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Designing the minimum data set of bipolar disorder: A basis for introducing the effective factors in managing, controlling, and monitoring the bipolar disorder

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Abstract:

BACKGROUND AND AIM: Bipolar disorder (BD) is one of the most challenging psychiatric disorders in the management area that can lead to functional, occupational, and cognitive disorders. Without proper care, this complication can lead to profound psychological challenges and even death. The aim of this study is to design a minimum data set (MDS) for BD.

MATERIALS AND METHODS: This descriptive cross-sectional study was conducted in two steps. In the first step, a survey was conducted in PubMed, Web of Science, and SCOPUS databases to identify the demographic, managerial, and clinical data elements. Then, the required data elements were extracted from the studies by the data extraction form and used in a questionnaire. In the second step, to confirm the data element set, the designed questionnaire was distributed and collected among 20 psychiatrists and subspecialists during a two-stage Delphi technique. Descriptive statistics (frequency and mean) were conducted to analyze the data.

RESULTS: Totally, 112 managerial and clinical data elements in 14 categories were extracted from the studies. Based on the experts' opinion and their consensus, 88 necessary data elements were considered to bipolar MDS. "Medication nonadherence," "history of suicide," and "substance abuse and addiction" were the most important data elements.

CONCLUSION: In this study, an MDS was designed for BD. Providing this MDS, in addition to improving the clinical processes, it is possible to help electronic system designers and health data managers to know what information should be included in the health systems or any kind of self-care or self-management software to meet the information needs of these patients.

Keywords:

Bipolar disorder, dataset, delphi technique, minimum data set, psychiatry

Introduction

Bipolar disorder (BD) is one of the most challenging psychiatric disorders because of common comorbid mental and physical illness[1] and is the fourth cause of psychiatric disability according to the World Health Organization.[2] Although this chronic disease has affected approximately 58.9 million people around the world,[3] there are little data and information about its sociological and clinical features.[4] Gathering sufficient and appropriate data and information can lead to the rapid diagnosis of BD, the correct and efficient treatment of patients, and the provision of appropriate care services.[5] The minimum data set (MDS) as a basis for collecting and managing the data and information has great potential to help provide proper care and disease control services.[6] In addition

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to data collection, this standard tool ensures access to precise and accurate health data.[7] It also improves using high-quality data and provides planning, development, monitoring, management, and operations evaluation.[8]

The MDS collects and exchanges information between health centers, facilitates interaction between care providers and decision-making,[9] and provides statistical data and reports at the national level based on care providers and financial goals.[10] Creating and using an MDS to collect standard and integrated data at the national level can be greatly significant;[7] its allows policymakers, programmers, software experts, and health data managers to know what information should be included in the system to collect data while designing the system.[10]

To our knowledge, no MDS for BD has been published, and only guidelines[11,12] and studies have been provided to identify and treat demographic, genetic, and environmental risk factors for the disease and its treatment.[13,14] Rowland and Marwaha[13] examined the epidemiology of BD along with cognitive, genetic, and environmental risk factors. They concluded that the genetic and environmental risk factors for BD are very high. Awareness of these risk factors enables physicians to easily identify patients with BD and better follow-up and treat them. Goodwin *et al*.[11] provided a clinical guideline for the treatment of BD. This guideline includes factors for diagnosing BD, clinical management, and medication use strategies. The guideline also provides advice to help clinicians make clinical decisions.

According to the mentioned advantage in background and since no MDS has been presented for BD so far, the aim of the present study is to design and present an MDS of BD to introduce effective factors in the management, control, and monitoring the BD.

Materials and Methods

Study design and setting

The present study was conducted in the following two steps.

Step 1: Extracting the data elements needed to design and present the minimum data set for bipolar disorder

Search method

First, a literature review was conducted on July 20, 2020, in three databases: PubMed, Web of Science, and SCOPUS to identify important demographic, managerial, and clinical data elements of BD. The "Bipolar Disorder (BD)" keyword was just used to retrieve related articles.

Inclusion and exclusion criteria

Inclusion criteria included publication of the articles in English, access to the full text of the articles, reference to data elements, and clinical parameters for BD. Exclusion criteria included articles focus on other aspects of BD and failure to provide clear information. Furthermore, the book and book chapters the letter to the editor and the conference abstract were excluded.

Classification and selection of the references

A total of 7744 articles were extracted from three databases: PubMed, Web of Science, and SCOPUS. The title, abstract, and keywords of all articles were studied. Then, based on the inclusion and exclusion criteria, 425 articles were included in the study. The full text of the articles were studied, and finally, the essential data elements were extracted to design and provide the MDS required for further management and monitor the BD. In this step, data were collected using data extraction form, which its validity was confirmed by two medical informatics and two psychiatrist experts. The data extraction form consisted of fields such as name of factor or data element, type of BD (I, II, cyclothymic disorder, or other types), purpose of study, and references. It should be noted that after the clinical and managerial data elements were extracted from the studies, two psychiatrists working in Shahid Beheshti Hospital affiliated to Kerman University of Medical Sciences examined them. The data collection process form was designed by the first author and then was approved and validated by two expert psychiatrists.

It should be noted that to extract the necessary data elements, in addition to using retrieved articles from three databases, PubMed, Web of Science, and SCOPUS, we also used the book "Diagnostic and Statistical Manual of Mental Disorders."[15]

Step 2: Final confirmation of the data elements based on psychiatrists' opinion

Study participants and sampling

The research sample included psychiatrists. We invited 28 psychiatrists working in hospitals affiliated to Kerman University of Medical Sciences to participate in the study. Invitations were sent to them via e-mail. Twenty of them accepted our invitation. It should be noted that due to the easy cooperation of these physicians with the researchers of the present study and having a history of treatment of patients with BD, the final confirmation of the data elements was done according to their opinion.

Data collection tool and technique

In this stage, a questionnaire was designed using the data elements identified in the previous step. The designed questionnaire consisted of two parts: (i) the demographic information of psychiatrists (four questions) and (ii) the data elements required to design and provide the MDS of BD (108 questions). These data elements were divided into 14 categories: "demographic items,"

"clinical history," "types of BD," "current episode type," "fuzzy changes in the current episode," "mania period characteristics and criteria," "major depression criteria," "subsidence types at the end of the mania, depression and mixed periods," "depression and mixed periods," "factors affecting disease recurrence," "reasons for high mortality rate," "medications," "nonpharmacological treatments," "laboratory tests," and "brain imaging." To determine these categories, we held three sessions with three psychiatrists at Shahid Beheshti Hospital and the Neuroscience Research Center affiliated to Kerman University of Medical Sciences. Each session lasted 1 h (3 h in total). In the first session, the data elements extracted from the studies were examined and analyzed; then, we asked each of the experts to categorize the data elements separately. In the second session, the experts expressed their views on each other's categories. Before the third session, we asked the experts to think more about the data elements and categories and to examine them more. In the third session, duplicate and unnecessary categories were removed, and a final agreement was reached on 15 categories.

Besides, to identify other data elements that were not mentioned in the questionnaire, an open-ended question was posed for each part of the questionnaire named "other data elements."

Number 1–5 was considered to score each data element.[16] The face and content validity of the questionnaire was confirmed by two medical informatics and psychiatrists experts. Based on the received opinions, some repetitive and unrelated data elements such as drugs cost, insurance type, type of consultation, dietary orders, origin hospital, destination hospital, and transfer time were excluded from the questionnaire. Furthermore, the reliability of the questionnaire was also carried out by test–retest methods and Spearman's rank correlation coefficient.[7,17] To ensure the reliability of the questionnaire, 20 psychiatrists completed it. Ten days later, we asked them to complete the questionnaire for the second time. The collected data were analyzed by SPSS 23 (IBM Corp., Armonk, NY, USA). Then, the reliability of the questionnaire was confirmed by Spearman's rank correlation coefficient with a value of 0.85. Then, the approved questionnaire was designed electronically.

To conduct the Delphi technique, the questionnaire link was sent to the psychiatrists on August 18, 2020. By August 28, all questionnaires were completed. After collecting the questionnaires, the data were entered in SPSS software version 23, and then, the frequency and mean of each were calculated. To decide on each data element in the first round of Delphi, agreement level was considered.

The data elements with a mean of 50%–75% were included in the second round of Delphi to be re-measured, and the data elements with a mean more than 75% were considered as the final element of the MDS without re-measuring in the second round of Delphi.[7]

For the second round of Delphi, the data elements with a mean of 50%–75% were included. This questionnaire link was sent to the same first round of Delphi 1 month after the first round of Delphi, on September 28, 2020. After calculating the frequency and mean of each data element, only the data elements with a mean more than 75% were considered as the final element for the MDS of BD, and the rest of the elements were excluded.[7]

Ethical considerations

To conduct the study, the code of ethics numbered IR.KMU.REC.1399.025 was obtained from the Ethics Committee of Kerman University of Medical Sciences. The physician's participation in the first and second round of Delphi was also completely voluntarily, and they had chance to leave the study at any time without any consequences.

Results

Twenty specialists and subspecialists in the psychiatry participated in this study. The demographic information of these physicians is presented in Table 1. Women frequency (75%) was higher than men. The highest age group was assigned to 27–36. More over, the frequency of specialist physicians was also reported higher than that of subspecialists.

108 data elements were divided into 15 categories [Table 2]. Of the 108 data elements identified, 84 data elements were finalized by experts as essential data elements for the design MDS of BD. Twenty-four data

Table 1: Frequency distribution of participants in the study based on demographic characteristics

Variables	Frequency (%)
Sex	
Male	5 (25)
Female	15 (75)
Age	
33-42	13 (65)
43-52	3 (15)
≥53	4 (20)
Education degree	
Specialist	14 (70)
Subspecialist	6 (30)
Years of service	
1-10	13 (65)
11-21	6 (30)
>21	1 (5)

Table 2: Clinical and administrative data primary categories for a minimum data set for bipolar disorder

Category	The number of data elements	First round of Delphi			Second round of Delphi			The number of data elements final
		<50%	50%-75%	>75%	<50%	50%-75%	>75%	
Demographic items	14	1	4	10	0	2	2	11
Clinical history	18	0	3	15	0	1	2	17
Types of bipolar disorder	3	0	0	3	0	0	0	3
Current episode type	4	0	0	4	0	0	0	4
Fuzzy changes in the current episode	6	0	0	6	0	0	0	6
Mania period characteristics and criteria	9	0	0	9	0	0	0	9
Major depression criteria	7	0	0	5	0	0	0	4
Subsidence types at the end of the mania, depression, and mixed periods	2	0	0	2	0	0	0	2
Factors affecting disease recurrence	6	0	0	6	0	0	0	6
Reasons for high mortality rate	3	0	0	3	0	0	0	3
Medications	12	0	4	8	0	4	0	8
Nonpharmacological treatments	10	0	2	0	0	2	0	8
Laboratory tests	11	0	7	4	1	5	1	5
Brain imaging	2	2	0	0	0	0	0	0

elements in the first and second rounds of Delphi were excluded from the study. Six data elements in the first round of Delphi with a mean <50% were excluded from the study. Besides, 18 data elements with a mean of <50% and <50%–75% in the second round of Delphi were excluded from the study.

As shown in Table 2, among the 14 introduced categories, the categories of "types of BD," "current episode type," "fuzzy changes in the current episode," "mania period characteristics and criteria," "subsidence types at the end of the mania," "depression and mixed periods," "factors affecting disease recurrence," and "reasons for high mortality rate" were among the categories which their data elements were confirmed according to the experts' opinion in the same first round of Delphi. "Brain imaging" was the only group that its data elements, namely magnetic resonance imaging and computed tomography, were excluded from the study in the first round of Delphi. Besides, the father's name was excluded from the "demographic items" group in the first round of Delphi.

In the group of "clinical history," the "attention deficit hyperactivity disorder" data elements, in the group of "major depression criteria," three data elements such as "weight gain," "sleep paralysis," and "sensitivity to rejection as a long-term pattern" were excluded from the dataset. In the "medications" group data elements such as "aripiprazole," "clonazepam," "lorazepam," and "lamotrigine anticonvulsant," were excluded from the data set. As well as, in the "nonpharmacological treatments" group, two data elements of "cognitive behavioral therapy for depression" and "mindfulness based cognitive therapy training" were excluded from the data set.

Moreover, in the group of "laboratory tests," the data elements for the measurement of "total bilirubin blood level," "thyroid-stimulating hormone," "fasting blood sugar test," "complete blood count," "blood urea nitrogen test," and "blood creatinine" were excluded from the data set in the second round of Delphi.

Among all the confirmed data elements, the data element of "medication nonadherence" from the group of "factors affecting disease recurrence" with a mean of 4.80 (96%) was recognized as the most important data element by experts. Besides, the data element of "history of suicide" from the group of the "clinical history" with a mean of 4.75 (95%) was ranked second level. "Substance abuse and addiction" from the "factors affecting disease recurrence" group with a mean of 4.70 (94%) was also ranked in third level.

Further, among all confirmed data elements, the "depression with mixed features" in the "fuzzy changes in the current episode" group and "quetiapine" in the "medications" group with a mean 3.80 (76%) had the lowest mean value.

Furthermore, in the section "Other data elements" and in the first round of Delphi, one of the specialists mentioned items such as "psychosis type," "hallucination," "delusion," and "medical centers for previous visits." The mean and standard deviation of these elements have been listed in the "Other data elements" group [Table 3]. Among these data elements, the mean for "hallucination" and "delusion" was reported higher than other elements. So, Of the 112 data elements identified, 88 data elements were finalized by experts as essential data elements for the design MDS of BD.

All confirmed and unconfirmed elements data with their calculated standard deviation and mean are shown in Table 3.

Table 3: Management and clinical data elements required to design and present the minimum data set necessary for the management of bipolar disorder

Category	Data elements	1st round Delphi		2nd round Delphi	
		Mean±SD	Accepted, rejected in the first round of Delphi or entry to the second round Delphi	Mean±SD	Final acceptance or rejection
Demographic items	Medical record number	3.40±1.04	*	4.05±1.09	√
	National code	3.95±1.35	√		√
	First name	2.65±1.18	*	3.10±1.16	×
	Last name	2.75±1.16	*	3.40±1.04	×
	Date of birth	4.15±0.74	√		√
	Father's name	2.30±1.08	×		√
	Gender	4.10±1.07	√		√
	Age	4.15±1.87	√		√
	Marital status (single, married, widowed, divorced)	4.05±0.82	√		√
	Education level	3.85±0.98	√		√
	Occupational status	3.90±0.96	√		√
	Socioeconomic status	3.85±0.95	√		√
	Place of residence: Province, city, village, street number plate	3.80±0.95	√		√
	Phone number	3.15±0.93	√		√
Clinical history	Underlying diseases	3.20±1.28	*	4.25±0.78	√
	Consumption of opium, cigarettes and alcoholic beverages, etc.	4.25±0.87	√		√
	Family history of mental disorder	4.65±0.59	√		√
	History of psychosis	4.65±0.59	√		√
	History of depression	4.65±0.48	√		√
	Mood stabilizers	4.65±0.48	√		√
	Duration of the disease	4.50±0.60	√		√
	Accompanied by other mental disorders	4.40±0.75	√		√
	Suicide history	4.75±0.44	√		√
	Time of the first period of hospitalization	4.25±0.71	√		√
	Hospitalization history in the last 6 months	4.10±0.78	√		√
	Time of discharge from the hospital	3.35±1.04	*	4.05±0.99	√
	Attention deficit hyperactivity disorder	3.75±0.96	*	3.60±0.99	×
	Drug therapy	4.60±0.50	√		√
	Medication taken and prescribed	4.60±0.59	√		√
	Nonpharmacological therapies (psychotherapy)	3.95±0.82	√		√
	Age of bipolar disorder	4.25±0.71	√		√
	Number of hospitalizations	4.20±0.69	√		√
Types of bipolar disorder	Type I bipolar disorder: With mania phases, major and mixed depression	4.50±0.51	√		√
	Type II bipolar disorder: At least one period of hypomania and at least one period of major depression	4.35±0.74	√		√
	Cyclothymic disorder (i.e., short-term hypomonic episodes and episodes of major depression)	4.30±0.65	√		√
Current episode type	Mania	4.60±0.82	√		√
	Hypomania	4.10±1.02	√		√
	Mixed	4.40±0.94	√		√
	Major depression	4.68±0.73	√		√

Contd...

Table 3: Contd...

Category	Data elements	1st round Delphi		2nd round Delphi	
		Mean±SD	Accepted, rejected in the first round of Delphi or entry to the second round Delphi	Mean±SD	Final acceptance or rejection
Fuzzy changes in the current episode	Depression to mania	4.15±1.04	√		√
	Mania to depression	4.10±0.96	√		√
	Mania to mix episode	4.05±0.94	√		√
	Depression with mixed features	4.10±0.91	√		√
	Episode mix to depression	3.80±0.89	√		√
	Episode mix to mania	4.05±0.94	√		√
Mania period characteristics and criteria	Talkative	4.35±0.74	√		√
	Violence	4.65±0.48	√		√
	High mood	4.60±0.59	√		√
	Reduce the need for sleep	4.60±0.68	√		√
	Self-aggrandizement and increased self-confidence	4.40±0.68	√		√
	Racing thoughts	4.45±0.82	√		√
	Distractions	4.15±0.81	√		√
	Increased activity related to psychomotor agitation	4.35±0.58	√		√
	Deal with pleasurable affairs regardless of their consequences	4.40±0.68	√		√
Major depression criteria	Physical changes (such as anorexia or bulimia, unexplained pain, restlessness or mental-motor slowness)	4.30±0.73	√		√
	Emotional symptoms (long-term discomfort, incessant crying, feelings of guilt, low self-esteem, frustration and feelings of worthlessness)	4.20±0.76	√		√
	Severe psychological reactions (irritability and aggression, anxiety and worry, pessimism, self-blame)	4.35±0.58	√		√
	Increase sleep hours	4.10±0.78	√		√
	Sleep paralysis	3.30±0.92	*	2.95±1.14	×
	Weight gain	3.75±0.78	*	3.65±0.74	×
	Sensitivity to rejection as a long-term pattern	3.40±1.27	*	3.20±0.83	×
subsidence types at the end of the mania, depression and mixed periods	Relative remission: Mania symptoms, major and mixed depression, but not all criteria	4.20±0.76	√		√
	Complete remission: Absence of any significant signs or symptoms of the disorder for the past 2 months	4.21±0.81	√		√
Factors affecting disease recurrence	Medication nonadherence	4.80±0.52	√		√
	Substance abuse and addiction (opioid compounds, cannabis, methamphetamine, and alcohol)	4.70±0.65	√		√
	Personality disorder (antisocial and narcissistic)	4.15±0.67	√		√
	Existence of accompanying psychiatric disorders (obsessive–compulsive disorder, panic and generalized anxiety disorder)	4.25±0.63	√		√
	Insomnia and lack of a regular sleep schedule	4.65±0.58	√		√
	Stressful life events (such as divorce, death of loved ones, job loss, pregnancy, and childbirth)	4.55±0.60	√		√

Contd...

Table 3: Contd...

Category	Data elements	1st round Delphi		2nd round Delphi	
		Mean±SD	Accepted, rejected in the first round of Delphi or entry to the second round Delphi	Mean±SD	Final acceptance or rejection
Reasons for high mortality rate	Suicide	4.60±0.50	√		√
	Concomitant diseases such as cardiovascular disease, metabolic nutrition disorders, obesity, diabetes, metabolic syndrome (endocrine diseases), thyroid dysfunction, menstrual dysfunction	4.10±0.71	√		√
	Excessive alcohol and opium use	4.45±0.60	√		√
Medications	Dosage of the drug	4.35±0.74	√		√
	Lithium	4.55±0.68	√		√
	Sodium valproate	4.50±0.60	√		√
	Carbamazepine	3.95±0.99	√		√
	Olanzapine	4.10±0.78	√		√
	Quetiapine	3.80±0.89	√		√
	Haloperidol	4.00±0.85	√		√
	Risperidone	4.20±0.69	√		√
	Aripiprazole	3.50±1.05	*	2.65±0.87	×
	Clonazepam	3.58±0.94	*	2.90±1.45	×
	Lorazepam	3.45±1.09	*	2.75±1.25	×
	Lamotrigine anticonvulsant	3.75±1.20	*	3.30±1.21	×
Nonpharmacological treatments	Supportive therapies	4.05±0.94	√		
	ECT	4.55±0.60	√		
	Increase adaptation skills and difficulty	3.90±0.91	√		√
	Individual psychoeducation	3.95±0.99	√		√
	Family psychoeducation	4.20±0.76	√		√
	Self-management techniques training	3.85±0.81	√		√
	Life skills training	3.90±0.85	√		√
	Training to recognize the early warning sign	4.40±0.68	√		√
	CBT for depression	3.5±0.88	*	3.50±0.88	×
	Mindfulness-based cognitive therapy training	3.40±0.88	*	3.35±0.93	×
Laboratory tests	Lithium levels in the blood	4.40±0.75	√		√
	Narcotic tests (morphine, cannabis, and methamphetamine)	4.30±1.03	√		√
	Liver tests (SGOT, SGPT, ALK phosphatase levels)	3.90±0.85	√		√
	TSH	3.95±0.75	√		√
	Total bilirubin blood level	3.05±0.88	*	2.30±1.21	×
	T3	3.15±0.87	*	3.40±1.09	×
	T4	3.30±0.73	*	3.90±0.92	√
	FBS	3.60±0.99	*	3.65±1.04	×
	CBC	3.20±1.15	*	3.45±1.19	×
	BUN	3.25±1.07	*	3.50±1.14	×
	Blood Cr	3.40±1.09	*	3.30±1.26	×
Brain imaging	CT	2.20±1.00	×		×
	MRI	2.21±0.85	×		×
Other data elements	Psychosis type			4.25±0.96	√
	Hallucination			4.30±0.65	√
	Delusion			4.30±0.65	√
	Medical centers for previous visits			3.90±0.71	√

*Assessment in second round of Delphi, ×=Final exclusion, √=Final Acceptance. ECT=Electroconvulsive therapy, CBT=Cognitive behavioral therapy, TSH=Thyroid stimulating hormone, T3=Triiodothyronine, T4=Thyroxin, FBS=Fasting blood sugar, CBC=Complete blood count, BUN=Blood urea nitrogen, Cr=Creatinine, MRI=Magnetic resonance imaging, CT=Computed tomography, SGOT=Serum glutamic oxaloacetic transaminase, SGPT=Serum glutamic pyruvic transaminase, ALK=Anaplastic lymphoma kinase, SD=Standard deviation

Discussion

In the present study, an MDS was designed and presented for the patient with BD.

Fifteen categories "demographic items," "clinical history," "types of BD," "current episode type," "fuzzy changes in the current episode," "mania period characteristics and criteria," "major depression criteria," "subsidence types at the end of the mania, depression, and mixed periods," "depression and mixed periods," "factors affecting disease recurrence," "reasons for high mortality rate," "medications," "nonpharmacological treatments," "laboratory tests," and "brain imaging" with 88 data elements were identified for BD MDS. Among all confirmed data elements, "medication nonadherence," "history of suicide," and "substance abuse and addiction" data elements were the most important.

Rowland and Marwaha[13] studied population, genetic, and environmental risk factors related to BD, focusing on the role of environmental triggers. They concluded that there are multiple risk factors for bipolar, both genetically and environmentally, but the incompatibility of results, low attributable risk, inability to determine the temporality of the relation, deficiency of a clear biologic mechanism and the nonspecific nature of numerous risk factors means that causation is hard to assign in an individual patient.[13] Potash *et al*.[14] collected and validated a database of phenotypic variables for patients with BD. These variables were collected from families with BD. The combined database of phenotypic variables contained 197 variables from 1177 families.[14] Unlike the present study, an MDS was not presented in these studies and most of the clinical and managerial data elements of BD were not considered as well. In Rowland and Marwaha's[13] and Potash *et al*.'s[14] study, only demographic, genetic, and environmental risk factors and phenotypic variables were identified, respectively. Moreover, in these studies, demographic, genetic, and environmental risk factors and phenotypic variables were confirmed only by reviewing the literature[13] or families with BD and not by psychiatrists.[14]

Guidelines were other studies that focused on factors influencing the treatment and control of BD. Goodwin *et al*.[11] developed an evidence-based guideline for the treatment of BD. This guideline includes the diagnosis of BD, clinical management, and tactics for the use of medicines: in short-term treatment of episodes, relapse prevention and halt treatment. Fountoulakis *et al*.,[12] conducted a study on background and methods of developing treatment of bipolar disorder guidelines. This study includes descriptions of the important clinical features of BD with emphasis on subjects that are important for the medical care considerations such as mixed and psychotic characteristics, predominant polarity, and fast cycling as well as comorbidity. In these studies,[11,12] as in the present study, experts were asked to confirm the effective factors; however, unlike the present study, these guidelines may provide more information about BD. However, since these guidelines are published in a file of more than 50 pages and their volume of information is very large, it may reduce the willingness of physicians and patients to use these documents.

According to the present study findings, among all the confirmed data elements, "medication nonadherence" was one of the most important data elements. Greenhouse *et al*.[18] stated that effective treatment for BD depends on medication adherence. Contrary to medical advice, Scott[19] reported that between 30% and 50% of people would stop taking prophylactic mood stabilizers medicine for at least a year. According to Ceylan *et al*.,[20] this may have been increased due to tolerability and atypical antipsychotics. Yen *et al*.[21] and Clatworthy *et al*.[22] believed that medication nonadherence would increase the risk of recurrence, increase the probability of hospital admissions, and increase length of hospital stay, prevalent, cost, and poor clinical outcome. Crowe *et al*.[23] also stated that medication nonadherence to BD is related with higher rates of recurrence, hospitalization, and suicide.

On the other hand, Berk *et al*.[24] believed that medicine adherence contributes to the efficacy–effectiveness gap of treatment in patients with BD. Increasing adherence to medication in a strong treatment alliance can be important in decreasing the disease recurrence, minimizing the negative effects on people's lives, and increasing their well-being.[23]

According to the other results of the present study, among the approved elements, after "medication nonadherence," the highest mean was for "suicide history." Anderson *et al*.[1] believed that BD has a negative effect on most patients' lives, which one of its most devastating effects is suicide. More than 6% of patient with BD die through suicide in the two decades later diagnosis. Miller and Black[25] stated that compared to other mental diseases, BD has the highest risk of suicide. Patients with this disorder are approximately 20–30 times more likely to commit suicide compared with the general population. The risk of suicide-related death in bipolar patients has also been reported about 20%.[5]

Further, the results of our study showed that "substance abuse and addiction" is an important data element in the design of MDS BD. Comorbid substance use disorder (SUD) and addiction are a regulation

among patients with BD and are no exception.[26] There is different evidence that substance abuse and alcohol addiction phenomenologically alters illness representation in BD and can lead to augmented chronicity and symptom hardness. Therefore, it has been introduced as an important data element in further understanding BD.[27] Some studies have shown that this data element can lead to the occurrence of two other data elements, namely "medication nonadherence" and "suicide." The existence of comorbid SUDs (misuse or addiction to substances and/or alcohol) is linked with delayed improvement from mood episodes, more fast relapse into continual mood episodes, augmented symptoms, functional disability, suicidality, forensic troubles, opposition "switching" into mania, medication nonadherence, and reduced quality of life.[28]

According to the above studies and the opinion of experts, it can be concluded that "medication nonadherence," "history of suicide," and "substance abuse and addiction" are the three basic data elements in BD MDS. Therefore, it is important that patients with BD have the necessary information and knowledge in this area. Increasing knowledge and awareness of the sociological and clinical features of BD can lead to improve the awareness of the health and disease status of individuals, diagnostic cases and BD better management.[29] It can be said that designing and presenting guidelines or exclusive MDS related to these three data elements can be very helpful to manage and control these two challenges.

Limitation and recommendation

The current study has some limitations. First, despite the variety of the healthcare aspects and disciplines served by the Delphi panel, the research sample only included psychiatrists working in hospitals of Kerman province. Therefore, it may not represent the views of all experts in the national and international field. It is suggested to conduct similar studies in the national and international level to introduce effective factors in the management, control and monitoring the BD with the participation of more psychiatrists. Second, people with BD were not as part of Delphi's participants, despite their experience, knowledge, and awareness could help us to achieve more accurate results. Therefore, it is suggested that patients with BD be included in the Delphi panel for the future studies. Next, in this study, only articles published in English were included in the study; it is suggested to use articles published in other languages in future studies. Further, after conducting a literature review, two psychiatrists decided on the categories and necessity of the data elements extracted from the studies. It is suggested that in other studies, more experts be included in the study to confirm the categories and necessity of data elements.

Conclusion

In this study, a bipolar disorder minimal data set to introduce effective factors in further management, control, and monitoring this disorder was designed and presented. By providing background knowledge and developing a management and treatment framework for physicians, this MDS can provide the possibility of continuous care for patients, and by providing and predicting the required services, it is possible to control and prevent further complications of this disease and decrease the treatment costs.

Besides, by providing this MDS, it is possible to help electronic systems designers and health data managers when designing these different systems such as registries, electronic health records, personal health records, and/or any kind of self-care or self-management program for patients with BD to know what information should be included in the system to meet the needs of these patients and enable the standardization of medical services in hospitals, clinics, and health centers. Furthermore, since cell phone-based technologies have become an essential part of human life, designing web applications of self-care and self-management based on extracted MDSs to manage and control these challenges can be very effective.

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Conflicts of interest

There are no conflicts of interest.

References

1. Anderson IM, Haddad PM, Scott J. Bipolar disorder. BMJ (Clinical research ed) 2012;345:e8508.
2. Fontana E, Mandolini GM, Delvecchio G, Bressi C, Soares JC, Brambilla P. Intravenous valproate in the treatment of acute manic episode in bipolar disorder: A review. J Affect Disord 2020;260:738-43.
3. Ali Z, Tegin C, El-Mallakh RS. Evaluating lurasidone as a treatment option for bipolar disorder. Expert Opin Pharmacother 2020;21:253-60.
4. Mitchell PB, Johnston AK, Corry J, Ball JR, Malhi GS. Characteristics of bipolar disorder in an Australian specialist outpatient clinic: comparison across large datasets. Aust N Z J Psychiatry 2009;43:109-17.
5. Baldessarini RJ, Vázquez GH, Tondo L. Bipolar depression: A major unsolved challenge. Int J Bipolar Disord 2020;8:1-13.
6. Sheykhotayefeh M, Safdari R, Ghazisaeedi M, Khademi SH, Seyed Farajolah SS, Maserat E, *et al*. Development of a minimum

data set (MDS) for C-section anesthesia information management system (AIMS). Anesth Pain Med 2017;7:e44132.
7. Moulaei K, Bahaadinbeigy K, Fatehi F. A novel minimum data set (MDS) for the management of diabetic foot: basis for introducing effective indicators to the better management, control and monitoring of diabetic foot. Clinical Diabetology 2021;10:1-12.
8. Zahmatkeshan M, Farjam M, Mohammadzadeh N, Noori T, Karbasi Z, Mahmoudvand Z, *et al.* Design of infertility monitoring system: Minimum data set approach. J Med Life 2019;12:56-64.
9. Sadoughi F, Shahi M, Ahmadi M, Davaridolatabadi N. The comparison of the minimum data set for elderly health in selected countries. Acta Inform Med 2015;23:393-7.
10. Ahmadi M, Mirbagheri E. Designing data elements and minimum data set (MDS) for creating the registry of patients with gestational diabetes mellitus. J Med Life 2019;12:160-7.
11. Goodwin GM, Haddad PM, Ferrier IN, Aronson JK, Barnes T, Cipriani A, *et al.* Evidence-based guidelines for treating bipolar disorder: Revised third edition recommendations from the British Association for Psychopharmacology. J Psychopharmacol 2016;30:495-553.
12. Fountoulakis KN, Young A, Yatham L, Grunze H, Vieta E, Blier P, *et al.* The international college of neuropsychopharmacology (CINP) treatment guidelines for bipolar disorder in adults (CINP-BD-2017), Part 1: Background and methods of the development of guidelines. Int J Neuropsychopharmacol 2017;20:98-120.
13. Rowland TA, Marwaha S. Epidemiology and risk factors for bipolar disorder. Ther Adv Psychopharmacol 2018;8:251-69.
14. Potash JB, Toolan J, Steele J, Miller EB, Pearl J, Zandi PP, *et al.* The bipolar disorder phenome database: A resource for genetic studies. Am J Psychiatry 2007;164:1229-37.
15. American Psychiatric Association A, Association AP. Diagnostic and Statistical Manual of Mental Disorders: DSM-5: Washington, DC: American Psychiatric Association; 2013.
16. Faber-Wildeboer AT, van Os-Medendorp H, Kooy A, Sol-De Rijk B. Prevalence and risk factors of depression and diabetes-related emotional distress in patients with type 2 diabetes: A cross-sectional study. J Nurs Educ Pract 2013;3:61.
17. Ahmadi M, Alipour J, Mohammadi A, Khorami F. Development a minimum data set of the information management system for burns. Burns 2015;41:1092-9.
18. Greenhouse WJ, Meyer B, Johnson SL. Coping and medication adherence in bipolar disorder. J Affect Disord 2000;59:237-41.
19. Scott J. Using health belief models to understand the efficacy-effectiveness gap for mood stabilizer treatments. Neuropsychobiology 2002;46 Suppl 1:13-5.
20. Ceylan MF, Erdogan B, Tural Hesapcioglu S, Cop E. Effectiveness, adverse effects and drug compliance of long-acting injectable risperidone in children and adolescents. Clin Drug Investig 2017;37:947-56.
21. Yen CF, Chen CS, Ko CH, Yeh ML, Yang SJ, Yen JY, *et al.* Relationships between insight and medication adherence in outpatients with schizophrenia and bipolar disorder: Prospective study. Psychiatry Clin Neurosci 2005;59:403-9.
22. Clatworthy J, Bowskill R, Parham R, Rank T, Scott J, Horne R. Understanding medication non-adherence in bipolar disorders using a necessity-concerns framework. J Affect Disord 2009;116:51-5.
23. Crowe M, Wilson L, Inder M. Patients' reports of the factors influencing medication adherence in bipolar disorder – An integrative review of the literature. Int J Nurs Stud 2011;48:894-903.
24. Berk L, Hallam KT, Colom F, Vieta E, Hasty M, Macneil C, *et al.* Enhancing medication adherence in patients with bipolar disorder. Hum Psychopharmacol 2010;25:1-16.
25. Miller JN, Black DW. Bipolar disorder and suicide: A review. Curr Psychiatry Rep 2020;22:6.
26. Gao K, Verduin ML, Kemp DE, Tolliver BK, Ganocy SJ, Elhaj O, *et al.* Clinical correlates of patients with rapid-cycling bipolar disorder and a recent history of substance use disorder: A subtype comparison from baseline data of 2 randomized, placebo-controlled trials. J Clin Psychiatry 2008;69:1057-63.
27. Bray JW, Zarkin GA, Dennis ML, French MT. Symptoms of dependence, multiple substance use, and labor market outcomes. Am J Drug Alcohol Abuse 2000;26:77-95.
28. Goldstein BI, Goldstein TR, Collinger KA, Axelson DA, Bukstein OG, Birmaher B, *et al.* Treatment development and feasibility study of family-focused treatment for adolescents with bipolar disorder and comorbid substance use disorders. J Psychiatr Pract 2014;20:237-48.
29. McCormick U, Murray B, McNew B. Diagnosis and treatment of patients with bipolar disorder: A review for advanced practice nurses. J Am Assoc Nurse Pract 2015;27:530-42.