Development and Validation of a Prehospital Triage Model for the Severely Injured Trauma Patient

In the United States, traumatic injury accounts for over 150,000 deaths and over 3 million non-fatal injuries per year. The development and utilization of a multi-tiered trauma activation system has been shown to improve clinical outcomes and decrease resource utilization. One major limitation in the development of a national guideline for activation criteria is the lack of a formalized definition of "major trauma." The historic definition of an Injury Severity Score (ISS) > 15 has many issues and does not consider the utilization of high level resources (ICU, OR, Angiography, massive transfusion). Given the ISS > 15 definition of "major" trauma is so ubiquitous and is only able to be calculated retrospectively, we propose to validate a new definition named "field major" trauma. This topic has been so vigorously debated over the past two decades that in 2010, the Eastern Association for the Surgery of Trauma (EAST) Triage Guideline Subcommittee attempted to develop a national consensus for trauma triage criteria. After a year, they were unable to make any level 1 recommendations. They conclude stating "Clearly, a more comprehensive definition of the trauma patient requiring advanced trauma center care needs to be developed." It is imperative that such a definition includes elements most strongly associated with undertriage mortality and early deaths, as these are most likely to be preventable. Previous models including the Netherlands Trauma Prehospital Model and American College of Surgeons Committee on Trauma six minimum (ACS-6) criteria rely solely on ISS, have poor compliance and require prospective validation. The lack of such information represents a significant knowledge and guality gap which leaves patients vulnerable to substantial under and overtriage rates, and ultimately, suboptimal resources for patients resulting in undertriage mortality.

We previously developed a novel definition for "field major" trauma [need for emergent intervention within 6 hours (NEI-6)] (Morris et al. *Journal of Surgical Research*, 2020). Unlike Need for Trauma Intervention (NFTI), NEI-6 does not include late outcomes such as death within 60 hours or mechanical ventilation within 3 days. We identified predictive physiologic, patient-level and mechanistic prehospital criteria to predict NEI-6 and ISS > 15, creating a predictive trauma triage model with an area under the receiver operating characteristics curve (AUROC) of 0.90 (Morris et al, *under review*). The overarching goal of this proposal is to validate and optimize usability of a **rapid and simple predictive tool** for "field major" trauma that would improve the triage of trauma patients and reduce undertriage mortality. We will accomplish this by the following two aims:

AIM 1: Prospective validation of the NEI-6 predictive model on multiple independent cohorts and comparison to the ACS six minimum criteria (ACS-6) and Netherlands Trauma Prehospital Model

In this aim, we will validate the NEI-6 model prospectively on multiple independent cohorts as a multicenter EAST study. We will utilize up to 10 trauma centers with 250 patients per trauma center (2,500 patients) and capture primary outcomes data on NEI-6 and the 20 NEI-6 predictive elements. We will compare trauma triage methods using the ACS-6, NEI-6 predictive model and Netherlands Trauma Prehospital Model. The primary outcome is NEI-6. Secondary outcomes are early mortality (<48 hours) and undertriage defined by ISS and NFTI. Model discrimination to predict NEI-6 will be quantified using the area under the receiver operating characteristic curve (AUROC), positive predictive value, negative predictive value, sensitivity and specificity. EMS providers will be given the mobile application, trained to use the mobile platform, and complete data input but results will not be used for triage decisions at this stage.

AIM 2: Perform usability testing for EMS providers of a clinical decision support (CDS) mobile platform for NEI-6 to assess usability and clinical utility

The objective of this aim is to assess and optimize the usability of the NEI-6 model platform by rapid cycle prototyping. We will evaluate the clinical decision support mobile platform by completing a cognitive walkthrough using 5 EMS providers at the home sites (Froedtert Hospital and North Memorial Hospital). We will also conduct an EMS provider acceptability survey guided by Unified Theory of Acceptance and Use of Technology (UTAUT), a validated technology acceptance theory, and the System Usability Scale (SUS) questionnaire at the 10 EAST multi-institutional study sites using EMS providers who have used the application 5 times or more to evaluate usability. An SUS score of 68 or will signal optimal usability.

<u>Impact and Future Directions</u>: The proposed study compares existing trauma triage models and will establish a new user-friendly platform for a trauma triage field predictive tool that will overcome current limitations of prior models and provide greater insight into the factors that affect resource utilization and undertriage mortality. Future directions include a clustered randomized controlled trial of EMS agencies comparing standard trauma

Development and Validation of a Prehospital Triage Model for the Severely Injured Trauma Patient triage platforms versus this validated, human-centered field platform to predict NEI-6. We anticipate this project will reduce undertriage mortality in the greater than 5.4 million trauma patients transported by EMS each year.

(A) Significance

Trauma is the leading cause of death in individuals under 45 years of age. Prehospital death rates range from 14.6% to 47.6%, of which 25.8% to 42.7% are possibly preventable.(1) The development and utilization of a multi-tiered trauma activation system has been shown to improve clinical outcomes and decrease resource utilization. Furthermore, the critical step of triage to the appropriate trauma activation tier is associated with improved rates of mortality, complications, and resource utilization.(2, 3) Given this finding, there is intense interest in identifying the ideal patient populations for each tier of the trauma team activation (TTA). This topic has been so vigorously debated over the past two decades that in 2010 the Eastern Association for the Surgery of Trauma (EAST) Trauma Triage Guideline Subcommittee attempted to develop a national consensus for trauma triage criteria.(4) After a year, they were unable to make any level 1 recommendations.

This significant knowledge gap precludes the development of an evidenced based national guideline. In an attempt to provide guidance for trauma centers, the American College of Surgeons Committee on Trauma (ACS COT) has put forward six elements for highest-level TTA based on expert opinion.(5) These elements form the foundation for a variety of institutional TTA criteria at many ACS COT verified level 1 and 2 trauma centers. Outside of these six elements, there are no written requirements or validated criteria for institutional TTA policy and minimal data to guide trauma centers. With no standardized trauma triage criteria and no agreed upon definition of the "major trauma" patient, trauma medical directors, Emergency Medical Service (EMS) providers, and Emergency Department (ED) physicians face an insurmountable task. There is a current need to evaluate each prehospital element's predictive value within a prospective, multi-institutional framework. This will quide the development of an evidenced based trauma activation criteria. The lack of such information represents a significant quality gap which leaves patients vulnerable to substantial under and overtriage rates. In the worst case, undertriage of patients results in suboptimal care with increased risk of mortality and morbidity. Despite a recommended national under-triage rate of less than 5% by the American College of Surgeons, current published rates of undertriage in the USA approach 35% to 40%.(6, 7) Prehospital prediction of patients needing the highest level of trauma activation based on EMS data is challenging based on existing metrics. A novel model predicting Injury Severity Score (ISS) > 15 was developed in 2019 in the Netherlands, but lacks prospective validation in Europe or the United States.(8)

	Undertriage Death	Early (<48 hr)	In-hospital
		Mortality	Mortality
	OR (95% CI) p	OR (95% CI) p	OR (95% CI) p
ISS	1.96	19.1	10.3
	(1.79-2.14) <0.001	(16.7-21.9) <0.001	(9.5-11.2) <0.001
NEI-6	3.72	31.0	15.7
	(3.36-4.11) <0.001	(27.1-35.3) <0.001	(14.5-17.0) < 0.001

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NFTI 3.15 16.1 10.9 One maior limitation in the (2.9-3.4) <0.001 (14.2-18.4) < 0.001 development of a national guideline for (10.1-11.8) < 0.001 activation criteria is the lack of a formalized definition of "major trauma." The historic definition of ISS > 15 has many issues. It was developed in 1987 because it was associated with a 10% all-cause mortality.(9, 10) However, trauma care has improved over the past three decades, as has trauma mortality. Furthermore, studies identified that patients with an ISS > 15 without the presence of an ACS COT six minimum criterion (ACS-6) had only a 4% undertriage mortality. In comparison, patients with an ACS-6 criterion had a 30% undertriage mortality.(11) This suggests that an arbitrary ISS-based definition of "major" trauma (and by extension, undertriage) is not associated with increased mortality. The lack of specificity precludes the development of national trauma triage guidelines based on ISS. An additional limitation of ISS is the reliance on retrospective data including imaging studies and operative findings which may not be available for weeks after injury. Lack of a simple and validated national trauma activation criteria has bred the development of hundreds of complex multi-tier institutional criteria, some with over 50 elements. This can lead to significant EMS and ED confusion especially when a single EMS service covers multiple hospitals. Lack of standardization results in poor compliance with ACS COT minimum activation criteria. Tignanelli et al. identified a low 66% compliance rate with institutional and ACS COT trauma criteria within the Michigan Trauma Quality Improvement Project (MTQIP) collaborative.(11) Centers with better compliance rates had improved risk-adjusted mortality, and improved compliance was shown to reduce undertriage rates.

In response, our preliminary data established a new criteria for trauma activation: Need for Emergent Intervention within 6 hours (NEI-6).(12) The goal of a full trauma activation is to mobilize resources for severely

injured patients. NEI-6 is associated with the lowest rate of undertriage when compared to Need For Trauma Intervention (NFTI) and ISS and best predicts early mortality, in-hospital mortality and late

Table 1: NEI-6 associated with mortality.

mortality (Table 1). <u>NEI-6 is the best metric of undertriage mortality and early mortality when compared to</u> <u>NFTI and ISS</u> (11) The advantage of our model is that NEI-6 integrates resource utilization and omits late outcomes included in NFTI. NEI-6 was validated in a large regional trauma collaborative, MTQIP.(13) Emergent intervention was defined as receiving one of the following interventions within 6 hours of presentation to the ED:1.) Transfusion of greater than 4 units of blood within 4 hours of arrival 2.) Emergent central line insertion 3.) Emergent operation or angiography 4.) Emergent intubation 5.) Emergent chest tube placement 6.) Emergent placement of an intra-cranial monitor. We also developed a predictive model based on prehospital physiologic, patient-level and mechanistic variables to predict NEI-6 and ISS with an area under the receiver operating characteristic curve (AUROC) of 0.90. This model shows good discrimination based on retrospective analysis, and includes actionable fields, but requires prospective validation. Therefore, we will optimize the model and create a usable clinical decision support (CDS) platform to validate and optimize predictors of NEI-6.

The overarching goal of this proposal is to create a <u>rapid and simple predictive tool</u> for "field major" trauma and reduce undertriage mortality.

(B) Innovation, Novel Technology, and/or Novel Approach

- Employs deep-learning capabilities with an electronic decision support platform integrating elements of NEI-6, ISS, ACS-6 criteria and the Netherlands prehospital prediction model.
- Deploys cutting-edge health information technology usability techniques with rapid-cycle prototyping used in real-time to determine the most appropriate level of trauma activation.
- Implements a novel electronic platform decision support tool with a field based application to bring this new trauma triage system to the patient bedside.

(C) Approach, Feasibility, and Environment

AIM 1: Prospective validation of the NEI-6 predictive model on multiple independent cohorts and integration with ACS six minimum criteria (ACS-6) and Netherlands prehospital model predictive elements

We developed a predictive model for NEI-6 using readily available EMS metrics. The elements of this model will be combined with ACS-6 and the Netherlands prehospital model elements to achieve optimal discrimination. The best single model or combination of elements will be validated and used as the final model. Upon completion of Aim #1, we will have a prospectively validated tool to predict NEI-6 which is widely applicable to multiple trauma systems. Further, the model will incorporate the unique decision-making processes involved in the decision to perform an emergent intervention across many hospitals and providers.

Development and Validation of a Prehospital Triage Model for the Severely Injured Trauma Patient Preliminary data: In our preliminary work, we developed a predictive model using over 73,000 patients from 35 hospitals in MTQIP. I employed a boosted tree regression analysis based on clinically relevant physiologic, mechanistic and patient-level variables (Figure 1). The best model was determined by the best average innerloop model performance (Morris; under review, Annals of Surgery). The prediction model showed an AUROC of 0.90 (Standard error [SE], 0.006) in the validation cohort for predicting NEI-6. The model also had an AUROC

of 0.94 for predicting ISS > 15. The model had good discrimination when externally validated (AUROC of 0.75), but requires optimization using multi-site data.

Limitations of previous models: A previous Netherlands paper by van Rein et. al developed and validated a prediction model for prehospital triage. Limitations of this model include exclusive use of ISS greater than 15, which underperforms when compared to NEI-6 (12), and reliance on regional European data which may not be applicable to United States trauma systems.(14) The authors suggested integrating the model into a mobile application for convenience, but this platform has not gained widespread use. Compliance with ACS-6 minimum criteria is suboptimal and undertriage is associated with increased mortality.(11). This illustrates failure of the attempted real-life application of the ACS-6 criteria. Therefore, this project is needed to create a practical, accurate, innovative and accessible trauma triage decision support tool. Missing Temperature Variable

Feasibility: Investigators Morris and Tignanelli have a history of successfully creating predictive models with mobile delivery platforms including Elderly Mortality After Trauma (EMAT).(15) Two level 1 trauma centers have agreed to Transport Time < 15 min participate in this study (Froedtert Hospital and North

Memorial Hospital). My team is well equipped to conduct this study. Statistical expertise will be provided by Dr. Sisi Ma at the

University of Minnesota. The PI is successful in large data analysis and statistical modeling. Mentorship is available from Dr. de Moya and Dr. Tignanelli in leading multi-center studies. Methods:

Unintentional Injury

Participants: 10 ACS-verified level 1 and level 2 trauma centers will be included encompassing approximately 2,500 patients. Inclusion criteria will be age greater than 16 years old and at least 1 valid International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM or ICD-10-CDM) trauma code. Exclusion criteria will be direct admission and no signs of life on presentation to the trauma bay.

Primary outcome: The primary outcome of this study is need for emergent intervention within 6 hours (NEI-6). Secondary outcomes: The secondary outcomes are in-hospital complications (ARDS, acute kidney injury, unplanned intubation, unplanned return to OR, bleeding, cardiac arrest, sepsis and surgical site infection), latemortality (>48 hours), early-mortality (<48 hours) as a surrogate for undertriage mortality, in-hospital mortality, icu admission and undertriage defined by ISS, NFTI, and NEI-6

Data collection: Prehospital elements collected will include type of transfer, method of transfer, ALS/BLS transport, all ACS-6, Netherlands and NEI-6 model elements, intentionality, demographics, level of trauma activation, mechanism of injury, GCS, and suspicion for significant chest, head and abdominal injury collected through the mobile application (Figure 2). Other outcomes to be exclusively extracted from trauma registry fields will include AIS, ISS, TRISS, and secondary outcomes as described above. Additional manual extraction will be required for additional data elements including the six emergent interventions comprising NEI-6. No personal health information will be collected or stored.

Figure 2: Mobile Application Screen Shot



Gender Fall Injury

0.000 0.001 0.002 0.003 0.004 0.005 0.006 mean([SHAP value]) (average impact on model output magnitude)

Class 1

Class 0

Development and Validation of a Prehospital Triage Model for the Severely Injured Trauma Patient Sample size justification: We will utilize 10 trauma centers with 250 patients per trauma center at centers with >

75% of the trauma volume from 1 EMS agency (2,500 patients). This is based on the requirement for at least 250 events (NEI-6 positive) and 250 non-events (NEI-6 negative) in external validation studies. In our previous study, 13% of patients in MTQIP were NEI-6 positive. Level one and level two trauma centers average 2,000-3,000 patients per year, therefore approximately 250-300 patients will be NEI-6 positive. If only, 10% of these patients are captured, 10 trauma centers would be required to achieve 250 events. A wide variety of trauma centers is needed to maximize generalizability and account for variability in prehospital care patterns. Traditional power calculation is not applicable to predictive models as sample size depends on the relative similarity of the populations studied and the desired AUROC in the validation cohort.

<u>Statistical analysis:</u> Multiple scores will be evaluated for a resulting risk score of greater than 0.25 for emergent intervention. We will optimize precision, recall, and AUROC with 10-fold cross-validation. Cross-validation will also be used to test model generalizability and overfitting. An AUROC of 0.80 or greater will signify adequate validation. Patients will be classified as NEI-6 positive or negative based on the need for emergent intervention within six hours and outcomes will be compared to the ACS-6 criteria and



Netherlands Trauma Prehospital model.(13) Overtriage, undertriage and mortality will be compared based on NFTI, ISS and NEI-6 criteria. The model will be evaluated based on its predictive performance in terms of undertriage mortality defined by early death (less than 48 hours after admission). Model discrimination to predict NEI-6 will be quantified using AUROC, positive predictive value, negative predictive value, sensitivity and specificity. Multiple methods of imputation will be explored to manage null or missing values, including k-nearest neighbor (KNN), carry forward, and mean value imputation. The feature space will be reduced to minimize the noise of the predictive model using least absolute shrinkage and selection operator (LASSO). The updated version of the model will replace AIS variables with more clinically available substitute variables, such as flail chest and head laceration, if necessary based on EMS provider feedback. We will compare the models with AIS variables, without AIS variables and with AIS substitute variables to obtain the model with the best discrimination and ease of use by EMS.

<u>Pitfalls/alternative approach</u>: It is possible that our predictive model will perform poorly on the external validation dataset. Such a finding would limit the generalizability of the model. This may result from different baseline characteristics (for example, more gunshot wound victims) or different missing data elements in the external validation patient population. Therefore, I will retrain the model with patients pooled from multiple sites (n-1) and validate the model on the remaining site (1). We will integrate additional unique patients from external populations until the model is widely generalizable.

AIM 2: Perform usability testing for EMS providers of a clinical decision support (CDS) mobile platform for NEI-6 to assess usability and clinical utility

We will develop a user-friendly decision support tool that displays real-time NEI-6 results before the patient arrives at the hospital based on our previously developed EMAT mobile application. The NEI-6 prediction score will be calculated using immediately available EMS metrics determined by our previous predictive model. Usability engineering methods are intended to improve the design and use of systems for end users.(16) A mixed approach combining multiple usability engineering methods has been shown to be most likely to ensure a comprehensive usability evaluation.(16, 17) A user-driven method involves the actual CDS end-users (EMS and EMS communications staff) evaluating usability to identify and prioritize usability problems.

<u>Preliminary Data/ Feasibility</u>: Our investigative group has a successful history of developing clinical decision support interventions in the trauma population.(18) Dr. Morris and Dr. Tignanelli developed the Elderly Mortality After Trauma (EMAT) user-friendly mobile application which is currently available for download on multiple platforms.(15) Dr. Collela and Dr. Conterato (our collaborators) are experts in EMS workflow, patient assessment and data gathering.

<u>User-driven usability methods</u>. In parallel to AIM 1, I will conduct an end user-driven usability evaluation using 2 simulated case scenarios. **Each session will include observations with a video-recorded think-aloud**

Figure 3: AIM 2 Approach

session, debriefing interview, and completion of a usability survey. During the first month (phase 1) of the rapid cycle prototyping, I will

Development and Validation of a Prehospital Triage Model for the Severely Injured Trauma Patient perform a video-recorded think-aloud evaluation of the prototype using 2 simulated case scenarios. 5 EMS providers will be called with a mock patient in an ambulance or pre-hospital environment, input specific prehospital data into the mobile platform, and recommend level of trauma activation. The purpose of these observations is to understand what steps users are taking to complete each task and how much time is spent



completing each task. Next, I will administer a validated unified theory of acceptance and use of technology (UTAUT) survey (copy available upon request) with a 5-point Likert scale (ranging from 1: debilitating usability issue to 5: mild usability issue) to generate an objective measure of CDS acceptability.(4) This questionnaire includes 10 reliable usability items.(19) Problem severity scoring will be used to prioritize usability problems identified. Within 12 hours of the video session, PIs Morris and Tignanelli will review the video-recorded interviews and UTAUT surveys focusing on the most severe prototype issues (1 and 2 on Likert scale). 24-hours later, EMS will be reinterviewed based on prior feedback to optimize the prototype by sequential explanatory design. Videos

will be stored on Medical College of Wisconsin secure cloud content management. Participants will be consented after IRB approval. Data will be deleted after one year (unless requested to be deleted earlier by subjects). In next 8 months (phase 2), I will send System Usability Scale (SUS) and UTAUT surveys to all EMS providers who have used the application 5 times or more at the 10 multi-institutional study sites to evaluate usability. Usability testing will be repeated until a SUS score of 68 or higher is achieved, signaling optimal usability. If we do not achieve a SUS score over 68, we will optimize the mobile application and then repeat phase 1 to obtain further feedback. We will then repeat SUS rapid iteration cycling (Figure 3) until a score of 68 or greater is achieved.

Multi-site Logistics. The NEI-6 predictive model is portable and convenient to use via the downloadable mobile application platform. It is freely available on multiple platforms for download without need for internet or on a publicly available website using the internet. Two level 1 trauma centers (Froedtert Hospital and North Memorial Hospital, letter of support available on request) have already agreed to participate. Communication between participating centers and the principal site will occur via weekly video conference meetings. The PI will be available via email for issues that occur in the interval timeframe. A standardized IRB will be provided to each site. We anticipate the IRB for this project will be waiver of informed consent for patients due to the noninterventional nature of the study and consent will be obtained for participating EMS providers undergoing videorecorded interviews. Data will be stored on the digital storage site hosted by the Medical College of Wisconsin with a unique de-identified subject ID based on the site (A-J) and the patient number (1-2,500). Data integrity and safety monitoring will occur monthly at each site by the site PI and quarterly by the study PI. Anticipated problems include poor EMS compliance with completion of data input and variation in prehospital practices. The mobile application improves EMS compliance by being readily available on multiple platforms. A teleconferencing meeting will be held with site EMS directors and/or PI prior to starting enrollment stating the goals and importance of the study. Feedback will be collected monthly via email from site PIs on impediments to data input and the mobile platform will be modified accordingly.

<u>Anticipated Results</u>. The proposed studies will establish a new user-friendly human-centered model platform for a trauma triage field predictive tool that will overcome current limitations and provide greater insight into the factors that affect resource utilization and undertriage mortality. Future directions include a clustered randomized controlled trial of EMS agencies comparing standard trauma triage platforms versus the NEI-6 platform. We anticipate this project will reduce undertriage mortality in the 30,000 patients per year who suffer from preventable death after traumatic injury in the United States. REFERENCES:

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