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Issues to Consider in Designing Health Care Information Systems: A User-centred Design Approach

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Abstract
Objectives: This paper presents a literature review of recent research on user-centred requirements of Healthcare Information Systems. Methods: Our aim is to identify key issues that should be considered when designing, developing, and implementing Healthcare Information Systems at the user level. Based on the literature, the paper describes a multi-dimensional framework that incorporates user requirements and perspectives to support the development and design process of Healthcare Information Systems. The framework serves to categorize the lessons learned from the literature review and the issues that healthcare organizations and Healthcare Information Systems' vendors might analyse before and during the implementation of such systems. Conclusion: Our literature review provides useful guidelines for healthcare organizations that plan to implement information systems as well as for organizations that have already implemented such systems but have found a mismatch between the systems and their work requirements. The guidelines presented herein serve as techniques or suggestions that might be helpful in addressing incompetent system design.

Keywords: Health informatics; User-centred design; User requirements approach

1 Introduction

Healthcare systems are facing several challenges such as increasing demand, rising costs, inconsistent quality of care, and inefficiently coordinated care processes [1]. To overcome these challenges, governments have been developing various strategies, one of which involves major investment in information systems in the healthcare sector. The use of information systems in the healthcare domain is a proven approach to improving the quality and effectiveness of care processes [2]. For example, recent healthcare reforms in the USA include plans to spend $18.9 billion to promote Healthcare Information Systems (HISs) and provide incentives to healthcare organizations for adopting information systems [1]. As a result, recent research has investigated different aspects of healthcare informatics and is making significant progress toward understanding the Information Technology (IT) phenomena in healthcare. Despite the many successes of health informatics research, there remain numerous challenges in the development, implementation, and evaluation of HISs [3].

It is evident that information systems offer tremendous opportunities to improve healthcare services by, for example, reducing clinical medication and diagnostic errors, supporting healthcare professionals in providing timely, up-to-date patient information, in-creasing the efficiency of care processes, and improving the quality of patient care [4]. However, several hazards continue to be associated with information systems in health-care. HISs may be inappropriately specified, have functional errors, or be unreliable and user-unfriendly. Such drawbacks may affect the working processes and decisions of healthcare providers, and thus cause harm to the patients [5, 6]. For example, HISs involve different methods for obtaining patient information, which can

affect the decisions of healthcare professionals [7]. It is well documented that poorly designed technology and poor information displays can lead to inefficient care, which may include redundant ordering of tests or missing information that is crucial to the diagnosis of the patient, thereby resulting in critical medical errors [2].

Recent research on HISs has reported a large number of system failures. Most of these failures are not due to flawed technology, but rather due to the lack of structured systematic consideration of human and other non-technology issues in the design and/or development processes [11]. Although such failure is sometimes attributed to human error, there is persuasive evidence that the fault more often lies with inadequate system design or shortfalls in the process followed in the development stages [8]. Only 61% of information system projects meet the requirements of customer specifications, whereas 63% of projects exceed their estimated budgets. The reasons cited most often are related to the inadequate initial analysis of user requirements [2]. Simply put, sufficient resources are not being allocated to basic design principles, especially in the early stages of information system projects. Fixing a problem in the development phase is estimated to cost 10 times more than fixing one in the design phase [9]. Therefore, deliberate processes in the early stages of system design and development would help to prevent many critical and sometimes unsolvable problems in the advanced stages.

Research shows that post implementation issues involving users and usability account for 80% of HIS maintenance costs [9]. In many cases, these problems are accompanied by low user satisfaction, [10] unrecognized benefits, low system usage, [11] or even user boycott. Such issues are then often attributed to the IT applications in terms of inappropriate design and low fit between systems and users or between systems and tasks. This discrepancy adversely affects patient care and may result in more time being spent on the computer than with the patient. Effective and efficient IT usage in a clinical environment depends on the fit between different attributes, including the attributes of the users, the attributes of the technology, and the attributes of the clinical tasks and processes [10]. Insufficient fit between these attributes is often the reason for problems encountered during both implementation and use.

These problems and the lack of user involvement in the early stages of HIS design arise mainly because software methodologies do not explicitly and effectively identify task and usability requirements and user needs before and during the development process of a system [12]. HIS developers often overlook relevant user characteristics and preferences, user tasks, and usability issues, resulting in systems that decrease productivity or simply remain unusable. In reality, usability is rarely given priority as the constraints of limited time for usability activities are usually invoked to explain the inability to actually per-form these activities. Consequently, system development teams tend to deprioritize usability issues to meet deadlines [2, 12].

In summary, health informatics is a multifaceted, complex discipline. The complexity of the healthcare field and the barriers related to health informatics research, such as methodology, multi-disciplinarily, and cost, have already been discussed and confirmed in previous studies [13]. At best, prior research indicates that the lack of required consideration of design principles centred in human factors leads to difficulty in learning and using HISs, and this difficulty along with other factors, such as technical issues, user support, IT training, and process change, might contribute to user resistance. In some cases, the HIS may be abandoned altogether or several human errors may occur because of incorrect usage [14].

These facts accentuate the need for a rigorous and structured consideration of the afore-mentioned requirements to successfully design, develop, and implement HISs. Successful design and development of HISs can increase efficiency and productivity while simultaneously reducing medical errors as well as support and training costs. Therefore, a more inclusive framework in the retrospective investigation of previous HIS development approaches is considered necessary to better understand and design a HIS. Effective con-sideration and identification of user requirements can not only guide decision making related to system development and implementation but also enhance the potential for averting system failure, thereby preventing unnecessary human and financial investment [15]. This study elaborates on a number of important issues and problems related to user evaluation and user-centred requirements with the aim of providing greater insights into HISs as well as the factors that should be considered in the design and evaluation of HISs.

2 Literature review

Research on user-centred design (i.e., the user requirements approach) is limited. Even when available (e.g., user-oriented studies of HIS development), it typically focus on is-sues other than end-user requirements, such as end-user experience, IT adoption, evaluation aspects, and post-implementation usage [16, 17, 18]. Prior research in this area can be classified into evaluation framework studies and user-centred design studies (i.e. development studies). Evaluation and development stud-

ies seem to be characterized by short-term projects with an emphasis on summative results [9, 12, 15]. These studies often lack a uniform approach to describing the contribution of the study results to system development.9 Therefore, there remains a lack of clarity regarding the extent to which research findings and related development work can contribute to a better understanding of user involvement and usability issues at the user level and/or from a user's point of view [16, 19]. In addition, prior user-centred design studies of HISs have shown that healthcare organizations and system designers place more emphasis on which method to use or "which method is better" when designing HISs, because the dominant culture in this industry continues to train people to adapt to poorly designed technology, rather than designing technology to fit their characteristics and work requirements [11].

Nonetheless, these studies highlight the importance of end-user participation in the design process as a key marginal investment to transform the cost related to the implementation of HISs into future benefits. The participation and involvement of relevant users in the early stages of the design process help to prevent post-implementation problems and provide an opportunity to address and resolve potential conflicts concerning the future system [2]. However, the involvement of end users in HIS development is often complicated, particularly when users have limited computer skills or user knowledge is tacit, which makes task description very difficult.

In addressing this complexity in the healthcare context, researchers have adopted different approaches to gaining new insights in the field including a technology design and a mixed approach. A technology design approach, which in most cases uses traditional methods in the design and implementation stages, where user involvement is either limited or completely omitted, and most of the design process is performed by system developers. A mixed approach, where traditional methods are used along with other system development approaches, such as the system engineering and user requirements approaches. These approaches are discussed below. However, no approach has demonstrated applicability in all work environments, particularly in the multifaceted environment of health informatics, which is further complicated by several conditions, such as people, technology, culture, and socio-technical factors.

In the healthcare context, the formulation of specifications for user requirements provides the basis for early assessment and evaluation of a particular system. This confirms the importance of the analysis phase of user needs and supports the inevitability of an extended and precise formulation of the task requirements of users. Hence, researchers have used user profiles and personas as methodological tools for informed design and development of consumer health technologies. The results show that user profiles and personae can facilitate a valuable methodological approach to developing a conceptual model of health technology design, which is crucial for development decisions [20].

Consequently, a methodological approach to designing a web-based information system was adopted in Ref. [9]. This approach integrates the values and practices of user-centred design activities into the principles of software engineering, which is considered an appropriate solution for the requirements engineering process in a particular domain of healthcare. Significant improvements were afforded by this approach, such as a user-friendly web interface that allows effective communication, thereby leading to the avail-ability of information on the effectiveness of a treatment, patient clinical data, and other disease-related information. In addition, information management processes associated with clinical practice were considerably improved.

The various techniques demonstrated in these studies serve as guidelines for healthcare technology developers in integrating conceptual user modelling with the design of software interfaces for users with specific healthcare needs. However, it is evident from these studies that dependence on only a single approach may lead to drawbacks in future systems. Every approach has its advantages and limitations. Therefore, a combination of techniques is considered useful because the effects of the drawbacks of individual methods would be reduced and emergent requirements would be easier to elicit [9]. Many examples of this multifaceted approach are available in the literature, either for designing new systems or for redesigning systems already implemented. A contextual design methodology in conjunction with user participation was proposed. This approach was first described in 1997 in an investigation of work environments with the aim of designing software that addresses the needs of users, as stated in [9]. The same approach was also integrated with a work process model. The new integrated approach facilitated physician and pharmacist ownership of the system, resulting in immediate uptake and ongoing use [21] as well as significant improvements in designing decision support systems. The final product was a real-time information browser and a decision support tool for the prescription of antibiotics.

Similarly, various methods used in the areas of computer science, cognitive science, psychology, and human-computer interaction were combined to formulate a framework for guiding the redesign process of an HIS.2 The study presented a framework for redesigning healthcare interfaces on the basis of user-centred

design principles. It also explained how, by using this framework, a system designed without considering user-centred de-sign guidelines can be redesigned to create a system that models the characteristics and tasks of users, and thus increases system usage and user satisfaction. The methods employed in the framework provided benefits in terms of system utility, information quality, and interface quality. In other words, employing the cardinal axioms of good design throughout the design life cycle facilitates the creation of systems that are easy to learn, increases user productivity, satisfaction, and acceptance, and reduces user errors and user training time. Conversely, when this framework is not used, systems often need to be redesigned.

Most of these studies emphasize the importance of user involvement during the early phases of the design and development processes of HISs, with the need for the design process to be modified to suit a case under study [22]. Consequently, a modified user-centred design approach the user-centred assessment method has appeared in recent studies. It includes three main aspects of analysis, namely, qualitative management, usability assessment, and performance analysis. This method helps to elicit feedback from a variety of potential users. The feedback obtained can be translated later into specifications to create systems that provide better a fit to user requirements. Consequently, studies that adopt combined approaches and/or integrated design techniques have emerged recently [23, 24]. In summary, user-centred design and other design and development approaches have attracted growing research interest in recent years. Various issues have been investigated with the aim of improving the development and design process of systems, and hence, their utility and usage frequency. The most important studies in this area are summarized below in Table 1, followed by a discussion of the main issues introduced in the literature review:

3 Discussion

The literature shows that the lack of a systematic consideration of human and other non-technological issues has led to a large number of HIS failures. HIS projects are not so much IT projects as human-oriented and human-centred computing projects. In other industries, such as aviation, nuclear energy, automobiles, and consumer software and electronics, human-centred design is a basic and routine practice. However, in healthcare, the dominant culture continues to focus on training people to adapt to poorly designed systems, instead of designing systems to fit their needs and characteristics [11].

A basic premise of successful HISs is the consideration of a multitude of technological and human factors related to the work process. The proper functioning of HISs requires an advanced health information linkage that supports clinical care, personal health management, the reduction of avoidable mistakes in patient health, and evidence-based medicine [42]. Only real users have the relevant knowledge and understanding of their work and its consequences. Therefore, achieving collaboration and mutual understanding between system designers and users is a useful investment that leads to better systems [43, 44, 45]. This collaboration has been proven necessary for the success of systems that increase efficiency and productivity, ease of use and learning, and user adoption, retention, and satisfaction, while reducing medical errors, development time and costs, and support and training costs [11].

The literature review revealed a major concern about HISs. Healthcare professionals work in increasingly team-oriented environments, and hence, there is a need for developing systems that support cooperative work [35]. However, in many cases, large-scale HISs were found to be incapable of supporting team collaboration, and a large number of HISs actually failed to support healthcare professionals in their work [43, 44]. This area requires the establishment of a common understanding among HIS vendors and healthcare professionals in terms of work routines, task processes, and information demands. This is particularly important in developing systems to support complex cooperative work processes, where users with different backgrounds, professions, tasks, and objectives must ensure the continuity of healthcare for patients [45].

The majority of user-centred design studies are either user-evaluation-based framework studies or case studies. Evaluation studies are very often conducted at the end of the system development and implementation process, [41] and they are not likely to provide much help in system design and improvement because the main choices have already been made and much of the implementation effort has been expended [46]. Moreover, there is a general lack of studies that both show the design evolution of such systems and explain the rationale for the choices made.

In many cases, evaluation studies are often based on case studies that report before-and-after assessments of health IT as interventions. Although they can provide rich details of particular examples, they are often focused on certain aspects of the cases at hand [47]. In addition, because of their focus on the process and impact of implementation, they offer limited insight into the underlying factors and conditions that shape well-fitting HISs. As mentioned previously, understanding

Study scope/ theme	Methods/ approach	Significant findings/contributions	Source / reference
A user-centred approach for the design and implementation of HIS	A system development method	Proposed a user-centred approach, based on the unified process from the field of the Software Engineering and human computer interaction to study system design and implementation of HISs	[18, 20, 25, 27, 26, 28, 30, 34, 38]
Socio-technical design methods and systems engineering	Literature review	Combined different methods from different fields to formulate a framework for guiding the HIS redesign process and facilitating the integration of socio-technical systems engineering with existing systems and software engineering approaches. Outlined theories and methods used in IS research to help understand health care IT applications.	[2, 8, 11, 17, 23, 41]
Investigating user requirements engineering, user interactions and user involvement	Qualitative methods	The usability of HISs is an important factor in HCI. Designing interfaces with a high grade of usability and functionality must be in high priority. A lack of systematic consideration of human and other non-technology issues throughout HIS design process is a major reason for HIS failures and unsuccessful results	[9, 21, 24, 32, 35, 37, 39, 40]
Shifting the focus of health informatics research and support onto user needs and requirements	Quantitative	Applying multi-perspective methodologies is an effective way to study user interactions of HIS. An active participation of real users in healthcare might be difficult to achieve, but very crucial for system design	[29, 33, 36]

Table 1: Selected studies on user centred design of health informatics

user work tasks is the key to achieving effective systems. How users can best work with systems cannot be discovered until the systems are built, whereas systems should be built based on the knowledge of users and how they work. The solution to this apparent paradox is to design iteratively by conducting usability studies of prototypes and revising the system over time.

An evaluation undertaken at the end of a design project is usually referred to as a summative evaluation because it summarizes the work done thus far. At best, however, these efforts allow the in-depth study of only a fraction of the user-system interaction. As a result, they fail to capture much of the context (the system, the user, or the task) and do not provide a holistic understanding of the factors under investigation. Nevertheless, one of the main contributions of evaluation studies on health informatics is the establishment of the relationship between system failures and the limited understanding of developers regarding human factors and system processes [15].

Overall, the evaluation frameworks that have appeared in the literature thus far complement each other in that they evaluate different aspects of HISs that are pertinent to human, organizational, and technological factors. These frameworks differ in terms of generality and specificity as well as timing based on the system development phases and theoretical underpinnings. Furthermore, these studies do not provide explicit evaluation categories of the factors that should be considered in the evaluation studies of HISs [40]. In addition, they do not provide insight into the prevention of poor design and poor system attribute when developing and implementing HISs.

3.1 Appropriateness of user centred design approach for health informatics

The success of any software system depends on how well it fits the needs of its potential users and their environment. Requirements engineering refers to the process by which these needs are determined. Within the field of IT development, there are several approaches to designing IT applications. The user-centred design approach is concerned with incorporating the perspectives of users into the software development process in order to achieve a desirable system [9].

User-centred design is a multidisciplinary design approach based on active involvement of the user to improve the understanding of user and task requirements [15]. The approach represents a modern human-computer interaction (HCI) design philosophy and a multi-stage, problem-solving process in which the needs, desires, and limitations of users are determined and analysed [20]. One advantage of this approach is that it incorporates more aspects than traditional usability engineering and human-computer interaction approaches, which are primarily concerned with only user interfaces [11].

As a process, user-centred design is an approach to interactive system development that focuses specifically on making systems usable, empowering users, and motivating them to learn and explore new system solutions. Focusing on users, tasks, and environments when a prototype is designed, tested, and modified reduces the risk that the resulting sys-tem will under-deliver or even fail. The benefits include increased productivity, enhanced quality of work, and reduced support and training costs.

User-centred design is discussed in the IT literature, and as further evidence of internationally endorsed best practices, the approach is defined in the documents of the International Organization for Standardization (ISO), including ISO 13407, [48], which specifies that four design activities need to start at the earliest stages of system development. The activities include understanding and specifying the context of use, specifying the user and organizational requirements, producing design solutions, and evaluating designs against requirements. However, most of these activities are carried out in any design method, which limits the guidance offered by the above standard. These activities seem incomplete, thus signalling the need for a more inclusive and detailed view of all other user-related factors at the stage when user requirements should be solicited.

Researchers state that systems should be built based on the knowledge of users and how they work, [46], which requires advanced knowledge before the system is developed. Other design approaches involve users in advanced stages after the design and development process is completed, and these are often followed by evaluation studies. User-centred design approaches must start before the design process, which means that all the important issues related to the system and users must be considered before proceeding to the advanced stages of system development and implementation [46].

Unlike traditional IT development methods that adopt a systematic approach for conducting analysis, user-centred design does not necessarily use a specific user model. Users are important sources of design information and may be partners in the design process to ensure that the technology is useful, usable, elegant, and desirable. User-centred design is particularly relevant in addressing the concerns of traditional system analysis and design because it considers the user central to the design of the system. In this approach, a product is designed, evaluated, and modified with real users repeatedly in quick iterations (see Figure 1). Therefore,

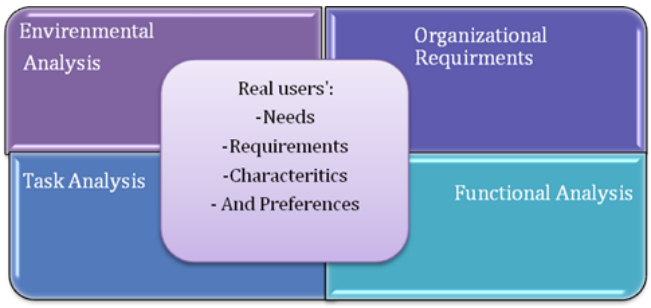

Figure 1: Components of the user-centred design analysis

user-centred design is considered an appropriate method to design, develop, and implement HISs. Previous studies indicate that a lack of communication and shared understanding with end user groups is a major problem in the requirements gathering process [11, 33].

In the healthcare domain, the user-centred design approach might offer a new perspective on system design, including and going beyond usability engineering and human factors. Its aim is to create systems that are modelled in accordance with the characteristics and tasks of potential users. This approach has given rise to many forms of design prac-tices in which various characteristics of the context of use are considered. In particular, in the medical informatics domain, several authors emphasize the potential benefits of the approach and argue for early user involvement to produce more usable systems [11, 33].

A usable HIS should allow reliable and accurate interaction between users and the system and help to enhance usability aspects, such as learnability, flexibility, and user-friendliness. This system must also support quick and precise inquires and allow more efficient and reliable data entry [49]. For example, in emergency medical services, a system must allow for quick and accurate information processing by the medical staff, who must enter new data and monitor the required patient information [49]. Therefore, a user-centred design should include analyses of other related factors, such as user characteristics analysis, environmental analysis, task analysis, and functional analysis. Each analysis provides different, but necessary, components for designing the initial prototype or redesigning a flawed system. For example, user characteristics analysis helps to identify the characteristics of existing and potential users, such as expertise, knowledge, computer skills, education level, cognitive capacity, age, cultural background, and willingness to learn and train. Furthermore, user characteristics analysis can help to design systems that have functionalities, interfaces, and information characteristics that match those of the users and their tasks [11].

Environmental analysis examines not only the environment in which the users work but also their social and cultural milieu. Task analysis considers the tasks and goals of the users. Functional analysis is a high-level process that focuses on the structure of the work and the cognitive activities of the users. Finally, representational analysis considers the optimum information display format for each task. These steps are usually performed during the initial design process [2]. In summary, the design process should analyse all relevant factors, not only those mentioned above. Combining these factors in the analysis is necessary to design systems that will more likely fit the requirements of all system stakeholders. Such a combination must consist of people, tasks, process, technology, and organization, as shown in Figure 2.

3.2 HIS critical factors : Lessons learned from literature

3.2.1 USD in practice: Discrepancy and possibility for improvement

Although the user-centred approach is useful, it is noteworthy that such an approach has some disadvantages with regard to the development process, such as the time involved and inability to gain access to appropriate users. In addition, research has shown that there is a misunderstanding of and discrepancy in the methodological processes of this approach [24]. As noted by researchers in many cases, the approach is not applied appropriately as system designers and/or practitioners usually adopt a systematic approach without necessarily using a specific user model that personalizes the system to one or more user groups [50]. In other words, there is a significant discrepancy between what is applied and what is believed to be applied, in addition to the need for improving the user-centred approach in the first place [20]. To remedy this situation, researchers have proposed the use of different techniques, such as ethnographic practices and human factors engineering, [50], which are discussed later in this section.

System design and redesign aims at optimizing system utility and usability [24]. Utility and usability issues are the top priorities of most IT development projects. It has been estimated that usability is addressed in as many as 60% –70% of projects. If this is true, it is expected that over two thirds of implemented applications are easily used and well utilized by the end users. However, in practice, this is far from reality, especially in the healthcare domain, where numerous instances of system failure, IT inefficiency, user resistance, and dangerous IT-based work situations have been documented [51]. For instance, 98% of software designed for the US

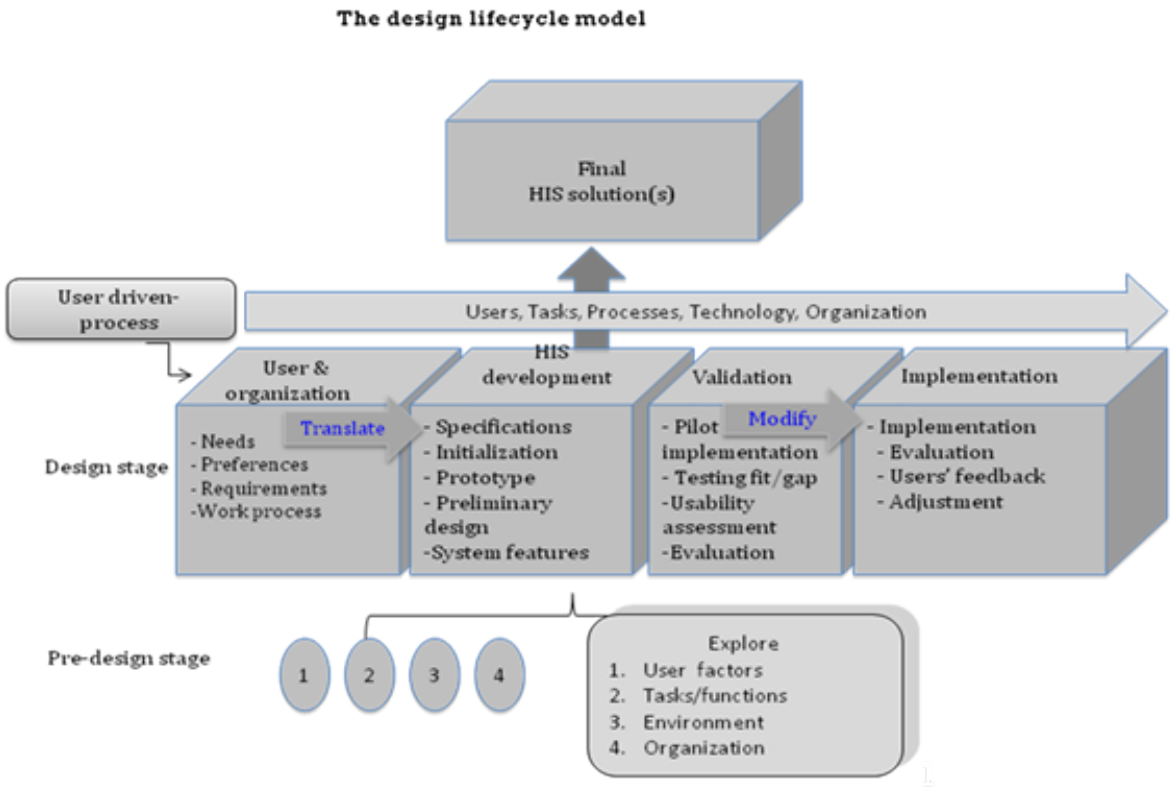

Figure 2: The proposed approach of the HIS design

government was "unusable as delivered," and the same problem was found in clinical information systems [2].

From a designer's perspective, recent research on usability issues has reported difficulties in actually integrating and performing user tasks in real design projects. Constraints such as limited time and the lack of expert resources are often invoked to explain the inability to actually perform these activities. In particular, when it comes to decisions about the development strategy or the work process, usability is rarely given priority by most organizations [24]. Most system developers choose to give up on usability matters when there is a conflict of priority between usability and development resources, as meeting deadlines is mandatory. This is probably due to a poor understanding of the concepts and methodology of usability, too often considered as "frosting a cake" [52].

Nevertheless, most organizations try to involve users in software development through direct interactions between development teams and volunteering user representatives. However, this involvement is not sufficiently challenging for the successful implementation of this approach. User involvement in software development is rarely efficient. It has proven difficult to find the right users and to maintain their involvement. Data obtained through direct interactions and dialogue between the users and the software team are not always useful. In summary, although user involvement is accepted as essential in usability matters, actually fixing usability problems requires more than direct dialogue between the software team and the software users, particularly in discovering implicit factors and issues that users cannot articulate [24]. Therefore, integrating different methods and techniques throughout the stages of software development is considered a more appropriate approach. Such techniques can be incorporated into the main user-centred approaches of the ethnographic and human factors engineering methods, thus enhancing their capabilities.

Some researchers have presented an ethnographic method focusing on observational techniques that can be used to understand other factors, such as social and organizational requirements that make important contributions to a complex set of communication behaviors and needs [50]. This technique helps to discover implicit requirements that reflect the actual rather than the formal process in which people are involved. Researchers have found that in many cases, users might experience difficulties in describing their tasks. Hence, applying the ethnographic method can help to observe and analyse user tasks in order to deduce the requirements [50]. The ethnographic method also provides a useful solution for all healthcare organizations that have already implemented HISs but have found a mismatch between the systems and the work requirements. The method describes some techniques for addressing incompetent system design; however, these techniques are expensive.

Human factors engineering (HFE) methods have been shown to support the design or redesign of a system, with the aim of optimizing its utility, usability, and acceptance. Therefore, the HFE method is now considered an essential component in the development of interactive software, especially software that is used in a complex work environment. A good example of the HFE method is presented in [24], which describes how a company involved users in the software lifecycle and how the collaboration between HFE experts and the software team took place. This collaboration led to a better interpretation of the problems observed and user requests as well as reduced training costs.

Some researchers have described a complete HFE approach that combines the usability optimization of the IT solution and the identification of key organizational and cognitive factors in the redesign process [22, 25] Their approach also seems promising for the improvement of patient safety. In addition, a usability assessment of the product to be implemented is mandatory for identifying potentially dangerous usability flaws and fixing them before the installation. However, to achieve this goal, it is necessary to link the analysis of the existing system and its potential redesign to the actual identification of adverse events. In conclusion, the literature on HIS design and development has made useful contributions. Some problems were identified and solutions to these problems were provided in different types of HIS settings. Many design approaches and techniques have appeared in the literature, including those discussed in this paper. All these approaches have shown usefulness, even though they have their disadvantages. However, none has achieved universal acceptance in terms of comprehensiveness and suitability to various systems or settings. Researchers continue to struggle to fully understand this matter and identify the links underlying design issues in the development and implementation of HISs. This challenge is evident from the large number of project failures and dissatisfaction of healthcare organizations. Therefore, we argue that applying the principles of the user-centred approach might facilitate the resolution of these issues. However, the approach needs further support and collaboration by both system designers and organizations. Incorporating other design approaches and integrating other principles would provide a more inclusive, multifaceted approach, which could be more effective than a single approach. Such an approach would proceed from the premise of reducing

failures and producing systems that suit user needs and organizational requirements, in addition to optimizing the usability and utilization of such systems.

3.3 The need for shifting development approach and research methodology

Currently, most system development efforts involve a traditional technology-centred approach, which automates the functions that the technology is able to perform. Historically, this approach provides what is technically possible without paying proper attention to the remaining human's task [53]. For a complex system with safety concerns, this approach, which has matured over decades has reached the limits of its capacity. On the other hand, the human-centred approach provides three times the capacity of the technology-centred approach by incorporating more factors and relevant issues to system design, making it a viable alternative. This Furthermore a characteristic of the traditional IT design approach is the limitation of user participation to a consultative role, whereas the bulk of the design decisions are made by IT developers.

Traditional IT development adopts a systematic approach without necessarily using a specific user model that personalizes the system to one or more user groups. Although research and practice of end-user computing development have emphasized the importance of end-user participation and involvement, much attention has not been paid to formalized conceptual models of users as a design methodology [20]. On the other hand, in the health informatics context, many HIS methodologies use a techno-centric approach, denying any role for the human and social components of an information system [54]. Hence, shifting the methodology design of HISs is considered desirable.

With regard to research methodology used in prior research, a review of informatics studies shows that quantitative methods dominated the evaluation studies carried out to investigate HISs at an advanced post-implementation stage [7]. Overall, 83% of the 813 studies considered used a quantitative methodology, and only 5% used a qualitative methodology, where both focused on the organizational and social effects of HISs. The user-centred approach focuses on identifying user needs and exploring significant issues to be considered in the design. Thus, a qualitative approach would be more appropriate in the early stages of system design. Qualitative methods are functionality-centric and by definition involve the user context. Thus, systems that are designed and developed using qualitative methods effectively reflect the needs of users, and consequently, they may be more successful than systems that do not reflect the user's perspective [15].

Researchers have also argued that treating a HIS as a technical problem leads to meaningless conclusions, whereby important aspects of systems and organizations are ignored. Because some important benefits of HISs are often qualitative and intangible, evaluations must look beyond a narrow quantification of costs and benefits to an analysis of the opportunities presented by such systems. Therefore, a mixed and interpretive approach would allow for a deeper understanding and inspire a greater commitment to evaluation [55]. This approach would also facilitate greater user participation and user response with regard to what exactly needs to be considered in designing a HIS.

A possible solution is to select an adequate integrated method for answering the study questions because neither objectivist nor subjectivist approaches can answer all the questions [4]. Thus, a multi-faceted and multi-disciplinary approach that considers a triangulation of methods, data sources, investigators, and theories would be more appropriate and have the potential to provide more reliable outcomes and results.

4 Conclusion

This paper provides evidence of the value of ensuring extensive user involvement during the early stages of HIS design and development. The main conclusions drawn from our paper can be summarized as follows:

4.1 HIS research level

This study provides evidence of the value of conducting extensive user research and investigations during the early stages of HIS development, even before the design process begins. Fixing a problem in the development phase is estimated to cost 10 times more than fixing one in the design phase [2]. A broad and wide-ranging approach to data collection, followed by a focused analysis of the characteristics of potential users and their tasks, would provide information that system developers find useful and applicable. Therefore, this type of study is necessary for convincing HIS vendors and developers of the benefits of adopting user-centred design principles. This information would make a positive contribution to product development and would increase the likelihood of producing HISs that are effective, easy to use, and satisfactory [56].

For these reasons, other strategies that look beyond user requirements should be adopted to promote the use of HISs. These include training healthcare professionals to use the systems or simply providing training materials to professionals who struggle to integrate them into

their practice [1]. Furthermore, if HISs are to fulfill their potential, it is imperative to ease their adoption by obtaining evidence to support the integration of work practice and the functionality of HISs.

Studies in the relevant literature also commented on the time taken to develop and implement projects. IT projects typically require a long time to complete and provide re-turns. Therefore, it is not sufficient to implement a technology and then immediately measure the effects of the implementation. The implementation of any new system to full operation is estimated to take approximately 18 months [57]. Therefore, users and workflows need sufficient time to get used to new tools and exploit the new possibilities. Hardware or software modifications for improving system usability or functionality may also change the use and the effects of the technology. Thus, evaluation results can change during this first period of use. For example, an evaluation study of the quality of nursing documentation after IT introduction showed significant changes in several quality indicators after 3 and 9 months of use. Thus, the evaluator may have to wait much longer than the typical wash-in period needed in clinical trials [4].

4.2 HIS vendors and designers

Our paper provides insights for designers to focus on early user involvement and incorporate user requirements in the technological design of HISs. Our study can help designers to understand and systematically address their needs, visions, and expectations in designing effective HISs. For example, interviews with users before designing and developing a system would provide an in-depth understanding and useful knowledge about the desired system in advance. Such meetings would encourage user feedback on the proposed systems and help to validate further developments.

Software vendors should bear part of the responsibility for slow uptake owing to their in-ability to effectively deliver reliable HISs. For example, they currently offer off-the-shelf products with little room for customization. Quantifying the extent of HIS failures explained by technological problems has proven a challenging and controversial undertaking. Some authors report that technical factors explain 5% of HIS failures [58]. Some estimate technical factors at 20%, whereas others report that the problems are not likely to be related to the technology itself but to the lack of socio-technical consideration [16]. However, the fact that technical problems definitely explain some failures in HIS implementation should not be viewed as a problem of technology exclusively, but instead, a problem of user needs, task requirements, and training needs [59].

Although user requirements constitute the most significant basis for system development, satisfying them is not sufficient for developing a usable system. Adopting a “user-oriented procedure” is essential for developing satisfactory and usable HISs. This procedure focuses on users throughout “the whole lifecycle stages of a system” by identifying, planning, prototyping, designing, testing, and developing the systems [49].

IS vendors that develop and commercialize HISs may decide to involve the users in the development process for better understanding of user needs and optimization of their products. However, vendors’ dialogues are not sufficient to ensure a proper understanding of user needs. It is also necessary for such vendors to involve human factor specialists to analyse users’ expressions of their needs and to properly formalize these requirements into technical specifications for design purposes [24]. This is considered an essential component of the development of interactive systems that are sufficiently compatible with user activities and aim at optimizing system utility and usability [24].

Pilot implementations are very useful for developing HISs and can undoubtedly lead to significant improvements in system design because they are less complicated and risky than regular, full-scale implementations. Therefore, it is recommended that HIS designers use this approach to avoid failure and improve the possibility of successfully implementing a final and regular system [60, 61, 62]. Furthermore, IS vendors need to understand the tasks and interactions between health professionals and a task-friendly HIS. For example, a graphical interface that employs icons facilitates user-friendly interactions with the sys-tem, thereby allowing for easier use, reducing system complexity, saving time, and in-creasing usability [49].

4.3 Health organizations level

Organizations often involve users at the implementation stage of a system, assuming that it is sufficient to gain their insights into the benefits of an HIS. However, this assumption is incorrect in many cases. Although user involvement at the implementation stage has proven an essential factor underlying greater system usage and benefits after implementation, the consideration of user requirements and users’ needs remains crucial in the early stages of designing and developing a system before the system provides returns. Doing so will help to design suitable systems, thus avoiding many issues such as the time and cost associated with training people to adapt to poorly designed systems. The goal should be to design systems that fit people’s needs and characteristics [11].

We believe that it is not too late for organizations that have implemented HISs but have found a mismatch in terms of the user and task requirements. There is a good chance to improve and salvage these systems. Moreover, those who have already implemented HISs without considering a human-centred design can successfully redesign their systems, but at significant cost. Researchers have proposed a user-centred framework for the redesigning process, which outlines the main issues that need to be considered, such as tasks, user factors, and system functionality [2, 62]. Despite their apparent promise, the successful implementation of HISs has proved difficult. This literature review reveals that barriers are also associated with organizational management. Further research is needed to provide evidence of the cost-effectiveness, end-user competencies and skills, structure, and work process issues involved in realizing the benefits of HISs [1].

Problems related to user productivity, user satisfaction, user acceptance and utilization, user errors, user frustration, and user training requirements are often caused by mis-matches between the mental models of designers and users of HISs. To improve the quality of healthcare and reduce errors, healthcare organizations, researchers, and system developers must work together to integrate the knowledge of user-centred design into new HISs. This approach is promising for quality healthcare applications in that clinicians can focus on integrating the knowledge gained from the use of these systems and not on their mechanics [2]. Finally, evaluation framework studies that use both quantitative and qualitative approaches, particularly those that use qualitative methods early in the system development cycle, have the potential to enhance user acceptance and, ideally, will prevent system failure.

Conflicts of Interest

None declared.

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