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Changing practice: implementation of a venous thromboembolism prophylaxis protocol at an academic medical center

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Abstract

Background—The Institute of Medicine has identified a “quality chasm” between existing evidence and actual clinical practice. The Venous Thromboembolism Prevention Study (VTEPS) has shown that enoxaparin prophylaxis is a safe and effective way to prevent post-operative venous thromboembolism (VTE). Here, we present a “how-to” guide for implementation of a VTE prophylaxis protocol.

Methods—The VTEPS prophylaxis protocol included provision of post-operative, prophylactic dose enoxaparin for the duration of inpatient stay. “Compliance” was considered at the individual patient level, and was defined as appropriate provision of protocol-appropriate enoxaparin prophylaxis.

Multiple simultaneous interventions to improve protocol compliance were undertaken. Both physician and physician assistant “champions” were identified. Interventions included staff and surgeon educational sessions, discussion of VTE-themed articles at journal club, and monthly email reminders specific to the protocol, among others. Compliance rates over time were compared using the chi-squared test.

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Results—We reviewed medical records from 945 consecutive admissions to the plastic surgery service who met VTEPS eligibility criteria over a 30-month period. Initial education sessions significantly increased compliance over baseline (55% vs. 10%, $p<0.001$). After formal protocol adoption, compliance increased steadily over the first nine months and peaked by one year. In the absence of any direct intervention, compliance remained stable at 90% for the final 12 months of the study. This was significantly increased when compared to the period of time immediately following protocol adoption (90% vs. 77%, $p<0.001$).

Conclusions—This manuscript provides readers with a practical approach for implementation of a VTE prophylaxis protocol at their hospital.

Keywords

system and process improvement; quality improvement system; evidence based medicine; implementation; champion; clinical protocol; venous thromboembolism; deep venous thrombosis; pulmonary embolus; plastic surgery

BACKGROUND

In 2001, the Institute of Medicine released its landmark publication entitled “Crossing the quality chasm: a new healthcare system for the 21st century”. In a bleak assessment of our current system, the report concluded that “between the health care that we now have and the health care that we could have lies not just a gap, but a chasm...the nation’s health care delivery system has fallen far short in its ability to translate knowledge into practice”. The IOM report specifically noted that it takes, on average, 17 years for randomized-controlled trial (RCT) data to be disseminated into general practice ¹.

Implementation represents a major barrier for physicians who attempt to cross this quality chasm. Evidence-based medicine (EBM) has become a priority in organized plastic surgery. EBM is feasible in day-to-day practice and the quality of evidence in major plastic surgery journals has improved slightly over time ²⁻⁴. Leaders of our specialty recently held an EBM summit to identify “next steps” to promote data-driven practice ⁵. National organizations often develop and release clinical practice guidelines. However, few manuscripts or organizations instruct end-users on how to implement their recommendations ⁶.

The existing clinical implementation literature focuses on time-sensitive interventions, such as acute management of sepsis with early fluid management, central venous access, and intravenous antibiotics ^{7, 8}, decreasing door-to-balloon time in ST-elevation myocardial infarction ⁹, and rapid initiation of therapeutic hypothermia for out-of-hospital ventricular fibrillation arrest ¹⁰. The goal of these interventions is to improve outcomes in patients with life-threatening medical conditions; left unchecked, these afflictions would result in significant morbidity or mortality ¹¹. Protocol-driven interventions have been shown to decrease time to critical maneuvers being performed and improve patient survival.

Venous thromboembolism (VTE) has been identified as a major patient safety issue by policymakers and third-party payers ¹²⁻¹⁴. Ten percent of patients with symptomatic pulmonary embolus (PE) will be dead within 60 minutes; survivors can be plagued by right ventricular dysfunction or failure ¹⁵. Patients with deep venous thrombosis (DVT) can develop the post-thrombotic syndrome, known to be associated with worsened quality of life ¹⁶. Hospitalized patients often receive inadequate VTE prophylaxis ¹⁷⁻²¹. Plastic surgeons under-utilize chemoprophylaxis in high risk patients and may fail to recognize or modify major VTE risk factors ²²⁻²⁶.

In 2008, VTE risk stratification and prevention was identified by the Plastic Surgery Foundation (PSF) Research Oversight Committee as the top patient safety research priority in our specialty. VTE has remained among the top 10 research priorities every year since that time (Keith Hume, ASPS Vice President of Research and Development, personal communication, December 2010). In 2008, the PSF funded the Venous Thromboembolism Prevention Study (VTEPS), which was conducted over a 30-month period at four tertiary care facilities. VTEPS demonstrated that post-operative, inpatient enoxaparin reduces 60-day rates of symptomatic VTE without changing rates of re-operative hematoma ²⁷⁻²⁹. Based on data from VTEPS and the plastic surgery literature, the PSF's Committee on VTE released its prophylaxis guidelines to ASPS members. However, provision of guidelines alone is insufficient to affect practice.

VTE prophylaxis has been shown to be effective and safe, placing plastic surgeons on the "evidence" side of the IOM's quality chasm. This report seeks to provide plastic surgeons with the support and knowledge necessary to cross the quality chasm between evidence and clinical practice. To aid this crossing, we present a "how-to" guide for the actual implementation of a VTE prophylaxis protocol based on a single academic center's experience. This implementation project was conducted in parallel with the larger VTEPS effort.

METHODS

Approval was obtained from the University of Michigan Institutional Review Board prior to performing this study.

VTEPS study methodology has previously been described in detail ²⁷ and its primary results are being presented separately ^{28,29}. VTEPS was a multicenter study conducted at the University of Michigan, the University of Texas-Southwestern, Regions Hospital in Minneapolis-St. Paul, and the University of Pittsburgh. The study was funded by the PSF in early 2008. Data acquisition concluded in December 2010.

The VTEPS protocol was developed as a collaborative effort between the VTEPS sites. The study's inclusion criteria were age ≥ 18 , surgery under general anesthesia, and post-operative hospital admission to the plastic surgery service. Additionally, patient's baseline VTE risk was moderate to high, as indicated by a Caprini score of ≥ 3 ³⁰. Eligible patients received VTE prophylaxis using post-operative, prophylactic-dose enoxaparin. Enoxaparin was initiated between 6 and 8 hours after surgery and was provided for the duration of the patient's inpatient stay.

Creation of protocol

VTEPS co-investigators collectively developed the study protocol, based on their review of the best available evidence from plastic surgery and other surgical specialties. However, protocol implementation at each site was the responsibility of the site principal and co-investigators. The individual interventions discussed below are shown in timeline format in Figure 1.

Identification of "Champions" and key stakeholders

The "Champion" concept is well described in the implementation literature ^{31, 32}. The project champion is an individual or individuals who has commitment to the project, has adequate time and energy to devote to the innovation, and, most importantly, serves as a vocal and visible advocate regarding change ³². Previous work has demonstrated that projects that have both a physician and non-physician champion ³¹ can be particularly effective. At our site, VTEPS was championed by three individuals, including two

physicians and one physician assistant (PA). The physician champions were charged with identifying and educating key stakeholders. This was performed using a “top-down” approach. “Buy-in” was obtained from the Section head. Educational sessions were then conducted with all staff surgeons. “Buy-in” was initially obtained from 10 of 11 staff surgeons at our institution. Subsequently, a separate educational session was held for the plastic surgery residents, who are the primary order-writers for post-operative patients (Figure 1, yellow arrows). Ongoing education was provided by the physician champions to staff, residents, and plastic surgery PA’s using monthly emails and journal clubs (see below).

The PA champion undertook three major interventions to promote VTE prophylaxis per the protocol. First, the PA champion educated other PA’s who staff the pre-operative history and physical clinic on the change in plastic surgery protocols. The clinic PA’s subsequently performed a pre-operative Caprini risk stratification and dictated the Caprini score and protocol-appropriate prophylaxis into their documentation for all patients³⁰. Second, the PA champion performed individual-level education with primary order-writers who had not previously rotated on plastic surgery. Specifically, this included off-service residents (from general surgery, otolaryngology, and orthopaedic surgery), as well as integrated plastic surgery residents in their first year of training. Finally, the PA champion performed daily review of orders for patients newly admitted to the plastic surgery service. Inappropriate prophylaxis was changed to meet protocols and direct feedback was provided to the primary order writer.

Additional interventions

Our Section holds a monthly journal club for staff and resident surgeons. In the six months surrounding the protocol’s activation date, multiple articles on VTE were presented at this venue (Figure 1, green arrows). These presentations were also used as opportunities to discuss the upcoming, Section-wide change in our VTE prophylaxis policy.

Between February 2009 and December 2009, all resident surgeons and PA’s received a monthly reminder email that contained a summary of the new VTE prophylaxis protocol and a review article on the Caprini Risk Model³⁰ (Figure 1, blue arrows). These emails were discontinued after December 2009 to examine whether the change in prophylaxis pattern would be stable over time without direct intervention (Figure 1, orange arrows).

Efforts to implement a VTE prophylaxis protocol within the Section of Plastic Surgery did not occur in isolation. At approximately the same time, our hospital’s administration and VTE prevention committee undertook several hospital-wide measures; these interventions were completely independent of our Section’s effort. Our institution had previously launched a fully integrated online order entry system. In June 2009, our hospital mandated that a Caprini risk score be calculated for all patients prior to order entry (Figure 1, purple arrows). The ability to enter orders online was blocked until Caprini risk score was entered. Prophylaxis was not mandated based on risk score. Physicians remained free to choose mechanical prophylaxis and/or chemoprophylaxis. Although the hospital-wide efforts were not a part of our Section’s plan for protocol implementation, they are mentioned here for completeness.

Ongoing feedback

VTEPS required 60 days of post-operative follow-up, and data acquisition was performed retrospectively. Thus, we were unable to provide real-time feedback on global protocol compliance. However, when individual order errors were recognized, feedback was provided in real time by the PA champion to primary order writers, as discussed above.

Outcomes

The primary outcome of this study was patient-level compliance with the VTEPS enoxaparin protocol. “Compliance” was defined as 1) no provision of pre- or intra-operative enoxaparin, 2) initiation of enoxaparin 6 to 8 hours after surgery, 3) daily administration of prophylactic-dose enoxaparin until hospital discharge and 4) no provision of post-discharge enoxaparin. Patients who received appropriate, though non-protocol, chemoprophylaxis regimens (such as subcutaneous, unfractionated heparin three times per day)^{30, 33}, were coded as “not compliant”. Similarly, patients who received mixed chemoprophylaxis regimens (unfractionated heparin which was switched to enoxaparin during hospitalization or vice-versa) were coded as “not compliant”. Compliance was not tracked for the one staff surgeon who initially declined to adopt the VTEPS prophylaxis protocol.

Data collection and analysis

Our institution’s operative schedule was used to identify all plastic surgery patients who met VTEPS inclusion criteria for the 30-month period between July 1, 2008 and December 31, 2010. For eligible patients, three separate records were analyzed, including 1) pre/intra-operative anesthesia medication administration record, 2) inpatient pharmacy record and 3) discharge summary, which included a complete list of prescribed discharge medications. Record review allowed provision of enoxaparin to be classified into “compliant” or “not compliant” as above.

Statistical analysis

Analyses were performed using the Stata11 statistical package (StataCorp LP, College Station Texas). Comparisons of protocol compliance between periods and between quarters were performed using the chi-squared test. Significance was considered as $p \leq 0.05$.

RESULTS

Between July 1, 2008 and December 31, 2010, 945 patients who met VTEPS inclusion criteria were admitted to the plastic surgery service. Period 1 was examined as a baseline and was defined as prior to discussion of the new prophylaxis protocol. Period 2 was defined as the period of time when educational sessions were conducted prior to formal protocol implementation. Period 3 was defined as the period of time after protocol adoption when monthly email reminders were sent to primary order writers. Period 4 was defined as the period of time after protocol adoption when monthly email reminders were discontinued (Figure 1).

Educational sessions conducted prior to formal protocol adoption increased provision of post-operative enoxaparin over baseline (55% vs. 10%, $p < 0.001$) (Table 1). After formal protocol adoption, compliance increased steadily over the first nine months. The monthly email reminder was discontinued after nine months, corresponding with the junction between periods three and four. When compared to period three, compliance was significantly increased in period four despite the monthly email reminder being discontinued (90% vs. 77%, $p < 0.001$).

Average compliance in the final 12 months was 90% with no significant differences noted between quarters. Of note, the PA champion was out of town for six weeks of Q3 2010, which may account for the non-significant decrease in compliance to 86%. Global compliance increased to 91% upon the PA’s return in Q4 2010 (Figure 1).

DISCUSSION

Our data demonstrate that implementation of a VTE prophylaxis protocol is feasible at an academic medical center through a multi-faceted approach. The majority of our interventions were inexpensive and required minimal resources. We were able to achieve global compliance of 90% within nine months of formal protocol adoption. The protocol became fully integrated into local culture within nine months. This was demonstrated by stable compliance with the protocol during Period 4, in the absence of additional educational sessions or email reminders. Our global compliance rate of 90% in Period 4 was similar to protocol compliance rates recently published by Murphy and colleagues (87-95%) for perioperative antibiotics in abdominoplasty and panniculectomy patients³⁴.

Historic perspectives on VTE prophylaxis in plastic surgery

Prior to VTEPS, survey research identified plastic surgeon's attitudes and practice patterns for VTE prophylaxis. A post-operative death from PE has been reported by 7% of surgeons who perform post-bariatric body contouring, 4% of surgeons who perform autogenous tissue breast reconstruction, and 3% of surgeons who perform combined abdominoplasty and liposuction. In addition, 34%, 25%, and 13% of surgeons, respectively, have personally diagnosed one of their patients with PE after surgery. Despite this, 75% of reconstructive breast surgeons and at least 40% of surgeons who perform post-bariatric body contouring do not use post-operative chemoprophylaxis. Additionally, 60-70% of surgeons who perform combined cosmetic procedures do not use any form of VTE prophylaxis²²⁻²⁶. Among surgeons who do not provide chemoprophylaxis, the majority cite risk of re-operative hematoma and lack of evidence specific to plastic surgery patients as reasons²³.

Since 2008, the plastic surgery literature has been inundated with VTE-themed papers. These have included publications which address VTE after post-bariatric body contouring^{23, 35, 36}, breast reconstruction^{22, 37-40}, head and neck cancer reconstruction^{41, 42}, maxillofacial surgery⁴³, and the general plastic surgery population^{26, 44-51}. Additionally, the VTEPS study was designed to address surgeon-reported concerns with chemoprophylaxis—specifically, whether post-operative enoxaparin can prevent VTE in plastic surgery patients and whether enoxaparin changes the risk of re-operative hematoma. Future survey work could examine the attitudes and practice patterns of surgeons toward VTE risk stratification and prophylaxis, in light of significant recent advances in the field.

Why accept the proposed change—comparison of plastic surgery with a classic case study

The sociologist's diffusion model examines how and why innovations are accepted by the population. This model was first described in a classic 1943 article by Ryan and Gross on dissemination of hybrid corn in two Iowa farming communities⁵².

When compared to available corn strains, hybrid corn was more tolerant of drought conditions and produced consistently higher crop yields. Hybrid corn was a rapidly adopted novelty. Within ten years of hybrid corn's first introduction, 75% of the corn grown in Iowa was hybrid corn. For comparison, the IOM's 2001 "Quality Chasm" document stated that, on average, 17 years are required for a RCT's results to be implemented by the general practitioner¹. Total adoption of a practice over time has been shown to produce an "S-shaped", or logistic, curve⁵³⁻⁵⁵. Ryan and Gross' article discussed the key components of why innovations will be adopted, many of which are as relevant to VTE prophylaxis as they were to hybrid corn. Specifically:

1. *The outcome is improved (and has been shown by your peers)*—“[Hybrid corn’s] advantages were visible not only in account books; they showed up tangibly to every drought-wearied farmer who passed by”. Similarly, data from VTEPS have been presented to a “jury of our peers” at several national plastic surgery meetings. Strict protocols are known to increase prophylaxis compliance and decrease rates of VTE ^{28, 34}.
2. *The outcome is easily obtainable*—“Also of importance was the very ease by which [hybrid corn] could be adopted. Its use required few changes in routine or equipment.” Similarly, enoxaparin is on formulary at most hospitals and recently became available in generic form. Its use in-hospital is covered by most insurance policies. Simple and inexpensive means to promote chemoprophylaxis use (discussion of VTE articles at staff meetings and journal club, monthly emails regarding the new protocol, etc.) are also discussed in this article.
3. *The change in practice is safe, as shown by others*—“The early acceptors provided a community laboratory from which neighbors could gain some vicarious experience with the new seed over a period of some years”, although “visible and time-consuming self-demonstration was [often] required even after visible evidence and objective comparisons were readily available to all”. VTEPS has functioned as sort of a “community laboratory” for plastic surgeons and has shown both the effectiveness and safety of the proposed change in practice ^{28, 29}. By reporting our results, we hope to minimize the “visible and time-consuming self-demonstration” required by others.
4. *Published literature supports the change*—“In Iowa...the Extension Service aided the movement in a number of ways, but notably through the publication of comparative corn yield tests”. Similarly, the VTEPS findings have been presented at national meetings and will be submitted for publication in the plastic and general surgery literature.
5. *Economic incentives are present for adoption*—“The reduction of corn acreage associated with a ‘pegged price’ was certainly favorable to the more productive type of seed” which would, in turn, help to maximize profits. VTE has been identified as a quality of care indicator ^{12-14, 56, 57}. Major payers like CMS are “pegging” prices for surgical procedures and are considering withholding payment for treatment of complications (like VTE) that they consider potentially preventable ^{14, 58}. On average, the initial diagnosis and management of VTE can cost over \$20,000 ⁵⁹. Low-molecular weight heparin prophylaxis has been shown to be cost-effective ⁶⁰.

How can the change occur?

Post-operative enoxaparin for VTE prophylaxis has been proven to be both safe and effective ^{28, 29}. Here, we have provided readers with a practical approach toward implementation of a VTE prophylaxis protocol at their institution. We achieved 90% compliance with our VTE prophylaxis protocol within 9 months of adoption through a multi-faceted approach that included:

1. Creation of dual (physician and non-physician) “champions”
2. Obtaining “buy-in” from Section of Plastic Surgery leadership
3. Initial structured and targeted educational sessions in a “top-down” fashion
4. Ongoing education of primary order writers new to our clinical service
5. Daily review of post-operative orders

6. Provision of directed feedback to primary order-writers in real time
7. Regular email reminders about the new protocol

For a more general perspective on how to disseminate healthcare innovations, we recommend Berwick's 2003 review article ⁵⁴. Cabana and colleagues' review on barriers to physician adoption of clinical practice guidelines is also highly recommended ⁶¹.

CONCLUSION

The VTEPS study has previously demonstrated that post-operative enoxaparin is both effective and safe in reducing post-operative VTE. This manuscript provides readers with a practical approach for implementation of a VTE prophylaxis protocol at their hospital. At our institution, global protocol compliance of 90% was reached within nine months and was subsequently maintained for one year through a multi-faceted approach.

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Figure 1. Patient-level compliance with VTE prophylaxis protocol over time. Arrows indicate interventions which were performed during the study.

Table 1

Comparison of protocol compliance between periods.

	Period 1 (n=100)	Period 2 (n=177)	Period 3 (n=287)
Period 4 (n=381)	90% vs. 10% p<0.001	90% vs. 55% p<0.001	90% vs. 77% p<0.001
Period 3 (n=287)	77% vs. 10% p<0.001	77% vs. 55% p<0.001	
Period 2 (n=177)	55% vs. 10% p<0.001		