GLOBAL GESTATIONAL WEIGHT GAIN STANDARDS PROJECT

Eligibility criteria for the inclusion of study datasets into the pooled underlying database

Final report

November 2023
Acknowledgement

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Contents

1 Introduction ............................................................................................................................. 5

2 Rationale for the study-level eligibility criteria ...................................................................... 8
   2.1 Ethics committee/board approval ..................................................................................... 8
   2.2 Year of data collection ..................................................................................................... 8
   2.3 Study design ..................................................................................................................... 9
   2.4 Sample size ..................................................................................................................... 11
   2.5 Type of data .................................................................................................................... 13
   2.6 General characteristics of the study ............................................................................... 15
      2.6.1 Number of weights during pregnancy ..................................................................... 15
      2.6.2 Initial weight ............................................................................................................ 16
      2.6.3 Maternal height ........................................................................................................ 18
      2.6.4 Gestational age ........................................................................................................ 20
      2.6.5 Missing data ............................................................................................................. 22
      2.6.6 Reproductive technologies ...................................................................................... 23
      2.6.7 Multiple pregnancies ............................................................................................... 24
      2.6.8 Maternal age ............................................................................................................ 25
      2.6.9 Birth outcomes ........................................................................................................ 26
      2.6.10 Maternal health conditions ................................................................................... 27
      2.6.11 Postpartum data ..................................................................................................... 28

References ................................................................................................................................ 30

Annex ....................................................................................................................................... 33

   Annex 1. List of mandatory variables to be requested in each dataset eligible for the pooled database. ............................................................................................................................... 33

   Annex 2. List of important variables to be requested in each dataset eligible for the pooled database. ............................................................................................................................... 36
1 Introduction

The World Health Organization (WHO) is carrying out a 3-year project to develop gestational weight gain (GWG) standards (as close as data allow) and to identify cut-offs on the standards that define optimal GWG ranges. The project will involve two phases: **Phase 1.** Development of global GWG standards according to gestational age and stratified by pre-pregnancy body mass index (BMI); **Phase 2.** Identification of ranges on the GWG curves associated with the lowest risks of adverse maternal and infant outcomes. At the end of these phases, WHO plans to update existing recommendations for GWG monitoring during the antenatal care period.

The project will involve the secondary analysis of global data in both phases. These data may be researcher-collected or administrative data. For **Phase 1,** the individual datasets will be harmonised into a pooled database. Thus, to develop the standards, it is necessary to define the eligibility criteria for the inclusion of datasets (study-level eligibility criteria) into the pooled database as well as the individual-level eligibility criteria that will be the basis for developing the standards. The study-level eligibility criteria must be chosen by considering characteristics that will allow us to obtain a sample of pregnant individuals with low risk of adverse outcomes for mothers and infants. The individual-level eligibility criteria will be developed later and are beyond the scope of this document.

This document reports the final study-level eligibility criteria to identify studies that will be part of the pooled database to develop the GWG standards (**Phase 1**). These criteria have been defined after an extensive review by the TAG-GWG members, followed by a discussion with the participants of the GWG Steering Committee. In this discussion, the approach of the Steering Committee with regards to receiving datasets for future sensitivity analyses and further discussions with the TAG-GWG working groups, is to be as flexible as possible.

The defined study-level eligibility criteria are listed in **Box 1,** and the rationale behind this list is described in detail in the following section. The list of criteria for studies presented here is based on core variables critical for identifying studies/datasets that adhere to specific characteristics in terms of target population groups and data quality. An extended list of variables to be requested from each dataset is also attached to this document (**Annex 2**), including variables that will be relevant to inform individual-level eligibility criteria. The list of mandatory variables in **Annex 1** does not exactly match the eligibility criteria described in
this document. This is because although some of the variables are relevant for creating GWG standards, they may not be available in several studies, which will make it impossible to obtain relevant datasets.

**Box 1.** Summary of the proposed eligibility criteria for a dataset to be included in the pooled cohort to develop the GWG standards (Phase 1).

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<tbody>
<tr>
<td>1.</td>
<td>Ethics committee/board approval</td>
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<td>Data collected after a research ethics committee/board approval</td>
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<td>2.</td>
<td>Year of data collection</td>
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<td></td>
<td>Data collected during or after 1990</td>
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<td>3.</td>
<td>Study design</td>
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<td>Observational studies, including prospective and retrospective cohorts; administrative/clinical databases; and control arms of randomized clinical trials receiving placebo, standard care, or no interventions at all</td>
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<td>4.</td>
<td>Sample size</td>
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<td>Minimum 200 subjects</td>
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<td>5.</td>
<td>Type of data</td>
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<td>Individual participant data collected by the research team following a standardized protocol and/or collected through clinical/public health care encounters</td>
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<tr>
<td>6.</td>
<td>General characteristics of the studies</td>
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<tr>
<td>6.1</td>
<td>Studies and administrative datasets with at least two visits where maternal weight and accompanying gestational ages are documented. A minimum of two weight measurements in different trimesters is required. These two visits during pregnancy do not include the initial weight.</td>
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<td>6.2</td>
<td>With pre-pregnancy (initial) weight data</td>
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<td></td>
<td>• <strong>Ideal:</strong> measured before or close to (maximum 3 months before) the conception</td>
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<td></td>
<td>• <strong>Acceptable:</strong> measured in the first trimester (up to 13+0 weeks)</td>
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<td>• <strong>Acceptable:</strong> self-reported</td>
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<td>6.3</td>
<td>With maternal height data</td>
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<td>• <strong>Ideal:</strong> measured in the first pregnancy trimester, with the measurement procedure used</td>
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<td></td>
<td>• <strong>Acceptable:</strong> measured during pregnancy or after delivery, with the measurement procedure used and, if available, the date or gestational age at the measurement</td>
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<tr>
<td></td>
<td>• <strong>Acceptable:</strong> abstracted from medical records with the measurement procedure used and, if available, the date or gestational age at the measurement</td>
</tr>
<tr>
<td></td>
<td>• <strong>Acceptable:</strong> self-reported</td>
</tr>
</tbody>
</table>
6.4 With gestational age (in days or the data required to calculate it) at the weight measurements and at delivery
  ● **Ideal:** dates of weight measurements (and any other date of data collection), dates of ultrasound measurements, gestational age at ultrasound measurements, and date of delivery
  ● **Acceptable:** gestational ages or dates of weight measurements (and any other gestational age/date of data collection) and gestational age at delivery estimated by an ultrasound scan performed before 24 weeks gestational age
  ● **Acceptable:** gestational ages or dates of weight measurements (and any other gestational age/date of data collection) and gestational age at delivery estimated by the last menstrual period (LMP) date confirmed by an ultrasound scan performed before 24 weeks
  ● **Acceptable:** dates of weight measurements (and any other date of data collection), date of delivery, and LMP date confirmed by an ultrasound scan performed before 24 weeks

6.5 For research studies, no more than 20% of listwise missing data across the following key variables: maternal height, maternal age, pre-pregnancy weight, gestational weight, gestational age at weight measurements, date of delivery or gestational age at delivery, birth weight, and sex of the newborn. The WHO team will check this percentage after receiving the datasets

6.6 With information regarding the use of assisted reproductive technologies (such as in vitro fertilisation) (ideally) and not conducted exclusively among individuals who conceived through assisted reproductive technologies

6.7 With information on singleton/multiple pregnancies and not conducted exclusively among non-singleton pregnancies

6.8 With maternal age data and not conducted exclusively among adolescents (10.0 – 18.0 years old at conception)

6.9 With data available on birth outcomes: sex of the child, birth weight, date of birth or gestational age at birth, and vital status of the newborn

6.10 Studies not conducted exclusively among women with hypertensive disorders (before or during pregnancy) or diabetes mellitus/gestational diabetes. It is desirable to provide information on maternal pre-existing health conditions (at least hypertension and diabetes) and complications during pregnancy (at least hypertensive pregnancy disorders and gestational diabetes)

6.11 Ideally, with at least one measurement of maternal and/or child weight at or beyond six months postpartum and the dates of those measurements
2 Rationale for the study-level eligibility criteria

2.1 Ethics committee/board approval

Proposed criterion:
Data collected after a research ethics committee/board approval.

TAG-GWG members’ comments:
Not applicable. This criterion was added to the list after the TAG-GWG members reviewed it.

GWG steering committee decision and rational:
Only datasets from studies approved by research ethics committees/boards can be incorporated into the database, according to WHO regulations.

Final criterion:
Data collected after a research ethics committee/board approval.

2.2 Year of data collection

Proposed criterion:
Studies conducted in or after 2000. This year refers to the data collection period, not protocol/manuscript publication.

TAG-GWG members’ comments:
“Year of data collection, namely 2000 or later is relevant for contemporariness. Depending on the data sets available, perhaps a sensitivity analysis, with data after 2010 can be performed, not only to make it as recent as possible, but also to factor for the improvements in medical care practice, which do impact the materno-fetal outcomes, irrespective of their association or causality with Gestational Weight Gain (GWG)”.

“Considering the rapid changes in dietary habits in recent years, there might be variations in weight gain patterns during pregnancy between older and more recent studies. I understand that any definition would be arbitrary. If you keep 2000 as the
limit year, it is important to test the possible impact on weight trajectories due to the year of the study”.

“We may want some flexibility here. Perhaps we say "most" data collected during or after 2000. Some cohorts (e.g., Project VIVA) may have STARTED data collection before 2000 but continued enrolling during and after 2000”.

**GWG steering committee decision:**
Incorporating as many datasets as possible would be beneficial at this initial stage. Thus, the committee decided that the study-level eligibility criteria should be broader to facilitate data acquisition. The first aim of this project is to develop global standards for GWG; therefore, the pooled database's representativeness and contemporariness are essential to accomplish this goal. The decision to broaden the time frame for studies conducted from 1990, although arbitrary, acknowledges the significance of the 1990s as an essential starting point for GWG recommendations, with the publication of the first GWG guidelines by the US Institute of Medicine.

**Final criterion:**
Studies with data collection periods in or after 1990. This year refers to the data collection period, not protocol/manuscript publication.

**Rationale:**
Although the choice of the year 1990 is arbitrary, there is evidence in favor of excluding older studies because of changes in obstetrical care (e.g., gestational age estimation, which is fundamental for the construction of the standards) and the definition of outcomes (e.g., preterm birth, large- and small-for-gestational-age) (1, 2). To be more flexible, studies starting in 1990 will be accepted, and the year of the data collection will be considered during heterogeneity assessments and sensitivity analyses.

**2.3 Study design**

**Proposed criterion:**
Observational studies, including prospective and retrospective cohorts; administrative/clinical databases (which can be considered retrospective cohorts); and control arms of randomized clinical trials receiving placebo, standard care, or no interventions at all.
TAG-GWG members’ comments:
“I guess we need something about source population: population-based selection? Also, for sensitive analysis. Control arms of intervention studies might be too selected? No need to contribute to each arm, I guess?”

“Steps to evaluate the quality of the administrative and clinical databases for GWG analysis are going to vary quite a bit relative to research studies”.

“How will data from different clinical/administrative data sources from different country contexts be standardized? One way to do this is to consistently use ICD-10 codes and develop a standard algorithm to identify pregnancy episodes, type of birth outcomes, and measures of weight/height collected during pregnancy”.

“The standard of care and/or placebo groups in RCTs can vary quite a bit as well. It will be important to plan for methods to account for heterogeneity in the placebo/control groups in sensitivity analyses as well”.

GWG steering committee decision:
The quality of the data is crucial to construct GWG standards. Therefore, administrative data is a matter of concern and should be carefully evaluated before being considered for the pooled database. The WHO will attempt to perform a pilot study using administrative datasets of known good quality to establish the validity of accepting administrative data. Only control arms of randomized controlled trials will be eligible, and all relevant information about the study protocol, including a comprehensive description of the intervention and placebo, will be requested. The criteria will remain as initially proposed, and all the raised issues will be considered when the datasets become available.

Final criterion:
Observational studies, including prospective and retrospective cohorts; administrative/clinical databases (which can be considered retrospective cohorts); and control arms of randomized clinical trials receiving placebo, standard care, or no interventions at all.

Rationale:
Prospective cohorts are the preferred study design as they usually have a more standardized protocol for collecting maternal weight and height measurements, as
required for constructing the GWG BMI-specific charts. Also, neonatal outcomes needed to achieve the project's objectives are often collected in this type of study. Control arms of randomized clinical trials will be eligible. Intervention arms will be excluded because of the difficulty in determining whether an intervention has a clinically meaningful effect on GWG. This type of assessment will not be feasible within the project timeframe. The plan is to limit the inclusion of individuals from the control arms of randomized clinical trials to those who received standard care, placebo, or no intervention at all. Eligible studies must provide information on the treatment received by the control arm to be considered in future sensitivity analyses.

2.4 Sample size

Proposed criterion:
Minimum 100 subjects per pre-pregnancy BMI category. Large (e.g., national, sub-national, multi-centric) or local studies (e.g., conducted in a specific neighbourhood or hospital-based) are eligible. Studies will be accepted if the data are available for only one pre-pregnancy BMI category. The BMI categories that will be considered are: underweight (< 18.5 kg/m²); normal weight (≥ 18.5 and < 25.0 kg/m²); overweight (≥ 25.0 and < 30.0 kg/m²); obese (≥ 30.0 kg/m²) (3).

TAG-GWG members’ comments:
“What is the statistical basis for keeping a minimal sample size of 100 per BMI category?”.

“The WHO categorization for overweight and obese on the basis of BMI is lower for South Asia. This should be factored for, especially in view of the rapid escalation of Non-Communicable Diseases in these settings”.

“I understand that to define the trajectories of gestational weight gain for each pre-pregnancy BMI, at least it is necessary 100 cases in each group. However, I can't entirely agree with merging all women with obesity in the same category. Suppose the reason for this is to avoid a smaller sample. In that case, I suggest that women with grade 1 and grade 2 obesity be separated from those with grade 3 obesity since gestational weight gain is heterogeneous among them”.
“I wonder if classes (I, II, III) of obesity also can be included, as we recently showed that outcomes are different in the three classes of obesity for different GWG ranges”.

“Note pre-pregnancy BMI will in many perinatal databases not be available. Only BMI at the 1st antenatal visit will be available (median at gestational week 8)”.

“The requirement of a minimum of 100 women per BMI category may limit the inclusion of studies in countries with a low prevalence of underweight or obesity. It would be helpful to clarify whether studies with at least 100 women in any BMI category will be accepted. If so, the wording in Item 3 of Box 1 needs revision for clarity”.

“I would recommend a minimum of N = 100 but NOT require >= 100 in each wt status category. BMI should be measured. However, I fear that we'll lose a lot of valuable data if we make this requirement”.

“This isn't clear in number 3 above. Agree it should be acceptable if data available for only one category”.

“I understand the rationale for this. However, is it reasonable to expect 100 subjects in the obese category in all contexts? 100 subjects overall makes sense but given population-level heterogeneity in distribution of maternal pre-pregnancy BMI, I suspect that population-representative datasets from resource-limited settings may not have at least 100 subjects per pre-pregnancy BMI category”.

“I would caution against excluding datasets based on the absolute number per BMI category. Excluding datasets based on the absolute number per BMI category may disproportionately limit representation of data from LMICs”.

**GWG steering committee decision:**

A large global database is essential to construct GWG standards per BMI category. However, the sample size criterion for a study to be eligible can be more flexible, following the TAG's proposal. The WHO will explore heterogeneity of datasets with smaller sample sizes, and sample size calculation will be performed to provide a statistical basis for each BMI category once datasets become available. The BMI categories to be adopted in this project will be addressed by a TAG-GWG working
group in further discussions, but there is a concern within the GWG steering committee regarding having too many different charts and their usability in clinical practice.

**Final criterion:**
Minimum 200 subjects. Large (e.g., national, sub-national, multi-centric) or local studies (e.g., conducted in a specific neighbourhood or hospital-based) are eligible.

**Rationale:**
The GWG standards may be pre-pregnancy BMI-specific (3, 4, 5). Therefore, it is desirable to define a minimum sample size *a priori* to have enough data to construct GWG standards stratified by pre-pregnancy BMI, especially for those categories with fewer subjects, such as underweight or obesity (6). After data cleaning and applying the individual-level eligibility criteria, some small studies may end up with an even smaller sample size. By defining 200 as a minimum sample size, we avoid situations where a dataset will contribute few women (< 50) to the harmonized pooled database, which could add more heterogeneity to the GWG distribution (7). This decision is also influenced by human-resource considerations, i.e., data cleaning and harmonization should focus on studies with larger sample sizes, including more diversity within the specific context.

**2.5 Type of data**

**Proposed criterion:**
The priority is to use data collected for research purposes following a standardized protocol. Data abstracted from medical records (collected through clinical/public health care encounters) will also be eligible. In this case, evidence that the data was collected following a protocol or that the weight measurements during pregnancy are not self-reported should be provided.

**TAG-GWG members’ comments:**
“The precision of routine clinical or administratively collected data, particularly in some settings, is likely to be an issue that will impact the GWG ranges, particularly at the extremes. If possible, this may be dispensed with, unless Technical Errors of Measurement are available, or a sensitivity analysis after including or excluding this source, should be done.”
“Very general; what kind of data would not fit? (questionnaires?)”.

“Page 9, 2.4 Type of data section. The statement: “Self-reported weights throughout pregnancy will not be acceptable” This statement appears to contradict the summary in Box 1, which states that self-reported weight/height would be acceptable”.

“In data abstracted from medical records: How will data from different clinical/administrative data sources from different country contexts be standardized? One way to do this is to consistently use ICD10 codes and develop a standard algorithm to identify pregnancy episodes, type of birth outcomes, and measures of weight/height collected during pregnancy”.

GWG steering committee decision:
Clinical and administrative data may have limitations regarding the standardization of data collection. Therefore, it is essential to require a protocol containing information on how the variables were collected. The consensus was to maintain the proposed eligibility criteria for clinical and administrative datasets, requiring the research protocol, and conducting a sensitivity analysis once the datasets are available.

Final criterion:
The priority is to use data collected for research purposes following a standardized protocol. Data abstracted from medical records (collected through clinical/public health care encounters) will also be eligible. In this case, evidence that the data was collected following a protocol or that the weight measurements during pregnancy are not self-reported should be provided.

Rationale:
We aim to work with measured data for all variables, except pre-pregnancy weight and maternal height, which can be self-reported (see items 2.6.2 and 2.6.3). Self-reported weights throughout pregnancy will not be acceptable. Weights abstracted from medical records will be eligible because they are likely to be measured, and measurement errors are small (8, 9). Moreover, in prospective studies from high-income countries, it is common to observe weights abstracted from medical records (10, 11).
2.6 General characteristics of the study

2.6.1 Number of weights during pregnancy

**Proposed criterion:**
We will select studies with 3 or more visits that collected data on weight and accompanying gestational ages (besides the initial weight – please see item 2.5.2). For administrative datasets, a median of at least 5 measurements is necessary. For both cases, at least one weight measurement in each trimester is required.

**TAG-GWG members’ comments:**
“The restriction of including only studies with at least one weight measurement per trimester, as mentioned in Box 1, Item 5.1, could significantly impact studies conducted in countries like Brazil, where many women begin prenatal care after the first trimester”.

“Is there a strong rationale for at least five weight data points in the observational studies? Could this be aspirational rather than required as again, this will severely limit the date sets? In our significant experience of modelling gestational weight gain trajectories, we were less rigid with these criteria and were able to include more data sets and still generate accurate, reproducible weight gain trajectory chance, by BMI category, and ethnicity”.

“Necessity for weight measurement in each of 3 trimesters will result in the exclusion of a large number of high-quality trials with relevant data available, particularly extending beyond pregnancy and birth”.

**GWG steering committee decision:**
The group acknowledges the benefits of the TAG’s proposal to include more studies. The eligibility criteria will be changed to accept studies with two weight measurements at different trimesters in addition to the initial weight. The group also discussed the ideal of having three or more weight measurements to construct trajectories, but this could limit the inclusion of studies from low- and middle-income countries.

**Final criterion:**
We will select studies and administrative datasets with 2 or more visits that collected measured weight and accompanying gestational ages (in addition to the initial weight - please see item 2.6.2). At least two weight measurements in different trimesters are required.

Rationale:
One data point is insufficient to describe an individual’s weight gain trajectory, and impossible to identify implausible values (outliers) in the trajectories (12). Datasets with a median of 5 measurements per individual are more suitable to accurately estimate weight gain centiles throughout pregnancy, especially the more extreme ones (e.g., the 3rd and the 97th percentiles), (7, 13). Including datasets with fewer measurements per individual can lead to curves capturing cross-sectional effects (10).

2.6.2 Initial weight

Proposed criterion:
With pre-pregnancy (initial) weight data:

- Ideal: measured before or close to (maximum 3 months before) the conception
- Acceptable: measured in the first trimester (up to 13 weeks)
- Acceptable: self-reported

TAG-GWG members’ comments:
“Self-reported weight and height is prone to substantial errors, especially in some LMIC settings. A similar comment for routine recordings in health centers, where the instruments are not always calibrated or standardized as per guidelines”.

“We have demonstrated in a cohort of >35000 pregnancies from highly diverse ethnic backgrounds that there is minimal error from preconception weight and that a relatively simple calculation can account for the small anticipated gestational weight gain in the first trimester”.

“The use of self-reported height and weight is limitations”.

“I think not correct to have first trimester as proxy for prepregnancy, because or perform sens. analysis”.
“It will be important to publish the validation study comparing self-reported and measured weight to demonstrate the potential for (or lack thereof) measurement bias based on the country/population context for self-reported weight”.

**GWG steering committee decision:**
Studies with pre-conception measured weight can be prioritized, but they are rare. Based on previous studies, the validity of using self-reported pre-pregnancy weight or first trimester measured weight to calculate pre-pregnancy BMI is recognized. However, the group will attempt to perform an agreement analysis when datasets are available to support the decision on the initial weight.

**Final criterion:**
With pre-pregnancy (initial) weight data:
- Ideal: measured before or close to (maximum 3 months before) the conception
- Acceptable: measured in the first trimester (up to 13 weeks)
- Acceptable: self-reported

**Rationale:**
An initial weight is needed to calculate pre-pregnancy BMI and GWG. One key decision is the choice of initial weight used to calculate both (14). The ideal would be a measured weight obtained close to conception. However, this information is rarely available, even in high-income countries. Thus, weights recorded in early pregnancy or self-reported pre-pregnancy weight are often considered a proxy of preconception weight (4).

The most recent GWG standards published by INTERGROWTH-21st considered initial weight as the value measured between 9-14 weeks (15). This has two significant implications. First, it does not account for any weight change during the first trimester (16), which would introduce error to this initial weight measurement, decreasing its value as a proxy of the weight at conception. Second, in many low- and middle-income countries, women start their prenatal care after 14 weeks, and a reliable measurement of weight in the window from 9 to 14 weeks is rarely available, which makes the adoption of the curves impractical.
There is ongoing debate in the literature about use of self-reported pre-pregnancy weight (17, 18). Recent results using researcher-collected and administrative data from Brazil have found that self-reported pre-pregnancy weight can be used to calculate BMI and GWG with minimal errors (17). In addition, analyses conducted with a pooled dataset from 56 low- and middle-income countries studies showed similar results (data not published, report available upon request). Nevertheless, a comprehensive discussion regarding the initial weight to calculate BMI and GWG is beyond the scope of this document. Thus, we propose using broader eligibility criteria at the study acquisition stage and considering the different scenarios after individual data are obtained.

Sensitivity analyses will be performed considering corrections for self-reported pre-pregnancy and measured first-trimester weights to obtain values closer to the weight at conception after the database is established. Thomas et al. (19) have proposed equations to correct self-reported pre-pregnancy weight for North American women that could be tested in the pooled database.

2.6.3 Maternal height

Proposed criterion:

With maternal height data:

- Ideal: measured in the first pregnancy trimester, with the measurement procedure used

- Acceptable: measured during pregnancy or after delivery, with the measurement procedure used and, if available, the date or gestational age at the measurement

- Acceptable: abstracted from medical records with the measurement procedure used and, if available, the date or gestational age at the measurement

- Acceptable: self-reported.

Some studies use multiple methods to measure the same construct. In these cases, the above pre-defined hierarchy will be considered to construct the pooled database.
TAG-GWG members’ comments:
“Self-reported weight and height is prone to substantial errors, especially in some LMIC settings. A similar comment for routine recordings in health centers, where the instruments are not always calibrated or standardized as per guidelines”.

“The use of self-reported height and weight is a limitation”.

“Timing of height not relevant?”.

GWG steering committee decision:
Despite the limitations of self-reported height, this measure has a smaller impact on pre-pregnancy BMI classification. Therefore, the group has opted to maintain the proposed criteria.

Final criterion:
With maternal height data:

- Ideal: measured in the first pregnancy trimester, with the measurement procedure used
- Acceptable: measured during pregnancy or after delivery, with the measurement procedure used and, if available, the date or gestational age at the measurement
- Acceptable: abstracted from medical records with the measurement procedure used and, if available, the date or gestational age at the measurement
- Acceptable: self-reported.

Some studies use multiple methods to measure the same construct. In these cases, the above pre-defined hierarchy will be considered to construct the pooled database.

Rationale:
Maternal height is necessary for BMI calculation (3) and the standards and recommendations will be BMI-specific (4, 5). We will consider a variety of maternal height data. Ideally, it should have been measured in the first pregnancy trimester because the biological changes that occur during pregnancy may affect this measurement. For example, the normal lordosis of pregnancy reduces maternal height as pregnancy progresses (3). However, differences in height measured in early compared to late pregnancy may be low and not substantially influence BMI.
calculation. Therefore, maternal height measured during pregnancy or after delivery, abstracted from medical records, or self-reported will also be accepted. Note that the date or gestational age at the measurement and the procedure used are required for all height measurements.

2.6.4 Gestational age

Proposed criterion:
With gestational age (or all the required data to calculate it) at the weight measurements and at birth

- Ideal: dates of weight measurements (and any other date of data collection), dates of ultrasounds, gestational age at ultrasound scans, and date of delivery
- Acceptable: gestational ages or dates of weight measurements (and any other gestational age/date of data collection) and gestational age at delivery estimated by an ultrasound scan performed before 24 weeks
- Acceptable: gestational ages or dates of weight measurements (and any other gestational age/date of data collection) and gestational age at delivery estimated by the last menstrual period (LMP) date confirmed by an ultrasound scan performed before 24 weeks
- Acceptable: dates of weight measurements (and any other date of data collection), date of delivery, and LMP date confirmed by an ultrasound scan performed before 24 weeks

(Some studies use multiple methods to measure the same construct. In these cases, the above pre-defined hierarchy will be considered to construct the pooled database)

TAG-GWG members’ comments:
“The method of determination of gestational age will elicit some controversy. Both methods (LMP dating and ultrasound) deserve inclusion with potential for later segregation. Ultrasound and LMP are circular arguments with no clear-cut unanimity. The USG uses foetal size as a surrogate of gestation, which under-estimates the gestation in settings with lower maternal and foetal anthropometry. There is a need to
define a tolerance level in gestational age between LMP and USG, if a confirmation by USG is considered mandatory”.

“I do agree with ultrasound measurement to estimate gestational age. But the definition of the gestational cut point (24 wk) needs to be clarified since the probability of introducing measurement error increases as gestational age increases, especially in women with obesity”.

“It is not clear how the date of the last menstruation period will be utilized. If confirmation of gestational age based on ultrasound scans performed before the 24th week is required, shouldn’t that be the preferred method? Additionally, what are the criteria for confirmation of the estimated date based on the date of LMP?”.

“Some countries still don’t have access to u/s. Suggest LMP self-reported is sufficient.”

“I am aware that some studies have shown self-reported LMP correlates highly with ultrasound measures”.

**GWG steering committee decision:**
The use of ultrasound-confirmed gestational ages and the 24-week cut-off are recommendations of the WHO and should be followed in this project. Therefore, this criterion will not be flexible.

**Final criterion:**
With gestational age (or all the required data to calculate it) at the weight measurements and at birth.

- Ideal: dates of weight measurements (and any other date of data collection), dates of ultrasounds, gestational age at ultrasound scans, and date of delivery
- Acceptable: gestational ages or dates of weight measurements (and any other gestational age/date of data collection) and gestational age at delivery estimated by an ultrasound scan performed before 24 weeks
- Acceptable: gestational ages or dates of weight measurements (and any other gestational age/date of data collection) and gestational age at delivery estimated by the last menstrual period (LMP) date confirmed by an ultrasound scan performed before 24 weeks
Acceptable: dates of weight measurements (and any other date of data collection), date of delivery, and LMP date confirmed by an ultrasound scan performed before 24 weeks

(Some studies use multiple methods to measure the same construct. In these cases, the above pre-defined hierarchy will be considered to construct the pooled database).

Rationale:
Gestational age is fundamental for developing the GWG standards. Ultrasound-based values are not reliable if the exam is performed after 24 weeks. For this reason, the WHO recommends one ultrasound scan before 24 weeks of gestation to estimate gestational age (20). In high-income countries, most ultrasound scans will occur in early pregnancy, but in many low- and middle-income countries, the exam can be performed after 24 weeks because access to ultrasound is more difficult. Nevertheless, it is necessary to establish this 24-week cut-off to work with reliable gestational age estimates.

Estimating gestational ages based on LMP dates may result in miscalculating gestational ages since individuals can have irregular periods and present bleeding even after conception (21, 22). Thus, only LMP dates confirmed by ultrasound scans will be accepted.

2.6.5 Missing data

Proposed criterion:
For research studies, no more than 20% of missing data listwise across the following key variables: maternal height, maternal age, pre-pregnancy weight, gestational weight, gestational age at weight measurements, date of delivery or gestational age at delivery, birth weight, and sex of the newborn.

TAG-GWG members’ comments:
“The figure of 20% missing data is far too high and will introduce significant risk of bias”.

“May lead to lots of missings; if women enroll after first trimester (not random group) they cannot be included because of the missings?”.

**GWG steering committee decision:**
Determining acceptable key variable missing data is essential for the construction of the GWG standards. The proposed criteria will remain, and the WHO team will also perform the identification of missing data after data acquisition.

**Final criterion:**
For research studies, no more than 20% of missing data listwise across the following key variables: maternal height, maternal age, pre-pregnancy weight, gestational weight, gestational age at weight measurements, date of delivery or gestational age at delivery, birth weight, and sex of the newborn. The WHO team will check this percentage after receiving the datasets.

**Rationale:**
Defining the percentage of missing data for the mandatory variables in research studies is a crucial decision because it is not desirable to include longitudinal studies with a high percentage of missing data in specific variables and loss to follow-up (attrition). Studies with missing data introduce concerns that individuals with missing data differ systematically from those with available data, particularly if the reason for the missing data is unclear.

### 2.6.6 Reproductive technologies

**Proposed criterion:**
With data regarding the use of assisted reproductive technologies (such as *in vitro* fertilization) (ideally) or not conducted exclusively among individuals who conceived through assisted reproductive technologies.

**TAG-GWG members’ comments:**
“Not clear to me what second part of sentence means”.

**GWG steering committee decision:**
The sentence was rephrased to improve clarity.
Final criterion:
With information regarding the use of assisted reproductive technologies (such as *in vitro* fertilization) (ideally) and not conducted exclusively among individuals who conceived through assisted reproductive technologies.

Rationale:
The use of assisted reproductive technologies indicates underlying maternal health issues (sub-fertility), so studies conducted only among those are not eligible for the development of the GWG standards.

2.6.7 Multiple pregnancies

Proposed criterion:
With information on singleton/twin pregnancies (ideally) or not conducted exclusively along non-singleton pregnancies.

TAG-GWG members’ comments:
“The text “singleton/twin pregnancies” may be changed to “singleton/multiple pregnancies”.

“Change the word “along” to among”.

GWG steering committee decision:
The sentence was rephrased to improve clarity.

Final criterion:
With information on singleton/multiple pregnancies (ideally) and not conducted exclusively among non-singleton pregnancies.

Rationale:
The GWG standards will be restricted to natural singleton pregnancies (not twins, triplets, etc.). GWG trajectories among individuals in non-singleton pregnancies can be systematically different from singleton pregnancies.
2.6.8 Maternal age

Proposed criterion:
With maternal age data and not conducted exclusively among adolescents (10 – 19 years old at delivery).

TAG-GWG members’ comments:
“The GWG is also likely to be different for pregnancies in older women (say above 35 years). Do we want to include data restricted to such pregnancies?”.

“I do not understand the adolescents remark if we stratify on age”.

GWG steering committee decision:
The construction of GWG standards for adolescents is beyond the scope of this project. The lower age limit for pregnant adolescents and the upper one for older pregnant women, where GWG does not differ significantly from adult pregnant women, are currently unknown. The WHO growth curve for adolescent girls is flat between 18 and 19.9 years of age, which could also mean that pregnant adolescents at 18 may follow a GWG pattern similar to that of pregnant adult women. Thus, studies conducted in individuals with 18.0 years of age will be eligible for inclusion in this project. A sensitivity analysis regarding the upper age limits will also be carried out. This approach will allow for a more comprehensive understanding of patterns of GWG in different age groups.

Final criterion:
With maternal age data and not conducted exclusively among adolescents (10.0 – 18.0 years old at delivery).

Rationale:
The GWG standards underlying sample will exclude individuals aged 10-18 years who are considered adolescents by the WHO (23). In the 2009 guidelines (4), the US Institute of Medicine did not have enough evidence to provide different GWG ranges for adolescents, but studies have shown a difference in GWG for this group (24, 25) and, more importantly, the effect of GWG on adverse outcomes differs by age. The development of GWG standards for adolescents is beyond the scope of this project.
2.6.9 Birth outcomes

Proposed criterion:
With data available on birth outcomes: sex of the child, birth weight, date of birth, or gestational age at birth – please see item 2.5.4, and the vital status of the newborn.

TAG-GWG members’ comments:
“Recording of progeny’s essential birth characteristics is undoubtedly important. However, the differences in the various available classifications’ categorization for SGA and LGA will need to be factored for at the analytic stage”.

“It may be worthwhile to add similar criteria for “Ideal” and “acceptable” data types with respect to birth outcome and postpartum maternal/child outcome. For example, other newborn outcomes, such as stillbirth, perinatal mortality, and neonatal mortality, and maternal outcomes, such as postpartum hemorrhage, would be ideal. Another important biological measure during pregnancy is hemoglobin concentration during pregnancy, so be able to exclude participants with anemia (as measured by hemoglobin concentration) from the GWG standards”.

“It would be helpful to elaborate on the following statement: “The newborn’s sex and birth weight are needed because it may be necessary to exclude pregnancies that result in the birth of a small- or large for-gestational-age infant.” Even in healthy pregnancies (e.g., INTERGROWTH-21st newborn size standards) where infants 90th percentiles by definition would be considered at SGA and LGA. Excluding these infants may potentially overestimate the optimal GWG ranges”.

“It would be ideal to have measures of other anthropometric outcomes”.

GWG steering committee decision:
These criteria will be important for the second phase of the project when determining the optimal weight gain ranges. However, the study needs to provide information on maternal and neonatal outcomes in the study-level eligibility criteria, as the aim of the project is to develop GWG standards using a sample that represents healthy pregnancies, also resulting in healthy newborns. Other outcomes, such as those related to anaemia, neonatal mortality, etc., are covered in the list of important variables described in Annex 2 but are not considered mandatory. The reference to define
outcomes such as small- and large-for-gestational-age will be selected in future TAG-GWG working group discussions.

**Final criterion:**
With data available on birth outcomes: sex of the child, birth weight, date of birth, or gestational age at birth, and the vital status of the newborn.

**Rationale:**
This information is necessary to apply the eligibility criteria for individuals to be included in the standards underlying sample. The date of delivery may be required to help derive the gestational age at the time of weight measurement (item 2.6.4). The newborn’s sex and birth weight are needed because it may be necessary to exclude pregnancies that result in the birth of a small- or large-for-gestational-age infant. The criteria to be used to define SGA or LGA will be decided in the discussions of the TAG-GWG working groups.

**2.6.10 Maternal health conditions**

**Proposed criterion:**
Ideally, with data available on maternal pre-existing health conditions (at least hypertension and diabetes) and complications during pregnancy (at least hypertensive pregnancy disorders and gestational diabetes).

**TAG-GWG members’ comments:**
“The argument for recording information on hypertensive disorders of pregnancy and GDM is sound. However, there is also a need to inform clinical practice about GWG ranges in women with these relatively common disorders of pregnancy”.

“This is challenging as in many high-risk populations as prevalence of GDM is between 20 and 30%. These are often the women who have the highest rate of gestational weight gain before this time. RCTs do not exclude these women from the data sets. It is acknowledged there is a treatment affect for GDM but probably not for hypertensive disorders”.

“There is no indication of the definitions to be used relating to hypertension in pregnancy and GDM. These vary considerably by country and are not necessarily
comparable across studies; no indication if these outcomes are to be self-reported or if they are to be validated and how this will occur”.

**GWG steering committee decision:**
This criterion is not mandatory for a study to be included in the pooled database. There are challenges in assessing these variables, especially in studies conducted in low- and middle-income countries. Transforming those into mandatory will restrict the pool of available studies. It is also impractical to standardize the criterion to define those conditions. Thus, these variables will remain as “ideal” in the study-level eligibility criteria and will continue to be considered in the list of important (but not mandatory) variables.

**Final criterion:**
Studies not conducted exclusively among women with hypertensive disorders (before or during pregnancy) or diabetes mellitus/gestational diabetes (GDM). It is desirable to provide information on maternal pre-existing health conditions (at least hypertension and diabetes) and complications during pregnancy (at least hypertensive pregnancy disorders and gestational diabetes).

**Rationale:**
This type of data is necessary to apply the eligibility criteria for developing the standards. Removing individuals who presented those complications during pregnancy from the charts is crucial since they can be affected by and affect GWG. There is a known reverse causation between GWG, hypertensive disorders, and gestational diabetes. i.e., after the diagnosis of those conditions, individuals tend to change their GWG trajectories (26).

**2.6.11 Postpartum data**

**Proposed criterion:**
With postpartum information on the mothers and children (at least one measurement of maternal and/or children’s weight at or beyond six months postpartum and the dates of those measurements).
TAG-GWG members’ comments:
“In many perinatal databases, only weight at 6-8 wks postpartum is available. In these cases, should not inter-pregnancy weight change be allowed?”.

“In 2.5.11: I believe this is "ideally" with postpartum information...”.

“This is likely to severely limit the date set - could I suggest this is preferable but not essential, as long-term outcomes are still a separate question to pregnancy outcomes, which can still be answered with a dataset that does not include postpartum data”.

“Measurement of weight 6 months beyond birth in woman / child – again there are many studies that have this data, which may not have the required 3 data points in pregnancy, which will be excluded”.

GWG steering committee decision:
Postpartum information is not a mandatory criterion for a study to be included. It is an important information to be requested, given its relevance for the construction of GWG standards.

Final criterion:
With postpartum information on the mothers and children (at least one measurement of maternal and/or children’s weight at or beyond six months postpartum and the dates of those measurements).

Rationale:
This information is necessary to apply the eligibility criteria for individuals to be included in the charts. When developing GWG standards, long-term outcomes, such as excess postpartum weight retention and child obesity, should be considered in the eligibility criteria for individuals. Excess postpartum weight retention is also the major maternal outcome that happens within a short period after birth because other outcomes, such as metabolic syndrome or type 2 diabetes, may not appear for years.
References


Annex

Annex 1. List of **mandatory variables** to be requested in each dataset eligible for the pooled database.

<table>
<thead>
<tr>
<th>NAME OF THE VARIABLE</th>
<th>DESCRIPTION</th>
<th>TYPE</th>
<th>OBSERVATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-pregnancy weight</td>
<td>in kg, measured before/close to the conception or self-reported or measured in the first trimester (up to 13+0 weeks), preferably with an accompanying variable describing how it was obtained</td>
<td>Continuous, up to 2 decimals</td>
<td>Pre-pregnancy weight measurement method: type of assessment used to measure maternal weight (i.e., measured by study staff, maternal report, based on chart review, or multiple methods)</td>
</tr>
<tr>
<td>Maternal height</td>
<td>in cm, measured in the first pregnancy trimester, or measured during pregnancy or after delivery, with the date or gestational age at the measurement or abstracted from medical records (if available, include the date or gestational age at the measurement) or self-reported, preferably with an accompanying variable describing how it was obtained</td>
<td>Continuous, no decimals</td>
<td></td>
</tr>
<tr>
<td>Gestational weight</td>
<td>in kg, measured during pregnancy, and at least one measurement in each trimester. All the available weight measurements are welcome</td>
<td>Continuous, up to 2 decimals</td>
<td>Weight measurement method: type of assessment used to measure maternal weight (i.e., measured by study staff, maternal report, based on chart review, or multiple methods)</td>
</tr>
<tr>
<td>NAME OF THE VARIABLE</td>
<td>DESCRIPTION</td>
<td>TYPE</td>
<td>OBSERVATIONS</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------</td>
<td>------</td>
<td>--------------</td>
</tr>
</tbody>
</table>
| Gestational age      | *Ideal:* dates of weight measurements (and any other date of data collection), dates of ultrasounds, gestational age at ultrasounds, and date of delivery  
*Acceptable:* dates of weight measurements (and any other date of data collection), gestational age at birth/delivery estimated by ultrasound performed before 24+0 weeks  
*Acceptable:* dates of weight measurements (and any other date of data collection) and gestational age at birth estimated by the last menstrual period (LMP) date confirmed by an ultrasound performed before 24+0 weeks  
*Acceptable:* dates of weight measurements (and any other date of data collection) and LMP date confirmed by an ultrasound performed before 24+0 weeks | Dates in DD/MM/YYYY format | If gestational ages already calculated are provided (according to the acceptable rules), the measurement must be in days (integer variable) |
| Maternal age         | *Ideal:* maternal date of birth and date of conception  
*Acceptable:* In years, at conception | Dates in DD/MM/YYYY format  
Continuous, up to 1 decimal | |
<table>
<thead>
<tr>
<th>NAME OF THE VARIABLE</th>
<th>DESCRIPTION</th>
<th>TYPE</th>
<th>OBSERVATIONS</th>
</tr>
</thead>
</table>
| Date of delivery or gestational age at delivery | *Ideal:* dates of weight measurements (and any other date of data collection), dates of ultrasounds, gestational age at ultrasounds, and date of delivery  
*Acceptable:* dates of weight measurements (and any other date of data collection), gestational age at birth/delivery estimated by ultrasound performed before 24+0 weeks  
*Acceptable:* dates of weight measurements (and any other date of data collection) and gestational age at birth estimated by the last menstrual period (LMP) date confirmed by an ultrasound performed before 24+0 weeks  
*Acceptable:* dates of weight measurements (and any other date of data collection) and LMP date confirmed by an ultrasound performed before 24+0 weeks | Dates in DD/MM/YYYY format | If gestational age already calculated is provided (according to the acceptable rules), the measurement must be in days (integer variable) |
| Birth weight | In grams, measured at the study or obtained from medical records, preferably with an accompanying variable describing how it was obtained | Continuous, no decimals |  |
| Sex of the newborn | Male/female/unknown, evaluated by the study researcher or obtained from medical records, preferably with an accompanying variable describing how it was obtained | Categorical |  |
Annex 2. List of important variables to be requested in each dataset eligible for the pooled database.

<table>
<thead>
<tr>
<th>NAME OF THE VARIABLE</th>
<th>DESCRIPTION</th>
<th>TYPE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother ID</td>
<td></td>
<td>char</td>
</tr>
<tr>
<td>Country</td>
<td>Country where the data collection occurred</td>
<td>char</td>
</tr>
<tr>
<td>City</td>
<td>City where the data collection occurred</td>
<td>char</td>
</tr>
<tr>
<td>Location</td>
<td>Whether the data was collected in an urban/rural context</td>
<td>char</td>
</tr>
<tr>
<td>Study type</td>
<td>Indication of prospective cohort, retrospective cohort/administrative data, clinical trial</td>
<td>char</td>
</tr>
<tr>
<td>Intervention assignment</td>
<td>If an intervention study, whether the participant was assigned as intervention or control arm. Please provide details if control arms received placebo or standard care</td>
<td>char</td>
</tr>
<tr>
<td>Date of study enrolment</td>
<td>Date of the study enrolment or baseline visit</td>
<td>date in DD/MM/YYYY format</td>
</tr>
<tr>
<td>Visit date</td>
<td>Date of follow-up visit</td>
<td>date in DD/MM/YYYY format</td>
</tr>
<tr>
<td><strong>Socio-demographic variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternal race/ethnicity</td>
<td>Race/ethnicity of the mother</td>
<td>char</td>
</tr>
<tr>
<td>Maternal education (years)</td>
<td>Number of maternal schooling years</td>
<td>integer</td>
</tr>
<tr>
<td>Maternal occupation</td>
<td>Type of occupation that the mother was engaged in prior to or during pregnancy</td>
<td>char</td>
</tr>
<tr>
<td>Wealth index</td>
<td>An aggregate index of wealth, typically based on characteristics of the household. Description for each study should be sent.</td>
<td>float, with at least one decimal</td>
</tr>
<tr>
<td>Family income (monthly)</td>
<td>Monthly family income</td>
<td>float, with at least one decimal</td>
</tr>
<tr>
<td>Family Income Currency Unit</td>
<td>Unit for Monthly family income for ex. 'Taka', 'Rupees', 'Dollar' etc.</td>
<td>char</td>
</tr>
<tr>
<td>Marital status</td>
<td>Maternal marital status during pregnancy</td>
<td>char</td>
</tr>
<tr>
<td>Partner’s education</td>
<td>Number of the partner’s schooling years</td>
<td>integer</td>
</tr>
<tr>
<td>Partner’s occupation</td>
<td>Type of occupation that the partner was engaged in prior to or during pregnancy</td>
<td>char</td>
</tr>
<tr>
<td>Family violence</td>
<td>Please inform the instrument used</td>
<td>integer</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>-----------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Social support during pregnancy</td>
<td>Please inform the instrument used</td>
<td>integer</td>
</tr>
</tbody>
</table>

### Maternal variables

<table>
<thead>
<tr>
<th>Date of last menstrual period</th>
<th>Date of the last menstrual period</th>
<th>date in DD/MM/YYYY format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of delivery</td>
<td>Date when the infant was born</td>
<td>date in DD/MM/YYYY format</td>
</tr>
<tr>
<td>Type of delivery</td>
<td>Whether the delivery was spontaneous vaginal delivery, assisted, or caesarean</td>
<td>char</td>
</tr>
<tr>
<td>Type of C-section</td>
<td>Emergency vs. elective</td>
<td>integer</td>
</tr>
<tr>
<td>Parity</td>
<td>No. of previous births</td>
<td>integer</td>
</tr>
<tr>
<td>Gravidity</td>
<td>Number of pregnancies including the current pregnancy</td>
<td>integer</td>
</tr>
<tr>
<td>Smoking status (Pre-pregnancy)</td>
<td>Maternal smoking status before pregnancy (previous year)</td>
<td>integer</td>
</tr>
<tr>
<td>Smoking amount (Pre-pregnancy)</td>
<td>Maternal smoking amount before pregnancy</td>
<td>char</td>
</tr>
<tr>
<td>Smoking status during pregnancy</td>
<td>Maternal smoking status during pregnancy - if available, separated by trimester</td>
<td>integer</td>
</tr>
<tr>
<td>Smoking amount during pregnancy</td>
<td>Maternal smoking amount during pregnancy - if available, separated by trimester</td>
<td>char</td>
</tr>
<tr>
<td>Alcohol status during pregnancy</td>
<td>Maternal alcohol intake during pregnancy - if available, separated by trimester</td>
<td>integer</td>
</tr>
<tr>
<td>Alcohol amount during pregnancy</td>
<td>Maternal alcohol amount during pregnancy - if available, separated by trimester</td>
<td>char</td>
</tr>
<tr>
<td>Physical activity during pregnancy</td>
<td>Maternal physical activity during pregnancy - if available, separated by trimester</td>
<td>integer</td>
</tr>
<tr>
<td>Physical activity frequency during pregnancy</td>
<td>Maternal physical activity frequency during pregnancy - if available, separated by trimester</td>
<td>char</td>
</tr>
<tr>
<td>Iron-Folic Acid supplementation</td>
<td>Did the participant receive IFA supplementation during pregnancy?</td>
<td>integer</td>
</tr>
<tr>
<td>IFA supplementation duration (Days)</td>
<td>Number of days the participant consumed IFA</td>
<td>integer</td>
</tr>
<tr>
<td>Maternal haemoglobin (g/dL)</td>
<td>Maternal haemoglobin status</td>
<td>float, with at least one decimal</td>
</tr>
<tr>
<td>Date of maternal haemoglobin collection</td>
<td>Date of the maternal haemoglobin exam</td>
<td>date in DD/MM/YYYY format</td>
</tr>
<tr>
<td>History of spontaneous foetal loss</td>
<td>Miscarriage and stillbirth (not abortion)</td>
<td>integer</td>
</tr>
<tr>
<td>History of miscarriage</td>
<td>Whether the mother has previously had a miscarriage, defined as the spontaneous loss of a foetus prior to 20 weeks gestation</td>
<td>integer</td>
</tr>
<tr>
<td>History of preterm birth</td>
<td>Whether the mother has had a previous preterm birth (defined as birth &lt;37+0 weeks GA)</td>
<td>integer</td>
</tr>
<tr>
<td>History of stillbirth</td>
<td>Whether the mother has had a previous stillbirth and, if available, the gestational age of this occurrence.</td>
<td>integer</td>
</tr>
<tr>
<td>History of induced abortion</td>
<td>Whether the mother has had a previous induced abortion</td>
<td>integer</td>
</tr>
</tbody>
</table>

**Pre-existing maternal conditions**

| Maternal hypertension | Pre-existing hypertension (SBP ≥ 140 OR DBP ≥ 90) or reported as Hypertensive, or on medication to control blood pressure | integer |
| Maternal diabetes | Pre-existing diabetes mellitus | integer |
| Maternal thyroid illness | Pre-existing thyroid disorders | integer |
| Maternal HIV status | Maternal HIV status | integer |
| Maternal eating disorders | Pre-existing eating disorders and instruments used to assess those | integer |
| Maternal bariatric surgery | Whether the mother underwent bariatric surgery and the date of the procedure | integer |

**Complications during the current pregnancy**

<p>| Maternal gestational diabetes | Maternal clinically diagnosed with GDM, definition and parameters used to characterize GDM (e.g., glucose tolerance test) | integer |
| GDM Diagnosis Date | | date in DD/MM/YYYY format |
| Maternal systolic blood pressure (mmHg) | Systolic blood pressure during pregnancy (average of two readings) | float, with at least one decimal |
| Maternal diastolic blood pressure (mmHg) | Diastolic blood pressure during pregnancy (average of two readings) | float, with at least one decimal |
| Date(s) of blood pressure collection | | date in DD/MM/YYYY format |
| Maternal proteinuria | Proteinuria during pregnancy as measured by dipstick test or any other method. | integer |</p>
<table>
<thead>
<tr>
<th>Maternal Preeclampsia</th>
<th>Maternal clinically diagnosed with pre-eclampsia (HBP and protein in urine), define definition used</th>
<th>integer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preeclampsia Diagnosis Date</td>
<td>date in DD/MM/YYYY format</td>
<td></td>
</tr>
<tr>
<td>Maternal Hypertension</td>
<td>Maternal hypertension during pregnancy based on SBP and DBP</td>
<td>integer</td>
</tr>
<tr>
<td>Maternal Hypertension Diagnosis Date</td>
<td>date in DD/MM/YYYY format</td>
<td></td>
</tr>
<tr>
<td>Chronic Hypertension</td>
<td>Maternal hypertension before 20 weeks based on SBP &gt;=140 or DBP &gt;=90 or on the use of medication to control blood pressure</td>
<td>integer</td>
</tr>
<tr>
<td>Maternal depression in pregnancy</td>
<td>Please inform the instrument used</td>
<td>integer</td>
</tr>
<tr>
<td>Maternal depression Diagnosis Date</td>
<td>date in DD/MM/YYYY format</td>
<td></td>
</tr>
<tr>
<td>Maternal stress during pregnancy</td>
<td>Please inform the instrument used</td>
<td>integer</td>
</tr>
<tr>
<td>Maternal quality of sleep during pregnancy</td>
<td>Please inform the instrument used</td>
<td>integer</td>
</tr>
<tr>
<td>Maternal hookworm infection (<em>Necator Americanus</em>)</td>
<td>Egg count test result of ≥ 1</td>
<td>integer</td>
</tr>
<tr>
<td><em>Ascaris</em> sp. Infection</td>
<td>Egg count test result of ≥ 1</td>
<td>integer</td>
</tr>
<tr>
<td><em>Trichurus</em> sp. Infection</td>
<td>Egg count test result of ≥ 1</td>
<td>integer</td>
</tr>
<tr>
<td>Maternal malaria</td>
<td>Maternal malaria during pregnancy, define criteria use</td>
<td>integer</td>
</tr>
<tr>
<td>Maternal malaria diagnosis method</td>
<td>Method used to diagnose maternal malaria during pregnancy</td>
<td>char</td>
</tr>
<tr>
<td>Maternal malaria diagnosis date</td>
<td>date in DD/MM/YYYY format</td>
<td></td>
</tr>
<tr>
<td>Maternal diarrhoea</td>
<td>Maternal experience with diarrhoea during pregnancy, define criteria used</td>
<td>integer</td>
</tr>
<tr>
<td>Maternal nausea/vomiting</td>
<td>Maternal nausea/vomiting, defined measurement window and criteria used</td>
<td>integer</td>
</tr>
<tr>
<td>Other complications and intercurrences</td>
<td>Other complications such as hyperemesis gravidarum, anorexia, bulimia, with the instrument used to assess those</td>
<td>integer</td>
</tr>
</tbody>
</table>

**Nutrition-related variables**

<p>| Household food security during pregnancy | Please inform the instrument used - if available, separated by trimester | integer |</p>
<table>
<thead>
<tr>
<th>Dietary diversity during pregnancy</th>
<th>Variable definitions possible.</th>
<th>integer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary intake during pregnancy per day</td>
<td>As assessed by 24-hour recall or food frequency questionnaire - please inform instrument used and if available, separate by trimester</td>
<td>integer</td>
</tr>
<tr>
<td>Quality of the diet</td>
<td>Please inform the instrument used - if available, separated by trimester; the gestational age/date of evaluation</td>
<td>integer</td>
</tr>
<tr>
<td>Dietary counselling during pregnancy</td>
<td>Please inform whether the individual received any type of dietary counselling during pregnancy, the type and frequency of counselling received</td>
<td>integer</td>
</tr>
<tr>
<td><strong>Perinatal outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vital status</td>
<td>Categorical variable that identifies whether the pregnancy under observation resulted in live birth/stillbirth</td>
<td>integer</td>
</tr>
<tr>
<td>Singleton/twin birth</td>
<td>Whether pregnancy resulted in single or multiple births</td>
<td>integer</td>
</tr>
<tr>
<td>Neonatal death</td>
<td>Death within the first 28 days from birth</td>
<td>integer</td>
</tr>
<tr>
<td>Physiological Foetal Loss</td>
<td></td>
<td>integer</td>
</tr>
<tr>
<td>Miscarriage</td>
<td>Spontaneous loss of a foetus prior to 20 weeks gestation</td>
<td>integer</td>
</tr>
<tr>
<td>Abortion</td>
<td>Induced abortion</td>
<td>integer</td>
</tr>
<tr>
<td><strong>Postnatal variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length/height (cm)</td>
<td>Length or height of the infant at follow-up</td>
<td>float, with at least one decimal</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>Weight of the infant at follow-up</td>
<td>float, with at least one decimal</td>
</tr>
<tr>
<td>Date of the follow-up for the infant</td>
<td></td>
<td>date in DD/MM/YYYY format</td>
</tr>
<tr>
<td>Maternal weight (kg)</td>
<td>Weight of the mother at follow-up</td>
<td>float, with at least one decimal</td>
</tr>
<tr>
<td>Date of the follow-up for the mother</td>
<td></td>
<td>date in DD/MM/YYYY format</td>
</tr>
</tbody>
</table>