TO: NQF Members and Public

FR: NQF staff

RE: Addendum voting report of Patient Safety-Complications Phase I project

DA: May 21, 2012

ACTION REQUESTED

The Joint Commission has requested reconsideration of two measures focused on Venous Thromboembolism (VTE) in a letter received on May 2, 2012 (attached). These two measures were not recommended for endorsement by the Patient Safety - Complications Steering Committee following the member and public comment period, and therefore were not released for member voting with the set of recommended measures from Phase I of the Patient Safety - Complications Endorsement Maintenance project. However, due to the importance of the measures for patient care and the lack of similar measures in the NQF portfolio, the CSAC Chair and Vice Chair would like to ballot the measures in order to gain additional input from the NQF membership. Accordingly, measures #0371 and #0376 are being released for a supplemental member vote, the results of which will be reviewed by the CSAC prior to its final decision.

Measures Not Recommended:

- 0371: Venous Thromboembolism Prophylaxis
- 0376: Incidence of Potentially Preventable Venous Thromboembolism

Additional background information on the reconsideration request and CSAC response are below.

BACKGROUND

The Patient Safety - Complications Endorsement Maintenance project seeks to identify and endorse measures that specifically address complications of health care for accountability and quality improvement in all settings of care. In addition, NQF-endorsed patient safety consensus standards that were endorsed prior to 2009 are undergoing maintenance review.

A 26-member Steering Committee representing a range of stakeholder perspectives was selected to evaluate 5 newly submitted measures and 45 measures undergoing maintenance review against NQF's measure evaluation criteria. These measures are being considered in two phases – the current phase includes 26 measures undergoing maintenance review. The Steering Committee recommended 15 measures for endorsement, and four measures were withdrawn by their measure stewards.

The <u>Phase I draft report</u> was posted for member voting on April 13, 2012. The CSAC reviewed the member voting results and made final recommendations during its May 14 conference call on fourteen of the fifteen measures (one measure will be discussed on a future CSAC call due to a competing measure in another project). In order to ensure due process for The Joint Commission's request for reconsideration,

the two measures (#0371 and #0376) were removed from CSAC consideration pending resolution of the request by the CSAC Chair and Vice Chair.

NQF PROCESS

NQF policy states that "measures not approved by the Steering Committee will be reviewed by the CSAC Chair and Vice-Chair, who have the option of requesting additional expert input. If the CSAC Chair and Vice-Chair both concur that a measure not advanced by the Steering Committee should be reinstated, the disputed measure(s) will be included in the slate for balloting."

NEXT STEPS

The CSAC Chair and Vice-Chair reviewed the Patient Safety - Complications Steering Committee's evaluation and voting of the criteria on measures 0371 and 0376 as well as the rationale for no longer recommending the measures for endorsement following comment. The Committee expressed concerns about the measures' acceptance of mechanical prophylaxis as a satisfactory means of venous thromboembolism (VTE) prevention. Many members stated that the evidence supported the use of mechanical prophylaxis only if pharmacological prophylaxis is contraindicated. Yet as currently specified, mechanical prophylaxis would satisfy measure 0371 even if pharmacological prophylaxis is not contraindicated, which some Committee members interpreted as being inconsistent with the most recent American College of Physicians (ACP) and American College of Chest Physicians (ACCP) guidelines. The ACCP's updated guidelines on VTE prophylaxis were released during the NQF member and public comment period (February 2012). Regarding measure 0376, Committee members were not convinced that the measure reflects truly preventable events, and many believed that it would be better to have a risk-adjusted outcome measure. In addition, Committee members believed that the measure could be labor-intensive for providers and that it would be difficult to capture data in a consistent fashion given its reliance on the review of paper medical records. Based on those concerns and the updated ACCP guideline, the Committee voted to no longer recommend the measures:

- 0371 (Venous Thromboembolism Prophylaxis)
 - o Final Steering Committee Recommendation for Endorsement: Y-10; N-13
- 0376 (Incidence of Potentially Preventable Venous Thromboembolism
 - o Final Steering Committee Recommendation for Endorsement: Y-8; N-14

The CSAC Chair and Vice Chair noted that VTE is an important, high impact clinical area, with significant implications for the safety of patient care; that the recent release of guidelines were not inconsistent with the current measures and the developers would not have been able to realistically update and revise the measures during the NQF process; and that there are no other similar measures addressing these areas within the NQF portfolio. Given these circumstances, the CSAC Chair and Vice Chair would like to gain additional input on the two measures from the NQF membership. Accordingly, measures 0371 and 076 are being released for a supplemental member vote, the results of which will be reviewed by the CSAC prior to its final decision.

Details on the Patient Safety-Complications Steering Committee's evaluation of measures 0371 and 0376 are included in the Patient Safety - Complications Endorsement Maintenance: Phase I-Addendum report attached below.

PATIENT SAFETY MEASURES – COMPLICATIONS ENDORSEMENT MAINTENANCE: PHASE I

Draft Technical Report

Addendum

INTRODUCTION

Americans are exposed to more preventable medical errors than patients in other industrialized nations. It's estimated that preventable errors cost the United States \$17-\$29 billion per year in healthcare expenses, lost worker productivity, and disability. The costs are passed on in a number of ways—premiums, taxes, lost work time and wages, and health threats, to name a few. Proactively addressing medical errors and unsafe care will protect patients from harm and lead to more affordable, effective, and equitable care.

The Patient Safety Measures - Complications Endorsement Maintenance project will be executed in two phases, each addressing a number of specific complication-related domains. The first phase will focus on medication safety, venous thromboembolism, surgery, and care coordination, while the second phase will focus on falls, pressure ulcers, healthcare associated infections, and mortality. The Complications project builds on the work an earlier Patient Safety Measures project launched in 2009, which focused on healthcare-associated infections and radiation safety, among other issues. Endorsement maintenance provides the opportunity to harmonize specifications and to ensure that an endorsed measure represents the best in class. Composite and outcome measures and measures sensitive to the needs of vulnerable populations, including racial/ethnic minorities and Medicaid populations, were a priority.

MEASURE EVALUATION

On December 15-16, 2011, the Patient Safety - Complications Steering Committee evaluated one new measure and twenty four measures undergoing maintenance review against NQF's standard evaluation criteria. As discussed in the accompanying memo, the following two measures were not recommended by the Steering Committee following the member and public comment period. However, they are being released for a supplemental member vote in response to a reconsideration request, as directed by the Chair and Vice-Chair of the Consensus Standards Approval Committee (CSAC). The Patient Safety - Complications Steering Committee's discussion and ratings of the criteria following the comment period are summarized in the evaluation tables below.

0371 Venous Thromboembolism Prophylaxis

Measure Submission Form

Description: This measure assesses the number of patients who received venous thromboembolism (VTE) prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission. This measure is part of a set of six nationally implemented prevention and treatment measures that address VTE (VTE-2: ICU VTE Prophylaxis, VTE-3: VTE Patients with Anticoagulation Overlap Therapy, VTE-4: VTE Patients Receiving UFH with Dosages/Platelet Count Monitoring, VTE-5: VTE Warfarin Therapy Discharge Instructions and VTE-6: Incidence of Potentially-Preventable VTE) that are used in The Joint Commission's accreditation process.

Numerator Statement: Patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given:

•the day of or the day after hospital admission

•the day of or the day after surgery end date for surgeries that start the day of or the day after hospital admission

Denominator Statement: All discharged hospital inpatients

Exclusions:

0371 Venous Thromboembolism Prophylaxis

- •Patients less than 18 years of age
- •Patients who have a length of stay (LOS) less than two days and greater than 120 days
- •Patients with Comfort Measures Only documented on day of or day after hospital arrival
- Patients enrolled in clinical trials
- •Patients who are direct admits to intensive care unit (ICU), or transferred to ICU the day of or the day after hospital admission with ICU LOS greater than or equal to one day
- •Patients with ICD-9-CM Principal Diagnosis Code of Mental Disorders or Stroke as defined in Appendix A, Table 7.01, 8.1 or 8.2
- •Patients with ICD-9-CM Principal or Other Diagnosis Codes of Obstetrics or VTE as defined in Appendix A, Table 7.02, 7.03 or 7.04
- •Patients with ICD-9-CM Principal Procedure Code of Surgical Care Improvement Project (SCIP) VTE selected surgeries as defined in Appendix A, Tables 5.17, 5.19, 5.20, 5.21, 5.22, 5.23, 5.24

Adjustment/Stratification: No risk adjustment or risk stratification; Not applicable; Not Applicable, the measure is not stratified.

Level of Analysis: Facility, Population: National

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data: Electronic Health Record, Paper Records Each data element in the data dictionary includes suggested data sources.

The data are collected using contracted Performance Measurement Systems (vendors) that develop data collection tools based on the measure specifications. The tools are verified and tested by Joint Commission staff to confirm the accuracy and conformance of the data collection tool with the measure specifications. The vendor may not offer the measure set to hospitals until verification has been passed. **Measure Steward:** The Joint Commission

STEERING COMMITTEE MEETING 12/15-16/2011

1. Importance to Measure and Report: Y-20; N-1

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-8; M-1; L-0; I-0; 1b. Performance Gap: H-8; M-1; L-0; I-0

1c. Evidence Quantity: H-8; M-1; L-0; I-0; Quality: H-8; M-1; L-0; I-0; Consistency: H-8; M-1; L-0; I-0

Rationale: There is strong evidence to support the measure and recent reporting indicated a performance gap of 17%. However, the Committee stated that the measure has a limited ability to impact outcomes since it lacks a validated risk assessment model and remains vague. Yet, the Committee agreed that it would encourage hospitals to have standardized policies for VTE prophylaxis among inpatients.

2. Scientific Acceptability of Measure Properties: Y-17; N-4

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-5; M-4; L-0; I-0; 2b. Validity: H-7; M-2; L-0; I-0

Rationale: The measure was considered a good starting point for examining whether patients were given prophylaxis. However, the Committee expressed concern about the measure's lack of specificity on how risk is assessed. Patients at low risk as well as certain other populations, such as renal patients and older patients, should not be given prophylaxis since it increases the risk of bleeding. The American College of Chest Physicians is expected to release new guidelines (ACCP-9) around VTE prophylaxis in February 2012; these guidelines may offer additional direction to providers. Additionally, the Committee expressed reservations regarding the lack of a definition for "effective prophylaxis". Hospitals may vary in their interpretation of this language; therefore, the measure may not be limited in its usefulness for comparison. It was suggested that in the future the measure could be further specified and improved. While there were concerns with the specificity of the measure, the measure as specified demonstrated reliable results and face validity was provided.

3. Usability: H-3; M-14; L-4; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

3a. Public Reporting: H-8: M-1: L-0: I-0

3b. OI: H-8: M-1: L-0: I-0

<u>Rationale</u>: This measure is part of a VTE measure set that will be implemented nationally in January 2013. While the Committee questioned whether the measure alone will provide useful information to consumers, members agreed that measuring VTE prophylaxis will lead to quality improvement.

4. Feasibility: H-8; M-10; L-3; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

- 4a. Byproduct of Care Processes: H-8; M-1; L-0; I-0
- 4b. Electronic data sources: H-3; M-2; L-3; I-0

0371 Venous Thromboembolism Prophylaxis

- 4c. Suscep inaccuracies, consequences: H-5; M-4; L-0; I-0
- 4d. Data collection strategy: H-7; M-1; L-0; I-1

<u>Rationale</u>: Creating a risk assessment model would have made data collection more complicated, which would further limit feasibility. The measure will be reevaluated and updated every six months by the developer.

Steering Committee Recommendation for Endorsement: Y-17; N-4

Rationale: The measure recognizes that VTE prophylaxis is an important part of the process of care for a variety of diagnoses and treatment plans. While there are concerns about the implementation and usefulness of the measure, the Committee agreed that it continues to be a good starting point in the assessment of hospital performance related to VTE prophylaxis.

Public and Member Comment

Comments included:

- A request for this measure to be split out to address surgical and non-surgical patients separately
- Suggestion to separate reporting of anticoagulation prophylaxis from reporting of mechanical prophylaxis
- Need greater discernment between adequate prophylaxis and any prophylaxis
- Should not encourage VTE prophylaxis in individuals whose risk of bleeding exceeds the risk of thrombosis
- Measure should reflect prophylaxis across the patient stay, rather than only upon admission to the hospital or transfer to the ICU

The submitted comments prompted a Steering Committee discussion regarding "adequate" or "effective" prophylaxis, among other issues. A number of Committee members voiced concerns about the measure's acceptance of mechanical prophylaxis as a satisfactory means of VTE prevention. Many members stated that the evidence supported the use of mechanical prophylaxis only if pharmacological prophylaxis is contraindicated. Yet as currently specified, mechanical prophylaxis would satisfy measure 0371 even if pharmacological prophylaxis is not contraindicated, which some Committee members interpreted as being inconsistent with the most recent American College of Physicians (ACP) and American College of Chest Physicians (ACCP) guidelines. ACP and ACCP guidelines also recommend administration of prophylaxis only if the benefits outweigh the risks. Because there is currently no validated tool for VTE risk-assessment, some Committee members were hesitant to recommend a measure that may encourage VTE prophylaxis in lower-risk patients. For this reason, the Committee was more comfortable with measure 0372, which applies to the higher-risk population of patients in the ICU. In addition, some Committee members agreed that administration of prophylaxis should be measured across the patient stay, and that a single order or day of administration, which is how the measure is currently specified, was not necessarily reflective of quality care. In general, the Committee viewed the measure as being useful for internal quality improvement efforts, but were concerned that publicly-reported performance on the measure may not lead to valid judgments regarding the quality of care. The Steering Committee agreed to hold a reconsideration vote on the measure.

Developer response: Adequate prophylaxis is individualized for each patient scenario. Stratification treatment based on risk assessment is a consideration, however, consensus regarding a standard risk assessment tool or method has not yet been reached. This measure has been specified to collect data in the designated time frame to reduce abstractor burden. These current paper-based measures have been specified to collect data in the designated time frame in order to reduce abstractor burden. Electronic specifications for these measures have been developed and the measures have been included as clinical quality measures for Stage 1 of Meaningful Use.

Vote Following Consideration of Public and Member Comments

- 1. Importance to Measure and Report: Y-17; N-3
- 2. Scientific Acceptability of Measure Properties: Y-10; N-11
- 3. Usability: H-2; M-11; L-8; I-0
- 4. Feasibility: H-2; M-13; L-5; I-0

Steering Committee Recommendation for Endorsement: Y-10; N-13

Rationale: The measure recognizes that VTE prophylaxis is an important part of the process of care for a variety of diagnoses and treatment plans. However, concerns about implementation issues and the usefulness of the measure, as well as questions about whether the measure truly reflects providers' quality of care, led the Committee to decide against recommending the measure for endorsement.

0376 Incidence of Potentially Preventable Venous Thromboembolism

Measure Submission Form

Description: This measure assesses the number of patients with confirmed venous thromboembolism (VTE) during hospitalization (not present at admission) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date. This measure is part of a set of six prevention and treatment measures that address VTE (VTE-1: VTE Prophylaxis, VTE-2: ICU VTE Prophylaxis, VTE-3: VTE Patients with Anticoagulation Overlap Therapy, VTE-4: VTE Patients Receiving UFH with

Dosages/Platelet Count Monitoring by Protocol, and VTE-5: VTE Warfarin Therapy Discharge Instructions).

Numerator Statement: Patients who received no VTE prophylaxis prior to the VTE diagnostic

test order date

Denominator Statement: Patients who developed confirmed VTE during hospitalization. The target population includes patients discharged with an ICD-9-CM Secondary Diagnosis Codes for VTE as defined in Table 7.03 or Table 7.04.

Exclusions: Patients less than 18 years of age

- Patients who have a length of stay greater than 120 days
- Patients with Comfort Measures Only documented
- · Patients enrolled in clinical trials
- Patients with ICD-9-CM Principal Diagnosis Code of VTE as defined in Appendix A, Table 7.03 or 7.04
- Patients with VTE Present at Admission
- Patients with reasons for not administering mechanical and pharmacologic prophylaxis
- Patients without VTE confirmed by diagnostic testing

Adjustment/Stratification: No risk adjustment or risk stratification; No risk adjustment or risk stratification as intermediate outcome; Not Applicable

Level of Analysis: Facility, Population: National

Type of Measure: Outcome

Data Source: Administrative claims, Paper Records Each data element in the data dictionary includes suggested data sources. The data are collected using contracted Performance Measurement Systems (vendors) that develop data collection tools based on the measure specifications. The tools are verified and tested by Joint Commission staff to confirm the accuracy and conformance of the data collection tool with the measure specifications. Verification must be completed and passed before the vendor can offer the data collection tool to hospitals.

Measure Steward: The Joint Commission

STEERING COMMITTEE MEETING 12/15-16/2011

1. Importance to Measure and Report: Y-20; N-2

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-8; M-0; L-0; I-1; 1b. Performance Gap: H-6; M-2; L-0; I-1

1c. Evidence Quantity: H-6; M-2; L-0; I-0; Quality: H-6; M-1; L-1; I-0; Consistency: H-6; M-1; L-1; I-0

Rationale: The measure is important because it indicates the adequacy of the hospital's risk assessment profile by reporting the rate at which patients acquired VTE and did not receive prophylaxis. The measure presented an aggregate performance gap of 13.2% and stated that the gap would ideally be reduced to 0%. However, the Committee expressed concern that the measure did not gauge the adequacy of the prophylaxis. They also recognized that patients receiving adequate prophylaxis could still develop adverse events regardless of the quality of the provider's care.

2. Scientific Acceptability of Measure Properties: Y-20; N-1

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-7; M-1; L-1; I-0; 2b. Validity: H-6; M-3; L-0; I-0

Rationale: The measure as specified includes the rate of patients who had a confirmed VTE that was not present on admission – the Committee was interested with the idea that while the measure focused on those patients who had a treatment failure (i.e., were not assessed and treated resulting in a VTE), the denominator itself also provided valuable information. Reliability and validity were demonstrated.

3. Usability: H-7; M-14; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-7; M-2; L-0; I-0

3b. QI: H-7; M-2; L-0; I-0

Rationale: The measure will assist hospitals with quality improvement by reporting patients not risk-assessed for VTE.

0376 Incidence of Potentially Preventable Venous Thromboembolism

4. Feasibility: H-7; M-13; L-1; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-8; M-1; L-0; I-0

4b. Electronic data sources: H-4; M-5; L-0; I-0

4c. Suscep inaccuracies, consequences: H-5; M-3; L-1; I-0

4d. Data collection strategy: H-6; M-2; L-1; I-0

<u>Rationale</u>: The measure is currently being collected and no concerns with feasibility were raised.

Steering Committee Recommendation for Endorsement: Y-20; N-2

Rationale: The measure indicates whether facilities are adequately assessing patients for their risk of developing VTE and provide important information on the incidence of VTEs that could have potentially been avoided through appropriate assessment and treatment.

Public and Member Comment

Comments included:

- Measure should be restricted to non-surgical patients
- Concern that use of the present on admission indicator could exclude patients who acquired VTE as a result of a previous hospital admission
- "Potentially preventable" events should be restricted to those patients who received prophylaxis according to the institutional protocol in order to capture instances of inadequate prophylaxis
- Only pulmonary embolism and lower extremity DVT should be included

After reviewing the comments and the developer's response, the Steering Committee revisited its decision on this measure and held further discussion on the measure's strengths and weaknesses. Committee members agreed that identification of patients with hospital-acquired VTE was a good idea, and that looking back to determine whether adequate prophylaxis was given could be useful for internal quality improvement efforts. However, the Committee was concerned about use of the measure for accountability purposes as the measure looks retrospectively at the care of patients who have developed VTE and determines whether prophylaxis was provided in those cases. Committee members were not convinced that the measure reflects truly preventable events, and many believed that it would be better to have a risk-adjusted outcome measure. In addition, Committee members believed that the measure would be labor-intensive for providers and that it would be difficult to capture data in a consistent fashion given its reliance on the review of paper medical records. The Steering Committee decided to hold a reconsideration vote after the call; upon reconsideration, measure 0376 was not recommended for endorsement. Final voting results are available in the draft report.

Developer response: Due to the fact that standardized risk assessment and standardized protocols for VTE Prophylaxis have not been widely endorsed, this measure evaluates the use of any prophylaxis used to be adequate, leaving the method of prophylaxis decision making up to the care provider. The population used for this measure consists of discharges with an ICD-9-CM Other Diagnosis Codes of VTE as defined in Appendix A, Table 7.03 or 7.04 [in the measure submission]. This includes all populations, including surgical patients that are not populated into the SCIP-VTE 1 measure. Without the use of an Electronic Health System, prior hospitalization data is not available to the present organization in question. The technical advisory panel felt that a greater population of potentially preventable VTE be included in this measure, as this provides valuable data on all VTEs for the organization to use in a process improvement plan.

This measure targets those patients who have developed VTE while hospitalized in order to assess whether VTE prophylaxis was instituted prior to the development of the VTE. Presumably, organizational performance assessment activities performed when investigating measure results would identify if VTE development was as a result of antecedent events immediately prior to hospitalization.

Vote Following Consideration of Public and Member Comments

- 1. Importance to Measure and Report: Y-19; N-2
- 2. Scientific Acceptability of Measure Properties: Y-12; N-9
- 3. Usability: H-4; M-9; L-8; I-0
- 4. Feasibility: H-2; M-8; L-11; I-0

Steering Committee Recommendation for Endorsement: Y-8; N-14

0376 Incidence of Potentially Preventable Venous Thromboembolism

Rationale: The measure has the potential to indicate whether facilities are adequately assessing patients for their risk of developing VTE and to provide important information on the incidence of VTEs that could have been avoided through appropriate assessment and treatment. However, Committee members felt that the measure requires burdensome data collection efforts and were concerned that those efforts would not yield the intended results. The Committee expressed their preference for a risk-adjusted outcome measure over this kind of process measure.

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PATIENT SAFETY - COMPLICATIONS ENDORSEMENT MAINTENANCE: PHASE I

APPENDIX A:

MEASURE SPECIFICATIONS

	0371 Venous Thromboembolism Prophylaxis
Steward	The Joint Commission
Description	This measure assesses the number of patients who received venous thromboembolism (VTE) prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission. This measure is part of a set of six nationally implemented prevention and treatment measures that address VTE (VTE-2: ICU VTE Prophylaxis, VTE-3: VTE Patients with Anticoagulation Overlap Therapy, VTE-4: VTE Patients Receiving UFH with Dosages/Platelet Count Monitoring, VTE-5: VTE Warfarin Therapy Discharge Instructions and VTE-6: Incidence of Potentially-Preventable VTE) that are used in The Joint Commission's accreditation process.
Туре	Process
Data Source	Administrative claims, Electronic Clinical Data: Electronic Health Record, Paper Records Each data element in the data dictionary includes suggested data sources. The data are collected using contracted Performance Measurement Systems (vendors) that develop data collection tools based on the measure specifications. The tools are verified and tested by Joint Commission staff to confirm the accuracy and conformance of the data collection tool with the measure specifications. The vendor may not offer the measure set to hospitals until verification has been passed. Attachment VTE 4.0 ManualF-634469565251741848.pdf
Level	Facility, Population : National
Setting	Hospital/Acute Care Facility
Numerator Statement	Patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given: the day of or the day after hospital admission the day of or the day after surgery end date for surgeries that start the day of or the day after hospital admission
Numerator Details	Five data elements are used to calculate the numerator: 1. Reason for No VTE Prophylaxis – Hospital Admission - Documentation why mechanical or pharmacologic VTE prophylaxis was not administered at hospital admission. Allowable values: Yes or No/UTD. 2. Surgery End Date - The date the surgical procedure ended after hospital admission. 3. Surgical Procedure - A surgical procedure was performed using general or neuraxial anesthesia the day of or the day after hospital admission. Allowable values: Yes or No/UTD 4. VTE Prophylaxis - The type of venous thromboembolism (VTE) prophylaxis documented in the medical record. Allowable values: 1 - 7 or A - None of the above, not documented or UTD. 5. VTE Prophylaxis Date - The month, day, and year that the initial VTE prophylaxis (mechanical and/or pharmacologic) was administered after hospital admission.
Denominator Statement	All discharged hospital inpatients

Details

Denominator Time Window: Episode of care

Eleven data elements are used to calculate the denominator:

- Admission Date The month, day and year of admission to acute inpatient care.
- 2. Birthdate - The month, day and year the patient was born.
- Clinical Trial Documentation that during this hospital stay the patient was enrolled in a clinical trial in which patients 3. with VTE were being studied. Allowable values: Yes or No/UTD
- Comfort Measures Only Physician/advanced practice nurse/physician assistant (physician/APN/PA) documentation of comfort measures only. Commonly referred to as "palliative care" in the medical community and "comfort care" by the general public. Palliative care includes attention to the psychological and spiritual needs of the patient and support for the dying patient and the patient's family. Comfort Measures Only are not equivalent to the following: Do Not Resuscitate (DNR), living will, no code, no heroic measure. Allowable values represent the earliest physician/APN/PA documentation: Day 0 or 1, Day 2 or after, Timing unclear or Not Documented/UTD.
- Discharge Date The month day and year the patient was discharged from acute care, left against medical advice or expired during the stay.
- 6. ICD-9-CM Other Diagnosis Codes The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes associated with the diagnosis for this hospitalization.
- 7. ICD-9-CM Principal Diagnosis Code The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code associated with the diagnosis established after study to be chiefly responsible for occasioning the admission of the patient for this hospitalization.
- ICD-9-CM Principal Procedure Code The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code that identifies the principal procedure performed during this hospitalization. The principal procedure is the procedure performed for definitive treatment rather than diagnostic or exploratory purposes, or which is necessary to take care of a complication.
- ICU Admission Date The day, month and year that the order was written for the patient to be directly admitted or transferred (from a lower level of care) to the intensive care unit (ICU).
- ICU Admission or Transfer Documentation that the patient was admitted or transferred to the intensive care unit (ICU) at this hospital. The definition of an ICU for the purpose of the measures noted above is that used by the CDC in the NHSN Patient Safety Project. An intensive care unit can be defined as a nursing care area that provides intensive observation, diagnosis, and therapeutic procedures for adults and/or children who are critically ill. An ICU excludes nursing areas that provide step-down, intermediate care or telemetry only and specialty care areas.
- ICU Discharge Date The day, month and year that the order was written to discharge the patient from the intensive care unit (ICU), left against medical advice (AMA) or expired.

Exclusions

- Patients less than 18 years of age
- Patients who have a length of stay (LOS) less than two days and greater than 120 days
- Patients with Comfort Measures Only documented on day of or day after hospital arrival
 - Patients enrolled in clinical trials
- Patients who are direct admits to intensive care unit (ICU), or transferred to ICU the day of or the day after hospital admission with ICU LOS greater than or equal to one day
- Patients with ICD-9-CM Principal Diagnosis Code of Mental Disorders or Stroke as defined in Appendix A, Table 7.01, 8.1 or 8.2
- Patients with ICD-9-CM Principal or Other Diagnosis Codes of Obstetrics or VTE as defined in Appendix A, Table 7.02, 7.03 or 7.04
- Patients with ICD-9-CM Principal Procedure Code of Surgical Care Improvement Project (SCIP) VTE selected surgeries as defined in Appendix A, Tables 5.17, 5.19, 5.20, 5.21, 5.22, 5.23, 5.24

Exclusion **Details**

- The patient age in years is equal to the Admission Date minus the Birthdate. Patients less than 18 years are excluded.
- Length of stay (LOS) in days is equal to the Discharge Date minus the Admission Date. If the LOS is greater than 120 days or equal to or less than 2 days, the patient is excluded.
- Patients with Comfort Measures Only allowable value of 1 (Day 0 or 1) are excluded.
- Patients are excluded if "Yes" is selected for Clinical Trial.
- The data element ICU Admission or Transfer is used to determine if the patient was admitted to the ICU. If "Yes" is selected, the case flows to the ICU Admission Date. If the ICU Admission Date is equal to the hospital admission or the ICU Admission Date is the day after the hospital admission date, the ICU Admission and ICU Discharge Date are used to determine if the patient was in the ICU for one or more days. If the LOS is less than one day, the patient is excluded from VTE-1. In addition, if the patient's ICU Admission Date is prior to the hospital admission day, the patient is excluded (direct admit to ICU).
- Patients with ICD-9-CM Principal Diagnosis Code of Mental Disorders or Stroke are excluded.
- Patients with ICD-9-CM Principal or Other Diagnosis Codes of Obstetrics or VTE are excluded.
- Patients with ICD-9-CM Principal Procedure Code of Surgical Care Improvement Project (SCIP) VTE selected surgeries are excluded.

Risk Adjustment

No risk adjustment or risk stratification Not applicable

Stratification

Not Applicable, the measure is not stratified.

Type Score Algorithm

Rate/proportion better quality = higher score

- Start processing. Run cases that are included in the VTE Initial Patient Population and pass the edits defined in the Transmission Data Processing Flow: Clinical through this measure.
- Calculate Length of Stay. Length of Stay, in days, is equal to the Discharge Date minus the Admission Date.
- 3. Check Length of Stay
- If Length of Stay is less than 2 days, the case will proceed to a Measure Category Assignment of B and will not be in a. the measure population. Stop processing.
- If Length of Stay is greater than or equal to 2 days, continue processing and proceed to ICD-9-CM Principal Diagnosis Code.
- Check ICD-9-CM Principal Diagnosis Code
- If the ICD-9-CM Principal Diagnosis Code is on Table 7.01, 8.1, or 8.2, the case will proceed to a Measure Category Assignment of B and will not be in the Measure Population. Stop processing.
- If the ICD-9-CM Principal Diagnosis Code is not on Table 7.01, 8.1, or 8.2, continue processing and proceed to ICD-9-CM Principal or Other Diagnosis Code.
- Check ICD-9-CM Principal or Other Diagnosis Code
- If at least one of the ICD-9-CM Principal or Other Diagnosis Code is on Table 7.02, 7.03, or 7.04, the case will proceed to a Measure Category Assignment of B and will not be in the Measure Population. Stop processing.
- If none of the ICD-9-CM Principal or Other Diagnosis Code is on Table 7.02, 7.03, or 7.04, continue processing and proceed to ICD-9-CM Principal Procedure Code.
- Check ICD-9-CM Principal Procedure Code
- If the ICD-9-CM Principal Procedure Code is on Table 5.17, 5.19, 5.20, 5.21, 5.22, 5.23, or 5.24, the case will proceed to a Measure Category Assignment of B and will not be in the Measure Population. Stop processing.
- If the ICD-9-CM Principal Procedure Code is missing or not on Table 5.17, 5.19, 5.20, 5.21, 5.22, 5.23, or 5.24, continue processing and proceed to Comfort Measures Only.
- **Check Comfort Measures Only**
- If Comfort Measures Only is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- If Comfort Measures Only equals 1, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing.
- If Comfort Measures Only equals 2, 3, or 4, continue processing and proceed to Clinical Trial. C.
- 8. Check Clinical Trial
- If Clinical Trial is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop a. processing.
- If Clinical Trial equals Yes, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing.
- If Clinical Trial equals No, continue processing and proceed to VTE Prophylaxis.
- 9. Check ICU Admission or Transfer

- a. If ICU Admission or Transfer is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- b. If ICU Admission or Transfer is equal to 2 or 3, the case will proceed to VTE Prophylaxis.
- c. If ICU Admission or Transfer is equal to 1, continue processing and proceed to ICU Admission Date.
- 10. Check ICU Admission Date
- a. If ICU Admission Date is missing, the case will proceed to a Measure Category Assignment of X and will be rejected.
 Stop processing.
- b. If ICU Admission Date equals Unable to Determine, the case will proceed to a Measure Category Assignment of D and will be in the Measure Population. Stop processing.
- c. If ICU Admission Date equals a Non Unable to Determine Value, continue processing and proceed to the Initial ICU Day calculation.
- 11. Calculate Initial ICU Day. Initial ICU Day, in days, is equal to ICU Admission Date minus Admission Date.
- 12. Check Initial ICU Day
- a. If the Initial Day is less than 0 days, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing.
- b. If the Initial Day is equal to 0 days or 1 day, the case will proceed to ICU Discharge Date.
- If the Initial Day is greater than or equal to 2 days, continue processing and proceed to VTE Prophylaxis.
- 13. Check ICU Discharge Date only if Initial ICU Day is less than or equal to 1 day
- a. If the ICU Discharge Date is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- b. If the ICU Discharge Date equals Unable to Determine, the case will proceed to a Measure Category Assignment of D and will be in the Measure Population. Stop processing.
- c. If the ICU Discharge Date equals a Non Unable to Determine Value, continue processing and proceed to the ICU LOS calculation.
- 14. Calculate ICU LOS. ICU LOS is equal to ICU Discharge Date minus ICU Admission Date.
- 15. Check ICU LOS
- a. If ICU LOS is less than zero days, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- b. If ICU LOS is greater than or equal to 1 day, the case will proceed to a Measure Category Assignment of B and will not be in the Measure Population. Stop processing.
- c. If ICU LOS is equal to zero days, the case will proceed to VTE Prophylaxis.
- 16. Check VTE Prophylaxis
- a. If VTE Prophylaxis is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- b. If VTE Prophylaxis is equal to A, continue processing and proceed to check Reason for No VTE Prophylaxis Hospital Admission.
- 1. If Reason for No VTE Prophylaxis Hospital Admission is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- 2. If Reason for No VTE Prophylaxis Hospital Admission equals No, the case will proceed to a Measure Category Assignment of D and will be in the Measure Population. Stop processing.
- 3. If Reason for No VTE Prophylaxis Hospital Admission equals Yes, the case will proceed to a Measure Category Assignment of E and will be in the Numerator Population. Stop processing.
- c. If VTE Prophylaxis is equal to 1,2,3,4,5,6,7 and not equal to A, continue processing and proceed to VTE Prophylaxis Date.
- 17. Check VTE Prophylaxis Date
- a. If the VTE Prophylaxis Date is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- b. If the VTE Prophylaxis Date equals Unable to Determine, the case will proceed to a Measure Category Assignment of D and will be in the Measure Population. Stop processing.
- c. If the VTE Prophylaxis Date equals a Non Unable to Determine Value, continue processing and proceed to the Initial Prophylaxis Day calculation.
- 18. Calculate Initial Prophylaxis Day. Initial Prophylaxis Day, in days, is equal to the VTE Prophylaxis Date minus the Admission Date.
- Check Initial Prophylaxis Day
- a. If Initial Prophylaxis Day is less than zero days, the case will proceed to a Measure category Assignment of X and will be rejected. Stop processing.
- b. If Initial Prophylaxis Day is equal to zero days or 1 day, the case will proceed to a Measure Category Assignment of

E and will be in the Numerator Population. Stop processing. If Initial Prophylaxis Day is greater than or equal to 2 days, continue processing and proceed to Surgical Procedure. 20. Check Surgical Procedure If Surgical Procedure is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. a. Stop processing. If Surgical Procedure equals No, the case will proceed to a Measure Category Assignment of D and will be in the Measure Population. Stop processing. If Surgical Procedure equals Yes, continue processing and proceed to Surgery End Date. 21. Check Surgery End Date If the Surgery End Date is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing. If the Surgery End Date equals Unable to Determine, the case will proceed to a Measure Category Assignment of D and will be in the Measure Population. Stop processing. If the Surgery End Date equals a Non Unable to Determine Value, continue processing and proceed to the Initial Surgical Prophylaxis Day calculation. Calculate Initial Surgical Prophylaxis Day. Initial Surgical Prophylaxis Day, in days, is equal to the VTE Prophylaxis Date minus Surgery End Date. 23. Check Initial Surgical Prophylaxis Day a. If the Initial Surgical Prophylaxis Day is greater than or equal to 2 days, the case will proceed to a Measure Category Assignment of D and will be in the Measure Population. Stop processing. If the Initial Surgical Prophylaxis Day is equal to zero days or 1 day, the case will proceed to a Measure Category Assignment of E and will be in the Numerator Population. Stop processing. Attachment 2zq_VTE1.pdf Copyright The Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual) is the result of the collaborative efforts of the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission to publish a uniform set of national hospital quality measures. A primary objective of this collaborative effort is to promote and enhance the utility of these measures for all hospitals. No royalty or use fee is required for copying or reprinting this manual, but the following are required as a condition of usage: 1) disclosure that the Specifications Manual is periodically updated, and that the version being copied or reprinted may not be up-to-date when used unless the copier or printer has verified the version to be up-to-date and affirms that, and 2) users participating in the QIO supported initiatives, the Hospital Inpatient Quality Reporting Program, and Joint Commission accreditation; including performance measures systems; are required to update their software and associated documentation based on the published manual production timelines. Example Acknowledgement: The Specifications Manual for National Hospital Inpatient Quality Measures (Version xx, Month, Year] is the collaborative work of the Centers for Medicare & Medicaid Services and The Joint Commission. The Specifications Manual is periodically updated by the Centers for Medicare & Medicaid Services and The Joint Commission. Users of the Specifications Manual for National Hospital Inpatient Quality Measures must update their software and associated

	0376 Incidence of Potentially Preventable Venous Thromboembolism
Steward	The Joint Commission
Description	This measure assesses the number of patients with confirmed venous thromboembolism (VTE) during hospitalization (not present at admission) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date. This measure is part of a set of six prevention and treatment measures that address VTE (VTE-1: VTE Prophylaxis, VTE-2: ICU VTE Prophylaxis, VTE-3: VTE Patients with Anticoagulation Overlap Therapy, VTE-4: VTE Patients Receiving UFH with Dosages/Platelet Count Monitoring by Protocol, and VTE-5: VTE Warfarin Therapy Discharge Instructions).
Туре	Outcome
Data Source	Administrative claims, Paper Records Each data element in the data dictionary includes suggested data sources. The data are collected using contracted Performance Measurement Systems (vendors) that develop data collection tools based on the measure specifications. The tools are verified and tested by Joint Commission staff to confirm the accuracy and conformance of the data collection tool with the measure specifications. Verification must be completed and passed before the vendor can offer the data collection tool to hospitals.

documentation based on the published manual production timelines.

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	0376 Incidence of Potentially Preventable Venous Thromboembolism Attachment VTE 4.0 ManuaLF-634469532965647398.pdf
Laval	· ·
Level	Facility, Population : National
Setting	Hospital/Acute Care Facility
Numerator	Patients who received no VTE prophylaxis prior to the VTE diagnostic
Statement	test order date
Numerator Details	Time Window: Episode of Care
Details	One data element is used to calculate the numerator:
	VTE Prophylaxis Status - Documentation of VTE prophylaxis (mechanical and/or pharmacologic) administration between the
	hospital admission date and the day before the VTE diagnostic test order date. Allowable Value (AV): 1 There is
	documentation that VTE prophylaxis was administered between the day of admission and the day before the VTE diagnostic
	test order date, 2 There is no documentation that VTE prophylaxis was administered between the day of admission and the
	day before the VTE diagnostic test order date or unable to determine from medical record documentation, or 3 There is physician/advanced practice nurse/physician assistant (physician/APN/PA) or pharmacist documentation of a reason for not
	administering mechanical and pharmacological VTE prophylaxis during hospitalization.
Denominator	Patients who developed confirmed VTE during hospitalization. The target population includes patients discharged with an ICD-
Statement	9-CM Secondary Diagnosis Codes for VTE as defined in Table 7.03 or Table 7.04.
Denominator	Time Window: Episode of Care
Details	Time window. Episode of Gale
	Ten data elements are used to calculate the denominator:
	1. Admission Date – The month, day and year of admission to acute inpatient care.
	2. Birthdate - The month, day and year the patient was born.
	3. Clinical Trial - Documentation that during this hospital stay the patient was enrolled in a clinical trial in which patients with
	the same condition as the measure set were being studied. Allowable values: Yes or No/UTD 4. Comfort Measures Only - Physician/advanced practice nurse/physician assistant (physician/APN/PA) documentation of
	comfort measures only. Commonly referred to as "palliative care" in the medical community and "comfort care" by the general
	public. Palliative care includes attention to the psychological and spiritual needs of the patient and support for the dying patient
	and the patient's family. Comfort Measures Only are not equivalent to the following: Do Not Resuscitate (DNR), living will, no
	code, no heroic measure. Allowable values represent the earliest physician/APN/PA documentation: (AV 1) Day 0 or 1, (AV 2)
	Day 2 or after, (AV 3) Timing unclear or (AV 4) Not Documented/UTD.
	5. Discharge Date – The month day and year the patient was discharged from acute care, left against medical advice or
	expired during the stay. 6. ICD-9-CM Other Diagnosis Codes - The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-
	9-CM) codes associated with the Secondary diagnoses for this hospitalization.
	7. ICD-9-CM Principal Diagnosis Code - The International Classification of Diseases, Ninth Revision, Clinical Modification
	(ICD-9-CM) code associated with the diagnosis established after study to be chiefly responsible for occasioning the admission
	of the patient for this hospitalization.
	8. VTE Confirmed – Documentation by a physician/advanced practice nurse/physician assistant (physician/APN/PA) that a
	diagnosis of VTE [deep vein thrombosis (DVT) and/or pulmonary embolism (PE)] was confirmed in a defined location. Allowable values: Yes or No/UTD
	9. VTE Diagnostic Test – Documentation that a diagnostic test for VTE was performed. Allowable values: Yes or No/UTD
	10. VTE Present at Admission - Documentation by a physician/advanced practice nurse/physician assistant
	(physician/APN/PA) that VTE was diagnosed or suspected on admission. Allowable values: Yes or No/UTD.
Exclusions	. Patients less than 18 years of age
	Patients who have a length of stay greater than 120 days
	Patients with Comfort Measures Only documented Patients with Comfort Measures Only documented
	• Patients enrolled in clinical trials
	 Patients with ICD-9-CM Principal Diagnosis Code of VTE as defined in Appendix A, Table 7.03 or 7.04 Patients with VTE Present at Admission
	Patients with reasons for not administering mechanical and pharmacologic prophylaxis
	Patients without VTE confirmed by diagnostic testing
Exclusion	The patient age in years is equal to the Admission Date minus the Birthdate. The month and day portion of the admission date
Details	and birthdate are used to yield the most accurate age. Patients less than 18 years are excluded.

0376 Incidence of Potentially Preventable Venous Thromboembolism the patient is excluded. • Patients are excluded if allowable value 1, 2 or 3 is selected for Comfort Measures Only. • Patients are excluded if "Yes" is selected for Clinical Trial. Patients with a Principal ICD-9-CM Diagnosis Code on Table 7.03 or 7.04, are excluded. Patients are excluded if "Yes" is selected for VTE Present at Admission. • Patients are excluded if allowable value "3" is selected for VTE Prophylaxis Status. Patients are excluded if "No" is selected for VTE Diagnostic Test. Patients are excluded if "No" is selected for VTE Confirmed. Risk No risk adjustment or risk stratification Adjustment No risk adjustment or risk stratification as intermediate outcome Stratification Not Applicable Type Score Rate/proportion better quality = lower score Algorithm Start processing. Run cases that are included in the VTE Initial Patient Population and pass the edits defined in the Transmission Data Processing Flow: Clinical through this measure. 2. Check ICD-9-CM Principal Diagnosis Code a. If the ICD-9-CM Principal Diagnosis Code is on Table 7.03 or 7.04 (VTE, Obstetrics-VTE), the case will proceed to a Measure Category Assignment of B and will not be in the Measure Population. Stop processing. b. If the ICD-9-CM Principal Diagnosis Code is not on Table 7.03 or 7.04, continue processing and proceed to ICD-9-CM Other Diagnosis Code. 3. Check ICD-9-CM Other Diagnosis Codes a. If all ICD-9-CM Other Diagnosis Codes are missing or none of them on Table 7.03 or 7.04, the case will proceed to a Measure Category Assignment of B and will not be in the Measure Population. Stop processing. b. If at least one of the ICD-9-CM Other Diagnosis Codes is on Table 7.03 or 7.04, continue processing and proceed to VTE Present at Admission. 4. Check VTE Present at Admission a. If VTE Present at Admission is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing. b. If VTE Present at Admission equals Yes, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing. c. If VTE Present at Admission equals No, continue processing and proceed to Comfort Measures Only. 5. Check Comfort Measures Only a. If Comfort Measures Only is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing. b. If Comfort Measures Only equals 1, 2, or 3, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing. c. If Comfort Measures Only equals 4, continue processing and proceed to Clinical Trial. 6. Check Clinical Trial a. If Clinical Trial is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing. b. If Clinical Trial equals Yes, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing. c. If Clinical Trial equals No, continue processing and proceed to VTE Diagnostic Test. 7. Check VTE Diagnostic Test a. If VTE Diagnostic Test is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing. b. If VTE Diagnostic Test equals No, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing. c. If VTE Diagnostic Test equals Yes, continue processing and proceed to VTE Confirmed. 8. Check VTE Confirmed a. If VTE Confirmed is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing. b. If VTE Confirmed equals No, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. 9. Check VTE Prophylaxis Status A if VTE Prophylaxis status is missing, the case will proceed to a Measure Category Assignment of X and will be

	0376 Incidence of Potentially Preventable Venous Thromboembolism
	rejected. Stop Processing. b. If VTE confirmed equals 3, the care will proceed to a Measure Category Assignment of B and will not be in the measure Population. Stop Processing. c. If VTE Prophylaxis Status equals 1, the case will proceed to a Measure Category Assignment of D and will be in the Measure Population. d. If VTE Confirmed equals 2, the case will proceed to a Measure Category Assignment of E and will be in the Numerator Population. Stop Processing. Attachment 2zv_VTE6.pdf
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