NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism: Policy, Preferred Practices, and Initial Performance Measures

A CONSENSUS REPORT

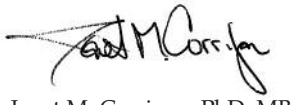
Foreword

Venous thromboembolism (VTE) is the most common preventable cause of hospital death in the United States. Despite the fact that several clinical interventions are available for preventing and treating VTE, which encompasses deep vein thrombosis and pulmonary embolism, only about one-third of all patients at risk for the condition who are appropriate candidates for prophylactic treatment actually receive it.

Since the first set of projects it undertook, the National Quality Forum (NQF) has recognized and targeted VTE as a serious patient safety threat. Two practices identified in its 2003 report, *Safe Practices for Better Healthcare: A Consensus Report*, address VTE. And while those practices are important and recently have been updated, VTE prevention and care remain woefully inadequate and quality measurement remains underdeveloped. National consensus standards addressing risk assessment, prevention, diagnosis, and treatment of VTE have not existed previously, and there remains a dearth of performance measures for assessing adherence to nationally accepted, evidence-based guidelines for the prevention and care of VTE.

This report endorses a statement of organizational policy identifying 4 specific domains of VTE prevention and care, 17 key characteristics of preferred practices, and 2 measures of VTE prophylaxis for surgery patients. It establishes a framework for the development of a set of performance measures for VTE prevention and care. It also provides guidance for institutions that are seeking to take immediate action to address the devastating consequences of this silent and deadly disease while positioning themselves for compliance with the VTE performance measures that will follow in the second phase of this project.

We thank the members of the Steering Committee and the Technical Advisory Panel for their dedication to improving the prevention and care of VTE, and we thank NQF Members for their collective commitment to improving VTE prevention and care.



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National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism: Policy, Preferred Practices, and Initial Performance Measures

Executive Summary

Venous thromboembolism (VTE), which encompasses deep vein thrombosis (DVT) and pulmonary embolism (PE), is the most common preventable cause of hospital death in the United States; most hospitalized patients have one or more risk factors for VTE, and about two-thirds of VTE-related deaths are the result of hospital-acquired disease. Recent estimates show that more than 900,000 Americans suffer VTE each year, with about 400,000 of these being DVT and 500,000 manifesting as PE. In about 300,000 persons, PE proves fatal, making it the third most common cause of hospital-related death in the United States. Despite the fact that several clinical interventions, including the use of mechanical and pharmacologic therapies, are known to be effective in preventing and treating VTE, only one-third of all patients at risk for VTE who are appropriate candidates for prophylactic treatment actually receive such treatment.

Recognizing that VTE is a significant patient safety issue despite the availability of effective interventions, the National Quality Forum (NQF) endorsed Safe Practices 17 and 18 in its 2003 report, *Safe Practices for Better Healthcare: A Consensus Report*. The consensus standards in this VTE report, as an outgrowth, specifically, of Safe Practice 17, were endorsed to further advance VTE prevention and care and to develop measures for public reporting.

This report details the first phase of a VTE project in which NQF endorses 2 process measures for prophylaxis in surgical patients, a statement of organizational policy, and 17 key characteristics of preferred practices that healthcare organizations must address in their efforts to ensure quality VTE prevention and care. The statement of policy and key characteristics of preferred practices also provide a framework within which a set of performance measures to evaluate adherence to preferred practices in VTE–DVT/PE assessment, prophylaxis, diagnosis, and treatment can be identified or developed.

Relationship to the Future Prevention and Care of VTE Performance Measure Set

This set of consensus standards establishes a framework for the assessment, prevention, diagnosis, and treatment of VTE. The second phase of NQF's VTE project focuses on performance measure development and is under way in collaboration with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). During this phase, additional performance measures have been selected from among the candidate measures, and JCAHO, under contract to NQF, is developing and testing them. Throughout this process, areas in which additional research is needed to improve the quality of VTE prevention and care will be identified and advanced within the framework of the key characteristics of preferred practices.

National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism[1]

Statement of Policy

Every healthcare organization shall have a written policy appropriate for its scope that is evidence based and that drives continuous quality improvement related to venous thromboembolism (VTE) risk assessment, prophylaxis, diagnosis, and treatment.

Key Characteristics of Preferred Practices

The key characteristics include general characteristics and characteristics in each of the four domains.

General

1. ensure that multidisciplinary teams develop institutions' protocols and/or "adopt" established evidence-based protocols;
2. have in place a documented system for ongoing quality improvement (QI) that demonstrates acting on evidence-based guidelines/practices (rationale for departing from guidelines should be documented unless documentation itself is for some reason contraindicated);
3. include provision for risk assessment/stratification, prophylaxis, diagnosis, and treatment;
4. include appropriate QI activity/monitoring for all phases of care with periodic (as defined by institutional policy) assessment of compliance with policies and measures; and

[1]See the full report for additional discussion, background, and reference material.

5. provide for a system of provider education that encompasses all aspects of VTE prevention and care, including primary and secondary prevention, risk assessment and stratification, prophylaxis, diagnosis, and treatment.

Risk Assessment/Stratification

1. provide for risk assessments on all patients based on evidence-based institutional policy (institutions have the flexibility to determine how patient risks are assessed/stratified); and
2. require documentation in the patient's health record that risk assessment/stratification was completed.

Prophylaxis

1. provide for type and intensity of prophylaxis based on and commensurate with assessment and documentation of risk/benefit and efficacy/safety for the patient; and
2. be based on formal risk assessment and be consistent with nationally accepted, evidence-based measures/guidelines including NQF-endorsed™ Safe Practice 28 (formerly 17).

Diagnosis

1. include a requirement to establish a diagnosis of VTE using specific objective diagnostic testing in order to justify treatment continued beyond the initial empiric treatment; and
2. include institution-specific algorithm(s) for establishing diagnosis and require the documentation of contraindications if the algorithm(s) is not followed.

Treatment and Monitoring

1. ensure that anticoagulation is administered safely and that the setting in which anticoagulation occurs is part of the safety consideration;
2. incorporate NQF-endorsed Safe Practice 29 (formerly 18);
3. provide for the initiation of treatment based on empiric evidence with a high degree of suspicion and assessment of safety concerns that, for continued therapy, is confirmed with objective testing based on facility policy/guidelines (also see diagnosis, above);

4. provide for accurate verbal and written patient education that is appropriate to the setting and patient reading levels (that includes some assessment of understanding versus simple documentation—especially important for outpatients);
5. provide for guideline-directed therapy addressing:
   a. initiation and monitoring of heparin and oral anticoagulation therapy, including timing of initial dose, dose and dose schedule, duration of heparin/oral anticoagulation overlap, and total duration of therapy;
   b. appropriate indications for placement and retrieval of an inferior vena cava filter;
   c. appropriate indications for thrombolytic therapy and venous embolectomy (includes pulmonary artery embolectomy);
   d. prevention of post-thrombotic syndrome; and
   e. monitoring for the development of and early intervention for chronic thromboembolic pulmonary hypertension; and
6. provide for guideline-directed therapy that addresses care setting transitions.

Performance Measures*

- Surgery patients with recommended venous thromboembolism (VTE) prophylaxis ordered.
- Surgery patients who received appropriate venous thromboembolism (VTE) prophylaxis within 24 hours prior to surgery to 24 hours after surgery.

*Detailed specifications required to implement these measures are provided in the full report.

National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism: Policy, Preferred Practices, and Initial Performance Measures

Introduction

Venous thromboembolism (VTE), which encompasses deep vein thrombosis (DVT) and pulmonary embolism (PE), is the most common preventable cause of hospital death.[1,2,3] Recent estimates show that more than 900,000 Americans suffer VTE each year, with about 400,000 of these having DVT and 500,000 manifesting as PE.[4] In about 300,000 Americans, PE proves fatal; it is the third most common cause of hospital-related death in the United States.[5] Survivors are at risk for recurrence and other serious long-term complications, including post-thrombotic syndrome and chronic thromboembolic pulmonary hypertension.[6]

[1] Heit JA, O'Fallon WM, Petterson TM, et al., Relative impact of risk factors for deep vein thrombosis and pulmonary embolism, *Arch Intern Med*, 2002;162:1245-1248.

[2] Tapson VF, Hyers TM, Waldo AL, et al., Antithrombotic therapy practices in US hospitals in an era of practice guidelines, *Arch Intern Med*, 2005;165:1458-1464.

[3] Clagett GP, Anderson FA, Heit JA, et al., Prevention of venous thromboembolism, *Chest*, 1995;108:312-334.

[4] Heit JA, Cohen AT, Anderson FA Jr, et al., Estimated annual number of incident and recurrent, non-fatal and fatal venous thromboembolism (VTE) events in the US, *Blood (ASH Annual Meeting Abstracts)*, 2005;106:Abstract 910.

[5] Ibid.

[6] Davidson BL, Sullivan SD, Kahn SR, et al., The economics of venous thromboembolism prophylaxis: a primer for clinicians, *Chest*, 2003;124:393-396.

About two-thirds of all VTE events are related to hospitalization.[7] Although VTE is often clinically silent, with as many as 25 percent of cases presenting as sudden death from PE, needless mortality and morbidity occur due to underdiagnosis and underutilization of prophylaxis.[8] Despite the fact that several clinical interventions, including the use of mechanical and pharmacologic therapies, are known to be effective in preventing and treating VTE, only one-third of all patients at risk for VTE who are appropriate candidates for prophylactic treatment actually receive such treatment.[9]

Prophylaxis is only one component involved in preventing DVT; however, 30 to 50 percent of patients diagnosed and hospitalized with DVT had received prophylaxis. While the improvement to 50 percent occurred with or without continuing medical education (CME), the greatest percentage of improvement occurred with CME, suggesting that increasing provider education can save many lives.[10]

Improvements in the quality of VTE prevention and care—in hospitals in particular—have the potential to benefit many, given the number and variety of clinical conditions or circumstances that place individuals at risk for VTE. Most hospitalized patients have one or more risk factors for VTE.[11] Risk factors include advancing age, recent major surgery, trauma (especially fractures of the pelvis, hip, or leg), cancer, prolonged immobilization from any cause, obesity, history of thromboembolism, hypertension, pregnancy, congestive heart failure, acute myocardial infarction, stroke and other debilitating neurological conditions, mechanical ventilation, smoking, use of oral contraceptives or estrogen hormone

[7] Heit JA, Cohen AT, Anderson FA Jr, et al., Estimated annual number of incident and recurrent, non-fatal and fatal venous thromboembolism (VTE) events in the US.

[8] Heit JA, O'Fallon WM, Petterson TM, Relative impact of risk factors for deep vein thrombosis and pulmonary embolism.

[9] Clagett GP, Anderson FA, Heit JA, et al., Prevention of venous thromboembolism.

[10] Anderson FA, Wheeler HB, Goldberg RJ, et al., Changing clinical practice: prospective study of the impact of continuing medical education and quality assurance programs on use of prophylaxis for venous thromboembolism, *Arch Intern Med*, 1994;154(6):669-677.

[11] Geerts WH, Pineo GF, Heit JA, et al., Prevention of venous thromboembolism; the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy, *Chest*, 2004;126(3)Suppl:338S-379S.

therapy, and various inherited conditions.[12,13,14] Moreover, about two-thirds of VTE-related deaths are the result of hospital-acquired disease.[15]

Although preventing VTE is a significant patient safety issue, there is little public awareness of the life-threatening conditions of its components, DVT and PE. With respect to DVT, for example, a 2002 survey conducted on behalf of the American Public Health Association suggests that 75 percent of Americans have little or no awareness of DVT, and fewer than 50 percent of respondents could identify any risk factors associated with its development.[16] Recognizing the lack of public awareness, several organizations have mobilized to increase consumer knowledge of the risks, signs, and symptoms of VTE through increased media visibility. In addition to increasing public awareness, efforts to reduce the occurrence of VTE also include improved provider education. Several specialty provider organizations have developed,[17,18] or are developing, guidelines to promote appropriate screening and prophylaxis for at-risk patients. Despite these efforts, however, wide variation in the prevention and care of VTE persists.

National Voluntary Consensus Standards for Prevention and Care of VTE

To improve VTE prophylaxis and treatment and save patient lives, this National Quality Forum (NQF) report provides a set of consensus standards that includes a statement of policy that sets forth the domains of prevention and care; key characteristics of preferred practices; and an initial set of two surgical prophylaxis performance measures.

Relationship to Other NQF-Endorsed™ Consensus Standards

This report builds on previously endorsed NQF consensus standards for the prevention and care of VTE. In its 2003 report, *Safe Practices for Better Healthcare: A Consensus Report*,[19] NQF endorsed 30 safe practices to improve patient safety and reduce the occurrence of preventable adverse healthcare events. In recognition of the glaring underuse of prophylaxis for VTE, one of the 30 NQF-endorsed safe practices specified that upon admission to the hospital and regularly thereafter, each

[12] Goldhaber SZ, Tapson VF, A prospective registry of 5,451 patients with ultrasound-confirmed deep vein thrombosis, *Am J Cardiol*, 2004;93:259-262.

[13] National Heart, Lung, and Blood Institute, *What Makes Deep Vein Thrombosis More Likely?* Available at www.nhlbi.nih.gov/health/dci/Diseases/Dvt/DVT_WhoIsAtRisk.html. Last accessed January 2006.

[14] Goldhaber SZ, Morrison RB, Pulmonary embolism and deep vein thrombosis, *Circulation*, 2002;106:1436.

[15] Heit JA, Cohen AT, Anderson FA Jr., et al., Estimated annual number of incident and recurrent, non-fatal and fatal venous thromboembolism (VTE) events in the US.

[16] American Public Health Association, *Deep-Vein Thrombosis: Advancing Awareness to Protect Patient Lives*, White Paper, Public Health Leadership Conference on Deep-Vein Thrombosis, Washington, DC; February 26, 2003.

[17] Hirsh J, Guyatt G, Alberts GW, et al., Evidence-based guidelines: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy, Chest, 2004;126(3)Suppl;172S-173S.

[18] Agus GB, Allegra C, Arpaia G, et al., Guidelines for the prevention and treatment of thromboembolic disease, *Int Angiol*, 2001;20(2)Suppl. Available at www.flebologia.unisi.it/lineeguida/guidelines-TVP.htm. Last accessed January 2006.

[19] National Quality Forum (NQF), *Safe Practices for Better Healthcare: A Consensus Report*, Washington, DC: NQF; 2003.

patient should be evaluated for the risk of developing VTE-DVT and that clinically appropriate methods to prevent VTE-DVT should be utilized. Safe Practice 17 further specified that risk assessment and prevention planning should be documented in patient records and that explicit organizational policies and procedures should be in place for the prevention of VTE-DVT.

Safe Practice 18 specified that organizational policies and procedures should provide for antithrombotic services (see box A, below, for Safe Practices 17 and 18). It was beyond the scope of that report, however, to identify a set of model organizational policies, preferred practices, and performance measures for the prevention and care of VTE.

Box A – NQF-Endorsed Safe Practices 17 and 18: 2003

Safe Practice 17

Evaluate each patient upon admission and regularly thereafter for the risk of developing DVT-VTE. Utilize clinically appropriate methods to prevent DVT-VTE.

Additional Specifications

- Document the VTE risk assessment and prevention plan in the patient's record.
- Explicit organizational policies and procedures should be in place for the prevention of VTE.

Applicable Clinical Care Settings

Acute care hospitals, long-term care facilities, and nursing homes.

Example Implementation Approaches

- Depending on the level of risk, different specific methods may be more appropriate or more effective than other methods. For example, in postoperative patients, mechanical methods such as graduate compression stockings or intermittent calf compression may be preferred to anticoagulants.

Safe Practice 18

Utilize dedicated antithrombotic (anticoagulation) services that facilitate coordinated care management.

Additional Specifications

Explicit organizational policies and procedures should be in place regarding antithrombotic services.

Applicable Clinical Care Settings

All care settings.

Example Implementation Approaches

- Ensure that staff are dedicated and experienced in monitoring anticoagulant therapy.
- Implement reliable patient scheduling and tracking.
- Employ accessible, accurate, and frequent Prothrombin Time, International Normalized Ratio (PT/INR) testing.
- Utilize patient-specific decision support and interaction.
- Implement ongoing patient education.

Although Safe Practices 17 and 18 were important first steps, additional work to improve the quality of VTE prevention and care clearly was needed. Until now, there have been no nationally recognized model organizational policies for the prevention of VTE. National consensus standards that identified preferred practices in VTE risk assessment, prevention, diagnosis, and treatment—applicable to a variety of healthcare settings—did not exist. Likewise, there had been no widely agreed-upon performance measures to assess adherence to accepted guidelines for the prevention and care of VTE. Given the mortality and morbidity attributed to VTE, the need for such standards is compelling.

Recognizing that quality improvement efforts take place within a broad organizational context, NQF views organizational policies and practices as unique vehicles for advancing healthcare quality. The domains of VTE prevention and care and the key characteristics of preferred practices have the potential to enable improvement by providing guidance in areas that have a dearth of performance measures, while the work to identify and develop performance measures is being done. Additionally, they may drive future research and measure development, while offering healthcare organizations a framework for immediate action.

Still, although policies and practices offer a framework for early improvements in the quality and care of VTE, performance measures are critical. Given the relatively immature state of performance measurement for all aspects of VTE prevention and care and the enormous need for performance measures in this area, NQF formed a unique collaboration with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to draw upon its expertise in measure specification, development, and testing. Performance measures identified through this initiative will be available for consideration in 2007 by NQF under the Consensus Development Process (CDP).

This report represents the first phase of work to endorse—pursuant to the NQF CDP (appendix E)—a set of voluntary consensus standards for VTE prevention and care. It sets forth 4 domains of prevention and care (within a statement

of policy), 17 key characteristics of preferred practices, and 2 surgical prophylaxis performance measures. The key characteristics of preferred practices address elements of each domain across the continuum of VTE prevention and care—including risk assessment/stratification, prophylaxis, diagnosis, and treatment—and they set forth expectations for ongoing monitoring. The domains and their attendant key practice characteristics are applicable across care settings and should permit each healthcare organization to adopt them in a manner consistent with the setting in which it delivers care and with the scope of services provided.

Identifying the Initial Set

NQF convened a Steering Committee (appendix C) to establish the initial approach to developing consensus standards for the prevention and care of VTE. A framework that demonstrates the relationship among policies, practices, and performance measures was identified, as were the purpose of the initial set of policy and practice statements and the scope and priorities of the set of voluntary consensus standards.

A Framework for VTE Prevention and Care

The objectives of the VTE project framework are to ensure that:

- the endorsed set of model organizational policies, preferred practices, and performance measures covers the full spectrum of prevention and care services that impact quality;
- the needs of all stakeholders are addressed and the knowledge that is provided is useable by all stakeholders;
- the endorsed set of model organizational policies, preferred practices, and performance measures builds upon the criteria set forth in *Safe Practices for Better Healthcare: A Consensus Report* and is generalizable (i.e., it may be applied in multiple clinical care settings and/or for multiple types of patients);
- the endorsed set of organizational policies, preferred practices, and performance measures reflects strong evidence that such practices can improve quality of care and reduce the incidence and/or complications of VTE–DVT/PE;

- the processes and criteria for the recommendation of policies, practices, and measures are standardized and precisely defined;
- the reporting and implementation of the consensus standards are performed in a way that will maximize impact; and
- the policies, practices, and measures will leverage opportunities for significant improvement in the prevention and care of VTE–DVT/PE by identifying critical points in the clinical course and progression of this condition.

Purpose

As noted, this report encompasses a framework that delineates the domains of VTE prevention and care, characteristics of preferred practices, and performance measures. Specifically:

- The statement of policy, with its four domains of prevention and care, provides a framework within which the characteristics of preferred practices are explicated and a comprehensive set of performance measures related to evidence-based guidelines is identified or developed and tested to evaluate adherence to practices.
- The purpose of the 17 key characteristics of preferred practices for the prevention and care of VTE is to inform internal quality improvement efforts and to provide guidance to hospitals and other healthcare providers as they strive to provide the highest quality of care to patients at risk of, and those being treated for, VTE.
- The purpose of the two performance measures for VTE surgical prophylaxis is public accountability.

Scope

The voluntary consensus standards for the prevention and care of VTE–DVT/PE encompass those that:

- are fully open source;
- include the entire continuum of care, from prevention through diagnosis, treatment, secondary prevention, and management of high-risk populations;
- are applicable across healthcare organizations that provide care to persons at risk for VTE;
- can be used for quality improvement;
- reflect those aspects of VTE prevention and care over which healthcare organizations and providers have control, including transitions of care between healthcare providers along the continuum of care;
- address the six NQF-endorsed aims for healthcare (i.e., safe, beneficial, patient centered, timely, efficient, and equitable);
- address the need for education and awareness programs; and
- with respect to performance measures, are fully developed.

Priority Areas for VTE Prevention and Care Policy, Practices, and Performance Measures

In identifying the policy, practice statements, and performance measures for the prevention and care of VTE, priority was given to those that:

- are likely to lead to significant improvement in the prevention and care of VTE;
- build upon NQF-endorsed voluntary consensus standards;

- are applicable to multiple levels of the healthcare system;
- address priorities for national healthcare quality;
- are suitable for accountability and efficiency;
- relate to prevention, early identification, and treatment; and
- address disparities in care.

Criteria for the Selection of Consensus Standards

Two NQF reports, *A Comprehensive Framework for Hospital Care Performance Evaluation: A Consensus Report*[20] and *Safe Practices for Better Healthcare: A Consensus Report*, provided a framework for the evaluation of the candidate practices and measures. The criteria detailed in these reports were used to evaluate each candidate practice (box B) and each performance measure (box C).

Box B – Criteria for Inclusion in the Set – Practices

In considering new candidate practices, as well as establishing boundaries and priorities for gaps that may exist, the following four domains, derived from earlier NQF work, were used: importance, scientific acceptability, usability, and feasibility. Furthermore, to be included in the set, the key characteristics of practices were evaluated against the specific criteria from Safe Practices for Better Healthcare: A Consensus Report, *which are as follows:*

Specificity. The practice must be a clearly and precisely defined process or manner of providing a healthcare service. All candidate safe practices were screened according to this threshold criterion. Candidate safe practices that met the threshold criterion of specificity were then rated against four additional criteria relating to the likelihood of the practice improving patient safety.

Benefit. If the practice were more widely utilized, it would save lives endangered by healthcare delivery, reduce disability or other morbidity, or reduce the likelihood of a serious reportable event (e.g., an effective practice already in near universal use would lead to little new benefit to patients by being designated a safe practice).

Evidence of Effectiveness. There must be clear evidence that the practice would be effective in reducing patient safety events. Such evidence may take various forms, including the following:

- research studies showing a direct connection between improved clinical outcomes (e.g., reduced mortality or morbidity) and the practice;
- experiential data (including broad expert agreement, widespread opinion, or professional consensus) showing the practice is "obviously beneficial" or self-evident (i.e., the practice absolutely constrains a potential problem or forces an improvement to occur, reduces reliance on memory, standardizes equipment or process steps, or promotes teamwork); or
- research findings or experiential data from non-healthcare industries that should be substantially transferable to healthcare (e.g., repeat-back of verbal orders or standardizing abbreviations).

Generalizability. The safe practice must be able to be utilized in multiple applicable clinical care settings (e.g., a variety of inpatient and/or outpatient settings) and/or for multiple types of patients.

Readiness. The necessary technology and appropriately skilled staff must be available to most healthcare organizations.

[20] NQF, *A Comprehensive Framework for Hospital Care Performance Evaluation: A Consensus Report*, Washington, DC: NQF; 2003.

Box C – Criteria for Inclusion in the Set – Performance Measures

Measures are evaluated for suitability based on four standardized criteria endorsed by NQF in 2003[21]—important, scientifically acceptable, useable, and feasible.

Important. This set addresses the extent to which a measure reflects a variation in quality or low levels of overall performance and the extent to which it captures key aspects of the flow of care.

- The measure addresses one or more key leverage points for improving quality.
- Considerable variation in the quality of care exists.
- Performance in the area (e.g., setting, procedure, condition) is suboptimal, suggesting that barriers to improvement or best practice may exist.

Scientifically acceptable. A measure is scientifically sound if it produces consistent and credible results when implemented.

- The measure is well defined and precisely specified. Measures must be specified sufficiently to be distinguishable from other measures, and they must be implemented consistently across institutions. Measure specifications should provide detail about cohort definition, as well as the denominator and numerator for rate-based measures and categories for range-based measures.
- The measure is reliable, producing the same results a high proportion of the time when assessed in the same population.
- The measure is valid, accurately representing the concept being evaluated.
- The measure is precise, adequately discriminating between real differences in provider performance.
- The measure is adaptable to patient preferences and a variety of contexts of settings. Adaptability depends on the extent to which the measure and its specifications account for the variety of patient choices, including refusal of treatment and clinical exceptions.
- An adequate and specified risk-adjustment strategy exists, where applicable.
- Consistent evidence is available linking the process measures to patient outcomes.

Useable. Usability reflects the extent to which intended audiences (e.g., consumers, purchasers) can understand the results of the measure and are likely to find them useful for decisionmaking.

- The measure can be used by the stakeholder to make decisions.
- The differences in performance levels are statistically meaningful.
- The differences in performance are practically and clinically meaningful.
- Risk stratification, risk adjustment, and other forms of recommended analyses can be applied appropriately.
- Effective presentation and dissemination strategies exist (e.g., transparency, ability to draw conclusions, information available when needed to make decisions).
- Information produced by the measure can/will be used by at least one healthcare stakeholder audience (e.g., public/consumers, purchasers, clinicians and providers, policymakers, accreditors/regulators) to make a decision or take an action.
- Information about specific conditions for which the measure is appropriate has been given.
- Methods for aggregating the measure with other, related measures (e.g., to create a composite measure) are defined, if those related measures are determined to be more understandable and more useful in decisionmaking. Risks of such aggregation, including misrepresentation, have been evaluated.

[21] Ibid.

Box C – Criteria for Inclusion in the Set – Performance Measures (continued)

Feasible. Feasibility is generally based on the way in which data can be obtained within the normal flow of clinical care and the extent to which an implementation plan can be achieved.

- The point of data collection is tied to care delivery, when feasible.
- The timing and frequency of measure collection are specified.
- The benefit of measurement is evaluated against the financial and administrative burden of implementation and maintenance of the measure set.
- An auditing strategy is designed and can be implemented.
- Confidentiality concerns are addressed.

The NQF-Endorsed National Voluntary Consensus Standards for Prevention and Care of VTE

The NQF-endorsed set is composed of a broad statement of policy identifying 4 specific domains of VTE prevention and care, 17 key characteristics of preferred practices that clarify an expectation of the action in each domain, and 2 measures of VTE prophylaxis (appendix A) intended for institutional public accountability. These consensus standards are intended for hospital use and—as applicable to the setting of care and the scope of services—all other healthcare facilities.

The domains and key characteristics of practices also provide a framework for the development of a comprehensive set of performance measures that will be identified in the next phase of the project and that will supplement the two endorsed measures in this phase.

NQF endorsement of this set:

- enables the early promulgation of policy that includes the adoption of the domains and practices into which performance measures can be integrated as they are selected, developed, and endorsed;
- facilitates assessment, prophylaxis, diagnosis, and treatment services as well as patient education and organizational monitoring of VTE prevention and care services; and
- enables organizational accountability for the appropriate VTE prophylaxis of surgical patients.

Statement of Policy and Domains of Care

The following statement of policy identifies the four domains of VTE prevention and care and sets expectations about the approach to be taken by all organizations providing care to those at risk of, or being treated for, VTE–DVT/PE.

Every healthcare organization shall have a written policy appropriate for its scope that is evidence based and that drives continuous quality improvement related to venous thromboembolism (VTE) risk assessment, prophylaxis, diagnosis, and treatment.

Key Characteristics of Preferred Practices

While the overarching statement of policy (above) calls for specific organizational action to address the four domains of VTE prevention and care (risk assessment, prophylaxis, diagnosis, and treatment), the key characteristics of preferred practices expand the policy statement by setting out general characteristics and characteristics to be addressed in each of the four domains of VTE prevention and care, as well as a monitoring function. The characteristics are arrayed as follows:

- **General.** The five key characteristics in this area focus on the use of multidisciplinary teams to establish approaches to all aspects of VTE prevention and care and provider education across all domains.
- **Risk Assessment/Stratification.** The two key characteristics of practice in this domain require that risk assessment and documentation thereof be included in an institutional policy and be carried out.
- **Prophylaxis.** The two key characteristics of practice in this domain address the requirement for risk assessment and set out the expectation that VTE prophylaxis will be based on evidence-based guidelines and include Safe Practice 28 (formerly 17). As all domains will be, this domain is amplified by the two performance measures specified in this report.
- **Diagnosis.** The two key characteristics of practice in this domain set expectations regarding methods for establishing diagnosis, attendant documentation, and provider education.
- **Treatment (and Monitoring).** The six key characteristics of preferred practices in this domain speak to the initiation of therapy, the confirmation of VTE using institutional-approved testing protocols, the safe administration of guideline-directed therapy, patient education, the use of Safe Practice 29 (formerly 18), and an expectation for monitoring.

Thus, with appropriate consideration of the setting of care and scope of services, organizational practices related to the prevention and care of VTE should be documented in policy and should include the following key characteristics:

General

1. ensure that multidisciplinary teams develop institutions' protocols and/or "adopt" established, evidence-based protocols;
2. have in place a documented system for ongoing quality improvement (QI) that demonstrates acting on evidence-based guidelines/practices (rationale for departing from guidelines should be documented unless documentation itself is for some reason contraindicated);
3. include provision for risk assessment/stratification, prophylaxis, diagnosis, and treatment;
4. include appropriate QI activity/monitoring for all phases of care with periodic (as defined by institutional policy) assessment of compliance with policies and measures; and
5. provide for a system of provider education that encompasses all aspects of VTE prevention and care, including primary and secondary prevention, risk assessment and stratification, prophylaxis, diagnosis, treatment, and monitoring.

Risk-Assessment/Stratification

1. provide for risk assessments on all patients based on evidence-based institutional policy (institutions have the flexibility to determine how patient risks are assessed/stratified); and
2. require documentation in the patient's health record that risk assessment/stratification was completed.

Prophylaxis

1. provide for the type and intensity of prophylaxis based on and commensurate with assessment and documentation of risk/benefit and efficacy/safety for the patient; and
2. be based on formal risk assessment and be consistent with nationally accepted, evidence-based measures/guidelines including NQF-endorsed Safe Practice 28.

Diagnosis

1. include a requirement to establish a diagnosis of VTE using specific objective diagnostic testing in order to justify treatment continued beyond the initial empiric treatment; and
2. include institution-specific algorithm(s) for establishing diagnosis and require the documentation of contraindications if the algorithm(s) is not followed.

Treatment and Monitoring

1. ensure that anticoagulation is administered safely and that the setting in which anticoagulation occurs is part of the safety consideration;
2. incorporate NQF-endorsed Safe Practice 29;
3. provide for the initiation of treatment based on empiric evidence with a high degree of suspicion and assessment of safety concerns that, for continued therapy, is confirmed with objective testing based on facility policy/guidelines (also see diagnosis, above);
4. provide for accurate verbal and written patient education that is appropriate to the setting and patient reading levels (that includes some assessment of understanding versus simple documentation—which is especially important for outpatients);
5. provide for guideline-directed therapy addressing:
   a. initiation and monitoring of heparin and oral anticoagulation therapy, including timing of initial dose, dose and dose schedule, duration of heparin/oral anticoagulation overlap, and total duration of therapy;
   b. appropriate indications for placement and retrieval of an inferior vena cava filter;
   c. appropriate indications for thrombolytic therapy and venous embolectomy (includes pulmonary artery embolectomy);
   d. prevention of post-thrombotic syndrome; and
   e. monitoring for the development of and early intervention for chronic thromboembolic pulmonary hypertension; and
6. provide for guideline-directed therapy that addresses care setting transitions.

Performance Measures

Two process measures for prophylaxis in the surgical patient were endorsed. They are as follows:

- Surgery patients with recommended venous thromboembolism (VTE) prophylaxis ordered.
- Surgery patients who received appropriate venous thromboembolism (VTE) prophylaxis within 24 hours prior to surgery to 24 hours after surgery.

The developer of the measures is the Centers for Medicare and Medicaid Services. Because these are measures developed by a federal government entity, they are in the public domain.

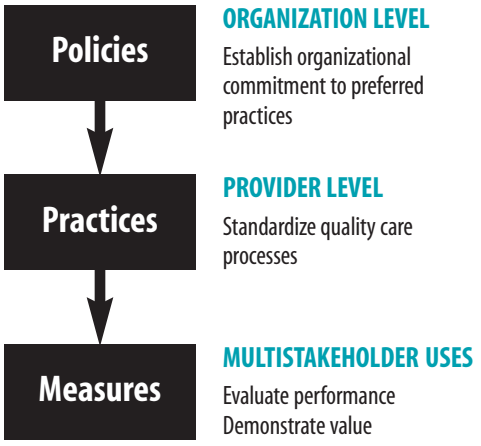
The specifications for each of the measures are included in appendix A.

Relationship Among Organizational Policies, Preferred Practices, and Performance Measures

A construct was developed and implemented in this project to demonstrate the relationship among organizational policies, preferred practices, and performance measures (figure 1).

- ***Organizational policies*** are statements of required institutional practices or organizational regulations that are included in a standard operating guide. They establish preferred practices as expected institutional behaviors and signal an organizational commitment to ensure that care processes are consistent with preferred practices. In instituting such policies, leadership demonstrates a voluntary commitment to quality and accountability.
- ***Preferred practices*** encompass a broad range of clinical decisionmaking tools that guide a healthcare professional in the prevention, diagnosis, or management of DVT. They are evidence based or represent expert consensus on quality healthcare practices. Preferred practices guide daily practice to ensure consistent, quality care. Some examples of preferred practices include the use of risk assessment instruments, clinical protocols, and patient care guidelines.
- ***Performance measures*** report the degree to which care processes conform to established care standards, including clinical guidelines.

Figure 1 – Relationship Among Organizational Policies, Preferred Practices, and Performance Measures



The relationship among the three types of proposed consensus standards should be dynamic—that is, data from performance measures should be used to inform modifications to policies and/or practices. Similarly, new evidence related to practices may well emerge and demand that the specifications for measure(s) be modified.

Relationship to the Future Prevention and Care of VTE Performance Measure Set

During the course of assessing the availability of model policies, preferred practices, and performance measures for the prevention and care of VTE, it became clear that much work remains to be done to advance quality in this area. While many

of the candidate practices addressed important aspects of VTE prevention and care, none systematically addressed each domain of care. However, taken as a whole, the preferred practices informed efforts to identify the set of key characteristics of preferred practices included in this report.

Similarly, while some performance measures related to VTE prevention and care exist, a comprehensive set of performance measures that evaluates quality across each domain of care is currently lacking. However, the second phase of the NQF VTE project is under way, and additional performance measures will be selected from among the candidate measures that JCAHO is developing and testing. Throughout this process, areas in which additional research is needed to improve the quality of VTE prevention and care will be identified and advanced within the framework of the key characteristics of preferred practices.

Acknowledgments

This work was supported by a grant from sanofi-aventis.

Appendix A

Specifications of the National Voluntary Consensus Standards for Venous Thromboembolism Prophylaxis in the Surgical Patient

The following table summarizes the specifications for each of the National Quality Forum (NQF)-endorsed™ venous thromboembolism performance measures. All information presented has been derived directly from measure sources/developers without modification or alteration (except when the measure developer agreed to such modification during the NQF Consensus Development Process) and is current as of October 16, 2006.

All NQF-endorsed voluntary consensus standards are open source, meaning they are fully accessible and disclosed. References to related risk-adjustment methodologies and definitions are provided to assure openness and transparency.

Appendix A – Specifications of the National Voluntary Consensus Standards for Venous Thromboembolism Prophylaxis in the Surgical Patient

Measure Name	IP Owner	Numerator	Denominator	Inclusions/Exclusions	Risk Adjustment
1. Surgery patients with recommended venous thromboembolism (VTE) prophylaxis ordered[1]	Centers for Medicare and Medicaid Services (CMS)	Surgery patients with recommended VTE prophylaxis ordered during the admission	All selected surgery patients	*Denominator inclusions:* ■ *ICD-9-CM Principal Procedure Code* of selected surgeries (refer to Specifications Manual, National Healthcare Quality Measures, appendix A, table 5.10 for ICD-9-CM Codes) **AND** ■ *ICD-9-CM Principal Procedure Code* of selected surgeries (refer to Specifications Manual, National Healthcare Quality Measures, appendix A, table 5.17-5.24 for ICD-9-CM Codes) *Denominator exclusions:* ■ Patients who are less than 18 years of age ■ Patients with procedures performed entirely by laparoscope ■ Patients whose total surgery time is less than or equal to 30 minutes ■ Patients who stayed less than or equal to 24 hours postoperatively ■ Burn patients (refer to Specifications Manual, National Healthcare Quality Measures, appendix A, table 5.14 for ICD-9-CM Codes) ■ Patients who are on warfarin prior to admission ■ Patients with contraindications to both mechanical and pharmacological prophylaxis ■ Patients whose ICD-9-CM Principal Procedure occurred prior to the date of admission	*None*
2. Surgery patients who received appropriate venous thromboembolism (VTE) prophylaxis within 24 hours prior to surgery to 24 hours after surgery[2]	CMS	Surgery patients who received appropriate VTE prophylaxis within 24 hours prior to *Surgical Incision Time* to 24 hours after *Surgery End Time*	All selected surgery patients	*Denominator inclusions:* ■ *ICD-9-CM Principal Procedure Code* of selected surgeries (refer to Specifications Manual, National Healthcare Quality Measures, appendix A, table 5.10 for ICD-9-CM Codes) **AND** ■ *ICD-9-CM Principal Procedure Code* of selected surgeries (refer to Specifications Manual, National Healthcare Quality Measures, appendix A, table 5.17-5.24 for ICD-9-CM Codes) *Denominator exclusions:* ■ Patients who are less than 18 years of age ■ Patients with procedures performed entirely by laparoscope ■ Patients whose total surgery time is less than or equal to 30 minutes ■ Patients who stayed less than or equal to 24 hours postoperatively ■ Burn patients (refer to Specifications Manual, National Healthcare Quality Measures, appendix A, table 5.14 for ICD-9-CM Codes) ■ Patients who are on warfarin prior to admission ■ Patients with contraindications to both mechanical and pharmacological prophylaxis ■ Patients whose ICD-9-CM Principal Procedure occurred prior to the date of admission	*None*

[1]For complete measure information including description, rationale, numerator and denominator detail, prophylaxis recommendations by surgery type and level of risk, and algorithms, see www.qualitynet.org/dcs/ContentServer?cid=1157485287169&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page, and from "Section 2.4," select "SCIP-VTE-1." ICD-9-CM Codes are also available from the "Appendices" section at this web location.

[2]For complete measure information including description, rationale, numerator and denominator detail, prophylaxis recommendations by surgery type and level of risk, and algorithms, see www.qualitynet.org/dcs/ContentServer?cid=1157485287169&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page, and from "Section 2.4," select "SCIP-VTE-2." ICD-9-CM Codes are also available from the "Appendices" section at this web location.

Appendix B
Commentary

Introduction

In January 2005, the National Quality Forum (NQF) formally initiated a project to achieve consensus on an initial set of voluntary consensus standards comprising model organizational policies, preferred practices, and performance measures for the prevention and care of venous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and pulmonary embolism (PE). As with other NQF consensus projects, a Steering Committee (appendix C) representing key healthcare constituencies—including consumers, providers, purchasers, and research and quality improvement organizations—was convened. In December 2005, the Steering Committee recommended a statement of policy that identified 4 domains of VTE prevention and care, a set of 17 key characteristics of preferred practices around the 4 domains, and 2 performance measures for endorsement as voluntary consensus standards in accordance with NQF's Consensus Development Process (appendix E). A Technical Advisory Panel (TAP) (appendix C) assisted the Steering Committee and NQF staff with the evaluation of the policy, practices, and measures; advised the Steering Committee on the technical aspects of all candidate items; advised and assisted the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)[1] in the development and testing of performance measures; and made recommendations to the Steering Committee. This appendix summarizes the deliberations of the Steering Committee and the TAP during the first phase of this project.

[1] The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is a subcontractor to the National Quality Forum for the development and testing of performance measures for this project.

This set of consensus standards is intended to:

- enable the early promulgation of policy that includes the adoption of the domains and practices into which performance measures can be integrated as they are selected, developed, and endorsed;
- facilitate assessment, prophylaxis, diagnosis, and treatment services, as well as patient education and organizational monitoring of VTE prevention and care services; and
- enable organizational accountability in the area of prophylaxis of surgical patients.

Relationship to Other NQF Voluntary Consensus Standards

This project grew from discussions that recognized that the 2003 NQF-endorsed™ Safe Practices 17 and 18, while representing a start to raising awareness regarding the need to evaluate patients for VTE–DVT/PE and to providing prophylaxis in a structured and rigorous way, did not fill the gap in guidance. In mid-2004, guidelines for conducting individual patient risk assessments, national consensus guidelines for VTE–DVT/PE prevention and care, and widely agreed-upon performance measures to assess adherence to preferred practices did not exist.

Recognizing that patients present to hospitals with VTE–DVT/PE and that a significant percentage of patients develop these problems during their hospital stay, Safe Practice 17 set the expectation that all patients admitted to acute care hospitals, long-term care facilities, and nursing homes would be evaluated upon admission and regularly throughout their hospitalization. Safe Practice 18 moved the agenda further by specifying that services should be in place to assure that care management is provided in a coordinated fashion.

This project involves a multifaceted, multiphased approach to improving prevention and care for patients at risk for or diagnosed with VTE–DVT/PE by establishing a standardized approach to prevention and care, setting forth a statement of policy that identifies four domains of prevention and care, and achieving evidence-based consensus on practices and performance measures in order to make guidance and tools on prevention and care available that go well beyond those provided by the 2003 NQF-endorsed Safe Practices 17 and 18.

Approach to Identification, Screening, and Evaluation

The Steering Committee's approach to policy, practice, and measure screening and evaluation followed a six-step process:

1. Establish a conceptual framework that clarifies the aims and approach to the set.
2. Agree on a purpose statement for the set.
3. Identify the scope of the policies, practices, and measures set in order to identify domains to be addressed.
4. Identify priority areas in order to assure a parsimonious and feasible set of policies, practices, and measures in the final set.

5. Use the criteria for evaluating policies and practices set forth in *Safe Practices for Better Healthcare: A Consensus Report*[2] and for evaluating measures as detailed in *A Comprehensive Framework for Hospital Performance Evaluation: A Consensus Report*.[3]
6. Make recommendations to NQF Members on these matters and offer any accompanying recommendations.

Framework for VTE Prevention and Care

To set a framework in which policies, preferred practices, and performance measures could be considered, the Steering Committee drew upon previous NQF-endorsed frameworks.[4,5] The Steering Committee's recommended framework, like those of other NQF projects, also revolves around the six NQF-endorsed aims for healthcare—that it be safe, beneficial, patient centered, timely, equitable, and efficient.

Additionally, the Steering Committee affirmed that the framework should ensure that:

- the endorsed set of measures, preferred practices, and model organizational policies is comprehensive and covers the full spectrum of prevention and care services that impact quality;
- the needs of all stakeholders are addressed and the knowledge provided is useable by all stakeholders;
- the endorsed set of preferred practices and model organizational policies builds upon the criteria set forth in the *Safe Practices* report and is generalizable (i.e., they may be applied in multiple care settings, and/or with multiple types of patients);
- the endorsed set of organizational policies, practices, and measures reflects strong evidence of effectiveness in preventing and/or reducing the incidence and/or complications of DVT;
- the processes and criteria for the recommendation of policies, practices, and measures are standardized and precisely defined;
- the reporting and implementation of the consensus standards are performed in a way that will maximize their impact; and
- the measures, practices, and policies leverage opportunities for significant improvement in the prevention and care of DVT by identifying critical points in the clinical course and progression of this condition.

Finally, the construct describing the relationship among policy, practices, and performance measures (figure 1, in the report) was used as a reference during the development of the statement of policy and the characteristics of preferred practices. It also will be used by the TAP and the Steering Committee as they look toward recommending a comprehensive measure

[2] National Quality Forum (NQF), *Safe Practices for Better Healthcare: A Consensus Report*, Washington, DC: NQF; 2003.

[3] NQF, *A Comprehensive Framework for Hospital Care Performance Evaluation: A Consensus Report*, Washington, DC: NQF; 2003.

[4] Ibid.

[5] NQF, *A National Framework for Healthcare Quality Measurement and Reporting: A Consensus Report*, Washington, DC: NQF; 2002.

set that will complete the tools that, once implemented, should improve the prevention and care of VTE in an evolutionary fashion.

Purpose and Scope

Steering Committee members spent considerable time discussing the purpose and scope of the project. It was their consensus that limiting the scope to DVT would exclude the potentially fatal complication of PE and that a more expansive description of, and approach to, the project were important to the development of the products that would be forthcoming. At the same time, the Committee recognized that the terms *DVT* or *blood clots* generally are used to raise patient and consumer awareness of the problem and that removing the term *DVT* would detract from those advances. The Committee further noted that:

- the purpose statement should be concise and specific, yet comprehensive enough to enable all stakeholders to understand the project and its purpose;
- the term *VTE*, which encompasses DVT and PE, is more appropriate than DVT; and
- a large and concerted effort will be needed to educate healthcare stakeholders regarding the appropriate assessment, prevention, diagnosis, and treatment of DVT/PE.

The Committee concluded that VTE, encompassing both DVT and PE, should be used to convey the full problem to be addressed and recommended the following purpose statement:

> The purpose of the prevention and care measures, practices, and policies set for deep vein thrombosis (DVT) and pulmonary embolism (PE), which together comprise venous thromboembolism (VTE), is to inform all healthcare stakeholders about the quality of VTE prevention and treatment activities across the continuum of healthcare and to identify opportunities to improve these activities in order to reduce death, disability, suffering, and the economic burden from VTE, including complications.

In addition to expanding the project to include both DVT and PE, the Steering Committee engaged in a broad and far-reaching discussion on themes that provided focus to the project scope. Two of the areas—future research and implementation—received less emphasis in this report, but the Committee noted that more emphasis will be placed on future research and implementation during the next phase of the project. The themes that guided the Committee's deliberations were as follows:

- **Consumer/patient education.** Rates of consumer awareness of DVT should be increased.
- **Evidence-based medicine.** The project should focus on evidence-based processes that will improve the implementation of proven prophylaxis, including non-pharmacological methods.
- **Research.** Future research should address the lack of clarity surrounding the prevention, diagnosis, and treatment of VTE (e.g., type of patient who should receive prophylaxis, appropriate dosage of appropriate medications, and appropriate length of administration).

- **Risk assessment tools.** There is a critical need to develop appropriate VTE risk assessment tools that can be incorporated into the general screening process. While adequate data exist to determine absolute risk, there is insufficient evidence to support the use of a specific risk assessment tool. Additionally, there is no validated tool at this time for ranking risk factors in patients who have multiple risks.
- **Care settings.** Measures, practices, and policies should address multiple care settings. Both inpatient and outpatient settings must be addressed, because of the high incidence of DVT after hospital discharge.
- **Policies and practices.** Given the dearth of current performance measures in this area, emphasis should be placed on evaluating and endorsing policies and practices.
- **Implementation.** Although a potential disconnect exists between measure sets and future implementation, the focus should remain on measure development/identification within a framework of policies and practices.

To help ensure that the TAP's and the Steering Committee's consideration of practices and performance measures would address the full spectrum of approaches to prevention and care across the domains, a Steering Committee co-chair constructed a tool entitled "Clinical Logic for Venous Thromboembolism," which the TAP found useful in its discussion of the domains of care (table 1, at the end of this commentary).

Priority Areas

At the outset of the project, the Steering Committee recognized that a broad array of potential policies, practices, and measures that fall under the umbrella of the prevention and care of VTE could be available for analysis. Accordingly, the Committee set priorities to ensure that the areas of special importance for improving the prevention and care of VTE could be recommended without causing an undue data collection burden. Informed by prior NQF work in this regard, the Steering Committee set seven priorities (see the list in the report section entitled *Priority Areas for VTE Prevention and Care Policy, Practices, and Performance Measures*) and determined that the candidate policies, practices, or measures that did not reflect these priorities but that fell within the scope of the project could be eliminated or returned to the developers for refinement.

Criteria for Selection

To evaluate practices, the Steering Committee drew upon NQF's consensus report *Safe Practices for Better Healthcare* for the threshold criterion of specificity and the additional criteria of benefit, evidence of effectiveness, generalizability, and readiness to evaluate practices. With respect to performance measures, the TAP and the Steering Committee used the NQF-endorsed criteria from *A Comprehensive Framework for Hospital Performance Evaluation*—that is, that the measures should be important, scientifically acceptable, useable, and feasible.

Identifying the Set

In January 2005, NQF and JCAHO issued a joint "Call" for model organizational policies, preferred practices, and performance measures that was sent to the more than 260 NQF member organizations (at that time) and the public. Specifically, the "Call" sought model organization policies and practices for the prevention and care of DVT. Regarding candidate practices, the "Call" specified that the practices must 1) demonstrate strong evidence of their effectiveness in reducing the likelihood of developing DVT or PE; 2) be generalizable across multiple care settings and/or for multiple types of patients; and 3) be in the public domain. The "Call" also sought candidate structure, process, or outcome performance measures for risk assessment, prevention, and treatment of DVT, with the requirement that they be fully developed for use (i.e., with research and testing complete) and open source.

In addition to the "Call," a literature review was conducted, and NQF and JCAHO engaged in targeted outreach through solicitation to individuals, organizations, and governmental jurisdictions that had indicated that they had an interest in the general topic area or had asked to be advised of new projects. A second "Call for Measures" was conducted jointly in August 2005.

Model Organizational Policies

No model organizational policies were received in response to the January 2005 solicitation. However, the TAP and the Steering Committee believed strongly that, based on its prevalence and the number of hospital-related deaths related to the disease, an overarching statement of policy would signal to all healthcare facilities the need for explicit, documented guidance in the form of policy and practices around the four domains of VTE prevention and care.

Although no candidate policies were available for its review, the TAP recommended that a statement should be identified that would make clear the expectation that all organizations that treat patients at risk for VTE should have appropriate policy(ies) in place. TAP members viewed five points as key: 1) any proposed policy statement should provide guidance without being overly prescriptive; 2) each phase or domain of caring for VTE should be addressed separately; 3) how institutions execute risk assessment, prophylaxis, diagnosis, and treatment should not be specified; however, local, evidence-based policies should address each of these components of care; 4) statements of policy and practice should not be limited to inpatient hospital settings; and 5) ultimately, the adoption of performance measures linked to practice guidelines will drive practice and motivate providers to adhere to institutional policies.

The policy statement recommended by the TAP—that "every healthcare organization will have a written policy appropriate for its scope that addresses venous thromboembolism risk assessment, prophylaxis, diagnosis, and treatment"—was further refined by the Steering Committee to make explicit the expectation that an institution's policy should be written, should be evidence based, and should drive quality improvement.

During the review period, two organizations, each with a different rationale, asked that language mandating specific organization policies related to VTE be removed from the policy statement. One raised concerns about possible certification or marketing consequences that might result if surveyors do not find an organization policy. The second viewed the requirement as burdensome and as a waste of resources, voicing the concern that such a policy would require that changes be made as advances in knowledge occur, but that such changes presumably could be handled more easily in guidelines or in order sets. However, from its first meeting, the TAP felt strongly that institutional policy is needed; this was supported by the Steering Committee. Each concern, while considered seriously, was believed to have straightforward institutional solutions that would not increase burden unduly.

Key Characteristics of Preferred Practices

Nine healthcare organizations submitted procedures, guidelines, or practices. Not unexpectedly, all submissions were facility or system specific; none covered all domains of VTE prevention and care. Although none of the submitted procedures, guidelines, or practices was recommended specifically, each was essential in shaping the framework, policy statement, and key characteristics of preferred practices. That is, when considered together, they helped crystallize the statement of policy, including the four domains as well as the key characteristics of preferred practices. In fact, the recommendations developed in July 2005 by the TAP were changed little through this phase; only one item was dropped from consideration—a statement regarding the use of identification bracelets for outpatients on anticoagulation therapy, which was removed because TAP members did not agree on its value to the set.

In its deliberations related to preferred practices, the TAP recommended that 17 characteristics should be reflected in institutional practices for the prevention and care of VTE: 5 of these characteristics were in the general category; 2 were in the category of risk assessment/strategy; 2 were in the category of prophylaxis; 2 were in the category of diagnosis; and 6 were in the category of treatment and monitoring.

The Steering Committee further refined the characteristics and (as noted earlier) eliminated the item related to identification bracelets. In finalizing its recommendations, the Steering Committee focused on ensuring that the key characteristics were based on nationally accepted, evidence-based guidelines, that the need for provider education across all domains of care was emphasized, and that the statements clearly specified what local practice guidelines should address. More specifically, the Steering Committee's changes were designed to make clear that provider education in all domains is needed; to tease apart compound characteristics in order to assure clarity (as in the case of prophylaxis); and to spell out specific areas in which guideline-directed therapy should be used.

During the review period, comments regarding the addition of three characteristics

of practices were received. Although proposed standards for endorsement cannot be added after the review period, the Steering Committee believed that the fundamental intent of at least two of the recommendations already was included in the proposed set. A number of comments related to revising the key characteristics in order to omit the requirement for risk assessment/stratification. The TAP and the Steering Committee consistently have affirmed the need for risk assessment in order to avoid missing patients who should receive prophylaxis and provide appropriate prophylaxis; therefore, no change was made.

A comment regarding the treatment and monitoring characteristic recommendations suggested that the recommendation related to dedicated antithrombotic services is not needed as long as protocols are in place. The "safe practice" referenced has been updated and does not require a dedicated service, although it does include very specific requirements to assure appropriate care. A recommendation was made to remove the treatment and monitoring recommendations about guideline-directed therapy addressing indications for thrombolytic therapy and venous embolectomy (treatment and monitoring characteristic 5.e) on the basis that consensus does not exist. Although this recommendation indicates that guideline-directed therapy needs to be addressed, specific guidelines are not identified, and provision for institutional selection of evidence-based guidelines provides latitude. Additionally, the inclusion of "pulmonary artery embolectomy" in treatment and monitoring characteristic 5.c was made based on the recommendation of a Steering Committee member and approval by the Committee as a whole. Also, during the review period, a suggestion was made (and accepted) to remove the term *bridging* from the last treatment and monitoring characteristic recommendation in order to avoid confusion regarding its meaning. Separate from the comments, it was noted that typographical errors had occurred in the number and array of characteristics in one paragraph of this commentary. A correction was made to indicate a total of 17 key characteristics, which are properly arrayed and reflected in the report.

Performance Measures

The initial "Call for Measures" yielded 19 candidate performance measures: 8 for prevention, 4 for treatment, and 7 related to the occurrence of DVT during or following an episode of inpatient care; the initial review determined that few met the specified criteria, in particular as related to the level of detail of the specifications and whether the measure had been tested.

Because the measures submitted did not adequately address all the domains of care and the prevention of VTE-DVT/PE, the TAP, believing that measures were available that would address areas of particular importance, recommended a second "Call for Measures." The Steering Committee concurred, and a second "Call" in targeted areas was issued in an attempt to obtain a comprehensive set of measures. The areas targeted in the "Call" were as follows:

- risk assessment/stratification/secondary prevention, including measures for completed risk assessment and unnecessary screening at discharge;

- prophylaxis/primary prevention, including measures for stroke, heart failure, cancer, and patients over age 60 hospitalized in medical units; multiple trauma, joint replacements, and hip fracture in the surgical population; postoperative discontinuation of prophylaxis; postdischarge prophylaxis; mechanical prophylaxis; and inferior vena cava filters; and
- therapy measures for patients with acute VTE started on fast-acting anticoagulants and with therapeutic partial thromboplastin time within 24 hours of therapy initiation; monitoring of appropriate dose of unfractionated heparin; overlap—inpatient to outpatient; treatment or dosage determination based on appropriate testing; initiation of warfarin; and warfarin monitoring.

Although 19 additional measures were received, this did not result in a comprehensive set of fully developed and tested measures when evaluated against the criteria.

However, two process measures from the initial solicitation that focused on prophylaxis for surgical patients ultimately were recommended by the Steering Committee. The TAP recommended that the measures, submitted by the Centers for Medicare and Medicaid Services (CMS) from its Surgical Care Improvement Project, be further developed by JCAHO along with de novo development of measures to address the other domains. The Steering Committee concluded, however, that sufficient testing had occurred to demonstrate their validity and reliability, in particular because CMS and JCAHO had agreed to minor modifications to the specifications. In making its recommendation, the Steering Committee noted that the two measures should work well with and complement measures that will be developed and tested by JCAHO in the next phase of this project.[6]

Two commenters suggested that the measure related to recommended prophylaxis ordering should be excluded on the basis that the intervention, not the order, is important. During the deliberations that resulted in advancing this measure, the TAP and the Steering Committee noted that the emphasis of the measure is "recommended" prophylaxis, reinforcing the idea that orders and treatment should be evidence based.

Research Recommendations

The statement of policy that sets out the four domains of prevention and care and the key characteristics of preferred practices, which were derived from clinical guidelines and the collective experiences of the TAP and the Steering Committee members, provides an umbrella under which all of the domains of care and prevention will be specified through performance measures. The research areas will be addressed more fully during the next phase of the project through the de novo development and testing that is being performed by JCAHO.

[6] Because the understanding of the state of the science at the initiation of this project suggested that a paucity of measures could occur, the project included a subcontract with JCAHO to develop detailed measure specifications for measures relevant to hospital settings and to conduct alpha and pilot testing of measures for which development was done.

Appeal

The statement of organizational policy, 17 key characteristics of preferred practices, and 2 performance measures of surgical prophylaxis for public reporting were endorsed by the NQF Board of Directors in May 2006. Subsequently, NQF received one letter of appeal from the American College of Chest Physicians (ACCP) Quality Improvement Committee appealing the endorsement of 6 of the 17 key characteristics of preferred practices as they related to risk assessment/ stratification.

In October 2006, the Board voted to deny the appeal based upon the following: ACCP's appeal asserted that while risk assessment is ideal, it is not clinically practical and will present barriers to implementation. The organization also noted there is not a standardized approach to risk stratification and recommended that the consensus standards should require physicians to deliver prophylaxis to all medical and surgical inpatients or document why none was given rather than expect risk assessment/stratification.

The Board acknowledged the ACCP concern and recognized that there is not a single universal standard for risk assessment; however, there are nationally accepted, evidence-based guidelines that can enable institutions to develop appropriate organizational policies related to the prevention and care of VTE, including risk assessment. The Board accepted the position of the Steering Committee that while most patients are candidates for prophylaxis, all who need it should receive the appropriate treatment. The Committee felt that without risk assessment, appropriate individualized prophylaxis could not be reliably determined and that providing prophylaxis absent a thoughtful evaluation of each patient's needs and the setting in which each patient would be receiving prophylaxis is not appropriate.

Table 1 – CLINICAL LOGIC FOR VENOUS THROMBOEMBOLISM

RISK GROUPS AND FACTORS (risk assessment)	PRIMARY PREVENTION	DIAGNOSIS	ACUTE THERAPY	SECONDARY PREVENTION (risk assessment)
Community Travel **Inpatients** Surgery Acute medical illness **Long-term care facility** **Outpatients** **Common risk factors for incident event** Patient age Body Mass Index Active cancer Extremity paresis Trauma/fracture Central venous catheter/transvenous pacemaker Superficial vein thrombosis Oral contraceptives Hormone therapy Pregnancy/postpartum Other*	**Risk factor modification** **Screening** Thrombophilia Imaging **Drug prophylaxis** Agent Dose/schedule Start time Duration Adjuvant Monitoring **Mechanical prophylaxis** Start time Duration Foot vs. calf vs. leg **Complications of prophylaxis** Bleeding Heparin-induced thrombocytopenia (thrombosis) (HIT(T)) **Prophylaxis failure**	**Pre-test probability** **D-dimer** **Imaging** Deep vein thrombosis Duplex unltrasound Venogram Computerized axial tomography/ magnetic resonance imaging (CT/MRI) Pulmonary embolism (PE) Lung scan CT Pulmonary angiogram MRI **For PE assessment of right heart function** Hypotension If normotensive ?Echo ?BNP ?cardiac troponin	**Anticoagulation** **Heparin** Unfractionated heparin vs. low molecular weight heparin (LMWH) vs. fondaparinux Start Dose/schedule In- vs. outpatient Monitoring Duration/overlap **Warfarin** Start Loading dose Monitoring **Thrombolysis** Catheter-directed thrombolysis Mechanical thrombectomy **Complications** Bleeding HIT(T) **Therapeutic failure**	**VTE recurrence** Risk assessment Type of prophylaxis LMWH vs. warfarin Duration Intensity Monitoring **Venous stasis syndrome** Risk assessment Compression therapy **Chronic thromboembolic pulmonary hypertension** **Complications of 2°** **Prevention** Bleeding Osteoporosis **2° prevention failure** Diagnosis of recurrence Modification of 2° prevention
Education Increased patient satisfaction Increased community awareness Increased use of guidelines by physicians				
Venous thromboembolism (VTE) epidemiology Decreased incidence Decreased recurrence Improved survival Decreased complications				

*See the introduction to this report.

Appendix C
Steering Committee, Technical Advisory Panel, and Project Staff

Steering Committee

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Appendix E
Consensus Development Process: Summary

The National Quality Forum (NQF), a voluntary consensus standards-setting organization, brings together diverse healthcare stakeholders to endorse performance measures and other standards to improve healthcare quality. Because of its broad stakeholder representation and formal Consensus Development Process (CDP), NQF-endorsed™ products have special legal standing as voluntary consensus standards. The primary participants in the NQF CDP are NQF member organizations, which include:

- consumer and patient groups;
- healthcare purchasers;
- healthcare providers, professionals, and health plans; and
- research and quality improvement organizations.

Any organization interested in healthcare quality measurement and improvement may apply to be a member of NQF. Membership information is available on the NQF web site, www.qualityforum.org.

Members of the public with particular expertise in a given topic also may be invited to participate in the early identification of draft consensus standards, either as technical advisors or as Steering Committee members. In addition, the NQF process explicitly recognizes a role for the general public to comment on proposed consensus standards and to appeal healthcare quality consensus standards endorsed by NQF. Information on NQF projects, including information on NQF meetings open to the public, is posted at www.qualityforum.org.

Each project NQF undertakes is guided by a Steering Committee (or Review Committee) composed of individuals from each of the four critical stakeholder perspectives. With the assistance of NQF staff and

technical advisory panels and with the ongoing input of NQF Members, a Steering Committee conducts an overall assessment of the state of the field in the particular topic area and recommends a set of draft measures, indicators, or practices for review, along with the rationale for proposing them. The proposed consensus standards are distributed for review and comment by NQF Members and non-members.

Following the comment period, a revised product is distributed to NQF Members for voting. The vote need not be unanimous, either within or across all Member Councils, for consensus to be achieved. If a majority of Members within each Council do not vote approval, staff attempts to reconcile differences among Members to maximize agreement, and a second round of voting is conducted. Proposed consensus standards that have undergone this process and that have been approved by all four Member Councils on the first ballot or by at least two Member Councils after the second round of voting are forwarded to the Board of Directors for consideration. All products must be endorsed by a vote of the NQF Board of Directors.

Affected parties may appeal voluntary consensus standards endorsed by the NQF Board of Directors. Once a set of voluntary consensus standards has been approved, the federal government may utilize it for standardization purposes in accordance with the provisions of the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113) and the Office of Management and Budget Circular A-119. Consensus standards are updated as warranted.

For this report, the NQF CDP, version 1.7, was in effect. The complete process can be found at www.qualityforum.org.

National Quality Forum Publication Information

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