

Request for Expression of Interests (EoIs) for data contribution to a collaborative secondary analysis on ‘Hypothyroidism in Pregnancy’

Context

Hypothyroidism is among the most common endocrine disorders affecting women of reproductive age with pregnancy increasing vulnerability due to increased thyroid hormone and iodine demands. The burden of maternal hypothyroidism is notably high in India. Untreated or inadequately managed hypothyroidism in pregnancy can have far-reaching consequence including miscarriage, preeclampsia and placental complications in the mother as well as preterm birth, low birth weight and impaired neurodevelopment in the child. Emerging evidence suggests that hypothyroidism in pregnancy is shaped not only by iodine deficiency but by a confluence of nutritional (iron, selenium), environmental (endocrine-disrupting chemicals), metabolic (obesity) and autoimmune factors. These interrelated influences underscore the need for a more comprehensive understanding of risk pathways and outcomes in Indian women.

Against this backdrop, the Indian Council of Medical Research (ICMR) invites researchers and institutions to contribute data from ongoing or completed pregnancy cohort studies or randomized controlled trials (RCTs) toward a national collaborative effort aimed at understanding hypothyroidism during pregnancy among Indian women. The objective is to generate high-quality evidence to provide deeper insights into hypothyroidism during pregnancy, based on current reference ranges for thyroid function.

Primary objectives

1. To estimate the prevalence of hypothyroidism (overt and subclinical) among pregnant women across diverse Indian populations using current trimester-specific reference ranges.
2. To identify risk factors associated with hypothyroidism in pregnancy.
3. To assess the associations between subclinical hypothyroidism (SCH) and adverse pregnancy and fetal outcomes (e.g., preeclampsia, gestational hypertension, gestational diabetes, stillbirth, low birth weight, preterm birth etc.).
4. To develop normative reference values for thyroid function parameters in Indian pregnant women.

Eligibility for data contribution

To be considered for pooled analysis, contributing datasets must meet the following criteria:

1. Study design: Prospective pregnancy cohort, cross sectional, case-control or randomized controlled trial (RCT).
2. Study period: Data collected after 2000.
3. Sample size: At least 300 pregnant women or evidence of an appropriate power calculation for smaller studies.
4. Availability of biochemical data on thyroid function and/or availability of corresponding bio-samples.

5. Availability of relevant clinical outcome data (e.g., maternal or neonatal health indicators).
6. A data dictionary must be provided

Mandatory data elements

1. Thyroid parameters: TSH (and where available, FT4), measured during pregnancy (preferably in all three trimesters).
2. Cut-offs used for defining thyroid status.
3. Gestational age at sample collection (preferably by ultrasound or early LMP confirmation).
4. Maternal characteristics: Age, parity, BMI/weight, hemoglobin, iodine status (if available).
5. Pregnancy outcomes:
 - Maternal: preeclampsia, gestational hypertension, gestational diabetes, anemia, miscarriage etc.
 - Neonatal: gestational age at delivery, birth weight, spontaneous abortions, miscarriages, stillbirth, congenital anomalies, early neonatal death etc.
6. Study population information: Geographic region, rural/urban setting and recruitment criteria.

Optional data (if available):

Autoimmune markers (anti-TPO, anti-Tg), trimester-specific hormone assays, postpartum thyroid status, neonatal TSH or thyroid function measures, newer risk factors like environmental toxins (for e.g., phthalates, bisphenols, organochlorine pesticides) micronutrient deficits (notably iron and selenium), infections (tuberculosis, UTI etc.), chronic infections/conditions, **TSH or thyroid function measurements in postpartum period** etc.

Data contribution and governance

- Contributors will provide de-identified datasets under a formal Data Use Agreement (DUA) between ICMR and the contributing institution.
- Contributors will retain full ownership of their original data.
- Institutional Ethics Committee (IEC) approval for secondary use of data must be confirmed or obtained as per the contributor's institutional policy.

Participation benefits

This is a **non-funding, scientific collaboration**. Contributors will receive:

- Co-authorship in all publications arising from this work, following *ICMJE* authorship criteria.
- Acknowledgement in all ICMR policy briefs, technical reports and guidelines emerging from the findings.

Submission process

Interested researchers may submit their Expression of Interest (EOI) by completing the prescribed format (available on the ICMR website) and providing details of their dataset, study design, and relevant data elements.

Review and selection

All EOIs will be reviewed by a Technical Advisory Group (TAG) constituted by ICMR. Final inclusion of datasets in pooled analyses will be based on data completeness, methodological quality and relevance to the study objectives as determined by the TAG.

Approach to inclusion criteria

Final criteria for pooled analysis will be developed collaboratively by ICMR, contributing partners and the Technical Advisory Group (TAG) after review of the contributed datasets.

When and how to submit:

The data should be submitted through **ONLINE MODE ONLY** by the Principal Investigator. Interested PIs should fill out the Google Form available at the link below:

<https://docs.google.com/forms/d/e/1FAIpQLSdq5OSxMv1BiV9sqigrDjYjQzFEOVuuzcJkUvqzucT3uPIXOA/viewform?usp=publish-editor>

Please note: ***Only shortlisted PIs*** will be contacted via email for data submission.

Submission Timeline:

- Start Date: 04 November 2025 | Time: 05:00 PM
- End Date: 01 December 2025 | Time: 05:00 PM

For any inquiries please contact: **Dr. Tanica Lyngdoh, Scientist-E** at icmr.adm@gmail.com