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# Reduction in Venous Thromboembolism Events: Trauma Performance Improvement and Loop Closure Through Participation in a State-Wide Quality Collaborative



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- BACKGROUND:** The Michigan Trauma Quality Improvement Program (MTQIP) is a collaborative quality initiative sponsored by Blue Cross Blue Shield of Michigan and Blue Care Network (BCBSM/BCN). The MTQIP benchmark reports identified our trauma center as a high outlier for venous thromboembolism (VTE) episodes. This study outlines the performance improvement (PI) process used to reduce the rate of VTE using MTQIP infrastructure.
- STUDY DESIGN:** Trauma patients admitted for > 24 hours, with an Injury Severity Score (ISS)  $\geq$  5, were included in this study. We performed a preliminary analysis examining prophylaxis drug type to VTE, adjusted by patient confounders and timing of first dose, using MTQIP data abstracted for our hospital. It showed that patients receiving enoxaparin had a VTE rate that was half that of those receiving unfractionated heparin (odds ratio 0.46, 95% CI 0.25 to 0.85). Guided by these results, we produced the following plan: consolidation to single VTE prophylaxis agent and dose, focused education of providers, initiation of VTE prophylaxis for all patients—with clear exception rules—and dose withholding minimization. Results were monitored using the MTQIP platform.
- RESULTS:** After implementation of our focused PI plan, the VTE rate decreased from 6.2% (n = 36/year) to 2.6% (n = 14/year). Our trauma center returned to average performance status within MTQIP.
- CONCLUSIONS:** Participation in MTQIP provided identification of trauma center outlier status for the outcome of VTE. Analysis of MTQIP data allowed creation of a local action plan. The MTQIP infrastructure supported execution and monitoring of the action plan consistent with loop-closure practices, as advocated by the American College of Surgeons Committee on Trauma, and a positive performance improvement result was achieved with VTE reduction. (*J Am Coll Surg* 2015;221:661–668. © 2015 by the American College of Surgeons)
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Severely injured trauma patients are at increased risk for a venous thromboembolic event (VTE).<sup>1,2</sup> Despite this fact, very little is known about risk-adjusted rates of VTE in trauma centers. The introduction of the American College of Surgeons Trauma Quality Improvement Program

has given trauma centers a means to benchmark process measures such as type of drug and timing of initiation of VTE prophylaxis.<sup>3-6</sup> Within our statewide trauma collaborative quality initiative (CQI) we have focused on provision of feedback on risk-adjusted VTE rates

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### Abbreviations and Acronyms

BCBSM/BCN	= Blue Cross Blue Shield of Michigan and Blue Care Network
CQI	= collaborative quality initiative
LMWH	= low molecular weight heparin
MTQIP	= Michigan Trauma Quality Improvement Program
PI	= performance improvement
VTE	= venous thromboembolism

and comparisons of VTE prophylaxis practices to participating hospitals.<sup>7</sup>

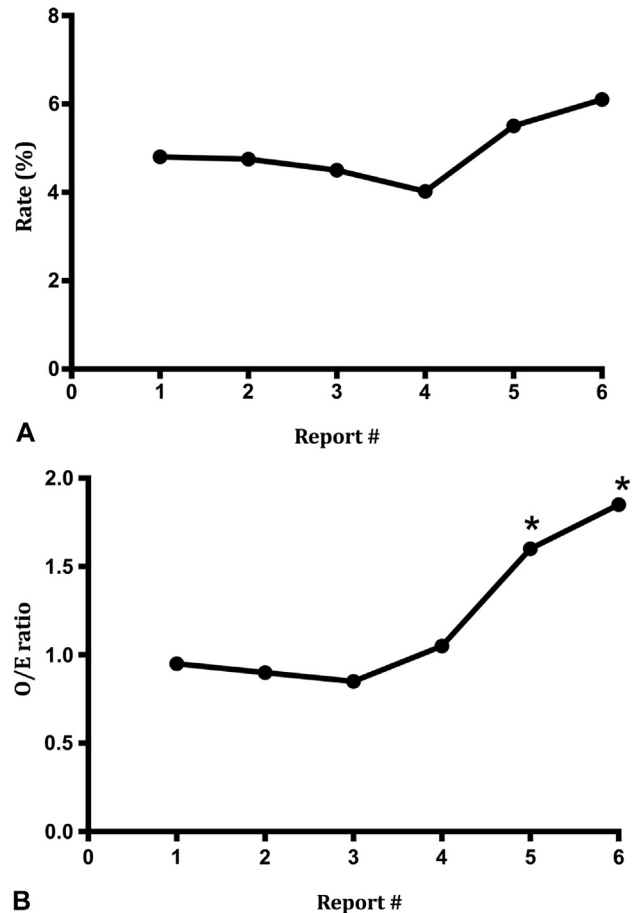
The Michigan Trauma Quality Improvement Program (MTQIP) is a statewide CQI focused on improving trauma care delivery. MTQIP began in 2008 as a pilot program among 6 participating hospitals, and is now a Blue Cross Blue Shield of Michigan/Blue Care Network (BCBSM/BCN)-sponsored CQI that includes 27 American College of Surgeons Committee on Trauma verified level 1 and 2 trauma centers.<sup>5</sup> The program involves regular scheduled face-to-face meetings with all participant trauma centers for information sharing and collaboration, provision of hardcopy and web-based risk-adjusted feedback performance reports, a robust data validation program, and statewide as well as individual hospital-specific quality improvement efforts using baseline outcomes data and defined targets for reduction of adverse events.

For 2 consecutive MTQIP benchmark reports, the University of Michigan Trauma Service was identified as having an increase in VTE events and was denoted as being a statistically significant high outlier within the collaborative (Fig. 1). This triggered a trauma center performance improvement review. The data presented in this manuscript detail the mechanism of inquiring into and exploring MTQIP data to address the question of why we experienced a VTE event increase. We describe the formulation and implementation of an action plan to address the problem of increased VTE events, and subsequent monitoring of our results using information provided as part of participation in MTQIP.

## METHODS

### Michigan Trauma Quality Improvement Program

The University of Michigan Health System initiated data collection for trauma quality improvement in August 2004, using the methodology of the National Surgical Quality Improvement Program (NSQIP). MTQIP began in 2008 as a pilot study among 6 trauma centers in Michigan and expanded into a formal CQI with funding from



**Figure 1.** University of Michigan venous thromboembolic event (VTE) rates during reporting periods before implementation of the VTE action plan. (A) Crude VTE for all patients 18 years and older, admitted to the trauma service, with an Injury Severity Score  $\geq 5$  and at least 24 hours of survival on admission. (B) Risk-adjusted observed-to-expected VTE (O/E) ratio of performance of our trauma center within the Michigan Trauma Quality Improvement Program (MTQIP). \* $p < 0.05$  logit-MTQIP analysis.

BCBSM/BCN in 2011. Data are entered into the existing trauma registry using standardized data elements and definitions for all adult trauma patients.<sup>8</sup> A data definitions manual that is published online is maintained by MTQIP, updated annually, and references already existing national sources (NSQIP, National Trauma Data Standard, and Centers for Disease Control) whenever possible to achieve data consistency.<sup>9,10</sup> Three times per year, face-to-face collaborative meetings are held, at which feedback reports are distributed, data are reviewed, results are discussed, and best practices are shared. Feedback reports are risk adjusted and detail a center's performance with regard to mortality and morbidity. Each report has a two-thirds overlap with data previously analyzed, and

one-third of the patients are newly entered for each block of time covered (1 year).

### Data accrual

Data for analyses were abstracted from the MTQIP database for years 2004 to 2013. Each MTQIP center undergoes an annual data validation audit. Written feedback reports detailing audit performance and areas for improvement are provided. Inclusion criteria to form the analysis patient cohort are as follows:

1. Age  $\geq$  18 years.
2. At least 1 valid trauma International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) code in the range of 800 to 959.9, excluding late effects (905 to 909.9), superficial injuries (910 to 924.9), and foreign bodies (930 to 930.9).
3. Primary mechanism of injury classified as either blunt or penetrating. Blunt is defined as an injury in which the primary E-code is mapped to the following categories: fall, machinery, motor vehicle traffic, pedestrian, cyclist, and struck by/against. Penetrating is defined as an injury in which the primary E-code is mapped to the following categories: cut/pierce, and firearm.
4. Calculated Injury Severity Score (ISS)  $\geq$  5.
5. Emergency department discharge disposition and/or hospital discharge disposition must be known.
6. Hospital admission for  $\geq$  24 hours or death.

Patients with no signs of life at initial evaluation (emergency department systolic blood pressure = 0 mmHg, pulse = 0 bpm, Glasgow Coma Scale Score = 3) were excluded.<sup>5</sup>

### Data analyses

#### Risk-adjusted venous thromboembolism rate

The primary outcome of interest was occurrence of a venous thromboembolic event during hospitalization. The MTQIP coordinating center performs risk and reliability adjustment using a 2-stage approach. Multivariable logistic regression modeling was used to account for differences in baseline characteristics and injury severity, allowing for risk adjustment at the patient level.<sup>10,11</sup> Potential predictors for the outcome of interest on bivariate analysis were entered into the model. A logit equation was derived based on the significant covariates using forward selection. The order of variable entry was determined by the c-index, which measures the ability of a parameter to discriminate outcome. Reliability adjustment used a Bayesian random effects model to account for sample size differences between hospitals. Expected risks of a VTE were calculated for each patient using the modeled

**Table 1.** Multivariate and Propensity Score Analysis of the Michigan Trauma Quality Improvement Program Pilot Data (2004 to 2008) for Venous Thromboembolic Events and Type of Venous Thromboembolic Event Chemoprophylaxis

Analysis, VTE prophylaxis agent	n	DVT		PE		Total VTE*	
		n	%	n	%	n	%
Multivariate, OR 0.46 (95% CI 0.25–0.85)							
SQ heparin	552	41	7.4	14	2.5	49	8.9
SQ enoxaparin	381	13	3.4	5	1.3	15	3.9
Propensity match, OR 0.5 (95% CI 0.26–0.95)							
SQ heparin	345	22	6.4	10	2.9	28	8.1
SQ enoxaparin	345	12	3.5	5	1.5	14	4.1

\*Some patients may have both DVT and PE.

DVT, deep vein thrombosis; OR, odds ratio; PE, pulmonary embolism; SQ, subcutaneous injection; VTE, venous thromboembolic event.

logit equation. Adjusted rates of VTE for each time period were calculated by multiplying the ratio of observed-to-expected events for a hospital by the overall collaborative rate. In some instances, specific incidents had missing values for potentially important covariates (Glasgow Coma Scale motor score, systolic blood pressure, and pulse rate). Because missing data were not absent randomly, these missing values were imputed using multiple imputation techniques to minimize bias.

#### Effect of type of prophylaxis on venous thromboembolism rate

Data used in this analysis consisted of University of Michigan MTQIP data from August 2004 to July 2005 and August 2006 to July 2008. Date and type of first dose of chemical VTE prophylaxis was abstracted at the time of entry into the trauma registry and was available for analysis in this dataset. Date of diagnosis for a pulmonary embolism or deep VTE event was also recorded. Excluded were patients who died before hospital admission or did not receive any chemical VTE prophylaxis during their hospital stay. Patients who had systemic heparin or other systemic anticoagulation agents as their first dose type were also excluded. The type of chemical VTE prophylaxis (heparin 5,000 units tid vs enoxaparin 40 mg qd) was evaluated using multivariate logistic regression to adjust for confounding variables. Propensity scores were generated and type of VTE prophylaxis was also compared in a 1:1 propensity score-matched cohort using matched pairs analysis.<sup>11</sup> Statistical analyses were performed using Stata 12.0 software (StataCorp). This study was reviewed and received approval notification from IRBMED of the University of Michigan Health System, HUM00041947. All privileged medical information is

encrypted and protected, following institutional, state, and federal regulations.

## RESULTS

### The problem

In the MTQIP report issued on October 11, 2011 (Report #5, data from November 2009 to October 2010), the University of Michigan Trauma Center was a high outlier for VTE, with a crude rate of 5.6% (Fig. 1). Previously, we exhibited average performance, with a VTE rate between 4% and 4.8% and a 1.0 observed-to-expected ratio of events. In the next report, issued February 14, 2012 (Report #6, data from February 2010 to January 2011), our center had an even higher crude VTE rate of 6.0%, which triggered our investigation, analysis, and performance improvement action plan.

### The response

The response to these MTQIP reports consisted of a review of the data by the MTQIP Surgical Champion, the Trauma Medical Director, and the Director of the Trauma and Burn ICU. A list of potential circumstances responsible for this increase in VTE events was compiled.

1. De-emphasis by providers in choosing enoxaparin 40 mg qd as the preferred agent for VTE prophylaxis for trauma patients.
2. Electronic patient order entry pick-list placement of the order for 5,000 units of subcutaneous heparin tid first and enoxaparin 40 mg qd second for trauma patient VTE prophylaxis.
3. Potential poor compliance with timely initiation of VTE prophylaxis once bleeding contraindications were alleviated.
4. No feedback on results or measurement of compliance with the existing trauma service guideline for VTE prophylaxis.
5. Excessive holding of VTE prophylaxis drug doses due to uncertainty surrounding operative interventions and procedures.

It was decided to retrospectively abstract VTE prophylaxis drug type and timing for patients in a previous early set of MTQIP data. An analysis was then conducted to examine the relationship of drug type with adjustments made for timing of the first dose of VTE prophylaxis.

### Data analysis

Patients receiving enoxaparin experienced half the rate of VTE events when compared with those who received

heparin after multivariate adjustment (Table 1). The same finding was obtained in the propensity-matched cohort.

### The plan

After accounting for injury severity and patient factors, prophylaxis with enoxaparin was associated with a significantly decreased rate of VTE events compared with heparin for patients admitted to our trauma center. This preliminary analysis was shared with trauma service faculty, the Office of Clinical Affairs, and the hospital VTE subcommittee in the winter/spring of 2012. An education session for providers was held with William H Geerts, MD, an expert on VTE prophylaxis, during a visit to the Michigan Surgical Quality Collaborative—another BCBSM/BCN-sponsored CQI—specifically in regard to evidence supporting the use of enoxaparin (low molecular weight heparin [LMWH]) dosing of 30 mg bid in trauma patients.<sup>12</sup> Our standard at that time was a single, 40-mg qd enoxaparin dose with morning administration. However, the use of a single morning dose operationally led to 48- to 72-hour lapses in VTE prophylaxis coverage, especially if a dose had been held for procedures. Review of CQI data at MTQIP meetings and survey results showed many trauma centers to be preferentially using LMWH as their chemical prophylaxis agent. Additionally, an article published by an MTQIP participant trauma center showed that traumatic brain injured patients can safely receive VTE prophylaxis once a stable clinical and radiologic exam is achieved.<sup>13</sup> The following action plan was formulated and initiated in May 2012:

1. One drug for VTE prophylaxis: enoxaparin
2. One dose: 30 mg bid (AM and PM timing)
3. Education and inclusion of subspecialty providers (neurosurgery and orthopaedics).
4. The only exceptions to initiating VTE prophylaxis were bleeding contraindication, unstable traumatic brain injury/epidural hematoma, or low-risk patient (ambulatory and likely to be discharged home).
5. We aimed to minimize holding of drug doses. For a next day procedure, the last dose is 30 mg, given in the evening the day before a scheduled procedure. The dose in the morning on the day of the procedure is held. Dosing is resumed in the evening of the day of procedure unless problems are encountered (bleeding).
6. Monitoring of VTE prophylaxis drug type and timing of first dose given was conducted using the MTQIP data platform.

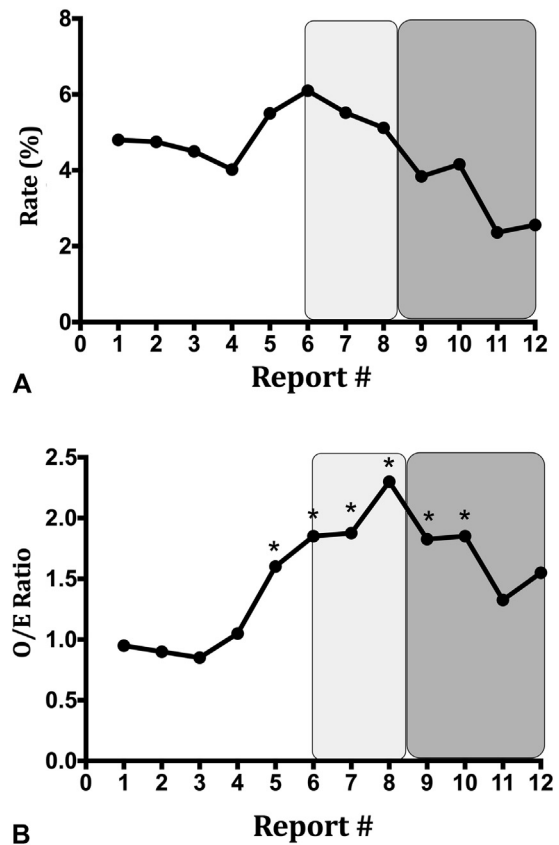
### Monitoring the action plan and sustaining the result

After intervention, the crude VTE rate decreased from 6.2% ( $n = 36/\text{year}$ ) to 2.2% ( $n = 14/\text{year}$ ), and subsequent MTQIP feedback reports (Report #11, data from November 2011 to October 2012) showed a return to average performance and elimination of high-outlier for VTE events status (Fig. 2). Web-based MTQIP dashboard reports allowed us to monitor compliance with our action plan after its implementation, by semester of queried year. From a safety standpoint and as can be seen in Figure 3, selection criteria of patients for no-VTE prophylaxis appeared appropriate given that few patients in this group have suffered any VTE event. The use of enoxaparin as the preferred VTE prophylaxis drug has significantly increased in concert with a decline in the use of heparin and withholding of chemoprophylaxis (Fig. 3). The incidence of VTE events remains considerably higher in the heparin group compared with the LMWH group. Additionally, there has been steady improvement in timely administration; the first dose of VTE prophylaxis for patients is given within 48 hours of admission (Fig. 4). Implementation of our performance improvement program for VTE prophylaxis allowed us to shift from high outlier status (2010) to average performance (2013) within the collaborative (Fig. 5).

### DISCUSSION

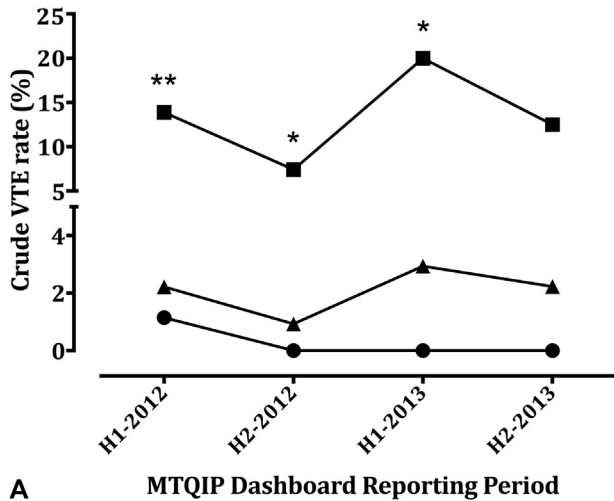
Using performance improvement methods outlined in the Resources for Optimal Care of the Injured Patient<sup>14</sup> manual, we were able to successfully identify a problem with VTE in our patients, address the problem, and reduce our rate of VTE on the trauma service. Unique to our use of the continuous performance improvement (PI) process was the integration of results and monitoring derived from a statewide quality collaborative initiative into the PI cycle consisting of recognition, assessment, and correction. Benchmarking within MTQIP allowed for continuous risk adjustment, identification of outlier status, consultation with peers about best practices, and monitoring results after implementation of the formulated action plan.

Evidence-based medicine is a powerful tool for guiding therapeutic choices in a hospital system. However, many factors can arise that are unique to each individual institution and present barriers to consistent implementation. We were well aware of the published work of Kahn and associates<sup>4</sup> and Geerts and colleagues<sup>12</sup> outlining the superiority of LMWH to prevent VTE events in trauma patients. Our trauma service elected to use the LMWH enoxaparin as the preferred agent in trauma patients

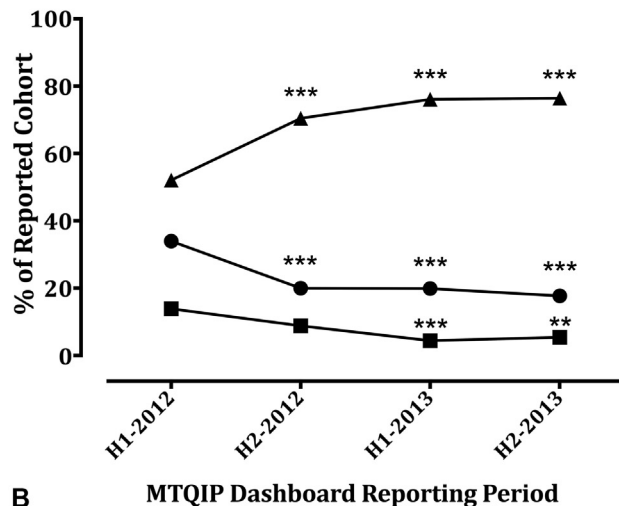


**Figure 2.** Stepwise phase implementation of venous thromboembolic event (VTE) Action Plan at the University of Michigan Trauma Service showed a favorable outcome in VTE rates. (A) Impact on crude VTE rates per Michigan Trauma Quality Improvement Program (MTQIP) feedback reporting period. (B) Risk-adjusted observed-to-expected VTE (O/E) ratio of performance of the University of Michigan within the MTQIP collaborative. Light gray box, investigation phase, design, education, and promotion; gray box, implementation of VTE Action Plan. \* $p < 0.05$  logit-MTQIP analysis.

who required VTE chemoprophylaxis. However, we encountered 3 major obstacles in full implementation of this practice. First, our hospital declined to offer 30 mg twice per day dosing on the basis of presumed equivalency with 40 mg once per day dosing of enoxaparin and pharmacy concerns over cost. Second, when a new institutional electronic order entry system went into effect, unfractionated heparin 5,000 units subcutaneously 3 times per day, was listed as the first option in the pick list, followed by LMWH. Last, our neurosurgical service had published a clinical trial of enoxaparin use initiated preoperatively in craniectomy patients with cancer; the trial found that LMWH increased the rate of postoperative intracranial hemorrhage compared with mechanical prophylaxis alone.<sup>15</sup> However, this trial was an observational retrospective study that was not conducted in



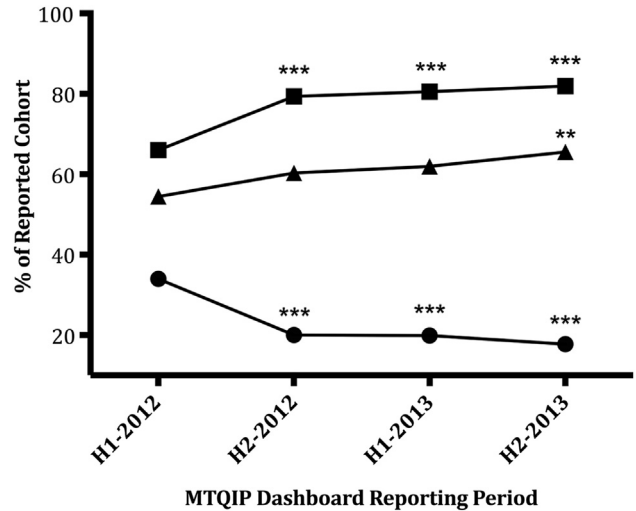
**A** MTQIP Dashboard Reporting Period



**B** MTQIP Dashboard Reporting Period

**Figure 3.** Michigan Trauma Quality Improvement Program (MTQIP)-dashboard webpage allowed continued monitoring after implementation of the VTE Action Plan at the University of Michigan Trauma Service. (A) Crude VTE rate per VTE prophylaxis type, Fisher exact test of subgroup vs combination of other modalities; \* $p < 0.05$ , \*\* $p < 0.01$ . (B) VTE chemoprophylaxis usage. Fisher exact test of current reporting period vs start of program; \*\* $p < 0.01$ , \*\*\* $p < 0.001$ . Triangle, low molecular weight heparin; square, heparin; circle, no chemoprophylaxis. H1, first half; H2, second half; VTE, venous thromboembolic event.

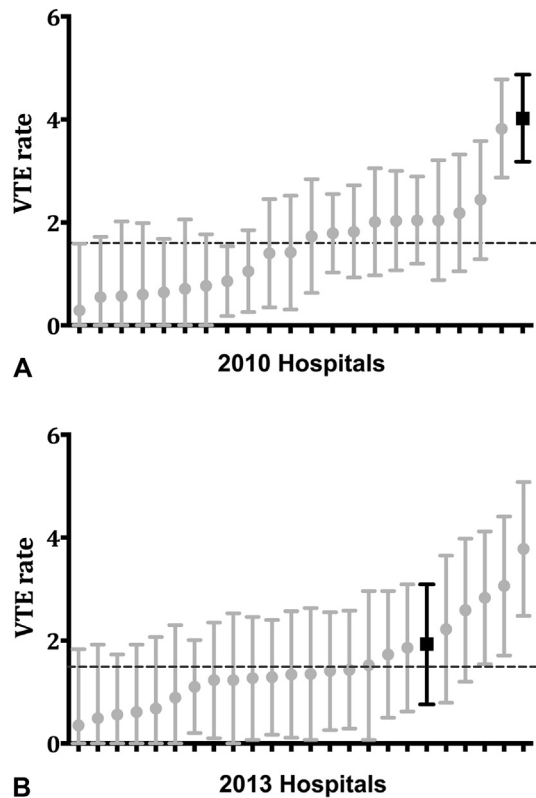
trauma patients and did not compare LMWH with unfractionated heparin. Nevertheless, extrapolation of these results to traumatic brain injured patients in the trauma setting did occur. All of these factors combined to produce the clinical picture outlined in the data such that the trauma service usage of unfractionated heparin increased and that of LMWH decreased despite this being at odds with our internal protocol.



**Figure 4.** Implementation of the venous thromboembolic event (VTE) Action Plan showed an improved compliance of program goals (reduction of withholding VTE chemoprophylaxis, increase in VTE chemoprophylaxis usage, and start of VTE chemoprophylaxis within 48 hours of admission). Fisher exact test of current reporting period vs start of program; \*\* $p < 0.01$ , \*\*\* $p < 0.001$ . Circle, no chemoprophylaxis; square, VTE prophylaxis; triangle, VTE prophylaxis < 48 hours of admission. H1, first half; H2, second half; MTQIP, Michigan Trauma Quality Improvement Program.

Measurement alone does not change behavior. This has been illustrated by 2 recent publications citing NSQIP data.<sup>16,17</sup> It is not really a surprise because the “report” has very little to do with the heavy lifting required to successfully implement performance improvement. Donald Berwick stated, in his editorial comments to these 2 articles, that capturing local individual stories and within-organization trends is as important as calculating p values for relative differences between groups.<sup>9</sup> Risk-adjusted reports serve as a dashboard warning light and are useful in subsequent monitoring. It is up to the clinician to dive into the data, interpret the findings, and formulate a rational performance improvement action plan if a problem truly exists. Reading reports and then placing them on the coffee table in the office is unlikely to move the quality improvement dial. Instead, it is important to identify a specific problem, publicize it, develop an action plan based on data and diverse input, and be aware of barriers to implementation.

The MTQIP is focused not only providing information on risk-adjusted outcomes, but also on processes used in caring for trauma patients. This allows for critical analysis of differences between hospitals and in relation to the mean that can drive performance improvement by providing answers on “what to do.” Important components of the program, which continues to evolve, include



**Figure 5.** Implementation of VTE Action Plan showed a return to average performance for VTE rates from hospitals in (A) 2010 compared with (B) 2013 for the University of Michigan within the Michigan Trauma Quality Improvement Program (MTQIP) collaborative. Bold bar, University of Michigan. VTE, venous thromboembolic event.

scheduled meetings in which data are unblinded and discussed openly among peers, selection of group and individual site-specific quality improvement projects with setting of baseline and target data, use of detailed reporting that focuses on processes of care in addition to outcomes, and a strong robust annual data validation program. Funding is provided by BCBSM/BCN, which has access to aggregate, but not site-specific, data.

This study has several limitations, which must be acknowledged. The methodology used to screen and diagnose trauma patients with VTE events varies among trauma centers.<sup>2,18-21</sup> The University of Michigan trauma service VTE assessment protocol is focused on obtaining studies in symptomatic patients. If we clinically suspect a pulmonary embolus, a CT pulmonary angiogram and/or extremity deep venous thrombosis scan is obtained. In patients with unexpected unilateral extremity swelling, on physical exam or subjective history, an extremity deep venous thrombosis scan is obtained. No formal changes were made to our VTE assessment protocol during the

historic or study time periods. Second, there is the possibility of a Hawthorne or observer effect occurring, whereby clinicians modified their behavior in response to being observed alone.<sup>22-24</sup> Third, we do not know exactly which components of our 6-part action plan were specifically responsible for reducing the VTE rate. We also do not know the individual impact or weight of each part of the action plan. Last, whether or not this change in reducing the VTE rate is sustainable is an open question. Ongoing monitoring of MTQIP data up to November 1, 2014 demonstrated a crude VTE rate of 2.3% for the University of Michigan. All of these discussed limitations illustrate representative difficulties encountered when conducting a quality improvement project in the clinical setting.

## CONCLUSIONS

The most important message of this study was not the reduction of VTE rates by a single hospital, but instead, the process involving statewide CQI-derived information that allowed identification of a clinical problem, consultation on solutions with peers and experts, deployment of an action plan, and evaluation of outcomes to monitor results and sustain progress. This process is consistent with loop closure PI practices advocated by the American College of Surgeons Committee on Trauma and is an example of the power of statewide or regional CQI programs to achieve quality improvement.

## Author Contributions

Study conception and design: Machado-Aranda, Jakubus, Wahl, Cherry-Bukowiec, To, Park, Raghavendran, Napolitano, Hemmila

Acquisition of data: Machado-Aranda, Jakubus, Hemmila  
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Critical revision: Machado-Aranda, Hemmila

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