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Development of minimal basic data set to report COVID-19

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Abstract

Background: Effective surveillance of COVID-19 highlights the importance of rapid, valid, and standardized information to crisis monitoring and prompts clinical interventions. Minimal basic data set (MBDS) is a set of metrics to be collated in a standard approach to allow aggregated use of data for clinical purposes and research. Data standardization enables accurate comparability of collected data, and accordingly, enhanced generalization of findings. The aim of this study is to establish a core set of data to characterize COVID-19 to consolidate clinical practice.

Methods: A 3-step sequential approach was used in this study: (1) an elementary list of data were collected from the existing information systems and data sets; (2) a systematic literature review was conducted to extract evidence supporting the development of MBDS; and (3) a 2-round Delphi survey was done for reaching consensus on data elements to include in COVID-19 MBDS and for its robust validation.

Results: In total, 643 studies were identified, of which 38 met the inclusion criteria, where a total of 149 items were identified in the data sources. The data elements were classified by 3 experts and validated via a 2-round Delphi procedure. Finally, 125 data elements were confirmed as the MBDS.

Conclusion: The development of COVID-19 MBDS could provide a basis for meaningful evaluations, reporting, and benchmarking COVID-19 disease across regions and countries. It could also provide scientific collaboration for care providers in the field, which may lead to improved quality of documentation, clinical care, and research outcomes.

Keywords: Minimum basic data set, Minimum data set, COVID-19

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Introduction

In December 2019, a series of cases of pneumonia with mysterious etiology was first identified in Wuhan, China. On January 7, 2020, the novel Coronavirus (COVID-19), previously known as Severe Acute Respiratory Syndrome Coronavirus2 (SARS-CoV-2 or 2019-nCoV) was identified as the causal organism (1-3). COVID-19 is classified

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↑What is "already known" in this topic:
There is no established national core data set for the COVID-19 in Iran, which has led to a lack of standardization and variable assessment criteria being used across the country. This hinders the quality and monitoring of COVID-19.

→What this article adds:
Using a structured approach, we developed a minimal dataset to underpin COVID-19 documentation and practice. It is anticipated that the MBDS will facilitate a more consistent approach to COVID-19 practice. This dataset can also be used by other researchers to apply statistical analyses and machine learning algorithms to compare the characteristics of the pandemic among different countries and to identify characteristics that could bring new insights about the pandemic and how to fight it.

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as a type of RNA virus, belonging to the family of coronaviruses, which primarily leads to a respiratory system infection and is extensively transmitted among humans and mammals, causing numerous conditions that range from the ‘‘common’’ influenza to death (4, 5). COVID-19 seems to be extremely communicable. The World Health Organization (WHO) has recently confirmed the COVID-19 a public health emergency (6). The WHO is warning countries to expand their efforts to contain the disease and safeguard health care environments and notes that a solution calls for a worldwide ’aggressive preparedness’ (7).

Early, systematic, and active emergency management practices are key points in epidemic prevention and control. The effective surveillance of this emerging outbreak heavily relies on regulatory management and coordinated interventions, which include comprehensive and directed surveillance, antimicrobial stewardship program, education and training, research and epidemiological studies, and policymaking, etc. These interventions highlight the importance of rapid, valid, and reliable information sharing across hospitals and public health authorities for monitoring crisis and early warning. In this situation, high-quality datasets are the prerequisite of necessary analysis for public health, which is inherently a data-intensive domain (8-12). In Iran, most organizations have developed different processes and infrastructure for management and subsequent data collection of COVID-19 patients (13-17). Although current efforts to report COVID-19 are a good start, the absence of information management viewpoint regarding which data elements are critical to be recorded leads to significant inconsistent, unreliable, redundant, or duplicate reports. Thus, this precludes data integration, which limits the share of data across multiple health information systems (18, 19).

Further, standardized clinical documentation is an essential factor for electronic health records (EHRs) and for supporting secondary use of data gathered in the context of clinical daily workflows for other purposes than patient care, eg, for clinical research, quality management, epidemiologic studies, patient outcomes, and interoperability initiatives. MBDS is a data collection tool that aims to identify the common components of data sets as one of the first and most basic steps in foundation and implementation of numerous information systems through minimizing duplication of effort and improving data quality (20-24). COVID-19 monitoring depends on clinical data and reports from widely scattered public and hospital information systems as data input (eg, Hospital information systems (HIS), Iranian Electronic Health Record (so-called SEPAS), Iranian Integrated Health System (known as SIB), and other clinical information systems). Accordingly, as we are in the primary step of this emergency, the need to establish a supportive, standardized, accurate, and updated dataset is of paramount importance. Adopting such dataset is an important step in promoting data (capture) and data exchange with regard to COVID-19. Thus, we conducted a systematic literature review combined with a Delphi survey to establish a minimal dataset that would be regarded as a standardized method of reporting COVID-19 disease, and thus it is expected to improve the quality of clinical and research outcomes.

Methods

Design

In this study, a 3-step sequential approach was used. First, an elementary list of data was collected from the existing information systems and datasets. Next, a search strategy was developed to identify data items for establishing COVID-19 MBDS from an evidence-based perspective. These sources were continuously reviewed until data saturation (maximum data set). Finally, the data included from the review were analyzed using a 2-round Delphi survey to achieve consensus on optimal data set (minimum data set).

Data collection

The initial data elements were extracted from the medical records of patients with COVID-19, reports from Corona National headquarters, and other clinical and public health organizations affiliated to the Iranian Ministry of Health as well as official dataset provided by international organizations, such as the World Health Organization (WHO) reports, European Centre for Disease Prevention and Control dataset (ECDC), Chinese Center for Disease Control and Prevention (Chinese CDC). In addition to mapping available evidence supporting the development of minimal dataset, a systematic review was also conducted to identify probable data elements for inclusion in COVID-19 MBDS. To that end, PubMed, Scopus, Web of Science, and Google Scholar databases were reviewed by the following search terms (designed using English MeSH keywords and Emtree terms): “COVID-19”, “Novel coronavirus 2019”, “2019 nCoV”, “clinical characteristics”, “clinical features” and “clinical findings”. In Table 1, the systematic search strategy is proposed based on Boolean search operators, keywords, and search fields (advance

Table 1. Search strategy details

Databases	Search details
PubMed	((((((((((((("covid-19 "[Title]) OR "novel coronavirus"[Title]) OR "2019 nCoV"[Title]) AND clinical characteristics ([Title/ Abstract]) OR clinical features [Title/ Abstract]) (English [lang]), limited to 2019-2020.
Scopus	(TITLE (covid-19) OR TITLE (novel AND coronavirus) OR TITLE (2019 nCoV) AND TITLE-ABS-KEY (clinical AND features) OR TITLE-ABS-KEY (clinical AND characteristics)) AND (LIMIT-TO (PUBSTAGE, "final")) AND (LIMIT-TO (PUBYEAR, 2020) OR LIMIT-TO (PUBYEAR, 2019)) AND (LIMIT-TO (DOCTYPE, "ar")) AND (LIMIT-TO (LANGUAGE, "English")).
Web of Science	TITLE: (COVID-19) OR TITLE: (novel coronavirus) OR TITLE: (2019 nCoV) AND TOPIC: (clinical findings) OR TOPIC: (clinical characteristics) Refined by: DOCUMENT TYPES: (ARTICLE) AND PUBLICATION YEARS: (2019-2020))
Scholar	allintitle: (COVID-19 OR "novel coronavirus") AND ("clinical features" OR "clinical characteristics") AND English [lang], limited to 2019- 2020.

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search interface).

Data material

Two authors independently performed electronic literature searches for study identification and screening. The results of the initial search strategy were first screened based on the title and abstract. The full-texts of relevant articles were examined for inclusion and exclusion criteria. This research included all full-text articles extracted from reliable sources in English between December 2019 and April 2020. Short articles, letters to the editor, accepted papers in conferences, thesis, and reports extracted from blogs were not included in this study. The main criterion for selection of research articles was the relevancy of their content with the research title. Due to the large number of available research articles, several criteria were considered for selecting articles and introducing clinical core data elements to report COVID-19. Hence, full articles with at least 2 of the following data classes related to the main objectives of reporting of COVID-19 were selected: (1) clinical, (2) laboratory, (3) radiology, and (4) epidemiological features. Finally, probable data elements to be included in COVID-19 MBDS were introduced in a checklist.

Questionnaire development

A questionnaire was developed using the data elements of the checklist and included 5 columns: “very important”, “important” “neutral”, “slightly important”, and “very slightly important” for each data item. 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. To add necessary data elements by experts, a blank row was provided at the end of the questionnaire. Test-retest (at an 8-day interval) was done to determine the reliability of the questionnaires, based on experts’ answers, including 2 health information management (HIM) and 2 medical informatics experts. Finally, the collected data were analyzed using SPSS 16, with the questionnaire showing a Cronbach's alpha of 0.86.

Delphi phase

The data elements were validated using 2 rounds of the Delphi survey by a group of multidisciplinary medical experts (Table 2). The experts participating in the study were asked to score the tabulated list of data elements in terms of their importance using a 5-point Likert scale (ranging from 1:“very slightly important” to 5:“highly important”. The level of agreement was considered to be a criterion for the acceptance of the data elements. Thus, after initial ranking, data elements with ≤50% agreement were excluded in the first round, those with 50%-75% agreement entered the second round, and data elements with ≥75% agreement were included in the primary round.

Results

A total of 643 articles were obtained from the literature review. After removal of duplicate articles and applying the exclusion criteria, 38 articles were included in the analysis (Fig. 1).

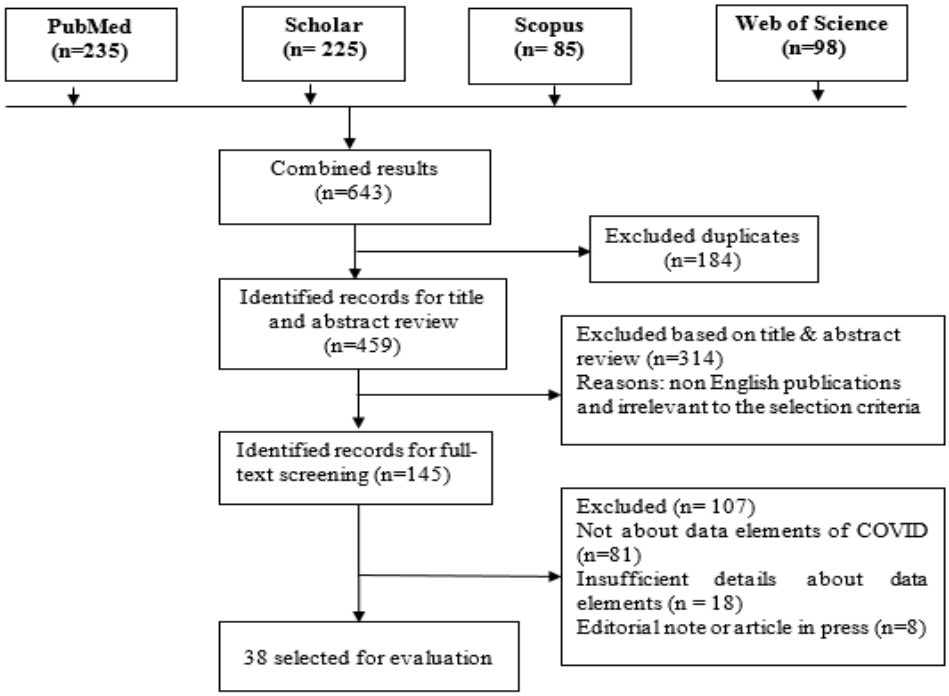

Fig. 1. Flow diagram showing publication selection process

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Table 2. Demographic characteristics of Delphi participants

Variables	Frequency	Percentage
Specialty		
Infectious disease	6	31.58
Internal medicine	5	26.31
Radiologist	4	21.05
Epidemiologist	4	21.05
Gender		
Female	6	31.58
Male	13	68.42
Age (years)		
30–40	6	31.58
40–50	7	36.84
50–60	5	26.31
>60	1	5.27
Work experience (years)		
<10	7	36.84
10–20	8	42.10
20–30	3	15.78
>30	1	5.27
Total	19	100

The demographic data of the study participants are presented in Table 2. The potential participants consisted of 25 medical specialists involved in COVID-19 care, treatment, and research domains. However, 6 specialists did not participate in the study. Thus, 19 experts contributed.

Overall, 3 data categories, 19 data classes and 149 data items were extracted from the related comprehensive literature review (maximum dataset). These data categories were epidemiological, clinical, and paraclinical. Epidemiological data contained 4 categories, including basic information, exposure history, transmission mode, and susceptible populations. The clinical data category consisted of clinical manifestations, coexisting conditions, treatment and supportive care, physical examinations, complications, time intervals, disease severity, disease status, and outcome data classes. Finally, the paraclinical category was divided into 2 laboratory and radiology indicators. The definitive numbers of data elements for epidemiological, clinical and paraclinical classes were 25, 73, and 51 respectively (Table 3).

Table 3. COVID-19 minimum basic data set

Literature review results		Specialists perspectives ✓ : Accepted in first round × : Rejected in first round ○: Refer to second round			
		First round		Second round	
Data classes / items	Frequency	Mean (percentage)	Initial decision	Mean (percentage)	Final decision
A. Epidemiological data					
Basic information					
Age (2-4, 25-44)	23	4.26 (85.2)	✓		Accept
Sex (2-4, 25, 27-29, 31-44)	21	3.90 (78)	✓		Accept
Occupation (40, 42)	2	2.1 (42)	×		Refuse
Nationality / race (40, 42)	2	3.37 (67.36)	○	3.32 (66.31)	Refuse
Exposure information					
Exposure history (33, 35, 36, 41, 42, 45)	6	4.52 (90.52)	✓		Accept
Uncertainty (32, 36, 39, 46)	4	4.32 (86.31)	✓		Accept
Living in epidemic area (2, 4, 32-34, 46)	6	4.21 (84.21)	✓		Accept
Recent travelling (2, 4, 32, 34, 37, 42, 44)	7	4.26 (85.20)	✓		Accept
Contact with suspicious person (2, 4, 32-34, 46)	6	4.36 (87.36)	✓		Accept
Transmission mode					
Person-person (2, 33-35, 42, 46-48)	7	3.9 (77.90)	✓		Accept
Nosocomial (34, 35, 42, 46, 48)	5	4.26 (85.2)	✓		Accept
Inhalation (aerosols) (35, 42, 48)	3	3.32 (66.32)	○	2.79 (55.79)	Refuse
Food / water born (35, 42, 48)	3	3.37 (67.36)	○	1.87 (37.40)	Refuse
Contaminated surfaces (33, 35, 42, 47)	4	4.16 (83.15)	✓		Accept
Sporadic occurrence of zoonotic (35, 42)	2	1.07 (21.4)	×		Refuse
Other (35, 42)	2	3.95 (78.95)	×		Accept
Susceptible population	2	3.95 (78.95)	✓		Accept
Elderly people (32, 36, 39, 46)	4	4.47 (89.48)	✓		Accept
Current pregnancy (32, 36, 40, 45)	4	4.53 (90.53)	✓		Accept
Poor immune function (32, 40, 45)	3	3.84 (76.84)	✓		Accept

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Literature review results		Specialists perspectives ✓ : Accepted in first round × : Rejected in first round ○: Refer to second round			
Data classes / items	Frequency	First round Mean (percentage)	Initial decision	Second round Mean (percentage)	Final decision
A. Epidemiological data					
Susceptible population	2	3.95 (78.95)	✓		Accept
Chronic co-morbidities (32, 36, 46)	3	3.79 (75.8)	✓		Accept
Long-term use of immunosuppressive (32, 40)	2	4.26 (85.2)	✓		Accept
Surgery history (32, 40)	2	2.79 (55.79)	○	3.32 (66.31)	Refuse
Active smoker (32, 39, 40)	3	4.37 (87.37)	✓		Accept
Other (32, 40)	2	3.95 (78.95)	✓		Accept
B. Clinical data					
Clinical manifestations					
Fever (2-4, 25-27, 29-37, 39-45, 47-54)	29	4.53 (90.53)	✓		Accept
Dry cough (2-4, 25, 26, 29-37, 39-43, 45, 47-54)	27	4.37 (87.37)	✓		Accept
Sputum / expectoration (2-4, 26, 29, 31, 34, 39, 40, 43, 44, 48-53)	16	3.58 (71.57)	○	3.98 (79.6)	Accept
Dyspnea (2-4, 25-27, 29-37, 39, 40, 42-45, 47-54)	27	4.26 (85.2)	✓		Accept
Myalgia or fatigue (2-4, 25-27, 29, 31-34, 36, 39, 41-44, 48-54)	22	4.05 (81)	✓		Accept
Headache (2-4, 25, 26, 29, 30, 32-36, 39, 42-44, 48-52)	20	2.47 (49.47)	×		Refuse
Sore throat (2-4, 25, 26, 29, 31, 32, 34-36, 39, 40, 42-44, 48-53)	21	3.84 (76.84)	✓		Accept
Dizziness (2, 3, 26, 37, 40, 43, 44, 48, 50)	9	2.42 (48.42)	×		Refuse
Rhinorrhea (2, 3, 26, 32, 40, 43, 44, 48, 49, 52)	10	3.53 (70.53)	○	3.95 (79)	Accept
Chest pain (2, 3, 25, 26, 32, 34, 35, 40, 42-44, 48, 49, 54)	14	2.47 (49.47)	×		Refuse
Pharyngeal congestion (30, 34, 36, 43, 44, 48, 52, 53)	8	3.78 (75.79)	✓		Accept
Chill (2-4, 34, 44, 48)	6	3.35 (67)	○	3.65 (73)	Refuse
Abdominal pain (29, 31, 32, 34, 39, 42, 43, 48, 54)	9	2.37 (47.37)	×		Refuse
Diarrhea (2-4, 25-27, 29-33, 36, 37, 39, 40, 43, 44, 48-52, 54)	23	2.15 (43.16)	×		Refuse
Anorexia (2-4, 26, 32, 36, 42, 44, 48-50, 52)	12	2.73 (54.73)	○	2.87 (57.4)	Refuse
Vomiting and nausea (4, 29-33, 35, 39, 42-44, 48, 52, 53)	14	3.15 (63)	○	3.48 (69.60)	Refuse
More than one sign or symptom (26, 34, 36, 48)	4	4.58 (91.59)	✓		Accept
No sign or symptom (asymptomatic) (42, 47, 48, 52)	4	4.16 (83.16)	✓		Accept
Co-existing conditions					
Hypertension (3, 25, 26, 28, 29, 31, 32, 34, 36, 38-40, 42-44, 48-50, 54, 55)	20	3.84 (76.84)	✓		Accept
Cardiovascular (3, 25-29, 31, 32, 34, 36, 38-40, 42, 43, 48-50, 54, 55)	20	4.32 (86.32)	✓		Accept
Cerebrovascular (3, 25, 26, 40, 43, 49, 50, 54, 55)	9	4.05 (81.05)	✓		Accept
Diabetes (3, 25-29, 32, 34, 36, 38, 43, 44, 49, 50, 53-55)	17	3.84 (76.84)	✓		Accept
Gastrointestinal disease (26, 36, 50, 51)	4	3.26 (65.26)	○	3.97 (79.40)	Accept
Malignant tumors (3, 25, 26, 28, 31, 34, 38, 43, 49, 50, 54, 55)	12	4.05 (81.05)	✓		Accept
Neural system disease (25, 26, 29, 34, 39, 40, 43, 49, 50, 53, 54)	11	3.05 (61.05)	○	3.63 (72.63)	Refuse
Pulmonary disease (25, 26, 28, 31, 34, 38, 43, 49, 50, 53, 54)	12	4.84 (96.84)	✓		Accept
Chronic liver disease (28, 29, 34, 38, 40, 43, 50, 53-55)	11	4.53 (90.53)	✓		Accept
Chronic kidney disease (28, 29, 34, 38-40, 42, 43, 50, 53-55)	12	3.79 (75.8)	✓		Accept
HIV / immunodeficiency (26, 39, 43, 50, 53)	5	3.84 (76.84)	✓		Accept
Virus - bacterial coinfection (26, 36, 50, 51)	4	3.84 (76.84)	✓		Accept
None (28, 39)	2	3.79 (75.8)	✓		Accept
Treatment & supportive					
Mechanical ventilation					
Non-invasive (NMV) (4, 26, 30, 34, 36, 38, 40-42, 48, 51-53)	13	4.11 (82.10)	✓		Accept
Invasive (IMV) (4, 26, 30, 34, 36, 38, 40, 41, 44, 48, 51-53)	13	4.21 (84.21)	✓		Accept
Extracorporeal Membrane (ECMO) (4, 26, 30, 34, 38, 40, 51, 52)	8	4 (80)	✓		Accept
Both ECMO and IMV (30, 42, 51)	3	3.84 (76.84)	✓		Accept
Prescription					
Antibiotic (4, 26, 34, 36, 38, 40, 41, 44, 48, 49, 52, 53)	12	3.79 (75.8)	✓		Accept
Antifungal (4, 26, 34, 36, 42, 44, 48, 49, 52, 53)	10	1.84 (36.84)	×		Refuse
Antiviral (4, 26, 34, 40, 42, 44, 48, 49, 51-53)	11	4.21 (84.21)	✓		Accept
Glucocorticoids (4, 26, 34, 36, 38, 44, 49, 51)	8	3.79 (75.8)	✓		Accept
Immunoglobulin (4, 26, 34, 38, 44, 49, 52)	7	4.26 (85.2)	✓		Accept

Finally, 149 primary data elements were included in the Delphi survey, of which 112 data elements were finalized in the first round and 15 were rejected. A total of 22 data elements progressed to the second round of the Delphi survey. Of them, 9 were approved in round 2. Thus, on completion of the survey, 125 data elements were approved. Accordingly, the final data elements for epidemiological, clinical, and paraclinical categories were 22, 57,

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		First round		Second round	
Data classes / items	Frequency	Mean (percentage)	Initial decision	Mean (percentage)	Final decision
B. Clinical data					
Physical examination					
Body temperature (25, 26, 29, 32, 34, 36, 42, 45, 51-53)	10	4.11 (82.11)	✓		Accept
Respiratory rate (per minute) (32, 34, 36, 51)	4	3.95 (78.95)	✓		Accept
Heart rate (beats/ per minute) (32, 34, 36, 51)	4	3.84 (76.84)	✓		Accept
Body Mass Index (BMI) (36, 51)	2	2.42 (48.42)	×		Refuse
Systolic blood pressure [mmHg] (32, 34, 36, 51)	4	3.95 (78.95)	✓		Accept
Lung auscultation (sounds) (34, 36, 51)	3	2.47 (49.47)	×		Refuse
Disease Complication					
ARDS (31, 34, 36, 38, 39, 41, 43, 49, 51-53, 55)	12	4 (80)	✓		Accept
Acute heart injury (31, 34, 36, 38, 41, 43, 49, 51, 52)	9	4.26 (85.2)	✓		Accept
Liver abnormality (34, 36, 38, 39, 43, 49, 51, 52)	8	3.42 (68.42)	○	4.05 (81.05)	Accept
Acute kidney injury (31, 36, 38, 41, 43, 49, 51-53, 55)	10	4.05 (81.05)	✓		Accept
Secondary infection (31, 34, 36, 38, 43, 51, 52)	7	3.89 (77.89)	✓		Accept
Shock (31, 34, 36, 38, 41, 43, 49, 51-53, 55)	11	4.32 (86.31)	✓		Accept
Other (31, 34, 36, 38, 43, 51, 52)	7	3.89 (77.89)	✓		Accept
Disease severity					
Mild (27, 28, 30, 32, 47, 49, 50, 53)	8	3.79 (75.8)	✓		Accept
Moderate (27, 28, 30, 32, 47, 49, 50, 53)	8	3.95 (78.95)	✓		Accept
Severe (27, 28, 30, 32, 47, 49, 50, 53)	8	4 (80)	✓		Accept
Critical (27, 28, 30, 32, 47, 49, 50, 53)	8	3.84 (76.84)	✓		Accept
Disease status					
Active (32, 36, 45, 46)	4	3.89 (77.89)	✓		Accept
In active(32, 36, 45, 46)	4	4.05 (81.05)	✓		Accept
Recovered (32, 36, 45, 46)	4	4 (80)	✓		Accept
Outcome					
Remained in hospital (4, 31, 34, 36, 38, 41, 47, 51, 53)	10	3.79 (75.8)	✓		Accept
Healed / discharged (4, 31, 34, 36, 38, 41, 47, 51, 53)	9	3.84 (76.84)	✓		Accept
Referred (32, 39, 46, 52, 55)	5	3.12 (62.40)	○	3.63(72.63)	Refuse
Critical condition / ICU (4, 31, 34, 36, 38, 41, 47, 51, 53)	9	4 (80)	✓		Accept
Death (4, 31, 34, 36, 38, 47, 51, 53, 55)	9	3.89 (77.89)	✓		Accept
Partial recovery / follow up (32, 37, 39, 42, 46, 49, 52, 55)	8	2.22 (44.40)	×		Refuse
Time interval					
Exposure to symptom onset (3, 35-37, 39, 42)	6	4.05 (81.05)	✓		Accept
Illness to start treatment (3, 35, 37, 39, 42)	5	4.19 (83.80)	✓		Accept
Median incubation period (29, 46, 48, 49)	4	3.79 (75.8)	✓		Accept
Hospitalization date (37, 42)	2	2.37 (47.36)	×		Refuse
Diagnosis date (36, 37, 39, 42)	4	4.21 (84.21)	✓		Accept
Hospital day (36, 51)	2	2.31 (46.31)	×		Refuse
Discharge date (3, 37, 42)	3	3.95 (78.95)	✓		Accept

and 46, respectively.

Discussion

This study reports the basic required data items originally derived from studying the COVID-19 patients' medical records, existing official data sets, and through conducting a systematic literature review, and Delphi survey. The aim of this study was to identify a set of parameters believed to be essential and sufficient to assist the uniform reporting of data on COVID-19. Through the designed COVID-19 MBDS, it is possible to meet some of the data requirements regarding care practice, leading to reliable framework on which health care experts can base their documentation. These elements give both the clinicians and researchers high-quality data to support diagnosis and analysis, respectively. The resulting MBDS is therefore more likely to be acceptable and practical in clinical practice and biomedical research. It has also the potential to homogenize data capturing among public and medical information systems, so that clinical data on COVID-19 can be merged and compared. In addition, data exchange and interoperability can be enhanced using a proper and reliable data set (60). Development of a required data set is the most fundamental step for construction of any information system in the health care sector. Determining these data elements based on viewpoints and real requirements of their customers or users can help designers and vendors of information systems to facilitate and accelerate the development of such systems and reduce the possibility of their failure (61). Thus, the MBDS established in this study can be used as a basis for developing different information systems for collection and management of COVID-19 data.

In the context of COVID-19, huge volumes of data are

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Literature review results		Specialists perspectives ✓ : Accepted in first round × : Rejected in first round ○: Refer to second round			
Data classes / items	Frequency	First round Mean (percentage)	Initial decision	Second round Mean (percentage)	Final decision
C. Paraclinical Data					
Laboratory indicators					
Blood routine tests					
T lymphocyte count ×109/L ↑↓ (26, 30, 32, 34, 35, 38, 39, 42, 43, 48, 49, 56)	12	4.26 (85.26)	✓		Accept
Platelet count ×109/L ↑↓(26, 30, 32, 34, 35, 37-39, 42, 43, 48, 49, 56)	13	3.26 (65.26)	○	3.79 (75.8)	Accept
Hemoglobin level (g/L) ↑↓(26, 30, 32, 34, 38, 39, 42, 43, 48, 49, 56)	11	4.21 (84.21)	✓		Accept
D-dimer (ug/ml) ↑↓(26, 29, 30, 32, 34, 39, 49, 56)	9	4.16 (83.16)	✓		Accept
Prothrombin times, s ↑↓ (29, 30, 34, 42, 43, 49)	7	3.37 (67.37)	○	3.32 (66.31)	Refuse
Blood chemistry					
ALT (U/L) ↑↓ (26, 29, 30, 32, 37, 39, 42, 43, 48, 49, 56)	11	4.31 (85.31)	✓		Accept
AST (U/L) ↑↓ (26, 29, 30, 32, 37, 39, 42, 43, 48, 49, 56)	12	4.42 (88.42)	✓		Accept
Blood Urea Nitrogen (mmol/L) ↑↓(26, 37, 42, 43, 48, 56)	6	4.26 (85.2)	✓		Accept
Serum creatinine (umol/L) ↑↓ (34, 39, 42, 43, 48)	5	3.84 (76.84)	✓		Accept
Lactate dehydrogenase (U/L) ↑↓(26, 29, 30, 32, 34, 39, 42, 49, 56)	3	3.63 (72.63)	○	4.26 (85.26)	Accept
Albumin (g/L) ↑↓(32, 34, 42, 49, 56)	5	3.59 (71.58)	○	3.70 (74)	Refuse
Globulin (g/L) ↑↓(32, 34, 42, 49, 56)	5	3.42 (68.42)	○	3.03 (60.6)	Refuse
Total bilirubin(umol/L) ↑↓ (26, 29, 30, 32, 34, 39, 42, 49, 56)	9	3.53 (70.53)	○	3.68 (73.68)	Refuse
Direct bilirubin(umol/L) ↑↓(4, 31, 50)	3	2.42 (48.42)	×		Refuse
Infection-related biomarkers					
C-reactive protein (mg/L) ↑↓(26, 30, 32, 37, 42, 43, 48, 49, 56)	9	3.95 (78.95)	✓		Accept
Procalcitonin (ng/ml)↑↓(26, 29, 30, 32, 34, 39, 42, 43, 48, 49, 56)	11	2.95 (58.95)	○	3.11 (62.11)	Refuse
Interleukin 6 (pg/ml) ↑↓ (32, 34, 38, 39, 42, 43, 56)	8	4.63 (92.63)	✓		Accept
RT-PCR (3, 4, 26, 28-30, 32, 33, 35-38, 40-42, 44-46, 48, 49, 51-54, 57-59)	28	4.47 (89.47)	✓		Accept
Radiology information					
Radiology procedure					
Chest X-ray (41, 49, 50)	3	2.63 (52.63)	○	2.75 (55)	Refuse
CT scan (2-4, 25, 31, 32, 40-43, 52, 58, 59)	12	4.05 (81.05)	✓		Accept
Lung ultrasound (41, 50)	2	3.52 (70.53)	○	3.84 (76.84)	Accept
Pattern of the lesion					
Ground glass opacity (2-4, 25, 29-32, 40-43, 45, 48, 49, 52, 58, 59)	17	4.47 (89.47)	✓		Accept
Consolidation (2-4, 25, 32, 41-43, 45, 48, 49, 52, 58, 59)	14	4.42 (88.42)	✓		Accept
Both (2, 25, 42, 45, 49, 58)	6	3.95 (78.95)	✓		Accept
Patchy shadow (3, 41, 42, 52, 58, 59)	6	3.84 (76.84)	✓		Accept
Lymphadenopathy (3, 32, 41, 42, 45, 49, 58, 59)	8	3.90 (77.9)	✓		Accept
Pleural effusion (32, 41, 42, 45, 49, 58, 59)	7	4.15 (83.15)	✓		Accept
Crazy paving (32, 41, 42, 45, 49, 58, 59)	7	3.95 (78.95)	✓		Accept
Bronchiectasis (3, 32, 42, 45, 52, 58, 59)	7	4.16 (83.15)	✓		Accept
Interlobular septal thickening (3, 41, 42, 45, 52, 58, 59)	7	4.05 (81.05)	✓		Accept
Reticulation (3, 41, 42, 52, 58, 59)	6	3.68 (73.68)	○	3.89 (77.9)	Accept
Other (3, 41, 52, 58)	5	3.78 (75.79)	✓		
Lesion distribution					Accept
Unilateral (4, 25, 26, 29, 31, 32, 38, 42, 43, 45, 48, 52, 58, 59)	14	4.42 (88.42)	✓		Accept
Bilateral (4, 25, 26, 29, 31, 32, 38, 42, 43, 45, 48, 52, 58, 59)	14	4.42 (88.42)	✓		Accept
Lesion morphology					
Patchy / nodular (25, 32, 45, 47, 48, 52, 58, 59)	8	4.42 (88.42)	✓		Accept
Spherical (25, 32, 45, 47, 48, 52, 58, 59)	8	3.89 (77.9)	✓		Accept
Both (25, 32, 45, 58, 59)	5	4.10 (82.10)	✓		Accept
No lesion (32, 45, 47, 52, 58, 59)	6	3.68 (73.69)	○	3.95 (78.95)	Accept

generated every day in clinical and public health domains. In such big data area, what can be collected is not an issue; rather attention should be paid to the depth and statistical power of collected data to confirm or disprove a hypothesis, and answer specific questions (62, 63). The anticipated hypothesis and questions to be addressed by a health information system or clinical registry should determine the data items that are preferred, and resource accessibility should inform the scope of the data collected to respond to the expected queries. Part of the problem can be due to lack of comparable data derived from limited sharing, unstructured reporting, and lack of standardized data capture strategies (64, 65). To resolve this, new advances in data collection instruments improve the fundability, accessibility, interoperability and reusability (FAIR) of data, highlighting the need for uniform data that can be integrated from different fragmented resources (66-69). In this regard, the anticipated benefits of the COVID-19 MBDS for investigators can include accelerating study initiation, facilitating data exchange and accumulation, and good data management to reach FAIR data. The COVID-19 MBDS aims to facilitate FAIR data collection

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Table 3. Ctd

Literature review results		Specialists perspectives ✓ : Accepted in first round × : Rejected in first round ○: Refer to second round			
		First round		Second round	
Data classes / items	Frequency	Mean (percentage)	Initial decision	Mean (percentage)	Final decision
C. Paraclinical Data					
Lesion staging					
Early (30, 32, 45, 52)	4	3.84 (76.84)	✓		Accept
Progressing (30, 32, 45, 52)	4	4.11 (82.10)	✓		Accept
Severe (30, 32, 45, 52)	4	3.89 (77.9)	✓		Accept
Lesion location					
Peripheral (2, 25, 32, 41, 45, 58, 59)	7	3.84 (76.84)	✓		Accept
Central (2, 25, 32, 41, 45, 58)	6	3.79 (75.8)	✓		Accept
Both (2, 25, 32, 58, 59)	5	4 (80)	✓		Accept
Random / diffuse (2, 32, 45, 58)	4	3.79 (75.8)	✓		Accept
Involved lobe					
Right upper lobe (2, 25, 32, 42, 45, 58, 59)	7	4.32 (86.31)	✓		Accept
Right middle lobe (2, 25, 32, 42, 45, 58, 59)	7	4.05 (81.05)	✓		Accept
Right lower lobe (2, 25, 32, 42, 45, 58, 59)	7	4.05 (81.05)	✓		Accept
Left upper lobe (2, 25, 32, 42, 45, 58, 59)	7	3.95 (79)	✓		Accept
Left lower lobe (2, 25, 32, 42, 45, 58, 59)	7	4.21 (84.21)	✓		Accept
Peripheral/central (2, 25, 32, 41, 42, 45, 58, 59)	8	3.89 (77.9)	✓		Accept

from COVID-19 individuals with the context of care, evaluation, and research to improve the comparability of data, interdisciplinary communication, and collaboration within the field of COVID-19.

For developing this MBDS, we performed an extensive literature review to identify COVID-19 variables from an evidence-based perspective in a multiresearch study. Then, a 2-round Delphi methodology narrowed down opinions until consensus was reached, during which parameters that may have importance for some applications were excluded from consideration.

This study reported the development of the first MDS-COVID-19 based on state-of-the-art evidence as well as consultation with future users (experts and clinicians). This method could contribute to establishing a balance between scientific theoretical knowledge and technical knowledge as well as applied wisdom from clinical practice to inform the data set. The resulting MBDS is therefore more possible to be satisfactory and practical in clinical practice. We identified the variables required to analyze fundamental aspects, such as transmission patterns, severity, clinical phenotype, prognostic factors, the effectiveness of therapeutic plans and complications, survival estimation, as well as incidence and prevalence of disease across the country.

The literature review only incorporated the search published in the first 4 months of COVID-19 disease during the review period. A more systematic review may have identified additional relevant studies. However, given that the literature review is aimed to identify potential items for inclusion in the MBDS (rather than identifying every paper that considered COVID-19 parameters), and we drew on the collective wisdom of experts in the COVID-19 field throughout the consensus process, it seems unlikely that any important aspects of COVID-19 would have remained overlooked.

Conclusion

To conclude, the developed MBDS used structured agreement methods that integrated a literature review and expert opinion to consolidate COVID-19 documentation, research, and practice. Data collection in line with the configuration presented in this MBDS contributes to unified reporting, probably leading to improved quality of patient documentation, augmented continuity of care, and improved health outcomes regarding COVID-19. COVID-19 MBDS is not proposed to be inclusive; it is what the consulted professionals arbitrated to be a manageable, minimal, and essential set that would ideally be provided in all COVID-19-related research studies. This core set can be augmented in each particular project according to the project's purpose and available resources. Future testing in other health care settings is recommended. In the future, further strategies, including a comprehensive search of the literature, should be considered to enhance this MBDS.

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Conflict of Interests

The authors declare that they have no competing interests.

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