

Project Title: Enhancing the Safety of Warfarin in the Nursing Home

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Structured Abstract

Purpose: The goal of this study was to improve warfarin management among nursing home residents through the use of a standardized nurse-physician communication tool. We sought to test the effectiveness of such a tool, as it could also serve as a model for improving the safety of other medication categories associated with high rates of preventable adverse drug events.

Scope: More than 1.7 million Americans currently reside in nursing homes; as many as 12% receive long-term anticoagulant therapy with warfarin. Prior research has demonstrated compelling evidence of safety problems with warfarin therapy in this setting, often associated with suboptimal communication between nursing home staff and prescribing physicians.

Methods: We conducted a randomized trial of a warfarin management protocol using facilitated telephone communication between nurses and physicians in 26 nursing homes in Connecticut in 2007-2008. Intervention facilities received a warfarin management communication protocol using the "Situation, Background, Assessment, and Recommendation" (SBAR) approach. The protocol included an SBAR template to standardize telephone communication about residents on warfarin by requiring information about the situation triggering the call, the background, the nurse's assessment, and any recommendations.

Results: In total, 435 residents received warfarin therapy during the study period for 55,167 resident days in the intervention homes and 53,601 in control homes. In intervention homes, residents' international normalized ratio (INR) values were in the therapeutic range a statistically significant 4.5% more time than in control homes (95% CI, 0.31%, 8.69%). There was no difference in obtaining a follow-up INR within 3 days after an INR value ≥ 4.5 (OR, 1.02; 95% CI, 0.44, 2.4). Rates of preventable warfarin-related adverse events were lower in intervention homes, although this result was not statistically significant; the incident rate ratio for any preventable warfarin-related adverse event was .87 (95% CI, .54, 1.4).

Key words: warfarin, long-term care, nursing homes, communications, SBAR

Purpose

Objectives of the study

Long-term oral anticoagulant therapy with warfarin is essential for the prevention of strokes and other thromboembolic events related to various medical conditions that increase in prevalence in older persons. However, the desire to initiate anticoagulant therapy in an older patient is tempered by concerns about the risk of bleeding. The residents of nursing homes are among the most frail patients in the geriatric population and are at increased risk for drug-related iatrogenic injury not only because of the physiologic declines and pharmacologic changes that occur with aging but also because of the special clinical and social circumstances that characterize this setting of care for more than 1.7 million Americans who reside in an estimated 16,000 nursing homes across the United States.

We had previously shown that the prevalence of conditions for which warfarin is indicated among nursing home residents is high, use of warfarin among this population is common, and the quality of management of this therapy is suboptimal. As many as 12% of nursing home residents receive warfarin for various reasons (nearly 200,000 nursing home residents nationwide).

Our prior research conducted under the auspices of an AHRQ-funded Center of Excellence for Patient Safety Research and Practice demonstrated overwhelming evidence of safety problems with warfarin therapy in the nursing home setting. Based on that work, we conservatively estimated that there may be as many as 34,000 fatal, life-threatening, or serious adverse events related to warfarin per year in the nursing home setting, the majority of which may be preventable. These include both bleeds and thromboembolic events. Errors in warfarin prescribing and monitoring are responsible for nearly all the preventable events; inadequate communication of information regarding prior international normalized ratio (INR) values and interacting medications played an important role in many of these events.

The premise underlying this intervention study is that errors in prescribing and monitoring warfarin for nursing home residents are related to problems in the system of care. The system of medication management in the nursing home includes the nursing staff within the facility and the physicians, laboratories, and pharmacy vendors (generally external to the nursing home) who interact to provide services to the residents. Although an adverse drug event in this setting may be directly linked to a "human error," the root cause may be defined as the defect in the system that permitted such an error to occur. In the case of warfarin therapy management for nursing home residents, an important root cause is poor information flow. One example is a telephone call to a covering physician about a resident with a urinary tract infection without providing crucial information that the resident is taking warfarin. The result may be an order for an antibiotic that interacts with warfarin, leading to an increased risk of a bleeding complication.

Many system-level interventions have been suggested to address the challenges of warfarin therapy management. At the present time, technology-based strategies, such as computerized physician order entry with clinical decision support, are less amenable to widespread adoption by nursing homes. Other options, such as specialized anticoagulation services, are logistically difficult to implement and expensive. In addition, our prior research has suggested that such services do not yet have broad acceptance for use in the nursing home setting. Given these limitations, we proposed a low-technology intervention for improving the safety of anticoagulation in the nursing home. The intervention focused on maximizing the effectiveness of communication between the nursing staff and physicians of nursing home residents on warfarin. The intervention built on an established approach for situation briefing drawn from the

US Armed Forces: **SBAR** – an acronym standing for **S**ituation, **B**ackground, **A**ssessment, and **R**ecommendation. We tested the effectiveness of this approach and its level of adoption and acceptance through a randomized trial, and we produced and disseminated a toolkit that can be applied in other nursing homes. This approach could also serve as a model for improving the safety of other medication categories associated with high rates of preventable adverse drug events and for protecting nursing home residents at special risk for medication-related problems.

We conducted a matched, cluster-randomized trial, with randomization at the level of the nursing home, with the following specific aims:

1. To determine whether a nursing home warfarin management protocol with facilitated communication to physicians would improve the quality of anticoagulation management. Quality of anticoagulation management was assessed utilizing two principal quality measures:
 - a) the proportion of time that nursing home residents receiving warfarin have their international normalized ratios (INRs) within the target therapeutic range; and
 - b) the time to next INR measurement after an out-of-range INR.
2. To determine whether a nursing home warfarin management protocol with facilitated communication to physicians would lower the rates of adverse events (bleeds and thromboembolic events) among warfarin-treated residents of intervention group nursing homes compared with control nursing homes.
3. To produce a toolkit for use by nursing homes that would allow dissemination of this approach to enhancing the quality and safety of warfarin in the nursing home setting.

Scope

Background

As many as 12% of the 1.7 million American nursing homes residents receive long-term oral anticoagulant therapy with warfarin to prevent strokes and other thromboembolic events. Prior research has demonstrated compelling evidence of safety problems with warfarin therapy in nursing homes resulting from suboptimal warfarin management and errors in prescribing and monitoring. In our previous studies, we estimated that there may be as many as 34,000 fatal, life-threatening, or serious adverse events related to warfarin per year in the nursing home setting, the majority of which may be preventable. An important contributor to many of these events appeared to be the lack of key information regarding prior international normalized ratio (INR) values, warfarin dosing, and interacting medications.

Decisions about medical care in nursing homes, including decisions about prescribing, often occur in the context of brief telephone discussions between physicians and nursing staff, as physicians are frequently off site when such decisions occur. Thus, the system of medication management in this setting relies heavily on the quality of communication between nursing staff within the facility and the physicians who provide medical care to individual residents. Studies focused on communication between physicians and nursing staff in long-term care facilities have identified challenges in communicating all the relevant information required to make optimal clinical decisions. Therefore, in an effort to improve the quality and safety of anticoagulation management in the nursing home setting, we conducted a randomized trial of a warfarin management communication protocol. The approach was standardized communication of **S**ituation, **B**ackground, **A**ssessment, and **R**ecommendation (SBAR).

SBAR was originally developed by the US Armed Forces to structure situation briefings. It has been implemented in a number of healthcare settings where communications between nurses and physicians are critically important for patient safety.

Context/Settings/Participants

Twenty-six study nursing homes were enrolled from among facilities that have an ongoing relationship with Qualidigm, a leading quality improvement organization located in Connecticut. These nursing homes are representative of those across the United States (see Table 1).

The population was derived from long-stay residents of the study nursing homes and included all residents who received warfarin for any indication.

Table 1. Comparison of Study Nursing Homes with Facilities in Connecticut and the United States

Characteristic	Intervention Homes (N=13)	Control Homes (N=13)	CT Nursing Homes (N=245)	US Nursing Homes (N=16,1001)
No. of Beds				
Mean ± SD	137.5 ± 56.5	135.5 ± 63.6	113.7	107.6
% Female residents				
Mean ± SD	75.0 ± 5.6	70.6 ± 11.3	67.3	71.2
Ownership				
For profit (%)	46.2	84.6	77.6	61.5
Nonprofit	46.2	7.7	21.6	30.8
Government	7.6	7.7	0.8	7.7
Staffing				
Licensed nursing staff hours per resident per day				
Mean ± SD	1 h 25 m ± 12 m	1 h 27 m ± 24 m	1 h 24 m	1 h 18 m
Nursing assistant staff hours per resident per day				
Mean ± SD	2 h 31 m ± 31 m	2 h 26 m ± 22 m	2 h 18 m	2 h 18 m

Methods

Study Design

The study was conducted in 26 nursing homes in the state of Connecticut in 2007-2008. Patients in short-term care areas of the facilities (e.g., subacute care, hospital-level care, or rehabilitation) were not included in the study. The study was approved by the institutional review board of the University of Massachusetts Medical School.

Nursing homes were randomized to intervention or control status within blocks according to bed size (fewer than 150, 150 to 249, 250 or more) using a random number generator. Table 1 (above) provides characteristics of the intervention and control homes compared with all facilities in Connecticut and across the United States.

Interventions

Facilities randomized to the intervention group received a warfarin communication protocol developed around the SBAR approach. The protocol included customized methods of identifying and highlighting residents taking warfarin, systematic procedures for tracking and communicating international normalized ratio (INR) results, a targeted training program for nursing staff focused on using the SBAR approach for telephone-based communication, and message templates to standardize telephone communication about residents on warfarin between nursing staff and physicians. The message templates were provided on printed forms designed to facilitate use of the SBAR approach. Control homes continued with usual care. A representative of each nursing home participated in initial training, after which all materials were shipped to the home in preparation for the facility's selected start date. Each nursing home participated in the study for 1 year. The assigned representative participated in monthly calls with the central project office at the University of Massachusetts Medical School and periodic cross-facility conference calls.

Data Sources/Collection

Information on INR values, warfarin dosing, and warfarin-related incidents was identified through quarterly reviews of nursing home records by trained nurse abstractors for each eligible resident of a participating facility who was receiving warfarin at any time during the 1-year period of the home's participation in the study. Abstractors identified possible warfarin-related incidents based on specified triggers: INR values of 4.5 or greater, evidence of overt bleeding, hematocrit decreases of 3% or greater, orders for vitamin K, a stroke or thromboembolic event, and emergency department visits or hospitalizations. For each trigger identified, the abstractors completed an abstraction form describing the incident and all related INR values, medications and medication changes.

Measures

Two measurements were used to assess quality of anticoagulation management: (1) the proportion of time that nursing home residents receiving warfarin had INR values within the target therapeutic range (defined as 2.0 to 3.0) and (2) the rate at which the response to an INR value of 4.5 or greater was a follow-up INR value within 3 days. We identified preventable adverse events associated with warfarin therapy, defined as injuries resulting from the use of warfarin, including hemorrhagic events as well as thromboembolic events that were associated with subtherapeutic INR values. Warfarin-related adverse events were considered to be preventable if they were judged to be due to an error and were preventable by any means available. Errors could occur during the ordering, dispensing, administration, and monitoring stages of warfarin management. Error types were further categorized as wrong dose, wrong drug, missed dose, wrong frequency, extra dose, wrong resident, known drug interaction, inadequate laboratory monitoring, or delayed response to laboratory evidence of an out-of-range INR value. We also identified potential warfarin-related adverse events, defined as instances in which the INR value was 4.5 or greater with an associated error in warfarin management but without patient injury. Warfarin-related incidents were presented to pairs of physician-reviewers who were blinded to the intervention status of the resident's nursing home. Reviewers independently classified incidents, including whether a warfarin-related adverse event or a potential warfarin-related adverse event was present, whether the event was preventable, and the severity of the event. The severity of warfarin-related adverse events was classified according to modification of the criteria of Landefeld and colleagues, as used by White and colleagues. The severity of warfarin-related adverse events was categorized as minor, serious, life threatening, or fatal. Minor events were those with no medical consequence (e.g., bruising). Serious events were those that required specific treatment or a medical evaluation.

Life-threatening events included the need for a surgical intervention to stop the bleeding, irreversible sequelae (e.g., myocardial infarction or stroke), or any two of the following: transfusion of three or more units of blood, hypotension, critical anemia, or acute bleeding (<3 days).

When the two reviewers disagreed on the classification of an incident, its preventability, or its severity, they met and reached consensus. Consensus was reached in all instances. We compared the initial assessments of the physician reviewers and calculated inter-rater reliability using the kappa statistic, with kappa values of 0.93 for judgments regarding the presence of a warfarin-related adverse event, 0.61 for preventability, and 0.74 for severity. A kappa score of 0.4 to 0.6 reflects “moderate agreement”; 0.6 to 0.8 reflects “substantial agreement”; and 0.8 to 1.0 is considered “almost perfect.”

Statistical analysis

We hypothesized that warfarin management among residents in the intervention nursing homes would be superior to that in the control nursing homes, leading to higher percent time in the therapeutic range and higher rates of follow-up to INR values ≥ 4.5 within 3 days. Conservative sample size estimates suggested that the study would be able to find differences in these rates of 20% or greater statistically significant at the 0.05 level. We also tracked rates of preventable warfarin-related adverse events and potential warfarin-related adverse events, although we recognized that our sample size was insufficient for identifying moderate differences in these rates. Based on data from our previous study of warfarin management in Connecticut nursing homes, we estimated that a sample size of 40 nursing homes per arm would have been required to detect a 20% reduction in preventable warfarin-related adverse events. Our original power calculations were based on a reduction in overall warfarin-related adverse events rates and not simply preventable ones, which led to the target sample size of nursing homes used in our study.

The primary analyses are intention-to-treat analyses comparing the intervention and control nursing homes with regard to the percentage of time within the therapeutic range for residents taking warfarin; the rate of follow-up to INR values ≥ 4.5 within 3 days; and the rates of preventable warfarin-related adverse events and potential warfarin-related adverse events. All analyses accounted for the clustering of individuals within the randomized nursing homes.

Specific person-time within the therapeutic range in each nursing home was computed according to the method of Rosendaal, which assigns an INR value to each person-day based on interpolated values between measurements. We excluded periods from analysis when a resident was not taking warfarin or was absent from the home. We stopped interpolating INR values at the last INR before an excluded period and did not restart until the first INR value after that period. Analyses comparing the percentage of time spent in the therapeutic range between intervention and control homes were modeled using a generalized estimating equation model to account for residents clustered within nursing homes and to control for resident characteristics, including age, gender, race, and comorbidity, as well as abstractor. To control for the potential impact of the length of time that residents were on warfarin during the study, we developed two models that provided consistent estimates of the intervention effect: a mixed model with individual resident INR values weighted by total days taking warfarin during the study and a mixed model adjusted for total days. Comparisons of the rates of follow-up INRs occurring within 3 days after an INR value of 4.5 or greater used logistic regression analyses modeled with generalized estimating equations clustered within nursing homes and adjusted for the resident characteristics and abstractor.

To determine crude rates of events, the outcome measures (i.e., numbers of preventable warfarin-related adverse events, serious or more severe preventable warfarin-related adverse

events, and potential warfarin-related adverse events) were divided by the total number of nursing home resident days on warfarin during the study period. These were estimated by obtaining census data for all eligible residents on warfarin throughout the course of the study, accounting for absences from the nursing homes and breaks in warfarin use. Comparisons of the rates between intervention and control homes were modeled using Poisson regression and generalized estimating equations to account for clustering within nursing homes. All models controlled for the resident characteristics and abstractor.

Results

Principal Findings

The 26 nursing homes continued to participate for the full 1-year follow-up period, and all were included in analyses of outcomes. Across the 26 homes, 435 residents received warfarin therapy during the study period, contributing 55,167 days of observation in the intervention homes and 53,601 days in the control homes. Approximately 71% of residents in the intervention homes were female compared with 65% in the control homes, with an average age of 83 years in intervention homes and 82 years in control homes. The most common indication for warfarin therapy in both groups of homes was prevention of stroke due to atrial fibrillation (66%).

Among the intervention homes, residents had INR values within the therapeutic range for 53.1% of their time on warfarin compared with 50.0% among residents in the control homes, for an absolute difference of 3.1%. With adjustment for clustering within homes, length of time on warfarin, characteristics of the residents, and abstractor, the difference in the percent time in therapeutic range was 4.5% (95% confidence interval (CI), 0.3%, 8.7%). For a patient taking warfarin for a full year, this represents 16 additional days in the therapeutic range (95% CI, 1, 32 days). The adjusted intracluster correlation for nursing homes was 0.01.

In the intervention homes, 64.6% of INRs ≥ 4.5 were followed by another INR measure within 3 days, whereas, in the control homes, the result was 71.7%. To further assess this finding, we adjusted for clustering within homes, length of time on warfarin, characteristics of the residents, and abstractor. The odds ratio for follow-up in more than 3 days comparing residents in intervention nursing homes with those in control homes was 1.02 (95% CI, 0.44, 2.4). The adjusted intracluster correlation for nursing homes was 0.10.

Nurse abstractors identified 782 possible warfarin-related incidents during the study. There were 83 classified as preventable warfarin-related adverse events and 183 as potential warfarin-related adverse events. Rates of preventable warfarin-related adverse events were lower in intervention homes, although this result was not statistically significant. Expressed as rates per 100 resident months, the rate of preventable adverse events related to warfarin in the intervention homes was 2.26, whereas the rate in the control homes was 2.38. The rate of serious preventable events was 0.39 in intervention homes and was 0.62 in control homes. The rate of potential warfarin-related adverse events (situations in which the INR was 4.5 or greater and no injury occurred, but an error in warfarin management was identified) was 4.52 in the intervention homes and was 5.74 in the control homes. The adjusted incident rate ratio (IRR) for any preventable warfarin-related adverse event was 0.87 (95% CI, 0.54, 1.4); for a serious preventable warfarin-related adverse event, the IRR was 0.50 (95% CI, 0.17, 1.5). For potential warfarin-related adverse events, the IRR was 0.77 (95% CI, 0.45, 1.3).

Table 2. Warfarin-related Adverse Events in Intervention and Control Nursing Homes

	Intervention	Control	Rate	Adjusted Rate Ratio
	Nursing	Nursing	Ratio	(95% CI)
	Homes	Homes		
Preventable warfarin-related adverse event	41	42	0.95	0.87 (0.54, 1.4)
Preventable serious, life-threatening or fatal warfarin-related event	7	11	0.62	0.50 (0.17, 1.5)
Potential warfarin-related adverse event	82	101	0.79	0.77 (0.45, 1.3)

*Adjusted for nursing home; abstractor; and resident's age, sex, race, and Charlson comorbidity score

Outcomes

In this randomized trial, a warfarin management communication protocol based on SBAR modestly improved the time that residents were maintained in the therapeutic range and appeared to lower the rates of preventable warfarin-related adverse events, although the latter findings are not statistically significant. However, the intervention had no impact on the rate of 3-day follow-up after INR values ≥ 4.5 with a subsequent INR.

Discussion

Several interventions have been developed to improve warfarin management, including use of dosing algorithms, anticoagulation clinics, patient home monitoring, and pharmacist-based management. However, there are logistical, financial, informational, and even regulatory challenges associated with providing specialized anticoagulation services to multiple nonaffiliated nursing homes across a geographic region. In a previous study surveying physicians caring for residents of nursing homes, we actually found some resistance to external management of warfarin for their patients who reside in nursing homes. Furthermore, prior warfarin management interventions have been tested in the hospital and ambulatory setting but have not been evaluated in the nursing home setting. Although highly technological interventions to improve warfarin prescribing and monitoring are an option for select nursing homes, it is not an option for many nursing homes, because financial, structural and cultural barriers to full adoption of computerized order entry and electronic medical records remain in these facilities.

For these reasons, and because quality of communication has been shown to affect quality of medication prescribing in nursing homes, our study evaluated an innovative, low-technology

intervention to improve warfarin management in nursing homes by implementing structured communication. Based upon an established approach for situation briefing drawn from the US Armed Forces, the SBAR approach to nurse-physician communication has been promoted for use in a variety of clinical settings to improve patient safety. SBAR establishes a standardized structure for medical communication, ensuring that critical information that directly affects physician decision making is transmitted in a predictable manner. Its use is particularly well suited to telephone communication in the nursing home, where medication management involves the critical flow of communication between nursing staff and off-site physicians. Frequently, decisions about warfarin dosing and INR measurement are made during brief telephone conversations, with inadequate information about prior INR values, warfarin doses, and interacting medications available to the decisionmaker. In this study, we operationalized SBAR in a template that requires nurses to collect information and consider their own assessment of the resident's situation before placing calls to physicians about residents on warfarin to report INR values, indicators of possible adverse events, infections such as urinary tract infections, or medication issues. The template guides the user through communication in a consistent and concise fashion, using standard language, saving time for healthcare providers and improving efficiency.

Conclusions

We conclude that use of a communication protocol based on SBAR can modestly improve the quality of warfarin management in nursing homes, as reflected by increased time in therapeutic range. This low-technology approach may also serve as a model for improving the safety of other medications associated with high rates of preventable adverse drug events and for improving safety for vulnerable nursing home residents at special risk for medication-related problems.

Our study does have several limitations, including inadequate power to identify the intervention's impact on preventable adverse events. However, the intervention was associated with a statistically significant and clinically meaningful higher percent of time in the therapeutic range, indicating better warfarin management with the potential for reduction in risk of both thromboembolic and hemorrhagic events. Our study relied entirely on information abstracted from existing medical records within each study nursing home and, thus, is subject to those limitations. This may have caused us to miss some information relevant to warfarin-treated residents. To overcome this potential problem, we trained abstractors to search for and report on a variety of indicators of possible events from multiple sources in the nursing homes. We used the subsequent physician review process to cull incidents that were not found to identify a warfarin-related event.

Significance

The study has several important strengths. It is set among 26 community-based nursing homes that are similar to nursing homes across the United States, so our results should be broadly generalizable. The study design is a randomized controlled trial, providing assurance that the impact is not confounded by underlying differences in the facilities' staff, infrastructure, management, or overall patient safety culture.

Publications/Products

Tjia J, Mazor KM, Field T, Meterko V, Spenard A, Gurwitz JH. Nurse-physician communication in the long-term care setting: perceived barriers and impact on patient safety. *J Patient Saf.* 2009 Sep;5(3):145-52.

Purpose: Clear and complete communication between health care providers is a prerequisite for safe patient management and is a major priority of the Joint Commission's 2008 National Patient Safety Goals. The goal of this study was to describe nurses' perceptions of nurse-physician communication in the long-term care (LTC) setting.

Methods: Mixed-method study including a self-administered questionnaire and qualitative semistructured telephone interviews of licensed nurses from 26 LTC facilities in Connecticut. The questionnaire measured perceived openness to communication, mutual understanding, language comprehension, frustration, professional respect, nurse preparedness, time burden, and logistical barriers. Qualitative interviews focused on identifying barriers to effective nurse-physician communication that may not have previously been considered and eliciting nurses' recommendations for overcoming those barriers.

Results: Three hundred seventy-five nurses completed the questionnaire, and 21 nurses completed qualitative interviews. Nurses identified several barriers to effective nurse-physician communication: lack of physician openness to communication, logistic challenges, lack of professionalism, and language barriers. Feeling hurried by the physician was the most frequent barrier (28%), followed by finding a quiet place to call (25%) and difficulty reaching the physician (21%). In qualitative interviews, there was consensus that nurses needed to be brief and prepared with relevant clinical information when communicating with physicians and that physicians needed to be more open to listening.

Conclusions: A combination of nurse and physician behaviors contributes to ineffective communication in the LTC setting. These findings have important implications for patient safety and support the development of structured communication interventions to improve quality of nurse-physician communication.

Terry S. Field, Jennifer Tjia, Kathleen M. Mazor, Jennifer L. Donovan, Abir O. Kanaan, Leslie R. Harrold, George Reed, Peter Doherty, Ann Spenard, Jerry H. Gurwitz. Randomized Trial of a Warfarin Communication Protocol for Nursing Homes: an SBAR-based Approach. *American Journal of Medicine.* 2011 Feb;124(2):179.e1-7.

Background: More than 1.6 million Americans currently reside in nursing homes. As many as 12% receive long-term anticoagulant therapy with warfarin. Prior research has demonstrated compelling evidence of safety problems with warfarin therapy in this setting, often associated with suboptimal communication between nursing home staff and prescribing physicians.

Methods: We conducted a randomized trial of a warfarin management protocol using facilitated telephone communication between nurses and physicians in 26 nursing homes in Connecticut in 2007-2008. Intervention facilities received a warfarin management communication protocol using the approach "Situation, Background, Assessment, and Recommendation" (SBAR). The protocol included an SBAR template to standardize telephone communication about residents

on warfarin by requiring information about the situation triggering the call, the background, the nurse's assessment, and any recommendations.

Results: In total, 435 residents received warfarin therapy during the study period for 55,167 resident days in the intervention homes and 53,601 in control homes. In intervention homes, residents' international normalized ratio (INR) values were in the therapeutic range a statistically significant 4.5% more time than in control homes (95% CI, 0.31%, 8.69%). There was no difference in obtaining a follow-up INR within 3 days after an INR value ≥ 4.5 (OR, 1.02; 95% CI, 0.44, 2.4). Rates of preventable warfarin-related adverse events were lower in intervention homes, although this result was not statistically significant: the incident rate ratio for any preventable warfarin-related adverse event was .87 (CI, .54, 1.4).

Conclusion: Facilitated telephone communication between nurses and physicians using the SBAR approach modestly improves the quality of warfarin management for nursing home residents.

Jennifer Tjia, Terry S. Field, Kathleen M. Mazor, Jennifer Donovan, Abir Kanaan, Peter Doherty, Leslie R. Harrold, Jerry H. Gurwitz. Relationship between Nurse Staffing, Health Inspection Deficiencies and Adverse Drug Events in Nursing Homes. In Submission.

Background: Despite widespread dissemination of nursing home (NH) quality of care process measures, validity studies of these measures evaluate few patient outcomes.

Objectives: To examine the association between nurse staffing time and NH deficiencies with adverse drug event incidence.

Research Design: Prospective cohort embedded in a clinical trial.

Subjects: 435 residents using warfarin in 26 Connecticut NHs.

Measures: NH structural characteristics (bed size, for-profit status), nurse staffing time, and NH deficiencies (pharmacy, administrative, quality of care, and all other deficiencies) reported on the Nursing Home Compare website. Warfarin indication, use, and signals of toxicity (vitamin K administration, INR > 4.5 , hospitalizations, and bleeding) collected from quarterly medical record review. Physician reviewers determined occurrence of adverse warfarin events (AWEs; injuries resulting from warfarin use) potential AWEs (INR > 4.5 and management error), and AWE preventability. Multivariable regression was used to determine the independent association of nurse staff time and deficiencies with potential and preventable AWEs using generalized estimating equations, accounting for clustering within NHs.

Results: After adjustment, residents in NHs with greater RN/LPN time ($>$ median minutes [83] per resident per day relative to $<$ median minutes per resident per day) had fewer potential and preventable AWEs (adjusted incidence rate ratio [IRR], 0.65; 95% confidence interval [CI] 0.45-0.93). Having a pharmacy deficiency was not associated with potential or preventable AWEs (adjusted IRR, 0.94; 95% CI 0.68-1.29).

Conclusion: Risk of potential and preventable AWEs is associated with RN/LPN nurse staff time. Our findings have implications for quality of care reporting and patient safety.

Jennifer Tjia, Terry S. Field, Kathleen M. Mazor, Jennifer Donovan, Abir Kanaan, Peter Doherty, Leslie R. Harrold, Jerry H. Gurwitz. Dementia and the Incidence of Adverse Drug Events in the Nursing Home. In Preparation

Background: The use of warfarin in NH residents with dementia is controversial. Little is known about the quality of warfarin monitoring and risk of drug injury in this population.

Objectives: To examine the association between dementia and adverse warfarin events in NH residents.

Research Design: Prospective cohort embedded in a clinical trial.

Subjects: 435 residents using warfarin in 26 Connecticut NHs.

Measures and Analysis: The main outcome variables were nonpreventable AWEs and potential and preventable AWEs due to medication errors. The main predictor variable was dementia. We used a series of Poisson regression with generalized estimating equations to examine the independent association between nonpreventable AWEs and potential/preventable AWEs, adjusting for resident and NH facility characteristics. The initial model adjusts for resident characteristics (age, sex, race, and baseline comorbidity score); the final model additionally adjusts for NH characteristics found to be different between the dementia and nondementia groups at baseline (nursing staff time and NH deficiencies [indicator variables for pharmacy service, quality of care, administrative, and any other deficiency]) and case-mix adjustors (% bed bound and % of NH residents on warfarin). Both models adjusted for abstractor and accounted for clustering within nursing homes and time on warfarin.

Results: Across the 26 homes, 435 residents received warfarin therapy, including 218 with dementia. Residents with dementia were older and were more likely to reside in NHs with less RN and LPN time and with more pharmacy and quality-of-care deficiencies on state survey. NH residents with dementia were using warfarin for fewer total days during the observation period than residents with no history of dementia (238.6 days vs. 261.5 days; $p < 0.05$), but there was no difference in the number of INR tests. There was also no difference in the percentage of days with subtherapeutic, therapeutic, and suprathreshold INRs. The adjusted association of dementia with nonpreventable AWEs was IRR=1.48 (95% CI 1.20, 1.82) in fully adjusted models and with possible/preventable AWEs was IRR=1.36 (95% CI 1.06, 1.76).

Conclusion: NH residents with dementia are at higher risk of nonpreventable and preventable AWEs but had no difference in quality of monitoring or maintenance in therapeutic range.

Jennifer Tjia, Kathleen M. Mazor, Terry Field, Peter Doherty, Ann Spenard, Jerry H. Gurwitz. Predicting Nursing Home Adherence to Clinical Trial Intervention. In Preparation

Purpose: To describe factors predictive of nursing home (NH) adherence to a clinical trial intervention, including NH structural characteristics, NH quality of care, NH leadership turnover, and response to a pre-intervention questionnaire.

Methods: Post-hoc analysis of a cluster-randomized controlled trial of a structured communication intervention to improve nurse-physician telephone communication in 26 Connecticut NHs. A priori, we measured NH characteristics hypothesized to affect trial outcomes, including profit-status, bed size, nursing staff time, NH quality, and leadership turnover. We examined the adherence to the trial intervention by these NH characteristics and by the response to a pre-intervention nursing staff questionnaire. Adherent NHs were defined as an NH with active trial participation for at least 3 months of the 12-month intervention. We used t-tests for continuous measures and chi-square tests for categorical measures to examine the relationship intervention adherence and predictors.

Results: Of 13 intervention homes, seven were adherent to the intervention. Three factors were significantly different between the adherent and nonadherent NHs: 1. turnover of the director of nursing (nonadherent NHs [50%] vs. adherent NHs [0%], $p < 0.03$); 2. NH staffing rating (range, 1-5) by the Centers for Medicare and Medicaid Services scale (nonadherent NHs [mean rating, 3.7; standard deviation (SD) 0.5] vs. adherent NHs [mean rating, 4.3; SD 0.5]), $p < 0.05$); and 3. pre-intervention questionnaire response rate (nonadherent NH [15.6%, SD 10.0] vs. adherent NH [34.2%, SD 12.1], $p = 0.02$). Profit status, bed size, and number of NH deficiencies on state surveys were not significantly associated with adherence to the intervention.

Conclusion: CMS NH staffing rating, leadership turnover, and nursing staff response rate are associated with adherence to a clinical trial intervention. Pre-trial evaluation of NH staffing rating by CMS and of response to a questionnaire can help investigators improve trial efficiency by screening for NHs likely to be adherent to a trial intervention.

Dissemination:

Our team has worked closely with the Clinician-Consumer Health Advisory Information Network (CHAIN) to disseminate the *Warfarin Communication Toolkit*. CHAIN is an online educational, informational, and resource dissemination program operated as a collaborative effort of the Centers for Education and Research on Therapeutics (CERTs) Educational Consortium. The CHAIN website is an online resource for healthcare professionals and consumers. Resources submitted to CHAIN for consideration of inclusion on the site go through a careful peer review process before acceptance and posting. The *Warfarin Communication Toolkit* has been reviewed and can be found on the Clinician-Consumer Health Advisory Information Network (CHAIN) online website at http://www.chainonline.org/content.cfm?content_id=1401. The online toolkit includes two streaming presentations:

- *Structured Communication About Warfarin and Patient Safety*—covering basic clinical management principles for the safe use of warfarin in treating problems related to heart disease and circulatory problems.
- *Focused Assertive Communication for Nurses*—covering common problems that nursing professionals working in long-term care settings (e.g., nursing homes, rehabilitation facilities) may confront in trying to facilitate communication between busy physicians and patients who often have problems (e.g., hearing problems, cognitive deficits) that confound efforts to maintain safe medication regimens.

Also, by clicking on the *Supplemental Resources* tab located on the entry page to each of the two presentations, learners can access additional resource materials on the topics. These may

be of value in helping clinical professionals to address issues around safe use of warfarin and in adopting effective patient-to-provider and provider-to-provider communication strategies—especially in situations in which improper use of therapeutics poses risks to patients. Nurses who complete the learning exercises and a brief post-test are eligible to receive continuing education credit for these learning activities. At the most recent count, over 300 nurses had done so.

CHAIN staff recently developed a detailed marketing plan in an effort to further promote the *Toolkit*. The plan focuses on nurses in particular but also takes into account the fact that the Toolkit and the associated SBAR materials can be used to address a variety of communication challenges in different settings and involving personnel from a range of disciplines. The marketing plan identifies a number of strategies for optimizing professional outreach and target audience participation in these online programs. The Toolkit will be announced on the home page of the CHAIN online website, with a link to an internal page containing both information about the Toolkit and a link to the Toolkit itself. CHAIN staff propose to contact a number of national and state organizations, such as the American Association of Homes and Services for the Aging, the National Association of Directors of Nursing Administration in Long-term Care, American Medical Directors Association, and many other organizations. These organizations will be asked to help disseminate the Toolkit through their e-newsletters and other organizational channels. CHAIN staff will also send e-mail announcements via the listservs and seek to place announcements in selected electronic publications.

We also conducted a Webex training in conjunction with the state of New York Quality Improvement Organization (IPRO)'s New York Warfarin Safety Series on October 20, 2009. The Safe Warfarin-Antibiotic Testing project (SWAT) is a statewide initiative that seeks to improve the quality of warfarin management through the promotion of proactive monitoring and improved follow-up, particularly in instances in which patients are prescribed antibiotics known or suspected to interact with warfarin. The SWAT project seeks to raise public awareness regarding the hazards of suboptimal warfarin management practices and promote the widespread adoption of high-quality warfarin management systems. Part of the Toolkit was shared in this Webex presentation, focusing on warfarin safety in nursing homes and introducing the use of SBAR for warfarin safety to over 125 registrants, including physicians, nurses, pharmacists, physician assistants, and nurse practitioners. This was followed up with promotion or introduction of the SBAR toolkit during outreach efforts by IPRO.

Figure 1. Template for SBAR communication

Telephone communication for resident on warfarin Date: _____ Time: _____																	
Originator of call: _____ I am calling about warfarin patient <resident name >, one of Dr. <MD name>'s patients at <nursing home>.		S ituation															
The issue I am calling about (select from the following options) is:																	
New INR Result INR result: _____	Change in Condition <input type="checkbox"/> fall with potential injury <input type="checkbox"/> skin tear with potential complication <input type="checkbox"/> fever <input type="checkbox"/> ANY bleeding or bruising <input type="checkbox"/> other injury: <input type="checkbox"/> other medication issue: <input type="checkbox"/> abnormal UA test results <input type="checkbox"/> abnormal chest Xray results <input type="checkbox"/> other, specify: _____		Fall without injury/ Minor skin tear <input type="checkbox"/> fall <input type="checkbox"/> no injury noted <input type="checkbox"/> no bleeding/bruising <input type="checkbox"/> skin tear <input type="checkbox"/> no redness noted <input type="checkbox"/> no drainage <input type="checkbox"/> size: apx ____ cm <small>If calling for one of these situations, skip to the Recommended Action section</small>														
↓ ↓																	
Last 2 INR test results <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">INR Date</td> <td style="width: 15%;">INR</td> <td style="width: 30%;">Dosing Pattern</td> <td style="width: 15%;">Date from</td> <td style="width: 25%;">Date to</td> </tr> <tr> <td>_____</td> <td>_____</td> <td>Current _____ mg</td> <td>_____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> <td>Previous _____ mg</td> <td>_____</td> <td>_____</td> </tr> </table>		INR Date	INR	Dosing Pattern	Date from	Date to	_____	_____	Current _____ mg	_____	_____	_____	_____	Previous _____ mg	_____	_____	B ackground
INR Date	INR	Dosing Pattern	Date from	Date to													
_____	_____	Current _____ mg	_____	_____													
_____	_____	Previous _____ mg	_____	_____													
Indication for warfarin: <input type="checkbox"/> AFIB <input type="checkbox"/> DVT/PE <input type="checkbox"/> MECHANICAL HEART VALVE <input type="checkbox"/> OTHER _____ Other important medications the resident is taking (any in past 3 days): <input type="checkbox"/> antibiotics: <input type="checkbox"/> NSAIDs (e.g. ibuprofen, motrin, piroxicam, indocin, meloxicam, etc): <input type="checkbox"/> aspirin or Plavix (clopidogrel)																	
↓		A ssessment															
<input type="checkbox"/> No concerns <input type="checkbox"/> I'm uncomfortable about this patient because: <input type="checkbox"/> high INR <input type="checkbox"/> bleeding/bruising <input type="checkbox"/> other <input type="checkbox"/> low INR																	
↓		R ecommended Action <small>Based on Nurse Assessment</small>															
Say what you think would be helpful or needs to be done, which might include: <input type="checkbox"/> No new orders needed INR/Warfarin Recommendations <input type="checkbox"/> Tell me if the warfarin dose should be changed or held <input type="checkbox"/> Tell me when to repeat the INR <input type="checkbox"/> In 3 days? <input type="checkbox"/> In 7 days? <input type="checkbox"/> Other? Other Recommendations <input type="checkbox"/> Tell me whether to order an antibiotic <input type="checkbox"/> If so, should we adjust the warfarin dose? <input type="checkbox"/> When should we schedule the next INR test? <input type="checkbox"/> Tell me whether to order other tests <input type="checkbox"/> Should we send the patient to the emergency department? When do you want us to call again (or under what conditions)?																	
ENTER ALL ORDERS DIRECTLY ONTO THE PHYSICIAN ORDER SHEET																	
Response from MD or office Who responded: _____ Date: _____ Time: _____																	

Signature _____ Date _____