Pre-Hospital Use of the HEART Score and Point-of-Care Troponin to Predict Cardiovascular Events (PARA-HEART)

BY

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### LIST OF ABBREVIATIONS

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<th>Description</th>
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<tr>
<td>AA</td>
<td>African American</td>
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<tr>
<td>ACS</td>
<td>Acute Coronary Syndrome</td>
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<td>ADP</td>
<td>Accelerated Diagnostic Protocol</td>
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<td>BMI</td>
<td>Body Mass Index</td>
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<td>CABG</td>
<td>Coronary Artery Bypass Grafting</td>
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<td>CAD</td>
<td>Coronary Artery Disease</td>
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<td>Cath</td>
<td>Cardiac Catheterization</td>
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<td>CHF</td>
<td>Congestive Heart Failure</td>
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<td>CMR</td>
<td>Cardiac Magnetic Resonance Imaging</td>
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<td>cTn</td>
<td>cardiac Troponin</td>
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<tr>
<td>DM</td>
<td>Diabetes Mellitus</td>
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<td>ED</td>
<td>Emergency Department</td>
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<td>EHR</td>
<td>Electronic Health Record</td>
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<tr>
<td>EKG</td>
<td>Electrocardiogram</td>
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<td>EMS</td>
<td>Emergency Medical Services</td>
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<td>ET3</td>
<td>Emergency Triage, Treat and Transport</td>
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<tr>
<td>f</td>
<td>Female</td>
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<tr>
<td>HCL</td>
<td>Hyperlipidemia</td>
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<tr>
<td>HE-MACS</td>
<td>History and EKG-only Manchester Acute Coronary Syndrome</td>
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<tr>
<td>HEAR</td>
<td>History, ECG, Age, Risk factors score</td>
</tr>
<tr>
<td>HEART</td>
<td>History, ECG, Age, Risk factors, Troponin score</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>hr</td>
<td>hour</td>
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<tr>
<td>hs</td>
<td>high sensitivity</td>
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<td>HTN</td>
<td>Hypertension</td>
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<tr>
<td>Lab</td>
<td>Laboratory</td>
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<tr>
<td>LOD</td>
<td>Level of Detection</td>
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<tr>
<td>m</td>
<td>Male</td>
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<tr>
<td>MACE</td>
<td>Major Adverse Cardiac Event</td>
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<tr>
<td>mHEART</td>
<td>modified HEART Score</td>
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<tr>
<td>MI</td>
<td>Myocardial Infarction</td>
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<tr>
<td>min</td>
<td>minutes</td>
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<tr>
<td>NCDI</td>
<td>North Carolina Death Index</td>
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<tr>
<td>NLR</td>
<td>Negative Likelihood Ratio</td>
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<tr>
<td>NPV</td>
<td>Negative Predictive Value</td>
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<td>NSTEMI</td>
<td>non-ST-segment elevation myocardial infarction</td>
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<td>OCT</td>
<td>Objective Cardiac Testing</td>
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<td>PARA-HEART</td>
<td>Pre-Hospital Use of the HEART Score and Point-of-Care Troponin to Predict Cardiovascular Events</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>PCI</td>
<td>Percutaneous Coronary Intervention</td>
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<tr>
<td>PLR</td>
<td>Positive Likelihood Ratio</td>
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<tr>
<td>POC</td>
<td>Point of Care</td>
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<tr>
<td>PPV</td>
<td>Positive Predictive Value</td>
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<tr>
<td>PVD</td>
<td>Peripheral Vascular Disease</td>
</tr>
<tr>
<td>STEMI</td>
<td>ST-segment elevation myocardial infarction</td>
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<tr>
<td>T-MACS</td>
<td>Troponin-only Manchester Acute Coronary Syndrome</td>
</tr>
<tr>
<td>URL</td>
<td>Upper Reference Limit</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
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<tr>
<td>WFBH</td>
<td>Wake Forest Baptist Health</td>
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Abstract

Background: Chest pain is a common reason for ambulance transport. However, paramedics lack validated tools for risk stratification. The modified History, ECG, Age, Risk factors, Troponin score (mHEART) is validated in the Emergency Department (ED), but has yet to be prospectively tested in the prehospital setting. The objective of this study is to establish the feasibility and performance of prehospital mHEART assessment using point-of-care (POC) troponin (cTn).

Methods: A prospective observational study of adults with non-traumatic chest pain was conducted in 3 Emergency Medical Services agencies (12/2016-1/2018). Paramedics excluded patients with ST-elevation myocardial infarction (STEMI) on ECG. During ambulance transport paramedics initiated intravenous access, drew blood, used a POC device (i-STAT; Abbott Laboratories) to measure cTn, and calculated mHEART on each patient. Patients were classified as non-low risk if they had a mHEART >3 or elevated POC cTn. In the hospital central lab, prehospital blood was analyzed for cTn (AccuTnl+3 assay (Beckman Coulter) or cTnl-Ultra assay (Siemens)). The primary outcome was index major adverse cardiac events (MACE: composite of cardiac death, myocardial infarction, and coronary revascularization), which was adjudicated by 3 experts. Test characteristics (sensitivity, negative predictive value (NPV), etc.) for detection of MACE were calculated for mHEART and POC cTn measurement.

Results: During the study period, 506 patients were accrued, with index MACE occurring in 16.8% (85/506). Prehospital POC cTn measurement was attempted in 99% (501/506) of patients, with 83.2% (421/506) receiving numeric results and 15.8% (80/506) receiving error codes. mHEART assessments were completed in 87.5%
(443/506) of patients. Prehospital mHEART with POC cTn was 91.1% (95% CI 82.6-96.4%) sensitive for detection of index MACE with a NPV of 94.4% (95% CI 88.7-97.7%). Paramedic mHEART combined with central lab cTn from prehospital blood yielded 100% sensitivity and NPV for index MACE. Prehospital POC cTn alone was 96.8% (95% CI 94.3-98.3%) specific for index MACE.

**Conclusions:** POC cTn measurement and mHEART calculation by paramedics during ambulance transport is feasible and moderately sensitive for MACE. These results suggest that structured prehospital risk assessments may facilitate earlier identification of patients with MACE.
CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

Introduction:

Coronary heart disease represents a major public health threat. It is the leading cause of death and affects 15.8 million people in the United States (US). The most common symptom associated with coronary heart disease is acute chest pain. Each year, US Emergency Departments (ED) care for 8-10 million patients with a complaint of chest pain. Of all patients presenting with chest pain, almost two thirds will be admitted to the hospital, but only 10% of these patients are ultimately diagnosed with coronary heart disease or an acute coronary syndrome (ACS). This over-triage has been estimated to cost $10-13 billion annually.

Patients presenting to the ED with chest pain receive a screening 12-lead electrocardiogram (EKG) as soon as possible upon ED arrival. This has become the standard of care and is performed by nursing on a standing order. The ED physician quickly reviews this EKG to identify ST-segment elevation myocardial infarction (STEMI) criteria, which requires an interventional cardiologist to emergently revascularize a blocked coronary artery. In all other patients (>90% of total), evaluation continues with a provider performing a history and physical exam and ordering additional tests. This includes cardiac troponin (cTn) measurement to identify patients with non-ST-segment elevation myocardial infarction (NSTEMI).

The need for emergency physicians to quickly diagnose whether a patient is having a myocardial infarction (MI) has led to point of care (POC) cTn testing making its way into the ED. This modality has the ability to rapidly assist clinicians in the early diagnosis of MI. Unfortunately, a review in 2017 that evaluated studies using POC cTn assays
concluded that they are less sensitive than standard cTn assays and produce no clear benefit to patients despite their increased speed.\textsuperscript{13,14} A systematic review evaluating POC tests in suspected myocardial infarction (MI) showed that the ideal POC test for MI diagnosis in the early hours of symptoms does not yet exist, but tests with improved sensitivity should be considered for further study.\textsuperscript{15,16}

There are several companies working to improve their POC device’s cTn sensitivity. A large group of researchers from Europe evaluated the diagnostic accuracy of the Minicare cTn (Philips) compared to both the i-Stat cTn (Abbott) and the high-sensitivity (hs) central laboratory cTn (Architect, Abbott).\textsuperscript{17} They found that the Minicare cTn POC assay had higher clinical concordances to the hs-cTn performed in the central lab (92%) than the i-STAT cTn (83%). The results are very encouraging, but have yet to be externally validated in the US and are not FDA approved.

Despite advances in cTn technology, in most patients with chest pain the results of their EKG, cTn, and radiographs from the ED evaluation are normal or non-specific and unable to exclude ACS. Decisions regarding admitting or discharging these patients after the completion of a normal or nonspecific evaluation is notoriously very difficult for ED physicians. While ~90% of these patients do not have a cardiac cause of their chest pain it is difficult to distinguish them from the ~10% who ultimately rule-in for ACS. It has been estimated that 4% of patients with MI are inappropriately discharged from the ED and missed MI is the top cause of medical malpractice against emergency physicians.\textsuperscript{5} These patients, inadvertently discharged home with ACS, have higher mortality compared to those hospitalized\textsuperscript{6}, emphasizing the importance of making the correct diagnosis the first time. Thus, discharging these patients is often thought of as a form of
“Russian roulette.” So, to prevent missing ACS most patients, even at low-risk for ACS, have traditionally been admitted to the hospital for serial cTn measurement and objective cardiac testing (OCT - stress testing or angiography). This pattern of excess admissions contributes to hospital and ED crowding, which has been linked to an overall decrease in quality of care.\textsuperscript{18,19} This inefficiency also taxes the US in other ways such as lost productivity for affected patients and unnecessary invasive procedures. Equally important, this inefficiency consumes finite resources that could be used for other health interventions.

In an effort to improve the quality and value of chest pain care, decision aids and accelerated diagnostic protocols (ADP) have been developed for ED use. These tools take a combination of patient’s presenting complaints, electrocardiogram (EKG) findings, past medical risk factors, and biomarkers into account to determine a patient’s risk of developing a major adverse cardiac event (MACE – death, MI, coronary revascularization) during the initial evaluation period and out as far as a year.\textsuperscript{20-23} These tools are designed to assist clinicians to safely and efficiently evaluate ED patients with chest pain. They have diverse approaches and have been studied head-to-head for their ability to detect MACE and achieve the sensitivity and negative predictive value (NPV) necessary to safely discharge patients without further testing.\textsuperscript{20-27} These tools continue to evolve as biomarker technology (i.e. high sensitivity cTn assays) improves and becomes available to EDs in the US.

The HEART Pathway is an example of a chest pain ADP that was designed to risk stratify patients with chest pain or related symptoms without OCT (Figure A).\textsuperscript{21,28} The HEART Pathway is based on a risk score with five components: History, EKG, Age,
Risk factors, and arrival cTn (Figure B).\textsuperscript{28,29} The HEART Score has been validated in over 5,000 patients, demonstrating a negative predictive value for MACE of 98.3\% at six weeks.\textsuperscript{28-30} The HEART Pathway is an ADP that combines the HEART Score with second cTn measurement at 3 hours run in the hospital central laboratory which improves the ADP’s sensitivity and NPV. In a randomized control trial, completed by Mahler et al at Wake Forest, comparing the HEART Pathway to usual care, use of the HEART Pathway decreased objective cardiac testing at 30 days by 12.1\% (68.8\% vs 56.7\%, \(p=0.048\)), length of stay in the hospital by 12 hours (9.9 vs 21.9 hours, \(p=0.013\)), and increased early discharges by 21.3\% (39.7\% vs 18.4\%, \(p<0.001\)). Its sensitivity and negative predictive value for MACE was 100\%,\textsuperscript{31-33} as no patients identified for early discharge had MACE at 30 days.\textsuperscript{33} The HEART Pathway has become the preferred chest pain risk stratification tool in many EDs across the country.
Figure 1. The HEART Pathway
Other ADPs and risk scores have been developed and validated to improve chest pain risk stratification. The Troponin-only Manchester Acute Coronary Syndrome (T-MACS) tool is an ADP from the United Kingdom that integrates cTn measures at 0 & 3 hours. Recently, T-MACS was validated using a POC cTn assay demonstrating a NPV and sensitivity of 100% for detecting MACE in ED patients complaining of chest pain.4

Though this study needs validation, their combination of a sensitive POC cTn assay and a risk stratification tool may have important implications as ED ADPs begin to be translated to the prehospital setting.

**Prehospital Chest Pain Care:**

Chest pain is a very common reason that causes people to activate the 911 emergency system.25 Up to 46% of patients that seek care in the ED for concerns of heart attack arrive
Civilian Emergency Medical Services (EMS) in the US dates back to 1865 in Cincinnati. The focus then and even now in many instances has been on getting the ill and injured to the ED where patients can be cared for by a physician. As time has passed, an opportunity to provide life-saving interventions on emergency scenes and during transport to the hospital was appreciated and therefore the paramedic certification and curriculum was created. Over the years, the paramedic’s scope of practice has expanded to include the administration of medications, intravenous access, and 12-lead EKGs. Current paramedic chest pain protocols focus on rapidly obtaining a 12-lead EKG to screen for a STEMI, much like an emergency physician does in the ED. Rapid 12-lead EKG screening, EMS cardiac catheterization laboratory activation, and transport directly to the catheterization laboratory has been shown to improve STEMI outcomes.

Unfortunately, no further risk stratification is performed for patients with EKGs that lack criteria for a STEMI. The paramedics’ gestalt and their agnostic treatment protocols and destination plans are their only guidelines for patient care. Most paramedics will give all patients with chest pain aspirin and nitroglycerin while monitoring them en route to the closest ED. However, when patients transported to hospitals without interventional cardiology capabilities are diagnosed with ACS in the ED, they frequently require transfer to a tertiary medical center for definitive management. The transfer process is costly and inefficient. Thus, a tremendous opportunity exists to identify patients early that are at high risk for ACS and transport them initially to a facility with interventional cardiology capabilities. Furthermore, it is possible that patients at lower risk can be safely triaged to the closest hospital matching patient risk to hospital destination. In addition,
there may be an opportunity to transport a subset of patients to urgent care centers or even rule out some patients for ACS at home with close outpatient follow-up.

None the less, there is a need to continue to bring hospital-based assessments and tests to the prehospital environment. The paramedic’s professional medical ability and the health system’s need to be more efficient are driving the paramedic’s scope of practice and the number of informed decisions they make that reach far beyond the historically based goal of “ambulance drivers” simply transporting a person to the hospital. To date there is limited evidence to inform an objective prehospital assessment in patients with acute chest pain and without STEMI. Decision aids and point of care cTn testing, which are commonly used in the ED, have yet to be translated to prehospital setting. Recently, a group out of the United Kingdom took a bold approach in developing a decision aid without cTn measurement. The History and EKG-only Manchester ACS (HE-MACS) decision aid was able to identify 9.4% of their ED patients that are so low risk that they may have the potential to be ruled out for ACS without blood work or OCT. The study team suggests that the HE-MACS tool has the potential to be used to improve triage accuracy and may even prevent referral to the ED. While designed for prehospital use this tool has yet to be validated in the prehospital setting.

The prehospital use of a more traditional ADP which includes cTn measurement would require the prehospital use of a POC device. The development cTn measurement devices that are small enough to be portable opened a new chapter in POC cTn testing. Thus far, the data on conducting POC cTn measurement in the prehospital setting is very limited, but has shown proof of concept.44-47 The accuracy of and ability to use a POC device to determine a cTn level in the back of a moving ambulance was tested by an Illinois based
study team. They took blood drawn from patients in the ED and moved it to a moving ambulance to perform the cTn assay on an Abbott POC device on “simulated runs.” The study team found some encouraging results that there was no significant difference in results between assays performed in the moving ambulance and those performed in the ED (intraclass coefficient 0.997; 95CI 0.994-0.998; p <0.005).

The FamouS Triage group out of the Netherlands has made some additional rudimentary steps to explore the feasibility to rule out MI at first medical contact in the prehospital setting using a modified HEART Score calculated by cardiology residents. Their study was a prospective observational cohort study that completed a prehospital risk assessment score and a follow up “on-site” cTn measurement in 700 patients. MACE for the entire cohort at 45 days was 16.6%. MACE in the low-risk group at 45 days was 2.9% with a 1.2% incidence of MI. They plan to complete a prospective, interventional study to determine if patients can be safely risk stratified into a low risk group that doesn’t need transport to a hospital. Unfortunately, it is unlikely to be successful because the preliminary results lack the sensitivity and NPV to rule a patient out and leave them at home.

A Danish group of researchers found that paramedics could perform a POC-cTn (Roche Diagnostics, GmbH, Mannheim, Germany) 88 minutes (58-131 minutes) before the traditional blood sample was drawn in their ED. They enrolled 985 prehospital patients over a twelve-month period. Unfortunately, the cTn had a sensitivity for MI of 39% (95% CI, 32-46%) and a diagnostic accuracy of 0.67 (95% CI 0.64-0.71). These test characteristics fall well below the acceptable level to be acted upon clinically, but as POC
cTn devices continue to improve great potential exist for the prehospital use of this important biomarker.

Over the past decade the current prehospital treatment paradigm has been challenged extensively due to the opportunity for prehospital providers to provide much more than transport from an emergency scene to the hospital ED. Innovative collaborative programs such as community paramedicine and telemedicine have the potential to tailor treatment to better achieve patient centered care. Centers for Medicare & Medicaid Services recently introduced the Emergency Triage, Treat and Transport (ET3) Model which is a voluntary payment model that seeks to allow for payment to EMS agencies that transport patients to destinations other than the ED or to use alternate modalities such as telehealth following a 911 call. It will be very interesting to see how this extremely innovative approach will impact prehospital care.

**Objectives:**

Studies are needed to determine whether prehospital providers can feasibly and accurately use an ADP incorporating a POC cTn measurement to risk-stratify patients complaining of chest pain. The birth of civilian EMS in the Department of Transportation has historically limited prehospital provider’s focus on transporting patients to the hospital rather than further differentiating patient’s morbidity and mortality risk. With the current paradigm showing signs of shifting toward a system that appreciates patient-centered care, appropriate use of resources and increased EMS system efficiency, the time is now to equip prehospital providers with evidence-based risk stratification tools. This PARA-HEART project is a natural extension of our prior work with the HEART Pathway. Pre-hospital utilization of an ADP has the potential to improve the accuracy of
triage (matching the risk of the patient to the type of facility the patient is transport to), speed care delivery to patients at high-risk of adverse events, and increase the efficiency of their care once they arrive at a medical facility.

The primary objective of this prospective cohort study is to establish the feasibility and accuracy of prehospital HEART score assessment using a POC cTn assay (Abbott’s i-STAT®) performed completely by a paramedic prior to ED arrival. If feasibility and accuracy can be established, the HEART score with POC cTn testing may allow modification of triage and destination plans so that patients can be transported to the most appropriate medical facility. This will improve the access of high-quality ACS care at reduced cost with better morbidity and mortality outcomes. In this new paradigm, patients with a positive cTn or a high HEART score could be triaged to facilities with on-site cardiac catheterization laboratories, avoiding costly and inefficient inter-facility transfers.

Several secondary objectives will be explored in this study. First the agreement of HEART score assessment between paramedic and ED provider will be studied. It is important to establish whether or not the paramedics risk stratification agrees with the well validated ED provider’s assessment. Another objective will compare POC cTn measurements in the ambulance vs hospital blood gas laboratory vs. central laboratory. This analysis will explore agreement and assay performance. The cTn cut point of 0.080 ng/mL will be studied to see if a new cut point is necessary in this prehospital cohort. Finally, we will assess whether early risk stratification with the HEART Score or POC cTn, is likely to result in downstream efficiency gains; decreasing the ED length of stay for patients with low-risk chest pain. As seen in a study in Denmark there was an 88-
minute time benefit in obtaining a cTn result when prehospital blood was used. A significant time benefit could reduce ED overcrowding and improve access to care.

References:


CHAPTER 2: Pre-Hospital Use of the HEART Score and Point-of-Care Troponin to Predict Cardiovascular Events (PARA-HEART)*

*Formatting is based on the requirements of the Journal: Annals of Emergency Medicine (planned submission).

Short Title: PARA-HEART Pilot Implementation

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Reprints not available from the authors

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ABSTRACT

**Background:** Chest pain is a common reason for EMS transport. The modified History, ECG, Age, Risk factors, Troponin (mHEART) score is validated in the Emergency Department but has yet to be prospectively tested in the prehospital setting. The objective of this study is to establish the feasibility and test the performance of prehospital mHEART using point-of-care (POC) troponin (cTn).

**Methods:** A prospective cohort study of adults with non-traumatic chest pain without ST-segment elevation myocardial infarction was conducted in three Emergency Medical Service agencies between 12/2016-4/2018. During ambulance transport paramedics drew blood, measured POC cTn (i-STAT; Abbott Laboratories) and calculated a mHEART score. Patients were classified as non-low risk for mHEART >3 or elevated POC cTn. Prehospital blood was also analyzed in the hospital core lab for cTn. The primary outcome was index visit major adverse cardiac events (MACE: composite cardiac death, myocardial infarction (MI), coronary revascularization).

**Results:** 506 patients were accrued, with index MACE occurring in 16.8% (85/506). Prehospital POC cTn was attempted in 99% (501/506) of patients, with 83.2% (421/506) receiving results; mHEART assessments were completed in 87.5% (443/506). Prehospital mHEART with POC cTn was 91.1% (95% CI 82.6-96.4%) sensitive for index MACE. Paramedic mHEART with cTn measured in the core lab on prehospital blood yielded 100% sensitivity (95% CI 95.8-100%). Prehospital POC cTn alone was 99.1% (95% CI 97.5-99.8%) specific for MACE.

**Conclusions:** POC cTn measurement and mHEART calculation by paramedics during ambulance transport is feasible and moderately sensitive for index MACE. Specificity of POC cTn for index MACE was high.
Prehospital Use of the HEART Score and Point-of-Care Troponin to Predict Cardiovascular Events (PARA-HEART)

Introduction

Chest pain is a common reason for emergency medical services (EMS) activation, and nearly half of all patients with acute coronary syndrome (ACS) come to the emergency department (ED) via ambulance.\textsuperscript{1,2} The prehospital assessment of patients with chest pain is largely focused on the detection of ST-segment elevation myocardial infarction (STEMI) via prehospital 12-lead electrocardiogram (ECG). However, STEMIs are present in only seven percent of patients transported to the hospital by EMS.\textsuperscript{3,4}

Prehospital care for the remaining patients, with chest pain and without STEMI, is driven by treatment protocols and destination plans, which do not differ based on patients’ short-term risk for other adverse cardiac events. Therefore, high and low-risk patients, without STEMI, receive the same prehospital treatment and are transported to healthcare facilities based on patient or EMS provider preference, rather than risk. High-risk patients are often transported to facilities without interventional cardiology capabilities, and those who are later found to have non-STEMI ACS, require subsequent transfer to a tertiary medical center for urgent revascularization.\textsuperscript{5} Furthermore, low-risk patients are often transported directly to a crowded tertiary care facility, despite a lack of need for interventional cardiology or advanced cardiac imaging capabilities. Accurate prehospital risk stratification, beyond evaluation for STEMI, could prevent costly and inefficient transfers and avoid crowding of tertiary care center EDs.\textsuperscript{6}

Our investigative team has previously demonstrated that the History, ECG, Age, Risk Factors, and Troponin (HEART) score and related HEART Pathway are safe and effective risk stratification tools within the ED setting.\textsuperscript{7-13} Prehospital utilization of the
HEART score with quantitative point of care (POC) troponin (cTn) measurement has the potential to improve the accuracy of triage, by tailoring care delivery and destination for patients with acute chest pain based on their short-term risk of adverse events. However, the HEART score has yet to be validated in the prehospital setting. Furthermore, translation of the HEART score to EMS would require the reliable measurement of serum cTn in the field. Studies evaluating quantitative POC cTn testing in the prehospital environment are limited, especially in the US.\textsuperscript{14-16} Therefore, the objective of this study is to establish the feasibility and accuracy of a prehospital HEART score assessment including a POC cTn measurement at identifying patients at risk for adverse cardiac events.

**Methods**

*Study design*

We conducted a prospective cohort study within three EMS systems from December 2016 to January 2018. Over 150 paramedics were trained to calculate a HEART score and to use the i-STAT device (Abbott Laboratories, Chicago IL) for POC cTn measurement. In this study, paramedic HEART score assessment including POC cTn measurement results were not used clinically to alter treatment or destination protocols. Study blood collection was within the scope of practice of paramedics, who routinely perform venipuncture and conduct POC testing (i.e. blood glucose) on acutely ill patients. Thus, this study was performed under a waiver of informed consent obtained from the Institutional Review Board.\textsuperscript{9}

*Study Setting*
This study was conducted in three central North Carolina county EMS agencies. Forsyth County EMS, an urban agency has approximately 80 paramedics and 16 ambulances, completes about 35,000 patient transports annually. Stokes County EMS, a rural agency, has 34 paramedics, 5 ambulances, and completes 6,000 transports each year. Surry EMS, also a rural agency, has 73 paramedics, 7 ambulances, and completes approximately 17,000 transports annually. Participation was limited to patients transported to Wake Forest Baptist Medical Center (WFBMC), the coordinating medical center ED. WFBMC is a tertiary care center, level 1 trauma center for adults and pediatrics with 821 licensed beds, full specialty/subspecialty availability, and full cardiac catheterization lab capability. The ED has 47 beds with an annual volume of approximately 114,000 visits. The ED is staffed by board certified or board eligible emergency physicians 24 hours per day, 7 days a week who directly provide care and oversee care provided by residents and advance practice providers.

Participants

The target population was a convenience sample of adult patients ≥21 years old with acute, non-traumatic chest pain and without evidence of STEMI on ECG (ST-segment elevation in contiguous leads on any electrocardiogram (≥ 1 mV)) transported to the coordinating medical center. Patients being transferred from other acute care facilities and those with scene and transportation times anticipated to be less than 5 minutes were excluded. Patients with concomitant non-cardiac medical, surgical, or psychiatric emergencies, those receiving hospice care, and patients with unstable vital signs; hypotension (systolic < 90 mm Hg), tachycardia (HR>120), bradycardia (HR<40), and
hypoxemia (<90% pulse-oximetry on room air or normal home oxygen flow rate) were also excluded.

Risk Assessments

Paramedics were trained to identify subjects appropriate for inclusion and to calculate a mHEART score through in-person teaching as well as self-learning video refresher modules. Training regarding use of the i-STAT device was conducted by the manufacturer’s trainers. This included the proper storage, maintenance, calibration, use, and the interpretation and reporting of results.

Following training, 18 ambulances across the three agencies were equipped with an i-STAT device, blood collection supplies, and a room-temperature cooler (Koolatron; Ontario, Canada) to store reagents. In eligible patients, paramedics collected blood into a single Lithium Heparin tube. This prehospital blood sample was used to measure POC cTn during patient transport on an i-STAT device secured to the paramedic’s work station in the ambulance. Remaining prehospital blood was stored for core lab measurement on arrival to WFBMC. Paramedics used a worksheet to obtain the historical and clinical data needed to calculate a modified HEART (mHEART) score. The HEART score has five components: History, Electrocardiogram (ECG), Age, Risk factors, and initial Troponin.17,18 The mHEART assessment uses the first four component values to generate a HEAR score. Patients were considered low-risk if their HEAR score was less than four in combination with a POC cTn measurement below the 99th percentile upper reference limit (URL; 0.080 ng/ml). If the HEAR score was greater than three, or if the POC cTn value was equal to or greater than the URL, the patient was considered non-low risk (See Figure 3).
Protocol driven routine chest pain care, triage and destination plans for participating EMS counties included obtaining intravenous access, an ECG, and the administration of aspirin, nitroglycerin, and supplemental oxygen. The paramedics were instructed that the POC cTn and mHEART score results were not to be used to alter the patient’s transportation, destination, or care. Paramedics were not blinded to POC cTn results and therefore were not prevented from sharing their results with the ED care team as part of their typical transfer of care reports. This transfer of information was done using a study specific form, which clearly stated that the POC troponin value was for research purposes only and was not to be used to alter a patient’s clinical care. While the ED care team received report on the POC cTn results (as well as the patient’s clinical features and ECG, as part of a normal EMS verbal report), the ED care team remained blinded to paramedics’ mHEART scores. ED providers completed their own mHEART score calculation independent of the EMS assessment as part of the standard ED care for patients with acute chest pain.

While in the ED, participants received a standard ED chest pain evaluation including an ECG and serologic studies. As part of normal care, blood obtained in the ED at presentation and 3 hours following presentation were used for cTn measurement using the coordinating medical center’s core lab [AccuTnI+3 assay (Beckman Coulter, California) or TnI-Ultra assay (Siemens, Munich Germany)].

Outcomes

The primary objectives of this project were to determine a) the feasibility of paramedics completing mHEART score assessments and b) to evaluate the ability of a prehospital mHEART score assessment to predict major adverse cardiac events (MACE) during the
Feasibility was defined as paramedics obtaining an i-STAT cTn result in more than 50% of patients, and a mHEART assessment in greater than 80%. Medical record review and phone follow-up was conducted for each patient 30-90 days following their pre-hospital encounter to screen for MACE events at index and within the 30-day study period. Based on prior studies we expected >90% to have complete 30-day follow-up data from the electronic medical record or phone follow up calls. MACE was defined as the composite outcome of cardiac death, MI, or coronary revascularization. MACE and its components were evaluated during the index visit and through 30 days of follow-up. Cardiac death was based on the modified Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial definition. MI was defined using the Joint European Society of Cardiology/American College of Cardiology Foundation/American Heart Association/World Health Federation Task Force universal definition. All components of the primary MACE composite were adjudicated by three cardiovascular experts (two primary reviewers and one secondary reviewer). Any discrepancies among the two primary reviewers were resolved by the third reviewer. Participants without follow up data were searched for in the North Carolina Death Index (NCDI). Those not found in the NCDI were considered free from adverse events.

Data Analysis

The percentage of patients in which the paramedics successfully obtained an i-STAT cTn result and completed a mHEART score assessment was calculated. Among patients with completed assessments the percentage of patients identified by paramedics as low risk or non-low risk and the percentage of patients with each component of the HEART score were calculated. Test characteristics, including sensitivity, specificity, positive and
negative predictive values (PPV and NPV), and positive and negative likelihood ratios (+LR and –LR) for MACE at index and 30 days were determined for the mHEART score. A pre-planned comparison of the test characteristics for the prehospital mHEART assessment with a prehospital HEAR (no cTn component included) score and mHEART + core cTn (mHEART score combined with the measurement of cTn on prehospital blood using the core lab cTn assay) was performed. Test characteristics for index and 30-day MACE were also calculated for prehospital POC cTn used alone (without a HEART score). Corresponding exact binomial 95% confidence intervals were computed for sensitivity, specificity, PPV and NPV. For the +LR and -LRs, 95% confidence intervals were calculated using the method of Simel et al.\textsuperscript{21} Patient characteristics were summarized and compared between those with and without MACE using t-tests or chi-square tests. Analyses were performed using SAS 9.4 (SAS Institute, Cary, North Carolina) or R 3.5.1 (www.R-project.org).

**Results**

From 12/2016-4/2018, seventy-nine paramedics from three EMS agencies accrued 506 eligible patients. Patient characteristics in the cohort and among those with and without index MACE are described in Table 1. Prehospital POC cTn measurement was attempted in 99% (501/506) of patients, with 83.2% (421/506) receiving numeric results and 15.8% (80/506) resulting in error codes. mHEART score assessments were completed by paramedics in 87.5% (443/506) of patients. (Figure 3.) Among patients with completed prehospital mHEART score assessments 17.8% (79/443) had index MACE events: 0 deaths, 73 MIs, and 23 revascularization events. MACE at 30 days (including index MACE) occurred in 19.2% (85/443) with 1 death, 79 MIs, and 24 revascularization
events. 4.3% (22/506) of patients were lost to follow-up, none of which were found in the North Carolina Death Index. The frequency of HEART score components are summarized in Table 2.

The prehospital mHEART score identified 28.0% (124/443) of patients as low risk and 72.0% (319/443) as non-low risk. Among the 124 patients identified as low risk, 7 had index MACE yielding a NPV of 94.4% (95%CI 88.7-97.7%). Sensitivity for the detection of index MACE was 91.1% (95% CI 82.6-96.4%) with a specificity of 32.1% (95% CI 27.4-37.2%). The combination of prehospital mHEART with core lab cTn measurement of blood collected in the ambulance yielded 100% sensitivity (95% CI: 95.7-100%) and NPV (95% CI 95.8-100%) for index MACE. Prehospital POC cTn alone was highly specific for index MACE (96.8%; 95% CI 94.3-98.3%). A summary of the test characteristics for the prehospital mHEART assessment for the detection of MACE at index and 30 days are presented in Table 3. The seven patients identified as low risk by paramedics who had MACE, are described in Table 4.

Limitations

This analysis included patients from three EMS agencies that were transported to a single academic medical center. Although we suspect there are many similarities between our EMS agencies, medical center, and patients to those across the US, our results may not be generalizable to all agencies, centers, and patients. In addition, because our cohort was accrued by treating paramedics as a convenience sample, this study is limited by selection bias. Although our index MACE rate of 17.8% is higher than most ED cohorts, it is similar to other studies focused on EMS chest pain care.5,22,23 The time of patient’s chest pain onset relative to calling 911 and paramedic arrival was not collected. This
prevented the ability to differentiate early presenters from late presenters. However when EMS blood was tested by the more sensitive core lab instrument and combined with a prehospital mHEART Score the sensitivity and NPV for MACE reached 100%, suggesting that this approach might be useful among both early and late presenters.

**Discussion**

This is the first study to demonstrate that a prospective prehospital assessment of a mHEART score including a POC cTn completed by paramedics during ambulance transport is feasible. Greater than 80% of the patients had a paramedic mHEART assessment and POC cTn result. The results from this study prove that paramedics are capable of conducting prehospital chest pain risk stratification beyond STEMI recognition and that a full-scale implementation of mHEART and POC cTn is possible. Paramedic mHEART risk assessments with POC cTn measurement resulted in ~91% sensitivity of MACE at index visit and 30 days. While this sensitivity is insufficient to exclude MACE, it may be adequate for the purpose of triaging patients to a referral hospital based on a low-risk assessment. Furthermore, as newer, more sensitive, POC cTn assays become available in the US, the sensitivity of a prehospital mHEART assessment could improve.\(^{24,25}\) Our data evaluating the combination of mHEART with a core lab cTn measure from prehospital blood demonstrate that achieving very high sensitivity (100%) and negative predictive value (100%) is possible by combining the prehospital HEART score with a more sensitive cTn assay.

The prehospital POC cTn measure using the Abbott i-STAT was highly specific for index visit MACE (with a high positive predictive value and positive likelihood ratio). This suggests that an elevated POC cTn in the prehospital setting indicates a very high
likelihood that the patient will be diagnosed with an adverse cardiac event upon arrival to the hospital. Thus, our results support the concept of using POC cTn in the prehospital setting for the early identification of non-STEMI ACS. Patient with elevated POC cTn measures could be treated more aggressively and triaged to facilities with on-site cardiac catheterization laboratories. This practice could avoid costly and inefficient downstream inter-facility transfers and may improve patient outcomes. Conversely, patients without an elevated prehospital POC cTn measure, who are at low risk to develop MACE by mHEART, could be safely cared for at local community hospitals that do not have interventional cardiology services.

In the future, mobile integrated healthcare models which incorporate EMS risk stratification algorithms may allow patients who are very-low-risk of MACE to avoid transport to a hospital ED. With advances in POC cTn and well-validated algorithms a subset of patients with acute chest pain could be effectively ruled-out for adverse cardiac events by an on-scene paramedic and a telehealth provider. These patients could be scheduled to for a rapid outpatient follow-up appointment avoiding ambulance transport and ED evaluation.²⁶ The Emergency Triage, Treat and Transport (ET3) Model, a voluntary payment model recently announced by CMS, allows for payment to EMS agencies that transport patients to destinations other than ED or use telehealth following a 911 call. This policy change may enable EMS agencies to execute more efficient EMS chest pain risk stratification protocols once they are further validated.

In conclusion, POC cTn measurement and mHEART calculation completed by paramedics during ambulance transport is feasible. The sensitivity of mHEART with POC cTn for index MACE was moderate and may enable the triage of low-risk patients
to referral hospitals without interventional cardiology capabilities. Specificity of POC cTn for index MACE was high. These results suggest that a structured prehospital risk assessment with POC cTn may facilitate earlier identification of patients with MACE allowing earlier treatment and triage to tertiary care facilities with interventional cardiac catheterization laboratory availability. Additional multisite validation of a prehospital mHEART assessment with POC cTn is needed prior to broad implementation.
<table>
<thead>
<tr>
<th>Patient Characteristic</th>
<th>Total N=506</th>
<th>Patients with MACE n=85</th>
<th>Patients without MACE n=421</th>
<th>MACE vs. no MACE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age years – mean ± SD</td>
<td>58.6 ± 15.3</td>
<td>63.3 ± 13.1</td>
<td>57.5 ± 15.5</td>
<td>P &lt;0.0001</td>
</tr>
<tr>
<td>Sex (female)</td>
<td>258 (51.0%)</td>
<td>33 (38.8%)</td>
<td>225 (53.4%)</td>
<td>P = 0.017</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td>P = 0.173</td>
</tr>
<tr>
<td>Caucasian</td>
<td>250 (49.7%)</td>
<td>42 (50.0%)</td>
<td>208 (49.6%)</td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>226 (44.9%)</td>
<td>35 (41.7%)</td>
<td>191 (45.6%)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>4 (0.8%)</td>
<td>3 (3.6%)</td>
<td>1 (0.2%)</td>
<td></td>
</tr>
<tr>
<td>Native American</td>
<td>2 (0.4%)</td>
<td>0 (0%)</td>
<td>2 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>21 (4.2%)</td>
<td>4 (4.8%)</td>
<td>17 (4.1%)</td>
<td></td>
</tr>
<tr>
<td>Ethnicity (Hispanic)</td>
<td>20 (4.0%)</td>
<td>3 (3.5%)</td>
<td>17 (4.1%)</td>
<td>P = 0.366</td>
</tr>
<tr>
<td>Risk factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoking</td>
<td>128 (25.3%)</td>
<td>20 (23.5%)</td>
<td>108 (25.6%)</td>
<td>P = 0.785</td>
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<tr>
<td>Hypertension</td>
<td>335 (67.4%)</td>
<td>65 (77.4%)</td>
<td>270 (65.4%)</td>
<td>P = 0.041</td>
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<tr>
<td>Hyperlipidemia</td>
<td>141 (27.9%)</td>
<td>29 (34.1%)</td>
<td>112 (26.6%)</td>
<td>P = 0.185</td>
</tr>
<tr>
<td>Diabetes</td>
<td>146 (28.9%)</td>
<td>28 (32.9%)</td>
<td>118 (28.0%)</td>
<td>P = 0.361</td>
</tr>
<tr>
<td>Family history of CAD</td>
<td>118 (23.3%)</td>
<td>19 (22.4%)</td>
<td>99 (23.5%)</td>
<td>P = 0.889</td>
</tr>
<tr>
<td>BMI &gt;30 (kg/m²)</td>
<td>232 (47.2%)</td>
<td>36 (42.4%)</td>
<td>196 (48.2%)</td>
<td>P = 0.342</td>
</tr>
<tr>
<td>Prior coronary disease</td>
<td>148 (29.7%)</td>
<td>43 (50.6%)</td>
<td>105 (25.4%)</td>
<td>P &lt;0.0001</td>
</tr>
<tr>
<td>Prior MI</td>
<td>96 (19.2%)</td>
<td>31 (36.5%)</td>
<td>65 (15.7%)</td>
<td>P &lt;0.0001</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>76 (15.3%)</td>
<td>22 (25.6%)</td>
<td>54 (13.1%)</td>
<td>P = 0.005</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>50 (10.0%)</td>
<td>9 (10.6%)</td>
<td>41 (9.9%)</td>
<td>P = 0.843</td>
</tr>
<tr>
<td>Prior CHF</td>
<td>68 (13.6%)</td>
<td>17 (20.2%)</td>
<td>51 (12.3%)</td>
<td>P = 0.057</td>
</tr>
<tr>
<td>Prior PVD</td>
<td>23 (4.6%)</td>
<td>6 (7.1%)</td>
<td>17 (4.0%)</td>
<td>P = 0.250</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>47 (9.3%)</td>
<td>7 (8.2%)</td>
<td>40 (9.5%)</td>
<td>P = 0.839</td>
</tr>
</tbody>
</table>

CAD – coronary artery disease, PVD – peripheral vascular disease, BMI – body mass index, MI – myocardial infarction, PCI – percutaneous coronary intervention, CABG – coronary artery bypass grafting, CHF – congestive heart failure
Table II. Frequency of Prehospital HEART Score Determinants

<table>
<thead>
<tr>
<th>Risk Stratification Measure</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEART Score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>History</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slightly suspicious (0 points)</td>
<td>125</td>
<td>26.2%</td>
</tr>
<tr>
<td>Moderately suspicious (1 point)</td>
<td>172</td>
<td>36.0%</td>
</tr>
<tr>
<td>Highly suspicious (2 points)</td>
<td>181</td>
<td>37.9%</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;45 (0 points)</td>
<td>80</td>
<td>16.6%</td>
</tr>
<tr>
<td>45-65 (1 point)</td>
<td>247</td>
<td>51.1%</td>
</tr>
<tr>
<td>&gt;65 (2 points)</td>
<td>156</td>
<td>32.3%</td>
</tr>
<tr>
<td>ECG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal (0 points)</td>
<td>305</td>
<td>65.0%</td>
</tr>
<tr>
<td>Nonspecific changes (1 point)</td>
<td>129</td>
<td>27.5%</td>
</tr>
<tr>
<td>Acute ischemic changes (2 points)</td>
<td>35</td>
<td>7.5%</td>
</tr>
<tr>
<td>Number of Risk Factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 (0 points)</td>
<td>50</td>
<td>10.5%</td>
</tr>
<tr>
<td>1-2 (1 point)</td>
<td>166</td>
<td>34.7%</td>
</tr>
<tr>
<td>≥ 3 (2 points)</td>
<td>262</td>
<td>54.8%</td>
</tr>
<tr>
<td>Troponin</td>
<td></td>
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<tr>
<td>Negative (0 points)</td>
<td>384</td>
<td>93.2%</td>
</tr>
<tr>
<td>1-3x normal limit (1 point)</td>
<td>15</td>
<td>3.6%</td>
</tr>
<tr>
<td>&gt; 3x normal limit (2 points)</td>
<td>13</td>
<td>3.2%</td>
</tr>
<tr>
<td>Total HEART Score</td>
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<tr>
<td>0</td>
<td>7</td>
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</tr>
<tr>
<td>1</td>
<td>27</td>
<td>6.7%</td>
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<td>2</td>
<td>36</td>
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<tr>
<td>3</td>
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<td>5</td>
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<td>7</td>
<td>23</td>
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<tr>
<td>8</td>
<td>9</td>
<td>2.2%</td>
</tr>
<tr>
<td>9</td>
<td>2</td>
<td>0.5%</td>
</tr>
<tr>
<td>10</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>mHEART Score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low-Risk (HEAR ≤3 and negative initial cTn)</td>
<td>124</td>
<td>28.0%</td>
</tr>
<tr>
<td>Non-Low Risk (HEAR &gt;3 or positive initial cTn)</td>
<td>319</td>
<td>72.0%</td>
</tr>
</tbody>
</table>

ACS - acute coronary syndrome, cTn – cardiac troponin
Table III. Test characteristics for paramedic risk assessment for index and 30-day MACE

<table>
<thead>
<tr>
<th></th>
<th>HEAR (95%CI)</th>
<th>mHEART - POC (95%CI)</th>
<th>mHEART - Core (95%CI)</th>
<th>EMS POC cTn (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(95%CI)</td>
<td>90.0% (81.2-95.6%)</td>
<td>91.1% (82.6-96.4%)</td>
<td>100% (95.4-100%)</td>
<td>24.7% (15.3-36.1%)</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(95%CI)</td>
<td>31.7% (37.4-42.1%)</td>
<td>32.1% (27.4-37.2%)</td>
<td>26.3% (21.6-31.4%)</td>
<td>99.1% (97.5-99.8%)</td>
</tr>
<tr>
<td><strong>NPV (95%CI)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>94.7% (89.8-97.7%)</td>
<td>94.4% (88.7-97.7%)</td>
<td>100% (95.8-100%)</td>
<td>86.3% (82.5-90.5%)</td>
</tr>
<tr>
<td><strong>PPV (95%CI)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>23.0% (18.5-28.1%)</td>
<td>22.6% (18.1-27.6%)</td>
<td>24.5% (19.9-29.5%)</td>
<td>85.7% (82.4-89.5%)</td>
</tr>
<tr>
<td><strong>-LR (95%CI)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.270 (0.138-0.527)</td>
<td>0.276 (0.134-0.568)</td>
<td>0 (0.39-0.84)</td>
<td>0.760 (0.667-0.897)</td>
</tr>
<tr>
<td><strong>+LR (95%CI)</strong></td>
<td>1.430 (1.286-1.590)</td>
<td>1.343 (1.217-1.482)</td>
<td>1.357 (1.272-1.447)</td>
<td>28.603 (8.650-94.578)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>HEAR (95%CI)</th>
<th>mHEART - POC (95%CI)</th>
<th>mHEART - Core (95%CI)</th>
<th>EMS POC cTn (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(95%CI)</td>
<td>90.7% (82.5-95.9%)</td>
<td>91.8% (83.8-96.6%)</td>
<td>100% (95.8-100%)</td>
<td>23.1% (14.3-34.0%)</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(95%CI)</td>
<td>37.7% (32.8-42.8%)</td>
<td>32.7% (27.8-37.8%)</td>
<td>26.7% (17.8-31.9%)</td>
<td>99.1% (97.5-99.8%)</td>
</tr>
<tr>
<td><strong>NPV (95%CI)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>94.7% (89.8-97.7%)</td>
<td>94.4% (88.7-97.7%)</td>
<td>100% (95.8-100%)</td>
<td>85.0% (81.1-88.3%)</td>
</tr>
<tr>
<td><strong>PPV (95%CI)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>24.9% (20.2-30.1)</td>
<td>24.5% (19.8-29.5%)</td>
<td>26.3% (21.6-31.5%)</td>
<td>85.7% (63.7-97.0%)</td>
</tr>
<tr>
<td><strong>-LR (95%CI)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.247 (0.126-0.484)</td>
<td>0.252 (0.122-0.520)</td>
<td>0 (0.39-0.84)</td>
<td>0.776 (0.687-0.878)</td>
</tr>
<tr>
<td><strong>+LR (95%CI)</strong></td>
<td>1.455 (1.312-1.614)</td>
<td>1.363 (1.238-1.501)</td>
<td>1.366 (1.279-1.458)</td>
<td>26.385 (7.969-87.361)</td>
</tr>
</tbody>
</table>

NPV – negative predictive value, PPV – positive predictive value, -LR – negative likelihood ratio, +LR positive likelihood ratio, POC – point of care
Table IV. Description of low-risk patients by prehospital mHEART who had MACE

<table>
<thead>
<tr>
<th>Age</th>
<th>Sex</th>
<th>Race/Ethnicity</th>
<th>Comorbidities</th>
<th>EMS HEAR Score</th>
<th>i-STAT cTn</th>
<th>Peak cTn</th>
<th>Event</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>54 yr</td>
<td>M</td>
<td>Latino</td>
<td>Known CAD</td>
<td>3</td>
<td>0.02</td>
<td>0.053</td>
<td>Type II NSTEMI</td>
<td>Cocaine abuse</td>
</tr>
<tr>
<td>43 yr</td>
<td>F</td>
<td>AA</td>
<td>HTN, HCL, DM, Obesity</td>
<td>2</td>
<td>0.01</td>
<td>0.053</td>
<td>Type II NSTEMI</td>
<td>Hypoxic asthma exacerbation with demand ischemia</td>
</tr>
<tr>
<td>42 yr</td>
<td>M</td>
<td>AA</td>
<td>Smoker, HTN</td>
<td>2</td>
<td>0.05</td>
<td>0.109</td>
<td>Type II NSTEMI</td>
<td>Hypertensive urgency with demand ischemia</td>
</tr>
<tr>
<td>45 yr</td>
<td>F</td>
<td>White</td>
<td>HTN</td>
<td>2</td>
<td>0</td>
<td>0.045</td>
<td>Type II NSTEMI</td>
<td>Hypertension with demand ischemia</td>
</tr>
<tr>
<td>53 yr</td>
<td>M</td>
<td>AA</td>
<td>HTN, known CAD</td>
<td>3</td>
<td>0</td>
<td>0.044</td>
<td>Type II NSTEMI</td>
<td>Hypertensive heart and kidney disease, demand ischemia</td>
</tr>
<tr>
<td>35 yr</td>
<td>M</td>
<td>AA</td>
<td>Smoker, HIV</td>
<td>2</td>
<td>0</td>
<td>0.045</td>
<td>Type II NSTEMI</td>
<td>Methamphetamine abuse</td>
</tr>
<tr>
<td>53 yr</td>
<td>M</td>
<td>White</td>
<td>Smoker, DM, HTN, HCL, Obesity</td>
<td>2</td>
<td>0</td>
<td>0.086</td>
<td>Type I NSTEMI</td>
<td>Stent placed in left circumflex for 90% stenosis</td>
</tr>
</tbody>
</table>

M – male; F – female; AA – African American; CAD – Coronary Artery Disease; HTN – Hypertension; HCL – Hypercholesterolemia; DM – Diabetes Mellitus; cath – catheterization; HIV – Human Immunodeficiency Virus Infection; NSTEMI – non-ST Elevation Myocardial Infarction; CMR – Cardiovascular Magnetic Resonance imaging
**Figure 3. HEART Score Sheet**

<table>
<thead>
<tr>
<th>High Risk Features</th>
<th>Low Risk Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middle or left-sided</td>
<td>Well localized</td>
</tr>
<tr>
<td>Heavy chest pain</td>
<td>Sharp pain</td>
</tr>
<tr>
<td>Diaphoresis</td>
<td>Non-exertional</td>
</tr>
<tr>
<td>Radiation</td>
<td>No diaphoresis</td>
</tr>
<tr>
<td>N/V</td>
<td>No N/V</td>
</tr>
<tr>
<td>Exertional</td>
<td></td>
</tr>
<tr>
<td>Relief of symptoms by sublingual nitrates</td>
<td></td>
</tr>
</tbody>
</table>

- **Highly Suspicious**: 2 points
- **Moderately Suspicious**: 1 point
- **Slightly Suspicious**: 0 points

**ECG**
- **New ischemic changes**: 2 points
- **Non-specific changes**: 1 point

- **Ischemic ST-segment depression**
- **New ischemic T-wave inversions**
- **Reperfusion abnormalities**
- **Non-specific T-wave changes**
- **Non-specific ST-segment depression or elevation**
- **Bundle branch blocks**
- **Rearrhythmia**
- **LVH**
- **Early repolarization**
- **Digoxin effect**

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Obesity (BMI ≥30)</td>
<td>2 points ≥ 65 years old</td>
</tr>
<tr>
<td>Current or recent (≥ 90 days) smoker</td>
<td>1 point 45-64 years old</td>
</tr>
<tr>
<td>Family history of CAD (1st degree relative &lt; 55 y.o.)</td>
<td>0 points &lt; 45 years old</td>
</tr>
<tr>
<td>Diagnosed and/or treated hypertension</td>
<td></td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td></td>
</tr>
</tbody>
</table>

- **≥2 risk factors listed above OR any of the following**: 2 points
  - Known CAD = 2 points
  - Prior stroke = 2 points
  - Peripheral arterial disease = 2 points
  - No risk factors = 0 points

**Tropinon (initial)**
- 0.001-0.240 ng/ml: 2 points >3 times the normal limit
- 0.001-0.240 ng/ml: 1 point 1-3 times the normal limit
- ≤ 0.001 ng/ml: 0 points < normal limit

**HEART Score (total points)**

Add points from each category above

**HEART Risk Level**
- **High Risk**: HEART score 4 or more, or a positive troponin.
- **Low Risk**: HEART score 0-3 and negative troponin

**Paramedic Signature**: __________________________
**Date**: ______________
**Paramedic Name**: __________________________
**Figure 4. Study flow diagram**

**References:**
CHAPTER 3: ADDITIONAL ANALYSES/FUTURE DIRECTIONS

Agreement between Medic and Provider

In this analysis we investigate the agreement between paramedic and Emergency Department (ED) provider History Electrocardiogram Age and Risk factor (HEAR) score. As part of routine clinical care, ED providers complete HEAR scores in patients with acute chest pain in the electronic health record (EHR). During this study ED providers were blinded to the paramedic HEAR score assessments. To assess inter-observer agreement, we compared the ED provider HEAR scores from the EHR with paramedic assessments and Kappa scores were calculated. A Kappa of >0.75 was established a priori as excellent agreement, 0.60-0.74 as acceptable agreement, and <0.59 as unacceptable agreement. The Kappa of the HEAR score and its components are shown in Table V. Agreement was unacceptably low for the HEAR score and all of its components, with the exception of the “Age Score,” which had excellent agreement.

These findings are consistent with a prior study demonstrating poor agreement between ED physicians and cardiologist (kappa = 0.13) when calculating HEART score.

However, these findings differ from the acceptable agreement found by Mahler et al between ED providers (kappa = 0.63). When considered with prior studies our results suggest that HEAR/mHEART score assessments have poor agreement when comparing assessments of health care providers from different disciplines and different levels of training.
Table V. Agreement between EMS provider and ED Provider Scores

<table>
<thead>
<tr>
<th>Overall Score Comparison</th>
<th>Kappa (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEAR score (Total)</td>
<td>0.4070 (0.2839 - 0.5301)</td>
</tr>
<tr>
<td>HEAR score (Total) + cTn</td>
<td>0.4383 (0.3317 - 0.5449)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component Score Comparison</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>History score</td>
<td>0.2611 (0.1641 - 0.3581)</td>
</tr>
<tr>
<td>EKG score</td>
<td>0.3722 (0.2644 - 0.4800)</td>
</tr>
<tr>
<td>Age Score</td>
<td>0.9427 (0.9060 - 0.9794)</td>
</tr>
<tr>
<td>Risk Score</td>
<td>0.3796 (0.2790 - 0.4803)</td>
</tr>
</tbody>
</table>

It has previously been shown that paramedics document the necessary information to calculate a mHEART score with high NPV within the EMS medical record. Despite the possibility the ED physician’s assessment could be in error, the analysis presented here considers the ED provider score to be the “gold standard.” However, regardless of which provider calculated the HEAR score “correctly,” it is clear that prior to routine prehospital use, HEAR score agreement between paramedic and ED assessments must be improved.

Admittedly, the initial training paramedics received on the approach to calculate a mHEART score was limited. Like anything new, there is a learning curve to reach proficiency. In addition, there are some subtle intricacies within the mHEART score that can produce variability between users. The history component score is likely the best example of this. It is well known that patient histories change over time when questioned by different providers. In addition, paramedics may not have placed great importance on their training because they knew this was a research study and was not going to be used clinically.

It has previously been shown that paramedics are particularly facile at identifying the criteria for ST-elevation myocardial infarction (STEMI). The disagreement with the EKG score is an indicator that paramedics may need additional training on differentiating
the three different EKG categories (i.e. ischemic EKG abnormalities, left ventricular hypertrophy, early repolarization) or that they need additional resources to differentiate new changes compared to chronic abnormalities. As the prehospital EHR continues to improve its ability to link to hospital-based EHR systems it is likely that the ability to evaluate prior records including EKGs will become possible in the future.

Finally, ED providers have access to the EHR to assist in the identification of historical risk factors that a patient may have forgotten or denies inadvertently in the face of the chest pain they are experiencing and the anxiety of an ambulance transport. Thus, in future studies of prehospital mHEART assessment it is clear that the approach (including access to an EHR) and the training provided would need to be more extensive.

Test characteristics for Troponin assays for index MI

In addition to the new mHEART assessment, the use of a POC i-STAT device was new for the paramedics. While few studies have previously evaluated the use of POC troponin assays in the prehospital environment, they each demonstrated feasibility. Consistent with prior studies we established that prehospital POC i-STAT measurement was feasible. The paramedics within this pilot were successful in obtaining a cTn result in 83% (421/506) of patients. Table VI is a complete comparison of the test characteristics for cTn assay detection of index MI using the i-STAT and central laboratory assays at the prehospital (EMS), first (ED arrival) and 3-hour clinical blood draws.
Table VI. Test characteristics for cTn assay detection of index visit MI at each blood draw

<table>
<thead>
<tr>
<th>Blood Draw</th>
<th>EMS</th>
<th>ED Arrival</th>
<th>3-Hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay</td>
<td>i-STAT</td>
<td>Central</td>
<td>i-STAT</td>
</tr>
<tr>
<td>Sensitivity (95%CI)</td>
<td>26.5% (16.5-38.6%)</td>
<td>67.2% (54.0-78.7%)</td>
<td>35.1% (22.9-48.9%)</td>
</tr>
<tr>
<td>Specificity (95%CI)</td>
<td>99.2% (97.5-99.8%)</td>
<td>93.2% (89.7-95.8%)</td>
<td>99.2% (97.3-99.9%)</td>
</tr>
<tr>
<td>NPV (95%CI)</td>
<td>87.5% (83.9-90.6%)</td>
<td>93.2% (89.7-95.8%)</td>
<td>87.5% (83.2-91.0%)</td>
</tr>
<tr>
<td>PPV (95%CI)</td>
<td>85.7% (63.7-97.0%)</td>
<td>67.2% (54.0-78.7%)</td>
<td>90.9% (70.8-98.9%)</td>
</tr>
<tr>
<td>+LR (95%CI)</td>
<td>31.15 (9.43-102.83)</td>
<td>9.91 (6.27-15.67)</td>
<td>45.79 (11.01-190.39)</td>
</tr>
<tr>
<td>-LR (95%CI)</td>
<td>0.74 (0.64-0.86)</td>
<td>0.35 (0.25-0.50)</td>
<td>0.65 (0.54-0.79)</td>
</tr>
</tbody>
</table>

Among the 506 patients included in the study, a clinical troponin measurement at ED arrival was obtained in 89.1% (451/506). Among the 421 patients with an EMS POC troponin result (without an error code) the sensitivity of the i-STAT cTn measure for index MI was 26.5% (95%CI 16.5-38.5%) compared to a sensitivity of 67.2% (95%CI 54.0-78.7%) for central lab cTn analysis of the same blood sample. Among these patients, 84.6% (356/421) had a research ordered in-hospital i-STAT test (p<0.0001).

Sensitivity of the i-STAT POC measurement from the ED arrival blood sample for detection of index MI was 35.1% (95%CI 22.9-48.9%) compared to a sensitivity of 75.9% (95%CI 65.0-84.9%) for the central laboratory troponin measurement (p<0.0001).

A 3-hour clinical cTn measurement was obtained in 80.2% (406/506) of patients, but only 31.5% (128/406) of these patients had a 3-hour in-hospital i-STAT measurement. Sensitivity of the i-STAT measurement for index MI on the 3-hour blood draw was 35.3% (95%CI 19.7-53.5%) compared to 85.9% (95%CI 76.2-92.7%) for the central laboratory cTn assay (p=0.0001).
These data demonstrate the improved sensitivity of troponin measurements with increased time (from blood drawn in the prehospital setting to the 3-hour sample) (Figure 5). This is consistent with prior studies demonstrating that troponin measurement with more time from presentation and symptom onset is more sensitive for the detection of MI.\textsuperscript{10-12} During MI ischemic heart muscle cells lyse and release troponin into the blood. As time moves forward more troponin is released and therefore it is easier to detect. Current conventional troponin assays are often unable to detect troponin among patients early in the evolution of a MI event, therefore serial troponin measurement is made to improve sensitivity. Recently FDA approved high sensitivity troponin assays reduce the time required to detect troponin in blood. POC assays which have lower sensitivity than contemporary central laboratory assays, can require up to 6 hours to detect troponin release from MI.\textsuperscript{13}
Figure 5. Sensitivity for detection of index MI for POC vs. Central Lab cTn Assays at EMS, Arrival and 3-Hour blood draws

**Agreement between Troponin assays**

Agreement (on elevated vs negative results) between i-STAT POC troponin measurement and central lab assay for the EMS blood sample occurred in 85.9% (95%CI 81.4-89.6%) with a Kappa of 0.34 (95%CI 0.20-0.48) (Table VII). Most disagreements occurred in patients with elevated central lab troponins and negative POC results (13.5%, 95%CI 9.9-17.8%). For the blood draw on ED arrival, agreement between i-STAT POC troponin measurement in the hospital blood gas lab and central lab assay occurred in 89.7% (95%CI 85.7-92.9%) yielding a Kappa of 0.54 (95%CI 0.40-0.68). All disagreements occurred in patients with elevated central lab troponins and negative POC results (10.3%, 95%CI 7.1-14.3%). Agreement between i-STAT POC troponin measurement and central lab assay for the 3-hour blood sample occurred in 84.1% (95%CI 76.6-90.0%) with a
Kappa of 0.47 (95%CI 0.28-0.65). Again, most disagreements occurred in patients with elevated central lab troponins and negative POC results (15.1%, 95%CI 9.3-22.5%). All kappa assessments were below the a priori definition of “acceptable” agreement (0.60).

Table VII. Agreement between i-STAT and central lab troponin assays

<table>
<thead>
<tr>
<th>Troponin Comparison</th>
<th>Kappa (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prehospital blood draw on EMS i-STAT vs Central lab</td>
<td>0.34 (CI: 0.20-0.48)</td>
</tr>
<tr>
<td>assay</td>
<td></td>
</tr>
<tr>
<td>ED arrival draw, blood gas lab i-STAT vs Central lab</td>
<td>0.54 (CI: 0.40-0.68)</td>
</tr>
<tr>
<td>assay</td>
<td></td>
</tr>
<tr>
<td>3-hour clinical draw Blood gas lab i-STAT vs Central</td>
<td>0.47 (CI:0.28-0.65)</td>
</tr>
<tr>
<td>lab assay</td>
<td></td>
</tr>
</tbody>
</table>

This lack of agreement in all three i-STAT comparisons (prehospital and blood gas lab) suggests that poor agreement is due to the low sensitivity of the POC i-STAT assay. However, since the prehospital blood draw had the lowest agreement it is possible that paramedics’ lack of experience with the i-STAT device and the movement/vibration in the back of the ambulance had some adverse effects on troponin results. We suspect that the use of a POC cTn assay with improved sensitivity by paramedics with greater training will be able to achieve acceptable agreement.

New i-STAT cut point for POC Troponin

For our primary analysis of the performance of the i-STAT POC troponin was tested using a cut point of 0.08 ng/mL, which corresponds to the published 99th percentile upper reference limit (URL) for the assay to declare a result positive or negative. A planned post-hoc analysis of troponin cut points was carried out to evaluate the performance of the POC troponin using the level of detection (LOD) as the cut point. Results of this analysis are shown in Table VIII.
Table VIII. Performance of mHEART using the cTn at the LOD vs URL for index MACE

<table>
<thead>
<tr>
<th>Cut point</th>
<th>EMS mHEART</th>
<th>LOD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td>Sensitivity (95%CI)</td>
<td>91.1% (82.6-96.4%)</td>
<td>95.1% (88.0-98.7%)</td>
</tr>
<tr>
<td>Specificity (95%CI)</td>
<td>32.1% (27.4-37.2%)</td>
<td>26.6% (22.1-31.4%)</td>
</tr>
<tr>
<td>NPV (95%CI)</td>
<td>94.4% (88.7-97.7%)</td>
<td>96.0% (90.2-98.9%)</td>
</tr>
<tr>
<td>PPV (95%CI)</td>
<td>22.6% (18.1-27.6%)</td>
<td>22.5% (18.2-27.3%)</td>
</tr>
<tr>
<td>+LR (95%CI)</td>
<td>1.343 (1.217-1.482)</td>
<td>1.296 (1.197-1.402)</td>
</tr>
<tr>
<td>-LR (95%CI)</td>
<td>0.276 (0.134-0.568)</td>
<td>0.183 (0.070-0.485)</td>
</tr>
</tbody>
</table>

This change in cut point improved the sensitivity from 91.1% to 95.1% (p=0.25) while decreasing the specificity from 32.1% to 26.6% (p<0.0001). NPV increased from 94.4% to 96.0% (p=0.22 using the weighted generalized score statistic proposed by Kosinski). It is likely that even if the mHEART assessment was augmented by a 3-hour repeat troponin as directed by the HEART Pathway, the assessment would not be sufficiently sensitive to rule the patient out for MACE. Furthermore, these improvements in sensitivity and NPV are not clinically or statistically significant.

**Potential impact of Paramedic assessment and blood draw on Length of Stay**

Thus far our analyses focused on feasibility and performance of a prehospital risk assessment tool with a POC troponin device. However, a prehospital risk assessment has the potential to expedite ED care for patients with chest pain by starting the evaluation earlier. In this analysis, we explore the potential reduction in ED length of stay that could be achieved if the ED and hospital central lab teams used blood drawn in the prehospital setting for their initial troponin measurement. Among the 506 patients in this study, 401 (79.2%) had both a prehospital i-STAT troponin and an initial ED clinical draw troponin. This sub group of patients is described in Table IX.
We previously showed that the EMS blood run in the central lab has similar performance to the ED arrival clinical draw (see Table VI above). In addition, we demonstrated that the mHEART performance using EMS blood run in the central lab had a sensitivity and NPV of 100% for index and 30-day MACE (see Table 3 from chapter 2). These results support the concept of initiating the HEART Pathway (a standard practice in many EDs) in the prehospital setting by starting the cTn time clock once blood is drawn by EMS.

(Figure 6)

Table IX. PARAHEART patient characteristics of patients with EMS i-STAT & ED arrival blood draw

<table>
<thead>
<tr>
<th>Patient Characteristic</th>
<th>Total N=401</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age years – mean ± SD</td>
<td>60.1 ± 14.9</td>
</tr>
<tr>
<td>Sex (female)</td>
<td>209 (52.1%)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>205 (51.1%)</td>
</tr>
<tr>
<td>African American</td>
<td>172 (42.9%)</td>
</tr>
<tr>
<td>Asian</td>
<td>4 (1.0%)</td>
</tr>
<tr>
<td>Native American</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Other</td>
<td>17 (4.2%)</td>
</tr>
<tr>
<td>Ethnicity (Hispanic)</td>
<td>15 (3.7%)</td>
</tr>
<tr>
<td>Risk factors</td>
<td></td>
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<tr>
<td>Current smoking</td>
<td>96 (23.9%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>240 (59.9%)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>118 (29.4%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>131 (32.7%)</td>
</tr>
<tr>
<td>Family history of CAD</td>
<td>97 (24.2%)</td>
</tr>
<tr>
<td>BMI &gt;30 (kg/m²)</td>
<td>124 (30.9%)</td>
</tr>
<tr>
<td>Prior coronary disease</td>
<td>124 (30.9%)</td>
</tr>
<tr>
<td>Prior MI</td>
<td>83 (20.7%)</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>60 (15.0%)</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>42 (10.5%)</td>
</tr>
<tr>
<td>Prior CHF</td>
<td>59 (14.7%)</td>
</tr>
<tr>
<td>Prior PVD</td>
<td>20 (5.0%)</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>41 (10.2%)</td>
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</table>

CAD – Coronary Artery Disease, PVD – Peripheral Vascular Disease, BMI – Body Mass Index, MI – Myocardial Infarction, PCI – Percutaneous Coronary Intervention, CABG – Coronary Artery Bypass Grafting, CHF – Congestive Heart Failure
The mean time between EMS blood collection and arrival to the ED was 20.3 minutes (SD 12.3 min). The mean time between ED arrival and the first ED clinical blood draw is 52.2 minutes (SD 34.9 min). The mean difference in the length of stay using the EMS i-STAT run time plus three hours and ED’s first clinical draw time plus three hours is 72.5 minutes (SD 35.7 min). Thus, the use of the blood that EMS collects has the potential to shorten a patient’s length of stay by nearly an hour and fifteen minutes. This benefit is most applicable to the group of people that have the potential to be discharged from the emergency department after the repeat troponin drawn three hours after the first. Standard practice at WFBH is to use the HEART Pathway in low-risk patients and order an initial and 3-hour troponin to ensure the patient is appropriate for early discharge from the ED instead of being admitted for objective cardiac testing. When the same analysis was performed on just low risk patients (60 patients) with both EMS i-STAT result and ED clinical draw one the mean time difference was similar at 76.3 minutes (SD 37.9 min).

The current practice of medicine is burdened by ED overcrowding and poor access to care. If a busy ED could safely discharge low risk patients an hour and fifteen minutes earlier and that time was compounded by every similar patient with low-risk chest pain,
access to care for all patients would certainly improve. This intervention has the potential to decrease the left without being seen rate, decrease waiting room times, improve patient satisfaction, and increase revenue for hospitals. This theory needs to be tested prospectively with a collaborative intervention allowing prehospital blood draw time to be the initial time stamp for patients’ chest pain evaluation.

**Future Directions**

Based on the results of this study it is clear that there are several future investigations that should be undertaken. First, this study should be repeated with a more sensitive POC cTn assay and with greater focus on paramedic training in an effort to improve the sensitivity of the mHEART assessment. Second, an EMS destination plan informed by mHEART to provide “Smart EMS triage” can be pilot tested immediately in EMS agencies that are required to make decisions about transporting patients with chest pain to local hospitals or to tertiary centers with cardiac catheterization capabilities. This intervention would rely on the high specificities found in this study. Another opportunity that can be grasped immediately is an intervention to collaborate with paramedics to draw a vial of blood that can be tested for cTn level in the hospital central laboratory much earlier than the blood drawn upon arrival in the ED. The predicted benefit of 72 minutes needs to be confirmed. Finally, this study lays significant groundwork for a protocol to evaluate and rule out patients that are determined to be very low risk for MACE by mHEART at “home” without evaluation in the ED. This “home rule out” strategy could provide patient focused care that will reduce healthcare resource overutilization.
References:


NAME: Jason P. Stopyra, M.D.

ADDRESS: Department of Emergency Medicine
Wake Forest School of Medicine
Medical Center Boulevard
Winston-Salem, NC 27157-1010
(336) 713-7050 (office)
(336) 716-5438 (fax)
E-mail: jstopyra@wakehealth.edu

EDUCATION:
1992-1996 Cornell University, Ithaca, NY
B.S. Biology

1996-2000 University of Buffalo, Buffalo, NY
M.D.

2016-2019 (Expected) Wake Forest University
Winston-Salem, NC
M.S. Candidate - Clinical and Population Translational Sciences

POSTDOCTORAL TRAINING:
2000-2001 Intern Emergency Medicine
Wake Forest University Baptist School of Medicine
Winston-Salem, NC

2001-2003 Resident/Chief Resident Emergency Medicine - Wake Forest University Baptist School of Medicine
Winston-Salem, NC

PROFESSIONAL LICENSURE:
2001-present State of North Carolina, #200101499
2001-present DEA # (available on request)
2012-2016 State of Virginia, #0101251801

SPECIALTY CERTIFICATION:
2004, 2014 Emergency Medicine (EM) Diplomate,
American Board of Emergency Medicine

2015 Emergency Medical Services (EMS)
Diplomate, American Board of Emergency Medicine
EMPLOYMENT:

Academic Appointments:

*Wake Forest School of Medicine, Wake Forest University:*

2011-2013 Adjunct Volunteer Assistant Professor
Department of Emergency Medicine
Wake Forest School of Medicine
Winston-Salem, North Carolina

2013-Present Assistant Professor
Department of Emergency Medicine
Wake Forest School of Medicine
Winston-Salem, North Carolina

Professional Experience

1992-1996 Member/Crew Chief/Equipment Officer/Director
Cornell University EMS, Ithaca, NY

1995-1996 Advanced EMT-III
Bangs Ambulance, Ithaca, NY

1995-1996 Emergency Department Tech/Clerk
Cayuga Medical Center, Ithaca NY

2003-2013 Emergency Department Physician
Physician Scheduler
Mt. Airy Emergency Physicians
Northern Hospital of Surry County, Mt. Airy, NC

2004-2019 EMS Medical Director & Medical Examiner
Surry County Emergency Services, Mt. Airy, NC

2005-2019 Tactical Physician
Mt. Airy Police Department
Surry County Sherriff’s Department

2011-2017 EMS Program Medical Director – Surry
Community College, Dobson, NC

2011-2016 Staff Physician – Mountain Valley Hospice &
Palliative Care, Mt. Airy, NC

2011-Current Assistant Medical Director
AirCare Critical Care Transport
2013-Current Emergency Department Physician
Wake Forest Baptist Health, Winston Salem Campus
Winston Salem, NC 27157

2013-Current Emergency Department Physician
Wake Forest Baptist Health, Lexington Campus
Lexington, NC 27292

2014-Current EMS Medical Director
Randolph Co Emergency Services, Asheboro, NC

2015-Current Medical Director
Surry Co Health and Nutrition Center, Dobson, NC

2016-2017 EMS Medical Director – Interim
Iredell Co Emergency Services, Statesville, NC

2016-Current EMS Medical Director
Region I North Carolina

Editorial Boards: NC Journal of Prehospital Care
Forensics Section Editor (2013 – 2015)

Pedi-STEPPS; Bomb/Blast MCI, Resident Training for On-line Medical Control

Advisory Boards: Performance Improvement Committee Surry County EMS
Chair (2004-2019)

NC State Paramedic Competition
Medical Director (2005-2016)

NCCEP EMS Committee
Protocol Working Committee
Member (2009-Current)

Project Lazarus of Surry
Co-Founder/Chair/Member (2011-2018)

Surry Community College EMS Program Advisory Committee
Chair (2012-2017)
NAEMSP North Carolina Chapter
Member (2013-Current)

ABEM Oral Certification Examiner
Exams: Spring 2013, Fall 2014, Fall 2015

Performance Improvement Committee Randolph County EMS
Chair (2014-Current)

Surry County Opioid Advisory Council
Member (2017-2019)

Randolph County Opioid Collaborative Council
Member (2017-Current)

**National Committees**

National Association of EMS Physicians MIH/CP Committee
Vice-Chair (2015-2017)
Member (2015-Current)

Member (2015-Current)

National Association of EMS Physicians Programming Comm.
Member (2015-2017)

National Association of Emergency Medical Technicians MIH/CP Committee
Member (2015-2016)

National Association of EMS Physicians MIH/CP Pre-conference Co-Director
2016 – San Diego
2017 – New Orleans
### ADMINISTRATIVE SERVICE:

**School of Medicine:**

<table>
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<th>Years</th>
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<tr>
<td>2016-Current</td>
<td>Wake Forest School of Medicine Faculty Development Committee Chair, 2018-2019</td>
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**Institutional Service:**

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<tr>
<td>2004-2013</td>
<td>Northern Hospital of Surry County - Mt Airy Emergency Physicians Continuing Quality Improvement Officer</td>
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<tr>
<td>2010-2011</td>
<td>Northern Hospital of Surry County - Mt Airy Emergency Physicians Electronic Medical Record Consultant - Meditech</td>
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<td>2014-2016</td>
<td>Wake Forest Baptist Health Cardiovascular Service Line Liaison to Prehospital Agencies</td>
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<td>2016-Current</td>
<td>Wake Forest Baptist Health Emergency Medicine Representative for Chest Pain Center Accreditation by The Joint Commission</td>
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**Departmental Committee Service:**

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<thead>
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<tr>
<td>2012-Current</td>
<td>Wake Forest Baptist Health Emergency Medical Service Fellowship Committee Faculty</td>
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<tr>
<td>2014</td>
<td>Wake Forest Baptist Health Ebola Preparedness Response Committee</td>
</tr>
<tr>
<td>2014-2016</td>
<td>Wake Forest Baptist Health Emergency Medicine Education Committee</td>
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<td>2014</td>
<td>Wake Forest Baptist Health Emergency Medicine Shift Alignment Working Group</td>
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### Professional Memberships and Service:

<table>
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<tr>
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<tr>
<td>1996-2003</td>
<td>American Medical Association</td>
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<td>1997-Current</td>
<td>American College of Emergency Physicians</td>
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<td></td>
<td>EMS, Aeromedical and Tactical Sections</td>
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<tr>
<td>1999-Current</td>
<td>Society for Academic Emergency Medicine</td>
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<td>2001-2003</td>
<td>American Academy of Emergency Medicine</td>
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<td>2007-Current</td>
<td>National Association of EMS Physicians</td>
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### Honors and Awards:

<table>
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<tr>
<th>Year</th>
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<tr>
<td>2000</td>
<td>Dean’s Award, University of Buffalo</td>
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<td>2000</td>
<td>Society for Academic Emergency Medicine – Excellence in Emergency Medicine Award</td>
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<td>2001</td>
<td>Customer Service Award, Wake Forest Baptist Medical Center</td>
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<tr>
<td>2002</td>
<td>James Byrum, MD Academic Excellence/Resident Research Award, Wake Forest University</td>
</tr>
<tr>
<td>2003</td>
<td>James Byrum, MD Academic Excellence/Resident Research Award, Wake Forest University</td>
</tr>
<tr>
<td>2010</td>
<td>NHSC Excellent Service Star Award</td>
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<tr>
<td>2014</td>
<td>Best Educational Experience 2014 WFSoM Clerkship Class</td>
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</table>
2014 MSIII Clerkship "Best Teachers & Role Models" Recognition - December

2016 North Carolina Doctor of the Year, North Carolina Medical Society

2016 Excellence in Teaching Award, EM Resident Graduation Ceremony
Wake Forest School of Medicine Department of Emergency Medicine

GRANTS

Current Active Grants:

16-00646 / GTS 43837 (Mahler, SA, P.I., Stopyra, JP, Co-I, 5%)
6/1/2016-11/30/2018 $162,306/ year direct cost
Can Pre-Hospital Use of the HEART Score and Abbott i-STAT® Point-of-Care Troponin Predict Major Adverse Cardiovascular Events: the PARA-HEART Pilot Implementation Abbott Point of Care: Investigator Initiated

(Stopyra JP, P.I., Mahler SA, 5%)
4/1/2018-3/31/2019 $40,000
Can pre-hospital providers to calculate the HEART Pathway score, EDACS score, revised Geneva score, and PERC score to accurately predict patient outcomes in patients with chest pain.
CTSI: Pilot

1R01HL118263-01 (Miller) 06/01/2013 – 01/31/2020 As required NIH / NHLBI $471,033
Cardiac Magnetic Resonance Imaging Strategy for the Management of Patients with Acute Chest Pain and Detectable to Elevated Troponin (CMR-IMPACT) The objective of this trial is to improve outcomes by optimizing healthcare delivery processes for patients with detectable to elevated serum troponin. This study will test whether a CMR-guided strategy compared to customary inpatient care reduces the composite of death, nonfatal MI, and cardiac-related hospital readmission over the study duration, and whether a CMR-guided strategy compared to customary inpatient care reduces invasive angiography, coronary revascularization, recurrent cardiac testing, and cardiac-related ED visits.
Role: Co-Investigator
Vitamin D to Improve Outcomes by Leveraging Early Treatment (VIOLET)
The objective of this trial is to assess the efficacy and safety of early
administration of vitamin D3 (cholecalciferol) in reducing mortality and morbidity
for vitamin D deficient patients at high risk for ARDS and mortality.
Role: Co-Investigator

CLINICAL INNOVATIONS AND INITIATIVES

Clinical Innovations

2014-Current
Team Focused CPR, Randolph County EMS Medical Director
Local county implementation
Return of Spontaneous Circulation in cardiac arrest used to measure success

Quality Improvement Initiatives

2015-2016
Drug Assisted Intubation, Surry County EMS Medical Director
Local county implementation
First pass success; lack of failed airway and post-DAI cardiac arrest events

BIBLIOGRAPHY:

Peer-Reviewed Publications:


Invited Publications:


Miscellaneous Publications:


7. Sempsrott J, **Stopyra JP**, “Not Just Another ReNAD.” Randolph County Emergency Services Newsletter, December 2014


11. Beaver B, **Stopyra JP**, “EMS Fellow/Assistant Medical Director.” Randolph County Emergency Services Newsletter, April 2015


15. Beaver B, **Stopyra JP**. “It’s all about you.” Randolph County Emergency Services Newsletter, July 2015

17. Beaver B, **Stopyna JP**. “Cardiac Arrest: Exciting Opportunities.” Randolph County Emergency Services Newsletter, August 2015


22. **Stopyna JP**. “It’s that time of year again!” Randolph County Emergency Services Newsletter, December 2015


31. Smith AB, Stopyra JP, Mell HK. “A Review of the International Liaison Committee on Resuscitation First Aid Guidelines, Dissecting the evidence behind the recommendations: Stroke Recognition” ACEP Now, October 2016 p 12, 35.

32. Stopyra JP. “Joy to the World!” Randolph County Emergency Services Newsletter, December 2016


34. Stopyra JP. “SODOTO in Randolph County” Randolph County Emergency Services Newsletter, January 2017


37. Stopyra JP. “HIV/AIDS” Randolph County Emergency Services Newsletter, March 2017


39. Stopyra JP. “ALS Awareness” Randolph County Emergency Services Newsletter, May 2017


41. Stopyra JP. “Summer time means it’s Trauma time” Randolph County Emergency Services Newsletter, July 2017

42. Powell S, Davis C, Stopyra JP. “The Opioid Crisis – a brief look from our eyes..” Randolph County Emergency Services Newsletter, September 2017
43. Davis C, Powell S, Stopyra JP. “Hocus POCUS? The Magic of Sonography” Randolph County Emergency Services Newsletter, October 2017

44. Davis C, Powell S, Stopyra JP. “All that gurgles is not GI.” Randolph County Emergency Services Newsletter, November 2017

45. Stopyra JP. “RCEMS ‘2017 in Review’” Randolph County Emergency Services Newsletter, December 2017

46. Stopyra JP. “Re-view, Re-shape, Re-inforce, Re-new, Re-invest, Re-ward!” Randolph County Emergency Services Newsletter, January 2018

47. Stopyra JP. “Really, what am I supposed to do?” Randolph County Emergency Services Newsletter, February 2018

48. Ashburn N, Stopyra JP. “Your value in Prehospital Medical Research and Quality Improvement” Randolph County Emergency Services Newsletter, March 2018

49. Phillips J, Stopyra JP. “Protocol Review - Bradycardia” Randolph County Emergency Services Newsletter, April 2018

50. Bozeman WP, Stopyra JP, Corn P, Moser JT. “Protected Health Information and Use-Of-Force Investigations” FBI Law Enforcement Bulletin, 87(4); April 2018


52. Phillips J, Stopyra JP. “Disaster Triage” Randolph County Emergency Services Newsletter, June 2018

53. Stopyra JP. “TSOP 2018” Randolph County Emergency Services Newsletter, September 2018

54. Phillips J, Stopyra JP. “Spiders and Snakes, Oh My!” Randolph County Emergency Services Newsletter, October 2018

55. Stopyra JP. “World Diabetes Day” Randolph County Emergency Services Newsletter, November 2018

56. Ashburn N, Stopyra JP. “Prehospital Obstetrical Emergencies in Randolph County” Randolph County Emergency Services Newsletter, December 2018

57. Phillips J, Stopyra JP. “Brrrr!! Hypothermia” Randolph County Emergency Services Newsletter, January 2019
58. Ashburn N, **Stoprya JP**. “The Broken Heart Syndrome” Randolph County Emergency Services Newsletter, February 2019

PRESENTATIONS AT PROFESSIONAL MEETINGS:

1. Broderick KB, **Stoprya JP**. “Prospective Urine Dipstick Study.” Presented at ACEP 1998, San Diego


INVITED EXTRAMURAL PRESENTATIONS AND SEMINARS:

“Venomous Bites & Stings” South Carolina Emergency Care Symposium – April 2009.
“Heat & Cold Emergencies” South Carolina emergency Care Symposium – April 2009

“Methamphetamine: Clan Lab Awareness” South Carolina Emergency Care Symposium – April 2010

“Pediatric Nightmares: Scenarios You Better Be Ready For!” South Carolina Emergency Care Symposium – April 2010

“Excited Delirium Syndrome” CIT Course – Surry County – May 2010

“More Pediatric Nightmares: Scenarios You Better Be Ready For!” South Carolina Emergency Care Symposium – April 2011

“Excited Delirium Syndrome” South Carolina Emergency Care Symposium – April 2011


“Excited Delirium Syndrome” CIT Course – Surry County – April 2012

Key Note Speaker – Surry Community College Paramedic Graduation – May 2012

RACE CARS Lecturer – March 12, 2014
Lecture Topics: Acute Grief Life Support, RACE EMD, Induced Hypothermia, Team Focus CPR & Science behind CPR

“Excited Delirium Syndrome” NC Highway Patrol EMT Refresher Course – April 2014

“Performance Improvement” Medical Directors Update - EM Today – October 2014


“Capnography in Emergency & Critical Care” Piedmont Triad Regional Trauma & Acute Care Symposium, Winston-Salem NC – May 2016

“Mobile Integrated Health/Community Paramedicine – A Win, Win, Win” Society of Cardiovascular Patient Care 19th Congress, Miami, Florida – May 2016

“How Outcomes Open the Door to Research” ESO User Group 2016, Raleigh, NC – August 18, 2016
“EMS Safety” – EMSPRIDE, Greensboro, NC – August 2016

“Cardiac Arrest and Electrical Therapy” – South Carolina Rural EMS Conference, Lexington SC – September 23, 2016

“Opening the Door to Research & Improvement Through Shared Data” – WAVE 2016, Austin TX – November 2016

“Breaking Data Barriers with ESO HDE” – WAVE 2016, Austin TX – November 2016


“You can survive cardiac arrest!” South Carolina Emergency Care Symposium – March 2017

“HEART Pathway” – Wake Forest Baptist Medical Center The Joint Commission Survey – August 2017

“Opioid Abuse and its Impact on Emergency Management” – Randolph County Opioid Crisis Symposium – August 2017

Health Professions Education Grand Rounds Panelist – Wake Forest University School of Medicine – September & November 2017

“I Don’t Know Nothin’ About No Research, but I Sure Do Want to Improve Quality!” – WAVE 2018, Austin TX – February 2018

INVITED PRESENTATIONS AND SEMINARS (COMMERCIAL):

Southeastern Emergency Equipment Paramedic Refresher Course – February 2014 Lecture Topics: Preventing Peri-Intubation Deaths, Pediatric Nightmares, Excited Delirium

Southeastern Emergency Equipment Paramedic Refresher Course – July 2014 Lecture Topics: Preventing Peri-Intubation Deaths, Pediatric Nightmares, Excited Delirium

Southeastern Emergency Equipment Paramedic Refresher Course – March 2015 Lecture Topics: Preventing Peri-Intubation Deaths, Pediatric Nightmares, Excited Delirium, Toxicology

Southeastern Emergency Equipment Paramedic Refresher Course – March 2016 Lecture Topics: Paramedic Assessment, Excited Delirium, Shock
Southeastern Emergency Equipment Paramedic Refresher Course – July 2016
Lecture Topics: Paramedic Assessment, Excited Delirium, Shock

Southeastern Emergency Equipment Paramedic Refresher Course – November 2016
Lecture Topics: Paramedic Assessment, Excited Delirium, Shock

Southeastern Emergency Equipment Paramedic Refresher Course – March 2017
Lecture Topics: Pediatric Emergencies, Excited Delirium, Human Trafficking, EMS Safety

Southeastern Emergency Equipment Paramedic Refresher Course – August 2017
Lecture Topics: Pediatric Emergencies, Shock, Human Trafficking, ROSC, Now what?

MENTORING RELATIONSHIPS:

<table>
<thead>
<tr>
<th>Graduate Students:</th>
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<tbody>
<tr>
<td>2013-Current</td>
<td>Adam McHone, NP-C</td>
</tr>
<tr>
<td></td>
<td>Doctorate in Nursing Practice</td>
</tr>
<tr>
<td></td>
<td>Thesis advisor</td>
</tr>
<tr>
<td>2014-2016</td>
<td>Tyson Higgins</td>
</tr>
<tr>
<td></td>
<td>Medical Student</td>
</tr>
<tr>
<td></td>
<td>Research Advisor</td>
</tr>
<tr>
<td>2016-Current</td>
<td>Nella Hendley</td>
</tr>
<tr>
<td></td>
<td>Medical Student</td>
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<tr>
<td>2016-Current</td>
<td>Julia Prokesova, MD</td>
</tr>
<tr>
<td></td>
<td>Medical Student/Resident</td>
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<td>Research Advisor</td>
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<tr>
<td>2016-Current</td>
<td>James F. Scheidler, MD</td>
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<tr>
<td></td>
<td>Emergency Medicine Resident</td>
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<td>Research Advisor</td>
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<tr>
<td>2016-Current</td>
<td>Nicklaus Ashburn, MD</td>
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<tr>
<td>2016-Current</td>
<td>Andrew Starnes, MD</td>
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<tr>
<td>2016-2018</td>
<td>Jennifer Beatty, MD</td>
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<tr>
<td>2015-2018</td>
<td>Shannon Mumma, MD</td>
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<tr>
<td>2015-2018</td>
<td>Jeremiah Gaddy, MD</td>
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<tr>
<td>2015-2017</td>
<td>Jonah Gunalda, MD</td>
</tr>
<tr>
<td>2013-2015</td>
<td>Justin Semsrott, MD</td>
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<tr>
<td>2014-2016</td>
<td>Bryan Beaver, MD</td>
</tr>
<tr>
<td>2014-Current</td>
<td>Christopher A. Davis, MD</td>
</tr>
<tr>
<td>2014-2016</td>
<td>Steven Walton, MD</td>
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2014-2016

Alex Nickle, MD
Emergency Medicine Resident
Research Advisor
15th Annual James Byrum, MD
Academic Excellence/Resident
Research Award, Wake Forest
University – 2014-2015

2014-2015

Julio Arrieta, MD
Emergency Medicine Resident
Research Advisor

2014-2016

William S. Harper, MD
Emergency Medicine Resident
Research Advisor
16th Annual James Byrum, MD
Academic Excellence/Resident
Research Award, Wake Forest
University – 2015-2016

Faculty
2016-Current
Bryan Beaver, MD, Instructor
Faculty Mentor, EMS Medical Director
Iredell County

PUBLIC OUTREACH:

1. 2012-2016
Guest Teacher
Rural Hall Elementary School, Rural
Hall, NC
Lecture Topics: Bones, Muscles, Skin, &
Ears

2. 2012-Current
Summer Camp Nurse/Counselor
Park Springs Christian Camp,
Providence, NC
Junior I, Short-timers, Buddy Camps

3. 2014-2017
Guest Teacher for Tammy Whitt
East Surry High School, Pilot Mountain,
NC –
“Careers in Medicine” “War Stories from
the ER”
4. August 2014
Guest Lecturer
PPG Industries, Lexington, NC
Lecture Topic: Heat Exhaustion

5. June 2016
Key Note Speaker
Rural Hall Elementary Graduation Ceremony

COMMUNITY ACTIVITIES AND SERVICE:

F3 Winston Salem – Fitness, Fellowship, Faith
Site leader, May 2018 - Current

Jefferson Church of Christ, Rural Hall, NC
Deacon, 2010 – 2011
Elder, 2011 – 2019
Chairman of Elders, 2016

Watch Dog Program for Fathers
Rural Hall Elementary, 2014 - 2016

Initiative to place AEDs in Churches and Camps – 2014
Westside Christian Church
Park Springs Christian Camp

ALS Association Care, Cure & Commitment Council
Founding Member, December 2013

Forsyth County Beekeepers Association – Swarm Removal 2012 - 2016

Ardmore Co-op
Member & Supplier of Farm Fresh Chicken eggs & pork – 2012-2016

ALS Half-Marathon Run – 2011 – Charlotte – Thunder Road
Fundraiser - $2500

Melanoma Foundation – Myrtle Beach Marathon 2010
Fundraiser - $1000

Tragedy Assistance Program for Survivors (TAPS) Run 2009
Fundraiser - $1000