GLOBAL CALL FOR DATA

Development of Gestational Weight Gain Standards (Phase 1)

1. Background

Currently there exists no global tool for GWG monitoring or international recommendations on optimal weight gain. The World Health Organization (WHO) antenatal care (ANC) guideline references the use of the 2009 Institute of Medicine (IOM) guidelines to monitor GWG. However, these guidelines were created for pregnant individuals from the USA, and their generalizability to other settings globally is uncertain. Further, most GWG charts published to date were primarily derived from populations in high-income countries or did not cover the entire range of pre-pregnancy body mass index (BMI).

The global call aims to gather data from various sources (i.e., published and unpublished studies and routine/administrative systems) to develop global guidance and tools for gestational weight gain (GWG) monitoring. The data will be stored in a secure repository managed by the World Health Organization (WHO) specifically for this endeavour.

This initiative will be led by a GWG Steering Committee, composed of the WHO Departments of Nutrition and Food Safety (NFS) and Sexual and Reproductive Health and Research (SRH) in partnership with a group of scientists, including researchers from the Federal University of Rio de Janeiro (Brazil), Cornell University (USA), and the University of British Columbia (Canada). The GWG Steering Committee will be supported by a Technical Advisory Group composed of global experts in GWG, perinatal epidemiology, and statistical modelling. The WHO NFS Department has extensive experience in developing growth standards, which puts the organization in a privileged position to lead the development of the global GWG standards and subsequent rollout.

2. Objectives of the project

1) Develop GWG standards for monitoring maternal weight gain during antenatal care in diverse global settings.
2) Identify the ranges on the GWG standards associated with the lowest risk of maternal and infant adverse outcomes to inform the development of global, BMI-specific GWG recommendations.

NOTE: This global call will focus on obtaining data for the project's first objective

3. Characteristics of the required data

Studies (datasets) must meet mandatory criteria to be included in the pooled database; these criteria are listed in **Box 1**. A dictionary containing all variables and the study protocols/main manuscripts must be provided. Data collected from routine/administrative systems will be accepted only upon submission of the data collection protocols or other detailed description of data collection methods. Data obtained for this project will be harmonized and pooled into a global cohort.

Box 1. Summary of the study-level eligibility criteria to be included in the pooled database (Phase 1).

1. Ethics committee/board approval
   Data collected after a research ethics committee/board approval

2. Year of data collection
   Data collected after 1990

3. Study design
   Observational studies, including prospective and retrospective cohorts; administrative/clinical databases; and control arms of randomized clinical trials receiving placebo, standard care, or no interventions

4. Sample size
   Minimum 200 subjects

5. Type of data
   Individual participant data collected by the research team using a standardized protocol and/or collected through clinical/public health care encounters

6. General characteristics of the studies

6.1 Studies with at least two visits where maternal weight and accompanying gestational ages are documented.

6.2 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

6.3 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

6.4 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 ultrasounds, 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 ultrasound 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 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 performed before 24 weeks

6.5 For research studies, no more than 20% of listwise missing data across the following key variables: maternal height, 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 data regarding the use of assisted reproductive technologies (such as in-vitro fertilization) 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 (10–18 years old at delivery)

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 Ideally, with data available on maternal pre-existing health conditions (at least hypertension and diabetes) and complications during pregnancy (at least hypertensive disorders of pregnancy and gestational diabetes) and not conducted exclusively among individuals with those conditions

6.11 Ideally, with at least one measurement of maternal and/or children's weight at or beyond six months postpartum and the dates of those measurements

The lists of mandatory and important variables and their description are available in the ***Data Sharing Standards (DSS)*** (https://cdn.who.int/media/docs/default-source/nutrition-and-food-safety/technical-advisory-group-on-gestational-weight-gain/data-sharing-standards.pdf).

4. Procedures for data sharing

The principal investigator (PI) interested in sharing the data must complete an ***online form*** (https://forms.office.com/e/tFd1VEhFFp). After the revision of the forms, WHO will contact the PI responsible for those approved datasets and invite them to proceed with data sharing. The PI will need to sign a standard data-sharing agreement included in the ***DSS***, and the data-sharing process will adhere to standard and safe procedures also outlined in the ***DSS.***

WHO will manage the data repository and have access to the shared datasets. The PIs collaborating with this project will have access to their own raw data. WHO will only use the data to achieve the goals of this project (i.e., it will not be used in other projects nor to answer other questions). The management of the repository and any updates will be the sole responsibility of WHO. In addition, datasets will not be retained beyond the dates outlined in each data sharing agreement. This project may contribute to endorsing WHO guidelines for antenatal care updates or any other new WHO guideline on GWG recommendations.

5. Steps to be taken with the shared datasets

Each shared dataset will be rigorously cleaned and harmonized, including standardization of anthropometric measurements and assessment of biologically implausible values. This process will ensure that the data from different sources are standardized and will be potentially combined into a unique database.

The overall tasks involved in the data harmonization process comprise, but are not limited to, the following activities:

1. Data completeness checks with the revision of the incoming data (completeness in terms of documentation and variables needed).
2. Data monitoring after the data are transferred to the designated repository, with the programming group working with the contributors to resolve data-related queries.
3. Programming activities include creating programming practices, working with analysts on creating and modifying specifications, data reproducibility, code generation, and review.
4. Data corrections and finalization, including working with the analysts to make modifications and corrections where needed.

After the datasets are harmonized and combined, the data analyses will consist of several steps. The heterogeneity of key variables (such as weight and height) across datasets and countries will be carefully considered. Different modelling strategies will be considered to construct GWG curves, including cross-sectional approaches (e.g., Generalized Additive Models for Location, Scale and Shape (GAMLSS) and longitudinal approaches (e.g., fractional polynomials with multi-level models), with the final model selected based on both clinical and statistical considerations.

For any inquiries about the repository or data, please contact us at globalgwg@who.int.