Protocol for the
Global Burden of Diseases, Injuries, and Risk Factors Study (GBD)

Institute for Health Metrics and Evaluation

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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 Study (GBD) 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: www.ihmeuw.org/gbdprotocol.

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, as well as applicable federal, state, and local laws.

Purpose and goals of the GBD

The GBD is an approach to global descriptive epidemiology. It is a systematic, scientific effort to quantify the comparative magnitude of health loss due to diseases, injuries, and risk factors by age, sex, and geographies for specific points in time. The GBD is led by IHME at the University of Washington. Comparison is at the heart of the GBD approach. For decision-makers, health-sector leaders, researchers, and informed citizens, the GBD provides an opportunity to see the big picture, to compare diseases, injuries, and risk factors, and to understand in a given place, time, and age-sex group, what are the most important contributors to health loss. 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 ill health and disability.

The GBD produces regular estimates of all-cause mortality, deaths by cause, years of life lost due to premature mortality (YLLs), years lived with disability (YLDs), and disability-adjusted life years (DALYs) for a cause list. The cause list is agreed annually by the Scientific Council. The critical milestones for ongoing estimation include regular updates to the GBD estimates, referred to as the GBD round. For each round, the entire time series back to 1990 will be 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 will provide cutting-edge and timely results through scientific papers, policy reports, web content, and interactive visualizations. The GBD will use and build upon the infrastructure of methodology, datasets, and tools that were outlined in the most recently published GBD Study which builds upon the methodology first presented in the GBD 2010 Study\(^7\)\(^8\). Any proposed updates to methodology or cause lists will be approved by a GBD Scientific Council, as detailed on page 11.

The GBD engages a network of individual collaborators with expertise on all-cause mortality; specific diseases, injuries, risk factors, and impairments; and country-specific epidemiology. GBD Collaborators are selected through an open call and referrals. There are many different ways for GBD Collaborators to contribute to the GBD Study. GBD Collaborators indicate their own areas of expertise. Based upon their ascribed area(s) of expertise, GBD Collaborators are then invited to collaborate in the following ways:

- Assess data sources being used and suggest new data sources, including those from literature, surveys, administrative data, hospital data, registries, and other related sources
- Provide data of their own to integrate into the analyses
• Critique results from the estimation
• Suggest new causes, risk factors, and risk-outcome pairs
• Give feedback on covariates and modeling approaches
• Provide critique and feedback on manuscripts
• Contribute to papers and participate as authors
• Carry out related analyses using GBD data
• Disseminate results at conferences, workshops, and other avenues of interest
• Participate in media outreach
• Refer colleagues as collaborators
• Jointly pursue funding opportunities of mutual interest
• Take part in select training opportunities and be alerted of opportunities to expand the impact of the GBD through conferences, networks, and calls for abstracts

The time commitment for GBD Collaborators is flexible. GBD Collaborators are given the opportunity to participate in all of the above, 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.
SECTION 2. KEY PRINCIPLES AND ASSUMPTIONS

The GBD is embedded with key principles and assumptions 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 and assumptions. Any changes to the principles and assumptions will be presented to and discussed by the GBD Scientific Council; accepted changes will be added as a modification to this protocol.

Comprehensive comparisons

1. The GBD cause list is a set of mutually exclusive and collectively exhaustive hierarchical categories.
2. Results from the GBD are intended to facilitate comparison.
3. 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.

Uncertainty

1. 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).
2. The GBD estimates uncertainty distributions for each quantity and reports various metrics of uncertainty, such as 95% UI.

Internal consistency

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

Iterative approach to estimation

1. New data and methodological innovation lead to revision of estimates.
2. 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.
Data synthesis principles

1. All available relevant sources of data for a given disease, injury, and risk factor and for all-cause mortality should be identified.
2. For all data sources identified, the sampling method, case definitions, and potential for bias should be assessed.
3. For cause of death data, variants of the ICD should be mapped and garbage codes are redistributed.
4. 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.
5. 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.
6. 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.
7. All appropriate data should be synthesized using statistical methods that can handle both sampling and non-sampling error.
8. The statistical methods employed should improve predictions where data are sparse by allowing for use of covariates and by borrowing strength across time or geography.
9. All estimates should be generated with 1,000 (or more) draws of the quantity of interest from the posterior distribution.
10. Where possible, validity of the statistical methods should be demonstrated by using out-of-sample prediction.
SECTION 3. KEY PRODUCTS

The GBD produces comprehensive estimates of burden of diseases, injuries, and risk factors by country, year, age, and sex. For more information on the causes, ages, and other dimensions used by GBD, refer to “Section 7. GBD Country list, age and sex groups, and cause lists” starting on page 17. The GBD releases the point estimates and 95% UI by country, age, and sex for the at least the following:

- All-cause mortality rates
- Deaths by cause
- Years of life lost due to premature mortality (YLLs) by cause
- Years lived with disability (YLDs) by cause
- Years lived with disability (YLDs) by sequela
- Disability-adjusted life years (DALYs) by cause
- Prevalence of exposure to each risk factor
- Relative risks of mortality for each risk-outcome pair
- Deaths attributable to the independent effects of risk factors and clusters of risk factors
- YLLs attributable to the independent effects of risk factors and clusters of risk factors
- YLDs attributable to the independent effects of risk factors and clusters of risk factors
- DALYs attributable to the independent effects of risk factors and clusters of risk factors
- Healthy life expectancy (HALE)

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

- Publications in peer reviewed journals
- Publications aimed at policymakers and other audiences
- Presentations detailing the results and methodology
- Datasets available for download or upon request, as outlined in “Section 8. Data” on page 19

The exact timing and release of results are determined by the GBD Management Team under the leadership of the GBD Study Principal Investigator (PI).
SECTION 4. GBD ROLES AND RESPONSIBILITIES

The GBD includes a Scientific Council, a Management Team, a Core Analytic Team, and a robust network of GBD Collaborators working together to produce the most accurate, up-to-date, and comparable estimates of burden worldwide.

The entire GBD Study is managed by the GBD Management Team under the leadership of the Principal Investigator (PI), Dr. Christopher Murray. The GBD Management Team also leads the analytic development and direction of the GBD Study. It is staffed and supported by IHME. In addition, an Independent Advisory Committee chaired by Dr. Peter Piot advises the IHME Board and the GBD Study.

**GBD Scientific Council**

The GBD Scientific Council is a mechanism for key scientific decision-making internal to the GBD; it is not a substitute for peer-review of publications nor for periodic views from independent groups not involved in the GBD. The Council Chair for the GBD Scientific Council is Dr. Christopher Murray, and the Council is comprised of leading experts in fields relating to the GBD. This GBD Scientific Council provides direct oversight 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 published methods.
- Deciding whether to incorporate data into the estimates that become available after the data cutoff deadline for that particular round.
- Adjudicating disputes on: estimates for mortality, specific diseases, injuries, risk factors, impairments, or geographies; data sources included; methodological approaches.
- Reviewing and voting on proposed modifications to the cause lists and ranking cause lists.
- Reviewing and voting on modifications to the list of covariates available for analyses.
- Reviewing and voting on changes to the existing published set of risk-outcome pairs used for measuring attributable burden of risk factors or risk factor clusters.
- Discussing recommendations from outside groups.
- 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 3-year renewable terms. Terms may be truncated for any Council members inactive for greater than a 6-month period. In selecting Council members, the Council Chair seeks to reflect the diversity of expertise in diseases, injuries, risk factors, countries, or related methodology across the membership of the GBD, including senior members of the Core Analytic Team. Referrals and nominations for Council members are welcome and should be sent to the Council Secretary. The Council Secretary is selected by the Council Chair. The
current GBD Scientific Council members and the Council Secretary are listed on the IHME website at the following URL: http://www.healthdata.org/gbd/about/scientific-council.

The Council Chair convenes regular Council meetings, as needed, with the Council Secretary facilitating its proceedings. The meetings are attended by Council members, a subset of individuals from the GBD Management Team as appropriate, the Council Secretary, as well as other GBD Collaborators, Core Analytic Team members, and related IHME staff, as needed. Council members who are unable to attend have 72 hours to provide feedback or vote by email. Majority vote prevails. All Council members are eligible to vote. Votes are collected at the meeting as well as accepted by email for 72-hours following the meeting. The Council Chair is responsible for producing the agenda for each Council meeting. Agenda items are made known to all Council members and other individuals participating in the meeting at least 48 hours prior to the meeting taking place. Decisions of the GBD Scientific Council are posted on the IHME website at the following URL: http://www.healthdata.org/sites/default/files/files/Projects/GBD/GBD_Scientific_Council_Decisions.pdf

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 members of the GBD Management Team and the designated point of contact are listed on the IHME website at the following URL: http://www.healthdata.org/gbd/about/management-team. The GBD Management Team is responsible for overseeing the GBD Core Analytic Team and for reviewing and approving the final GBD results.

GBD Core Analytic Team

Under the direct guidance of the GBD PI and the GBD Management Team, the GBD Core Analytic Team carries out data seeking, management, and estimation for the GBD. Core Analytic Team members include individuals working on one or more of the following key areas:

1. **GBD Senior Core Analytic leadership**
   The GBD Senior Core Analytic Leadership includes, at minimum, the institutionally designated faculty leads for the mortality, causes of death, non-fatal health outcomes, and risk factor estimation areas. Appointed by the GBD PI, the Senior Leadership provide direct oversight to the estimation.

2. **Production of estimates**
   A team of individuals (including faculty, fellows, researchers, and other IHME staff, among others) is responsible for applying the GBD methods to calculate all results for the study, including those for all-cause mortality, cause-specific mortality, cause-specific morbidity, risk factors, and healthy life expectancy. These Core Analytic Team members are primarily responsible for identifying data sources used, applying the relevant methodologies, systematically documenting sources and approaches, and producing and vetting results for each GBD round.
3. **Data incorporation**
   A team of individuals (including analysts, reviewers and IHME staff, among others) is responsible for central database management. This includes seeking data and managing core central datasets and databases, such as the covariates database, cause of death database, epidemiology database, risk factor database, hospital and outpatient datasets, cancer and other disease registries, household surveys, and many other data source types. It also includes conducting systematic reviews of the published and unpublished literature, as outlined in “Section 8. Data” on page 19, to support the ongoing data needs.

4. **Development and implementation of central computation**
   A team of individuals (including analysts and IHME staff, among others) is responsible for managing, implementing, and developing the complex central machinery for computation.

5. **Central integration**
   A team of individuals is responsible for ensuring the timely actualization of the GBD production process.

Core Analytic Team members involved in modeling may additionally work with GBD Collaborators as the primary point of contact to solicit feedback and to jointly test analytic suggestions. When appropriate, together the Core Analytic Team members and GBD Collaborators present any proposed changes to methodology to the GBD Scientific Council for their guidance and approval/disapproval as determined by a majority vote.

Core Analytic Team members are designated by the GBD Management Team. Some members are designated to work on specific diseases, injuries, risk factors, and impairments and be paired with GBD Collaborators accordingly. Where GBD Collaborators for specific countries have been identified, Core Analytic Team members also are specifically assigned to work with these collaborators in reviewing country-specific estimates.

**GBD Collaborators**

IHME engages a large network of individual collaborators with specialties in various topic areas. Individuals are appointed the title of “GBD Collaborator” for a particular area of expertise; GBD Collaborators may be enrolled in more than one area of expertise. GBD Collaborators are comprised of specialists in particular topic areas related to the GBD and their expertise generally falls into one of three categories:

1) Expertise on all-cause mortality
2) Expertise on a particular disease, injury, risk factor, or impairment
3) Expertise on the epidemiology for a specific country

More details specific to each of these types of collaborators are provided later in this section.

**Role of the GBD Collaborator**

The role of the GBD Collaborator is to review and provide timely feedback and suggestions related to interpretation of GBD results, data sources, and/or methodological approaches pertaining to their area of enrolled expertise. GBD Collaborators work together with Core Analytic Team members, sometimes
aided by the help of IHME staff. GBD Collaborators can contribute to the GBD in a range of ways, including, but not limited to:

1. Providing expertise, access to, and feedback on the data used for:
   a. all-cause mortality estimation
   b. the analyses of specific diseases, injuries, risk factors, or impairments
   c. country-specific results
2. Providing expertise and feedback on the validity and interpretation of results generated for:
   a. the all-cause mortality envelope
   b. specific diseases, injuries, risk factors, or impairments
   c. a specific country
3. Helping to generate subnational estimates for specific countries that are consistent with the overall global and national estimates produced annually.
4. Translating the results of the GBD, in order to maximize policy uptake and action. For example:
   a. speaking to the media about results
   b. giving presentations on the GBD to key public health stakeholders and/or academic audiences
   c. working with IHME to develop policy-relevant materials based on GBD findings
5. Participating in periodic learning opportunities about the GBD approach and specific components of the GBD
6. Co-authoring a variety of manuscripts using the GBD methods and results.

In cases where the GBD Collaborator and Core Analytic Team members jointly feel that substantial methodological updates are required to achieve the highest quality results, those suggestions are formally presented by the GBD Collaborator and the Core Analytic Team member to the GBD Scientific Council for their review and approval. Legitimate scientific debate may arise across different mortality, disease, injury, risk factor, and country collaborators; disagreements regarding any aspects of the analyses should be addressed following the protocol outlined in “Section 5. Adjudication” on page 14. 

**GBD Collaborator enrollment**

GBD Collaborators are identified and enrolled through two avenues:

1. **Core Analytic Team members, GBD researchers, and other GBD collaborators 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.**
2. **IHME holds a regular open call for applications from interested individuals. Each applicant must submit a curriculum vitae that demonstrates the specific area(s) of expertise for which he/she is applying. Collaborators are asked to specify areas of expertise that later determine their**
eligibility for contribution to certain publications and presentations about the GBD results. Open call applications are reviewed and approved by the GBD Management Team.

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.

Specific types of GBD Collaborators

The following provides more detail on the roles for each of the specific type of GBD Collaborator:

1. **GBD Collaborators on all-cause mortality**

   GBD Collaborators on all-cause mortality are consulted on their specific area of contribution, ranging from general methodological approaches to country- or age-specific mortality expertise. GBD Collaborators on all-cause mortality work with the Core Analytic Team member(s) estimating the all-cause mortality envelope to review the data sources, model input data, and penultimate all-cause mortality estimates. They can offer feedback and suggestions and may work with the Core Analytic Team member(s) to jointly develop any alternative all-cause mortality modelling approaches if necessary.

2. **GBD Collaborators on a particular disease, injury, risk factor, and/or impairment**

   GBD Collaborators on a particular disease, injury, risk factor, or impairment are consulted on their specific area of contribution. Each GBD Collaborator is paired with the Core Analytic Team member(s) responsible for modeling that area. Core Analytic Team members update the individual models for each disease, injury, risk factor, and impairment and consult with relevant GBD Collaborators regarding data sources, modeling approaches, and iterative results. Once individual models have been completed and central computation processes have been run, IHME provides GBD Collaborators with penultimate corrected results for their area of contribution. The GBD Collaborators can then review and offer feedback and suggestions and may work with the Core Analytic Team member(s) to jointly develop any alternative modeling approaches if necessary.

3. **GBD Collaborators on a particular country**

   GBD Collaborators on a particular country are consulted on the high-level indicators (deaths, YLLs, YLDs, prevalence, DALYs, and burden attributable to risk factors) for their country of expertise and on data. Core Analytic Team members consult with relevant GBD Collaborators regarding modeling approaches and iterative results for a particular cause, injury, or risk factor within each country of expertise. Once individual models have been completed and central computation processes have been run, IHME provides GBD Collaborators with the crude data, model input data, and penultimate corrected results for their country of expertise. The GBD Collaborators with country expertise can then review and offer feedback and suggestions and may work with the Core Analytic Team member(s) to jointly develop any alternative modelling approaches if necessary.
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, with a specific mandate to:

i. Review the strengths and weaknesses of different methods and results.

ii. 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.

iii. Advise the IHME Board about opportunities for strengthening collaboration and ownership of the GBD.

iv. Engage in dialogue with other efforts on global health estimates.

v. Advise the IHME Board on guidelines for access to and use of the GBD databases globally, regionally, and nationally.

vi. Report annually to the IHME Board.

The inaugural Chair of the Independent Advisory Committee for the Global Burden of Disease is Dr. Peter Piot, with an initial appointment of five years. The Chair is responsible for nominating members with the Executive Committee of the IHME Board then appointing members for renewable terms of up to three years. The King Baudouin Foundation formally hosts and facilitates the convening of the Independent Advisory Committee. The members of the IAC can be found at the following URL.

http://www.healthdata.org/gbd/about/independent-advisory.
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 aims 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 geography**
   Differences in opinion may arise regarding estimates, data sources, and/or approaches for a particular country or region. Since the modeling effort is focused on specific diseases, injuries, risk factors, and impairments, the total picture for a given geographic region is dependent upon the sum total model outputs. Data are not equally available for all diseases, injuries, risk factors, and impairments across all geographies. Model performance, therefore, may not be the same for all diseases, injuries, risk factors, and impairments for all countries. 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 country.

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 the majority of differences in opinion can be managed in 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 GBD 2013
Study, 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 to render a decision about the particular 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 still 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: [http://www.healthdata.org/gbd/about/scientific-council](http://www.healthdata.org/gbd/about/scientific-council)). The GBD Scientific Council will review all such requests and make a determination.

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. ESTIMATION FLOW

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\(^1\)–\(^8\), unless otherwise approved by the GBD Scientific Council. The flowchart below illustrates the flow of the key components of the GBD estimation process, including:

- incorporation of appropriate covariates (1)
- all-cause mortality estimation (2-4)
- causes of death estimation (5-9)
- estimation of disease sequelae prevalence, incidence, and duration (10-11)
- cross-validation of impairment levels (12)
- analysis of the nature and external cause of injury (13)
- assignment of disability weights for health states (14)
- assignment of severity distributions for the main disabling conditions (15)
- simulation of comorbidity (16)
- estimation of healthy life expectancy (17)
- computation of YLLs, YLDs, and DALYs from diseases and injuries with uncertainty (18a-18c)
- risk factor estimation (19-21)
- computation of YLLS, YLDs, and DALYS attributable to risk factors (22a-22c)
SECTION 7. GBD COUNTRY LIST, AGE AND SEX GROUPS, AND CAUSE LISTS

Countries

Point estimates with 95% UI are released for a set of countries, the list of which can be found on the IHME website at the following URL: http://www.healthdata.org/sites/default/files/files/Projects/GBD/GBDRegions_countries.pdf

Requests to add additional geographies should be directed to the Secretary of the GBD Scientific Council. Over time, estimates at the subnational level may be generated for a number of countries, pending mutual interest, availability of data, and identification of funding mechanisms to support this work.

Age groups

The minimum set of age groups for which estimates are generated can be found on the IHME website at the following URL: http://www.healthdata.org/sites/default/files/files/Projects/GBD/GBDAges.pdf.

Requests to generate results for more aggregated age groups should be directed to the GBD Management Team.

Sex

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

Cause and risk factor lists

Extensive cause lists have been developed detailing the diseases and injuries, sequelae, and risk factors used in the GBD. The sections below provide an overview of the cause lists for diseases and injuries and for risk factors. Should a circumstance arise where an individual has substantial scientific justification to propose an addition or modification to one of the cause lists, this individual should contact the GBD Management Team for consultation. Any changes that are mutually agreed upon by the individual and the GBD Management Team must be presented to the GBD Scientific Council for approval.

Diseases and injuries cause list

The GBD cause list has been designed to include the diseases, injuries, and sequelae that are most relevant for public health policymaking. 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.

The most up-to-date cause list can be found on the IHME website at the following URL: http://www.healthdata.org/sites/default/files/files/Projects/GBD/GBDcause_list.pdf. Revisions to the cause list will be based on causes not currently included where there is substantial health care provider
demand and expenditure. All proposed changes to the cause list are reviewed and approved or rejected by the GBD Scientific Council.

Risk factor list

The GBD risk factor list has been designed to include the risk factors that are most relevant for public health policymaking. 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 and collectively exhaustive at every level of aggregation; risk factors not individually specified are captured in residual categories.

The most up-to-date risk factor list can be found on the IHME website at the following URL: http://www.healthdata.org/sites/default/files/files/Projects/GBD/GBDriskfactor_list.pdf. All proposed changes to the risk factor list are reviewed and approved by the GBD Scientific Council.
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. This necessitates continuous extraction of studies from the literature and the addition of key data sources throughout the GBD.

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

1. **Crude data**
   Crude data include the raw data as released by source, identified through both literature reviews and other key centrally collected sources.

2. **Model input data points**
   In order to be included in the GBD, data may need to be adjusted to match the format and quality necessary. For example, data presented in different age aggregations may need to be split into the age groups used for modeling in the GBD. Similarly, any garbage codes included in cause of death data are redistributed following previously published methods for redistribution.

3. **Final results**
   Final results include the point estimates and 95% uncertainty intervals, where appropriate, for the quantities of interest detailed in “Section 3. Key Products” on page 7.

To maximize the use of this resource as a global public good, crude data, model input data points, and final results will be made available where legally permissible for non-commercial use of the data.

**Crude data sources**
The GBD Study is committed to citing crude data sources used in the study. The Core Analytical Team is responsible for producing citation lists for the capstone papers and other centralized papers produced by the Study; crude data sources provided by GBD Collaborators and other collaborators should be accompanied by sufficient information so that the data may be unambiguously cited.

**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 iteration, our rotation strategy ensures that new literature sources for all conditions are included on a routine basis. Our literature review processes uses 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 useable data meeting predefined standards will be downloaded, extracted, and entered into centralized databases. Core Analytic Team members will be able to access the data pertinent to the disease, injury, risk factor, or impairment they are modeling through the database interface as well as identify and exclude outlier studies.
Other crude data sources

The Core Analytic Team is responsible for systematically collating and cataloguing data from sources such as vital registration, hospital data, disease registry data (i.e., from cancer registries and registries for other diseases), surveillance systems, censuses, and large-scale household surveys. It is expected that GBD Collaborators are crucial to identifying gaps in data sources and helping to attain access for the GBD relating to locally specific sources of this nature in particular. GBD Collaborators are also likely to be especially helpful in identifying novel subnational or point-in-time sources that otherwise would not be readily apparent through a centralized review effort. In all cases, IHME bears responsibility for cataloguing the data, ensuring that appropriate data use procedures are followed, and ultimately making available the citation source of the data used in estimates.

Data access parameters

General access parameters for crude data

All sources that provided data for the estimation of GBD estimates are catalogued as legally permissible in IHME’s public data catalog, the Global Health Data Exchange (GHDx) found at the following URL: http://ghdx.healthdata.org/. Anyone that is looking for data on a particular cause, risk, or country can search the GHDx and retrieve relevant crude data sources. Information provided includes: title; geography and period of time covered; contributors; a summary description of the dataset; and information about the data provider where interested parties can inquire about data access. Data cataloguing happens on a continuous basis as legally permissible, and all entries are expected to be made publicly available once the results have been published.

General access parameters for model input data points

Before being used in the GBD, crude data may undergo various preparation processes, such as age and sex splitting or redistribution of garbage codes. The resulting model input data points that are used for each GBD annual analysis are shared, where legally permissible. These data points may have originated in peer-reviewed papers, publications, or reports, or were calculated from crude data. All data points are linked to the full metadata for the crude data source in the GHDx where legally permissible. The model input data points are expected to be released once the results have been published, except for cases when copyright or data use agreements may prevent us from sharing selected input data points.

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 in two stages. First, updated visualization tools are released concurrent with publication of the capstone papers. Data will not yet be made available to the public for download to allow members of the GBD sufficient time to submit manuscripts using the updated results to which they have contributed. The tabular form of the data is to be released to the public once the results have been published.

Data access for GBD Collaborators

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

By participating in the GBD as a GBD Collaborator, GBD Scientific Council member, GBD Management Team member, and/or Core Analytic Team member, individuals are provided multiple opportunities for authorship on GBD publications.

The following sections provide more details specific to the process by which different types of publications will be created as well as specific criteria for authorship. In all cases, eligible 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.

**Negotiated publication arrangements with journals**

**Capstone papers presenting overall estimates**

Following on the demand and interest generated by the triple issue in *The Lancet* devoted entirely to the GBD 2010, IHME and *The Lancet* have entered a strategic partnership to produce a similar set of capstone papers for future iterations of the GBD, should manuscripts be accepted through the normal peer review process of *The Lancet*. *The Lancet* aims to produce a set of capstone papers that will present the updated estimates, describe any methodological innovations, and highlight a selection of particularly policy-relevant topics.

*The Lancet* will publish a set of capstone papers providing a detailed analysis of the following indicators, which are subject to change:

1. all-cause mortality and causes of death
2. non-fatal health outcomes
3. DALYs and HALE
4. risk factors

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.

**Regular updates of disease-specific, risk factor-specific, and country-specific papers published as part of negotiated arrangements with journals**

In addition to the capstone papers presenting overall estimates, IHME has negotiated the regular publication of updates on targeted causes, risk factors, and country-specific GBD results with a number of key public health and epidemiological journals. For each of these papers, a writing committee will be
formed. Coordinating Authors named by the GBD PI will drive the overall writing process for the regular update papers.

As appropriate, IHME will provide support for the writing process in terms of data preparation, writing and editing, figure and table development, and process management.

**Other papers**

In addition to the negotiated journal publications outlined in the section above, IHME highly encourages the publication of a robust set of additional manuscripts that examine more closely:

1. the results and trends for all-cause mortality and specific diseases, injuries, or risk factors
2. data sources, lay descriptions, or methodological enhancements for disability weights
3. innovations in methodology used

These manuscripts can be spearheaded either by GBD Collaborators or by GBD Core Analytic Team members.

**Timeline for publication of other papers**

The GBD capstone papers will typically be published before any of the regular update papers or other papers. Once a capstone paper is published, the data for that capstone paper are also published and made available to the public. Any GBD Collaborator may draft a paper about their enrolled area of expertise using published data. In all cases and at all times, the GBD Management Team must be formally notified in writing of all publications utilizing GBD data, methods, and/or results. While a GBD Collaborator may take the initiative to draft a paper on their own, IHME encourages continued collaboration within the GBD Collaborator Network and therefore suggests that if a GBD Collaborator would like to collaborate on the development of a publication with other GBD Collaborators or Core Analytic Team members, they submit a publication plan to the GBD Management Team. The GBD Management Team in concert with the GBD PI will review proposals on an ad-hoc basis to determine the feasibility of a proposed publication collaboration, and if approved, the nature and extent of the collaboration. For example, in some cases, a paper may require novel analyses to be conducted by IHME to produce the desired results. These analyses may or may not be feasible given competing priorities, including capstone paper timelines, workload, and computational priorities. The GBD Management Team will determine if/when such analyses are feasible. In select cases, IHME may provide support for the manuscript preparation in terms of writing, editing, and process management.

**Formation of writing committees for GBD paper production**

To ensure the timely publication of rigorously generated results and to provide GBD Collaborators with multiple opportunities to engage with the work, the GBD PI will look for opportunities to organize the manuscript writing effort through writing committees. This writing committee process could apply to any of the following categories of publications:

- Capstone papers presenting overall estimates or all-cause mortality
- Regular updates of disease-specific, risk factor-specific, and country-specific papers published as part of negotiated arrangements with journals
• Other papers

This work will be conducted as follows:

**Coordinating Authors**

The GBD PI will select one or several Coordinating Authors from within the GBD Collaboration. Coordinating Authors will be required to:

- Drive the overall content, analysis, paper writing, and figure selection
- Provide guidance on key messages
- Oversee development of all methods and generation of all results for the paper
- Choose the members of and supervise the work of the Writing Committee
- Invite individuals to participate in the process as Collaborating Authors

**Writing Committee members**

The Writing Committee will comprise a small number of individuals who will be responsible for producing the content of the paper with assistance from additional Collaborating Authors, where appropriate.

**Collaborating Authors**

To be considered as a Collaborating Author, individuals will be required to do one or more of the following:

- Participate in overall scientific decision-making for the GBD study
- Participate in overall data-seeking, management, and estimation for the GBD study
- Contribute intellectually to the computation or estimation process or to novel methods for estimation related specifically to the topic of the paper in question
- Contribute to data identification and collection related specifically to the topic of the paper in question
- Contribute to methods development and analysis related specifically to the topic of the paper in question
- Provide cause-specific, risk-specific, location-specific, and/or methodological feedback and approval for the paper
- Participate in drafting or revising the paper
- Assist in responding to comments from peer reviewers regarding their particular area of expertise

Collaborating Authors will be solicited through outreach to GBD Collaborators who have indicated (via their completed GBD Collaborator survey) their expertise in the topic of the publication. In addition to relevant GBD Collaborators, Collaborating Authors will include all Writing Committee members, as well as Core Analytic Team members, Scientific Council members, and other individuals who meet the above criteria.

**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. All authors listed on
publications from the GBD study should meet those criteria. All eligible authors will need to submit an authorship form in accordance with the journal regulations in order to be included. The title of Collaborating Author assumes a level of engagement in the GBD process, whether by contributing to data identification and collection, methods development and analysis, or participating in the writing or revision process for manuscripts. Periodically, the GBD PI and GBD Management Team will jointly assess Collaborating Authors’ levels of engagement in order to determine authorship eligibility. Note that journals vary in their standards for authorship; some journals may allow fewer authors than others. Authors may choose to opt out of authorship at any point in time prior to acceptance of the submitted manuscript. The GBD PI, in consultation with the GBD Management Team, will decide the final authorship eligibility and order and will resolve any disagreements over authorship criteria.

Authorship criteria for other papers that become joint publication collaborations between a GBD Collaborator and IHME will be determined by the same principles outlined above. The GBD PI, in consultation with the GBD Collaborator making the proposal, may or may not choose to establish a writing committee with Coordinating and Collaborating Authors.

**GBD citation**

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 citation:

“This research has been conducted as part of the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD), led 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.”
SECTION 10. POLICY REPORTS AND PRESENTATIONS

In addition to peer-reviewed academic publications, IHME also strongly encourages the robust production of policy materials, posters, and presentations that provide important insight and implications from the GBD data.

Policy materials
IHME will produce materials intended to reach non-academic audiences such as policymakers and donors. The materials will include policy reports, policy briefs, graphic illustrations, videos, and website content. Prior to the public release of the GBD data, these materials will be produced by IHME and may be jointly produced with other stakeholders. They may summarize results overall or for a specific region, disease, injury, or risk factor. From the GBD 2010 Study, a good example of this is the publication titled “The Global Burden of Disease: Generating Evidence, Guiding Policy”. During this period there will be no specific author attribution on these materials. Instead, they will be listed with corporate authorship and will explicitly reference the GBD. Individuals who play a significant role in the content creation and assembly will be noted in the acknowledgments, where appropriate.

Posters
In select cases – and only with the permission of the GBD Management Team – conference poster abstracts may be allowed to use preliminary (not-yet published) GBD results. All requests to use preliminary results should be formally submitted to the GBD Management Team at gbdsec@uw.edu. In cases where a request to use preliminary results is granted, approved posters must be labeled with:


In general, authorship on the abstract should follow the same principles as described above for the appropriate topic-specific subcategory of peer-reviewed publications.

Presentations
Presentations of already published methodology can be made at any time; however, in select cases – and only with the permission of the GBD Management Team – presentations may be allowed to use preliminary (not-yet published) GBD results. All requests to use preliminary results should be formally submitted to the GBD Management Team at gbdsec@uw.edu. In cases where a request to use preliminary results is granted, each slide in the presentation must be labeled with:


and the presentation must include the full study citation listed on page 25 in “Section 9. Publications.”
REFERENCES


