

An Integrated Model of Care Management, Innovative Technology, and Pharmacy Solutions to Improve Transitions of Care for Patients with Acute Venous Thromboembolic Disease

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Abstract

Patients diagnosed with acute venous thromboembolic disease (VTE) are at high risk for complications during post-discharge transitions of care (TOC). The primary goal of this project is to develop and validate a novel **VTE Transitions of Care Bundle** that will build on existing care management strategies by integrating innovative and interactive patient-facing technology and telemedicine tools into care management and post-discharge patient care. This project will utilize an innovative, cloud-based, patient-centered smart phone app to collect patient-generated data and facilitate communication with the care team. Data from this app and other bundle components will be aggregated in an EMR-integrated **VTE Electronic Dashboard** to allow for real time monitoring of medication adherence, patient-reported symptoms, and appropriate follow-up. This project will optimize inpatient care by enforcing evidence-based practices for treatment of acute VTE, facilitating safe post-hospitalization TOC by educating patients and engaging them in their care, improving medication adherence, and promoting shared accountability between the patient and the care team. This project will target inpatients on the medical service with a primary or secondary diagnosis of acute VTE. The impact of the bundle on acute VTE care, recurrent VTE and bleeding complications during post-discharge TOC, cost, and utilization will be evaluated.

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OVERALL GOAL AND OBJECTIVES

Patients diagnosed with acute venous thromboembolic disease (VTE) are at high risk for complications during post-discharge transitions of care (TOC). The primary goal of this project is to develop and validate an innovative **VTE Transitions of Care Bundle** that will build on existing care management strategies by integrating innovative and interactive patient-facing technology and telemedicine tools, and will utilize an EMR-integrated **VTE Electronic Dashboard** to allow for concurrent patient data collection and tracking. The project will optimize inpatient care by enforcing evidence-based practices and facilitating safe post-hospitalization TOC by educating patients and engaging them in their care, improving medication adherence, and promoting shared accountability between the patient and the care team.¹ The impact of the bundle on adherence to acute VTE care best practices, patient safety during post-discharge TOC, cost, and utilization will be evaluated. The goals of this project are consistent with Mount Sinai Hospital's dedication to improving transitions of care, implementing novel patient safety and care management programs,² and providing care in innovative settings.³⁻⁸ The **VTE Transitions of Care Bundle** and **VTE Electronic Dashboard** align with the Joint Commission's focus on the development and adoption of novel evidence-based approaches to improve the safety and effectiveness of acute patient care and movement from one care setting to another.

Objectives:

- 1)** Develop and implement a novel **VTE Transitions of Care Bundle** that includes:
 - a. An acute VTE medication order set in Epic, a national inpatient and outpatient integrated electronic medical record used at Mount Sinai Hospital.
 - b. A bedside visit by the **VTE Transitions Navigator**, a dedicated care manager who will be hired for this project.
 - c. An Epic EMR-linked **HealthPROMISE** app⁹, an innovative and patient-centered smart phone app developed at Mount Sinai that will be customized for VTE.
 - d. An enhanced discharge summary using the **Safe Transitions for Anticoagulation Report (STAR)** to address the need for clear communication of anticoagulant dosing to outpatient providers to minimize the risk of adverse drug events.
 - e. A **VTE Electronic Dashboard** which will aggregate data into Epic from each bundle component and allow the transitions navigator and care providers to monitor treatment adherence, medication utilization, and patient-reported symptoms in real time.
- 2)** Reduce hospital readmissions, emergency department visits, and recurrent VTE and bleeding complications, and decrease cost in the post-discharge period.
- 3)** Monitor the rate and type of post-discharge follow-up, patient engagement and medication adherence.
- 4)** Validate the role of patient-facing technology and telemedicine as an adjunct to existing care management models for patients with VTE.

- 5) Identify the optimal caseload for the transitions navigator in a risk stratified TOC management model using novel technological modalities.

These key objectives are intended to address the established need of improving TOC and outpatient care management in this population to address several identified practice gaps, including readmissions, complications (i.e., recurrent VTE and bleeding), and utilization and cost of post-discharge care. The TOC Navigator will utilize the VTE Electronic Dashboard to closely monitor the project cohort and interact with the patient through the HealthPROMISE app. The VTE Transitions of Care Bundle will greatly improve inpatient VTE care and will also enhance outpatient care by facilitating access to the clinical team via the transitions navigator and HealthPROMISE.

The proposed project uses innovative technological and collaborative approaches that include the electronic integration of VTE-specific patient-facing technology and pharmacy collaboration to facilitate care management. This approach is novel and has cost-effective and sustainability potential in comparison to traditional care management models.¹ The proposed project also builds on several ongoing innovative programs at Mount Sinai Hospital to reduce replication of efforts and to leverage and integrate existing resources, including: the HealthPROMISE app,⁹ the well-established Mount Sinai Visiting Doctor's Program, Mount Sinai's collaboration with a large national pharmacy retail chain, the existing Preventable Admissions Care Team (PACT) program,² the STAR initiative,¹³ as well as existing care management initiatives at the outpatient clinical sites. The proposed project will provide better care for patients without placing additional time constraints on healthcare providers through the use of patient-facing technology and the dedicated transitions navigator.

TECHNICAL APPROACH

Assessment of Need in Target Area: Mount Sinai Hospital is an urban academic medical center serving a socio-economically diverse population. In 2014 there were 472 admissions coded with a diagnosis of acute VTE from the Department of Medicine comprising 446 unique patients. These patients were discharged to: home or self-care (39%), home with home care services (29%), and to skilled nursing and rehabilitation facilities (18%). VTE discharge drug utilization included: novel oral anticoagulants (30%), warfarin only (24%), enoxaparin and warfarin (18%), and enoxaparin only (16%). The average inpatient cost per case was \$35,836 (median: \$16,728).¹⁰ Outpatient metrics demonstrate opportunities for improved TOC in this population and identify several practice gaps. The all-cause 30-day readmission rate in 2014 was 16% (Observed/Expected = 1.14) with an overall complication rate O/E of 2.7 (O/E based on top quartile performance).¹⁰ The overall rate of post-discharge recurrent VTE and bleeding complications was 12% (8% and 4%, respectively). Acute VTE patients were among the highest utilizers of post-discharge care with 1,483 ED visits and 3,552 admissions per 1,000 patients. The average total outpatient cost was \$106,000 (median: \$74,880), with a drug cost of \$1,449 (median: \$750).¹¹

All data and gap analyses were obtained from robust data management platforms used at Mount Sinai to identify utilization, cost, efficiency and quality opportunities.^{10, 11} Premier Quality Advisor is a web-based product that compiles administrative and clinical data to connect quality, safety and cost.¹⁰ Crimson Continuum of Care is a web-based software solution that evaluates a broad range of measures to provide physician performance analysis as well as patient-level data related to quality, utilization, and cost.¹¹

Acute VTE patients will be the direct beneficiaries of this innovative care management project. Other patients with acute diseases that require care management may also benefit from this novel TOC model in the future. The TOC strategies validated by this project can serve as a model for hospitals and health systems in planning system-wide TOC programs for VTE and other high-risk diagnoses.

The proposed project will meet the goal of developing approaches that have the capacity to improve the safety and effectiveness of TOC by actively monitoring and tracking the VTE patient cohort using a novel technology-based adjunct to traditional care management strategies. This approach has potential to improve medication adherence and ease of communication with healthcare providers, thus decreasing complication rates and engaging patients in their care. This care management model also has potential to decrease hospital readmission rates through more efficient triage of acute patient complaints and improved ease of access to the outpatient care team.

PROJECT DESIGN AND METHODS

Patient identification: The proposed project will utilize a prospective cohort design. Patients admitted to the inpatient medicine service with a new diagnosis of VTE will be eligible for enrollment. Patients who develop VTE as a complication of hospitalization will also be eligible. Patients will be identified through an EMR-driven surveillance algorithm that will be developed specifically for this project.

Risk stratification: Enrolled patients will be risk stratified into low-risk, intermediate (or rising-risk), and high-risk groups for readmission and complications using the Healthcare Hotspotting technique, an established data-driven method that uses administrative datasets to identify patients or sub-populations with extreme utilization.¹² The Healthcare Hotspotting technique was developed by The Camden Coalition to gain a better understanding of the patterns of healthcare utilization. Using hospital claims data as well as admission/discharge/transfer (ADT) data from the health system, this technique allows for real time population health surveillance and tracking. The Camden Coalition model utilizes daily reports to identify individuals currently admitted to the hospital who are eligible for one of many community-based care management interventions; eligible individuals have had two or more inpatient admissions in the past six months and have high-risk components of their medical and social histories. This methodology will be validated for use with the VTE patient population at Mount Sinai. Specific aspects of the proposed project bundle will be triggered based on individual utilization patterns and risk level identified using this model.

Overview of the VTE Transitions of Care Bundle elements: Diagnosis of VTE will trigger the activation of the **VTE Transitions of Care Bundle** with several key features that are described in detail below: **1)** A dedicated **VTE order set** with suggested anticoagulant dosing and bridging guidelines; **2)** Automatic notification of the **VTE transitions navigator**, a dedicated care manager who will enroll, track, and assist in management of patients based on their assigned risk group; **3)** The **HealthPROMISE** app with VTE-specific features such as daily medication reminders, a patient-centric medication log, a call button linked to the post-discharge telephone hotline, telemedicine features allowing live consultation with the care team, and educational information regarding VTE treatment and medications;⁹ **4)** An enhanced discharge summary to accurately reflect the expected VTE treatment plan, and best practice alerts (Epic's medical logic modules that provide up-to-date local situational awareness) at discharge to ensure proper medication reconciliation modeled after the **Safe Transitions Anticoagulation Report** (STAR) developed at Mount Sinai.¹³ Data from each modality will be integrated into the **VTE Electronic Dashboard** and reviewed by the care team in real time. The dashboard will allow providers and the transitions navigator to monitor treatment adherence, medication utilization, and patient-reported symptoms from the HealthPROMISE app.⁹ In addition, real time prescription utilization data from a newly established collaboration with a large national pharmacy retail chain will also enable medication monitoring and adherence via claims surveillance and bedside and home delivery of anticoagulants.

VTE order set: During the first three months of the project, a VTE order set will be developed and implemented and will include enhancements to the existing inpatient EMR orders for anticoagulants utilized for the treatment of acute VTE. These order sets will ensure adherence to best practices and dosing guidelines. Specifically, activation of the order set will provide both bridging and dosing guidelines for commonly used inpatient anticoagulants and display relevant laboratory data. The order set will also be linked to the Safe Transitions Anticoagulation Report (STAR) described below.

Patient enrollment and Transitions Navigator bedside visit: Once a patient is identified as being eligible for the proposed project, the VTE Transitions Navigator will reach out to the individual at the hospital bedside. At this time, the transitions navigator will introduce the patient to the project and obtain informed consent. The transitions navigator will work in conjunction with the inpatient primary clinical team once the anticipated discharge treatment plan is formulated in order to identify potential barriers to care, such as medication cost and availability, transportation issues, and other psychosocial barriers to care. The transitions navigator will also engage the primary clinical team in bedside VTE education with the patient and their family or caregivers. In addition, the transitions navigator will assist the installation and use of the HealthPROMISE app during the inpatient admission and will educate the patient and local family members on how to log medication use and communicate electronically with the team after discharge.⁹

The transitions navigator will also conduct a bedside visit on the day of discharge for rising and high risk patients. During the discharge visit, the transitions navigator will confirm the discharge

anticoagulation plan with the inpatient clinical team, ensure medications have been delivered to the patient's bedside or are in stock at the local pharmacy (based on the hospital's ongoing collaboration with a large national retail chain), review the post-discharge therapeutic and transition plan with the patient and their family, review how to use the HealthPROMISE app, and schedule follow-up visits and ensure home services are in place, if applicable.

HealthPROMISE App: The HealthPROMISE app is a cloud-based patient-reported outcome and decision support platform developed at the Mount Sinai AppLab and is available for Android and iOS (Apple) at no-cost. Patients will track their medication utilization and symptoms using the app and the transitions navigator will visualize and review this data in real time via the EMR-integrated dashboard, to allow ongoing monitoring of VTE patients in the project cohort. The HealthPROMISE app will be customized for VTE to address unique challenges for this patient population, and will include patient education materials (on disease information, recurrence risk, medication information, care management, patient and caregiver support), medication adherence support (through periodic reminders and a patient-facing dose log), symptom-tracking for post-discharge complication surveillance (including bleeding complications), and diet monitoring for patients on warfarin (i.e., foods containing vitamin K). The HealthPROMISE app will also have built-in technologies to facilitate communication between the patient, providers, and the transitions navigator, such as secure and HIPAA compliant texting, chat, and video calling capabilities. The transitions navigator will ensure all clinical data from the app reaches the appropriate clinician in a timely manner.

Safe Transitions Anticoagulation Report (STAR) discharge summary: The STAR report was designed at Mount Sinai as a structured, efficient method to report inpatient use of anticoagulant medications and the anticipated post-discharge anticoagulation plan to outpatient providers. The report addresses a need for clear communication of anticoagulant dosing to outpatient providers and aims to minimize the risk of adverse drug events related to anticoagulation during TOC. STAR was developed for patients discharged on warfarin, and includes daily medication doses and INR values for seven days post-discharge and lists bridging anticoagulation medications, if applicable. The report is automatically created in the EMR system at the time of discharge and is included in the discharge summary as well as the printed materials provided to the patient. The proposed project will build upon this report to include all anticoagulants for VTE to reflect the diversity of medications prescribed for this patient population. Patients enrolled in the project will benefit from the integration of this report into their discharge summary for use during the transition from inpatient to outpatient care. The STAR report will also serve as additional educational material for the patient and their family.

VTE Electronic Dashboard: The VTE Electronic Dashboard will provide a centralized and EMR-integrated visual tracking system for patients with acute VTE enrolled in the project. The VTE Transitions Navigator and outpatient providers will use this dashboard to view patient-generated data, notifications/alerts, and messaging from HealthPROMISE, prescription utilization data from our health system's ongoing pharmacy collaboration, as well as demographic and outpatient appointment data. This dashboard will facilitate ease of patient monitoring and identification of patients in need of follow-up.

Specific Elements of the VTE Bundle stratified by risk level: For all VTE patients, once the VTE Transitions of Care Bundle is triggered, providers will order anticoagulants through the dedicated order sets. All enrolled patients will also benefit from care coordination through the transitions navigator and will utilize the HealthPROMISE app to communicate with the care team. Patients who do not wish to use technology to assist in their care will receive all other appropriate elements of the bundle based on their risk group with the assistance of the transitions navigator (Table 1). Patients who choose not to enroll in the proposed project will continue to be followed by the research team and will receive the current standard of care.

Low-risk patients (approximately 60-80% of the project cohort) will interact with the transitions navigator post-discharge primarily through the HealthPROMISE app telemedicine functionality. These patients will also track medication adherence, new symptoms, and diet through the app. To promote shared provider-patient accountability for post-discharge care, a telemedicine visit or phone call via the HealthPROMISE app will be arranged if the patient does not interact with the care team or log medication use as planned.

For patients at rising risk (15-30% of the project cohort) utilization of the HealthPROMISE app will be similar to the use in the low-risk group. However, given the increased risk for post-discharge readmissions and complications in this group, the transitions navigator will also schedule planned weekly check-in telemedicine visits, which will include a review of proper medication use and identification of all medications in the patient's home; this list will be communicated to the patient's primary outpatient provider for reconciliation and surveillance for potential drug interactions or redundant medications. In addition, the transitions navigator will check-in with the patient after each follow-up visit and will verify the date and time of the next visit. The transitions navigator will also offer to be "present" electronically for follow-up visits via the app's telemedicine functionality, to assist the patient in following the clinical plan. Regular check-ins between the patient and transitions navigator will improve medication adherence and decrease the likelihood of readmission.

The highest level of care management will be reserved for patients at highest risk (5-10% of the project cohort). For these patients, the transitions navigator will be present at all post-discharge visits (if allowed by the patient). They will also engage in twice weekly telephone or app-based check-ins with the patient.

The transitions navigator will also schedule as needed home visits through the existing Visiting Doctors Program for homebound patients,³⁻⁸ and as-needed outpatient visits for ambulatory patients. For all patient-initiated contacts, the transitions navigator will triage the call as clinical or nonclinical. All clinical issues (e.g., pain, medication questions) will be directed to the appropriate care provider as outlined below. All logistical questions (e.g., date/time of follow-up appointment) will be handled by the transitions navigator. All patients in the project cohort will be followed for 90 days post-discharge. Patients that require ongoing care management services will be enrolled in an appropriate existing care management program.

Table 1. Summary of TOC Bundle Elements Stratified by Risk			
<i>Element</i>	<i>Low Risk</i>	<i>Rising Risk</i>	<i>High Risk</i>
VTE order set	x	x	x
TOC Transitions navigator	x	x	x
HealthPROMISE app – medication and diet logging	x	x	x
STAR discharge summary	x	x	x
Weekly check-in by navigator via app or telephone		x	x
Electronic presence of navigator at post-discharge appointments (if desired by patient)		x	x
Transitions navigator physically present at all post-discharge visits (if desired by patient)			x
Twice weekly check-in by navigator via app or telephone			x

Outpatient and transitions navigator workplan: The proposed project leverages existing resources at Mount Sinai so that there is no replication of efforts. Workplans for the integration of the proposed TOC program into each of the existing programs are outlined in detail below.

Mount Sinai Doctors Faculty Practice Associates (FPA): The physician and nursing staff at the FPA has a comprehensive electronic system for tracking and managing patients on anticoagulants. For the project cohort, the transitions navigator will communicate electronically with the FPA clinical staff regarding follow-up visits and any outstanding clinical care issues via the internal messaging system in Epic. This communication system is how the nurses and physicians at FPA currently communicate with each other to ensure timely care management and follow-up. The transitions navigator will remain part of the communication thread to allow facilitation of any medication changes, diagnostic testing, or patient follow-up for patients in the project cohort. Specifically, the transitions navigator will address any cost, transportation, or psychosocial barriers and facilitate the clinical plan decided by the treatment team and communicate with the

patient via HealthPROMISE or by phone. For patients already enrolled in care management programs, the transitions navigator will collaborate with the care team and ensure adherence to the VTE treatment plan.

Mount Sinai Internal Medicine Associates (IMA): The Mount Sinai Internal Medicine Associates is an attending physician and resident integrated practice. IMA has a similar electronic system as the FPA practice for tracking patient calls and clinical issues. The project transitions navigator will interact electronically with the clinical care team at IMA in a similar workflow as in the FPA. The transitions navigator will facilitate implementation of the care plan and serve as the primary link between the clinical team and the patient. Similar to the patients enrolled in FPA, the transitions navigator will collaborate with any existing care management services (including PACT, the existing care management program for high-risk patients) and ensure adherence to the VTE treatment plan.

Visiting Doctors: The Mount Sinai Visiting Doctors Program cares for homebound patients who cannot travel to a physician's office for ongoing care. This practice also has a robust existing care management infrastructure. For patients enrolled in the project cohort who have existing Visiting Doctors healthcare providers, the transitions navigator will collaborate with the existing providers and care managers to ensure adherence to the VTE treatment plan and will be available as dictated by the patient's risk level. For patients enrolled in the cohort who are homebound and without a healthcare provider, the VTE navigator will make a referral to the visiting doctors program.

Mount Sinai Urgent Care Center Collaboration: The Mount Sinai Health System has a new collaboration with several local urgent care centers. For patients who reach out to the transitions navigator after normal clinic hours, the transitions navigator will arrange for urgent evaluation in this urgent care setting.

EVALUATION DESIGN

Primary and secondary outcomes will be calculated at 30 and 90 days post-discharge and will be compared to baseline data to determine if the identified practice gaps were addressed. The primary outcome is the composite complication rate comprised of recurrent VTE and major bleeding. Secondary outcomes include 30- and 90-day readmission rates, frequency of emergency department visits, and post-discharge cost. Robust fiscal analysis will compare costs incurred under the current standard of care with those incurred under the proposed project bundle, using a similar patient population pre-intervention as a control. The amount of change expected from this project is to be within the top quartile of hospitals in performance measures in 18 months (expected values) and top decile by 24 months. Process measures will include the proportion of patients who appropriately fill their anticoagulant prescriptions, rate and type of outpatient follow-up, and frequency and type of in-person and electronic patient interaction. The project manager and study staff will collect and analyze data via data management platforms,^{10, 11} patient surveillance via the VTE Electronic Dashboard, and surveys. Patient

satisfaction scores will be obtained from surveys designed for this study and will ascertain the impact of each project component (e.g., the HealthPROMISE app, telemedicine, home visits, etc.). Target audience engagement will be measured by analyzing the usage of the HealthPROMISE app as well as through patient feedback provided on the satisfaction surveys that will be designed specifically for this study. Project findings will be disseminated at national healthcare quality and hospital medicine meetings and will be submitted for publication in a peer-reviewed journal.

DETAILED WORKPLAN AND DELIVERABLES SCHEDULE

The first three months of the project period will be used to obtain baseline data for cost, and to validate the Hotspotting risk stratification methodology for our VTE patient population. During this time, the VTE Bundle and Dashboard will be developed and the HealthPROMISE app will be customized for use with the VTE patient population. Patients will be recruited for participation by the third month and will be followed throughout the project period.

Table 2. Deliverables and Schedule for Completion*	
<i>Deliverable</i>	<i>Scheduled Completion</i>
Patient Hotspotting validation	December 31, 2015
VTE Bundle/Order Set/ Dashboard development	December 31, 2015
HealthPROMISE app customization	December 31, 2015
Patient enrollment	January 1, 2016 - ongoing
Preliminary findings dissemination	October 1, 2016
Patient enrollment and tracking	Ongoing
Final report and dissemination	September 30, 2017
*Schedule assumes October 1, 2015 start date	

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