

Meeting Summary

Prevention of Hospital-Acquired Venous Thromboembolism (HA-VTE) Expert Panel Meeting

Convened by the Division of Blood Disorders (DBD)
Centers for Disease Control and Prevention (CDC)

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CDC Thomas R. Harkin Global Communications Center
1600 Clifton Rd NE, Atlanta, GA

For future reference, meeting participants suggested the use of “hospital-associated” in place of “hospital-acquired” because VTEs diagnosed in hospitals are not necessarily acquired there. Also, VTEs that occur in the first 3 months following discharge from a hospital can be regarded as hospital associated, but are not necessarily hospital acquired.

This is not an official recommendation statement. The findings and opinions expressed in this report are those of the individual speakers and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Conflict of interest statements

Dr. Raskob and Dr. Geerts reported that they are paid consultants to manufacturers of anticoagulants used for VTE prophylaxis or therapy.

The meeting agenda is included as Appendix 1.

A list of meeting participants can be found in Appendix 2.

Opening Remarks

Althea Grant, PhD, Chief of the Epidemiology and Surveillance Branch, Division of Blood Disorders (DBD), Center for Disease Control and Prevention (CDC), gave welcoming remarks and an overview of CDC/DBD activities addressing venous thromboembolism (VTE) (activities of other CDC programs listed later) <http://www.cdc.gov/ncbddd/dvt/aboutus.html>.

- Surveillance and burden of disease—CDC/DBD has
 - Put out a funding announcement and will award funds for one or more pilot population-based surveillance projects (two awarded April 1, 2012).
 - Performed analyses of administrative data.
 - Conducted literature reviews.
- Identification of risk factors and epidemiologic research—CDC/DBD has
 - Conducted case-control studies (e.g., GATE study) addressing racial disparities, genetics, and family history.
 - Funded studies through a network of thrombosis centers.
- Development and contribution to implementation of guidelines and policies—CDC/DBD will
 - Review existing prevention guidelines for hospital-associated VTE.
 - Publish recommendations and a report from this meeting.

Coleen Boyle, PhD, Director of the National Center on Birth Defects and Developmental Disabilities (NCBDDD), which includes the Division of Blood Disorders (DBD), noted that the name of the center does not reflect the current range of its mission, but was determined by the U.S. Congress. She stated that prevention of VTE, especially HA-VTE, is a priority for both the center and for CDC's Director, Dr Thomas Frieden. She emphasized NCBDDD partnerships with two other CDC units with overlapping interests in this area, the Division of Healthcare Quality Promotion (DHQP) and the Division of Heart Disease and Stroke Prevention (DHDSP)

Hani Atrash, MD, MPH, Director of the Division of Blood Disorders, commented on the challenge that reliable estimates of the VTE burden are lacking which makes it difficult to be able to measure the impact of VTE prevention efforts. That is why CDC emphasizes the need for population-based surveillance.

Presentations

1. Hospital-Acquired Venous Thromboembolism

In the opening presentation, Gary Raskob, PhD, Dean of the College of Public Health, University of Oklahoma, talked about the disease burden of VTE. He stated that there is no systematic surveillance system for deep vein thrombosis (DVT) and pulmonary embolism (PE). He also stated that, based on local surveillance studies, the incidence of VTE in the United States appears to be 250,000–300,000 new cases each year of clinically symptomatic VTE. A modeling study by Heit et al. suggested that as many as 900,000 cases and 300,000 deaths occur annually in the United States, almost all of which are attributed to PE. The Surgeon General's Call to Action in 2008 suggested the number of deaths to be perhaps 100,000; Gary Raskob thinks the actual range might be 100,000–300,000 deaths per year. He doesn't think the exact number is important because VTE is either among the top five or top three causes of death in the United States.

Gary Raskob went on to explain that many risk factors for VTE are well established: age, hospital admission, surgery, prior VTE, and cancer. He also stated that 60% of incident VTE cases are associated with a recent hospitalization within the previous 3–6 months (including stays at long-term care facilities).

Gary Raskob provided the following additional information. The Agency for Healthcare Research and Quality (AHRQ) in 2001 (<http://www.ncbi.nlm.nih.gov/books/NBK43908/pdf/TOC.pdf>) identified VTE prevention as a priority to improve patient safety. An analysis of 2003 AHRQ Health Care Utilization Project (HCUP) (www.ahrq.gov/qual/vtguide) hospital discharge data by Anderson et al. (2007) calculated that 31% of hospital patients were at moderate or high risk of VTE, which represents an important opportunity for prevention.

The risk period for HA-VTE often extends far beyond the hospital stay. When a clot becomes symptomatic or even originates (i.e., after discharge) is less important in determining whether it resulted from a hospitalization. Hospitalization is an opportune access point to implement prevention, regardless of when the VTE actually occurs following admission or discharge.

As far as cost and cost-effectiveness are concerned, it is estimated that the United States spends \$5–\$8 billion in direct medical costs on VTE each year, not including the costs of long-term complications. It is not necessary to show cost savings from prevention, but cost-effectiveness in terms of good value does need to be shown. While early studies showed that prophylaxis was cost saving relative to no prophylaxis, clinical practice has changed over time and those data are old. There have been 40 cost-effectiveness analyses published on primary or secondary VTE prevention, most of which compared the effectiveness of different anticoagulant drugs. Gary Raskob interjected that he would like to estimate quality-adjusted life-years (QALYs), not just the cost per case prevented. VTE has serious effects on quality of life, as well as on death (quantity of life). He further stated that he thought the most important analytic perspective to use is that of Medicare (or, a payer perspective). Gary Raskob stated that if it could be shown that VTE prevention is cost-effective and perhaps cost saving to Medicare, he was confident that that would get the attention of policy makers. Post-thrombotic syndrome (PTS) and chronic complications of pulmonary embolism and their associated costs and quality of life effects also need to be factored in. He was confident that there are many prevention strategies that cost less than the commonly used thresholds of \$50,000 (or £30,000) per QALY to assess cost-effectiveness.

Gary Raskob stated that in his opinion VTE is a “winnable battle”. He further asserted that the health care community needs to improve the use of proven effective measures. He indicated that he is particularly concerned about the higher risk of VTE in certain patient subgroups, notably cancer patients. He quoted a colleague at the University of Oklahoma, Dale Bratzler, as saying that colorectal cancer surgical patients are particularly unlikely to be given prophylaxis. Medical (non-surgical) patients also need more attention for prophylaxis. Finally, he suggested that increasing use of outpatient surgery (e.g., for knee arthroplasty) is a concern; those patients should be targeted for prophylaxis as well.

Duration of anticoagulation is another issue. Whenever patients with idiopathic (primary or unprovoked) VTE go off therapy, whether it is at 3, 6, or 12 months, they once again become at elevated risk of recurrent VTE. Long-term anticoagulation strategies need to be improved.

During Q&A, Alan Brownstein, MPH, National Blood Clot Alliance (<http://www.stopthecлот.org/>), asked what can be done to facilitate the approval of new oral anticoagulants for VTE.

2. Current Status of VTE Prophylaxis Among Hospitalized Patients

This topic was addressed by William (Bill) Geerts, MD, FRCPC from the University of Toronto, Canada, who noted that he is the national lead for VTE prevention in Canada. He also represented the Venous Disease Coalition at the workshop (<http://www.venousdiseasecoalition.org/>). Bill Geerts stated that in his opinion VTE

is (or should be) a public health priority for the United States. At least 312,000 VTE incident cases occur each year, which he calculated by taking an incidence of 1 per 1,000 people per year and multiplying by 312 million Americans. Of those, 187,000 are hospital-associated, assuming 60% of VTE are hospital-associated.

Bill Geerts further stated that there are more randomized controlled trials (RCTs) for VTE prevention than for almost any other area of medicine, over 400 by his count. Moreover, clinical guidelines calling for routine prophylaxis among hospital patients have been available since 1986. Based on these facts, he questioned why we still needed to have this meeting.

He stated that the use of low molecular weight heparin (LMWH) is now dominant over low-dose unfractionated heparin (LDUH), at least in Canada, because it is both cheaper and more effective than unfractionated heparin. Newer oral anticoagulant agents which are alternatives to injectable LMWH or LDUH are beginning to come into use. One of those, rivaroxaban, received Canadian approval in January 2009, after which its use as prophylaxis following orthopedic surgery has been adopted quickly at his hospital; he said that the orthopedists there greatly prefer it.

Bill Geerts cited Stein et al. (Chest, 2011) as showing an increasing trend over time in the frequency of secondary DVT hospital diagnoses, which is often used as an indicator of HA-VTE. He suggested that this implies that hospital prevention efforts in the United States have not been successful in reducing numbers of events. [Editorial comment: That inference presumes that *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* codes are reliable indicators of HA-VTE, which other speakers in the meeting questioned.]

Bill Geerts went on to cite multiple studies indicating low rates of appropriate prophylaxis. He also noted that Amin et al. (*Thrombosis Research*, 2010) showed that high-risk patients receiving prophylaxis according to American College of Chest Physicians (ACCP) guidelines have lower total hospital costs.

Bill Geerts raised the question of why prophylaxis is still being underused, and then provided the following reasons why he believes this is happening.

Individual Practitioner Level—He doesn't think bleeding risk is perceived as a major concern for most practitioners, nor is concern about drug costs. Instead, he thinks underappreciation of VTE risk and the importance of prophylaxis as an effective prevention method are more important barriers to the prescription of anticoagulants. The biggest impediment, in his opinion, is that the decision of whether to prescribe anticoagulation is treated as an individual MD-patient decision rather than as a standard protocol. Inertia and forgetting are also important barriers. He noted that VTE prevention is not yet part of the culture of care in most hospitals, which he thinks is needed to overcome the individual-level barriers.

Organization Level—Lack of senior leadership commitment and institutional priority for VTE prevention are crucial barriers at the organizational level. There needs to be an organization-wide strategy that includes mandatory use by hospital physicians of order sets. Making prevention protocols too complex is another problem, as is emphasizing mechanical prophylaxis or treating it as equivalent to pharmacologic prophylaxis.

National Level—At the national level, there is currently no national standard of care in either Canada or the United States; that is, no national VTE strategies exist and there are multiple patient safety priorities. Canada has various national quality guidelines that mention VTE, including a surgical safety checklist that is mandatory in Ontario, but these do not yet comprise a national standard of care.

Accreditation Canada came out in 2011 with a Required Organizational Practice on VTE prophylaxis (www.accreditation.ca/uploadedfiles/ROP%20Handbook%20EN.pdf) that all Canadian hospitals must satisfy to

be accredited, and that must be reassessed every 3 years. The work group that advised Accreditation Canada, chaired by Bill Geerts, came up with five tests for compliance. The hospital must document that it:

1. Has an organization-wide, written thromboprophylaxis policy or guideline.
2. Identifies patients at risk for VTE and provides appropriate, evidence-based VTE prophylaxis.
3. Has established measures for appropriate thromboprophylaxis use, and audits their implementation and uses this information for quality improvement.
4. Identifies major orthopedic surgery patients who require post-discharge prophylaxis and provides it.
5. Educates health professionals and patients about VTE and its prevention.

This has had a huge effect in getting the attention of hospital management because every hospital needs to address these tests to get reaccredited every 3 years.

There also are provincial VTE initiatives in British Columbia and Alberta.

Bill Geerts suggested that risk assessment needs to be either simplified or dropped. Approximately 95% of hospital patients are at risk for VTE and should be prescribed anticoagulants. In his opinion, it is better to make prophylaxis the default for anyone with a hospital stay of 2 days or more unless there is a clear contraindication.

He also suggested simplifying prophylaxis options, to make it easier for staff to understand and follow. He recommended that dosing be simplified. At his hospital, almost everyone gets the same dose. Bill Geerts cited a study by Gaylis et al. (*American Journal of Medical Quality*, 2010) as showing that the best predictor of physician use of hospital VTE prophylaxis is mandatory use of a standardized, pre-printed medical order set in which a prescription for prophylaxis is embedded. Bill Geerts' hospital does monthly electronic audits, which take about half an hour to run, and shares results with hospital leaders. He has found that about 80%–85% of patients currently are receiving appropriate prophylaxis, but the goal is 100%.

The lesson that Bill Geerts took from Canada's experience for the United States is that a coordinated national strategy is needed in which each federal organization "sings from the same song sheet" using a single set of guidelines. He argued that this should be legislated as a standard of care and that there should be consequences—whether in terms of accreditation or reimbursement—for non-adherence. Whether at the local, regional, or national levels, credible leadership, mentorship, and sharing of tools are needed.

During the Q&A, Geno Merli, MD, Thomas Jefferson University Hospital, suggested that mandatory public reporting concentrates the attention of hospital managers. Bill Geerts responded that reporting of HA-VTE is difficult to do because the majority of clinically relevant VTE occurs after discharge and hospitals don't track those occurrences unless they result in a readmission.

3. Designing and Implementing Effective VTE Prevention Protocols

In the third presentation, Greg Maynard, MD, University of California, San Diego (UCSD) and the Society of Hospital Medicine (SHM) (<http://www.hospitalmedicine.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentID=17773>), reviewed the UCSD Health Sciences experience with promotion of a standardized risk assessment and prophylaxis protocol that began with a grant he received from AHRQ in 2005. At the time, the UCSD had a protocol that recommended mechanical prophylaxis. Implementation of the protocol was facilitated by Greg Maynard being in charge of all hospitalists at UCSD. He showed a graph depicting the changes over time in the rate of appropriate prophylaxis (as defined by adherence to the ACCP guideline) at his hospital as it successively implemented various interventions. The hospital went from 55% of patients with appropriate prophylaxis at baseline to 70% within one year after implementing a voluntary,

consensus-based approach. The subsequent introduction of a mandatory order set quickly raised the rate to 80%, which over the course of the second year increased to 90% as a result of making adjustments to the order set and various quality improvement (QI) activities. Finally, the hospital raised uptake of appropriate prophylaxis to 95%–98% through additional steps classified as “measure-vention” described below. See <http://www.ahrq.gov/qual/vtrepresentation/maynardtxt.htm> for a similar presentation.

Greg Maynard shared experiences from multiple collaboratives he has been involved with that have, to date, included over 250 hospitals in the United States and Canada. These collaboratives have involved SHM, AHRQ and its affiliated quality improvement organizations (QIOs), such as Island Peer Review Organization (IPRO) based in New York, the Institute for Healthcare Improvement (IHI) Expedition; British Columbia Hospital Medicine; and the American Society of Health-System Pharmacists (ASHP). The British Columbia collaborative for VTE prevention is a voluntary initiative that includes all hospitals in the province with hospitalists on staff. The results achieved by the collaboratives, which have followed a guide developed for AHRQ (<http://www.ahrq.gov/qual/vtguide/vtguide.pdf>) have demonstrated that high levels of VTE prophylaxis are achievable in all types of hospitals: those using electronic or paper records, teaching or community hospitals, and large or small (in terms of number of beds) hospitals.

In Greg Maynard’s opinion, institutional support is the most important factor for success in VTE prevention. Team management with physician leadership also was emphasized. Hospitals need to seek help with accurate measurement and have a will to standardize the process. If there is no will to standardize, mediocre results are guaranteed. Other important components include standard risk assessment and prophylaxis protocols integrated into order sets, education, ongoing refinement and revision of protocols, identification of suboptimal care, and quality improvement activities.

Maynard and Stein (*Journal of Thrombosis and Thrombolysis*, 2010) came up with a hierarchy of reliability of interventions to promote hospital VTE prophylaxis. They believe that it is possible to get to about 40% rate of prophylaxis use by doing nothing. This figure then can be raised to 50% by introducing decision support tools on a voluntary, ad hoc basis. With standard protocols introduced into order sets at the point of care, the rate of uptake of prophylaxis can be raised to 65%–85%. Adding QI can raise this figure to 90%.

If suboptimal care is identified and addressed in real time through “measure-vention”, as this process is referred to by SHM, one can get prophylaxis use up to 95%–98%, as has been the case at UCSD. This requires that nurses be encouraged to report apparent failures and not fear retribution. Also, at UCDS electronic records are color coded to indicate patients not on prophylaxis who do not have clearly defined low risk and find out what is going on.

Greg Maynard reviewed types of order sets and stated that simpler is better. Complicated forms are likely to be ignored by most physicians.

During the Q&A for this segment, Vicki Agramonte, RN, MSN, commented that IPRO’s experience has been that hospitals can implement this approach very quickly (in less than a year) with dramatic results in terms of increased use of appropriate prophylaxis.

4. Establishing a System-wide Approach to VTE Prevention: United Kingdom Experience

In the fourth presentation, Roopen Arya, MD, PhD, King’s College Hospital, King’s Thrombosis Centre / NHS VTE Exemplar Centre Network (London, England) shared about the United Kingdom (UK) National Health Service (NHS) and the National VTE Prevention Programme in England (which does not extend to Scotland, Wales, or Northern Ireland). Preventing VTE has become a top clinical priority for hospitals in the NHS since Professor Sir Bruce Keogh, who is currently the Medical Director of the NHS, took over the NHS VTE portfolio 2 or 3 years ago. It is estimated that VTE costs the NHS at least £640 million per year and that £110 million has been spent so far on litigation relating to HA-VTE.

The Department of Health (in England) VTE team has established a standardized protocol and a risk assessment tool. It's a single tool that every hospital is supposed to use for all patients at admission, again after 24 hours, and every time a patient's clinical situation changes (e.g., change in level of mobility).

In January 2010, the National Institute for Health and Clinical Excellence (NICE) published a reference guide (www.nice.org.uk/media/7F5/32/VTEQualityStandard.pdf) on how prophylaxis should be used to reduce VTE risk among hospitalized patients.

The NHS has not mandated prophylaxis, but instead has been trying to use financial inducements to local hospital trusts to influence use. The NHS has a program called Commissioning for Quality and Innovation (CQUIN) (www.dh.gov.uk/en/publicationsandstatistics/DH_091443), which is a national framework for locally agreed on quality improvement schemes. The national CQUIN 2010–2011 goal is to reduce avoidable death, disability, and chronic ill health resulting from VTE. The NHS decided to use as a performance measure the proportion of patients receiving risk assessment rather than prophylaxis. If a local hospital trust cannot demonstrate that at least 90% of adult inpatients each year are assessed at admission for VTE risk using the national tool, it stands to lose up to 1.5% of revenue from the local primary care trust, which in the case of Roopen Arya's hospital would be a loss of about £1 million. CQUIN data showed that, after one year, about 80% of inpatients were being assessed for risk (up from 50% at baseline), and about 60% of hospital trusts met the 90% target. For national CQUIN 2011–2012, the target has been altered to 90% of patients being risk assessed each month rather than over the course of a whole year.

The standard NHS contract for acute hospital services requires that all hospital trusts conduct clinical audits of appropriate prophylaxis and a root-cause analysis of hospital-associated VTE.

NICE, which traditionally has done cost-effectiveness analyses for drug coverage, now is producing quality guidelines for the National Quality Board. One of the first was prepared for VTE. The NICE quality standard for VTE prevention defines high-quality care using seven quality standards (see following). The NHS has not yet decided how to monitor compliance with these standards, which probably will be assigned to the Care Quality Commission.

QS1. Assess VTE risk at admission.

QS2. Provide oral or written information on VTE prevention at admission.

QS3. Use compression (or anti-embolism) stockings.

QS4. Reassess VTE and bleeding risk within 24 hours of admission.

QS5. Administer VTE prophylaxis according to risk.

QS6. Collect oral or written information on VTE prevention at discharge.

QS7. Provide extended thromboprophylaxis as required.

Regarding QS2 (provision of patient information), the program at King's has developed VTE information flyers, which are given to all inpatients at admission. QS3 (promotion of compression stockings) has been particularly challenging because it is necessary not just to promote use of these stockings, but also to ensure their appropriate fit.

The staff at King's conducts a root-cause analysis of all cases of hospital-associated thrombosis (HAT), which is the UK term for HA-VTE. Admitting physicians have to fill out and submit forms that include information from several hospital departments, including diagnostics, laboratory, and pathology. About 75% of these forms have been turned in to date.

During 2010–2011, at King's they found a total of 243 cases of HAT; that is a rate of 5 per 1,000 admissions. The 243 cases of HAT are equivalent to approximately two-thirds of all VTE episodes among inpatients at King's

during the same period. The majority of cases were among medical (non-surgical) patients. There were 51 deaths among HAT patients, of which 16 were attributed specifically to PE (of which 12 were diagnosed on autopsy). A root-cause analysis found that 56% of the 243 patients with HAT did not undergo risk assessment at admission. Over all, roughly one-third of patients with HAT were not prescribed anticoagulant prophylaxis (39% of medical and 8% of surgical patients), another one-third received inadequate prophylaxis, and the final one-third received recommended prophylaxis. Roopen Arya interpreted the last finding as indicating a need for better risk classification and prophylaxis.

Roopen Arya talked about the NHS England VTE Exemplar Centres network (<http://www.kingsthrombosiscentre.org.uk/cgi-bin/kingsthrombosis/vteexemplarcentres.pl>), which he heads. It is a voluntary network that hospitals apply to join; no funding is made available as an inducement for hospitals to join. Currently, 20 hospitals and 2 strategic health authorities participate in the network. He uses public recognition of individuals identified as VTE Champions to help motivate people. Among other resources, his group has developed a 15-minute online training course on VTE prevention for use by junior physicians. The group's website hosts educational materials from all participating exemplar centres.

Roopen Arya said that it is too soon to be able to show success from the England VTE prevention initiative. A prior UK national VTE guidance issued in 2004 that targeted obstetric patients resulted in a drop from 1.9 VTE-related maternal deaths per 100,000 maternities during the period 2003–2005 to 0.8 per 100,000 during the period 2006–2008 according to a recent analysis by the Centre for Maternal and Child Enquiries (CMACE, BJOG 2011). As a result, VTE dropped from the leading cause of maternal death to only the third direct cause of maternal deaths in the United Kingdom.

During the Q&A period for this section, someone asked whether UK physicians are doing enough, in light of the fact that nearly half the clots were considered to be potentially preventable. Can more be done? Roopen Arya responded that the United Kingdom is interested in developing a VTE registry to record and learn from cases of HAT. He also said that there is a need to better understand how to prevent HAT because many of those on prophylaxis had the wrong form, dose, or duration of anticoagulant prophylaxis. Bill Geerts added that existing prophylaxis is not sufficient for some subgroups, but that it is difficult to determine which ones require higher doses.

5. Hospital Systems-Level Interventions for VTE Prevention: Summary

Gregory Piazza, MD, MS, Brigham and Women's Hospital and the North American Thrombosis Forum (www.natfonline.org), after citing the Surgeon General's Call to Action and the 8th edition of the ACCP guidelines, presented estimates of the magnitude of HA-VTE in the United States using data from his 2009 article in *Thrombosis and Haemostasis*. That article used 2003 HCUP data and estimated 196,000 VTE events occur each year among US hospitalized medical patients (a rate of 2 per 100 medical patients) and that 41,000 deaths result. Gregory Piazza and colleagues projected that 60% of HA-VTE could have been prevented by universal VTE prophylaxis.

Gregory Piazza also presented on an analysis of a randomized controlled trial done at Brigham and Women's Hospital of electronic alerts for VTE prophylaxis. In that analysis, Kucher et al. (*NEJM*, 2005) found a 41% reduction in symptomatic VTE among patients for whom an electronic alert regarding VTE risk and the need for prophylaxis was issued compared with control patients for whom no such notification was issued. As the Brigham and Women's researchers began to design a second study to replicate their electronic alert experience in a larger multicenter study, they realized that many medical centers did not have the resources needed to develop such a computerized decision support strategy. Accordingly, they devised a multicenter randomized controlled trial of "human" alerts that was less resource intensive and that could be implemented more readily by

other medical centers. Although these “human” alerts resulted in a doubling of the frequency of prescription of prophylaxis, an analysis by Piazza et al. (*Circulation*, 2009) found no significant reduction in symptomatic VTE. The conclusion drawn by Piazza from this experience was that computerized alerts might be inherently more effective than non-electronic alerts.

Simply prescribing prophylaxis is not sufficient for improving VTE prevention; providers must ensure that patients receive the prophylactic measures. Another study at Brigham and Women’s Hospital by Fanikos et al. (*American Journal of Medicine*, 2010) demonstrated that up to 15% of clinician-ordered prophylactic anticoagulant doses were not administered and that patient refusal was the most common reason (40%–45%) for missed doses. Study researchers hypothesized that patients were not educated adequately about the rationale for VTE prophylaxis and refused doses because of anticipated discomfort, inconvenience, or anxiety. A patient education prospective cohort study resulted in a reduction of patient refusal from 44% to 29%.

Comments

During a Q&A that followed Roopen Piazza’s presentation, Greg Maynard asked about the risk assessment criteria used, which Roopen Piazza agreed could be improved.

Cynthia Reilly, BS Pharm, American Society of Health-System Pharmacists, then asked about the timing of patient education. Gregory Piazza replied that, although ideally this would take place prior to the first dose of prophylaxis, staff almost always get to the patients before the second dose is received 24 hours after the first dose.

Marc Moote, MS, PA-C, University of Michigan, commented that one of the major reasons for patient refusal at his hospital was that admissions nurses were telling patients that prophylaxis wasn’t really very important.

Gregory Piazza finished by stating that standardization of the VTE prevention messages provided by providers to patients is crucial.

Summary of All Presentations

Recommendations

Meeting attendees recommended:

- Integrating VTE prevention guidelines into hospital QI Initiatives.
- Combining standardized risk assessment tools with provider order entry sets.
- Encouraging regular measurement of the effects of VTE prevention initiatives.
- Emphasizing patient participation by making education central to QI Initiatives for VTE prevention.

Unmet Needs

Meeting attendees recognized the following as unmet needs that need to be addressed:

- Strategies to address VTE prophylaxis underutilization among vulnerable medical patient populations.
- Adherence to clinician-prescribed VTE prophylaxis among hospitalized patients.
- Identification of medical patients who remain at risk for VTE after discharge and who would benefit from extended VTE prophylaxis.

Facilitated Discussion on Systems-Level Interventions

1. What hospital systems-level Interventions are most effective in improving VTE prophylaxis among hospitalized patients?

Peter Kaboli, MD, MS, Iowa City Veterans Affairs Health Care System, said that at the Veterans Affairs hospital in Iowa he and his colleagues started with a checklist risk assessment, but physicians were reluctant to fill it out. After consulting with Greg Maynard, they decided to skip the separate formal risk assessment and go straight to the order set (a simplified risk assessment is included in the order set).

Marc Moote said that he thought that there could be a problem if risk assessment is oversimplified. At the University of Michigan hospitals, the Caprini risk assessment model is used and he and his colleagues feel that the quantitative information is valuable for patient management.

Gregory Piazza said that, to have successful VTE prophylaxis, physicians have to understand and accept whatever risk factor assessment tool is used. If that is an electronic risk assessment form, it might scan electronic health records (EHRs) to populate some of the risk assessment fields and thereby reduce the burden on the physician, but the physician still needs to understand how risk is scored.

Julie Atay, PharmD, MBA, Brigham and Women's Hospital, suggested that risk assessment should focus on the small number of low-risk patients to be excluded from prophylaxis. It is imperative that risk assessment be easy so that physicians and other healthcare professionals will do it.

Alpesh Amin, MD, MBA, University of California, Irvine, agreed with the exclusionary approach to risk assessment, which he argued will require a culture shift. Implementation is a challenge in U.S. health care. He indicated that there's a lot of evidence that VTE prophylaxis works, but physicians need to understand the process, and risk assessment can help them understand.

Vicky Agramonte said that, in her experience, if physicians don't understand the risk factors for a patient, they are reluctant to order prophylaxis.

Lynn Oertel MS, ANP, CACP, Massachusetts General Hospital, suggested that patient education is as important as the hospital system level factors. At her hospital, a hand hygiene campaign has been highly successful based on patient education beginning at patient intake.

Alan Brownstein said that messages to patients beginning during preadmission are crucial. The patient should start the conversation with his or her physician, "What blood thinners will I need?" Specialist physicians often are focused narrowly on their specialty. Nurses, pharmacists, and others often have a more patient-centered approach and they need to be brought in as well.

Cynthia Reilly noted that there are competing priorities for the prevention of hospital-associated conditions and that making VTE prevention more similar to other activities might increase buy-in.

Stephan Moll, MD, University of North Carolina School of Medicine and Clot Connect (www.clotconnect.org/), suggested that, to motivate hospital physicians to provide prophylaxis, it is important to provide feedback, in particular to document among PE deaths which patients had not received prophylaxis.

Greg Maynard noted that there are gray areas for which it is unclear what is the best practice, but a national guideline is needed to move forward. He suggested the focus be on identifying the low-risk patients who don't need prophylaxis.

Geno Merli asked what was meant by "transition to care". In response, Althea Grant stated that this term indicates transition from acute hospital care to care by a physicians in the community or, as added by Scott

Grosse, PhD, Division of Blood Disorders, CDC, in long-term care facilities. Geno Merli said that discharge planning in the United States for patients with conditions such as cancer or congestive heart failure currently is very bad.

Stuart Haines PharmD, University of Maryland School of Pharmacy, stated that, in his opinion, the most important thing is to build consensus around a standardized approach, starting with risk assessment and order set. He also asserted that, without buy-in from hospital staff, even a great order set won't work.

Bill Geerts said that before thinking about complicated risk assessment and discharge planning there is a need to focus on the basics: namely, on increasing the use of appropriate prophylaxis among patients during hospital stays.

Peter Kaboli said that in their collaborative they came up with a stratified approach during the Olympics. Bronze level means a hospital simply adopts a standard order set tool. Silver level goes beyond that to building a local committee. Reaching the Gold level requires a “measure-vention” approach.

Stephan Moll pointed out, in response to Bill Geerts, that one-third of VTEs occur within 30 days after patient discharge and, hence, there is a need to think about discharge planning.

Alan Brownstein added that more publicity is needed about success stories of blood clot prevention in the United States. There are frequent news stories from the United Kingdom on VTE prevention, but not from the United States.

MaryAnne Cronin, PharmD, North Shore University Hospital at Glen Cove, spoke via telephone about her experience at her community hospital on Long Island in New York. She and her colleagues started in 2005 with a year-long review of all VTE cases, and the data caught prescribers' attention. They put together a committee and developed a simple paper order set. Once it was in place, it was essential to do semiannual reviews to see what was not working. They were finding too many VTEs among their morbidly obese patients who were on prophylaxis. As a response, published literature recommending increased doses of enoxaparin during bariatric surgery was reviewed, resulting in the hospital's adopting a policy of administering enoxaparin 40mg SC q12h for patients with morbid obesity (body mass index >40). The hospital now requires physicians to fill out the order set within 24 hours of patient admission.

Marta Render, MD, Inpatient Evaluation Center, Veterans Health Affairs (VA), emphasized hospital leadership and bundling multiple strategies because any one strategy in isolation likely won't work. She asked for the simplification of VTE prevention clinical guidelines. Minor differences among the published guidelines are problematic for hospitals.

Arun Mohan, MD, MBA, Emory University School of Medicine & Emory Healthcare who works with Dr. Jason Stein, said that a simple order set and “measure-vention” make up a bundled approach. Using “measure-vention”, they have found that a key variable explaining differences in performance across hospital units has been teamwork; structured team care on each ward is crucial to maintaining VTE prophylaxis at the highest level.

Scott Flanders, MD, University of Michigan and Blue Cross Blue Shield of Michigan, felt that participation in regional or national learning collaboratives is crucial. Learning from other hospitals' successes and failures is important.

Consuelo Dungca, RN, EdD, New York City Health and Hospitals Corporation (NYCHHC), said that her organization is comprised of 11 acute care hospitals. Her organization started several years ago with a small VTE task force with physician champions. One of the lessons learned at NYCHHC was that risk assessment is needed. A couple of hospitals decided to skip it and put everyone on prophylaxis on the same dose, but they still had many VTEs among patients who had prophylaxis. The Corporation now requires all hospitals to do risk

assessments first. They also do patient education, including a 15-minute informational video that is shown to all new inpatients.

Jeff Brady, MD, Center for Quality Improvement and Patient Safety, AHRQ, concluded this discussion by adding that while simplicity is an important goal for quality improvement for all hospitals, more detail and complexity may be needed for circumstances in which in health care quality research is occurring. He observed that everything physicians and other health care providers are asked to do takes time that has a cost. For routine practice, if too much information is required for quality improvement initiatives, the end result may be that nothing will happen.

2. What are the core interventions that hospitals should implement to improve appropriate VTE prophylaxis among hospitalized patients?

Gregory Piazza recommended engaging providers in doing risk assessments, while Julie Atay stated that education is needed at all levels.

Arun Mohan was of the opinion that patient advocacy and high-level mandates for known effective hospital interventions are needed.

Alpesh Amin agreed on the need for mandates, stating that “We can’t let everyone do what they want.” He also felt that there is a need to recognize that prophylaxis is not a one-time decision. Patients need to be evaluated continually. The Surgical Care Improvement Project (SCIP) indicators address prophylaxis only within 24 hours of admission, but do not track whether patients continue to receive prophylaxis postoperatively.

Geno Merli, noting that hospitals are required to report all hospital-associated infections (HAIs) to CDC, asked why they are not required also to report HA-VTE?

Gary Raskob commented that this discussion was supposed to focus on hospital-level practices with policy to be discussed later during the meeting.

MaryAnne Cronin said that someone is needed within each institution to lead and that it doesn’t have to be a physician, it could be, for example, a pharmacist. She further stated that standardization of practice is absolutely essential for success.

Roopen Arya questioned whether U.S. hospitals are mandated to report VTEs. Someone responded that that would require legislative action at the state level. [Editorial Comment: Regulatory agencies can also mandate reporting.]

3. What would need to be in place or what would need to occur for those recommendations to be implemented?

Keith Hoots, MD, director of the Division of Blood Diseases and Resources at the National Heart, Lung, and Blood Institute, noted that handwashing campaigns work well during epidemics but are harder to sustain afterwards because people forget the ongoing need to educate about it.

Stephan Moll stated that a big hurdle in the United States is identifying who is going to pay for all of the staff time required for effective VTE prevention, including informing patients and extracting charts.

Lisa Moores, MD, The American College of Chest Physicians (ACCP), indicated that she felt that it is very difficult to share tools or data across hospitals. She also stated that common data standards and infrastructure, including for EHRs, are needed.

Stuart Haines stated that incentives and disincentives—and not just financial ones—are needed and that these incentives must be aligned across multiple levels.

Richard White, MD, University of California, Davis, seconded the notion that pressure needs to be put on hospital management from the state level and that public mandates are needed.

Robert Pendleton, MD, University of Utah Healthcare, agreed with Greg Maynard and emphasized the point that a dedicated VTE committee is needed within each hospital. A general hospital QI task force or even an anticoagulation committee might have too many different interests to focus on VTE prevention and be as effective.

Julie Atay suggested the need for a catchy phrase or abbreviation, which has worked well with other patient safety or quality initiatives.

Vicky Agramonte stated that hospitals around the country have said that they want and need standard tools or tool kits on how to carry out VTE prevention.

Greg Maynard noted that attempts to use The Joint Commission (TJC) and other VTE measures have not been very effective because they are not sufficiently specific. Hospitals can check off prophylaxis as having been done without indicating either the type or level of prophylaxis. More detailed measures need to be reported. Greg Maynard felt that the Canadian accreditation model described by Bill Geerts is more promising.

Greg Maynard said that at the health system level, there is a need for EHRs that include standard VTE measures in order sets as a default. He said that many vendors are making this difficult by charging hospitals to customize their EHR to include VTE.

Stephan Moll said that the pharmaceutical industry has done a lot to raise awareness about VTE burden and risk, but that a pharmaceutical company has credibility problems. There needs to be an independent agency to come up with objective numbers of the burden of VTE. He said that many physicians think that efforts to promote VTE prevention are being driven by the pharmaceutical industry to sell more drugs.

David Garcia, MD, University of New Mexico Cancer Center and the American Society of Hematology, agreed with Stephan Moll. He stated that what is needed are independent analyses of VTE burden and the effectiveness of different VTE prophylaxis strategies (including both pharmacologic and mechanical) to be carried out by groups that do not rely on industry funding and, therefore, have credibility. Physicians are using the perception that prophylaxis is being promoted by manufacturers as an excuse to not use it.

Marta Render said that CDC recommendations are very influential.

Peter Kaboli stated that health providers want to do a good job. However, they need to be shown data to convince them that HA-VTE is a serious problem that is preventable. A good job has been done in raising awareness of HAIs, but not for HA-VTE. State-level guidance is needed so that hospitals all will measure the same thing.

Barry Aaronson MD, FACP, SFHM, Virginia Mason Medical Center in Seattle, felt that there is a need for standards with federal support. However, there was concern that the standards be appropriate. He said that the “Meaningful Use” standards for EHRs set by the Office of the National Coordinator for Health Information Technology include a VTE indicator, although he said he didn’t know where that indicator came from. Also, in his opinion, the VTE indicator is not clinically well informed. Greg Maynard agreed.

Alan Brownstein said that what is needed is for each health care institution to have a champion for HA-VTE prevention, preferably a hospitalist, pharmacist, or nurse practitioner. Champions should be recruited for each hospital. He also suggested that CDC could provide funding to states to develop DVT prevention plans.

Cynthia Reilly noted that health care providers need to be more proactive on information technology (IT) because the EHR software that is available commercially isn't adequate for monitoring VTE prevention. Clinicians don't like what is being offered by IT firms, but they haven't done anything about it. She called on CDC to work with the National Committee for Information Technology Standards to induce IT firms to provide better VTE information in EHR software.

Lynn Oertel said that when The Joint Commission in 2008 called for hospitals to have an anticoagulation standard, that call got the attention of hospitals. However, standards must be crafted to fit hospitals of all sizes.

Gregory Piazza stated that cardiac units have to report bad outcomes (specifically, deaths). He asked why there should not also be a mandate that hospitals have to report cases of HA-VTE.

Jeff Brady spoke about patient safety organizations enabled by the Patient Safety and Quality Improvement Act of 2005 (www.ahrq.gov/qual/psoact.htm). This legislation also provides for the promulgation of uniform, standardized formats (Common Formats) for reporting. He said that AHRQ has developed Common Formats for several specific event types, and is in the process of developing a specific event Common Formats for VTE reporting that would soon be issued (https://www.psoppc.org/web/patientsafety/version-1.2_documents). Recognizing that data reporting has a cost, the AHRQ is trying to keep the VTE Common Format as simple as possible and thereby minimize the burden and time that is necessary for users to report patient safety events.

Greg Maynard said that the adoption of EHRs actually can make things worse for VTE prevention. One hospital he knows had developed a very good VTE order set. The leadership for their system of 15 hospitals recently announced that the system was going to adopt a commercial EHR with a standard VTE prophylaxis order set that, in his opinion, is dysfunctional and won't work nearly as well as the existing order set the particular hospital was using.

Barry Aaronson further noted that EHR vendors in the United States say that they can't provide support to hospitals to make changes to allow for useful VTE prophylaxis indicators, but in the United Kingdom they apparently are willing to do so in order to make the sale. Roopen Arya said that in the United Kingdom people also have to find local solutions.

Geno Merli mentioned that almost all university hospitals across the United States submit data to UHC (formerly the University Hospital Consortium), including data on VTE, but he doesn't think anything is being done with the information. He thinks CDC could have a huge impact if it were to require reporting by hospitals of deaths from PE. When hospitals were required to report deaths from central line infections, it got the attention of hospital CEOs because it became a performance measure affecting their pay. He would like infection control to be a model for VTE prevention in hospitals.

MaryAnne Cronin said that a mandate is needed for hospitals to implement prevention, including not just the "what" and "why" of prophylaxis, but "how" it needs to be done. However, a mandate alone is not sufficient. Hospitals also need VTE teams with leaders or champions. MaryAnne Cronin also questioned whether a definition of "appropriate prophylaxis" would be forthcoming. The 2008 ACCP guideline and the 2007 American Academy of Orthopaedic Surgeons (AAOS) guideline appear to contradict each other, at least with regard to aspirin use.

Alpesh Amin said that much of what has been talked about in terms of what hospitals should do to prevent VTE would cost millions of dollars to implement, and the cost of such changes would cause delay. He argued that we need to simplify hospital protocols to make VTE prevention affordable.

Marc Moote added that payers such as Blue Cross Blue Shield of Michigan and patients at the state level need to be engaged to advocate for change.

Coleen Boyle accepted the need to keep things simple. She asked for clarification about the apparently conflicting clinical guidelines and what should be done.

Stephan Moll suggested condensing the ACCP guideline from roughly a thousand pages to maybe 20 pages and have CDC and everyone else endorse the simplified guideline.

Marta Render suggested getting the ACCP and orthopedic surgeons together to come up with a single guideline, then come up with a simplified algorithm acceptable to all.

Lisa Moores said that the ACCP is working to condense the guideline that, in the future, will be updated continually rather than being updated only every 3 to 5 years. The evidence review would remain as a resource. The committee preparing the next edition of the ACCP guideline has worked hard with other stakeholders, including orthopedic surgeons, to minimize confusion.

Gary Raskob countered that the multiplicity of guidelines is an issue that really isn't an issue. He added that the vast majority of guidelines agree except for a prominent disagreement between the ACCP and AAOS about anticoagulant prophylaxis that might be hard to resolve. He didn't think there was value in trying to work out the details of the guidelines. He felt, instead, that the focus should be on the 90% of agreement.

Althea Grant added that CDC staff had created a matrix of the published guidelines (that is, published prior to August 2011) and found a great deal of similarity. To this, Gary Raskob replied that it would be useful for CDC to share that information, to publish it. Althea Grant agreed and stated that CDC would publish an updated tabular comparison of VTE prevention guidelines in conjunction with the MMWR Recommendations and Reports on hospital VTE prevention.

Bill Geerts said that at the conclusion of the meeting he would like to see something useful emerge. Specifically, he would like CDC to issue a strong statement about the urgency of hospital VTE prevention that would serve as a national reference.

6. Performance Monitoring

Richard White presented on performance monitoring for hospital VTE prevention, which he noted is not as straightforward as might be assumed, particularly if it is used to make publicly reported comparisons. The simplest way to assess the “quality” of anticoagulant prophylaxis is to measure the process (was thromboprophylaxis given, yes or no?) and the key outcome (did a hospital-associated VTE event occur?). However, the simplest approach is not the best.

He cited two methodological challenges to using the reported occurrence of HA-VTE as a performance measure: (1) “risk adjustment” is needed to determine the underlying severity of illness, and (2) a definition of what constitutes an “HA-VTE event” is needed. Regarding risk-adjustment, he continued that it is one thing to qualitatively assess risk to guide prophylaxis and another thing to quantitatively predict VTE risk. For example, two patients might both be assessed in the same risk bucket, one recently diagnosed with pancreatic cancer and another with mild congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD). However, the patient with the cancer is much more likely to develop VTE than is the CHF patient. Another example is total knee replacement; the risk of VTE after bilateral replacement is significantly higher than for unilateral knee replacement.

The outcome of HA-VTE—which Richard White thinks should be defined as “hospital-associated”, not “hospital-acquired”, VTE—needs to be rigorously defined. Issues that need to be resolved include:

- Must it be “symptomatic” (that is, must it exclude events that are picked up by screening or are unsuspected but found on an imaging study)?

- Must it be in a lower extremity (versus an upper extremity), and in any vein (a soleal or gastrocnemius muscular vein)?
- Can it be associated with use of a catheter?
- Should patients with suspected VTE who cannot be imaged (no documented clot) be counted?

White noted that there is a lot to consider before quality measures are developed for VTE prevention.

First, which process measures are important needs to be determined; for example:

- Does risk assessment need to be done or is it sufficient to check to see if a physician ordered any prophylaxis?
- What type of prophylaxis (including dose, timing, and duration) needs to be used?
- Is mechanical prophylaxis equal to pharmacological?
- Should any contraindication to prophylaxis be documented?

Second, which groups of patients should be monitored?

- All or only those who have no contraindication to pharmacological prophylaxis.
- All those who can receive mechanical prophylaxis.
- Those with or without cancer.

Richard White asserted that existing performance measures have serious limitations. He reviewed two major national sets of indicators. First, SCIP—sponsored by the Centers for Medicare & Medicaid Services (CMS) for the original purpose of reducing postoperative infections—has two process-oriented VTE indicators. SCIP VTE-1 assesses whether VTE prophylaxis is ordered and SCIP VTE-2 measures if VTE prophylaxis was started. These measures look only at processes, not outcomes.

Richard White continued by saying that the AHRQ has developed a set of hospital Patient Safety Indicators (PSIs), one of which—PSI-12—is specific to postoperative HA-VTE. PSI-12 is assessed on the basis of administrative data and ICD-9 codes, with no process measures to indicate whether prophylaxis was prescribed or administered. This kind of outcome measure has its own set of problems because it relies on hospital “coders” who, in turn, must interpret physician records. Using the current software, the PSI-12 for “Post-operative DVT or PE” has low positive predictive value (<40%–50%); however, this should improve very soon once V4.3 is released by the AHRQ, as it will use more specific ICD codes and require cases to have a present on admission (POA) flag of “N” (“not present on admission”) or “U” (“unclear if present on admission”). Without robust risk adjustment, though, and at a minimum stratified by the presence of cancer or not, making comparisons of VTE incidence between hospitals using administrative data still will be problematic. On the other hand, administrative data and software can help hospitals identify cases coded as having HA-VTE for internal quality improvement analyses.

He also mentioned the hospital-acquired conditions (HAC) defined by CMS to refuse payment for “potentially preventable” complications.

Drs. White and Maynard together, prior to the workshop, prepared a document outlining a proposed algorithm for HA-VTE using ICD-9 codes and POA flags or indicators with administrative data included here as Appendix 3.

7. VTE Performance Measurement: The Joint Commission’s Experience

Ann Watt, MBA, The Joint Commission, spoke about TJC’s experience with VTE measures. TJC currently has 10 sets of core measures and, since 2002, hospitals have been required to use some subset of these for hospital

accreditation. All of the TJC core measures also are endorsed by the National Quality Forum (NQF) (www.qualityforum.org). The VTE core measure set was developed, starting with a January 2005 National Consensus Standards for the Prevention and Care of Deep Vein Thrombosis (DVT) project. The VTE core measure set was developed jointly by the NQF and TJC and was sponsored by Sanofi-Aventis. The six VTE measures were endorsed by the NQF in 2008 and became effective in October 2009, but are not mandatory. Only 67 hospitals currently are reporting the VTE measures. Ann Watt noted that the set includes a measure of whether VTE prophylaxis was received by a patient (or a reason was given why prophylaxis was not administered), but the measure does not address the type of prophylaxis or its appropriateness.

Ann Watt also shared quarterly data for the reporting hospitals from late 2009 through late 2010. During that period, there was an increase in reported prophylaxis and a decrease in the quasi-outcome measure of percentage of VTE cases classified as potentially preventable (defined as those cases among patients who received NO prophylaxis prior to the VTE diagnostic test order date).

Ann Watt mentioned the following as possible future steps:

- CMS is considering requiring hospitals to report using the NQF measures by 2013 for reimbursement for Medicare inpatient care as part of the Hospital Inpatient Quality Reporting Program.
- Meaningful Use—integrating VTE core measures in EHRs
- The VTE measure set is undergoing endorsement maintenance review by the NQF. Within the next 6 months there will be an opportunity for public comment.

8. Using CDC's National Healthcare Safety Network (NHSN) To Monitor Hospital Performance

Daniel Pollock, MD, Division of Healthcare Quality Promotion, CDC, provided the following comments. The National Healthcare Safety Network (NHSN) (www.cdc.gov/nhsn) was begun by CDC as a voluntary reporting system for HAIs by health care facilities, chiefly hospitals. The NHSN in its present form as a Web-based reporting system was created in 2005 by merging multiple legacy systems. It has three components: patient safety (primarily HAIs), health worker safety, and hemovigilance (blood safety). Some reporting is now mandatory by states, with 4,500 hospitals reporting; 26 states and the District of Columbia mandate reporting for some infections. Most information is reported by paper, but electronic reporting to NHSN is possible and encouraged. He said that currently about 10% of hospitals participating in NHSN use industry-standard electronic reporting.

Facilitated Discussion of Recommendations for Prevention Monitoring and Reporting

1. How do you monitor rates of appropriate prophylaxis among different patient groups?

2. What are areas of agreement around measuring appropriate prophylaxis?

Greg Maynard stated that the NQF VTE measures of prophylaxis can't be used to monitor VTE prophylaxis because of lack of sufficient detail; they measure only whether prophylaxis was started, not whether it was done appropriately or continued. He suggested not trying to define appropriate prophylaxis as a single measure to use across hospital systems, because doing so is not practical. Instead, he thought it would be better for a monitoring system collecting data from many different hospitals (e.g., the NHSN) to record separately how many patients are on pharmacological anticoagulation prophylaxis and how many are on mechanical prophylaxis. The two are not equivalent, as the UCSD experience demonstrated: UCSD previously had a policy to put almost all patients on mechanical prophylaxis, but they still had high rates of HA-VTE.

Barry Aaronson stated that It is hard to tell who actually is getting anticoagulation prophylaxis if order sets indicate only who was prescribed anticoagulation prophylaxis; his institution has switched to the use of administrative data (pharmacy records) to check on the actual receipt of medications.

Melinda Murphy, RN, MS, NE-BC, National Quality Forum, said that the two SCIP measures endorsed by the NQF recently were reviewed by a panel of experts in surgery care. The first one, about prophylaxis ordering, likely will be discontinued. Of the eight measures proposed in 2005, six were endorsed. All six measures are up for reconsideration now. The NQF would like additional individuals with expertise in VTE to participate in that effort. They would like people to send in comments when the report that includes these measures is sent out for comment in about 6 months. Additionally, the NQF would welcome submission of new VTE measures.

Alpesh Amin noted that when hospitals use the ACCP guideline as the benchmark (including adherence to the specified types, dosages, and durations of anticoagulation prophylaxis), the recorded use of prophylaxis typically declines by more than 50% compared to conventional measures of whether any anticoagulation was prescribed. In his opinion, a quality measure for VTE prevention must assess whether care actually is meeting evidence-based quality criteria.

David Garcia stated that “appropriate” implies that the physician appropriately has taken into account risk factors for adverse events. He stated that he thought that often what is appropriate for an individual patient in terms of anticoagulation prophylaxis versus mechanical prophylaxis is unknown. He would like to see routine monitoring for the occurrence of heparin-induced thrombocytopenia (HIT) and bleeding following use of anticoagulation prophylaxis. Without prospective head-to-head comparisons of mechanical vs. pharmacologic prophylaxis (in which the important benefits AND risks of both strategies are measured), it is difficult to be certain about what is the “appropriate VTE prophylaxis strategy” for a given patient.

Richard White added that anything that can be derived from EHRs is doable, whereas anything that requires paper chart review is likely to be deemed unfeasible and too laborious for routine use in monitoring performance.

Peter Kaboli voiced disagreement with some of these other comments and said that agreement on appropriate prophylaxis was not achievable and should not be attempted.

Alpesh Amin further argued that the SCIP criteria are useless. He said that any patient who is in the hospital 7 days and gets only one dose during the first 24 hours is counted as having received prophylaxis. To prevent VTE among at-risk patients, they need to receive recommended care.

Marc Moote felt that mechanical prophylaxis should be considered only as an adjunct, not as primary prophylaxis.

3. How are rates of hospital-acquired VTE monitored among different patient groups?

4. What are the areas of agreement around monitoring hospital-acquired VTE?

Greg Maynard began by stating that although administrative data are inferior to charts, they might be the only practical source for use in performance monitoring at the national level. He and Richard White have drafted an algorithm using a combination of ICD and POA codes. This algorithm is appended at the end of this report as Appendix 3.

Richard White noted that risk adjustment is needed if administrative data on the occurrence of HA-VTE are going to be used to assess performance across hospitals as a measure of hospital quality. For example, a hospital with a larger percentage of cancer patients is going to look like it has a higher rate of HA-VTE when it might not. Greg Maynard added that they also had discussed the need to adjust for hospital screening practices. If hospitals screen trauma patients for PEs, they will find many more VTEs.

Joel Handler, MD, Kaiser Permanente, stated that in his system most VTE cases (DVTs and some low-risk PE patients) are treated on an outpatient basis. Consequently, it is difficult to use hospital readmissions with a

diagnosis of VTE as an indicator of the occurrence of HA-VTE because most such events would not be recorded.

MaryAnne Cronin noted that patients might be receiving warfarin prophylaxis, but if the international normalized ratio (INR) is too low (<2.0) it will have no effective anticoagulation protection. Any patient receiving such a dose should not be recorded as having received prophylaxis. Her hospital employs bridging of warfarin with enoxaparin to ensure adequate thromboprophylaxis until the INR is >2.0 for 2 days.

Geno Merli said that he is very concerned about the use of imaging technologies to screen for VTE in hospitals and thinks that the practice should not be encouraged.

9. Partnership for Patients

Chesley Richards, MD, MPH, Office of the Associate Director for Policy, CDC, spoke about the Partnership for Patients, which is a multiagency initiative led by CMS. It includes CMS funding of \$1 billion, with \$500 million for patient safety and \$500 million for prevention of readmissions. It involves all DHHS agencies. CDC is represented by Chesley Richards. Agencies are looking at how they can help support the goals of the Partnership for Patients with their own resources.

It is projected that reducing targeted hospital-acquired conditions by 40% could save 60,000 lives over 3 years. There are nine specific priorities, one of which is VTE.

Henry Ford Health System's No Harm Campaign led to a substantial reduction in all-cause adverse events.

The first funding for patient safety was awarded by CMS in December 2011. CMS at that time funded a number of organizations to create a total of 26 Hospital Engagement Networks (HENs) which represent more than 2,000 hospitals (<http://www.jcrinc.com/CMS-Hospital-Engagement-Network/>). Technical contractors will support the HENs. The funding is provided by the CMS Innovation Center (Center for Medicare and Medicaid Innovation or CMMI, <http://innovations.cms.gov>). CMMI is also developing a national patient education initiative as part of the Partnership. <http://www.healthcare.gov/compare/partnership-for-patients/index.html>

Facilitated Discussion on Policy, Health Care Systems and Payers

Marc Moote stated that Blue Cross Blue Shield Michigan has been very engaged because they see the cost savings from VTE prevention. Payers in other states have been less engaged.

Peter Kaboli asked about CDC's experience with reporting and preventing HAIs, as well as what CDC believes to have been the most successful approach the agency has been involved in to date.

Dan Pollock, responding to Dr. Kaboli's questions, indicated that the HAI model has worked well. Central line-associated bloodstream infection (CLABSI) is the poster child for how well the HAI model has worked. Dan Pollock continued by stating that CMS began by requiring reporting of CLABSI. Public reporting was then leveraged for prevention. This approach required CDC to work closely with CMS and he thinks this is a good model for quality promotion.

Chesley Richards pointed out that, as of 2002–2003, HAI was perceived by many people as inevitable, guidelines to prevent it generally were ignored, and clinicians thought that only about one-third of HAIs were preventable. What changed was consumer involvement, led by the Consumers Union and other groups. Energized consumer advocacy groups got legislation passed in states over the opposition of doctors and hospitals. This was driven by the anger and anguish of family members who had lost loved ones to HAIs. Chesley Richards said that he doesn't hear any of that anguish about VTE.

Gary Raskob advocated for the creation of a coalition to lobby Congress for resources for patient safety and VTE prevention.

Alan Brownstein said that, in future years, August 19, 2011, would be looked back on as the beginning of something important. NBCA this year released a consumer survey which found that only 16%–22% of people knew the terms DVT or PE, but 82% knew what a blood clot is (<http://www.stoptheclot.org/News/article282.htm>). That is why his organization changed its name from the National Alliance for Thrombosis and Thrombophilia to the National Blood Clot Alliance. He said that we need to get the message across about stopping clots. He urged a revitalization of the U.S. Surgeon General's Call to Action and a reengagement with the Surgeon General's office.

Closing remarks

Scott Grosse summarized key points from the day's presentations and discussion.

- VTEs are a major public health problem, an important cause of deaths and disability.
- A large percentage of VTEs are associated with hospitals or long-term care facilities.
- A large percentage of hospital-associated VTEs are preventable through appropriate prophylaxis.

He also elucidated some of the challenges

- There is a lack of reliable data on the numbers of people affected by VTEs. Population surveillance data—not just hospital discharge information—are needed. The majority of VTEs occur outside hospitals.
- The burden of VTE is underappreciated greatly because it is a silent killer and most deaths from PE can be diagnosed only by autopsy, and few autopsies are done. Only 28,000 deaths in 2009 listed PE on death certificates.
- There are no estimates of the numbers of quality-adjusted life years or life years lost from VTEs. Most people with fatal PEs are older and have other illnesses (such as cancer) that reduce life expectancy.

Challenges for VTE prophylaxis include a lack of consensus about risk assessment, prophylaxis protocols, and performance measures. We need to reach agreement on how to standardize these.

CDC is working on a VTE module for the NHSN, and its development will require input from subject matter experts. Development of this module is an opportunity to standardize performance measures. In addition, widespread use of the VTE module in the NHSN by hospitals might depend on states mandating its use, similar to how HAI reporting is now mandated in many states.

The Partnership for Patients is an exciting opportunity, but it remains to be seen how VTE measures will be defined and monitored.

Scott Grosse and Coleen Boyle concluded with a discussion of the meeting report. CDC publishes a MMWR Recommendations and Reports series, which typically takes 12 months from the time a meeting is held, which is one option. Hani Atrash noted that this meeting is only the beginning.

Appendix 1: Meeting Agenda

Meeting Purpose: To develop recommendations to improve appropriate VTE prophylaxis in hospitalized patients.

TIME	TOPIC	OBJECTIVES
9:00 – 9:40	<p>Opening Session</p> <p>Welcome and Purpose of Meeting, Althea Grant, PhD; Coleen Boyle, PhD; Hani Atrash, MD, MPH, CDC/NCBDDD</p> <p>Overview of Agenda and Introductions, Diane Schlachter, EdD, Facilitator</p>	<p><i>To set the stage for a productive session</i></p>
9:40 – 10:00	<p>Hospital-Acquired Venous Thromboembolism</p> <p>Presentation by Gary Raskob, PhD, University of Oklahoma Health Sciences Center, College of Public Health</p> <p>Questions for clarification</p>	<p><i>To frame the problem of HA-VTE in a public health perspective and describe the opportunities for prevention and cost savings</i></p>
10:00 – 10:20	<p>VTE Prophylaxis in Hospitalized Patients</p> <p>Presentation by Bill Geerts, MD, FRCPC, University of Toronto</p> <p>Questions for clarification</p>	<p><i>To describe the current status of VTE prophylaxis in hospitalized patients, including strategies, barriers, challenges, facilitators, and lessons learned</i></p>
10:35 – 11:45	<p>Experiences Improving the Use of Appropriate VTE Prophylaxis</p> <p>The AHRQ/SHM approach, presentation by Greg Maynard, MD, SHM /UC San Diego</p> <p>The National VTE Prevention Programme in the UK, presentation by Roopen Arya, MD, PhD, King's Thrombosis Centre, UK</p>	<p><i>To provide a brief overview of the AHRQ/SHM approach and lessons learned</i></p> <p><i>To provide a brief overview of the National VTE prevention program in the UK and lessons learned</i></p>
12:45 – 2:30	<p>Hospital Systems-level Interventions</p> <p>Rapporteur comments by Gregory Piazza, MD, MS, Brigham and Women's Hospital</p>	<p><i>To summarize key points from the morning presentations about improving the use of appropriate VTE prophylaxis and present reflections and comments</i></p>
1:00	Facilitated Discussion	<p><i>To discuss recommendations for systems-level interventions that most effectively improve appropriate VTE prophylaxis in hospitalized patients</i></p>

TIME	TOPIC	OBJECTIVES
2:45 - 4:00	<p>Performance Monitoring</p> <p>Performance Monitoring, presentation by Richard White, MD, UC Davis</p> <p>Joint Commission Performance Measures Data, presentation by Ann Watt, MBA</p> <p>The National Healthcare Safety Network, presentation by Daniel Pollock, MD, CDC/OID/NCEZID</p>	<p><i>To provide a brief overview of performance monitoring methods for appropriate VTE prophylaxis and HA-VTE</i></p> <p><i>To present the data on The Joint Commission VTE prophylaxis and HA-VTE performance measures including challenges and limitations</i></p> <p><i>To highlight a system for collecting data to monitor hospital performance</i></p>
3:20	Facilitated Discussion	<i>To discuss recommendations for performance monitoring and reporting</i>
4:00 – 4:40	<p>Roles of Public Policy, Healthcare Systems, and Payers</p> <p>Partnership for Patients, presentation by Chesley Richards, MD, MPH, CDC/OD/OADP</p>	<i>To describe the current federal efforts to engage partners in improving VTE prophylaxis at the population level</i>
4:15	Facilitated Discussion	<i>To discuss recommendations for leveraging public policy, payers, and health care systems to improve the prevention of HA-VTE</i>
4:40 - 5:00	<p>Wrap-up and Closing Remarks</p> <p>Led by Scott Grosse, PhD, CDC /NCBDDD</p>	<i>To conclude the meeting with wrap-up of day's work and next steps</i>

Appendix 2: Participants

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Appendix 3

Tracking Outcomes – Hospital Acquired/Associated VTE

Richard H White (UC Davis) and Greg Maynard (UC San Diego)

Administrative data are imperfect for tracking outcomes, but coding changes in October 2009 improved administrative coding, and this is the most practical method of tracking the outcomes of VTE related to hospitalization.

After some discussion, we favor the use of the term Hospital Associated VTE, vs the term Hospital Acquired VTE. This semantic nuance can be argued, but Hospital Associated VTE seems to be a more general term acknowledging that VTE are often due to underlying illnesses rather than specific events that occur during hospital stay.

Hospital Associated VTE criteria: the event should not have been symptomatic or likely present at the time of admission. Hence the event should be coded with the “Present on Admission” (POA) indicator = N. Unknown (U) codes are also to be considered Hospital Associated. See also discussion below re: Patients being re-admitted for new diagnosis of VTE.

415.11 iatrogenic PE and infarction

415.19 other PE and infarction

451.11 Phlebitis and thrombophlebitis of deep vessels of lower ext Femoral Vein (Deep) (Superficial)

451.19 Phlebitis and thrombophlebitis of deep vessels of lower extremities; other, Femoropopliteal vein, Popliteal vein, Tibial vein

451.81 Phlebitis and thrombophlebitis of other sites= Iliac Vein

453.40 Acute venous embolism and thrombosis of unspecified deep vessels of lower extremity

453.41 Acute venous embolism and thrombosis of deep vessels of proximal lower extremity

453.42 Acute venous embolism and thrombosis of deep vessels of distal lower extremity

453.89 Acute venous embolism and thrombosis of other specified veins (most nonspecific code)

Denominator = Adult inpatient discharges for specified time frame (or patient days)

Numerator = Include all cases with specified Lower VTE or PE codes with POA = N, U

Point of discussion: Many VTE become clinically apparent in the time period after hospital discharge. These VTE may also be considered hospital associated, although some of the VTE may be more related to underlying risk factors that continue post discharge, and may or may not have been present in subclinical form prior to discharge. The VTE risk slowly returns to baseline risk post discharge. We would at least consider including in the numerator, all cases discharged from the index hospital and that are readmitted to a hospital within 30 days with a new acute LE VTE or PE (usually principal diagnosis, coded with POA = Y, W) or who are seen in an Emergency Department < 30 days after discharge from the index hospital and have a new principal diagnosis of LE DVT (98% of PEs will be admitted and not be entered in that hospital's ED data base). Cases transferred directly to a rehabilitation hospital and who are coded as having an acute DVT or PE that is not present on admission (POA=N, U) < 30 days after the index hospital stay should also be classified as having a hospital

associated VTE event. If the VTE event is coded as POA=Y at the time of the contiguous rehabilitation or other acute care hospitalization, interpretation becomes difficult. These VTE events may have been not coded during the index admission, or picked up by a screening US at the time of the rehabilitation/hospital stay. We would tend to count these cases as hospital-associated VTE events but there may be some who disagree. Hospitals are likely to find only those cases that are readmitted to their own hospital with VTE < 30 days, but if more comprehensive “linked” data is available from a state data base or Medicare data base, these admissions should also count as reflecting a hospital associated VTE event. The 30 days time period is a reasonable, albeit arbitrary cut-off, but two weeks sounds too short and 60 days too long.. If someone is readmitted to a hospital for a different reason do not develop VTE, they should be censored and not counted even if they subsequently are diagnosed with VTE that is still within 30 days of the index admission Also, this definition is institution-centric rather than a public health approach, but we think hospitals don’t want to take responsibility for VTE events that may have been associated with another hospital stay.

We advocate Tracking UE DVT separately in the same fashion.

Upper Extremity DVT = 453.82 453.83 453.84 453.85 453.86 453.87 and could use 451.83 (thrombophlebitis of deep veins of the UE)

UE DVTs are significant sources of morbidity, and should be tracked as well. However, given that upper extremity events are predominately catheter related, and given that the evidence for efficacy of chemical prophylaxis is unconvincing for UE DVT, we would track these separately.

When feasible to do so, we recommend validation of coding with manual chart review on a sampling of patients, and excluding cases diagnosed by screening US.

Potentially Preventable Hospital Associated VTE: Situations in which recommended thromboprophylaxis was not in place prior to VTE diagnosis.

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