Complexity in Home Medical Equipment Design

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Abstract

Home medical devices are developing into a major industry worldwide that covers monitoring, diagnostic, disease prevention, treatment, alleviation of disease and rehabilitation equipment. Services are being moved out to the community and into the home; self management is replacing hospitalization and visits to the doctor's clinic; and custom-tailored medicine is making inroads into normative treatment. These developments have great implications for the scope and design of home medical equipment.

The paper will discuss the unique and complex nature of home medical devices, from a human–environment–machine perspective focusing on the changeable unpredictable nature of users, the unknown, amorphous home environment and the level of intricacy of tasks performed by patients having various diseases and disabilities.

The design of home/personal medical equipment should be guided by the need to make it compatible with the needs of different users and diverse residences. The selection of medical equipment should not be determined by passing trends, technological fashions, or search for innovative and hi-tech applications and gadgets.

We call for increased awareness and active, ongoing research by multidisciplinary teams of healthcare personnel, end user patients, caregivers, psychologists, social workers, and especially, the architects and designers who will be involved from the first stages of concept development through to the final stages of medical device marketing. Design of home/personal medical equipment should follow principles of inclusive design (design for all, universal design) criteria, following user-centered design methodologies. It should accommodate the dynamic, uncertain and complex profile of the widest range of users and environments.

Keywords

home care; medical devices; healthcare design; medical equipment; inclusive design; design for all; user-centered design

Medical device design, manufacture and use constitute a growing industry worldwide, having great economic impact and spilling over into various fields, and serving as a driving force for innovation (Klatzky, Kober & Mavor, 1996; The World Health Report 2008). The traditional way medicine as a whole is packaged and delivered is changing enormously. Services are being moved out to the community and into the home; E-health services, remote monitoring technology and self management are replacing hospitalization and visits to the doctors' clinics; custom-tailored medicine is making inroads into normative treatment (Bogner, 1999; Grundersen, 1999). These developments have great implications for the scope and design of home medical equipment.

In parallel, our society is graying as a result of increased life expectancy and a decrease in birth rates. Aging is being accompanied by a rise in chronic diseases such as diabetes, heart diseases, hypertension, COPD (Chronic Obstructive Pulmonary Disease), arthritis, osteoporosis, etc. (Lathan et al., 1999; The World Health Report, 2008). Chronic diseases can be controlled and prevented by patients who care for themselves via self care and monitoring, thus making the care process a more continuous collaborative relationship between patients and doctors. The assertion that "Health is a state of complete physical, psychological and social well being; not only the absence of illness" (WHO), combined with improved technology, primarily in the field of Information Communication Technology (ICT), is further spurring the expansion of the medical device market. This phenomenon is in line with the concept of "Social Design ", proclaimed by Papanek in "Design for the Real World" (1984). It is not surprising, therefore, that the investments made in the hi-tech

medical device industry have been among the most successful commercial ventures, even during these dark days of today's global economic crisis.

Nevertheless, design of medical equipment is a unique field, with its own specific design demands. The design of for-home-use devices is an even more complicated issue for planners and designers.

This paper will discuss the unique nature of for-home-use medical devices, and focuses on evaluating the issues of their complexity that are related to the nature of users, the environment and the task performed.

Home Medical Equipment

Medical devices are "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacture to be used for human beings for the purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease" (European Medical Device Directive (93/42/EEC) (Martin et al., 2008). While hospital equipment is becoming more sophisticated and specific, significant numbers of medical devices are moving out of hospitals into community and residential settings for use by the public. This new situation raises problems and dilemmas not faced in the hospital setting.

Monitoring and diagnostic devices are present in every home, from simple universal devices such as thermometers and weight scales (e.g., routine weight watching, pregnancy follow-up) to specific devices such as blood pressure meters, glucometers, "Holter" type devices, INR meters (for patients under anticoagulant therapy), pulse oximeters, peak flow meters (e.g., asthma), macular degeneration detection systems and portable EKG/pulse meters. These devices enable remote and frequent monitoring of patients' clinical status and help in maintaining peoples' well being. Diagnostic self-test kits such as pregnancy tests or urinary tract inflammation tests are a fast developing sector of homecare products, thanks to innovative technologies.

Documentation of clinical and personal data (e.g., personal electronic medical records), linkage to information sources, on-line connection and consultation with physicians and medical/social staff, together with the use of ICT, empower patients and help close the loop among patients, devices, laboratories, data bases and physicians (Rollins &Rayburn, 2003). Taken altogether, these form a "disease management team".

Disease prevention, treatment and disease alleviation devices extend the responsibility for preventing illness, impeding further deterioration and hospitalization from hospitals and clinics to the home and work place. This category includes a range of devices, from simple machines such as inhalators and wound healing equipment to advanced equipment such as CPAP masks (e.g., for sleep apnea), liquid oxygen tanks, oxygen generators, catheters, infusion pumps, pain relief and analgesia devices, and even home dialysis machines.

Rehabilitation home equipment may enable frequent, around the clock treatment in a private and comfortable environment, but requires redesigning of rehabilitation gear. Rehabilitation home devices are in line with the concept of 'well being' and part of the trend of gym and fitness equipment that has also moved to the house setting.

Medical device are subject to complex regulations that vary considerably across the world, making compliance a complex and difficult process (Martin et al., 2008).

The use of home medical equipment and services empower patients, shifting them from passive recipients of care services to active participants. Several studies have suggested that interactive health services in which patients continuously take care of their own clinical data will improve management and control of chronic diseases, promote earlier discharge from acute care settings (replaced with continuous home services), improve clinical outcome, reduce the number of clinic visits, increase patient satisfaction, and shift care process towards more continuous collaborative relationships between patients and providers (Barlow et al., 2007; Garcia-Lizana & Sarria-Santamera, 2007; Rollins, & Rayburn (2003). Nonetheless, a new approach to the equipment is needed, given that most medical devices for at-home use are miniaturized, simplified, portable and some times colourful versions of the original professional hospital apparatus (Bogner, 1999; Wilcox 2005).

Users of Home Medical Equipment

Patients are not the users of medical equipment in hospitals and clinics (they are forbidden to operate the equipment by themselves). Professional staff—the nurse, technician or physician—operate the equipment. They are all experienced, dedicated, and trained users who are physically fit and healthy. They receive guidance and technical assistance during equipment operation (or have professionals on standby to call upon). Those who benefit from the use of healthcare devices neither order nor purchase the devices. Healthcare administrations, insurance companies and regulatory bodies such as the FDA decide what medical devices and technology will be accepted and purchased for the healthcare facility, based on economic, social and institutional factors (Wilcox, 2003).

On, the other hands, the users of home medical devices are heterogeneous groups of the patients themselves (self-care) or family members and care givers supporting the patient. The diverse profile of users includes experienced and untrained/occasional patients, family members ranging from spouses to grandchildren and caregivers of different levels of professionalism who may have conflicting interests and needs (Klatzky, Kober & Mavor, 1996; Lathanet al., 1999).

Common diseases and disabilities such as motor dysfunction (e.g., Parkinson disease, essential tremor, arthritis), visual impairment (e.g., diabetes retinopathy, cataract), loss of tactile sensation (e.g., diabetes neuropathy), cognitive impairment (e.g., dementia), auditory decay (phonal trauma, Presbycusis, deafness), speech disabilities (e.g. stroke) and equilibrium and balance disorders may impair a person's ability to operate the equipment. Motor restriction may disrupt the ability to perform simple functions on the device interface such as turning a knob, moving a slider, or pushing a bottom, or to complete procedures such as puncturing the finger for blood sample and wearing the blood pressure cuff. Visual decline will prevent reading the check-up results or following the color indicator and auditory dysfunction will prevent following the sound indicator (e.g., signaling the start and end of measurement). Cognitive deterioration will disturb various stages from the initial steps of the decision whether to perform the procedure or remembering how to perform it, to final steps of remembering the results of the checkup and reporting them correctly (Bogner, 1999; Wilcox, 2005).

Side effects of medications may further impair the user's ability to operate the equipment. This includes changes in visual sensation (e.g., anti-cholinergic drugs), auditory abilities (streptomycin), alertness (anti-allergic drugs), tactile sensation (chemotherapy), perception, cognition and information processing abilities (psychiatric drugs) and more. Anxiety, fatigue, loss of sleep and depression contribute to decreased attention and performance on the part of both the patients and family members (Klatzky, Kober & Mavor, 1996).

In contrast to the professional personnel at hospitals or clinics, patients may be by and large 'unstable'—going through unpredictable and/or frequent changes in clinical status and performance during the period they use the equipment (Bogner, 1999). Chronic patients and elderly people may have multiple disabilities and disorders that complicate the situation, mandating a tradeoff between modes of actions and display configurations of the medical equipment (Mclaughlin, Rogers & Fisk, 2004).

This diversity, unpredictability and fluctuation in users' profiles and abilities further complicates the design of domestic medical devices, their modes of operation and display options in comparison to the stable, known professional profile of hospital equipment operators (Bogner, 1999; Klatzky, Kober & Mavor, 1996; Lathan et al., 1999; Mykityshyn, Fisk & Rogers , 2002; Wilcox, 2005).

The Home Environment

The hospital environment is a constantly regulated setting, under supervision, with strict regulations and inspection protocols. Environmental variables that are controlled in healthcare facilities include sterility (with separation between isolated sterile and non-sterile zones), illumination levels and glare, electromagnetic disturbances, temperature regulation, moisture

and vapor control, background noise (alarms, equipment operation, paging), furniture congestion and more.

As opposed to the controlled healthcare facility milieu, household and community settings are heterogeneous, unpredictable and uncontrolled environments, which introduce elements of complexity and uncertainty into the equation of location, performance and design of medical devices. Each user's home is unique, as opposed to the controlled and standard environment of hospitals. The positioning of medical devices at home, the possibility of electrical disturbances, interaction with other home devices, a non-sterile environment, unpredictable levels of illumination and glare, background noise, crowding of family members, specific maintenance constraints related to varied temperature, moisture, vapors and sunlight, and the need for transportation are some of the factors complicating the design of medical home devices. These factors are less relevant for the design of hospital medical equipment.

In addition to technological and ergonomic issues (Klatzky, Kober & Mavor, 1999), healthcare equipment used at home is also charged with issues of esthetics, design trends, styles and fashion, to the same degree that any consumer product is. For-home-use equipment design considerations are also compounded by the need to avoid images of sickness or disability (Wilcox, 2005).

Conclusion:

This paper presented some of the complex issues involved in designing home healthcare equipment resulting from by the special nature of users and their diverse and dynamic abilities (and especially disabilities) and the mismatch between the atmosphere and design of the house and the image and outlook of the medical equipment. In order to cope with the complexity, and overcome some of the dilemmas in the field of home medical devices, we need the active and continuous involvement of multidisciplinary teams of healthcare personnel, end user patients and caregivers, psychologists, social workers, and primarily architects and designers. The latter group especially will be most involved with concept development through to marketing the medical device(s) as life style articles.

It is necessary to define the objectives of healthcare devices and services at home in terms of life style and "all family" use. Design of home/personal medical equipment should follow principles of inclusive design (design for all, universal design) criteria, so that devices will be usable by the widest possible array of users operating in the widest range of conditions, following user-centered design methodologies (Arsand & Demiris, 2008; Klatzky, Kober, Mavor, 1996; Lathan et al., 1999; Wilcox, 2005).

The selection of medical equipment *should not* be determined by passing trends and technological fashions, or by a search for innovative and hi-tech appliances merely for their own sake. Moreover, design should not be transferred from the medical milieu to the homecare setting (with slight changes) or directly moved from one medical domain to another without first testing the compatibility with the heterogeneous profile of users and the residential environment.

It is expected that in the near future innovative technologies, computing, ICT and virtual reality will enable a holistic approach to medical equipment as an integrated part of the overall surrounding (Lathan et al., 1999). Aware houses (smart homes) and wearable computers will enable optimal personalized performance for each user and improved compliance with maximal integration with the environment whether this is the home, office or a mobile environment (Chan, Estève, Escriba & Campo, 2008).

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