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Instructional Design, Development and Evaluation of Congenital Hypothyroidism Registry System

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Abstract

Congenital hypothyroidism is the most common congenital endocrine disorder, which can lead to preventable mental retardation. Creating and developing patient information recording systems provides standardized and organized methods for systematically collecting their clinical data based on predetermined purposes. This developmental study aimed at designing, developing, and evaluating a congenital hypothyroidism management system. This study was conducted in 2018-2019 to design architecture and develop software from the ADDIE model consisting of five steps analysis, design, development, implementation, and evaluation. The User Experience Questionnaire that is an instrument of high validity and reliability was used to evaluate the registry system. Relational database was created in MS SQL Server 2012. Tables and their relationships (10 data tables) were created. A table was assigned to the roles. A total of five user groups were drawn. After designing and creating the tables and database, the table relationships were created. Successful establishment of registry system for congenital hypothyroidism patients was done with an appropriate web-based design. This system can be used as a tool for recording and storing patient information, disease surveillance, epidemiological studies, as well as helping to standardize screening methods and improve the quality of patient care.

Keywords

Congenital hypothyroidism; Client server architecture; Web-based; Design; Development

Introduction

Thyroid hormone has a great impact on most organs of the body's systems and also plays an important role in the development of the nervous system (Wassner & Brown, 2015). The leading preventable cause of mental retardation is congenital hypothyroidism and the global prevalence of the disease is 1 per 1500-4,000 population (Klein, Meltzer, & Kenny, 1972). Most cases of congenital hypothyroidism are unavoidable, although side effects can be prevented by early diagnosis and treatment(Tariq et al., 2018). The screening program to screen children for selected disorders (congenital hypothyroidism) aims to prevent morbidity and mortality in the first few days of life (Howson et al., 2018). The disease registry provides standardized and organized methods for systematically collecting clinical data based on predetermined objectives (Gliklich, Dreyer, & Leavy, 2014). The disease registry has a high potential for describing and presenting information, the burden of diseases, treatments and outcomes and can be used to improve patient care (Liu, Rutherford, Smoyer-Tomic, Prichard, & Laplante, 2015).

Registry data describes the natural history, epidemiology, and boundaries of the disease, location of treatment, as well as regional or national changes in treatment and the obtained results contribute to improve the safety, quality, and value of patient care (LaBresh, Gliklich,

Liljestrand, Peto, & Ellrodt, 2003). Registry use is inevitable because of its convenience, reliability and low cost (Rustagi & Singh, 2012). Registries also have many benefits for physicians and health managers and decision-makers because of their availability, information accuracy, and ease of use (Pourasghar, Malekafzali, Koch, & Fors, 2008). The information stored in the registry helps identify possible risk factors and associated anomalies, and improve diagnosis and the quality of treatment for congenital hypothyroidism patients (Workman, 2013).

Creation of a congenital hypothyroidism the information management system also enables us to conduct extensive research on the disease and associated anomalies, to establish platforms for clinical trials, to promote knowledge about the disease, to identify its risk factors, to identify the disease genes and common genes with congenital anomalies, as well as to determine the prevalence of the disease (Hoque et al., 2017; Olivieri & Hypothyroidism, 2009). Given the high prevalence of congenital hypothyroidism in Iran (Seddighi, 2010), and the necessity of identifying risk factors for the disease and prevent its complications, it is essential to develop a registry system for congenital hypothyroidism patients.

Materials and Methods

This developmental study aimed for designing, developing, and evaluating a congenital hypothyroidism registry system was conducted in 2018-2019 to design architecture and develop software from the model Analysis, Design, Development, Implementation, and Evaluation ADDIE (ADDIE) consisting of five steps analysis, design, development, implementation and evaluation (Almomen et al., 2016).

Step One:

Analysis: In this step, a descriptive study was conducted. By searching for and reviewing scientific evidence, existing registries and related articles on congenital hypothyroidism, the primary dataset on the disease was examined and the primary data elements were drawn. To determine the validity and reliability of the data elements of the questionnaire, CVI (content validity index) and CVR (content validity relative coefficient) were used. To determine how to calculate the CVR, experts were asked to examine each item on the basis of a two-dimensional spectrum (unnecessary and necessary), and then the responses were calculated based on the formula. If the calculated value is greater than the predefined value of the table, its content validity will be accepted. The CVI was calculated by dividing the total number of experts who selected the choice fully relevant and those who selected the choice Relevant but requiring review by the total number of experts (Table 1). Then, a Likert scale (from absolutely disagree to absolutely agree) containing the obtained dataset was administered to 12 neonatal specialists and pediatricians (all of the research community), so that the data elements with an agreement of over 60 percent were determined as fields that should be mandatory filled with values (necessary data elements) in the system (Table 2).

Step Two:

Design. After determining the necessary data elements, according to the Scrum methodology (the Scrum methodology was selected with respect to time and cost savings as well as stakeholder feedback), opinion elicitation sessions were held with the presence of relevant experts. The functional requirements of the system were identified. Non-functional requirements were identified by understanding the overall nature of the system and its productivity features, and then the appropriate architecture was selected.

Step Three:

Software Development. Model design and creation, data tabulation, and system design were conducted using client-server architecture (due to the necessity to use health centers throughout the province, this type of architecture was adopted). The design pattern is MVC software. The system design was done using Microsoft visual studio 2013 software and SQL Server 2012 and C# language.

Table 1. Determine the validity and reliability of the data elements of the questionnaire

No.	Title	Necessary	Unnecessary	CVI	CVR
1	Date at delivering care	11	1	91%	83%
2	Date at follow-up	12	0	100%	100%
3	Weight at delivering different care	11	1	91%	83%
4	Height at delivering different care	11	1	83%	83%
5	Head circumference at delivering different care	10	2	75%	66%
6	Dosage of levothyroxine during different care	12	0	100%	100%
7	TSH level during different care	12	0	100%	100%
8	T4 or free T4 levels at delivering different care	12	0	100%	100%
9	Conditions during treatment	11	1	91%	83%

Step Four:

Implementation: At this step, the system was uploaded to the relevant domain and provided with different usernames and passwords.

Step Five:

Evaluation: Holding of opinion elicitation sessions and resolution of periodical drawbacks were conducted continuously. Initial system test was accomplished by entering the data, and final evaluation was done using the UEQ (User Experience Questionnaire) and comparison of the results with previous studies.

Results

A total of 108 data elements were identified in the last step for users to register the data.

Table 2. Patient follow up data elements (Experts response)

No	Title	1	2	3	4	5	Likert result
1	Date at delivering care	0	0	1	6	5	11
2	Date at follow-up	0	1	1	5	5	10
3	Weight at delivering different care	0	0	1	5	6	11
4	Height at delivering different care	0	0	1	5	6	11
5	Head circumference at delivering different care	0	0	1	5	6	11
6	Dosage of levothyroxine during different care	0	0	0	3	9	12
7	TSH level during different care	0	0	0	2	10	12
8	T4 or free T4 levels at delivering different care	0	0	0	1	11	12

In the first step, a relational database was created in MS SQL Server 2012. Tables and their relationships (10 information tables) were created (Figure 3). A table is assigned to the roles so that we have a total of 5 user groups. After the design and creation of the tables and the database, the relationship of the tables was created in accordance with it.

The proposed system was then implemented in Visual Studio 2013 using MVC technology as a web-based program. The code is written in C# language. We used LINQ-to-database technology to connect the database to Visual Studio. This technology is capable of relating database tables and performing CRUD (creation, reading, updating, and deletion) operations. Finally, the system was loaded in order to enter the data and carry out the server performance goals.

On the first page, a username and password are required to log in. Validation and access permissions vary by role (Figure 1). The system determines five different user roles, each of which has different access levels. The system administrator is granted access to the various sections. For ease of use and avoiding typing errors, a special format was designed for all data elements. Some data elements are optional and others are numerical, for numerical data, the specific range was defined.

Figure 1. User login tab

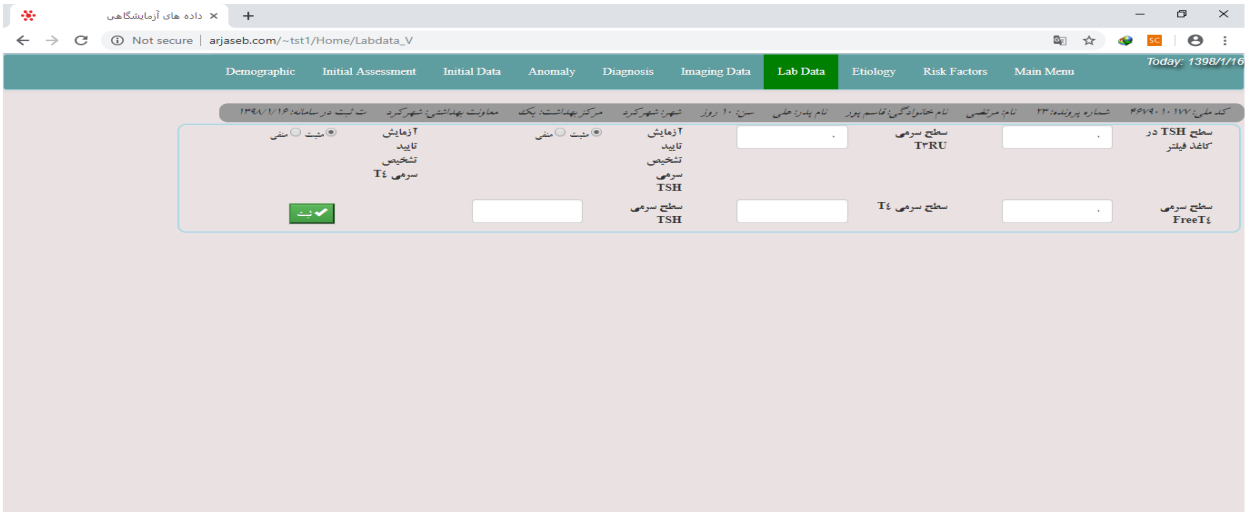

Figure 2. Lab data header

The results of the design phase are presented in 10 tables. Patient medical information was codified in 9 pages. Headers include demographic data, baseline assessment, baseline data, associated anomalies, diagnosis, imaging data, laboratory data, etiology and risk factors (Table 3).

Table 3. Essential Data elements for congenital hypothyroidism registry

Form Name	Form Summary
Demographic data	Demographic data: Patient identification information including birth date, family name, father's name, date of birth, age, cell phone number, telephone number, file number, gender, race, university, county, health center and postal address
Initial evaluation	Referral to Focal Physician, Serum Diagnosis Confirmation Test, the Dosage of the Prescribed Drug, Levothyroxine Dosage in Subsequent Primary Evaluation Periods
Associated anomalies	Developmental retardation ،mental retardation- language retardation- Congenital heart defects- Microsomia- Hearing impairment- Congenital anomaly of digestive-system- Genito-urethral malformations- Anomaly kidney- other
Primary data	Birth weight, Birth height, Birth head circumference, Time of first sampling, Infant age at start of treatment, Primary data
Risk factors for the disease	Newborn sex, maternal disease (hyperthyroidism or hypothyroidism), mother's age at delivery, gestational age (week), neonatal weight greater than 4000 g or less than 2500 g, iodine deficiency in the region, inheritance, consanguineous marriage, birth order, neonatal jaundice, twin or multiple pregnancy, birth season, consumption of certain medicines, improvement of laboratory diagnostic methods, use of anti-thyroid drugs in mother, maternal iodine excess, use of amiodarone, cytokines, dopamine, agonists, history of consumption of betadine, consumption of vegetables and fruits containing goatrogens in mother, history of blood transfusion in newborn, Down syndrome, Hepatic hemangioma, Hormonal dysfunction, Gestational diabetes, Hormone metabolism detects, History of hospitalization, The type of delivery, Duration of pregnancy, Risk factors for the disease
Laboratory data	TSH level on paper, serum TSH confirmation test, serum T4 serum, Serum TSH level, serum T3RU level, serum free T4 level, laboratory data
Imaging	Thyroid ultrasound, Knee x-ray scintigraphy thyroid
Clinical symptoms of the disease	Development delay, Mental retardation, Infantile cerebral palsy, Umbilical hernia, Constipation, Short stature, Jaundice, Abdominal distension, Hypotonia, Common cold
Etiology of the disease	Dysfunction of thyroid gland development, thyroid ultrasound

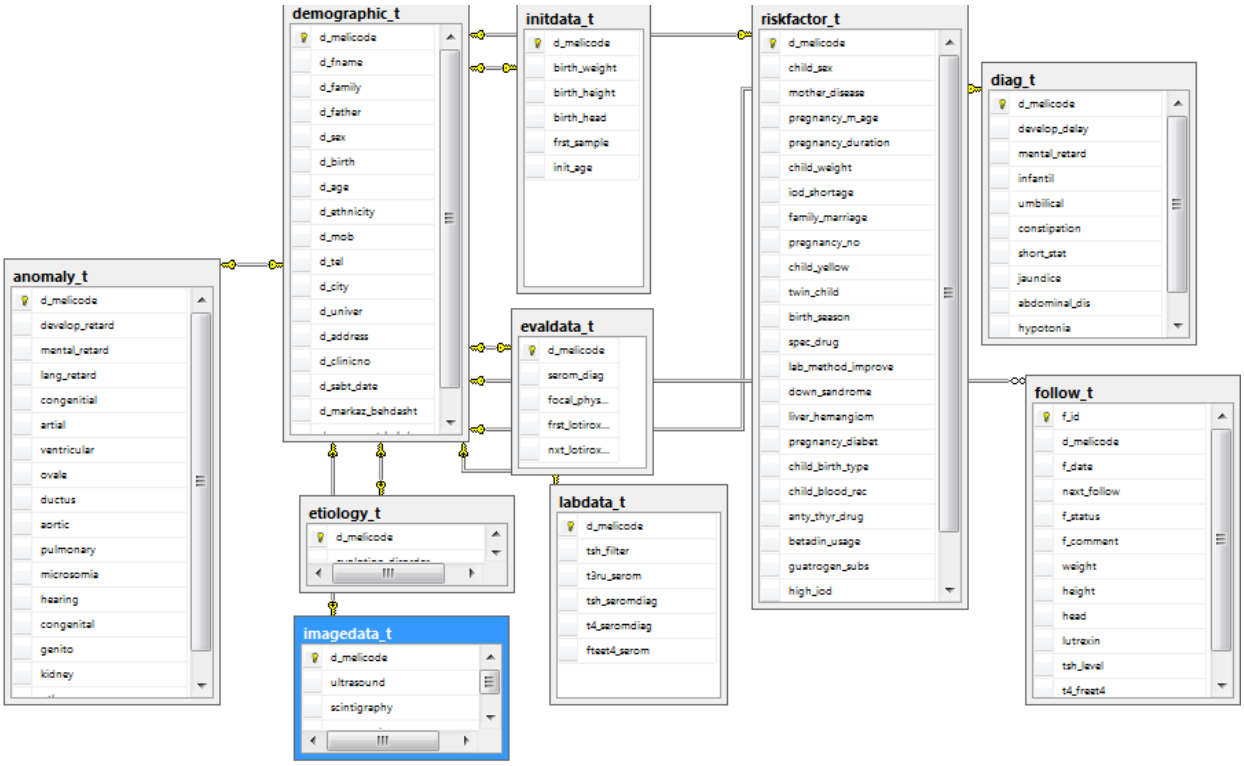

Figure 3. Database Relationships and Tables

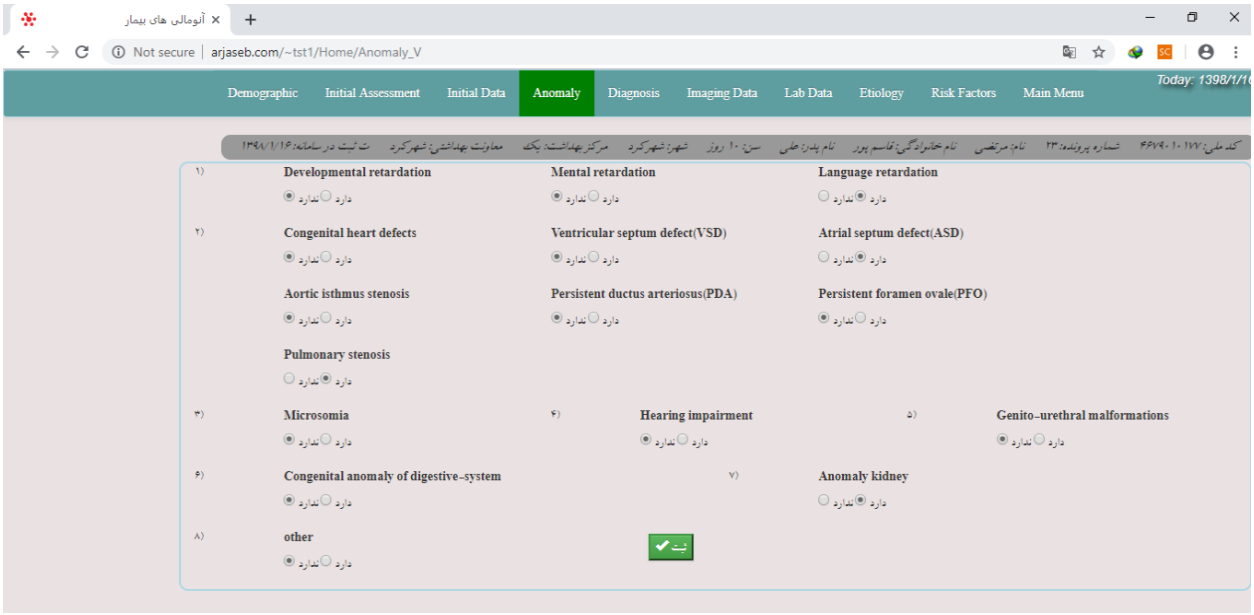

Figure 4. Anomaly header

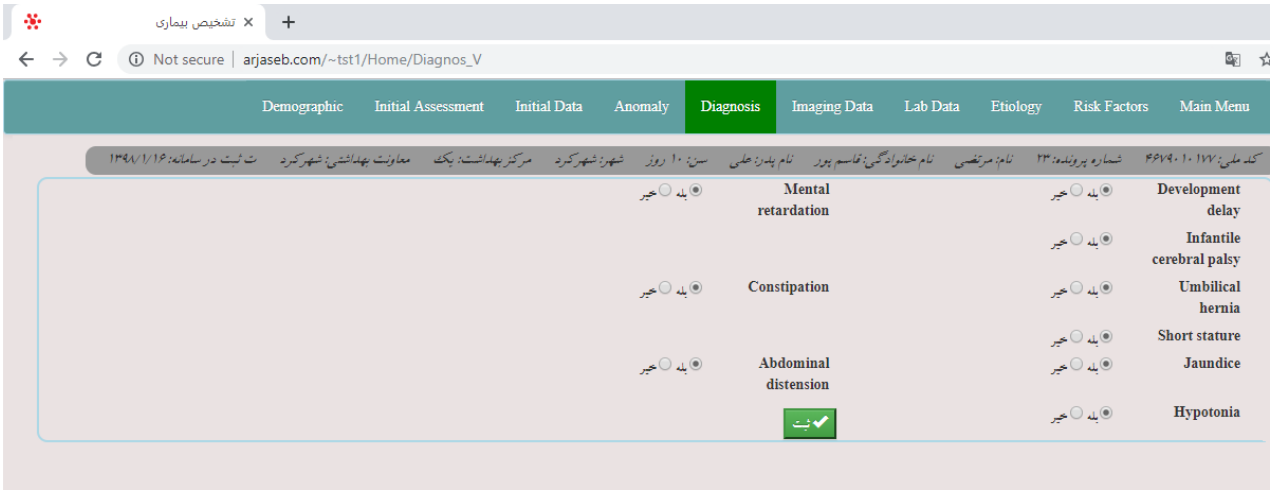

Figure 5. Diagnosis header

The initial performance test was conducted by entering experimental data on 656 patients (These data was related to patients with a diagnosis of congenital hypothyroidism in five cities of Chaharmahal va Bakhtiari province from 2010 to 2017). Information on each city for six months was entered separately in the Excel. After the data was consolidated into an Excel form the data was pre-processed. Noise and incompatibility of the data were corrected, duplicate and irrelevant data were deleted, and information fields without value were completed.

In the next step, data consolidation was performed and data were categorized and coded. The system was assessed using the User Experience Questionnaire (UEQ), a 26-item questionnaire of high validity and reliability (Nawaz, Helbostad, Chiari, Chesani, & Cattelani, 2015).

In this study, a short version of the questionnaire was used, including 8 items, the first 4 of which were related to the quality of system use and the next four items related to system design quality (Table 4). The questionnaire was administered to and completed by 15 physicians and users of the Health Center as well as the medical informatics of the health deputy who used the system.

The results of the evaluation of user experiences indicate that the system has achieved higher than average scores in terms of quality of design and use, and is within the range of 10 percent of best results (Figures 6 and 7).

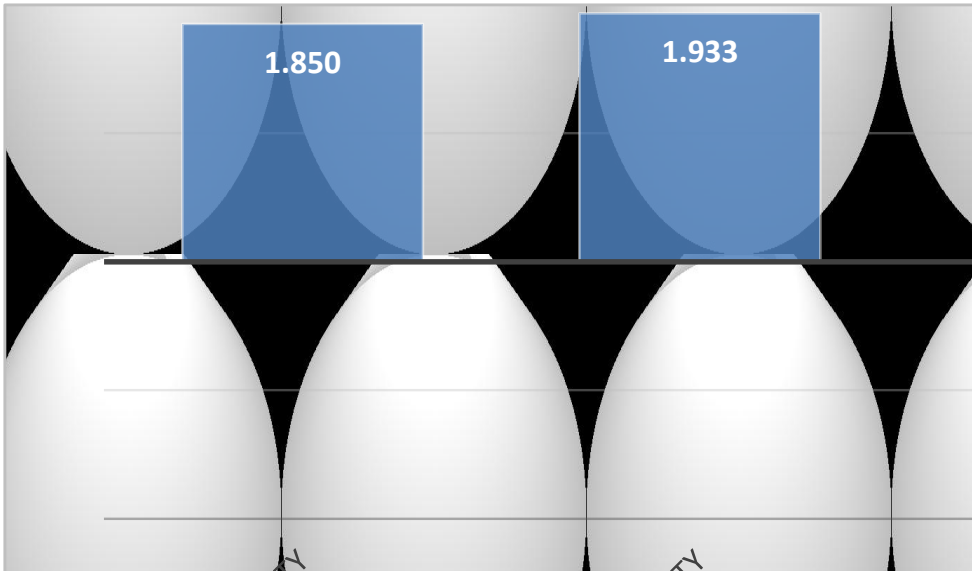

Figure 6. Bar illustration of mean values of qualitative measures

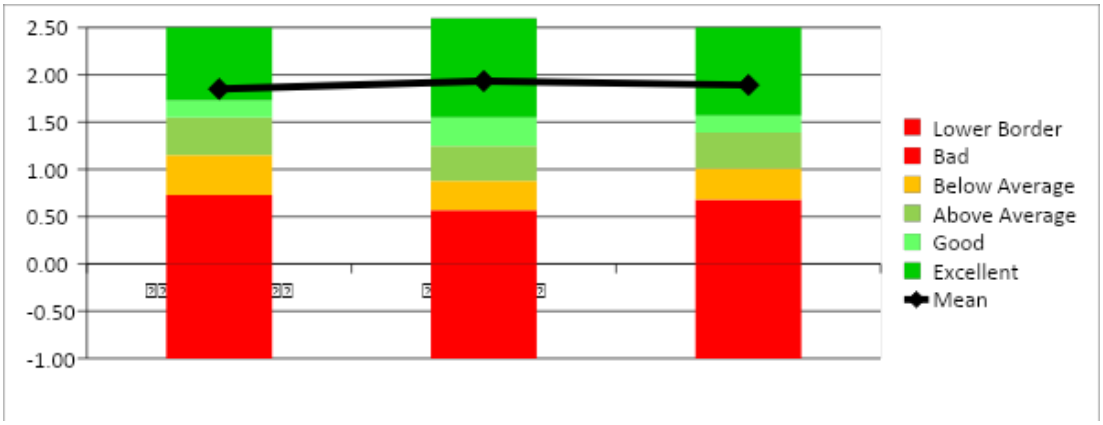

Figure 7. Comparison of the results with previous studies' results

Table 4. Items quality of system uses and the next 4 items related to system design quality

Item	Mean	Variance	Std. Dev.	No.	Negative	Positive	Scale
1	2.3	0.4	0.6	15	Obstructive	Supportive	Pragmatic quality
2	1.7	0.5	0.7	15	Complicated	Easy	Pragmatic quality
3	1.9	1.0	1.0	15	Inefficient	Efficient	Pragmatic quality
4	1.5	0.6	0.7	15	Confusing	Clear	Pragmatic quality
5	1.9	0.7	0.8	15	Boring	Exciting	Hedonic quality
6	2.1	0.5	0.7	15	Not interesting	Interesting	Hedonic quality
7	1.7	0.4	0.6	15	Conventional	Inventive	Hedonic quality
8	2.1	0.8	0.9	15	Usual	Leading Edge	Hedonic quality

Discussion

With reference to the request of the Deputy the Health of Shahrekord University of Medical Sciences and given the high prevalence of congenital hypothyroidism which is higher than the national average and almost ten times the global average (based on data obtained from the data of Shahrekord University of Medical Sciences), The design of the registry system for congenital hypothyroidism patients on previous studies was initiated.

An important issue in the registry is the several variables and data items (Zachary et al., 2015). Researchers (Kalankesh, Dastgiri, Rafeey, Rasouli, & Vahedi, 2015; Shahraki et al., 2018) have introduced the design of a minimum dataset as the first step in establishing a disease registry and consider the quality of sharing patient care data to be dependent on integrating patient data. In the present study, a Likert questionnaire and survey of specialists were conducted to identify essential data elements.

In a study consistent with the current study, the minimum dataset needed for management of cancer information was designed by Safdari et al. in Iran (Sadoughi, Ghazisaeedi, Ramzan Ghorbani, Meraji, & Safdari, 2013). In Lenti et al.'s study in Italy aimed to evaluate stroke patients, standard evaluation of patients required the collection of all necessary data elements (Lenti et al., 2008).

The Scrum methodology was chosen due to a number of advantages, including time and cost savings and stakeholder feedback. The Scrum process facilitates the saving of lessons learned during product development for key stakeholders (Ali et al., 2018). In line with the current study, Shahraki et al. (2018) in the design of a registry of stroke patients, used the Scrum Methodology and MVC pattern (Shahraki et al., 2018). The client-server system architecture was used in the development of the current system due to the need for implementation in all health centers of the province. With this architecture, it is possible to use a combination of installed local and remote servers. In the client-server architecture, internet connection and network are activated in response to the client request.

As the request is received, the connection is established between the client and the server (Civanlar & Haskell, 1999). In a similar study using the client-server architecture for the purpose of linking system components as well as providing access to various information sources(Bouju, Stockus, Bertrand, & Boursier, 1999), MVC design pattern was used.

MVC is a new pattern and has many advantages (including flexibility, code reusability, ease of development and maintenance) over the previous three-layer architecture (Ping, Kontogiannis, & Lau, 2003). Using the web-based platform is on the agenda given its many benefits including high availability through internet-connected systems, easy development, installation and maintenance, and greater security. Similar to the current study, Napier KRet al.'s study was

aimed to establish a web-based Angelman Syndrome Registry Study, but unlike the current study, the design was modular that has the potential to evolve over time (by adding new modules). In addition, the open source registry platform enables future improvements (Napier et al., 2017).

Similar research has shown that web-based software enables access to registry's data at any time and place by removing geographical restrictions and also enables immediate data entry, updating and reporting (Subhani & Al-Rubeaan, 2010). Being web-based is also associated with convenient content sharing system and ease of accessibility.

The study of Subhani and Al-Rubeaan (2010) confirms the findings of the present study that usernames and passwords should also be used to ensure data security and integrity as well as to determine access levels (Taivalsaari & Mikkonen, 2011) . Based on the results of the registry evaluation, the characteristics of question (e.g., software design quality, quality of software use, etc.) obtained higher-than-average scores, indicating high quality of registry design and use. The results of another similar study are those of the study Laing, Bruce, Aldous, and Clarke, (2014) aimed to design, create, and implement an electronic trauma registry, and one year after its implementation, a total of 2640 patients were recorded, with results showing compliance at approximately 80 percent and high user satisfaction.

Conclusion

Successful establishment of information management system for congenital hypothyroidism patients was done with appropriate web-based design. It is a tool for recording, storing, displaying information, monitoring disease and epidemiological studies. Standardization of screening methods, quality improvement, and management of patients' treatment and promotion of disease knowledge are also possible with this system. Evaluation results show that different users agree and the system productivity is high. The system can also be very important in policymaking and decision-making (for prevention) at the regional, provincial and national levels. Advantages of this system are achieving many goals including epidemiology, disease surveillance and disease incidence and prevalence.

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