

Human Factors and Ergonomics for a Safe Transition to Digital Health

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Abstract. In this paper we elaborate a preliminary framework to fill this gap and describe the potential contributions of HFE to improve digital health interventions, at the macro, meso and micro level of a health system. Researchers present a practical approach, integrated with some limited reflections on methodological aspects, recently covered in a position paper [8], while previously in conference series and handbooks. This paper presents a HFES perspective on digital health - from the macro, meso and micro level to improve patient safety and delivery of quality care. Experts in HFE can play a key role in creating evidence for an ethical and effective design of digital health intervention and providing support to their implementation and evaluation at the macro, meso and micro level. This framework may help to integrate HFE at the different levels of the system and following the tracks of organization, technology and human factors.

Keywords. Digital health, human factors and ergonomics, patient safety

1. Introduction

“Health care delivery systems are complex by design and prone to errors. Human factors are a core element in most cases of harm, operating in systems where procedures and practices are poorly designed. Punitive cultures of blaming individuals prevent reporting of safety-related incidents and impede learning. Certain patient groups are more vulnerable to safety incidents, including the elderly, children, migrant populations, patients with chronic conditions and those in palliative care” [1].

The “Global action on patient safety”, approved at the World Health Assembly in 2019, clearly recognizes the role of human factors in affecting the delivery of care, by stating that a poor design of procedures and practices is a core element of most cases of harm. We would have preferred to read the same sentence in positive terms, but to date research in human factors and ergonomics (HFE) in healthcare has been more effective to show the dark side of patient safety rather than the wide opportunities for improvement at all levels of the system.

Digital health is one of the areas where we accumulated evidence of failures and few examples of effective interventions.

As previously argued [2], programs for the development and implementation of digital healthcare, have sometimes failed miserably despite the investments and

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commitment of key stakeholders [3], due to inconsistencies generated on the clinical, organizational and institutional level or to open confrontation between professionals, managers and policy makers for decision-making power on technological innovation [4]. Also, the intrinsic quality of IT products for health care is sometimes lacking, both in terms of functionality, and above all of ergonomics and systems integration [5]. Consequently, the transition to digital systems to manage internal and external communications have been much slower in health services than in other industrial sectors, even in high income countries.

Not surprisingly, while WHO recognizes the relevance of human factors in negative terms as a key risk for patient safety, no reference is made to the potential contribution of HFE in the development and implementation of digital health interventions, neither in the WHA resolution [6] nor in the most recent guideline just released [7].

In this paper we elaborate a preliminary framework to fill this gap and describe the potential contributions of HFE to improve digital health interventions, at the macro, meso and micro level of a health system. We present a practical approach, integrated with some limited reflections on methodological aspects, recently covered in a position paper [8], while previously in conference series and handbooks.

Therefore the goal of this paper is to present a HFES perspective on digital health - from the macro, meso and micro level to improve patient safety and delivery of quality care.

2. Framework for HFE in digital health

From the point of view of HFE, the transition to digital health is a complex process with multiple interactions between policies, systems and practices, generated through decisions and actions of a relevant quantity of qualified and non-qualified actors, using a huge number of applications and devices accumulated over time in busy and highly variable working environments. In order to clarify and classify the potential interventions to support and improve the transition, a functional distinction between a macro, meso and micro level is proposed, taking the perspectives of users and the goal of safety and efficiency that are the basic principles of HFE. For each level, we address 3 critical interactions to improve the transition to digital health, related to organization (O), technology (T) and human factors (H). Therefore, our framework can be applied either following a horizontal (O-T-H) or a vertical sequence (macro-meso-micro).

2.1. Macro level

At the macro level we recognize and report the following critical interactions: national and international policies, systems features and infrastructure, stakeholder's profiles and power.

At the macro level we can affirm that digital health interventions are not a substitute for functioning health systems and should complement and enhance health system functions.

So it is important understanding the ecosystem and its ability to absorb digital interventions, understanding in the local context, the contributing factors related to ergonomics and human factors which are fundamental for a successful implementation of the technology, such as the health domain area and associated content; the available

software and communication channels; the ICT infrastructure, with a special attention to the understanding of the *work as done vs the work as imagined*.

In the next paragraphs we report current problems and discuss potential opportunities for HFE interventions.

2.1.1. National and international policies - O

Taking into account the current policies of WHO and EU to the transition to digital health, we observe first of all a late recognition of the digital revolution that has been occurring in the past few years. On one side, we observe the spread of computer supported clinical and administrative procedures in health services, on the other side, we see the rise of the web as an enormous knowledge base and relational context for health problems. The WHO issued guidelines for the use of digital technologies based mainly on identifying digital health interventions, primarily available via mobile devices, able to address health system challenges in order to support the promotion of UHC. The understanding of ergonomics and human factors for improving its use and the impact on patient safety it is actually not a main focus of the elaborated recommendations from WHO. Nevertheless, it is emphasized how it is important to address some enabling layers in order to have success in the implementation of the digital interventions. Especially, at the system level, a country should consider to establish a clear leadership and powerful governance based on the development of a common strategy and adequate investments. This should be the basis for creating a national infrastructure, or at least interoperable systems based on common standards and shared services and applications to use in all the different parts of the healthcare system. These prerequisites bring in immediately the issue of HFE, which are key factors in order to create a robust enabling environment, without this kind of environment, there is the risk of a proliferation of unconnected systems and a severe impact on the effectiveness and sustainability of the health intervention.

The European Commission, in a recent document (November 2018) related to an expert panel on effective ways of investing in health underlined how governments could be more active in optimizing the decision making process and the related outcomes [9]. In this document the EU emphasizes the need to find a balance in the development of the digitalization between promoting centralized and decentralized activities. It is also important to deal with all the aspects that can prepare the health sector to accept the transition to the digitalization like education of the main stakeholders, the introduction of specific regulatory conditions, the implementation of monitoring systems to monitor its effects on health system performance. All this aspects are interconnected and need a systemic approach, typical of the human factors discipline, in order to be developed synergically and to guide the transition to digitalization successfully. It is also important to build a European repository. Further investment in developing and sharing methods and evidence on evaluations of digital health are also considered as a recommended actions from the EU, and we argue that in this sense the adoption of the HFE approach can help in introducing consolidated methods of evaluation for understanding the impact of an innovation into a specific context.

2.1.2. Systems features and infrastructure - T

Digital technologies are introducing a powerful group of innovations that can support healthcare in the realization of some important purposes, such as:

- Bridging gaps in care delivery systems (through the use of mobile applications that can reach everyone in the most remote places) and supporting the UHC to ensure the quality, accessibility and affordability of health services;
- Facilitating communications to individuals in order to generate demand and broaden contact coverage;
- To give to healthcare workers more immediate access to clinical protocols and telemedicine consultations with other health workers.

But, at the moment, these innovations are a big challenge to realize as the current situation represents some relevant limits to their diffusion. First of all, the adopted applications are isolated one from the other and not integrated with the main clinical documentation, in primis with the clinical record. In the development of these applications, as well as for the development of digitalized clinical documentation, there are no established standards, both at the international and national/regional level. Usually the usability of a digital solution, is considered only when healthcare workers, while using it, face a practical problem that affect their performance. Then the approach to the evaluation of such solutions is usually a reaction to a bad events or a bad user-experience. The reactive mode is dominant comparing to a proactive way to design and develop technology by embedding the principles of HFE into this process. There is also a lack of competencies on this field inside the healthcare systems, which facilitate the lack of attention to this aspect while designing information systems. The presence of experts in HFE among the professionalities involved in the project team for the transition to digitalization and the consideration in a proactive way of these aspects during the analysis and design of a clinical care process into an informative system, are essential elements for avoiding primarily adverse events and secondly underqualified performances and inefficiencies.

2.1.3. Stakeholder's profiles and power - H

At the macro level, the strategic functions we discussed in the previous paragraph, especially the establishment of a strong leadership, an effective governance, some transparent regulator mechanisms, are dependent from the key stakeholders at the international and national level. The challenge here for the national institutions and regulators is to overcome a consolidated technology and administrative driven approach, where the main skills involved in the design for transition to digitalization are usually engineeristic and normative/administrative. These skills are more addressed to satisfy the organization's needs in terms of having a reliable infrastructure and a legal protection instead of looking also at the users' needs (both healthcare workers and patients) in terms of transparency, usability, effectiveness of the clinical performance. HFE approach helps stakeholders to consider the system with a wider perspective and introduces methodologies that can favor the design of the informative system according to the real world of the daily practices rather than according to the organization as imagined.

Another critical point concerning the stakeholders' role at the national level is the difficulty in setting up a clear agenda for the transition to the digital era for the healthcare system. Usually national programs are too generic and fail in including specific goals and controls over their use.

There is also a lack of awareness about safety and security of personal data, and how to manage it with a potential clash between data protection and patient safety. These criticalities can be overcome only if the transition to digitalization is seen as an occasion for triggering a deep innovation process.

2.2. Meso level

At the meso level of the system, that is the context where health organizations are set up to manage important amount of public and private resources to deliver care services, we recognize three main themes: development, selection and purchase of systems; management and integration of information systems and devices; fitness with strategies and goals to deliver safe and quality care.

At this level, the transition to digital health is generally an incremental process, where new software or digital devices are added to current clinical practices and pre-existing tools without a clear and integrated vision about opportunities and threats related to the presumed innovation.

2.2.1. Development, selection and purchase of systems - O

HFE principles may help decision makers within health organizations to develop, select and purchase systems. If we take the example of electronic patient record, a significant amount of literature is already available to suggest some basic principles that can be applied to integrate HFE at this level:

- Co-development
- Continuous evaluation and iterative design
- Service dominant logic

First of all, the digital solutions, where considered an integrated part of the care process, can be co-developed between providers and health organizations by performing basic and applied research before and after the release of any digital solutions. As it is common with medications or surgical techniques, the cooperation between producers, researchers and users is fundamental to guarantee safety, effectiveness and hopefully sustainability of any intervention. A well-known systematic review of electronic patient records conducted in the United States has promoted only a very limited number of products, highlighting how the few co-developed products between computer scientists and clinicians within healthcare facilities were superior to commercial products [4]. This is HFE in practice, given that the participatory approach to design of any artifact, especially to address complex problems, is the standard strategy included in the national and international norms on principle of HFE, such as ISO 6385:2016 Ergonomics principles in the design of work systems.

Secondly, while selecting any digital intervention, a continuous evaluation must be considered in order to support dynamic interactions with the new technology and a contribution to a recurrent design at least of the digital interfaces. End-user products are routinely selected according to their recognized capacity to adapt to different situations and be updated according to user experience and feedback. Health organizations need to be prepared to have pro-active facilitators who can collect, analyze and report data about user-experience so to systematically evaluate the digital intervention and pretend a human centered iterative design of each tool, well summarized in the manifesto for an ethical design [10].

A service dominant logic [11] should substitute any remaining traditional way of contracting the purchase of products between health organizations and providers of digital solutions. A “one size for all” product seldom exists for interventions where the capacity of the health organization to succeed and survive strongly depends to its connections with macro-level strategies on one side and with local practices on the

micro-level. Therefore, in a service dominant logic a digital intervention is at the same time compliant within a highly regulated institutional environment and flexible to respond to emerging needs of fast changing communities and personalization of care [12].

2.2.2. Management and integration of information systems and devices - T

Despite the density of information systems and devices in health organization, we still see relevant problems of integration and lack of coordination between software and devices. An extensive evaluation program of the digitization process of health information systems conducted in the UK has shown all the limitations of existing products and even the new risks that may result in clinical activities (eg errors of prescription of medications induced by automatisms in the data entry) and managerial (eg prolonged waits for exam results due to difficulties in finding relevant information), as well as the ways that operators and managers use to override software limitations, through routine violations of procedures and good working practices (eg transcription of operational notes on paper notes to prepare the letter of discharge, use of commercial applications for internal communications such as handover or consultancies) [4].

On the other hand we have very good examples of a strong integration of systems and practices in the development of chronic care models, where health organization have established care plans for people affected by chronic conditions, such as diabetes or hypertension, that are based on the growing use of wearable or implantable devices, connected to a patient record, integrated in a network of interactions between professionals and services capable of providing effective and timely response to the needs of an empowered patient [13].

2.2.3. Fitness with strategies and goals to deliver safe and quality care - H

Measuring quality and safety is a fundamental duty for health organizations. Nowadays, the collection and analysis of data on health processes and outcomes are included in authorization and accreditation schemes all around the world, in order to guarantee patient safety and value of health services. These activities are often based on extensive review of paper-based records or on the production of data for the unique goal of measurement. Many human and technical resources are spent for data processing, even the time of clinicians is absorbed more by documentation than by direct patient care. Besides, both the impact of accreditation systems the publication of data on strategies and goals of health organization on performances are still debated [14].

In any case, from an HFE perspective, we consider measurement as a basic requirement to understand the fitness between strategies, goals and the delivery of care. The problem is more about how and what to measure and who is involved in doing measurement. New technologies provide new opportunities to look at measurement as part of the managerial and clinical work, rather than as an additional duty to be performed for accreditation purposes. The intrinsic characteristic of digital technologies allow them to support workflows and at the same time to produce data about process performance, as it is well known in manufacturing. So any software or device, co-developed with the health organization and contracted in a service dominant logic, can also automatically produce useful data on performance just if it fits with strategies and goals of quality and safety improvement. Technology driven approaches cannot help because they are not necessarily aligned with the responsibilities of a health organization to deliver safe and

quality care, according to its institutional context and resources, communities needs and demands [15].

2.3. Micro level

The Micro level is where real people interact and health eventually flourishes thanks to individual decisions and behaviors, organizational capacities to address and act against accidents and diseases, institutional and communal resources to sustain people needs and desires.

When we look at our three themes about HFE for digital health at the micro level we see: users and designers interactions; flexibility of workflows; availability and characteristics of hardware and infrastructures. The transition is very fast at this level and often outside of the deliberate control of an institution or an organization, especially as a consequence of the development of mobile technologies and internet connections.

2.3.1. Flexibility of workflows - O

Patient pathways are spread throughout home care, community services and hospitals. The fragmentation of information systems and accountability for care interventions negatively affects workflow and patient experiences. In high income countries, the hyper-specialization of medical treatments has contributed to the success of life saving procedures, sometimes at the expenses of an holistic approach to care and cure, that integrates illness as the personal experience along with the classification, diagnosis and eventual resolution of a disease. In low and middle income countries, as well as in poor and deprived sector of HIC, contacts with providers are less systematic and often patients and their families take the clinical and social burden of a disease on their shoulder, in an attempt to compensate limited availability of specialized services with traditional remedies based on cultural heritage that are difficult to connect with western medicine. In this scenario, dissemination of mobile devices and access to the internet give an opportunity to connect people in needs and health providers in new ways, yet to be explored in their full potential along with their risks. Knowledge about health promotion and disease prevention can be designed and delivered through the web, from accountable health organizations and providers to fit with user needs, old and new habits about personal care and life styles. Moreover, for diagnosis, treatments and rehabilitation, HFE can contribute to the design of health plans with flexible workflows for health professionals, built around health profiles of selected populations, mixing traditional with digital consultations and integrating patients activation in performing tasks and reporting data about their health and care experiences.

2.3.2. Availability and characteristics of hardware and infrastructures - T

Hardware and infrastructure to support the transition to digital health has been developing much slower in health systems than in other industrial sectors, where user experience pushed systems to change such as in banking, commerce or travel services. More and more health professionals report to use their personal devices to help decision making, to communicate with peers and patients, to record relevant information about a treatment, in place of official tools provided by the health organizations. Investment in health information technologies is still very low, compared to the budget for medications or biomedical devices, despite the evidence related to how communication may negatively affect patient care [16] and efficient workflows [17]. Provided enough

security in terms of data protection and continuity of services at the macro and meso level, a distributed decision making process about hardware and infrastructures can help to hardwire the provision of digital health within the local microsystem, by creating lean and adaptable infrastructures open to low cost hardware solutions that can host software and devices aligned with user habits and needs (users = patients and professionals), fully integrated within flexible workflows.

2.3.3. Users and designers interactions - H

Traditionally, digital interventions, especially based on software to support and manage information flows, have generated a tension on the clinical level between standardization and personalization of care, as well as some preoccupations about organizational control over the autonomy of health professionals to take decisions about diagnosis and treatments. Medicine is still considered an art and the doctor a special kind of human with the capacity to integrate intuition rooted in experience with complex reasoning related to a wide knowledge base. Certainly, medicine has got an artistic component in the creative processes of decision-making and actions in practice that help to solve complex problems with limited information and tools, and doctors are probably the professionals who dedicate more time to education and training than any other to be prepared to face daily tens of patients with multiple and highly variable conditions. Anyway, from our perspective, acceptability and usability of digital interventions in healthcare can be addressed by improving the interactions between users and designers. Therefore, the macro level principle to consider organization as it is rather than organization as imagined, it may unfold in daily practices as the users become designers of the systems and designers walk in the shoes of the users through the application of classical HFE techniques such as cognitive walkthrough or scenario based design [18]. To close the gap between users and designers, both professionals and patients have to spend time to express their needs about effective interactions with software and devices. On the other hand designers have to access actionable knowledge about those interactions. The contribution of expert in HFE is critical to analyze real context and represent user needs.

3. Potential application and limits of the framework

The "health system" in Western countries has an urgent need to implement innovative organizational models and reallocate resources optimally between the various care settings.

Digital technology can be an enabling tool to respond to these needs with a profound structural change in care and assistance models, starting with the strengthening of interactions and the integration between the health world and the social world at the micro-level of the system.

The evolution of IT tools provides solutions of proven efficacy to address the core functions of care, that is to assist professionals and patients in their daily work, using accessible digital technologies within flexible workflows, fitted to institutional and organizational strategies and goals.

However, the change will take time; it is necessary to set a multi-year implementation plan, in which a strategic regional and national vision is combined with the priorities of the local contexts, with the involvement of all the stakeholders: policy

regional makers, doctors and health professions, technologists, citizen associations, suppliers. Experts in HFE can play a key role in creating evidence for an ethical and effective design of digital health intervention and providing support to their implementation and evaluation at the macro, meso and micro level. Our framework, summarized in table 1, may help to integrate HFE at the different level of the system and following the tracks of organization, technology and human factors.

Table 1. The HFE contribution to the transition to digital health.

Areas of interventions	Macro-level	Meso-level	Micro-level
Organization	<i>National and international policies</i> • creating a national infrastructure, or at least interoperable systems based on common standards and shared services and applications to use in all the different parts of the healthcare system. • create a robust enabling environment, for avoiding the risk of proliferation of unconnected systems and a severe impact on the effectiveness and sustainability of the health intervention	<i>Development, selection and purchase of systems</i> Three principles to integrate HFE in the development: • Co-development • Continuous evaluation and iterative design • Service dominant logic	<i>Flexibility of workflows</i> • contribute to the design of health plans with flexible workflows for health professionals, built around health profiles of selected populations • mixing traditional with digital consultations and integrating patients activation in performing tasks and reporting data on their health experiences
Technology	<i>Systems features and infrastructure</i> • promoting a proactive way to design and develop technology by embedding the principles of HFE into this process. • including experts in HFE among the professionals involved in the project team for the transition to digitalization	<i>Management and integration of information systems and device</i> • strong integration of systems and practices in the development of chronic care models, • connection of wearable or implantable devices, with a patient record, integrated in a network of interactions between professionals and services capable of providing effective and timely response to the needs of an empowered patient	<i>Availability and characteristics of hardware and infrastructures</i> • creating lean and adaptable infrastructures open to low cost hardware solutions • software and devices aligned with user habits and needs (users = patients and professionals), fully integrated within flexible workflow
Human Factors	<i>Stakeholder's profiles and power</i> • overcoming a consolidated technology and administrative driven approach, and introduce a systemic approach • value digitalization as an occasion for triggering a deep innovation process	<i>Fitness with strategies and goals to deliver safe and quality care</i> • adopting measurement as a basic requirement to understand the fitness between strategies, goals and the delivery of care • align data produced with software or device on performance to strategies and goals of quality and safety improvement	<i>Users and designers interactions</i> • Application of classical HFE techniques such as cognitive walkthrough or scenario based design • Analyze real context and represent user needs

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