Chest Pain Wave I

Ruling Patients Out:
Do We Need Chest Pain Protocols and Coordinated Care Pathways?

Presenters
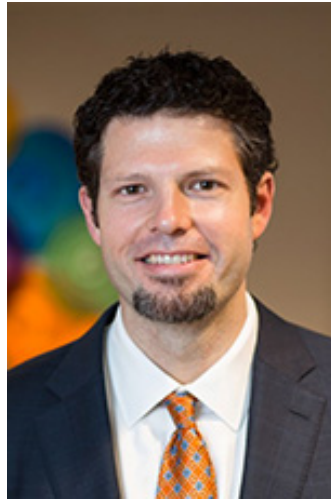
Erik P. Hess MD MSc

W. Franklin Peacock, MD

Simon A. Mahler, MD, MS

Throughout these E QUAL talks, we've emphasized the need to use CDR's for standardized risk assessments...are we now saying that it is all bunk?

Ruling out AMI: Troponin Only Pathways

Erik P. Hess MD MSc
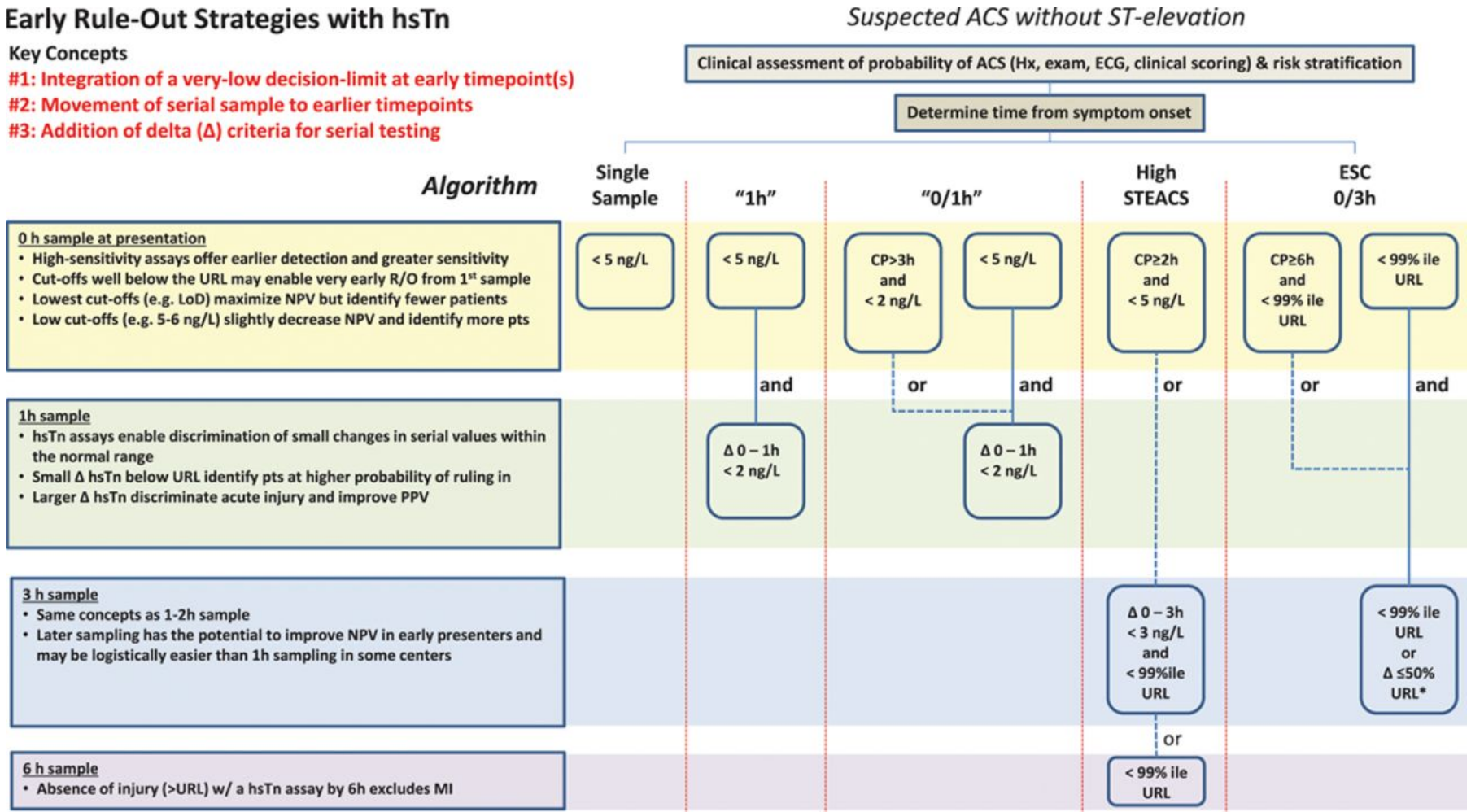### Professor of Emergency Medicine

Overview

Five rule-out strategies using high-sensitivity assays for troponin (hsTn) and key concepts

Early Rule-Out Strategies with hsTn

Key Concepts
#1: Integration of a very-low decision-limit at early timepoint(s)
#2: Movement of serial sample to earlier timepoints
#3: Addition of delta (Δ) criteria for serial testing

Suspected ACS without ST-elevation

Clinical assessment of probability of ACS (Hx, exam, ECG, clinical scoring) & risk stratification

Determine time from symptom onset

Algorithm	Single Sample	"1h"	"0/1h"		High STEACS	ESC 0/3h	
0 h sample at presentation • High-sensitivity assays offer earlier detection and greater sensitivity • Cut-offs well below the URL may enable very early R/O from 1st sample • Lowest cut-offs (e.g. LoD) maximize NPV but identify fewer patients • Low cut-offs (e.g. 5-6 ng/L) slightly decrease NPV and identify more pts	< 5 ng/L	< 5 ng/L	CP>3h and < 2 ng/L	< 5 ng/L	CP≥2h and < 5 ng/L	CP≥6h and < 99% ile URL	< 99% ile URL
		and	**or**	**and**	**or**	**or**	**and**
1h sample • hsTn assays enable discrimination of small changes in serial values within the normal range • Small Δ hsTn below URL identify pts at higher probability of ruling in • Larger Δ hsTn discriminate acute injury and improve PPV		Δ 0 − 1h < 2 ng/L		Δ 0 − 1h < 2 ng/L			
3 h sample • Same concepts as 1-2h sample • Later sampling has the potential to improve NPV in early presenters and may be logistically easier than 1h sampling in some centers					Δ 0 − 3h < 3 ng/L and < 99%ile URL		< 99% ile URL or Δ ≤50% URL*
					or		
6 h sample • Absence of injury (>URL) w/ a hsTn assay by 6h excludes MI					< 99% ile URL		

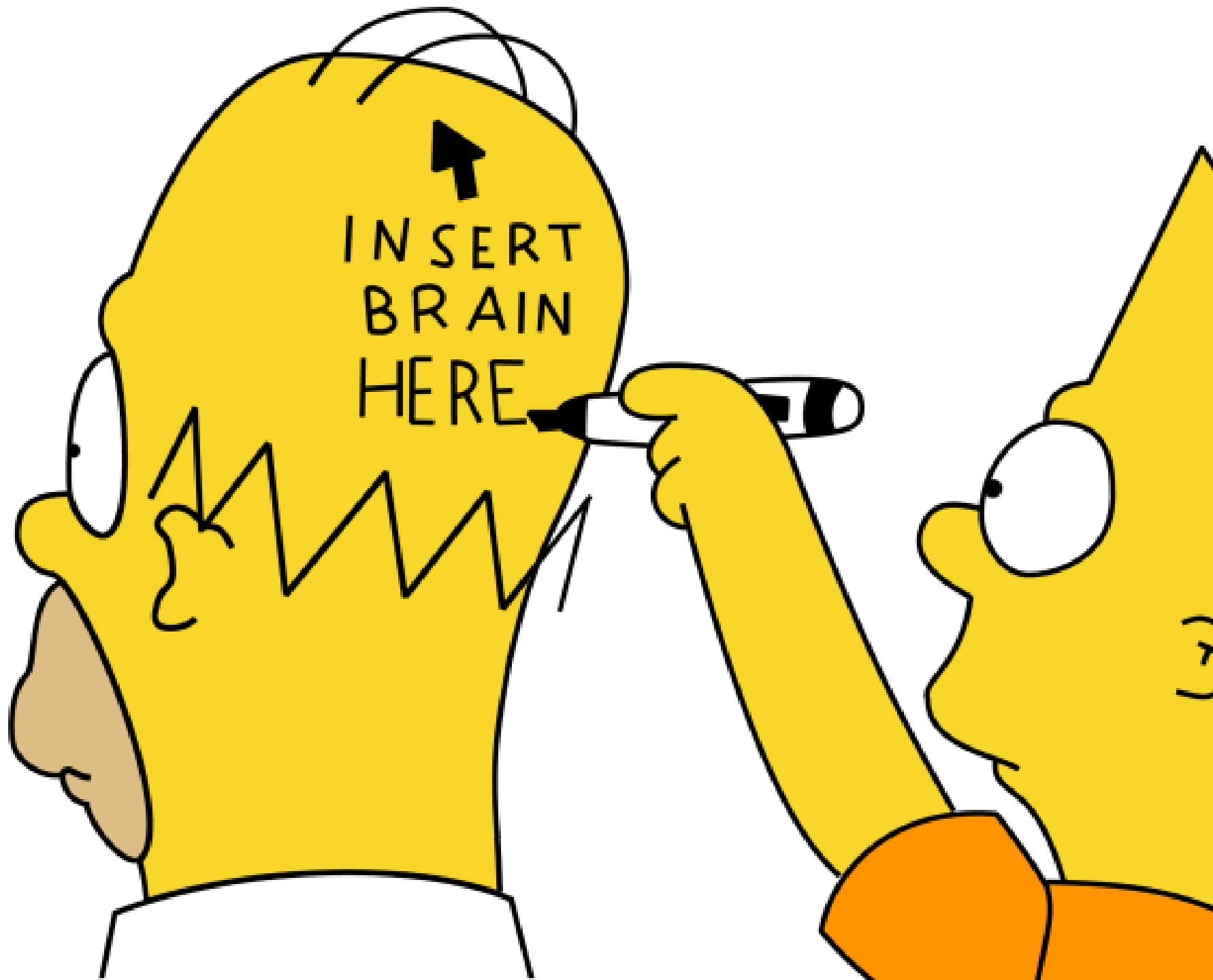David A. Morrow Circulation. 2017;135:1612-1616

American Heart Association

Definitions

- Limit of blank (LOB): cTn concentration in zero calibrator sample (e.g., "water")

- Limit of detection (LOD): lowest measurable cTn concentration

- 99th percentile upper reference limit (URL): 99th percentile value from reference control (healthy) population

INSERT
BRAIN
HERE

hsTn: More sensitive *and* more rapid
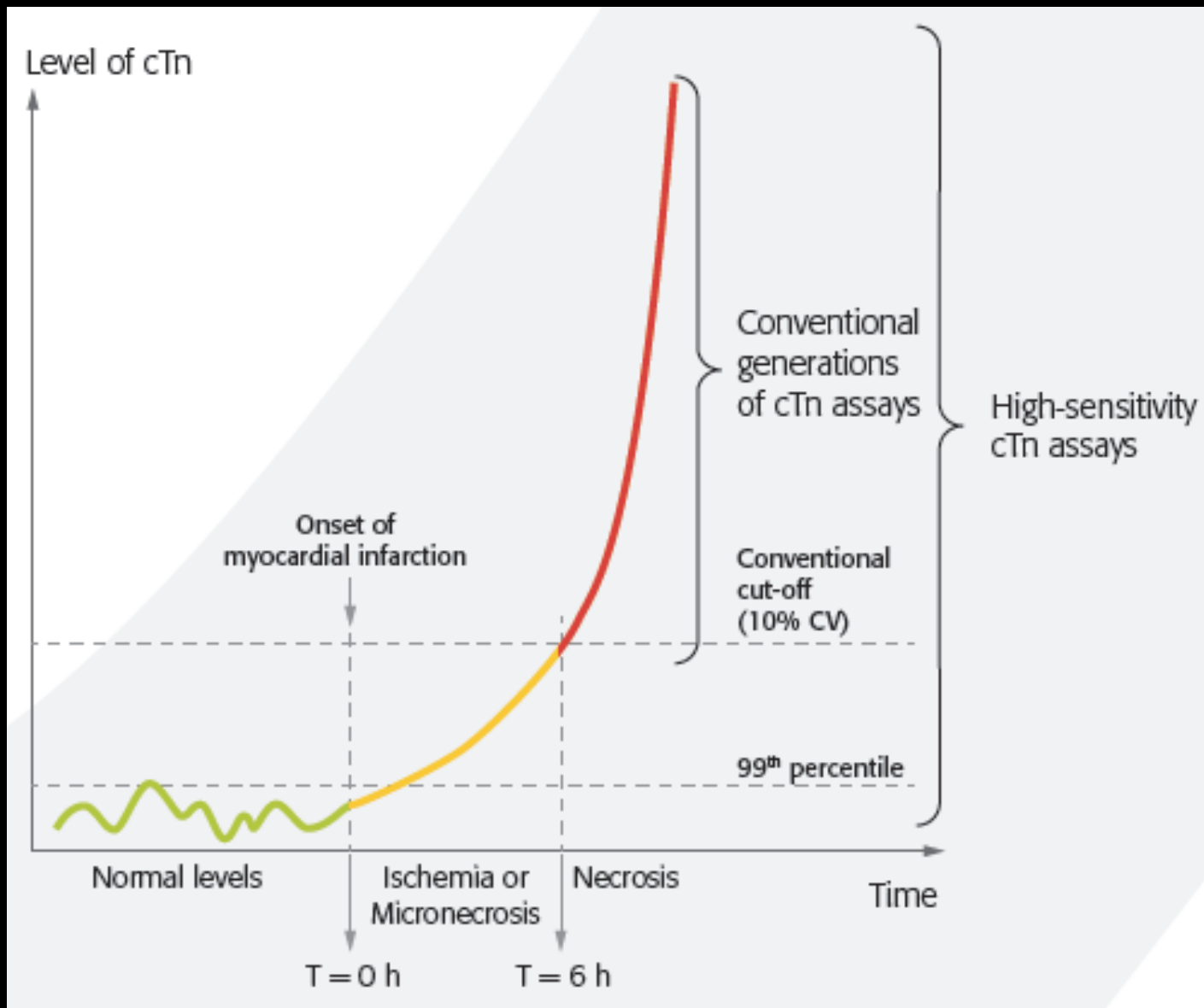
Multiple causes of Tn elevation!!

Analytical

- Heterophilic antibodies
- Rheumatoid factor
- Microparticles
- Fibrin clots in the sample
- Hemolyzed, lipaemic of icteric samples
- Analytical failure

Clinical (cardiac)

- Myocarditis and pericarditis
- Pathologies of cardiac valves
- Hypertrophic cardiomyopathy
- Severe arrhythmias
- Severe heart failure
- Cardiac trauma
- Chemotherapy toxicity
- Cardiac amiloidosis and sarcoidosis
- Rejection of heart transplantation

Clinical (extra-cardiac)

- Pulmonary embolism
- Acute pulmonary oedema
- Severe hypertension or hypotension
- Chronic renal failure
- Hypothyroidism
- Stroke
- Sepsis
- Snake venom
- Sickle Cell Disease
- Physical exercise
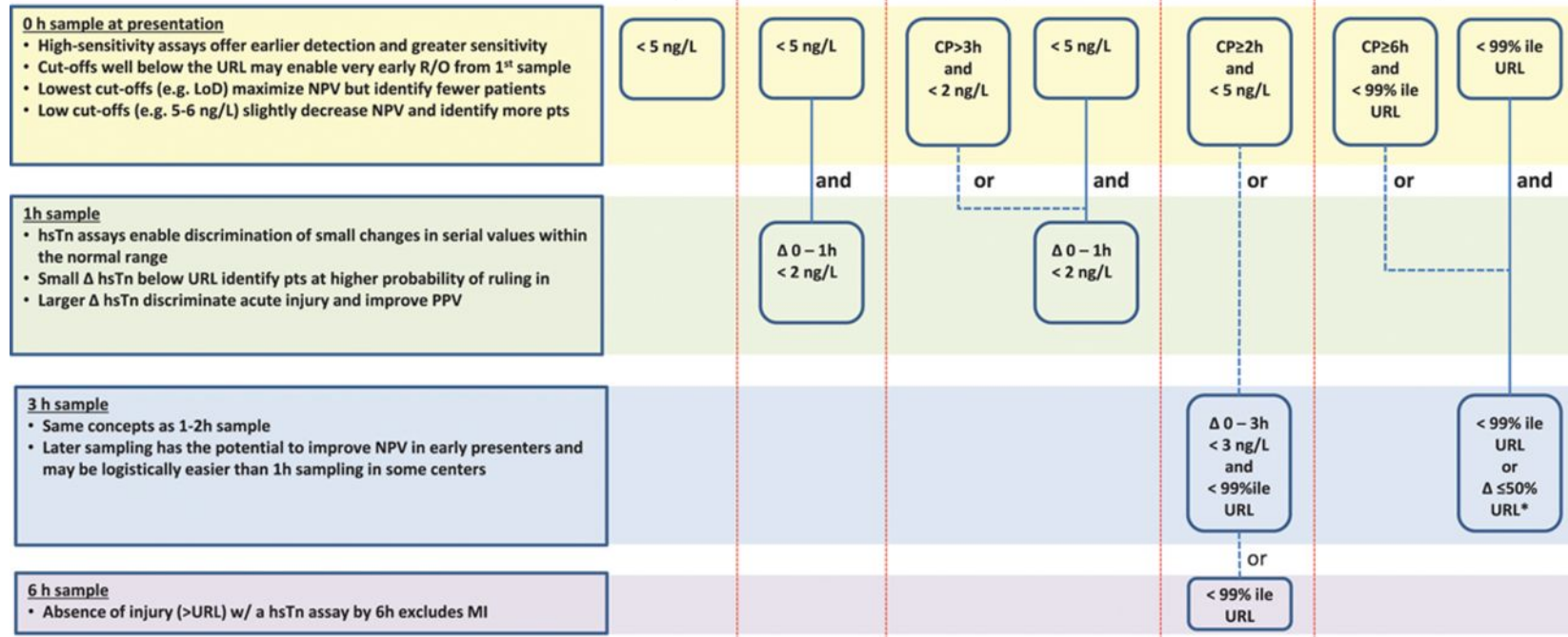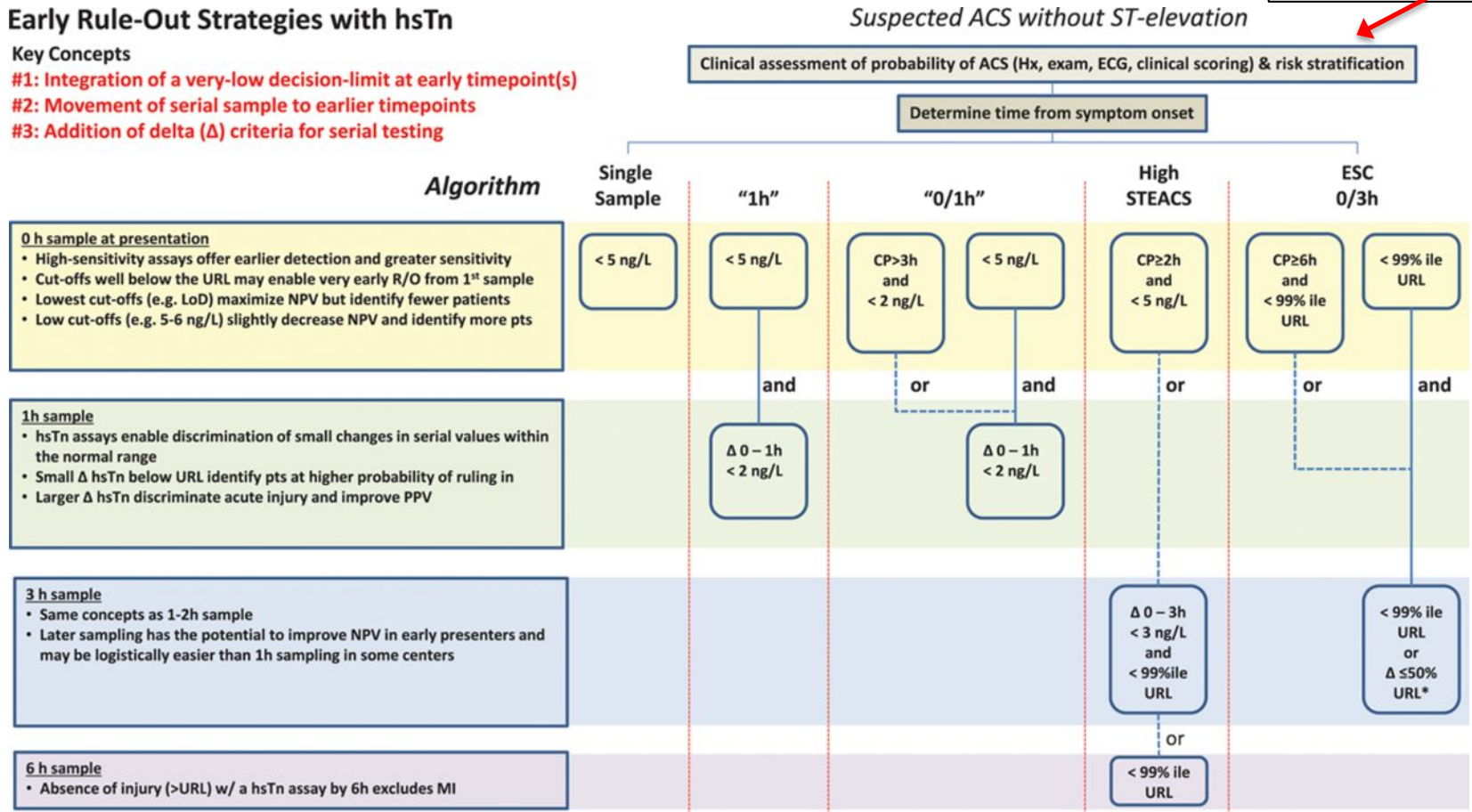- Ketoacidosis
- Carbon monoxide poisoning

Schematic representation of five variations of rule-out strategies using high-sensitivity assays for troponin (hsTn) and the key concepts that underlie each element.

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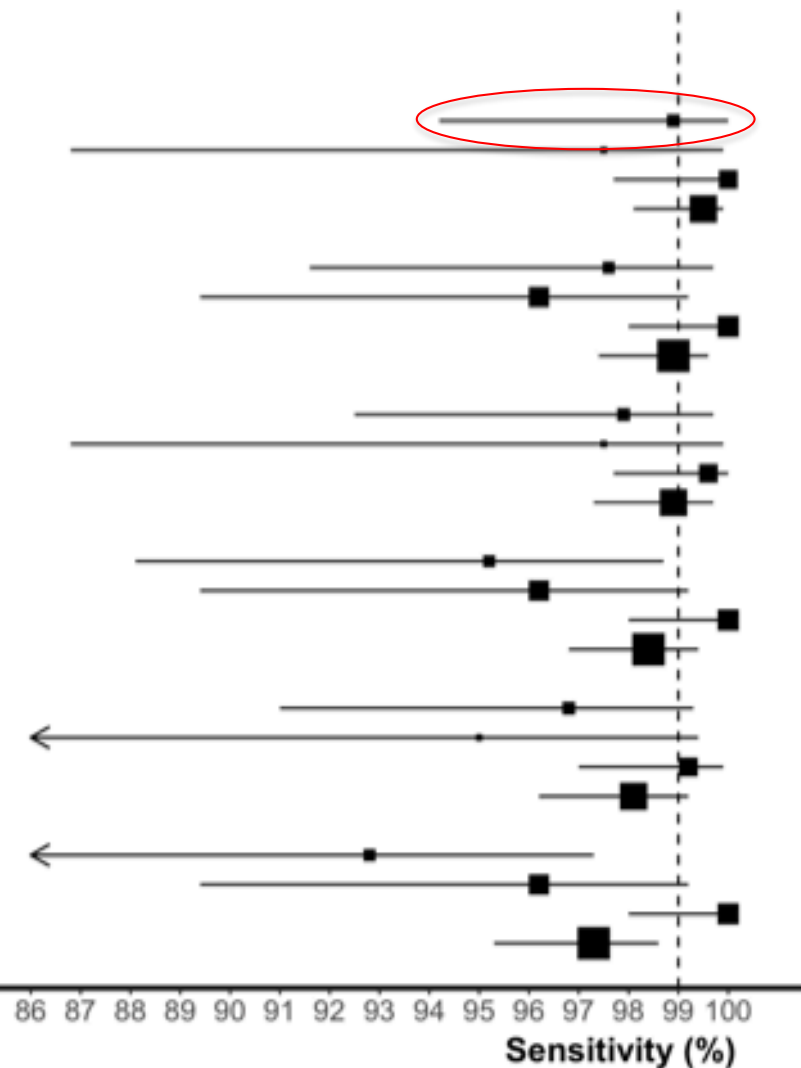#3: Addition of delta (Δ) criteria for serial testing

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and / or / and / or / or / and

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6 h sample
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High STEACS: < 99% ile URL

Boeddinghaus et al.　　　　Chapman et al.

American Heart Association.

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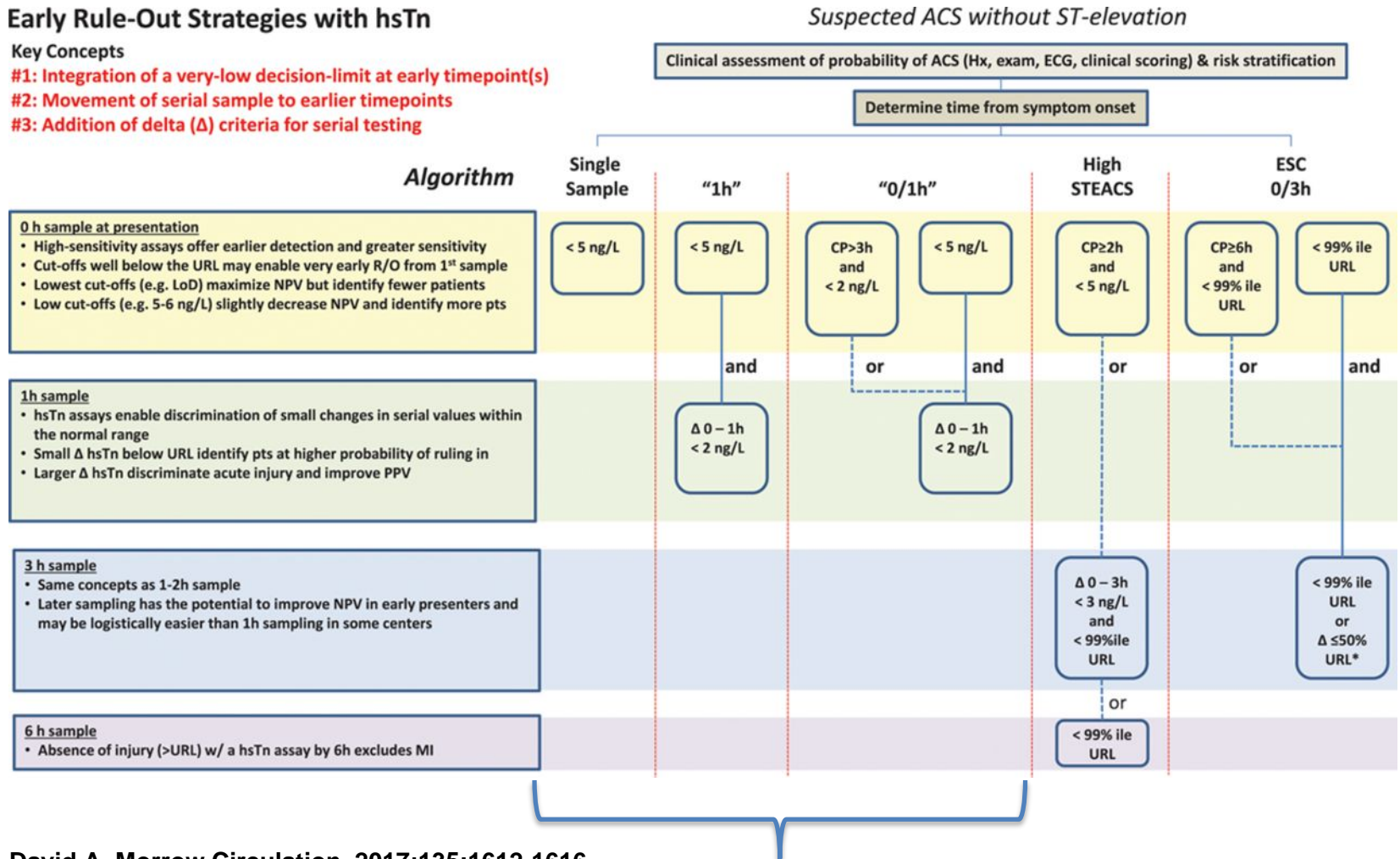

Watts Carlton et al.

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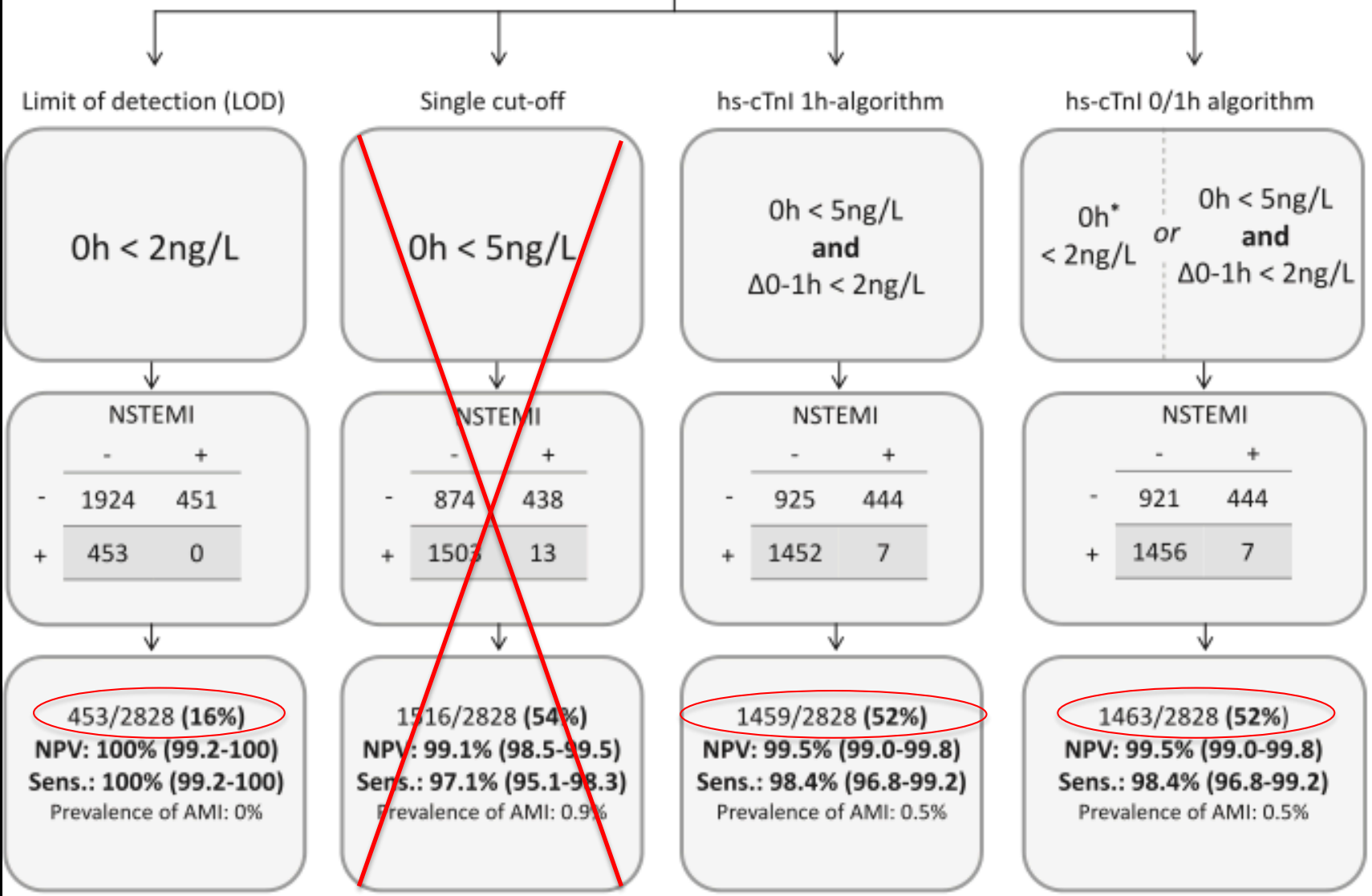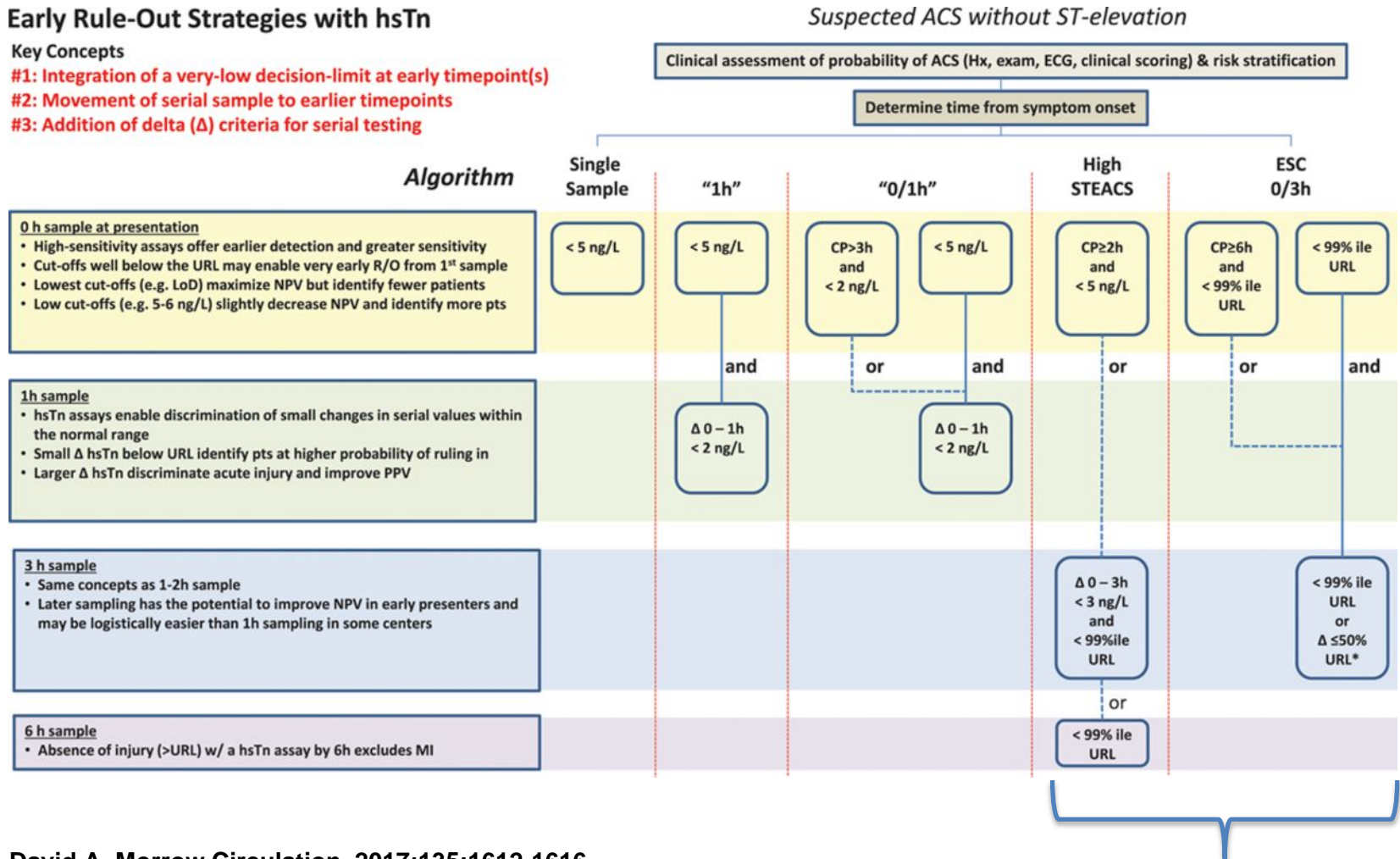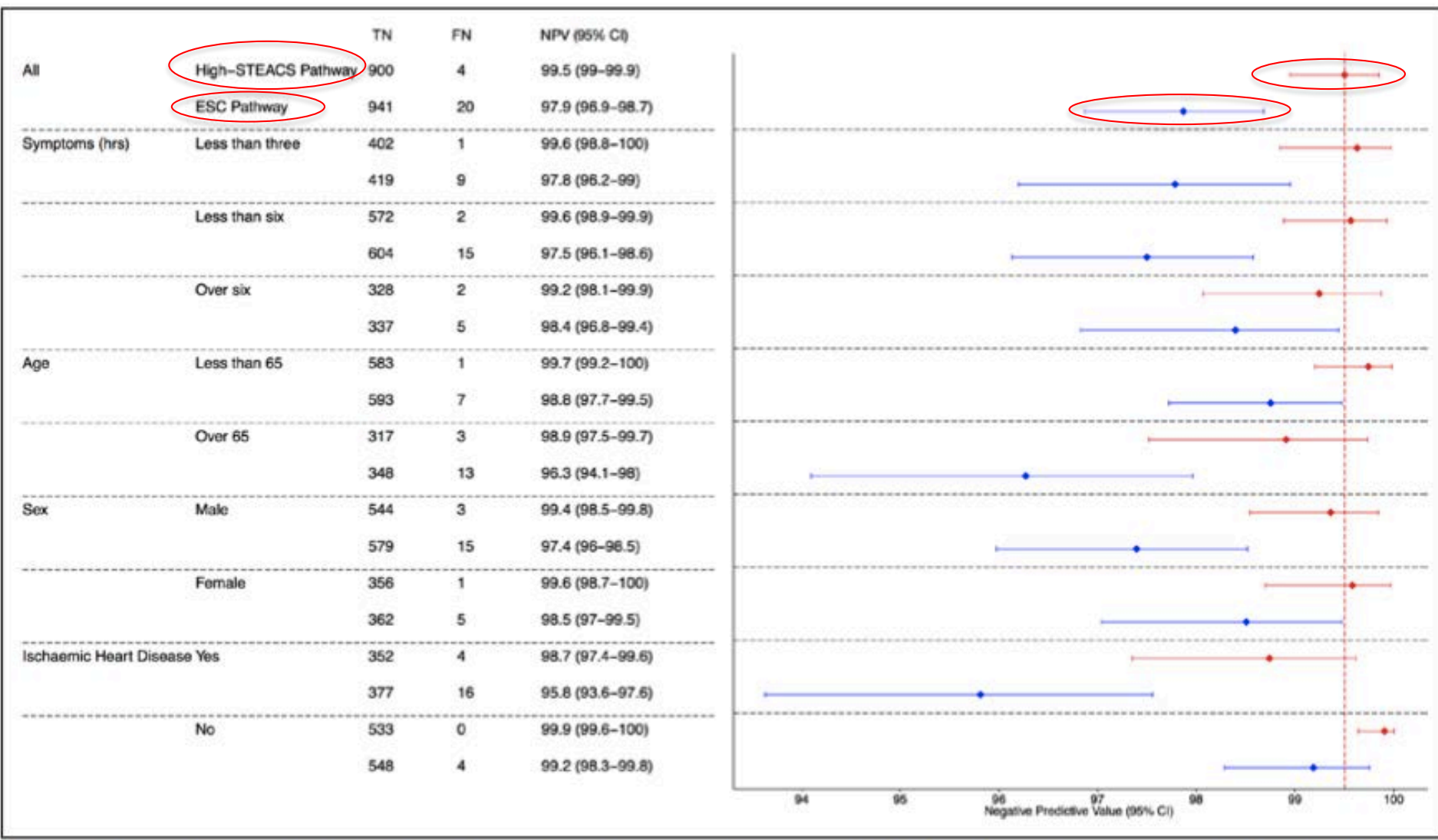#2: Movement of serial sample to earlier timepoints
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American Heart Association.

Group	TP	FP	FN	TN
hs-cTnT <= LoD and TIMI=0				
UK	93	634	1	193
AU	39	549	1	115
NZ	242	1036	0	256
Combined	374	2219	2	564
hs-cTnI <= LoD and TIMI=0				
UK	81	531	2	253
AU	77	1251	3	433
NZ	282	1358	0	264
Combined	440	3140	5	947
hs-cTnT <= LoD and TIMI <= 1				
UK	92	575	2	252
AU	39	405	1	259
NZ	241	920	1	372
Combined	372	1900	4	883
hs-cTnI <= LoD and TIMI <= 1				
UK	79	419	4	365
AU	77	804	3	877
NZ	282	1254	0	368
Combined	438	2477	7	1610
hs-cTnT <= LoD and TIMI <= 2				
UK	91	547	3	280
AU	38	372	2	292
NZ	240	817	2	475
Combined	369	1736	7	2783
hs-cTnI <= LoD and TIMI <= 2				
UK	77	336	6	448
AU	77	804	3	80
NZ	282	1162	0	460
Combined	433	2216	12	1871

Sensitivity (%): 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

Watts Carlton et al., Heart 2017.

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David A. Morrow Circulation. 2017;135:1612-1616

Boeddinghaus et al.

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Chapman et al.

American Heart Association®

		TN	FN	NPV (95% CI)
All	High-STEACS Pathway	900	4	99.5 (99–99.9)
	ESC Pathway	941	20	97.9 (96.9–98.7)
Symptoms (hrs)	Less than three	402	1	99.6 (98.8–100)
		419	9	97.8 (96.2–99)
	Less than six	572	2	99.6 (98.9–99.9)
		604	15	97.5 (96.1–98.6)
	Over six	328	2	99.2 (98.1–99.9)
		337	5	98.4 (96.8–99.4)
Age	Less than 65	583	1	99.7 (99.2–100)
		593	7	98.8 (97.7–99.5)
	Over 65	317	3	98.9 (97.5–99.7)
		348	13	96.3 (94.1–98)
Sex	Male	544	3	99.4 (98.5–99.8)
		579	15	97.4 (96–98.5)
	Female	356	1	99.6 (98.7–100)
		362	5	98.5 (97–99.5)
Ischaemic Heart Disease	Yes	352	4	98.7 (97.4–99.6)
		377	16	95.8 (93.6–97.6)
	No	533	0	99.9 (99.6–100)
		548	4	99.2 (98.3–99.8)

Negative Predictive Value (95% CI)

Chapman et al. Circulation 2017.

Summary

- AMI diagnosis: more rapid, sensitive, and precise with hs-cTn

- Rule out AMI at LOD with single cTn (CP onset > 3 hrs)

- Other strategies: Cut-point < 99th percentile (except ESC) + 1-3 hr delta strategy + risk score

OK – so the troponin only approach can tell us who did not have an MI...but what about risk stratifying for CAD or CVD events?

You Need To Include a Decision Rule!

W. Frank Peacock, MD, FACEP, FACC
Professor, Emergency Medicine
Associate Chair and Research Director
Baylor College of Medicine

Background

"We've considered every potential risk except the risks of avoiding all risks."

- Safely reducing ED LOS or DC rate in patients with ACS symptoms
  - Mixed success
  - Gestalt never wins
    - it may not lose, but it never wins

- ADP's: NOT about diagnosis
  - ECG, Tn x2, Risk score
  - Few large prospective evaluations have been performed
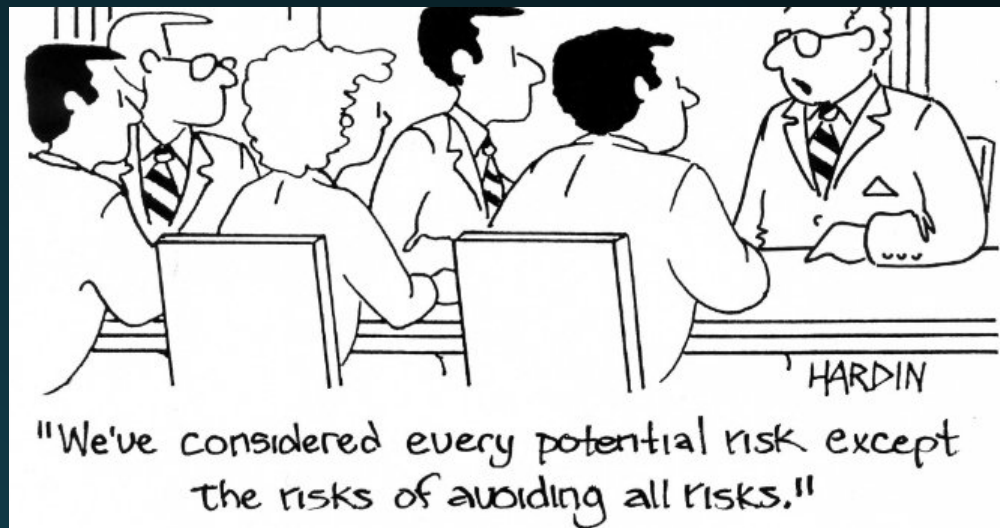
TIMI Risk Score: 2 week MACE

Risk factors:

- Age ≥65
- ≥3 CAD risk factors
- Coronary stenosis ≥50%
- ST-segment deviation
- ≥2 anginal events in last 24 hours
- ASA in last 7 days
- Elevated trop
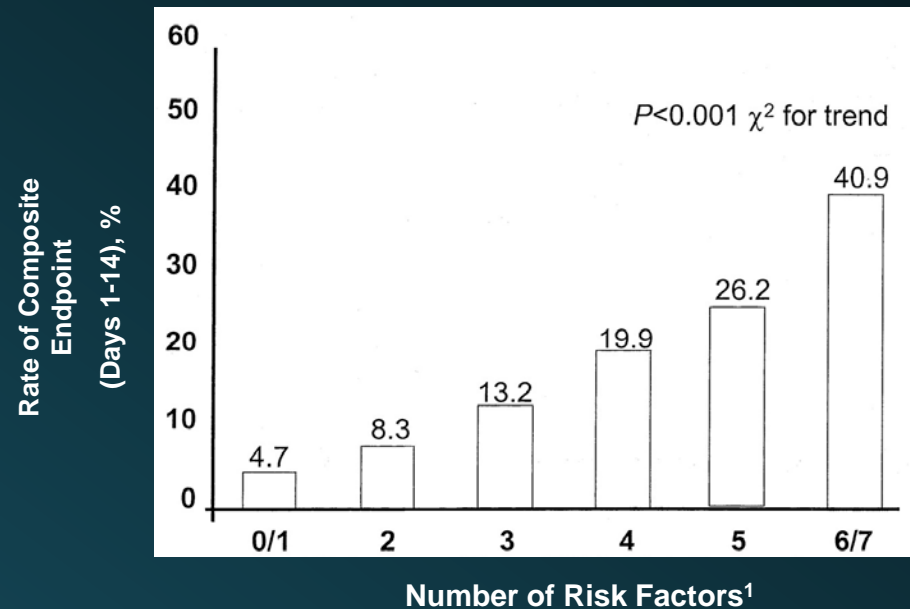
Each risk factor is = 1 point, and total represents TIMI Risk Score

Event rates (all-cause mortality, MI, or UTVR) increase with each 1-point increase in score

Antman EM et al. *JAMA*. 2000;284:835-842.

HEART Score for 6 week MACE

MACE = AMI, PCI, CABG, (+) cath, death

Hx: Hi =2, Mod =1, Slight =0

ECG: Sig ST dep =2, NS repol =1, NI =0

Age: ≥65 =2, 45-65 =1, ≤ 45 =0

Risks: ≥3 =2, 1-2 =1, 0=0

RISKS
Hyperchole, HTN, DM Tobacco (+) FH, Obesity

Tn: ≥3x ULN =2
    1-3 ULN =1
    ≤ ULN =0

Low risk = 0-3; <2% MACE risk

Backus BE. Int J Cardiol. 2013 Oct 3;168(3):2153-8.

EDACS
ED Assessment of Chest Pain Score

Characteristic	Parameter	Points
History	18-50 yo with CAD, or >2 risk factors	+4
Age	18 to >85	+2 to +20
Sex	Male	+6
Signs and Symptoms	Diaphoresis	+3
	Arm or shoulder radiation	+5
	Pain occurred or worsened with inspiration	-4
	Pain is reproduced with palpation	-6

Low Risk Criteria
- EDACS Score <16
- No new ECG ischemia
- Negative 0 and 2h Tn

Than MP. Ann Emerg Med. 2016 Jul;68(1):93-102.

Comparing Scores

- PEARL data set
  - 7 EDs

- Patient with suspected ACS

- Dr. had to document risk of MI BEFORE Tn as:
  - Low
  - Moderate
  - High Risk

- N=458

Singer AJ. AJEM 35(2017) 704-09
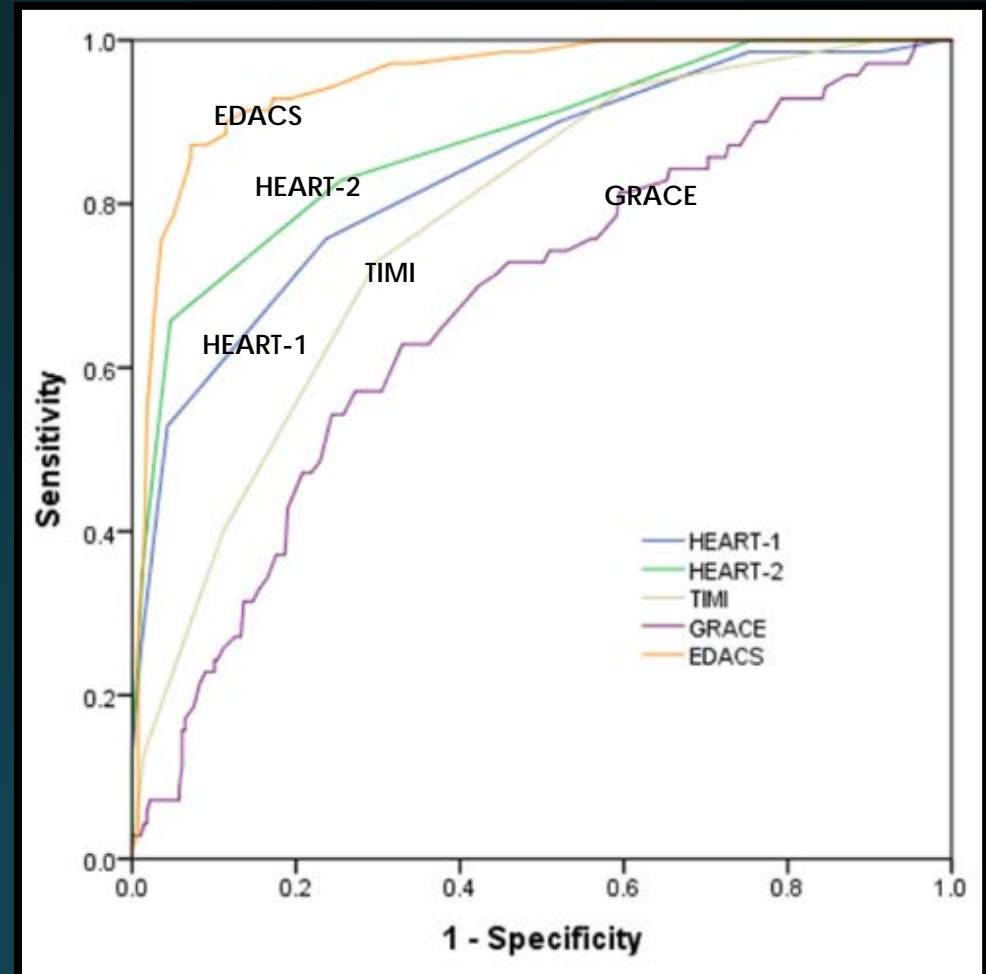
ADP Performance Perspective

	Standard cutpoint		Sensitivity set at 99%	
	Low risk (n) Definition	Missed AMI, %	Cutoff	% Low Risk
Clinical	--	5.9 (3.0-11.2)	--	--
HEART-1	3	4.7 (2.1-9.9)	0	1
HEART-2	3	4.1 (1.9-8.7)	0-2	18.9
TIMI	0	0 (0-12.9)	0	7
GRACE	50	7.1 (1.3-31.5)	49	3.2
EDACS	15	1.0 (0.2-4.1)	12	34.3

Singer AJ. AJEM 35(2017) 704-09

Real life change is hard……..
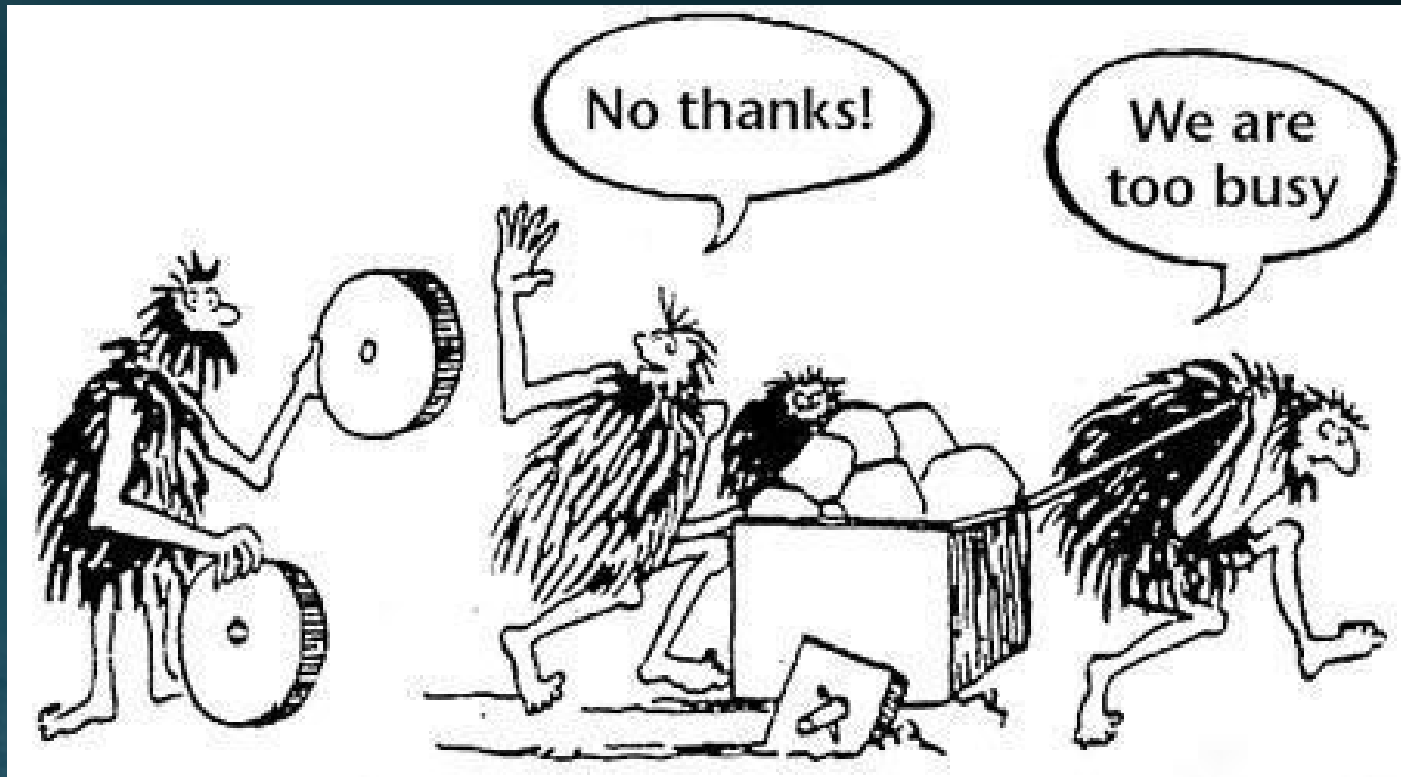
Step Wedge:

Pro: Work in real life?
Learn from experience
Avoids seasonal variation

Con: No blinding
or randomization

Hospital	Planned timing															
1																
2																
3				Gestalt								Intervention				
4																
5																
6																
7																
months	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

pre-implementation   post-implementation
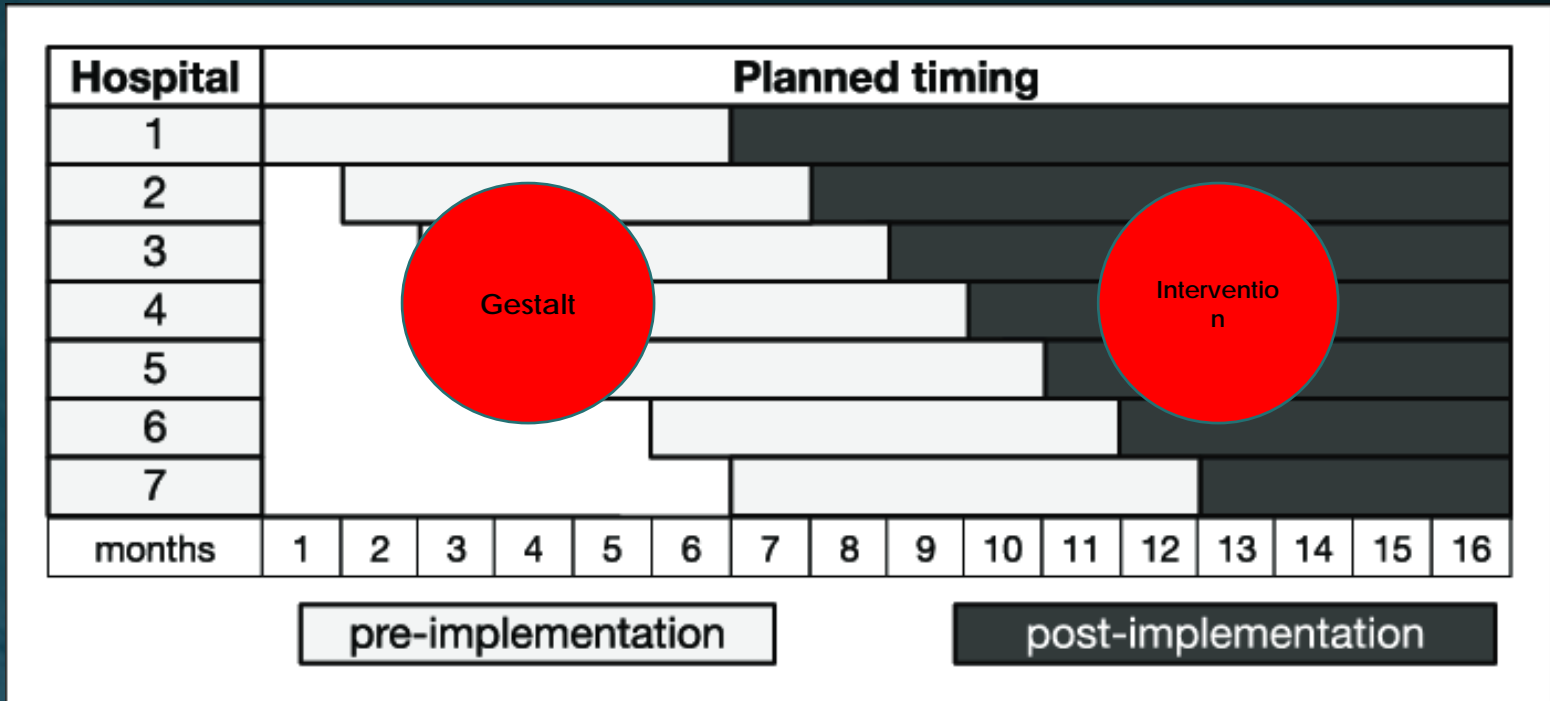
Than MP. *Circulation. 2017 Nov 14. pii: CIRCULATIONAHA.117.031984*

Effect of Using the HEART Score in Patients With Chest Pain in the ED
A Stepped-Wedge, Cluster Randomized Trial

- N=3648 (1827 SOC vs 1821 HEART score)
  - Low-risk cohort; MACE = 2.0% (95% CI, 1.2% to 3.3%)

- **No difference in ………..**
  - **Early discharge**   **Readmissions**
  - **ED revisits**   **Outpatient visits**

- Dr's were hesitant to refrain from admission and diagnostic tests in low risk HEART score patients.

- **Conclusion:** Using the HEART score in CP patients is safe, but the effect on health care resources is limited.

Poldervaart JM. *Ann Intern Med.* 2017;166:689-697

ICare-ACS
Improving Care Processes for Patients With Suspected ACS

A Study of Cross-System Implementation of a National Clinical Pathway

- New Zealand = 4.6 million people

- In early 2014, Ministry of Health instructed all hospitals to implement a clinical pathway

- Must incorporate an ADP, for the assessment of patients with possible ACS

Than MP. *Circulation. 2017 Nov 14. pii:* CIRCULATIONAHA.117.031984

Methods

- Multicenter pragmatic trial stepped-wedge, before and after trial
  - 7 acute care hospitals
  - 31,332 suspected ACS patients

- Monitored for >4 months after vs usual care in 6 before

- The main outcome measure odds of safe D/C within 6 hours of presentation

Than MP. *Circulation. 2017 Nov 14. pii: CIRCULATIONAHA.117.031984*

Methods

- 7 Hospitals

- <u>Agnostic: Tn platform/timing</u>
  - 4 Roche Gen 5 hsTnT
  - 1 Abbott Architect hsTnI
  - 2 Siemens Ultra TnI

- <u>Agnostic: Risk Stratification Tool</u>
  - 5 EDACS (low risk <16)
  - 2 TIMI (Low risk = 0)

Than MP. *Circulation. 2017 Nov 14. pii:*
CIRCULATIONAHA.117.031984

Methods

+
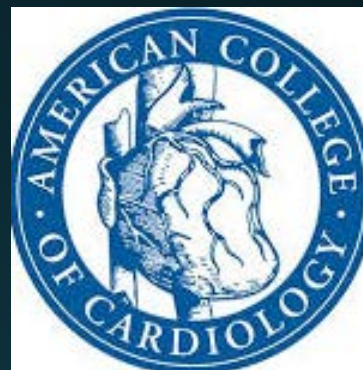
= AMB

- Implementation of a <u>clinical pathway</u> for the assessment of suspected ACS that included:
    - ✓ A clinical pathway document
    - ✓ Structured risk stratification
    - ✓ Specific times for ECG & serial Tn w/in 3 hrs of arrival
    - ✓ Directions for combining risk stratification, ECG, and Tn in an ADP

Than MP. *Circulation. 2017 Nov 14. pii: CIRCULATIONAHA.117.031984*

Results

- Pre-implementation: N=11,529
  - (range, 284–3465)

- Post-implementation: N=19,803
  - (range, 395–5039)

- Mean 6-hour D/C rate increased
  - from 8.3% (range, 2.7%–37.7%) to 18.4% (6.8%–43.8%).

- Odds of being D/C within 6 hours = 2.4 higher
  - 95% confidence interval, 2.3–2.6

Than MP. *Circulation. 2017 Nov 14. pii:
CIRCULATIONAHA.117.031984*

Results

- In patients without ACS, median LOS decreased by 2.9 hrs
  - (95% confidence interval, 2.4–3.4)

- If D/C by 6 hrs;
  - No change in 30-day MACE rates
    - SOC=0.52% vs ADP=0.44% (P=0.96)

- No adverse events occurred when clinical pathways were correctly followed

Than MP. *Circulation. 2017 Nov 14. pii: CIRCULATIONAHA.117.031984*

MACE if D/C'd by 6 hrs

5 SOC (0.52%)

1 NSTEMI
4 all cause deaths

16 ADP (0.44%)

8 NSTEMI
1 STEMI
1 stable VT
1 asystolic pause requiring a
     pacemaker
5 all-cause deaths

ADP MACE:
14/16 protocol violations
   12   (+) troponin
    2   (+) risk scores

2 coding errors
   Coded as readmission NSTEMI
   Actually were planned stress test
visits
      One (+), one (-)

Than MP. *Circulation. 2017 Nov 14. pii:
CIRCULATIONAHA.117.031984*

Conclusions

- Implementation of <u>clinical pathways</u> for suspected ACS
  - Reduces ED LOS
  - increases the rate 6 hr safe D/C's

Than MP. *Circulation. 2017 Nov 14. pii: CIRCULATIONAHA.117.031984*

You Need To Include ~~a~~ ~~Decision Rule!~~

an ADP!

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Well, it's hard to argue with that evidence but, findings are thoroughly discouraging from a pragmatic standpoint. What is needed to make this actually work?

ADP Research is Easy Implementation is Hard:
Moving from Evidence to Adoption & Adherence

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Director of Clinical Research
Associate Professor
Department of Emergency Medicine
Wake Forest School of Medicine

Wake Forest® School of Medicine

Disclosures

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  - NIH: Heart Lung and Blood Institute
  - NCATS: National Center for Advancing Translation Sciences
  - Donaghue Foundation/ Association of American Medical Colleges
  - Duke Endowment
  - Abbott Laboratories
  - Siemens Healthcare
  - Roche Diagnostics

- Author for Up-to-Date

- Chief Medical Officer: Impathiq, Inc.

How to go from the literature to adoption
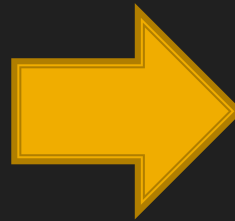
- Validated Tool
  Evidence-based

- Implementation
  Adoption / Adherence
  Desired Outcomes

"The best big ideas is only going to be as good as its implementation"

Jay Samit

HEART Score Implementation

Effect of Using the HEART Score in Patients With Chest Pain in the Emergency Department

A Stepped-Wedge, Cluster Randomized Trial

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Background: The HEART (History, Electrocardiogram, Age, Risk factors, and initial Troponin) score is an easy-to-apply instrument to stratify patients with chest pain according to their short-term risk for major adverse cardiac events (MACEs), but its effect on

weeks, 1 hospital was randomly assigned to switch to "HEART care," during which physicians calculated the HEART score to guide patient management.

Measurements: For safety, a noninferiority margin of a 3.0% absolute increase in MACEs within 6 weeks was set. Other outcomes included use of health care resources, quality of life, and cost-effectiveness.

Results: A total of 3648 patients were included (1827 receiving usual care and 1821 receiving HEART care). Six-week incidence of MACEs during HEART care was 1.3% lower than during usual care (upper limit of the 1-sided 95% CI, 2.1% [within the noninferiority margin of 3.0%]), Looking at low-risk patients, incidence of

Conclusion: Using the HEART score during initial assessment of patients with chest pain is safe, but the effect on health care resources is limited, possibly due to nonadherence to management recommendations.

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Results

- 3% reduction in hospitalizations – not significant
- No difference in median length of stay
- ~10% increase in outpatient clinic visits
- 36% of low-risk HEART score patients had prolonged observation.
- Non-adherence occurred in 41% of low-risk patients and 12% of high-risk patients.

Interpretation?

a) The HEART score doesn't work

OR

b) Their implementation didn't work

Keys to successful ADP implementation

- Stakeholder buy-in
  - Champions
  - Education
- Consider Work Flow and balancing measures
- Tracking Outcomes and Adherence

HEART Pathway: Key Stakeholders

- Health System Administrators
- Health Informatics
- Nursing & Advanced Practice Clinician Leadership
- Physician Leadership
  - Cardiology
  - Primary Care
  - Hospitalists
  - Emergency Medicine

HEART Pathway EMR Integration

- Decision support integrated into EMR on 11/3/2014
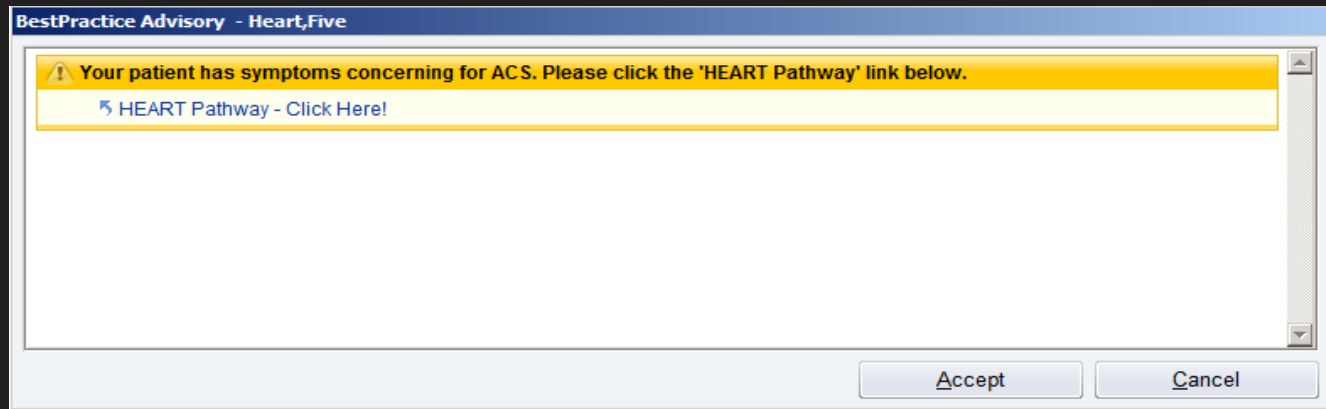
- Right Patient

- Right Provider

- Right Time

Tracking Adherence

- Weekly reports
- Corrective education

Date, Time		--	--	Provider
11/3/14 1707		--	--	BRYAN
11/4/14 0733		--	--	JON
11/4/14 1027		--	--	JULIE
11/5/14 0835		--	--	ROBERT
11/5/14 1117		--	--	AARON
11/5/14 1021	No Action Taken	--	--	REBECCA
11/5/14 0746		--	--	JOHN
11/5/14 1442		--	--	SCOTT
11/6/14 1034		--	--	MATT
11/6/14 1122		--	--	DEREK
11/6/14 1912		--	--	DEREK

Tracking Outcomes

- Risk distribution
  - Utilization rates
    - Hospitalization
    - Stress testing
    - Recurrent care
- Safety
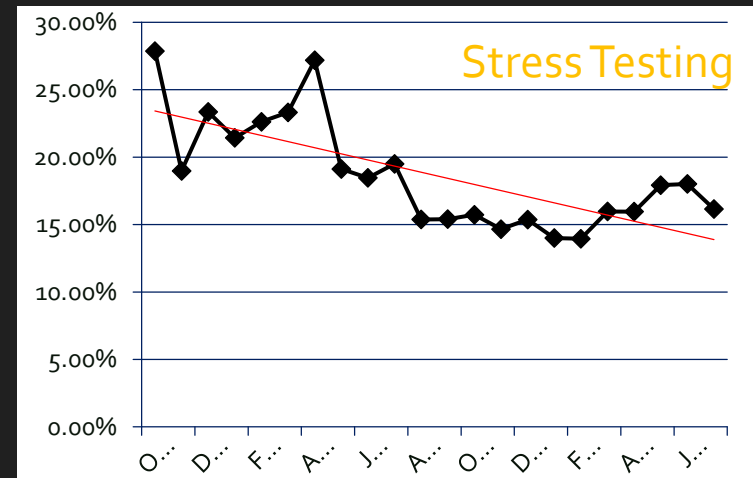
Barriers to EMR integration

- Getting all stakeholders to agree

- Limited IT resources
  - Lack expertise for custom CDS builds
  - Time and prioritization
  - Maintenance of CDS

EMR App Store Model

EPIC APP Orchard

SMART FHIR App

The HEART Pathway EMR App

Contextual Launch from EMR workflow

Point-of-Care Clinical Decision Support

Data Analytics

Summary

- ADP will only perform well if implemented well

- Stakeholder buy-in
- Consider EMR implementation
- Track Outcomes and Adherence

Questions? Contact the E-QUAL team at equal@acep.org