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Common data elements and features of brucellosis health information management system

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ABSTRACT

Introduction: A key step in constructing any health information management system (HIMS) is to decide on a set of minimal yet comprehensive data items. The consensus dataset would be homogenous between healthcare settings and can pave the way for scientific collaborations. Iran is the fourth endemic country for brucellosis in the world. Despite its huge burden on society, the economy, and the environment, there is no agreed-upon minimum data set (MDS) for reporting this disease, and the data collected are rarely homogenous or directly comparable.

Objective: To establish the brucellosis MDS that may enable homogeneity in data collection, data reporting, and data exchange among various HIMSs.

Methods: A two-step process, including an extensive literature search and a two-round Delphi survey, was performed to foster consensus about the required data items. The collected data were analyzed using SPSS V22 (SPSS Inc., Chicago, IL).

Results: The final MDS platform of our study contained 134 items divided into five main categories of administrative information, epidemiology, diagnosis investigation, complications, and signs and symptoms.

Conclusion: This study provided a practical MDS for brucellosis that can help collect unified and comprehensive data for electronic health record systems (EHRs), disease surveillance, and registries, and easily integrate them with other HIMSs. The developed MDS can promote the collaboration of policy-makers, healthcare providers, and researchers to prevent, control, and manage brucellosis.

1. Introduction

Brucellosis is a significant zoonotic infectious disease, which is considered a major concern for public health and global trade. It originated from the facultative intracellular pathogens of the genus Brucella named in honor of the physician David Bruce [1–3]. According to the World Health Organization (WHO), more than 500,000 new cases of brucellosis are annually reported worldwide [4]. The occurrence of recurrent brucellosis also has risen [5]. Apart from being a physical disability, it poses a huge burden on the economy, mainly in areas where the economy relies on livestock [6]. While the total prevalence of brucellosis has been decreasing in the last decade, it is still endemic in some developing countries including Iran [5]. Iran is the fourth endemic country of brucellosis, and this poses a serious public health problem in this country [7].

Timely and responsive public health surveillance for zoonotic diseases such as brucellosis heavily depends on integrated interventions from public health settings, hospitals, and animal-related organizations. These interventions necessitate a consistent, reliable, and interoperable dataset across involved organizations [8,9]. The absence of an effective health information management system (HMIS) hinders precise assessment of the actual frequency rate and distribution of brucellosis and delays control efforts [10,11]. Accordingly, the enhancement of data management strategies to improve the measurement of the real disease burden and affect the results of interventions has garnered global attention [12].

Iran's Ministry of Health and Medical Education (MOHME) has decided to implement the Iranian electronic health record (EHR) project

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(known as the SEPAS, abbreviated in Persian). A barrier to the extensive adoption of SEPAS is the difficulty related to recording structured information from clinicians who desire to document via free-text clinical notes [13,14]. The SEPAS system is fed by clinical data and reports from broadly dispersed public health and hospital-based systems including hospital information systems (HISs), the Iranian integrated health system (known as the SIB project, abbreviated in Persian), and other related clinical subsystems as the data input. However, the health information systems in Iran are fragmented across different platforms, and integration and interoperability between them are still challenging [15–18].

Brucellosis, which represents a public health threat, highlighted the need for a streamlined and consistent data reporting tool, also known as a minimum dataset (MDS), adherence to EHR data standards, and integration of data from clinical and laboratory sources [19]. The MDS is a structured reporting framework in which healthcare experts themselves decide on which data elements and criteria are appropriate for being documented according to their competence and knowledge within the specific domain to aggregate the use of data [20]. The establishment of an MDS is a key step in developing an information system [21]. As stated by Kowal et al., MDS is a harmonious set of data elements used for uniform collection and report [22]. Determining the MDS is a principal and effective step in designing an information system that directly determines its failure or success [23]. Many studies have stressed the importance of MDS for implementing national information systems and supporting data exchange across health information sectors [24,25].

Several studies have been conducted to standardize the reporting and data exchange of infectious diseases [12,26–30]; however, as there was no established MDS for brucellosis within the healthcare system, the current study aimed to develop one. Brucellosis MDS can guide clinicians in structured reporting, improve patients' outcomes, and facilitate further communication between healthcare organizations across the country. It can also enable homogeneity of both data and their meaning between various information sources.

2. Methods

2.1. Study design

The study was applied research conducted in 2021. A step-wise refinement method, including two steps, was carried out. First, a literature review was performed to draft the preliminary dataset. Second, the data included from the prior stage were analyzed using a two-round Delphi method with content validation by an expert panel.

1) Literature review

We conducted a literature review to identify the potential data elements in brucellosis studies, reporting systems, and patient medical records. To this end, first, a wide literature review was carried out in scientific databases such as the Web of Science, PubMed, ProQuest, Scopus, Magiran, and SID to identify the data elements with the potential to be included in the finalized brucellosis MDS. The review was conducted by using advanced search strategies and refining the results. Studies were reviewed by keywords including ["Core data element" OR "Core data set" OR "Minimal basic data set" OR "Minimum data set" OR "Minimum data element"] AND ["Zoonotic diseases" OR "Brucellosis disease"] AND ["Information system" OR "Registry system", OR "Surveillance system"]. The inclusion criteria were full-text journal articles, conference papers, scientific reports, forms, and theses in Persian and English, with the publication date ranging from 2000 to 2021. Any study that investigated risk factors, diagnosing, prevention, treatment, follow-up, or any other aspect of brucellosis was included. Data elements were extracted from the retrieved resources and entered into a checklist with two administrative and clinical sections. In the second step, the medical records of brucellosis patients at Ayatollah Talleghani Hospital affiliated with Abadan University of Medical Sciences (Iran) were assessed, and relevant data were entered into the checklist. The sources were continuously reviewed in this step until data saturation was achieved and no new data element emerged from the sources.

2) Delphi phase

The initial data elements were validated by a two-round Delphi method as follows. Delphi is a well-known technique for establishing an expert agreement in a specific domain [31]. The Delphi method is an iterative process whereby expert belief is transformed into an agreement among experts [32,33]. Specialists are requested to fill out questionnaires in several rounds. These questionnaires are completed anonymously, and the collective results are shared with participants in subsequent rounds [34,35].

2.2. Participants

Participants for the determination of brucellosis MDS were experts in infectious diseases, epidemiology, public health, and clinical laboratory selected using purposive sampling. The selection criteria for the participants were having at least two years of work experience as faculty members at universities of medical sciences (in Khuzestan Province) with research interest in topics related to infectious diseases, Table 1 shows the demographic characteristics of the experts.

Table 1: Demographic characteristics of the experts.

2.3. Ethical considerations

The director of the research facility of the university approved the research protocol (ethics ID: IR.ABADANUMS.REC.1400.119). All participants were required to sign a privacy agreement and study participation consent form before joining the expert panel. We assured the participants that their participation in this research was entirely voluntary.

2.4. Questionnaire development

The initial literature review provided a working basis for developing a questionnaire to elicit the expert panel's individual opinions about the essential data elements of brucellosis MDS. The importance of each data element for the final MDS was judged by a two-round Delphi survey. The experts who participated in the survey were requested to assign a

Table 1
Demographic characteristics of Delphi participants.

Variables	Frequency	percentage
Gender		
female	14	41.18
male	20	58.82
Total	34	100
Field		
Physician specializing in infectious diseases(attend)	3	8.81
Infectious Diseases Specialist	7	20.59
Clinical laboratory expert	5	14.71
Epidemiology expert	6	17.65
Infectious disease staff in universities	6	17.65
Other specialists	7	20.59
Total	34	100
Work experience in clinical field (years)		
<10	7	20.59
10–15	8	23.53
15–20	7	20.59
20–25	8	23.53
>25	4	11.76
Total	34	100
mean SD		
Age	36.4	± 6.4
Work experience in clinical field (years)	15.66	± 4.5

priority value to each data element to be included in the brucellosis MDS using a five-point Likert scale. Based on this scale, a score of 1 represented the "lowest level of importance" and a score of 5 represented the "highest level of importance". The scores of every participant were anonymous throughout the survey. Finally, the participants were asked to propose new items that were not listed in the initial dataset for subsequent prioritization. The content validity of the questionnaire was assessed by an expert panel, including two health information management and three infectious diseases experts. Furthermore, a test-retest was made to evaluate the reliability of the questionnaire. The questionnaire designed in our study is consistent with previously developed questionnaires for brucellosis surveillance and registry systems in China [36], France [37], and Iran [10]. The proposed questionnaire contained five sections, including demographic, clinical (disease and diagnosis, signs and symptoms), laboratory and evaluation, and disease complications. The questionnaire initially had 380 items in Delphi; for each question, five columns of "quite unimportant", "unimportant", "of medium importance", "highly important" and "very highly important" with a score of 1–5, respectively, were considered. At the end of each section, a blank row was provided to let the experts add necessary data elements.

2.5. Delphi survey rounds

After initial ranking, based on an item's importance, items with <60% agreement (average score of 3 out of 5) were deleted; those with >75% agreement were excluded from the second round, and those with a 60–75% agreement were surveyed in the second round. The checklists were individually presented to the experts who were blind to the scores of other experts, and if there was a 75% consensus over a data element, it was included in the final MDS.

2.6. Statistical analysis

The data were analyzed using the Statistical Package for Social Sciences software, version 25 (SPSS V25 Chicago, USA). SPSS was used to summarize respondents' characteristics and demographic details. The mean was calculated for each item outcome. To rank the scores, the mean for each item outcome was calculated. Statistical significance was set to $p < 0.05$.

3. Results

In the present study, after performing a literature review, data elements required for reporting brucellosis were identified. The initial review in the selected database yielded 188 studies. A total of 122 studies remained after removing the duplicates. Of them, 18 articles [10,11, 38–53] were finalized and identified as eligible studies after applying inclusion criteria, including written in English and Persian, publication date between 2000 and 2021, and document type criteria. Finally, the full text of the articles was studied, and a primary data list was extracted. The criteria for selecting the studies was to refer to the elements of brucellosis reporting data in the context of information systems such as registry and surveillance systems.

After searching scientific databases and studying patients' medical records, we extracted a set of data elements and validated it via a two-round Delphi survey for inclusion in the final MDS of brucellosis. In the first stage of the survey, the extracted elements were measured and the experts' response rate to the survey was 100%. All the questions (100%) were answered. The number of participants in the Delphi stage was 34 individuals, of whom 41.18% were female and 79.41% had more than 10 years of working experience. The mean age of the participants and the mean years of work experience in clinical settings were 36.4 (±6.4 SD) and 15.66 (±4.5 SD), respectively (See Table 1).

In this stage, all factors related to brucellosis were extracted and a pool of data was formed. After preparing the initial pool of data, similar data items were removed. A 380-items questionnaire was sent to the participants. In the first Delphi round, decisions were made about 380 items of the questionnaire. In this round, 152 items were removed, while 100 items entered the second phase of Delphi. In the second Delphi round, 94 items were removed and six items were accepted. Finally, from the 380 items, 246 items were removed. In the Delphi phase, the Wilcoxon test with Bonferroni correction was conducted to reduce type I error and ensure the accuracy of the answers (Table 3). Finally, 134 items were deemed important for inclusion in the brucellosis MDS, grouped as follows:

1) Administrative data: This category includes 14 data elements such as the patient's name, identifier number, sex, religion, and additional demographic data (Table 2).

   Table 2: Administrate data elements.

2) Epidemiology: This category includes seven data elements to identify factors affecting brucellosis. These elements are related to the process of contracting the disease, progression of the disease in humans, disease outbreak, and intensification of symptoms. Data elements are effective on the incidence and outbreak of brucellosis directly and indirectly. We determined that the main epidemiology subclass is the pathogenicity of *Brucella* species, modes of transmission, sources of infection, classification of brucellosis, history, risk factor, incubation period, and the onset of symptoms (Table 3).

   Table 3: Epidemiological data elements.

Table 2
Administrate class.

Data items	Content definition		Field format
Patient name			string
Identification number			integer
Gender	Male, Female	(Male: 1, Female: 0)	binary
Age			integer
Birth date			date
Marital status	Married		categorical
	Single		
	Divorced		
	Widow		
	Other, unspecified		
Occupation/Job	Laboratory worker		categorical
	Abattoir workers		
	Animal husbandry		
	Slaughterhouses		
	Veterinarians and Animal Caretakers		
	Farmers		
	agricultural engineers		
	animal dealers		
	cattle ranchers		
	Shepherds		
	Dog owners and handlers		
	Dairy workers		
	Other Occupations		
Admission date			Date
Region	Country		string
	Provence		
	City		
	Urban		
	Rural		
Education level	Illiterate		categorical
	Elementary		
	High school		
	University		
Home address			string
Healthcare setting name			string
blood group type	A+, A-		categorical
	B+, B-		
	O+, O-		
	B+, B-		
	AB+, AB-		
Rh type	Rh+, Rh-	(Rh+:0, Rh-: 1)	Binary

Table 3
Epidemiology class.

Data items	Content definition		Field format
Pathogenicity of Brucella Species	Brucella melitensis		Categorical
	B. suis		
	B. abortus		
	B. canis		
Incubation Period			integer
Modes of transmission	Oral Route	Drug	Categorical
		Consumption ingestion of milk and its products	
		Consume uncooked animal products	
	Cutaneous Route		
	Respiratory Route		
	Conjunctival Route		
	Auto-inoculation		
	Bone Marrow Transplant		
	Blood Transfusion		
	Sharing needles among drug addicts		
	Trans-placental transmission		
	Sexual transmission		
	Transmission Via Breast Milk		
	Vaginal discharges		
	Urine		
Source of infection	Food Animals		Categorical
	Dogs		
	Vaccines		
Classification of Brucellosis	Old	Old:1, New: 0	Binary
	New		
Duration of illness	acute		Category
	sub-acute		
	chronic		
History and Risk factor	Animal contact	Direct	Category
		In direct	
	Family history of brucellosis		
	HIV		
	Immune system defects		
	Drug using	Anti-acid drugs	
		Drugs that suppress the immune system	
	Region endemic	Dwell region endemic	
		Transfer to region endemic	
	Season	Spring	
		winter	
		summer	
		autumn	
	Intrauterine Transmission		
	Breast milk		
	Processing milk		
	climate condition		
	hygienic environment		
	economic and social conditions		
	Hepatitis		
	Diabetes mellitus		
	Splenectomy		
	Livestock		

3) Brucellosis signs and symptoms: This category includes 35 data elements of common clinical features. It comprises the common signs and symptoms of brucellosis, but the signs and symptoms of this disease can vary depending on the organ involved, which we have discussed further in the discussion of complications. In this study, all common signs and symptoms of brucellosis were placed in this category (Table 4).

Table 4: Signs and symptoms data elements.

Table 4
Signs and symptoms class.

Data item	Content definition		Field format
Symptoms	Fever	(1: yes, 0: no)	Binary
	Headaches	(1: yes, 0: no)	
	Chills	(1: yes, 0: no)	
	Anorexia	(1: yes, 0: no)	
	Weakness	(1: yes, 0: no)	
	Sweating	(1: yes, 0: no)	
	Cough	(1: yes, 0: no)	
	Joint pain	(1: yes, 0: no)	
	Nausea and vomiting	(1: yes, 0: no)	
	Abdominal pain	(1: yes, 0: no)	
	Weight loss	(1: yes, 0: no)	
	Malaise	(1: yes, 0: no)	
	Sore throat	(1: yes, 0: no)	
	Back pain	(1: yes, 0: no)	
	Myalgia	(1: yes, 0: no)	
	Constipation	(1: yes, 0: no)	
	Joint and back pain	(1: yes, 0: no)	
	Spinal tenderness	(1: yes, 0: no)	
	Diarrhea	(1: yes, 0: no)	
Signs	Lymphadenopathy	(1: yes, 0: no)	
	Hepatomegaly	(1: yes, 0: no)	
	Splenomegaly	(1: yes, 0: no)	
	Arthritis	(1: yes, 0: no)	
	Pneumonia	(1: yes, 0: no)	
	Conjunctivitis	(1: yes, 0: no)	
	Skin rash	(1: yes, 0: no)	
	Positive blood culture	(1: yes, 0: no)	
	Cardiac murmur	(1: yes, 0: no)	
	Central nervous system	(1: yes, 0: no)	
	abnormalities	(1: yes, 0: no)	
	Jaundice	(1: yes, 0: no)	
	Testicular pain/epididymo-orchitis		
	Rash	(1: yes, 0: no)	
	Sleep disturbances III appearance	(1: yes, 0: no)	
	Pallor	(1: yes, 0: no)	

4) Diagnostic test: This category includes 26 data elements and comprises diagnostic tests that play a key role in the diagnosis of brucellosis and the impact of this disease on the involved organs. We determined that the main subclass categories are laboratory investigations and imaging investigations (Table 5).
5) Complications; This category includes 52 data elements, comprising all the complications due to brucellosis that can involve organs (Table 5).

Table 3: Diagnostic tests and complications data elements.

4. Discussion

In this study, to adhere to data quality criteria in EHR, the basic data elements were determined for reporting brucellosis. An extensive search along with a two-round Delphi survey was performed to determine which data elements should be included or omitted and how the data elements should be classified. The brucellosis MDS was designed in the form of two main categories of administrative and clinical information with five main data classes and 134 data elements. Due to the inclusion of various non-clinical, clinical, environmental, and epidemiological data elements in the current MDS, it has extensive application in the management of brucellosis at macro and interdisciplinary levels. The MDS developed in our study can homogenize data collection in diverse healthcare organizations, and improve data quality, brucellosis data preparation, and investigation. Another benefit of the brucellosis MDS is that it collects essential data in a standard format and allows them to be directly collected from SEPAS, thereby significantly preventing human involvement.

This study is the first of its kind that directly highlights the importance of a brucellosis data collection tool. Kazerooni et al. (2018) concluded that developing a standard, integrated, and scientific MDS is a

Table 5
Diagnosis tests and complications class.

Data items	Content definition		Field format
Laboratory Investigations	(CBC and CBC diff) PLT, RBC, WBC, HB, HCT, MCV, MCH, MCHC, RDW, MPV, PDW, Absolute neutrophil count, Absolute lymphocyte count, Absolute monocyte count, Absolute eosinophil count, Absolute basophil count	(0: normal, 1: abnormal (1–0: rise, 1-1: decrease)	Category
	Erythrocyte sedimentation rate (ESR)	(0: normal, 1: rise)	Binary
	Blood biochemical tests	(0: normal, 1: abnormal (1–0: rise, 1-1: decrease)	Category
	Serological tests a) standard tube agglutinins (STA)	(0: negative, 1: positive)	Binary
	b) Agglutination Tests (0: positive, 1: negative)	(0: negative, 1: positive)	
	c) Micro agglutination Tests	(0: resistant, 1: sensitivity (	
	d) Complement Fixation Test	(0: normal, 1: rise)	
	e) Fluorescent Antibody Test	(0: negative, 1: positive)	
	f) Rose Bengal Test	(0: negative, 1: positive)	
	g) Skin Test Antigens	(0: negative, 1: positive)	
	h) the 2-mercoptoethanol agglutination test (2 ME)	(0: negative, 1: positive)	
	i) Coombs' test	(0: negative, 1: positive)	
	j) ELISA and PCR	(0: negative, 1: positive)	
	k) A high specific IgG titer indicates active disease	(0: negative, 1: positive)	
	l) CRP (0: yes, 1: No)		
	Blood cultures		Free text
	Other body fluid cultures		Free text
	Tissue biopsy cultures		Free text
	Histopathological findings		Free text
	Coagulation tests PT, INR, PTT, Fibrinogen level, Thrombin time, Bleeding time, FDP, FSP.	(0: normal, 1: rise)	Binary
Imaging Investigations	Ultrasonography, Echocardiography, X-ray, Isotope bone scintigraphy, Computed tomography (CT), Magnetic resonance imaging		Free text

Complications class

Data items	Content definition		Field format
Hematological	Anemia	(1: yes, 0: no)	binary
	Leukopenia	(1: yes, 0: no)	
	Thrombocytopenia	(1: yes, 0: no)	
	Pancytopenia	(1: yes, 0: no)	
	'Microangiopathic hemolytic anemia'	(1: yes, 0: no)	
	'Disseminated Intravascular Coagulation (DIC)'	(1: yes, 0: no)	
Osteoarticular	Arthritis	(1: yes, 0: no)	binary
	Spondylitis	(1: yes, 0: no)	
	Paravertebral and psoas abscesses	(1: yes, 0: no)	
	Extraspinal brucellar osteomyelitis	(1: yes, 0: no)	
	Bursitis	(1: yes, 0: no)	
	Tenosynovitis	(1: yes, 0: no)	
	Myalgia and myositis	(1: yes, 0: no)	
	Granulomatous myositis and rhabdomyolysis	(1: yes, 0: no)	
Cardiovascular	Brucellar endocarditis	(1: yes, 0: no)	binary
	Brucellar myocarditis	(1: yes, 0: no)	
	Brucellar pericarditis	(1: yes, 0: no)	
	Brucellar mycotic aneurysms	(1: yes, 0: no)	
	Brucellar thrombophlebitis	(1: yes, 0: no)	
Respiratory	Pleurisy and pleural effusions	(1: yes, 0: no)	
	Pulmonary granulomata lung abscess and miliary shadowing	(1: yes, 0: no)	binary
	Hilar and mediastina lymphadenopathy	(1: yes, 0: no)	

(*continued on next page*)

Table 5 (*continued*)

Complications class			
Data items	Content definition		Field format
	Dry cough	(1: yes, 0: no)	
	Pneumonia	(1: yes, 0: no)	
Gastrointestinal	The liver disorder	(1: yes, 0: no)	binary
	The spleen disorder	(1: yes, 0: no)	
	Brucellar Peritonitis	(1: yes, 0: no)	
	The gallbladder disorder	(1: yes, 0: no)	
	The pancreas disorder	(1: yes, 0: no)	
Genitourinary	Epididymo-orchitis	(1: yes, 0: no)	binary
	The ovary disorder	(1: yes, 0: no)	
	The kidney disorder	(1: yes, 0: no)	
	The prostate disorder	(1: yes, 0: no)	
Endocrinal	The pituitary Gland disorder	(1: yes, 0: no)	binary
	SIADH in brucellosis	(1: yes, 0: no)	
	The testes disorder	(1: yes, 0: no)	
	The placenta disorder	(1: yes, 0: no)	
	The mammary Gland disorder	(1: yes, 0: no)	
	The thyroid Gland disorder	(1: yes, 0: no)	
	The adrenal disorder	(1: yes, 0: no)	
	Hypercalcemia	(1: yes, 0: no)	
Pregnancy	Abortion	(1: yes, 0: no)	binary
Cutaneous and Soft Tissue	Primary: (Macular, Maculopapular, Papulonodular, contact dermatitis, Erythema nodosum-like, Ulcers, Vasculitis and superficial thrombophlebitis Abscesses)	(1: yes, 0: no)	binary
	Secondary: (Purpura, Photosensitivity, Herxheimer reaction (tetracycline), Bursitis, Fistula, Musculoskeletal and renal abscesses, Fasciitis-panniculitis Infected subcutaneous cysts Association with CREST and psoriasis)	(1: yes, 0: no)	
	Papulonodular lesions	(1: yes, 0: no)	
	Subcutaneous nodules	(1: yes, 0: no)	
	Ulcers	(1: yes, 0: no)	
	Cutaneous sinus formations	(1: yes, 0: no)	
Ocular	Pure brucellar ophthalmopathies a) Direct spread via conjunctivitis (occupational): (Conjunctivitis, Keratoconjunctivitis, Corneal abscesses, Cataract, Uveitis, Panophthalmitis, Progression of systemic brucellosis)	(1: yes, 0: no)	binary
	b) Haematogenous spread: (Anterior uveitis (with/without granulomata), Scleritis, Choroiditis, Vitritis, Cystoid macular oedema, Retinal detachment, Panophthalmitis	(1: yes, 0: no)	
	Neuro-ophthalmic brucellosis and others a) Secondary to meningitis or brain abscess (Papilloedema, Optic neuritis) External ophthalmoplegia b) Secondary to thrombocytopenia c) Secondary to brucellar endocarditis	categorical	
others			string

crucial measure to solve the under-reporting and untimely reporting problems of the brucellosis surveillance system in Iran [54]. In another study, Shanbehzadeh et al. (2022) designed a standard and customized reporting template to provide interoperability between zoonotic diseases information systems (ZDISs) in Iran. They developed an MDS in two non-clinical and clinical sections with five and seven data classes and a total of 38 and 57 data elements, respectively [12].

Dong et al. reported that a standard brucellosis reporting template improves data integrity, interoperability, accuracy, and reusability for the patient care process, care quality, and research [55]. Rodríguez et al. also developed a hospitalization minimum data set (CMBD) to standardize the documentation of brucellosis data in two clinical and non-clinical sections and seven data elements, including age, sex, the type of residence, admission type, discharge type, length of stay (LOS), and cause of hospitalization [56]. Moreover, Moradi et al. designed the structure and content of the national brucellosis surveillance system for Iran's electronic health (e-health) system to improve epidemiological studies and clinical research. The designed template consisted of 28 data elements in the form of basic and demographic, geographical and environmental, epidemiological, clinical, and paraclinical classes [11].

Shirzadi et al. also designed a uniform data template to efficiently report the geographical distribution of brucellosis by age, place of residence, living environment, contact with pets, history of pasteurization, contact history of infected people, and disease complications [51]. In another study, Keramat et al. developed a registry system for recording recurrences and complications of brucellosis in demographic, history, contact and risk factors, signs and symptoms, and disease complications classes for Iran [10].

The data collected from one healthcare setting are reliable and valid when they are consistent and comparable with the data collected from others [57]. Inconsistent data items and diverse reporting structures may impede the use of data for patient care and prevent data re-use for many other applications [58]. Furthermore, manual free-text data recording is a time-consuming and error-prone process. In contrast, a structured MDS can provide a fruitful source to collect data features that potentially affect the outcomes and allow for multivariable analysis to determine the primary predictors of interest, particularly when these variables are uniformly defined and collected [59]. The analytical power of any study lies in generalizable and high-quality data. When credible and consistent data collection tools capture the data about a disease's natural progress, researchers can plan their study more reliably and detect eligible participants [60].

We believe that the MDS developed in this study will be an effective tool to collect higher-quality data on brucellosis that may lead to better clinical decision-making. This dataset can guide future experimental operational research on these unexplored areas which will be relevant to decision-making for brucellosis policy-making. It would also allow meaningful comparison of research results and objective assessment of research population representativeness and potential bias. Further, the need for joint analysis of data from diverse and multicenter sources necessitates a certain degree of consistency and integrity in the data collected. Besides, access to efficient, applicable, and feasible data collection approaches may improve evidence-based decision-making, accelerate data sharing, and facilitate benchmarking between organizations.

4.1. Limitations and implications for future studies

Interoperability is a salient feature of any health information system that avoids redundant data entry and decreases the workload on clinicians [61,62]. In this paper, the brucellosis MDS with a list of its possible values was identified as a basic step toward interoperability and data sharing between medical and research-related information systems regarding brucellosis. However, the template designed in the present study can only meet the requirements of interoperability at the initial level (machine-portable data). It is, therefore, suggested that in future studies, the maximum interoperability levels (machine-interpretable data) be met by standardizing the structure and content of the proposed MDS. This requirement becomes even more important since maximum interoperability is the main prerequisite for the effective implementation of public health surveillance and registry systems.

Besides, forthcoming research should address the technical dimensions of data sharing to computerized data pooling in the EHR. For this purpose, widespread network infrastructure such as the internet of things (IoT) with cloud computing involvement can be used for flexible data exchange, without time and space constraints [63].

Further extensions and modifications are essential; thus, conducting an experimental study by including a supplementary Delphi phase to improve the dataset is recommended. Moreover, this data template should be assessed from the standpoints of a greater panel of experts to be adopted nationwide.

The methodological strength of developing this MDS lies in the use of an extensive literature review along with a stepwise Delphi survey involving a multidisciplinary team. In both steps, the respondents were ensured that they should choose only data elements that they perceived as important for both clinical research and care purposes. We performed the Delphi survey to reach an agreement on brucellosis MDS. This method has been proven to be fit for assessing information systems' necessities [64]. Still, one of its limitations is that most opinions are marginalized. Despite the abovementioned limitations, this data collection tool offers a homogenous and approved dataset on brucellosis to accrue patients, so steadily larger cohorts will be obtainable in the future. Furthermore, this dataset can collect generalizable variables from multi-center organizations and lay the basis for conducting an exhaustive analysis based on machine learning (ML) methods about many aspects of brucellosis. Moreover, it is projected to accelerate better scientific partnerships for brucellosis.

5. Conclusion

The brucellosis MDS provides a standardized data collection tool, promotes data comparability across fragmented information systems, and enables combined analyses and meaningful assessments to respond to clinical research questions. Further, access to efficient, applicable, and feasible data collection approaches may improve evidence-based decision-making, accelerate data sharing, and facilitate benchmarking between organizations. An experimental study including a further Delphi step before implementation is advisable to refine some data categories.

Declarations

The design and performance of our study are described and justified in a research protocol. The protocol includes information regarding funding, sponsors (funded), institutional affiliations, potential conflicts of interest, incentives for subjects, and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. This protocol is as follows:

Authors' contributions

M SH (1) and H KA performed a literature review to define the MDS-brucellosis parameters. M SH (1), H KA performed a Delphi survey. H KA development brucellosis -MDS. MSH (1) evaluated the developed system. M SH (1) and H KA contributed to the interpretation of the results. H KA and M SH took the lead in writing the manuscript. M SH (2) revised the manuscript and prepare to submit it. All authors provided critical feedback and helped shape the research, analysis, and manuscript. All authors read and approved the final manuscript.

Conflict of interest declaration and author agreement form

We have no conflict of interest to declare.

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