The hospital emergency department (ED) is a 24-hours-a-day, 7-days-a-week destination, which never lacks for patients.

Patients arrive at different times as do cardiac biomarkers.

- There are over 120 million visits to U.S. emergency departments each year which translates to over 40 visits per 100 persons.¹
- Over the past decade, emergency department visits have increased 36%.²
- Chest and abdominal pain are the most common reasons that persons aged 15 years and over visit the emergency department.³ Because both emergency and nonemergency care are provided, symptoms vary widely in their acuity.⁴
- It has been demonstrated that patients who present with chest pain when the ED is crowded are more likely to experience adverse events.⁵
- The ECG is often non-diagnostic with a sensitivity of less than 60%.¹⁰
- Atypical symptoms often seen in the elderly, women, and patients with diabetes make the clinical diagnosis even more difficult.¹¹,¹²,¹³
- Recent data for NSTEMI shows an average of 2.6 hours from symptom onset until patients reach the hospital. Even though this is the average, 59% of patients had delays exceeding 2 hours while 11% of patients waited more than 12 hours to seek treatment.¹⁴

The National Academy of Clinical Biochemistry (NACB) guideline states:
A multi-marker strategy that includes measurement of 2 or more pathobiologically diverse biomarkers in addition to a cardiac troponin may aid in enhancing risk stratification in patients with a clinical syndrome consistent with ACS.¹⁵

Prolonged laboratory results may delay recognition of critically ill patients and initiation of appropriate therapies.⁶,⁷ It has been shown that quicker treatment times are associated with improved patient outcomes due to an earlier diagnosis.⁸ A point-of-care, serial multi-marker testing strategy has been shown to facilitate the rapid diagnosis and management of chest pain patients in the emergency department.⁹

A rapid diagnosis is critical to improving outcomes.

Quidel Triage Solutions. Find strength in our numbers.

Many factors make diagnosing chest pain difficult.
Chest pain is costly. Guideline recommendations.

- At discharge, it is estimated that as many as 85% of chest pain patients do not have a cardiac diagnosis and myocardial infarction was missed in 2% - 8%.\(^{17,18}\)
- A recent study published in *Academic Emergency Medicine* cited acute myocardial infarction as one of the health conditions associated with the highest claims for emergency medicine malpractice. The largest share of overall indemnity was attributed to errors in the diagnostic process.\(^{19}\)

**RECOVERY AUDIT CONTRACTORS (RAC)**
- Auditors under the oversight of the Centers for Medicare and Medicaid (CMS) have been hired to insure that providers are facilitating an evidence-based healthcare structure.
- This program was demonstrated in a few states and then implemented nationwide in the year 2010.\(^{20}\)
- RAC audits recovered $610.9M in 2008 in overpayments to providers in the demonstration states.\(^{20}\) Now that the program is nationwide, an estimated $34 billion in improper Medicare fee-for-service payments were identified in 2010.\(^{21}\)
- RAC has identified Chest Pain MS-DRG 313 as one of the service types with the highest amount of improper payments. Over 86% of the improper chest pain payments were determined to be due to medically unnecessary services.\(^{21}\)

A recent study demonstrated decreases in the magnitude of STEMI and increases in the rate of NSTEMI.\(^{22}\) According to 2008 MedPar data, NSTEMI accounted for 70% of all MI’s in the U.S.\(^{23}\)

Current guidelines support the use of serial biomarkers for early NSTEMI presentations.

**AMERICAN COLLEGE OF EMERGENCY PHYSICIANS (ACEP)**
- No single serum marker used alone has sufficient sensitivity or specificity to reliably identify or exclude acute myocardial infarction (AMI) within 6 hours after symptom onset.\(^{24}\)
- Measurements of myoglobin in the first few hours after onset appear to have better sensitivity with lower specificity when compared with CKMB and the troponins.\(^{24}\)

**AMERICAN COLLEGE OF CARDIOLOGY (ACC)**
- For patients who present within 6 hours of symptoms suggestive of ACS, myoglobin in conjunction with CKMB mass or troponin when measured at baseline and 90 minutes may be considered.\(^*\)\(^{25}\)

\(^*\)The Quidel Triage Cardiac Panel is FDA cleared to aid in the diagnosis of myocardial infarction.

Chest pain is a target for RAC due to the historical lack of documentation to support a hospital admission.

Establish the diagnosis early and appropriately. Troponin alone is not enough.
The following timeline represents a typical patient who presents to the ED with symptoms of chest pain.

Research has demonstrated that by utilizing a point-of-care, serial multi-marker strategy, the patient can be evaluated and sent home in a few hours.

7:02 AM
56-year old man experiencing burning chest pain, belching, and mild epigastric discomfort

9:14 AM
Patient arrives at ED

9:22 AM
ECG performed and shows no signs of ischemia

9:35 AM
Patient in room and blood drawn for cardiac markers

9:55 AM
First draw results using Triage Solutions:
- Myoglobin: 70 ng/mL
- CKMB: 2.4 ng/mL
- TnI: 0.08 ng/mL
- TIMI Score = 1

11:25 AM
Second set of markers drawn

11:46 AM
Second draw results using Triage Solutions:
- Myoglobin: 72 ng/mL
- CKMB: 2.2 ng/mL
- TnI: 0.07 ng/mL

12:57 PM
ED rules out MI. Patient discharged after negative stress test.

*Two other panels are available: The Quidel Triage CardioProfiler®, which includes myoglobin, CKMB, troponin I, and BNP, and the Quidel Triage Profiler SC® Panel which includes myoglobin, CKMB, troponin I, BNP, and D-dimer.
When evaluating the clinical utility of a test, you must establish the clinical endpoint and the cut-off. Only then can clinical sensitivity and specificity be evaluated.

The Triage Cardiac Panel was developed for use in the emergency department (ED).

The table below shows Package Insert clinical sensitivity and specificity data for the Triage TnI assay compared to three laboratory TnI methods.

<table>
<thead>
<tr>
<th>TnI Assay</th>
<th>Cutoff nL/L</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Rule-in Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quidel TnI&lt;sup&gt;®&lt;/sup&gt;</td>
<td>0.4</td>
<td>96%</td>
<td>90%</td>
<td></td>
</tr>
<tr>
<td>Beckman Accu Tnl&lt;sup&gt;®&lt;/sup&gt;</td>
<td>0.5</td>
<td>96%</td>
<td>94%</td>
<td></td>
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<tr>
<td>Abbott ARCHITECT Tnl&lt;sup&gt;®&lt;/sup&gt;</td>
<td>0.6</td>
<td>94%</td>
<td>98%</td>
<td></td>
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<tr>
<td>Ortho Vitros (EC) Tnl&lt;sup&gt;®&lt;/sup&gt;</td>
<td>0.12</td>
<td>70%</td>
<td>89%</td>
<td></td>
</tr>
<tr>
<td>Abbott ARCHITECT Tnl&lt;sup&gt;®&lt;/sup&gt;</td>
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<td>60%</td>
<td>78%</td>
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<tr>
<td>Beckman Accu Tnl&lt;sup&gt;®&lt;/sup&gt;</td>
<td>0.5</td>
<td>46%</td>
<td>93%</td>
<td></td>
</tr>
<tr>
<td>Quidel TnI&lt;sup&gt;®&lt;/sup&gt;</td>
<td>0.4</td>
<td>100%</td>
<td>94%</td>
<td></td>
</tr>
<tr>
<td>Ortho Vitros (EC) Tnl&lt;sup&gt;®&lt;/sup&gt;</td>
<td>0.12</td>
<td>96%</td>
<td>94%</td>
<td></td>
</tr>
</tbody>
</table>

*Numbers represent data obtained from the manufacturer’s product inserts. Sensitivities and specificities in clinical use may vary depending on the cut-off. Only then can clinical sensitivity and specificity be evaluated.

A 2008 retrospective analysis from three HCA hospitals in Dallas, Texas, tested chest pain patients using the Quidel Triage Cardiac Panel at one to three hour intervals. Rule-in criteria were (1) any TnI above the AMI cutoff on any draw; (2) a 50% increase in myoglobin levels with any detectable TnI on the last draw; or (3) a 50% increase in myoglobin with a concomitant increase in CKMB. The serial, multi-marker algorithm used was evaluated against the discharge with the following results:

- **Negative Biomarkers and Positive AMI**: 3
- **Positive Biomarkers and Negative AMI**: 12
- **Positive Biomarkers and Positive AMI**: 151
- **Negative Biomarkers and Negative AMI**: 5,039

Total Patients = 5,205

<table>
<thead>
<tr>
<th>Total Patients</th>
<th>0</th>
<th>1500</th>
<th>2500</th>
<th>3500</th>
<th>4500</th>
<th>5500</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Negative Biomarkers and Positive AMI</strong></td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Positive Biomarkers and Negative AMI</strong></td>
<td>12</td>
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<td></td>
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</tr>
<tr>
<td><strong>Positive Biomarkers and Positive AMI</strong></td>
<td>151</td>
<td></td>
<td></td>
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<td>2500</td>
<td>3500</td>
<td>4500</td>
<td>5500</td>
<td>5500</td>
</tr>
</tbody>
</table>

In this retrospective study, most patients were safely evaluated and dispositioned in 3 hours or less. In the same 3-hour window, rule-in patients were identified with a clinical sensitivity of 98.1%. Specificity was 98.1%, accuracy 99.7%; the PPV (positive predictive value) was 92.6%, and the NPV (negative predictive value) was 99.9%.* ^

Chest pain diagnostic protocols can greatly impact hospital efficiency. Introducing diagnostics such as simple laboratory testing into the ED can improve patient flow.

A before and after study at AtlantiCare Regional Medical Center (ARMC), a 567-bed teaching hospital in New Jersey demonstrated operational efficiencies gained by implementing the Quidel Triage Cardiac Panel with a 0, 2 and 4 hour protocol. The goal of the ED was to expedite the disposition of patients presenting with chest pain symptoms and move patients to the appropriate treatment pathway.

The study demonstrated a reduction of 60 patients (36%) coded as DRG 143* (non-specific chest pain), freeing up needed beds in the ED. The average length of stay for the ED was shortened by 122 minutes (31%). Additionally, NSTEMI patients were ruled in more quickly with a 41% reduction in their length of stay.**

*DRG 143 is now known as DRG 313

**D RG = Diagnosis related group
NSTEMI = Non-ST-segment elevation myocardial infarction

Operational Outcome Using Serial Point-of-Care Cardiac Multi-markers

<table>
<thead>
<tr>
<th></th>
<th>Number of Patients at Baseline</th>
<th>Number of Patients Admitted</th>
<th>Actual Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of DRG 143 patients</td>
<td>174</td>
<td>114</td>
<td>60</td>
</tr>
<tr>
<td>Average ED Length of Stay (minutes)</td>
<td>395</td>
<td>273</td>
<td>122</td>
</tr>
<tr>
<td>- NSTEMI</td>
<td>408</td>
<td>240</td>
<td>168</td>
</tr>
<tr>
<td>- PCI</td>
<td>345</td>
<td>187</td>
<td>158</td>
</tr>
<tr>
<td>- DRG 313</td>
<td>397</td>
<td>345</td>
<td>52</td>
</tr>
<tr>
<td>Average Inpatient Length of Stay (days)</td>
<td>4.5</td>
<td>3.1</td>
<td>1.4</td>
</tr>
<tr>
<td>- NSTEMIs</td>
<td>6.3</td>
<td>5.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Number of PCIs</td>
<td>4.9</td>
<td>4.4</td>
<td>0.5</td>
</tr>
</tbody>
</table>

By implementing this protocol, the estimated annual savings impact was $491,363 for this institution.***

*This is a single study and results may vary.

***DRG 143 is now known as DRG 313

**D RG = Diagnosis related group

NSTEMI = Non-ST-segment elevation myocardial infarction
Over 60% of U.S. hospitals use a Quidel Triage product.1,14

Quidel Triage Solutions
Find strength in our numbers.

References


30 Predicting and measuring economic and operational outcomes with POCT cardiac multimarkers. Presented at the 10th Annual Society of Chest Pain Centers Congress. April 25-28, 2007, Nashville, TN.
