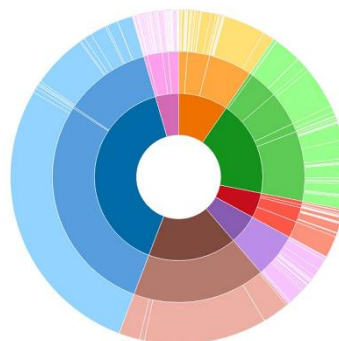

PROTOCOL FOR THE GLOBAL BURDEN OF DISEASES, INJURIES, AND RISK FACTORS STUDY (GBD)

Institute for Health Metrics and Evaluation

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Executive summary

This protocol outlines the Global Burden of Disease, Injuries, and Risk Factors (GBD) study. It covers the key principles and assumptions, products, roles and responsibilities, processes, and architecture. The most current version is posted on the IHME website at the following URL:

<http://www.healthdata.org/gbd/about/protocol>.

Overview

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. IHME serves as the coordinating center for the GBD and affiliated projects. 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 (for a more detailed list of all products of the GBD see “SECTION 3. KEY PRODUCTS”). 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 and best available methods to ensure the most complete and highly 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:** Led by the GBD Principal Investigator (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.
- **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.
- **Collaborators:** The GBD and affiliated projects engage a network of individual collaborators with a wide variety of areas of expertise. Collaborators are selected through an open call and referrals, and play a critical role throughout the GBD estimation cycle. Collaborators are also the central vessel for promoting the GBD and affiliated projects, and translating results to be relevant for policymakers.
- **Independent Advisory Committee:** The Independent Advisory Committee for the Global Burden of Disease advises the Board of the Institute for Health Metrics and Evaluation on the Global Burden of Disease and affiliated projects to ensure the highest scientific rigor of the study, facilitate dialogue with other efforts in global health, identify ways to increase collaboration and ownership, and guide decisions regarding access and use of the GBD and affiliated projects.

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 may raise issues for debate, and if not resolved through other channels may request that the issue be brought to the Scientific Council.

GBD 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, unless otherwise approved by the GBD Scientific Council. The flowchart in SECTION 6. GBD ESTIMATION FLOW illustrates the flow of the key components of the GBD estimation process

Data

The data associated with the GBD are immense. Input data to the GBD and affiliated projects are compiled through continuous extraction of studies from the literature and the addition of key data sources throughout the GBD. The GBD study has and will continue to develop a substantial data repository, including crude data (as released by the original source), model input data points, and final results.

The GBD produces point estimates and 95% uncertainty intervals for every cause of the cause list, every country/location, all ages and a select number of age groupings, each sex separately and aggregated, and every year from 1990 to the current round. Details of the cause list, locations, ages, and years can be found on the IHME website at www.healthdata.org.

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 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.

Dissemination

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 and dissemination of these findings.

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 GBD aims to publish each year "capstone papers" presenting overall estimates, and regular updates to disease-, risk-factor-, and country-specific papers. Other papers may be

written by the collaborators or the Core Analytic Team at any time; different types of collaborator-led papers are outlined in “SECTION 9. DISSEMINATION.”

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 for policymaking and priority setting. To learn more about ways that 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 its affiliated projects, 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: <http://www.healthdata.org/gbd/about/protocol>.

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 and affiliated projects

The GBD 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. 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, 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 poor health and disability. A main goal of the GBD enterprise is to ensure that the most current, detailed, comprehensive results are used by policymakers to make decisions to improve population health.

The GBD enterprise provides cutting-edge and timely results through scientific papers, policy reports, web content, and interactive visualizations. The GBD itself uses and builds upon the infrastructure of methodology, datasets, and tools that were outlined in the most recently published GBD study¹⁻⁶, which builds upon the methodology first presented in the GBD 2010 study⁷⁻¹⁴. Any proposed updates to methodology or cause lists will be approved by the GBD Scientific Council, as detailed in Section 4.

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

SECTION 2. KEY PRINCIPLES AND ASSUMPTIONS

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 (for a more detailed list of all products of the GBD see “SECTION 3. KEY PRODUCTS”). The cause list is agreed upon annually by the Scientific Council. The critical milestones for ongoing estimation include regular updates to the GBD estimates, referred to as the “GBD cycle.” For each cycle, 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 embedded with eight 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

- 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, such as 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

- All available relevant sources of data for a given disease, injury, and risk factor and for all-cause mortality should be identified.
- 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 or geography.

- All estimates should be generated with 1,000 (or more) draws of the quantity of interest from the posterior distribution.
- 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 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
- 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
- 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)
- 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
- 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
- Years lived with disability (YLDs) by impairment
- Probability of death by cause
- Prevalence by sequelae
- Incidence 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: <http://www.healthdata.org/gbd/publications>
- 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 will be updated as these projects evolve, but 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, a Core Analytic 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. 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 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. 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. As an institute of the University of Washington (UW), 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.

The GBD Scientific Council is primarily responsible for:

- Reviewing and voting on all proposed updates to published methods.
- 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. 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. 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. 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:

<http://www.healthdata.org/gbd/about/scientific-council>.

In addition, Scientific Council members must commit to attending at least one of the GBD estimate review weeks in person.

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 GBD Core Analytic Team 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.

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. Cause- or topic-specific estimation

Multiple teams of individuals (including varied combinations of faculty, fellows, researchers, and other IHME staff, collaborators, or others) are 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, healthy life expectancy, and other major extensions of the GBD. 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 for their cause or estimation area of focus.

2. Data management and incorporation

A team of individuals (including analysts, indexers, and other IHME staff, or others) is responsible for central database management. This includes seeking data, cataloging 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 23, to support the ongoing data needs.

3. Development and implementation of central computation

A team of individuals (including analysts, software architects, engineers, and other IHME staff, or others) is responsible for managing, implementing, and developing the complex central machinery for the GBD and affiliated projects. This work includes creation, maintenance, and documentation of tools for data intake, data analysis and modeling environments, outputs databases, and visualization tools.

4. Central coordination, publication, training, and engagement

Multiple teams of individuals are responsible for ensuring the timely actualization of the GBD production process; for preparing scientific publications, reports, and outreach to the media; for translating the GBD results for policy use and impact; and for managing the GBD Collaborative Network and liaising with other key stakeholders.

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 different ways for GBD Collaborators to contribute to the GBD and affiliated studies. GBD Collaborators consist of specialists in particular topic areas related to the GBD. 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 particular diseases, injuries, risk factors, or impairments
- 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 geography or methodological framework as a whole.
3. **Preliminary results:** Providing feedback on the validity and interpretation of preliminary results before they are finalized for that estimation cycle.
4. **Capstone publications:** Commenting on drafts of the GBD capstone 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, in order 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. working with IHME to develop 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. Webinars, communications and information, the GBD Online Course, specialized visualization tools, and other opportunities and resources are made available to collaborators to facilitate their understanding and use of the GBD and affiliated projects.

Furthermore, as collaborators, individuals gain access to preliminary results for review and comment. Webinars, collaborator-exclusive communications and information, and specialized visualization tools are also available to collaborators to further the GBD and affiliated projects.

Facilitating communications within the GBD Collaborative Network

IHME may contribute to facilitating communications among collaborators with specific areas of work and/or in specific countries and formulating in-country networks. In select cases, and only with the permission of the GBD Management Team, a GBD Collaborator may develop an in-country network of GBD Collaborators. Contact gbdsec@uw.edu for procedures and expectations for formulating in-country networks of collaborators.

GBD Collaborator enrollment & minimum requirements

GBD Collaborators are identified and enrolled through two avenues:

Referrals: 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, 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 Collaborative 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 in a relevant field (at least a Bachelor's degree) or relevant work experience:
 - a. Medicine
 - b. Epidemiology
 - c. Demography
 - d. Public health
 - e. Public policy
 - f. Health systems
 - g. Health administration
 - h. Economics
 - i. Geography
 - j. Environmental science
 - k. Data science
 - l. Computer science
 - m. Statistics/math
 - n. Other relevant field
2. Applicant must work in a relevant sector (academic; local, national or international governance; health care delivery; private or nonprofit sector), in one or more of the fields specified above.
3. Applicant must be in good professional standing with all relevant licensing bodies and professional boards.
4. Conflicts of interest with the Global Burden of Disease enterprise must be individually disclosed.

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 be in compliance 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.

Collaborators shall be notified in writing of their removal.

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:

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:

- 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 Board about opportunities for strengthening collaboration and shared ownership.
- IV. Engage in dialogue with other efforts on global health estimates.
- V. Advise the Board on guidelines for access to and use of the Global Burden of Disease, forecasting, and geospatial mapping databases globally, regionally, and nationally.
- VI. Report annually to the Board.

The members of the IAC can be found at the following URL:

<http://www.healthdata.org/gbd/about/independent-advisory>.

GBD Secretariat

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. The GBD Secretariat is the central point of contact for all inquiries about the GBD and affiliated projects. 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 geography

The GBD enterprise follows international standards laid down by the World Health Organization on naming conventions.

Differences in opinion may arise regarding estimates, data sources, and/or approaches for a particular location, 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 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 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 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 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>). 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.

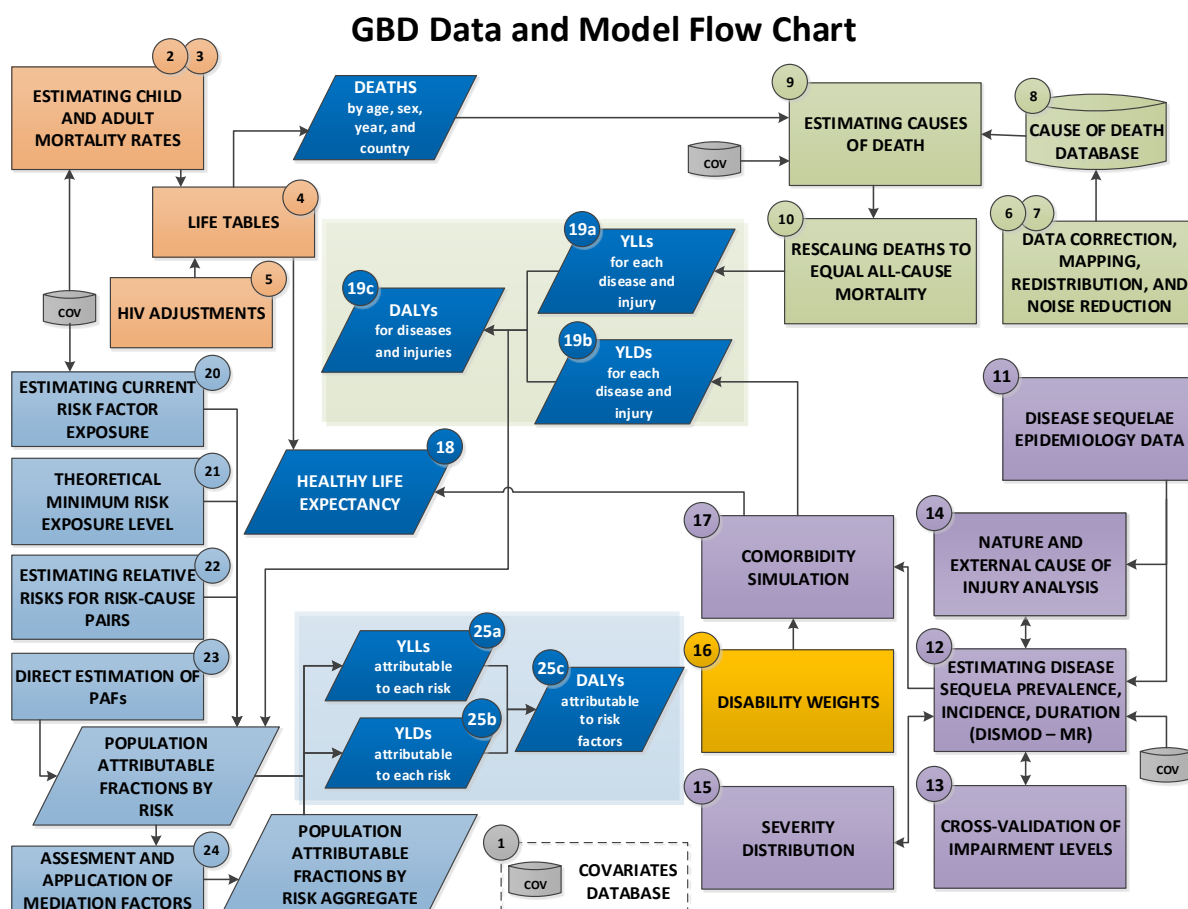
SECTION 6. GBD ESTIMATION FLOW

This section outlines the GBD estimation flow in particular; GBD-affiliated projects may have separate estimation cycles and processes.

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. 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)

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

Point estimates with 95% UI are released for a set of locations, the list of which can be found on the IHME website in the GBD Results Tool (see: "Codebook"): <http://ghdx.healthdata.org/gbd-results-tool>

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. Estimation at

the subnational level is conducted 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.

Requests to add additional geographies or to undertake subnational analysis 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.

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.

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 the cause or risk 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 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 in the GBD Results Tool (see “Codebook”): <http://ghdx.healthdata.org/gbd-results-tool>.

All proposed changes to the cause list are reviewed and approved 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 in the GBD Results Tool (see “Codebook”): <http://ghdx.healthdata.org/gbd-results-tool>.

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. 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 includes, but is 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 catalogue metadata for all sources including data type, key descriptions, time period over which data was collected, and region covered. We formulate a citation from the metadata, and make sure the catalogued information for all input datasets that we use is available publicly in the GHDx. We make all input data sources available unless prohibited by a formal data use agreement from the data holder. Where formal data agreements required by the original data holders prohibit sharing the input data, we will provide instructions as to how users can request the data from the original provider. IHME maintains and will continue to maintain an active dialogue with data providers to encourage them to grant permissions for the greatest possible sharing of data. Data from this work will be subject to the same data sharing agreements as other projects within IHME for sources where such agreements are already in existence.

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. All results will be publicly and freely available for non-commercial use in data formats amenable for researchers to use in subsequent investigations (e.g., as tabular data hosted on the GHDx for aggregated results as TIFF or Binary Float data available for download of final estimates). We will submit for publication manuscripts that detail the methodology used and results generated by these analyses, all of which will be published in peer-reviewed journals. Final results may also be made available through the visualizations, reports, and/or other written materials as appropriate to the project at hand.

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/gbd-data-input-sources>). Input 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, the rotation strategy ensures that new literature sources for all conditions are included on a routine basis. 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 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, as well as identify and exclude outlier studies.

Other data sources

The Core Analytic Team 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.

Data access parameters

General access parameters for 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 raw 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, cause, risk, and location can be accessed through the GBD Sources Tool (<http://ghdx.healthdata.org/gbd-data-input-sources>). An updated GBD Sources Tool is released concurrent with the publication of results for each cycle 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 model input data points

Before being used in the GBD, input data may undergo various preparation processes, such as age and sex splitting or redistribution of garbage codes. The resulting intermediate data 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 have been calculated from input data. All data points are linked to a record in the GHDx which contains full metadata where legally permissible. The model input data points for each annual cycle 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 through an updated results query tool (<http://ghdx.healthdata.org/gbd-results-tool>) and updated visualizations, which are both released concurrent with publication of the capstone papers. Additionally, 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 the input data and intermediate 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.

SECTION 9. DISSEMINATION

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, as well as disseminations of the results, for example via presentations and posters.

Publications

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 to participate in GBD publications.

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. Anyone interested in publishing specifically on the results of the GBD enterprise is strongly encouraged to apply to be a Collaborator. 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 cycle (all-cause mortality, causes of death, non-fatal health outcomes, DALYs, HALE, risk factors, healthcare access and quality, global health financing, etc.). They 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, or risk factors
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 GBD Collaborators or by GBD core analytic team members. All papers must be formally registered prior to beginning writing to avoid duplicate publication and to ensure equitable opportunities. 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).

In order to qualify for authorship, potential authors must meet the following criteria:

1. Contributing substantially to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.
2. Drafting the work or revising it critically for important intellectual content.
3. Giving final approval of the version of the manuscript to be submitted.
4. Agreeing 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. Any journal-specific criteria.

All authors on GBD and GBD-affiliated papers, other than IHME faculty or staff, must be registered GBD collaborators prior to collecting authorship forms. It is the responsibility of the lead author to ensure that all members of the writing team are collaborators. If registration as a GBD collaborator would pose a conflict of interest (e.g., for World Health Organization employees), exceptions must be requested in advance by contacting GBD Secretariat.

GBD papers may indicate authors' contributions (by category) toward individual papers in the supplementary appendix for each paper. 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 and GBD-affiliate papers are typically published using group authorship (individual authors are listed at the end of paper and are credited in PubMed) in recognition of the many diverse contributions to the research project.

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.

Presentations and posters

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

Preliminary Results: In select cases, and only with the permission of the GBD Management Team, presentations or posters 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 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>.”

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), 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.”

Use in policy

In addition to disseminating findings via peer-reviewed academic publications, presentations, and posters, IHME also supports the use of GBD evidence in policy dialogues and documents.

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.

To learn more about ways that GBD Collaborators are using findings from the study to inform decision-making, see IHME’s [Acting on Data](#) blog, which includes case studies from countries such as [Ethiopia](#), [Ghana](#), [Norway](#), [Ukraine](#), the [United Kingdom](#), the [United States](#), and others.

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.

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 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 will be noted in the acknowledgments, where appropriate.

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