



A Comparative Study of the National Infertility Registry System and the Proposed Model for Iran

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Abstract

Objectives: The national registry system of infertility has been established at various levels in different countries over the years due to the high prevalence of infertility in the world, as well as its social and economic effects on communities. Therefore, the present study was conducted to provide a model of the National Infertility Registry System for Iran.

Materials and Methods: This comparative study was conducted in 2016, and the sample data included those related to the infertility registry systems in the United States, Canada, and England. Based on the aim of the study, different articles, databases, books, and the related websites were searched and national and international experts were consulted with in order to investigate the infertility registry system in developed countries (e.g., the United States, Canada, and England). Then, based on economic, cultural, and geographical conditions of Iran, an infertility registry system was proposed including 7 main axes and 20 sub-axes. Finally, the proposed model was validated using the Delphi technique at two stages, showing an agreement coefficient of 85%.

Results: In this study, the model for the Iranian National Registry System was proposed based on seven aspects encompassing the objectives and the structure of the system, data elements, the criterion of the registry, the process of data collection and reporting, as well as data quality control and classification.

Conclusions: In general, due to the importance of the infertility registry in taking health measures, the proposed model can improve the management of infertile patients, in terms of providing a system to follow the results, and the effectiveness of the treatment, health family planning, and controlling the factors which influence infertility.

Keywords: Infertility, National registry system, Infertility registry system

Introduction

Infertility is a medical condition that has health implications for afflicted individuals and is associated with the human rights of the individuals (1). In addition, infertility is defined by the World Health Organization as no conceiving after two years of exposure to pregnancy (2). Further, the International Classification of Disease system (ICD-10) describes infertility as pregnancy incapability or sterility (3). There are also other medical and demographic definitions. For example, the Practice Committee of the American Society for Reproductive Medicine (ASRM) refers to infertility as a disease characterized as a failure to become pregnant successfully after 12 months or more of regular unprotected intercourse (4). Almost 72.4 million couples around the world are anticipated to suffer from primary or secondary infertility (5) and the rate of infertility is about 5% to 30% in different countries (6).

Infertility in the United States of America had a downward trend from 11.2% in 1965 (7) to 9% (range: 3.5%-16.7%) in 2007 (5). Furthermore, about 10% to 15% of couples in the United Kingdom are estimated to have infertility problems (8, 9), including 2.4% who have

unresolved infertility (10). This rate is about 8.5% in Canada as measured by the Royal Commission for New Reproductive Technologies (11). Moreover, the average prevalence rate of lifetime infertility in Iran is 10.9% with 3.3% of the population having current infertility (12) while the incidence of infertility in the Middle East is estimated between 10% to 15% (13). However, almost one-third of couples cannot conceive after one year in the central and southern parts of Africa (14).

Infertility is approached and cured using various methods such as medicine, surgery, intrauterine insemination, or assisted reproductive technology (ART) which are frequently combined together (15). Since 1973, ART has been considered as an alternative for many prospective parents. It refers to an intervention in which eggs and sperms are manipulated in vitro to help a woman conceive (16). ART procedures occasionally involve using donor eggs (eggs from another woman), donor sperms, or previously frozen embryos. The feature of infertility treatment requires collection, storage, continuous analysis of the large quantity of specialized data, as well as the assurance of the possibility of quick access (17).

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Therefore, having a database to collect, process, and distribute the data seems essential to fulfill the following objectives: (18).

- Supporting operationalization programs directed towards preventing infertility or diminishing the socio-cultural and health impact on individuals and the health care system;
- Improving the consistency of the collection of infertility information by specialized health care providers;
- Enhancing infertile patient management, improving the effectiveness of treatment, and reducing the risk (19).

Considerations about the safety and efficacy of ART have caused a number of countries to set up monitoring or surveillance schemes in order to provide information for policymakers, healthcare staff, and visitors (20). Accordingly, different countries have realized the importance of the registry over the years and established a registry at various levels owing to a globally high incidence of infertility and its social and economic influences on communities. For instance, infertility registry process has been performed in different ways in America since the creation of infertility clinics. In 1992 (21), the US Congress passed the Fertility Clinic Success Rate and Certification Act which required all the ART clinics to provide and report the data with regard to their activities with National ART Surveillance System (NASS), the Center for Disease Control and Prevention (CDC). NASS is a database about all the patients who are treated using ART. The data collected in NASS including patient characteristics, ART procedure information, and treatment outcomes are recorded and can be used to answer important research questions about using ART (22).

States Monitoring Assisted Reproductive Technology is performed by Monitoring Assisted Reproductive Technology Collaborative. This technology aims to establish, evaluate, improve, and promote the state-based surveillance of ART, infertility, and related activities. This surveillance can be used to monitor and study maternal and infant health outcomes related to ART (23).

In the American ART surveillance, the data are kept confidential under the Public Health Act Section 308 (d) thus the primary ID such as the name or ID number of the patients is not included in the system (20) and CDC can provide limited access to restricted data files (22).

In the United Kingdom, the human fertilization and embryology authority (HFEA) began collecting data from clinics having licensed ART treatments. Such data were valuable resources for clinics, policymakers, and researchers and were collected using paper forms which were encoded by the HFEA staff into a database. However, such paper-based activities were withdrawn by introducing electronic data interchange. The HFEA Register is a large database which has evolved over time (24) and is nowadays registered to be the largest of its type all over the world.

Additionally, the HFEA keeps the record of all those who are under treatment and the treatments related to ART, donating embryos or delivering an infant, are allowed donates in licensed British fertility clinics. By 2004, the HFEA announced that Data Register has enhanced significantly and launched a Historic Audit Project to guarantee the accuracy of the treatment information. In addition, HFEA used the data to observe and monitor treatments, provide information, and keep a confidential registry of information for ART-born children. Further, its registry contained patient and partner names, patient reference numbers, treatment dates and the details of sperm and egg donors. This personal information was kept confidential (25).

The Canadian Assisted Reproductive Technologies Register (CARTR) was initially launched in 1999 to gather treatment cycle data from Canadian fertility centers. The IVF Directors Group of the Canadian Fertility and Andrology Society led to the CARTR program, which was financially reinforced by ART centers. In the ART centers, the data provided by infertility clinics were electronically sent to the coordinating center of CARTR. In this section, the accuracy, completeness, corrections, or clarifications were requested from the centers (26). Therefore, a national registry of infertility was completed in Canada. This national registry sent a report to the regional registers which subsequently provided the data for the global report produced by the International Committee for Monitoring Assisted Reproductive Technology after reviewing and ensuring the accuracy of the data (27). However, no certain and efficient system exists for the registry of infertility in Iran. The patients' information is kept separately in the databases of infertility research centers. In addition, the patients' information is limited to the centers they attend to since many of them refer to hospitals and women's private medical centers. However, since there are no databases to identify the born people by the technique of infertility, the issue of possible genetic diseases is of paramount importance in terms of planning for their control. Thus, a system is required to meet the healthcare needs of the country in this area. Therefore, the ultimate objective of the present study was to provide a model for the National Registry System of Infertility in Iran.

Materials and Methods

The current comparative study including sample population of infertility registry systems of the United States, Canada, and England was conducted during 2016. No sampling procedure was implemented and the sample size was in accordance with the population size. The researchers utilized articles and some databases like PubMed, Scopus, and Google Scholar, as well as books, related websites, and consultation with national and international professionals to evaluate the infertility registry system in developed countries including the

United States, Canada, and England. Furthermore, they proposed an infertility registry system for Iran encompassing 7 main axes and 20 sub-axes based on economic, cultural, and geographical conditions of Iran.

To this end, a questionnaire was developed including 21 questions related to the axes of the proposed model. Its validity and reliability was estimated through content validity and using the test-retest technique, respectively. Then, the questionnaire was administered to 15 individuals including three experts of health information management professionals, 2 experts in medical informatics, five gynecologists, and five managers of infertility clinics. An agreement coefficient of 85% was considered for deciding upon the main axes and sub-axes. The axis remained on the list if more than 85% of the experts necessitated its existence. Otherwise, the axis was deleted or modified. Responses obtained from the first stage of Delphi highlighted some disagreements. Accordingly, a second questionnaire containing 18 questions was developed based on these disagreements and sent to the experts. Then, the collected data were analyzed by SPSS using descriptive statistics. The final model was proposed using the Delphi technique in two states with an agreement coefficient of 85%.

Results

As previously mentioned, the proposed model for the

national infertility registry system of Iran was designed in 7 main axes and 20 sub-axes. In the main axes, 100% agreement was obtained and an agreement coefficient of 85% was obtained for all sub-axes except for the following issues. Table 1 demonstrates the experts' opinions respecting the main axes and sub-axes of the proposed model for the infertility registry system of Iran by 2 stages of Delphi. As shown in Table 1, an agreement coefficient of 80% is obtained regarding the responsible organization which is part of the system axis while the observed disagreement is concerned with replacing the Ministry of Health with the University of Medical Sciences. Moreover, as regards the time of sending the report which is a part of the process of axis collection and reporting, an agreement coefficient of 73.3% is observed. The disagreement is associated with not sending the statistics and data to the office of the national infertility registry system monthly. Instead, a period of 3 months should be considered in this respect. Finally, an agreement coefficient of 66.7% is achieved concerning the axis classification system.

Therefore, the International Classification of Disease system (ICD-10) is proposed to be used and changed to ICD-10-CM instead of using ICD-11 (Table 1). Considering that disagreement in all proposed axes and failure in obtaining the desired agreement coefficient, the second stage of Delphi is conducted, which fails to result in omitting any of the main axes or sub-axes. Based

Table 1. Frequency Percentage of the Experts' Opinions About the Proposed Model of Infertility Registry System in Iran by First and Second Stages of Delphi

Proposed Axis		Experts' Opinions							
		Agreement				Disagreement			
Main Aspects	Subordinate Aspects	Delphi							
		First stage		Second stage		First stage		Second stage	
		No.	(%)	No.	(%)	No.	(%)	No.	(%)
Purposes of the system	Main purposes	14	93.3	14	93.3	1	6.7	1	6.7
	Responsible organization	12	80	14	93.3	3	20	1	6.7
	Supervisory Committee	14	93.3	14	93.3	1	6.7	1	6.7
Structure of the system	Members of the committee	13	86.7	13	86.7	2	13.3	2	13.3
	Type of registry system	14	93.3	14	93.3	1	6.7	1	6.7
	Methods of organization	14	93.3	14	93.3	1	6.7	1	6.7
	Location of the registration region	13	86.7	13	86.7	2	13.3	2	13.3
	Central location of registration	14	93.3	14	93.3	1	6.7	1	6.7
Information elements	Organizations of the national registry system	14	93.3	14	93.3	1	6.7	1	6.7
	Type of data	15	100	15	100	0	0	0	0
Registration criterion	Data resources	13	86.7	13	86.7	2	13.3	2	13.3
	Acceptance criterion	15	100	15	100	0	0	0	0
Collection and reporting process	Collection method	13	86.7	13	86.7	2	13.3	2	13.3
	Time of sending the report	11	73.3	15	100	4	26.7	0	0
	Method of reporting	13	86.7	13	86.7	2	13.3	2	13.3
Classification	Method of confidentiality	14	93.3	14	93.3	1	6.7	1	6.7
	Classification system	10	66.7	15	100	5	33.3	0	0
Data quality control	Duplication avoidance	15	100	15	100	0	0	0	0
	Organization supervising the control	14	93.3	14	93.3	1	6.7	1	6.7
	Quality indices	13	86.7	13	86.7	2	13.3	2	13.3

on the data provided in Table 1, some modifications are applied to three axes. Eventually, the final proposed model is developed with an agreement coefficient of 85%, the details of which are presented in Table 2.

Table 2 presents 7 main axes, along with the sub-axes of the final proposed model of the National Infertility Registry System for Iran.

Discussion

As mentioned earlier, the disease registry system includes collection, analysis, and the interpretation of data in a coherent systematic method for the diseases and timely

distribution of the processed and stored information. Additionally, the processed data are important for designing, implementing, and evaluating public health and clinical activities (28). In other words, providing precise data about the prevalence and causes of infertility is of utmost importance in every population. Epidemiological national data and information about the geographic differences act as contributors to the organizations and policymakers in order to understand the trends of public health in each area and improve the health prevention and resource allocation programs (12). Moreover, the management of information related to the process or

Table 2. The Proposed Model of the National Infertility Registry System for Iran

Main Aspects	Subordinate Aspects	Suggestions
The purposes of the system	The main purposes	Epidemiological studies, comparing different used methods, studying the outcome of ART, increasing patient safety, reducing costs, evaluating the quality of patient care, determining the geographic distribution, identifying the population having high risk, implementing prevention programs, and evaluating the effectiveness of planning, education, and research
	Responsible organization	The Ministry of Health
	Supervisory Committee	The review committee of the registry of infertility at the national level as the organization of developing policies and procedures
	Members of the committee	Epidemiologists, gynecologists, obstetricians, statisticians, and health information management and medical informatics professionals
The structure of the system	Type of registry system	The presence of hospital and clinic-based systems when establishing the national registry and population-based systems during the evolutionary period
	Methods of organization	The method of organizing the registration centers in a semi-centralized way
	Location of the registration of region	The Health Department of the University of Medical Sciences as the location of registration centers
	Central location of registration	The Health Department of the Ministry of Health as the location of the National Registry
Information elements	Organizations of the national registry system	Data resources (e.g., infertility clinics and hospitals, as well as sperm, egg, and embryo banks), the center of infertility registry in the towns, the center of infertility registry in provinces, the regional center of infertility registry, Disclosure Committee, the Review Committee, the national registry of infertility, and the Ministry of Health
	Type of data	Demographic, geographic, diagnosis, pregnancy history, the details of treatment, the complications of pregnancy and births, along with the details of eggs and sperm donors
The criterion of registration	Data resources	Clinics, hospitals, and infertility centers in the country in addition to the sperm, egg, and embryo banks
	Criterion of acceptance	The codes of N46 and N97 are for male and female infertility, respectively There are some other codes for defining the causes of infertility (e.g., N97.0-N97.9)
The process of collection and reporting	Collection method	Using both active and inactive methods based on the conditions and facilities
	Time of sending report	Sending the data to the national registry system of infertility once every three months
	Method of reporting	Developing the agenda of reporting for paper electronically and in the form of paper
	Method of confidentiality	Developing guidelines on the disclosure of information and establishing a disclosure committee to monitor the disclosure policies
Classification	Classification system	Currently, using ICD-10 and converting it to ICD-10-CM after having access to the relevant resources
	Duplication avoidance	Assigning an identification code to infertile patients to avoid duplications
Controlling the data quality	Supervising organization	Forming a professional committee under the committee of the data quality control (i.e., the sub-group of Review Committee of registration)
	Quality indices	Determining the data quality control (i.e., the completeness and accuracy without duplicating the data)

ART: Assisted reproductive technology; ICD: International classification of disease system.

consequences of the infertility disease is necessary because it probably contributes to the comparison and evaluation. Obviously, data about each person should be compared in accordance with the same procedure. Thus, each country needs to establish such a system considering national laws and requirements (18).

In the present study, the objectives of the national registration system of infertility were first compared in America, England, and Canada in order to provide the required strategy for infertility prevention and sufficient knowledge to improve the treatment and quality of life (18, 29). Therefore, to determine the structure of infertility data registry in the above-mentioned countries, special criteria were introduced including the responsible organization for collecting the data, the location of the responsible organization, the committee of the organization, the type of registration system, and the methods of organizing centers, reporting, and controlling the quality (18,29, 30). A registry must have several objectives and integrate the data from different sources (31). Additionally, data collection can be effective in providing optimum care, reducing costs, and developing health policies based on the outcomes and side effects of ART (32). The proposed model was designed in a way to reduce these problems to a minimum respecting data collection process. In the structure of the proposed model, accessing the most accurate information was probably predicted regarding the network of infertility data registry in towns, provinces, regions, and the ministry of health. Each of these centers should somehow play a role in the process of collecting and analyzing the feedback. In this model, developing an agenda for reporting and providing information was recommended in paper and electronic forms. In this regard, the information privacy and disclosure rules were considered under "Disclosure Committee". The agenda of controlling data quality was developed so that the data could be complete and correct without any repetition and forming a Data Monitoring Committee was proposed accordingly.

The purposes of the infertility data registry of epidemiological studies are to compare different utilized methods, study the outcome of the ART, increase patient safety, reduce costs, evaluate the quality of the patient care, determine the geographic distribution, identify the population who are at high risk, implement prevention programs, and finally, to evaluate the effectiveness of planning, education, and research (21,29). Therefore, such purposes can be applied to the infertility data registry of Iran. The proposed data encompassed demographic, geographic, and diagnosis elements, as well as the history of pregnancy, the details of treatment, the side effects, and the complications of pregnancy and births (26). Furthermore, the national identification code assigned to infertile patients was considered necessary for avoiding duplications. Similar to the selected countries, hospitals, infertility centers, and clinics are regarded as important

sources of data in Iran as well (21,24,26). In this system, the acceptance criterion was proposed based on the infertility codes of males, females, and other causes of infertility in the International Classification of Disease system (ICD) (29). Therefore, sending the seasonal data to the National Registry System of Infertility was suggested in the data registry system in Iran. This issue is addressed annually in countries under investigation, resulting in qualitative and quantitative analyses and problem-solving in a shorter period of time. In addition, using ICD-10 and ICD-10-CM, if possible, were proposed for classifying the infertility rate of the country.

Accordingly, it is necessary to form the Review Committee of Infertility Registry at the national level with the aim of providing consulting services, supervising, developing, and implementing policies. Further, the presence of epidemiologists, gynecologists, obstetricians, statisticians, and information management and medical informatics professionals was proposed in the committee. Moreover, the regional center of infertility registry was suggested to be located in the Health Department of the University of Medical Sciences of the region. Furthermore, the Ministry of Health was considered to be in charge of the National Registry System of Infertility of Iran.

In addition, most of the developed countries have egg, embryo, and sperm donation banks in which the specifications of the donors are registered and kept confidential forever. Thus, the identity of born babies can be identified by infertility techniques if necessary, which is of great importance in the next genetic issues, especially when they get married or fertile. Unfortunately, Iran has not taken measures to establish such banks thus the community may fail to control the genetic disease input of such individuals after their marriage in the future. Therefore, in the proposed model, forming egg, embryo, sperm banks and the bank links is suggested to the registry of infertility for identifying the true identity of those born by fertility techniques in order to prevent possible genetic diseases related to the marriage of future generations.

Conclusions

In general, taking several actions are highly important in infertility registry including collecting, storing, processing, organizing, analyzing, and distributing all the infertility data from all infertility treatment clinics or centers in a particular population as well as providing valuable information on the prevalence, time regional distribution of infertility, and improvement of health measures. Accordingly, creating and benefiting from an electronic health record system or database is one of the most important requirements of each country. Therefore, the proposed model can improve the management of infertile patients concerning providing a system to follow the results and improve the effectiveness of the treatment, health family planning, and controlling the factors that have an influence on infertility. Thus, the

policymakers and the Ministry of Health are suggested to actively attempt to create a data registry of infertility about egg, embryo, and sperm banks in Iran and to provide the necessary infrastructures for the development of this system which should include representatives from universities, government, and the private sector for achieving its purposes.

Conflicts of Interest

None to declare.

Ethical Issues

None to declare.

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