



Development of Inflammatory Bowel Diseases Registry Software

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ABSTRACT

BACKGROUND

With an increase in the prevalence and incidence of inflammatory bowel diseases (IBDs), they have become a global challenge. The IBD registry provides complete and timely data, thereby greatly contributing to the estimation of the burden of these diseases and development of control and prevention programs. We aimed to develop an IBD registry software.

METHODS

The present applied-developmental study had two main stages: determining user requirements, and developing the IBD registry software. The software was created using a Web-based software development technology called ASP.NET Core 2. The programming language in this framework was #C, and the SQL Server 2017 was employed to create a strong and integrated software databank in the relational form.

RESULTS

When determining user requirements, the data elements were classified into two main categories of patient information and visits and tests. Moreover, in this stage, registry functions, including case ascertainment, abstracting, follow-up, quality control, and reporting were identified. In the registry software development stage, the object-oriented conceptual model was designed with five use case diagrams and 59 classes. The user interface comprised the following main sections: add patient, find patient, complete source report, report, staff, and drugs. Precise user authentication and authorization were also employed to enhance the security of the developed software.

CONCLUSION

Development of an IBD registry which can precisely record patients and estimate the incidence, prevalence, and socioeconomic burden of these diseases can assist in planning for the control and prevention of IBD in healthcare systems.

KEYWORDS:

Inflammatory Bowel Diseases, Registry, Registry software.

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INTRODUCTION

Inflammatory bowel diseases (IBDs) are a group of chronic diseases of the digestive system, the most prevalent of which is Crohn's disease (CD) and ulcerative colitis (UC).¹⁻³ These diseases are autoimmune, life-long, and



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idiopathic, usually appearing in the second and third decades of life and leading to the inflammatory destruction of the digestive system.^{4,5} About 21-41% of patients with IBDs experience the systematic manifestations of this disease throughout their lives; manifestations that involve all organs, including the cardiovascular system, lungs, skin, joints, and eyes.^{5,6} IBDs dramatically impact life quality, life expectancy, social interactions, performance, and medical expenses.^{7,8} Affliction with these diseases before 20 years of age reduces life expectancy by about 7-13 years.⁷

The highest prevalence of IBD is in North America, Europe, and Oceania. More than 1 million individuals in the US and 2.5 million in Europe suffer from these diseases. The prevalence of IBD in the West is approximately 50-200 for CD and 120-200 for UC per 100,000 populations. The prevalence and incidence of IBD are increasing in Asia, South America, and Africa. In the 21st century, IBDs have become a global disease because of their heavy socioeconomic burden.⁹⁻¹¹

To estimate the burden of IBDs and their socioeconomic outcomes, and identify their causes, it is essential to develop and expand national IBD registries.^{3,12} Registries offer complete data, thus greatly assisting the adoption of effective health-related policies for the better identification of problems related to IBD and provision of patient-centered care.⁷

The IBD registry aims to identify and record cases diagnosed with IBD, calculate the burden of the diseases in order to provide optimal healthcare for all patients, identify the incidence of the disease in all geographical locations, and monitor the trend of the diseases.¹³

Bernstein expresses that registries are developed to meet a pre-determined scientific, clinical, or political goal, and various large IBD registries have been developed in North America and Western Europe. These registries are rich sources for research, offering guidelines for determining the incidence and prevalence of IBDs, understanding their burden, comorbidities, outcomes, and even etiology.¹⁴

Malekzadeh and colleagues regard the development of IBD registries to be an important step for examining possible risk factors and etiology as well as conducting studies necessary for understanding the history, phenotype, response to treatment, complications, and survival of patients with IBDs.¹⁵

In the world, IBDs are becoming a major health challenge.¹⁶ The number of patients, the effect of IBDs on

health, budget, and social resources must be specified in order to adopt effective policies for the prevention and reduction of the burden of IBDs.^{17,18} Therefore, considering the increasing trend in the prevalence and incidence of IBD in Iran, and the role of IBD registry software for planning the level of healthcare resources required for dealing with these diseases,¹³ we aimed to develop an IBD registry software program in the Research Institute for Gastroenterology and Liver Diseases of Shahid Beheshti University of Medical Sciences, Iran.

MATERIALS AND METHODS

The present applied-developmental study aimed at developing an IBD registry software program in the following two stages:

1. Determining user requirements

In this stage, through literature review, data elements of IBD registries and the functions for the development of registries were identified, and a questionnaire was designed accordingly. This questionnaire was distributed among gastroenterologists and IBD registry users. The content validity of the questionnaire was examined, and the test-retest method was adopted for measuring its reliability ($r = 0.89$). The questionnaire was given to five gastroenterologists and two users, and their opinions were sought regarding the necessity of keeping the items.

2. Development of the IBD software: This stage comprised four steps

1.2. Designing the object-oriented conceptual model

In this step, using the results of the previous stage, an object-oriented conceptual model consisting of structural, operational, and behavioral models was designed based on the Unified Modeling Language (UML).

2.2. Validating the object-oriented conceptual model

The developed conceptual model was given to five experts in health information management, five experts in medical informatics, and five gastroenterologists. If more than 75% of the respondents agreed on an item of the model, that item would be confirmed. If the agreement was 50-75%, the item would be examined in the next round, and if it was $< 50\%$, it would be eliminated from the proposed model.

3.2. Development of the software

After finalizing the conceptual model, the software was created using a Web-based software development technology called ASP.NET Core 2. The programming language in this framework was #C, and the SQL Server 2017 was employed to create a strong and integrated software databank in the relational form. The connection between the software and the databank was formed using Entity Framework 6 with the Code First methodology. In this software, the user interface was developed on the basis of UI/UX principles and the principle of appropriate user experience in a step-by-step manner and with the direct opinion of the main system users.

4.2. Software testing for debugging

After the coding steps, a debugging test was performed to ensure the accurate functioning of the developed software and identify the probable errors in the operational environment. This test is among the most important tests in the software development process which identifies the possible defects of the software before delivering it to the end user. Moreover, to ensure the accurate functioning of the software, after developing the first version, each user performed some pre-determined tasks using the software and offered his/her opinions about the software, functioning, problems, and ideas. Subsequently, based on the results of the preliminary analysis, modifications were applied and the last version of the software was developed.

RESULTS

The findings of the study are presented below in two stages of determining user requirements and development of the registry software.

1. Findings Related to Determining User Requirements:

After examining user requirements, the following data elements and processes of the IBD registry software were identified:

1.1. Data elements: Data elements were classified into two main categories of patient information and visits and tests.

- Patient Information: Basic Information, Patient Personal Information, Data Source, Secondary Contact,

Medical History, Family History of IBD, Habitual History, Diagnosis Identification, Symptoms & Signs at Onset, Past Drug History, Death Information

- Visit and Tests: Symptoms & Signs, Complication, Endoscopy, Pathology, Drugs, Hospital Admission, Doctor Visit, Small Bowel Follows Through, Barium Enema, Plain Abdominal Radiograph, Laboratory Test

2.1. Registry processes: Five major steps must be followed in creating any registry: case ascertainment (case finding), abstracting, follow-up, quality control, and reporting.

- Case ascertainment (case finding): Based on the data inputted to the software system, the statistics of new cases of IBD per year are provided.

- Abstracting: The software can create a summary of the patient files based on each center's requirements with the fields specified by the doctors in that center

- Follow-up: Patient follow-up is one of the main processes of registries. For this purpose, the user should only enter the exact date for the patient's next visit. Three days before this date, an automatic notification is sent to the user, and the patient's telephone number immediately appears on the screen, so that he/she can be contacted without having to refer to his/her file.

- Quality control: To control the quality of the data inputted to the system, a form of validation has been added to all data fields so that only the type of data or data interval previously specified can be entered; otherwise, an error message will appear. Moreover, required fields must be filled in; otherwise, the user cannot proceed to the next step (required fields and data types are created under the direct supervision of the registrar). Moreover, there is a section called 'Alert' in the software which automatically notifies the registrar of the existence of incomplete files, and the user can view and complete all incomplete files at one glance without having to examine all files.

- Reporting: A major part of this software is the query builder. In the query builder, the user can create a query comprising any number of tables, with selected fields, and relationships among tables. The output of this query can take the .csv, .pdf, Microsoft Word, Excel, and other formats.

2. Developing of the registry software

1.2. Designing of the object-oriented conceptual model

In the object-oriented conceptual model, five use case diagrams were designed (the general use case diagram

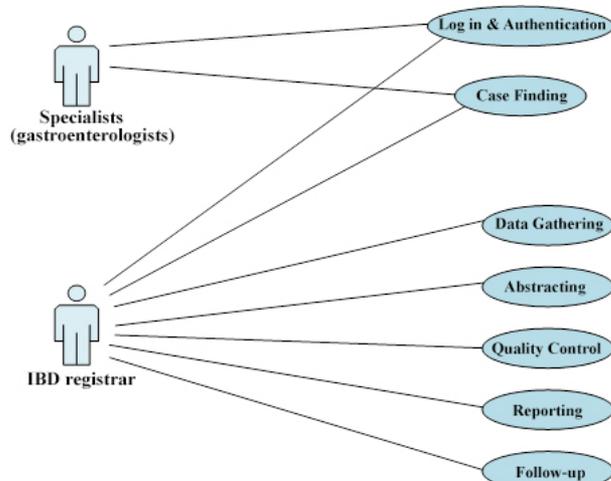


Fig. 1: The general use case diagram of the IBD registry software

of the IBD registry software, the use case diagram related to case ascertainment, reporting, quality control, and abstracting). Figure 1 illustrates the general use case diagram of the IBD registry software, in which the IBD specialist and registrar have been selected as the main actors of the electronic registry system. Then, for modeling the relationships among data, the class diagram with 59 classes was plotted as the conceptual diagram of the IBD registry (a sample of these classes is presented in Figure 2).

2.2. Development of the IBD registry software

The IBD registry software requires an effective and simple user interface due to its practical nature. The user interface comprises the following main sections: add patient, find patient, complete source report, report, staff, and drugs (figure 3). Moreover, on the main page of the software, there is a section entitled 'Notes' which enables the user to write separate notes in files. In this section, the registrar can add any note to the files if needed. This note can include reminders, specific reports, the explanation of an activity for examination by the doctor, or the patient's next visit. In addition to patient files, these notes are also viewed in the software's management dashboard.

Due to the importance of data security, authentication and authorization were employed to enhance the security of the developed software, and it is impossible for a third party to gain access to the software. No person can use the system without having a username and password, and in the case of multiple unsuccessful logins, the

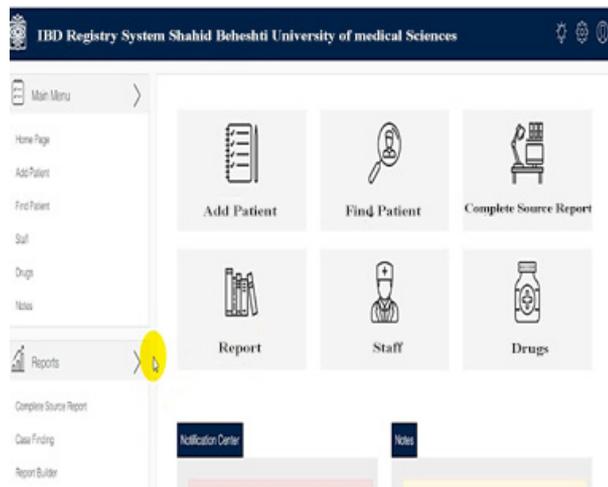


Fig. 3: The user interface of the IBD registry software

person's access to the system will be blocked to ensure security. Furthermore, the database is also provided in a secure Web-based manner and can be accessed only by those with authorized access and determined passwords.

DISCUSSION

Registries are ideal ways to collect healthcare and monitoring data, and are essential tools for stakeholders of the healthcare system in order to provide improved high-quality outcomes for patients. The development and customization of a registry for diseases require the cooperation of key stakeholders, including doctors, clinical units, healthcare services, and hospitals. In addition, the development of a disease registry needs accurate data and appropriate tools and methods for structuring it.^{19, 20}

The present study classified the data required for the IBD registry into two main categories of patient information and visit and tests. In a study on IBD registries, the main data element groups in the registries of Australia, Germany, Spain, and Europe were also classified into two main categories of patient demographics and diseases and treatment data.²¹ In this study, because of the importance of data elements for understanding the etiology of IBDs, evaluation of treatment models, monitoring safety, and studying different outcomes for expressing the value of interventions,²² the data elements were accurately identified based on users' and specialists' expectations.

The IBD registry was developed in five stages of case ascertainment, abstracting, follow-up, quality

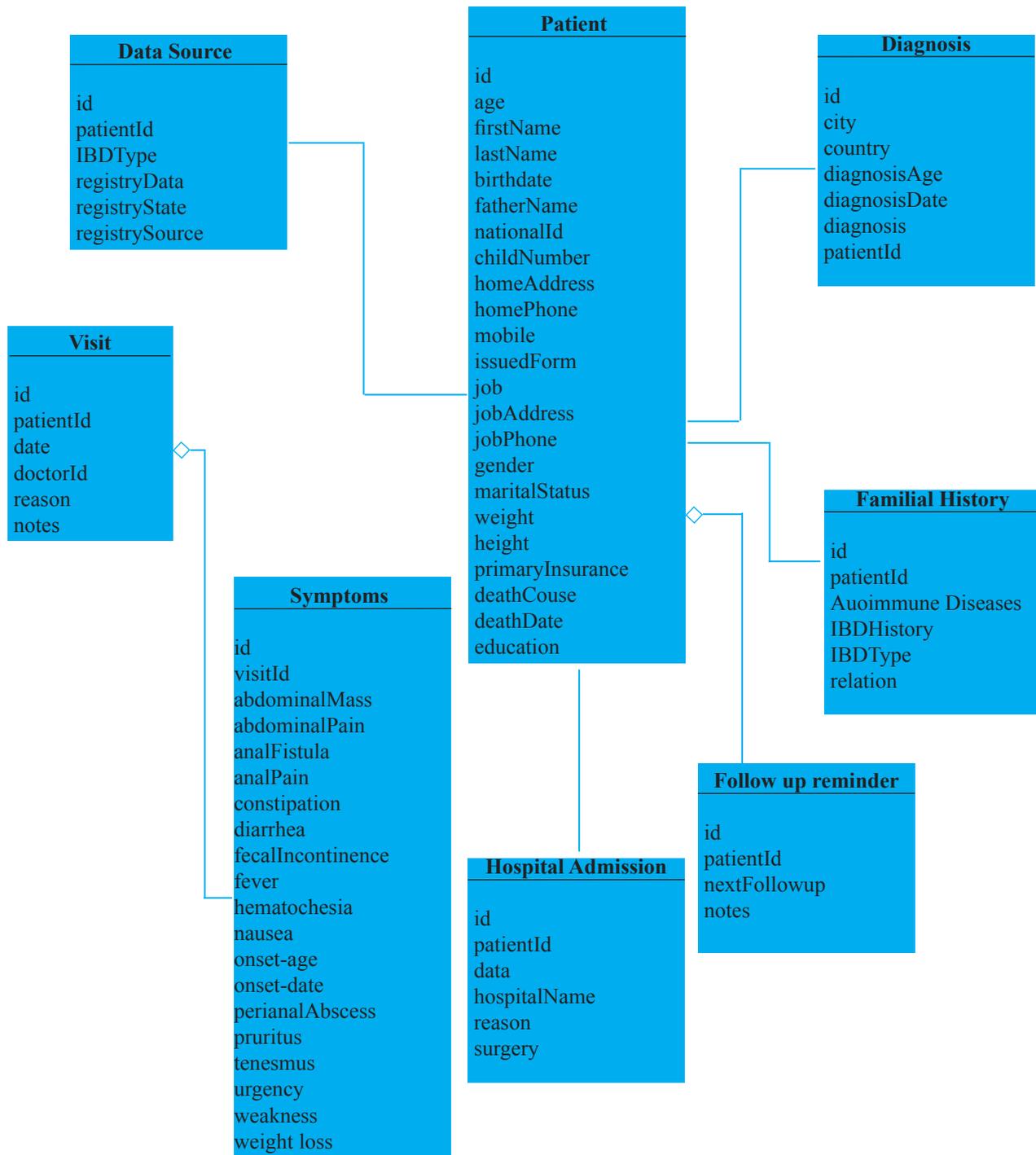


Fig. 2: The class diagram of the IBD registry software

control, and reporting. Similarly, in the Surveillance, Epidemiology, and End Results (SEER) Program (a program focusing on monitoring, epidemiology and final outcomes of diseases in the US), the procedures for creating

the registry included case ascertainment, abstracting, follow-up, quality control, and reporting.²³

A key process in registries is the quality control of the data. The quality of the data stored in the databases of

registries is essential for managers in decision-making and identification of functions and improvement of processes.^{24, 25} The data quality is often discussed in relation to completeness, accuracy, consistency, relevance, and timeliness.^{22, 25} Irrespective of the registry type, the high data quality requires effective oversight and managerial mechanisms.²⁶ In the IBD registry software, to control the quality of registry data, a validation mechanism for the inputs and completeness of data through specific notices was provided in the system.

Another key process in developing a registry is reporting. According to Bray, registries must facilitate the provision of statistics, conducting research, and decision-making purposes. Another important objective of registries is producing up-to-date statistics on a specific disease in a defined population.²⁷ In the present study, to meet these objectives, a query builder was provided in the software to create different outputs from the software in various formats in the reporting section, which is an advantage of this software.

A good conceptual model is of utmost importance, not only for producing a good product, but also for product development processes.²⁸ According to Al-Fedaghi, the object-oriented conceptual model is a natural method for expressing concepts which, by a realistic representation, allows the user to perceive it in a real way.²⁹ The formation of this perception is an important part of training for using the software.²⁸ In the present study, the conceptual model of the system was developed based on the object-oriented conceptual model (structural, operational, and behavioral model) and UML diagrams, which are the other advantages of the software. Moreover, model evaluation demonstrated that, using this model, we can design and implement the IBD registry software based on the users' requirements.

Another key feature of this software was an appropriate user interface. User interface is the key aspect of human-computer system interactions.³⁰ Designing an effective and appropriate user interface helps users to better find their way around databanks and improves the performance of the entire system.^{30, 31} According to Splitz, the effective design of a user interface increases the system's acceptance by users. On the other hand, an inappropriate user interface design negatively impacts

the users (leading to fatigue, confusion, and waste of time).³² The advantages of the system designed in this study in terms of the user interface was the simplicity of the processes.

Attention to the security of the IBD registry software was another feature of this software. Software security is a key element of data security management for any organization. Software vulnerability facilitates external attacks, and individuals will find unauthorized access to data, systems, and services.³³ Authentication and authorization are both methods for guaranteeing the security of software programs and applications. Authentication guarantees that no unauthorized user can enter the system, and authorization ensures that no user can access unauthorized resources by mistake.³⁴ In the present study, to ensure software security, both mechanisms of authentication and authorization were employed, so that unauthorized users would not access the data in the system.

Despite the mentioned features, IBD registry software can only be used on Windows-based servers and Linux server cannot support all software capabilities because of the programming language and query builder used in this software.

Regarding software upgrade, new needs of software users will be collected and new features will be added to IBD registry software considering users' needs annually. Also, the potential problems will be resolved by fixing bugs and errors. The performance and stability of software will improve by solving these problems. Since the IBD registry software is web-based, the software will be upgraded on the server and all users can access and receive the new version of IBD registry software.

CONCLUSION

Considering the increased number of patients with IBDs, it is essential to accurately record patient data in a registry. Thanks to its features such as improved user interface, using a programming language, up-to-date technology and database, a query builder to create custom outputs, high level of security, special notices for incomplete files and patient visits, the ability to add notes to patient files, and the ability to add and edit the doctors and medications in the system, the registry developed in this study can greatly contribute to future planning for the

control and prevention of IBDs in the healthcare system.

ETHICAL APPROVAL

There is nothing to be declared.

CONFLICT OF INTEREST

The authors declare no conflict of interest related to this work.

REFERENCES

1. Bassi A, Dodd S, Williamson P, Bodger K. Cost of illness of inflammatory bowel disease in the UK: a single centre retrospective study. *Gut* 2004;**53**:1471-8.
2. Conley S, Redeker N. A systematic review of self-management interventions for inflammatory bowel disease. *J Nurs Scholarsh* 2016;**48**:118-27. doi: 10.1111/jnu.12189.
3. Kotze PG, Underwood FE, Damião AOMC, Ferraz JGP, Saad-Hossne R, Toro M, et al. Progression of Inflammatory Bowel Diseases Throughout Latin America and the Caribbean: a Systematic Review. *Clin Gastroenterol Hepatol* 2020;**18**:304-12. doi: 10.1016/j.cgh.2019.06.030.
4. Laass MW, Roggenbuck D, Conrad K. Diagnosis and classification of Crohn's disease. *Autoimmun Rev* 2014;**13**:467-71. doi: 10.1016/j.autrev.2014.01.029.
5. Petrey AC, Carol A. Hyaluronan in inflammatory bowel disease: cross-linking inflammation and coagulation. *Matrix Biol* 2019;**78-79**:314-23. doi: 10.1016/j.matbio.2018.03.011.
6. Massart A, Hunt DP. Pulmonary Manifestations of Inflammatory Bowel Disease. *Am J Med* 2019;**133**:39-43. doi: 10.1016/j.amjmed.2019.07.007.
7. Calderón M, Minckas N, Nuñez S, et al. Inflammatory bowel disease in Latin America: a systematic review. *Value Health Reg Issues* 2018;**17**:126-34. doi: 10.1016/j.vhri.2018.03.010.
8. Con D, De Cruz P. Mobile phone apps for inflammatory bowel disease self-management: a systematic assessment of content and tools. *JMIR Mhealth Uhealth* 2016;**4**:e13. doi: 10.2196/mhealth.4874.
9. Chou JW, Lai HC, Chang CH, Cheng KS, Feng CL, Chen TW. Epidemiology and Clinical Outcomes of Inflammatory Bowel Disease: A Hospital-Based Study in Central Taiwan. *Gastroenterol Res Pract* 2019;**2019**:4175923. doi: 10.1155/2019/4175923.
10. Ghadiri A, Esmacili H, Hashemi SJ, Masjedizadeh A, Alavi Nejjad P, Shayesteh AA. A Study On Epidemiological Features And Clinical Manifestations Among Crohn And Ulcerative Colitis Patients Admitted To Treatment Centers of Ahvaz, Iran. *Jundishapur Sci Med J* 2016;**15**:19-33.
11. Plevinsky JM, Greenley RN, Fishman LN. Self-management in patients with inflammatory bowel disease: strategies, outcomes, and integration into clinical care. *Clin Exp Gastroenterol* 2016;**9**:259-67. doi: 10.2147/CEG.S106302.
12. Valpiani D, Manzi I, Mercuriali M, Giuliani O, Ravaioli A, Colamartini A, et al. A model of an inflammatory bowel disease population-based registry: The Forlì experience (1993–2013). *Dig Liver Dis* 2018;**50**:32-6. doi: 10.1016/j.dld.2017.09.120.
13. Taghavi SA, Lankarani KB, Moini M, Hamidpour L, Ardebili M, Mansoorabadi Z. Establishment of a population-based registry of inflammatory bowel diseases in Fars province, Iran. *Middle East J Dig Dis* 2012;**4**:97-101.
14. Bernstein CN. Large registry epidemiology in IBD. *Inflamm Bowel Dis* 2017;**23**:1941-9. doi: 10.1097/MIB.0000000000001279.
15. Malekzadeh MM, Sima A, Alatab S, Sadeghi A, Ebrahimi Daryani N, Adibi P, et al. Iranian Registry of Crohn's and Colitis: study profile of first nation-wide inflammatory bowel disease registry in Middle East. *Intest Res* 2019;**17**:330-9. doi: 10.5217/ir.2018.00157.
16. Malekzadeh MM, Vahedi H, Gohari K, Mehdipour P, G Sepanlou S, Ebrahimi Daryani N, et al. Emerging epidemic of inflammatory bowel disease in a middle income country: A nation-wide study from Iran. *Arch Iran Med* 2016;**19**:2-15.
17. Ganji A, Malekzadeh F, Safavi M, Nassri-Moghaddam S, Nourie M, Merat S, et al. Digestive and liver disease statistics in Iran. *Middle East J Dig Dis* 2009;**1**:56-62.
18. Malekzadeh F, Sepanlou SG, Poustchi H, Naghavi M, Forouzanfar MH, Shahrzad S, et al. Burden of Gastrointestinal and Liver Diseases in Iran: Estimates Based on the Global Burden of Disease, Injuries, and Risk Factors Study, 2010. *Middle East J Dig Dis* 2015;**7**:138-54.
19. Bellgard MI, Macgregor A, Janon F, Harvey A, O'Leary P, Hunter A, et al. A modular approach to disease registry design: Successful adoption of an internet-based rare disease registry. *Hum Mutat* 2012;**33**:E2356-66. doi: 10.1002/humu.22154.
20. Somanath M, Nair A, Mohanty R, Braick U, Gowda A, Patil A. Good practices in the conduct of a patient registry. *Int J Med Res Health Sci* 2016;**5**:22-6.
21. Halfvarson J, Cummings F, Grip O, Savoye G. Inflammatory bowel disease registries for collection of patient iron parameters in Europe. *World J Gastroenterol* 2018;**24**:1063-71. doi: 10.3748/wjg.v24.i10.1063.
22. Gliklich RE, Dreyer NA, Leavy MB. Registries for evaluating patient outcomes: a user's guide: 3rd ed., Vol.2. Government Printing Office, 2014.
23. Jensen OM, Parkin DM, MacLennan R, Muir CS, Skeet R. Cancer registration: principles and methods. Lyon, France: IARC 1991.
24. Gliklich RE, Dreyer NA, Leavy MB. Registries for evaluating patient outcomes: a user's guide: 3rd ed., Vol.1. Government Printing Office, 2014.
25. Sidi F, Panahy PHS, Affendey LS, Jabar AM, Ibrahim H,

- Mustapha A. Data quality: A survey of data quality dimensions, In 2012 International Conference on Information Retrieval & Knowledge Management, IEEE, 2012.
26. Kodra Y, De La Paz MP, Coi A, Santoro M, Bianchi F, Ahmed F, et al. Data quality in rare diseases registries. *Adv Exp Med Biol* 2017;**1031**:149-64. doi: 10.1007/978-3-319-67144-4_8.
 27. Bray F, Znaor A, Cueva P, Korir A, Swaminathan R, Ullrich A, et al. Planning and developing population-based cancer registration in low-and middle-income settings. IARC 2014.
 28. Johnson J, Henderson A. Conceptual models: Core to good design. *Synthesis Lectures on Human-Centered Informatics* 2011;**4**:1-110. doi: 10.2200/S00391ED-1V01Y201111HHC1012.
 29. Al-Fedaghi S. Thinging vs objectfying in software engineering. *International Journal of Computer Science & Information Security (IJCSIS)* 2018;**16**.
 30. Ommati E, Alipour A. Important elements in the design of user interface, usability and technical issues of databases during the years 2014-2016. *J Mod Med Info Sci* 2016;**2**:63-74.
 31. Punchoojit L, Hongwarittorn N. Usability studies on mobile user interface design patterns: a systematic literature review. *Advances in Human-Computer Interaction* 2017;**2017**:1-22. doi: 10.1155/2017/6787504.
 32. Splitz AR, Balis UJ, Friedman MBA, Tuthill JM. Use of the LIS Functionality Assessment Toolkit: A Methodology for Assessing LIS Functionality and Enabling Comparisons Among Competing Systems. Association for Pathology Informatics (API). 2013. <https://www.semanticscholar.org/paper/Use-of-the-LIS-Functionality-Assessment-Toolkit-%3A-A-Splitz/39d7331ad31545c5032a2d308a24da4df650fa59>.
 33. Asadi F, Paydar S. Presenting an evaluation model of the trauma registry software. *Int J Med Inform* 2018;**112**:99-103. doi: 10.1016/j.ijmedinf.2018.01.013.
 34. Mishra P. User interface design: for existing system monitoring application. Media Engineering. *Bachelor's Degree: Helsinki Metropolia University of Applied Sciences* 2013:56. [Thesis]