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Telemedicine to promote patient safety: Use of phone-based interactive voice response system (IVRS) to reduce adverse safety events in predialysis CKD

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Abstract

Chronic kidney disease (CKD) patients have several features conferring upon them a high risk of adverse safety events, which are defined as incidents with unintended harm related to processes of care or medications. These characteristics include impaired renal function, polypharmacy, and frequent health system encounters. The consequences of such events in CKD can include new or prolonged hospitalization, accelerated renal function loss, acute kidney injury, end-stage renal disease and death. Health information technology administered via telemedicine presents opportunities for CKD patients to remotely communicate safety-related findings to providers for the purpose of improving their care. However, many CKD patients have limitations which hinder their use of telemedicine and access to the broad capabilities of health information technology. In this review we summarize previous assessments of the pre-dialysis CKD populations' proficiency in using telemedicine modalities and describe the use of interactive voice-response system (IVRS) to gauge the safety phenotype of the CKD patient. We discuss the potential for expanded IVRS use in CKD to address the safety threats inherent to this population.

Indexing words

chronic kidney disease; telemedicine; patient safety; self-care; healthcare disparities

Introduction

CKD affects approximately 10% of the adult population worldwide.[1] Along with the expanding number of CKD patients are an increasing proportion of patients who are elderly

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and have multiple comorbidities requiring many prescription medications. These complex medical regimens may only have marginal benefits, but in the context of decreased renal function, can lead to adverse safety events, defined as unanticipated complications of medical treatment.[2] Identifying and reducing adverse safety events in CKD patients have the potential to improve the outcomes of this disease population. In this review, we discuss current telemedicine applications in pre-dialysis CKD patients. We describe a role for IVRS in evaluating patient-reported safety outcomes and the need for more research to implement this technology in the care of CKD patients.

The Safety Phenotype of CKD

In addition to hospitalization and death, CKD-specific adverse safety events can include hypoglycemia, hyperkalemia, dizziness, falls, acute kidney injury and medication errors.[3–5] These events occur frequently in both outpatient and inpatient settings and can lead to accelerated renal function loss, acute kidney injury, and end-stage renal disease (ESRD).[6] Evaluations of the medication regimens of CKD patients have revealed a substantial medication burden, which is a likely contributor to adverse safety events unique to this disease. Studies have reported a median number between 8–10 medications daily necessitating 25 pills or more per day.[7,8] Fraser and colleagues found approximately 20% of patients age 70 and older reported taking 10 or more medications.[9] Patients have difficulty adhering to these sizable regimens that often come with complex instructions.[10] Non-adherence, in turn, has been shown to be a significant threat to patient safety increasing the risk of adverse events in CKD.[11] Solutions are needed to facilitate medication reconciliation, adherence, and monitoring of adverse effects related to the heavy medication burden.

Telemedicine as an adjunct to chronic medical care

Telemedicine, defined as the ability to provide healthcare from a distance, is increasingly being developed in pursuit of improving ambulatory chronic disease management and may offer a new opportunity to address the high frequency of adverse safety events observed in CKD.[12] Telemedicine technologies provide a framework for the introduction of health information technologies (IT) to enhance patient self-management, education, and access to provider communication and consultation.[13–15]

Telemedicine technology based on expanded wireless telecommunication and fiber optic networks has become increasing available to consumers in recent years. 85% of American adults use the internet.[16] As of October 2014, 64% of American adults owned a smartphone and at least 90% of American adults owned a cell phone with 81% using their phone for text messaging.[17] Smartphones are becoming a standard tool for instantaneous access to the internet with 7% of US population relying solely on their smartphone for internet connection, particularly individuals in minority and lower-income populations, many of whom are at increased risk for developing CKD and ESRD.[18,19] These powerful communication conduits provide enormous potential to introduce a vast array of health IT to patients. However, few studies have investigated the use of health IT in the pre-dialysis CKD population (see Table 1), with most existing studies addressing the monitoring and treatment of the dialysis population.[20]

Promise and limitations of Telemedicine in CKD

As developers and investigators turn their attention to use of telemedicine modalities and health IT in pre-dialysis CKD, it will be important to incorporate interactive elements into new applications as this has been reported to increase the likelihood for successful use in chronic disease populations.[21] The iNEPHRO study demonstrated how sustained usage of health IT applications are a challenge in CKD. iNephro investigators distributed a free smartphone application to German-speaking CKD patients to assist them in medication adherence and documentation of BP.[22] After 11,688 smartphone users downloaded the application, and demonstrated initial engagement, significant drop-off in use of the application was reported at 2-months. Less than 1% (10/1095) used the application at least weekly one year after download. Multiple explanations were offered for the attrition rate. Users may have found a different application, or found the application difficult to use or of limited value after mastering their medication regimen. Another explanation for the decline in application use was that participants sought out more inter-personal interactions. For example, permitting participants either to look up information about the safety or dosing of medications to share with their provider or to use the application in conjunction with visits to their doctor may have enhanced the application's use.[23] Other studies in the CKD population have incorporated interactive elements to better engage patients, but have not necessarily shown significant improvement in outcomes.[24]

Studies evaluating blood pressure control show limited improvement in treatment goals. Rifkin and colleagues conducted a 6-month trial randomizing CKD patients into an arm using a Bluetooth-enabled sphygmomanometer with blood pressure (BP) readings transmitted to health care providers regularly versus usual care where participating patients recorded BP readings at home, which they shared with providers. Participants whose remotely transmitted BP readings were above goal were contacted for treatment modifications. The authors found improvement in BP in both groups with no statistically differences.[25] Participants using the home-based tele-monitoring device transmitted significantly more readings to their providers than the usual care participants reported at clinic. The intervention was well received by both participants and clinicians, and was determined to be cost-effective. Margolis and colleagues reported on a cluster-randomized trial of home BP tele-monitoring (8 clinics) vs usual care (8 clinics) of hypertensive patients followed at each center.[26] This study included patients with and without CKD. They found significantly improved BP control in the intervention group, but also found hypotension-related events in CKD and diabetic patients with more stringent BP goals.

In a diet assessment pilot project by Murali and colleagues, participants with CKD independently used an online program that calculated adherence to disease-specific nutrition recommendations from a 24-hour meal history.[27] Participants brought a printout of the results to regular nephrology appointments for discussion. Confidence in diet self-management did not improve after 6 weeks of access to the program and may have been related to the perception of some participants that their diet was not adequately discussed. Specifically, patients felt alerts from the diet program were deemphasized if lab results were within normal ranges. Such patient feedback can help to enhance future health IT

applications designed for nutrition or physical measurement assessments and could help to improve the utility of the conveyed health information.

The first sizable randomized control trial evaluating a comprehensive CKD intervention was recently published.[28] Ishani and colleagues randomized 601 veterans with CKD to a tele-monitoring system with direct management by an interdisciplinary team versus usual care. The interdisciplinary team was charged with managing and evaluating BP, volume status, proteinuria, diabetes, cholesterol, depression, health literacy and patient activation.[28] With a 12-month study duration, there was no significant difference between groups for the primary composite outcome of death, hospitalization, emergency department (ED) visit, and nursing home admission.[24,28] The study findings failed to show a benefit to aggressive monitoring and management, even with successful patient participation (only 3.8% failed complete the year of monitoring). However, it is important to note that the evidence for the effectiveness of aggressive CKD management is relatively limited. Additionally, the authors have pointed out that control group participants may have received more aggressive therapy than expected through new Veteran Affairs (VA) initiatives starting at the time of the study and limiting the potential treatment effect of the intervention.[24,28] One important limitation to this study was the monitoring system had to be used at home with restricted mobility due to the larger size of the required device. This is in contrast to an application using a smartphone application or an IVRS as discussed below. Additionally, high costs would be necessary to implement the intervention making a negative or marginal positive outcome from the study a weak justification for broad dissemination.[24,28]

Ong and colleagues[29] developed an interactive smartphone application CKD self-management and evaluated it in a proof-of-principle study. The application was designed to help patients monitor their BP, medication reconciliation, lab results and symptoms (fatigue, nausea, loss of appetite shortness of breath and ankle swelling). Results in the form of summary reports were made available to care providers for review prior to appointments. Most (more than 80%) of 47 CKD patients who used the application for 6-months in the pilot demonstrated adherence with more than 80% of required data collection elements. Based on survey responses, providers regarded the application favorably (better clinic visits, focus on high-risk patients, and identification of medication errors). Home BP readings improved and 27% of patients with normal BPs in the clinic were found to have masked hypertension. Reported symptoms allowed for patient care management between clinic visits, and medication monitoring allowed for the detection of 127 medication discrepancies in reconciliation of which 59% required intervention to prevent harm.[29] An accompanying editorial commended the application for allowing patients a more active role in their care with implications for improving patient safety, but also expressed concerns for the ability of lower income patients to have access to the smart phone application.[30]

Matching the health information technology to the user

Despite the growing numbers of studies using various telemedicine modalities under controlled conditions, broad and enduring dissemination of these may be disappointing in the CKD population. It is worth noting, people managing multiple chronic conditions are less likely to go on-line to explore the internet. Sixty-eight percent of patients with one

chronic disease use the internet versus 52% of adults reporting either two or more chronic diseases.[31] While the reasons for less internet use among patients with multiple illnesses are not fully known, a lack of access, and not a lack of interest, has been reported.[32] People with chronic diseases are more likely to use the internet to access health information online compared to people without chronic diseases when resources permit, but in populations who are characteristically underserved and of lower socio-economic status, reliable access to the internet or wireless networks may be difficult to maintain.[12,31–33] Half of US smartphone-users with no other access to the internet had to cancel or shut off their cell phone service for a period of time due to financial concerns.[34] Without affordable and user-friendly access to such resources, smartphones and the internet may have limited utility as telemedicine modalities for CKD patients who are characteristically poor, underserved and with multiple co-morbdities.[35]

The great potential of health IT needs to be tailored to the highly variable capabilities of the CKD population to ensure effective participation of patients in routine clinical practice. In one study of 108 CKD patients, only 28.7% visited an informational website about CKD safety after personal instruction on how to access the website.[36] Reasons for the low participation rate were not clear. Diamantidis and colleagues tested a medical inquiry system to guide the safe use of medications.[37] The system was developed as an application to be used on 3 platforms: the internet, cell phone (with text entry), and smartphone. Twenty participants were asked to interrogate the system to inquire as to whether specific medication can either be used safely, used with caution, or not at all. Although the majority of sequential tasks required to execute the inquiry could be completed, there were tasks on each of the platforms that participants required additional help to complete. Easy to use modalities will be vital to implementing a successful telemedicine intervention in CKD.

CKD patients will also need to be evaluated for their ability and interest in participating in more comprehensive self-management interventions such as the studies described above.[28,29] A focus group of CKD patients was assembled for the purpose of developing the framework for My KidneyCare Centre, a self-management application intended to help CKD patients take more ownership of their medical care.[38] The focus group offered insights on the prospect of adoption of health IT applications by CKD patients. The resulting application was designed to educate patients about CKD, and allow self-monitoring of health and permit goal setting. The focus groups findings revealed that the CKD patients were less inclined to work with an application independently at home than with a passive or collaborative protocol in conjunction with their providers. The resulting application relies on patients reporting concerns and symptoms, and choosing topics for discussion with their providers. The application adoption protocol was established for patients to acclimate to the application by first using a touch-screen kiosk in the renal clinic waiting room, with immediate feedback from their doctor about entries made during the waiting-room assessment thereby taking advantage of a preference for collaboration. This first step was intended to enhance patient engagement, and to encourage an understanding of how the program could be used remotely via the internet and mobile devices more independently in the future.

Interactive voice response system (IVRS): matching the tool to the user

IVRS as a telemedicine modality may address some of the current limitations of purely internet and smartphone-based technologies. IVRS uses basic telephone transmission to allow patients to respond to a variety of questions through either a touch-tone keypad or voice responses. Such a system has two characteristics.[39,40] First, it utilizes the more ubiquitous and low-cost platform of the public-switch telephone service using landlines with voice and digital transmission via standard hand-set or cellular phone. Secondly, this type of access permits a substantial degree of interactivity, which includes either one-way transmission of information or an interactive collection of data where patients respond to questions. Although a loss of phone service can interrupt the use of an IVRS, the ability to use both landlines and simple cellphones can greatly avert financial disruptions to service. IVRS has been used broadly in the commercial domain, and with various patient populations, including underserved and difficult-to-reach subjects,[40] and as a platform for many disease-focused applications, including diabetes care, asthma assessment, blood pressure control, smoking cessation, behavioral health evaluation, and medication adherence.[41–45] Examples of services provided by IVRS outside of patient-entered data collection include provision of educational information, proper dosing of medications, behavioral counseling tips such as for smoking cessation, appointment scheduling, and the offering of means to obtain lab results.[39]

The ability for IVRS to promote change in patients' behavior utilizes the modality's feature of interactivity.[39] Patients that respond to calls infrequently or fail to self-initiate calls could be targeted by clinical teams for concerns of patient safety and lapses in adherence.[41,46] Since communications are provided to patients using pre-recorded materials, IVRS permits standardized education and data collection limiting human error and variability.[39] This consistency optimizes the patient-system interaction resulting in more efficient calls and leaving more time for patients to provide feedback on care, which may help with adherence.[40] Mundt and colleagues have suggested that an IVRS is likely to be most beneficial in treating frequently occurring problems with daily impacts to health.[47] The complex daily concerns of CKD patients related to blood pressure and glycemic control, medication adherence, and healthy food habits, along with their preponderance of co-morbidities, and lower socio-economic status make them good candidates for an IVRS application.

Recording patient reported safety events in CKD: a task well-suited for IVRS

Collecting patient-reported adverse safety events have been recognized as a valuable means of ensuring medication pharmacovigilance in research and clinical settings.[48–50] Patients can recognize potentially hazardous drug or treatment side-effects, when incipient or under-appreciated by care providers. Such alerts can avert worse outcomes and improve the safety of care.[48,49,51] A recent panel convened in Europe discussed collecting patient-reported measures in both dialysis and pre-dialysis patients. The discussion emphasized the need for renal-specific evaluations such as comparing health survey results to laboratory values and

using measures for kidney specific symptoms such as the Kidney specific Kidney Disease Quality of Life (KDQOL™-36) survey developed for dialysis patients.[52] A separate discussion sponsored by the NKF and US FDA recognized the need for renal disease-specific measures such as tools for evaluating swelling and anasarca in nephrotic syndrome and urinary symptoms for polycystic kidney disease.[53] Patient-reported outcomes in the general CKD population are largely non-specific except in the realm of adverse safety events for which there is great opportunity to monitor the hazards of ill-advised medical treatments, polypharmacy, and countervailing treatment recommendations.

A recent study evaluated patient-reported safety-specific outcomes related to medication use, medical instructions or medical care in stage 3–5 CKD using an IVRS.[54] Fifty-two consecutive pre-dialysis CKD patients from the established Safe Kidney Care (SKC) cohort (NCT01407367) were recruited for a 6-month observational study. Participants were crossed-over from use of a paper-based diary to record safety outcomes with an IVRS diary programmed with a more extensive protocol to document such events. Participants were auto-called weekly and also permitted to self-initiate calls to report adverse events. Monthly reports of adverse events for each participant were reviewed by two physician adjudicators for their clinical significance. Participants were followed over a total of 1384 weeks with more than 90% participation in weekly calls. Twenty-eight events were reported using the IVRS vs 8 events with the paper diary. Hypoglycemia was the most common adverse event reported using either method. Other common symptoms included leg swelling, fall, fatigue, and dizziness. Adjudication of the events found approximately half of the 80 reports reviewed were considered clinically significant in that they warranted further clinical investigation or a therapy change.

Most of the IVRS participants reported they would recommend its use to other CKD patients, and more than 90% chose the “agreed” or “strongly agreed” response to the question asking if the IVRS was easy to use. Although user participation did not decrease over time, the number of outcomes reported did decline. This could imply a patient learning effect or alternatively could reflect therapy adjustments as a result of clinicians’ increased awareness of symptoms. Patients may have also chosen to report less symptoms to expedite scheduled weekly data collection in place of appropriately reporting symptoms (user-fatigue). More research is needed to evaluate the role of symptom-reporting by IVRS in preventing outcomes such as hospitalization and mortality, and patient and provider satisfaction with using IVRS with routine medical care.

Conclusion

The future implementation of telemedicine to disseminate health IT applications in pre-dialysis CKD needs to be based on evidence that such interventions successfully engage patients in their care and lead to improved outcomes in a cost-effective and enduring manner. Using telemedicine for the management of CKD faces many barriers due to socioeconomic limitations and the need for user-friendly interventions that address a range of adverse events and comorbidities in CKD. As a relatively simple, inexpensive, and ubiquitous technology, IVRS may represent a powerful health IT solution for management of CKD. Use of IVRS can serve as a useful monitor in the important and prominent domain

of patient-reported safety outcomes in CKD. IVRS use can be extended beyond simply recording adverse events and symptoms to more interactive procedures designed to safeguard medical care through improved medication reconciliation and avoidance of harmful drug interactions. Nevertheless, more research is needed to determine if these applications improve clinical outcomes. In time, the CKD population will "evolve" in its acceptance and use of more advanced and powerful telemedicine modalities as younger people develop the disease. This may broaden the scope of acceptable health IT tools for use in CKD, but for years to come, IVRS stands as a reliable telemedicine platform for delivery of high impact health IT with great promise for improving CKD outcomes.

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Clinical Summary

1. CKD patients experience many safety events related to complex medication regimens and decreased renal function.
2. Health information technology administered via telemedicine in pre-dialysis CKD is in the early stages of development and requires more investigation for the appropriate roles telemedicine can have in reducing important clinical outcomes such as mortality and hospital admissions.
3. IVRS, a widely accepted health information technology, have been underused in CKD, and can be used to elicit patient-reported outcomes related to safety.

Table 1

Telemedicine interventions for patient safety in pre-dialysis CKD

Study	Measurements	Design	Intervention	Control	Outcome	Cost
Fink 2016[35] Baltimore, MD	Symptoms	Observational cohort, cross over	IVRS	Paper diary	28 reported events using the IVRS vs1 8 with the paper diary, hypoglycemia most common	N/A
Ong 2016[52] Toronto, Canada	BP, medications, lab results and symptoms	6-month pilot study of 45 stage 4 and 5 CKD patients	Smart phone application: Bluetooth-enabled BP monitoring and symptoms monitoring by algorithm, monthly medication reconciliation, lab review capabilities	None	Statistically significant improvement in BP readings (SBP −3.4 mmHg; 95% CI −5.0 to −1.8 and DBP −2.1 mmHg; CI −2.9 to −1.2), 127 medication discrepancies, interventions for symptoms	N/A
Ishani 2016[50] Minnesota, USA	BP, volume status, proteinuria, diabetes, cholesterol, depression, health literacy, patient activation	12-month RCT of 601 veterans with CKD	451 participants; Home telemedicine touch screen computer with peripheral devices (including stethoscope and web camera) to monitor blood pressure, pulse oxygen, weight and sugar. Daily review of high risk patients with weekly review otherwise by care team	150 participants; Usual clinical care	Death, hospitalization, ED visit, nursing home admission with no differences between intervention and control	N/A
Murali 2013[47] California, USA	Diet	6-week pilot study in 12 pre-dialysis stage 5 CKD participants	Use of web-based dietary assessment (DietDay) for adherence to CKD diet based on KDOQI guidelines	None	All patients had deficiencies in dietary knowledge. 25–30% participants had severe non-adherence to all nutrients assessed. 25% felt more confident in managing dietary intake and 25% felt less confident after using DietDay once	N/A
Margolis 2013[43] Minnesota, USA	BP	12-month cluster randomized clinical trial of 450 participants with uncontrolled BP (19% CKD)	228 participants; Home BP monitor (A&D Medical 767PCautomated oscillometric) with evaluation by a clinical pharmacist	222 participants; Usual clinical care determined by PCP	Improved control of BP in intervention group, no specific CKD-related outcomes	$1350 per patient/year
Rifkin 2013[37] California, USA	BP	6-month RCT of 43 veterans with Stage 3 or greater CKD and uncontrolled BP Intervention	28 participants; Telemonitoring device pairing a Bluetooth-enabled BP cuff	13 participants; Usual clinical care	78% of intervention participants provided BPs over 6 months versus 20% in the control group. Trend of improved blood pressure in intervention group	$229 of fixed cost, internet service costs
Becker 2013[45] Germany	Medication adherence	Observational study of any smartphone	Medication management application called	None	11688 people downloaded the program. Application	N/A

Study	Measurements	Design	Intervention	Control	Outcome	Cost
		user who chose to download free application	"Medication Plan" made available after initial advertising through the German Society of Nephrology		use decreased over the first two months with few active applications 1 year after deployment	
Diamantidis 2013[49] Baltimore, MD	Medication safety	Pilot study of 20 CKD patients to evaluate different modalities of a medication inquiry system	20 participants performed tasks to extract information about medications using three modalities: mobile device with text, personal digital assistant, web site	None	Similar error rates between modalities; 50% of participants preferred the web site, 30% the PDA and 20% the texting	N/A
Cottrell 2012[56] Stoke-on-Trent, UK	BP	3-month non-randomized trial of patients either with CKD stages 3–4 (19%) or age over 50 without CKD	124 participants; Interactive text messaging service (Florence) with automated messages and review by care providers	364 matched participants; Usual clinical care determined by PCP	No significant improvement in BP between groups of CKD participants	N/A

Abbreviations: BP, blood pressure; CI, confidence interval; DBP, diastolic blood pressure; IVRS, interactive voice response system; SBP, systolic blood pressure; PCP, primary care provider; RCT, randomized control trial