Human Factors and Organizational Issues in 2015: The Increasing Complexity of the Healthcare Domain Calls for More Comprehensive Approaches

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Summary
Objective: To summarize significant research contributions on human factors and organizational issues in medical informatics published in 2015.
Methods: An extensive search using PubMed/Medline and Web of Science® was conducted to identify the scientific contributions published in 2015 that address human factors and organizational issues in medical informatics. The selection process comprised three steps: (i) 15 candidate best papers were first selected by the two section editors, (ii) external reviewers from internationally renowned research teams reviewed each candidate best paper, and (iii) the final selection of five best papers was conducted by the editorial board of the Yearbook.
Results: Noteworthy papers in 2015 emphasize the increasing complexity of the healthcare environment. They call for more comprehensive approaches and evaluation studies. All provide a real added-value in this direction.
Conclusion: There is no more need to promote the contribution of human factors and ergonomics (HFE) approaches to health IT-related risks and patient safety. However, there is still a need for research on HFE methods to adapt health information technology tools to the complexity of the healthcare domain.

Keywords
Human factors, ergonomics, health information technology, usability

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Introduction
“Human Factors and Ergonomics” (HFE) has become a central theme in medical informatics as illustrated by the growing number of contributions published every year in the field. HFE has a long tradition of involvement in helping assess and solve performance, quality, and safety problems in health care [1]. Many reports and studies point out that the increasing complexity of socio-technical systems in healthcare poses unique challenges to HFE professionals and researchers [2]. The design and the implementation of health information technology (IT) have to be supported by a detailed understanding of this complexity. A further integration of the different dimensions and elements of socio-technical systems is necessary to be able to anticipate the impact of health IT on healthcare environments and to safely design and implement the systems.

In 2015, the selection of papers on Human Factors and Organizational Issues (HFOI) intends to illuminate current progress of HFE research in medical informatics. Each of the five selected best papers emphasizes the healthcare environment complexity and some of the challenges they raise for health IT-related risks for patient safety.

Paper Selection Method
Two electronic databases were searched, PubMed/Medline and Web of Science®. Searches were performed in November and December 2015 to identify peer-reviewed journal articles published in 2015, in the English language, related to HFE research in medical informatics. In addition to the search of electronic databases, manual searches of key themes were performed in major biomedical journals (e.g., Journal of the American Medical Informatics Association, Methods of information in medicine, Journal of Medical Internet Research, etc.). Keywords used included both free-text and coded keywords. Free-text keywords were listed as regards to the questions addressed by the section. Corresponding relevant MeSH terms were identified. Pubmed was queried to test keywords in an iterative process. Consequently, two queries were built: one based on MeSH terms used as major topic in the Pubmed/Medline database, the second one based on free-text keywords searched in title or abstracts through Pubmed/Medline and Web of Science® databases.

One of the two section editors performed the searches. Database searches yielded 1,151 papers, and manual searches identified 169 papers, giving a total of 1,320 references. The two section editors undertook independently the initial screening of titles and abstracts to identify papers relevant to the field of interest. Both section editors classified the papers into three categories: accepted, rejected, or pending. They then reviewed in detail the accepted and pending full-text articles to finally reach a consensual list of 15 candidate papers. Papers were considered...
according to their originality, innovativeness, scientific and/or practical impact, and scientific quality.

In accordance with the IMIA Yearbook selection process, the 15 candidate best papers were evaluated by the two section editors and by additional external reviewers (at least four reviewers per paper). Five papers were finally selected as best papers (Table 1). A content summary of the selected best papers can be found in the appendix of this synopsis.

## Conclusions and Outlook

Noteworthy papers in 2015 emphasize the increasing complexity of interconnected health IT, socio-technical information systems, interlinked organizational issues, and strong legal regulations which increase the complexity of the healthcare environment. They call for more comprehensive approaches and evaluation studies. Each one provides a real added-value in this direction.

Ammenwerth [3] campaigns for Evidence-Based Health Informatics in a position paper based on the invited keynote lecture she gave at the Medical Informatics Europe conference (MIE 2014). She argues that only high quality evidence will lead to higher confidence in health IT. She calls for more comprehensive, well-designed, published, and locatable evaluation studies aggregated in systematic reviews and meta-analyses. She identifies and discusses eight challenges to take up and provides interesting perspectives in the years to come. Numerous studies and reports have shown that health IT is not as evidence-based as it should be [4]. But very few of them have discussed achievements, challenges, and needs for action.

As stated before, the complexity of the healthcare domain challenges the limits of health IT tools that should be designed, and widens the range of system elements and dimensions that need to be considered. Based on the Distributed Cognition framework, Furniss et al [5] provide an excellent illustration of how to investigate the different elements of the environment to feed the design of a medical device. Based on an observational study of clinicians using a newly introduced glucometer on an oncology ward, they describe the basic mechanisms of the system, incremental design considerations, and larger design considerations. They propose and apply an approach enabling to analyze how devices and context of use are mutually dependent, i.e. devices influence practices, practices influence the design and use of the device.

Singh et al [6] posit that events must be understood within the full context of the socio-technical work system, which refers to the many interacting technical and non-technical variables. This raises a key challenge when developing valid and feasible strategies to measure safety concerns related to health IT. They propose exactly this type of initiative providing a conceptual foundation for health IT-related patient safety measurement, monitoring, and improvement.

Jensen et al [7] state that health IT is extremely complicated due to the complexity of organizations, work practices, and physical environments in healthcare. Therefore, the impact of systems on clinical work practices is also difficult to assess. The authors present a methodological approach for clinical simulations with real users enacting realistic clinical work scenarios in relation with the development and evaluation of clinical information systems. They strongly contribute to the scientific community while addressing an emerging area of biomedical informatics knowledge and practice concerned with the use of simulation methods as a means of evaluating the usability and utility of clinical information systems.

Vincent et al [8] focus on the scenario-based design method from the Human Computer Interaction (HCI) domain. Scenarios are tools representing how systems are used, that help the design and development of solutions. They enable the representation, analysis, and anticipation of how a system may impact users’ activities and experiences. Scenarios are particularly relevant medium for supporting the match between the device and the surrounding environment. The authors investigate and reflect on challenges and opportunities in bridging the gap between usability standards for medical devices and scenario-based design. They perform exactly the type of work that needs to be done to bring HCI methodologies into practice in healthcare. Based on a case study for infusion pumps, they stress the need to understand how to integrate the two domains and be mindful of limitations.

The ten remaining selected papers focus on similar current research themes: figure out the complexity of socio-technical systems in order to design and evaluate safe, efficient, and effective health IT.

In the hospital setting, Islam et al. [9] developed an integrated approach to understand and measure clinical complexity by incorporating both task and patient complexity components. Magrabi et al. rely on their methodology of analysis of incidents reports to identify patient safety problems associated with IT in General Practice [10]. They identified 90 incidents involving IT, which had an observable impact on the delivery of care, including actual patient harm as well as near miss events. In the same line,
Carayon et al [11] succeed in showing the electronic health record (EHR) impact on the work and workflow of physicians. And Carberry et al. achieve the integration of the outcome measurement into the clinical workflow through the customization of an existing EHR [12].

Usability remains a flag theme. The concern is no longer to demonstrate its importance, but rather to (i) look at the user-centered design process of EHR vendors to improve their practices [13], and (ii) develop and test models of effective technology use [14].

A growing trend is the graphical representation of work processes and/or patient journeys. Ajmi et al. [15] analyzed the patient path in a pediatric emergency department through a model-driven approach.

We must be aware that humans are the only element of a work system able to adapt himself depending on the situation. Non-technical skills are critical in that sense to support this adaptation. Rosen et al. [16] present a framework to facilitate the measurement of teamwork in healthcare, which is recognized to have a strong impact on patient safety.

Two papers deal with non-hospital settings. The paper of Rajkomar et al. [17], in the same line as the one of Furniss et al. [5], presents a detailed description of how patients interact with a home hemodialysis technology relying on the distributed cognition framework. The number of publications on mobile health apps continues to increase in 2015. Mendiola et al. [18] present a nice study on the main app features and characteristics associated with positive users’ rating.

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References

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Summary of Best Papers
Selected for the 2016 Edition of the IMIA Yearbook, Section Human Factors and Organizational Issues

Ammenwerth E
Evidence-based Health Informatics: How Do We Know What We Know?

Ammenwerth presents a very useful paper for the community providing motivation, vision, and history of evidence-based health informatics. She discusses achievements, challenges, and needs for action. She claims that the increasing complexity of interconnected health IT, the socio-technical information systems, the interlinked organizational issues and the increasing legal regulations increase the complexity of healthcare and call for more comprehensive evaluation studies and approaches. She identifies eight challenges that need to be addressed: quality of studies; publication bias; reporting quality; availability of publications; systematic reviews and meta-analyses; training of health IT evaluation experts; translation of evidence into health practice; and post-market surveillance.

Furniss D, Masci P, Curzon P, Mayer A, Blandford A
Exploring medical device design and use through layers of Distributed Cognition: How a glucometer is coupled with its context?
There is a need for more studies that reflect on findings at broader socio-technical and policy levels. Misattributing medical devices issues to the wrong part of the socio-technical system can hinder corrective action. A critical challenge for research and development is also to develop appropriate analytic tools to keep abreast of device design and use issues. The Distributed Cognition (DCog) approach promised much as a framework for analysis. But, according to Furniss et al., the absence of an off-the-shelf methodology and of an appropriate analytical tool has hindered it reaching its potential. Furniss et al. introduce a multi-layer framework, which is a method that facilitates DCog analyses. They present a rigorous and well-conducted study that illustrates perfectly well how this type of analysis should be performed.

**Jensen S, Kushniruk AW, Nohr C**

**Clinical simulation: A method for development and evaluation of clinical information systems**

*J Biomed Inform 2015;54:65-76*

EHealth is an extremely complicated principle because of the substantial complexity of organizations, work practices, and physical environments in healthcare. These matters greatly influence the development and application of IT in the healthcare domain and may endanger the patient safety if not considered during the design. On the other side, the impact that health IT may have on clinical work practices is difficult to assess and it necessitates the application of qualitative approaches. Jensen et al provide a methodological approach for clinical simulations along with the key issues for a successful simulation. This approach can be a beneficial method for the development and evaluation of clinical information systems as it attempts to re-create characteristics of the real work or processes in controlled environments, without the risk of injuring real patients.

**Singh H, Sittig DF**

**Measuring and improving patient safety through health information technology: The Health IT Safety Framework**

*BMJ Qual Saf 2015;0:1-7*

Despite recent efforts to define the nature and scope of health IT-related safety concerns, the conceptual foundation of measuring such concerns is nowadays stammering. Because health IT is integrated in all aspects of care delivery and supports a complex work environment, causal relationships between health IT-related risks and adverse events are difficult to prove. Singh et al. provide some of the first framework to enable the rigorous measurements that help achieve the safety benefits of health IT in real-world clinical settings. The Health IT Safety (HITS) framework follows both Continuous Quality Improvement and socio-technical approaches and calls for new measures and measurement activities to address safety concerns in three related domains: concerns that are unique and specific to technology; concerns created by the failure to use health IT appropriately or the misuse of health IT; and the use of health IT to monitor risks, health care processes and outcomes, and identify potential safety concerns before they can harm patients.

**Vincent CJ, Blandford A**

**Usability standards meet scenario-based design: Challenges and opportunities**

*J Biomed Inform 2015;53:243-50*

The usability engineering process for medical devices required in the IEC 62366 standard states the need for scenarios, but does not necessarily overlap with a scenario-based approach. From an Human Computer Interaction (HCI) perspective, scenarios are a tool to represent how systems are used, feeding the development of such technical systems. They represent needs and constraints in an accessible way, by allowing people from different backgrounds contribute to the design. From a medical device design perspective, scenarios may support a formal risk management process; they are used to test the potential for use errors. In this context, the use of scenarios is less flexible and differs from user-centered design in which the aim of scenarios is to provide the freedom to explore multiple solutions and capture the issues behind each solution. The study investigates how scenarios can be constructed to explore some of these issues. The authors stress the importance of the understanding of the skills, motivations, and understanding of the different types of users, as well as policies of local and national healthcare organizations along with the characteristics of the wider environment.