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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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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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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.