Study Protocol

Quality Evaluation of National Cancer Registry System in Iran: Study Protocol

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Abstract

Background: Cancer registry can be a very important component of health information system in developing countries. Routine collection of data and ongoing monitoring of their quality can have a crucial role in priority setting and evidence-based policy making for controlling cancers and trends follow-up in low and middle-income countries. Evaluation of cancer registered data consists of four important components including: comparability, completeness, validity, and timeliness. Similar frameworks are utilized in different countries all over the world.

Methods and Materials: We will use the national annual cancer registry reports in Iran alone or perhaps along with other Iranian published reports about childhood cancer incidence to determine the stability and trend of incidence rates over time and compare above mentioned reports with childhood cancer incidence data reported by other countries through a systematic review as well as in some cases meta-analysis in order to assess data quality. Data will also be collected from other sources such as death certificates to estimate mortality rates and other different methods will also be additionally applied, by use of which death certificates would be utilized to assess the quality of data, too.

Conclusion: As the first step for proper measuring incidence rate of all types of cancers all over the country, we will assess and evaluate reported national cancer registry data in Iran in order to estimate the national burden of cancers in 1990 – 2013.

Keywords: Cancer registry, Iran, quality assessment

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Introduction

One of the goals of National and Sub national Burden of Diseases, injuries and risk factors from 1990-2013 (NASBOD) is to estimate the burden of cancer at national and sub national levels;[1] the basic information needed to meet this goal is to estimate cancer incidence and prevalence in age and sex categories through evaluating quality of cancer registered data and computing accurate and complete national and sub national cancer incidence and prevalence estimations.

Population-based cancer registries are the first and undeniably the most important databases that can be used to estimate the incidence rate of cancer, which is the initial step for computing burden of malignancies and the most robust basis for health policy making and scientific research.[2] It also helps public health professions in programming and implementing policies to control burden of cancers more effectively.[3] Actually, the quality of data collected through the cancer registry is based on four inherent characteristics of cancer registry systems: Comparability, Completeness, Validity, and Timeliness of registered data.

Comparability is the extent to which coding and classification of procedures recorded in the registry, together with the definitions of specific data items are compatible with agreed international guidelines.[4] Completeness is the extent to which all the cases of cancers incident in the population are included in the registry database[4] also as an assessment method, is an extremely important at tribute of a cancer registry and is used frequently in many countries.[5–17] Maximum completeness in case-detection procedures will certify that incidence rates and survival proportions are close to their true values.[17] Validity is defined as the proportion of cases with a given characteristic in a dataset that truly have the attribute.[4] Timeliness or rapid reporting of cancer cases is another priority for cancer registries. Quick access to cancer information is of clear benefit for health providers and researchers; moreover, the early provision of data usually enhances the robustness of the registry.[4]

Cancer data reporting in Iran dates back to 1956, when the first report of cancer frequency data was prepared and published by Prof. Abdollah Habibi, an Iranian pathologist working at Cancer Institute of Iran. The report was based on data collected from pathologic centers. It included cancer data from 1945 – 1956 with an incidence rate of 28/100,000 in south and 42/100,000 in north of Iran.[18–19] Although passive cancer data registration has been started since around 1999 in the Center for Disease Control

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/ Ministry of Health and Medical Education, as it did not cover all pathology labs and other departments that had related data about cancerous patient all over the country, the first results of national reports were not accurate for national estimation. For example, the first report had only 18 % coverage.[19] Thereafter, pathologic based registration continued until the last national reports in 2009 that claimed coverage of more than 86 %. Nevertheless, these reports are based on data from the majority of pathologic labs, but not all of the centers. There are just a few population-based data in all parts of the country. There are also some independent scientific departments like research centers that have domestic data about cancer cases, which are population based and reported separately.

As there is still only one center, ministry of health, in Iran that gathers data on cancer incidence for national reports in the country; in this study we are going to quantify the quality of cancer registered cases within the national annual data in Iran.

Methods and materials

Overview

This paper, as a national report, aims to evaluate the quality of cancer registered data in certain dimensions including: comparability, completeness, validity, and timeliness.

Comparability

As mentioned in the introduction, to evaluate cancer data comparability, data should be reviewed in terms of system of classification and coding, definition of incidence, and discrimination of primary tumor from invasion, metastasis or recurrence of an existing one in asymptomatic patients.[4]

Timeliness

Although there is no international standard guideline for timeliness in cancer registration, since analyzed data are used for the estimation of survival rate, and also for epidemiologic studies on the burden of diseases to control cancer, several American agencies have set out specific standards based on the time of first contact, time of the first contact recorded in cancer registry, and the period of time between first diagnosis and reporting complete recording of the case.[4]

Completeness

This part of quality assessment is practically conducted in two different ways: qualitative (semi-quantitative) method, which investigates the registry centers and the process of registration over time; and quantitative method, which provides parametric evaluations.[4]

Semi quantitative methods based on four separate strategies provide numbers, which show the degree of registered data completeness:[17] (These methods are based on historic data, though they can't actually quantify the number of missing cases.)

I. Historic data methods include four assumptions: stability of incidence rates over time, shape of age-specific curves, comparison of incidence rates between different populations, and incidence rates of childhood cancers;

II. Incidence Mortality(IM) ratios: for this section we will need not only the cancer incidence rates reported in national annual reports but also the cancer specific mortality rate reported based on national death registry;

III. Number of sources/notifications per case;

IV. Histological verification of diagnosis: Morphologically case verified (MV %) is the percentage of observed compared to expected values.

Quantitative evaluation includes three methods to estimate the degree of completeness in the registration: independent case ascertainment, capture–recapture method, and death certificate method. We are going to use the last method, which consists of two parts: DCN/IMI method and the 'flow' method.[17] In the first one, the degree of completeness may be estimated as:

$$\frac{\text{Final registrations}}{\text{Final registrations} + d}$$

Where "d" is the number of people who are registered neither in death nor in cancer registry; the final registrations cover those who are registered in cancer registry or death registry or both of them. To calculate this measure, we need other indicators including the proportion of DCN (Death Certificate Notification), IM (Incidence Mortality) ratio and true IM ratio. To measure these items, we require the number of people who were registered in registration systems. The flow method (the second one) covers cases that didn't have death certificates. These patients are divided into two groups including patients who are alive and still unregistered (missing) and the those who have died without being registered during life, and remain unregistered because there is no mention of cancer on their death certificate (lost). The mathematical analysis and method are reported completely somewhere else.[17,20]

For the first two parts (comparability and timeliness), we will use the national annual cancer registry reports alone or maybe along with other published Iranian sub national reports about childhood cancer incidence. However, for the last part (completeness), childhood cancer data should be collected from other countries through systematic reviews and in some necessary cases, meta-analysis. Then systematic review results along with the regional standards published in "Cancer Incidence in Five continents (CI5)" will be utilized as two comparable sources of childhood cancer incidence statistics of Iran to estimate how much it is complete, over- or underestimated[21–22] in defined periods of time.

Since national cancer registry of Iran claims that cancer registry is population-based, there should be source/notification documents for every recorded case, which will be used to fulfill these two goals (the third and forth parts of the semi quantitative methods).

Organizing working group

Our teamwork consists of Iranian experts in the field of cancer registry and epidemiology, who are familiar with ICD-10 codes for cancer. Both groups are professional in systematic review and methods of meta-analysis using STATA software. However, we may need experts' views at other stages as well.

Diseases definition

This paper just focuses on childhood malignancies originating in all parts of body. Malignancies topographies and morphologies are defined and classified according to International Classification Diseases (ICD) version 10. "Childhood" means ages between 0 – 14 years old and it is classified into three age-groups of 0 – 4, 5 – 9, 10

– 14. "Incidence" is defined as new registered cases in a defined period of time; the unit of measurement will be Age Standardized Rate (ASR) overall and in age groups as Incidence Rate (IR) or Age Specific Rate. Both sexes are included (Table 1).

Data sources

There are two main sources of data: Iranian national published data and internationally published data from other countries. Both sources address the incidence of childhood cancer. It is worth mentioning that the Iranian national data may not be electronically available on the internet, since they may be in printed formats.

Search strategy

As for the first data source (National Report of Iran), we will use Annual National Report of cancer registry system, which is published every year by the Ministry of Health and Medical Education (MOH & ME) of Iran. It is based on pathologic data recorded from 2000 to the present, that have been collected from all pathologic labs all over the country (including those labs that have accepted to send data of cancer samples to cancer units in Medical Universities), and population based data in some provinces from 2009. These reports have been used to estimate incidence rates of children malignancies in ages 0 – 14 and categorized as 0 – 4, 5 – 9, 10 – 14 year-olds, by sex, as annual national records.

As for the second data source, we'll need to estimate the incidence rates of malignancies in ages 0 – 14 in other countries, if available. So we should have a search strategy with inclusion and exclusion criteria and we should conduct a systematic review using the electronic databases including: Pub Med, ISI web of sciences, and Scopus. The search terms and strategies are explained in details in Table 2.

As the first available published Report of Iran dates back to 2000, our search strategy is limited to the time period between January 01, 2000 and December 31, 2014, utilizing alert system of all databases.

The major inclusion criteria consist: date, disease, age group, gender, measurement indicator, and type of data gathering source (Table 3).

Table 1. Practical Definition Of Cancer Registry Data Quality Evaluation components, Quality Evaluation of National Cancer Registry system-Iran

Comparability	the extent to which the coding and classification procedures, the definitions of recording and reporting specific data items are consistent with international guidelines
Validity	the proportion of cases in a dataset with a given characteristic which truly have the attribute
Timeliness	rapid reporting of cancer cases
Completeness	the extent to which all the incident cancers occurring in the population are included in the registry database
DCN	death certificate mentioned but already registered via other sources
DCI	Death Certificate mentioned but could be registered via other sources
DCO	Just only death certificate mentioned and registered
ICDO-10	International Classification of Diseases For Oncology-versoin10
Incidence Rate	Rate of new cases in a definite population and definite time
Children	Individuals aged between 0-14 years

Table 2. Search Activity In Search Engines, Quality Evaluation of National Cancer Registry system-Iran

PubMed	All Mesh Terms would be searched in "all field"
ISI(Web of Science)	All Mesh Terms and Entry terms would be searched in "Topic"
Scopus	All Mesh Terms, Entry terms would be searched in "Title, Abstract, Keyword"

· Mesh Terms: Cancer, children, incidence; Entry Terms: Tumor, tumors, neoplasia, neoplasm, cancers, cyst, child, childhood, epidemiology, incidences; Emtree: no new one found; All key words mentioned above in Mesh Terms will be combined with "and" and all key words mentioned above in Entry Terms will be combined with "OR" in all engines as follow: (((Tumor OR Tumors OR Neoplasia OR Neoplasm OR Cancer OR Cancers OR Cyst)) AND (epidemiology OR incidence OR incidences)) AND (Child OR Childhood OR Children)))

Table 3. Paper exclusion and inclusion Criteria, Quality Evaluation of National Cancer Registry system-Iran

Including	**Criteria**	Additional information
	Date	1th Jan 2000 to 31th Dec 2014
	Disease	Every kind of malignancy, cancer, malignant tumor with topography and morphology as well as related codes based on ICD-10
	Age group	covering 0-14 years in groups 0-4, 5-9, 10-14 years of age
	Gender	Both male and/or female
	Measurement indicator	Incidence Rate (IR, ASR), if incidence is estimated by number, population size reference should be requested for mathematical analysis
	Type of data gathering source	pathologic and/or population sources
Excluding	**Date**	Before 1th Jan 2000
	Age group	not covering 0-14 years of age
	Measurement indicator	Any other than Incidence Rate
	Type of data gathering source	Not mentioned as pathologic and/or population sources
	Study design	Any study with sampling biases such as cohort studies without population base data, case-control studies, clinical trial studies, comparing studies like ethnic based, interventional studies

Table 4. Data Extraction Options in STATA sheet, Quality Evaluation of National Cancer Registry system-Iran

General information	Title
	Authors' names(Surname of First)
	Corresponding author's name and emails
	publishing Year
	Country
	Article address: site , journal, volume, issue, page, doi
Specific information	Study Type
	Years of study (start & finish)
	Reference population (per 100000,or 1000000)
	Cancer type
	Cancer coding based on ICD-10
	Measurement unit (IR, ASR)
	Number of new cases
	Incidence rate per age group and /or sex
	Age groups(<1,1–4,0–4,5–9,10–14,0–14)
	Sex (male, female, both)
	CI (95%) of rate

The general information presented below will be extracted from data sources (Table 4):

- Journal characteristics: name, date of publishing, issue, page, web address
- Study name, authors' names, date of the publication, data source, scope and coverage of Study, Doi (if exists), contact address of corresponding author(s)
- Population properties: population size, sample size
- Country: name of country , city, urban or/rural areas
- Data coverage: national or sub-national
- Frequency of reports: annual, every five–years and so on.

Exclusion criteria are (Table 3):

- Unknown source of data
- Data from sample groups with special characteristics
- Study design that may create sampling bias such as cohorts without population based data, case-control studies, clinical trial studies, comparative ethnic based studies
- Measuring indicators other than incidence (e.g. prevalence)

It is worth mentioning that studies written in any language other than English will be included if they match the inclusion criteria.

Statistics and analysis

This study uses the semi-quantitative and quantitative methods approved by IARC (International Agency for Research on Cancer) and also follows experiences in other countries in this field, to evaluate the quality degree of our national cancer registry data. Data will be entered in Excel sheets and will then be analyzed using Stata 12 (StataCorp, College Station, TX, USA) software.

Discussion

Although cancer is one of the most important non-communicable diseases with high incidence and prevalence in Iran, there is not any national scientific documentation in this area. Accordingly, we are going to assess and evaluate the reported national cancer registry data as the first step for measuring accurate incidence rate, burden, and trend of all cancers in the country from 1990 to 2013 in collaboration with experts inside and outside of the country.

Most of cancer quality assessment researches, done worldwide, have compared national or sub national data to sub national one; for example a study in Gambia National Cancer Registry using capture-recapture method showed that the estimate of completeness overall 50.3%,18% of clinically reregistered centers and 45 % of pathological reports and death certificate the estimate of MV% 18.1 in male and 33.1 in female and DCO % 6.6 in male compare to 3.6 in female for the period of 2000 – 2009, considerably lower than international standard references.[23]

As prior studies in Iran, a study has compared completeness of reported and estimated data of cancerous patients diagnosed by pathology during 2000-2007 and population-based during 2007 – 2009 in south of Iran that showed 22.68 % to 118.7 % differences in data coverage quality.[24] Another population-based study in northwest of Iran using capture-recapture method showed that the under-ascertainment rate for all cancers in the Cancer Registry Center of Northwestern of Iran has been 16.1 % over a three–year period, from 2008 to 2010. The completeness has been 48 % based on the national report of the Iranian Cancer Registry Center, and 6.9 % combining both resources.[25]

These studies have assessed just one of cancer registered data, completeness, and only in limited provinces data, so in this paper we are going to evaluate quality of all components of national cancer data such as completeness, comparability, validity and timeliness and compare national data to international ones.

Determining accurate data measures such as incidence rate is highly essential for estimating the burden of diseases, needed for disease control programming at national level. All of the available data should be checked and ascertained by experts. Even though we will not assess the quality of all parts of the registry system through all proven methods due to challenges and lack of enough time, we have the chance to evaluate the quality involving comparability, validity, and timeliness and to evaluate completeness through semi qualitative and quantitative methods as the most important components of evaluation.

Strength of our study is using the most available methods for assessing the quality of cancer registry for the first time among the Iranian population. Moreover, computing cancer incompleteness in two ways, quantitative and qualitative, is the other important one. Actually, final results provide us with a more accurate estimation of the national cancer incidence in Iran.

The limitations of this study are as follows. First of all, in our

systematic review there may be limited access to the full texts of certain published or unpublished epidemiological studies, as one of the main data sources. Furthermore, many data sources cover only a number of demographic characteristics such as age or sex groups, or only national or sub national populations. Therefore we cannot claim that we will be able to estimate the true incidence rates ultimately.

In conclusion, the present study is the first comprehensive systematic effort for assessing the quality of cancer registry system among Iranian population. Thus, we are going to present a probably new method to calculate the real nationwide cancer incidence using cancer registry data completeness assessment, in order to estimate the trends of prevalence and burden of cancerous diseases from 1990 to 2013 at national and sub-national levels, in Iran. This study is a sub-component of National and Sub-national Burden of Diseases, injuries and risk factors from 1990 to 2013 (NASBOD).[1]

Abbreviations

NCDs: Non-communicable Diseases; NASBOD: National and Sub national Burden of Diseases, injuries and risk factors; GBD: Global Burden of Disease; IARC: International Agency for Research on Cancer; ICDO-10: International Classification of Diseases for Oncology version 10.

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Competing interests

The authors declare that they have no competing interests.

Authors' Contributions

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Designing of systematic review: *Mitra Modirian, Shadi Rahimzadeh, Zahra Cheraghi,Farshid Farzadfar.*

Paper revision: *Mitra Modirian, Shadi Rahimzadeh, Zahra Cheraghi, Farshid Farzadfar and all other co-authors. Mitra Modirian, Shadi Rahimzadeh, Zahra Cheraghi had equal Contribution as first author.*

Note: *All first authors and correspondent have given approval to the final version of the manuscript.*

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