Using Process Measures to Improve Patient Safety Practices to Prevent Pulmonary Embolism

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Abstract

Pulmonary embolism (PE), or venous thromboembolism (VTE), is one of the most common and potentially preventable causes of hospital death. PE reduction is a key strategy to improving patient safety in hospitals. A pilot study involving six hospitals in New York State was conducted to implement targeted methods to improve physician compliance with known prophylaxis strategies and increase awareness of whether PE events were associated with proper prophylaxis or not. While the specific processes varied among participating hospitals, key components included: support of administration, physician champions, training on available tools, followup on patient risk assessment and guideline adherence, utilization of the process measures data collection tool, use of audit and feedback data, and a plan to address barriers to acceptance/adoption. Findings show a significant increase in prophylaxis utilization. Thus, for patients suffering adverse events, the increased use of process measures improves patient safety and outcomes in hospitals.

Introduction

In recent years, there has been an increasing amount of national attention paid to patient safety, especially in response to the two landmark reports by the Institute of Medicine: *To Err is Human: Building a Safer Health System* (1999)[1] and *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001).[2]

The Agency for Healthcare Research and Quality, in their published report *Making Health Care Safer: A Critical Analysis of Patient Safety Practices* (2001),[3] ranked patient safety interventions on the strength of the evidence supporting more widespread implementation. One of the highest ranked patient safety practices was appropriate use of prophylaxis to prevent venous thromboembolism (VTE) in patients at risk. Similarly, the Surgical Care Improvement Project, a national quality partnership that aims to improve surgical care through the reduction of postoperative complications,[4] listed the prevention of VTE for surgical patients as one of four targeted areas.

The rationale for thromboprophylaxis in hospitalized patients is based on solid principles and scientific evidence. First, the incidence of VTE is significant because most adult patients admitted to the hospital have risk factors for VTE. Second, the adverse consequences of unprevented VTE include:

- Symptomatic deep vein thrombosis (DVT) and pulmonary embolism (PE).
- Fatal PE.
- Costs of investigating symptomatic patients.
- Costs of treatment.
- Risks of treatment, especially bleeding.
- Increased future costs of treating recurrent VTE.
- Chronic post-thrombotic syndrome.

Third, thromboprophylaxis is highly effective at reducing the frequency of symptomatic VTE and mortality from PE; and the cost-effectiveness of prophylaxis has been repeatedly demonstrated.[5]

PE is a common, potentially preventable cause of hospital deaths, and reducing mortality from PE is one of the most important objectives to improve patient safety in hospitals.[6] However, despite national attention to VTE prophylaxis, it continues to be underutilized in hospitalized patients at risk, with lower compliance in medical patients.[7, 8, 9]

The New York State Department of Health (NYSDOH) undertook a pilot project in 2004 to address utilization of PE prophylaxis in acute care hospitals located within New York State. The pilot project took the form of an evaluation of the impact of intensive training of hospital personnel on the importance of prophylaxis among those at risk for PE, linked to review of unprevented PE at each hospital to assess whether prophylaxis had been given. The goals of the study were to enhance professional knowledge and modify practice patterns in risk assessment and the use of prophylaxis for acute PE, thereby enhancing the quality of care for patients and reducing the incidence of future events.

Methods

Data for the study were collected through the New York Patient Occurrence Reporting and Tracking System (NYPORTS).[10] NYPORTS is maintained by the New York State Department of Health as a mandatory patient event reporting system intended primarily for acute care hospitals. The system was implemented statewide in 1998 and requires hospitals to provide detailed information to the Department on serious adverse events, including PE, among acute care hospital patients.

Hospitals throughout the State were invited to participate in the study. Positive responses were received from numerous hospitals, and seven were selected for inclusion in the project. (One hospital ended its participation prior to the conclusion of the baseline study period.) The participating institutions were selected to ensure inclusion of hospitals from different geographic areas of the State, teaching and nonteaching institutions, and large- and medium-sized providers. Hospitals that were known to be timely submitters of the standard administrative inpatient data needed for the project were also favored. The final set of 6 hospitals included two very large hospitals (>700 beds), two large facilities (400 - 600 beds), and two medium-sized facilities (150 - 399 beds). Four different regions of the State were represented, with two hospitals located

on Long Island, one in New York City, two in the Western part of the State, and one in the Central New York region. All but one of the six hospitals are classified as "teaching" by the NYSDOH.

The study intervention at each of the six participating hospitals included staff training on PE risk assessment and prophylaxis protocol. This intervention was facilitated by a toolkit for VTE safety practices that was also developed and disseminated to all hospitals participating in the project.

Each hospital adapted the prophylaxis protocol presented in the hospital training toolkit to fit its facility's care process. The tool kit contained the following items: consensus guidelines developed by the Rochester Regional Thromboembolism Collaborative[11]; a Microsoft PowerPoint® slide deck used in education sessions by Strong Memorial Hospital (Rochester, New York); the study supplemental data collection tool and its associated data dictionary; a poster; a pocket card; other decision-support tools; and a bibliography with reference articles.

Although the final prophylaxis processes varied among participating hospitals, each included a number of key components: support of hospital administration identification of a physician champion, an educational program (i.e., written curriculum, didactic/interactive sessions, reference tools and materials), a plan for patient risk assessment and guideline adherence, the use of audit and feedback techniques, and a plan to address and correct barriers to acceptance/adoption. Table 1 outlines the methods used to implement the risk assessment and prophylaxis protocol for VTE, methods of compliance monitoring and feedback to physicians, and barriers identified or lessons learned.

In addition to the standard NYPORTS reporting requirements, hospitals were asked to submit detailed information on all adult PE patients. For each identified hospital-associated PE, hospital staff provided detailed descriptive data, including information on the type of prophylaxis given, timing of the administration, the admission service (e.g., cardiology, gynecology, medicine, orthopedics, general surgery), the method of PE diagnosis, and both major and minor risk factors. Patients were classified as either medical or surgical using information available in the supplemental information provided. A case was defined as surgical if either the admission service variable indicated "surgery" or operating room time was reported. The supplemental data collected also contained information on the treatment outcomes of patients. Included were indications of transfer to a higher level of care, major bleeding, extended length of stay, and in-hospital death. Hospitals made the determination as to whether cases met the criteria for required reporting to the Department of Health.

Cases included in the study are those with a PE, defined as any "new acute PE not present on admission, unless associated with a hospitalization within previous 30 days." The method of diagnosis (e.g., V/Q scan, spiral CT, or angiogram) was not analyzed as part of this study. Chemoprophylaxis was defined as the patient receiving any one of five anticoagulant medications: argatroban (Novastan®), heparin (SQ or IV), dalteparin (Fragmin®), enoxaparin (Lovenox®), or warfarin (Coumadin®). Administration of the drug had to occur either prior to admission or during the hospital stay but prior to the occurrence of PE. Use of any of three other

Table 1. Methods of prophylaxis implementation, monitoring and lessons learned

Methods of risk assessment and prophylaxis implementation	Compliance monitoring and feedback	Barriers/lessons learned
Standardized risk assessment tool (guideline) for use in office setting and hospital	Peer review process	Takes a lot of leg work or up front investment
Standardized history & physical	Utilizing case managers	Need to standardize process outside the hospital setting
Standard or preprinted order sets	Daily concurrent review of physicians' orders	Need to educate on effective and appropriate use of IPCs as an alternate prophylaxis intervention
CPOE	Random record reviews	No decrease in VTE rate despite compliance with protocols – may be due to increased awareness and testing
Use of teams and physician champions	Specific memos to physicians regarding a case	VTE more prevalent in certain types of patients such as cancer patients or certain procedures (CABG or Orthopedic)
Electronic charting and force functions	Weekly report cards	No national guidelines for ambulatory setting
Use of posters, charts and pocket cards	Quarterly audits	Need for education of coders
Develop new Joint Center of Excellence Program for reducing hematoma post surgery and VTE	QA Review Committees	Underutilization of VTE prophylaxis for OB patients

H&P = history and physical; IPC – intermittent pneumatic compression; CPOE = computerized physician order entry; VTE = venous thromboembolism; CABG = coronary artery bypass graft; QA = quality assessment; OB = obstetric

modalities also qualified as prophylaxis. These nonpharmacologic (mechanical) modalities included intermittent pneumatic compression (IPC), graduated compression stockings, or inferior vena cava (IVC) filter. Individual hospitals determined which type of prophylaxis was used for each patient. Patients receiving only aspirin, either pre- or post-admission, were classified as not prophylaxed. Contraindications for chemoprophylaxis were also reported through the supplemental data provided by the study hospitals. Major contraindications for anticoagulant utilization among PE patients included active uncontrolled bleeding, cerebrovascular hemorrhage, dissecting aortic aneurysm, cerebral aneurysm, bacterial endocarditis, active gastric ulcer or ulcerative GI lesion, severe uncontrolled hypertension, and severe head trauma. For such patients, mechanical prophylaxis was usually appropriate with rare exception.

To ensure that hospitals reported information for all PEs, records meeting diagnostic criteria identifying PE were selected from the NYSDOH Statewide Planning and Research Cooperative

System (SPARCS) inpatient discharge data. Potential PE cases were identified on a quarterly basis for each of the six study hospitals if they met any of three criteria:

1. PE and infarction (ICD-9-CM code of 415.1X) or obstetrical blood clot embolism (673.2X) reported in any of 14 secondary diagnosis fields as not present at the time of admission.
2. PE and infarction (415.1X) or obstetrical blood clot embolism (673.2X) as a principal diagnosis, along with a hospitalization less than 31 days prior to the admission date associated with the target discharge.
3. Any secondary diagnosis of PE and infarction (415.1X) or obstetrical blood clot embolism (673.2X) reported as present on admission, along with a hospitalization less than 31 days prior to the admission date associated with the target discharge.

Discharges meeting any of the three criteria were compiled in a hospital-specific listing of potential PEs. The lists were sent to the project staff at each hospital along with a request for further details on the status of each case. Of the 522 SPARCS-identified cases, 50 percent were determined to be nonreportable events; 51.9 percent in the baseline, and 48.4 percent in the post-intervention period. Supplemental study data were then provided for all remaining cases on the lists. For PE cases that were considered reportable but had not yet been entered into NYPORTS, hospital staff also submitted the NYPORTS-required reports.

The baseline period for the study was June 1, 2003 to May 31, 2004. The impact of the intervention on prophylaxis practice at the six participating hospitals was assessed through a comparison of the rate of PE during the baseline period to the rate during the post-intervention period of July 1, 2005 to June 30, 2006. Relationships among measures were assessed using Fisher's exact test with $P < 0.05$ denoting statistical significance.

The prophylaxis rate was expected to increase for all PE patients, with a greater increase expected among high-risk patients. As a result, one-tailed tests of statistical significance were used to assess the impact of the study intervention. Tests of statistical interaction between patient characteristics and study period were conducted to determine whether the level of change in the rate of prophylaxis between the study periods varied by the level of risk for PE. No hospital-specific analyses were conducted due to the relatively small number of observations available at each site.

Results

The baseline period comprised 117 PE patients reported through NYPORTS and/or identified through SPARCS case review; 144 PE patients were identified in the post-intervention period. There were no statistically significant differences between the two periods in terms of the patients' sex or race.

A number of risk factors appeared infrequently in the study data (Table 2). Four patient characteristics showed the presence of a higher risk condition in less than 4 percent of total cases, with six characteristics showing elevated risk in less than 7 percent of cases. The relative frequency of each risk factor was similar between periods, with 10/12 factors showing no statistically significant difference. Severe sepsis/infection did show a significant difference

between periods, increasing from 0 (0.0 percent) to 9 cases (6.3 percent) ($P = 0.01$). The number of central venous access cases increased significantly from 1 (0.9 percent) during the baseline period to 17 (11.8 percent) in the post-intervention period ($P < 0.001$).

The relationship between patient characteristics and the use of prophylaxis is summarized in Table 3. Overall, 83.1 percent of patients at risk for PE received some form of prophylaxis. Among the 12 patient characteristics signaling increased risk for PE, a statistically significant relationship with the use of prophylaxis was found for only two. Patents reported as having a prior DVT/PE received prophylaxis in 94.3 percent of cases, while those without a prior event had a prophylaxis rate of 81.4 percent. Admission service, classified as surgical or medical, showed surgical patients having an 87.4 percent prophylaxis rate compared to a rate of 77.3 percent among medical patients.

Table 4 shows that the prophylaxis rate among patients with a NYPORTS reportable PE event increased from 76.1 percent to 88.9 percent ($P < 0.01$) following the study intervention. Tests for statistical interaction (available from the authors) revealed no significant differences in the magnitude of change in the prophylaxis rate associated with the different levels of the individual patient characteristics, including prior DVT/PE and admission service type. This suggests that the increase in the use of prophylaxis following the intervention did not reflect an emphasis on selected patient characteristics or conditions, many of which are established markers of elevated PE risk. Table 4 also shows that 24 (11.1 percent) of 217 patients prophylaxed during the study period had conditions for which pharmacologic methods of prophylaxis were contraindicated according to the guideline. During the baseline period, 9/12 patients (75.0 percent) nevertheless received pharmacologic prophylaxis, either alone or in combination with a mechanical prophylaxis device. Patients having contraindications and treated during the post-intervention period received pharmacologic prophylaxis with or without mechanical prophylaxis in 7/12 cases (58.3 percent). This difference in rates between the study periods was not statistically significant.

Patient Outcomes

The supplemental data on PE cases provided by hospitals contained a number of patient care outcomes. These included transfer to a higher level of care during the hospitalization, the occurrence of major bleeding, an extended length of stay, and in-hospital death.

Table 5 shows that there was no significant change in the proportion of cases transferred to a higher level of care (12.8 percent vs. 13.2 percent) or in those developing major bleeding (2.6 percent vs. 2.1 percent). Extended lengths of stay due to PE occurred in 10.3 percent of cases during the baseline period and in 5.6 percent of patients following the intervention. Death among PE patients during the baseline period was 6.8 percent with a similar rate of 4.9 percent in the post-intervention period. None of the changes in outcome rates between the two study periods was statistically significant.

Table 2. Patient risk factor and treatment by study period

	Baseline		Post-intervention		
	Number of Patients	Percent	Number of Patients	Percent	
Total	117	44.8	144	55.2	***P*-Value**
Age					
≤60	40	34.2	50	34.7	0.93
>60	77	65.8	94	65.3	
Prior DVT/PE					
No	103	88.0	123	85.4	0.58
Yes	14	12.0	21	14.6	
Malignancy					
No	80	68.4	100	69.4	0.89
Yes	37	31.6	44	30.6	
Hypercoaguable state					
No	113	96.6	141	97.9	0.70
Yes	4	3.4	3	2.1	
Prolonged immobility					
No	96	82.1	124	86.1	0.39
Yes	21	17.9	20	13.9	
Myocardial infarct					
No	110	94.0	137	95.1	0.79
Yes	7	6.0	7	4.9	
Heart failure					
No	112	95.7	141	97.9	0.47
Yes	5	4.3	3	2.1	
Severe sepsis/infection					
No	117	100.0	135	93.8	0.01
Yes	0	0.0	9	6.3	
Stroke, nonhemorrhagic					
No	111	94.9	140	97.2	0.35
Yes	6	5.1	4	2.8	
Central Venous Access					
No	116	99.1	127	88.2	<0.001
Yes	1	0.9	17	11.8	
Service					
Medical	51	43.6	59	41.0	0.71
Surgical	66	56.4	85	59.0	
Surgery >45 min[b]	66		85		
No	23	34.8	25	29.4	0.49
Yes	43	65.2	60	70.6	

a Two-tail Fisher's exact test.

b Includes all cases with operating room time ≠ 0.

DVT = deep vein thrombosis; PE = pulmonary embolism

Table 3. Prophylaxis by patient risk factor and treatment

	Total	Prophylaxis administered		*P-value*[a]
		N	%	
Total	**261**	**217**	**83.1**	
Age				
≤60	90	71	78.9	0.12
>60	171	146	85.4	
Prior DVT/PE				
No	226	184	81.4	0.04
Yes	35	33	94.3	
Malignancy				
No	180	147	81.7	0.22
Yes	81	70	86.4	
Hypercoaguable state				
No	254	210	82.7	0.27
Yes	7	7	100.0	
Prolonged immobility				
No	220	183	83.2	0.56
Yes	41	34	82.9	
Myocardial infarct				
No	247	206	83.4	0.43
Yes	14	11	78.6	
Heart failure				
No	253	209	82.6	0.22
Yes	8	8	100.0	
Severe sepsis/infection				
No	252	208	82.5	0.18
Yes	9	9	100.0	
Stroke, non-hemorrhagic				
No	251	208	82.9	0.47
Yes	10	9	90.0	
Central venous access				
No	243	200	82.3	0.16
Yes	18	17	94.4	
Service		85	77.3	
Medical	110	132	87.4	0.02
Surgical	151			
Surgery > 45 minutes[b]				
No	48	42	87.5	0.60
Yes	103	90	87.4	

a Two-tail Fisher's exact test.

b Includes all cases with operating room time ≠ 0.

Table 4. Prophylaxis by study period

	Totals		Baseline		Post-intervention		
	Number of patients	%	Number of patients	%	Number of patients	%	*P*-value[a]
Total number of patients	261	100	117		144		
Number of patients receiving prophylaxis	217	83.1	89	76.1	128	88.9	0.01
Number of patients with a major contraindication[b]	34	13.0	20	17.1	14	9.7	0.06
Number of patients with a major contraindication receiving prophylaxis[c]	24	70.6	12	60.0	12	85.7	0.11
Type of prophylaxis used							0.15
Anticoagulant only	9	37.5	7	58.3	2	16.7	
Prophylaxis device only	8	33.3	3	25.0	5	41.7	
Both	7	29.2	2	16.7	5	41.7	

a One-tail Fisher's exact test
b Condition for which prophylaxis via anticoagulant is contraindicated.
c Percentages based on number of patients with major contraindication for prophylaxis.

Table 5. Patient outcome by study period

	Baseline		Post-Intervention		
	Number of Patients	Percent	Number of Patients	Percent	*P*-value[a]
Total	**117**		**144**		
Transfer to higher level of care	15	12.8	19	13.2	0.54
Major bleeding	3	2.6	3	2.1	0.55
Extended length of stay	12	10.3	8	5.6	0.12
Death	8	6.8	7	4.9	0.33

A One-tailed Fisher's exact test.

Discussion

The implementation of a risk-factor assessment and prophylaxis protocol at six hospitals produced a significant, short-term increase in the use of prophylaxis among PE patients. The post-intervention prophylaxis rate of 88.9 percent was higher and statistically significant compared with the baseline rate of 76.1 percent (Table 4). In other words, the rate of prophylaxis omission declined by over 50 percent, from 23.9 percent to 11.1 percent, from baseline to post-intervention.

Both the baseline and post-intervention prophylaxis rates compare favorably to published rates. For example, one study of surgical patients with diagnosed hospital-acquired VTE showed that only 44 percent had received prophylaxis prior to the event.[12]

Despite the efforts applied at the six hospitals, a prophylaxis rate ceiling of approximately 90 percent was found. We have no information on trends in the prophylaxis rate during the post-intervention period, which may be higher or lower. One possible explanation is that the systematic use of prophylaxis takes longer to implement than allowed by the study's observation period. Another reason could be that clinicians perceived patients to be at lower risk or more fully ambulatory than our collection of risk factors—according to the prophylaxis guideline—suggested.

Yet another potential explanation is that the hospital's ability to reliably respond to the identified risk factors is difficult to maintain in the face of staff and trainee turnover. A more effective way to ensure continued compliance with thromboprophylaxis is through a forcing function, such as a mandatory pathway in computerized physician order entry systems (CPOE) or other decision support tools that provide a reminder to clinicians.[13]

In addition, the "right rate" for prophylaxis using any specific guideline may not be 100 percent. By their nature, guidelines simplify patient categorization and clinician choices. As a result, practices that deviate from the guideline might not always be incorrect (in part, one of the factors differentiating guidelines from "rules" or "protocols"). For example, the guideline assumes that virtually all hospitalized patients with risk factors are not sufficiently active for ambulation to serve as the protection from VTE. The guidelines also tend not to explicitly incorporate situations where prevention of VTE is not consistent with goals of care (e.g., end-of-life care targeting comfort and eliminating or minimizing medications).

An opportunity for improved care also exists in reducing the number of patients with a major contraindication to anticoagulants who receive prophylaxis with anticoagulants rather than mechanical devices. In both the baseline and post-intervention periods, more than half of patients with a reported major contraindication to anticoagulants received such prophylaxis. Clinicians might not have noted the presence of or appreciated the significance of the major contraindications to anticoagulant use. While no information is available on the reasons for anticoagulant protocol use among these patients, it is conceivable that some of those receiving pharmacologic prophylaxis in the face of a major contraindication were nevertheless appropriate to receive anticoagulant prophylaxis (e.g., the risk reduction of VTE with anticoagulants instead of mechanical prophylaxis might have exceeded the risk of bleeding).

This study had a number of limitations. The generalizability of our findings is limited by our sample size of only six hospitals. Although the volume of patients at high risk in hospitals is substantial, as illustrated by the number of PE events available for analysis, this small number of hospitals allows only an aggregate level assessment of the effectiveness of the PE intervention. A study population of six organizations does not support meaningful examination of hospital variation in prophylaxis improvement. There is no evidence that among the six study hospitals, a single provider was responsible for the observed improvements in PE prophylaxis. However, it was likely that the diffusion of a standardized protocol for prophylaxis would be uneven and that the impact of the intervention would attenuate at different rates among hospitals. A larger sample

of hospitals with a longer followup period would provide opportunities to examine important variations among hospitals.

The smaller number of patients at the higher level of risk for the selected individual patient characteristics limits our ability to assess the true level of improvement among subsets deriving the greatest benefit from prophylaxis (e.g., patients with hypercoaguable state or heart failure).

We chose to study those patients that experienced a PE to focus hospitals' attention on prevention efforts by analyzing undesired adverse outcomes. This would tend to include more patients at higher risk. Conversely, to the extent that prophylaxis was effective, focusing on patients with PE events could include more patients where prophylaxis was not given or failed for some reason. It is possible that a different population—e.g., all patients at high or moderate risk for thromboembolic disease at the time of admission and prior to any thromboembolic event—would provide a different result, i.e., higher or lower prophylaxis rates.

Conclusion

Venous thromboembolic disease is a life-threatening complication that is potentially preventable. For many years, efforts have been made to increase the utilization of prophylaxis and to improve documentation explaining why prophylaxis was not utilized in a given case, e.g., identify systems barriers or clinical contraindications.

In this study of six New York hospitals agreeing to participate, additional tools were utilized along with additional resources and efforts to increase attention to the occurrence of PE and the appropriate utilization of VTE prophylaxis. Mixed results were achieved. It is not surprising that the largest improvements were achieved in those areas where prophylaxis was lowest. Minimal improvements were noted in areas where prophylaxis was already higher. It is also important to note that little improvement was achieved in reducing the use of anticoagulant prophylaxis in patients with contraindications among those who nevertheless developed a PE.

CPOE was utilized in only a single institution. Although the number of patients with PE was small, this particular hospital did evidence improved rates of prophylaxis. This anecdotal evidence provides hope for further improvement based on both synchronous decision support and improvement in documentation for contraindications.

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