

BUILDING A SURGICAL EXPERTISE IN INFORMATICS

Improved Prophylaxis and Decreased Rates of Preventable Harm With the Use of a Mandatory Computerized Clinical Decision Support Tool for Prophylaxis for Venous Thromboembolism in Trauma

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Objective: Venous thromboembolism is associated with substantial morbidity and mortality and is largely preventable. Despite this fact, appropriate prophylaxis is vastly underutilized. To improve compliance with best practice prophylaxis for VTE in hospitalized trauma patients, we implemented a mandatory computerized provider order entry–based clinical decision support tool. The system required completion of checklists of VTE risk factors and contraindications to pharmacologic prophylaxis. With this tool, we were able to determine a patient’s risk stratification level and recommend appropriate prophylaxis. To evaluate the effect of our mandatory computerized provider order entry–based clinical decision support tool on compliance with prophylaxis guidelines for venous thromboembolism (VTE) and VTE outcomes among admitted adult trauma patients.

Design: Retrospective cohort study (from January 2007 through December 2010).

Setting: University-based, state-designated level 1 adult trauma center.

Patients: A total of 1599 hospitalized adult trauma patients with a hospital length of stay greater than 1 day.

Main Outcome Measures: The primary outcome measure was the proportion of patients who were ordered risk-appropriate guideline-suggested VTE prophylaxis. The secondary outcome measure was the proportion of patients with any preventable VTE (defined as VTE in a patient not ordered guideline-appropriate VTE prophylaxis), pulmonary embolism, and/or deep vein thrombosis.

Results: Compliance with guideline-appropriate prophylaxis increased from 66.2% to 84.4% ($P < .001$). The rate of preventable harm from VTE decreased from 1.0% to 0.17% ($P = .04$).

Conclusions: Implementation of a mandatory computerized provider order entry–based clinical decision support tool significantly improved compliance with VTE prophylaxis guidelines in hospitalized adult trauma patients. This improved compliance was associated with a significant decrease in the rate of preventable harm, which was defined as VTE events in patients not ordered appropriate prophylaxis.

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VENOUS THROMBOEMBOLISM (VTE), which includes pulmonary embolism (PE) and deep vein thrombosis (DVT), is one of the most common¹ and deadly complications among trauma patients. Although some VTE events are unavoidable,² data suggest that most events are preventable with proper prophylaxis.^{3,4} Studies,^{5,6} however, have repeatedly shown that most hospitalized patients are not given appropriate DVT prophylaxis. Goldhaber equates the “disconnect between evidence and execution as it relates to DVT

prevention . . . to a public health crisis.”⁷ The Agency for Healthcare Research and Quality suggests that appropriate VTE prophylaxis is the number one patient safety initiative needed to prevent in-hospital death.⁸

See Invited Critique at end of article

Many strategies have been attempted to improve adherence to evidence-based VTE prophylaxis in different patient populations, thereby trying to improve the quality of medical care. A systematic review of

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these strategies showed that passive dissemination and education alone are unlikely to improve VTE prophylaxis. They suggested that a reminder to clinicians to assess the patient for VTE risk and help with their selection of the appropriate prophylaxis would likely be the strategy to achieve the best outcomes.⁹ A preemptive reminder to use VTE prophylaxis in surgical patients did increase adherence rates, but it did not change VTE outcomes.¹⁰ A computerized alert system that warns physicians after prophylaxis has been omitted has shown some benefit; however, this system reacts to, rather than defends against, a potential error.¹¹

Clinical decision support (CDS) tools improve the application of evidence-based medicine to patient care,¹² including within the realm of VTE prevention specifically.^{13,14} However, the Director of the Agency for Healthcare Research and Quality notes that “despite their clear advantages, uptake and motivation to acquire CDS systems remain low.”¹⁵ The widespread application of computerized provider order entry (CPOE) systems is an appropriate platform in which to build a CDS tool that targets VTE prevention. However, these systems must be seamlessly integrated into provider workflow to be successful.^{15,16} Our study evaluates the effect of a CPOE-based mandatory CDS module on physician compliance with evidence-based VTE prophylaxis and on VTE outcomes in an adult trauma patient population. We hypothesized that implementation of the VTE CDS module would increase the proportion of trauma patients receiving evidence-based VTE prophylaxis, would decrease the proportion of VTE events, and would decrease the rate of preventable harm from VTE.

METHODS

STUDY DESIGN AND SETTING

Our study retrospectively analyzed the effect of a mandatory CPOE-based, CDS-enabled VTE order set on provider compliance with prophylaxis guidelines and on outcomes among adult trauma patients. The computerized VTE order set was implemented on December 17, 2007, at the Johns Hopkins Hospital and a specific module was used for trauma patients.¹⁷ The Johns Hopkins Hospital is part of an academic medical center, with a state-designated level 1 trauma center, serving an urban community in Baltimore, Maryland. We searched the Johns Hopkins Hospital Adult Trauma Center registry (Collector Trauma Registry, Digital Innovation, Inc) for patients who were admitted directly to the adult trauma service between January 1, 2007, and December 31, 2010, and hospitalized for more than 1 day. Patients admitted in 2007 served as our baseline group, and we compared them with patients in the postimplementation group (ie, patients admitted between 2008 and 2010). Our study was approved by the Johns Hopkins University School of Medicine institutional review board.

VTE ORDER SET

The mandatory CPOE-based, CDS-enabled VTE order set was developed to improve compliance with best practice VTE prophylaxis for all hospitalized patients. Once the ordering provider entered the CPOE, they had to complete short checklists of VTE risk factors and contraindications to pharmacologic VTE prophylaxis. The order set then deployed an evidence-based al-

gorithm to identify the patient's risk stratification level and recommended the appropriate VTE prophylaxis regimen (eFigure, <http://www.archsurg.com>). Prophylactic enoxaparin sodium (low-molecular-weight heparin) was the preferred drug suggested for the majority of trauma patients without a documented contraindication to pharmacologic prophylaxis. Mechanical prophylaxis with sequential compression devices was suggested for trauma patients with contraindications to pharmacologic prophylaxis (eFigure). Providers were not required to follow the CDS suggested order. The algorithm was initially developed using previous iterations of evidence-based guidelines^{4,18} and has been re-examined and modified as guidelines are updated.³

DATA COLLECTION

We extracted the following variables for all patients from the adult trauma registry: demographics (age, race, and sex), injury characteristics (Injury Severity Score, Glasgow Coma Scale score at admission; trauma type [blunt or penetrating]; whether there was shock at admission, which was defined as a systolic blood pressure of <90 mm Hg; and Abbreviated Injury Scale score by body region), admitting service, hospital length of stay, and VTE events.

For the baseline period (2007), one researcher (F.S.K.) reviewed each patient's medical record to collect the following VTE-related variables: provider documentation of VTE risk stratification, patient VTE risk factors, contraindications to pharmacological prophylaxis, and written orders for prophylaxis (pharmacological and/or mechanical) within 24 hours of admission. For the postimplementation period (2008-2010), these variables were extracted directly from the CPOE system. Compliance with appropriate best practice VTE prophylaxis was defined as adherence to our trauma service-specific VTE prevention algorithm.

STATISTICAL ANALYSIS

Descriptive data were summarized as proportions. We compared the demographic characteristics, injury characteristics, and VTE prophylaxis data (risk stratification, appropriate prophylaxis order, and type of prophylaxis) of patients during the baseline period with those of patients during the postimplementation period, using the 2-sided χ^2 test for categorical variables and unpaired *t* tests for continuous variables; interquartile ranges were reported for the Injury Severity Score and hospital length of stay. Because VTE event rates were relatively small, we used the 2-sided Fisher exact test to compare proportions of patients with VTE, DVT, and/or PE during the baseline period with proportions of patients with VTE, DVT, and/or PE during the postimplementation period.

We defined the incidence of a potentially preventable VTE as a DVT or PE event occurring in a patient who was not ordered the guideline-appropriate prophylaxis for their specific VTE risk factors. This definition was based on the Centers for Medicare and Medicaid Services requirements for meaningful use of Electronic Health Record systems and other suggested approaches for reporting preventable harm.¹⁹⁻²¹ Using this definition is well accepted by clinicians and in quality/safety research. Providers are not penalized for VTE cases that occur in patients who were ordered best practice prophylaxis measures because it is well accepted that VTE events occur in this population.² Quality/safety experts are able to identify reasonable targets for improvement, and the goal of zero “preventable harm” is reasonable.

Data from the trauma registry were linked to results from the manual chart review (baseline) and results from the CPOE (postimplementation) using a relational database (Microsoft Access; Microsoft, Inc), matching the patient's first and last names,

Table 1. Characteristics of 1599 Hospitalized Adult Trauma Patients

Characteristic	Baseline Period, 2007 (n = 399)	After 2008 (n = 412)	After 2009 (n = 389)	After 2010 (n = 399)	Postimplementation Period, 2008-2010 (n = 1200)	P Value ^a
Age, mean (SD), y	36.0 (17.7)	34.9 (16.7)	36.0 (17.3)	36.3 (17.6)	35.7 (17.2)	.78
Race, No. (%) of patients						
White	83 (20.8)	83 (20.1)	94 (24.2)	112 (28.1)	289 (24.1)	.20
Black	291 (72.9)	308 (74.8)	269 (69.2)	254 (63.7)	831 (69.3)	.18
Hispanic	15 (3.8)	17 (4.1)	19 (4.9)	17 (4.3)	53 (4.4)	.67
Other	8 (2.0)	4 (1.0)	7 (1.8)	16 (4.0)	27 (2.3)	.93
Male sex, No. (%) of patients	328 (82.2)	323 (78.4)	304 (78.1)	303 (75.9)	930 (77.5)	.06
Hospital LOS, median (IQR), d	4 (2-7)	4 (2-9)	4 (2-7)	4 (2-8)	4 (2-8)	
ISS, median (IQR)	9 (4-16)	9 (4-14)	9 (4-16)	9 (4-17)	9 (4-16)	
Blunt trauma	205 (51.4)	228 (55.3)	207 (53.2)	226 (56.6)	661 (55.1)	.22
AIS score >2, No. (%) of patients						
Head/neck	57 (14.3)	68 (16.5)	66 (17.0)	64 (16.0)	198 (16.5)	.33
Chest	120 (30.1)	104 (25.2)	93 (23.9)	112 (28.1)	309 (25.8)	.10
Abdomen	58 (14.5)	46 (11.2)	43 (11.1)	57 (14.3)	146 (12.2)	.25
Extremities	59 (14.8)	72 (17.5)	55 (14.1)	57 (14.3)	184 (15.3)	.85
GCS score <15, No. (%) of patients	61 (15.3)	69 (16.7)	41 (10.5)	40 (10.0)	150 (12.5)	.18
In shock on admission, No. (%) of patients	18 (4.5)	24 (5.8)	29 (7.5)	26 (6.52)	79 (6.6)	.17

Abbreviations: AIS, Abbreviated Injury Scale; GCS, Glasgow Coma Scale; IQR, interquartile range; ISS, Injury Severity Score; LOS, length of stay.
^aRepresents 2007 data vs combined data for the 2008-2010 period; statistical significance set at $P < .05$.

medical record number, and admission date (± 1 day). All statistical analyses were performed using STATA version 11.0 (StataCorp).

RESULTS

We identified 1603 hospitalized adult trauma patients meeting our study criteria between 2007 and 2010. The paper medical records for 4 patients from 2007 (baseline) were not available, resulting in a total 1599 patients being included in our analysis. The trauma patient populations in the baseline and postimplementation periods were similar in mean age, distribution by race, the majority being male, the proportion with blunt trauma, the proportion presenting in shock or with a decreased Glasgow Coma Scale score, and hospital length of stay (**Table 1**).

VTE RISK STRATIFICATION

Documentation of VTE risk stratification within the first 24 hours of admission was identified in only 3.0% of the baseline group (12 of 399 patients). This proportion increased dramatically to 97.8% (1174 of 1200 patients) in the postimplementation group ($P < .001$).

COMPLIANCE WITH EVIDENCE-BASED VTE PROPHYLAXIS

The compliance rate for evidence-based VTE prophylaxis was 66.2% at baseline compared with 84.4% for the overall postimplementation period ($P < .001$) (**Figure 1**). The compliance rate decreased to 46.7% in the first postimplementation quarter (compared with 72.2% in the first quarter in 2007 [$P < .001$]) and then increased to more than 90.0% by the third quarter of 2008 ($P < .001$). The highest quarterly compliance rate (95.6%) occurred in 2009.

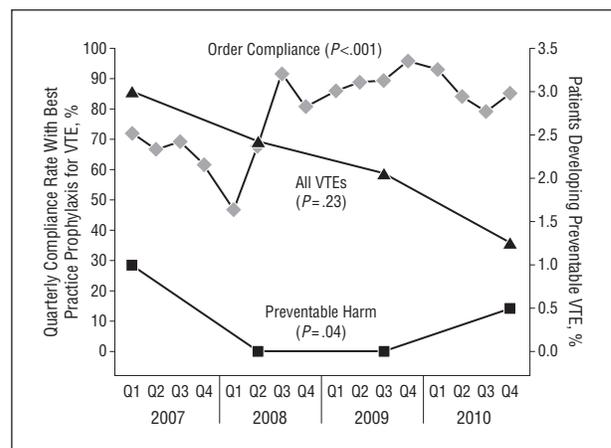


Figure 1. Trends in venous thromboembolism (VTE) prophylaxis and events in hospitalized adult trauma patients. The quarterly compliance rates for prophylaxis orders during the baseline period (2007) and the postimplementation period (2008-2010), in which the mandatory computerized provider order entry–based clinical decision support module was implemented, are compared. Also shown is the downward trend in the annual proportion of patients with VTE events during the same time period. Q indicates quarter.

The overall percentage of patients who received enoxaparin (the preferred prophylaxis for most trauma patients) was 35.8% at baseline compared with 48.8% for the postimplementation period ($P < .001$) (**Figure 2**). In the postimplementation period, the rate increased from 43.4% in 2008 to 52.6% in 2010 ($P < .001$). Orders for sequential compression devices were high for the entire study period. One exception was the first quarter of 2008, when the rate dropped below 50% (data not shown).

In 2007, 2.8% of hospitalized trauma patients were not ordered any prophylaxis. The number of patients not ordered any prophylaxis increased in 2008 to 10.4%, and this increase occurred almost entirely during the first-quarter postimplementation period (44.4%). For the re-

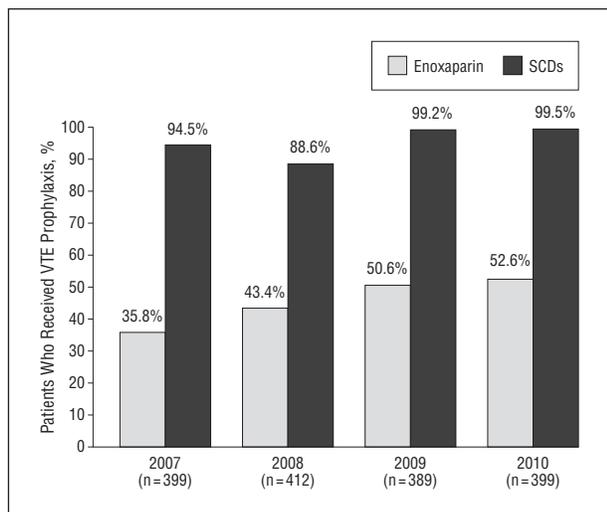


Figure 2. Proportion of hospitalized adult trauma patients who received venous thromboembolism (VTE) prophylaxis. The proportion of hospitalized adult trauma patients who received pharmacologic prophylaxis (enoxaparin) are compared with the proportion of hospitalized adult trauma patients who received sequential compression devices (SCDs). The baseline period was 2007, and the postimplementation period was 2008, 2009, and 2010 (when the mandatory computerized provider order entry–based clinical decision support module was implemented).

remainder of 2008, 99.1% of patients were ordered some form of prophylaxis ($P = .13$), and this number increased in 2009 and 2010 to 99.7% and 99.5%, respectively ($P < .001$).

When examining trauma patients with and without documented contraindications to pharmacologic prophylaxis, we found that the compliance rates remained high for those with a documented contraindication during the entire study period (**Figure 3**). In patients without a documented contraindication, compliance rates increased from 40.6% at baseline to 74.2% for the postimplementation period ($P < .001$) (Figure 3).

VTE EVENTS

Of 1599 patients, 35 (2.18%) had experienced VTE events; 12 patients (0.75%) experienced PE-only events, and 21 patients (1.31%) experienced DVT-only events. Two patients in the postimplementation period experienced both DVT and PE events. The proportion of VTE events were 3.0% at baseline compared with 1.25% for the final postimplementation year ($P = .23$) (**Table 2**). The PE rate remained relatively constant during the study period, whereas the DVT rate decreased from 2.26% at baseline to 0.25% for the final postimplementation year (ie, 2010) ($P = .02$).

POTENTIALLY PREVENTABLE VTE EVENTS

In the baseline year, 4 patients (1.00%) experienced potentially preventable VTE events (a patient with VTE was not ordered risk-appropriate prophylaxis) compared with 2 patients (0.17%) who experienced potentially preventable VTE events during the 3-year postimplementation period, representing an 83% relative risk reduction in preventable harm ($P = .04$) (Table 2). All 4 events in 2007

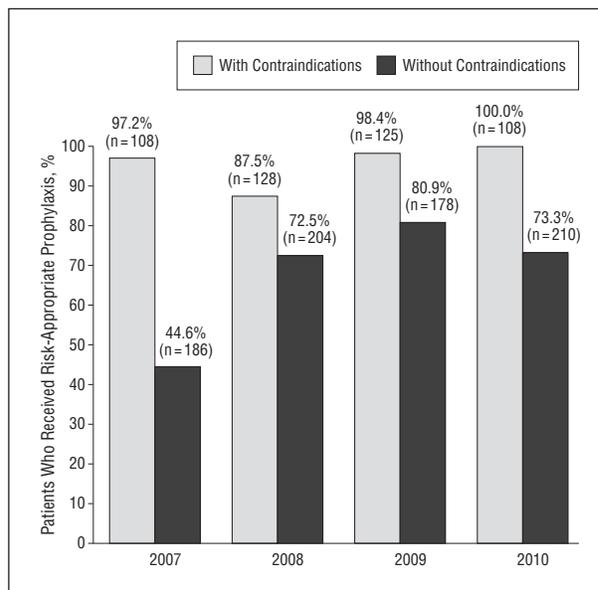


Figure 3. Compliance rates among hospitalized adult trauma patients, stratified by those with or without documented contraindications to pharmaceutical prophylaxis for venous thromboembolism. The baseline period was 2007, and the postimplementation period was 2008, 2009, and 2010, in which the mandatory computerized clinical decision support tool was used to increase compliance with prophylaxis ordering.

were DVT events (2 large symptomatic and 2 asymptomatic), and both patients who experienced preventable VTE harm in 2010 had a symptomatic PE. There were no potentially preventable VTE events identified in 2008 and 2009.

COMMENT

We found that implementation of a CPOE-based, mandatory CDS module significantly improved compliance with evidence-based VTE prophylaxis orders for hospitalized adult trauma patients. The majority of this improvement stemmed from increased compliance rates among patients without contraindications to pharmacologic prophylaxis. Patients with contraindications were consistently ordered sequential compression devices, resulting in high compliance rates. We also found a decrease in VTE events over time after the tool was implemented, with a 36% relative risk reduction in VTE events and an 83% relative risk reduction in preventable harm, defined as VTE events occurring in patients not ordered appropriate prophylaxis.

Despite evidence demonstrating the beneficial effects of prophylaxis, VTE prophylaxis remains underutilized across many patient populations.⁵ Trauma patients are at very high risk,¹ and we should be vigilant about prophylaxis. Few large studies have looked at VTE compliance in trauma. In a retrospective review of data from 18 level 1 trauma centers across the United States, we noted about an 80% prophylaxis compliance rate.^{22,23} This finding is in stark contrast to another study that reported prophylaxis orders in 25% of patients within 48 hours after receiving trauma.²⁴ These data and our baseline compliance rate suggest that trauma patients may be getting VTE prophylaxis at higher rates than other medical and surgi-

Table 2. Trauma Patients With Venous Thromboembolism (VTE) Events From 2007-2010

Event	Patients, No. (%)					P Value ^a
	2007 (n = 399)	2008 (n = 412)	2009 (n = 389)	2010 (n = 399)	2008-2010 (n = 1200)	
VTE	12 (3.01)	10 (2.43)	8 (2.06)	5 (1.25)	23 (1.92)	.23
DVT only	9 (2.26)	6 (1.46)	5 (1.29)	1 (0.25)	12 (1.00)	.07
PE only	3 (0.75)	3 (0.73)	2 (0.51)	4 (1.00)	9 (0.83)	.74
PE and DVT	0 (0.00)	1 (0.24)	1 (0.26)	0 (0.00)	2 (0.17)	.99
Preventable VTE ^b	4 (1.00)	0 (0.00)	0 (0.00)	2 (0.50)	2 (0.17)	.04

Abbreviations: DVT, deep vein thrombosis; PE, pulmonary embolism; VTE, venous thromboembolism.

^aRepresents 2007 data vs combined data for the 2008-2010 period; statistical significance set at $P < .05$.

^bDefined as a VTE in patients not receiving appropriate VTE prophylaxis.

cal patients.^{5,6} Perhaps a well-defined protocol for trauma care, which has been shown to improve outcomes in trauma,^{25,26} also helps to increase compliance with VTE prophylaxis. In our study, we observed nearly a 2-fold improvement in prophylaxis orders among patients with no contraindications to enoxaparin. This group likely benefited the most from the computer-based CDS module. These rates, however, are still well below the 100% goal of providing appropriate prophylaxis for all patients that we should strive to achieve.

Although many types of interventions have attempted to increase the use of prophylaxis, our proactive, mandatory approach has been shown to be one of the most effective. More passive strategies, such as laminated cards or educational efforts, are likely familiar to many providers but were found to be relatively ineffective in increasing prophylaxis compliance rates.⁹ Computer-generated alerts that search for omitted prophylaxis orders have shown some improvement¹¹; however, this still provides a window of time wherein the patient remains at risk for a VTE event. The CDS VTE order set at our hospital was a mandatory field in the CPOE system, forcing providers to complete the VTE risk stratification module. The only way to avoid completing the module was to abandon the entire admission order set. The CDS tool then suggests the correct prophylaxis regimen and makes ordering easy. We saw significant increases in prophylaxis orders once the CPOE-based module was implemented. We mandate risk stratification (a joint commission mandate at the time of implementation) for all admitted adult patients during the initial ordering process at admission.

The cost of quality improvement interventions must always be considered when deciding on where to expend time, energy, and financial resources. We recognize that our approach requires the existence or implementation of an electronic health record system, which is the largest expense. The development of specific VTE prophylaxis algorithms for different patient populations would result in a relatively small incremental cost above that of the electronic health record base system. This proof-of-concept shows a glimpse into the future at how computerized CDS can effect other areas of quality, patient safety, and efficiency.²⁷ Implementation of this successful CDS tool would satisfy one of the core measures of meaningful use, enabling health care organizations to take advantage of financial incentives, perhaps offsetting the cost of implementing such a system.¹⁹

Paper-based CDS has a clinically beneficial history in health care, but a computerized tool is likely a far superior approach. The Director of the Agency for Healthcare Research and Quality has suggested that CDS systems “help clinicians make better decisions by increasing adherence to evidence-based knowledge and reducing variations in clinical practice.”¹⁵ As CPOE systems are promulgated across the country, integrating CDS is a natural and more efficient next step. Inpatient computerized CDS has improved some process measures.²⁸ We demonstrated similar improvements in process measures, including risk stratification for VTE and ordering of appropriate prophylaxis. Moreover, we went further to show clinical outcome benefits with significantly lower preventable VTE event rates. Not many studies have shown improvements in specific clinical outcomes, particularly an outcome that is clinically relevant and currently reported nationally in many regards as an accepted quality measure.

Even with all the suggested benefits, there are some inherent limitations in the design, implementation, and effectiveness of computerized CDS. Our study, similar to others,^{29,30} saw a temporary worsening in process measure compliance during the learning phase when the CDS tool was first implemented. Nonetheless, compliance rebounded and improved to well above baseline levels. In addition, our data suggest that compliance waned slightly with time, prompting our group to reinstitute an ongoing educational program about the importance of VTE prophylaxis. Our findings support the systematic review showing that a combination of methods is the best approach.⁹ We chose to link the patient type to the parent order set used, which provided specific prophylaxis recommendations, rather than having the provider choose the exact patient type (eg, trauma, surgery, medicine, orthopedics, or obstetrics). Physicians treating trauma patients could have chosen another order set (eg, general surgery), which could give different prophylaxis suggestions; some providers may have ordered an alternative prophylaxis (ie, unfractionated heparin) that was considered noncompliant for trauma. When the VTE CDS tool was being designed, we initially hoped to implement a program in which the suggested VTE prophylaxis would be automatically ordered, while giving the provider a chance to opt out. However, some clinicians and administrators thought this would remove too much clinician autonomy, and we were forced to use a different approach that gave a suggestion that the provider could choose to accept or ignore. Ultimately, the deci-

sion to order VTE prophylaxis remains entirely with the ordering provider. Perhaps this opt-in approach is less effective.^{23,31}

There were several limitations to our study. First, our baseline data collection required paper chart review, wherein there was no prompt to document VTE risk stratification (which is shown by the 3% documentation rate of VTE risk assessment). Second, overall VTE rates remained too low to provide sufficient power to detect statistically significant decreases in PE, DVT, or overall VTE events. Third, surveillance bias exists when considering reporting of DVT after trauma. There is wide variation in practice patterns regarding the use of surveillance duplex ultrasound in high-risk asymptomatic trauma patients, which has effected the DVT rate identified after major trauma.^{20,25,32-34} Although this is a known limitation in many studies of DVT as an outcome, our study is partially protected from this bias because it was performed at a single institution with a well-established standardized protocol to screen high-risk asymptomatic trauma patients for DVT. This protocol was instituted years before the beginning of this study. Moreover, there was no change in protocol that would suggest that we found higher rates of DVT because we looked more aggressively in certain patient populations.³²

Rates of VTE have been used and suggested as a measure of quality of medical care; however, there are potential pitfalls in their use.^{2,20} Although some complications (eg, central line-associated bloodstream infections) can be eliminated with the adoption of best practices and simple interventions, such as checklists,^{35,36} VTE is inherently different. The prevention for VTE (ie, the use of low-dose anticoagulants) comes with associated risks and cannot simply be used for all patients. In addition, even these medications are not 100% effective at preventing all VTEs.² We agree that continued improvements in prophylaxis are needed to decrease rates of DVT and PE, but VTE cannot be classified as a “never event.” Newer definitions of preventable harm that link an adverse event to a lapse in best practices is the preferred approach.^{2,21,37} This methodology has been adopted by the US government in their “meaningful use” for health care information technology when describing VTE.¹⁹ This definition of preventable harm places VTE in patients not receiving prophylaxis in the numerator and all patients in the denominator, giving a proportion with “preventable harm,” which we agree can have a goal of zero. Using this definition, we demonstrated a dramatic decrease in preventable harm from VTE (1.0%-0.17%; $P = .04$) for admitted adult trauma patients, including 2 full years with no preventable harm VTE events.

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Online-Only Material: The eFigure is available at <http://www.archsurg.com>.

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