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Development of a Minimum Data Set for Dental Implants Registry

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A B S T R A C T

Objectives: Registries are powerful tools for the collection and distribution of valid and reliable data. The initial step in health information management is to design a minimum data set that can improve the collection of high-quality data from the registry. The present pilot study aimed to determine the optimal minimum data set for dental implants to effectively utilize at Tehran University of Medical Sciences, Tehran, Iran.

Materials and Methods: This descriptive cross-sectional study was conducted in 2019 at Tehran University of Medical Sciences. A minimum data set checklist was developed based on our previous systematic review. The content validity of the minimum data set was approved by the recruited experts and the final minimum data set was established using the Delphi technique.

Results: The minimum data set for dental implants consists of two separate sections - administrative and clinical data. The administrative portion includes two main segments: patient demographic data and clinic data, consisting of 12 data elements. The clinical part includes five main segments (patient clinical data, implant data, implant complications, implant loss, and implant follow-up), and contains 96 data elements.

Conclusion: This study suggests a minimum set of data for dental implants that can aid in efficient management of information, facilitate evidence-based decision-making, and enable high-quality clinical research, evaluation of treatment results, monitoring, and benchmarking of care.

Keywords: Dataset; Dental Implants; Registries

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INTRODUCTION

Dental implants have evolved as a strategy to rebuild missing teeth [1] and bring back chewing function and aesthetics to patients [2]. The success rate of this procedure is 82.9% after 16 years of follow-up [3]. Furthermore, over the previous decades, this approach to oral restoration has become commonplace worldwide [4]. As a result, the rate of dental implants has increased from 0.7% during 1999-2000 to 5.7% during 2015-2016. Dental implant statistics are predicted to grow to 23% in 2026

[5]. On the other hand, complications of dental implants can appear at early or late stages. Infection, pain, and failure to restore soft tissue are identified as early complications of dental implants [6]. Another complication is peri-implantitis, which is quickly increasing with the increase of dental implants [7]. It has grown as one of the most common complications of dental implants. The prevalence rate of peri-implantitis is within the range of 5-63.4%. In patients with a 10-year history of dental implants, the chance of peri-implantitis is approximately 10-50% [8].

It should be noted that reporting dental implant complications, including peri-implantitis, also has some challenges [7]. These challenges are related to small sample sizes, short time follow-up, and various study settings [9]. These issues make determination of the global incidence of dental implant complications very difficult [9]. Moreover, rare studies have been performed on the therapeutic results of various implants, the long-term treatment outcomes on different populations, the surgical method, prosthetic materials, and procedures [10].

With the tendency of dentists to make evidence-based decisions, the need for high-quality reports is increasing [11]. In Sweden [12], the USA [13-17], Canada [18], Germany [19], Finland [20], Australia [21], and South Korea [22], a dental implant registry is used to overcome these challenges [7]. Registries are powerful means for data collection from a broader population base. Therefore, their findings have great external validity for clinical research, evaluation of treatment outcomes, clinical follow-up, monitoring the performance of healthcare providers, maintenance of healthcare at an optimal level, and increase of patient safety [10,23,24].

The product of a registry is data, and quality in the registry refers to the quality of data for presentation to policymakers, planners, and health service providers [25]. Data quality has been judged by completeness, validity, coherence, comparability, accessibility, efficiency, usefulness, timeliness, representativeness, and prevention of duplicate records [26]. One of the issues that affect data quality is the absence of uniformity of data. Uniform and predetermined data sets are very useful for multi-institutional studies [24].

Many countries, to achieve quality data, use the developed Minimum Data Set (MDS) [24], which is a standard instrument for benchmarking, reporting, clinical and strategic planning, return on investment, data sharing, and obtaining new and better clinical knowledge [27]. However, dental implant data is not centrally collected, and is not accessible for analysis by dentists in Iran [28] and many developing countries. Therefore, setting an MDS improves the collection of high-quality data from the registry [25].

Given that there has not been a registry system for dental implants in Iran until now, the development of an MDS seems to be necessary. Therefore, we took the first step to determine the MDS at the level of Tehran University of Medical Sciences (TUMS) as a pilot study. Provided that the findings of this research are positive and useful, our team has decided to implement them on a larger scale at a national level in the future. Moreover, it is imperative that we gather the opinions of experts from other universities in Iran to ensure a complete and holistic approach to creating an MDS.

MATERIALS AND METHODS

This study was approved by the Research Ethics Committee of Tehran University of Medical Sciences (IR.TUMS.SPH.REC.1397.295) and performed in the following steps: a) systematic review and preparation of drafts of MDS, b) calculation of validity of the checklist, and c) presentation of the final version of MDS through the Delphi technique.

Systematic review and preparation of the Minimum Data Set drafts

Initially, a systematic review of the dental implant registry system was carried out to define the MDS of dental implants. In this regard, an investigation was performed in the databases of Web of Science, Embase, PubMed, and Scopus up to February 2019 [29]. After selection of the articles based on inclusion criteria, the studies were categorized and the dental implants data elements were listed. In addition, by referring to the Dental Implant Research Center of TUMS, the medical records of the patients referred during in the first quarter of 2019 were reviewed and their data elements were collected. Afterward, the data elements found in various sources were entered

into the Excel spreadsheets and after removal of the duplicates, the list was provided to the members of the research team (including two dentists with experience in the field of dental implants). Several meetings were held with the research team, after which the drafts of data elements were prepared.

Calculation of the validity of the checklist

Data draft elements consisted of two parts, namely the administrative data (17 data elements) and the clinical data (105 data elements). To calculate the content validity ratio) CVR (the proposed MDS was based on the opinions of 11 TUMS specialists (including four oral, maxillofacial surgeons, four periodontics, and three prosthodontics). Experts were asked to categorize each proposed data element based on a Likert scale (essential, useful but unnecessary, and unnecessary scale). After the collection of the views of experts, this formula was used to confirm the CVR:

$$CVR=(Ne-N/2)/(N/2)$$

In this formula, 'Ne' expresses the number of 'essential' choices, and 'N' expresses the total number of specialists. According to the number of experts who evaluated the data elements (11 experts in this study), the minimum acceptable CVR value was determined based on the Lawshe table value for each data element [30]. Data elements whose calculated CVR value was less than the desired value, given the number of experts evaluating the proposed MDS, were excluded. Since they were based on CVR, they did not have acceptable validity.

The data elements for which the calculated CVR value was higher than or equal to the desired value according to the number of experts evaluating the proposed MDS remained in the list of data elements since based on the obtained CVR, they had acceptable validity. After calculation of the CVR for each data element, elimination of some of the data elements, and application of the proposed corrections, a five-point Likert scale ranging from 1 (very low importance) to 5 (very high importance) was prepared for determination of the level of agreement or disagreement of the dentists on each data element. It should be noted that a five-point Likert scale was used to minimize the central bias and also encourage experts to express different opinions [31].

Presentation of the final version of the Minimum Data Set through the Delphi technique

Research experts for the determination of the final data elements of the dental implant registry were oral and maxillofacial surgeons, periodontists, and prosthodontists, who were all faculty members of dentistry affiliated to TUMS. The Delphi technique was used to collect their opinions and reach a census [32]. The census approach was used within 3 months for the 55 experts in the abovementioned fields, 27 of whom completed the checklist (Table 1).

Table 1. Demographic characteristics of participants in the Delphi technique

Characteristics		N
Specialty	Oral and maxillofacial surgeons	9
	Periodontics	7
	Prosthodontics	11
	Total	27
Gender	Female	10
	Male	17
Age group (years)	20-29	1
	30-39	7
	40-49	9
	50-59	10
Work experience (years)	<5	5
	5-10	6
	10-20	6
	>20	8

Results were evaluated and the MDS of the dental implant registry system was determined by calculation of the level of agreement or disagreement from the points of view of dentists for each data element. For data analysis, obtained agreement scores were entered into SPSS software (version 23) and the midpoint for each data element was calculated. In this way, data elements that had less agreement than the midpoint (0-2.5) were removed from the checklist, and agreements between 2.5-3.75 were entered into the second round of Delphi to be re-examined and revised. Besides, if the middle point of each data element was 3.75-5, it remained in the checklist and was entered into the next round of Delphi. Since in this study, all data elements obtained

an agreement above 3.75, the Delphi was performed in one round.

RESULTS

Systematic review and preparation of the Minimum Data Set drafts

In total, 5,565 studies were extracted in our initial search. After the removal of the duplicates and screening based on inclusion and exclusion criteria, 11 studies were included in the systematic review [29]. According to these 11 studies, MDS of dental implants was suggested with a total of 122 data elements that were divided into administrative and clinical parts.

1) The administrative part consisted of two main sections, as follows:

1.1. Clinic data

1.2. Patient demographic data

2) The clinical part consisted of five main sections, as follows:

2.1 Patient clinical data with three sub-sections, as follows:

a) Medical history, b) Oral health, c) Bone data

2.2 Implant data

2.3 Implant complications with three sub-sections, as follows:

a) During or after surgery complications, b) Prosthetic events, c) Biological events

2.4 Implant loss

2.5 Implant follow-up.

Data elements of Branemark Clinic, Sweden [12], some universities of the USA [13-17], Toronto, Ontario, Canada [18], Department of Oral Surgery and Implantology of the Frankfurt University Germany [19], Finland [20], Royal Dental Hospital in Melbourne, Australia [21], and Yonsei University, South Korea [22], and the medical records of Dental Implant Research Center of TUMS are summarized in Tables 2 and 3. In the administrative section, gender and date of birth data elements observed in all countries were included in the study. Based on the findings, the date of operation, implant brand, implant region, total implant placements, and follow-up dates in the clinical section were observed in 100% of the data elements.

Calculation of validity of the checklist

The critical value of CVR for 11 experts was 0.59, according to the Lawshe table. In this study, the criterion for maintenance or elimination of the proposed data elements was considered with the same amount. As described in the methods section, data elements with a CVR of less than 0.59 were deleted, and data elements with a CVR of greater than or equal to 0.59 remained in the study.

Tables 2 and 3 show the list of data elements along with the CVR value obtained for each data element. Data elements of the administrative section included 17 items that were reduced to 12 items after CVR. After calculation of the CVR for each data element in the administrative section, the code, address, and telephone number of the dental office were removed from the clinic data section, and also the place of birth and marital status were removed from the demographic section (Table 2).

The clinical data elements were 105 cases, which were reduced to 96 after the calculation of the CVR (Table 3). Therefore, in the medical history subsection, Down syndrome, menopausal status, and history of hospitalization/surgery were excluded. Furthermore, the type of modeling was removed from the implant data section. Moreover, from the prosthetic events subsection, "loose opposite over-denture" and the "distorted implant platform body" were excluded. Besides, follow-up by a dental practitioner or dental hygienist was removed from the implant follow-up section.

Presentation of the final version of the Minimum Data Set through the Delphi technique

After the calculation of the CVR and elimination of 14 data elements from the administrative and clinical section, the rest of the data elements were sent to the research experts to determine the final MDS. The experts for determination of the final data elements of the dental implant registry were 27 dentists. Table 1 tabulates the demographic characteristics of the experts.

According to the explanation given earlier in the methods section, all data elements reached an agreement above 3.75; therefore, there was no need to hold further rounds, and this phase of the study was performed in one step. All of these data elements (108 items) after the calculation of the CVR earned the third quartile (3.75-5) score. The results of the Delphi technique and agreement mean scores are summarized in Tables 2 and 3.

Table 2. Content validity ratio and mean value in administrative minimum data set for dental implants

Administrative data	Category	N	Minimum Data Set	Branemark Clinic, Sweden [12]	Columbia University, USA [13]	Veterans Affairs, USA [14]	Mayo Clinic, USA [15]	Jacksonville Clinic, USA [16]	Arizona, USA [17]	Toronto, Ontario, Canada [18]	Frankfurt, Germany [19]	National Institute for Health in Finland [20]	Melbourne, Victoria, Australia [21]	Yonsei University, Seoul, Korea [22]	Clinical records & consultation with dentists	Content validity ratio	Accept/Reject	Mean
	Clinic data	1	Name of the dental office	✓	✓	✓	✓✓	✓	✓	✓	✓		✓	✓	✓	0.66	✓	3.88
		2	Code of the dental office												✓	0	*	-
		3	Address of the dental office												✓	0	*	-
		4	Telephone number												✓	0	*	-
		5	Dental specialist affiliation	✓	✓	✓					✓	✓	✓	✓	✓	0.66	✓	4.44
	Demographic data	6	Patient ID											✓	✓	0.66	✓	4.23
		7	First name												✓	0.66	✓	4.03
		8	Last name												✓	0.66	✓	4.03
		9	Gender	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.66	✓	4.29
		10	National Code									✓			✓	0.66	✓	3.88
		11	Address (country, city, telephone, cell phone, email)												✓	0.66	✓	4.03
		12	Date of birth	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.66	✓	4.25
		13	Place of birth												✓	0	*	-
		14	Occupation												✓	0.66	✓	3.81
		15	Marital status												✓	0	*	-
		16	Education												✓	0.66	✓	3.85
		17	Insurance												✓	0.66	✓	3.76

According to the Lawshe table, the content validity ratio value for 11 experts was 0.59.
If the obtained content validity ratio is less than 0.59, it will be deleted and marked with *.
If the obtained content validity ratio is higher than 0.59, it is accepted and marked with a check mark.

Table 3. Content validity ratio and mean amount in clinical minimum data set

Category		No	Minimum Data Set	Branemark Clinic, Sweden [12]	Columbia University, USA [13]	Veterans Affairs, USA [14]	Mayo Clinic USA [15]	Jacksonville Clinic, USA [16]	Arizona, USA [17]	Toronto, Ontario, Canada [18]	Frankfurt, Germany [19]	National Institute for Health in Finland [20]	Melbourne, Victoria, Australia [21]	Yonsei University, Seoul, Korea [22]	Clinical records & consultation with	Content validity ratio	Accept/Reject	Mean
Patient clinical data	Medical history	1	Cardiovascular condition		✓		✓		✓		✓			✓	✓	0.83	✓	4.51
		2	Abnormal blood pressure		✓		✓							✓	✓	0.83	✓	4.44
		3	Hematologic disease												✓	0.83	✓	4.38
		4	Anemia												✓	0.66	✓	4.29
		5	Brain disease												✓	0.66	✓	4.11
		6	Digestive disease				✓								✓	0.66	✓	4.14
		7	Thyroid disease												✓	0.83	✓	4.40
		8	Kidney disease												✓	0.66	✓	4.37
		9	Respiratory disease												✓	0.83	✓	4.22
		10	Hepatitis												✓	1	✓	4.53
		11	Metabolic condition				✓								✓	0.83	✓	4.48
		12	Diabetes mellitus		✓		✓		✓				✓	✓	✓	1	✓	4.66
		13	Mental illness								✓				✓	0.83	✓	4.59
		14	Immunosuppressive condition				✓								✓	1	✓	4.62
		15	Human immunodeficiency virus		✓		✓								✓	1	✓	4.62
		16	Malignant neoplasm				✓								✓	0.66	✓	4.40
		17	Rheumatoid arthritis				✓								✓	0.83	✓	4.51
		18	Parkinson's disease				✓								✓	0.66	✓	4.44
		19	Oral bisphosphonate therapy				✓		✓						✓	0.66	✓	4.51
		20	Chemotherapy/radiotherapy				✓		✓						✓	0.66	✓	4.55
		21	Transplant				✓								✓	0.66	✓	4.59
		22	Osteoporosis				✓						✓	✓	✓	0.66	✓	4.55

		23	Allergy				✓							✓	0.66	✓	4.22
		24	Down syndrome			✓								✓	0.33	*	-
		25	Blood transfusions or blood products											✓	0	*	-
		26	Pregnancy											✓	0.66	✓	4.22
		27	Postmenopausal status			✓								✓	0.16	*	-
		28	History of other diseases		✓		✓							✓	0.66	✓	4.26
		29	History of hospitalization/surgery											✓	0	*	-
		30	Smoking habits/alcohol consumption		✓			✓	✓	✓		✓		✓	1	✓	4.70
		31	Medication consumption	✓	✓					✓				✓	0.66	✓	4.3
	OH	32	Oral hygiene (good/fair/poor)		✓				✓					✓	1	✓	4.81
	OH	33	Decayed, missing, and filled teeth											✓	0.83	✓	4.25
	OH	34	Periodontics condition		✓		✓		✓		✓			✓	1	✓	4.77
	Bone	35	Bone volume	✓				✓	✓	✓				✓	1	✓	4.81
	Bone	36	Bone quality	✓			✓		✓	✓	✓		✓	✓	1	✓	4.81
Implant data		37	Date of operation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.83	✓	4.44
Implant data		38	Implant placement reason						✓					✓	0.66	✓	4.14
Implant data		39	Cause of tooth loss										✓	✓	0.66	✓	4.29
Implant data		40	Implant brand	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.83	✓	4.4
Implant data		41	Implant system (bone level/tissue level)	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	1	✓	4.48
Implant data		42	Implant length	✓	✓				✓	✓	✓	✓	✓	✓	✓	1	✓	4.48
Implant data		43	Diameter of implant	✓	✓				✓	✓	✓	✓	✓	✓	✓	1	✓	4.55
Implant data		44	Abutment type	✓				✓	✓	✓	✓		✓		✓	0.66	✓	4.5
Implant data		45	Internal or external connection		✓			✓		✓			✓		✓	0.83	✓	4.22
Implant data		46	Implant region	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1	✓	4.55
Implant data		47	Implant proximity											✓	1	✓	4.4
Implant data		48	Type of implantation		✓			✓	✓					✓	1	✓	4.62
Implant data		49	Total implant placements	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.66	✓	4.25
Implant data		50	Installation procedure (one stage, two stages)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.83	✓	4.51
Implant data		51	Type of anesthesia					✓	✓					✓	0	*	-

		52	Implants supportive technique for hard tissue	✓	✓			✓	✓		✓			✓	✓	✓	1	✓	4.55
		53	Implant supportive technique for soft tissue	✓	✓			✓	✓		✓			✓	✓	✓	1	✓	4.55
		54	Required time for healing			✓			✓		✓			✓	✓	✓	0.83	✓	4.4
		55	Prosthetic design	✓	✓	✓			✓	✓	✓				✓	✓	1	✓	4.5
		56	Attachment to the natural teeth													✓	0.83	✓	4.23
		57	Loading time	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓	1	✓	4.61
		58	Type of molding	✓												✓	0.5	*	-
		59	Cement/screw-retained prosthesis	✓	✓			✓	✓	✓	✓			✓		✓	0.66	✓	4.23
		60	Uncovering time			✓			✓	✓	✓				✓	✓	0.66	✓	4.44
		61	Sinus perforation											✓	✓	✓	0.83	✓	4.48
		62	Neural damage											✓		✓	0.83	✓	4.51
		63	Mobility							✓						✓	1	✓	4.59
		64	Dehiscence											✓	✓	✓	0.83	✓	4.51
		65	Proximity													✓	0.83	✓	4.48
		66	Soft tissue enlargement													✓	0.83	✓	4.55
		67	Gingival recession					✓								✓	0.83	✓	4.55
		68	Suppuration and abscess											✓	✓	✓	0.83	✓	4.55
		69	Other complications					✓			✓			✓	✓	✓	0.66	✓	4.3
		70	Lip/cheek biting													✓	0.66	✓	4.3
		71	Inappropriate fixture position		✓									✓		✓	0.83	✓	4.44
		72	Change in opposing dentition													✓	1	✓	4.28
		73	Loose opposite denture													✓	0.83	✓	4.32
		74	Loose screw								✓			✓		✓	0.66	✓	4.46
		75	Fractured screw						✓					✓		✓	0.83	✓	4.42
		76	Loose O-rings													✓	1	✓	4.46
		77	Abutment screw loosening													✓	0.66	✓	4.42
		78	Abutment screw fracture											✓		✓	0.83	✓	4.42
		79	Multiple abutment screw fracture													✓	0.83	✓	4.36
		80	Multiple abutment screw loosening													✓	0.66	✓	4.36
		81	Sub-prosthesis cleaning problem		✓									✓		✓	0.66	✓	4.28

	82	Prosthesis/tooth fracture							✓			✓			✓	0.66	✓	4.3
	83	Prosthesis tooth wear													✓	0.83	✓	4.3
	84	Broken tooth on opposite denture													✓	0.66	✓	4.19
	85	Broken opposite denture													✓	0.83	✓	4.26
	86	Loose opposite denture													✓	0.66	✓	4.11
	87	Loose opposite over-denture													✓	0.5	*	-
	88	Fractured acrylic base													✓	0.66	✓	4.15
	89	Distorted implant platform/body		✓											✓	0.5	*	-
	90	Other complications		✓				✓	✓			✓			✓	0.66	✓	4.04
Biological events	91	Inflammatory lesions caused by implant		✓			✓	✓	✓			✓	✓		✓	1	✓	4.57
	92	Paresthesia													✓	0.83	✓	4.53
	93	Periapical radiolucency													✓	1	✓	4.5
	94	Infection		✓				✓	✓			✓	✓		✓	1	✓	4.61
	95	Mobile implant						✓	✓						✓	1	✓	4.65
	96	Other complications													✓	0.83	✓	4.34
Implant Loss	97	Time of implant removal	✓		✓	✓		✓	✓	✓	✓	✓	✓		✓	0.83	✓	4.62
	98	Reason for removal						✓	✓	✓	✓	✓	✓	✓	✓	1	✓	4.62
	99	Follow-up by a general practitioner, a dental specialist, or a dental hygienist		✓											✓	0.33	*	-
	100	Follow-up dates	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.83	✓	4.33
	101	Clinical/radiological manifestations	✓	✓				✓	✓	✓			✓		✓	0.83	✓	4.48
	102	Survival rate			✓	✓	✓	✓	✓		✓	✓	✓		✓	0.66	✓	4.4
	103	Success rate			✓					✓	✓				✓	0.83	✓	4.55
	104	Implant condition (mobility, bleeding on probing, & bone loss)		✓			✓	✓		✓	✓	✓	✓		✓	1	✓	4.51
	105	Treatment for possible complications					✓								✓	0.83	✓	4.37

Implant follow-up

According to the Lawshe table, the content validity ratio value for 11 experts was 0.59.
If the obtained content validity ratio is less than 0.59, it will be deleted and marked with *.
If the obtained Content Validity Ratio is higher than 0.59, it is accepted and marked with a check mark
OH: Oral health

Ultimately, the proposed MDS for the dental implants was specified. In the proposed MDS in Table 2, in the clinic data section, the dental specialist name had the highest mean value (4.44) while in the demographic data section, the gender had the highest mean value (4.29); however, the insurance had the lowest mean value (3.76). In the subsection of medical history, the highest mean value was related to smoking habits/alcohol consumption (4.7), while the lowest mean value was related to brain disease (4.11).

In the oral health subsection, oral hygiene had the highest mean value (4.81), and the lowest mean value was related to decayed, missing, and filled teeth (DMFT) (4.25). In the bone data subsection, bone volume and bone quality had the highest mean values (4.81). In the implant data section, the highest mean value was related to the type of implantation and implant supportive technique for hard tissue (4.62), while the lowest mean value was related to cause of tooth loss (4.14). In the subsection of during or after surgery, the highest mean value was related to mobility (4.59), and the lowest mean value was related to other complications (4.3).

In the prosthetic events subsection, the loose screw and loose O-rings had the highest mean value (4.46), while the lowest mean value was related to other complications (4.04). In the biological events subsection, the highest mean value was related to the mobile implant (4.65), and the lowest mean value was related to other complications (4.34). In the implant loose section, the time of implant removal and the reason for the removal had the highest mean values (4.62). In the implant follow-up section, the highest (4.55) and lowest (4.33) mean values were related to the success rate and follow-up dates, respectively (Table 3).

DISCUSSION

Dental implants have become commonplace throughout the world. However, according to previous studies, dental implant data have not been collected in a standard way in many countries, including Iran. Based on our findings, the MDS for dental implants consists of administrative and clinical sections. The administrative section includes clinic data and patient demographic data subsections. Moreover, the clinical section had five subsections, including patient clinical data, implant data, implant complications, implant loss, and implant follow-up.

Similar to other MDS in the field of orthopedic injuries [33], burn injuries [34], and speech therapy [35], the MDS of dental implants was divided into administrative and clinical sections. In the administrative section, most of the dental implant registers reviewed data elements of the dental office names as well as the affiliation, gender, and date of birth of dental specialists [12-16]. In Finland, in addition to the data elements mentioned above, the national code was also included as one of the data elements [20]. In the present study, based on the opinions of experts, in addition to the above-mentioned data elements, several other items were considered as data elements in the administrative section, including patient ID, first name, last name, address, occupation, education, and insurance.

The database of Mayo Clinic in Rochester, Minnesota contained the following data elements as a systemic condition: cardio-vascular condition, abnormal blood pressure, digestive disease, metabolic condition, diabetes mellitus, immunosuppressive condition, human immunodeficiency virus, malignant neoplasm, rheumatoid arthritis, Parkinson's disease, oral bisphosphonate therapy, chemotherapy/ radiotherapy, trans-plant, osteoporosis, Down syndrome, postmenopausal status, and other diseases. This study was performed to examine the relationship between systemic conditions and dental implant failure [15]. In the current investigation, these data elements were placed in the medical history subsection. Down syndrome and postmenopausal status scored less than 0.59 and were eliminated from the proposed data set, and the rest of the data elements were approved by the experts. All implant survival studies included the date of operation, implant brand, implant region, and total implant placement elements [12, 14, 16,17,19,21]. In the present study, these data elements were considered in the final data elements with a score higher than 3.75.

The Royal Dental Hospital of Melbourne database for the assessment of dental complication types consists of sinus perforation, neural damage, dehiscence, suppuration and abscess, inappropriate fixture position, loose screw, fractured screw, abutment screw fracture, sub-prosthesis cleaning problem, prosthesis/tooth fracture, inflammatory lesions caused by implant, infection, and other complications elements [21]. Complications of dental implants in the present study were divided into three categories, namely complications during surgery, biological complications, and prosthetics complications. All of these complications along with a wide range of complications extracted from the medical records of the Dental Implant Research Center of TUMS were approved by experts. Only two data elements, loose opposite over-denture and distorted implant platform/body, were removed from the proposed MDS with a CVR score of less than 0.59. The follow-up date was also one of the elements that were present in all the included studies [12-17] and was confirmed by experts in the present study.

The International Organization for Standardization [36] describes an MDS for dental implants on the topic (ISO 16498) since 2013, which includes patient identification, clinician identification, implant bodies, connection of components, adjunctive devices, and superstructure sections [36]. It should be noted that we did not have access to details of ISO 16498 to compare data elements of implant bodies, connection of components, adjunctive devices, and superstructure sections. However, the proposed MDS in the present study included implant complications, implant loss, and implant follow-up sections which are not defined in ISO 16498. This study was conducted to customize data elements based on the specific objectives, rules, conditions, standards, and stakeholder views of the registry, as these factors heavily influence its scope and design [37,38]. The results of the current investigation align with the data elements found in oral health MDS, particularly regarding information related to age, gender, mental illness, diabetes mellitus, and heart disease. The oral health section in this study consisted of tooth problems, periodontal problems, mouth pain, and any oral/dental problem [39]. In the present research, the oral health section contained oral hygiene, DMFT, and periodontics condition data elements. Moreover, chewing and swallowing problems were not considered in the data elements of this study.

Ireland et al. [39] claimed that in England, dentists and organizations of primary dental care reached an agreement regarding MDS in primary dental care using the Delphi technique, to measure oral health situation. The Delphi technique is a fast and effective method to obtain the opinion of a group of experts [40]. Therefore, in this study, this technique was utilized to assemble the viewpoints of experts and stakeholders.

Consensus of stakeholders on the MDS of the registry is one of the key principles for registry success and is strongly advised since the involvement of stakeholders in MDS design can lead to data completion [23]. Currently, in this study, the consensus of oral, maxillofacial surgeons, periodontics, and prosthodontics was used for MDS suggestion. However, it should be noted that all the experts in this research were affiliated with TUMS. Since this study was financed by the Dental Implant Research Center of TUMS as a pilot study, the data elements of the present study are consistent and limited to the needs and objectives of the registry in this university.

In the next steps, opinions of experts from other universities and provinces of Iran should be collected to provide a comprehensive MDS that can be expanded at the national level. If the goals and needs of the stakeholders are not identified and the stakeholders do not participate in the determination of the MDS, it will result in the resistance of dentists to complete the data and the failure of the registry.

One of the limitations of this study was the unavailability of the full texts of seven papers that were included in our systematic review. However, investigation of the clinical records on dental implants and consultation with dentists helped us to overcome this limitation. Another limitation of this study was the small number of articles in the field of dental implant registry as well as the absence of details and data elements of the registry, which led to their exclusion from

the study at the screening stage.

The data elements utilized in this study were derived from a comprehensive analysis of data elements from existing registries worldwide. We also incorporated expert consensus via the Delphi technique. It should be noted that the method of data element selection in the included studies was not specified. While our investigation collected relevant data elements based on the research objectives, not all data elements from registries were included. Furthermore, while expert input was solicited, the study solely consulted with experts affiliated with TUMS. To strengthen the robustness of future studies, it is recommended that expert opinions from other universities are also sought.

CONCLUSION

Numerous countries, including Iran, face the challenge of incomplete and inconsistent data sets for collecting, analyzing, and reporting information. With the introduction of the MDS for dental implants, dental professionals can utilize trustworthy and reliable data to make informed decisions, establish comparisons over time, and increase their knowledge. This MDS incorporates an administrative and clinical data section, including 122 essential data elements, ensuring accuracy and quality data reporting. Future studies at the national level are recommended to provide a comprehensive MDS.

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CONFLICT OF INTEREST STATEMENT

None declared.

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