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Design-for-User Acceptance of IOT Home Use Medical Device: A Design Process for IOT Home Use Medical Device

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ABSTRACT

Medical devices are migrating from hospital use to home use along with health professional users to lay users. Internet-Of-Things technology enables the home use medical devices to seamlessly detect and connect home patient health status and health activities allowing the patients to remotely connect and share their health data to friends, family, and healthcare staff. Developing IOT medical devices for home patients to use in daily life routines is critical to the success of device development. This study proposes Design-for-user Acceptance of IOT Home use medical device (DfAIH), a design process targeted to use at the conceptual design phase to convey ideas of IOT functions implementation in home use medical device development and verification to gain user acceptance. The process was constructed using an extended Hierarchical Value Map (HVM) model, termed T-A-C-V-I-U, as a design model. DfAIH aimed to assist device developers with less-experienced human factor engineering to consider how determined IOT functions would affect user acceptance or how to select the suitable functions to improve user acceptance.

Keywords: Design-for-x, User acceptance, User research, Design process, IOT, Home use, Lay user, Home patient, Medical device, Hierarchical value map

INTRODUCTION

Medical devices are migrating from hospital use to home use along with health professional users to lay users. Discharging from hospital to continue medical care at home benefits the quality of life of the patient, possibly enhancing the health of the patient because they are in familiar and comfortable location, helping the public to reduce cost of care, and free up medical services to other people (Holekamp, 2018; FDA, 2010). Since the Covid-19 pandemic, the demand for home healthcare has increased more than ever. Home healthcare helps to support non-severe Covid-19 patients when hospitals face bed and medical staff shortages or chronic condition patients who choose to stay receiving care at home until a vaccine is found (Rusch et al., 2021). Further, the situation has accelerated the adoption of digital health

technologies by healthcare systems such as telemedicine and Internet-Of-Things (IOT) (Rusch et al., 2021). IOT is presently integrated with smart home and home use medical devices to monitor and communicate patients' health conditions, engaging and motivating patients to actively care for their health and well-being (Spanakis et al., 2018). IOT devices are typically small, fast, and easy-to-operate, assisting in reducing cost and time compared to testing at central laboratories, and the number of hospital visits.

However, developing a home use medical device is complicated and challenging. In home setting, the home-use environment is not controlled as in a laboratory or healthcare facility. Ambient light, sound, or noise can distort the alarming sound or display of the device (FDA, 2010). Home users with different backgrounds and experiences in medical devices and self-care may differ in physical, sensory, emotional, cognitive capabilities, preference, and lifestyle (FDA, 2010; Aydin, 2014). Furthermore, home patients, not the doctor, are responsible for their self-care, taking an active role in engaging their daily health activities (Burton and Hudson, 2001; Swan, 2012; Thongprasert and Jiamsanguanwong, 2021).

The Role of Patient as a Consumer in Existing Medical Device Development

Some studies in medical device development (MDD) were dedicated to understanding safe and effective use of medical devices by lay-users in home settings (Rajkomar et al., 2014; Pounder et al., 2016). Some studies pointed out that user acceptance plays a significant role in medical device adoption and benefits to chronic disease patients who showed a high interest in using the devices (Gao et al., 2015; Li et al., 2019). The findings suggested that the next generation of home use medical devices must be safe and effective use and encourage home patients to have more self-determination in pursuing, taking responsibility for their medical treatment (Swan, 2012). Hence, recognizing home patients as consumers who have their own in making decisions is a shifting paradigm of MDD. Many studies proposed the concept as "consumer medical devices," bringing the consumer product development concept to use in MDD and empowering lay users to engage more in self-care (Garge et al., 2017).

Moreover, several design processes applied human factor engineering (HFE) to help analyze how users interact with the device. However, the application of HFE in existing MDD was still limited only when it is mandatory by regulating agencies (Money et al., 2011), and in improving safe and effective use (Rajkomar et al., 2014; Pounder et al., 2016). Nevertheless, how to develop a device to increase user acceptance was not primarily mentioned in the existing design process (Thongprasert and Jiamsanguanwong, 2021). Therefore, this study proposed a concurrent design process constructed based on Design-for-X (DfX) (Huang, 1996), which employed a consumer product development concept with Means-End chain (Russell et al., 2004; Reynolds and Gutman, 1988; Gutman, 1982) for IOT home use medical device development.

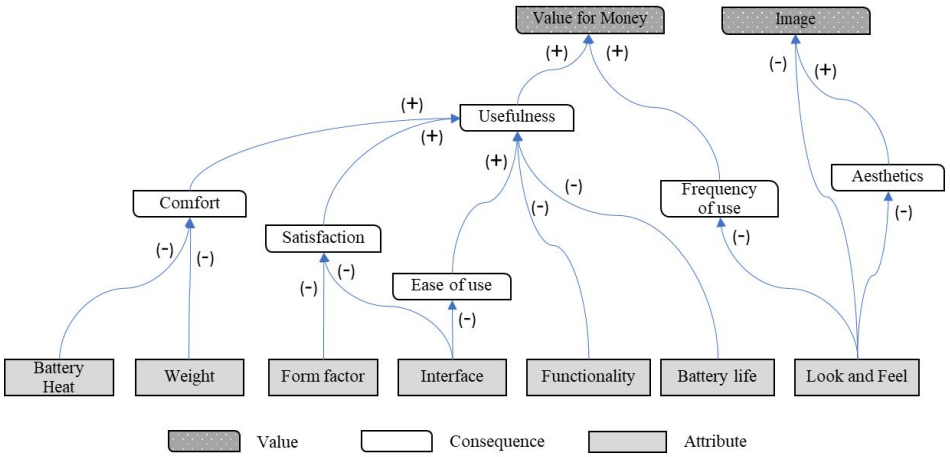

Figure 1: HVM of Smartwatch inhibiting factors for working group users (Adapa et al., 2018).

Means-End Chain for Consumer Product Development

Means-End Chain (MEC) theory is a methodology based on cognitive theory explaining that consumers will choose products containing *attributes (A)* that stimulate motivation for the behavioral response, *consequence (C)*, to achieve their *personal value (V)* (Russell et al., 2004; Reynolds and Gutman, 1988; Gutman, 1982). *The individuals' A-C-V ladder chains are aggregated and summarized as a hierarchical value map (HVM)*. The theory and its applications are useful for a new product or service development in eliciting the meaning behind its essential attributes and motivation to choose the product or service. The MEC is applied in several consumer products and services, such as food, smartphones, and wearable devices to monitor patients' health data and maintain their good health behaviors (Adapa et al., 2018). Previous studies (Basoglu et al., 2009; Chiu, 2005) had extended the hierarchical value map (HVM) to combine with the Technology Acceptance Model (TAM), targeting the intention to use. Further studies adapted MEC by adding technological level as ideation of attributes to extend the model to *T-A-C-V-I-U model* (Basoglu et al., 2009; Chiu, 2005). The model provided a construct to understand the technology functions, attitudes, consequences, and values that lead from technology characteristics to attitude and intention to use the system. This can assist device developers to match a device or system with user goals at the lower end of the MEC, which are generally less complex and easier to elicit. An example of the HVM of Smartwatch in working group users is exhibited in Figure 1.

Though the previous studies illustrated a potential to elicit the linkage behind the consumer decision process, the methodologies were not yet applied or integrated with a design process. This study aims to explore a new design process and design model that can provide a guideline to consider how IOT functions and IOT device attributes can improve targeted positive factors or reduce the unwanted negative factors resulting in gaining user acceptance. Consequently, the device can encourage patients to have more autonomy in

pursuing, taking responsibility for their health activities. The next session will explain the process and methodology to construct the design process proposed in this study.

SYNTHESIS METHODOLOGY

Construct DfAIH Design Process

Result from previous study (Thongprasert and Jiamsanguanwong, 2021), the target of the proposing design process and design model should provide a comprehensive guideline with manual, and methodology to verify or validate the idea prototype in the conceptual design phase. Therefore, this study applied the T-A-C-V-I-U model to link IOT functions to user acceptance of IOT home use medical devices and followed a Design for X (DfX) framework (Huang, 1996) to construct as a design process. First, a systematic literature review was conducted of new product development processes, design processes, and design methodologies for IOT home use medical devices (Thongprasert and Jiamsanguanwong, 2021). Then in this study, following the DfX shell (Huang, 1996), further literature reviews were included to create priori lists of IOT functions, device attributes, consequences, and values. Information was gathered and synthesized. Finally, a *design for user acceptance of IOT home use medical device* (DfAIH) was proposed, as exhibited in Figure 2. The process consists of five stages: Discover & Define, Design, Prototype, Verification, and Design transfer.

A) Discover & Define. The first stage involves understanding the product, its context of use, its intended user, and IOT technology embedded or will be embedded in the device. A device developer team will gather information about the project and define needs and elements to conduct a DfAIH process. The design team can use the DfAIH to consider which IOT functions will affect target personal value or how specific IOT functions affect the user. A basic project charter can be used to describe relevant detail of the product development to prepare all tasks to conduct the design process, including where and when to conduct user research, number of lead users needed, where to find groups of lead users, duration, and resources needed.

B) Design. The second stage will focus on the conceptual design of the product. Priori lists of IOT functions presented in a morphological chart (Börekçi, 2018; Dragomir et al., 2016) is proposed as a guideline for less experienced designers to select available IOT functions for the new device development. The design team can enhance the list by adding or removing parameter(s) specific to their device, technology, or target users. Design(s) will be selected for the next stage.

C) Prototype. In the third stage, a rapid prototype can be used to convey the conceptual design ideas. In a broader interpretation, a prototype can be concrete or abstract objects or pictures, engineering sketches, or presenting a partial function or attribute from existing devices. For instance, in the case of Bluetooth technology selected in the new design, a demonstration of Bluetooth pairing and usage from existing devices with similar performance can be used as a prototype if it can communicate the idea design.

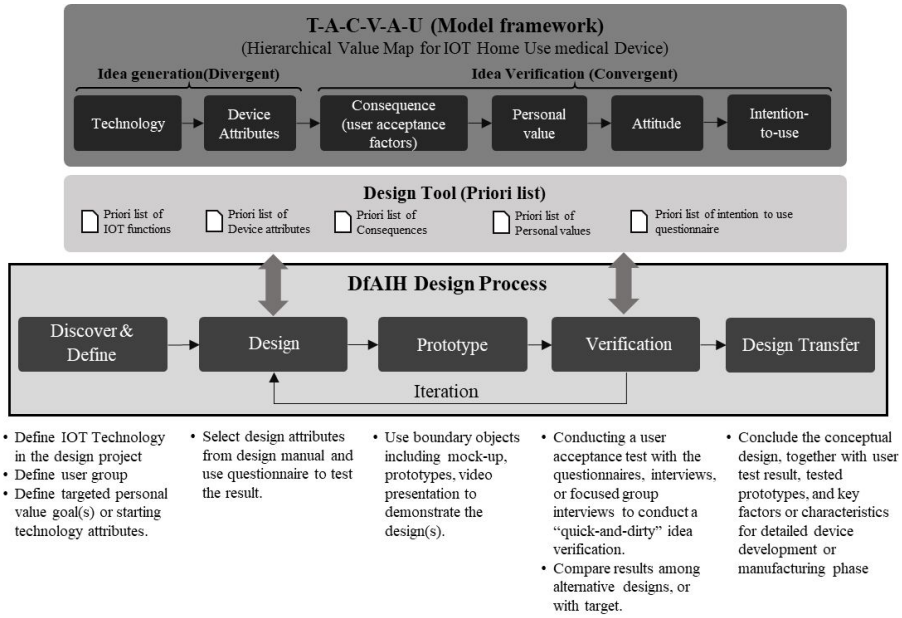

Figure 2: exhibits the Design-for-user Acceptance of IOT Home use medical device, DfAIH, proposed in this study.

D) Verification. The verification stage involves user research to demonstrate the prototypes to intended users. A questionnaire, in-depth interview, or focused group interview will be conducted to elicit factors and relationships among them laddering up to intention to use. Priori lists of device attributes, consequences, personal values, and questions related to intention to use were proposed as a design tool in the form of manual checklists. Designers can also modify the lists depending on specific project requirements. The construction of priori lists, questionnaire of consequences, values, and subjective questions regarding user acceptance measures will be described more later in this paper. If the results do not meet the target requirements, the design team can go back to the Design stage, re-design the device using different combinations of the IOT functions and iteratively repeat the process.

E) Design transfer. The final stage is to wrap up the design proposed to the back-end new product development process. Product verification, suggestions, and improvement areas in each step will be documented. Prototypes of the verified design will be transferred to the engineering/design team in the next phase to ensure that the key concepts, the attributes, technology selected, and acceptance results will be considered in the product development in the manufacturing and commercial phase.

Develop the Priori Lists

The five stages of DfAIH provides a step-by-step framework to design and verify IOT home use medical device. The core design concept to gain user acceptance is based on the extended Hierarchical Value Map, T-A-C-V-A-U. DfAIH provides precoded priori lists of IOT functions, device attributes,

Table 1. Priori lists precoded with the DfAIH and its references.

Priori lists	Number of items proposed	Reference
IOT Functions	29 items	(Adapa, 2018; Bhuvaneswari and Porkodi, 2014; Samie et al., 2016; Yin et al., 2016)
Device Attributes	14 items	(Adapa et al., 2018; Sun and Rau, 2015; Ten Haken et al., 2018; Dicianno et al., 2017; Baudier et al., 2019; Peruzzini and Germani, 2014; Alppay and Hedge, 2015; Papetti et al., 2016)
Consequences	17 items	(Gao et al., 2015; Zhang et al., 2017; Davis, 1989; Li et al., 2019; Gao and Bai, 2014; Venkatesh and Davis, 2000; Pal et al., 2018; Kim et al., 2019)
Personal value	9 items	(Kahle and Kennedy, 1988)
Intention to use	2 items	(Davis, 1989)

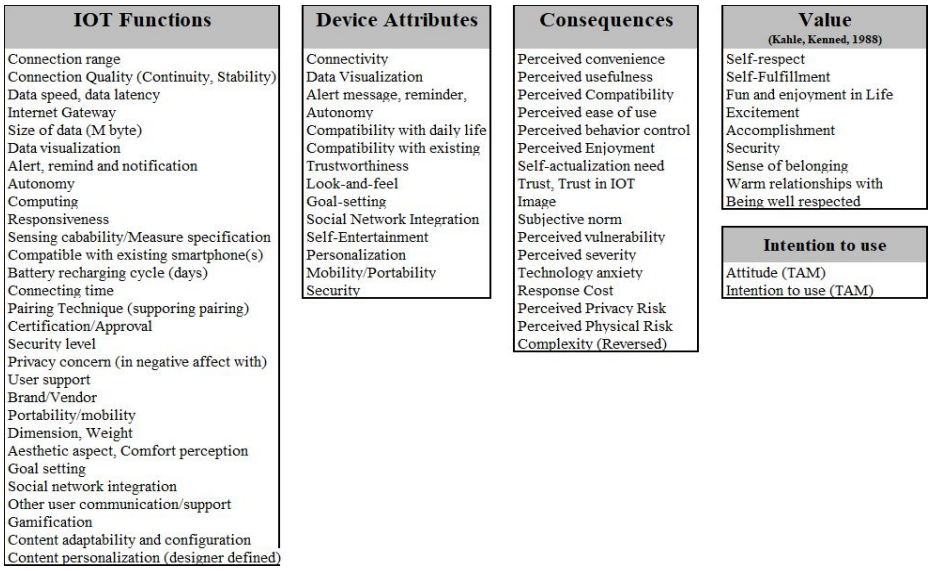

Figure 3: Exhibited priori lists of T-A-C-V-A-U model.

consequences, values, and intention to use. The priori lists will help designers with less experience in user research conduct a user acceptance test by laddering up to assembling the T-A-C-V-A-U model. The priori lists can be a starting point for soft- and hard-laddering. In addition, the designers can add more items from literature review, experience, or items elicited from an interview. This study reviewed related literature in IOT, medical device development, factors influencing user acceptance, technology acceptance model, and health belief model, then synthesizing to five (5) priori lists as shown in Table 1.

CONCLUSION

This study proposed a design process to ensure that user acceptance will be considered in the early phase of IOT home use medical device product development, termed "Design for user Acceptance of IOT Home use medical device," DfAIH. The process aimed to be: 1) easy to understand and implement by a design team with low resources and less experience in user research, such as by technology startup companies. Further, the process must provide 2) a quick and dirty framework to create a linkage from IOT functions up to user acceptance of an IOT home use medical device and, 3) a guideline for divergently idea generation from IOT functions using a morphological chart to match user goals at the device attributes level, and 4) a measure results based on human factor methodology.

For the number of IOT and device characteristics in a new design, DfAIH suggested concentrating on 4-5 functions and attributes as successful innovative medical devices had innovation on an average of 3.2 categories, which is mainly improving features of the devices in the area of architecture, environmental interactions, and user interactions (Holtta-Otto et al., 2010). DfAIH will benefit a new design or re-design of existing home use devices by adding IOT communication and improving user acceptance. Accordingly, the applications of DfAIH aim to either be used for the development of newly IOT home use medical devices that ensure the technology will be accepted by home users or re-design a new version of devices to improve user acceptance. In DfAIH, though presented in sequential and linear steps, the designer is encouraged to conduct the design iteratively and comparatively. As the most effective design process will involve several rounds of design and test, this design process also endorses the iterative steps when conducting a design generation and user test. The number of iterative rounds would depend on time, budget, resources, and target of the product development defined in the first stage. In a comparative scheme, this design process recommends that a design team have 2-3 versions of product designs to compare product preference and use triadic sorting approaches (Reynolds and Gutman, 1988).

The proposed design process and design model are still at the theoretical level. It does not yet be verified or validated with actual device development. Further empirical studies should be conducted to validate the concept with actual devices and users. In addition, more detailed methodologies, tools, manuals, or instructions should be added to ensure that the design process will be effective and easy to use, resulting in gaining user acceptance of the IOT home use medical device.

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