lancet, Volume 387, Issue 10018, 2016, Pages 574-586,

Lawn, J.E., Blencowe, H., Pattinson, R., Cousens, S., Kumar, R., et al. (2011). Stillbirths: Where? When? Why? How to make the data count? The Lancet, 377(9775), 1448-1463.

Lawn JE, Blencowe H, Waiswa P, Amouzou A, Mathers C, Hogan D, et al. Stillbirths: rates, risk factors and potential for progress towards 2030. Lancet 2016;387:587–603.

McClure EM, Nalubamba-Phiri M, Goldenberg RL. Stillbirth in developing countries. Int J Gynaecol Obstet 2006;94:82–90.

Munjanja, SP. Ministry of Health and Child Welfare Zimbabwe Maternal and Perinatal Mortality Study 2007

Newcombe RG (2013). Confidence Intervals for Proportions and Related Measures of Effect Sizes. CRC Press, Boca Raton, FL.

Ngwenya, S. Reducing fresh full term intrapartum stillbirths through leadership and accountability in a low‑resource setting, Mpilo Central Hospital, Bulawayo, Zimbabwe. BMC Res Notes (2017) 10:246

Peduzzi, P., J. Concato, E. Kemper, T. R. Holford and A. R. Feinstein (1996). "A simulation study of the number of events per variable in logistic regression analysis." J Clin Epidemiol 49(12): 1373-1379.

Reinebrant HE, Leisher SH, Coory M, Henry S, Wojcieszek AM, Gardener G, Lourie R, Ellwood D, Teoh Z, Allanson E, Blencowe H, Draper ES, Erwich JJ, Frøen JF, Gardosi J, Gold K, Gordijn S, Gordon A, Heazell AEP, Khong TY, Korteweg F, Lawn JE, McClure EM, Oats J, Pattinson R, Pettersson K, Siassakos D, Silver RM, Smith G, Tuncalp O, Flenady V. Making stillbirths visible: a systematic review of globally reported causes of stillbirth. BJOG 2018;125:212–224.

Tachiweyika, E., Notion, G., Shambira, G., Chadambuka, A., Tshimamga, M., Zizhou, S., Determinants of perinatal mortality in Marondera district, Mashonaland East Province of Zimbabwe, 2009: a case control study. The Pan African Medical Journal 2011. http://www.panafrican-med-journal.com/content/article/8/7/full/

UNICEF (2015) https://data.unicef.org/wp-content/uploads/country_profiles/Zimbabwe/country%20profile_ZWE.pdf

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. BMJ. 2007;335:806–8.

WHO: Making Every Baby Count Audit and review of stillbirths and neonatal deaths: Geneva: World Health Organization; 2016a

WHO: The WHO application of ICD-10 to deaths during the perinatal period: ICD-PM Geneva: World Health Organization; 2016b

13. Appendices

Appendix 1: Case Report Form

Case Report Form

Health Facility name:	**Form completed by:**	**Date:**

Ctry	**Section 1: Identification and social status**	
M, T, Z, ZB	Hospital number:	Contact telephone number:
	Mother 's year of birth: (indicated first day of the year in case full date if unknown)	Mother's age (in years): (automatic calculation)
	Education: ☐ never been to school; ☐ primary; ☐ secondary; ☐ higher; ☐ vocational; ☐ other: specify_____; ☐ unknown / not recorded	
	Civil status: ☐ Married / living with partner; ☐ Single; ☐ Divorced; ☐ Widowed; ☐ unknown / not recorded	
	Mothers profession: ☐ Formally employed; ☐ Informally employed; ☐Self-employed; ☐ Student; ☐ Unemployed / housewife; ☐ unknown / not recorded	
	Partner profession: ☐ Formally employed; ☐ Informally employed; ☐Self-employed; ☐ Student; ☐ Unemployed; ☐ unknown / not recorded	
ZB	**Water source/ sanitation**: ☐ tap/ bottle; ☐ stream, river or dam; ☐ bore hole	
M, T, Z, ZB	**Religious** affiliation: ☐ Christian (specify below) - ☐ Muslim - ☐ Other - ☐ unknown / not recorded ☐ Catholic; ☐ Anglican; ☐ Apostolic; ☐ Pentecostal; ☐ Seventh Adventist church; ☐ Evangelical	

Section 2: Access to care			
M, T, Z, ZB	Area of residence:		
	Type of care available: ☐ Comprehensive EmOC; ☐ Basic EmOC; ☐ First aid; ☐ Home delivery		
M, T, Z, ZB	Distance travelled from home to HF / referral hospital - (filled either time or km)		Distance travelled from HF to referral hospital (filled either time or km)
	In Km: ☐ Within 5 km ☐ 6-10 Km ☐ 11-20 Km ☐ More than 21 Km	In Km: ☐ Within 5 km ☐ 6-10 Km ☐ 11-20 Km ☐ More than 21 Km	In Time: ☐ within 30 min ☐ 31 min – 1 hour ☐ 1 hour to 2 hours ☐ over 2 hours	In Km: ☐ Within 5 km ☐ 6-10 Km ☐ 11-20 Km ☐ More than 21 Km

☐ Unknown ☐ Unknown ☐ Unknown ☐ Unknown

M, T, Z, ZB Mode of travel to facility (if no information provided, put unknown)

☐ Car; ☐ Ambulance; ☐ Public transport (specify:……..); ☐ Foot; ☐ Bicycle; ☐ Motorbike; ☐ Other (specify……); ☐ Unknown

Section 3: ANC and health conditions

Source: Health passport / Labour Reg, Case note, Partograph

M, T, Z, ZB Antenatal care: ☐ Booked; ☐ Un-booked;

If un-booked, were they booked anywhere else? ☐ yes / ☐ no

If **yes**, provide the health facility name: _____and type:_____

T, Z, ZB When was the **first contact in this pregnancy** with the health professional? (month / year)_____

M, T, Z, ZB Was this a **self – referral**: ☐ yes / ☐ no

If yes, provide reasons for referral:

If **referred for medical review**, provide details about:

date of referral_____

time of referral:_____

Reason for referral:

M, T, Z, ZB Gestation at booking: _____Weeks;

☐ 1st trimester; ☐ 2nd trimester; ☐ 3rd trimester

Number of ANC visits:

☐ 6 or more; ☐ 5 ; ☐ 4 ; ☐ 3 ; ☐ 2 ; ☐ 1 ; ☐ No visits; ☐ unknown

T, Z, ZB Any psychiatric / mental illness i.e. depression: ☐ yes ; ☐ no ; ☐ unknown

Provide details of diagnosis (ex. schizophrenia, bipolar etc.):

T, Z, ZB Mother smoked cigarettes :

☐ Yes; ☐ No ; ☐ Unknown

Mother drank alcohol: ☐ Yes; ☐ No ; ☐ Unknown

M, T, Z, ZB Iron supplement: ☐ Yes; ☐ No; ☐ Unknown

Please list all prescribed medication:

Folic acid supplements: ☐ Yes; ☐ No; ☐ Unknown

Mebendazole: ☐ Yes; ☐ No; ☐ Unknown

Diagnosed with anaemia: ☐ Yes; ☐ No; ☐ Unknown

Section 4: Test during this pregnancy

Source: Health passport

M, T, Z, ZB **Malaria** prophylaxis:

☐ Not needed; ☐ IPT3+; ☐ IPT2; ☐ IPT1; Not received; ☐ Unknown

Tetanus toxoid vaccination

☐ TT2+; ☐ TT1

☐ Not received; ☐ unknown

M, T, Z, ZB **HIV status**

☐ HIV-negative; ☐ HIV-positive

☐ Not done; ☐ unknown

HIV-positive action

☐ HAART; ☐ Option B+; ☐ unknown; ☐ no action

☐ Other, specify _____

M, T, Z, ZB **Syphilis test** during pregnancy

Gestational age at testing (weeks):_____

Test: ☐ Negative ; ☐ Syphilis positive; Not done; ☐ Unknown

Treated: ☐ yes / ☐ no - With partner: ☐ yes / ☐ no

M, T, Z, ZB **Diabetes** (test): ☐ yes / ☐ no - If yes: ☐ Type I; ☐ Type II; ☐ Gestational

If yes, was a Glucose tolerance test done: ☐ Yes; ☐ No; ☐ Unknown / unrecorded

Section 5: Previous obstetric history Source: Health Passport

M, T, Z, ZB Gravida (n.) Parity (n.) Total live births (n.):

N. Neonatal deaths: N. abortions (miscarriage):

N. Stillbirths: _____provide the following information for each stillbirth

- ☐ None
- ☐ 1st → Gestation (weeks)_____ ☐ Fresh; ☐ Macerated
- ☐ 2nd → Gestation (weeks)_____ ☐ Fresh; ☐ Macerated
- ☐ 3rd → Gestation (weeks)_____ ☐ Fresh; ☐ Macerated

Section 5.1: Current obstetric history Source: Health Passport

M, T, Z, ZB Mother LMP DD MM YYYY ☐ unknown

Type of pregnancy: ☐ Singleton; ☐ Twin; ☐ Higher multiple: specify n._____

Weight at the last ANC visit (kg): _____ ; ☐ Unknown

M, T, Z, ZB Last weight (kg): _____ ; ☐ Unknown

T, Z, ZB Height (cm): _____ ; ☐ Unknown BMI: _____ (self-calculation by Redcap)

T, Z, ZB Booking blood pressure:_____ ; ☐ highest BP during pregnancy; ☐ Unknown

T, Z, ZB Booking HB: _____; ☐ Unknown Later HB: _____ ; ☐ Unknown

Section 6: Details of delivery

M, T, Z, ZB Date of admission to this facility: _____ Time of admission to this facility (hh: mm):_____

M, T, Z, ZB Time of first assessment in this HF (hh: mm) _____

M, T, Z, ZB Attendant at delivery (if not recorded check with health professionals)

☐ Midwife; ☐ Nurse; ☐ Nurse-midwife; ☐ Licentiate; ☐ Clinical officer; ☐ General doctor; ☐ Obstetrician; ☐ TBA; ☐ relative, specify_____ ☐ Other, specify_____ ☐ Unknown; ☐ No one

M, T, Z, ZB Highest Blood pressure during labour: _____

Proteinuria in labour: ☐ Yes; ☐ No; ☐ Unknown / not recorded

M, T, Z, ZB Mode of delivery/ birth:

☐ SVD; ☐ Vacuum extraction; ☐ Forceps; ☐ Breech; ☐ Other : _____ ☐ Unknown

☐ C/S; specify ☐ Elective; ☐ Emergency

M, T, Z, ZB For C/s and Vacuum Extraction: time from decision to deliver to birth of the baby

☐ n/a; ☐ <30mins; ☐ 30-60min ; >60 min; ☐ unknown

M, T, Z, ZB Length of first stage of labour (hh:mm):

Length of second stage of labour (hh:mm):

M, T, Z, ZB Placental weight (g):

Placental abnormalities recorded (specify): _____

T, Z Maternal **near-miss case** defined as *"a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy. In practical terms, women are considered near-miss cases when they survive life-threatening conditions (i.e. organ dysfunction).*

Any severe maternal complications reported? ☐ Yes; ☐ No; ☐ Unknown

If yes, specify:

- ☐ Severe post-partum haemorrhage
- ☐ Severe pre-eclampsia
- ☐ Eclampsia
- ☐ Severe systemic infection or sepsis
- ☐ Uterine Rupture
- ☐ Other (specify):

Section 7: Details about birth

M, T, Z, ZB Date of birth (baby) DD MM YYYY ☐ unknown

M, T, Z, ZB Time of birth (hh: mm): _____ Gestational age (weeks): _____; ☐ unknown

M, T, Z, ZB Method of determination of gestational age:

☐ Dates calculated by LMP; ☐ Estimated LMP dates; ☐ Fundal height measurement (cm) ; ☐ USS

M, T, Z, ZB Woman had an ultrasound: ☐ yes; ☐ no – if yes specify below:

☐ Early Ultrasound / if known provide details of report →

☐ unknown

M, T, Z, ZB ☐ Late Ultrasound / if known provide details of report →

☐ unknown

M, T, Z, ZB Onset of labour: ☐ spontaneous; ☐ induced; ☐ none (c/s elective); ☐ unknown;

if induced; ☐ medical; ☐ traditional ; ☐ unknown

M, T, Z, ZB Any experience of Reduced Fetal Movements

☐ No

☐ Yes, gestational (weeks): _____

☐ Unknown

Reported last fetal movement

☐ Before admission to facility

☐ In hospital / facility

If known: Date_____ time _____

☐ unknown

M, T, Z, ZB Was the partograph available? ☐ No; ☐ yes

M, T, Z, ZB Was the partograph used? ☐ No; ☐ yes ; ☐ Not required; ☐ unknown

M, T, Z, ZB Partograph completion (All sections should be completed, if not consider partial completed)

☐ Fully complete; ☐ Partial complete

M, T, Z, ZB Baby condition:

☐ live birth; fill in section 7.1 - ☐ stillbirth; fill in section 7.2; ☐ neonatal death; fill in section 7.3

Section 7.1: Details of the live fetus / baby

T, Z, ZB Fetal heart present on admission: ☐ yes; ☐ no; ☐ unknown

Apgar score at 1 min (0-10)_____ At 5 min (0-10)_____

Any resuscitation measures taken: ☐ yes ; ☐ no; ☐ unknown

Sex of baby: ☐ male; ☐ female; ☐ undetermined Birth weight (g).

Length of baby (cm): Head circumference (cm):

Section 7.2: Details of the Stillbirth baby

M, T, Z, ZB Fetal heart present on admission: ☐ yes; ☐ no; ☐ unknown

M, T, Z, ZB Sex of baby: ☐ male; ☐ female; ☐ undetermined Birth weight (g).

M, T, Z, ZB Length of baby (cm): Head circumference (cm):

M, T, Z, ZB Date of delivery (baby) DD MM YYYY Time:

M, T, Z, ZB Timing of death: ☐ before onset of labour; ☐ during labour; ☐ unknown

Specify the type of stillbirth: ☐ Fresh stillbirth; ☐ Macerated stillbirth; ☐ unknown

M, T, Z, ZB Cause of SB death: Investigations performed:

M, T, Z, ZB Was an autopsy / post - mortem performed? ☐ Yes ; ☐ No ; ☐ unknown

M, T, Z, ZB Main maternal condition:

☐ PROM ; ☐ Sepsis/ Infection; ☐ Obstructed labour ; ☐ Pre-eclampsia / eclampsia; ☐ SGA ; ☐ APH;

☐ Other, specify: _____ ; ☐ Unknown

☐ M1: Maternal complications of pregnancy ;
☐ M2: Complications of placenta, cord and membranes
☐ M3: Other complications of labour and delivery
☐ M4: Maternal medical and surgical conditions; noxious influences
☐ M5: No maternal condition; Other_____; ☐ Unknown

Section 7.3: Details of neonatal death

T, Z, ZB Fetal heart present on admission: ☐ yes; ☐ no; ☐ unknown

T, Z, ZB Sex of baby: ☐ male; ☐ female; ☐ undetermined Birth weight (g).

T, Z, ZB Length of baby (cm): Head circumference (cm):

T, Z, ZB Date of delivery (baby) DD MM YYYY Time:

T, Z, ZB Timing of death: ☐ before onset of labour; ☐ during labour; ☐ unknown

T, Z, ZB Cause of death (infant):

a) Congenital
b) Antepartum complications
c) Intrapartum complications
d) Complications of prematurity
e) Other specify_____
f) Unknown / unspecified

g) Infections:
☐ Tetanus ☐ Syphilis
☐ Sepsis ☐ Diarrhoea
☐ Pneumonia ☐ Other, specify:
☐ Meningitis

T, Z, ZB Investigations performed:

T, Z, ZB Was an autopsy / post - mortem performed? ☐ Yes; ☐ No ; ☐ unknown

T, Z, ZB Main maternal condition:

☐ PROM; ☐ Sepsis/ Infection; ☐ Obstructed labour; ☐ Pre-eclampsia / eclampsia; ☐ SGA ; ☐ APH;
☐ Other, specify: _____ ; ☐ Unknown

☐ M1: Maternal complications of pregnancy;
☐ M2: Complications of placenta, cord and membranes
☐ M3: Other complications of labour and delivery
☐ M4: Maternal medical and surgical conditions; noxious influences
☐ M5: No maternal condition; Other_____; ☐ Unknown

Section 8: Critical delays and modifiable factors

	Critical delays	Not identified	Identified	Unknown / unrecorded
M, T, Z, ZB	Delay 1 in recognizing need for care	☐	☐	☐
	Delay 2 in seeking care	☐	☐	☐
	Delay 3 in receiving care	☐	☐	☐

M, T, Z, ZB Actions to address the critical delays, following maternal and perinatal death surveillance and response (MPDSR):

M, T, Z, ZB **Modifiable factors** (If any factor is identified, please specify)

Family related e.g.

- late/no antenatal care; no knowledge of danger signs; attempted termination; smoking / drug / alcohol abuse;
- cultural inhibition to seeking care; partner restricts care-seeking; use of traditional/ herbal medicine; financial constraints;

☐ Not identified
☐ Unknown / unrecorded
☐ Identified (specify):

M, T, Z, ZB Administration-related e.g.

- neonatal facilities; theatre facilities; resuscitation equipment;
- blood products; lack of training; insufficient staff numbers; anaesthetic delay; no antenatal documentation; etc.

☐ Not identified
☐ Unknown / unrecorded
☐ Identified (specify):

M, T, Z, ZB Provider-related e.g.

- partogram not used; action not taken; inappropriate action taken; iatrogenic delivery;
- delay in referral; delay in calling for assistance; inadequate monitoring; Inappropriate discharge; etc.

☐ Not identified
☐ Unknown / unrecorded
☐ Identified (specify):