Formerly
Society of Cardiovascular Patient Care (SCPC)
Troponin Essentials: Implementing the Guidelines

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Accreditation Review Specialist
Objectives

• **Identify** guideline-driven best practice recommendations on the use of biomarkers in the treatment of Acute Coronary Syndrome (ACS)

• **Review** updates to the Myocardial Infarction (MI) Definition and Non-ST elevation Acute Coronary Syndromes (NSTE-ACS) guidelines

• **Discuss** troponin turn-around-time (TAT) recommendations and documentation requirements

• **Share** quality practices that optimize the care and outcomes of ACS patients
ACC Position Statement: Laboratory

• Focuses on ID and Management of MI and ACS
• Each facility responsible for vendors
  – ACC provides Guidance and Education
• Facility should know the recommendations
• Facility should review their protocols for Troponin
FREQUENTLY ASKED QUESTION:

“Does ACC Accreditation Services monitor or validate concordance between POCT and Central Lab Analyzers?”

POSITION:

We do not promote or endorse lab based testing or point-of-care testing (POCT) rather focuses on processes and protocols for the identification and management of the Myocardial Infarction (MI) and Acute Coronary Syndrome (ACS) continuum.

Hospitals are responsible to ensure all appropriate policies and protocols for correlations, validations and assay concordance are in place per laboratory regulatory requirements (i.e.: CLIA, CAP, TJC, DNV...).
ACC Goals

Establish a comprehensive quality improvement solution to hospitals and other facilities that combines accreditation and ACC’s registry services, quality initiatives and education.

To develop and share quality practices that optimize the care and outcomes of patients with acute cardiovascular disease worldwide through innovative cross-disciplinary processes and education by...

Taking Science to the Bedside™
Background: Chest Pain Accreditation

Chest Pain Center (CPC) Accreditation tool is a strategic planning document:

- Assessment of all Acute Coronary Syndrome (ACS) conditions
- Previously defined as “cycles”
  - incorporates expectations from previous cycles
- Emphasis on education and annual reinforcement
- Metrics used to validate ongoing performance improvement
- New programs changed to “versions”
  - updated in a more timely manner versus every 3 years
Definitions for Reperfusion

• **Percutaneous Coronary Intervention (PCI)** – most frequently used invasive method of treating the narrowing, or stenosis, of coronary arteries; performed in cardiac catheterization facilities (cath lab) at acute care hospitals

• **Primary PCI (PPCI)** – also known as (aka) emergency angioplasty, is a life-saving intervention performed during a heart attack (STEMI)

• **Non-primary PCI** – aka: elective angioplasty, scheduled intervention to relieve the narrowing of the artery; goal of preventing a heart attack from occurring in the future

Key Point: All laboratorians should be very familiar with the protocols and facility diagnostic capabilities (cath lab, PPCI, thrombolytics, transfer) to address acute cardiac events.
Continuum of Improvement

RAISING THE BAR
WITH A ‘VALUE-ADDED’ APPROACH

ENGAGE
CYCLE I
2003

UNDERSTAND
CYCLE II
2006

IMPROVE
CYCLE III
2009

COLLABORATE
CYCLE IV
2012

FOCUS
Version 5
2015

EFFICIENT
Version 6
2018

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Accreditation Benefits

- Standardize Inter-facility Processes
- Requires Accountability
- Breaks Down Silos
- Improves Communication
Accreditation Supports

- Defined Pathways for the ACS Patient
- Consistent Approaches to risk stratification
- Improved Performance on quality indicators
- Aligning Practices to reduce readmissions
Accreditation Drives

- Evidenced Based Processes
- Improved Quality Outcomes
- Greater Cost Efficiency
- Higher Patient Satisfaction
3rd Universal Definition of (MI)

1st worldwide consensus document

- TROPONIN (I or T) - preferred biomarker overall
- Diagnosis of acute MI = a rise and/or fall
- 99th percentile URL designated as the decision level
- Coefficient of Variation (CV) <20% at the 99th %ile
- > 20% CV at URL should not be used
- Blood samples 1st assessment; repeated 3–6 h later

Third Universal Definition of Myocardial Infarction (MI)
Kristian Thygesen, Joseph S. Alpert, Allan S. Jaffe, Maarten L. Simoons, Bernard R. Chaitman and Harvey D. White
Circulation. published online August 24, 2012
Q: When the test is run multiple times on the same sample, how frequently do you get the same result?

A: The standard answer is...rarely, if ever.

In real world terms, measured by running sample at least 20 times and identifying the percentage (%) of variation within that set of results.

The 3rd Universal of MI allows from 10% to 20%
High Accuracy, Different Precision

Contemporary Cardiac Troponin Assays are more precise

18% CV

10% CV
99th Percentile

Troponin is unique!
- One of few analytes where 99th % ile reference range is recommended

The reason:
- Goal of early prediction to pick up results early in the elevation cycle

Example:
In the case of Analyzer X the published 99th % URL is 0.07 ng/ml, meaning that when 100 "normal" pts. were tested 99 of the results fell between 0 and 0.07.
- Results outside that range would then be considered "positive"; rise and fall assessment required
Think “HEART” NOT “MI”!

Not all elevations are acute myocardial infarction
Dr. Fred Apple:

Currently, the guidelines are predicated on the 99th percentile of cardiac troponin, and we use that 99th percentile first to say, any increase above that is indicative of myocardial injury, number one.

Secondly, we use that cutoff to say that in the clinical setting of myocardial ischemia and an increasing cardiac troponin above the 99th percentile, those two criteria are enough to make the call of a diagnosis of myocardial infarction.
“….use the 99th% to say...any increase above that is indicative of myocardial injury...”  
Fred Apple

“...in the clinical setting of myocardial ischemia an increasing Troponin above the 99th%ile....is enough to make the diagnosis of myocardial infarction...”  
Fred Apple

Clinical evidence of acute myocardial ischaemia with rise and/or fall of cardiac troponin

Myocardial injury

Myocardial infarction

Cardiac procedure

Tachy-/brady-arrhythmia

Heart failure

Renal failure

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Thygesen K et al. Circulation 2012;126:2020-2035
"Non-ST-Elevation Acute Coronary Syndromes (NSTE-ACS)"

Emphasizes continuum between Unstable Angina (UA) and Non-ST Elevation Myocardial Infarction (NSTEMI)...UA and NSTEMI can be indistinguishable and ...considered together.

NSTE-ACS 2014 Guidelines

- **Full revision** of the 2007 ACCF/AHA CPG for the management of patients with UA and NSTEMI and the 2012 focused update

- Supports the **3rd Universal Definition of MI** for Troponin and Serial Testing

2014 AHA/ACC NSTE-ACS Guidelines:
0, and 3 – 6 hours

**Universal Definition of MI:**
0, 3, 6 hours

NSSTE-ACS 2014 Guidelines

Class I

• Cardiac-specific troponin (troponin I or T when a contemporary assay is used) levels should be measured at presentation and 3 to 6 hours after symptom onset in all patients who present with symptoms consistent with ACS to identify a rising and/or falling pattern. (Level of Evidence: A)

• Additional troponin levels should be obtained beyond 6 hours after symptom onset in patients with normal troponins on serial examination when electrocardiographic changes and/or clinical presentation confer an intermediate or high index of suspicion for ACS. (Level of Evidence: A)

• If the time of symptom onset is ambiguous, the time of presentation should be considered the time of onset for assessing troponin values. (Level of Evidence: A)

Class III: No Benefit

• With contemporary troponin assays, creatinine kinase myocardial isoenzyme (CK-MB) and myoglobin are not useful for diagnosis of ACS. (Level of Evidence: A)

Standing orders/Cardiac panel should no longer include:
CK-MB
MYO
Total CK

Clinical implications of the Third Universal Definition of Myocardial Infarction
White HD, Thygesen K, Alpert JS et al
Heart 2013;00:1–9. doi:10.1136/heartjnl-2012-302976

Summary:

- Comparative update from previous 2000 and 2007 Universal Definitions to the 2012 Third Universal Definition of MI
- Overview of the recommendations by category with a focus on clinical implications and practice considerations

“The new MI definition has important changes, which have been achieved by international consensus. It is hoped that they new definition will be embraced worldwide and be used to improve patient care.”
How to Use High-Sensitivity Cardiac Troponins in Acute Cardiac Care
Kristian Thygesen et al
European Heart Journal doi:10.1093/eurheart/ehs154 PDF online 2012

Summary Regarding Use of hsCardiac Troponin in Clinical Routine:

• Use 99th%ile concentration

• Serial testing...a minimum change of >20% in follow-up testing is required

• Blood sampling ...admission and 3 h later...repeated 6 h after admission in patients of whom the 3 h values are unchanged but...clinical suspicion of AMI is still high.

• Other markers, such as myoglobin or creatine kinase MB no longer needed
Cardiac Troponin Serial Ordering Recommendations: For Today and Tomorrow
Sara Love, PhD and Fred Apple, PhD
Clinical Lab News, May 2014, vol 40, no. 5

Summary:

- Implementation practices by facility addressing updated 2012 MI definition

“...serial cTn ordering is a critical component of acute MI diagnosis readily understood in terms of timing, frequency and duration of cTn measurements...”
Guideline Updates:

“...As the field continues to absorb the guidelines, panelist and others advised laboratorians to take time to know the documents so they can have constructive discourse about them with physicians...”

Clinical Lab News, Feb 2014, vol 40, no 2
### Survey Results
(For discussion purposes only)

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Protocols and Reperfusion Strategy

• Assist laboratorians to understand role in facility reperfusion strategy

• Laboratorians should present Process Improvement (PI) projects relevant to guideline changes.

• Laboratorians should be familiar with the protocols and diagnostic capabilities to address acute cardiac events, to include:
  - Cath lab
  - Primary PCI versus non-primary PCI
  - Thrombolytics
  - Transfer and Receiving protocols
  - Registry Requirements
  - Accreditation Requirements
### Understanding the Differences

**Not interchangeable**

- Troponin T (cTnT) and **Troponin I (cTnl)**
- cTnl and cTnl

No single reference standard in laboratory medicine for cardiac troponin I assays

- POC and NPT and Central Lab

<table>
<thead>
<tr>
<th>cTnl</th>
<th>cTnT</th>
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<tbody>
<tr>
<td>POCT/NPT</td>
<td>Central Lab</td>
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Understanding the Differences

Troponin results from one facility to the next are not interchangeable.

Transfer Facility

Troponin Type X*

Receiving Facility

Troponin Type Y*

* Unless pre-determined to be the same assay and analyzer – typically within a system
Understanding the Differences

Troponin results within the facility require comparison studies and protocols

POC/NPT

Central Lab
IFCC Example

The International Federation of Clinical Chemistry (IFCC)

Supporting documentation on all assays specifications

Last update: Nov 2014

Website: http://www.ifcc.org

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<th>Commercially available assays - Company/ platform(s)/ assay</th>
<th>LoB (^a) (µg/L)</th>
<th>LoD (^b) (µg/L)</th>
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\(^a\) Lower Limit of Blank

\(^b\) Lower Limit of Detection

\(^c\) Value for males

\(^d\) Value for females

\(^e\) Value for healthy patients

\(^f\) Value for patients with known cardiovascular disease
March 2017:
The Food and Drug Administration (FDA) granted 510 (k) clearance to Roche for its Elecsys Troponin T (TnT) Gen 5 Stat:

FDA term to be used: **Next Generation** vs. high-sensitivity

Test characteristics: <10% CV at the 99th%-ile

Key Point Relative to Accreditation:
Turn-Around-Time (TAT) assessments are still required with any analyzer; it is about the “process” as a whole from door-to-result for each test performed...not one variable!
CPC: Patient Population Focus

Dual Challenge with Managing Chest Pain Patient Populations

Vague Symptomology

Combining ‘Rule Out’ Process with ‘Diagnosis’ Process
(treat as ACS until proven otherwise)

RISK STRATIFICATION IS THE KEY

- LOW-RISK/Observation
- NSTE-ACS
- STEMI
CPC: Risk Stratification Model

Emergent Risk Assessment Must Include:

1. Symptomology Evaluation

2. ECG Completed and Read within 10 Minutes

3. Troponin: Turn Around Time (TAT)*

4. Risk Scoring Mechanism: ex. TIMI, GRACE, or other form founded in science

1. Facility Defined Evidence-Based Risk Stratification Model
2. Consistently Utilized and Documented by Facility’s Providers (order-set, flowcharts, patient’s chart)

*Turn-around time requirements are explained in the appropriate accreditation tools

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Risk Stratification: LOW-RISK

Emergent Risk Assessment Must Include:

**Entry into the Bucket**
- Chief Complaint Suggestive of ACS
- EKG Read in <10 Minutes
- Troponin Resulted* in <1 hour
- Facility Defined Risk Score

**The Bucket**

**The Low Risk Bucket**

80% REMAIN LOW RISK

= 6,000,000 Annual Population

**Removal from the Bucket**
- STEMI + EKG
- Troponin Positive for NSTE-ACS

*Turn-around time requirements are explained in the appropriate accreditation tools
Facility Considerations

ED ECG for STEMI determination

Troponin determinations for the in-patient utilizing Central Lab, per facility protocols and assay type
CPC Framework

Early Stabilization/Acute Care

- INITIAL ASSESSMENT
- LOW RISK
- NSTE-ACS

Staffing Responsibilities
Protocols
Risk Stratification Process

Laboratory POC/NPT and Central Lab Troponin assessments

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MI and Serial Strategy

Clinical Lab News, May 2014:

Implementation practices by facility addressing updated 2012 MI definition and the use of the 99th percentile and serial strategies

“....serial cTn ordering is a critical component of acute MI diagnosis readily understood in terms of timing, frequency and duration of cTn measurements...”

Cardiac Troponin Serial Ordering Recommendations: For Today and Tomorrow Sara Love, PhD and Fred Apple, PhD Clinical Lab News, May 2014, vol 40, no. 5
Understanding the Differences

Troponin assay protocols:

Protocols must be implemented for serial strategy assessments if using POC in ED and/or Dedicated Observation area versus Central Lab for in-patient

For Example:

A policy directive to hold blood from the patient’s original blood-draw in the main/central lab:

- For re-base-lining
- To be comparable to subsequent determinations, once the patient is admitted to the hospital

Adapted from: Lexington Medical Center Laboratory Bulletin and ACC Accreditation Troponin Brochure
Laboratory engagement in the LOW-RISK and NSTE-ACS processes of care for serial Troponin strategies is vital in multiple areas to include the entire ACS continuum for ED, Observation and In-Patient.
Laboratory engagement in Risk Stratification strategies will be assessed to include adherence to the guidelines for standardization in timing, use of 99th percentile; eliminating outdated markers and “grey-zone”; providing interpretive results.
Accelerated Diagnostic Protocols

Per Amsterdam et al in a Circulation 2010 article:

“Testing of Low Risk Patients Presenting to the ED with Chest Pain”

“...current studies have confirmed that contemporary troponin assays can identify the majority of MI’s within 3 hours of ED arrival...”
Serial Strategy Assessment

Key Term: “Standardized throughout the facility...” transitioning process between ED and inpatient Facilities may use a 0-6-12 strategy however it will most likely be listed as an “opportunity” for review and consideration to accelerate the diagnostic protocol, per the updated guideline recommendations, and impact on length-of-stay (LOS)

EC4.M1d7

Policies, protocols or orders for Troponin testing demonstrating the facility serial strategy. Facilities cannot use a serial strategy that is q8x3 as this is no longer the recommendation in the guidelines. The serial strategy must be standardized as demonstrated on the order-sets and flowcharts. Also refer to EC4M4a2.

Timing between serial troponins are standardized throughout the facility
(Examples of timing strategy may include: 0, 2, 6 - 0, 3, 6 - 0, 3, etc. Duration of serial strategy may also be as short as three 3 hours using sensitive troponins, or troponin deltas if provocative cardiac testing or imaging takes place)
CPC Troponin Assessments

For both CENTRAL LAB and POC/NPT Troponin

- Manufacturer
- Analyzer
- 99th Percentile
- CV at 99th%
- Review use of outdated assays
- Troponin Turn-Around-Time (TAT) % Door-to-Result – 60 minutes

- Reviewing the *Interpretive Comments test results* print out
  - Assess guideline adherence

- IFCC
- *Instructions for Use (IFU)*
  - Ensuring facilities are no longer using or referencing outdated WHO criteria from IFU
The infamous “Grey Zone” of Troponin Testing
Troponin History

- Early = CKMB
- **1999**: Troponin – poor assay precision created 2+ cut-points
  The history of the grey zone was born!

“That set the stage for using whatever cutoff you want, and the field has never recovered from it.” Jaffee et. Al. Clinical Chemistry 2008

- **2005**: Intro to 99%ile and CV <= 10%
- **2007**: Lab guidelines first attempt - cTn standardized
- **2012**: 3rd Universal Definition of MI

Excerpt from internet presentation n.d. “Cardiac Markers: Why all the Confusion?” by R. Heitsman, Radiometer, National Accounts Manager
Decision cut points for positive test for both central lab and POC (where applicable)

Guidance Statement

The Lab must be consulted for these items. The facility must provide a policy, procedure or protocol to show the decision point for a positive test. The facility may also provide the Interpretive Comments for Troponin results. Troponin test interpretive comments are what the clinicians see once the Troponin test is resulted. If the facility is using both central lab and a Point-of-Care (POC) analyzer, information for both assays is required.

Decision cut points must be clearly documented by the facility and not open to interpretation.

(These items are a progression from the CIV Facility Information Booklet (FIB) into the actual body of the tool and requires documentation, where the FIB did not.)
Interpretive Comments Assessment

- **TROPONIN T (TnT) 0.01 – 0.05 mg/L**
  Indicates minimal myocardial damage which with the appropriate clinical and ECG findings may be of prognostic significance in patients with ACS. However levels within this range may also be due to non-ACS causes e.g. *pulmonary embolus, heart failure, CRF, severe sepsis* etc.
  In ACS TnT starts to rise at 3-4h and reaches maximum sensitivity at 12-18h post symptoms and can remain elevated for up to 7-8 days. For exclusion of ACS levels should not be taken before 12h post symptoms.

- **TnT >0.05 mg/L would support a diagnosis of AMI**

**Using the 99th% ile for decision point?** Need more information (see IFCC or other document)

**Using a “Grey Zone”?** No, there is a negative and a positive
TROPOIN I

- *<0.04* No evidence of myocardial damage provided sample is at least 12h post symptoms (event).
- 0.04 – 0.48 Suggest minor myocardial damage provided at least 12h post event
- *>0.49* Indicates major myocardial damage

- Using the 99th% ile for decision point? **Need more information (see IFCC or other document)**
- Using a “Grey Zone”? **YES**
Interpretive Comments Assessment

TROPONIN I

- **<0.04**: Troponin appears normal or minor myocardial damage or other cause
- **>0.04**: Consistent with Myocardial Infarction

This information is based on the recommendations of the 2012 Third Universal Definition of Myocardial Infarction for Troponin to be at least one value above the 99th percentile upper reference limit.

- Using the 99th% ile for decision point? **Probably** (see IFCC or other document) – also cite the source (may see website links or PDF links)
- Using a “Grey Zone”? **No, there is a negative and a positive**
Accountability

Changing Perspectives of Turn-Around-Time (TAT) Tracking: Accreditation requirements
Cardiac Biomarker Requirements

• Measuring TAT is and has been a guideline driven recommendation for many years

• No previous TAT requirements from any organization until...
  – 2012: CMS OP 16 requiring compliance for “Door-to-Result in 60 minutes”
    • initiated and then revoked
    • not reinstated to date

• ACC Accreditation Services (formerly SCPC) requirement started in 2012 and will continue
  • CPC track and demonstrate improvements
Accreditation: Process Requirements

“To the extent that laboratory test TAT is only one factor impacting ED length of stay and patient outcomes, it is unlikely that POCT alone, in the absence of an interdepartmental approach to ED operations, will produce measurable improvements in outcomes.”


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Turn-around-Time (TAT) Defined?

- Physicians  “brain to brain”
- Laboratorians “receipt to result”
- Nurses “door or draw to result”
- Phlebotomist “collect to receipt in lab”
TAT Tracking: Healthcare Implications

July 2014 Clinical Laboratory News: Volume 40, Number 7
What Does Turnaround Time Say About Your Lab?

Key Quotes:

- “Every laboratorian knows that their colleagues in medicine see TAT as something almost as important as the quality of test results themselves.”

- “In fact, surveys have found that 80% of labs get complaints about TAT.”
Studies and research support the following:

- Assessing the “whole process” (i.e.: arrival)
- Standardizing the definitions of turn-around-time (TAT)
- Assessing TAT with patient outcomes and length of stay
TAT Tracking: Healthcare Implications


Proposed new concepts for TAT in the diagnostic process:

As a “Patient-oriented” view or the “whole process”

- **Diagnostic TAT** – arrival to reporting of results
  - outcomes median 122 min
- **Clinical TAT** – arrival to order
- **Laboratory TAT** – order to report/resulted
TAT Tracking: Healthcare Implications

In *Academic Emergency Medicine, 2010:17*, Hwang et al noted:

“Guidelines do not exist delineating time frames for when a troponin test should optimally be resulted in association with improved patient outcomes.”

“Prolonged laboratory TAT may delay recognition of conditions in the acutely ill, potentially affecting clinician decision-making and the initiation of timely treatment.”

– Outcomes median 107 minutes; “ordered to resulted”
TAT Assessed

• Know the starting point:
  – Door vs. Order

• Know the goal time for each phase:
  – Door to Result = 60 minutes *(Accreditation Requirement)*
  – Order to Result = 60 minutes
  – Received to Result = 30 minutes (or less)

• Know the compliance goal:
  – Door to Result = 60 minutes *(Accreditation Requirement) / 75%*
  – Order to Result = 60 minutes / 90%
# Time is muscle - think HEART!

<table>
<thead>
<tr>
<th>OLD</th>
<th>NEW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Door to ECG = 10 minutes</td>
<td>Door to ECG READ within 10 minutes</td>
</tr>
<tr>
<td>Door to Reperfusion = 90 minutes</td>
<td>Door to Reperfusion &quot;as soon as possible&quot;</td>
</tr>
<tr>
<td></td>
<td>First Medical Contact (FMC) to Reperfusion Less than 90 minutes</td>
</tr>
</tbody>
</table>

| TRANSFER: Door in - Door out = 30 minutes | Door in - Door Ready = 25 minutes |
| Door to Thrombolytics = 30 minutes | Same consideration; low utilization |
| Lab received to results = 60 minutes | Door to Troponin Results in 60 minutes Facility sets % compliance - recommend setting at 75% |
| Order/Collect to results = 60 minutes | Order/Collect to results: % compliance = 90% |

**NEW CONCEPTS: GOLDEN HOUR for the HEART**

STEMI is a heart trauma: think 60 minutes from "door"

**NEW GOAL: Door to Reperfusion in 60 minutes (60%)**

Troponin decision: think 60 minutes from "door"
Acute Coronary Syndrome Resources

In keeping with its mission to lead the fight against Acute Coronary Syndrome (ACS), the American College of Cardiology (ACC) provides several accreditations designed to help facilities improve their care of patients with ACS. These include: Chest Pain Center Accreditation and Cardiac Cath Lab Accreditation for individual hospitals and hospital systems and FreeStanding ED Cardiac Care Certification for freestanding emergency departments. As a partner to the healthcare community, ACC offers additional resources of interest to the dedicated individuals who are drivers of innovation in the continuum of care. The publications and resources included in this section are intended for clinicians and hospital administrators who are involved in managing patients with ACS.

Guidelines

ACC provides the following links, which are known to be the current guidelines and recommendations for the care of patients with ACS.

Guidelines

ACC/AHA 2014 Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes
Resources

Guidelines

ACC provides the following links, which are known to be the current guidelines and recommendations for the care of patients with ACS.

Guidelines

ACC/AHA 2014 Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes

ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures

2013 ACCF-AHA Guideline for the Management of STEMI

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction

Comprehensive listing of all ACCF/AHA current guidelines

ESC/ACCF/AHA/WHF Third Universal Definition of Myocardial Infarction
Resources: www.acc.org
Science tells us what we can do
Guidelines tell us what we should do

Accreditation is the roadmap to implement the “should do”

Registries measure performance on the “should do”

Quality Initiatives & Education are the levers to improvement
Thank you!

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