Association of Community Cancer Centers
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ACCC
Association of Community Cancer Centers

VENOUS THROMBOEMBOLISM

Identifying Cancer Patients at Risk

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Introduction

Collectively, deep vein thrombosis (DVT) and pulmonary embolism (PE) are classified as venous thromboembolism (VTE). The Centers for Disease Control and Prevention (CDC) estimates that up to 100,000 Americans die from VTE each year.[1] In cancer patients, VTE increases the likelihood of death by two- to six-fold.[2] Inpatient hospital protocols have been designed to assess VTE risk in cancer patients and have corresponding order sets to implement proper prophylaxis in high-risk patients; however, structured risk assessments for VTE and order sets for prophylaxis are generally not used in the outpatient oncology setting. In fact, a recent survey of Association of Community Cancer Centers (ACCC) membership revealed that identification and evaluation of cancer patients who are at high risk for VTE are under recognized—particularly in the outpatient setting. To address this, ACCC launched an educational initiative to understand the issues surrounding proper identification, evaluation, prevention, and management of VTE in cancer patients receiving treatment in the outpatient setting. Support for this project was provided by Janssen Pharmaceuticals, Inc.

Background

A National Blood Clot Alliance (NBCA) DVT-PE Awareness Study shows that among 500 cancer patients surveyed, only 24 percent are aware of the term DVT and only 15 percent are aware of the term PE.[3] Moreover, oncology outpatient departments report significantly lower utilization of DVT-PE prophylaxis compared to cancer inpatient departments: 31 percent to 52 percent of cancer patients treated in the inpatient setting received prophylaxis while only 6 percent to 22 percent of cancer patients treated in the outpatient setting received prophylaxis.[4] Currently, routine DVT/PE prophylaxis is not recommended for most oncology outpatients. However, National Comprehensive Cancer Network (NCCN) guidelines for Venous Thromboembolic Disease call for appropriate VTE risk stratification and prevention in high-risk cancer patients, given the significant morbidity and mortality associated with VTE.[5]

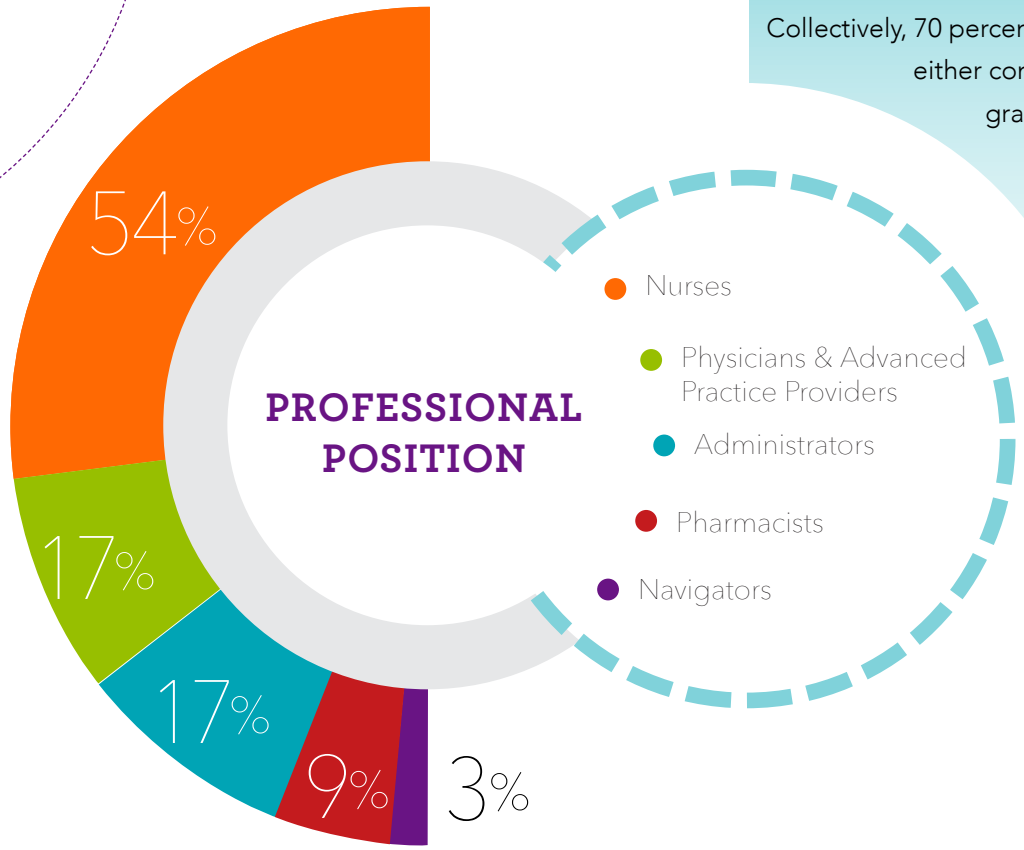
Focus Group and Survey Participants

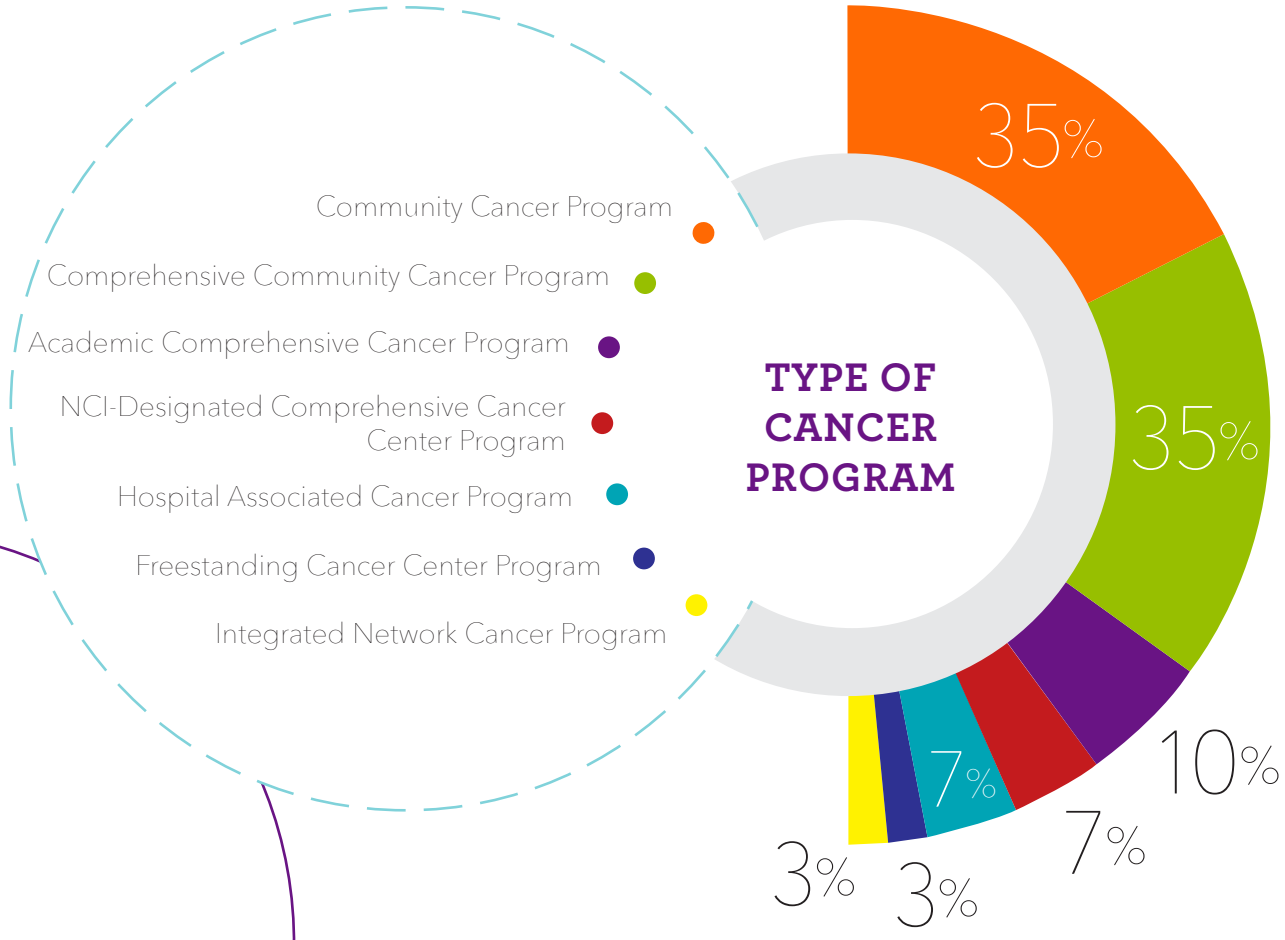
On March 3, 2016, ACCC facilitated a two-hour focus group discussion around the process of assessing risk and preventing and managing VTE in cancer outpatients. The participants consisted of oncologists, nurses, pharmacists, and administrators. These stakeholders discussed their experiences and the operational issues associated with VTE assessment and identification of at-risk cancer patients within oncology practices and outpatient infusion centers. The discussion explored current standards of care and the challenges that exist with addressing VTE in cancer patients treated in the outpatient setting.

In May 2016, ACCC conducted an online membership survey (n=37) to further assess current practices in the identification and evaluation of high-risk VTE patients treated in the outpatient setting. Information derived from the expert stakeholder focus group informed the development of the survey questions. Those who responded to the survey represented a wide range of disciplines with the majority (54 percent) being nurses, 17 percent physicians and advanced practice providers, and 17 percent administrators.

Collectively, 70 percent of survey respondents worked in either comprehensive community cancer programs or community cancer programs. The remaining worked in a range of programs from academic centers to freestanding programs.

Those responding to the survey had varying levels of work experience, with the largest group (35 percent) being those with 11 to 20 years of working experience, while those respondents with less than 5 years, 5 to 10 years, and 21 years or more experience each represented 21.6 percent.





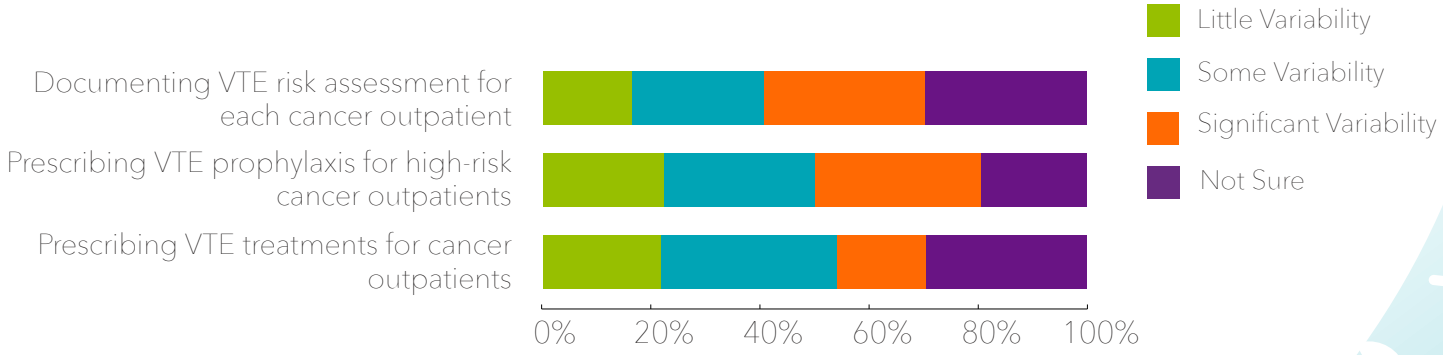
VTE Risk Assessment

The process of assessing VTE risk in the outpatient setting appears to vary based on the type of cancer and treatment that is prescribed. Currently, most oncology programs do not use any type of structured risk assessment or formal scoring system in the outpatient setting. Although these clinicians may be thinking about VTE, the lack of documentation makes it difficult to know how they are assessing VTE risk and whether high-risk patients are being identified for prophylaxis. Clinicians working in an inpatient setting are accustomed to structured order sets with clinical alerts indicating VTE risk and prevention strategies. Focus group and survey participants indicated that these health IT tools are not being leveraged in the outpatient setting.

The Khorana Predictive Model for Chemotherapy-Associated VTE was published in 2008 and identifies the following cancers as high-risk: stomach, pancreas, lung, lymphoma, gynecologic, bladder, and testicular.[6] Studies based on the Khorana model reveal that cancer patients who have a low score (0) have up to a 3 percent risk of symptomatic VTE while those with an intermediate score (1 or 2) have up to an 8.4 percent risk, and those with a high score (3 or higher) have up to a 41 percent risk.[7,8,9] The 2015 NCCN Guidelines for Venous Thromboembolic Disease recommend prophylaxis for patients with multiple myeloma who are receiving thalidomide or lenalidomide.[5] The NCCN guidelines also suggest having conversations with patients about the risks and benefits of VTE prophylaxis in patients with a Khorana score of 3 or higher because of their increased risk for VTE.[5] However, many clinicians in the oncology outpatient setting are not in the routine practice of formally calculating or documenting Khorana scores.

ACCC focus group participants explained that VTE risk assessment and documentation can vary in a single program because clinicians are not using any type of standardized risk-assessment tool or templated progress note in their EHRs. In many cancer programs, clinicians are not in the habit of regularly documenting VTE risk for their cancer patients who receive treatment in the outpatient setting. Although clinicians may be discussing VTE risk with their patients, the lack of documentation makes it difficult to know how clinicians are assessing VTE risk and whether high-risk patients are being appropriately identified for prophylaxis in the outpatient setting.

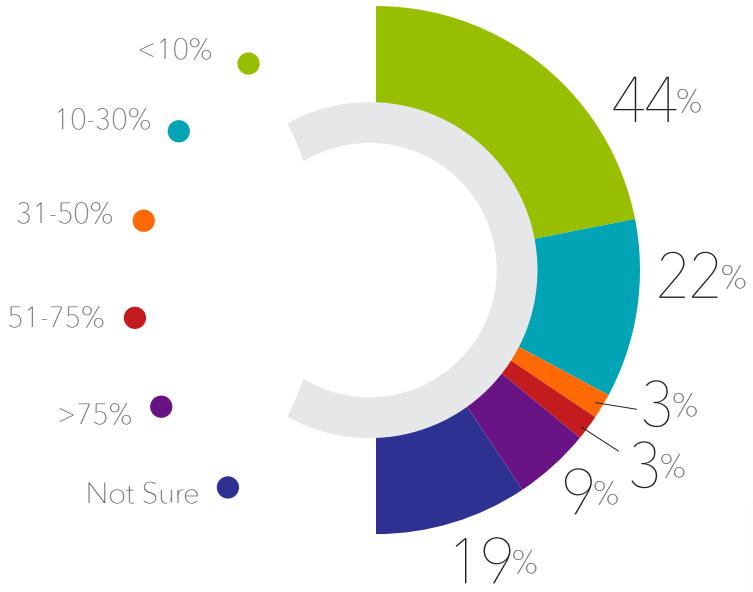
ESTIMATED VARIABILITY IN VTE DOCUMENTATION AMONG ONCOLOGY PROVIDERS



Survey respondents echoed similar sentiments and noted the following:

- Only 13 percent indicated that their cancer programs have a formal policy, progress note template, or other clinical decision-support tool to guide oncology practitioners when performing and documenting VTE risk assessment in cancer patients treated in the outpatient setting.
- 30 percent reported a significant amount of variability in how VTE risk is documented in outpatient records; only 16 percent reported little variability.
- 44 percent reported that less than 10 percent of their cancer patients treated in the outpatient setting have clear documentation of their VTE risk (e.g., low, intermediate, or high risk) in their medical records.
- Only 9 percent reported that their oncology practitioners or nurses use a structured risk-assessment tool that calculates and quantifies VTE risk in cancer patients treated in the outpatient setting.

PERCENTAGE OF CANCER OUTPATIENTS WHO HAVE CLEAR DOCUMENTATION OF VTE RISK IN THEIR CHART



When survey respondents were asked about the top challenges when assessing VTE risk in cancer patients treated in the outpatient setting, the majority indicated that the lack of a formal risk assessment protocol remains the biggest challenge. Survey respondents also indicated that it would be most useful for their team to have printed protocols, pocket-sized algorithms, and additional education for their clinicians.

Opportunities for Improvement:

- Develop a formal VTE risk assessment protocol for use in the outpatient setting. This may include VTE risk calculators and other algorithms built into the EHR.
- Incorporate structured order sets or progress note templates to prompt clinicians to assess and document VTE risk. Given that VTE risk is higher for certain types of malignancies, consider building electronic clinical decision-support tools around those specific cancers that trigger additional fields for VTE assessment and prevention.

- Involve all members of the cancer care team in identification of VTE risk. Nurses who provide education about chemotherapy, side effects, and other aspects of clinical management may be discussing the general risk of VTE with their patients, but they are not making recommendations regarding prophylaxis for high-risk patients. Infusion nurses may also be the ones who identify thrombosis associated with chemotherapy access ports.
- Provide formal education to nurses, pharmacists, and other clinical staff to improve how the multidisciplinary team assesses VTE risk in cancer patients treated in the outpatient setting. This way, patients who are identified as being high-risk may be evaluated for prophylaxis.

Patient Education

ACCC focus group participants indicated that their clinicians do not routinely use clinical decision aids or printed materials in the outpatient setting when educating cancer patients about VTE risk and prevention. Those responding to the ACCC survey also reported a range of variability in when and how their clinicians educate patients about VTE.

- 59 percent reported that clinical staff spends less than 5 minutes typically discussing VTE risk and anticoagulation with cancer patients treated in the outpatient setting.
- 22 percent reported that VTE is often not routinely discussed; 22 percent reported that VTE is discussed during the initial consultation; 25 percent indicated discussion about VTE during the treatment consent process; and 41 percent reported discussing VTE during the chemotherapy education session.

Survey respondents were asked to indicate what types of tools and education materials their clinicians typically use when educating patients about VTE. The majority indicated that their clinicians primarily speak about VTE risk and do not typically use any type of formal tools or printed materials. Survey respondents also indicated that it would be most useful for their team to have printed educational materials for their patients.

Opportunities for Improvement:

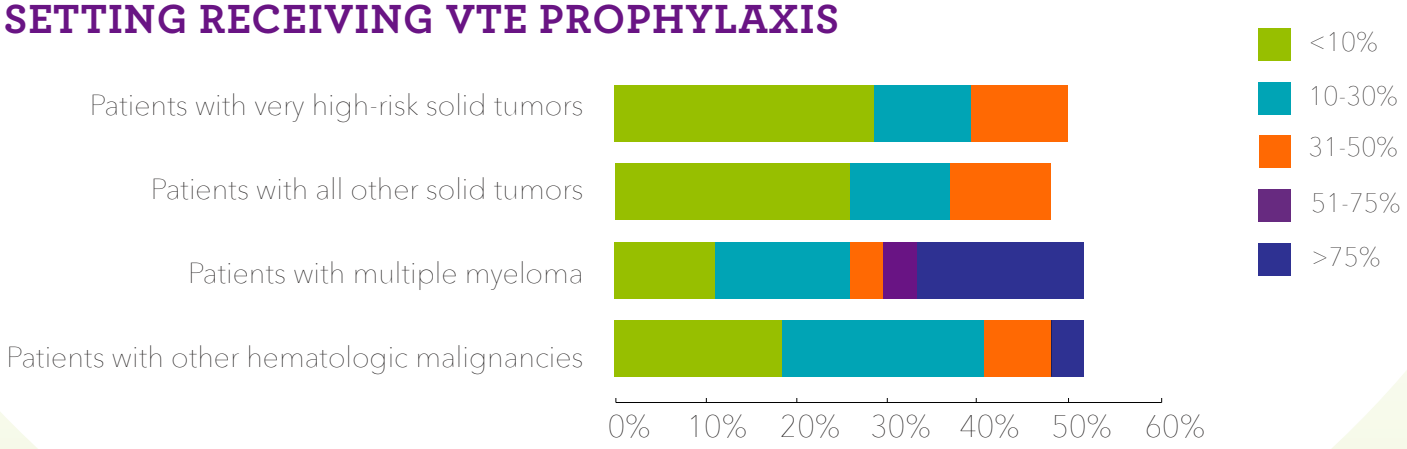
- Emphasize VTE risk when educating patients about their cancer care plan.
- Modify patient consent forms to mention the importance of VTE risk. This may prompt clinicians to spend more time stratifying patients and help to educate patients about their risk for VTE.
- Consider the use of visual aids, charts, infographics, posters, handouts, or other educational tools when explaining VTE risk to patients.

VTE Prophylaxis

ACCC focus group participants and survey respondents indicated that their medical oncology physicians and advanced practice providers do not routinely prescribe VTE prophylaxis in the outpatient setting.

- 29 percent of survey respondents indicated that over 90 percent of patients treated in the outpatient setting with very high-risk solid tumors do not receive VTE prophylaxis.
- 19 percent reported that more than 75 percent of their patients with multiple myeloma receive VTE prophylaxis.
- 30 percent reported a significant amount of variability across their oncology providers prescribing VTE prophylaxis for cancer patients treated in the outpatient setting; only 22 percent reported little variability.

PERCENTAGE OF CANCER PATIENTS TREATED IN THE OUTPATIENT SETTING RECEIVING VTE PROPHYLAXIS



Several of the focus group participants indicated that their outpatient EHR has order sets around certain multiple myeloma medications that automatically trigger an alert to order VTE prophylaxis. However, they also noted that patients need to receive a better explanation about the duration of the prophylaxis since this information may cause some to express strong opinions about their preference towards injected vs. oral agents.

Less than half (37 percent) of survey respondents indicated that their oncology practitioners or nurses assess and incorporate patient preferences into VTE prophylaxis and treatment decisions made in the outpatient setting. When asked to estimate the frequency of specific treatments used for prophylaxis of VTE in high-risk cancer patients treated in the outpatient setting, they indicated that the most commonly used drug was aspirin followed by LMWH (low molecular weight heparin) or fondaparinux. Examples of LMWH include enoxaparin, dalteparin, and tinzaparin, among others.

Of survey respondents 23 percent indicated that aspirin is used in the majority of cancer outpatients who require VTE prophylaxis; 9 percent indicated that LMWH or fondaparinux is used in the majority of cancer outpatients who require VTE prophylaxis.

The least frequently used agents (used less than 10 percent of the time) were warfarin and direct/novel oral anticoagulants (DOAC/NOAC). Examples of DOAC/NOAC include direct thrombin inhibitors (dabigatran) and factor Xa inhibitors (rivaroxaban, apixaban, and edoxaban).

When survey respondents were asked about the top challenges around VTE prophylaxis in cancer outpatients, the majority indicated that the lack of a formal policy or protocol remains the biggest challenge.

Opportunities for Improvement:

- Assess whether certain electronic order sets (e.g., for certain multiple myeloma treatment regimens) should be updated to incorporate a trigger for VTE prophylaxis.
- Explain prophylaxis for VTE clearly to patients. Some patients may not understand how long they will need to receive VTE prophylaxis.
- Employ different VTE prophylaxis strategies for cancer patients based on their preferences for injected vs. oral agents. If patients knew how long they would be required to receive VTE prophylaxis, they might express more opinions about their preferences towards injected vs. oral agents. Patient-centered and patient-driven care partially depends on incorporating patient preferences into their care plans.
- Support documentation, including substantiating the medical need for treatment, to help avoid denials for injectable VTE prophylaxis medications.

VTE Management

In the community setting, there is wide variability in how oncologists treat cancer patients with VTE. Some follow NCCN guidelines strictly, while others may choose treatment decisions that are largely driven by patient preferences. When cancer patients treated in the outpatient setting develop VTE, they receive short-term treatment and long-term secondary prophylaxis. The types of treatments recommended and the duration of secondary prophylaxis are addressed in several published guidelines from ASCO, NCCN, and CHEST:

- The ASCO guidelines primarily recommend the use of LMWH for both the initial and long-term secondary prophylaxis when cancer patients develop VTE.[10]
- The NCCN guidelines recommend LMWH for the initial treatment and suggest warfarin if patients will require ongoing prophylaxis beyond six months.[5]
- The CHEST guidelines suggest LMWH over warfarin for patients with cancer and also indicate that the risk reduction for recurrent VTE with all NOACs appear to be similar to the risk reduction with warfarin.[11]

Despite these guidelines, a presentation delivered at ASH 2015 suggests that in the real-world setting, oncology practitioners are using a wide range of agents to treat cancer outpatients with VTE. The researchers found that cancer patients treated in the outpatient setting received anticoagulation with either LMWH (25 percent), LMWH/warfarin (19 percent), warfarin (29 percent), or rivaroxaban (24 percent).[12]

ACCC focus group participants indicated that their clinicians primarily adhere to the NCCN guidelines for VTE management and most cancer patients treated in the outpatient setting receive LMWH. Similarly, in the ACCC survey, 77 percent indicated that their clinicians primarily follow the NCCN guidelines for VTE management.

However, other factors mentioned in the focus group may impact how VTE is managed in the outpatient setting. When cancer patients present with VTE during an office visit, a clinician's ability to fill the initial prescription for an oral agent vs. injectable agent is dependent on several factors, including:

- Whether there is an on-site or local dispensing pharmacy that will dispense the anticoagulation drug.
- Insurance prior authorizations, possible denials, or insurance companies directing the use of specific pharmacies for dispensing.
- Whether the patient will receive the initial doses now and future doses through mail-order pharmacies.
- Whether the outpatient setting has access to medication samples that they can provide to patients.
- Out-of-pocket costs.

These factors may impact how a practitioner may initially choose to treat VTE, and then possibly transition the patient to another medication for long-term treatment. Patient preferences for oral vs. injectable medications may also impact treatment decisions and long-term adherence.

Survey respondents also indicated the following:

- 30 percent reported a significant amount of variability across their oncology providers prescribing VTE treatments for cancer patients treated in the outpatient setting; only 22 percent reported little variability.
- Only 17 percent reported that their cancer program has a formal policy, templated forms, or standardized electronic order set to guide oncology providers when treating patients with VTE in the outpatient setting.

Survey respondents were also asked about their top challenges around VTE management in cancer patients treated in the outpatient setting. The majority focused around the financial barriers associated with the cost of medications. Some continue to struggle with insurance approvals for certain drugs while others serve patient populations that have difficulty with drug out-of-pocket costs.

Opportunities for Improvement:

- Provide more education to cancer patients who develop VTE regarding their treatment plan and treatment choices. Help patients understand how long they will require anticoagulation medication and how the different treatments are administered, potential interactions, and monitoring parameters.
- Address out-of-pocket costs by providing financial counseling and navigation services for patients who require VTE treatment.
- Form a taskforce or workgroup to evaluate the practice patterns of providers treating VTE in the outpatient setting. This group could assess the variability of treatment patterns and also assess how often treatments are being personalized based on shared decision-making conversations with patients.

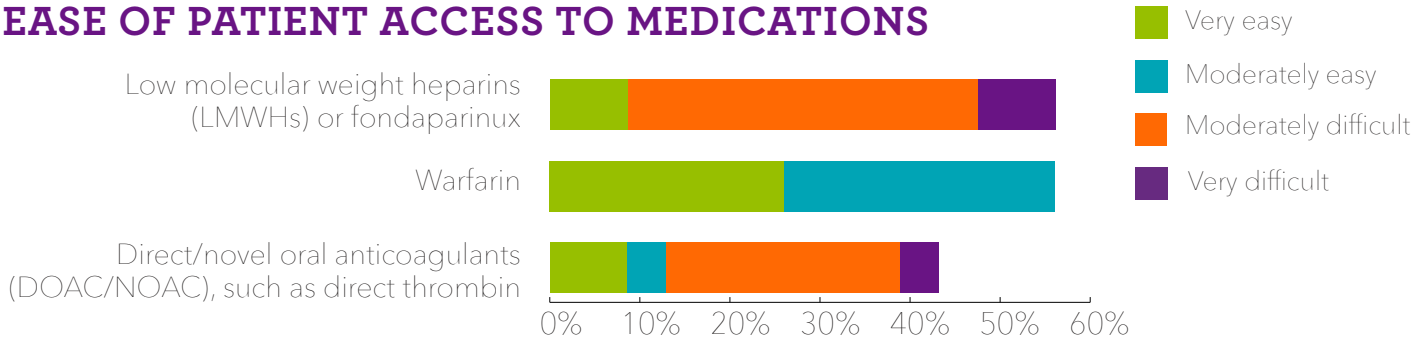
Access to Treatments

Since some anticoagulation agents are given orally while others are administered as subcutaneous injections, the assessment of patient preferences can impact treatment decisions and patient adherence to prescribed agents. During the focus group, several people indicated that their patients sometimes experience insurance denials for injectable VTE prophylaxis medications. These denials may be due to suboptimal documentation to substantiate the medical need for the treatment. The prior authorization process can also take up significant staff time.

Moreover, access to these treatments is another consideration that may impact workflow. During the focus group, a few participants indicated that the initial treatment of VTE may be dependent on the time of day, since this also affects when certain pharmacies are open. Unless the prescribed medications are readily available on site as samples, patients may require initial treatment with one drug and may then be prescribed a different drug that they will receive through the mail.

- 26 percent of survey respondents indicated that warfarin is very easy and simple for patients to access.
- 9 percent reported that LMWH are very easy and simple to access.
- 9 percent reported that NOACs are very easy and simple to access.

EASE OF PATIENT ACCESS TO MEDICATIONS



Insurance denials or high out-of-pocket costs for drugs were the top barriers identified by survey respondents.

Opportunities for Improvement:

- Be cognizant that some cancer patients may need to be started on one therapy based on immediate availability, but then may switch to a different agent for long-term prophylaxis or treatment.
- Clearly document medical need for VTE prophylaxis based on patient's level of risk to avoid insurance denials.
- Provide access to financial advocates and counselors who can help patients find patient assistance programs for their medications.

Patient Monitoring

ACCC focus group participants indicated that cancer patients who are taking warfarin for VTE management may receive monitoring and dose adjustments through a Coumadin Clinic or their medical oncologists. Nurses or pharmacists may also apply dose-adjustment guidelines for patients taking warfarin. DOACs/NOACs do not require the same kind of regular monitoring and/or dose adjustments.

Survey respondents also indicated a range of monitoring programs:

- 38 percent make scheduled follow-up appointments.
- 14 percent use anticoagulation clinics.
- 10 percent rely on the primary care provider to monitor patients.
- 5 percent make scheduled phone calls.

Opportunities for Improvement:

- Spend more time educating patients about the importance of adherence to VTE prophylaxis, as adherence may be suboptimal for a number of reasons.
- Follow-up with patients regularly to ensure engagement and adherence.
- Discuss patient preference and options for VTE prophylaxis to ensure long-term adherence.

Conclusion

VTE is a leading cause of death among cancer patients, but is largely preventable if high-risk patients are appropriately identified and given prophylaxis. The current landscape of VTE prevention and treatment in the cancer outpatient setting has room for improvement given the considerable amount of clinical variability that often deviates from published guidelines. Clinicians must remember that VTE risk in cancer patients is multifactorial and all the members of the multidisciplinary cancer care team can play a role to ensure that high-risk cancer outpatients are identified and receiving appropriate VTE prophylaxis. Furthermore, patient-driven factors and preferences may make a greater impact in how providers choose to prevent and manage VTE in the outpatient setting since these variables may impact adherence to treatments. This project has identified some of the potential issues and opportunities to enhance clinician education and clinical workflow processes and to employ effective practices for outpatient VTE risk assessment, prophylaxis, and management in the community setting.

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About the Association of Community Cancer Centers

The Association of Community Cancer Centers (ACCC) is the leading advocacy and education organization for the multidisciplinary cancer care team. Approximately 22,000 cancer care professionals from 2,000 hospitals and practices nationwide are affiliated with ACCC. Providing a national forum for addressing issues that affect community cancer programs, ACCC is recognized as the premier provider of resources for the entire oncology care team. Our members include medical and radiation oncologists, surgeons, cancer program administrators and medical directors, senior hospital executives, practice managers, pharmacists, oncology nurses, radiation therapists, social workers, and cancer program data managers.

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