

Study Protocol

NASBOD 2013: Design, Definitions, and Metrics

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Abstract

Background: Iran has witnessed a substantial demographic and health transition, especially during the past 2 decades, which necessitates updated evidence-based policies at national and indeed at subnational scale. The National and Subnational Burden of Diseases, Injuries, and Risk Factors (NASBOD) Study aims to provide the required evidence based on updated data sources available in Iran and novel methods partly adopted from Global Burden of Disease 2010.

Objective: This paper aims at explaining the motives behind the study, the design, the definitions, the metrics, and the challenges due to limitations in data availability.

Methods: All available published and unpublished data sources will be used for estimating the burden of 291 diseases and 67 risk factors from 1990 to 2013 at national and subnational scale. Published data will be extracted through systematic review. Existing population-based data sources include: registries (death and cancer), Demographic and Health Surveys, National Health Surveys, and other population-based surveys such as Non-Communicable Diseases Surveillance Surveys. Covariates will be extracted from censuses and household expenditure surveys. Hospital records and outpatient data will be actively collected as two distinct projects.

Due to lack of data points by year and province, statistical methods will be used to impute the lacking data points based on determined covariates. Two main models will be used for data imputation: Bayesian Autoregressive Multi-level models and Spatio-Temporal regression models. The results from all available models will be used in an Ensemble Model to obtain the final estimates. Five metrics will be used for estimating the burden: prevalence, death, Years of Life Lost due to premature death (YLL), Years of Life Lost due to Disability (YLD), and Disability-Adjusted Life Years Lost (DALY). Burden attributable to risk factors will be estimated through comparative risk assessment based on Population Attributable Fraction (PAF). Uncertainty Intervals (UIs) will be calculated and reported for all aforementioned metrics.

Results: We will estimate trends in terms of prevalence, deaths, YLLs, YLDs, and DALYs for Diseases, Injuries, and Risk Factors province from 1990 to 2013.

Conclusion: Results of the present study will have implications for policy making as they address health gaps in Iranian population and their inequality between provinces.

Keywords: Burden of disease, national, sub-national

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Introduction

The National and Sub-national Burden of Diseases, Injuries, and Risk Factors (NASBOD) is a systematic effort for estimating the magnitude of health loss due to diseases, injuries and risk factors first at national and subsequently at sub-national levels in a comparative methods and definitions with Global Burden of Diseases 2010.¹⁻⁸ Health policy makers at national and sub-

national levels, health sector leaders, researchers and citizens could directly use the produced estimates in NASBOD 2013. The NASBOD 2013 provides a “bird’s eye view” of health status of populations across the country to compare the burden of different diseases and their distributions at once. This paper aims to explain the motives behind the study, the design, the definitions, the metrics, and the challenges due to limitation in data availability.

Background

The World Bank commissioned the first round of GBD study in 1992 for providing a comparative and comprehensive assessment of the disease burden in 1990. The study was done for the world and for 8 regions.⁹⁻¹²

The methods, measures and findings of the 1990 GBD study were accepted globally. The investigators believed that all sources of health data contain useful information on epidemiology of diseases and for those with some source of selection or information bias, using a few mathematical and statistical methods they could be used to provide unbiased representative estimates includes incidence, prevalence, duration, and mortality for almost 500 squalors of diseases, injuries and risk factors.^{10,13}

Many diseases, for example, psychiatric diseases and sense or-

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gan disorders may cause significant contribution in the non-fatal outcomes of health but no or few fatal outcome. Therefore measures of survival or mortality are not providing a broad picture of health status of the population. Burden of diseases study needed a measure, which combines fatal and non-fatal outcomes. To measure the burden of disease, the 1990 GBD study used a metric that measures both premature mortality (years of life lost because of premature mortality or YLL) and disability (years of healthy life lost due to disability or YLD, disability weight was based on expert opinions). The sum of the two components is called DALYs.^{10,14}

The main criticism of the GBD study focused on the structure of DALYs¹⁵⁻¹⁷ particularly the social choices pertaining to age weights and severity scores for disabilities.

The criticism of the 1990 GBD, especially of the assessing the disability weights, changed to use of population-based valuation rather than expert opinion as used in the 1990 study.¹⁸⁻¹⁹ In addition, improved population datasets such as national surveys, censuses, surveillances, and electronic medical records have led better estimations and less dependency to the models. The other advancement in 2001 GBD compare to 1990 GBD was major methodological progress for quantification of the attributed burden to major risk factors.²⁰ The final development in 2001 GBD was the quantification of the uncertainty in the estimates.

In 2010 GBD estimates provided from 1990 to 2010 for 291 diseases 67 risk factors, 1,167 sequelae in 187 countries from 21 regions around the world by sex and 20 age groups.^{5-7,21-24} Institute for Health Metrics and Evaluation conducted 2010 GBD, in collaboration with, Harvard University, Imperial College London, John Hopkins University, University of Queensland, University of Tokyo, and World Health Organization. In this new iteration of GBD, there were many modifications in methods and advancements in results. In methods, the new DISMOD were used, which is a more flexible version with more capabilities. There are also a few changes in the measures. For example in the new DALY, age weight and discount weight are not employed and disability weights are estimated using a new approach. In the results, the estimations were for a broader range of diseases and risk factors, age groups, countries, and time period.^{5-7,21-24}

Iran burden of diseases study for the first time has been conducted in 2003,²⁵ by estimating burden of diseases for 213 diseases and no success to estimate the attributed burden to risk factors. The study was a cross sectional study for 2003 at national level and for six provinces. The estimates were reported without uncertainty interval and no success to estimate the burden attributable to risk factors. A decade after the first burden of disease study in Iran needs for assessing the burden of diseases and their distribution was enough to motivate Ministry of Health to conduct a new round of the burden of diseases study called NASBOD 2013. This round aims to provide estimates from 1990 to 2013 at national and provincial levels.

Why NASBOD study is needed?

The NASBOD study aims to estimate the burden of 290 diseases and injuries and 67 risk factors from 1990 to 2012 at national and provincial levels. The NASBOD study provides information that can be used to evaluate the progression in health status over time within a province or relative performance across provinces. In this case, NASBOD should be considered as other developmental indicators in economics such as national income and product ac-

counts,²⁶ which had a great contribution to economic knowledge in United Kingdom.

The NASBOD is the main resource that could be used for identifying the national and sub-national priorities. Many national interventions are implemented in Iran health system that could be cost-effective and addresses the health problem for some geographic area but not all sub-national geographic areas.²⁷ Providing the distribution of diseases and risk factors at sub-national level would be a guide for selecting the interventions that address main health problems among sub-national populations.

Medical and public health schools in Iran are dedicating a number of credits for their students to work on specific research topics. Due to sub-optimal data availability, especially from national surveys, and due to lack of a navigating system for research on health, most all those potential of knowledge generation resources are not well utilized. The NASBOD study will addresses both sub-optimal data availability and lack of navigating system for the health research in Iran.

NASBOD organization

The NASBOD 2013 study is ordered and supported by Ministry of Health, deputy minister for public health and is conducted by a steering committee includes principle investigator, top policy makers from Ministry of Health, those managers in Ministry of Health with more focus on diseases, and those scientist with more focus on population health. An external evaluation committee includes international experts and representative of international organizations such as World Bank and World Health Organization EMRO with interests of the burden of diseases.

The executive part of NASBOD organization includes a core team, which is responsible for providing the definitions on measures, standardizing processes and protocols such as systematic review protocol, training all researchers involved in NASBOD, data hunting and gathering, data cleaning, modeling, interpreting results and providing reports, and 34 technical teams which are responsible for providing the practical definition of diseases and risk factors, and contributing in accessing surveys datasets, interpreting of results and preparing the reports (Figure 1).

Core team responsibilities

The core team was formed to prepare all needed basic functions in NASBOD study in a way that all technical teams are able to function well. The core team provided all needed basic definitions include technical measures, time period, age groups, sub-national level, and a comprehensive list of diseases, injuries and risk factors. The NASBOD study needs considerable research-related skills include searching, epidemiologic, and quantitative skills and the core team is responsible for training related skills for those who are involved in a specific part of the NASBOD study. The list of the training courses is provided. Data hunting and gathering is another task for the core team. A systematic search to obtain all published data on the distribution of diseases, injuries and risk factors is a part of this task. A considerable surveys have been conducted in health and non-health domain at national and sub-national during last two decades which the core team will attempt to have access to their datasets. For a few domains that reliable data do not exist such as hospital data, the core team plans to collect data and use them for estimating the NASBOD ultimate measures. The data scarcity especially at sub-national level, inevitably, pushes the core team for providing the models, which

make us enable for imputing the data. The other models will be developing in parallel with the main models which are responsible for increasing the rate of data availability including cross walk models. Producing the results and converting them to the graphs and tables, which make them easier to be interpreted, is another responsibilities of core team. In the final part, core team will invite each technical team and other related experts to discuss the results and find any possible contradictions in the preliminary results and in last stage, core team will prepare the final report in collaboration with the technical team on each specific disease, risk factor, or injury group.

Technical teams responsibilities

The technical team members include at least one or more experts from the core team and also most prominent research centers or individuals in the field of a specific disease or a group of diseases, risk factors and injuries in Iran. Each technical team also will include public health or epidemiology experts who already have worked on that specific field and will be able to help on the practical definitions, systematic search, modeling, and interpretation of the results. The main tasks of the technical team are finalizing the diseases, risk factor, or injuries list of that specific group and providing the practical definition of each disease, risk factor, and injuries. The list includes all diseases, risk factors, or injuries, which this specific technical team will estimate their burden or their attributed burden. The other task of technical team is contributing in systematic search for published data and using its network to have access in unpublished data such as national and sub-national datasets. Technical teams will provide recommendations on the results and modeling and will have contribution in preparing final report. All technical teams will enjoy of at least an international consultant to make sure that the chosen path is the most efficient one.

Definitions

The NASBOD will use DALY (Disability Adjusted Life Years), YLD (Years Lost due to Disability), YLL (Years Life Lost) and death as measure in rate and cause fraction to depict the fatal and non-fatal health outcomes of diseases, risk factors, and injuries. DALY, YLD and YLL will be estimated without considering age weight and discount rate to make the estimates compatible with GBD 2010.²⁸ The age limit will be 86 years for both male and female and YLD will be estimated based on the prevalence of diseases rather than their incidence. All measures will be provided for both sexes and 20 age groups at national and provincial levels.

Functions

Following functions are the main processes of the NASBOD:

Standards and regulations

The core team provides standards for the processes of choosing diseases, risk factors and injuries that their burden will be estimated, systematic searches, and intellectual properties. Based on standards provided by the core team, all systematic searches have to be done for PubMed, ISI Web of Sciences, and Scopus among all international search engines and IranMedex, SID, and Iran.doc among all domestic search engines. The reason for choosing these search engines was their effective coverage of almost most papers published about Iran's diseases, risk factors, and injuries's distribution among general population. Standards for search terms pro-

vides also by the core team. The details of systematic searches and search terms are explained for each group of diseases, risk factors and injuries in other papers published in this issue.²⁹⁻³⁸

Visual Impairment Burden in Iran; VIBI study protocol. The other standards that have to be determined by the core team are those that will explain how the technical teams have to choose diseases using GBD list and expert opinion in the way that diseases be chosen that have the highest burden for Iranian population. The last list of standards will be involved with the intellectual properties since the NASBOD study is formed through teamwork with collaborations of more than 300 researchers. The standards will determine the rights of researchers on the produced reports and publications.

Training

The NASBOD study needs expertise and knowledge from different disciplines. Since most of researchers in the NASBOD study are not familiar with all needed skills, designing and conducting workshops and courses related to the needed skills and expertise regarding the NASBOD study is crucial. Workshops on the systematic review with focus on burden of diseases, comparative risk assessment, demographic methods on child and adult mortality estimations, burden of diseases and DISMOD II, modeling, multilevel analysis models, spatio-temporal models, dealing with incompleteness and misclassification of death and cancer registry systems, Gaussian Process Regression models, and other needed packages in R and Stata are designed and gradually will be held for those who need to participate in these workshops.

Data gathering

The NASBOD study will use all possible data sources that help estimating prevalence and incidence of diseases, or premature deaths by cause. The existing data sources in Iran includes all published data, death³⁷ and cancer.³⁹ registry systems, national and sub-national surveys within health sector, mostly focused on behavioral, lifestyle, and metabolic risks among general populations such as NCDSS 2005 – 2009 and 2011,⁴⁰⁻⁴¹ NHS 1991 and 2000,⁴² DHS 2000,⁴³ House Hold Expenditure,⁴⁴⁻⁴⁵ IHHP 2001 and 2007,⁴⁶ TLGS 2001 up to now, MONICA 2003,⁴⁷ national and sub-national surveys among non-health sectors, mostly focused on the demographic, human capital, expenses, and other needed covariates (such as household expenditure survey.⁴⁸⁻⁵⁰ Censuses are another source for NASBOD study, which provides needed demographic data and includes some useful health data.

The health information system in Iran does not support hospital and outpatient data in the way that makes them useful in the NASBOD study. The core team designs and conducts a national survey on inpatient data to obtain a representative valid data from all 863 hospitals (all existing hospitals) admissions from 1996 to 2011. The details of the Hospital Data Survey are explained in other paper in this issue.⁵¹ For outpatient data the NASBOD study will use a representative sample of all prescription (23 million samples) for last 5 years, which are obtainable in the Drug and Food Organization.⁵²⁻⁵⁴ Drug and Food Organization could provide all data on medicine purchasing from pharmacies at district level too. The other data source in Drug and Food Organization is on special diseases since the patients with special diseases are eligible for the cash transfer program as subsidy for their medicine.

Materials and Methods

YLL and YLD estimates are prerequisites for estimating DALY. Figure 1, 2 and 3 depict all data sets, processes and computations in NASBOD study for YLL, YLD, and attributable DALYs to risk factors, respectively. For estimating the YLL, we mostly rely on death registration system, which is administered by Ministry of Health and provides deaths counts by age, sex, and causes. Since death registration system in almost all developing countries are suffering from a degree of incompleteness and misclassification, the core team decided to address the incompleteness and misclassification problems of death registration system. For more explanations of the methods, details are provided somewhere else.³⁷ Since death registration system is available since 2004, we need to address the missing data for years from 2003 back to 1990. We will explain the models for imputation briefly later in this paper. For YLD and so prevalence of diseases, risk factors and injuries, the core team focuses on the published data, cancer registry, national and sub-national surveys, Hospital Data Survey, and outpatient data sources. However, due to data scarcity at national and sub-national levels, the core team needs to address the sub-optimal data availability for prevalence of diseases, risk factors and injuries. After using models for imputing missing data, YLD will be estimated for diseases in the list of NASBOD. Summation of YLLs and YLDs will provide DALYs caused by each disease.

Comparative risk assessment will be used for estimating population attributable fraction for each diseases risk factor pair and the attributed DALY to each pair will be calculated and finally all those attributed DALYs to each risk factor will be summed to estimate the burden attributed to each risk factor.

Statistical methods for data imputation are discussed in more details somewhere else.⁵⁵⁻⁵⁶ These methods are sophisticated regression models, which are using existing data, models for age, models for hierarchical pattern of data, spatial and temporal pattern of data, and covariates to impute and estimate for the missing data. There are technical challenges for each method in the NASBOD context that might be interests of those with quantitative concentration. Covariates needed for these models will be gathered during data gathering phase and it's estimated that about 84 covariates will be created to be used in the imputation methods.

In the imputation models, we will use two dependent variables includes rate and cause fraction. We will fit models for these two dependent variables and those two methods (multilevel autoregressive and spatio-temporal) using a few covariates, which ends up with hundreds of models. The NASBOD study has no intention to throw out some of those models with performance worse off than others. Instead, the core team will rank all those models based on their performance and using the rank will produce a weight for each model. The weights will be used to sum up all results from all models as imputed values.

Interpretation of the results

The final results will be discussed in technical teams and after modification the models if it's necessary, they will be shared with experts, epidemiologists, clinicians and policy makers in a conference on the NASBOD study.

Publications

The compiled results for diseases, injuries and risk factors will be published as report for Ministry of Health. We also will publish

all papers as individual papers or series based on clinical, epidemiologic, and health policy interests in international or domestic journals.

Policy implications

The NASBOD study addresses health gaps among Iranian population and their differences between provinces. Burden of diseases study will provides vast data on diseases, injuries and risk factors levels and distributions, which navigates policy makers for resource allocations. The next step in the research domain might be to estimate the cost of each disease, injury, and risk factor for the health system and comparing distribution the burden with the distribution of the costs. These two pieces of information along with health system performance assessment will provide all needed evidence for policy making in health system. The other application of the NASBOD study will refer to its implications in the health insurance industry. Knowing the distribution of diseases and average cost of treatment will provide the opportunity for premium estimation at sub-national levels.

Conclusion

The NASBOD study is a systematic effort to quantify the distribution of diseases, injuries, and risk factors. The NASBOD study is one of the pioneers of burden of disease studies, which aims to estimate the burden of diseases, injuries and risk factors at sub-national levels. This study collects almost all data sources regarding deaths, prevalence, incidence, and burden of diseases in Iran and will compile them in a standard format. All estimates produced in the NASBOD study will be provided with their uncertainty intervals. Based on our preliminary search on the data sources, the study faces sub-optimal data availability and needs to use statistical methods to address the scarcity of data. We strongly recommend Ministry of Health to take a systematic approach for establishing a comprehensive data gathering process in the near future to make sure that all needed data regarding policy making is produced and available. The other concern of the core team of the NASBOD is the quality of produced data. Considerable missing data among variables in the datasets, inconsistencies in questions among repeated surveys, inappropriate sampling and weighting, low reliability on the results due to sub-optimal standards and supervision, lack of identifier for district and province of the observations, and no consistency in the sampling method among population are major concerns of the quality of national surveys and registry systems, which has to be address by Ministry of Health.

Abbreviations

BODS: Burden of Oral Diseases Study; DALY: Disability-Adjusted Life Years; GBD: Global Burden of Disease; NASBOD: National and Sub-national Burden of Disease; YLL: Years of Life Lost due to premature mortality; YLD: Years of Life Lost due to Disability.

Competing Interests

The authors declare that they have no competing interests.

Authors' Contributions

General design prepared by Farshad Farzadfar and Bagher Lri-jani. The primary draft was prepared by Farshad Farzadfar and revised by all co-authors. All authors have given approval to the final version of the manuscript.

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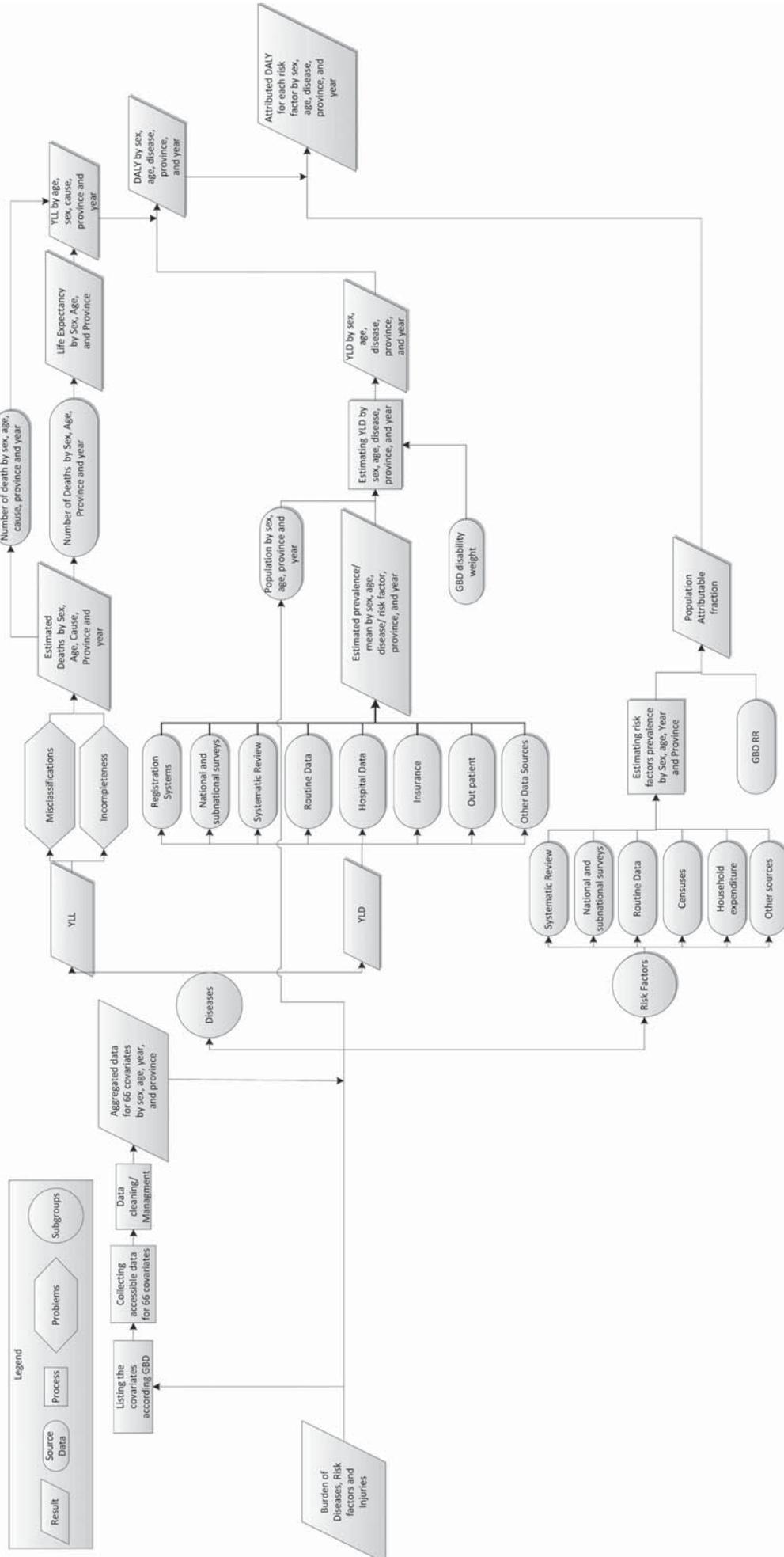
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Appendix 1: General scheme of National and Sub-national Burden of Diseases study



Appendix 2: scientific scheme of processes, data sources and obtainable estimation in National and Sub-national Burden of Diseases

