Improving hypertension surveillance from a data management prospective: Data requirements for implementation of population-based registry

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Abstract:

BACKGROUND: Hypertension (HTN) has become a major public health problem which can cause serious complications when it is not well-controlled. Prevention and effective care of HTN require a population-based registry. Thus, establishing this registry can be used to collect comprehensive, timely, and reliable data on epidemiology cases. The aim is to create a registry for the collection of highly required prospective data that will present an in-depth analysis of the characteristics of all individuals with HTN and track them over a particular chronological interval.

MATERIALS AND METHODS: The study was divided into three phases: At first, a comprehensive literature review was conducted to determine the proposed data classes and data fields. Then, the final minimum data set was designed by a two-round Delphi consensus approach of 20 experts of cardiologists, nephrologists, nutritionist, and health information management. Finally, a web-based registry system was developed by a Structured Query Language environment.

RESULTS: A total of two clinical and nonclinical data categories with nine data classes and 68 data fields were selected for their inclusion in the registry following the consensus phase. A web-based registry was designed with a modular and layered architecture.

CONCLUSIONS: This study provides an appropriate information infrastructure for active tracing and monitoring of individuals with HTN. It has provided a practical information system allowing quality improvement, aggregate reporting for planning, and research purposes.

Keywords:

Hypertension, minimum data set, registry system

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Introduction

Hypertension (HTN) or high blood pressure is a physiological condition considered as the most important and well-known determinant of cardiovascular diseases. HTN can often be a preliminary phase to develop coronary heart disease, stroke, sudden death, heart failure, peripheral artery disease, and end-stage renal disease, which are likely to raise the risk of death and disability.[1-3] HTN is known as the silent killer since it is considerably or completely asymptomatic; individuals with HTN may not know they have it or may not view their condition as a serious problem.[4,5] It affects more than 1 billion people worldwide and is currently ranked as the leading cause for more than 10 million largely preventable deaths globally each year.[6,7] Studies have reported a high incidence of this condition; it was reported to be 14%–34% in Iran.[8,9] In Iran, the National Blood Pressure Control Program was implemented throughout the country

from May 17, 2018 (coinciding with the World Blood Pressure Control Day) to 6 July.

Given the significant burdens associated with HTN, the decision was made to adopt public health informatics approaches for the promotion of HTN surveillance. Clinical registry is one of such population-based health promotion programs. Clinical registries facilitate studying the real clinical practice, capturing quality metrics, monitoring the disease and health-care delivery patterns, and tracing clinical outcomes. They also provide real highly generalizable data and can be used to improve population health surveillance and research support. In other words, clinical registries are essential for integrating research and clinical practice and eventually translating them into therapeutic solutions.[10-15] The population-based HTN registry has been considered in Iran due to the high prevalence of HTN and the need for effective monitoring.[16] To the best of our knowledge, there has been limited investigation on the features of HTN registry from a data management perspective in Iran. In order to address the above-mentioned issues, our objective is to determine HTN required data elements and then its clinical registry.

Materials and Methods

Clinical registries, albeit being valuable instruments, are difficult to initially develop and implement, requiring the involvement of a multidisciplinary team.[17] This project was structured in two phases: initially, the aim was to define the variables required to be included in the HTN registry; the second goal was establishing the registry.

The choice of data elements for inclusion in clinical registry is a critical component which defines the quality and clinical usefulness of the eventual output. For this purpose, a literature review coupled with the expert consensus was performed. Initially, a comprehensive review of the HTN literature was conducted to determine a preliminary data element of HTN.[18-21] Data sources for this stage were papers, reports, and forms on the internet. In this stage, a checklist was used to extract the data fields and their variables. To find materials relevant to the subject, Google Scholar, Elsevier, Science direct, Scopus, Cochran, and PubMed Data bases were explored. In this study, all resources related to minimum data set (MDS), registry, and data fields of HTN were examined, and the main data field and their variables were extracted.

The studies were identified by keywords including "Minimum data," "Minimum Data Set," "Data field," "MDS," "Hypertension," "High blood pressure," "HTN," "Registry," and "Surveillance system." Sampling was not performed at this stage, while all the relevant literature was retrieved and evaluated based on the inclusion criteria (English language resources between 2009 and 2019, in full text from valid sources). Short articles, letters to the editor, papers accepted in conferences, and reports extracted from blogs were not included in this study.

To determine the final data elements of MDS related to HTN registry, data elements were chosen by 20 experts of cardiologists, nephrologists, and specialists in health nutrition and health information management (HIM) through the Decision Delphi technique in two rounds. Biostatistician support was also required to enable a robust analysis of acquired data.

The participating experts were asked to score the items according to the importance perceived by them based on a five-point Likert scale. In this scale, a score of 1 naturally represented the "lowest level of importance" while a score of 5 represented the "highest level of importance." The content validity of the questionnaire was evaluated by four experts, including two HIM experts and two cardiologists. Test-retest reliability (with a 10-day interval) was performed to determine the reliability of the questionnaire. The collected data were analyzed using Statistical Package for the Social Sciences (SPSS) version 19 (IBM corporation: USA, New York), where a Spearman's rank correlation coefficient of 84% was achieved. Through the decision Delphi technique in two rounds, decisions on the included data fields were based on the agreement level. Accordingly, data fields with <50% agreement were excluded in the first round while those with >75% agreement were included in the primary round. Those with 50%–75% agreement were surveyed in the second round, and if there was 75% consensus over a subject, it was regarded as a final data field.

An Agile software development model was utilized for this project. The Agile model comprises increasing the development of functionality and frequent feedback from the user, allowing for adjustment to uncertain or changing requirements.[22] The development tools utilized in this project were as follows.

Due to the benefits of web-based applications, including cost savings, productivity, efficiency, improved communication, data security, scalability, and accessibility, most of the world's registry systems have been developed on the web platform.[23] Thus, this platform has been used in this study to develop the system. Meanwhile, Structured Query Language (SQL) server database was used to store the data; capabilities of SQL Server database can be relational data bank, Extensive Markup Language support, unlimited record volume and number, online analytical processing, full text search, quick information retrieval, and use of natural language in searches. The C # programming

language was also used in the NET4.5 technology platform for high-level interface programing.

Results

The results of this study are divided into three parts, including determining a preliminary list of data elements for HTN registry, identifying final MDS for HTN registry, and design the HTN registry system.

Proposed minimum data set of review studies

In order to identify a preliminary list of data elements, an extensive literature review was done. The MDS designed in this study included data categories (general level), data classes (detailed level), and data fields (atomic level). Following the literature review, the proposed MDS consisted of two data categories (nonclinical and clinical), nine data classes, and 91 data fields.

Final minimum data set of Delphi survey

To determine the final data elements of the HTN registry, data fields were chosen by 20 samples of attending experts through the Decision Delphi technique in two rounds. Table 1 presents the attending expert's demographic characteristics.

Table 2 indicates A number of data elements were excluded after the second round of Delphi. Table 3 shows

the final necessary data classes and data fields along with data type and content for HTN in clinical and nonclinical categories.

The final MDS was composed of two data categories, nine data classes, and 68 data elements [Table 3]. Data categories included both clinical and nonclinical. The clinical data category consisted of seven data classes and 46 data fields including physical examination (seven data fields), laboratory tests (ten data fields), ECG evaluation (seven data fields), patient history (six data fields), family history (four data fields), signs and symptoms (eight data fields), and treatment recommendations (four data fields). On the other hand, the socio-demographic data (13 data fields) and life style (9 data fields) were the only nonclinical classes. In general, the final MDS was divided into two data categories, including clinical and nonclinical with seven and two data classes along with 46 and 22 data fields, respectively.

The hypertension registry framework

In the software development phase, the emphasis has been laid on accessibility and user-friendliness of the system to shorten the reporting time. The designed system used an advanced search capability to enable quick search of data for research purposes. Where possible, check boxes and radio buttons have been used, and free text data fields avoided.

Access to the registry was given to registered members. Each user had a unique identification number and password to log into the database. The purpose of all the above-mentioned measures was to maximize the accuracy of data. On login, the system home page would be displayed. This page included patient list, search, reporting, and user management menus. Figures 1 and 2 show the web-based registry of HTN.

Discussion

In the present study, initially, we determined the MDS required for entry into the HTN registry based on the expert's consensus. Data collection is an important step for information management and design of information systems in clinical and research domains. The required MDS is a coherent set of data elements established for mandatory reporting at the national level, which is very important to be determined in a standard and integrated way from a scientific perspective.[24-26] Integrating data between research and clinical systems are a major challenge. Clinical trials are often not integrated with clinical care. Poor integration leads to the repetition of activities and limited learning of health care.[27] In addition, the quality of research results depends on good data. A very important step in clinical research is the collection of accurate and reliable data to ensure valid results.[28,29]

Table 1: Demographic characteristics of the samples

Delphi analyzers	
Samples	Frequency
Academic field	
Nephrologist	5
Cardiologist	5
Nutritionist	5
Health IT	5
Literacy rate	
BS	1
MSc	3
Medical specialist	15
PhD	1
Sex	
Male	11
Female	9
Age group (years)	
20-30	4
30-40	6
40-50	7
>50	3
Work experience (years)	
<5	4
5-10	8
10-15	5
>15	3
Total number of participations	20

IT: Information technology

Table 2: Delphi results for clinical and nonclinical hypertension registry categories

| Categories	Data classes	Proposed data fields	First round of Delphi			Second round of Delphi			Final data fields
			<50%	50%-75%	>75%	<50%	50%-75%	>75%	
Nonclinical	Sociodemographic	16	3	2	11	1	0	1	13
	Life style	12	2	2	8	1	1	0	9
Clinical	Physical examination	8	1	1	6	0	0	1	7
	Laboratory test	14	3	2	9	1	1	0	10
	ECG evaluation	7	0	2	5	0	1	1	7
	Patient history	9	2	3	4	1	1	1	6
	Family history	7	2	2	3	1	1	0	4
	Sign and symptoms	10	1	3	6	1	1	1	8
	Treatment recommendations	8	3	1	4	1	0	0	4

ECG=Electrocardiogram
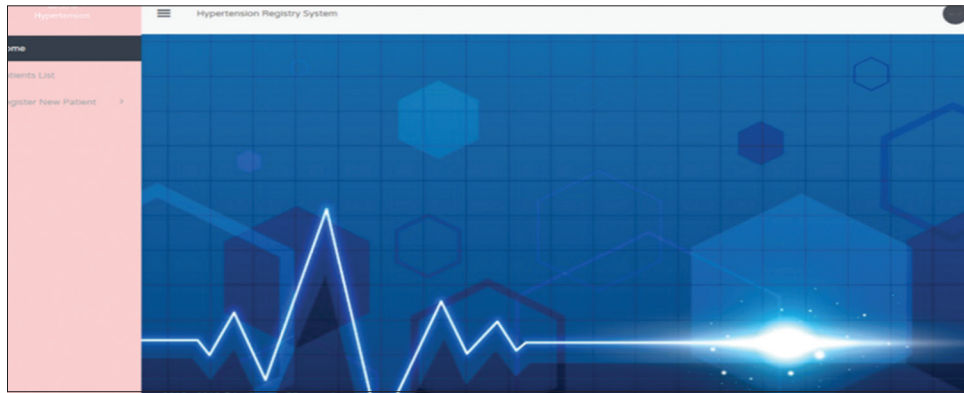
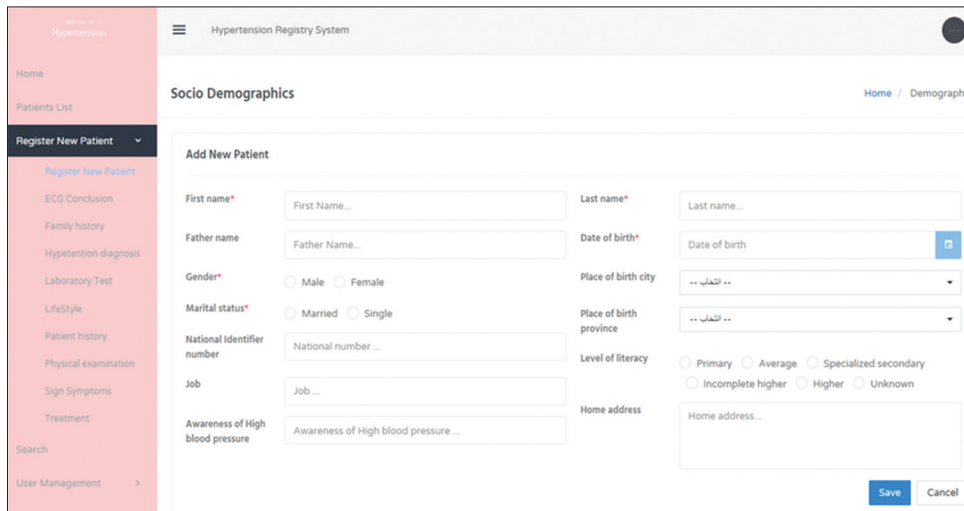**Figure 1:** Home page of hypertension registry

Figure 2: "Register new patient" menu of hypertension registry

HTN registry is central for studying the epidemiological characteristics of volunteers eligible to HTN in Iran. Many research findings have indicated that most risk factors for HTN are related to individuals' behavior, awareness, and educational programs.[30] By designing and implementing HTN registry, we were able to establish an active tracking system which improved treatment monitoring for individuals with HTN.[31] In fact, the HTN registry is a secondary solution for managing HTN, which can be important in studying and evaluating the relation of HTN with other diseases, as well as improving the quality of care and follow-up among the patients continuously. A well-designed registry encompasses a set of chronological collected and stored data focusing on a specific condition. Its practicality and reliability depend directly on the completeness and validity of the data contained therein.[32-36] Since the most effective design for a new registry is web based,[37] the registry framework in this study has also been web-based, offering a cost-effective alternative to paper-based disease tracking.

Table 3: Final data classes, field format, and content for hypertension registry

Data class	Data field	Data field format	Field content
Socioeconomical Sociodemographic data	Name and Surname	Entity name	Free text
	National Identifier No	Numeric	x-xxxxxx-x
	Birth date	Date	DD.MM.YYYY
	Date of registration	Date	DD.MM.YYYY
	Place of birth	String	Free text
	Sex	Binary	Male, female
	Marital status	Categorical	Married, single, widow, other
	Occupation	String	Free text
	Address	String	Free text
	Education	Categorical	Illiterate, under diploma, diploma, bachelor, master or above, un specified
	Social category	Categorical	Working, pensioner, disabled, other, unknown
	Activity type	Categorical	Physical, mental, not work, unknown
Life style	Cigarette smoking	Categorical	Current smoker: <1 cigarettes/day, Current smoker: 1-9 cigarettes/day, Current smoker: 10-19 cigarettes/day, Current smoker: 20-39 cigarettes/day, Current smoker: ≥40 cigarettes/day, former smoker, never smoked, unknown
	Stress level	Categorical	No stress, asymptomatic stress, symptomatic stress, unknown
	Salt intake	Categorical	<2300 mg/day, between 2300 and 3500 mg/day, between 3500 and 4700 mg/day, >4700 mg/day, unknown
	Dietary potassium	Categorical	<2300 mg/day, between 2300 and 3500 mg/day, between 3500 and 4700 mg/day, >4700 mg/day, unknown
	Hyposmolality or Hyponatremia	Binary	<120 mmol/L, between120 and 135 mmol/l, between 135 and 145 mmol/l, >145 mmol/l, unknown
	Alcohol consumption	Categorical	No alcohol drinking, alcohol drinking: <20 g/day, alcohol drinking: 20-59 g/day, alcohol drinking: 60-139 g/day, alcohol drinking: 140-179 g/day, alcohol drinking: ≥180 g/day, unknown
	The amount of exercise	Categorical	No exercise, <15 min/day, between 15 and 30 min/day, between 30 and 45 min/day, >30 min/day, unknown
	Balanced diet	Categorical	Carbs, protein, fat, fiber, vitamins, minerals and water intake, unknown
	BMI	Categorical	<18.5 kg/m^2, between 18.5 and 24.9 kg/m^2, between 25 and 29.9 kg/m^2 Above 30 kg/m^2, Unknown
Physical examinations	Waist circumference	Categorical	<35 inches, between 35 and 40 inches, above than 41 inches, unknown
	Systolic blood pressure	Categorical	<120 mmHg, between 120 and 129 mmHg, between 130 and 139 mmHg, >140 mmHg, unknown
	Blood pressure	Categorical	<80 mmHg, between 80 and 89 mmHg, >90 mmHg, unknown
	Brachial index	Categorical	<0.5, between 0.5 and 0.8, between 0.8 and 0.9, >1, unknown
	Rate (HR)	Categorical	<60 bpm, between 60 and 100 bpm, over than 100 bpm, unknown
	Palpation	Categorical	Bilateral ankle swelling, ripple of jugular veins, hepatojugular reflux hepatomegaly
	Auscultation	Categorical	Rattling in the lower lung, rattling on all lung fields, the third tone in heart beat
Laboratory test	Fasting blood glucose	Categorical	<100 mg/dl (5.6 mmol/L), From 100 to 125 mg/dl (5.6-6.9 mmol/L), 126 mg/dl (7 mmol/L) or higher, unknown
	Low-density lipoproteins	Categorical	<100 mg/dl, between 100 and 129 mg/dl, between 130 and 159 mg/dl, above than 159 mg/dl, unknown
	High-density lipoproteins	Categorical	<40 mg/dl, from 41 to 59 mg/dl, Above than 60 mg/dl, Unknown
	Total cholesterol	Categorical	<200 mg/dl, between 200 and 239 mg/dl, above 240 mg dl, unknown
	Albumin creatinine ratio	Categorical	<3.0 mg/mmol, between 3.0 and 30.0 mg/mmol, >30.0 mg/mmol
	Glomerular filtration rate	Categorical	<60 mL/min, between 60 and 89 ml/min, >90 ml/min, unknown
	Blood urea nitrogen	Categorical	Between 7 and 20 mg/dl, between 21 and 60 mg/dl, >60 mg/dl, Unknown
	Uric acid	Categorical	<2.5 md/dl, between 2.5 and 7 mg/dl, above than 7 mg/dl, unknown
	Triglycerides	Categorical	<150 mg/dl, between 150 and 200 mg/dl, above than 200 mg/dl, unknown
	Duplex ultrasound	Categorical	<50%, between 50% and 90%, >90%, unknown

Contd...

Table 3: Contd...

Data class	Data field	Data field format	Field content
ECG evaluation	Ventricular hypertrophy	Binary	Yes, no
	Signs of Q-wave infarction	Binary	Yes, no
	Non-Q-wave infarction	Binary	Yes, no
	Tachyarrhythmia	Binary	Yes, no
	Other violations	String	Free text
	Atrioventricular block	Binary	Yes, no
	Atrial fibrillation	Binary	Yes, no
Patient history	Myocardial infraction	Binary	Yes, no
	Stroke	Binary	Yes, no
	Diabetes	Binary	Yes, no
	Heart failure	Binary	Yes, no
	Chronic kidney disease	Binary	Yes, no
	Other disease	String	Free text
Family history	Cardiovascular disease	Binary	Yes, no
	Hypertension	Binary	Yes, no
	Diabetes	Binary	Yes, no
	Other disease	String	Free text
Sign and symptom	Severe headache	Binary	Yes, no
	Fatigue or confusion	Binary	Yes, no
	Nausea	Binary	Yes, no
	Irregular heartbeat	Binary	Yes, no
	Chest pain	Binary	Yes, no
	Dyspnea	Binary	Yes, no
	Vision problems	Binary	Yes, no
	Other conditions	String	Free text
Treatment recommendation	Hypertension diagnosis	Categorical	Normal, under control, elevated (Stage 1 HTN, Stage 2 HTN), essential (primary) HTN, secondary HTN, unknown
	Life style modification	Categorical	Weight reduction, dietary approach to stop hypertension, dietary sodium reduction, physical activity, other
	Current medication	String	Free text
	Surgical or medical procedure	String	Free text

BMI=Body mass index, HTN=Hypertension, ECG=Electrocardiogram, HR=Heart rate

The web-based application was compatible with the workflow of HTN visit, and it is very easy to use in terms of data entry and requesting reports.

Manual data entry is a time-consuming and error-prone process, so an accurate data entry process is essential for high quality research. Information should also be comprehensive so that it can be recorded in a few clicks. Consideration should be given to the format in which a data element is recorded to guarantee its use for secondary applications such as epidemiological research and reporting. From the physicians' point of view, it is easier to analyze the data elements that are compulsory options rather than free text data.[38] In this study, the designed registry system has been convenient and reliable, and even manual data entry has been avoided.

We believe that valid data on the frequency and distribution of the HTN can offer a clear understanding of the improvement in care quality of patients. Likewise,

it can support researches that are conducted to addresses high-priority issues. This promotes a deeper understanding of how HTN behaves in epidemiological aspects in Iran. This registry system stands to be a major benefit to researchers, as it will enable them to undertake increasingly sophisticated investigations more easily. However, in order to take advantage of improved data availability, we must first create effective systems to extract, store, utilize, and protect this information with thoughtfully designed disease-specific databases and informatics infrastructures.[39] Population based registry is an appropriate method to HTN monitoring. The registry in this study is a web-based HTN registry that offers a cost-effective alternative to paper-based disease tracking. However, this work does have a limitation. It is not probable to comprehensively capture all the data items which limit the practicality of the MDS; however, this will be outweighed by providing the most necessary data elements and possible subcategories.

Conclusions

International experience proves that the development of an HTN registry has a pivotal role in public health promotion.[40] This registry provides a wealth infrastructure for capturing data on HTN; the next steps are to carry out an in-depth analysis on collected data, in particular looking at the pattern history of the condition. We have adopted some new methods and technologies that can facilitate the capture and auditing of data which also have the potential to be used for future quality-improvement initiatives.

In the near future, a wider use of HTN registry would be desirable to better understand the nature and behavior of HTN in Iran. We hope that the knowledge generated from the HTN registry can be useful worldwide. Although the database is already a useful resource for many investigators, it has a limitation; it is not yet fully inclusive or complete.

Conflicts of interest
There are no conflicts of interest.

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