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Investigation of Clinical Information System in Gastrointestinal and Liver Diseases Research Centers: Challenges and Solutions

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Abstract

Objectives: Today, medical research centers are recognized as the bases for development of high-quality medical knowledge in societies. In this regard, application of clinical iinformation system (CIS) facilitates the achieving of this goal. This study aimed to investigate the challenges and solutions of CIS in the gastrointestinal and liver diseases (GILD) research centers.

Materials and Methods: This descriptive-fundamental research was conducted on gastrointestinal and liver diseases academic research centers of Tehran. Research sample was in line with the community, and the data were collected through interviews and using a questionnaire. In addition, validity and reliability of the questionnaire were confirmed via content validity and test-retest, respectively.

Results: The results of the study showed that gastrointestinal and liver diseases research centers contained various service-providing sections, including endoscopy, colonoscopy and liver, gastrointestinal and inflammatory bowel diseases, and cancer and each of which had a separated and independent software with no connections to other software and HIS. Moreover, the software had no warning mechanism to track the patients for referral in due time. This mechanism was important since lack of timely referral of the patients could complicate the treatment process and reduce the general health level of the patients.

Conclusions: It seems that the designers of CIS must consider the essential and acceptable standards and frameworks in designing and improving this system.

Keywords: Clinical iinformation system, Gastrointestinal diseases, Liver diseases, Research centers, Iran

Introduction

Today, research in health area has laid the foundation for evidence-based decision making by using new technologies and has improved knowledge expansion. This issue has not only improved the lifestyle of individuals through enhancing their health but also is regarded as a necessity for economic and social development (1). This emphasis on academic research has led to the establishment of research centers in specialized sections in the field of health (2). In fact, medical research centers are the major components of development of high-quality medical knowledge in the societies. In general, there is an increasing trend of gastrointestinal and liver diseases (GILD) and the subsequent complications. Centers for Disease Control and Prevention (CDC) and United European Gastroenterology (UEG) have reported that (3), GILD cause one million deaths in Europe across all ages every year (4). Attention to the activities of GILD research centers is an important step toward improving the quality of life of the patients. These centers play a significant role in promoting community health through optimizing research and updating clinical services. Using clinical information system (CIS) in these organizations is considered as a perspective to move towards modern medicine.

The application of such systems supports the management of healthcare outcomes, pharmacological interventions, order registrations, and electronic records of vital signs which are regulated by the physicians. The key progress of CIS can act as a catalyzer for early intervention in disease processes improve the outcomes of health care and care management, reduce medical errors, and increase productivity and patient satisfaction (5-8). Evidence shows that this technology has a considerable potential for positive productivity in provision of the health care. Automated medical records and other

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emerging tools and systems for management of clinical information are the new evidence-based and patient-centered paradigms in health cares. According to the literature, implementation of a multipurpose CIS can be associated with actual benefits including the increase of instruction-based services and monitoring in the field of health as well as the decrease of medical errors and productivity (9). In large organizations, CIS provides an opportunity for increasing the care quality and safety and decreasing the relevant costs and work duration. Despite these advantages, they might fail owing to the complexity of the system as well as the size and growth of the number of users (10).

Most of the failures are due to the lack of compatibility of the users with technology which reflects the weakness of technology integration with the work system and leads to disconnected workflow. Occurrence of such problems in health care system results in lack of technology application by the users (11). Currently, studies have demonstrated serious concerns about inappropriate data resources for clinical trials. Application of CIS by health care providers is an opportunity for facilitation and improvement of clinical trial management and documentation of clinical resources. Weisskopf et al mentioned that CIS is a supporting tool for managing and carrying out clinical trials. Moreover, their results indicated that management of clinical trials was facilitated by adding some tools including warning tools for management, online request, and automatic identification of eligible patients in CIS. These tools clarify clinical trials conducted in the hospitals (12). Nevertheless, obtaining these benefits are difficult in practice. In this regard, Paré et al pointed out that about 50% of health care organizations have failed to implement the new technology of CIS in the United States (13). However, successful implementation of this system leads to the significant economic and competitive benefits along with innovation. Currently, there is insufficient data on the cause of failure of implementing these systems (14).

Despite the importance of CIS in improving communications between health care providers for each patient, reducing costs, improving treatment quality, providing easy access to patient information and continuing care, and also managing data and better decision-making, there are still problems in the use of CIS. Therefore, researchers aimed to identify the problems of using CIS in gastrointestinal tract and liver transplantation centers and to investigate the related challenges and solutions.

Materials and Methods

This descriptive-fundamental research was conducted on CIS of the GILD research-academic centers located in Tehran, Iran. There was no sampling conducted in this research and sample size was in accordance with the size of the community. Furthermore, a structured questionnaire was applied to collect data, the design of which required keyword searching (i.e., clinical information and health information technology systems) in databases of ISI (the institute for scientific information), PubMed, Google Scholar and Scopus in the time interval 2000-2017. Following that, a list of properties as well as the weaknesses and strengths of CIS was prepared according to relevant studies (11,13,15-20) and a 24-item questionnaire was designed and distributed into 5 categories of management, organizational, functional, and technical and quality factors. Items of each group were designed based on the above-mentioned specific areas and there were 2 responses of "Yes" and "No" for each item. The validity of the research instrument was estimated by content validity carried out based on library studies and the above-mentioned databases and also the opinions of 6 relevant experts including three specialists in Health Information Management (HIM) as well as Medical Informatics (MI) and three gastroenterologists. To determine the reliability of the questionnaire, retest was applied to provide the study tool for 10 specialists and users of CIS who were not among the subjects of the research, and to obtain their responses. After 15 days, the questionnaires were completed by the mentioned individuals for the second time and the results were assessed, according to which the reliability of the research instrument was confirmed by the correlation coefficient of 0.91. Data were collected through observing systems and evidences and also interviewing with experts of the GILD research centers. Moreover, data analysis was performed through SPSS (Statistical Package for the Social Sciences) software, version 16 using descriptive statistics (frequency and percentage).

Results

According to the results, gastrointestinal research centers had various service-providing units including endoscopy, colonoscopy, liver, gastrointestinal and inflammatory bowel diseases, and cancer. Each unit had a separate and an independent software which was not connected to the other software of the units. It was recognized as the CIS software in half of the centers. In addition, there was no integration between HIS (hospital information system) sand CIS to transfer information and prevent the entrance of repeated data in these research units. Furthermore, the ability to interact with other HISs and subsystems was not considered. According to the results of Table 1, quality control programs in addition to prospective and preventive monitoring of CIS were not applied in any of CIS of the research units. However, the goal of management plan for all the research units was to design a CIS tailored according to the needs of the center.

As can be seen in Table 2, independent use of CIS by research centers did not guarantee the support of processes related to clinical trials while complying with all the privacy laws. Therefore, other tools were applied by research centers.

Table 1. Frequency Distribution of Management and Organizational Factors Used in Clinical Information System in Research Units

Based Factors	Status			
	Yes		No	
	No.	%	No.	%
CIS design based on needs	4	100	0	0
Presence of control and prospective monitoring programs in the use of CIS	0	0	4	100
Ability to change programs and software based on results	3	75	1	25
Ability to improve communication and receive feedback from clinical specialists	2	50	2	50

Table 2. Frequency Distribution of Functional Factors in Research Units

Based Factors	Status			
	Yes		No	
	No.	%	No.	%
Existence of a clinical trials registration plan	4	100	0	0
Ability to apply for and participate in a clinical trial online	0	0	4	100
Ability to warn the management about clinical trial contributions	0	0	4	100
Access to electronic medical records for clinical supervision	0	0	4	100

In terms of reporting high-quality data, the results revealed that the warning ability regarding the defects or incompleteness of the designed information elements had been regarded in CIS where it was aimed at adhering to safety and confidentiality terms by providing personal passwords and defining authorized users. In these centers, national code of the patients was used to determine their medical files. Regarding the reporting ability, the results showed the lack of designing any specific plan for reporting based on treatment time. This need was separately met by an operator spending extra time. The results of this study also demonstrated the incomplete list of all the needed information elements and the presence of defects in the data.

Discussion

The CISs are the cornerstone of changing the paradigm in health care area. Implementation of affordable, advanced, and new programs in evidence-based medicine leads to management of the health care, improvement of health outcomes of the patients, and also cost-effective care. According to the results of the current research, CIS of GILD research centers were dependent and had no connection with the software and HIS was performed as separated systems. In addition, the software lacked a warning mechanism regarding the follow up of patients for referral at due time, which can complicate the treatment process and reduce the health level of the societies in case of the lack of patient referral. Moreover, use of national codes for recognition of patients was legally and formally challenging since it was a private and personal number for all the political, social, and cultural backgrounds and could not be used to follow up medical records. Other challenges in the CIS of these units were as follows: 1) lack of reporting ability; 2) lack of reporting based on treatment results; 3) lack of data quality control programs; and also 4) defect in data elements. Information technology was regarded as one of the potentials of health organizations and used to manage the pressure caused by increased demand for improving the services.

Nevertheless, there were some difficulties in implementing of information systems in health and treatment area. In addition to its complexity, implementation of this group of systems was dependent on organizational, structural, technological, and human factors. Besides, assessment of the systems was crucial to ensure their success (21). Meanwhile, attention to the areas of system and information quality management had been emphasized in the successful model of information system by Delone and Mclean (22). Patient consent for health information exchange were found to affect the completeness of the information for exchange. In addition, according to them, the structure, process, and users played a key role in this exchange (23). However, according to the results of the present study, half of CIS of research units lacked the ability to communicate and exchange information. One of the goals of the research centers was to create the interactions among students, faculty members, researchers, and industry to promote research chances, academic priority, knowledge development and distribution as well as problem solving in real world. Therefore, the ability to communicate, exchange information, and receive feedback for clinical practitioners in CIS have been reported to be essential in several studies (24-26). Furthermore, user participation was due to betterment in designing interface, CIS defects identification, development of new modules in system workflows, and defining necessary changes to apply into the system. Although user involvement for achieving CIS implementation was a critical factor, there were some challenges as well (27).

Given the high concerns regarding inappropriate data

resources for clinical trials, the increase of CIS by health care providers resulted in facilitation and improvement of clinical trial management and documentation of clinical resources. According to the studies presented by university hospitals, CIS provided the proper condition for support of clinical studies by implementing some instruments. In the University Hospital of Zürich, the set of tools applied in the CIS to support clinical trials included 1) a plan to record the trials in order to document metadata related to clinical trials conducted by the hospital; 2) a tool for determining the trial of a patient to label c those patients who were listed on the medical electronic chart as specific contributors; 3) medical record templates for documenting studies on related activities and visits; 4) an online request for participation in a trial; 5) availability of electronic medical records for clinical supervision; 6) the warning tool for awareness of the hospital management about trial contributions; 7) recognition of potentially eligible patients at the planning stage for controlling the needs assessment of clinical test to support the application of the patients; and 8) the order of the set for facilitation of accurate and complete performance of the studies (12). Additionally, the study carried out by Shimizu et al revealed that physicians' diagnostic errors were significantly reduced by the use of information systems or computer-based systems (28).

In CIS of the evaluated research centers, the only emphasized issue was the ability to record clinical trials. In addition, these systems were faced with many challenges including lack of ability to request for participation in clinical trials online and to warn the manager about clinical trial contributions and also lack of access to electronic medical files for clinical supervision. Or et al introduced 3 technical-social dimensions of barriers to the implementation of CIS including (*a*) infrastructure-based obstacles related to 1) inconsistency between government rules and the system regarding the functional requirements of the users; 2) the absence of financial support; 3) contradiction between work policy, workflow, and method, and also 4) lack of technical support and software-hardware infrastructure; (*b*) process-based obstacles about 1) incompatibility between activity, technology, workflow, and communications; 2) down system speed, availability, and stability; 3) lack of computer literacy, more skill in the health care practice, inadequate and inaccessible clinical content, and poorly designed system interface; and (*c*) achievement-based obstacles related to lack of monitoring and evaluating of system effectiveness. In addition, in the aforementioned research it was indicated that, the ability of CIS for proposed changes and its compatibility with essential needs were significantly important. Moreover, it (CIS) could provide guidelines for future policies and strategies (11).

In the studied CIS, none of the research units developed quality control programs as well as prospective and preventive monitoring in the CIS despite the fact that it was aimed to be included in the management program of all the research units for designing and implementing a CIS tailored according to the needs of the center. Furthermore, the ability to create mutual communication and interaction between the CIS with other systems and subsystems of information system of the hospitals, laboratories, digital images, and other CIS was of paramount importance. Having this feature, systems can support analyzes and clinical reports, guides, and statistics. In addition to supporting the documents and different needs, it can assist clinical specialists, nursing personnel, and the whole health care team in medical care (18). In the research centers investigated, each unit had its own separate and independent software which had no connection with other software. Its set was recognized as CIS software. In addition, no integration was observed between HIS hospital systems and CIS in the research units to transfer information and to prevent the repeated data. Besides, some of the challenges of CIS including lack of unity of the system with HIS or lack of control and prevention of entering the repeated data and also lack of ability to interact with other HIS systems and subsystems were not considered in these centers.

Some studies have suggested several solutions for improving the implementation of CIS: 1) physical tools of the system (e.g., user interface, executable software, storage and interactive servers and tools, and security and support) must be considered in a CIS; in addition, 2) clinical aspects of describing functional data, facilitation of knowledge management, patient description and condition, specialized vocabulary, and data related to clinical decisions and some metadata for searching and reporting must be regarded in clinical content; 3) regarding the user interface, his/her ability to interact with the system can facilitate workflow. In this regard, some measures must be included in the methods to present the data, physical design, and other ergonomic topics; 4) some individuals such as the users, managers, and designers must be involved in the process of system design; concerns regarding using this group of people including resistance to change and required skills of the users must be considered as well; 5) moreover, considering that cultural and functional factors and organizational policies can affect the implementation, execution, application, and evaluation of the system, external factors such as national regulations and laws, motivational programs, and availability of the experts must be taken into account in implementation of the system. Besides, 6) system monitoring and evaluation should be carried out regarding the accessibility, usage as well as wanted and unwanted related results (11,29,30). At the end, it was found that ICS with real-time compatibility designed by a clinical team was more efficient (31). Therefore, health care organizations must emphasize the broader execution of this technology and policy makers must determine public policy to recognize and eliminate the barriers to the implementation of CIS.

Conclusions

The GILD have been recognized as major causes of disability and mortality across the world, therefore, timely diagnosis and treatment of these diseases can lead to their better management. The CIS were found to be the most important supporting tools in the health area. According to fundamental role of CIS in policy making in the health area and the existing challenges, it seems that essential and acceptable standards and frameworks of CIS must be considered by its designers. The complete potential of CIS in terms of validity, reliability, unity, increased quality and safety in patient care, and necessary flexibility for supporting the studies on GILD is provided by creating an interactive portal for CIS and linking it to the HIS and also to the collective wisdom between the leaders and health system managers in designing and developing this system.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

Ethical Issues

Confidentiality in gathering data from GILD Research Centers and information of participating individuals in the research was observed.

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