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Strategies to improve the quality of foetal monitoring and intrapartum care in high-volume, low-resource maternity units

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Strategies to improve the quality of foetal monitoring and intrapartum care in high-volume, low-resource maternity units

Foetale bewaking en intrapartum zorg in drukke verloskamers in lage-inkomens landen: studies naar het verbeteren van de kwaliteit van zorg
(met een samenvatting in het Nederlands)

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Chapter 1

General Introduction

Global burden of stillbirths and neonatal deaths

Worldwide, 2.1 million stillbirths, 2.6 million neonatal and 300,000 maternal deaths occur each year - more than 98% of which occur in low- and middle income countries (LMICs).[1,2] In addition, countless years are lost to disability, and parents and societies endure psychosocial and economic costs.[3] Although significant progress has been made by halving both child and maternal mortality, Millennium Development Goals 4 and 5 - to reduce child mortality by two thirds and maternal deaths by three quarters - were not achieved. In fact, neonatal mortality rates remained virtually unchanged and now constitutes half of under-5 mortalities.[2,4] While reducing neonatal deaths is included as an explicit target in the Sustainable Development Goals, stillbirths remain unmentioned.[5] In 2014, 194 countries endorsed the World Health Organisation's (WHO's) Every Newborn Action Plan national targets for the reduction of stillbirth rate (≤10 per 1000 total births) and neonatal mortality rate (≤10 per 1000 live births) by 2035. However, at the current pace, efforts need to drastically increase along the continuum of care in pregnancy, childbirth and postnatal periods to reach these targets.[6]

Perinatal deaths and care at birth

In low-income countries, half of the number of stillbirths and a quarter of neonatal deaths are estimated to occur intrapartum.[7–11] Good quality care given at the time of childbirth by skilled birth attendants, including routine and emergency obstetric and neonatal care, is estimated to prevent a large proportion of mortality: 46% of maternal deaths, 27% of stillbirths and 18% of neonatal deaths.[12] To improve essential care at birth, WHO issued a campaign for women to access and deliver in a health facility with skilled birth attendance. In addition, production of clinical guidelines was accelerated to assist skilled birth attendants in delivering supportive care, and close monitoring of labour progress, maternal and foetal conditions to allow early detection of complications and initiation of basic and comprehensive emergency obstetric and newborn care interventions if needed.[13]

The promise of better care and survival resulted in an influx of women seeking intra-facility delivery; the rate of which rose from 62% to 81% between 2000-2018 globally.[14] Crucially, this has not been matched by improvements of quality of skilled birth attendance and birth outcomes – in particular not so in Sub-Saharan Africa, which experiences the highest rates of both fertility and adverse pregnancy outcomes.[1,3,15]
For example, the latest Tanzanian Demographic and Health Survey shows that for over a decade, there has been an almost universal antenatal care coverage (98%, with 51% achieving at least four visits) and a steady increase in facility-based deliveries from 47% to 63%. Nonetheless, the country's maternal and perinatal mortality rates remain high: 556 per 100,000 and 21 per 1000 total live births respectively.[4,16,17] As such, poor quality of intra-facility care is a crucial roadblock to ending preventable mortality and morbidity.
Staff and resources are foremost health-system bottlenecks to provide 'safe, effective, timely, efficient, equitable and people-centred care'.[18,19] Without additional support, skilled birth attendants remain unable to provide the high standard of care set by international guidelines for a positive pregnancy and birth experience, and mistreatment of women and human rights violations are widespread in many labour wards. [20–22] Thus, improving coverage of maternal care services alone is not sufficient; quality of care need to follow suit.

Intrapartum foetal monitoring and hypoxemia

Monitoring of foetal wellbeing is central to midwifery and obstetric care. It is usually done through assessment of foetal heart using cardiotocography or intermittent auscultation. The latter is the most commonly used method in LMICs. Foetal surveillance is crucial to avoid both too-much, too-soon care and too-little, too-late care, i.e. the confirmation of adequate foetal oxygenation and avoidance of unnecessary (harmful) obstetric interventions and timely identification of foetal hypoxia, enabling prompt intervention.[23] Prolonged lack of foetal oxygenation leads to dangerous hypoxemia resulting in hypoxia, metabolic acidosis and tissue injury and is therefore important to recognise and reverse timely.[24] Intrapartum-related birth asphyxia is thus a major direct cause of perinatal death contributing to an estimated 23% and 50% of stillbirth and neonatal deaths, respectively.[7,12] It also results in 1.15 million babies with neonatal encephalopathy in 2010; a quarter of whom died and a third survived with neurodevelopmental impairment.[25] Important contributors to birth asphyxia include abnormal uterine contractions, maternal haemorrhage, obstructed labour, and umbilical cord accidents.[26,27] There is a tendency to focus interventions and resources on emergency care and neglecting the crucial routine management, which can avoid emergencies. Some studies have shown poor inadequate foetal monitoring in LMIC – a limitation to early identification and prevention of irreversible foetal hypoxia.[28–31] This is an issue that lacks attention in the major campaigns and publications aimed at promoting better quality of intrapartum care and improved birth outcomes.[9,32] Possibly, this is due to the lack of evidence for optimal strategies of intrapartum foetal monitoring to improve outcomes in any setting. For example studies in high-income countries showed that cardiotocography has poor positive predictive value and specificity and thus does not improve perinatal outcomes but leads to unnecessary interventions such as caesarean section.[33]

Thesis objective

The main objective of this thesis was to explore context-specific strategies to improve the quality of intrapartum care, with particular focus on foetal monitoring, that are locally acceptable, achievable and accessible in high-volume, resource-limited labour wards in LMICs. We hypothesised that locally-tailored, context-specific interventions were necessary to improve quality of intrapartum care, including foetal heart rate monitoring. Most studies of this thesis were conducted in Zanzibar's Mnazi Mmoja Hospital (MMH), which is an example of such a busy labour ward. The studies were carried out between January 2015 and May 2018 within a collaboration between the birth attendants at MMH, UMC Utrecht and the PartoMa project of the University of Copenhagen.

The PartoMa project was initiated in 2014 to context-modify international intrapartum guidance to meet the needs of local healthcare providers and strengthen their ability to deliver the best possible care with the limited resources available. During the four years of the PartoMa initiative, the author of the present work was heavily involved in the various stages of the project, including the development process of the PartoMa guidelines, data collection, organisation and conducting three-monthly seminars for implementing the guidance. One of the problems identified by the PartoMa project in the study setting was the lack of intrapartum foetal surveillance that sometimes resulted in babies dying unnoticed and/or in untimely or unnecessary caesarean sections.[34]

Maternal health care in Zanzibar

Zanzibar is an archipelago of Tanzania (Figure 1) and has autonomy in certain matters including health care, which is governed by the Ministry of Health, Zanzibar. Most health services are delivered by public health centres. Maternal and child healthcare is officially free, but lack of supplies makes it costly for women and their families (30% of household expenditure).[35] The percentage of pregnant women receiving antenatal care at least once during pregnancy is high (93%), but the percentage receiving skilled birth attendance is lower (69%).[35] In 2016, there were 42 health facilities providing obstetric and neonatal care: 38 primary health units, four of which offered basic and comprehensive emergency obstetric care. Zanzibar's only tertiary facility, MMH, attends to a third of all facility deliveries with approximately 12000 births annually.[35] Until 2017, maternity care at MMH was provided in the old maternity ward that consisted of one common labour ward with 18-19 beds and one delivery room with three beds. A full detailed description of structure, processes of care and labour outcomes of this maternity unit is provided in chapters 2 and 9. The institutional maternal mortality ratio in this hospital was 647 per 100,000 live births in 2016. The most prominent direct causes were obstetric haemorrhage and hypertensive disorders.[36] Neonatal mortality rates were not reliable as babies who died minutes after birth were not counted.

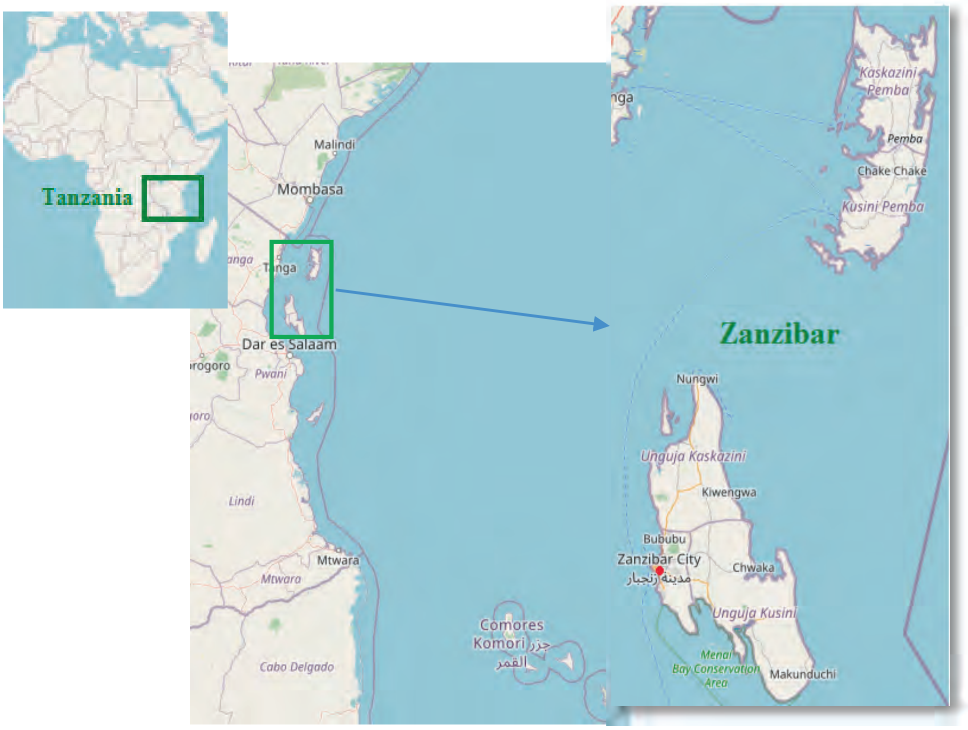

Figure 1. Map showing Zanzibar in the Republic of Tanzania. Mnazi Mmoja Hospital is located in Stone Town in Zanzibar City on the Unguja island. Source: © OpenStreetMap contributors

Thesis outline

Figure 2 depicts the developmental phases of this thesis (outer circle), inspired by the Knowledge To Action Framework,[37] and its outline (the inner circle). The thesis has four parts:

- ***Part 1: Baseline quality of care and context***

  This part provides an introduction to the baseline quality of care at the study site (chapter 2), an exploration of the biopsychosocial impact of stillbirths on mothers (chapter 3), the daily challenges skilled birth attendants face in providing labour care (chapter 4), a specific example from a Malawian setting (chapter 5), and the acceptability of task-shifting of intrapartum foetal heart rate monitoring to lay health workers in a referral hospital (chapter 6).
- ***Part 2: Evidence for intrapartum foetal surveillance during labour***

  This part presents analyses of the available evidence for intrapartum foetal monitoring in low resource settings with input from international experts in the field (chapters 7 and 8).
- ***Part 3 The PartoMa intervention study***

  This part presents effects of the context-tailored clinical guidance and training PartoMa intervention on birth outcomes (chapter 9) and the continued challenges in providing quality care (chapter 10), with a letter of reflection on the ethical dilemmas of the use of direct labour observations to assess quality of care (chapter 11).
- ***Part 4: Prediction of intrapartum perinatal death***

  This part explores challenges in data surveillance and classification of perinatal deaths (chapter 12) and combines various factors in a prognostic model to predict intrapartum-related perinatal deaths for the development of a risk assessment and obstetric triage system (chapter 13).

Figure 2. Structure of the thesis: the developmental phases (outer circle) and outline (inner circle).

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Part 1
Baseline quality of care and context

Photo by Nanna Maaløe

Chapter 2

Stillbirths and quality of care during labour at the low resource referral hospital of Zanzibar: a case-control study

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Abstract

Background To study determinants of stillbirths as indicators of quality of care during labour in an East African low resource referral hospital.

Methods A criterion-based unmatched unblinded case-control study of singleton stillbirths with birthweight ≥2000 grams (n=139), compared to controls with birthweight ≥2000 grams and Apgar score ≥7 (n=249).

Result The overall facility-based stillbirth rate was 59 per 1000 total births, of which 25% was not reported in the hospital's registers. The majority of singletons had birthweight ≥2000 grams (n=139; 79%), and foetal heart rate was present on admission in 72 (52%) of these (intra-hospital stillbirths). Overall, poor quality of care during labour was the prevailing determinant of 71 (99%) intra-hospital stillbirths, and median time from last foetal heart assessment till diagnosis of foetal death or delivery was 210 min. (interquartile range: 75 - 315 min.). Of intra-hospital stillbirths, 26 (36%) received oxytocin augmentation (23% among controls; odds ratio (OR) 1.86, 95% confidential interval (CI) 1.06-3.27); 15 (58%) on doubtful indication where either labour progress was normal or less dangerous interventions could have been effective, e.g. rupture of membranes. Substandard management of prolonged labour frequently led to unnecessary caesarean sections. The caesarean section rate among all stillbirths was 26% (11% among controls; OR 2.94, 95% CI 1.68-5.14), and vacuum extraction was hardly ever done. Of women experiencing stillbirth, 27 (19%) had severe hypertensive disorders (4% among controls; OR 5.76, 95% CI 2.70-12.31), but 18 (67%) of these did not receive antihypertensives. An additional 33 (24%) did not have blood pressure recorded during active labour. When compared to controls, stillbirths were characterised by longer admissions during labour. However, substandard care was prevalent in both cases and controls and caused potential risks for the entire population. Notably, women with foetal death on admission were in the biggest danger of neglect.

Conclusions Intrapartum management of women experiencing stillbirth was a simple yet strong indicator of quality of care. Substandard care led to perinatal as well as maternal risks, which furthermore were related to unnecessary complex, time consuming, and costly interventions. Improvement of obstetric care is warranted to end preventable birth-related deaths and disabilities.

Introduction

More than a quarter of a million women and 2.7 million newborn babies lose their lives during pregnancy and childbirth annually [1,2]. Though often invisible in global estimates, an additional 2.6 million stillbirths add profoundly to the tragedy, of which half are estimated to occur during labour[3]. In all three groups, the vast majority of deaths are caused by largely avoidable obstetric complications with the highest risk at the time of birth [1–3]. Many more women continue to suffer from birth-related injuries, infections, and disabilities, and an estimated one million survivors of birth asphyxia may end up with cerebral palsy, learning difficulties, or other disabilities [4,5]. The world's highest burden of maternal and perinatal deaths and other birth-related complications remains in sub-Saharan Africa and Asia [1–3].

In the Millenium Development Goals' era, the global strategy mainly aimed at skilled birth attendance, which resulted in campaigns for women to deliver in health facilities. The increasing proportion of facility births, however, has not been matched with improvements in the quality of intra-facility labour care [6,7]. Notably, reports from referral hospitals in sub-Saharan Africa suggest ample room for improvement even at the tertiary level of the health care sector [8–11]. Importantly, these are the facilities where most of the countries' future health care workers are trained, and if quality of care was improved, they could possibly be a lever for achieving nationwide health care improvements. Hence, in-depth insight into contextual challenges in delivering intrapartum quality of care is vital.

This paper is part of a baseline study for the PartoMa project, which aims at improving labour outcome for women and their offspring at the referral hospital of Zanzibar, Mnazi Mmoja Hospital. The project focuses on understanding direct and underlying determinants of substandard quality of care as well as strengthening monitoring and decision-making during labour [12]. We here present a case-control study of intrapartum management when the outcome was stillbirth. Although intrapartum stillbirths are considered a sensitive indicator of quality of care at the time of birth, there are few such studies from low income settings [3,8,11,13,14].

Methods

Setting

The Zanzibar archipelago, a semiautonomous part of Tanzania, struggles with poverty and a resource constraint health system. Half of the 1.3 million Zanzibarians live below the poverty line [15]. In 2011, the maternal mortality ratio was reported at 287 deaths per 100 000 live births, of which the majority occurs during or shortly after childbirth [16]. Though little is known about perinatal mortality, estimates from 2010 suggest a rate of 50 perinatal deaths per 1000 total births, as opposed to 36 per 1000 in mainland Tanzania [17].

The governmental Mnazi Mmoja Hospital is the only tertiary care facility on the archipelago, and at the time of data collection, the only hospital on the biggest island providing comprehensive obstetric and neonatal care around the clock.

In 2014, 13 291 women delivered in the hospital, corresponding with an average of 36 deliveries daily. Of these, 16% were caesarean sections (CSs), and 44 maternal deaths were counted. According to the official registers, 41 babies were stillborn in 2014 per 1000 total births, and 17 neonatal deaths occurred up to discharge per 1000 live births.

The hospital plays a leading role in clinical training of future Tanzanian health care providers. Yearly, approximately 60 intern doctors do their initial clinical rotations at the department, and more than 200 Tanzanian nursing and medical students are trained.

Intrapartum care is located in two rooms only. In the labour room's 18 beds, women are assisted during the first stage of labour. Postpartum women needing extra surveillance stay in this room as well. When women reach the second stage of labour, they walk 15 meters to the delivery room with only three beds. There is one, occasionally two, theatres available for obstetric surgery. For more than a decade, it has been the aim to apply the World Health Organization's (WHOs) composite partograph for all women in labour, which is a graphic monitoring sheet including foetal heart rate (FHR), labour progress, and maternal vital signs during latent and active phase of labour [18]. A treatment and observation sheet for severe hypertensive disorders has been available since June 2014 and includes evidence-based guidelines on anticonvulsant and antihypertensive treatment [19].
After uncomplicated delivery, the woman and baby are usually observed in the labour room for two hours before referral to the postnatal ward for another four hours where no routine observations are done. Babies with birth asphyxia, with birthweights <1500 grams (g), or delivered by CS are admitted to the Neonatal Intensive Care Unit, which is adjacent to the delivery room.
At day time, there are on average three nurse-midwives and two registrar doctors on duty in the labour and delivery rooms as well as a fluctuating number of intern doctors. During evenings and nights, there are two or three nurse-midwives on duty for all obstetric patients and one registrar doctor assisted by two interns are in charge of the entire department, which also includes an average of 30 gynaecological patients. A second doctor is on call from home. At the department, there are two specialist obstetricians, of which one is member of the study team (TM).

Study population

All stillbirths defined as late foetal deaths ≥1000 g [20] were identified between 1st October 2014 and 31st January 2015 in the admission, delivery, and theatre registers, and their case files were searched for. In addition, to give the best possible estimate of the actual hospital-based stillbirth rate, non-registered stillbirths were sought by systematically going through all case files from the four months. Due to a breakdown in the hospital's storage system of case files prior to October 2015, four months was the maximum feasible period for the study. The control group was identified in the same registers and from the same period. The first control included in October 2014 was selected by throwing dices and afterwards every tenth delivery was identified, resulting in a case-control ratio of approximately 1:4. These tasks were conducted by three research assistants (NH, RSK, and AGM), who had weekly meetings with TM or NM to assure quality of files retrieval. Afterwards, all case files were checked individually by NM to determine whether the inclusion criteria were met for in-depth criterion-based audit (Figure 1).

All singleton stillbirths were included for the audit and divided into three groups: birthweight 1000-1999 g (very preterm stillbirths) [21]; birthweight ≥2000 g without positive FHR on admission (pre-hospital stillbirths), and birthweight ≥2000 g with positive FHR on admission (intra-hospital stillbirths). Hence, pre-hospital stillbirths included not only cases in which the stillbirth diagnosis was made on admission, but also cases where there was no documentation of FHR (neither present nor absent) during the admission. While deliveries from multiple gestations were included in the overall estimation of the stillbirth rate, they were not included in the further audit process as their case files were often too ambiguous; e.g. frequently only one FHR was registered throughout labour. The 2000 g cut-off was decided as this reflects gestational age of 32-34 weeks, where lung maturity no longer plays a major role in survival, and the newborn is less dependent on dexamethasone treatment prior to delivery as well as advanced intensive neonatal care [22]. Data on the very preterm stillbirths are only presented in additional file 1.

Inclusion criteria for controls were singletons with birthweight ≥2000 g and Apgar score ≥7; hence a group with immediate good neonatal outcome. It varied whether one, five or 10 minutes (min.) Apgar scores were recorded. It was therefore decided to use the latest. The case-control study was unblinded.

Criteria of realistic best quality of care

Criteria reflecting locally best possible labour management with the available resources were formulated and agreed upon. This developmental process was conducted by a participatory approach including both local skilled birth attendants and seven external specialists in midwifery and obstetrics. It was decided that the standards should include routine labour care as well as management of frequent complications of labour, related to FHR and foetal distress, labour progression by dilatation and descent, and maternal vital signs with specific focus on severe hypertensive disorders and fever. Selected criteria were adapted from the Active management of labour package, modified by WHO, and supplemented with other evidence-based guidelines [23–31]. Frequency of routine assessments was reduced to reflect local reality. For example, FHR assessments every 30 min. for all women in active labour were kept as optimal practice, but assessments within intervals of <90 min. were applied as an acceptable audit criterium.

In addition, information was collected on background and admission characteristics as well as outcome parameters. Finally, if information was available, time from last FHR assessment till delivery or diagnosis of intrauterine foetal death was calculated, as well as the admission to delivery interval.

Data extraction and analysis

Data were extracted into a structured entry form based on the pre-selected audit criteria, using EPI INFO 7 software (Centres for Disease Control and Prevention, Atlanta, GA, USA). Differences were analysed by logistic regression in SAS Enterprise Guide 6.1 (SAS Institute, Inc., Cary, NC). P-values <0.05 were considered statistically significant.

Results

During the four months studied, 216 stillbirths occurred out of 3690 total births. This corresponds to an overall hospital-based stillbirth rate of 59 per 1000 total births, of which 53/216 (25%) were not reported in the hospital's official registers. Case files of 186/216 (86%) stillbirths and 301/364 (83%)

controls could be retrieved, of which 175/186 (94%) and 293/301 (97%) were from singleton gestations.

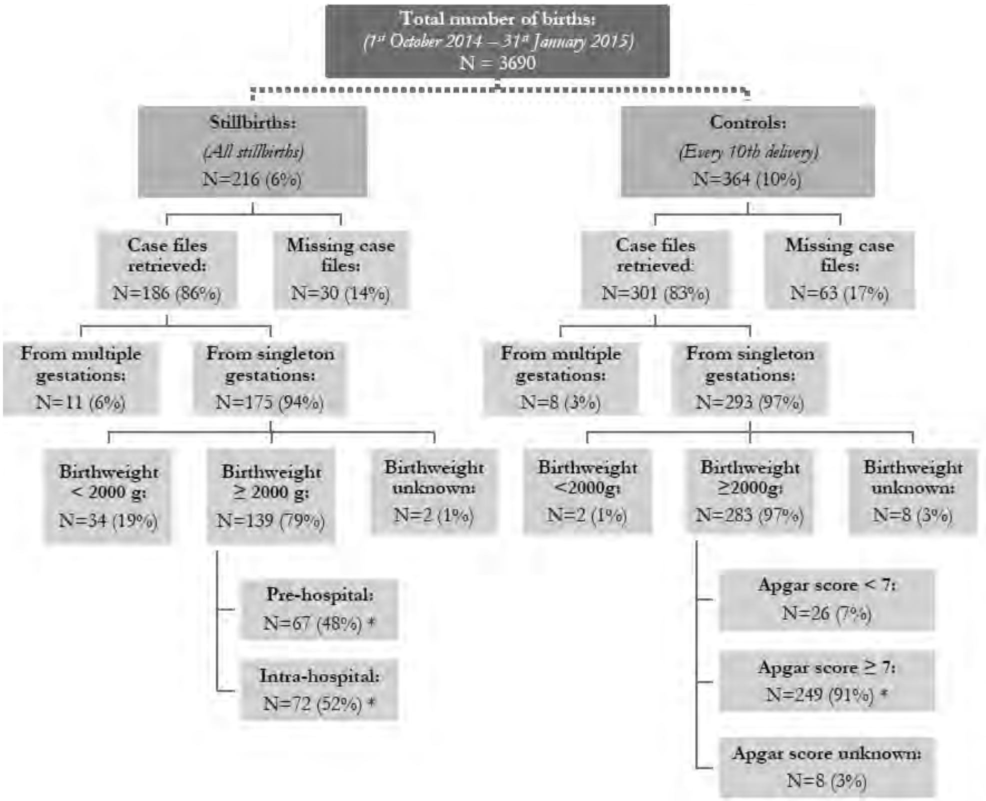

Figure 1 Sampling of case files. Facility-based stillbirth rate was 59 per 1000 total births.
Stillbirths: All late foetal deaths with birthweight ≥1000 grams; Pre-hospital stillbirths: No documented positive foetal heart rate on admission; Intra-hospital stillbirths: Documented positive foetal heart rate on admission. * Groups compared by the case-control study.

Of the singleton stillbirths, 139/175 (79%) had a birthweight ≥2000 g and were included in the case-control study. Of these, 72/139 (52%) had a positive foetal heart on admission (intra-hospital stillbirths), with only one having a congenital abnormality that may have been incompatible with life. Of the 67 pre-hospital stillbirths, 20/67 (30%) had no documentation of FHR readings during the admission. Classification in ‘fresh’ and ‘macerated’ stillbirths was not recorded in 77/139 (55%) stillbirths, and it was therefore not useful for determining the rate of intrapartum deaths. Of controls, 249 met the inclusion criteria (Figure 1).

Background characteristics

Among intra-hospital stillbirths, 39/72 (54%) were nulliparous versus 14/64 (22%) pre-hospital stillbirths (odds ratio [OR] 4.22, 95% confidence interval [CI] 1.99-8.96) and 105/239 (44%) controls (OR 1.51, 95% CI 0.89-2.56). All women, except one, had attended antenatal care at least once. Of women experiencing stillbirth, 69/119 (58%) had attended at least four visits, versus 103/214 (48%) controls (OR 1.49, 95% CI 0.95-2.34). Cases with missing information are excluded from these comparisons (Table 1).

Of multiparous women experiencing stillbirth, 30/83 (36%) had also previously experienced the loss of one or more children, compared to 30/134 (22%) controls (OR 1.96, 95% CI 1.07-3.59). A history of previous CS occurred in 19/83 (23%) compared to 18/134 (13%) controls (OR 1.91, 95% CI 0.94-3.90; table 1).

Of stillbirths, 35/135 (26%) were delivered by CS, compared to 26/244 (11%) controls (OR 2.94, 95% CI 1.68-5.14). While 10/35 (26%) of the CSs resulting in stillbirth were performed in the second stage of labour, this was never the case for controls. Only one baby was delivered by vacuum extraction. Of intra-hospital stillbirths delivered by CS, 10/20 (50%) had FHR documented at the time of deciding on CS. In 5 of these 10 women, FHR were absent. Foetal distress was recorded as an indication for CS in only one case.

Indications for CSs resulting in stillbirth were: 21/35 (60%) for prolonged labour, of which one was also due to foetal distress; 8/35 (23%) due to antepartum haemorrhage, of which three had severe pre-eclampsia; an additional 2/35 (6%) solely due to severe pre-eclampsia; 2/35 (6%) due to cord prolapse; and 2/35 (6%) due to ≥2 previous CSs. Concerning the prolonged labour group, 1/21 (5%) had signs of obstructed labour on admission and another 6/21 (29%) developed uterine rupture; half had signs of rupture on admission, of which two were referrals, and three ruptures occurred at the study site. Four of the women with uterine rupture had a history of previous CS (Table 2).

There were three maternal deaths in the study population. They were all associated with stillbirth and suffered from severe delays in intrahospital surveillance and management (additional file 2).

Table 1 Characteristics of delivering women

	Case-control study	*BW ≥2000 grams*, N (%)	
	Cases Pre-hosp. Stillbirths	**Cases** Intra-hosp. Stillbirths	**Controls** *Apgar 7-10*
Of all women in the study:	*(n=67)*	*(n=72)*	*(n=249)*
Age			
<20 years	2 (3.0%)	7 (9.7%)	26 (10.4%)
20-29 years	26 (38.8%)	35 (48.6%)	122 (49.0%)
30-39 years	27 (40.3%)	28 (38.9%)	83 (33.3%)
≥40 years	8 (11.9%)	2 (2.8%)	15 (6.0%)
Information missing	4 (6.0%)	0 (0.0%)	3 (1.2%)
Parity on admission			
Para 0 ‡	14 (20.9%)	39 (54.2%)	105 (42.2%)
Para 1-4	33 (49.3%)	23 (31.9%)	99 (39.8%)
Para ≥ 5	17 (25.4%)	10 (13.9%)	35 (14.1%)
Information missing	3 (4.5%)	0 (0.0%)	10 (4.0%)
Antenatal care			
≥4 visits	31 (46.3%)	38 (52.8%)	103 (41.4%)
1-3 visits	23 (34.3%)	26 (36.1%)	111 (44.6%)
Not attended	0 (0.0%)	1 (1.4%)	0 (0.0%)
Information missing	13 (19.4%)	7 (9.7%)	35 (14.1%)
HIV			
Negative	54 (80.6%)	62 (86.1%)	211 (84.7%)
Positive	0 (0.0%)	2 (2.8%)	0 (0.0%)
Information missing	13 (19.4%)	8 (11.1%)	38 (15.3%)
Gestational age			
No information on LMP/gestation weeks	46 (68.7%)	49 (68.1%)	181 (72.7%)
Previous obstetric history			
Of multiparous women:	*(n=50)*	*(n=33)*	*(n=134)*
Previous death of child/children * ‡‡	18 (36.0%)	12 (36.4%)	30 (22.4%)
1 previous CS	7 (14.0%)	8 (24.2%)	8 (6.0%)
≥2 previous CSs	2 (4.0%)	2 (6.1%)	10 (7.5%)

* Documentation was insufficient to clearly distinguish perinatal deaths from deaths later in life. ‡ Difference between pre- and intra-hospital stillbirths: OR 4.22, 95% CI 1.99-8.96; ‡‡ Difference between stillbirths and controls: OR 1.96, 95% CI 1.07-3.59 ; BW = birthweight; CI = confidence interval; CS = caesarean section; LMP = last menstrual period; OR = odds ratio

Table 2 Mode of delivery, maternal outcome, and appearance of stillborn babies

	Case-control study; *BW ≥2000 grams;* N (%)		
Mode of delivery	**Cases** Pre-hosp. Stillbirths	**Cases** Intra-hosp. Stillbirths	**Controls** *Apgar 7-10*
Of all women in the study:	*(n=67)*	*(n=72)*	*(n=249)*
Spontaneous vaginal	45 (67.2%)	46 (63.9%)	213 (85.5%)
Vaginal breech	3 (4.5%)	5 (6.9%)	5 (2.0%)
Vacuum extraction	1 (1.5%)	0 (0.0%)	0 (0.0%)
Caesarean section * ‡	15 (22.4%)	20 (27.8%)	26 (10.4%)
Mode of delivery unknown	3 (4.5%)	1 (1.4%)	5 (2.0%)
Maternal outcome			
Of all women in the study:	*(n=67)*	*(n=72)*	*(n=249)*
Maternal deaths	2 (3.0%)	1 (1.4%)	0 (0.0%)
Post-partum haemorrhage ‡‡	7 (10.4%)	10 (13.9%)	14 (5.6%)
Episiotomy/spontaneous tears ** ‡‡‡	6 (9.0%)	19 (26.4%)	79 (31.7%)
Of vaginal deliveries:	*(n=49)*	*(n=51)*	*(n=218)*
Prolonged admission, ≥1 day ‡‡‡‡	9 (18.4%)	0 (0.0%)	3 (1.4%)
Of caesarean sections:	*(n=15)*	*(n=20)*	*(n=26)*
Prolonged admission, ≥5 days	1 (6.7%)	3 (15.0%)	2 (7.7%)
'Fresh' versus 'macerated' stillbirths			
Of all women in the study:	*(n=67)*	*(n=72)*	*(n=249)*
Classification not recorded	36 (53.7%)	41 (56.9%)	NA

* Overall, 9/35 (26%) of the caesarean sections with stillbirth were done prior to active labour, and 10/35 (29%) in second stage. Among controls, this was the case for 13/26 (50%) and 0/26 (0%), respectively.

** Information was insufficient to distinguish between spontaneous vaginal tears and episiotomies.

‡ Difference between stillbirths and controls: OR 2.94, 95% CI 1.68-5.14

‡‡ Difference between stillbirths and controls: OR 2.34, 95% CI 1.12-4.90

‡‡‡ Difference between pre-hospital stillbirths and controls: OR 0.21, 95% CI 0.09-0.51

‡‡‡‡ Difference between pre-hospital stillbirths and controls: OR 16.13, 95% CI 4.18-62.17

BW = birthweight; CI = confidence interval; NA = not applicable; OR = odds ratio

Admission and partograph use

Women experiencing intra-hospital stillbirths were admitted particularly early; 42/71 (59%) before the active phase of labour, compared to 68/246 (28%) controls (OR 3.79, 95% CI 2.19-6.57). Their median time from admission to delivery was 11 hours and 36 min. (interquartile range (IQR): 5 hours and 42 min. to 21 hours and 55 min.). Rates of referrals were similar among pre- and intra-hospital stillbirths. The referral rate among stillbirths (21/139; 15%) was higher than the rate among controls (12/249 (5%); OR 3.52, 95% CI 1.67-7.39; Table 3).

Table 3 Admission and partograph use

	Case-control study; *BW ≥2000 grams,* N (%)		
	Cases Pre-hosp. stillbirths	**Cases** Intra-hosp. Stillbirths	**Controls** *Apgar 7-10*
Progress on admission and referrals			
Of all women in the study:	*(n=67)*	*(n=72)*	*(n=249)*
Before labour pain ‡	5 (7.5%)	2 (2.8%)	12 (4.8%)
Latent phase of labour * ‡	18 (26.9%)	40 (55.6%)	56 (22.5%)
First stage of labour	23 (34.3%)	29 (40.3%)	153 (61.4%)
Second stage of labour	15 (22.4%)	0 (0.0%)	25 (10.0%)
Stage of labour on admission unknown	6 (9.0%)	1 (1.4%)	3 (1.2%)
Referral from smaller health centre ‡‡	10 (14.9%)	11 (15.3%)	12 (4.8%)
Partograph use			
Of women in first stage of labour:	*(n=39)*	*(n=69)*	*(n=207)*
The partograph at least partially applied ‡‡‡	27 (69.2%)	66 (95.7%)	183 (88.0%)
Of women with the partograph applied:	*(n=27)*	*(n=66)*	*(n=183)*
First cervical dilatation in active labour plotted correctly on the alert line	18 (66.7%)	53 (80.3%)	166 (90.7%)

* Cervical dilatation <4 centimeter

‡ Difference in women admitted before active labour between intra-hospital stillbirths and controls: OR 3.79, 95% CI 2.19-6.57

‡‡ Difference between intra-hospital stillbirths and controls: OR 3.52, 95% CI 1.67-7.39

‡‡‡ Difference between pre-hospital stillbirths and both intra-hospital stillbirths and controls: OR 9.78, 95% CI 2.56-37.42, and OR 3.39, 95% CI 1.52-7.56, respectively.

BW = birthweight; CI = confidence interval; OR = odds ratio

Of women reaching active labour and admitted before second stage, significantly more in the pre-hospital stillbirth group did not have a partograph filled in, when compared to both intra-hospital stillbirths (OR 9.78, 95% CI 2.56-37.42) and controls (OR 3.39, 95% CI 1.52-7.56; Figure 2). In all groups, 237/276 (86%) women with a partograph applied had the first cervical dilatation appropriately plotted on the alert line (Table 3).

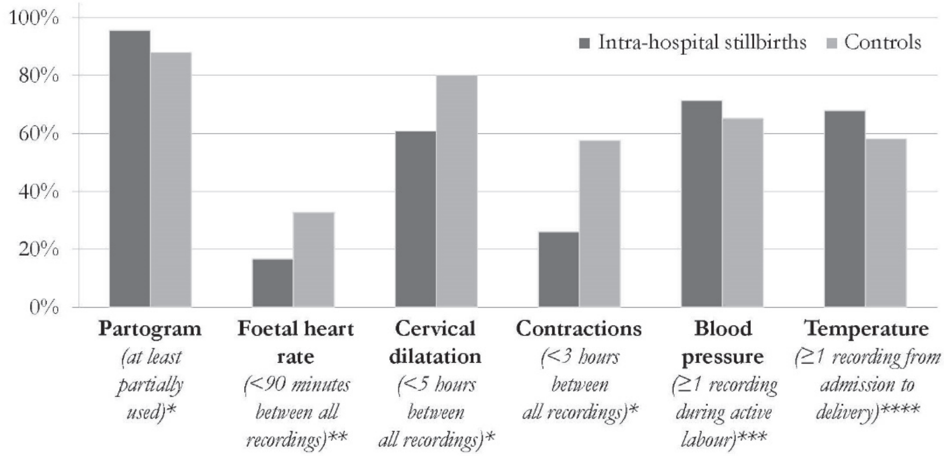

Figure 2 Proportion of labouring women reaching each of six criteria for minimal acceptable routine surveillance during labour. Significant differences were found in FHR (OR 0.41, 95% CI 0.21-0.81), cervical dilatation (OR 0.37, 95% CI 0.21-0.68,) and contractions (OR 0.26, 95% CI 0.14-0.47).Intra-hospital stillbirths: documented positive FHR on admission. Controls: Apgar score ≥7.

* Of all women at the hospital during active first stage of labour (n=69 and n=207, respectively).
** Of women with at least one FHR reading (n=72 and n=204, respectively).
*** Of women reaching active phase of labour (n=70 and n=235, respectively).
**** Of all women in the study (n=72 and n=249, respectively).
FHR, foetal heart rate; BP, blood pressure; Temp, temperature

Foetal heart rate (FHR)

In all intra-hospital stillbirths, FHR was reassuring on admission. However, in 60/72 (83%) >90 min. elapsed between FHR assessments during active phase of labour, which was the case for 137/204 (67%) controls (OR 2.45, 95% CI 1.23-4.85; Figure 2). Among 63 intra-hospital stillbirths, median time from last FHR recording till delivery or detected intrauterine foetal death was 3 hours and 30 min. (IQR: 1 hour and 15 min. - 5 hours and 15 min.), compared to 2 hours and 0 min. in 176 controls (IQR: 1 hour and 3 min. - 3 hours and

58 min.). For each one-hour increase in duration from last FHR assessment, the odds of stillbirth increased 20% (OR 1.20; 95% CI 1.08-1.34).

In 58/72 (81%) of the intra-hospital stillbirths, there was no documentation of foetal distress or foetal death prior to delivery (Table 4).

Table 4 Intrapartum surveillance of the foetus

	Case-control study; *BW ≥2000 grams;* N (%)	
	Cases Intra-hosp. Stillbirths	**Controls** *Apgar 7-10*
Of women with at least one FHR reading:	*(n=72)*	*(n=204)*
FHR in normal range on admission (110-160 beats per min.)	72 (100.0%)	202 (99.0%)
Foetal distress detected prior to delivery	15 (20.8%)	0 (0.0%)
<90 min. between any 2 recordings of FHR ‡	12 (16.7%)	67 (32.8%)
Median time from last FHR till delivery or detected IUFD (min.) * ‡‡	210	120

* It was possible to calculate average time from last FHR till delivery in 63 (86%) cases and 176 (86%) controls. The interquartile ranges were 75-315 min. and 63-238 min., respectively.

‡ Difference between intra-hospital stillbirths and controls: OR 0.41, 95% CI 0.21-0.81

‡‡ For each one-hour increase in duration from last FHR assessment, the odds of stillbirth increased 20% (OR 1.20; 95% CI 1.08-1.34)

BW = birthweight; CI = confidence interval; FHR = foetal heart rate; min. = minutes; OR = odds ratio

Labour progress

The highest proportion of women admitted in the latent phase of labour with no cervical assessments recorded during active labour occurred among pre-hospital stillbirths: 14/23 (61%) compared to 24/68 (35%) controls (OR 2.85, 95% CI 1.08-7.55; Table 5).

In 27/69 (39%) women experiencing intra-hospital stillbirth, ≥5 hours elapsed between any two vaginal examinations during active labour, compared to 40/207 (19%) controls (OR 2.68, 95% CI 1.48-4.86, Figure 2). This resulted in delays in diagnosing poor labour progress, which was a common complication among intra-hospital stillbirths when compared to controls (Table 5). After crossing the alert line, in 18/33 (55%) and 9/51 (18%), respectively, ≥3 hours elapsed before next vaginal examination (OR

5.60, 95% CI 2.07-15.13). After crossing the action line, in 2/16 (13%) intra-hospital stillbirths and 9/21 (43%) controls, membranes were still intact, and in an additional 3/16 (19%) and 5/21 (24%), there was no information regarding membranes. Moreover, severe delays in surveillance were found after crossing the action line.

Table 5 Intrapartum surveillance of labour progress

	Case-control study, *BW ≥2000 grams,* N (%)		
	Cases Pre-hosp. Stillbirths	**Cases** Intra-hosp. Stillbirths	**Controls** *Apgar 7-10*
Surveillance in latent phase of labour			
Of women admitted before active labour:	*(n=23)*	*(n=42)*	*(n=68)*
Assessment of cervical dilatation during active labour * ‡	9 (39.1%)	37 (88.1%)	44 (64.7%)
Assessment of labour progression			
Of women in first stage of active labour:	*(n=39)*	*(n=69)*	*(n=207)*
<5 hrs. between any 2 recordings of cervical dilatation in active labour ‡‡	39 (100.0%)	42 (60.9%)	167 (80.3%)
<3 hrs. between any 2 recordings of uterine contractions ‡‡‡	33 (84.6%)	18 (26.1%)	120 (58.0%)
Alert line crossed ‡‡‡‡	2 (5.1%)	33 (47.8%)	51 (24.5%)
Action line crossed ‡‡‡‡‡	1 (2.6%)	16 (23.2%)	21 (10.1%)

* If a vaginal examination was done in latent phase ≤4 hours prior to delivery, this was registered as acceptable
‡ Difference between pre-hospital stillbirths and controls: OR 0.35, 95% CI 0.13-0.93
‡‡ Difference between intra-hospital stillbirths and controls: OR 0.37, 95% CI 0.21-0.68
‡‡‡ Difference between intra-hospital stillbirths and controls: OR 0.26, 95% CI 0.14-0.47
‡‡‡‡ Difference between intra-hospital stillbirths and controls: OR 2.80, 95% CI 1.59-4.95
‡‡‡‡‡ Difference between intra-hospital stillbirths and controls: OR 2.67, 95% CI 1.30-5.49
BW = birthweight; CI = confidence interval; OR = odds ratio

Oxytocin for labour augmentation was administered in 26/72 (36%) of intra-hospital stillbirths, compared to 58/249 (23%) controls (OR 1.86, 95% CI 1.06-3.27). However, in 8/26 (31%) of those, there was no indication for augmentation, and in an additional 7/26 (27%) the infusion was started between the alert and action line with the membranes still intact. Likewise, 34/58 (59%) controls had the infusion started before crossing the alert line (Figure 3). In none of the cases, information on oxytocin titration and maintenance dose was documented, and FHR and contractions were never assessed half-hourly after starting the infusion. Preceding 13/35 (37%) of CSs resulting in stillbirth, oxytocin was started for labour augmentation. This was also the case in 4 of 6 uterine ruptures, of which three had a history of one previous CS.

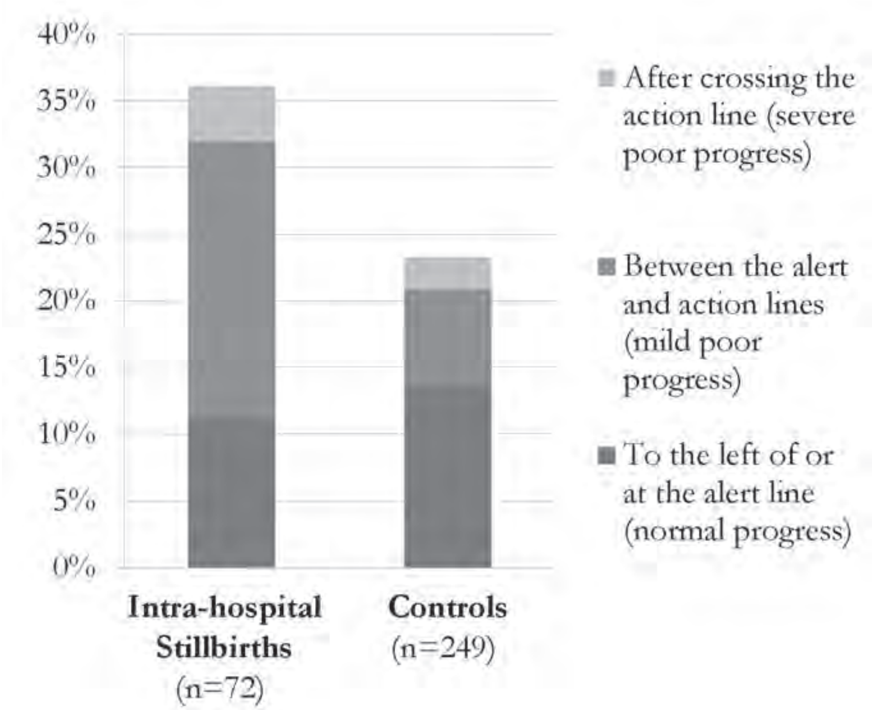

Figure 3 Initiation of oxytocin for labour augmentation, according to labour progress. The difference in overall use of oxytocin for labour augmentation between intra-hospital stillbirths and controls was significant with the stillbirth cases receiving the treatment more often (OR 1.86, 95% CI 1.06-3.27).

Intra-hospital stillbirths: Documented positive foetal heart rate on admission.

Controls: Apgar score ≥7.

Maternal vital signs

Prevalence of severe hypertensive disorders was significantly higher among women experiencing stillbirth (27/139, 19%) than in controls (10/249, 4%; OR 5.76, 95% CI 2.70-12.31). An additional 33/130 (25%) and 81/235 (35%) of women reaching active phase of labour, had no recordings of blood pressure during active labour (OR 0.65, 95% CI 0.40-1.04; Figure 2). Overall, 13/27 (48%) of all stillbirth cases with severe hypertension had significant proteinuria (≥2+ on urine dipstick). However, urine analysis was not recorded in an additional 6/27 (22%) cases, and information about clinical symptoms was too sparse to analyse for signs of organ failure. In 18 (67%) of all 27 stillbirth cases with severe hypertension, there were no recordings of relevant antihypertensive treatment. Of the severe pre-eclampsia cases, 4/13 (31%) had no documentation of having received magnesium sulphate.

In 43/139 (31%) stillbirths and 104/249 (42%) controls, there was no maternal temperature recording from admission till delivery (OR 0.63, 95% CI 0.40-0.97; Figure 2). Intrapartum fever or infection were rare diagnoses with five stillbirths related to infection and none among controls.

Discussion

The overall facility-based stillbirth rate was 59 per 1000 total births. Approximately 80% of the singleton stillbirths had a birthweight ≥2000 g. In half of these, the FHR was still present after hospital admission. In all groups, major challenges were identified in intrapartum surveillance, timely decision-making, and documentation. This resulted in stillbirths as well as unacceptable maternal and neonatal risks for all women and babies. The findings are largely in line with the limited number of other stillbirth studies from sub-Saharan Africa [3,11,13,14]. Our study provides a more in-depth assessment of intrapartum care, which may contribute to effectively target interventions to reduce risks through improved quality of care (box 1).

Causes of stillbirths

As suggested in other studies, the high number of intra-hospital stillbirths appeared primarily to be a sensitive indicator of substandard quality of care [3,32,33]. For instance, primigravid women suffered an increased risk of intra-hospital stillbirths, which may be associated with their admission earlier in labour, and longer and more complicated labour duration [34]. In addition, increased vulnerability and need for quality care among all women experiencing intra-hospital stillbirth is emphasised by the association with severe hypertension and prior loss of child.

While staff often referred to late referral of women as a major cause to adverse labour outcome, 85% of women experiencing intra-hospital stillbirth directly sought care at the study site, and 58% were admitted before active labour.

As found in other East African studies [8,11,35], not only was correct management often delayed, unnecessary and even harmful management was sometimes initiated. The presence of under- as well as over-treatment became particularly apparent when reviewing cases with poor progress of labour, where CSs often were found unnecessary. Yet, as only 4% of foetuses had a documented positive FHR when deciding to perform CS, it is doubtful how big an impact e.g. possible delays in the decision-to-delivery interval for CS had on causing stillbirths; the unnecessary CSs may rather have caused avoidable maternal risks. In contrast, the under-use of vacuum extraction may be seen as an indicator of poor FHR monitoring, leading to undisclosed foetal distress in the second stage of labour.

Likewise, there appeared to be a dangerous over-use of oxytocin for labour augmentation. This is similar to studies from Bangladesh and Pakistan, where misuse of oxytocin was associated with stillbirth and birth asphyxia [36,37]. Notably, the Pakistani study draws attention to the danger of insufficiently trained healthcare workers administrating this highly potent drug [36].

Similar to intrapartum care, antenatal visits did not appear consistent with effective antenatal surveillance and treatment, and as in other studies, this appeared to be a central determinant of both pre- and intra-hospital stillbirths [33]. For instance, while nearly all women attended antenatal care at least once, a severe hypertension prevalence of 19% among stillbirths suggests missed opportunities [38]. Furthermore, the fact that less than half of the study population had attended four antenatal care visits indicate a lost chance for continuity in care [39].

Maternal risks

Substandard quality of risk assessment on admission as well as poor intrapartum surveillance and decision-making were associated with profound maternal risks and appeared to be major determinants of the death of three women (Additional file 2). Women with foetal death on admission were the most neglected. While they were in particular high intrapartum risk due to the often underlying morbidity and further at increased postpartum risk of e.g. obstetric fistula, labour progress and vital signs were often undocumented throughout active labour [40,41].

CS is generally not indicated when there is foetal death [42]. However, a high proportion of CSs were done on doubtful indications, and many were related to insufficient management of prolonged labour. Thus, 26% CSs among stillbirths is unacceptably high; in particular as the vast majority had either foetal death diagnosed or did not have FHR recorded prior to surgery. Except for an even higher rate found at three hospitals in Mozambique [11], this is markedly higher than other studies from low- and middle-income countries [33]. A high proportion of CSs were done in the second stage of labour without an attempt of operative or destructive vaginal delivery. While short- and long-term maternal risks of suboptimally treated prolonged labour and unnecessary CSs are widely established [34,43,44], lack of transparency as to when to perform CS is found in other African studies too [11,45,46].

Six women suffered from uterine rupture. When considering the low level of surveillance in 14% of stillbirth cases with one or more previous CSs, and the misuse of oxytocin, many more appeared at risk of rupture. Furthermore, while foetal bradycardia is an early sign of impending rupture [47], substandard FHR assessments made it less useful in timely detection.

Of the 19% with severe hypertensive disorders experiencing stillbirth, more than half had severe pre-eclampsia or eclampsia. A Nigerian study found a similar prevalence and comparable insufficient antenatal and intrapartum surveillance and treatment of these dangerous conditions [48]. Recent data from well-resource settings emphasise suboptimally treated severe hypertension as an important contributor to maternal mortality [38]; in our study, 67% of women with severe hypertension did not receive any antihypertensive treatment.

Clinical implications

At this East African referral hospital, facility births were frequently not accompanied by skilled intrapartum attendance. While widespread insufficiency in quality of routine and emergency labour care may partly be caused by massive structural constraints, suboptimal care often resulted in more risk associated, complicated, and resource-draining interventions. Some of the revealed deficiencies may be addressed even without high costs in manpower and other resources, and the main risks and determinants are crucial in effectively designing low cost interventions (box 1).

For many years, effectiveness of using the WHO partograph has been questioned [49,50]. Yet, when analysing quality of intrapartum care at low resource facilities, partograph use for timely surveillance and decision-making appears central in ending preventable complications [11,14,18,35]. In 86% of all cases where the partograph was applied, first cervical dilatation in active phase of labour was plotted correctly on the alert line, and knowledge on accurate recording did not appear to be a major challenge. However, similar to other studies, WHO's recommendations for frequency of recordings were not followed and also did not seem achievable with the resources available [35,51,52]. In the present study, even though the majority of intrapartum decision-making did not seem influenced by partograph use or evidence-based guidelines, it would be premature to conclude ineffectiveness of the WHO partograph. However, for the partograph to assist in surveillance and management, it must be coupled to a locally achievable and relevant labour management protocol. Although often not prioritised in evaluations of partograph use, this has previously proven effective [14,18]. For instance, when considering the low resources at the study

site, it seems unrealistic to assure close monitoring and titration of oxytocin augmentation if more than a few women are treated simultaneously [53].
This study identified 25% underreporting of stillbirths in the official hospital registers, and even though a systematical surge was conducted through all piles of case files, a considerable number of files remained missing (Figure 1). Initially, it was the intention also to include early neonatal deaths in the study. However, data collection revealed frequent default record keeping between the obstetric and neonatal units as well as substantial underreporting of very early neonatal deaths in all registers, which resulted in reluctance to include them. Furthermore, missing documentation in medical records – or “blanks” – was a frequent finding, which is likely to have affected patient care and labour outcomes. Incomplete health information systems are notoriously linked with poor health outcomes [3,54]. It is warranted that the underlying factors for these “blanks” in medical recording are evaluated, and that quality of documentation and record keeping as well as use of the data are improved.

Strengths and limitations

The present pragmatic study was found suitable as a structured, simple, and low-cost method to identify central challenges in intrapartum care at this real-world setting with limited information available. Classification in pre- and intra-hospital stillbirths was a useful, more achievable, and simple alternative to ‘fresh’ versus ‘macerated’ stillbirths, which, as in a study from Ghana, was found unreliable [55]. Moreover, intra-hospital stillbirths may be seen as an even stronger indicator of intra-hospital quality of care than ‘fresh’ stillbirths. However, in 30% of pre-hospital stillbirths there was no FHR documentation on or after admission, which may potentially hide an even higher proportion of intra-hospital stillbirths.
Selected audit criteria were unambiguously applicable. Yet, though intensive efforts were made for adapting international evidence-based guidelines to reach local reality, some criteria, such as <90 min. between FHR recordings, might be too optimistic as a sensitive audit standard for detecting quality improvements at this setting.

A central limitation to the study is that a criterion-based audit does not allow exploration of underlying determinants of substandard care, such as structural needs for supplies, space, and knowledge/skills among staff. Another limitation is the varying quality of data, which might bias results; there may be a tendency of staff to forget reporting given care or to under-report mismanagement. Participant observations during the study period also identified the issues presented in the current paper, and qualitative analysis opened up to a complex tangle of both structural and process related underlying challenges influencing health providers' ability to deliver acceptable quality of care.

Conclusion

Stillbirths are both a devastating burden of avoidable lost lives in itself and a strong and easy to assess indicator of quality of antenatal and intrapartum care. Substandard care led to substantial maternal and perinatal risks, which furthermore were related to resource draining interventions that were not always necessary. Furthermore, 25% underreporting of stillbirths in hospital registers indicates a poor health information system. These findings are largely in line with other reports from sub-Saharan Africa, and improvement of intra-hospital obstetric knowledge, care, and documentation is central to end preventable birth-related deaths and disabilities. Considering referral hospitals' major teaching tasks for future health providers, it is warranted to address the tertiary level in order to achieve quality improvement of the entire health care sector.

Box 1 Seven target areas for improving intrapartum quality of care at the study site.

1. Strengthened risk assessment on admission, with particular focus on foetal heart rate, blood pressure, temperature, and previous obstetric history.
2. Improved routine surveillance during latent and active phase of labour, regarding all key parameters (foetal heart rate, dilatation of cervix and descent, contractions, maternal vital signs, and urinary output).
3. Increased prioritization of women with already diagnosed intrauterine foetal death for routine assessments during labour.
4. Timely prevention and management of prolonged labour, with focus on alternative and less harmful interventions than oxytocin infusion for labour augmentation (e.g. artificial rupture of membranes and emptying of bladder), and more restrictive dosages and improved surveillance when oxytocin is administered.
5. Reduction of caesarean sections after intrauterine foetal death, by improved management of prolonged labour, and enforcement of vacuum extraction and craniotomy use.
6. Improved management of severe hypertensive disorders, with particular focus on antihypertensive treatment.
7. Better intrapartum documentation as well as record keeping.

Ethics approval Ethical approval was obtained from the Zanzibar Medical and Research Ethical Committee (ZAMREC/0001/JUNE/014) and Mnazi Mmoja Hospital, and the PartoMa project is registered with ClinicalTrials.org (NCT02318420, 4th November 2014). In this baseline study of case file review, all patient identities were anonymised and assigned a research number. Individually obtained informed consent was therefore not required.

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Contributors NM formulated the study design, managed data acquisition, analysed and interpreted data, and drafted the paper. NH participated substantialy in acquisition, analysis, and interpretation of data, and in criticaly revising the paper draft. ICB, JvR, TM, and BBN contributed substantially to the study design, analysis and interpretation of data, and they critically revised the paper draft. RSK and AGM participated substantialy in acquisition of data and in criticaly revising the paper draft. All authors have approved to the final version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Additional file 1: Data on very preterm stillbirths (birthweight <2000 grams):
Additional file 2: Intra-hospital management preceding the three maternal deaths

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Chapter 3

The biopsychosocial impact of stillbirths on mothers: a cross-sectional study in a low-resource setting

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Abstract

Objective Maternal mental disorders following childbirth occur more frequently with stillbirths. This study investigated maternal psychosocial health and daily functioning of women who experienced a stillbirth in a low-resource setting.

Design A mixed-methods, cross-sectional study using semi-structured interviews and screening tools: mental health (PHQ-9 and HTQ-16), disability (WHODAS 2.0), perceived social support (HSCL-25) and birth experience (BSS-R). Descriptive and regression analyses were used to test associations. Qualitative data was processed using interpretative phenomenological analysis.

Setting Zanzibar, Tanzania, March to July 2018

Participants Postpartum women who delivered 3-6 months prior at Zanzibar's referral hospital, Mnazi Mmoja Hospital.

Primary outcome measures Depression (PHQ-9 score), post-traumatic stress disorder (HTQ-16 score), and disability (WHODAS 2.0 score)

Results 246 women participated: 132 with healthy infants and 114 with stillbirths. Of these, 73% (n=96) of women with healthy infants and 75% (n=86) with stillbirths had symptoms of depression and 23% (n=31) and 24% (n=27) screened positive for depression respectively. Also, 80% (n=105) of women with healthy infants and 96% (n=110)) of women with stillbirths had one or more symptoms of PTSD; 4% of all women screened positive for PTSD (no stillbirth: 3% (n=4), stillbirth: 5% (n=6), p=0.52).
Women with stillbirths had significantly lower birth satisfaction (Odds ratio: 0.93, CI 0.89-0.98). Sociodemographic characteristics (age, marital status and employment) and care around birth were independent risk factors for

mental health problems and disability. Social and spiritual support was positively viewed.

Conclusion This study highlights the susceptibility of all mothers to mental health problems in low resource settings. Respectful and bereavement care during and following childbirth to help mothers cope with their birth experiences and prevent psychological distress need to be developed in such settings.

Introduction

Maternal mental disorders are among the most common complications affecting women during and after pregnancy and include post-traumatic stress (PTSD), anxiety, eating, personality, depressive and psychotic disorders.[3] Stillbirth is one of the most emotionally distressing experiences and a cause of mental health decline in women as the anticipation of a healthy baby is changed into grief and mourning.[9] Stillbirths also have extensive direct and indirect costs on women's family and society including negative effects on relationships, finances and siblings' survival and development. Notably, these are aggravated by common taboos around both stillbirths and mental illnesses. [1–4,10–15]

Compared to high-income countries, estimates of mental health disorders in low and middle-income countries (LMICs) are harder to obtain due to a dearth of studies. However, higher prevalence of nonpsychotic mental disorders has generally been reported with estimated prevalence of 15.9% during pregnancy and 18.9% in the postpartum period.[3–6] Mental health problems in LMICs are related to social and economic contexts, gender-based risks, and general and reproductive health, including adverse birth outcomes.[4,7,8] While the majority (98%) of the two million stillbirths annually occur in LMICs, only a few studies focusing on the impact of stillbirths on mental health have been conducted in such setting.[13,16] This reflects the lack of attention and focus on both maternal mental health and stillbirths.[17,18,19]

Using the dynamic biopsychosocial model as a framework, this study investigated the psychological and physical impact of stillbirths on maternal health and the roles of social support and birth experience in a low-resource setting (Figure 1). [20]

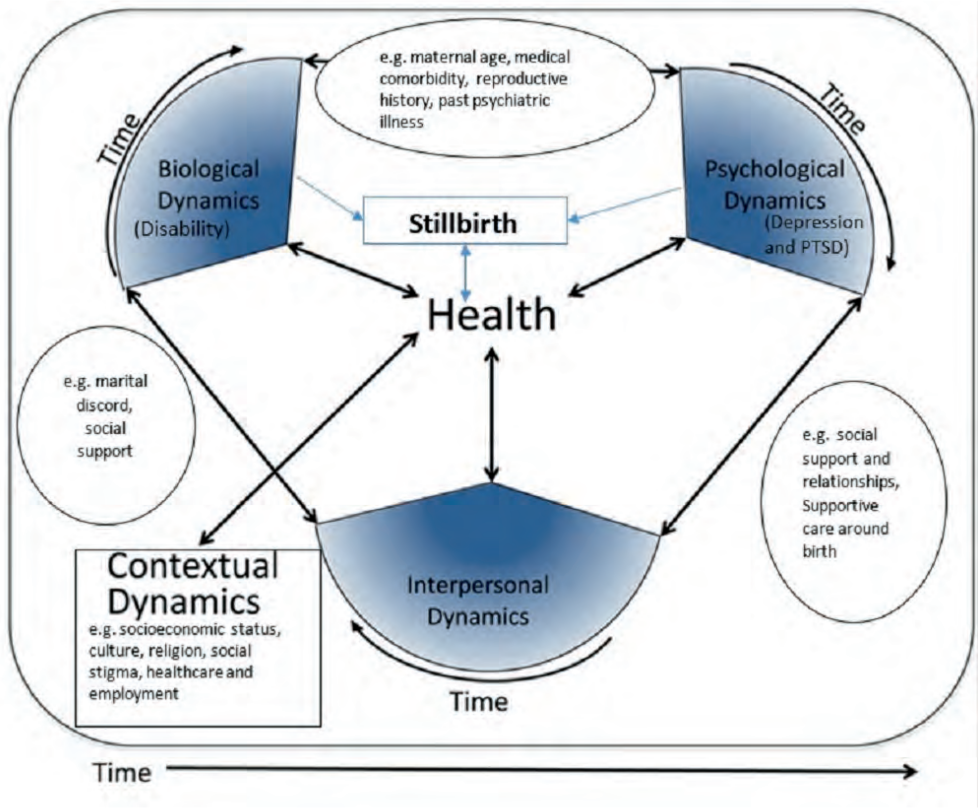

Figure 1. The Dynamic Biopsychosocial model. To understand the impact of stillbirth, this study used an adaptation of this model, in which three dynamics need to be considered for the generation of health outcomes: the biological, the psychological and the social. These dynamics influence each other to bring about the current state of health and all these factors change over time. As such, the state of health may lead to stillbirth and consequently, stillbirth experience may affect health. In this study, disability, depression and posttraumatic stress disorder (PTSD), and perceived social support received from healthcare workers, family and community members represented the biological, psychological and interpersonal dynamics, respectively. Adapted from Lehman et al, 2017, with permission.[20]

Methods

Study Design

This was a cross-sectional study taking a sequential explanatory mixed-methods approach.[21] Data was collected from March to July 2018 and included women who delivered 3 to 6 months prior (i.e., between October 2017 and March 2018). The study adhered to a predefined protocol and incorporated the STROBE and COREQ standards for reporting.[22,23]

Setting

The study was conducted in Mnazi Mmoja Hospital (MMH), a tertiary referral hospital serving 1.3 million people on the islands of Zanzibar, United Republic of Tanzania. Tanzania has an estimated stillbirth rate of 19 per 1000 total births, of which 47% occur intrapartum.[16,24] Reports from mainland Tanzania show high levels of mental health disorders in pregnancy: 33.8% depression, 4.9% moderate/severe PTSD symptoms and 0.32% puerperal psychosis.[25–27]

Participants

The study population consisted of two groups of women who delivered at MMH: women who experienced a stillbirth, and women with a living newborn of at least 2000g with Apgar score ≥7 at one minute. Exclusion criteria were as follows: <18 years old, currently pregnant, twin delivery with one surviving child, maternal near-miss[29], birth before arrival to MMH, or history of diagnosed psychiatric illness.

Women with stillbirths were identified from birth certificates and patient files. For each woman with stillbirth listed in the delivery book, the next woman with a healthy live-born, a listed contact number and who delivered within the same week was selected for comparison. If a woman without stillbirth was not traceable, we replaced her with the next eligible woman in the registry book. If a stillbirth woman could not be contacted, the respective woman without stillbirth was still included in the study. Of the women with stillbirth, a subset was conveniently sampled for further in-depth semi-structured interviews. The interviews were conducted until uniformity and saturation of concepts among interviews were established.

Variables

The main explanatory variable was a stillbirth experience, defined as a baby of ≥ 1000g birthweight and no sign of life at birth.[30] The primary outcomes were depression, PTSD and daily functionality. Confounding variables considered were socio-demographic characteristics (age, education, marital and working status), parity, previous foetal loss, mode of delivery, assessment time point, social support and, birth satisfaction.

Data source and measurement

Depression was screened using the Patient Health Questionnaire (PHQ-9), an internationally-accepted tool that was also available in Swahili.[31] The scale consists of 9 statements about the respondents' wellbeing in the preceding 2 weeks. PHQ-9 scores represent none or minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19), and severe depression (20-27).[32] Based on clinical treatment recommendations, the categories were collapsed to form three groups (none (<5), mild-moderate (5-14) and severe depression(>14).[33]

PTSD was assessed using the Harvard trauma questionnaire (HTQ-16), based on the DSM-III-R/IV criteria.[34] Participants were asked to what extent PTSD symptoms including re-experiencing/intrusion, numbing/avoidance and arousal/hypervigilance have bothered them in the past week. The chosen mean cut-off score was 2.5 as recommended for clinical settings.[35]

Disability was assessed and scored using the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) short form, which contains 12-item questions. It measures the level of functioning, regardless of medical diagnosis, in six domains: cognition, mobility, self-care, getting along with others, life activities and participation in society.[36]

The birth satisfaction scale – revised version (BSS-R) was used to assess the birth experience of the participants. It is a 10-items questionnaire rated on a 5-point Likert scale measuring the perceptions of i) quality of care provided

ii) women's personal attributes and iii) stress experienced during labour.[37] Social impact of stillbirths was assessed using the Hopkins Symptom Checklist-25 (HSCL-25) Social Support scale. This eight-question scale has been validated and adapted to Tanzania,[38,39] and assesses the relationships with friends and family, ability to confide in someone and get help when needed.

A semi-structured interview topic guide with open questions was developed by authors based on literature and preliminary analysis of quantitative data. The topic guide consisted of open question related to women's mental wellbeing, daily routine, birth experiences, social support and relationships, and coping mechanism.

All data collection tools except the PHQ-9 were translated into Swahili by local psychologists, then back-translated by medical doctors. The translated tools were pilot-tested on healthy mothers in the maternity ward and amended.

Ethical consideration

The study received ethical approval from the Zanzibar Medical and Research Ethical Committee. (Protocol no. ZAMREC/004/AGUST/17). This study was linked to another cohort study and thus participants were first informed about this study at the time of admission to the labour ward and gave permission to be contacted later on for participation. Then, after hospital discharge, women were contacted again and invited to participate via telephone. Informed written consent was also sought before commencement of interviews and participants had the opportunity to withdraw at any stage. Interviews took place in private at convenient locations and time for the women, mostly at their homes, both in urban and rural areas. For confidentiality, all data were anonymised.

Study procedures

All questionnaires were administered face-to-face by four trained Zanzibar counsellors who held diploma in either psychology or social studies and had prior experience in conducting interviews and counselling. However, they could not make clinical diagnosis of mental disorders. The process of screening could cause anxiety and distress hence, using the WHODAS manual as a guide, a role-play approach was used to train interviewers administer screening tools appropriately and deal with emotions. This included providing immediate support and referral to a psychologist based on arising emotional issues, clinical intuition, participant's wish or screening positive for a mental health disorder. Free-text feedback from participants informed the qualitative data collection. Daily meetings were held with all interviewers for feedback, which contributed to the iterative process.

Qualitative data collection of women who experienced stillbirths was done after a preliminary analysis of quantitative data from 102 respondents in the stillbirth group. Women were asked open-ended questions about their mental, physical and social wellbeing from the time of childbirth until the present. Three authors (NAO, NH, and RM) conducted semi-structured interviews. The interviews lasted between 30 and 75 minutes and were digitally recorded after consent was sought, and notes were made in English and Swahili. Recordings were transcribed verbatim and translated to English by an independent translator. Each transcript was compared with the hand-written notes for accuracy.

Bias

First, a three-to-six-months interval minimised normal physiologic postpartum symptoms and normal grieving process for women with stillbirths, both of which often resemble symptoms of mental health illness. Second, eligibility criteria of women were clearly defined before the study commenced and followed strictly to avoid selection bias. This also ensured comparability of participants and possible confounders were part of the data collection. Measures to reduce information bias included using the same respondents for quantitative and qualitative data, and extensive translation of interview tools and training of interviewers. Also, participants were interviewed at their homes to encourage more freedom of expression.

Sample size calculation

The prevalence of depression in mothers who experienced perinatal death (38%) and mothers who did not (22%) were derived from an ongoing maternal near-miss study at MMH.[40] They were used to calculate a sample size of 260 women, 130 exposed and 130 unexposed, for detecting an odds ratio of 2.17 at power of 80% and alpha of 5%.

Statistical methods

Quantitative data was entered with KoboToolbox and R version 3.5.3 was used for statistical analysis.[41] Descriptive analysis included prevalence percentages, mean and standard deviation for normally distributed data, median and inter-quartile range for non-normally distributed data. The distribution of individual symptoms of depression, PTSD and disability were also analysed. Univariable and multivariable analyses were used to test for differences in baseline characteristics and identify risk factors for mental health problems and disability.

Qualitative data analysis used interpretative phenomenological analysis for qualitative data. It consisted of 6 steps: 1) Familiarisation with the transcripts by re-reading the transcripts and notes with the participants sociodemographic in mind. 2) Coding was done by one researcher (NAO) using Atlas.ti 8 and preliminary themes were formed on a case-by-case basis. 3) Codes were collapsed/grouped to form themes. 4) Superordinate themes containing subordinate themes were developed based on commonalities and contraindications. 5) The integration of all cases '*moving from one transcript to the next while comparing and contrasting the themes to check for emerging patterns from the sample as a whole*'.[42] 6) Finally, the quantitative and qualitative analysis was interpreted entirely by triangulation. Some characteristics of these women are used to denote quotes from the interviews (A=age, G=number of pregnancies, P=number of deliveries).

Results

Participants

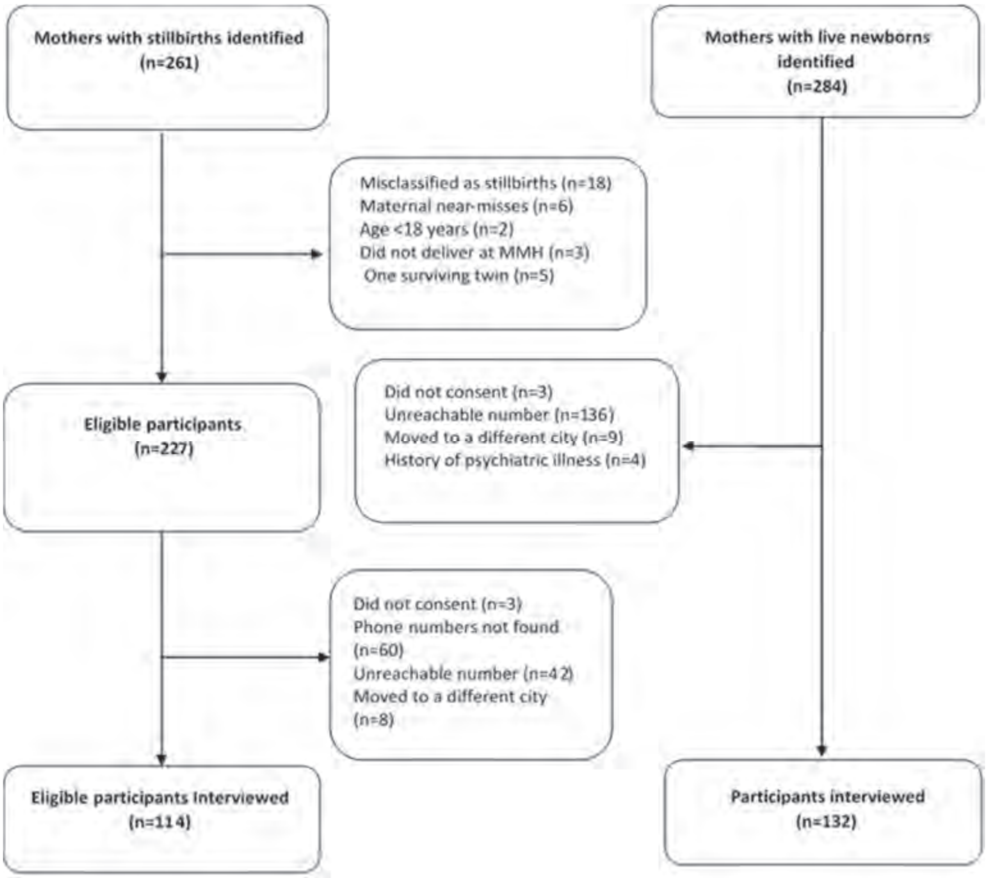

Figure 2 Flowchart of participant selection

Of the eligible 261 women who delivered a stillborn and 284 control women who fulfilled the criteria, 114 (67%) and 132 (46%) were available for the interview and included in the study (Figure 2).

The background characteristics of participants are shown in Table 1. There was no significant difference in sociodemographic, pregnancy characteristics, social support (HSCL-25 scale) and assessment time points between the two groups. Women with stillbirth were more likely to have had previous pregnancy loss (p=0.01) and scored significantly lower on the

BSS-R in comparison to women with healthy neonates (p=0.003), particularly in reported stress and quality of labour care. Both groups scored lowest on their personal attributes component of the BSS-R scale which included women's feeling of control.

Table 1 Pregnancy characteristics, birth satisfaction, social support among women with and without stillbirths

Variable	**Stillbirth N(%)** No n = 132	Yes n = 114	**P-value (Chi-square)**
Median age in years(IQR)	29 (24-34)	30 (25-34)	0.17[a]
Marital status			
Not married	13	9	0.76
Married	119	105	
Education in years (IQR)	10(10-12)	10(10-12)	0.68[a]
Work status			
Paid work	16 (12)	16 (14)	
Self employed	39 (30)	45 (39)	0.17
Home maker	77 (58)	53 (46)	
Assessment time point			
3 months	51 (39)	47 (41)	
4 months	39 (30)	39 (34)	0.44
6 months	42 (32)	28 (25)	
Parity (IQR)	2.5(1-5)	3(1-5)	0.41[a]
Previous foetal loss			
No	87(66)	56(49)	0.01
Yes	45(34)	58(51)	
Pregnancy type			
Singleton	127 (96)	111 (97)	0.73[b]
Twins	5 (4)	3 (4)	
Mode of delivery			
Vaginal	111 (84)	97 (85)	0.97
Caesarean section	21 (16)	17 (15)	
Bss-r score, mean (SD)	24.9 (5.4)	22.7 (5.8)	0.003[c]
Quality of care provided (IQR)	14 (13 – 16)	13 (12 – 15)	0.01[a]
Stressed during labour, mean (SD)	8.1 (3.1)	6.9 (3.5)	0.01[c]
Women's personal attributes (IQR)	3 (1 – 4)	3 (1 – 4)	0.77[a]
Hscl-25 score(IQR)	24 (19.5 – 27)	24 (21 – 28)	0.17[a]

Values presented as number(percentage) unless otherwise specified
[a] Kruskal-Wallis test, [b] Fisher's exact test, [c]T-test
IQR = interquartile range, SD= standard deviation, HSCL-25 = Hopkins Symptom Checklist-25 (Social Support scale)

Psychological health outcomes

Figures 3-5 show the distribution of mental health symptoms among women with and without stillbirths. Overall, about three quarters (n=182) had at least one symptom of depression (73%, n=96/132 without stillbirth and 75%, n=86/114 with stillbirth). "Feeling down, depressed, or hopeless" of PHQ-9 scale was significantly higher in the stillbirth mothers (p= 0.045), who were also over twice more likely to have suicidal ideation (p=0.081) (Figure 3). In addition, 64% (n=117/182) reported that symptoms made it difficult to do things at home or get along with other people (63%, n=60/96 without stillbirth and 66%, n=57/86 with stillbirth).

Women with and without stillbirth had similar PHQ-9 scores and about a quarter of them screened positive for depression (Table 2). The majority of those who screened positive had mild-moderate depression. Independent risk factors for higher PHQ-9 depression scores were unemployment, unmarried marital status and low birth satisfaction (BSS-R) score (Table 3).

Table 2 Outcomes among women with and without stillbirths

Variable	**Stillbirth** **No** **n = 132**	 **Yes** **n = 114**	**Kruskal-Wallis test** **P- value**
PHQ-9 score, Median (IQR)	1 (0 – 4)	2 (1 – 4)	0.2932
Depression (%)			
None (<5)	101 (77)	87 (76)	0.596*
Mild – Moderate (5 – 14)	29 (22)	23 (20)	
Moderately severe (>14)	2 (2)	4 (4)	
HTQ-16 score, Median (IQR)	1.25 (1.06 – 1.53)	1.5 (1.25 – 1.81)	<0.001
PTSD (%)			
No (<2.5)	128 (97)	108 (95)	0.521*
Yes (≥2.5)	4 (3)	6 (5)	
WHODAS 2.0, Median (IQR)	1 (0 – 6.5)	2.5 (0 – 7)	0.038

* Fisher's exact test

**Chi-squared test

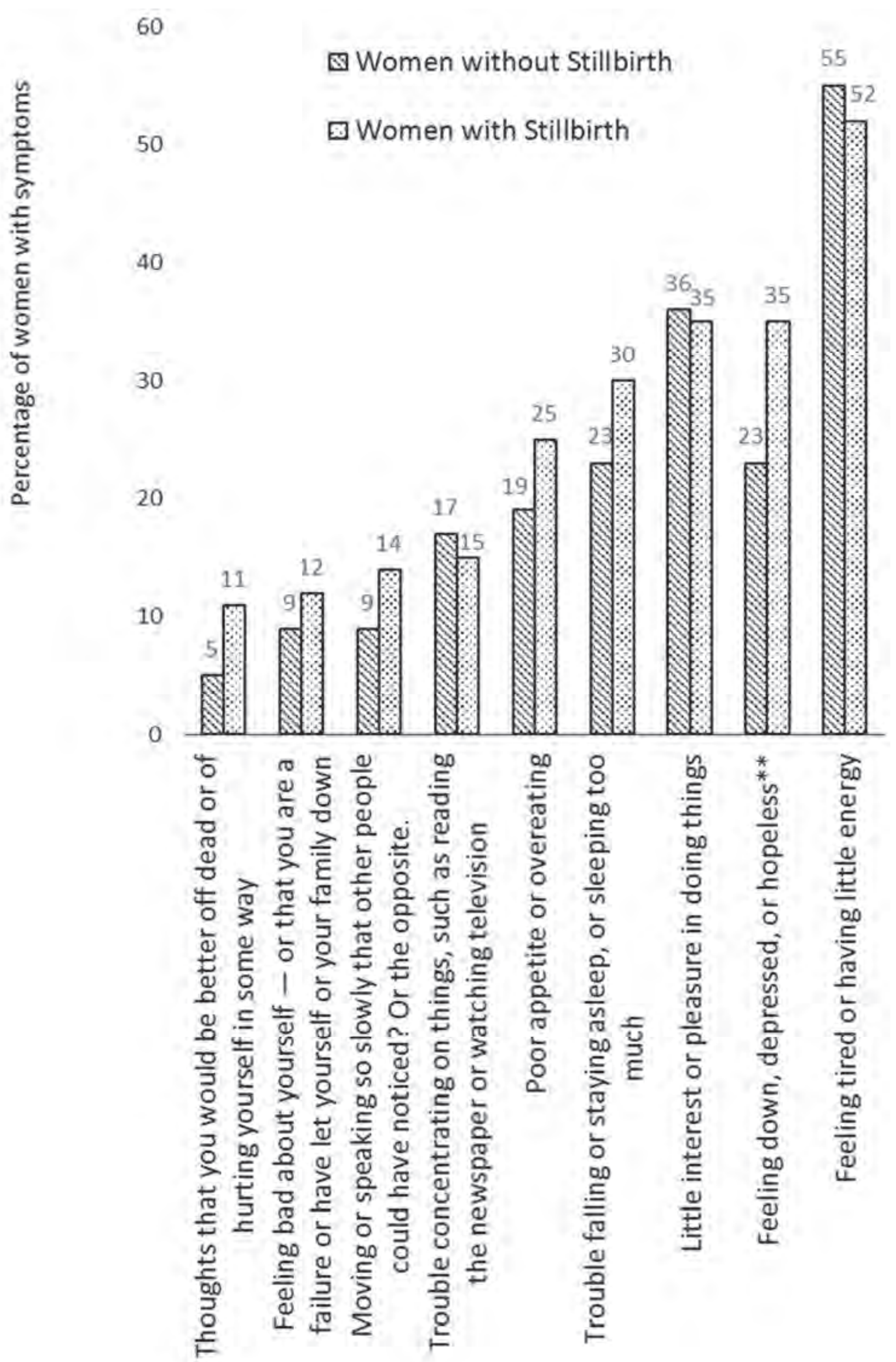

Figure 3 Frequency of symptoms in women without (n=132) and with stillbirths (n=114): PHQ-9 (depression); **Significant difference between the two groups

Of all women, 87% (n=215) had one or more symptoms of PTSD (no stillbirth: 80% (n=105), stillbirth: 96% (n=110)). Stillbirth mothers scored significantly higher in 8 out of 16 items of the HTQ-16 (Figure 4). Women with stillbirth had a significantly higher median HTQ-16 score. Four percent of all women screened positive for PTSD (Table 2). However, there was no significant difference in proportion of women that screened positive for PTSD between both groups (Table 2). Nearly all women who screened positive for PTSD (n=9/10) also screened positive for depression., Independent risk factors HTQ-16 (PTSD) scores were stillbirth, caesarean section and birth low satisfaction score (Table 3).

Seventy participants (28%) were referred to the mental health services based on clinical intuition or screening positive for a mental disorder, or participants' wish; albeit it was determined that the majority did not contact counselling services. Due to low events of PTSD, analysis for risk factors was limited to HTQ-16 scores and a composite outcome of mental health disorder (i.e. depression and/or PTSD). Univariate association between risk factors and HTQ-16 score (PTSD), PHQ-9 score (depression) and WHODAS 2.0 score (disability) are shown in Supplementary file Table S1. Independent risk factors for screening positive for a mental health disorder were: age, unemployment, caesarean section and low birth satisfaction (BSS-R) score. (Table 3)

Functioning

Sixty-three percent of women (n=156) reported at least one symptom of disability or reduced functioning (59% (n=78/132) without stillbirths and 68%(n=78/114) with stillbirths, Figure 5). Women with stillbirth were more likely to have more impaired function (median WHODAS-2.0 score were: no stillbirth, 1.0 (IQR: 0-6.5); stillbirth, 2.5 (IQR: 0-7), p=0.038, table 3). Independent risk factors for increased disability score were unemployment and birth satisfaction (Table 3).

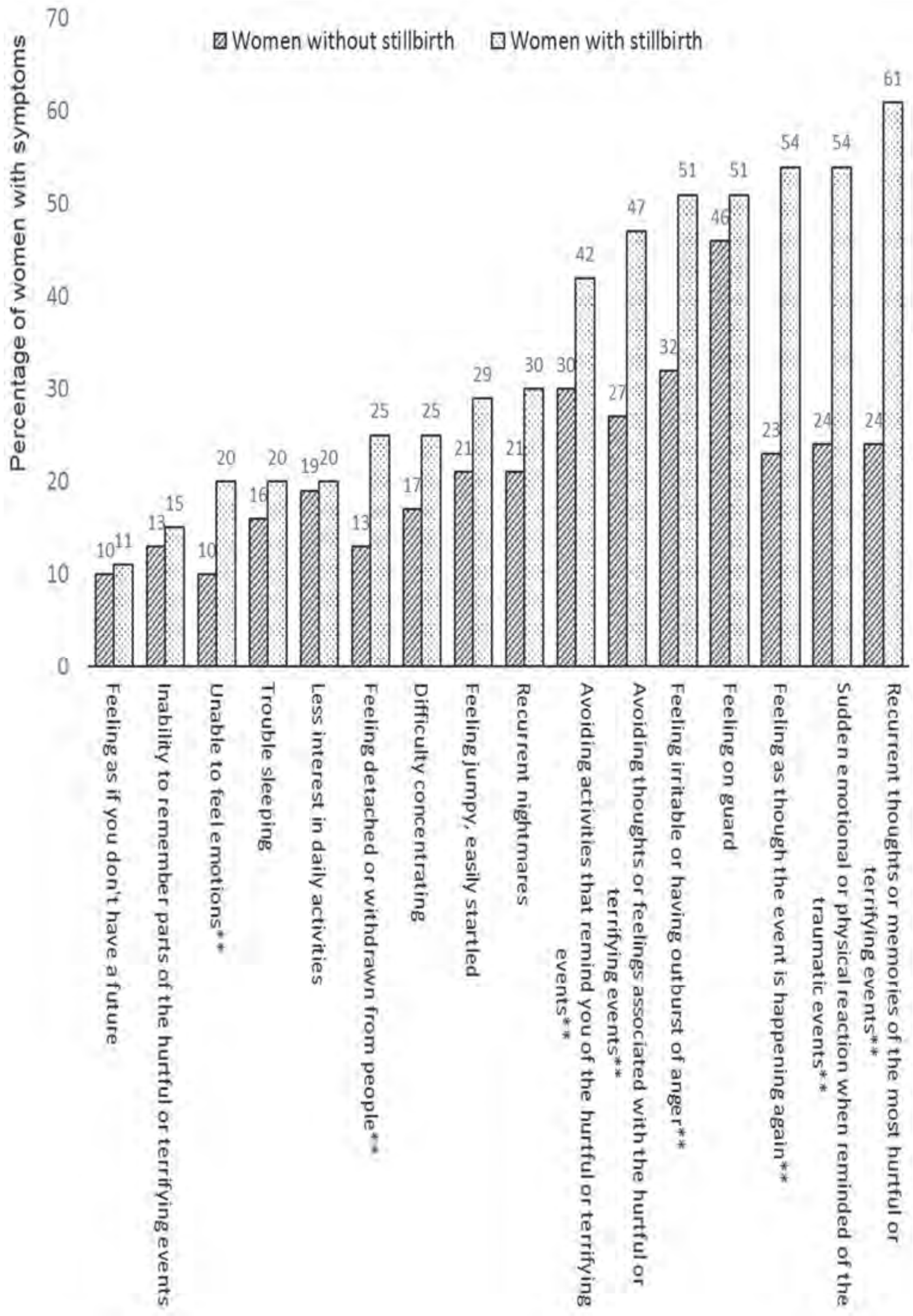

Figure 4 Frequency of symptoms in women without (n=132) and with stillbirths (n=114): HTQ-16 (Posttraumatic stress disorder) **Significant difference between the two groups

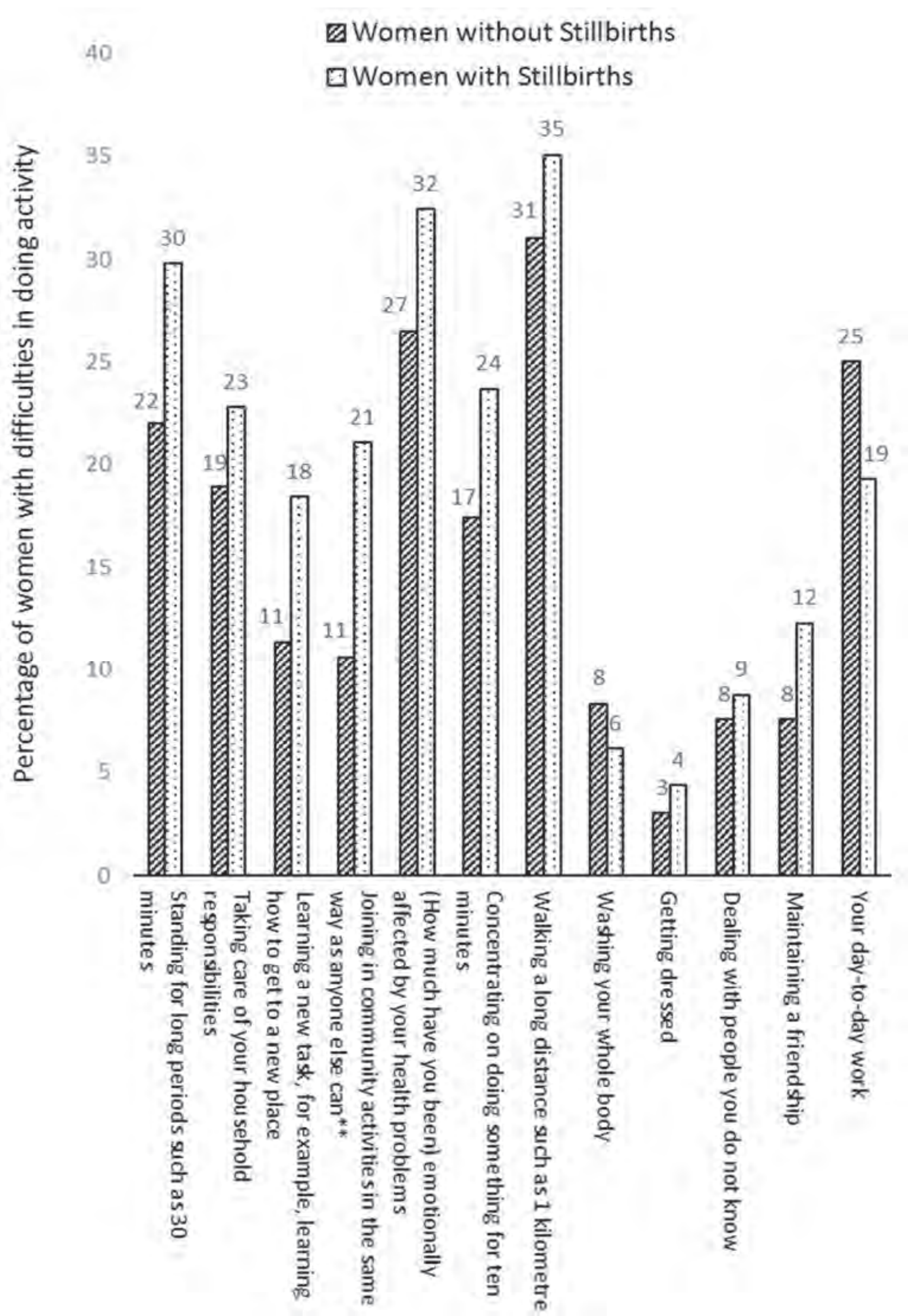

Figure 5. Frequency of symptoms in women without (n=132) and with stillbirths (n=114): WHODAS (Disability) **Significant difference between the two groups

Table 3. Multivariate association between risk factors and psychological and physical outcomes				
	PHQ-9 score β Coefficient(95% CI)	**HTQ-16 score β Coefficient(95% CI)**	**WHODAS 2.0 score β Coefficient(95% CI)**	**Mental disorders** Odds ratio (95% CI)**
Age	0.11(-0.004 - 0.23)	0.01(-0.002 - 0.03)	0.15(-0.04 - 0.33)	1.10 (1.01 - 1.20)*
Parity	-0.11(-0.46 - 0.23)	-0.01(-0.05 - 0.03)	0.13(-0.43 - 0.69)	0.91(0.71 - 1.16)
Marital status(unmarried)	1.631(0.01 - 3.27)*	0.11(-0.08 - 0.30)	1.50(-1.13 - 4.14)	2.43(0.82 - 7.30)
Education in years	-0.08(-0.22 - 0.06)	-0.01(-0.02 - 0.01)	-0.03(-0.26 - 0.20)	0.93(0.83 - 1.03)
Employed(yes)	-2.12(-3.56- -0.67)*	-0.1(-0.26 - 0.07)	-2.67(-5.00 - -0.34)*	0.14(0.03 - 0.50)*
Previous foetal loss(yes)	0.85(-0.17 - 1.86)	0.02(-0.10 - 0.14)	0.73(-0.91 - 2.37)	1.25(0.60 - 2.60)
Caesarean	1.13(-0.13 - 2.39)	0.23(0.08 - 0.37)*	0.69(-1.34 - 2.71)	2.49(1.05 - 5.84)*
Assessment time point				
3 months	Ref	Ref	Ref	Ref
4 months	0.03(-1.06 - 1.11)	0.06(-0.12 - 0.13)	-0.17(-1.91 - 1.57)	0.68(0.30 - 1.25)
6 months	-0.08(-1.22 - 1.07)	0.07(-0.09 - 0.17)	-0.64(-2.48 - 1.20)	0.74(0.31 - 1.73)
Stillbirth(yes)	-0.14(-1.08 - 0.80)	0.19(0.08 - 0.30)*	0.79(-0.73 - 2.31)	0.62(0.30 - 1.25)
Birth satisfaction (BSS-R)	-0.19(-0.27 - -0.10)*	0.01(-0.03 - -0.01)*	-0.31(-0.44 - -0.18)*	0.84(0.78 - 0.90)*
Social support(HSCL-25)	-0.01(-0.11 - 0.09)	0.006(-0.02 - 0.01)	-0.09(-0.26 - 0.07)	1.02(0.95 - 1.09)

*Statistically significant

**Depression and/or PTSD (yes/no)

Abbreviations: CI= Confidence interval, HTQ-16= Harvard trauma questionnaire 16 for posttraumatic stress disorder, PHQ-9= Patient Health Questionnaire 9 for depression, WHODAS 2.0= World Health Organisation Disability Assessment Scale 2.0 for disability/functionality

Qualitative findings

Thirteen women with stillbirth participated in the semi-structured interviews. Their characteristics are shown in supplementary file Table S2. They reported persisting symptoms of overthinking, pain, sadness and sorrow, and avoidance of hurtful memories about the stillbirth or childbirth experience.

"This morning, I went to visit a woman who delivered, I went and saw her, and left to sit outside." (A23, G3P0).

Other recurring themes included negative self-image (e.g. 'uselessness') resulting in self-neglect (e.g. body hygiene); physical illnesses (body pains, palpitation, constipation, and weight gain). Some women reported that they were physically affected by their emotions.

"I have difficulties doing things because I remember things that happened during birth." (A19, G1P0)

The hospital staff did not offer explanation for the stillbirth to any of the women. However, some searched for physical reasons (e.g. eating too much sugar or having hypertension during pregnancy). Women attributed the stillbirth to the will of God, mostly without blaming anyone or being blamed by others. Some blamed either the hospital staff, themselves or family members. One woman said:

''…I think the main reason is the hospital that caused my child to die''. (A38, G7P6)

Support around the time of birth

Both groups of women had concerns about the care they received during childbirth. The majority of women recounted negative perceptions of care including disrespect and maltreatment, inequitable treatment, and inadequate staff and facilities. Recurring terms used to describe healthcare providers' behaviour include "rude", "careless", "disrespectful", "humiliating", and "hurtful". Women wished for healthcare providers to be "respectful", "hospitable" and show "integrity" by using polite language; adequate and timely communication; providing privacy, counselling services, and separation of stillbirth mothers from those with healthy babies. Additional issues expressed by women with stillbirths was the lack of bereavement. For example, women felt that breaking of the bad news was not done in an appropriate, compassionate and timely manner. A woman described her experience:

''…after delivery, you wait, and your child is not being brought because he/she has already died, and you are not aware. They should look for another way of informing us''. (A34, G3P2)

Another woman narrated:

''…the news being delivered suddenly really hurts because when they told me I was really hurt. My heart has never healed to date''. (A38, G7P6)

A woman who lost both her twins only overheard the staff in theatre discussing that one of the babies died intrauterine. Later, she was informed by her neighbour (a hospital staff) that the other baby had also died. A few women also reflected about being in the same ward as other women and their babies. One woman felt alone:

"I felt sad because I looked at myself and thought that all the rest had their children." (A19, G1P0)

Most women reported receiving medical care as the most common type of support given e.g. oxytocin. Some women expressed positive reviews of the caring support they received, and praised the recent improvement in the quality of care and certain individuals:

"That lady [midwife] after being in the ward and seeing the difficulty that she was in, I loved her. I thank her a lot because at that time she was alone, and she did not rest until she left in the morning. And to the people she was helping to deliver she was not harsh, answering rudely or insulting the mothers". (A29, G4P3)

Positively perceived support was mainly the hospital staff offering condolences, 'sorry' and reassuring women that they will get another child. One woman said:

"The greatest help I got is being comforted in the hospital by the doctors". (A27, G6P5)

All women with stillbirths (n=114) were asked what they remembered of their babies. All but one knew the sex of her baby; 77% (n=88) saw their babies and 27% (n=31) touched or held their babies. The majority of women remembered having the desire to see their babies (80%, n=91); and half of them remembered wanting to hold their stillborn babies (51%, n=58). However, 79% (n=72/91) and 41% (n=24/58), respectively, had these wishes fulfilled. Reasons for not seeing/holding their stillborn babies included mothers not making a request and birth attendants not offering mothers the opportunity. Women did not ask because they either assumed they would be shown or were too afraid to look at their stillborn babies. Thus, babies were wrapped up immediately and relatives took them for burial. One woman said:

"I was afraid of seeing or holding the baby because I was afraid of it as it had already died". (A19, G1P0)

The women also felt the need for additional care for those mothers who experienced stillbirths:

"I felt that there is special care that those who hadn't gotten children should have been given." (A19, G1P0)

Social support and coping with the loss

Women found support in family, community and religion. Most women reported that there was no difference in the relationship with their family members before and after pregnancy. However, some women described feeling alone and not spending enough time with partners; another reported violent behaviour towards her other child:

"I used to abuse my child and beat her whether she has done something wrong or not" (A38, G3P2)

They all mentioned receiving support from family members including female relatives (e.g. mothers, siblings and in-laws who came to live with them), husbands, friends and neighbours. Most of the participants described the kind of support received as emotional and practical, mainly daily visitations at the hospital and home, and words of encouragement and assistance with housework. As one participant said:

''They used to help me with the housework. My mother was here and my husband [also] used to help''. (A34, G4P3)

''They [**family*****] helped me by encouraging me…They [*****family*****] told me to take heart I will get another child''. (A38, G3P2)***

Women found spending time alone invited intrusive thoughts of their loss, hence they generally busied themselves with housework and being round conversations with relatives and neighbours. However, women did not generally mention or talk about their loss. Yet, one woman felt relief and comfort when she spoke to her neighbour about her stillborn experience and another felt relief after talking to her partner and finding out the loss affected him too. One woman wanted to get pregnant as quickly as possible as she felt having another child would help her forget the current loss. When asked how she coped with her loss one woman narrated:

"I go to a place where people are talking, and I sit together with them…I just sit here with people and we talk and the thoughts go away". (A25, G2P0)

Religion seemed to play a big role in helping them accept the loss of their babies. They reported that losing their baby was God's plan and felt comforted that they would get another child. They also took comfort from remarks/well-wishes by people, prayers and reading religious scriptures. One woman explained how her faith affected her emotions:

"…I couldn't get angry [after I lost my baby] because I have religious faith… I tried my best to focus on God because he is the one that gives and takes." (A34, G3P2)

None reported using mental health services or traditional healer. However, most of the participants expressed the desire to receive counselling services but lacked information. Some, despite not screening positive for a mental illness wished to seen by the psychologist. They all expressed appreciation of the home visits and interviews as it helped them feel like someone cared about their situation.

Discussion

This mixed-method study explored the biopsychosocial impact of stillbirths on mothers - the first of its kind in an LMIC. Very high prevalence of mental health symptoms (depression: 74%; PTSD: 87%) and disorders (depression: 24%; PTSD: 4%) remained long after delivery, also among women with good neonatal outcomes. Depression was also found to be a comorbidity of PTSD;

highlighting the importance of screening for concurrent mental health issues. Both groups perceived similar levels of social support at home. In contrast, daily functionality and support around the time of birth were significantly lower in women with stillbirth. Sociodemographic characteristics (age, marital status and employment) and care around the time of birth (mode of delivery and birth satisfaction) were independent risk factors for mental health problems and disability, with stillbirth also being a risk factor for PTSD. The qualitative aspect provided an in-depth understanding of the support mothers received around the time of birth at home and the mechanism they used to cope with their loss.

Strengths and Limitations

Using the biopsychosocial model and a mixed-methods approach, which included standardised tools, enabled us to gain an in-depth exploration of impact of stillbirths on mothers' mental health, daily functioning and support received by mothers. Interviews took place in participants' homes, which eliminated courtesy bias and enabled expression of feelings and contextualisation of findings. The rigorous translation process of the interview tools, involvement of local researchers who were familiar with the culture and face-to-face interviews ensured that participants understood and could relate to the questions.

Limitations of the study related to the limited time and difficulties in contacting women which did not permit follow-up of women and attainment of the calculated sample size. The sample size calculation was based on depression, which had a much higher prevalence; thus analysis for risk factors was limited, especially for PTSD. Also, the screening tools were not compared with diagnostic clinical interviews questioning their validity in this setting. With the very high rate of mental symptoms in women with live-born babies, qualitative interviews in this group (and further studies) would add value in explaining maternal mental health problems in this setting. Lastly, expectations of childbirth experience and how mental health symptoms are defined, expressed and perceived are influenced by contextual factors including social and cultural norms and thus differ across settings – as also shown in our chosen theoretical framework (Figure 1). As such, these results are might not be generalisable to other low-ressource settings and this calls for further studies in other low resource settings.

Interpretation

Prevalence of positive-screened depression in both groups was higher than generally reported in sub-Saharan women during pregnancy and after pregnancy: 11.3% (95% CI 9.5-13.1%) and 18.3% (95% CI 17.6–19.1%).[5] There was most likely a high level of background symptoms unrecognised and untreated prenatally, with previous psychiatric history being one of the strong predictors for postnatal mental health.[4,5,43] Importantly, in this study, socioeconomic status was generally low and it is evident that poverty is a strong risk factor for depression.[4] Women who also deliver in tertiary hospitals are more likely to have complications and interventions, which are likewise associated with mental health symptoms, including PTSD.[44,45]

Chronic postpartum PTSD (i.e. 3-6 months post-delivery) rates were found to be 4.6% in community samples and 6.7% in studies including at-risk samples and are slightly higher than the prevalence in this study (3-5%).[44] There was no relationship found between previous pregnancy loss (i.e., miscarriage or stillbirth) and mental health symptoms, but the current stillbirth and care around the time of birth (lower birth satisfaction and caesarean section) were significant factors of PTSD. From previous studies, it seems that the strongest risk factors for PTSD are previous psychiatric history, depression, previous traumatic events (e.g. childhood abuse), interpersonal violence, and a negative birth experience.[46,47]

Although the overall birth satisfaction score was quite average (mean score of 24 out of 40), it most likely does not indicate good quality of care. Lack of respectful support during labour is an overarching problem in LMICs and is perpetuated by lack of measures and inadequate staffing for respectful care – and, notably, women with diagnosed foetal death are at higher risk of neglect.[48–50] Studies show that high satisfaction rating of poor quality care is common in LMICs.[51] A possible explanation could be low expectations of quality of care instigated by the lack of information, inexperience with high-quality care and low agency of women.[51] In line with many studies, negative birth experiences were associated with higher levels of anxiety, depression and PTSD as well as physical disability in mothers.[45,52] Women, particularly those with stillbirths, found labour and delivery to be a distressing experience with feeling of a lack of control.

Lack of additional support left women with stillbirth experiencing disenfranchised grief due to inadequate empathy, confidentiality, privacy, communication and counselling.[53] This was evident through the perceived inappropriate manner of breaking of bad news, the lack of private space for grieving parents and unfulfilled desire of the women to see or hold their stillborn babies. The time of childbirth is thus a critical time for preventing maternal mental health illnesses and should include bereavement services.[12] Antenatal and postnatal periods are also ideal opportunities for screening, referral and treatment of common perinatal mental health disorders.

Evidence shows that social support and interpersonal care play an important role in protecting women from mental health illnesses in LMICs.[4,52] Family was an important source of support, with a relatively high average score of perceived social support received at home in both groups. This suggests that support experienced by women with stillbirth was not differentiated but was quite like the traditional postpartum support received by women who delivered healthy babies. Findings of high social support score also suggest that women with stillbirth did not feel stigmatised in their society nor experience social isolation - in contrast to other LMICs and of different cultures where women report stigmatization.[12,13,54] However, similar to other findings in LMICs, women were unable to talk about their loss and grief and were encouraged to forget.[13] These findings may suggest a society that has come to accept perinatal loss as a normal occurrence. As such, women and their families found help and comfort in their faith,[55] and in condolences and hopes of getting another baby, all of which were common supportive care strategies both in the hospital and the community. In other LMIC settings, such behaviour did not comfort bereaved mothers but led to disenfranchised grief as women felt unrecognised with a perception of indifference to their experiences.[15,12,54] Additionally, women tried to forget their loss through social interaction, chores and avoidance. In this setting, the short- and long-term impact on maternal health of the displayed coping mechanisms or maternal mental health treatments are unknown. Evidence in positive psychology showed that enhancing both gratitude and mindfulness has positive effect on mental health symptoms, such as depression and anxiety, and increases well-being.[56–58] For example, in rural India, mindfulness-based intervention in perinatal grief after stillbirth led to significant reductions of perinatal grief and mental health symptoms.[59,60]

The women in this study, especially those who were grieving, appreciated the home visit and the opportunity to talk about their birth experiences and expressed desire for counselling. However, they were impeded from using mental health services either due to lack of awareness or information or due to existing mental health stigma in the community.[28,64] The higher referral rates, compared to screening positive, also suggest that women were affected severely by specific symptoms; hence, interventions should be based on clinically significant symptoms and women's desire to seek help rather than particular diagnoses of mental health disorders. Home visits by community health volunteers could be an effective and feasible intervention to alleviate mental health burden by screening women for persisting symptoms and referring to mental health services.

Maternal mental health is linked to various Sustainable Development Goals (SDGs), including those addressing maternal and child mortality and non-communicable diseases (SDG 3.1, 3.2 and 3.4). In this study and other findings, women with stillbirths experienced more symptoms of PTSD, sadness and suicidal ideation. Many women also become chronic sufferers of physical and mental symptoms, reduced daily function, and have recurrent and more severe symptoms, and more health problems in consecutive pregnancies. These represent a loss of healthy years, which is not estimated in the global burden of disease and thus may have little impact on priority setting decisions.[13,14,18,54,65–79] The renewed focus on mental health in the SDGs is an opportunity to better understand maternal mental health illnesses in LMICs, as well as de-stigmatise, diagnose and treat evidence-based.

Conclusion

This study highlights the vulnerability of all postpartum mothers to mental health illnesses in low resource settings. Caregivers should be educated that both uncomplicated childbirth and stillbirth can affect mental health of women, and birth attendants must be supported to provide respectful and compassionate supportive care around the time of birth to help alleviate maternal distress and cope with loss of newborn. To make this possible, policy-makers need to warrant sufficient number of skilled and motivated healthcare workers. Given the high prevalence, there is a need for screening mental health problems during and after pregnancy and link women to counselling services via effective referral pathways and community visits. Lastly, research should explore locally-shared culture, norms and practices, and their long-term effects on maternal mental health and bereaved parents' needs and desired interpersonal care. This may help de-stigmatisation and inform strategies of uptake and of improving maternal mental health services.

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Author contributions

NH conceived and designed the experiment, carried out data acquisition, analysed the data, interpreted the results, drafted the first version of the manuscript and led the drafting process of the manuscript. NAO conceived and designed the experiment, carried out data acquisition, analysed the data, interpreted the results and drafted the manuscript and critically revised the manuscript. RM carried out data acquisition, contributed to interpretation of the results and critically revised the manuscript. CM conceived and designed the experiment, contributed to interpretation of the results and critically revised the manuscript. MJM contributed to interpretation of the results and critically revised the manuscript. TM contributed to interpretation of the results and critically revised the manuscript. AF contributed to interpretation of the results and critically revised the manuscript DEG contributed to interpretation of the results and critically revised the manuscript. MJR conceived and designed the experiment, contributed to interpretation of the results and critically revised the manuscript. JLB conceived and designed the experiment, contributed to interpretation of the results and critically revised the manuscript. All authors approved and agreed to be accountable for the final version to be published.

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Ethics approval and consent to participate

The study received ethical approval from the Zanzibar Medical and Research Ethical Committee. (Protocol no. ZAMREC/004/AGUST/17). All participants provided written informed consent.

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Supplementary files (Table S1 and Table S2)

Univariate association between risk factors and psychological and physical outcomes

	Depression(yes/no) Odds ratio (95% CI)	PTSD(yes/no) Odds ratio (95% CI)	PHQ-9 score β Coefficient (95% CI)	HTQ-16 score β Coefficient (95% CI)	WHODAS 2.0 score β Coefficient (95% CI)
Age	1.04(1.00-1.09)	1.07(0.97-1.18)	0.07(-0.004-0.14)*	0.01(0.001-0.02)*	0.16(0.04-0.28)*
Parity	1.14(1.01-1.30)*	1.23(0.95-1.57)	0.24 (0.03-0.45)*	0.03(0.004-0.05)*	0.55(0.22-0.88)*
Marital status (unmarried)	3.06(1.22-7.51)*	8.07(1.92-30.99)*	2.25(0.58-3.92)*	0.16 (-0.04-0.36)	2.43(-0.29-5.14)
Education in years	0.91(0.84-0.99)*	0.92(0.80-1.08)	-0.16(-0.28- -0.03)*	-0.01(-0.03-0.001)	-0.21(-0.42- -0.002)*
Employed(yes)	0.30(0.07-0.88)*	0.30(0.002-2.43)	-1.52(-2.95- -0.09)*	-0.04(-0.21-0.13)	-1.91 (-4.22-0.39)
Previous foetal loss(yes)	1.69(0.93-3.06)	2.15(0.60-8.60)	1.283(0.32-2.25)*	0.14(0.02-0.25)*	1.95(0.39-3.51)*
Mode of delivery					
Caesarean	1.88(0.87-3.93)	2.46(0.51-9.32)	1.353(0.02-2.68)*	0.26(0.10-0.41)*	1.14(-1.02-3.29)
Assessment time point					
3 months	Ref	Ref	Ref	Ref	Ref
4 months	0.88(0.43-1.75)	0.94(0.18-4.39)	0.085(-1.07-1.24)	0.011(-0.13-0.15)	-0.04(-1.90-1.82)
6 months	0.80(0.38-1.64)	1.05(0.20-4.92)	-0.06(-1.25-1.13)	0.02 (-0.12-0.16)	-0.51(-2.43-1.41)
Stillbirth(yes)	1.01(0.56-1.82)	1.78 (0.5-7.11)	0.42(-0.56-1.38)	0.24(0.13-0.35)	1.63(0.08-3.18)*
Birth satisfaction (BSSR)	0.86(0.81-0.91)*	0.86 (0.76-0.96)*	-0.21(-0.29- -0.13)*	-0.03(-0.04- -0.02)*	-0.35(-0.48- -0.22)*
Social support(HSCL-25)	0.95(0.90-1.01)	0.85(0.75-0.96)*	-0.11(-0.21- -0.01)*	-0.01(-0.02-0.001)	-0.21(-0.36- -0.05)*

*Statistically significant

**Depression and/or PTSD (yes/no)

Abbreviations: CI= Confidence interval, HTQ-16= Harvard trauma questionnaire 16 for posttraumatic stress disorder, PHQ-9= Patient Health Questionnaire 9 for depression, WHODAS 2.0= World Health Organisation Disability Assessment Scale 2.0 for disability/functionality

Characteristics of the thirteen women with stillbirth who participated in the semi-structured interviews

Assessment time point (months)	**Age**	**Marital Status**	**Years spent studying**	**Work status**	**Type of Pregnancy**	**Mode of delivery**	**Gravidity**	**Parity**	**Living children**
3	27	Married	9	Housewife	Singleton	C/S	6	6	5
3	25	Married	10	Housewife	Singleton	C/S	2	2	0
3	23	Married	10	Housewife	Singleton	SVD	3	3	0
3	38	Cohabiting	7	Housewife	Singleton	SVD	7	7	6
3	33	Married	12	Employed	Singleton	SVD	3	3	2
3	29	Married	7	Employed	Singleton	SVD	4	4	3
3	29	Married	7	Employed	Singleton	SVD	4	4	3
3	30	Married	16	Employed	Singleton	SVD	1	1	0
4	34	Married	17	Housewife	Twins	C/S	3	3	2
4	19	Single	11	Unemployed	Singleton	SVD	1	1	0
6	34	Married	12	Housewife	Twins	SVD	4	4	3
6	38	Married	15	Employed	Singleton	SVD	3	3	2
6	34	Married	11	Housewife	Singleton	SVD	3	3	2

Chapter 4

Factors influencing quality of labour care in a Sub-Saharan referral hospital: the perspectives of women and health professionals

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Abstract

Background Skilled birth attendance is essential to reduce maternal and perinatal deaths. This study aimed to explore the challenges that hinder delivery of quality intrapartum care, including foetal heart rate (FHR) monitoring in a high-volume referral hospital in a low resource setting.

Methods A qualitative study, supplemented by a Likert scale questionnaire, was employed consisting of structured questionnaires, focus group discussions, semi-structured interviews with stakeholders at different levels of the health system in Zanzibar, Tanzania between July-August 2016. Quantitative survey results were descriptively analysed; qualitative data were analysed using thematic analysis.

Results Forty-three skilled birth attendants of the maternity unit (24 nurse-midwives, seven junior doctors, 12 permanent doctors), 45 mothers (15 antenatal, 30 post-delivery) and seven policymakers were included. All groups felt there was lack of safe and respectful care which contributed substantially to poor birth outcomes. Reported obstacles to care provision were: 1) the high number of labouring women, work overload and inadequate staff; 2) Lack of equipment and supplies; 3) Poor labour ward infrastructure; 4) Lack of teamwork, job allocation, motivational support, and supervision; 5) Negative attitude, lack of knowledge, commitment and sense of responsibility.

Conclusion Frontline healthcare staff and pregnant women faced various challenges that restrict the provision of quality and respectful intrapartum care including FHR monitoring. Most identified contributing factors to poor intrapartum care were related to the healthcare system. Interventions should target the areas identified with the involvement of care providers and service users.

Introduction

The majority of the 300,000 annual maternal and five million stillbirths and neonatal deaths are preventable. With the persistently high maternal and newborn mortality rates in low- and middle-income countries (LMIC), maternal and newborn health remains a top priority in global agenda - particularly in Sub-Saharan Africa, which is burdened with the highest fertility rates and most severe maternal and new-born mortality and morbidity rates.[1–4] Reduction of maternal and newborn deaths has also been a priority in Tanzania.[5–7] Tanzania has seen tremendous progress in reducing under-5 mortality, with achievement of Millennium Development Goal 5.[1,6,8] However, progress lags in reducing maternal and newborn deaths.[1,8] For over a decade in Tanzania, there has been an almost universal antenatal care coverage (98%, with 51% achieving at least four visits) and a steady increase in facility-based deliveries from 47% to 63%. Yet, maternal and perinatal mortality rates remain high: 556 per 100,000 live births and 39 per 1000 total births 2015-2016.[9] Thus, improving coverage of maternal care services alone is not sufficient; quality of care needs to significantly improve.

Birth in the presence of a skilled birth attendant (SBA) and availability of (basic and comprehensive) emergency obstetric and neonatal care are essential to avert intrapartum-related morbidity and mortality.[10] In most LMIC, management of labour with partograph and intermittent auscultation (IA) of foetal heart rate (FHR) is the standard intrapartum care for monitoring and decision-making. However, these tools are substantially underused, and their effectiveness is questioned. [11–17] Moreover, many labour wards lack the supporting structures required to provide respectful care according to international standards and evidence-based recommendations.[18–20]

This mixed-method study aimed to assess the challenges associated with providing intrapartum care including foetal heart monitoring by intermittent auscultation. While many of the key issues and challenges to quality healthcare in LMIC are known, this paper is part of a comprehensive assessment of quality of care at a maternity ward in low-resource tertiary hospital, its determinants and related outcomes to develop context-specific interventions to address some of the challenges. The other components of the assessment consisted of a record-based assessment and structured direct labour observation. [21,22]

Methods

Study setting

This study was conducted at the maternity ward of the Mnazi Mmoja Hospital (MMH) in Zanzibar, Tanzania. The Zanzibar healthcare system, including MMH, is governed by the Ministry of Health Zanzibar and autonomous from mainland Tanzania. The hospital is the sole referral hospital in Zanzibar and supported by public and private primary and secondary health centres. It provides medical care to a population of 1.3 million. The maternity ward at MMH has an average of 11500 deliveries per year. Details of the structure of the labour ward including the physical layout, staff and composition are described elsewhere.[22] Intrapartum foetal wellbeing is mainly assessed by IA using Pinard and hand-held Doppler. Previous studies in this hospital found suboptimal intrapartum care, including the lack of foetal surveillance and high rates of maternal mortality (647 per 100,000 livebirths)[23] and perinatal mortality rates (stillbirth rate of 59 per 1000 total births). [21,22]

Study design

A qualitative study, supplemented by a Likert scale questionnaire, was applied among multilevel stakeholder groups to comprehensively explore and understand perceptions of care provision, experiences and factors affecting quality of care, with a specific focus on FHR monitoring. Individual structured questionnaires (5-point Likert scale and open-ended questions) and focus group discussions were held with SBAs active in labour care (i.e. nurse-midwives, registrar doctors and intern doctors); semi-structured interviews were conducted with prenatal and postnatal women and in-depth interviews with key informants at managerial levels. This allowed opportunity for triangulation, construction and linkage of themes, consolidation and authentication of results. Data collection took place between July and August 2016. Reporting of the study was guided by Consolidated criteria for reporting qualitative research (COREQ).[24]

Participant selection

Purposive sampling was used to select antenatal and postnatal women according to pre-determined criteria. Antenatal women, with confirmed viable foetus at ≥28 weeks were included in order explore wishes and expectations of labour care in the upcoming delivery. Also, exit interviews were conducted with post-delivery women to explore recent experiences of care. The following women were excluded: less than 18 years of age, diagnosed intra-uterine foetal death on admission, never reached active phase of labour (e.g. elective caesarean sections), women rushed to caesarean sections upon admission, referral cases from another birth facility with labour, not physically fit to undergo interview and women who had impaired consciousness during childbirth and therefore unable to recollect experiences during childbirth. The sample size of women was decided upon using theoretical saturation (at which point the new data is no longer providing any new information with regards to the research question).

All SBAs (i.e. nurse-midwives, doctors and interns) working at the maternity ward were invited to participate in the study. Snowballing sampling was used to identify policymakers, i.e. people involved in formulation of policies pertaining to healthcare provision at MMH hospital, for in-depth interviews.

Data collection and tools

Interview guides and questionnaires were developed by researchers, translated into Swahili by native speakers and pilot-tested. For all interviews, questionnaires and FGD, initial questions consisted of participants' background information, perceptions of general quality of labour care provided or received, challenges to quality care and improvement solutions. Next specific questions exploring quality, barriers and solutions to foetal monitoring were posed to participants. The Likert scale questionnaire was based on a 5-point scale (i.e. 1. strongly disagree, 2. disagree, 3. neither agree nor disagree, 4. agree and 5. strongly agree). Data collection techniques were employed iteratively, with the results from previous interviews or FGD feeding into the adjustment of subsequent tools and data collection. Both structured and unstructured non-participatory observations were conducted for contextualisation of research tools and results.

Face-to-face interviews were considered appropriate for antenatal and postnatal women to uncover their personal feelings and perspectives regardless of literacy level. The interviews were conducted in Swahili by two trained female psychology students who were native speakers and two female Dutch social science students (MAJ and RMN) who facilitated the interviews. None of the researchers knew the participants and rapport was established during participant recruitment and interviews. Notes were written down during interviews both in Swahili and English. Interviews took place in a quiet and private room and women were allowed to breastfeed their babies during the interviews. Interviews lasted 45-60 minutes. One author (NH), a medical doctor employed at the MMH maternity unit for three years at the time, held key-informant interviews with policymakers in English.

Individual SBAs' perceptions were assessed first by using anonymous self-administered structured questionnaires consisting of Likert scale and open-ended questions with freedom to express true personal feelings to avoid interviewer bias. The SBAs then discussed the topics during the focus group discussions (FDG) in more elaborate and communal way to ascertain social norms and group perspectives about topics that affected the entire group. The FGDs were conducted outside participants' working hours in separate groups of 6-10 SBAs and lasted between 90-120 minutes. The discussions were mainly held in Swahili and moderated by a local male doctor (RSK) who was not known to the participants. Interviews and FDGs were audio-recorded with permission from participants, while notes were being taken. Audio recordings were transcribed and translated to English by native speakers of the Kiswahili language with good grasp of English. The interviews with policymakers were registered by notes.

Data analysis

Simple descriptive analysis was performed on background information and Likert scale responses (Supplementary file). Qualitative analysis was conducted by NH, AM and MR throughout the data collection period and afterwards using thematic synthesis analysis.[25] This consisted of six steps: 1) familiarisation with data through multiple reading and comparison of field notes and full transcripts, 2) manual open coding to generate initial codes; 3) searching for themes by collating relevant codes using tables and thematic maps; 4) reviewing themes by revisiting the coded extracts and dataset; 5) defining and naming themes and 6) producing the report that includes extract examples.[25]

Ethical consideration

The study was approved by the governing ethical board (ZAMREC/0002/May/016). Written informed consent was obtained from antennal, post-delivery women and hospital staff, before commencing interviews, questionnaires and FGD. Oral informed consent was obtained from policymakers. All information was kept anonymous and confidential.

Results

Participants

There were 45 participating mothers (30 post-delivery and 15 antenatal), all women were married, and most were housewives with secondary education and living in urban regions. Almost 45% had a prior delivery at MMH maternity (Table 1). The majority (90%, n=43/48) of SBA at the maternity unit participated (24 nurse-midwives, seven intern doctors, 12 permanent doctors). They were mostly young (median age of 30 (IQR 28-32)), married and female (86%, n=37) with experience in labour care of ≤5 years (91%, n=39) (Table 2). In total there were six focus group discussions (three with midwives, two with doctors, and one with interns). In addition, seven policymakers participated in the study: hospital management (n=3), ministry of health (=3) and educational institution (n=1).

Table 1. Sociodemographic characteristics of antenatal and postnatal women

	Antenatal women n=15	Postnatal women n=30	Total n=45
Median age(IQR)	24(22-28)	25(22-32)	25(22-30)
Residence			
Urban	9(60)	22(73)	31(69)
Rural	6(40)	8(27)	14(31)
Education			
No formal education	0(0)	2(7)	2(4)
Primary	3(20)	3(10)	6(13)
Secondary	10(67)	22(73)	32(71)
Advanced	2(13)	3(10)	5(11)
Profession			
Housewife	13(87)	24(80)	37(82)
Self-employed	0(0)	1(3)	1(2)
Employed	2(13)	5(17)	7 (16)
Marital status			
Married	15(100)	30(100)	45(100)
Not Married	0(0)	0(0)	0(0)
Parity			
Null/Prime	5(33)	16(53)	21(47)
Multiparity	10(67)	14(47)	24(53)
Previous perinatal death			
No	12(80)	28(93)	40(89)
Yes	3(20)	2(7)	5(11)
Mode of delivery	-		
Vaginal		21(70)	-
Vacuum		3(10)	
Caesarean		6(20)	
Birth outcome*	-		-
Alive		29(93)	
Dead		2(7)	
Prior delivery at birth at MMH			
Yes	7(47)	13(43)	20(44)
No	8(53)	17(57)	25(56)

Values are represented as number(percentages) unless indicated; *one pair of twins; MMH = Mnazi Mmoja Hospital

Table 2. Sociodemographic characteristics of SBAs

	Midwives(n=24)	Interns (n=7)	Doctors(n=12)	Total(n=43)
Response rate*	24/29(83)	7/7(100)	12/12(100)	43/48(90)
Median Age(IQR)	30 (28-35)	30 (28-31)	31 (28-35)	30(28-32)
Sex				
Female	24 (100)	3 (43)	10 (83)	37 (86)
Male	0 (0)	4 (57)	2 (17)	6(14)
Marital status				
Married	17 (72)	6 (86)	9 (75)	32(74)
Not Married	7 (29)	1 (14)	3 (25)	11(26)
Previous birth at MMH				
Yes	14 (82)	1 (14)	3 (25)	18(42)
No	3 (29)	1 (14)	5 (42)	9(21)
N/A	7 (18)	5 (71)	4 (33)	16(37)
Years of experience with labour care				
< 1 year	6 (25)	7 (100)	8 (67)	21(49)
1 – 5 years	14 (58)	0 (0)	4 (33)	18(42)
6 – 10 years	2 (8)	0 (0)	0 (0)	2(5)
> 10 years	2 (8)	0 (0)	0 (0)	2(5)

Values are represented as number(percentages) unless indicated
*The response rate indicates how many of the SBAs at the maternity, all of whom were invited, participated in the study.

Experience of care

The majority of women (93%, 28/30) indicated that they received adequate care at the maternity ward. One woman narrated:

"The care at Mnazi Mmoja Hospital maternity ward was sufficient because I delivered safely and my baby is okay" (age 21, primegravida).

With further prompting, the majority of the postnatal women reported many examples of desired care as well as good and unpleasant care they experienced (Table 3). Women would also like more beds, clean environment, and hospital supplies to be (freely) available such as water, gloves, and medication, some of which they have to pay for now.

Both antenatal and postnatal women commonly expressed the desire for clean environment, monitoring and timely interventions as well as physical and emotional support, better communication with staff, privacy and kind treatment, polite language and not being ignored. Nine women did not know the type of care to expect and one them reported:

“I would like to give birth at this hospital in order to receive good care like other women receive. I can’t say what type of care I want because this is my first pregnancy; anything which is good for my baby and me.” (22 years, primigravida)

When asked directly about birth companionship, virtually all post-delivery women were isolated from their relatives upon admission and had no birth companionship (29/30). One woman mentioned this as an example of unpleasant care. The majority (70%, 28/40) would like birth companionship: from their mother or other female relatives (n=19), husband (n=7) or a doula (n=5). About a quarter of women (11/40) preferred care from skilled birth attendants only during birth and for the relatives to wait outside. They commonly acknowledged that the lack of space and privacy did not allow birth companionship.

When asked specifically about monitoring of their babies, mothers reported frequencies of FHRM that varied greatly and appeared to be unstructured but increased in frequency when a woman experienced serious complications. Half of the women reported they were not adequately informed about the condition of their baby throughout birth, if at all. Two of the women who reported being adequately informed were not directly told, but either heard the doctor discussing or saw foetal activity on ultrasound. One woman reported not to have been involved in the decision-making for a vacuum delivery, neither was she informed. She remained concerned about the effect on the baby’s future health. Women who experienced poor perinatal outcomes reported delayed communication about the condition of the newborn following birth.

Table 3 Examples of experience of care mentioned by women				
	Type of care mentioned:	As example of care desired (n=45)	As example of good care experienced (n=30)	As example of care not given or bad care experienced (n=30)
Structure of care ***(see details under section Staff, stuff and space)***	Availability of adequate supplies, staff and beds	21	0	21
	No Fees for supplies and medicine, services	5	0	8
	Cleanliness and privacy of labour room environment	5	0	7
	Female caregivers	3	0	2
Supportive care	Emotional support: e.g. politeness, kind, hospitable and encouraging words/treatment	15	10	3
	Assistance with newborn care post-delivery	9	2	0
	Welcoming reception on admission to the labour ward	8	8	7
	Assistance with personal hygiene and going to the toilet during labour and after delivery	7	3	1
	Communication e.g. to be update of condition of mother and baby during and after birth; to be instructed on ways to cope with pain, help progress of labour and delivery (e.g. breathing, exercises, positions and pushing)	7	3	5
	Given attention and not ignored	3	1	3
	Birth companionship and/or attended by staff during labour and delivery	2	3	1
	Consented or informed care	2	0	2
	Discrimination/preferential treatment		1	2
	Physical abuse (slapping)	0	0	1
	Privacy during examination and delivery	0	0	2
	Good collaboration between women and skilled birth attendants and between interprofessional relations	2	0	2
Clinical care	Timely care and intervention e.g. oxytocin, emergency and CS	15	1	2
	Monitoring of Mother and baby	10	3	3
	Analgesia during labour and episiotomy repair	3	1	0
	Prompt discharge from hospital	1	0	1

Perception of quality of care provision

All healthcare groups agreed there was suboptimal intrapartum care at the maternity ward including maternal and foetal surveillance, supportive care and management of obstetric conditions. All groups of SBAs unanimously considered FHRM during labour and delivery an important element of intrapartum care, and that it could help to prevent stillbirths and neonatal deaths (nurse-midwives: 88% (21/24), interns 100% (7/7) and doctors: 100% (12/12)) (Figure 1). Individual answers showed midwives believed FHRM was performed adequately, but policymakers, registrar and intern doctors did not agree (nurse-midwives: 79% (19/24), intern: 25% (2/7), doctors: 28% (3/12). (figure 1) However, during FGD, all stakeholder groups, including midwives, agreed that it was impossible to perform FHRM at the internationally recommended half-hourly intervals. Although individual responses showed that midwives and intern doctors thought they were able to perform their tasks adequately (Midwives:79% (19/12), doctors: v42% (5/12), interns: 100%(7/7)), all cadres reported inability to provide emotional support and loving care.

Challenges affecting skilled birth attendant's ability to deliver quality care

The main challenges evident to stakeholder groups in the vicinity of the labour ward (micro-environment) affecting SBAs' ability to provide quality care, and the underlying health system support factors at hospital and external levels (meso- and macro-environment) are organised and summarised in Figure 2.

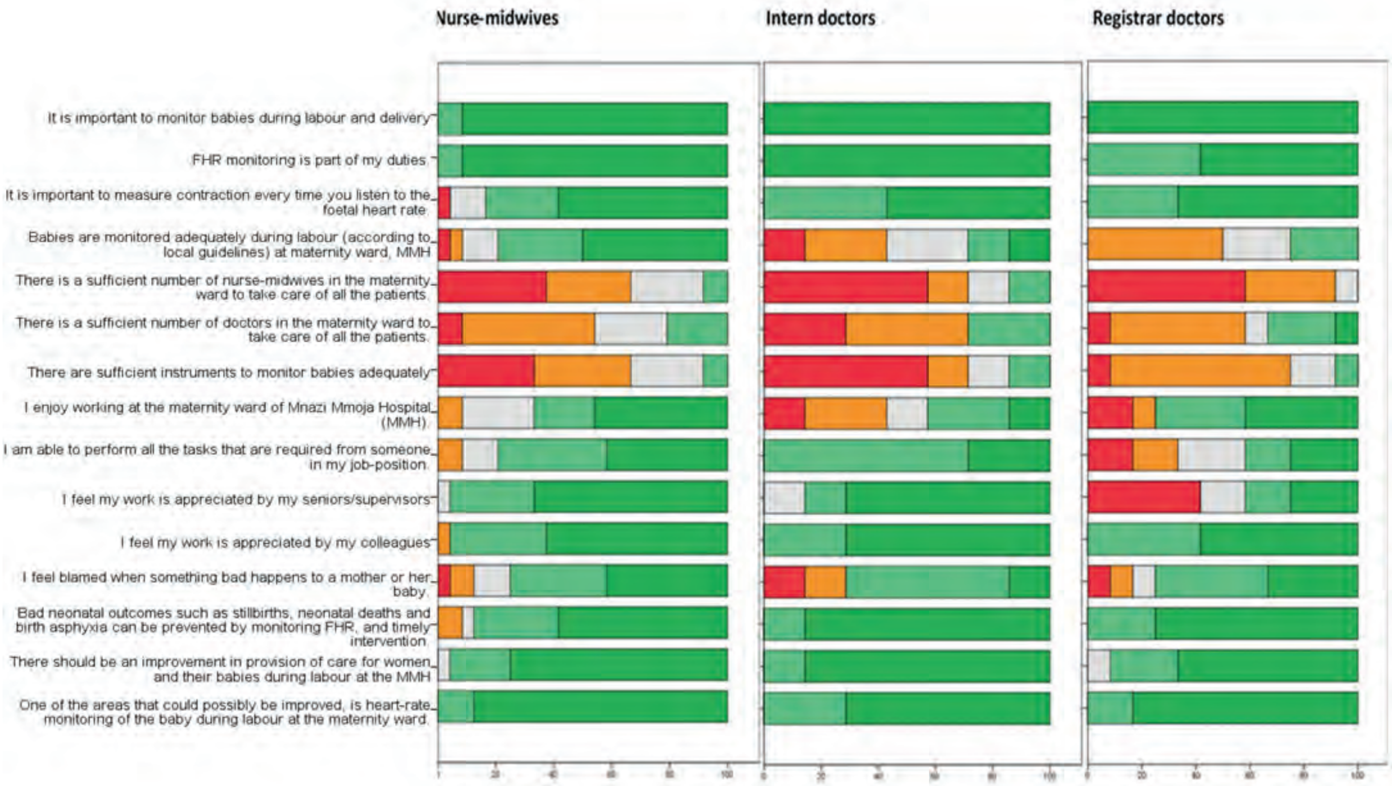

Figure 1. Perception of FHR-monitoring and current care provision separated by cadre: A= Nurse-Midwives (N=24), B= Intern doctors (N=7), C = Registrar Doctors (N=12)

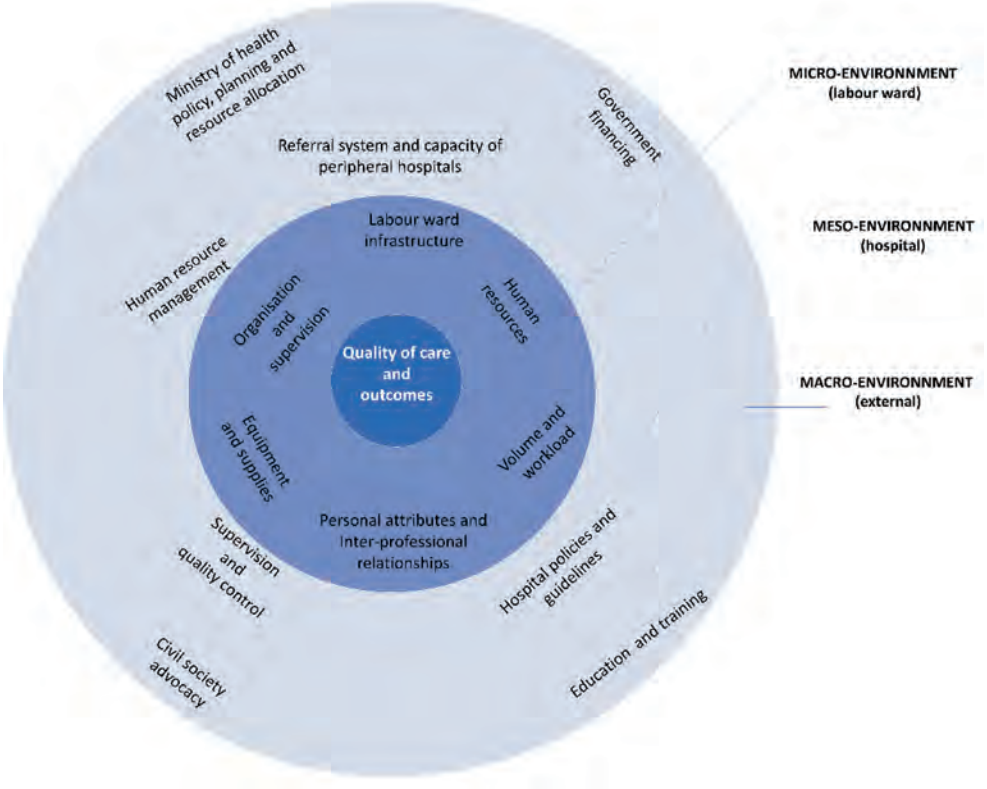

Figure *2*. Factors affecting quality of intrapartum care

Staff, stuff and space

Challenges in the labour ward commonly mentioned were 1) high volume of women and inadequate staff (i.e., high women to staff ratio) which resulted in work overload; 2) insufficient number of equipment and supplies; and 3) infrastructure of the labour ward. Participants particularly acknowledged the lack of nurse-midwives (midwives: 67% (16/24); doctors: 92%% (11/12), Interns: 71% (5/7)). Figure 1

"First, there are a lot of pregnant women and too few staff and lots of wards: antenatal, postnatal and labour. So, to monitor FHR every half an hour is impossible." (Nurse-midwife, FGD)

Often two to three women shared a single-size bed as the number of women exceeded the capacity of the ward. SBAs described the labour ward as "too open" and "lacking privacy", "unhygienic", "congested", "chaotic" and "disorganised" and thus it was difficult for them to access, assess and communicate with women. Women were expected to walk to a more private room during the second stage of labour for their delivery. However, due to lack of staff in this delivery area, women often delivered in the main labour ward. One woman mentioned:

"They didn't get the chance to take me there (delivery room) because the delivery was sudden" (27 years old, para 2).

The instruments for FHRM were Pinard and DeLee stethoscopes, Doppler and sometimes ultrasound. Problems with these instruments included their quantity, quality and lack of consumables such as gel and batteries. Both SBA and policymakers viewed these instruments as too "local" or "old-fashioned" and "unreliable" especially for a referral hospital and a noisy and busy environment.

"…you know a referral hospital is supposed to have new model equipment." (Intern doctor, FGD)

"You would start by using a stethoscope, then you find out it is unreliable because you cannot distinguish the foetal heart rate from the mother's heart rate, then you try the ultrasound but you are not skilled, you subsequently lose time calling for help, and there is a lot of delay and ultimately, you lose the baby. Sometimes, you just don't know, and then you do a caesarean because you are in doubt, and sometimes it turns out to be unnecessary" (Doctor, FGD).

Other supply shortages included partographs, essential and life-saving drugs, water, gloves, blood pressure machines and blood products. In addition, responding to emergencies such as foetal distress was difficult and often delayed because of busy staff and theatre as well as unavailability of consumables:

“Another thing is that there are no consumables, for example, you already detected foetal distress, you try your best but there is no intravenous cannula or fluid or no emergency (caesarean section) set. And at 2 am at night you don’t know where to get one. So as a doctor you have to come in to work at night with a cannula. You spend your salary buying supplies to care for the women.” (Intern doctor, FGD)

Personal attributes and attitude

In general, it seemed that, apart from interns, individual midwives and doctors enjoyed their job at the maternity ward (nurse-midwives:67% (16/24), doctors:75% (9/12), (interns:43%(3/7)). However, all groups of SBAs and policymakers identified personal attributes such as lack of interest and passion for the nursing profession, sense of responsibility, motivation and commitment as a major problem among SBAs. They insisted that they lacked intrinsic and extrinsic motivation to perform well.

Leadership, supervision and teamwork

“There is a problem with the management and leadership. There is a lack of overseeing and observation at maternity with a lack of strong leadership at maternity ward. (Policymaker 6, education level)

All groups of SBA and policymakers also expressed lack of on-the-job supervision at ward level. For example, intern doctors had huge responsibility for a significant amount of a woman’s care, yet they clearly felt inadequate and overwhelmed as they felt they lacked knowledge and experience, and yet were left working long hours unsupported and unsupervised especially during night shifts. All groups perceived mismanagement of resources, poor supervision and leadership at multiple levels, including at the department, hospital management, professional bodies, education and ministry of health.

When asked individually, SBAs felt that they were appreciated by their colleagues and seniors (figure 1). However, SBA during FDG and policymakers identified poor interprofessional relationship, cooperation and teamwork between different cadres (i.e., nurse-midwives and doctors) as major problems. For example, assigning responsibility of specific tasks was not clear and so different cadres often shared tasks. Nurses also expressed that doctors were putting a lot of blame on them and did not consider their more experienced advice. Also, all groups of SBA felt that there was a lack of professionalism, trust and respect towards one another. Some thought that staff were too friendly at work and afraid to criticise each other and enforce accountability. Yet, all groups felt unfairly blamed when something bad happened to a mother or a baby (Nurse-midwife: 75 (18/24), doctor:75% (9/12), intern: 71%(5/7)).

System support

Human resource management

Mismanagement of human resources was a commonly mentioned. Both SBA and policymakers acknowledged the high turnover rates and loss of skills of SBA and attributed it to maldistribution within and outside the department and hospital. However, the policymakers at hospital management level felt that they were unable to make decisions concerning issues related to staff hiring, retention, deployment and salary as these were under the ministry of health.

"There are very few staff. One nurse has to take care for 10 patients. That is the main reason and so administration cannot force them because they are too few. It would not be fair." (Policymaker 4, hospital level).

There were no (evident) guidelines indicating delineated roles and job description and responsibilities for health cadres. Thus accountability was difficult to reinforce. Furthermore, the staff felt underpaid, under-appreciated and demotivated as there was no reward system to acknowledge their hard-work. Midwives, for example, felt even more underpaid compared to doctors and questioned the reasons why doctors get extra pay to work at night and weekend while nurses did not. Insufficient pay was linked to private practice, lack of motivation and poor performance.

Capacity of peripheral hospitals

SBAs and policymakers identified weak referral system and the poor performance of peripheral hospitals as two major system failures contributing to the high-volume and congestion in the MMH maternity unit. Referral policies, e.g. care of low-risk women at lower birth centres, were not implemented as nearly half of post-delivery women had no indication for delivering at MMH (n=12). In addition, ill-equipped and poor functioning of supporting facilities were able to provide the expected basic and/or comprehensive emergency obstetric and newborn care leading to preventable referrals and by-pass to MMH for more accessible, "specialised" and "best" care.

"The problem is that at these hospitals, patients go and they don't find staff there as they just come in the morning and the rest of the day they go home and have to be called to attend patients. So patients get discouraged and go straight to MMH" (Doctor, FGD)

Ministry and government planning and policies

Policymakers said that the hospital was dependent on the Ministry of Health and the central government for budget and supply of staff, consumables, medication and equipment. They suggested that this limited the authority of the hospital over the acquisition, retention, professional development, distribution and deployment of staff. While SBAs and policymakers at hospital level looked for more (human) resources from the ministry, policymakers at the Ministry level expressed their willingness to help but referred to the government budget as a limitation. They mentioned that the government prioritised the health sector in terms of budget and employment of personnel, in particular maternal and child - reducing maternal mortality was their number one priority. However, the economic status of the country was the main limiting factor of the budget. Other policymakers argued that they employed enough staff but they were not committed to working or were deployed to the wrong department or hospital, or have been sent for further studies or training.

Policymakers at hospital and ministry levels also expressed the huge gap between policies and what was realistically achievable. They provided the example of free maternal healthcare policy which is not fully implementable with the current allocated budget. This affected the availability of resources such as consumables and equipment and thus results in out-pocket resourcing from patients and sometimes doctors. Cost-sharing was an alternative but remained a controversial policy with the government especially for maternal and child health.

"The challenge of policy is the realistic nature on the ground. Free maternal health, it is not possible in reality" (Policymaker 7, Ministry level)

Education and training

Both SBA and policymakers identified major problems with the education and training doctors and nurses received during undergraduate studies which left them unprepared for the reality they were to face. For example, they pointed out the different levels of degrees of nurse-midwives possess as contributing factor to quality of care (e.g. diploma and degree). They also doubted the in-depth knowledge SBA have on intrapartum care such as the technique assessment and interpretation of FHRM. Doctors and nurse-midwives gave examples of when FHR was monitored on paper but the baby was found to be macerated during a caesarean section.

"There is a problem regarding monitoring of labour, we see the mother is pushing, we think monitoring of contraction and cervical dilation and we are done, we don't consider much about the person who needs to come out, the baby." (Registrar doctor, FDG)

Some policymakers have suggested there was lack of medical ethics being taught in undergraduate programs, including women's right to compassionate, dignified and respectful care, and they linked this to the *know-do gap* e.g., in providing privacy, confidentiality and communication.

Mothers agreed that staff lacked education on how to provide compassionate care. It was further argued that a contributory factor to this was the lack of supervision and clinical instructors in the practical training of the nursing program. One policymaker also suggested that staff needed to initiate self-directed continuous learning outside their formal studies and work.

Some policymakers argued that staff were "over-trained" as many organisations conducted various maternal health training programmes in Zanzibar. However, they thought these service trainings were not effective because they were *"disjointed"*, *"not well-orchestrated"* with each other and healthcare workers' attendance was motivated only by the monetary incentives provided. Also, there was lack of post-training follow-up resulting in problems of knowledge translation to practice (the know-do gap).

Community involvement, advocacy and agency

Both antenatal and post-delivery women, especially prime-gravidity, commented that they did not know what kind of care to expect during labour. Although many women perceived care received as adequate, when asked further, they were able to express their preferred care and undesired care. With regards to FHRM monitoring, women knew little. One woman commented that it was considered bad luck to know what was going on with the baby while still in the womb*: "traditionally, we do not know what happens in the womb."*

Policymakers also suggest that patients do not know their rights.

"We need community auditing, educate the community what they should expect from us." (Policymaker 7, Ministry of Health)

Some policymakers believed that the society, familial and sociocultural issues and norms, and belief system affected SBA performance and lack of accountability at work.

"It is common that people here say that whatever bad outcomes, they say it was pre-planned by God." (Policymaker 1, Hospital level)

"The problem is we don't put God first. The inner side of belief in God has reduced in people. Hence, when there is no money, you [SBA] don't work to full potential but instead you rush to private hospital." (Policymaker 6, Education level)

All stakeholder groups agreed there should be general improvement in care (nurse-midwives: 96% (23/24), doctors: 92%(11/12), interns: 100%(7/7)) with unanimous agreement for the need to improve FHRM among SBA (figure 1). Various solutions to the identified challenges were proposed (Table 4). All groups of participants recognised the need to increase the number of SBAs, particularly midwives, salaries and remunerations, better labour ward infrastructure and sustained essential supplies. SBA and women stressed the need to provide women with "tender, love and care".

Policymaker pointed to efforts that were underway for hospital service improvement. These included a policy to give MMH a semi-autonomous status that would allow its management to acquire, retain and train their staff as needed and the freedom to generate incomes from various revenues, manage budgeting and staff wages. Also, renovation of the current maternity ward and an additional new maternity ward was under construction and was expected to improve the infrastructure, provide more space and privacy for women. However, they also acknowledged and demanded the need to increase the number of staff from the ministry of health as the maternity unit expands. Policymakers at the ministry of health however expressed that:

"The challenge is mobilising resources. We can easily recruit but it takes time to mobilise resources from the central government. The problem is the budget is not enough." (Policymaker 3, hospital level)

Other important suggested solutions included the need to set-up a system of accountability and appraisal, reduction of workload through effective referral mechanism and support of peripheral hospitals and more supervision and more support in the labour, team-building and, bed or patient allocation, triage system.

Certain policymakers also highlighted the need for community advocacy and engagement such as community education and auditing of care. Specific interventions directed at improving FHRM included: advanced FHRM monitoring equipment or "machines", more frequent on-the-job training, FHRM task allocation to specific nurse-midwives (either routine or locum), and more achievable recommendations of frequency of monitoring (e.g., every hourly).

Table 4. Suggested solutions among the stakeholder groups

Problem	Suggested solutions
Resources	• Increase number of staff (especially nurse-midwives), space, supplies e.g. high-tech foetal monitoring devices and consumables for FHR monitoring and blood pressure machines. • Better organisation of the labour ward according to risk and phases (e.g. pre-labour, latent phase of labour, active phases and post-delivery) • Maternity blood blank
Supervision and teamwork	• More supervision of staff • Allocate staff to patients and tasks • Teamwork building activities
work overload and congestion	• Strengthen capacity of lower level hospitals to decongest the tertiary centre • Strengthen referral mechanism • Strengthen antenatal care for preventive care to reduce complicated cases
Education and training	• Training on intrapartum care including FHR monitoring, technique, interpretation and response to FHR abnormalities • Better screening of prospective healthcare workers for commitment and motivation at entry to school and job • More clinical instructors for student teaching and supervision during clinical rotation. • Leadership training • Introduce medical ethical education • Evaluation and post-training follow-up • Integration and better communication among the various training programs offered in Zanzibar.
Policies and guidelines	• Clear policies and guidelines in place including job description and clinical guidance
Responsibility and accountability	• Provide motivation include better salaries, incentives and professional development for staff • Strengthen system of accountability and appraisal. • Conduct community auditing, educate the community what they should expect from health care services.

Discussion

We explored the quality of care, challenges in day-to-day practice and the multi-level factors that influence the provision of intrapartum care, with a specific focus on FHRM, in a tertiary hospital in Zanzibar, Tanzania. The care provided and experienced was considered suboptimal and was thought to contribute substantially to poor birth outcomes. Key challenges in the labour ward were high number of women, work overload, human resource constrains resulting in too little supervision, organisation, teamwork and poor inter-professional relationships; lack of essential supplies; and poor labour ward infrastructure, including inadequate space. Multiple underlying systemic factors were identified and included inadequate pre-service education and in-service training, referral mechanism, leadership and accountability, human resource management, ministry and government policy, planning and budgeting/financing. Suggested key strategies were directed at addressing these structural challenges and factors.

Strengths and limitations

The multiple stakeholder groups including a large group of women, SBAs and policymakers provided maximal variation of perspectives, insight, experiences and comprehensive analysis of health-system factors influencing ability to provide quality of care as well as offering suggestions about possible measures for improvement. However, exit interviews may not have allowed women the freedom to express their true opinions on health providers' interpersonal behaviour as they still depended on them for care.[26] Also, multiple interviews with the same women outside the hospital would have allowed increased familiarity, confidence and trust between interviewers and women and thus more critical and detailed insight and less socially desirable options could have been expressed freely.[27]

It has been argued that mistreatment of women during labour is a symptom of structural violence that stems from structural gender inequality in society where both mothers and the mostly female SBAs come from.[27] As such, future studies could further explore maternal factors such as socioeconomic status, knowledge and health-seeking behaviour as well as in-depth exploration of societal factors including religion and culture and domestic situations of stakeholders and the effect on quality of care. These are important factors because they determine how women are treated as well the normalisation of mistreatment during labour.[27–29]

The 2016 and 2018 WHO recommendations for antenatal and intrapartum care for a positive pregnancy experience explicitly recognise two complementary domains of good quality care: the *provision* of care and the *experience* of care.[30–32] Knowing how a woman in labour would define good quality care is essential when trying to encourage women to deliver in health facilities and improve their experience at the hospital. Indeed, it appears that there are some key determinants of maternal satisfaction with the quality of care received. These relate to the physical environment of the health facility, availability of medical drugs and equipment, privacy, gender of the health care provider, provider competency, costs, or delivery outcome, and interpersonal behaviour. This interpersonal behaviour is related to courtesy, and being treated with respect, empathy, politeness and good communication. Thus, to improve maternal and child health care it is essential that women feel respected, supported emotionally, and are treated with dignity if one wants these patients to feel comfortable returning to the hospital in case of emergencies. As such, when given the choice, the majority of women wanted someone beside them during childbirth: a loved one (e.g., partner or mother, sister), or a trained community worker while others wanted sufficient support from the skilled birth attendant. These are all within the universal rights of women and recommended to achieve better outcomes and a positive childbirth experience.[30,31,33,34]

Women initially perceived care as adequate or satisfactory. Yet, after more critical thinking, women identified and described unwanted and disrespectful experiences while giving birth in this hospital – maltreatment and abuse too often experienced by women in other parts of Tanzania and LMICs.[27,35–39] Also, in the same study setting and period, findings from direct labour observations and record-based assessment showed suboptimal monitoring and treatment and supportive care with women often being unattended/abandoned during labour, including at the time of delivery.[22] Studies in other LMICs have also reported huge disparities between observed and self-reported measures of mistreatment during labour and this may reflect normalised maltreatment of labouring women.[40,41] Women may have needed encouragement to voice their negative opinion, being hesitant to express complains – especially while still in hospital.[26,27,35] It is also common in LMIC that patients have high satisfaction rating of poor quality, particularly those with lower education.[42] Adaptive preferences is a theory that could explain this phenomenon and is defined as "(1) Preferences inconsistent with basic flourishing (2) that are formed under conditions nonconducive to basic flourishing and (3) that we believe people might be persuaded to transform upon normative scrutiny of their preferences and exposure to conditions more conducive to flourishing".[43] Adaptive preferences in this setting may be the result of social conditions and values, the lack of information and choice, inexperience with high-quality care and limited agency of women.[29,42] For example, separation of women from their loved ones from the time of admission may have stripped women of their agency, left women voiceless, disempowered, detracted of their confidence, fearful during labour and delivery.[44] Women were physically and mentally vulnerable to stress and maltreatment which have negative impact on birth outcomes and maternal mental health and health-seeking behaviour.[45–48]

Likewise, although there was consensus during FDGs, among all groups of SBA on their inability to provide adequate labour care and findings of which were supported through record-based assessment and labour observation, individual responses showed that SBA, particularly interns and nurses, were reluctant to admit that they were unable to deliver the required care. Perhaps, this is because of fear of being blamed and seen as incompetent.[18] Also, the SBA may have also thought that they were performing duties beyond their capacity or what should be expected of them.

Women's compliance or silence does not legitimatise those norms of treatment and forms of oppression. One concern of adaptive preferences in this setting is that it may jeopardise women's health and policymakers' response to improve maternal healthcare services when individuals report that they are satisfied with the status quo of quality of care provision and women and babies will continue to suffer. This emphasises the need for community education, quality monitoring and advocacy for the rights of pregnant women.

The provision of effective, safe and respectful care depends largely on the availability of a well-trained responsive health workforce and adequately equipped health facilities.[49] Like many other settings, human resource was identified as the major contributor to poor quality care, affecting the SBAs' ability to monitor mother, baby and progress of labour, provide supportive care and also handle arising emergencies.[18] Specifically, SBAs in this hospital were too few, young, not adequately trained and inexperienced to manage the heavy and complex workload associated with this busy referral hospital and with minimal supervision and support.[18] Thus supportive and respectful care may often be forgotten or not prioritised during care, training and routine monitoring of quality of care.

The physical structure, overcrowding and the lack of space, beds and hygiene also compromised monitoring and intervention, women's safety, privacy, confidentiality, dignity and mental wellbeing. Disrespectful working conditions may also result in negative attitude, demotivation, demoralisation, and burnout leading to inability to provide compassionate and respectful care. In such a system, SBAs become both the abuser and abused. They may struggle with feelings of helplessness/hopelessness and are unable to go beyond their clinical roles to being advocates of patients' right, accountability and political commitment for quality improvement.[35,36,50–53] SBAs also recognised the need for teamwork, and poor inter-professional relationship but needed support and mentorship to organise themselves.

The lack of essential commodities, particularly for emergencies caused time-wasting, out-of-pocket financing, increased workload and caused delays and insufficient treatment of high-risk women and life-threatening complications. Likewise, the lack of skilled healthcare workers and supplies across nearly all health facilities in Zanzibar contributes to unnecessary patient load to this tertiary hospital.[19] Thus, well-functioning facilities that can provide basic emergency and comprehensive obstetric and neonatal care and good referral mechanism are necessary to reduce preventable and unnecessary referrals and decongestion of the only tertiary hospital.

The birth attendants' ability to provide proper quality of care is also further hampered in systems where there is no recognition, appreciation of their devotion and hard-work, not adequately remunerated and instead are blamed and shamed for system failures where accountability is often lacking.[52–56]

Health financing, leadership and governance are underlying causes of inadequate hiring, disrespectful working conditions, poor pay, mal-distribution and rotation and out-migration of staff. [18] The maternal and child free healthcare policy in Zanzibar is a crucial strategy that should not be compromised. Such policy has been shown to increase health-seeking behaviour and decrease mortality and risk the opposite impact if abandoned. The goal should be to explore strategies to make maternal health wholly free with sustained supplies so that women and families, most of whom of low social economic status, do not have to bear the cost of supplies with their lives. Hospital managers did not feel empowered to address health system issues such as salary, recruiting, retaining and professional development of their staff and procurement of supplies. They believed that to achieve the Sustainable Development Goals sub-target (3c) of "substantially increase health financing and the recruitment, development, training and retention of the health workforce…", improve infrastructure and essential supplies, they as a hospital, need to achieve significant autonomy from the central government. This is critical because the physical structure of the new maternity unit of several labour rooms and expected increase in the volume of women seeking delivery demands investment in skilled human resources – number of midwives in particular. Such investment has high short and long-term returns. As an educational institute where future health care workers are trained, there is also a need for specialists and senior practitioners and professional bodies to participate in training and teaching, mentoring, shaping curriculum, advocacy and empowerment of practitioners as agents for service improvement.

Conclusion This study showed that SBAs in an East African tertiary, high-volume hospital face considerable challenges, pertaining to their working environment, (human) resources, knowledge and training, and health system context. These are barriers to providing quality care and integrated multifaceted approaches are required to address health system issues. This will include staff's and women's demand for increased skilled health professionals, better working conditions, recognition, motivation, accountability, inter-professional relationships and teamwork, job allocation, organisation, support and supervision, strengthening primary centres and better referral mechanism and technological solutions. The study also illustrates that women need support and education to improve agency and act as co-creators of healthcare solutions.

Ethics approval and consent to participate Approval from the local ethics committee (ZAMREC) was obtained (ZAMREC/0002/May/016). Written informed consent in Swahili was sought from all participating women.

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Authors' contributions NH, JB and MJR conceived the experiment. NH, JB, AM, MR and MJR designed the experiment.
NH, AM, MR, and RSK carried out data acquisition. NH, AM and MR analysed the data. NH interpreted the results with substantial contribution from JB, AM, MR, LAJ AR, TM and MJR. NH drafted the manuscript. All authors revised, approved and agreed to be accountable for the final version to be published.

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Chapter 5

Birth asphyxia following delayed recognition and response to abnormal labour progress and foetal distress in a 31-year-old multiparous Malawian woman

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Summary

Reducing neonatal mortality is one of the targets of Sustainable Development Goal 3 on Good Health and Well-being. The highest rates of neonatal death occur in sub-Saharan Africa. Birth asphyxia is one of the major preventable causes. Early detection and timely management of abnormal labour progress and foetal compromise are critical to reduce the global burden of birth asphyxia. Labour progress, maternal and foetal wellbeing are assessed using the WHO partograph and intermittent foetal heart rate monitoring. However, in low-resource settings adherence to labour guidelines and timely response to arising labour complications is generally poor. Reasons for this are multifactorial and include lack of resources and skilled health care staff. This case study in a Malawian hospital illustrates how delayed recognition of abnormal labour and prolonged decision-to-delivery interval contributed to birth asphyxia, as an example of many delivery rooms in low-income country settings.

Case presentation

A 31-year-old woman was admitted to the labour ward in a rural Malawian mission hospital at 9.40 a.m. in August, 2017. Earlier, at 4.00 a.m., she presented to a health centre 19 kilometers away in active stage of labour with eight cm cervical dilatation. She was diagnosed with poor progress of labour and there was a decreased foetal heart rate (FHR). She was therefore referred by ambulance. She was estimated at 38 weeks gestation based on fundal height. Her obstetric history revealed three previous pregnancies resulting in three healthy vaginally born children who were still alive. Her last pregnancy had been complicated by postpartum hemorrhage. No complications had occurred during her current pregnancy. She had visited antenatal care once and had no medical conditions. She was divorced and had not received any formal education. On examination, her membranes had already ruptured and liquor was clear. Regular contractions with a frequency of three per minute were present and the cervix remained at eight cm dilatation. The woman's vital signs were normal. The FHR was 104 beats per minute (bpm), but 126 bpm during the next confirmation auscultation

45 minutes later. As part of routine care in this hospital, a urinary catheter was inserted to facilitate emptying of the bladder during progress of labour. Saline was administered intravenously. According to the local guidelines, oxytocin augmentation was contraindicated as foetal distress was suspected. During the following two hours, the FHR was auscultated on two occasions by different health care workers. At 11:30 a.m., the woman was fully dilated, but the descent of the foetal head was only 2/5 and the FHR was abnormally decreased to 84 bpm. At 11:45 a.m., the clinical officer assessed the woman and made the decision for emergency caesarean section because of foetal distress and suspected cephalopelvic disproportion. At 2:00 p.m. a hypotonic baby boy of 3600 grams was born covered in meconium stained liquor. The Apgar scores at one and five minutes were five and seven, respectively. Oropharyngeal suctioning was performed. The baby was admitted to the neonatal care unit for further oropharyngeal suctioning and oxygen supply. The next day, he developed seizures and received a loading dose of 73 mg intravenous phenobarbital. Oxygen was supplied for two days. No subsequent seizures occurred. The baby was discharged after four days and was taken home by his mother, who had recovered quickly. Five months after discharge the baby had no major developmental problems. We were unable to follow-up with a detailed assessment.

Global health problem list

• Low-income countries such as Malawi are still far from meeting Sustainable Development Goal 3’s target to end preventable deaths of newborns and reduce neonatal mortality to at least as low as 12 per 1,000 live births, because of persisting suboptimal intrapartum care.

• Birth asphyxia is a major preventable cause of neonatal morbidity and mortality in low-income countries and forms a large global burden.

• Adequate intrapartum routine care and timely emergency obstetric and newborn care can prevent birth asphyxia, but in many settings adherence to labour guidelines and timely response to arising labour complications is poor.

Global health problem analysis

The global burden of birth asphyxia

In accordance with Sustainable Development Goal 3's second target (SDG 3.2) and Every Newborn Action Plan, all countries should end preventable deaths of newborns and reduce neonatal mortality to at least as low as 12 per 1000 live births by 2030.[1-2] Currently, an estimated 2.6 million newborns die every year worldwide (19 per 1000 live births), with large global inequities: from 3 per 1000 live births in Northern America and Europe to the highest rates in Central and Southern Asia (27 per 1000 live births) and sub-Saharan Africa (28 per 1000 live births).[3] To realise SDG 3, understanding and addressing the numbers and causes of neonatal death and stillbirths is essential.[4] Globally, birth asphyxia is one of the leading causes of neonatal mortality, next to prematurity and severe infections.[5,6]

Birth asphyxia is a medical condition resulting from oxygen deprivation during the perinatal period, often leading to brain injury in the newborn infant. This is reflected by the development of insults during the first hours after birth, and in the most severe cases permanent developmental disorders such as cerebral palsy, mental retardation, epilepsy, or death.[7] The pathophysiology of birth asphyxia is complex. Generally, it occurs due to reduced oxygen delivery to the infant's brain, as a result of impeded placental blood flow.[8] Primary management consists of resuscitation with bag and mask ventilation or intubation depending on the severity of birth asphyxia. After resuscitation, treatment consists of maintaining stable vital signs.[9] In some cases and settings, therapeutic hypothermia can be indicated.

The number of deaths due to birth asphyxia is much higher in low- and middle-income countries compared to high-income countries (25% versus 7%).[10] Birth asphyxia forms a large global burden of disease with 50.2 million disability-adjusted life years (DALY).[11] In low- and middle-income countries, an estimated 50% of birth asphyxia survivors are affected with neurodevelopmental impairment, resulting in less school learning potential and economic productivity.[12-13] Malawi has made slow progress on reducing neonatal death[13] during the Millennium Development Goals period, but the country is still far from meeting SDG 3.2. Strengthening access and quality of health remain major challenges. Currently, the neonatal mortality rate is 23/1000 live births[14] and the stillbirth rate is 24/1000.[15] Asphyxia accounts for 22% of neonatal death [16], although the incidence might be higher due to misclassification and underreporting of early neonatal death.[7] Malawi's SDG 3 index score is 42.8, signifying the country's position between the worst (0) and the best or target (100) outcome. This score is currently not meeting the growth rate needed to achieve SDG 3 by 2030.[17] To meet SDG 3.2 and reduce the global burden of birth asphyxia, prevention, early detection, and timely response in labour are critical.

Prevention of birth asphyxia: adequate routine intrapartum foetal monitoring coupled with timely emergency obstetric care

Prolonged labour, maternal haemorrhage, obstructed labour and umbilical cord accidents are important determinants of birth asphyxia.[18-19] For timely intervention in case of abnormal labour and foetal distress during labour, early detection is key. There is insufficient evidence for the effectiveness of various techniques of monitoring foetal wellbeing. Yet, in all labour guidelines, the condition of the foetus can be assessed through foetal heart rate monitoring (FHRM) with or without the aid of a confirmatory test. FHRM can be performed through either intermittent auscultation (IA) by Pinard or hand-held Doppler or continuous cardiotocography (CTG). In low-income countries, IA is often the only available and safest FHRM method for the mother because advanced methods are associated with higher false positive rates of foetal distress and unnecessary caesarean sections.[20-22] There is no evidence regarding the optimal frequency of IA, but a frequency of at least every 15 to 30 minutes during the active first stage and at least every five minutes in second stage for at least one-minute duration are often recommended.[23-24] A normal FHR is generally regarded as 120-160 bpm.[25] While these frequencies are echoed in the Malawi national guidelines,[26] regular assessment of the FHR can be challenging. For example, in a referral hospital in the capital Blantyre, the FHR was monitored every two hours or not at all.[16] Similar patterns have been described for other low-resources settings, such as a referral hospital in Tanzania, where half of stillbirths were intra-hospital, the median time interval from last FHRM to delivery was 210 minutes in 2015[27] and in a hospital in Mozambique, where FHR was monitored on partographs in just 50% of labours, regardless if women had risk factors for asphyxia.[28] A study in Nepal also showed inadequate FHR monitoring during labour that was associated with increased risk of intrapartum stillbirths.[29] Poor adherence to guidelines may cause late detection of foetal compromise and could therefore lead to poor neonatal outcome.

If foetal distress is detected, the following interventions should be considered according to local hospital guidelines: supplying oxygen therapy, placing the woman in left lateral position and administering fluid bolus. If the FHR does not improve, operative delivery should be performed within 30 minutes.[26,30] Although evidence of correlation of decision-to-delivery-interval (DDI) and perinatal outcome is currently lacking,[31] in case of foetal distress any delay may worsen intra-partum hypoxia and is therefore unjustified.[32] A DDI below 30-75 minutes has been widely recommended,[33-35] although this seems not always feasible in low-resource settings.[36-38] In two studies performed at tertiary hospitals in Nigeria, mean DDI in case of foetal distress was 2.9 (±2.5) hours[39] and 68.7 (±39.7) minutes, respectively.[32]

Various reasons for delay in DDI have been previously described and are multifactorial. They include lack of labour staff, delay in transfer to theatre, unavailability of operating theatre, anesthesiologist or the surgeon and performing caesarean section under regional anesthesia instead of general anesthesia.[39-41] The low use of assisted vaginal delivery options in low-income countries might also contribute to a longer DDI and poor perinatal outcome.[42-43]

Perinatal audits may help to identify delaying or sub-optimal care obstacles and implement appropriate solutions at a local setting.[44-45] Simulation training in case of emergency caesarean section and training in assisted vaginal delivery may help to shorten DDI.[46] In the presented case, irregular assessment of the foetal condition, the timing of diagnosing abnormal labour progress and the decision-to-delivery interval of 135 minutes probably contributed to the poor neonatal outcome. Both mother and child did not develop serious complications, although the long-term outcome of the baby remains undetermined.

Challenges faced in providing timely and quality obstetric care in low-income settings

The hospital where this case was presented is a secondary level facility with 220 beds. There are six beds available at the labour ward. On a regular day, there are four clinicians/ medical officers, four nurses and two patient attendants assigned to the maternity ward; one clinician, two nurses and two patient attendants stay at the labour ward, the other staff members are assigned to either antenatal or postnatal care. The patient attendants do not deliver medical care but help for example with measuring the mothers' vital signs and cleaning the delivery room. On average, there are nine deliveries a day, leading to more than 3000 deliveries a year. This results in a nurse: labouring woman ratio of 1: 3-4. During a regular clinical morning meeting all nurses (n=10) explained that the labour ward was often so crowded that on daily basis women were sent outside to await progression of labour with their relative within hospital grounds. Monitoring the FHR every 30 minutes was practically impossible due to lack of staff. Also, alternations of staff taking care of the women might lead to delays and inconsistent FHR monitoring. The reasons for the delayed DDI were not discussed.

Previously described causes of non-adherence to labour guidelines and suboptimal care consist of lack of resources, shortage of staff, inadequate training as well as structural and organisational deficiencies in healthcare facilities and professionals. In addition, low motivation and job dissatisfaction may result from high workloads, low salaries, poor living conditions and inadequate support from supervisors and leaders.[16, 47-48] These are examples of commonly described 'supply-side' barriers in the 'three delays model.[49] Malawi experiences severe shortage of health care staff and essential medical products, technologies and logistics. Contributing factors include inadequate funding, high burden of disease and weak supply chain management. Only 53% of hospitals and 5% of health facilities can provide a full package of comprehensive and basic emergency obstetric and neonatal care services. There are persistent gaps in human resource capacity across all districts and health care levels within Malawi's public sector, with a 45% vacancy rate.[50] With a density of 3 doctors, nurses and midwives per 10,000 population, Malawi is far from meeting the minimum threshold of 23 established by the WHO to ensure essential maternal and child health services.[51] In addition, Malawi's health sector faces uneven distribution of health care staff, with only a few doctors working in local district hospitals. Retaining health care staff is impeded by inadequate management support,[52] concerns about increased workload and staff shortages. Critical shortages of skilled staff inhibit timely and quality obstetric care, which has a significant impact on maternal and neonatal outcomes.[53] Clearly, there is urgent need for training, employing and retaining of more healthcare workers, as well as improving healthcare facilities to accommodate the increasing number of facility-based deliveries and to improve neonatal outcomes. Motivation and adherence to intrapartum guidelines can also be improved when labour staff members are involved in developing intrapartum guidelines and when these guidelines are better adapted to the local setting.[54]

Learning points/take home messages

1. Early detection and timely management of abnormal labour progress and foetal distress are essential to reduce the global burden of birth asphyxia and neonatal mortality rates in low-income countries.
2. Foetal heart rate monitoring could be useful in preventing birth asphyxia if appropriate and timely response to foetal distress is available.
3. Reasons for delay and suboptimal perinatal care in low-income settings are multifactorial and include shortage of resources and skilled health care staff leading to increased workload and job dissatisfaction.
4. Evaluations of quality of labour and perinatal care should be performed to identify delaying and sub-optimal care factors and implement appropriate solutions to problems identified at local settings.
5. Availability of more healthcare workers with an adequate skills set, resource allocation and improving education of intrapartum and emergency obstetric care are key.

Patient consent for publication Obtained**.**

Patient's perspective

"I understood that my baby had asphyxia. I was worried about the outcome and felt detached. Generally, my experience at the health centre and hospital was good, although I would be happy if the team at the health centre dedicates more time to patient monitoring. I would recommend quick decision-making in cases like this."

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Chapter 6

Acceptability of task-shifting of intrapartum foetal heart rate monitoring to lay health worker in a referral hospital: a mixed-methods study

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Abstract

Background Lack of intrapartum foetal monitoring is a major contributor to the problem of intrapartum death, often caused by a lack of human resources in low and middle-income countries. Shifting basic tasks from higher- to lower-trained cadres could be a strategy to improve intrapartum foetal heart rate (FHR) monitoring. The objective of this study was to establish whether task-shifting of FHR monitoring to lay health workers would be a locally acceptable intervention to pregnant women, skilled birth attendants and policymakers in a busy birth centre in Zanzibar, Tanzania.

Methods A mixed-methods study consisting of structured questionnaires, focus group discussions, and semi-structured interviews was conducted among stakeholders at different levels of the health system between July-August 2016. Quantitative survey results were descriptively analysed; qualitative data were coded and analysed according to the theoretical framework of acceptability.

Results Forty-three skilled birth attendants of the maternity unit (24 nurse-midwives, seven junior doctors, 12 permanent doctors), 45 mothers (15 antenatal, 30 post-delivery) and seven policymakers were included. Women positively viewed task-shifting FHR monitoring to lay workers as a beneficial intervention to improving quality of care. The multiple stakeholder groups raised many concerns about the intervention: 1) effectiveness of the intervention (lack of medical training, competency and safety), 2) ethicality (confidentiality, policy and regulatory support), 3) opportunity costs (loss of FHR monitoring skills for midwives, and costs of the intervention), 4) affective attitude (liability concerns, professional protectionism, jealousy, mistrust, disrespect and blame), 5) burden on existing cadre (training and supervision, conflict and strained interprofessional relationships, roles and limitations).

Conclusion Task shifting of foetal heart rate monitoring to lay workers was considered a suboptimal solution to the health care staff shortages. Therefore, and given the persistent health system's constraints in providing adequate numbers of nurse-midwives, further efforts are needed to find alternative strategies to optimise FHR monitoring.

Introduction

An estimated 2.65 million stillbirths and 3 million neonatal death occur yearly worldwide, of which >98% in low resource settings.[1,2] Almost half of the number of stillbirths in low-income countries (LIC) occur intrapartum. Skilled care at birth is the core of modern obstetrics and a right for every woman.[3,4] Monitoring of mothers and their babies during labour is vital to ensure early detection of signs of foetal distress, complications and prompt interventions to prevent perinatal deaths.[5] Foetal heart rate (FHR) monitoring can either be monitored by intermittent auscultation (IA, using Pinard, foetoscope or hand-held Doppler) or by electronic foetal monitoring (using cardiotocography). The Pinard, hand-held Doppler and partograph are strategies reported as simple, safe, low-tech and low-cost and often the only method available in low-resource settings.[6–8]

Generally, guidelines recommend assessment of FHR by intermittent auscultation every 15 or 30 minutes in active phase of first stage of labour, and after every contraction or every 5 minutes in second stage for 30-60 seconds (i.e. from active pushing until birth of infant). Contractions are recommended to be determined every 30 minutes over a 10-minutes duration by palpation.[6,8,9] As such, these recommended standards of intrapartum care are labour intensive, difficult to carry out in busy maternity wards and are sub-optimally performed particularly in low resource settings[10–12] due to the high-volume of labouring women, limited and inadequately trained human resources, shortages in monitoring devices and their consumable, and a non-conducive environment.[13]

While urgent in intrapartum care, this is reflective of the health human resource situation in many other sub-Saharan African health care settings and is a barrier to achieve the Sustainable Development Goals's ambitions to improve maternal and newborn health outcomes.[14]

A possible solution to the persistent human resource shortage is 'task-shifting' or 'task optimisation'. Task-shifting is defined as "the delegation of medical and health service responsibilities from higher to lower cadres of health staff, in some cases non-professionals".[15] Task-shifting has been used within and beyond maternity care in low- and middle-income countries to cover gaps in obstetric care coverage.[16–18] It has been shown in various Sub-Saharan countries to be safe and cost-effective to bridge the human resource gap and has low turnover rate and high retention rate and takes less time to train.[19–21] Examples of successful task shifting in maternity care include the training of physicians, midwives and assistant medical officers to perform obstetric emergency care including caesarean section. [20] Other possible benefits could enable the engagement of communities as a resource to help with health care needs. Specifically, the World Health Organisation recommends the use of selected members of the community (i.e. lay health workers) to promote reproductive health services including family planning, provide labour support and prevention of postpartum haemorrhage.[16] While solutions for FHR monitoring have focused on innovative technology,[6,22–26] task-shifting of FHR monitoring to trained lay health workers has not been considered.

Mnazi Mmoja Hospital in Zanzibar is an example of a large, busy and resource-constrained hospital where the few skilled birth attendants struggle to provide labour care to the 13000 births throughout the year. In this referral hospital, intrapartum foetal wellbeing was mainly assessed by IA using Pinard and hand-held Doppler by both nurse-midwives and doctors. Previous research documented a lack of foetal surveillance quality and frequency (i.e. a median time from last FHR recording till delivery or detected intrauterine foetal death of three hours and 30 minutes and two hours in healthy newborns). The stillbirth rate in 2014 was 59 per 1000 total births, of which a significant proportion occurred intrapartum. [6] This mixed-method study aimed to determine whether creating a new cadre to task-shift FHR monitoring would be a locally-acceptable intervention of foetal surveillance in this setting.

Methods

Proposed intervention

The type of task-shifting proposed by the present study can be described as "the extension of the scope of practice of community health workers or lay providers in order to enable them to assume some tasks previously undertaken by more senior cadres, e.g. nurses and midwives, non-physician clinicians or doctors".[15] Lay health workers are thus people who receive specific training for the tasks they are asked to perform (i.e. FHR and contraction monitoring) but have received no formal professional or paraprofessional education.[27] Before development of the intervention, assessment of its acceptability need to be established from local stakeholders' perspectives. Acceptability of an intervention is defined as the perception among stakeholders that an intervention is agreeable.[28]

Study design, participant selection and data collection

Methods of this study were described in details elsewhere.[29] Briefly, a mixed-method approach was used among different stakeholders at Mnazi Mmoja Hospital (MMH) in Zanzibar, Tanzania between July and August 2016. Skilled birth attendants participated through self-administered structured questionnaires with Likert scale questions and focus group discussion (FGD). Prenatal and postnatal women were invited for face-to-face semi-structured interviews. In-depth interviews were held with policymakers who held positions at the level of the hospital, ministry of health and institution of health education. Interviews and FDGs were audio-recorded, transcribed and translated to English. Data collection tools were developed and included participants' background information, feelings and thoughts, and anticipated advantages and disadvantages of the proposed interventions.

Data analysis

Simple descriptive analysis was performed on background information and Likert scale responses. Qualitative data analysis was conducted according to the theoretical framework of acceptability (TFA) of health interventions which consists of seven component constructs: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy (Box 1).[30]

Ethical consideration

The study was approved by the governing ethical board (ZAMREC/0002/May/016). Written informed consent was obtained from antennal, post-delivery women and hospital staff. Oral informed consent was obtained from policymakers. All information was kept anonymous and confidential.

Box 1 Definitions of Construction of the theoretical framework of acceptability [30]

Construct	Definition
Perceived effectiveness	The extent to which the intervention is perceived as likely to achieve its purpose
Affective attitude	How an individual feels about the intervention
Burden	Perceived amount of effort that is required to participate in the intervention
Ethicality (and recognition)	Extent to which the intervention has good fit with an individual's value system
Intervention coherence	The extent to which the participant understands the intervention and how it works
Opportunity costs	The extent to which benefits, profits or values must be given up to engage in the intervention
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention.

Results

Participants characteristics

There were 45 participant mothers (30 post-delivery and 15 antenatal). All women were married, and most were housewives with secondary education and lived in urban regions. Skilled birth attendants consisted of 24 nurse-midwives, 7 intern doctors and 14 registrar doctors. There were six FGD with skilled birth attendants: three with midwives, two with doctors, and one with interns. The majority of SBA at the maternity unit were female ((86%, n=37), with a median age of 30 (IQR 28-32)) years, married with few years of experience in labour care (≤5 years, 91%, n=39). Seven policymakers participated in the study, from the hospital administration/management (n=3), Ministry of Health (=3) and educational institutions (n=1).

Acceptability of task shifting foetal heart monitoring to lay health workers

The majority of women expressed that they would gladly welcome a trained lay health worker to keep track of the baby's condition (87%, 39/45). Self-administered questionnaire showed individual SBA had mixed feelings and thoughts about the intervention (figure 1). FGDs revealed that SBA along with policymakers did not favour the proposed interventions. The acceptability of the intervention are summarised according to the seven theoretical constructs of TFA (Table 1).[30]

Perceived Effectiveness

The self-administered questionnaire showed individual SBA had mixed opinions on the effectiveness of task shifting to improve the health of mothers and babies (58% (14/24) midwives, 72% (5/7) of intern doctors and 17% (2/12) of registrar doctors agreed it could be effective): (Figure 1). SBA and mothers identified the main potential benefits of the new cadre as early detection of foetal distress, subsequent intervention and reduction of adverse perinatal outcomes (e.g. fresh stillbirths and neonatal deaths). However, the non-medical nature of the new cadre also raised concerns among all groups of SBA about the quality of training including practical skills and competency, safety of the baby if the new workers are unable to detect foetal distress and “medical ethics” in terms of confidentiality and privacy. Policymakers and SBA also felt that the limited skills and function/role of the new cadre and their inability to respond to foetal distress makes this intervention ineffective. Also, further delays were foreseen due to the lack of consumables for intrauterine resuscitation and operative delivery. Thus, the majority of policymakers and SBA felt that the single most important solution to improving FHR monitoring and quality of care was to increase the number of skilled birth attendants accompanied by training in foetal heart monitoring.

Intervention coherence

All stakeholder groups demonstrated clarity on the purpose of the intervention: the role of the new cadre would be to perform FHR and contraction monitoring and report findings to SBA. While nurse-midwives and interns agreed a new cadre could be useful for women, doctors and nurse-midwives (figure 1), this would be mostly in providing *supportive care* to women, cleaning of the labour ward and running errands (e.g. fetching laboratory investigations and blood products). Supportive care was perceived as important but lacking in this maternity unit.[29] Both women and SBA were open to the new cadre providing both psychological and physical to women such as emotional support, helping the women go to the toilet, eating and drinking, ambulation and alerting the doctor of danger signs.

Ethicality

While FHR monitoring was not perceived as solely a nurse-midwife's responsibility but a collective effort of the maternity team (nurse-midwives: 63% (15/24), intern doctors 72% (5/7) and registrar doctors 25% (3/12), figure 1), nurse-midwives were very concerned that their task would be taken away from them and given to someone else. Yet, they perceived it as devaluing the midwifery profession and losing their respect among hospital staff, supervisors, patients and community as they were not able to perform FHR monitoring themselves. While emphasising the need for all parties to recognise the roles and responsibility of the new cadre, midwives in particularly predicted that the new cadre would go beyond their duties and responsibilities and would additionally want or be requested to carry other clinical care such as deliveries, which was unwanted. Policymakers and nurses also believed that the new cadre would likely engage in community private practice as traditional birth attendants which would be an undesired effect of the intervention.

There were resonating concerns about confidentiality issues and how the new cadre would be integrated into the healthcare system. Particular issues related to their recognition, accreditation and licencing, roles and function, accountability and involvement of regulatory bodies were raised.

Opportunity costs

SBA voiced their concern that they would lose their skills in FHR monitoring if the task was taken away from them. Although SBA acknowledged that the new cadre would be more affordable to hire than formally educated staff, both SBA and policymakers raised questions regarding costs including sources of funds for supplies such as job aids, foetal monitoring devices and consumables, and task-appropriate remuneration. They were therefore concerned with the implementation strategy and sustainability of the intervention.

Burden

Task shifting could help and free up midwives and interns doctors to focus on providing other complex tasks (figure 1).[20] However, SBA also indicated that bringing more people to the ward would increase workload, over-crowdedness, conflict, mistrust and cooperation issues between midwives, interns, and doctors (figure 1). Midwives mentioned that the existing relations among nurse-midwives and doctors were already problematic; examples include hierarchical structures, communication and tensions among healthcare professionals which cause delays in reporting and managing complications - increasing the risk of stillbirth, neonatal death and caesarean section rates. Introduction of a new cadre in the same conditions could exacerbate this situation. All SBA worried that nurse-midwives may become “over-dependent” on the new workers with the risk of them becoming unfairly treated and overburdened. Nurse-midwives also felt that the new cadre would likely be vulnerable to blame, overwork and emotional/psychological trauma of the working conditions in the maternity unit. Thus, if implemented, SBA encouraged the use of appreciation (e.g. remuneration/incentives) and supportive strategies to motivate, satisfy and take care of the wellbeing of the new cadre.

Affective attitude

The intervention raised strong feelings among SBA, particularly midwives, regardless of its perceived effectiveness: feelings of “blame”, “hurt” (nurse-midwives: 50% (12/24), intern doctors: 42% (3/7) and doctors: 33% (4/12) (figure 1), guilt, “mistrust”, “uselessness”, jealousy, disrespect, and “disvalue” of the midwifery profession. Trust between different cadres also emerged here: midwives thought that the new cadre came to take over their duty because they were not good at it, nurse-midwives and doctors expected to ‘double-check’ FHR. Liability concerns were raised in the case that the new cadre would not be competent enough with adverse events such as perinatal death as a result. However, also midwives recognised the need to keep the new cadre motivated, incentivised and supported with adequate psychological, remuneration, and physical support.

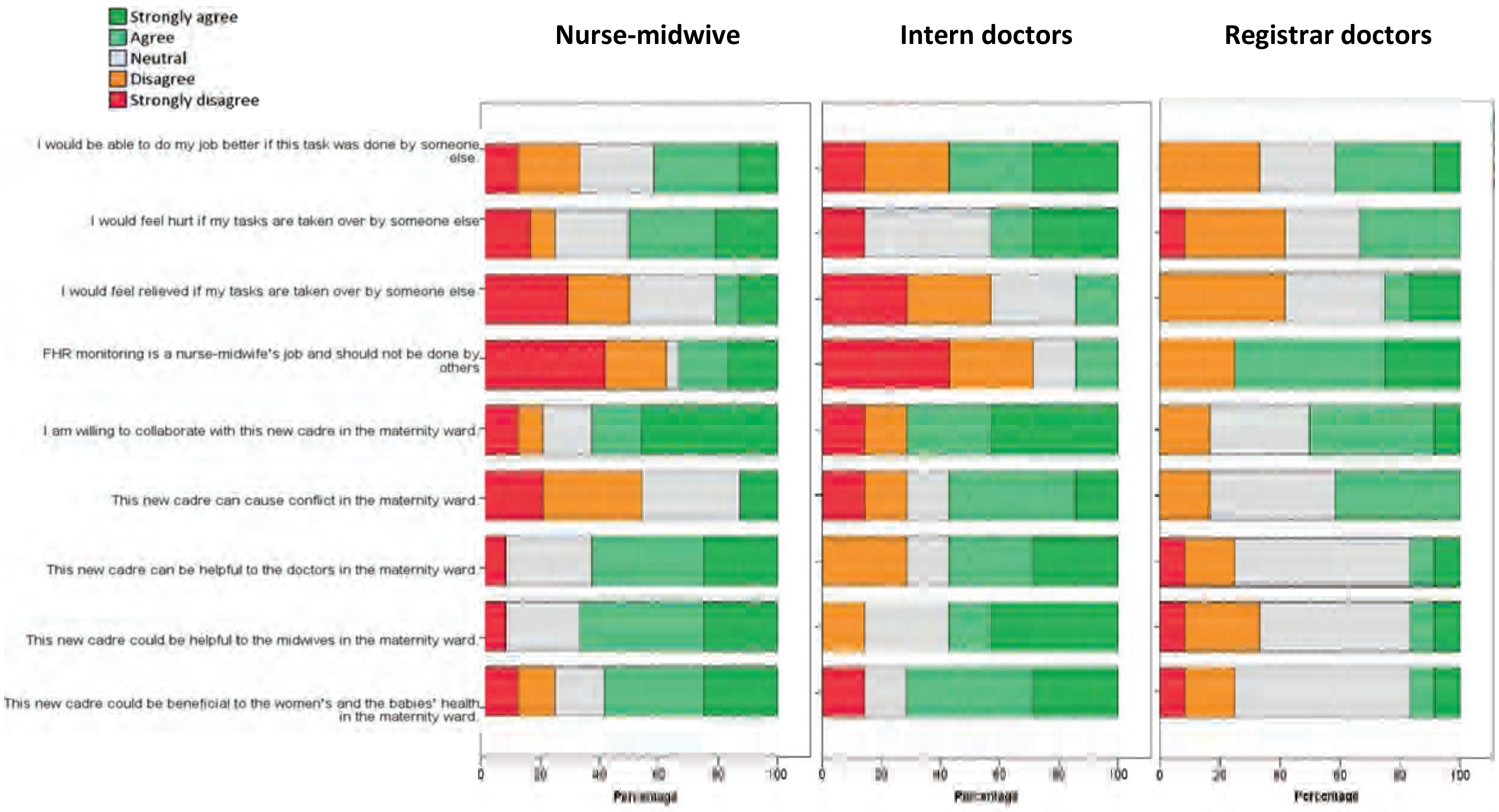

Figure 1 Perception of task-shifting foetal heart rate monitoring to lay health workers separated by cadre: A= Nurse-Midwives (N=24), B= Intern doctors (N=7), C = Registrar Doctors (N=12)

Table 1 Acceptability of task-shifting of foetal monitoring to trained lay health workers among stakeholder groups

Construct	**Potential benefits**	**Concerns/threats**	**Illustrative quotes**
Perceived effectiveness	• Effect on perinatal outcome: early detection foetal distress and reduce number of perinatal deaths. [NMW, RD, ID] • Improve performance of skilled birth attendance with more time to spend on other care. [NMW, RD, ID]	• No change or worsened perinatal outcomes due to: • Inadequate training, skills and experience leads to incompetency, delay or misdiagnose of foetal distress (false negative and positive) [PM, NMW, RD, ID] • Limited scope of skills to only FHR monitoring means inability/delayed action-taking for FHR abnormalities e.g. intrauterine resuscitation [PM, NMW, RD, ID] • Lack of foetal heart monitoring devices [PM, NMW, RD, ID] • Lack of essential supplies for intrauterine resuscitation and operative delivery. [NMW, RD, ID]	*"They would have two tasks: first as a friend to support a patient, and secondly as an assistant to the doctor"* (32 years old mother, para 4). *"We have done this job for many years and FHR confuses me. How about those who just got training? Will they have the skills?"* (NMW, FGD). *"It will not help as they will not be able to act. Yes, they can detect foetal distress but can't give fluids. They have to report to the one who can but they might be too busy. So, it is better to increase the number of staff." (PM6, Hospital level)* *"When there is foetal distress, there is no intravenous cannula, fluid and no emergency (caesarean section) set." (ID, FDG)*
Intervention coherence	• Other suggested functions of new cadre: 1. Labour companionship for physical and emotionall support [women, NMW, ID, RD] 2. Detection and report of danger signs of mother due to close proximity [NMW, ID, RD] 3. Cleanliness and hygiene [women, NMW]	• Does not address underlying health system issues: number of SBAs, equipment and supplies and teamwork. [PM, NMW, RD, ID]	*"You will feel bad because you will realise that me, I am not a good worker, there are things I am lacking, you will not feel that it is just a shortage of staff and overcrowding of mothers, you will feel there is something you do not do well that's why they brought someone to do that job." (NMW, FDG)*
Ethicality (and recognition)	Can be accommodated within the health system ministry as are auxiliary nurses, traditional birth attendants and traditional healers. [PM]	• Confidentiality and medical ethics [PM, NMW, RD, ID] • Concerns of how the intervention can fit in the health system including policy and regulatory support: 1. for certification, accreditation and licensing [PM, NMW] 2. Supervision and evaluation [PM, NMW] 3. Regulatory body, responsibility and accountability [PM, NMW] 4. Function, role and limitations: Task deviation to providing other clinical care such as deliveries; private practice in community. [PM, NMW, RD, ID]	*"My concern is ethical issues, confidentiality issues, licensing and recognition." (PM2, hospital level)* *"Also the new cadre are not bind to oath and even if they are, they can expose confidential matters to the community such as HIV status" (PM2, hospital level)* *"As a policymaker, I cannot disallow it. I have no problem, we have community workers, yes, some are substandard. We use them, keep them and train them. We had auxillary workers. It is a practise as long as agreed on and based on evidence. We recognise traditional healers and appreciate their efforts and are recognised by law and we accommodate for them." (PM, Ministry of Health)* *"Hospital has received many volunteers before. The volunteers came for one task but ended up doing treatments and other tasks, then they go to the community and open dispensaries and clinics with practices like circumcisions" (PM, hospital level)*

Opportunity costs	Cost-effective [NMW, RD]	• Concern for long-term sustainability of training and follow-up [PM, NMW] • Concerns about amount, sources and sustainability of salaries/compensation [PM, NMW] • discomfort, disturbance and reduced freedom of mobilisation for mothers due frequent FHR monitoring [NMW] • Midwives becoming "lazy" and complacent, "over-dependent" [NMW] • Midwives' loss of skills of FHR monitoring [NMW] • Loss of respect from patients, supervisors and community [NMW]	*"First my job being given someone else, you know our job comes with experience, so if you abandon it for a while you don't do it, you don't know it anymore, then that skill of FHR monitoring you lose it." (NMW, FDG)* *"Also if they care coming from the community, we already know the attitude of our staff, they will not do just that job (FHR), we ourselves we will allocate them to deliver, admit patients and the ward will be left to them while the staff goes to the shop." (NMW, FGD)* *"If they don't do their job well, I would feel bad and outsiders will say it is the midwives to blame' (NMW, FDG).*
Burden	• Reduced workload for SBAs leading to more time for other tasks and improved job performance [NMW, RD]	• Increase workload due to the need for supervision and support [NMW, RD, ID] • For new cadre it can be emotionally and physically demanding; may receive abuse and mistreatment from health cadres. [NMW] • Can cause conflict and poor teamwork among cadres. [NMW, RD, ID] • Work environment: increase over-crowdedness and noise [NMW, RD, ID] Can cause unnecessary caesarean sections. [PM, NMW, RD, ID]	*"A midwife cannot do all her tasks, so this would shift some responsibility away from her" (RD, FGD).* *"One disadvantage is that they will increase the workload on us because even after they have been trained we will have to teach them as well. So instead of helping us they will increase the workload for us." [NWM]*
Affective attitude	• Feeling of relief [NMW, ID]	• Do not support the idea of lay health workers to be employed at hospital level [PM, NMW] • Feelings of "blame", "hurt", guilt, "mistrust", "uselessness", "disvalued" and jealousy [NMW].	*"Patients will think that these new people are doing everything and that good results are all because of them" (NMW, FGD).* *"You study for years to specialise, and one day someone comes in, and takes it [your job] away from you, this is painful and feels as if you cannot do anything and as if you have no knowledge" (NMW, FGD).* *"For me I will not feel bad or that I was disrespected or disvalued. I will feel I have heavy burden of responsibility which I need help with in order to do my job well." (NMW, FGD).* Midwives:21%, doctors: 25%, interns:14
Self-efficacy	• Willingness and readiness to supervise and train [NMW, RD]	• Not willing to supervise and train [NMW]	

Abbreviations fhr = foetal heart rate, NMW = nurse-midwives, ID = intern doctors, RD = registrar doctors, PM = policymakers

Self-efficacy

The majority of women stated that they would allow non-medically trained staff to monitor their baby's heart rate during labour as long as they are well-trained, competent, kind and respectful. Moreover, when asked, half of the women would be interested in being trained to perform this task (22/45), a quarter (11/45) would not and another quarter (12/45) was not asked. The majority of SBA and policymakers viewed the intervention as not appropriate; the main barrier being the non-medical background of the new cadre and considerations previously mentioned. However, if the intervention would be implemented, many SBA expressed their willingness to engage with the task shifting intervention (nurse-midwives: 63% (15/24), intern doctors: 71.5% (5/7), registrar doctors: 50% (6/12) in terms of training, mentorship and supervision and assessment and evaluation.

Discussion

In response to the previously documented inadequate intrapartum foetalFHR monitoring by SBA because of severe (human) resource and health system's constraints, [29] this mixed methods study explored task-shifting FHR monitoring to a new cadre of trained lay workers as a possible intervention to improve monitoring and hopefully improve birth outcomes. While women were accepting of this intervention, SBA and policymakers did not find task-shifting of foetal heart to non-medical staff an acceptable intervention. Many concerns were raised regarding the effectiveness of the interventions, ethicality, opportunity costs, affective attitude, and burden on existing cadre. Of particular concern was the limited ability to manage diagnosed foetal distress either due to skills and function of new cadre, unavailability of skilled birth attendants or emergency supplies and equipment. Thus, although all health staff members and policymakers acknowledged the need to increase human resources for monitoring and supportive care of women, there was a strong preference for new staff to have a medical background such as (nurse)midwives.

Strengths and limitations

Strengths of the study include overall approach to explore acceptability of a possible intervention among diverse stakeholder groups (i.e. women, SBAs and policymakers) *prior* to intervention development, and methodological approaches that allowed exploration of opinions and differences among groups and individuals. Assessment of prospective acceptability allows involvement of stakeholders early on to identify, priority areas for improvement and locally-acceptable and context-appropriate intervention for future research. Considering the presented views of stakeholder groups, further exploration of this intervention was not feasible in this setting. However, such findings may not be generalisable in other settings and might also be time-dependent.

Interpretation

Task shifting is a common strategy in maternal health care proven advantageous, safe and cost-effective in bridging the human resource gap in various Sub-Saharan countries.[19,20] However, healthcare professionals and women have raised genuine concerns about crucial factors that could determine the success of task-shifting. These issues are particularly important with such innovative solution as explored in this study, and with task-shifting of clinical care from trained professional to lay health workers. The concerns raised by the multiple stakeholder groups are aligned with key facilitators for effective task shifting in maternal and newborn health care identified and prioritised previously.[31] These key components include: 1) policy and regulatory support such as gaining recognition of the shifted tasks to new cadres outlining scope of practice/function, accreditation and licencing requirement, engagement and support from regulatory bodies which may require evidence of effectiveness of intervention; 2) determination of roles, functions, and limitations to maintain safety of women and babies, manage expectations among labouring women, and support a positive work relations among the different cadres; 3) determination of requisite skills and qualifications for the shifted tasks; 4) education and training programs that allows continuous adequate standardised training, assessment and quality checks to build and maintain competency and safety standards; and 5) service delivery support that includes management and supervision, material and psychological support, remuneration, ideally with the involvement of existing cadre and other stakeholder groups in mentorship, supervisory and regulatory roles. As such, a pre-design acceptability study allows us to identify specific concerns and possible unintended consequences among stakeholders,[32] and even if a certain intervention is considered acceptable, integrate these lessons in the design, implementation and evaluation phase.

The theoretical framework of acceptability (TFA) used to approach the acceptability exploration includes the deliberate exploration of affective attitude of the professionals working at a hospital, women and policymakers. This is an essential factor playing into successful task-shifting intervention programs, especially because negative emotions can jeopardise the 'buy-in', uptake and mitigate potential areas of conflict.[33–35] This is particularly relevant as new cadres are integrated into an existing health care context of the labour ward and its (hierarchical) team dynamics, social, political and cultural structures. The expressed feelings of jealousy are quite common when specific tasks that define someone's professional identity are being taken over by outside help. [33–35] However, if such interventions are shown to be effective or not harmful, the focus of new strategies to address quality of care needs to be on value-based and woman-centred maternity care rather than institution- or profession-centred. [36–38]

Task shifting could offer a solution to a persistent human resource shortage and may improve foetal heart monitoring in many low resource settings. However, improved FHR monitoring alone is not sufficient to improve quality of care and birth outcomes as observed in other foetal monitoring studies in Sub-Saharan Africa.[39–42] Skilled birth attendants questioned the effectiveness and safety of introducing a new cadre of staff in a weak health system in which pre-existing interprofessional relations and teamwork are problematic, roles and function are blurred and a lack of adequate structures for timely response to foetal distress and accountability mechanisms.[34,43] As noted by SBA and policymakers, the wider health systems approach to improve quality of care requires governance and leadership, financing, increase in the number of SBAs (particularly midwives), and interventions to improve knowledge and skills, staff motivation and teamwork, and access to commodities including reliable FHR monitoring devices and supplies for emergency obstetrics and newborn care.[16,44] Interestingly, while task-shifting of FHR monitoring to lay health workers was not positively viewed for provision of care, mothers and SBA acknowledged the intervention's beneficial contribution to the women's experience of care. The shift towards "value-based maternal and newborn care" is increasingly recognised in high-income countries, but requires investment of resources in high-value care provision and as indicated by this study, it is therefore not yet common practice in many LMIC. [38,45]

Conclusion

Foetal heart monitoring is a neglected part of intrapartum care in many low resource settings. Skilled birth attendants in a busy referral hospital in Zanzibar did not consider task shifting to lay workers of foetal heart rate monitoring an acceptable solution because it did not address the underlying health system dysfunction and personal feelings, burden and opportunity cost of the intervention. However, given the desire of women for continuous caring support during childbirth and the persistent health system's constraints in providing the adequate number of nurse-midwives, further research should continue to investigate alternative strategies to optimise FHR monitoring and respectful maternity care in these settings.

Ethics approval and consent to participate Approval from the local ethics committee (ZAMREC) was obtained (ZAMREC/0002/May/016). Written informed consent in Swahili was sought from all participating women.

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Authors' contributions NH, JB and MJR conceived the experiment. NH, JB, AM, MR and MJR designed the experiment.
NH, AM, MR, and RSK carried out data acquisition. NH analysed the data. NH interpreted the results with substantial contribution from JB, AM, MR, LAJ AR, TM and MJR. NH drafted the manuscript. All authors revised, approved and agreed to be accountable for the final version to be published.

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Part 2

Evidence for intrapartum foetal surveillance during labour

Photo by Tarek Meguid

Chapter 7

Strategies of Intrapartum Foetal Surveillance in Low- and Middle-Income Countries: A Systematic Review

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Abstract

Background The majority of the five million perinatal deaths worldwide take place in low-resource settings. In contrast to high-resource settings, almost 50% of stillbirths occur intrapartum. The aim of this study was to synthesise available evidence of strategies for foetal surveillance in low-resource settings and associated neonatal and maternal outcomes, including barriers to their implementation.

Methods The review was registered with Prospero (CRD42016038679). Five databases were searched up to May 1st, 2016 for studies related to intrapartum foetal monitoring strategies and neonatal outcomes in low-resource settings.
Two authors extracted data and assessed the risk of bias for each study. The outcomes were narratively synthesised. Strengths, weaknesses, opportunities and threats analysis (SWOT) was conducted for each monitoring technique to analyse their implementation.

Findings There were 37 studies included: five intervention and 32 observational studies. Use of the partograph improved perinatal outcomes. Intermittent auscultation with Pinard was associated with lowest rates of caesarean sections (10-15%) but with comparable perinatal outcomes to hand-held Doppler and Cardiotocography (CTG). CTG was associated with the highest rates of caesarean sections (28-34%) without proven benefits for perinatal outcome. Several tests on admission (admission tests) and adjunctive tests including foetal stimulation tests improved the accuracy of foetal heart rate monitoring in predicting adverse perinatal outcomes.

Conclusions From the available evidence, the partograph is associated with improved perinatal outcomes and is recommended for use with intermittent auscultation for intrapartum monitoring in low resource settings. CTG is associated with higher caesarean section rates without proven benefits for perinatal outcomes, and should not be recommended in low-resource

settings. High-quality evidence considering implementation barriers and enablers is needed to determine the optimal foetal monitoring strategy in low-resource settings.

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Introduction

Over two million stillbirths are estimated to occur yearly worldwide, of which >98% are in low-resource settings [1,2]. Almost half of the number of stillbirths in low- and middle-income countries (LMICs) occur during labour, whereas most stillbirths in high-income countries (HICs) take place during the antenatal period [3,4]. The time of labour and delivery is a challenging period for the foetus and can result in foetal asphyxia and associated irreversible organ damage and mortality [5–8]. Intrapartum foetal monitoring allows for prompt and effective intervention when needed, and avoids unnecessary interventions like caesarean sections (CS) by offering confirmation of a favourable foetal condition [9]. Methods of foetal surveillance include foetal heart rate (FHR) monitoring by intermittent auscultation (IA), cardiotocography (CTG) with foetal blood sampling and foetal electrocardiogram with ST-wave analysis [10,11]. Nearly all methods are considered to be high-tech, complex in operation, and require significant financial resources [12,13].

Although global consensus exists that some form of foetal monitoring should be used during labour to improve maternal and neonatal outcomes, there is no evidence for an ideal foetal monitoring system [8,11,14]. Studies on foetal monitoring have been primarily conducted in HICs and, based on variable level of evidence, consensus-based guidelines were developed for foetal surveillance, which may not be readily applicable to LMICs due to context-specific factors [11,15–17]. Thus, in many low resource settings, low-cost and low-tech methods such as IA by Pinard stethoscope or hand-held Doppler, are the only accessible methods [18]. A review on intrapartum foetal surveillance (implementation) strategies for LMICs is not available.

Therefore, the aim of this systematic review was to synthesise the available evidence for intrapartum foetal surveillance in low resource settings and a SWOT analysis was applied to analyse the implementation.

Methods

This review was registered with the PROSPERO registry for systematic reviews (CRD42016038679). It adhered to PRISMA guidelines [19] and was conducted according to the Cochrane methodology [20].

Research questions

This review aimed to answer two research questions: (1) what is the available evidence for strategies of intrapartum foetal surveillance in low- and middle-income countries and their associated neonatal and maternal outcomes? (2) what are the strengths, weaknesses, opportunities, and threats (SWOT) associated with the implementation of these intrapartum foetal surveillance strategies?

Eligibility criteria

Observational or intervention studies concerning women receiving intrapartum foetal surveillance with reported neonatal outcomes in low resource settings were eligible for inclusion. These included studies on admission tests, which were defined as tests performed to determine foetal wellbeing upon arrival in labour in a birth facility. Low resource settings were defined as low-income, lower-middle- and upper-middle income countries (LICs, L-MICs, and UMICs respectively), according to the World Bank classification [21]. Conference abstracts, reports, editorials, presentations, and project protocols were excluded.

Information sources and search

The search was conducted in the following electronic databases: Pubmed/MEDLINE, The Cochrane Library, EMBASE, POPLINE and Global Health Library to include all articles up to May 1st, 2016. For every database, a search string was developed with the support of a librarian specialised in medical sciences, using pre-defined search (Title/Abstract) and MeSH/Emtree terms when applicable. References were manually searched for additional studies. Only for the Global Health Library, limits were used (humans/English). The full search strings are available in S1 Appendix.

Study selection

Mendeley reference software was used to remove duplicates. Subsequently, two reviewers (MCP and NH) independently screened articles based on title and abstract, after which full-text screening was performed. In case of disagreement, a third reviewer (MJR) was consulted. Authors were contacted once in case of inaccessible full-texts, and a study excluded if no reply was received.

Data collection process

Data extraction of the included studies was conducted by one reviewer (MCP) and double-checked for accuracy by a second reviewer (NH). A standardised data extraction sheet was created. SWOT analysis was applied to the methods, results and discussion sections of the selected articles whenever mentioned and recorded in the same extraction sheet as all other outcomes. Outcome measurements were noted as percentages and calculated when possible in case of different reporting strategy. Sensitivity, specificity, positive and negative predictive values (PPV and NPV respectively) were collected when available. The corresponding author or organisation was emailed once in case of incomplete data. In case of disagreements during the extraction process, other members of the review team were contacted (JB, MJR).

Risk of bias assessment

The level of bias was assessed for each study using the Cochrane Risk of Bias Tool and the Newcastle-Ottawa Quality Assessment Scale for intervention and observational studies, respectively [20,22,23]. Colour coding of the table was assigned as red, green and yellow for high, low and unclear (Cochrane) or intermediate (Newcastle-Ottawa) risk respectively. Judgement of bias was determined (MCP) and double-checked for accuracy (NH). Any disagreement during this process was resolved by contacting other members of the review team (JB, MJR).

Data synthesis

Due to heterogeneity in domains, determinants, study designs and reported outcomes, a senior statistician from the Cochrane Collaboration advised not to conduct a meta-analysis. This review, therefore, consists of a narrative analysis of strategies for intrapartum foetal surveillance and their corresponding outcomes. The quantitative results of all studies were summarised according to study design: intervention and descriptive studies. For each method of foetal monitoring, SWOT findings were summarised according to each component.

Results

A total of 10,195 articles were obtained after removal of duplicates and including nine articles from cross-referencing (Fig 1). After title- and abstract screening, 518 articles were screened in full-text, of which 38 were included. Two publications reported on the same study [24,25]. The final 37 included studies consisted of five (13.5%) intervention studies (three randomised controlled trials (RCT)[26–28] and two clustered RCT [24,25,29]), and 32 (86.5%) observational studies (23 cohort studies, six cross-sectional studies, and three case-control studies) [30,31,40–49,32,50–59,33,60,34–39]. The studies were conducted in Africa (n=16), Asia (n=21) and Europe (n=1) and were from LICs (n=6), L-MICs (n=21) and UMICs (n=11). Many studies were from urban settings (urban: n=16, rural: n=1, both: 2), for 18 studies this could not be determined. Studies were on: admission tests and early intrapartum (CTG, n=7, IA: 1, other methods, n=6) [35,36,61,38,40–43,51,55,58], ongoing intrapartum FHR monitoring (IA, n=8; CTG, n=11) [26,27,47,49,50,52–54,57,28,30,31,33,37,44–46], adjunctive tests (n=9) [32,37,47,49,50,52,53,56,59] and partograph (n=5) [24,25,29,34,48,60] (Table 1-3).

Risk of bias of studies

A summary of quality assessment for intervention studies is provided in Table 1 and for observational studies in Table 2. Study performance of the five intervention studies was overall moderate, however, blinding of the participants or researchers was not done (5/5 high risk) and confounders were often not considered (1/5 high risk; 3/5 unclear risk and 1/5 low risk). Quality of observational studies was low to moderate; classified as low risk in: 81.3% for selection process, in 25% for comparability and in 25% outcome/exposure of studies.

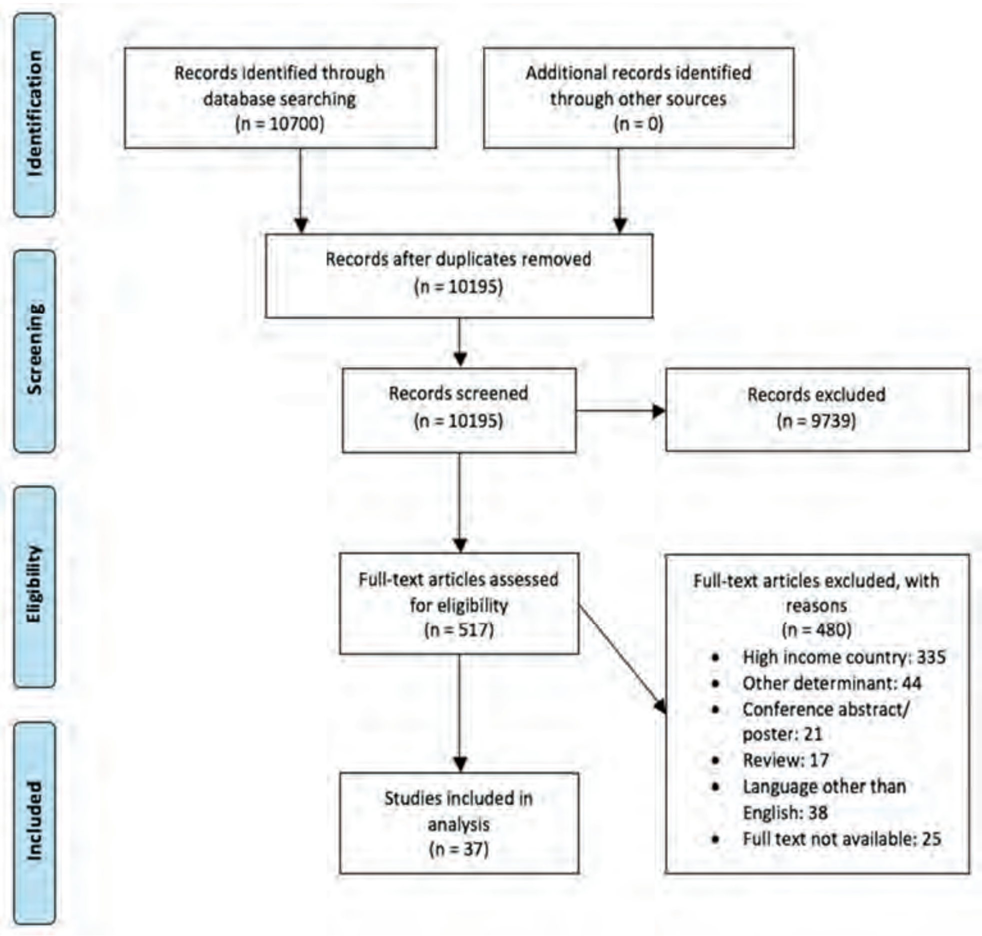

Figure 1. Flow diagram of search results.

Table 1. Quality assessment of randomised controlled trial

Randomised controlled trial	Intervention	Population characteristics	Sequence generation	Allocation concealment	Blinding of participant/ researcher	Selection of study population	Completeness of data	Origin of data	Clear definition of outcome?	Confounders taken into account?
Byaruhanga et al. 2015 (Uganda)[13]	Wind-up Doppler vs Pinard	1971, singleton, cephalic, >37 weeks, mixed-risk	Unclear risk	Unclear risk	High risk	Low risk	Low risk	Low risk	Low risk	High risk
Fahdhy et al. 2005 (Indonesia)[33]*	WHO partograph and training	625 low risk	Low risk	Low risk	High risk	High risk	Low risk	Low risk	Low risk	Unclear risk
Madaan et al. 2006 (India)[32]	IA vs Continuous CTG	100 post caesarean section singleton	Unclear risk	Unclear risk	High risk	Low risk	Low risk	Low risk	Low risk	Unclear risk
Mahomed et al. 1994 (Zimbabwe)[30]	Intermittent CTG, Doppler, Pinard	1255 singleton, cephalic, >37weeks, mixed-risk	Unclear risk	Low risk	High risk	Low risk	Low risk	Low risk	Low risk	Low risk
WHO, 1994 & Lennox, 1998 (Southeast Asia)[27,29]*	WHO Partograph	35 484, mixed-risk	Unclear risk	Unclear risk	High risk	Low risk	Low risk	Low risk	Low risk	Unclear risk

Colour coding: Green = Low risk, Red = High risk and Yellow= Unclear risk. Abbreviations: CTG = Cardiotocography, IA = Intermittent Auscultation;
*Clustered randomised control trial

Cohort studies	Method/ strategy	Population characteristics*	Selection process	Comparability	Exposure
Aboulghar et al. 2013, Egypt [30]	CTG	High risk	4	0	2
Bakr et al. 2005, Egypt [32]	FPO vs FBS	Unclear	4	0	2
Chittacharoen et al. 2000, Thailand [35]	FAST and Admission CTG	High risk	4	0	3
Chittacharoen et al. 1997, Thailand [61]	FAST	Unclear	4	0	3
David et al. 2014 India [36]	Admission CTG	Low risk	4	0	2
Duhan et al. 2010, India [37]	MSAF and CTG	Unclear	3	1	2
Dujardin et el, 1992, Senegal [60]	Partograph	Unclear	4	0	2
Goldenberg et al. 2013, Multi-country [38]	Admission IA(Doppler)	Unclear	4	0	2
Goonewardene et al. 2011, Sri Lanka [39]	FAST and Admission CTG	Low risk	4	0	2
Gupta et al, 1997, India, [59]	MSAF	Mixed-risk	3	0	2
Howarth et al. 1992 (South Africa)[41]	UADV	Unclear	4	0	3
Kulkarni et al. 1998 India [42]	Admission CTG	High risk	4	0	2
Kushtagi et al. 2011 India [43]	Admission AFI	Mixed-risk	4	0	3
Langli Ersdal et al. 2012, Tanzania [44]	IA	Mixed-risk	4	2	2
Odendaal et al. 1977, South Africa [45]	CTG	unclear	4	2	2
Odendaal et al. 1994, South Africa [46]	CTG	High risk	4	2	2
Odongo et al. 2010, Kenya [47]	CTG and MSAF	Unclear	3	1	2
Rahman et al. 2012, India [40]	Admission CTG	Mixed risk	4	2	2
Rathore et al. 2011, India [52]	FSST, IA and MSAF	High risk	4	2	2
Raouf et al. 2015, Iran [51]	CTG	Low risk	3	0	2
Rotich et al. 2006, Kenya [53]	IA and MSAF	Mixed-risk	3	2	3
Roy et al. 2008, India [54]	CTG	Unclear	4	0	3
Shaktivardhan et al, 2009, India [55]	Admission CTG	High risk	4	0	2
Stuart et al. 1993, South Africa [56]	UADV	High risk	4	0	
Tongprasert et al. 2006,Thailand [58]	rBPP	Mixed-risk	4	0	3

Colour coding: Green = Low -, Red = High - and Yellow = Intermediate risk of bias. Maximum points to be allocated (Cohort/ cross-sectional/ case-control): Selection process (4/5/4), Comparability (2/2/2), Outcome (3/3/-), Exposure (-/-/3).

AFI= Amniotic fluid index, CTG=cardiotocograph, FAST= Foetal acoustic stimulation test, FBS= Foetal blood sampling, FPO= Foetal pulse oximetry, FSST= Foetal scalp stimulation test, MSAF= Meconium-staining amniotic fluid, NST= Non-stress test, rBPP= rapid Biophysical Profile, UADV= Umbilical artery Doppler velocity

*Pregnancy risk determination was based either: author's specific mention of "low risk" and "high risk" pregnancies OR based on maternal and foetal risk factors described in the text. If no information available on maternal factors for "singleton, cephalic, >37" pregnancies the risk was status was defined as unclear.

Table 3. Quality assessment of the observational studies (Cross sectional and case control studies)

Cross-sectional studies	Method/strategy	Population characteristics	Selection process	Comparability	Outcome
Adanikin et al. 2016 Nigeria [31]	IA	Mixed-risk	4	2	2
Bolbol-Haghighi et al. 2015, Iran [34]	Partograph	Low risk	4	0	2
Ogwang et al. 2009 Uganda [48]	Partograph	Unclear,	4	0	2
Oladapo et al. 2009 Nigeria [49]	IA and MSAF	Mixed-risk	4	2	2
Parveen et al. 2010 Pakistan [50]	CTG and MSAF	Low risk	5	0	1
Tasnim et al. 2009 Pakistan [57]	CTG	Mixed-risk	4	0	2
Case-control					
Bogdanovic et al. 2014 Bosnia [33]	CTG	Unclear	2	0	3

Colour coding: Green = Low -, Red = High - and Yellow= Intermediate risk of bias. Maximum points to be allocated (Cohort/ cross-sectional/ case-control): Selection process (4/5/4), Comparability (2/2/2), Outcome (3/3/-), Exposure (-/-/3).
AFI= Amniotic fluid index, CTG=cardiotocograph, FAST= Foetal acoustic stimulation test, FBS= Foetal blood sampling, FPO= Foetal pulse oximetry, FSST= Foetal scalp stimulation test, MSAF= Meconium-staining amniotic fluid, NST= Non-stress test, rBPP= rapid Biophysical Profile, UADV= Umbilical artery Doppler velocity
*Pregnancy risk determination was based either: author's specific mention of "low risk" and "high risk" pregnancies OR based on maternal and foetal risk factors described in the text. If no information available on maternal factors for "singleton, cephalic, >37" pregnancies the risk was status was defined as unclear.

Narrative synthesis of quantitative results

A summary of the FHR monitoring strategies and their outcomes is provided in Table 3. Detailed results of each intervention and descriptive study are presented in S3-S5 Table.

Admission tests

Neonatal outcomes

We identified only observational studies for admission tests. The study of IA on admission (n=1) showed that absent FHR by hand-held Doppler was associated with a much higher perinatal mortality (938/1000 deliveries) compared to when FHR was present (13/1000 deliveries) [38].

Admission CTG, a 20-minute recording, was assessed in seven studies in Asia. Studies were on low risk (n=3) [36,39,51], high risk (n=3) [35,42,55], and mixed-risk pregnancies(n=1) [40]. Abnormal CTG traces were associated with intrapartum FHR abnormalities (foetal distress) [36,40,42,51,55], meconium-stained liquor [36,40]; low Apgar scores at 5 minutes [36,39,40,51,55], perinatal deaths [40,51,55], and admission to neonatal intensive care unit (NICU) [36,40,51,55]. Test performance of admission CTG varied across studies: PPV of 19% to 88%, while the NPV was between 88.6% to 100% [35,36,39,40,55].

Maternal perception of sound-provoked foetal movement (i.e. foetal acoustic stimulation, FAST, n=2) performed well in predicting foetal distress, perinatal death, Apgar score <7 at 5 minutes, admission to NICU [39,61]. It also improved the test performance of CTG in two studies (PPV: 45.2% to 65.5%, 19% to 73.6%, NPV: 94.2% to 96%, 100% to 100%) [35,39]. Admission amniotic fluid index (aAFI) performed worse than admission CTG (specificity: 64% and 92% respectively, n=326) [43]. In one study (n=330) rapid Biophysical profile (rBPP i.e. combination of sound-provoked ultrasound-detected foetal movement and AFI) had PPV (50%) and NPV (99.1%) for poor neonatal outcomes [58]. Umbilical artery Doppler velocity (UADV) in labour did not predict neonatal outcomes in two studies [41,56].

Maternal outcomes

Only studies on admission CTG reported mode of delivery. Abnormal traces increased CS rates compared to reactive CTG traces (between 42.7% to 100% and 20.7% to 30%, respectively, p<0.05) [36,40,42,51].

Ongoing intrapartum foetal surveillance

Neonatal outcomes

There were three RCTs comparing IA and CTG: Uganda (n=1971) [27], Zimbabwe (n=1255) [26], India (n=100) [28]. In Uganda, hand-held Doppler and Pinard stethoscope were compared [27]. The RCT in Zimbabwe had four arms: 1) intermittent CTG traces(n=318), 2) hand-held Doppler (n=312), 3) Pinard (n=310) and 4) routine monitoring with Pinard (n=315). In the first three groups, research midwives ensured they assessed FHR every 30 minutes for 10 minutes per study protocol and caregiving midwives were supposed to adhere to the same frequency by following hospital protocol [26]. Continuous CTG monitoring (n=50) was compared to IA (n=50) in women with a history of CS in India [28]. In these studies, detection of FHR abnormalities was significantly different in Pinard, Doppler and CTG groups (Table S1). However, no significant changes in perinatal deaths, low Apgar scores at 1 and 5 minutes and admission to NICU were observed [26–28].

The study in Zimbabwe reported fewer cases of neonatal seizures and hypoxic-ischaemic encephalopathy (HIE) in the hand-held Doppler group compared to the Pinard groups (zero vs 15; and one vs 17 respectively) [26]. Although foetal distress was diagnosed in the three treatment groups, protocol violations, delays or unavailable operative deliveries led to the majority of perinatal deaths [26].

One observational study (Tanzania, n=10271) showed that detection of an absent or abnormal FHR with foetal stethoscope was strongly associated with fresh stillbirths, neonatal deaths, low Apgar score and neonatal resuscitation [44]. In observational studies, pathological CTG traces were associated with low Apgar score at one minute [30,47], umbilical cord indices [30,57] and HIE [33] as compared to normal traces. However, contrasting findings were seen for umbilical cord indices (PPV 11.6% vs 100%) [50,57] and five minutes Apgar scores [30,45].

Several studies identified adjunctive tests for FHR monitoring. Foetal pulse oximetry had a comparable test performance compared to foetal blood sampling (n=150) [32]. Meconium was mostly effective in predicting neonatal outcomes when combined with abnormal FHR [47,49,50,53]. Foetal scalp stimulation test (FSST) combined with IA were good predictors of perinatal outcomes: umbilical cord pH, Apgar score at one and five minutes, neonatal death and NICU admission [52].

The multi-centre partograph-intervention study in Southeast Asia which included 35 484 women showed a significant reduction in intrapartum stillbirths (0.50% to 0.31%, p=0.024), but no significant reduction in Apgar scores, neonatal deaths, NICU, and resuscitation [24,25]. Training midwives to use the partograph reduced low Apgar scores at 1 minute but no improvement in other perinatal outcomes [29]. Observational studies showed that crossing the alert and action lines on the partograph was associated with a higher incidence of neonatal resuscitation and fresh stillbirths [34,60]. Substandard use of partograph was associated with low Apgar score [48].

Maternal outcomes

The RCT in Zimbabwe showed that CTG and hand-held Doppler significantly increased CS rates due to foetal distress compared to Pinard. (63%, 67% and 41% respectively) [26]. The RCT in India showed a trend towards increasing CS rate in the CTG group due to foetal distress compared to IA (47% vs 18%) [28]. The Uganda RCT showed no difference in overall CS rates between hand-held Doppler and Pinard [27]. No clear difference was observed for operative vaginal delivery [26,28]. Duration of labour [26]. postpartum haemorrhage, maternal fever, ruptured uterus and maternal death [28] were similar. Meconium was associated with increased CS rates in India (clear liquor 17% vs meconium 33%) [37,47]. Nonreactive FSST detected by IA was associated with a significant increase in operative vaginal deliveries and CS rates [52]. Two clustered RCT on the partograph showed that training and the use of partograph led to significant reduction in length of labour and obstructed labour and oxytocin use but no changes in CS rate or maternal mortality [24,25,29]. There was no increased CS rate due to foetal distress. There was a reduction in vaginal examinations but no change in postpartum haemorrhage and maternal sepsis.[27,33] The partograph significantly increased the number of referrals of women in labour to higher level centres [29].

Narrative synthesis of SWOT analysis

Detailed SWOT results of the given foetal monitoring methods are provided in table 4. Admission CTG were recommended for triaging labours and resource allocation when resources are scarce [36,40,55]. The Pinard, hand-held Doppler and partograph were strategies reported as simple and low-cost [25–27,38,44,60]. IA allowed for greater mobility of the women than CTG and was easily accessible, but difficult to carry out in busy maternity wards [50]. The hand-held Doppler may be more mother- and user-friendly than the Pinard [27,38] but required consumables [44]. Some of these challenges were eliminated when using the wind-up Doppler. The use of CTG required a high level of skills, resources, and costs [26,31]. Combining FHR monitoring with simpler adjunctive tests such as meconium, FAST, FSST, and FPO may provide non-invasive and reliable ways to confirm foetal wellbeing, avoiding unnecessary interventions [32,35,39,52,61].

Strengths of the partograph were its low-cost, pictorial overview of labour allowing timely recognition for complications and action [25,29,34,48,60]. A major threat was an underuse of partograph due to a shortage of staff, lack of knowledge, training, and guidelines, unavailability of copies and hesitant attitudes of staff [29,48,60]. Opportunities to increase partograph use lie in providing partograph copies, training, and appropriate management guidelines [25,29,48,60]. A major threat to all intrapartum foetal surveillance studies was limited or unavailability of intervention including timely operative deliveries [26,27,31,44].

Table 3. Foetal monitoring methods as predictors of birth outcomes							
Method			**Predicts perinatal outcomes/foetal distress[1]**	**Improves perinatal outcomes[1]**	**Predicts mode of delivery**	**Increases operative deliveries**	**Improves maternal morbidity/mortality**
Admission test		CTG(n=7)					
		IA (Doppler, n=1))					
		Admission AFI (n=1)					
		FAST (n=3)					
		rBPP(n=1)					
		UADV(n=2)					
Ongoing intrapartum foetal monitoring	FHR	IA Pinard(n=6) REFERENCE[2]					
		IA Doppler(n=3)					
		CTG(n=11)					
		Partograph(n=5)					
	Adjunctive tests	MSAF(n=7)					
		FSST(n=1)					
		FBS(n=1)					
		FPO(n=1)					
		UADV(n=1)					

Green= Yes; Red=No; Orange= Unclear (i.e. outcome not reported or the evidence conflicts across studies)
AFI= Amniotic fluid index, CTG=cardiotocograph, FAST= Foetal acoustic stimulation test, FBS= Foetal blood sampling, FPO= Foetal pulse oximetry, FSST= Foetal scalp stimulation test, MSAF= Meconium-staining amniotic fluid, rBPP= rapid Biophysical Profile, UADV= Umbilical artery Doppler velocity
[1]Perinatal outcomes any of the following: Apgar score at 1 or 5 minutes, umbilical cord blood pH/gases, need for neonatal resuscitation, stillbirth (intrapartum/fresh), neonatal deaths before discharge/within 24hours, admission to neonatal care unit, hypoxic-ischaemic encephalopathy
[2]Pinard was used as a reference test for which Doppler and CTG were compared to.

Table 4: SWOT Analysis of methods of intrapartum foetal monitoring

	Strengths	Weaknesses	Opportunities	Threats
IA	-Detection of non-viable foetuses[36,59] -Lower cost and sustainable -Can detect ir/regular rhythms, accelerations and decelerations[26,27,31,41] -Allows mobility of the women[31] -Requires no additional resources/electricity (Pinard/wind-up Doppler)[27,36] *Hand-held Doppler:* -Gives a steady number of beats per minute[26,27] -Device easy to use with minimal training[26,36,59] -Audible to both mother and caregiver (even in noisy labour wards) [27]	-False results due to poor equipment [36] -Cannot detect subtle abnormalities or changes in FHR e.g. baseline variability[31,41,53] -Difficult to use, time-consuming and labour intensive[27,36] -Uncomfortable for the mother and staff (Pinard)[26,36] -Maternal heart rate may occasionally be counted[26]	-Allows planning for safer delivery if intrauterine foetal death (on admission)[59] -Can be used as an intrapartum stillbirth indicator for monitoring quality improvement of care for interventions (on admission)[59] Can lead to prompt emergency obstetric and neonatal care obstetrical[36] -Coupling of IA and partograph for monitoring[26,27,45] -Training may improve performance[59] -Doppler may be preferred by care providers and pregnant women[26,27] - Promotes ''hands-on'' support to the labouring woman[31]	-Limited human resources[36] -Not always used on admission/intrapartum[36,59] -False results due poorly trained staff[36,46,59] -Lack of foetal monitoring protocol[46] -Non-adherence to frequency, duration of monitoring and documentation[31]-Underutilisation of partograph[27,40] -Delays in action taking (long diagnosis to delivery time) [26,27,31] -Unavailability of operative delivery[26] -Unavailability of FBS and cord blood analysis to confirm foetal compromise - May require repair and additional resources (Doppler)[26,27] -Responsible of large proportion of CS are due to suspected foetal distress[31,41]
CTG	-Non-invasive(external) -Able to detect subtle changes in FHR e.g. baseline variability -Continuous traces of FHR [26,28,30,34,37–39,43,44,47,48,50,53,56–58,60] -Several pathological features are predictive of foetal acidosis [26,28,30,34,37–39,43,44,47,48,50,53,56–58,60]	-Associated with high false positivity for foetal distress[26,28,30,34,37–39,43,44,47,48,50,53,56–58,60] -Low inter-observer agreement[47] -Admission CTG might not predict foetal distress several hours after admission. [32,48] -Susceptible to technical and mechanical failure resulting in poor quality of traces and interpretation[26]	-Can be used intermittently during labour [26] *Admission test:* -Screening test for foetal distress on admission[32,34,44,48] -Prevent unnecessary delay in intervention[32]-Triaging: allows selection of patients for closer monitoring during limited resources[32,34,44,48]	-Potential increase in unnecessary interventions (e.g. caesarean section)[30,34,38,39,47,50] -Requires maintenance -Costly [26]-Non-adherence of staff to protocol - Limited or unavailability of CTG machine[31,34,41] - Delays in action taking (long diagnosis to delivery time) [26] -No facility to perform FBS[41,50] -Unstable electricity supply[31] - Medicolegal climate[47]
Foetal stimulation tests	-Non-/less- invasive[56] -Fast, simple and cheaper[45,60,61] -No additional device necessary (scalp stimulation)[45] -No rupture of membranes required[45]	-Poor maternal perception of subtle foetal movement[60,61]	-Safer to use in over-distended and scarred uterus [60] - Can be used to increase diagnostic accuracy of FHR monitoring: IA [45] or EFM[32,34,48,56,60]and MSAF[45] as an alternative to FBS[45,61] -Screening tool in early labour[60,61]	-Contraction may impair maternal perception of foetal movement[61]
rBPP	-Simple and fast -Relatively inexpensive[51]	-Not adequate as a screening test[51]	-May be used as an additional back up test[51]	
UADV	-Feasible and no discomfort in labour[33] -Non-invasive and simple[33,49]	-Not useful in detecting foetal acidosis during labour[49]		
MSAF	- A warning sign that closer attention is warranted[58]	-Highly unreliable when used alone[43,45] -Require ruptured membranes[39]	-More reliable when combined with FHR monitoring (IA [31,41,46] and CTG[39,43,58])	- Association with an increase in caesarean[39,58]
FBS and FPO	FPO is less invasive than FBS[42]	-Recordings take 30 minutes (time-consuming)[42]	-May decrease unnecessary interventions (e.g. CS) -FPO may be an alternative to foetal blood sampling[42]	
Partograph	- Provides recording of the foetal and maternal parameters[25,29] - Single page[55] - Visual presentation with clear overview of progress of labour[55] -Accompanied by management protocol[25]	-Too detailed[40] -Requires intensive and repeated training[40] -Applicable mostly in first stage of labour[25,54,55]	-Encourages supportive care to women [24] -Helps interpret findings[40] -Training and supervision improves use[29,54] -Helps communication and hand-over of patients between staff [25,40] -Permits evaluation of quality of care[40] -Timely referral[29] -Early diagnosis of complications and early decision making[40] -Labour wards can opt for adapted local management protocols[25] -Universal application[25,40]	-Incorrect and/ incompletion of partographs: e.g. due to lack of time, motivation, human resources[24,29,40,54] -Loss of partographs[54] -The need for photocopying[40] -Lack of updated versions[40] -Removal of latent phase causes incomplete follow-up and difficulty in diagnosing prolonged latent phase[29] -Unavailability of guidelines in labour wards[40] -Non-adherence to protocol[29] -Lack of training and supervision[40] -Lack of appropriate intervention[26,27] -High rates of referral[25,29]

CTG = cardiotography, CS = caesarean, IA = Intermittent Auscultation, FBS = Foetal blood sampling, FHR = Foetal heart rate, FPO = Foetal pulse oximetry, MSAF = Meconium-staining amniotic fluid, rBPP = Rapid biophysical profile, SWOT = Strengths, Weaknesses, Opportunities, Threats, UADV = Umblical artery Doppler velocity.

Discussion

Main findings

This systematic review and SWOT analysis provide an overview of the evidence of intrapartum foetal monitoring strategies in low-resource settings on perinatal and maternal outcomes. The use of CTG increased the rates of CS but had no effect on adverse perinatal outcomes compared to IA [26,28]. IA and the partograph is the preferred method in low-resource settings for FHR monitoring.

The observational studies in this review suggest that admission tests (including CTG, IA or FAST) can predict adverse outcomes in LMICs, and mode of delivery in both low and high-risk pregnancies [35,36,39,40,42,55,61]. We suggest that admission tests might have a much better use in low resource settings because of: 1) the incidence of intrapartum stillbirths could modify the predictive test results [11], 2) inadequate risk assessment and stratification during antenatal care, making admission tests a good screening tool to identify high-risk foetuses and 3) a triaging tool for better allocation of resources in settings with heavy workload and scarce (human) resources [36,40,42,55].

The overall evidence shows that CTG does not improve outcomes but increases the number of CS compared to IA. It is unclear whether hand-held Doppler improves neonatal outcomes, and it may increase CS rate. Similar findings on CTG and hand-held Doppler are reported in the Cochrane meta-analyses [11,62]. A study in South Africa showed pregnant women preferred hand-held Doppler over Pinard or CTG [63]. However, the number of CS presents real concerns for maternal safety in low resource settings [64–68]. Foetal heart monitoring may have false positivity for foetal distress leading to unnecessary intervention. The current review identified simple and cheap strategies to strengthen the test performance of intrapartum FHR monitoring including foetal stimulation tests (FAST and FSST) and meconium. However, their effectiveness is not known and should be tested in future studies. Contrary to a Cochrane review, which did not include the large study in South East Asia [69], the partograph was useful for monitoring and decision-making for the intrapartum care of the mother, foetus and labour progress, and was associated with reduced intrapartum stillbirths in low-resource settings [25,29,34,48,60]. The BOLD initiative and WHO guidelines stress the importance of supportive, person-centred care during labour and childbirth rather than focus on cervical dilatation only [70–72].

Challenges exist in up-scaling effective interventions in low-resource settings [18,73]. Given the resource constraints, the SWOT analysis shows that the ideal method of intrapartum foetal monitoring should be: simple, affordable, robust, safe, reliable and sustainable [18,74]. Yet, most monitoring systems require maintenance and adequate staffing who need to be trained and supervised. For example, although IA and partographs are low-tech and -cost technology, they highly depend on human resources. A strong commitment to investing in high quality research of existing and new strategies of real-life implementation for intrapartum foetal monitoring is required. These may include new ways to monitor foetal well-being, context-appropriate guidelines, and healthcare workforce strengthening [15,75]. A substantial time-lag between recognition of foetal compromise and delivery as a major cause of severe asphyxia and death was identified in this review [26,27,31,44]. Importantly, emergency obstetric and newborn care including operative vaginal deliveries and neonatal resuscitation should be readily available to ensure both prompt diagnosis and successive intervention.

Strengths and limitations

A strength of this review is the systematic assessment of neonatal and maternal outcomes and SWOT analysis. Although an extensive and inclusive search in five international databases was conducted, studies performed in low-resource settings and published in national journals might not have been indexed in the searched databases. Limitations are also inherent in the reviewed articles and include the quality of the evidence, the lack of detailed reporting of implementation factors and relevant outcomes such as contraction monitoring, maternal morbidity and mortality, CS rates, professional and maternal opinion. RCTs did not guarantee appropriate and timely interventions which confounded the results. We intended to evaluate evidence for all intrapartum foetal monitoring strategies in low-resource settings using a meta-analysis, however, due to heterogeneity in designs and outcomes, only a narrative review could be performed.

Conclusion Of the foetal monitoring strategies that have been studied in LMICs, the partograph and intermittent auscultation is the preferred strategy for intrapartum foetal surveillance in low-resource settings because of reduced intrapartum stillbirths (partograph), lower caesarean section rates (Pinard) and easier implementation. CTG is associated with higher caesarean section rates without proven benefits for perinatal outcomes, and should not be recommended in low-resource settings until new research delivers evidence for better perinatal outcomes. The benefit and harms of admission tests, adjunctive tests and hand-held Doppler on perinatal and maternal outcomes should be determined in future studies in low resource settings. High-quality RCT studies of foetal monitoring should include clear management protocols with timely interventions. Moreover, there is a need to harmonise core outcomes in foetal monitoring studies. Consideration of implementation factors will also be essential to determine the real-world optimal foetal monitoring approach.

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Article Selection: NH, MP, MJR. Analysed the data: NH, MP. Wrote the paper: NH, MP, JB, MJR. Critically reviewed the drafted manuscript and approved the final version of the manuscript: NH, MP, JB, TM, KK, BEK, AF, DEG, MJR.

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S1 Appendix: Search Strategy
S2 Appendix: Data extraction sheet (fragmented Excel)
S3 Table. Table. Summary of quantitative resultsS5 Table.
S4 Table. Characteristics and results of the randomized controlled trials (n=5).
S5 Table. Characteristics and results of the observational studies (n=32)

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Chapter 8

Delphi consensus statement on intrapartum foetal monitoring in low-resource settings

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Abstract

Objective To determine acceptable and achievable strategies of intrapartum foetal monitoring in busy low-resource settings.

Methods Three rounds of online Delphi surveys were conducted between January 1 and October 31, 2017. International experts with experience in low-resource settings were asked to score the importance of intrapartum foetal monitoring methods.

Results 71 experts completed all three rounds (28 midwives, 43 obstetricians). Consensus was reached on (1) need for an admission test, (2) handheld Doppler for intrapartum foetal monitoring, (3) intermittent auscultation (IA) every 30 minutes for low-risk pregnancies during the first stage of labour and after every contraction for high-risk pregnancies in the second stage, (4) contraction monitoring hourly for low-risk pregnancies in the first stage, and (5) adjunctive tests. Consensus was not reached on frequency of IA or contraction monitoring for high-risk women in the first stage or low-risk women in the second stage of labour.

Conclusion There is a gap between international recommendations and what is physically possible in many labour wards in low-resource-settings. Research on how to effectively implement the consensus on foetal assessment at admission and use of handheld Doppler during labour and delivery is crucial to support staff in achieving the best possible care in low-resource settings.

Introduction

Almost all perinatal deaths occur in low- and middle-income countries (LMIC), and half occur intrapartum.[1] The daily reality of many low-resource health facilities prevents timely and high-quality labour care.[2,3] On admission, women have unknown or insufficiently known risk status owing to inadequate prenatal care and suboptimal assessment at first contact with a skilled birth attendant.[4,5] During labour, women receive suboptimal support, including poor monitoring of their babies, who may die unnoticed.[2,6] Foetal monitoring may provide crucial information on the adequacy of foetal oxygenation during labour for timely and appropriate management.[7]

Evidence is lacking to develop an ideal intrapartum foetal monitoring system to improve perinatal outcomes. Practice is guided by expert consensus and obstetric culture, which often originate in high-income countries.[8] For low-risk pregnancies, assessment of foetal heart rate (FHR) by intermittent auscultation (IA) for 30–60 s is commonly recommended every 15 or 30 minutes in the active phase of the first stage of labour, and after every contraction or at 5-minute intervals in the second stage. The strength and frequency of contractions are generally determined every 30 minutes over a 10-minute period. For high-risk pregnancies, continuous cardiotocography (CTG) is recommended (Table 1).

A substantial mismatch exists between international guidelines and what is locally achievable. In high-volume low-resource settings, the ratio of skilled birth attendants (SBAs) to deliveries often exceeds 1 to 3.[9,10] The challenges in labour monitoring are well known, yet current recommendations do not take into consideration the limited (human) resources in settings where one-to-one care and/or CTG are not feasible. Poor performance may result from an overwhelming workload and demotivation caused by unrealistic expectations.[11]

Feasible implementation strategies are needed to support overwhelmed SBAs and help them to manage the high number of deliveries. Evidence indicates that clinical recommendations that are realistic, simple, and easy to understand have a greater chance of translation into practice.[12] WHO encourages regional, national, and subnational adaptation of their guideline.[13] It is therefore paramount to explore how international guidelines can be adapted to more closely reflect the reality at the targeted maternity units that need the most guidance.

With use of a Delphi procedure, we aimed to determine a package of achievable strategies of intrapartum foetal monitoring for busy low-resource maternity wards with a focus on admission tests, FHR monitoring, adjunctive tests, and contraction monitoring in relation to low- and high-risk pregnancies in the first and second stage of labour.

Materials and methods

The online Delphi study was conducted among nurses/midwives, obstetricians, and paediatricians in accordance with predefined objectives, criteria for expert panel selection, and statistical methods. Three Delphi rounds took place between January 1 and October 31, 2017. The Core Outcome Set-Standards for Reporting was used.[14] The ethics board of the University Medical Center Utrecht (reference, WAG/nt/16/033902) decided that no formal ethical approval was required.

A project steering committee was established to coordinate the different phases of the project and consisted of four obstetricians (GHAV, GBT, TM and MJR), one epidemiologist (JB), and two methodologists (JH and NM) with experience in consensus methods (Figure 1).

Table 1 Fetal and contraction monitoring recommendations in renowned international and national guidelines.

Guideline [a]	Pregnancy risk status	Intermittent auscultation		
		Frequency during first stage	Frequency during second stage	Timing
1. FIGO, 2015	Low	15 min	Every 5 min	During and at least 30 s after contracti
	High	Continuous EFM		
2. WHO IMPAC, 2000	Low	Every 30 min	Every 5 min	After contraction
	High	No recommendation		
3. NICE, 2014, UK	Low	At least every 15 min	At least every 5 min	After contraction
	High	Continuous EFM		
4. RANZCOG, 2014, Australia/New Zealand	Low	Every 15–30 min	After contraction or at least every 5 min	Commence toward end of contraction, and continue for at least 30–60 s after contraction
	High	Continuous EFM		
5. ACNM, 2010, USA	Low	Every 15–30 min	Every 5–15 min	After contraction
	High	Continuous EFM		
6. ACOG, 2009, USA	Low	At least every 15 min	At least every 5 min	Not stated
	High	Continuous EFM		
7. SOGC, 2007, Canada	Low	15–30 min	5 min	After contraction
	High	Continuous EFM		
8. RCOG, 2001 UK	Low	At least every 15 min	At least every 5 min	After contraction
	High	Continuous EFM		

Abbreviation: EFM, electronic fetal monitoring.

[a]References to the guidelines are given at the end of the reference list

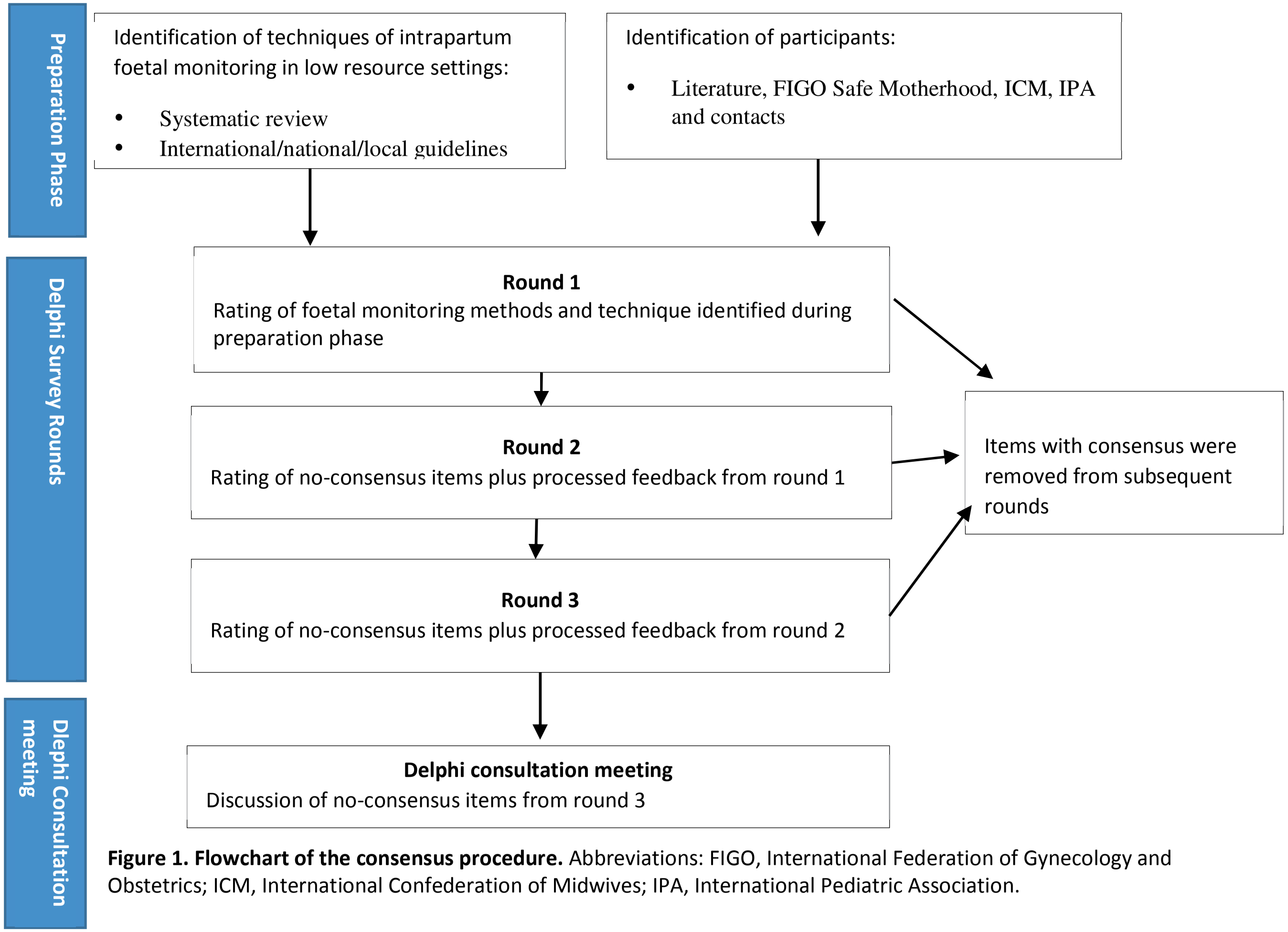

Figure 1. Flowchart of the consensus procedure. Abbreviations: FIGO, International Federation of Gynecology and Obstetrics; ICM, International Confederation of Midwives; IPA, International Pediatric Association.

A systematic review was conducted to identify the different foetal monitoring techniques available in LMIC (registered in PROSPERO: CRD42016038679). Five electronic databases (Pubmed/MEDLINE, Cochrane Library, EMBASE, POPLINE, and Global Health Library) were searched to identify studies with a title or abstract containing MeSH/Emtree terms related to “intrapartum,” “foetal surveillance,” “outcomes,” and “low- and middle-income countries.” In addition, international, national, and local guidelines were searched for recommendations on the frequency and duration of FHR and contraction monitoring (Table 1).[9] The definitions used to guide participants are given in Box 1, and the outcomes are listed in Supplementary Tables S1 and S2.

A three-round electronic Delphi survey is a well-established consensus method allowing anonymous consultation with controlled feedback.[15] The invited stakeholder groups included midwives, obstetricians, and paediatricians (i.e., neonatologists or paediatricians involved in neonatal care) with work experience in low-resource settings, and/or experts in fetal monitoring.

To identify suitable experts, international professional organisations were contacted by email and asked to forward the invitation to its members. Additional experts were identified through published clinical research of relevance. A formal email invitation was sent to all experts identified. The Delphi survey was developed in SurveyMonkey and pilot-tested by members of the project steering committee with subsequent adjustments. Three rounds were conducted, each with an average closing date of 4 weeks. Stakeholders who did not participate in a round were not invited for subsequent rounds.

Box 1 Definitions of terms provided to participants during the Delphi rounds.

Low-resource setting	Busy maternity ward with limited (human) resources, where birth attendants have many women in labour to take care of at the same time
Low maternal risk pregnancy	Uncomplicated prenatal history (with no previous caesarean section)
Low foetal risk pregnancy	Based on the expert's clinical judgment, which may include a favourable admission test
High foetal risk pregnancy	Based on the expert's clinical judgment, which may include an unfavourable admission test or intrapartum events, for example, oxytocin usage or meconium
Low-risk pregnancy	Uncomplicated prenatal history (with no previous cesarean) and low foetal risk pregnancy
Admission test	Admission test here means ANY one or more foetal assessments performed when a pregnant woman in labour is admitted to the maternity unit. It may include physical examination or bedside tests
First stage of active phase of labour	*Cervical dilatation from 4 to 10 cm*
Second stage of active phase of labour	*Fully dilated and pushing*
Adjunctive test	Supplemental/additional test next to foetal heart rate monitoring for confirming foetal wellbeing
Amniotic fluid index assessment	Estimation of the amount of amniotic fluid by ultrasound
Foetal acoustic stimulation test	Detection of foetal response to sound stimulation by a vibroacoustic stimulator
Foetal pulse oximetry	Monitoring of the foetal hemoglobin oxygen saturation
Foetal scalp stimulation test	Assessing foetal response to stroking of the foetal scalp via vagina
Rapid biophysical profile	Ultrasound detection of foetal movement and amniotic fluid index
Biophysical profile	Nonstress by cardiotocography and ultrasound assessment of: foetal movement, foetal tone, foetal breathing, and amniotic fluid volume
Umbilical artery Doppler assessment	Doppler ultrasonography of the umbilical arteries
Normal/reassuring	Foetal heart rate between 110 and 160 bpm
Suboptimal/non-reassuring foetal heart rate by intermittent auscultation	A baseline foetal heart rate of 100–109 or 161–180 bpm
Abnormal foetal heart rate by intermittent auscultation	A baseline foetal heart rate <100 or >180 bpm or repetitive or prolonged decelerations >3 min
Intrauterine resuscitation	Measures aimed at increasing oxygen delivery to the foetus; e.g., stopping oxytocin, maternal repositioning, and administration of intravenous fluids and oxygen

The stakeholders were asked to make recommendations that were minimal, safe, and achievable for birth attendants in low-resource settings (i.e., busy maternity units with limited (human) resources, where one SBA provides care for multiple labouring women simultaneously). Throughout the rounds, options were presented for the following areas of foetal monitoring: admission tests, low- and high-risk pregnancies, first stage of active phase and second stage of labour, suboptimal and abnormal FHR, adjunctive tests, and contraction monitoring.

Stakeholders were asked to quantify their level of support for potential recommendations via a 5-item Likert scale (1, strongly disagree; 2, disagree; 3, neutral; 4, agree; 5, strongly agree) and to answer additional multiple-choice questions. Space was provided for free-text feedback.

Survey responses were analysed with SPSS version 23.0 (IBM, Armonk, NY, USA). For each outcome, frequencies and percentages of level of agreement were calculated per stakeholder group. In subsequent rounds, the individual and stakeholder group results were relayed back. For each round, all comments were analysed and suggestions were added to subsequent rounds (i.e., clarifications, rewording of sentences, or additional definitions).

Consensus was defined a priori as at least 70% of stakeholders scoring an item as “agree/strongly agree” and less than 15% scoring it as “disagree/strongly disagree.” Exclusion of items required at least 70% of stakeholders scoring the item as “disagree/strongly disagree” and less than 15% scoring it as “agree/strongly agree.” Items that did not meet these criteria were classified as “no consensus.” For multiple-choice questions, a level of 70% agreement was used. If consensus was reached, participants were informed and the outcome was left out from subsequent rounds. Outcomes that nearly reached consensus were discussed by the steering committee for a final decision. Attrition analysis was performed by comparing the medians of outcomes among those who participated in subsequent rounds to the medians of those who did not.

After completion of the three Delphi rounds, an expert consultation meeting was held in The Netherlands with an online dial-in option (January 4, 2018). All participants who completed the third round were invited. In total, seven obstetricians, six midwives, and all members of the steering committee attended. The final results of the Delphi rounds were discussed, but no further attempt to reach consensus was taken. After each round, including the consultation meeting, open coding was performed on all free-text comments by highlighting and constructing themes, and the text was summarised.

Results

In total, 215 experts were invited to participate in the Delphi survey, consisting of 83 (38.6%) midwives, 92 (42.8%) obstetricians, and 40 (18.6%) paediatricians; 51 (23.7%), 82 (38.1%), and 82 (38.1%) originated from low-, middle-, and high-income countries, respectively. In the first round, 107 (49.8%) responded; in the second round, 84 (79%) responded; and in the third round, 71 (90%) responded (Table 2).

The respondents, of whom 83%–88% had experience in low-resource settings (90% for more than 1 year), originated from 39 different countries. 13 participants without experience in low-resource settings were recommended by the consultation organisations on the basis of their expertise in foetal monitoring. Because only five paediatricians responded in the second round, this group was deemed too small to reach meaningful consensus in subsequent rounds and was therefore not invited to the third round.

Table 2 Characteristics of the participants by round [a].

Characteristic	Round 1 (n=215)	Round 2 (n=107)	Round 3 (n=79)
No. of respondents	107 (50)	84 (79)	71 (90)
Profession			
Nurse/midwife	48 (45)	35 (42)	28 (39)
Obstetrician	49 (46)	44 (52)	43 (61)
Pediatrician	10 (10)	5 (6)	0 (0)
Experience in low/middle income country			
Yes	94 (88)	72 (86)	59 (83)
<1 y	8 (7)	8 (10)	5 (7)
1–5 y	27 (25)	21 (25)	17 (24)
6–10 y	23 (21)	14 (17)	12 (17)
>10 y	36 (34)	29 (35)	25 (35)
Sex			
Male	43 (40)	35 (42)	29 (41)
Female	64 (60)	49 (58)	42 (59)
Age, y			
25–35	16 (15)	12 (14)	8 (11)
36–45	29 (27)	23 (27)	20 (28)
46–59	34 (32)	25 (30)	21 (30)
≥60	28 (28)	24 (29)	22 (31)
No. of countries of origin [b]	39	35	30
Low income	10 (9)	7(8)	5 (7)
Middle income	36 (34)	27 (32)	22 (31)
High income	61 (57)	50 (60)	44 (62)
Involved in patient care	84 (79)	66 (79)	57 (80)
Involved in research	55 (51.4)	48 (57)	42 (59)
Involved in teaching/training	76 (71)	57 (68)	48 (68)
Involved in guideline developments	78 (73)	63(75)	53 (75)

[a] Values are given as number (percentage) or number.

[b] Participating countries: Afghanistan, Australia, Bangladesh, Barbados, Belgium, Brazil, Canada, Colombia, Denmark, Eritrea, Ethiopia, France, Germany, Indonesia, Italy, Kenya, Lesotho, Malawi, Malaysia, Namibia, Netherlands, New Zealand, Nigeria, Norway, Philippines, Portugal, Russia, South Africa, Sri Lanka, Suriname, Sweden, Tanzania, The Gambia, Tunisia, The United Kingdom, Uruguay, United States of America, Venezuela, and Zambia.

Table 3. Summary of consensus for the various outcomes (i.e. in/out/no consensus)

	Minimum set of intrapartum monitoring *(round of consensus)*	**Outcomes not included *(round of exclusion if consensus reached)***
Admission tests	Fetal movement by maternal perception *(round 2)* Gestational age *(round 1)* Fundal height *(round 1)* Maternal blood loss *(round 1)* Intermittent auscultation by: hand-held Doppler *(round 1)* or Pinard stethoscope *(round 2)* Meconium-staining of amniotic fluid *(round 3)*	CTG Amniotic fluid index Fetal acoustic stimulation test Fetal scalp stimulation test *(round 3)* Fetal movement by ultrasound detection Fetal pulse oximetry *(round 3)* Rapid Biophysical Profile *(round 3)* Umbilical artery Doppler velocity *(round 3)*
Fetal heart rate monitoring	**Low-risk pregnancies in 1st stage of active phase of labor**	
	Method**:** hand-held Doppler *(round 1)* or Pinard *(round 2)* Frequency: every 30 minutes *(round 3)*	CTG - non invasive CTG - invasive *(round 1)* Duration of IA
	Low-risk pregnancies in 2nd stage of labor	
	Method**:** hand-held Doppler *(round 1)* or Pinard *(round 2)*	CTG - non-invasive CTG - invasive *(round 1)* Frequency of IA Duration of IA
	High-risk pregnancies in 1st stage of active phase of labor	
	Method**:** Doppler (round 1) or Pinard[a] *(round 3)* Duration**:** 60 seconds *(round 2)*	CTG - non-invasive CTG - invasive *(round 3)* Frequency of IA
	High-risk pregnancies in 2nd stage of labor	
	Method**:** Doppler *(round 1),* non-invasive CTG[b] or Pinard[c] *(round 3)* Frequency**:** After every contraction *(round 2)* Duration**:** 60 seconds *(round 2)*	CTG invasive *(round 3)*
	Suboptimal FHR	
	Frequency in 2nd stage**:** After every contraction *(round 2)*	Frequency of IA in 1st stage of active phase of labor
	Abnormal FHR	
		Within how many minutes should fetal heart be confirmed?
Adjunctive tests	**Normal FHR**	**Normal/suboptimal/abnormal FHR in 1st & 2nd stage of labor[d]**
	Meconium *(round 3)* Maternal wellbeing *(round 2)* None: No additional test, continue monitoring FHR *(round 2)* **Suboptimal FHR (in 1st stage of active phase and 2nd stage of labor)** Meconium *(round 1 & 3 respectively),* intrauterine resuscitation *(round 2 & 3 respectively)* **Abnormal FHR** *1st stage of labor:* meconium, intrauterine resuscitation *(round 2)* *2nd stage of labor:* intrauterine resuscitation, no additional test, immediate delivery *(round 3)*	Amniotic fluid index Fetal acoustic stimulation test Fetal scalp stimulation test Fetal movement by maternal perception Fetal movement by ultrasound detection Fetal pulse oximetry Rapid Biophysical Profile Umbilical artery Doppler velocity None: No additional test, continue monitoring FHR None: No additional test, immediate delivery
Contraction monitoring	**Low-risk pregnancies in 1st stage of active phase of labor**	
	Frequency: hourly *(round 3)* Duration: 10 minutes *(round 3)*	
	High-risk pregnancies in 1st stage of active phase of labor	
	Duration:10 minutes *(round 3)*	Frequency

[a] Agree: midwives:77.8%, obstetricians:73.2%. Disagree: midwives:11.1%, obstetricians:19.5%
[b] Agree: midwives:69.2%, obstetricians:73.8% .Disagree: midwives:11.5%, obstetricians:14.3%
[c] Agree: midwives:73.1%, obstetricians:78.6%. Disagree: midwives:15.4%, obstetricians:14.3%
[d]See Table S1 and S2 for consensus out/ no consensus according to FHR and stage of labor
CTG = Cardiotocography, FHR = Fetal heart rate monitoring, IA = Intermittent auscultation

A summary of outcomes is shown in Table 3, and all details on agreement are given in Supplementary Tables S1 and S2. Feedback given during the rounds and consultation meeting related to clarification of definitions, additional outcomes to consider, achievability of recommendation, lack of evidence, and need for implementation research to inform clinical context-specific practice in low-resource settings (Table 4). Attrition analysis showed similar scores between rounds (Supplementary Table S4).

Table 4 Feedback from participants of Delphi rounds and/or consultation meeting

Theme	Details
Definitions	-clarification on e.g. low-resource setting, admission test, low/high risk, suboptimal/abnormal FHR.
Additional outcomes	- E.g. what should constitute admission tests and adjunctive tests; frequency of FHR and contraction monitoring -Emphasis on structured approach, technique and interpretation of assessments including timing FHR with contractions and simultaneous palpation of maternal pulse. -Maternal positional change and reducing contractions as the most relevant procedures of intrauterine resuscitation. -discouragement of routine rupture of membranes to check for meconium, i.e. check only when membranes are already ruptured. -Encourage use of vacuum/forceps in second stage of labour
Achievability	-Recommended frequency of monitoring likely not achievable and hence not respectful to the overwhelmed healthcare professionals. -Context should be stratified according to availability of resources to inform the development of context-specific, achievable guidance. -Advantages and disadvantages of monitoring devices including: -Prerequisite for use of CTG: availability of equipment and consumables, trained personnel for interpretation and access to theatre; able to detect subtle changes in FHR e.g. variability -Invasive tests: infection -Pinard: comparable to hand-held Doppler but requires high skills and quiet setting. -Hand-held Doppler: costly but user- and mother-friendly
Evidence	-Unavailability of evidence as an inherent limitation on expert-opinion -The need for further research: -Research priorities: Impact of admission tests, methods of IA, stimulation tests, maternal perception of foetal movement, intrauterine resuscitation and decision-delivery time on perinatal outcomes. - implementation research, adaptive clinical trials and qualitative approaches on the experiences of health professionals and patients in order to tackle research questions on intrapartum monitoring in low resource settings. - investment in innovating appropriate technologies which are affordable and functioning under all conditions

CTG = Cardiotocography, FHR = Foetal heart rate monitoring, IA = Intermittent auscultation

Participants strongly favoured an admission test for all women who present in labour (midwives, 27/28 [96%]; obstetricians, 41/42 [98%]), consisting of history taking and physical examination including IA. Intermittent auscultation by handheld Doppler was widely recommended for both low- and high-risk pregnancies in the first and second stage of labour, whereas Pinard stethoscope was considered primarily acceptable for low-risk pregnancies.

For low-risk pregnancies in the first stage (active phase) of labour, the frequency of IA should be every 30 minutes. For high-risk pregnancies in the second stage, including those with suboptimal/non-reassuring FHR, use of handheld Doppler was favoured after every contraction. Participants also recommended the use of continuous CTG for high-risk pregnancies in the second stage (, 18 of the 26 midwives who completed this item [69%]; obstetricians: 31/42 [74%]). The recommended duration of IA for high-risk pregnancies was at least 60 seconds. For low-risk pregnancies in the first stage of labour, consensus was reached that contractions should be checked for 10 minutes at least every hour. In the case of ruptured membranes, meconium-stained liquor could be used as an adjunctive test for foetal wellbeing, irrespective of FHR. Similarly, the foetal reaction to intrauterine resuscitation (defined in Box 1) should be considered in the case of a suboptimal or abnormal FHR. If FHR is abnormal in the second stage, immediate delivery should be expedited rather than further monitoring.

No consensus was reached on the frequency of monitoring for (1) high-risk pregnancies (17/26 [65%] midwives and 31/42 [74%] obstetricians suggested every 15 minutes); (2) suboptimal FHR in the first stage (17/26 [65%] midwives and 33/42 [79%] obstetricians suggested after every contraction); and (3) low-risk pregnancies in the second stage (19/26 [73%] and 5/26 [19%] midwives; 21/42 [50%] and 15/42 [36%] obstetricians suggested after every contraction or every 5 minutes, respectively). No consensus was reached on the duration of IA in low-risk pregnancies. There was also no agreement on the frequency of contraction monitoring in high-risk pregnancies (20/26 [77%] midwives, every 30 minutes for 10 minutes; 26/42 [62%] obstetricians, every hour for 10 minutes).

There was no consensus on monitoring after an abnormal FHR is detected in the active phase of labour. However, the majority of participants thought that foetal compromise should be confirmed within 5 minutes with a decision of whether or not to expedite immediate delivery (midwives,18/26 [69%]; and obstetricians, 23/42 [55%]).

Foetal acoustic stimulation and scalp stimulation tests (defined in Box 1) were mostly excluded as forms of foetal monitoring on admission to the labour ward or as adjunctive tests. Midwives strongly favoured, but obstetricians opposed, the use of maternal perception of foetal movement in the intrapartum period (agreement in the first stage for normal, suboptimal, and abnormal FHR was, respectively, 23/26 [89%], 21/26 [81%], and 22/26 [85%] for midwives versus 23/42 [55%], 16/42 [38%], and 5/42 [12%] for obstetricians) (Supplementary Table S1).

Discussion

The international Delphi procedure with input from experts from 39 countries resulted in consensus on five aspects of intrapartum foetal monitoring for busy low-resource maternity units: (1) need for an admission test, (2) handheld Doppler as the recommended method of intrapartum FHR monitoring, (3) frequency of IA for low-risk pregnancies during the first stage of labour and frequency of IA for high-risk women in the second stage, (4) frequency of contraction monitoring for low-risk pregnancies in the first stage of labour, (5) adjunctive tests to FHR monitoring. There was no consensus on the frequency of FHR or contraction monitoring for high-risk women in the first stage of labour, nor for low-risk pregnancies in the second stage. There was disagreement between midwives and obstetricians on the use of adjunctive tests, maternal perception of foetal movements, and foetal stimulation. Feedback from participants suggested two main reasons for disagreement: lack of evidence to guide expert opinion, and no single definition of “busy low-resource setting.”

The study involved a substantial group of participants (n=107) representing 39 countries. Importantly, the majority (>80%) of experts had experience of labour care in low-resource settings. The subsequent attrition of particularly midwives and paediatricians is, however, a limitation. These two stakeholder groups were not represented in the steering committee, and the effect of this cannot be ruled out. Although effort was taken to include a proportionate representation of experts from LMIC, the response rates of these experts were lower than those in high-income countries, possibly owing to access to the online survey. An inherent limitation is linked to the expert-based approach, which was chosen because of the lack of scientific evidence. However, the results may provide a foundation for future studies to generate evidence. Variation in the experts’ definitions of pregnancy risk status, low-resource setting, and suboptimal/abnormal FHR, as well as their preferred methods in their clinical practice, might also have influenced responses.

In the present study, foetal assessment on admission and monitoring during the second stage of labour were identified as key intrapartum points for perinatal survival, enabling triage and expedited instrumental vaginal delivery, respectively.[16] A rapid, low-cost, low-technology triage algorithm based on the findings of risk assessment and physical examination — for example, an adapted version of the Intelligent Structured Intermittent Auscultation framework[17] — to triage labouring women into appropriate levels of foetal monitoring in low-resource settings might support the implementation of these recommendations. Furthermore, IA on admission is a simple quality-of-care indicator to evaluate and improve intra-hospital care.[2,18]

Although a Pinard stethoscope was considered acceptable, handheld Doppler was seen as the preferred method for FHR monitoring. The Pinard stethoscope is easily available in all settings and requires no consumables, such as batteries or gel. Users, however, might struggle to hear FHR in busy and noisy wards. The effect of handheld Doppler on operative delivery rates is not well established, and the instrument may not be readily available in low-resource settings owing to the associated consumables and associated costs.[19] Innovations are being developed to overcome such problems.[20]

Cardiotocography was considered useful only for high-risk pregnancies during the second stage. This contrasts with the international guidelines summarised in Table 1, which all advice continuous CTG monitoring for high-risk women during the whole period of labour (apart from the WHO, which does not express an opinion on this matter). In the present survey, however, concerns were raised about the validity and feasibility of CTG, even for high-risk women in the second stage, owing to a lack of evidence of improvement in perinatal outcomes and increased rates of cesarean in high-income countries, high costs and maintenance, regular training of staff, and difficulties in the interpretation of CTG traces.[8,21] Nonetheless, this consensus reveals the underlying urgent need for optimal FHR surveillance and timely management (e.g., instrumental deliveries) in the second stage, which may prevent stillbirth or severe birth asphyxia.[22] Meeting this need calls for novel FHR monitoring innovations as an alternative to CTG, such as the Moyo monitor (Laerdal Global Health, Stavanger, Norway) for intermittent prolonged monitoring of FHR.[23]

In the absence of evidence on optimal and minimal safe frequencies and duration of IA and monitoring of contractions, there was little deviation from established guidelines, except for the recommended hourly monitoring of contractions. A key methodologic finding of the study may be how clearly difficult it is for experts to deviate from international guidelines or common practice (culture and tradition) in order to reach reality. Yet, the actuality of the gap in human resources in many labour wards in LMICs implies that such guidelines are physically unachievable.[6,9,24] If one SBA simultaneously attends three labouring women with FHR according to the recommended 30-minutes interval, there would be no time for any other activities. Respectful patient care during labour requires high frequency and sufficient communication about foetal monitoring. Until human resource needs are met and rigorous evidence is available, respectful guidance for overworked health providers requires an achievable frequency of assessments for routine intrapartum care.[9] Therefore, it should be explored how future Delphi studies can better include the "reality-based evidence," including task prioritisation, in the decision-making for best possible management in resource-constrained settings.

Invasive adjunctive tests were discouraged because of concerns of improper procedures and interpretation, higher risk of infection, and sustainability. For an abnormal FHR, a change in maternal position and use of affordable tocolytic drugs (if available) to stop or reduce contractions were considered important, particularly in the case of a long decision-to-delivery interval. Non-invasive alternative adjunctive tests, including maternal perception of foetal movements, and foetal acoustic and scalp stimulation tests, received little support from the experts. Strikingly, obstetricians opposed the use of maternal perception of foetal movement during labour. Likely reasons are its apparent absence in actual clinical practice and limited evidence.[25] During the consultation meeting, however, it was suggested that the presence of foetal movement helps to confirm foetal wellbeing and might aid in guiding clinical management, a point that was agreed among midwives.

In conclusion, consensus was reached that intrapartum foetal monitoring in low-resource settings might benefit from a standard admission test and the use of IA by handheld Doppler in both stages of labour. With regard to the study's consensus on FHR assessment frequencies, reality proves them to be unachievable in many high-volume maternity units in low-income countries. This emphasises the unacceptable reality and calls for more and well-trained staff. Implementation research on how to strengthen admission assessment and intrapartum surveillance, and related effects on perinatal survival is paramount. Consideration should be given to clinical experience, patient preference, and locally derived data for developing achievable context-specific guidelines toward reducing intrapartum morbidity and mortality in low-resource settings.

Author contributions NH, MP, JB, and MJR conceived and designed the Delphi Survey with contributions from JVH, NM, TM, GBT, GHAV, DEG, and AF. NH carried out data acquisition and analysis. NH interpreted the results with substantial contributions from GHAV, MJR, and DEG. NH drafted the manuscript; MP, JB, JVH, NM, TM, GBT, GHAV, DEG, AF, and MJR revised the manuscript. All authors reviewed, approved, and agreed to be accountable for the final manuscript.

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Table S1 Results per stakeholder group and per round (Likert scale)
Table S2 Results per stakeholder group and per round (Multiple choice questions)
Table S4 Attrition analysis

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PART 3
The PartoMa Intervention Study

Photo by Tarek Meguid

Chapter 9

Effect of locally tailored labour management guidelines on intrahospital stillbirths and birth asphyxia at the referral hospital of Zanzibar: a quasi-experimental pre-post study (The PartoMa study).

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Abstract

Objective To evaluate effect of locally-tailored labour management guidelines (PartoMa guidelines) on intrahospital stillbirths and birth asphyxia.

Design Quasi-experimental pre-post-study investigating the causal pathway through changes in clinical practice.

Setting Tanzanian low-resource referral hospital, Mnazi Mmoja Hospital.

Population Facility deliveries during baseline (1st October 2014 till 31st January 2015) and the ninth till twelfth intervention month (1st October 2015 till 31st January 2016).

Methods Birth outcome was extracted from all cases of labouring women during baseline (n=3690) and intervention months (n=3087). Background characteristics and quality of care were assessed in quasi-randomly selected subgroups (n=283 and n=264, respectively).

Main Outcome Measures Stillbirths and neonates with 5-minutes Apgar score ≤ 5.

Results Stillbirth rate fell from 59 to 39 per 1000 total births (RR 0.66, 95% CI 0.53-0.82), and subanalyses suggest that this was primarily due to reduction in intrahospital stillbirths. Apgar score between 1-5 fell from 52 to 28 per 1000 live births (RR 0.53, 95% CI 0.41-0.69). Median time from last foetal heart assessment till delivery (or foetal death diagnosis) fell from 120 minutes (IQR 60–240) to 74 minutes (IQR 30-130) (Mann Whitney test for difference, p<0.01). Oxytocin augmentation declined from 22% to 12% (RR 0.54, 95% CI 0.37-0.81) and timely use improved.

Conclusion While low human resources and substandard care remain major challenges, PartoMa guidelines were associated with improvements in care, leading to reductions in stillbirths and birth asphyxia. Findings furthermore emphasise the central role of improved foetal surveillance and restricted intrapartum oxytocin use in safety at birth.

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Introduction

Annually, 303 000 maternal deaths occur globally, with the majority around the day of birth.[1] Likewise, three million babies die on the day of birth, as intrapartum stillbirths or early neonatal deaths.[2,3] The majority occurs in the poorest countries.[1–3] Though the global proportion of facility births is increasing, it has not been matched with improvements in the quality of intra-facility labour care.[4–6] This is a key priority in the post-2015 era.[7] Even at the tertiary level where birth attendants are expected to have received a certain level of training, reports from sub-Saharan Africa show ample room for improvement.[8–12]

A central barrier for enhancing evidence-based care at resource-constrained hospitals is discrepancies between international recommendations and contextual realities: non-realistic guidance may cause either no use or unpredictable individual adaptations, which may both lead to variable and risky performance.[7,13–17] A literature gap exists on contextually-tailored guidelines development, implementation, and use in low-resource settings.[16] Furthermore, while several short training packages, which are often guidelines-based, have been evaluated in low-income countries, their sustainability and long-term effect on quality of care is questionable.[18–21] All in all, sustainable implementation of clinically effective guidelines is warranted for supporting birth attendants at resource-constrained hospitals in providing quality care and ending avoidable intrapartum-related deaths and disabilities.[7,22,23]

The low-resource referral hospital of Zanzibar is no exception to the challenge of delivering acceptable care during birth. Findings from our pre-intervention study suggested, however, that practice could potentially be improved by low-cost strengthening of intrapartum monitoring and decision-making, even without additional health providers and supplies.[24] Acknowledging contextual constraints, a participatory and internationally peer-reviewed guidelines development process was conducted to formulate partograph-associated, locally achievable, and easy-to-use guidelines for common intrapartum care. This resulted in the PartoMa guidelines booklet, which was launched together with reoccurring quarterly seminars.[16] We here present an analysis of the associated effect on rates of stillbirth and birth asphyxia, through behavioural changes in clinical practice.

Methods

Setting

At the governmental referral hospital of Zanzibar, Mnazi Mmoja Hospital, approximately 12 000 women deliver annually. Resources are scarce. Throughout the study, average ratio of birth attendants to labouring women was 1:4 at daytime and 1:6 during evenings and nights. Birth attendants include medical doctors and nurse-midwives in permanent positions, as well as intern doctors. Staff turn-over is massive: 40% of doctors and 25% of nurse-midwives in permanent positions during the first six months of the PartoMa intervention were no longer working at the department when finalizing the 12th intervention month. Intern doctors stay six weeks only, but constitute more than 30% of birth attendants. In addition, more than 200 Tanzanian nurse-midwifery and medical students conduct their obstetric training at the department each year. At baseline, no intrapartum guidelines were routinely applied, but use of the World Health Organization's (WHOs) composite partograph was encouraged for all labouring women.[25] Approximately 50 maternal deaths occur annually (420 deaths per 100 000 live births). While the facility-based neonatal death rate is unknown, our baseline study revealed a stillbirth rate of 59 per 1000 total births, of which approximately half were alive at the time of admission.[24]

Intervention

We here present a health system quality improvement project aiming at strengthening intrapartum surveillance and decision-making by use of the eight-paged PartoMa pocket booklet. The internationally peer-reviewed guidelines were developed in close collaboration with staff to assure that they present integrated partograph-based decision-support for intrapartum management, including both routine and emergency care, and is achievable and easy to use when considering local resources. An elaborate description of the guidelines' development process, content, and staff's perceptions is presented elsewhere.[16]

The PartoMa guidelines were launched at the initial PartoMa seminars (27th-28th January 2015). The seminars have been conducted quarterly ever since, in a communal room at the hospital and facilitated by hospital staff and members of the study team. Each seminar lasts four hours and commences after work. The guidelines implementation strategy focuses on motivation of individual providers to improve quality of care voluntarily: no per diems are paid, but free food and the guidelines booklet are provided. To assure that all staff has opportunity to participate, each seminar is conducted twice. The main part of the seminar is case-based training at five work stations, each lasting 30 minutes and including main topics of partograph-associated labour management, in accordance with PartoMa guidelines. During the study, an average of 74% of doctors and 62% of nurse-midwives from the obstetric division participated at each seminar round. Of all approximately 60 intern doctors at the hospital, 37% in average attended seminars, including nearly all currently working in obsetrics.

The PartoMa guidelines are available on posters and often used during discussions at the department's daily clinical meetings.

Study design

We conducted a quasi-experimental pre-post study comparing all women delivering at the study site during baseline (1st October 2014 till 31st January 2015) with the ninth till twelfth intervention month (1st October 2015 till 31st January 2016). Donabedian's quality of medical care framework was applied, including evaluation of birth outcomes, process of care delivery, and structural setting and resources.[26]

The study's primary outcome measures were stillbirths (foetal deaths ≥ 1000 g) and neonates with Apgar score between 1-5. Six of the authors carefully went through all available case files from baseline and intervention months. Additional cases, where the case file was lost, were searched for by a twice repeated review of the admission, delivery, and operation theatre registers. A reduction in stillbirths with intrauterine foetal death on admission would be outside the intervention's scope. Therefore, a sub-analysis of foetal heart rate (FHR) on admission was conducted on all available case files of singleton stillbirths in the intervention months to approximate the proportion with positive FHR on admission (intrahospital stillbirths). This was previously done for the baseline.[24] Notably, classification in fresh and macerated stillbirths was earlier found unreliable and therefore not applied.[24] Multiple pregnancies were excluded from the sub-analysis of FHR due to unclear recording (e.g. often only one FHR was registered). Five-minutes Apgar score between 1-5 was applied as indicator of birth asphyxia with possibly serious adverse consequences.[27] However, 5-minutes Apgar score was not always available, and in such cases 1- or 10-minutes was used.

Secondary outcomes included maternal deaths, and rates of caesarean sections and vacuum extractions. Due to substantial underreporting of very early neonatal deaths in all registers and flaws in record keeping between obstetric, and neonatal units, neonatal deaths were not included.[24]

To study comparability between baseline and intervention months and quality of care, quasi-randomly selected subgroups were identified from the baseline and intervention months. Due to time and budget constraints, it was not feasible to conduct these in-depth analyses on all women (N=6777).

To obtain a representative sample, every tenth delivery in the department's admission, delivery, and operation theatre registers was identified. Intensive efforts were made to retrieve the case files, of which all women delivering singletons with birthweight ≥2000 gram were included. The 2000 gram cut-off for the subgroup evaluation was chosen as it reflects gestational age 32–34 weeks where survival is less dependent on lung maturation and advanced intensive neonatal care.[28] Very preterm gestations might influence decisions on intrapartum care, which our pre-selected audit criteria did not take into account. From subgroup cases, all available background characteristics were extracted, and intrapartum practice was analysed against pre-selected criteria: foetal surveillance, labour progress, and maternal vital signs, of which blood pressure and temperature were selected for analysis. These criteria were successfully applied for the baseline study and methodological details have been presented elsewhere.[24]

Structural changes, which potentially could be contextual mediators or confounders to practice and outcome changes, were assessed quarterly during the study: availability of emergency obstetric and neonatal care signal functions, number of health care providers in each cadre of staff, and introduction of other interventions to improve maternal and perinatal health.

Sample size calculation

To avoid possible season variations, we wanted to compare the baseline with identical months of the intervention year (the ninth till twelfth intervention month). We could not extend the baseline further back in time due to a long lasting breakdown in the hospital's storage system of case files. Power was calculated based on a 2-sided comparison of two proportions, using the baseline's intrahospital stillbirth rate (positive FHR on admission) of 28 per 1000 total births in 3690 total deliveries and an expected 40% reduction by the intervention with a significance level of 5%.[24] Assuming that at least 3000 women would deliver in the four intervention months, this resulted in a power of 88%.

Statistical analyses

Data was entered into a structured entry form (EPI INFO 7 software, Centres for Disease Control and Prevention, Atlanta, GA, USA). Statistical analyses were performed in SAS Enterprise Guide 6.1 (SAS Institute, Inc., Cary, NC). Data on background characteristics for baseline and intervention months were compared using Fisher exact test. Birth outcomes and quality of care were compared by relative risk (RR) with 95% confidence interval (CI) for categorical variables and Mann-Whitney for numeric variables.

Ethical considerations

The PartoMa study received ethical approval from Zanzibar Medical and Research Ethical Committee (ZAMREC/0001/JUNE/014). The project is registered with ClinicalTrials.org (NCT02318420). While birth attendants were highly engaged, patients were not involved in the study design.

Results

At baseline, 3690 women delivered, and 3087 in the intervention months. Of these, 364 (10%) from baseline and 315 (10%) from intervention months were identified for subgroup comparison of background characteristics and quality of care. It was possible to retrieve case files of 301/364 (83%) and 282/315 (90%), respectively, of which 283/301 (94%) and 264/282 (94%) were singletons with birthweight ≥ 2000 gram (Figure 1).

Background characteristics

Within the subgroups, age and parity were approximately equally distributed. Approximately 15% of multiparous women in both periods had previously had one or more caesarean sections. Of multiparous women, 35/150 (23%) at baseline and 23/146 (16%) in intervention months had lost one or more children (p=0.11). Labour progress on admission and rates of referrals were comparable between baseline and intervention months (Table 1).

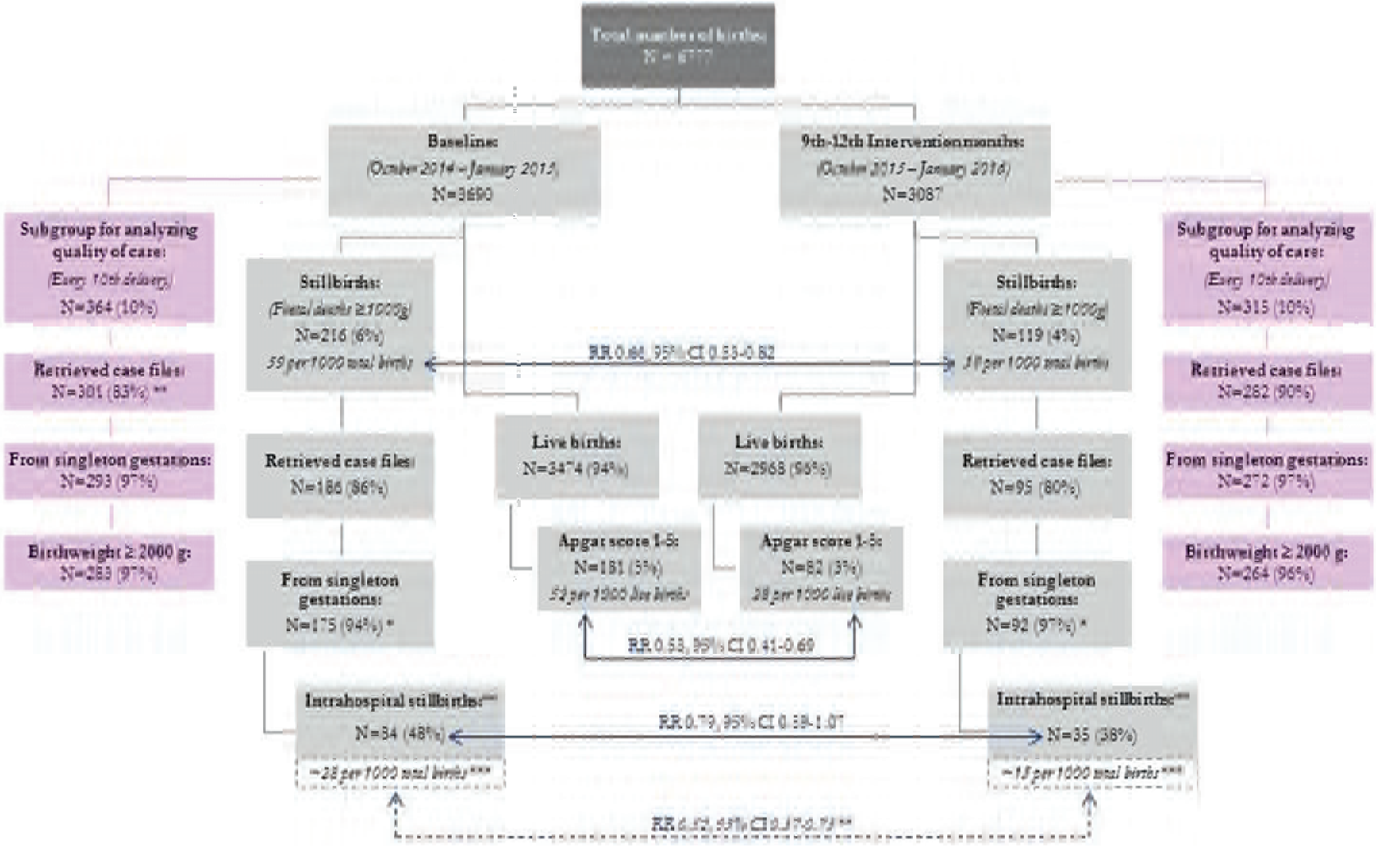

Figure 1 Participant flow for analyzing birth outcome (grey color) and for the subgroup comparisons of background characteristics and quality of care (pink colour). Percentages are based on the number immediately above. *Of the included singleton gestations at baseline and in intervention months, 34 and 30, respectively, had birthweight <2000 g. **Documented positive foetal heart rate during the admission. ***Based on extrapolation from an analysis of singleton stillbirths with retrievable case files (175/216 (81%) at baseline and 92/119 (77%) in the intervention months): (59/1000)*0.48 and (39/1000)*0.38, respectively. CI = confidence interval; RR = relative risk.

Table 1 Background characteristics. Comparison of women quasi-randomly selected at baseline (October 2014-January 2015) and during the ninth till twelfth intervention month of the PartoMa study (October 2015-January 2016).

	Baseline N (%)	9th-12th Intervention Month N (%)	p-value*
Of all women in the subgroups:	(n=283)	(n=264)	
Age			
< 20 years	28 (9.9%)	26 (9.8%)	0.26
20-29 years	142 (50.2%)	148 (56.1%)	
30-39 years	94 (33.2%)	82 (31.1%)	
≥ 40 years	16 (5.7%)	7 (2.7%)	
Information missing	3 (1.1%)	1 (0.4%)	
Parity on admission			
Para 0	123 (43.5%)	107 (40.5%)	0.38
Para 1-4	113 (39.9%)	123 (46.6%)	
Para ≥ 5	37 (13.1%)	30 (11.4%)	
Information missing	10 (3.5%)	4 (1.5%)	
Antenatal care			
≥ 4 visits	119 (42.0%)	127 (48.1%)	0.42
1-3 visits	125 (44.2%)	115 (43.6%)	
Not attended	0 (0.0%)	1 (0.4%)	
Information missing**	39 (13.8%)	21 (8.0%)	
HIV			
Negative	243 (85.9%)	242 (91.7%)	0.12
Positive	0 (0.0%)	4 (1.5%)	
Information missing**	40 (14.1%)	18 (6.8%)	
Severe hypertensive disorders			
Severe hypertension (BP ≥ 160/110)	16 (5.7%)	17 (6.4%)	0.72
Of multiparous women in the subgroups:	(n=150)	(n=146)	
Previous obstetric history			
Previous death of child/children***	35 (23.3%)	23 (15.0%)	0.11
1 previous caesarean section	11 (7.3%)	14 (9.2%)	0.54
≥ 2 previous caesarean sections	10 (6.7%)	8 (5.2%)	0.81
Of all women in the subgroups:	(n=283)	(n=264)	
Progress on admission			
Before active phase of labour ****	77 (27.2%)	83 (31.4%)	0.56
First stage of active phase of labour	176 (62.2%)	156 (59.1%)	
Second stage of labour	27 (9.5%)	23 (8.7%)	
Information missing	3 (1.1%)	2 (0.8%)	
Referrals	14 (4.9%)	10 (3.8%)	0.54

* Fisher exact test, ** Significantly fewer women had missing information in the intervention months regarding number of antenatal care visits (RR 0.58, 95%, CI 0.35-0.95) and HIV status (RR 0.48, 95% CI 0.28-0.82). *** Documentation was inadequate to differentiate perinatal deaths from deaths later in life **** Cervical dilatation <4 cm, BP = blood pressure

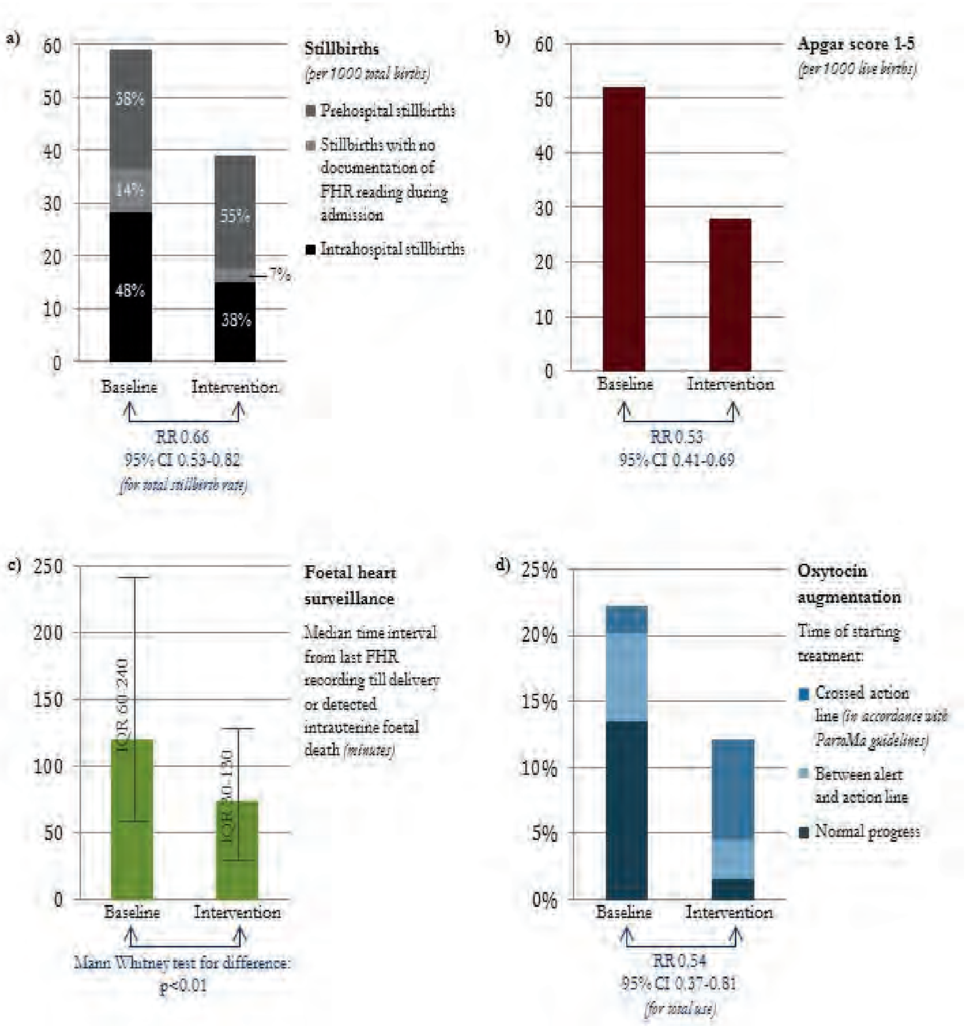

Figure 2 Key findings – comparison of baseline (October 2014-January 2015) and the ninth till twelfth intervention month of the PartoMa study (October 2015-January 2016). **a)** Stillbirths (foetal deaths ≥ 1000 g). The division into prehospital (no FHR on admission) and intrahospital (positive FHR during admission) stillbirths is based on extrapolation from an analysis of singleton stillbirths with retrievable case files (175/216 (81%) at baseline and 92/119 (77%) in intervention months): (59/1000)*0.48 and (39/1000)*0.38, respectively. **b)** Signs of birth asphyxia. **c)** Quality of foetal heart surveillance, assessed in the quasi-randomly selected subgroups. **d)** Quality of treatment with oxytocin augmentation in women not induced, assessed in the quasi-randomly selected subgroups. CI, confidence interval; FHR, foetal heart rate; IQR, interquartile range; RR , relative risk.

Birth outcomes

At baseline, 216 stillbirths occurred in 3690 total births (59 per 1000 total births), compared to 119 in 3087 in intervention months (39 per 1000 total births) (RR 0.66, 95% CI 0.53-0.82). Neonates with Apgar score between 1-5 nearly halved: from 52 to 28 per 1000 live births (RR 0.53, 95% CI 0.41-0.69) (Figure 2, Table 2).

It was possible to retrieve case files of 175/216 (81%) singleton stillbirths at baseline and 92/119 (77%) in intervention months. Of these, 84/175 (48%) at baseline and 35/92 (38%) in intervention months had positive FHR during admission (RR 0.79; 95% CI 0.59-1.07) (Figure 1). Of the remaining stillbirths at baseline, in 67/175 (38%) intrauterine foetal death was clearly documented on admission, and 24/175 (14%) had no documentation of FHR readings during the admission and could potentially also be intrapartum. In the intervention months, this was the case for 51/92 (55%) and 6/92 (7%), respectively. The proportion of intrahospital stillbirths among retrieved and the approximately 20% non-retrieved case files might differ, but if assuming similar proportions, this would imply an almost halving of intrahospital stillbirths occurring after admission [(59/1000)*0.48] and (39/1000)*0.38, respectively] from 28 to 15 intrapartum stillbirths per 1000 total births (RR 0.52; 95% CI 0.37-0.73) (Figure 2a, Table 2).

Maternal deaths were largely unchanged, from 15 in 3474 live births to 16 in 2968 (RR 1.25, 95% CI 0.62-2.52) (mortality causes are listed in Table S1).

Proportion of vacuum extractions increased from 10/3690 (0.3%) to 37/3087 (1.2%) (RR 4.42, 95% CI 2.20-8.88), and caesarean sections from 431/3690 (11.7%) to 489/3087 (15.8%) (RR 1.36, 95% CI 1.20-1·53) (Table 2).

Birth outcomes delineated to the subgroups are available as supporting information (Table S2).

Quality of care

In both subgroups, more than 90% of women reaching active labour and admitted before second stage had a partograph started, and more than 90%

of these had first cervical dilatation appropriately plotted on the alert line (Table 2).

At baseline, 233/283 (82%) had at least one FHR recorded, versus 244/264 (92%) in intervention months (RR 1.12, 95% CI 1.05-1.20). Median time from last FHR recording till delivery (or till detected intrauterine foetal death) was 120 minutes at baseline (IQR 60–240 minutes), versus 74 minutes in intervention months (IQR 30–130 minutes) (Mann Whitney test for difference, p<0.01) (Figure 2c, Table 2).

Oxytocin use for labour augmentation when not induced, decreased significantly from 63/283 (21%) at baseline to 32/264 (12%) in intervention months (RR 0.54, 95% CI 0.37-0.81). More specifically, oxytocin use before crossing the action line fell (RR 0.23, 95% CI 0.12-0.41), and its use increased after crossing the line (RR 3.57, 95% CI 1.46-8.76) (Figure 2c). Meanwhile, 25/239 (11%) of women in first stage of active labour at baseline versus 42/219 (19%) in intervention months crossed the action line (RR 1.83, 95% CI 1.16-2.90) (Figure 2d, Table 2).

Surveillance of blood pressure and temperature were unchanged (Table 2).

Structural mediators and confounders

There were no other obstetric or neonatal interventions introduced during the 12 intervention months. Only one birth attendant received additional formalised training externally, and there was neither in-house training organised in neonatal resuscitation nor in postpartum haemorrhage. Daily clinical meetings with supervision by a senior obstetrician were launched seven months prior to the baseline. These were similar throughout the study period and mainly attended by doctors. While maternal death audits commenced in August 2015, presentations of findings were first initiated after ending the twelfth intervention month. Parameters to be measured and findings of the PartoMa study, including baseline data, were only presented after the twelfth intervention month. During the study period, there were nearly no differences observed in staff numbers, including foreign staff, continuous shortages of supplies, and available emergency obstetric and neonatal care signal functions (Table S3). However, there were 16% fewer deliveries in intervention months.

Table 2 Birth outcomes and quality of intrapartum care. Birth outcomes are evaluated for all women and their offspring during baseline (October 2014-January 2015) and the ninth till twelfth intervention month of the PartoMa study (October 2015-January 2016). Quality of care is evaluated within the quasi-randomly selected subgroups.

	Baseline	**9th-12th Intervention Month**	
Birth outcomes *(evaluated on all women and offspring)*	Rate (N/Total)	Rate (N/Total)	RR (95% CI)
Perinatal outcome			
Stillbirth rate per 1000 total births	59 (216/3690)	39 (119/3087)	0.66 (0.53-0.82)
Intra-hospital stillbirth rate per 1000 total births*	~28 (104/3690)	~15 (45/3087)	0.52 (0.37-0.73)
Apgar score ≤5 rate per 1000 live births	52 (181/3474)	28 (82/2968)	0.53 (0.41-0.68)
Maternal outcome			
Maternal deaths per total live births	- (15/3474)	- (16/2968)	1.25 (0.62-2.52)
Mode of delivery			
Vacuum extraction rate (%)	0.3 (10/3690)	1.2 (37/3087)	4.42 (2.20-8.88)
Caesarean section rate (%)	11.7 (431/3690)	15.8 (489/3087)	1.36 (1.20-1.53)
Process of intrapartum care delivery *(evaluated on women and offspring included in the subgroups)*	N (%)	N (%)	RR (95% CI)
Overall partograph use			
Of women in first stage, active phase of labour:	*(n=239)*	*(n=219)*	
The partograph at least partially applied	213 (89.1%)	209 (95.4%)	1.07 (1.02-1.13)
Of women with the partograph applied:	*(n=213)*	*(n=209)*	
First cervical dilatation in active labour plotted correctly	192 (90.1%)	195 (93.3%)	1.04 (0.98-1.10)
Foetal surveillance			
Of all women in the study:	*(n=283)*	*(n=264)*	
At least one FHR reading	233 (82.3%)	244 (92.4%)	1.12 (1.05-1.20)
Of women with at least one FHR reading:	*(n=233)*	*(n=244)*	
< 90 min. between any 2 FHR recordings	96 (41.2%)	121 (49.6%)	1.20 (0.99-1.47)
Of women in active phase of labour and positive FHR:	*(n=269)*	*(n=244)*	

Time from last FHR till delivery calculated	235 (87.4%)	224 (91.8%)	1.05 (0.99-1.12)
Last FHR till delivery (min.); median time [IQR]**	120 [60-240]	74 [30-130]	
Labour progress			
Of women admitted before active labour:	*(n=77)*	*(n=83)*	
Cervical dilatation assessed in active labour ***	51 (66.2%)	52 (62.7%)	0.95 (0.75-1.19)
Of women in first stage, active phase of labour:	*(n=239)*	*(n=219)*	
<5hrs. between any 2 cervix recordings	191 (79.9%)	192 (87.7%)	1.10 (1.01-1.19)
<3hrs. between any 2 contraction recordings	138 (57.7%)	141 (64.4%)	1.12 (0.96-1.29)
Alert line crossed	57 (23.8%)	78 (35.6%)	1.49 (1.12-1.99)
Action line crossed	25 (10.5%)	42 (19.2%)	1.83 (1.16-2.90)
Of all women in the study:	*(n=283)*	*(n=264)*	
Oxytocin augmentation, total use ****	63 (22.3%)	32 (12.1%)	0.54 (0.37-0.81)
Oxytocin augmentation, before action line	57 (20.1%)	12 (4.5%)	0.23 (0.12-0.41)
Oxytocin augmentation, after action line	6 (2.1%)	20 (7.6%)	3.57 (1.46-8.76)
Maternal vital signs			
Of women in active phase of labour and positive FHR:	*(n=269)*	*(n=244)*	
BP recorded at least once during active labour	182 (67.7%)	161 (66.0%)	0.98 (0.86-1.10)
Of all women in the study:	*(n=283)*	*(n=264)*	
≥1 temperature recording before delivery	165 (58.3%)	141 (53.4%)	0.92 (0.79-1.06)

* Based on extrapolation from an analysis of singleton stillbirths with retrievable case files (173/216 (80%) at baseline and 92/119 (77%) in the evaluation months): (59/1000)*0.48 and (39/1000)*0.38, respectively.

** Time interval from last FHR recording till delivery or detected intrauterine foetal death. Mann Whitney test for difference: p<0.01.

*** If vaginal examination was performed in latent phase ≤4 hours prior to delivery, this was registered as acceptable.

**** Women receiving induction of labour are excluded from analyses of oxytocin augmentation.

BP, blood pressure; CI, confidence interval; FHR, foetal heart rate; min., minutes; RR, relative risk

Discussion

Main Findings

We found a risk reduction of 34% in stillbirths, corresponding to 20 prevented stillbirths per 1000 total births, and 47% in Apgar score between 1-5, resulting in 24 less neonates with signs of birth asphyxia per 1000 live births. Consistently, and in line with PartoMa guidelines, FHR surveillance and timely oxytocin augmentation improved significantly. Considering contextual mediators and confounders, and high satisfaction with guidelines[16] and seminars, it is likely that the PartoMa intervention catalysed these behavioural changes. We have no knowledge about other studies evaluating effect of locally-tailored intrapartum guidelines on perinatal outcome in low-resource settings.[16]

Strengths and Limitations

This pragmatic and low-cost pre-post study was designed to suit limitations in data and budget, and the variables may be of inspiration for developing realistic core outcomes for low resource settings.[29] While there are specific restrictions to each sub-analysis, multiple variables enabled triangulation and exploration of the guidelines' pathway through practice to changes in birth outcome.[26,30] To strengthen causality further, we undertook knowledge tests, but tests were anonymous in order not to expose participants, which made evaluation at individual level impossible.

Comparison of delivery modes between subgroups and total numbers (Tables 2 and S2) suggests subgroups to be representative of the entire population. Likewise, comparable background characteristics of women in baseline and intervention subgroups strengthens internal validity. Two baseline time points would have explored possible time-related changes, but this was hampered by break-down in the hospital's case file storage system.[24] The 16% reduction in total deliveries might have enabled more timely care. While no other formalised training activities were conducted, discussions at daily clinical meetings might have influenced practice independently of PartoMa. Moreover, conducting a quality improvement project might have influenced practice independently of the intervention.[31] However, the Hawthorne effect was minimised by avoiding systematic direct observations of care, and study parameters and results were not presented before finalizing this study.

Intrahospital stillbirths would have been a more delineated primary outcome, but time of death in stillbirth cases could only be analysed in approximately 80% due to poor case file storage. The pre- versus intrahospital stillbirth proportions are therefore an extrapolation with risk of bias. The reduction in the intrahospital stillbirth proportion from 48% to 38% is, however, an important indication of the likelihood that the overall stillbirth reduction is associated with improved intrapartum care. Notably, this is further supported by the simultaneous reduction in birth asphyxia.

A major strength was motivation to learn and improve among many birth attendants, e.g. as revealed by high seminar attendance. This is consistent with the PartoMa intervention's focus on individuals' personal wish to improve. It may be explored further whether staff motivation was the pathway's starting point, or whether motivation was stimulated by PartoMa. While it is unlikely that the intervention had been effective without motivation, particularly nurse-midwives not applying guidelines[16] were a challenge for team work and further improvement. Non-participants may e.g. have contributed to unchanged routine blood pressure and temperature surveillance, which are mainly monitored by nurse-midwives. Additional methodological considerations were previously discussed.[24]

Interpretation

The PartoMa study indicates that intrahospital stillbirths can be partially reduced by implementation of locally-tailored guidelines, without increasing the alarmingly suboptimal staff numbers or introducing additional medical technology. Simultaneous reduction in birth asphyxia suggests that the babies survived in a reassuring medical condition. While results from intervention months show that care is still far from following the PartoMa guidelines optimally, significant progress has occurred since baseline. This is in line with parts of PartoMa guidelines being highly rated among staff.[16] Intervals from last FHR recording till delivery were reduced significantly. Consistently, our baseline study revealed an increase of 20% in the odds of stillbirth for each one-hour increase in FHR assessment interval.[24] Our baseline study furthermore identified inappropriate oxytocin augmentation as a predisposing factor for intrahospital stillbirths.[24] It appeared unrealistic to assure close monitoring of oxytocin augmentation if multiple women were treated simultaneously, and PartoMa guidelines therefore recommend reserving intrapartum oxytocin for women crossing the partograph's action line.[16] Consistently, overall oxytocin augmentation decreased significantly from 21% to 12% with reduced use prior to the action line and increased use when crossing the line. Moreover, this indicates improvement in partograph use for timely surveillance and management of labour progress.[25] Associated with reduction in oxytocin augmentation, there was an expected increase in women with slow labour progress. The subgroup evaluation indicated that the increase in caesarean sections was not caused by more cases of prolonged or obstructed labour.

While still suboptimal, a 1.2% rate of deliveries by vacuum extraction is an encouraging significant improvement.[32] Recommendations for vacuum extraction were adapted and included in PartoMa guidelines,[33] and this might be associated with the increase.

The caesarean section rate increased from 12% to 16%. While an elaborate pre-post analysis of caesareans' indications will require a detailed study, the subgroup evaluation did not raise concern for increase in unnecessary surgeries. Moreover, if timely performed, the increased rate may have aided in reducing perinatal risk.

Our results suggest that the PartoMa intervention was well tailored to the needs of staff, presenting a realistic aim for quality care. At baseline, multiple international and national evidence-based guidelines were available, but staff rarely applied these. As reported from comparable settings, informal sharing of knowledge and experience dominated decision making.[15,34] Reasons for translation of PartoMa guidelines to practice may be multifactorial and concern both guidelines content and implementation. The content was developed in close collaboration with staff to assure that the guidelines are contextually achievable and easy to use.[16] Contrary to the passive strategy whereby guidelines are often disseminated,[14,16] PartoMa guidelines were actively applied at daily meetings and taught at seminars. It is likely that this reoccurring low dose training may have boosted guidelines use, particularly when considering massive staff turnover. Conversely, appropriate guidelines curriculum appears crucial for effective training.

Fourteen months post-implementation, a local voluntary steering group took over distribution of PartoMa guidelines and organizing seminars.

Guidelines are still requested – both by staff at the study site and from other hospitals – and many staff still attend seminars.

In addition to foetal surveillance and labour progress, PartoMa guidelines' management of severe hypertensive disorders was highly appreciated among doctors,[16] and we are currently studying associated changes in practice. Additional next steps may include assessing feasibility at comparable hospitals, optimizing guidelines content further, developing a training of facilitators' course, assessing guidelines users on key competencies, and discussing voluntary versus compulsory training. While the evaluation here presented applies a narrow definition of quality care, the PartoMa intervention also focuses on respectful patient care, which needs further evaluation, including engagement of labouring women. Finally, adding to the overall cost-effectiveness of stillbirth reduction,[35] it may be relevant to study facility-based cost-effectiveness of PartoMa.

Conclusion

At the referral hospital of Zanzibar, the PartoMa study addresses the need for sustainable implementation of effective intrapartum guidelines. The locally-tailored PartoMa guidelines were well accepted and sought by staff,[16] and they were associated with improvements in practice, leading to significant reductions in stillbirths and birth asphyxia. While low human resources and substandard care remain major challenges, results emphasise the central roles of enhanced foetal surveillance and restricted intrapartum oxytocin use in improving survival – and indicate the effectiveness of the partograph when closely coupled with management guidelines. Two years post-implementation, the PartoMa intervention is still running.

Contribution to authorship

NM and ICB formulated the study design. NM managed the data acquisition, analysed and interpreted data, and drafted the paper. ICB contributed substantially to analyses and interpretation of data, and critically revised the paper draft. NH participated substantially in acquisition, analyses, and interpretation of data, and in critically revising the paper draft. JvR, TM, and BBN contributed substantially to the study design, analyses, and interpretation of data, and they critically revised the paper draft. RSK, AGM, MMA, and SMS participated substantially in acquisition of data, and contributed to the analyses and interpretation of data, and in revising the paper draft. AKGJ contributed substantially to the statistical part of the study design and analyses, data interpretation, and revising of the paper draft. In addition, all authors have approved the final version to be published and agree to be accountable for all aspects of the work.

Details of ethics approval Ethical approval was attained from the Zanzibar Medical and Research Ethical Committee (ZAMREC/0001/JUNE/014, 7th October 2014) and Mnazi Mmoja Hospital, and the project is listed in ClinicalTrials.org (NCT02318420, 4th November 2014).

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Table S1 Causes of maternal deaths

Table S2 Birth outcome for women and their offspring

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Chapter 10

Quality of intrapartum care: direct observations in a low-resource tertiary hospital

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Abstract

Background The majority of the world's perinatal deaths occur in low- and middle-income countries. A substantial proportion occurs intrapartum and is avoidable with better care. At a low-resource tertiary hospital, this study assessed the quality of intrapartum care and adherence to locally-tailored clinical guidelines.
Methods A non-participatory, structured, direct observation study was held at Mnazi Mmoja Hospital, Zanzibar, Tanzania, between October and November 2016. Women in active labour were followed and structure, processes of labour care and outcomes of care systematically recorded. Descriptive analyses were performed on the labour observations and compared to local guidelines and supplemented by qualitative findings. A Poisson regression analysis assessed factors affecting foetal heart rate monitoring (FHRM) guidelines adherence.

Results 161 labouring women were observed. The nurse/midwife-to-labouring-women ratio of 1:4, resulted in doctors providing a significant part of intrapartum monitoring. Care during labour and two-thirds of deliveries was provided in a one-room labour ward with shared beds. Screening for privacy and communication of examination findings were done in 50% and 34%, respectively. For the majority, there was delayed recognition of labour progress and insufficient support in second stage of labour. While FHRM was generally performed suboptimally with a median interval of 105 (interquartile range 57 -160) minutes, occurrence of an intrapartum risk event (non-reassuring FHR, oxytocin use or poor progress) increased assessment frequency significantly (rate ratio 1.32 (CI 1.09-1.58)).

Conclusions Neither international nor locally-adapted standards of intrapartum routine care were optimally achieved. This was most likely due to a grossly inadequate capacity of birth attendants; without whom innovative interventions at birth are unlikely to succeed. This calls for international and local stakeholders to address the root causes of unsafe intrafacility care in low-resource settings, including the number of skilled birth attendants required for safe and respectful births.

Introduction

An estimated 300,000 maternal deaths and five million perinatal deaths occur yearly worldwide, with >98% in low- and middle-income countries (LMICs).[1] Although childhood mortality has been reduced significantly, Millennium Development Goal 4 was not met in Sub-Saharan Africa, as neonatal deaths went mostly ignored and now make up 40% of under-5 mortalities.[1,2] Almost half the number of stillbirths and 23% of neonatal deaths in LMICs are intrapartum-related, in contrast to high-income settings.[3,4] Hence, ending intrapartum deaths by improved quality of intra-facility care is pivotal.[5] Yet, in Sub-Saharan Africa, the increasing numbers of facility-based deliveries, have not resulted in better intrapartum care and progress to improve perinatal health outcomes is slowest.[6–8] Instead, in many facilities, international standards of intrapartum care have become more difficult to implement in the day-to-day reality.

As found in our hospital, after unrealistic international guidelines were adapted to better suit the local resource-limited reality, significant improvements were observed in quality of care, stillbirths were reduced by one-third and the number of neonates with birth asphyxia nearly halved (Box 1).[9]

Quality of intrapartum care has mostly been assessed by retrospective analysis of existing medical records.[10] However, written records (e.g. partographs) in low-resource settings are often incomplete, missing or inaccurate,[10] and therefore might not reflect the actual care. The gold standard for clinical quality assessment is direct observation that captures the real-life experiences and behaviour of birth attendants; yet, they are rarely used.[10,11] . Similarly, few studies have assessed the adequacy of intrapartum foetal monitoring in low-resource settings.[12–16] This study used continuous direct observation to assess the quality of intrapartum care, with a specific focus on foetal monitoring and the structural requirements to delivering intrapartum quality care.

Box 1. Summary of the PartoMa intervention at Mnazi Mmoja Hospital, Zanzibar

The PartoMa Project was initiated at Zanzibar's tertiary hospital, Tanzania in January 2015. Its objective was to improve quality of care and perinatal outcomes. Skilled birth attendants were involved in focus groups discussions, adapting international labour management guidelines to better suit their local situation and participation in trainings. Prior to the PartoMa intervention, the stillbirth rate was 59 per 1000 total births (52% had positive foetal heart rate on admission) and the rate of Apgar score of ≤5 was 52 per 1000 live births.

At the 12th intervention month, stillbirth rate had decreased to 39 per 1000 total births (relative risk 0.66, 95% CI 0.53-0.82; intra-hospital singleton stillbirths reduced from 28 to 15 per 1000 total births) and Apgar score ≤5 fell to 28 per 1000 live births (relative risk 0.53, 95% CI 0.41-0.69). This was associated with improved quality of care, including improved foetal heart rate surveillance (a reduction in median time interval from last FHR to delivery from 120 (IQR 60-240) to 74 (IQR 30-130) minutes), more judicial use of oxytocin and improved management of women with severe hypertensive disorders.

Methods

Study design

This was a prospective study consisting of labour observations at the maternity ward of Mnazi Mmoja Hospital (MMH) in Zanzibar, the United Republic of Tanzania, from October to November 2016. The study adhered to a pre-determined protocol and STROBE standards of reporting.[17] This manuscript is part of the larger PartoMa Project initiated in 2015 to improve quality of care (Box 1).[9]

Setting

About 12,000 annual deliveries are assisted at MMH, and it is the only tertiary hospital on the Zanzibar archipelago.[12] At the time of the study, the labour unit consisted of an admission room, a one-room labour ward with 19 beds, a three-bed delivery room, two postnatal rooms, and one theatre (Figure 1). For privacy reasons, women were not allowed to have a companion during childbirth in the busy labour ward. Skilled birth attendants (SBAs) comprised 27 nurse-midwives (diploma-level in nursing, except three seniors with university-level degree), 13 resident doctors (general doctors) and six intern doctors (total n=46) who together provided routine labour care and comprehensive emergency obstetric and newborn care. On average, six to eight nurse-midwives and five doctors were allocated to the maternity unit in the morning shifts and a total of six SBAs were in the remaining shifts (including weekends). These were the main roles of nurse-midwives: assessment on admission; intrapartum and postpartum care including supportive care, routine monitoring, administration of medication, vaginal deliveries, and perineal repair; maintenance of ward hygiene, and delivery sets. The roles of the doctors involved providing labour and postpartum care to high risk women and complicated deliveries and performing obstetric and gynaecological operations. Direct supervision was provided by two senior midwives and two senior (visiting) doctors, only during morning shifts. In addition, there were three obstetricians who could be consulted and called for emergencies (Additional file 1, cadre definitions). Standards for labour management was according to the peer-reviewed PartoMa Pocket Guide version 1.2.[9] where, in collaboration with the SBAs, international guidelines had been tailored to the situation at the hospital, including reductions in information load, ambiguity, and frequency of clinical assessments (Additional file 2, comparison of FHRM recommendations).[9] The stillbirth rate was 39 per 1000 total births, of which 38% occurred during intra-hospital care.[9]

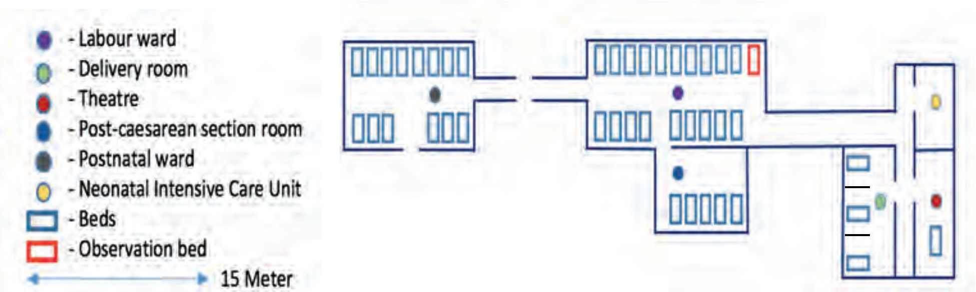

Figure. 1 Layout of the maternity unit of Mnazi Mmoja Hospital (MMH) in Zanzibar, the United Republic of Tanzania (2016)

Participants

The first women to reach active phase of labour (≥ 4cm cervical dilatation), either at admission or already in the ward, were selected for inclusion. Exclusion criteria were absent foetal heart rate (FHR) on admission, elective or emergency caesarean section (CS) decided immediately after admission, and known congenital foetal anomaly incompatible with life. Shifts of inclusion were planned beforehand to ensure representation of morning, evening, and night shifts throughout the week. Labours were observed until delivery or diagnosis of intrauterine foetal death.

Ethical approval

Approval from Mnazi Mmoja Hospital and Zanzibar Medical and Research Ethical Committee the local ethics committee (ZAMREC) was obtained (ZAMREC/0002/May/016). Written informed consent in Swahili was sought from all participating women. The aim of the study and the role of observers were introduced to all staff before commencing the study (not to cause blame or undermine the staff's devotion to labouring women). In case observers had concerns about the safety of a woman, they could express these concerns to the staff on duty and a senior staff could be called for assistance if needed.

Variables

The study qualitatively described and quantified structural indicators and processes of intrapartum care, as described in the Donabedian model.[18] It focused on the aspects of intrapartum monitoring and supportive care (Figure 2). In addition, the study determined adherence to the local FHRM guidelines (in terms of frequency and technique),[9] and the effect of five pre-identified predictors on FHRM frequency: pregnancy risk status (Box 2); occurrence of intrapartum risk events (Box 2);[19] parity (nulliparity and multiparity); SBA's years of experience with maternity care; and shift of inclusion. Predictors were adopted from the NICE [19] and local PartoMa guidelines, and from the hypothesis that they would alter the frequency of observations and/or the quality of care. Adherence to FHRM guidelines meant that the number of FHRMs was at least equal to the expected frequency. Expected frequencies of FHRM for low-risk labours, high-risk labours, and non-reassuring/abnormal FHR were set at 60, 30, and 15 minutes, respectively.[9] These were based on first stage of labour guidelines, because the start of second stage was often unknown. Other variables recorded consisted of socio-demographic characteristics, risk assessment variables (Box 2), cervical dilatation, and FHR on admission.

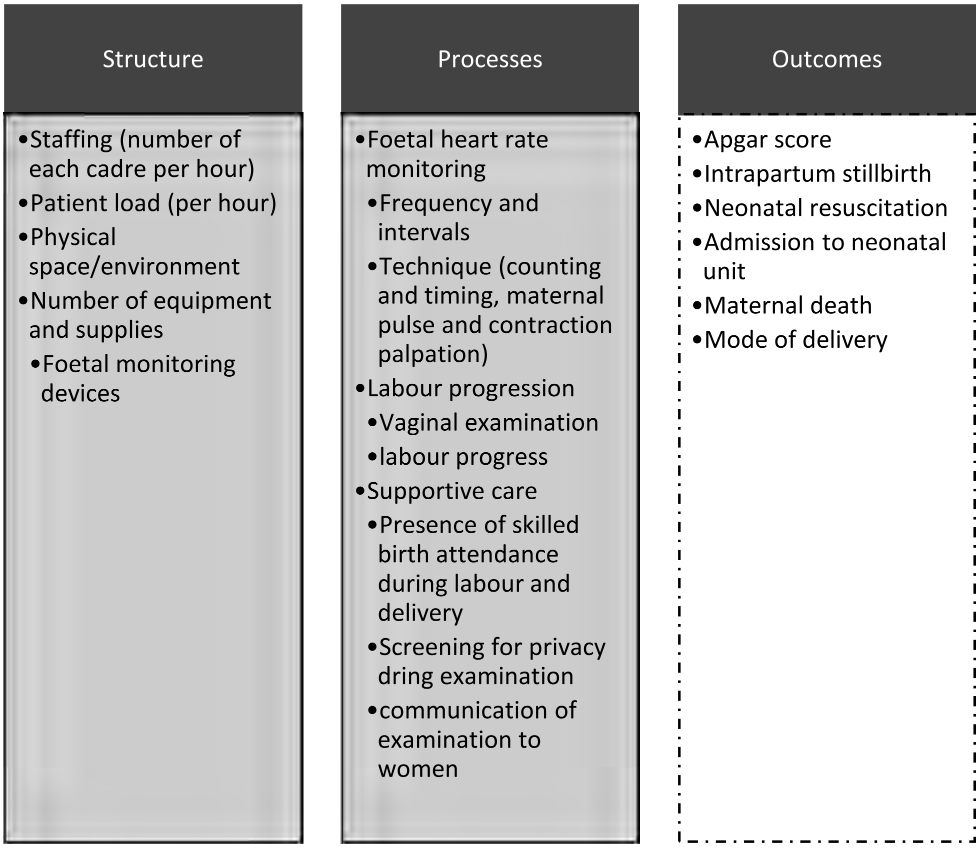

Figure 2 Variables measured in the study, related to structure and processes of care, by the Donabedian framework.

Data sources/measurement

The five observers were not qualified to act as birth attendant. One of the observers was a foreign final year medical student. The other four observers were newly graduated local medical students who had recently completed their studies and awaiting approval to start clinical internships. Therefore, none of the observers were permitted to provide medical care in this setting. Two observers per shift, both located in the labour room, conducted non-participatory direct observations. They recorded all care provided to each woman and performed hourly counts of the structural indicators (Figure 2). When a woman was taken to the delivery room or theatre, one observer followed her until birth. Sociodemographic characteristics, risk assessment variables, assessments on admission and birth outcomes were collected using the women's records (antenatal card and hospital file). Two data collection forms were created, pilot tested, and used for the systematic recording;[18] one for processes of care provided per woman as well as cadre of staff who provided the care and birth outcomes, and one for hourly counts of number of birth attendants, labouring women, and functioning FHRM devices. Both forms provided space for free-text description of e.g. supportive care (staff's and women's behaviour, presence of SBA during delivery), decision-making, medical treatment, and physical space/environment.

Box 2 Definitions of high-risk labours and intrapartum risk events

High-risk factors	**Intrapartum risk events**
Previous caesarean section Medical complications (e.g. hypertensive disorders, diabetes or fever) Grand-multiparity (>4 previous deliveries) Prematurity (<37weeks) Post-term pregnancy (>42 weeks) Prolonged rupture of membranes (>24hours) Multiple pregnancy Breech presentation Meconium-staining of the liquor Abnormal vaginal bleeding	Oxytocin/misoprostol use Vaginal bleeding Maternal fever Non-reassuring/ abnormal foetal heart rate (Supplementary file 2) Meconium-staining of the liquor Cord prolapse

Bias

Observer bias was a major concern. Observers could have underreported assessments made by SBAs or could have been involved in providing labour care. To minimise these biases, they were trained to recruit women into the study, make objective structured assessments with minimal intervention in care provision, and record their observations on the forms. They worked in pairs and observed a maximum of eight labouring women at a time. Also, the presence of observers could have altered the behaviour and improved performance of the SBAs (the Hawthorne effect).[20] However, this effect was likely to be minimal because the labour ward was extremely busy. Also, observations were made from an adequate distance, rather than by following the SBA.

Study size

The a priori sample size was estimated to be 150 labours plus 10% to account for potential hindsight exclusion based on a maximum of five predictors, with the aim to detect a single predictor with an assumed effect size of a risk ratio of 1.3, power of 80% and alpha of 5%.

Analysis

First, descriptive analyses were conducted on women's characteristics and number of staff, women, care provision, and FHRM devices. Means were reported with standard deviations (SDs), medians with interquartile ranges (IQRs), and frequencies with percentages. Then, the proportion of observations adhering to local FHRM guidelines, privacy standards and communication practices were calculated using the following formula: number of observations divided by number of expected observations, given the duration of labour. Four intervals were calculated: between two adjacent FHRMs, vaginal examinations, contractions and the last FHR-to-delivery interval. Differences between work shifts (day/evening/nights) were tested using one-way-ANOVA for the number of staff, equipment and labouring women and chi-square test for composite adverse perinatal outcomes (i.e. stillbirths and Apgar score <7 at 1 minute). Furthermore, univariate and multivariate generalised linear models for Poisson distributions were performed with the number of FHRMs for each woman as an outcome to estimate the effect of the pre-selected predictors on local guidelines adherence (i.e. pregnancy risk status (Box 2), occurrence of intrapartum risk events (Box 2), parity, SBA's years of experience with maternity care and shift of inclusion). In the multivariate analysis, the predictor intrapartum risk event was dichotomised. Results from the analysis were reported as rate ratios (RRs) with 95% confidence intervals and corresponding p-values. For this study, a RR may be interpreted as the increase in the number of FHRMs either compared to a reference category or when a continuous predictor increases by one unit. The set frequency of FHRM was hourly and women with a total pre-delivery observation of less than one hour were excluded from this analysis. The statistical software used was SPSS version 23, and SAS 9.4. Free-text comments were used to supplement quantitative findings on human resources, physical space, equipment, monitoring, and supportive care.

Results

Participants and birth outcomes

The majority of the 161 women observed (95.0%, n=153) came directly from home, at term (39 (±2.8) weeks), and with a median cervical dilatation of five (IQR: 3-7) cm. Inclusions were spread evenly between morning, evening, and night shifts (34.2%, n=55; 30.4%, n=49; and 35.4%, n=57, respectively). Fifty-one women (31.7%) were classified as high-risk on admission; the most common risk factors being hypertensive disorders (10.5%, n=17), prematurity (8.1%, n=13), breech presentation (6.8%, n=11, including two singletons and one twin pregnancy diagnosed close to delivery), previous uterine scar (5.6%, n=9) and grand multiparity (5.6%, n=9). In addition, 38.2% (n=42/110) of the remaining labouring women experienced one or more intrapartum risk events. Of the 42 (26%) labours augmented with oxytocin, two thirds (n=28) had crossed the action line of the partograph (i.e. poor progress). There were no maternal or neonatal deaths before hospital discharge, but there were four stillbirths (2.4%) and 23 (14.3) babies with Apgar score less than seven at one minute (Table 1). There was no statistical significance in composite perinatal outcomes between shifts of delivery (p=0.70).

Table 1. Pregnancy and labour characteristics and outcomes

Parameter	N(%)*
Maternal age in years, mean (SD)	26.4 (6.3)
Parity	
Nulliparous	86 (53.4)
Multiparous	75 (46.5)
Singleton	157 (97.5)
Twin	4 (2.5)
Presentation	
Cephalic	150 (93.2)
Breech	11 (6.8)
Number of antenatal care visits, mean (SD)	3.7 (1.3)
Referral pathway	
From home	153 (95.0)
Referral from another health facility	8(5.0)
Known gestational age by last menstrual period/Ultrasound	72 (44.7%)
Gestational age by last menstrual period/ultrasound, in weeks, mean (SD)	39.0 (2.8)
Fundal height in cm, mean (SD)	34.4 (3.5)
Cervical dilatation on admission	
< 4cm cervical dilatation	51 (31.5)
≥4cm cervical dilatation	110 (67.9)
Cervical dilatation at admission in cm, median (IQR)	5 (3-7)
Duration of observation in minutes, median (IQR)	290 (135-570)
Risk category on admission	
Low-risk	110(68.3)
High-risk	51 (31.6)
Intrapartum risk events	
None	92 (57.1)
Meconium-stained liquor	20 (12.4)
Abnormal FHR	8 (5.0)
Oxytocin use (including induction of labour)	51 (31.7)
Maternal pyrexia	2 (1.2)
Action line on partograph crossed	37 (25.0)
Mode of Delivery	
Spontaneous vaginal delivery (SVD)	134 (83.2)
Vacuum	5 (3.1)
Caesarean Section	21 (13.0)
SVD and Caesarean Section (twin)	1 (0.6)
Delivery Location	
Labour ward	90 (55.6)
Delivery Room	46 (28.4)
Theatre	24 (14.9)
Delivery Room and Theatre (twin)	1(0.6)
Perinatal outcomes (Total number of neonates=165)	
Birthweight, grams, mean (SD)	3152.6 (535)
Apgar score <7 at 1 minute**	23 (14.3)
Apgar score <7 at 5 minute**	4 (2.5)
Resuscitation**	9 (5.6)
Admission to neonatal unit**	13 (8.3)
Intrapartum stillbirth (i.e. presence of foetal heart rate on admission)***	4 (2.4)
Neonatal deaths before discharge	0 (0.0)

*Unless otherwise specified values are given as number (percentage), **of the live births, *** one stillbirth was delivered macerated.

Structure: Context in which care was provided

Human resources

The majority of nurse-midwives and doctors (89%, n=41/46) had a maximum of five years' experience in labour care (< 1 year: 41%, n=19/46; 1-5 years: 48%, n=22/46; >5 years: 11%, n=5/46). Observation at hourly intervals showed an average of nine labouring women and two to three nurse-midwives in the labour and delivery rooms throughout the day (nurse/midwife-to-labouring-women ratio of 1:4). Nurse-midwives performed all admission assessments, conducted 32.6% (134/411) of intrapartum monitoring and the majority of vaginal deliveries (67.1%, n=94/140) (Table 3). The resident doctor on duty also monitored women in labour (38.9% of examinations, n=160/411) and handled gynaecological and obstetric emergencies such as CS, obstetric haemorrhage and eclampsia. Sharing of information within cadres occurred during handover rounds, and two clinical meetings in the morning shift in which mainly doctors attended. Several SBAs regularly worked at a continuous pace and attended to women; while others showed signs of exhaustion, such as decreased work speed, resting for long periods, sleeping during night shifts, and uncourteous behaviour towards women and colleagues, only offering help when women became too loud or in the presence of a senior. Students and cleaners also shared tasks; they assisted during deliveries, offered psychological support, helped women with food and facilitated communication between women, SBAs and their families who were restricted access to the maternity unit.

Equipment and supplies

Partograph copies were available throughout the study period and were used in at least 87% (n=140) of labours; the remaining were either lost after delivery (9.3%, n=15) or not used at all (3.7%, n=6). Difficulties encountered with FHRM devices were their scarcity or misplacement (Table 2), unavailability of gel for hand-held Dopplers and ultrasound, and non-functioning hand-held Dopplers (n=6). Other intermittent shortages included lack of essential medication (e.g. antihypertensive), and supplies for vacuum extraction, CS and normal delivery sets.

Table 2. Cadre of staff, women and equipment available per shift

	Type of shift Morning	Evening	Night	p-value
Number of birth attendants per hour	5.9(1.35)	4.0(1.2)	3.4(0.82)	0.001*
Nurse-midwives	2.6(0.70)	2.2(0.55)	2.2(0.44)	0.36
Resident doctors	1.4(0.60)	1.0(0.64)	0.8(0.4)	0.18
Intern doctors	1.2(0.68)	0.6(0.48)	0.4(0.46)	0.02*
Seniors (doctor)	0.8(0.63)	0.2(0.26)	0.0(0.07)	0.002*
Instruments per shift	7.8(1.83)	6.8(1.69)	7(1.55)	0.37
Pinard stethoscope	2.2(1.0)	2.7(0.68)	2.5(0.84)	0.47
DeLee stethoscope	2.7(1.0)	1.8(0.79)	2.3(1.2)	0.25
Hand-held Doppler	1.1(1.05)	0.5(1.3)	0.2(0.41)	0.23
Mobile Ultrasound	2.0(0.0)	1.8(0.42)	2.0(0.0)	0.22
Labouring women per hour	9.0(2.92)	9.3(2.31)	8.6(2.25)	0.89

Values are given as mean (standard deviation)

*Significant level at 0.05: there were less senior doctors in the evening and night, and less intern doctors at night compared to morning shifts.

Table 3. Care and provider at each provider-to-woman contact point

Care provided	Nurse-Midwives	Residents	Intern	Visiting doctors	Multiple cadres	Others[f]	Total
FHR[a] assessments	22(25.9)	34(40.0)	9(10.6)	17(20.0)	3(3.5)	0(0.0)	85
VE[a,b]	65(45.5)	59(41.3)	8(5.6)	3(2.1)	2(1.4)	5(3.5)	143[d]
FHR and VE[a]	47(25.7)	67(36.6)	23(12.6)	27(14.8)	15(8.2)	3(1.6)	183[d]
Other labour care[c]	43(37.1)	37(31.9)	13(11.2)	5(4.3)	9(7.8)	9(7.8)	116
Conducting delivery[d]	94 (58.4)	40 (24.8)	6 (3.7)	10 (6.2)	-	11(6.8)	161

Values are given as number (percentage) or number.

Abbreviations: FHR = Foetal Heart Rate, VE= vaginal examination,

[a] Alone or with other labour care.

[b] Only VE for first stage of labour included

[c] This mostly consisted of: IV fluids/drugs administration, urinary catheterisation and blood pressure measurement.

[d] Only main person conducting delivery was recorded.

[e] One examination in for which cadre was not recorded

[f] Nurse students except for one delivery by a cleaner

Physical space

The single-room labour ward was noisy and crowded, and consisted of women in all stages of labour and post-delivery. The number of women typically exceeded the number of beds, thus women often shared and changed beds. Although specific areas of the room were reserved for high risk women and specific stages of labour, this localisation was not consistently used. Two thirds of vaginal deliveries took place in the shared labour ward (64.3%, n=90/140), while 32.9% (n=46/140) reached the three-bed delivery room that had more privacy (Table 1).

Processes of routine care delivery

527 provider-woman contact points were observed during labour and delivery, which included 411 examinations consisting of FHRM (n=268), vaginal examinations (n=326), and other forms of care (n=116) (Table 3). Maternal blood pressure and/or temperature were measured at 180 of these time points. The median decision-delivery time interval for the 27 emergency operative deliveries was 60 (IQR: 25- 81) minutes.

Caring support

Labouring women were provided intermittent care collectively by the SBAs on duty. They often called for attention, especially during contractions and when they felt the need to push. This prompted examination and diagnosis of second stage of labour in the majority of women who delivered vaginally (95.0%, n=133/140). In more than a quarter of women (27.9%, n=39/140), support during second stage was not provided until ≤5 minutes before delivery; six of whom delivered unattended. Six of the 39 women were admitted with <4cm cervical dilatation and also went through the entire first stage of labour unobserved. Other actions associated with caring support, including use of a screen for privacy and communication during and after examinations (FHRM and/or vaginal examination) were conducted in 50.1% (n=206/411) and 34.1% (n=140/411) respectively. (Table 4)

Table 4. Adherence to local guidelines

	Adhered to local guidelines (frequency, %)		
	Low-risk	**High-risk**	**Total**
FHR monitoring	4/110 (3.6)	1/51 (2.0)	5/161 (3.1)
Maternal pulse palpation during FHR assessment	7/164 (4.2)	8/104 (7.7)	15/268 (5.6)
Timing of FHR with the clock	63/164 (38.4)	31/104 (29.8)	94/268 (35.0)
Contraction palpation during FHR assessment	24/164 (14.6)	19/104 (18.3)	43/268 (16.0)
Screen used for privacy	120/262 (45.8)	86/149 (57.7)	206/411 (50.1)
Communication after exam	85/262 (32.4)	55/149 (36.9)	140/411 (34.1)

Legend: FHR = Foetal heart monitoring, frequency was calculated per labour. Maternal pulse, timing and contraction is for each FHR assessment. Communication and use of screen is calculated for each time point of examination (FHRM and/or vaginal examination)

Routine monitoring of labour progress and foetal heart rate

The median duration of labour observation was 290 (IQR:135-570) minutes in which the median frequency of FHRM was one (IQR: 0-3) and of vaginal examination two (IQR:1-3). The median interval between two vaginal examinations in the first stage of labour was 125 (IQR 56-225) minutes. In none of the cases, the strength and frequency of contractions were assessed by 10-minutes palpation per abdomen.

Two-thirds of FHRM were conducted with a DeLee or Pinard stethoscope (69.4%, n=186/268; DeLee: n=117, Pinard: n=64, both: n=5). Ultrasound was primarily used in 23.5%, (n=63/268) of cases, while hand-held Doppler was rarely used (1.9%, n=5/268). In the remaining cases, ultrasound, following use of stethoscope, was used to confirm FHR (5.2%, n=14/268). In 37.9% (n=61) of labours, FHRM was only recorded on admission. For labours with more than one FHRM (n=254), the median interval between two FHRMs was 105 (IQR 57 -160) minutes, with 30% (n=76/254) of intervals within 60 minutes, and 42.5% (n=108/254) beyond two hours. The median interval between the last FHRM and delivery was 87 (IQR:41-170) minutes (Table 5). Of all FHRMs observed, they were counted with a clock in 35.0% (n=94/268), mmaternal pulse simultaneously palpated in 5.6% (n=15/268), and contraction palpated in 16.0% (n=43/268). The locally recommended one-hour frequency of FHRM was adhered to in 3.1% (n=5) women throughout labour (Table 4). There was no difference in last FHRM to delivery intervals between morning, evening, and night shifts. The presence of intrapartum risk events led to an increase in the number of FHRMs observed, with a rate ratio (RR) of 1.33 (CI 1.11-1.64), when a non-reassuring/abnormal FHR was detected (RR 1.59; CI 1.19-2.13), oxytocin was used (RR 1.25; CI 1.02-1.54, and when labour crossed the action line on the partograph (RR 1.25; CI 1.00-1.56) (Additional file 3).

Table 5. Times intervals between foetal heart rate assessments and vaginal examination

	Median(IQR)*
Foetal heart monitoring (hours and minutes):	
FHR interval between admission and next FHR assessment**	162(70-261)
FHR interval	100(51-193)
≤15minutes n(%)	23(9.1)
16 to ≤30 minutes n(%)	19(7.5)
31 to ≤60 minutes n(%)	34(13.4)
61 ≤ 120 minutes n(%)	70(27.6)
>120 minutes n(%)	108(42.5)
Overall last FHR to delivery interval	87(41-170)
Last FHR to delivery interval: Morning	83(35-145)
Last FHR to delivery interval: Evening	84(45-162)
Last FHR to delivery interval: Night	98(36-216)
Vaginal Examination time intervals in first stage	125(56-225)
≤2hours n(%)	188(47.7)
≤4hours n(%)	127(32.2)
>4hours n(%)	79(20.1)

* Unless otherwise specified, results are presented as median (IQR), **Excludes women admitted with < 4cm cervical dilatation

Discussion

This direct observation study reports on intrapartum care provided to 161 women in a congested tertiary hospital in Sub-Saharan Africa. It shows suboptimal birth attendance and adherence to local and international guidelines on timely care, including surveillance of the woman's vital signs, FHR, and labour progress. Substantial findings of this study were the discontinuous care. Lack of support and respectful care were reflected by a significant absence of communication, privacy, and support at the time of delivery. Structural challenges observed were high workload compared to staff numbers, an unconducive environment and scarcity of monitoring devices. However, despite this congested and unconducive environment, SBAs showed ability to provide evidence-based triage; they prioritised the monitoring of women who were recognised to have an intrapartum risk event (non-reassuring/abnormal FHR, oxytocin use, and crossing the action line) leading to a significant increase in frequency of FHR assessments.

Lack of attendance and delay in diagnosing second stage of labour in the majority of women was the rationale behind our conservative approach to determine FHRM guidelines adherence. We only compared FHRM to first stage expected frequencies, which were lower than second stage frequency. Although this approach underreports the problem, the findings highlight the challenge of adhering to guidelines in these settings. In other resource-limited settings of Sub-Saharan Africa, randomised control trials on innovative FHRM devices failed to show improvement in perinatal outcomes due to non-adherence to FHRM international guidelines and obstetric response.[21–24]

In this hospital, international guidelines were adapted to locally-acceptable minimum standards.[9] Compared to the situation before local guidelines were implemented, 20 months prior, there was sustained multiple improvements in monitoring: including higher FHRM frequency, notably in women with intrapartum risk events, more timely oxytocin use for augmentation, improved care for women with severe hypertensive disorders, and lower intrapartum stillbirth rates. [9,12] An earlier study showed that these guidelines were positively viewed and were used by local staff.[25] However, they are still far from being adhered to optimally which present an ethical dilemma of whether such guidelines can further reduce frequency of assessments.

Inadequate number of health workers, as reflected in the hourly mid-wife-to-labouring women ratio, remained the major bottleneck to following internationally agreed evidence-based standards of care optimally. For example, with one nurse-midwife attending four women simultaneously, there is insufficient time to palpate contractions in accordance to international recommendations (every 30 minutes for 10-minutes duration), not to mention time for any other care or rest. Providing support throughout birth was thus an overarching challenge, notably of women in early labour who were not considered as yet eligible for routine intrapartum care. However, women in general, including in Sub-Saharan Africa, favour continuous birth companionship.[26] Evidence suggests that it is the most significant intervention during birth associated with positive effects on perinatal outcomes and women's experience of birth.[27] As such the lack of support in this study, including in the second stage of labour, meant that women were likely to have had significant distress and negative birth experience. In addition to suboptimal care, this inevitably leads to a workforce with moral distress, burnout, and compassion fatigue hence, even less capable of giving compassionate care.[28]

In order to cope with the high workload, resident doctors performed a significant part of routine intrapartum care that is usually conducted by midwives. However, this may have impaired the ability to provide obstetric care to the large number of high-risk women and further disrupted midwifery-led supportive care. The lack of adequately trained SBAs, in particular nurse-midwives, may have been exacerbated by lack of inter-professional collaboration and supervision of junior staff, as well as by inefficient organisation of space, workforce and tools.[29] Consequently, care remained severely suboptimal and the stillbirth rate persistently high, emphasising the need to first improve the basic structure of care. Achieving minimal standards of care would require efficient allocation of available resources, organisation, supervision and teamwork as well as an adequate increase in human resources. Moreover, birth companionship is a challenge in open and overcrowded labour wards. Efforts should also be placed on how e.g. relatives and traditional birth attendants may assist the overstrained skilled birth attendants in providing continuous support during labour and delivery.

Strengths, limitations and ethical consideration

We here report the labour observation aspect of a broader work that included an ethnographic study and a locally co-created intervention to improve quality of labour care. Measurement of the quality of labour care is essential for identifying gaps, developing context-tailored interventions and monitoring of quality improvement processes. This unique systematic observation of intrapartum routine care overcomes the shortcomings of records-based studies in assessing quality of care. It allowed evaluation of the interactions between labouring women and their birth attendants, and the structural context care was provided in. The findings are supported by record-based quantitative PartoMa findings and also by mainly qualitative findings that showed similar suboptimal structural challenges to processes of care in numerous areas across Sub-Saharan Africa and other low resource-settings. [12,29–31] However, observations are more resource-consuming than record-based assessments, hold a higher risk of the Hawthorne effect, and may pose ethical dilemmas about the non-participatory nature of the observer and their moral responsibility to participant safety in understaffed settings. Thus, a trade-off of biased results for participant safety may be necessary. As the observers were not qualified birth attendants, they expressed any concerns on patient safety, including imminent delivery, to the staff on duty and in emergency situations, they assisted the staff when requested.

Observations show it was common practice for birth attendants to wait until signs of imminent delivery before attending to women in the second stage of labour. Thus a few women delivered unattended, as a result of preventable delays to respond to women's call for help and not the mere absence of skilled birth attendants from the labour ward.

Limitations included the observer bias and Hawthorne effect described above. Also, the study aimed to measure and identify challenges, rather than detect differences in outcomes for varying quality of care. Hence, it was still unable to determine the effect foetal monitoring has, if any, on birth outcomes.[16] The results should then lead to adequately-powered studies including clinical auditing in other LMICs to estimate the quality of the intrapartum (foetal) monitoring and linking it to birth outcomes. Moreover, we were not able to determine the effect of staff experience and time of day on the quality of care as women were cared for by several birth attendants across multiple shifts. The admission assessment was retrieved from the patient file and not observed. Numerous findings on admission which included smaller-than expected fundal height, undiagnosed twins, breech presentation, and intrauterine foetal death until close to delivery indicate inadequate risk assessment and suggests admission time as an important point for improvement to explore.

Conclusion

In this reality check of intrapartum care, the quality of basic routine care in a Tanzanian referral hospital remained unacceptable. It was not possible to provide respectful and safe care, and even to optimally follow locally adapted clinical guidelines, which took the local resources into account. This was particularly due to the disproportionate birth-attendant-to-labouring women ratio. Ensuring a safe and positive birth experience requires local stakeholders and international community to urgently address the structural barriers in Sub-Saharan Africa and invest in sufficient numbers of adequately trained and motivated staff for continuous support during labour.

Ethics approval and consent to participate Approval from the local ethics committee (ZAMREC) was obtained (ZAMREC/0002/May/016). Written informed consent in Swahili was sought from all participating women.

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Authors' contributions NH, MP, JB and MJR conceived and designed the experiment. NH, MP, AGM and SMS carried out data acquisition. NH, MP and NPAZ analysed the data. NH and MP interpreted the results with substantial contribution from JB, TM, NPAZ, AF and MJR. NH drafted the manuscript with substantial contribution from MP, JB, NM, TM, AF and MJR who revised the drafted manuscript on multiple occasions. All authors reviewed, approved and agreed to be accountable for the final version to be published.

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Additional file 1 Definitions of specific terms in the study
Additional file 2 Comparison of foetal and contraction monitoring recommendations in international, national and local (PartoMa) guidelines
Additional file 3 Predictors of the frequency of FHR** monitoring

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Chapter 11

Ethical dilemmas of direct observations of care in assessing quality in low-resource labour wards.

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We laud the efforts of Bohren et al for using standardised structured direct labour observations, triangulated with survey data, in a multi-national study to measure mistreatment during childbirth. Their findings show that four in ten women experience a type of abuse during labour.[1] Direct observations offer a unique opportunity to assess quality of care as they can capture the structural, clinical and experience of care dimensions.[2–4] However, the article by Bohren and colleagues could have benefitted from a discussion about how patietns' rights and welfare were upheld during observations.

Ethical dilemmas of observations depend on the type of observer (non-clinician or qualified clinician), his/her role in the clinical care process (non-participatory or participatory) and the clinical setting. For qualified clinicians, the non-participatory nature of observations may conflict with the bioethical principles of non-maleficence and beneficence that binds them to acting first as clinicians to patients participating in research, safeguarding their health, well-being and rights.[4,5] Although non-clinicians acted as observers in the study of Bohren et al, prior arrangements would have been necessary to address their perceptions of threat to participants' health and safety during observations.[6] Non-participatory observations may instigate negative feelings, including helplessness and discomfort, in a by-stander role that could result in psychological trauma for the observer and negative health-care experiences by patients if women feel ignored or neglected by observers especially in settings where privacy measures are absent.[4] Staff may also experience feelings of intimidation, being judged, blamed and a false sense of safety with the presence of clinically non-competent observers, or may alter their behaviour in care provision, risking patient safety and/or validity of the observations.[4,7]

Our experiences in measuring quality of care in a low-resource, busy, labour ward show various steps can be taken to make direct labour observation safe, respectable, and non-blaming. This includes consideration of observer selection and role especially in settings lacking clinicians, extensive training in (research) ethics to support the informed consent process and overall conduct, stakeholder engagement to establish trust and contextualise findings, establishment of protocols with guidance for the observer in case of emergencies, regular reflection throughout the research with open and supportive channels of communication, and availability of psychological support. [8,9] Given the number of dilemmas and sensitivity inherent to observations, specific ethical conduct guidance is required, based on principles of research ethics.[5,6]

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Part 4
Prediction of intrapartum perinatal deaths

Photo by Tarek Meguid

Chapter 12

The application of WHO ICD-PM: feasibility for the classification of timing and causes of perinatal deaths in a busy birth centre in a low-income country.

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Abstract

Objective To assess the feasibility of the application of International Classification of Diseases-10 - to perinatal mortality (ICD-PM) in a busy low-income referral hospital and determine the timing and causes of perinatal deaths, and associated maternal conditions.

Design Prospective application of ICD-PM

Setting Referral hospital of Mnazi Mmoja Hospital, Zanzibar, United Republic of Tanzania

Population Stillbirths and neonatal deaths with a birth weight above 1000 grams born between October 16th 2017 to May 31st 2018.

Methods Clinical information and an adapted WHO ICD-PM interactive excel-based system were used to capture and classify the deaths according to timing, causes and associated maternal complications. Descriptive analysis was performed.

Main outcome measures Timing and causes of perinatal mortality and their associated maternal conditions.

Results There were 661 perinatal deaths of which 248 (37.5%) were neonatal deaths and 413 (62.5%) stillbirths. Of the stillbirths, 128 (31%) occurred antepartum, 129 (31%) intrapartum and for 156 (38%) the timing was unknown. Half (n=64/128) of the antepartum stillbirths were unexplained. Two-thirds (67%, n=87/129) of intrapartum stillbirths followed acute intrapartum events, and 30% (39/129) were unexplained. Of the neonatal deaths, 40% died after complications of intrapartum events.

Conclusion Problems of documentation, lack of perinatal death audits, capacity for investigations, and guidelines for the unambiguous objective assignment of timing and primary causes of death are major threats for accurate determination of timing and specific primary causes of perinatal deaths.

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Introduction

With more than 5 million cases each year, perinatal death remains a significant global health problem. The countries with the highest absolute numbers of stillbirths and neonatal deaths are in Asia and sub-Saharan Africa [1]. Despite increasing attention and investment to address the main causes and to end preventable deaths, perinatal deaths are often poorly recorded and classified in low-income countries [2,3]. In response to the existence of over 80 widely varying classification systems of perinatal deaths in definition, classification of (underlying) causes of death, comprehensiveness, utilization, accessibility, reliability and alignment to WHO's International Classification of Diseases (ICD), the 'WHO application of ICD-10 to perinatal mortality' (ICD-PM) was developed [4,5]. ICD-PM is based on the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10). Its main purpose is to internationally harmonise the classification of perinatal deaths and produce data that can be used for targeting programmes that address perinatal mortality [5,6]. The three distinct features of the ICD-PM are 1) the capture of timing of death (antepartum, intrapartum or neonatal), 2) the multilayered approach for classification of the causes of death reflecting varying levels of available information depending on the setting, and 3) linking of the contributing maternal condition to the perinatal death. After pilot studies in middle-income country South Africa (SA) and the United Kingdom (UK), the ICD-PM was identified as a globally applicable perinatal death classification system

[6–8]. However, there is very limited experience of the use of ICD-PM in low-income countries, where the burden of perinatal deaths is greatest.

Since the WHO recommends using the ICD-PM on a global scale, we evaluated the feasibility of ICD-PM application in Zanzibar's tertiary hospital, a busy birth centre in a low-income country setting.

Methods

Study design

This study of perinatal deaths was linked to a prospective study of pregnant women who delivered between October 16th 2017 to May 31st 2018 at Mnazi Mmoja Hospital (MMH), Zanzibar, Tanzania.

Study setting

MMH is the only tertiary care hospital of Zanzibar and provides comprehensive obstetric and neonatal care around the clock. Approximately 11500 women deliver annually. The department was under-resourced and understaffed with an average ratio of birth attendants to labouring women of 1:4.[9] The stillbirth rate was 39 per 1000 total births and the neonatal mortality was unknown.[10] Intrapartum care was mainly provided in three shared labour rooms and three private delivery rooms. Intermittent auscultation with Pinard, hand-held Doppler and sometimes ultrasound was used for foetal heart rate assessment on admission and throughout labour. Babies with low Apgar scores, birth asphyxia, birthweights < 1500 grams or delivered by caesarean sections (CS) were referred to the upstairs Neonatal Intensive Care Unit (NICU) with a handover sheet. The NICU consists of three rooms: the neonatal care room with four radiant heaters, seven incubators and six cots; the observation room with 14 cots, and the kangaroo care room with eight beds. Two separate perinatal death certificates/notification forms existed. The first form recorded stillbirths and newborns who died immediately after birth in the maternity ward. It provided the following information: the parents' names, address and occupation, sex of the baby, type of pregnancy (single or multiple), date of birth, birth weight and whether the baby was born dead or alive. The second was a national WHO-adapted death certificate form that captured neonatal deaths in the NICU and recorded the mother's name and address, date and place of death as well as causes of death. In general, they were filled by nurse-midwives and doctors respectively. Once a week the neonatal deaths were discussed in the perinatal mortality meeting. Stillbirths were usually classified according to appearance of skin changes as either macerated or fresh, as commonly practised in low-income countries.[11] No routine investigations were performed to establish perinatal cause of death.

Patient selection

Cases of perinatal death were identified using the pre-existing MMH death certificates and selected using predefined inclusion- and exclusion criteria. All stillbirths and neonatal deaths born in MMH who died before discharge from the hospital with a birth weight above 1000 gram were included.[1] Perinatal deaths with a birth weight below 1000 grams were excluded. An exception was made for twins; if one of the babies weighed more than 1000 grams and the other one less, both babies were included. Also, deaths with an unknown birthweight were included in the study because babies weighing less than 1000 grams were not issued a birth notification or death certificate as they were considered miscarriages. Home deliveries, births before arrival to the maternity unit and referred neonates were excluded since the timing, cause of death and maternal condition would be impossible to determine.

Sources of information

The total number of live births was obtained from the hospital birth notification forms. The stillbirths and neonatal deaths were identified mainly using the MMH death certificates, which were routinely completed by the nurses. Additional stillbirths were manually searched through patient files and the hospital registry book. Determination of the timing and cause of death used information gathered from multiple sources such as maternal and neonatal files, nurses' reports, attending clinical meetings and perinatal and maternal mortality audits. Socio-demographic information, obstetric history and pregnancy characteristics were obtained from maternal and neonatal files. All perinatal deaths and the cases were anonymised with unique codes.

Application of the ICD-PM

Two reviewers (AS and NH) independently reviewed the information available and used the ICD-PM three-step to first assign the timing of death as antepartum, intrapartum or postpartum. Subsequently, the cause of death was assigned to one of the six, seven or eleven groups of ICD-PM perinatal cause of death under the antepartum, intrapartum and neonatal groups, respectively.[5] The main ICD-PM perinatal cause of death was then linked to ICD-10 codes of broad and specific causes of death. The third step in the process was to identify the main maternal condition or disease affecting the foetus or infant. Five main maternal groups exist and each group has subgroups to specify the maternal condition. The main perinatal and/or maternal condition was defined as the condition that started the chain of events leading to the death.[1] The definitions in S1 Table were used to standardise the classification. An obstetrician (MJR) helped resolve any disagreement between the two reviewers.

The WHO recommended interactive based Excel system (S1 Figure), ICD-PM documentation provided by WHO, and ICD-10 were used to extract and classify the perinatal deaths.[5] The excel system contains the minimum set of indicators for perinatal deaths, timing and ICD-PM and ICD-10 codes of causes of death. To assist the classification, we added extra columns in the excel system for the following information: mother's age, fresh/macerated stillbirth, foetal heart rate on admission (pre- or intra-hospital death), cervical dilatation on admission, whether the partograph was available and used, the mother's haemoglobin (Hb) on admission and the Apgar score after one and five minutes. For this study, various indicators were triangulated to classify the timing of stillbirth as antenatal or intrapartum:

the presence/absence of foetal heart rate or foetal heart activity on admission and/or during labour, and the physical appearance at birth (i.e.fresh or macerated).

When the timing remained unclear, an attempt was still made to determine the cause of death and the presence of maternal complications. As almost half of the women in Tanzania are anaemic and the prevalence is highest in Zanzibar,[12] we classified only severe anaemia (Hb <7.0 g/dl) as a maternal condition of ICD-PM group M4: maternal medical and surgical conditions (maternal circulatory and respiratory diseases).[13]

Feasibility

To assess the extent to which the ICD-PM classification can be practically carried out in this low-resource tertiary hospital, data sources were identified and challenges during data collection and classification process were systematically recorded.[14]

Analysis

Simple descriptive data analysis consisted of the mean (standard deviation (SD)), median (interquartile range (IQR)), and frequency (percentages) in SPSS version 23.

Details of Ethics Approval

This study was approved by the Zanzibar Medical Research Ethics Committee (ZAMREC/0004/AGUST/17). All information was retrieved from hospital records and thus no consent was sought from included women.

Results

Baseline characteristics

There were 9333 total births retrieved from the birth notification forms between October 16th 2017 to May 31st 2018. Of the 744 perinatal deaths found, 661 had a birthweight of ≥1000g and were born in MMH during the study period (Figure 1). This corresponded to an overall hospital-based perinatal death rate of 71 per 1000 total births (stillbirth rate of 44 per 1000 total births, n=413 and neonatal death rate of 27 per 1000 live births, n=248).

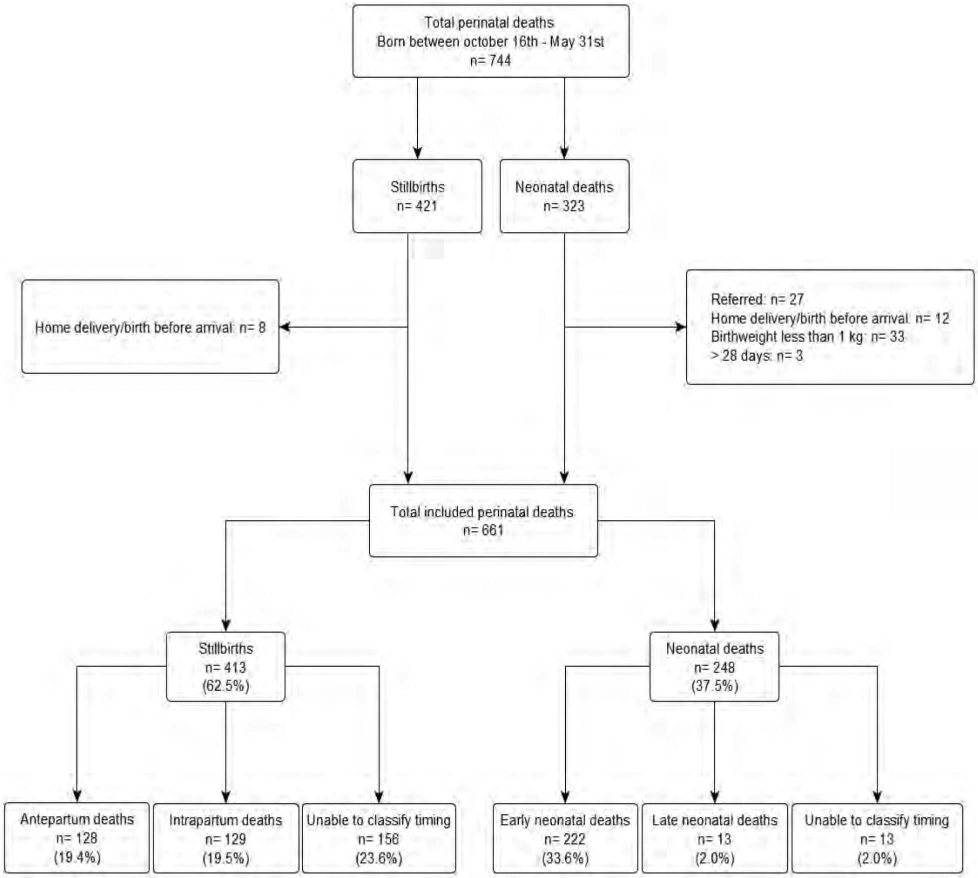

Figure 1 Flowchart of perinatal deaths

Table 1 Baseline characteristics of perinatal deaths

Variable		**Stillbirths n=413 (62.5)**	**Neonatal deaths n=248 (37.5)**	**All n=661 (100)**
Age	Mean (SD)	29.1 (6.6)	28.0 (6.2)	28.8 (6.5)
Residence	Urban	103 (24.9)	76 (30.6)	179 (27.1)
	Mixed	149 (36.1)	79 (31.9)	228 (34.5)
	Rural	80 (19.4)	49 (19.8)	129 (19.5)
	Unknown	81 (19.6)	44 (17.7)	125 (18.9)
Gravidity	Median (IQR)	3 (1-5)	2 (1-4)	2 (1-5)
Parity	Median (IQR)	2 (0-4)	1 (0-3)	1 (0-3)
Number of ANC visits	0	0 (0.0)	0 (0.0)	0 (0.0)
	1 – 3	158 (38.3)	50 (20.2)	208 (31.5)
	4 or more	104 (25.2)	54 (21.8)	158 (23.9)
	Unknown	151 (36.6)	143 (57.6)	294 (44.5)
Type of pregnancy	Singleton	376 (91.0)	179 (72.2)	555 (84.0)
	Twin	25 (6.1)	35 (14.1)	60 (9.1)
	Higher order multiple	2 (0.5)	3 (1.2)	5 (0.8)
	Unknown	10 (2.4)	31 (12.5)	41 (6.2)
Maternal HIV status	Positive	4 (1.0)	2 (0.8)	6 (0.9)
	Negative	271 (65.6)	173 (69.8)	444 (67.2)
	Unknown	138 (33.4)	73 (29.4)	211 (32.0)
Gestational Age	Preterm	98 (23.7)	78 (31.5)	176 (26.6)
	Term	47 (11.4)	49 (19.8)	96 (14.5)
	Postterm	12 (2.9)	4 (1.6)	16 (2.4)
	Unknown/fundal height only	256 (62.0)	117 (47.2)	373 (56.4)
Method of GA assessment	LMP	77 (18.6)	43 (17.3)	120 (18.2)
	USS	73 (17.7)	50 (20.2)	122 (18.5)
	Clinical examination/FH	129 (31.2)	60 (24.2)	189 (28.6)
	Unknown	134 (32.4)	95 (38.3)	229 (34.6)
Mode of delivery	SVD	243 (58.8)	137 (55.2)	380 (57.5)
	Vacuum	5 (1.2)	4 (1.6)	9 (1.4)
	Caesarean section	63 (15.3)	73 (29.4)	136 (20.6)
	Unknown	102 (24.7)	34 (13.7)	136 (20.6)
Sex	Male	216 (52.3)	136 (54.8)	352 (53.3)
	Female	187 (45.3)	110 (44.4)	297 (44.9)
	Unknown	10 (2.4)	2 (0.8)	12 (1.8)
Birthweight (g)	Mean (SD)	2439 (924)	2425 (1013)	2434 (958)
	<2500	180 (43.6)	112 (45.2)	292 (44.2)
	2500-3999	153 (37.0)	85 (34.3)	238 (36.0)
	≥4000	22 (5.3)	18 (7.3)	40 (6.1)
	Unknown	58 (14.0)	33 (13.3)	91 (13.8)

Values presented as number(percentage) unless otherwise specified.
ANC= antenatal care, GA= gestational age, LMP= last menstrual period, USS= ultrasonography, FH= fundal height, SVD= spontaneous vaginal delivery.

Baseline characteristics of the perinatal deaths are shown in Table 1. The mean age of the mothers was 28.8 (SD 6.5) years and the median parity one (IQR 0-3). The median number of ANC visits was 2 (IQR 1-5). The overall maternal HIV status was 0.9% (n=6/661). The mean birthweight of perinatal deaths was 2434 (SD 958) grams.

Timing of perinatal deaths

Of all 661 perinatal deaths, 62.5% (n=413) were stillbirths of which 31.0% (n=128) were antepartum, 31.2% (n=129) intrapartum and 37.8% (n=156) of unknown timing; and 37.5% (n=248) were neonatal deaths that occurred before hospital discharge. The most common reason for 'unable to classify the timing' (n=156) was missing maternal files (63.5%, n=99). (Figure 1 and Table 2)

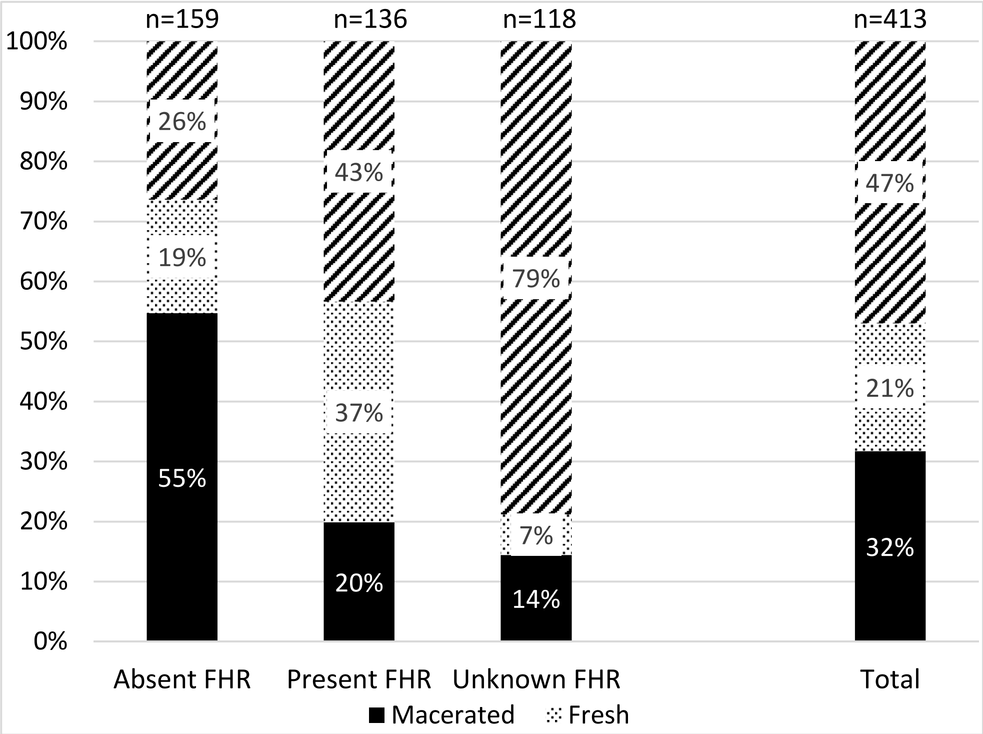

Figure 2. Proportions of stillbirths macerated, fresh and foetal heart detection

Table 2. ICD-PM main groups of perinatal causes of deaths and associated maternal conditions

Maternal condition	M1: Complications of placenta, cord and membranes	M2: Maternal complications of pregnancy	M3: Other complications of labour and delivery	M4: Maternal medical and surgical conditions	M5: No maternal condition identified	Unable to classify	Total (%)
Perinatal cause of death							
			Antepartum death (A)				
A1: Congenital malformations, deformations and chromosomal abnormalities	0	1	0	1	2	0	4 (3.1)
A2: Infection	0	0	0	1	0	0	1 (0.8)
A3: Antepartum hypoxia	19	1	1	38	0	0	59 (46.1)
A4: Other specified antepartum disorder	0	0	0	0	0	0	0 (0.0)
A5: Disorders related to foetal growth	0	0	0	0	0	0	0 (0.0)
A6: Foetal death of unspecified cause	5	7	0	2	50	0	64 (50.0)
Total (%)	24 (18.8)	9 (7.0)	1 (0.8)	42 (32.8)	52 (40.6)	0 (0.0)	**128 (100)**
			Intrapartum death (I)				
I1: Congenital malformations, deformations and chromosomal abnormalities	0	1	0	0	1	0	2 (1.6)
I2: Birth trauma	0	0	0	0	0	0	0 (0.0)
I3: Acute intrapartum event	27	2	24	26	8	0	87 (67.4)
I4: Infection	0	0	0	0	0	0	0 (0.0)
I5: Other specified intrapartum disorder	0	0	0	0	0	0	0 (0.0)
I6: Disorders related to foetal growth	0	1	0	0	0	0	1 (0.8)
I7: Intrapartum death of unspecified cause	0	5	3	0	31	0	39 (30.2)
Total (%)	27 (20.9)	9 (7.0)	27 (20.9)	26 (20.2)	40 (31.0)	0 (0.0)	**129 (100)**
			Stillbirths of unknown timing				
Unable to classify (%)	7 (4.5)	2 (1.3)	2 (1.3)	11 (7.1)	35 (22.4)	99 (63.5)	**156 (100)**
			Neonatal death (N)				
N1: Congenital malformations, deformations and chromosomal abnormalities	1	4	0	2	12	0	19 (7.7)
N2: Disorders related to foetal growth	0	0	0	0	1	0	1 (0.4)
N3: Birth trauma	0	0	0	0	0	0	0 (0.0)
N4: Complications of intrapartum events	17	2	25	16	38	0	98 (39.5)
N5: Convulsions and disorders of cerebral status	0	0	0	0	0	0	0 (0.0)
N6: Infection	1	0	1	4	7	0	13 (5.2)
N7: Resp. and cardiovascular disorders	3	4	1	9	17	1	35 (14.1)
N8: Other neonatal conditions	0	0	0	1	1	1	3 (1.2)
N9: Low birth weight and prematurity	2	10	0	5	5	0	22 (8.9)
N10: Miscellaneous	0	0	0	0	1	0	1 (0.4)
N11: Neonatal death of unspecified cause	0	1	1	1	9	0	12 (4.8)
Unable to classify	0	0	0	1	5	38	44 (17.7)
Total (%)	24 (9.6)	21 (8.5)	28 (11.3)	39 (15.7)	96 (38.7)	40 (16.1)	**248 (100)**
Total perinatal deaths (%)	82(12.4)	41(6.2)	58(8.8)	118(17.9)	223(33.7)	139(21.0)	661(100)

Causes of perinatal deaths and associated maternal conditions

The most common cause of perinatal death was hypoxia (Table 2). Hypoxia was classified as antepartum hypoxia for the antepartum deaths (46.1%, n=59/128), as acute intrapartum events for the intrapartum deaths (67.0%, n=87/129) and as complications of intrapartum events for the neonatal deaths (39.5%, n=98/248).

A third of mothers had no associated maternal complications (33.7%, n=223/661). The most common conditions were maternal medical and surgical conditions (17.9%, n=118/661), mainly hypertensive disorders (88.2%, n=105/118) and complications of placenta, cord and membranes (12.4%, n=82/661). There were sixteen maternal deaths associated with perinatal deaths. Files were missing in 21.0% (n=139/661) of mothers so maternal conditions could not be assigned for these cases.

Antepartum

Of the 128 antepartum deaths, half (50.0%, n=64/128) were classified as foetal deaths of unspecified cause, mostly to mothers without an identified condition (78.1%, n=50/64). In 46.1% (n=59/128) death followed after antepartum hypoxia. There were two main associated maternal conditions in these cases: maternal medical and surgical complications (64.4%, n=38/59), mainly hypertensive disorders, and complications of placenta, cord and membranes such as placental abruption and praevia (32.2%, n=19/59). (Table 2 and S1 Text: Case 5)

Intrapartum

Of the 129 deaths that occurred intrapartum most followed an acute intrapartum event (67.4%, n=87/129). These deaths were often associated with a maternal condition (90.1%, n=79/87): complications of placenta, cord and membranes (31.0%, n=27/87) mainly placental abruption and cord prolapse; maternal medical and surgical conditions (29.9%, n=26/87), often hypertensive disorders; and other complications of labour and delivery such as malpresentation, malposition and disproportion and uterine rupture (27.6%, n=24/87). In addition, 30.2% (n=39/129) deaths were of unspecified cause often with unknown events between the last foetal heart rate and delivery (Table 3 and S1 Text Case 6). No maternal complication was identified in 79.5% (n=31/39) of the mothers with stillbirths of unspecified cause and in 31.0% (n=40/129) of all intrapartum deaths. (Table 2)

Neonatal deaths

The neonatal deaths were classified as either early (89.5%, n=222/248) or late neonatal deaths (5.2%, n=13/248). The most common perinatal causes of death were complications of intrapartum events, including birth asphyxia and intrauterine hypoxia (39.5%, n=98/248) and respiratory and cardiovascular disorders (14.1%, n=35/248). No maternal complication was identified for 38.7% (n=96/248) of mothers; 15.7% (n=39/248) had a maternal medical and surgical condition, commonly hypertensive disorders (Table 2).

Feasibility of ICD-PM implementation

Issues with implementing ICD-PM in this setting are highlighted in in Figure 2, Table 3 and are also illustrated with specific examples in S1 Text. The most common reason for 'unable to classify' either the timing or cause was missing files. Also, there were difficulties in determining the timing of perinatal death especially due to non-documentation and conflicting evidence. For example, 22% (n=93) of stillbirths had no documentation of both foetal heart rate and maceration. Also, the appearance of stillbirth (macerated/fresh) was unknown in nearly half of the number of cases (47%, n=194) and thus the recording of foetal heart rate classified more stillbirths. In addition, 14% (57) of stillbirths had conflicting evidence of foetal heart rate and skin appearance (macerated/fresh, Figure 2 and S1 Text Case 1). S1 Text

Table 3. Issues in implementing ICD-PM in a low-resource setting

Issue	Description	Potential solutions
Unable to classify timing of death due to missing or conflicting data	Poor monitoring or documentation of: foetal heart rate (FHR), maceration, and cervical dilation e.g.: - Inadequate intrapartum assessment of women who arrive in early or advanced stage of labour (Text S1, Case 2 and 3). - No FHR or appearance of stillbirth recorded, only Apgar score - Conflicting data of FHR and maceration stillborn baby (fresh/macerated). - Only one FHR usually recorded in multiple gestation (Text S1, Case 4). - Vaginal examination not performed, mostly due to per vaginal bleeding. - Missing files	At a clinical level: FHR (on admission and labour) and stillborn appearance should be assessed and documented accurately. Filing system in place for proper storage of files. ICD-PM classification system: Develop standardised and operationalised definition for determining timing of death as antepartum and intrapartum stillbirths.
Unable to assign code to perinatal deaths of unknown timing	Determining timing of death is a pre-requite to assigning ICD-PM categories of perinatal causes of death; if timing is unknown you cannot assign cause of death. (Text S1, Case 1-4)	Develop a new category for perinatal death of unknown timing e.g. as suggested by Aminu et al.[14]
High proportion of antepartum deaths of Unspecified causes	A high proportion of antepartum deaths were of unspecified causes and no identified maternal condition (Text S1, Case 5). This may be due to missing data. However, similar findings were seen across settings (including high income countries).	ICD-PM classification system: difficult to make suggestions since other perinatal death classifications also have high proportion of unspecified antepartum death. At a clinical level: improve history taking, physical examination and investigations. ICD-PM classification system: especially for low resource setting it may be programmatically useful to identify modifiable causes of death in the antenatal period
Intrapartum deaths of Unspecified cause of death	A high proportion of intrapartum deaths were of unspecified causes which could be related to suboptimal quality of intrapartum care (Text S1, Case 6).	Modifiable causes are not captured in ICD-PM system. Especially for low resource setting it may be programmatically useful to include a separate category for modifiable causes such as delay in monitoring and intervening.
Variable interpretation of causes of death	This occurs when there are competing perinatal conditions present e.g. in cases of birth asphyxia and meconium aspiration; prematurity/low birth and respiratory and circulatory disorders (Text S1, Case 7). There may also be competing maternal conditions present e.g. the presence of hypertension and placental abruption /twin pregnancy/complications of labour and delivery (Text S1, Case 8 and 9)	Although ICD-10 defines main cause of death as the condition that started the chain of events leading to the death, it can be difficult to determine primary cause. Thus, further guidance and criteria for assigning cause of perinatal death may be required as suggested by Goldenberg et al.[23] Training of staff to use ICD-PM may reduce subjectivity.
Unable to classify ICD broad and specific categories of causes of death	After identifying ICD-PM broad groups of causes of perinatal death, it is important to identify specific causes of death but missing data limited further classification..	At a clinical level: improved history taking, physical examination, documentation and investigations.

Assigning the primary cause of death in neonates with multiple events was challenging. For example, in babies with very low Apgar score after birth and meconium-staining of the liquor, we consistently assigned birth asphyxia over meconium aspiration as the cause of death because it was difficult to differentiate between the two (S1 Text, Case 7). It was also difficult to diagnose intrauterine growth restriction because gestational age was often unknown (56.4%, n=373/661) due to unknown last menstrual period and absent (early) dating scan. In addition, problems were encountered in assigning specific ICD-PM maternal conditions considered to contribute most to the perinatal death when competing conditions were present e.g. abruption placenta was often associated with hypertensive disorders. (Table 3 and S1 Text Cases 8 and 9).

Discussion

Main findings

Using a cohort of 661 perinatal deaths, we evaluated the feasibility of ICD-PM application in a busy birth centre in a low-income country setting. Nearly two-fifths were neonatal deaths, and three-fifths were stillbirths. A large proportion of stillbirth (38%) had unknown timing and of those with known timing, half occurred antepartum and half were intrapartum. Half of the number of antepartum deaths were unexplained and 67.4% and 39.5% of intrapartum and neonatal deaths, respectively, occurred after intrapartum events. Often mothers were healthy across all three time periods, although the most frequent maternal complications were medical and surgical conditions (mainly hypertensive disorders (16%)) and complications of placenta cord and membranes. Although useful in capturing main causes of death and associated maternal conditions, the feasibility of using ICD-PM and other perinatal death classification systems in a busy low-resource hospital, like MMH, is hugely dependent on diagnostic capacity, documentation and record-keeping practices.

Strengths and limitations

We applied the ICD-PM to all perinatal deaths in a busy referral birth centre in a low-income country. In doing so, we carried out the largest ICD-PM study to date that includes both stillbirths and neonatal deaths in a low-resource setting. We also clearly demonstrated in detail, with specific examples, the issues that exist in implementing the ICD-PM classification and offered recommendations at various levels to improve its applicability in in low-resource settings (Figure 2, Table 3 and S1 Text). We were able to accurately determine the perinatal mortality rate in this hospital and assign main causes of death. Prior to this study the neonatal mortality rate was not available. The independent review process reduced misclassification. However, there was a much higher rate of missing information compared to other ICD-PM studies. There was no filing system in place leading to misplacement of files and as such the most common reason for 'unable to classify' was missing maternal files. Missing information was also due to inadequate assessment and undocumented observation, e.g. of foetal heart rate, low Apgar score, birth weight and maceration/fresh [15] - which is also a likely contributor to poor birth outcomes. Also, in this hospital, due to the high number of stillbirths and neonatal deaths, only selected neonatal deaths were discussed in audit meetings which were also held and attended irregularly and many times lacked the people involved in routine care.[16] The issue of missing information likely caused misclassification of timing and causes of perinatal deaths. Efforts were made to reduce the rate of missing data by using multiple data sources including: maternal files, death certificates, clinical and audit meetings and daily report books. In addition, the results obtained and the need to improve clinical documentations and record-keeping were shared with hospital staff during perinatal deaths audits.

Interpretation

Tanzania is a major contributor to the global burden of perinatal and maternal mortality [17]. The institutional perinatal death rate of this referral hospital was very high, and therefore the rates highlighted in this manuscript were not comparable to national levels [18]. While the stillbirth rate was comparable to those found in various Sub-Saharan Africa hospitals, the neonatal death rate was much higher in this high-volume low-resource referral hospital [19]. An overview of timing and causes of perinatal deaths in ICD-PM studies performed in low-, middle- and high-income countries is shown in S2 Table [6,20–22]. In these studies, in the UK and SA where women received better intrapartum care, almost all stillbirths were antepartum (91%, 81-82%), and in line with our findings, at least half of stillbirths in low-income countries were intrapartum (51-78%) – a picture that resembles national and global estimates [17,23–25]. Although the rates vary, stillbirth classifications, including ICD-PM (50-89%), show that most antepartum deaths were of unspecified cause and without identified maternal condition particularly in low and middle income countries [3,17,26]. This presents a global challenge in identifying causes of perinatal deaths and targeted interventions in the antenatal period.

In our study, while the perinatal cause of death was often hypoxia, we identified hypertensive disorders and 'complications of placenta, cord and membranes' as important maternal conditions associated with perinatal deaths across all periods – these findings are similar to other studies including ICD-PM [17]. Thus, linking perinatal deaths to maternal conditions in the ICD-PM classification identifies areas for interventions to prevent perinatal deaths – a major strength of ICD-PM [3,6,17,26]. Although it is difficult to estimate gestational age in low resource settings, prematurity and/or low birth weight was an important cause of neonatal death across all the studies (29-37%) which emphasises the fact that preterm labour is a global target for intervention to reduce perinatal deaths [27,28]. Specifically, for low and middle-income countries, the high numbers of stillbirths and neonatal deaths related to intrapartum causes identifies this period as highest risk and for quality improvement programmes [3,15,29,30].

Subjectivity of methods used for classification across studies and varying quality of data may partly explain the differences observed between ICD-PM studies. While ICD-PM is readily applicable to settings with established country-wide perinatal surveillance and classification systems, challenges exist in accurate application in low-income settings [6,20–22]. In low-income countries, missing information on obstetric history and clinical data presents a widespread threat to the application of the various perinatal classifications and identifying specific causes of death with up to 57.4% of stillbirths remaining unclassified [21,22,26]. Missing files, undocumented or conflicting evidence between foetal heart rate and appearance of stillborn (macerated/fresh) leads to problems in the determination of the timing of stillbirths (Table 3) – the first step in the ICD-PM classification without which assigning ICD-PM perinatal cause of death is impossible [11,15,22,31]. Studies showed that foetal heart assessment by auscultation, particularly on admission, was a reliable means of determining foetal viability and timing of stillbirth [15,16,32]. Yet, as we have also shown in previous studies, conflict of foetal heart rate detection and skin appearance of stillbirth occur and is preventable with adequate assessment e.g. of foetal heart rate on admission [9,15].

Although death certificates and perinatal death audits are central in gathering information for ICD-PM classification [5,33], many neonatal deaths and stillbirths are still not recorded or issued death certificates in low resource settings [33]. This is not the case in MMH hospital where we commend the use of death certificates and distinction between stillbirths and neonatal deaths. However, death certificates were often incomplete, and missing relevant perinatal indicators such as gestational age, birth weight, causes of stillbirths and maternal complications. Apart from obstetric history and clinical data, accurate determination of the cause of death may also require laboratory tests, imaging, and autopsy which were (commonly) absent in all ICD-PM studies in low-income countries [34], making it more difficult if not impossible to accurately determine important causes of death such as infections and congenital anomalies.[34–36] A study in Mozambique found that minimally invasive tissue sampling showed a large concordance with complete autopsy and could be useful for the determination of the cause of death in low-income countries [37].Other challenges may also be inherent to the ICD-PM and other classification systems. There was ambiguity in assigning primary cause of death when two or more competing primary causes of death or associated maternal complications are applicable e.g. abruption placenta was often associated with hypertensive disorders and birth asphyxia with meconium [34]. Also, an extension of the ICD-PM system is required to capture potentially modifiable factors such as delays in monitoring and providing emergency obstetric and newborn care in these type of settings. It remains to be seen how ICD-PM can be incorporated in perinatal death audits for better capture and analysis of perinatal deaths and continuous quality improvement. With the overwhelming number of deliveries, the lack of staff in this setting remains a major contributing factor to perinatal deaths and is multi-level obstacle limiting the application of perinatal death classifications including ICD-PM in routine clinical practice.

Conclusion

It was possible to determine maternal medical and surgical conditions, hypertensive disorders in particular, and intrapartum events as major causes of both intrapartum stillbirths and neonatal deaths in a busy maternity unit in a low resource setting. However, a high number of perinatal deaths were classified as deaths of unspecified timing and cause. In low-income countries, missing clinical information and investigations are the major threats to perinatal death classifications. Thus, better clinical assessment and documentation from the time of admission, including foetal heart rate, is crucial. There is a need to train additional staff, strengthen death certificate record-keeping and perinatal death audits of both stillbirths and neonatal deaths according to established guidelines, accompanied by the prospective use of the ICD-PM system. Lastly, global applicability of ICD-PM requires standardised operationalised definitions and harmonised guidance on assigning timing of death and primary and contributory causes of death, including when the time of death remains unknown.

Disclosure of interests The authors have no conflict of interest.

Contribution to Authorship NH, AS, JB and MJR conceived and designed the study. NH, AS and MB carried out data acquisition. AS and NH analysed the data and interpreted the results. AS and NH drafted the manuscript. MB, TM, JB and MJR revised the drafted manuscript. All authors reviewed, approved and accept responsibility for the paper as published.

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S1 Table: Definitions of terms used during classification

Term	Definition
Timing of perinatal death	
Antepartum	Foetal death at ≥28weeks of gestation or birth weight ≥1000g that occurred before the start of labour
Intrapartum	Foetal death at ≥28weeks of gestation or birth weight ≥100g that occurred during childbirth
Neonatal death	Newborn death that occurred before hospital discharge
Early neonatal death	Neonatal death that occurred within 7 days of birth
Late neonatal death	Neonatal death that occurred between 8-28 of birth
Unable to classify the timing	If no information was available to determine timing, for example, because of missing files, unmeasured foetal heart rate or contradicting evidence
Macerated stillbirth	A stillbirth that shows skin and soft tissue changes such as redness, peeling, skin discolouration
Fresh stillbirth	Stillbirth with intact skin and other no signs of maceration
Main perinatal causes of death	ICD-PM groups of the main condition in the foetus/newborn according to the timing of death
Perinatal death of unspecified cause	No information is available that would permit a more specific cause of death to be assigned
Unable to classify cause of perinatal death	Perinatal deaths with missing files and no information for classification
Miscellaneous causes	Neonatal deaths that appeared to have multiple contributing factors leading to the death and unable to establish the main cause of death
Maternal condition	ICD-PM groups of main maternal complication that is closely linked as a cause of the perinatal death

S1 Text: Examples of cases that illustrate challenges in applying ICD-PM classification

Unable to classify timing of death

Conflicting data of FHR and maceration stillborn baby (fresh/macerated).

Case 1: A gravida 5 para 4 was admitted in labour pain. On admission, her blood pressure was 135/82, pulse rate 7, haemoglobin of 8.1 g/dL, fundal height was 29cm, FHR of 136bpm and cervix was 3cm dilated. She delivered a macerated baby weighing 1800g. The timing of the death couldn't be classified for this case, and thus neither the cause of death. No major maternal condition seemed present so the maternal condition assigned was M5: no maternal condition.

Inadequate intrapartum assessment of women who arrive in early or advanced stage of labour

Case 2: A prime gravida was admitted to the labour ward with blood pressure was 142/92, pulse 104 bpm and haemoglobin of 13.6. Fundal height was 32cm, FHR was 150bpm and the cervix was closed on admission. No further assessments were documented and it was unknown when labour started and how long after admission she delivered. She delivered macerated stillborn weighing 1700g. The timing of the death couldn't be classified for this case, and thus neither the cause of death. The maternal complication was classified as M4: maternal medical and surgical conditions (foetus and newborn affected by maternal hypertensive disorders).

Case 3: A gravida 2 para 1 was admitted to the labour ward. She was fully dilated on admission and assessments such as foetal heart rate, blood pressure, haemoglobin measurements were not done. She delivered a stillborn female baby with a birth weight of 2400 grams. The timing of the death couldn't be classified for this case, neither the cause of death. No major maternal condition seemed present so the maternal condition assigned was M5:no maternal condition identified.

Only one FHR usually recorded in multiple gestations

Case 4: A gravida 4 para 3 was admitted in labour pain with a twin pregnancy and gestational age of 40+0 weeks by last menstrual period. On admission, blood pressure was 176/125, FHR was 145 bpm and only recorded for one baby (unknown which one) and cervix was 2cm dilated with a breech presentation of the first twin. The next and last FHR of only one of the babies was recorded 5 hours later when she was 4 cm dilated. The mother delivered vaginally 9 hours after onset of labour. The first baby was alive with Apgar score of 7 at one minute and 9 at ten minutes. The second baby was a macerated stillbirth. Both weighed 2900 g. We were unable to determine timing of the stillbirth as antepartum or intrapartum and also the perinatal cause of death. The maternal complication was classified as M5: maternal medical and surgical conditions (foetus and newborn affected by maternal hypertensive disorders).

Antepartum deaths of Unspecified cause of death

Case 5: A gravida 1, para 0 with a gestational age of 30 weeks by fundal height was admitted. On admission, the FHR was absent while the cervix was 1 cm dilated. She delivered a male baby of 2200 g, no information about the appearance of the baby was written down. The timing was assigned as antepartum and the cause of death as A6: foetal death of unspecified cause. No maternal condition was reported so the maternal condition was classified as M5: no maternal condition identified.

Intrapartum deaths of Unspecified cause of death

Case 6: A gravida 1 para 0 was admitted to the labour ward. The foetal heart rate on admission was 140 beats per minute and the cervical dilation was 2cm. On the partograph the last foetal heart rate of 130 bpm was recorded 2 hours before delivery when the cervical dilatation was 9cm. A stillborn male baby with a birth weight of 3400 grams was born. It remains unclear what happened between the last recorded foetal heart rate and delivery. The timing for this case was classified as 'intrapartum' and the cause of death was assigned as I7: foetal death of unspecified cause since not enough information was available to determine the cause of death. The mother was considered healthy so the maternal condition was classified as M5: no maternal condition identified.

Variable interpretation of causes of death

Case 7: A gravida 1 para 0, 40+5 weeks known by using the last menstrual period was admitted to the hospital. During labour there were non-reassuring FHR and thick meconium. A caesarean section was done due to foetal distress. A 2800gram female baby was born with an Apgar score of four in one minute and six in five minutes. The neonate was referred to the NICU where the following vital signs were measured: temperature 34.5 ℃, saturation 73% and a pulse rate 121 beats per minute. Also, meconium secretions were removed from the mouth. The baby started convulsing and de-saturating the same day, she died one day later. The timing of death was classified as early neonatal. There were two possible perinatal causes of death: N4: Complications of intrapartum events (birth asphyxia) and N7: Respiratory and cardiovascular disorders (meconium aspiration). The cause of death was assigned as N4: complications of intrapartum events (birth asphyxia). The mother was considered healthy so the maternal condition was classified as M5: no maternal condition identified.

Case 8: A gravida 3 para 1 presented to the labour ward with a twin pregnancy at 33 weeks of gestation (by LMP). On admission, blood pressure was 134/116 with proteinuria, FHR were absent and cervix was 6cm dilated. She delivered vaginally soon after and both twins were male fresh stillbirths and weighed 1300g and 1500g. Post-delivery the mother was diagnosed with pulmonary oedema due to peripartum cardiomyopathy. The timing of the death was intrapartum. The ICD-PM group of perinatal death was acute intrapartum event (intrauterine hypoxia). There were multiple maternal conditions identified: M2: Maternal complications of pregnancy (twin pregnancy); M3: Other complications of labour and delivery (preterm labour and delivery); and M:4 maternal medical and surgical conditions (Foetus and newborn affected by maternal hypertensive disorders). We chose the latter as the main maternal condition affecting the foetus.

Case 9: A gravida 2 para 1 presented to the labour ward with pregnancy at 37weeks of gestation (by ultrasound). On admission, blood pressure was 173/115 with proteinuria and several symptoms of severe preeclampsia. FHR was 135 bpm and cervix was 3cm dilated. She developed PV bleeding 7 hours after admission. After another 5 hours, she delivered vaginally, male fresh stillbirths and weighing 2500g. The timing of the death was intrapartum. The ICD-PM group of perinatal death was acute intrapartum event (intrauterine hypoxia). There two maternal conditions identified were: severe preeclampsia and abruptio placenta. The maternal complication was classified as maternal medical and surgical conditions, specific group “Foetus and newborn affected by maternal hypertensive disorders”.

S2 Table. Main causes of perinatal deaths in the ICD-PM studies (6,20–22)

		High-income countries	Middle- and low- income countries				
		United Kingdom (2016)	South-Africa (2016)	South Africa (2018)	Multicountry* (2019)	Zambia (2019)	Tanzania (Zanzibar,2020)
Number of total deaths		9067 perinatal deaths	689 perinatal deaths	26810 perinatal deaths	1267 stillbirths	75 perinatal deaths	661 perinatal deaths
Timing of death	Antepartum	48.3%	50%	58.2%	42%	9.3%	19.4%
	Intrapartum	5%	11%	14.0%	50.7%	33.3%	19.5%
	Neonatal	46.7%	39%	27.8%	-	57.3%	37.5%
	Unable to classify	0%	0%	0%	7.3%	0%	23.6%
Main causes antepartum deaths		-Foetal death of unspecified cause (A6) 60% -Congenital malformations, deformations and chromosomal abnormalities (A1) 22%	-Antepartum Hypoxia (A3) 53% -Foetal death of unspecified cause (A6) 42%	-Foetal death of unspecified cause (A6) 67.5% -Other specified antepartum disorder (A4) 18.9%	-Foetal death of unspecified cause (A6) 89% -Infections (A2) 8.6%	-Foetal death of unspecified cause (A6) 71% -Antepartum Hypoxia (A3) 14% -Congenital malformations, deformations and chromosomal abnormalities (A1)14%	-Foetal death of unspecified cause (A6) 50.0% -Antepartum Hypoxia (A3) 46%
Main causes intrapartum deaths		-Acute intrapartum event (I3)65% -Intrapartum death of unspecified cause (I7) 26%	-Acute intrapartum event (I3) 93%	-Acute intrapartum event (I3) 69.2% -Intrapartum death of unspecified cause (I7) 10.0%	Intrapartum death of unspecified cause (I7) 61% -Acute intrapartum event (I3) 31%	Acute intrapartum event (I3) 84% -Congenital malformations, deformations and chromosomal abnormalities (A1) 16%	-Acute intrapartum event (I3) 67% -Intrapartum death of unspecified cause (I7) 30%
Main causes neonatal deaths		-Low birth weight and prematurity (N9) 32%, -Congenital malformations, deformations and chromosomal abnormalities (N1) 27% -Neonatal death of unspecified cause (N11) 27%	-Respiratory and cardiovascular disorders (N7) 35% -Low birth weight and prematurity (N9) 29%	Complications of intrapartum events (N4) 29.3% -Low birth weight and prematurity (N9) 28.5% -Respiratory and cardiovascular disorders (N7) 19.2%		-Complications of intrapartum events (N4) 44% -Low birth weight and prematurity (N9) 37%	-Complication of intrapartum events (N4) 40% -Respiratory and cardiovascular disorders (N7) 14.4%
Main maternal condition		M5: 49.8% M1:21% M2: 10.6%	M5: 36% M4: 25.7% M3: 17.9%	M4: 32.7% M5: 31.1% M1: 17.8%	M1: 26.7% M3: 25.5% M5: 23.7%	M3: 53.5% M5: 34.9% M2: 9.3%	M5: 33.7% M4: 17.9% M1: 12.4%

*Kenya, Malawi, Sierra Leone and Zimbabwe

Abbreviations: M1= Complications of placenta, cord and membranes, M2= Maternal complications of pregnancy, M3=Other complications of labour and delivery, M4= Maternal medical and surgical conditions, M5= No maternal condition identified

Search string in PubMed on 30/01/2020:

((("stillbirth"[MeSH Terms] OR "stillbirth"[All Fields]) OR ("perinatal death"[MeSH Terms] OR ("perinatal"[All Fields] AND "death"[All Fields]) OR "perinatal death"[All Fields] OR ("perinatal"[All Fields] AND "deaths"[All Fields]) OR "perinatal deaths"[All Fields])) OR ("perinatal death"[MeSH Terms] OR ("perinatal"[All Fields] AND "death"[All Fields]) OR "perinatal death"[All Fields] OR ("neonatal"[All Fields] AND "deaths"[All Fields]) OR "neonatal deaths"[All Fields])) AND ((("classification"[Subheading] OR "classification"[All Fields] OR "classification"[MeSH Terms]) OR ("international classification of diseases"[MeSH Terms] OR ("international"[All Fields] AND "classification"[All Fields] AND "diseases"[All Fields]) OR "international classification of diseases"[All Fields])) OR ICD-PM[All Fields]) AND (("2016/01/01"[PDAT] : "2020/01/31"[PDAT]) AND "humans"[MeSH Terms])

Chapter 13

Prediction of perinatal death in low resource settings: external validation and development of a prediction model

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Abstract

Objectives To develop a clinical prediction model to identify patients at risk of intrapartum-related perinatal deaths in low-resourced settings, by (1) external validation of an existing prediction model, and subsequently (2) development of a novel model.

Study design Prospective cohort study

Setting Maternity unit of Zanzibar's tertiary hospital, Mnazi Mmoja Hospital, the Republic of Tanzania.

Participants 5610 pregnant women who presented consecutively at the maternity unit for delivery between October 2017 and May 2018.

Predictors and outcomes Candidate predictors included antenatal and intrapartum maternal and foetal characteristics obtained from routine history and physical examination at the time of admission to the labour ward. The outcomes were intrapartum stillbirths and neonatal before hospital discharge.

Statistical analysis An existing stillbirth prediction model was applied to the Zanzibar cohort to assess its discrimination and calibration performance. A new prediction model was developed using multivariable logistic regression. Model performance was evaluated through internal validation and corrected for overfitting using bootstrapping methods.

Results The original model showed poor predictive performance (c-statistic 0.57(0.56-0.58)). The new model consisted of 15 clinical predictors and showed very good calibration and high discriminative ability before and after internal validation (c-statistic of 0.80 and 0.78, respectively).

Conclusion The new model consisted of predictors easily obtained through history-taking and physical examination. It had good performance in predicting risk of perinatal death in women admitted in labour wards. Therefore, it has the potential to assist skilled birth attendance to triage women for appropriate management during labour. Before routine implementation, external validation and usefulness should be determined in future studies.

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Introduction

The majority of the five million perinatal deaths globally occur during intrapartum care in resource-poor countries and are avoidable.[1–3] Most of intrapartum-related deaths can be averted by identification and appropriate management of women at high risk of labour complications, skilled birth attendance for monitoring throughout childbirth and effective interventions such as emergency obstetric and new-born care.[4] However, skilled birth attendants (SBA) in low-resource settings encounter substantial challenges due to the high volume of labouring women, inadequate number of trained staff, insufficient amount of equipment and supplies, and lack of space.[5,6] As a result, labour support, monitoring and timely management for all women is often impossible.

The first contact with an SBA on admission to the labour ward is a key moment in intrapartum care.[7,8] Evidence suggests that clinical tests performed on admission such as cardiotocography, intermittent auscultation and maternal perception of foetal movement could be useful in low and middle income countries (LMIC). This is because these countries tend to have inadequate screening and care during antenatal and intrapartum periods, resulting in a higher incidence of intrapartum-related morbidity and mortality.[9] As such, clinical tests performed on admission could identify high-risk foetuses early and triage them for appropriate monitoring and management strategies More generally, risk stratification upon admission may help to optimize resource allocation in settings with heavy workload and scarce (human) workforce. Ideally, risk stratification is not merely based on the results from a single test, but also accounts for multiple maternal and foetal characteristics. [7,8,10–14] Yet, prognosis models that combine multiple predictors to identify women at risk of adverse birth outcomes for prompt interventions are extremely rare in LMIC.[15]

The overall aim of this study was to contribute to the development and evaluation of low-cost, easily-applicable prognostic models for predicting perinatal deaths, through 1) external validation of an existing model for stillbirth; 2) improvement of the performance of this existing model in the new clinical setting if required; and 3) development and internal validation of a new prediction model for perinatal deaths if necessary.

Methods

Description of the original dataset

The reporting of the study adheres to the TRIPOD guidelines (Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis).[16] First, we performed an external validation and updating of a previously published prognostic model for stillbirths in Nigeria.[17] Briefly, this model was developed in a retrospective cohort of 6,573 pregnant women in the Federal Medical Centre Bida, a tertiary hospital in Niger state, Nigeria, from January 2010 to December 2013. There were 443/6,956 (6.4%) stillbirths, defined as birth of a baby who died intrauterine after 20 completed gestational weeks. The original prediction model was developed using multivariable logistic regression and comprised of six predictors.[17] After internal validation, the model showed excellent performance in terms of discrimination (C-statistic: 0.80, 95 % CI 0.78-0.83) and calibration in predicting stillbirths.[17]

Description of validation and new model development dataset

The dataset collected for this study comprised a prospective cohort of labouring women at gestational age of ≥ 28 weeks, consecutively recruited as they were presented for delivery at the maternity unit of Zanzibar's tertiary hospital, Mnazi Mmoja Hospital, the Republic of Tanzania between October 2017 and May 2018. The following women were excluded from the study: confirmed intrauterine foetal death before or at the time of admission to the maternity unit and women who did not undergo intrapartum care in the hospital, i.e. women admitted for elective or emergency caesarean section or post-delivery.

Sources of data

At the time of admission, trained research nurses collected routinely-measured predictors from antenatal care (ANC) card, history from the patient, in-patient file, and results of physical examination as assessed by routine nurses and they assessed outcomes mainly using in-patient files in the maternity and neonatal care units. For the variable of maternal perception of foetal movement, a specific questionnaire was newly-developed (supplementary file 1). Answers were recorded on a pilot-tested paper form, and visually inspected for inconsistencies and missing information. Corresponding data were then entered in a password-protected preformed electronic database (KobotoolBox).

Outcomes

For validation of the existing model, the outcome was stillbirth, and defined as intrapartum death ≥28 weeks gestational age, in line with the WHO definition as this is more applicable in LMICs.[12] We focused on intrapartum stillbirths (i.e. stillbirths who had a positive foetal heart rate on admission) because we aimed to build a model to reduce intrapartum-related deaths.[18] For the new model development, the outcome was perinatal deaths, i.e. stillbirths and neonatal deaths before hospital discharge.[19]

Table 1. Candidate predictors of perinatal death for new model development

	Predictors	Definition	Operationalised definitions and coding of variables
1.	Place of residence	The place where the patient resides permanently	0 = Urban 1 = Rural
2.	Maternal occupation	Main occupation	0 = Unemployed 1 = Self-employed 2 = Employed
3.	Parity	Number of previous pregnancies carried beyond 28 weeks gestational age	0 = up to four previous pregnancies 1= more than four previous pregnancies (grand multipara)
4.	Maternal comorbidity score which consisted of:		
	Hypertensive disorders	Blood pressure of 140/90 mmHg and above as measured in antenatal care visits and/or on admission	0 = No hypertensive disorders 1 = Mild hypertension/preeclampsia: systolic blood pressure of 140-159 or diastolic 90-109 mm Hg, plus proteinuria ≥ ++ for pre-eclampsia 2 = Severe hypertension/(pre)eclampsia: systolic blood pressure ≥160mmHg or diastolic blood pressure ≥110mmHg, plus proteinuria ≥ ++ and/or seizures for (pre)eclampsia
	Diabetes	Blood Sugar (Fasting blood sugar) > 7 mmol/L or Random blood sugar> 11.1 mmol/L*	0 = No 1 = Yes
	Sickle cell disease	Presence of haemoglobin SS, SC or S β-thalassemia*	0 = No 1 = Yes
	Renal disease	Presence of clinical features, ultrasound findings, and elevated serum urea and creatinine*	0 = No 1 = Yes
	Thyroid disease	Presence of clinical manifestations and elevated serum free thyroxine and triiodothyroxine concentration*	0 = No 1 = Yes
	HIV status	HIV negative/positive*	0 = No 1 = Yes
	Syphilis	Diagnosed using Venereal Disease Research Laboratory test*	0 = No 1 = Yes
5.	Bleeding	Vaginal bleeding during the current pregnancy	0 = No 1 = Yes
6.	Foetal presentation	Part of the foetus closest to the pelvic inlet	0 = Cephalic 1 = Abnormal Presentation (Breech/oblique or transverse)
7.	Previous caesarean section	A previous delivery via caesarean section	0 = No 1 = Yes
8.	Multiple gestations	Number of babies carried in this pregnancy	0 = Singleton 1 = Multiple
9.	Gestational age	Duration of pregnancy on admission as estimated by ultrasound or last menstrual period	1 = Very preterm: 28 to <32 weeks 2 = Moderate to late preterm: 32 to <37 weeks 0 = Term: 37-42 weeks 3 = Post-term: ≥42 weeks [20,21]
10.	Number of ANC visits	Number of ANC visits	Continuous
11.	Fundal height	The distance on the longitudinal axis of the abdomen from the top of the fundus to the upper border of the symphysis pubis	1 = Small: ≤30cm (i.e.<2500g) 0 = Normal: 31-38cm 2 = Large: >38cm (i.e. >4000g).[22]
12.	Prolonged rupture of membranes	Rupture of membranes ≥24 hours before the onset of labor[23]	0 = No 1 = Yes
13.	Foetal heart rate	Foetal heart beat as measured on admission using intermittent auscultation (Pinard/hand-held Doppler)	0 = Normal: 110-160 beats/minute 1 = Abnormal: <110 beats/minute or >160 beats/minute.[11,24]
14.	Maternal perception of foetal movement	Maternal sensation of any discrete kick, flutter, swish or roll of the foetus	0 = Normal 1 = Reduced 2 = Absent 3 = Not sure
15.	Meconium stained liquor	Yellow or green discolouration of amniotic fluid[25]	0 = No 1 = Yes

*Predictors were mostly patient-reported or diagnosis was documented in patient-held records; diabetes, HIV and syphilis were routinely screened during ANC.
Abbreviations: ANC = Antenatal care, HIV = Human Immunodeficiency Virus,

Predictors

For external validation, predictors consisted of the six predictors included in the Nigerian model and were similarly defined. However, the maternal comorbidity of pelvic inflammatory disease was not included in the co-morbidity score because the information was not available in our setting.

The new model development included all recorded candidate predictors from the Nigerian model, and additional predictors that were identified from the literature,[9] via an international expert-based Delphi consensus,[11] as well as factors important in our clinical setting (Table 2).

Determination of gestational age is challenging in this setting, and other similar settings, as most pregnant women do not have (an early) antenatal ultrasound and may also not recall their last menstrual period accurately.[26,27] Thus, estimation of gestational age reflected the clinical reality whereby the most accurate available method of determination was used in the following order: 1) early ultrasound (up to 12 weeks), 2) the last menstrual period, 3) second trimester (up to 22 weeks), 4) 3rd trimester ultrasound.[28] When none of these methods were available, gestational age was considered unknown and multiple imputation was used (see section on missing data). Concerns regarding the quality of data, e.g. gestational age, fundal height and foetal heart rate led to the decision to categorise these continuous variables (Table 2).

Ethical consideration

The study was approved by the Zanzibar Medical Research Ethical Committee (ZAMREC/0004/AGUST/17). Informed written consent was obtained from pregnant women in Kiswahili upon admission. Participant information was anonymised using unique identification codes.

Sample size

It has been recommended that external validation studies include at least 100, but preferably 200 or more events.[29] Around 12000 women deliver at MMH annually, and the stillbirth incidence was around 4%.[30] Aiming to include at least 200 events, 5,263 participants were required, corresponding to a seven-month period of data collection.

Missing data

Multiple imputation was applied to account for missing data using the MICE package in R. The imputation accounted for all predictors and outcomes in the dataset. This resulted in 20 multiply imputed datasets.[31,32] All analyses were repeated across the 20 datasets with pooling of estimates and their uncertainty measures using Rubin's rules.[33]

Statistical analysis

Categorical variables were described using frequencies and percentages. As in the Nigerian study, all continuous data were summarised using medians and interquartile ranges (IQR) which allowed comparison of baseline characteristics between the Nigerian and Zanzibar datasets. Descriptive statistics were generated for the original data (before imputation) and the proportion of missing values was calculated for all candidate predictors. For all continuous variables, non-linear predictor-outcome associations were explored using restricted cubic splines.

Predictive performance

For all (existing and newly developed) models, we assessed calibration and discrimination performance. Calibration was visually assessed using a calibration plot, comparing the agreement between observed frequencies of stillbirth (original and updated models) and perinatal deaths (new model) in the new dataset and the predicted risks. The ability of the models to discriminate between women with and without stillbirth (original and updated models) and perinatal death (new model) was assessed using the concordance (c)-statistic (which is equivalent to the area under a receiver operating characteristic (ROC) curve).[14,34–38]

Updating the original model

The original model was adjusted to the new cohort using recalibration methods (adjustment of the intercept and adjustment of both intercept and the slope) previously described.[36,37]

Prognostic modelling

For the new model development, multivariable logistic regression was used with all candidate predictors.[38] This strategy is preferred over stepwise selection methods, which often lead to model instability and overfitting.[14] All predictors (including all comorbidities) were entered individually in the initial model. Subsequently, hypertensive disorder and sickle cell were presented as individual predictors in the final model because they were the maternal co-morbidity with highest estimated risk, whereas the remaining maternal conditions were included together in the comorbidity score (i.e. adding up of comorbidities).

Internal validation and shrinkage

Model optimism was assessed via bootstrap resampling. Briefly, the aforementioned prediction model was refitted (i.e. re-estimation of the coefficients) in 200 bootstrap samples, and the performance of these models was then evaluated in the original sample. This yielded a shrinkage factor which was used to adjust both the regression coefficients and c-statistic of the original model for optimism.[39]

All analyses were performed in R version 3.5.3 (The R Foundation for Statistical Computing, 2019).[40]

Presentation of the model

Methods previously described were used to derive a point score system for the newly developed prognostic model.[41,42] Risk estimates were organised into clinically meaningful categories.

Results

Participants

Between October 2017 and May 2018, 7708 pregnant women delivered at the maternity ward of Mnazi Mmoja hospital and 5610 women were included in the study (a total of 5747 babies, (Figure 1)). Table 1 depicts the characteristics of these women and compares them to the women of the

Nigerian dataset. The majority of women in both datasets lived in urban areas. The Zanzibar validation dataset had a lower median age and parity. It had higher literacy and unemployment rates. The majority of women in both datasets had singleton pregnancies with cephalic presentation but the Nigerian dataset had more multiple gestations and abnormal presentations. The median gestational age was higher than the derivative dataset and could not be determined in 12.9%(n=721) of cases.

In addition, the most common maternal comorbidity in the Zanzibar cohort was hypertensive disorders (16%, n=899, see supplementary file 2 for prevalence of all comorbidities). Number of antenatal care (ANC) visits significantly increased with the following measures of socioeconomic status: living in an urban region, higher levels of education, being married and being employed and was linearly related to the outcome. Therefore, the number of ANC visits (continuous) was used as a single proxy for socioeconomic status, indicating an important pathway in which socioeconomic status influences pregnancy outcome. The majority of women presented in early phases of labour (median 4 (IQR:2-6) cm dilatation). The caesarean section rate was 7% (n=392), and there were 16 vacuum deliveries (0.3%). There were 191 intrapartum stillbirths (3.3%), and 102 neonatal deaths (1.8%) that occurred before hospital discharge in the Zanzibar cohort. Of all live births, 8.7% (n=468/5556) had an Apgar score between 1-6 at one minute, which decreased to 2.2% (n=120/5556) at five minutes. There were five women who died postpartum in the cohort. Missing data ranged from 0-17.8% (maternal height).

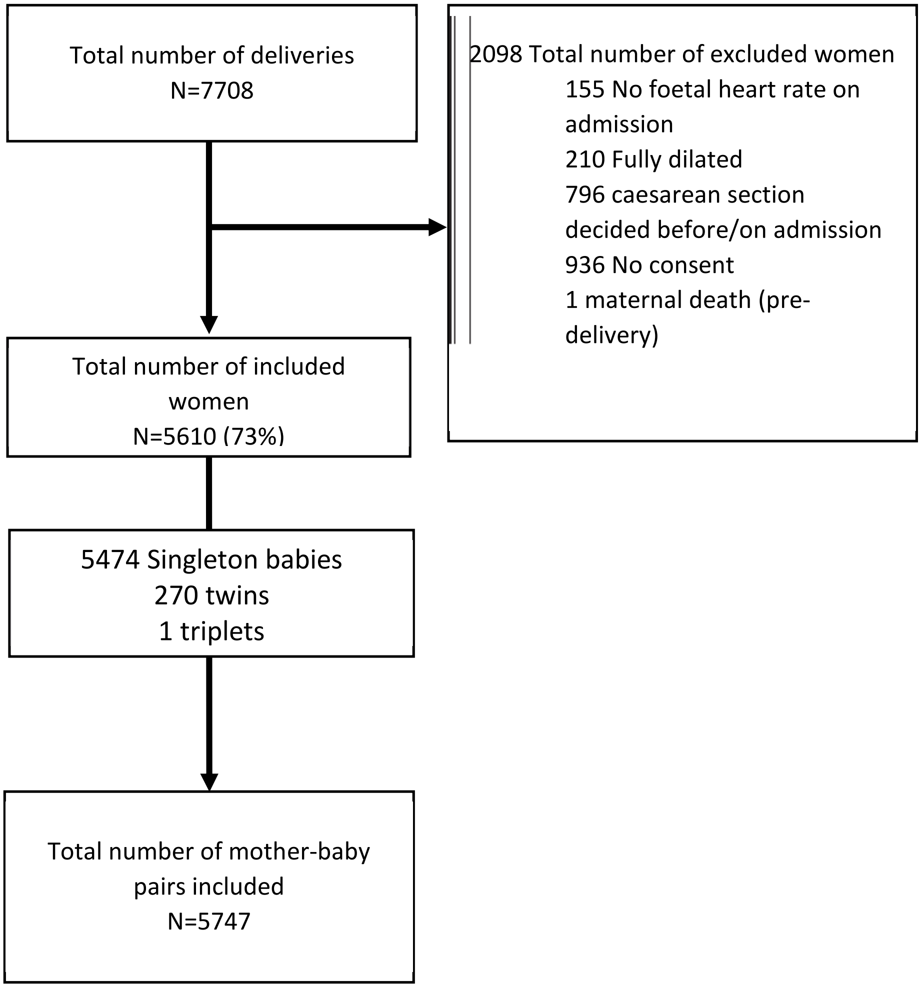

Figure 2. Flowchart of participant inclusion

Table 2 General characteristics of the study population

Characteristics	Development cohort of the existing model[17]	Cohort for external validation, updating and new development				
	All women N=6573	All women N=5610	Missing data N (%)	Live infants N=5454 (94.9)	Stillbirths N=191(3.3)	Neonatal deaths N=102(1.8)
Socio-demographic and socio-economic characteristics						
Maternal age in years	27 [24-30]	26 [22-31]	8 (0.1)	26 [22-31]	28 [23-32]	26 [23-31]
Maternal height (cm)	156 [153-160]	158 [154-161]	997 (17.8)	158 [154-161]	157 [153-161]	158 [155-160]
Maternal weight on admission (kg)	65 [57-75]	67[60-76]	496(8.8)	68(60-76)	66[60-76]	69[60-79]
Place of residence						
Urban	5707 (89.1)	4515(80.9)	29(0.5)	4395((80.9)	149(79.3)	68(70.8)
Rural	700 (10.9)	1065(19.1)		1037(19.1)	39(20.7)	28(29.2)
Maternal education						
Not educated	3284 (63.8)	5340(96.4)	67(1.2)	5227(96.4)	161(95.3)	81(97.6)
Educated	1866 (36.2)	202(3.6)		197(3.6)	8(4.7)	2(2.4)
Maternal occupation						
Not-employed	2894 (49.6)	4164(74.8)	73(1.3)	4052(75.1)	152(81.7)	65(71.4)
Self-employed	1969 (33.8)	966(17.4)		938(17.4)	26(14.0)	23(25.3)
Employee	968 (16.7)	406(7.3)		403(7.5)	8(4.3)	3(2.3)
Marital status						
Married	N/A	5401(96.7)	22(0.4)	5254(96.3)	182(95.3)	97(95.1)
Not married	N/A	186(3.2)		179(3.3)	9(4.7)	3(2.9)
Obstetrics history						
Parity	2(0-3)	1(0-4)	112(2.0)	1(0-3)	1(0-3)	1(0-3)
0-4	N/A	4810(87.5)		4677(87.5)	160(85.1)	93(91.2)
≥5	N/A	687 (12.5)		666(12.5)	28(19.9)	9(8.8)
Number of previous foetal loss	0 [0-1]	0[0-0]	66(1.2)	0[0-0]	0[0-0]	0[0-0]
Number of previous caesarean sections	0 [0-0]	0[0-0]	0	0[0-0]	0[0-0]	0[0-0]
Pregnancy characteristics						
Number of antenatal visits	N/A	4[3-4]	74(1.3)	4[3-4]	3[2.5-4]	4[2.8-4]
Maternal comorbidity*	0 [0-0]	0[0-1]	72(1.3)	0[0-1]	0[0-1]	0[0-1]
Bleeding in pregnancy						
No	6,406 (94.9)	5552(99.0)	0	5434(99.1)	167(87.4)	84(82.4)
Yes	341 (5.1)	57(1.0)		20 (0.4)	24(12.6)	18(17.6)
Gestational age (days)	265 [137-276]	280[266-280]	721(12.9)	278[259-280[	267[231-280]	268[228-280]
Very preterm	N/A	118(2.4)		92(1.9)	21(14.9)	15(20.0)
Moderate to late preterm	N/A	715(14.6)		714(14.9)	29(20.6)	9(12.0)
Term	N/A	3820(78.1)		3754(78.4)	85(60.2)	46(61.3)
Post-term	N/A	236(4.8)		229(4.8)	6(4.3)	5(6.7)
Fundal height(cm)	N/A	34[32-36]	260(4.6)	34[32-36]	33[30-36]	34[30-38]
Small	N/A	673(12.6)		604(11.6)	52(28.6)	24(28.9)
Normal	N/A	4218(78.8)		4120(79.1)	109(59.9)	42(50.6)
Large	N/A	459(8.6)		485(9.3)	21(11.5)	17(20.5)
Birthweight (kg)	3.1[2.7-3.4]	3.1[2.8-3.4]	211(3.8)	3.1[2.8-3.4]	2.5[1.8-3.1]	2.6[1.7-3.1]
Number of babies						
Singleton	6201 (89.2)	5474 (97.6)	0	5214(95.6)	180(94.7)	80(78.4)
Multiple	754 (10.8)	135(2.4)		240(4.4)	11(5.8)	22(21.6)
Foetal presentation						
Cephalic	6506 (93.7)	5359(97.4)	107(1.9)	5207(97.2)	171(95.5)	91(92.9)
Breech	334 (4.8)	137(2.5)		144(2.7)	6(3.4)	6(6.1)
Others	100(1.4)	6(0.1)		4(0.1)	2(1.1)	1(1.0)
Sex of neonate						
Male	3,506 (51.4)	2704(49.5)	150(2.7)	2640(49.6)	94(53.1)	46(46.9)
Female	3,310 (48.6)	2755(50.5)		2679(50.4)	83(56.9)	52(53.1)
Cervical dilatation on admission	N/A	4(2-6)	244(4.3)	4(2-6)	3(2-5)	3(2-5)
Abnormal foetal heart rate on admission						
No	N/A	4897(98.6)	597(10.6)	4860(89.1)	113(77.9)	78(97.5)
Yes	N/A	94(1.4)		36(0.7)	32(22.1)	2(2.5)
Prolonged rupture of membranes						
No	N/A	5483 (99.1)	74(1.3)	5205(99.3)	178(97.3)	93(97.9)
Yes	N/A	52(0.9)		37(0.7)	5(2.7)	2(2.1)
Meconium-staining of amniotic fluid						
No	N/A	5349(99.2)		5343(99.1)	182(97.3)	89(93.7)
Yes	N/A	43(0.8)	217(3.9)	46(0.9)	5(2.6)	6(6.3)
Maternal perception of foetal movement						
Normal	N/A	4631(83.4)	53(0.9)	4583(84.5)	101(56.1)	58(58.8)
Reduced	N/A	544(9.8)		495(9.1)	44(24.4)	19(22.4)
Absent	N/A	38(0.7)		23(0.4)	17(9.4)	1(1.2)
Not sure	N/A	343(6.2)		325(6.0)	18(10.0)	7(8.2)
Referral pathway						
Home	N/A	5325(99.0)	228((4.1)	5179(99.0)	177(98.3)	100(99.0)
Referred	N/A	56(1.0)		54(1.0)	3(1.7)	1(1.0)

Continuous variables are given as median [Interquartile range] and categorical variables as frequency (percentages)
N/A = information not available

Performance of the original model

After applying the original Nigerian model to the new dataset, the predicted probabilities of the original Nigerian prediction model were systematically too high in the Zanzibar validation set (Figure 2 and Table 3). The discriminative ability of the model was much lower in the validation set (0.57(0.56-0.58)) than in the original development dataset (0.80 (95 % CI 0.78–0.83)).

Table 3 Updating of original model

	Original model	Update 1 (intercept only)	Update 2 (intercept and slope)
Calibration intercept	-	-1.053± (0.006)	-1.894(± 0.043)
Calibration slope	-	-	0.609 (±0.007)
Intercept	-3.6486	-4.6948	-5.5426
Maternal co-morbidity	0.7077	0.7077	0.4305
Place of residence			
Urban			
Rural	1.3047	1.3047	0.7937
Employment			
Homemaker/unemployed			
Self-employed	-0.3022	-0.3022	-0.1838
Public/private employment	-0.3788	-0.3788	-0.2304
Parity	0.0797	0.0797	0.0485
Bleeding			
No			
Yes	2.1579	2.1579	1.3127
Presentation			
Cephalic			
Breech	0.9616	0.9616	0.5850
Other presentation	2.0588	2.0588	1.2524

Updating of original model

After recalibration, model performance was still not satisfactory as calibration could not be corrected by updating of the intercept and common slope (Figure 2C), and neither could the low c-index be improved. This motivated de novo model development in this study.

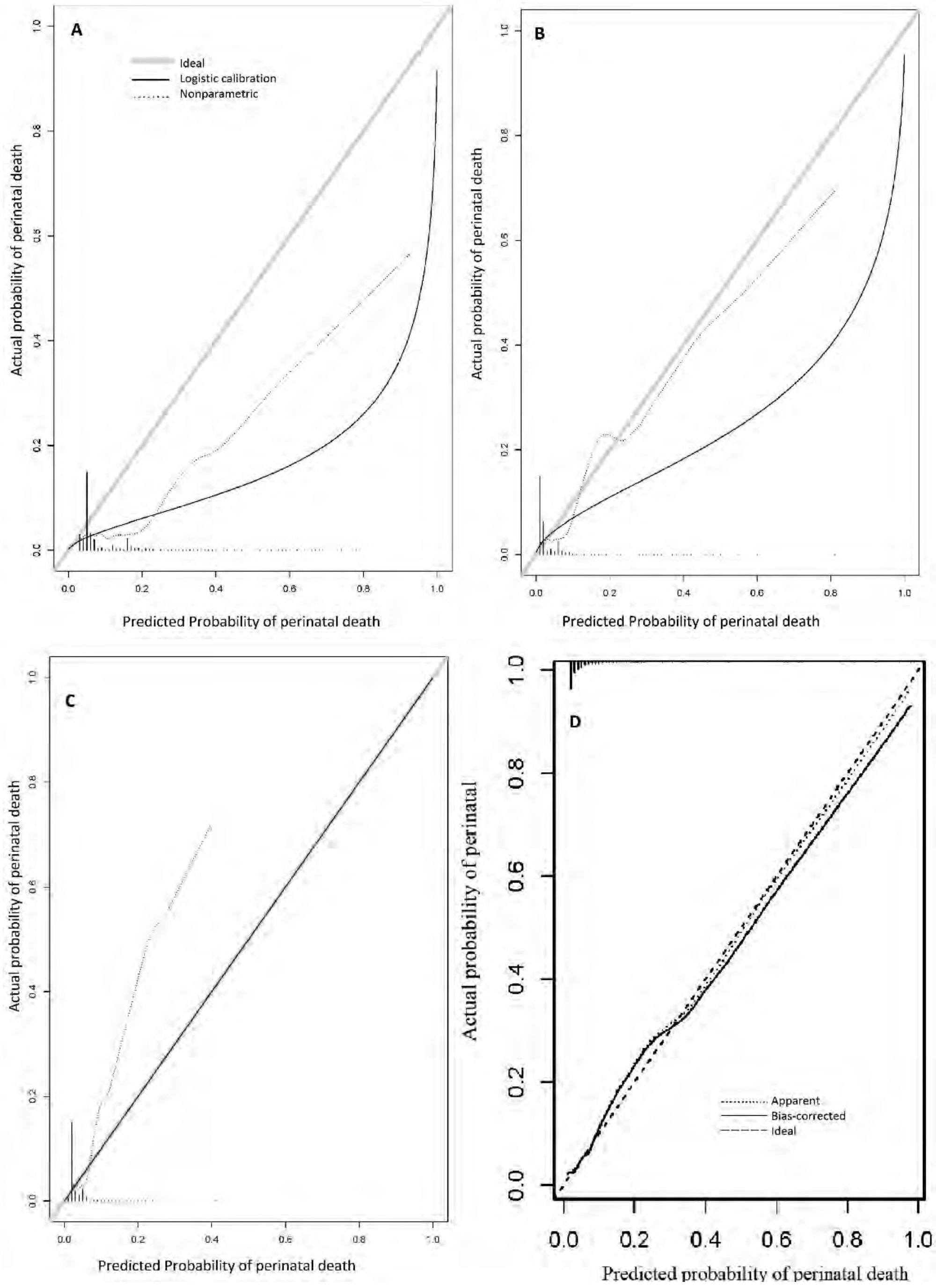

Figure 2 Calibration plots. **A**. Original prediction model, **B**. Update of intercept of original model, **C**. update of intercept and slope of original model. **D.** New model

Table 4 Final new model				
Coefficient	Unadjusted coefficient*	Adjusted coefficient	Standard error	Adjusted Odds ratio*
Intercept	-3.651	-3.593	0.261	
Number of antenatal care visits*	-0.112	-0.105	0.062	0.894
Hypertensive disorders				
No hypertensive disorders	Reference category			
Mild hypertension	0.128	0.120	0.252	1.137
Severe hypertension	0.720	0.677	0.180	2.054
Sickle cell anaemia	2.649	2.491	1.003	14.139
Other comorbidities†*	0.723	0.680	0.434	2.062
Gestational age				
Term	Reference category			
very preterm	1.780	1.674	0.255	5.931
mild-moderate preterm	0.177	0.167	0.196	1.194
Post-term	0.297	0.280	0.331	1.346
Fundal height				
Normal	Reference category			
Small	0.749	0.704	0.178	2.115
Large	0.353	0.332	0.230	1.424
Abnormal/non-reassuring FHR	2.520	2.370	0.296	12.425
Rupture of membranes >24hours	0.916	0.862	0.437	2.500
Meconium-staining of amniotic fluid	1.237	1.163	0.486	3.445
Maternal perception of foetal movement				
Normal	Reference category			
Reduced	1.060	0.997	0.177	2.885
Absent	1.830	1.721	0.440	6.236
Unsure	0.759	0.714	0.241	2.137
Bleeding	3.322	3.124	0.334	27.720
Grand-multiparity (≥5 parity)	0.059	0.055	0.209	1.061
Previous scar	0.403	0.379	0.283	1.497
Abnormal presentation	0.056	0.053	0.388	1.058
Multiple pregnancy	0.621	0.584	0.266	1.860

*Unadjusted coefficient. denotes coefficient before shrinkage; Adjusted denotes coefficient after shrinkage.
**Odds ratio per one antenatal care visit
***Odds ratio per comorbidity
† Other comorbidities: diabetes, HIV, thyroid disease, renal disease, syphilis

Model specification:
Risk of perinatal death = 1/(1+exp (-(-3.593 + -0.105 *(Number of antenatal care visits)+ 0.120 * (Mild hypertension) + 0.677 * (Severe hypertension) + 2.491 * (Sickle cell anaemia) + 0.680 * (Other comorbidities) + 1.674 * (very preterm) + 0.167*(Mild-moderate preterm) + 0.280 * (post-term) +0.704 * (small) + 0.332 * (large) + 2.370 * (Abnormal Foetal heart rate) + 0.862 * (rupture of membranes >24hours) + 1.163 * (meconium-staining of amniotic fluid) + 0.997 * (Reduced foetal movement) + 1.721 * (Absent foetal movement) + 0.714 * (Unsure of foetal movement) + 3.124 * (Bleeding) + 0.055 * (grand-multiparity) + 0.379 * (Previous scar) + 0.053 * (Abnormal presentation) + 0.584 * (Multiple pregnancy))))

Worked example: for a para 6 with 4 antenatal care visits who presented at term with preeclampsia, history of bleeding and reduced foetal movement
Risk of perinatal death = 1/(1+exp(-(-3.593 + (-0.105 * 4 + 0.120*0 + 0.677*1 + 2.491*0 + 0.680*0 + 1.674*0 + 0.167*0 + 0.280*0 + 0.704*0 + 0.332*0+ 2.370*0+ 0.862*0+ 1.163*0+ 0.997*1 + 1.721* 0+ 0.714*0 + 3.124*1+ 0.055* 1+ 0.379*0 + 0.053*0 + 0.584*0))))
=1/(1+exp (-0.84))
Risk of perinatal death = 0.70, which corresponds to 70%

Risk Factor	Categories	Points
Number of antenatal care visits*	0-3 4-7 ≥8	1 0 -2
Hypertensive disorders	None Mild Severe	0 0 2
Sickle cell anaemia	No Yes	0 7
Other comorbidities†*	0-1 2-3	0 4
Gestational age	Normal very preterm mild-moderate Post-term	0 4 0 1
Fundal height	Normal Small Large	0 2 1
Abnormal/non-reassuring FHR	No Yes	0 6
Rupture of membranes >24hours	No Yes	0 2
Meconium-staining of amniotic fluid	No Yes	0 3
Maternal perception of foetal movement	Normal Reduced Absent Unsure	0 3 5 2
Bleeding	No Yes	0 8
Grand-multiparity (≥5 parity)	No Yes	0 0
Previous scar	No Yes	0 1
Abnormal presentation	No Yes	0 0
Multiple pregnancies	No Yes	0 2

Risk groups

Point total	Risk category	Risk level category
≤ -2	≤ 1.4%	Low
-1 to 1	1.5-4.4%	Moderate
≥ 2	≥ 4.5%	High

Point total	**Estimate of risk**
-2	0.010
-1	0.015
0	0.021
1	0.031
2	0.045
3	0.063
4	0.090
5	0.126
6	0.174
7	0.236
8	0.310
9	0.397
10	0.490
11	0.584
12	0.672
13	0.750
14	0.814
15	0.865
16	0.903
17	0.932
≥18	≥0.952

Figure 3 Point score system for risk of perinatal death on admission to the labour ward.
*In women who have attended eight or more antenatal visit, points should only be deducted if no risk factor has been identified.
Worked example: for a para 6 with 4 antenatal care visits who presented at term with severe preeclampsia, history of bleeding and reduced foetal movement: 0+0+0+2+8+3=13; risk probability=0.75.

Development of new model

All 5747 babies were used to develop the new prognostic model with 15 predictors for perinatal deaths (i.e. stillbirths and neonatal deaths). Bootstrap validation yielded a shrinkage factor of 0.95, which was applied to shrink the coefficients of the final model. Model performance was very good in terms of calibration and discriminative ability with c-statistic of 0.80 and 0.78 before and after internal validation. (Table 4 and Figure 2D). Risk estimates were organised into clinically meaningful categories. An example is given which also illustrates the correspondence between the risks estimated by the multivariable model directly and those approximated by the points system (Figure 3).

Discussion

We carried out a prospective cohort study of 5610 women (5747 new-borns) to develop a model for predicting perinatal deaths in women who arrive for delivery at a tertiary hospital in a low-resource setting. We first externally validated and updated the Nigerian stillbirth model, and observed poor predictive ability in this new population (c-statistic of 0.57). We therefore used the information gained from this previous model,[17] a literature review,[9] consensus-based recommendations[11] and clinical reasoning to develop and internally validate a new model to prognosticate both intrapartum stillbirths and early neonatal deaths. The model consisted of 15 predictors and showed very good calibration and discriminative ability after internal validation (c-statistic of 0.78). Our results further emphasise the importance of antenatal care, and comprehensive assessment on admission including accurate assessment of gestational age, blood pressure, history of sickle cell anaemia, bleeding, maternal perception of foetal movement and foetal heart rate in predicting perinatal outcomes.

Strengths and Limitations

To our knowledge, this is the first model which quantified the predictive value of obstetric characteristics obtained on admission to the labour ward, and one of the few clinical prediction models developed for use in pregnant women in low and middle income countries.[15] The comprehensiveness of the model by including both maternal and foetal characteristics makes it relevant to neonatal and maternal survival. All predictors included in the new model can be obtained through history-taking and physical examination at the time of admission and are thus simple, minimally-invasive and readily available, making the model applicable for low-resource settings. The prospective design reduced missing data and allowed the inclusion of maternal perception of foetal movement – an important yet often neglected predictor in the clinical setting.[9,11] It may seem more clinically useful to develop a prognostic model to predict adverse perinatal outcomes in women with seemingly normal pregnancy (e.g. term, singleton foetus, cephalic presentation), whose risks are harder to predict. However, we chose broad inclusion criteria for more generalisability of the model to all women admitted to the labour ward. Since admission is usually the first contact point with an SBA, it is paramount for all women to be examined for conditions that may not have been detected in ANC as well as newly-arising problems. Supporting this approach are our results from our prior study that showed inadequate risk assessment on admission, with delayed detection of problems such as twins, breech presentation, and intrauterine foetal death until close to delivery.[5] This emphasises the need to strengthen assessment of all women on admission to the labour ward in these types of settings.

Data quality is a major concern because the data was collected within the inherent limitations of the clinical situation. Thus, inaccuracies existed in measuring predictors such as gestational age, fundal height and foetal heart rate. This led to categorisation of these continuous variables which may have caused loss of information about the relation between the predictors and the outcome.[14] Also, measurement error may have occurred because many maternal comorbidities such as diabetes mellitus, renal disease and sickle cell disease were not tested but depended on patient-report or absence of documented diagnosis. Also, maternal infection screening was commonly not done. Hence, there was probable misclassification of maternal conditions which may have affected (diluted) the effects of predictors.

Thirdly, determination of stillbirth as intrapartum relied on the accurate auscultation of foetal heart rate on admission. It was highly probable that there was misclassification of stillbirths because of unchecked or inaccurate FHR assessment (false positive and negative FHR detection). In addition, the definition of perinatal death included late neonatal deaths (occurring after seven days), whose causes are more likely to differ to those of stillbirths and early neonatal deaths (<7 days). However, during the same study period, it was found that the overwhelming majority of neonatal deaths born in this hospital were early neonatal deaths, and only about 5% (13/248, data submitted for publication) were late neonatal deaths. Finally, we included a relatively large number of predictors in the new model. To limit the potential impact of overfitting, we adopted shrinkage methods and adjusted estimates of model performance for over-optimism.

While 15 is a large number of model predictors, these are easily available, rapid to assess and are all necessary for the assessment of every woman who is admitted in the labour ward.

Interpretation

Poorer performance of a prediction model is expected when tested in new subjects as compared to the original dataset and thus underscores the relevance of external validation before model implementation in clinical practice.[43] In this study, poor performance of the Nigerian model was most likely caused by multiple factors: 1) the observed difference in case mix of predictor variables and outcome occurrence between the development and validation samples; 2) the original model omitted important predictor variables and also the new model excluded pelvic inflammatory disease in the comorbidity score; 3) the validation study indicates that the model's predictive mechanisms are completely different in the validation population, perhaps due to major differences in outcome definitions and routine care and thus the model was poorly transported.[44] The original model provided useful information which we leveraged for a new model development.

Simple prediction tools which are based on clinical maternal and foetal characteristics have high predictive ability for the risk of adverse birth outcomes.[13,45] They may help SBA combine multiple factors and interpret intrapartum findings such as poor progress of labour or foetal heart rate abnormalities during the course of labour to facilitate better decision-making.[13] An example of a prediction tool in obstetrics is the universally used Apgar score that informs the need for neonatal resuscitation and further management.[46] There is also a need for a standardised obstetric risk assessment tool in conjunction with clinical decision aid (guidance/protocol) for consistent, safe and efficient triaging of pregnant mothers and their foetuses.[11,47,48] Notably, women with obstetric complications may be at higher risk of being overlooked, delayed and neglected as resources and screening are redirected towards COVID-19, the symptoms of which mimic obstetric emergencies.[49] This further emphasises the need for a obstetric triaging tool. We used the prediction model to develop a point score system which is simple, low-tech and easy-to-use for risk assessment and stratification. The tool may assist SBAs rapidly assess all women on admission to the labour ward, and provide risk-based effective management including decision-making on type and frequency of monitoring and or (immediate) treatment intervention.[41,42,50] It may also improve patient flow and documentation, reduce delays and increase pregnant women's satisfaction.[47,48,51]

Before use, the model (and simplified tools) needs to be externally validated and tested both quantitatively and qualitative alongside context-specific clinical guidelines to determine its impact on birth outcomes, implementation issues and user experience. Interventions such as anti-hypertensive and anti-convulsive treatments and operative delivery may lower the estimated risk of perinatal death, whereas other treatment such as oxytocin augmentation may increase the risk and therefore alter model performance.[52] It is also highly plausible that routine care includes some form of prioritisation of identified high(er) risk women which allows closer monitoring/follow-up and quicker intervention, e.g. a higher proportion of pregnancies with abnormal presentation (32%) were delivered by a caesarean section which may also have reduced the effect size. Thus, future studies will need to continue to explore the development of dynamic models, in which intrapartum interventions and treatment quality that alter model performance can be incorporated so that the model can be routinely updated based on developing clinical information.[52] The usefulness of assessment tools can also be improved by increasing the number of staff, space and equipment for assessment on admission, interprofessional collaboration as well as training triage nurse-midwives on essential skills such as history-taking, rapid and accurate assessment including estimation of gestational age by whatever means available, identifying problems, acuity rating and prioritisation; decision-making; allocation of resources; and management of emergencies.[53,54]

Conclusion

We externally validated a Nigerian prognostic model for stillbirths and found a substantial reduction in predictive performance. Subsequently, we developed and internally validated a new prognostic model for predicting perinatal death using easily-available parameters in low-resourced, busy labour wards. Before the model can be implemented, external validation and implementation studies need to be carried out to determine its performance in different clinical settings and its impact on birth outcomes. Future studies should also include dynamic prediction modelling to account for the various interventions during labour which modify the risk of adverse birth outcomes.

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Author contributions NH conceived and designed the experiment, carried out data acquisition, analysed the data, interpreted the results, drafted the manuscript. MJR conceived and designed the experiment, contributed to interpretation of the results and critically revised the manuscript.
NHN carried out data acquisition and critically revised the manuscript.
KG contributed to design of experiment, data analysis and critically revised the manuscript. CD contributed to data analysis, interpretation of the results and critically revised the manuscript. TD contributed to data analysis, interpretation of the results and critically revised the manuscript. TM contributed to data collection, interpretation of the results and critically revised the manuscript. AF conceived and designed the experiment, contributed to interpretation of the results and critically revised the manuscript DEG conceived and designed the experiment, contributed to interpretation of the results and critically revised the manuscript. JLB conceived and designed the experiment, contributed to interpretation of the results and critically revised the manuscript.

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Ethics approval and consent to participate The study received ethical approval from the Zanzibar Medical and Research Ethical Committee. (Protocol no. ZAMREC/004/AGUST/17). All participants provided written informed consent.

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Supplementary files

Supplementary file 1: Assessment of maternal perception of foetal movement

Question	Answer
2.44 When did you last feel your baby move? *Lini mara mwisho uliskia mtoto anacheza?*	Date *Tarehe*: _____ / _____ / _____ Time *Muda* : _____ : _____ I don't know *Sijui* ☐
2.45 How strong are your baby's movements today? *Kwa nguvu gani mtoto wako anacheza leo?*	**1.** Stronger than usual *Kwa nguvu zaidi ya kawaida* ☐ **2.** Less strong than usual *Pungufu kuliko kawaida* ☐ **3.** The same as usual *Sawasawa kama kawaida* ☐ **4.** No movement *Hakuna uchezaji* ☐ **5.** I don't know *Sijui* ☐
2.46 How often is your baby moving today? *Kwa mara ngapi mtoto wako anacheza leo?*	**1.** More often than usual *Mara kwa mara zaidi ya kawaida* ☐ **2.** Less often than usual *Mara chache kuliko kawaida* ☐ **3.** The same as usual *Sawasawa kama kawaida* ☐ **4.** No movement *Hakuna uchezaji* ☐ **5.** I don't know *Sijui* ☐
2.47 If not the same, when did the movements change? *Kama haiko kawaida, ni lini uchezaji ulibadilika?*	**1.** Today *Leo* ☐ **2.** Yesterday *Jana* ☐ **3.** ________ days ago *Siku________ zilizopita* ☐ **4.** I don't know *Sijui* ☐
2.48 Was there a time when your baby was very active then stopped moving? *Je kuna wakati ulihisi mtoto kucheza zaid, halafu ndo akawa hachezi?*	**1.** No *Hapana* ☐ **2.** Yes *Ndio* ☐ ↓ Date *Siku* : _____ / _____ / _____ Time *Muda*: _____ : _____ **3.** I don't know *Sijui* ☐
2.49 In yourself, do you feel that your baby is… *Wewe binafsi, unahisi mtoto wako yuko je…*	**1.** Well *Vizuri* ☐ **2.** Not well *Hayuko vizuri* ☐ **3.** Not sure *Sina uhakika* ☐

Supplementary file 1 Prevalence of comorbidities in the validation dataset N (%)

Maternal comorbidity	**All women N=5610**	**Live infant N=5454(94.9)**	**Stillbirth N=191(3.3)**	**Neonatal deaths 102(1.8)**	**Missing data (%)**
Diabetes	12(0.2)	11(0.2)	1(0.5)	0	0
Sickle cell disease	6(0.1)	3(0.1)	3(1.6)	0	0
Hypertension	899(16.0)	845(15.5)	71(37.2)	21(20.5)	60(1.1)
Renal disease	5(0.1)	5(0.1)	1(0.5)	0	0
Thyroid disease	3(0.1)	2(0.0)	1(0.5)	0	0
HIV status	30(0.5)	27(0.5)	3(1.6)	0	0
Syphilis	3(0.1)	3(0.1)	0	0	0
Previous caesarean section	258(4.6)	240(4.4)	16(8.4)	6(5.9)	128(2.3)

Chapter 14
General Discussion

The objective of this thesis was to explore context-specific strategies to improve the quality of intrapartum care, with a focus on foetal monitoring, in busy low-resource labour wards. The work was an iterative process whereby findings from the baseline quality of care assessment and the context (part 1), as well as synthesis of current evidence and expert opinion (part 2), helped inform acceptable strategies (parts 3 and 4). This iterative process is described below and depicted in Figure 1.

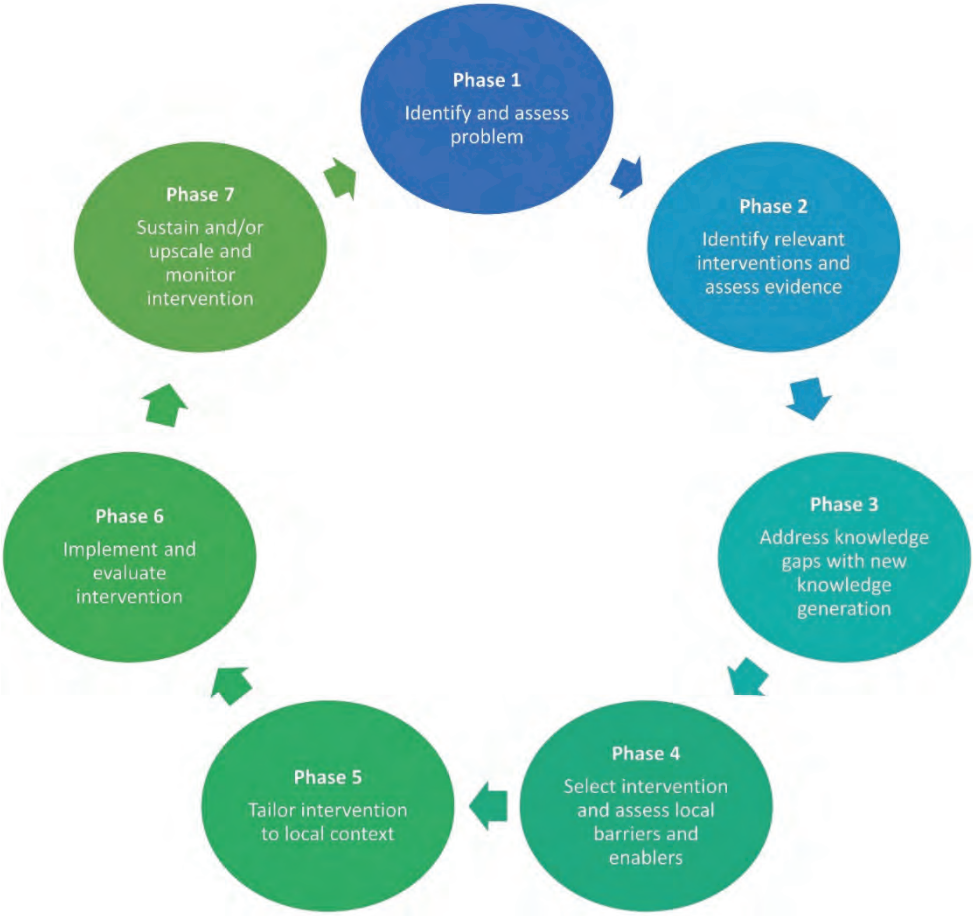

Figure 1 Iterative process of thesis development and contextualisation of intervention

Phase 1: Identify and assess the problem

To comprehensively analyse perinatal outcomes, their causes and clinical determinants in a tertiary hospital in Zanzibar, Tanzania, we triangulated data from mixed methodological approaches and multiple perspectives (chapters 2-4 and 9). We analysed in depth the associated structural and health system challenges that affected the day-to-day provision of intrapartum care. Mnazi Mmoja Hospital experiences high maternal mortality rate (647 per 100,000 livebirths)[1] and perinatal mortality rates (e.g. stillbirth rate of 59 per 1000 total births, chapter 2)). Poor quality of routine documentation, weak data and surveillance systems have blurred the true estimates and causes of perinatal deaths (chapters 2 and 12). However, it was apparent that a significant proportion of intrapartum deaths were associated with hypertensive disorders and acute intrapartum events, such as antepartum bleeding and birth-related complications; with poor care being a major contributing factor to the majority of these deaths (chapters 2 and 12). Suboptimal intrapartum care included inadequate maternal and foetal surveillance (e.g. median time of 210 minutes from last foetal heart assessment till diagnosis of foetal death or delivery (interquartile range: 75–315 min.)), treatment and interventions, and lack of support for both women and skilled birth attendants (chapters 2 and 9).[2]

Pregnancy and childbirth are key events in the lives of women and families with both personal and cultural significance, but also it is a time of immense risk and vulnerability for women and children. Maltreatment of women during labour is visible and widespread – with estimates that up to 30% of women experience disrespect and abuse,[3] but remain unaddressed issue in these facilities. Women experienced poor interaction with their skilled birth attendants in terms of communication, abandonment/neglect, non-confidential and non-consented care, and discrimination - and even verbal and physical abuse (chapters 3, 4 and 10).[3–9] While ideally a positive experience,[10] childbirth can lead to long-term psychological, physical and social morbidity and mortality in women.[11–31] In fact, perception of care at birth was the single most important risk factor for physical[1] and mental health issues among women, with negative experience contributing to the high rates of depressive and post-traumatic stress symptoms (chapter 3).

The biggest challenge to provide respectful and safe maternal care in many hospitals in Sub-Saharan Africa is the human resource crisis in healthcare. It is fuelled by push factors such as inadequate training, poor working conditions, lack of supervision and support, inefficient organisation, poor salaries, socioeconomic factors, maldistribution of health personnel within and across borders, lack of accountability and political instability (chapters 4 and 10).[32] This is compounded by underlying health system factors that hinders high quality health service delivery: health information systems, essential supplies and technologies, health financing and leadership and governance (chapter 4).[33]
These conditions have made it difficult for the skilled birth attendants to adhere to and effectively use the WHO partograph and internationally recommended clinical intrapartum guidelines and severely impaired their ability to provide respectful care.[10,34] For example, the lack of structural support for monitoring, diagnosis and successive response to foetal compromise remains a barrier to foetal monitoring and improving perinatal outcomes.[35–39] We thus concluded that poor foetal monitoring was a symptom of the complex underlying health system bottlenecks and part and parcel of the unacceptable quality of intrapartum care. While fighting for additional resources, there is therefore an urgent need for strategies to strengthen workforce capacity and support skilled birth attendants to provide the best possible care with the limited resources currently available.

Phases 2 and 4: Identify relevant interventions and assess evidence, local barriers and enablers

The initially proposed intervention of this thesis was to support skilled birth attendants perform FHRM adequately by task shifting FHRM to trained lay workers (chapter 6). However, the intervention was generally not positively viewed as acceptable or useful by healthcare providers in early stages of intervention development.

Therefore, a broad systematic review and a Delphi consensus procedure to identify intrapartum foetal surveillance strategies were undertaken (chapters 7 and 8). The review provided insufficient impact evidence and guidance for specific foetal monitoring practices (e.g. devices and timings) and expert opinion remains divided. [35–39] Yet, they identified two integrated, broad-based interventions as essential to support clinical decision-making: 1) the WHO partograph accompanied by clinical guidelines, knowledge and skills; and 2) a standard test to strengthen risk assessment and triage of women on admission to the labour ward.

Phases 5-7: Tailor, implement, evaluate, sustain, upscale interventions

Although international clinical guidelines on clinical maternity care are abundant, they are rarely contextualised to suit reality. Consequently, their direct implementation leaves health workers with guidelines that are unachievable, ill-perceived and often unused, and the care provided to women is left to chance and unsupported by evidence. Research on effective development and implementation of clinical guidelines tailored for maternity care in low-income countries is scarce. [40–42]

The PartoMa intervention (Chapter 9) is a unique example of "living guidelines" that illustrates how a co-creation process can be used to continually adapt international guidelines to meet local realities. Lessons learnt from this process include the co-creation and active participation of skilled birth attendants in development of the guidelines and implementation strategy; a simple, low-cost and accessible pocket booklet for clinical decision support accompanied by an integrated implementation strategy of low-dose, high frequency in-house training. One year after implementation, quality of care during birth had improved, stillbirths decreased by 33% and babies born with asphyxia almost halved compared to baseline. As a result of high acceptance and interest among Zanzibari birth attendants and its positive health effects, a body of volunteers consisting of skilled birth attendants from Mnazi Mmoja Hospital (the PartoMa Steering Committee) continue to organise and upscale the seminars supported by the Zanzibar Ministry of Health, United Nations Population Fund (UNFPA), and the World Health Organisation (WHO). However, although the intervention helped gain incremental improvements in quality of care and birth outcomes, the guidelines were still far from being adhered to optimally and thus stresses the need to increase the number of competent skilled birth attendants.

Phase 3. Address knowledge gaps with new knowledge generation

Risk-based medicine, in which care is based on an individual's risk for having or developing a certain health outcome, is increasingly being employed in high-income countries to improve patient outcomes.[43,44] Prognostic models can support risk assessment and inform decision-making because they take multiple factors into account.[45] Yet, prediction research is rare in LMICs, though it may prove to be of even greater benefit here in managing the high workload and limited resources.[45] Based on readily and easily available maternal and foetal predictors identified in a previous model, the systematic review and the consensus-based procedure, we developed a prediction model that performed well (c-static of 0.78) in predicting perinatal deaths on admission of a woman to the labour room (Chapter 13). We anticipate that in the future, the prediction model may be key in developing a triage system to tailor care and assist skilled birth attendants in decision-making. It may be particularly useful in the following areas of decision-making: 1) mode and intensity of monitoring (e.g. with Pinard/hand-held Doppler or continuous monitoring using the Moyo Doppler or cardiotocography),[35,38,46,47] 2) interpretation of single findings during the course of labour, such as non-reassuring FHR which has high false positive rates for foetal compromise,[45,48,49] 3) allocating limited resources and interventions according to individual needs in a more timely, efficient and equitable manner and 4) directing patient flow and referral mechanism.

The way forward

Addressing health system problems of the scale and complexity presented in this thesis demands interdisciplinary, multilevel (trans-national, national, local) collaborative actions and both top-down and bottom-up approaches.[50] However, pledged resolutions will not be achieved in a short period of time. It is an obligation of all players "to move as expeditiously and effectively as possible", even in the face of resource constraints, towards full realisation of women's rights.[51,52] As the proverb goes *"the best is the enemy of the good"* and thus short- and long-term solutions must include simple, low-cost and low-tech strategies to urgently assist skilled birth attendants to provide the best possible care in their existing contexts. As such, this thesis contributes to 'progressive realization' of the global ambitions to improve maternal and perinatal health developed by key players in (global) health governance.[53] It sets an example of how contextualisation and use of evidence can be approached: by involving a collaborative and interdisciplinary team of local and international researchers for capacity building, frontline healthcare workers and service users and using an iterative process with mixed-methodological approaches (Figure 1). In doing so, it resulted in triaging systems to better support the right woman receiving the right care at the right moment amidst the persistent low (human) health care resources, and coupled with contextual adaptation of guidelines as key interventions towards improvement of maternal and newborn health.

Pragmatic, yet rigorous, study designs combined with qualitative evidence are essential to evaluate effectiveness and implementation strategies and upscale of interventions in the real-life context of healthcare.[40–42,54–58] (Chapter 6). We recommend the use of this approach to validate the developed prognostic tool in other settings and evaluate its impact: its ability to improve triage, patient- and work-flow, risk management and birth outcomes when combined, in a user-friendly format, with contextualised clinical support aids, such as the PartoMa guidelines and novel foetal monitoring strategies/devices. In addition, a lot can be learned from and built on a proper set-up of routine data and surveillance systems including mortality and near-miss audits.[59] Such integrated approaches along a continuum of care from antenatal, intrapartum and postpartum/neonatal period are more likely to improve pregnancy outcomes.[60]

While identification and prioritisation of high-risk pregnancy is essential, many complications are not easily predictable and there is a need to improve the baseline quality of care for all women including access to emergency obstetrics and newborn care in case of unexpected adverse events. Thus, we call on international and local stakeholders to address the root causes of unsafe intrafacility care in low-resource settings, including the number of skilled birth attendants and essential medical supplies required for safe and respectful births.

With increasing intra-facility deliveries, there is a welcomed shift towards improving intra-facility quality of care. The WHO framework defines quality of care as consisting of two essential components: *provision* of care and *experience* of care with now particular emphasis and prioritization of 'positive pregnancy and child birth experience' as the core of the new strategies.[10,61,62] This reinstates respectful maternity care as a human right and disrespect and abuse of childbearing women as unethical and violations of these rights.[63]

Going back to the principle of progressive realisation, there are immediate and longterm actions that can be taken to tackle maltreatment of women during childbirth:

1) Education of women and communities to nurture women's agency (the ability to speak for themselves, stand up for themselves, and be their own agent).[64]
2) Pre-graduate and in-service training of healthcare workers and development and/or implementation of toolkits to provide the best possible clinical care, compassionate care, effective communication, shared decision-making, caring support and preserve women's privacy and dignity.
3) Have policies in place for respectful maternity care.

4) Routine assessment of respectful maternity care as health outcomes.
5) Birth companionship as an affordable intervention that responds to the basic emotional and physical needs of a woman during painful labour, associated with positive effects on perinatal outcomes and women's experience of childbirth. [65,66]

Most of these measures do not require significant resources or change in structure and are thus achievable in a relatively short period of time. However, for the latter, existing structures are a barrier to its use, mostly due to privacy, confidentiality and safety concerns (Chapters 3 and 9). Thus, strategies are required on how existing and future structures of maternity units can provide respectful maternity care across low- and middle-income countries. Community (e.g. lay health workers) and patient involvement in care might be the only realistic solution to addressing the human resource gap. And as clinicians, we owe it to our women, most of them poor and vulnerable, to form coalitions and advocate for the necessary changes to achieve humane, safe and dignified care.[53]

Conclusion

Skilled birth attendance is key to reducing pregnancy-related deaths. Thus, interventions that improve access and quality of facility care have the largest improvement in reducing birth-related deaths. While the proportion of births with skilled birth attendance has increased in low and middle-income countries, poor quality of care in birth facilities means perinatal and maternal mortality remain high. Key priorities for action to meet Sustainable Development Goals for maternal and neonatal mortality is the need for sufficient numbers of well-trained skilled birth attendants to deliver both routine and emergency obstetric care in well-resourced health facilities supported by a resilient health system. Contextualised evidence and strategies for incremental improvement in quality of care are instrumental and include risk-based obstetric triage, context-appropriate guidelines and community involvement. It is expected that this thesis will convey the experiences and perspectives of skilled birth attendants and women to advocate priority-setting, decision-making and action for maternal health care at national and global levels.

Key recommendation to improve intrapartum care in low-resource settings and by whom

General recommendations:

1. Better intrapartum documentation, quality data and surveillance systems and regular perinatal death audits and classification of perinatal deaths to determine causes of death and identify effective interventions. (Skilled birth attendants, policymakers at hospital and ministry levels)
2. Capacity building of local researchers and involvement of local stakeholder groups such as skilled birth attendants and women perspectives. (policymakers at hospital level and researchers)
3. Sufficient numbers of adequately trained and motivated staff (policymakers at hospital, ministry and government levels)
4. Use of high quality pragmatic designs which incorporate both quantitative and qualitative data to evaluate and contextualise interventions. (policymakers at hospital level and researchers)

Specific recommended research areas:

1. Context adaptation of international clinical guidelines
2. Impact evaluation of foetal monitoring devices and maternal perception of foetal movement
3. External validation and impact studies of the admission prediction rule for obstetric triage.
4. Interventions for promoting respectful maternity care and eliminating maltreatment and abuse e.g. through education and training, routine monitoring, and birth companionship by trained lay health workers.

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Chapter 15

Summary

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Summary in English

Almost all maternal and perinatal deaths occur in low and middle countries; the majority of which occur around the time of birth and are thus preventable by good quality care at birth with a skilled birth attendant for support, monitoring and emergency obstetric and neonatal care. Interventions to improve quality of care are paramount to better birth outcomes. The study setting at Mnazi Mmoja Hospital, Zanzibar, is a typical example of a high-volume maternity unit in low and middle income countries.

In **part 1** we explore the baseline quality of care and the context in which care is provided.

In **chapter 2**, we use a retrospective record-based case-control study of stillbirths to assess the baseline quality of intrapartum. We find a facility-based stillbirth rate of 59 per 1000 total births, of which a half die in the hospital. Overall, there is suboptimal quality of care in both live and stillborn babies. The seven key findings and target areas for interventions are as follows: 1) admission assessment of maternal foetal characteristics and wellbeing; 2) routine surveillance of maternal and foetal wellbeing (e.g. the median time from last foetal heart assessment until diagnosis of foetal death or delivery was 210 minutes (interquartile range: 75–315 minutes)) and progress of labour during both latent and active phases, particularly, 3) women with pre-hospital intrauterine foetal death were at highest risk of neglect; 4) substandard diagnosis and management of hypertensive disorders and 5) prolonged labour; 6) unnecessary caesarean section and 7) substandard intrapartum documentations.

In **chapter 3,** we investigate maternal psychosocial health and daily functioning of women who experience a stillbirth and compare them to women with healthy newborns. The results show high levels of mental health symptoms regardless of newborn outcome: 1) 73% (96/132) of women with healthy infants and 75% (n=86/114) with stillbirths have symptoms of depression and 23% (n=31) and 24% (n=27)

of these screen positive for depression. Also, 80% (n=105/132) of women with healthy infants and 96% (n=110/114)) of women with stillbirths have one or more symptoms of posttraumatic stress disorder (PTSD); 4% of women screen positive for PTSD. Women with stillbirths have significantly lower birth satisfaction. Sociodemographic characteristics (age, marital status and employment) and care around birth are independent risk factors for mental health problems and disability. Social and spiritual support are positively viewed.

In **chapter 4**, we investigate factors affecting quality of care through interviews and focus discussions with women, skilled birth attendants and policymakers. Factors influencing quality of care are: 1) the high number of labouring women, work overload and inadequate staff; 2) lack of equipment and supplies; 3) poor labour ward infrastructure; 4) lack of teamwork, job allocation, motivational support, and supervision; 5) negative attitude, lack of knowledge, commitment and sense of responsibility. Also, multiple underlying systemic factors are identified: inadequate pre-service education and in-service training; referral mechanism; leadership and accountability; human resource management; ministry and government policies, planning, and financing. We conclude that frontline healthcare staff and pregnant women face various challenges that restrict the provision of quality and respectful intrapartum care including FHR monitoring. Contributing factors to poor intrapartum care are related to the healthcare system. Interventions should target the areas identified with the involvement of care providers and service users.

In **chapter 5**, we present a case study of a 31-year-old multiparous Malawian whose baby has birth asphyxia following delayed recognition and response to abnormal labour progress and foetal distress in a Malawian hospital. We conclude that countries in Sub-Saharan Africa are still far from meeting Sustainable Development Goal 3's target to end preventable deaths of newborns and reduce neonatal mortality because of persisting suboptimal intrapartum care.

In **chapter 6**, we describe discussions with pregnant women, skilled birth attendants and policymakers to determine whether task-shifting of FHR monitoring to lay health workers is a locally-acceptable intervention. Many concerns are raised about this task-shifting intervention: 1) effectiveness of the intervention (lack of medical training, competency and safety), 2) ethicality (confidentiality, policy and regulatory support), 3) opportunity costs (loss of FHR monitoring skills for midwives, and costs of the intervention), 4) affective attitude (liability concerns, professional protectionism, jealousy, mistrust, disrespect and blame), 5) burden on existing cadre (training and supervision, conflict and strained interprofessional relationships, roles and limitations). We conclude that task shifting of foetal heart rate monitoring to lay workers is a suboptimal solution to the health care staff shortages. Therefore, given the persistent health system's constraints in providing adequate numbers of nurse-midwives, further efforts are needed to find alternative strategies to optimise FHR monitoring.

In **part 2** we synthesise the available evidence for intrapartum foetal monitoring and try to fill in gaps in existing evidence by eliciting expert opinion in a consensus procedure (Delphi study).

In **chapter 7**, we conduct a broad systematic review of strategies for foetal surveillance in low-resource settings and associated neonatal and maternal outcomes, including barriers to their implementation. There are 37 studies included: five intervention and 32 observational studies. Use of the partograph improved perinatal outcomes. Intermittent auscultation with Pinard is associated with lowest rates of caesarean sections (10-15%) but with comparable perinatal outcomes to hand-held Doppler and Cardiotocography (CTG). CTG is associated with the highest rates of caesarean sections (28-34%) without proven benefits for perinatal outcome. Several tests on admission (admission tests) and adjunctive tests including foetal stimulation tests improve the accuracy of foetal heart rate monitoring in predicting adverse perinatal outcomes. We conclude that from the available evidence, the partograph is associated with improved perinatal outcomes and we recommend its use with intermittent auscultation and disrecommend the use of CTG for intrapartum monitoring without proven benefits in low-resource settings.

In **chapter 8**, we aim to determine acceptable and achievable strategies of intrapartum foetal monitoring in busy low-resource settings using a Delphi consensus process among international experts with experience in low-resource settings. Seventy-one experts completed all three rounds (28 midwives, 43 obstetricians). Consensus is reached on: 1) the need for an admission test, 2) hand-held Doppler for intrapartum foetal monitoring, 3) intermittent auscultation (IA) every 30 minutes in low-risk pregnancies during first stage and after every contraction in high-risk pregnancies in second stage of labour, 4) contraction monitoring hourly in low-risk pregnancies in first stage of labour and, 5) adjunctive tests. Consensus is not reached on frequency of IA and contraction monitoring for high-risk women in first stage, low-risk pregnancies in second stage of labour. We conclude that there is a gap between international recommendations and what is physically possible in many labour wards in low-resource-settings. Therefore, further research is needed on assessment of foetal wellbeing on admission and to support staff in achieving best possible care in low-resource contexts. In **part 3**, we adapt international guidelines of clinical care to the local context.

In **chapter 9**, we evaluate the effect of locally tailored labour management guidelines (PartoMa guidelines) on clinical practice and intrahospital stillbirths and birth asphyxia using a quasi-experimental pre-post study. Stillbirth rate fell from 59 to 39 per 1000 total births (RR 0.66, 95% CI 0.53–0.82), mainly due to reduction in intrapartum stillbirths. Apgar scores between 1 and 5 fell from 52 to 28 per 1000 live births (RR 0.53, 95% CI 0.41–0.69). Median time from last foetal heart assessment till delivery (or foetal death diagnosis) fell from 120 minutes (IQR 60–240) to 74 minutes (IQR 30-130), $p < 0.01$). Oxytocin augmentation declined from 22% to 12% (RR 0.54, 95% CI 0.37–0.81) and timely use improved. We conclude that although low human resources and substandard care remain major challenges, PartoMa guidelines are associated with improvements in care, leading to reductions in stillbirths and birth asphyxia. Findings furthermore emphasise the central role of improved foetal surveillance and restricted intrapartum oxytocin use in safety at birth.

In **chapter 10**, we assess the quality of intrapartum care and adherence to locally-tailored clinical guidelines using a non-participatory, structured, direct observation study. We observe care in 161 labouring women. We find a nurse/midwife-to-labouring-women ratio of 1:4, which result in informal task-sharing of with for a significant part of intrapartum monitoring. There is a lack of respectful care with screening for privacy and communication of examination findings being done in 50% and 34%, respectively. For the majority, there is delayed recognition of labour progress and insufficient support in second stage of labour. Foetal heart monitoring is suboptimally assessed in terms of quality of frequency with a median interval of 105 (interquartile range 57 -160) minutes. However, the occurrence of an intrapartum risk event (non-reassuring FHR, oxytocin use or poor progress) increase assessment frequency significantly (rate ratio 1.32 (CI 1.09-1.58)). We conclude that neither international nor locally-adapted standards of intrapartum routine care are optimally achieved. This is most likely due to a grossly inadequate capacity of birth attendants; without whom innovative interventions at birth are unlikely to succeed. This calls for international and local stakeholders to address the root causes of unsafe intrafacility care in low-resource settings, including the number of skilled birth attendants required for safe and respectful births.

In **chapter 11**, through a letter of correspondence to authors who used a similar method in a study to measure mistreatment during childbirth in low resource settings, we reflect on how respect and concern for participants' rights and welfare can be upheld when qualified clinicians or non-clinicians use non-participatory direct labour observations to assess quality of care. Using our experiences in chapter 10, we suggest various steps to be taken to make direct labour observation safe, respectable, and non-blaming: 1) by considering observer selection and role especially in settings lacking clinicians; 2) extensive training in (research) ethics to support the informed consent process and overall conduct, 3) stakeholder engagement to establish trust and contextualise findings, 4) establishment of protocols with guidance in case of emergencies, and psychological support supportive for the observer; and 5) development of specific ethical conduct guidance based on principles of research ethics.

In **part 4**, perinatal deaths are classified according to Classification of Diseases-10 - to perinatal mortality (ICD-PM) and we develop a prognostic model to predict intrapartum-related perinatal deaths.

In chapter 12, we first assess the feasibility of the application of International Classification of Diseases-10 - to perinatal mortality (ICD-PM), which classifies perinatal deaths according to timing, causes and associated maternal conditions, in the study setting of a busy low-resource referral hospital. We find that of the 661 perinatal deaths, 248 (37.5%) are neonatal deaths and 413 (62.5%) stillbirths. Of the stillbirths, 128 (31%) occur antepartum, 129 (31%) intrapartum and for 156 (38%) the timing is unknown. Half (n=64/128) of the antepartum stillbirths are unexplained. Two-thirds (67%, n=87/129) of intrapartum stillbirths follow acute intrapartum events, and 30% (39/129) are unexplained. Of the neonatal deaths, 40% die after complications of intrapartum events. We face challenges in gathering sufficient information for classification. Thus, we conclude that better clinical assessment and documentation from the time of admission, including foetal heart rate, and perinatal death audits are crucial for any classification and identifying target areas for interventions. Also, global applicability of ICD-PM requires standardised operationalised definitions and harmonised guidance.

In **chapter 13** we also conduct a large prospective cohort study of 5610 pregnant women being admitted to the labour ward. We use their maternal and foetal characteristics obtained through routine care to develop a clinical prediction model to identify patients at risk of intrapartum-related perinatal deaths in low-resourced settings, by 1) external validation of an existing prediction model, and subsequently 2) development of a novel model. We find that the original model was not suitable for our study setting and so a new model consisting of 15 clinical predictors is developed which show high performance in terms of calibration and discrimination ability (c-statistic of 0.8). We conclude that the new model has the potential to assist skilled birth attendants to triage women for appropriate management during labour and thus it should be further evaluated in future studies.

Chapter 14 is a general discussion and synthesis of all our results, with subsequent recommendations to practice and policy.

Samenvatting

Bijna alle sterfte rondom de geboorte, van zowel moeder als kind, vinden plaats in laag- en middeninkomens landen, waarvan het merendeel tijdens de geboorte. De meeste sterfte is dan ook te voorkomen door het bieden van kwalitatief goede zorg gedurende de geboorte namelijk een bekwame zorgverlener, adequate maternale en foetale bewaking, de toegang tot acute verloskundige zorg en goede neonatale opvang. Het is dan ook essentieel dat interventies zich richten op het verbeteren van de kwaliteit van zorg om geboorte uitkomsten te verbeteren. Onze onderzoeksetting, in het Mnazi Mmoja Ziekenhuis te Zanzibar, Tanzania, is illustratief voor de grootschaligheid van verloskundige zorginstellingen in laag- en middeninkomens landen.

In **deel 1** exploreren we de kwaliteit van zorg en de context waarin de zorg wordt verleend als uitgangspunt.

In **hoofdstuk 2** verrichten we een retrospectief, case-control onderzoek op basis van dossiers waarbij we de kwaliteit van zorg tijdens de bevalling beoordelen bij vrouwen met en zonder een foetale sterfte. De foetale sterfte ratio in het ziekenhuis bedraagt 59 per 1000 geboortes, waarbij de helft in het ziekenhuis overlijdt. De zorg is suboptimaal bij zowel levende als doodgeboren baby's. De zeven belangrijkste bevindingen en mogelijkheden voor interventies zijn: 1) bij opname de maternale en foetale conditie beoordelen; 2) routinematig de maternale en foetale conditie bewaken (de mediane tijd tussen de laatste foetale monitoring en diagnose van de foetale sterfte of bevalling bedroeg 210 minuten, IQR 75-315 minuten) en de ontsluiting beoordelen in zowel de latente als de actieve fase; 3) vrouwen bij wie de foetale sterfte al vóór ziekenhuisopname werd vastgesteld liepen het grootste risico op verwaarlozing; 4) de diagnose en behandeling van hypertensieve aandoeningen was suboptimaal; 5) langdurige bevallingen kwamen veel voor; 6) er waren onnodige sectio caesarea en 7) documentatie tijdens de ontsluitingsfase was onvoldoende.

In **hoofdstuk 3** onderzoeken we de psychosociale gezondheid en het dagelijks functioneren van vrouwen die een foetale sterfte hebben meegemaakt en vergelijken dit met vrouwen met gezonde pasgeborenen. Het niveau van psychische symptomen bleek hoog, ongeacht de uitkomst van de pasgeborene: 73% (n = 96/132) van de vrouwen met een gezonde baby en 75% (n = 86/114) met een foetale sterfte hebben symptomen van depressie, waarbij ze in 23% (n = 31) en 24% (n = 27) positief screenen op een depressie. Daarnaast werden één of meer symptomen van posttraumatische stressstoornis (PTSS) gezien bij 80% (n = 105/132) van de vrouwen met gezonde baby en 96% (n = 110/114)) van de vrouwen met een foetale sterfte, hierbij screende ze in 4% positief op PTSS. Vrouwen met een foetale sterfte hebben een significant minder goede ervaring van de bevalling. Sociaal-demografische kenmerken (leeftijd, burgerlijke staat en werk) en zorg rond de geboorte zijn onafhankelijke risicofactoren voor psychische problemen en complicaties. Sociale en spirituele ondersteuning worden door vrouwen als positief ervaren.

In **hoofdstuk 4** verrichten we interviews en focus-groep gesprekken met (bevallen) vrouwen, ervaren verloskundigen en beleidsmakers en beoordelen we de factoren die de kwaliteit van zorg beïnvloeden. Factoren die van invloed zijn hierop zijn: 1) het hoge aantal bevallende vrouwen, overbelasting en onbekwaam personeel; 2) gebrek aan materiaal en spullen; 3) slechte infrastructuur van de verloskamers en afdeling; 4) gebrek aan teamwerk, taakverdeling, motiverende ondersteuning en supervisie; 5) negatieve houding, gebrek aan kennis, betrokkenheid en verantwoordelijkheidsgevoel. Daarnaast worden meerdere onderliggende systemische factoren geïdentificeerd: slechte vooropleiding, geen bijscholing, geen duidelijk verwijzingssysteem, onvoldoende leiderschap en verantwoordelijkheidsgevoel, gebrek aan personeel, en onvoldoende steun en financiering vanuit de overheid. We concluderen dat zowel zwangere vrouwen als zorgpersoneel in de frontlinie worden geconfronteerd met uitdagingen die ervoor zorgen dat kwalitatieve, respectvolle zorg tijdens de bevalling (inclusief FHR-monitoring) onmogelijk is. Daarnaast draagt het huidige zorgsysteem bij aan de slechte zorg die wordt gegeven. Interventies moeten zich daarom richten op de beïnvloedbare factoren, waarbij zowel de zorgverleners en zwangere vrouwen betrekken dienen te worden.

In **hoofdstuk 5** presenteren we een casus van een 31-jarige vrouw in een ziekenhuis in Malawi wiens baby door asfyxie overlijdt als gevolg van vertraagde herkenning van langzame vordering en foetale nood. We concluderen dat landen in Sub-Sahara Afrika nog ver weg staan van het bereiken van de Duurzame Ontwikkelingsdoelstelling 3. Door de suboptimale zorg tijdens de baring worden vermijdbare sterfte van pasgeborenen en neonaten niet voorkomen.

In **hoofdstuk 6** bespreken we met zwangere vrouwen, zorgverleners (verloskundigen) en beleidsmakers of foetale bewaking uitbesteed zou kunnen worden aan personeel zonder medische vooropleiding, gezien het groot tekort aan zorgpersoneel. De volgende zorgen over deze taakverschuiving (task-shiften) worden benoemd: 1) effectiviteit van de interventie (gebrek aan medische achtergrond, competenties en veiligheid), 2) ethiek (vertrouwelijkheid, beleid en regulatie), 3) alternatieve kosten (verlies van FHR-monitoringvaardigheden voor verloskundigen, en kosten van de interventie), 4) affectieve houding (zorgen over aansprakelijkheid, zorgverlening protectionisme, jaloezie, wantrouwen, gebrek aan respect en schuld), 5) druk op bestaande kader (opleiding en supervisie, conflicten en gespannen relaties tussen zorgverleners, rollen en beperkingen). We concluderen dat het uitbesteden van foetale bewaking aan niet-medisch onderlegd personeel geen oplossing is voor het gebrek aan zorgpersoneel. Aangezien het gezondheidssysteem beperkt blijft in het leveren van voldoende zorgpersoneel, zullen alternatieve strategieën moeten worden bedacht om foetale bewaking te optimaliseren.

In **deel 2** verzamelen we het beschikbare bewijs voor foetale bewaking gedurende de partus en proberen de hiaten in kennis op te vullen door met experts consensus te bereiken (Delphi-studie).

In **hoofdstuk 7** verrichten we systematische review naar de strategieën voor foetale bewaking tijdens de partus in landen met beperkte middelen en de bijbehorende neonatale en maternale uitkomsten. Daarbij evalueren we de beperking ervan met betrekking tot implementatie. Er zijn 37 studies meegenomen in de review: vijf interventie- en 32 observationele studies. Deze laten zien dat het gebruik van het partogram perinatale uitkomsten verbetert. Intermitterende auscultatie met een Pinard wordt geassocieerd met het laagste percentage sectio caesarea (10-15%), en tegelijkertijd met vergelijkbare perinatale uitkomsten vergeleken met de handmatige doppler en cardiotocografie (CTG). Het CTG is geassocieerd met het hoogste percentage sectio's (28-34%) zonder bewezen voordelen voor de perinatale uitkomst. Verschillende onderzoeken bij binnenkomst en aanvullende diagnostiek tijdens opname (waaronder foetale stimulatietests), verbeteren de nauwkeurigheid van foetale bewaking en het voorspellen van ongunstige perinatale uitkomsten. We concluderen, op basis van het beschikbare bewijs, dat het partogram geassocieerd is met betere perinatale uitkomsten en raden intermitterende auscultatie aan. Het gebruik van het CTG voor foetale monitoring tijdens de partus wordt afgeraden, aangezien er geen bewezen voordelen zijn in laag inkomens landen met beperkte middelen.

In **hoofdstuk 8** presenteren we de Delphi-studie die ernaar streeft om consensus te bereiken onder internationale experts over welke foetale bewaking strategieën aanvaardbaar en haalbaar zijn in laag inkomenslanden met drukke verloskamers, weinig personeel en beperkte middelen. Eenenzeventig experts hebben alle drie de rondes doorlopen (28 verloskundigen, 43 obstetrici). Er wordt consensus bereikt over: 1) de noodzaak van een toetsing bij opname, 2) gebruik van de draagbare doppler voor foetale bewaking tijdens de partus, 3) intermitterende auscultatie (IA) bij partus van vrouwen met een laag risico, waarbij elke 30 minuten tijdens de ontsluiting en na elke wee tijdens de uitdrijving wordt geausculteerd, 4) elk uur de frequentie, duur en kracht van weeën beoordelen tijdens de ontsluitingsfase van laag risico bevallingen en 5) aanvullende testen. Er wordt geen consensus bereikt over de frequentie van IA en beoordelen van de weeën tijdens de ontsluitingsfase bij vouwen met een hoog risico en tijdens de uitdrijving bij vrouwen met een laag risico. We concluderen dat er een kloof is tussen internationale aanbevelingen en wat fysiek mogelijk is op de werkvloer (met beperkte middelen). Er is om deze reden verder onderzoek nodig naar de mogelijkheden van foetale bewaking tijdens de partus in zorginstellingen met beperkte middelen, waarbij tegelijkertijd aandacht besteed dient te worden aan het ondersteunen van zorgpersoneel in het verlenen van de best mogelijke zorg.

In **deel 3** passen we internationale richtlijnen aan naar de lokale context.

In **hoofdstuk 9** evalueren we het effect van lokaal, op maat gemaakte, verloskundige richtlijnen voor tijdens de partus (PartoMa-richtlijnen). We voeren een quasi-experimentele pre-post studie uit waarbij we kijken naar het effect van de richtlijnen op de klinische praktijk, foetale sterfte in het ziekenhuis en vóórkomen van asfyxie. De foetale sterfte daalde van 59 tot 39 per 1000 totale geboorten (RR 0.66, 95% BI 0.53-0.82), voornamelijk door een afname van intra-partum foetale sterfte. Lage Apgar-scores (1 t/m 5) daalde van 52 naar 28 per 1000 levendgeborenen (RR 0.53, 95% BI 0.41-0.69). De mediane tijdsduur tussen het vaststellen van de foetale sterfte en de laatste keer dat de foetale hartslag werd beoordeeld daalde van 120 minuten (IQR 60-240) tot 74 minuten (IQR 30-130), p <0.01. Bijstimulatie met oxytocine daalde van 22% naar 12% (RR 0.54, 95% BI 0.37-0.81), terwijl het juist vaker werd toegediend als het nodig was. We concluderen dat ondanks dat een tekort aan personeel en suboptimale kwaliteit van zorg een grote uitdagingen blijven, de PartoMa-richtlijnen verbeteringen in de zorg hebben teweeggebracht, wat heeft geleid tot minder foetale sterfte en een betere start bij de geboorte. Verder wordt benadrukt hoe foetale bewaking en beperkt gebruik van oxytocine bijdragen aan veilige verloskunde.

In **hoofdstuk 10** beoordelen we de kwaliteit van zorg tijdens de baring en de mate waarin de lokale, op maat gemaakte, richtlijnen worden toegepast. We observeren middels een niet-participerende observationele studie de kwaliteit van verloskundige zorg bij 161 vrouwen die bevallen. De verhouding van verpleegkundige en verloskundige ten opzichte een barende vrouw bedroeg 1 op 4, wat ertoe leidt dat foetale bewaking vaak wordt uitbesteed aan niet-medisch personeel. Respectvolle zorg wordt beperkt nageleefd, zo wordt er in 50% van de gevallen rekening gehouden met privacy en in 34% wordt het onderzoek aan de patiënt door gecommuniceerd. In het merendeel wordt een langdurig beloop van de baring niet herkend en is er onvoldoende ondersteuning tijdens de uitdrijving van de baring. De frequentie van het bewaken van de foetale conditie is suboptimaal met een mediaan interval van 105 (IQR 57-160) minuten. Het optreden van een complicatie of risicovolle interventie tijdens de partus, zoals foetale bradycardie, oxytocinegebruik of een traag verloop van de baring, zorgt echter wel voor een toename in frequentie waarmee de maternale en foetale conditie worden beoordeeld (rate ratio 1.32, 95%CI 1.09-1.58). We concluderen dat noch internationale, noch lokaal aangepaste richtlijnen bedoeld voor de zorg tijdens de partus worden nageleefd. Dit is grotendeels te wijten aan de zeer beperkte hoeveelheid personeel, zonder wie innovatieve interventies bij de geboorte niet zullen slagen. Deze bevindingen roepen internationale en lokale belanghebbenden op om de oorzaken van onveilige zorg in ziekenhuizen in laaginkomens landen aan te pakken, waaronder het aantal bekwame zorgverleners dat nodig is voor veilige en respectvolle zorg tijdens de partus.

In **hoofdstuk 11** reflecteren we, middels een correspondentie brief, op de ethiek rondom de observatie van mishandeling tijdens de bevalling in landen met beperkte middelen. Hierbij delen we onze bezorgdheid met betrekking tot respect voor de rechten en het welzijn van de zwangere en hoe deze gehandhaafd kunnen blijven als clinici en niet-clinici observaties doen met betrekking tot de kwaliteit van zorg. Naar aanleiding van onze ervaringen in hoofdstuk 10, stellen we verschillende stappen voor die genomen kunnen worden om directe observaties veilig, met respect en zonder verwijten te maken: 1) door nauwkeurige selectie van waarnemers en hun rol in overweging te nemen, vooral in situaties met weinig zorgverleners; 2) uitgebreide training in (onderzoeks)ethiek ter ondersteuning van het geïnformeerde toestemmingsproces en algemeen gedrag, 3) betrokkenheid van lokale belanghebbenden om vertrouwen te scheppen en bevindingen te contextualiseren, 4) het opstellen van protocollen voor noodgevallen, inclusief psychologische ondersteuning van de waarnemer; en 5) ontwikkeling van specifieke ethische gedragsrichtlijnen op basis van de principes van onderzoek ethiek.

In **deel 4** classificeren we perinatale sterfte volgens de International Classification of Diseases-10 - Perinatal Mortality (ICD-PM) en ontwikkelen we een prognostisch model om foetale sterfte tijdens de bevalling te voorspellen.

In **hoofdstuk 12** evalueren we de toepasbaarheid van de ICD-PM in een setting met beperkte middelen. De ICD-PM is een classificatiesysteem, ontwikkeld door de WHO, dat perinatale sterfte groepeert op basis van tijd, oorzaken en bijbehorende maternale aandoeningen. Van de totaal 661 perinatale sterfte, zijn 248 (37.5%) neonataal en 413 (62.5%) foetaal. Van de foetale sterfte vinden 128 (31%) antepartum plaats, 129 (31%) intra-partum en voor de resterende 156 (38%) is de tijd van sterfte onbekend. De helft (n = 64/128) van de antepartum sterfte blijft onverklaard. Twee-derde (67%, n = 87/129) van de intra-partum sterfte is het gevolg van een acute complicatie tijdens bevalling en 30% (n = 39/129) blijft onverklaard. Neonatale sterfte is in 40% van de gevallen het gevolg van intra-partum complicaties. Het achterhalen van informatie om perinatale sterfte te classificeren blijkt de belangrijkste uitdaging in onze studie setting. We concluderen daarom dat een betere klinische beoordeling en documentatie vanaf het moment van ziekenhuisopname, inclusief registratie van de foetale hartslag en perinatale sterfte-audits, cruciaal zijn voor het adequaat classificeren en het identificeren van hiaten voor interventies. Daarnaast zijn gestandaardiseerde classificatie regels en universele definities een vereiste om de ICD-PM wereldwijd toepasbaar te maken.

In **hoofdstuk 13** verrichten we een grote observationele prospectieve cohortstudie, om een predictiemodel te ontwikkelen om vrouwen met een verhoogd risico op een foetale sterfte tijdens de partus in laaginkomens landen met beperkte middelen te identificeren. We volgen 5610 zwangere vrouwen op die opgenomen worden op de verloskamers en verkrijgen de perinatale data vanuit routinematige zorg. We verrichten initieel externe validatie van een bestaand predictie-model verricht, en ontwikkelen vervolgens een nieuw predictiemodel. Het bestaande predictie model blijkt onvoldoende passend in onze studie setting. Het nieuw ontwikkelde model, op basis van 15 klinische voorspellers, geeft een goede kalibratie en een goed onderscheidend vermogen (c-statistiek van 0.8). We concluderen dat dit nieuwe model de potentie heeft om zorgverleners te ondersteunen bij de triage van patiënten met een verhoogd risico op intra-partum foetale sterfte. We raden aan dit predictie model in de toekomst in vergelijkbare landen te evalueren en te valideren.

Hoofdstuk 14 vormt de algemene discussie en kritische beoordeling van de studies die wij hebben verricht, met daarbij aanbevelingen voor de dagelijkse praktijk en beleid.

Ufupisho kwa Kiswahili

Karibu vifo vyote vya mama wajawazito na watoto wachanga katika nchi za uchumi wa kati na wa chini, ambavyo vingi vyao hutokea wakati wa kuzalisha na kwa hivyo vingeweza kuzilika kwa kupewa huduma bora wakati wa kujifungua, na mkunga au mtoa huduma mwenye taaluma na ujuzi wa kuangalia, kuamua na kuchukua hatua kwa wakati pale dharura inapotokea kwa mama na mtoto azaliwae. Jitihada za kuboresha utoaji wa huduma bora ni njia sahihi kuwezesha matokea bora ya uzalishaji kinamama.

Utafiti huu katika hospitali ya mnazi mmoja Zanzibar, ni mfano sahihi wa hospitali na wadi ya mama wajawazito katika nchi za uchumi wa chini na kati.

Katika **sehemu ya 1** tuliangalia jinsi utolewaji na ubora wa huduma na muktadha wake.

Katika **sura ya 2** tumetumia taarifa za nyuma zilizoorodheshwa kwenye hifadhi za taarifa za mgonjwa kwa kulinganisha mama anaetafitiwa taarifa zake na mama anaelinganishwa nae ambae hakupata tatizo wakati wa kujifungua yeye na mtoto hai na aliefia tumboni kupima ubora wa huduma ambazo walipatiwa wakati wa kujifungua.Tumegundua vifo vilivyotokea ndani ya hospitali ni 59 kwa kila vizazi 1000 kati ya hivyo nusu hufa ndani ya hospitali.Kwa ujumla, kuna chini ya kiwango ubora wa huduma wanazopata vizazi hai na vifo vya watoto wachanga pia.Mambo saba makuu ambayo tumeyaona na yanayohitaji kufanyiwa kazi ni: 1)Uchunguzi wa awali wa hali na jinsi maendeleo ya mtoto wakati mama analazwa kwaajili ya kujifungua.2) ufuatiliaji wa kawaida wa ustawi wa mama na mtoto (kwa mfano, wakati wa wastani kutoka tathmini ya mwisho ya moyo wa mtoto hadi utambuzi wa kifo cha mtoto au kujifungua ilikuwa dakika 210 (IQR: dakika 75-315)) na maendeleo ya uchungu wakati wa awali na kukaza kwa uchungu mpka utayari wa kujifungua . 3) wanawake waliofika mtoto akiwa ameshafariki kabla ya kufika hospitali walikuwa katika hatari kubwa ya kutelekezwa; 4) utambuzi duni na usimamizi wa shida ya shinikizo la damu na5) uchungu uliopitiliza muda; 6) Upasuaji wa uzazi usio wa lazima na 7) Kiwango cha chini cha Uandishi wa taarifa za huduma za uangalizi za mama na mtoto wakati wa kujifungua.

Katika **sura ya 3**, tunachunguza kisaikolojia afya ya kinamama na utendaji wa kila siku wa wanawake ambao walizaa watoto wafu, na kuwalinganisha na kinamama waliozaa watoto wachanga wenye afya na hai. Matokeo yanaonyesha viwango vya juu vya dalili za afya ya akili bila kujali matokeo ya watoto wachanga: 1) 73% (96/132) ya wanawake walio na watoto wachanga wenye afya na 75% (n = 86/114) walio na kuzaliwa wakiwa na dalili za unyogovu na 23% (n = 31) na 24% (n = 27) ya hizi walichunguzwa mapema na kukutwa na tatizo la unyogovu. Pia, 80% (n = 105/132) ya wanawake walio na watoto wachanga wenye afya na 96% (n = 110/114)) ya wanawake walio na kuzaa kwa mtoto mchanga wana dalili moja au zaidi ya shida ya wasiwasi wa baadaye (PTSD); 4% ya wanawake waliochunguzwa walikutwa na tatizo la PTSD. Wanawake waliokosa watoto wanaathari kubwa ya kutoridhishwa na hali ya uzazi. Tabia za kijamii (umri, hali ya ndoa na ajira) na huduma wakati wa kuzaa na kuzalishwa ni hali hatarishi zinazojitegemea kuweza kusababisha athari za afya ya akili na ulemavu. Msaada wa kijamii na kiroho unatazamwa kuwa na msaada na kusaidia athari hizo au hatari hizo.

Katika **sura ya 4**, tumechunguza sababu zinazoathiri ubora wa huduma kupitia mahojiano na mazungumzo kwa makundi kuzingatia na mama waliokwishajifungua, wakunga wa uzazi wenye ujuzi na watunga sera/sheria. Sababu zinazoathiri ubora wa huduma ni: 1) idadi kubwa ya wanawake waliokua na uchungu, kazi nyingi bila wafanyakazi wa kutosha; 2) ukosefu wa vifaa na visaidizi; 3) miundo mbinu duni ya wodi ya wazazi; 4) ukosefu wa ushirikiano pamoja wa kazi, mgawanyo wa kazi, msaada wa motisha, na usimamizi; 5) mtazamo hasi, ukosefu wa maarifa, kujitolea na hisia ya uwajibikaji. Pia, sababu nyingi za kimfumo zinatambuliwa: elimu duni ya kabla ya ajira na mafunzo ya kazini; utaratibu wa rufaa; uongozi na uwajibikaji; usimamizi wa rasilimali watu;

sera za wizara na serikali, mipango, na ufadhili. Tunahitimisha kwa kutambua kua wafanyikazi wa mstari wa mbele wa huduma ya afya na wanawake wajawazito wanakabiliwa na changamoto anuwai zinazozuia utoaji wa huduma bora na za heshima za ndani ikiwa ni pamoja na ufuatiliaji wa mapigo ya moyo ya mtoto awapo tumboni mwa mama yake. Sababu zinazochangia ufuatiliaji duni wa huduma za mama mjamzito wakati wa kujifungua huhusiana na mfumo wa huduma ya afya. Urekebishaji na jitihada unapaswa kulenga maeneo yaliyotambuliwa na ushiriki wa watoa huduma na watumiaji wa huduma.

Katika **sura ya 5**, tunawasilisha uchunguzi wa kesi ya Mmalawi mmoja mwenye umri wa miaka 31 ambaye amezaa mara zaid ya mbili ambaye mtoto wake amezaliwa na kupata shida kufuatia kuchelewa kutambuliwa na kuchukua hatua kwa wakati pale maendeleo ya uchungu hayakua ya kawaida na shida ya mapigo ya moyo ya mtoto akiwa tumboni katika hospitali ya Malawi. Tunamalizia kuwa nchi zilizo Kusini mwa Jangwa la Sahara bado ziko mbali kufikia lengo la Maendeleo Endelevu Lengo la 3 kumaliza vifo vinavyoweza kuzuilika vya watoto wachanga na kupunguza vifo vya watoto wachanga kwa sababu zinazojulikana za uangalizi na ushuhulikiaji duni wa kina mama na watoto wakati wa kuzalisha.

Katika **sura ya 6**, tunaelezea majadiliano na wanawake wajawazito, wakunga wenye ujuzi na watunga sera ili kubaini ikiwa mabadiliko ya kazi ya ufuatiliaji wa mapigo ya moyo ya mtoto (FHR) kwa wafanyakazi wa afya ni njia inayokubalika katika mazingira yetu ya kazi. Wasiwasi mwingi umetolewa juu ya uingiliaji huu wa kubadilisha kazi: 1) ufanisi wa utendaji na upimaji wa hayo mapigo ya moyo, (ukosefu wa mafunzo ya kitabibu, umahiri na usalama), 2) maadili (usiri, sera na msaada wa kisheria), 3) gharama za fursa (kupoteza ujuzi wa ufuatiliaji wa FHR kwa wakunga, na gharama za ziada kwaajili ya hao watakaokua wanafany kazi hiyo), 4) mtazamo unaofaa (wasiwasi wa dhima, ulinzi wa kitaalam, wivu, kutokuaminiana, kutoheshimu na lawama), 5) mzigo kwa kada iliyopo (mafunzo na usimamizi, mizozo na uhusiano uliodidimia wa kitaalam, majukumu na mapungufu). Tunamaliza kuwa mabadiliko ya kazi ya ufuatiliaji wa kiwango chamapigo ya moyo ya mtotoi kwa wafanyikazi wasio na ujuzi ni chini ya suluhisho la msingi kwa upungufu wa wafanyikazi wa huduma ya afya. Kwa hivyo, kutokana na vikwazo vinavyoendelea vya mfumo wa afya katika kutoa idadi ya kutosha ya wauguzi-wakunga, juhudi zaidi zinahitajika kupata mikakati mbadala ya kuongeza ufuatiliaji wa FHR.

Katika **sehemu ya 2** tunaunganisha ushahidi uliopo wa ufuatiliaji wa maendeleo ya mtoto na kujaribu kujaza mapengo katika ushahidi uliopo kwa kushawishi maoni ya wataalam katika utaratibu wa makubaliano (Utafiti wa Delphi).

Katika **sura ya 7**, tunafanya mapitio mapana ya kimkakati ya ufuatiliaji wa maendeleo ya mtoto katika hospitali zenye rasilimali ndogo na matokeo yanayohusiana na watoto wachanga na wajawazito, pamoja na vizuizi vya utekelezaji wao. Kuna masomo 37 yaliyojumuishwa: matano ya kiutekelezaji, na 32 ya uchunguzi wa kuangalia. Matumizi ya patografu yameboresha matokeo ya kuzaa. Usikilizaji wa kutumia Pinard unahusishwa na kuwezesha kupunguza na kuwa na viwango vya chini kabisa vya sehemu za uzalishaji wa upasuaji (10-15%) lakini na matokeo yanayofanana ya kutumia usikilizaji kwa Doppler na kadiotokografi (CTG). CTG inahusishwa na viwango vya juu zaidi vya uzazi wa upasuaji (28-34%) bila faida iliyothibitishwa kwa matokeo ya vizazi vyao. Vipimo kadhaa wakati wa kulazwa (vipimo vya kulazwz) na vipimo viambatisho pamoja na vipimo vya kusisimua mtoto huboresha usahihi wa ufuatiliaji wa kiwango chamapigo ya moyo wa mtoto katika kutabiri matokeo ya kuzaliwa mtoto. Tunahitimisha kuwa kutokana na ushahidi uliopo, patografu inahusishwa na matokeo bora ya kuzaa na tunapendekeza matumizi yake yakiambatana na usikilizaji wa kutumia pinadi na kutopendekeza matumizi ya CTG kwa ufuatiliaji wa uangalizi wakati wa kujifungua bila kuthibitisha faida zake katikanchi na maeneo ya rasilimali chache na zakiwango cha chini.

Katika **sura ya 8**, tunakusudia kuamua mikakati inayokubalika na inayoweza kufikiwa ya ufuatiliaji wa mtoto ndani ya maeneo yenye rasilimali chache kwa kutumia mchakato wa makubaliano ya Delphi kati ya wataalam wa kimataifa walio na uzoefu katika mipangilio ya rasilimali duni. Wataalam sabini na moja walimaliza raundi zote tatu (wakunga 28, madaktari wa uzazi 43). Makubaliano yalifikiwa juu ya: 1) hitaji la vipimo au uchunguzi wa awali wakati wa kulazwa, 2) kipima mapigo cha kubeba mkononi cha kuangalia wakati wa huduma za wakati wa uchungu wa kujifungua kwa ufuatiliaji wa maendeleo ya mtoto, 3) kusikiliza mapigo kila baada ya muda (IA) kila dakika 30 kwa wajawazito wa hali hatarishi ndogo wakati wa hatua ya kwanza ya uchungu, na baada ya kila mkazo wa uchungu kwa wajawazito wa hali hatarishi kubwa katika hatua ya pili ya uchungu, 4) ufuatiliaji wamkazo wa uchungu kila saa katika ujauzito wa hali hatarishi ndogo katika hatua ya kwanza ya uchungu, na, 5) vipimo ambatanishi na vya awali wakati wa kulazwa. Makubaliano hayafikiwi juu ya mzunguko wa IA na ufuatiliaji wa mkazo wa uchungu kwa wanawake walio katika hali hatarishi ndogo katika hatua ya kwanza, ujauzito wenyehali hatarishi kubwa katika hatua ya pili ya uchungu. Tunahitimisha kuwa kuna pengo kati ya mapendekezo ya kimataifa na kile kinachowezekana kimwili katika vituo vingi vya kazi na wafanyakazi katika mazingira ya rasilimali duni. Kwa hivyo, utafiti zaidi unahitajika juu ya tathmini ya ustawi wa mtotoi juu ya usajili wakati wa kulazwa na kusaidia wafanyakazi katika kupata utunzaji na uangalizi bora katika mazingira ya rasilimali duni.

Katika **sehemu ya 3**, tunabadilisha miongozo ya kimataifa ya huduma za kiungalizi kwa muktadha wa eneo.

Katika **sura ya 9**, tunatathmini athari za miongozo ya uangalizi na huduma wakati wa uzalishaji uliotokana na mazingira halisi ya hospitali yetu (miongozo ya PartoMa) juu ya huduma za kliniki na kuzalishwa watoto wafu na wenye matatizo ya kupata hewa baada ya kuzaliwa na kwa kutumia uchunguzi wa majaribio ya mapema. Kiwango cha wazaliwa wafu kilishuka kutoka 59 hadi 39 kwa jumla ya vizazi 1000 (RR 0.66, 95%

CI 0.53-0.82), haswa kwa sababu ya kupunguzwa kwa kuzaliwa kwa watoto waliofia tumboni. Alama za Apgar kati ya 1 na 5 ilishuka kutoka 52 hadi 28 kwa kila wazaliwa 1000 (RR 0.53, 95% CI 0.41-0.69). Wakati wa wastani mara ya mwisho kusikiliza mapigo ya moyo ya mtoto hadi kugundua mtoto kafia tumboni hadi kujifungua (au utambuzi wa kifo cha mtoto tumboni) ilishuka kutoka dakika 120 (IQR 60-240) hadi dakika 74 (IQR 30-130), p <0.01). Uongezaji wa oksitokini ulipungua kutoka 22% hadi 12% (RR 0.54, 95% CI 0.37-0.81) na matumizi ya wakati ulioboreshwa. Tunamalizia kuwa ingawa rasilimali watu na huduma duni zinaendelea kuwa changamoto kubwa, miongozo ya PartoMa inahusishwa na uboreshaji wa utunzaji, na kusababisha kupunguzwa kwa kuzaliwa kwa watoto waliokufa na ugonjwa wa shida ya kupata hewa mapema baada ya kuzaliwa. Matokeo zaidi yanasisitiza jukumu kuu la uboreshaji wa ufuatiliaji wa watoto kabla ya kuzaliwai na kuzuia matumizi ya dawa ya kuongeza uchungu(oksitosini) kwa usalama wa uzalishaji.

Katika **sura ya 10**, tunachunguza ubora wa huduma za wakati wa kuzalishana uzingatiaji wa miongozo ya kuchukua hatua wakati wa uangalizi wa kuzalisha uliotokana na kufanywa katika hospitali yetu, uliopangwa, na uchunguzi wa moja kwa moja uangalizi uliopangwa na kua usio shirikisha moja kwa moja. Tunachunguza kwa kuangalia huduma za wakti wa kuzalisha kwa kinamam a waliokwenye uchungu wanawake 161. Tumepata uwiano wa muuguzi / mkunga-kwa-kufanya kazi-wanawake wa 1: 4, ambayo inasababisha kugawana kazi isiyo rasmi na sehemu kubwa ya ufuatiliaji wa ndani. Kuna ukosefu wa utunzaji wa heshima na uchunguzi wa faragha na mawasiliano ya matokeo ya uchunguzi yanayofanywa kwa 50% na 34%, kama mfuatano zilivyotajwa. Kwa wengi, kuna kuchelewa kutambuliwa kwa maendeleo ya uchungu na ufungukaji wa njia na msaada wa kutosha katika hatua ya pili ya uchungu. Ufuatiliaji wa mapigo ya moyo wa mtoto hupimwa mara kwa mara kulingana na ubora wa masafa na muda wa wastani wa dakika 105 (IQR: 57 -160). Hatahivyo, kutokea kwa tukio la hatarishi ya ndani muendelezo wa uangalizi wa uzazi (mapigo mtoto yasiyofuatiliwa kiusahihi FHR, matumizi ya oksitosini au maendeleo duni) huongeza mzunguko wa tathmini kwa kiasi kikubwa (kiwango cha kiwango cha 1.32 (CI 1.09-1.58)). Tunahitimisha kuwa viwango vya kimataifa au vya kawaida vya huduma ya kawaida ya ndani havijafanikiwa. Hii inawezekana kwa sababu ya uwezo duni wa wakunga wa kuzalisha; bila ambaye uingiliaji wa ubunifu wakati wa kuzalisha hauwezekani kufanikiwa. Hii inatoa wito kwa wadau wa kimataifa na wa ndani kushughulikia sababu kuu za utunzaji salama wa nguvu katika mazingira ya rasilimali ndogo, pamoja na idadi ya wakunga wa uzazi wenye ujuzi wanaohitajika kwa uzazi salama na wa heshima.

Katika **sura ya 11**, kupitia barua kwa waandishi ambao walitumia njia kama hiyo katika utafiti kupima unyanyasaji wakati wa kuzaa katika mazingira ya rasilimali duni, tunatafakari juu ya jinsi heshima na kujali haki za washiriki na ustawi zinaweza kudhibitiwa wakati wakunga waliohitimu au wasio -watabibu hutumia uchunguzi wa uchungu wa moja kwa moja usioshiriki kutathmini ubora wa huduma. Kutumia uzoefu wetu katika sura ya 10, tunashauri hatua anuwai zichukuliwe kufanya uchunguzi wa moja kwa moja wa uchungu wa uzazi uwe salama, wenye heshima, na sio wa kulaumu: 1) kwa kuzingatia uteuzi wa waangalizi na jukumu haswa katika mipangilio inayokosa wakunga; 2) mafunzo ya kina katika maadili ya (utafiti) kusaidia mchakato wa idhini ya habari na mwenendo wa jumla, 3) ushiriki wa wadau ili kuanzisha uaminifu na kuweka muktadha wa matokeo, 4) kuanzishwa kwa itifaki zilizo na mwongozo ikiwa kuna dharura, na msaada wa kisaikolojia unaomsaidia mwangalizi; na 5) maendeleo ya mwongozo maalum wa mwenendo wa maadili kulingana na kanuni za maadili ya utafiti.

Katika **sehemu ya 4**, vifo vya watoto wachanga vimewekwa kulingana na Uainishaji wa Magonjwa-10 - hadi vifo vya watoto wachanga (ICD-PM) na tunakua na mtindo wa utabiri wa kutabiri vifo vya watoto wachanga vinavyohusiana na huduma za wakati wa kujifungua au kuzalisha.

Katika **sura ya 12**, kwanza tunatathmini uwezekano wa matumizi ya Uainishaji wa Kimataifa wa Magonjwa-10 - kwa vifo vya watoto wachanga (ICD-PM), ambayo huainisha vifo vya watoto wachanga kulingana na wakati, sababu na hali za mama zinazohusiana, katika mazingira ya utafiti wa shughuli nyingi hospitali ya rufaa ya rasilimali duni. Tunapata kuwa kati ya vifo vya watoto wachanga 661, 248 (37.5%) ni vifo vya watoto wachanga na 413 (62.5%) kuzaliwa wakiwa wamekufa. Kati ya watoto waliozaliwa wakiwa wamekufa, 128 (31%) hutokea kabla ya kuzaliwa, 129 (31%) wkati wa kuzaliwa na kwa 156 (38%) muda haujulikani. Nusu (n = 64/128) ya watoto waliozaliwa kabla ya wakati sababu haijaelezewa. Theluthi mbili (67%, n = 87/129) ya kuzaliwa kwa watoto wafu hafla wakati wa zoezi la uzalishaji, na 30% (39/129) hazielezeki. Kati ya vifo vya watoto wachanga, 40% hufa baada ya shida za hafla za ndani. Tunakabiliwa na changamoto katika kukusanya habari za kutosha kwa uainishaji. Kwa hivyo, tunahitimisha kuwa tathmini bora ya huduma za kliniki na uboreshaji wa usajili wakati wa kulazwa na muendelezo wa huduma wakati wa uzazi, pamoja na kiwango cha ufuatiliaji wa mwendo wa mapigo ya moyo wa mtoto, na ukaguzi wa kifo cha mtoto ni muhimu kwa uainishaji wowote na kutambua maeneo lengwa ya kuyafanyia kazi ya uboreshaji. Pia, matumizi ya kimataifa ya ICD-PM inahitaji ufafanuzi uliowekwa kwa viwango ufafanuzi na mwongozo ulioanishwa.

Katika **sura ya 13** pia tunafanya utafiti mkubwa wa kikundi cha wanawake wajawazito 5610 wanaolazwa katika wodi ya wazazi. Tunatumia sifa zao za mama na vizazi vyaoi zilizopatikana kupitia utunzaji wa kawaida kukuza mtindo wa utabiri wa kliniki kutambua wagonjwa walio katika hatari ya vifo vya kuzaa vinavyohusiana na mtoto ndani ya mazingira yenye rasilimali ndogo, na 1) uthibitisho wa nje wa mfano uliopo wa utabiri, na baadaye 2) maendeleo ya mfano wa riwaya. Tunapata kuwa mtindo wa asili haukufaa kwa mpangilio wetu wa utafiti na mazingira yetu na kwa hivyo mtindo mpya ulio na watabiri 15 umetengenezwa ambao unaonyesha utendaji wa hali ya juu kulingana na uwezo wa upimaji na ubaguzi (takwimu ya 0.8). Tunahitimisha kuwa mtindo mpya una uwezo wa kusaidia wakunga wenye ujuzi kuwaonyesha wanawake kwa usimamizi unaofaa wakati wa uchungu na kwa hivyo inapaswa kutathminiwa zaidi katika tafiti zijazo.

Sura ya 14 ni majadiliano ya jumla na ujumuishaji wa matokeo yetu yote, na mapendekezo ya baadaye ya kufanya mazoezi na sera.

Résumé en Francais

Presque tous les décès maternels et périnataux se produisent dans les pays de faible et de moyen revenu; la majorité d'entre eux se produisent au moment de la naissance et peuvent donc être évités grâce à des soins de bonne qualité à la naissance, avec une aide qualifiée pour le soutien, la surveillance et les soins obstétriques et néonatals d'urgence.

Les interventions visant à améliorer la qualité des soins sont primordiales pour obtenir de meilleurs résultats lors de l'accouchement. Le cadre de l'étude à l'hôpital Mnazi Mmoja, à Zanzibar, est un exemple typique d'une maternité à grand volume dans les pays à faibles et moyens revenus.

Dans **la première partie**, nous examinons la qualité de base des soins et le contexte dans lequel les soins sont fournis.

Dans **le chapitre 2**, nous utilisons une étude rétrospective cas-témoins basée sur les dossiers des mortinaissances pour évaluer la qualité de base de l'accouchement.

Nous trouvons un taux de mortinatalité dans un hôpital de 59 pour 1000 naissances totales, dont la moitié meurt à l'hôpital. Dans l'ensemble, la qualité des soins est sous-optimale, tant pour les bébés vivants que pour les mort-nés. Les sept principaux résultats et les domaines cibles des interventions sont les suivants:

1) évaluation des caractéristiques et du bien-être de la mère et du fœtus à l'admission; 2) surveillance systématique du bien-être de la mère et du fœtus (par exemple le temps moyen entre la dernière évaluation cardiaque fœtale et le diagnostic de la mort fœtale ou de l'accouchement était de 210 minutes (intervalle interquartile: 75-315 minutes) et l'avancement du travail pendant les phases latente et active, en particulier; 3) les femmes ayant subi une mort fœtale intra-utérine préhospitalière étaient les plus exposées au risque de negligence; 4) le diagnostic et la gestion des troubles hypertensifs étaient inférieurs aux normes et; 5) le travail prolongé;

6) la césarienne était inutile et 7) des documents (dossiers) intrapartum de qualité inférieure aux normes.

Dans **le chapitre 3**, nous étudions la santé psychosociale maternelle et le fonctionnement quotidien des femmes qui connaissent un accouchement d'un mort-né et nous les comparons aux femmes dont les nouveau-nés sont en bonne santé. Les résultats montrent des niveaux élevés de symptômes de santé mentale, quelle que soit l'issue du nouveau-né: 1) 73 % (96/132) des femmes ayant un nouveau-né en bonne santé et 75 % (n=86/114) des femmes ayant accouché d'un enfant mort-né présentent des symptômes de dépression et 23 % (n=31) et 24 % (n=27) d'entre elles sont dépistées positives pour la dépression. En outre, 80 % (n=105/132) des femmes ayant des enfants en bonne santé et 96 % (n=110/114) des femmes ayant un mort-né présentent un ou plusieurs symptômes de stress post-traumatique; 4 % des femmes sont dépistées positives pour le stress post-traumatique. Les femmes avec un mort-né ont un taux de satisfaction de l'accouchement nettement inférieur. Les caractéristiques sociodémographiques (âge, état civil et emploi) et les soins apportés à la naissance sont des facteurs de risque indépendants pour les problèmes de santé mentale et le handicap. Le soutien social et spirituel est considéré comme positif.

Dans **le chapitre 4**, nous étudions les facteurs affectant la qualité des soins par le biais d'entretiens et de discussions ciblées avec des femmes, des accoucheuses qualifiées et des décideurs politiques. Les facteurs qui influencent la qualité des soins sont les suivants: 1) le nombre élevé de femmes en travail, la surcharge du travail et le personnel insuffisant; 2) le manque d'équipement et de fournitures; 3) la mauvaise infrastructure des salles de travail; 4) le manque de travail en équipe, d'attribution des tâches, de soutien motivationnel et de supervision; 5) l'attitude négative, le manque de connaissances, d'engagement et de sens des responsabilités. De plus, de multiples facteurs systémiques sous-jacents sont identifiés: éducation initiale et formation continue inadéquates; mécanisme d'orientation; leadership et responsabilité; gestion des ressources humaines; politiques, planification et financement du ministère et du gouvernement. Nous concluons que le personnel de santé de première ligne et les femmes enceintes sont confrontés à divers défis qui limitent la fourniture de soins intrapartum de qualité et respectueux, y compris le suivi du Bruits Cardiaque Foetal (BCF). Les facteurs qui contribuent à la médiocrité des soins intrapartum sont liés au système de santé. Les interventions doivent cibler les domaines identifiés avec la participation des prestataires de soins et des utilisateurs de services.Au **chapitre 5**, nous présentons une étude de cas d'une multipare malawienne de 31 ans dont le bébé souffre d'asphyxie à la naissance à la suite d'un retard de reconnaissance et de réaction à une progression anormale du travail et à une détresse fœtale dans un hôpital du Malawi.

Nous concluons que les pays d'Afrique subsaharienne sont encore loin d'atteindre la cible de l'objectif 3 du développement durable, à savoir mettre fin aux décès de nouveau-nés évitables et réduire la mortalité néonatale, en raison de la persistance de soins intrapartum sous-optimaux.

Au **chapitre 6**, nous décrivons les discussions avec les femmes enceintes, les accoucheuses qualifiées et les décideurs politiques pour déterminer si le transfert des tâches de suivi des Bruits Cardiaque Foetal (BCF) à des agents de santé non professionnels est une intervention localement acceptable. De nombreuses préoccupations sont soulevées à propos de cette intervention de transfert des tâches:

1) l'efficacité de l'intervention (manque de formation, de compétence et de sécurité médicales); 2) l'éthique (confidentialité, soutien politique et réglementaire); 3) les coûts d'opportunité (perte des compétences de surveillance du rythme cardiaque fœtal pour les sages-femmes, et coûts de l'intervention); 4) l'attitude affective (problèmes de responsabilité, protectionnisme professionnel, jalousie, méfiance, manque de respect et blâme); 5) la charge pesant sur le cadre existant (formation et

supervision, conflits et relations interprofessionnelles tendues, rôles et limites).

Nous concluons que le transfert de la tâche de surveillance du rythme cardiaque fœtal aux travailleurs non professionnels est une solution sous-optimale due à la pénurie de personnel de santé. Par conséquent, étant donné les contraintes persistantes du système de santé à fournir un nombre adéquat d'infirmières sages-femmes, des efforts supplémentaires sont nécessaires pour trouver des stratégies alternatives afin d'optimiser le suivi des BCF.

Dans **la deuxième partie**, nous synthétisons les preuves disponibles pour la surveillance intrapartum du fœtus et nous essayons de combler les lacunes des preuves existantes en obtenant l'avis d'experts dans le cadre d'une procédure de consensus (étude Delphi).

Dans **le chapitre 7**, nous effectuons un vaste examen systématique des stratégies de surveillance fœtale dans les milieux à faibles ressources et des résultats néonatals et maternels associés, y compris les obstacles à leur mise en œuvre. Il y a 37 études incluses: cinq études d'intervention et 32 études d'observation. L'utilisation du partographe a amélioré les résultats périnataux. L'auscultation intermittente avec Pinard est associée aux taux les plus faibles de césariennes (10-15 %), mais avec des résultats périnataux comparables à ceux du Doppler et de la cardiotocographie (CTG) à main. La CTG est associée aux taux les plus élevés de césariennes (28-34 %) sans que l'on puisse prouver qu'elle a un effet bénéfique sur les résultats périnataux. Plusieurs tests à l'admission (tests d'admission) et tests complémentaires, y compris les tests de stimulation fœtale, améliorent la précision de la surveillance du rythme cardiaque fœtal dans la prévision des résultats périnataux indésirables. Nous concluons que, d'après les preuves disponibles, le partographe est associé à une amélioration des résultats périnataux et nous recommandons son utilisation avec l'auscultation intermittente et nous déconseillons l'utilisation du CTG pour la surveillance intrapartum sans avantages prouvés dans les milieux à faibles ressources.

Dans **le chapitre 8**, nous cherchons à déterminer les stratégies acceptables et réalisables de surveillance intrapartum du fœtus dans des environnements à faibles ressources et très fréquentés, en utilisant un processus de consensus Delphi parmi les experts internationaux ayant une expérience des environnements à faibles ressources. Soixante et onze experts ont participé aux trois cycles (28 sages-femmes, 43 obstétriciens). Le consensus est atteint sur : 1) la nécessité d'un test d'admission, 2) le Doppler portatif pour la surveillance intrapartum du fœtus, 3) l'auscultation intermittente (AI) toutes les 30 minutes dans les grossesses à faible risque pendant le premier stade et après chaque contraction dans les grossesses à haut risque pendant le deuxième stade du travail, 4) la surveillance chaque heure des contractions dans les grossesses à faible risque pendant le premier stade du travail et, 5) les tests complémentaires. Il n'y a pas de consensus sur la fréquence de l'assistance médicale et de la surveillance des contractions pour les femmes à haut risque au cours de la première phase, et pour les grossesses à faible risque au cours de la deuxième phase du travail. Nous concluons qu'il y a un écart entre les recommandations internationales et ce qui est physiquement possible dans de nombreuses salles de travail dans les régions à faibles ressources. Par conséquent, il est nécessaire de poursuivre les recherches sur l'évaluation du bien-être du fœtus à l'admission et d'aider le personnel à obtenir les meilleurs soins possibles dans les contextes à faibles ressources.

Dans **la troisième partie**, nous adaptons les directives internationales de soins cliniques au contexte local.

Dans **le chapitre 9**, nous évaluons l'effet des directives de gestion du travail adaptées au contexte local (directives PartoMa) sur la pratique clinique et sur les mortinaissances et asphyxies à la naissance en milieu intrahospitalier à l'aide d'une étude pré-post quasi expérimentale. Le taux de mortinatalité est passé de 59 à 39 pour 1000 naissances totales

(RR 0,66, IC 95% 0,53-0,82), principalement en raison de la réduction des mortinatalités intra-partum. Les scores d'Apgar entre 1 et 5 sont passés de 52 à 28 pour 1 000 naissances vivantes (RR 0,53, IC à 95 % 0,41-0,69). Le temps médian entre la dernière évaluation cardiaque du fœtus et l'accouchement (ou le diagnostic de mort fœtale) est passé de 120 minutes (RR 60-240) à 74 minutes (RR 30-130), p < 0,01). L'augmentation de l'ocytocine est passée de 22 % à 12 % (RR 0,54, 95 % IC 0,37-0,81) et l'utilisation en temps voulu s'est améliorée. Nous concluons que, bien que la faiblesse des ressources humaines et la médiocrité des soins restent des défis majeurs, les directives de PartoMa sont associées à des améliorations des soins, ce qui entraîne une réduction des mortinaissances et des asphyxies à la naissance. Les résultats soulignent en outre le rôle central de l'amélioration de la surveillance fœtale et de la limitation de l'utilisation de l'ocytocine intrapartum en sécurité à la naissance.

Au **chapitre 10**, nous évaluons la qualité des soins intrapartum et le respect des directives cliniques adaptées aux conditions locales à l'aide d'une étude non participative, structurée et d'observation directe. Nous observons les soins chez 161 femmes en travail. Nous constatons un ratio infirmière/sage-femme/ femmes en travail de 1:4, ce qui se traduit par un partage informel des tâches avec pour une part importante du suivi intra-partum. Il y a un manque de soins respectueux de la vie privée et de la communication des résultats de l'examen dans 50 % et 34 % des cas, respectivement. Pour la majorité, on constate un retard dans la reconnaissance du progrès du travail et un soutien insuffisant au cours de la deuxième phase du travail. La surveillance cardiaque fœtale est évaluée de manière sous-optimale en termes de qualité de la fréquence avec un intervalle médian de 105 (intervalle interquartile 57 -160) minutes. Cependant, la survenue d'un événement à risque intrapartum (FBC non rassurant, utilisation d'ocytocine ou progrès médiocres) augmente considérablement la fréquence d'évaluation (rapport de taux 1,32 (IC 1,09-1,58)). Nous concluons que ni les normes internationales ni les normes adaptées au niveau local en matière de soins de routine intrapartum ne sont respectées de manière optimale. Cela est très probablement dû à une capacité nettement insuffisante des accoucheuses, sans lesquelles les interventions innovantes à la naissance ont peu de chances de réussir. Il faut donc que les parties prenantes internationales et locales s'attaquent aux causes profondes des soins dans les établissements s’averant dangereux dans les milieux à faibles ressources, notamment en ce qui concerne le nombre d'accoucheuses qualifiées nécessaires pour des accouchements sûrs et respectueux.

Dans **le chapitre 11**, par le biais d'une lettre de correspondance adressée aux auteurs qui ont utilisé une méthode similaire dans une étude visant à mesurer les mauvais traitements pendant l'accouchement dans des environnements à faibles ressources, nous réfléchissons à la manière dont le respect et le souci des droits et du bien-être des participants peuvent être maintenus lorsque des cliniciens qualifiés ou des non cliniciens utilisent des observations de travail direct non participatif pour évaluer la qualité des soins. Sur la base de l'expérience acquise au chapitre 10, nous suggérons différentes mesures à prendre pour que l'observation directe du travail soit sûre, respectable et non accusatoire : 1) en envisageant la sélection et le rôle de l'observateur, en particulier dans les contextes où les cliniciens font défaut ; 2) une formation approfondie en éthique (de la recherche) pour soutenir le processus de consentement éclairé et la conduite générale, 3) l'engagement des parties prenantes pour établir la confiance et contextualiser les résultats, 4) l'établissement de protocoles avec des conseils en cas d'urgence et un soutien psychologique pour l'observateur ; et 5) l'élaboration de conseils spécifiques en matière de conduite éthique, basés sur les principes de l'éthique de la recherche.

Dans **la partie 4**, les décès périnataux sont classés selon la Classification des maladies-10 - à la mortalité périnatale (CIM-PM) et nous développons un modèle de pronostic pour prédire les décès périnataux liés à l'accouchement.

Dans **le chapitre 12**, nous évaluons d'abord la faisabilité de l'application de la Classification Internationale des Maladies-10 - à la mortalité périnatale (CIM-MP), qui classe les décès périnataux selon le moment, les causes et les conditions maternelles associées, dans le cadre d'une étude menée dans un hôpital de référence à faibles ressources et à forte activité. Nous constatons que sur les 661 décès périnataux, 248 (37,5 %) sont des décès néonatals et 413 (62,5 %) des mortinaissances. Parmi les mortinaissances, 128 (31%) ont lieu antepartum, 129 (31%) intrapartum et pour 156 (38%) le moment de la naissance n'est pas connu. La moitié (n=64/128) des mortinaissances antepartum sont inexpliquées. Deux tiers (67%, n=87/129) des mortinaissances intrapartum suivent des événements intrapartum aigus, et 30% (39/129) sont inexpliquées. Parmi les décès néonatals, 40 % sont dus à des complications d'événements intrapartum. Nous sommes confrontés à la difficulté de recueillir suffisamment d'informations pour la classification. Ainsi, nous concluons qu'une meilleure évaluation clinique et une meilleure documentation dès l'admission, y compris la fréquence cardiaque fœtale, et des audits des décès périnataux sont essentiels pour toute classification et pour identifier les domaines cibles des interventions. En outre, l'applicabilité mondiale de la CIM-MP exige des définitions standardisées et des orientations harmonisées.

Au **chapitre 13**, nous menons également une vaste étude de cohorte prospective sur 5610 femmes enceintes admises en salle de travail. Nous utilisons leurs caractéristiques maternelles et fœtales obtenues à travers des soins de routine pour développer un modèle de prédiction clinique afin d'identifier les patientes à risque de décès périnatal lié à l'accouchement dans des environnements à faibles ressources, par 1) la validation externe d'un modèle de prédiction existant, et ensuite 2) le développement d'un nouveau modèle. Nous avons constaté que le modèle original n'était pas adapté au contexte de notre étude et avons donc développé un nouveau modèle composé de 15 prédicteurs cliniques qui présentent des performances élevées en termes de capacité de calibrage et de discrimination (c-statistique de 0,8). Nous concluons que le nouveau modèle a le potentiel d'aider les accoucheuses qualifiées à trier les femmes pour une prise en charge appropriée pendant le travail et qu'il devrait donc être évalué plus en détail dans de futures études.

Le chapitre 14 est une discussion générale et une synthèse de tous nos résultats, avec des recommandations ultérieures pour la pratique et la procedure.

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-Tupo Pamoja-

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Curricum Vitae

Natasha Housseine is the mother of two daughters, Nur Malika Hadji Ahamada and Nur Madina Hadji Ahamada. She was born on 23rd October 1988 in Comoros. At the age of 10, she moved to Norwich, United Kingdom, where she was raised by her uncle and graduated from secondary school at City of Norwich School, 2007. She was then awarded the Malaysian International Scholarship and studied Medicine (MBBS) at the International Islamic University Malaysia, Malaysia, 2008-2012. After completion of the MBBS, she moved to the United Republic of Tanzania, where she underwent her internship at Zanzibar's referral hospital, Mnazi Mmoja Hospital (MMH). During her time there she met and was mentored by Prof Tarek Meguid, an obstetrician at the Department of Obstetrics and gynaecology and associate professor at the State University of Zanzibar (SUZA). Natasha became the main research assistant in the PartoMa Project, working closely with Dr. Tarek and the principle investigator Dr. Nanna Maaløe, 2014-2018. In 2015, while completing her internship, dr. Meguid introduced Natasha to Prof. Arie Franx and Dr. Marcus Rijken who were visiting MMH. Natasha Housseine applied for the UMC Fellowship and started her PhD studies with a Masters in Epidemiology in 2015. She is now a postdoctoral researcher at the University of Aga Khan, East Africa in the upscale PartoMa Research Project in Dar es Salaam.

List of Publications

- Maaløe N, Housseine N, Bygbjerg IC, Meguid T, Khamis RS, Mohamed AG, Nielsen BB, van Roosmalen J. Stillbirths and quality of care during labour at the low resource referral hospital of Zanzibar : a case-control study. *BMC Pregnancy Childbirth* 2016; **16**: 1–12.
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- Housseine N, Punt MC, Mohamed AG, Said SM, Maaløe N, Zuithoff NP, Meguid T, Franx A, Grobbee DE, Browne JL, Rijken MJ. Quality of intrapartum care: direct observations in a low-resource tertiary hospital. *Reprod Health* 2020.
- Dmello BS, Housseine N, Akke T van den, Roosmalen J van, Maaløe N. Impact of COVID-19 on maternal and child health. *Lancet Glob Heal* 2020; : 30328.
- Housseine N, Rijken MJ, Punt MC, Meguid T, Franx A, van der Graaf R, Browne JL. Mistreatment during childbirth. *Lancet* 2020; **396**: 816–7.
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The Dutch Working Party ‘International Safe Motherhood and Reproductive Health’ aims to contribute to improvement of the reproductive health status of women around the globe, in particular by collaborating with local health workers (http://www.safemotherhood.nl). The Working Party is part of both the Dutch Society of Obstetrics and Gynaecology (NVOG) and the Dutch Society for International Health and Tropical Medicine (NVTG). The activities that are undertaken under the umbrella of the Working Party can be grouped into four pillars: education, patient care, research and advocacy.

Research activities are undertaken by (medical) students, Medical Doctors International Health and Tropical Medicine and many others. Some research activities develop into PhD-trajectories. PhD- candidates all over the world, Dutch and non-Dutch, work on finding locally acceptable and achievable ways to improve the quality of maternal health services, supervised by different members of the Working Party. Professor Jos van Roosmalen initiated the Safe Motherhood Series, which started in 1995.

The Safe Motherhood Series

- Safe motherhood: The role of oral (methyl)ergometrin in the prevention of postpartum haemorrhage. (Akosua N.J.A. de Groot), Nijmegen, 1995
- Safe motherhood: Perinatal assessment in rural Tanzania. (Gijs E.L. Walraven), Nijmegen, 1995
- Safe motherhood: Confidential enquiries into Maternal Deaths in the Netherlands, 1983-1992. (Nico W.E. Schuitemaker), Leiden, 1998
- Safe motherhood: Confidential enquiries into Maternal Deaths in Surinam. (Ashok S. Mungra), Leiden, 1999
- Safe motherhood: Reproductive health matters in rural Ghana. (Diederike W. Geelhoed), Leiden, 2003
- Safe Motherhood: Vaginal birth after caesarean section in Zimbabwe and The Netherlands (Wilbert A. Spaans), Amsterdam AMC, 2004
- Safe Motherhood and Health systems research: Health care seeking behaviour and utilisation of health services in Kalabo District (Jelle

sociotherapie in Rwanda, Oost-Congo en Liberia (Cora Bakker), VU University Amsterdam, the Netherlands, 2016

- Safe Motherhood: Severe acute maternal morbidity, risk factors in the Netherlands and validation of the WHO Maternal Near-Miss Tool (Tom Witteveen), Leiden University Medical Center, the Netherlands, 2016
- Safe Motherhood: Getting the job done, providing lifelong HIV-treatment in settings with limited human resources for health: innovative approaches (Marielle Bemelmans), VU University Amsterdam, the Netherlands, 2016
- Safe Motherhood: Identifying needs for optimizing the health work force in Ethiopia (Tegbar Yigzaw Sindekie), VU University Amsterdam, the Netherlands, 2017
- Safe Motherhood: Improving frontline health workers' performance in low resource settings; the case of Ethiopia (Firew Ayalew Desta), VU University Amsterdam, the Netherlands, 2017
- Safe Motherhood: Increasing access to anesthaesia in Ethiopia: task shifting (Sharon J.N. Kibwana), VU University Amsterdam, the Netherlands, 2017
- Safe Motherhood: Diagnostic and clinical decision support systems for antenatal care: is mHealth the future in low-resource settings? (Ibukun-Oluwa O. Abejirinde), VU Amsterdam, the Netherlands, 2018
- Safe Motherhood: Assisting birth attendants in providing acceptable care under unacceptable clinical realities: The Partoma Intervention Study at Zanzibar's Tertiary Hospital (Nanna Maaløe), University of Kopenhagen, Denmark, 2019
- Safe Motherhood: Severe Maternal Morbidity and Mortality in Eastern Ethiopia (Abera Kenay Tura), University Medical Centre Groningen, the Netherlands, 2019
- Safe Motherhood: Maternity Waiting Homes in Ethiopia to improve women's access to maternity care (Tienke Vermeiden), University Medical Centre Groningen, the Netherlands, 2019
- Safe Motherhood: Improving access to quality maternal and newborn care in low-resource settings: the case of Tanzania (Dunstan Raphael Bishanga), University Medical Centre Groningen, the Netherlands, 2019
- Safe Motherhood: Towards better prognostic and diagnostic strategies for major obstetric haemorrhage (Ada Gillissen), Leiden University Medical Center, the Netherlands, 2019

- Safe Motherhood: Hospital based audit of obstetric care and birth preparedness in rural Rwanda (Richard Kalisa), VU University Amsterdam, the Netherlands, 2019
- Safe Motherhood: Re-introduction of vacuum extraction in a tertiary referral hospital in Uganda (Barbara Nolens), VU University Amsterdam, the Netherlands, 2019
- Safe Motherhood: Health system determinants of maternal and neonatal health in Rwanda (Felix Sayinzoga), Radboud University Nijmegen, the Netherlands, 2019
- Safe Motherhood: Context-appropriate innovative solutions for improving the access to quality intra- and immediate postpartum care in India (Somesh Kumar), University Medical Centre Groningen, the Netherlands, 2019
- Safe Motherhood: Quality of maternal and newborn health care in health facilities in Afghanistan (Nasratullah Ansari), VU University Amsterdam, the Netherlands, 2019
- Safe Motherhood: Improving the quality of maternal and perinatal health care in a rural hospital in Tanzania (Rob Mooij), University Medical Centre Groningen, the Netherlands, 2020
- Strategies to improve the quality of foetal monitoring and intrapartum care in high-volume, low-resource maternity units (Natasha Housseine), UMC Utrecht, the Netherlands, 2020
- Maternal mortality in Suriname: Implementation of Maternal Death
- Surveillance and Response to reduce preventable maternal deaths (Lachmi
- Kodan), UMC Utrecht, the Netherlands, 2020
- Maternal mortality, near-miss and stillbirths in Suriname: time to respond
- (Kim Verschueren), UMC Utrecht, the Netherlands, 2020