Transforming the Medication Regimen Review Process of High-Risk Drugs Using a Patient-Centered, Telemedicine-Based Approach to Prevent Adverse Drug Events in the Nursing Home

Principal Investigator Sandra L. Kane-Gill, PharmD, MS, FCCM, FCCP

Research Team Members

Richard D. Boyce, PhD Colleen Culley, PharmD Steven Handler, MD, PhD, CMD John A. Kellum, MD, FACP, MCCM David Nace, MD Subashan Perera, PhD Maureen D. Reynolds, PhD

University of Pittsburgh School of Pharmacy

Project Period: 09/01/2015 - 09/30/2018 Federal Project Officer: DEBORAH PERFETTO Grant Award Number: R18 HS24208

This project was funded under grant number R18 HS24208 from the Agency for Healthcare Research and Quality (AHRQ), US Department of Health and Human Services. The opinions expressed in this document are those of the authors and do not reflect the official position of AHRQ or the US Department of Health and Human Services.

Abstract

<u>Purpose</u>. Aims of the project were to (1) evaluate the effect of pharmacist-led medication management service using patient-centered telemedicine on adverse drug events (ADEs) and 30-day hospital readmissions and (2) evaluate patient-reported outcomes and perception of physicians for pharmacist's performance of the enhanced services.

<u>Scope</u>. Patient-centered medication reconciliations/reviews with telemedicine were conducted on admission to the nursing home (NH) when high-risk drugs were prescribed and medication regimen reviews (MRRs) occurred during the residents' NH stay with the prompt of an alert. Clinical decision support alerts were developed to inform pharmacists of inappropriate prescribing and monitoring of high-risk drugs for the prevention of ADEs.

<u>Methods</u>. Our quality improvement project used a cluster-randomized, step-wedged design and was conducted in four NHs within the health system. Upon intervention completion, a review of medical records was conducted to identify ADEs and 30-day hospital readmissions. Surveys regarding the residents' interactions with consultant pharmacists were administered at a usual care site and to physicians before and after the intervention.

<u>Results</u>. There was a 92% lower incidence of ADEs in the intervention group compared with usual care (9 vs 31; 0.14 vs 0.61/1,000 resident days; AIRR=0.08; p=0.0022). Alert rates were significantly less for the intervention period compared with usual care period (2.60 and 9.52 per 1,000 resident days; p=0.0098). Hospital admissions within 30 days of NH admission were similar between the groups (110 vs 102; 1.72 vs 2.00/1,000 resident days; AIRR=1.21; p=0.4227). NH residents and physicians rated pharmacists more positively after the intervention.

Key Words. Adverse drug event, telemedicine, nursing home, pharmacist

Purpose

We conducted a quality improvement project using a cluster, stepped-wedge design to determine the impact of patient-centered, telemedicine-based, pharmacist-led medication management service for high-risk medications on adverse drug event (ADE) occurrence in four nursing homes (NHs). Our project addressed current medication safety gaps by first prospectively identifying NH residents who were either newly admitted with or subsequently prescribed a high-risk drug during their NH stay. With support from AHRQ, our research team previously developed a clinical decision support system (CDSS) in a commercially available EMR-agnostic platform for use in the NH setting for ADE detection. We modified this CDSS to automate prevention of ADEs resulting from inappropriate prescribing and monitoring of high-risk drugs. We also introduced the novel application of telemedicine for medication management during care transition to improve timely access to consultant pharmacists when high-risk drugs were prescribed. Telemedicine was used by the consultant pharmacist to directly interact with the resident and engage him/her in education to recognize and prevent ADEs associated with high-risk drugs. Finally, consultant pharmacists provided structured feedback and recommended medication changes to the resident's attending physician.

The Specific aims of our project were as follows:

Aim 1: Evaluate the effect of pharmacist-led medication management service using patientcentered telemedicine for residents receiving high-risk drugs commonly associated with ADEs. We conducted a quality improvement project using a cluster, stepped-wedge design to determine the impact of patient-centered care on ADE reduction in four NHs. This evaluation compared the intervention arm, pharmacist-led medication reconciliation and medication regimen review (MRR) initiated within 72 hours of NH admission for those on high-risk drugs, including the use of pharmacist-to-resident interactions via telemedicine as well as MRRs for targeted events throughout the resident's stay identified using the above-mentioned CDSS, versus usual care that used retrospective pharmacist-led MRRs conducted every 30 days for NH residents. Our hypotheses were that:

H1: NH residents in the intervention group would have fewer ADEs (i.e., bleeding, hypoglycemia, mental status changes, and AKI) than residents receiving usual care; *H2:* NH residents in the intervention group would have fewer 30-day hospital readmissions and/or hospital readmissions during the evaluation period than residents receiving usual care. Determining ADEs and hospital readmission rates required comprehensive medical record review.

Aim 2: Evaluate patient-reported outcomes and the perception of the physician for pharmacist performance of enhanced services. Our hypotheses were that:

H1: Residents exposed to the pharmacist-led medication management service would report greater satisfaction with pharmacist care compared with when they were receiving usual care. H2: Physicians would report greater perceived performance with pharmacist care after the intervention period. Determining service satisfaction and pharmacist performance by the NH residents and physicians was accomplished via validated surveys. The product of this research is a generalizable EMR-agnostic MRR model, including decision support rules and structured communication tools to optimally execute the consultant pharmacist's role in ADE prevention in the NH.

Scope

<u>Background</u>. An ADE is defined as an injury resulting from medical intervention related to a drug. The National Action Plan for Adverse Drug Event Prevention identified the nearly 16,000 NHs as a clinical setting where ADE prevention strategies are lacking for high-risk drug classes. Various approaches have been taken to minimize the occurrence of ADEs, including federal regulations requiring residents' drug regimen to be free from unnecessary drugs (F-Tag 329) and a consultant pharmacist to conduct a Medication Regimen Review (MRR) on each resident at least monthly (F-Tag 428). More frequent MRRs are required for residents with additional risk factors, such as receiving high-risk drug classes that place them at a higher risk for ADEs. Collectively, F-Tags 329/428 constitute the primary regulations that are considered usual care in NHs at the time of this quality improvement project. In November 2018, there were some changes to the F-tags, with minimal alterations to F-Tags 329/428, now referred to as F756.

A recent Office of Inspector General (OIG) report estimated that 37% of all harmful adverse events are related to drugs, of which two thirds are preventable. The National Action Plan calls for focus on three high-risk drug classes, anticoagulants, diabetic agents, and opioids, which account for most preventable ADEs. Our prior work confirmed the frequent occurrence of hypoglycemic events in NHs (9.5 events per 1,000 resident-days). This work also showed that drug-associated acute kidney injury (AKI) occurs at a rate of 4.1 events per 1,000 resident-days in the NH, underscoring the need to also include AKI in ADE prevention strategies.

<u>Context</u>. Current strategies fail to improve medication safety in NH residents because 1) MRRs are almost always conducted retrospectively and often not in time for residents whose stay is <30 days; 2) consultant pharmacists are usually not involved in MRR on admission to the NH, even though pharmacists have been shown to likely be the most appropriate clinicians to conduct MRRs during transitional care; 3) prior to the aforementioned reports, there has not been consensus regarding high-risk drug classes that require hypervigilant monitoring for ADE prevention; and 4) the MRR process is not patient centered, as most consultant pharmacists never interact directly with the resident.

<u>Settings</u>. UPMC Senior Communities is the largest long-term care organization in Southwestern PA and is also the largest long-term care organization nationally that is part of an integrated healthcare delivery system. UPMC Senior Communities has approximately 2,500 beds, of which 549 are located in the NH setting. UPMC NHs are nonprofit, academically affiliated, and not part of a national chain. The NHs included in the project were two in urban settings and two in suburban settings. The average number of beds in these NHs was 137 (range, 80-174). These facilities also provide specialized skilled nursing and transitional rehabilitation services for those recovering from surgery or other medical treatments. Participants. Inclusion criteria for the evaluation were all residents admitted to the four facilities within the period November 1, 2016, through October 31, 2017, with at least one high-risk medication (HRM) prescribed as well as any current resident for whom an HRM was subsequently prescribed or for whom the CDSS identified as at risk for an ADE relevant to an HRM. For the purposes of the project, HRMs were identified as anticoagulants, antidiabetic agents, opioids, and nephrotoxins. During the first quarter (nonactive, usual care), there were 492 admissions to the four facilities. During the Intervention period (February 1 through October 31, 2017), there were 1,506 admissions; of these, at least 1,205 (80%) were prescribed an HRM. Residents were excluded from the intervention if they were cognitively impaired, as indicated by a score of 7 or less on the Brief Interview for Mental Status (BIMS) or any positive responses on the Confusion Assessment Method (CAM), were unable to respond, were unable to understand English, or refused to participate.

Methods

<u>Study Design</u>. In cluster RCTs, groups or clusters of individuals, rather than an individual, are randomized to intervention and usual care groups. The outcomes are still measured on the individuals within those clusters. This method is particularly useful in implementation studies, health information technology assessment, and studies conducted in the NH setting. Our quality improvement project included clusters of individual NHs, and we included them in the intervention using a stepped-wedge design. Figure 1 provides a description of the stepped-wedge inclusion of the NHs.

NH	20	16					2017						
	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	
1		199		197		187			199				
2		203		2	45		23	232			231		
3		253		2	239		232			225			
4		288		3	04		28	30		273			

Figure 1. Stepped-Wedge Inclusion*

NH is nursing home site, NH 1-4. Horizontal lines indicate the run-in period. Dark shading indicates active period. *Indicates number of distinct residents in the facility each quarter.

During the first 3 months of run-in (November 1, 2016, through January 31, 2017), no consultant pharmacist interventions were conducted. This run-in period was utilized to interview residents and physicians at all facilities that were considered as having preintervention usual care in the survey analysis. This run-in period also allowed for workflow management of the consultant pharmacists to be coordinated. Randomization of the facilities was conducted using a random number generator available in SAS to determine the order of the facilities in which the intervention would be initiated. The active period was initiated in February 2017; the intervention included residents in NH1 for 0 months, NH2 for 3 months, NH3 for 6 months, and NH4 for 9 months, and the usual care included residents in NH1 for 9 months, NH2 for 6 months, NH3 for 3 months, and NH4 for 0 months. The active period was used for analysis of the ADEs and rehospitalizations. Resident surveys for the intervention were completed after each telemedicine interaction considered as a post-intervention case. Resident surveys for the usual care group were continued in NH1 for the duration of the active period. Physician surveys were completed after the completion of the active period in December 2017 through February 2018.

Data Sources/Collection.

Theradoc Alerts. The documentation of alerts was generated by the clinical decision support system, hosted in TheraDoc (Premier, Inc., Charlotte, NC), an electronic health record (EHR)agnostic platform with which our study team has significant experience. Alerts were formulated with the intention to advance current CDS systems by building new alerts focused on 1) inappropriate prescribing, as defined by CMS (e.g., excessive dose, lack of monitoring, therapeutic duplication), of high-risk medications based on prevention strategies recommended in the National Action Plan and published literature and 2) absence alerts when laboratory monitoring did not occur as recommended. Alerts were generated and provided to the consultant pharmacist in real time during normal weekday working hours (i.e., 0900-1700, Monday-Friday) or were batched and sent at 0900 the next business day. A flow diagram of the CDS alerts is in Figure 2.

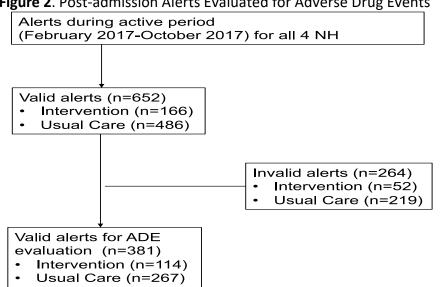


Figure 2. Post-admission Alerts Evaluated for Adverse Drug Events

Telemedicine Communications. Documentation of the resident interaction for the project was completed within the EHR for each resident contacted by the project in the NH. A form was created by system administrator, entitled the "Pharmacist Intervention Form," in which the consultant pharmacist documented the medication reconciliation or medication regimen review, the SBAR (Situation, Background, Assessment, Recommendation) and communication with the resident's physician, as well as the outcome of the telemedicine interaction with the resident. Project staff also documented the results of the cognitive assessment of the resident (BIMS and CAM), telemedicine eligibility, and details of the telemedicine interaction. This was created and included in the EHR for the NH so that clinicians caring for residents would have access to the medication list completed from the medication reconciliation.

Survey of Residents' Satisfaction. Residents prescribed HRMs who did not meet exclusion criteria were asked by a project member to complete an anonymous survey regarding pharmacy services in the four NHs. Residents were surveyed using a published, validated instrument – the modified Patient Satisfaction Questionnaire (PSQ). The survey included 10 questions within two domains, friendly explanation and managing therapy, ranked on a scale of excellent to poor. Residents in the intervention NHs were surveyed after the telemedicine interaction with the consultant pharmacist. Intervention residents also answered six questions regarding the telemedicine interaction. Residents in all four NHs in the run-in period and residents in the NH with the usual care arm (NH1) during the active period who received a high-risk drug on admission were also approached to complete the PSQ survey. A final question on the survey queried, if the resident were to speak with a pharmacist (again) during their NH stay, which mode of interaction would they prefer: in-person, telemedicine, or either. Survey administration was via Qualtrics, a web-based survey service that allows users to collect and store data securely and that meets University of Pittsburgh Data Security standards, on an iPad.

Survey of Healthcare Provider Satisfaction. A modified version of the 10-item PSQ survey was provided to the physicians and advanced practice providers at each facility before the intervention was initiated and 3 months post-intervention. Additional items were included to examine the perceived quality of the interaction with the consultant pharmacists. Survey administration was via Qualtrics, a web-based survey service that allows users to collect and store data securely and that meets University of Pittsburgh Data Security standards, emailed directly to the physician and provided as paper copies that were left in sealed envelopes in the physician mailboxes/medical records room at the facility in which the provider primarily practiced and mailed to their practice office.

Interventions. Alerts were generated by the TheraDoc CDSS when a resident was admitted to the four target NHs as well as when any change or new prescription for a high-risk medication occurred among current residents in the NHs. Admission alerts were reviewed by the consultant pharmacists or project staff for prescriptions of the high-risk medications and communicated via secure email to all project pharmacists and staff. Pharmacists conducted medication recommendations to confirm the list of medications at care transition between hospital and nursing home. Pharmacists performed an MRR for inappropriate prescribing or monitoring of high-risk medications. Post-admission alerts were reviewed by consultant pharmacists to determine if alerts were actionable. Consultant pharmacists conducted MRRs on post-admission alerts in the active period for the intervention NHs, as per the steppedwedge design, and communicated via secure texts to project staff about which residents to visit. Project staff located each identified resident and conducted BIMS and CAM to determine project eligibility. If the patient was eligible and willing, the staff texted the pharmacist to engage the telemedicine interaction. Using an iPad with a MobileIron security program and Vidyo telemedicine secure software, the consultant pharmacist interviewed the resident regarding their medication regimen, reviewed possible side effects of their medications, and educated residents about their medications. Video information about any newly prescribed medications was also made available to residents immediately after the telemedicine interaction with the pharmacist.

Residents who were hearing impaired were provided a headset and portable amplifier (Pocketalker) so that they could properly hear the pharmacist. After the telemedicine visit and video (if recommended), the project staff administered the Survey of Residents' Satisfaction on the iPad. Consultant pharmacists performed MRRs according to standardized protocols to ensure consistency in recommendations. Consultant pharmacists then communicated any medication change recommendations to the prescribing provider via SBAR, sent via secure email or secure text message, depending on the emergent need for change. If changes could be made by the pharmacist, or if the resident expressed a desire for a PRN medication, the pharmacist would communicate directly with the unit nursing staff regarding the resident's request.

In the usual care facility (NH1) during the active period, project staff members approached all new admissions who were identified as having an HRM prescribed and all postadmission alerts identified through TheraDoc. Staff explained the project using an introductory script and administered the Survey of Residents' Satisfaction.

<u>Process Measures.</u> The frequency of pharmacist interventions and physician acceptance was evaluated. To evaluate the potential impact of these interventions, the study team created criteria to evaluate the potential severity of harm that the intervention averted (no error, minor, moderate major). These criteria were reworked until consensus within the study team was achieved and were based on previous work and formulated to be specific for the NH. At the end of the study period, interventions were separated into individual recommendations (i.e., one SBAR with multiple interventions was separated into individual interventions). Two clinical pharmacists then evaluated all interventions. A third reviewer was consulted in cases of disagreement.

<u>Outcome Measures</u>. **ADEs.** Screening for all potential ADEs was conducted by a trained pharmacist blinded to the intervention status of each facility. The pharmacist searched NH resident EHRs for the following indicators of potential ADEs: changes and discontinuations of prescribed medications; clinical documentation by other staff describing changes in symptoms or new clinical events, such as bleeding, falls, confusion, and gastrointestinal problems; clinical documentation by another clinician describing a potential ADE; and any unplanned hospitalization and emergency department evaluations or discharge summaries. The reviewer assessed the NH residents' medical records to determine whether an actual ADE was present using the Adverse Drug Reaction Probability Scale. Adverse drug events were defined as injuries resulting from a medication. **Readmissions to the Hospital.** All residents were evaluated for readmissions within 30 days of the NH admission and throughout the study period to one of the 20 hospitals within the UPMC health system.

<u>Limitations</u>. The volume of admissions and project staff dedicated to the project facilitating telemedicine made it difficult to conduct the MRRs and telemedicine interactions within the projected 48-hour post-alert window, so we extended the window to 72 hours. Most residents when first admitted undergo multiple evaluations by nursing home staff (admitting nurse, PT, OT, wound care, social work, etc.) during the same window and were sometimes unavailable to

project staff for the intervention. Some patients refused the intervention during that time because they were unwell or tired, and others did not manage their own medications at home and felt they could not adequately discuss the medications with the pharmacist. In some instances, the telemedicine interaction was conducted with a family member who managed the resident's medications when that family member was available at the NH. It was a challenge to secure physicians' responses for the surveys. Another, limitation is the potential for cross-contamination of the providers within the NH if they perform clinical care at more than one NH. We believe that this is not a concern, as cases of this would be extremely rare. Finally, although we designed our recommendation severity and ADE criteria to be as exhaustive as possible using an interdisciplinary group, there may be cases that were miscategorized by our criteria. With regard to the severity evaluation, we opted to make our criteria more lenient (i.e., more likely to categorize as a lower severity).

Results

Principal Findings

Table 1. Characteristics of distinct residents during the active intervention and usual care phases: mean ± standard deviation or N (%)

Characteristic	Intervention	Usual Care	P Value
	N=1,130	N=997	
Age	77.2±13.6	76.9±13.0	0.4969
Gender (male)	390 (34.5)	351 (35.2)	0.9390
Race (White)	850 (75.2)	791 (79.3)	0.1718
ADL dependence score	15.5±2.6	15.1±3.1	0.3039

To compare continuous resident characteristics, such as age and ADL dependence score, between intervention and usual care, we fitted linear mixed models using distinct residents as observations, group as the sole fixed effect, and a facility random effect. For dichotomous characteristics, we fitted generalized estimating equations models with group as the sole independent effect and an exchangeable working correlation structure to account for clustering by facility.

Process Outcomes

Pharmacists conducted 553 medication reconciliations and MRRs, including 401 telemedicine interactions, on admission for residents receiving a high-risk medication. Additionally, pharmacists performed another 114 MRRs for post-admission alerts, with 32 more telemedicine interactions. Consultant pharmacists provided 769 recommendations for medication management during the study period, as there was more than one recommendation per pharmacist review in some cases. Of note, telemedicine interactions were conducted that did not result in an intervention, and not all interventions were from telemedicine interactions (could be from an MRR for post-admission alerts, a patient who refused the telemedicine interaction, or a patient was unable to communicate). Details on the severity evaluation of the potential consequences, as well as provider responses, are detailed in Table 2.

Table 2 . Severity evaluation and provider response to consultant pharmacist interventions										
	Provi	Provider response to intervention, n (%)								
Severity evaluation	Accept	Reject	No response	Resident discharged						
Unable to evaluate (n=11)	9 (81.8)	1 (9.1)	N/A	1 (9.1)						
Minor (n=146)	92 (63.0)	38 (26.0)	13 (8.9)	3 (2.1)						
Moderate (n=505)	277 (54.9)	149 (29.5)	65 (12.9)	14 (2.8)						
Major (n=107)	61 (57.0)	33 (30.8)	11 (10.3)	2 (1.9)						
Total (n=769)	439 (57.1)*	221 (28.7)	89 (11.6)	20 (2.6)						

* Increased to 66.5% after excluding no responses and resident discharged.

There were 11 recommendations that were unable to be assessed for severity due to lack of detail provided in the documentation. Discontinuation of a medication was the most common recommendation (n=200, 26.0%), followed by starting a therapy (n=166, 21.6%) and dose changes (n=107, 13.9%). Discussing their recommendation with the provider took a median of 5 minutes (IQR 5, 5), while enacting the recommendation took a median of 5 minutes (IQR 5, 5), while enacting the recommendation took a median of 5 minutes (IQR 5, 5).

We were able to identify 73 resident-reported symptoms (9.5%) that occurred during resident-pharmacist telemedicine interactions and that resulted in a pharmacist recommendation to the provider. <u>This highlights that patient-centered communication with residents using telemedicine offered insight into ADEs that may not otherwise have been identified.</u> Examples included a rash that was associated with cefuroxime use and diarrhea that was associated with ciprofloxacin, which was later determined to be *Clostridium difficile*. Eleven of the recommendations were determined to be major (15.1%), 37 were moderate (50.7%), 24 were minor (32.9%), and one was not an error (removal of naproxen allergy from record). The majority of these recommendations were accepted (n=41, 56.2%), although 19 were rejected (26.0%) by providers. None of the rejected recommendations had major consequences, although two that were deemed to have major consequences resulted in no response by the providers.

Aim 1: Evaluate the effect of pharmacist-led MRRs using patient-centered telemedicine for residents receiving high-risk drugs commonly associated with ADEs.

H1: NH residents in the intervention group would have fewer ADEs (i.e., bleeding, hypoglycemia, mental status changes, and AKI) than residents in the usual care group. *Results for ADEs:* During the active period, there were 166 alerts in 63,947 resident days in the intervention and 486 alerts in 51,056 resident days in usual care, resulting in rates of 2.60 and 9.52 per 1,000 resident days, respectively (adjusted incident rate ratio or AIRR=0.53; p=0.0098). Intervention had a 92% reduced incidence of ADEs compared with usual care (9 vs 31; 0.14 vs 0.61/1,000 resident days; AIRR=0.08; p=0.0022).

H2: NH residents in the intervention group would have fewer 30-day hospital readmissions than residents in the usual care group.

Results for 30-day hospital readmissions: Hospital admissions were similar between the groups (149 vs 138; 2.33 vs 2.70/1,000 resident days; AIRR=1.06; p=0.7544), as were the hospitalizations within 30 days of nursing home admission (110 vs 102; 1.72 vs 2.00/1,000

resident days; AIRR=1.21; p=0.4227). Sensitivity analysis with a Poisson model did not meaningfully alter the results.

For the main between-group comparisons, we fitted a series of generalized linear mixed models using the active period data with each of the outcomes as the dependent variable; natural logarithm of number of resident days as an offset to account for exposure; negative binomial distribution and a logarithmic link function; group, time period (quarter 1/2/3) and facility-level baseline summary of outcome from the run-in period as fixed effects; and a facility random effect. Upon observing numerical difficulties in estimation algorithm convergence, we fitted a simpler yet reasonable model with facility as another fixed effect and a resident random effect. Incident rate ratios for the group effect and their statistical significance were used to draw main conclusions. Finally, we conducted a sensitivity analysis using Poisson instead of the negative binomial distribution to evaluate the robustness of our findings. SAS^{*} software version 9.3 (SAS Institute, Inc., Cary, North Carolina) was used for all statistical analyses.

Nursing Home and	Run-in Period		Active Period	
Outcome	Quarter 1:	Quarter 2:	Quarter 3:	Quarter 4:
	November	February 2016-	May 2016-	August 2016-
	2016-	April 2017	July 2017	October
	January 2017			2017
Nursing Home 1:				
Facility resident days	8,401	7,819	8,038	7,707
Alerts	96 (11.43)	50 (6.39)	53 (6.59)	62 (8.04)
Valid alerts	28 (3.33)	28 (3.58)	38 (4.73)	40 (5.19)
ADEs (possible and	1 (0.12)	0 (0.0)	3 (0.37)	5 (0.65)
probable)				
Possible ADEs ¹	1 (0.12)	0 (0.0)	3 (0.37)	5 (0.65)
Probable ADEs ¹	0 (0.00)	0 (0.0)	0 (0.0)	0 (0.0)
Hospital admissions (all)	23 (2.74)	18 (2.30)	25 (3.11)	18 (2.34)
Hospital admissions	13 (1.55)	13 (1.66)	18 (2.24)	16 (2.08)
(within 30 days)				
Nursing Home 2				
Facility resident days	9,029	8,799	9,006	9,305
Alerts	86 (9.52)	98 (11.14)	115 (12.77)	16 (1.72)
Valid alerts	30 (3.32)	44 (5.00)	54 (6.00)	11 (1.18)
ADEs (possible and	3 (0.33)	5 (0.57)	5 (0.56)	0 (0.00)
probable)				
Possible ADEs ¹	3 (0.33)	5 (0.57)	5 (0.56)	0 (0.00)
Probable ADEs ¹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.00)
Hospital admissions (all)	20 (2.22)	23 (2.61)	27 (3.00)	23 (2.47)
Hospital admissions	7 (0.78)	16 (1.82)	17 (1.89)	20 (2.15)
(within 30 days)				

Table 3: Descriptive statistics of study outcomes in intervention (shaded) and usual care(unshaded) periods: number (rate per 1,000 resident days)

L0,122	9,687	10,357	9,685
L26 (12.44)	108 (11.15)	33 (3.19)	7 (0.72)
57 (5.63)	63 (6.50)	26 (2.51)	7 (0.72)
5 (0.60)	13 (1.34)	1 (0.10)	1 (0.10)
5 (0.60)	12 (1.24)	1 (0.10)	1 (0.10)
0 (0.0)	1 (0.10)	0 (0.0)	0 (0.0)
22 (2.17)	27 (2.79)	26 (2.51)	26 (2.68)
L4 (1.38)	22 (2.27)	24 (2.32)	19 (1.96)
L1,150	11,131	11,686	11,783
L09 (9.78)	74 (6.65)	29 (2.48)	7 (0.59)
59 (5.29)	47 (4.22)	23 (1.97)	7 (0.59)
Ə (0.81)	6 (0.54)	1 (0.09)	0 (0.00)
5 (0.54)	6 (0.54)	1 (0.09)	0 (0.00)
3 (0.27)	0 (0.00)	0 (0.00)	0 (0.00)
30 (2.69)	27 (2.43)	26 (2.22)	21 (1.78)
18 (1.61)	17 (1.53)	13 (1.11)	17 (1.44)
	26 (12.44) 7 (5.63) (0.60) (0.60) (0.0) 2 (2.17) 4 (1.38) 1,150 09 (9.78) 9 (5.29) (0.81) (0.54) (0.54) (0.27) 0 (2.69)	$\begin{array}{c cccc} 26 & (12.44) & 108 & (11.15) \\ \hline 7 & (5.63) & 63 & (6.50) \\ \hline (0.60) & 13 & (1.34) \\ \hline (0.60) & 12 & (1.24) \\ \hline (0.0) & 1 & (0.10) \\ 2 & (2.17) & 27 & (2.79) \\ 4 & (1.38) & 22 & (2.27) \\ \hline \\ 1,150 & 11,131 \\ 09 & (9.78) & 74 & (6.65) \\ 9 & (5.29) & 47 & (4.22) \\ \hline (0.81) & 6 & (0.54) \\ \hline (0.54) & 6 & (0.54) \\ \hline (0.27) & 0 & (0.00) \\ 0 & (2.69) & 27 & (2.43) \\ \hline \end{array}$	26 (12.44) $108 (11.15)$ $33 (3.19)$ $7 (5.63)$ $63 (6.50)$ $26 (2.51)$ (0.60) $13 (1.34)$ $1 (0.10)$ (0.60) $12 (1.24)$ $1 (0.10)$ (0.0) $1 (0.10)$ $0 (0.0)$ $2 (2.17)$ $27 (2.79)$ $26 (2.51)$ $4 (1.38)$ $22 (2.27)$ $24 (2.32)$ $1,150$ $11,131$ $11,686$ $09 (9.78)$ $74 (6.65)$ $29 (2.48)$ $9 (5.29)$ $47 (4.22)$ $23 (1.97)$ (0.81) $6 (0.54)$ $1 (0.09)$ (0.54) $6 (0.54)$ $1 (0.09)$ (0.27) $0 (0.00)$ $0 (0.00)$ $0 (2.69)$ $27 (2.43)$ $26 (2.22)$

¹Assessment using the Naranjo causality instrument

Valid alert=confirmation that resident was in the NH at the time of alert, confirmation that the resident was administered the drug, etc.

We used appropriate descriptive statistics to summarize resident characteristics by facility, time period, and participation in intervention, and we expressed outcome rates on a per 1,000 resident-days basis.

Aim 2: Evaluate patient-reported outcomes and the perception of physician for pharmacist performance of enhanced services.

H1: Residents in the intervention group would report greater satisfaction with pharmacist care.

Results for Resident Satisfaction: Table 4.1 presents a summary of survey administration during the active period (months 3 through 12, or Q2-4) of the project to the NH residents, including reasons for exclusions.

Site	Adm	Adm	Post-adm	Exclude	Complete	Completed all	Refused	Unable to
	Alert w/	Approached	Approached	(low	ТМ	questions	Survey	Participate
	HRM			BIMS)	Question	(including	Participation	
						those about		
						pharmacist)		
NH1	242	207	1	31	187	3*	8	5
NH2	107	107	19	50	77	74	33	9
NH3	205	180	30	49	148	144	34	7
NH4	355	335	44	100	272	265	47	7

Table 4.1: Resident Screening and Survey by NH Site

After completion of the telemedicine interaction during the active period, residents were surveyed regarding the pharmacist interaction. The response scale was a 5-point scale ranging from 1=Poor to 5=Excellent. Residents in the usual care facility (NH1) throughout the active period were also surveyed IF they reported that they had discussed their care while in the NH with a pharmacist. *As indicated in Table 4.1, only three residents in the usual care facility spoke with a pharmacist during their NH stay and could answer the pharmacist services questions in the survey; thus, 190 were considered complete at NH1. Mean scores for each of the survey items are presented in Table 4.2.

		Mean	responses	
		NH2		
	NH1	TM (3	NH3	NH4
Site	no TM	mos)	TM (6 mos)	TM (9 mos)
	n=3	n=69		
The availability of the pharmacist	4.33	4.55	n=121	n=234
to answer your questions	(1.16)	(.697)	4.78 (.524)	4.58 (.756)
How good the pharmacist is at	n=2	n= 71		
explaining things in a way that	4.67	4.58	n=144	n=258
you understand	(.577)	(.669)	4.78 (.508)	4.55 (.737)
	n=3	n=43		
How well the pharmacist	4.33	4.60	n=82	n=134
answers your questions	(1.16)	(.660)	4.78 (.445)	4.56 (.771)
		n=22		
How well the pharmacist instructs you	n=1	4.55	n=53	n=76
about how to take your medications	5.00	(.596)	4.66 (.649)	4.34 (.932)
		n=74		
The privacy of your conversations with	n=3	4.47	n=141	n=265
the pharmacist	5.00 (0)	(.879)	4.62 (.808)	4.57 (.800)
The pharmacist's efforts to ensure	n=2	n=61		
that your medications do what	4.50	4.49	n=118	n=223
they are supposed to do	(.707)	(.698)	4.62 (.703)	4.53 (.804)
The pharmacist's efforts to solve	n=2	n=34		
problems that you have with	4.00	4.50	n=69	n= 111
your medications	(1.41)	(.862)	4.74 (.656)	4.59 (.768)
The pharmacist's ability to advise you		n=48		
about problems that you might have	n=1	4.71	n=91	n=167
with your medications	3.00	(.544)	4.73 (.539)	4.49 (.842)
	n=2	n=58		
How well the pharmacist explains	4.00	4.55	n=102	n=187
what your medications do	(1.41)	(.680)	4.62 (.732)	4.36 (.878)
	n=2	n=61		
How well the pharmacist	3.50	4.48	n= 103	n=181
explains possible side effects	(.707)	(.673)	4.52 (.778)	4.45 (.903)

Table 4.2: NH Resident Mean	(sd) Satisfaction Responses
-----------------------------	-----	--------------------------

Residents also completed survey questions regarding the process of the telemedicine interaction with the pharmacist. Table 4.3 presents the mean responses on the same 5-point scale.

Question	NH1	NH2	NH3	NH4
	No	N= 76	N= 145	N=270
	ΤM			
How easily you can talk to the pharmacist		n=75	n=145	n=269
	N/A	4.63 (.731)	4.77 (.574)	4.64 (.696)
How easily you can hear the pharmacist		n=75	n=145	n=270
	N/A	4.47 (.827)	4.66 (.689)	4.38 (.944)
I can see the pharmacist as if we met		n=75	n=144	n=269
in person.	N/A	4.45 (.827)	4.50 (.946)	4.46 (.891)
I find the consultation with the pharmacist				
using telemedicine an acceptable way to		n=74	n=143	n=266
receive healthcare services.	N/A	4.53 (.848)	4.60 (.920)	4.50 (.972)
Overall, I am satisfied with the quality of				
service being provided by the pharmacist via		n=76	n=145	n=266
telemedicine.	N/A	4.61 (.834)	4.74 (.646)	4.68 (.732)

 Table 4.3:
 Resident Mean (sd) Responses to Telemedicine Process

Finally, residents at all sites were asked about the use of telemedicine for interactions with the pharmacist in the future. Responses of residents from the intervention sites were compared with those in the usual care site regarding the preference for telemedicine, in person, or either telemedicine or in person using the chi-square statistic. Intervention site residents were significantly more likely than residents in the usual care site to respond telemedicine or either telemedicine or in person (χ^2 =47.845, df=2, p<.001). Table 4.4 provides the responses by site.

	NH1		N	NH2 M		H3	NH4	
	N=	187	N=	-77	N=	148	N=	272
	Ν	%	Ν	%	Ν	%	Ν	%
Telemedicine	12	6.4	15	19.5	25	16.9	44	16.2
In Person	94	50.3	17	22.1	32	21.6	69	25.4
Either TM or In								
Person	81	43.3	45	58.4	91 61.5		159	58.5

Table 4.4: Residents' Communication Preference with Pharmacist in the Future

H2: Physicians in the intervention group would report greater perceived performance with pharmacist care.

Results for Physician Satisfaction: Physicians and advanced practice providers were surveyed regarding their communication with the consultant pharmacists at the nursing home prior to the implementation of the intervention program and following completion of the intervention. Table 4.5 includes information about the respondents at both collection periods.

		Pre-Inte	rvention		Post intervention			
Number completing	19				13			
survey								
Male		8	3			3	3	
Female		1	1			1	0	
MD	12				8			
DO	1 1							
CRNP		6	5			2	1	
Number respondents	NH1	NH2	NH3	NH4	NH1	NH2	NH3	NH4
from each NH	5	3	4	7	3	3	6	3
Frequency of contact with consultant RPh in past 6 months	<10 t 1	imes 6		imes 3	3 3 6 3 <10 times			

Table 4.5: Healthcare Providers Completing Surveys

Providers completed a satisfaction survey of their interactions with the consultant pharmacists that had items similar to those completed by the residents and the nursing staff. A summary of the pre- and post- intervention mean responses by usual care vs intervention NH sites are provided in Table 4.6.

	Pre-Inte	ervention	Post-Int	ervention	Mean D	ifference
Site	UC	I	UC	_	UC	I
1. The availability of the						
pharmacist to answer your	4.0	3.25	4.33	4.14		
questions	(.816)	(1.035)	(.577)	(.900)	+.33	+.89
2. How well the pharmacist						
explains medication problems to	4.0	3.11	4.33	4.33		
you	(.816)	(.928)	(.577)	(.816)	+.33	+1.22
3. How well the pharmacist	4.0	3.63	4.33	4.29		
answers your questions	(.816)	(1.061)	(.577)	(.951)	+.33	+.66
4. How well the pharmacist						
instructs you about residents'	4.25	3.38	4.33	3.80		
medication changes	(.500)	(.916)	(.577)	(1.304)	+.08	+.42
5. The pharmacist's efforts to						
ensure that the residents'						
medications do what they are	4.0	3.33	4.33	4.25		
supposed to do	(.816)	(.866)	(.577)	(.957)	+.33	+.92
6. The pharmacist's efforts to						
solve problems that the resident	4.25	3.25	4.33	4.50		
has with their medications	(.957)	(.707)	(.577)	(.837)	+.08	+1.25

Table 4.6: Healthcare Providers' Mean (sd) Satisfaction with Consultant Pharmacist

	Pre-Intervention		Post-Intervention		Mean Difference	
Site	UC	I	UC	-	UC	I
7. The pharmacist's ability to advise you about problems that you might have with residents' medications	4.5 (.577)	3.45 (1.036)	4.67 (.577)	4.17 (.983)	+.17	+.72
8. How well the pharmacist helps	(.577)	(1.050)	(.577)	(.505)	/	1.72
you to manage the residents'	4.25	3.20	4.67	3.57		
medications	(.500)	(.919)	(.577)	(1.272)	+.42	+.37

UC=Usual Care; I=Intervention

Providers were also provided the opportunity to make qualitative comments regarding their communications with the consultant pharmacists at pre- and post-intervention times, with specific questions, "What do you like LEAST about your communications with the pharmacist?" and "What do you like MOST about your communications with the pharmacist?" Table 4.7 provides a sample of the comments made both before and after the intervention by the providers.

Table 4.7: Providers' Qualitative Comments Regarding Communication with the Consultant

 Pharmacist

What do you like LEAST about your communications with the pharmacist?				
Pre-Intervention	Post-Intervention			
Nonexistent	Sometimes there is a long wait time			
	when calling.			
I don't see her more than once, maybe	In general, I am pleased with the			
twice a month.	communication on a pharmacist-physician level.			
I wish that the communication was	Paperwork faxed to my outside office			
more often two-way via email, not				
notes. I do not know what happens to				
the notes after I answer/sign.				
Need to first talk to nurses and	The blanket recommendations, some are			
patients before ok by doctor asked	warranted, but many do not take the			
	whole patient into consideration.			
Too much time needed	I'm afraid I'm bothering them if I email			
	too often or that I'm burdening one			
What do you like MOST about your communications with the pharmacist?				
Pre-Intervention	Post-Intervention			
Easy	Helpful, knowledgeable			
Nonexistent	Readily available, always helpful			

What do you like MOST about your communications with the pharmacist?			
Pre-Intervention	Post-Intervention		
I know that I will see her at monthly antipsychotic meetings. Other times that she is there, she is always open for questions.	The willingness to find the information I am looking for and/or help me troubleshoot meds & issues		
Drug interactions	Always available by phone to answer a question		
Some useful recommendations	I think it is helpful when the pharmacist suggests to draw a lab, such as A1C, LFTs, or BMP, to monitor medication safety. In one notable situation, the pharmacist was instrumental in flagging medication reconciliation issues between home, prior hospitalization, and nursing home even before I saw the patient.		

Discussion

Data from the Office of Inspector General report evaluating ADEs in NHs demonstrate that 66% of ADEs are preventable, meaning harm could be avoided through improved assessments or alternative actions. Reasons for preventable events included appropriate treatment provided in a substandard way (i.e., prescribing errors), patient progress inadequately monitored, necessary treatment not provided (i.e., prescribing errors of omission), error related to medical judgment, or the patient's health status was not adequately addressed. The *National Action Plan for Adverse Drug Event Prevention* identified priority drug class targets based on frequent occurrence of ADEs, clinical significance, and preventability. *Overall*, recommendations from the *National Action Plan* include a focus on ADE prevention in high-risk patient populations, namely the elderly, and in high-risk settings where ADE prevention is lacking, such as NHs. This project addressed ADE prevention of these high-risk drugs in this high-risk population.

Consultant pharmacist services have been required in NHs since 1974. CMS outlines the expectations of the NH consultant pharmacist in the State Operations Manual (SOM), Tags F329, F332, F333, F425, F428, and F429. The SOM states that 1) the drug regimen of each resident must be reviewed at least monthly by a consultant pharmacist; 2) the pharmacist reports any irregularities, including the presence of ADEs to the attending physician; and 3) attending physicians act upon the pharmacists' reports within 30 days. Retrospective MRRs can lead to the attending physician not receiving timely notification (i.e., as much as a 30-day lag in receiving and responding) about potential ADEs. Regulations also indicate that more frequent MRRs are needed depending on the resident's condition and risk for ADEs; however, execution of this regulation varies, because there are a finite amount of pharmacist resources. Evaluating prescribing during transitions of care, when residents are at a known risk for ADEs, and correcting the prescribing/monitoring of high-risk drugs should prevent ADEs. This project addressed a faulty retrospective 30-day MRR process and provided a model for more frequent MRR when residents were prescribed a high-risk drug during their stay to prevent ADE occurrence using a patient-centered telemedicine technology. The telemedicine model we applied transforms the current MRR process and allows for timely access to consultant pharmacists. This permits more frequent interactions with the resident pharmacist in a resource-efficient manner. Reports of telemedicine services provided by pharmacists have not

been conducted in the NH until this evaluation. Telemedicine services provided by a pharmacist to improve prescribing offer patient safety and financial benefits but are limited to settings other than the NH.

Conclusions

This is the first evaluation of the impact of pharmacist-led, patient-centered telemedicine services in the nursing to manage high-risk medications during care transition and throughout the resident's NH stay. The telemedicine model we applied transformed the current consultant pharmacist process and reduced the incidence of ADEs compared with usual care. Pharmacist-led telemedicine resulted in the identification of ADEs that may otherwise have been overlooked. Nursing home resident exposure to pharmacist-led telemedicine resulted in more residents willing to have future resident-pharmacist communication using telemedicine, as opposed to the typically preferred method of in-person communication in the usual care group. Changing the process of care provided by consultant pharmacists to include telemedicine and clinical decision support improves medication safety.

Significance

Pharmacist-led, patient-centered telemedicine during care transition and throughout the resident's NH stay resulted in a significant reduction in ADEs for nursing home residents receiving high-risk medications. Also, pharmacists' reviews of residents' medications on admission significantly reduced subsequent post-admission clinical decision support alerts, endorsing the value of a medication reconciliation and MRR on admission as an approach to potentially prevent ADEs.

At least 9.5% of the recommendations by the pharmacist would not have been identified without resident-pharmacist communication. This finding highlights that patient-centered communication with residents using telemedicine offers a method of identifying ADEs that may otherwise have been missed with medication regimen review.

Resident apprehension toward telemedicine may have occurred in the usual care group, with a preference for in-person communication between residents and pharmacists; this appears to be overcome by exposure to telemedicine, with significantly more residents receptive to telemedicine communication in the intervention group. Additionally, residents were highly satisfied with the resident-pharmacist communication.

Implications

These data question the current model of practice for consultant pharmacists and provide evidence to support the use of telemedicine for patient-centered communication when performing medication reconciliation and regimen reviews at care transition on admission to the nursing home and during the resident's stay for those residents receiving high-risk medications. The product of this research is a generalizable, EHR-agnostic medication management model that includes decision support rules and structured communication tools to optimally execute the consultant pharmacist's role in ADE prevention in the NH.

List of Publications and Products

Publications

- Kane-Gill SL, Niznik J, Kellum JA, Culley CM, Boyce RD, Marcum Z, He H, Perera S, Handler SM. Use of telemedicine to enhance pharmacist services in the nursing home. *Consult Pharm* 2017;32(2):93-98. PMID: 28569660
- Kane-Gill SL, Wong A, Culley CM, Perera S, Reynolds MD, Handler SM, Kellum JA, Aspinall M, Pellett M, Long K, Nace D, Boyce RD. Transforming the medication regimen review process of high-risk drugs using a patient-centered telemedicine-based approach to prevent adverse drug events in the nursing home. (in preparation)
- 3. Wong A, Reynolds MD, Aspinall M, Pellett M, Akerberg H, Perera S, Boyce RD, Culley CM, Handler SM, Kellum JA, Kane-Gill SL. Resident and provider perceptions of using telemedicine for pharmacist communication in the nursing home. (in preparation)

Poster Presentations

- Akerberg HA, Wong A, Reynolds MD, Aspinall M, Pellett M, Boyce RD, Culley CM, Dziuba G, Handler SM, Kellum JA, Perrera S, Kane-Gill SL. Resident perceptions of using telemedicine for resident-pharmacist communications in the nursing home. Presented at the ACCP 2018 Annual Meeting, Seattle, WA.
- Reynolds M, Kane-Gill SL, Culley CM, Boyce RD, Perera S, Wong A, Aspinall M. Transforming the Medication Regimen Review Process of High-Risk Drugs Using a Patient-Centered Telemedicine-Based Approach to Prevent Adverse Drug Events in the Nursing Home. Society for Prevention Research 27th Annual Meeting, San Francisco, CA.

Oral Presentations

- March 2019. Impact of Pharmacy Services using Telemedicine and Clinical Decision Support in Nursing Home. Research Colloquium, Department of Biomedical Informatics, School of Medicine, University of Pittsburgh, Pittsburgh, PA. (Kane-Gill)
- February 2019. Impact of Pharmacy Services using Telemedicine and Clinical Decision Support in Nursing Homes, Geriatric Conference, Division of Geriatrics, School of Medicine, University of Pittsburgh, Pittsburgh, PA. (Kane-Gill)
- 3. November 2018. Expanding pharmacist services using telemedicine; Telehealth panel, American Society of Consultant Pharmacists Annual Meeting, Washington, DC. (Kane-Gill)
- 4. October 2018. Population Health and Telemedicine Approaches to Commonly Encountered Conditions: Telemedicine Approaches in the Ambulatory Care Setting ACCP Annual Meeting, Seattle, WA. (Kane-Gill)
- October 2017. American Society of Consultant Pharmacists Annual Meeting, Kissimmee, Florida. Get tech-savvy with <u>Dr. Steven M. Handler</u> at the 2017 Peter P. Lam Memorial Lecture. Dr. Handler chatted with Dr. Nicole Brandt, executive director of the Peter Lamy Center on Drug Therapy and Aging, about a new model of care focused on the use of telemedicine, and the importance of translating research into practice. <u>http://annual.ascp.com/2017/</u>