Optimal Use of Troponin & Creatinine Kinase and Other Adventures in Laboratory Utilization

Jeff Pearson, MD
System Medical Director, Laboratories and Pathology
Bronson Methodist Hospital
Information in this presentation is for educational purposes only and is not intended to be promotional in nature.

This presentation contains information not reflective of Roche products. Refer to Roche Package Insert for Roche Troponin T performance claims.

Images Created by Koeus Solutions.

Speakers have been paid an honorarium.
Endometriosaurus Rex
Educational Objectives

• Discuss how a blood utilization management program complements laboratory utilization

• Examine strategies to limit the cost of send out testing to boutique reference laboratories

• Share ways to reduce Troponin turnaround times without implementing point-of-care

• Explain the optimal use of troponin and creatinine kinase
Bronson’s Service Area
Bronson Healthcare

- 3 hospitals, 797 licensed beds
- 7,690 staff (FTE’s)
- 1,100+ medical staff
- Pediatric and Neonatal Intensive Care Units
- High Risk Pregnancy Center
- Level I Trauma, Certified Stroke Center
- Cycle IV Chest Pain Emergency Center
Utilization Management

- Discuss how a blood utilization management program complements laboratory utilization
- Examine strategies to limit the cost of send out testing to boutique reference laboratories

Cardiac Testing

- Share ways to reduce Troponin turnaround times without implementing point-of-care
- Explain the optimal use of troponin and creatinine kinase
Why Blood Conservation?

- Cost containment?
- Better patient outcomes?
Expense of Blood

- Continues to be a major expense
  - Acquisition cost - ~$200
  - Lab testing - $55
- Studies estimate all direct and indirect costs as high as $1183\textsuperscript{1,2} per-RBC-unit
- Charge to Patient - $845

Blood conservation is about more than saving money

• Restricting transfusions in ICU patients:
  ▪ Mortality 22% 7.0 g/dL vs. 28% 10.0 g/dL; p=.05
  ▪ 52% fewer transfusions in 7.0 group¹

• “In patients with critical illness… using a hemoglobin trigger of <7 g/dL significantly reduces cardiac events, rebleeding, bacterial infections, and total mortality”²

Thoracic surgery Intra/Post RBC Transfusions

2010 2011 2012 2013 2014

Bronson
STS
Like Group
Cardiothoracic and orthopedic surgery were first on board

Thromboelastography

Haemonetics Cell Saver

Image of the TEG®5000 Thrombelastograph® Hemostasis Analyzer System is used by permission of Haemonetics Corporation. Image of the Cell Saver®5+ Autologous Blood Recovery System is used by permission of Haemonetics Corporation.
Hospitalists: Double Unit RBC Transfusions

1. In 2012 49% of RBCs transfused as double units

2. 76% of these double unit transfusions resulted in hemoglobin levels outside guidelines after the second unit was administered (8 g/dL – 11 g/dL)

3. Stable, non-symptomatic patients can tolerate hemoglobin levels of 7 g/dL or less
## Hospitalist Transfusion Report Card

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**Change in Double Unit Transfusion:** ▼ 100%, ▼ 79%, ▼ 61%, ▼ 22%, ▼ 89%
Score Card Effect on Double Unit Transfusions

67% decrease in double-unit transfusions
35% decrease in transfusions given to patients with hemoglobin levels greater than 7 g/dL
Adult Inpatient RBC Transfusions at BMH

2,036 fewer units in 2013 translates to a cumulative savings of $509,000-$2,408,588 (Acquisition costs vs. estimated “actual” cost of RBC units)
What about hematology/oncology?

- Most outpatient transfusions are done for patients with cancer
- Double unit transfusions of red blood cells and platelets are common place
Establish a Lab Utilization Committee

- We piggy-backed on the Blood Conservation Committee
- Include hospitalists and intensivists
  - Cash in on that human capital you have been building up
- Include an executive, nursing and lab leadership
- Consider meeting at breakfast or lunch and providing nourishment
Successful Lab Utilization is Dependent upon Successful Relationships

- Participate in committees: Credentials, Medical Staff Quality, Performance Improvement, Medical Executive
- Set up regular meetings with hospital executives
  - Meet with COO on a monthly basis
- Assist clinicians whenever you can
  - Build human capital that you can draw upon
- Be a visible member of the hospital team
Get out and deliver the message
Build a groundswell of support

• Medical Executive Committee
• Medical Directors Forum
• Board of Directors
• Section Meetings
• Grand Rounds
• Medical school teaching
Agenda

Utilization Management

- Discuss how a blood utilization management program complements laboratory utilization
- Examine strategies to limit the cost of send out testing to boutique reference laboratories

Cardiac Testing

- Share ways to reduce Troponin turnaround times without implementing point-of-care
- Explain the optimal use of troponin and creatinine kinase
Smaller for-profit labs that bypass our lab and market directly to physicians
Tests are universally more expensive
May charge list price to the lab that draws and sends the test
Most physicians are unaware of the costs
Reference Lab and Boutique Labs

- Reference Lab Charges: $1,676,931
- Referral Charges: $314,091
### Top 20 Boutique Lab Send Out Tests

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Teichoic Acid Antibody

• Surrogate marker for Staph infections
• Literature is from the 1970s
• Obsolete test sent to Focus Labs at a cost of nearly $100 per test
• We sent 151 in 2013 at a cost of $15,000
• Bronson was the number one user of this test in the entire country
• We made this test non-orderable
Proprietary IBD, sgi Diagnostic

- Used to differentiate Crohn’s Disease vs. Ulcerative Colitis
- It is proprietary
- Color interpretive reports
- Costs $646 per test
- Primary Reference Lab IBD panel is $110
Figure 1. Overlay of receiver-operating curve (ROC) for individual test components and combined Prometheus inflammatory bowel disease (IBD) sgi test presented as Figure 5 from the Prometheus IBD sgi monograph, with summary ROC curve for perinuclear anti-neutrophil cytoplasmic antibody (pANCA)+, or anti-Saccharomyces cerevisiae antibody (ASCA)-IgA+ or IgG+ with data from Reese et al. (3) meta-analysis. Sensitivity and specificity of individual studies included in the meta-analysis are shown as black dots.
## Tests in Blue:

*Alternatives Available at our Primary Reference Lab*

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<th>2013 Charges</th>
<th>Average Charge per Test</th>
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<tbody>
<tr>
<td>Prometheus Thiopurine Metabolites</td>
<td>130</td>
<td>$34,840.00</td>
<td>$268.00</td>
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<tr>
<td>Meningoencephalitis Comprehensive Panel, CSF</td>
<td>45</td>
<td>$22,878.36</td>
<td>$508.41</td>
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<tr>
<td>Fungitell Assay for (1,3)-B-D-Glucans</td>
<td>125</td>
<td>$18,783.00</td>
<td>$150.26</td>
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<tr>
<td>Calprotectin</td>
<td>92</td>
<td>$18,476.45</td>
<td>$200.83</td>
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<tr>
<td>PROMETHEUS IBD sgi Diagnostic</td>
<td>26</td>
<td>$16,796.00</td>
<td>$646.00</td>
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<tr>
<td>Teichoic Acid Antibody, Quantitative, ID</td>
<td>151</td>
<td>$14,826.69</td>
<td>$98.19</td>
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<tr>
<td>MVista Histoplasma Antigen, Serum</td>
<td>132</td>
<td>$14,388.00</td>
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<td>MuSK Antibody</td>
<td>15</td>
<td>$13,150.59</td>
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<td>MVista Histoplasma Antigen, Urine</td>
<td>119</td>
<td>$12,971.00</td>
<td>$109.00</td>
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<td>Serotonin Release Assay, Unfractionated Heparin</td>
<td>28</td>
<td>$9,626.00</td>
<td>$373.79</td>
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<td>Folate, RBC</td>
<td>106</td>
<td>$5,565.00</td>
<td>$52.50</td>
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<td>Mycoplasma pneumoniae DNA, Qualitative Real-Time</td>
<td>24</td>
<td>$4,584.24</td>
<td>$191.01</td>
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<td>Prometheus TPMT Genetics</td>
<td>11</td>
<td>$4,185.50</td>
<td>$380.50</td>
</tr>
<tr>
<td>Angiotensin Converting Enzyme, CSF</td>
<td>45</td>
<td>$4,145.85</td>
<td>$92.13</td>
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<td>Infliximab Concentration and Anti-Infliximab Ant</td>
<td>9</td>
<td>$3,825.00</td>
<td>$425.00</td>
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<tr>
<td>Dihidropyrimidine Dehydrogenase (DPD) Gene Mutat</td>
<td>13</td>
<td>$3,737.50</td>
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<td>VAP Cholesterol</td>
<td>54</td>
<td>$3,240.00</td>
<td>$60.00</td>
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<td>Atypical Pneumonia Panel</td>
<td>19</td>
<td>$3,234.75</td>
<td>$170.25</td>
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<tr>
<td>Meningoencephalitis Comprehensive Panel (CSF)</td>
<td>6</td>
<td>$3,107.04</td>
<td>$517.84</td>
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<tr>
<td>Mullerian Inhibiting substance (MIS) Results</td>
<td>16</td>
<td>$2,843.68</td>
<td>$177.73</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td>1,166</td>
<td>$215,204.65</td>
<td>$184.57</td>
</tr>
</tbody>
</table>
Boutique Lab Testing Policy

- If a Boutique Lab test has an analogous test performed at our lab or our reference lab it will be automatically converted.
- Tests not meeting criteria for evidence-based medicine will be placed on a list of non-approved tests.
- Tests that meet criteria for evidence-based medicine will be added to a pre-approved list.
- We will no longer send tests to certain high-cost labs.
  - Require the boutique lab to bill patient insurance.
- It is analogous to having a formulary.
# Results of Boutique Lab Policy

<table>
<thead>
<tr>
<th></th>
<th>Volume</th>
<th>Charges</th>
<th>Avg Charge Per Test</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Referral Tests</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>May 2013-Apr 2014</td>
<td>1,706</td>
<td>$315,286</td>
<td>$184.81</td>
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<tr>
<td>May 2014-Apr 2015</td>
<td>1,078</td>
<td>$204,961</td>
<td>$190.13</td>
</tr>
<tr>
<td><strong>Change</strong></td>
<td>(628)</td>
<td>$(110,325)</td>
<td>$5.32</td>
</tr>
<tr>
<td><strong>% Change</strong></td>
<td>-37%</td>
<td>-35%</td>
<td>3%</td>
</tr>
<tr>
<td><strong>% of Total</strong></td>
<td>3.1%</td>
<td>11%</td>
<td></td>
</tr>
</tbody>
</table>
Results of Boutique Lab Policy

<table>
<thead>
<tr>
<th>Year</th>
<th>Ref Charges</th>
<th>Referral Charges</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>$1,676,931</td>
<td>$314,091</td>
</tr>
<tr>
<td>2014</td>
<td>$1,655,026</td>
<td>$204,961</td>
</tr>
</tbody>
</table>
Utilization Management Summary

- It is not about gate-keeping, but about utilizing the best tools to create shorter lengths of stay, fewer expenses and better patient outcomes
- A blood conservation program pays for itself
- Restrict send out testing to one reference laboratory
- Analyze your send out testing
- Develop a formulary approach
Agenda

Utilization Management

• Discuss how a blood utilization management program complements laboratory utilization
• Examine strategies to limit the cost of send out testing to boutique reference laboratories

Cardiac Testing

• Share ways to reduce Troponin turnaround times without implementing point-of-care
• Explain the optimal use of troponin and creatinine kinase
Bronson Emergency Dept & Troponin

- Level 1 Trauma Center, approx. 100,000 visits/yr.
- Lab volume approx. 2 million billable tests/yr.
- ED connect to Laboratory by pneumatic tube system.
- HIS = Epic, LIS = Sunquest
- Society of Cardiovascular Patient Care (SCPC) Accreditation
We Needed to “Raise the Bar” for Troponin TAT

- Society of Cardiovascular Patient Care (SCPC)
  - On-site Chest Pain Center
  - Accreditation Inspection
- First half of 2012:
  - Average door-to-result time for initial troponin was 75 minutes:
    - 41 minutes in the ED
    - 34 minutes in the Lab
  - Only 48% of cases had results within 60 minutes.
  - Point-of-Care testing was proposed as the only solution.
Troponin in the Emergency Dept

- Core Lab or Point-of-Care?
- What is better for the patient?
- What is more cost effective?
General Considerations for POCT

- Faster
- More expensive
- Less accurate; greater coefficient of variation
  - Back up in core lab? Duplicate testing?
- Lab tests run by non-laboratorians
- Innumerable staff in the ED raises competency issues
- Troponin I vs T
POCT Troponin Testing Option:

It is not “just like doing a blood glucose on the meter”

• Analysis time:
  ▪ cTnI cartridge: 600 seconds (10 min.)

• Cartridges for Troponin I/cTnI
  ▪ Skin puncture: not recommended.
  ▪ Venipuncture: Fresh heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin. Collection tubes must be filled at least half full.
Early and late outcome prediction of death in the emergency room setting by point-of-care and laboratory assays of cardiac troponin I
Per Venge, MD, PhD, Claes Öhberg, MD, Mats Flodin, BSc, and Bertil Lindahl, MD, PhD Uppsala, Sweden

Background Point-of-care (POC) assays of cardiac troponins are common in the emergency department setting. The question raised was as follows: What is the clinical impact of the results of POC assays of cardiac troponins as compared with sensitive laboratory assays?

Methods Patients admitted consecutively to the emergency department (N = 1,069) and on whom cardiac troponins were requested as part of their clinical work-up were included. Cardiac troponin I (cTnI) was measured by the POC assays—i Stat (Abbott Diagnostics, Abbott Park, IL) and Stratus CS (Siemens Healthcare Diagnostics, Deerfield, IL)—and by the laboratory assays—Access AccuTnl (Beckman Coulter, Fullerton, CA) and Architect cTnl (Abbott Diagnostics). Results were related to early (14 days) and late outcome (median 3.3 months, range 0.1-35) as to death.

Results The laboratory assays identified more patients (P < .001) with elevated levels than the two POC assays (39%-74% vs 20%-27%). Adopting the 99th percentiles upper reference limit, the Access AccuTnl identified 88% and Architect cTnl identified 81% of all patients who died of cardiovascular disease as compared with 50% and 54% for iStat and Stratus CS, respectively (P < .001). Negative predictive values for the laboratory assays were 97% as compared with 89% to 93% for the POC assays. Negative likelihood ratios were 0.25 (CI 0.15-0.41) and 0.59 to 0.68 (CI 0.47-0.79), respectively.

Conclusions The current POC cTnl assays are less sensitive for outcome prediction of patients with myocardial injury. The clinical judgment of the patient with suspected myocardial ischemia should not solely rely on results from POC assays. If a clinical suspicion of myocardial injury remains despite negative cTnl results with the POC assays, such results should be complemented by results from sensitive laboratory assays. [Am Heart J 2010;160:835-41]
Comparisons of Clinical Performance

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Diagnostic Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CL</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access, 0.04 mg/L</td>
<td>86% (CI 77 - 92%)</td>
<td>72% (CI 69 - 75%)</td>
</tr>
<tr>
<td><strong>CL</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Architect, 0.028 mg/L</td>
<td>82% (CI 73 - 89%)</td>
<td>77% (CI 74 - 80%)</td>
</tr>
<tr>
<td><strong>POC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stratus CS, 0.07 mg/L</td>
<td>54% (CI 44 - 64%)</td>
<td>66% (CI 63 - 69%)</td>
</tr>
<tr>
<td><strong>POC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i-Stat, 0.08 mg/L</td>
<td>43% (CI 34 - 52%)</td>
<td>64% (CI 61 - 67%)</td>
</tr>
</tbody>
</table>

The central lab troponin tests had a higher sensitivity and greater diagnostic accuracy.
Point-of-Care or Central Lab?

One central lab assay is faster than certain POC assays

cobas® systems assays run at 9 minutes

1. CAP TODAY: Survey on automated immunoassay analyzers, HCG STAT, June 2012.
POCT Troponin Testing Option
Why Compromise with POC Testing?

Advantages of POC systems must be weighed against:
Quality control and training of ED personnel

ED Troponin Turnaround Time
Kaizen Event
August 6th – August 10th, 2012
Kaizen event

- Any action whose output is intended to be an improvement to an existing process.
- Kaizen Events are commonly referred to as a tool that:
  1. Gathers operators, managers, and owners of a process in one place
  2. Maps the existing process (using a deployment flowchart, in most cases)
  3. Improves on the existing process
  4. Solicits buy-in from all parties related to the process
“Lab Only” Process Improvements

• First laboratory in the nation to implement the Roche cobas 8000.

• Analyzer time for Troponin went from 18 to 9 minutes.
MPA-7 and cobas 8000 Configuration
Lab Only Troponin TAT Process Improvements Over the Years

- OL Monitor – detect delays and outliers before ER does
- Dedicated pneumatic tube station for ER/stat
- Yellow bordered LIS labels to readily identify ED specimens
- Post monthly TAT values for Lab Rec’d to Result.
STAT Troponin Process Flow

[Diagram showing process flow with key steps and time intervals marked, including Pre-Kaizen, STAT Tube Station, Centrifuge, Load, Timer (not forgotten), and Post-Kaizen.]
Specimen Draws

**Straight Draws**
Less than 1 minute

**IV Draw**
3:33 Minutes After >1 minute of setup
Avoiding Hemolysis

Some things to realize so the sample won’t hemolyze:

- **Stop Hemolytic**
  - After sample is drawn, transfer blood to tubes immediately. "Linger not or it will clot"

- Don’t Pop Me!
  - When drawing blood with a syringe, pull back slowly on plunger. Never force flow when transferring blood into a tube. “Watch the flow, take it slow”

- Avoid use of small gauge needles and multiple connections. “Needle size can hemolyze”

*Hemolysis is the rupture of red blood cells during sample collection*
Chest Pain Protocol

Chest Pain Patient Arrives

Triage
Protocol Ordered

EMS
Charge RN:
Broadcast CPP
PCA: Call Phleb

Patient in Bay 4
• PCA: Call Phleb & perform EKG
• Phleb: Draw, label, double check, send

Patient transferred to room
• PCA: Broadcast CPP

Nursing team completes CPP

No Phleb? No Problem!
1) Utilize Secondary Triage PCA
2) Broadcast Red Team for Draw
3) Take Pt. to Room Post EKG for
   a) Straight draw by floor PCA
   b) Use blood from IV start if RN

Patient to Room
• PCA: Perform EKG
• Phleb: Draw, label, double check, send

Nursing team completes CPP
Results: Cumulative September 2012 through present

- Average door to result time for initial troponin is 38 minutes
- 96% of cases have results within 60 minutes
- Point of Care Troponin testing is not needed
Percentage Troponin Under 60 minutes from Door to Result
Agenda

Utilization Management

• Discuss how a blood utilization management program complements laboratory utilization
• Examine strategies to limit the cost of send out testing to boutique reference laboratories

Cardiac Testing

• Share ways to reduce Troponin turnaround times without implementing point-of-care
• Explain the optimal use of troponin and creatinine kinase
Antiquated Lab Tests

- Bleeding Time
  - Never could predict surgical bleeding
- Bands
  - Imaginary cells that cannot be accurately counted
- H. pylori IgG serology
  - Use breath test or stool antigen
- Red blood cell folate
  - Lack of discriminatory power
Requiem for a Heavyweight
The Demise of Creatine Kinase-MB
Amy K. Saenger, PhD; Allan S. Jaffe, MD

The development of rapid, automated, and accurate laboratory testing for creatine kinase MB (CK-MB) revolutionized the treatment of patients with acute cardiac events in the 1970s and 1980s. To clinicians, CK-MB values augmented a thorough history, physical, and ECG findings, and elevations rapidly became the gold standard for identifying cardiac injury. CK-MB allowed earlier diagnosis of acute myocardial infarction (AMI), and detection of reinfection, and measurements could be used to provide a facile clinical estimate of infarct size. Elevations of CK-MB were never intended to be synonymous with myocardial infarction, only indicative of cardiac injury. However, because of the relative insensitivity of measurements, increased concentrations occurred predominantly with larger insults such as those associated with acute ischemic heart disease. For that reason, AMI was rarely diagnosed, assuming appropriate timing of the samples, in the absence of a CK-MB elevation.

Creatine Kinase–MB: The Journey to Obsolescence
Gurmukh Birigh, MD, PhD, MBA; Parameswar B. Bawaja, MD

Abstract and Introduction

Objectives. To evaluate the clinical utility of and demand for the creatine kinase (CK)–MB assay.

Methods. We examined the number of CK-MB tests from 2007 through 2013 while we progressively deemphasized their use. We first removed CK-MB from the acute coronary syndrome (ACS) panel and then from the main menu and observed the demand for the test. We also reviewed patient medical records to assess the appropriateness of its use.

Results. After removing CK-MB from the ACS panel, the test volume dropped from around 12,000 per year to about 150 per year. In reviewing the records of 171 patients who had CK-MB determination done over a 28-month period, we discovered that CK-MB contributed to the diagnosis in only one patient, although it was not essential. Since removing CK-MB from the laboratory menu, two CK-MB tests were ordered in 4 months, and neither added value.

Conclusions. CK-MB determinations do not add value to information available from the troponin assay and can be safely removed from the laboratory menu.
Cardiac Biomarker Kinetics

- Troponin (large MI)
- CKMB
- Troponin (small MI)
- 99th percentile with 10% CV

Days after onset of AMI

Multiples of the AMI cutoff limit
CK-MB and Troponin

• CKMB and Myoglobin for Acute Coronary Syndrome
  - Multi-center study looked at 30,000 patients
  - 28% Discordant for Troponin and CKMB
  - Troponin was more sensitive, as 18 percent had elevated troponin but normal CK-MB values
  - 10 percent had false positive CK-MB elevations
  - Compared to patients who were negative for both biomarkers, in-hospital mortality was not increased in patients who were Tn-negative and CK-MB-positive

• Troponin is the preferred marker for the diagnosis of myocardial injury for all diagnostic categories because of its increased specificity and better sensitivity compared to CK-MB

• The improved tissue specificity of the troponins compared with CK-MB and other conventional markers is well established

CK-MB Outcome at Bronson

- Cardiology eventually agreed to remove CK-MB from all protocols
- CK-MB still available ala carte
Cardiac Testing Summary

- Troponin TAT can be accomplished in less than 60 minutes without resorting to point-of-care testing
- Engaging stakeholders outside of the lab is critical
- Troponin has replaced CK-MB as the preferred marker for the diagnosis of myocardial injury
Questions?