

**Form "EAST Multicenter Study Proposal"**

**Details #118** (submitted 10/14/2020)

<b>Study Title</b>	Intravascular access in hypotensive trauma patients: an Eastern Association for the Surgery of Trauma multicenter prospective observational trial using trauma video review
<b>Primary investigator / Senior researcher</b>	Ryan P. Dumas MD, FACS
<b>Email of Primary investigator / Senior researcher</b>	ryan.dumas@utsouthwestern.edu
<b>Co-primary investigator</b>	Michael A. Vella MD
<b>Are you a current member of EAST?</b>	Yes
<b>If you selected "No" above please identify a Sponsor that is an active EAST member:</b>	
<b>My Multicenter Study proposal is...</b>	Prospective

Intravascular access (IV) access remains a challenge in hypotensive trauma patients in hemorrhagic shock. Observational and prospective data suggest that the challenges associated with IV access include obesity, clinician experience and the absence of a palpable vein(1-3). In trauma patients, these difficulties are amplified due to the increased vascular tone and vascular collapse associated with hemorrhagic shock. While peripheral intravenous catheters (PIV) remain the most common form of IV access(4), other methods have emerged throughout the 20th century. Intraosseous (IO) cannulation has gained increasing popularity in the 21st century largely due to the incorporation of rapid IO access recommended during cardiopulmonary resuscitation. Furthermore, IO cannulation has gained increasing traction within the military community(5). While the flow rates of these different techniques have been studied(6,7) and traditional Advanced Trauma Life Support (ATLS) teaching continues to advocate for “two large-bore IVs,” the time it takes to establish IV access and the success rates of different types of IV access in trauma patients remains largely unknown. Delays and failures to establish IV access in trauma patients in hemorrhagic shock may lead to delays in life-saving interventions. In hypotensive ED patients, Clarke et al found that each additional minute spent in the ED increased the probability of death by 0.35%(8).

**Use this area to briefly  
(1-2 paragraphs only)  
outline the burden of the  
problem to be examined**

Using trauma video review (TVR), we conducted a pilot study as part of a quality improvement initiative in 2016, the results of which were published in 2018(9). We found that IO access was as fast as PIV and twice as likely to be successful. In addition, CVC cannulation takes longer than PIV and IO and is much less likely to be successful. However, as a single institution study with relatively narrow inclusion criteria, the way in which these findings may be generalizable to other institutions remains unclear.

Despite a strong conceptual underpinning and impactful preliminary data, there is still a critical knowledge gap in our understanding of how long it takes to establish intravascular access and which modality is the most successful in hypotensive injured patients. The long-term goal of our research is to improve the speed and success of IV access in trauma patients in hemorrhagic shock.

SA1a: To determine the time to intravascular access (IO, PIV, CVC) in trauma patients presenting with an initial systolic blood pressure of less than 90mm Hg.

Hypothesis: IO access is faster than PIV or CVC access attempts in this patient population.

## Primary aim

SA1b: To determine the success rates of intravascular access (IO, PIV, CVC) in trauma patients presenting with an initial systolic blood pressure of less than 90mm Hg.

Hypothesis: IO access attempts have higher success rates than PIV or CVC access attempts in this patient population.

SA2: To define the variability in practice in IO utilization across a of network of trauma centers in the United States.

## Secondary aims

Hypothesis: Significant center and provider variability in IO utilization exists across the United States.

Patients presenting to the hospital in shock, defined for the purposes of this study, as an initial systolic blood pressure <90 mmHg.

## Inclusion Criteria

## Exclusion Criteria

Patients <16 years of age. Patients that arrive with prehospital IV access in place and do not undergo any additional access attempts.

## Therapeutic Interventions

Vascular access: categorized as: peripheral IV (PIV) (any location), Intraosseous (including tibial and humeral), central venous catheter (CVC) (including femoral, subclavian and internal jugular).

The primary outcome of interest is: duration of IV access attempt, measured by start (visualized needle insertion) and access attempt stop (visualized flushing of IV access) times.

## Primary Outcome

## **Secondary Outcomes**

The secondary outcomes of interest are: success of the access attempt, median duration of failed IV access attempts, time to resuscitation initiation (defined by visualization of IVFs or blood administration), time to IV access placement (defined by first visualized flushing of any IV access type), time to first medication administration, time to transfusion completion, time to next phase of care, return of spontaneous circulation and mortality.

## **List specific variables to be collected & analyzed**

Patient level variables collected for this study will include demographic information (age, sex, race), mechanism of injury, injury severity (as measured by Injury Severity Score [ISS], New ISS [NISS] and physiology data). We will also collection patient outcomes data. We will collect provider level variables including discipline (EMT, physician, nurse) as well as training level (resident, fellow, or attending) for physician providers. Resuscitation metrics such as number of participants and trauma teamwork scores using the T-NOTECHS(10) scoring system will also be collected. Data regarding vascular access attempts and times recorded in the electronic medical record, if available, will also be recorded.

To collect the above outcomes, we will abstract data from audiovisual recordings of patients arriving in hemorrhagic after injury using a standardized template housed in the clinical data collection software (REDCap, Vanderbilt University, TN) or a database collection tool sponsored by a professional academic society i.e. AAST Data Collection Tool.

A critical barrier to the study of timing to establish IV access is the speed at which resuscitations occur and the inherently chaotic nature of some of these resuscitations. These factors make collecting data real time especially challenging. Furthermore, the use of research personnel to collect data for these events is further impeded by the emergent and unpredictable nature of these resuscitations. Additionally, as these investigators have previously shown(11) the electronic medical record is often incomplete and/or inaccurate when it comes to documentation time-stamps of performed procedures during trauma resuscitations, particularly with respect to IV access attempts which are not successful.

The use of a continuously recording high-definition audiovisual system overcomes this challenge while at the same time capturing all data within the field of the camera(s). The use of audiovisual recordings allows researchers to collect dynamic real-time data in the trauma bay in a similar fashion to prospective real-time data collection except with the ability to pause, rewind, and re-review areas of ambiguity or data points missed on the first analysis. Our prior work(9) has demonstrated that it is possible to use video data to quantify IV access duration down to the second. This method of data collection has been made more feasible over the past decade by advances in technology and the numbers of centers using TVR has increased(12). In a national survey of the Eastern Association for the Surgery of Trauma membership, these investigators have identified centers that utilize TVR technology making recruitment of participating centers easier. Currently, nearly 30% of responding Level I and level II centers have active TVR programs and an additional 30% are planning on starting TVR programs in the future(12). These investigators have started to form a network of collaborators that use TVR. As part of this proposal, we have submitted nine "Letters of Intent" from centers that use TVR and are interested in participating in this specific trial.

**Outline the data collection plan and statistical analysis plan succinctly**

Statistics:

Demographics and descriptors of care will be presented using descriptive statistics. The distribution of continuous data will be tested for normality using Shapiro-Wilk test. We will compare non-normally distributed continuous data using Kruskal-Wallis test adjusted for multiple comparisons. Categorical outcomes will be compared using  $\chi^2$  or Fisher's exact test. We will define two-tailed statistical significance as  $\alpha < 0.05$ .

Sample Size & Power Estimates

We performed a power analysis based on our previously published data(9).

Power analysis assuming a PIV duration of 0.88 minutes. Calculated sample size to detect a statistically significant difference in access speed (PIV vs IO) ranging from 0.49-0.09 minutes

n P0 PIV time(min)P1 IO time (min)% differenceaPower

66 0.880.39 .49 0.5 0.8

102 0.880.49 .39 0.5 0.8

180 0.880.59 .29 0.5 0.8

414 0.880.69 .19 0.5 0.8

1830 0.880.79 .09 0.5 0.8

Using a sample size of 200, we will be able to detect a 20 second difference in IV access duration between IV and IO access with 80% power.

**Outline consent procedures here, if applicable**

As this is a prospective observational study, designed to prospectively collect data on patients whose resuscitations are already being recorded under separate institutional consent. After institution-specific Institutional Review Board review, a waiver of informed consent will be requested to review and abstract data from this data source.

The main risk associated with this type of prospective observational study is a data breach. We will mitigate this risk through appropriate data handling as outlined in each individual IRB application.

**Succinctly outline a risk/benefit analysis**

Benefits of this study include a clearer picture of vascular access in hypotensive trauma patients. It is difficult to establish IV access in this patient population. The literature instructs that even one minute of hypotension worsens patient outcomes. This study has the potential to change practice and increase IO utilization in much the same way that IO utilization has increased dramatically for Advanced Cardiovascular Life Support. It will also help establish important benchmarks for PIV and CVC placement and define center-level and provider-level variability in practice.

1. Jacobson AF, Winslow EH. Variables influencing intravenous catheter insertion difficulty and failure: an analysis of 339 intravenous catheter insertions. *Heart & lung : the journal of critical care* 2005;34:345-59.

2. Juvin P, Blarel A, Bruno F, Desmonts JM. Is peripheral line placement more difficult in obese than in lean patients? *Anesthesia and analgesia* 2003;96:1218, table of contents.

3. Sebbane M, Claret PG, Lefebvre S, et al. Predicting peripheral venous access difficulty in the emergency department using body mass index and a clinical evaluation of venous accessibility. *The Journal of emergency medicine* 2013;44:299-305.

4. Kalso E. A short history of central venous catheterization. *Acta Anaesthesiol Scand Suppl* 1985;81:7-10.

5. Engels PT, Erdogan M, Widder SL, et al. Use of intraosseous devices in trauma: a survey of trauma practitioners in Canada, Australia and New Zealand. *Can J Surg* 2016;59:374-82.

6. Verhoeff K, Saybel R, Mathura P, Tsang B, Fawcett V, Widder S. Ensuring adequate vascular access in patients with major trauma: a quality improvement initiative. *BMJ Open Qual* 2018;7:e000090-e.

## **Include a brief listing of key references**

7. Barcelona SL, Vilich F, Cote CJ. A comparison of flow rates and warming capabilities of the Level 1 and Rapid Infusion System with various-size intravenous catheters. *Anesthesia and analgesia* 2003;97:358-63, table of contents.

8. Clarke JR, Trooskin SZ, Doshi PJ, Greenwald L, Mode CJ. Time to laparotomy for intra-abdominal bleeding from trauma does affect survival for delays up to 90 minutes. *J Trauma* 2002;52:420-5.

9. Chreiman KM, Dumas RP, Seamon MJ, et al. The intraosseous have it: A prospective observational study of vascular access success rates in patients in extremis using video review. *J Trauma Acute Care Surg* 2018;84:558-63.

10. Dumas RP, Vella MA, Chreiman KC, et al. Team Assessment and Decision Making Is Associated With Outcomes: A Trauma Video Review Analysis. *J Surg Res* 2020;246:544-9.

11. Dumas RP, Chreiman KM, Seamon MJ, et al. Benchmarking emergency department thoracotomy: Using trauma video review to generate procedural norms. *Injury* 2018;49:1687-92.

12. Dumas RP, Vella MA, Hatchimonji JS, Ma L, Maher Z, Holena DN. Trauma video review utilization: A survey of practice in the United States. *Am J Surg* 2020;219:49-53.



## Surgical Critical Care Fellowship

Letter of Intent to participate in an Eastern Association for the Surgery of Trauma Multi-Institutional  
Trial

10/5/2020

Dear EAST Multicenter Trials Committee:

I am currently an Assistant professor and the Program Director of the Surgical Critical Care Fellowship at The George Washington University School of Medicine and Health Sciences. We are a level one trauma center that evaluates approximately 2400 traumas annually. We have been using Trauma Video Review (TVR) for 15 years. We currently record approximately 100% of our resuscitations. We review many of our videos in performance and quality improvement conferences.

This platform offers a wealth of data about the resuscitations of acutely injured trauma patients. We are interested in participating in this proposed EAST MCT entitled: *Intravascular access in hypotensive trauma patients: an Eastern Association for the Surgery of Trauma Multicenter prospective observational trial using video review*. We believe this trial will provide invaluable data about a patient population in which it is often challenging to establish venous access. We hope that trials such as this lead to further implementation and research using trauma video review. Please feel free to reach out to me with any further questions.

Regards,

A handwritten signature in black ink, appearing to read 'J. Estroff', written over a white background.

Jordan M. Estroff, MD FACS

Jordan M. Estroff, MD, FACS-Program Director  
Rob Pakan-Program Administrator

Jestroff@mfa.gwu.edu  
rpakan@mfa.gwu.edu

2150 Pennsylvania Avenue NW Suite 6B-402  
Washington, D.C. 20037

Phone 202-741-3157

Fax 202-741-3285



September 10th, 2020

RE: Letter of Intent to Participate in an Eastern Association for the Surgery of Trauma Multi-Institutional Trial

Dear EAST Multicenter Trials Committee:

It is with great enthusiasm that I offer my support for Dr. Dumas' MCT proposal entitled **“Intravascular access in hypotensive trauma patients: an Eastern Association for the Surgery of Trauma Multicenter prospective observational trial using video review”**

My name is Dan Holena I am currently an associate professor of surgery and epidemiology at the University of Pennsylvania where I also serve as the director of our Trauma Video Review (TVR) program. Our level I trauma center evaluates approximately 2900 traumas annually, and we have been using TVR for over 20 years without interruption. We currently record 100% of our resuscitations and use these recordings for education, quality improvement, and research.

In my opinion, there is no better way to obtain granular data on process measures and outcomes germane to trauma resuscitation than TVR, and we have successfully used this platform for single-institution efforts similar to the one proposed here, underscoring the feasibility of Dr. Dumas' proposal. We are excited to participate and believe this trial will provide invaluable data about a patient population in which it is often challenging to establish vascular access. We hope that trials such as this lead to further implementation and research using trauma video review.

Regards,

Sincerely,

Daniel Holena, MD, MSCE, FACS  
Associate Professor, Surgery, Perelman School of Medicine  
Associate Professor, Biostatistics and Epidemiology, Perelman School of Medicine  
University of Pennsylvania



**PennState Health**  
Milton S. Hershey Medical Center

**Trauma, Acute Care  
and Critical Care Surgery**

Department of Surgery

Mail Code H075, Room H5516

500 University Drive

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717-531-7161 Tel

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Letter of Intent to participate in an Eastern Association for the Surgery of Trauma Multi-Institutional Trial

Date: 09 September 2020

Institution: Penn State Health Hershey Medical Center

Name: Scott B. Armen, MD, FACS, FCCM

Title: Charlene J. Smith Professor of Surgery

Dear EAST Multicenter Trials Committee:

My name is Scott Armen and I am currently a Professor of Surgery and Chief of the Division of Trauma, Acute Care and Critical Care Surgery at the Penn State Health Hershey Medical Center (HMC). HMC is a Level 1 Adult and Pediatric Trauma Center that evaluates approximately 4500 traumas annually. We have been using Trauma Video Review (TVR) for seven years. We currently record approximately 70% of our resuscitations and review them in performance and quality improvement conferences.

This platform offers a wealth of data about the resuscitations of acutely injured trauma patients. We are interested in participating in this proposed EAST MCT entitled: *Intravascular access in hypotensive trauma patients: an Eastern Association for the Surgery of Trauma Multicenter prospective observational trial using video review*. We believe this trial will provide invaluable data about a patient population in which it is often challenging to establish venous access. We hope that trials such as this lead to further implementation and research using trauma video review.

Regards,

Scott B. Armen, MD, FACS, FCCP, FCCM

COL, MC USAR

Charlene J. Smith Professor and Vice-Chair for Clinical Affairs

Chief, Division of Trauma, Acute Care, & Critical Care Surgery

Department of Surgery, Penn State University College of Medicine

Surgical Director, Quality & Patient Safety

Medical Director, Adult Trauma Program

Penn State Health Hershey Medical Center





**Reading Hospital**

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**Letter of Intent to participate in an Eastern Association for  
the Surgery of Trauma Multi-Institutional Trial**

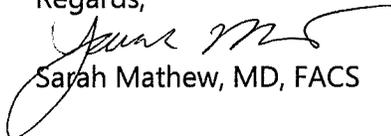
**October 7, 2020  
Reading Hospital  
Sarah Mathew, MD, FACS  
Clinical Assistant Professor  
Division of Trauma  
Department of Surgery  
Penn Trauma at Reading**

**Dear EAST Multicenter Trials Committee:**

My name is Sarah Mathew and I am currently a Clinical Assistant Professor at Reading Hospital. Reading Hospital is a level 1 Trauma Center that evaluates approximately 4000 traumas annually. We have been using Trauma Video Review (TVR) for 2 years. We currently record all of our resuscitations and review 0.6% of them in performance and quality improvement conferences.

This platform offers a wealth of data about the resuscitations of acutely injured trauma patients. We are interested in participating in this proposed EAST MCT entitled: *Intravascular access in hypotensive trauma patients: an Eastern Association for the Surgery of Trauma Multicenter prospective observational trial using video review*. We believe this trial will provide invaluable data about a patient population in which it is often challenging to establish venous access. We hope that trials such as this lead to further implementation and research using trauma video review.

Regards,

  
Sarah Mathew, MD, FACS

Department of Surgery  
Acute Care Surgery

Michael A. Vella, MD, MBA  
Assistant Professor of Surgery



MEDICINE *of* THE HIGHEST ORDER

Letter of Intent to Participate in an Eastern Association for the Surgery of Trauma Multi-Institutional Trial

Date: 8 September 2020

Institution: University of Rochester Medical Center

Name: Michael A. Vella, MD

Title: Assistant Professor of Surgery

Dear EAST Multicenter Trials Committee:

My name is Michael Vella, and I am currently an assistant professor of surgery in the Division of Acute Care Surgery and Trauma at The University of Rochester Medical Center (URMC). The Kessler Level I Trauma Center at URMC evaluates approximately 3,000 traumas annually. We recently installed a state of the art audiovisual recording system in our trauma bay and are in the process of implementing a Trauma Video Review (TVR) program. This is a joint effort between the Trauma Division and Department of Emergency Medicine, and we plan to review all level I and level II trauma activations for performance improvement purposes.

Although TVR is new to URMC, I have extensive experience with TVR from previous institutions and very much look forward to utilizing this technology here.

The TVR platform offers a wealth of data about the resuscitations of acutely injured trauma patients. We are interested in participating in this proposed EAST MCT entitled: *Intravascular access in hypotensive trauma patients: an Eastern Association for the Surgery of Trauma Multicenter prospective observational trial using video review*. We believe this trial will provide invaluable data about a patient population in which it is often challenging to establish venous access. We hope that trials such as this lead to further implementation and research using trauma video review.

Regards,

Michael A. Vella, MD



**Zoë Maher, M.D.**  
Assistant Professor of Surgery  
Director, Global Surgery

**Department of Surgery**  
**Division of Trauma Surgery**  
3401 N. Broad Street  
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Philadelphia, PA 19140

phone 215-717-3688  
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Letter of Intent to participate in an Eastern Association for the Surgery of Trauma Multi-Institutional Trial

Date: 9/11/20

Institution: Temple University Hospital

Name: Zoë Maher

Title: Assistant Professor of Surgery, Division of Trauma

Dear EAST Multicenter Trials Committee:

My name is Zoë Maher I am currently an Assistant Professor of Surgery at Temple University Hospital. Temple University Hospital Center is a level 1 trauma center that evaluates approximately 2,700 traumas annually. We have been using Trauma Video Review (TVR) for 5 years. We currently record approximately 100% of our resuscitations and review them in performance and quality improvement conferences.

This platform offers a wealth of data about the resuscitations of acutely injured trauma patients. We are interested in participating in this proposed EAST MCT entitled: *Intravascular access in hypotensive trauma patients: an Eastern Association for the Surgery of Trauma Multicenter prospective observational trial using video review*. We believe this trial will provide invaluable data about a patient population in which it is often challenging to establish venous access. We hope that trials such as this lead to further implementation and research using trauma video review.

Regards,

A handwritten signature in blue ink, appearing to be 'Zoë Maher'.

Zoë Maher, MD



Vanderbilt University School of Medicine  
Division of Trauma, Surgical Critical Care and  
Emergency General Surgery  
Department of Surgery

Letter of Intent to participate in an Eastern Association for the Surgery of Trauma Multi-Institutional Trial

Date: September 16, 2020

Institution: Vanderbilt University Medical Center  
Name: Michael Lallemand, MD and Bradley Dennis, MD  
Title: Fellow and Associate Professor

Dear EAST Multicenter Trials Committee:

We are Michael Lallemand, a fellow, and Bradley Dennis an associate professor and the interim Chief of the Division of Trauma at Vanderbilt University Medical Center. Vanderbilt University Medical Center is a level I center that evaluates approximately 5500 traumas annually. We have been using Trauma Video Review (TVR) since 1997. We currently record all of our level I and level II activations which comprises approximately 45% of our trauma service encounters and review them in performance and quality improvement conferences.

This platform offers a wealth of data about the resuscitations of acutely injured trauma patients. We are interested in participating in this proposed EAST MCT entitled: *Intravascular access in hypotensive trauma patients: an Eastern Association for the Surgery of Trauma Multicenter prospective observational trial using video review*. We believe this trial will provide invaluable data about a patient population in which it is often challenging to establish venous access. We hope that trials such as this lead to further implementation and research using trauma video review.

Regards,

A handwritten signature in black ink, appearing to read 'ML' followed by a stylized flourish.

Michael Lallemand, MD  
MAJ, USA  
Trauma/ACS Fellow  
Vanderbilt University Medical Center

A handwritten signature in black ink, appearing to read 'BD' followed by a long horizontal flourish.

Bradley Dennis, MD  
Associate Professor of Surgery  
Interim Chair of the Division of Trauma  
Vanderbilt University Medical Center

Letter of Intent to participate in an Eastern Association for the Surgery of Trauma Multi-  
Institutional Trial  
Date: 7 October 2020  
Institution: Indiana University School of Medicine

Dear EAST Multicenter Trials Committee:

My name is Erik Streib and I am currently an Associate Professor and the Chief of Trauma Services at the Smith Level 1 Shock Trauma Center at Eskenazi Health. We are the public hospital that serves Indianapolis and central Indiana, and evaluate approximately 2000 trauma admissions annually. We have had the capability of using Trauma Video Review (TVR) since moving to our new facility at the end of 2013. Approximately 54% of our patients are highest level activations that are amenable for TVR. We currently record and review resuscitations sporadically. We are interested expanding this in a more structured manner to evaluate both team performance and quality improvement efforts. This study provides a framework to begin a TVR program.

Video review offers a wealth of data about the resuscitations of acutely injured trauma patients. We are interested in participating in this proposed EAST MCT entitled: *Intravascular access in hypotensive trauma patients: an Eastern Association for the Surgery of Trauma Multicenter prospective observational trial using video review*. We believe this trial will provide invaluable data about a patient population in which it is often challenging to establish venous access. We hope that trials such as this lead to further implementation and research using trauma video review.

Sincerely,



Erik Streib, MD  
Associate Professor of Clinical Surgery  
Chief of Trauma Services  
Smith Level 1 Shock Trauma Center  
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# THE UNIVERSITY OF KANSAS HEALTH SYSTEM

## Surgery

Letter of Intent to participate in an Eastern Association for the Surgery of Trauma Multi-Institutional Trial

Date: 10/5/2020

Institution: The University of Kansas Health System

Name: Stepheny Berry, MD, FACS

Title: Associate Professor of Surgery

Dear EAST Multicenter Trials Committee:

My name is Stepheny Berry, MD. I am currently an associate professor and the trauma medical director at The University of Kansas Health System. The University of Kansas Health System is a level 1 Trauma Center that evaluates approximately 2800 traumas annually. We have been using Trauma Video Review (TVR) for 6 months. We currently record approximately 100% of our resuscitations and review them in performance and quality improvement conferences.

This platform offers a wealth of data about the resuscitations of acutely injured trauma patients. We are interested in participating in this proposed EAST MCT entitled: *Intravascular access in hypotensive trauma patients: an Eastern Association for the Surgery of Trauma Multicenter prospective observational trial using video review*. We believe this trial will provide invaluable data about a patient population in which it is often challenging to establish venous access. We hope that trials such as this lead to further implementation and research using trauma video review.

Regards,

Stepheny Berry, MD, FACS  
Associate Professor  
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