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SPECIFIC AIMS:

Pay for performance and public reporting of quality are growing exponentially. Yet, implicit in these systems is the assumed presence of a valid measure of clinical quality. Identifying valid outcome measures is challenging and requires a surveillance system to capture numerators (number of events) and denominators (number of patients at risk). Surveillance is increasingly important when events are clinically silent (not detected on routine examination), but have the potential for devastating consequences. Surveillance bias (also known as ascertainment or detection bias) may occur when one group is followed more closely than another group. Rates of events identified and reported may merely reflect levels of vigilance.

Deep vein thrombosis (DVT) is a significant cause of morbidity and mortality in trauma patients, even with appropriate prophylaxis. DVT may be completely asymptomatic until the clot embolizes and causes sudden death from massive pulmonary embolism (PE).

Many national agencies (AHRQ, JCAHO, NQF) have suggested DVT incidence as a metric of health care quality, but none has recommended a standardized screening approach. Duplex ultrasound serves an important role as a noninvasive diagnostic tool for detection of DVT. However, screening asymptomatic trauma patients for DVT is somewhat controversial and these practices likely vary widely among trauma centers.

In the absence of standardized surveillance, DVT rates may be influenced more by how often caregivers look for these events rather than the quality of care provided, a classic example of surveillance bias. Higher DVT rates may not be a marker of poor quality of care, but rather an outcome of more aggressive screening practices. Providers who look harder by ordering more duplex ultrasounds, may report higher rates of DVT, and appear to provide poorer quality of care than those providers who order fewer duplex ultrasounds. The effect of surveillance bias on estimates of the quality of care can result in misinformation and cannot be ignored.

We hypothesize that significant inter-hospital variation in practice patterns exist related to screening asymptomatic trauma patients for DVT. This variation may lead to surveillance bias in rates of DVT reported. Therefore, DVT rates reported (and potentially used for pay-for-performance initiatives and hospital benchmarking) may be unreliable.

SA1) To examine the impact of hospital-level ultrasound rates on DVT rates reported after major trauma.

1A) To confirm variations across hospitals in hospital-level rates of duplex ultrasound performed after major trauma.

1B) To examine the correlation between hospital-level duplex ultrasound rates and DVT rates reported after major trauma.

SA2) To determine whether hospital duplex and DVT rates correlate with the presence of a hospital duplex ultrasound screening protocol for high-risk trauma patients.

SA3) To determine if patients are more likely to have DVT diagnosed and reported based on hospital characteristics, controlling for known patient-level DVT risk factors.

3A) To determine if trauma patients are more likely to be diagnosed with DVT depending on if treatment is received at hospitals with higher rates of duplex ultrasound.

3B) To determine if trauma patients are more likely to be diagnosed with DVT depending on if treatment is received at a hospital with a protocol for screening high-risk asymptomatic trauma patients for DVT with duplex ultrasound.

BACKGROUND AND SIGNIFICANCE

The Institute of Medicine's report, Crossing the Quality Chasm, released in 2001, identified, measurement of outcomes and performance as one of its recommendations for improving health care quality. (1) The Agency for Healthcare Research and Quality (AHRQ) in line with the recommendations of the IOM has identified four main priority areas of research, including "Patient Safety and Quality" as well as "Payment and Organization." (2) Within these priority areas, research is encouraged to study threats to patient safety, how to capture this information, and how to incentivize improvement of these problems.

Post-operative Deep Vein Thrombosis (DVT) has been identified as a marker for quality of care, and is listed by the AHRQ as one of its Patient Safety Indicators (PSI). The National Quality Forum as well as other consumer organizations have also listed DVT as a potential indicator of quality. (3-4) However, identifying measures of quality through evidence-based medicine remains difficult, and has resulted in significant controversy.

DVT has been considered a quality metric, mainly because the majority of hospital DVTs and the subsequent sequelae are considered preventable with appropriate prophylaxis. DVT prophylaxis is aimed at preventing further complications including, pulmonary embolus, the most serious complication, as well as permanent swelling and venous insufficiency. Incidence rates for DVT in trauma patients reported in the literature vary widely (0.36% to 58%), and depend significantly on diagnostic procedures, equipment, patient demographics, severity of injury, medications, among other factors. (5-10) The Eastern Association for the Surgery of Trauma (EAST) guidelines regarding the prevention of venous thromboembilism after trauma are clear on the suggested mechanical and chemical prophylaxis for DVT.

However, these well accepted guidelines do not clearly state that duplex ultrasound should or should not be used for screening asymptomatic trauma patients. (11) Ongoing debate continues regarding the screening of asymptomatic trauma patients for occult DVT due to conflicting studies on the topic. Some studies indicate that routine screening of asymptomatic patients in high-risk populations may have some benefit. (12-15) The benefit may be seen in patients who have their DVT identified early, who can be treated appropriately to avoid fatal pulmonary embolism and the long-term sequelae after DVT. Brasel et. al. suggests that routine screening for DVT with ultrasound is more cost-effective in preventing PE than not performing any intervention or inserting prophylactic vena cava filters. (16) Other authors claim that screening of asymptomatic patients is not warranted. Cipolle et al. (17) suggested that strict adherence to DVT prophylactic guidelines makes more of a difference than screening ultrasounds in the prevention of venous thromboembolism (VTE), but also mentions that screening ultrasounds may have been effective in preventing PE in the population studied. Other studies emphasize that routine screening is cost prohibitive (18-20) These studies agree with the conclusion that in the presence of appropriate prophylaxis, routine surveillance in high risk patients is not cost-effective or is not effective in preventing clinically relevant VTE. One study concludes that ultrasound should be reserved for symptomatic or spinal injury patients only. (21)

As a result, there is anecdotal evidence that there are wide practice variations in the use of screening duplex ultrasound for DVT in high-risk asymptomatic trauma patients. It has been suggested that DVT rates may vary among hospitals because of variations in screening practices alone and that DVT rate is much more a function of surveillance bias than an indicator of quality. (22) Surveillance bias is a type of selection or information bias that occurs when an exposure (duplex ultrasound) may result in a higher probability of detection (of DVT) in exposed patients. (23) Szklo and Nieto (23) give the example of a case-control study examining the relationship between oral contraceptives and diabetes. Patients taking oral contraceptives have more healthcare contact than similar patients who do not take oral contraceptives. As a result, the patients taking oral contraceptives who have subclinical diabetes are more likely to have their disease identified due to their higher frequency of medical encounters. This can result in the false conclusion that oral contraceptives are associated with diabetes. Surveillance bias causes any data acquired and reported to be called into question.

Measuring quality in healthcare is at the foreground in American medicine. Many national providers are implementing pay-for-performance programs. The AHRQ is playing a major role in determining quality measures (including DVT) used in such a program. The AHRQ currently suggests methods of risk stratification when using the DVT as a quality metric, however, this may not be sufficient to overcome the problem of surveillance bias. DVT rates may be more influenced by how often caregivers look for these events rather than the quality of care provided. Providers who screen more aggressively by ordering more duplex ultrasounds may identify more cases of DVT and appear to provide worse quality of care than those providers who order fewer duplex ultrasounds. The use of DVT rate as an independent indicator of quality of care metric for hospital benchmarking and for pay-for-performance programs may be questionable.

PRELIMINARY STUDIES

Our first exploratory analysis of the hypothesis that DVT rates reported may be related to rates of screening asymptomatic patients for DVT with duplex ultrasound was presented at a national trauma meeting, The Eastern Association of the Surgery of Trauma (EAST), in January 2007 and was published in the Journal of Trauma in November 2007. We performed a retrospective review of trauma registry and hospital discharge data from a single academic level 1 trauma center. (22,24) Patients admitted to the Adult Trauma Service were divided into two groups, those admitted before and those admitted after implementation of a written guideline for DVT prophylaxis and duplex ultrasound screening of asymptomatic high-risk patients. Data were compared between these two groups. Significantly more duplex ultrasound exams were performed in the later period (20.9 vs. 81.5 per 1000 trauma admissions, $p<0.0001$). This outcome was expected based on the implementation of our new guideline. The proportion of DVTs diagnosed increased 10-fold between periods (0.7 to 7.0 per 1000 admissions, $p=0.0024$). (figure 1) We propose that these data are evidence of the presence of surveillance bias. We actively screened asymptomatic patients and therefore identified a higher proportion of DVTs. This preliminary study has some limitations. It was performed in a single institution, which may not see a representative population of trauma patients. The study was a retrospective analysis based on trauma registry data, which may not have recorded all DVT/PE diagnoses, and hospital discharge data that may have missed some duplex studies performed. We also were unable to completely control for patient characteristics which are known to influence DVT rates. We did identify some differences between patient groups, but these small patient differences alone (age, gender, and penetrating rate) cannot fully explain a 10-fold increase in DVT rate. This preliminary data was published by [redacted] in JAMA as an example of "whether the benefits of measurement outweigh the costs." (22) Payers and policy makers will have to make difficult decisions such as this and may need to invest significant resources to identify valid measures of quality. (27 [redacted] also recently cited this paper and stated that "aggressive screening strategies can markedly increase case-finding rates without an effect on quality of care. The absence of a standardized surveillance system could lead to a spurious association between more preventable harm and lower-quality care." (28)

Our next preliminary study was presented at the foremost national trauma meeting, The American Association of Trauma Surgery (AAST), in September 2007 and is accepted for publication in the Journal of Trauma. It was also the focus of an article about our research team entitled "Screening Variances Skew Interpretation of DVT Rates" in Surgery News, The Official Newspaper of the American College of Surgeons. (29) This route of investigation was a hospital level analysis of duplex ultrasound and DVT rates in the largest trauma database available, the National Trauma Data Bank (NTDB). We divided hospitals into quartiles based on their rates of DVT per trauma patient admission and compared the DVT rate reported from hospitals in each quartile. Hospitals in the highest quartile by duplex rate reported a DVT rate 7-fold higher than the average DVT rate in the first three quartiles (1.52% vs. 0.22%, $p<0.001$) (figure 2). One plausible explanation for the large disparity in DVT and ultrasound rates between quartiles was practice variation between hospitals in screening asymptomatic trauma patients. The DVT rate increased significantly and correlated with duplex ultrasound rate at hospitals that had a 2% or greater ultrasound rate. Among hospitals with a duplex rate of 2% or greater, we estimated that the median DVT rate increases by +1.07% for every 1% increase in duplex rate after controlling for trauma level and teaching status (95% CI: 1.05, 1.09) $p<0.001$. (figure 3) At hospitals with less than a 2% ultrasound rate, there was no significant association between DVT and duplex ultrasound rates. This study also has some inherent limitations. There was only a subset of hospitals available (n=147 hospitals, n=578,252 patients) for analysis due to trauma centers which do not report duplex ultrasound and/or complications (neither of which is a mandatory data field). The study was on a hospital aggregate level only and did not attempt to control for any patient level factors, which may also influence DVT rates. (25)

These two preliminary studies have raised many new questions. The importance of this topic was recently highlighted in an invited editorial of the Society of Critical Care Medicine. (30) EAST meeting participants and reviewers of the manuscript based on the first preliminary study emphasized the potential differences in patient populations and individual patient characteristics which may influence rates of DVT after trauma. We agree with these valid points and propose to answer these questions by performing specific aim 3. We will control for patient characteristics (such as age, gender, injury severity score, injury mechanism, procedures, and comorbidities) and examine the independent predictive value of duplex ultrasound screening rates on DVT identification. The NTDB is the ideal database in which to do this because of its large size and that it contains the necessary data pertaining to individual patient characteristics. NSCOT may be another excellent resource since its stringent entry criteria and standardized data reporting mechanisms should lead to much less missing data than the other national databases.

Figure 1 The comparison of rates of trauma patients having a duplex ultrasound and diagnosed with Deep Vein Thrombosis (DVT) per year increased significantly ($p<0.0001$ and $p=0.0024$ respectively) between the periods before vs. after implementation of a written guideline for DVT surveillance.

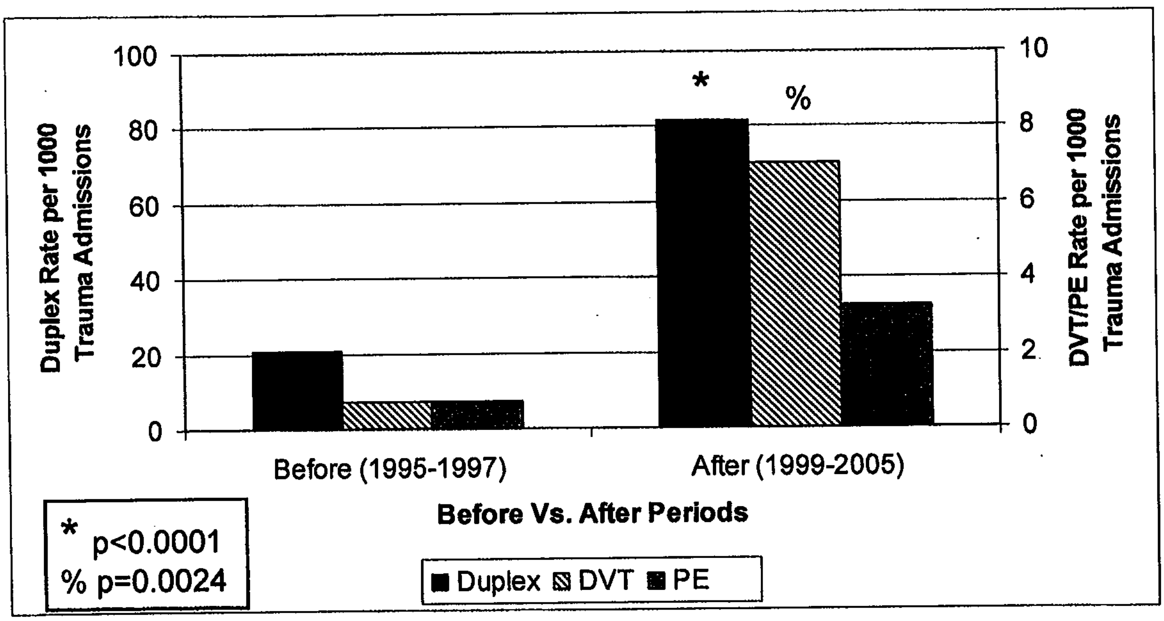

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Figure 2. NTDB Hospitals were divided into quartiles based on duplex ultrasound rates. Average deep vein thrombosis (DVT) rates were graphed by quartile. The DVT rate in the highest quartile was 7-fold higher than the average combined DVT rate in the first three quartiles (1.52% vs. 0.22%, p<0.001).

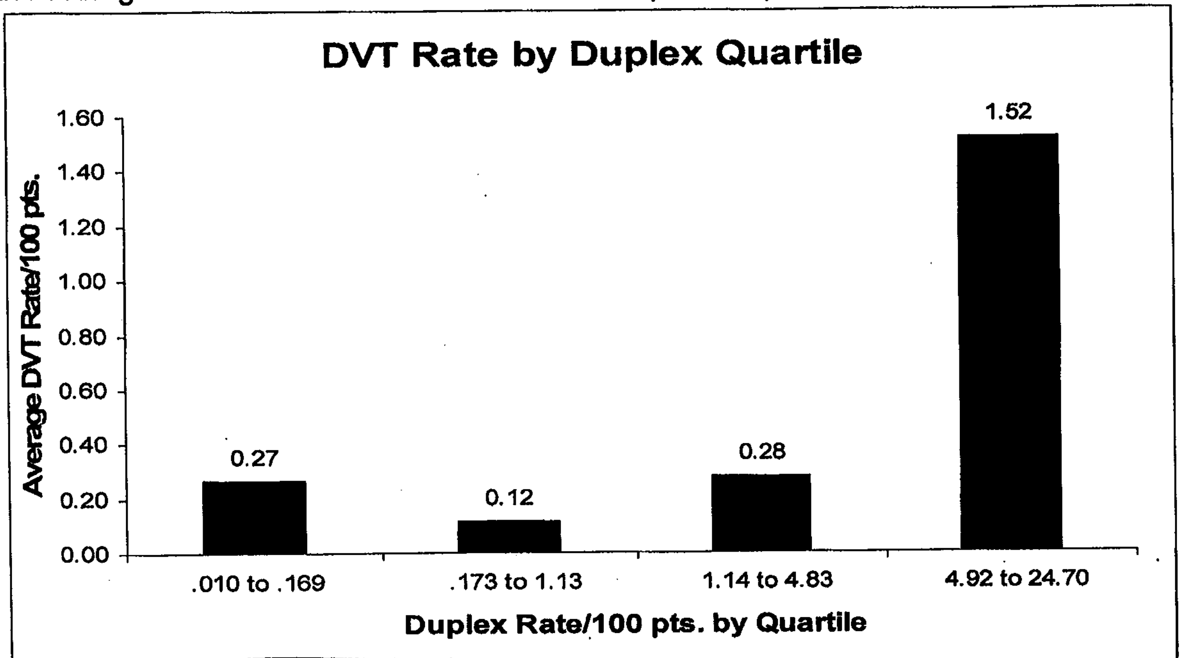

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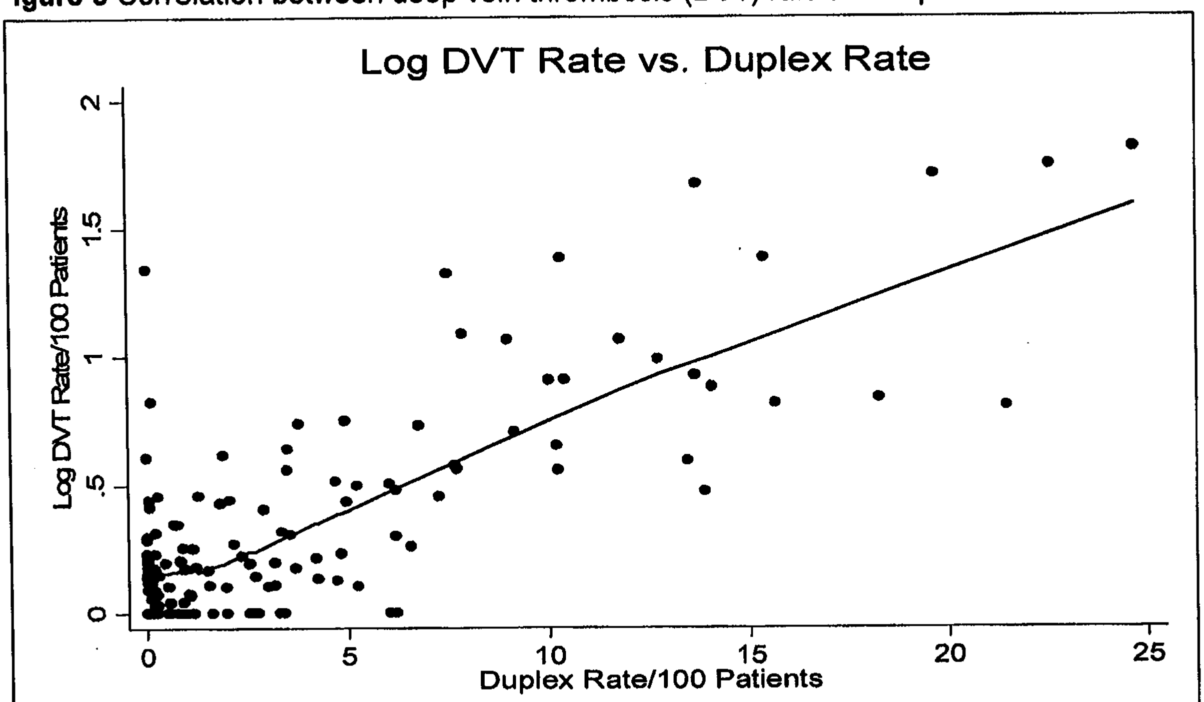
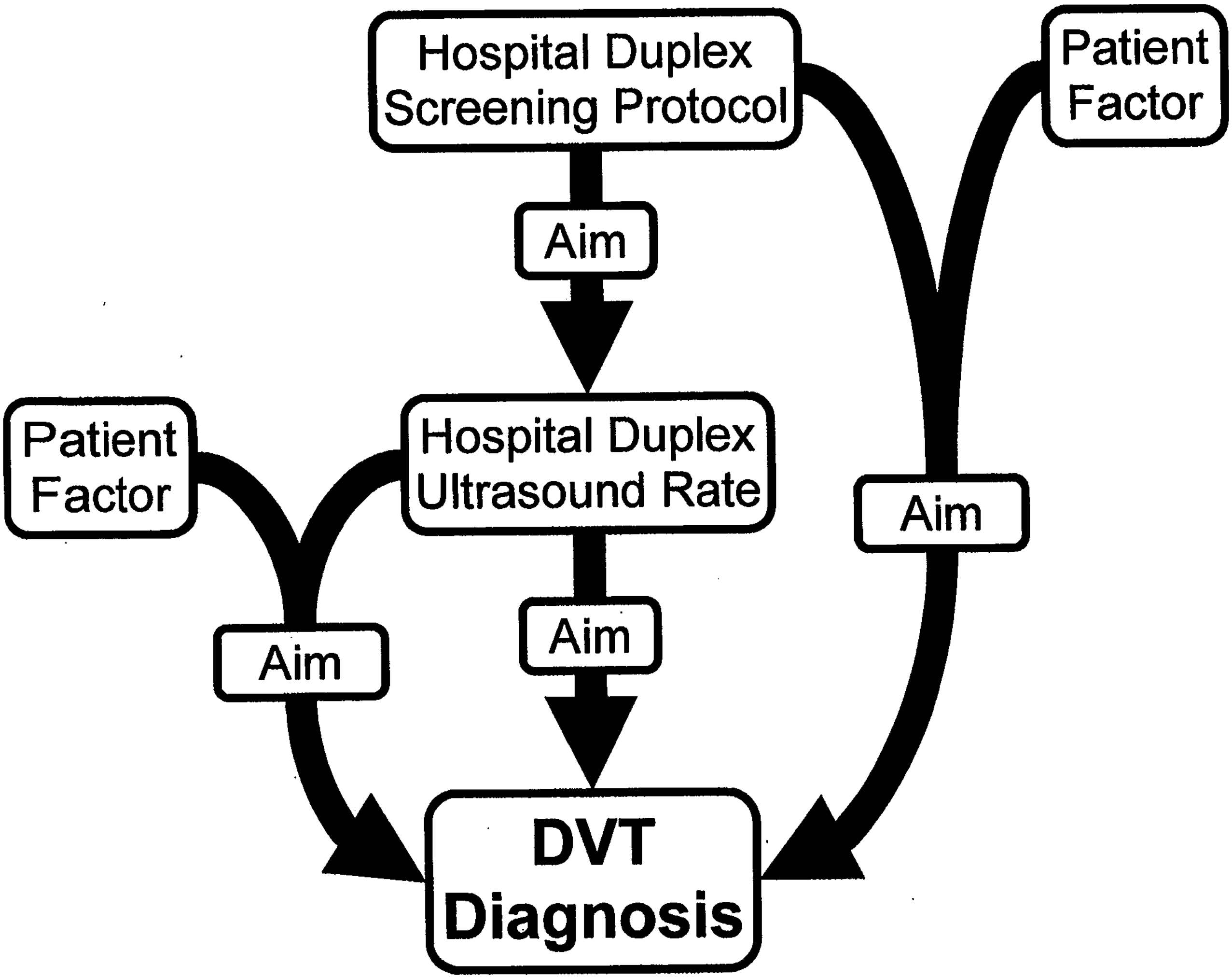
Figure 3 Correlation between deep vein thrombosis (DVT) rate and duplex ultrasound rate at NTDB hospitals.



From Pierce CA, Haut ER, Kardooni S, Chang DC, Efron DT, Haider AH, Pronovost PJ, Cornwell 3rd EE. Deep vein thrombosis surveillance patterns in the National Trauma Data Bank: The more we look, the more we find. J Trauma. 64:932–937, 2008).

RESEARCH DESIGN AND METHODS

This study will involve secondary data analysis of multiple databases, utilizing the unique strengths of each different database to answer different questions. The hypotheses of this study are based on the following conceptual framework:



Specific Aim 1: To examine the impact of hospital-level ultrasound rates on DVT rates reported after major trauma.

Both sub-aims of Specific Aim 1 will be performed on a hospital-level unit of analysis to replicate the current ongoing national agendas, which suggest that unadjusted hospital-level DVT rate alone can be used to measure quality of care.

Specific Aim 1A: To confirm variations across hospitals in hospital-level rates of duplex ultrasound performed after major trauma.

The Nationwide Inpatient Sample (NIS) will be used for this specific aim to confirm our previous findings using the National Trauma Data Bank (NTDB). The NIS is a representative 20% sample of hospital discharge records from 37 states, which includes both trauma and non-trauma centers, in contrast to the NTDB which includes only trauma centers. We have already obtained an exemption for analysis of the NIS from the Institutional Review Board at Johns Hopkins. Trauma patients will be identified per commonly used methodology, by ICD-9 diagnosis codes of 800-959 in the primary position, excluding 905-909 (late effects of injury), 930-939 (foreign body), 940-949 (burn), and 958 (early complications of trauma). The outcome of interest will be the occurrence of duplex ultrasound, as identified by ICD-9 procedure code 88.77, "Dx Ultrasound-Vascular," in any procedure field. Rates of duplex ultrasound per 100 patient admissions will be calculated for each hospital, and the variation in these rates will be described.

Specific Aim 1B: To examine the correlation between hospital-level duplex ultrasound rates and DVT rates reported after major trauma.

The NIS database will be used again for this specific aim. Trauma patients will again be identified by ICD-9 diagnosis codes of 800-959 in the primary position, excluding 905-909, 930-939, 940-949, and 958. The outcome of interest will be the rates of DVT reported for each individual hospital, as identified by ICD-9 diagnosis codes of 451.11, 451.19, 451.2, 451.81, 451.9, 453.40, 453.41, 453.42, 453.8, 453.9, in any field, among trauma patients at that hospital. The primary independent variable will be rates of duplex ultrasound performed at each hospital, as defined and calculated in specific aim 1A by procedure code 88.77 in any procedure field. Association between the duplex ultrasound performance and DVT rates reported will be assessed and quantified using graphical displays, measures of correlation (Spearman rank correlation coefficient) and Poisson regression models.

Specific Aim 2: To determine whether hospital duplex and DVT rates correlate with the presence of a hospital duplex ultrasound screening protocol for high-risk trauma patients.

A valid issue that has been raised by manuscript and grant reviewers as well discussants at two national meetings is the question of whether duplex ultrasounds were indeed done for screening asymptomatic high-risk trauma patients or whether they were done for patients with symptoms. This question cannot be addressed using the NTDB since no data exists regarding this issue on either a patient or hospital level in this data set. However this limitation within the NTDB can be overcome by performing an analysis of the National Study on Costs and Outcomes of Trauma (NSCOT) data. NSCOT was conducted in 69 hospitals (18 trauma centers and 51 non-designated hospitals) in 14 states. This large prospectively collected database contains information on hospital and patient-level characteristics. There are several reasons to use the NSCOT database instead of the NTDB. First, the NSCOT database has a hospital level variable, obtained prospectively from hospital surveys, which defines whether a hospital has a duplex screening protocol or guideline. Second, the NSCOT study had stringent entry criteria and standardized data reporting mechanisms which should lead to much less missing data than the other national databases.

The NSCOT database allows us to correlate and thus validate the reported hospital ultrasound rate with the reported hospital ultrasound screening practice. Hospital-level ultrasound rate will be calculated as before, by dividing the counts of patients with at least one vascular ultrasound (ICD-9 procedure code of 88.77), by the total number of trauma patients treated at that hospital. We hypothesize that the reported ultrasound rates and DVT rates reported at hospitals that have a routine ultrasound screening protocol to be significantly higher than rates at hospitals that reported not having such a protocol. We will test for differences using the relative rate of ultrasounds and DVT diagnosis comparing hospitals that report having a routine ultrasound screening protocol to those who do not.

Specific Aim 3: To determine if patients are more likely to have DVT diagnosed and reported based on hospital characteristics, controlling for known patient-level DVT risk factors.

Specific Aim 3A: To determine if trauma patients are more likely to be diagnosed with DVT depending on if treatment is received at hospitals with higher rates of duplex ultrasound.

For this specific aim, we need detailed clinical data that are not available in an administrative database like the NIS. Therefore we will access the National Trauma Data Bank (NTDB) as we have done in the studies in our preliminary data,

The NTDB was formed through a collaboration of various professional organizations and is currently run by the American College of Surgeons. It is the largest trauma database ever created, and includes hospital and patient information from 904 participating centers encompassing nearly two million patient records. Reporting to the NTDB is voluntary, and all the information is de-identified. The Johns Hopkins University institutional review board for human research subjects has granted us an exemption for research using the NTDB.

A multi-level retrospective analysis of NTDB, version 6.2, from 2001 to 2005, will be performed. Inclusion criteria will be patients treated at hospitals reporting at least one duplex ultrasound (defined as ICD-9 procedure code of 88.77) and one DVT (as identified from the complications file of the NTDB). These inclusion criteria are based on our recent work that highlights the need to carefully select numerators and denominators when examining complication rates in the NTDB. (26)

Variables
The primary outcome measure will be the reporting of a diagnosis of DVT. The independent variables will include hospital-level ultrasound rate, and patient-level risk factors. Hospital-level ultrasound rate will be calculated by dividing the counts of patients with at least one vascular ultrasound (ICD-9 procedure code of 88.77), by the total number of trauma patients treated at that hospital. "Screening hospitals" will be initially defined as a hospital which performed vascular ultrasounds on at least 2% of admitted trauma patients, based on our previous work (25). Patient-level risk factors will be replicated from Knudson et al.(6), which included age >=40 years, presence of severe extremity injury (as defined by AIS >=3 in body region five), presence of severe head injury (as defined by AIS >=3 in body region one), ventilator days >3 days, venous injury (defined by ICD-9 diagnosis codes of 900.1, 900.81, 901.2, 901.3, 902.1, 902.10, 902.11, 902.19, 902.3, 902.31, 902.32, 902.33, 902.34, 902.42, 902.52, 902.54, 902.56, 902.82, 903.02, 904.2, 904.3, 904.42, 904.52, 904.54), and major surgery (including operations on the nervous system (ICD-9 diagnosis codes 01.xx to 05.xx), respiratory system (30.xx to 34.xx), cardiovascular system (35.xx to 39.xx), hematopeotic and lymphatic system, i.e., spleen operations (40.xx to 41.xx), digestive system (42.xx to 54.xx), urinary system (55.xx to 59.xx), significant musculoskeletal procedures (77.xx, 78.xx, 81.xx, 83.xx, and 84.xx).

Analysis
The initial hospital-level analysis will include a comparison of DVT rates among all patients admitted to "screening" vs "non-screening" hospitals. This analysis will then be extended to the hospital and patient-level analysis by including the patient risk factors described above. Multi-level multiple logistic regression analysis will be performed where the model will include a random hospital effect, the indicator of screening vs. non-screening hospital and the patient-level covariates.

We will perform three sets of sensitivity analyses. First, sensitivity analyses will be performed for both the hospital-level and the hospital and patient-level analysis, by re-defining "screening hospitals" at different thresholds of ultrasound rates per admitted patient (5%, 10%, 15%). Second, sensitivity analyses will be performed by substituting the outcome measure of DVT reporting, with venous thromboembolism (VTE - defined as either DVT and/or PE as identified from the complications file of the NTDB). Third, sensitivity analysis will be performed on the subset of patients with lengths of stay greater than or equal to 3 days, with the hospital ultrasound and DVT rates re-calculated accordingly. We selected this population as a potnetially correct denominator of patients eligible for screening, since patients with very short length of stay would not in general be screened (26)

Specific Aim 3B: To determine if trauma patients are more likely to be diagnosed with DVT depending on if treatment is received at a hospital with a protocol for screening high-risk asymptomatic trauma patients for DVT with duplex ultrasound..

We will repeat a multi-level retrospective analysis as performed in Specific Aim 3A utilizing the NSCOT database. The primary outcome measure will again be the reporting of a diagnosis of DVT. The primary independent variables will be whether the treating hospital has a protocol for duplex ultrasound screening of high-risk trauma patients. Other independent variables will include patient-level risk factors which again will be replicated from Knudson et al. (6), (age >=40 years, presence of severe extremity injury, presence of severe head injury, ventilator days >3 days, venous injury, and major surgery). The NSCOT database has all the necessary data elements to answer this ultimate question.