BMJ Open

Cohort profile of the ICMR-Stillbirth Pooled India Cohort (ICMR-SPIC): estimating prevalence, analysing risk factors and developing prediction models for stillbirths in India

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To cite: ICMR-SPIC Consortium, Mukherjee R. Cohort profile of the ICMR-Stillbirth Pooled India Cohort (ICMR-SPIC): estimating prevalence, analysing risk factors and developing prediction models for stillbirths in India. *BMJ Open* 2025;**15**:e099401. doi:10.1136/bmjopen-2025-099401

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2025-099401).

Received 16 January 2025
Accepted 23 July 2025

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ABSTRACT

Purpose Stillbirth is a significant public health problem in India, yet comprehensive epidemiological data on its prevalence and risk factors are lacking. The objectives of this research were to develop a dataset pooled from 10 well-characterised pregnancy cohorts across urban and rural India to estimate the prevalence of stillbirths, identify and quantify risk factors and develop a predictive risk stratification model for evidence-based clinical decision-making in high-risk pregnancies.

Participants Pregnant women were enrolled during the antenatal period in 10 existing cohorts across India. Enrolment occurred through either health facilities or community settings at four urban, four rural and two mixed urban–rural sites spanning nine states. All participants were enrolled before childbirth, with follow-up completed at least until delivery.

Findings to date The Indian Council of Medical Research (ICMR) stillbirth pooled India cohort (ICMR-Stillbirth Pooled India Cohort Dataset (SPIC)) comprises 229 695 pregnant women. The mean (SD) maternal age at recruitment was 24.8 (4.5) years. 22.2% were underweight (body mass index (BMI)<18.5 kg/m²) and 16.6% were overweight or obese (BMI≥23 kg/m²). Short stature (<145 cm) was observed in 6.9% of participants. The mean (SD) gestational age at birth was 38.4 (2.1) weeks. One-third of the participants (33.3%) experienced moderate-to-severe anaemia during pregnancy (haemoglobin<95 g/L), 52.8% were multiparous and 27.6% conceived within 18 months of their previous childbirth. Core maternal risk factors such as short stature, BMI, parity, prior stillbirths and anaemia during pregnancy were recorded in all cohorts. Additional variables, including gestational weight gain, pre-eclampsia/eclampsia, antepartum haemorrhage and fetal distress, were available for over 80% of the cohorts, ensuring robust data coverage for risk factor analysis and modelling.

Future plans ICMR-SPIC will be used to conduct individual-level pooled data analyses to estimate prevalence, identify key risk factors and develop predictive models for stillbirths. Findings will inform policies, clinical guidelines and targeted interventions for high-risk pregnancies. The harmonised ICMR-SPIC dataset is a landmark collaborative effort to advance maternal and newborn health in India.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The harmonised Indian Council of Medical Research-Stillbirth Pooled India Cohort Dataset pooling individual-level data from 10 diverse pregnancy cohorts is India's most comprehensive resource on prevalence and determinants.
⇒ The cohort design facilitates identification of at-risk populations by longitudinal assessment of risk factors.
⇒ A rigorous data harmonisation protocol was followed, ensuring consistency and quality across datasets.
⇒ Despite standardisation variability in data collection tools, definitions and missing data across cohorts may affect comparability and model performance.

INTRODUCTION

The WHO defines stillbirth as a baby born with no signs of life at or after 28 weeks of gestation or with a birth weight of less than 1000 g.[1] Stillbirths before the onset of labour are classified as antepartum stillbirths, whereas those during labour and childbirth are grouped as intrapartum stillbirths. The Every Newborn Action Plan endorsed by the World Health Assembly in 2014 set a target of reducing the stillbirth rate (SBR) to <12/1000 total births by 2030.[1] Furthermore, India pledged to reduce stillbirth and early neonatal mortality rates to <10/1000 births by 2030 through a focused strategy proposed in the 2014 India Newborn Action Plan.[2] Despite notable progress, most low- and middle-income countries (LMICs), including India, remain off track to achieve global targets for stillbirth reduction. The Global Burden of Disease study confirmed that India contributed the highest number (397 300) of stillbirths globally in 2021.[3 4] Over the past two decades, India has achieved an average rate of reduction of 4% in SBRs, culminating in a 53% decline in

2019 compared with 2000 (29.6 stillbirths per 1000 total births in 2000 vs 13.9 in 2019).[5] However, the most recent estimates indicate that the burden remains unacceptably high, underscoring the need for intensified efforts to enhance maternal and perinatal healthcare systems to address persistent inequities.[6 7]

Several challenges must be addressed to achieve the goal of reducing stillbirths in India. Notably, stillbirth targets are absent from global policy agendas, including the Sustainable Development Goals, and the definition of stillbirth varies across healthcare contexts, leading to misclassification and impeding international comparisons (online supplemental table 1). This variation also contributes to discrepancies in stillbirth prevalence reported in different Indian registries.[8 9] Additionally, mechanisms for documenting stillbirths in LMICs, including India, remain suboptimal. For instance, the National Family Health Survey in India conflates stillbirths, miscarriages and abortions as it relies on maternal self-reports,[8] often introducing bias due to low maternal education and knowledge about stillbirths. Furthermore, there is limited epidemiological evidence on the burden and risk factors for stillbirths across India's diverse regions,[10 11] which is essential for designing tailored interventions. Generating comprehensive evidence on the prevalence and risk factors for stillbirths at a national scale necessitates coordinated, large-scale efforts that surpass the capacity of individual investigators, requiring multi-institutional collaboration, standardised methodologies and robust data systems.

A collaborative, team-based approach is essential for generating robust evidence on stillbirths in India. The Indian Council of Medical Research (ICMR) formed a consortium of pregnancy cohort studies to generate a harmonised dataset to estimate stillbirth prevalence, identify risk factors and develop models to predict pregnancies at high risk of stillbirths in India. This initiative also aims to standardise the definition of stillbirth, enabling accurate burden estimation and advocacy. By aligning with India's Every Newborn Action Plan, this effort is pivotal in developing evidence-based policies, interventions and clinical guidelines to reduce preventable stillbirths.

Here, we outline the process of harmonising data from multiple pregnancy cohorts to develop the ICMR-Stillbirth Pooled India Cohort Dataset (SPIC) and provide a concise description of the cohort profile. The ICMR-SPIC aims to estimate the national SBRs in India, assess the associations between specific risk factors and stillbirths to evaluate their relevance for the Indian population and calculate the population attributable fraction for each risk factor to identify those with the most significant impact. Additionally, we will develop a risk prediction model for the early identification of pregnancies at high risk of stillbirth. This comprehensive approach provides a robust framework for generating actionable insights to reduce SBR in India.

COHORT DESCRIPTION

Selection of studies

In 2023, the ICMR coordinated the forming of a consortium of investigators leading pregnancy cohorts in India, with the primary goal of pooling and harmonising data across all existing relevant cohorts. The dataset will be used for estimating the burden and determinants of stillbirths in India at the national level and for developing and validating a risk prediction model for identifying pregnancies at high risk of stillbirths that could benefit from targeted interventions. 10 investigator groups managing pregnancy cohorts joined the ICMR-SPIC consortium; details are provided in online supplemental table 2. The consortium commenced its work in April 2024 after confirming the involvement of researchers, the availability of ethics and regulatory approvals and signing agreements for sharing de-identified cohort data with the ICMR.

For a cohort study to be included in the pooled analysis, the study should have fulfilled the following criteria:

1. The study must be conducted in India. Pregnant women could be recruited in health facilities or community settings.
2. The cohort studies should have appropriate ethics and regulatory approvals, including participant consent for sharing data with third parties for secondary analysis.
3. Pregnant women should have been recruited before the birth of their child and followed longitudinally until a birth outcome (live birth, stillbirth, medical or spontaneous abortion) was recorded.
4. The cohort studies must provide detailed descriptions of the study methods, including recruitment and sampling strategies, inclusion and exclusion criteria and detailed definitions for all the variables shared with the consortium, to enable data harmonisation and accurate interpretation of the results.
5. The dataset must include a core set of 'required' variables, such as gestational age at childbirth (GA), along with methods determining GA (last menstrual period or ultrasonography), and a set of socio-demographic variables, such as maternal age at childbirth, education levels.
6. While desirable, the availability of details of medical conditions, obstetrical complications and behavioural factors was not considered mandatory.

Data sources for ICMR-SPIC

Ten datasets were included in the pooled ICMR-SPIC database (see table 1 for details), spanning 17 sites across nine Indian states representing North, West, Central, South and North-Eastern India. One study (MaatHRI) included study sites in the North, North-East and Central Indian regions. 8 out of 10 studies followed an observational study design. Among the two intervention studies that were included, the WINGS cohort contributed data only from the control arm. In contrast, the CalPreg cohort contributed data from both the control and intervention arms, as the intervention differed only in the

Table 1 Details of pregnancy cohort studies included in the ICMR-SPIC harmonised dataset

Sr. no	Short title	Key studies (PMID)	State/region in India	Location	Study duration	Study design	Sample size*
1	CalPreg	34 819 147 38 197 817	Karnataka/South	Urban	2018–2021	Intervention	10 544
2	GARBHINI	39 021 476 30 770 926 33 931 016 37 492 417 39 030 058	Haryana/North	Mixed	2015–2020	Observational	7002
3	LIFE	27 649 805 30 400 845 31 819 983 31 854 166 35 923 508	Telangana/South	Rural	2010–2018	Observational	1269
4	MAASTHI	36 130 760 31 828 224 31 920 399 33 292 687	Karnataka/South	Urban	2016–2019	Observational	3280
5	MaatHRI	33 500 775 34 607 867 34 585 123 35 934 263 37 651 649 38 757 059 39 513 665	Assam and Meghalaya/ North-East; Chhattisgarh, Uttar Pradesh, Himachal Pradesh/North; Maharashtra/ Central	Mixed	2018–2023	Observational	10 109
6	MNHR-Belagavi	22 738 806 25 177 075 26 063 586 26 063 292 33 334 337 33256783 33 256 770	Karnataka/South	Rural	2010–2020	Observational	111 645
7	MNHR-Nagpur	35972913 31383691 30093518 33334356 33334337	Maharashtra/ Central	Rural	2010–2020	Observational	82 232
8	PMNS	34 610 922 12 586 996 11 285 330	Maharashtra/ West	Rural	1994–1996	Observational	770
9	REVAMP	36 275 827 38 965 425 37 129 568	Maharashtra/ West	Urban	2017–2022	Observational	1745
10	WINGS	36 288 808 38 165 408	New Delhi/North	Urban	2017–2020	Intervention – control group	1099

*Number of pregnancies included in the ICMR-SPIC dataset.
ICMR, Indian Council of Medical Research; SPIC, Stillbirth Pooled India Cohort.

dose of calcium administered during pregnancy. 4 out of 10 cohorts' recruited participants from community settings and the remaining 6 were hospital-based. While there was an equal representation of the number of sites contributing data from urban and rural areas (four each from urban and rural areas, and two with mixed urban and rural populations, see table 1), the majority of participants, in absolute numbers (91.8% unweighted and 57.7% weighted, table 3), were from rural areas.

Data harmonisation and data cleaning

A preliminary draft of the data dictionary and codebook that listed the essential and desirable variables to be included in the ICMR-SPIC dataset was prepared

including their proposed definitions and harmonised variable names. This draft was shared with all the consortium partners for review and comments. The consortium members discussed, modified and mutually agreed on the final list of variables and their definitions. The updated data dictionary and codebook was shared with all the consortium members for mapping and recoding their data into the final data template. Each cohort performed thorough data cleaning to adhere to the definitions and codes and prepared detailed notes on how data on each variable was collected and categorised to minimise variations in measurement methods that could impact the interpretation of results. If the teams were unable to adhere to the harmonised definitions, they provided a detailed description of the discrepancy compared with the requested format, definition or assessment method. Each cohort then uploaded the cleaned and final dataset along with the annotated codebook on a secure web server managed by ICMR.

The core statistical analysis team then reviewed each dataset to ensure fidelity to the harmonisation template. Data managers of the respective cohorts corrected any errors highlighted by the analysis team. Some cohorts had recruited the same participant across multiple pregnancies. In these cases, a decision was made to represent each row as a unique pregnancy, with one column linking pregnancies belonging to the same participant. Multifetal gestations were reported as individual rows for each fetus, with a column indicating singleton or multiple gestation for each observation. This allowed the team to assess the outcome of each birth from all pregnancies while accounting for the fact that not all participants were independent in the combined dataset, which can be accounted for by using appropriate statistical methods during the analysis. Summary statistics and histograms/bar graphs were plotted for each derived variable and their component raw variables to identify outliers and missing data were examined. Codes were written to check for range and logical errors for each variable, and any data or coding errors were corrected with help from the respective cohort's data managers. The final verified datasets were then sequentially appended to the master dataset one at a time using code prepared in Stata V.16 (StataCorp, College Station, USA) or R V.3.3.3 (R Core Team, 2023; https://www.R-project.org/). The only major exclusion was missing outcome data (live/stillbirth) or if the fetus was naturally or medically aborted. The harmonised dataset was accessible to all consortium members through password protected access controls to the secure server.

Definitions

The final list of variables and their definitions is presented in table 2. GA calculation was prioritised from ultrasound data when available and from last menstrual period if ultrasound data was not available. GA was used to determine what proportions of births were preterm and to calculate the time period (or GA) of measurement of each risk factor during the pregnancy. This was done to enable adjustments for time-varying exposures in statistical models, as many risk factors are known to have differential effects on stillbirth outcome depending on the stage at which they affect pregnancy.

Primary outcome measure: stillbirth

The consortium considered various definitions of stillbirth and made a decision to adopt the WHO definition of stillbirth (birth of a fetus without any sign of life at or after 28 weeks of gestation), which is recommended for international comparisons.

Principles and plans for statistical analysis

A detailed study flow diagram outlining the analytical decisions that progressed from the total participant pool across all cohorts to the final analytical dataset is presented in online supplemental figure 1. For each objective, a statistical analysis and reporting plan was formulated in collaboration with the Technical Advisory Group of the ICMR-SPIC consortium. This plan delineated the statistical techniques, underlying assumptions and procedural steps, ensuring systematic and transparent analyses (details will be reported in subsequent papers). The harmonised dataset will be analysed using a one-stage meta-analysis, an individual-level pooled analysis of all available data. Given heterogeneity in data availability across cohorts, primary risk factor analyses will use complete case analysis to ensure methodological consistency. Sensitivity analyses using multiple imputation will be considered for variables with moderate missingness to assess robustness.

Using a weighted sample, the SBR will be calculated as the number of stillbirths divided by the total number of births expressed per 1000 total births. To account for differences in sample sizes across cohorts, each cohort will be weighted, with weights computed as the inverse of the ratio of the individual cohort sample size to the overall pooled cohort sample size. The total number of births will be defined as the sum of live births (regardless of GA) and stillbirths. SBR will be reported along with the 95% CIs. In addition, a sensitivity analysis using a two-stage fixed-effects and random-effects meta-analysis will be conducted to estimate the pooled stillbirth prevalence. Subgroup analyses will be performed by geographical region and study year

Assessment of risk factors for stillbirths in India

To assess the association and estimate the risk ratios (RRs) of various socio-demographic and antenatal risk factors for stillbirth, generalised linear mixed-effects model (GLMM) with Poisson distribution, log link and robust variance will be used to estimate adjusted RRs for stillbirth, a GLMM with a Poisson distribution, log link and robust variance estimation will be used to obtain adjusted RRs. The study cohort will be included as a random intercept to account for clustering. Directed acyclic graphs will be drawn to understand the pathways

Table 2 List of variables and harmonised definitions

Sr. no.	Variable	Harmonised variable description
Outcome measure		
1	Stillbirth	Categorical; yes/no/not collected
Maternal socio-demographic factors		
1	Maternal age	Continuous; completed years
2	Location	Categorical; urban/rural/not collected
3	Maternal education in years	Continuous; completed years; level of maternal education (primary, secondary, etc, if completed years not available)
5	Consanguineous marriage	Categorical; yes/no/not collected
6	Fuel type for cooking or heating	Categorical; LPG/natural gas/kerosene/coal/charcoal/wood/dung cakes/straw/shrub/grass/agricultural crop waste/biogas/other/combination of any of the above
7	Source of drinking water	Categorical; piped water into dwelling/public tap/tubewell, borehole or hand pump/open well/closed well/tanker truck/surface water/bottled water/rain water/other/combination of any of the above
Maternal health history		
1	Weight (during pregnancy)	Continuous; in kg
2	Height (during pregnancy)	Continuous, in cm
3	Biceps skinfold thickness	Continuous, in cm
4	Triceps skinfold thickness	Continuous, in cm
5	Subscapular skinfold thickness	Continuous, in cm
6	Mid-upper-arm circumference	Continuous, in cm
7	Parity	Discrete; count
8	Inter-pregnancy interval	Continuous; completed months
9	Previous history of stillbirth	Categorical; yes/no/not applicable/not collected
10	History of previous abortion	Categorical; yes/no/not applicable/not collected
11	Prior caesarean section	Categorical; yes/no/not applicable/not collected
12	Pre-existing hypertension	Categorical; yes/no/not collected
13	Family history of diabetes/hypertension/cardiovascular disorders	Categorical; yes/no/not collected
14	Artificial reproductive techniques	Categorical; yes/no/not collected
15	Infertility treatment	Categorical; yes/no/not collected
Maternal health behaviours		
1	Tobacco consumption	Categorical; yes/no/not collected
2	Alcohol consumption	Categorical; yes/no/not collected
3	Passive smoking	Categorical; yes/no/not collected
4	Number of ANC visits	Discrete; count
Maternal health during pregnancy		
1	Stress or depressive symptoms	Continuous; raw score from tool of choice (EPDS/PHQ-9)
2	Overt diabetes	Categorical; yes/no/not collected
3	Glycated haemoglobin	Continuous; %
4	Gestational diabetes (GDM)	Categorical; yes/no/not collected
5	GDM time of diagnosis	Continuous; completed weeks of gestation
6	Haemoglobin	Continuous; g/dL
7	Haemoglobin – method of assessment	Categorical; autoanalyser/point of care testing/Sahli's method/photometric method/not collected
8	Fasting plasma glucose	Continuous; mg/dL

Continued

Table 2 Continued

Sr. no.	Variable	Harmonised variable description
9	1-hour plasma glucose: oral glucose tolerance test	Continuous; mg/dL
10	2-hour plasma glucose: oral glucose tolerance test	Continuous; mg/dL
11	Systolic blood pressure	Continuous; mm Hg
12	Diastolic blood pressure	Continuous; mm Hg
13	Urinary protein	Continuous; g/dL
15	Gestational hypertension (GH)	Categorical; yes/no/not collected
16	Time of diagnosis: GH	Continuous; completed weeks of gestation
17	Pre-eclampsia	Categorical; yes/no/not collected
18	Time of diagnosis: pre-eclampsia	Continuous; completed weeks of gestation
19	Eclampsia	Categorical; yes/no/not collected
20	Time of diagnosis: eclampsia	Continuous; completed weeks
21	Thyroid disorder	Categorical; hypothyroidism/hyperthyroidism/euthyroid/not collected
Maternal infections during pregnancy		
1	Asymptomatic bacteriuria	Categorical; yes/no/not collected
2	Reproductive tract infection	Categorical; yes/no/not collected
3	Syphilis	Categorical; yes/no/not collected
4	HIV	Categorical; yes/no/not collected
5	Malaria	Categorical; yes/no/not collected
6	Rubella	Categorical; yes/no/not collected
7	Varicella	Categorical; yes/no/not collected
8	Toxoplasma	Categorical; yes/no/not collected
9	Hepatitis B	Categorical; yes/no/not collected
10	Tuberculosis	Categorical; yes/no/not collected
11	Cytomegalovirus	Categorical; yes/no/not collected
Obstetrical factors at the time of childbirth		
1	Date of childbirth	Date variable; DD/MM/YYYY
2	Mode of childbirth	Categorical: vaginal/assisted/caesarean
3	Place of childbirth	Categorical; institutional/non-institutional/not collected
4	Gestational age (GA) at childbirth	Continuous, in weeks
5	GA at childbirth in days	Continuous, in days
6	Method of dating GA	Categorical; ultrasound sonography (USG)/last menstrual period/others
7	USG method of dating GA	Categorical; crown-rump length/other fetal biometry/not applicable
8	GA at dating (weeks)	Continuous, in weeks
9	GA at dating (days)	Continuous, in days
10	Date of dating	Date variable; DD/MM/YYYY
11	Ultrasound evidence of fetal heart activity just before onset of labour or rupture of membranes	Categorical; yes/no/not collected
12	Perception of fetal movements just before onset of labour or rupture of membranes	Categorical; yes/no/not collected
13	Obstructed or prolonged labour or failure to progress	Categorical; yes/no/not collected
14	Mal-presentation at childbirth	Categorical; yes/no/not collected
15	Antepartum haemorrhage	Categorical; yes/no/not collected

Continued

Table 2 Continued

Sr. no.	Variable	Harmonised variable description
17	Amniotic fluid disorders (AFD)	Categorical; oligohydramnios/polyhydramnios/normal/not collected
18	Time of diagnosis: AFD	Continuous; completed weeks of gestation
Maternal blood biomarkers during pregnancy (available in a subset)		
1	Vitamin B_{12}	Continuous; pg/mL
2	Folate	Continuous; ng/mL
3	Ferritin	Continuous; ng/mL
5	Soluble transferrin receptor	Continuous; mg/mL
6	Vitamin D	Continuous; ng/mL
7	Vitamin B_6	Continuous; ng/mL
8	Zinc	Continuous; µg/dL
9	Selenium	Continuous; µ/L
10	C-reactive protein	Continuous; mg/L
11	hs-CRP	Continuous; mg/L
12	Calcium	Continuous; mg/dL
13	Magnesium	Continuous; mg/dL
14	Methyl malonic acid	Continuous; ng/mL
15	Cortisol	Continuous; µg/dL
16	Total cholesterol	Continuous; mg/dL
17	Low-density lipoprotein	Continuous; mg/dL
18	High-density lipoprotein	Continuous; mg/dL
19	Triglycerides	Continuous; mg/dL
20	Homocysteine	Continuous; µmol/L

ANC, Antenatal Care; EPDS, Edinburgh Postnatal Depression Scale; hs CRP, HIgh Sensitivity C Reactive Protein; LPG, Liquefied Petroleum Gas; PHQ-9, Patient Health Questionnaire-9.

of the known risk factors. To quantify the impact of each risk factor, the population attributable fraction will be estimated using Miettinen's formula,[12] expressed as: $PAF = P_e(RR-1)/RR$, where P_e is the proportion of stillbirth cases exposed to the risk factor and RR is the adjusted relative risk for that risk factor.

In the case of potential effect measure modification, we will evaluate interactions between key risk factors by including interaction terms in the regression models and assess the absolute excess risk due to interaction.[13]

Where data on clinical complications and behavioural risk factors are available only in specific cohorts, we will conduct subgroup-specific secondary analyses to explore clinical and behavioural risk factors available in select cohorts, and we will interpret the findings with caution due to potential selection bias.

Development and internal validation of a risk prediction model to identify pregnancies at high risk of stillbirth

A clinical prediction model will be developed to predict the risk of stillbirth in pregnant women visiting healthcare facilities using their baseline (fixed) and modifiable risk factors, aimed to support clinicians in medical decision-making. The optimal set of predictors that contribute significantly to predicting stillbirths will be identified by domain knowledge-based and data-driven approaches, such as Least Absolute Shrinkage and Selection Operator (LASSO) or other regularisation methods.

Using a naive Bayesian framework, a dynamic model[14] will be used to dynamically assess the personalised risk of stillbirth. The initial baseline probability will be derived from the estimated prevalence of stillbirth for the study population. Thereafter, conditional probabilities will be computed for each new predictor using Bayes' theorem to update the risk of stillbirth for each pregnant woman. The model will be internally validated by randomly splitting the harmonised dataset into a training set (60%) and an internal validation set (40%). Performance will be evaluated on the held-out validation set. Given the dynamic nature of the prediction model, we will assess model performance within clinically defined time windows using the validation dataset. This will allow us to evaluate how the model performs across different stages of pregnancy, reflecting real-world clinical decision-making scenarios. The model will be evaluated for quantifying the error in prediction (root mean squared error, mean absolute error and calibration-in-the-large, discrimination ability

Table 3 Socio-demographic and health characteristics of the ICMR-SPIC cohort

Variable		N (data available)	Unweighted % (N)/ mean±SD	Weighted %/ mean±SD
Maternal demographic and anthropometric characteristics				
Maternal age (years)		227 020	23.5±3.3	24.8±4.5
Maternal education (years)		226 555	7.3±4.8	10.0±4.2
Maternal height (cm)		223 632	152.2±5.6	152.9±5.6
Stature	Normal (>145 cm)		93.0 (208 047)	93.2
	Short (<145 cm)		6.8 (15 585)	6.9
BMI (kg/m²)		224 835	20.3±3.3	21.5±3.9
BMI categories (WHO)	Normal		61.4 (138 140)	61.2
	Underweight		30.5 (68 508)	22.2
	Overweight		8.1 (18 187)	16.6
BMI categories (South Asia specific)	Normal		52.6 (118 318)	48.3
	Underweight		30.5 (68 508)	22.2
	Overweight		16.9 (37 009)	29.5
Location/residence		219 635		
Categories	Rural		91.8 (201 635)	57.7
	Urban		8.2 (18 000)	42.3
Household and lifestyle factors				
Type of cooking fuel		1 01 977		
Categories	Clean fuel		55.5 (56 628)	86.4
	Biomass		44.4 (45 349)	13.6
Inter-pregnancy interval (months)		56 822		
Categories	≥18 months		77.4 (44 017)	72.4
	<18 months		22.5 (12 805)	27.6
Parity		227 021		
Categories	Nulliparous		47.2 (107 153)	
	Multiparous		52.8 (119 868)	
Passive smoking		77 306	27.8 (21 532)	13.5
Alcohol consumption		23 497	1.6 (389)	2.1
Pregnancy characteristics				
Gestational age at childbirth (weeks)		227 313	38.7±2.5	38.4±2.1
Weight gain per week (kg)		28 362	0.4±0.4	0.4±0.8
Maximum HbA1c (%)		9298	5.4±0.5	5.2±0.5
Gestational diabetes		17 265	5.8 (1000)	3.8
Pre-eclampsia		30 266	2.9 (889)	2.8
Eclampsia		33 036	0.2 (69)	0.3
Gestational hypertension		219 536	2.9 (6470)	3.2
Antepartum haemorrhage		206 152	0.5 (1032)	0.9
Malpresentation		208 254	2.0 (4277)	2.8
Previous abortion		12 767	26.1 (3342)	17.9
Previous stillbirth		224 228	1.8 (4057)	2.1
Moderate or severe anaemia at any time point in pregnancy (<Hb 7–9.5 g/dL)		175 040	33.3 (58 291)	33.3
Thyroid disorders		23 450		

Continued

Table 3 Continued

Variable		N (data available)	Unweighted % (N)/ mean±SD	Weighted %/ mean±SD
Categories	Euthyroid		94.5 (22 174)	94.6
	Hypothyroidism		5.0 (1179)	5.0
	Hyperthyroidism		0.4 (97)	0.4

BMI, body mass index; Hb, haemoglobin.

using the area under the receiver operating characteristics curve, sensitivity, specificity and decision curve analysis. We will evaluate the performance of the prediction models in external prospective cohorts.

Patient and public involvement statement

No patients or members of the public were directly involved in the design, conduct or analysis of this secondary data analysis. However, the ICMR-SPIC consortium includes representatives from India's research, practice and policy communities to ensure that the study aligns with national health priorities and addresses key public health concerns. Dissemination efforts will focus on engaging future mothers and their families, the general public, non-governmental organisations dedicated to preventing stillbirths and improving maternal and child health and other relevant stakeholders. Study findings will be communicated through diverse channels, including local audio-visual media, print media and social media platforms, with messages specifically tailored to inform future mothers and their families about stillbirth risk factors and effective strategies for prevention and management.

Findings to date

The harmonised ICMR-SPIC dataset comprises individual-level data from a large sample of 229 695 pregnant women on maternal socio-demographic, health, lifestyle and household factors, as well as characteristics of previous and current pregnancies and objective measures of birth outcomes (table 3). The descriptive characteristics are presented using both unweighted (uw) and weighted (w) estimates

Maternal socio-demographic and anthropometric characteristics

The mean (SD) maternal age at enrolment was 23.5±3.3 years (uw)/24.8±4.5 years (w). Education duration varied widely, with a mean (SD) of 7.3 (4.8) years (uw) and 10.0 (4.2) years (w), which is expected for the profile of women visiting public health facilities in India or residing in urban-poor or rural community settings. The mean (SD) maternal height was 152.2 (5.6) cm (uw), 152.9 (5.6) cm (w) and with 6.8% (uw) and 6.9% (w) being of short stature (<145 cm), a known risk factor for adverse pregnancy outcomes, including stillbirth.[15] Using criteria specified for the South Asian population, 30.5 % (uw), 22.2% (w) of women were underweight (<18.5 kg/m^2) while 16.9% (uw) and 29.5 % (w) were overweight (≥23 kg/m^2). The majority of the participants—91.8% (uw) and 57.7% (w)—live in rural areas.

Maternal household and lifestyle factors

Biomass fuel—known to contribute to indoor air pollution and respiratory health issues—was used by 44.4% (uw) and 13.6% (w) of the participants. An inter-pregnancy interval of <18 months, a factor associated with a higher risk of adverse maternal and child health outcomes, was reported in 22.5% (uw) and 27.6% (w) of mothers; however, data for this variable was available for only a quarter of the total sample (N=56 822). The distribution of parity was balanced, with 47.2% of women being nulliparous and 52.8% multiparous—the former being reported as a risk factor for stillbirths.[16] Passive smoking was observed in 27.8% (uw) and 13.5% (w) and alcohol consumption during pregnancy was observed in 1.6% (uw) and 2.1% (w) of the mothers. However, data for these factors were available in a small subset of the total population (table 3).

Pregnancy characteristics

Although information about the history of abortion was available only for 12 767 women, 26.1% (uw) and 17.9% (w) of these women reported having experienced a previous abortion. In contrast, information about previous stillbirths was available for almost all participants (N=224 228), with 1.8%(uw) and 2.1 % (w) reported experiencing at least one previous stillbirth. The mean (SD) GA at childbirth was 38.7 (2.5) weeks and 38.4 (2.1) weeks, and gestational weight gain per week was 0.4 (0.4) kg (N=28 362). The prevalence of pregnancy complications computed from smaller subsets of the data was noted as follows: gestational diabetes was observed in 5.7% (uw) and 3.8% (w) of women (N=17 265), gestational hypertension in 2.9% (uw), 3.2% (w) (n=219 536), pre-eclampsia in 2.9% (uw), 2.8% (w) (N=30 266); and eclampsia in 0.2% (uw) and 0.3% (w) (N=33 036). Antepartum haemorrhage was reported in 0.5% (uw) and 0.9% (w) (N=206 152) and fetal malpresentation was observed in 2.0% (uw) and, 2.8% (w) (N=208 254) of women. The data also revealed substantial and concerning rates of anaemia, with 33.3% of women having moderate or severe anaemia during pregnancy. Additionally, the data indicated that 5% of women had thyroid disorders (diagnosed with hypothyroidism).

Strengths and limitations

The ICMR-SPIC dataset represents a landmark collaborative initiative consolidating data from 10 well-characterised pregnancy cohorts spanning diverse regions of India. This harmonised dataset, encompassing 229 695 participants from both urban and rural settings, is the largest of its kind in the country, which will facilitate robust analyses of stillbirth prevalence, associated risk factors and predictive models for high-risk pregnancies. Using standardised methodologies and harmonised definitions enhances the dataset's reliability, allowing national and regional estimates to support evidence-based policy formulation and targeted intervention design. These high-quality data will directly inform policy decisions, such as guiding potential updates to High-Risk Pregnancy (HRP) screening guidelines, enabling the India Newborn Action Plan to better prioritise high-risk groups, and supporting the more precise targeting of maternal health interventions in underserved regions. This evidence-based approach ensures that resources and strategies are aligned with the areas and populations of greatest need, ultimately improving maternal and newborn health outcomes. The findings will underscore critical maternal health challenges leading to a high burden of stillbirth in the country, including a high prevalence of malnutrition, anaemia, pregnancy complications such as gestational diabetes and pre-eclampsia and significant exposure to passive smoking and biomass fuels. However, the dataset highlights notable gaps in representation, mainly from eastern India and tribal populations and inconsistencies in data collection methods across cohorts, highlighting the need for future studies in these areas. Despite rigorous efforts to harmonise data, variations in the measurement methods for certain modifiable risk factors (eg, reproductive tract infections, preeclampsia and haemoglobin concentrations) may result in residual misclassification, potentially affecting the precision of some risk analyses. A notable limitation of the dataset is the lack of detailed data in several cohorts to distinguish between antepartum and intrapartum stillbirths, or assess the quality of care during labour and childbirth. This restricts the ability to provide robust prevalence estimates or identify specific determinants for the two types of stillbirths. An important limitation of our dataset is the variable availability of data on clinical complications and behavioural risk factors across cohorts. While efforts were made to harmonise definitions and retain all relevant data, some variables were only available in specific cohorts. As such, these will be analysed in secondary, subgroup-specific analyses and findings will be interpreted with caution due to potential selection bias. Another limitation of the cohort is the reliance on last menstrual period for GA estimation, which may lead to misclassification of GA. Although the unweighted dataset was predominantly rural (~90%), adjustments were made to better reflect the underlying population distribution. This improves representativeness, though caution is warranted when applying findings to urban settings. These factors necessitate careful consideration during data analysis and interpretation to ensure accurate and meaningful insights. Despite limitations, including incomplete data on pre-conception factors, intrapartum care and variability in measurement methods, the scale and scope of the ICMR-SPIC dataset offer an unprecedented opportunity to develop predictive models and design context-specific interventions and is a major step forward in collaborative research within India.

The ICMR-SPIC demonstrates the value of large-scale collaborative data harmonisation approaches to address critical public health challenges like stillbirth in India. By pooling data from diverse pregnancy cohorts, this unique effort enables robust, generalisable insights into the prevalence and region-specific risk factors for stillbirths and facilitates the development of a prediction model to identify pregnancies at high risk of stillbirths. These efforts will inform evidence-based clinical guidelines, interventions and policymaking, thereby addressing the goal of reducing rates of preventable stillbirths in India and achieving the national and global targets.

Collaboration

All contributing research teams have acknowledged that the pooled data can only be used for collaborative activities within the ICMR-SPIC consortium, with no transfer of ownership. Data from the individual cohorts are available on reasonable request. Researchers interested in accessing the data can request it by directly contacting the principal investigator of the relevant cohort.

Acknowledgements We sincerely thank the study participants for sharing valuable information and biological samples for the conduct of this study. Additionally, each cohort team thanks the research staff for supporting the preparation of the harmonised dataset (online supplementary table 2). We are thankful to the primary funding agencies of the cohorts for granting permission to share the data for this exercise. The ICMR-SPIC Consortium would also like to thank the technical advisory group members (online supplementary table 3) for their support in conceptualising the specific objectives and statistical analysis plan for this study.

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Funding This study was funded by the Indian Council of Medical Research to create a harmonised pooled dataset across 10 pregnancy cohorts in India and to conduct secondary analysis using this dataset. The funder did not influence the results/outcomes of the study despite author affiliations with the funder.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Ethical approval was obtained individually by each cohort's principal investigator from their respective Institutional Ethics Committees, both for conducting their original studies and for sharing data for this pooled analysis. All cohorts had appropriate ethics and regulatory approvals, including participant consent to address research questions on stillbirth and other adverse pregnancy outcomes. The IEC ID numbers are mentioned below as follows: Cohort (in alphabetical order); Name of the Ethics Committee; and Reference ID. (1) CalPreg cohort; Institutional Ethical Review Board, St. John's Medical College, Bangalore 560034; Ref. No. 197/2017 (14 September, 2017; original); amendments and extensions: 1 January, 2018; 24 July, 2018; 9 September, 2018; 30 April, 2020; 5 June, 2020; 12 November, 2020. (2) GARBHINI cohort; Institutional Ethics Committee, Translational Health Science and Technology Institute, Faridabad, India, and Institutional Ethics Committee, Gurugram Civil Hospital, Haryana, India; THS/1.8.1/(71), dated 26 August 2019, GHG/IEC letter, dated 3 September 2019. (3) LIFE cohort; MediCiti Ethics Committee, MediCiti Institute of Medical Sciences Campus, Ghanpur, Medchal Mandal, Telangana 501401; (1) Initial study approved by IEC vide its letters dated 26 May 2008; 7 June 2008; (2) Children follow-up for 6–7 years approved by Ethics Committee vide its letter dated 31 January 2017; (3) Children follow-up for 8–16 years approved by IEC vide its letter dated 4 October 2018. (4) MAASTHI cohort; Institutional Ethics Committee at Bangalore campus of Indian Institute of Public Health - Hyderabad; Indian Institute of Public Health - Hyderabad Technical Review Committee Institutional Ethics Committee - 091-2015, dated 13 November 2015. Renewed annually until 2020. (5) MNHR-Belagavi cohort; Institutional Ethics Committee of KLE Academy of Higher Education and Research, Belagavi; Ref. No.: MDC/IECHSR/2007-08/D-6989-7002, dated 19 January 2008. (6) MNHR Nagpur cohort; Research Ethics Review Committee, Lata Medical Research Foundation, Nagpur, India; LMRF/SGCT/RPC01/01/04/2009. (7) PMNS cohort; King Edward Memorial Hospital Research Center, Pune, Maharashtra, India; KEMHRC/LFG/Dir.Offi/Adhoc/2175-A, dated 22 March 2024. (8) REVAMP cohort; Bharati Vidyapeeth Medical College Institutional Ethical Committee; IEC/2015/37, dated 3 October 2015. (9) WINGS cohort; Ethics Review Committee of the Society for Applied Studies, New Delhi, and Vardhman Medical College and Safdarjung Hospital, New Delhi, and WHO, Geneva; SAS/ERC/LG/2017 dated 3 June 2017, IEC/SJH/VMMC/PROJECT-2017/694, ERC.0002934. (10) MaatHRI cohort (Institution, Reference number and date of approval): Gauhati Medical College & Hospital: No. MC/190/2007/Pt-I/126, dated 18 January 2018. Mahatma Gandhi Institute of Medical Sciences: No. MGIMS/IEC/OBGY/118/2017, dated 15 December 2017. Institute of Medical Sciences, Banaras Hindu University: No. Dean/2018/EC/290, dated 2 January 2018. Nazareth Hospital: Ref. NH/CMO/IEC/COMMUNICATIONS/18-01, dated 2 January 2018. Emmanuel Hospital Association, New Delhi: No. 167, dated 19 January 2018. Dr Rajendra Prasad Government Medical College (Dr RPGMC), Kangra at Tanda, Himachal Pradesh, India: No. HFW-H DRPGMC/Ethics/2020/034, dated 25 June 2020. Oxford Tropical Research Ethics Committee (OxTREC): OxTREC Ref. 7-18, dated 19 April 2018. Government of India's Health Ministry's Screening Committee, the Indian Council of Medical Research, New Delhi: No. 2018-0152, dated 1 May 2018.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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