Original Article

From designing minimum data set to developing kidney transplantation registry in Iran

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Abstract

Objective: Currently, population growth and increasing life expectancy are becoming one of the biggest public health challenges in the world, which has increased the prevalence of chronic diseases such as end-stage renal disease and the need for kidney transplantation. The use of a variety of registries has the potential to determine the effectiveness of clinical care and costs and improve the quality of patient care. The aim of this study is to design minimum data set to develop a kidney transplantation registry in Iran to improve the quality of care for people with end-stage renal disease. **Methods:** The present research is descriptive-applied. The minimum data set was reviewed and evaluated in expert panel meetings. The various elements of the minimum data set were discussed, and specialists in urology, nephrology, health information management, and medical informatics presented their views. **Results:** The characteristics of the kidney transplantation registry in the form of eight axes of purpose, structure, data sources, minimum data set, classification systems, data processing and reporting, distribution and access to information, and data quality were extracted and finally these characteristics were approved by experts. The relevant tables were validated and were within the acceptable range from the point of view of experts. **Conclusion:** In developing a kidney transplantation registry in Iran, the necessary requirements and features for designing a web-based registry have been considered. The prototype of this registry in the country will help to collect higher quality data. It is hoped that by developing this registry, a step will be taken to better manage the information on people with end-stage renal disease, provide better services to these patients, and facilitate related research.

Keywords: End-stage renal disease, kidney transplantation, minimum data set, registry

Introduction

The purpose of developing a kidney transplantation registry is to collect the necessary information to "identify, locate and investigate the occurrence, recurrence, prevalence, cause, effect and predict the onset of the end-stage renal disease."[1] In addition, the data and reports obtained from these systems can be used to implement a variety of disease information systems, conduct demographic research to identify risk factors for end-stage renal disease, plan health care, education, and improve diagnosis and treatment stages of this disease.[2] The use of these registries for patients and their support organizations will lead to a better and more complete understanding of the natural course of the disease and help to develop treatment guidelines in this area. The analysis of data recorded in these systems can

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be used to prepare activity reports, create research hypotheses, and improve patient care.[3]

Methods

The present research is descriptive-applied. The minimum data set was reviewed and evaluated in expert panel meetings. The various elements of the minimum data set were discussed, and specialists in urology, nephrology, health information management, and medical informatics presented their views.

For 4 months, 2-hour meetings were held each week by the Strategic Planning Management System Committee with the participation of two urologists, four nephrologists, and one of the Ministry of Health and Medical Education's coordinators. Also in each session, a health information management or medical informatics specialist was responsible for coordinating the content of the session.

At the beginning of each session, a proposed model was introduced and each section was presented for discussion. Discussions about each of the data elements continued until a consensus was reached. Then the required minimum data set was recorded in the proposed model and based on their relationship and priority in the desired location. It should be noted that the set of all items in the minimum data set was considered, meaning that common and uncommon items (literature review) were all included in the first draft. All the experts present at the meeting focused on the following questions:

- Are the essentials in the original draft removed or changed?
- Are the items that should be included in the initial draft very important in terms of decision-making?
- Should each of the classification sets be the most appropriate group?

Based on the suggestions, opinions, and recommendations collected from experts, the minimum data set was organized and includes all the data that can include important categories of patient types for kidney transplantation management.

This minimum data set was reexamined for the following:

- Does each element of the minimum data set play an important role in evaluating clinical performance and decision-making?
- What is the accessibility of data for most patients? (This is important because if most patients do not have access to this data, it will be impossible to fill it out and the minimum data set would be useless.)
- Is there a clear definition for each data to avoid ambiguity after completing the minimum data set?
- Are the data elements particularly focused on outcomes, side effects, and care pathways, especially in the discussion of transplant survival?
- Is the minimum data set in the transplantation registration network hierarchically structured and can record an unlimited number of steps?

Therefore, the following seven steps were performed to design a minimum data set and develop a kidney transplantation registry:

I. Defining the purpose of developing a registry: Accurate, explicit, and clear statements of the purpose of developing a registry are one of the vital steps in developing it. That is, what is the purpose of data collection and what is its purpose? A clear definition of purpose helped prevent misconduct by members of the team that developed the registry. In other words, it ensured that everyone involved in the process was performing their duties with the same goal in mind. The registry can have one or more purposes. At this stage, it became clear what questions the registry wanted to answer. Careful examination of these questions and the provision of appropriate answers identified the type of registry, the data elements required for collection, and the analysis required.
II. Clear definition of the population to be registered: The target population in the registry was determined based on geographical area, environment, time period, and various characteristics such as sex, race, and diagnosis. This step would be crucial if the purpose of developing a registry is to estimate the prevalence, incidence, or other specific population-based variables. Geographical area means local, regional, national, or global registry. Environment means a place where the data of patients and researchers are recorded in the registry, for example, a hospital, clinic, or doctor's office. The time period refers to the time required to collect data in the registry to achieve its desired goals.
III. Determining the method of identifying registrable items: Identifying registrable items in registries is known as another important step in developing these systems. This process included screening the study population or its subsets, identifying patients who had been to medical centers, and finally reviewing medical records recorded by specialists in the field of study.
IV. Data selection method: The data collected for the registry should be limited and based on the objectives set for a registry. In this step, the validity of the collected criteria was considered. The goals of the registry were written as a list. The main themes of the data were then identified to achieve the objectives. Each goal specified what data should be collected. The minimum data required to achieve each goal was determined. The definition of each topic was discussed in detail. These definitions specified what the minimum data required was for that topic.
V. Data collection methods: Data collection methods include interviews, case reviews, and direct clinical observations such as clinical trials. In each of these methods, the data collection method often specified which data could be collected reliably. The method of data collection also showed the effect of the collector's job position on the type of data he was collecting. For example, a specialist who had a busy work schedule was less likely to collect data unrelated to his or her patient's clinical condition.
VI. How to store data and its availability: This step included some technical issues such as estimating the size of the database,

ensuring data security, determining who has permission to access the database, and facilitating the use of organized data.

VII. Implementation of processes related to data quality control: Data quality control was a critical step in ensuring the usefulness of the existing data of the registry, although unfortunately this step is often not properly planned when developing a registry.

Results

Since there is currently no standard and uniform minimum data set in the country, this minimum data set is based on comparative evaluation tables of minimum data sets for kidney transplantation and a model approved by experts in a format consisting of 13 sections in forms of contexts with structured arrangements, considering coded responses and using the concurrence of expert panel, the design and characteristics of the kidney transplantation registry in Iran were identified. Set of features required to design this registry from the perspective of urology, nephrology, health information management, and medical informatics, in the form of eight axes of purpose, structure, data sources, minimum data set, classification systems, data processing and reporting, distribution access to information and data quality was confirmed and 211 data elements were extracted. Also, the list prepared for the characteristics of the registry from the perspective of urology experts in the form of two axes of minimum data set and reporting components and 195 data elements were reported. These extracted features provided the basis for designing conceptual and logical models and designing a model for the kidney transplantation registry in Iran. The design of the kidney transplantation minimum data set included the following [Table 1].

The application of a standardized procedure will make the scientific registries in kidney transplantation reliable data that will help us modify and improve our clinical practice. Thus the graph of questions and concepts to take into account in registries that are implemented in clinical practice is here [Figure 1].

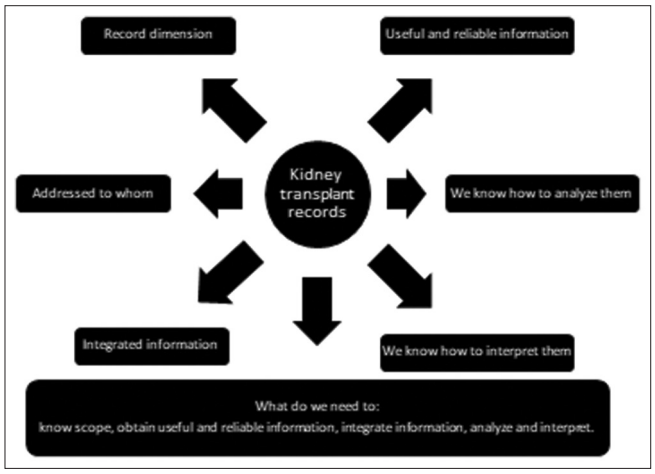

Figure 1: Graph of questions and concepts

Discussion

In 2021, Miri *et al.*[4] conducted a study entitled "Kidney transplantation registry program in Mashhad University of Medical Sciences; design and rationale." In this comparative study, using interviews, Delphi and document analysis, the objectives, stakeholders, and minimum data set for the design and pilot operation of the kidney transplantation registry were identified. In this study, only extracting the requirements and initial steps of developing a registry (determining the minimum requirements such as goals, stakeholders, and minimum data set for the design and pilot operation of the kidney transplantation registry) and designing conceptual and logical models provide a template of kidney transplantation registry in Iran, and its evaluation has not been studied.

Goldberg *et al.*[5] in a study entitled "Registry evaluation methods: a review and case study" presented a variety of appropriate methods for verifying the completeness and validity of registry data. For Goldberg, data completeness means the proportion of all items registered in the target community. The validity of the data also means the correct evaluation of data elements such as age, sex, and disease classification.

In other sources, in addition to the items mentioned that should be considered in designing and developing a registry, other steps such as determining the main stakeholders of the project, building a project team and finally, the project plan to develop a registry are also given. The main stakeholders of the project can be patients, health care providers, and health care officials.[6] Stakeholders can be primary or secondary. The primary stakeholders are those responsible for the development, financial investment, and legal discussions of the registry. Secondary stakeholders are those who use the knowledge gained from the data recorded in the registry, such as patients and their physicians. Stakeholder interaction during the project ensures that the registry moves in line with the set goals.[7] Building a project

Table 1: Section names and data elements

#	Section name	Data elements
1	General information of the transplant candidate patient (waiting list)	21
2	Medical information of the transplant candidate patient (waiting list)	23
3	General information about the donor	12
4	Medical information about the donor	16
5	Patient status before transplantation	8
6	Listing time information until transplantation	10
7	Clinical information at the time of transplantation	18
8	Clinical information after transplantation	13
9	Primary immunosuppressive drugs (induction)	6
10	Immunosuppressive maintenance drugs at discharge (daily dose in batches one to four)	25
11	Post-transplant tracking information	13
12	Problems after transplantation	9
13	Immunosuppressive drugs reject acute transplantation	21

team is another important factor in designing and developing a registry. Different types of specializations and skills are required to design and develop a registry. Depending on the size, scope, and goals of the registry, people with different specialties such as project managers, specialists in the field of study, statisticians and epidemiologists, database managers, and data collection managers can be present in the project team.[8] Creating a project plan is usually known as the last step in designing the development of a registry. Creating this work plan is very important because the project team has a roadmap as a guide along with their efforts.[9] At this stage, it is determined what to do, by whom, in what period of time, and using what resources and credits.[10]

Since recording systems are formed for specific purposes, data collection for which there is no program for analysis should be avoided. The design of a registry requires a precise definition of the objectives of that registry and the close cooperation between its disciplines such as epidemiology, health outcomes, vital statistics, and clinical specialties. Given that domains have a very high impact on the desired outcomes, so after setting goals should be precisely defined.[11] Registries typically include personal information, exposures, and outcomes.[12] Examples of these are:

- Personal information: Contains data that describes the characteristics of the person or patient, such as the patient's demographic information, medical history, and health status.
- Exposures: Includes the background and experience of the person or patient in relation to various exposures, including products, diseases, devices, actions, or services in the registry. Exposure or intervention can include other treatments that affect the outcome. Although such interventions do not necessarily pursue the goals of the registry, their collection is important as a distortion.
- Outcomes: Contains information that describes the disease outcomes of the registry. Outcomes include two groups of primary and secondary outcomes and are part of the overall goals of the registry.[13]

In addition to paying attention to the desired goals and outcomes, when the above various domains are identified, it is necessary to specify their sub-domains. Measuring and collecting confounding factors that are related to both exposure variables and outcomes are of great importance for controlling the results in the analytical stages of the data.[14]

Understanding reference time is critical for all data elements that can change over time to identify cause-and-effect relationships. For example, a medication taken by a patient after the onset of an illness cannot cause the illness. The reference time period for changing data elements can be displayed with start and end dates or displayed in categories. That is, the period of grouping includes pre-hospital, hospital emergency measures, treatment, hospitalization, discharge, and follow-up after discharge.[15]

Designing a minimum data set is a crucial step in designing and developing a registry that allows a medical institution to identify patients from each other and meet their government requirements and internal needs, and ultimately the medical community.[16] Creating a minimum data set is a standard method for collecting and using data elements with unique definitions that facilitate their comprehension and make it possible to compare this data.[17]

The minimum data set is used for the integration of health care in hospitals, nursing homes, and health care institutions. Another application of the minimum data set is the collection of data related to research in a specific field.[18] Determining the minimum data set leads the project team to limit data variables by emphasizing the objectives of the registry and avoiding collecting additional data that is not necessary.[19,20]

If there is standard clinical data for a disease, the steps of selecting the minimum data set for the registry will be easier. In the presence of such standards at the international level, it is recommended that registries use these standards in order to be more involved in the production of medical knowledge.[21] Standard data not only improves the efficiency of recording systems but also enables the sharing, aggregation, and connection of data from different sources. Therefore, the use of well-defined standard minimum data makes data concepts in different systems have similar meanings.[22] In the absence or availability of desirable international standard data elements, registry stakeholders should consider local rules and standards in order to determine data elements. In this case, they should consider the possibility of converting and merging data outside the database to compare the minimum data set in several countries as a requirement.[23]

The primary purpose of creating the minimum data set for the kidney transplantation registry is to collect and use accurate and uniform diagnostic criteria and other data elements such as patient identity and demographic information and reports of service providers.[24] Due to the different sources of data collection and the goals of developing a kidney transplantation registry, their minimum data sets are also usually different from each other.[25] In general, the minimum data set in the kidney transplantation registry includes items such as patient demographic data, data centers of service providers, disease measurement parameters, diagnostic data, data therapy, and even medical history.[26,27]

In Iran in 2019, with the establishment of the Coordinating Center for Kidney Transplantation and the creation of a minimum data set in a university of medical sciences, the first step was taken to standardize the data collection process in kidney transplantation centers. This minimum data set included a variety of data elements such as clinical, diagnostic, and demographic information of the participants, which have been collected retrospectively from kidney transplantation centers since 2009. Using this standard method of collecting data elements creates a very powerful platform for multilateral collaboration between service providers. Using the minimum data set, the documentation of the records is done in a more appropriate way.

In addition, the possibility of extracting new research hypotheses has been facilitated, which leads to the implementation of a variety of research on a larger scale.[28]

Data is recorded in the registry in two ways (active and passive) and automatic. In the active data entry method, data is collected directly from their sources. In this method, the staff of the registry obtains data from the main sources or by copying existing documents and finally summarizes the information in data collection forms. The passive manual method is based on medical staff. These people are required to complete reporting files or copy papers. In practice, a combination of active and passive methods is useful.[29]

The automated registration method is the process by which data is received, validated, selected, and collected. This method is used to update the database in the registry. In this method, by removing duplicate information or overlapping items, the best information for each data item is provided to the user. This feature can be implemented with a set of algorithms, predefined rules as well as several available electronic data sources.[30]

Conclusions and Implications

Available, reliable, up-to-date and related data on the end-stage renal disease are essential to facilitate the prevention, early detection, diagnosis, and treatment of this disease. In addition to providing this data, worldwide kidney transplantation registries have played an important role in planning, service management, disease monitoring, and research facilitation.

Developing an end-stage renal disease registry requires an overview of the goal, careful planning, adequate funding for deployment, and approved governance structures for sustainability. Given the global expansion of the use of registries, the development of a kidney transplantation registry in Iran is a wise investment to improve understanding of the disease, provide better services, and facilitate related research in the country.

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Conflicts of interest

There are no conflicts of interest.

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