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Preventing venous thromboembolism for ambulatory patients with cancer: Developing the form and content of implementation strategies

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Abstract

Background: For ambulatory cancer patients receiving systemic chemotherapy, adherence is low to recommended venous thromboembolism (VTE) prevention interventions. Previously, we identified implementation strategies to address barriers to adherence, including (1) conducting clinician education and training; (2) developing and distributing educational materials for clinicians; (3) adapting electronic health records to provide interactive assistance; and (4) developing and distributing educational materials for patients. The objective of this study was to develop these implementation strategies' form (i.e., how and when) and content (i.e., information conveyed) as a critical step for implementation and dissemination.

Methods: To design and develop the form and content of the implementation strategies, we conducted multidisciplinary stakeholder panels with oncology clinicians, pharmacists, and hematologists. Over several panel discussions, we developed a low fidelity prototype. Participants performed preliminary usability testing, simulating patient care encounters. We also conducted interviews with three patients who provided additional feedback.

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CRedit authorship contribution statement

Karlyn A. Martin: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Writing – original draft, Writing – review & editing. **Kenzie A. Cameron:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – review & editing. **Jeffrey A. Linder:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – review & editing. **Lisa R. Hirschhorn:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.tru.2024.100168>.

Results: The form and content for each strategy, respectively, included (1) concise training with a slide deck; (2) succinct summary of evidence for the interventions and support for anticoagulation management; (3) automated VTE risk-assessment and clinical decision support, including bleeding risk assessment and anticoagulation options; and (4) patient education resources. During development, audit and feedback was identified as an additional strategy, for which we created report cards to implement.

Conclusion: With stakeholder input, we successfully developed the form and content needed to put the implementation strategies into practice. The next step is to study the effect on the uptake of ambulatory VTE prevention recommendations in oncology clinics.

Keywords

Cancer; Implementation science; Prevention; Venous thromboembolism; Anticoagulation

1. Introduction

Venous thromboembolism (VTE) is a common complication of cancer and cancer-directed therapy: of an estimated 900,000 VTE events diagnosed annually in the US, about 25% occur in people with cancer [1,2]. Cancer-associated thrombosis increases morbidity and is a leading cause of death in people with cancer. Efforts have been made to reduce the burden of VTE in people with cancer, including the creation and validation of VTE risk-assessment scores to identify those at highest risk of VTE. The most widely known risk-assessment score, the Khorana Score, uses 5 clinical factors at initiation of systemic cancer-directed therapy to estimate the 6 month risk of VTE [3]. Randomized trials demonstrated the safety and efficacy of primary anticoagulation thromboprophylaxis for people with cancer at high risk of VTE by Khorana Score [4,5]. Based on these data, professional guidelines recommend two evidence-based interventions (EBIs) for VTE prevention: (1) assessment of VTE risk for all patients starting systemic therapy using a validated risk-scores, such as the Khorana Score, and (2) consideration of anticoagulation prophylaxis for those considered to be high risk of VTE [6-8]. However, these VTE prevention EBIs are substantially underused in clinical oncology practice [9,10]. Such underuse has led key leaders in oncology and VTE prevention to call for the use of implementation science to help increase uptake in clinical practice [11,12].

Implementation science is a field focused on understanding barriers and facilitators to EBI use and the identification and testing of strategies designed to address these factors to achieve uptake of EBIs [13]. A key step prior to formal testing of implementation is the design of implementation strategies' form (i.e., how and when) and content (i.e., specific information conveyed). Reporting specific details on this design of the implementation strategy is critical to implementation research, so the proposed implementation strategies both can be tested and compared in research as well as reproduced for use in clinical practice [14].

Our prior work identified barriers to underuse of EBIs for VTE prevention in ambulatory oncology, including clinicians' lack of knowledge and/or familiarity of supporting evidence or negative perception of the evidence, concern of bleeding with anticoagulation, time

limitations to discuss VTE prevention, and/or their desire to ensure that patients' cancer remained the priority during clinical discussions [15]. We also found facilitators to getting these EBIs into practice, which included the existence of supportive evidence for the interventions, clinicians' willingness to change, and clinicians' self-efficacy in carrying out the EBIs [15]. Subsequently, we used the Implementation Research Logic Model (IRLM) – which combines implementation frameworks and can be used as a planning tool– with additional input from oncology clinicians and patients, to identify overarching implementation strategies designed to overcome identified barriers and leverage facilitators (Fig. 1) [16]. For this study, we focus on four of our previously identified implementation strategies that target clinical (e.g., lower VTE rates), system (e.g., integration of VTE risk-assessment into clinical workflow), and/or implementation outcomes (e.g., adoption, acceptability) [16,17], and for which stakeholders' input into the form and content was deemed critical (Fig. 1, Panel C). We describe the development of the specific form and content of the four selected implementation strategies to address barriers to the uptake in clinical practice of EBIs for VTE prevention for ambulatory patients with cancer prior to testing in clinical practice.

2. Methods

2.1. Study design overview

We conducted multidisciplinary stakeholder panel discussions with clinicians and semi-structured interviews with patients to iteratively design the form and content of the four selected implementation strategies (Fig. 2): (1) Conduct clinician education and training on risk-assessment models and anticoagulation thromboprophylaxis; (2) Develop and distribute educational materials for clinicians about the Khorana score, VTE risk, and anticoagulation counseling; (3) Adapt electronic health records (EHR) to provide interactive assistance; and (4) Develop and distribute educational materials for patients. This study was approved by the Northwestern University Institutional Review Board.

2.2. Setting and participants

The study was conducted at Northwestern Medicine, including a tertiary academic based clinic and an affiliated community-based site. Three panels of clinicians were assembled, recruited from the Division of Hematology and Oncology at Northwestern via email, which included mention of the research goals. Panel 1 consisted of oncologists, classical hematologists, and an oncology clinical pharmacist in an academic setting; Panel 2 consisted of three oncology advanced practice professionals in an academic setting; and Panel 3 consisted of oncologists and oncology advanced practice professionals in a community-based setting. Patient participants were recruited from Northwestern Medicine Hematology/Oncology clinics and had diagnoses of both VTE and malignancy.

One female study investigator (KAM, hematologist) conducted panel discussions with clinicians and interviews with patients. The study investigator was known to the clinicians but was not known by or to the patient participants.

2.3. Panel discussions

We created an interview guide for clinicians to provide input into designing the form and content of the implementation strategies chosen to address priority barriers. Interview guides had clinicians identify the factors that could affect the success of each strategy from their practice perspective and provide input into the form - i.e., how and when (e.g., presentations versus emails for clinician education) - and content-i.e., information conveyed (e.g., what information to provide and in how much detail) - of each strategy. We conducted the clinician panel discussions in person between December 2022 and March 2023, with each discussion lasting approximately 60 min. We met four times each with the two separate academic clinician panels (for a total of eight meetings with academic clinicians), with the end goal of having a prototype for the final session. In the first meeting with each academic panel, we reviewed guidelines and evidence to support the use of VTE risk assessment and anticoagulation prophylaxis in patients with cancer and shared barriers and facilitators identified in our earlier work, including those that the four implementation strategies addressed. During subsequent meetings, we introduced the implementation strategies and then iteratively designed their form and content. In the final academic panel meetings, clinicians were presented a low-fidelity prototype of the package of implementation strategies, using a slide deck with embedded links to the education handouts in PDF form. They were asked to perform exploratory usability testing through simulated patient care encounters. We then conducted one meeting with a community-based clinician panel, in which they gave feedback on the low-fidelity prototype materials and performed exploratory usability testing.

2.4. Patient interviews

We conducted patient interviews in April and May 2023. We created an interview guide for patients based on the IRLM and conducted individual semi-structured interviews with three patients over video to obtain feedback on the form and content of relevant implementation strategies and patient-facing education resources.

3. Results

3.1. Overview

Several general aspects of the form and content of the package of implementation strategies emerged from the stakeholder discussions. Clinicians preferred parts of the intervention to be arranged by activity rather than by a specific person/role. For example, for the component, “VTE education delivered to patient,” clinicians noted that the person delivering the education could be either a physician, advanced practice professional, or nurse, depending on a given clinic’s resources and preferences. Clinician participants also valued maximum clinical-decision support by the EHR, to minimize manual work and efficiently and accurately perform the intervention (further details in Implementation strategy 3 below). Clinicians and patients suggested delivering the intervention at an initial standard oncology appointment dedicated to teaching patients about their cancer-directed therapy (“chemo-teaching appointment”). Clinicians suggested having an EHR order to schedule a follow-up appointment to monitor anticoagulation. Clinicians also suggested the need for

a fifth strategy, Audit and Feedback (see Implementation strategy 5), as being crucial for sustainability, and as a process to hold themselves accountable for EBI use.

Based on participant discussion, a workflow diagram providing an overview of the integration of risk-assessment and relevant prophylaxis in clinical practice was created; clinicians reviewed and gave feedback resulting in the workflow in the final diagram (Fig. 3). The workflow begins with assessed VTE risk based on the Khorana score (grouped into low risk and high risk) and functions as a pathway indicating management actions and applicable materials for both patient and clinicians.

3.2. Implementation strategies

Strategy 1: Conduct clinician education and training on risk-assessment models and anticoagulation thromboprophylaxis.—The objective of this strategy is to facilitate easy learning by clinician users about the EBIs. Implementation strategy 1 addresses multiple barriers, including clinicians' (a) lack of knowledge of the evidence-based intervention, (b) negative perception of quality/validity of evidence in certain cancers and in settings of higher risk of bleeding, and (c) unfamiliarity with professional society guidelines for VTE prevention. Clinician participants recommended the form be a succinct slide deck, with the content summarizing available evidence and data on VTE risk-assessment and prophylaxis, including Khorana Score elements, risk of VTE by Khorana score, data from phase III trials regarding safety and efficacy of prophylaxis for high-risk patients, and recommended guidance for VTE prevention by professional societies. Based on feedback, one investigator (KAM) prepared a 5-slide deck. At subsequent panel discussions, clinicians provided input and revisions to the content and appearance and approved a final version (Supplement, Appendix 1). Clinicians recommended the training be delivered at tumor board conferences, small group research/logistics meetings (attended by physician, advanced practice professional, nurses, and pharmacists), and Division faculty meetings. They further recommended embedding links to educational materials for clinicians within the EHR (incorporated into Strategies 2 and 3 below) (Table 1).

Strategy 2: Develop and distribute educational materials for clinicians for Khorana score, VTE, and anticoagulation counseling.—Addressing similar barriers to strategy 1, this strategy focused on creation of supporting materials to facilitate learning about and delivering the EBIs. Clinicians requested educational materials be available both to accompany the initial training (Strategy 1) and to provide ongoing support and reminders. They prioritized a concise and easily available form, recommending creation of a succinct document, available as a PDF linked within the EHR clinical decision support (CDS, Strategy 3), a physical hand-out, and/or a pocket-sized card. The content included a summary of evidence supporting the intervention and recommendations for anticoagulation prophylaxis based on assessed VTE risk. Clinicians were presented with a draft of the hand-out; based on their feedback, the final content approved by the clinician panels incorporated proportionally more information about anticoagulation management than the first draft, such as peri-procedural anticoagulation management recommendations and a list of interactions between anticoagulants and common drugs used in oncology practice (Supplement, Appendix 2).

Strategy 3: Adapt electronic health records to provide interactive assistance.

—This strategy supports clinicians in performing the EBIs, with the goal to facilitate the uptake of the EBIs and use them as intended. It addresses the barrier of time limitations relative to volume of information to be discussed and leverages the facilitators of existing supportive evidence for VTE risk assessment and primary prophylaxis and oncologists' self-efficacy in carrying out the EBIs. Clinicians recommended the CDS be integrated within chemotherapy order sets, as these order sets are universally accessed for the target patient population (i.e., patients starting systemic therapy). Broadly, clinicians suggested the form of the interactive assistance include an automatically calculated risk-assessment score by the EHR, CDS for management based on the calculated score, and templates for clinical documentation regarding decision-making and counseling for VTE risk-assessment and anticoagulation prescription. EHR templates would further serve as a reminder to address VTE prevention in future appointments (i.e., to ask about anticoagulation adherence or to re-evaluate starting anticoagulation if the initial decision was made to not start due to bleeding risk). In addition, clinicians suggested the CDS content include a method to assess bleeding risk, prepopulated options for anticoagulation thromboprophylaxis, links to resources for peri-operative/procedure anticoagulation management, and a list of interactions between anticoagulants and common drugs used in oncology practice. Drafts of clinical documentation templates for various scenarios (e.g., low risk of VTE, no prophylaxis recommended; high risk of VTE, prophylaxis recommended; high risk of VTE, no prophylaxis recommended (Supplement, Appendix 3); were presented to clinicians in the last panel session and subsequently approved. Finally, clinicians recommended embedding links to summary material about data and recommendations (Strategies 1 & 2) within the EHR CDS tool, for those who wanted easy access to that information.

Strategy 4: Develop and distribute educational materials for patients.—This

strategy focuses on developing supporting material to make it easier for patients to learn about VTE, risk of VTE, and anticoagulation. It addresses a previously identified barrier of a culture lacking emphasis on VTE prevention relative to cancer care and leverages the finding that patients value VTE prevention [16]. Clinicians and patients recommended the form to be a concise one-page resource providing content in lay-person language. Patients prioritized content that included defining a VTE, why they were at risk, and practical information such as recognizing worrisome complications (for example, VTE symptoms or bleeding with anticoagulation) that should prompt a call to their oncology team. Clinician and patient participants recommended that the educational materials be provided to patients both in existing “chemotherapy education” booklets and sent in after-visit appointment instructions through the EHR. We developed two separate patient-facing educational materials: one for VTE and one for anticoagulation. Drafts were shown to patient participants, who recommended increased lay language descriptions throughout. A final version was approved by patient and clinician participants (Supplement, Appendix 4 and Appendix 5).

Strategy 5: Audit and feedback.—Audit and feedback as an implementation strategy

was not previously identified by our study group when mapping implementation strategies to barriers, but emerged during stakeholder panel discussions when clinicians were asked how to best sustain the use of the VTE prevention interventions. Clinicians valued holding

themselves accountable for using the EBIs. They recommended a personalized report card as the form of the implementation strategy, with the content consisting of a comparison of their use of appropriate VTE prevention to themselves over time, as well as to their peers. Additionally, clinicians wanted data indicating rate of initial anticoagulation prophylaxis for their high risk VTE patients and rate of sustained anticoagulation prophylaxis for their high risk VTE patients.

4. Discussion

In partnership with clinician and patient stakeholders, we developed the form and content of a package of implementation strategies to increase the uptake of EBIs for VTE prevention in oncology practice. Building on our prior work, this package of strategies is designed to address barriers and leverage facilitators to the use of VTE prevention interventions and seeks to close the large gap between guideline recommendations and their use in clinical practice.

This stepwise work using implementation science methods to move from identified barriers and facilitators to identified strategies to design of strategies is an important and effective approach to comprehensively and systematically develop the package of strategies to address these implementation gaps. The underuse of VTE prevention in oncology practice is well described [9,10,18], despite the recommendation via professional society guidelines, which are based on randomized phase III trials demonstrating both safety and efficacy [4,5]. Importantly, by using implementation science methods, we developed strategies that can address barriers that have been consistently identified across institutions [12,15]. In doing so, consistent with the goals of implementation research, we aimed to create generalizable knowledge that can serve as a foundation to expedite implementation into clinical practice, which we will test in future work. We hope that by including our “toolkit” (Supplemental Appendices 1-5), we preclude the need for others to “start from scratch,” and instead these findings and resources can be used in future work to test whether they advance the uptake of VTE prevention EBIs in clinical practice.

There is a paucity of data addressing how to improve use of VTE prevention interventions in ambulatory oncology clinics. While the identified strategies were similar, the form and content of the implementation strategies presented in this paper differ from a previously published program out of the University of Vermont (“Vermont model”) [10]. In contrast to the Vermont model, which required manual input, the proposed VTE risk-assessment calculation in our study is automated. Additionally, in our model the CDS for management recommendations based on the assessed risk is embedded within the EHR and carried out by oncology clinicians; in the Vermont Model, high risk patients are referred to a thrombosis specialist for management. The differences between the form of the implementation strategies may be due to our design process; whereas the Vermont Model was initiated based on observed low rates of prophylaxis and designed by a multidisciplinary team, we first used qualitative methods to identify barriers and facilitators to VTE prevention directly from clinicians and patients, and then used multidisciplinary stakeholder input to design the form and content of the implementation strategies. Having oncology clinicians carry out the EBI, rather than thrombosis specialists, emerged directly from preferences expressed

by oncology clinicians. Similarly, the automated risk calculation and embedded CDS management resulted from feedback from stakeholders across academic and community-based practice settings. By designing the form and content of the implementation strategies with feedback from both multidisciplinary academic and community-based stakeholders, we aimed to make the design more generalizable to a broader range of oncology practices, and, in particular, non-academic ones. Further, while creating the form and content, we did not specify the role/person to carry out each element, so that the implementation strategies could be adapted to an individual practice's personnel, resources, and preferences.

A strength of this study is that by including clinician stakeholders with various degrees, roles, and who work in different practice settings, the resulting findings are applicable to a variety of practice settings. Our inclusion of patients in the design phase was aimed to develop acceptable implementation strategies for intervention recipients. We also used principles from implementation science to choose strategies designed to address identified barriers and then adapted them based on feedback from end-users and other key stakeholders.

Our study had limitations. It was conducted in a single healthcare system, although it included different practice settings (academic and community-based). In addition, the CDS is still in a prototype stage (i.e., not yet built into the EHR); future work will complete the build and test the effectiveness of this package of strategies, along with the effectiveness of the other strategies previously identified not developed in this study, in improving appropriate anticoagulation rates.

5. Conclusions

With stakeholder input from multidisciplinary clinicians and patients, we developed the form and content of a package of implementation strategies designed to address barriers to uptake of VTE prevention recommendations in oncology clinics. By using implementation research methods, our goal was to create implementation strategies that lead to local change and contribute to generalizable knowledge to accelerate closing the implementation gap of VTE prevention and treatment in ambulatory oncology. Next steps are to conduct a study to test the implementation strategies in clinical practice to measure impact on increasing the uptake and delivery of these evidence-based interventions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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List of abbreviations

VTE	Venous thromboembolism
IRLM	implantation research logic model

EHR	electronic health record
EBIs	evidence-based interventions
CDS	clinical decision support
AC	anticoagulation

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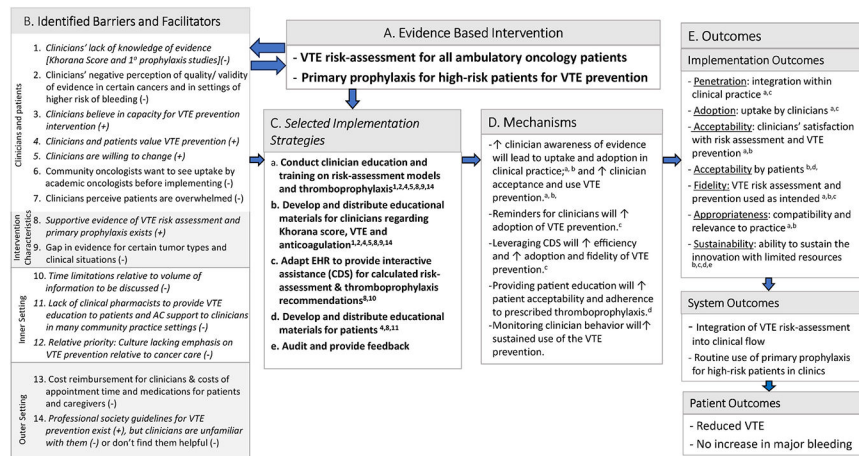


Fig. 1. Implementation Research Logic Model applied to VTE prevention in ambulatory oncology practice, modified to selected implementation strategies. *Expanded version published in Res Pract Thromb Haemost 2023; 7: 102173.*

Key: (+), Facilitator; (-), Barrier; EHR, electronic health record; 1^o, primary; CDS, clinical decision support; VTE, venous thromboembolism; ↑, increase.

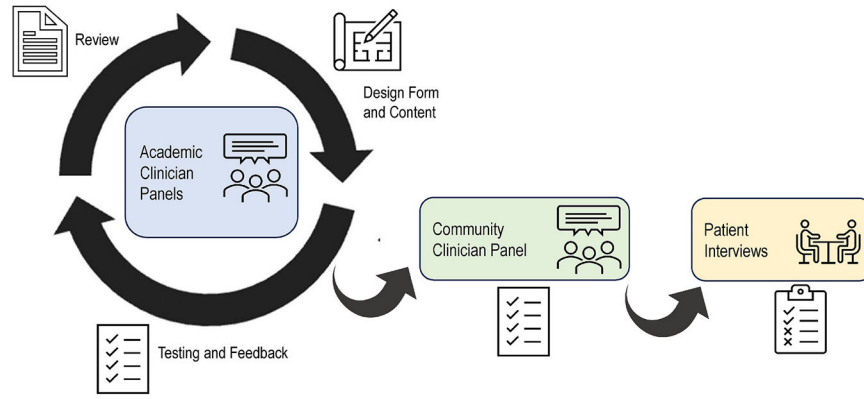


Fig. 2. Study overview to design the form and content of implementation strategies. Academic clinician panels consisted of oncologists, classical hematologists, pharmacists and oncology Advanced Practice Professionals (APP); community clinician panels consisted of oncologists and APPs.

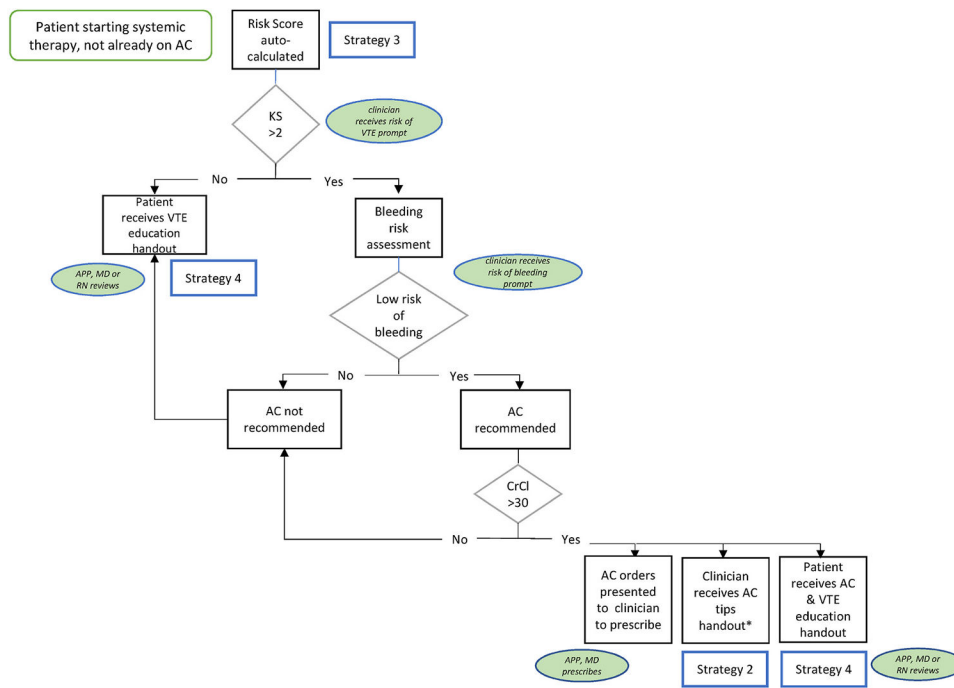


Fig. 3. Clinical workflow integrating VTE risk assessment and primary prevention, showing where implementation strategies work to support care delivery; Strategies 1&5 work throughout. Legend: AC, anticoagulation; KS, Khorana Score; VTE, venous thromboembolism; CrCl, creatinine clearance; APP, advanced practice professional; RN, registered nurse; *including interacting medications and peri-procedural anticoagulation.

Table 1

Selected details of form and content of implementation strategies.

Implementation Strategy	Form and Content Selected Details
1. Conduct clinician education and training on risk-assessment models and anti coagulation thromboprophylaxis	<ul style="list-style-type: none"> Concise slide deck reviewing evidence and recommendations
2. Develop and distribute educational materials for clinicians for Khorana score, VTE, and anticoagulation counseling	<ul style="list-style-type: none"> Succinct handout summarizing evidence and recommendations Incorporate content of peri-operative/peri-procedure AC management and commonly used drug interactions into EHR and in handout that can easily be referenced
3. Adapt EHR to provide interactive assistance for calculated risk-assessment & thromboprophylaxis recommendations	<ul style="list-style-type: none"> Automatic calculation of Khorana Score (or other validated score) by EHR; based on score, prompt to (1) management recommendations, (2) patient and clinician materials; and (3) clinical documentation templates Incorporate bleeding risk assessment in the form of a prompt within EHR to review bleeding risk factors at time of AC ordering Prepopulated options for AC prophylaxis if appropriate
4. Develop and distribute educational materials for patients	<ul style="list-style-type: none"> Make available in “Chemotherapy education” booklets as well as in after-appointment instructions Include content describing VTE and VTE risk for patients with cancer; include practical information about what to watch for and what to do
5. Audit and feedback	<ul style="list-style-type: none"> Provide peer and self-comparison with “report cards” including rates of initial and sustained AC prescription for high risk VTE patients

EHR, electronic medical record; AC, anticoagulation; VTE, venous thromboembolism.