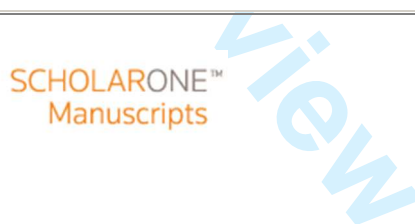




Remote usability testing and satisfaction with a mobile health medication inquiry system in CKD

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Title: Remote usability testing and satisfaction with a mobile health medication inquiry system in chronic kidney disease (CKD)

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ABSTRACT:

Background and objectives: Inappropriate medication use is common in the care of patients with chronic kidney disease (CKD). We examined the feasibility of a simple mobile health tool designed to advise patients on safe medication usage in CKD.

Design, setting, participants and measurements: Participants with pre-dialysis CKD (defined as an estimated glomerular filtration rate $<60\text{mL}/\text{min}/1.73\text{m}^2$) in the Safe Kidney Care (SKC) cohort study were recruited for home usability testing of a novel medication inquiry system (MIS) between January and September 2013. Testing was via two mobile platforms: 1) short messaging service (SMS) text, or 2) personal digital assistant (PDA; e.g. iPod Touch™). Twenty participants (half assigned to one device and half to the other) were enrolled and received an in-center tutorial on device usage prior to the end of the study visit. Participants were subsequently mailed 3 sample pill bottles with the name of randomly selected medications and asked to input these medications into the MIS. The MIS response options were as follows: 1) Safe in chronic kidney disease, 2) Not safe in chronic kidney disease, 3) Use with caution, speak with your healthcare provider, or 4) An error message (for an incorrectly inputted medication). Participants were asked to record the response issued by the MIS for each medication sent for usability testing. A user satisfaction survey was administered after completion of protocol.

Results: All participants owned a mobile phone, but few owned a smartphone. Of 60 total medication queries, there were only 3 recorded errors, 2 of which occurred in the SMS texting group. Overall satisfaction with the application was high, with slightly higher satisfaction noted in the PDA group compared to the SMS group.

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3 **Conclusions:** The mobile health MIS application had general ease of use and high acceptance
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5 across two platforms among individuals representative of the CKD population. Tailored mobile
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7 health technology may improve medication safety in CKD.
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INTRODUCTION

Improperly dosed or ill-advised medication usage are a significant hazard in the care of individuals with chronic kidney disease (CKD),(1) which is likely partially attributable to failed recognition or under-appreciation of CKD by both providers and patients.(2-5) Despite electronic health record (EHR) prescription monitoring systems that reduce the likelihood of drug-related problems, the complex care of CKD patients, often characterized by interactions with diverse health systems and health providers requires innovative means that place the patient in the center of their care for self-management and enable them to safeguard themselves from drug-related problems and other medical errors.

Mobile devices such as cellular phones or tablets may provide new tools with the potential to reduce unsafe practice in CKD management. As an explosion of new technologies has provided consumers with access to a myriad of applications and portals to access health information, how well the target population can effectively utilize such applications has not been adequately assessed. Integration of mobile devices into CKD health management requires an iterative user-center design which incorporates usability testing and user feedback in the final development process to improve the potential effectiveness of the tool. While in-center usability testing provides valuable insight into the functionality of developing technologies, it does not incorporate home-based processes of care that may influence a user's ability to navigate the technology under more real-life circumstances.

In this study, we set out to build on prior scripted in-center usability testing which has been previously reported (6) of a disease-specific application designed as a medication inquiry system (MIS) offering patients information on the safety of drugs in CKD. The current study

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3 evaluates home-based usability of two mobile health MIS platforms including: short messaging
4 service (SMS) text or an application (app) embedded in a personal digital assistant (PDA), and
5 reports on the acceptance of the mobile health (mHealth) platform by usability participants.
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10 11 **METHODS**

12 13 14 *Medication Inquiry System (MIS)*

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18 The MIS application was developed as a patient-centered tool to assist patients with pre-
19 dialysis CKD in identifying the safety of their medications with impaired renal function.

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22 Features available for the SMS text platform have been previously described (6) and include the
23 ability to send the name of a medication via SMS text message and to receive a response text
24 informing the patient of the medication's safety in CKD with the three potential responses
25 including: "not safe in chronic kidney disease", "use with caution, speak with your healthcare
26 provider", and "safe in chronic kidney disease." The PDA application platform allows users to
27 search by the medication name or class (e.g., ibuprofen or pain medication). PDA responses
28 include traffic light imagery and text to emphasize safety responses; a red light complemented
29 text stating that a medication is "not safe in chronic kidney disease," a yellow light for "use with
30 caution, speak with your healthcare provider," and a green light for medications deemed "safe in
31 chronic kidney disease" (**Figure 1**). Both platforms had a fourth ability to display an error
32 message if a medication was incorrectly inputted into the device.
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48 49 *Study participants*

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52 The Safe Kidney Care (SKC) Cohort Study (ClinicalTrials.gov NCT 01407367) is an
53 ongoing observational cohort of individuals with pre-dialysis CKD intended to assess the
54 frequency of adverse safety events with protocol previously described.(7) To be eligible for SKC
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3 participants required two measures of renal function with an estimated glomerular filtration rate
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5 (eGFR) of less than 60 mL/min/1.73m² at least 90 days apart and no more than 18 months prior
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7 to enrollment. Participants were excluded if they are expected to reach end-stage renal disease
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9 (ESRD) or die within one year from enrollment. As an ancillary study SKC participants were
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11 invited at an annual SKC study visit to participate in home usability and feasibility testing of the
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13 mobile device-based MIS with a target of 20 participants. The SKC study and its ancillary study
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15 were approved by the University of Maryland School of Medicine Institutional Review Board
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17 and the Veterans Affairs Maryland Health Care System Baltimore Research and Development
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19 committee. Informed consent was obtained from all participants in accordance with the
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21 Declaration of Helsinki.
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26 27 28 *Remote Usability Testing* 29

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31 Between January and September 2013, a total of 20 usability participants were randomly
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33 assigned one of two mobile devices to bring home, 1. a traditional cellular phone (flip-phone)
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35 with SMS texting capabilities, or 2. a PDA without mobile phone capabilities (iPod Touch™) on
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37 which the MIS application had been previously loaded. At enrollment, all participants were
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39 given an in-person tutorial on device usage as well as printed instructions on MIS application
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41 usage for the PDA participants that they were encouraged to take home. After the initial visit,
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43 usability participants were mailed sample pill bottles with the names of 3 hypothetical
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45 medications which had been randomly selected for each participant from the available MIS
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47 database of medications in order to mimic the method by which many patients receive their
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49 home medications. Although the PDA platform included a comprehensive database of
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51 medications, the SMS texting platform prototype was only available for use with 8 pre-specified
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3 medications. Therefore, the sample pill bottles consisted of randomly selected medications
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5 which were only available from the 8 medications programmed into the SMS texting prototype.
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9 Participants were asked to input each of the 3 medications into the respective MIS
10 application and to record the device's responses on a paper diary. At one month participants
11 returned to turn in their devices, review the paper diary, and complete a user satisfaction survey.
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13 Participants were compensated \$50 for their time at the completion of the protocol.
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17 18 19 *eHealth Literacy* 20

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22 MIS remote usability testing results were linked with core demographics from the parent
23 SKC cohort study as well as information pertaining to participants' access to and characteristics
24 of computer and mobile phone usage. As part of this e-literacy assessment, all participants were
25 administered the eHealth Literacy Scale (eHEALS), an 8-item measure of eHealth literacy
26 developed to measure individuals' combined knowledge, perceived skills at finding, evaluation
27 and applying electronic health information to health problems.(8) Participants were asked to rate
28 their level of agreement with various statements such as, "I know how to find helpful health
29 resources on the Internet", "I know how to use the health information I find on the Internet to
30 help me", "I can tell high quality from low quality health resources on the Internet." The
31 questionnaire has been previously validated on HIV patients and healthcare trainees.(9, 10) The
32 eHEALS survey can be scored in its entirety based on the cumulative responses to 8 questions
33 (the first 2 eHEALS questions serve as supplementary questions to understand general interest in
34 eHealth and are not included in overall score), or each question can be evaluated independently.
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36 Cumulative scores range from 8-40, with higher scores reflective of higher levels of eHealth
37 literacy.
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Statistical Analysis

No formal hypothesis testing was conducted in this analysis, and descriptive analyses were consistent with the applied qualitative study methods of usability testing. Sample size was consistent with target samples for usability testing.(11) Continuous variables were presented with mean and standard deviation (SD). Binomial and categorical variables were presented as N (%). Frequency of errors was presented per platform type.

RESULTS

Ten participants were assigned to each device and all completed home usability testing of the MIS. Demographic characteristics grouped by device assignment are shown in **Table 1**. Usability participant ages ranged from 47-76. Participants were predominantly Black with a high proportion reporting a history of diabetes or cardiovascular disease. Although most reported earning more than a high school diploma, annual household income levels were predominantly \leq \$50,000. The vast majority reported access to a computer and prior Internet use, and while all participants owned a mobile phone, few owned a smartphone. There was high variability in reported mobile phone uses, with text messaging and camera use being the two most commonly reported, while few reported participating in social networking via their mobile device among all usability participants.

Mean eHEALS score was 29 out of possible 40 (SD 9.4). While on the screening questions the majority of participants reported that the Internet was a useful source of health information and felt it was important to access health resources on the Internet, more detailed responses regarding individual comfort with using the Internet for health information showed greater variability (**Table 2**). For example, 80% of participants agree they know what Internet

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3 health resources are available but only 55% of participants agree they know where to find helpful
4 health resources on the Internet. Whereas the majority of participants feel they have the skills
5 they need to evaluate Internet health resources, only a minority of participants agree they can tell
6 high quality from low quality health resources or that they feel confident using Internet
7 information to make health decisions.
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16 MIS error rates were low using either type of device. With both devices the small
17 number of errors was with those medications where there are no renal-specifications to dosing.
18 Of 60 medication queries inputted into the MIS platforms (30 respectively for each device), there
19 were only 3 recorded errors. Two of these errors occurred in the SMS group and were recorded
20 by a single participant (age >65 years of age, $\leq 6^{\text{th}}$ grade education, no prior Internet use) as a
21 malfunction with device output; the error in the PDA group occurred as an inaccurate output
22 response to the reportedly queried medication (participant was >65 years of age, high school
23 graduate, with no prior Internet use). Seven of 30 (23%) queries in the PDA group were
24 searched via medication class rather than medication name. Participant satisfaction survey
25 responses for each MIS platform were fairly similar, with slightly higher overall satisfaction in
26 the PDA group (41 out of possible 42 [range 39-42]) than the SMS group (39.5 out of possible
27 42 [range 34-42]). Satisfaction survey responses are further detailed in **Figure 2**. Testimonials
28 following usability testing are shown in **Table 3**.
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47 DISCUSSION

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50 In this study we set out to evaluate the performance of patients with CKD on a prototype
51 mobile health application when users were tested in their home environment. Our findings
52 demonstrate relatively high aptitude for usage of the mobile health system across both platforms.
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3 Perceived comfort with searching for and processing digital health information was highly
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6 variable in the study population.
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9 Delivery of care for kidney disease patients has changed from a provider-center
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11 framework to a patient-centered framework with emphasis on shared decision-making and
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13 patient empowerment.(12-14) This shift in focus has resulted in a growing emphasis on patient
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15 engagement and the incorporation of digital solutions to support patient self-management
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17 practices.(15, 16) Individuals with CKD, often characterized by low disease awareness, limited
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19 health literacy, and frequent interactions with the healthcare system (17, 18) are at high risk of
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21 adverse safety events related to their care such as drug-related problems. This opens potential to
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23 introduce tailored digital tools to this population as patient-initiated safeguards. (7, 19-22)
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26 Mobile technologies such as cellular phones provide “instant access” to information which
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28 previously was not promptly available to patients. Recent studies examining mobile health tools
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30 across various diseases have demonstrated significant improvement in medication adherence,
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32 weight management, glycated hemoglobin levels, stress levels, smoking quit rates, and self-
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34 efficacy,(23-29) although the long term sustainability of such interventions remains less
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36 clear.(30) The general or disease-specific health information, such as medication safety, on such
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38 devices may increase patients’ interest in self-care, raise their awareness regarding their personal
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40 medical conditions, and overcome barriers of a wide range in literacy in the target population.
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47 Despite general proficiency with the mobile health MIS application, the current study
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49 suggests that individuals with CKD have variable eHealth literacy, which is an important finding
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51 with direct relevance on the future development of health information technology (IT)
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53 applications designed to engage and safeguard individuals with CKD. It has been shown that
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55 more eHealth literate individuals derive greater benefit from digital health information than those
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3 less eHealth literate, which creates new inequities in digital health education and contributes to
4 the notion of the ‘Digital Divide.’(31) The positive results of our remote usability testing
5 suggest that individuals with CKD are capable of correctly using mobile health technologies if
6 provided with accurate tutorials on proper device usage, even if testing is performed in the
7 absence of a trained moderator. In a manner similar to traditional health literacy, tailored and
8 simplified approaches to health education may be more effective in promoting understanding of
9 complex of health concepts than a one-size-fits-all approach,(32, 33) as prior studies support the
10 belief that digital learning ability is not restricted only to young healthy users.(34) The MIS tool
11 presented here has been developed with the capabilities of the target population in mind:
12 simplified dialogue, universal imagery, and the ability to be used across various platforms. Such
13 an application for general use in CKD would need to incorporate a significantly broader
14 pharmacopeia of medications and require pilot testing in the target population. How use of such
15 an application might be imbedded in the self-management practices of kidney disease patients
16 and how best to incorporate its relevance in the care provided by other members of a
17 multidisciplinary CKD team (such as pharmacists) remains uncertain. The challenge for future
18 projects is to evaluate whether patients will actually adhere to the technology and to whether
19 medication safety can be improved for CKD patients by such a system.
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44 The home usability testing described has limitations related to the descriptive and
45 qualitative nature of the study. The small sample size limits hypothesis testing but is consistent
46 with the number of participants recommended for usability testing.(35, 36) Further, the MIS
47 testing described here was specific in its intent to assess usability rather than validity, and may
48 limit the generalizability of the findings to other health IT applications in kidney disease,
49 particularly given the limited number of medications available within the prototype system. It is
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3 unclear if familiarity of the inputted medications by study participants impacted the recorded
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5 MIS responses given the lack of errors noted in the renal-pertinent medication categories, and
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8 requires further study. The MIS provides information based on published safety guidelines of
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10 medications in CKD, but does not have the functionality to incorporate tailored provider
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12 judgement into the programmed recommendations which may differ from guidelines based on
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14 individual risk assessment (for example, the use of aspirin in individuals with coronary artery
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16 disease). Finally, while mobile phone and PDA usage is considered commonplace, we anticipate
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18 that some individuals will be unfamiliar with the usage of these devices or with limited cellular
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20 service availability, which may limit acceptance of the MIS tool to the target population.
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24 Further work needs to go into understanding the human-device interactions that are unique to this
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26 patient population and refining the platform by which we expect that patients will use to
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28 communicate with their health providers and access relevant health information.
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32 Novel strategies are needed to promote patient engagement and self-directed patient
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34 safety among the high risk population with CKD. Mobile devices may provide a ubiquitous and
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36 powerful conduit through which health information can be easily accessed. Further studies are
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38 needed to assess the potential benefit of such mHealth strategies in improving patient safety
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40 outcomes in CKD.
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3 **Figure 1. Personal digital assistant (PDA) platform Medication Inquiry System (MIS)**
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6 Introduction screen, search screen, and result screen of PDA application
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10 **Figure 2. Medication Inquiry System (MIS) satisfaction survey by device type**

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12 Percent of participants in agreement with satisfaction survey questions.
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Table 1. Usability participant demographics by device type

	SMS (n=10) n	PDA (n=10) n	Total N (%)
Age			
≤ 65	7	6	13 (65)
>65	3	4	7 (35)
eGFR (mL/min/1.73m²)			
≥ 45	6	4	10 (50)
< 45	4	6	10 (50)
Gender			
Male	5	7	12 (60)
Female	5	3	8 (40)
Race			
Black	8	7	15 (75)
Non-black	2	3	5 (25)
Self-reported comorbidity			
Diabetes	6	8	14 (70)
CVD	7	6	13 (65)
Cancer	1	2	3 (15)
Education			
≤ high school diploma	2	4	6 (30)
>high school diploma	8	6	14 (70)
Annual household income			
≤ \$50K	1	2	13 (65)
>\$50K	9	8	7 (35)
Computer Usage			
Access to computer			
No	1	1	2 (10)
Yes	9	9	18 (90)
Ever used Internet			
No	1	4	5 (25)
Yes	9	6	15 (75)
Mobile Phone Usage			
Mobile Phone Type			
Cell Phone	7	9	16 (80)
Smartphone	3	1	4 (20)
Used only for calls			
No	4	5	8 (42)
Yes	6	5	11 (58)
Mobile Phone Uses			
Text messaging	6	4	10 (50)
Mobile Web	3	2	5 (25)
Social networking	2	1	3 (15)
Apps	3	1	4 (20)
Email	4	1	5 (25)
Camera	6	4	10 (50)
Abbreviations: SMS = short messaging service, PDA = personal digital assistant, eGFR = estimated glomerular filtration rate, CVD = cardiovascular disease			

Table 2. eHEALS survey results

How useful do you feel the Internet is in helping you in making decisions about your health?	n	%
Not useful at all/Not useful	3	15
Unsure	2	10
Useful/ Very Useful	15	75
How important is it for you to be able to access health resources on the Internet?		
Not important at all/Not important	3	15
Unsure	0	0
Important/Very Important	17	85
Q1. I know what health resources are available on the Internet.		
Strongly Disagree/Disagree	2	10
Undecided	2	10
Agree/Strongly Agree	15	80
Q2. I know where to find helpful health resources on the Internet.		
Strongly Disagree/Disagree	4	20
Undecided	5	25
Agree/Strongly Agree	11	55
Q3. I know how to find helpful health resources on the Internet.		
Strongly Disagree/Disagree	5	25
Undecided	1	5
Agree/Strongly Agree	14	70
Q4. I know how to use the Internet to answer my questions about health.		
Strongly Disagree/Disagree	5	25
Undecided	2	10
Agree/Strongly Agree	13	65
Q5. I know how to use the health information I find on the Internet to help me.		
Strongly Disagree/Disagree	4	20
Undecided	3	15
Agree/Strongly Agree	13	65
Q6. I have the skills I need to evaluate the health resources I find on the Internet.		
Strongly Disagree/Disagree	4	20
Undecided	2	10
Agree/Strongly Agree	14	70
Q7. I can tell high quality health resources from low quality health resources on the Internet.		
Strongly Disagree/Disagree	4	20
Undecided	7	35
Agree/Strongly Agree	9	45
Q8. I feel confident in using information from the Internet to make health decisions.		
Strongly Disagree/Disagree	3	15
Undecided	8	40
Agree/Strongly Agree	9	45

Table 3. MIS usability participant testimonials

Device	Testimonials
SMS	<ul style="list-style-type: none"> - "Very easy to understand the process and procedures." - "I would have liked more explanation on how to work the system." - "System helped me to understand medications that may or may not be good for my health." - "Would have preferred to use a computer instead of the cell phone. Also would have liked to see more content such as vitamins, health foods, supplements, etc." - "Did not like the cell phone. Letters too small for fingers and difficult to read." - "As a senior, I felt very uncomfortable using the cell phone. I had to get help with the texting. I would only recommend this device if the cell phone had bigger letters." - "I became more aware of medicines that might be harmful. Also, I am a low reader but I found it easy to use the device." - "Keyboard on the cell phone is too small. Overall process of looking up information was very easy."
PDA	<ul style="list-style-type: none"> - "No I wouldn't like to see anything changed. Study is very informative." - "No changes needed. Really enjoyed using the iPod Touch. System was very educational." - "I would like to see more categories such as lab work and more variety of medications." - "I would like only to use the iPod Touch device. It was easy to handle." - "I would like to have had a bigger key pad. Also an electronic pointer. Would like to see the study on a bigger scale." - "No changes needed. The letters on the app needs to be bigger." - "Should be easier to get from where to find the app to the typing. Buttons were too small. Provide a class on application usage." - "Would like to see more information regarding the medicines on the search system. For example what are the side effects of each medicine."

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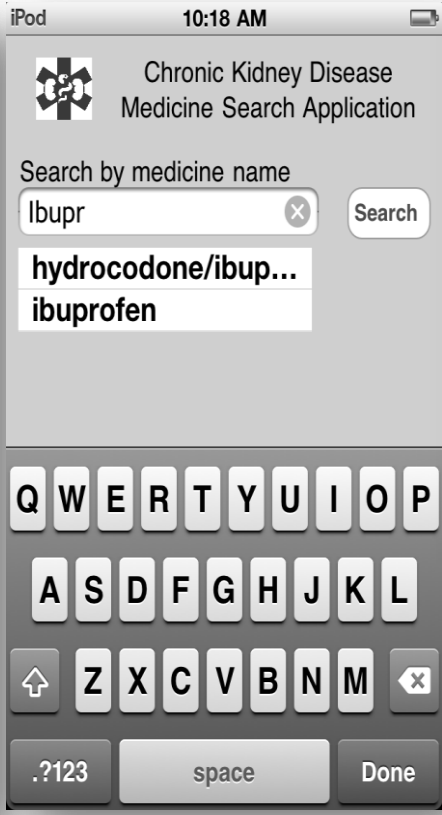
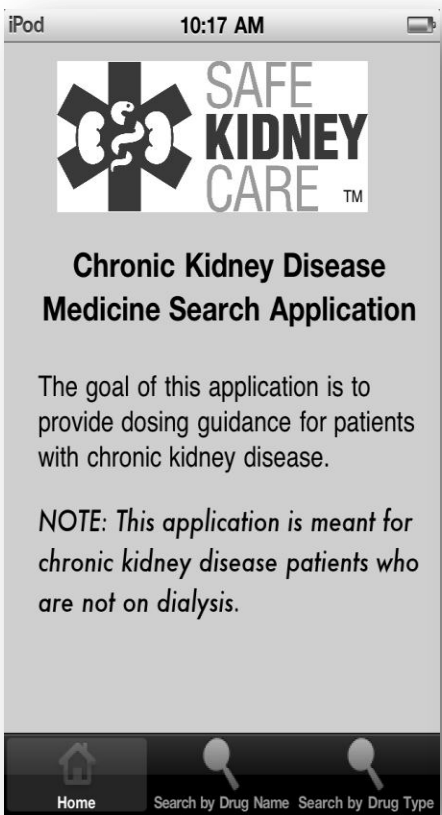
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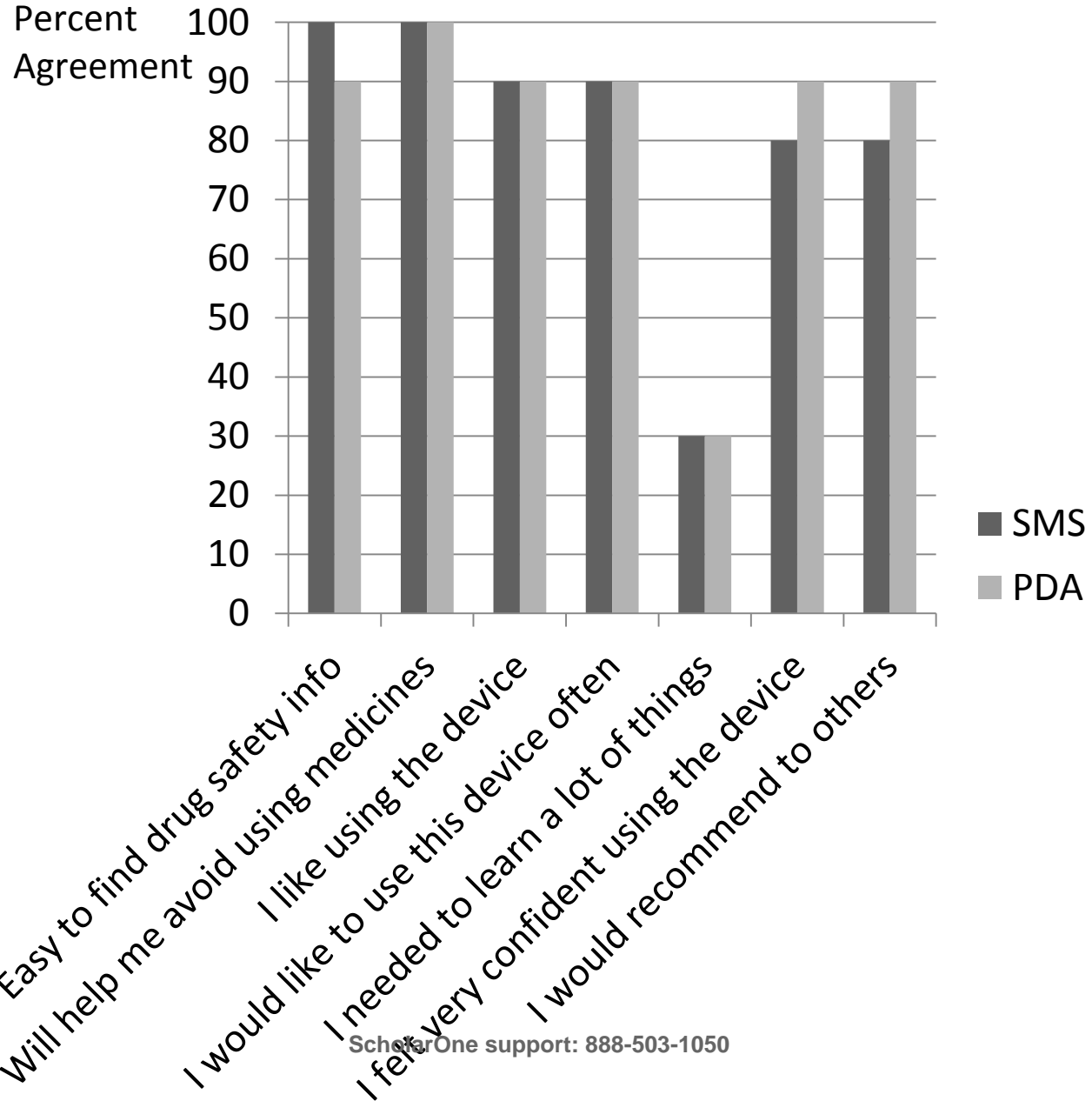
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