Thrombosis Research 163 (2018) 146–152

Contents lists available at ScienceDirect

Thrombosis Research

journal homepage: www.elsevier.com/locate/thromres

Full Length Article

Transition of care for patients with venous thromboembolism: Rationale, design and implementation of a quality intervention project conducted at American Thrombosis and Hemostasis Network (ATHN) affiliated sites

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ARTICLE INFO

Keywords:
Venous thromboembolism
Anticoagulation
Transition of care
Quality intervention

ABSTRACT

Introduction: Medication errors frequently occur during transition from the inpatient to outpatient setting. Anticoagulants are associated with serious medical errors, including major bleeding. Standardized transition of care (TOC) techniques in patients with venous thromboembolism (VTE) have not been developed.

Methods: This ongoing project conducted by the American Thrombosis and Hemostasis Network (ATHN) aims to improve TOC for newly diagnosed VTE patients on anticoagulation from the inpatient to outpatient setting, and identify characteristics of patients on direct oral anticoagulants (DOACs) and their TOC. There are two main phases, a Pre-Intervention and a Quality Intervention Phase. For both phases data are collected regarding patient demographics, VTE characteristics, and patients' knowledge and feedback regarding their VTE and anticoagulant discharge instructions. In addition, for the Quality Intervention Phase, a standardized comprehensive discharge instruction module specific for each anticoagulant is administered followed by a one-week phone call.

Results: Sixteen ATHN-affiliated sites are participating. There are 218 patients enrolled in the Pre-Intervention Phase. The majority are adults (58.5%), women (52.4%) and non-Hispanic ethnicity (82.2%). The main risk factors for VTE were length of hospital stay of more than seven days and obesity in the pediatric and adult population respectively. Enoxaparin and DOACs were predominantly prescribed for the pediatric and adult population respectively.

Conclusion: This TOC quality intervention initiative for newly diagnosed patients with VTE aims to demonstrate that implementation of a standardized TOC model is feasible and can improve patient knowledge, satisfaction, compliance, reduce anticoagulant complications and hospital readmissions in both the pediatric and adult populations.

1. Introduction

Transitions of care (TOC) across multiple health care settings make patients vulnerable to serious medical errors [1,2]. Discharge from the acute care hospital to an outpatient ambulatory setting is increasingly recognized as a time of heightened vulnerability for lapses in safety and quality. Poorly executed transitions contribute to hospital readmissions resulting in annual Medicare costs estimated at $17 billion [3]. Medication errors are one of the most common causes of medical errors during transition from the inpatient to the outpatient setting [4]. Therefore, the Institute for Safe Medication Practices (ISMP) continually updates a list of “high-alert medications” for which healthcare professionals should put extra safeguards in place to prevent errors [5–7]. Anticoagulants, specifically warfarin and heparins, are

Abbreviations: ATHN, American Thrombosis and Hemostasis Network; CDIM, comprehensive discharge instruction modules; DOAC, direct oral anticoagulant; DVT, deep vein thrombosis; EMR, electronic medical record; HTC, hemophilia treatment center; QI, quality intervention; TOC, transition of care; VTE, venous thromboembolism

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https://doi.org/10.1016/j.thromres.2018.01.043
Received 7 November 2017; Received in revised form 20 January 2018; Accepted 24 January 2018

commonly associated with serious errors [8,9]. Recently, the ISMP also has identified direct oral anticoagulants (DOACs) as posing serious clinical concerns for patients due to storage issues, specific medication administration instructions, and dosing-related errors [10].

With the epidemic of venous thromboembolism (VTE) among hospitalized patients, anticoagulants are being increasingly prescribed to prevent and treat VTE [11,12]. The most concerning side effect of anticoagulant therapy is major and fatal bleeding, affecting up to 11% of patients within 30 days of hospital discharge [13]. The Joint Commission has recently mandated institutions to have policies and procedures in place for the safe use of anticoagulation. The availability of DOACs has markedly changed the landscape of the treatment of VTE. Patients initiated on DOACs have a shorter hospital length of stay, which may also pose challenges with education on dosing and TOC [14]. Furthermore, patients prescribed DOACs do not need routine anticoagulation monitoring, patients may be discharged from the hospital without proper medical follow up. Therefore, there are serious concerns that anticoagulant therapy related errors will continue to increase. Thus, there is an urgent need to develop DOAC-specific strategies that will ensure patient safety during TOC from the inpatient to the outpatient setting.

Qualitative studies have shown that patients are often unprepared for their self-management role in the next care setting. Since patients and caregivers form the common thread while navigating through TOC, there is increasing thrust to actively involve them as a member of healthcare team during medication reconciliation at the time of discharge [15]. Patients may receive conflicting advice regarding chronic illness management, are often unable to reach appropriate health care practitioners who have access to their care plan when questions arise, and have minimal input into their care plan [16–19]. Unfortunately, effective discharge and transition care planning is also limited by low health literacy [20]. Previous studies have demonstrated the importance of vigilant TOC at improving patient reported outcomes and adherence to antithrombotic therapies [21,22].

To address this clinical care gap, a funding opportunity was announced in February of 2015 through a collaboration between The Joint Commission and Pharmaceutical Industry Pfizer Independent Grants for Learning & Change, Bristol-Myers Squibb Independent Medical Education with an intent to develop safe TOC processes for patients with VTE [23].

One of the recipients of this award was the American Thrombosis and Hemostasis Network (ATHN), a nonprofit organization in the United States that is dedicated to improving the lives of people affected by disorders of hemostasis and thrombosis. ATHN designed this project to improve the TOC for pediatric and adult patients with newly diagnosed VTE from the inpatient hospital setting to an outpatient setting through patient education, enhanced communication systems, and accountability. The project is named ATHN 4 VTE Quality Intervention Project. The primary intervention consists of providing patient and caregiver education about their anticoagulation therapy and VTE through one-on-one teaching by a healthcare provider with knowledge in thrombosis management. This report summarizes the rationale and design, as well as preliminary results, of this national quality intervention project.

2. Methods

2.1. Aims and outcomes

The primary aim for this project is to improve the TOC from the inpatient to outpatient setting for patients diagnosed with their first VTE by standardizing care using anticoagulation educational materials and education delivery. We hypothesize that patients who received standardized discharge instructions and a follow up telephone call will have a better understanding of their anticoagulant therapy.

Secondary aims include quantifying the number and characteristics of patients prescribed DOACs compared to other anticoagulants, and compare their TOC outcomes. Differences in numbers and characteristics of patients with VTE, as well as those on DOACs, will be analyzed for both pediatric and adult patients separately. We also aim to evaluate physician prescribing practices, thrombophilia screening, presence of VTE risk factors, bleeding and recurrent thrombotic events on various anticoagulants. Of note, comparison data between PI and intervention phase results for institutions that already utilize inpatient and outpatient anticoagulation management services prior to ATHN 4 enrollment may be difficult to obtain due to initial study design.

2.2. Study organization

This multi-center quality intervention (QI) project, named ATHN 4, was developed through the ATHN Thrombosis Committee. ATHN, as described above, is a nonprofit network of over 140 federally funded hemophilia treatment centers (HTCs), which treat both adult and pediatric patients with hemostatic and thrombotic disorders. Centers are either university-based, at children's hospitals or freestanding. ATHN provides infrastructure and opportunities for national and regional clinical research and surveillance projects via studies, surveillance projects, research projects and other projects, such as ATHN 4. The ATHN Thrombosis Committee is a multi-disciplinary group consisting of pediatric and adult hematologists, nurses, pharmacists, researchers and data managers who ensure the scientific integrity of core terminology, projects and publications related to thrombosis within the ATHN community.

ATHN 4 is being conducted at 16 ATHN-affiliated sites throughout the U.S. All patients or patient's parents or guardians sign an authorization or informed consent to have their de-identified data shared within the ATHNdataset (see below). Principal Investigators were instructed to follow their institution's requirements for determination of exempt status and subsequent submission to their institutional review board (IRB), if required. For the majority of sites, the project did not require formal submission to their IRB for approval. Five institutions required the project to be reviewed by their IRB, and of these, some required patients to sign an informed consent to participate in ATHN 4 in addition to authorizing release of their data for purposes of inclusion in the ATHNdataset.

2.3. Patient population

Adult and pediatric patients diagnosed with their first VTE, admitted to one of the participating sites, and discharged on an anticoagulant were eligible for inclusion in the project. Patients seen in an emergency department and discharged home without a hospital admission were deemed ineligible.

Screening data were not formally collected, i.e., screening logs were not utilized for this project. However, sites reported anecdotal issues with screening when clarifications were needed. Enrollment of patients hinged primarily on staff communication within each site to ensure that patients being discharged were able to be approached prior to discharge. Eligibility criteria are listed in Table 1.

Since all study participants, regardless of age, were subject to the same pre-intervention and intervention phases, data will be presented for both pediatric and adult patients, and when appropriate, stratified by age.

2.4. Study design and data collection

A secure database was created by ATHN, named Clinical Manager, which is an electronic medical record (EMR) and provides the foundation and data for the ATHNdataset. The ATHNdataset houses pertinent medical information for patients with disorders of hemostasis and thrombosis. As of June 2017, over 33,000 patients are included in the ATHNdataset.

Table 1
Eligibility criteria for ATHN 4 study.

Inclusion criteria	• Diagnosed with their first venous thromboembolism (VTE) • Admitted to a hospital either at VTE diagnosis or immediately afterwards (within 24 h of diagnosis) • Discharged on anticoagulant therapy • Amenable to follow up upon hospital discharge for at least 30 days
Exclusion criteria	• Prior history of VTE • First arterial occlusion without VTE present • Receiving chronic anticoagulation at the time of hospital admission • Participating in another clinical trial using anticoagulants • Patients seen in an Emergency Department and discharged to home without a hospital admission.

This prospective QI project consists of four phases: startup, pre-intervention, QI and analysis/reporting (Fig. 1). The startup phase consisted of developing (1) an inpatient to outpatient transition policy, (2) comprehensive discharge instruction modules (CDIM) for specific anticoagulants (Table 2), (3) patient/parent VTE knowledge questionnaire, (4) patient/parent feedback questionnaire on discharge education and (5) data collection forms.

During the start-up phase a transition policy was formulated. Data forms and questionnaires used in the pre-intervention and QI phase (Table 2) as well as education materials for the QI phase (CDIM) were developed. All patient questionnaires and educational materials were made available in English and Spanish. The CDIMs provide written instructions on signs and symptoms of VTE, information on each anticoagulation therapy (including monitoring and side effects), follow-up appointments and contact information for their HTC.

The pre-intervention (PI) phase assessed baseline patient/parent VTE knowledge and satisfaction regarding their discharge education. All eligible ATHN 4 patients had a thorough medical record review regarding their demographics, medical history, VTE diagnosis, VTE risk factors (medical, environmental) and VTE treatment during their hospitalization. VTE risk factor categories developed and agreed upon by the ATHN Thrombosis Committee were applied to this project. Data were recorded into Clinical Manager, and flagged for inclusion in the ATHNdataset. During the PI phase, each participating institution's current process for discharge instructions and TOC to the home setting after a first episode VTE was utilized. Questionnaires regarding VTE knowledge and satisfaction of discharge education were administered to patients at their first hematology follow-up visit. Data were also collected at this time point to assess for any adverse events or side effects due to the anticoagulation or the VTE itself, such as bleeding or thrombosis recurrence.

During the QI phase, a new cohort of eligible patients is being identified during their hospitalization for VTE. Prior to hospital discharge, patients are receiving education by dedicated staff using ATHN 4 standardized CDIM specific for each anticoagulant as opposed to generic TOC discharge education typically provided by each individual institution during the PI phase. The staff utilized to conduct patient education varies at each institution but may include nurses, physicians, research coordinators, data managers and any other trained staff prior to initiation of the intervention phase. The following information is provided at the time of discharge as part of the CDIM: Reiterate signs and symptoms of VTE, review the specific type of anticoagulant and administration they/their child are being discharged home with, as well as signs and symptoms of bleeding. This information is provided to the patient/parent at the time of patient discharge from the hospital.

Additionally, patients/parents are phoned 1 week after discharge to provide reinforcement of the instructions and supplemental education if needed. Identical data are recorded from medical record review into ATHNdataset as during the Pre-Intervention Phase. Patients also answer the same VTE knowledge and feedback questionnaire at their first follow-up visit but only the knowledge questionnaire within 1 week post-discharge. Differences in numbers and characteristics of patients with VTE, as well as those on DOACs, will be analyzed for both pediatric and adult patients separately.

Measurement to quantify adherence to anticoagulation therapy for this study will be captured using a designed questionnaire related to percentage of time medication was taken at home, if patients followed up on lab testing requirements as determined by the study investigator, and indirectly, by lab results obtained specific to an individual's anticoagulant prescribed at discharge. No formal, validated, disease-specific or generic adherence measurement tools were utilized.

2.5. Statistical plan

For the final analysis of the primary aim, we will examine the patient knowledge questionnaire and use two-sample z-tests to confirm whether or not TOC leads to a better understanding of VTE signs and symptoms, and a higher adherence to anticoagulant therapy

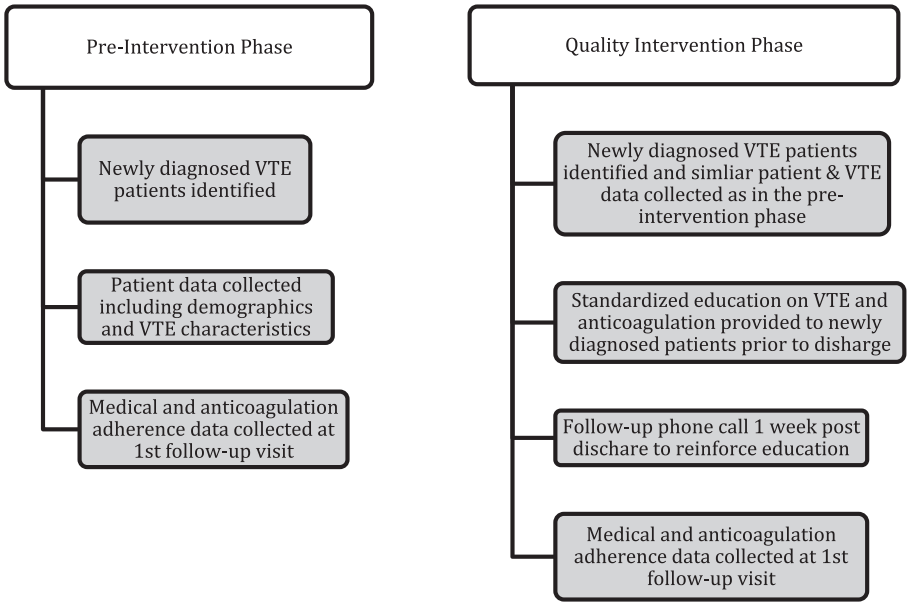


Fig. 1. ATHN 4 Pre-Intervention Phase and Quality Intervention Phase activities.
VTE, venous thromboembolism.

Table 2
Data form and questionnaire collection intervals.

Name of data form/questionnaire	Pre-Intervention Phase	QI phase
Demographics form ● Gender, date of birth, race/ethnicity ● Education level	While hospitalized	While hospitalized
VTE characteristic form ● Type of VTE ● Location of VTE ● Risk factors (thrombophilia, disease-related, medication-related) ● Treatment (anticoagulation, VTE interventional procedure)	1st hematology outpatient visit	1st hematology outpatient visit
Patient knowledge questionnaire ● Adverse events (bleeding, recurrence, readmission) ● Anticoagulant name, dose, frequency, adherence, laboratory monitoring	1st hematology outpatient visit	Within 7 days post-discharge and at 1st hematology outpatient visit
Patient feedback questionnaire ● Education on VTE ● Education on anticoagulation ● Quality of hospital care	1st hematology outpatient visit	1st hematology outpatient visit
Educational intervention ● VTE education ● Anticoagulant education, including side effects and contact information	No (per institution's current practice)	While hospitalized

QI, quality intervention; VTE, venous thromboembolism.

administration. The utilization of a *t*-test will allow us to compare total scores on Patient Feedback Questionnaire between two independent study cohorts (pre-intervention and intervention) to determine if patients receiving the intervention will demonstrate more satisfaction.

To fulfill the secondary objective, a model-based approach, like a logistic regression, will formulate a causal relationship between TOC and VTE knowledge if it exists after adjusting differences in patient characteristics, anticoagulant prescriptions and physician practices. Descriptive analysis will be applied to evaluate VTE characteristics, risk factors, treatment, thrombosis recurrence and bleeding.

3. Results Pre-Intervention Phase

Sixteen ATHN-affiliated HTCs are participating in this project, with representation spanning from the Northeast, South, Midwest, and Western states of the U.S. A total of 218 patients enrolled in the Pre-Intervention Phase from May 2016 until the end of May 2017 (Fig. 2). At the interim analysis time point (end of the Pre-Intervention Phase), data were available for 212 patients for demographic characteristics and 162 patients for VTE characteristics analyses. Data from the patient knowledge and feedback questionnaires were not analyzed at this time.

3.1. Demographics

The majority of these patients, 124 (58.5%), were ≥18 years of age, female 111 (52.4%) and predominantly non-Hispanic 176 (82.2%) ethnicity. There were a variety of payer types in the cohort. The most frequent payer type was private insurance in 101 (47.6%), followed by Medicaid in 46 (21.7%). Full demographic characteristics are shown in Table 3.

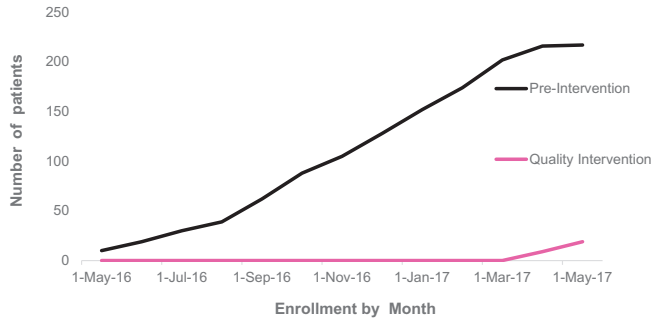


Fig. 2. ATHN 4 project accrual as of May 2017.

Table 3
Demographic characteristics of the cohort of adults and children with thrombosis enrolled in the ATHN4 Pre-Intervention Phase (n = 212).

Demographics	Number	Percent, %
Age at diagnosis		
< 18 years	88	41.5
≥18 years	124	58.5
Gender		
Female	111	52.4
Male	101	47.6
Race		
American Indian	1	0.5
Asian	7	3.3
Black	23	10.9
Mixed	1	0.5
White	161	75.9
Unknown	19	9
Payer type		
Medicaid	46	21.7
Medicare	24	11.3
Private	101	47.6
Other	30	14.2
Uninsured	10	4.7
Unknown	1	0.5

3.2. Venous thromboembolism characteristics and risk factors

VTE characteristic forms were completed for 162 (76.4%) patients at the time of interim analysis. Median hospital length of stay for patients diagnosed with a VTE was 7 days (IQR 3–14 days). Thirty-six (22.5%) patients had a hospital-acquired VTE. A total of 43 (26.5%) patients reported deep venous thrombosis (DVT) of the lower extremity or pelvis, 25 (15.4%) DVTs of the upper extremity or thorax, 2 (1.2%) DVTs of both lower and upper extremities, 46 (28.4%) pulmonary embolism, 8 (4.9%) cerebral sinus venous thrombosis, 7 (4.3%) abdominal vein DVTs (4 mesenteric, 2 renal, and 1 portal), 12 (7.2%) both DVT and PE, and 18 (11.1%) other.

Screening data for inherited thrombophilia were available for 106 patients. The thrombophilias tested included antithrombin, protein C or S deficiency, elevation in Factor VIII, lipoprotein(a) or homocysteine, and Factor V Leiden and prothrombin gene mutations. The most

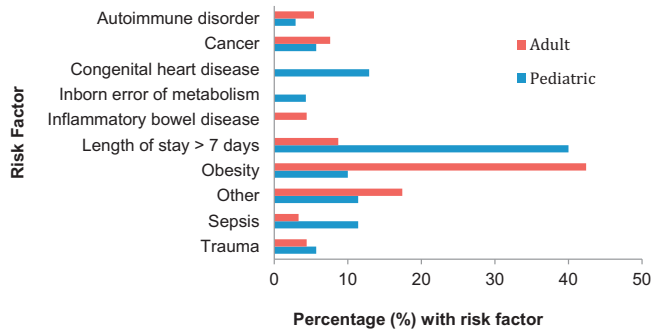


Fig. 3. Comparison of medical risk factors between pediatric and adult VTE patients in the Pre-Intervention Phase (n = 162).

common inherited thrombophilia reported was an elevated factor VIII activity in 9 (12.2%) of 74 patients tested, followed by heterozygote mutation of Factor V Leiden in 8 (8.7%) of 93 patients tested.

Risk factors for VTE were classified into two categories, medical and environmental. These categories were determined prior to study design by the ATHN Thrombosis Committee. The majority of patients, 115 (71%), were found to have at least one medical risk factor, and 36 (29%) patients had more than one risk factor. As shown in Fig. 3, pediatric patients were more likely to have congenital heart disease ($p < 0.001$), sepsis ($p = 0.041$), inborn error of metabolism ($p = 0.046$), or prolonged hospital stay ($p < 0.001$) whereas adults were more likely to be obese ($p < 0.001$).

Environmental risk factors were reported in 106 out of the 162 (65.4%) patients (Fig. 4). Compared with adult patients, pediatric patients were more likely to have a central venous catheter ($p < 0.001$) or cardiac catheterization ($p = 0.046$) as VTE risk factors. Environmental risk factors for adult patients were more likely to be recent travel ($p = 0.007$) or smoking ($p = 0.002$).

Other risk factors reported include anatomic abnormalities known to be associated with thrombosis and a history of a first-degree relative with VTE. Anatomic risks identified for VTE included 2 (1%) patients with May-Thurner Syndrome, 4 (3%) with Paget Schroetter/Thoracic Outlet Syndrome, and 3 (2%) with other vascular anomalies. Approximately 19 (12%) of patients had a first-degree relative with a history of VTE.

3.3. Venous thromboembolism treatment and side effects

Anticoagulation therapy prescribed at time of discharge was varied. The most frequently prescribed anticoagulant at discharge was a DOAC at discharge in 52 (32%) patients. However, treatment patterns significantly differed between pediatric and adult patients (Fig. 4, $p < 0.001$). Children were more likely prescribed enoxaparin and adults were more likely to be prescribed a DOAC, followed by warfarin.

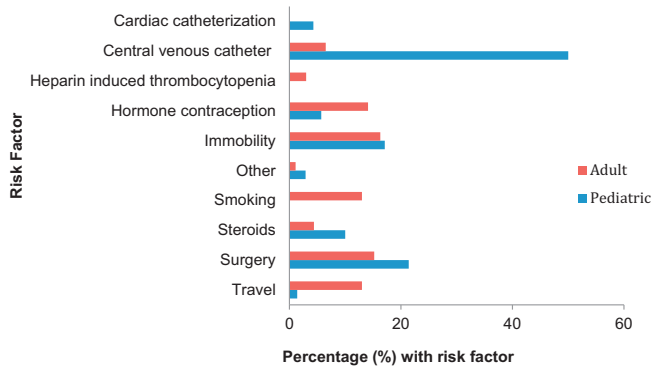


Fig. 4. Comparison of environmental risk factors between pediatric and adult VTE patients in the Pre-Intervention Phase (n = 162).

Adults were more likely to have multiple medication changes after discharge compared to pediatric patients (Fig. 5).

In addition to anticoagulation, interventional procedures were performed to treat VTE. A total of 18 patients had an intervention with several patients having multiple interventions. Interventions included inferior vena cava filter placement (8 adult), thrombectomy (4 adult, 4 pediatric), angioplasty (2 adult, 5 pediatric) and stent placement (4 adult, 1 pediatric).

A total of 6 (8.6%) pediatric patients and 9 (9.8%) adult inpatients experienced bleeding. One pediatric and 5 adult patients had major bleeding during hospitalization and the rest of the 9 bleeding events were minor.

4. Challenges

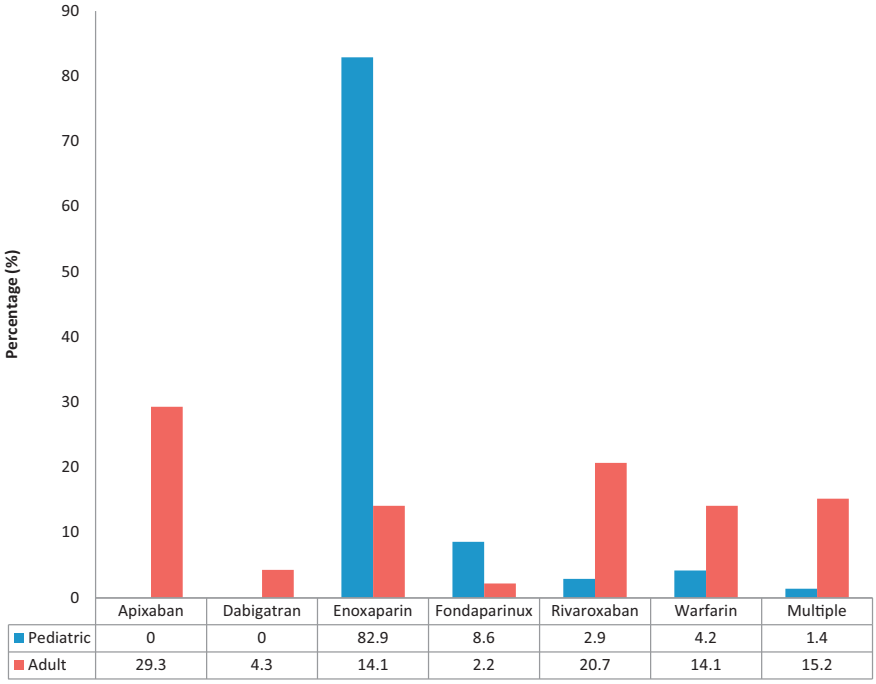
This project was originally proposed as a quality improvement project and thus anticipated to be exempt from IRB approval. However, at five centers the IRB deemed this project as research and required IRB review and approval, and subject enrollment was contingent upon obtaining informed consent. This requirement was not anticipated and significantly delayed startup and limited initial enrollment of subjects.

A lack of infrastructure at various institutions impeded the initiative; issues included lack of dedicated staff to provide patient education and follow up, lack of personnel needed to consent and track patients, and support personnel to perform data entry. In spite of significant efforts to identify and enroll patients in both the Pre-intervention and QI phases, there are persistent barriers to enrollment. These barriers include lack or delayed communication between the discharge team and site investigator(s) responsible for the study. Often patients are discharged before education can be provided, and patients have expressed unwillingness to participate due to time commitment. For the intervention phase, suggestions to mitigate some of the challenges encountered in the PI phase include: weekly review of electronic medical records to identify suitable patients for enrollment in the study, creating an inpatient hematology consult team dedicated to thrombosis patients within an individual treatment center, and routinely conducting team meetings to discuss progress with data capture for patients enrolled in the study.

5. Conclusion

The incidence of VTE is rising, as the population is growing older [24]. Moreover, the incidence of VTE is also increasing in the pediatric and adolescent population due to improved survival of chronically ill children, increased placement of central venous catheters, prevalence of obesity in children and adolescents and improved VTE imaging techniques [25]. Management of VTE in the United States is variable and is dependent on the type of medical facility, available resources, third party payers, and knowledge of and adherence to published VTE guidelines [26]. 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 [27–30]. TOC is a critical component of appropriate healthcare delivery and studies have shown that gaps in transitioning care can result in medication errors and adverse outcomes, thus increasing morbidity and mortality. The differing models of management of VTE inherently create potential problems with TOC, and specifically, outcomes after VTE.

This novel project is the first multicenter thrombosis study conducted by ATHN to simultaneously implement a uniform standard TOC model at pediatric and adult centers across the United States. This project also provides the unique opportunity to study thrombotic risk factors and VTE treatment in both pediatric and adult patients concurrently. We hope to improve patient education and understanding of VTEs and their prescribed anticoagulant. By identifying a dedicated team and providing easy to understand discharge instructions both



	Apixaban	Dabigatran	Enoxaparin	Fondaparinux	Rivaroxaban	Warfarin	Multiple
Pediatric	0	0	82.9	8.6	2.9	4.2	1.4
Adult	29.3	4.3	14.1	2.2	20.7	14.1	15.2

Fig. 5. Comparison of prescribed anticoagulants in pediatrics and adults in the Pre-Intervention Phase.

orally and in the written form, we expect to decrease complications from anticoagulant therapy and follow-up appointments.

Preliminary data reveal pediatric patients diagnosed with a VTE are more likely to have congenital heart disease, inborn errors of metabolism or a prolonged hospital stay when compared to adult patients. Children are also more likely to have a central venous catheter-related VTE or cardiac catheterization-related VTE. Adult patients are more likely to be obese, smokers or have recently traveled. Treatment differences for children versus adults revealed pediatric patients are more likely to be prescribed enoxaparin for anticoagulation, while adult patients were more likely to be prescribed oral anticoagulants, mostly DOACs, followed by vitamin K antagonists. The decreased use of DOACs in children compared to adult patients is most likely secondary due to the lack of FDA approval of DOACs in pediatric patients.

Upon completion of enrollment in the QI phase, a final data analysis, including evaluation of patient knowledge and feedback questionnaires will be performed. We hope that all data elements from this project will not only improve TOC for patients diagnosed with a VTE, but also help identify regional differences and barriers to TOC and differing patterns of TOC across adult and pediatric populations. We anticipate results from this study will provide increased understanding on the impact of DOACs on TOC as compared to standard anticoagulants such as vitamin K antagonists and low molecular weight heparins. Moreover, we expect this project will offer ATHN a platform to create the largest national registry of patients with thrombosis and thrombophilia in the United States. With proper education and VTE awareness we anticipate the burden of VTE and complications related to anticoagulation therapy will decrease in the United States.

Acknowledgements

We would like to acknowledge the ATHN 4 investigators and site staff, the members of the ATHN Thrombosis Committee and Diane Aschman, former president and CEO of ATHN, for their support and guidance with this project.

Funding

This work was supported by the Pfizer Independent Grants for Learning & Change (IGLC) and Bristol-Myers Squibb (20694075) Independent Medical Education. The Joint Commission provides administrative oversight for the grant.

Declaration of interest

Dr. Jaffray is a member of the steering committee for the Hokusai Edoxaban pediatric clinical trial and Dr. Patel is a member of the data safety monitoring board for the Hokusai Edoxaban pediatric clinical trial.

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