Student Name: Sean Desrochers **Date:** 08/06/2017

Project Title: The Development of a Virtual Electronic Ward for use in Patients with End Stage Renal Disease.

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Summary (250 words max single spaced):

Chronic Kidney Disease affects over 3 million Canadian adults and is a significant burden on both the patients and the health care system. A vulnerable period has been identified in patients approaching, or who have just begun dialysis which could potentially benefit from more careful monitoring. The goal of our project was to develop a Virtual ward Incorporating Electronic Wearables (VIEWER) to monitor patients within this vulnerable period. In addition to creating this system, we conducted feasibility testing using 8 healthy volunteers who were then administered a survey (System Usability Scale) which allowed for the objective scoring of their experience with the device, along with the survey feedback on the device was collected.

Through a partnership with eQOL (a Canadian healthcare company) we were able to develop a working platform. The beta testing of our product produced a score of 90/100 which is encouraging, and allows us to move forward using the device with real patients suffering from end stage renal disease. Finally, feedback collected from participants was utilized to plan future changes to the kit allowing it to be more user friendly.

Student Signature

Primary Supervisor Signature

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Introduction

Chronic kidney disease (CKD) affects more than 3 million Canadian adults, with the later stages of CKD (stages 4-5) representing more than 100,000 of these individuals. Approximately 10,000 of these patients will experience kidney failure annually and the vast majority of these patients will rely on renal replacement therapy of some sort to survive.[1] The most common renal replacement therapy is dialysis, which in addition to being a heavy burden on the healthcare system financially ($50,000-200,000 per patient each year), results in a complete shift in the livelihood of patients requiring them to be in hospital undergoing treatment on average 3 times a week for hours at a time.

The transition from non-dialysis CKD to end stage renal disease (ESRD) requiring renal replacement therapy is a difficult and vulnerable time for patients. An ideal transition is one in which the patient begins dialysis electively, at the point when uremic symptom burden is becoming significant, but before serious complications such as volume overload or hyperkalemia supervene requiring emergency treatment ("crash start"). This narrow optimal start window spanning the interval between early symptoms and emergent complications is elusive and often missed for many patients. Between 25-50% of patients with CKD followed by a nephrologist in clinic have a non-optimal, emergent start, often through the emergency department, and usually precipitated by either unanticipated drop in kidney function, acute volume overload, hyperkalemia, or acutely worsening symptoms (often called "hitting the uremic wall"). Data from Manitoba has shown that there is a 10-fold increase in emergency department visits by patients 30 days prior to initiation of dialysis. These data suggest that in many patients the optimal start window has been missed. Moreover, emergent starts are associated with lower rates of survival and higher morbidity when compared to patients who receive optimal starts. In addition, emergent starts are costly, with the average unplanned start costing an additional $17,000 to the Canadian healthcare system, over and above the costs of a planned start.

Prevention of such unplanned starts should be a high priority. Because the onset of either a rapid decline in kidney function, or a sudden increase in uremic symptoms, is inherently unpredictable, very close monitoring, ideally daily, of patient status is required. Development of a telemonitoring system to closely observe patients during this vulnerable window could serve to predict the decline that is often missed prior to renal failure requiring RRT. This would allow for intervention to occur prior to a crash start in the emergency department and potentially could avoid many of the complications and costs that result from an unplanned dialysis start. Traditional telemonitoring systems, however, have been prohibitively expensive, and this has reduced enthusiasm for the testing and application of such systems.[2,3] The recent proliferation of inexpensive, commercially available wearable health monitoring technology sharply reduce the technological and monetary barriers to home telemonitoring. The objective of the present study, therefore, was to develop and perform preliminary feasibility testing of a home monitoring platform for daily home monitoring of high risk patients with CKD.

<u>Role of the Student</u>

The role of the student in this project begun with determining the important characteristics of any devices to be used with the population. From there, the student researched devices attempting to select those which best suited the needs of the platform. Over the course of the project the student was responsible for communicating with the partner company eQOL to refine the application and express to the software developers the requirements from the researcher's perspective. Over the course of the study the student aided in developing the VIEWER platform through testing and feedback in addition to this the student created a simplified user manual for participants. Finally, the student was responsible for demonstrating the feasibility of the

VIEWER platform by developing and carrying out a beta testing of the devices as described below.

Methods

Platform development

The goal in developing the telemonitoring platform was to create a simple suite of wearable monitors, integrated using a tablet based app, to accurately and reliably collect patient information and upload these data to a "portal" accessed by the healthcare team. In developing the platform, we prioritized the following core qualities in the selection of hardware and software:

1. Ability to monitor standard clinical parameters. The devices to be used in the platform needed to collect a number of vitals important and standard clinical monitoring of CKD patients (blood pressure, weight changes, activity level, pulse rate, and oxygen saturation).
2. Ease of use: The target population for our platform are patients with advanced CKD, and are often afflicted with multiple comorbidities, which could include cognitive or physical disabilities that would make working with the application and/or the devices difficult.[4] Therefore in designing the application simplicity was paramount. Any application used would need to be not only simple and intuitive to use but would also need to take into account the comorbidities of the patients' using it. For example, poor eyesight would require larger text and buttons to be used, patients with arthritis could have issues utilizing the application or manipulating the various devices in the kit
3. Simple interconnectivity: It was of utmost importance that the devices selected be as interconnected and simple as possible while still collecting potentially useful vital information.
4. Use of consumer devices: One of the main goals of our project was to maximize the use of consumer devices as opposed to more specialized medical equipment. Medical equipment is expensive and unintuitive for patients to use, whereas consumer electronics are designed specifically to be easy to use, and are mass produced at lower cost.

We collaborated closely with eQOL, a Canadian health technology company based in Toronto, on the development of this platform we eventually called VIEWER (Virtual ward Incorporating Wearables).

Numerous wearables and tablets were researched including chest monitors that would also allow for cardiac monitoring, and more simple pedometers. When determining the main tablet device to be used factors such as accessibility due to eye-sight, cost, and ease-of-use were all taken into account. Special attention was given to the interconnectivity of the devices, in order for the devices to be as simple to use as possible we wanted to avoid the need for patients to enter any data manually, with the goal being to connect all devices wirelessly allowing for automatic recording and tracking of vital statistics. This would make the system much less cumbersome to use and would prevent any errors during manual input.
During our research of applications and devices particular attention was paid to the user instructions and manuals. We found that most of the manuals created for applications were incredibly detailed and lengthy. While this may prove useful for an experienced user, or for someone providing tech support, we felt for the average user this was excessive and did not prove useful. Therefore, in developing the system we felt it necessary to create a simplified manual which would provide only the essential details for your average patient to use the VIEWER kit day-to-day.

Feasibility Testing

Preliminary Beta testing of version 1.0 of the VIEWER kit was conducted on 8 healthy volunteers. The intent of this testing was to assess multiple components of the platform through a patient lens, including:

1. Ease of use
2. Potential technical glitches
3. Feasibility
4. Perceived usefulness
5. Potential barriers to use

The testing was conducted over a series of 2 weeks with the beta testers attempting to use the VIEWER kit in the same manner that a future patient would (daily measurements and logging of vitals).

Participants were instructed to complete the 10 item System Usability Scale (SUS) which is a well validated tool to assesses the usability, feasibility, perceived usefulness and helps identify any technical problems in the system.[5],[6] According to a systematic review of over 3,500 surveys within 273 studies of varying technologies a grading scale was created. The average reported score of surveys reviewed in this study was 69.5, it was concluded that any score below this was indicative of major flaws that needed to be addressed. The highest graded category was >90 which the study described as “Excellent” (>85) along with assigning a grade of A to systems scoring above 90.[7] (see fig. 1)

Beta testers were also asked to keep detailed notes throughout the study to address any issues with using the system, and note any suggestions for improvements. Instructions in terms of what was considered appropriate feedback was purposefully left vague in order to gauge what different testers deemed important in making a device easy to use. As the accuracy and validity of the vitals collected were not the objective of this phase of feasibility testing, individual readings and results were not stored or analyzed.

Analysis:

Continuous variables were summarized as means (SD). Because of the small N, significance testing was performed sparingly. A qualitative thematic analysis of all participant feedback was performed and the results summarized.

Results

VIEWER Kit Specification and functionality (see fig. 2 and table 1)

We determined the best touch screen device to centre the VIEWER kit around was the iPad mini. The reasoning for this was that unlike a smartphone the iPad had a larger screen which made the text larger and allowed for larger buttons to be pressed. We felt this was important for patients with impairments in vision or manual dexterity. The wearable selected was a wristband pedometer specifically produced for the VIEWER kit. The wearable band closely resembles many similar products on the market and therefore patients are likely to be familiar with it’s functioning. The devices selected were all readily available consumer items and included a blood pressure cuff, pulse oximeter, and weight scale. All devices used in the kit were Bluetooth compatible and were synchronized to the iPad therefore allowing for wireless recording of vital statistics. This is reflected in that the VIEWER platform is based on a readily available iPad mini, and that the wearable device is modelled directly after the very common and popular FitBits available on the market. All of the other devices used as a part of the VIEWER platform (Blood pressure cuff, weigh scale, and pulse oximeter) are available easily to consumers and were selected due to their ease of use.

All applications were eliminated from the iPad leaving only the eQOL application for the patients to use. The unlocking of the iPad main screen was made as simple as the operating system would allow, with the removal of any kind of pin or password, requiring the patients simply to press a button to unlock the device. System settings were modified so that patients have minimal ability to alter any important settings potentially compromising data collection. It is important to note however that unique log-in information was required to enter the eQOL application which prevents unrestricted access to patient data.
A single page user manual which utilizes colour coding and a simple to follow step-by-step flow chart that relies heavily on pictures of the kit was created. The manual should allow patients a simple reference and reminder when using the kit without assistance (see fig. 3)
Implementation of a symptom survey is currently being done on the VIEWER kits with the next version including the Edmonton Symptom Assessment Survey (ESAS) which will allow patients to report their symptoms directly in the application.

Feasibility Testing

Population Characteristics

We performed a prospective observational study which served as a beta testing of the VIEWER platform. The testing was performed using 8 healthy volunteers The age of participants ranged from 23 to 65 years old, 50% were female.

System Usability Scale

The average System Usability Scale score (SUS) for all participants was 90/100. Analysis of the individual questions within the SUS showed consistently high scoring across all of the questions, with the mean adjusted score out of 4 of all questions falling between 3.25 and 4 (standard deviation 0.25) (see table 2 and fig. 4) The lowest scoring question (3.25) was “8. I found the VIEWER kit very cumbersome to use” suggesting some difficulty by participants in actually using the kit.

No trends were observed between age groups in terms of SUS scores. The average score across both age groups being 90. A study by McLellan et al. reported concerns with SUS measurements based on the prior comfort or experience level of participants.[8] However, no correlation between SUS score and comfort level with wearable devices could be demonstrated in our population (r^2=0.058 p=0.076). All survey participants reported feeling comfortable with smartphones or tablet computers and no significant difference was observed between gender’s (Female: 91.3; Male: 88.8).

Qualitative user feedback

(See table 3)
Open ended survey questions resulted in participants reporting issues that were classified into 4 categories:

1. Technological issues (6 out of 8 users reported)
   Common complaints involve Bluetooth synching problems, with problems being reported with the scale, blood pressure cuff, and wearable step counter. Participants reported being able to input the results manually however expressed concern at the cumbersome, and potentially error prone nature of this method.
2. Lifestyle Conflicts (4 out of 8 users reported)
   The wearable devices comfort and strap usability were the most common complaint with 3 of the 4 participants commenting on this. The lack of portability of the VIEWER kit which required the participants to be home everyday to log information was raised, the concern for travelling while using the device was brought forward as well. Finally,

concerns about the use of the device in certain activities or occupations was voiced by some testers.

3. Battery Life Issues (3 of 8 users reported)
   The battery life of the wearable step counter was the most common complaint as users frequently did not notice that it had died. Users reported concerns about the changing of batteries in the scale, pulse oximeter, and blood pressure cuff and who would be responsible for the battery costs.
4. User challenges (5 out of 8 reported)
   Participants frequently reported forgetting to take measurements, or to wear the step counter. Issues with misplacing or losing the wearable step counter were also frequently reported.

Discussion

Our study provides strong proof of concept for the VIEWER platform as a useful tool for daily patient telemonitoring. The VIEWER platform scored well in a validated system usability scale, and additional shortcomings identified by open ended feedback appear easily fixable. These findings are encouraging, and auspicious for the future success in patients with CKD.

Our viewer platform scored 90/100 on a validated system usability scale (SUS) assessing effectiveness, efficiency, and user satisfaction. Importantly, scores were high across all domains of the SUS. A systematic review of over 273 studies using this SUS concluded that any score below 69.5 was indicative of major flaws whereas a score >90 was indicative of a highly useable system.[7] In addition, a high SUS score is also predictive of a system with high learnability.[9] Open ended feedback from study participants identified additional important weakness in 4 areas of system usability. These included technical issues with connectivity or malfunctioning of devices, lifestyle conflicts, battery life and user error. The technical issue most frequently reported related to device connectivity and specifically with unpairing of the Bluetooth connection between the remote devices (e.g. bluetooth scale) and the tablet. The option to manually input data mitigated the impact of these unpairings, as did a simplified instruction set on re-pairing. Nevertheless, further software development is in progress to address this issue. Lifestyle conflicts presented a unique challenge for integrating this system in clinical practice. User's frequently reported forgetting to take their vitals or perform the necessary tasks everyday. It was suggested numerous times by participants that notifications on the iPad, on the wearable, or patients phone would be helpful and this functionality will be added to revised version of the VIEWER application.

The concept of remotely monitoring patients suffering from high risk chronic diseases is not a new one. Studies in North America and Europe have demonstrated the efficacy of virtual wards in improving outcomes in some patient groups but not others with this strategy.[10,11] A pilot trial conducted in Toronto aimed to use a "Virtual Ward" to monitor patients on home hemodialysis. They identified the gaps in care that existed within this population and aimed to address them through weekly phone calls where a symptom survey was delivered. Through this pilot study they demonstrated the feasibility of using a virtual ward with this patient population.[12] Our goal is to build on this concept of a virtual ward, while instead of weekly phone calls we aim to monitor the vitals of the patients directly in the hope of preventing the same adverse events that the Raphael et. al. aimed to prevent.

Our approach to a virtual ward is much more intensive than a weekly phone call. This comes with advantages and disadvantages. It will allow us to monitor patients more closely, to catch signs of an adverse events that a symptom survey may miss, and also would not require the human resources that would be required to make these phone calls as the system would

monitor health statuses independently. Another advantage is the ability to monitor health status objectively through the reading of vital signs instead of relying on the self-reporting of patients. The application of such a comprehensive system could be accompanied by some pitfalls and complications. The introduction of new health technology often has to overcome many different complications and concerns. Some examples of these are encountered early on in the development process, the main being the safety of the technology being developed. The VIEWER kit utilizes exclusively consumer products therefore the concerns regarding safety are limited. Assessing if the new technology is suitable for use under real world conditions often presents a unique challenge as it is difficult to imagine all the variables which could effect the usability once in the hands of real patients. Mytton et al. reported the use of active surveillance as the best method to smooth the transition of a new technology into the patient population, therefore training of health staff, and the creation of a support team for the VIEWER kit, especially early on in it's deployment could prove helpful.[13]

The implications for future use of the VIEWER platform are promising. With the demonstration that the platform functions effectively and efficiently with healthy subjects the logical next step is introducing the technology to patients with ESRD who are approaching, or who have just begun renal replacement therapy. Through this process an algorithm can be developed which utilizes some, or all of the vitals being collected from the system to predict an adverse event, with the final goal being to prevent these events and therefore reduce the burden on both the patient and on the system.

The concept of utilizing a virtual ward to reduce hospital admissions and subsequently save on health care costs has been established in England, where the use of virtual wards is significantly more widespread. In 2011 the community of Wyre Forest underwent a risk stratification of residents which identified the most at-risk of being hospitalized. The implementation of a virtual ward involving these high risk patients reduced the hospitalization rate by 10% in that community over the next year and saved the National Health Service (NHS) over £1.2 million.[14] With the average emergent dialysis start in Manitoba costing $17,000 it is easy to imagine that the savings created by a virtual ward on patients with ESRD could be significant.
It is conceivable that one day clinicians could use the VIEWER platform with patients approaching kidney failure to monitor their status between visits. The patients' vital statistics would be available to the patients' circle of care through an online portal which would come equipped with a red flag system which would alert caregivers of the possibility of an adverse event prior to it occurring allowing for intervention.

Our small feasibility study has numerous strengths. We believe the age range of our population to be one of those strengths. While we were unable to test the device on anyone in the 65+ age range, a number of subjects within the age range of 55-64 utilized the devices, this is consistent with the age of the population that is currently or soon to begin dialysis (62.5 in the USA (2014)).[15] The use of the System Usability Scale provides a simple but powerful tool that has been well validated even in small populations and is easy to compare to industry standards. Finally, through the use of consumer electronics with a high degree of interconnectivity we feel we have taken the majority of the burden off of the VIEWER platform user and created a powerful and potentially useful platform that can be easily implemented in a clinical setting.

Our study also has certain limitations that should be borne in mind. The limited sample size of the beta testing is one limitation of the study. Unfortunately, due to the cost of the VIEWER kit the initial testing numbers were limited. The participants were members of a healthy, well educated user group that were used due to accessibility, therefore it could be difficult to

generalize results from this group to that of dialysis patients. We plan to address this with phase 3 of the study which aims to conduct testing with 100 VIEWER kits on patients nearing dialysis. Another limitation of the study is the lack of comorbidities present within the sample population. Patients with ESRD experience physical, psychological, and cognitive difficulties which could make using the platform more challenging.[16] As described earlier precautions were taken to make the devices as simple to use as possible, however, certain comorbities could present additional challenges.

Conclusion

The survey results obtained from the beta testing of the VIEWER kit are promising for the future application of the platform in a research and eventually clinical setting. Future work should focus on making the device more easily integrated into the lives of patients with notifications and more ergonomic wearables. Next steps for the platform should revolve around the use of the device by patients with ESRD allowing for it to be demonstrated as feasible with this unique patient population. Following that, the validity of the vital statistics as predictors of negative outcomes needs to take place in order for the eventual goal of the VIEWER kit to serve as a clinical predictor of negative outcomes in patients with ESRD to be achieved.

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Tables and Figures

Figure 1 - Bangor et al. System Usability Scale adjective rating scale.

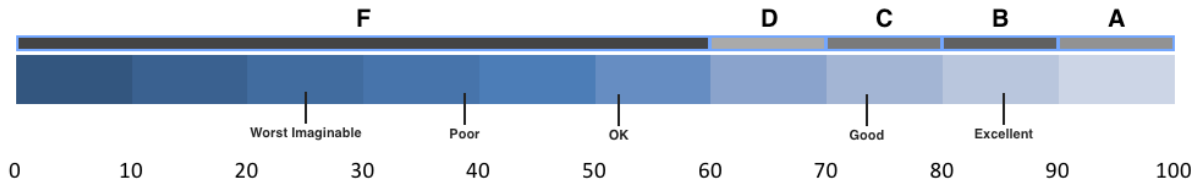

Table 1 - Overview of VIEWER kit items

ITEM	DESCRIPTION
32 GB IPAD MINI	Basis of platform with eQOL app preloaded
WEARABLE STEP COUNTER	Brand-less wearable watch step counter
PULSE OXIMETER	Bluetooth equipped pulse oximeter with heart rate
WEIGH SCALE	Bluetooth equipped auto-on weigh scale
AUTOMATIC BLOOD PRESSURE CUFF	Bluetooth equipped blood pressure cuff

Figure 2 - VIEWER kit

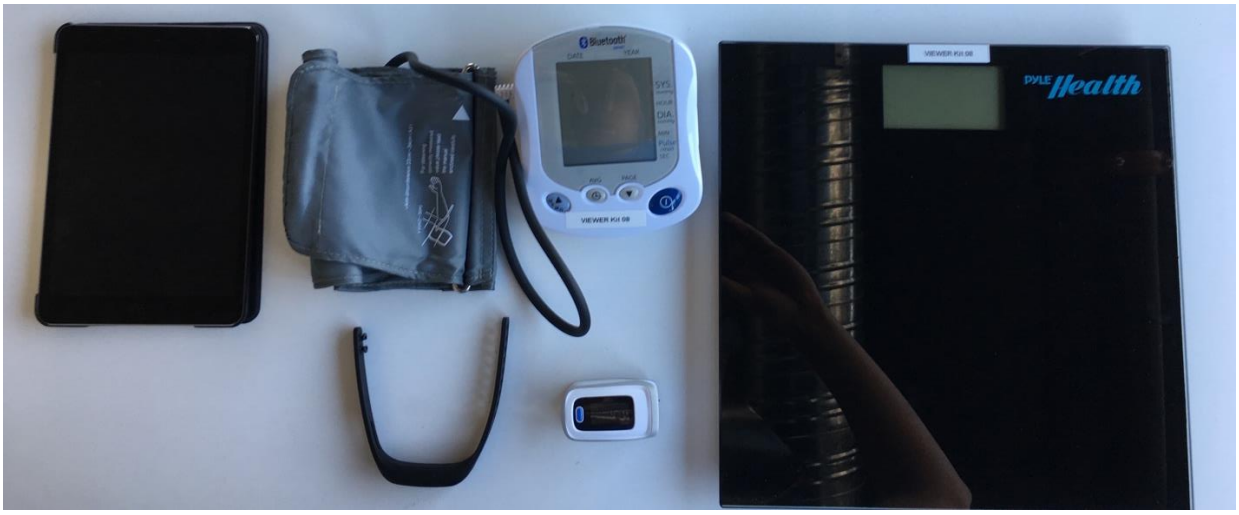

Figure 3 - Simplified VIEWER user manual

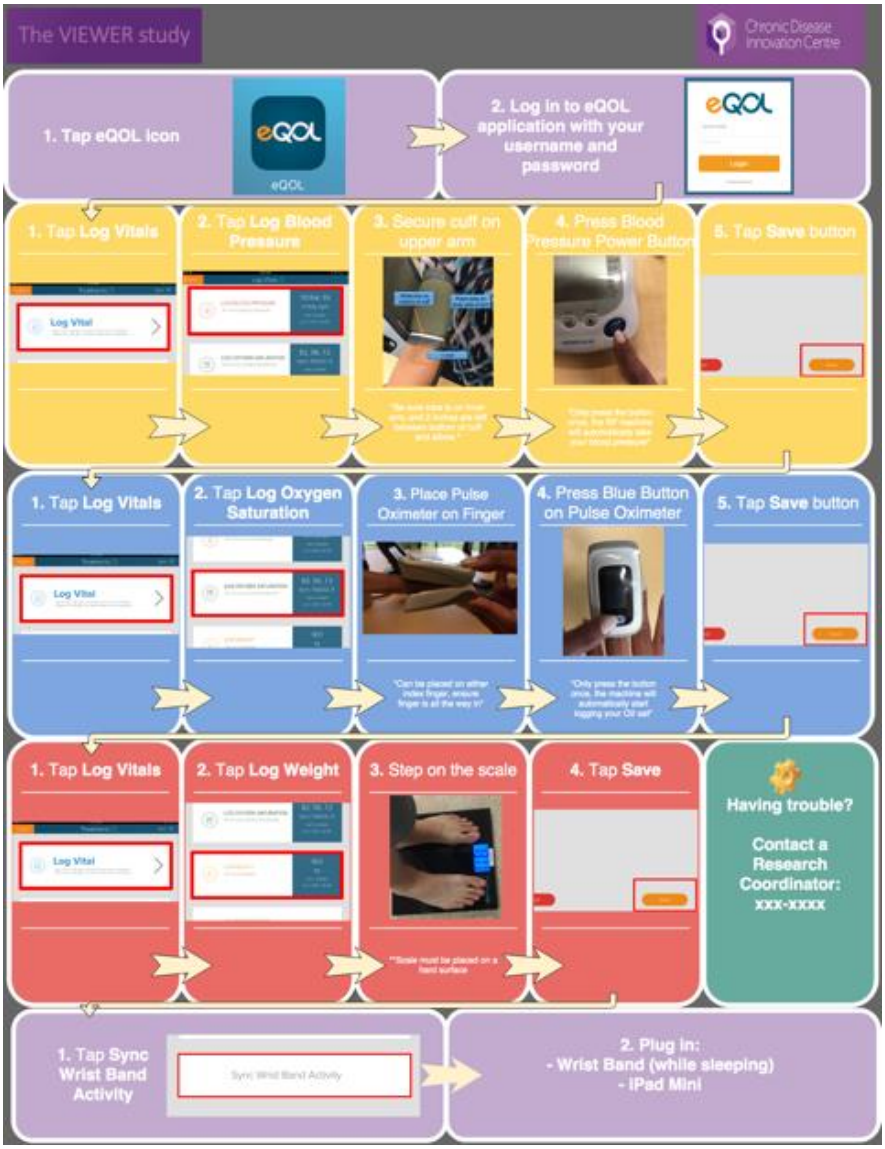

Table 2 - Summary of survey results and SUS scores according to age and gender.

		% OF PARTICIPANTS (%)	MEAN SUS* SCORE	MEAN SMARTPHONE COMFORT LEVEL (0-5)	MEAN WEARABLE COMFORT LEVEL (0-5)
AGE	18-24	37.5	90	5	5
	25-34	12.5	90	4	4
	55-64	50	90	5	3
GENDER	F	50	91.2	5	3.3
	M	50	88.8	4.8	4.8
TOTAL		n=8	90	4.9	4

Figure 4 - System Usability Scale questions and mean adjusted score.

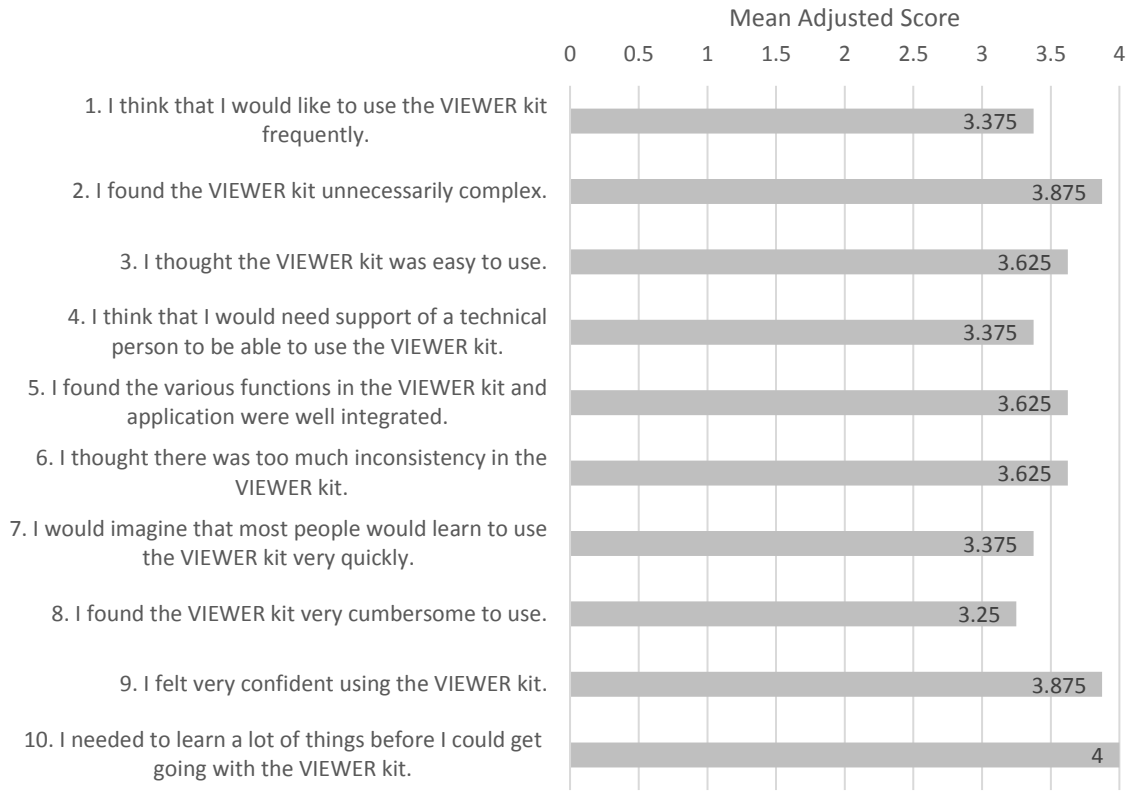

Table 3 - Summary of qualitative user feedback

	EXAMPLES OF COMPLAINTS
TECHNOLOGICAL ISSUES *(6 OF 8 USERS REPORTED)*	Unable to synch watch to iPad while charging. Blood pressure reading fluctuations. Blood pressure and scale Bluetooth malfunction. Inconsistent scale readings. Unexpected shutting off of blood pressure device.
LIFESTYLE CONFLICTS *(4 OF 8 USERS REPORTED)*	Watch band difficult to fasten and falls off. Does not track activity levels other than walking. Difficult to travel with due to size.
BATTERY LIFE *(3 OF 8 USERS REPORTED)*	Watch battery was insufficient. Batteries in scale, blood pressure and pulse oximeter require changing. Not noticing that watch battery has died.
USER CHALLENGES *(5 OF 8 USERS REPORTED)*	Blood pressure cuff difficult to position correctly. Difficulty remembering to complete vitals. Kit has to stay at home, therefore patient must return home daily. Watch frequently misplaced.