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Original Article

Determining minimum data set for implementation of a ureteral stent registry system

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Abstract

***Background & Aims*:** The primary treatment for ureteric obstruction in modern urological practice is the placement of a ureteral stent. Likewise, a standard tool is needed for collecting the data to ensure the ureteral stent is removed. The purpose of this study is to identify the minimum data set (MDS) required for the ureteral stent registry at Urmia University of Medical Sciences.

***Materials & Methods*:** This research is a cross-sectional descriptive study conducted in two phases. The first phase extracted relevant data elements based on previous studies. In the second phase, a Delphi questionnaire was compiled and given to 20 urologists and experts in medical informatics and health information management using the data elements obtained from the first phase. The MDS of the system was determined during two Delphi steps. This study used descriptive statistics and SPSS software for data analysis.

***Results*:** A total of 78 data items were identified through analyzing various articles. After evaluating the results of the two stages of the Delphi questionnaire, the MDS for the ureteral stent registry was finalized with 63 data elements in 7 categories, including demographic information, social history, medical history, clinical information, diagnostic measures, treatment measures, and patient discharge.

***Conclusion*:** This study aimed to propose a MDS for the ureteral stent registry system. This data can greatly assist in effectively organizing information, supporting evidence-based decision-making, and facilitating high-quality clinical research. Furthermore, it enables the evaluation of treatment outcomes, monitoring of progress, and comparison of care standards.

***Keywords*:** Minimum data set, Registry system, Ureteral stent

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Introduction

In urologic surgery, ureteral stents are helpful devices. The primary objective of the ureteral stent is to allow urine to pass, reducing early or late complications associated with urinary tract obstruction (1). The implantation of ureteral Double-J (DJ) stents is one of the most frequently performed operations in routine urological practice (2). Depending on the manufacturing material, most DJ stents must be removed after their maximum safe life. Following this, the success of ureteral stent implantation in medical centers can only be confirmed if the stents are removed without delay. Delayed removal of the stent or forgotten stent is associated with increased patient

morbidity and complications that are difficult to manage (3, 4) and patients may experience pain, infection, and encrustation from retained ureteral stents (RUS). As a result, using ureteral stent needs prompt follow-up to prevent higher morbidity, mortality, and medical costs (5). Usually, a stent should be removed within 3 months after placement, but some stents should remain in the body for a longer period depending on the patient's condition. According to investigations, 12% or more of all ureteral DJ stents are still in use or maintained (6).

To prevent forgetting to remove the stent on time and the complications caused by a stent remaining, in the body, IT tools can be helpful. One of these tools is registry systems (7). Therefore, various stent tracking and registry methods, such as paper card registries, electronic patient registries, and computer-based email or short message service (SMS) reminders, have been created to help with this issue (8-10).

Registries are efficient tools for gathering data from a more extensive demographic base. Furthermore, their findings offer strong external validity for clinical research, treatment outcome assessment, clinical follow-up, performance evaluation of healthcare professionals, high-quality healthcare maintenance, and patient safety (11-13).

The standardized data of a specific population with a particular disease or condition are gathered and used for scientific, clinical, and health policy-making objectives in an organized disease registry system (14).

The initial step in gathering high-quality data and constructing registry systems is the minimum data set (MDS) (15, 16). The developed MDS, a standard instrument for comparison, reporting, data exchange, and obtaining new and improved clinical information, is used by many countries to acquire high-quality data (17). The MDS provides a crucial and suitable set of items that should be employed to gather trustworthy and comparable data. The necessity of MDS for implementing integrated information systems and supporting data interchange among entities involved in patient care has been emphasized in many research projects (18-21).

Urologists in Iran and many developing countries need help accessing stent data for analysis since it is not centrally collected. Setting an MDS improves the registry's high-quality data (12, 22).

Considering the complications of a forgotten stent, there is no registry system that can monitor and follow up patients with ureteral stents. Therefore, it is necessary to develop such a registry system. To design a registry system, the necessary data elements must first be specified. This study aimed to identify minimum data set for implementation of the ureteral stent registry system.

Materials & Methods

The present study is a descriptive-sectional study that was conducted in two phases in 2023.

First phase: We conducted a literature review from 2014 to 2023 using the databases of Scopus, PubMed, and Science Direct. The keywords used in this process included ureteral diseases, ureteral stent, forgotten stents, minimum data set, and registry systems. According to the review of articles, data elements related to ureteral stents were extracted. Finally, 13 articles were obtained for modeling.

Second phase: According to the articles obtained in the first phase, the minimum data set was extracted during a focus group meeting with the presence of five experts (urologists, health information management, and medical informatics experts), and the classification of data elements was determined. After categorizing the data elements, two stages of the Delphi questionnaire were used to evaluate the minimum data set. Based on the definitions, Delphi is a research survey technique used to collect data from respondents within their domain of expertise, aiming to deal with divergent opinions or controversial issues to achieve consensus concerning real knowledge. According to the investigations carried out in the first phase of identifying data items and the categories of data elements suggested by experts, the questionnaire was designed to include demographic information, social history, medical history, clinical information, diagnostic measures, treatment measures, and patient discharge information. The first part of the designed

questionnaire includes the specifications of participants (four questions), and the second part asks for opinions about the importance of the minimum data set. At the end of each category, there is an empty line to insert suggested items that experts consider necessary, and that should be included in the categories. The questionnaire was designed based on the Likert scale (lowest score = 1 to highest score = 5), and the experts were asked to rate the importance of maintaining each data element. Incoordination and cooperation with the university research center and surgeons at Imam Khomeini Hospital, we provided the questionnaire to urologists and HIT experts.

In both stages of the Delphi questionnaire, the selection of experts was targeted (number = 20 people). The doctors and experts selected to answer the questionnaire, were fully familiar with the functioning of registry systems, had previously used similar systems, and possessed sufficient knowledge of using such systems.

After collecting the questionnaires, we used SPSS version 20 to analyze the data using descriptive statistical methods (percentage, frequency, median). According to the analysis done with the software's help, the items with a median of 3.75 or higher were accepted, and the items with a median of less than 2 were eliminated. The items that had a median between 2 and 3.75 entered the second stage of the Delphi questionnaire. In the second Delphi phase, we sent these questionnaires to the specialists and experts via email, and after successive follow-ups, all 20 participants cooperated in completing the questionnaires. After completing the questionnaire, the items accepted in the second stage of Delphi, along with those accepted in the first stage, were chosen as the minimum data set for the ureteral stent registry. We sent the data analysis report to the experts after the end of each stage. In a focus group meeting with urology surgeons from Imam Khomeini Hospital and experts in medical informatics and health information technology, the final minimum data set for the ureteral stent registry was approved. The content validity of the questionnaire was evaluated by five experts (urologists, health information management, and medical informatics experts). Test–retest reliability (with a 10-day interval) was performed to determine the reliability of the questionnaire. The collected data was analyzed using SPSS 20, and a correlation coefficient of 80% was achieved.

Results

After reviewing various studies, articles, and forms, all data elements related to forgotten ureteral stents were extracted. In this study, a two-stage Delphi questionnaire was sent to 20 urologists and experts in health information technology and medical informatics who were fully familiar with the functioning of registry systems, had previously used similar systems, and had sufficient knowledge about utilizing these systems. The demographic information of these professionals is presented in Figure 1.

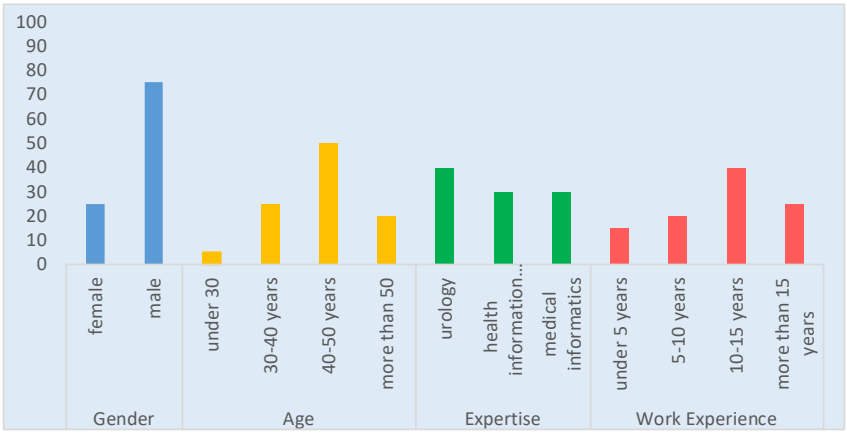

Fig. 1. Demographic characteristics of participants in the Delphi technique

According to Figure 1, men participated in the Delphi study more frequently than women. Additionally, most of the participants were in the age group of 40-50 years. Among the responding specialists and experts, the frequency of urology specialists was higher than that of other groups, and the highest rank of work experience ranged from 10 to 15 years.

After considering the sources and extracting data in a focus group meeting, 78 data elements were selected and categorized. In the first phase of the Delphi study, specialists agreed on 60 out of the 78 items that could be rated. They also removed 11 items, such as language, different organ history in diseases, diabetes history, medicine dosage, BMI, etc. In the second stage of Delphi, four items that did not pass the threshold, along with those suggested by doctors, were re-evaluated. In this stage, some items, such as religion, work phone number, pregnancy history, and pictures of radiology reports were deleted and finally, three items out of seven items were selected. The information for all the mentioned categories is presented in Table 1.

Table 1. Data elements examined in the first and second steps of Delphi

Categories	Number of primary data elements	First phase			Second phase			Number of final data elements	Percentage of accepted data elements
		< 50	50-75	> 75	< 50	50-75	> 75		
Demographic information	18	4	1	13	0	0	1	14	77.77%
Social history	8	2	2	4	0	1	1	5	62.5%
Medical history	7	1	0	6	0	0	0	6	85.71%
Clinical information	25	2	2	21	1	1	0	21	84%
Diagnostic measures	4	0	0	4	0	0	0	4	100%
Treatment measures	10	1	2	7	1	0	1	8	80%
Patient discharge information	6	1	0	5	0	0	0	5	83.33%

With the collective agreement of doctors and health information technology experts, 63 items were selected as the essential minimum data set for the ureteral stent registry system. These data were categorized into seven groups: demographic information, social history, medical history, clinical information, diagnostic measures, treatment measures, and patient discharge information. All the categories with their elements and mean scores are listed in Table 2.

Table 2. The final minimum data set of the ureteral stent registry system

Categories	Data Elements	Mean Score
Demographic information	Register date	85%
	Name	100%
	Family name	100%
	Father's name	95%
	National code	100%
	Date of birth	90%

Categories	Data Elements	Mean Score
	Province of birth	75%
	Gender	75%
	Marital status	75%
	Level of education	95%
	Type of insurance	95%
	Patient code	70%
	Mobile phone number	100%
	Address	80%
Social history	Patient job	75%
	Socio-Economic status of the family	85%
	Smoking and tobacco use	90%
	History of alcohol use	90%
	The amount of drinking water	100%
Medical history	Patient history	100%
	Hospitalization history	100%
	Cause of hospitalization	100%
	Medications being taken	100%
	Allergy of medication	100%
	Medicine name	100%
	Food allergy	70%
	Name of allergen	90%
	Family disease history	80%
	Type of disease	75%
Clinical information	Systolic pressure	100%
	Diastolic pressure	100%
	Blood group	85%
	RH	85%
	Pulse	100%
	Signs and symptoms	100%
Diagnostic measures	Hematology	100%
	Biochemistry	100%
	Urine analysis	100%
	Sonography reports	100%
Treatment measures	Surgeon name	85%
	Name of the surgery	100%
	Main diagnosis	100%
	Result of Surgery	75%
	Stent size	100%
	Date of stent placement	100%
	Stent remove date	100%

Categories	Data Elements	Mean Score
	Stent type	80%
Discharge information	Discharge date	100%
	Discharge patient status	85%
	Need for stent replacement	90%
	Nutritional counseling	75%
	Advice on the necessity of adherence to treatment	75%

Discussion

The MDS designed in the present study aimed to cover the essential data for the stent registry system. For health policymakers, researchers, and clinical experts, using a comprehensive MDS and a systematic approach to data collection for the implantation of stents can provide valuable information.

Akhlaghi et al. wrote an article about data elements for kidney transplantation in Iran. They organized the minimum data set based on the suggestions, opinions, and recommendations collected from experts. This set includes various categories of patient management which shows the important role of data elements in evaluating clinical performance, accessibility of data, and informing healthcare providers about the patient's condition (23). This finding showed that most of the data in the MDS consists of two sections: demographic and clinical. Demographic information is collected to recognize and communicate with patients, which is considered necessary data for identifying, calling, and following up with patients. Regarding clinical data, it should be acknowledged that these data are obtained during the process of diagnosis and treatment; in addition to being the basis of direct patient care, they aid in reimbursement, planning, and research in the field of healthcare (24, 25). According to the findings of our study, the MDS for the ureteral stent includes demographic information, social history, medical history, clinical information, diagnostic measures, treatment measures, and patient discharge, all of which were agreed upon by experts.

Various studies have emphasized the importance of standardized clinical documentation, especially for urology patients who require close monitoring and follow-up (16-18). Furthermore, it is crucial to take early intervention and treatment to prevent any potential long-term complications. A registry system is quite applicable for clinical and administrative purposes. Every day, a large volume of data is produced in managing and caring for patients with stents in healthcare facilities. It will be easier to select the minimum data set for a registry if there are standard clinical data on an individual disease or problem (23, 26).

In a study conducted by Rana et al. (2016) to make changes in the data elements in the stent registry system of Shija hospitals in India, the necessity of certain data elements was determined to increase the quality of the system. For example, in the demographic information category, they used two phone numbers to inform the patient and equipped the system with an alert notification that notifies the staff after the maximum stent life of stent placement. In contrast to the new registry system which had a failure rate of only 1.3%, the old registry system did not record 27.3% of cases of ureteric stent removal. The incidence of delayed removal of the stent decreased from 22.8% to 3%, and the incidence of complications associated with the stent decreased from 9.7% to 1.3%, due to the new registry system (27). In the present study, one of the data element classes that, according to experts' opinions, should be considered in the registry system is how to notify the patient to refer for stent removal.

A study conducted by Østergaard et al. in 2014 demonstrated that the effective utilization of radiology information in registries and clinical trials can enhance physicians' understanding of its advantages. Furthermore, it could enhance the management of patients with ureteral stents by facilitating better control and prediction of the disease's progression

through improved clinical and laboratory procedures (28, 29). In our study, radiology reports are also important data elements, and surgeons can access these reports to better manage the patient's status.

As the European Commission Joint Research Center suggests, the best platform for Rare Disease Registry (EURD Platform) and the set of common data elements for rare disease registries include, personal information like name, age and gender, patient status, disease history, diagnosis, diagnostic measures like the patient's biological samples, and patient disabilities according to the illness (30). These parameters were also expected in our study to select the necessary MDS for the system.

In a study, Narayan et al. developed an urology stent recall registry and presented all MDS for their systems (31). We tried to use some essential data elements, but these data elements have yet to be considered in Iran. When extracting and using the data elements of other countries, the country's conditions, local and regional issues, and the possibility of collecting information should be considered. By providing the possibility of continuous care of patients and recording their information in a reliable database, communication between care providers can be improved. This provides the opportunity to analyze the effectiveness of care for patients and the community of patients suffering from forgotten stents. In this way, it is possible to reduce complications and death, provide and predict the necessary services, and control and prevent the occurrence of this disease and its costs.

Tarantino et al. concluded that the number of claims would be reduced by accurate documentation and appropriate informed consent (16, 32). Clinical data, such as diagnosis, medical and family history of patients, laboratory tests, X-rays and devices, etc., are presented in the developed MDS for ureteral stents. This could improve quality and reduce the total cost for the patient and the number of legal and insurance claims.

Consequently, the system allows physicians to quickly identify patients with stents (type and length), provide effective treatment, track outcomes, and manage treatment complications. The web-based registry will facilitate health research by collecting clinical data and providing regular patient follow-up.

Overall, it can be concluded that the information obtained from the minimum data set provides valuable resources for evaluation, treatment planning, and continuous assessment of the patient's progress and performance (33).

Conclusion

In order to facilitate the prevention, early detection, diagnosis, and treatment of ureteral disorders, there is a need for available and reliable information on stents as well as related data. The first step of any information system that results in improved quality of care and disease control is the design and implementation of an MDS at healthcare facilities. The analysis of the result shows that determining the minimum data set of the ureteral stent registry by surveying experts in this field is a practical step towards integrating patient follow-up and treatment. It provides the means to improve the management of urology patients' information. It is advisable for future research at the national level to conduct a comprehensive MDS that covers all aspects.

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Authors' Contributions

Sh.N. and M.J. conducted the study and drafted the manuscript. M.J., B.R. and S.F conceptualized and supervised the study. All authors collaborated in data analysis and finally read and approved the final manuscript.

Data Availability

The data supporting this study's findings are available on request from the corresponding author.

Conflict of Interest

The authors declare no conflict of interest in conducting the present study.

Ethical Statement

The authors confirm that the research presented in this article met the ethical guidelines of Iran, including adherence to the legal requirements, and received approval from the Institutional Review Board of Urmia University of Medical Sciences (IR.UMSU.REC.1402.057).

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