Improving Medication Management Practices and Care Transitions through Technology

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1. Structured Abstract

Purpose: To conduct a randomized trial to examine the effectiveness of a multifaceted information technology (IT) intervention to improve management for patients at risk due to the complexity of their medication regimen.

Scope: We conducted the study at a large, urban, nonprofit home healthcare organization – with final intent-to-treat samples of 500 home health nurses and 7,919 home health patients identified as having complex medication regimens on admission.

Methods: Nurses were randomized to usual care or intervention upon identification of an eligible patient. The intervention combined clinical information systems, clinician alerts, and a clinical decision support (CDS) tool – complemented by patient education materials in English and Spanish. Primary analyses were completed on three samples: full intent-to-treat; a survey subsample; and the intervention group, in which we examined the effect of nurses' CDS use versus nonuse on patient outcomes. Data sources included patient health records, interviews, and administrative data. The magnitude of intervention effects was estimated by comparing regression-adjusted outcomes for the respective groups.

Results: The full intent-to-treat and survey sample analyses did not show a positive intervention impact. However, nurses' use of CDS (compared with nonuse) within the intervention group was associated with more patients moving below the medication complexity risk threshold and lower patient hospitalization rates. CDS use was affected by both nurse and patient characteristics. Outcomes could be improved by increasing knowledge, comfort, and motivation to use IT of nurses paid on a per-visit basis, thus improving continuity of care and avoiding short lengths of stay.

Key Words: medication complexity, MRCI, clinical decision support, home care

2. Purpose (Objectives of Study).

Home health organizations provide post-acute care to a predominantly Medicare population characterized by multiple chronic conditions. The number of drugs and complexity of medication regimens found among home health patients pose significant management problems for both nurses and patients. Proven information and communication strategies to improve medication management in the home health setting are needed but have been lacking. Our study sought to contribute to a much-needed knowledge base by testing a multifaceted, IT-based intervention designed to better support nurses as well as patients. The tested intervention included an automated algorithm to identify patients with complex medication regimens; an automated clinical alert notifying the home health nurse of the patient's high-risk status; an electronic decision support tool for the home care nurse, including high-risk medication management recommendations that were integrated into the clinician's visit documentation system and electronic patient health record; and patient educational material. The three specific aims of the study were:

- 1. To examine the relative effects of the intervention on workflow and medication management practices of home healthcare nurses.
- 2. To examine the relative effects of the intervention on the outcomes and service use of patients in the intervention group compared with usual care.
- 3. To estimate the costs associated with the interventions and subsequent care and to compare these costs relative to usual care.

3. Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

Background

Older adults referred for home health services are frequently characterized by multiple chronic conditions, multiple medications, and some degree of functional impairment.¹ As a result, they and their caregivers grapple with complicated medication management issues every day.

Medications are the most common healthcare intervention, and virtually all studies of patient safety have identified poor medication management as one of the greatest contributors to adverse patient events.²⁻⁴

Missing doses, not taking medications at the correct time, or not following the correct administration instructions can result in the patient receiving suboptimal clinical outcomes. Lack of adherence to medication has been estimated to cause at least 10% of hospital admissions in the United States.⁵ The World Health Organization suggests that improving adherence would result in more health benefits than would developing new medical treatments.⁶

Multiple studies have identified a link between management complexity of a medication regimen and nonadherence.⁷⁻⁹ Higher number of medications and complicated schedules or special instructions (e.g., time of day, food interactions) can all contribute to greater patient difficulty in following treatment recommendations. Complexity is one of the main root causes of patients' nonadherence. Simplification of complexity and/or greater attention to managing complexity are potentially remedial factors for poor adherence.

In 2004, Johnson George and colleagues developed the Medication Regimen Complexity Index (MRCI), a tool for quantifying multiple features of drug regimen complexity.¹⁰ The MRCI was built on the concepts and factors developed for the Medication Complexity Index¹¹ by assigning weights to dosage forms, dosing frequencies, and additional instructions. The aim was to create a reliable tool to quantify regimen management complexity using information found in patient charts and prescriptions for research and practice applications.¹⁰ For this study, we automated the MRCI in order to identify potential at-risk home care patients upon admission.

Home health organizations and home health nurses are well positioned to provide a bridge for chronically ill patients who may be buffeted from institution to community, hospital to physician, and back with little information or preparation to navigate confusing and sometimes dangerous transitions. However, the number of drugs and the complexity of medication regimens found among home health patients pose significant management problems for nurses, patients, and informal caregivers. A significant number of home health organizations have begun to adopt "point-of-service" computing. Yet, proven, cost-effective IT and other support strategies to improve care planning and medication management have not been systematically adapted to or adopted in the home health setting. Our intervention sought to provide intervention nurses with support in their medication management assessment, teaching, and intervention. The intervention components we designed were in line with the features Kawamoto and colleagues¹² found to be significant and independent predictors of improve clinical practice after reviewing 70 studies; these include IT support tools that are 1) computer generated, 2) provided as part of clinician workflow, 3) offering recommendations rather than just assessments, and 4) delivered at the time and location of decision making.

We hypothesized that patients who had nurses randomized to the intervention group would have a reduced medication regimen complexity risk, would demonstrate a greater increase in self-management knowledge and skills, and would be less likely to have an emergency department visit or hospitalization 60 days post home care admission compared with patients who had nurses randomized to a usual care group.

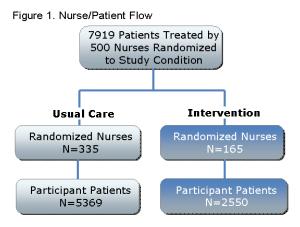
Context/Setting

The home healthcare industry is composed of over 10,000 Medicare-certified home health agencies (HHAs) providing post-acute and long-term care services to a heterogeneous population. Home health patients, disproportionately female and elderly, are clinically diverse.¹³ Home health patients are an especially vulnerable population by virtue of their advanced age, multiple comorbid conditions, and functional dependencies. In 1980, there were 2.9 million users of Medicare-certified home health agencies; by 2006, users exceeded 8 million.¹⁴ Skilled

nursing services are the core service provided by HHAs, which provided over 121 million home health visits to Medicare beneficiaries in 2008.¹³

The study described here was conducted at the Visiting Nurse Service of New York (VNSNY) – a large, urban, nonprofit home healthcare organization that employs over 6,000 staff, including 2,600 RNs, who serve an average daily census of over 30,000 patients living in the New York City region. In 2010, the agency provided 2.4 million professional visits – including nursing, rehabilitation, and social work services – to over 140,000 patients. Its professional workforce, like that employed by most HHAs, is mainly generalist, is widely dispersed, and receives infrequent in-person or onsite clinical supervision.

Participants



The study population consisted of 500 home healthcare nurses employed by the VNSNY and 7,919 newly admitted adult post-acute care (non-hospice) study-eligible patients served by those nurses – see Figure 1. Patients needed to be 18 years of age or older, reside in the study catchment area, and have high medication regimen complexity (as measured by the Medication Regimen Complexity Index [MRCI] score of \geq 24.5). Patients were excluded if their clinical record indicated a diagnosis of Alzheimer's, dementia, or other organic brain disorder. Secondary data on this full intent-to-

treat sample were collected and analyzed. In addition, data on a stratified subsample of patients (N=826) who completed in-person interviews were collected and analyzed. Patients who were recruited for the in-person interviews were English or Spanish speaking; did not have a diagnosis of Alzheimer's, dementia or other organic brain disorder; and passed a brief cognitive assessment.

Incidence/Prevalence

In preparation for this study, we analyzed medication data on a sample of new admissions to the agency adult post-acute care program in 2008 who were taking at least one medication. The sample consisted on 89,694 admissions. MRCI scores were tabulated, and the sample was segmented into deciles. We linked this data with emergency department (ED) use and hospitalization data to determine the threshold of medication complexity that determined a patient's higher risk for these outcomes. We found that patients with MRCI scores in the top 2 deciles (20% of the patients; n=17,806) were at significantly higher risk for ED use and hospitalization than were those with lower MRCI scores.

4. **Methods** (Study Design, Data Sources/Collection, Interventions, Measures, Limitations). **Study Design**

The study employed a cluster, randomized design to assess the effectiveness of an organizational intervention compared with usual care. VNSNY nurses were randomly assigned to either the control (usual care) or the intervention group upon identification of an eligible patient. Randomization allocation was in a 1-to-2 sequence: for every one nurse randomized to the intervention group, two nurses were randomized to usual care. Randomization occurred at the patient's formal transition to home healthcare, when the plan of care was transmitted to the agency mainframe. At that point, the computerized MRCI algorithm identified eligible patients

and their assigned nurses. A nurse's initial random assignment determined the status for all eligible patients allocated to that particular nurse's care for the duration of the study.

Description of Usual Care

All professional field staff in the VNSNY post-acute division are equipped with pen-based Lenovo convertible personal computers (the "tablet") with a mobile point-of-care platform that runs a secure electronic health record called the Patient Care Record System (PCRS). Information on new referrals and continuing patients is regularly updated and uploaded onto the tablet from the VNSNY mainframe. The database folder in which the application resides is encrypted. The PCRS application is a store-and-forward design, enabling the clinician to document in the patient's home or offline, communicating her documentation work when and where he or she chooses.

Multiple modules within the PCRS inform the work of the nurse in the field. The critical modules are 1) the Plan of Care. 2) the Visit Module. and 3) the Medications Module. The Plan of Care (which constitutes the federally required CMS Form 485) contains the physician's orders and informs the other modules of the time point at which treatment should be delivered. The Visit Module is where the nurse records the day-to-day work of patient encounters. It is composed of two sections: (i) the Clinical Assessment, which includes the Outcomes Assessment Information Set (OASIS) for the appropriate time point, and (ii) a set of Patient Care Plan Problems, in which care goals, interventions, and progress are recorded for each visit. At the start of care, the PCRS "pushes" a list of the patient's Care Plan Problems to the nurse. The nurse then uses her clinical judgment to decide what issues to communicate to the patient's physician, which problems to "pull down" from the PCRS, and in what order. The problem list is driven by MD orders in the Plan of Care, by patient diagnoses and medications, and by selected assessment items. The Medications Module consists of (i) an electronic medications database provided by a commercial source (First DataBank) widely used in hospitals and pharmacies; (ii) drug utilization review (DUR) algorithms (also provided and updated by First DataBank) that identify all potential drug-to-drug interactions and duplicative medications; and (iii) an alert system that flags three levels of DDI severity (Level 1=critical, Level 2=severe, Level 3=moderate), as well as instances of duplicative therapy. Before and/or during each patient visit, the nurse reviews the patient's Plan of Care, reviews and updates the patient's current medications, and enters the Visit Module to document progress on the patient Care Plan Problems selected to be worked on.

The Intervention

The intervention consisted of three computer-automated components: (i) a computerized risk algorithm to identify patients with high medication complexity and thus the potential for a serious medication problem; (ii) a clinical alert – an email delivered to the tablet of the home health nurse that identifies a specific at-risk patient and directs the clinician to the appropriate place in the Visit Module of the tablet-based PCRS; (iii) a "high-complexity-risk" medication Patient Care Plan Problem integrated into the Visit Module of the tablet-based PCRS with specific recommendations for nursing goals and interventions appropriate to the high-risk patient with multiple comorbidities and a complex medication regimen, as well as embedded documentation requirements. Additionally, the intervention was augmented with patient/family caregiver educational material.

<u>Computerized Risk Algorithm.</u> The study team worked with the agency Information Systems department to automate the MRCI. The index takes into account and provides different weights to the dosing frequency, the number of different administration routes (e.g., oral, inhalant, injection), and the number of different special instructions a patient may need to remember (e.g., take with meals, take on alternative days, dissolve). The MRCI allows for a more nuanced indicator of complexity above a simple medication count. This index was integrated into the

VNSNY IT system using medication data that are electronically collected as part of usual care when patients are first admitted. This allowed for the almost instantaneous computation of a medication regimen complexity index (MRCI) score for each patient after admission to care. <u>Clinical Alert.</u> Once a patient was identified through the computerized risk algorithm, nurses in the intervention group received an email alert on their tablet identifying one of their particular patients as someone at risk of a potential medication problem. The initial alert was sent in the patient's first week of care. A follow-up alert was sent 4 days later. The content of the initial email is below:

This email is part of a VNSNY initiative to provide you and your patient with additional support for complex care management.

Your patient, *Jane Doe (case #: xxxxxx)*, has a **complex medication regimen.** In addition to many medications, complexity may come from:

- High number of doses per day
- High number of routes for medication administration
 AND/OR
- Special instructions the patient needs to remember (e.g., take with meals, cut in half, take every other day)

[Only showed up if this is applicable:] Your patient also takes the following high risk medication(s): anti-diabetic medication anti-coagulant medication anti-seizure medication digitalis preparation

A new Complex Medication Management Problem module is now available on your tablet to help guide assessment and interventions in this area. Please review this module for support on strategies to improve your patient's adherence and self-management practices while potentially lowering their risk for adverse events. Educational material to share with your patient is also being sent to you via interoffice mail. Feel free to email the MedicationManagementImprovementGroup@vnsny.org if you have any questions. Thank you for your participation in this important initiative.

<u>Clinical Decision Support (CDS) Tool – Complex Medication Management Care Plan.</u> A committee was established to help develop the complex medication management module. The committee consisted of study team collaborators, representatives from the agency's quality management division, and staff from the agency's Information Technology department group. This was a multidisciplinary committee with representation from nursing, pharmacy, social work, research, and technology. The module was set up like the other care management problems in the PCRS, using the sections of (i) assessment, (ii) provision, (iii) teaching, (iv) management, (v) support, and (vi) evaluation. The recommended nurse actions focused on comprehensive medication adherence and barrier assessment, medication reconciliation, regimen simplification, and self-management guidance.

<u>Patient/Family Caregiver Educational Material.</u> A hardcopy paper workbook for a specific patient was sent to the field nurse. The nurse was asked to bring the material to the next visit and review. Workbook topics included the importance of maintaining an accurate medication list and tips on how to do so; use of organizational aides or social support; tips on how to communicate

with health provider to address concerns. The workbook was prepared at the 5th-grade reading level in English and in Spanish.

Data Sources/Collection

We made use of data from five main sources: 1) the Outcomes Assessment and Information Set (OASIS) (electronic); 2) the medications database (electronic); 3) the patient care record system (information on per visit encounters)(electronic); 4) a patient survey conducted at a fixed point (60 days) after assignment to the study (paper survey entered into database tables); and 5) administrative and service use data routinely collected by the agency's billing and human resources departments (electronic). Data from these different sources, which are stored on separate database tables, were retrieved and merged to establish the analytic file.

Data on Nurse Characteristics and Care Management Practices

Data from the VNSNY human resources (HR) database were obtained on the gender, age, level of education (e.g., licensed, bachelor's, or master's level RN), job tenure, and employment status (salary versus per diem) of the nurses in the respective study groups. These HR data were used to construct control and predictor variables for the nurse and patient analyses. Service use data were used to construct patient caseload variables for each nurse each time s/he had an eligible patient. The caseload measures were also used as control and predictor variables. Intervention nurse use of the CDS tool - the Complex Medication Regimen Care Module - was collected from the PCRS database. These data are captured at the patientspecific encounter level, making it possible to construct and aggregate measures per visit, per home health episode, per patient, and per nurse.

Data on Patient Characteristics and Patient Outcomes

The CMS-mandated OASIS instrument was the source of data on patients' clinical and functional statuses as well as on patient demographics, living arrangements, and informal supports. The specific items included comorbidities and symptom severity, risk factors, prognosis, therapies, pain status, wounds, neurological/cognitive/behavioral statuses, activities of daily living (ADLs), and instrumental activities of daily living (IADLs). These data, collected at start of care as part of usual care, were used in developing risk adjustment models to adjust for any potential differences in patient severity between the study's intervention and control groups. Follow-up OASIS assessment data were used to identify patients' hospitalization and emergency department use for the full intent-to-treat sample. Start-of-care medication data collected in the PCRS were used to initially identify patients with complex medication regimens eligible for the study. A second abstraction at patient discharge or 60 days (whichever was earlier) was used to assess changes in the MRCI score. Additional process of care, medication adherence, and outcome data were collected by "study group-blinded" interviewers from 826 patients who completed an in-person interview conducted approximately 60 days after home care admission.

Measures

For Intent-to-Treat Sample

Medication Regimen Complexity Index (MRCI)

An MRCI score of 24.5 or above was used to identify the target population. The cutoff score was established through simulation of 2008 data that indicated that this number determined those in the two highest deciles of complexity severity and that these two deciles were related to the highest emergency room and hospitalization use after home care admission. MRCI scores were re-tabulated for study participants with data from their EHR 60 days after admission or at discharge, whichever was earlier. We examined the percent of patients who moved under the 24.5 MRCI risk threshold at the follow-up assessment point.

Hospitalizations and Emergency Department Visits

The measures were derived from the evaluation of the OASIS assessments after admission. We used an approach similar to that used for the CMS Outcome-Based Quality Improvement (OBQI) reports.¹⁵ For patients in each randomized group, we collected hospitalization and ED visit data from follow-up assessment up to discharge or 60 days after admission, whichever was earlier.

Analysis of primary outcomes

We determined nurse and patient characteristics that differed between the two study groups using a chi-square test for categorical variables and t tests for continuous variables. Characteristics that were significantly different at a 0.2 level were included in multivariate models. We modeled the effect of the study intervention on the three patient outcomes using three separate Generalized Estimating Equations (GEE) models to adjust for clustering at the nurse level and adjusting for nurse and patient characteristics that differed significantly across study groups.

For Patient Survey Sample

As mentioned above, a subsample of patients was interviewed 60 days after home care admission so that we could collect and analyze a broader array of measures. To the maximum extent possible, the survey instrument relied on readily available, validated measures. These measures included:

- Items on home care nurse teaching of medication management (investigator-generated measure)
- Patient report of understanding purpose of medications and knowledge of administration (selected items from the Care Transitions Measure¹⁶)
- Morisky medication adherence scale¹⁷
- Medication adherence self-efficacy scale (MASES)¹⁸
- Patient report on discussions with doctor about simplifying complex regimen (investigatorgenerated measure)

For Intervention Group–Only Samples

Intervention group nurses along with the patients they served were divided into CDS-use versus no-CDS-use groups. Nurses were classified as CDS users if they documented in the teaching or management section of the Complex Medication Management Care Plan module (the CDS tool) at least one use for one of their patients. Data were tabulated on how many nurses used the tool at least once and on the percentage of patients whose record indicated that their nurse used the tool for their care management. Various nurse and patient characteristics were assessed to evaluate their association with or prediction of CDS use.

Because the nurses in the intervention group could choose whether to use the CDS or not (they were not randomly assigned to use or nonuse), we used propensity scores, defined as the conditional probabilities of using CDS given patients' and nurses' characteristics, to balance these characteristics in the use/nonuse groups and reduce potential bias through regression adjustment. We later used the propensity scores as covariates when estimating the effect of CDS on the OBQI hospitalization and emergency department visit measures.

Limitations

Several limitations should be considered when considering the implementation and methods of this intervention. First, the decision support module created for this initiative was integrated into the patient care record system that the nurses use as part of usual practice. Depending on the number and type of a patient's comorbidities, a number of other care modules are presented to the nurse for each patient, addressing a variety of clinical concerns. The nurse uses his or her clinical judgment to decide which care module(s) to use to guide her practices and to document her interventions during the course of the home care episode. Although nurses received an

email alert about their patient's medication complexity, use of our newly introduced complex medication management module was not mandatory, and other more urgent clinical situations (e.g., a worsened pressure ulcer) with their associated modules may well have taken precedence.

Second, the study was conducted in the real-world setting of an active home care agency – where patient service delivery needs and operational constraints, of necessity, may have impeded the "purity" of our intervention and affected nurses' exposure to the intervention or their opportunity to pursue a sustained effort to address medication complexity. For example, our study protocol identified the nurse who was assigned as the coordinator of care (COC) for the newly admitted patient and proceeded to transmit the electronic components of the intervention (intent-to-treat approach). Sometimes, however, the COC was changed during the course of care (e.g., in case of the clinician's illness or leave of absence) and, in many patient care episodes, more than one nurse provided visits to the patient. Subsequent analysis found that, in our sample, the COC was changed during the course of the care episode in 19% of the cases; 7% of these changes were to a COC that was in a different randomized group than the original index COC. Thus, clearly there was some 'contamination' of the intervention that was not reflected in our intent-to-treat analysis. The length of stay was also variable among the study population. About 23% of patients were discharged within 14 days of admission, which did not give the nurse much of an opportunity to conduct many interventions.

5. **Results** (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications).

Below, we present and discuss our primary analyses on three groups: 1) full intent-to-treat sample; 2) survey sample; and 3) intervention group only.

Principal Findings and Outcomes Full Intent-to-Treat Sample

In total, 500 nurses who served 7,919 eligible patients were randomized in this study. Nurse Study Population

For every two usual care nurses, one nurse was assigned to the intervention group. The characteristics of the nurses assigned to the usual care and intervention groups are reported in Table 1. The usual care group had a higher percentage of female nurses than the intervention group did. Nurses randomized to the usual care group were slightly older than those randomized to the intervention group and were employed by the study agency longer, but the differences were not statistically different.

Table 1. Basic Characteristics of the Full Intent-to-Treat Nurse Population (N=500)				
	Usual Care	Intervention		
	(n=335)	(n=165)	P value	
Female (%)	90%	83%	0.04	
Mean age in years (SD)	46.3 (10.6)	44.7 (9.8)	0.10	
Race/ethnicity (%)			0.17	
Black, non-Hispanic	41%	33%		
Hispanic	9%	14%		
White, non-Hispanic	29%	33%		
Other or unknown	20%	20%		
Per Diem – paid per patient visit (%)	35%	40%	0.27	
Mean years of employment (SD)	10.8 (7.8)	9.6 (7.5)	0.10	
Educational level (%)			0.60	
Diploma	10%	8%		
Associate	26%	32%		
Bachelor	55%	51%		
Advanced degree	6%	5%		
Missing	3%	4%		
Number of eligible patients (%)			0.53	
Only one	5%	2%		
Only two	1%	2%		
Only three	3%	4%		
Four or more	91%	92%		

Patient Population

Selected sociodemographic and baseline health characteristics of the 7,919 patients who were included in the intent-to-treat analysis are reported in Table 2. The majority of the targeted patients were female and 65 years of age or older. These patients had on average three chronic conditions with an average of three deficits in being able to independently perform activities of daily living (ADLs) or instrumental activities of daily living (IADLs). A large number of these patients (45%) lived alone. The usual care arm had slightly younger patients and had a higher proportion of Black, non-Hispanic patients and patients with Medicaid coverage compared with the intervention arm. The baseline health status also appeared to be poorer for the usual care patients. All these characteristics were controlled for in the multivariate analysis presented below.

Table 2. Key Sociodemographic and Baseline Health Characteristics of Full Intent-to-Treat	t
Patient Sample	

	Usual Care Intervention		
	(n=5,369)	(n=2,550)	P value
Sociodemographic Characteristics			
Female (%)	61%	61%	0.92
Age			
Mean age in years (SD)	67.1 (14.4)	68.4 (14.1)	<0.001
65+(%)	59%	63%	<0.001
Race/ethnicity (%)			<0.001
Black, non-Hispanic	31%	24%	
Hispanic	30%	30%	
White, non-Hispanic	33%	40%	
Other or unknown	6%	6%	
Medicaid enrollee (%)	36%	33%	0.001
Lives alone (%)	44%	46%	0.14
Baseline Health Status			
Chronic condition comorbidity score, mean (SD) ^a	2.8 (1.2)	2.7 (1.2)	0.01
ADL/IADL score, mean (SD) ^a	3.0 (1.9)	3.1 (1.9)	0.03
Baseline Medication Profile			
No. of medications, mean (SD)	12.8 (3.2)	12.9 (3.2)	0.59
^a Scores and ratings were based on a standardized start of	of care assessme	ent data com	oleted
by a home care pured blinded to study group. Higher vel	una indianta araa	tor dischility	The

^aScores and ratings were based on a standardized start of care assessment data completed by a home care nurse blinded to study group. Higher values indicate greater disability. The Chronic Condition Score was based on the tabulation of up to 18 conditions.

Patient Outcomes

The change in the MRCI risk threshold from baseline (patient's admission to home care) to discharge or 60 days, whichever was earlier, was evaluated. Just over 6% of the patients from each randomized groups went below the MRCI risk threshold; almost 17% had an ED visit, and around one out of five patients had a hospitalization (see Figure 2). No statistically significant differences were found between the randomized groups for any of the three outcomes.

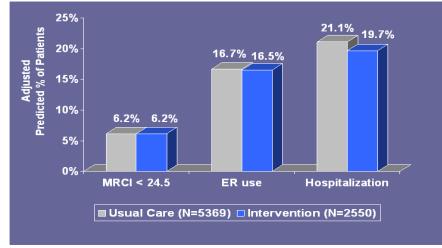


Figure 2. Patient Outcomes by Study Group - Full Intent-to-Treat sample

Cost-Effectiveness Analysis

CEA analysis was not pursued, because the intent-to-treat analysis did not show a clinical benefit of the intervention.

Survey Sample

Characteristics of Patients Completing In-Person Interview

The survey subsample was similar to the full-intent-to-treat sample in age, number of chronic conditions, and activity of daily living limitations but had a higher proportion of Hispanic participants and a larger proportion who lived alone. Within the survey population, the usual care group had a higher proportion of patients without a high school education compared with the usual care group (44% vs. 35%, P<0.05) and a higher proportion of Medicaid recipients (43% vs. 35%, P<0.05) but a lower proportion of patients with a household income of less than \$10,000 (68% vs. 77%, P<0.001). The survey participant groups were similar in gender, age, race, and health status.

Patient Survey Sample Findings

Supplemental information collected from a subsample of patients is reported in Table 3. There were no statistically significant differences between usual care and intervention group patient reports on nurse teaching or on patient knowledge and understanding of their medication regimen, adherence, actions for simplification, or regimen burden. Comparative analysis on the main outcomes of ED visits, hospitalization, and complexity threshold was completed. There were not statistical differences between the randomized groups.

Table 3. Unadjusted Patient Survey Process of Care, Knowledge, and Burden Results(N=826)

(N=020)			
	<u>Usual Care</u> (n=403)	Intervention (n=423)	P value
Patient report on nurse teaching (%)	, , ,	, , ,	
Nurse talked with patient about ways to manage			
his/her medications	78%	78%	0.96
Nurse provided patient with educational			
materials to help him/her manage their			
medications	42%	42%	0.97
Nurse helped patient set specific goals to	200/	200/	0.40
improve adherence to the medication regimen	60%	62%	0.40
Nurse helped patient to make a plan that would	E00/	E20/	0.65
help him/her manage their medications Patient understanding of medications (%)	52%	53%	0.65
Patient strongly agrees that they clearly			
understand the purpose for each medication			
they take	47%	44%	0.32
Patient strongly agrees that s/he clearly	-170		0.02
understands how to take each medication,			
including how much should be taken and when	49%	46%	0.28
Patient report on adherence to medication			
regimen (%)			
Patient never/rarely had any difficulty			
remembering to take all of his/her medications	41%	39%	0.53
Patient took medication exactly as prescribed			
100% of the time in the 7 days before the			
interview	49%	53%	0.34
Adherence Self-Efficacy Scale (MASES), mean			
(SD) – higher scores=higher self-efficacy	32.0 (7.7)	32.4 (7.8)	0.55
Patient reports keeping medication list and			
on having a discussion with doctor about simplifying complex regimen (%)			
Patient has a list of the medication's s/he takes	71%	72%	0.61
Patient spoke with doctor about reducing the	7 1 70	12/0	0.01
number of medications the s/he needs to take	32%	33%	0.69
Patient spoke with doctor about reducing how	0270	0070	0.00
often s/he needs to take the medications	21%	22%	0.80
Patient report on medication management			
burden			
Patient sometimes feels hassled about sticking			
to treatment plan (%)	31%	28%	0.36
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Intervention Group Only

Use of the electronic decision support tool by intervention nurses

All intervention nurses were given access to an electronic decision support tool after a newly admitted home care patient with a complex medication regimen was identified on their caseload. The CDS tool allowed them to choose among multiple actions in the areas of education and management; see Table 4 for a distribution of nurses' actions. Most nurses had multiple targeted patients come on to their caseloads over the course of the study, but nurses did not document in the tool with every one of their eligible patients; nor did they document all actions for patients for whom they used the tool. Overall, 80% of the 165 intervention nurses documented an action within the tool with at least one of their targeted patients. However, only 42% of the 2,550 patients had an intervention nurse action documented in their record.

In only one of every three records did an intervention nurse document that s/he advised the patient to keep their medication list up to date, and in only one of three records did s/he document that s/he had taught the patient to bring it with them for every medical appointment. In about 30% of patient records the nurse documented that s/he taught the patient the importance of medication adherence, developing a system or plan to obtain refills on time, removing/discarding old and/or expired medications, and contacting the physician with any immediate concerns about medications or side effects. Only 10% of the patients' records indicated that the nurse advised the patient to discuss medication simplification with their physician, and less than 2% indicated that the nurse contacted the physician directly to discuss medication simplification.

Table 4. Intervention Nurse Use of Electronic Clinica	I Decision Support Too	ol		
	% of nurses who			
	documented	% of patient		
	teaching at least	records in the		
	one of their patients	intervention		
	in target population	group		
	(N=165)	(N=2,550)		
Patient Instructions				
Indicator that nurse taught at least one thing from				
decision support tool	82%	44%		
Importance of adherence to the medication				
regimen	78%	33%		
To keep the medication list up to date	79%	39%		
To bring the medication list to each physician visit	81%	39%		
To develop system or plan to obtain medication				
refills on time	69%	31%		
To remove/discard old and/or expired medications	75%	33%		
To contact physician with any immediate concerns				
about medications or side effects	74%	31%		
To work with pharmacist to synchronize refills	60%	22%		
To use one pharmacy if possible	72%	30%		
To discuss medication simplification with physician	48%	11%		
Strategies to help with medication adherence	64%	24%		
Management				
Contacted physician to discuss medication				
simplification	13%	2%		
Provided medication list	58%	15%		
Provided prepour box	50%	11%		

Comparison of nurses who used the CDS vs. non-CDS users

Table 5 shows the characteristics of nurses in the use and nonuse groups. Nurses who were older, those who had a greater number of years of employment, and those with a greater number of patients in the study were more likely to use the CDS tool. Nurses who get reimbursed on a per-visit basis (per diem) were less likely than staff (salaried) nurses to use the CDS tool.

Table 5. Basic Characteristics of Nurse Population (N=165)					
	No CDS	CDS Use			
	<u>use</u> (n=29)	(n=136)	P value		
Female (%)	76%	85%	0.26		
Mean age in years (SD)	41 (8)	45 (10)	0.03		
Race/ethnicity (%)			0.38		
Black, non-Hispanic	28%	34%			
Hispanic	21%	13%			
White, non-Hispanic	24%	34%			
Other or unknown	27%	19%			
Per Diem – paid per patient visit (%)	55%	37%	0.07		
Mean years of employment (SD)	8.0 (5)	9.9 (8)	0.08		
Educational level (%)			0.62		
Diploma	10%	7%			
Associate	38%	31%			
Bachelor	48%	51%			
Advanced degree	0%	7%			
Missing	4%	4%			
Borough (%)			0.55		
Bronx	17%	21%			
Brooklyn	10%	20%			
Manhattan	38%	32%			
Queens	35%	27%			
Mean number of patients in study (SD)	14 (8)	19 (9)	0.003		
Mean caseload (cases) (SD)	20 (7)	21 (8)	0.37		
Mean caseload (visits) (SD)	51 (25)	58 (27)	0.18		

<u>Patient-level predictors of CDS use</u> All variables included in the prediction models were significant at P<0.2 in bivariate models, in addition to sex, sum of chronic conditions, and sum of ADL/IADL, which were forced into the models (see Table 6).

Table 6. Patient-level predictors of CDS use, multivariate models. Measures for Patient Sample (N=2,550)				
		P value	OR**	P value
	(95% CI)	0.00	(95% CI)	0.00
Age	0.99 (0.98, 1.003)	0.20	1.00 (0.99, 1.004)	0.30
Female sex	1.06 (0.88, 1.28)	0.51	1.07 (0.91, 1.27)	0.40
Race (vs. White)				
Black, non-Hispanic	0.53 (0.40, 0.69)	<0.001	0.65 (0.49, 0.88)	0.01
Hispanic	1.00 (0.72, 1.39)	0.98	0.99 (0.70, 1.33)	0.84
Other	1.31 (0.85, 2.04)	0.21	1.24 (0.80, 1.91)	0.34
Payer (vs. Medicare only)				
Private	0.69 (0.50, 0.94)	0.01	0.68 (0.53, 0.87)	0.003
Dually Eligible	1.02 (0.76, 1.36)	0.91	1.00 (0.79, 1.29)	0.97
Medicaid only	0.66 (0.51, 0.87)	0.003	0.73 (0.57, 0.92)	0.01
Other	0.52 (0.28, 0.96)	0.04	0.65 (0.37, 1.14)	0.13
Language (vs. English- blank)				
Spanish	0.95 (0.69, 1.31)	0.76	0.88 (0.66, 1.18)	0.39
Other	1.25 (0.84, 1.87)	0.27	0.88 (0.61, 1.28)	0.51
Number of medications	1.02 (0.99, 1.05)	0.20	1.02 (1.00, 1.05)	0.06
Discharged from acute	· · · · · · · · · · · · · · · · · · ·			
hospital within 14 days of				
home care admission?	1.06 (0.87, 1.29)	0.54	1.11 (0.94, 1.31)	0.21
Discharged from inpatient	· · · · · · · · · · · · · · · · · · ·			
rehabilitation hospital or				
unit within 14 days of				
home care admission?	1.23 (0.92, 1.63)	0.16	1.24 (0.96, 1.60)	0.10
AIDS	0.76 (0.26, 2.20)	0.61	0.97 (0.43, 2.20)	0.95
Cancer	0.77 (0.55, 1.08)	0.13	0.78 (0.59, 1.01)	0.06
Hypertension	1.21 (0.96, 1.52)	0.11	1.22 (0.95, 1.56)	0.12
Cardiac condition	1.48 (1.10, 1.98)	0.01	1.43 (1.10, 1.86)	0.01
Stroke	1.53 (1.07, 2.19)	0.02	1.49 (1.08, 2.05)	0.01
History of falls (2 or more				
falls, or any fall with an				
injury, in the past year	1.11 (0.86, 1.44)	0.40	1.03 (0.81, 1.30)	0.83
The patient is stable with				
no heightened risk(s) for				
serious complications and				
death (beyond those				
typical of the patient's				
age).	0.89 (0.67, 1.20)	0.46	1.09 (0.83, 1.44)	0.55
The patient is temporarily		-		
facing high health risk(s)				
but is likely to return to				
being stable without				
heightened risk(s) for				
serious complications and				
death (beyond those				
typical of the patient's age)	1.04 (0.82, 1.32)	0.74	1.08 (0.89, 1.30)	0.44

OR patient's situation is unknown or unclear				
Cognitive function	1.06 (0.83, 1.34)	0.66	1.00 (0.84, 1.19)	0.99
Ever short of breath	1.23 (1.02, 1.47)	0.03	1.22 (1.04, 1.42)	0.01
Human assistance needed with oral medications	1.11 (0.90, 1.36)	0.32	0.96 (0.82, 1.13)	0.65
Number of RN visits	1.03 (1.01, 1.04)	<0.001	1.01 (1.003, 1.02)	0.01
Index COC changed	0.66 (0.53, 0.82)	<0.001	0.71 (0.56, 0.90)	0.004
Sum of chronic conditions	0.91 (0.83, 0.99)	0.03	0.92 (0.86, 0.98)	0.01
Sum of ADL/IADL	0.94 (0.89, 0.99)	0.04	0.97 (0.93. 1.02)	0.22
Length of stay	1.02 (1.01, 1.03)	<0.001	1.03 (1.02, 1.03)	<0.001
*Not adjusting for clustering				
**Adjusting for clustering at the COC level				

The CDS tool was more likely to be used on patients with a higher number of medications; those discharged from an inpatient rehabilitation hospital within 14 days of home care admission; those with a hypertension, cardiac condition or stroke diagnosis; and those with shortness of breath at admission. The CDS tool was also more likely to be used with patients who had a longer length of stay in home care and a higher number of nurse visits. The CDS tool was less likely to be used with African American patients, Medicaid beneficiaries or those with private insurance, patients who had a cancer diagnosis, or patients with a greater number of chronic conditions. The CDS was also less likely to be used when a patient's Coordinator of Care changed.

Patient Outcomes by CDS Group Use - Intervention Group Only

Figure 3 shows the adjusted predicted probabilities (%) from logistic regression models predicting our three main outcomes, adjusted by patient and nurses characteristics and propensity scores. Patients whose nurse used CDS for their cases had significantly lower hospitalization rates and better MRCI outcomes.

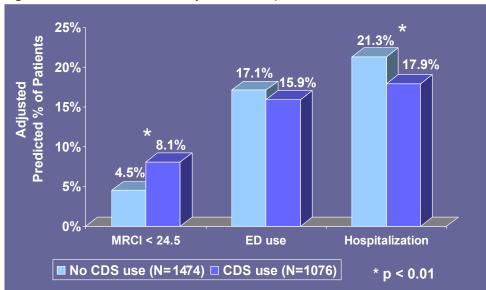


Figure 3. Patient Outcomes by CDS Group

Discussion

The purpose of this initiative was to implement a medication health IT intervention designed to provide patient level alerts and CDS to nurses and to evaluate its impact in a particularly vulnerable population – chronically ill older adults receiving health services at home. Our intervention pulled together strategies successfully used to address other clinical concerns and adapted them to address the medication complexity concern. We previously demonstrated improvement in home care nurse use of evidence-based practices to improve heart failure and pain management using the strategies of automated identification of high-risk patients and email clinical alerts. In addition to these two strategies, we provided an electronic decision support tool in a way that was based on proven evidence. The four features that Kawamoto and colleagues¹² found to be significant and independent predictors of improved clinical practice after reviewing 70 studies are 1) computer generation; 2) provided as part of clinician workflow; 3) offering recommendations rather than just assessments; and 4) delivered at the time and location of decision making. Our intervention fulfilled all four conditions.

For our assessment of the intervention's impact, we reviewed intervention nurse use of the provided tool as well as several patient-level outcomes – reduction in medication complexity and reduction in emergency department visits and hospitalizations. We also interviewed a subset of patients to evaluate the impact of the nurse interventions on increasing patient understanding and adherence to medication regimens and reducing burden. We were unable to demonstrate that our interventions impacted patient outcomes in our full intent-to-treat analysis.

The intervention processes of identifying high-risk patients and transmitting the clinical alert, along with opening access to the electronic decision support tool, were automated processes. They were tested thoroughly prior to the study and were monitored throughout, so we are confident that there was fidelity to these aspects of the planned intervention. Nurse use of the decision support tool once he or she received a patient alert was discretionary and was less than anticipated. In addition to the study limitations noted above (potential contamination between intervention and nonintervention nurses and lack of continuity of nursing care), there are several other potential reasons for this outcome. First, the clinical alerts and access to the electronic decision support tool were "turned on" without prior explicit orientation for the field nurses about the evidence linking medication complexity to poorer outcomes or about the

strategies recommended to address complex regimens. In a complex organizational and regulatory environment, the study organization has to keep up with a multitude of continuing education initiatives, computer/software upgrades, and regulatory updates. Furthermore, each time there is an imperative reason for nurses to come in to the office is time away from service delivery. In this environment of competing priorities – and given the agency's overall focus on comprehensive medication management as part of good care - the issue of medication complexity per se did not rise to the level judged to warrant its own training session. Instead, general information about the intervention and its rationale was provided to field managers and education staff so that they could address any questions coming from intervention field nurses, and all intervention materials were designed to be as self-explanatory as possible. A second factor to reflect on in considering suboptimal nurse uptake is the limited time a post-acute patient has in home care. Medication management is a big component of what home care nurses address in their usual practice. The primary focus is on making sure that medication reconciliation occurs and that a drug-to-drug and drug-to-medical condition contraindication review is completed at the start of care and at all transitional care points, teaching the patient/caregivers about side effects and assessing knowledge of the treatment regimen. We introduced a new component of medication management - addressing medication complexity. Thus, the effectiveness of our CDS intervention was judged relative to a comparatively high level of usual care, not to no medication management tools at all. Finally, the average length of stay in the home care is fewer than 45 days. The nurses have multiple care management modules to consider using during the patient's episode of care and may have chosen to focus on other clinical issues.

Within the intervention group, there was variability in the CDS care management actions that nurses chose to act on. The most frequent documented actions were the nurse advising the patient to keep their medication list up to date and to bring the list with them to their doctors' appointments. Far fewer records indicated that the nurse advised the patient to speak with the doctor about simplifying their medication regimen, and only a small number of records indicated that the nurse reached out to the doctor directly to work on simplification. These differences are likely due to nurse level of comfort with the different care management practices. Advising patients about straight-forward self-management practices, such as medication list maintenance, is a simple thing to do within a visit. These practices and the others that were more likely to be implemented were a focus in the patient workbook that was sent to intervention nurses to support their work with their patients. Simplification of a medication regimen takes more time and knowledge. It involves considering questions, such as "Are any of the medications available in a combination tablet? Can any be changed to a sustained-release formula? Can the regimen be synchronized so that the patient only needs to take medications two times a day?" Although the usual home care nurse would not change any of the regimens directly (most nurses do not have prescribing authority), the nurse may want to determine whether something could be simplified before asking the physician to do it or before advising the patient to speak to the doctor. If the nurses do not have this knowledge or comfort level, they may be hesitant to take these actions.

When the CDS tool was used and an action taken, patients benefited. A significantly larger percentage of patients moved below the complexity risk threshold and were less likely to be hospitalized when a nurse indicated that she addressed the medication complexity issue with the patient. The nurse characteristics associated with CDS use seem consistent with what we know about practice constraints. Nurses with more agency experience and those who were in salaried staff positions (versus nurses paid per visit [per diem]) were more likely to use the tool at least once. The former presumably had greater opportunity to establish comfort with the agency's electronic health record. Compared with per-diem nurses, they also may spend a little more time at each visit with the patient, allowing them additional time to review more complicated care management strategies with patients, although this is not readily measured

with available information. The more patients a nurse had in the study, the more likely she was to use the CDS tool. An email alert was sent to an intervention nurse for every patient identified as at risk. The alert directed the nurse to the CDS tool. Repeated prompts may have encouraged use of the tool.

Several patient characteristics were found to predict CDS use by the nurse. Some of the characteristics seem easily interpretable, whereas others are not. When patients were in home care service longer and had a greater number of nurse visits, the CDS was more likely to be used with them. This may have been because the nurse had more opportunity to use the tool or it may have been the product of using the tool. Nurses used the tool more often with patients taking a greater number of medications. Although all patients for whom the nurses received an alert had complex medication regimens, it is possible that a nurse was "more convinced" of the patient's risk when the number of medications was greater. It is unclear why nurses would use the tool more often with patients with shortness of breath at admission or those with diagnoses of hypertension, a cardiac condition, or stroke; it is possible that the importance of good medication and other self-management strategies for improved outcomes for these conditions motivated the nurse to incorporate the teachings from the new CDS tool into the patient's overall care plan. Our most disconcerting finding was the lower use of the tool with African American patients. Our team discussed this at length and could not come up with a definitive explanation. It is possible that the race variable was a surrogate for other sociodemographic factors that were not measured. For example, if the African American population in this study population had more socioeconomic problems or less education than patients of other races, it is possible that the nurses spent more time helping the patient manage other issues affecting their health instead of focusing on more advanced strategies, like simplifying medication regimens or synchronizing refills. This may or may not be a similar reason for the lower use with Medicaid beneficiaries. Often patients with private insurance have a narrowly defined purpose for their home care services, so nurses caring for patients with private insurance may have felt more restricted in their scope of practice. Nurses were less likely to use the tool with patients with a cancer diagnosis and those with higher number of chronic conditions. Many cancer patients are on medications that will be time limited, so nurses may have concentrated on helping them understand the purpose and administration instructions of these medications as opposed to simplifying the regimen and focusing on the long-term management strategies offered in the CDS tool. It is likely that nurses gave higher priority to other care management problems of patients than to the complex medication regimen care management problem with a greater number of comorbidities. When the nurse in charge of a patient's care was changed during the course of a care episode, the CDS tool was less likely to be used. The original nurse assigned to the case received the email alert and access to the CDS tool. Lack of continuity in care may have affected use of the tool.

Conclusions

We were unable to demonstrate that our interventions impacted patient outcomes in our full intent-to-treat analysis. Use of the CDS tool within the intervention group was limited. However, when CDS tool use or nonuse was examined within the intervention group, it was found that nurse use was associated with decreases in patients' risk thresholds and lower patient hospitalization rates. CDS use was affected by both nurse and patient characteristics – some understandable and some not; some remediable and some not. Strategies to increase use of CDS tools need to be explored in order to provide greater benefit to more patients.

Significance

It has been demonstrated that polypharmacy and medication regimen complexity are associated with poorer adherence and higher risk of adverse events. Reducing the frequency that a patient needs to remember to take a medication each day and simplifying administration instructions

are strategies that can potentially lower the risk. Additional attention to managing complex regimens that cannot be changed, such as using reminder systems, maintaining accurate medication lists, using only one pharmacy, and synchronizing prescription refills, are other potential risk-lowering strategies. All these strategies merit additional attention. In home care, electronics in the field have been largely used for the purpose of collecting administrative, assessment, and clinical data on patients. This is generally a one-sided process in which the nurse provides the agency with information but the nurse does not receive much information back or discuss it with the patient. However, one main tool used in EHRs is the medication database that checks for drug-to-drug interactions and duplications in therapy. Nurses are familiar with this computer interaction, so they may be open to getting more "advice" on medications, such as what was delivered the CDS tool created for this study. There is still a lot to learn about how information technology can be maximized to provide information and assistance to clinicians to influence care provision and improve patient outcomes. Health information technology is a quickly evolving field, and it will have a significant presence in all service settings.

This study provides new information on the predictors of CDS use and the impact of CDS use on patient outcomes. Our findings suggest that CDS use and patient outcomes could be improved by improving continuity of care; avoiding very short lengths of stay; and increasing per-diem nurses' knowledge, comfort, and motivation to use IT.

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6. List of Publications and Products *MANUSCRIPTS*

McDonald MV, Peng TR, Sridharan S., Foust JB, Kogan P, Pezzin LE, Feldman PH. Automating the medication regimen complexity index. *J Am Med Inform Assoc* 2012 Dec 25. [Epub ahead of print]

McDonald MV, Feldman PH, Barron-Vaya Y, Peng TR, Sridharan S, Pezzin LE. Outcomes of clinical decision support (CDS) and correlates of CDS use for home care patients with high medication regimen complexity: a randomized trial. *J Eval Clin Pract* 2016 Feb;22(1):10-19.

PRESENTATIONS AT NATIONAL MEETINGS

"Exploring the potential contribution of an automated Medication Regimen Complexity Index (MRCI)"

AHRQ Health Information Technology conference; June 2010; Washington, DC (poster presentation)

"Automating the Medication Regimen Complexity Index (MRCI)" AcademyHealth Annual Research Meeting; June 2010; Boston, MA (poster presentation)

"Complex medication regimens and increased risk of rehospitalization among post-acute home health patients"

AcademyHealth Annual Research Meeting; June 2010; Boston, MA (poster presentation)

"Nurse Use of a Clinical Decision Support Tool and Patient Outcomes" AcademyHealth Annual Research Meeting; June 2012: Orlando, FL (podium presentation)