A Review of Multiple User Center Design Methods for New Product Development in Smart and Connected Health Applications

Noshad Rahimi, Maria Ibarra
Dept. of Engineering and Technology Management, Portland State University, Portland, OR - USA

***Abstract*--Evidences across industries including telecommunication, retail and trading, suggests many benefits are to be gained from automation. To obtain these benefits in the field of healthcare, there have been vast amount of studies conducted on utilization of technological capabilities during the past few decades. From medical information systems to Telemedicine to ubiquitous computing, smart and connected health applications are designed to have a positive impact on current and future health care practices. While there have been a lot of successful innovations in these applications, there have also been a lot of failure. Study of these applications highlights the importance of user involvements from the very early stage of new product development. This paper utilizes the categories identified in Smart and Connected Health (SCH) terminology recognized by National Science Foundation (NSF) to conduct a holistic study of different technological applications developed for healthcare to identify major barriers inhibiting their diffusion. The User Centered Design (UCD) methodologies proven valuable in industrial contexts are reviewed to highlight their characteristics and capabilities to facilitate user involvement. It references cases where they have been valuable toolkits to address barriers recognized. Finally, the study categorizes the major barriers captured throughout the study and recommends best user centered design(s) approaches to be deployed for superior front-end management of healthcare solution innovation.**

I. INTRODUCTION

From cost saving and reduction of errors to streamlining and improving the quality of service, health care can gain significant efficiencies and effectiveness enjoyed by other industries. This, in combination with increasing demand for healthcare services, create a great opportunity and demand for Smart and Connected Health solutions. Computing Community Consortium (CCC), a subsidiary of CRA[1], often serving as NSF[2] consultant to help employ scientific researches into advancing healthcare[3] provides the main categories of SCH. According to CCC, Smart and Connected Health (SCH) is the application of computing, information, and networking technologies in healthcare with the goal of preventing disease, enhancing the quality of care and decreasing overall cost [4]. This paper uses the categories of SCH for a comprehensive study into different applications of technology in healthcare with attempt to capture inclusive set of barriers to successful adoptions related to the user involvement in product development process.

Secondly, the paper introduces five different methodologies dominating the field of UCD that can be utilized when designing solutions for SCH applications. The conducted studies make it evident that UCD methods can be instrumental in development of SCH products and solutions as they help to reveal users' needs and to understand different drivers such as users' preferences, knowledge, expectations and attitude.

Finally, given the characteristics of the user centered design (UCD) methods introduced, the paper attempts to recommend UCD approaches that best addresses the identified barriers for each category of SCH. It utilizes the result of the studies conducted to suggest the appropriate UCD method(s) that suit(s) best for overcoming challenges during user involvement in the design of SCH solutions. The authors of this paper hope that these recommendations can help in some small ways in successful diffusion of SCH innovations by highlighting the UCD approaches and the importance of user involvements in the front end management of innovative product development of smart and connected health.

In general, this study looks at the management of service innovation. In particular, it explores the challenge of public services and argues that there is a need for new approaches to the ways, which engage users as more active co-creators within the innovation process[5].

II. SMART AND CONNECTED HEALTH (SCH) CONCEPTS

The umbrella of SCH covers solutions (products, services, and systems) intended to enhance delivery of healthcare. Successful development of smart and connected health applications requires the fulfillment of medical and clinical needs coming from diverse set of users health care professionals, patients, and their caregivers or family members, and other stakeholder). Additionally these solutions should satisfy the constraints caused by social behaviors and interactions, heterogeneous data, and the limitations of current practices. Thus, design and development teams for SCH applications need to address issues ranging from technical and scientific knowledge to understanding users' behaviors, and clinical practices [6].

In the following subsections, user related barriers and challenges for the design and adoption of SCH applications will be detailed across all applications of information technologies in healthcare.

A. Real-Time Monitoring

Real-time monitoring in healthcare refers to sensing and monitoring devices (wearable and/or wireless) that allow vast amounts of patients' data to be collected, and transferred via secure computing networks in real time directly to medical health records. Data is available to be supervised by doctors and patients, permitting doctors to remotely monitor and advise patients. The automatic collection and reporting of the data is intended to trigger healthcare alarms when it is necessary and to reduce the cost and inconvenience of regular visits to the physician.

The potential benefits this technologies can provide to healthcare have been well acknowledged, and many studies have focused on the technical aspects of these applications, accounting for requirements such as: interoperability between systems, reliability of the sensors and robustness of the network, and security to keep the privacy of the collected data [7]. However, few studies have aimed to determine the extent users desire their functionalities [8].

An article from Steele et al. [9] reported a survey on concerns that might affect the acceptance of healthcare monitoring devices and networks by elderly people. The study reported six major themes, identified from the elderly participants' comments that are expected to serve as guidance to open communications channels between researchers regarding functionalities that users might consider as desirable, inadequate, or incomplete. The themes include (1) the need for a sense of independence, in relation to the possibility to remain at home for as long as possible, (2) impact on the quality of life, (3) user's personal preferences, (4) concerns associated to the technology implications such as cost, social and health impacts, privacy, systems reliability, (5) design preferences regarding sensor implementation (wearable sensors, ambient monitoring and embedded sensors); and (6) external factors such as type of care that the particular elderly individual is receiving, and the elderly person's housing situation.

The design and development of SCH applications should transcend beyond the technicalities and involve the users perspectives to address the multiple levels of concerns that come not only from the users directly interacting with the devices, but also from other user such as healthcare professionals, and also caregivers.

B. Telemedicine

Telemedicine is the delivery of clinical medicine through electronic communication systems including internet (and phone as a more traditional channel). The purpose of telemedicine is to provide cost effective yet convenient healthcare services that transcends the geographical boundaries. It covers wide range of services from consulting to examinations to even remote medical procedures.

As the technological advancements continue to provide more delivery channels, the automatic delivery tools are becoming increasingly more accessible at home and anywhere else using devices like mobile handhelds and tablets for patients to interact with providers from anywhere.

Although telemedicine technology has started out over forty years ago[10] there are still barriers in complete utilization of this major invested technology.

A large number of studies suggest knowledge barriers to be one of the main factors inhibiting the diffusion of telemedicine solutions[11]. It's argued that telemedicine success is not only dependent on creating new knowledge but also its adoption among all stakeholders involved. Like any other technology, for telemedicine to be accepted and actually used it must be perceived as useful and easy to use[12]. These perceptions can be formed by involvement of clinicians and users during the design of the solution. An example of this effort is PURR (Prescription Software for Use in Recovery and Rehabilitation using Microsoft Kinect) for patients following serious brain injury or stroke to rehabilitate them. Richard case is overhauling the development of this ludic engagement product as the result of users' and healthcare providers' feedbacks who found the first release hard to use[13].

Some other studies highlight cognitive and usability issues as the main barriers in the use of telemedicine. This is particularly acute in the case of seniors. As healthcare information is one of the main reasons for seniors to access internet[14], and if there are enough understandings of their cognitive capabilities and usability needs during the design (as well as development of tutorial and training programs for that matter) the system will be successful since there is strong motivation for use[15].

Telemedicine provides a great cost effective healthcare solution to widest range of demographics from children[16] to elderly[17] and various applications. This application diversity introduces extraneous usability challenges that make it imperative to study and incorporate users needs prior to the design of any telemedicine solution. It's not surprising that the American Telemedicine Association has started to introduce the concept of user centered design in its courses on Human Factors in TeleHeath[18].

C. Personalized Medicine

Personalized Medicine is a branch of smart and connected health that facilitates customized healthcare treatments specific to the patients needs. It includes a variety of tools involving machine learning and predictive modeling that study medical data to recognize patterns and find causal relationship that can result in more tailored and improved medical discovery that innovates better and more precise treatments[1].

Studies point out some major barriers in successful implementation and adoption of personalized medicine to be as: 1) Blockbuster model of the pharmaceutical industry that is resisting the transformation to the more personalized. 2) Lack of regulation and enforcement of the practice of personalized medicine. (e.g. Policies incorporating the biomarker and other diagnosis tests into drug regulation) 3) Dysfunctional payment system that reward per activity as opposed to performance. 4) Physician's habit continuing the traditional trial and error practice of prescribing medicine.

While most of these issues are unrelated to the users of the personalized medicine technologies, one important and related factor inhibiting the success of this technology is physician's habit to continuing with the traditional trial and error practice of prescribing medicine[19]. Researches in patients' behavior also indicate their interest in receiving and trying a medicine as an outcome of their time and money invested to visit the doctor[20].

While Molecular Medicine (MM) (one of personalized medicine technology) has gained widespread support, unless there will be changes implemented in the current financial and delivery of healthcare as well as physician behavior and consumers acceptance, it will not be widely used. Researchers and developers should **participate** actively in every stage of the MM technology development for its success is dependent on the acceptance and actual usage[21][12].

D. Clinical Decision Support Systems (CDSS)

CDSS support patient care by providing computerized and specialized decision making algorithms that use patient data to generate specific advice regarding their diagnostics and treatment. Health care professionals, patients themselves or others concerned about them can improve their healthcare decisions quality by using decision aids. CDSS can provide guidance through broad options for treatment, and help to prevent diagnostic errors [22]. Studies suggest that there are many barriers to the implementation and adoption of these systems [23], [24]. According to Liu et al. these failures are caused by insufficient clinical and patient involvement[25].

Liu [25] and Jeng [26] argue that the design and development of many existing CDSS has been mainly technology-driven with little relevance to the 'real world', and in some cases without confirming whether a clinical need exist. Studies about the implementations of CDSS report that the barriers are manifold such as: physicians concerns about negative impact on clinical workflow, and the need for work duplication during the transition from a systems to another [23]. Moreover factors such as lack of consideration of organizational factors, insufficient communication with and between users [12]-[27], lack of integration with best available knowledge and disconnection to high quality clinical data [25] harm successful implantation of CDSS.

Successfully adopted CDSS have proven to follow the trends like being completely understood by clinicians, supported by the prevailing clinical culture as well as by patients and peer groups, being fast, and able to interoperate with electronic patient records [25]. In addition, Stacey et al. [24] found that healthcare professionals have positive attitude towards the use of the CDSS when they were aware the system did not take too much effort from them and it was easy to learn.

E. Computer-Aided Surgery

Computer aided surgery encompasses applications where computer and robotic technology are used to develop devices that make surgery more accurate and potentially less invasive. For example, a surgical robot is a self-powered, computer-controlled manipulator that can be programmed to aid in positioning and manipulating surgical instruments. Robotic-assisted surgical techniques can enable surgeons to carry out more complex tasks.

Athanasiou et al. argue that despite the benefits robotic technology can bring to current surgery practices (greater dexterity and accuracy, tremor elimination, scalable motions, and improved patient outcomes), the adoption of this technology is not as extensive as initially anticipated due to some negative drivers and constraints[28]. There are some barriers that are associated with organizational factors, specially related to the high upfront cost necessary to acquire the technology. But from the users' perspective, Athanasiou et al. identified the demanding learning curve surgeons have to undergo to achieve clinical proficiency, as one of the main barriers for this technology adoption. Coping with new devices, adapting new kinds of instrumentation, and learning new operative maneuvers may imply that surgeons have to interrupt their practice to attend seminars, and training sessions.

In addition, some surgeons believe traditional practices are sufficient to treat their patients, thus the clinical results of computer aided surgery should be comparable to current results reported from more conventional techniques and standard practice. A study of barriers to the adopting of robotic-assisted surgery by BenMessaoud et al. highlighted conflicts between current practices and the procedures required when using robots in surgery during an operation. For example, surgeons were accustomed to feeling the organs and the amount of pressure being applied to an organ during an operation. However, that tactile feedback is lost with robotic technology. Hence, for the design and development of this technology, it is necessary to provide users with a feedback than can be similar in a way to what the users are already used to[29].

Finally, there is a lack of people who know about both healthcare and robotics, thus the development of successful computer aided surgery applications requires individuals with a mixture of skills such as clinical and technical knowledge and leadership to implement novel techniques and scientific models of innovative healthcare practice[30].

F. Population-Based Care & Ubiquitous Computing

Population Based Care is identified as systems that are aimed to provide cost effective health services to all people. These are including affordable monitoring devices that enables easy collection of wide range of data from large population minimizing the administrative as well as research costs[6].

As population based care encompasses the capability of providing healthcare to a large populations it is imperative that it can provide care for individual patients in the context of the culture[31]. The applications include services that promote health, assist in disease prevention and provide general public health care.

Ubiquitous Computing is the advanced technology allowing the patient data to be securely and confidentially stored, transferred and accessed from anywhere. Using the cloud storage and secure channels, pervasive computing allows patients, their family and the professional care providers to conveniently access patients information anytime anywhere.

While population based care is a different application as ubiquitous computing, (one involves monitoring devices with automatic data collection capabilities versus the other focusing on secure and confidential data accessibility from a virtual source), they both involve large group of users beyond demographic and geographical limits. In either case, there is the need for the technology to fit with normal user life style. Market everyday observes a better, more practical and easier to use Activity Tracker[32]. As Sonny Vu, the CEO of Misfit Wearable reveals it was through studying how people are using their activity tracker that they noticed the main use, and designed Shine to best deliver that[33].

Studies suggest that adoption of ubiquitous computing imposes different challenges from technical to social and organizational ones[34]. Unless those social and organizational barriers are studied and carefully addressed, the shift to ubiquitous computing will face uncertainty. Also the challenges imposed by Ubiquitous computing with respect to data security and privacy has a root in social values that unless is being resolved in the design of those products they will not become successful[34].

When it comes to elderly, the key obstacle to the diffusion of pervasive computing is the users cognitive decline limiting their usability of the systems. This barrier makes it imperative to reconsider the assumptions as well as requirements for the overall design and specification of ubiquitous computing solutions[36].

G. Web-based tools/ Health 2.0

Health 2.0 is the use of specific set of web applications to allow patients and healthcare professionals to virtually interact and generate content regarding experiences, symptoms and treatments.

Many applications for health 2.0 have been developed combining healthcare trends and consumer demands, including social networks, health content aggregators, medical and wellness applications, and tools to enable health-related searches [37].

The readiness of the supporting technology, and their users familiarity has driven multiple users to engage and interact with these applications. However, Gibbons state the existence of disparities in the adoption and utilization of various forms of health IT among different user communities (including different types of users and different demographic considerations), for example, young tech savvy users are more willing to adopt health 2.0 applications than other users that might have to go through demanding learning curves in order to perceive a benefit from using the system[38]. According to Jimison's et al. research, it is clear that the users' perception of benefits, convenience, and integration into daily activities facilitates the successful use of the interactive technologies for the elderly, chronically ill, and underserved[39].

At the same time, health care professionals and their organizations find challenges in adopting some Health 2.0 applications when there is no clarity about the value they would yield [40], negative impact on clinical workflows and the absence of technical assistance for office staff and physicians have also been found to negatively impact physician adoption rates of these applications [41].

The design and development of inclusive health care opportunities must aim to integrate several perspectives; the provider and healthcare system perspective, the perspective of patients, families, and caregivers; and the setting environment (hospital/clinic, home/community, or safety-net organization) in which the technology is used.

H. Automated care, assisted living robotics and mobile devices

Due to the recent increase and emphasis in the development of various solutions for assisted living, smart homes and other automated care, this paper dedicated a section for this category in addition to the categories acknowledge by CCC [4]. Systems for assisted living are aimed to help the elderly and people with disability live more independently by supporting their care in two main ways: (1) to assist the patients and/or their caregivers in daily activities such as eating, bathing, toileting, getting dressed and mobility; (2) to help monitor and assess their behavior and health [42].

Studies investigating barriers and challenges for the adoption of assisted living technologies specially by the elderly claim the importance of understanding the moral and ethical implications of these technologies, as well as the complete consideration of the users physical and emotional needs and their interactions with the environment and other people [42]. Ballegaard et al. argue that when designing for assisted living there is a need to seriously take into account the qualities of the end users' domestic setting in both design and deployment, and that social as well as clinical aspects must be considered[43]. The results of their research showed that the physical qualities of certain equipment might be in conflict with how people want to present themselves and their homes, which might negatively impact the technology acceptance. The design of assisted living technologies requires the customization of the technology to different users' lifestyle needs and different settings or environment, such as home and community, in the sense of appearance and in the sense of social aspects.

The above identified barriers for the adoption and implementation of SCH applications enable an evidence-based approach to the design, development, and deployment of appropriate tools and product or service solutions for SCH. They also serve as guidelines to facilitate targeted, tailored, and user-centered approaches to the development of SCH application, and the evaluation of the outcomes.

III. USER CENTERED DESIGN (UCD)

In an interview with Wired magazine about designing global health, when Melinda Gates[44] was asked what innovation is changing the most lives in the developing world, she answered: "*Human-centered design..*"[45]. Bessant et.al argue that a potentially valuable toolkit can be found in the field of design human methods[5]. By their nature, design tools are used to help articulate needs and give them shape and form; as such they are critical to the "front end" of any innovation process. UCD encompasses several methodologies aiming to involve users' perspectives right from the beginning and through the whole product cycle. UCD methods allow gaining deeper insights into users' needs, desires, values and behaviors.

The conducted studies make it evident that UCD methods can be instrumental in development of SCH products and solutions as they help to understand different drivers such as users' needs and preferences, organizational challenges, knowledge, expectations and attitude.

A. Lead User Method

The lead user method calls for the identification of users who face needs that have not yet being recognized by the bulk of the market. According to von Hippel lead users differ from ordinary users with respect to two characteristics: First, lead users experience new needs of the market and do so significantly earlier than the majority of the customers in market segment. Second, lead Users benefit strongly from innovations that provide a solution to those needs[46]. Because no products existing in the market are yet able to fulfill their sophisticated needs, lead users may develop initial product concepts that satisfy their requirements in an acceptable way. The greater the benefit the users can obtain from fulfilling these needs, the greater will be their effort to develop a solution. Then, lead users are possibly able to develop solutions for radical innovations.

To identify a valuable sample of lead users, R&D teams need to have a deep understanding of the market and technical trends in the applied field. Lead users, as defined by von Hippel, can be found within and beyond a specific target market, because users of different markets may face similar problems in more extreme forms. The lead user method collects information about extreme needs and solutions from users at the leading edge of the selected trends, but also from users in other markets who experience more extreme situations on a trend relevant to a target market [47]. Additionally, Lead users are not exclusively the ones that provide ideas or concepts for entire products, but also the ones that could deliver insights regarding features or attributes of a product given specific needs derived from a particular application of the product. The evidence of products modified by users serves as a proxy measure to identify lead users and their "high expected benefits"[48].

Companies or organizations looking for innovative ideas can invite identified lead users to join R&D personnel in the product development process. Lead users engage with the product development team in problem identification and solution sessions. The outcomes of these sessions are product concepts that respond to the lead user needs, the manufacturers concern of technical feasibility, and market appeal. To evaluate the commercial appeal of the concepts derived from the lead user method, concepts are tested against a population of more traditional or mainstream users.

Empirical studies reveal that lead users indeed exist in several industries and that they are able to develop novel solutions which lead to the 'next generation products'[47], [48]. Ideas generated from lead user methods have been found to have significantly higher novelty, and address more original newer customer needs, contributing to radical innovation or major product breakthrough. Those ideas often go beyond the technical aspects and may involve related channels and business model changes that may help to diffuse the innovation rapidly. Lead users are found to be early adopters and important contributors to the early diffusion of products[48]. In addition, applications of the lead user method have suggested using this method, ideas can be derived much faster and less costly than with other traditional methods[49].

Critics of lead user method warn organizations and R&D teams against over-emphasizing the findings from a small number of users and developing over-customized product that will interest only a few group of users[50]. Since lead users experience specific needs prior to the rest of the market, the actual size of the market and its nature as well as risks involved are often not clear for organizations [51].

Numerous successful innovations have been generated from the lead user method in development of "breakthrough" new products in healthcare, such as surgical drapes [52], surgical hygiene products [53], X-ray systems, and new biocompatible implants [54].

B. Ethnography

Adopted from social science techniques, Ethnography is an effective research method to learn and understand user perspectives in the early stages of new product development. As the research is based on careful observation of (often) potential users, it provides a great opportunity to understand culture and context as a basis to identify needs and problems that can lead to innovation. Ethnography taps into the underlying drivers that form one's preferences by studying the customer in relation to her/his environment. Ethnography may result in discoveries and insights well beyond what original inquiries aimed for.

In design-oriented ethnographic studies, number of participants is usually smaller than that of other user center designs. However, to confirm the finding and the theories formed more traditional market research can be supplemented [55]. Careful selection and training of the ethnographers team is key in a successful study as the quality of insights obtained are dependent in the competence and the intuition of the observers.

During the study, flexibility is important as the observation may take the observer to a totally new discovery that wasn't originally planned for, yet the new discoveries may provide much more valuable insights or a new direction unknown originally into the customer needs and problems. Ethnography studies often involves: 1) identification of the objectives for the study, analysis and reporting, 2) specification of the most appropriate approaches for the study (e.g. direct observation vs. discrete), 3) selection and recruitment of the appropriate respondents for the study (e.g. for product enhancement only need to focus on a sample of current consumers often less than 25), 4) definition of the boundary inquiry (the specific issue being investigated), 5) collection of information by conducting the study(often involved open interviews with shared control for a complete discovery and understandings), 6) analysis of information and presentation of the findings (presentation may include auditory evidences for proving points).

One caveat to this method is its potential high cost depending on the depth of study. However literature provides many cases of great success that more than justified the investments[55]. As Rein [56] stated: "Being able to effectively integrate ethnographies into the innovation process could prove as fundamental to future innovation success as more traditional quests for synergy between marketing and research and development."

In 1999, Intel in its quest to explore technologies to help people reach a higher quality of healthcare chose ethnographic studies. Intel's research aimed to understand the needs of both the healthcare providers in the clinical settings as well as elderlies struggling with cognitive decline [57]. Through this Ethnographic research, Intel was able to identify challenges encountered by cognitively impaired elderly and their informal care network inhibiting the full usage of ubiquitous computing[36].

When studying to overcome the barriers to early detection with pervasive computing, It was through ethnographic study that the partnership of Intel and MIT recognized the importance of the integration of solutions to promote their adoption. Utilizing this study, Morris et. al. concluded that the monitoring systems are more likely to be adopted if they are integrated with preventive and compensatory health application such that the overall system can offer services beyond assessment[58].

C. Empathic Design

Since Harvard's Dorothy Leonard as an innovation theory shaped it first, empathic design is promoted as a highly qualitative design method for the discovery of real behavior in the field as opposed to assumptions drawn from the survey research questions[59].

Empathic design techniques contribute to the flow of ideas for further investigation and consideration. It opens a window into consumers' behavior and feeling, providing a unique body of data that wouldn't be available otherwise. This set of data enables researchers to observe existing problems or potential opportunities for innovation that otherwise couldn't be easily articulated with words or discovered in laboratories. There has been numerous cases where empathic design has shed light to product issues or signaled innovating products needed by customer that were unknown otherwise. Although empathic design is not meant to replace the traditional market research, it provides insight not obtainable by other market research that is based on inquiry.

The observation attribute of this method allows collection of the information that couldn't be gathered through inquiry. This is mainly due to various constraints involved in the inquiring process. Some of the issues are due to the fact that consumers are often not able to articulate their preference or behavior reliably. This in particular applies when these behaviors are based on the feelings about the intangible characteristics of the products or services they are using. They are often not even aware of those feelings and unless they are being observed during the process of consumption, this information can't be discovered.

The other type of challenges in discovering innovative ideas through inquiry methods are sourced on the fact that people's perception of their needs are biased and driven by their experience. They accept the surrounding deficiencies normal as they get used to them. They are also unable to ask for something if they don't know it's technologically feasible[60].

Some of the issues arise in the inquiry methods are related to the very nature of questioning process. Questions often reflect conscious or unconscious assumptions of the inquirers. They also often disrupt the natural flow of the consumption activity and it limits the responses to only specific answers to the questions asked. These questions tend to drive the answer toward the direction inquirers give. As the observation base nature of empathic design allows, these concerns are addressed which makes this methodology a great way to spark innovative ideas for concept generation in new product development process. Steps to conduct empathic design generally contain: 1) specifying the group of customers, non customers, end user, etc. for the study, 2) selecting a group of observers consist of diverse set of expertise in different disciplines, 3) observe in the real life atmosphere (or as close as possible to it), 4) capture the observed data (preferably in visual form for its capacity to store vast subtle information that can't be easily articulated), 5) reflect and analyze the captured data to identify all of the customers' potential needs and issues, 6) brainstorm on the analysis to transform the observation into visually identifying potential solutions, 7) develop prototypes of potential solutions and use them to clarify the concept and stimulate reaction among and communication with the potential customers[61].

The advantage of empathic design is that it promotes radical innovations, as the needs and not the specifications are derived from customers. Behavior observation allows the identification of those needs that can't be articulated. The disadvantage of empathic design is the vast amount of data gathered that often adversely affects idea generation process time.

McDonagh et. al. in the study of designing for, with and by people with disabilities, argue that as the user expectation of products grows there is an increasing need for more balanced approach to functionality. And given that, the design should no longer be for the users, and rather it needs to be designing intimately with the users. This design approach will guarantee the generation of a more natural and intuitive solution[62].

It was only through empathic design that Hewlett-Packard's developer observed the, neither articulated nor complained, interruptions that surgeons were experiencing during the surgery. The observation of the issue of visual interruption sparked the invention of lightweight helmet that could suspend the images a few inches in front the surgeon. The designer, knowing the technology and understanding of the need, was able to develop a substantially improved product[18].

Taylor et. al. used empathic approach to study the effects of variations among ethnic minority consumers of healthcare to identify the barriers in the adoption of healthcare related solutions. They divided the consumers into subgroups based on their religion and generations for the study. Empathic study resulted in identifying a first generation subgroup having difficulties in the adoption of services particularly healthcare solutions which led to another study in the effort of lowering those barriers in the design of healthcare solutions[63].

D. Participatory Design (or co-design)

Participatory design/co-design (PD) explores user active involvement in the design and introduction of products and services. Developing team looks for opportunities to involve users along all the stages of the developing process, based on the idea that skills and experiences of users need to be present in the design of products. This will help with finding better fits between product and the way people want to perform their work. PD practiced at the early front end of the design development process can have positive, long-range consequences[64]. During the initial exploration and problem definition, co-designer users help define the problem and to focus ideas for solution, and during development, they help evaluate proposed solutions (such as prototypes).

PD has its roots in the 1970s in Scandinavia. In Norway, Sweden and Denmark the Collective Resource Approach was established to increase the value of industrial production by engaging workers in the development of new systems for the workplace. The approach put together the expertise of the systems designers/researchers that cooperated with people from trade unions[65]. In the PD approach, key stakeholders are invited to share experiences and challenges around specific issues and devise ideas and actions to address these issues, tapping into the available skills and resources to do so. As a result, PD creates ownership of the outcomes for key stakeholders who became part of the solution.

PD tools and techniques promote a practice where product developers are able to learn about users, and where users are able to take an active part in the product design. Several authors have proposed different methodologies and techniques for participatory process. Grønbæk et al. present an approach, Cooperative Experimental Systems Development (CESD) that is focused on active user involvement throughout the entire development process, matching prototyping experiments to work situations and use scenarios[66]. Kensing et al. developed the MUST method that provides guidelines for the design and implementation of computer-based systems, focusing on cooperation between users, managers, and IT personnel[67].

In general, PD brings advantages to new product development because innovative products generated from this approach can have a higher rate of usage and integration in the market, and less re-design, re-development and re-testing of the products rates. Despite the recognized potential benefits, several authors state that PD in product development face barriers because of the problem of identifying and getting access to key users [68], and the users' fundamental interest in participate [69].

PD has been applied for the creation of multiple applications for healthcare, because it allows diverse key stakeholders (e.g. patients, caregivers, healthcare professionals) to get involved in the ideation and creation of clinical/medical innovative solutions. For example, Participatory co-design has been used in development of assistive technology for people with dementia. These projects involved representatives from different groups from patients, caregivers, professionals working in the field, to engineering designers to generate product concepts that support the needs of dementia patients and their caregivers (from personal to professional ones). This involvement of different perspectives contributed to the creation of products that better fit the requirements and lifestyles of the subject population[70],[71].

Clemensen et al. present the experience in conducting participatory in developing a technological solution to support the treatment of patients at home. Health care professionals, engineers, patients and relatives brought diverse set of experience and insight that, as the author concluded, increased the likelihood of user acceptance in later stages of the product development[72].

Design of patient services [73], and development of health information systems [74], are some other successful implementations of participatory or co-design in the development of healthcare applications.

E. Contextual Design

Contextual Design (CD), first introduced by Wixon et al. [75] is a user centered approach with a structured methodology for investigating the users work environment and practices, for the purpose of designing solutions that will address the needs of those users. CD deals with the front end of product development, from identification and understanding who the users are to testing a specific solution for them. This methodology incorporates traditional ethnography approaches however, unlike traditional ethnography; it does not require extensive training [76]. CD is intended to go beyond simple verbal data collection, because user inquiries are obtained while observing the users performing their work, engaging them in uncovering unarticulated aspects of their work, and developing a shared understanding with the users about the aspects of work that matter.

This technique studies a few carefully selected individuals in depth to arrive at a fuller understanding of the work practice across a particular group of users. Field interviews with users regarding structure of their own practice are conducted to ensure that developing team captures the actual business practices and all daily activities of the people that will be interacting with the product, service or system. The developing team, aiming to capture key points and draw models representing the users' work practice, discusses results of the interviews. Data from individual users is consolidated to show a larger picture of the work of the target user population[77]. The key points from all the users are brought into an affinity diagram, a hierarchical representation of the issues labeled to reflect user needs.

Work models show the work of individuals and organizations in diagrams. The first model, flow model, depicts the coordination of work and flow of information. The cultural model describes the social behaviors, values, and relationships. The artifact model shows the existing products or applications that support work. The Physical model describes the physical environment that supports the work. The sequence model details the activities performed to accomplish a task.

Finally, all the data gathered serves as basis for deciding which needs are to be addressed that construct idea solutions. The outcomes of the method consist of product concepts and early prototypes validated by the interaction with the target users.

Contextual design aims at supporting the development of products in a timely and cost effective way; however product development teams implementing this method need to be aware that there is also no formal data-analysis in this method, and the overwhelming amount of data that needs to be analyzed may require great amount of resources (time, money and labor) that are very critical for organizations. Another criticism of CD is that the process may become “designer-centered” rather than “user-centered” as the designer is central to the process and may influence the development through pre-conceptualization. To limit the potential bias of this approach, users need to be invited to validate the data and models obtained from the observations.

Some successful applications of contextual design in the development of Healthcare solutions have been related to the design of information systems. Coble et al. used this technique to collect physician requirements for a comprehensive clinical information system, and indicated that this approach allowed them to obtain a more comprehensive analysis of the user needs, than the results obtained from traditional techniques such as surveys, questionnaires, and focus groups [78]. Thursky et al. also used CD for the design of an antibiotic decision support system. Their results showed that the process promoted user ownership of the system that resulted in immediate uptake and ongoing usage[79].

IV. DISCUSSION

Technological advancements and their proven benefits in healthcare industries create a great opportunity for SCH to revolutionize the future of healthcare. Despite this promising future, literature reveals a very high rate of SCH project failure. Close to 50% of Electronic Medical Record implementations fail, resulting in significant financial losses, skepticism and lost opportunities for improved patient care, Keshavjee et. al identified that negotiation and dialogue between different stakeholders and between stakeholders and technology is quite prominent[80]. Haslina Mohd et. al argued that the resistance and low level acceptance by healthcare providers are among the main factors of failure[81].

Moreover, studies by Massaro[82] and Keil et. al[83] reveal that failing healthcare implementations are due to the requirements simply assumed and not sourced by the actual users, and successful implementations are those that are broadly supported by their stakeholders. Thus, involving users in the development of SCH applications encompasses a variety of benefits that can contribute highly to the creation of potentially successful medical solutions. Accessing users' perspectives (e.g., user needs, knowledge, expectations, problems, experiences, attitudes, satisfaction, and rejection) can help in improving user interfaces, identifying deficiencies and potential problems of product concepts, and suggesting changes that expand the overall functionality, effectiveness, usability, design and quality of the solutions being developed. Additionally, users' insights at early stages of product development can help to reduce re-development cost when products do not meet customer expectations or needs[84].

Review of user centered design methods applications described above provides compelling case as to their effectiveness in the successfully incorporating user requirements into the new product design and development. Through the study of different categories of smart and connected health technologies recognized by NSF, this paper attempted to capture most of user related barriers to the successful diffusion of technology in the field of healthcare. The studies showed that the barriers to the success of these solutions could be very similar across different categories as they are related to the user and factors involved. These obstacles are mainly related to factors such as: having various users (healthcare professionals, patients, families, and caregivers) with different requirements, needs and perspectives; several social and cultural implications; perceptions of the technology; and the setting or environment (hospital/clinic, home/community, or safety-net organization) in which the technology is used and the care is delivered and/or received. The study proves that user involvement is an imperative in the successful design and development of new products or solutions in healthcare, and that user centered design benefits are evident for incorporating users' needs, behaviors, values, emotions, social and cultural factors, and the requirements in relations to the environments, current practices and settings.

Through the study of different user centered design methodologies, this paper highlights their characteristics and issues they address. Although the list of barriers obtained from this study might not be exhaustive, given the pattern observed, the issues found seem to be the most prominent ones. Based on these information gathered, here the paper recommends user centered design methodology(ies) best fit to resolve the barriers identified through the study. The table in the appendix provides a summary of the recommendations of user centered design methodologies based on the main categories of the barriers as described below.

Patients Demographics Diversity

For a healthcare solution that is providing service to users from different regions and demographics with divers set of skills and knowledge, the design should capture different requirements from articulated ones to those unarticulated pertaining to the environment and the context of the usage. For those needs both **empathic design** and **ethnography** can capture wealth of information as a result of observing different user groups in the environment where the solution is going to be used.

User Group Diversity (Healthcare professionals (HCP), patients & caregivers)

When different user groups interacting with the system for different functions and purpose the set of requirements could be very different. Systems such as electronic medical record are used for different purposes, such as by physicians for analysis of historical data and diagnosis; by nurses for data collection or work order access; by billing department for invoicing; and by patients and their family to access the record. For such systems with various users, **participatory design** allows involvement of diverse set of users and obtainment of all the requirements. This would not only help with capturing all the needs but also gives sense of ownership to those groups as a result of their involvement which often translate to easier adoption. **Empathic and contextual design** are also recommended for these environments as observation of the usage in the context of the environment can provide a great picture as to the needs of different groups that could be incorporated into the design.

Social & cultural implications

Often people's needs and behaviors are driven by their culture and social values they have grown up with. Also the environment they live in and their socioeconomic status can influence their behavior in relation to their surroundings. For a healthcare solution that can successfully deliver those needs, a complete understanding of the underlying social and cultural values required. **Ethnography** is the recommended approach as its observation-based method provides the opportunity for collection of all these subtle information and translation to the user requirements and opportunities for successful product concepts. Ethnography is particularly a beneficial method when the users are unable to articulate their needs and or their needs are different than those generally assumed in the market (E.g. elderly).

Users' practices & behaviors

As observed earlier, the usage is often not derived by the accuracy promised by the perfect technological solution but how similar those systems are to the existing operation. To incorporate those established medical and clinical practices or behaviors and needs, **participatory** or **contextual design** approaches are recommended. Also to capture more subtle needs derived by the behavior and habits, **empathic design** is recommended.

Environment & settings

When the concerns are related to settings and environments where the technology is being used (e.g. elderly living environment or rural daily activities) or to capturing the interactions with other people and artifacts, **contextual** and **empathic** design are proven to be instrumental.

Design preferences

Similar to when dealing with diverse group of users (whether different patients demographics or various group of users with different needs from physicians to nurses to patients) in cases when barrier to successful acceptance of smart and connected health solutions is involved with multiple design preferences, **participatory** Design and **contextual** Design are recommended.

Perceived values

Users' perception of usefulness, ease of use, accuracy, reliability and confidentiality can make or break the adoption of a SCH system. As Davis in his technology acceptance model suggests, users' perception of usefulness and ease of use directly influence their behavior and actual usage of the system[12]. For the users to perceive a SCH system as one that provides adequate values, it needs to ensure that it provides those values important to them. **Participatory design** and **contextual design** engage users in order to not only incorporate those values important to them but also ensure designing a solution that is perceived as useful and easy to use.

Cognitive, knowledge & learning curves

A major identified barrier in diffusion of pervasive computing (along with other SCH solutions) is cognitive decline (particularly among seniors and people with disability). Successful product development of smart and connected health requires reconsideration of the traditional market assumptions. In these cases, **ethnography** is a recommended approach for obtaining full understandings required to bridge the gap between users ability and needs, and designer's assumptions.

Also to be able to design solutions that require least technological knowledge and learning curves **empathic design** is recommended. This observation base method provides insights to the current practices that help product team to design a solution as close as possible to the current practices.

Technical expectations

When deep scientific knowledge is required for designing of smart and connected health systems, **lead user design** is recommended. The greater the lead users involved the greater the obtained benefits particularly when those solutions are radical innovations.

Organizational factors

As identified, various organizational factors can prevent a smart and connected health solution to disseminate. While these barriers are not all related to the users of the systems, but rather their stakeholders, **contextual** and **participatory** design provides opportunities to understand the whole environment and the needs of various players. These holistic understanding of the current processes and organizational drivers can lead to design of a solution that can satisfy those various stakeholders.

V. CONCLUSIONS AND IMPLICATIONS

Since the consumers of healthcare are more than ever becoming the locus of priority in today's world of healthcare, it is evident that unless the smart and connected health solutions are designed with the user being the center in its design, those solutions will be deemed to fail. This study identified that one of, if not the most important barrier inhibiting the diffusion of smart and connected health, is the adoption issue among its consumers. By studying many applications of SCH, it's apparent that the issue impeding the complete acceptance and employment of SCH applications are often their inability of obtaining acceptance by consumers. And this phenomenon was due to their inability to deliver the service in a way that users are willing or can actually use them. For this issue to be resolved, the needs, usability, capabilities and preferences should be studied at the core of how to deliver the healthcare service. It's not surprising that McDonagh et. al argue that one should no longer design for the users but rather design with them to ensure a more intuitive solution[62].

This paper highlights the imperative of user center design impact on the successful diffusion of any technological solutions for effective and efficient delivery of healthcare. Given that, the writers of this paper hope that the protagonists of healthcare to recognize the importance of utilizing user involvement in every stage of solution design from exploration and idea generation to concept design and usability study. Although user centered design approaches are costly with additional burden on the current pressed resources on health care, this study makes it evident that the investment is justified as it more than pays off for itself in the long run and ensures the successful acceptance and usage of the solution.

REFERENCES

[1] "CCC - Computing Community Consortium." [Online]. Available: http://www.cra.org/ccc/. [Accessed: 14-Nov-2013].

[2] "nsf.gov - National Science Foundation - US National Science Foundation (NSF)." [Online]. Available: http://www.nsf.gov/. [Accessed: 11-Dec-2013].

[3] "US NSF - About the National Science Foundation." [Online]. Available: http://www.nsf.gov/about/. [Accessed: 11-Dec-2013].

[4] Computing Community Consortium, "Smart health and wellbeing." [Online]. Available: http://www.cra.org/ccc/files/docs/Natl_Priorities/web_health_spring.pdf. [Accessed: 10-Nov-2013].

[5] J. Bessant and L. Maher, "DEVELOPING RADICAL SERVICE INNOVATIONS IN HEALTHCARE — THE ROLE OF DESIGN METHODS," *Int. J. Innov. Manag.*, vol. 13, no. 04, pp. 555–568, Dec. 2009.

[6] National Science Foundation, "Smart and Connected Health (SCH)." [Online]. Available: http://www.nsf.gov/pubs/2013/nsf13543/nsf13543.htm. [Accessed: 15-Nov-2013].

[7] J. A. Stankovic, Q. Cao, T. Doan, L. Fang, Z. He, R. Kiran, S. Lin, S. Son, R. Stoleru, and A. Wood, "Wireless sensor networks for in-home healthcare: Potential and challenges," in *High confidence medical device software and systems (HCMDSS) workshop*, 2005, pp. 2–3.

[8] R. Steele, C. Secombe, and W. Brookes, "Using wireless sensor networks for aged care: the patient's perspective," in *Pervasive Health Conference and Workshops, 2006*, 2006, pp. 1–10.

[9] R. Steele, A. Lo, C. Secombe, and Y. K. Wong, "Elderly persons' perception and acceptance of using wireless sensor networks to assist healthcare," *Int. J. Med. Inf.*, vol. 78, no. 12, pp. 788–801, Dec. 2009.

[10] "What is Telemedicine." [Online]. Available: http://www.americantelemed.org/learn/what-is-telemedicine. [Accessed: 11-Dec-2013].

[11] H. Tanriverdi and C. S. Iacono, "Knowledge Barriers to Diffusion of Telemedicine," in *Proceedings of the International Conference on Information Systems*, Atlanta, GA, USA, 1998, pp. 39–50.

[12] F. D. Davis, "Perceived Usefulness, Perceived Ease of Use, and User Acceptance of Information Technology," *MIS Q.*, vol. 13, no. 3, p. 319, Sep. 1989.

[13] S. Simmons, R. McCrindle, M. Sperrin, and A. Smith, "Prescription software for recovery and rehabilitation using Microsoft Kinect," presented at the 2013 7th International Conference on Pervasive Computing Technologies for Healthcare (PervasiveHealth), 2013, pp. 323–326.

[14] B. W. Hesse, D. E. Nelson, G. L. Kreps, R. T. Croyle, N. K. Arora, B. K. Rimer, and K. Viswanath, "Trust and sources of health information: the impact of the Internet and its implications for health care providers: findings from the first Health Information National Trends Survey," *Arch. Intern. Med.*, vol. 165, no. 22, p. 2618, 2005.

[15] D. R. Kaufman, J. Starren, V. L. Patel, P. C. Morin, C. Hilliman, J. Pevzner, R. S. Weinstock, R. Goland, and S. Shea, "A Cognitive Framework for Understanding Barriers to the Productive Use of a Diabetes Home Telemedicine System," *AMIA. Annu. Symp. Proc.*, vol. 2003, pp. 356–360, 2003.

[16] J. P. Marcin, J. Ellis, R. Mawis, E. Nagrampa, T. S. Nesbitt, and R. J. Dimand, "Using Telemedicine to Provide Pediatric Subspecialty Care to Children With Special Health Care Needs in an Underserved Rural Community," *Pediatrics*, vol. 113, no. 1, pp. 1–6, Jan. 2004.

[17] C. C. S. Lindberg, "Implementation of In-home Telemedicine in Rural Kansas Answering an Elderly Patient's Needs," *J. Am. Med. Inform. Assoc.*, vol. 4, no. 1, pp. 14–17, Jan. 1997.

[18] "American Telemedicine Association." [Online]. Available: http://www.americantelemed.org/home. [Accessed: 11-Dec-2013].

[19] M. G. Aspinall and R. G. Hamermesh, "Realizing the promise of personalized medicine," *Harv. Bus. Rev.*, vol. 85, no. 10, p. 108, 2007.

[20] N. Ashraf and N. Kindred, *Uptake of Malaria Rapid Diagnostic Tests*. 2011.

[21] P. A. Deverka, T. Doksum, and R. J. Carlson, "Integrating molecular medicine into the US health-care system: opportunities, barriers, and policy challenges," *Clin. Pharmacol. Ther.*, vol. 82, no. 4, pp. 427–434, 2007.

[22] Newman-Toker, David E and P. J. Pronovost, "Diagnostic errors—the next frontier for patient safety," *JAMA J. Am. Med. Assoc.*, vol. 301, no. 1, pp. 1060–1062, 2009.

[23] M. H. Trivedi, E. J. Daly, J. K. Kern, B. D. Grannemann, P. Sunderajan, and C. A. Claassen, "Barriers to implementation of a computerized decision support system for depression: an observational report on lessons learned in 'real world' clinical settings," *BMC Med. Inform. Decis. Mak.*, vol. 9, no. 1, p. 6, 2009.

[24] Stacey, Dawn, M.-P. Pomey, A. M. O'Connor, and I. D. Graham, "Adoption and sustainability of decision support for patients facing health decisions: an implementation case study in nursing," *Implement. Sci.*, vol. 1, no. 1, p. 17, 2006.

[25] J. Liu, J. C. Wyatt, and D. G. Altman, "Decision tools in health care: focus on the problem, not the solution," *BMC Med. Inform. Decis. Mak.*, vol. 6, no. 1, p. 4, 2006.

[26] D. J.-F. Jeng and G.-H. Tzeng, "Social influence on the use of Clinical Decision Support Systems: Revisiting the Unified Theory of Acceptance and Use of Technology by the fuzzy DEMATEL technique," *Comput. Ind. Eng.*, vol. 62, no. 3, pp. 819–828, Apr. 2012.

[27] Castillo, Víctor H, A. I. Martínez-García, and J. R. G. Pulido, "A knowledge-based taxonomy of critical factors for adopting electronic health record systems by physicians: a systematic literature review," *BMC Med. Inform. Decis. Mak.*, vol. 10, no. 1, p. 60, 2010.

[28] T. Athanasiou, H. Ashrafian, S. P. Rowland, and R. Casula, "Robotic cardiac surgery: advanced minimally invasive technology hindered by barriers to adoption," *Future Cardiol.*, vol. 7, no. 4, pp. 511–522, 2011.

[29] C. BenMessaoud, H. Kharrazi, and K. F. MacDorman, "Facilitators and barriers to adopting robotic-assisted surgery: contextualizing the unified theory of acceptance and use of technology," *PloS One*, vol. 6, no. 1, 2011.

[30] C. Y. C. Chang, M. Díaz, and C. Angulo, "The Impact of Introducing Therapeutic Robots in Hospital's Organization ," *Ambient Assist. Living Home Care*, pp. 312–315, 2012.

[31] R. Halpern and P. Boulter, "Population-based health care: definitions and applications," *Tufts Manag. Care Inst. Novemb.*, 2000.

[32] G. R. Skinner and M. G. Lehman, "Time and activity tracker," 662211616-Sep-2003.

[33] "Misfit Shine: an elegant, wireless activity tracker | Indiegogo." [Online]. Available: http://www.indiegogo.com/projects/misfit-shine-an-elegant-wireless-activity-tracker. [Accessed: 12-Dec-2013].

[34] K. Lyytinen and Y. Yoo, "Ubiquitous computing," *Commun. ACM*, vol. 45, no. 12, p. 63, 2002.

[35] H. Löhr, A.-R. Sadeghi, and M. Winandy, "Securing the e-Health Cloud," in *Proceedings of the 1st ACM International Health Informatics Symposium*, New York, NY, USA, 2010, pp. 220–229.

[36] M. Morris, J. Lundell, E. Dishman, and B. Needham, "New perspectives on ubiquitous computing from ethnographic study of elders with cognitive decline," in *UbiComp 2003: Ubiquitous Computing*, 2003, pp. 227–242.

[37] B. Hughes, I. Joshi, and J. Wareham, "Health 2.0 and Medicine 2.0: tensions and controversies in the field," *J. Med. Internet Res.*, vol. 10, no. 3, 2008.

[38] M. C. Gibbons, "Use of health information technology among racial and ethnic underserved communities.," *Perspect. Health Inf. Manag. Am. Health Inf. Manag. Assoc.*, vol. 8, no. Winter, 2011.

[39] H. Jimison, P. Gorman, S. Woods, P. Nygren, M. Walker, S. Norris, and W. Hersh, "Barriers and Drivers of Health Information Technology Use for the Elderly, Chronically Ill, and Underserved.," 2008.

[40] J. Sharp, "Social media in health care: barriers and future trends," *iHealthbeat*, May-2010. [Online]. Available: http://www.ihealthbeat.org/perspectives/2010/social-media-in-health-care-barriers-and-future-trends.

[41] E. Ammenwerth, C. Iller, and C. Mahler, "IT-adoption and the interaction of task, technology and individuals: a fit framework and a case study," *BMC Med. Inform. Decis. Mak.*, vol. 6, no. 1, p. 3, 2006.

[42] A. Sharkey and N. Sharkey, "Granny and the robots: ethical issues in robot care for the elderly," *Ethics Inf. Technol.*, vol. 14, no. 1, pp. 27–40, Jul. 2010.

[43] S. A. Ballegaard, J. Bunde-Pedersen, and J. E. Bardram, "Where to, Roberta?: reflecting on the role of technology in assisted living," in *Proceedings of the 4th Nordic conference on Human-computer interaction: changing roles*, 2006.

[44] "Bill & Melinda Gates Foundation." [Online]. Available: http://www.gatesfoundation.org/. [Accessed: 10-Dec-2013].

[45] "The Human Element: Melinda Gates and Paul Farmer on Designing Global Health - Wired Science." [Online]. Available: http://www.wired.com/wiredscience/2013/11/2112gatefarmers/?mbid=synd_gfdn_bgfb. [Accessed: 10-Dec-2013].

[46] E. von Hippel,, "Lead users: a source of novel product concepts," *Manag. Sci.*, vol. 32, no. 7, pp. 791–805, 1986.

[47] G. L. Lilien, P. D. Morrison, K. Searls, M. Sonnack, and E. Von Hippel, "Performance Assessment of the Lead User Idea-Generation Process for New Product Development," *Manag. Sci.*, vol. 48, no. 8, pp. 1042–1059, 2002.

[48] G. L. Urban, "Urban, G.L., von Hippel, E., 1988. Lead user analyses for the development of new industrial products. Management Science 34 (5), 569–582," *Manag. Sci.*, vol. 34, no. 5, pp. 569–582, 1988.

[49] C. Herstatt and E. von Hippel,, "From Experience: Developing New Product Concepts via the Lead User Method: A Case Study in a 'Low-Tech' Field," *J. Prod. Innov. Manag.*, vol. 9, pp. 213–221.

[50] J. Stewart and R. Williams, "The Wrong Trousers? Beyond the Design Fallacy: Social Learning and the User," *User Involv. Innov. Process. Strateg. Limit. Socio-Tech. Perspect.*, pp. 195–221, 2005.

[51] P. D. Morrison, J. H. Roberts, and D. F. Midgley, "The nature of lead users and measurement of leading edge status," *Res. Policy*, vol. 33, no. 2, pp. 351–362, Mar. 2004.

[52] E. Von Hippel, S. Thomke, and M. Sonnack, "Creating breakthroughs at 3M," *Harv Bus Rev*, pp. 47–57, 1999.

[53] C. Luthje, "Customers as co-inventors: An empirical analysis of the antecedents of customer-driven innovations in the field of medical equipment.," presented at the 32nd European Marketing Academy Conference (EMAC), Glasgow, UK, 2003.

[54] C. Lettl and H. G. Gemünden, "The entrepreneurial role of innovative users," *J. Bus. Ind. Mark. - 346*, vol. 20, no. 7, pp. 339–346, 2005.

[55] S. R. Rosenthal and M. Capper, "Ethnographies in the Front End: Designing for Enhanced Customer Experiences*," *J. Prod. Innov. Manag.*, vol. 23, no. 3, pp. 215–237, May 2006.

[56] G. L. Rein, "FROM EXPERIENCE: Creating Synergy between Marketing and Research and Development*.," *J. Prod. Innov. Manag.*, vol. 21, no. 1, pp. 33–43, 2004.

[57] Intel, "Intel's Approach to innovation and healthcare." 06-Jun-2007.

[58] M. Morris, S. S. Intille, and J. S. Beaudin, “Embedded assessment: Overcoming barriers to early detection with pervasive computing,” in *Pervasive Computing*, Springer, 2005, pp. 333–346.

[59] P. H. Jones and I. H. ExPERIENCE, “Design for care,” *Innov. Healthc. Exp. Rosenfeld Media Brooklyn*, 2013.

[60] D. Leonard and J. F. Rayport, “Spark innovation through empathic design,” *Harv. Bus. Rev.*, vol. 75, pp. 102–115, 1997.

[61] G. Robert, *Bringing User Experience to Healthcare Improvement: The Concepts, Methods and Practices of Experience-based Design*. Radcliffe Publishing, 2007.

[62] D. McDonagh, J. Thomas, L. Khuri, S. H. Sears, and F. Peña-Mora, “Empathic Design Research Strategies: Designing For, With and By People with Disabilities.”

[63] S. P. Taylor, C. A. Nicolle, and M. Maguire, “Culture and context: an empathic study of the needs of ethnic consumers in the UK,” 2011.

[64] E. B.-N. Sanders and P. J. Stappers, “Co-creation and the new landscapes of design,” *CoDesign*, vol. 4, no. 1, pp. 5–18, Mar. 2008.

[65] S. Bødker, “Creating conditions for participation: Conflicts and resources in systems development,” *Hum.-Comput. Interact.*, vol. 11, no. 3, pp. 215–236, 1996.

[66] K. Grønbæk, M. Kyng, and P. Mogensen, “Toward a Cooperative Experimental System Development Approach.,” *Comput. Des. Context*, pp. 201–238, 1997.

[67] F. Kensing and J. Blomberg, “Participatory design: Issues and concerns,” *Comput. Support. Coop. Work CSCW*, vol. 7, no. 3–4, pp. 167–185, 1998.

[68] J. Grudin, “Obstacles to participatory design in large product development organizations.,” *Particip. Des. Princ. Pract.*, pp. 99–119, 1993.

[69] P. Kraft and J. Bansler, “The collective resource approach: the Scandinavian experience." 6 (1994): 71-71.,” *Scand. J. Inf. Syst.*, vol. 6, no. 1, pp. 71–84, 1994.

[70] R. Orpwood, “User Involvement in Dementia Product Development,” *Dementia*, vol. 3, no. 3, pp. 263–279, Oct. 2004.

[71] L. Tan and D. Szebeko, “Co-designing for dementia: The Alzheimer 100 project,” *Australas. Med. J.*, pp. 185–198, Nov. 2008.

[72] J. Clemensen, S. B. Larsen, M. Kyng, and M. Kirkevold, “Participatory Design in Health Sciences: Using Cooperative Experimental Methods in Developing Health Services and Computer Technology,” *Qual. Health Res.*, vol. 17, no. 1, pp. 122–130, Jan. 2007.

[73] P. Bate and G. Robert, “Experience-based design: from redesigning the system around the patient to co-designing services with the patient,” *Qual. Saf. Health Care*, vol. 15, no. 5, pp. 307–310, Oct. 2006.

[74] I. Scandurra, M. Hägglund, and S. Koch, “From user needs to system specifications: Multi-disciplinary thematic seminars as a collaborative design method for development of health information systems,” *J. Biomed. Inform.*, vol. 41, no. 4, pp. 557–569, Aug. 2008.

[75] D. Wixon, K. Holtzblatt, and S. Knox, “Contextual design: an emergent view of system design,” in *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*, 1990, pp. 329–336.

[76] M. Blechner, V. Monaco, I. Knox, and R. S. Crowley, “Using Contextual Design to Identify Potential Innovations for Problem Based Learning,” in *Proceedings of the*, 2003.

[77] H. Beyer and K. Holtzblatt, “Contextual design,” *interactions*, vol. 6, no. 1, pp. 32–42, 1999.

[78] Coble, J. M., Maffitt, J. S., Orland, M. J., and Kahn, M. G., “Contextual Inquiry: Discovering Physicians’ True Needs.,” in *Proceedings o the*, 1995, vol. 38(3), pp. 469–473.

[79] K. A. Thursky and M. Mahemoff, “User-centered design techniques for a computerised antibiotic decision support system in an intensive care unit,” *Int. J. Med. Inf.*, vol. 76, no. 10, pp. 760–768, Oct. 2007.

[80] K. Keshavjee, J. Bosomworth, J. Copen, J. Lai, B. Kucukyazici, R. Lilani, and A. Holbrook, “Best Practices in EMR Implementation: A Systematic Review,” *AMIA. Annu. Symp. Proc.*, vol. 2006, p. 982, 2006.

[81] H. Mohd and S. M. Syed Mohamad, “Acceptance model of electronic medical record,” *J. Adv. Inf. Manag. Stud.*, vol. 2, no. 1, pp. 75–92, 2005.

[82] T. A. Massaro, “Introducing Physician Order Entry at a Major Academic Medical Center: Impact on Organizational Culture and Behavior,” in *Evaluating the Organizational Impact of Healthcare Information Systems*, Springer, 2005, pp. 253–263.

[83] M. Keil, P. E. Cule, K. Lyytinen, and R. C. Schmidt, “A Framework for Identifying Software Project Risks,” *Commun ACM*, vol. 41, no. 11, pp. 76–83, Nov. 1998.

[84] S. G. S. Shah and I. Robinson, “Benefits of and barriers to involving users in medical device technology development and evaluation,” *Int. J. Technol. Assess. Health Care*, vol. 23, no. 1, pp. 131–137, 2007.

APPENDIX – USER CENTERED DESIGN BASED ON BARRIERS

Barrier	Detail	User Centered Design
Patients Demographics Diversity	Different customer requirements due to different patients demographics. Large group of users beyond geographical limits. Patients with divers set of skills interacting with the system.	Empathic Design Ethnography
User Diversity (HCP, patients & caregivers)	Different user groups interacting with the system for different functions & purposes.	Participatory Design Empathic Design Contextual Design
Social & cultural implications	Social and ethical impacts & implications. Different values and beliefs. Users with different socioeconomic and geographical needs.	Ethnography
Users' practices & behaviors	Understanding of users daily activities and impacts on quality of life. Physicians and patients behavior rooting for tangible treatment such as medicine trial-and-error. Integration with current medical/clinical practices (Physician and other HCP behaviors, preference & practices). The need to fit with normal user life style.	Contextual Design Empathic Design Participatory Design
Environment & settings	Consideration of settings and environments where the technology is being used (e.g. housing situations, clinics/hospitals). Understanding the environment where end users (patients) live, understand their daily activities. Capturing interactions with other people and artifacts Impacts of external factors such as type of care received by the patients.	Contextual Design Empathic Design
Design preferences	Multiple preferences for designs	Participatory Design Contextual Design
Perceived values	Users' perception of usefulness, ease of use, accuracy, reliability and confidentiality.	Participatory Design Contextual Design
Cognitive, knowledge & learning curves	Cognitive decline, disability and usability barriers to effective use of technology, especially among seniors and people with disability. Knowledge barrier on how to use and adopt the system. Learning curves for transitioning from current practices to new ones imposed by the technology.	Ethnography Empathic Design
Organizational factors	Understanding of organizational factors & practices (e.g. financial system, pharmaceutical industry, Insurance industry, government policies and regulations)	Contextual Design Participatory Design
Technical expectations	Deep scientific knowledge required for designing of systems	Lead User Design