**Evaluation of Venous Thromboembolism Prevention Practices in U.S. Hospitals**

**OMB/agency number (0920-XXXX)**

**Supporting Statement A- New**

Nimia L. Reyes, MD, MPH  
Medical Officer

Centers for Disease Control and Prevention (CDC)

National Center on Birth Defects and Developmental Disabilities (NCBDDD)

Division of Blood Disorders  
Phone: (404) 498-6733

Fax: (404) 498-6798  
Email: [NReyes@cdc.gov](mailto:NReyes@cdc.gov)

**February 9, 2021**

* **Goal of the study:** The overall goal of this project is to support a framework for improving hospital venous thromboembolism (VTE) prevention practices through the evaluation of current VTE prevention practices in U.S. adult general medical and surgical hospitals.
* **Intended use of the resulting data:** Improve understanding of VTE prevention practices (including risk assessment) in U.S. adult general medical and surgical hospitals, improve understanding of the capacity of hospitals to track VTE risk assessment, and inform evaluation and development of VTE risk assessment as a performance measure to reduce the burden of hospital-associated VTE.
* **Methods to be used to collect:** Selected hospitals will complete a questionnaire that is administered electronically through the QualtricsXM platform.
* **The subpopulation to be studied:** Random sample of U.S. adult general medical and surgical hospitals.
* **How data will be analyzed:** Standard descriptive and multivariate analysis will be conducted.

**Table of Contents**

[A.1. Circumstances Making the Collection of Information Necessary](#_Toc15926284) 4

[A.2. Purpose and Use of Information Collection](#_Toc15926285) 6

[A.3. Use of Improved Information Technology and Burden Reduction](#_Toc15926286) 6

[A.4. Efforts to Identify Duplication and Use of Similar Information](#_Toc15926287) 7

[A.5. Impact on Small Businesses or Other Small Entities](#_Toc15926288) 7

[A.6. Consequences of Collecting the Information Less Frequently](#_Toc15926289) 7

[A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5](#_Toc15926291) 8

[A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside](#_Toc15926291) the Agency……………………………………………………………………….……8

[A.9. Explanation of Any Payment or Gift to Respondents](#_Toc15926292) 8

[A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents](#_Toc15926293) 8

[A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions](#_Toc15926294) 10

[A.12. Estimates of Annualized Burden Hours and Costs](#_Toc15926295) 10

[A.13. Estimates of Other Total Annualized Costs Burden to Respondents or Record](#_Toc15926297) Keepers 12

[A.14. Annualized Costs to the Federal Government](#_Toc15926297) 12

[A.15. Explanation for Program Changes or Adjustments](#_Toc15926298) 12

[A.16. Plans for tabulation and Publication and Project Time Schedule](#_Toc15926299) 12

[A.17. Reason(s)Display of OMB Expiration Date is Inappropriate](#_Toc15926301) 15

[A.18. Exceptions to Certification for Paperwork Reduction Act Submissions](#_Toc15926301) 15

**Attachments**

Attachment 1 – Authorizing Legislation

Attachment 2 – 60-day Federal Register Notice

Attachment 3 – Screenshots of questionnaire in QualtricsXM

Attachment 4 – PDF of questionnaire

Attachment 5 – Implementation email and project information sheet

Attachment 6 – Characteristics of pilot sites

Attachment 7 – Recruitment communications

Attachment 8 – Non-research determination

Attachment 9 – Privacy Act checklist

Attachment 10 – Determination of non-applicability of Privacy Act

**Supporting Statement Part A. Justification**

**A. Justification**

***Section A.1. Circumstances Making the Collection of Information Necessary***

This Information Collection Request is submitted under the classification “New”. The length of data collection requested for OMB-PRA approval is one year. The Centers for Disease Control and Prevention (CDC) is making this request as authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) as the authorizing law (**Attachment 1**).

**Background:** Venous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), is an important and growing public health problem. Each year in the U.S., it is estimated that VTE affects as many as 900,000 people, is responsible for up to 100,000 deaths, and is associated with healthcare costs of approximately $10 billion (CDC, 2019a). Recurrence after a VTE is common and complications include post-thrombotic syndrome and chronic thromboembolic pulmonary hypertension (CDC, 2019b).

Over half of VTE events are associated with recent hospitalization or surgery and most occur after discharge (CDC, 2019a). An analysis of the National Hospital Discharge Survey from 2007 to 2009 estimated that almost 550,000 U.S. adult hospitalizations had a discharge diagnosis of VTE each year (CDC, 2019a). Hospital-associated VTE (HA-VTE) is often preventable but VTE prevention strategies are not applied uniformly or systematically across U.S. hospitals and healthcare systems (Kahn et al., 2013).

The Agency for Healthcare Research and Quality (AHRQ) published a guide for preventing HA-VTE in 2016 (Maynard, 2016). The framework for improving VTE prevention in hospitalized patients includes a hospital VTE prevention policy, an interdisciplinary VTE team, standardization of VTE prevention processes, monitoring of processes and outcomes, and VTE prevention education for providers and patients. A VTE prevention protocol includes VTE risk assessment, bleeding risk assessment (risk of bleeding with anticoagulant prophylaxis) and clinical decision support for appropriate prophylaxis (i.e., ambulation, anticoagulant prophylaxis, and/or mechanical prophylaxis) based on both VTE and bleeding risk assessments.

Despite evidence-based guidelines for VTE prophylaxis in at-risk hospitalized patients, there is systemic underuse of appropriate VTE prophylaxis (ISTH, 2016). As many as 70% of HA-VTE events are potentially preventable but less than half of hospitalized patients receive appropriate VTE prophylaxis (CDC, 2019a). An implementation gap exists between evidence-based guidelines for VTE prophylaxis in hospitalized adult patients and implementation of those guidelines in real-world hospital settings (Maynard, 2016; ISTH, 2016). The 2008 Surgeon General’s Call to Action to Prevent DVT and PE included instituting formal systems related to risk assessment and the provision of prophylaxis to high-risk hospitalized patients (OSG, 2008). For World Thrombosis Day in 2016, the International Society on Thrombosis and Haemostasis (ISTH) issued a call to clinical leaders, hospitals, and payers to work together to make VTE risk assessment for all hospitalized patients a priority.

In England, The National Venous Thromboembolism Prevention Programme was launched in 2010 with the goal of reducing preventable HA-VTE morbidity and mortality (Roberts, 2017). VTE risk assessment was mandated for all adult patients on admission to an acute hospital utilizing a previously developed national VTE risk assessment tool/model. Hospitals were required to report VTE risk assessment rates, with a financial incentive applied to achieve a target of 90%. This resulted in an impressive, sustained increase in VTE risk assessment rates with a corresponding increase in anticoagulant prophylaxis. There was evidence of significant reductions in HA-VTE and associated mortality following implementation of this program.

Unlike England, the U.S. has no national VTE prevention program with hospital risk assessment rates tied to financial incentives and no national VTE risk assessment tool/model. Various VTE risk assessment models (RAMs) have been developed and published to identify hospitalized patients whose risk for VTE is high enough to offset the risk of bleeding with anticoagulant prophylaxis. However, there is no standardized RAM currently in use across U.S. hospitals and healthcare systems. Implementation of risk assessment varies in terms of the patient population (e.g., medical vs. surgical), time frames (e.g., on admission, on transfer to another unit), method of administration (i.e., electronic vs. paper), person/s performing the risk assessment (e.g., physician, nurse, pharmacist), type of RAM (e.g., quantitative vs. qualitative), and linkage to a clinical decision support tool for appropriate VTE prophylaxis.

An evaluation of the extent to which U.S. hospitals utilize VTE risk assessment is needed to better understand the landscape around VTE prevention practices in real-world hospital settings in order to guide efforts and inform interventions to reduce the burden of HA-VTE. CDC is funding The Joint Commission to evaluate VTE prevention practices in U.S. hospitals. The Joint Commission has had a role in patient safety through standards and performance measurement. It is the measure steward for two electronic clinical quality measures (eCQMs) on VTE prevention available for Center for Medicare and Medicaid Services Inpatient Quality Reporting and Joint Commission hospital accreditation since 2016. However, these two VTE prevention eCQMs only address the initiation of VTE prophylaxis within a specified timeframe; they do not assess the patient’s level of VTE risk or the appropriateness of prophylaxis.

For this project, The Joint Commission, in collaboration with CDC, developed a survey on hospital VTE prevention practices. The survey questionnaire was piloted in 9 hospitals and their feedback was used to improve the questionnaire. After OMB approval, the survey will be implemented by The Joint Commission as a one-time data collection in a nationally representative sample of U.S. adult general medical and surgical hospitals. No individual-level data will be collected. CDC will not receive any individual or hospital identifiable information.

***Section A.2. Purpose and Use of Information Collection***

The overall purpose of this project is to evaluate current VTE prevention practices, including risk assessment, in U.S. hospitals (American Hospital Association [AHA] adult general medical and surgical service category) in order to support a framework for HA-VTE prevention. The information collected in this hospital survey will be used to improve understanding of hospital VTE prevention practices, which will guide efforts and inform interventions to reduce the burden of HA-VTE. Specifically, the information collected on VTE prevention policy and protocol, VTE prevention team, VTE data collection and reporting, VTE risk assessment, VTE prophylaxis safety considerations (i.e., bleeding risk assessment), ambulation protocol, VTE prevention education for providers and patients, and VTE prophylaxis monitoring and support will be used to assess the extent to which hospitals apply these components of the HA-VTE prevention framework at the hospital level and in adult general medical and surgical units. The responses to specific VTE prevention practices can be used to assess VTE prevention practices by hospital characteristics (e.g., bed size, urban vs. rural location, teaching vs. non-teaching status) to better target efforts or interventions to improve HA-VTE prevention. Information collected on the barriers to establishing a hospital-wide VTE prevention policy will be helpful in addressing these challenges. Information will be collected on both adult general medical and surgical units since VTE prevention practices differ by specialty. Information on VTE risk assessment (e.g., who conducts the assessment, when is it performed, mandatory or optional, format, type of RAM) will improve understanding of real-world hospital VTE risk assessment practices. Information on the capacity of hospitals to collect data on VTE risk assessment will be helpful in determining the feasibility of VTE risk assessment as a VTE prevention performance measure. The data collected can also serve as a baseline for evaluation of future HA-VTE prevention initiatives.

The negative consequence of not collecting this information is the continuation of limited knowledge/understanding of the gap between evidence-based guidelines on HA-VTE prevention and the implementation of HA-VTE prevention practices, particularly VTE risk assessment, in hospitals. This continued gap will have a negative impact on decreasing the burden of HA-VTE.

***Section A.3. Use of Improved Information Technology and Burden Reduction***

Participants/respondents in the project will complete an electronic questionnaire (**Attachment 3**) that will be administered through a platform called QualtricsXM ([Provo, UT](file:///C:/Users/schmalts/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/2GLPGOYZ/Provo,%20UT), <https://www.qualtrics.com>). A PDF version of the questionnaire (**Attachment 4**) was created to give participants the opportunity to review the survey questions and obtain input from other hospital staff (if necessary) before starting or while completing the electronic questionnaire. The questionnaire is designed to ascertain only information related to VTE prevention practices at the hospital level and in adult general medical and surgical services/units. It has computer generated skip patterns in order to reduce burden on participants. The platform is user friendly and it is possible to answer some questions, stop, and resume where the participant left off. Some data elements, such as demographic information, are available from an existing source, so they are not asked on the questionnaire, which will reduce the burden on participants.

An implementation email (**Attachment 5**) will be sent to each eligible participant. The email includes a hyperlink to the Project Information Sheet (**Attachment 5**) that describes in more detail what the project entails and why it is important, as well as a hyperlink to a pdf of the questionnaire. The information sheet includes the elements needed for online survey consent.

***Section A.4. Efforts to Identify Duplication and Use of Similar Information***

Our survey is designed to gather comprehensive data/information on VTE prevention practices, including risk assessment, in a nationally representative sample of U.S. hospitals. No similar data/information is available. No other federal agencies collect this type of data/information.

We searched for similar studies in the literature (PubMed) and found studies that collected limited information on risk assessment and/or prophylaxis/HA-VTE prevention but they were non-U.S. studies, not nationally representative or single site studies, and/or did not collect the level of information required to better understand hospital VTE prevention practices in relation to components of the HA-VTE prevention framework.

In addition, the Joint Commission had discussions with several hospitals that have ongoing VTE quality improvement initiatives as identified by The Joint Commission Pioneers in Quality webinar series. Pioneers in Quality™ is a Joint Commission collaborative program to improvehealth care quality and patient safety through education, innovation and recognition of pioneering practices for Joint Commission quality measurement stakeholders. However, the Pioneers in Quality program only highlights single-site quality improvement initiatives.

***Section A.5. Impact on Small Businesses or Other Small Entities***

The nationally representative sample of hospitals asked to complete the questionnaire will likely include hospitals that meet the definition of a small business (<https://www.sba.gov/federal-contracting/contracting-guide/size-standards#section-header-0>). To the extent that a small hospital may be considered a small business, the impact of this hospital survey on any such hospital is assessed to be minimal. Data collection will occur one time. We anticipate it will take less than one hour for a member of the hospital to complete the questionnaire; smaller hospitals will require less time than larger hospitals because fewer people will be involved, and systems may be less complex. Similarly, small organizations may have fewer VTE relevant practices; given the computer-generated skip patterns, they would probably have fewer questions to answer, which will take less time.

***Section A.6. Consequences of Collecting the Information Less Frequently***

Each respondent will be asked to respond one time. Therefore, there is no consequence of collecting the information less frequently. There are no legal obstacles to reduce the burden.

***Section A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5***

This request fully complies with regulation 5 CFR 1320.5.

***Section A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency***

1. A 60-day Federal Register Notice was published on November 19, 2020, Vol. 85, No. 224, pp. 73716-73718 (**Attachment 2**). CDC did not receive public comments related to this notice.

B. There were no representatives from organizations outside of CDC (other than the contractor, The Joint Commission) consulted and asked to review the data collection instruments for this project. The tool was piloted tested by The Joint Commission in 9 hospitals and this information is included in Supporting Statement B.

***Section A.9. Explanation of Any Payment or Gift to******Respondents***

No payment or gift will be provided to respondents

***Section A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.***

* 1. Privacy Impact Assessment

The CIO’s Information Systems Security Officer, Cindy Allen, reviewed this submission, including the Privacy Act Checklist (**Attachment 9**), on January 14, 2021, and determined that the Privacy Act does not apply (**Attachment 10**).

Activities do not involve the collection of individually identifiable information. The data being collected for this project are organization-level data. The type of information being collected at an organizational level includes whether the hospital has a VTE prevention policy and protocol, VTE prevention team, VTE data collection and reporting, VTE risk assessment, VTE prophylaxis safety, an ambulation protocol, VTE prevention education, and VTE prophylaxis monitoring and support. (**Attachments 3 &** **4**). Hospital demographic information from the AHA data set (e.g., bed size, location, teaching status) that will be used to select the sample will be stored for analysis purposes but will not be asked of respondents.

Project activities do not involve the collection of identifiable information about individuals other than the name, title, and email address of the hospital contact/target respondent. The proposed data collection will have no effect on the respondent’s privacy. For the purpose of sending the questionnaire to the target respondent, The Joint Commission will obtain information about the title, name and email address of the respondent from the Definitive Database (Framingham, MA. URL https://[www.definitivehc.com](http://www.definitivehc.com)). This information along with a project-specific hospital identifying code number will be kept in a separate file by The Joint Commission research project team and will not be sent to CDC. CDC will only receive the project-specific coded hospital identifier. Within the questionnaire, respondent role or title is requested but no other personal information about the respondents.

***Controls and safeguards designed to minimize the possibility of unauthorized access, use, or dissemination of the information being collected.***

CDC will not receive any individually identifiable or hospital identifiable data. The key to the hospital identifier codes will be kept at the contractor site (The Joint Commission Department of Research). Data will be deidentified by the contractor before it is sent to the CDC.

*At The Joint Commission*:

The Joint Commission utilizes several physical, technical and administrative controls to minimize the possibility of unauthorized access, use, or dissemination of the information being collected.

Physical controls include 24/7 security officers at the front desk with a closed-circuit TV system. All staff must wear identification badges when in the building and key cards are required for building access.

The Joint Commission also has an active information security program that is designed to meet HIPAA regulations and more than 18 privacy and security policies that address privacy and data security. International, federal and state laws regulate the access, use, maintenance, transfer and destruction of individual personally identifiable information maintained by The Joint Commission. All systems used during the implementation of this contract are consistent with Federal Information Security Management Act (FISMA) security compliance requirements.

To protect personally identifiable information, all Joint Commission personnel undergo training annually that addresses the following topics: awareness of any personal information with which they work; understanding the legal and contractual limitations on the use of personal information; collection, use and disclosure of personnel information consistent with the law and Joint Commission policies; proper storage or transport of personal information; and reporting of any unauthorized access, use or disclosure.

Regarding archiving and long-term preservation of electronic data, The Joint Commission maintains an information technology network that protects any confidential information it creates, uses, maintains, or possesses, against any reasonably anticipated threats or hazard to its security and integrity. Due to the high rate of evolution regarding technological implementations, these systems and safeguards are regularly assessed to ensure their on-going effectiveness.

*Protecting data collected specifically for this project*

The participants in the project will complete a questionnaire that is administered electronically through the QualtricsXM ([Provo, UT](file:///C:/Users/schmalts/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/2GLPGOYZ/Provo,%20UT), <https://www.qualtrics.com>) platform. Each participant will receive a unique link to the questionnaire which is non-sharable and only usable by the targeted respondent. There will be no face to face interaction.

Data will be stored in a password-protected electronic format securely accessed only by research project staff.

In order to protect the confidentiality of participants, research findings will be de-identified in all reports and publications. All results will be reported in aggregate only. No information that identifies facilities will be released without specific permission from participating organizations. Project data will be retained for five years after the completion of the project.

It is possible that some hospitals participating may be accredited by The Joint Commission and may have concerns about whether this response will relate to accreditation activities. Respondents will be informed during recruitment using the project information sheet that participation in this research is completely unrelated to The Joint Commission’s accreditation process. There is a firewall between the data received from research and accreditation-related activities. Thus, data collected as part of this project will be not be shared with persons other than those directly involved in this project.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

Not applicable. There will be no websites with website content directed at children under 13

years of age.

***Section A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions***

Institutional Review Board Approval

A proposal describing the project was submitted to Scott Campbell, BSN, MSPH, Health Scientist, Centers for Disease Control and Prevention. It was reviewed by the NCBDDD Human Subjects Contact and on November 18, 2018 it was determined to be Non-Research: Public Health Practice—Surveillance (**Attachment 8**). Since the project is not considered to be research, no further action is required by CDC for human subjects protections in accordance with federal regulation for the protection of human subjects in research. In addition, this project does not involve the collection of sensitive information.

***Section A.12. Estimates of Annualized Burden Hours and Costs***

Based on statistical power analyses, the desired number of respondents is at least 384.

Each respondent will take approximately one hour to complete the questionnaire. The estimated response burden is 384 hours. There are no costs to respondents other than their time and efforts. Based on the pilot test of the electronic questionnaire (N=9), the average time to complete the questionnaire was 61 minutes (min=20; max=150, median=60, range=130, standard deviation=37). We can expect variation in the time it takes a respondent to complete the questionnaire during the implementation phase. Variation may be related to factors such as hospital size as well as the complexity and comprehensiveness of VTE risk assessment practices. Small organizations may have fewer VTE relevant practices therefore, given the computer-generated skip patterns, they may need to answer fewer questions which will take less time.

**Estimated Annualized Burden Hours**

***A.12.A. Estimated Annualized Burden Hours***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Respondents** | **Form Name** | **No. of Respondents** | **No. Responses per Respondent** | **Average Burden per Response (in hours)** | **Total Burden**  **Hours** |
| The Director of Patient Safety and Quality, the Chairperson of the Patient Safety Committee, or other quality improvement professional | Online questionnaire (**Attachment 3**) | 384 | 1 | 1 | 384 |

The annualized cost burden is shown in Table A.12.B. The mean hourly wage rate is based on the most recent (May 2019) National Occupational Employment and Wage Estimates for

Medical and Health Services Managers, published on the Bureau of Labor Statistics website, which is $48.55. The 2019 median pay is $100,980 and the pay per hour is $48.55 (

<https://www.bls.gov/ooh/management/medical-and-health-services-managers.htm#tab-1>).

***A.12.B. Estimated Annualized Burden Costs***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondents** | **Form Name** | **Total Burden Hours** | **Hourly Wage Rate ($)** | **Total Respondent Cost ($)** |
| The Director of Patient Safety and Quality, the Chairperson of the Patient Safety Committee, or other quality improvement professionals | Online questionnaire | 384 | $48.55 | $18,643 |

***Section A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers***

There are no costs to respondents associated with either capital and startup efforts or operation and maintenance of services for this project.

***Section A.14. Annualized Cost to the Federal Government***

The average annualized cost to the Government to collect this information is $140,147.

***A.14. Average Annualized Cost to the Government***

|  |  |  |
| --- | --- | --- |
|  | | **Total ($)** |
| **Federal Government**  **Personnel costs** | CDC Project Officer | $3,899 |
| CDC Co-Principal Investigator | $2,915 |
| **Contractor**  **Direct Labor** | Personnel salary and wages | $14,093 |
| **Other**  **Contractor**  **Direct Cost** | Supplies (also: travel, equipment, subcontractor, and consultant fees) | $115,441 |
| **Total Indirect Cost** | Fringe and indirect | $3,799 |
| **Total** | Budget total | $140,147 |

***Section A.15. Explanation for Program Changes or Adjustments***

This is a new data collection.

***Section A.16. Plans for Tabulation and Publication and Project Time Schedule***

|  |  |
| --- | --- |
| **Project Time Schedule** | |
| **Activity** | **Timeframe** |
| Identify Participants | 1–2 months after OMB approval |
| Initiate implementation | 3-5 months after OMB approval |
| Collect and Review Data | 3-7 months after OMB approval |
| Analyze Data | 8 months after OMB approval |
| Draft Report | 9-10 months after OMB approval |
| Final Report | 11-12 months after OMB approval |

* Identify participants: During the first month after OMB approval, the participants will be identified by using a representative sample from the AHA database. The sample will be representative of all U.S. adult general medical and surgical hospitals. The sampling approach will be a stratified random sample.
* Implementation: The target respondent is the Director of Quality and Safety at each hospital. We will obtain their email address from the Definitive Healthcare (Framingham, MA. URL https://[www.definitivehc.com](http://www.definitivehc.com)) database. The research team will send a project information sheet and a link to the electronic questionnaire via the QualtricsXM ([Provo, UT](file:///C:/Users/schmalts/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/2GLPGOYZ/Provo,%20UT), <https://www.qualtrics.com>) platform. The project information sheet will include a background and description of the project, topics included in the questionnaire, estimated time to complete the questionnaire, role of the respondent and potential benefits and risks for participation to enable the respondents to be well informed before making the decision to click on the link to the QualtricsXM ([Provo, UT](file:///C:/Users/schmalts/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/2GLPGOYZ/Provo,%20UT), <https://www.qualtrics.com>) online questionnaire. The QualtricsXM ([Provo, UT](file:///C:/Users/schmalts/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/2GLPGOYZ/Provo,%20UT), <https://www.qualtrics.com>) platform can provide information regarding who has received, opened, started and completed the questionnaire. We will use this information to monitor online questionnaire uptake. We will send reminders two weeks after the initial QualtricsXM ([Provo, UT](file:///C:/Users/schmalts/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/2GLPGOYZ/Provo,%20UT), <https://www.qualtrics.com>) link is sent out and a second reminder two weeks following that. To enhance perception of authenticity and boost response rate, we will include email and telephone contact information of the research project director in all communications to targeted respondents. This will allow respondents the ability to verify authenticity if in doubt by directly contacting the research team.
* Collect and review data: During the mid to late months of data collection, data cleaning and analysis will begin. Incoming questionnaires will be examined for missing or inconsistent information; when needed, requests for clarification will be sent by e-mail to the contact person. Data cleaning include checks for duplicate survey submissions, incomplete surveys, out of range values, large amounts of missing data, and skip logic inconsistencies in responses.
* Analyze data: After the survey implementation period, preliminary analyses will include basic aggregate descriptive statistics for each question (frequencies and means etc. as appropriate). The team will then select key questionnaire items for further examination. Using matched demographic data from the AHA dataset obtained during the sample selection process, we will stratify the data to compare frequencies and means by groupings of hospital characteristics such as bed size categories, teaching status and rural/urban location. As appropriate, multivariate regression analyses will be performed to identify factors that most influence the key items.

All analyses will be conducted using SAS statistical software, version 9.4 (SAS Institute, Cary, North Carolina) and R Foundation for Statistical Computing, Vienna, Austria (R Core Team (2014). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/). The number of missing responses will be reported in the text whenever 10 or more responses were missing. A 2-tailed P value of less than 0.05 will be used to indicate statistical significance.

Sample Table: Characteristics of Hospitals in the Respondent Universe, Hospitals Invited to Participate, and Hospitals that Participated in the Survey

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Characteristic | All Hospitals \* | Hospitals Invited | P-Value † | Hospitals that Participated | P-Value †† |
|  | n | n (%) |  | n (%) |  |
| **Location** |  |  |  |  |  |
| Urban |  |  |  |  |  |
| Rural |  |  |  |  |  |
| **Bed Size** |  |  |  |  |  |
| <100 |  |  |  |  |  |
| 100-399 |  |  |  |  |  |
| ≥ 400 |  |  |  |  |  |
| **Teaching Status** |  |  |  |  |  |
| Major Teaching |  |  |  |  |  |
| Minor Teaching |  |  |  |  |  |
| Non-teaching |  |  |  |  |  |

\* Defined as adult general medical-surgical hospitals in AHA database in 2010

† P value for chi-square test of proportion of population invited

†† P value refers to the distribution of response rates

Sample Table: Weighted Prevalence of Hospital-level VTE Prevention Practices and Association with Hospital Bed Size

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Hospital VTE Prevention Practice | Hospitals Answering Affirmatively | Hospital Bed Size (95% CI), % | | | P-Value |
|  | (95% CI), % | <100 | 100-399 | ≥400 |  |
| Hospital has a VTE prevention policy |  |  |  |  |  |
| Hospital has a VTE prevention team |  |  |  |  |  |
| Hospital reviews HA-VTE events |  |  |  |  |  |
| Hospital reviews adverse events and complications from anticoagulant prophylaxis |  |  |  |  |  |

Sample Table: VTE Prevention Practices by Service/Unit

|  |  |  |  |
| --- | --- | --- | --- |
| VTE Prevention Practice | Adult General  Medical  (n, %) | Adult General Surgical  (n, %) | P-value |
| Patients are routinely assessed for VTE risk |  |  |  |
| VTE risk assessment is standardized |  |  |  |
| VTE risk assessment is mandatory on admission |  |  |  |
| Patients are routinely assessed for bleeding risk |  |  |  |
| Ambulation protocol |  |  |  |
| VTE prevention education provided to clinicians |  |  |  |
| VTE prevention education provided to patients |  |  |  |
| Admission order sets address VTE prophylaxis |  |  |  |
| Clinical decision support tools guide selection of appropriate VTE prophylaxis |  |  |  |
| VTE prophylaxis monitoring and support are integrated into quality and safety checklists |  |  |  |
| VTE risk assessment or prophylaxis reminders/alerts |  |  |  |
| VTE prophylaxis audits and feedback |  |  |  |

* Draft report: This report will include descriptive findings of VTE prevention practices in U.S. hospitals as reported by participating hospitals. It will also include an analysis describing the extent to which U.S hospitals utilize standardized risk assessment and related practices in their VTE prevention activities.
* Final report: This report will include the background, methods, results, discussion, and conclusions.

***Section A.17. Reason(s) Display of OMB Expiration Date Is Inappropriate***

The display of the OMB expiration date is not inappropriate.

***Section A.18. Exceptions to Certification for Paperwork Reduction Act Submissions***

There are no exceptions to the certification.

**References:**

* CDC (2019a). “Learn About Healthcare-Associated Venous Thromboembolism”. Retrieved on January 29, 2020 from: <https://www.cdc.gov/ncbddd/dvt/ha-vte.html>
* CDC (2019b). “Deep Vein Thrombosis & Pulmonary Embolism”. Retrieved on January 29, 2020 from: <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-by-air-land-sea/deep-vein-thrombosis-and-pulmonary-embolism>
* Kahn, S.R., Morrison, D.R., Cohen, J.M., Emed J., Tagalakis, V., Roussin, A., and Geerts, W. (2013). Interventions for implementation of thromboprophylaxis in hospitalized medical and surgical patients at risk for venous thromboembolism. *Cochrane Database of Systematic Reviews, 7*(CD008201). DOI: 10. 1002/14651858.CD008201.pub2.
* Maynard G. (2016). *Preventing hospital-associated venous thromboembolism: a guide for effective quality improvement (2nd ed*.). AHRQ Publication No. 16–001-EF. Rockville, MD: Agency for Healthcare Research and Quality.
* ISTH Steering Committee for World Thrombosis Day (2016). Venous thromboembolism: A call for risk assessment in all hospitalised patients. *Thromb Haemost,* 116, 777-779.
* Office of the Surgeon General (US); National Heart, Lung, and Blood Institute (US) (2008). *The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism*. Rockville (MD): Office of the Surgeon General (US). Roberts, L., Durkin, M. and Arya, R. (2017). Annotation: Developing a national programme for VTE prevention. Br J Haematology, 178,162-170.
* Roberts, L., Durkin, M. and Arya, R. (2017). Annotation: Developing a national programme for VTE prevention. Br J Haematology, 178,162-170.
* Size standards. The SBA’s size standards determine whether or not your business qualifies as small. *U.S. Small Business Administration*, (<https://www.sba.gov/federal-contracting/contracting-guide/size-standards#section-header-0>)