Original Article

Risk Factors Associated with Preterm Birth at a Tertiary Teaching Hospital in Dar es Salaam, Tanzania: An Unmatched Case-Control Study

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Abstract

Background
Preterm birth contributes to significant neonatal and under-five mortality and morbidities. This study assessed the risk factors associated with preterm births at a tertiary teaching hospital in Dar es Salaam, Tanzania.

Methods
Case-control study to compare risk factors of preterm birth amongst 140 women with preterm deliveries as cases and 280 women with term deliveries as controls. A structured interviewer-administered questionnaire was used. Univariate and multivariable logistic regression analyses were done using STATA version 17 software.

Results
The proportion of preterm deliveries was 17.9%. Women with less than four antenatal visits were three times more likely to have a preterm birth than those with four or more attendances (aOR 3.6, 95% CI 1.95–6.57, P < 0.001). The odds of preterm birth increased among women who experienced antepartum haemorrhage (aOR 25.7, 95% CI 12.72–52.03, P < 0.001), pre-eclampsia/eclampsia (aOR 29.9, 95% CI 7.78–115.41, P < 0.001) and preterm membrane rupture (aOR 62.8; 95% CI 23.51–168.21, P < 0.001). Among multiparous women, short interpregnancy intervals, prior preterm birth, or stillbirth increased the odds of preterm birth.

Conclusion
Poor antenatal attendance, obstetric complications, and premature rupture of membranes were among the identified risk factors. All could be addressed by quality antenatal care.

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Keywords: preterm birth, case-control study, risk factors

Introduction

Preterm birth is a birth before 37 completed weeks of gestation or fewer than 259 days since the first day of the woman's last normal menstrual period.[1] In 2015, it was approximated that 15 million babies were born prematurely, over 80% of these are in Asia and sub-Sahara African countries.[1-5] Prematurity is amongst the leading cause of neonatal and under-five deaths globally, contributing to approximately 14% of under-five deaths.[4,6,7]

Babies born prematurely have missed an important intrauterine growth and maturation period and are more likely to suffer from respiratory distress,

intraventricular haemorrhage, poor thermoregulation, necrotizing enterocolitis, and sepsis within the first 48 hours of life.[8-10] Consequently, preterm babies have prolonged hospital stays, may need assisted ventilation, and have higher death rates than term babies.[9,11,12] Preterm babies who survive the neonatal period have a higher risk of long-term morbidities such as sensory deficits, learning disabilities and chronic respiratory diseases, including asthma, later in life, resulting in significant physical, psychological, and economic consequences.[8,12,13] Compared to term babies, preterm babies require more resources from the individual woman, family and the health system; for example they may require: admission to a neonatal intensive care unit, use of surfactant for lung maturation, oxygen therapy or other advanced management, which are not readily available in many low and middle-income countries.[12-14]

The risk factors for preterm births are complex and multifactorial but can be grouped into socio-demographic, maternal and foetal factors.[13,15] Risk factors include extremes of maternal age,[16] low education level, preterm premature rupture of membranes,[17] previous preterm birth,[18] short interpregnancy interval, inadequate antenatal care, antepartum haemorrhage (APH), maternal diseases such as pre-eclampsia/eclampsia [19,20]and multiple pregnancies.[21,22] Some of these risk factors are preventable and efforts to understand and address them may result in better maternal and newborn health.

Tanzania is among countries with high preterm birth rates, and complications from preterm birth account for 10% of deaths among children under five years.[2, 23] Eleven per cent of all babies are born prematurely. The reported incidence range is not homogeneous, but it varies by facility and Region of Tanzania. However, most studies have looked at the magnitude of preterm births and recurrence of preterm birth from hospital registry, or individual risk factors.[19,24,25]

This study aimed at determining local and context-specific factors associated with preterm deliveries at a tertiary teaching hospital in Dar es salaam, Tanzania, and it offers baseline data and significant risk factors that can be used in future studies to demonstrate any changing trends.

Methods

Study design, setting and population

An unmatched hospital-based case control design study was conducted at Muhimbili National Hospital (MNH) in Dar es salaam, Tanzania between 23rd October and 3rd December 2015 [six weeks]. The city has approximately 4 million people, two-thirds of women delivering in health facilities.[26] MNH is a tertiary, teaching and referral hospital receiving a mixed population of women: those directly from home and those referred from primary and secondary level facilities. The MNH maternity unit includes a labour ward, a high dependency maternity unit, antenatal and postnatal wards. A fully equipped obstetric theatre with two operating rooms is semi-detached and near the maternity building. There are approximately 30 to 40 deliveries per day.

The maternity unit also hosts a neonatal unit with 130 beds including, 20 beds for intensive care. The neonatal unit is equipped with four mechanical ventilators, 16 radiant warmers, nine cardiac monitors, 15 CPAP machines, wall mounted oxygen and 20 infusion pumps. Monthly admissions in the neonatal unit ranges from 500–600 with 120–280 being preterm babies. Approximately a third of these preterm babies are delivered at MNH.

Service provision is done by midwives, medical doctors, residents and obstetricians/gynaecologists. Being the national hospital, MNH has approximately 28 obstetricians/gynaecologist and over 25 residents working in the department. The medical teams are organized to work on 24-hour calls led by a consultant obstetrician/gynaecologist, one specialist, two residents and two medical doctors.

The midwifery cadres work on three shifts. There are 2 neonatologists, 9 paediatricians, 4 neonatology fellows, 3 paediatric residents, 6 registrars, 2 intern doctors and 25 nurses.

Women presenting with labour pain are admitted to the labour ward, assessed, and allocated a bed. All monitoring and delivery procedures are done as per hospital guidelines. After delivery, women are observed for two hours in the labour ward and are later transferred to an interim postnatal ward to be discharge after 24 hours. Women who delivered by caesarean section area are transferred to postnatal ward and stay for a minimum of three days post-delivery. Women with preterm babies stay longer as their neonates are admitted in the neonatal ward. All deliveries are entered in a labour ward delivery registry book that document delivery number, maternal characteristics, pregnancy outcome and ward where the mother and newborn are transferred for care.

Sample Size and Sampling procedure

We used an online statistical program Open Epi for sample size estimation for case-control. With a case-control ratio of 1:2,[17] 80% power and 5% error, an estimated sample size of 420 women, 140 cases, and 280 controls were reached. Only women who delivered at MNH were eligible for the study. Cases were women who delivered preterm babies between 28 and 36 weeks of gestation, and controls were women who delivered term babies at 37 or more completed weeks of gestation. A convenience sampling method was used; for each case recruited, two consecutive women who delivered at 37 or more weeks were recruited as controls.

Data collection

The lead investigator used the labour ward delivery book and identified women who were cases and controls who delivered within the last 24-hours. Eligible women were followed in their respective wards, where the lead investigator approached them and explained the study aim and asked for consent to participate in the study. All participants gave a written consent.

The lead researcher interviewed women using a paper-based Swahili questionnaire that was adapted from a similar study,[18] translated into Swahili by fluent speaker and modified to fit the context.[18] Back translation of the questionnaire was done to ensure correct meaning in the Swahili version and piloted to test comprehension. The questionnaire had three parts. Part one was on social demographic factors such as age, education, employment; part two was on obstetrics factors including gestation age, parity, antenatal care booking and number of antenatal clinic visits, known obstetric risks such as prior preterm birth and infections, such as hypertensive diseases of pregnancy, and antepartum haemorrhage; and the third part was on foetal conditions. Information from the case notes and antenatal cards was used to supplement the interviews. Gestation age was estimated from the first day of the last normal menstrual period using Naegele's formula,[27, 28] and for those not sure of dates, extrapolations from gestation age on booking recorded on the antenatal care (ANC) was done. This was also supported by previous ultrasound results that were taken before 20 weeks of gestation when available.

Study variable

Independent variables were the occurrence of preterm birth as delivery between 28 weeks and less than 37 completed weeks of gestation or term delivery as delivery at or after 37 completed weeks of gestation. Dependant variables were maternal age in years categorized as less than 20, 20 to 34 and 35 and above. Education was categorized into no formal, primary, secondary, and above. The number of antenatal care visits were categorized as less than four visits and four or more visits. Interpregnancy interval for those with higher parity was categorized as less than or equal to 12 months and above 12 months. Binary independent variables were diagnosis of antepartum haemorrhage, premature membrane rupture, pregnancy-induced hypertension, and diagnosis of infections such as urine infection, malaria, or human immune deficiency, each with a yes/no response. Prior preterm birth and prior stillbirths were also collected among women who had prior delivery. Referral groups were: 20 to 34 years category for maternal age, no formal education for education level, and multiparous for parity.

All other factors in the referent category were those who did not report the specific factor.

Analysis

Data were cleaned and entered in a database, and analysis was done using Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC. Continuous data were summarized using mean and standard deviation while frequencies and proportions was used for categorical data. Chi squire test and Fisher's exact test where applicable were used to determine the association between dependent and independent variables. Univariate and multivariate logistic regression models were used to determine the odds ratios and P values for factors associated with preterm birth. For multivariable analysis, we considered factors of which the P values were < 0.2 on univariate analysis. We also included maternal factors: maternal age, parity (nulliparous/multiparous) and education level in the multivariable analysis as these are also known to affect preterm births. Factors with a P value of ≤ 0.05 were taken to be significant in the multivariable analysis. A subset analysis of multiparous women was done to find association of prior preterm birth, stillbirth and short interpregnancy interval with preterm birth. Results are reported as crude and adjusted odds ratio with 95% Confidence Interval (CI) and P values for each variable. For all analysis P ≤ 0.05 was considered statistically significant.

Ethical consideration

Ethical clearance was obtained from Muhimbili University of Health and Allied Sciences, Senate ethical committee for research and publication. Informed written consent was sought from all the patients who were eligible for the study. Participation was voluntary and participants were informed that withdrawal from the study at any stage of the interview was acceptable if they so desired without any consequences or prejudice. All participants were given information on probable risk factors of preterm birth.

Results

In the six weeks of data collection 891 women delivered at MNH, of whom 160 (17.9%) had preterm deliveries. Twenty women with preterm births during the study period were excluded due to sick baby or refusal to participate. The study sample consisted of 140 women with preterm deliveries and 280 women with term deliveries. The mean age of participants was 27.99 (SD 6.05) years for women with preterm deliveries and 28.46 (SD 6.18) years for women with term deliveries as shown in Table 1. Median parity was 2 [IQR 1, 3] for both cases and controls. Mean gestation age for the cases was 33.0 (SD 2.40) weeks and 38.9 (SD 1.40) weeks for the control group.

Table 1. Socio-demographic and baseline characteristics of participants

Variable	Cases n=140 (%)	Control n=280 (%)
Participant's age (years)		
< 20	13 (9.3)	21 (7.5)
20-34	101 (72.1)	203 (72.5)
≥ 35	26 (18.6)	56 (20.0)
Mean Age ± S. D	*27.99 ± 6.05*	*28.46± 6.18*
Education level		
No formal education	4 (2.9)	21 (7.5)
Primary education	66 (47.1)	128 (45.7)
Secondary and above	70 (50.0)	131 (66.8)
Marital status		
Single	12 (8.6)	17 (6.1)
Married/cohabiting	128 (91.4)	263 (93.9)

Table continued on next page

IQR Interquartile range: SD standard deviation

Table 1. continued

Variable	Cases n=140 (%)	Control n=280 (%)
Participant's occupation		
Housewife	57 (40.7)	95 (33.9)
Self-employed	56 (40.0)	117 (41.8)
Employed	27 (19.3)	68 (24.3)
Parity		
1	54 (38.6)	97 (34.6)
2-4	80 (57.1)	168 (60.0)
≥ 5	6 (4.3)	15 (5.4)
Median Parity [IQR]	2 [1, 3]	2 [1, 3]

IQR Interquartile range: SD standard deviation

Table 2. Factors associated with preterm birth

Variable	Cases n=140(%)	Controls n=280(%)	OR (95% CI)	*P* Value
Maternal age (years)				
<20	13 (9.3)	21 (7.5)	1.2 (0.59–2.59)	*0.588*
20–34	101 (72.1)	203 (72.5)	1	
≥ 35	26 (18.6)	56 (20)	0.9 (0.55–1.57)	*0.795*
Parity				
Primipara	54 (38.6)	97 (34.6)	1.2 (0.76–1.79)	*0.429*
Multiparous	86 (61.4)	183 (65.4)	1	
Education level				
No formal education	4 (2.9)	21 (7.5)	1	
Primary education	66 (47.1)	128 (45.7)	2.7 (0.89–8.21)	***0.079***
Secondary and above	70 (50.0)	131 (46.8)	2.8 (0.93–8.49)	***0.068***
Booking GA (weeks)				
≤12 weeks	29 (21.2)	59 (21.5)	1	
> 12 weeks	108 (78.8)	216 (78.5)	0.9 (0.60–1.66)	*0.947*
Number of ANC visits				
< 4 visits	87 (62.1)	67 (23.9)	5.2 (3.37–8.09)	**<0.001**
≥ 4 visits	53 (37.9)	213 (76.1)	1	
Infections (index pregnancy)				
HIV positive	9 (6.4)	16 (5.7)	1.1 (0.49–2.63)	0.771
Had UTI	39 (27.9)	58 (20.7)	1.5 (0.93–2.36)	**0.102**
Had malaria	29 (20.7)	69 (24.6)	0.8 (0.49–1.31)	0.370
Obstetric complication				
APH	13 (9.3)	4 (1.4)	7.1 (2.26–22.09)	**< 0.001**
Pre-eclampsia/ eclampsia	69 (49.3)	32 (11.4)	7.5 (4.59–12.37)	**< 0.001**
Preterm PROM	45 (32.1)	8 (2.9)	16.1 (7.33–35.39)	**< 0.001**
Prior pregnancy factors				
Short interpregnancy interval (≤12 months)[a]	13 (15.3)	9 (5.0)	3.4 (1.39–8.33)	**0.007**
Prior preterm birth[a]	23 (16.4)	14 (5)	4.4 (2.14–9.10)	< 0.001
Prior stillbirth[a]	13 (9.3)	5 (1.8)	6.3 (2.18–18.42)	< 0.001
Foetal factors				
Multiple pregnancy	13 (9.3)	12 (4.3)	2.3 (1.01–5.15)	0.046
Congenital malformation	1 (0.7)	3 (1.1)	0.7 (0.68–6.44)	0.745

ANC: Antenatal clinic visits number, APH: Antepartum haemorrhage, HIV Immunodeficiency virus, PROM: Premature rupture of membrane, UTI: Urinary tract infection [a] *Among women with prior deliveries only (n=269),** eight women missing gestation age at antenatal clinic booking*

Table 2. shows results of univariate analysis in which maternal age and parity were not associated with risk of preterm birth. Women with more than primary education had a P value of < 0.2 and were considered in the multivariable analysis. Women who reported to have antepartum haemorrhage in the current pregnancy had significantlyhigher odds of having preterm births (OR 7.1, 95% CI 2.26–22.09, P <0.001) than those without antepartum haemorrhage. Likewise, women with obstetrics complications like pre-eclampsia/eclampsia had higher odds of preterm birth 7.5 (95% CI 4.59–12.37, P < 0.001). Women who reported premature rupture of membrane had significantly higher odds of preterm birth (OR 16.1, 95% CI 7.33–35.39, P < 0.001). For women with prior deliveries, interpregnancy interval, prior preterm birth and stillbirth, were statistically significant associated with preterm birth.

In multivariable analysis we entered factors with P value < 0.2, as well as maternal age, education level and parity in the model (Table 3).

Women who made less than four antenatal visits were 3.6 times more likely to have preterm birth compared to those with four or more antenatal visits (CI 1.95–6.57, P < 0.001). Likewise, women who experienced antepartum haemorrhage were 30 times more likely to have preterm birth compared to those who did not report this complication (aOR 29.9, 95% CI 7.78–115.41, P < 0.001). Women who reported to have pre-eclampsia/eclampsia during index pregnancy were 26 times more likely to experience preterm birth compared to those who were normotensive (aOR 25.7, 95% CI 12.72–52.03, P < 0.001). Women with preterm membrane rupture reported higher odds of preterm birth (aOR 62.8, 95% CI 23.51–168.21, P < 0.001). Women with prior deliveries, short interpregnancy interval, prior history of preterm birth or prior stillbirth had statistically significant higher odds of preterm birth than those without these factors.

Table 3. Multivariable analysis of factors associated with preterm birth

Variables	cOR (95% CI)	aOR (95% CI)	*P* Value
Maternal age (years)			
< 20	1.2 (0.59–2.59)	1.1 (0.40–3.15)	0.808
20–34	1	1	
≥ 35	0.9 (0.55–1.57)	1.1 (0.52–2.45)	0.756
Parity			
Nulliparous	1.2 (0.76–1.79)	0.7 (0.31–1.40)	0.286
Multiparous	1		
Education level			
No formal education	1	*1*	
Primary education	2.7 (0.89–8.21)	3.7 (0.86–16.16)	0.078
Secondary and above	2.8 (0.93–8.49)	3.5 (0.79–15.36)	0.097
Number of ANC visits			
< 4 visits	5.2 (3.37–8.09)	3.6 (1.95–6.57)	**<0.001**
≥ 4 visits	1	1	
Had UTI (index pregnancy)	1.5 (0.93–2.36)	1.8 (0.89–3.6)	0.101
Obstetric complication			
APH	7.1 (2.26–22.09)	29.9 (7.78–115.41)	**<0.001**
Pre-eclampsia/eclampsia	7.5 (4.59–12.37)	25.7 (12.72–52.03)	**<0.001**
Preterm PROM	16.1 (7.33–35.39)	62.8 (23.51–168.21)	**<0.001**
Foetal factors			
Multiple pregnancy	2.3	4.6 (1.39–15.01)	**0.012**
Previous pregnancy factors			
Short interpregnancy interval (≤12 months) [a]	3.4 (1.39–8.33)	6.1 (1.15–24.72)	**0.011**
Prior preterm birth[a]	4.4 (2.14–9.10)	6.3 (1.48–26.95)	**0.013**
Prior stillbirth[a]	6.3 (2.18–18.42)	8.54 (1.26–57.17)	**0.028**

Abbreviations: ANC, Antenatal clinic; APH, Antepartum haemorrhage; PROM, Premature rupture of membrane; UTI, Urinary tract infection ; [a]Among women with prior deliveries only (n=269); Eight women missing gestation age at antenatal clinic booking

Discussion

This study reported on factors contributing to preterm birth at a tertiary facility in Tanzania. Women with fewer than four antenatal care visits, and those with obstetric complications such as antepartum haemorrhage, pre-eclampsia/eclampsia and preterm membrane rupture had higher odds of preterm births than women without these complications. For multiparous women, prior history of preterm birth, stillbirth and short interpregnancy interval were associated more than three times the risk of preterm birth. Women with multiple pregnancy were highly associated with preterm birth. We did not find association between maternal age, parity, education level and infections like malaria, HIV with preterm birth.

Other population and hospital-based studies have documented the increased risk of preterm births among women with few antenatal care visits irrespective of gestation age at birth.[17,19,22,29,30] While women with preterm births may not have time to complete the recommended number of antenatal visits, they still had a smaller number of visits than what was expected at their specific gestation. Few antenatal care visits highlight a missed opportunity in the care of such women, to identify, prevent and intervene early.

Women with third-trimester antepartum haemorrhage had an increased risk of having preterm births. Similar findings were reported in studies within the country and also within the East African region and globally irrespective of whether the preterm birth was spontaneous or elective delivery.[15,17,19,20,22,31] Women with antepartum haemorrhage are usually delivered early to avert consequences of severe prolonged bleeding. Spontaneous preterm labour can also occur from the underlying cause of bleeding. Having a diagnosis of antepartum haemorrhage such as abruptio placenta or placenta previa, especially when maternal or foetal life is endangered may necessitate intervention leading to preterm birth. Furthermore, women with APH may have an underlying abnormal placentation that results in intrauterine foetal growth restriction, pre-eclampsia and preterm births.[32,33]

Our study reports that women with maternal complications such as hypertension, pre-eclampsia were more associated with preterm births, similar to other studies.[17,19,20,34,35] This group of women have vascular damage from hypertension leading to decreased blood flow and nutrients to the foetus through the placenta usually prompting induced or spontaneous preterm birth.[36] Women who are at risk of such conditions such as primigravida, those with a family history of hypertension and diabetes mellitus, multiple gestations require to be followed up and ensure they get effective antenatal care and early treatment when required to minimize adverse outcomes.

Women with premature rupture of membrane had a much higher risk of preterm birth. Similar finding was found in hospital- and population-based studies of different methods.[15,17-19,22] When women present with premature rupture of membrane there is usually an underlying infection or inflammation causing a release of cytokines that initiate uterine contractions. Interventions such as thorough and routine screening and early treatment of pregnant women for risk factors for premature rupture of membrane may reduce the occurrence of preterm birth.

Prior history of preterm birth is a reported significant risk for preterm birth compared with women who delivered term infants in their previous pregnancy consistent with other studies in the country and the region.[18,21,22,25,38,39] Although the mechanism has not been well elucidated, recurrent spontaneous preterm birth may result from a combination of factors such as a short cervix,[40] a positive foetal fibronectin test,[41] PROM and obstetrics complications that place the mother and/or foetus at risk necessitating medical induction before term. Thus, women with a previous history of preterm birth, regardless of the cause must be identified early during pregnancy and a close follow-up ensured, which involves early identification and management of treatable risk factors,

as one way of preventing preterm birth.

Similarly, mothers with a history of stillbirth have increased risk of having preterm birth in the current pregnancy.[18,19,35,42,43] This observation is expected since stillbirth and preterm birth share some of the risk factors such as APH, hypertension and infections. This means that women with a history of stillbirth in absence of other risk factors in the index pregnancy should be regarded as at-risk women who require regular follow up coupled with health education on possible prevention and recognition of warning signs.

In addition to maternal risk factors, we found an association between multiple gestations and preterm birth similar to other studies. [21] The mechanism is unknown, but these observations are plausible, as some of the factors, including stretch, placental hormones and lung maturity factors, that may lead to the increased foetal and placental mass, have been thought to be a stimulus to the onset of parturition.[21, 37] Multiple gestations should therefore be regarded as high-risk pregnancies requiring comprehensive prenatal care in specialized facilities where labour can be safely delayed preventing preterm birth.

We did not find any association between maternal age and preterm birth. This lack of association has also been reported in other studies.[16,17] However, findings vary from other studies using population data from sub-Saharan African countries which reported that women aged < 20 years,[38] and those with advanced age (> 40 years), have slightly higher preterm birth rates. [30, 39,40] The variability in study findings depends on the population and cut-off age; most of our study participants were between 18 and 34 years old, and this age group is considered to have a lower risk of preterm birth compared to teenage mothers and women over 40 years.[39-42]

Study limitations

This study has some limitations, the first being a possible recall bias as in other case control studies. We estimated gestation age based on the documented last normal menstrual period or extrapolated from the booking gestation age. Most women may not recall their exact date of last normal menstrual period and therefore we may have misclassified some of the cases and controls. However, since this could have also affected the controls that would have been classified as cases, the effect is likely to have evened out and may not have affected the result. Secondly, we did not collect information on foetal factors such as birth weight and sex of the neonate, or whether the preterm birth was induced or spontaneous. These could have added more information to the analysis.

We found the incidence of preterm birth to be at 17.9% of all deliveries at this tertiary hospital. Being a hospital-based study at a tertiary centre, the results might indicate a larger burden than is the case in the general population. Other studies in tertiary facilities in the country report on an increased trends in preterm birth rate in the last ten-years [18,19,22,25]with repeat preterm birth to be 24%.

Strength of our study

This study is among the few that looked at factors associated with preterm birth in a tertiary and national hospital in Tanzania. The case-control design enabled the identification of some of the risk factors for preterm deliveries. We used the recorded last normal menstrual period to estimate the gestation age using Naegele's rule.[28,29] This method is a well-known and accepted and used in similar studies and settings. We think our gestation age estimation was within range. A more robust measure of gestation age would have been neonatal assessment; however, this was not possible during data collection.

Conclusion

Identifiable risk factors associated with preterm birth in our setting were antepartum haemorrhage, pre-eclampsia/eclampsia, premature rupture of membrane, prior history of preterm birth and stillbirth, multiple gestations and fewer antenatal visits. Most of these risk factors can be identified and addressed during antenatal care, potentially reducing preterm birth.

This study highlights the need for antenatal care risk assessment and follow-up of women with preterm deliveries beyond the postpartum period to impart knowledge on their future risks and mitigation for subsequent preterm deliveries. We recommend further studies to understand the changes and trends of risk factors that lead to preterm birth. Further studies with a larger sample size should be devised to be able to establish the contribution of a combination of these risk factors on preterm birth.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MRN conceptualized the study, methodology and data collection with close inputs from FAA. MRN drafted the first draft with inputs from FAA and HN. All authors contributed to the manuscripts equally and agree to the submission.

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