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Protocol for the development of the WHO gestational weight gain charts

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ABSTRACT

Introduction Gestational weight gain (GWG) is an important indicator of maternal nutrition to be monitored during pregnancy. However, there is no evidence-based tool that can be used to monitor it across all geographic locations and pre-pregnancy body mass index (BMI) categories. The WHO is undertaking a project to develop GWG charts by pre-pregnancy BMI category, and to identify GWG ranges associated with the lowest risks of adverse maternal and infant outcomes. This protocol describes all the steps that will be used to accomplish the development of these GWG charts.

Methods and analysis This project will involve the analysis of individual participant data (researcher-collected or administrative). To identify eligible datasets with GWG data, a literature review will be conducted and a global call for data will be launched by the WHO. Eligible individual datasets obtained from multiple sources will be harmonised into a pooled database. The database will undergo steps of cleaning, data quality assessment and application of individual-level inclusion criteria. Heterogeneity of maternal weight and GWG will be assessed to verify the possibility of combining datasets from multiple sources and regions into a single database. Generalized Additive Models for Location, Scale and Shape will be applied for the construction of the centile curves. Diagnostic measures, internal and external validation procedures will also be performed.

Ethics and dissemination This project will include an analysis of existing study de-identified data. To be included in the pooled database, each included study should have received ethics approvals from relevant committees. Manuscripts will be submitted to open-access journals and a WHO document will be published, including the GWG charts and cut-offs for application in antenatal care.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Some of the unique aspects of this project are the diversity of populations to be used, including global data from low-, middle- and high-income countries, the possibility to stratify the charts according to body mass index categories, and the use of longitudinal data.

⇒ The analytical approaches to be used include the recommended methods to construct centile curves and to run diagnostic and validation analyses. Several steps to ensure the high quality of the harmonised data will also be taken.

⇒ This project will rely on the use of secondary data and include administrative datasets. These data were not collected with the aim of creating gestational weight gain (GWG) curves and may be prone to measurement error or lack important variables for the study. Some of these datasets may also be small and not representative of the country or region. We will take the necessary measures to ensure the balance between the GWG data across regions, such as the use of sampling weights in the analysis.

⇒ The curves will be restricted to adults with singleton pregnancies, mainly because of an anticipated lack of global data for other groups (non-singleton, adolescents). Nevertheless, these curves will address an important gap in the field, which is the lack of a global tool for GWG monitoring that is applicable to most pregnancies worldwide.

INTRODUCTION

Pregnancy is a unique period in the lifecycle for implementing interventions to optimise longer-term maternal and child health. Pregnant women's contact with the healthcare system and strong motivation to optimise their health make pregnancy 'an especially powerful teachable moment' for many lifestyle factors, including healthy eating and physical activity.[1] Among these factors, maternal weight and gestational weight gain (GWG) are particularly important indicators of maternal nutritional status, as deviations in GWG are linked to adverse maternal and infant outcomes.[2] Despite the recognised importance of monitoring GWG, there are currently no internationally accepted charts

for tracking this measure and no global recommendations for optimal weight gain.

The most common GWG guidelines adopted worldwide are the 2009 Institute of Medicine (IOM).[3 4] However, these guidelines were created for US pregnant women, and their generalisability to other settings is uncertain.[5] More importantly, many countries have no clear policy on monitoring weight during pregnancy.[4] The IOM guidelines were developed primarily from the findings of observational studies from high-income countries (HICs).[5] Although based on the best available evidence at that time, the guidelines nevertheless had several limitations. For example, there was insufficient evidence on the potential effect of weight gain on the development of gestational diabetes mellitus, pre-eclampsia, preterm birth and longer-term maternal and child health outcomes.[5] Therefore, questions have been raised about the comprehensiveness of these guidelines and their generalisability to populations from low- and middle-income countries (LMICs).

The INTERGROWTH-21st project provided weight gain charts during pregnancy in a healthy population from diverse regions, including LMICs and HICs.[6] These charts, however, are only available for pregnant women with normal-weight body mass index (BMI, 18.5–24.9 kg/m^2) in the first trimester. Because pregnant women with underweight, overweight and obesity were excluded from the INTERGROWTH-21st cohort, the chart does not apply to nearly 50% of pregnant women globally.[7] Further, it does not allow the assessment of weight gain in the first pregnancy trimester (as the chart starts at the 14th gestational week) and does not specify which weight-gain ranges are associated with the lowest risk of adverse pregnancy outcomes. Other GWG charts have been published addressing some of these limitations, but these charts were primarily derived from populations in HICs.[8–11] Like the IOM guidelines, their generalisability to most LMICs may be limited.

In response to the lack of an evidence-based tool for monitoring GWG that can be used across all geographic locations and pre-pregnancy BMI categories, the WHO is conducting a project to develop GWG standards. The project will involve two phases: *Phase 1.* Development of global GWG charts according to gestational age and stratified by pre-pregnancy BMI; *Phase 2.* Identification of GWG ranges on the charts associated with the lowest risks of adverse maternal and infant outcomes. At the end of these phases, GWG standards as per the WHO definition will be created. A technical advisory group was formed to support this task after an open call for membership applications. This group is acting as an advisory body to the WHO in both project phases. This protocol describes all the steps necessary to accomplish phase 1 after discussions with the TAG members and within the project Steering Committee.

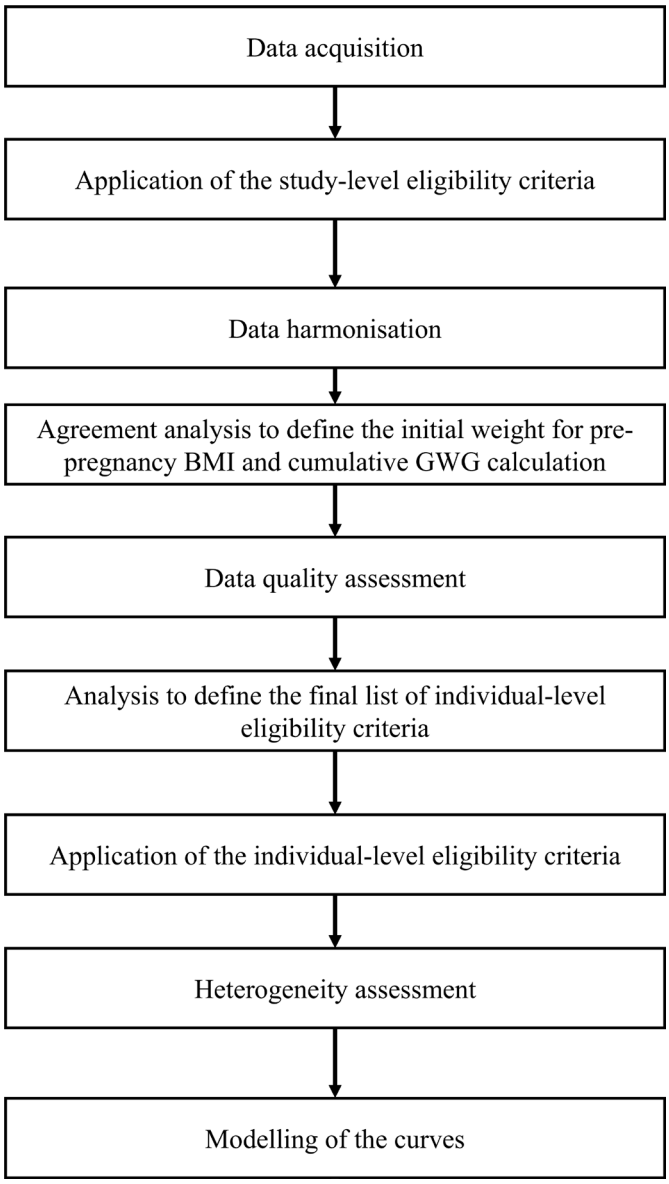

Figure 1 Workflow for phase 1: development of the gestational weight gain charts. BMI, body mass index; GWG, gestational weight gain.

METHODS AND ANALYSIS

The complete flow of steps for phase 1 is shown in figure 1. Each of the steps is described in detail in the following sections.

Data acquisition

This project will involve a secondary analysis of existing data. These data may be researcher-collected or administrative data (ie, data collected through clinical/public healthcare encounters).

A global call for data will be issued to acquire data for Phase 1. The aim of the call will be to obtain datasets containing relevant GWG data from various geographical regions and sources (ie, published and unpublished studies and routine/administrative systems). The call will include an online screening form to obtain information on the study eligibility criteria and principal investigators

(PIs). For studies that meet eligibility criteria, the WHO secretariat will contact the PIs and initiate the process of signing data sharing agreements and obtaining the datasets.

In addition to the global call for data, the team will initiate a process to identify studies with GWG data based on several supplementary sources. First, the team will use the results of a systematic literature review described in Liu *et al*.[12] This review aimed to identify studies with GWG data undertaken in LMICs. Several studies identified in this review were shared with the Gates Foundation (GF) in their data repository. The WHO team will work with the GF to obtain access to those datasets. For the datasets not shared with the GF, the team will contact the PIs and invite them to participate. In addition, studies included in the list of references from four systematic reviews: Goldstein *et al*,[2 13] Rogozińska *et al*[14] and Patel *et al*[15] will also be considered. The list of studies from the Lifecycle project used to create international GWG charts[11] will also be incorporated into these searches. The PIs from eligible studies will also be invited to contribute data to the project.

Study-level eligibility criteria

To develop the charts, it is necessary to first define study-level eligibility criteria, which are the eligibility criteria for the inclusion of datasets into the pooled database. The study-level eligibility criteria were defined by considering characteristics that would allow us to obtain a sample of pregnant individuals with a low risk of adverse outcomes for mothers and infants. These characteristics included information on maternal health before and during pregnancy, at delivery and in the postpartum period, and child health during pregnancy, delivery and postpartum. The defined study-level eligibility criteria are listed in box 1.

Data harmonisation

The individual datasets obtained from these multiple sources will be harmonised into a pooled database. The overall tasks involved in the data harmonisation process will include, but are not limited to, the following activities:

1. Data programming (extraction, transformation and loading procedures) to create datasets from raw data in a machine-readable format.
2. Data completeness check with the revision of the incoming data (completeness in terms of documentation and variables needed).
3. Data monitoring after the data are transferred to the designated repository, with the programming group working with the contributors to resolve data-related queries.
4. Programming activities, including creating programming practices, working with analysts on creating and modifying specifications, data reproducibility, code generation and review.
5. Data corrections and finalisation, which include working with the analysts to make modifications and corrections where needed.

Box 1 Eligibility criteria for a dataset to be included in the pooled database to develop the gestational weight gain charts

1. Ethics committee/board approval
   Data collected after a research ethics committee/board approval or waived of approval (administrative data)
2. Year of data collection
   Data collected during or after 1990
3. Study design
   Observational studies, including prospective and retrospective cohorts; administrative/clinical datasets; and control arms of randomised clinical trials receiving placebo, standard care or no interventions at all
4. Sample size
   Minimum 200 subjects
5. Type of data
   Individual participant data collected by the research team following a standardised protocol and/or collected through clinical/public healthcare encounters
6. General characteristics of the studies
   - 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
   - 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+0 weeks).
     - *Acceptable*: self-reported.
   - 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
   - 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 of 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
   - For research studies, no more than 20% of listwise missing data across the following key variables: maternal height, maternal

Continued

Box 1 Continued

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
- With information regarding the use of assisted reproductive technologies (such as in vitro fertilisation) (ideally) and not conducted exclusively among women who conceived through assisted reproductive technologies
- With information on singleton/multiple pregnancies and not conducted exclusively among non-singleton pregnancies
- With maternal age data and not conducted exclusively among adolescents (10.0–18.0 years old at conception)
- 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
- 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)
- Ideally, with at least one measurement of maternal and/or child weight at or beyond 6 months post partum and the dates of those measurements

The complete flow for the data harmonisation process is shown in figure 2. After the data sharing agreement is signed for and on behalf of the PI's institution and the WHO, the datasets will be shared in a secure environment. Each dataset will be checked to confirm that all necessary variables were included. The PIs may be contacted with follow-up questions about their datasets. After this process, metadata from each study will be collected and shared in a unique file to facilitate future reviews, and the dataset will go into the harmonisation phase.

As part of the harmonisation process, steps of checking and cleaning will be applied to all datasets. Data checking will include, but is not limited to, the verification of the sequence of date variables, the existence of inconsistencies and gross entry errors in variables (eg, values 9999), and the utilisation of different measurement units (eg, weight in kilograms vs pounds). At the end of the data checking steps, all the files for each dataset will be verified by one or more members of the WHO team.

Two key variables to be derived in the harmonisation process are gestational age (in days) and GWG. For gestational age, the variables will be standardised in each dataset before the data are combined into a unique database. This process will involve first checking the plausibility and order of dates of prenatal care visits and the methods available in each dataset for gestational age calculation (eg, ultrasound data, date of the last menstrual period (LMP)). The WHO recommends using an ultrasound before 24 weeks of pregnancy to estimate gestational age accurately,[16] thus, women without an estimate of gestational age confirmed by ultrasound <24 weeks will be excluded. When more than one source of gestational age is available, an algorithm for gestational age calculation will be considered.[17] In addition, when calculating gestational ages, a variable indicating the origin of the measurement (ultrasound or LMP) will also be created, to allow for sensitivity analysis in the future.

Cumulative GWG (ie, GWG calculated as the difference between the weight in each prenatal care visit and pre-pregnancy/early pregnancy weight) will be the indicator used in the development of the charts. In such cases, it is important to define the baseline weight (weight at

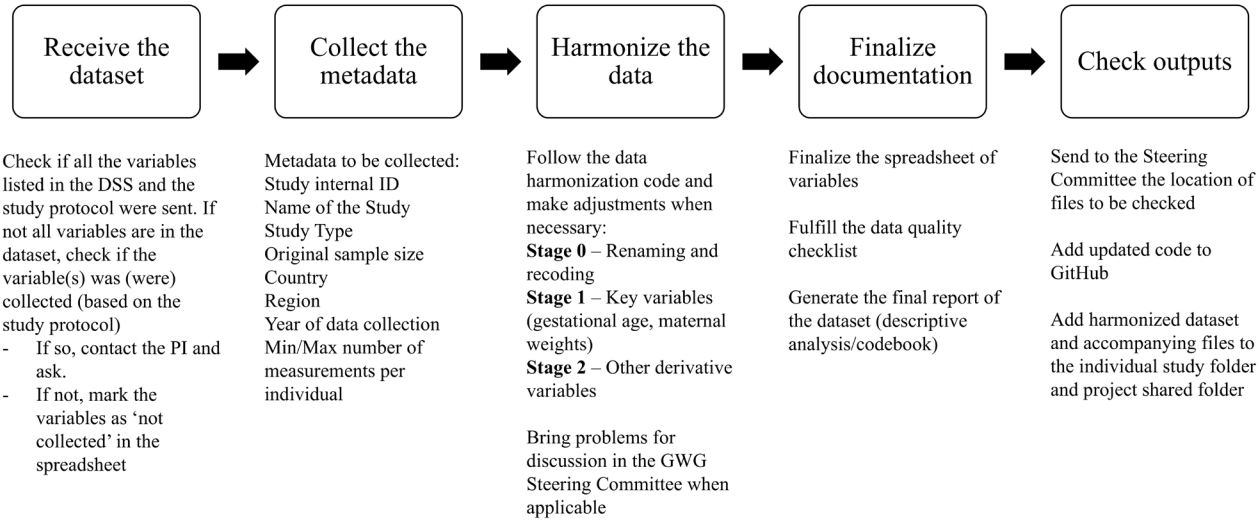

Figure 2 Data harmonisation workflow. The final report of each dataset will include a descriptive analysis of all variables available in the dataset. For continuous variables, histograms, boxplots, mean, median, SD, quartiles, and asymmetry and kurtosis measurements will be presented. For categorical variables, bar graphs will be constructed. DSS, data sharing standards; GWG, gestational weight gain; ID, identification; PI, principal investigator.

conception) to calculate GWG and the pre-pregnancy BMI. Several types of baseline weight measurements are available (ie, measured pre-pregnancy weight, self-reported pre-pregnancy weight and first measured weight in early pregnancy). Several scenarios will be tested to establish the feasibility of calculating baseline weights using pre-pregnancy weight from multiple sources and to decide the range of dates in the first trimester at which measured weight can be considered a proxy for weight at conception (without meaningful error introduced by GWG).

Before considering any corrections to pre-pregnancy/first-trimester weight, an agreement analysis between weights will be performed. The following comparisons will be performed:

a. For studies with measured pre-pregnancy weight, weights measured 3 months prior to conception will be compared with measured first-trimester weight (up to 6, 8, 9, 13 weeks). As a secondary analysis, weights measured 6 months prior to conception will also be considered.
b. Self-reported weight vs measured first-trimester weight (up to 6, 8, 9, 13 weeks).

The variables to be used in this analysis are weights (and accompanying gestational ages), differences between weights, BMI and BMI classification. The analysis will be stratified by BMI category using the WHO cut-offs,[18] countries, education/income and maternal age. If possible, a comparison between women with weights at 6 and 3 months prior to conception will be conducted, and the time when the self-reported weight was obtained will be considered.

The agreement between continuous and categorical measurements will be considered using predefined statistical techniques. Bland and Altman plots[19] will be used to perform the agreement analysis between continuous variables (weights and BMI). Kappa coefficients[20] with 95% CIs (calculated via bootstrap) will be used to examine the potential for misclassification of BMI category. The agreement for continuous variables will be considered good if the differences between weights are <−2 and >+2 kg and no systematic differences according to pre-pregnancy BMI category and other variables such as income, education and ethnicity are observed. The ±1 kg and other thresholds will also be explored in sensitivity analyses based on the results of the analysis between measured pre-pregnancy vs measured first-trimester weight.

Decisions on how to proceed with data with low agreement or lower-than-expected agreement will be made based on these results. This will involve exploring the implications of exclusions and looking at the proportion of different types of weights (self-reported/measured) in the datasets before establishing the hierarchy to be considered for pre-pregnancy BMI and GWG calculation.

Data quality assessment

Data quality will be assessed using a checklist that includes items related to the completeness of the dataset relative to key variables, percentage of missing data, digit preferences/heaping.[21 22] The key variables to be considered in this step are gestational age, maternal weight, height and pre-pregnancy BMI. Data quality assessment will be performed in each individual dataset before inclusion in the pooled database.

Individual-level eligibility criteria

After applying the study-level eligibility criteria and performing data harmonisation, cleaning and data quality assessment, individual-level inclusion criteria will be applied to the final pooled database. To develop prescriptive GWG charts, it is necessary to restrict the study population to women with optimal conditions for weight gain during pregnancy, whose neonates did not experience adverse health outcomes and who did not develop any conditions during postpartum associated with non-optimal GWG. For this reason, a broad list of GWG determinants and outcomes is proposed for consideration (online supplemental table 1). The list of determinants and outcomes is based on the framework proposed by the IOM for GWG determinants and outcomes[5] and two recent reviews on outcomes related to GWG.[23 24]

To identify the final inclusion/exclusion criteria for the GWG charts, a pragmatic approach that aims to balance theoretical considerations with practical data availability issues will be adopted. In this approach, all determinants and outcomes of inadequate/excessive GWG will be retained for consideration in the initial stage. A primarily data-driven approach will be used for identifying individual-level inclusion/exclusion criteria, in which a determinant or outcome will be retained only if the exclusion of women with the determinant or outcome meaningfully changes the weight gain charts' percentiles.

To evaluate the extent to which the determinants/outcomes meaningfully impact the weight gain chart's percentiles, each determinant/outcome was reviewed to operationalise what cut-off values/categories should be used as inclusion/exclusion criteria. The review of determinants/outcomes was performed using a triaged approach. The complete list of determinants and outcomes (online supplemental table 1) was divided into three levels based on their likely availability in studies meeting study-level eligibility criteria. Group 1 included determinants and outcomes listed as mandatory in the study-level eligibility criteria. Group 2 contained determinants and outcomes that will likely be available in most studies or at least in part of them. Group 3 included determinants and outcomes that will likely not be available in most studies, because they are complex to measure or unlikely to be available (eg, media influence). The operationalisation of group 1 and 2 variables is described in online supplemental table 2. Group 3 determinants/outcomes will be reviewed as needed, given availability in the final pooled database.

The decision on the final individual-level eligibility criteria for the development of the GWG charts will be made after evaluating the impact of each of the

variables on the GWG distribution. The 10th, 50th and 90th percentiles of the last GWG measurement before delivery will be compared before and after removing women with risk factors for, or outcomes of, inadequate/excessive GWG. For example, we will assess the impact of excluding women who gave birth to preterm neonates (gestational age at birth <37+0 weeks) by comparing the selected percentiles (and 95% CIs for those percentiles) in women with any gestational age at delivery to the percentile values among women who did not give birth to preterm neonates. Initially, analyses will be performed on the entire cohort (ie, for all BMI categories combined), but a second stage of stratified analyses according to pre-pregnancy BMI categories will be considered.

A variable will be retained for further examination if the difference between any of the 10th, 50th and 90th percentiles of GWG is >0.75 kg before compared with after removing women with risk factors for, or outcomes of, inadequate/excessive GWG. The 0.75 kg threshold was defined as meaningful from a clinical perspective, as systematic reviews and meta-analyses of pregnancy weight gain interventions have shown that mean weight gain changes of this amount are not associated with a significant reduction in the risks of maternal and infant adverse outcomes.[25 26] The 0.75 kg threshold will be converted into a percent difference of the median kg of weight gain at 40 weeks for normal-weight women and this percent will be used for all BMI categories and gestational weeks.

A final decision on the identification of a variable as an inclusion/exclusion criterion will be made considering the amount of change over 0.75 kg, the sample size, the number of abnormal measurements out of the five selected percentiles and the width of the CI estimates. This two-stage approach is necessary because the sample sizes available for each variable will play a role in the interpretation of results and will be considered on a case-by-case basis.

Quantile regression will be used to estimate the percentiles and respective 95% CIs at each gestational age in the last weight measurement before delivery. To account for the non-linear relationship between GWG and gestational age, the best-fitting powers for the GWG curves using fractional polynomials will be identified. These fitting powers will be further modelled in quantile regressions with robust errors.[27] Predicted GWG values in each gestational week during the third trimester and accompanying CIs for the 10th, 50th and 90th percentiles will be extracted. Other percentiles (5th/95th, 25th/75th) will also be calculated and examined. Bootstrapped 95% CIs will be calculated.

Analyses will be limited to studies in which a given variable was collected and is available for at least 80% of participants. A complete-case analysis will be performed; that is, only women with complete information on the selected variable (as well as GWG and gestational age) will be included in the analysis. In addition, a core list of determinants and outcomes that will be retained as inclusion/exclusion criteria for reasons of face validity will also be identified a priori, irrespective of whether they meaningfully impact the weight gain chart's percentiles or not (eg, stillbirth).

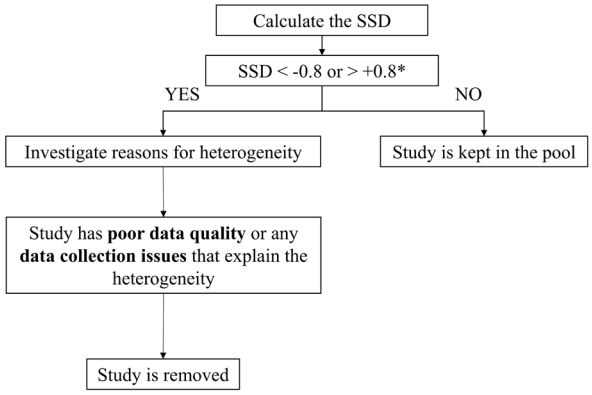

Figure 3 Workflow for heterogeneity assessment. *A variation of ±10% in the SSD thresholds to decide the studies that will be considered heterogeneous will be accepted. SSD, standardised site difference.

Analytical approaches

Heterogeneity assessment

When combining data from multiple sources and regions, it is necessary to assess the heterogeneity of key variables (such as maternal weight or GWG) across studies, countries and regions before analysing them as a single dataset.

In this step, we will use the calculation of the variance in the measurements (eg, GWG) explained by the origin of the data through multilevel models, including gestational age and studies as covariates, as an exploratory approach.[6] Then, the standardised site differences (SSD) will be calculated. The SSD compares the distribution of the selected variable across datasets by calculating the z scores for the means of the variable in gestational age groups in relation to the pooled means and SDs for each age group, a similar approach to that adopted in other studies developing growth curves.[28] The proposed workflow for heterogeneity assessment is presented in figure 3.

To calculate the SSD, intervals of 4 gestational weeks will be used, but the initial time point in the first trimester of gestation is yet to be defined, based on the results of the agreement analysis. The first gestational age interval (8/9–13 weeks) will probably be wider (>4 weeks) than the others. Means and SDs of weight/weight gain by gestational age intervals will be calculated. The distribution of measurements per gestational week within the 4-week period will be checked and the use of predicted weight/weight gain means and SDs to deal with measurements concentrated in specific gestational weeks will be considered.

Datasets with an SSD of more than ±0.8 will be considered heterogeneous. This value was chosen to ensure that several studies from different regions are included in the final database. A variation of ±10% in the SSD thresholds (corresponding to a range between 0.72 and 0.88) to

decide the studies that will be considered heterogeneous will be accepted. In addition, to consider a dataset heterogeneous, it must have the SSD values consistently lying outside the thresholds in all gestational age intervals. For datasets lying outside the limits in some intervals (but not all), the number of points to define a study as heterogeneous will be defined based on the number of points that would be expected to fall outside the intervals at random.

These analyses will be repeated by subgroups (eg, by region) after the complete pooled analysis and we will investigate the reasons for heterogeneity before performing any exclusions of studies. Also, the GWG trajectories will be examined (sensitivity analysis) before any further decisions on the treatment of heterogeneity, if any.

Construction of the centile curves

Two studies have provided an extensive review of statistical models available to construct growth charts.[29 30] It is important to mention that models for curves of cumulative GWG are being considered.

Based on the list of methods described in those reviews and the desired characteristics of the resulting GWG charts, several models were selected for testing in the pooled database. The main desired characteristic that guided the selection of these models was the need for equations to calculate z scores (and consequently, percentiles) of GWG. Other guiding considerations include an accurate fit of the model and model parsimony. In addition, the chosen model must be valid across all BMI categories.

Generalized Additive Models for Location, Scale and Shape (GAMLSS) will be considered for the construction of the centile curves. The use of GAMLSS allows modelling up to four parameters of the GWG distribution, that is, mu (mean), sigma (SD), nu (asymmetry) and tau (or lambda, kurtosis).[31] The Lambda-Mu-Sigma (LMS) (based on Box-Cox Cole Green distribution), LMST (an extension of LMS with four parameters being modelled, based on Box-Cox t distribution) and LMSP (an extension of LMS to model four parameters, but using Box-Cox Power Exponential distribution) models can be fitted. The availability of several distributions and smoothers in these models makes GAMLSS a flexible option. Many WHO anthropometric standard charts were constructed with GAMLSS, using Box-Cox Power Exponential distributions.[32] GAMLSS were also used in INTERGROWTH-21st curves[33] and several GWG curves.[11 34 35]

The choice of the final model will consider aspects such as the model diagnostics, the internal validation of the model (ie, the estimates of the percentage of measurements below and above selected percentiles (3, 10, 25, 50, 75, 90, 97)), and the shape of the centiles. To evaluate overfitting, the degrees of freedom of each parameter in each model will be examined when automatic functions available in the statistical software are used to ensure high values (>10) were not used in the model adjustment. In addition, the following diagnostic measurements will be determined: graph of the fitted parameters against gestational age; graph of the residuals from the models against fitted values of μ, kernel density estimate and normal QQ plots; plot of fitted distribution of GWG for specific values of gestational age; summary of quantile residuals and Q-stats[36]; and worm plots.[37]

The most important consideration for identifying the final model to be used to create the curves (beyond the shape of the resulting centiles) is its internal validity. For that, the percentage of measurements below and above some selected percentiles (3, 10, 25, 50, 75, 90, 97) will be calculated.[38 39] The internal validation will be considered satisfactory if the CIs for the observed proportion of women above/below the selected centiles include the expected value.[40] Diagnostic and internal validation procedures will be examined for the whole sample and by geographical region.

External validation procedures will be undertaken by using datasets not included in the development of the charts, pending data availability. Potential external validation datasets could include datasets that were not available in time for data harmonisation procedures for Phase 1 (eg, due to delays in the data sharing agreement process) or datasets with women who did not meet the defined eligibility criteria for the charts. In this external validation database, the percentage of pregnant women above/below the selected percentiles will also be determined. If the models are not overfitted to the development dataset, the percentages above/below those values in the validation data would be similar to the expected values.

Finally, to avoid a small number of studies with very large sample sizes having a disproportionate influence on the values of the charts, we will consider weighting observations to prevent imbalances, particularly by geographic distribution. Weights by country or geographic regions will be defined using estimates of women of reproductive age by BMI category and applied to the analysis.[7]

The work described in this protocol was initiated in 2022. The global call for data and the identification of studies was already conducted. The data sharing process is ongoing, and the data harmonisation is expected to be finalised in the first semester of 2025. The complete timeline for the development of this protocol is 3 years.

Patient and public involvement

Patients and the public were not involved in any step of this project.

ETHICS AND DISSEMINATION

This project will include an analysis of existing study de-identified data. To be included in the pooled database, each included study should have received ethics approvals from relevant committees with assurance that the data could be used for secondary analysis. De-identified datasets will be added to a secure environment at the WHO servers. This secure environment is confidential,

follows the WHO data policies and complies with the General Data Protection Regulation. Access to de-identified datasets will be granted to authorised researchers only and the datasets will not be used for other purposes not considered in Phases 1 and 2. Manuscripts from this project will be submitted to open-access journals. In addition, a final WHO document will be published, including the outputs from Phases 1 and 2.

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