

Designing a National Haemodialysis Registry Model for Iran

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ABSTRACT

Introduction: The global prevalence of End-Stage Renal Disease (ESRD) requiring therapeutic dialysis is on the rise. Haemodialysis is the main therapeutic dialysis method. Evaluating its effectiveness and planning to promote the quality of care and epidemiological research necessitate the development of registries as the main management tool.

Aim: To design a national haemodialysis registry model for Iran.

Materials and Methods: This was an applied descriptive study. Based on a review of articles and information sources, and a comparative study of national hemodialysis registries in developed countries, a national haemodialysis registry model was designed for

Iran. After confirming the reliability and validity of the questionnaire, the designed model was given to nephrologists in a two-stage Delphi technique, and their comments were applied to the final model.

Results: The presented national haemodialysis registry model main components consist of: goals, structure, data sources, minimum dataset, standards, and processes, all of which received 100% expert consensus.

Conclusion: This registry is a powerful database for the progress of treatment, understanding changes in the treatment and outcomes, examining the factors affecting prognosis and quality of life.

Keywords: Database, Dialysis, End-stage renal disease

INTRODUCTION

Damage to human kidneys happens gradually and over a long time, and can create toxins in the body. Renal diseases can also cause numerous other health problems [1-3] such as increased morbidity and mortality, decreased quality of life and enormous economic costs [4]. This disease inflicts about 10% of the world population, and its prevalence is on the rise [1-3]. As a type of renal disease, Chronic Renal Disease (CRD) is a serious and prevalent disease with numerous complications such as early mortality, increased incidence of cardiovascular disease, hyperlipidemia, anaemia and metabolic bone disease and ESRD [5]. CRD is of medical and economic importance due to its numerous complications, and its increasing prevalence is associated with a rise in the population at risk of diabetes and hypertension [6]. In fact, diabetes is the main cause of CRD and a global health emergency, which eventually leads to ESRD [5]. Statistics show that the mean annual incidence of ESRD is 171, 336, and 100 per one million in Europe, the United States (US), and the United Kingdom (UK), respectively. In Iran, the statistics increased from 38.5 per 1 million in 1998 to 49.9 in 2000, indicating its increasing trend [7]. The heaviest global burden of CRD occurs in Low and Middle-Income Countries (LMICs). It is estimated that about 500 million people suffer from CRD, the majority of whom (80%) residing in LMICs [8].

Worldwide, among people aged 65-74 years, one in five men and one in four women are estimated to have CKD [9]. The global prevalence of ESRD requiring therapeutic dialysis or kidney transplant is still on the rise [10]. The net increase in the number of dialysis patients in Japan suggests that 95% of these patients need haemodialysis, and 4.9% require peritoneal dialysis [11]. In the UK, the number of elderly patients who require therapeutic dialysis is increasing [12]. The population of patients with ESRD in Asia (Pakistan) who need dialysis is expanding at a rate higher than the rest of the world [13].

Due to the high prevalence and incidence of renal diseases and the extensive use of dialysis worldwide, suitable measures should be taken to manage and plan this disease in order to realise different

health-related and therapeutic goals [14]. As the main tool for disease data management, registries reduce healthcare provision costs and improve healthcare processes by using the available clinical guidelines and standards [15-17]. A registry of patients with renal failure can help estimate and distribute the patients, understand the characteristics of ESRD and therapeutic dialysis and their outcomes or complications based on scientific evidence, improve the quality of therapeutic dialysis, provide information about socio-economic health management and treatment plans, and assist future research [18-20].

Almost all countries developed an increasing number of registries between 1999 and 2005 [21]. Although these countries markedly differ in terms of the methods of registry implementation, all these registries aim to improve healthcare quality [21]. In Denmark, The Danish Nephrology Registry is used to evaluate treatment quality, therapeutic activity process, and scientific research [22]. By developing a dialysis and kidney transplant registry, the US examines the rising trend of prevalence and incidence of ESRD in kidney transplant treatment and its relationship with Gross Domestic Product (GDP: The Gross Domestic Product price index measures changes in the prices of goods and services produced in the United States), life expectancy at birth, and the percentage of population aged >65 years [23]. Since 2015, the UK Renal Registry has collected data on patients with renal failure who undergo haemodialysis from renal care centers across England, Wales, Northern Ireland, and Scotland through a kidney registry. The goal of this registry is to perform a national-level statistical analysis of the number and duration of dialysis sessions and dialysis sufficiency [24]. The Australia and New Zealand Dialysis and Transplant Registry also have national coverage of everyone undergoing renal therapeutic measures in either country since 1963 [25].

Due to the prevalence of CRD in more than 20% of the adult population in Iran, the necessity of haemodialysis for survival and it is the main dialysis method in the country as well as other countries, suitable measures should be adopted to create a national registry [26]. This registry can help estimate healthcare and treatment costs and efficiency; assist epidemiological research, decision-making, organisation, and planning; examine the incidence trend;

identify at-risk populations; evaluate the effectiveness of prevention and intervention programs; and calculate disability-adjusted life years and years of life lost [15]. In the present study, a model was designed for creating a national registry of patients undergoing haemodialysis.

MATERIALS AND METHODS

The present applied descriptive study was conducted in 2020 and followed the mentioned steps:

- 1) A review of articles was performed by using library sources and relevant sources in PubMed, Scopus, Science Direct, Wiley, and Embase databases, as well as a review of registries in pioneering countries (such as the US, UK, Denmark, and Canada) by using the keywords renal registry, kidney registry, and haemodialysis registry from 2000 to 2021.
- 2) A national haemodialysis registry model for Iran was designed based on the review of articles and information sources, conducting a comparative study of national dialysis registries in developed countries (these countries had a long history implementation, and thus, their valuable experience was used in this study) and considering the process of haemodialysis in Iran and the involved organisations.
- 3) This model was developed in the form of a researcher-made questionnaire consisting of questions based on the model dimensions [27]. The questions had two options of Agree and Disagree with blank space provided for suggestions. The questionnaire was given to eight experts (five health information management experts and three nephrologists), and their comments were received for validity determination. Furthermore, Cronbach's alpha was calculated to determine the reliability of the questionnaire. A Cronbach's alpha of >0.7 is acceptable in scientific domains ($0.9=\alpha$). As this value was 95% in the present study, the validity of the questionnaire results was high. After reliability and validity confirmation, the proposed model was given to 15 nephrologists, faculty members with >8 years of works experience in treatment centers. The nephrologists' comments on the registry model were collected, and the agreement coefficient of 75% was set as the criterion for model acceptance. Then, expert comments were applied to the proposed model. In the second step of the Delphi technique, an expert panel with five nephrologists and health information management experts was formed to finalise the proposed model.

STATISTICAL ANALYSIS

Data analysis was performed through descriptive statistics percentage and mean, using Statistical Package for the Social Sciences (SPSS) software version 19.0.

RESULTS

The review of articles revealed that the most important processes in national haemodialysis registries include case finding, data gathering and cleaning, data quality control, processing, reporting, and patient follow-up. In addition, the goals, structure, data sources, and minimum dataset of the national haemodialysis registry should be clearly stated. A list of the findings of the proposed national haemodialysis registry model is presented in [Table/Fig-1]. The experts' opinions about the validation of the model are given in [Table/Fig-1].

In the second Delphi stage, a questionnaire was developed based on the suggestions of the first Delphi stage and items that had achieved a score of 75-100%. This questionnaire was given to the expert panel. All the components of the model were confirmed by 100% of the experts. By applying the suggestions to the initial model, the final model was developed.

Objectives		ESRD epidemiological research, the general condition of haemodialysis, and predicting the transplant waiting list Analysing the haemodialysis treatment outcomes Evaluating and promoting the quality of care provided for haemodialysis patients Study of the survival and mortality rate of haemodialysis patients Planning and managing socio-economic health and future treatment plans	
Data sources		Hospitals, clinics, and dialysis centers	
Structure	The organisation in charge	The Center for Management of Special Diseases and Organ Transplantation, the Ministry of Health and Medical Education	
	Organisation method	Centralised	
	Registry centers	Urban centers of haemodialysis registry Provincial centers of haemodialysis registry National centers of haemodialysis registry	
	Participating organisations	State-run and private haemodialysis hospitals and clinics, haemodialysis registry centers	
	Supervisory committees	The haemodialysis registry data quality control committees The haemodialysis registry data disclosure committees The haemodialysis registry steering committee	
Minimum dataset		Demographic data Patients' medical history and diagnostic data Data related to laboratory tests Venous access data Haemodialysis device data Patient evaluation data during and after haemodialysis Blood product and medication data	
Standards	Terminology and classification system	ICD-10 [28]	
	Nomenclature system	SNOMED-CT [29]	
	Information exchange and messaging model	HL7 [30]	
Registry processes	Case finding	Active	
	Data gathering and cleaning	Based on the manual and electronic report form by the registry officials at the registry centers	
	Quality of data	Quality control index	Completeness, timeliness, accuracy, consistency
		Quality control methods	Examining duplicates, mandatory data, and auditing the medical records of haemodialysis patients
	Data processing	Examining the survival and mortality rate of haemodialysis patients Frequency distribution of ABO blood types among haemodialysis patients Mean age of haemodialysis patients ESRD patients' geographical distribution analysis Calculating the percentage of the most prevalent underlying diseases in haemodialysis patients	
	Reporting	Reporting method	Telephone calls Written reports Online reports
		Reporting period	Monthly-quarterly -semi-annual -annual
		Types of reports	Managerial, case finding, financial, and follow-up reports
	Patient follow-up	Goal of follow-up	Evaluating the outcomes of therapeutic haemodialysis Developing prevention criteria Following the patients' regular visits at least once a year
		Follow-up methods	Telephone calls, sending reminder letters to patients, electronic communication (online)

[Table/Fig-1]: The proposed national haemodialysis registry model [28-30].

ESRD: End stage renal disease; ICD 10: International statistical classification of diseases and related health problems; SNOMED CT: Systematize nomenclature of medicine-clinical term; HL 7: Health level 7

[Table/Fig-2] suggests that the goals, standards and processes of the national haemodialysis registry achieved 100% expert consensus.

The Expert agreement of the components examined by the National Registry	Percentage	Agree	Disagree	Notes
Objectives	100	0	-	
Data sources	85	15	-	
Registry structure	75	25		Regional haemodialysis centers were recommended for inclusion in the structure.
Minimum dataset	85	15	-	
Standards	100	0		It was recommended that a data dictionary be developed for the precise description of the data. It was also suggested that the coding system be changed to ICD-11 based on the changed coding standard.
Registry processes	100	0	-	

[Table/Fig-2]: Brief results of the first Delphi stage

DISCUSSION

The first step to create an effective program and disease prevention is developing a disease registry [31]. By developing a suitable registry system and analysing its data, effective measures can be proposed for improving the status of patients with CRD [32].

Haemodialysis registries are used to determine haemodialysis prevalence and increase in the country, specify therapeutic haemodialysis in different geographical regions, and determine the factors affecting treatment outcomes [33]. In the model presented here, the objectives of the national haemodialysis registry are:

- ESRD epidemiological research, the general condition of therapeutic haemodialysis, and predicting the transplant waiting list
- Analysing the haemodialysis treatment outcomes
- Evaluating and promoting the quality of care provided to haemodialysis patients
- Examining the survival and mortality rate of haemodialysis patients
- Planning and managing socio-economic health and future treatment plans

The goals of prevention, screening programs, and disease control in healthcare centers can be realised only if complete and timely patient data are collected [34]. The minimum dataset is a valuable and comprehensive source for the continuous evaluation of healthcare and treatment quality improvement. The minimum dataset is a fundamental step towards registry development and marks a clear path towards data collection and reporting [27]. Seven general categories of the minimum dataset are developed in the national haemodialysis registry model:

- Demographic data
- Patients' medical history and diagnostic data
- Data related to laboratory tests
- Venous access data
- Haemodialysis machine data
- Patient evaluation during and after haemodialysis data
- Blood product and medication data

The main activities that should be considered in designing the national registry include case-finding, data gathering and cleaning, data quality control, reporting, and patient follow-up [27].

The case-finding processes are essential to define the inclusion and exclusion criteria [35]. Based on the objectives of the registry, case-finding may be extensive or limited [36]. Since active case-finding systems identify a higher percentage of people meeting the inclusion criteria, this active process was included in the model designed here [35].

Data collection methods vary across countries, for instance in Australia and New Zealand Dialysis and Transplant Registry, the data are regularly collected from registry centers and sent to the national registry. The data are sent in real-time through a secure web-based portal or on paper [25]. In the Shanghai Dialysis Registry, the data are collected from all the urban dialysis centers. The report forms are sent by the Shanghai haemodialysis quality control center and collected via email in the first quarter of every year [37]. In the registry designed in the present study, the data were collected based on manual and electronic report forms.

The implementation of a data quality assurance program that includes all the regular and pre-planned methods before, during, and after data collection can help improve quality in a database [38]. The value of a registry depends on the quality of data. Quality control processes should focus on data completeness, preventing duplication, data timeliness, and data interpretation and reporting accuracy [39]. Therefore, in the present study, a major component of the national haemodialysis registry was creating data quality control criteria.

Patient follow-up is a key function of registries to evaluate treatment outcomes, develop prevention criteria, and ensure the patients' regular visits [5,40]. In the present study, the patients' regular and annual visits were taken into account with the component of patient follow-up.

Limitation(s)

The main limitation of this study was the lack of access to different haemodialysis registries of other countries.

CONCLUSION(S)

The national haemodialysis registry is an effective tool for providing regular and comprehensive healthcare, and informs many healthcare providers about the effective integration and use of health information technology in healthcare settings. This registry is a powerful database for the progress of treatment, understanding changes in the treatment and outcomes, examining the factors affecting prognosis and quality of life, and describing healthcare patterns, including the suitability of care, inequality in care provision, healthcare service planning, effectiveness evaluation, safety and injury monitoring, and healthcare quality assessment.

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