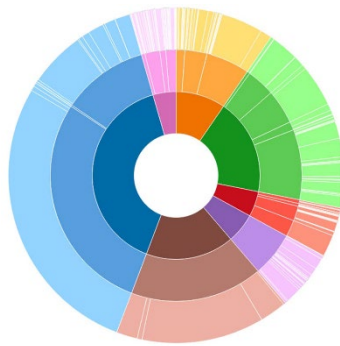

GLOBAL BURDEN OF DISEASES, INJURIES, AND RISK FACTORS STUDY (GBD)
PROTOCOL

Institute for Health Metrics and Evaluation
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Executive summary

This protocol outlines the key principles, assumptions, products, roles and responsibilities, processes, and architecture for Global Burden of Diseases, Injuries, and Risk Factors (GBD) study. The current version is posted on the IHME website at the following URL: <https://www.healthdata.org/research-analysis/about-gbd/protocol>.

Overview

The GBD is an analytic framework for global descriptive epidemiology in which the combined impact of fatal and non-fatal health impacts is weighted comparably across diseases, injuries, and risk factors. It is a systematic, scientific effort to quantify the comparative magnitude of health loss due to diseases, injuries, risk factors, impairments, and etiologies by age, sex, and geographic location for specific points in time. IHME helms the GBD study and regularly produces estimates for a set of key population health indicators. The critical milestones for ongoing estimation include regular updates to the GBD estimates, referred to as the “GBD round” or “GBD cycle.” For each round, the entire time series back to 1990 will be re-estimated using all available data and best available methods to ensure the most complete and comparable set of estimates possible.

Roles and responsibilities

Different groups have significant roles and responsibilities in the GBD estimation process, outlined here:

- **Scientific Council:** The GBD Scientific Council is a mechanism for key scientific decision-making internal to the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD); it is not a substitute for peer-review of publications or for periodic reviews from independent groups not involved in the GBD.
- **GBD Management Team:** Oversees the implementation of the GBD enterprise under the leadership of the IHME Director. The Team members are individually and collectively responsible for the annual production and publication of high-quality, policy-relevant GBD estimates and related deliverables on time and in accordance with the GBD Protocol. The Team is responsible for the monitoring, planning, and allocation of resources expressly for that purpose accordingly. Individuals are accountable to one another to ensure that each team has the components it needs to complete its work on time, that risks to the timely delivery of high-quality outputs are identified and communicated, and that solutions are implemented effectively and efficiently after consideration of the appropriate trade-offs.
- **Collaborators:** The GBD Network is IHME’s primary mechanism for individual collaboration; the Institute engages a network of individual collaborators with a wide variety of areas of expertise. Collaborators are selected through an open call as well as referrals and play a critical role throughout the GBD estimation cycle. They are also responsible for developing, promoting and translating results of the GBD to be relevant for policymakers. This may take various forms such as:
 - Reviewing, identifying, and assessing data sources related to each GBD round with a view to ensuring that they are as robust as possible
 - Critiquing estimates and methods to ensure the highest-quality science
 - Identifying opportunities for scientific innovation
 - Co-authoring and/or leading official GBD publications
 - Disseminating GBD results and contributing to their uptake and application around the world
 - Developing policy briefs to guide the utilization of the GBD in different contexts

- Participating in scientific consultations
- Promoting and translating results to relevant policymaker and health system decision-maker audiences
- Leading institutional partnerships and/or subnational burden of disease studies
- Independent Advisory Committee: The Independent Advisory Committee for the Global Burden of Disease will advise the Board of the Institute for Health Metrics and Evaluation on Global Burden of Disease, Forecasting, and Geospatial Analysis research areas with the following terms of reference:
 - Advise on the overall vision and strategic direction of the Global Burden of Disease, Forecasting, and Geospatial Analysis projects
 - Review the strengths and weaknesses of different methods and results
 - Identify areas in which, on the basis of available evidence, new data collection and analysis would help to improve particular estimates and make recommendations for how to instigate and support such efforts
 - Advise the IHME Board about opportunities for strengthening collaboration and shared ownership
 - Advise on the strengths and weaknesses of other efforts on global health estimates
 - Act as a conduit for the discussion of criticisms raised about the GBD methods and estimates
 - Provide guidance on the integration of new components and features into the GBD project
 - Advise on the wider communication of the GBD outputs and engagement with end users, with a focus on the use of GBD evidence to inform policy and program decision-making and implementation
 - Report annually to the IHME Board

Adjudication

Given the complex scope of the GBD, estimates, trends, or approaches may lead to diverging scientific opinion. A detailed process for resolving disagreements is described in SECTION 5. ADJUDICATION. Any member of the GBD or general public may raise issues for debate, and, if these are not resolved through other channels, may request that the issue be brought to the Scientific Council.

GBD analytic strategies

Ongoing GBD estimation follows the methodology outlined in the most recently published GBD study. The flowchart in SECTION 6. GBD ANALYTIC STRATEGIES illustrates the flow of the key components of the GBD estimation process.

Data

A key premise of the GBD is that it incorporates all available relevant data into its analyses. That includes data from literature, vital registration, surveys, censuses, administrative records, registries, individual studies, reports, and satellite imagery. The GBD study has and will continue to develop a substantial data catalog with complete citations.

To maximize the use of the GBD and affiliated projects as global public goods, crude data, model input data points, and final results will be made freely available where legally permissible for non-commercial use of the data in IHME's public data catalog, the Global Health Data Exchange (GHDx, available at <http://ghdx.healthdata.org/>).

GBD Collaborators may be granted privileged, confidential access to the input data and intermediate data upon request where legally permissible, as well as the final results with 95% uncertainty intervals as applicable pertaining to their enrolled area of expertise.

Citation

When using GBD results in analyses, presentations, and papers, please cite them in the following format:

Global Burden of Disease Collaborative Network.

Global Burden of Disease Study (GBD) [YEAR] Results.

Seattle, United States: Institute for Health Metrics and Evaluation (IHME), [YEAR].

Available from <https://vizhub.healthdata.org/gbd-results/>.

Dissemination and policy use

The GBD is a critical resource for policymakers, researchers, donors, and others to make informed decisions and guide priorities using the most current information possible. To maximize the benefit of the GBD as a global public good, IHME strongly encourages the robust production of publications that provide important insight and implications from GBD results and dissemination of these findings.

By participating in the GBD as a GBD Collaborator, GBD Scientific Council member, or GBD Management Team member, individuals are provided multiple opportunities for authorship on GBD publications. The GBD aims to publish each round “capstone papers” presenting overall estimates, and regular updates to disease-, risk-factor-, and country-specific papers. Other papers may be written by the collaborators. The process for collaborator-led papers is outlined in “SECTION 9. DISSEMINATION AND POLICY USE.”

The GBD conforms to the principles of authorship, disclosure, and scientific integrity as outlined in the requirements of the individual peer-reviewed journal to which a given publication is submitted, as well as to the overall criteria of the International Committee of Medical Journal Editors.

In addition to disseminating findings via peer-reviewed academic publications, presentations, and posters, IHME strongly encourages collaborators to share the findings with decision-makers to raise awareness of GBD as a valuable resource.

IHME encourages collaborators to engage with decision-makers in their countries and/or focus area(s) to demonstrate how GBD can be an important tool to help turn evidence into health impact via policymaking as well as program development and implementation.

To learn more about ways that partners and GBD Collaborators are using findings from the study to inform decision-making, see IHME’s [Acting on Data](#) blog. To facilitate joint learning across the Collaborator Network and beyond, IHME encourages collaborators to share other ways that GBD is being used to inform policy. Furthermore, collaborators can use policy-focused materials created by IHME, or can create GBD materials (such as presentations, one-pagers, and reports) that are tailored to decision-makers in their country and/or focus area.

SECTION 1. INTRODUCTION

This protocol outlines the key roles, responsibilities, decision-making processes, and deliverables included in the Global Burden of Diseases, Injuries, and Risk Factors (GBD) Study and is intended for all individuals directly engaged in the GBD. The most current version is posted on the IHME website at the following URL: <https://www.healthdata.org/research-analysis/about-gbd/protocol>.

Purpose and goals of the GBD: The GBD is a systematic, scientific effort to quantify the comparative magnitude of health loss due to diseases, injuries, risk factors, impairments, and etiologies by age, sex, and geographic locations over time. It is founded on the belief that everyone, everywhere deserves to live a long life in full health. IHME serves as the coordinating center for the GBD and affiliated projects.

Comparison is at the heart of the GBD approach. For decision-makers, health-sector leaders, researchers, and informed citizens, the GBD and affiliated projects provide an opportunity to see the big picture, to compare diseases, injuries, risk factors, impairments, and etiologies, and to identify, for a given place, time, and age-sex group, the most important contributors to health loss, as well as disparities. To ensure a health system is adequately aligned to a population's true health challenges, policymakers must be able to compare the effects of different conditions that kill people prematurely and cause poor health and disability. A central goal of the GBD enterprise is to ensure that the most current, detailed, comprehensive results are used by policymakers, donors, and others to make decisions to improve population health. The GBD enterprise provides cutting-edge and timely results through scientific papers, reports, presentations, web content, and visualizations. The GBD uses and builds on the infrastructure of methodology, datasets, and tools outlined in the most recently published GBD study,¹⁻⁶ which builds on the methodology first presented in the GBD 2010 study.⁷⁻¹⁴ Any proposed updates to published methods or cause, risk factor, impairment, or etiology lists will be approved by the GBD Scientific Council, as detailed in Section 4.

The GBD relies on a network of individual collaborators with expertise on all-cause mortality; specific diseases, injuries, risk factors, impairments, and etiologies; country-specific epidemiology; health systems; and health policy. Collaborators, and those who contribute to and utilize the GBD, are part of a global effort to improve population health and inform evidence-based decision-making, with the goal of improving population health around the world.

SECTION 2. KEY PRINCIPLES AND ASSUMPTIONS

The GBD regularly produces estimates of key population health indicators (for a more detailed list of all products of the GBD see "SECTION 3. KEY PRODUCTS"). Each set of comprehensive new estimates to the GBD indicators is referred to as the "GBD round." For each round, the entire time series back to 1990 is re-estimated using all available data to ensure the most complete and highly comparable set of estimates possible. Previous results will be archived every time new results are released.

The GBD and its affiliated projects are conducted based upon eight key principles to ensure the highest quality and most useful set of results. The data used and the analytic strategies applied to generate the results are consistent with these principles. Any changes to the principles will be presented to and discussed by the GBD Scientific Council; accepted changes will be added as a modification to this protocol.

Comprehensive comparisons

- The GBD cause list is a set of mutually exclusive and collectively exhaustive hierarchical categories.
- Results from the GBD are intended to facilitate comparison.
- All quantities of interest are estimated in all time periods. An uncertain estimate, even when data are sparse or not available, is preferable to no estimate because no estimate is often taken to mean no health loss from that condition.

Communicate the strength of the evidence

- Because the GBD produces estimates for a mutually exclusive and collectively exhaustive set of disease and injury causes, it is important to convey to users the strength of the evidence for each quantity through the reporting of uncertainty intervals (UI).
- The GBD estimates uncertainty distributions for each quantity and reports various metrics of uncertainty, including 95% UI.

Internal consistency

- The sum of cause-specific mortality, defined according to the International Classification of Diseases (ICD) underlying cause rules, must equal all-cause mortality.
- The sum of cause-specific estimates of impairments, such as blindness, must equal estimates of all-cause impairments.
- Where incidence, prevalence, remission, duration, and excess mortality are not changing over time, rates are required to be internally consistent.

Iterative approach to estimation

- New data and methodological innovation lead to revision of estimates.
- Burden of disease estimation is an iterative process. Revisions result in a re-estimation of the entire time series so that results are always available over time using consistent data and methods.

Identify all relevant data sources

- Strive to include available relevant sources of data for a given disease, injury, risk factor, impairment, and etiology and for all-cause mortality, population, and fertility.
- For all data sources identified, the sampling method, case definitions, and potential for bias should be assessed.

Compare like with like

- For cause of death data, variants of the ICD should be mapped to one another.
- For data on incidence, prevalence, remission, and excess mortality, statistical methods should be used to characterize the relationship between different case definitions, diagnostic technologies, recall periods, etc.
- These relationships should be used to transform data into comparable units, definitions, or categories. Wherever possible, uncertainty is propagated in these mappings into the UI for the measurement.
- Some measurements may have to be excluded because they cannot be made comparable to the rest of the measurements or have fundamental problems of validity.

Correct for errors

- All appropriate data should be synthesized using statistical methods that can handle both sampling and non-sampling error.
- For cause of death data, garbage codes are redistributed.

Pick the best model based on performance

- The statistical methods employed should improve predictions where data are sparse by allowing for use of covariates and by borrowing strength across time and/or geography.
- All estimates should be generated with draws of the quantity of interest from the posterior distribution.
- Where possible and appropriate, validity of the statistical methods should be demonstrated by using out-of-sample prediction.

SECTION 3. QUANTITIES OF INTEREST

The GBD produces comprehensive estimates of burden of diseases, injuries, impairments, etiologies, and risk factors by geographic location, year, age, and sex. This list of estimates is agreed upon annually by the Scientific Council. For more information on the causes, ages, and other dimensions used by GBD, refer to Section 7 of this document. The GBD releases the point estimates and 95% uncertainty intervals by location, age, year, and sex for at least the following:

- All-cause mortality rates
- Population
- Age-specific fertility rate
- Total fertility rate
- Net reproductive rate
- Live births
- Deaths by cause
- Years of life lost due to premature mortality (YLLs) by cause
- Years lived with disability (YLDs) by cause
- Disability-adjusted life years (DALYs) by cause
- Relative risks of mortality for each risk-outcome pair
- Population attributable fractions of risk factors
- Deaths attributable to risk factors
- YLLs attributable to risk factors
- YLDs attributable to risk factors
- DALYs attributable to risk factors
- Healthy life expectancy (HALE)
- Life expectancy
- Prevalence by cause
- Incidence by cause
- Summary exposure value (SEV) by risk factor
- Maternal mortality ratio (MMR) by maternal cause
- Deaths by etiology
- Population attributable fractions of etiologies
- Years of life lost due to premature mortality (YLLs) by etiology
- Years lived with disability (YLDs) by etiology

- Disability-adjusted life years (DALYs) by etiology
- Prevalence by impairment
- Years lived with disability (YLDs) by impairment
- Probability of death by cause
- Prevalence by sequelae
- Incidence by sequelae
- Years lived with disability (YLDs) by sequelae

These results are made available at least through the following mechanisms:

- GBD tools and visualizations: <http://www.healthdata.org/gbd/data-visualizations>
- Publications in peer-reviewed journals: <https://www.healthdata.org/research-analysis/gbd-research-library>
- Publications aimed at policymakers and other audiences: <http://www.healthdata.org/gbd/publications>
- Presentations detailing the results and methodology: <http://www.healthdata.org/gbd/news-events>
- Datasets available for download (<http://ghdx.healthdata.org/gbd-results-tool>) or upon request, as outlined in Section 8 of this document
- GBD code published in repositories, as outlined in Section 8 of this document: <http://ghdx.healthdata.org/> (See “IHME data.”)

Starting with GBD 2015, the GBD study is fully compliant with the Guidelines for Accurate and Transparent Health Estimates Reporting (GATHER). GATHER defines best practices for documenting studies that synthesize evidence from multiple sources to quantitatively describe past and current population health and its determinants. These practices include documenting and sharing data inputs, analyses, and methods, and results. Documenting the input data on which estimates are based, and the methods by which estimates are derived, is essential for the accurate interpretation and use of results. For more information, visit the GATHER website at <http://gather-statement.org/>.

The exact timing and release of results are determined by the GBD Management Team under the leadership of the GBD Study Principal Investigator (PI).

Additionally, the GBD Enterprise may expand to include new affiliated projects as they develop. The protocol may be updated as these projects evolve, and collaborators may be contacted based on their areas of expertise during any stage of these works to determine their interest in participating.

SECTION 4. GBD ROLES AND RESPONSIBILITIES

The GBD includes a Scientific Council, a Management Team, and a robust network of collaborators working together to produce the most accurate, up-to-date, and comparable estimates of burden worldwide. The GBD study is managed by the GBD Management Team under the leadership of the Principal Investigator (PI), Dr. Christopher Murray. Guidance is additionally provided by the Independent Advisory Committee to the IHME Board.

GBD Scientific Council

The GBD Scientific Council is a mechanism for key scientific decision-making internal to GBD; it is not a substitute for peer-review of publications or for periodic reviews from independent groups not involved in the GBD. The Council Chair for the GBD Scientific Council is Dr. Christopher Murray, and the Council is composed of leading experts in fields relating to the GBD. This GBD Scientific Council provides direct oversight over and has decision-making ability on methodological advancements produced as part of the GBD.

The GBD Scientific Council is primarily responsible for:

- Reviewing and voting on all proposed updates to methods.
- Adjudicating disputes on estimates for mortality, specific diseases, injuries, impairments, etiologies, risk factors, or geographies; data sources included; and methodological approaches.
- Reviewing and voting on proposed modifications to the cause, risk factors, impairments, and etiologies lists.
- Reviewing and voting on changes to the existing published set of risk-outcome pairs used for measuring attributable burden of risk factors.
- Discussing recommendations from outside groups.
- Reviewing and approving membership in Tiers 3 and 4 of the Collaborator Network.
- Reviewing and discussing feedback from the Independent Advisory Committee to the GBD.
- Reviewing and voting on new data sources, lay descriptions, and changes in methods to be used in analyses for recalculating disability weights.

The Council Chair selects and enrolls GBD Scientific Council members for three-year renewable terms. In selecting Council members, the Council Chair seeks to reflect the diversity of expertise in demography (mortality, population, or fertility), diseases, injuries, risk factors, impairments, etiologies, countries, or related methodology across the membership of the GBD, including leaders from select partner institutions. The Council Chair convenes regular Council meetings, as needed, with the Council Secretary facilitating its proceedings. The meetings are attended by Council members and the Council Secretary. GBD Collaborators and other GBD-affiliated individuals can be invited to attend as needed. The Council will take decisions based on majority of votes; all Council members are eligible to vote. Further details of the GBD Scientific Council, including current members and recent activities, are posted on the IHME website at the following URL: <https://www.healthdata.org/research-analysis/about-gbd/governance-scientific-council>.

GBD Management Team

Led by the GBD PI, the GBD Management Team facilitates the GBD production process including managing use of IHME computational capacity dedicated to the GBD, ensuring that the study is meeting critical deadlines, and confirming that the estimation meets the computational requirements as outlined within this protocol. The GBD Management Team is responsible for overseeing the execution of the GBD cycles and for reviewing and approving the final GBD results. Additionally, the GBD Management Team oversees the coordination between teams to ensure processes, data, infrastructure, terms and definitions, and analytical decisions are aligned, consistent, and efficient.

IHME staff, consultants, and contractors

A cross-section of IHME staff, consultants, and contractors contribute significantly to the GBD study in a multitude of ways, including operations, engineering, data management, modeling, etc. In the course of

their normal work, they adhere to this protocol and are considered for attribution and co-authorship in the same manner as collaborators.

GBD Collaborators

The GBD enterprise relies on a large network of individual collaborators with specialties in various topic areas. Collaborators are critical throughout, from data analysis to policy uptake, and there are many ways for GBD Collaborators to contribute to the GBD and affiliated studies. Their expertise generally falls into one or more of the following broad categories:

- 1) Expertise on demography (all-cause mortality, population, fertility, or migration)
- 2) Expertise on diseases, injuries, risk factors, impairments, or etiologies
- 3) Expertise on the epidemiology for a specific country or countries
- 4) Expertise in health policy
- 5) Other expertise as necessary to achieve the aims of the GBD study and affiliated projects

GBD Collaborators may be enrolled in one or more topic areas of expertise. IHME will engage collaborators on topics according to the areas of expertise they specify in their GBD Collaborator profile.

The time commitment for GBD Collaborators is flexible. GBD Collaborators are given the opportunity to participate in a range of projects and activities but may decide their own time commitment. They will receive regular notifications relevant to their areas of ascribed expertise. They may opt out at any time. This section outlines the role of the collaborator in the GBD estimation process; but collaborators may also be involved in affiliated projects which may have their own timelines.

Collaborator role in the GBD estimation process

Fundamentally, collaborators participate in six major areas of activity throughout the GBD estimation cycle:

1. **Input data:** Providing access to and knowledge of input data sources. This can range from recommending new data sources to be incorporated, to contributing to the interpretation and understanding of the data available.
2. **Methods improvement:** Providing technical expertise on methodological approaches, assumptions, and model development. This can be specific to a disease, risk factor, injury, or impairment of expertise, or to a geographic location or methodological framework.
3. **Results:** Providing feedback on the validity and interpretation of results before they are finalized for that estimation cycle.
4. **GBD publications:** Commenting on and participating as co-authors on drafts of the GBD publications with a focus on the presentation, discussion, and implications of key results.
5. **Outreach and policy uptake:**
 - a. Translating the results of the GBD to maximize policy uptake and action. For example:
 - i. Speaking to decision-makers and influencers about how the GBD results can be used to support evidence-based decision-making
 - ii. Supporting policy dialogues and presenting GBD results relevant to specific policy discussions
 - iii. Developing policy-relevant materials based on GBD findings
 - b. Utilizing GBD publications and visualization tools, including with key public health stakeholders and/or academic audiences.

- c. Sharing the GBD via events such as seminars and workshops.
 - d. Speaking to the media as appropriate, after completing relevant GBD media training.
6. **Additional analyses and publications:**
- a. Conducting additional analyses or further research that builds upon GBD results.
 - b. Publishing academic papers utilizing GBD results.

Opportunities for collaborators

Collaborators are invited to participate in learning opportunities about the GBD approach and specific components of the GBD and affiliated projects. Interactive online courses, webinars, visualization tools, consultative meetings, and other opportunities and resources are made available to collaborators to facilitate their understanding, use and dissemination of the GBD and affiliated projects.

Furthermore, all collaborators receive access to results for review, comment, and to help develop GBD publications ahead of the public.

Facilitating communication within the GBD Collaborator Network

While there are clear lines and means of communication between the GBD Collaborator Network and IHME, communication among collaborators is more nuanced. To promote networking among collaborators who wish to engage at this level, IHME may contribute to facilitating communication among collaborators with specific interests, projects, and areas of work. IHME may also support communication among collaborators in specific countries.

GBD Collaborator enrollment and minimum requirements

GBD Collaborators are identified and enrolled through two avenues:

Referrals: GBD Collaborators and any member of the IHME staff or others working with them on the GBD may refer colleagues or submit nominations for GBD Collaborator membership to the GBD Management Team via email at gbdsec@uw.edu. All referrals and nominations are reviewed periodically throughout the year as needed by the GBD Management Team, and anyone referred or nominated will be required to complete the relevant application and enrollment forms and meet all admissions criteria.

Applications: IHME holds a regular open call for applications from interested individuals. Each applicant must complete the GBD Collaborator application form, available at the [Call for Collaborators](#). Applicants are asked to specify areas of expertise that later determine their eligibility for contribution to certain publications and presentations about the GBD results. Applications are reviewed and approved by the GBD Management Team.

Applicants to the GBD Collaborator Network must meet all of the following minimum requirements. If the applicant does not meet the minimum requirements, they may be admitted following favorable review by GBD leadership.

1. Education or work experience in a relevant field.
2. Clearly state interest in and reason for wanting to be a collaborator.
3. Applicant is at least 18 years of age and has attained at minimum a bachelor's degree or its equivalent.
4. Applicant must be in good professional standing with all relevant licensing bodies and professional boards.
5. Applicant must not have received money from the tobacco industry in the last five years.

6. Have successfully achieved a certificate indicating satisfactory completion of the online Introduction to the GBD course training.

GBD Collaborator departure or removal from the Network

GBD Collaborators may leave the Collaborator Network at any time if they so wish. To opt out, a GBD Collaborator must submit a formal request to the GBD Management Team via email at gbdsec@uw.edu. GBD Collaborators may also be removed from the Collaborator Network at any time if they are found to:

1. Not comply with the minimum requirements.
2. Have misrepresented themselves in the application process or in other communications.
3. Have violated any of the conditions outlined in the GBD Protocol, detailed on the Collaborator Portal, or in other formal GBD communications.
4. No longer be in good professional standing with all relevant licensing bodies and professional boards.
5. Begin to receive compensation from the tobacco industry.

Collaborators shall be notified in writing of their removal.

Scientific misconduct allegations

The GBD study's success in meeting its objectives is dependent on the scientific integrity of everyone who contributes to it. Accusations of misconduct, including scientific fraud, against members are taken very seriously. Claims of misconduct should be presented in writing to gbdsec@uw.edu and accompanied by supporting documentation. Any member of the network against whom a claim has been made will be notified in writing and is responsible for refuting the allegations with supporting documentation. All documentation will be reviewed by a sub-committee of the Scientific Council. During this process, the individual(s) in question will not be included in any GBD activities including publication opportunities and webinars. If the allegation is not, or cannot, be refuted, the individual(s) in question will be removed from the network. If the allegation is refuted, the individual who made the claim will be informed in writing and, pending the outcome of further investigation, appropriate action will be taken.

Independent Advisory Committee for the GBD

In accordance with a resolution of the Board of the Institute for Health Metrics and Evaluation, the Independent Advisory Committee for the Global Burden of Disease (IAC) advises the IHME Board and the Global Burden of Disease enterprise. The terms of reference and members of the IAC can be found at the following URL: <https://www.healthdata.org/about/governance-iac>.

GBD Secretariat

The GBD Secretariat refers to staff from IHME's Global Engagement and Outreach Team and Scientific Publications Team, who together form the central point of contact for all inquiries about the GBD. Under the direct guidance of the GBD Principal Investigator, the GBD Secretariat is responsible for official communication with GBD Collaborators. The GBD Secretariat sends official correspondence, receives and responds to inquiries, maintains the GBD Collaborator database, and coordinates all aspects of enrollment and membership in the Collaborator Network. The GBD Secretariat can be contacted at gbdsec@uw.edu.

SECTION 5. ADJUDICATION

Estimation disagreements

Given the complex scope of the GBD, estimates, trends, or approaches may lead to diverging scientific opinion. Generally, these instances can be classified in the following four ways:

1. Disagreements about data sources included

The GBD and affiliated projects aim to collate all available relevant data for each indicator. Data sources with implausible patterns relative to other related sources may be excluded from the analysis. Differing opinions may arise regarding which data points should be excluded from the estimation process.

2. Differing opinions about methodological approaches

As the initial approach for estimation, the GBD utilizes the methodological approaches outlined in the most recently published GBD study. Disagreement may arise regarding methodological innovations or directions for subsequent revisions.

3. Disagreement about estimates for a particular disease, injury, risk factor, or impairment

Within a given disease, injury, risk factor, or impairment there may be disputes about the estimates of overall prevalence, by age, or by sex. These disputes normally rest at the model performance level.

4. Disagreement about a particular geographic location

In alignment with the World Health Organization, the GBD enterprise follows international standards laid down by the United Nations on naming conventions.

Differences in opinion may arise regarding estimates, data sources, and/or approaches for a particular geographic location. Since the modeling effort is focused on specific diseases, injuries, risk factors, impairments, and etiologies, the total picture for a given geographic region is dependent upon the sum total of model outputs. Data are not equally available for all diseases, injuries, risk factors, impairments, and etiologies across all geographies. Model performance, therefore, may not be the same for all diseases, injuries, risk factors, impairments, and etiologies for all locations. As a result, methodological experts and GBD Collaborators with country expertise may have differing opinions about the level of all-cause mortality for a particular location.

Adjudication process

To resolve such disagreements, steps should be pursued in the following order:

1. For any of the types of disagreement, resolution should first be sought through discussion between the individuals with differing opinions. IHME believes most differences in opinion can be managed this way, resolved through the usual process of scientific testing and iteration. This will be especially true in instances where the dispute is about the inclusion of data or of the effects of different analytic strategies, as each of the different viewpoints can often be tested and the results compared with one another. IHME expects that such discussions will take place in a spirit of respectful academic disagreement. If a proposal to change methodology or analytic approach remains unresolved, then in the interim the approach used in the most recent GBD round, or the most recently approved subsequent proposal, will prevail until final resolution is reached.
2. If the individuals with a disagreement are not able to resolve the issue through discussion, they may ask the GBD Management Team for assistance in facilitating a resolution. Barring consensus

between the individuals with differing opinions, the GBD Management Team may decide about the topic at hand. All decisions made by the GBD Management Team will be based upon the principles outlined in this protocol and will rely to the degree possible on an objective evaluation of the empirical evidence. In some cases, informed judgment will need to be applied. In such cases, the rationale for the final decision will be made explicit to all individuals formerly in dispute.

3. If steps 1 and 2 have been properly pursued and disagreement persists, any member of the GBD may request that the issue be brought to the GBD Scientific Council. This formal request should be made via email to the Council Secretary (contact information for the current Council Secretary is listed on the IHME website at the following URL: <https://www.healthdata.org/research-analysis/about-gbd/governance-scientific-council>). The GBD Scientific Council will review all such requests and make a decision.

Additional disagreements may arise pertaining to areas outside of the scientific scope of the project, such as the overall process, publication or presentation plans, or translation of results for policymakers. In this scenario, the involved individuals should attempt to jointly reach a resolution. If consensus is not reached in this way, the matter should be brought to the GBD Management Team, which will render a decision on the disagreement.

SECTION 6. GBD ANALYTIC STRATEGIES

Ongoing GBD estimation follows the methodology outlined in the most recently published GBD study, which builds upon the methodology first presented in the GBD 2010 study, unless otherwise approved by the GBD Scientific Council.

For detailed flowcharts, code, and documentation on the estimation process for a given cause or risk factor, consult the capstone paper appendices, as well as the most recent GBD round's section under "IHME Data" on the Global Health Data Exchange (<http://ghdx.healthdata.org/>).

SECTION 7. GBD LOCATION, AGE, SEX, CAUSE, AND RISK FACTOR LISTS

Locations

Over time, estimates for select countries at the subnational level may be generated as part of the overall GBD cycle, using the same methodologies and computational infrastructure as national estimates, and on the same timeline as the overall GBD effort in order to maintain internal consistency between the national and subnational results. The Scientific Council is responsible for reviewing recommendations to expand the number of geographic locations for any given cycle.

Requests to add additional geographic locations that are routinely estimated as part of GBD cycle should be submitted to the GBD Management Team via the GBD Secretariat at gbdsec@uw.edu. Requests will be formally decided upon by the GBD Scientific Council. For more information about subnational analysis, contact gbdsec@uw.edu.

Equally likely is that subnational estimates for a given country are generated using complementary methods that still meet the GBD framework criteria and accord with its principles but separate from the formal GBD cycle. In such cases when IHME is involved in the estimation, all subnational results will collectively add to national results along all dimensions. We encourage similar efforts by collaborators to do the same.

Age groups

The minimum set of age groups for which estimates are generated can be found on the IHME website in the GBD Results Tool (see “Codebook”): <http://ghdx.healthdata.org/gbd-results-tool>.

Requests to generate results for more aggregated age groups should be directed to the GBD Secretariat and will be formally decided upon by the GBD Management Team.

Sex

Calculations are made separately by sex; point estimates are reported by sex and for both sexes combined.

Causes, risk factors, impairments, and etiologies

The diseases, injuries, sequelae, risk factors, impairments, and etiologies included in the GBD are those which are most relevant for public health policymaking and for which sufficient data are available. All proposed changes to the cause, risk factor, impairments, and etiologies lists are reviewed and approved by the GBD Scientific Council. Should a circumstance arise where an individual has substantial scientific justification to propose an addition or modification to the lists, this individual should contact the GBD Management Team via the GBD Secretariat at gbdsec@uw.edu. Proposals will be formally decided upon by the GBD Scientific Council.

Diseases and injuries cause list

The cause list is organized in a hierarchical structure so that different levels of aggregation are included. The cause list is mutually exclusive and collectively exhaustive at every level of aggregation; causes not individually specified are captured in residual categories.

Risk factor list

The risk factor list is organized in a hierarchical structure so that different levels of aggregation are included. The risk factor list is mutually exclusive.

Impairments list

The GBD impairments list includes unique health states that are sequelae for multiple diseases.

Etiologies list

The GBD etiologies list includes etiologies that lead to the development of certain diseases or conditions included in the GBD.

The most up-to-date cause, risk factor, impairment, and etiology lists can be found in the GBD Results Tool: <http://ghdx.healthdata.org/gbd-results-tool>.

SECTION 8. DATA

High-quality, ongoing estimation requires a constant stream of the most up-to-date data available for a wide range of indicators. The GBD analyses aim to incorporate all relevant available data. That includes but

is not limited to data from literature, vital registration, censuses, surveys, studies, administrative systems, registries, reports, and satellite imagery.

Definitions

The GBD study has and will continue to develop a substantial data repository, including the following:

1. Input data

Input data are microdata or tabulated data obtained directly from data holders or publications. Input data have not been corrected by IHME for known bias or processed in any other way. Input data include, but are not limited to, administrative records (e.g., hospital and other health facility data), censuses, clinical trials, demographic surveillance (e.g., birth, death, migration, and cause of death data), disease registries, environmental monitoring (e.g., satellite data), epi surveillance (e.g., case notifications about a disease outbreak), financial records, surveys, and vital registration (e.g., birth and death registration data). These data are available through scientific journals, reports, online databases, books, news reports, and other resources. Not all input source types are used for all analyses. For input data, we catalog metadata for all sources including data type, key descriptions, time period over which data were collected, and region covered. We formulate a citation from the metadata, and make sure the cataloged information for all input datasets that we use is available publicly.

2. Intermediate data

These are data generated from the input data as part of the analytic process. They are the result of cleaning, geolocating, aggregating (e.g., of unit-record data), redistribution, and other operations that transform the input data into intermediate data to be used in the final modeling processes. Intermediate data are specific to our analytic process but can be useful for external audiences to provide context for interpreting final results and facilitating replication studies.

3. Final results data or estimates

The final results generated by this project – also referred to as estimates – are fully imputed datasets providing detailed information.

Literature reviews

Literature reviews for each disease, injury, and risk factor are performed on a rotating cycle based on the proliferation of literature and impact of the condition. While each condition will not receive a fully updated review every round, the rotation strategy ensures that new literature sources for all conditions are included routinely. The literature review processes use broad search terms to ensure that all relevant data are captured from a large collection of peer-reviewed scientific and medical journals. These journals are known to publish relevant data on prevalence, incidence, mortality, causes of death, risk factors, and other relevant indicators. All articles containing usable data meeting predefined standards will be downloaded, extracted, and entered into centralized databases. Reporting of systematic reviews is documented using PRISMA flow diagrams and checklists. These tools ensure that review and analysis work being done throughout the Institute is documented thoroughly, transparently, and to external standards.

Other data sources

IHME is responsible for systematically collating and cataloging data from sources such as administrative records (e.g., hospital and other health facility data), censuses, clinical trials, demographic surveillance (e.g., birth, death, migration, and cause of death data), disease registries, environmental monitoring (e.g., satellite data), epi surveillance (e.g., case notifications about a disease outbreak), financial records, surveys, and vital registration (e.g., birth and death registration data). It is expected that GBD Collaborators will actively identify gaps in data sources and help obtain access for the GBD relating to their area of expertise. GBD Collaborators are also likely to be especially helpful in identifying novel subnational or point-in-time sources, as well as providing interpretation, context, and additional information about relevant data sources that otherwise would not be readily apparent through a centralized review effort. In all cases, IHME bears responsibility for cataloging the data, ensuring that appropriate data use procedures are followed, and ultimately making available the citation source of the data used in estimates.

Citation of data sources

The GBD study is committed to citing input data sources used in the study in accordance with the GATHER guidelines (<http://gather-statement.org/>). Citations and additional metadata for input sources are available in the GBD Sources Tool (<http://ghdx.healthdata.org>). Input data sources provided by GBD Collaborators and other collaborators should be accompanied by sufficient information so that the data may be unambiguously cited.

Data access parameters

General access parameters for input data

All sources that provided data for the estimation of GBD results are cataloged as legally permissible in IHME's public data catalog, the Global Health Data Exchange ("GHDx," <http://ghdx.healthdata.org/>). Data cataloging happens on a continuous basis as legally permissible, and all GHDx entries for data sources used in GBD are made publicly available by the time GBD results are published. For many data sources, agreements with data providers inhibit direct sharing of input data with third parties, but interested parties can use the GHDx to identify the official data provider.

GHDx entries for data sources by GBD component and location can be accessed through the GBD Sources Tool (<http://ghdx.healthdata.org/>) or via the GHDx. An updated GBD Sources Tool is released concurrently with the publication of results for each round of GBD. The tool provides metadata about input sources including citations, provider and access information, and other relevant metadata about the input sources as suggested in the [Guidelines for Accurate and Transparent Health Estimates Reporting \(GATHER\)](#).

General access parameters for intermediate data

Before being used in the GBD, input data may undergo various preparation processes, such as age and sex splitting or redistribution of garbage codes. All data points are linked to a record in the GHDx which contains full metadata where legally permissible. The intermediate data for each round of GBD are released once the results for that cycle have been published, except for cases when copyright or data use agreements may prevent sharing selected input data points. The data points are made available through updated visualizations (<http://www.healthdata.org/results/data-visualizations>) released concurrent with publication of the capstone papers.

General access parameters for final GBD results

The final point estimates with 95% UI (where possible) of the GBD quantities of interest are made available to the public for non-commercial use through the Results Tool (<http://ghdx.healthdata.org/gbd-results-tool>), GHDx, and/or updated visualizations, which are released concurrently with publication of the capstone papers. Additionally, analytic code used to generate the GBD results is released for public access, as suggested by the GATHER statement.

Data access for GBD Collaborators

GBD Collaborators may be granted privileged, confidential access to preliminary versions of intermediate data, where legally permissible, as well as the point estimate results with 95% uncertainty as applicable pertaining to their enrolled area of expertise, ahead of the publication of capstone papers and the public release. This exclusive access is explicitly intended to encourage publication and the involvement of GBD Collaborators in furthering jointly held academic interests while achieving widespread dissemination of GBD results in a multitude of settings.

SECTION 9. DISSEMINATION AND POLICY USE

The GBD is a critical resource for policymakers, researchers, donors, and others to make informed decisions and guide priorities using the most current information possible. To maximize the benefit of the GBD as a global public good, IHME strongly encourages the robust production of publications that provide important insight and implications from GBD results. IHME also promotes widespread and varied methods of dissemination of the results, for example via presentations, posters, and publications.

Publications

By participating in the GBD as a GBD Collaborator, GBD Scientific Council member, GBD Management Team member, or the larger team at IHME working on the GBD, individuals are provided multiple opportunities to participate in GBD publications. All GBD Collaborators will have the opportunity to review and contribute to GBD manuscripts within their areas of expertise. Senior, Lead, and Principal Collaborators will have the opportunity to submit proposals to lead GBD manuscript development. All paper proposals must be submitted to and approved by IHME before potential authors begin working on them.

All authors must conform to the criteria as specified by the [International Committee of Medical Journal Editors](#) (ICMJE) and the individual journals to which the publications are submitted.

Details on specific publications processes are provided in separate policy documents, available on the GBD Collaborator Portal. Questions on this should be directed to gbdsec@uw.edu.

Capstone papers

Capstone papers accompany the initial release of comprehensive estimates for a new GBD round. The capstone papers are circulated to the entire Collaborator Network for review and are published at regular intervals.

The GBD PI will oversee the analysis and writing process for these papers. IHME will provide support for the writing process in terms of data preparation, writing and editing, figure and table development, and process management.

Capstone papers are published following standard peer-review and revisions.

Other papers

IHME highly encourages the publication of a robust set of additional manuscripts that examine:

1. The results and trends for all-cause mortality and specific diseases, injuries, risk factors, impairments, or etiologies
2. The results and trends for a country or set of countries
3. The results of subnational analyses
4. The results and trends for a specific age group
5. Innovations in methodology
6. Custom analyses using GBD estimates

The writing teams for these papers may be led by Senior, Lead, and Principal Collaborators or a senior staff member designated by the GBD Management Team. All GBD papers must be formally registered with IHME prior to beginning writing to avoid duplicate publication and to ensure equitable opportunities. Additionally, all GBD manuscripts must be circulated to members of the GBD Collaborator Network with related expertise prior to journal submission. Details of the procedure for leading a publication can be found on the GBD Collaborator Portal.

Authorship

Criteria for GBD publications

The GBD conforms to the principles of authorship, disclosure, and scientific integrity as outlined in the requirements of the individual peer-reviewed journal to which a given publication is submitted, as well as to the overall criteria of the [International Committee of Medical Journal Editors](#) (ICMJE).

To qualify for authorship, potential authors must meet the following criteria:

1. Contribute substantially to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.
2. Draft the work or review it critically for important intellectual content.
3. Give final approval of the version of the manuscript to be submitted.
4. Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
5. Satisfy any journal-specific criteria.

Some paper may have co-authors from outside the formal Collaborator Network. They must meet the same authorship criteria, be identified by the senior or lead author, and register their relevant personal details with IHME in advance of submission.

GBD papers may indicate authors' contributions using CRediT taxonomy (by category) toward individual papers in the supplementary appendices. This accurately and equitably recognizes the many varied contributions of all authors.

Specific authorship processes are available on the GBD Collaborator Portal.

Order of names in author lists

GBD papers must be published using group (also known as corporate) authorship (e.g., GBD 2021 Diabetes Collaborators). Individual authors are typically listed at the end of paper or in a supplemental appendix and are credited in PubMed in recognition of the many diverse contributions to the research project. Combination of individual names and a group/corporate author name in the byline of a publication is not permitted.

Authors are typically listed in alphabetical order, with non-alphabetical listing reserved for select authors at the beginning and end of the author list in recognition of their role in leading the paper. The non-alphabetical designations are selected by the writing team lead.

GBD for policy guidance

Engaging decision-makers

IHME encourages collaborators to engage with decision-makers in their countries and/or focus area(s) around key findings from the GBD that may be applicable to policymaking and priority setting in various contexts.

Policy documents

Collaborators may utilize published GBD findings to inform policy dialogues or contribute to policy-relevant documents (such as reports, briefs, and presentations) that are tailored to decision-makers in their country and/or focus area. If collaborators wish to utilize unpublished GBD findings for policy purposes, they must contact gbdsec@uw.edu.

IHME may help produce materials for non-academic audiences, such as policymakers, nonprofits, donors, and other decision-makers, that can be helpful to collaborators as they engage with decision-makers. Materials may include reports, briefs, graphic illustrations, videos, and website content. These materials may be jointly produced with other stakeholders or collaborators. They may summarize results overall or for a specific region, disease, injury, or risk factor, or highlight select trends that are relevant for policymakers in a given health area or geographic region. There will be no specific author attribution on these materials; instead, they will be listed with corporate authorship and will explicitly reference the GBD and/or affiliated projects. Individuals who play a significant role in the content creation and assembly may be noted in the acknowledgments, where appropriate.

To facilitate joint learning across the Collaborator Network and beyond, IHME encourages collaborators to share other ways that GBD is influencing decision-making with IHME by emailing gbdsec@uw.edu. IHME may include this information on its [Acting on Data](#) blog and/or may invite the collaborator(s) to speak at a policy-focused event. Using Preliminary Results

Preliminary results: In select cases, and only with the permission of the GBD Management Team, collaborators may be allowed to use preliminary (not-yet-published) GBD results in peer reviewed publications, as well as for presentations and posters. In cases where a request to use preliminary results is granted, each slide in the presentation or section of the poster must be labeled with:

“Preliminary results from the Global Burden of Disease. Source: Institute for Health Metrics and Evaluation, <http://www.healthdata.org/gbd>.”

Published results: Presentations and posters of already published methods and results can be made at any time.

Accessing preliminary results

All requests to use preliminary results should be formally submitted to the GBD Management Team at gbdsec@uw.edu. Such requests are generally approved if the preliminary results will be used for internal policy or priority setting purposes.

GBD acknowledgment

All publications and presentations – including those that use data derived from the GBD effort and those that are a product of individual GBD Collaborators using data as part of their privileged access to GBD data and results – must include the following acknowledgement:

“This research has been conducted as part of the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD), coordinated by the Institute for Health Metrics and Evaluation. The GBD was partially funded by the Bill & Melinda Gates Foundation; the funders had no role in the study design, data analysis, data interpretation, or writing of the report.”

Policy acknowledgment

As an institute of the University of Washington (UW), the Institute for Health Metrics and Evaluation (IHME) is subject to the policies and procedures of the UW. Accordingly, the GBD shall be conducted in full compliance with UW policies and procedures and applicable federal, state, and local laws. The UW endorses and supports academic freedom.

Use of insignia, photos, trademarks, and logo

IHME’s insignia, photos, trademarks, and logos may only be used by separate and specific written agreement. If desiring to do so, please contact gbdsec@healthmetrics.org.

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