VIA MEDICA
RESEARCH PAPER
ISSN 2450–7458
E-ISSN 2450–8187

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Developing a 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

ABSTRACT

Diabetic foot is the most common side-effect and the most financially expensive complication of diabetes, which increases the fatality risk of diabetic patients by two to four times. Without proper medical attention, this condition can lead to a plethora of complications, including scarring, infection, gangrene, amputation, and even death. Therefore, this study was performed with the purpose of designing and presenting the Minimum Data Set (MDS) required to introduce effective indicators in the better management, control, and monitoring of diabetic foot. First, we conducted a comprehensive review of different databases to identify the MDS. The necessary managerial and clinical data were extracted from the studies and then formulated using a questionnaire. In the second stage, the questionnaire was distributed to 15 specialists of fields of endocrinology, physical medicine, infectious diseases, and surgery, and three general practitioners and medical informatician experts during two rounds of the Delphi technique. Out of 105 proposed data elements of managerial and clinical data in 14 groups, 90 data elements were ultimately confirmed with consensus and collective agreement according to the opinion of experts, while 12 data elements were mentioned in the open question section of the questionnaire. The aforementioned MDS can assist policymakers, software developers, and health data managers in recognizing the type of information that should be in the system when starting to design different systems and/or software programs for patients diagnosed with diabetes. This system should be able to meet the needs of these patients, enable the standardization of medical services in hospitals, clinics, and health centers, and provide grounds for data collection.
(Clin Diabetol 2022, 11; 3: 135–145)

Keywords: diabetic foot, minimum data set (MDS), management, control, monitoring

Introduction

Diabetic foot is the most prevalent side-effect and the most financially expensive complication of diabetes, which increases the fatality risk of diabetic patients by two to four times [1, 2]. Without proper medical attention, this condition can lead to a plethora of complications, including scarring, infection, gangrene, amputation, and even death [3]. Foot ulcers and infections are among the most important causes of disability in

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Clinical Diabetology 2022, 11; 3: 135–145
DOI: 10.5603/DK.a2021.0053
Received: 11.01.2021 Accepted: 7.10.2021

patients with diabetes [4, 5]. These ulcers and infections most have slow healing rates and disrupt the lifestyle, social activities, health, and quality of life of the patients as well as their caregivers [6, 7] while imposing high medical and nursing costs on patients [8, 9].

As the most common condition of diabetes [10], diabetic foot complications increase the need for hospitalization and mortality rate among diabetic patients [1, 11] while leading to limitations on movement, social isolation, interruption of recreational and occupational activities, sleeping disorders, depression and poor quality of life within patients [12]. Therefore, identifying the causes of this complication can lead to an increased possibility of early recovery within this class of patients. Boulton showed in his research that up to nearly 50% of diabetic foot ulcers and amputations can be prevented through effective diagnosis, training, and management [13]. Diagnosis, management, and follow-up treatment of complications related to the diabetic foot require ongoing clinical examination and monitoring, constant input of information, and frequent contact with health care providers, which can prove to be costly for such patients (especially those living in rural areas) in order to be transferred to medical centers [13]. Information management using standard tools and a shared language enables smooth collection and exchange of information between different medical institutions and service providers [14]. MDSs are among the emerging data collection instruments that are capable of providing accurate access to health data and recording the most relevant and updated inputs regarding patients' health [15, 16]. As a graceful foundation for medical information management, MDSs can achieve great potential in helping provide high-quality medical care and disease control [17]. MDSs facilitate accurate, comprehensive, and persistent data collection in a specific field, and offers the possibility for comparing data at different national and international levels [18]. As a prerequisite for effective disease management in the health industry, MDSs can increase approaches to optimizing the quality of medical care [18].

Since effective decision-making in health care depends on instant access to correct and reliable data and information [19, 20], the current study was performed with the purpose of designing and providing the minimum data set essential to the management of diabetic foot for introducing effective indicators in better management, control and monitoring of diabetic foot. This study can provide grounds for access to correct and reliable data and information in order to improve clinical and research applications (with the aim of improving the health status of patients with diabetes, hence preserving time and money). Also, the basic knowledge presented in this study enables providers to adopt effective decisions and to control and prevent the exacerbation of complications through anticipating the required services according to e-health technologies.

Research methodology

The present study was performed in the following two stages:

Stage 1: Extracting the data elements required for designing and offering the minimum data set necessary for the management of diabetic foot

Search method

In order to perform this stage, a comprehensive review of studies was conducted to identify the necessary data elements pertaining to diabetic foot from January 2 to January 29, 2020, from four databases, namely IEEE, PubMed, Web of Science, and Scopus.

Keywords

The keywords that were used in combination in this research for search as well as an example of a search strategy in the PubMed database are summarized in Table 1.

Inclusion and exclusion criteria

Inclusion criteria in this study included the publication of the paper in the English language, having access to the full text of the articles, reference to data elements, and necessary parameters related to diabetic foot. Moreover, exclusion criteria also included articles on other aspects of diabetes, and failure to provide clear information on diabetic foot. Moreover, books and chapters of the book, letters to the editor, and the conference abstract were excluded from this research.

It is noteworthy that articles published in scientific journals and conferences (in case of access to full text) were included in this study.

Classification and selection of resources

First, 500 papers were extracted from four databases: IEEE, PubMed, WEB OF SCIENCE, and SCOPUS, using keywords derived from Table 1. Titles, abstracts, and keywords of papers were examined. Then, according to the inclusion and exclusion criteria, 38 articles were included in the study. The full text of the papers were downloaded and finally the necessary data elements for designing and presenting the minimum data set in the management of diabetic foot were extracted. At this stage, data collection was performed using a data extraction form, the validity of which was confirmed

Table 1. Keywords and Search Strategy

No	Keywords
1	Diabetes, type 2 diabetes, type 1 diabetes, neuropathy, diabetic neuropathies
2	Diabetic foot, diabetic feet, diabetic neuropathies, foot ulcer, plantar ulcer, neuropathic ulcers, ischemia, wounds, osteomyelitis
3	Telehealth, telemedicine, telemonitoring, tele wound care, tele-homecare, e-health, smartphone OR mobile health, wearable electronic devices, Minimum Data Set (MDS)
Search strategy	[(1) AND (2) AND (3)]

based on the opinions of two medical informatics expert and one health information technology expert.

Stage 2: Final approval of data elements necessary for designing and providing the minimum data set for the management of diabetic foot from the views of experts

At this stage, a questionnaire was used to collect data, which was initially devised by putting the data elements recognized in the previous step. The questionnaire consisted of two parts: the first part included the demographic information of specialists, while the second part consisted of 105 essential data elements to design and provide the minimum data set. The data elements were classified in 14 subcategories, namely Demographic Items, Hospitalization, Laboratory tests and examinations, Risk factors, History, Amputation, Symptom and sing Medication, Treatment, and processes, Prevention, Remote services, Laser therapy, Rehabilitation, and Lifestyle. A five-level Likert scale was considered for scoring each data element [20]. The face validity and content validity of the questionnaire was confirmed based on the opinions of two physicians, a surgeon, a general practitioner, and a medical informatician expert. Based on the received feedbacks, some synonymous and unrelated data elements were excluded from the study. The reliability of the questionnaire was evaluated by Cronbach's alpha method and was confirmed to have a value of 0.952.

Owing to the fact that in most Delphi-based research, 15 to 20 experts are asked to complete the questionnaires, the sampling was done using random methods and finally, 15 specialists and subspecialists from four fields of endocrinology (n = 2), physical medicine (n = 3), infectious diseases (n = 2) along with surgeons (n = 5) and three general practitioners and medical informatics specialists were included in this study [21].

The following inclusion criteria were used for the participants:

- Being employed in educational and medical centers affiliated to Kerman University of Medical Sciences
- Having more than four years of work experience in the field of diabetes and diabetic foot
- Being committed to performing a second round of Delphi

In the first round of Delphi, the questionnaire was distributed and then collected among experts in the educational and medical centers affiliated with Kerman University of Medical Sciences from February 15, 2020, to February 25, 2020. The second stage Delphi questionnaires were distributed and collected among the same specialists from the first stage Delphi one month after the aforementioned intervention, i.e. on March 25, 2020. Owing to the outbreak of the coronavirus pandemic, the questionnaires were not distributed in person and were distributed electronically. Also, in order to identify other important data elements, an open question entitled "Other data elements" was asked from the experts. After collecting the questionnaires, the data were inputted to SPSS v. 23, then the frequency and the mean of each item were calculated and analyzed. In order to decide on each data element from the first stage, an agreement level was considered. Thus, data elements with a mean of less than 50% in the first round were removed, while data elements with a mean of 50% to 75% are inputted to the second stage Delphi, and finally, data elements with a mean of more than 75% were considered as the final elements of the minimum data set, without further need to be re-measured in the second round of Delphi [22].

Ethical considerations

To conduct this study, the ethics code no. IR.KMU.REC.1399.038 was obtained from the ethics committee of Kerman University of Medical Sciences. Also, before participating in the study, informed consent was orally gained from the participants in the first round of Delphi and the evaluation process.

Results

In this study, 15 specialists and subspecialists of four fields of endocrinology, physical medicine, infectious dis-

eases, and surgery, and three general practitioners and medical informatics specialists participated in the study, the demographic information of which is presented in Table 2. According to this table, the percentage of male participants was higher than female ones in all four types of specialization (80% to 20%). The highest age group in this study were participants aged 46-55. The frequency of surgery specialists (33.3%) was higher than that of the other specialists.

As mentioned in the methodology section, the 105 identified administrative and clinical data elements were divided into 14 groups according to Table 3. Out of the 105 data elements identified, 90 data elements were eventually recognized by experts as the necessary data elements for designing the MDS of diabetic foot. Fifteen data elements were excluded from the study during the first and second rounds of Delphi. Seven data elements in the first phase of Delphi were excluded from the study due to having a mean of less than 50%, while further eight data elements were excluded due to achieving a mean of less than 75% in the second round of Delphi.

As can be seen from Tables 3 and 4, out of the 14 main categories introduced, the three categories of Risk factors, Amputation, and Remote services with 18, two, and four data elements, respectively, were the only categories that all of their data elements were approved in the first round in Delphi according to experts. In the category of Demographic Items, three data elements, namely Father's name, Marital status, and Indigenous status were excluded from the study due to having means of less than 50%. Moreover, drug dose from the Medication category, the Metabolic Control data element from the Prevention category, the Ulcer management from the Laser therapy category, and adequate sleep and rest from the Lifestyle category were excluded from the study due to the same aforementioned reason.

Table 2. Frequency Distribution of Participants in the Study Classified Based on Demographic Characteristics

Variable	Frequency	Percentage
Gender		
Male	12	80.0
Female	3	20.0
Age		
36–45	6	40.0
46–55	7	46.7
> 55	2	13.3
Level of education		
Specialist	12	80.0
Subspecialist	3	20.0
Specialty		
Endocrinologist	2	13.3
Physical medicine	3	20.0
Surgery	5	33.3
Infectious diseases	2	13.3
Medical informatics	3	20
Work experience		
1–10	7	46.7
11–21	6	40
> 21	2	13.3

Table 3. Clinical and Administrative Primary Data Groups for a Minimum Data Set for Diabetic Foot

Primary data groups	The Number of Data Elements	1st round Delphi			2nd round Delphi			The final number of data elements
		< 50%	50–75%	75% <	< 50%	50–75%	75% <	
Demographic Items	8	3	0	5	0	0	0	5
Hospitalization	4	0	1	3	0	1	0	3
Laboratory tests and examinations	7	0	3	4	0	1	2	6
Risk factors	18	0	0	18	0	0	0	18
History	15	0	2	13	0	1	1	14
Amputation	2	0	0	2	0	0	0	2
Symptoms and signs	18	0	3	15	1	2	0	15
Medication	5	1	0	4	0	0	0	4
Treatment and processes	11	0	1	10	0	1	0	10
Prevention	5	1	0	4	0	0	0	4
Remote services	4	0	0	4	0	0	0	4
Laser therapy	2	0	1	1	0	1	0	1
Rehabilitation	2	1	0	1	0	0	0	1
Life style	4	1	0	3	0	0	0	3

Consequently, eight data elements were also discarded during the second round of Delphi, namely, bedsores from the Hospitalization category, microalbuminuria test from the Laboratory tests and examinations category, history of osteoporosis from the History category, diabetic distress, skin conditions, and leftness or rightness of the sore feet from the Symptom and signs category, type of wound dressing from the treatment and category, and the left or right foot of the Laser therapy category were the elements that not approved in the second round of Delphi and were thus excluded from the minimum data set.

It is also noteworthy that abnormalities in blood lipids levels and Body Mass Index (BMI) in the category of Laboratory tests and examinations, and type of diabetes (type 1, type 2, and gestational diabetes) in the category of History were three data elements that obtained a mean of 50 to 75 in the first round of Delphi and were thus reevaluated in the second round, during which they obtained a mean of more than 75 by expert and were hence considered in the minimum data set for the diabetic foot.

All the data elements (both approved and unapproved) along with their standard deviation and mean are shown in Table 4. Among all the confirmed data elements, critical ischemia was recognized as the most important data element by experts with a mean of 4.86 (97%). The data elements of foot ulcer, peripheral artery disease, and the presence of infection in the foot were all ranked second with a mean of 4.80 (96%). Also, among all data elements, the lowest mean values pertained to abnormalities in blood lipids levels, body mass index, and type of diabetes with an average of 3.86 (77%).

Also, the inventory had an open-ended question at the end titled "Other data elements", which was added with the purpose of considering any data elements forgotten by the researchers. In this section, a physician specializing in physical medicine referred to issues such as the prevalence and incidence of diabetes and diabetic foot, obesity, family history, and age. An endocrinologist also cited complications such as Impaired Glucose Tolerance (IGT), illiteracy, anxiety and depression, dermatitis between the toes or itchiness of the skin, diabetic foot burns, and impaired nail growth, poor blood circulation in the body, and the number of amputated toes. These data elements were eventually excluded, as they received a mean of less than 50 in the second round of Delphi.

Discussion

As the research findings indicated, out of a total of 105 administrative and clinical data elements that were classified into 14 groups of Demographic Items, Hospitalization, Laboratory tests and examinations, Risk factors, History, Amputation, Symptom and signs Medication, Treatment and processes, Prevention, Remote services, Laser therapy, Rehabilitation, and Lifestyle Finally, an agreement was achieved on 90 data elements. Also, a number of other parameters were mentioned in the open question section. Lazzarini et al. presented a minimum data set to improve the healthcare of patients with diabetic feet in Australia. Although this study covered more data elements than the present study, the data elements were not validated and presented through a two-round Delphi technique in a paper like the current study but published in the form of a 60-pages file as a Minimum Dataset Dictionary [23]. Al-Rubeaan et al. [24] focused on the complications of the diabetic foot and its risk factors in their study, in which the identified information of individuals in a registry was used to identify complications and risk factors, and thus the opinion of experts in this field was not employed. Also, unlike the present study, this study did not provide a minimum set of data and did not consider all the details related to the complications and risk factors of diabetic foot, as it rather emphasized issues such as the overall prevalence of diabetic foot complications, foot ulcer, gangrene and amputation, peripheral vascular disease(PVD), neuropathy, diabetes duration years, insulin use, retinopathy, nephropathy, age 45 years, cerebral vascular disease(CVD), poor glycemic control, coronary artery disease(CAD), male gender, smoking, and hypertension.

In a study by Golinko et al. [25], A database of diabetic foot ulcers based on wound electronic medical records was presented with the purpose of reducing amputations. In this study, a data set with the administrative and clinical features were not presented, but rather a database with five dimensions related to (1) demographics, medical history, and baseline laboratory values; (2) vascular testing data; (3) radiology data; (4) wound characteristics; and (5) wound debridement data including pathology, culture results, and amputation data. Alexander et al. [26] proposed an approach to better management of the diabetes dataset. This approach does not put emphasis on collecting all the dimensions and data elements related to diabetic foot, as only a small portion of this approach is devoted to diabetic foot data elements. Therefore, it should be noted that this study, like other studies, did not focus exclusively on a data set for diabetic foot.

In light of the above arguments, three categories of studies may be presented regarding the diabetic foot dataset, namely (1) Studies that have completely designed the minimum set of diabetic foot data. In this case, we can refer to the study of Lazarini et al. [27]. However, as previously mentioned, this study was not

Table 4. Administrative and Clinical Data Elements Essential for Designing and Presenting the Minimum Data Set for the Better Management of Diabetic Foot Based on Data Elements

Category	Data elements	1st round Delphi		2nd round Delphi	
		Mean (± SD	Final approval or rejection of entry to the second round of Delphi	Mean (± SD)	Final approval or rejection
Demographic Items	Patient's name	4.57 (± 0.53)	√		√
	Patient's family	4.57 (± 0.53)	√		√
	Date of birth	3.83 (± 0.71)	√		√
	Gender	4.53 (± 0.51)	√		√
	Medical record number	3.83 (± 0.71)	√		√
	Father's name	2.36 (± 1.12)	×		×
	Marital status	2.41 (± 0.51)	×		×
	Indigenous status	2.33 (± 0.88)	×		×
Hospitalization	The main reason for hospitalization	4.53 (± 0.63)	√		√
					×
	bedsore	3.60 (± 1.12)	*	2.57 (± 1.27)	√
	Surgery	4.33 (± 0.72)	√		√
	Deep wounds, infections, and amputations	4.54 (± 0.51)	√		
Laboratory tests and examinations	Hemoglobin A1C	4.27 (± 0.88)	√		√
	microalbuminuria test	3.53 (± 1.06)	*	3.29 (± 1.89)	×
	Pathologic tests	3.83 (± 0.71)	√		√
	Blood pressure (systolic or diastolic)	3.80 (± 0.86)	√		√
	Abnormalities of blood lipid levels	3.40 (± 1.05)	*	3.86 (± 1.46)	√
	Body mass index	3.60 (± 1.05)		3.86 (± 1.46)	√
	Diagnosis of neuropathy	4.57 (± 0.64)	√		√
Risk factors	High blood sugar	4.53 (± 0.51)	√		√
	Existence of neuropathy	4.57 (± 0.64)	√		√
	critical ischemia	4.86 (± 0.36)	√		√
	Foot deformity	4.60 (± 0.63)	√		√
	Peripheral Arterial Disease	4.80 (± 0.41)	√		√
	Osteomyelitis	4.67 (± 0.61)	√		√
	Callus	3.87 (± 0.83)	√		√
	Charcot's foot	4.27 (± 1.03)	√		√
	Foot temperature and anatomical location involved	4.57 (± 0.75)	√		√
	Foot plantar pressure and anatomical location involved	4.07 (± 0.82)	√		√
	Dry feet	4.14 (± 0.77)	√		√
	Sufficient moisture in the feet	4.21 (± 0.69)	√		√
	Unfitting shoes	4.64 (± 0.63)	√		√
	Failure to wash and dress wounds regularly	4.20 (± 0.77)	√		√
	Foot ulcers	4.80 (± 0.41)	√		√
	Existence of infection and inflammation in the foot	4.53 (± 0.64)	√		√
	Gangrene	4.73 (± 0.45)	√		√
	Amputation	4.73 (± 0.45)	√		√
	Proper rest and sleep	2.44 (± 0.63)	×		×

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Table 4 (cont.). Administrative and Clinical Data Elements Essential for Designing and Presenting the Minimum Data Set for the Better Management of Diabetic Foot Based on Data Elements

Category	Data elements	1st round Delphi		2nd round Delphi	
		Mean (± SD	Final approval or rejection of entry to the second round of Delphi	Mean (± SD)	Final approval or rejection
History	Type of diabetes (type 1, type 2, and gestational diabetes)	3.80 (± 0.86)	*	3.86 (± 1.46)	√
	Duration of suffering from diabetes	4.53 (± 0.74)	√		√
	Duration of suffering from foot ulcers	4.67 (± 0.48)	√		√
	Hospitalization (date of first and last time of hospitalization and frequency of hospitalizations)	4.66 (± 0.48)	√		√
	Date of last foot examination	4.47 (± 0.64)	√		√
	Number of foot examinations during the last month	3.87 (± 0.83)	√		√
	Date of last vascular examination of lower extremities	4.00 (± 0.84)	√		√
	History and presence of foot ulcers	4.53 (± 0.64)	√		√
	History of disease and osteoporosis	3.00 (± 0.84)	*	×	
	History of foot surgery	4.33 (± 0.72)	√		√
	History and presence of foot sores	4.60 (± 0.63)	√		√
	Amputation	4.73 (± 0.45)	√		√
	Other high-risk diseases (for example, high-risk cardiovascular disease, retinopathy, nephropathy, atherosclerosis, etc.)	4.43 (± 0.64)	√		√
	Start date of previous treatment	4.53 (± 0.64)	√		√
	End date of previous treatment	4.40 (± 0.82)	√		√
Amputation	Left foot or right foot	4.53 (± 0.64)	√		√
	Anatomical location of site amputated	4.60 (± 0.63)	√		√
Symptom and sing	Swelling, blisters, and redness on the feet	4.53 (± 0.64)	√	3.29 (± 1.89)	√
		4.40 (± 0.63)	√	2.83 (± 1.32)	√
	Vital signs of the patient	3.58 (± 0.90)	*	2.43 (± 1.61)	
	Diabetic distress	3.27 (± 1.03)	*		
	Skin conditions	4.40 (± 0.63)	√		√
	Wound burning, numbness,	4.53 (± 0.51)	√		√
	weakness, cramping, or pain in	4.60 (± 0.73)	√		√
	the legs	3.60 (± 1.29)	*		*
	Wound type (neuropathy or	4.53 (± 0.74)	√		√
	non-neuropathy)	4.67 (± 0.61)	√		√
	Wound severity	4.33 (± 0.72)	√		√
	Wounded foot (left or right)	4.53 (± 0.64)	√		√
	exact anatomical location	4.53 (± 0.64)	√		√
	Involvement of tendon or bone	4.27 (± 0.88)	√		√
	Number of wounds	4.21 (± 0.80)	√		√
	Length of wound	4.21 (± 0.80)	√		√
	Depth of wound	4.80 (± 0.41)	√		√
	Smell of wound	4.40 (± 0.91)	√		
	Ipsilateral foot				
	Contralateral foot				
	Infection on the foot				
	Anatomical location of the involved infection				

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Table 4 (cont.). Administrative and Clinical Data Elements Essential for Designing and Presenting the Minimum Data Set for the Better Management of Diabetic Foot Based on Data Elements

Category	Data elements	1st round Delphi		2nd round Delphi	
		Mean (± SD	Final approval or rejection of entry to the second round of Delphi	Mean (± SD)	Final approval or rejection
Medication	Analgesics	4.21 (± 0.80)	√		√
	Systemic antibiotics	4.47 (± 0.64)	√		√
	Administered insulin	4.53 (± 0.51)	√		√
	Medication adherence	4.53 (± 0.51)	√		√
	Drug dose	2.37 (± 0.84)	×		×
Treatment and processes	Pharmacotherapy	4.13 (± 0.74)	√		√
	critical ischemia	4.73 (± 0.59)	√		√
	Controlling infections and wound ulcers	4.47 (± 0.64)	√		√
	Surgical intervention	4.33 (± 0.72)	√		√
	Proper medical footwear	4.64 (± 0.63)	√		√
	Removal of callus	3.87 (± 0.83)	√		√
	Regular and periodic foot examination by a doctor	4.53 (± 0.63)	√		√
	Wound debridement	4.60 (± 0.63)	√		√
	Ulcers healed	4.67 (± 0.61)	√		√
	Type of wound dressing (Hydrogel dressing, Alginate dressing, Hydrofibre dressing, Foam dressing, Hydrocolloid dressing, and Other dressings)	3.71 (± 0.82)	*	3.71 (± 0.95)	√
	washing and dressing wounds over a period of time (e.g. week or month)	4.07 (± 0.70)	√		√
Prevention	Medical advice to patients	4.33 (± 0.61)	√		√
	Educating patients	4.60 (± 0.50)	√		√
	Metabolic Control	2.41 (± 0.51)	×		×
	Preventive Foot Wear	4.64 (± 0.63)	√		√
	Preventive Surgery	4.66 (± 0.48)	√		√
Remote services	pictures of the sole of the foot and its wounds	4.60 (± 0.50)	√		√
	videos of the sole of the foot and its wounds	4.29 (± 0.82)	√		√
	remote screening services	4.00 (± 0.96)	√		√
	Media and social networks as a tool for communicating with providers	4.60 (± 0.50)	√		√
Laser therapy	Left or right foot	3.60 (± 1.29)	*	2.83 (± 1.32)	×
	Precise anatomical site	4.60 (± 0.63)	√		√
Rehabilitation	Ulcer management	2.33 (± 0.82)	*		*
	Post-amputation rehabilitation	4.60 (± 0.63)	√		√
Life style	Smoking and alcohol consumption	4.33 (± 0.90)	√		√
	Nutrition	4.13 (± 0.91)	√		√
	Level of physical activity during the day	4.21 (± 0.97)	√		√
	Proper rest and sleep	2.44 (± 0.63)	×		×

Note: * Assessment in Second Round of Delphi, ×: Final exclusion and √: Final Acceptance

performed in the format of a paper; (2) Studies that have identified the complications and risk factors of diabetic foot. Nonetheless, these studies have not offered any data sets and have considered only a small number of data elements related to the complications and risk factors of diabetic foot [24]; and (3) Studies that have introduced the data elements of diabetes itself and have also mentioned a limited number of data elements regarding diabetic foot complication [26].

Based on the findings of the study, among all the confirmed data elements, ischemia or critical ischemia was recognized as the most important data element by experts. After critical ischemia, peripheral artery disease(PAD) and the presence of infection in the foot were both ranked second, having equal means. Kalish and Hamdan [28] identified ischemia, neuropathy, and infection as the three most significant pathological components of the diabetic foot leading to acute complications in the foot. Mays [29] also stated that the three important components of peripheral arterial disease, ischemia, and infection lead to tissue necrosis and formation of a wound in the foot. Weck et al. [30] reported that patients with a diabetic foot would be at higher risk for amputation if they had critical ischemia, especially if timely revascularization of the limb is not performed. Correspondingly, this complication can lead to high medical costs and severe pains within the patients.

Naemi et al. [32] also identified diabetic foot infection is a prevalent complication in patients with diabetes as well as an important risk factor for amputation. The significance of this data element is such that it has been reported in some studies that about 10 to 15% of diabetic patients suffer foot infections during their lifetime [28]. According to the above statement, since each of the above data elements can lead to complications such as the high risk of tissue necrosis and ulceration of the foot, as well as high medical costs, severe pains within the patient, amputation, and even death, the importance of these issues was not ignored by the participants, as ischemia, peripheral artery disease and the presence of infection in the foot were met with highest scores by the experts.

Moreover, among all data elements, the lowest mean score pertained to abnormalities in blood lipids levels and body mass index, and type of diabetes with an average of 3.86 (77%). Pei et al. concluded in their study that HDL cholesterol has a significant relationship with diabetic foot syndrome, but there was no significant relationship evident between diabetic foot and LDL, TC, or TG cholesterol levels [33]. Sohn et al. showed that there is a significant relationship between diabetic foot ulcers and BMI [34]. However, there may be no correlation between BMI and duration of hospital stay in the studied patients [35]. After studying the impact of the type of diabetes on diabetic foot in some studies, their authors have concluded that the type of diabetes has no statistically significant effect on the frequency of amputations or the time needed for the wound to heal [36]. Therefore, according to these studies and the lowest mean scores obtained by researchers for these three elements in the current, it should be said that although abnormalities in blood lipids levels, BMI, and type of diabetes may not have significant effects on the exacerbation of diabetic foot, since the diabetic foot is the most important and financially expensive complication of diabetes, these important data elements should nonetheless not be neglected in the treatment of people with diabetic foot [1, 2].

Among the limitations of this study is that according to the rudimentary surveying of the author, no prior minimum data set with a focus on patients with the diabetic foot has been proposed thus far, and therefore, other minimum data sets related to diseases other than the diabetic foot was employed to gain primary insight into MDSs. Therefore, it is recommended to conduct similar studies in accordance with the culture, needs, and clinical facilities of each country to introduce effective indicators in the better management, control, and monitoring of diabetes. Moreover, in order to prove the applicability of this data set, it is suggested that in case researchers are willing to design and evaluate any software or systems related to the management and control of the diabetic foot, this MDS be used as basic knowledge and foundation for designing the system and software. The experts participating in the first and second rounds of Delphi in this study were 15 people. More comprehensive results are likely to be obtained if more participants were included in the study. furthermore, the reliability of the questionnaire was assessed by having it completed by only 15 people, yet a larger sample size would yield more accurate results regarding its reliability.

Conclusions

In this study, a minimum data set was designed and presented with the purpose of providing a foundation for the identification of effective indicators in the management, control, and monitoring of diabetic foot. By proposing this MDS as a practical framework, policymakers, planners, software developers, and health data managers are assisted in designing different systems or software programs (based on computers or web and mobile applications), such as registries, electronic health records, personal health records, or any type of self-care or self-management program for patients

with diabetes, ultimately enabling the professionals to know what information should be included in their system to meet the needs of patients with diabetes. Moreover, this MDS enables the standardization of medical services in hospitals, clinics, and health centers and emphasizes on collection of data related to diabetic foot as basic knowledge. This MDS can also be employed to obtain comprehensive insights into the various health care policies related to the issues of the diabetic foot, which will, in turn, lead to improved quality of care and reduced costs.

Acknowledgments

The authors would like to hereby express their gratitude to the Student Research Committee of Kerman University of Medical Sciences for the financial support (grant number: 98000963).

Conflict of interest

None declared.

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