The Human Factors Engineering Approach to Biomedical Informatics Projects: State of the Art, Results, Benefits and Challenges

M.-C. Beuscart-Zéphir[1], Peter Elkin[2], Sylvia Pelayo[1], Regis Beuscart[1]
[1]Evalab & CERIM, EA 2694, University Hospital and School of Medicine, Lille, France
[2]Division of General Internal Medicine, Mayo Clinic College of Medicine, Rochester, MN, USA

Summary

Objectives: The objective of this paper is to define a comprehensible overview of the Human Factors approach to biomedical informatics applications for healthcare. The overview starts with a presentation of the necessity of a proper management of Human factors for Healthcare IT projects to avoid unusable products and unsafe work situations. The first section is dedicated to definitions of the Human Factors Engineering (HFE) main concepts. The second section describes a functional model of an HFE lifecycle adapted for healthcare work situations. The third section provides an overview of existing HF and usability methods for healthcare products and presents a selection of interesting results. The last section discusses the benefits and limitations of the HFE approach.

Methods: Literature review based on Pubmed and conference proceedings in the field of Medical Informatics coupled with a review of other databases and conference proceedings in the field of Ergonomics focused on papers addressing healthcare work and system design.

Results: Usability studies performed on healthcare applications have uncovered unacceptable usability flaws that make the systems error prone, thus endangering the patient safety. Moreover, in many cases, the procurement and the implementation process simply forget about human factors: following only technological considerations, they issue potentially dangerous and always unpleasant work situations. But when properly applied to IT projects, the HFE approach proves efficient when seeking to improve patient safety, users' satisfaction and adoption of the products.

Conclusions: We recommend that the HFE methodology should be applied to most informatics and systems development projects, and the usability of the products should be systematically checked before permitting their release and implementation. This requires the development of Centers specialized in Human Factors for Healthcare and Patient safety in each Country / Region.

Keywords

Human Factors Engineering, usability, socio-technical approach, healthcare IT applications, computer-controlled medical devices, patient safety, IT

Introduction, Background

In the Healthcare domain, Information Technology (IT) is steadily spreading through each and every working environment, and it is progressively integrated with (or substituted to) the other working devices used by healthcare professionals. In addition, most of the medical devices have been more or less automated, thus incorporating some kind of man-machine interface for programming and using devices such as smart infusion pumps, Patient Controlled Analgesia (PCA) devices, Bar Coding Medication (BCMA) systems, monitors, surgical robots, radiology systems and so on. Many of those automated devices can be interfaced with and integrated in the IT applications. As a consequence, many healthcare professionals now work in a highly computerized and/or automated environment, and IT applications support the management of a continuously increasing quantity of medical data and information.

Along the years, IT has constantly aimed at improving the availability and reliability of administrative, logistic and medical information, thus bringing in substantial benefits for the institutions, the healthcare professionals and ultimately for the patients themselves. In this context, the continuous progress in IT has been considered an essential contributor to patient safety, especially when considering prevention of medi-

cation errors [1-5]. A handful of US institutions have been able to demonstrate the benefits of their homegrown health IT systems in the following domains: (1) quality improvement by increasing adherence to guidelines, enhancing disease surveillance and decreasing medication errors and (2) efficiency benefits due to reduced utilization of care [6]. Whether these benefits hold with commercial products and for other, smaller institutions is unclear [1;7-9].

In the past ten years, IT has increasingly impacted physicians' and nurses' work, with critical applications that directly affect the practice of medicine like Computerized Physician Order Entry (CPOE) and Clinical Decision Support Systems (CDSS). The particular example of medication ordering – dispensing – administration systems is illuminating: with this new generation of systems, IT is totally mingled with physicians' and nurses' daily workflow through an interaction with complex expert cognitive processes [10;11].

The problem in many current IT systems designs is that those critical clinical applications were designed utilizing the same premises used in the development of previous Hospital Information Systems (HIS) products, i.e. considering primarily the logistic process and workflow and incorporating simplistic idealized models of work processes [12-14], therefore ignoring

a user-centered and safety oriented design approach. Moreover, most of the products are designed without consideration of basic Human Computer Interface (HCI) ergonomics principles [15]. Finally, those products are sometimes implemented in highly complex work environment without anticipation of their profound impact on the work processes, or of possible conflicts with existing organizations or policies [16; 17]. Not surprisingly, the installation of those complex products may generate unexpected consequences, most of them bearing negative effects on the healthcare professionals work or on patient outcomes [18]. These negative consequences usually express themselves through two main manifestations: (1) Users reluctance to use the system or product. Unfortunately, unless this reluctance turns to overt rebellion constraining the managers to abandon the system [19], users' resistance is often underestimated and rarely well enough analyzed and documented per se. The part of this resistance attributable to actual usability problems of the application, or to organizational weaknesses while implementing the system, or to a global psycho-sociological negative attitude toward any technological change is rarely made clear.

(2) Negative outcomes in terms of patient care and patient's safety, because of unexpected (however sometimes temporary) increase of medical errors [16;20]. This of course is both an ironic and dramatic paradox, when the very tool meant to increase patient safety, once installed, turns out to worsen that safety. Unfortunately, this is not unusual: many work situations incorporating computerized or automated products have been found error prone. A number of such cases have been documented, i.e. for medication Computerized Provider Order Entry (CPOE) systems [16;20], handheld e-prescribing tools [21], smart

infusion pumps and PCA [22-24]. Most often, the introduction of new technologies has the potential for both positive and negative effects. It may improve individual human performances (physicians' or nurses') but at the same time IT may disrupt existing collective work practices and information flows, thus weakening the overall reliability of the care process [25-28].

It is worth noting that in most of the cases, these unexpected negative consequences are attributed to a poor management of human and organizational factors [29;30]. Indeed there are more and more papers in the Healthcare and medical informatics field describing a user-centered approach to the design and installation of clinical applications [31;32], and promoting the systematic use of Human Factors Engineering (HFE) methods to address patient safety problems due to human medical errors [33;34]. But it seems that these HFE theories and methods have not actually permeated the field of medical informatics, as it has for other safety-sensitive domains such as aviation, railway transportation, or nuclear power plants. Facing disastrous consequences of poor Human Factors and ergonomics in healthcare, a growing number of authors forcefully argue (see Box 1) for a systematic integration of Human Factors in the design of the work situation and of the IT applications and electronic devices to be integrated in this work situation [35-41].

In the field, health care institutions and companies commercializing the systems usually address these human factors difficulties by "training the users" in order to accommodate the new system, workflow and business process, or to enhance compliance to constraining and sometimes inapplicable safety procedures. The efficiency of this training is often limited due to the usually large numbers of users, the turn over rate,

the proportion of part-time healthcare professionals (especially physicians), the negative attitude of some users resistant to the installation of new applications, and so on. Obviously, a Human Factors response to these Human Factors problems seems much more appropriate and is likely to be more effective.

The objective of this paper is to define a comprehensible overview of the Human Factors approach to biomedical informatics applications for healthcare. The first section is dedicated to definitions of the main HFE concepts. The second section describes a functional model of an HFE lifecycle adapted for healthcare work situations featuring computerized/automated products. The third section provides an overview of existing HF and usability methods that have been used for the further development of healthcare products and presents a selection of interesting results. Finally, the last section will discuss the benefits and limitations of the HFE approach and what are the areas that require further research and important applied initiatives.

Human Factors (HF) and Human Factors Engineering (HFE): Definitions

According to the International Ergonomics association (IEA) [44], Human Factors equals Ergonomics, and Ergonomics (or HF) can be defined as "the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance". In this definition, "the *system* represents the physical, cognitive and organizational artifacts that people interact with. The system can be a technology

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Box 1 The need for HFE in Healthcare. Citations from authors calling for a HFE approach to healthcare IT applications.

WHY do we urgently need a Human Factors Engineering approach to healthcare IT applications and computer-controlled medical devices?

1/ Because all the experts say so:

« Virtually all of the medical experts who have written on this topic have stated that the key to improving patient safety is to apply system design principles from human factors engineering. This discipline aims to tailor the design of technology to human nature rather than to expect people to contort and adapt to technology" [42]

2/ Because our lack of consideration for Human factors has progressively got us hectic and dangerous healthcare workplaces

"After reading all the articles, one might ask a number of questions, such as who made all our "puzzle rooms?" How did it happen that so many device components "masquerade" as each other yet perform very distinct functions? What are the procurement systems that gave us medication containers, tubing, and connectors that are hard to see and easy to misconnect?" [39]

3/ Because healthcare products are not checked for usability before being released

"Manufacturer-firms that develop equipment tend to be market-driven [. . .] Evaluating products in terms of their usability has not been a priority" [40]

"When human factors practitioners and researchers examine typical human interface of computer information systems and computerized devices in healthcare, they are often shocked. What we take for granted as the least common denominator in user-centered design and testing of computer systems in other high-risk industries (and even in commercial software development houses that produce desktop educational and games software) seems to be far too rare in medical devices and computer systems. . . . Computer displays, interfaces and devices exhibit "classic" human-computer deficiencies [i.e.] design problems that are well understood, . . . and the means to avoid these problems are readily available" [43]

4/ Because such usability flaws and Human Factors problems can be dangerous

[About infusion pumps]

"The complexity of the menu structure, the menuspace of these devices, appear to defy any attempts at mastery. . . . These traits cause experienced device operators to frequently become lost while programming, have difficulty tracking device states, and misinterpret device function"

"With these outcomes, we can use such knowledge to confirm the ICU nurses' verbal reports of the severe problems that are known to exist with the device used in their daily routine" [22]

5/ Because an HFE approach to these problems IS efficient

"Progress can be shown in many areas inside healthcare organizations and companies, including the following: (1) usability testing and procurement (2) improving analysis and reporting by teaching HFE to front line practitioners and students (3) more HFE activity and nationwide guidance for the medical industry" . . . "[this] should provide hope and incentive for you to develop or hire HFE expertise as a necessary component of a patient safety program or a health care system's design team" [39]

"Recommendations for Organizations in implementing CPOE: Organizations implementing CPOE or considering doing so could evaluate potential systems on the basis of evidence for human-centred design. An organization interested in addressing human factors issues as they relate to CPOE might, for example, familiarize itself with the basics of human factors, usability, and with existing evaluation methods for CPOE; . . . and ask potential vendors how they have address human factors in their CPOE systems." [9]

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or device; a person, a team, or an organization; a procedure, a policy, or guideline; or a physical environment" [33]. In this definition, the word *system* refers in fact to the *socio-technical system*. Given the particular meaning of the word system in biomedical informatics, which often refers to an *IT system*, we'll always mention the qualifier *socio-technical* when referring to the *socio-technical system*[1]. The socio-technical system incorporates the *work situation* which can be characterized by three main elements: the people,

their tasks, and the physical-technical environment in which they work (Fig 1). This representation is adapted from the Theory of Activity [48;49] and therefore emphasizes users' activities which refer to the way People achieve their Tasks using a given Technology. When considering People and Tasks, we can identify individual and collective habits of work that determine the way tasks are achieved. When considering People and Technology, we face the major question of adoption / acceptance of the new technologies by the healthcare professionals and the patients, which is closely related to the usability of these technologies and to the training of the users. Finally, the relation between Tasks and Technology refers to a continuous evolution of the

technical way to perform a set of tasks and sub-tasks.

In healthcare, the work situation is dynamic. It is determined essentially by the patient's condition and by the speed of the evolution of this condition i.e. the patient's physiological status. The categories of healthcare professionals involved, the tasks to be performed, and the technology to be used will be very different in Emergency / ICU departments, in acute care, in long term care, in primary care, or in homecare. The work situation is also constrained and impacted by a series of influences at the local and national/international levels. At the local level, i.e. the institution (hospital, clinic, GPs' practice etc.), the work situation is influenced by local policies, budget limitations, human

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[1] An overview of existing models of *socio-technical system* can be found in [45]. Principles for a socio-technical approach to design are presented in [46], and Marc Berg [47] explains how these principles could be applied for healthcare IT applications and work situations
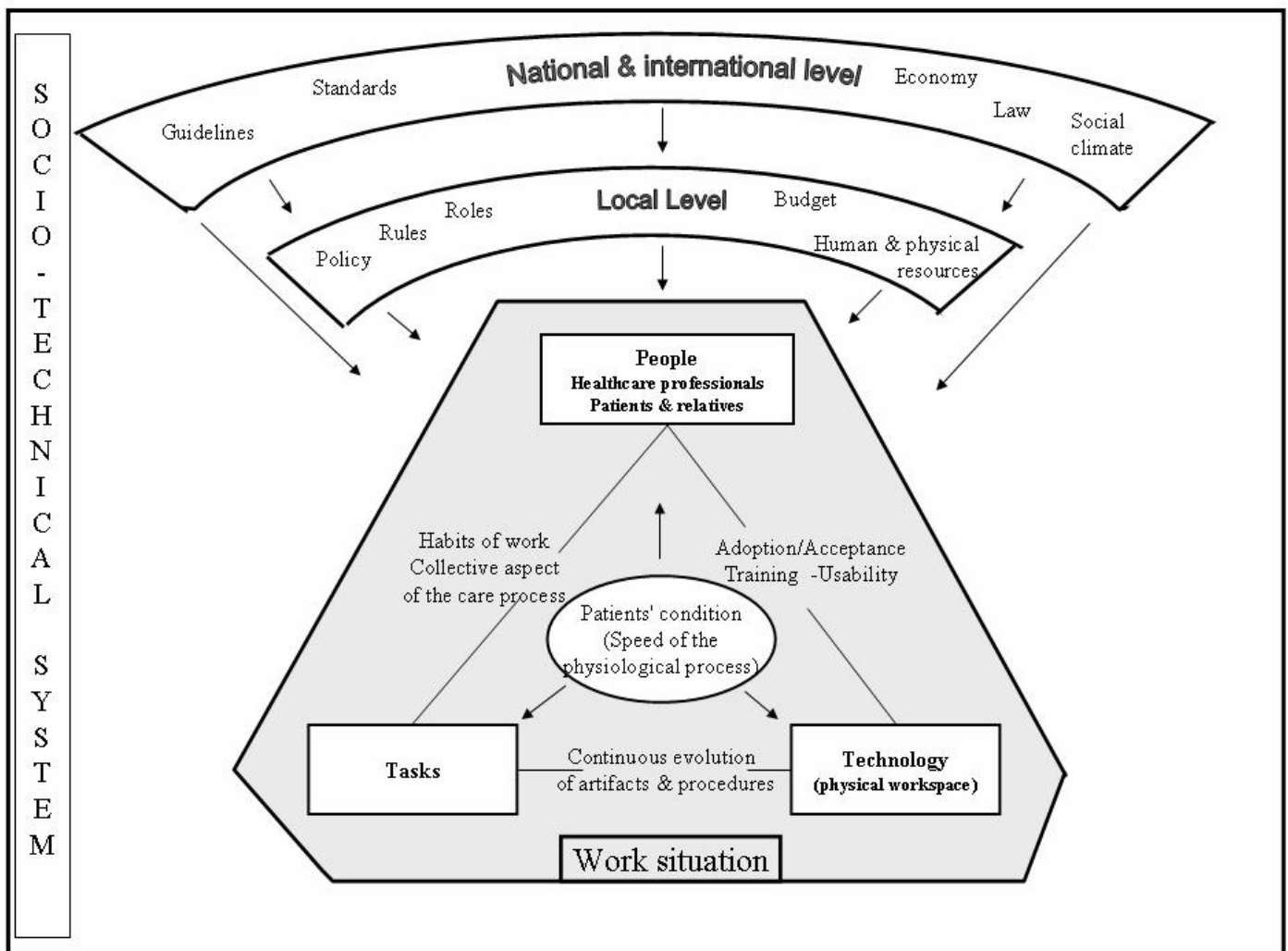
Fig. 1 The work situation and the socio-technical system

and physical resources management, and prescribed rules and roles. The work situation is also informed and influenced by national and even international factors, such as advances in knowledge (i.e. guidelines) or standards, the economic aspects of the healthcare market and so on.

From this description of the work situation, it becomes obvious that any important technology change, such as the implementation of a new IT system or a new computer-controlled medical device will impact the entire work situation. Therefore, any IT project in healthcare must be considered prima-

rily as a **re-design of the work situation.** Applying Human Factors, or in other words, adopting a *user-centered* approach to the design of a work situation refers to Human Factors Engineering (HFE). According to PC Cacciabue [50], HFE should be defined as a "technology concerned with the analysis and optimization of the relationship between people and their activities, by the integration of human sciences and engineering in systematic applications, in consideration for cognitive aspects and socio-technical working contexts". Therefore in healthcare, HFE is fundamentally a matter of optimizing the

relationship between the healthcare professionals and their work situation / working activities (the healthcare process), with the aim of optimizing human (healthcare professionals) performances.

The International Ergonomics Association [44] acknowledges three domains of specialization within the discipline of Human Factors:

(1) Physical ergonomics

(2) Cognitive ergonomics "that is concerned with mental processes, such as perception, memory, reasoning, and motor response, as they affect interactions among humans and other ele-

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ments of a system. Relevant topics include mental workload, decision-making, skilled performance, human-computer interaction, human reliability, work stress and training as these may relate to human-system design" [ibid]. (3) Organizational ergonomics that is concerned with "the optimization of sociotechnical systems, including their organizational structures, policies, and processes" [ibid].

The focus of HFE depends of the domain or category of work situations to which it applies. In the healthcare domain, when we deal with projects of implementing new clinical applications in the work situation, cognitive and organizational ergonomics are necessarily called for. Therefore, a Human Factors Engineering technology applied to any project of implementing or modifying a clinical application must rely primarily on cognitive and socio-technical models and methods. However, in some sensitive working environment such as emergency rooms, ICU, operating rooms or nursing rooms, physical ergonomics should not be overlooked, because the physical arrangement of computers, mobile tools and other medical devices is of importance for the performance of the healthcare professionals and for the safety of the care process [51]. In the medical informatics domain, as we deal with IT-based work devices, *usability* methods are also mandatory. According to the International Standard Organization (ISO 9241) [52], Usability is the "effectiveness, efficiency and satisfaction with which a specified set of users can achieve a specified set of tasks in a particular environment". In this definition, *effectiveness* refers to the accuracy and completeness with which users achieve specific goals, *efficiency* to the resources expended in relation with effectiveness, *satisfaction* to the comfort and acceptability of use as subjectively experi-

enced by the end-users, *context of use* to the users, goals, tasks, equipment, physical and social environment, and *work system* to the set and organization of users, equipment, tasks environment, in which a product is used. The *task* can be defined as a goal (what's to be done) and the conditions (constraints) to reach the goal, while the *activity* refers to the set of actions (mental and behavioral) carried out by the user to perform the task [53]. Usability tends to focus on the product: it is a dimension of this product, which can be assessed, and improved. Specific methods have been developed to achieve the usability of a product or application within a *usability engineering* approach [54]. In order to present a comprehensible overview of the HF approach to medical informatics, we'll rely on a functional framework describing the HFE tasks and how they can be integrated in biomedical informatics projects on both the institution side (i.e. hospitals) and the industry side (developers and editors of ICT applications for healthcare).

A Framework for Achieving Human Factors Engineering for Healthcare ICT Applications

HFE and the Business Process Reengineering (BPR)

HFE can be linked to or incorporated in a standard BPR approach that considers overarching sociotechnical and political factors and constraints such as local regulations and standards for acceptable clinical practice. This informs a generalized continuous quality improvement activity of Business Process Reengineering (see Figure 2), divided into subsequent steps:

- Functional requirements for the system
- Analysis of the workflows
- Description of the general level of education including knowledge skills of the target workforce.

This preliminary analysis identifies strengths and weaknesses of the current processes along with opportunities and potential and real threats.

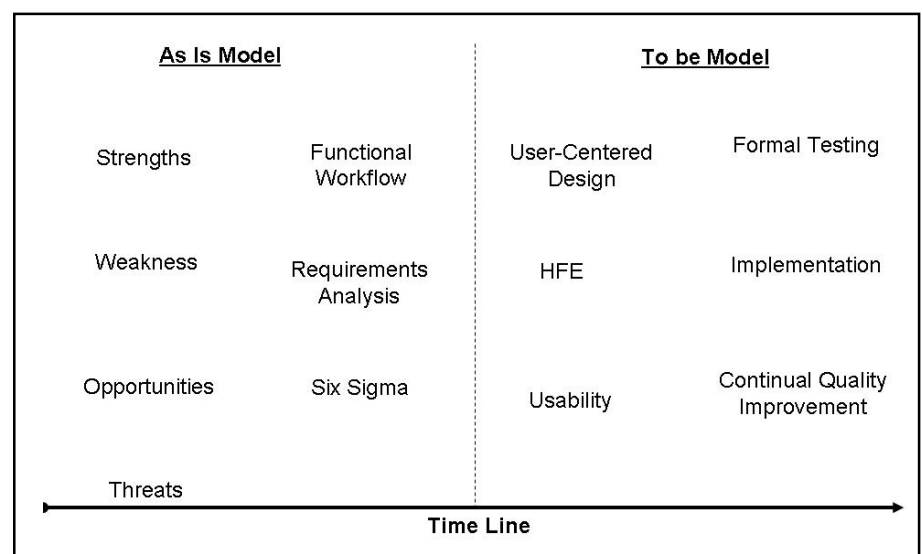One of the major goals of the re-

As Is Model		To be Model	
Strengths	Functional Workflow	User-Centered Design	Formal Testing
Weakness	Requirements Analysis	HFE	Implementation
Opportunities	Six Sigma	Usability	Continual Quality Improvement
Threats			

Time Line

Fig. 2 Business Process Re-engineering showing where HFE fits in the software quality assurance lifecycle, between sociotechnical and HFE methodologies

engineering is to decrease error with a goal of six standard deviations from the mean (Six Sigma) being the standard level of error (whereas current error levels in many today's healthcare processes are on the order of two to three sigma). In order to move from this analyzed *as is model* to an envisioned *to be model* it is necessary to employ a user-centered design methodology which integrates Human Factors Engineering and specific usability evaluations. This should lead to formal testing of health IT solutions based on a specified implementation strategy. Once deployed a program of Continuous Quality Improvement (CQI) should be implemented that involves regular evaluations of the health IT solution to ensure that it still functions acceptably in the ever changing healthcare environment into which it has been deployed.

The Human Factors Engineering Lifecycle Framework

The Human Factors Engineering lifecycle framework itself provides structured methods and tasks to achieve the optimization of the work situation and to inform its re-design: human well-being, usability of the products or work devices, overall work performance and **safety** of the care process. Figure 3 describes a framework of the Human Factors tasks to be integrated in the healthcare IT projects.

The first task of Human Factors experts (ergonomists) in a project is the **analysis of the demand**. HF experts have to understand the goals and expected benefits as they are phrased by the investors and stakeholders, the project managers and the members of the project team. It is important to understand the main preoccupations of the people that are leading the project: quality of care, human performance, and productivity, users' resistance to change, usability, innovation or re-engineering of a product, and so on. Most often, the persons in the group do not have exactly the same representation of the goals, and they do not emphasize the expected benefits in the same way. Then this first step usually leads to clarify the motivations of the team members and to set the best possible consensus on the objectives of the project. From there on, it is possible to circumscribe the boundaries of the work situation concerned by the project. For example, the evaluation and re-design of an infusion pump will not involve as many users, tasks and devices as the implementation of a complete medication ordering – dispensing – administration system.

The second task of the HFE approach is the **analysis of the work situation or socio-technical system.** This is the core task of any HFE approach. It requires the understanding, description, analysis and if possible modeling of the work situation. This description must incorporate the diagnosed problems from the Human Factors point of view, and propose recommendations to fix these problems or at least mitigate their potential negative impact. These recommendations must be confronted with the institution / designers / developers capabilities, leading to a **cooperative design** of the expected, re-engineered work situation featuring the new product / IT application. This design phase should generate a model of the re-engineered work situation, incorporating organizational, socio-technical and us-
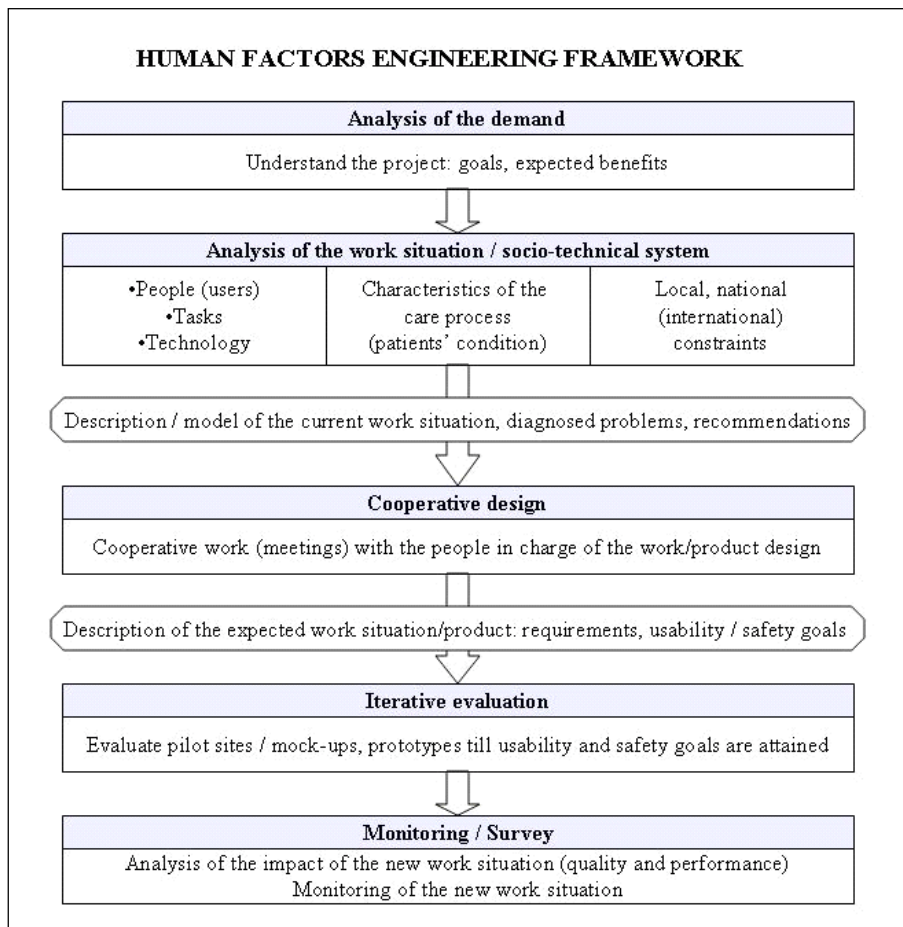
HUMAN FACTORS ENGINEERING FRAMEWORK

| **Analysis of the demand** |
| Understand the project: goals, expected benefits |

| **Analysis of the work situation / socio-technical system** | | |
| •People (users) •Tasks •Technology | Characteristics of the care process (patients' condition) | Local, national (international) constraints |

Description / model of the current work situation, diagnosed problems, recommendations

| **Cooperative design** |
| Cooperative work (meetings) with the people in charge of the work/product design |

Description of the expected work situation/product: requirements, usability / safety goals

| **Iterative evaluation** |
| Evaluate pilot sites / mock-ups, prototypes till usability and safety goals are attained |

| **Monitoring / Survey** |
| Analysis of the impact of the new work situation (quality and performance) Monitoring of the new work situation |

Fig. 3 Sequence of Human Factors tasks to be performed in a Human Factors based approach to healthcare IT projects

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ability goals that can be translated, as far as possible, into detailed requirements for the future product / work situation. As soon as early prototypes or advanced mock-ups are available, or as soon as pilot sites start functioning, an **iterative evaluation** phase starts, that aims at identifying discrepancies between the expected work situation or application, and the observed one. Human factors or usability problems are identified and reported, along with suggestions for fixing the problems. When the new work situation / application meets all the HF and usability requirements, the product may be released or the new organization generalized throughout the institution. Finally, a

final phase of **monitoring and survey** of the new work situation helps assess the actual impact of the new work situation on the quality of care and on the overall performance of the socio-technical system. It also allows identifying new potential threats to patient safety that could not have been anticipated.

Integration of HF Tasks in the IT Healthcare Projects

It is important that this human factors framework be closely intertwined in the IT healthcare projects. In healthcare, these projects are of two kinds. Projects of designing new products are usually

initiated by the Industry or by institutions with "homegrown" systems, while projects of implementing new (commercially available) systems or devices are initiated by the institutions (i.e. hospitals) and usually rely on a procurement process. Figures 4 and 5 describe the integration of the HFE framework in those projects.

Figure 4 describes the integration of HF tasks in a design or redesign lifecycle of an IT application or computer-controlled medical device. The description or model of the work situation incorporating HF problems and users' needs must be confronted to the designers' and developers' knowledge / representation of these needs in order to inform the
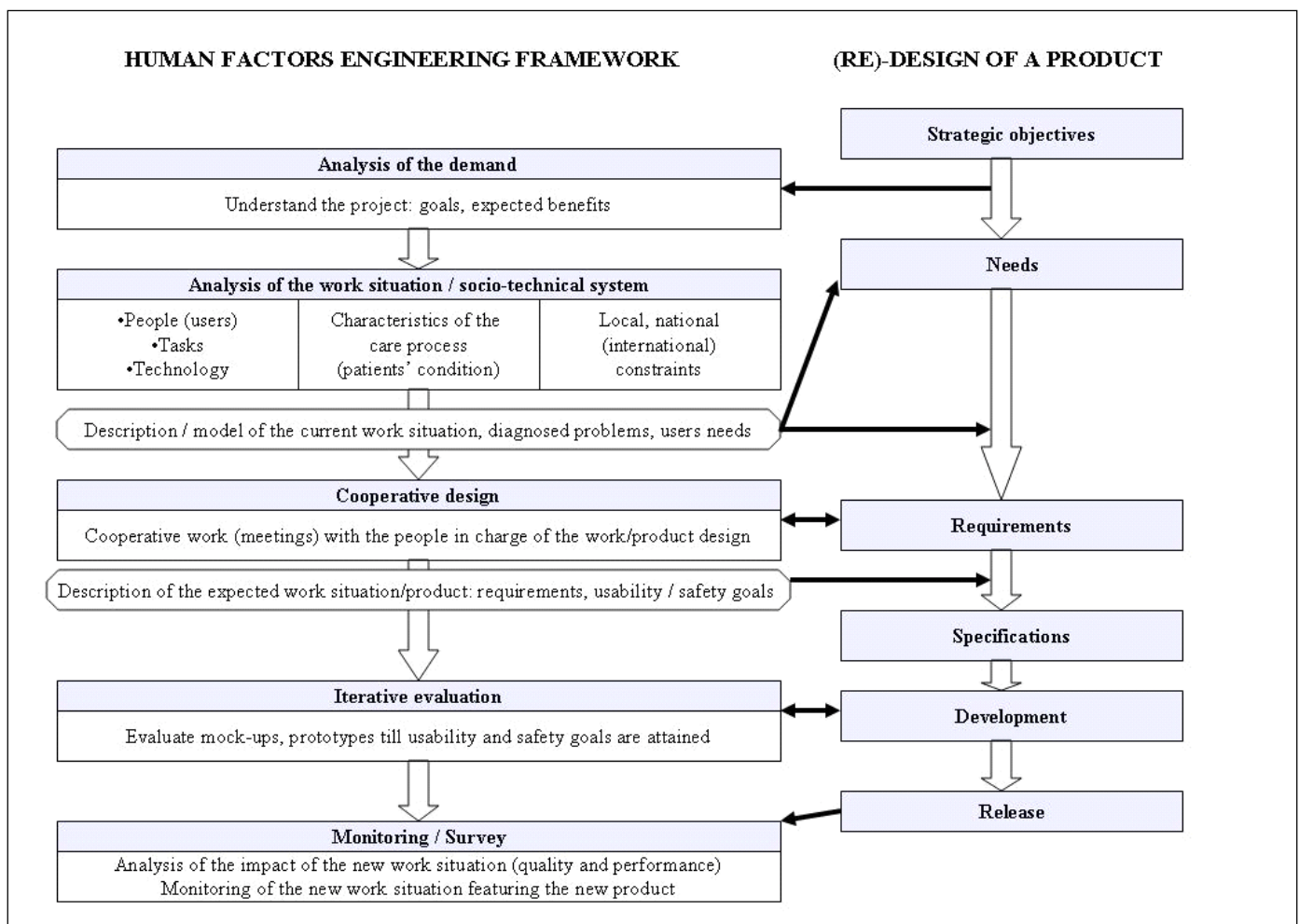

Fig. 4 Integration of the HFE framework in a project of (re)-designing a product

requirements phase. When the project concerns the re-design of an existing product, the analysis of the work situation must also include a thorough usability evaluation of the existing product and a list of the usability problems identified along with the appropriate recommendations for fixing the problems. Usability engineers are supposed to provide the designers and developers with comprehensive, detailed and if possible quantified requirements, easy to understand and to turn into quantitative engineering specifications [55]. This is a difficult part of the usability engineering approach, and very little has been published on the subject, at least in the healthcare domain. When dealing with simple usability problems such as the violation of basic heuristics like *consistency* or *workload*, it is possible to provide designers with "detailed-quantified" requirements. Most of the time, ergonomists accompany these requirements with propositions of mock-ups to support their expression of the requirements [32;56]. But when it comes to the design of complex applications or to difficult usability problems such as a lack of compatibility between the system architecture or data model with the fundamental cognitive processes of the users, these "detailed-quantified" requirements become more difficult to achieve. Moreover, HF experts and designers/developers have their own representations of the application and its usage; they rely on different models and languages, so there is a risk of misunderstanding: this can result in an improper implementation of the recommendations, leading again to iterative evaluations and modifications. This difficulty can be overcome by opting for a cooperative design of the new application (see [32] for illustration). Other solutions involving adapted software engineering models have been explored and seem promising [57;58].

During the development phase, it is recommended to perform iterative usability evaluations of mock-ups and prototypes delivered by the developers in order to identify early in the development potential usability flaws [54]. In the biomedical informatics domain, there are a few papers reporting on such human-centered design studies [32]. Some papers focus more on the problem of utilizing HF and usability findings to inform the requirements and specification phases [32;59-61]. Several papers report on successful HF-based re-design of existing applications such as anesthesia clinical systems [62-65], infusion pumps [24], web-based medical records [66], family history tracking programs [67] and Internet-based health information and communication systems[68].

However, projects involving the design of a completely new clinical application are not so frequent. Most of the time, the projects concern existing applications suffering from ergonomics problems that the users as representatives of their institution on the one hand, or the vendors and designers on the other hand perceive the need for improvement. This situation proves to be even more complex than the user-centered design of a new product. In a re-engineering project, there are numerous constraints that do not exist in a "from scratch" design project.

Re-designing a commercially available system is a challenging task. Usually the clinical application to be re-engineered is used in more than one medical department of a given hospital and not uncommonly in more than one hospital. Those different departments and institutions are characterized by different organizations and habits of works that interact with the product to be assessed and improved. Then the analysis of the work situation must be expanded to identify key features of the different organizations that

are of interest for the re-engineering project. Similarly, organizational recommendations should be specified for each identified organizations.

When an application has been in use for some period of time in multiple sites, the usability interest of future and ancient users might be contradictory. Ancient users have overcome the sometimes painful learning process of the application. They usually want to limit the re-engineering to the problems they have identified. On the contrary, newcomers' interest could require a more radical transformation of the HCI to make the man-machine dialog more friendly and intuitive. Studies designed to address these issues need to run on a broad set of typical users who would experience the application.

The usability problems of the application under re-engineering are rarely simple cosmetic problems of the HCI. Usually, we deal with cognitive ergonomics problems that question the compatibility between the users expert knowledge and reasoning and the often inadequate and too poor knowledge encapsulated in the application's data model and procedures. It is an understatement to say that the Companies and their developers are reluctant both to open up their data model and to modify their interfaces.

A complete re-engineering cycle can take time (e.g. in some cases, 2-4 years for a CPOE like application) and requires resources. The return on investment is qualitative as well as financial, but can be difficult to evaluate.

Figure 5 describes **the integration of HF tasks in an institution project of acquiring and installing a new commercially available IT application or computer-controlled device**. Institutions rarely acknowledge this kind of projects for what they really are: **a re-design of the work situation** (sometimes a re-design of the entire socio-technical system)

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featuring the new product. They usually focus on the two operational processes of procurement and implementation, which may result in a technology-driven modification of the work situation. Integrating Human Factors tasks in these procurement and implementation processes helps re-focus on the necessary work design task. The description of the work situation is confronted with the project managers' representations of needs and requirements, and helps incorporate detailed operational usability specifications in the Call for proposal. It is recommended to have meetings with the people in charge of the redaction of the Call in order to help them understand what is at stake in terms of work design. An additional HF task is necessary to support the choice of a product among the bidders' proposals: **the comparative HF / usability evaluation of the products**. Once a product has been chosen, HF tasks concern mainly the implementation process. Human factors models for implementation exist that help maximizing the probability of adoption or acceptance of the new technology [17;69-73]. During the preliminary phase of implementation, relying on the model of the expected work situation which has been agreed upon by the members of the team project, pilot sites can be monitored and checked for unexpected HF or safety problems. When all usability and safety goals are attained in the pilot sites, the application can be disseminated throughout the institution.

Several papers have described the integration of HF & usability methods in the procurement process for infusion pumps [74], complete hospital medical records [75] or specialized clinical information systems for anesthesia [76]. This method proves very useful to reach a rapid consensus on the product to choose, and to ensure that the best devices are selected for the end users and to ensure patient safety. Return on investment appears to be positive on both the qualitative and financial points of view. Other papers describe a human-factors based approach to the implemen-
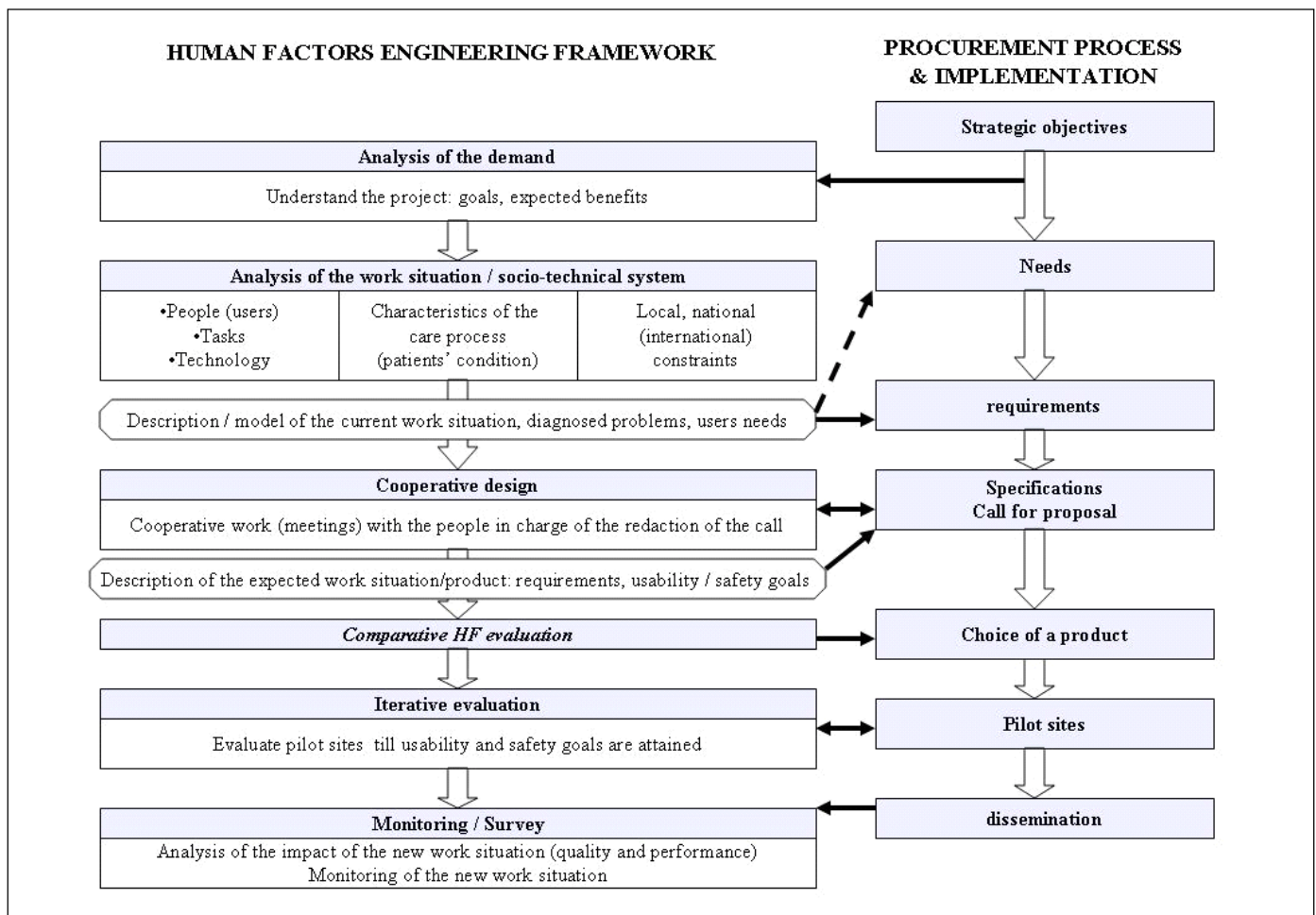

Fig. 5 integration of the HFE framework in a procurement & implementation process

tation process oriented toward the prevention of errors with new infusion pumps [77;78]. This approach resulted in work situations presenting all the characteristics of High Reliability Organization. On the overall, the integration of Human Factors methods in the biomedical informatics projects appear to be efficient to prevent unexpected new errors, to support adoption and acceptance, and to acquire the most easy to learn and easy to use products of the market. However, this requires some expertise. The analysis of the great variety of existing work situations requires a number of different sophisticated methods for the collection, analysis and interpretation of the data. Similarly, specific methods have been developed to evaluate and improve the usability of the products. The following section provides an overview of the existing methods and of their use for healthcare IT applications and computer-controlled medical devices.

HF & Usability Methods for Healthcare Products and Examples of Results

The purpose of this paper is not to provide extensive descriptions of the concepts, theories and methods of HF and usability but rather to indicate the most usable and practical resources to the interested reader. Therefore this section is organized in three tables summarizing the methods for the analysis of the work situation (table 1), the usability methods (table 2) and some examples of interesting results (table 3).

Analysis of the Work Situation

Table 1 provides an overview of methods that have been used to analyze the healthcare work situations. In most of the cases, the observed situations feature some sort of IT systems and / or computer-controlled medical devices, but sometimes they are analyzed before the implantation of such systems or products, therefore relying on ancient paper-based systems or older technologies. The methods used are mostly qualitative, and refer principally to ethnographic observations and Cognitive Task Analysis (CTA) methods. There are a great number of different methods, and most of them have been adapted for specific healthcare work situations and environments. In addition, some empirical reports may bring in valuable knowledge about the work situation featuring a particular system (example in [99]).

In some cases, specific methods from cognitive psychology are necessary to support the elicitation of experts' mental representations, structures of knowledge and thought processes and procedures:

(1) Elicitation of experts' mental representation while performing a complex task with SAGAT «Situation Awareness Global Assessment Technique» (SAGAT) [100]

(2) Elicitation of expert structures of knowledge with the Card Sorting technique [101] that may be supported by specific software such as Card Sword [102]

(3) Elicitation of experts' thought processes and procedures with various techniques such as Think Aloud Protocols [103]; «withheld information technique» [104]; «question-answering procedure» [105] or «the why and how technique» [106]

The choice of methods and techniques for data collection and data analysis depends on the characteristics of the project and of the situation under scrutiny, but all the studies share some fundamental features. All in all there is a kind of consensus on the necessity to use ethnographic methods, especially when it comes to understand the collective and cooperative dimensions of the healthcare work [47;84]

Observing, analyzing, interpreting describing and sometimes modeling appropriately the work situation requires **a double expertise, in ergonomics and in healthcare**. These methods require trained and competent observers [107] who will be able to observe without interfering with the work processes or the users' activities, to grasp the important elements, to record and note them objectively, to rely on modeling languages and theories or frameworks to analyze these data. This also requires a prior global knowledge of healthcare work situations, of the people, their jargon, the usual work devices and tools, etc. The reliability of the data collected during ethnographic or naturalistic observations should be checked [ibid.], either via inter-raters reliability assessment or by any validating phase of these data by competent healthcare professionals. Unfortunately, not all the studies apply such verifications.

The analysis of the data collected is not easier. It usually necessitates the elaboration of sophisticated coding schemes. The more "open" the observation, the more difficult is the elaboration of the coding scheme. Open naturalistic observations may be completed with more focused observations relying on pre-established coding scheme, which will provide data more reliable and easy to analyze and interpret. Again, when using a coding scheme on the data, inter-coders reliability is recommended. Finally, these methods are obviously time-consuming. But the results of the analysis of the work situation are necessary in the early phases of the projects (cf. figure 3 and 4). This means that Human Factors experts should be called in **very early** in the projects, and not only when HF problems show up in the field. Unfortunately, projects managers have difficulties to understand that

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Table 1 Methods for the analysis of the work situation

Methods for data collection	Corresponding methods for data analysis	Comments
Semi-structured interviews [25;79-81]	Elaboration of a coding scheme (categorization of the contents in meaningful units) Grounded theory	Most of the ethnographic methods can be informed or structured by models or theories such as: distributed cognition, [82;83] display-based cognition [84] and taxonomy of medical errors [85]
Handwritten time-stamped detailed field notes: record of observable behaviors and verbalizations, of incidents, of the display of information on the application etc. [25;81;86;87]	Elaboration of a coding scheme (categorization of events, actions, attitudes, environmental features etc.) Grounded theory Analysis of communications between the members of the team (diagrams Lightweight Rich Pictures) [79]	Triangulation of methods is recommended (interviews combined with ethnographic observations and questionnaires etc.) [43;81]
Opportunistic interviews (embedded in the observations, to have the user explain his thoughts while completing or just having completed a task) [86].		Interviews and documents review can also be embedded in the observation process [80]
Time and motion studies: ▪ Handwritten notes on predetermined spreadsheet [88] ▪ Computer supported data collection (i.e. handheld with a coding scheme of tasks, events, location etc. to be observed) [87]	Analysis of the data following the pre-established coding scheme Link analysis, "Cognitive pathways" [87]	May be supported by specialized software (ex: Actogram Kronos™) [89]
Structured observation supported by recording sheets incorporating a coding scheme (action/ place/location, incidents, errors etc. [90;91]	Analysis according to the pre-established coding scheme, deviations from the standard expected procedure	It is necessary to distinguish between *prescribed tasks* and *tasks that are actually carried out* [53;92]
Naturalistic or focused observations supported by video and audio recording	Transcripts of protocols reconciling actions, verbalizations, systems responses, errors, etc., usually synchronized with a timeline [28;87]	Video Analysis may be supported by specialized software (The Observer® Noldus, Studiocode®, etc.) For detailed Protocol analysis, for example in the form of <predicate-arguments>, specialized software such as Mc Shapa are useful. See [93] for more details
Documents review, charts review [28;62]	Elaboration of a coding scheme [28;87]	
Analysis of log files, review of electronic data entered in the application [94]	Elaboration of a coding scheme Categorization of the users according to their pattern of usage [94]	
Questionnaires (open / closed ended) [81] Questionnaire survey [95]	Statistical and content analysis	
Hierarchical task analysis [96;97]	Elaboration of diagrams representing tasks, sub-tasks and actions in a hierarchical way	
Critical decision method (structured interview to support the recall and analysis by the user of a past / recent incident [79]	Elaboration of a coding scheme, informed by cognitive theories [28]	
Cognitive work analysis framework for healthcare applications and computer-controlled medical devices [98]: Work domain analysis, Control task analysis, Strategies analysis, Social organization analysis, Worker competencies analysis		

the sooner ergonomists are in, the better and the more efficient the results of their intervention.

Usability Studies

Table 2 provides a list of usability methods that have been used for healthcare applications and devices. Most are standard usability methods, but they have been sometimes adapted for the healthcare settings.

In addition to this specific healthcare content, the interested reader will find valuable and pragmatic information in the following books or chapters of handbooks for usability testing [108-111], usability inspections [112] and Cognitive Walkthrough [113].

Usability assessment of IT applications usually requires the use of complementary methods: usability inspections and usability tests. Both categories of methods aim at identifying usability problems in the system and at proposing solutions to fix the problems. Usability inspections are performed by usability engineers (inspectors) and do not require the participation of the users.

Usability tests on the contrary involve users achieving as realistic as possible tasks with the application.

The most popular usability inspection method is heuristic evaluation. Several independent evaluators inspect the application's Graphic User Interface (GUI) according to a set of heuristics or ergonomic criteria, and draw up a list of usability problems, characterized by their violation of one or more heuristics. These problems are rated on a four-point scale for their severity considering the characteristics of the end-users' activity. At the end of the inspection, a mean score is calculated for each criterion, thus clearly identifying usability flaws and strengths of the application. The heuristics are culled from established guidelines or standards. In order to perform a reliable usability inspection, it is necessary to provide the inspectors with a scenario of use or a list of structured tasks. These scenarios are informed by both (i) the description of the current context of use and work system and by (ii) the description of the new system (functions).

In healthcare, given the importance of cognitive processes in the (medical) decision making/ planning and execution of care, the cognitive walkthrough method may prove useful to identify dangerous cognitive usability flaws. The cognitive walkthrough method necessitates a model of the end user' cognitive structure of goals and sub-goals when accomplishing a task with the system. This hypothetical cognitive model is compared with the system's procedures and structure of actions required to perform the task. For each action the inspector assesses the probability for the user to perform the correct action. Usability problems are recorded when this probability is too low, and linked with problematic features of the Human Computer Interface

(HCI). A cognitive walkthrough requires more expertise than the heuristic evaluation, along with a good knowledge of the users background and computer experience. It also requires to carefully define the tasks for the walkthrough.

Usability Tests involve trained observers watching and recording end-users dialoguing with the interface while doing real or simulated tasks based on clearly defined scenarios. Users are usually asked to « think aloud» while carrying out these tasks, and the entire activity is recorded with audio-visual equipment. The users actions and verbalizations are then reported in a protocol and analyzed, to identify usabil-

Table 2 Methods for usability studies. Most of the usability studies are part of a usability engineering approach. Therefore they usually incorporate a significant number of methods for the preliminary analysis of the work situation. These methods are presented in table 1. Table 2 is limited to specific usability methods.

Usability Testing

Overview of the usability engineering lifecycle [54;67;114]

Identification of evaluation objectives [114]

Sample (users) selection [114;115]

Study design [114;115]

Scenario: selection of representative tasks and context for the simulation [114;115]

Selection of background questionnaire [114]

Data collection: video-recording [114;115]

Data collection, verbal protocols (Think aloud method) [114;116]

Coding analysis of the data: elaboration or application of a coding scheme, macro and micro analysis [28;114-117]

Interpretation for usability tests findings [114]

Running a usability test [118]

Iterative input into design: translating usability findings into system requirements [114]

Usability tests with a portable lab; equipment required [119]

Onsite adapted usability tests (portable lab) [117]

Adapted usability tests for handheld applications [21]

Adapted usability procedures and coding of data for identifying usability problems linked with (or engendering) medical errors or specific performance problems [21;120;121]

Usability tests under time pressure [122]

Usability Inspection (1) Heuristic Evaluation

Presentation of heuristics / ergonomics criteria/ usability guidelines for heuristic evaluation [22;23;114;123;124]

Inspection procedures [22;23;114]

Severity rating [22;23;114]

Adapted simplified heuristic evaluation method for paper-based mock-ups or screenshots [123]

Usability Inspection (2) Coginitive Walkthrough

Identifying end-users and their background and computer experience [114]

Defining the tasks for the walkthrough [114]

Identifying the correct (expected by the system) sequence of actions for achieving each task [11;125]

Performing the walkthrough [114]

Summarization of the walkthrough results [11;114;125]

Adapted cognitive walkthrough informed by distributed cognition model [11]

Triangulation of usability inspection and testing methods [11;114;117;125]

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ity problems. Again these usability problems are rated according to their severity and potential negative impact on the end-user. Usability tests can be performed in a usability lab or with portable labs, for example when it is necessary to perform onsite usability tests (at home with the patients, in the clinical departments). Usability tests necessitate a careful detailed preparation including: (i) the identification of evaluation objectives (ii) the selection of representative end users (iii) the design of scenarios integrating representative tasks and contexts (iv) the choice of the data to be collected (v) the elaboration of a coding scheme to analyze the data.

The main advantage of usability studies is their extraordinary ability to demonstrate and make obvious hidden usability flaws of IT systems and devices. These methods prove very useful to inform the procurement process, because they provide quantitative as well as qualitative data, making easy the comparison between several products. Usability studies are also mandatory in any re-design or re-engineering project of a product. Unlike the observational methods used to describe the socio-technical aspect of the work situation, usability methods are better standardized, faster, and easier to learn. For example, non HF experts can be trained in heuristic evaluations, making it possible for users' representatives to assess themselves some aspects of the usability of the tools they are supposed to use [22]. Beside formal usability labs featuring one-way mirrors and recording devices, cheap portable equipments are now available that prove very efficient for onsite evaluations (see table 2).

The question of inter-analysts or inter-testers reliability may be explored, and the answers are not always satisfactory [126]. But in healthcare, when usability studies are informed by a robust model of users' activities, inter-raters reliability is adequate [22]. Unfortunately, too few studies check for inter-raters reliability. In any case, triangulation of several usability methods is recommended to ensure both the validity and the reliability of the results. Usability testing usually involves "think aloud" methods along with video recording. These methods result in complex protocols which require sophisticated coding schemes sometimes supported by specific software (see Tables 1 and 2). Again this part of usability studies requires a sound human factors expertise, completed by a good knowledge of the work situation and of users' activities.

Examples of Results

Table 3 contains just some examples of illuminating results of HFE approaches to Healthcare IT projects or computer-controlled medical devices. Other key features of IT applications have been studied:

(1) Barriers to adoption of clinical reminders by physicians [81;94; 99;127; 128]. All the studies demonstrate that these barriers are a mix of usability, cognitive and socio-technical problems: user interface may suffer from poor usability, systems lack flexibility, they disrupt physician-patient and physician-nurse communication, they are not well enough integrated in the EMR or Clinical Information System, they may interfere with the physician's thought processes during the decision making phase. Moreover, these negative features may generate unintended negative workaround strategies such as using the reminders while completing the documentation after the clinical encounter and not being with the patient. However, it seems that these barriers may be overcome when adopting a user-centered approach respecting the physician's cognitive processes and the decision making cognitive phases [99].

(2) Computer-based documentation functions [120;129]. When healthcare professionals have difficulties documenting medical data with a computer, cognitive based approaches are useful to identify whether these difficulties are due to user interface problems, or problems with the representation of knowledge or problems due to terminology contents.

(3) Use of IT systems by the patient [117]. These studies require adapted on site usability testing methods and sophisticated protocols analysis coding schemes. They demonstrate the great variability of users' competencies, thus making it a tremendous usability challenge to design adaptive systems that could be usable and useful for a great range of patients.

In sum, all these results support the claims cited in Box 1: IT systems for healthcare and computer-controlled medical devices are not checked for their usability, thus resulting in systems presenting unacceptable numbers of violations of established standard usability guidelines; they are not user-centered designed which may make them error prone, nor is their implementation user-centered which provokes adoption and safety problems along with a high probability of negative workarounds. Solutions DO exist: when institutions adopt a user-centered design of the work situation featuring a new IT system or computer-controlled device, the results are much better and even sometimes excellent in terms of patient safety and users adoption. In the same way, user-centered design of systems or medical devices makes them much more usable and safe.

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Table 3: Examples of results

Product considered	Goal of the study	HF methods applied	Techniques, design	Results
**Infusion pumps**				
Infusion pumps [23]	Evaluation of the usability of infusion pumps	Heuristic evaluation	- Zhang's adapted set of heuristics - Comparison of two 1-channel pumps - 4 analysts	- Pump 1: 192 violations, 2 catastrophic and 38 major ones - Pump 2: 121 violations, 1 catastrophic and 26 major ones
Infusion pumps [22]	Evaluation of the usability of infusion pumps	Heuristic evaluation	- Zhang's adapted set of heuristics - One 3-channel pump - 4 analysts	231 violations, 9 catastrophic and 61 major ones
Patient Controlled Analgesia (PCA) [24]	HF guided re-design of an infusion pump	Comparative evaluation of old (commercially available) pump vs. re-designed pump	- High fidelity simulation, scenario (# usability test) - Evaluation of deviations / correct procedures & sequences of actions - Number of errors categorization of errors	- old pump = 29 errors; new pump = 13 errors - most dangerous errors have been removed - further on site tests are required
Infusion pumps [60]	HF approach to the design phase Methods for better identifying users needs and requirements	- "Situational research" - Cognitive Task Analysis (CTA) - Translation to Requirements	- Think aloud protocols from subject reviewing scenarios involving errors with an infusion pump - Coding scheme for identification of modifiable, partly modifiable, non modifiable errors and their dependency to device or organization	- List of errors categorized according to their modifiability and their relation to the device / organization - Corresponding requirements for the design: (1) of the infusion pump's HCI (2) of the work situation featuring the infusion pump
Infusion pumps [77;78]	H F driven implementation process Prevention of errors	Failure Mode and Effects Analysis (FMEA) = systematic review of potential errors involving the infusion pump	- Multidisciplinary team - Identification and categorization of potential errors - Decision / barriers to errors → recommended actions - continuous monitoring of the actions taken to prevent errors	- List of potential errors - list of corresponding counter measures: training, organizational changes, software and hardware re-design, parameterization - evaluation of the efficiency of counter measures: significant and continuous diminution of errors - the new work situation presents most of the Highly Reliable Organization (HRO) characteristics = successful and safe implementation process
Infusion pumps [74]	HF driven procurement process Usability based comparison of 3 Vendors infusion pumps	- Heuristic evaluation - Task analysis - Usability tests	- 1 analyst for inspection - 17 (end-users) participants in the usability test - Record of errors = deviations from correct programming	- Usability scores for each product - Number of errors during usability tests - Consensus for the choice of the most usable and safe product, relying on the usability studies
**Medication e-prescribing and administration applications, CPOE**				
Handheld e-prescribing application [21]	Usability assessment of a commercially available product with a focus on errors	Usability test	- Adapted method for mobile devices (special technique and equipment) - Specific double coding scheme to link identified usability problems with actual errors	- 73 usability problems uncovered - 27 actual errors - certain categories of usability problems are highly associated with errors
In use Medication CPOE [11]	Assessment of the cognitive complexity of ordering functions	Cognitive walkthrough Usability tests Task analysis Distributed cognition	2 analysts Think aloud 7 subjects familiar with the system	Qualitative detailed report on system failures from the distributed cognition point of view: excessive amount of information displayed, memory workload problems, etc. No subject could produce an error free set of orders
In use medication CPOE [26;27;56]	Comparative assessment of computer-based and paper-based work situations for the medication ordering task	Ethnographic methods, Self-confronting interviews, On site usability tests Heuristic evaluation	Adapted techniques for onsite non intrusive observations (portable labs) 3 analysts	Usability problems with the display of current medication orders: loss of overview, increased workload, increased risk of errors Hidden variables leading to negative consequences: impairment of the doctor-nurse cooperation

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| Bar Coded Medication Administration BCMA [86] | Identify types and extent of workaround with the use of BCMA | Ethnographic methods | -3 observers, 28 nurses, acute and long care sites
- time stamped detailed field notes of nurses actions and BCMA display
- review of electronic data
- opportunistic interviews for identification of perceived facilitators and barriers | - in long term care, high proportion (10/13) of nurses adopting unsafe workaround strategies for administration (pre-pour some medication, bar coding dissociated from the actual administration)
- analysis of the work situation identifies root causes for unsafe workarounds: worn out difficult to scan patients bar-coded wristbands, non mobile scanners, unreliable batteries for mobile devices, double data entry required (BCMA + Paper Medication Administration Records), etc. |
| Laboratory Order Entry system [125] | Usability assessment of the system on pilot sites before full implementation | Cognitive walkthrough (CW), usability tests | Systematic comparison of CW and usability tests results | 33 usability problems, 25 problems uncovered by both methods, several problems may generate errors Implementation failed, system was abandoned. |

Discussion – Conclusion: What Needs to Be Done

Extend and Expand Research on HFE Methods

(1) The analysis of the socio-technical system and work situation is a highly complex task requiring a great number of various qualitative methods. Most of the authors develop their own method or at least adapt in their own way existing methods. This leads sometimes to an unnecessary diversity of descriptions and labeling of fundamentally similar methods. Similarly, the results of these qualitative methods are delivered in innumerable diverse formats. This diversity is probably useful to depict all the nuances of the observed work situations and environments, but it impedes the legibility of the results for the people they are delivered to: project managers, users' representatives, IT designers and developers, Industry, etc. Some standardization of the methods and of the format of the results would reinforce the utility and efficiency of HF experts' contribution to Healthcare IT projects.

(2) HF people are very good at making diagnosis and issuing corresponding recommendations. But translating HF and usability recommendations into comprehensible, detailed, quantitative, operative requirements and specifications remains a difficult and challenging task. To date, it seems that a cooperation relying on face to face meetings with ergonomists and people in charge of the work / IT design is the only way of ensuring a proper comprehension and integration of HF recommendations. Some research is needed here to develop languages and methods supporting the dialog between HF experts and designers.

(3) Finally, although the overall impression is that of a very positive impact of the HF approach to Healthcare IT and patient safety, very little has been made to evaluate this impact and demonstrate or quantify the benefit. When possible, it would be useful to couple the HFE approach to a Healthcare IT project with a rigorous evaluation process aiming at demonstrating the benefits and limits of this approach.

Support and Expand the HFE Approach to Healthcare ICT Projects

In spite of the above cited limitations, consideration of the results already obtained demonstrates that HFE methods are efficient in supporting and informing the reengineering process of healthcare work situations and IT systems to make them safer and more productive.

Then one can wonder why this successful and efficient approach remains limited to a small number of projects and applications.

(1) Most of the studies referred to in this paper describe an incredible diversity of healthcare work procedures and socio-technical systems across different countries, different hospitals within a same country, and even across different departments within a same hospital. This observed diversity is more the result of particular history and evolutions of these socio-technical systems than an inevitable consequence of the healthcare work in itself. Moreover, HF studies show that a great number of these organizations and work procedures are neither safe nor productive. Then the necessary redesign efforts of those socio-technical systems and of their work situations should be coordinated to aim at some sort of standardization incorporating proven good work procedures and good individual and collective work practices. Integration of HF experts can help moving forwards towards such desirable Highly Reliable Organizations.

Another negative consequence of the current diversity of healthcare socio-technical systems is the impossibility of designing and developing the corresponding variety of IT systems tailored for each specific situation. Therefore the tailor-

ing of the IT system for each work situation relies on the parameterization and configuration functions of the system. As a consequence those critical functions are becoming more and more complex, and very little attention (if none) has been paid to their usability.

(2) New (and existing) healthcare IT applications and computer-controlled medical devices must be assessed for their usability, and when severe usability flaws are uncovered, they must be fixed via appropriate re-engineering. This should be part of any validation or accreditation process of these safety sensitive products. It's been demonstrated that existing and even new healthcare products are NOT systematically checked for their usability before being released and put in use and that they indeed suffer from a great number of usability problems potentially leading to dangerous errors (see table 3). This situation is specific to healthcare. In any other risky environment (aviation, railway transportation, nuclear power plant etc.) new IT applications or computer controlled devices are carefully checked for their usability before being released. Moreover, they are usually designed with mandatory participation of HF experts. This is true also for products or applications that are not safety sensitive like toys, computer games, kitchen tools etc. Then the healthcare situation regarding IT systems and computer controlled devices is both incomprehensible and unacceptable.

(3) Not all the institutions (nor all the Companies editing IT systems or commercializing medical devices) are in a position of recruiting HF experts on a permanent basis. Centers of Human Factors and usability for healthcare should be created in each Country (or Region) so that institutions or companies, whatever the scope of their project, could be able to hire the necessary HF

expertise specialized for healthcare from these centers. A limited number of such centers already exist (or are emerging) in Europe: France (Evalab – Lille), Norway, Denmark. In the U.S., the government initiative for quality and safety in healthcare via the Agency for Healthcare Research and Quality [130] resulted in the development or reinforcement of existing HF teams for healthcare and generated numerous robust and efficient studies (see tables 1-3). Other centers of excellence in HFE exist in the U.S. as exemplified by the Mayo Clinic Usability laboratory. In Europe, at least one center per country and language should be created. This is an important challenge and it will require some support from European structures, governments, healthcare institutions and Companies commercializing healthcare IT applications and medical devices.

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Correspondence to:
Marie-Catherine Beuscart-Zéphir
Evalab, Faculté de Médecine
1, Place de Verdun
F-59045 Lille Cedex
France
E-mail: mcbeuscart@univ-lille2.fr