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Review

New Product Development Processes for IOT-Enabled Home Use Medical Devices: A Systematic Review

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Abstract. Background: In the new forefront of healthcare at patients' homes, medical devices developed to use at home setting by lay users are essential. The adoption of home-use medical devices will benefit both patients and public healthcare services in terms of quality of life, enhanced outcomes, and reduced cost of care. Home use medical devices associated with Internet-Of-Things (IOT) technology assists patients in performing self-care as well as providing health information remotely to health care professionals. However, adopting technology requires understanding the nature of the medical device and medical device development (MDD). Existing studies concerning the new product development (NPD) processes or design processes were systematically reviewed to explore knowledge and expertise to provide a framework for IOT engineers or designers to adopt IOT technology to home use medical devices.

Objective: This study aimed to review the published literature to explore the current studies in the field of the NPD process, design process, design methodology, and outcome of the device affecting user acceptance.

Methods**:** A systematic review following PRISMA guidelines of the English language literature from four electronic databases and academic search engines published from 2007 to 2018 was conducted. The papers were screened and assessed following predefined inclusive and exclusive criteria. The results were analyzed according to the research questions.

Results: The findings revealed state-of-the-art in the NPD process and design process (n=4), the design methodology (n=23), and the resultant outcomes of empirical or clinical research in the validation stage (n=14) of medical device development (MDD). The findings also delineated existing studies in NPD, design process, and design methodologies aimed to ensure that medical devices would be effective and safe. Human factor engineering (HFE), cognitive method, ethnographic, and other methodologies were proposed to understand users, uses and context of use. Barriers, constraints, and multidisciplinary communication were addressed. Tools, processes, and methodologies were proposed to overcome the barriers.

Conclusion**:** As home-use medical device development (MDD) and the adoption of IOT technology is now at a crossroads. This study addresses the necessity for future academic studies related to IOT adoption to MDD, including unique risks, multidisciplinary problems, emerging from IOT technology. Finally, future studies aimed at fabricating the NPD process or design process for IOT home-use medical devices to gain user acceptance were outlined.

Keywords: Medical device development, home use medical devices, new product development process, user acceptance, IOT.

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1. Introduction

Home healthcare is now becoming the new forefront of healthcare services, both in terms of benefits to patients themselves [1]–[3] and public services [4]. The U.S. Food and Drug Administration (FDA) [1] expected that more patients would be discharged from the healthcare facility to continue their medical care at home. Home healthcare can provide significant benefits to the patients, both in terms of improving quality of life, enhanced outcomes, and reduced cost of care [1]–[3]. Patients who receive their care at home may enjoy it because they are in a familiar and convenient venue [1]. In terms of public service, as some people engage more self-care at home, it could free up medical service at hospitals or healthcare facilities to other people [4]. The home healthcare service also provides prevention to reduce the risk factors associated with diseases, including non-communicable diseases (NCDs), in the first place [5].

World Health Organization (WHO) [5] revealed that NCDs, such as cardiovascular diseases, cancers, chronic diseases, and diabetes, caused 15 million premature deaths every year. The organization under the 2030 Agenda for Sustainable Development targets to reduce premature deaths from NCDs by one-third by 2030. An effective way to control the NCDs is to prevent through healthier lifestyles, reducing the risk factors, detecting, screening, and treating these diseases at the early stage [5]. Primary care is now migrating from healthcare facilities to any place at the patients' points to allow them to perform the medication or health activities as a part of daily life to prevent chronic illness and improve their health and quality of life.

In the clinical-setting, medical device development (MDD) tends to focus on response to the needs of the customers, who are persons who make the purchase decision rather than the actual users, such as patients or operational staff [6], [7]. User research was conducted only when it is mandatory, mainly at the product review stage, and involve only senior healthcare staff in the fee-based consulting service [8]. In the home setting, home users may have differences in physical, sensory, emotional, and cognitive capabilities [1]. They will perform the health activities in non-controlled environments, for instance, at home, in the office, while traveling, and by themselves without or with minimum training experience and support [1], [9]–[11]. Further, home patients are responsible for their treatment and care [12], [13]. The patients or people have to take an active and voluntary role in pursuing their medical treatment [13]. Consequently, the term "consumer medical product" or "patient as a consumer" has been coined by several studies [14], [15]. The studies implied that home medical devices must be designed to empower patients to be responsible for their own health condition, treatment, and health activities.

Internet-Of-Things (IOT) devices, for example, smartphones, wearable devices, wireless sensors, are recently used to engage patients with chronic diseases in self-management and to improve clinical integration [16], [17]. The devices allow home patients and their physician to share information and decision resulting in better medical treatment [18]–[20], automated telephone care and blood pressure monitoring improving outcomes for hypertensive patients [21], and tracking activity to help people become more active [22]. The technology has had the potential for transformative change in many aspects of consumers' lives [23]. It improves citizen empowerment, engagement, and motivation to responsible for their health activities in daily lifestyles and well-being [24].

Many studies contribute to the knowledge of the home medical device, for instance, the usability of the device [25], user acceptance [22], doctor-patient relationship [26]. Moreover, the home-use medical device requires adequate training and labeling for the users [1]. However, this study focused on extending a research boundary to adopt IOT technology to home-use medical device development as the primary objective. Accordingly, existing literature related to the definition of IOT technology, the nature of medical device development, and user acceptance of the technology were reviewed. Then academic studies that provide a framework to adopt IOT technology to the device had been evaluated. The methodology, results, data analysis, and their implication led to suggestions in future studies in the next section.

2. Literature Review

2.1. IOT Technology in Medical Device

IOT is commonly defining as a network of infrastructure connecting various connected sensors or smart objects and allowing more data interoperability, device management, communicating, and sharing information for application purposes [27]–[29]. The IOT devices include smartphones, smart sensors, wearable devices, home appliances, medical and industrial instruments. IOT shows its potential in creating new capabilities from both technical and business aspects in many industries and markets [30], [31]. The term Internet-Of-Things (IOT) has been used as a subject and topic in several medical device studies. Common terms were used, for instance, IOT-based system for homecare/personal healthcare [32]–[34]; Internet of Health Things (IoHT) [15], [35]; Internet of Medical Things (IoMT); and Ubiquitous healthcare or U-healthcare [36]–[38]. According to a survey by Accenture [35], Internet of Health Things (IOHT) will have a market value of 163 billion USD by 2020 with a Compound Annual Growth Rate of 38.1 percent, projected to be number one in the top 10 industries for the IOT app development. An example of IOT devices, the wearable device has been adopted by individuals, starting from monitoring personal health to become part of the treatment 'prescription' [22]. In 2018, the introduction of Apple Watch Series 4 with a feature of electrocardiogram (ECG) readings with the FDA clearance [39], [40], was another step of IOT technology in the home use medical device. The IOT devices can sense, monitor, and manage people's health

status and contribute to a healthcare paradigm change [24]. The devices allow healthcare professionals to remotely monitor the progress of a patient's treatment and health condition at home and reduce the number of hospital visits [41], [42]. Telemedicine and sensor technology assist seniors in managing their chronic diseases and dependent living [43].

The IOT has several technologies involved. The technologies have differences in specifications, topologies, range, data communication rate, security, cost, and so on [44]–[49]. An IOT technology comparison table is exhibited in Table 1 [44]–[49]. The table categorized IOT technology into five groups following their main features, characteristics, and standards. NFC and RFID communication provide reliable short-range communication currently equipped in smartphones for payment and access control communication. NFC and RFID technology involves a passive NFC/RFID tag that can contain a small amount of data [45]. The technologies extend the role of smartphones in communication between users and objects in healthcare applications [50], such as using in the identification of drugs and enabling communication of blood pressure monitoring devices with smartphones [51]. Wireless Personal Area Network (WPAN), such as Bluetooth, has been embedded in medical devices to provide device-to-device data transfer in medium-range communication. Home devices ranging from weighting scale [52], wearable devices [53], Point-of-Care Testing device [42], [54], can provide remote monitoring via smartphone connection [55]. The WPAN has its advantage in low-cost, having high enough throughput to stream audio and data, presenting and becoming one of the standards in several applications [45], [50].

While Wireless Local Area Network (WLAN) such as WIFI and Wireless Wide Area Network (WWAN) work as heterogeneous infrastructure in integrating multiple monitoring systems connecting healthcare devices to the internet [44], [45], [56], [57]. The technologies provide a reliable, secure, continuous, and large amount of data communication for healthcare applications such as Telemonitoring and Telemedicine services [45], [58], [59]. WWAN communication, such as 5G technology, through mobile devices, offers audio, video, text, and data sharing remotely from different physical locations. The technology will play an essential role in reducing health care costs and the need to access healthcare data remotely [60]. Low-Power Wide Area Network (LPWAN) is one of the promising IOT technologies. Its low-cost, low-power consumption, and coverage in the broad area were considered to provide healthcare infrastructure [45], [61]. However, a concern of the technology is its low data rate and low latency. It may not be suitable for data steaming. From the technical aspect, the selection of IOT technologies in medical device development will depend on several technical factors such as range, reliability, security, data rate of communication, and so on.

IOT product embedded with the IOT technology will have different characteristics from those of general products. The characteristics of IOT products will affect users' objective cognition (functional experience) and subjective emotions (emotional experience) [62], [63]. Therefore, to implement such technological innovation on a large scale, the devices, systems and services need in a process to make information available and usable for the users, make them empowered, trusted, accepted, and enjoyed [24]. The adoption of IOT technology to home-use medical devices is a challenge. It requires further academic study and industrial practice. In this review, existing studies of medical device development were exhibited to provide more understanding in both academic and industrial aspects.

2.2. Nature of medical device development

The medical device industry is complex and unique. The development of medical devices requires multidisciplinary, technological, and capital intensive, and several incremental iterations with each model slightly different from its previous generation [64]. Referring to the U.S. FDA premarket-approval process, a new and high-risk medical device must pass the Premarket Approval Application (PMA), while an incremental development will pass 510K process [65], [66]. In the listed FDA devices until 2016, 35% of the products have passed 510K compared to 1% with the PMA process [67]. From the innovativeness aspect, Holtta-Otto [68] studied innovation characteristics of 51 award-winning hardware-related medical consumer products from 2003-2008. The products illustrated the characteristics of incremental improvements, which are 67%, 67%, and 63% in Environmental Interactions, Architecture, and User Interaction category, respectively. While the products only exhibited 20% in additional function related to radical innovation and 6% in cost reduction. Therefore, the findings indicated the nature of MDD as incremental innovation in both statistics and innovativeness.

New technologies in the medical device industry are driven by the technology push usually brought to market by startups companies from university spin-off. In contrast, incumbent companies develop successive iterations of the existing devices. [64]. However, there is only one success from three thousand raw ideas, and finally, 90% of invention-based startups failed [69]. Notably, medical device startups are usually relied on a single technology or product but need many years of development to pass required certification/approval [64], [69]. During product development, startups may face the situation of "valley of death," typically happens when they are running out of funding and time [69]. Moreover, in the commercial phase, a failure in the marketplace may cause the company to be ceased. Some of the top reasons that make start-ups failed are inferior products and ignore customers [69]. In medical device startups, user acceptance is crucial to its survival and marketability [69]. Involving users at an early stage to achieve uses' willingness to use the device is a challenge and a compulsory.

Table 1. Comparison table of IOT technologies.

Network	Proximity	WPAN	WLAN	WWAN	LPWAN
Example Technologies	NFC, RFID	Bluetooth, BLE, LoWPAN, Zigbee, EnOcean, ANT+, NIKE+, Z-wave, RF4CE	Wi-Fi, Wi-Fic Hallow, HEW	Cellular Tech: 2G/3G/4G/5G/LTE /MTC, UMITS, GPRS, GSM EDGE,	NB-IOT, LTE-Cat M, LoRa, SIGFOX, LoRa, Telensa, PTC, SIG, Ingenu, DASH7
Network topology	P2P	Scatternet, Star, Tree, Mesh	Mesh, star	Mesh	Mesh, star, star-of-stars
Range	<20cm	1-30m	4-800m (Wi-Fi <20m)	>5km (Cellular network coverage)	<10km
Coupling	Magnetic Coupling	RF Coupling	RF Coupling	RF Coupling	RF Coupling
Data rate	6.6k-424kbps	up to 1Mbps (BLE 1Mbps)	1.2k-100Mbps (Wi-Fi up to 100Mbps)	1.8M-72M, up to 1Gbps for 5G	100 bps (Sigfox), up to 50kbps (LoRa)
Protocol ownership	Standard	Standard, proprietary	Standard	Standard	Standard, Partially proprietary
Accessibility	Low	Low	Moderate	Good	Good
Reliability/ Stability	Moderate	Moderate	High	High	Low
Power consumption	Very low (NFC <1mW)	Good (BT 1-100mW)	High (Wi-Fi >1,000mW)	High	Low
Energy-efficiency	NFC (1-50 nJ/bit)	Zigbee (5 nJ/bit), BT (15 nJ/bit)	Wi-Fi (5 nJ/bit)	3G (~12.5 uJ/bit)	LoRa (1 uJ/bit)
Battery recharging cycle (days)	Not require (tag), 50mA (reader), low power consumption	<=30mA, low power consumption	High power consumption	High power consumption	Low power consumption
Security	Moderate	Moderate	High	High	Relatively unknown
Cost adder	Very low (NFC <1USD)	Low (BT 2-5 USD, Zigbee 5 USD)	High (Wi-Fi ~25 USD)	Very High	Low
Application	Payment, access control, share, initiate service, easy setup	Wireless headsets, network for data exchange, smart home, smart industry, health, sport, and fitness,	Sensor networks, building, and industrial automation, internet, multimedia, point-to-point connectivity	Cellular phones, telemetry, high-quality video & audio transfer	Street lighting, energy meters. Sensor networks
Advantage	Reliable in short-range communication, easy to pair, compatible with the smartphone.	Compatible with existing IT devices, provide stable communication for near body range.	Compatible with existing IT devices, e.g., Smartphone, PC, Laptop	High data rate, large data transfer, Long-range, nationwide coverage	Low cost, Low power consumption, provides longer battery life, Large coverage area
Limitation	Short-range	Power consumption, limited range.	Power consumption and cost.	Power consumption and cost.	Limited in high data rate or data latency

2.3. User Acceptance of the IOT Device in Medical and Well-Being Application

Adopting new technology is often hindered by users' unwillingness to accept and use caused by factors such as education level, age, ease-of-use, cost, or technology anxiety [70]–[73]. For the benefits to patients, smart home medical devices have a greater benefit to chronic disease patients who showed a high interest in using the devices [74]. Developing a product to achieve user acceptance is considered a critical success factor of medical devices [22], [23], [75], [76].

People tend to accept to use a technology influenced by several subjective factors. Based on the technology acceptance and health behavior theories, numerous academic researches contributed to study the factors influencing people to accept home-use IOT devices, mHealth, and wearable devices for personal healthcare [77]–[79]. Several studies revealed factors affect intention to use the devices such as perceived ease-of-use [22], [75], [80], perceived usefulness, perceived value [22], [80]–[86], compatibility [22], [75]; social influence [79], [80], perceived privacy risk [23], [76], [87]–[89], perceived threat [76], and patient-physician relationship [20]. Though perceived usefulness and perceived ease-of-use were found most repeatedly as demonstrated in the systematic review by Azhar and Dhillon [90], the other factors also play an important role in influencing user acceptance. Remarkably, those factors may vary and differ depending on the type of the device, demographic, socio-economy, age of users, the objective of use, health condition of user, and so on [90]. In Table 2, some studies highlighted that

the factors influencing user acceptance might vary depending on the demographic, socio-economy, objective of uses, and so on. For example, a study of technology acceptance of wearable devices by Guo, Li, and Luo [76] revealed that even the type of studying device was the same (wearable device), but the target user group and application were different (fitness and medical use), the factors influencing user acceptance would also be different. Likewise, the study by Deng, Mo, and Liu [82] underlined the difference in factors varied by the user group's age. Even the other conditions were the same.

In practice, user research tends to be conducted at the product review stage [8]. Studies suggested that conducting user research at the early stage of the design will reduce subsequent development cost and time overrun [91], [92]. Although the above studies underlay the influencing factors by validating the completed products with targeted users, the studies do not provide any framework to apply those finding factors to medical device development. The area of interest of this study is to review existing literature in the medical device product development and design process in search of any framework that provides a guideline to adopt IOT technology in home-use medical device development to gain user acceptance.

2.4. The New Product Development Process (NPD) for Medical Device Development (MDD).

The NPD process, for instance, the 13-step model [93] and the stage-gate model [94], were developed to be an effective tool to manage, direct, and control product-innovation efforts. The processes purposely provide a broad range of knowledge, guidelines, methodologies, and understanding of complications to comply with the standards or regulations needed. A model proposed by Rochford and Rudelius [95] adopted the 13-step model [93] for MDD. To introduce design controls in every step of the medical device design, the FDA presented a Waterfall model [96] as a reference for medical device manufacturing. Several studies in the medical device design process have been published, for instance, Design for Validation (DFV) V-Model [97], [98], Designing usability into a medical product [99], Medical device design proposed by Ogrodnik [100]. Several studies generally refer to the FDA guidance to ensure that the device under development will meet the standard requirements [97], [98], [101]–[103]. Some of the existing studies [92], [104], [105], and standard [106] have laid their focus on users as a center of the design.

While the NPDs and design processes provide frameworks to develop medical devices to comply with complex and rigor regulations, the NPD process as the process for bringing a new conceptual idea to the market has to adapt to fit and reflect the nature of the product [95]. Up-front user research, more iterative user feedback, consumer-oriented methodologies, and consumer-driven techniques are recommended in home use medical device development [3], [14], [15], [109]. Further, collaboration between multidisciplinary teams, rapid/iterative physical and digital prototypes as well as using user research methodology, for instance, user-centered design, user experience design, and human factors are crucial to uncovering the unmet or underserved needs that drive innovation [14]

The boundary of IOT technology covers from device, system, infrastructure, service, and all parts work together in harmony. Adopting IOT technology in the home use medical device offers the potential for substantially improving the device to assist home patients in performing health activities by themselves. However, many challenges remained. The challenges of the development are not only in applying the technology to the device, but the user acceptance of the new technology is also a significant concern to the survival of the product. Thus, inspired by the success of smartphones, wearable devices, and IOT devices, particularly in achieving the willingness of consumers to accept the devices to monitor health activity in daily life, this review study aimed to explore a new product development process or design process that could provide a reference framework in adopting IOT technology in home use medical device development, particularly in gaining user acceptance.

3. Research Methodology

3.1. Research Questions

Q1: What are the existing studies of the new product development (NPD) processes and design processes for medical device development (MDD) related to home use or connected medical devices targeted to use by lay-users?

Q2: What are the existing design methodologies for home use or connected medical devices targeted to use by lay-users?

Q3: What is the nature of incremental innovation in medical device development?

Q4: How can the reviewed studies provide a guideline for IOT technology to adopt home-use medical devices, including the design process to gain user acceptance?

Table 2. This table demonstrates the factors influencing user acceptance from some studies conducted in different conditions.

Objectives of the studies, devices, reference	Sampling and location	Goal	Factors influencing the dependent variable
Perception to access health informatics via mobile phone-based intervention [107]	700 of Singapore residential aging women (>=50 yr.)	Intention to use	Perceived user resource, subjective norm, perceived ease-of-use, perceived usefulness, compatibility, subjective norm
Comparison of the middle-aged and older users' adoption of mobile health services in China [82]	218 middle-aged respondents (age 40-59 yr.) and 206 older age respondents (age >=60 yr.) using a questionnaire survey in Wuhan, China	Intention to use	Middle-aged: Attitude, perceived value, perceived behavioral control, resistance to change (aging characteristic factors) Older-aged: Attitude, perceived value, perceived behavioral control, technology anxiety (aging characteristic factors), self-actualization (aging characteristic factors)
Technology acceptance of wearable devices for fitness and medical [76]	462 respondents (age 17 to 61) using an online survey in China	Intention to use	Medical: performance expectancy, self-efficacy, perceived severity, perceived privacy risk (-); Fitness: hedonic motivation, functional congruence, social influence
Post-adoptive use of healthcare wearable [23]	260 respondents (age 20 to >50) using an online survey in the United States	Extended use	mediating factors: problem-focused coping, emotion-focused coping, independent variable: Health concern, health information concern, privacy concern
Privacy risks influencing smartwatch usage [108]	229 respondents (averaged 28 yr.) using an online survey in Germany	Intention to use	[Intention to use] perceived usefulness, perceived privacy risk
Acceptance of IOT and Smart Homes for Elderly Healthcare [79]	239 elderly respondents (age >=55 yr.) using an online survey from India, Thailand, Malaysia, Indonesia	Intention to use	Effort expectancy, performance expectancy, perceived trust, perceived cost (-), technology anxiety (-)

3.2. Methods

A protocol of the electronic search, keywords, inclusion, and exclusion criteria was specified in advance following the PRISMA-P statement [110], [111], advised by an HFE expert and a librarian with expertise in database searching Fig. 1 shows the PRISMA flowchart of the study. A preliminary search using keywords had been done on ScienceDirect. Then keywords were modified in order to broaden the scope of the study, including removing the keyword "home use" to include all types of the hardware-related medical device. Then the keywords were used to search for research articles in four electronic databases and academic search engines: PubMed, Web of Science, ScienceDirect, and IEEE Xplore, only the title and abstract, for papers published during 2007 (the year that iPhone first introduced) to 2018 in the English language. The final search was retrieved between 29th December 2018 and 1st January 2019. A combination of keywords, thesaurus, and Boolean statements was used. The statement was varied depending on the search tools provided by each electronic database and search engines. An example of the Boolean statement used in the ScienceDirect advance search was shown in (Appendix A).

3.3. Eligibility Criteria

Inclusion criteria were journal papers in English concern product development process, design process, and design methodology of a medical device in the industrial design/industrial engineering domain, including theoretical study (without clinical outcome). Empirical studies (with a clinical outcome) related to user acceptance of medical devices intended to use in home-setting or by lay-users are inclusive. The inclusion criteria of eligible papers were: a paper which is in the field of industrial design, industrial engineering, biomedical engineering, or related disciplines which aim to embrace effective and safe use or to improve user acceptance of medical devices and other elements intended for use in non-healthcare facilities (home-use) by lay-users or both; concerning remote monitoring medical devices, network-connected medical devices, or IOT-enabled medical devices or related items.

Exclusion criteria were the papers that: did not publish in English, book review, commentaries, conference abstracts; papers concerning medical technology research, clinical or laboratory research, material, nanotechnology, bioengineering, or software engineering that did not relate to product development; design process that intended for high-risk medical devices such as the class I medical devices, surgery, or implant medical devices, which intend to use by specially trained

healthcare professionals only.

3.4. Data screening and Data Extraction

After removing duplicates, a total of 159 papers were identified. The papers were sorted from earliest to latest publication year using sorting function by spreadsheet software. A structural sampling of 20 studies, from paper number 2, 10, 18, …., to 154 were selected. The 20 studies were conducted a pilot test, screening using eligible criteria, then evaluating the result, and revising the criteria by the first review author, AT. Then, the two review authors, AT and AJ, screened a total of 159 searched papers based on the titles and abstracts against the inclusion and exclusion criteria. Papers included by either author were added to the next step. Sixty-two (62) papers were selected for full-text article assessment.

In the full-text article assessment, study eligibility, quality, and main study characteristics were assessed by the two authors. An interrater reliability test between two authors was done using Cohen's Kappa (K=0.39), which was interpreted as a fair strength of agreement between the two authors [112], [113]. The authors decided to resolve the disagreement by discussion. In cases where no agreement could be reached, the studies were included. A total of 41 studies were then included in this systematic review. Data extraction was done manually on a spreadsheet software by the first author, AT. The second author, AJ, checked the extracted data. At the data extraction stage, the included papers were categorized following the research questions.

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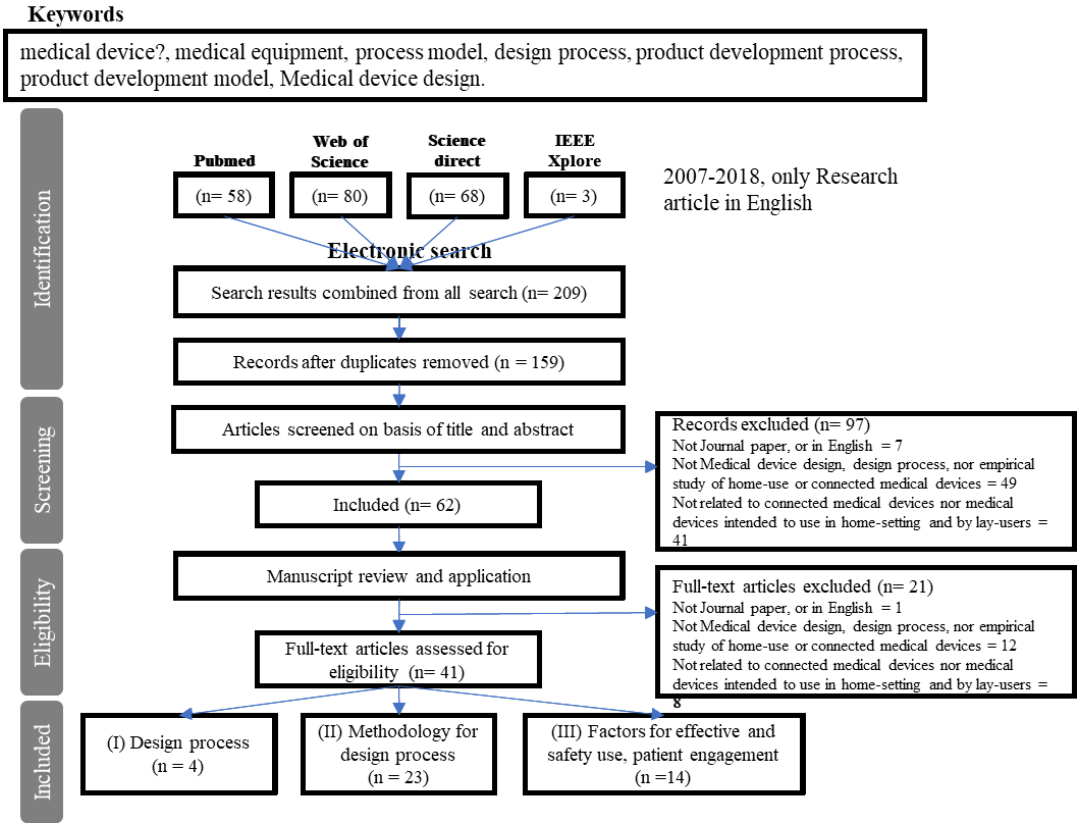

Fig. 1. PRISMA flow chart of the study.

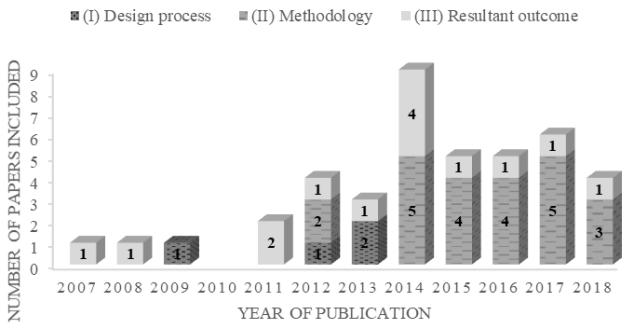

Fig. 2. Summary of the extracted studies (n =41).

4. Results

A summary of the extracted papers is presented in Fig. 2. Three review tables were constructed categorized from the study objectives: new product development process (4 papers), design methodology (23 papers), case/clinical study revealing the resultant outcome in the context of home use, or IOT-enabled medical device usage (14 papers). The review tables exhibit in appendix C. The papers were published mainly in journals of biomedical engineering, health and medicines, Engineering, and Design. Besides, thirty (30) papers (73%) were related to HFE, UE, and UCD in the medical device design process,

while fifteen (15) papers were dedicated to the context of home use or lay users.

4.1. New Product Development (NPD) Process

Four papers that proposed a new product development process or subprocess for a medical device were extracted, as shown in Appendix C, Table C-1.

Pietzsch et al. [114] collected information from medical device design professionals and created a stage-gate model for medical device design. The model demonstrates how to apply the iterative process and HFE in the waterfall model. Using the Design for X framework, Medina et al. [115] proposed a graphic comprehensive NPD process covering regulatory, standards, development process, patents, and medical specialty, a reference tool for novices to experience designers. Peijl et al. [92] proposed "design for risk control" by integrating IEC62366, ISO14971, and the user-centered design cycle to perform iterative UI development of existing Respiratory Care devices used by professionals in a trauma room, emergency department. De Ana [116] developed a spiral model for a front-end NPD process proposing to collect requirements from three distinct groups of stakeholders: voice of business (VoB), voice of customer (VoC), and voice of technology (VoT). Comparing stages of the NPD process from the four extracted studies and reference NPD processes are shown in Fig. 3.

4.2. Design Methodologies

Twenty-three papers (n=23) proposed design methodologies for the medical device new product development process. Extracted articles in medical device design methodology presented in Appendix C, Table C-2. Some studies propose design methodologies conducting user researches to understand user needs by applying formal usability engineering research in the new product development process [117]. Several studies used human factor engineering and a user-centered design process to minimize user risk and design flaws [118] and quantifying user requirement to a single figure to support evaluation and decision making [119].

Five articles contributed to exploring methodologies to break-down user tasks into smaller steps, which are: proposing a methodology work/task analysis to analyze interactive devices [120], a methodology for contextual user research in healthcare procedures [121], a principle to partition complex systems to subsystems to establish risk control [122], a Predictive User Error Analysis to identify and investigate potential incorrect actions of each step [123], and a framework based on distributed cognition for teamwork concentric layers (DiCoT-CL) to reveal couplings and dependencies that influence the performance of medical devices used at different layers of the socio-technical system [124].

Several papers proposed improvement in creativity and idea generation of new product development, which are: demonstrating the potential for using user-related medical device incidences from the FDA's MAUDE database as a source of ideas for medical device design [100]; using a patent search framework to create new ideas for any subsystem of a medical device [101]; proposing the integration of the C-K theory map for structuring concept development and TRIZ for structuring the design problem [102]. Boundary objects, such as personae, scenario, and storyboard content from user research and expert reviews [91], [103]–[105] were studied to provide user insight to designers and stakeholders. Prototypes in technology development and conceptual design were proven to be an effective tool for communicating ideas among designers, stakeholders, and users [93], [105]–[108]. A study in the participatory design proposed a conversational method (BRIDGE) that enables children to share their views and, by viewing, assent as a continual process [115].

Several studies explained that the MDD process and methodologies are necessarily involved in knowledge, expertise, and stakeholders across disciplines. [6], [89], [103], [109]. Factors, benefits, barriers, and constraints across the disciplines of the participants were also the topic of some studies [103], [109]. At the same time, some papers proposed methodologies to improve communication among designers, shareholders, and users [103], [105], [107], [110]. The methodologies and tools would be a vital part of overcome barriers among disciplines, which is one of the challenges in medical device development. Two papers were studied on the Knowledge management topic. One paper proposed an integrated semantic medical device framework integrating ontologies modeling engineering, medical, and patent knowledge to allow direct comparison of existing objects and methods across different disciplines [111]. Another one recommended a unified information model to facilitate knowledge capture and automated reasoning across domains [112]. A design-oriented web-based process case base system (WPCBS) [125], an ergonomic checklist to evaluate MTPCs at the early stage of the new product development process [113], and an extended protocol for the usability validation testing of a medical device were also proposed [114] to use as a validation tool.

The objectives of the extracted studies lie in the intention to improve the safety and effectiveness of medical devices [92], [114], to understand and respond to the design in developing interactive prototypes using digital technology to influence the engagement of stakeholders' voices [115], [116], and to provide a reference for new product development processes for designers [115]. Three papers [92], [114], [115] referred to FDA's waterfall model. Human factors engineering, usability engineering, ergonomics, or user-centered design, which are suggested by regulatory agencies, had been referred to or presented in the studies [92], [114], [116].

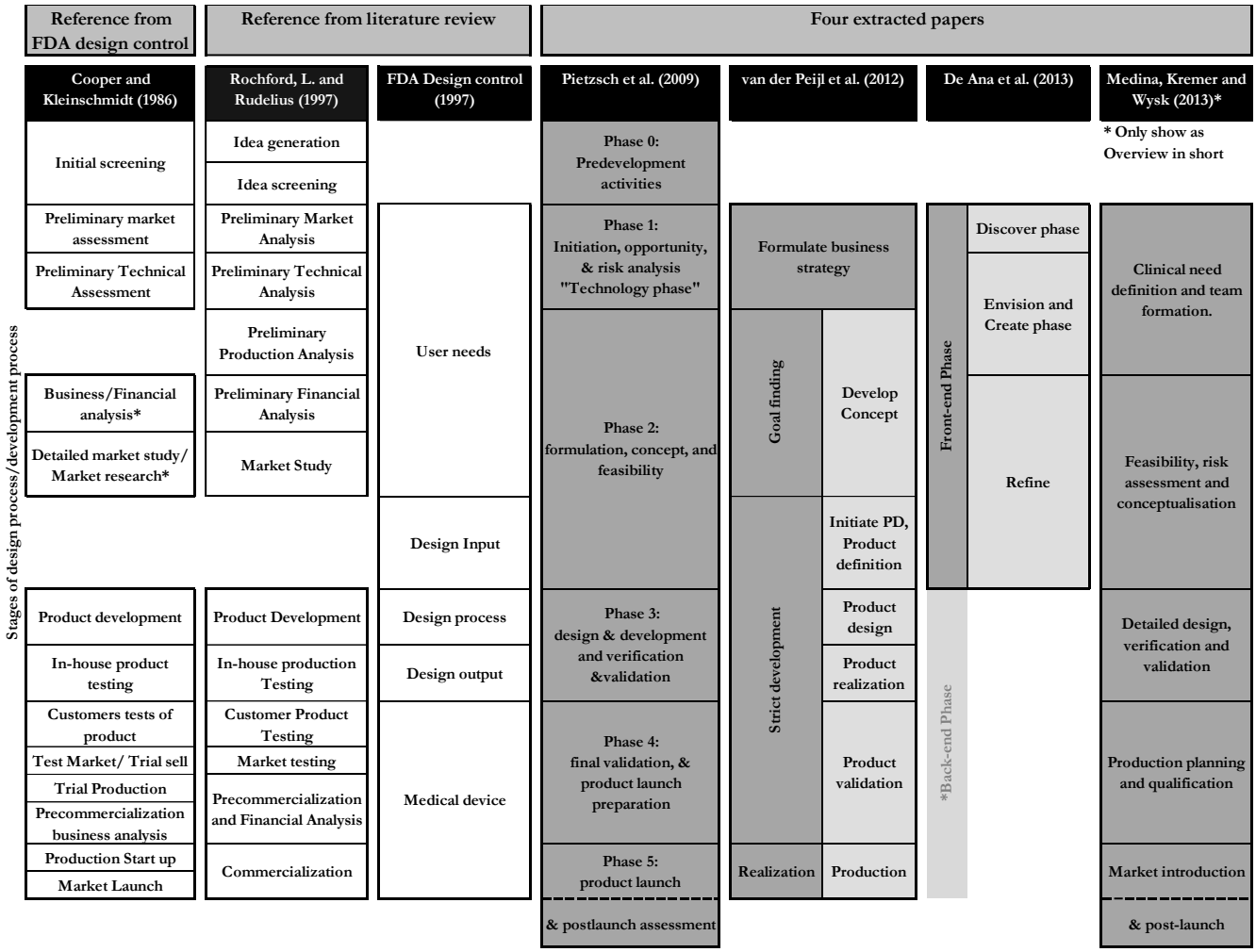

Fig. 3. Comparison of the stages of the new product development process from the four extracted studies and reference product development processes.

4.3. Implications of Guidelines for NPD or Design Process for Adoption of the IOT Technology in Home-Use Medical Devices Development

Summary of extracted papers related to case studies or clinical studies of the medical device that reveal resultant outcomes in user research and enhance user engagement and others are exhibited in Appendix C, Table C-3.

4.3.1. Human factor engineering in MDD

Of total forty-one (41) papers, thirty (30) articles proposed processes and methodologies or demonstrated resultant outcomes related to HFE, UE, UCD, ergonomics, ethnography, human-computer interfaces, user-centered design, or participatory design as shown in Fig. 4.

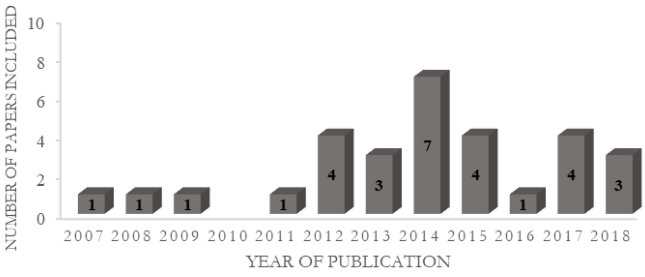

Fig. 4. Summary of the 30 studies referring to HFE/UE and related by publication year (n=30).

In the studies, HFE methodologies have been used to conduct formal user research, usability tests, and device verification and validation. Interviews or semi-structured interviews were widely used to collect user or patient insights [92], [117], [126]–[130] and, in some cases, photograph and videotaping were also used during the interviews [116], [118], [131]; surveys or online surveys were used to collect quantitative data from a larger group of users [116], [118]. Observation [92], [117], [126], [131], shadowing [116], [117], [127], focus groups [116], [117], [127], [132] and work/task analysis [116], [120], [124], [127], [133] were applied in the studies related to user-

centered design or participatory design. Schaeffer [118] and Pounder, Jones and Tanis [134] used data logs from actual device usages to analyze the behavior of patients in the home use setting. Table 3 exhibits the HFE and ethnographic methodologies used in the extracted studies.

HFE/UE methodologies can be applied to identify user errors in the early new product development process, making the solution simple and at a lower cost [92]. However, barriers and limitations to the implementation of HFE/UE were pointed out [8]. An outcome from Martin and Barnett's case study exhibited a problem in applying user research in a breakthrough technological product development process portraying the perception of the team to focus on technology development [117]. The case demonstrated that technology-intensive companies relied on the technology-push model and dedicating resources to technology development.

Table 3. HFE/ethnographic Methodologies used in the extracted studies.

HFE/ethnographic methodology	Author(s)
Interviews or semi-structured interviews	Martin and Barnett (2012); van der Peijl et al. (2012); Lang et al. (2013, 2014); Kelly and Matthews (2014); Vincent, C.J., Li, Y. and Blandford (2014); Alppay and Hedge (2015)
Photograph and videotaping	Schaeffer (2012); De Ana et al. (2013); Rajkomar et al. (2014)
Surveys or online surveys	Schaeffer (2012); De Ana et al. (2013)
Observation	Martin and Barnett (2012); van der Peijl et al. (2012); Kelly and Matthews (2014); Rajkomar et al. (2014)
Shadowing	Martin and Barnett (2012); De Ana et al. (2013); Vincent, C.J., Li, Y. and Blandford (2014)
Focus groups	Martin and Barnett (2012); De Ana et al. (2013); Vincent, C.J., Li, Y. and Blandford (2014); Sims (2018
Work/task analysis	De Ana et al. (2013); Campos, Doherty and Harrison (2014); Vincent, C.J., Li, Y. and Blandford (2014); Furniss et al. (2015); Hagedorn, Grosse and Krishnamurty (2015)

4.3.2. The Computer evolution in MDD

Furniss et al. [124] claimed the concept of computer evolution proposed by Grudin [135] occurred in MDD in the historical development of infusion pumps and Blood glucose meter. The computer evolution [135] explained that computer development could be separated into five layers; hardware, software, user interface, advanced interactions, and groups of users in a work setting. Once a layer is mastered, the designers can focus on the new challenges of the next layer with minimum change to previous layers. In this review, twenty-seven (n=27) papers provided detailed information concerning medical product development. Twenty (20) papers were classified as electronic devices and seven (7) papers as Non-electronic devices, as shown in Appendix B, Table B-1. Fifteen (15) papers on electronic devices demonstrated the incremental development with a new version or suggestion to improve the performance in layer 3, user interface, or above. The studies did not change or modify the core concept or medical technology, but rather improve usability and acceptance in the user interface and user interaction with the device using user research processes and methodologies. This finding provides an outline for further developing a new generation of a medical device, including the latest generation implementing IOT technology. More detail will be discussed in the discussion section.

4.3.3. Medical device development to use in home setting or by lay users.

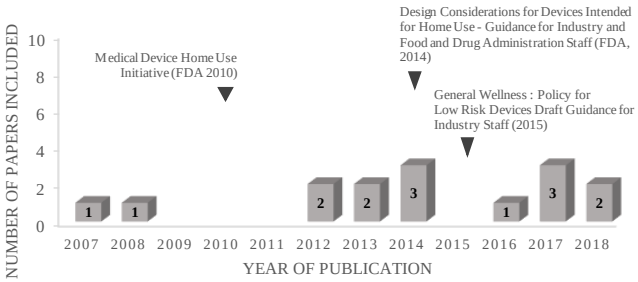

Fig. 5. This figure exhibits the extracted studies related to home use, lay users, and user acceptance.

Summary of extracted studies concerning a medical device intended to use in home-setting, by lay-users, or related to user acceptance exhibits Fig. 5. When a patient is at home, he/she wants to live and control her/his life and value the freedom that the device gives them [128], [130], [131]. Lang [128], [130] studied adolescent adherence to the handheld cystic fibrosis physiotherapy device revealed that adolescents want to be in control of their health and be independent. The adolescents want the device to be "fitting with teenage life" and be used outside the home. Kelly investigated the possibilities of overcoming barriers to use insulin injection systems and Hearing aids by relevant people who are not yet using the devices, "pre-user" [126]. Other than 'use,' a user-centered or ethnographically-informed NPD process should consider "the artefact multiple" (alternative interpretations of an artifact apart from that of use) and "Networks of practice" (to the consideration of practices which do not involve but could affect, use practices) [126].

Rajkomar gathered data from ethnographic observations and interviews to explore how home patients used home hemodialysis machines and how they adapted the use of technology to their lives and their home context [131]. Pounder [134] conducted a clinical study comparing

patient compliance in earlier and new generation of LIPUS bone healing therapy devices for home-patients, using over 12,000 data files retrieved from device recoding log files. Lyons retrieved 606 records associated with infusion devices reporting incidents from the UK National Reporting and Learning Service (2005–2015) to study factors related to the safe use of Infusion pumps being used in patients' homes [136]. A study by Haydock *et al.* [137] comparing two of the fluid infusion rate control devices highlighted that where despite objective evidence, subjective user perceptions (such as ease of use and preference) influence user acceptance of the medical devices. The study outlined that a medical device with a lack of user acceptance may have a significant barrier to user adoption. Some extracted papers described data supporting some factors affecting user acceptance and adherence, as presented in Table 4.

Table 4. This table presents factors affecting user acceptance and adherence from the extracted studies (n=6).

Factor(s)	Study subject	Author
Compatibility	CF physiotherapy device designed for adolescents	[128], [130]
Usefulness	A next-generation LIPUS bone healing product	[134]
Compatibility, Image, Social factors	A case study was conducted to adapt the user-centered design and participatory design methods to investigate the possibilities of overcoming any barrier to two home use medical devices.	[126]
Compatibility, Usefulness, Social factors	Possible design improvements to enhance the quality and safety of home hemodialysis.	[131]
Ease of use, Reliability, User's perception	The contrast in the subjective and objective measurement of two devices controlling IV fluid rate.	[137]
Usefulness. Social support	The study of records from adverse events of infusion devices occurring in private homes in the UK during 2005-2015.	[136]

4.3.4. IOT Technology in medical device development

In the studies regarding new technological product development for connected (Internet-of-things) medical devices, Caruso [138] delineated the concept of an established framework that integrates NIST SP 800-37,-53 with ISO 14971 to ensure that a connected medical device is safe and secure. Sjöman et al. created several iterative prototypes of an IOT-enabled inertial measurement unit (IMU) sensor as a wearable device for patients and athletes [139]. Lemke [140] demonstrated a case of iterative design in developing interactive prototypes using digital and NFC technology to influence the engagement of the constraint-induced movement therapy for chronic stroke patients.

5. Discussion

Results have shown that the NPD processes and design methodologies aim to work as frameworks for designers and engineers to design medical devices to be effective and safe use. The studies were conducted from both academic research and industrial practices, reflecting the vitality of the knowledge in this area to explore and improve the processes to develop better, safer, and more effective devices in the dynamic contexts, including the migration from clinical setting to home setting. Some studies also outlined the potential to design a medical device to have future functions associated with increasing patient acceptance. Adopting IOT technology in a home use medical device may provide sensing, computing, and connecting capabilities, which will help the medical device to perform better, more safely, or more effectively. However, risks from IOT technology in medical device development were not largely mentioned.

In the purpose of design for user acceptance, the device should encourage patients to have more autonomy in pursuing, taking responsibility for, and following their medical treatment. The device development can increase user acceptance by improving influencing factors, for instance, perceived usefulness, perceived ease of use, or by reducing other negative factors such as perceived privacy risks and privacy concerns.

5.1. Existing New Product Development and Design Processes

There were a few studies in the new product development process and design process during the reviewing period. Among the four (4) studies reviewed in NPD and design process, a study developed the process from industrial practices by experts in the field [114]. Another study emerged from document analysis and reviewed by subject matter experts [115], while two studies developed from the in-situ case study [92], [116]. The studies indicated that new product development processes and design processes for the medical device are not only being studied in academic research but also in the industrial practice to explore a new frontier in the domain. Three of the four studies mentioned the FDA waterfall model indicated that the model and concept of design for validation endorsed by the FDA were adopted as a backbone in medical device development. One of the reasons may because devices developers want to ensure that their development will follow the FDA guidelines and will pass FDA approval. Iteration in product development was also demonstrated in several studies. Many studies encouraged user involvement in the early stage of device development. Most studies pay attention to understand user needs and context of uses. In De ana's spiral model [116], the model extended to included stakeholder such as

reimbursement specialists to gain business process understanding which are important in some countries where the device will be paid by health insurance or government agencies.

5.2. Existing New Product Development, Design Processes, and Design Methodologies

The papers related to design methodologies provide methodologies and tools ranging from ideation to design and validation. In more complex devices with electronic or computing parts, the user interface is critical to safe and effective use. The intention to develop a medical device safer and more effective is crucial. The target of the new product development process, design process, and design methodologies reviewed in this study had shed light on the safety and effective use of the medical devices. In healthcare setting, where healthcare staff usually have pressure, limitation of time, or less training on the usage of medical devices, a mistake could happen. It may result in harm to patients or even the healthcare staff themselves. In non-healthcare setting, the medical devices are now more developed to use by lay users at non-healthcare facilities. Devices used in uncontrolled environment by lay users may be associated with risks created by limited knowledge of the lay users, the interaction between lay users and devices, potential harm resulting from misuses of the medical devices, vulnerabilities of the devices to uncontrolled environment, inappropriate periodically maintenance, or even obstacles to move or use the device at home. Alarm, light, or sound to notify the device's status may be interfered by ambient sound and light from other devices and activities at home, such as television, cooking, or pet.

Several studies demonstrated methodologies to explore users' insight, break-down tasks, and analyze user cognitive behavior [120]–[124] to help designers understand how the lay users use and interact with the device. Suggested by FDA and seen by many papers in the reviewing period, Human factor engineering was a domain that applied to understand lay users, uses, and context of use. FDA and those papers underlined the safety and effective use of the device as the primary goal of device development. Evidently, from reviewed papers, the studies revealed that thirteen medical products had been redesigned to improve user interface, device interactive, and device connection to the network to improve safety and effectiveness from their predecessor version. However, studies [6], [8] reported that in industrial practice to develop medical devices, human factor engineering, and user involvement would be done only when it is mandatory by regulating agencies. Further education in new regulation and increasing awareness of HFE plays an essential role in the success of future home use medical devices.

5.3. The Nature of Incremental Innovation in Medical Device Development

Several extracted papers pointed out that the development of the medical device was following the incremental innovation trajectory. MDD has its nature relied on several iterations improving from its predecessors. An interpretation is because MDD is complex, resource- and time-consuming, and involved rigid regulations and standards. Furniss [124] claimed that Computer evolution occurred in the historical development of the Blood glucose meter, as showed in Appendix B, Table B-2. The development trajectory of medical devices extracted from this review study supported the Computer evolution concept. Several studies highlighted the development of medical devices to improve user interface and user interaction based on previous version, as shown in Appendix B, Table B-3.

The concept can be a guideline for a new generation of IOT home use medical devices. The new generation can be re-designed to meet a specific goal in an interface, interaction, or communication with the device using IOT sensing and connecting functionalities. The capabilities of IOT can help to unlock some features and expand the usability of the device that the previous standalone generation is not able to do. The concept allows the design team especially, a small and medium-sized enterprise or medical startups who has a limited budget, time, and resources, to focus on important development target in the current and upper layer while keeping the previously approved layers remain untouched. Information gathered from previous versions, including adverse events reported by users, can be used as an idea generation for functionality in the next network-connected generation.

5.4. Adopting IOT Technology to Medical Device Development (MDD)

The convergence of new technologies has created new hope to extend the reach of- and empower- consumer to become a partner of healthcare service. The use of emerging technologies to support the achievement of self-test or home use medical device will help to transform the face of health service across the globe. Internet-Of-Things is one of the emerging technologies which has highly promising potential to deliver such capability. In the discussion here concerning the research question on the guideline to adopt IOT technology to MDD, the findings from this systematic review lead to further discussion underlining several important points regarding the adoption of IOT technology.

5.4.1. IOT technology is adding new unique risks to MDD

A medical device equipped with IOT technology is more complicated and vulnerable to risks in safety and privacy concern issues resulting from the technology. Device developers must concern what would happen if

the device lost connection with the internet, possibilities to create any harm to the users due to loss of connection and interference from other RF devices, susceptibility to cybersecurity attack, or uses of personal health information without consent by the users. Regulatory agencies require wireless medical devices must comply with RF regulations and standards. For instance, in the United States, FDA created a joint statement with the Federal Communications Commission (FCC), requested wireless medical device must comply under FCC Part 15 rules, as well as several standards and guidelines for risk consideration of wireless medical device development and operation such as AAMI/ANSI/IEC TIR 80001-2-3:2012, and FCC: Connect2HealthFCC - Wireless Health and Medical Devices Background [141]. Consequently, the development of IOT medical devices must concern the risks from IOT adoption and integrate risk management and control design to ensure the safe and effective use of the devices.

Table 5. This table presents the design attribute or design characteristics of medical devices affecting user adherence and acceptance.

Study	Device type	Intended user	Feedbacks on design attribute/design characteristics of medical devices regarding user acceptance.
Schaeffer (2012)	A new user interface design of t:slimTM insulin delivery system (insulin pump)	Professional & Lay users	Touch screen with a graphical user interface home screen, and active confirmation screens to prevent incorrect data entry
De Ana et al. (2013), AND	New design of low-intensity pulsed ultrasound (LIPUS) bone healing	Lay users	The simplicity of device operation.
Pounder, Jones and Tanis (2016)	(same device as De Ana et. al.)	Lay users	A visible and reminding calendar helps patients manage their treatment at home, and remote monitoring to support communication between families and professionals. Collected data logs from actual devices to analyze the behavior of patients.
Lang et al. (2013, 2014)	CF (cystic fibrosis) physiotherapy device.	Lay users	Feedback from the device, remote monitoring technologies, gaming and simulation, design for privacy, social acceptance
Rajkomar et al. (2014)	Home haemodialysis machines	Lay users	Features to help patients manage their dialysis (e.g., providing timely reminders of next steps) and features to support communication between families and professionals (e.g., through remote monitoring).
Kelly and Matthews (2014)	Insulin injection systems (Novo Nordisk), and Hearing aids (Oticon)	Lay users	Alternative interpretations of the medical devices apart of use but influencing the use of the device, e.g., the relationship between the user, device, his/her condition, healthcare professionals, and other users.
Lyons and Blandford (2018)	Infusion pumps being used in patients' homes	Professional & Lay users	Improving patient safety by providing better feedback to identifying troubleshoot problems and easy access to monitor and technical support by front-line professionals.

5.4.2. IOT technology is adding a new discipline to MDD.

Regarding the unique risks from wireless communication as discussed, a new discipline of IOT engineering is required to integrate with medical device development team. The selection of IOT technologies to embed in an IOT medical device may have a more profound perspective to consider. The advantages of the technologies and their limitation, privacy and safety concerns, or cost added to the device may need to select and consider by the design team members together thoroughly. Multidisciplinary problems may occur at either current medical device developers or with the IOT engineers. These barriers are difficult to overcome for either an existing medical device manufacturing or new medical device technology startups, especially for small, technology-led, or startup medical device companies with less experience and limited resources.

The tools and methodologies proposed by the reviewed study would help to be a guideline to improve communication, involvement, and collaboration among stakeholders. Design tools, for instance, boundary objects, persona, scenario, and so on, which are used in consumer products, were applied to MDD to improve communication among design members and help them to understand the user and user context. On the other hand, boundary objects like technology prototypes would also help designers and users who have no or minimum experience with IOT technology to understand how it

works. The studies from Lemke [140] and Sjöman [139] had developed prototypes to demonstrate the ideas to users and potential partners based on the Arduino toolkit. Further studies on technology prototypes to work as an intermediating representative and boundary object for IOT technology to help in home use medical device design may be an area to help close the communication gap between designers and users.

5.4.3. User research in the context of patient as a consumer

In the clinical setting, the customer and user may not be the same person. The customer usually was referred to purchase, senior healthcare staff involved in the purchasing decision of a medical device. While the user may be referred to healthcare staff who use the device or patient who received the medical service [6], [8]. Therefore, the medical device manufacturing allocated the resource to respond to the customers' needs (senior healthcare staff, reimbursement) who make the purchase decision rather than the user (patient or operational staff). Information collected from the user (through the customer) to develop a medical device might not entirely reflect real needs and wishes. In a home-use medical device, the patient is the person who is responsible for using the device and adhering to the routine health activities. The concept of patient as a consumer was introduced to understanding the user, use, and context of use [14, 15]. Therefore, the center of the design shifted from the healthcare staff to the user, as showed in Fig. 6. As medical devices migrate from healthcare facilities into patients' homes, some studies are centered on lay-users and the context of use in home setting, revealing other factors than effective and safe use influencing user adherence [126], [128], [130], [131], [134], [136]. Successful devices may require a different approach more than make devices usable. The empirical study by Haydock [137] confirmed that user acceptance influencing by subjective user perceptions plays a critical role in medical device adoption.

Even though user research is essential, the research is a time- and resource-consuming process, requiring specific knowledge, expertise, and experience. Besides, there is no guarantee that the outcome of any user involvement will be positive [91]. For technology-intensive spin-offs or small engineering companies who bought new technology to the market, the companies tentatively do not have enough resources or user research expertise. The companies may not focus on applying user research in the early phase of the development process. The outcome from a case study by Martin and Barnett [117] exhibited a problem in applying user research in a breakthrough technological product development process. The case also demonstrated that technology-intensive companies relied on the technology-push model and dedicating resources to technology development.

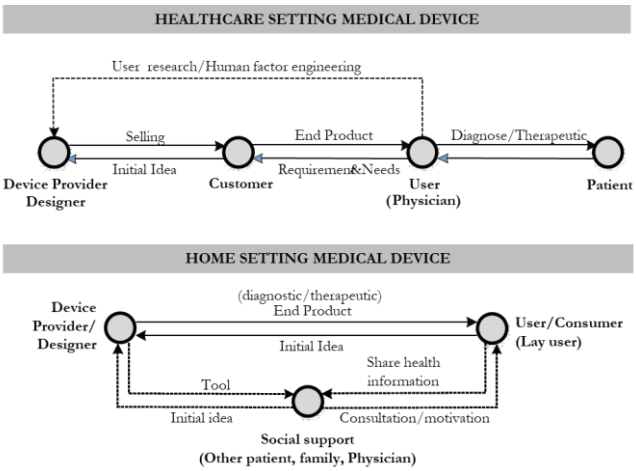

Fig. 6. This figure exhibits the relationship among stakeholder in clinical-setting and home-setting medical device development.

5.5. Developing IOT Home Use Medical Device to Gain User Acceptance

For home use medical devices, user acceptance becomes a critical step for home users to adopt the devices to use in their daily life. Previous studies contributed to exploring factors influencing user acceptance of connected, wearable, mobile-based, or IOT devices. Some studies in this review confirmed the factors, as exhibited in Table 4. Some studies uncovered the design attributes or design characteristics of the devices, leading to user acceptance, as demonstrated in Table 5. For example, IOT communication capabilities providing remote monitoring to a medical device may offer technical support, which results in increasing perceived ease-of-use. The communication function may also enhance the patient-practitioner relationship or help to share health information among family members, which may increase social support. Existing studies highlighted that IOT products implemented with IOT functions would have characteristics that affect users' feelings and understanding, including both functional experience and emotional experience, and resulting in intention to purchase [62], [63].

However, the new product development processes, design processes, and design methodologies extracted in this review did not consider those device characteristics, the factors, or frameworks to design a home use medical device to gain user acceptance in the early stage of the device development. The outcomes from the factors influencing user acceptance studies were not yet a subject matter when design a new IOT home use medical device. Another risk of home user not accepting to use a home use IOT device even if it has excelled objective functions cannot be overseen.

Finding from this review study pointed out that a design process for IOT home use medical devices to gain user acceptance should have a framework encompassing idea generation from IOT functions, IOT device attributes to factors influencing user acceptance. The design process should suggest a methodology to consider

how can IOT functions and IOT device attributes increase targeted positive factors (such as perceived ease-of-use, perceived usefulness, social norm) or reduce the unwanted negative factors (such as privacy concern) resulting in gaining user acceptance. Concerning that the factors may vary depend on demographic, socio-technology, objective of use, or the type of device, the design process should also provide a comprehensive guideline with concreted measurement, test, tools, or methodology to verify or validate the idea prototype in the new product development's conceptual phase. The process should be easy to understand and implement with low resources and less experience in user research design team, such as by technology startup companies.

The design process may either use for newly IOT home use medical device development to ensure the technology will be accepted by home users, or new version equipped with IOT technology from existing home use medical devices following Computer evolution concept.

6. Conclusions

This study focused on the development of IOT home use medical device, inspired by the remarkable increasing number of consumers decided to use smartphones, wearable devices, or IOT devices to assist in their daily health activities. The IOT home use medical devices already showed potential benefits to improve clinical outcomes of remote patient monitoring, telemedicine, and home healthcare [24], [41]–[43].

To the academic knowledge, this systematic review study encompassed from the definition of home use medical device, the needs in developing home use medical device for lay-users, and the potential of IOT technology in providing connecting, sensing, and ability to track health behavior to help people to maintain good condition and well-being. This study then narrowed down its interest to explore how to adopt IOT technology in medical device development. By reviewing journal papers related to the medical device new product development, design process, and design methodology, the PRISMA-P systematic review framework was applied to search and analyze existing studies related to medical device product development. The extracted studies delineated the advancement in medical device development during the reviewing period. The studies exhibited the nature of medical device development, existing new product development, design process, and design methodologies. The findings showed that the primary objective of medical device development was to design medical devices for safe and effective use. In the discussion, this study proposed the effect of IOT adoption on risk identification, risk management, multidisciplinary in MDD. Finally, a guideline to construct the design process for IOT home use medical devices to gain user acceptance was outlined.

7. Suggestion for Future Works

Although several processes, methodologies, and techniques were proposed, the body of knowledge in these areas is still emerging, fluid, and expanding, leaving a considerable gap in academic research on this topic. Several issues remain unidentified. Hence, this study proposed that future research in developing IOT home use medical devices to gain user acceptance may fall into two areas.

Firstly, future studies should be conducted to identify, assess, manage, and control unique risks emerging from adopting IOT to home use medical devices. The studies in integrating IOT discipline in device development, exploring barriers and problems in communication in a multidisciplinary design team, or using technical prototypes to solve the communication problems would benefit future IOT home use medical device development.

Secondly, further studies to construct a design process considering IOT functionalities and IOT device attributes to gain user acceptance of IOT home use medical device to the conceptual phase would help design teams, particularly from small technology-led companies with limited experience and low resources.

8. Limitations

Limitations in the review framework are around the minimum experience and skills of the first author in the academic research, the keywords used, limitations in the electronic databases used, and the protocol of the review. The eligible criteria to extract only journal papers published in English would limit the studies in other languages and conference papers.

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Conflicts of Interest

None declared.

Abbreviations

AAMI: the American association of medical instrumentation
ANSI: the American National Standards Institute
FDA: The Food and Drug Administration (refer to the U.S. FDA)
HFE: Human Factor Engineering
IOT: Internet-Of-Things
IOMT: Internet-Of-Medical-Things
LIPUS: low-intensity pulsed ultrasound
MAUDE: the FDA's Manufacturer and User Facility Device Experience
MDD: Medical device development

MTPCs: Medical Tablet Personal Computers
NCDs: non-communicable diseases
NPD: New product development
TRIZ: the Russian acronym for the Theory of Inventive Problem Solving [142]
UE: Usability Engineering
UCD: User-centered design

References

[1] FDA, "Medical Device Home Use Initiative," 2010.

[2] N. M. Holekamp, "Moving from clinic to home: What the future holds for ophthalmic telemedicine," *Am. J. Ophthalmol.*, vol. 187, pp. xxviii–xxxv, 2018.

[3] T. Kobayashi, H. Maita, and H. Kato, "Medical ecology in near future of rapidly aging Japan: Projected scenario," *Technol. Forecast. Soc. Change*, vol. 137, pp. 327-329, 2018.

[4] A. Ryan, A. Taylor, and S. Greenfield, "Factors associated with self-care activities among adults in the United Kingdom: A systematic review," *BMC Public Health*, vol. 9, no. 96, pp. 1–10, 2009.

[5] WHO, "Noncommunicable diseases," 2018. [Online]. Available: http://www.who.int/en/news-room/fact-sheets/detail/noncommunicable-diseases. [Accessed: 14-Sep-2018].

[6] A. G. Money, J. Barnett, J. Kuljis, M. P. Craven, J. L. Martin, and T. Young, "The role of the user within the medical device design and development process: Medical device manufacturers' perspectives," *BMC Med. Inform. Decis. Mak.*, vol. 11, no. 1, 2011.

[7] M. Privitera, "Designing industrial design in the highly regulated medical device development process. Defining our valuable contribution towards usability," *Des. J.*, vol. 20, no. sup1, pp. S2190–S2206, 2017.

[8] M. B. Privitera, M. Evans, and D. Southee, "Human factors in the design of medical devices – Approaches to meeting international standards in the European Union and USA," *Appl. Ergon.*, vol. 59, pp. 251–263, 2017.

[9] FDA, "Design Considerations for Devices Intended for Home Use - Guidance for Industry and Food and Drug Administration Staff," pp. 1–23, 2014.

[10] FDA, "Applying human factors and usability engineering to medical devices: Guidance for industry and FDA staff," pp. 1–37, 2016.

[11] A. S. Cifter, H. Donglong, and J. Barnett, "Designing home use medical devices: The challenges and its requirements," in *Proceeding of IASDR2011, the 4th World Conference on Desgin Reserach*, Oct. 2011, pp. 1–13.

[12] R. P. D. Burton and T. Hudson, "Achieving individually sustained commitment to treatment through self-constructed models of medical adherence," *Sociol. Spectr.*, vol. 21, no. 3, pp. 393–422, 2001.

[13] M. Swan, "Health 2050: The realization of personalized medicine through crowdsourcing, the quantified self, and the participatory biocitizen," *J. Pers. Med.*, vol. 2, no. 3, pp. 93–118, 2012.

[14] K. S. Karn and A. Golaszewski, "Power and value of consumer product development techniques when applied to medical devices," in *Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care*, 2016, vol. 5, no. 1, pp. 72–75.

[15] G. K. Garge, C. Balakrishna, and S. K. Datta, "Consumer health care: Current trends in consumer health monitoring.," *IEEE Consum. Electron. Mag.*, vol. 7, no. 1, pp. 38–46, 2017.

[16] E. Chiauzzi, C. Rodarte, and P. DasMahapatra, "Patient-centered activity monitoring in the self-management of chronic health conditions," *BMC Med.*, vol. 13, no. 1, pp. 1–6, 2015.

[17] S. Lomborg and K. Frandsen, "Self-tracking as communication," *Inf. Commun. Soc.*, vol. 19, no. 7, pp. 1015–1027, 2016.

[18] C. C. Quinn, R. Royak-Schaler, D. Lender, N. Steinle, S. Gadalla, and M. Zhan, "Patient understanding of diabetes self-management: Participatory decision-making in diabetes care," *J. Diabetes Sci. Technol.*, vol. 5, no. 3, pp. 723–730, 2011.

[19] C. C. Quinn, P. L. Sareh, M. L. Shardell, M. L. Terrin, E. A. Barr, and A. L. Gruber-Baldini, "Mobile diabetes intervention for glycemic control: Impact on physician prescribing," *J. Diabetes Sci. Technol.*, vol. 8, no. 2, pp. 362–370, 2014.

[20] C. C. Quinn, M. D. Shardell, M. L. Terrin, E. A. Barr, S. H. Ballew, and A. L. Gruber-Baldini, "Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control," *Diabetes Care*, vol. 34, no. 9, pp. 1934-, 2011.

[21] J. D. Piette *et al.*, "Hypertension management using mobile technology and home blood pressure monitoring: Results of a randomized trial in two low/middle-income countries," *Telemed. e-Health*, vol. 18, no. 8, pp. 613–620, 2012.

[22] K. Mercer, L. Giangregorio, E. Schneider, P. Chilana, M. Li, and K. Grindrod, "Acceptance of commercially available wearable activity trackers among adults aged over 50 and with chronic illness: A mixed-methods evaluation," *JMIR mHealth uHealth*, vol. 4, no. 1, p. e7, 2016.

[23] A. Marakhimov and J. Joo, "Consumer adaptation and infusion of wearable devices for healthcare," *Comput. Human Behav.*, vol. 76, pp. 135–148, 2017.

[24] E. G. Spanakis, S. Santana, M. Tsiknakis, K. Marias, V. Sakkalis, A. Teixeira, J. H. Janssen, H. de Jong, and C. Tziraki, "Technology-Based Innovations to Foster Personalized Healthy Lifestyles and Well-Being : A Targeted Review," *J. Med. Internet Res.*, vol. 18, no. 6, pp. 1–26, 2018.

[25] K. Philip and S. C. Peres, "Evaluation of home health care devices: Remote usability assessment," *JMIR Human Factors*, vol. 2, no. 1, p. e10, 2015.

[26] C. Grönloh, G. Myreteg, A. Cajander, and H. Rexhepi, "'Why do they need to check me?' Patient participation through ehealth and the doctor-patient

relationship: Qualitative study," *J. Med. Internet Res.*, vol. 20, no. 1, 2018.

[27] K. K. Patel and S. M. Patel, "Internet of Things-IOT : Definition, characteristics, architecture, enabling technologies, application & future challenges," *Int. J. Eng. Sci. Comput.*, vol. 6, no. 5, pp. 6122–6131, 2016.

[28] B. Xu, L. Da Xu, H. Cai, C. Xie, J. Hu, and F. Bu, "Ubiquitous data accessing method in IoT-based information system for emergency medical services," *IEEE Trans. Ind. Informatics*, vol. 10, no. 2, pp. 1578–1586, 2014.

[29] B. Dorsemaine, J. Gaulier, and P. Urien, "Internet of Things : A definition & taxonomy," in *2015 9th International Conference on Next Generation Mobile Applications, Services and Technologies*, 2015, pp. 72–77.

[30] F. Fleisch, E. Weinberger, and M. Wortmann, *Business Models and the Internet of Things*. Springer, Cham., 2014.

[31] C. Suppatvech, J. Godsell, and S. Day, "The roles of internet of things technology in enabling servitized business models: A systematic literature review," *Ind. Mark. Manag.*, vol. 82, pp. 70-86, 2019.

[32] S. Amendola, R. Lodato, S. Manzari, C. Occhiuzzi, and G. Marrocco, "RFID technology for IoT-based personal healthcare in smart spaces," *IEEE Internet Things J.*, vol. 1, no. 2, pp. 144–152, 2014.

[33] K. Natarajan, B. Prasath, and P. Kokila, "Smart health care system using Internet of Things," *J. Netw. Commun. Emerg. Technol.*, vol. 6, no. 3, pp. 37–42, 2016.

[34] Y. Liu, J. Niu, L. Yang, and L. Shu, "EBPlatform: An IoT-based system for NCD patients homecare in China," in *2014 IEEE Glob. Commun. Conf. GLOBECOM 2014*, 2014, pp. 2448–2453.

[35] Accenture Consulting, "Digital Health, Accenture 2017 Internet of Health Things Survey: Invest today to grow tomorrow," 2017.

[36] I. Brown and A. A. Adams, "The ethical challenges of ubiquitous healthcare," *Int. Rev. Inf. Ethics*, vol. 8, no. 12, pp. 53–60, 2007.

[37] W. Yuan, D. Guan, and S. Lee, "Using reputation system in ubiquitous healthcare," in *2007 9th International Conference on e-Health Networking, Application and Services*, 2007, pp. 182–186.

[38] F. Touati and R. Tabish, "U-Healthcare System: State-of-the-art review and challenges," *J. Med. Syst.*, vol. 37, no. 3, 2013.

[39] L. Goode, "Apple Watch 4 adds ECG, EKG, and more heart-monitoring capabilities,"*Wired.com*, pp. 1–11, 2018.

[40] C. Farr, "The Apple Watch is getting a new feature that can monitor heart health — here's why that matters," *TECH, CNBC.com*, pp. 1–5, Sep. 11, 2018.

[41] G. Manning and R. Donnelly, "Use of home blood-pressure monitoring in the detection, treatment and surveillance of hypertension," *Curr. Opin. Nephrol. Hypertens.*, vol. 14, no. 6, pp. 573–578, 2005.

[42] D. C. Christodouleas, B. Kaur, and P. Chorti, "From point-of-care testing to eHealth diagnostic devices (eDiagnostics)," *ACS Cent. Sci.*, vol. 4, no. 12, pp. 1600–1616, 2018.

[43] P. Khosravi and A. H. Ghapanchi, "Investigating the effectiveness of technologies applied to assist seniors: A systematic literature review," *Int. J. Med. Inform.*, vol. 85, no. 1, pp. 17–26, 2016.

[44] V. Bhuvaneswari and R. Porkodi, "The internet of things (IOT) applications and communication enabling technology standards: An overview," in *Proc. 2014 Int. Conf. Intell. Comput. Appl. ICICA 2014*, pp. 324–329.

[45] F. Samie, L. Bauer, and J. Henkel, "IoT technologies for embedded computing: A survey," in *2016 International Conference on Hardware/Software Codesign and System Synthesis (CODES+ ISSS)*, 2016, pp. 1–10.

[46] R. Sanchez-Iborra and M. D. Cano, "State of the art in LP-WAN solutions for industrial IoT services," *Sensors*, vol. 16, no. 5, 2016.

[47] M. S. Mahmoud and A. A. H. Mohamad, "A study of efficient power consumption wireless communication techniques/ Modules for Internet of Things (IoT) applications," *Adv. Internet Things*, vol. 06, no. 02, pp. 19–29, 2016.

[48] S. Sen, J. Koo, and S. Bagchi., "TRIFECTA: Security, energy efficiency, and communication capacity comparison for wireless IoT devices," *IEEE Internet Comput.*, vol. 22, no. 1, pp. 74–81, 2018.

[49] Y. Yin, Y. Zeng, X. Chen, and Y. Fan, "The internet of things in healthcare: An overview," *J. Ind. Inf. Integr.*, vol. 1, pp. 3–13, 2016.

[50] M. Paschou, E. Sakkopoulos, E. Sourla, and A. Tsakalidis, "Health Internet of Things: Metrics and methods for efficient data transfer," *Simul. Model. Pract. Theory*, vol. 34, pp. 186–199, 2013.

[51] S. M. R. Islam, D. Kwak, H. Kabir, M. Hossain, and K.-S. Kwak, "The Internet of Things for health care: A comprehensive survey," *IEEE Access*, vol. 3, pp. 678–708, 2015.

[52] R. Harte, L. Glynn, B. Broderick, A. Rodriguez-Molinero, P. Baker, B. McGuiness, L. O'Sullivan, M. Diaz, L. Quinlan, and G. ÓLaighin, "Human centred design considerations for connected health devices for the older adult," *J. Pers. Med.*, vol. 4, no. 2, pp. 245–281, 2014.

[53] F. Qureshi and S. Krishnan, "Wearable hardware design for the Internet of Things (IoMT)," *Sensors*, vol. 18, no. 11, p. 3812, 2018.

[54] M. D. Steinberg, P. Kassal, I. Kereković, and I. M. Steinberg, "A wireless potentiostat for mobile chemical sensing and biosensing," *Talanta*, vol. 143, pp. 178–183, 2015.

[55] J. Morak, H. Kumpusch, D. Hayn, R. Modre-Osprian, and G. Schreier, "Design and evaluation of a telemonitoring concept based on NFC-enabled mobile phones and sensor devices," *IEEE Trans. Inf. Technol. Biomed.*, vol. 16, no. 1, pp. 17–23, 2012.

[56] E. Jovanov and A. Milenkovic, "Body area networks for ubiquitous healthcare applications:

Opportunities and challenges," *J. Med. Syst.*, vol. 35, no. 5, pp. 1245–1254, 2011.

[57] S. M. R. Islam, D. Kwak, M. H. Kabir, M. Hossain, and K. S. Kwak, "The internet of things for health care: A comprehensive survey," *IEEE Access*, vol. 3, pp. 678–708, 2015.

[58] N. Mohammadzadeh and R. Safdari, "Mobile health monitoring," in *Mobile Health Technologies - Theories and Applications*. IntechOpen, 2016, pp. 79–96.

[59] H. Vanegas-Serna, J. C. Perez, and J. J. Andrade-Caicedo, "Managing heterogeneous medical data: Learning from experiences in telemedicine," in *VII Latin American Congress on Biomedical Engineering CLAIB 2016*, Bucaramanga, Santander, Colombia, 2017, pp. 670-673.

[60] G. J. Joyia, R. M. Liaqat, A. Farooq, and S. Rehman, "Internet of medical things (IOMT): Applications, benefits and future challenges in healthcare domain," *J. Commun.*, vol. 12, no. 4, pp. 240–247, 2017.

[61] P. A. Catherwood, D. Steele, M. Little, S. Mccomb, and J. Mclaughlin, "A Community-based IoT personalized wireless healthcare solution trial," *IEEE J. Transl. Eng. Heal. Med.*, vol. 6, no. May, pp. 1–13, 2018.

[62] Y. Chang, X. Dong, and W. Sun, "Influence of characteristics of the Internet of Things on consumer purchase intention," *Soc. Behav. Personal. an Int. J.*, vol. 42, no. 2, pp. 321–330, 2014.

[63] L. H. C. Pinochet, E. L. Lopes, C. H. F. Srulzon, and L. M. Onusic., "The influence of the attributes of 'Internet of Things' products on functional and emotional experiences of purchase intention," *Innov. Manag. Rev.*, vol. 15, no. 3, pp. 303–320, 2018.

[64] I. C. T. Santos, "Product development methodologies: The case of medical devices," doctoral dissertation, the Faculdade de Engenharia da Universidade do Porto, 2013.

[65] S. K. Gupta, "Medical device regulations: A current perspective," *J. Young Pharm.*, vol. 8, no. 1, pp. 6–11, 2016.

[66] M. Cheng, *Medical Device Regulations: Global Overview and Guiding Principles*. World Health Organization, 2003.

[67] J. A. Johnson, "FDA Regulation of Medical Devices," 2016.

[68] K. Holtta-Otto, M. Saunders, and C. Seepersad, "The characteristics of innovative, medical devices," in *Transactions of the ASME-W-Journal of Medical Devices*, vol. 4, no. 2, p. 027519, 2010.

[69] A. Manbachi *et al.*, "Starting a medical technology venture as a young academic innovator or student entrepreneur," *Ann. Biomed. Eng.*, vol. 46, no. 1, pp. 1–13, 2018.

[70] A. J. E. De Veer, J. M. Peeters, A. E. M. Brabers, F. G. Schellevis, J. J. J. Rademakers, and A. L. Francke, "Determinants of the intention to use e-Health by community dwelling older people," *BMC Health Serv. Res.*, vol. 15, no. 1, pp. 1–9, 2015.

[71] M. Cimperman, M. M. Brenčič, P. Trkman, and M. de L. Stanonik, "Older adults' perceptions of home telehealth services," *Telemed. e-Health*, vol. 19, no. 10, pp. 786–790, 2013.

[72] M. Cimperman, M. M. Brenčič, and P. Trkman, "Analyzing older users' home telehealth services acceptance behavior — Applying an extended UTAUT model," *Int. J. Med. Inform.*, vol. 90, pp. 22–31, 2016.

[73] C. Liddy, J. J. Dusseault, S. Dahrouge, W. Hogg, J. Lemelin, and J. Humber, "Telehomecare for patients with multiple chronic illnesses Pilot study Recherche Télé-monitorage à domicile pour patients souffrant de plusieurs maladies chroniques," *Can. Fam. Physician*, vol. 54, no. 1, pp. 58–65, 2008.

[74] J. Lee and J. Lim, "The prospect of the fourth industrial revolution and home healthcare in super-aged society," *Ann. Geriatr. Med. Res.*, vol. 21, no. 3, pp. 95–100, 2017.

[75] J. Li, Q. Ma, A. H. Chan, and S. S. Man, "Health monitoring through wearable technologies for older adults: Smart wearables acceptance model," *Appl. Ergon.*, vol. 75, pp. 162–169, 2019.

[76] Y. Gao, H. Li, and Y. Luo, "An empirical study of wearable technology acceptance in healthcare," *Ind. Manag. Data Syst.*, vol. 115, no. 9, pp. 1704–1723, 2015.

[77] F. A. Bin Azhar and J. S. Dhillon, "A systematic review of factors influencing the effective use of mHealth apps for self-care," in *2016 3rd Int. Conf. Comput. Inf. Sci. ICCOINS 2016 - Proc.*, pp. 191–196.

[78] M. Kalantari, "Consumers' adoption of wearable technologies: Literature review, synthesis, and future research agenda," *Int. J. Technol. Mark.*, vol. 12, no. 3, pp. 274–307, 2017.

[79] D. Pal, S. Funilkul, and N. Charoenkitkarn, "Internet-of-Things and smart homes for elderly healthcare: An end user perspective," *IEEE Access*, vol. 6, pp. 10483–10496, 2018.

[80] N. Sun and P. P. Rau, "The acceptance of personal health devices among patients with chronic conditions," *Int. J. Med. Inform.*, vol. 84, no. 4, pp. 288–297, 2015.

[81] R. B. Wiegard and M. H. Breitner, "Smart services in healthcare: A risk-benefit-analysis of pay-as-you-live services from customer perspective in Germany," *Electron. Mark.*, pp. 1–17, 2017.

[82] Z. Deng, X. Mo, and S. Liu, "Comparison of the middle-aged and older users' adoption of mobile health services in China," *Int. J. Med. Inform.*, vol. 83, no. 3, pp. 210–224, 2014.

[83] T. Prayoga and J. Abraham, "Behavioral intention to use IoT health device: The role of perceived usefulness, facilitated appropriation, big five personality traits, and cultural value orientations," *Int. J. Electr. Comput. Eng.*, vol. 6, no. 4, pp. 1751–1765, 2016.

[84] H. Lin, J. Chiou, C. Chen, and C. Yang, "Computers in human behavior understanding the impact of nurses' perception and technological capability on

nurses ' satisfaction with nursing information system usage : A holistic perspective of alignment," *Comput. Human Behav.*, vol. 57, pp. 143–152, 2016.

[85] H. Yang, J. Yu, H. Zo, and M. Choi, "User acceptance of wearable devices: An extended perspective of perceived value," *Telemat. Informatics*, vol. 33, no. 2, pp. 256–269, 2016.

[86] J. Li, Q. Ma, A. H. S. Chan, and S. S. Man, "Health monitoring through wearable technologies for older adults: Smart wearables acceptance model," *Appl. Ergon.*, vol. 75, pp. 162–169, 2019.

[87] M. Williams, J. R. C. Nurse, and S. Creese, "'Privacy is the Boring Bit': User perceptions and behaviour in the Internet-of-Things," in *15th Int. Conf. Privacy, Secur. Trust*, Aug. 2017.

[88] I. Psychoula, D. Singh, L. Chen, F. Chen, A. Holzinger, and H. Ning, "Users' privacy concerns in IoT based applications," in *Proc. 2018 IEEE SmartWorld, Ubiquitous Intell. Comput. Adv. Trust. Comput. Scalable Comput. Commun. Cloud Big Data Comput. Internet People Smart City Innov. SmartWorld/UIC/ATC/ScalCom/CBDCo*, pp. 1887–1894.

[89] H. Li, J. Wu, Y. Gao, and Y. Shi, "Examining individuals' adoption of healthcare wearable devices: An empirical study from privacy calculus perspective," *Int. J. Med. Inform.*, vol. 88, no. 555, pp. 8–17, 2016.

[90] F. A. Bin Azhar and J. S. Dhillon, "A systematic review of factors influencing the effective use of mHealth apps for self-care," in *2016 3rd International Conference on Computer and Information Sciences, ICCOINS 2016 - Proceedings*, 2016, pp. 191–196.

[91] S. Ghulam, 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.

[92] J. van der Peijl, J. Klein, C. Grass, and A. Freudenthal, "Design for risk control: The role of usability engineering in the management of use-related risks," *J. Biomed. Inform.*, vol. 45, no. 4, pp. 795–812, 2012.

[93] R. G. Cooper and E. J. Kleinschmidt, "An Investigation into the new product process: Steps, deficiencies, and impact," *J. Prod. Innov. Manag.*, vol. 3, no. 2, pp. 71–85, 1986.

[94] R. G. Cooper, "Stage-Gate Systems: A new tool for managing new products," *Bus. Horiz.*, vol. 33, no. 3, pp. 44–54, 1990.

[95] W. Rochford and L. Rudelius, "New product development process: Stages and successes in the medical products industry.," *Ind. Mark. Manag.*, vol. 26, no. 1, pp. 67–84, 1997.

[96] FDA, "FDA Design Control Guidance for Medical Design Manufacturers," 1997.

[97] K. Alexander and P. J. Clarkson, "Good design practice for medical devices and equipment, Part II : design for validation," *J. Med. Eng. Technol.*, vol. 24, no. 2, pp. 53–62, 2000.

[98] K. Alexander and P. J. Clarkson, "A validation model for the medical devices industry," *J. Eng. Des.*, vol. 13, no. 3, pp. 197–204, 2002.

[99] M. E. Wilcox and S. B. Wiklund, *Designing Usability Into Medical Products*. CRC Press, 2005.

[100] P. J. Ogrodnik, "Design models," in *Medical Device Design: Innovation from Concept to Market*. Academic Press, 2012, ch. 3.2, pp. 29–37.

[101] M. B. Privitera and D. L. Murray, "Applied ergonomics: Determining user needs in medical device design," in *Proceedings of the 31st Annual International Conference of the IEEE Engineering in Medicine and Biology Society: Engineering the Future of Biomedicine, EMBC 2009*, 2009, pp. 5606–5608.

[102] K. Alexander and P. J. Clarkson, "Good design practice for medical devices and equipment , Part I : a review of current literature," *J. Med. Eng. Technol.*, vol. 24, no. 1, pp. 5–13, 2000.

[103] D. Wynn and J. Clarkson, "Models of designing," in *Design Process Improvement*. London: Springer, 2005, ch. 1, pp. 34–59.

[104] J. A. Cafazzo, K. Leonard, and A. C. Easty, "The user-centered approach in the development of a complex hospital-at-home intervention," *Adv. Inf. Technol. Commun. Heal.*, vol. 143, pp. 328–334, 2009.

[105] R. Harte, L. Glynn, A. Rodríguez-molinero, P. M. A. Baker, and L. R. Quinlan, "A human-centered design methodology to enhance the usability, human factors, and user experience of connected health systems: A three-phase methodology," *JMIR Hum. Factors*, vol. 4, no. 1, p. e8, 2017.

[106] *Ergonomics of Human System Interaction-Part 210: Human-Centred Design for Interactive Systems*, International Standardization Organization (ISO), Switzerland, ISO9241-210: 2010, 2010.

[107] L. Xue *et al.*, "An exploratory study of ageing women's perception on access to health informatics via a mobile phone-based intervention," *Int. J. Med. Inform.*, vol. 81, no. 9, pp. 637–648, 2012.

[108] C. P. H. Ernst and A. W. Ernst, "The influence of privacy risk on smartwatch usage," in *Twenty-second Americas Conference on Information Systems, San Diego,* 2016, pp. 1–10.

[109] E. Grönvall and N. Verdezoto, "Beyond self-monitoring: Understanding non-functional aspects of home-based healthcare technology," in *Proceedings of the 2013 ACM International Joint Conference on Pervasive and Ubiquitous Computing*, 2013, pp. 587–596.

[110] A. Liberati *et al.*, "The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: Explanation and elaboration," *PLoS Med.*, vol. 6, no. 7, 2009.

[111] D. Moher *et al.*, "Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement," *PLoS Med.*, vol. 6, no. 7, pp. 1–6, 2009.

[112] V. Barbari, L. Storari, A. Ciuro, and M. Testa, "Effectiveness of communicative and educative

strategies in chronic low back pain patients: A systematic review," *Patient Educ. Couns.*, vol. 103, no. 5, pp. 908–929, 2020.

[113] J. Pérez, J. Díaz, J. Garcia-Martin, and B. Tabuenca, "Systematic literature reviews in software engineering—Enhancement of the study selection process using Cohen's Kappa statistic," *J. Syst. Softw.*, vol. 168, p. 110657, 2020.

[114] J. B. Pietzsch, L. A. Shluzas, M. E. Paté-Cornell, P. G. Yock, and J. H. Linehan, "Stage-gate process for the development of medical devices," *J. Med. Device.*, vol. 3, no. 2, p. 021004, 2009.

[115] L. A. Medina, G. E. O. Kremer, and R. A. Wysk, "Supporting medical device development: A standard product design process model," *J. Eng. Des.*, vol. 24, no. 2, pp. 83–119, 2013.

[116] F. J. De Ana, K. A. Umstead, G. J. Phillips, and C. P. Conner, "Value driven innovation in medical device design: A process for balancing stakeholder voices," *Ann. Biomed. Eng.*, vol. 41, no. 9, pp. 1811–1821, 2013.

[117] J. L. Martin and J. Barnett, "Integrating the results of user research into medical device development: Insights from a case study," *BMC Med. Inform. Decis. Mak.*, vol. 12, no. 1, 2012.

[118] N. E. Schaeffer, "The role of human factors in the design and development of an insulin pump," *J. Diabetes Sci. Technol.*, vol. 6, no. 2, pp. 260–264, 2012.

[119] S. N. Pedersen, M. E. Christensen, T. J. Howard, S. Nygaard, M. E. Christensen, and T. J. Howard, "Robust design requirements specification: A quantitative method for requirements development using quality loss functions," *J. Eng. Des.*, vol. 27, no. 8, pp. 544–567, 2016.

[120] J. C. Campos, G. Doherty, and M. D. Harrison, "Analysing interactive devices based on information resource constraints," *Int. J. Hum. Comput. Stud.*, vol. 72, no. 3, pp. 284–297, 2014.

[121] D. Healion, E. O. Dowd, and S. Russell, "The Development of a Methodology for Contextual User Research in Healthcare Design Projects," *Stud. Health Technol. Inform.*, vol. 256, pp. 239–249, 2018.

[122] B. R. Larson, P. Jones, Y. Zhang, and J. Hatcliff, "Principles and benefits of explicitly designed medical device safety architecture," *Biomed. Instrum. Technol.*, vol. 51, no. 5, pp. 380–389, 2017.

[123] L. O. Bligård and A. L. Osvalder, "Predictive use error analysis - Development of AEA, SHERPA and PHEA to better predict, identify and present use errors," *Int. J. Ind. Ergon.*, vol. 44, no. 1, pp. 153–170, 2014.

[124] D. Furniss, P. Masci, P. Curzon, A. Mayer, and A. Blandford, "Exploring medical device design and use through layers of Distributed Cognition: How a glucometer is coupled with its context," *J. Biomed. Inform.*, vol. 53, pp. 330–341, 2015.

[125] X. Guo, J. Wang, W. Zhao, and K. Zhang, "Study of medical device innovation design strategy based on demand analysis and process case base," *Multimed. Tools Appl.*, no. 24, pp. 14351–14365, 2016.

[126] J. Kelly and B. Matthews, "Displacing use: Exploring alternative relationships in a human-centred design process," *Des. Stud.*, vol. 35, no. 4, pp. 353–373, 2014.

[127] A. Vincent, C. J. Li, and Y. Blandford, "Integration of human factors and ergonomics during medical device design and development: It' s all about communication," *Appl. Ergon.*, vol. 45, no. 3, pp. 413–419, 2014.

[128] A. R. Lang, J. L. Martin, S. Sharples, and J. A. Crowe, "Medical device design for adolescent adherence and developmental goals: A case study of a cystic fibrosis physiotherapy device," *Patient Prefer. Adherence*, vol. 8, pp. 301–309, 2014.

[129] C. Alppay and A. Hedge, "Development of an Ergonomics checklist for the evaluation of medical tablet personal computers," *Procedia Manuf.*, vol. 3, pp. 21–28, 2015.

[130] A. R. Lang, J. L. Martin, S. Sharples, and J. A. Crowe, "The effect of design on the usability and real world effectiveness of medical devices: A case study with adolescent users," *Appl. Ergon.*, vol. 44, no. 5, pp. 799–810, 2013.

[131] A. Rajkomar, K. Farrington, A. Mayer, D. Walker, and A. Blandford, "Patients' and carers' experiences of interacting with home haemodialysis technology: Implications for quality and safety.," *BMC Nephrol.*, vol. 15, no. 1, pp. 1–12, 2014.

[132] T. Sims, "Participatory design of healthcare technology with children," *Int. J. Health Care Qual. Assur.*, vol. 31, no. 1, pp. 20–27, 2018.

[133] T. J. Hagedorn, I. R. Grosse, and S. Krishnamurty, "A concept ideation framework for medical device design," *J. Biomed. Inform.*, vol. 55, pp. 218–230, 2015.

[134] N. M. Pounder, J. T. Jones, and K. J. Tanis, "Design evolution enhances patient compliance for low-intensity pulsed ultrasound device usage," *Med. Devices Evid. Res.*, vol. 9, pp. 423–427, 2016.

[135] J. Grudin, "The computer reaches out: The historical continuity of interface design.," in *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*, 1990, pp. 261–268.

[136] I. Lyons and A. Blandford, "Safer healthcare at home: Detecting, correcting and learning from incidents involving infusion devices," *Appl. Ergon.*, vol. 67, pp. 104–114, 2018.

[137] M. D. Haydock, A. Mittal, C. F. Wilkes, D. H. Lim, E. Broadbent, and J. A. Windsor, "Interaction between objective performance measures and subjective user perceptions in the evaluation of medical devices: A case study," *Int. J. Technol. Assess. Health Care*, vol. 31, no. 5, pp. 297–303, 2015.

[138] R. J. Caruso and M. Masters, "Applying cyber risk management to medical device design," *Biomed. Instrum. Technol.*, vol. 48, no. s1, pp. 32–37, 2014.

[139] H. Sjöman, J. Kalasniemi, M. Vartiainen, and M. Steinert, "The development of 1Balance: A connected medical device for measuring human balance," *Technologies*, vol. 6, no. 2, p. 53, 2018.

[140] M. Lemke, E. R. Ramírez, and B. Robinson, "How can constraint-induced movement therapy for stroke patients be incorporated into the design of a tangible interface? The case study of the 'Biggest Hit,'" *Des. J.*, vol. 6925, pp. S2315–S2335, 2017.

[141] "Wireless Medical Devices," *Food and Drug Administration (FDA).* [Online]. Available: https://www.fda.gov/medical-devices/digital-health-center-excellence/wireless-medical-devices#7. [Accessed: 10-Nov-2020].

[142] T. Benjaboonyazit, "Systematic approach to arowana gender identification problem using algorithm of inventive problem solving (ARIZ)," *Eng. J.*, vol. 18, no. 2, pp. 13–28, 2014.

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Appendix A: The Boolean statement used in the ScienceDirect advance search of this study.

TAK= (("medical device design*" OR (("design process*" OR "Process model*" OR "product development model*" OR "Product development process*" OR "design practice*") AND ("medical device*" OR "medical equipment"))) AND (NOT ("bio*" OR "nano*)), for research articles refined by published year from 2007 – 2018, only in English.

Appendix B: Tables

Table B-1. Summary of studies referring to the medical device under development by type.

Type of device	Number of devices	Reference papers
Electronic: incremental from existing or previous version	17	van der Peijl et al. (2012), De Ana et al. (2013), Pounder, Jones and Tanis (2016), Schaeffer (2012), Campos, Doherty and Harrison (2014), Rajkomar et al. (2014), Bligård and Osvalder (2014), Kelly and Matthews (2014), Vincent and Blandford (2014, 2015), Alppay and Hedge (2015), Furniss et al., (2015), Schmettow, Schnittker and Schraagen (2017), Larson et al. (2017), Lyons and Blandford (2018)
Electronic: new kind of device	3	Martin and Barnett (2012), Lemke, E. R. Ramírez and Robinson (2017a, 2017b), Sjöman et al. (2018)
Non-Electronics	7	Lang et al. (2013, 2014), Motyl and Filippi (2014), Haydock et al. (2015), Gupta and Pidgeon (2016), Guo et al. (2016), Ríos-zapata et al. (2017), Sims (2018)

Table B-2. This table shows the development trajectory of the Blood Glucose meter following the layers of computer evolution.

The layer of computer evolution (Grudin, 1990)	Evolution of Blood Glucose meter	Period
Layer 1: Hardware	The first blood glucose monitoring meter, Ames Reflectance Meter.	The 1970s
layer 2: Software	The first digital glucose monitoring meter, Ames Dextrometer	The 1980s
layer 3: User interface	Small-sized, portable digital BGM with the various user interface	Late 1990s -2000s
layer 4: Interactive	Several models are equipped with a timely reminder to test, having a special design for adolescents, having audible test results for people who are visually impaired.	The 2000s and beyond
layer 3: Work setting	Capabilities to connect to network or smartphone, enabling health information sharing with remote healthcare professional and family	The 2010s

Table B-3. This table presents a list of electronic medical devices under development or study from extracted papers.

Study	Device type	Context of use	Intended user	Innovation process (Rothwell, 1994)	Computer Evolution level (Grudin, 1990)				
					1	2	3	4	5
van der Peijl et al. (2012)	The user interface for the new high usability version of the Respiratory Care device	Clinical setting	Professional	Market pull			X		
De Ana et al. (2013) Pounder, Jones and Tanis (2016)	New design of low-intensity pulsed ultrasound (LIPUS) bone healing	Home setting	Lay users	Coupling			X	X	
Schaeffer (2012)	The new user interface design of t:slimTM insulin delivery system (insulin pump)	Home setting	Professional & Lay users	Market pull			X	X	
Campos, Doherty, and Harrison (2014)	The user interface of Infusion pumps	Clinical setting	Professional	Market pull			X		
Rajkomar et al. (2014)	Home haemodialysis machines	Home setting	Lay users	Market pull			X	X	X
Bligård and Osvalder (2014)	The home ventilator of the type Continuous Positive Airway Pressure (CPAP)	Home setting	Lay users	Market pull			X	X	
Kelly and Matthews (2014)	Insulin injection systems (Novo Nordisk)	Home setting	Lay users	Market pull				X	
	Hearing aids (Oticon)	Home setting	Lay users	Market pull				X	
Vincent and Blandford (2014, 2015)	Infusion pumps in a healthcare facility	Clinical setting	Professional	Market pull			X	X	
Alppay and Hedge (2015)	Medical Tablet Personal Computers (MTPCs) used by medical doctors	Clinical setting	Professional	Market pull			X	X	X
Furniss et al. (2015)	New network-connected glucometer with interfacing its reading with a central database	Clinical setting	Professional	Market pull			X	X	X
Schmettow, Schnittker and Schraagen (2017)	New syringe pump interface	Clinical setting	Professional	Market pull			X		
Larson et al. (2017)	Open patient-controlled analgesia (OPCA) infusion pump device.	Clinical setting	Professional	Market pull	X	X	X		
Lyons and Blandford (2018)	Infusion pumps being used in patients' homes	Home setting	Professional & Lay users	Market pull			X	X	

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Appendix C. Table C-1. This table presented extracted papers in medical device design new product development process and design process (n=4).

Author(s), year	Principle finding	A key finding	Type of medical device presented in the case study	Research method	Refer or propose an application of HFE/UE/ Ergonomic	Refer to FDA waterfall model	Stage of design process focused
Pietzsch et al. (2009)	The comprehensive State-gate model coverages required processes, methodologies, and regulation for medical device design, shown how to apply the stage-gate process with deliverables and address the iterative process in the classic linear model including Verification and validation.	Apply the stage-gate process with deliverables and address the iterative process in the classic linear model	Ranging from surgical devices to in vitro diagnostic.	Interviews with 80 Professional staff and experts from FDA and medical device companies. ranged from startups to early- stage to major medical manufacturers	In Verification & Validation	Yes	Front-end to back end
van der Peijl et al. (2012)	Provide a detailed description of how to implement IEC62366, ISO14971, and add "definition of criteria" in the user-centered design cycle to perform Iterative UI development with users in the basic waterfall linear model.	"Design for Risk Control," implementation of IEC62366, ISO14971, and waterfall linear model.	UI for new high usability version of existing Respiratory Care device. Used by professionals in the trauma room, emergency department	Case study both formal (documented result) and informal (field observation) project deliverables, compared to design process models from the literature.	Applied IEC 62366 for use-related risk control design.	Yes	Front-end
De Ana et al. (2013)	The design process demonstrated the phases those including divergent and convergent state toward the funnel model. Starting from discovering phase, envision phase, creation phase, and refine phase, the process focused on listening to three distinct voices (VoC, VoB, VoT) to ensure that the final output provided value to all relevant stakeholders that could be considered influencers, decision-makers or users.	A design process that concerns the voices of stakeholders, allowing divergent and convergent state.	A low-intensity pulsed ultrasound (LIPUS) bone healing, to improve patient compliance from a large orthopedic company used by a lay user at home (non-clinical setting)	A case study of a multidisciplinary 17-person tactical team that included internal team members and external members from a product design consulting firm. The project took eight months to complete the research.	HFE specialist as a team member to conduct VOC research	No	Front-end
De Ana, Kremer and Wysk (2013)	A comprehensive design process coverage regulatory, standard, development process, patents, medical specialty aspects have been proposed using conceptual graphic representation in order to provide the need for process completeness and effective communication. The model provided a completed process, sub-processes, the relationship between sub-processes as s a reference tool from novice to experience designers who are new to the development of medical devices.	A comprehensive design process which can be used as a reference model.	General medical devices	The model developed by multiples iterations of document analysis, model reviews by Subject Matter Expert(SME), content validation (Perceived usability test using SUS and observation), and case study implemented in an academic setting to redesign a laparoscopic surgical instrument funded by a biomedical company.	No	Yes	Front-end to back-end

Summary of the studies, ordered by study proposed, then the year of publication.

Table C-2. This table presented extracted papers in medical device design methodology.

Author(s), year	Principle finding	Use, users and use environment	Type of medical device	Research method	Fields of study	Phase of Computer evolution	Stage of design process focused
Pedersen et al. (2016)	Usage of quality loss functions, based on robust design theory, as one of the five principles to visualize a complete set of required information quantified in a single figure.	Not specific	An existing product that had been recently marketed.	The case study at a larger medical device company, studying on Product Specification (PS) of 162 requirements which were analyzed and quantified using the RCI.	A quantitative method of user requirement development	1 to 2	Design, verification & validation process
Guo *et al.* (2016)	The research proposed a process innovation design strategy based on-demand analysis and process case base, constructed an innovation design-oriented web-based process case base system (WPCBS)	Clinical setting, professional users.	A new design of gasbag for Polymorphic rehabilitation training	The model was tested for Polymorphic rehabilitation training evaluation system developed by a university to improve the existing in domestic and foreign rehabilitation training robots	System model, demand/need analysis.	1 to 2	Concept development
Schmettow, Schnittker and Schraagen (2017)	An extended protocol for usability validation testing of a medical device, using normative path deviation and longitudinal dimensions to trace users' progress in the rate of performance improvement with the practice, which cannot be assessed in single-encounter studies.	Clinical setting, professional users.	new syringe pump interface	Conducting a usability validation on a new syringe pump interface with existing products, 25 participants asked to accomplish a set of eight tasks, repeated in three sessions, using the regression model to analyze data.	Usability testing, Human factor engineering, longitudinal test.	3	Design, verification & validation process, post-market.
Lemke, E. Ramírez and Robinson (2017b)	A case demonstrated iterative design. Results suggested by experts for further development, including focusing on "shape" (breaks down the motor objective in small steps) and the use of digital technology to collect usage data and feedback to a user, will help influence the engagement of the patient.	The non-clinical setting, lay users (stroke patient)	A self-directed CIMT for chronic stroke patients with an affected arm, facilitated by radio and digital technology.	A case study of iterative research through the design process to develop the different prototypes of radio and self-directed digital CIMT. The final prototype was evaluated by stroke therapists/clinical expertise in CIMT to validate its usability.	Human-Computer Interaction, industrial design	3 to 4	Concept development
Lemke, E. R. Ramírez and Robinson (20171a)	Traditional design approaches in the design concepts, resulting in five main elements: Restraining the movement, Enhanced repetition, the interaction needs to become more challenging over time, the Feedback Behavior contract, from six students' works on CIMT, showing potential to develop a future product.	Non-clinical setting, lay users (stroke patient)	Self-directed CIMTs for chronic stroke patients with an affected arm as everyday objects.	Six design solution by undergraduate students attended in a design course, for everyday objects CIMT that encourage the use of the affected arm, evaluated by therapists with experience in stroke rehabilitation.	Industrial design	1 to 4	Concept development

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Author(s), year	Principle finding	Use, users and use environment	Type of medical device	Research method	Fields of study	Phase of Computer evolution	Stage of design process focused
Sims (2018)	Conversational methods (BRIDGE) that enable children to share their views and by viewing assent as a continual process. Comparing to ID (based on current cognitive experience) and CI (which trying to treat children as an equal multidisciplinary partnership), child development theories that view children as cognitively immature adults, limiting their participation.	Non-clinical setting, lay users (children).	New prosthetic devices for children and young people by exploring stakeholder views. Parents	The research involved the children, parents, and professionals in children's upper limb prostheses in developing new prototype devices. Children's views sought first with other key stakeholders (parents and professionals) views investigated later in the design process.	Participatory design, engineering design process	3	User needs, concept development, design, verification & validation process
Sjöman et al. (2018)	Prototyping (iterative loops of design-build-test) can improve the communication across disciplines, showing the abstract thinking in concrete prototypes. The aims are also to distinguish and discuss design approaches that are suitable for connected devices, Internet of Things, connecting the external and internal data prototyping loops	Non-clinical setting, lay users (from patient to athlete)	Connected inertial measurement unit (IMU) sensor, Internet of Things.	Based on case studies research by Eisenhardt & Graebner. Participatory Technologies action research using Wayfaring-approach (educated guesses & testing) prototypes creating prototypes that yield that will act as a feedback for all of the multidisciplinary team.	Internet of things, engineering design process, computer engineering	1 to 4	Technology phase, concept development
Healion, Dowd and Russell (2018)	A methodology for contextual user research of human factors involved in healthcare procedures and presentation of the research findings consists of four stages: Project scope, Data collection (Observation, Interview, role-playing, etc.), Data analysis (Sense-making, analog storyboard, etc.), Data presentation (Journey maps, Task analysis, etc.)	Clinical setting, professional users.	Contextual user research finding in healthcare environments and presentation for further device development.	Methodology conducted from academic projects in which students develop solutions to real-world healthcare problems working in collaboration with clinicians, industry partners with direct access to healthcare environments.	Contextual user research, Task analysis, Human factors engineering, ethnographic.	3 to 5	User needs, Concept development
Martin and Barnett (2012)	A case study of conducting a usability engineering research in the product development process to identify clinical needs, target users, and barriers, etc. The research found barriers to implement user research in a design process, including formal decision making based on technical and user needs information.	Clinical setting, professional users.	A new medical imaging device funded by govt. the agency, developed by an experienced SME medical device developer.	The user research was studied using a descriptive in situ approach, as described by Yin. Semi-structured interviews, participant observation at development meetings, document analysis, e.g. of meeting minutes, project plans, and technical reports.	Contextual user research, usability engineering, design process.	3 to 4	Technology phase, user needs, concept development

Author(s), year	Principle finding	Use, users and use environment	Type of medical device	Research method	Fields of study	Phase of Computer evolution	Stage of design process focused
Schaeffer (2012)	A case applied a three-phase Human factors process, "prevention through design," conducting a user-centered design to minimize the user risks and design flaws that could lead to patient errors, adverse events, product recalls, as well as reducing the cost of modification after product launch and increasing ease of use which may increase patient's adherence.	Non-clinical setting, lay users (patient)	The new user interface design of t:slimTM insulin delivery system (insulin pump)	Multiple HF methodologies, e.g., surveys, focus groups, participant journals, video/audio tape recording, follow-up interviews, and real device use testing by SUS, had been used to collect user needs and usability of the new interface.	Human factors /usability engineering, user-centered design process, user interface.	3 to 4	User needs, concept development, design, verification & validation process
Campos, Doherty and Harrison (2014)	A methodology of work/task analysis for interactive devices providing a tool to analyze tasks, constraints, resources needed for a user to perform tasks effectively with concerning on constraint and affordance provide by the device and resource. The tool can be used to comparing to different devices on the same performing tasks.	Clinical setting, professional users.	Two Intravenous infusion pumps in a hospital context.	Comparison of the two Infusion pumps in common use in a hospital using the IVY tool.	Task analysis, Distributed cognition, Human-computer interaction	3 to 4	User needs, concept development, design, verification & validation process
Caruso and Masters (2014)	A template of cybersecurity controls (NIST SP 800-53) integrated with other safety controls forms (ISO 14971) has been proposed to ensure that a connected medical device is safe and secure. The baseline set of controls can also be used to evaluate each candidate technology and to be used as an assessment tool for existing devices.	Cyberspace, network-connected environment	Network-connected medical devices.	Treating each medical device as a network node makes a risk framework to evaluate the risks of network-connected medical devices. The study delineated the concept of an established framework that integrates NIST SP 800-37,-53 with ISO 14971.	Computer security, cybersecurity, risk management framework.	1 to 2	Technology phase, concept development, Design, verification process
Motyl and Filippi (2014)	The study demonstrated the integration of the C-K theory map and TRIZ as creativity enhancement tools in product design. In the conceptual phases of product innovation and development and to explore market information.	Non-clinical setting, professional users & lay users.	Development of a more "natural" knee for knee implants for total knee replacement - TKR - surgery.	C-K map used to create the structuring concept development. Then TRIZ tools such as Functional Analysis or Inventive Principles had been applied to create new design concept or overcome contradiction(s)	Creativity, engineering design process, C-K theory, TRIZ	1 to 3	Concept development,

Author(s), year	Principle finding	Use, users and use environment	Type of medical device	Research method	Fields of study	Phase of Computer evolution	Stage of design process focused
Vincent and Blandford (2014) AND Vincent and Blandford (2015)	Refer to the finding of Vincent, C.J., Li, Y. and Blandford (2014), a series of persona-scenario combinations were constructed based on several observation studies (most cases applied DiCoT methodology). The study was conducted to learn about the feasibility of delivering content to medical device developers, intended to outline a broad range of user needs (Vincent and Blandford, 2014, 2015). The scenario can also use to explain the "real use" in other stages of the product life cycle, e.g., marketing.	Clinical setting including hospital context, users (professional) and end-users (patients)	Infusion pump development for a UK research project	Persona content was created based on several observational studies. Patient representatives, e.g., healthcare professionals and HCI/HF/Ergonomics investigators involved in checking the persona content (Vincent and Blandford. 2014). Scenario content was also created under the same process (Vincent and Blandford, 2015).	Usability engineering, Human-computer interface, persona, user experience design	3 to 5	User needs, concept development, design, verification & validation process, product launch
Bligård and Osvalder (2014)	An analytical method for use error analysis, Predictive Use Error Analysis (PUEA), which employs a detailed process for breaking down the user's tasks into steps, then identify and investigate potential incorrect actions of each step. The PUEA method can be used for evaluating existing products or serving as an evaluation tool during the design process.	Non-clinical setting, lay users	The home-care ventilator of the type Continuous Positive Airway Pressure (CPAP).	An example case of using PUEA to predict, identify, and present use errors applying to a fictitious home-care ventilator of the type Continuous Positive Airway Pressure (CPAP).	Usability engineering, risk assessment, reliability engineering.	3 to 4	Concept development, design process.
Hagedorn, Krishnamurty and Grosse (2016)	A unified information model approach that broadly combines a detailed model of design elements, stakeholder requirements, capabilities of the customers in order to facilitate knowledge capture and automated reasoning across domains.	Clinical setting, professional users.	Surgical staplers and complexity matrix	Two case studies were selected to test the information model, surgical staplers, and complexity matrix (new design metrics formulated by the Information model).	Ontology, engineering design process, computer science, knowledge management	1 to 4	User needs, concept development
Hagedorn, Grosse and Krishnamurty (2015)	The CIFMeDD, an integrated semantic medical device framework integrated ontologies modeling engineering, medical, and patent knowledge. The model aimed to allow direct comparison of existing objects and methods across different disciplines in order to manage medical knowledge and incorporate it into the early phases of engineering design.	Clinical setting, professional users.	Two case studies: fat grafting and bariatric surgeries.	The model (CIFMeDD) has been proposed and examined. A subset of SNOMED CT classes and a number of specific patent classes were modified and interlinked with additional information and newly defined object properties.	Ontology, engineering design process, computer science, knowledge management	1 to 4	Concept development

Author(s), year	Principle finding	Use, users and use environment	Type of medical device	Research method	Fields of study	Phase of Computer evolution	Stage of design process focused.
Alppay and Hedge (2015)	An ergonomic checklist to evaluate MTPCs at the early stage of the design process. The checklist determined five main sections, Mobile Usage, Portability, Office Usage, Cleaning and disinfection, and hardware issues. Further, the MTPCs consist of 3 subsystems, electronic infrastructure, software and physical body, and need to conceptualize and analyze.	Clinical setting, professional users (doctors).	Medical Tablet Personal Computers (MTPCs) used by medical doctors	22-question interview was conducted face-to-face ergonomics evaluation by researchers with end-users (29 MDs with some degree of computer experience and knowledge) to collect data about user needs for an MTPC conceptual design.	Human factors and ergonomics, Systems engineering, Checklist, Engineering design process	3 to 4	User needs, concept development process.
Gupta and Pidgeon (2016)	A systematic approach consisted of 5 steps to conducting the database of reported medical device incidents searches, analyzing the data, and reporting the findings regarding user-related issues for new comparable medical device development. The information from reported incidents can be used as an idea or source of user-related information for new device development.	Clinical & Non-clinical setting, professional and patient users.	A single-use, disposable of autoinjector for the treatment of rheumatoid arthritis (RA).	An example of a systematic search of user-related issues of existing and comparable devices of new autoinjector for the treatment of rheumatoid arthritis (RA) in an FDA's MAUDE database.	Data mining, biomedical engineering, engineering design process	1 to 4	Idea generation, concept development process.
Furniss et al. (2015)	The research proposed a framework based on a system along with DiCoT's five themes and different concentric layers (DiCoT CL) to reveal couplings and dependencies that influence the performance of medical devices used at different layers of the sociotechnical system. The framework aimed to support more complex, more interconnected, and supported by fragmented organizational systems.	Clinical setting, professional users.	New network-connected glucometer, which has a capability of scanning staff and patients' barcode ID and its readings were uploaded to a central database.	A 150h-fieldwork, over 5 months observations and interviews at the Oncology Ward in Hospital on the use of a new network-connected glucometer. Data were organized under the five different DiCoT models.	Distributed cognition, human-computer interaction.	3 to 5	User needs, concept development, design process.

Author(s), year	Principle finding	Use, users and use environment	Type of medical device	Research method	Fields of study	Phase of Computer evolution	Stage of design process focused.	
Ríos-zapata et al. (2017)	Research express solution finder (RESF), a creative and idea generating method based on combination and mutation models, providing 5-step framework supporting patent search through patent analysis for finding solution for any subsystems of medical device,	Non-clinical setting, lay users (patient)	A new design of locking system (subsystem) in the TPAD brace (Thoracic Pelvic Anterior Distractor brace)	Applying RESF method for a new design of locking system (subsystem) in the TPAD brace	Idea generation tool, industrial design	1	Concept development (Idea generation)	
Larson et al.(2017)	A general principle for safety architecture designed to partition complex systems to smaller, simpler, clearer in define interfaces and interactions; to determine allocating safety-related functions to safety subsystem, and separate safety and operational subsystems. It typically is designed to support four actions four actions to establish risk control: detection, notification, mitigation, and recording.	Clinical setting, professional users	A model of open patient-controlled analgesia (OPCA) infusion pump device.	A case study demonstrated how to apply the concept of medical device safety architecture in AADL to a open patient-controlled analgesia (OPCA) infusion pump device model.	Biomedical engineering, system engineering, safety & risk management.	1 to 3	Concept development, design process	1 to

Table C-3. presented extracted papers related to case studies or clinical studies of the medical device that reveal resultant outcomes in user research and enhance user engagement and others related to the objectives of this review study.

Author(s), year	Study propose	Research method	Principle finding	Use, users and use environment	Type of medical device in the case study	Key research finding
Money et al. (2011)	Human factors/ usability/ ergonomic/ user-centered	In-depth interviews with representatives from 11 medical device manufacturers into what medical device manufacturers' attitudes toward engaging with users, perceived value, barriers, methods used, and what device manufacturers' attitudes towards employing such methods.	The concept of patient engagement method is still limited in practical use during the medical device design, only apparent when the use is mandatory. Medical device manufacturers did not see the benefit of employing formal human factors engineering methods within the MDD process.	Clinical setting and non-clinical setting, professional users and lay users.	Range from Orthopedics, Cardiology, Vital signs monitoring, to Wound care.	In clinical setting, where customer and user are not the same person. The resource will be allocated to respond to the needs of the customer (senior healthcare staff, reimbursement) rather than the user (patient or operational staff).
Lehoux et al. (2011)	Multidisciplinary design team	Eight face-to-face interviews with respondents who had been involved in the design and development of each medical device that covers a broad spectrum of clinical functions (therapeutic, decision support and monitoring) in either hospital or home care settings.	The study revealed further methodology to close the gap between heterogeneity of design participants by understanding the 'world' there are inhabit and contribute to the project, explaining that they engage into the design through their particular "lens" influenced by 3 aspects: knowledge and expertise, tasks and responsibilities, motivations and interests.	Clinical setting and non-clinical setting, professional users, and lay users.	A heart ablation catheter, Labor decision support software, and Home telehealth solution.	The successful design outcomes were from knowledge circulated, adapted, and transformed from one domain to another. The lead designer may act as a builder, an assembler, or an adapter (domain migrant), and the other design participants may play complementary roles. The motivations of the participants influencing what they see and value in the object to be designed.
Lang et al. (2013) AND Lang et al. (2014)	User engagement	The study of medical device design for adolescent adherence through a case study of the acapella CF physiotherapy device, using pictorial vignettes to stimulate the discussion in semi-structured interviews of 20 participants within a regional UK hospital trust.	Study of participants aged 11 to 20 years with previous or current experience of the acapella® revealed complications to the process of transitioning from child to adult, which needs a medical device designed to link with both adherence and achievement of adolescent goals, e.g., "fitting to teenage life."	Non-clinical setting (e.g., home, community), lay patent (adolescent with cystic fibrosis)	CF (cystic fibrosis) physiotherapy device.	Adolescents with CF want to be in control of their health and be independent. Suggestions for future functions of the device are, e.g., feedback from the device, remote monitoring technologies, gaming and simulation, design for privacy, social acceptance ("use in community") could increase adherence and long-term engagement.
Pounder, Jones and Tanis (2016)	User engagement	Over the 6-month and 12,000 data files retrieved from device recoding log files, clinical study was conducted to compare patient compliance of earlier and new generation of LIPUS bone healing therapy devices	Visual calendar and feedback on patients' successful completed treatment had shown the result in increasing significant compliance in short and long term (83.8% with the next generation compared with 74.2% for the previous version, $p<0.0001$).	Non-clinical setting, lay users.	In-home bone healing therapy devices (LIPUS)	User interface design that provides feedback on the patient compliance, affecting patient's engagement.

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Author(s), year	Study propose	Research method	Principle finding	Use, users and use environment	Type of medical device in the case study	Key research finding
Lyons and Blandford (2018)	User engagement	The 606 records of incidents associated with infusion devices from UK National Reporting and Learning Service (2005–2015 inclusive) reported incidents had occurred in a private home.	Results in two emergent themes: detecting and diagnosing incidents; and locating the patient, lay caregivers, and their family in incident reports. The majority of incidents were attributed to device malfunction resulted in the patient being under-dosed. Delays in recognizing and responding to problems were identified, alongside identifying the cause.	Non-clinical setting, lay users.	Infusion pumps being used in patients' homes	Medical devices for home-use should be designed for the unique environment of the home, e.g., more robust, providing better feedback to identify troubleshooting problems, and easy access to monitor and technical support by front-line professionals.
Kelly and Matthews (2014)	User engagement	The case study conducted to adapt the user-centered design and participatory design methods in the development of new products sponsored by two medical device companies. The target is to investigate the possibilities of overcoming any barrier to use the device by relevant people who are not yet using the devices, "pre-user."	Other than 'use,' the two additional strategies have been introduced to add in a user-centered/ethnographically-informed design processes: "the artefact multiple" (alternative interpretations of an artefact apart from that of use) and "Networks of practices" (to the consideration of practices which do not involve, but could affect, use practices).	Non-clinical setting, lay users.	Insulin injection systems (Novo Nordisk) and Hearing aids (Oticon)	The strategies will help to address the contextual conditions that influence the use of the device, e.g., the relationship between the user, device, his/her condition, healthcare professional, and other users. The strategies will broaden the space of alternatives explored in design resulted in enhancing the use of the device.
Rajkomar et al., 2014	User engagement	Data were gathered through ethnographic observations and interviews with 19 patients and their carers associated with four different hospitals in the UK, using five different HHD machines. Data were analyzed qualitatively, focusing on themes of how individuals used the machines and how they managed their safety.	Findings are organized by three themes: learning to use the technology, usability of the technology, and managing safety during dialysis. Possible design improvements including features to help patients manage their dialysis (e.g., providing timely reminders of next steps) and features to support communication between families and professionals (e.g., through remote monitoring).	Non-clinical setting, lay users.	Home hemodialysis machines	Home patients want to live their lives fully, and value the freedom and autonomy that HHD gives them; they adopt the use of the technology to their lives and their home context. Possible design improvements to enhance the quality and safety of the patient experience include features to help patients manage their dialysis (e.g., providing timely reminders of next steps) and features to support communication between families and professionals (e.g., through remote monitoring).

Author(s), year	Study propose	Research method	Principle finding	Use, users and use environment	Type of medical device in the case study	Key research finding
Haydock et al., 2015)	User engagement	A comparative analysis of two different flow rate control devices comparing objective measurement (e.g., device error, time to set rate) and subjective measurement (e.g., perceived accurate device, perceived ease of use)	Exploring discordance between objective and subjective measurement of new medical devices, while the objective performance was not significantly different, but the user perception could be different.	Non-clinical setting, professional users	Two devices controlling IV fluid rate used in a hospital.	The difference in subjective measurement that contrary to the objective measurement from the two devices may lead to design characteristics of a new medical device to respond to user's perception, "persuasive design."
Ghulam, Shah and Robinson (2007)	Human factors/ usability/ ergonomic/ user-centered	A literature review of peer-reviewed studies (1980 to 2005)	The benefits and barriers of user involvement in MDTD&E. Manufacturers engaged with users and users' needs, reducing subsequent development cost, complying with regulatory, but requiring time, money, and energy of both users and manufacturers. Barriers including user characteristics, limitations to understand complex technologies, etc.	Not specific	General medical devices	Some of the users of medical device technologies, e.g., disabled person, the elderly, and patients (lay users), may require additional encouragement and assistance to take part in MDTD&E. Medical device technology manufacturers also need a cultural shift in attitudes.
Vincent, C.J., Li, Y. and Blandford (2014)	Multidisciplinary design team	19 interviews conducted across a range of individuals involved in the design and development of medical equipment, e.g., engineers, practitioners, HFE engineers, team leaders. Thematic analysis was conducted to determine multiple overarching themes.	The study found there was a lack of common ground between disciplines, leaving gaps in effective implement HFE/UE tools in mutual understanding of shared reference point within "disciplinary silos" or "walled gardens." The use of mediating representations or boundary objects, e.g., personas and scenarios to support effective communication, has been proposed.	Not specific	Not specific	Communication between disciplines was one of the barriers to medical device design. Artefacts like personas and scenarios provide ways to understand how users behave, think, what they want to accomplish and why.
Whitney (2008)	Human factors/ usability/ ergonomic/ user-centered	3 Case studies of medical device design using user-centered to examine both the users' and the corporate perspective, done by the Institute of Design (ID), the Illinois Institute of Technology (IIT).	The study found that designers needed to understand patient-related issues and behavior as well as understand the corporate strategy problem.	One project was aimed at medical staff; the other two projects were for patients.	Patient information management, medication management, diet assistant.	Finding from the studies claimed that the success of medical device design was depended on the understanding from both users and corporate perspectives.

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Sharples et al. (2012)	User engagement	A model that illustrated the complex iteration between device design and user behavior based on a combination of existing human factor theories and five case studies which identified a potential link between device design and resultant user behavior.	A model demonstrated the relationship between the complex interaction between the user, the device, and various aspects of context, through mediating factors and the resultant consequences in the immediate and long term, framed by the constraints and opportunities and via different types of mediation, explaining "ways in which medical device communicates to the user."	Range from clinical to non-clinical setting, professional and lay users.	New ultrasound scanner, single-use devices, blood glucose meters, handheld CF clearance device, a medical imaging device.	The model highlighted the need to consider the range of stakeholders or users in determining efficiency, effectiveness, and satisfaction for the user, framed by the constraints and opportunities, i.e., financial, technical, regulatory and social, offered by the situation in which they are used or implemented; and not considering device design in isolation from the organizational or social context and
Privitera, Evans and Southee (2017)	Human factors/ usability/ ergonomic/ user-centered	A case study from a semi-structured interview of 18 leading employees involving the design process & human factor of medical device manufacturers in the US and EU, selected based on the size of the company, device specialty, user group, and use of industrial design.	The research indicates that regulatory agencies required the involvement of the user during the design process. Of the cases, 72% pay consulting fees for user involvement in main activities, e.g., device review workshops and labs, and HF evaluations. All of them engaged with a physician as a user.	Range from clinical to non-clinical setting, professional and lay users.	Surgical devices, orthopedic implants, cardiac assistive technologies, and general hospital equipment.	User involvement in the design process is still limited. Barriers in user involvement are difficult to access to the user, user's lack of understanding of feedback impact on the design process, contract formalities limiting user exchanges, user's attitude, and expected compensation could negatively impact on HF process.