

E•QUAL | EMERGENCY QUALITY NETWORK

Incorporating High-Sensitivity Troponin into Your ED Workflow

Presenters



Simon Mahler, MD



Deborah Diercks, MD



Christopher Baugh, MD

Mahler Disclosures

- Research funding:
 - NIH: Heart Lung and Blood Institute
 - Donaghue Foundation/ Association of American Medical Colleges
 - AHRQ: Agency for Healthcare Research and Quality
 - Abbott Laboratories
 - Roche Diagnostics
 - Siemens Healthcare
 - Creavo Medical Technologies
 - Ortho Diagnostics
- Author for Up-to-Date
- Chief Medical Officer: Impathiq, Inc.

Baugh, Financial Disclosure Information

AFFILIATION/FINANCIAL INTEREST – CORPORATE ORGANIZATIONS, MANUFACTURERS, PROVIDERS

CONSULTANT	JANSSEN PHARMACEUTICALS, US DOJ
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STOCK SHAREHOLDER	NONE
OTHER FINANCIAL OR MATERIAL SUPPORT	NONE
SPEAKER'S BUREAU	NONE
ADVISORY BOARD AND SPEAKER	SALIX PHARMACEUTICALS, JANSSEN PHARMACEUTICALS, ROCHE DIAGNOSTICS

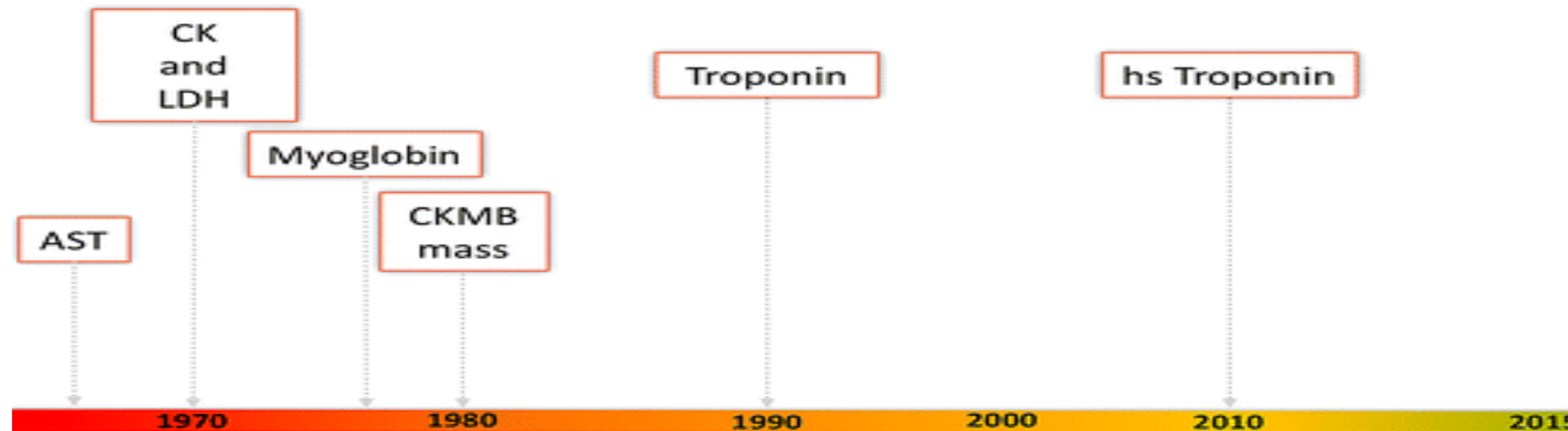
Diercks financial disclosures

2. Simon – can you give us a brief recap of what is different about hs Tn?

Brief summary of hs-cTn vs contemporary cTn

High Sensitivity Troponin Assays Defined

- Measure same cardiac troponin protein
- Are more precise, can detect lower levels; measurable levels in at least 50% of healthy patients



2017 FDA
approves hs-cTnT

2018 FDA
approves 2 hs-cTnI
assays

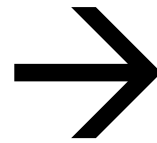
hs-cTn Units

Contemporary cTn measured in ng/ml

Hs-cTn measured in ng/L

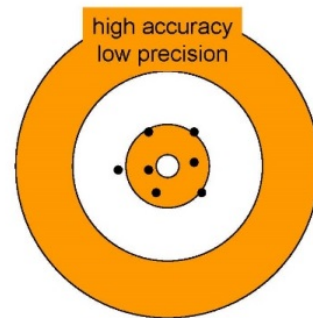
0.006 ng/ml \rightarrow 6 ng/L

0.040 ng/ml \rightarrow 40 ng/L

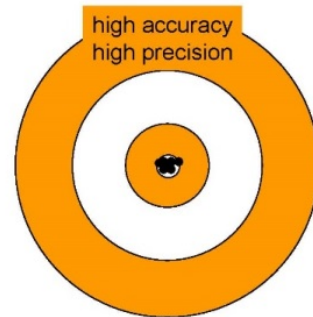


High Accuracy, Different Precision

Earlier Generation Troponin



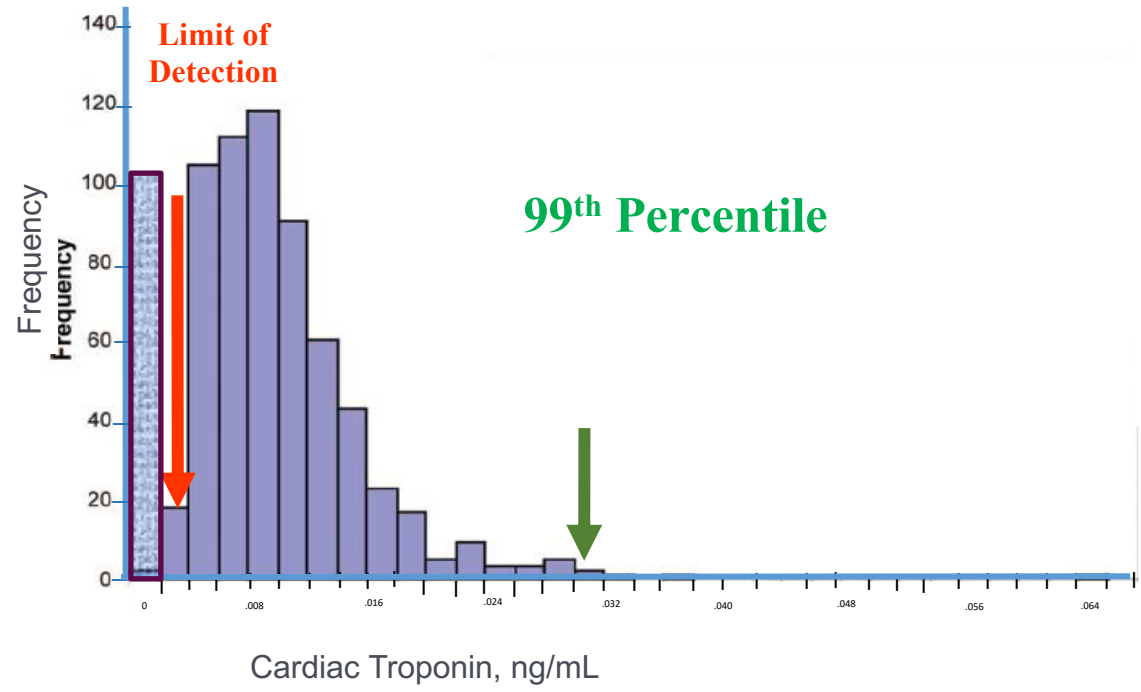
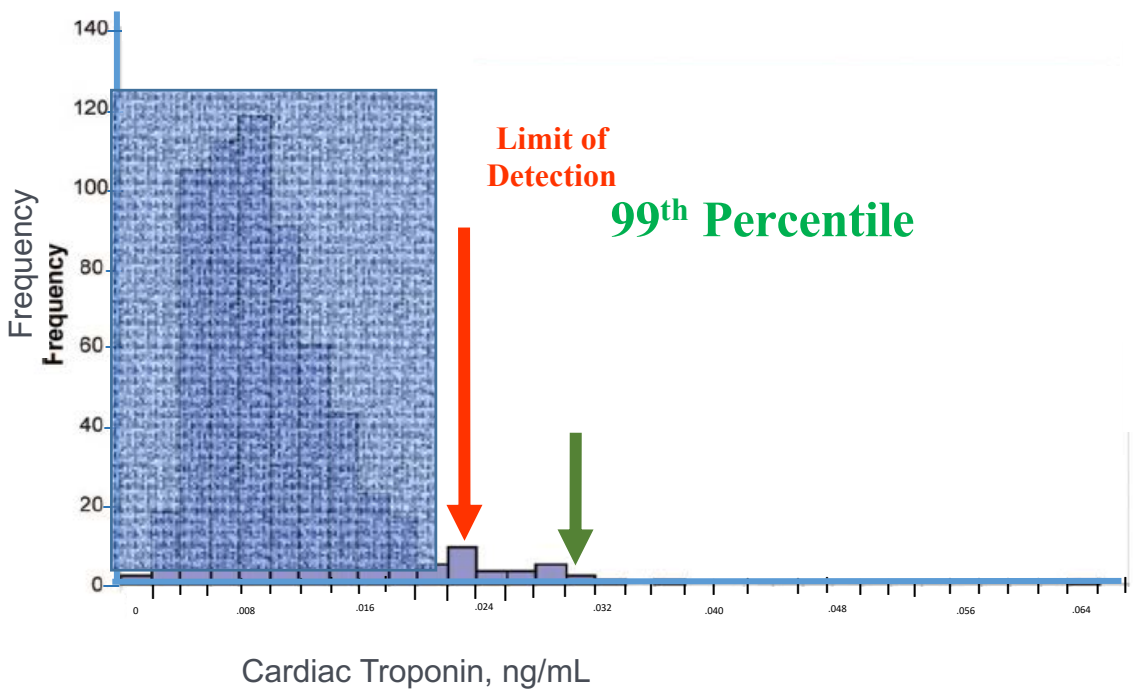
15% CV



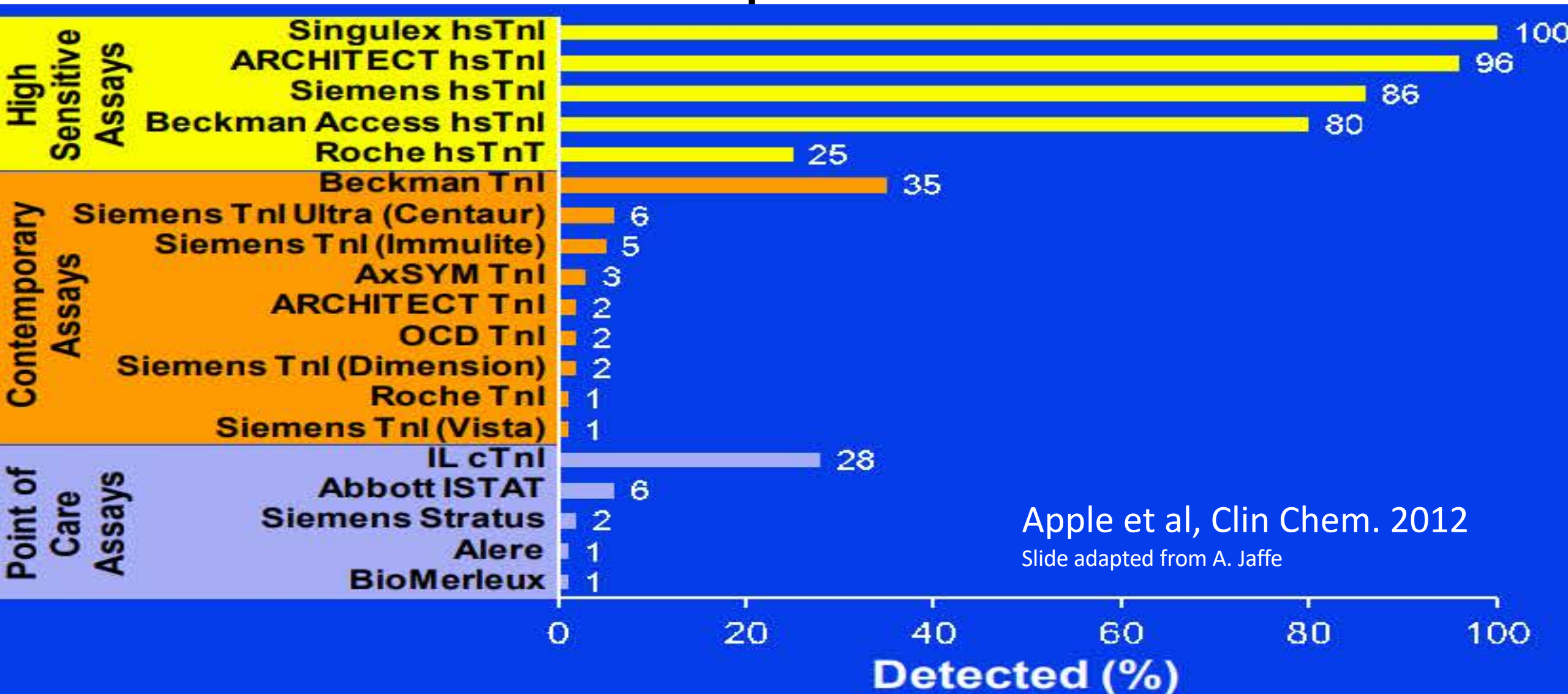
5% CV

High-sensitivity Troponin

Contemporary vs High-sensitivity Cardiac Troponin Assays



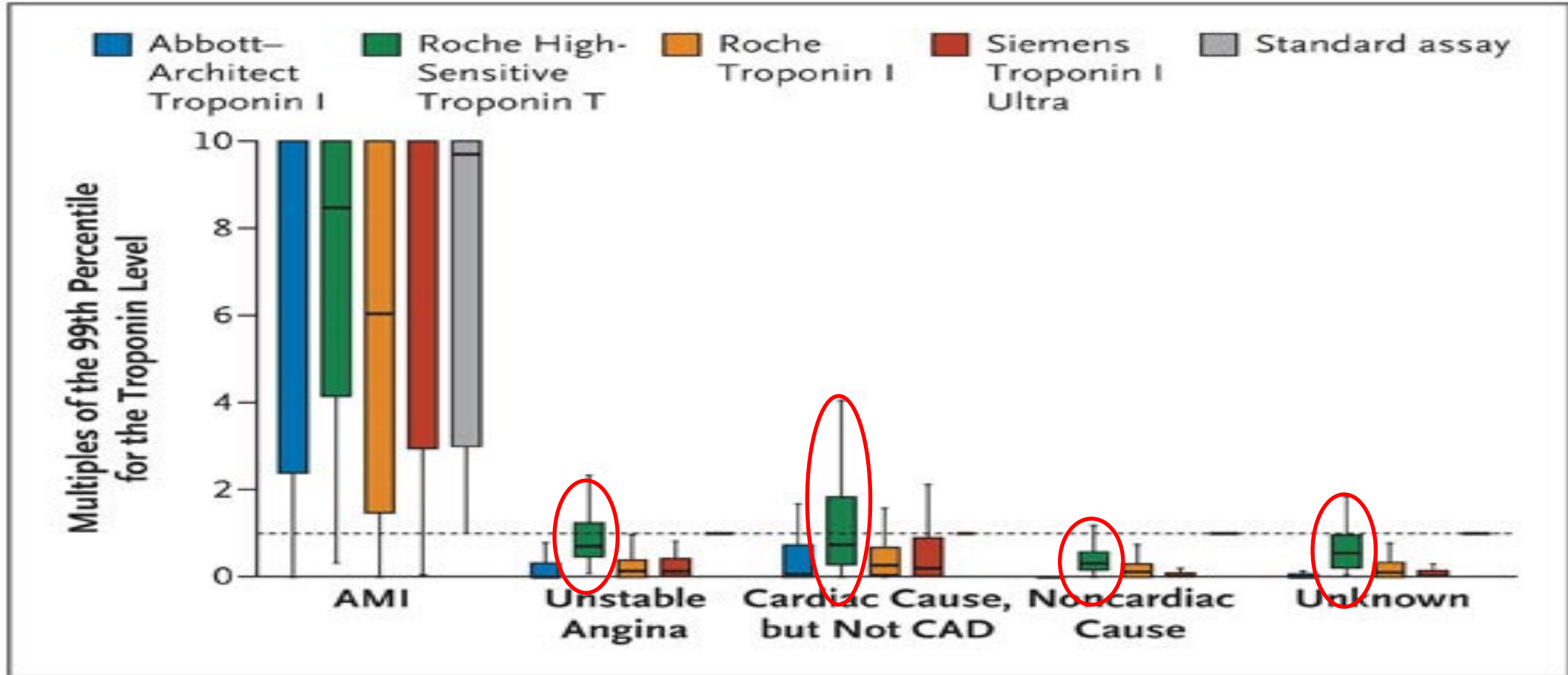
Percent of healthy Patients with Detectable Troponin



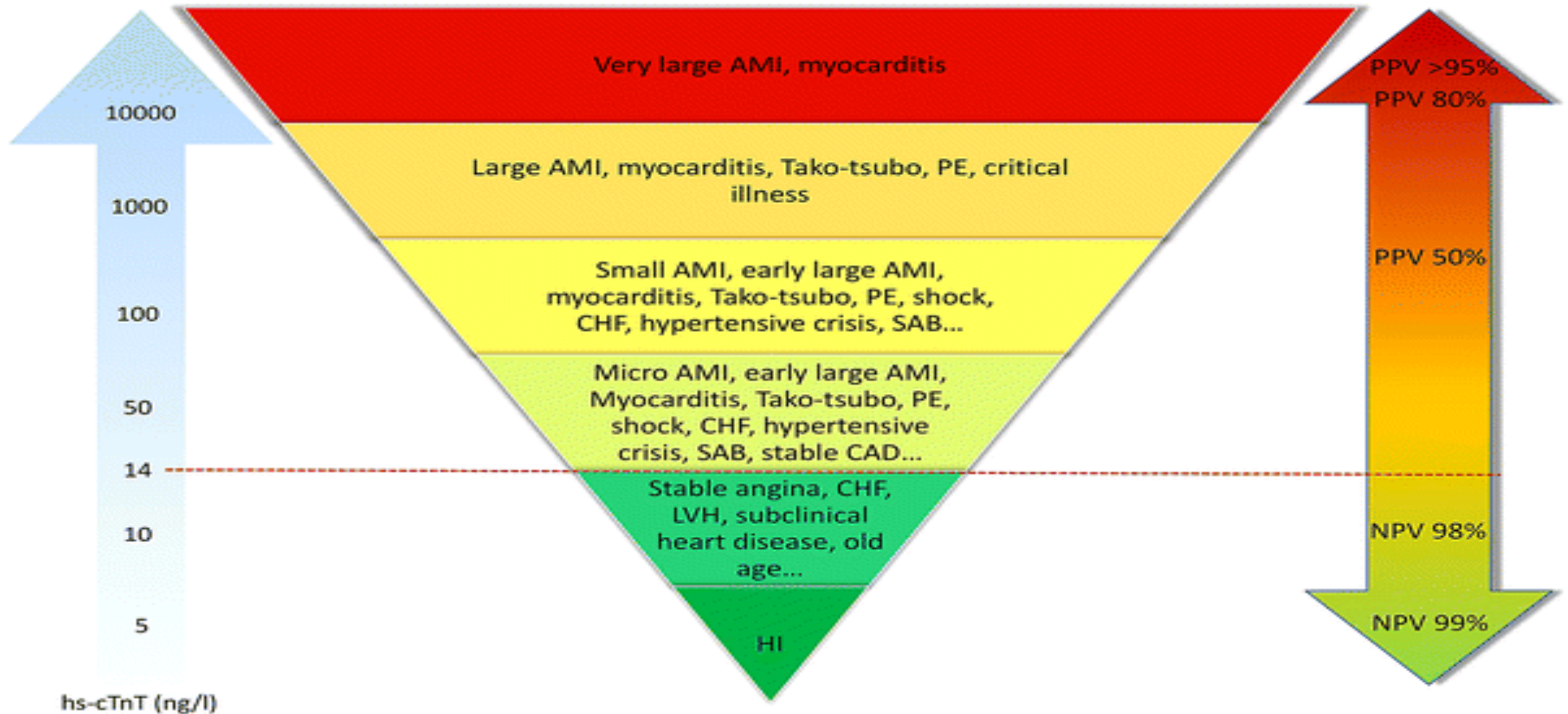
Apple et al, Clin Chem. 2012

Slide adapted from A. Jaffe

Detection of more patients with non-AMI cTn elevations

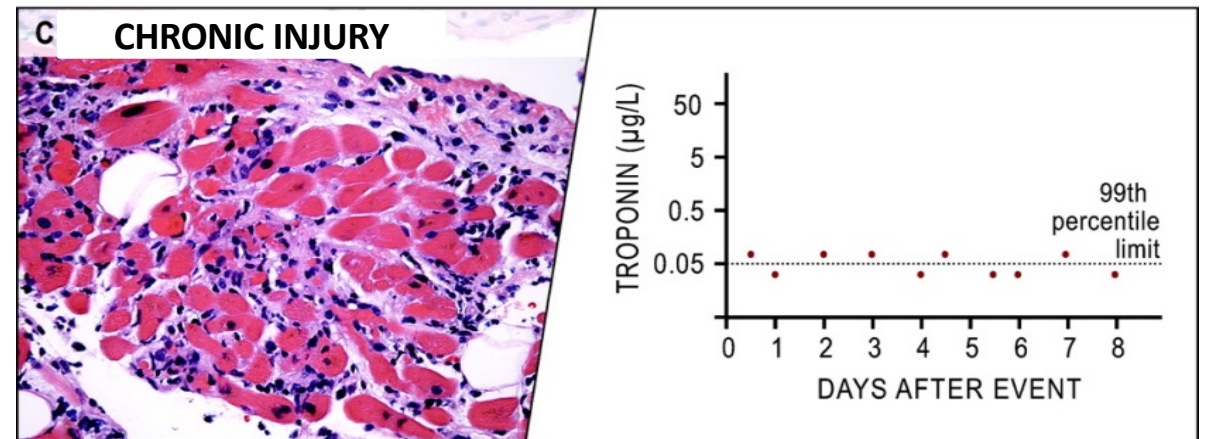
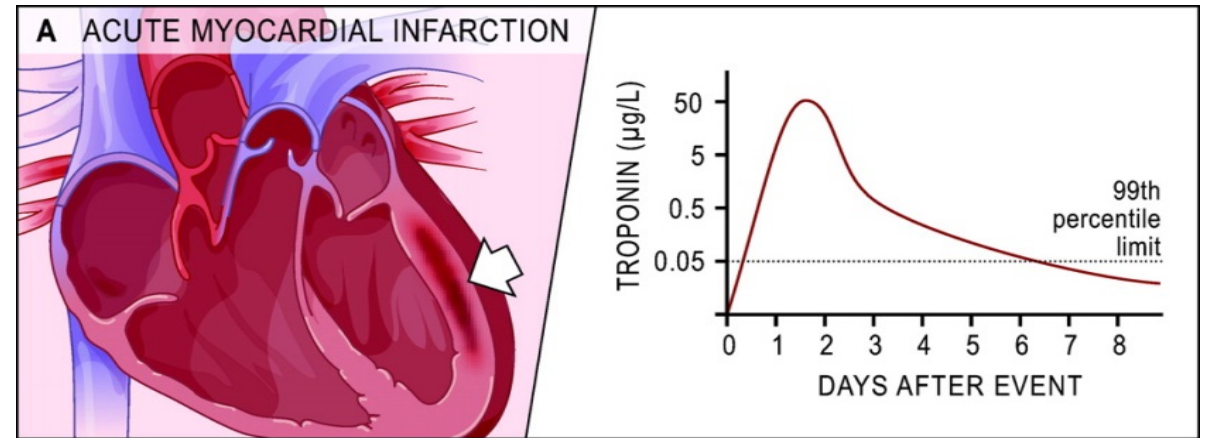


The larger the elevation the more likely it is from MI



Pattern of Elevation

- AMI differentiated from non-ischemic cTn elevations based on:
 - Pattern of elevation
 - Clinical context

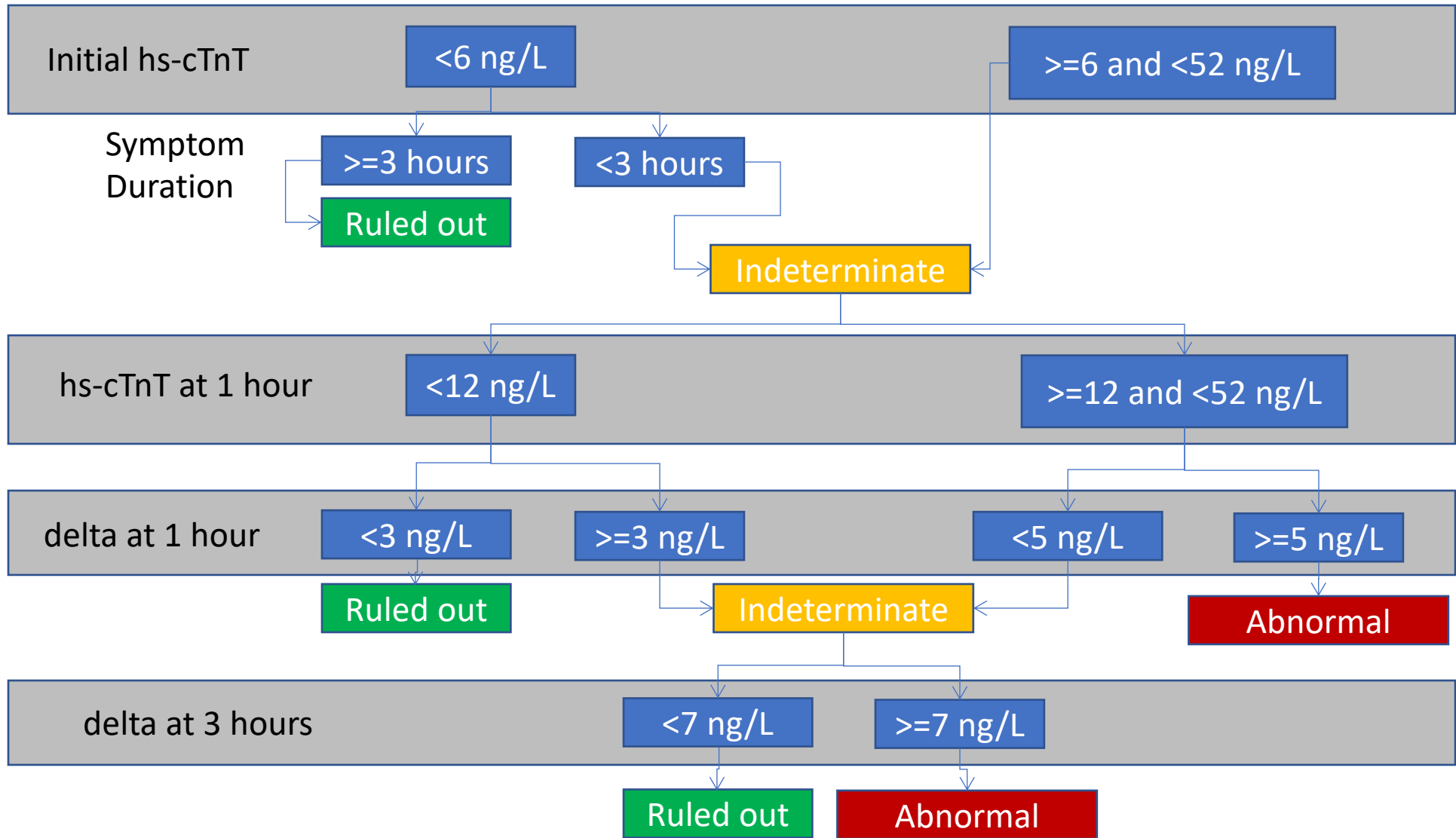


3. a. Great review, thanks Simon. Deb can you tell us about your experience with hsTn at UT Southwestern?

- How to Implement and what are the barriers

UTSW/Parkland Pathway

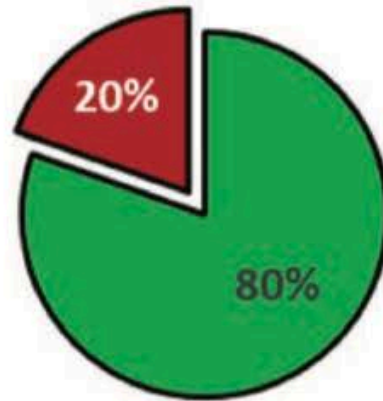
hs-cTnT ≥ 52 ng/L is abnormal



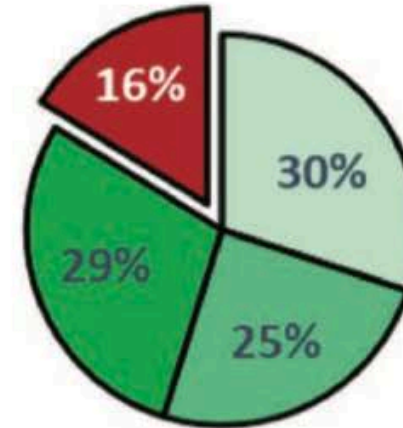
B

- Rule out baseline
- Rule out 1 hour
- Rule out 3 hours
- Abnormal

Conventional cTnT Algorithm



New hs-cTnT Algorithm



Sensitivity, % (95% CI)

Specificity

PPV

NPV

100% (70-100%)

82% (79-85%)

11% (5-16%)

100% (100 – 100%)

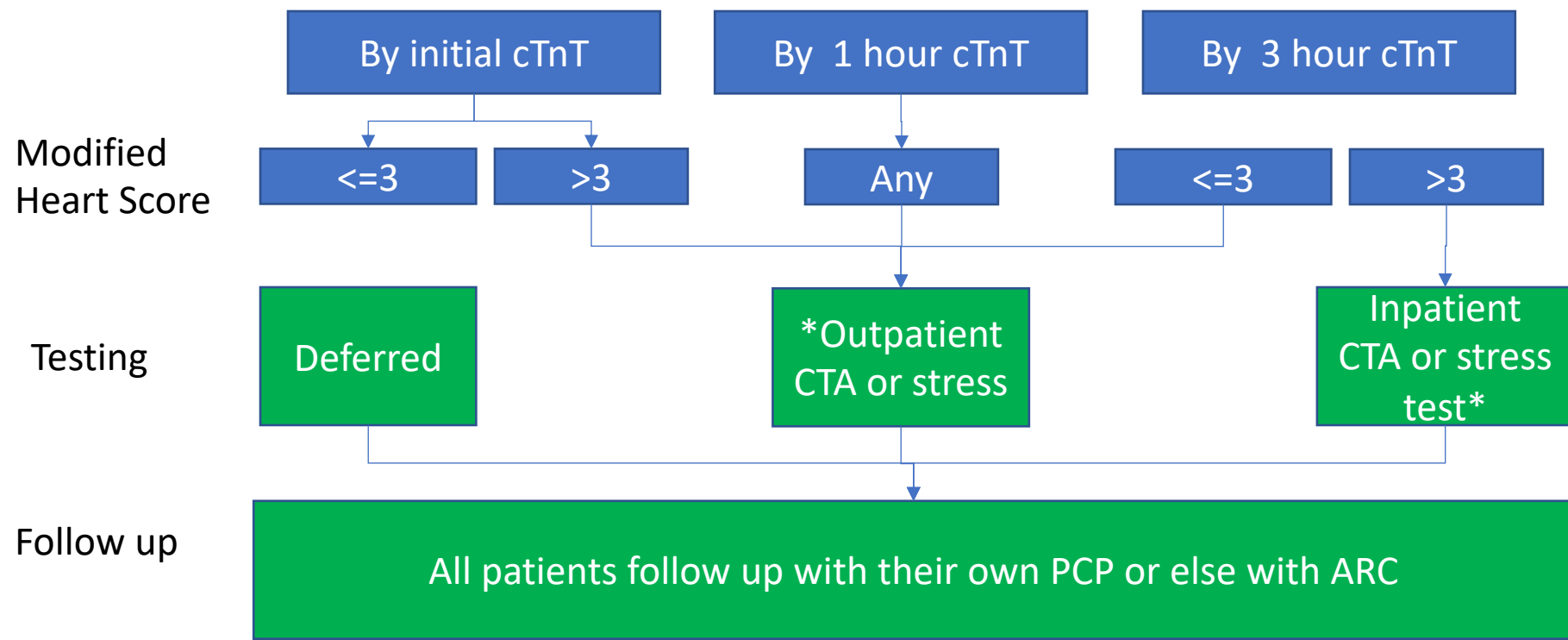
100% (70-100%)

86% (82-88%)

13% (6 – 20%)

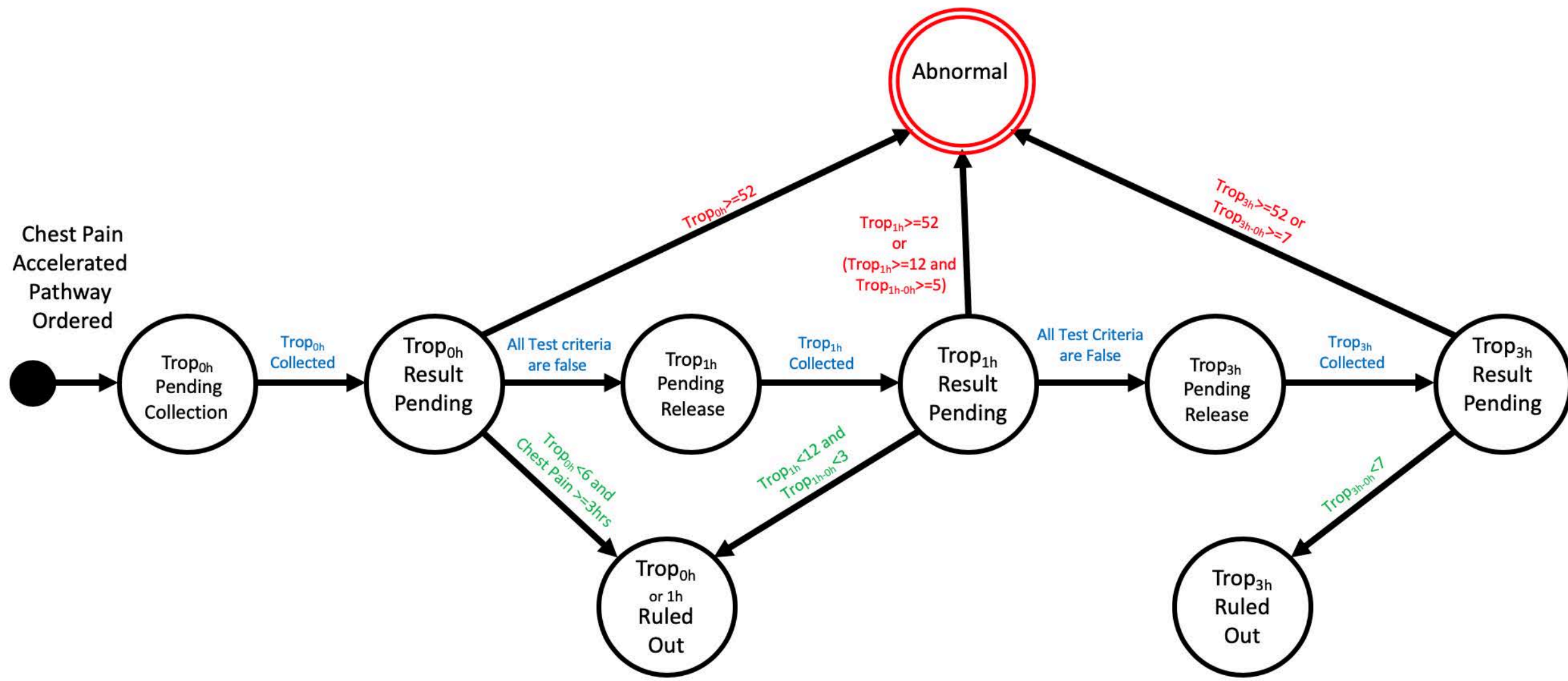
100% (100 – 100%)

Ruled out

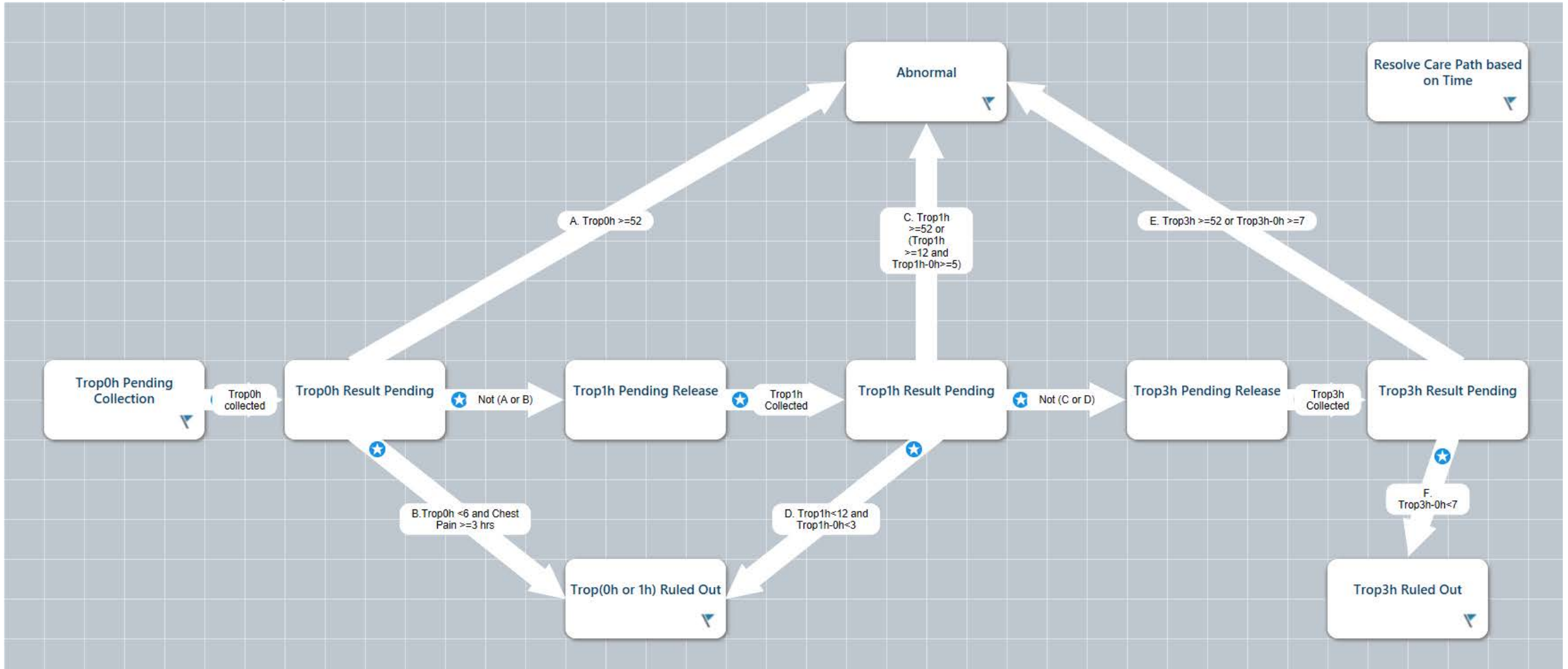


*if no stress test, CTA, or cath within the prior 6 months . This may be done in the inpatient setting based on ED attending discretion.

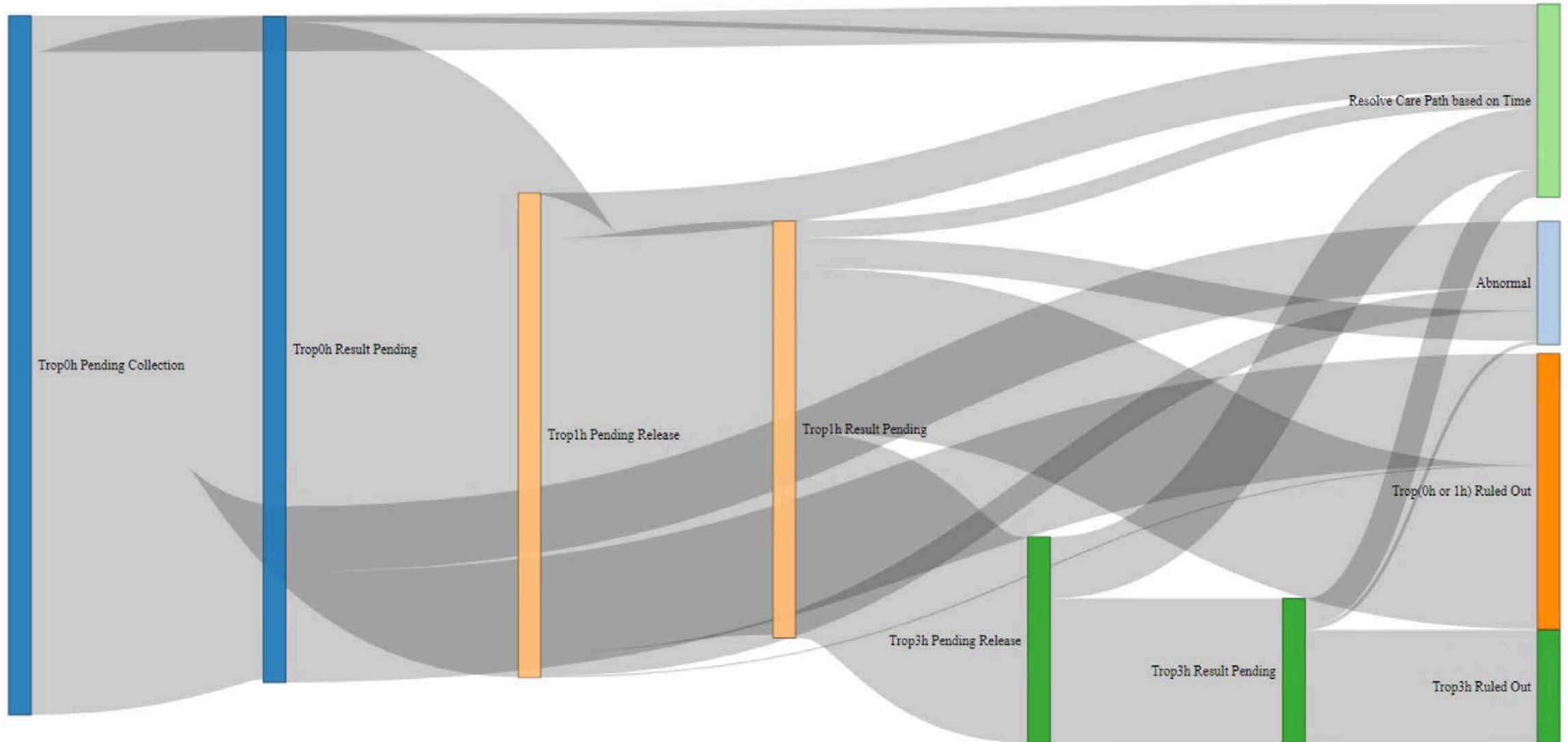
I . . . I D I . .



ED Troponin Care Path



Sankey Diagram



Results

	Care Path n=941	Manual Testing n=205	Difference (95% CI)	P value
Rate of Adherence	69%	46%	23% (15-31%)	<0.05
Rate of Excess Phlebotomy	16%	5%	11% (7-15%)	<0.05

Limited to those patients with CC: Chest Pain or Analog

0/1 Hour, Low Risk:

Ruled Out at 0/1 Hour:

No evidence of myocardial injury. Patient has a Low Risk Heart Score. No additional risk stratification is recommended.

0/1 Hour, Not Low Risk:

Rule Out at 0/1 Hour:

No evidence of myocardial injury. Patient has Moderate/High Risk Heart Score. Early outpatient stress test or CTA Coronary is recommended. Consider referral to Chest Pain Clinic: ###-###-####

3 Hour, Low Risk:

Rule Out at 3 Hours:

No evidence of myocardial injury. Patient has Low Risk Heart Score. Early outpatient stress test or CTA Coronary recommended. Consider referral to Chest Pain Clinic: ###-###-####

3 Hour, High Risk:

Rule Out at 3 Hours:

No evidence of myocardial injury. Patient has Moderate/High Risk Heart Score. Stress test or CTA Coronary is recommended prior to discharge.

- 3. b. Thanks Deb, that was fantastic! Let's move on to Chris. Chris, can you tell us about your experience with implementing hsTn at Brigham?

Brigham and Women's Hospital

- Academic, urban tertiary care hospital in Boston, MA
- ~62,000 annual adult visits
- 750 inpatient beds, 39 ED beds, 20 ED observation beds
- Launched high-sensitivity troponin in April, 2018

Four Settings to Consider



Emergency



Perioperative

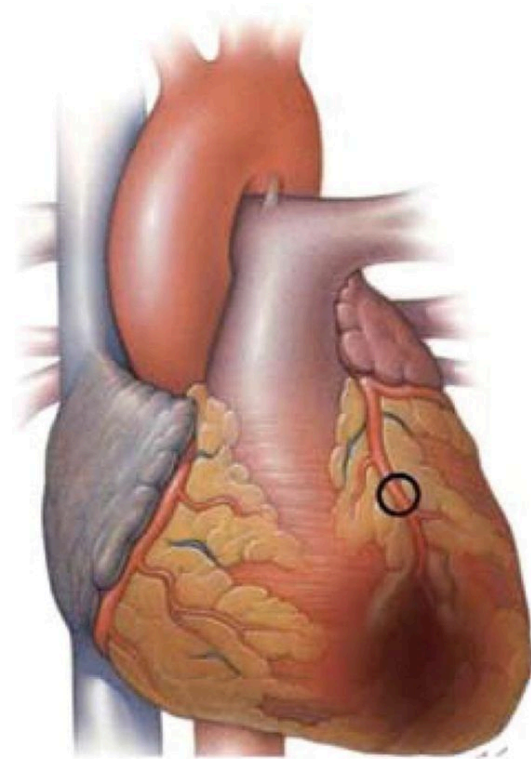


Inpatient



Clinic

ADPs: Focus on Type 1 MI



Plaque rupture with thrombus



MI Type 1

Vasospasm or endothelial dysfunction



MI Type 2

Fixed atherosclerosis and supply-demand imbalance



MI Type 2

Supply-demand imbalance alone

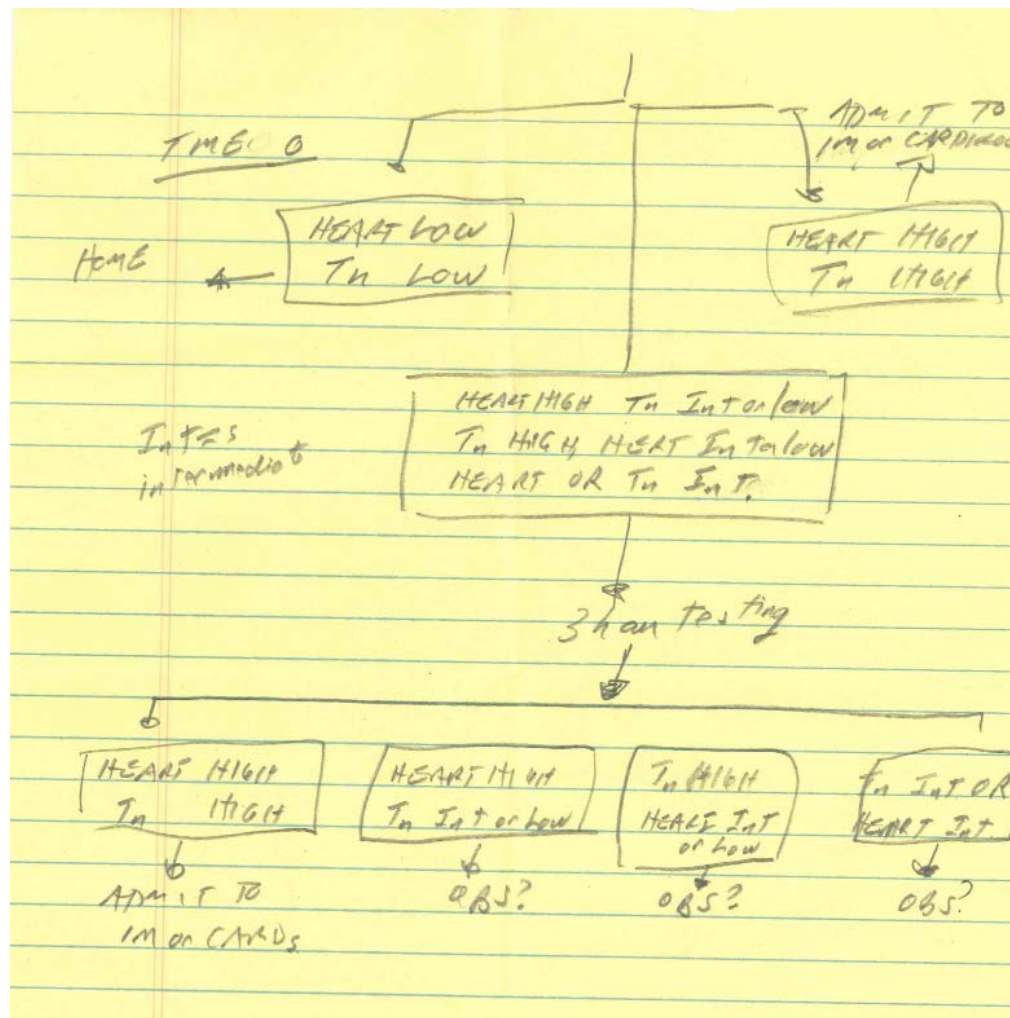


MI Type 2

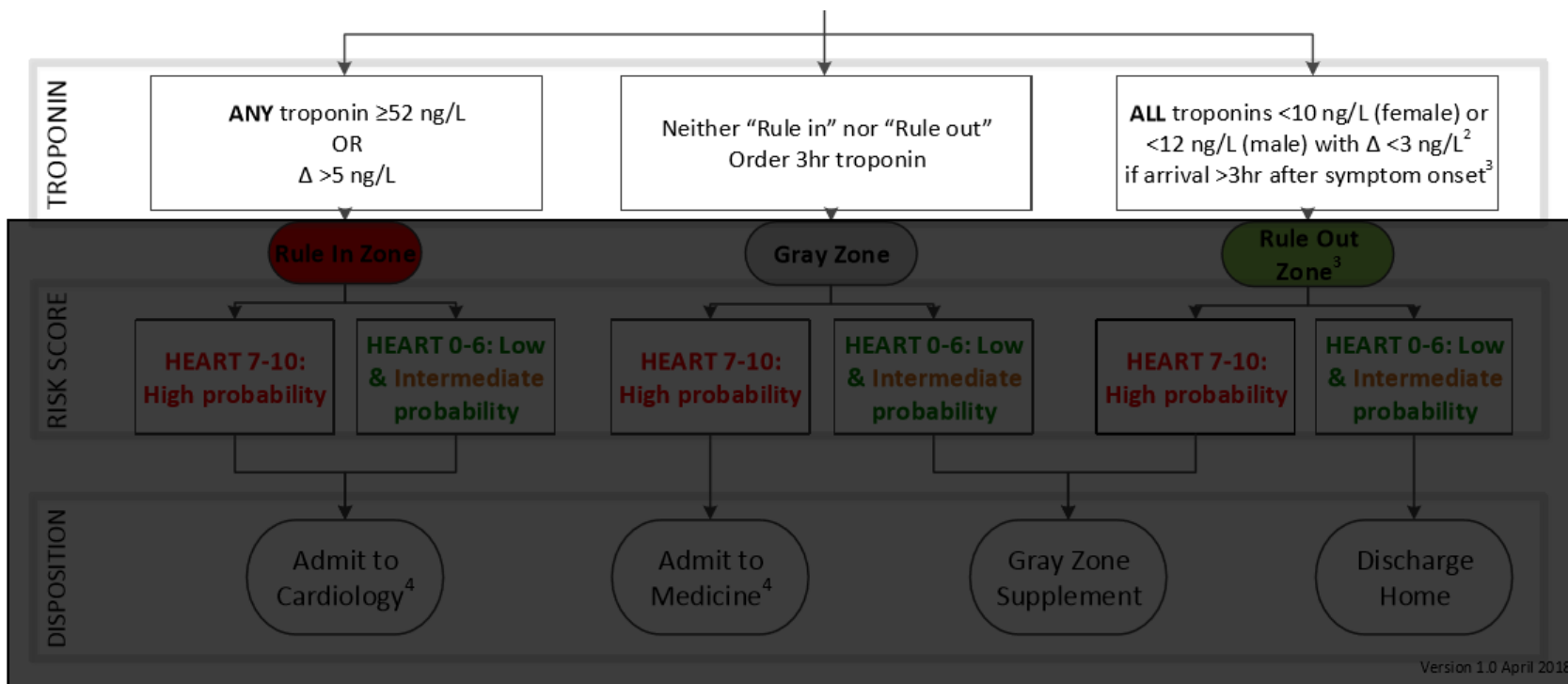
Typical Recommendations for 99th Percentile cutoffs

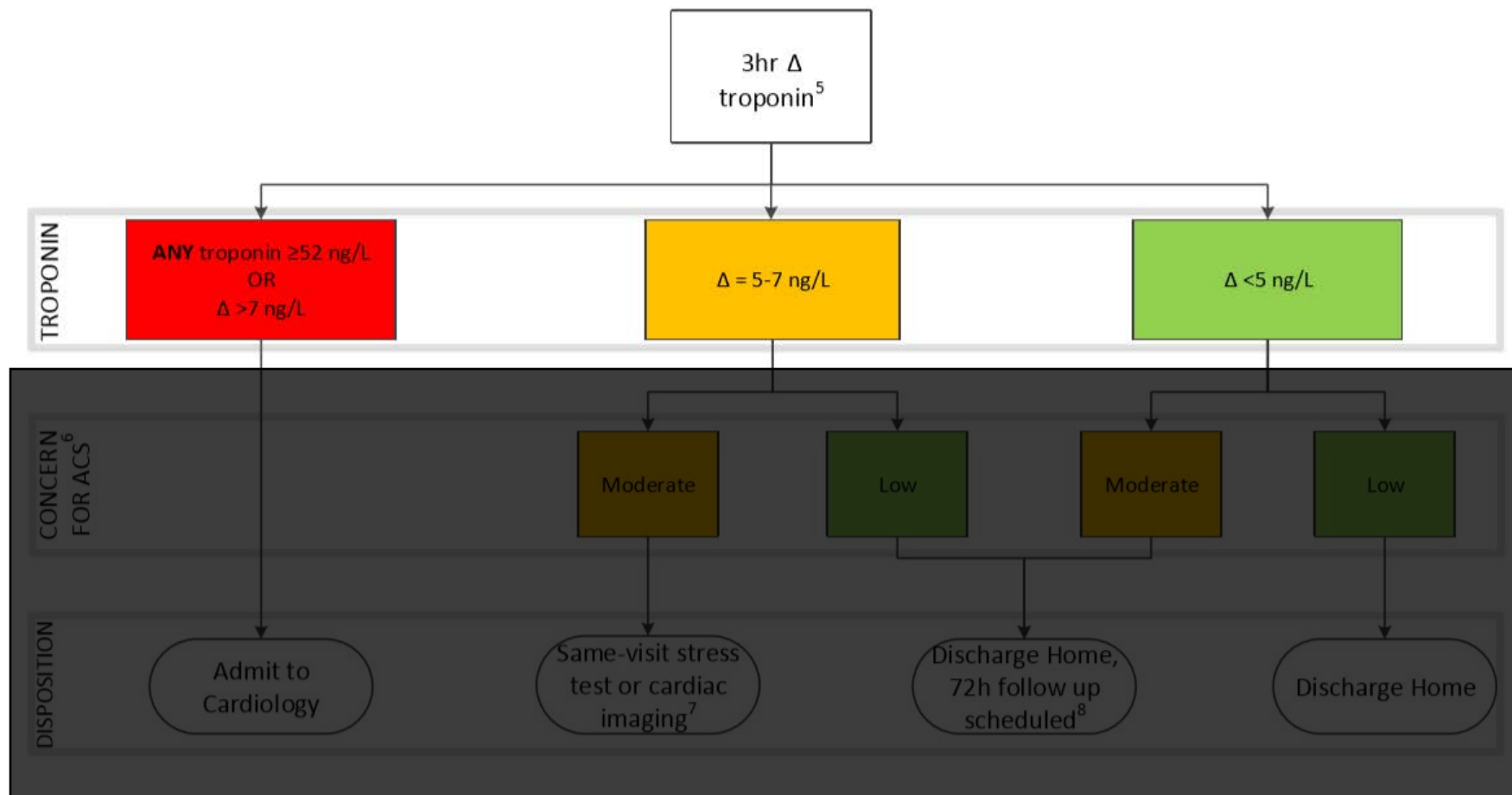
- Europe: 14 ng/L for both males and females
- US: variable, some use FDA value of 19 ng/L, others use lower and gender-specific values
- For example:
 - Females: 10 ng/L
 - Males: 15 ng/L

THE ELECTRONIC MEDICAL RECORD WILL FLAG AS
“ABNORMAL” AT THESE VALUES AND ABOVE; DOES NOT
NECESSARILY DEFINE AMI



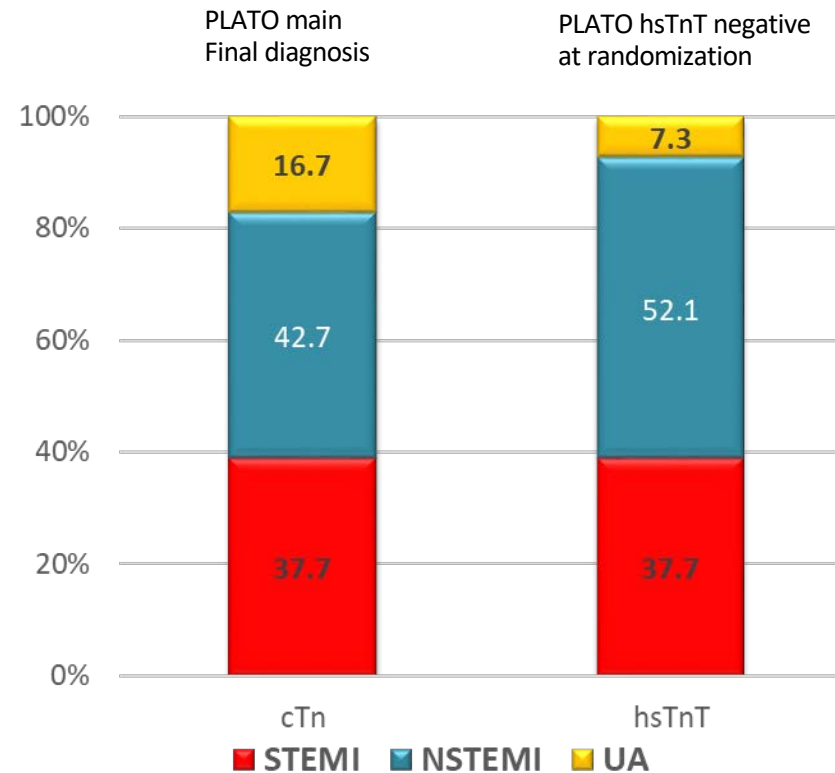
Partners Healthcare ADP: hsTnT





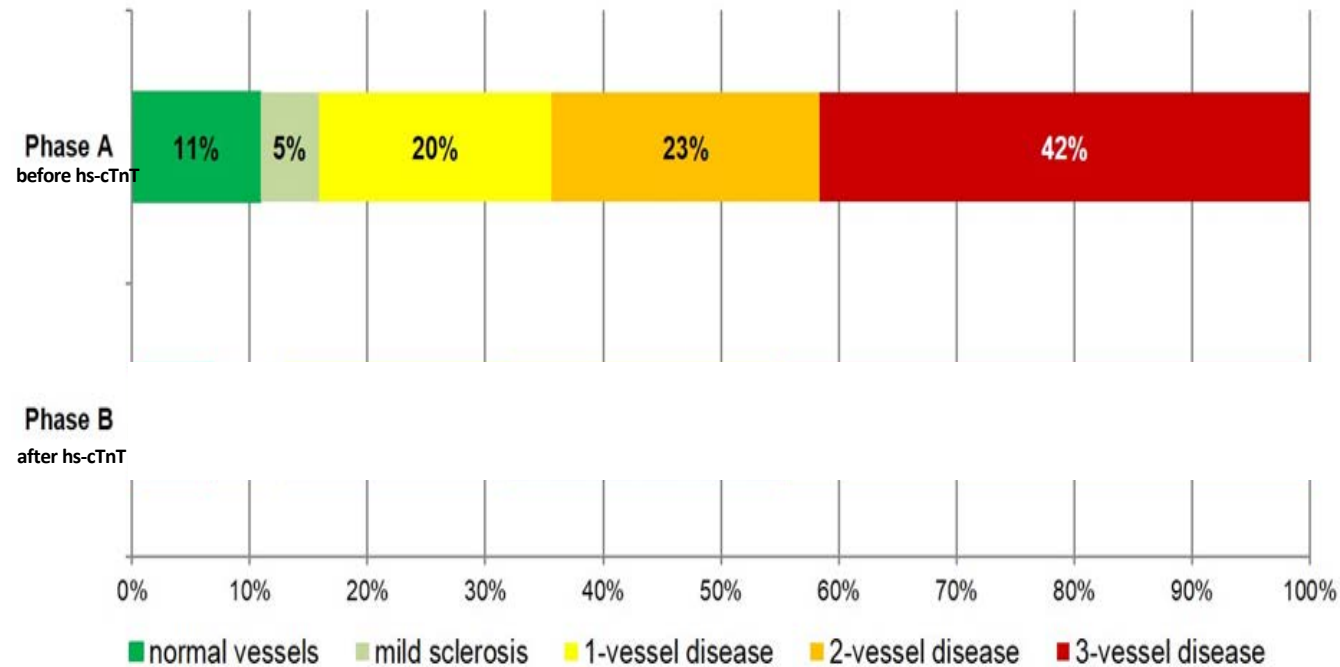
Unstable Angina – Lower Prevalence

Effect of use of hsTn instead of cTn on prevalence of UA in the [PLATO trial](#)



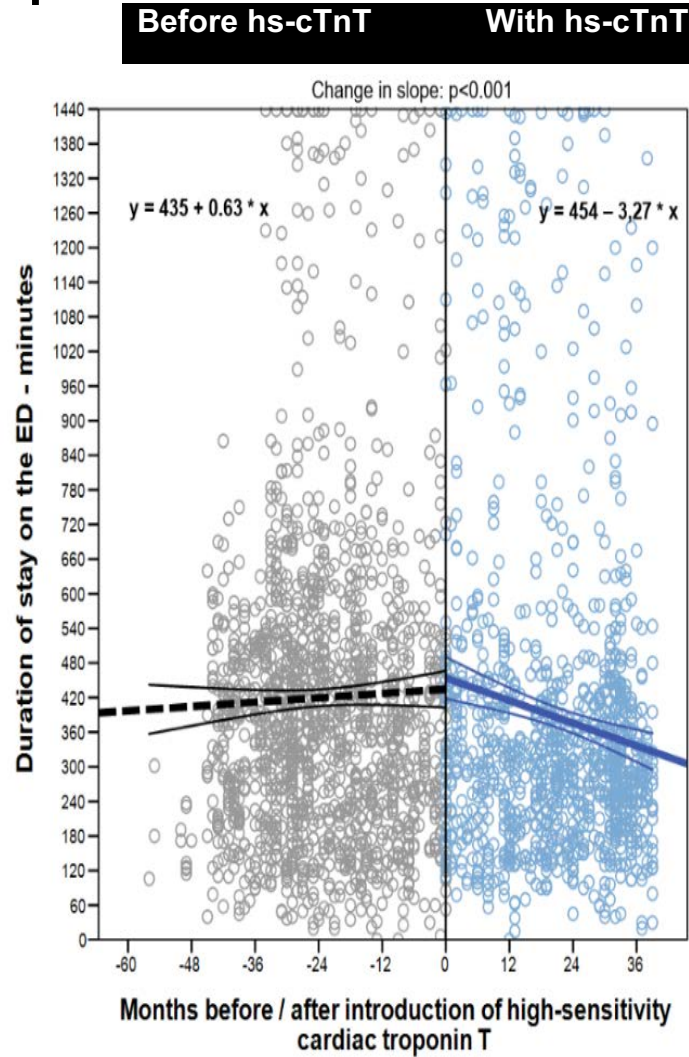
Giannitsis E, et al. Outcomes after planned invasive or conservative treatment strategy in patients with non-ST-elevation acute coronary syndrome and a normal value of high sensitivity troponin at randomisation: A Platelet Inhibition and Patient Outcomes (PLATO) trial biomarker substudy. *Eur Heart J Acute Cardiovasc Care*. 2017 Sep;6(6):500-510.

Findings of Coronary Angiography



Giannitsis E, et al. Outcomes after planned invasive or conservative treatment strategy in patients with non-ST-elevation acute coronary syndrome and a normal value of high sensitivity troponin at randomisation: A Platelet Inhibition and Patient Outcomes (PLATO) trial biomarker substudy. *Eur Heart J Acute Cardiovasc Care*. 2017 Sep;6(6):500-510.

Impact on ED LOS



- 20% reduction of ED LOS
- Change in trend
- 15% more out-patients

-79 minutes

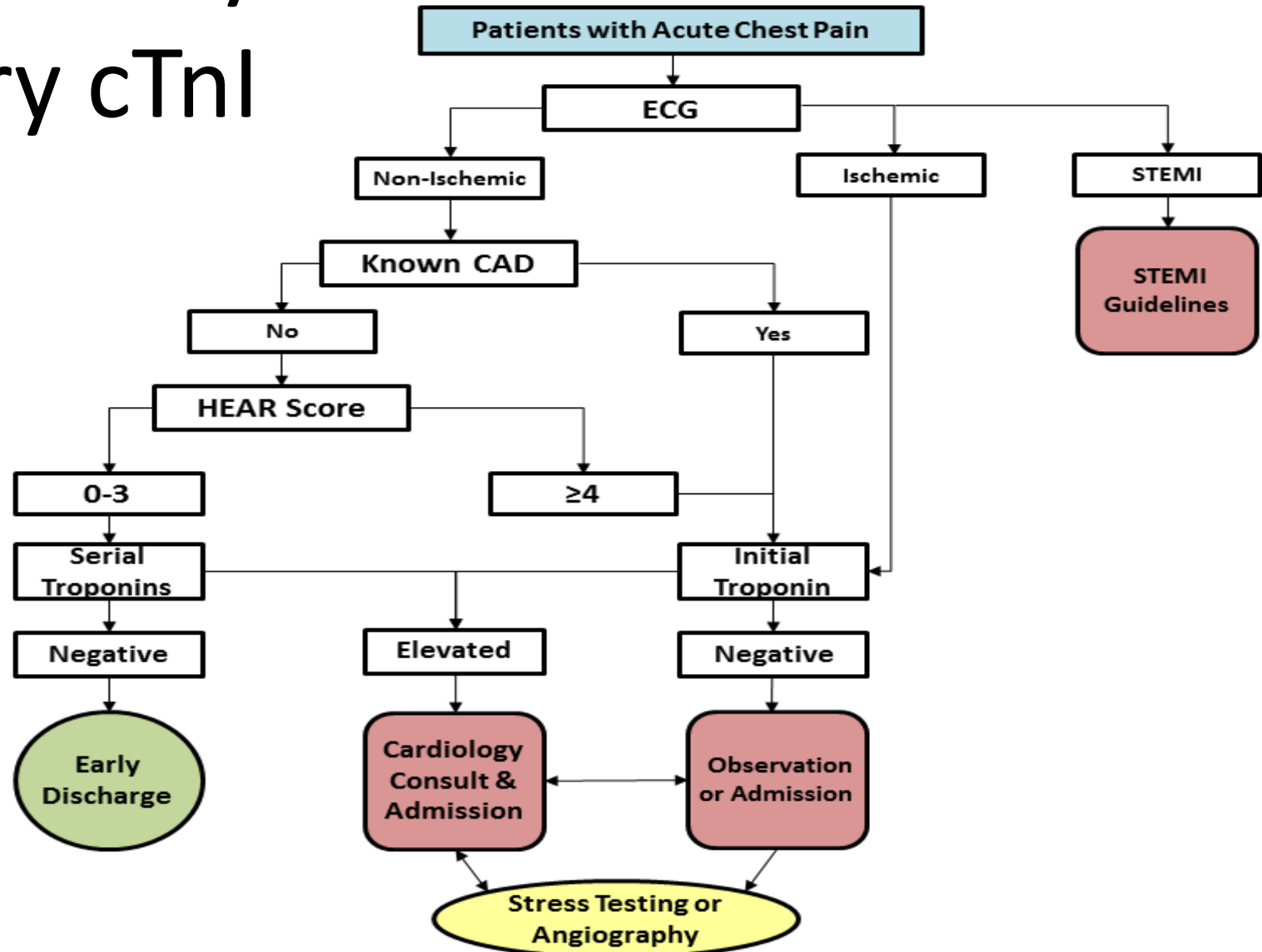


3.c. That was very interesting Chris, thanks.
Simon, how does Wake Forest plan on modifying
the HEART Pathway based on hs-cTn

Current HEART Pathway with contemporary cTnI

ADP version of the HEART score

- No ischemic ECG changes
- No known CAD
(prior AMI, revascularization, >70% coronary stenosis)
- Low risk = HEAR(t) score: 0-3
- Negative serial troponins



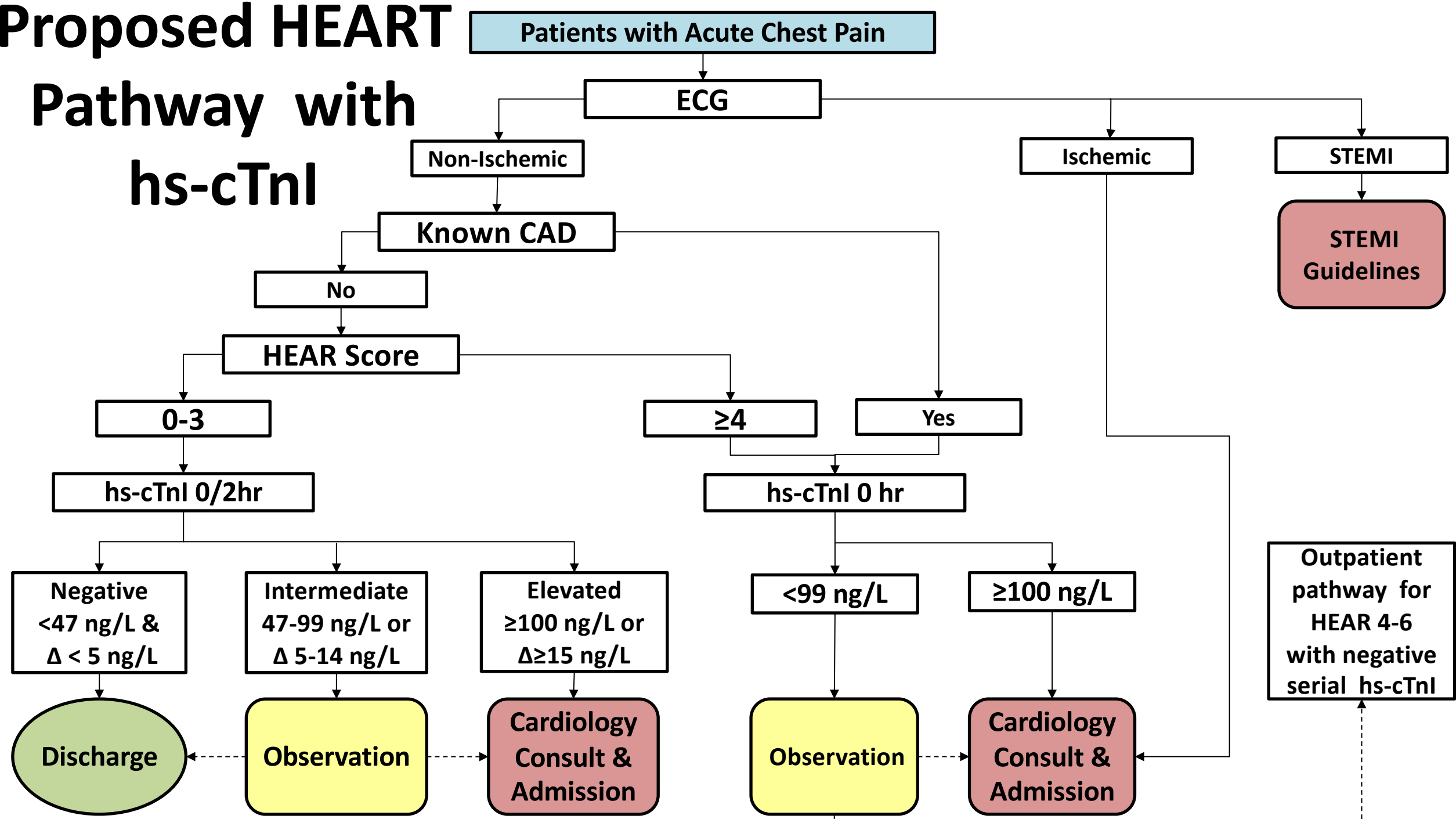
Mahler et. al, Crit Path Cardiol, 2011

Mahler et. al, Int J Cardiol, 2013

Mahler et al, Circ CVQO J, 2015

Mahler et al, Circulation, 2018

Proposed HEART Pathway with hs-cTnI



- 4. Thank you Deb, Chris, and Simon for sharing your experience and protocols. Simon you recently co-authored a paper in JACC on how to implement hsTn and what are the barriers. It is a great reference to use. Can you provide a synopsis of that paper.

Where to Start?

- Stakeholder Involvement
- Developing Institutional Algorithm
- Process Changes
- Timeline
- Defining Success
- Anticipating Pain Points
- Education

Engagement

- Define key leadership team
- Begin weekly meetings months prior to rollout
- Involve key stakeholders from around the hospital/health system

Stakeholders

- Clinical Administration – are health system leaders supportive?
- Laboratory – how will the new assay impact laboratory processes?
- IT – does IT have the expertise and time to build an algorithm into the EHR?
- ED – is ED leadership on board? Are they committed to the rollout and change in processes in the ED?
- Outpatient Clinics – is outpatient leadership willing to help with clinic access for ED patients?
- Inpatient Services – Are the cardiology services and hospital medicine involved and aware of changes in patient flow?



ED preparation

- How will hs-cTn results be integrated into clinical work flow, pathways, and protocols?
 - Which cut-offs will be used?
 - What time points?
 - Combined with decision aids?
- Follow-up plans in place
- Integration with the electronic health record?
- Educate clinicians regarding the transition



Lab preparation

- Is the lab ready to provide necessary analytical education?
- Has an assay been selected?
- Is assay performance acceptable in the local Clinical Laboratory?
- Is the Lab able to process samples within a reasonable time-frame?
- How are results reported in the EHR?

- 4. a. Excellent overview. A common concern is a sudden onslaught of new positive results. Relative to contemporary T_n , how many new positives can one expect and are do they represent true positives?
 - Deb

Item 4b

- 4. b. Chris, how did you manage this change at your hospital?
 - Change management, hospital staff education

Convene Multidisciplinary Workgroup

- Required: **EM, Cards, Pathology/Lab, IM, RN, APP, IS/project management**



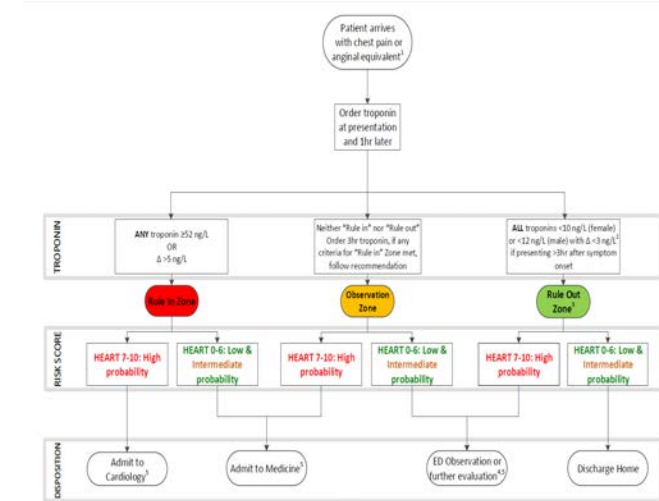
Required Work: The Punch List

- Set go-live date
- Which metrics will you use (collect baseline and post-launch)
- Create new pathway
 - Define 99th percentile for troponin
 - Delta strategy/sampling frame
 - Risk stratification tool
 - Use of ED observation unit
 - Role of consultants
 - Follow up guidance and resources
- IS compatibility; review order sets
- Provider education/messaging
- Go-live
- Post-go-live support
- Post-go-live data monitoring and QA



Phase 1	ACQUIRE DATA & SECURE LEADERSHIP	MONTHS				
		1-3	4	5-6	7-8	9+
	Define quality & operational metrics					
	Obtain baseline data					
	Make a clinical & business case for protocol to key leaders (e.g., Cardiology Leadership, Nurse Director, CMO)					
	Create project plan (include deliverables, roles, clinical charter plans)					
	Identify executive sponsors (who can assist with funding, challenge escalations problem solving)					
	Develop timeline					
	Obtain access to resources, (e.g., data analysts, admin. & IT support, educators)					
	Evaluate feasibility a follow-up clinic					
Phase 2		PLAN FOR PROTOCOL DEVELOPMENT				
	Perform literature search (start with ACEP-provided references)					
	Review protocols from peer institutions					
	Establish a interdisciplinary workgroup and assign roles					
	Identify & engage supportive key opinion leaders					
	Identify & engage staff likely to oppose pathway					
Phase 3		DEVELOP PROTOCOL & KEY COMPONENTS				
	Define inclusion & exclusion criteria					
	Determine expected interventions					
Phase 4		VERIFY & LAUNCH PROTOCOL				
	Present protocol to relevant stakeholder groups					
	Revise based on feedback					
	Pilot the protocol (if multiple sites available, select the most challenging)					
	Revise for gaps & barriers					
	Rollout protocol; publicize “go-live” event					
Phase 5		MAINTAIN PROTOCOL				
	Monitor data to ensure appropriate adherence					
	Report metrics to frontline staff & leadership					
	Integrate protocol maintenance activities into standing meetings					
	Revisit literature to ensure alignment with most recent scientific evidence					
	Perform annual revisions					

Summary: Putting it all Together



I. USE hs-TROPONIN

- IMPROVES RULE-OUT
- IMPROVES RULE-IN

II. IN THE RIGHT CONTEXT

- SUSPECTED AMI
- NOT A SCREENING TOOL
- CONSIDER TIMING OF SYMPTOM ONSET

III. WITH AN ADP

- BASELINE TROPONIN LEVEL AND DELTA
- CONSIDERS RISK SCORE
- USES OBSERVATION UNIT

- 4.b. With such a rapid protocol, does the new timing pose any issues?
 - Deb - Throughput issues - 0/1 hr protocol with an 3 hr Xray TAT - Deb - 2 min

Item 4c

- Besides timing, were there any other system level issues?
 - Chris - Administrative issues - I.T. etc.

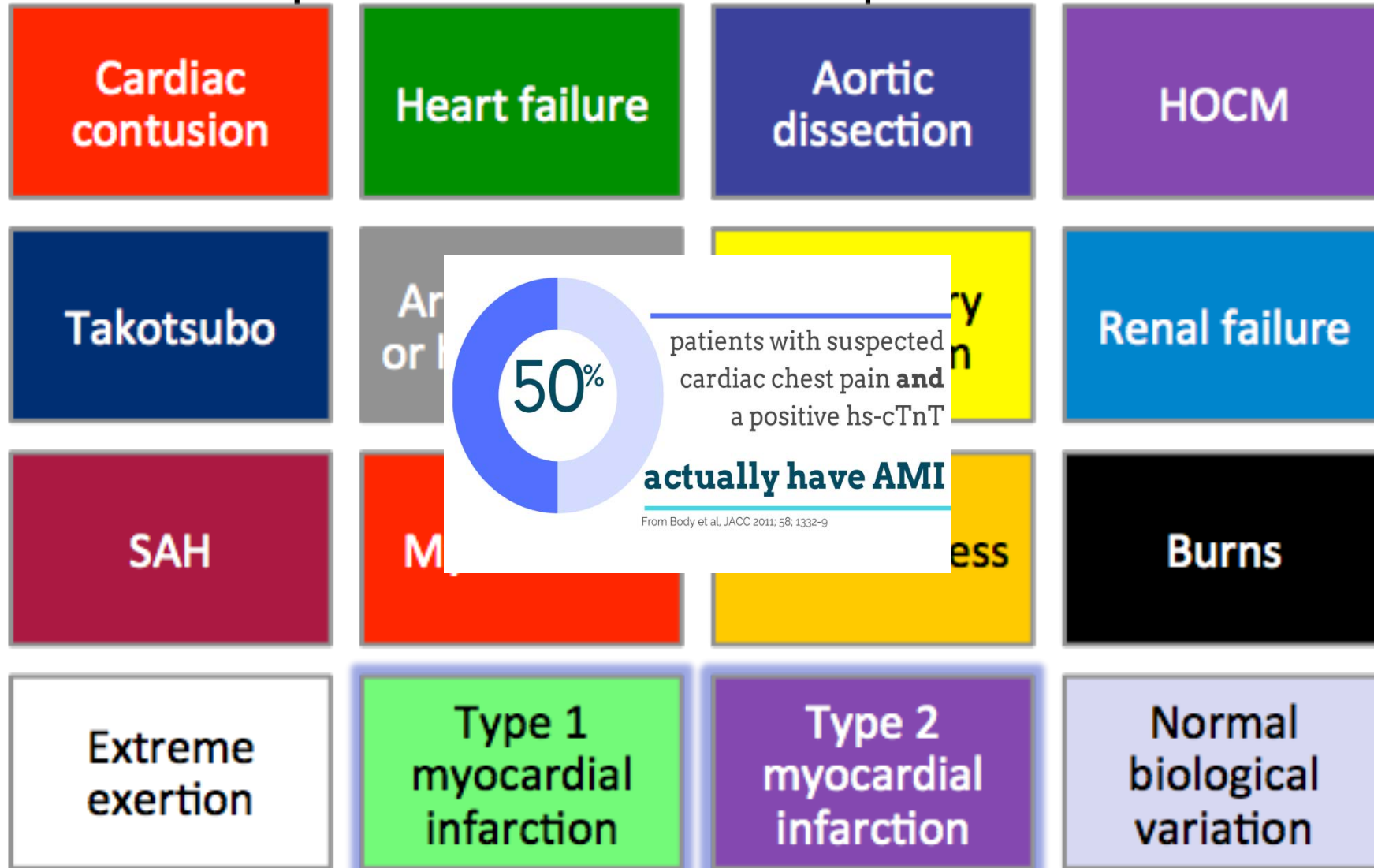
Beware of IT Delays



Item 4d

- 4.d. Okay so, how do you handle those slightly elevated (over 99th percentile) hsTn
 - Chris -

The Multiple Causes of Troponin Elevation

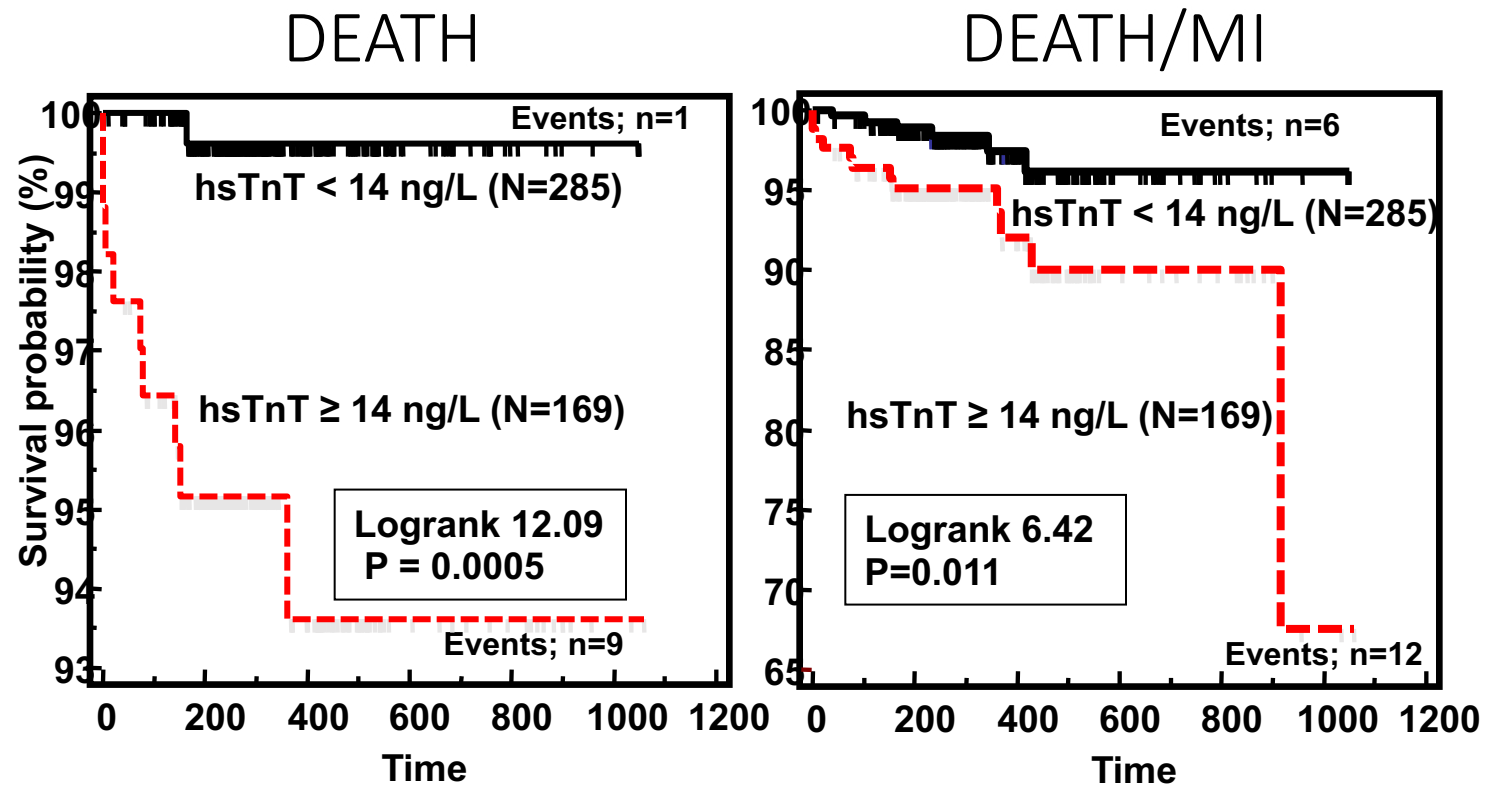


Delta Troponin Useful



- Definition: change in value between serial measurements
- Use combination of specific troponin values at 2 time points and an absolute difference between time points to confirm NSTEMI
- Absolute change better than relative percentage change

Outcomes in Patients with Undetectable Contemporary Troponin Values ($<0.01\mu\text{g/L}$)



Special Populations: Renal Disease

High-Sensitivity Cardiac Troponin and the Risk Stratification of Patients With Renal Impairment Presenting With Suspected Acute Coronary Syndrome

Eve Miller-Hodges,
MBChB, PhD*
Atul Anand, MBChB*
Anoop S.V. Shah, MBChB,
PhD
Andrew R. Chapman,
MBChB
Peter Gallacher, MBChB
Kuan Ken Lee, MBChB
Tariq Farrah, MBChB
Nynke Halbesma, MBChB
James P. Blackmur, MBChB
David E. Newby, MBChB,
PhD
Nicholas L. Mills, MBChB,
PhD
Neeraj Dhaun, MBChB,
PhD



4,726 patients; 904 (19%) with renal dysfunction (GFR <60 mL/min)

17% with renal dysfunction had a hsTnI <5 ng/L vs 56% of the patients without renal dysfunction

Specificity at the 99th percentile cutoff was 70.9% versus 92.1%

Hazard ratio 2.19 at 1 year for death or MI for values >99th percentile (24% versus 10%)

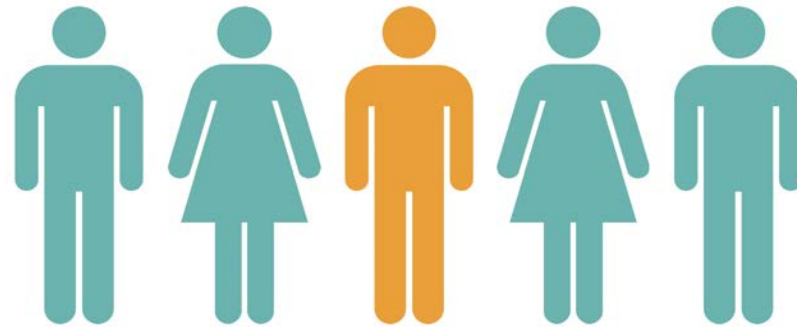
Item 4d

- 4.d. Okay so, how do you handle those slightly elevated (over 99th percentile) hsTn
 - Deb – what do you do at UT?

Item 5a

- 5. a. Very interesting! You know, the question that this begs, is do we really need an observation unit anymore with the advent of hsTn? Is this test so good that we can either discharge from the ED or cath everybody? Chris, what impact has this had on your practice and on your observation unit or observation admissions?

ED Observation Units



- Previous convention dictated that patients with “positive” troponin were always admitted
- Adoption of high-sensitivity troponin assay shifts patient cohorts to less resource-intensive settings; allows for higher-risk patients to receive observation care and reduces avoidable inpatient admissions

Downstream Impacts

- Consults
- Admissions
- Clinic Referrals



Cardiology Consult Attending

The Brigham Experience: 6 Months Later

- **Total tests and encounters**
- **Disposition changes**
- **ED length of stay**
- **Cardiology consult volume**
- **Stress testing**
- **MACE volume**

Item 5a

- 5. a. Great information Chris, thanks!
 - Deb, what impact has this had on your practice?

Challenges

- Time delay in starting
- Overall decrease in length of stay

Open forum



For More Information

- E-QUAL Website
 - ▶ www.acep.org/equal
 - ▶ equal@acep.org
- Contacts:
 - ▶ Nalani Tarrant: (Director)
 - ▶ ntarrant@acep.org
 - ▶ Dhruv Sharma: (Project Manager)
 - ▶ dsharma@acep.org

