Assessing Chest Pain Using Point-of-Care High-Sensitivity Troponin I in the Emergency Department

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Study Title: Assessing Chest Pain Using Point-of-Care High-Sensitivity Troponin I in the Emergency Department

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Background, Rationale and Context

Current care patterns for the 7 million patients who present to U.S. EDs with acute chest pain each year are heterogeneous and costly.[1-8] Over 50% of patients with chest pain are hospitalized, at a cost of $3 billion annually,[5] but ultimately <10% are diagnosed with acute coronary syndrome (ACS).[9] As one of the most common reasons for ED visits, chest pain evaluations are major contributors to ED and hospital crowding; straining health system resources and decreasing patient safety, access, and quality of care.[2,3,5,6,10,11] Strategies to safely optimize hospital resource use for patients with acute chest pain are needed to decrease overcrowding.

Use of POC testing in the Emergency Department (ED) has been previously established as a method to reduce the time-to-disposition-decision (TTD) making for emergency physicians,[12,13] which in-turn can reduce ED LOS[14] and time-to-treatment (TTT) of time sensitive conditions, such as myocardial infarctions (MIs).[15] Recently, new POC high sensitivity cardiac troponin I (hs-cTnI) assays have been developed which offer similar diagnostic performance to traditional central lab hs-cTnI testing. However, data examining POC hs-cTnI measurement in U.S. ED settings are limited. In particular, studies have yet to evaluate the potential impact of POC hs-cTnI implementation on time to troponin result (TTR), time-to-last-troponin-result (TTLT), TTD, TTT, and ED LOS. In addition, limited data exists on how best to implement POC hs-cTnI into ED clinical practice, such as whether POC hs-cTnI measures should be paired with a risk score or incorporated into an accelerated diagnostic protocol.

Clinical leaders within the Advocate Health ED and Cardiovascular Service Lines agree that POC hs-cTnI holds promise for expediting care with the ED setting but requires pilot testing prior to committing the resources needed to fully implement into clinical care. Full implementation of POC hs-cTnI, will require purchasing of multiple devices, expensive cartridges/reagents, and the hiring of dedicated staff to complete the testing. In order to justify costly investments in this new POC technology, we must first establish that their use is able to provide return on investment (e.g., reduced ED LOS). Therefore, we propose an observational pilot of the Abbott Alinity POC device across 3 Advocate Health EDs. Consistent with prior clinical pilots, such as prior testing of new troponin assays, we propose routine collection of a single 5ml blood tube from all patients presenting to the ED with chest pain or other symptoms concerning for acute coronary syndrome during their normal clinical blood draw and under a waiver of informed consent. This blood tube will be used for immediate testing on the Abbott Alinity POC device. However, the clinical team will be blinded to POC results and these results will not be used for clinical care. Data will be collected on the performance and possible time savings of the Abbott Alinity POC hs-cTnI results. These data will be used to inform implementation decisions within Advocate Health but are of high interest to Abbott Laboratories and the broader scientific community as generalizable knowledge. Therefore, we anticipate publishing the results of this observational clinical pilot in a peer-reviewed scientific journal and seek IRB approval to do so.

Objectives

The goal of this proposal is to investigate the potential impact of hs-cTnI testing in the Emergency Department (ED) setting and exploring how best to integrate POC hs-cTn into ED risk stratification workflows.

We hypothesize that the Abbott i-STAT Alinity POC hs-cTnI assay will decrease time-to-result (TTR) and ED length of stay (LOS), while increasing ED revenue for patients with acute chest pain compared to a strategy of central laboratory hs-cTnI testing.

Aim 1: Test whether the Abbott i-STAT Alinity reduces hs-cTnI TTR and TTLT compared to the clinical measures completed in the central laboratory and whether there is high correlation between hs-cTnI measurement strategies.
Aim 2: Determine the potential impact of Abbott i-STAT Alinity use on TTD and ED LOS in all enrolled patients and TTT among patients with a Type 1 NSTEMI diagnosis.
Aim 3: Explore strategies for implementing Abbott i-STAT Alinity hs-cTnI measures into ED risk stratification workflow for patients with acute chest pain.
3a. Evaluate optimal i-STAT Alinity hs-cTnI cut points for predicting index MI and 30-day cardiac death or MI.
3b. Test whether combining i-STAT Alinity hs-cTnI with chest pain risk scores improves diagnostic performance.
3c. Derive an accelerated diagnostic protocol using the i-STAT Alinity hs-cTnI that optimizes negative predictive value for 30-day cardiac death or MI and efficacy (the proportion identified for early discharge from the ED).

Methods and Measures

Overview: We propose a prospective multisite observational clinical pilot evaluating the potential implementation of the Abbott i-STAT Alinity POC hs-cTnI into the current workflow of the institutional care process.

- Participants: Adult ED patients with symptoms suggestive of acute coronary syndrome undergoing a standard-of-care evaluation possible ACS in the ED including blood testing for hs-cTnI (Beckman Coulter) completed in a core laboratory.

- Sites: Three busy tertiary care center EDs will be accrual sites. These include Wake Forest Baptist Medical Center (WFBMC), Carolinas Medical Center (CMC) and High Point Medical Center (HPMC) EDs.

Subject Selection

Adults (≥18 years old) presenting to the ED with symptoms concerning for ACS and an ECG and troponin ordered as part of standard of care, will be eligible for accrual. Patients with acute ST changes ≥1mm on ECG or unstable vital signs will be excluded. In addition, patients will be required to have a (extra) lithium heparin blood sample collected within ± 5 minutes of their clinical draw for hs-cTnI. Patients with central laboratory hs-cTnI testing or a hs-cTnI measure resulted prior to study accrual also be excluded.

Inclusion Criteria

- Age greater than or equal to18 years
- Symptoms suggestive of acute coronary syndrome
  - Acute chest, epigastric, neck, jaw or arm pain or discomfort or pressure without apparent non-cardiac source
  - Shortness of breath, nausea, vomiting, fatigue/malaise, or
  - Other equivalent discomfort suggestive of an MI
- ECG ordered as part of standard of care
- At least one troponin collected as standard of care
- Study specific blood sample collected within ± 5 minutes of clinical draw

Exclusion Criteria

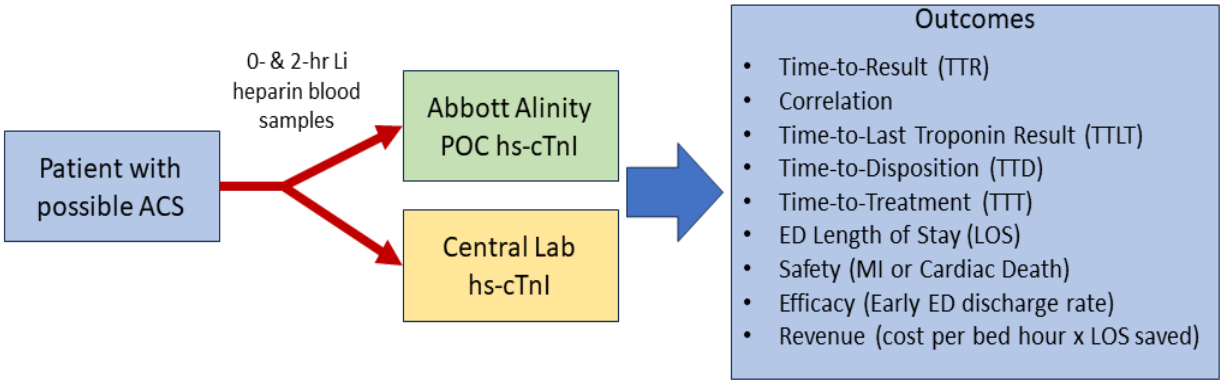
- STEMI Activation
- Unstable vitals signs: symptomatic hypotension at the time of enrollment (systolic < 90 mm Hg), tachycardia (HR>120), bradycardia (HR<40), and hypoxemia (<90% pulse-oximetry on room air or normal home oxygen flow rate)
- Central laboratory hs-cTn testing resulted or in process (>5 minutes) prior to study accrual
- Prior enrollment

Sample Size

A total of 600 patients will be accrued across the 3 sites.

Interventions and Interactions

Participants, accrued under a waiver of informed consent, will undergo a standard-of-care evaluation for possible ACS in the ED including blood testing for hs-cTnI (Beckman Coulter) completed in a central laboratory. During the study period all ED patients with chest pain will have an extra lithium heparin blood sample obtained for each troponin test ordered and collected in the ED (typically 2, but this may range from 1-3 troponin measures), which will be used for immediate hs-cTnI measurement by research personnel using an Abbott i-STAT Alinity. Clinicians will be blinded to the POC hs-cTnI results and will base clinical decisions on central laboratory hs-cTn measures. Blood draw times, result times for POC and central laboratory measures, patient ED arrival, patient ED bedded, ED disposition decision times, and ED discharge times will be recorded on all patients. Following each POC hs-cTnI measurement the treating attending physician will be surveyed regarding whether a negative or positive POC result would change ED disposition or treatment including time stamps to determine estimated TTD, ED LOS and TTT for the POC hs-cTnI measurement strategy. Data from these surveys will be compared to actual TTD, ED LOS and treatment times based on the central laboratory hs-cTnI measurement strategy.



Usual care: Accrued patients will have routine clinical care with lithium heparin samples collected for hs-cTnI measurement sent to the central lab for analysis on the Beckman Coulter Access 2 DXI platform. Electronic health record time stamps will be used to determine the result time, time of any treatment for type 1 NSTEMI (e.g., heparin ordered), and disposition time (e.g., admit or discharge) to calculate actual TTD, ED LOS, and TTT based on the central laboratory hs-cTnI measurement strategy.

Setting: Patients will be accrued from three EDs in North Carolina, each with a high prevalence of acute chest pain and robust research infrastructure. Across these sites we have broad racial and SES representation. The diversity of our sites and their patient populations will ensure that patient groups who are traditionally underrepresented are well captured in this trial and will ensure the generalizability of trial findings. WF is an academic tertiary care center with an ED volume of patients with chest pain exceeding 5,000 per year. CMC is academic tertiary care center located in Charlotte NC, which also has a similar high volume of chest pain. HPMC is a large community tertiary care center with 24/7 catheterization laboratory capability and an ED volume of approximately 4,000 chest pain patients annually

Data Collection and Endpoints

Experienced study staff at each site will collect and enter data using REDCap electronic case report forms (eCRFs). Trial eCRFs will be created and maintained by a dedicated database manager to facilitate timely, accurate, and complete data entry, and allow monitoring and quality control. This will ensure our database is kept up to date and minimize data cleaning. Consistent with our prior trials, we will ensure internal and external validity by including data fields relevant to the evaluation of patients with acute chest pain across the U.S. Baseline data will be collected by site study staff from the patient and clinician (in-person) and supplemented by EHR review. Follow-up data will be gathered by research staff by email, telephone follow-up calls, EHR review, and outside record requests at 30-days.

The primary outcome will be time-to-result (TTR) of hs-cTnI. TTR will be defined as the time from blood collection to result time of the hs-cTnI assay, as recorded by research staff for the i-

STAT Alinity POC and by the electronic health record for central lab Beckman Coulter Access 2 hs-cTnI measures. TTR will be collected for each troponin test ordered and collected in the ED (typically two tests per patient). A secondary outcome is time-to-last-troponin-result (TTLT), which will be defined as the time from ED arrival to the result time of the last hs-cTnI measure in the ED (by the POC and central lab strategies). Other secondary outcomes include time-to-disposition decision (TTD), Time-to-treatment (TTT), and ED length of stay (LOS). TTD is defined as the time from the patient being bedded in the ED to provider decision on disposition (discharge vs admission). TTT will be defined by the time from the patient being bedded in the ED to the provider's decision to initiate treatment for patients with a Type 1 NSTEMI diagnosis (e.g., heparin drip). ED LOS will be defined as the time from ED arrival to disposition (discharged, admitted, observation unit, left against medical advice, transfer, etc). We will also report ED LOS as bed-hours saved and calculate the associated ED revenue generated based on an average of $550 in revenue per bed-hour. In addition, we will monitor safety outcomes, including index MI and the composite of cardiac death or MI at index and 30-days. These endpoints will be determined by expert adjudicators based on the ACCORD trial definition for cardiac death and the Fourth Universal Definition of MI. The safety of diagnostic strategies using POC hs-cTnI will be assessed using these outcomes. Furthermore, the efficacy of diagnostic strategies, defined as the proportion of patients identified for early discharge, will be assessed

Adjudication Plan

The primary outcome, TTR and other time-based secondary outcomes, will not require adjudication. However, index and 30-day cardiac death or MI will be adjudicated. In patients with an adjudicated MI, reviewers will also determine MI type. Reviewers with expertise in cardiovascular emergencies will have access to the participant's records, results of relevant testing, follow-up call information, records obtained from follow-up, and study definitions, but will be blinded to the Abbott Alinity POC hs-cTnI results. Reviewers will complete a REDCap reviewer outcome form recording the occurrence of these endpoints. Any disagreements will be settled by consensus or involvement of a third independent reviewer. Triggers for adjudication will include a report of death, uncertain vital status due to incomplete follow-up information, or an elevated hs-cTn value during the follow-up period. We have successfully used these adjudication methods in prior trials.

Abbott i-STAT Alinity Implementation Strategies:

We will explore strategies for integrating Abbott i-STAT Alinity hs-cTnI measures into ED risk stratification workflows for patients with acute chest pain. This will include finding the optimal i-STAT Alinity hs-cTnI cut points for predicting index MI and 30-day cardiac death or MI. Specifically, we seek low cut points that achieve ≥ 99% negative predictive value (NPV) while maximizing efficacy (proportion identified for early discharge from the ED) and higher cut points that achieve a ≥ 65% positive predictive value (PPV). Next, we will determine the diagnostic performance (sensitivity, specificity, NPV, PPV, negative and positive likelihood ratios and efficacy) for cardiac death or MI of the i-STAT Alinity hs-cTnI when incorporated into the history, electrocardiogram, age, risk factors, and troponin (HEART) score and the emergency department assessment of chest pain score (EDACS). Finally, we will derive a novel accelerated diagnostic protocol using the i-STAT Alinity hs-cTnI that optimizes negative

predictive value for 30-day cardiac death or MI and efficacy (the proportion identified for early discharge from the ED).

Analysis Plan

TTR, TTLT, TTD, TTT, and ED LOS for each hs-cTnI measurement strategy (POC vs central laboratory) will be compared using paired t-tests and linear mixed models to adjust for potential confounders (age, sex, race, cardiovascular risk factors). The correlation between POC i-STAT Alinity hs-cTnI vs central laboratory hs-cTnI results will be estimated using Spearman's correlation coefficient. Test characteristics (sensitivity, specificity, NPV, PPV, negative and positive likelihood ratios and efficacy) will be reported along with 95% confidence intervals for the identified optimal i-STAT Alinity hs-cTnI cut points, for HEART and EDACS when incorporating i-STAT Alinity hs-cTnI, and for the novel accelerated diagnostic protocol using the i-STAT Alinity hs-cTnI.

Power and Sample Size

With 600 patients, there will be at least 80% power to detect a difference of 30 minutes in TTR between the POC and central laboratory strategies for a range of plausible scenarios. See Section 9 for additional details.

Human Subjects Protection

Subject Recruitment Methods

All adult ED patients who arrive with symptoms suggestive of acute coronary syndrome and without STEMI could be potentially evaluated for the implementation of the Abbott i-STAT Alinity. There is no determination between high vs. low risk for ACS and therefore, all sexes, races, and ethnicities will be eligible for inclusion. Pregnant women and minorities will have an equal opportunity of being enrolled.

Informed Consent

Written informed consent will not be obtained. The risk of harm or discomfort that may occur as a result of taking part in this observational pilot implementation study is not expected to be more than in daily life or from routine physical examinations or tests. The rights and welfare of study will be protected through the use of measures to maintain the confidentiality of study information. Study results will be presented or published in lieu of providing individual subjects additional information regarding the study.

Patients who are receiving a standard-of-care evaluation for ACS will have an extra lithium heparin blood sample drawn by trained clinical staff at the same time of their collection for the standard-of-care hs-cTnl lab. No extra draws will be done outside of the standard-of care collection times.

Request of a waiver of consent:

1) The research involves no more than minimal risk to participants. The risk of harm or discomfort that may occur as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. Patients

identified for participation in this study/quality surveillance will receive standard care. The primary risk of participation is a breach in privacy and confidentiality.

2) The waiver of informed consent will not adversely affect the rights and welfare of the participants. The rights and welfare of participants will be protected through the use of measures to maintain the confidentiality of study information.

3) The research could not practicably be carried out without the waiver of informed consent. To determine the effectiveness of POC hs-cTnI testing it must be utilized in a "real world" ED patient population. Our pilot implementation design minimizes selection bias, which can threaten the validity of an effectiveness study. Requiring informed consent from subjects would likely result in a biased sample and reducing the scientific validity of the study results. Furthermore, it would be impractical to perform informed consent on each ED patient undergoing troponin testing. Furthermore all participants will receive standard care, so this study does not have risks or benefits that will affect the participant's treatment decisions.

4) Whenever appropriate, the subjects will be provided with additional information after participation. Study results will be presented or published (if possible) in lieu of providing individual subjects additional information regarding the study.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, fully minimizing possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed 5 years after study completion consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Only trained and approved study staff will have access to the password protected RedCap where electronic case report forms (eCRF) will be completed and physician surveys will be entered. Trial eCRFs will be created and maintained by a dedicated database manager to facilitate timely, accurate, and complete data entry, and allow monitoring and quality control.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Although not expected, any unanticipated problems, serious and unexpected adverse events, deviations, or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

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Appendix
ACUTE Trial: Provider Survey **Patient**

_____

Time Stamp

_____

Troponin Draw: first, second, third

Please respond to the following statements:

1. An **ELEVATED** point-of-care high sensitivity troponin result from the i-STAT device would impact your disposition decision for this patient now.
   a) Strongly Agree
   b) Agree
   c) Neutral
   d) Disagree
   e) Strongly Disagree

2. If the result was **ELEVATED** (e.g., >100 ng/L) you would admit this patient now.
   a) Strongly Agree
   b) Agree
   c) Neutral
   d) Disagree
   e) Strongly Disagree

   IF a or b – please estimate the time of your admission decision _____
   IF c, d, or e –please explain why you would not be ready to admit this patient (circle all that apply): i. additional troponin needed, ii. other labs pending, iii. imaging pending, iv. Other: _____

3. If the result was **ELEVATED** (e.g., >100 ng/L) you would begin treatment of NSTEMI now, such as aspirin and an anticoagulant (e.g., heparin).
   a) Strongly Agree:
   b) Agree
   c) Neutral
   d) Disagree
   e) Strongly Disagree

   IF a or b – please estimate the time of your treatment decision _____

IF c, d, or e –please explain why you would not be ready to treat this patient

_____

4. A **NEGATIVE/NORMAL** point-of-care high sensitivity troponin result from the i-STAT device would impact your disposition of this patient.
   a) Strongly Agree
   b) Agree
   c) Neutral
   d) Disagree
   e) Strongly Disagree

5. If the result was **NEGATIVE/NORMAL** (e.g., <6 ng/L) you would discharge this patient now.
   a) Strongly Agree
   b) Agree
   c) Neutral
   d) Disagree
   e) Strongly Disagree

   IF a or b – please estimate the time of your discharge decision _____
   IF c, d, or e –please explain why you are not be ready to discharge this patient (circle all that apply): i. additional troponin needed, ii. other labs pending, iii. imaging pending, iv. Other:

   _____

6. I have high confidence in the accuracy of high sensitivity troponin measures from an FDA approved point-of-care device.
   a) Strongly Agree
   b) Agree
   c) Neutral/Don't Know
   d) Disagree
   e) Strongly Disagree

Patient ID_____
Date_____

HEAR Score

HISTORY: (2 points max)

High-Risk Features:

Yes	No		
☐	☐	Middle- or left-sided	☐ 2 Points (mostly high-risk features)
☐	☐	Heavy/Tight/Pressure chest pain	
☐	☐	Diaphoresis	
☐	☐	Radiation	
☐	☐	N/V	
☐	☐	Exertional	☐ 1 Point (mixture of high an
☐	☐	Relief of symptoms by sublingual nitrates	

Low-Risk Features:

Yes	No		
☐	☐	Well localized	
☐	☐	Sharp pain	
		Non-exertional	
		No diaphoresis	☐ 0 Points (mostly low-risk features)
		No N/V	

ECG: (1 point max)

Yes	No		
☐	☐	Normal	☐ 0 Points

☐	☐	Repolarization abnormalities/Early repolarization	
☐	☐	Non-specific T wave changes	☐ 1 Point
☐	☐	Non-specific ST-segment depression or elevation	
☐	☐	Bundle branch blocks	
☐	☐	Pacemaker rhythms	
☐	☐	LVH (left ventricular hypertrophy)	
☐	☐	Digoxin effect	

AGE: (2 points max)

☐ ≥ 65	☐ 2 Points
☐ 45-64	☐ 1 Point
☐ ≤44	☐ 0 Points

RISK FACTORS: (2 points max)

Yes to any of the following:

Yes	No		
☐	☐	Prior stroke	☐ 2 Points
☐	☐	Peripheral arterial disease (PAD)	
☐	☐	3 or more of the following risk factors:	

Yes	No	
☐	☐	Obesity (BMI ≥ 30)
☐	☐	Current or recent (≤ 90 days) smoker
☐	☐	Currently treated diabetes mellitus
☐	☐	Family history of CAD (1st degree relative <55 yo)
☐	☐	Diagnosed and/or treated hypertension
☐	☐	Hypercholesterolemia

1-2 of above Risk factors:	☐ 1 Point
No risk factors	☐ 0 Points

HEAR Score (no Troponin) (total points) ____/7 **Add points from each category above**

≤ 3 = low risk 4-6= moderate risk 7= high risk

	Yes	No
Acute Ischemic ECG[1]		
Known CAD[2]		

[1] New contiguous T wave inversions or ST depression ≥1mm
[2] Prior MI, stents, CABG, PCI, or ≥70% coronary obstruction

Attending Name (Printed)_____ Attending Signature _____

Patient ID_____
Date_____

Treating Provider Form- Subject Information

Did the Patient Have Chest Pain > 3 Hours Prior to Arrival? Yes No

Has the Chest Pain Been Constant for >3 hours? Yes No

What was the Duration of Most Recent Episode of Chest Pain? _____ Hours

Does the Patient have Any of the Following Associated Symptoms?

Select All That Apply

___ Chest Pain
___ SOB
___ Diaphoresis
___ Nausea
___ Vomiting
___ Lightheaded/ Syncope
___ Palpitations
Other: _____

Reproducible Chest Pain
Yes No

Pleuritic Chest Pain Yes No

Radiation of Chest Pain

___ Left Arm/ Shoulder
___ Right Arm/ Shoulder
___ Both Arms/ Shoulders
___ Jaw
___ Epigastrium
___ Back
___ None

More than 2 Anginal Events in Past 24 Hours
Yes No

Use of Aspirin in Past 7 Days Yes No

Ongoing Pain Yes No

Crescendo Pain Yes No

Training of Provider (Circle One):

PY1 PY2 PY3 PY4 Attending Advanced Practicing Provider Fellow

Provider Completing Form:

Print: _____ Signature: _____