Study Protocol

National and Sub-national Burden of Visual Impairment in Iran 1990–2013; Study Protocol

Elham Ashrafi MSc PhD Candidate[1,2,3], Seyed-Farzad Mohammadi MD MPH•[3,4], Akbar Fotouhi MD PhD[2], Alireza Lashay MD[3], Mohsen Asadi-lari MD MPH PhD[6], Alireza Mahdavi MD MPH[4], Mahmoud Jabbarvand MD[3], Sahar Sobhani MD[5], Farshad Farzadfar MD MPH DSc•[5,7]

Abstract

Background: Although Visual Impairment (VI) and its prevention is a public health issue, sub-optimal information about its magnitude in national level and its distribution is one of the impediments for visual health advocacy. In this article, we are detailing the approaches which will be taken to estimate the magnitude (prevalence, incidence, and burden), distribution, and trend (1990 to 2013) of low vision and blindness in Iran. Besides that, an attempt will be made to describe inequalities and their determinants.

Methods: After finalizing the list of diseases, a systematic search will be started using confirmed search terms and all published and unpublished data will be extracted. Other data sources, including data from hospital records will be added to the data extraction sheet. Using distinct statistical models including spatio-temporal model and multilevel autoregressive model, we will estimate rate of burden measures of eye disease and their uncertainty interval by sex, age, year, and province as well as social determinants of visual impairment inequality.

The results are to be reported in separated analyses of meta-analysis, trend, risk factors and diseases burden, inequality, Bayesian prediction modeling, and map for visualizing the results.

Conclusion: The results of the current study will address gaps in different regions and have implication for evidence-based policy making in Iran.

Keywords: Blindness, burden, DALY, eye diseases, visual impairment, social determinants of health

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Introduction

Visual Impairment (VI) is a global public health concern. The estimation of people suffering from VI all over the world is 259 million from which 42 million are blind and 217 million have low vision.[1] Eye diseases are responsible for 27.7 million Disability-adjusted life year (DALY), which constitutes 1.8% of total DALY of the world population. Eye diseases are placed in rank 14th in the world and 11th among developing countries. This position is estimated to shift up to rank 8th in 2020 (a proportion of about 2.7% DALY).[2]

Authors' affiliations: [1]Tehran University of Medical Sciences, International Campus (TUMS- IC), Tehran, Iran. [2]Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran. [3]Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran. [4]Center for Non-Communicable Diseases Control, Ministry of Health and Medical Education, Tehran, Iran. [5]Non-communicable Diseases Research Center, Endocrinology and Metabolism Population Science Institute, Tehran University of Medical Sciences, Tehran, Iran. [6]Department of Epidemiology and Biostatistics, School of Public Health, Iran University of Medical Sciences, Tehran, Iran. [7]Endocrinology and Metabolism Research Center, Endocrinology and Metabolism Research Institute, Tehran University of Medical Sciences, Tehran, Iran.

•Corresponding authors and reprints: Seyed-Farzad Mohammadi MD MPH, Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran. Address: First floor, Eye Research Center, Farabi Eye Hospital, Qazvin Square, Tehran 1336616351, Iran. Telefax: 98-21-55421002; E-mail: sfmohamm@razi.tuma.ac.ir. Farshad Farzadfar MD MPH DSc, Non-communicable Diseases Research Center, Endocrinology and Metabolism Research Institute, Tehran University of Medical Sciences, Tehran, Iran. Address: No. 4, 4th Floor, Ostad Nejatollahi St., Enqelab Ave., Tehran 1599666615, Iran, Telefax: 98-21-88913543; E-mail: f-farzadfar@tums.ac.ir.

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It has been shown that the prevalence of blindness in developing countries is higher than that of the developed countries and it is noteworthy that close to three quarters of the world's blindness is either curable or preventable.[3] The estimation of VI in Eastern Mediterranean Region is 24 million (blind: 5 million; low vision: 19 million).[4] The prevalence of blindness and low vision in Iran has been reported variably from 0.39% to 6.9%.[5–8]

It should be mentioned that these estimates are conservative; monocular blindness is not included in the definition of blindness but it has physical and psychological morbidities. Refractive error and presbyopia are difficult to be quantified. They are underrepresented in health condition and disease burden estimates despites being the most common health condition in the whole medicine.

Blindness and its accompanying disability could be devastating; in a child, it means a major life-long physical handicap and it ruins early childhood development,[9] and is a frequent element in the poverty syndemy.[10] Finally, in the aging population, it causes major psychological impacts like depression[11] and physically imposes risk of fractures and falls. VI is a prototype non-communicable disease especially in the aging population and a constant feature of 'epidemiologic transition'. Visual health is gaining an ever-increasing importance in the sight-intensive life of the third millennium overwhelmed with smartphones, digital media, etc. Dry eye is a new pandemy, increasingly being recognized and treated but not reflected in burden studies.[2] Last but not least, the connection between survival and visual health is now more than established; VI has been shown to be associated with poor survival in older persons and others reported improved survival following cataract surgery.[12–15] Modern statistical approaches, e.g., Bayesian

methods and sophisticated conceptual framing now allow us to make more reliable estimations and more valid comparisons in both national and provincial levels. The models enable us not just to describe a point but also to demonstrate trends. We are now close to generating comprehensive pictures on all of public health problems simultaneously.

To date – despite periodic 'Disease-Health Surveys' in Iran which include gross figures on blindness as well – no specific national survey has been conducted to report visual impairment status. However, there are many regional eye studies and surveys in which VI has been addressed.[5–8] These data need to be compared and pooled in order to make comprehensive generalizations. Lack of such projections and analyses has been stated as a leading obstacle in visual health advocacy and specifically, 'Vision 2020: The Right to Sight' initiatives in Iran. In this article, we are detailing the approaches we are to take in order to estimate the magnitude (prevalence, incidence and burden), distribution, and trend (1990 to 2013) of low vision and blindness in Iran. We also describe the lists and sources for national aggregate data on inequality and potential social determinants of health that might influence the prevalence of visual impairment. The whole project constitutes one of the lines of the National and Sub-national Burden of Disease.[16]

Materials and Methods

A multidisciplinary group is formed, comprising clinicians (ophthalmologists), clinician scientists, epidemiologists and public health specialists familiar with and expert in ophthalmic epidemiology, ophthalmic diseases natural course and therapeutic modalities, modern quantitative skills, visual impairment surveys, social determinants of health, health economics and disease control. Their affiliations are to the nation's premier eye hospital, School of Public Health, and Non-communicable Diseases Research Center of Tehran University of Medical Sciences, and the Ministry of Health Center for Non-communicable Diseases Control. The project is coordinated through the national research network on eye diseases by appointing an advisory committee to monitor the project's progress and to advise on qualitative aspects.

Research fund comes from three sources. The Ministry of Health approved to fund 50% of the whole national burden study research budget that applied to this track's funding as well. The Ashk Society for the Visually Impaired (http://www.iranashk.org/) approved to fund 40% of the research. The remaining 10% would be provided by the Tehran University of Medical Sciences.

Terms of references and eye conditions

International classification of disease (ICD-10) eye conditions and related diagnostic and therapeutic terms are reviewed and 44 entities are listed. The blinding entities of Vision 2020 discourse are extracted and added. MeSH terms of National Library of Medicine including Entry Terms related to visual impairment and blindness are accessed. These lists are pooled and through expert consultation, a reference list of terms and expressions are developed (Table 1). In sum, they are either a visual impairment expression or a specific blinding disease entity.

Data sources

A pilot evaluation of the sources identifies the following evidence:

Table 1. List of terms and expressions (search keywords).

English keywords	ICD-10 codes
Amblyopia	H53.0
Corneal Opacity	H17.0
Cataract	H25-H26
Glaucoma	H40
Refractive Error	H52.7
Myopia	H52.1
Hyperopia	H52
Astigmatism	H52.2
Diabetic Retinopathy	H36
Lens Opacity	H26.9
IOL Implantation	
Cataract Extraction	
Presbyopia	
Age Related Macular Degeneration	H52.4
ARMD	H35.3
AMD	
Retinal Vascular Disorder	
Keratoconus	H34
KCN	H18.6
Ocular Trauma	H18.6
Retinal Detachment	S05.7
RD	H33
Trachomous	A71
Trachoma	
Low Vision	H54
Reduced Vision	
Subnormal Vision	
Diminished Vision	
Vision Loss	
Low Vision	
Vision Impaired	
Visual Impairment	
Visual Defect	
Visual Loss	
Geographic location	
Iran	
IR	
Iranian	
Iranians	
Persian	
Persia	
31 provinces names	

Published epidemiological studies with either nationwide or region-wide population-based or hospital-based sampling frameworks. The design might be a cross-sectional or a population-based cohort study.

Unpublished data of epidemiological studies with data from hospital records. An independent sampling of 0.5% of all hospital inpatient records is to be conducted in the nation's 863 hospitals in the past 15 years with a study size of 367,500 records for all medical (inpatient) or surgical (ambulatory or inpatient) conditions.[17]

Surveys in specific cohorts such as diabetics, people with disability and single-center studies are not included.

Aggregate data on inequality and potential determinants for VI

These are retrieved from Iran Statistics Center, Demographic and Health Surveys (DHS) 2008 and 2012; details of which are shown in Table 2.

Systematic review

Search strategy

Published literature between January 1980 and December 2013 in Medline (PubMed), ISI Web of Science, Scopus, Iranian Digital databases of SID (http://www.sid.ir), Barakat knowledge network system (http://health.barakatkns.com), and Irandoc (www.

Table 2. Potential aggregate data and social determinants of health inequality.

Factors	Definition	Sources
Demographic Characteristics	Age groups, Ethnicity, Gender, Education, Life expectancy	Iran Statistics Center (censuses), Demographic and Health Survey (DHS), Household Expenditure Surveys (HHE)
Geographic Indices	Urbanization, Living in a Specific Geographic Region or Provinces, Geographic Coordinate (UV), Mean Sea Level	Iran Statistics Center (Censuses) National Geography Organization, National Cartography Center
Socioeconomic Status	Wealth Index (assets), Unemployment Rate, Dietary Pattern	Household Expenditure Surveys (HHE), Iran Statistics Center
Human Resources	Ophthalmologist and Optometrist Quantity and Distribution	Medical Council

irandoc.ac.ir) are included.

The reference list of terms and expressions (Table 1) will be looked up in the titles or abstracts of the documents in the aforementioned databases. Using a descending search strategy for a complete coverage, titles of references of the selected articles will be searched to identify potentially relevant articles. The search is further limited to Iran and to humans with no language restriction. Additionally, titles in the abstract books of the Iranian ophthalmology annual congresses from 2008 through 2010 and the titles of dissertations in Farsi will be surveyed. The former will be performed manually and the latter will be carried out in Irandoc database. Table of contents of all national medical research journals will be reviewed manually. Google Scholar and a specialized database on national ophthalmic literature by Noor Ophthalmology Research Center (http://iraneyedoc.com) will be accessed for further coverage.

Study selection criteria; assessment of relevance and validity

Studies that meet level 1 evidence criteria will be eligible for inclusion. Two reviewers independently assess articles based on the title, abstract text, and full-text content in a step-by-step fashion. Any disagreement will be resolved through discussion and seeking a third opinion. The articles will be critically appraised again independently by the two reviewers using a standard checklist; papers with quality scores calculated as "low" will be excluded. Studies with a sample size of less than 100 will be excluded, as would studies on patients referred to a tertiary care center without attribution to the reference population. A conscious effort will be made to ensure that the included studies will demographically represent the country's population in terms of geography and living conditions.

Data extraction

Data from included articles will be extracted and duplicate observations will be deleted. Apparent discrepancies in the sources and figures will be resolved in periodic meetings. The data extraction sheet will cover background information such as citations, publication year, study period, journal, and corresponding author. It will also include methodological aspects, such as study design, data source, scope of study such as urban, rural, slum, or nomadic, coverage of the study in a national, provincial, district, and community level, measurement tools, sample size, sampling method, and response rate. Endpoints will be identified as well. Quantitative observations consisting of proportion of the cases to study population or prevalence by sex, age groups, and multiple timepoints with 95% confidence interval will be extracted. Authors of the articles that have not presented results by age groups will be contacted to obtain age-specific data. Likewise, they will be contacted about the missing aspects.

Endpoints

Primary endpoints consist of two broad measures of VI (a functional condition) and blinding diseases. VI is categorized as mild, moderate, severe, and total blindness. Snellen chart, decimal, and metric scales are routinely used for reporting visual acuity. While different methods of measuring visual acuity do not consistently match, acceptable approximations are possible. Table 3 presents the equivalences of visual acuity along with their qualitative tags based on ICD-10 categories. The prevalence of different VI categories are calculated and presented along with a confidence interval by age and sex. Prevalence estimates by disease entities of cataract, glaucoma, diabetic retinopathy, age-related macular degeneration, corneal opacity/blindness, and refractive error and amblyopia are also calculated. Estimates on more specific or less common ophthalmic diseases will be attempted if enough evidence is available. Secondary endpoints are VI and blindness potential burden, components of which are shown in Table 3.

Burden of disease will only be projected according to the average and gross factors reported in the literature, which is measured by mortality and morbidity indices such as YLD and YLL, respectively.

Heterogeneity

There are possible sources of heterogeneity such as: 1) Variation in the definition of VI such as the cut-off figures for low vision and blindness and diagnostic criteria such as tools and technology used (see above), 2) Variation in the selection and sub categorization of blinding entities, 3) Variation in defining age groups, and 4) Study frameworks such as population-based studies, national screening programs and hospital data as well as demographic and living conditions variations.

Evidence is qualitatively examined for relevance and representativeness and validity of the study is assessed. Normality of the distribution of the crucial figures is tested and outliers are excluded.

Statistical methods and analysis plans and dealing with data gaps

We predict there will be missing data for many province-years. Surveys may not include all age groups, both sexes, and/or all living conditions. In order to address the missing data issue and to estimate rates, cause fraction measures and their uncertainty interval by sex, age, year, and province two distinct statistical models of spatio-temporal and multilevel autoregressive are developed.[18–19] Models will be fed by data of a specific age, year, and province as well as data from other ages, other years, and other provinces. For the provinces, which are geographically separated from others in the desired period of time, the problem of misaligned areal units does exist. The problem will be addressed in both models. Using two distinct models avoids model dependency in the results.

Table 3. Visual impairments definition and their equivalents.

Range of visual impairments	Metrics	Presenting Distance Visual Acuity in Better Eye		ICD-10 Codes
		Worse than	Equal to or better than	
Mild or no visual impairment	Decimal Notation		6/18(0.3)	H54.3 (Mild or no Visual Impairment, inocular)
	Snellen		20/60	
	Logmar Equivalent		0.5	
Moderate Visual Impairment	Decimal Notation	6/18(0.3)	6/60(0.1)	H54.2 (Moderate visual Impairment, Binocular)
	Snellen	20/60	20/200	
	Logmar Equivalent	0.5	1	
Severe Visual Impairment	Decimal Notation	6/60(0.1)	3/60(0.05)	H54.1 (Severe visual Impairment, Binocular)
	Snellen	20/200	20/400	
	Logmar Equivalent	1	1.4	
Blindness	Decimal Notation	3/60(0.05)	1/60 (0.02)	H54.4 (Blindness, Monocular)
	Snellen	Count fingers (CF) at 6 feet		
	Logmar Equivalent	1.4	1.8	
Blindness	Decimal Notation	1/60 (0.02)	Light Perception	H54.4 (Blindness, Monocular)
	Snellen	Count fingers (CF) at 3 feet		
	Logmar Equivalent	1.8	2	
Blindness	No Light Perception, hand motion			H54.0 (Blindness, Binocular) H54.4 (Blindness, Monocular)
Undetermined or unspecified				H54.9 (Unspecified Visual Impairment (Binocular))

Spatio-temporal Bayesian hierarchical model

This model is a conditional autoregressive (CAR) prior for spatial random effects.[18] Observations that are closer in space are assumed to be more correlated than observations farther away. This structure enables the model to "borrow information" from neighboring areal units to improve estimates for areas with missing values and/or small number of observations. In addition, we will employ spatio-temporal misalignment modeling to combine incompatible areal units between data sources and/or over the years. The model includes covariates effects, non-linear age trend, and study quality and source of data variations.

Bayesian multilevel autoregressive model

Another advanced method to handle previously mentioned data gap challenges is Bayesian multilevel autoregressive model.[19] In this framework, observations are hierarchically nested in districts, provinces, sub-regions, regions, and national levels, respectively. Here, higher levels borrow information to the lower levels and units of each level borrow information from each other depending on the degree of data availability. The model considers several different components, including linear time trends, nonlinear change over time, covariate effects, nonlinearity associated with age, heterogeneity of data sources, and age-by-study variability. Time-varying district-level or province-level covariates inform the estimates, if possible.

In this modeling framework, the Monte Carlo Markov Chain methods for their general applicability and ease of implementation will be used to perform Bayesian inference. All programs will be written in R statistical package (version 3.0.1).

Beside these challenges, another problem is about summary statistics that have been reported with different classification. By using regression models, we cross walk between continuous and categorical measures of interest.

Statistical testing

Associations of aggregate measures on inequality and potential determinants are tested with pooled estimates of VI and DALY (prior to data imputation).

Ethical considerations

Data sources will be fully cited. The funding bodies will be appropriately recognized in the project reports. Based on the sources of data and expertise that is being employed, appropriate credits will be given to organizations and respective scholars will be invited for formal contribution.

Deliverables

Based on the pool of expressions and keywords, a conceptual framework on the burden of ocular conditions is sketched and it is revised along the way in the systematic review. VI prevalence by categories, DALY attributable to the VI, individual prevalence of blinding disorders and their respective DALY are presented by time course, geography, sex, and age groups. Relative risks for VI and DALY by aggregate inequality data and social determinants of health are reported. Burden by secondary endpoints is presented as well.

In addition to formal submission of the results to the Ministry of Health, an online warehouse of primary data, the syntheses such as crude data, pooled estimates along with uncertainties, diagrams like Bayesian prediction modeling and map for visualizing the results based on Geographic Information System, relative risks, and bibliographies are to be created.

Here is the plan for the publication of the results: 1) Systematic review on VI and the blinding disorders in Iran, 2) Analysis of the national burden (DALY) of eye diseases by time course, districts, sex, and age, 3) Social determinants of VI and its burden in Iran.

Discussion

VIBI project is part of the national and sub-national burden diseases, injuries, and risk factors from 1990 to 2013[16] and the technical teams are supervised and coordinated by the core team. This ensures integrity in data and evidence and observation of minimal quality requirements. The technical teams (like VIBI group) have an important role in the selection of diseases and their definition and risk factors; they are indispensable for identifying data sources, interpretation of the findings and publication strategy.

In the Global burden of disease study in 2010, sense organ diseases including eye diseases (4 vision impairing entities) accounted for 1.24% (95% UI; 0.9, 1.68) of national DALY but Visual impairment did not account.[20] In addition, in the first national burden of disease and injury study for six selected provinces in Iran,[21] eye diseases were responsible for 69,884 disability adjusted life years while low vision and blindness were not addressed in specific categories, burden were not estimated for all provinces and its data resources were limited. Also, uncertainty and trends were not assessed.

Eye conditions burden is not all-inclusively considered in analyses and disease-health pictures. The authors would like to highlight the varied nature of end points related to eye health and expand them as follows: visual impairment (blindness and low vision; monocular and binocular), disfigured eyes, ocular discomfort ('blind painful eyes' and dry eye). This is in contrast to death that has one end-point. Due to the centrality of sight among senses and the incomparable value of eyes for human appearance and beauty, the aforementioned disabilities are paramount. As an example, it has been estimated that in terms of quality of life, severe dry eye syndrome is comparable with heart failure NY function class of three.[22]

One of difference of eye problems assessment in comparison to some other chronic diseases is that death directly attributable to eye disease is almost nil, and hence averts YLLs (but probably incurs some YLDs due to increasing the prevalence pool). Therefore, its burden is only based on YLDs.

One of the restrictions of this study is missing data in provinces and time levels. We will try to impute missing data using statistical methods or using proxy covariates and extrapolating to each district-year. Also, heterogeneity is integral to the nature of observations on which systematic reviews and burden estimations are made. That is why calculation of uncertainty is now considered a mandatory step in such efforts. Authors would do their best to apply optimal approximations.

In this paper, we wish to use detailed, consistent, and comparable data analyses and identified patterns by age, sex, and region as well as trend analysis. This study implies a strategy in generating burden of visual disease information considering the uncertainty in the resulting estimates at sub-national level for the first time in 31 provinces. Sub-national evidence analyses provide a more comprehensive picture for debate, discourse, and cooperation among different levels of government on health policies and allocation of resources to health programs, as well as for understanding disparities in health across regions. In addition, as there is only a small fraction of data in our published literature, addressing multiple sources of data to gather primary data is one of the helpful points of the current study. Finally, another advantage of this study is to confront other limitations like data scarcity by using appropriate mathematical models. In conclusion, this study is the first systematic attempt to fill the existing important gaps in knowledge on the epidemiology of main eye diseases in Iran. The results of the present study will have implications for evidence-based policy making; also, economical evaluation of current policies might be empowered by this data for eye health planning and management and resource allocation.

Competing interests

All of the authors declare that they have no actual or potential personal or financial competing interests.

Authors' contribution

General designing of paper: *Seyed Farzad Mohammadi, Farshad Farzadfar*

Research design and method implementation: *Seyed Farzad Mohammadi, Farshad Farzadfar, Akbar Fotouhi, Mohsen Asadi-Lari, Alireza Lashay, Elham Ashrafi*

Writing primary draft: *Elham Ashrafi, Seyed Farzad Mohammadi,*

Manuscript revision: *Seyed Farzad Mohammadi, Akbar Fotouhi, Farshad Farzadfar, Alireza Mahdavi, Mahmoud Jabbarvand, Sahar Sobhani*

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It is notable that the paper is part of PhD thesis of the first author [EA].

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