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Design and Usability of the Next Medical Devices for the Home Care

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Abstract: The growing complexity of instruments for health care and of medical devices for personal use has led to an intensification of the risks related to bad functioning and failure to function or misunderstanding how to use the interface, control and adjustment elements etc.

Besides, the general tendency to reduce hospitalisation to the minimum by transferring many of the patient's care stages at home has led to the involvement of "non experts". It follows that radical rethinking is required of the subjects involved, who will actually use the medical devices to care for and assist the patient.

Ergonomics in Design and Design strategies to orientate the design of new products and to satisfy the needs of the plurality of user profiles involved in home care.

This article presents part of the results of the research and experimentation performed by Florence University Laboratory of Ergonomics and Design.

Keywords: Product Design, Health Care Ergonomics, Human Centred Design, Design Thinking.

1. Introduction

The European Community defines social innovation as:

"the development and realization of new ideas (products, services and models) to satisfy the requirements of society and create new relations and social cooperation." (European Commission, 2013)

Social innovation and appropriate intervention strategies, to guarantee the adequacy of care and increase independency and participation of the frail in an active life, are some of the more significant themes of social policy and research in the international context.

It means that is necessary to find new solutions for the growing social needs concerning human interaction processes while at the same time improving general well-being. The main elements of social innovation can be summarized as follows:

- identification of new/unsatisfied/inadequately satisfied social requirements;

- development of new solutions in response to these social requirements;
- evaluation of the efficacy of new solutions in satisfying social requirements;
- increase of effective social innovations.

The risks resulting from errors in the use of medical devices and equipment, errors in reading/interpreting the use of drugs, errors in treatment procedures, incidents in many cases attributed to “human error” alone, damages to the patient’s health and the correct administration of treatment, are very topical subjects, brought to the attention of health workers and the public opinion by incidents that have occurred, often with serious consequences, caused by the poor functioning or failure to function of care apparatus, or errors in its use.

A markedly transversal field of study and intervention, in which the evaluation of risk conditions and definition of intervention strategies for the patient’s safety call for a close interrelation between medical, management and design competences.

Specific knowledge of care and assistance procedures is obviously a prerequisite for evaluating critical situations, which may give rise to the onset of so-called adverse events, just as knowledge of the conditions and method of using diagnostic and care instruments and apparatus is the starting point for any design intervention.

Among the many domains of study and intervention in the management of diagnostic, care and assistance procedures and the safeguarding of patients’ and operators’ safety, of current interest are the conditions of risk related to the bad design of products, apparatus and equipment for diagnostics and care used in the Home Care sector, in other words, in care and assistance activities that take place outside healthcare structures. (Ogrodnik, 2013) (Weinger et al., 2011)

Within this framework, the role of design is essential as a strategic instrument of innovation able to respond to the needs of man and society in general and, in this specific case, of persons with reduced independence and “non expert” users. Design can help to orientate the planning of home care products by taking safety and ease of use into special consideration. Essential aspects, such as the correct planning of visibility and legibility of information, management of manual controls, simplicity of reading and interpreting the digital interface, become a subject for Design and Ergonomics in Design.

2. Human-Centred Design for Home Care

Medical product design and the role of ergonomics and the human-centred design approach in evaluating and planning furnishings, products and services for the health sector, represent a current major issue, brought to the attention of health workers and public opinion following frequent dramatic incidents resulting from the bad functioning and/or incorrect use of devices, apparatus and aids, in hospitals and health-care structures and in the home.

In the case of Home Care, the growing complexity of the methods of using products and apparatus for health care and assistance and, similarly, medical devices for personal use, has led to a parallel intensification of the risks related to bad functioning and/or failure to function or misunderstanding how to use the interface, control and adjustment elements, assembly sequences, activation, etc.

Errors in the assembly and use stages, failure to carry out the procedures, failure to interpret or incorrect interpretation and understanding of information, are the cause of incidents with frequently serious or grave consequences.

The general tendency to reduce hospitalisation to the minimum by transferring many of the patient's care and assistance stages to the home environment has obviously led to the involvement of "non experts". It follows that radical rethinking is required of the subjects involved (in other words, the end-users, relatives, cohabitants, care-givers both specialized and otherwise) who will actually use the medical devices, apparatus and aids to care for and assist the patient, and the context – physical, technological, social – in which the devices and apparatus will be used.

The relationship between Ergonomics and Design, like the synergy between the methods of assessing the needs of Human Centred Design users and the Design Thinking approach (Cross, 2011), aimed at optimizing User Experience, represents a concrete opportunity in the field of social inclusion, both as a strategic instrument for the design of innovative products and services for care and assistance, able to satisfy the requirements of users (end users, carers, family members) and as a method of intervention to synthesize the various professional competences involved in the design and supply of health-care services and social integration.

Home Care differs in many ways from the assistance provided in hospitals and specialized structures.

One aspect concerns the difference between products for internal use in healthcare assistance structures and products for individual use.

In the first case, the equipment, machinery and devices are used by specialized staff who, depending on their role and competence, use each product for a specific purpose and, in general, adopt standardized procedures. The reference user base in this case is represented by persons with specific and easily identifiable competences and professionalism, whose activities are performed in an organized context within codified and controlled procedures. The function and methods of using each product, component or interface are therefore addressed to users who are easily identifiable and whose duties and level of competence can be known in advance. Similarly, evaluation of the conditions of risk in which incidents or damages to the health of the patients and/or operators - can occur or have occurred - can be based on knowledge of work procedures, organizational structure, individual duties and, lastly the environmental context (organization of healthcare area, equipment available, technologies and instrumentation used etc.).

In the case of products for personal use, as for example medical devices or medical equipment for home use, like pharmaceuticals, the reference user base is not made up of health workers, but rather of "laymen" whose characteristics and physical, perceptive or cognitive capabilities, like their knowledge or level of competence in using and understanding potential risk conditions are unknown *a priori*. In this case, the device – as occurs for daily use products – can be used "by anyone" and "anywhere and under any conditions". In addition the products, devices, drugs, etc. are used outside controlled procedures in often widely diversified physical contexts. Besides the direct users (patients), relatives and home care-givers must also be considered, in other words, all those people who are directly or indirectly involved in caring for the patient. Furthermore, it must be emphasized that most of the users of medical devices or care equipment, as also drugs for home therapy, are elderly persons, often with difficult or limited mobility, sight or hearing problems, memory or attention impairments, etc.

A second aspect concerns the great evolution of products, equipment and services for health care and assistance, in part identical to that encountered in other design fields and in part strongly characterized by the specificity of the sector.

Like many other product types (from household appliances to the automotive sector down to communications), over the last two decades the medical product sector has seen a strong technological acceleration, which has led to a profound change in the functions and performances

offered and the methods of interaction between user and product and, in particular, between user and the control/regulation/programming interface.

The diffusion first of electronics and later of information technology has given rise to the relatively rapid disappearance of mechanical controls and to their progressive replacement by informatics-based interfaces, with increasingly complex and widespread features, requiring the use of digital language and logic and a method of learning new functions and procedures based on the ability to establish immediate affinities with analogous dialogue systems (in other words, those used for mobile phones, vending machines, computer programmes, etc.).

If this is a very important phenomenon in the sphere of highly complex equipment and machinery for specialist use (consider, for example, machinery for diagnostic imaging), the use of digital interfaces has now become widespread for most medical devices, even those of average or low complexity (from devices for monitoring glycaemia and pregnancy test kits).

To the growing complexity of the vast number of products for everyday use, must be added, in the case of medical devices and healthcare products in general, the marked specificity of the requirements of users who, in the majority of cases, consist of elderly people with limitations or impairments in perception or attention and who are generally unfamiliar with digital interfaces.

The use of complex interfaces, with continuously evolving and revised procedures, on the one hand, and poor knowledge of and/or attention to the reference users' effective ability and level of familiarity with their use, lead, as a direct consequence, to a lack of or only a partial understanding of the methods of use and to the onset of possible risk situations followed by a condition of psychological insecurity, the need for assistance and support from family members and, in synthesis, a reduction in the level of personal independence.

3. Methodological Approach

The usability of medical devices, like mobility aids and medical furnishing systems widely used also in the home, represents an essential requisite for guaranteeing patients' safety and safeguarding and increasing their personal independence.

Usability, in its current meaning of "simplicity" and "comprehensibility", of the procedures for use and individual operations to be performed (with devices, it represents the equipment, aids and their mechanical and/or digital interfaces), is firstly the discriminating factor between the possibility of undertaking everyday activities and personal care relatively independently and safely, and in addition has important repercussions on reducing the family load and optimizing home services offered by healthcare and assistance structures.

With regard to Italian regulations, Legislative Decree no. 37/2010 (concerning "General Safety Requisites"), sanctions the close correlation between safety requisites and the "ergonomic characteristics of the device", including in the evaluation of said requisites, a reference to the "environment in which it is envisaged the device will be used" and consideration regarding the "level of technical knowledge, experience, education and training, in addition, depending on the case, to the medical and physical conditions of the users for whom the device is intended (design for common users, professionals, the disabled, or others)".

Major obstacles in the use of equipment and aids for mobility are encountered, for example, on account of the complexity of equipment assembly operations, or the difficulty in managing regulating

and operating elements, poor visibility and legibility of the instructions supplied with the product or the indications on controls.

There are, in fact, many aspects closely related to safety and usability conditions which, albeit with all the differences posed by interventions in single cases, share common conditions of use and methods of interaction between user and product in the health field and in particular the Home Care sector:

- the physical usability of parts and components, involving the anthropometric-dimensional study of the so-called physical interface (push-buttons, levels, operating elements, screens, etc.) and their accessibility, and verification of movements and effort required;
- the manageability of devices, aids, furnishing elements, their components and control and regulation elements. These aspects concern, for example the assembly and disassembly stages (integration or disassembly of parts and components, opening and closing of folding equipment, adjustment of height or inclination of tilting beds and armchairs, etc.);
- visibility and legibility of information involving strictly perceptive aspects (distinguishability between different products, visibility and detectability of parts and components, character size, use of colour, etc.) and cognitive aspects related to the correct interpretation of information;
- usability of regulation, programming and control interfaces, in other words, efficacy and comprehensibility of information supplied by the dialogue interface, especially with regard to digital interfaces (appropriateness of information, correct hierarchy of selection and choice procedures, understandability of dialogue/choice/selection options, presence of alerts and warning information, etc.).

The survey methods of Human Centred Design and in particular the methods of evaluation and usability and safety design are specifically appropriate in this sector, in which the “use stage of the product” is the main risk factor for users, and in which easy understanding of the method of use and aspects relating to safety in the use stages (assembly, disassembly procedures, adjustment and use of predominantly mechanical aids, procedures for accessing and use of digital interface apparatus) involve both the users’ capability and level of physical and sensorial independence, and cognitive aspects related to their ability to focus their attention and learn and to their memory capacity. The usability of devices must be evaluated by firstly taking into account the specific difficulties and limitations of end users. (Tosi, Rinaldi, 2015)

Of particular relevance are the methods of evaluation and intervention based on the involvement of users, aimed at identifying the specificity of the needs of different user profiles and different intervention contexts – environmental, technological and social.

One of these methods is Analysis, which refers to different user profiles involved in assistance and care activities. (Committee, 2011b)

In the case of Home Care activities, reference is made on the one hand to the activities of users who benefit from the service, mainly the elderly or people with impaired capabilities and limitations in mobility, perceptive capacities, attention, ability to learn new tasks and with short-term memory; on the other, to activities requested from external assistants and activities requested from family members and private care assistants. (see Table 1)

Table 1. (Committee, 2011a)

USERS OF HEALTH IT APPLICATIONS IN HOME CARE
<ul style="list-style-type: none"> ■ People who are well. These individuals engage in health practices in the home (e.g., eating well, scheduling regular health checkups, exercising) to maintain or improve their health state. ■ People who are ill or managing complex diseases. Half of all households have a resident with a health problem (e.g., a soldier returning with an injury, a child born with a congenital limitation, a well-functioning individual who takes medications to control a chronic condition). These individuals are the most common users of many consumer health information technologies. ■ Kids. Such technologies as games for health or interesting Websites can guide kids, sick or well, in the process of making healthy choices or help them keep track of complex medical regimens they need to sustain life. ■ People with disabilities. Such technologies as talking computers or motion-sensitive faucets make everyday life easier for people with physical or cognitive limitations. ■ People who are older. Today, 1 in 10 persons is over the age of 65; in 20 years, that number will grow to 1 in 8. Most older people have skills and strengths that can be enhanced by well-designed consumer health information technologies. Some individuals will use these applications alone, others with the help of caregivers. Not all consumer health information technologies will be used by people in the categories identified above. Sometimes family, friends, or health professionals provide assistive care. Designers and developers should also keep these people in mind when creating new equipment and technologies. ■ Informal caregivers. As many as 36 million family caregivers or friends help others manage their health and health care. Informal caregivers make meals, ensure on-time arrival to medical appointments, modify household layouts, and generally anticipate and act on the needs of the individual. ■ Formal caregivers. Formal caregivers serve as the source of professional guidance and intervention. Individuals may travel to visit a formal caregiver in a hospital or clinic or may communicate with them remotely.

Other survey methods, based on direct involvement of users, are essential, particularly user trials, direct observation and thinking aloud methods, which integrated with questionnaires and interviews, enable direct collection and through “in the field” surveys, in this case at home, of the plurality of users’ needs and expectations within their own domain of everyday life and collection of the requirements and expectations of outside operators.

The involvement, right from the stage of surveying and planning project alternatives and interventions, of firms in the medical sector and structures/firms operating in the field of personal assistance enables verification of the real feasibility of the proposed interventions both from the technical/productive point of view and service supply.

4. Results

The relation between Ergonomics and Design in the planning of products and services for health care and, more in general, in planning for independence and social inclusion, is one of the main subjects of research and experimentation developed by Florence University Laboratory of Ergonomics and Design.

In particular, with regard to Home Care, in recent years two research paths have been developed: one dealing with the “Pharmaceutical Packaging” (Fig. 1-2) and the other “Usability of medical devices and mobility aids” (Fig. 3-7).

Research was carried out by means of a detailed analysis of the requirements of the various groups of users involved in Home Care, together with an evaluation of the various devices available on the market.

The Human Centred Design and Design Thinking approach provided important cues not only for incremental innovation, but also for the radical innovation of existing products. Design experimentation also showed that there is still much to be done to improve User Experience in this sector and to simplify and improve usability of human-machine interaction.

The research and design experimentation experience represented an initial concrete opportunity for interdisciplinary confrontation on the subject of Design for healthcare, open to collaboration with firms and operators in the pharmaceutical and health sector.

Knowledge of the use context – starting point of the Human Centred Design process - materializes from an analysis and evaluation of the context variables, in other words, of all factors contributing to define the relation between individual and product/environment/system, or, by definition, the users, the activities performed and their objectives, the physical, organizational and technological environment of reference and the products considered.

In the case of products and aids for Home Care, it is a question of identifying the capacities, requirements and expectations of the main user profiles (direct users, family members, external assistants, home assistants) and, for each of them, to describe and evaluate the various activities and objectives with whom and for whom the products are intended.

The survey stage was conducted through a task analysis, developed for each user category, and by direct observation, questionnaires and interviews.

From the design point of view, furthermore, the key aspect is knowledge of the possible conditions of risk, of the most frequently recurring adverse events, particularly with regard to the description of exemplifying cases through evaluation of the causes leading to the occurrence of the incident and possible corrective intervention.

In other words, an understanding of the reasons - often complex, sometimes quite trivial - that lead to the failure to comprehend the information and/or the stages of correct usage of the product or equipment, to difficulties or impediments in their use, or erroneous reading/interpretation of instructions, information, warnings, etc.

The following concepts have been devised starting from a survey stage developed through evaluation by experts, analysis of tasks, trials and comparative analyses by users of various devices already present on the market. The projects regard medical devices for personal use (blood pressure monitors, heart rate monitors) and mobility aids.



Figures 01-02. Secondary and primary package for antiviral drug. Concept by: D. Ciampoli, M. Marseglia, S. Visconti



Figures 3-4. Pulse-oximeter ring, for measuring blood oxygen saturation and heart rate. The picture shows the device and the base charger, with integrated USB for data transfer. Concept by: C. Gasparri, J. Venturi

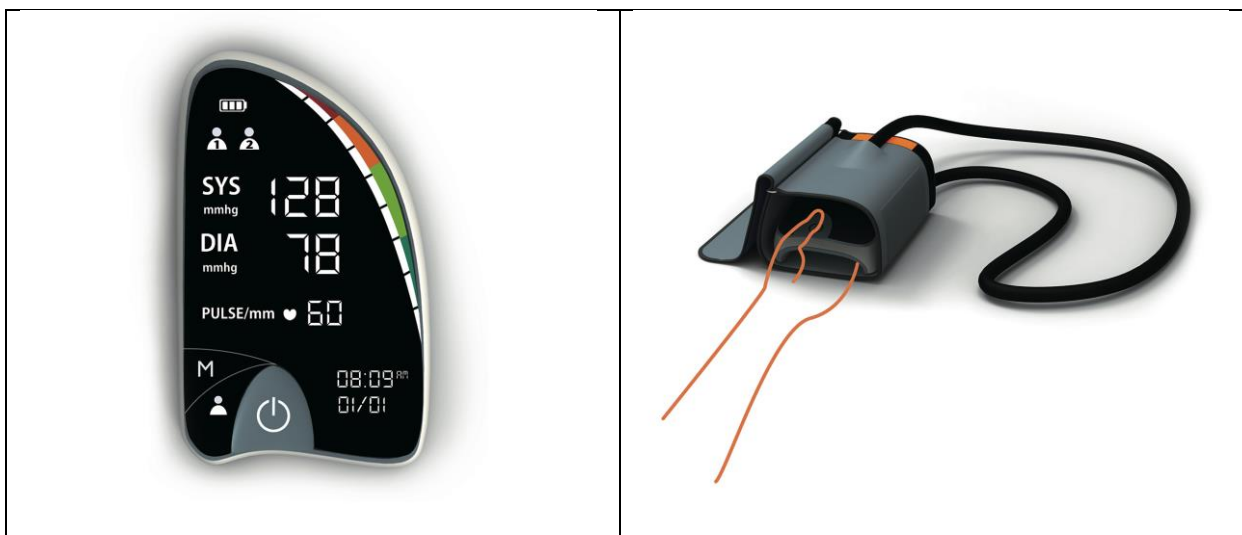


Figure 5-6. Sphygmomanometer. Rendering: general view of the monitor (left) and grasp simulation (right). Concept by: M. Jing, Q. Mengdi



Figure 7. Walker - opened and closed - with accessories, table top and soft seating. Concept by: A. Panebianco, L. Quercioli

5. Discussion and Conclusion

An essential aspect of the design research path was the relation between the HCD process and the process of formation and development of the product, in other words, the procedures – and the possibilities – for integrating the HCD method and intervention philosophy in the logic and restraints of industrial production. (see Table 2)

Company timing and costs obviously necessitate paying great attention to the rapidity of the analysis/evaluation stage and to the correct placing of the verification phase in the subsequent project conception and development stages.

The choice of materials, processing techniques and relative cost analysis, in turn call for great attention to making suitable choices for the product's technical and economic feasibility to ensure that it is competitive on the market.

The main aspect is therefore the choice of the most suitable and efficient evaluation methods to be applied in the different stages of product development and, simultaneously, evaluation of economic costs and the time necessary.

As from 2013, design research and experimentation has been conducted with firms in the medical sector, specialized in the production of medical devices and mobility aids.

The involvement of firms has enabled verification in the field of the technical feasibility of the design proposals and direct comparison with the series of restraints in the production process.

Although it is perhaps banal to underline that the costs of ergonomic intervention, which are however substantial, are economically sustainable during the initial stages of the design process (evaluation of needs/expectations, development of concept), when variations still concern the project elaboration stage, becoming progressively more significant in later stages, this aspect remains the most important hurdle to overcome for the diffusion of the HCD approach in small and medium-size firms.

To vary a product in the final design stage is obviously more complex; to vary a product in the production stage is in most cases impracticable.

Table 2. Design Research Course

DESIGN RESEARCH COURSE	
<p>■ Analysis of use context (HCD methods)</p>	<ul style="list-style-type: none"> • Who are the users • What is the product • How do users use the product • Where do users use the product • When do users use the product • Why do users use the product
<p>■ Analysis of products on the market/ benchmarking – comparative evaluation of:</p>	<ul style="list-style-type: none"> • Services offered • Materials used, • Technological solutions, • Production costs • Selling price • End user •
<p>■ Identification of critical elements</p>	
<p>■ Briefing stage – definition:</p>	<ul style="list-style-type: none"> • Requirements required • Objectives • Restraints (time, costs, materials and usable technologies, etc..) •
<p>■ Development of design/concept alternatives</p>	
<p>■ Evaluation of compliance with requisites and project restraints (HCD methods – evaluation on project)</p>	
<p>■ Choice of most appropriate solution/s and development of final project</p>	
<p>■ Final verification (HCD methods- evaluation on prototype)</p>	
<p>■ Production</p>	

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