

Community-based VTE Care Transitions Coordinated Through a Senior Services Organization

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Southern Illinois University Edwardsville School of Pharmacy (www.siu.edu)

J. Mark Ruscini, Pharm.D., Professor and Chair, Dept of Pharmacy Practice (**Principal Investigator**)

Maithili Deshpande, Ph.D., Assistant Professor, Dept of Pharmacy Practice

Christopher Lynch, Pharm.D., Professor & Dir. of Clinical Programs, Dept of Pharmacy Practice

Senior Services Plus of Alton, IL (www.seniorservicesplus.org)

Jonathan Becker, Executive Director

Hannah Tolan, MS, Lead Transitions Coach

Southern Illinois University School of Medicine (www.siumed.edu)

Zachariah Gurnsey, M.D., Associate Professor, Dept of Internal Medicine

Kristin Delfino, PhD, Statistical Research Specialist, Center for Clinical Research

Georgia Luckey, MS, Bioinformatics Support Specialist, Center for Clinical Research

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Abstract:

Medication-related problems occur routinely during transitions of care, increasing the risk for adverse drug effects, therapeutic failures, and early utilization of healthcare services post-discharge. This is particularly true for medication-intensive conditions, such as venous thromboembolism (VTE). To reduce medication-related problems and the associated negative consequences, we will integrate a clinical pharmacist into an existing community-based care transitions program. Senior Services Plus Healthy Connections program utilizes transition coaches to screen seniors discharged from four community hospitals located in southwestern Illinois. The coaches provide home visits post-discharge to empower patients and caregivers regarding: follow-up appointments, medication management, health safety plans, transportation, and linkage to community resources. Improving medication management has been identified as a quality initiative for the program, since medication-related problems are routinely encountered during the post-discharge home visits. We will conduct a prospective study including patients ≥ 60 years of age discharged with a diagnosis of VTE. Patients from two participating hospitals will serve as control subjects (one hospital no visit; one hospital transition coach only visit) and patients discharged from the remaining two hospitals will serve as intervention subjects (transition coach plus pharmacist visit). Targeted enrollment will be 120 patients per group and outcomes will be evaluated comparing: the number of and types of medication-related problems identified and resolved; VTE outcomes including recurrence and bleeding complication rates; and all-cause hospital readmission rates at 14, 30, and 60 days. The overall goal of the project is to improve the safety and effectiveness of medication use during care transitions from hospital to home for older adults treated for venous thromboembolism (VTE).

PURPOSE***PROJECT GOAL AND OBJECTIVES***

Medications are the most common intervention used to treat medical disorders and, as a result, medications are the most common cause of adverse events following hospital discharge. Medication-related problems (errors, discrepancies, drug interactions, adherence issues, side effects, lack of monitoring, etc.) occur routinely during transitions of care, increasing the risk of adverse drug effects, therapeutic failures, and utilization of healthcare resources post-discharge. Medication-intensive conditions, such as chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), myocardial infarction (MI) and also venous thromboembolism (VTE) are particularly prone to such problems. The Senior Services Plus Healthy Connections program utilizes transition coaches to screen seniors as they are discharged from four community hospitals in southwestern Illinois. The transition coaches provide home visits post discharge to empower older patients and caregivers regarding: follow-

up appointments, medication management, health safety plans, transportation, and linkage to community resources. Improving the medication management aspect of the program (safety, effectiveness, adherence, education, and communication) has been identified as a quality initiative, since medication-related problems are routinely encountered by the transition coaches during home visits. To reduce medication-related problems and the associated negative consequences, we plan to conduct a prospective study to integrate a clinical pharmacist into the existing Senior Services Plus (SSP) Healthy Connections care transitions program home visits and to evaluate the impact on outcomes of patients discharged with VTE. **The overall goal of the project is to improve the safety and effectiveness of medication use during care transitions from hospital to home for older adults treated for venous thromboembolism (VTE).**

The proposed project will address specific research questions related to overall medication safety during care transitions for patients with VTE, as well as, safety and effectiveness of oral anticoagulation therapy for patients with VTE. Integrating a pharmacist into the transition coach visits will provide an added dimension to SSP's existing transitions program and addresses an insufficiently met need of participants in the program, while supporting the missions of both Senior Services Plus and SIUE School of Pharmacy.

Key Objectives to Meet the Stated Goal:

Objective 1: To evaluate the number of and types of medication-related problems identified in patients with VTE post discharge during transition coach-only home visits (existing program) as compared with transition coach plus pharmacist home visits (intervention). (PRIMARY)

Rationale: One of the five primary points of emphasis in the existing Healthy Connections program through SSP is medication management. The transition coaches encounter medication-related problems routinely during home visits; however, they often feel ill equipped to resolve these issues. It is probable that many medication-related problems are not identified and missed entirely during home visits, due to a lack of medication expertise on the part of the transition coaches.

Objective 2: To evaluate the impact of the intervention on VTE outcomes, including VTE recurrence rates, bleeding complication rates, and all-cause hospital readmission rates at 14, 30, and 60-days comparing the transition coach plus pharmacist home visit group with the transition coach only home visit group and the no home visit group. (EXPLORATORY)

Rationale: Medication-related problems that occur during the early post-discharge timeframe that go unidentified and unresolved often lead to utilization of additional health care services (provider visit, emergency room visit, rehospitalization). By involving a pharmacist early in the post-discharge timeframe to identify and resolve medication-related problems, a reduced rate of complications and the subsequent need for early utilization of health care services may be observed.

Objective 3: To compare the rates of VTE outcomes (as in Objective 2) for patients treated with vitamin K antagonists (\pm heparin/LMWH) versus patients treated with novel oral anticoagulants. (EXPLORATORY)

Rationale: The vitamin K antagonist, warfarin, has been used historically to treat VTE. Its use requires intense monitoring due to the potential for numerous drug interactions, dietary interactions, and highly variable dose requirements in each patient. In general, the novel oral anticoagulants have been shown to be similarly effective for treating VTE when compared to warfarin; however, they are associated with a lower risk of major bleeding when compared to warfarin. Additionally, the need for monitoring with the novel oral anticoagulants is substantially less when compared to warfarin, due to a consistent dose-response in patients and significantly fewer drug and dietary interactions. It is unlikely that the small patient numbers in these subgroups will demonstrate significant difference in VTE outcomes; however, we plan to conduct this analysis for exploratory purposes.

Objective 4: To evaluate patient satisfaction with post-discharge home visits by a pharmacist to older adults discharge with VTE. (EXPLORATORY)

Rationale: Clinical outcomes are important measures of quality care; however, humanistic outcomes, such as patient satisfaction, are also useful measures of quality but are less often evaluated. There is limited data in the literature regarding patient satisfaction with pharmacist conducted home visits.

SCOPE

Assessment of Need/Scope of the problem

Senior Services Plus' Healthy Connections program has been in existence since January of 2014, serving mostly rural areas of St. Clair and Madison County in southwestern Illinois. Senior Services Plus employs three transition coaches who have developed working relationships with discharge planners and case managers at four community hospitals located in the area. The transition coaches currently screen seniors at discharge for participation in the Healthy Connections program. At the moment, patients discharged with one of five diagnoses (COPD, CHF, MI, Pneumonia, post knee/hip) are the focus of the program. Seniors who participate are visited by the transition coach within 48-72 hours post discharge. The emphasis of the visits is to empower patients and caregivers to take an active role in their treatment plan and to educate them on community supports and services available to help them stay healthy at home. During visits, the transition coaches address five primary elements: follow-up appointments, medication management, health safety plans, transportation, and linkage to community resources. In the year plus that the program has been in place, the transition coaches have identified *lack of knowledge with how to connect with community resources* and *medication management issues* as the two most common types of problems identified among participants. The transition coaches are adept at connecting patients and caregivers to community resources; however, they note that it is often difficult for them to recognize and assess complex medication issues at a depth necessary to prevent potential problems. As such,

improving medication management (safety, effectiveness, adherence, education, communication) has been identified as a quality initiative for the program.

In two small pilot projects we conducted between 2010-12 at a community-based teaching hospital in central Illinois, it was found that 96% of seniors ≥ 65 years of age taking five or more medications at discharge had at least one, and as many as eight, medication-related problem identified during a post-discharge home visit by a pharmacist (mean of approximately four problems/patient). Communication of problems to the primary care provider resulted in a change in therapy/acceptance of recommendations in $>90\%$ of occurrences and all patients receiving a pharmacist home visit rated the visit as 'improving the overall quality of care provided to them'. The most common types of problems identified (utilizing the Medication Discrepancy Tool©) included: 'discharge instructions incomplete or inaccurate' and 'conflicting information from different sources'. Although not significant due to small numbers, patients receiving a pharmacist home visit had a lower 30-day readmission rate than those who did not receive a visit (14% vs 27%, respectively). Detailed evaluation of all of the individual medication-related problems identified among the participants revealed that, under perfect circumstances, only 68% of the problems could have feasibly been recognized and prevented during hospital-based medication reconciliation and education. This suggests that, at least, one-third of medication-related problems would go undetected without post-discharge follow-up.

SSP partners with Telligen, the Quality Improvement Organization for the Centers of Medicaid and Medicare Services in Madison and St. Clair County, with the mission of building and sustaining a community coalition to improve transitions of care for Medicare beneficiaries in the service region. Telligen works with SSP and the hospitals to provide readmission data that helps to identify strengths, challenges and trends with the focus on preventing avoidable readmissions and overall improved patient care. For example, data obtained from Telligen showed that 30 day readmission rates for VTE discharges for two of the participating hospitals during the time period of November 2013 to November 2014 were 28.2% (20/71) and 35.8% (38/106). The 30 day readmission rates specifically for PE were higher in both hospitals (34.2% and 43.3%) relative to readmission rates for DVT (20% and 26.1%). These readmission rates are higher when compared to the conditions that are tracked for penalties (CHF, COPD, MI, hip/knee, and pneumonia), which trend between 17 and 22%, depending on the specific condition and hospital.

The primary audiences to benefit from this project include the participants, who stand to benefit from improved quality of care; the hospitals, who also stand to benefit from demonstrated improvements in quality of care; Senior Services Plus, who stands to benefit through demonstration of benefit to the hospitals and community with the implementation of their provided services; and also SIUE School of Pharmacy, through demonstration of the benefits pharmacists contribute to patient care and quality improvement.

DESIGN and METHODS

The project is a prospective study designed to complement/enhance the medication management aspect of the existing SSP Healthy Connections program by integrating a clinical pharmacist into the post-discharge home visits for seniors discharged with VTE.

Study Population

Currently, the SSP transition coaches, working with hospital discharge planners and case managers, screen older patients who are being discharged with one of five diagnoses (COPD, CHF, post knee/hip replacement, pneumonia, and MI) from each of the four participating hospitals. With the implementation of this project, the transition coaches will work with hospital staff to also screen for patients ≥ 60 years of age discharged with a diagnosis of DVT or PE for inclusion in the study. The target population will be: patients ≥ 60 years of age; discharge diagnosis of DVT/PE; residence in SSP catchment area of Madison and St. Clair counties, and not discharged to hospice/terminal diagnosis. Patients will be enrolled into one of three groups, based on the hospital from which they are discharged.

Study Sites

The four hospitals participating in the project include: Alton Memorial Hospital, OSF St. Anthony's Medical Center, Belleville Memorial Hospital, and Gateway Regional Medical Center. One of the transition coaches currently serves both Alton Memorial Hospital and OSF St. Anthony's Medical Center. These two facilities will serve as control facilities for the study. For one of the two control facilities (to be randomly assigned), study subjects will be identified by VTE discharge diagnosis, enrolled in the study, but will not receive a home visit (No Visit Group). For the second control facility, study subjects will be identified by VTE discharge diagnosis, enrolled in the study, and will receive a visit by the transition coach only (Coach Visit Group). For the two intervention facilities (Belleville Memorial Hospital and Gateway Regional Medical Center), study subjects will be identified by VTE discharge diagnosis, enrolled in the study, and will receive a home visit from the transition coach and the pharmacist (Coach + Pharmacist Visit Group) Each of the two intervention facilities has a separate transition coach assigned to it. Participants will be enrolled into the study only if they agree and are able to provide informed consent. The transition coaches, with assistance from the Project Coordinator, will be responsible for obtaining participant informed consent.

Study Enrollment

The target enrollment will be 60 patients (4 patients/month) from each of the two control facilities, and 120 patients (8 patients/month) combined from the two intervention facilities. The enrollment numbers were established as attainable targets for an 18-month intervention from estimates of discharges from the participating facilities. If enrollment proves to be slow, we will consider reducing the lower age limit for participation to ≥ 55 years. Additionally, both Senior Services Plus and SIUE have an existing relationship with another community hospital in close proximity to the planned region that could be considered for participation, if it becomes necessary.

Study Intervention

Once enrolled, the transition coaches (for the Coach Visit Group and the Coach + Pharmacist Visit Group) will be responsible for scheduling home visits to occur within 48-72 hours following discharge. The transition coaches will also be responsible for coordinating home visits with the pharmacist (for the Coach + Pharmacist Visit Group). During home visits, transition coaches will continue to focus on the five points of emphasis of the Healthy Connections program: follow-up appointments, medication management, health safety plans, transportation, and linkage to community resources. The pharmacist, in addition to communicating with the transition coach, will be responsible for communicating with hospital-based providers, evaluating medication management and identifying potential medication-related problems using the MDT, communicating medication-related concerns to the patient/caregiver and primary care physician to resolve problems, and ensuring appropriate follow-up care.

Data Collection

Data collection for general patient demographic variables will occur at the time of enrollment/consent or during the home visit and will be collected by the transition coach, with assistance from the project coordinator, when necessary. All medication-related problems identified (whether by the social worker or the pharmacist) will be documented using the Medication Discrepancy Tool© (Appendix A), including details of how and with whom the problems were resolved. The medication list and other related data will be collected at the time of the home visit, either by the transition coach or the pharmacist, depending on the group. Data regarding outcomes (recurrence, bleeding, readmissions) will be obtained from each hospital and/or through Telligen, which provides data directly to SSP regarding readmissions. Outcome data will be confirmed by follow-up phone calls to patients at intervals post-discharge. Satisfaction surveys will be left with patients following the pharmacist visit (patients in the Coach + Pharmacist visit group) with a pre-paid envelope to return the survey.

PLANNED EVALUATION DESIGN

Study Design and Measures

This is a prospective study with a quasi-experimental design. Participants will be in one of three groups, no visit, coach-only visit, or coach+ pharmacist visit. Group assignment will be determined by the hospital from which they are discharged. As such, all the patients in each visit group will have the same transition coach. This design was chosen to minimize the risk of contamination of the study intervention into the control groups. Data to be collected for the project is outlined below:

Study Data to be Collected

Variables	Categories	Source
Patient age	60+, continuous variable	Patient
Patient gender	Male/female	Patient
Patient race	Caucasian, African American, Hispanic, etc	Patient
Patient marital status	Married, divorced, widowed, single	Patient

Patient primary language	English, Spanish, etc	Patient
Patient health insurance	Private, Public, Uninsured	Patient
Primary discharge diagnosis	ICD-9 codes DVT or PE	Hospital
Etiology of VTE	Surgical; non-surgical	Hospital
Known active malignancy	Y/N	Patient
Hospital characteristics	Inpatient transition services offered; pharmacist educates at discharge, etc	Hospital
Home visit group	No visit, coach only, coach + R.Ph.	Hospital
Medication-related problems	Y/N, Numbers, MDT data*	Coach/Pharmacist
Medications names and total number of meds at discharge	Individual medications; number - continuous	Hospital discharge instructions to patient
Charlson comorbidity score	continuous	Patient/Hospital
Anticoagulants prescribed at discharge; specific drug and category	warfarin, heparin, enoxaparin, apixaban, dabigatran, rivaroxaban; category: VKA or NOAC	Hospital discharge instructions to patient
Recurrence of VTE within 14, 30, 60 days	Y/N; ICD-9 codes; ER utilization Y/N; Hospital readmission Y/N	Hospital; patient
Bleeding complications within 14, 30, 60 days	Y/N; ICD-9 codes; minor/major, MD visit, ER visit, hospital readmission;	Hospital; patient
Patient satisfaction with	Survey scale 1 (not at all satisfied) to 10 (highly satisfied).	Patient
Days to first primary care f/u visit	Days, continuous	Patient

Data Analysis

Objective 1: To evaluate the numbers of and types of medication-related problems identified during transition coach only visits (existing program) as compared with transition coach plus pharmacist visits (intervention). All medication-related problems that are identified, whether by the coaches or by the pharmacist, will be documented using the Medication Discrepancy Tool© (Appendix A). The data manager will create a scannable data collection form to facilitate ease and accuracy of data collection for the categorical components of this data element. Any text descriptions that accompany the MDT will also be maintained in the database. The MDT data will be summarized by group: 1) coach-ONLY 2) coach+pharmacist using descriptive statistics, including problem resolution rates. The mean number of medication related problems will be compared between the coach-only visit group and the coach+pharmacist visit group with an independent t-test. An ANCOVA model will be utilized to compare between the groups after adjusting for relevant covariates, such as patient demographics and hospital or patient characteristics.

Objective 2: To evaluate the impact of the intervention on VTE outcomes, including VTE recurrence rates, bleeding complication rates, and all-cause hospital readmission rates at 14,

30, and 60-days comparing patients with transition coach plus pharmacist home visit, transition coach only home visit, and no home visit. Data will be collected from hospital sources (including Telligen data) and also confirmed by patient follow-up phone calls to determine if any of the above outcomes have occurred. Bleeding complications will be categorized as minor bleeding or major bleeding, VTE recurrence rates and all-cause hospital readmission rates will be categorized into yes or no. All three measures will be calculated for within 14, 30, and 60 days. Minor bleeding will be defined as bleeding events that require a health care visit (primary physician or emergency room visit only) and major bleeding will be defined as bleeding events that require hospitalization. Descriptive statistics will be calculated for each outcome for the three groups: 1) no home visit 2) coach ONLY 3) coach+pharmacist. Comparisons between the groups will be done using chi-squared tests of independence. Logistic regression models will be utilized to look at the association between group and each outcome (VTE recurrence, bleeding and all-cause hospital readmission) after adjusting for patient demographics and hospital characteristics.

Objective 3: To compare the rates of VTE outcomes (as in Objective 2) for patients treated with vitamin K antagonists (\pm heparin/LMWH) versus patients treated with novel oral anticoagulants. Descriptive statistics will be computed for each VTE outcome for the groups: 1) vitamin K antagonist 2) novel oral anticoagulant. Comparisons between the groups will be done using Chi-Square Test or Fisher's Exact Test, depending on the sample size. Logistic regression will be used to look at the association between the type of anticoagulant used and each outcome (VTE recurrence, bleeding and all-cause hospital readmission) after adjusting for patient demographics and hospital. Additionally, in order to identify if a home visit from a coach and a pharmacist impacts the VTE outcomes regardless of the type of medication used, we will also perform logistic regression controlling for the type of anticoagulant medication, patient demographics and hospital characteristics.

Objective 4: To evaluate patient satisfaction with post-discharge home visits by a pharmacist to older adults discharge with VTE. (EXPLORATORY)

An eleven item survey will be used to assess patient satisfaction with pharmacist-provided home visits (Appendix B). The survey items were modified from a previously published survey developed to assess satisfaction with pharmacist-conducted home visits. The results of the surveys will be summarized using descriptive statistics.

Quantification of Change

Relative to medication-related problems identified during home visits, we anticipate that the pharmacist will find significantly more medication related problems as compared to the transition coaches. We also expect to find differences in the categories of medication-related problems identified when comparing the groups. Additionally, we anticipate the numbers of and types of medication-related problems specific to anticoagulant medications will differ between the visit groups.

For the VTE-related outcomes (recurrence, bleeding, readmission rates), we anticipate that the rates will be lower in the coach + pharmacist visit group, when compared to the no visit group

or the coach only visit group; however, we do not anticipate that this difference will be statistically different. Based on our calculations of sample size needed to achieve modest, but clinically important, reductions in these outcomes, a much larger sample size (400-500 patients per group) would be needed to demonstrate statistical significance. Similarly, for the evaluation of outcomes based on the type of anticoagulant medication used, we anticipate that we may find lower rates of the outcomes among participant who are treated with novel oral anticoagulants; however, the sample size will likely be insufficient to demonstrate statistical significance (particularly for the within group analyses). From estimates of the number of discharges for VTE from the four hospitals over a two-year study (71-106 patients per year/hospital), we do not have the ability to substantially increase the sample size to adequately power these analyses. As such, these analyses will be exploratory in nature.

RESULTS

The study was halted and we were not able to recruit an adequate number of individuals to analyze data.

PUBLICATIONS and PRODUCTS

No publications or products were developed as a

ORGANIZATIONAL DETAIL

Leadership and Organizational Capability

Southern Illinois University Edwardsville (SIUE)

SIUE is a Masters-granting public university located in southwestern Illinois with a mission to serve the people of central and southern Illinois. SIUE enrollment is \approx 14,000 students, with approximately 20% enrolled in graduate and professional programs. SIUE houses professional programs in Dentistry, Nursing, and Pharmacy and maintains close relationships with Southern Illinois University School of Medicine, which is part of the SIU system, and the School of Medicine's Center for Clinical Research. The mission of the School of Pharmacy is to prepare pharmacy professionals, scholars and leaders to improve the health and well-being of the region and beyond. Since its inception, the School of Pharmacy has striven to advance pharmacy practice and research to impact patient care in central and southern Illinois.

The leadership team at SIUE will include: Dr. Mark Ruscin, Pharm.D., Professor and Chair of the Department of Pharmacy Practice at SIUE, will serve as principal investigator and director of the project. Dr. Ruscin has 20 years of clinical experience in geriatric patient care and has been a principal investigator or co-investigator on several research projects, including large NIH and

AHRQ grants. Dr. Chris Lynch, Pharm.D., Professor and Director of Clinical Programs at SIUE will serve as a co-investigator and clinical coordinator for the project. Dr. Lynch also has nearly 20 years of experience as a clinical pharmacist providing care to patients, most recently providing home visits for home-bound seniors in affiliation with Southwestern Illinois Visiting Nurses Association. He also has experience as a co-investigator on several clinical research projects. Dr. Maithili Deshpande, Ph.D., Assistant Professor at SIUE and will serve as a co-investigator and data coordinator for the project. Dr. Deshpande has expertise in outcomes and health services research and has strong methodological and analytical skills. She holds an adjunct faculty appointment within the Department of Internal Medicine at SIU School of Medicine and maintains an office with the School of Medicine's Center for Clinical Research, providing her with access to the resources of the Center.

Senior Services Plus (SSP)

SSP, headquartered in Alton, IL is a non-profit 501 C-3 United Way agency established in 1973 to help enrich the lives of older adults through programs and services that encourage independent living through community care programs, meal programs, community outreach, and numerous other programs in largely rural parts of southwestern Illinois. SSP's mission is to provide opportunities and resources to individuals as they age. In 2014, SSP provided direct services for > 23,000 individuals, most of whom were aged 55 years and older. In January 2014, the Healthy Connections care transitions program was started through SSP to support seniors with successful transition services from the hospital to home in this part of the state. The program has experienced remarkable growth in a short amount of time and currently SSP care transitions staff are in 4 hospitals in Madison and St. Clair counties assisting in discharge planning and follow-up care for seniors as they transition home. SSP also partners with Telligen, the Quality Improvement Organization for the Centers of Medicaid and Medicare Services in Madison and St. Clair County with the mission of building and sustaining a community coalition focusing on improving transitions of care for Medicare beneficiaries in our service region. Telligen works with SSP and the hospitals to provide readmission data that helps to identify strengths, challenges and trends with the focus on preventing avoidable readmissions and overall improved patient care. The leadership team from SSP will include: Hannah Tolan, MS, SSP Lead Transition Coach, and John Becker, SSP Executive Director. Both Ms. Tolan and Mr. Becker have long-standing working relationships with the partnering hospitals through the existing program, which will greatly facilitate the implementation and execution of the project.