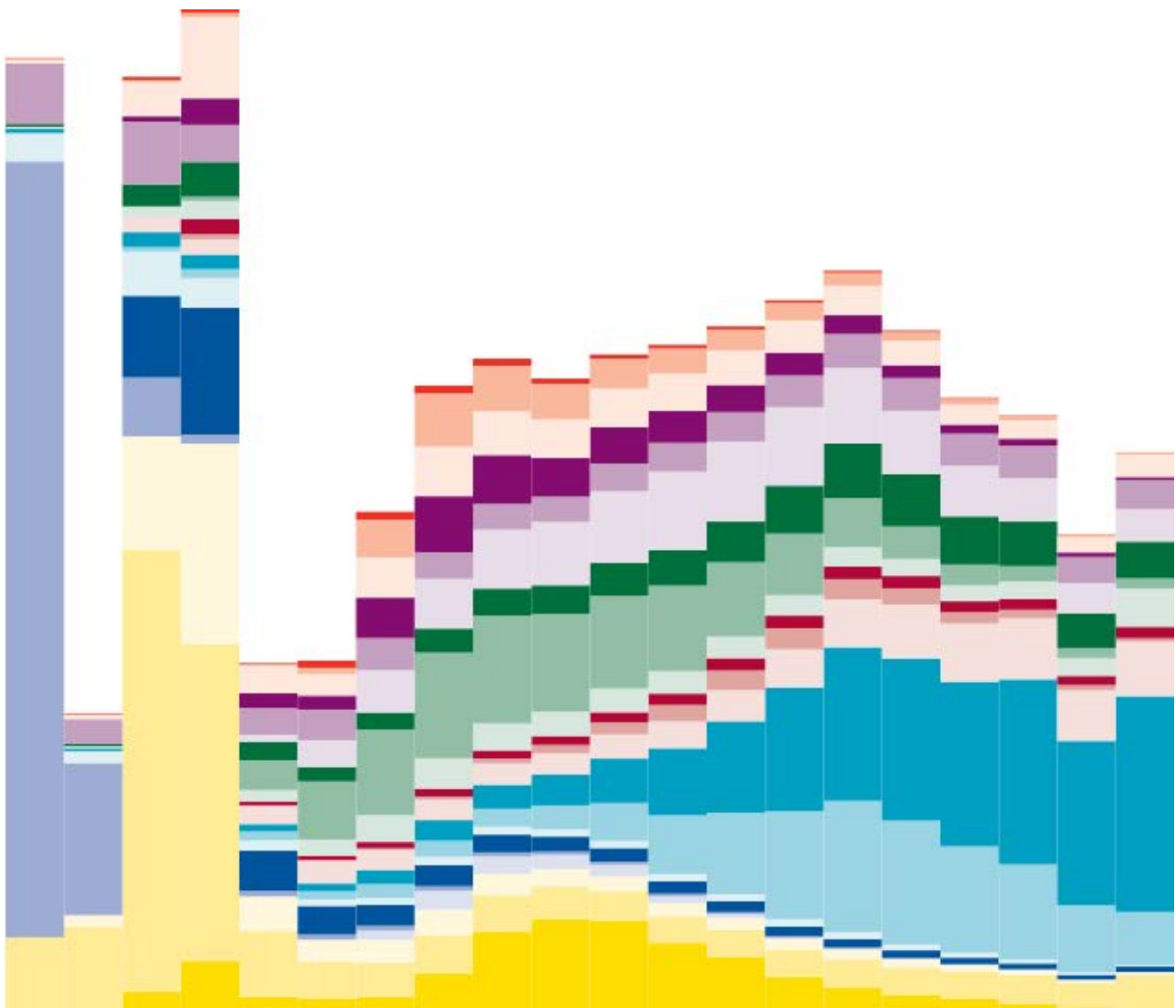


# GBD 2013: Global Burden of Diseases, Injuries, and Risk Factors

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## Protocol

July 24, 2013



This protocol outlines the key roles, responsibilities, decisionmaking processes, and deliverables included in the Global Burden of Diseases, Injuries, and Risk Factors Study 2013 (GBD 2013) and is intended for all individuals directly engaged in the GBD 2013. The protocol is valid throughout the duration of the GBD 2013; the protocol will be updated for subsequent iterations of the GBD taking into account lessons learned. The most current version will be posted at the following URL:

[www.ihmeuw.org/gbd2013protocol](http://www.ihmeuw.org/gbd2013protocol). The date of the most recent modification will be noted on the protocol.

As an institute of the University of Washington (UW), IHME is subject to the policies and procedures of the UW. Accordingly, the GBD 2013 shall be conducted in full compliance with UW policies and procedures, as well as applicable federal, state, and local laws.

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## Section 1. Introduction

### Purpose and Goals of GBD 2013

The Global Burden of Diseases, Injuries, and Risk Factors (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 the Institute for Health Metrics and Evaluation (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 approach 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 diseases that kill people prematurely and cause ill health and disability.

Going forward, the GBD will produce ongoing estimates of all-cause mortality, deaths by cause, years of life lost (YLLs), years lived with disability (YLDs), and disability adjusted life years (DALYs) for a comprehensive cause list-- including, at minimum, the 291 causes of diseases and injuries and the 67 risk factors estimated in the GBD Study 2010<sup>1</sup>. The core costs of the ongoing estimation are supported in part through funding from the Bill & Melinda Gates Foundation; the critical milestones for that support include annual updates to the GBD estimates. This protocol is specific to the next GBD update, the GBD 2013. When the new estimates for GBD 2013 are produced, 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 2013 will provide cutting-edge and timely results through creative and explanatory visualizations, updated with the most current data. The GBD 2013 will use and expand upon the infrastructure of methodology, datasets, and tools that were presented in the GBD Study 2010<sup>1-8</sup> in order to produce estimates that will provide policymakers, researchers, donors, and other decision makers with the most timely and up-to-date picture of population health to inform critical decisions. Any proposed updates to

methodology used in GBD 2010 or cause lists will be approved by a GBD Scientific Council, as detailed below.

### **Organization of the GBD 2013**

The GBD 2013 will include a Core Analytic Team, a Scientific Council, a management team, and a robust network of GBD Experts working together to produce the most accurate, up-to-date, and comparable estimates of burden world-wide. More information about each of these groups is listed below in the “**Roles and Responsibilities**” Section below.

IHME, the institutional home of the GBD 2013, envisions engaging individual collaborators as GBD Experts in a range of ways, including:

1. Providing expertise, access to, and feedback on the data used for all-cause mortality estimation.
2. Providing expertise and feedback on the results generated for the all-cause mortality envelope.
3. Providing expertise, access to, and feedback on the data used for the analyses of specific diseases, injuries, risk factors, or impairments.
4. Providing expertise and feedback on the validity and interpretation of results generated for specific diseases, injuries, risk factors, or impairments.
5. Providing expertise, access to, and feedback on the data used for country-specific results.
6. Providing expertise and feedback on the validity and interpretation results generated for a specific country.
7. Where possible, engaging even more closely to generate subnational estimates for specific countries that are consistent with the overall global and national estimates produced annually.
8. Translating the results of the GBD 2013, in order to maximize policy uptake and action.

## **Section 2. Key Principles and Assumptions**

The GBD 2013 will embed a set of key principles and assumptions to ensure the highest quality and most useful set of results possible. The data used and the analytic strategies applied to generate the results will be 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 2013 cause list is a set of mutually exclusive and collectively exhaustive hierarchical categories.
2. Results from the GBD 2013 are intended to facilitate comparison.
3. All quantities of interest will be 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 burden from that condition.

## Uncertainty

1. Because the GBD 2013 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.
2. The GBD 2013 estimates uncertainty distributions for each quantity and reports and visualizes various metrics of uncertainty, such as 95% uncertainty intervals.

## Internal Consistency

1. The sum of cause-specific mortality must equal all-cause mortality following ICD underlying cause rules.
2. The sum of cause-specific estimates of impairments, such as blindness, must equal estimates of all-cause impairments.
3. Where we believe incidence, prevalence, remission, duration, and excess mortality are not changing over time we require rates to be internally consistent

## Iterative Approach to Estimation

1. New data and methodological innovation will lead to revision of estimates.
2. Burden of disease estimation is an iterative process. Revisions will 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. We will identify all available relevant sources of data for a given disease, injury, and risk factor and for all-cause mortality.
2. For all data sources identified, we will assess the sampling method, case definitions, and potential for bias.
3. For cause of death data, we will map variants of the ICD and will redistribute garbage codes.
4. For data on incidence, prevalence, remission and excess mortality, we will use statistical methods to characterize the relationship between different case definitions, diagnostic technologies, recall periods, etc.
5. We will use these relationships to transform data into comparable units, definitions, or categories. Wherever possible, we will propagate uncertainty in these mappings into the uncertainty interval 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. We will synthesize all the appropriate data using statistical methods that can handle both sampling and non-sampling error.
8. The statistical methods employed will improve predictions where data are sparse by allowing for use of covariates and by borrowing strength across time or geography.
9. All estimates will be generated with 1000 (or more) draws of the quantity of interest from the posterior distribution.

10. Where possible, we will demonstrate validity of the statistical methods by using out-of-sample prediction.

### Construction of DALYs

1. DALYs will be computed following the definitions and value choices laid out in the GBD 2010<sup>4</sup>. DALYs in the GBD 2013 have no age-weighting, use a 0% discount rate, are based on prevalence, and take into account co-morbidity.
2. Disability weights will be based on samples of the general population using methods with valid psychometric properties. DALYs will be computed using a uniform set of disability weights across all populations and time periods to facilitate meaningful comparisons.
3. YLLs will be computed using a reference life table which will be the same for males and females, all countries and all time periods. The GBD 2013 will use the reference life table from the GBD 2010 study<sup>1</sup>.

## Section 3. Key products and timelines

### Products

The GBD 2013 will produce comprehensive estimates of burden of diseases, injuries, and risk factors by country, year, age, and sex. The GBD 2013 will release the point estimates and 95% uncertainty intervals by country for the following:

- All-cause mortality rates (1970-2013)
- Deaths by cause (1980-2013)
- Years of life lost due to premature mortality (YLLs) by cause (1990-2013)
- Years lived with disability (YLDs) by cause (1990-2013)
- Years lived with disability (YLDs) by sequelae (1990-2013)
- Disability-adjusted life years (DALYs) by cause (1990-2013)
- Deaths attributable to the independent effects of risk factors and clusters of risk factors (1990-2013)
- YLLs attributable to the independent effects of risk factors and clusters of risk factors (1990-2013)
- Prevalence of exposure to each risk factor
- Relative risks of mortality for each risk-outcome pair
- YLDs attributable to the independent effects of risk factors and clusters of risk factors (1990-2013)
- DALYs attributable to the independent effects of risk factors and clusters of risk factors (1990-2013)
- Healthy life expectancy (HALE) by country (1990-2013)

These results will be made available at least through the following mechanisms:

- Updates to the following set of tools and visualizations: GBD Compare, Mortality Visualizations, COD Visualizations, GBD Cause Patterns, GBD Arrow Diagrams, GBD Heatmaps, and GBD Uncertainty Visualization
- Multiple publications in peer reviewed journals; as part of this product, the GBD will strive to publish complete updated results in a series of capstone papers, in addition to other more detailed publications
- Presentations detailing the results and methodology of this research to academics and other interested audiences.
- Tabular datasets available for download, as outlined in the “**Data**” section below

The exact timing and release of results will be determined by the GBD Management Team (see below for details) under the leadership of the GBD Study Principal Investigator.

### General Timeline

The GBD Management Team, led by the GBD Study Principal Investigator, will make the final decision as to when estimates are ready for submission for publication. Given the complexities of the estimation process timelines may shift, though for illustrative purposes the following table provides the envisioned schedule. This timeline is only illustrative as experience has demonstrated that in a study as complicated and inter-connected as the GBD 2013, many unexpected items can emerge that may affect the timeline.



Envisioned Timeframe	Activity	Comment	Collaborator involvement
September 5- November 20	<ul style="list-style-type: none"> <li>Identifying data sources, data assessment, and data preparation</li> <li>Modeling causes of death, YLLs, YLDs, DALYs, HALE</li> </ul>	<ul style="list-style-type: none"> <li>Data seeking and integration will be continuous during this period</li> <li>Core Analytic Team modeling in consultation with GBD Experts on specific diseases, injuries, risk factors, and impairments</li> </ul>	<ul style="list-style-type: none"> <li>GBD Experts for specific diseases, injuries, risk factors, or impairments providing initial feedback to Core Analytic Team regarding data sources and/or results</li> <li>GBD Scientific Council meetings to review proposed changes to methodology or adjudicate disagreements as outlined in “Roles and Responsibilities” section</li> </ul>
September 5	<ul style="list-style-type: none"> <li>Preliminary all-cause mortality envelope</li> </ul>	<ul style="list-style-type: none"> <li>A preliminary all-cause mortality envelope should be ready to incorporate into the cause of death calculations</li> <li>All-cause mortality envelope will be sent to GBD Mortality Experts for feedback</li> </ul>	<ul style="list-style-type: none"> <li>Core Analytic Team produces all-cause mortality envelope and shares penultimate envelope results with GBD Mortality Experts</li> <li>GBD Mortality Experts review and provide feedback to the Mortality Core Analytic Team Members</li> <li>GBD Scientific Council continues regular meetings</li> </ul>
November 4	<ul style="list-style-type: none"> <li>Deadline for receiving feedback from GBD Mortality Experts</li> </ul>	<ul style="list-style-type: none"> <li>All feedback from GBD Mortality Envelopes should be finalized and provided</li> </ul>	<ul style="list-style-type: none"> <li>GBD Mortality Experts working in consultation with GBD Mortality Core Analytic Team Members</li> <li>GBD Scientific Council continues regular meetings</li> </ul>
December 16	<ul style="list-style-type: none"> <li>Review of penultimate results for causes of death, YLLs, YLDs, DALYs, HALE</li> </ul>	<ul style="list-style-type: none"> <li>The penultimate set of results for each specific disease, injury, risk factor, impairment, and country will be sent to the GBD Experts enrolled in that area of contribution.</li> </ul>	<ul style="list-style-type: none"> <li>GBD Experts in particular countries, diseases, injuries, risk factors, and impairments receive, review, and send final feedback on the results from their area of contribution</li> <li>GBD Scientific Council continues regular meetings</li> </ul>
January 10	<ul style="list-style-type: none"> <li>Finalize and submit first wave of papers</li> </ul>	<ul style="list-style-type: none"> <li>Paper submission to <i>The Lancet</i> will take place in two waves at the request of the</li> </ul>	<ul style="list-style-type: none"> <li>Core Analytic Team creates first drafts of publications</li> </ul>

February 1	<ul style="list-style-type: none"> <li>• Deadline for receiving all feedback from GBD Experts in particular countries, diseases, injuries, risk factors, and impairments.</li> </ul>	<p>journal. The first wave of publications will be submitted January 10<sup>th</sup>. Eligible authors that have contributed to the analyses being presented in the first wave of publications will receive drafts prior in order to review and return feedback</p> <ul style="list-style-type: none"> <li>• After this February 1<sup>st</sup> deadline, all estimates will be finalized taking into account feedback from GBD Experts as applicable</li> </ul>	<ul style="list-style-type: none"> <li>• GBD Experts that have contributed to the analyses being presented in the first wave will receive drafts and provide feedback</li> <li>• GBD Scientific Council continues regular meetings</li> <li>• GBD Experts in specific diseases, injuries, risk factors, and impairments return final feedback</li> <li>• Core Analytic Team consults with GBD Experts as final feedback is provided.</li> <li>• GBD Scientific Council meeting more frequently to review proposed changes to methodology or adjudicate conflicts as outlined in “Roles and Responsibilities” section</li> </ul>
February 1- March 3	<ul style="list-style-type: none"> <li>• Prepare and submit second wave of publications</li> </ul>	<ul style="list-style-type: none"> <li>• In the 2-3 month period before publication, the results will be finalized and the capstone papers will be drafted. These capstone papers, along with any other papers in the second wave of submissions, will be submitted by March 3<sup>rd</sup>. Eligible authors will receive the paper prior to submission in order to review and return feedback</li> </ul>	<ul style="list-style-type: none"> <li>• Core Analytic Team creates first drafts of publication</li> <li>• GBD Scientific Council continues regular meetings</li> <li>• GBD Experts receive drafts of the relevant capstone papers and provide feedback</li> </ul>
May 3	<ul style="list-style-type: none"> <li>• GBD results published and updated online visualization tools released</li> </ul>	<ul style="list-style-type: none"> <li>• In order to provide this information to the public in a timely manner to best inform current decision-making, while also providing sufficient time for collaborators to publish additional manuscripts on this work, visualization tools and publications/presentations will be released to the general public roughly 4 months in advance of the downloadable tabular datasets. When specific countries</li> </ul>	<ul style="list-style-type: none"> <li>• Core Analytic Team and GBD Management Team has the leading role in finalizing publications leading up to the May 3 publication date</li> <li>• IHME updates online visualization tools</li> <li>• GBD Scientific Council continues regular meetings</li> </ul>

September 3	<ul style="list-style-type: none"> <li>• Public release of crude data, input data and tabular results, as possible</li> </ul>	<p>or relevant policy actors ask for tabular results for policy formulation, we may make this available ahead of the general public, as an essential means to help fuel the use of the results for policy formulation.</p> <ul style="list-style-type: none"> <li>• Input data and the tabular form of the results published in May will be released to the public, with the exception of input data where legal restrictions like data use agreements prevent us from doing so</li> </ul>	<ul style="list-style-type: none"> <li>• IHME releases crude data, model input data, and tabular results as appropriate</li> <li>• GBD Scientific Council continues regular meetings</li> </ul>
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## **Section 4. Roles, responsibilities, and adjudication**

The GBD 2013 is led by the Principle Investigator, Dr. Christopher Murray. The home institution for the study is the Institute for Health Metrics and Evaluation (IHME) at the University of Washington. The GBD 2013 includes GBD experts, a Core Analytic Team, a GBD Management Team, and a GBD Scientific Council. The entire GBD Study is managed by the GBD Management Team under the leadership of the Principal Investigator. This group also leads the analytic development and direction of the GBD Study. It is staffed and supported by IHME. In addition, an Independent Advisory Committee has been assembled and is chaired by Dr. Peter Piot.

The following chart provides a high level summary of the roles and responsibilities for the groups working on or related to the GBD 2013, followed by more detailed descriptions.

	<b>Who</b>	<b>Expectations</b>	<b>Resources</b>	<b>Opportunities</b>
<b>GBD Scientific Council</b>	<ul style="list-style-type: none"> <li>• Chaired by the GBD Principle Investigator</li> <li>• Intellectual leaders of the main GBD components (mortality, non-fatal health outcomes, causes of death, risk factors)</li> <li>• Eminent scientists with a strong knowledge of relevant epidemiology, methods, and data</li> </ul>	<ul style="list-style-type: none"> <li>• Review and approve or not proposed methodological changes</li> <li>• Review and approve or not proposed modifications to disease, injury, and risk factor lists</li> <li>• Review and approve or not proposed modifications to the ranking lists of diseases, injuries, and risk factors</li> <li>• Review and approve or not proposed inclusion of new sequelae</li> <li>• Review and approve or not proposed new data sources, lay descriptions, and changes in methods used to recalculate disability weights</li> <li>• Review and approve or not proposed requests for additional covariates</li> <li>• Resolve disputes about data, methods, or estimates</li> <li>• Review and consider feedback from the Independent Advisory Committee</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
<b>Core Analytic</b>	<ul style="list-style-type: none"> <li>• Intellectual leaders of the</li> </ul>	<ul style="list-style-type: none"> <li>• Identify and extract all</li> </ul>	<ul style="list-style-type: none"> <li>• Central epidemiological</li> </ul>	<ul style="list-style-type: none"> <li>• Inclusion as authors on</li> </ul>

<p><b>Team</b></p>	<p>main GBD components (mortality, non-fatal health outcomes, causes of death, risk factors)</p> <ul style="list-style-type: none"> <li>• Faculty and research fellows who are expert in applying the analytic methods</li> <li>• Faculty, research fellows, and other staff who implement the routine central computational processes</li> <li>• Individuals who carry out the systematic reviews and maintain the key central databases</li> <li>• Largely though not exclusively located at IHME</li> </ul>	<p>available data from published and unpublished studies</p> <ul style="list-style-type: none"> <li>• Identify and extract data from key centralized source such as hospital data, vital registration, household surveys, etc.</li> <li>• Identify outliers in the data for a given disease, injury, or risk</li> <li>• Implement the agreed analytic strategy for each disease, injury, or risk</li> <li>• Regularly interact with GBD Experts to assess data, modeling approaches, and results</li> <li>• Carry out central computation to generate ultimate results</li> </ul>	<p>databases</p> <ul style="list-style-type: none"> <li>• Central covariates database</li> <li>• Central databases for data on causes of death, mortality, and other specialized data sources (e.g. disease registries, hospital data)</li> <li>• Bayesian metaregression tool (DisMod-MR or subsequently approved versions) for estimating non-fatal health outcomes</li> <li>• CODEm method used for estimating causes of death</li> <li>• Central computational processes</li> </ul>	<p>capstone papers as appropriate</p> <ul style="list-style-type: none"> <li>• Opportunities to develop papers on diseases, injuries, risks, and countries in collaboration with GBD experts</li> <li>• In-house training on methods</li> </ul>
<p><b>GBD Experts</b></p>	<ul style="list-style-type: none"> <li>• Individuals with expertise in a particular disease, injury, risk factor, or impairment</li> <li>• Individuals with expertise in all-cause mortality used in the GBD 2013</li> <li>• Individuals with expertise in the epidemiology and or health systems of a given country</li> </ul>	<ul style="list-style-type: none"> <li>• Assess and provide feedback on data sources used for estimates</li> <li>• Identify available data sources that have not been used but should be</li> <li>• Assess and provide feedback on results of the models</li> <li>• Work with Core Analytic Team member to assess results and suggest</li> </ul>	<ul style="list-style-type: none"> <li>• Privileged access to all data extracted from systematic reviews for the disease, injury, risk factor, impairment, method, or country of enrolled expertise</li> <li>• Privileged access to model results and the data used to generate them for the disease, injury, risk factor, impairment, or country</li> </ul>	<ul style="list-style-type: none"> <li>• Co-authorship on the capstone papers as appropriate</li> <li>• Opportunities for co-authorship on disease-, injury-, and risk factor-specific papers related to the area of enrolled expertise</li> <li>• Opportunity for co-authorship on country- and region-specific papers in which experts</li> </ul>

**GBD Management Team**

	<p>modifications to the analytic approach if needed and appropriate</p> <ul style="list-style-type: none"> <li>• Potentially make suggestions for modifications to the disease, injury, and risk factor lists where appropriate</li> <li>• Potentially make suggestions for additional covariates that could be used in deriving estimates where appropriate</li> </ul>	<p>of expertise</p> <ul style="list-style-type: none"> <li>• Direct contact with a Core Analytic Team member dedicated to the area of enrolled expertise</li> </ul>	<p>live or for which they have made a special contribution</p> <ul style="list-style-type: none"> <li>• Opportunities to conduct novel analyses on the data during a privileged access period before it is released to the public</li> <li>• Opportunities for co-writing grant proposals for projects using the data</li> <li>• Opportunities to present findings at external conferences</li> <li>• Opportunities to jointly develop and pursue subnational studies</li> <li>• Opportunities to jointly pursue complementary research studies, such as additional investigations into disability weights</li> </ul>
<ul style="list-style-type: none"> <li>• Led by the GBD Principle Investigator</li> <li>• Includes the intellectual leaders of the main GBD components (mortality, non-fatal health outcomes, causes of death, risk factors)</li> <li>• Includes key IHME staff</li> </ul>	<ul style="list-style-type: none"> <li>• Manage the GBD Study to ensure that critical deadlines are met and computational process are in compliance with the Study procedures outlined in this document</li> <li>• Review external requests for exceptions to present or publish prior to the GBD</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>

<p><b>Independent Advisory Committee</b></p>	<ul style="list-style-type: none"> <li>• Chaired by Dr. Peter Piot</li> <li>• Eminent scientists with a strong knowledge of relevant epidemiology, methods, and data that are not members of the GBD 2013 study</li> </ul>	<p>capstone papers</p> <ul style="list-style-type: none"> <li>• Clearly communicate the GBD Study and/or results to a wide variety of parties</li> <li>• Review the strengths and weaknesses of different methods and results</li> <li>• 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</li> <li>• Advise the IHME Board about opportunities for strengthening collaboration and ownership of GBD</li> <li>• Engage in dialogue with other efforts on global health estimates</li> <li>• Advise the IHME Board on guidelines for access to and use of the GBD databases globally, regionally, and nationally</li> <li>• Report annually to the IHME Board</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
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## GBD Scientific Council

The GBD Scientific Council will be a mechanism for key scientific decision-making internal to the GBD 2013; it is not a substitute for peer-review of publications nor for periodic views from independent groups not involved in the GBD. The GBD Scientific Council will be comprised of leading experts in fields relating to the Global Burden of Diseases, Injuries, and Risk Factors. This GBD Scientific Council provides direct oversight over and has decision-making ability on methodological advancements produced as part of the GBD. Dr. Christopher Murray serves as the Chair of the GBD Scientific Council.

The GBD Scientific Council will primarily:

- Provide feedback on and ultimately decide to approve or not all proposed updates to published methods
- Decide whether it is possible and of critical importance to incorporate data that become available after the GBD 2013 data cutoff deadline into the estimates
- Adjudicate disputes on: estimates for mortality, specific diseases, injuries, risk factors, impairments, or geographies; data sources included; methodological approaches
- Review and approve or not modifications to the diseases, injuries, and risk factor cause lists and ranking cause lists
- Review and approve or not modifications to the list of covariates available for analyses
- Review and approve or not changes to the existing published set of risk-outcome pairs used for measuring attributable burden of risk factors or risk factor clusters
- Discuss recommendations from outside groups
- Review and discuss feedback from the Independent Advisory Committee to the GBD
- Review and approve or not new data sources, lay descriptions, and change in methods to be used in analyses for recalculating disability weights

The GBD Scientific Council Chair will convene regular Council meetings. The GBD Scientific Council will also have a designated Secretary to facilitate its proceedings. The meetings will be attended by the Council, a subset of individuals from the GBD Management Team as appropriate, the Secretary to the Council, and other GBD Experts, Core Analytic Team members, and related staff as needed. Council members who are unable to attend will have 72 hours to provide feedback and/or votes by email. Majority vote prevails; eligible voters are those that are present at the meeting and those that respond with votes by email within 72 hours. The Council Chair will be responsible for producing the agenda for each Council meeting. Agenda items will be made known to all GBD Scientific 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 meetings will be posted on the study website:

[www.ihmeuw.org/gbd2013SCmtgs](http://www.ihmeuw.org/gbd2013SCmtgs).

The Council Chair will select and enroll the 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 will seek to reflect the diversity of expertise in diseases, injuries, risk factors, countries, and/or related methodology across the membership of the GBD 2013,

including senior faculty 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 will be selected by the Council Chair. The current GBD Scientific Council members and Secretary will be listed on the following website: [www.ihmeuw.org/gbd2013SCmember](http://www.ihmeuw.org/gbd2013SCmember).

## Core Analytic Team

The Core Analytic Team will carry out data seeking, management, and estimation for the GBD. There are 5 principle types of Core Analytic Team Members:

1. GBD Senior Core Analytic Leadership: the GBD Senior Leadership will include, at minimum, the institutionally designated faculty leads for the mortality, causes of death, non-fatal health outcomes, and risk factor estimation areas. The Senior Leadership is appointed by the Principle Investigator and provide direct oversight to the estimation
2. GBD Faculty, Fellows, and Researchers: a team of faculty, fellows, and researchers will be 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 will be primarily responsible for identifying data sources used, applying the relevant methodologies, systematically documenting sources and approaches, and producing and vetting results for each year's update
3. Analysts for Central Computation: a team of analysts will be responsible for managing, implementing, and developing the complex central machinery for computation
4. Systematic Review Group: to support the ongoing data needs, a team will continually conduct systematic reviews of the published and unpublished literature, as outlined in the **"Data"** section below.
5. Analysts for Central Database Management: A team of analysts will seek data and manage 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.

The Core Analytic Team members will work under direct guidance from the Principle Investigator and GBD Management Team. Core Analytic Team members involved in modeling will additionally work with GBD Experts as the primary point of contact to solicit feedback and to jointly test analytic suggestions. Together the GBD Experts and Core Analytic Team members will present any proposed changes to methodology to the GBD Scientific Council for their guidance and approval or not.

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

## GBD Experts

The GBD 2013 will engage a large network of experts with specialties in topic areas. Individuals will be appointed the title of “GBD Expert” for a particular area of expertise; GBD Experts may be enrolled in more than one area of expertise. GBD Experts are comprised of specialists in particular topic areas related to the GBD and generally fall into one of three categories: 1) experts on all-cause mortality; 2) experts for a particular disease, injury, risk factor, or impairment, or 3) experts on the epidemiology for a specific country. More details specific to each of these types of experts are provided later in this section.

The role of the GBD Expert is to review and provide timely feedback and suggestions related to interpretation of results, data sources, and/or methodological approaches pertaining to their area of enrolled expertise in accordance with the “**Timeline**” section above. The GBD Experts will work together with a Core Analytic Team member, sometimes aided by the help of IHME staff. In cases where the GBD Expert and Core Analytic Team members jointly feel that methodological updates are required to achieve the highest quality results, those suggestions will be formally presented by the GBD Expert and the Core Analytic Team member to the GBD Scientific Council for their review and approval or not. Legitimate scientific debate may arise across different mortality, disease, injury, risk factor, and country experts; disagreements regarding any aspects of the analyses should be addressed following the protocol outlined in the “**Adjudication**” section below.

GBD Experts will be identified and enrolled by the GBD Management Team for a 1 year voluntary term. Referrals and nominations are welcome and should be sent to the Management Team; there will additionally be an open call for applications from interested experts that will be published in *The Lancet*. A point of contact for the Management Team will be listed on the study website: [www.ihmeuw.org/gbd2013mgmt](http://www.ihmeuw.org/gbd2013mgmt). GBD Experts may list this official title among their affiliations if desired during the duration of their term. At the conclusion of the 1-year term, the GBD Expert and the GBD Management Team may mutually agree to renew the appointment, with no limit on the number of renewals possible.

The following provides more detail on the roles and timelines for each of the specific type of GBD Expert:

### 1. GBD Experts on all-cause mortality

GBD Mortality Experts will be consulted on their specific area of contribution, ranging from general methodological approaches to country- or age-specific mortality expertise. The GBD Experts will work with the Core Analytic Team member(s) estimating the all-cause mortality envelope to discuss feedback and suggestions and to jointly develop any alternative approaches if necessary.

The envisioned timeline for GBD Experts on all-cause mortality is as follows:

Expert feedback	September 5, 2013	Receive and begin to review the penultimate all-cause mortality estimates
	November 4, 2013	Final deadline for returning all final feedback to Core Analytic Team
Privileged access	September 5, 2013-September 3, 2014	GBD Experts on mortality will have privileged confidential access to the crude data, model input data, and results for their area of contribution. The period of exclusive access is explicitly intended to encourage publication and the involvement of experts in furthering jointly held academic interests while achieving widespread dissemination of GBD results in a multitude of settings. Note that manuscripts may not be published prior to the capstone papers
Publication	May 3, 2014-September 3, 2014	Once the capstone papers are published on May 3 <sup>rd</sup> , publication of additional manuscripts is welcomed.

See the “**Data**” and “**Publications and Presentations**” sections below for additional information.

## 2. GBD Experts on a particular disease, injury, risk factor, or impairment

GBD Experts on a particular disease, injury, risk factor, or impairment will be consulted on their area of contribution. These areas of contribution will be for specific diseases, injuries, risk factors, or impairments. GBD Experts in specific diseases, injuries, risk factors, or impairments will be paired with the Core Analytic Team member(s) responsible for modeling that area. The GBD Experts will work with the Core Analytic Team member(s) estimating that indicator to discuss feedback and suggestions and to jointly develop any alternative approaches if necessary.

Given the interrelated nature of the GBD modeling approach, each individual disease, injury, risk factor, and impairment result must be centrally corrected so that individual causes of death sum to equal the all-cause mortality results and so that non-fatal health outcome estimates are adjusted for comorbidity. Because of this approach, the GBD Experts in particular diseases, injuries, risk factors, or impairments will have two opportunities to provide feedback to members of the Core Analytic Team. The following details the envisioned schedule for GBD Experts in particular diseases, injuries, risk factors, or impairments:

Expert feedback	August 1, 2013- November 20, 2013	Core Analytic Team members will be updating the individual models for each disease, injury, risk factor, and impairment and consulting with relevant GBD Experts regarding modeling approaches and iterative results. We envision that this may involve iterative feedback between the relevant GBD Experts and Core Analytic Team members
	December 16, 2013	Once individual models have been completed and the central computation processes have been run, the GBD Experts will be provided the penultimate corrected results for their area of contribution.
	February 1, 2014	Deadline for returning all final feedback to the Core Analytic

		Team member(s).
Privileged access	November 4, 2013-September 3, 2014	GBD Experts on specific diseases, injuries, risk factors, or impairments will have privileged confidential access to the crude data, model input data, and results for their area of contribution. The November 4 <sup>th</sup> start date to this period reflects the internal deadline for incorporating new data into the GBD 2013 study. The period of exclusive access is explicitly intended to encourage publication and the involvement of experts in furthering jointly held academic interests while achieving widespread dissemination of GBD results in a multitude of settings. Note that manuscripts may not be published prior to the publication of the capstone papers.
Publication	May 3, 2014-September 3, 2014	Once the capstone papers are published on May 3 <sup>rd</sup> , publication of additional manuscripts is welcomed.

See the “**Data**” and “**Publications and Presentations**” sections below for additional information.

### 3. GBD Experts on a particular country

GBD Experts in a particular country will be consulted on the high level indicators (number of deaths, YLLs, YLDs, prevalence, DALYs, and burden attributable to risk factors) for their country of expertise. Country GBD Experts will provide feedback to the designated Core Analytic Team or GBD Management Team member. For feedback involving results for a particular cause, injury, or risk factor within the country, the GBD Country Expert will work with the appropriate Core Analytic Team member to explore alternative approaches or data inputs.

Expert feedback	December 16, 2013	GBD Experts on a particular country to receive and begin to review penultimate high level results for that country
	February 1, 2014	Final deadline for returning all final feedback to Core Analytic Team
Privileged access	November 4, 2013-September 3, 2014	GBD Experts on mortality will have privileged confidential access to the crude data, model input data, and results for their area of contribution. The November 4 <sup>th</sup> start date to this period reflects the internal deadline for incorporating new data into the GBD 2013 study. The period of exclusive access is explicitly intended to encourage publication and the involvement of experts in furthering jointly held academic interests while achieving widespread dissemination of GBD results in a multitude of settings. Note that manuscripts may not be published prior to the capstone papers.
Publication	May 3, 2014-September 3, 2014	Once the capstone papers are published on May 3 <sup>rd</sup> , publication of additional manuscripts is welcomed.

See the “**Data**” and “**Publications and Presentations**” sections below for additional information.

## GBD Management Team

A GBD Management Team, led by the Principle Investigator, will be assembled to manage the GBD 2013. The Management Team for the GBD 2013 includes: Christopher Murray (PI), Theo Vos, Mohsen Naghavi, Mohammad Forouzanfar, Haidong Wang, Marie Ng, Peter Speyer, Michael MacIntyre, and Summer Lockett Ohno. The GBD Management Team will facilitate the production process including managing use of IHME computational capacity dedicated to the GBD 2013, ensure that the study is meeting critical deadlines, and confirm that the estimation meets the computational requirements as outlined here. They will be responsible for supervising the Core Analytic Team. They hold the ultimate responsibility for reviewing and approving the final results. The point of contact for the GBD Management Team is listed on the following website: [www.ihmeuw.org/gbd2013mgmt](http://www.ihmeuw.org/gbd2013mgmt).

## Independent Advisory Committee

An external advisory body has been created and will be led by Dr. Peter Piot. 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 will advise the IHME Board and the Global Burden of Disease enterprise 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 ownership of GBD 2.0,
- IV. Engage in dialogue with other efforts on global health estimates,
- V. Advise the Board on guidelines for access to and use of the GBD databases globally, regionally, and nationally, and
- VI. Report annually to the 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 will nominate and the Executive Committee of the IHME Board will appoint members. Members will be appointed for up to three year renewable terms. The King Baudouin Foundation will host and facilitate the Independent Advisory Committee.

## Adjudication

### *Estimation disagreements*

Given the complex scope of the GBD, there may be estimates, trends, or approaches that lead to diverging scientific opinion. Generally these instances can be classified in the following 4 ways:

1. Disagreements about data sources included: The GBD 2013 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 on which data points should be excluded from the estimation process.
2. Differing opinions about methodological approaches: the GBD 2013 will utilize the most recently published GBD 2010 methodological approaches as the initial approach for estimation.

Disagreement regarding methodological innovations or directions for subsequent revisions may arise.

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 regarding estimates, data sources, and/or approaches for a particular country may arise. 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 for all geographies. Model performance may not be the same for all diseases, injuries, risk factors, and impairments for all countries. Similarly, methodological experts and country experts may have differing opinions about the level of all-cause mortality for a particular country.

#### *Adjudication process*

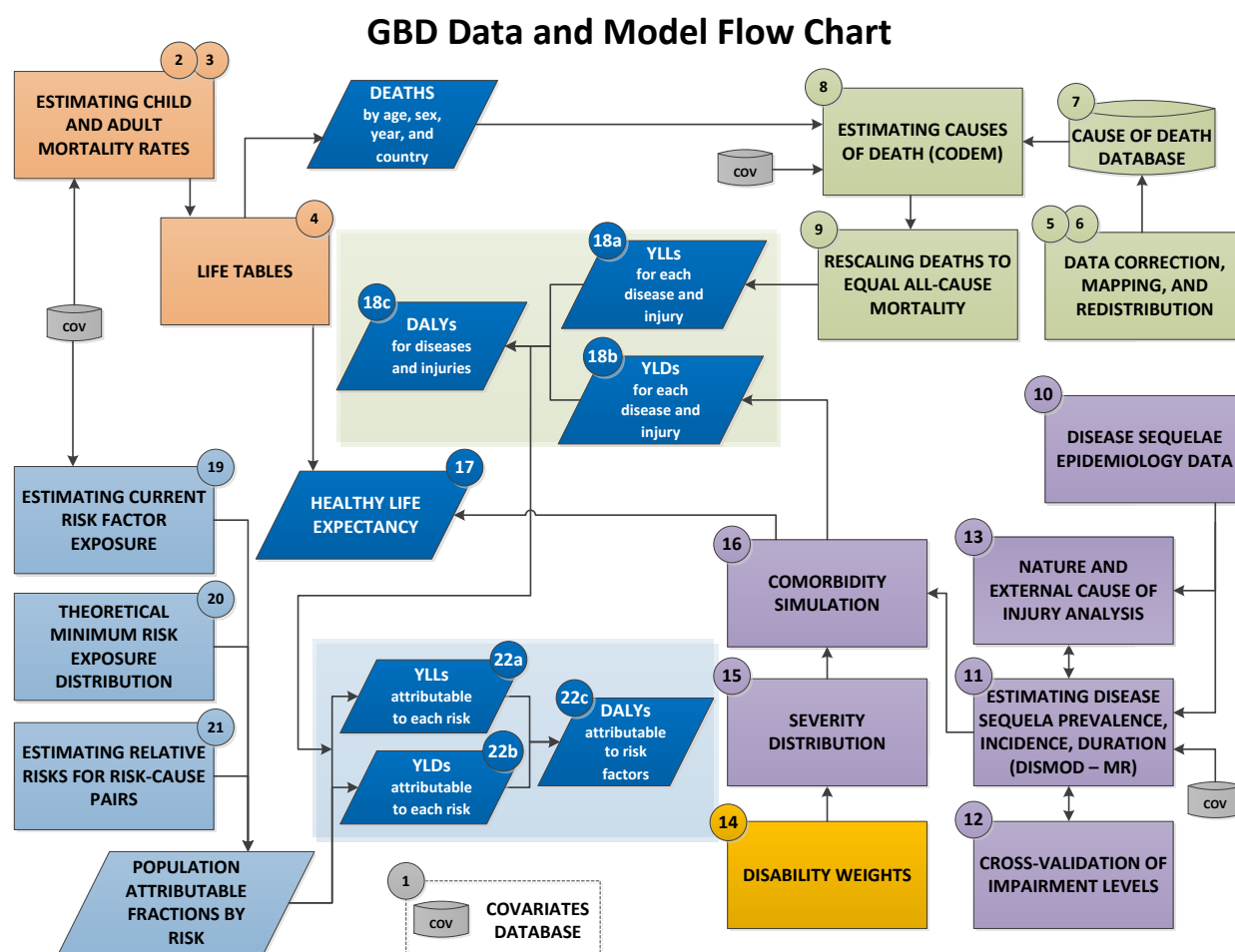
To resolve such disagreements, steps should be pursued in the following order:

1. For any of the types of disagreement, resolution should first be sought through discussion between the individuals with differing opinions. We believe that 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. We expect 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 2010 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 it through discussion, they may ask that the GBD Management Team help to facilitate a resolution to the debate. 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 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 taken should 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 2013 may request that the issue be brought to the GBD Scientific Council. This request should be made to the Council Secretary. 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 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 5. Estimation Flow

Ongoing GBD estimation will follow the methodology presented in the GBD Study 2010<sup>1-8</sup>, unless otherwise approved by the GBD Scientific Council. The following flowchart illustrates the flow of the key components of the GBD estimation process. The text below the flowchart provides additional detail and is numbered to match the numbered component(s) of the flowchart it describes.



### 1. Covariates database

A major component of the GBD is developing estimates for cause-specific mortality and disease/injury incidence, prevalence, and excess mortality in settings where there are sparse data or conflicting data from multiple sources. This estimation task is facilitated by the use of appropriate covariates that can be



used as independent variables in the modeling process. IHME will maintain a central database of covariates to ensure comparable use across all diseases, injuries, and risk factors; all models for all parts of the GBD computational process pull their covariates from this database, ensuring that a consistent set of covariates is used across the study as a whole. For each covariate in our covariate database we have a complete time series for each country, and by age and sex, where appropriate.

If Core Analytic Team member and GBD Experts wish to add a covariate to the database, they must make this proposal to the GBD Scientific Council through the Council Secretary; the GBD Scientific Council will approve or reject the request. Any approved new covariates will be directly added to the central Covariates Database maintained by IHME to be available for use across all relevant models. For the purposes of iterative modeling and experimentation, the GBD Management team decides in such instances the priority to be given to creation of new covariates, given competing priorities, the general scientific argument made in favor of the covariate, and the availability of both data and researcher time. In cases where the development of a new covariate requires new research, such covariates will only be made public after that research is published.

#### 2-4. Age-specific mortality rates

As a critical input to the GBD, analysis of age-specific mortality will be measured for the countries listed in the “**GBD 2013 Country List, Age and Sex Groups, and Cause Lists**” section below from 1970-2013 for the age groups specified within that section. The mortality rates will be estimated using the methods based on Wang et al.<sup>8</sup>.

#### 5-7. Cause of death database

The GBD 2013 will use the expanding cause of death database maintained by IHME, which maps data across various revisions and national variants of the International Classification of Diseases and Related Health Problems (ICD). Incorporated into this database are all relevant sources of cause of death data, including vital registration, verbal autopsies, census and survey data, police records, hospital data, surveillance systems, and population based registries for specific diseases.

#### 8. Estimating causes of death

Estimates for deaths by cause for all causes in the GBD 2013 cause list (see “**Cause List**” section below) will be generated for all countries (listed in “**Countries**” section below) for 1980-2013 using the methods published in Lozano et al.<sup>3</sup>. The vast majority of major causes of death will be estimated using the cause of death ensemble modeling (CODEm) method. For some causes, such as HIV/AIDS and some causes that rarely cause death, alternative methods will be used, refined, or developed. Causes where the GBD estimates etiological splits, including diarrhea, lower respiratory infections, and meningitis, a more complex modeling strategy will be employed. Any changes to the general GBD 2010 modeling strategy outlined in Lozano et al.<sup>3</sup>, or to subsequently approved methods, must be approved by the GBD Scientific Council.

#### 9. Ensuring consistency between cause-specific estimates and all-cause mortality estimates

In accordance with the published methodology, models will be developed for each cause of death separately; the estimates for each cause will then be combined into estimates for all causes

simultaneously that sum to the demographic estimates of all-cause mortality. Estimates of causes of death will be combined using a simple algorithm developed for the GBD Study 2010<sup>3</sup>.

#### **10. Disease sequelae epidemiology data**

To support estimation for each disease sequelae incidence, prevalence, duration, remission, and excess mortality, a database of available published and unpublished data will be developed and maintained by IHME. Key inputs into this database include systematic reviews of the published and unpublished literature, analysis of household survey data, antenatal clinic surveillance data, reportable disease notifications, disease registries, hospital admissions data, outpatient visit data, population-based cancer registries, active screening data, and other administrative data.

#### **11. Estimating disease sequelae prevalence, incidence, and duration**

Most estimates for disease incidence, prevalence, duration, and excess mortality will be calculated using the latest version of the GBD Bayesian meta-regression tool (DisMod-MR or subsequently approved version), which was designed to address some of the key challenges in burden of disease analysis. Core Analytic Team members will carry out this modeling. For some causes where more complicated models capturing more stages of disease progression are necessary, such as HIV, more elaborate natural history models will be used, refined, or developed.

There will be a continuous process for updating and enhancing the DisMod-MR machinery. The version of DisMod-MR developed in the GBD Study 2010 was designed to run on a sizable cluster of computers; this machinery will be updated with the ultimate goal of enhanced speed and computational ease. All proposed changes to methodology, including refinements proposed by the Core Analytic Team and GBD Experts or refinements to a new form of DisMod-MR, must be approved by the GBD Scientific Council.

#### **12. Impairment levels**

In the GBD 2013, impairment analysis will be undertaken for the following: vision loss, hearing loss, anemia, infertility, heart failure, intellectual disability, and epilepsy. In each case, the quality and extent of data on the overall impairment level has been determined to be stronger than the data on how individual etiologies or conditions lead to that impairment. Attribution to each underlying cause of the impairment will be performed after calculation of the total envelope for that impairment. This list matches that used in the GBD Study 2010 and may be revised in future.

#### **13. Nature and external cause of injury analysis**

The GBD 2013 will utilize the specialized methods developed for injuries because of the dual nature of injury assessment<sup>7</sup>. Each injury is characterized by the nature of injury such as a femur fracture or head trauma and the external cause of injury such as a road injury or a fall. To assess disability, data are required on the frequency of the nature of injury as well as follow-up data on reduced health functioning at certain points in time after the injury. Since the cause list assigns death and disability due to injury by external cause, we also need to capture data on the matrix between the nature of injury incidence and the external causes leading to these injuries. The analysis will include survey, hospital, and outpatient data on the incidence of external causes and perhaps more importantly multiple sources of long-term follow-up data to estimate the fraction of individuals with each nature of injury progressing to

permanent disability. Core Analytic Team members will be responsible for carrying out this computational exercise.

#### **14. Disability weights for health states**

Disability weights are the key mechanism in the GBD approach through which disease and injury sequelae are made comparable with each other and with time lost due to premature mortality. The GBD 2013 will use the disability weights for health states published in the GBD Study 2010<sup>5</sup>. Disability weights may be updated over time by expanding the original data sets with additional data from comparable population-based surveys and then re-analyzing the dataset as a whole. The GBD Scientific Council will be responsible for approving the inclusion of new data from comparable surveys, changes to lay descriptions, or changes to methods to be used in calculation before updated weights are generated. The GBD Scientific Council does not profess any opinion on the disability weights themselves as these are simply the product of the application of peer-reviewed and published methods on assembled data. A single, uniform, set of disability weights will be applied for all time periods and for all geographic estimates, be that global, regional, national, or subnational to ensure comparability.

#### **15. Severity distribution**

People affected by the main disabling conditions in GBD 2013 typically present with symptoms across a wide spectrum of severity. We will use methods based on the GBD Study 2010<sup>7</sup> to quantify this range of severity. We will try to find more national-level surveys with both diagnostic information and general health status to improve upon the measurement. Proposed changes to this approach will be made to the GBD Scientific Council.

#### **16. Comorbidity simulation**

The GBD uses microsimulations to take into account comorbidity; the GBD 2013 will utilize the published methods from the GBD Study 2010<sup>7</sup>. Wherever possible, the inputs to the micro-simulation for each country, age, sex, year group will be at the level of detailed sequelae. Proposed changes to the comorbidity simulation, such as to capture dependent comorbidity, will need to be reviewed and approved or not by the GBD Scientific Council.

#### **17. Healthy life expectancy**

Healthy life expectancy results provide an important summary of overall levels of health and help elucidate important trends such as the compression or expansion of morbidity. The GBD 2013 will follow the methods developed in the GBD 2010<sup>6</sup>; we will use the life tables developed in component 4 for each country and the comorbidity-corrected YLD rates to estimate healthy life expectancy for all countries (listed in the “**Countries**” section below) from 1990-2013 for males and females separately. Proposed changes to the methodology will be reviewed and approved or not by the GBD Scientific Council.

#### **18a-c. Computation of YLLs, YLDs, and DALYs from diseases and injuries with uncertainty**

Estimates by age and sex for mortality by cause, for disease prevalence taking into account comorbidity, and for disability weights, are used to compute years lived with disability (YLDs), years of life lost (YLLs) and their sum, disability adjusted life years (DALYs). These computations are conducted by the Core

Analytic Team centrally for all diseases and injuries. Each quantity in the GBD 2013 is estimated with uncertainty following the methods published in the GBD 2010 study; any proposed changes to these methods must be approved by the GBD Scientific Council.

### **Risk factor exposure database**

Analogous to the same principles used for work on disease sequelae, IHME has created and will continue to expand a database of published and unpublished sources on the prevalence of exposure. For some risks, innovative sources such as satellite imagery will be used following the experience in GBD 2010. For a number of risk factors, primary survey data will be collated and re-analyzed along with published studies.

### **19. Estimating the prevalence of exposure**

Exposure estimates will be developed for many risks using the GBD Bayesian meta-regression tool DisMod-MR, or a subsequently developed and approved version. For some risks such as ambient air pollution, alternative modeling strategies will be used. In all cases, the estimation of exposure prevalence will generate uncertainty distributions. Core Analytic Team members will carry out these analyses. Any changes to the methodological strategy outlined in the 2010 capstone paper<sup>2</sup> will be presented to the GBD Scientific Council for approval.

### **20. Theoretical minimum risk exposure**

In general, the theoretical minimum risk exposures used in the GBD Study 2010 will be applied in the GBD 2013. Where new data exists, we will update the theoretical minimum risk exposure using the same methods as used in the GBD Study 2010<sup>2</sup>. Any suggested changes to this approach must be presented for review to the GBD Scientific Council.

### **21. Estimating relative risks for risk-outcome pairs**

Risk-outcome pairs will be included where the evidence meets the criteria for convincing or probable evidence<sup>2</sup>. All risk-outcome pairs included in the GBD 2010 will be considered for GBD 2013. In addition, risk-outcome pairs proposed by members of the GBD 2013 will be considered. The methods used for GBD 2010 to estimate age-sex specific relative risks for risk-outcome pairs will be the basis for the analysis for GBD 2013. Changes to the risk-outcome pairs or the methodological approach will need to be approved by the GBD Scientific Council. Uncertainty in the relative risks for each risk-outcome pair by age and sex is propagated into all final estimates.

### **22a-c. Computation of attributable burden for each risk factor with uncertainty**

In the GBD 2013, risk factor burden will be assessed using the distributions of burden for each disease associated with a risk factor as outlined in the GBD 2010<sup>2</sup>. Uncertainty for risk factors will reflect both uncertainty from the disease and injury estimation and from the population attributable fractions. Any proposed changes to this methodology must be approved by the GBD Scientific Council.

## Section 6. GBD 2013 Country List, Age and Sex Groups, and Cause Lists

### Countries

Point estimates with uncertainty intervals will be released for at least the following set of countries:

Afghanistan	Congo	Hungary
Albania	Costa Rica	Iceland
Algeria	Cote d'Ivoire	India
Andorra	Croatia	Indonesia
Angola	Cuba	Iran
Antigua and Barbuda	Cyprus	Iraq
Argentina	Czech Republic	Ireland
Armenia	Democratic Republic of the Congo	Israel
Australia	Denmark	Italy
Austria	Djibouti	Jamaica
Azerbaijan	Dominica	Japan
Bahrain	Dominican Republic	Jordan
Bangladesh	Ecuador	Kazakhstan
Barbados	Egypt	Kenya
Belarus	El Salvador	Kiribati
Belgium	Equatorial Guinea	Kuwait
Belize	Eritrea	Kyrgyzstan
Benin	Estonia	Laos
Bhutan	Ethiopia	Latvia
Bolivia	Federated States of Micronesia	Lebanon
Bosnia and Herzegovina	Fiji	Lesotho
Botswana	Finland	Liberia
Brazil	France	Libya
Brunei	Gabon	Lithuania
Bulgaria	Georgia	Luxembourg
Burkina Faso	Germany	Macedonia
Burundi	Ghana	Madagascar
Cambodia	Greece	Malawi
Cameroon	Grenada	Malaysia
Canada	Guatemala	Maldives
Cape Verde	Guinea	Mali
Central African Republic	Guinea-Bissau	Malta
Chad	Guyana	Marshall Islands
Chile	Haiti	Mauritania
China	Honduras	Mauritius
Colombia		Mexico
Comoros		Moldova

Mongolia	Rwanda	Taiwan
Montenegro	Saint Lucia	Tajikistan
Morocco	Saint Vincent and the Grenadines	Tanzania
Mozambique	Samoa	Thailand
Myanmar	Sao Tome and Principe	The Bahamas
Namibia	Saudi Arabia	The Gambia
Nepal	Senegal	Timor-Leste
Netherlands	Serbia	Togo
New Zealand	Seychelles	Tonga
Nicaragua	Sierra Leone	Trinidad and Tobago
Niger	Singapore	Tunisia
Nigeria	Slovakia	Turkey
North Korea	Slovenia	Turkmenistan
Norway	Solomon Islands	Uganda
Oman	Somalia	Ukraine
Pakistan	South Africa	United Arab Emirates
Palestine	South Korea	United Kingdom
Panama	South Sudan	United States
Papua New Guinea	Spain	Uruguay
Paraguay	Sri Lanka	Uzbekistan
Peru	Sudan	Vanuatu
Philippines	Suriname	Venezuela
Poland	Swaziland	Vietnam
Portugal	Sweden	Yemen
Qatar	Switzerland	Zambia
Romania	Syria	Zimbabwe

Any requests for additional geographies to be added 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 will be generated is as follows:

0-6 days	15-19 years	45-49 years
7-27 days	20-24 years	50-54 years
28-364 days	25-29 years	55-59 years
1-4 years	30-34 years	60-64 years
5-9 years	35-39 years	65-69 years
10-14 years	40-44 years	70-74 years

75-79 years

80+ years

Point estimates may be released using more aggregated age groups. Any requests to receive results for more aggregated age groups must be directed to the GBD Management Team.

## Sex

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

## Cause 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.

At a minimum, the GBD 2013 cause list will build off of the GBD 2010 published cause list<sup>1</sup>, which contained 291 causes and 1,160 sequelae. Further 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 will be reviewed and approved or rejected by the GBD Scientific Council.

### Risk factor list

The GBD risk factor list is organized into a hierarchy with three levels. The GBD 2013 risk factor list will be based on the GBD 2010 risk factor cause list<sup>2</sup>, with slight modification to include 9 risks at Level 1, 43 risks at Level 2, and 15 risks at Level 3. Level 1 risks in the hierarchy are groups of risk factors that are related by mechanism, biology, or potential policy intervention. Most risks are presented at level 2 but in some cases such as occupational carcinogens calculations are done at a third level as there are many detailed but relatively small burden risks included in the grouping. The category of dietary risks clusters together some key behavioral risks. Physical inactivity has been separated from the dietary risks given the different policy implications. While not in time for the GBD 2013, we will be embarking on a major conceptual overhaul of risk factors to examine in detail the inclusion of socio-economic risk factors to be included in the future updates of the GBD. All proposed changes to the risk factor list will be reviewed and approved or rejected by the GBD Scientific Council.

## Ranking lists

For presentation of the leading causes of death, YLLs, YLDs, and DALYs, we need to choose the level in the cause hierarchy at which we rank conditions. We must separately do the same thing for risk factors. Because the leading causes of burden tend to have some influence on the perception of disease control priorities, the choice of aggregation is at once important and subject to debate. To help convey the complexity of the burden of disease results we have identified a ranking list selected to distinguish and cluster diseases and injuries together and one to cluster risks together that may have programmatic or public health significance. The ranking cause lists are flat; it is one set aggregation of causes or risks, not multiple levels of hierarchy like the main cause lists. For the disease and injury ranking list, we aggregate detailed causes within the broader categories of maternal causes, diarrheal diseases, lower respiratory infections, stroke, and road injury for this reason. The causes included in the ranking list do not include residual categories such as other parasitic or other cardiovascular because these categories represent complex aggregations of detailed causes for which there is no clear public health program. The causes on the ranking list along with the excluded residual categories are also mutually exclusive. For the risk factor cause list, we group all dietary risks as many of policy recommendations would be similar, while we separate physical inactivity within the ranking list given the different implications for public health strategies. For similar reasons, we group all occupational risks into a single risk within the ranking list. The GBD Scientific Council is responsible for approving changes to the causes within this ranking list.

## Section 7. Data

High quality, ongoing estimation requires a constant stream of the most up-to-date data available for a wide range of indicators. There will be continuous extraction of studies from the literature and key data sources throughout the Global Burden of Disease..

### *Industrialized literature reviews*

Given the robust scope of indicators being utilized throughout the GBD, standard systematic literature reviews for each disease, injury, and risk factor measured are not feasible. In order to continuously capture studies with key data for each of these indicators, we will undertake an industrialized approach to literature reviews. As described in a separate protocol on industrialized literature reviews, the Core Analytic Team will continuously monitor a large collection of peer-reviewed scientific and medical journals 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 key centralized data*

The Core Analytic Team at IHME will be responsible for systematically collating and cataloguing data from several generally centrally-collected sources such as vital registration, hospital data, cancer and other disease registry data, verbal autopsy, maternal surveillance systems, censuses and large-scale household surveys. It is expected that GBD Experts will be 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 Experts 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 will bear 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

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

1. Crude data: 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: the point estimates and 95% uncertainty intervals, where appropriate, for the quantities of interest detailed in the “**Products**” section above.

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.

This section outlines the access parameters for both the general public and for GBD Experts.

#### *General access parameters for crude data*

All sources that provided data for the estimation of GBD estimates will be catalogued as legally permissible in IHME’s public data catalog, the Global Health Data Exchange (GHDx). Anyone that is looking for data on a particular cause, risk, or country will be able to search the GHDx and retrieve relevant crude data sources. Information provided include: 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 will happen on a continuous basis as legally permissible, and are expected to be made publicly available on September 3, 2014.

#### *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 were used for GBD 2013 analysis will be 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 will be linked to the full metadata in the GHDx where legally permissible. The model input data points are expected to be released on September 3, 2014, 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% uncertainty intervals (where possible) of the GBD 2013 quantities of interest will be made available to the public in two stages. First, updated visualization tools will be 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 2013 sufficient time to submit manuscripts using the updated results to which they have contributed. As outlined in the “**Timeline**” section above, the tabular form of the data is envisioned to be released to the public on September 3, 2014.

### *Data access for GBD Experts*

For a designated period in advance of the general public, GBD Experts will be granted privileged, confidential access to the crude and model input data where legally permissible, as well as the final point estimate results with 95% uncertainty as applicable pertaining to their enrolled area of expertise. The period of exclusive access is explicitly intended to encourage publication and the involvement of experts in furthering jointly held academic interests while achieving widespread dissemination of GBD results in a multitude of settings. The timeline for this privileged access varies by GBD Expert type and is detailed in the “**GBD Experts**” section above.

## **Section 8. Publications and Presentations**

The GBD 2013 aims to provide the most comprehensive up-to-date estimates on burden. This resource serves as a critical tool for policy-makers, researchers, donors, and others to make informed decisions and guide priorities using the most current information possible. In order to maximize the impact and benefit of the GBD as a global public good, we envision and strongly encourage a robust collection of publications and presentations that provide important insight and implications from this data. The following information outlines the publication principles of the GBD 2013 up until September 3, 2014 when the data (as legally permissible) and tabular results are released to the public. Following this public release, appropriate standard publication and presentation procedures should be adhered to.

By participating in the GBD 2013 as a GBD Expert, GBD Scientific Council member, GBD Management Team member, or Core Analytic Team member, individuals are provided multiple opportunities for authorship. In certain cases, other individuals who have contributed meaningfully and meet journal eligibility for co-authorship may also be included. Following on the demand and interest generated by the triple issue in *The Lancet* that was devoted entirely to the GBD 2010, IHME and *The Lancet* have entered a strategic partnership to produce a similar issue for the GBD 2013, should manuscripts be accepted through the normal peer review process of the *Lancet*. *The Lancet* aims to produce a GBD 2013 issue that will present the updated estimates, describe any methodological innovations, and highlight a selection of particularly policy-relevant topics.

Until the annual issue with updated numbers is published, no other publications or presentations utilizing GBD results may be released. However, in order to accommodate ongoing research opportunities and conferences, requests for exceptions can be made to the GBD Management Team and may be accommodated. If exceptions are made, any estimates must be clearly labeled as preliminary results, and must adequately cite the GBD 2013, as detailed below. There will be roughly 4 months

between the publication of the capstone papers with the full estimates and the public release of the underlying datasets in order to encourage publication opportunities for members of the GBD 2013. In addition, GBD Experts will be provided the final estimates and data sources used earlier in the update cycle as part of the consultation process; see the “**GBD Experts**” section above for timeline information. Presentations of already published methodology can be made at any time. In all cases and at all times, the GBD Management Team must be formally notified in writing of all publications and presentations utilizing the GBD 2013 data, methods, and/or results.

All publications and presentations- including those that use data that are derived from the GBD 2013 effort and those which are a product of individual experts in the GBD 2013 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 2013 (GBD 2013), led by the Institute for Health Metrics and Evaluation. The GBD 2013 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.”

The GBD conforms to the principles of authorship, disclosure, and scientific integrity as outlined in the requirements of the peer-reviewed journal to which a given publication is submitted. All authors listed on publications from this study should meet those criteria. Each individual who is an author will be asked to state their specific contribution to the work presented in the publication. All individuals who are deemed eligible for authorship will have the opportunity to read the manuscript prior to submission and be able to provide specific feedback on it. Eligible authors may choose to opt out of authorship at any point in time prior to acceptance of the submission. Disagreements over authorship criteria should be handled in accordance with the process outlined in the “**Adjudication**” section above.

The following sections provide more detail specific to the process by which different types of publications or presentations will be created and the broad groups that will be considered for authorship. In all cases, eligible authors must conform to the criteria as specified by the journal.

### Capstone Papers Presenting Overall Estimates

As mentioned above, IHME and *The Lancet* intend to produce another single GBD issue for the GBD 2013 results, should the manuscripts be accepted through peer review. This issue will contain a set of capstone papers detailing at least the following indicators: all-cause mortality, causes of death, non-fatal health outcomes, healthy life expectancy, DALYs by disease and injury, and DALYs attributable to risk factors. The indicators will likely be grouped together for publication; for example, all-cause mortality and cause-specific mortality may be prepared as one manuscript. In each of these instances, the Principal Investigator will be responsible for assembling a group to develop the first draft of each manuscript, determining authorship order and identifying a corresponding author. Eligible co-authors must meet *The Lancet’s* criteria and will be generally selected as follows:

- All-cause mortality: Any GBD Expert specific to a country that has provided feedback on all-cause mortality. Any GBD Expert that contributed to the all-cause mortality estimates. Any Core Analytic Team member who contributed intellectually to the mortality estimation process

or novel methods for mortality estimation. Any Core Analytic Team member who contributed intellectually to the development of new covariates that were used to generate the mortality estimates. In certain cases, other individuals who have contributed meaningfully and meet journal eligibility for co-authorship may also be included.

- Causes of death: Any GBD Expert specific to a country that has provided feedback on causes of death or YLLs and any GBD Expert that contributed to a disease or injury that causes death. Any Core Analytic Team member specific to a country, disease, or injury or who contributed intellectually to the computation process or novel methods for cause of death estimation. Any Core Analytic Team member who contributed intellectually to the development of new covariates that were used to generate the cause of death estimates. In certain cases, other individuals who have contributed meaningfully and meet journal eligibility for co-authorship may also be included.
- Non-fatal health outcomes: Any GBD Expert specific to a country that has provided feedback on YLDs and any GBD Expert that contributed to a disease or injury that leads to non-fatal health outcomes. Any Core Analytic Team member specific to a country, disease, or injury or who contributed intellectually to the central computation process or novel methods for the estimation of non-fatal health outcomes. Any Core Analytic Team member who contributed intellectually to the development of new covariates that were used to generate the estimates of non-fatal health outcomes. In certain cases, other individuals who have contributed meaningfully and meet journal eligibility for co-authorship may also be included.
- DALYs by disease and injury: Any GBD Expert specific to a country that has provided feedback on DALYs and any GBD Expert that has contributed to a disease or injury that leads to either non-fatal health outcomes or causes death. Any Core Analytic Team member specific to a country, disease, or injury or who contributed intellectually to the central computation process or novel methods for the estimation of comorbidities and DALYs. Any Core Analytic Team member who contributed intellectually to the development of new covariates that were used to generate the estimates of non-fatal health outcomes or causes of death. In certain cases, other individuals who have contributed meaningfully and meet journal eligibility for co-authorship may also be included.
- DALYs attributable to risk factors: Any GBD Expert specific to a country that has provided feedback on risk factors and any GBD Expert that has contributed to a given risk factor. Any Core Analytic Team member specific to a country or risk factor who contributed intellectually to the central computation process or novel methods for the estimation of DALYs attributable to risk factors. Any Core Analytic Team member who contributed intellectually to the development of new covariates that were used to generate the estimates of risk factors. In certain cases, other individuals who have contributed meaningfully and meet journal eligibility for co-authorship may also be included.

Given the large authorship on the capstone papers the following authorship order is anticipated:

- First author: the lead of the research presented in the capstone paper

- Additional lead authors, when appropriate: given the robust scope of these papers there may be additional research leads listed at the beginning of the manuscript
- Co-authors: the bulk of the co-authors will be listed next in alphabetical order
- Senior author(s): given the robust scope of these papers there may be more than one senior author listed last
- Corresponding author: responsible for managing the publication submission process, responding to feedback to reviewers, and finalizing accepted papers with editors of the relevant journal.

All eligible authors will need to submit an authorship form in accordance with the journal regulations in order to be included. All authors will have the opportunity to opt out of being included on the publication prior to the time the manuscript is accepted.

### **Disease-specific, Risk Factor-Specific, Disability Weight, and General Methodology Papers**

We highly encourage the publication of a robust set of additional manuscripts. We envision that a large range of publications will be drafted that examine more closely: 1) the results and trends for specific diseases, injuries, or risk factors, 2) data sources, lay descriptions, or methodological enhancements for disability weights, and/or 3) innovations in methodology used. For such publications, any member of the GBD 2013 with an idea for a publication about their enrolled area of expertise should work with the relevant GBD Experts and members of the Core Analytic Team to jointly develop a plan for the publication, proposal of authorship order, and proposal of who will take the lead on preparing the first draft. To ensure that all individuals who have contributed to the research are properly acknowledged, this proposal should be formally submitted to the GBD Management Team for approval. Following the public release of tabular data, these stipulations no longer apply, though the GBD Management Team should still be formally notified of any publications from members of GBD 2013. These manuscripts can be led either by GBD Experts or by members of the Core Analytic Team. The GBD Management Team will resolve any disputes regarding authorship order or eligibility.

Eligibility for co-authorship will follow the principles as outlined in the requirements of the peer-reviewed journal to which a given publication is submitted. In general, those considered will be the full set of GBD Experts and Core Analytic Team members who have contributed significantly to the analyses and results for topic being described. In certain cases, other individuals who have contributed meaningfully and meet journal eligibility for co-authorship may also be included. All eligible co-authors will have the opportunity to contribute to the draft manuscript and comment on the accepted manuscript. In some cases, a paper may require novel analyses to be conducted to produce the results that are desired. In such cases, the authoring Core Analytic Team member(s) will be responsible for carrying out such analyses. In many cases they will have additional responsibilities for other analyses simultaneously and will need to sort those according to priorities, with input from the GBD Management Team as needed.

## Country-Specific, Region-Specific, and Global Age-Specific Papers

There will be instances where publications will use the comprehensive burden of disease estimates over all diseases, injuries, and risk factors for a particular geography or age group. Such country-specific, region-specific, or global age-specific publications will provide an important opportunity to wed GBD results for a geography or age group with more detailed context and policy implications.

In some of those cases, authorship on country-specific, region-specific, and global age-specific papers will be confined to those already within the GBD 2013. In other cases, such papers may involve individuals outside of the GBD 2013. The Principle Investigator, in consultation with appropriate GBD experts, will decide the authorship eligibility and order, as well as identify the individuals who will prepare the first draft, respond to reviewer comments, and revise the manuscript. For geography-specific publications, all GBD Experts who list their primary affiliation within the country/countries specified in the manuscript will be identified as eligible co-authors. If the country-specific or region-specific paper summarizes overall results by cause, the Principle Investigator may decide to exclude from eligibility any GBD Expert whose specific disease or injury expertise is not relevant to the country/countries discussed even if their primary institutional affiliation is within that geography - e.g. researchers based in a high-income country working on diseases only in low-income countries. In addition, any GBD Expert or Core Analytic Team member who has made significant intellectual contribution for the analyses meeting the standards for authorship of the target journal will be considered eligible.

## Policy Reports and Briefs

In addition to the more traditional, peer-reviewed academic publications, there are likely to be publications that are intended to reach non-academic audiences such as policymakers and donors. Prior to the envisioned public release of the data on September 3, 2014, these reports will be produced by IHME; reports may be jointly produced with other key stakeholders. They may summarize results overall or for a specific region, disease, injury, or risk factor. From the GBD Study 2010, a good example of this is the publication titled “The Global Burden of Disease: Generating Evidence, Guiding Policy”<sup>9</sup>. During this period there will be no specific author attribution on these publications. Instead, they will be listed with corporate authorship and will explicitly reference the GBD 2013. The writing and layout of said publications will be executed almost exclusively by those at IHME, in conjunction with other members of the GBD 2013 as desired. Individuals who play a significant role in the content creation and assembly will be noted in the acknowledgements of the publication.

## Posters

Many conferences solicit abstract submissions for research posters. These may cover any number of research topics related to the GBD. In general, authorship on the abstract should follow the same principles as described above for the appropriate topic-specific subcategory of peer-reviewed publications. All abstracts and resultant posters should make explicit reference to the GBD 2013, using the citation listed above. If individuals wish to use preliminary results in the poster prior to the publication of summary results in the Capstone Papers, they must make an explicit request for permission to the GBD Management Team. Requests will be granted on an exception basis; approved

poster exceptions must additionally be labeled with: “Preliminary results from the GBD 2013. Source: Institute for Health Metrics and Evaluation <http://www.healthmetricsandevaluation.org/gbd/2013>”. Poster abstracts may always use published results or methodologies. Following the publication of the capstone papers the GBD Management Team should still be notified of all posters that are presented using GBD 2013 methods or results.

## Presentations

Individuals may also wish to give presentations about analyses or methods in different venues. In general, presentations must use published results. Prior to the publication of the capstone papers, requests to use results in presentations should be directed to the GBD Management Team. In cases where a request to use preliminary results is granted, each slide in the presentation must be labeled with: “Preliminary results from the GBD 2013. Source: Institute for Health Metrics and Evaluation <http://www.healthmetricsandevaluation.org/gbd/2013>”. In addition, the presentation must include the full study citation listed near the beginning of the “**Publications and Presentations**” section. Following the publication of the capstone papers, the GBD Management Team should still be notified of all presentations using GBD 2013 methods or results.

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