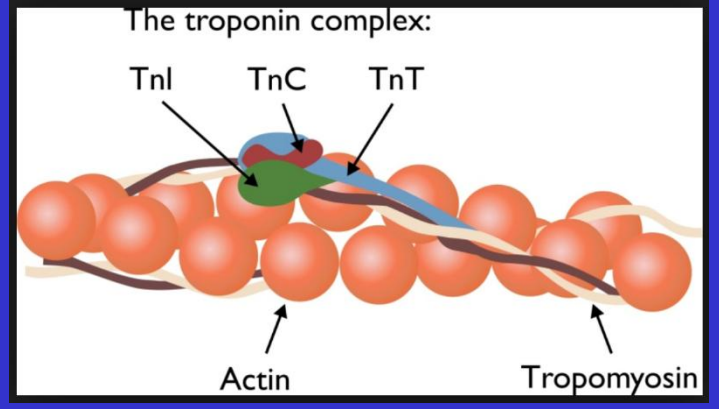


The Clinical Potential of Outpatient Point of Care hs-cTn

James McCord MD

Henry Ford Heart & Vascular Institute

Detroit, Michigan

2025

Disclosures

- Research Support: Roche, Abbott, Beckman, Polymedco.
- Consulting: Beckman, Roche, Abbott, Polymedco
- Most Significant Disclosure: Huge Cleveland Sports Fan

Outline: POC hs-cTn

I. Story: Dearborn, Michigan 1988
II. Studies: Outpatient MI
III. Hs-cTn in 2025: studies/guidelines
IV. Point of Care Troponin
V. Implementation Trial POC hs-cTn at Henry Ford Walk-In clinics


Settled 1786
Welcome to
DEARBORN

- 1988: I am an internal medicine intern at Henry Ford Hospital living in Dearborn
- A women in the neighborhood knocks on my door and tells me her husband has been having epigastric burning
- …

J Thromb Thrombolysis (2009) 27:18–23
DOI 10.1007/s11239-007-0153-2

The recognition of acute coronary ischemia in the outpatient setting

Zehra Jaffery · Michael P. Hudson · Sanjaya Khanal · Karthik Ananthasubramaniam · Henry Kim · Adam Greenbaum · Aaron Kugelmass · Gordon Jacobsen · James McCord

J Thromb Thrombolysis (2009) 27:18-23

Outpatient ACS

- Single Center HAP insurance pts 2004
- 331 patients had MI by ICD codes
- 190 (57%) were seen within 30 days prior by outpatient doctor
- 68 (36%) had outpatient notes available

J Thromb Thrombolysis (2009) 27:18-23

Outpatient ACS

- 68 patients:
  - 76% saw a primary care physician
  - 11% saw a cardiologist
  - 13% saw another IM specialist

J Thromb Thrombolysis (2009) 27:18-23

Outpatient ACS

- 2 Cardiologists reviewed the outpatient encounters and classified them as: ACS, stable angina, or neither
- 7 (10%) pts ACS
- 5 (7%) pts stable angina
- 56 (83%) neither
- Of 7 with ACS: 5 correctly identified, 2 not identified

J Thromb Thrombolysis (2009) 27:18-23

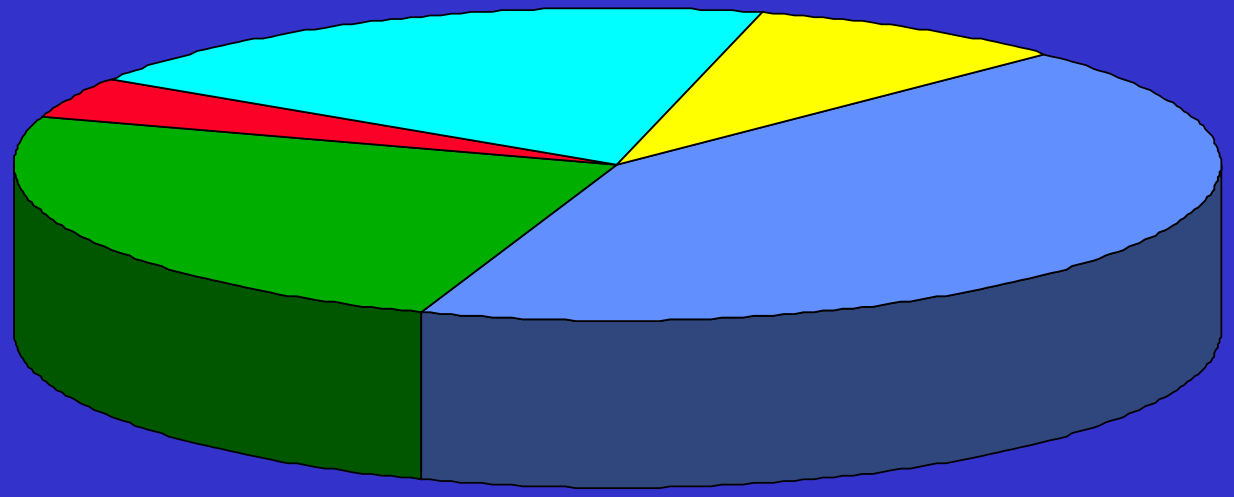
Chest Pain in Outpatient Clinic

- 3 studies: 2-4% of chest pain visits for unstable angina or AMI

Am Fam Physician 2020;102(12):721-727

Malpractice Claims by Specialty

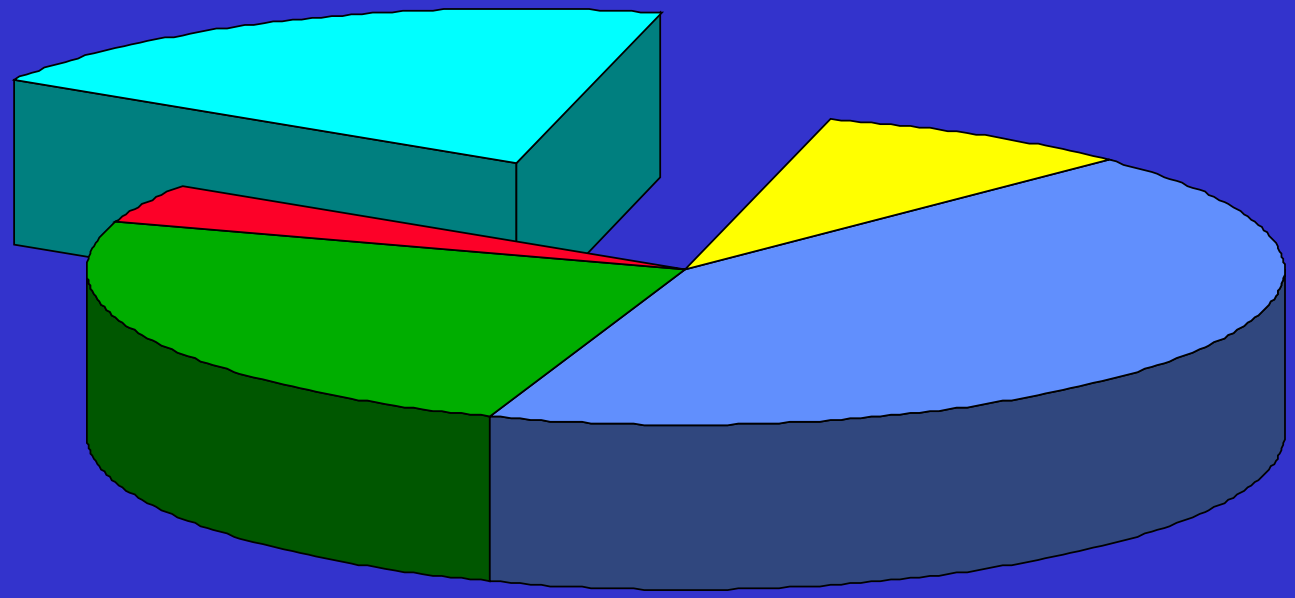
25% of malpractice dollars were for missed Myocardial Infarction



PIAA (Physician Insurers Association of America)

Malpractice Claims by Specialty
Missed MI - Diagnostic Misadventure

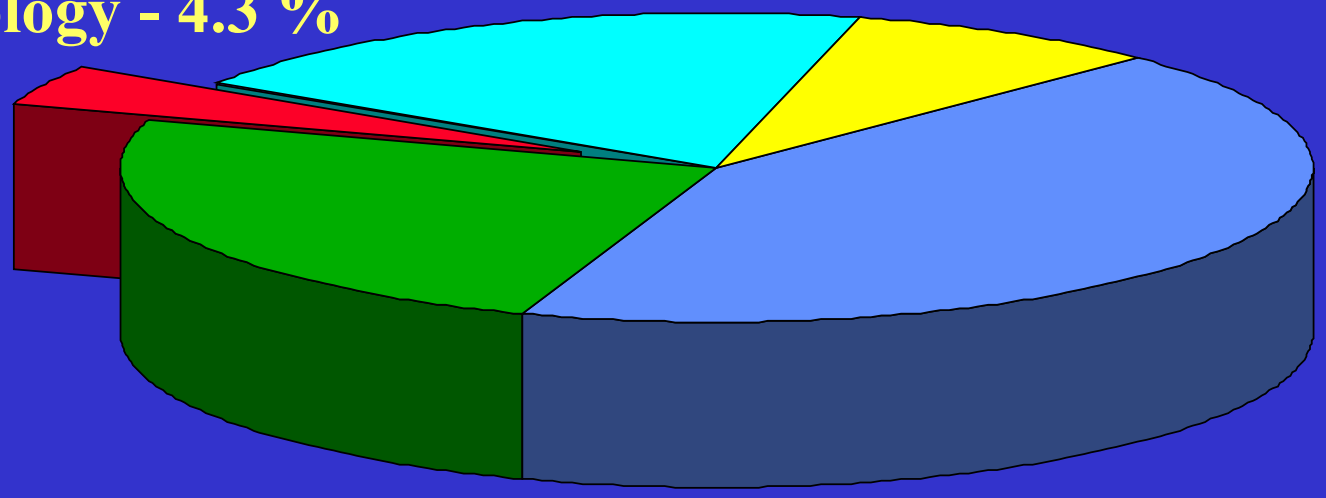
Emergency Medicine - 19.7 %



PIAA

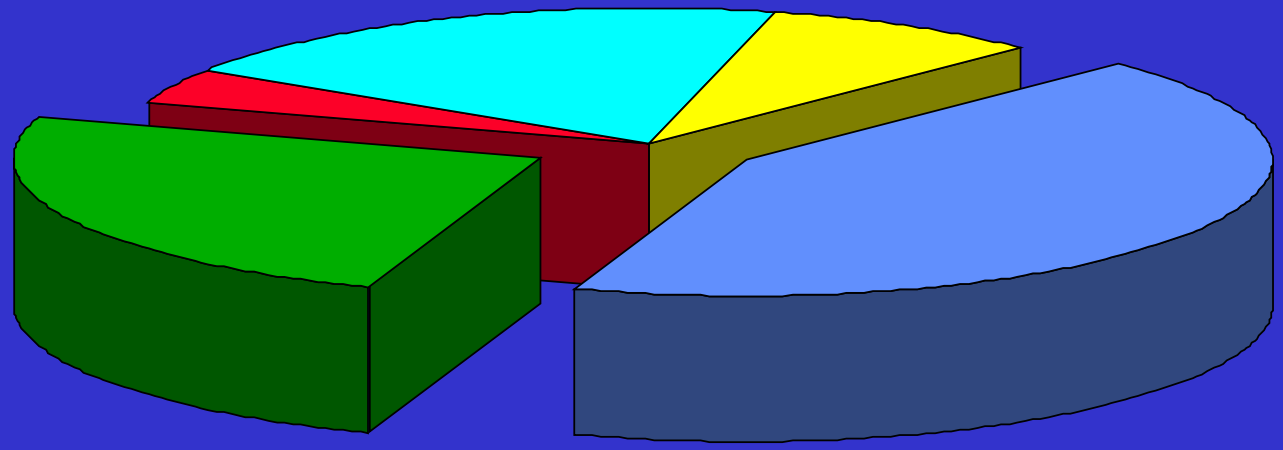
Malpractice Claims by Specialty
Missed MI - Diagnostic Misadventure

Cardiology - 4.3 %



PIAA

Malpractice Claims by Specialty
Missed MI - Diagnostic Misadventure



IM - 24.7 %

FP - 42.8 %

PIAA

Hs-cTn in 2025

- Studies
- Guidelines
- Diagnostic and **PROGNOSTIC** Power

Definition of hs-troponin

- Should be applied to assays that can can measure cardiac troponin values in at least 50 % of a reference population
- The coefficient of variation (CV) at the 99th percentile (MI threshold) should be ≤ 10%

J Am Coll Cardiol Feb 2013

ORIGINAL CONTRIBUTION

Implementation of a Sensitive Troponin I Assay and Risk of Recurrent Myocardial Infarction and Death in Patients With Suspected Acute Coronary Syndrome

JAMA 2011:305 (12):1210-1216

Implementation: Sensitive cTnI

- 2,092 consecutive pts evaluated for possible ACS
- Sensitive cTnI: Abbott Architect
- Validation Phase: 1,038 pts
- Implementation Phase: 1,054

JAMA 2011;305(12):1210-6

Implementation: Sensitive cTnI

- Pts stratified 3 groups by cTnI (ng/ml)
  - < 0.05
  - 0.05 – 0.2
  - > 0.2

  - Validation: only > 0.2 reported
  - Implementation: 0.05 – 0.2 reported

Validation vs Implementation: (0.05-0.2 ng/ml)

	Validation n=90	Implementation n=80	P - Value
Cardiology Referral	44%	74%	<0.001
Coronary Angiography	20%	46%	<0.001
Clopidogrel & ASA	31%	61%	<0.001
Statin	58%	80%	<0.005

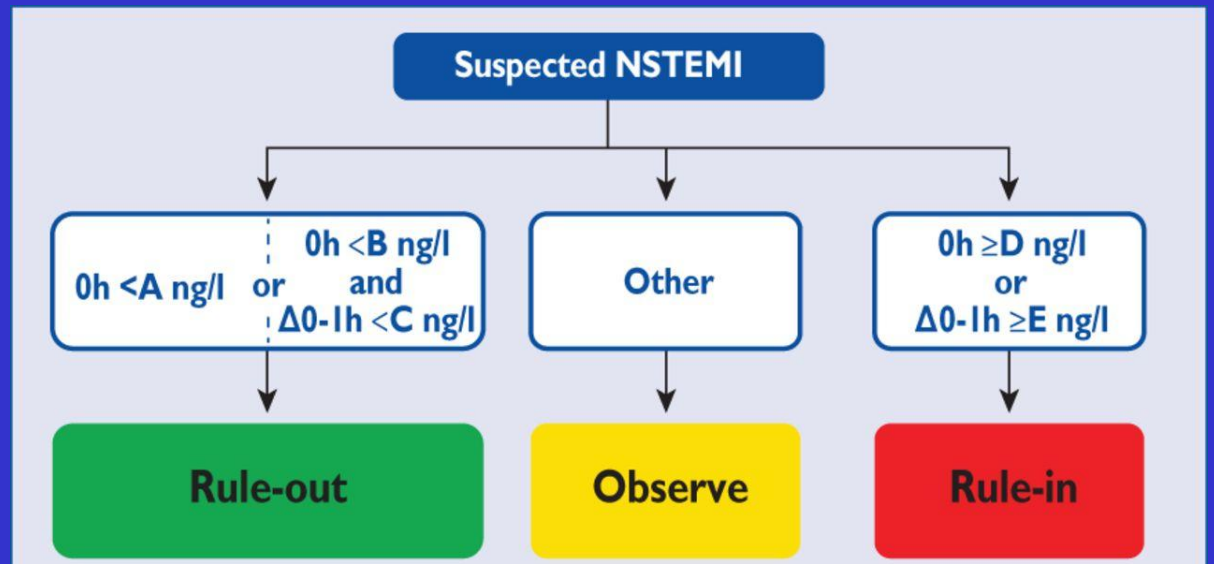
Adverse Events at 30 days

	Validation n=90	Implementation n=80	P-Value
Death	14(16%)	4(5%)	<0.05
MI	18(20%)	5(6%)	<0.05
Death or MI	24(27%)	9(11%)	<0.05

Rapid Rule-Out AMI Strategies

1. 1-hr delta protocol

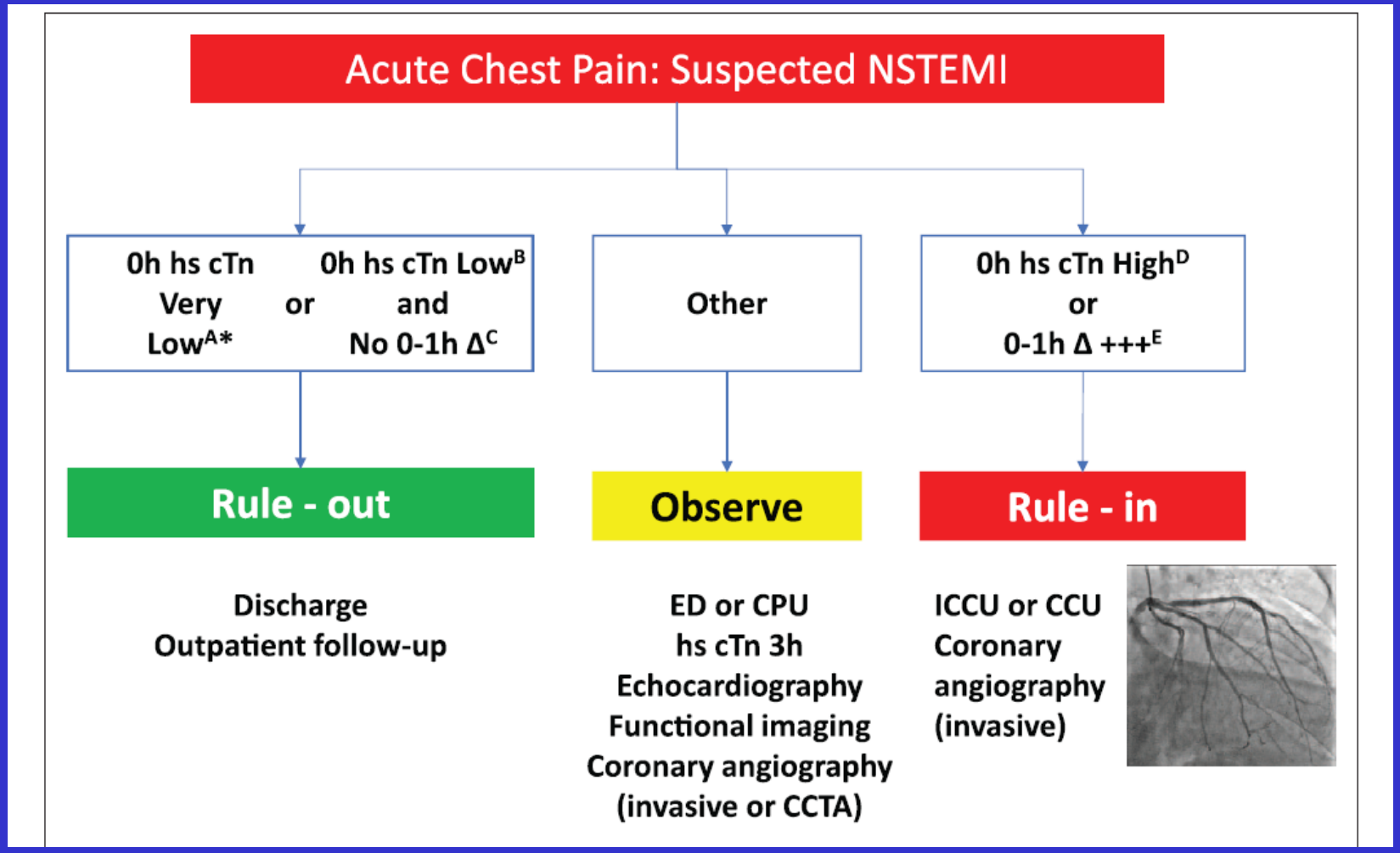
0 h/1 h rule-in and rule-out algorithms using high-sensitivity cardiac troponins (hs-cTn) assays in patients presenting with suspected non-ST-elevation myocardial infarction (NSTEMI) to the emergency department. 0 h and 1 h refer to the time from first blood test.



	A	B	C	D	E
hs-cTnT (Elecsys)	5	12	3	52	5
hs-cTnI (Architect)	2	5	2	52	6
hs-cTnI (Dimension Vista)	0.5	5	2	107	19

Authors/Task Force Members et al. Eur Heart J 2015;eurheartj.ehv320

European Heart Journal



European Society of Cardiology 2020

HFHS RACE-IT Study

- Rapid Acute Coronary Syndrome Exclusion using the Beckman Coulter Access high-sensitivity I Troponin.
- 32,609 Patients
- Primary Endpoint: Safe Discharge- no 30-day death/AMI
- Secondary: Cost, Length of Stay

RACE-IT

ARTICLE IN PRESS

CARDIOLOGY/ORIGINAL RESEARCH

Rapid Acute Coronary Syndrome Evaluation Over One Hour With High-Sensitivity Cardiac Troponin I: A United States-Based Stepped-Wedge, Randomized Trial

Joseph Miller, MD; Bernard Cook, PhD; Chaun Gandolfo, DO; Nicholas L. Mills, MD; Simon Mahler, MD; Phillip Levy, MD; Sachin Parikh, MD; Seth Krupp, MD; Khaled Nour, MD; Howard Klausner, MD; Ryan Gindi, MD; Aaron Lewandowski, MD; Michael Hudson, MD; Giuseppe Perrotta, MD; Bryan Zweig, MD; David Lanfear, MD; Henry Kim, MD; Shooshan Dangoulian, PhD; Amy Tang, PhD; Erika Todter, MS; Altaf Khan, MS; Catriona Keerie, MSc; Shane Bole, BS; Hashem Nasseredine, MD; Ahmed Oudeif, MD; Elian Abou Asala, MD; Mustafa Mohammed, DO; Ahmed Kazem, DO; Kelly Malette, MD; Gulmohar Singh-Kucukarslan, MA; Nicole Xu, BS; Sophie Wittenberg, BS; Thayer Morton, DO; Satheesh Gunaga, DO; Ziad Affas, MD; Kutiba Tabbaa, MD; Parth Desai, BS; Ayman Alsaadi, MD; Shazil Mahmood, MD; Andrew Schock, MD; Nicholas Konowitz, MD; Joshua Fuchs, DO; Kate Joyce, MD; Lance Shamoun, MD; Jacob Babel, DO; Andrew Broome, MD; Geoffrey Digiacinto, DO; Elizabeth Shaheen, MD; Gale Darnell, MD; Gregory Muller, MD; Gerard Heath, MD; Gust Bills, DO; Jason Vieder, DO; Steven Rockoff, DO; Brian Kim, MD; Anthony Colucci, DO; Elizabeth Plemmons, MD; James McCord, MD*; for the RACE-IT Research Group

*Corresponding Author. E-mail: jmccord1@hfhs.org.

Ann Emerg Med 2024

HFHS Guideline for HS-cTnI Testing in Emergency Department Patients with Suspected Myocardial Infarction

Henry Ford Health System
Department of Emergency Medicine

INITIAL Hs-cTn I <4ng/L

↓

NSTEMI CAN BE RULED OUT

↓

CONSIDER ALTERNATIVE DIAGNOSES

↓

Provide return precautions AND follow up with PCP

FURTHER TROPONIN TESTING SHOULD BE CONSIDERED IN PATIENTS WITH:

EKG FINDING CONCERNING FOR ISCHEMIA
OR
SHORT DURATION OF SYMPTOMS (<3 HOURS PRIOR TO TROPONIN TESTING).

INITIAL Hs-cTn I =4ng/L

↓

PERFORM 1 HOUR TROPONIN

↓

1 HOUR INCREASE ('DELTA') <4ng/L

↓

NSTEMI HAS BEEN RULED OUT

↓

CONSIDER ALTERNATIVE DIAGNOSES

↓

Provide return precautions AND follow up with PCP

IF 1 HOUR INCREASE ('DELTA') ≥4ng/L PROCEED TO ORANGE (NEXT) COLUMN

IF ANY REPEAT VALUE ≥ 18 ng/L PROCEEED TO RED (LAST) COLUMN

INITIAL Hs-cTn I ≥5 but <18ng/L

↓

REPEAT troponins at 1 HOUR AND 3 HOUR

↓

ALL VALUES REMAIN < 18 ng/L

↓

NSTEMI HAS BEEN RULED OUT

↓

CONSIDER ALTERNATIVE DIAGNOSES

HEAR ≤ 3
Provide return precautions and F/U with PCP

HEAR ≥ 4
Consider observation placement for further evaluations

'HEAR SCORE'
IS IDENTICAL TO 'HEART' SCORE BUT CAN ONLY BE APPLIED TO PATIENTS WITH ALL TROPONIN <99TH PERCENTILE (18 ng/L)

IF ANY REPEAT VALUE ≥ 18 ng/L PROCEEED TO RED (LAST) COLUMN

Hs-cTn I ≥18 ng/L (99th percentile) AT ANY TIME

AMI (NSTEMI type 1 or type 2) or acute cardiac injury diagnosis requires at least 1 hs-cTnI value above 99th percentile (18 ng/L) with a typical rise and/or fall in the hs-cTnI measurements and should be supported by at least 1 of the following:

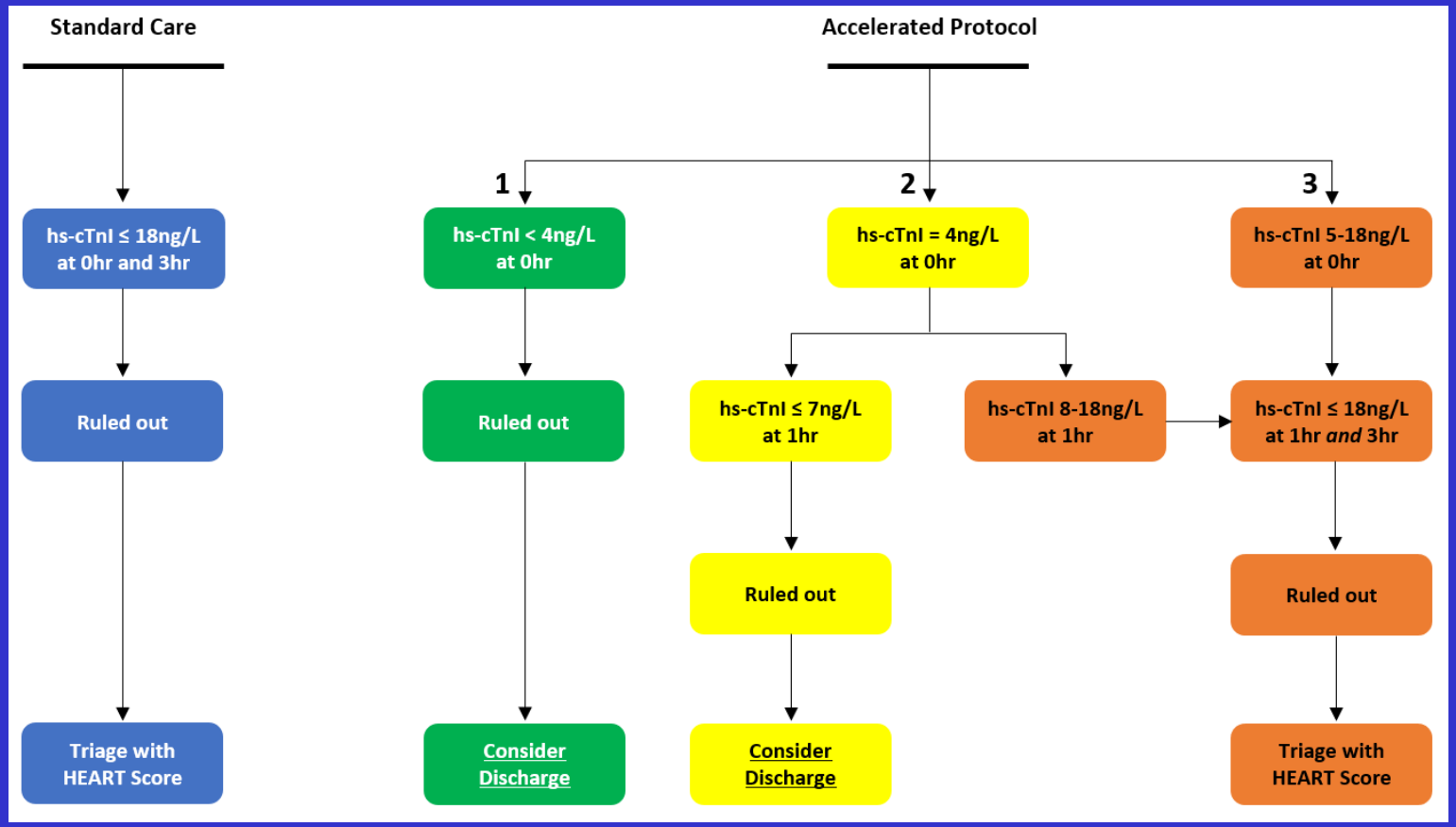
- clinical ischemic symptoms
- ECG findings
- cardiac imaging results.

Although NSTEMI can be diagnosed at any level above 99th percentile (18ng/L), levels ≥100 ng/L have been designated as the 'CRITICAL VALUE' for HFHS which will trigger lab notification to the treating physician.

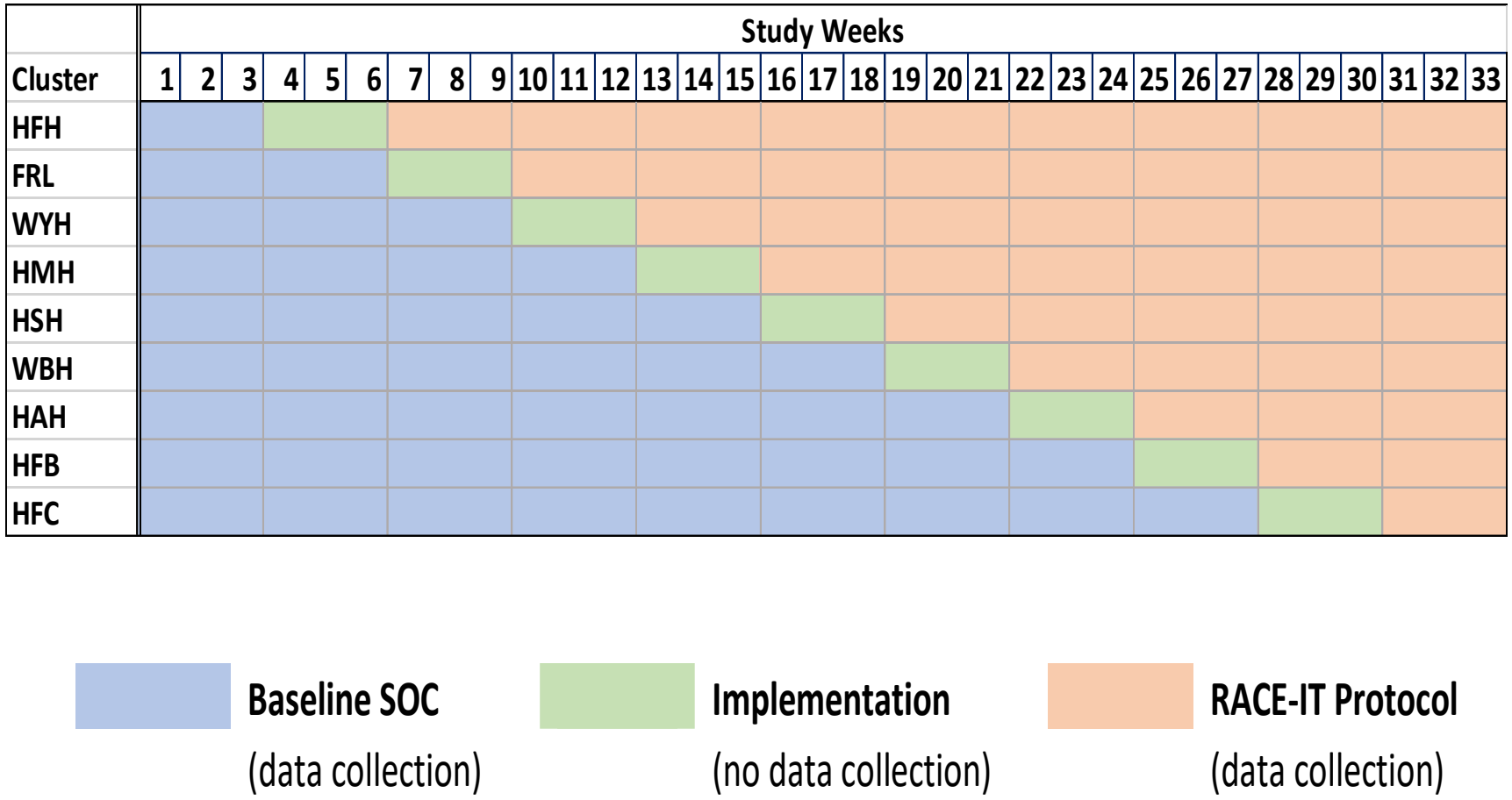
Increase/decrease in troponin from initial value by ≥15 ng/L (aka 'delta ≥ 15ng/L') at 1 hour increases likelihood of myocardial infarction/adverse cardiovascular events and should be considered for telemetry monitoring and cardiology evaluation.

Minimal increase/decrease from intial value by <15 ng/L (aka 'delta <15') at 1 hour is more likely the result of chronic cardiac injury.

0/1-hr vs 0/3-hr Protocol



RACE-IT: Stepped-Wedge Randomized



RACE-IT Study

Death or Myocardial infarction within 30 Days

	All	Standard Care	Accelerated Protocol	Adjusted Odds Ratio (95% CI)	P value
Participants, n	22,345	9,488	12,857		
Myocardial infarction/all-cause death	90 (0.40%)	38 (0.40%)	52 (0.40%)	0.84 (0.43-1.68)	0.630
All-cause death	64 (0.29%)	33 (0.35%)	31 (0.24%)	0.65 (0.29-1.47)	0.298
Type 1 MI	8 (0.04%)	4 (0.04%)	4 (0.03%)	0.67 (0.15-3.01)	0.590
Non-cardiac death	56 (0.25%)	29 (0.31%)	27 (0.21%)	0.53 (0.22-1.27)	0.152
Cardiac death	8 (0.04%)	4 (0.04%)	4(0.03%)	2.66 (0.29-24.87)	0.390

Safe ED Discharge

Ruled-Out	0/1-hr	0/3-hr	P-Value
Safe Discharge	74.1%	59.5%	<0.05

Safe Discharge= No 30-Day Death/MI

30-Day Cardiac Events:
0/1-hr Rule-Out Pts

- 1 Type MI
- 0 Cardiac Deaths
- AE Rate 1/10,445 (0.01%)

Determinants of troponin release in patients with stable coronary artery disease: insights from CT angiography characteristics of atherosclerotic plaque

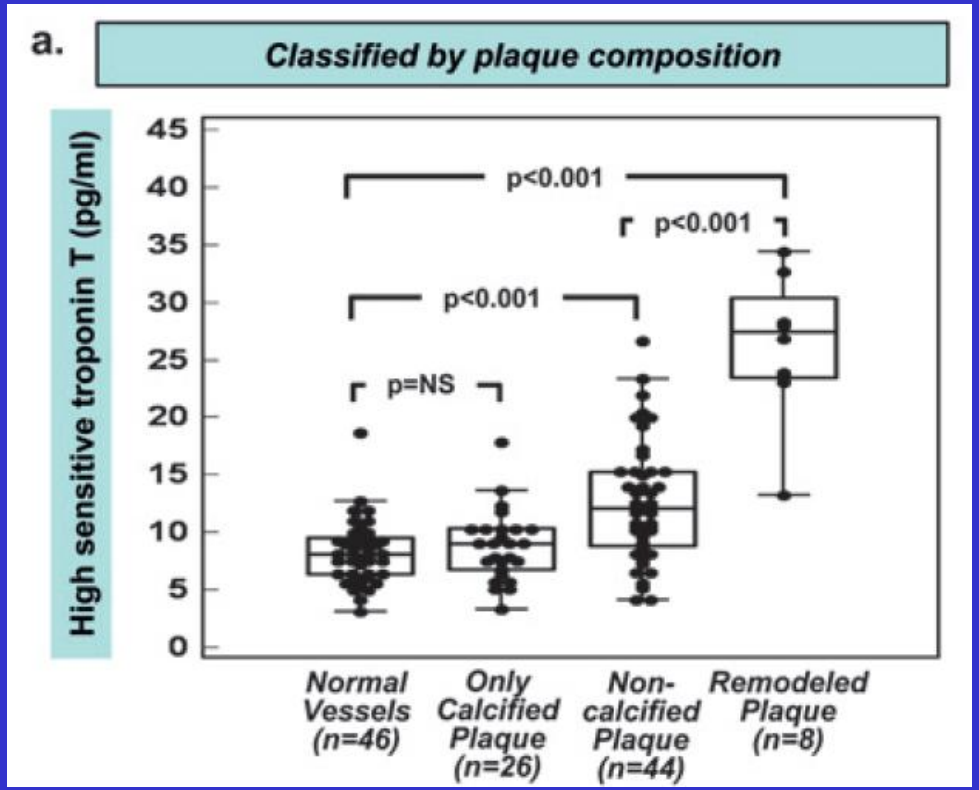
Grigorios Korosoglou,[1] Stephanie Lehrke,[1] Dirk Mueller,[2] Waldemar Hosch,[3] Hans-Ulrich Kauczor,[3] Per M Humpert,[4] Evangelos Giannitsis,[1] Hugo A Katus[1]

Heart 2011;**97**:823–831. doi:10.1136/hrt.2010.193201

Hs-cTnT and CTA

- 180 patients
- 256-slice CTA
- Hs-cTnT measurements
- Coronary calcification, stenosis, non-calcified plaque volume, plaque composition (soft or calcified), vascular remodeling

CTA & hs-cTnT


a.
Classified by plaque composition
High sensitive troponin T (pg/ml)
45
40
35
30
25
20
15
10
5
0
p<0.001
p<0.001
p<0.001
p=NS
Normal Vessels (n=46)
Only Calcified Plaque (n=26)
Non-calcified Plaque (n=44)
Remodeled Plaque (n=8)

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. ■, NO. ■, 2021

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CLINICAL PRACTICE GUIDELINE: FULL TEXT

2021 AHA/ACC/ASE/CHEST/SAEM/ SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain

A Report of the American College of Cardiology/American Heart Association
Joint Committee on Clinical Practice Guidelines

J Am Coll Cardiol November 2021

Recommendations for Biomarkers

COR	LOE	RECOMMENDATIONS
1	B-NR	1. In patients presenting with acute chest pain, serial cTn I or T levels are useful to identify abnormal values and a rising or falling pattern indicative of acute myocardial injury (1-21).
1	B-NR	2. In patients presenting with acute chest pain, high-sensitivity cTn is the preferred biomarker because it enables more rapid detection or exclusion of myocardial injury and increases diagnostic accuracy (17,21-25).
1	C-EO	3. Clinicians should be familiar with the analytical performance and the 99th percentile upper reference limit that defines myocardial injury for the cTn assay used at their institution (23,26).
3: No benefit	B-NR	4. With availability of cTn, creatine kinase myocardial (CK-MB) isoenzyme and myoglobin are not useful for diagnosis of acute myocardial injury (27-32).

JACC 2021

Time Interval to Exclude MI with hs-cTn

COR	LOE	RECOMMENDATIONS
1	B-NR	1. In patients presenting with acute chest pain and suspected ACS, clinical decision pathways (CDPs) should categorize patients into low-, intermediate-, and high-risk strata to facilitate disposition and subsequent diagnostic evaluation (1-14).
1	B-NR	2. In the evaluation of patients presenting with acute chest pain and suspected ACS for whom serial troponins are indicated to exclude myocardial injury, recommended time intervals after the initial troponin sample collection (time zero) for repeat measurements are: 1 to 3 hours for high-sensitivity troponin and 3 to 6 hours for conventional troponin assays (15-17).
2a	B-NR	5. For patients with acute chest pain, a normal ECG, and symptoms suggestive of ACS that began at least 3 hours before ED arrival, a single hs-cTn concentration that is below the limit of detection on initial measurement (time zero) is reasonable to exclude myocardial injury (13,25-29).

JACC 2021

Low Risk Patients Go Home

COR	LOE	RECOMMENDATIONS
1	B-NR	1. Patients with acute chest pain and a 30-day risk of death or MACE <1% should be designated as low risk (1-11).
2a	B-R	2. In patients with acute chest pain and suspected ACS who are deemed low-risk (<1% 30-day risk of death or MACE), it is reasonable to discharge home without admission or urgent cardiac testing (12-16).

JACC 2021

Definition of Low Risk

TABLE 8 Definition Used for Low-Risk Patients With Chest Pain

	Low Risk (<1% 30-d Risk for Death or MACE)
hs-cTn Based	
T-0	T-0 hs-cTn below the assay limit of detection or "very low" threshold if symptoms present for at least 3 h
T-0 and 1- or 2-h Delta	T-0 hs-cTn and 1- or 2-h delta are both below the assay "low" thresholds (>99% NPV for 30-d MACE)
Clinical Decision Pathway Based	
HEART Pathway (20)	HEART score ≤3, initial and serial cTn/hs-cTn < assay 99th percentile
EDACS (14)	EDACS score ≤16; initial and serial cTn/hs-cTn < assay 99th percentile
ADAPT (21)	TIMI score 0, initial and serial cTn/hs-cTn < assay 99th percentile
mADAPT	TIMI score 0/1, initial and serial cTn/hs-cTn < assay 99th percentile
NOTR (15)	0 factors

ADAPT indicates 2-hour Accelerated Diagnostic Protocol to Access Patients with Chest Pain Symptoms Using Contemporary Troponins as the Only Biomarkers; cTn, cardiac troponin; EDACS, Emergency Department Acute Coronary Syndrome; HEART Pathway, History, ECG, Age, Risk Factors, Troponin; hs-cTn, high-sensitivity cardiac troponin; MACE, major adverse cardiovascular events; mADAPT, modified 2-hour Accelerated Diagnostic Protocol to Access Patients with Chest Pain Symptoms Using Contemporary Troponins as the Only Biomarkers; NOTR, No Objective Testing Rule; NPV, negative predictive value; and TIMI, Thrombolysis in Myocardial Infarction.

JACC 2021

Implementation hs-cTn in USA

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 81, NO. 3, 2023

PUBLISHED BY ELSEVIER

ORIGINAL INVESTIGATIONS

Implementation of High-Sensitivity Cardiac Troponin Assays in the United States

Cian McCarthy, MB, BCh, BAO,[a] Shuang Li, MS,[b] Tracy Y. Wang, MD, MHS, MS,[b,c] Inbar Raber, MD,[d] Yader Sandoval, MD,[e] Nathaniel R. Smilowitz, MD, MS,[f] Jason H. Wasfy, MD, MPhil,[a] Ambarish Pandey, MD,[g] James A. de Lemos, MD,[g] Michael C. Kontos, MD,[h] Fred S. Apple, PhD,[i,j] Lori B. Daniels, MD, MAS,[k] L. Kristin Newby, MD, MHS,[b,c] Allan S. Jaffe, MD,[l,m] James L. Januzzi, Jr, MD[a,n]

J Am Coll Cardiol 2023;81:207–219

ACC Registry

- 550 participating hospitals: report hs-cTn use
- 1st Quarter 2019: 3 %
- 3rd Quarter 2021: 32 %
- No report if using accelerated protocols and reporting low values < 99th % (MI threshold).

J Am Coll Cardiol 2023;81:207–219

Point of Care Troponin

- Some ancient history
- Henry Ford Implementation Trial in Walk-In Clinics

POC: Trop, CK-MB, Myoglobin

Ninety-Minute Exclusion of Acute Myocardial Infarction By Use of Quantitative Point-of-Care Testing of Myoglobin and Troponin I

James McCord, MD; Richard M. Nowak, MD, MBA; Peter A. McCullough, MD, MPH; Craig Foreback, PhD; Steven Borzak, MD; Glenn Tokarski, MD; Michael C. Tomlanovich, MD; Gordon Jacobsen, MS; W. Douglas Weaver, MD

Sampling: 0, 90 mins, 3 hrs, 9 hrs

Circulation 2001;104:1483-1488

Point of Care: Trop, CK-MB, Myoglobin

Results: Sensitivity & NPV

- The combination of Myo and cTnI at 0 and 90 mins had the highest early negative predictive value and sensitivity
- Myo/cTnI (0 and 90 mins)
  Sens- 96.7%
  NPV- 99.6%
- Median time from sampling to reporting
  - Central Lab: 71 mins
  - POC: 24 mins
  - Implementation Trial Blocked by Central Lab

Implementation Trial Walk In Clinics

- HFH has 15 Walk-In clinics
- Trial will involve 2 Walk-In Clinics
- Some Background Data
- Will be checking hs-cTn and D-dimer
- So will exclude MI and Pulmonary Embolism

PATHFAST POC Device

Hs-cTnI-PATHFAST

Journal of the American Heart Association

RESEARCH LETTER

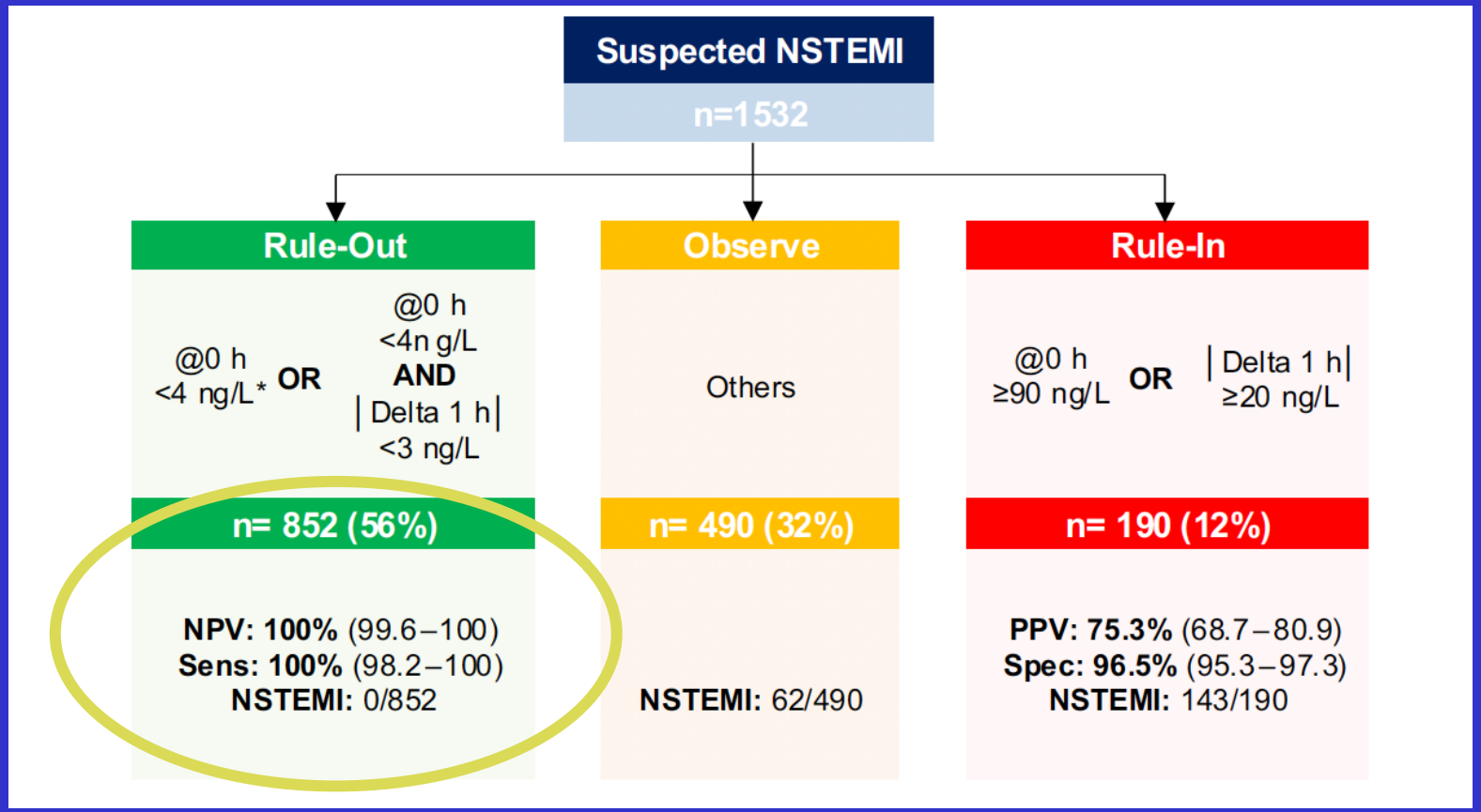
Impact of Food and Drug Administration Regulations on the Performance of Guideline-Recommended Pathways With an Approved Point-of-Care High-Sensitivity Cardiac Troponin I Assay

Luca Koechlin, MD*; Jasper Boeddinghaus, MD*; Pedro Lopez-Ayala, MD; Chiara L. Bianchi, MD; Thomas Nestelberger, MD; Karin Wildi, MD, PhD; Òscar Miró, MD; Michael Christ, MD; Katharina Rentsch, PhD; Felix Mahfoud, MD; Christian Mueller, MD; for the APACE investigators;†

Luca Koechlin and all, J Am Heart Assoc. 2025;14:e039164. DOI: 10.1161/JAHA.124.039164

JOURNAL OF THE AMERICAN HEART ASSOCIATION: Impact of Food and Drug Administration Regulations on the Performance of Guideline-Recommended Pathways With an Approved Point-of-Care High-Sensitivity Cardiac Troponin I Assay

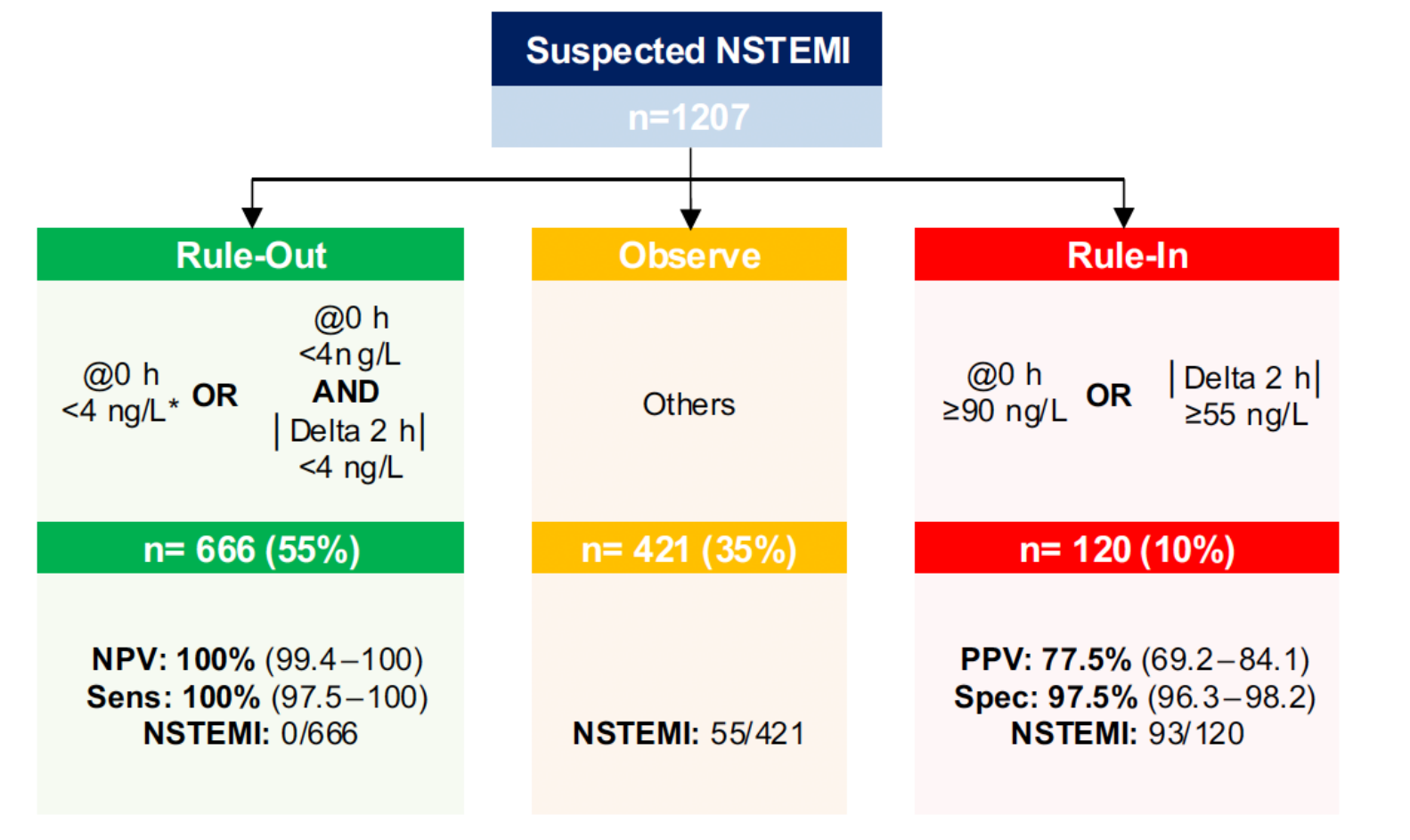
Objective 1: Reproducibility of a safe 0/1-hour algorithm from seminal 2019 Sorenson et al study



*Symptom onset >3h

JOURNAL OF THE AMERICAN HEART ASSOCIATION: Impact of Food and Drug Administration Regulations on the Performance of Guideline-Recommended Pathways With an Approved Point-of-Care High-Sensitivity Cardiac Troponin I Assay

Objective 2: Derivation and validation of a 0/2 h algorithm



*Symptom onset >3h

Walk In Clinic over 3 months: hs-cTnI

- 49 pts sent to the ER
- 27 (55%) hs-cTnI < 4 ng/L
- 34 (67%) discharged from ER
- 8 (16%) Observation Unit
- 5 (10%) admitted
- 2 (4%) has MI went to heart cath

Walk In over 3 months: D-Dimer

- 31 sent to the ER
- 20 (65%) has negative D-Dimer
- 20 (65%) discharged from ER
- 12 (39%) had CT scan
- 2 (6%) had PE by CT

Study Endpoints

- Resource Utilization Endpoint
- Outcomes Endpoint: “Missed” MI or PE in the Walk-In clinic

Summary

1. A significant number of patients with ACS symptoms are seen out-patient
2. Hs-cTn may allow many to be risk stratified quickly if available
3. The availability of POC hs-cTn in this setting would likely improve resource utilization and may improve outcomes

Thanks

JMCCORD1@HFHS.ORG