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Design and development of a web-based registry for Coronavirus (COVID-19) disease

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Abstract

Background: The 2019 coronavirus (COVID-19) is a highly contagious disease associated with a high morbidity and mortality worldwide. The accumulation of data through a prospective clinical registry enables public health authorities to make informed decisions based on real evidence obtained from surveillance of COVID-19. This registry is also fundamental to providing robust infrastructure for future research surveys. The purpose of this study was to design a registry and its minimum data set (MDS), as a valid and reliable data source for reporting and benchmarking COVID-19.

Methods: This cross sectional and descriptive study provides a template for the required MDS to be included in COVID-19 registry. This was done by an extensive literature review and 2 round Delphi survey to validate the content, which resulted in a web-based registry created by Visual Studio 2019 and a database designed by Structured Query Language (SQL).

Results: The MDS of COVID-19 registry was categorized into the administrative part with 3 sections, including 30 data elements, and the clinical part with 4 sections, including 26 data elements. Furthermore, a web-based registry with modular and layered architecture was designed based on final data classes and elements.

Conclusion: To the best of our knowledge, COVID-19 registry is the first designed instrument from information management perspectives in Iran and can become a homogenous and reliable infrastructure for collecting data on COVID-19. We hope this approach will facilitate epidemiological surveys and support policymakers to better plan for monitoring patients with COVID-19.

Keywords: Minimum data set, MDS, Registry system, COVID-19, Coronavirus

Conflicts of Interest: None declared
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Introduction

In December 2019, a series of cases of pneumonia with unknown etiology occurred in Wuhan, Hubei Province, China. On January 7, 2020, the novel coronavirus (COVID-19), previously known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or 2019-nCoV), was identified as the causative organism (1, 2). It is classified as a type of RNA virus that belongs to the family of coronaviruses, which primarily leads to a respiratory system infection (3). COVID-19 is highly contagious that rapidly spread to other countries. The World Health Organization (WHO) has recently declared the COVID-19 a public health emergency (4).

Given the significant burdens associated with COVID-19, decision was made to adopt information technology and data infrastructures to bolster efficient research, surveillance, and treatment of this emerging outbreak. Clini-

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↑What is "already known" in this topic:
Disease registries are collections of secondary data related to patients with a specific diagnosis, condition, or procedure, and they play an important role in clinical and managerial decisions.

→What this article adds:
COVID-19 registry facilitates studying the real clinical practice, capturing quality metrics, monitoring the disease and healthcare delivery patterns, and tracing clinical outcomes.

cal registry is one of such information platforms that standardize the collection of highly generalizable data and reinforce research infrastructure (5, 6). Clinical registries have a great potential for epidemiological surveillance, evaluating health-care delivery patterns, tracking clinical outcomes, describing disease natural progression, evidence-based therapy, and comparing the effectiveness of different interventions and post marketing drug surveillance. Moreover, clinical registries allow the study of the designed parameters and recruitment of participants for clinical trials (7-10). The COVID-19 registry will serve as a data source to standardize collection of comprehensive data related to many unclear aspects of COVID-19, such as transmission patterns, severity, clinical phenotype, prognostic factors, therapeutics' plans effectiveness and complications, survival estimation, incidence and prevalence of disease across country, and thereby allowing collaboration on research and surveillance of COVID-19.

However, despite the advantages afforded by clinical registries, some considerations need to be addressed from a data management perspective: the design of an effective data capture system and determination of the required data elements and validity of their corresponding values (11-13). Therefore, in this study, the required data elements for COVID-19 were defined and a clinical registry platform that met these requirements was designed.

Methods

This was a cross-sectional and descriptive study in 2020 that was conducted in two phases: in the first one, the aim was to identify required data elements and validated data capture template to be included in the COVID-19 registry, and the second one was designing a registry system for COIVD-19 on the web platform.

COVID-19 registry data element determination

Literature review

First, an extensive literature review to identify the COVID-19 MDS data elements was performed. In the first step to retrieve related resources, the Web of Science, ScienceDirect, Embase, Scopus, Elsevier, Cochran, PubMed and Google Scholar were reviewed, and the following search terms were used: (designed using English MeSH keywords and Emtree terms): "COVID-19" or "Novel coronavirus 2019" or "2019 nCoV" and "clinical characteristics" or "para clinical characteristics" or "epidemiological characteristics". After selecting the advance search interface in the mentioned databases using title, title/abstract, title/abstract/keyword and topic fields, and setting up Boolean operators (AND, OR) and implementing the input and output criteria (full text English articles from Dec 2019- Mar 2020), 18 articles were included in the study (3, 14-30). Data were extracted from the related retrieved resources and entered into the checklist with 2 administrative and clinical sections.

Questionnaire development

A questionnaire was developed using the data elements of the checklist and included 5 columns: "very important", "important" "neutral", "low important", and "very important" for each data item (eg, patient name, visit number, vital sign, exposure and etc.). To add necessary data elements by experts, a blank row was provided at the end of the questionnaire. The content validity of the questionnaire was assessed by an expert panel, including 2 infectious specialists and 3 health information management (HIM) experts. Also, test-retest was used to evaluate the reliability of the questionnaire.

Delphi phase

The initial MDS content was validated by Delphi technique using 2 rounds by a group of multidisciplinary experts working in hospitals affiliated to Ilam University of Medical Sciences (west of Iran). Table 1 shows the demographic characteristics of these experts. The experts were asked to review the initial data list to score each item according to their importance perceived by them based on a 5-point Likert scale, ranging from 1 to 5, where 1 indicated "not important" for inclusion and 5 indicated "highly important" for inclusion.

Agreement was reached for data elements based on experts' agreement level. After initial ranking, items with less than 50% agreement were deleted, those with more than 75% agreement excluded from the second round, and those with 50% to 75% agreement were surveyed in the second round. The checklists were individually presented

Table 1. Demographic characteristics of Delphi participants

Variables	Frequency	Percentage
Specialty		
Infectious disease	9	39.12
Internal medicine	8	34.79
Radiologist	6	26.09
Gender		
Female	8	34.79
Male	15	65.21
Age (years)		
30–40	9	39.12
40–50	6	26.09
50–60	6	26.09
>60	2	8.7
Work experience (years)		
<10	6	26.09
10–20	11	47.82
20–30	5	21.74
>30	1	4.35
Total	23	100

to the experts who were blind to the scores of other experts, and if there was 75% consensus over a subject, it was included into the final MDS.

COVID-19 registry software development tools

We used Visual Studio 2019 to design COVID-19 web-based registry because of its numerous benefits (eg, cost-effectiveness, scalability and accessibility, user friendliness, fast and convenience, custom search, improved intellicode, clipboard and refactoring attributes) (31, 32).The proposed system was implemented with cascading style sheets (CSS) technology as a web-based program. CSS, along with the Hypertext Markup Language (HTML), was used to describe the presentation of documents and set the document syntax, layout, display format, and visual effects (eg, font type, color, spacing, and sizes). The code was written in Java script language for designing the website. Finally, Structured Query Language (SQL) was used to create the relational database (RDB). SQL provides efficient and systematic storage of data with high performance, availability, scalability, flexibility, management, and security (33).

Results

The results of this study are divided into 3 phases:

Determining the proposed MDS for COVID-19

The proposed COVID-19 MDS was divided into the nonclinical section with 4 data classes, including 43 data elements, and the clinical data category with 4 data classes, including 44 data items. The nonclinical section includes sociodemographic, identification number, and patient disposition classes, and the clinical category includes diagnostic, exposure, physical examination, and medical / diagnostic procedure.

Determining final minimum data Set for COVID-19

The potential participants who determined the final data elements of the MDS of the COVID-19 registry were 25 medical specialists. However, 2 specialists did not participate in the study. Table 1 shows the demographic characteristics of the experts. The results of the 2 Delphi rounds

Table 2. Examples of nonclinical and clinical data classes for COVID-19 MDS

Data classes	Total number of elements	First round of Delphi			Second round of Delphi			Final
		< 50%	50-75%	75% <	< 50%	50-75%	75% <	
Administrative data category								
Sociodemographic characteristics	18	3	10	5	1	0	4	14
Identification	10	3	4	3	3	0	1	4
Patient disposition	15	2	10	3	1	0	2	12
Clinical data category								
Diagnostic	15	3	9	3	2	0	1	10
Exposure	8	3	2	3	2	0	1	3
Physical examination	11	3	4	4	2	0	2	6
Medical procedures	10	1	6	3	2	0	1	7
Total	87	18	45	24	12	0	12	56

Table 3. Weighting of data items after the second round of Delphi

Data classes	No	Data elements	Mean	Percentage	Final decision
Sociodemographic	1	Patient's name	4.1	82	Kept
	2	Father's name	3.85	77	Kept
	3	Spouse / partner's name	2.1	42	Removed
	4	Age (in years)	4.15	83	Kept
	5	Sex	4.5	90	Kept
	6	Date of birth	3.95	79	Kept
	7	Place of birth	4.25	85	Kept
	8	Marital status	4.09	81.8	Kept
	9	Income	2.3	46	Removed
	10	Religion	2.5	50	Removed
	11	Employment status	3.95	79	Kept
	12	Occupation	4.01	80.2	Kept
	13	Educational level	4.12	82.4	Kept
	14	Race/ nationality	3.55	77	Kept
	15	Home address	4.05	81	Kept
	16	Postal / zip code	3.93	78.6	Kept
	17	Phone number	3.88	77.6	Kept
	18	Fax no	1.8	36	Removed
Identified numbers	19	National ID	4.2	84	Kept
	20	Visit number	3.98	79.6	Kept
	21	Medical record number	2.5	50	Removed
	22	Social security number	3.9	78	Kept
	23	Physician ID	3.96	79.2	Kept
	24	Specimen ID	2.8	56	Removed
	25	Hospital ID	2.2	44	Removed
	26	Report ID	1.8	36	Removed
	27	Insurance ID	1.88	37.6	Removed
	28	Family ID	1.6	32	Removed

are presented in Tables 2 and 3.

The experts participated in 2 rounds by completing the questionnaire.

At the end of the first Delphi round, 18 data elements were deleted (< 50%), 45 moved to the next round (50%-75%), and 24 marked as definitive (75% <). In addition,

Table 3. Ctd

Data classes	No	Data elements	Mean	Percentage	Final decision
Patient disposition	29	Admission date	4.35	87	Kept
	30	Reason for admission	4.20	84	Kept
	31	Type of admission	4.09	81.8	Kept
	32	Readmission	4.22	84.4	Kept
	33	Length of stay	4.1	82	Kept
	34	Discharge date	4.3	86	Kept
	35	Discharge status	4.3	86	Kept
	36	Underlying cause of death	4.1	82	Kept
	37	Date of death	4.05	81	Kept
	38	Discharge location	3.8	76	Kept
	39	Discharge recommendations	2.4	48	Removed
	40	Discharge/ referral date	2.15	43	Removed
	41	Discharge /referral type	1.95	39	Removed
	42	Discharge Prescribed drugs	4.1	82	Kept
	43	Date of follow-up	4.23	84.6	Kept

Table 3. Ctd

Data Classes	No	Data elements	Mean	Percentage	Final Decision
Diagnostic	1	Disease history	4.8	96	Kept
	2	Comorbidity	4.6	92	Kept
	3	Family history	2.8	56	Removed
	4	Disease status	4.2	84	Kept
	5	Disease severity status	4.25	85	Kept
	6	Mental condition	2.2	44	Removed
	7	Case classification	4	80	Kept
	8	Vital sign	2.4	48	Kept
	9	Sing and symptoms	4.65	93	Kept
	10	symptoms types (if symptomatic)	4.6	92	Kept
	11	Symptom onset date	3.01	60.2	Removed
	12	Chief complaint	3.03	60.6	Removed
	13	Days from exposure to symptom onset	3.85	77	Kept
	14	Time between diagnosis and treatment	3.93	78.6	Kept
	15	Date of diagnosis	4.45	89	Kept
Exposure	16	Exposed to high risk agent	4.1	82	Kept
	17	Exposure type	2.85	57	Removed
	18	Cause of exposure	2.3	46	Removed
	19	Exposure history	4.78	95.6	Kept
	20	Activity on exposure	1.07	21.4	Removed
	21	Location of exposure	2.63	52.6	Removed
	22	Number of exposures	2.1	42	Removed
	23	Date of exposure	4.5	90	Kept
Physical Examination	24	Respiratory rate: per minute	4.4	85	Kept
	25	Pulse	2.6	52	Removed
	26	Waist circumference	2.7	54	Removed
	27	Temperature: °C	4.5	90	Kept
	28	Brachial Index	2.4	48	Removed
	29	Blood group	3.90	78	Kept
	30	Body Mass Index	3.05	61	Removed
	31	Blood pressure: mmHg	4	80	Kept
	32	Lung examination	4.15	83	Kept
	33	Heart rate: bit per minute	3.9	78	Kept
	35	Weight /height	1.8		Removed
Procedures	36	Quarantine / isolation	2.1	42	Removed
	37	Oxygen support	4.45	89	Kept
	38	Immunization/ vaccination	2.3	46	Removed
	39	Radiology	4.8	96	Kept
	40	CT features	4.95	99	Kept
	41	Lung segment involvement	4.5	90	Kept
	42	Prescription / medication	3.2	64	Removed
	43	LAB test name	4.9	98	Kept
	44	Test result	4.9	98	Kept
	44	Test time	3.89	77.8	Kept

no new data elements were suggested by the experts. After the second round, in general, 13 data elements for the nonclinical and 18 elements for the clinical category were excluded from the report template. Therefore, the experts agreed on 30 data elements from 43 data elements of the nonclinical category. The second category was the clinical data involving 4 data classes with 26 data elements. The ultimate data elements for the nonclinical and clinical categories were 30 and 26, respectively (Table 2). The results of weighing of data elements after the second round of Delphi are displayed in Table 3.

In Table 4, data classes, elements, and their formats and standard contents (recording template) were defined for 2 nonclinical and clinical data categories.

The COVID-19 registry framework

In the development of the software, our focus was on accessibility and user-friendliness of the system to expedite reporting time. Our designed system uses an advanced search capability to enable custom search, contact to site administrator, provide useful news about disease (prevention, self-care, treatment information, etc.), rendering daily statistics and multimedia instructions. Access to the registry is provided to registered members on the system home page (user name & password boxes). Each user has a unique identification password and username to log into the system. Figures 1 and 2 display the designed web-based registry screen of COVID-19.

Discussion

The lesson learned from previous global pandemics and the widespread prevalence of zoonotic viral diseases (eg, SARS and MERS), highlights the importance of patient registries in the field of new emerging outbreaks such as COVID-19 (34, 35). In this regard, for proper implementation of a public health surveillance system (PHSs), clini-

Table 4. Nonclinical and clinical MDS description for COVID-19 registry system

Administrative data category			Clinical data category		
Data elements	Content definition	Data Format	Data elements	Content definition	Data Format
Sociodemographic			Diagnostic		
Patient's name	First / middle / last name	String	Disease history	Free text	String
Father's name	First / middle / last name	String	Comorbidity	Free text	String
Age (in years)	⁎Infant: x<1y, ⁎child:1y<x<5y, ⁎teenage: 5y<x<17y, ⁎young: 17y<x<34y, ⁎middle age: 34y<x<65y, *aged: x>65y	Categorical	Disease status	⁎Active, ⁎inactive, ⁎recovered	Categorical
			Disease severity status	⁎General, ⁎severe , ⁎critical	Categorical
Sex	⁎M ⁎F	Categorical	Case classification	⁎Final, ⁎suspicious ⁎probable	Categorical
Date of birth	yyyy /mm/ dd	Date	Sing and symptoms	⁎Symptomatic, ⁎a symptomatic	Binary
Place of birth	Geographical location: province, city, village	Categorical	symptoms types (if symptomatic)	Free text	String
Marital status	⁎Single *married *widowed, *other	Categorical	Days from exposure to symptom onset	Number of days	Integer
Employment status	⁎Unemployed, ⁎employed, ⁎retired, ⁎student, ⁎other	Categorical	Time between diagnosis to treatment	number of days	Integer
Occupation	Free text	String	Date of diagnosis	yyyy /mm/ dd	Date
			Exposure		
Race/ nationality	Iranian: ⁎Persian, ⁎Kurdish, ⁎Turkish, ⁎other	Categorical	Exposed to high risk agent	⁎Yes, ⁎no, ⁎unknown	Categorical
Educational level	⁎Illiterate, ⁎ less than high school diploma, ⁎diploma, ⁎ bachelor, *master of science or above, ⁎unspecified	Categorical	Exposure history	⁎Person-to-person ⁎Animal-to-person ⁎Contact with contaminated surfaces ⁎ Food/water born ⁎Other, ⁎unknown	Categorical
			Date of exposure	yyyy /mm/ dd	Date
Home address	Province-city-street-alley-house no	String	Physical Examination		
Postal / zip code	Ten digits with dash	Integer	Respiratory rate: per minute	⁎ ≤ 24 breaths per min ⁎ >24 breaths per min	Categorical
Phone number	Ten digits with +98	Integer	Temperature: °C	⁎ <37.3, ⁎37.3 – 38, ⁎38.1 – 39, ⁎>39.0	Categorical
Identifier					
National ID	Validated numerical range	Integer	Heart rate: bit per minute	⁎ <60, ⁎between 60-100, ⁎ >100, ⁎unknown	Categorical
Visit number	Validated numerical range	Integer	Blood group	RH positive: A, B, AB, O RH negative: A, B, AB, O	Categorical
Social security number	Validated numerical range	Integer	Blood pressure: mmHg	⁎<120, ⁎between 120-129, ⁎between 130-139, ⁎>140, ⁎unknown	Categorical
Physician ID	Validated numerical range	Integer	Lung examination	⁎Clear/normal, ⁎rales, ⁎decreased breath sounds, ⁎rhonchi, ⁎wheezing	Categorical

Table 4. Ctd

Administrative data category			Clinical data category		
Data elements	Content definition	Data Format	Data elements	Content definition	Data Format
Patient Disposition			Medical / Diagnostic Procedures		
Admission date	yyyy /mm/ dd	Date	Oxygen support	*Non-invasive mechanical ventilator *invasive mechanical ventilator *Extracorporeal Membrane Oxygenation (ECMO) *other	Categorical
Reason for admission	Unstructured free text	String			
Type of admission	*Urgent, *programmed, *unknown	Categorical	Radiology	*Bilateral chest CT-scan *Unilateral chest CT-scan	Categorical
Readmission	*yes *no	Binary			
Length of stay	*≤7day, *>7 day	Force Choice	CT Features	*Ground-Glass Opacity (GGO)	Categorical
Discharge date	yyyy /mm/ dd	Date		*Consolidation interlobular thickening	
Discharge status	*Deceased, * full recovery, * partial recovery, * other	Categorical		*Crazy paving pattern	
Underlying cause of death	*Related to current disease *unrelated to current disease *not applicable * unknown	Categorical		*Bronchial wall thickening *Lymph adenopathy *pericardial effusion *pneumonia *pneumothorax *plural effusion *interstitial abnormalities *other	
Date of death	*yyyy /mm/ dd,	Date	Lung segment involvement	*unilateral *bilateral	Binary
Discharge location	*Deceased * home *other care facilities * unknown	Categorical	LAB test name	*Real time - PCR: RT- PCR *Complete Blood Count: CBC * alanine /aspartate transaminase :AST/ ALT *Blood Urea Nitrogen: BUN *C-reactive protein level: CRP *Platelet: PLT, * Lymphocyte: LYM * Neutrophil: NEU, * Creatinine: Cr *Lactate dehydrogenase: LDH, *other	Categorical
Discharge Prescribed drugs	Drug name	String	Test result	* Positive CoV * Negative CoV	Binary
Date of follow-up	yyyy /mm/ dd	Date	Test time	yyyy /mm/ dd	Date

cal registries offer enhanced progresses in systematic collection, analysis, comparison, and integration of population-based data. Clinical registries allow ongoing monitoring and benchmarking of clinical management and treatment outcomes, and thus are considered among the most effective strategies for quality healthcare improvement. They are powerful and comprehensive tools for conducting research and detecting eligible subjects to contribute in a particular study or clinical trial (5, 36-38). COVID-19 registry has been developed on the web platform enabling scientific teamwork in the field of COVID-19 and purposes to achieve a collaborative multi setting research study with a flexible registry structure. Moreover, no extra on-site software installation, configuration, or hardware is needed because of the web-based platform.

One of the basic steps in building a registry was determining a minimum and yet inclusive required data set that would be standardized across organizations and could pave the way for collaboration between researchers (39). To identify the necessary data on COVID-19 across clinical and public health information systems, initially a list of potential data elements gathered through conducting extensive literature review. Also, the number of data elements was reduced after the expert panel's discussion and vote, and ultimately the MDS were finalized for inclusion in the COVID-19 registry. The COVID-MDS aims to harmonize the collection process, and increase the comparability of clinical care data across COVID-19 registries and databases, and facilitate pooled analyses to address clinical research questions.

The quality of research results depends on generalizable and high quality data (40). As Ieva et al (2014) stated, "when reliable data capture system recording data regarding a disease natural history progression, researchers can design studies more creditably and identify suitable subjects." (41) Also, the International Conference on Harmonization (ICH) guideline E6 on good clinical practice (GCP) necessitates that clinical trials be conducted based precise, comprehensive and verifiable data to guarantee patient safety and data quality. Thus, the credibility of registry is emphasized by researchers (42). Studies derived from well-designed and well-implemented registries provide a more realistic view of clinical procedures, patient outcomes, safety and efficacy, and measurable effec-

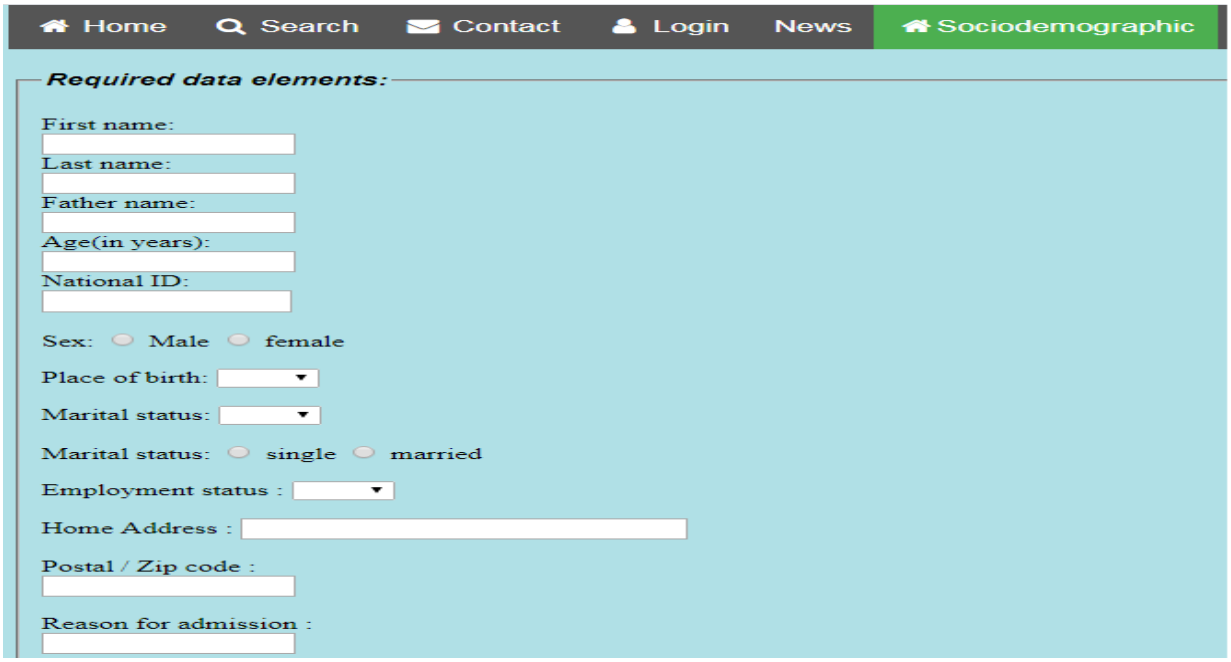

Fig. 1. Administrative data entry screen

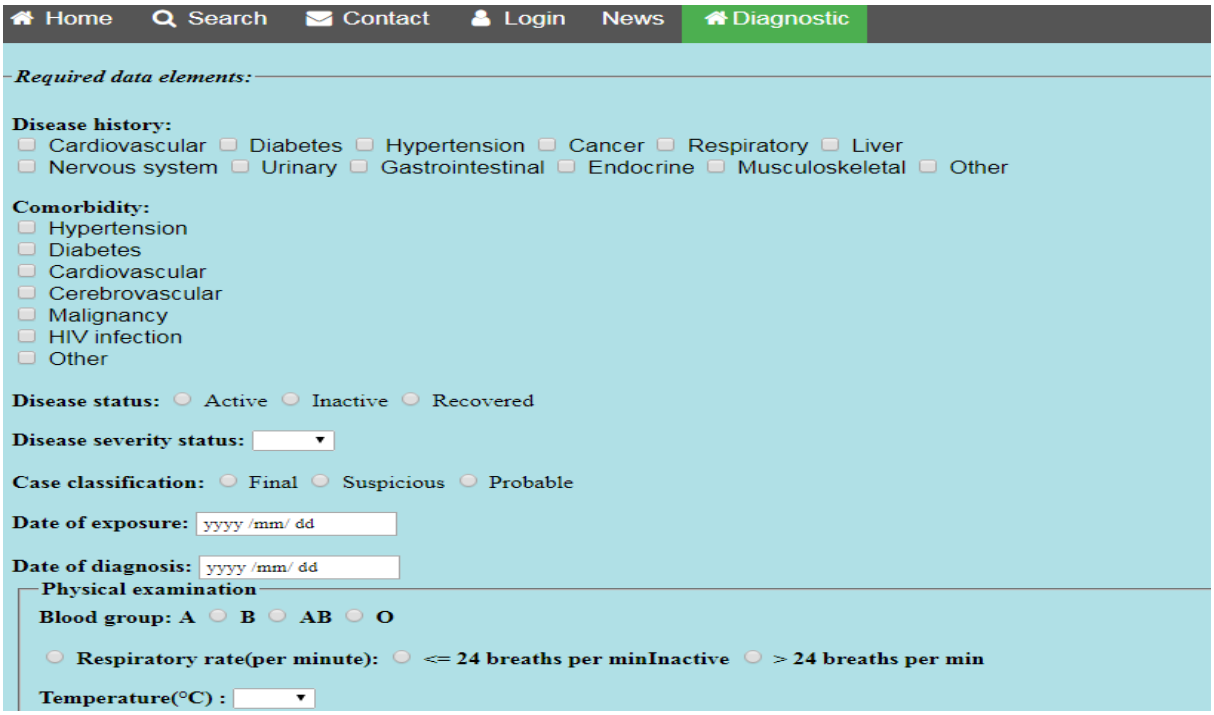

Fig. 2. Clinical data entry screen

tiveness, and support the decision-making and evidence-based design process (43).

The quality of clinical registers can be restricted due to poor uptake or unreliable data entry process. The manual data entry is time-consuming for clinical staff and is vulnerable to documentation errors, such as inaccuracies and omissions (9, 44). In COVID-19 registry, an electronic web-based data entry is provided to automatically reject incorrect values or those that are outside the range; furthermore, the manual entry of data is avoided as much as possible.

Furthermore, to comply with other data quality criteria, such as data consistency and comparability in COVID-19 registry, first, most required data elements and their values were determined for reporting COVID-19 in a consistent manner across Iran's health system. COVID-19 registry is comprehensive and can provide an in-depth description of specific patient cohorts rather than delivering epidemiological data. Another key feature for any registry is interoperability with other health information systems that

can be helpful to avoid duplication of data entry and reduce the workload on care givers. Bergin et al (2016) also recognized some possible challenges in developing a registry that hinder comprehensive and accurate data capture, including the increased workload of health care providers and proper integration of data capture into daily clinical workflow (45). Therefore, it is valuable to harmonize data elements, data descriptions, and process for uniform capturing of each item (46, 47). Thus, in this study, both COVID19 MDS and detailed categories (levels) and data formats for data capturing were defined. For future studies, working on technical aspects of data exchanging to automated pool data in the registry is the next challenge.

Given some unfamiliar aspects of the COVID-19, further development and adjustments are required; thus, conducting a pilot study, including a further Delphi step to refine the MDS, is recommended. Moreover, this MDS may need to be evaluated from the perspectives of larger group of medical and public health experts to be applicable at the national level. Further, we used the Delphi consensus approach to reach an agreement on COVID-19 MDS. This technique has been demonstrated to be suitable for assessment information systems requirements (48). However, one of its restrictions is that most views are marginalized. Despite the aforementioned limitations, this registry provides a standardized and agreed dataset on COVID-19 to accumulate patients, so gradually larger cohorts will be available in the future. In addition, this registry can collect large volumes of data from multiple settings and lay the foundation to conduct in-depth analyses by the artificial intelligence (AI) technique on many unfamiliar aspects of COVID-19. In addition, it is expected to push quickly towards better scientific collaboration for COVID-19. Registry implementation also allowed us to evaluate the quality of care and to help inform best practice in controlling COVID-19.

Conclusion

This study represents a fundamental effort towards building a national registry that uses information management approaches to improve accuracy, completeness, comparability, and interoperability of data about COVID-19 across the health care sector. This registry helps to conduct surveys to study various aspects of COVID 19 using a set of variables that were included in the registry according to the experts' opinions.

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Conflict of Interests

The authors declare that they have no competing interests.

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