Accepted: 9 January 2023 | Published Online 21 March 2023

DOI: 10.1111/1471-0528.17444

BJOG An International Journal of Obstetrics and Gynaecology

RESEARCH ARTICLE

General obstetrics

Risk factors for late preterm and term stillbirth: A secondary analysis of an individual participant data meta-analysis

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Funding information
Mercia Barnes Trust, Grant/Award Number: OG3713771; Cure Kids and Red Nose Australia, Grant/Award Number: 6601

Abstract

Objective: Identify independent and novel risk factors for late-preterm (28–36 weeks) and term (≥37 weeks) stillbirth and explore development of a risk-prediction model.
Design: Secondary analysis of an Individual Participant Data (IPD) meta-analysis investigating modifiable stillbirth risk factors.
Setting: An IPD database from five case–control studies in New Zealand, Australia, the UK and an international online study.
Population: Women with late-stillbirth (cases, $n = 851$), and ongoing singleton pregnancies from 28 weeks' gestation (controls, $n = 2257$).
Methods: Established and novel risk factors for late-preterm and term stillbirth underwent univariable and multivariable logistic regression modelling with multiple sensitivity analyses. Variables included maternal age, body mass index (BMI), parity, mental health, cigarette smoking, second-hand smoking, antenatal-care utilisation, and detailed fetal movement and sleep variables.
Main outcome measures: Independent risk factors with adjusted odds ratios (aOR) for late-preterm and term stillbirth.
Results: After model building, 575 late-stillbirth cases and 1541 controls from three contributing case–control studies were included. Risk factor estimates from separate multivariable models of late-preterm and term stillbirth were compared. As these were similar, the final model combined all late-stillbirths. The single multivariable model confirmed established demographic risk factors, but additionally showed that fetal movement changes had both increased (decreased frequency) and reduced (hiccoughs, increasing strength, frequency or vigorous fetal movements) aOR of stillbirth. Poor antenatal-care utilisation increased risk while more-than-adequate care was protective. The area-under-the-curve was 0.84 (95% CI 0.82–0.86).
Conclusions: Similarities in risk factors for late-preterm and term stillbirth suggest the same approach for risk-assessment can be applied. Detailed fetal movement assessment and inclusion of antenatal-care utilisation could be valuable in late-stillbirth risk assessment.

KEYWORDS
fetal death, individual participant data, perinatal death, prediction model, pregnancy, risk factors, stillbirth

Linked article: This article is commented on by J. Jardine, pp. 1071 in this issue. To view this mini commentary visit https://doi.org/10.1111/1471-0528.17469.

This article includes Author Insights, a video abstract available at: https://players.brightcove.net/3806881048001/default_default/index.html?videoId=6320088103112.

1 | INTRODUCTION

Stillbirth is a devastating event with far-reaching consequences for women, their families and health professionals.[1] Late-stillbirth ≥28 weeks' gestation in high-income countries has been prioritised for study, as babies born at these gestations would otherwise have a good chance of survival; at 28 weeks, 78% of newborns survive without serious morbidity, increasing to 91% at 32 weeks.[2] Late-stillbirth occurs in approximately three babies per 1000 births,[3] with many being potentially avoidable.[4,5] If women at high risk of stillbirth could be identified antenatally, increased surveillance and timely birth would be likely to prevent fetal death.[6]

The cornerstone of stillbirth prevention remains modification of risk factors (e.g. maternal obesity, cigarette smoke exposure), pregnancy monitoring and identifying at-risk pregnancies.[7] The challenge is identifying those at highest risk of stillbirth. Whereas stillbirth risk factors such as smoking, advanced maternal age and obesity have been described for all stillbirths,[8-12] predisposing factors for early stillbirth (<28 weeks' gestation) differ from late-stillbirth, with higher rates of infection, placental abruption and congenital anomalies.[13] Later in gestation, stillbirth associated with fetal growth restriction is more common and unexplained stillbirths increase.[14,15] Among late-stillbirths, it remains unclear whether preterm compared with term stillbirth have different aetiologies and different associated risk factors. This is important, as iatrogenic birth to prevent stillbirth at a preterm gestation has the potential for prematurity-related harm.[2]

Case–control studies of stillbirths are the most feasible study design to investigate risk factors in low-prevalence countries, as the rarity of stillbirth often precludes prospective designs due to the large number of participants required. Routinely collected data are often used but these studies are unable to adjust for some confounding variables.[9] The Collaborative Individual Participant Data (IPD) of Sleep and Stillbirth (CRIBSS) meta-analysis, combined line-by-line participant data from five case–control studies into a single dataset of 3108 participants (cases, n = 851; controls, n = 2257).[16,17] The IPD dataset with a large number of detailed harmonised confounding variables allows for exploration of risk factors or subgroups that were unable to be examined in the individual original studies.[11]

This study was a planned secondary analysis of the CRIBSS meta-analysis data. Our aims were to identify and compare independent and novel risk factors for late preterm (28–36 weeks) and term (≥37 weeks) stillbirth, and explore the development of a risk-prediction model for preterm and term late-stillbirth. We hypothesised that demographic and clinical risk factors for late preterm and term stillbirth would be different, with term stillbirth more likely to be associated with novel risk factors.

2 | METHODS

The CRIBSS IPD data includes five case–control studies, identified through a systematic literature review of maternal going-to-sleep position and late stillbirth.[16] Included studies were from New Zealand (The Auckland Stillbirth Study [TASS] and the Multi-centre Stillbirth Study [MCSS]), Australia (The Sydney Stillbirth Study [SSS]), UK (The Midlands and North of England Stillbirth Study [MiNESS]), and one international online study (Study of Trends and Associated Risks for Stillbirth Study [STARS]).[18-22] Four of the five studies were case–control studies where women who experienced a singleton non-anomalous late stillbirth (cases) were frequency-matched, based on the gestational age of the stillbirth to women with ongoing pregnancies (controls) within the same geographical region. Cases and controls were recruited during the same time interval. The STARS study was a nested case–control study based on a global web-based survey with unmatched controls who were in the third trimester of pregnancy or within 4 weeks of birth. The four case–control studies utilised interviewer-administered questionnaires to collect demographic, obstetric and pregnancy data, and data extracted from hospital records. The online survey was self-administered. Data were harmonised between studies using consistent rules. Further details of the individual studies and the harmonisation process have been published previously.[16-22]

Established and novel variables identified as potential stillbirth risk factors in the harmonised dataset were examined for completeness and quality. Variables within each study that had more than 15% missing data or a prevalence of <10% were checked for accuracy and were not included if assessed as low quality or very low prevalence (<1%). A priori risk factors that were unable to be included due to low prevalence or differing diagnostic criteria within the IPD were pre-existing maternal medical conditions, gestational diabetes, gestational hypertension, previous preterm birth, previous perinatal death and suspected small-for-gestational age (SGA) fetus. Data were not available for some variables of interest in some of the participating studies (Figure 1).

Risk factors included in the model development were maternal age (years), ethnicity (white, black, South Asian, South-East and East Asian, Māori, Pacific and others), maternal education (primary, secondary, university, postgraduate and non-university trade), body mass index (BMI), parity, cigarette smoking and/or exposure to second-hand smoke during pregnancy, antepartum haemorrhage (bleeding occurring after 20 weeks' gestation), adequacy of antenatal care (ANC) utilisation (described below), fetal movement variables (also described below), maternal going-to-sleep position (left, supine, right, variable, propped and other/unknown), getting up during the night, daily napping and maternal mental health (defined as a clinical diagnosis of depression or other major mental health conditions requiring treatment). Although we do not have granular data

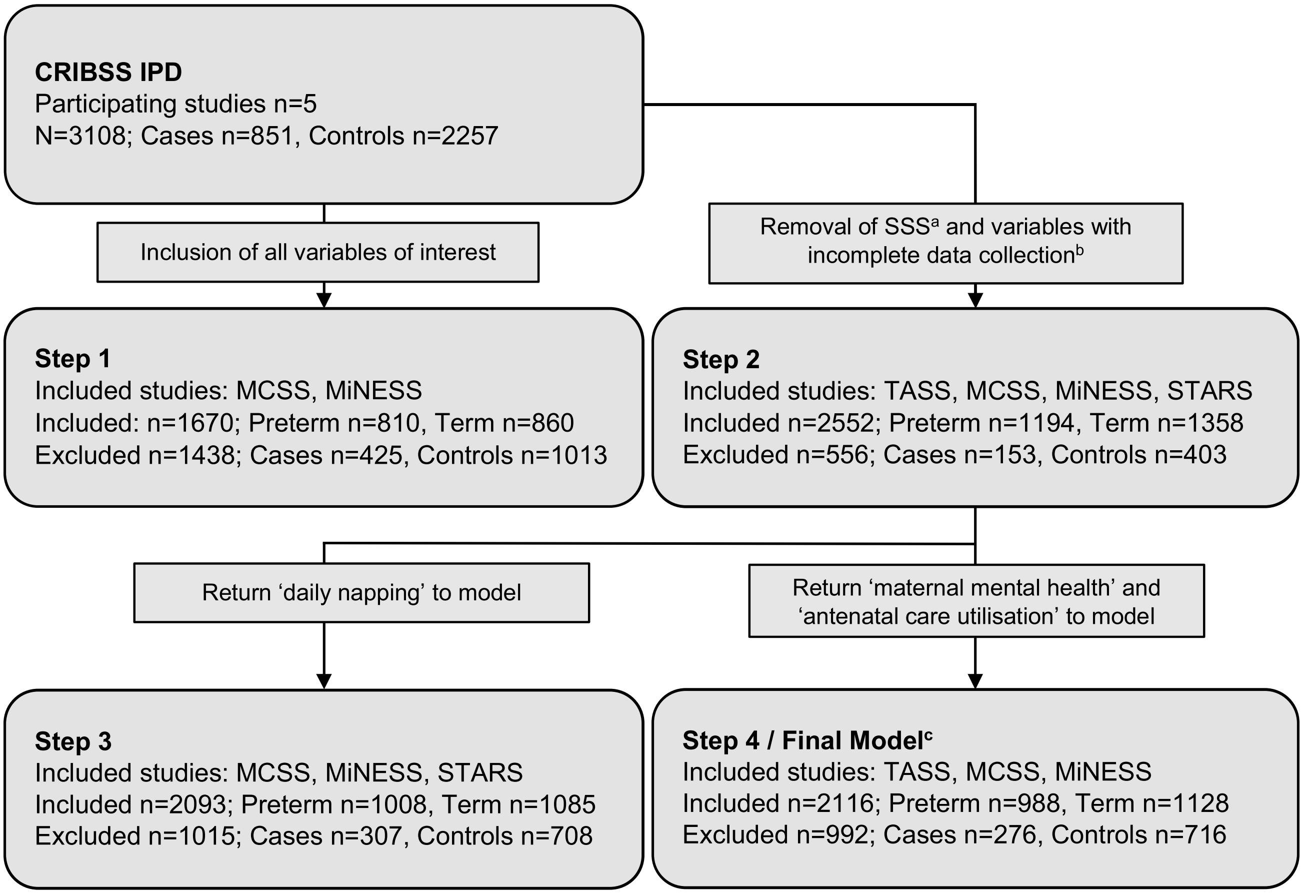

FIGURE 1 Multivariable model building. Sensitivity analyses occurred for each model. Flowchart continues PRISMA IPD flow diagram from Cronin et al.[17] CRIBBS, The Collaborative Individual Participant Data (IPD) of Sleep and Stillbirth meta-analysis; MCSS, Multicentre Stillbirth Study; MiNESS, Midlands and North of England Stillbirth Study; SSS, Sydney Stillbirth Study; STARS, Study of Trends and Associated Risks for Stillbirth Study; TASS, The Auckland Stillbirth Study. [a]SSS did not collect data for maternal mental health, second-hand smoke exposure, vigorous fetal movements, fetal hiccoughs, getting up during the night or daily napping. [b]Incomplete data collection for daily napping (not collected by TASS), maternal mental health and antenatal care utilisation (not collected by STARS). [c]Final model includes: maternal age, BMI, ethnicity, parity, education, maternal mental health, cigarette smoking, second-hand smoke exposure, adequacy of antenatal care utilisation, antepartum haemorrhage, fetal hiccoughs, vigorous fetal movements, prioritised fetal movements, maternal going-to-sleep position and getting out of bed during the night.[55]

on major mental health conditions available in the dataset, the majority of women with maternal mental health (MMH) conditions experienced depression (*n* = 145 of 167, 86.8%). Other major mental health conditions were experienced by 37 of 167 women (22.2%), including 15 women (9.0%) who had both depression and other major mental health condition(s).

Adequacy of ANC utilisation was defined using the 'Adequacy of Prenatal Care Utilization Index' by Kotlechuck.[23] This index classifies antenatal visits into four adequacy categories, adequate plus, adequate, intermediate and inadequate, depending on gestation at first visit as well as the percentage of visits attended (a ratio of observed to expected visits). This index is based on recommended frequency of visits and is adjusted based on gestational age at booking and birth. 'Adequate' utilisation is ANC begun by 16 weeks' gestation and 80–109% of the adjusted recommended number of visits, 'Adequate plus' utilisation is >109% recommended visits, 'Intermediate' utilisation is 50–79% of recommended visits and 'Inadequate' utilisation is <50% recommended visits or care started after 16 weeks' gestation. This method allows adequacy assessment of ANC utilisation in pregnancies that are truncated, as in the current study with preterm stillbirth and associated controls.

Fetal movement variables assessed maternal self-report of fetal movements over the 2 weeks preceding stillbirth or the data collection time-point for matched-controls with ongoing pregnancies. Changes in fetal movement strength and frequency were assessed as increased, decreased or remained the same. A prioritised strength-frequency variable was created based on the prevalence of responses in each variable and previous publications.[24,25] The order of priority was: increased strength, increased frequency, decreased frequency, no change in movement strength or frequency and unsure whether fetal movements had changed. Vigorous fetal movements were defined as more than usual vigorous movements in the preceding 2 weeks and, if yes, whether these occurred once only or more than once. Fetal hiccoughs were recorded as present or absent.

2.1 | Statistical analysis

Descriptive and univariable analysis of risk factors for late preterm and term stillbirth were performed using Student's *t*-test, Wilcoxon rank sums test and Chi-square analysis as appropriate (0.05 level of significance). Univariable odds ratios (ORs) with 95% confidence intervals were estimated from logistic regression, models were stratified for study and centres within studies according to the published protocol.[16] No imputation was undertaken for missing data.

2.1.1 | Multivariable modelling

Multivariable modelling using logistic regression created separate models for late preterm and term stillbirth with the largest possible combination of variables and participants (Figure 1). Step one included all variables of interest; however, as data were not collected in all studies for all variables, this led to the exclusion of three of the five studies. Step two excluded the SSS, as this study did not collect data for multiple variables of interest (MMH, second-hand smoke exposure, vigorous fetal movements, fetal hiccoughs, getting up during the night and daily napping). Included variables in step two were those collected within all other studies (daily napping was not collected by TASS, and MMH and ANC utilisation were not collected by STARS). This resulted in models with the largest sample size but fewer variables. Variables that were not collected by all studies (daily napping, MMH and ANC utilisation) were then re-introduced into the models one-by-one and sensitivity analyses were undertaken to assess the impact of new variables on model estimates for existing variables. Variables were left in the model if their inclusion caused minimal changes to model estimates for existing variables. Adjusted odds ratios (aORs) with 95% confidence intervals were estimated and receiver operating characteristic curves were generated for each model.

Estimates of risk factors within the separate multivariable models for late preterm and term stillbirth were compared, including testing for interactions between risk factors and preterm and term gestation. Subsequently, a single multivariable model that included gestation (preterm versus term) was created with step four variables. This included interaction terms for the two variables that were significantly different by gestation, namely, ANC utilisation and prioritised fetal movements. To enable the calculation of the aOR for variables with interactions, combined variables were created for gestation-ANC utilisation and gestation-prioritised fetal movements.

Statistical analysis was performed using SAS version 9.4 2020 (SAS Institute Inc.).

3 | RESULTS

The CRIBSS IPD contains data on 851 late stillbirth cases and 2257 controls (demographic and clinical data for each study see Table S1). Multivariable modelling for preterm and term stillbirth, including multiple sensitivity analyses, resulted in the final model including three studies (TASS, MiNESS and MCSS, and excluding SSS and STARS) studies and excluding the variable for daily napping (Figure 1).

The final study population included 2116 participants (preterm $n = 988$ and term $n = 1128$, Table 1). The preterm and term groups had similar characteristics, with preterm participants slightly less likely to be nulliparous (preterm 41.4%, term 48.6%) and have 'Adequate plus' ANC utilisation (preterm 43.7%, term 52.9%). Fetal movements among preterm participants were less likely to include fetal hiccoughs (preterm 53.1%, term 66.0%) and more likely to describe vigorous fetal movements (preterm 52.4%, term 43.9%) and increased strength of fetal movements (preterm 52.6%, term 39.1%). Most women got up during the night, but this was more common in women at term (preterm 79.1%, term 85.8%).

The multivariable late preterm and term stillbirth models showed similar point estimates, with most estimates differing by <1.5 standard errors (Table S2). Additionally, no significant interactions were observed between variables and preterm and term gestation except for ANC utilisation and prioritised fetal movements. A single multivariable model was therefore created.

In the final multivariable model of the combined outcome of all stillbirths (Table 2), independent demographic risk factors included advanced maternal age (35–39 years, aOR 1.55, 95% CI 1.09–2.22; >40 years, aOR 1.83, 95% CI 0.99–3.37), increasing BMI (for each increase in 5 BMI units aOR 1.21, 95% CI 1.08–1.34), nulliparity (aOR 1.92, 95% CI 1.25–2.95) and parity of three (aOR 1.91, 95% CI 1.03–3.55). Few women had a parity higher than 4 (4+), and while they had an increased aOR, the confidence internal included the null (aOR 1.54, 95% CI 0.77–3.07). Cigarette smoking beyond the first trimester conferred an almost two-fold increased odds of stillbirth (aOR 1.92, 95% CI 1.26–2.93), and exposure to second-hand cigarette smoke was associated with a 40% increased odds of stillbirth (aOR 1.42, 95% CI 1.05–1.91). Maternal supine going-to-sleep position was a major risk factor for late-stillbirth (aOR 3.14, 95% CI 1.86–5.30). Getting out of bed at night almost halved the odds of stillbirth (aOR 0.54, 95% CI 0.39–0.73) consistent with previous reports.[16,17,19] Maternal mental health conditions increased a woman's odds of experiencing a stillbirth (aOR 1.62, 95% CI 1.05–2.51). While ethnicity overall did not significantly contribute to stillbirth (*p value for ethnicity in the multivarible model* = 0.26), women who identify as black had a two-fold increased odds of stillbirth (aOR 2.38, 95% CI 1.09–5.20).

The two variables that differed by preterm and term gestation were maternal perception of fetal movements and ANC utilisation. With maternal fetal movement perception, the association with stillbirth was consistent between preterm and term gestations, with increased strength and frequency of movements protective, whereas a reduction in the frequency of fetal movements over the previous 2 weeks strongly associated with an increase in stillbirth odds (preterm aOR 4.20, 95% CI 2.44–7.22; term aOR 2.04, 95% CI 1.34–3.11). Reduced odds of stillbirth were observed with maternal report of fetal hiccoughs over the preceding 2 weeks (aOR 0.43, 95% CI 0.34–0.55), more than one episode of vigorous fetal movements

TABLE 1 Characteristics of term and preterm participants in final study CRIBBS study population (n = 2216; preterm n = 988 [46.7%]; term n = 1128 [53.3%]).

	Preterm, n (%)	Term, n (%)
Stillbirths (cases)	250 (43.5)	325 (56.5)
Maternal demographics		
Age (years)		
<20	36 (3.6)	41 (3.6)
20–24	138 (14.0)	153 (13.6)
25–29	291 (29.5)	297 (26.3)
30–34	326 (33.0)	379 (33.6)
35–39	162 (16.4)	207 (18.4)
≥40	35 (3.5)	51 (4.5)
Maternal BMI (kg/m^2)		
<25	478 (48.4)	525 (46.5)
25–30	272 (27.5)	295 (26.2)
30–35	121 (12.3)	181 (16.0)
>35	117 (11.8)	127 (11.3)
Ethnicity		
White	608 (61.5)	681 60.4)
Black	27 (2.7)	23 (2.0)
South Asian	128 (13.0)	138 (12.2)
South East and East Asian	52 (5.3)	57 (5.1)
Maori	59 (6.0)	82 (7.3)
Pacific	99 (10.0)	129 (11.4)
Other	15 (1.5)	18 (1.6)
Parity		
0	406 (41.1)	548 (48.6)
1	347 (35.1)	370 (32.8)
2	142 (14.4)	118 (10.5)
3	52 (5.3)	58 (5.1)
≥4	41 (4.1)	34 (3.0)
Education		
Primary	232 (23.4)	244 (21.6)
Secondary	147 (14.9)	169 (15.0)
University	397 (40.2)	479 (42.5)
Postgraduate	71 (7.2)	76 (6.7)
Non-university trade	141 (14.3)	160 (14.2)
Maternal mental health[a]	84 (8.5)	83 (7.4)
Maternal smoking		
Yes – beyond first trimester	136 (13.8)	137 (12.2)
No – stopped in first trimester	237 (24.0)	263 (23.3)
Non-smoker	615 (62.2)	728 (64.5)
Second-hand smoking	262 (26.5)	307 (27.2)
Adequacy of ANC utilisation[b]		
Adequate plus	432 (43.7)	597 (52.9)
Adequate	323 (32.7)	404 (35.8)
Intermediate	201 (20.3)	72 (6.4)
Inadequate	32 (3.3)	55 (4.9)
Antepartum haemorrhage	74 (7.5)	77 (6.8)
Fetal hiccoughs	525 (53.1)	744 (66.0)
Vigorous fetal movements		
Once	96 (9.7)	94 (8.3)
More than once	422 (42.7)	401 (35.6)
Never	470 (47.6)	633 (56.1)
Prioritised fetal movements		
Increased strength	520 (52.6)	441 (39.1)
Increased frequency (not strength)	52 (5.3)	48 (4.3)
Decreased frequency	113 (11.4)	175 (15.5)
Unsure strength or frequency	43 (4.4)	60 (5.3)
Same strength or frequency	260 (26.3)	404 (35.8)
Going-to-sleep position		
Left	476 (48.2)	569 (50.4)
Supine	53 (5.3)	53 (4.7)
Right	315 (31.9)	321 (28.5)
Variable	77 (7.8)	90 (8.0)
Propped	18 (1.8)	28 (2.5)
Other/Unknown	49 (5.0)	67 (5.9)
Out of bed at night	781 (79.1)	968 (85.8)
Daily nap	104 (10.5)	154 (13.7)

Note: Fetal movements were assessed as over the 2 weeks prior to interview/stillbirth.

aDefined as diagnosis of depression or other major mental health conditions requiring treatment.

[b]ANC = antenatal care, defined by Kotlechuck index.

(aOR 0.62, 95% CI 0.47–0.83) and increasing strength of fetal movements (preterm aOR 0.10, 95% CI 0.07–0.16; term aOR 0.27, 95% CI 0.18–0.40). A single episode of vigorous fetal movements was associated with an increased odds of stillbirth (aOR 2.81, 95% CI 1.90–4.17).

Similarly, the relation between ANC utilisation and stillbirth was consistent between preterm and term gestations, although ANC utilisation was statistically significant only for preterm gestations. Women who attended 'Adequate plus' antenatal visits had a reduction in the odds of stillbirth (preterm aOR 0.51, 95% CI 0.34–0.77; term aOR 0.84, 95% CI 0.59–1.19), whereas those with 'Inadequate' antenatal visits had a higher odds of stillbirth but crossed the null value (preterm aOR 2.56, 95% CI 0.93–7.04; term aOR 1.62, 95% CI 0.78–3.37). Overall, few women had inadequate ANC utilisation (preterm n = 32 [3.3%]; term n = 55 [4.9%]).

The area under the receiver operator curve (AUC) for the final model was 0.84 (95% CI 0.82–0.86; Figure 2). This was similar to the AUC for each step of the modelling procedure (range 0.83–0.86). Sensitivity analyses throughout the modelling showed minimal changes in variable effect size with

TABLE 2 Final adjusted multivariable risk factors for stillbirth from the CRIBBS IPD-characteristics of final model with univariable and multivariable odds ratios (OR and aOR; cases $n = 575$ [7.2%]; controls $n = 1541$ [72.8%]).

	Cases *n* (%)	Controls *n* (%)	Univariable OR (95% CI)	Multivariable aOR (95% CI)
Maternal age (years)				
<20	23 (4.0)	54 (3.5)	1.33 (0.79–2.23)	0.89 (0.44–1.80)
20–24	92 (16.0)	199 (12.9)	1.44 (1.07–1.95)	1.05 (0.68–1.61)
25–29	155 (27.0)	433 (28.1)	1.12 (0.87–1.44)	0.93 (0.67–1.28)
30–34	171 (29.7)	534 (34.7)	ref	
35–39	104 (18.1)	265 (17.2)	1.23 (0.92–1.63)	1.55 (1.09–2.22)
≥40	30 (5.2)	56 (3.6)	1.67 (1.04–2.69)	1.83 (0.99–3.37)
Maternal BMI (kg/m^2)				
BMI continuous[a]	28.1 (6.9)	26.3 (5.9)	1.04 (1.03–1.06)	1.04 (1.02–1.06)
BMI 5 units			1.23 (1.15–1.33)	1.21 (1.08–1.34)
BMI 10 units			1.52 (1.31–1.76)	1.46 (1.17–1.80)
Maternal ethnicity				
White	337 (58.6)	952 (61.8)	ref	ref
Black	17 (3.0)	33 (2.1)	1.46 (0.80–2.65)	2.38 (1.09–5.20)
South Asian	68 (11.8)	198 (12.9)	0.97 (0.72–1.31)	1.41 (0.92–2.15)
South-East and East Asian	22 (3.8)	87 (5.7)	0.72 (0.44–1.16)	0.99 (0.54–1.82)
Māori	41 (7.1)	100 (6.5)	1.16 (0.79–1.70)	0.73 (0.41–1.28)
Pacific	81 (14.1)	147 (9.5)	1.56 (1.16–2.10)	1.05 (0.63–1.74)
Other	9 (1.6)	24 (1.6)	1.06 (0.49–2.30)	0.94 (0.35–2.54)
Parity				
0	298 (51.8)	656 (42.6)	1.73 (1.25–2.41)	1.92 (1.25–2.95)
1	149 (25.9)	568 (36.9)	1.00 (0.71–1.42)	0.98 (0.63–1.51)
2	54 (9.4)	206 (13.4)	ref	ref
3	41 (7.1)	69 (4.4)	2.27 (1.39–3.70)	1.91 (1.03–3.55)
≥4	33 (5.8)	42 (2.7)	3.00 (1.74–5.17)	1.54 (0.77–3.07)
Maternal education				
Primary	162 (28.2)	314 (20.4)	1.43 (0.95–2.16)	1.17 (0.65–2.10)
Secondary	100 (17.4)	216 (14.0)	1.28 (0.83–1.98)	0.98 (0.54–1.79)
University	193 (33.6)	683 (44.3)	0.78 (0.53–1.17)	0.81 (0.48–1.38)
Postgraduate	39 (6.7)	108 (7.0)	ref	ref
Non-university trade	81 (14.1)	220 (14.3)	1.02 (0.65–1.59)	1.02 (0.56–1.85)
Maternal mental health[b]	62 (10.8)	105 (6.8)	1.65 (1.19–2.30)	1.62 (1.05–2.51)
Maternal smoking				
Yes – beyond first trimester	116 (20.2)	157 (10.2)	2.30 (1.75–3.01)	1.92 (1.26–2.93)
No – stopped in first trimester	132 (23.0)	368 (23.9)	1.11 (0.88–1.41)	0.96 (0.71–1.30)
Non-smoker	327 (56.8)	1016 (65.9)	ref	ref
Second-hand smoking	192 (33.4)	377 (24.5)	1.55 (1.26–1.91)	1.42 (1.05–1.91)
Gestation & ANC utilisation[c,d]				
Preterm				
Inadequate	18 (3.1)	14 (0.9)	3.08 (1.48–6.39)	2.56 (0.93–7.04)
Intermediate	83 (14.4)	118 (7.7)	1.69 (1.18–2.40)	1.62 (1.03–2.55)
Adequate	76 (13.2)	247 (16.0)	0.74 (0.53–1.03)	0.87 (0.57–1.32)
Adequate plus	73 (12.7)	359 (23.3)	0.49 (0.35–0.68)	0.51 (0.34–0.77)

(Continues)

TABLE 2 (Continued)

	Cases n (%)	Controls n (%)	Univariable OR (95% CI)	Multivariable aOR (95% CI)
Term				
Inadequate	24 (4.2)	31 (2.0)	1.85 (1.04–3.29)	1.62 (0.78–3.37)
Intermediate	17 (3.0)	55 (3.6)	0.74 (0.41–1.33)	1.00 (0.48–2.09)
Adequate	119 (20.7)	285 (18.5)	ref	ref
Adequate plus	165 (28.7)	432 (28.0)	0.92 (0.69–1.21)	0.84 (0.59–1.19)
Antepartum haemorrhage	57 (9.9)	94 (6.1)	1.69 (1.20–2.39)	1.81 (1.16–2.83)
Fetal hiccoughs	245 (42.6)	1024 (66.5)	0.38 (0.31–0.46)	0.43 (0.34–0.55)
Vigorous fetal movements				
Once	90 (15.7)	100 (6.5)	1.87 (1.37–2.55)	2.81 (1.90–4.17)
More than once	126 (21.9)	697 (45.2)	0.38 (0.30–0.47)	0.62 (0.47–0.83)
Never	359 (62.4)	744 (48.3)	ref	ref
Gestation and prioritised fetal movements[d]				
Preterm				
Increased strength	36 (6.3)	484 (31.4)	0.13 (0.09–0.19)	0.10 (0.07–0.16)
Increased frequency	11 (1.9)	41 (2.7)	0.47 (0.23–0.94)	0.39 (0.17–0.86)
Decreased frequency	83 (14.4)	30 (2.0)	4.84 (3.04–7.69)	4.20 (2.44–7.22)
Unsure	21 (3.7)	22 (1.4)	1.67 (0.89–3.14)	0.94 (0.43–2.03)
Same	99 (17.2)	161 (10.4)	1.08 (0.78–1.48)	0.88 (0.60–1.30)
Term				
Increased strength	58 (10.1)	383 (24.9)	0.27 (0.19–0.37)	0.27 (0.18–0.40)
Increased frequency	11 (1.9)	37 (2.4)	0.52 (0.26–1.05)	0.60 (0.27–1.33)
Decreased frequency	87 (15.1)	88 (5.7)	1.73 (1.21–2.48)	2.04 (1.34–3.11)
Unsure	22 (3.8)	38 (2.4)	1.01 (0.58–1.78)	0.88 (0.47–1.66)
Same	147 (25.6)	257 (16.7)	ref	ref
Going-to-sleep position				
Left	244 (42.4)	801 (51.9)	ref	ref
Supine	50 (8.7)	56 (3.6)	2.93 (1.95–4.41)	3.14 (1.86–5.30)
Right	159 (27.7)	477 (31.0)	1.09 (0.87–1.38)	0.96 (0.72–1.28)
Variable	52 (9.0)	115 (7.5)	1.48 (1.04–2.12)	1.26 (0.79–2.00)
Propped	17 (3.0)	29 (1.9)	1.93 (1.04–3.56)	2.06 (0.97–4.40)
Other/Unknown	53 (9.2)	63 (4.1)	2.76 (1.87–4.09)	2.71 (1.64–4.50)
Out of bed at night	442 (76.9)	1307 (84.8)	0.60 (0.47–0.76)	0.54 (0.39–0.73)

Note: Fetal movements assessed as over the 2 weeks prior to interview/ stillbirth.

[a]BMI continuous = mean (SD).

[b]Defined as depression or other major psychiatric disorder requiring treatment.

[c]ANC = antenatal care, defined by Kotlechuck index.[22]

[d]Multivariable aORs calculated for full model including pre-term versus term gestation and without interaction variables. Gestation-ANC utilisation and gestation-prioritised fetal movement interaction variables introduced individually to allow for aOR calculations.

the insertion and removal of variables that had missing values from entire studies. The omission of data from SSS and STARS had a minimal impact on the final model. To investigate the contribution of novel variables to the model, MMH, fetal movement and maternal sleep variables were removed, with a resulting AUC of 0.69. Of the novel variables, prioritised fetal movements contributed the most to the model (established risk factors plus prioritised fetal movements gave an AUC of 0.81).

4 | DISCUSSION

4.1 | Main findings

Clinical risk factors for late stillbirth are similar between preterm and term gestations, which has not previously been described. A single risk-assessment model for all late stillbirth is both appropriate and easier to use in a patient-facing clinical setting.

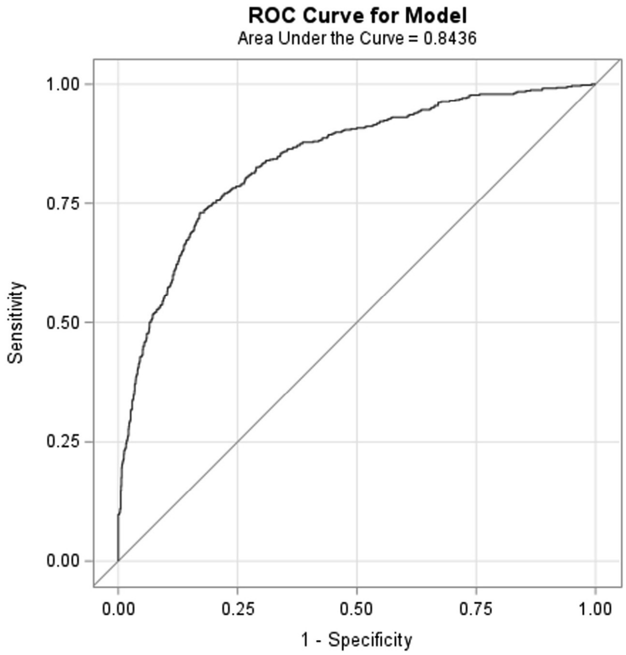

FIGURE 2 Receiver operator curve of CRIBBS IPD stillbirth model.

We identified strong effects of both increased and decreased odds of late stillbirth with detailed fetal movement changes and ANC utilisation, neither of which is included in standard stillbirth risk-assessment models.[11] Fetal movement changes and adequacy of ANC utilisation have stronger risk- and protective-associations with stillbirth at preterm gestations compared with term.

4.2 | Strengths and limitations

This IPD meta-analysis combined line-by-line participant data from multiple case–control studies, thus allowing analysis of novel risk factors for stillbirth including ANC utilisation and detailed fetal movement patterns that are not available in routinely collected data.

Individual studies collected data differently, meaning some variables were unable to be merged due to differing or missing variables. In this study, a priori variables that could not be harmonised included: previous perinatal death, previous preterm birth, pre-existing maternal hypertension or diabetes, gestational hypertension or pre-eclampsia, gestational diabetes and suspected small-for-gestational age (SGA) in the index pregnancy. Although the absence of these clinical risk factors means that the current model does not provide a complete clinical risk assessment for stillbirth, the relatively low prevalence of the missing risk factors and associations with other included variables, means their addition is unlikely to improve greatly on the overall discrimination of the model (AUC 0.84).

As with any case–control study, recall bias may contribute to the results, especially for variables such as sleep position or fetal movements. Unfortunately, there is no way to assess this in a case–control study. Importantly, maternal sleep position was not commonly known as a risk factor for stillbirth in the population at the time these studies were performed, potentially limiting the impact of recall bias in these data.

4.3 | Interpretation

Decisions around iatrogenic birth as an intervention to prevent stillbirth are different at preterm compared with term gestation, due to prematurity-associated morbidity and rare risk of mortality. This study suggests that risk assessment for late stillbirth should include the same components regardless of gestation.

Women whose gestation is >28 weeks and who experience fetal hiccoughs or increasing strength or frequency of fetal movements over a preceding 2-week timeframe have very low odds of late stillbirth. Our data support the inclusion of a more detailed fetal movement evaluation in stillbirth risk-assessment tools, particularly as the presence of protective patterns of fetal movements can provide a measure of reassurance. Prioritised fetal movements (in particular increased strength and frequency, and decreased frequency of movements over the previous 2 weeks) were the most valuable additions to established risk factors and are easily assessed clinically. A decrease in frequency of fetal movements is uncommon and associated with increased odds of stillbirth, particularly at earlier gestations.[26] At a population level, education around decreased fetal movements to pregnant women has not been shown to lower the risk of stillbirth,[27-30] but it does reduce perinatal death, NICU admissions and Apgar scores <7 at 5 minutes of age.[31] Importantly, women presenting with decreased fetal movements continue to require attention, as there remains an association with SGA pregnancies,[30,32] planned early term birth, induction of labour and emergency caesarean section.[32]

Our finding of an association between a single episode of vigorous fetal movements and stillbirth should be viewed with caution. Whether this was a single episode or will lead to multiple episodes of increased movements (experienced by 45.2% of controls and 21.9% of cases) which are protective for stillbirth,[33,34] can only be assessed in retrospect. Unfortunately, if the mother presented with a single episode of vigorous movements associated with an agonal fetal event, there are no data to suggest that intervention would have prevented stillbirth.[35,36]

While late initiation of antenatal care and poor antenatal visit attendance have been identified as risk factors for poor obstetric outcome[37,38] and sudden infant death syndrome,[39] most population-based stillbirth risk factor studies are not able to include this data. In this analysis, fewer antenatal visits were associated with an increased odds of late stillbirth, which could be due to unrecognised development of clinical risk factors such as SGA or pre-eclampsia. Conversely, 'Adequate plus' ANC utilisation was associated with an almost halving of odds of preterm stillbirth, with no reduction in risk at term. This may be due to the earlier identification of risk factors leading to increased surveillance and timely birth. This is supported by evidence that pregnancies with SGA identified antenatally have a lower risk of stillbirth than if SGA is unrecognised.[40,41] Although this analysis controlled for surrogates of socio-economic status that might influence ANC utilisation (including ethnicity, education and marital status), there may still be residual confounding.

While ethnicity overall was not independently associated with an increased risk of stillbirth, women who identify as black had a two-fold increased odds of stillbirth, consistent with the 2021 MBRRACE-UK Perinatal Mortality Surveillance Report, where babies born to women who identify as black and black British had twice the rate of stillbirth as babies born to women who identify as white.[42] A recent English national cohort study of 1 233 184 women demonstrated that socio-economic and ethnic inequities were responsible for a substantial proportion of stillbirths, with the largest inequities seen in women who identify as black and South Asian.[43] The causal reasons underlying ethnic disparities in stillbirths are unclear but they are not entirely explained by measured socio-economic disadvantage and are likely to be multifactorial.

Smoking cessation advice for the expectant mother and close contacts was again confirmed as an important part of antenatal care. In this analysis, both cigarette smoking beyond the first trimester and exposure to second-hand smoke increased the odds of stillbirth, and there is evidence of improved neonatal outcomes in a smoke-free environment.[44,45]

A clinical diagnosis of depression or other maternal mental health conditions requiring treatment increased a woman's odds of experiencing a stillbirth by 60%. Although it is unclear whether this is a disease effect or a medication effect (or more likely a combination) we do know that pregnancy, childbirth and caring for a new infant can be a particularly vulnerable time for women, and those with risk factors for mental health conditions require special care and attention.[46,47] Maternal depression and anxiety have been associated with an increased risk of preterm birth and fetal growth restriction.[48,49] Practitioners should remain mindful of the adverse effects of maternal mental health in pregnancy and continue to ensure their patients can access the appropriate care as needed, especially if there are future disruptions to services, such as those during the Covid pandemic.[46]

An anticipated clinical utility of this study includes furthering our understanding about the development of a stillbirth risk-prediction model with the potential for application in clinical practice. For example, this could be valuable at the time of presentation with reduced fetal movements or as a clinical risk predication in the third trimester as part of routine ANC. We have shown that a single risk-prediction model should include both late preterm and term stillbirth. To develop the risk-prediction model further, variables from the existing literature that were not included in this IPD analysis[8,50,51,52] should be included in future research. Validation of our model will be challenging due to the non-routine data included in this IPD, specifically a record of fetal movements, ANC utilisation and going-to-sleep position.[53] Although time intensive, prospective validation of our model in a setting with a high proportion of births and stillbirths is still possible. It is vital that any risk prediction model for a rare but serious outcome such as stillbirth, is robustly developed, as interventions such as induction of labour to prevent stillbirth carry risk of harm,[2,54] and most women with risk factors for stillbirth will not experience this devastating outcome.

5 | CONCLUSIONS

This IPD meta-analysis is the first to describe the similarities of risk factors for both late-preterm and term stillbirth. Maternal report of fetal movement assessment (both as risk- and protective-factors) and adequacy of ANC utilisation are important factors in the evaluation of late stillbirth risk. A single risk-prediction model for all late stillbirths is feasible, and although the current model has the potential to perform well for clinical risk prediction, these findings should be externally validated in an independent sample.

AUTHOR CONTRIBUTIONS

The conceptualisation of the IPD was undertaken by JMDT, ML, RSC, CHR-G, TS, LMO, EAM, LMEM and AEPH. JMDT, RSC, AG, CHR-G, TS, LMO, EAM, LMEM and AEPH were involved in the investigation and methodology of the initial studies. Verification of the underlying data from each of the individual studies included in the IPD was carried out by EAM, LMEM, AG, LMO and AEPH. Conceptualisation, study design and funding application for the current study was by RAT, LMEM and NHA. NHA, JMDT, JW and RAT performed the statistical analysis. RAT and NHA drafted the paper, with additional input from LMEM, CHR-G, EAM, RSC and JMDT. All authors have read and approved submission of the final article.

ACKNOWLEDGEMENTS

This study used data already collected in five international studies. Included studies were from New Zealand (two studies: The Auckland Stillbirth Study [TASS], and the Multi-centre Stillbirth Study [MCSS]), Australia (The Sydney Stillbirth Study [SSS]), UK (The Midlands and North East Stillbirth Study [MiNESS]), and an International online Study of Trends and Associated Risks for Stillbirth Study (STARS). Funding for these studies is detailed in the original publications. Open access publishing facilitated by The University of Auckland, as part of the Wiley - The University of Auckland agreement via the Council of Australian University Librarians.

FUNDING INFORMATION

This study received funding for assistance with the statistical analysis and publication costs from the Mercia Barnes Trust (MBT ID # OG3713771) and funding for CRIBBS IPD was from the 2016 Trans-Tasman Research Funding Grant by Cure Kids and Red Nose Australia (Grant 6601).

CONFLICT OF INTEREST STATEMENT

None declared. Completed disclosure of interest forms are available to view online as supporting information.

DATA AVAILABILITY STATEMENT

Data cannot be shared publicly beyond the Collaborative Individual Participant Data Meta-analysis of Sleep and Stillbirth (CRIBSS) group as no individual participating study obtained consent from participants to make the data publically available. Furthermore, because stillbirth is uncommon, there is potential for participants to be identifiable. Contact information for the CRIBSS Data Access Committee is The CRIBSS Data Centre, Department of Obstetrics and Gynaecology, Faculty of Medical and Health Sciences, University of Auckland, Private Bag 92019, Auckland Mail Centre, Auckland 1142. Email address for corresponding author Dr Ngaire Anderson is ngaire.anderson@auckland.ac.nz

ETHICS APPROVAL

Ethical approval was obtained by each individual study. Additional approval for the IPD meta-analysis was obtained from the New Zealand Health and Disability Ethics Committee (NTX/06/05/054/AM06).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Thompson RA, Thompson JMD, Wilson J, Cronin RS, Mitchell EA, Raynes-Greenow CH, et al. Risk factors for late preterm and term stillbirth: A secondary analysis of an individual participant data meta-analysis. BJOG. 2023;130(9): 1060–1070. https://doi.org/10.1111/1471-0528.17444