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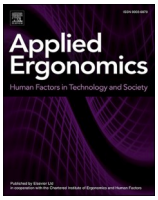

# Usability challenges in the use of medical devices in the home environment: A systematic review of literature

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A B S T R A C T

*Background:* Home care medical devices are the fastest-growing segment of the medical device industry with associated safety and usability challenges. Human factor studies in the home environment present many difficulties resulting in limited knowledge of device use in this setting. This systematic review aims to identify usability challenges reported directly by end-users in the home environment.

*Methods:* A systematic review of the literature was conducted concentrating on studies involving end user reporting. Reported challenges were grouped into a) device-user, b) device use environment and c) device-user interface challenges.

*Results:* 3471 studies were screened and 202 underwent full-text review. Only twelve studies had direct involvement of end users. Multiple challenges were identified, with device-user interface problems being the most common. No effective, standardised method was found to collect patient/user feedback on usability challenges in the post-market stage, leading to a knowledge gap.

*Conclusions:* This study brought together multiple usability challenges reported by individual studies. Involvement of medical device end-users in usability studies is essential and their experiences must be effectively utilised in device design.

## 1. Introduction

Care at home has seen a major growth in recent years influenced by changes in patient demographics, economic factors and technological advances (FDA, 2016; Lyons, 2018; Bitterman, 2011; Henriksen et al., 2009). The FDA (Food and Drug Administration) considers home care devices as the fastest growing segment of MD (medical device) industry (Lewis, 2001; K Bayer (BSI)). Similarly in UK and EU, the aging population has led to programmes aiming to empower patients and provide them with the means to take control over their health when possible with technology support (Ho, 2005; NHS England, 2017; MedTechEurope). In particular, management of chronic conditions has largely shifted into the community with technology support. These changes present multiple challenges in the safety, effectiveness and usability of technology by end-users (Lyons, 2018). An understanding of the interface and interaction between patients, carers and MDs is essential for achieving optimal device design leading to safe and user-friendly devices (Rajkomar and Blandford, 2015; Lyons, 2018).

A home use device (HUD) is any device labelled for use in any environment outside a professional healthcare facility including outdoor environments, offices, schools, vehicles, emergency shelters and independent living retirement homes (FDA, 2019; Kaufman-Rivi et al., 2010). HUDs sit at the boundary between traditional devices and consumer products (Kortum and Peres, 2015). They require safe monitoring and management at home, yet there is a recognised variability in the level of education and training that patients receive regarding their use (Allied Market Research, 2018; Hilbers et al., 2013). Furthermore, identification of problems (both clinical and technical) occurs at different rates depending on patient knowledge and experience (Hilbers et al., 2013; Henriksen et al., 2009) and their safe use is strongly associated with the compatibility of the user-device interface (Henriksen et al., 2009).

The primary users are likely to be a non-medical, heterogenous group including family members and carers. As a result, their background, age, level of training, physical and mental fitness and language knowledge vary considerably. Furthermore, the context of use is hard to predict and likely to be less-controlled, when compared to a healthcare setting where standardised procedures and protocols are usually in effect (Bitterman, 2011).

Trends over the past two decades have shown an increase in post-market events attributable to design issues and often related to the user interface. Whilst human factors engineering is not a new field, its application in healthcare has only been relatively recent (he growing role of; National Quality Board, 2013). Errors in the use of HUDs can lead to patient harm and may be related to poor device design especially where the device interface is complex (MHRA, 2017). Many of the

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devices used in the home environment are classified as drug-device combination products for example, insulin pumps and infusion pumps. These devices are recognised as having high risk of use related design issues that can result in patient injury (MHRA, 2017).

This systematic review seeks to identify problems encountered by end-users of medical devices in the home environment. The results of the review will enable further work on the development of methods for increasing direct patient involvement in the identification of usability problems.

## 2. Methods

### 2.1. Eligibility criteria

Studies with direct patient and carer involvement in establishing usability challenges of home use MDs were included. We excluded studies discussing implantable devices, telehealth, Internet of Things (IoT), rehabilitation technology and devices not marketed as a medical device. This was required to limit the study to home use MDs primarily used by end-users and thus enable generic factors across a similar set of devices to be assessed. Studies not available in the English language and those not in full publication were excluded. All studies published up to 31 January 2020 were included with no other time limitations.

### 2.2. Information sources

Searches were conducted between 1946 and 31 January 2020 using Medline, Embase, Pubmed, Google Scholar, Web of Science, Scopus and Engineering Village. The search criteria and keywords were arrived through consensus with all researchers. Hand searching, personal collections and exploding references were also used to augment the results. Some of the keywords used were “home use device”, “home diagnostic devices”, “challenges”, “home equipment”, “home use test”, “equipment and supplies”, “equipment safety, “home care services”, “self care” and “near patient testing”.

### 2.3. Study selection

The search strategy involved locating articles focused on studies involving patients as direct users. Abstract screening was first carried out. The study selection occurred based on the following criteria: (i) utilising a home use medical device, and (ii) assessment of direct end-user involvement. If these criteria were unclear from the abstract alone, papers were included for full review prior to inclusion in the study. The PRISMA method was utilised throughout. (Moher et al., 2009; Liberati et al., 2009). Study selection, data extraction and assessment of study quality according to SRQR (Standards for Reporting Qualitative Research) were carried out by the first author (AT) and reviewed by the second author (BV) and agreement was reached on the selection.

### 2.4. Data collection process

Data extracted included: (1) author details, (2) year of publication, (3) target age group, (4) type of home use medical device, (5) device-user challenges, (6) device use challenges and (7) device-user interface challenges. No assumptions were made during the selection to reduce the risk of bias. The classification of usability challenges was carried out in the format laid out by FDA (US Food and Drug Administration) (FDA, 2016). This is the method advised by regulatory bodies to manufacturers of medical devices. This method provides a structure for group usability factors into three groups, (1) device-user challenge, (2) device use environment challenge and 3) device-user interface challenge. This method was used to guide the data collection and analysis. A table of selected studies was created in Microsoft Excel and populated with the outcome measures of the study specified in the data items collected above. The results were reviewed by two authors independently (AT and BV) prior to inclusion. No disagreements were recorded.

## 3. Results

### 3.1. Study selection

A total of 3464 articles were found through the search. 7 further studies cited from the initial results were included. Following abstract review, 202 studies were included for full text review. 12 of these studies fulfilled the eligibility criteria for inclusion in this systematic review. Fig. 1 shows the PRISMA flow diagram for the study. Most excluded studies discussed the usability of a device under development as performed by a design engineer with no direct patient involvement.

### 3.2. Study characteristics

All studies (Table 1) were qualitative in nature and used interviews (6) or survey (1) techniques to gather data from end-users. Three studies used direct observation and evaluation of the user whilst two studies used both interviews and direct observation. Seven studies reported patients as the end users, four reported both patients and the community healthcare nurse, and one study reported the community healthcare professional.

All studies focussed on the use of HUDs by older age groups (>60 years of age). Four studies also included other age groups (Table 1). Studies varied in size between 1 and 75 participants. The largest dataset (Lyons, 2018) consisted of 606 NRLS incident reports on the use of home MDs.

*Types of devices* - The types of HUDs (home use devices) studied (Table 1) were those used in the monitoring and treatment of diabetes, infusion pumps, home dialysis machines, home ventilatory equipment, blood pressure monitors and peak flow meters. One study reviewed the use of home MDs and patient care at home in general. Five studies discussed more than one device.

### 3.3. Reported end-user challenges in using medical devices

The reported challenges were categorised into three groups (1) device-user, (2) device use environment and (3) device-user interface related. This categorisation followed the FDA recommendations on human factor engineering assessment of MDs (FDA, 2016).

Device malfunction was reported by all authors. Devices were reported as “failed to work” in 278 cases (46%)(Lyons, 2018). In one study (Mirel et al., 2011) 54 (72%) patients reported difficulties in the practical/technical use of the HUD. Often the appropriate device was not available for the right patient (Keller et al., 2017). Hence, care plans were at times not implemented resulting in threat to patient safety and unplanned hospital admissions. This led to stress, fear and frustration especially by older patients who felt undervalued and unsafe (Keller et al., 2017). However, 74/75 patients felt that MDs at home were very important in monitoring chronic disease despite the challenges faced (Mirel et al., 2011).

Emotional aspects of care lead to affective challenges including low mood and depression which in turn negatively influenced treatment compliance and device use (Lo et al., 2016). Fear and worry were most noticeable for large complicated devices such as home haemodialysis machines (Rajkomar and Blandford, 2015; Mirel et al., 2011; Beer et al., 2014). Table 2 presents the results of each study with regards to the usability challenges. These are discussed as follows:

a. Device user Challenges

All studies included in this systematic review had participants over 50 years of age with nine of the studies including patients over the age of 60. This carries the challenges of age-related problems such as a decline

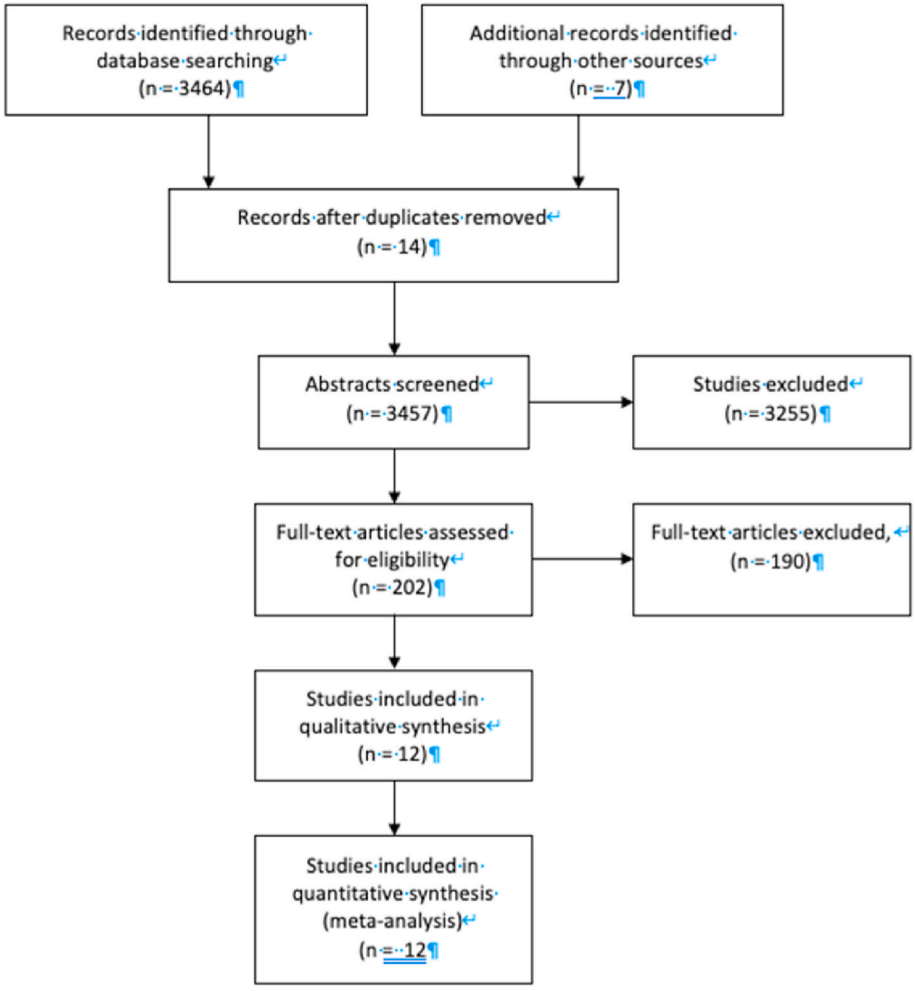


**Fig. 1.** Prisma flow diagram.

**Table 1**
Study characteristics.

| Author | Year | Number of Patients | Patient Age groups | Device (s) | End user |
|---|---|---|---|---|---|
| Gonzalez-Bermejo, J et al | 2019 | 1 | 62yrs | Home Ventilation | Patient |
| Lyons, I., Blandford, A | 2018 | 606 | All age groups | Infusion devices | Patient and Healthcare professionals |
| Keller, S.C et al | 2017 | 63 (24 patients 39 healthcare professional) | Mean age 71yrs | Group of Home use devices | Patients and Healthcare professionals |
| Rajkomar, A et al | 2015 | 19 | All age groups | Home Dialysis | Patients |
| Noble, Paul | 2015 | 2 | >65yrs | Home dialysis | Patients |
| Lo, Hsin-Chang et al | 2016 | 5 | 65–79yrs | Diabetic Devices | Patients |
| Goodman-Deane J et al | 2014 | 30 | 18-60+ | Diabetic Devices | Patients |
| Beer J M et al | 2014 | 16 | Older patient group (unspecified) | Infusion pumps, BP machines, home devices in general | Community Nurses |
| Rajkomar A et al | 2014 | 19 | 30-70+ | Home Haemodialysis | Patients and carers |
| Mirel S et al | 2011 | 75 | 10-80, mean age 55.8yrs | BP, BM, peak flow meter | Patients |
| Fex A et al | 2009 | 10 | >50yrs | Home Oxygen, Home dialysis | Patients |
| Fung C H et al | 2015 | 19 (9 patients, 10 healthcare professionals | >50yrs | CPAP | Patients and Healthcare professionals |

Keywords: BP = blood pressure, BM = Boehringer Mannheim (It refers to blood sugar measurement levels), CPAP = Continuous positive airway pressure therapy.

in memory, vision and hearing.

This review found that patients with chronic illness are disadvantaged in operating new technology (Mirel et al., 2011; Beer et al., 2014; Fung et al., 2015). The range of disability (in over 60 years) is varied and may include loss of sensation in the upper limbs, tremor and loss of fine motor movement which makes device use difficult leading to non-adherence with treatment (Fung et al., 2015).

Safe use of medical devices requires the user to have a certain level of physical, perceptual and cognitive abilities as the overall demands of using a MD go beyond its functional use. Technical procedures require sufficient cognitive capacity and physical skills (Goodman-Deane et al., 2014; Fex et al., 2009). This includes manual dexterity, disposing of

**Table 2**
Summary of published literature data on reported usability challenges.

| Author/ Year/Age group | Device user | Device use environment | Device-User interface |
|---|---|---|---|
| Gonzalez-Bermejo, J et al., 2019 62yrs old | Variability in patient requirements<br>Variable patient abilities | | Risk of accidental mistakes in device use<br>Use of incorrect adjuncts (connector) due unavailability<br>- lead to emergency hospital admission<br>Wrong device size<br>Inappropriate device design<br>Unsuitable material used |
| Lyons, I et al., 2018 All age groups | Lack of training of patient and carer<br>Failure to recognise malfunction or error<br>Delay in error correction<br>Delay in receiving correct treatment – not knowing how to manage the situation | Lack of technical support in the home environment | Alarms<br>- Important in alerting to an error<br>- Difficult to silence<br>- Failure to activate despite malfunctioning<br>Incorrect device programming<br>Incorrect set up of device or accessories<br>Damage and degradation of device<br>Incorrect information displayed on screen |
| Keller, S.C et al., 2017 Mean 71yrs | Lack of carer support/ accessibility<br>Difficulties related to cognitive impairment<br>Health beliefs between different age groups<br>Cultural beliefs<br>Lack of education and training<br>Different levels of acceptance of MDs<br>Perceptions and ideas about technology<br>Negative perception of healthcare<br>Physical ability to use the device | Lack of physician access<br>Lack of space within the home<br>Difficulties in moving large equipments<br>Difficulties accessing physician care at home | Application of practice from patient's learned experiences<br>Patients develop their own workarounds strategies |
| Rajkomar, A et al., 2015 All age groups | Difficulties in use by patients with no experience<br>Lack of education and training<br>Coping with other comorbidities<br>Abilities for technical maintenance of equipment | Lack of space within the home for equipment<br>Lack of space for storing supplies<br>Spatial isolation within the home<br>Lack of safety and support<br>Social structures needed to support patient and carer<br>Aesthetics and MD acceptance in the home environment | Machine messages not always understandable<br>Machine does not guide on course of action<br>Different colours required to distinguish between buttons<br>Little guidance on solution of alarms.<br>Design does not allow for easy interaction during emergencies<br>Lack of guidance on causes of alarms<br>Machine messages not always understandable<br>Patients develop their own workarounds strategies |

**Table 2** (*continued*)

| Author/ Year/Age group | Device user | Device use environment | Device-User interface |
|---|---|---|---|
| | | | Lack of feedback from the machine especially in an emergency |
| Noble, 2015 >65yrs | Lack of education and training<br>Failure to recognise malfunction<br>Resistance to adaptation/ equipment change<br>Monitoring and anticipation of resilience to device errors | Lack of active monitoring of device use<br>Lack of space within the home for equipment | Reliance on alarms |
| Lo, Hsin-Chang et al., 2016 65–79yrs | Physical demands and ability in using the device<br>Visual degeneration<br>User's culture and experience | | Design of perceptual information – unclear symbols<br>Small parts difficult to use<br>Provided information on assembly not clear<br>Choice of colour – inappropriate and leading to confusion |
| Goodman-Deane J et al. 2014 18–60yrs | Increased cognitive demand based on the instructions presented.<br>Educational level of patient/user<br>Problems with manual dexterity<br>Inadequate pain management by malfunctioning device<br>Inadequate medication dose administered by device<br>Varying levels of required cognitive demand | | Design of removable and non-removable parts was similar leading the wrong part being removed by mistake.<br>Instruction window too difficult to see<br>Confusing instructions for use<br>Print size on instructions too small<br>Confusing buttons thought to not be needed<br>Print paper too fine for users with manual dexterity problems<br>Inadequate skin contact- device activating whist not in contact with patient |
| Beer J M et al., 2014 Older patient groups | Lack of training and education<br>Different cognitive abilities<br>Perceptions on accuracy<br>Unprepared community staff looking after patients<br>Patient non-compliance with treatment<br>Lack of cognitive knowledge<br>Physical limitations<br>Incorrect set up of device | Contamination of device<br>Lack of maintenance of MD<br>Inappropriate environment leading to risk of infection<br>Lack of space in the home environment<br>Difficulty in transfer within the home<br>Inappropriate storage of device | Lack of feedback from device<br>Design of device does not allow users to perform the required task.<br>Unable to identify source of problem<br>Variability between devices<br>Device age – old devices in use |
| Mirel S et al., 2011 Mean 55.8yrs | Experience in using devices/technology<br>Level of education and training<br>Cognitive abilities<br>Physical ability | Improper calibration<br>Lack of equipment maintenance at home | Complexity of external functional buttons<br>Difficult to understand labels<br>Difficult to understand instructions for use |

(*continued on next page*)

**Table 2** (*continued*)

| Author/ Year/Age group | Device user | Device use environment | Device-User interface |
|---|---|---|---|
| | | | Faulty Battery/ uncharged battery |
| Fex A et al., 2009 >50yrs | Different cognitive ability<br>Difficulty participating in social events due to treatment timing<br>Physical ability to use the instrument/ device<br>Post upper limp amputation patients- increased difficulties in use of device<br>Visual degeneration<br>Sensory impairment | Hygiene restrictions in the home environment<br>Lack of space within the home<br>Transport difficulties<br>Location of equipment in the home | |
| Fung C H et al., 2015 >50yrs | Problematic use by patients<br>- Visual deficit<br>- Sensory deficit<br>- Motor disability<br>- Visual impairment<br>Post upper limp amputation patients- increased difficulties in use of device<br>Difficulties with multiple small parts requiring assembly | | Machine settings and position of controls only in visual or tactile formats<br>Difficulty using devices with small parts<br>Small parts would fall off during use as patient unable to use or hold them<br>Machine controls layout |
| Rajkomar A et al., 2014 30-70+ yrs | Forgetting steps in the process of device operation<br>- Cognitive impairment<br>- Remembering and memory | Lack of space and portability<br>Difficulty accessing support from home | Alarms not always helpful<br>Alarms not easy understood<br>Messages not easily understood<br>Access to screen and controls<br>Difficulty in reading screen<br>Use of clamps/ adjuncts affects accessibility<br>Time required for dialysis |

clinical waste appropriately and the associated cognitive demands of performing this task.

The home environment is less structured than other care settings. Patients often fail to recognise a malfunction or error leading to delays in rectifying that error and receiving the correct treatment. Human factor studies in the home environment are scarce leading to a poor understanding of these related risks (Keller et al., 2017; Valdez et al., 2017; Masotti et al., 2010).

Education and training of patients and relatives is essential as devices are not generally intuitive to use. The lack of specialist technical support was identified (Lyons, 2018; Keller et al., 2017) posing greater difficulties to patients with cognitive impairment (Keller et al., 2017). Community nurses also reported having inadequate training, largely related to the variability of device designs (Beer et al., 2014).

Home healthcare benefits the elderly population and allows them to maintain their independence and quality of life (Beer et al., 2014). However, correct use of MDs at home relies on providing adequate training tailored to individuals (Rajkomar and Blandford, 2015; Keller et al., 2017; Beer et al., 2014; Goodman-Deane et al., 2014; Noble, 2015). Additionally, different health and cultural beliefs can influence the rate of compliance and acceptance of a MD at home (Keller et al., 2017; Lo et al., 2016).

b. Device Use Environment Challenges

MDs were originally designed for use in a clinical setting by trained professionals (Beer et al., 2014). Reduced space, mobility and physical layout of the home may not support certain equipment and can impact safety measures. Patients value home aesthetics. This factor directly affects how they interact with technology, and its acceptance (Rajkomar and Blandford, 2015; Keller et al., 2017).

Large devices such as dialysis machines, bring additional challenges to the home environment. Furthermore, some devices may be pre-programmed for use in a hospital environment before transfer to home use. Nurses themselves reported difficulty with setting up certain devices such as infusion pumps due to pre-programming (Beer et al., 2014).

Other sources of frustration were old, broken or outdated equipment which are more likely to present challenges. Often the devices were not stored appropriately leading to them being unusable or contaminated (Beer et al., 2014).

c. Device-User Interface challenges

The variation in device interface generates inter-device data variability and difficulties in data interpretation (Beer et al., 2014; Gonzalez-Bermejo et al., 2019). The use of complex MDs at home is considered a socio-technical, safety–critical, and complex system (Rajkomar and Blandford, 2015). Hence, the patient's role on the process is essential (Rajkomar and Blandford, 2015). In a complex system, people are likely to make use of different strategies to complete a task. The same applies to HUDs (Rajkomar and Blandford, 2015).

During an 11 year period, 606 incident reports were recorded related to infusion devices used in the home environment. Healthcare professionals using devices such as infusion pumps in the patient's home found them to have a high rate of user-device interface problems and hence found them difficult to manage (Lyons, 2018). The authors (Lyons, 2018) explored the characteristics and circumstances in which problems occurred to inform future design. They suggested that HUDs should be designed specifically for the home environment, have a clear purpose for use, and be able to provide feedback to help patients and carers identify and troubleshoot problems (Lyons, 2018).

Although device alarms were useful in alerting the patient or carer of device malfunction, it was difficult to establish whether the cause was a technical or user error (Rajkomar and Blandford, 2015; Lyons, 2018). Another important aspect was the role and use of devices during an emergency situation at home. Patients suggested that the device should be designed with in-built prompts to guide them through an emergency scenario. The messages provided by the machine were not always clear and not suitable to the lay person (Rajkomar and Blandford, 2015; Noble, 2015).

The device is often not used as "prescribed" with patients developing their own strategies to resolve problems, which largely depends on their background and experience (Rajkomar and Blandford, 2015; Mirel et al., 2011; Keller et al., 2017). In some cases, MD use problems lead to non-compliance (Beer et al., 2014). The type of 'errors-in-use' varied between devices (Goodman-Deane et al., 2014). Frequently, the design was a major cause of confusion. For example, a blood glucose meter was designed with a cap and a button on opposite ends of the device. These looked similar to each other and the wrong part (i.e. button rather than cap) was often removed by mistake. Use errors often lead to devices failing to activate (Goodman-Deane et al., 2014). This may be attributed to inadequate instructions for use and labelling (up to 60% of cases) (Mirel et al., 2011).

Patient reaction to errors is unpredictable. In an attempt to rectify an error, users can cause adverse outcomes such as pain and disruptions of treatment. Expiry dates are often missed, leading to the delivery of poor

quality medication (Goodman-Deane et al., 2014; Fex et al., 2009).

The most commonly reported challenge relates to the design of the controls, buttons and screens. In particular, concerns were raised about reacting to the alarms without adequate guidance on locating the problem source and how to action it (Rajkomar and Blandford, 2015; Rajkomar et al., 2014). Recommendations include the use of colour coding (e.g. in the case of a dialysis machine, red for arterial blood and blue for venous blood) (Rajkomar et al., 2014). The poor design of the visual information included small text, unnecessary buttons, and unclear instructions (Mirel et al., 2011; Lo et al., 2016; Goodman-Deane et al., 2014). The machine settings and position of controls did not always consider patients with visual or sensory loss (Fung et al., 2015).

## 4. Discussion

This systematic review has highlighted a number of design and usability challenges faced by patients and end-users of medical devices in the home environment. Multiple challenges are reported in all three set categories.

Usability challenges are complex and multidimensional with each category identifying a number of requirements for the safe design of a medical device (MHRA, 2017). The home environment and capability of the end-user provides different challenges for MD manufacturers (Bitterman, 2011). It is thus essential that devices designed for home use are not only accurate but also appropriate for use by patients, carers and enable safe information sharing with clinicians. The process of interaction between the patient and MDs is important to understand their safety and usability (Rajkomar and Blandford, 2015).

To overcome challenges related to the use of HUDs, it is important to understand how people interact with technology and the impact of the user interface design (FDA, 2016). A well designed device-user interface will facilitate correct user actions and prevent use errors. These are better addressed by improved design rather than through the addition of poor labelling or training which may not always be accessible and relies on memory and ability (FDA, 2016).

The user group in the home environment is diverse. Therefore, the challenges vary depending on the primary user, their level of physical, cognitive and sensory capabilities and the level of training required for each group. The home environment is not designed with clinical characteristics and brings added risks in relation to its layout, size, lighting and noise. These characteristics have an effect not only on the use of the device but also on their safety and effectiveness (FDA, 2016).

Patients have a preference for automatic devices requiring minimal intervention and clear instructions with in-built assistance and prompts to identify and solve errors. These features may help to address challenges identified thus far and mainly targeting the elderly population with comorbidities. Overall, Great Britain has an adult population in which 3.5% has reduced vision, 1.9% has reduced reach, 4.8% diminished fine-finger manipulation and 5.7% has difficulty picking up and carrying objects (Waller et al., 2013). These measures of capability should form key aspects of the market evaluation in the process of device design. (he growing role of) Addressing these concerns may reduce the problems patients and carers have reported with general use of the device. At times, functional challenges may be reported as adverse events (Fung et al., 2015) which creates difficulties in addressing their causality due to the poor quality of adverse event data (Lyons, 2018).

The inter-patient variability related to social and personal circumstances, and varied health beliefs presents a more challenging task (Rajkomar and Blandford, 2015; Noble, 2015). Health beliefs play an important role in device acceptability and treatment compliance (Keller et al., 2017).

Patient factors such as health literacy and knowledge of their own health needs have important implications for successful self-care. In addition, medication management, infection control capability and practical use of the devices are important factors that need careful consideration and assessment. Speech and ability to communicate become critical in calling for help. Many elderly patients live alone, have limited interaction with others and often suffer from depression, anxiety and have particular beliefs regarding their own care (Lehoux, 2004; Henriksen et al., 2009). These factors affect how they interact with devices and their ability to use them correctly and safely.

The size, scale and cost of these problems is highlighted when considering devices such as infusion pumps. These have been associated with one of the highest rates of reported adverse events. In the US, between 2005 and 2010, 56,000 adverse events were reported in relation to infusion pumps leading to 87 model recalls for unsafe design and 710 deaths. Each model recall is estimated to have incurred a loss of $400–600 million for manufacturers. These numbers are not limited to home use devices, nevertheless a large number of home use devices not specifically designed for the home environment can present with similar concerns (CHI+MED Project, 2015; TUV SUV, 2017). It is reported that 44% of medical device recalls reported from FDA occur as a result of design problems (Williams, 2008).

Home devices need to accommodate the needs and capabilities of a broader range of users than do devices designed for healthcare professionals. The ability to operate a MD is based on patient factors such as experience, knowledge of their condition, memory, learning abilities and sensory function; and external factors such as training and information provided about the device (Lewis, 2001). Design of home devices needs to consider the interactions and constraints of the home environment, user-device interactions as well as accepting that patients may not always use devices as described (Rajkomar and Blandford, 2015; Lehoux, 2004).

When a user interacts with a medical device, they assess, interpret and process the information provided by the device to make a decision about their treatment. This process is highly dependent on the cognitive capabilities of the user, level of training and education and presence of pre-existing physical, visual or sensory deficit. For this group of patients, modifications to the setting should allow personalised input and subsequent feedback. The user is then required to consider this feedback and interact accordingly (FDA, 2016). For the next step in the process to work effectively, the feedback from the device needs to be readily understandable to the lay-person. This is a common problem reported by users who find that feedback from the machine is often either lacking or too complex (Rajkomar and Blandford, 2015; Mirel et al., 2011).

The less structured environment at home, compared to a professional care setting, increases the likelihood of adverse events (Masotti et al., 2010). The possibility of unintentional mistakes is a particular concern and may be associated with a lack of training. Other concerns are related to overlooking the suggested maintenance and calibration checks, taking shortcuts and overreliance on the device leading to more passive behaviour in monitoring their own health (Lyons, 2018).

Guidance (FDA, 2016; MHRA, 2017) exists on the design of user interfaces of medical devices and equipment however usability studies are often carried out in an institutional setting (Valdez et al., 2017) or in a controlled environment (Banerjee et al., 2013) whilst the less structured nature of care at home creates greater potential for adverse events (Valdez et al., 2017; Masotti et al., 2010). These “human aspects” are not always considered leading to reduced acceptability of devices (Motti and Caine, 2014). Human factors studies in the home environment are associated with difficulties in studying such a diverse environment (Keller et al., 2017; Valdez et al., 2017; Valdez et al., 2017, 2017; Masotti et al., 2010). Human factors based design methodologies are available for optimising home medical devices and they should be utilised accordingly (Fung et al., 2015).

In this study we considered the device-use system in three main components 1) device users, 2) device use environments and 3) device-user interfaces. These three aspects were repeatedly reported as problematic by end-users and their recognition poses difficulties for medical device manufacturers. (he growing role of) It is recognised that further work is needed to address these challenges. The assessment of all the above aspects is essential when applying human factors engineering to

any medical device and even more so in those devices intended for home use (Simeon and Keates, 2013).

Whilst the published literature has pointed out the usability challenges, options for improvement especially in the post market stage are limited and simply asking designers to adhere to the regulatory body criteria in device design may not be sufficient. This is because it is often missing the patient and the end user experience essential to guiding the human factors approach. Currently, there is no effective and standardised method of collecting such data from patients in the post market stage, perhaps due to the challenges in gaining access to patients, ethical approval for studies and the associated costs. (Keller et al., 2017; Valdez et al., 2017; Masotti et al., 2010).

The findings of this systematic review offer a platform for device designers and human factor specialists to focus on the main challenges faced by patients and inform the decision-making process on device prescription, and recommendations by clinical teams. The results will be used by the authors of this paper, in the process of developing a usability tool for evaluation of home use medical devices. There will be continuous patient involvement in this process to facilitate the development of a tool that aims to gather useful usability data and is acceptable to patients and relatives.

We believe that a better method of patient involvement in evaluation of home devices would inform both clinicians and manufacturers and allow for a more "personalised medicine approach" to the design and recommendation of medical technology based on patient needs.

### 4.1. Study limitations

The main limitation of this review is the small number of studies available. Although many published studies involve home use devices, the vast majority do not explore end-user experience. Most studies are small in size, although this is often the case with qualitative studies which may be time and resource consuming. None of the studies included patients with cognitive deficits, which is an important group of patients that would often benefit from home use MDs. Future studies should address issues related to such patient groups.

## 5. Conclusions

This study provides an understanding of the design and usability challenges that end-users face in the home environment whilst using MDs. There are limited human factors studies in the home environment. Treatment non-compliance and the risk of complications for patients may result. A better understanding of the home environment from a human factors perspective is required. A structured approach that includes human factors principles should be taken when assessing usability of medical devices especially those aimed for use by non-healthcare professionals. Improvement of patient safety and care at home must be a priority. Efficient methods of ensuring the involvement of patients and clinicians, along with other users is required to address this knowledge gap.

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## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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