A. 1. Transition of Care for Patients with Venous Thromboembolism at ATHN Affiliated Sites

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A. 2. Abstract:

This quality improvement project is designed to standardize and optimize the transition of care (TOC) for patients with venous thromboembolism (VTE) from the inpatient to the outpatient setting. It targets neonates, pediatric, adolescent and adult patients receiving care through 14 of the 135 federally-funded hemostasis and thrombosis treatment centers across the United States that are affiliated with the American Thrombosis and Hemostasis Network (ATHN). Five hundred sixty patients who are discharged on anticoagulant medications will be included. TOC quality improvement interventions include a standard transition protocol, written discharge instructions, medication reconciliation and a post discharge follow-up phone call to reinforce instructions. As a result of the TOC interventions, it is expected that patient knowledge of self-management will increase, hospital readmissions will decrease, and patient and health care provider satisfaction will improve. This project will be the first large scale multi-institutional study of its kind to simultaneously implement a uniform standard TOC model at pediatric and adult centers across the United States.

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C. 1. Overall Goals and Objectives

To standardize and optimize the transition of care (TOC) for patients with venous thromboembolism (VTE) from the inpatient to outpatient settings.
Our primary goals are:

1. To improve the transition of care from an inpatient to an outpatient environment in patients with VTE specifically looking at delivery and understanding of instructions regarding anticoagulant therapy at the time of discharge.
2. To evaluate patient/parent understanding of and adherence to anticoagulation therapy related instructions at approximately 1 week after initial VTE diagnosis and prescribing of anticoagulation with vitamin K antagonists (VKA), direct oral anticoagulants (DOACs) and low molecular weight heparins (LMWH).

Our secondary goals are:

1. To quantify the number and characteristics of patients prescribed direct oral anticoagulants (DOACs) compared to other anticoagulant therapies as the initial treatment for VTE and compare their impact on TOC.
2. To explore the appropriateness of the different antithrombotic regimens as prescribed to manage pediatric, adolescent and adult patients with VTE as they move from an acute to outpatient setting.

C. 2. Technical Approach

C. 2a.(i) Current Assessment of Need in Target Area:
The prevalence of VTE in the United States in adults is approximately 900,000 cases per year, and VTE is the third leading cause of cardiovascular morbidity and mortality[1,2]. **The incidence of VTE is rising, as the population is growing older[3]**. Moreover **the incidence of VTE is also increasing in the pediatric and adolescent population** due to improved chronic medical condition survival, an increase in interventions such as placement of central venous catheters, an epidemic of obesity, cardiovascular risk factors and prolonged periods of immobility secondary to the widespread use of electronic devices[4]. Management of VTE in the United States is variable and depends on the type of medical facility, available resources, third party payers, and knowledge of and adherence to published VTE guidelines[2,5]. Currently, the availability of DOACs has dramatically changed the landscape of VTE treatment in the adult population and it is anticipated that with several ongoing pediatric trials, the impact will be similar in children[6-9]. Adult patients are diagnosed and managed by a variety of specialists including community physicians, internists, vascular surgeons, intervention radiologists and hematologists. On the other hand, the pattern of VTE in children is very different with most cases diagnosed in tertiary care centers and managed by pediatric hematologists or co-managed with pediatric cardiologists [10]. Transition of care is a critical component of appropriate health care delivery and studies have shown that gaps in transitioning care can result in

medication errors, adverse outcomes increasing morbidity and mortality. The differing models of management of VTE inherently create potential problems with transitions of care, and specifically, outcomes after VTE.

Current known points of failure for transition of care are:

Patient-related failures:

- Lack of knowledge of common risk factors, signs and symptoms of VTE.
- Lack of knowledge of common signs of anticoagulant–related bleeding.
- Lack of adherence to therapy as prescribed.

Health-care systematic failures:

- Lack of standardized methodology in discharge instructions resulting in inadequate patient/family education in administering anticoagulant medications.
- Patients receiving prescriptions that cannot be filled because medications are not available in the outpatient environment as prescribed (e.g., specific formulations for children) or some anticoagulants are not covered by medical insurance.
- Large numbers of indigent and disadvantaged population who lack appropriate family and home support.

Medical knowledge-based failures:

- Undiagnosed predisposition to VTE recurrence (e.g., underlying thrombophilia) and risk factors for anticoagulant bleeding.
- VTE diagnosis in the younger population is underestimated, under diagnosed and undertreated.

Preliminary data

Several studies have been performed at *individual* medical programs highlighting that specific interventions/ procedures performed during transition of care improve patient outcomes.

Naylor et al demonstrated that specific instructions given by advanced-practice nurses to patients at discharge increased the time to readmissions and decreased the number of medication errors[11].

Dudas et al conducted a randomized study in patients admitted to the medical service who received pharmacy- assistant discharge instructions[12]. Patients were randomized to receive a phone call by a pharmacist 2 days after discharge. During the phone call, pharmacists asked patients about their medications, including whether they obtained and understood how to take them. Fewer patients from the phone call group returned to the emergency department within 30 days (10% phone call vs. 24% no phone call, $P < 0.005$) indicating that a phone call after discharge to review specific instructions is associated with increased patient satisfaction, resolution of medication-related problems, and fewer return visits to the emergency department.

Falconieri et al conducted a similar study in patients with VTE presenting to the emergency department. A specific transition-of-care (TOC) program was developed and implemented for these patients.[13] The TOC program included standardized discharge instructions and a follow-up phone call. After the implementation of this TOC program, there was significant improvement in patient knowledge and satisfaction and all patients were able to receive their anticoagulant therapy appropriately. Additionally there were no anticoagulant-related bleeding events.

With the advent of the DOACs, it is anticipated that the duration of hospital stay will be much shorter[14-16]. Although this decreases overall inpatient health costs, the effect on transition of care with this shorter duration of stay is currently unknown. Thus, although several small studies suggest that specific TOC programs work for optimal outpatient transition of VTE patients, large-scale studies that evaluate current knowledge of transition of care for VTE management are lacking. Additionally, studies that quantify the effect of introduction of DOACs on TOC are currently sparse. There is also a significant deficit in intervention and implementation studies in transition of care of VTE for pediatric thrombosis. To make a meaningful difference to a large number of patients at a national level, there needs to be a coordinated effort from *both* adult and pediatric physicians well versed in treating thrombosis. Thus there is a desperate need for the development of a large infrastructure that is capable of implementing interventions, monitoring the effects of such interventions and sustaining quality improvement over the long term. The American Thrombosis and Hemostasis Network (ATHN), a non-profit organization partnering with 135+ centers treating pediatric and adult populations affected by bleeding and thrombotic disorders, offers such an infrastructure.

C. 2a (ii) Target Population:

Neonates (1-28 days old), pediatric, adolescent and adult patients with a clinical diagnosis of VTE or an underlying inherited or acquired thrombophilia receiving care through one of the ATHN-Affiliated hemostasis and thrombosis centers (HTCs) comprise the target population. Included will be patients discharged on all types of anticoagulant agents. The initial pilot phase will include 14 centers that participate as members of the ATHN Thrombosis Committee and 560 patients (i.e., 20 patients from each center per phase). A secondary target audience are the physicians and nurses at each center responsible for the disease management of the patients during hospitalization.

C. 2b. Project Design and Methods

This project builds on the collaboration, infrastructure systems, data collection and dissemination strategies that have been successful at ATHN-Affiliate HTCs for bleeding disorders. It is estimated that 6,000 patients with VTE are seen at these centers; 3,000 of whom are currently documented in the ATHNdataset as diagnosed with VTE (76%) or thrombophilia (24%). Of the patients in the ATHNdataset, approximately one-quarter are 18 years or younger. Current analysis indicates that these represent approximately 12% of all patients currently followed by hematologists at HTCs[17]. Additionally, it is important to note that, currently, in the United States, ATHN is the only national pediatric registry and the only registry that has combined adult, adolescent and pediatric data on VTE and thrombophilia patients. This has immense implications as ATHN is not only in the unique position to develop

and implement effective algorithms for transition of care of patients with VTE but it can also assess differences in the transition patterns between children, adolescent and adults with VTE and regional variations.

Transition Models employed in this project will be based upon the following:
Project RED (Re-engineered Discharge)
Algorithm for Transitions of Care for Patients with Venous Thromboembolism (designed by ATHN Thrombosis Committee members – provided upon request)

Interventions:
The learning collaborative within and across participating ATHN-Affiliated HTCs will be the organizing structure for training of multi-disciplinary teams, sharing techniques, successes and challenges. Interventions will include:

- Institutional adoption of a transition protocol (Comprehensive Discharge Instructions Module, CDIM), applicable to all participating HTCs.
- Written discharge instructions in language the patient can understand (e.g., tools and educational vehicles such as user-friendly pamphlets and websites to support patient anticoagulation therapy self-management).
- Medication review and reconciliation prior to transition and hematology consultation to ensure that medications are available in the outpatient environment and available to the patient.
- Post discharge (within one week) follow-up phone call to patients to provide reinforcement of the instructions and provide supplemental education if there is not a clear understanding by the patient and/or patient's family.
- (Exploratory) Hematology consultation, short and long term hematology follow-up of VTE patients to assess for: 1) resolution of VTE signs and symptoms, 2) documentation of adverse events and adherence to anticoagulation 3) discussion of the duration of anticoagulation, 4) consideration of thrombophilia screening if appropriate and 5) delineation of periprocedural management and reversal of anticoagulation when necessary.

C. 2c. Evaluation Design

C2c (i) Quality Metrics: The following implementation and outcome measures will assess the delivery and impact of transition interventions. The selected measures, collected pre and post TOC quality intervention, are believed to be meaningful, credible, feasible and timely.

Intervention (Source of Data)	Implementation Measures
Provide Written Discharge Instructions in	% Of patients who receive written instructions prior to discharge about diagnosis, medication plan, problems to

Language Patient Can Understand (Staff documentation)	look out for, and what to do if problems arise
Identify Correct Medication Orders and Management (Hematology orders)	% Medication reconciliation completed (complete medication list communicated when transferred) % Of patients prescribed DOAC's as initial VTE treatment % Of prescriptions that are "modified" prior to discharge
Provide Telephone Reinforcement (Post discharge assessment phone call)	% Of patients/families called within 2 days to 1 week post discharge % Of patients receiving supplemental education to address specific problem areas
Expected Change (Source of Data)	**Outcome Measures**
Knowledge of Self-Management (Post discharge assessment phone call)	% Of patients who accurately recall the reason for their hospital visit post discharge % Of patients who know what symptoms to pay attention to post discharge % Of patients who recall how to take their medication post discharge
Hospital Reutilization (Chart extract)	% Readmissions (within 30 days of discharge) (Exploratory) % Of patients experiencing recurrent thrombotic symptoms, recurrent VTE or a bleeding event following anticoagulation (within 30 days of discharge)
Patient Satisfaction (Patient self-report during post discharge assessment phone call)	% Of patients who reported whether specific discharge information was provided % Of patients who reported that health care providers were responsive to their needs
Health care Provider Satisfaction (Provider survey)	% Of participating providers who find the approach feasible to deliver in routine care % Of participating providers who are more comfortable in appropriate management of these patients

Sources of Data: Staff will document delivery of standard discharge materials, education prior to discharge, completion of medication reconciliation and telephone calls to reinforce instructions. A post-discharge survey administered to patients by phone call from each site's project team will be used to document knowledge of self-management and to evaluate the patient's perceptions of information received and provider responsiveness. Chart extract will be used as the source of readmission information and exploratory clinical measurements. Demographic and disease characteristics will be obtained from chart abstract as described in more detail below to examine outcomes to identify important opportunities for improvement within subgroups of patients. A written survey of providers will assess their satisfaction with the process and identify areas for improvement.

Systems Used to Collect and Analyze Data: ATHN Clinical Manager and Study Manager systems are currently deployed at all ATHN-Affiliated institutions, including all participating centers. The systems will be modified to facilitate the collection and reporting of center-specific and comparative information needed.

Data Collection Methodology: Data will be collected and entered into electronic case report forms (e-CRFs) using the ATHN Study Manager, a secure system under the stewardship of ATHN. Where appropriate, data will be auto-populated from data resident in the HTC's Clinical Manager data and validated by the site prior to submission. Currently, more than 150 unique demographic, clinical and genetic mutation data elements per subject can be captured, codified and standardized in Clinical Manager. Standard pick lists in Clinical Manager will be used wherever possible, and system validations will be applied to help ensure data integrity. For this project, the standard components of the web-based infrastructure will be expanded to capture project-specific information to complement the more standard data fields required. All participating HTCs will have in place a current, executed Data Use and Business Associate Agreement (DUBAA) with ATHN. Site Personnel will be trained with respect to data collection parameters. Detailed instructions will be provided in the Manual of Operations to include specific instructions relating to data and date formats to be used, units of measure, and timing.

Measurements: Social determinants of health and salient clinical data about the patient's thrombotic disorder, its treatment and complications will be extracted from the medical record, reported using ATHN's Clinical Manager and Study Manager systems and used with the quality measures. Data types are shown in the table below. Data collected will include thrombosis site, first or recurrent thrombotic event and if the thrombotic event was provoked or unprovoked. Underlying inherited or acquired thrombophilia; risk factors for VTE including hereditary, anatomic, medical, surgical, drug/environmental, and family history of VTE in 1st and 2nd degree family member and age at thrombosis will be noted. Treatment characteristics will include anti-coagulation regimen(s) prescribed at discharge (oral and/or parenteral), doses, start/stop dates, reversal of anti-coagulation (medication, doses, start/stop), use of inferior vena cava (IVC) filters and use of thrombolytic therapy and/or thrombectomy. Bleeding events (major, clinically significant or minor) will be recorded. The transition approach (e.g., hospital to home) will be documented and the receipt of training at the time of transition. Outcomes will be measured as previously described.

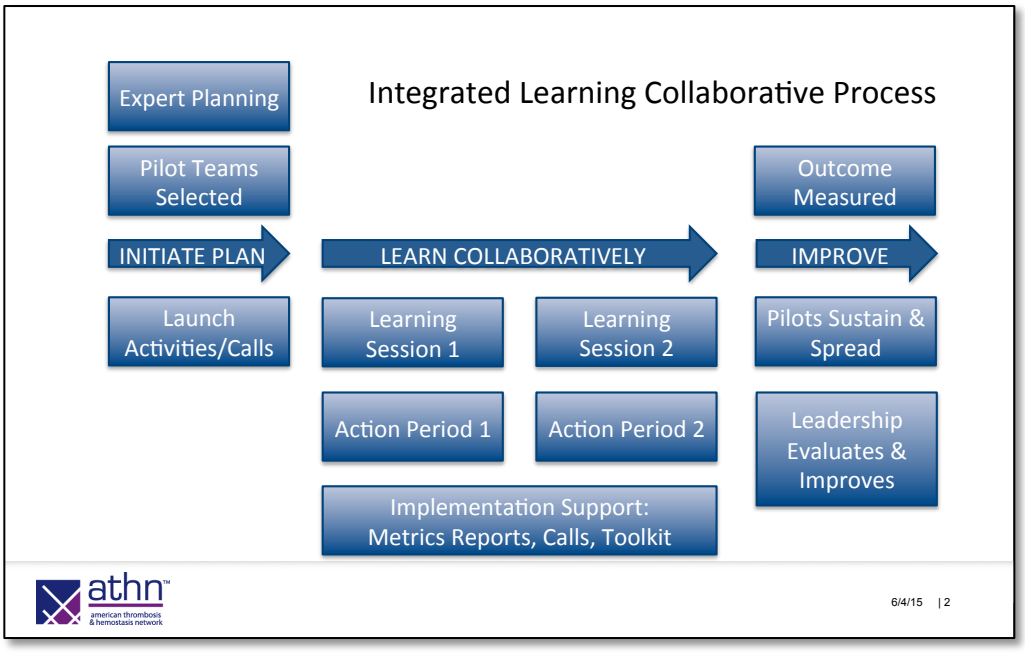
Social Determinants of Health	Disease Characteristics	Treatment Characteristics
Age	Clinical diagnosis	Hospitalization dates
Gender	1st or recurrent event	Use of interventional procedures
Race	Provoked or unprovoked	Anticoagulant agents at discharge
Ethnicity	Thrombosis site	Reversal of anticoagulation
3 digit-zip code	Risk factors for VTE	Bleeding events/other adverse events
Education level	Family history of VTE	TOC approach
Payer type	Thrombophilia	Receipt of training

C.2c. (ii) Expected Change:
Following implementation of the quality improvement intervention, a 10% improvement over baseline would be expected for all measures. To understand the effectiveness of the interventions by patient subgroup, the level of change will be assessed in relation to social determinants of health, disease and treatment characteristics in the table above.

C2c. (iii) Engagement of Target Audience:
In terms of the secondary target audience, a provider questionnaire will be administered to physicians and nurses involved in the medical management of the patient, the treatment plan, transition and post-discharge follow-up to assess feasibility of the transition process as part of routine care and improved comfort in managing patients at transition.

C.2c. (iv) Dissemination of Results:
Methods and outcomes will be shared across 135 ATHN-Affiliated centers at the annual ATHN Data Summit, a 2-day meeting attended by 2-3 individuals from each center, through the ATHN website and the ATHNreport newsletter. These communication vehicles are available to the multi-disciplinary teams at all ATHN-Affiliated treatment centers. The intervention materials will be accessible to centers through a password protected web-based resource center. As the success of the QI processes and materials are confirmed, other centers treating patients with VTE will be assisted in implementing the quality improvement process. Poster and oral presentations will be submitted to Thrombosis and Hemostasis Summit of North America (THSNA), American Society of Hematology (ASH), the International Society of Thrombosis and Hemostasis (ISTH), CHEST and the Partners education program. Publications in high impact medical journals are anticipated as well.

C. 3. Work plan and Deliverables Schedule



The project will be conducted in four phases

1. Start- up phase (Months 1-5):

The ATHN Thrombosis Committee will serve as subject matter experts in planning the quality improvement intervention. This multi-disciplinary committee comprised of physicians (both adult and pediatric), nurses and pharmacists has been involved in establishing the project framework and choosing the objective quality measure(s). Participating sites will form integrated care learning collaborative. Tasks that will be completed during start-up phase are:

- Develop a Comprehensive Discharge Instructions Module (CDIM): We will collect and review existing discharge materials from all participating pilot sites and develop a standardized CDIM. This module will be developed to include specific instructions such as consultation of care management for insurance screening; providing written discharge instructions on signs and symptoms of recurrent VTE; detailed written information about specific anticoagulants, monitoring and side-effects; Instructions for follow-up appointment (to be scheduled with a HTC provider within 30 days) and contact information for the HTC in case that an emergency occurs.
- Develop questionnaires to assess patient's knowledge and satisfaction: The committee will create standardized assessment tools/questionnaires to assess patient's knowledge (Patient Knowledge Questionnaire, PKQ) and patient's satisfaction (Patient Satisfaction Questionnaire, PSQ) based on previous published data[12,13].
- ATHN development team will customize its Clinical Manager/Study Manager system to collect demographic and clinical data related to target patients and quality measures.

2. Pre-Intervention Phase (months 6-11):

2. a HTCs will receive training on data collection for the pre-intervention phase.

2. b Collection of baseline data to assess for knowledge deficit (months 6-11): For the next 5 months, baseline data will be collected for inpatients with VTE who are being discharged to home. Each center will collect data on 20 subjects per phase (baseline and intervention) (total number of subjects 20 x 14 x 2= 560). This will include a post-discharge assessment administered at the time of the first hematology visit (at whatever time it has been scheduled per previous standard for the center), by phone to assess patient knowledge (PKQ) and patient satisfaction by using the PSQ. No standard intervention will be implemented during this phase.

3. QI Intervention phase (months 11-22):

3.a Following the baseline observation period and immediately prior to applying the interventions (CDIM, post-discharge follow-up call, etc.) as planned for a 12 month QI intervention period, participating sites will receive training regarding the baseline findings of gaps, quality improvement processes and the proposed interventions.

3.b. After the training period, participating HTCs will implement CDIM prior to discharge and during a follow-up phone call within 7 days. Each center will collect data on 20 subjects (total number of subjects 20 x 14= 280).The patients will be followed at the HTC within 30 days with a

hematology provider. These data will be entered into the ATHN Clinical Manager. Sites will be encouraged to review quality metrics and implementation measures frequently (every other week for the first two months, then monthly) to track progress and maintain momentum. Root cause analysis of patients with a bad outcome will be encouraged to identify underlying issues. Learning sessions will be held via interactive webinars with action periods during which time participants can access implementation support by conference calls and materials within ATHN's resource center. A questionnaire will be used to evaluate provider perceptions of the intervention and the QI process.

4. Analysis phase (22-24 months): During the final phase (2 months), QI results will be summarized. Demographic and clinical data will be analyzed and used to assess impact within sub-populations. The final report will be submitted and plan to sustain and spread the effort to other centers will be prepared based on the learning's. This project complements other initiatives funded by HRSA and CDC.

Anticipated Timeline: 24 months (2016-2017)

	Mo. 1-3	Mo. 4-6	Mo. 7-9	Mo. 10-12	Mo. 13-15	Mo. 16-18	Mo. 19-21	Mo. 22-24
Start-Up								
Contracting	X							
IRB Review	X							
Database Set-Up	X	X						
Materials for Intervention	X	X						
Create phone questionnaire	X	X						
Provider Training on project		X						
Pre-Intervention Phase								
Target patient demographic/clinical data		X	X					
Post-discharge assessment		X	X					
Medication Reconciliation		X	X					
Analysis of baseline data				X				
QI Intervention Phase								
Staff training on baseline data, QI methods & intervention				X				
Target patient demographic/clinical data				X	X	X	X	
Use of standard discharge instructions				X	X	X	X	
Post-discharge assessment				X	X	X	X	
Medication reconciliation				X	X	X	X	
Follow-up problem resolution, as needed				X	X	X	X	

Learning collaborative calls		X	X	X	X	
Provider survey of QI intervention & process						X
Analysis Phase						
Analysis demographic/clinical/QI data						X
Final report						X
Dissemination of findings						X

Innovation and Significance:
Currently several models of transition of care for VTE exist at individual centers. The project as it is currently described is innovative and has several significant implications

- This project would be the first to use ATHN as the coordinating and monitoring organization of transition of care at several adult and pediatric centers simultaneously using a uniform TOC model across pilot sites in the United States.
- This is innovative, as the results from this study will help identify regional differences and barriers to TOC. Additionally, differing patterns of TOC across adult and pediatric centers can also be compared.
- It is anticipated that given the ease of use of DOACs, the lack of specific monitoring needed and the faster time to discharge with DOACs, the use of DOACS will dramatically increase. However, the impact of DOACs on transition of care is not known and data from this project will allow for comparison of the impact of DOACs on TOC as compared to standard anticoagulants such as vitamin K antagonists and low molecular weight heparins.
- Moreover for this project we will also monitor the appropriateness of use of anticoagulants and compare it to the published Chest Guidelines[18,19]. This is important as many adult patients with VTE are initially managed and discharged by clinical services other than hematology, that may not be well versed in the dosing and monitoring of anticoagulant medications. These data will help identify gaps in knowledge of such services and then can be used to educate them.

As an exploratory aim, details on clinical features of VTE will be collected in a central database with details on thrombosis resolution, recurrence and thrombophilia. Although this is not the primary goal of this project, these data will serve to identify risk factors, treatment patterns and outcomes of VTE in both adult and pediatric sites. Such data have not been generated in a prospective manner in the United States. Several other countries such as Canada and the Netherlands have a national database where such data are routinely collected. However, such a database that prospectively follows patients with VTE does not exist in the United States where the population is extremely diverse. Based on this premise, the results from databases from other countries cannot be extrapolated to the United States population.

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