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Original Article

Home Hemodialysis

Human factors testing of the Quanta SC+ hemodialysis system: An innovative system for home and clinic use

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Abstract

Introduction: Uptake rates of home hemodialysis are the lowest among all modality types, despite providing patients with clinical and quality of life benefits at a lower cost to providers. Currently, there is a need to develop dialysis systems that are appealing to patients while also being suitable for use across the continuum of care. The SC+ hemodialysis system was developed by Quanta Dialysis Technologies Ltd. to provide patients with a dialysis system that is small, simple to use, and powerful enough to deliver acceptable dialysis adequacy.

Methods: As part of the SC+ design validation, human factors testing was performed with 17 Healthcare Professionals (nephrology nurses and healthcare assistants) and 15 Home Users (patients and caregivers). To assess usability and safety, the human factors testing involved between 4.5 and 6 hours of training and, after a period of training decay, a subsequent test session in which participants independently performed tasks on SC+.

Findings: Between the two user groups, there were only 29 errors observed out of 1216 opportunities for errors, despite minimal training. Errors that did occur were minor and attributed to an initial lack of familiarity with the device; none were safety related.

Discussion: Among prevalent dialysis patients and healthcare professionals, the SC+ hemodialysis system was easy to use, even with minimal training and a learning decay period, and had a high level of use safety. By taking into account human factors to optimize the user experience, SC+ has the potential to address systemic and patient barriers, allowing for wider self-care and home hemodialysis adoption.

Keywords: Home hemodialysis, human factors, usability, quality of life, end-stage renal disease

INTRODUCTION

In 2010, there were approximately 2.6 million individuals on some form of renal replacement therapy worldwide. Prevalence is expected to increase to 5.4 million by 2030, driven by an aging population, increased survival of those living with end stage renal disease (ESRD), and increasing rates of diabetes and hypertension.[1] In most developed countries, the majority of patients with ESRD are treated with traditional facility-based hemodialysis, typically administered in an outpatient dialysis facility for sessions of

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4 hours, three times a week. This type of treatment can be burdensome for patients and their support networks, as well as costly for healthcare payers and patients. In comparison, dialysis offered in the home setting, such as home hemodialysis (HHD), is a more cost-effective treatment option in the long term.[2,3] Furthermore, HHD provides patients with the ability to dialyze more frequently and/or for longer periods of time on a flexible schedule, which is generally associated with improved outcomes over traditional thrice-weekly in-center dialysis regimens,[4] and may also be associated with lower rates of dialysis-related complications, hospitalizations, and mortality.[5,6] Moreover, HHD also provides patients with greater autonomy and flexibility, allowing them to maintain a normal schedule without frequent dialysis facility or hospital visits, while also offering potential quality of life improvements.[7]

Despite the benefits that HHD offers, uptake rates are the lowest among all dialysis modality types, with reported utilization rates of 4.9% of dialysis patients in Canada,[8] 4.4% in the United Kingdom,[9] and 1.9% in the United States.[10] Compared to facility-based hemodialysis, HHD can present as a complex treatment method for patients, and the fear associated with self-managing treatments at home can be a significant barrier when deciding on modality type.[11] To improve HHD adoption rates and procure the associated benefits, it is imperative to develop patient-centered, accessible dialysis systems that will appeal to patients and encourage them to take control of their own treatments within the home setting, while also reassuring nephrology care teams that a wide scope of patients are capable of effectively and safely performing patient-led care. Such systems should be suitable for use across the continuum of care—from dialysis facilities to the home—to allow dialysis programs to balance and optimize clinical resources and transition patients from one treatment setting to the other without needing to modify dialysis systems or treatment prescriptions for different settings. To specifically meet these priorities, the SC+ was developed by Quanta Dialysis Technologies Ltd (Quanta) for self-care dialysis treatments within the facility and home settings.

Human factors testing (HFT) is used during the development of consumer products to evaluate how intended users will interact with new technologies in a real-world setting and is used in medical device development to provide insights into systemic factors that may affect usability and/or patient safety. This provides medical device manufacturers the opportunity to eliminate or mitigate potential safety and usability issues before bringing products to market at scale.[12]

The primary objective of this report is to present the results from the HFT performed using the SC+, which was conducted to critically evaluate whether this device can be used safely and effectively by prevalent dialysis patients, caregivers, dialysis nurses, and healthcare assistants within a simulated at-home setting, supported only by instruction for use (IFU) and minimal training.

MATERIALS AND METHODS

The Quanta SC+ hemodialysis system

The Quanta SC+ hemodialysis system was designed for self-care use in the home and facility settings, with the intent to simplify the interactions users have when using HHD systems. For the HFT described in this report, all activities occurred using the device pictured in Figure 1. The device is compact (height: 480 mm x width: 370 mm x depth: 450 mm) and weighs approximately 35 kg. The SC+ provides conventional high-flux, bicarbonate dialysate-based treatments, and like conventional dialysis systems, it uses standard consumables, including concentrates and a dialyzer. The only proprietary elements are the machine itself and a consumable set consisting of a nonsterile dialysate cartridge and a sterile blood tube set. The fluidic system is based around a single-use disposable cartridge to generate dialysate fluid on demand—achieved by dosing and mixing water and concentrates on the cartridge—and to accurately pump and deliver high

Figure 1 Quanta SC+ system, original design. [Color figure can be viewed at wileyonlinelibrary.com]

dialysate flow rates at 500 mL/min. This approach provides several benefits: enabling a smaller, lighter form factor of the machine, simplifying set-up and tear-down of consumables required for each treatment, negating the need for disinfection of the machine between treatments, and eliminating the need for regular descaling.

The SC+ is compatible with commonly used water sources used for dialysis treatments, including central water purification plants and ring-mains typically used in clinics and stand-alone reverse osmosis water purification devices used in home settings. This approach allows the system to provide virtually unlimited volumes of dialysate per treatment, avoiding the volume restrictions of other HHD systems. The SC+ features a touchscreen graphical interface that displays step-by-step instructions to control the functionality of the device to aid the patient's progression through treatment and to provide onscreen guidance for resolving alarms. The layout of the interface, screen progression, and menu hierarchy were designed to be uncluttered and intuitive, with a focus on simplifying the information presented to streamline workflows. An accompanying IFU manual was developed to be used both as training material as well as a reference for troubleshooting.

Participants

Participants in this study consisted of two groups of users: (1) Healthcare Professionals, including dialysis nurses and healthcare assistants, who would typically manage hemodialysis devices in a facility setting or provide HHD training to patients; and (2) Home Users, including current dialysis patients and their caregivers. All users had no previous training or experience using the SC+ system. The participants were recruited from across the United Kingdom, with study activities occurring over July and August 2016 at Smethwick Dialysis Centre in Birmingham, United Kingdom, and included 32 individuals—17 in group 1 (the "Healthcare Professionals"), and 15 in Group 2 (the "Home Users").

Human factors testing

The HFT process involved a training phase followed by a training decay phase and an evaluation phase. One-to-one training was provided to subjects by qualified instructors who advised participants on how to use the device using a predefined training program. After a training decay period, a standardized testing session was conducted to evaluate each subject's competency in performing the tasks required to operate the device.

Testing environment and protocol

The study consisted of a series of three, 2-hour training sessions for the Home Users and one 4.5-hour training session for the Healthcare Professionals. After training and prior to the evaluation session, there was a period of 3 to 9 days of training decay with the Home Users and 1 to 12 days with the Healthcare Professionals. The testing method employed in this study was adapted from IEC 62366-1:2015[13] and ANSI/AAMI HE75:2009.[14] Each participant provided informed consented to participate in the study and was trained by personnel from Quanta. Given that the HFT was used with an approved device, with low risk observations, ethics board approval was not sought.

The test room was consistent for each test session and was set up to adequately imitate a home environment, with the SC+ device as the focal point (Figure 2). Each participant received training on how to operate the SC+ system. The HFT assessed all tasks required to effectively set up, operate, and shut down the system, including handling and disposing of the consumable items and responding to alarms. Altogether, 34 individual subtasks related to administering dialysis treatment needed to be completed, as well as an additional four subtasks related to comprehension of the IFU. For analyses, the 38 subtasks were subsequently grouped into 15 broad task categories.

A study protocol provided detailed information on the testing methods, the testing equipment, the device and the consumables, as well as the evaluation criteria (Supporting Information Appendix S1). Table 1 lists the risk assessment terms and definitions used to evaluate the participants. Each participant was observed and then scored according to the pre-specified criteria. Five

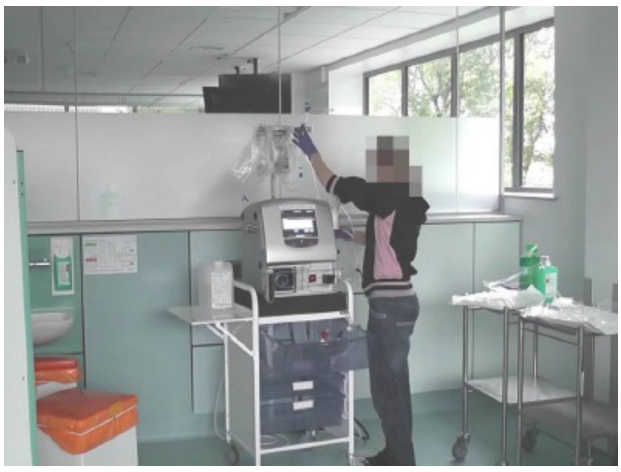

Figure 2 Test room set-up for Human Factors Testing of the Quanta SC+ home hemodialysis system [Color figure can be viewed at wileyonlinelibrary.com]

Table 1 Risk assessment terms and their definitions

Term	Definitions
Success	The participant was able to complete a task as requested without any issues, completely as per the instructions.
Success with difficulty	The participant managed to eventually complete the task as intended, but either deviated from the instructions for small subtasks or in sequencing, or had difficulties in completing the task, without a potential implication for safety.
Close call	The participant encountered initial use errors that did not result in an outcome, but managed to complete the task as intended by self-correcting (using the instructions).
Use error	The participant deviated from the instructions and was unable to complete the task as intended, or the task attempt itself was halted by the lead investigator.
Unperformed task	A task that was not completed either because of a previous use error (i.e., sequence error), or for another reason.

descriptive criteria were used to evaluate the degree to which participants attempted and completed each of the subtasks. If a participant successfully completed a subtask as per instructions within 10 minutes of beginning the attempt, the attempt was recorded as a "Success." If a participant managed to eventually complete a subtask as intended, but either deviated from the instructions, or had difficulties with completing the subtask without any potential implications for safety, then this was recorded as a "Success with Difficulty." For all subtasks attempted but not successfully completed by a participant, the evaluator classified the outcome into one of three categories. If the participant encountered initial use errors preventing task completion, but managed to finish the subtask as intended by self-correcting (e.g., by referring to the IFU), this was classified as a "Close Call." When a participant deviated from the IFU and was unable to complete a subtask as intended, or when the subtask attempt itself was halted by the lead investigator, this was categorized as a "Use Error." Attempts recorded as a Close Call or Use Error were initially treated as potentially safety related; these were then subsequently assessed using an impact analysis to make a final safety assessment. If it was not possible to complete a subtask (e.g., due to a use error in a preceding step), then the subtask was recorded as "Unperformed" and the user's comprehension of this task was assessed verbally.

RESULTS

Demographic characteristics

Table 2 presents the demographic characteristics of the participants. Of the 17 Healthcare Professionals participating in the study, 13 were dialysis nurses, and 4 were healthcare assistants. The group had a mean age of 42.5 years (with a range of 25–52 years), 70.6% were female, and had a mean of 9.6 years (with a range of 1–19 years) working in dialysis. In the Home Users group, there were 15 individuals: 7 caregivers and 8 patients. This group had a mean age of 43.7 years (range of 19–76 years), 46.7% of the group was female, and the group had a mean number of 4.65 years of dialysis experience (range of 2 months–19 years). The mean testing session length was 75.5 minutes (range of 55–99 minutes) for the Healthcare Professionals, and 99.5 minutes (range of 78–132 minutes) for the Home Users.

Results of the human factors testing

Tables 3 and 4 present the results of the HFT evaluation, showing how well participants in the Healthcare Professionals group and Home Users group performed the various subtasks within the 15 major task categories. Each of

Table 2 Participant demographic characteristics

Healthcare Professionals (n = 17)	
Renal nurses	n = 13
Healthcare assistants	n = 4
Mean age[a]	42.5 y old (25–52 y)
Sex (% females)	70.6%
Mean number of years of dialysis experience[a]	9.6 y (1–19 y)
Mean testing session length[a]	75.3 min (55–99 min)
Home Users (n = 15)	
Caregivers	n = 7
Patients	n = 8
Mean age[a]	43.7 y old (19–76 y)
Sex (% females)	46.7%
Mean number of years of dialysis experience[a]	4.65 y (2 mo-19 y)
Mean testing session length[a]	99.5 min (78–132 min)

[a]Range presented in brackets.

Table 3 Summary of recorded observations for the Healthcare Professionals group (n = 646 potential task attempts)

Task category	Success	Success with difficulties	Close call	Use error	Unperformed
Task 1: Turning on SC+	17	0	0	0	0
Tasks 2–4: Selecting dialyses mode	48	3	0	0	0
Tasks 5–6: Assembling consumables	33	1	0	0	0
Tasks 7–9: Loading the blood line	37	14	0	0	0
Tasks 10–17: Loading dialysate lines	120	11	0	1	4
Tasks 18–20: Priming	37	14	0	0	0
Tasks 21–23: Connecting the patient	43	7	0	1	0
Task 24: Starting treatment	16	1	0	0	0
Task 25: Responding to the low arterial pressure alarm	15	2	0	0	0
Task 26: Responding to the high venous pressure alarm	12	4	0	0	1
Task 27: Responding to the air in the blood alarm	7	7	0	2	1
Tasks 28–31: Ending treatment	55	8	0	0	5
Task 32: Disposing of consumables	11	6	0	0	0
Task 33: Manual washback	13	2	0	2	0
Tasks 34–38: Comprehension of the instructions manual	80	5	0	0	0
Total	544	85	0	6	11

the 32 participants was required to complete 38 individual subtasks, for a total of 1216 potential tasks to be completed: 646 by the Healthcare Professionals and 570 by the Home Users. Between the two user groups, there were 28 use errors (2.3%) and 1 close call (0.1%), for a total of 29 errors observed (2.4%).

In the Healthcare Professionals' group, 11 subtasks (1.7%) were unperformed, as were 5 subtasks (0.9%) in the Home Users' group. These were largely due to unrecoverable technical issues where the machine ended the treatment as intended to protect the patient, resulting in aspects of the session being skipped. In these situations, performance for subsequent subtasks was evaluated by asking the participants to report the steps following the error, and to provide an account of what they would do. None of these technical issues were assessed as being safety related.

Table 4 Summary of recorded observations for the Home Users (patients and caregivers) group (n = 570 potential task attempts)

Task category	Success	Success with difficulties	Close call	Use error	Unperformed
Task 1: Turning on SC+	15	0	0	0	0
Tasks 2–4: Selecting dialyses mode	42	3	0	0	0
Tasks 5–6: Assembling consumables	26	4	0	0	0
Tasks 7–9: Loading the blood line	33	9	1	2	0
Tasks 10–17: Loading dialysate lines	105	13	0	1	1
Tasks 18–20: Priming	33	11	0	0	1
Tasks 21–23: Connecting the patient	23	19	0	3	0
Task 24: Starting treatment	14	1	0	0	0
Task 25: Responding to the low arterial pressure alarm	14	1	0	0	0
Task 26: Responding to the high venous pressure alarm	7	7	0	1	0
Task 27: Responding to the air in the blood alarm	3	5	0	7	0
Tasks 28–31: Ending treatment	44	12	0	3	1
Task 32: Disposing of consumables	10	3	0	0	2
Task 33: Manual washback	5	8	0	2	0
Tasks 34–38: Comprehension of the instructions manual	64	8	0	3	0
Total	438	104	1	22	5

Healthcare Professionals

Out of 646 potential tasks for the Healthcare Professionals group, six use errors were observed across four task categories, producing an error rate of 0.9%. None of these errors were assessed as being safety related. One error occurred in the category "Loading the dialysate lines," as well as one in the category "Connecting the patient." Two use errors occurred in each of the following categories: "Responding to the air in the blood alarm" and "Manual washback."

Home Users (patients and caregivers)

Out of 570 potential tasks for the patient and caregiver group, 22 (3.9%) use errors were observed across eight task categories. In addition, there was 1 close call (0.1%), providing a total of 23 errors observed (4.0%).

Three errors occurred in the category "Loading the blood lines"; one was a "close call," and the other two were use errors. In the "Loading the dialysate lines" category, one use error occurred, whereas three use errors occurred in the "Connecting the patient" category. One use error occurred during the task of "Responding to a high venous pressure alarm." The task category where the highest number of use errors occurred was in the category of "Addressing the air in the blood alarm"—a total of seven participants performed this subtask with a use error. Three use errors were observed during the task category "Ending the treatment," while two use errors occurred in the "Manual washback" category. Lastly, during the tasks evaluating the "Comprehension of the instructions for use," three use errors occurred. Subsequent risk analyses of all errors determined that none of the observed errors were safety related.

DISCUSSION

Using a well-characterized HFT protocol and defined evaluative criteria, SC+ has demonstrated excellent levels of user safety and competency, despite minimal up-front training and significant training decay time. The SC+ system achieved an overall task-specific success rate of 97.4% among Healthcare Professionals, and 95.1% among Home Users. The vast majority of the errors made were attributed to an initial lack of familiarity with the device, rather than safety-related design flaws.

Issues highlighted in this study have led to usability improvements for SC+, resulting in an updated design of the device (Figure 3). Specifically, this includes a new design for the graphic user interface, improved color coding of the consumables and clamps, repositioning of the treatment drain to a higher location on the rear door and

Figure 3 Quanta SC+ system, updated design. [Color figure can be viewed at wileyonlinelibrary.com]

optimizations to the 'air in blood' alarm. Furthermore, an important component of the HFT included evaluating participants' comprehension of the instructions for use, and by extension, evaluating their health literacy as it relates to risk management. For the majority of the use errors that occurred in the two user groups, changes were made to the IFU and/or the training documentation to clarify proper procedures, such as how to properly connect the two saline bags and how to resolve the air in the blood alarms.

Despite being a cost-effective treatment option that may improve patients' health and psychosocial outcomes,[15–17] HHD has relatively low uptake rates in many developed countries.[18] When deciding on which modality type to pursue, patients value autonomy, as well as quality and quantity of life as the most pivotal factors.[19,20] However, there are a number of barriers that have the potential to prevent patients from choosing HHD, including being wary of "medicalizing" their homes, wanting trained medical personnel to deliver treatments because of fears associated with making errors,[19] as well as not having the physical space within their homes to store the dialysis system and equipment.[21] Additionally, low HHD uptake rates may also partially be a reflection of the dialysis population's high rates of multiple comorbidities and their social characteristics that can impact their ability to self-manage dialysis treatments at home. For example, 55% of the dialysis population has some form of diabetes,[8] which in turn is associated with peripheral neuropathy, carpal tunnel syndrome, arthritis, and macular degeneration. Additionally, given that the overall mean age at dialysis initiation is approximately 64 years old,[8] rates of cognitive impairment are estimated to affect a significant proportion of dialysis patients;[22–24] cognitive impairment affects a person's judgment and dexterity,

hindering their ability to self-manage complicated HHD systems. Moreover, although self-care can promote self-empowerment, an individual's support network often needs to be involved in a patient's care; and indeed this is reflected in several studies that suggest home dialysis users tend to be younger and married or cohabitating, with fewer comorbidities.[6,25,26]

Given low uptake rates of HHD in developed countries, it is imperative for the design of HHD systems to address the needs of patients and caregivers of different ages and abilities to help overcome some of these barriers and successfully increase HHD uptake. SC+ was designed with the intention of being a simple HHD system that delivers adequate dialysis power when compared to traditional hemodialysis systems, while having a compact size and an approachable appearance, so that patients can integrate the system within their homes with ease, without necessarily overly "medicalizing" the home environment. Furthermore, to make facility-based self-care HD and HHD more accessible to a wider range of patients, SC+ was designed as a user-friendly, easy to learn, and easy to use system. In this HFT study, SC+ demonstrated that a broad spectrum of prevalent patients and caregivers can easily learn how to use this new dialysis platform, even with minimal training and after experiencing significant training decay. SC+ was also meant to be adaptable for use across the continuum of care—from in-center HD, to self-care within a facility, to self-care at home—to allow for patients to transition between care settings with ease.

Before arriving to market, new medical technologies generally undergo rigorous testing during their development stages to ensure that the technology is safe, easy to use, and appealing to patients. HFT is one methodology that allows manufacturers and researchers to observe how real users naturally behave with technology, which is especially pertinent during the design validation of HHD systems to avoid training and technique failures attributed to system design flaws. Similar methodologies have been employed for other HHD systems to assess the clinical safety and performance of the systems within controlled clinical environments prior to roll-out in home settings. For example, HFT was conducted for the recently developed Tablo hemodialysis system with Healthcare Professionals and patients.[27]

This HFT study does have certain limitations; although the home is the principle target environment for use of SC+, usability testing is difficult to execute in the home. However, our simulated home environment was deemed an adequate representation, particularly because it included similar distractions that would be found in a home, such as televisions, noise from patients and staff, and variation in lighting conditions (i.e., bright sunlight hitting the screen, as well as low ambient lighting conditions). Furthermore, the average age of our patient sample was younger than the average age of patients starting dialysis, limiting generalizability. As well, our study population only included prevalent patients and caregivers—not naïve users. Additionally, although this HFT study was cross-sectional, further longitudinal clinical testing is currently ongoing to evaluate the clinical usability and safety of the SC+. This is in addition to formative usability studies that were performed prior to the HFT conducted in this current study, which identified safety issues that led to redesigning of various aspects of SC+, such as enhanced labeling and revised instructions, to ensure that the final design of the device is optimized for human factors.

In conclusion, the HFT results presented in this report demonstrate that, with minimal training, the SC+ hemodialysis system is easy to use and has acceptable user safety with intended users. We anticipate that the simple, easy to use design of the SC+ might make HHD a more appealing treatment option for a broader range of patients, some of whom might otherwise choose facility-based hemodialysis. Therefore, bringing the SC+ hemodialysis system to market has the potential to support the growing movement of shifting dialysis care from the clinical setting into the home, in turn enhancing patients' quality of life, while mitigating the cost burden associated with facility-based dialysis.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1 Supporting Information.