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# Reducing the Population Health Burden of Cardiovascular Disease

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NYU School of Medicine

Disclosures: K23 HL116787 Award from National Heart, Lung, and Blood Institute; Consultant for CardioDx, Inc

# Learning Objectives

1. Describe the public health burden of cardiovascular disease in the US and the role of cardiovascular diagnostic testing

2. Explain the comparative cost and cost-effectiveness of diagnostic technologies vs. public health interventions for reducing cardiovascular disease morbidity and mortality

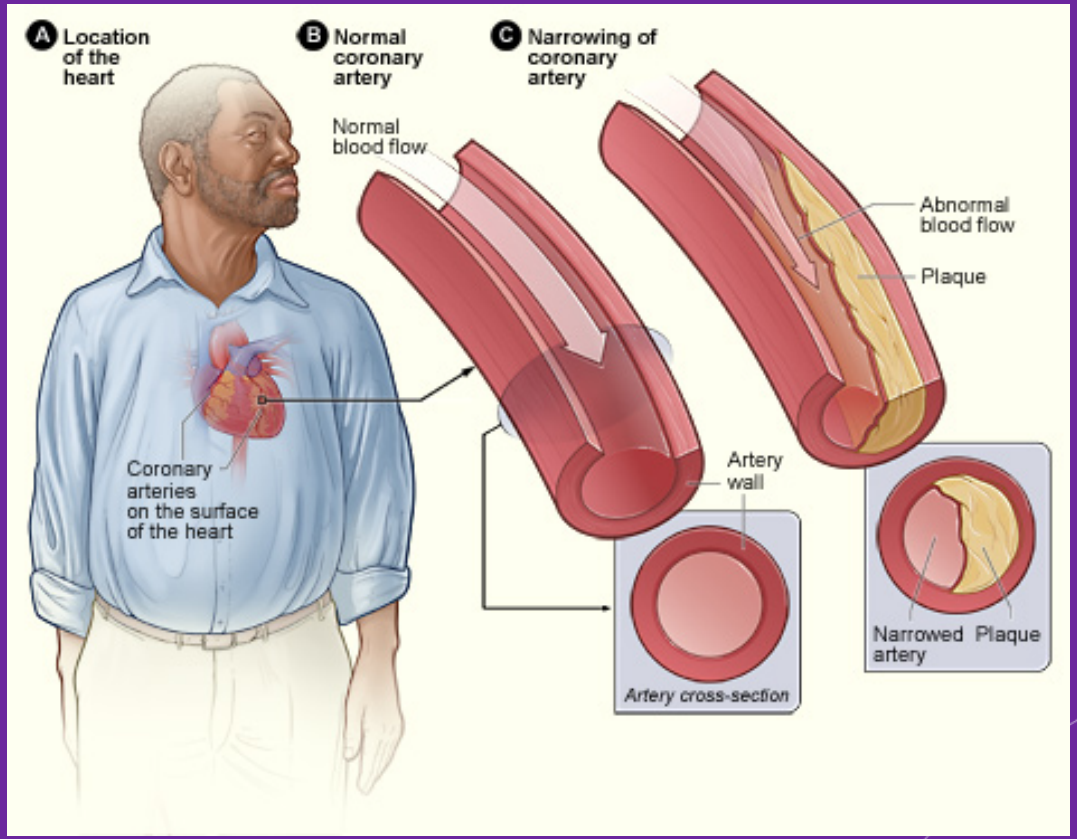
3. Identify the policy implications of recent utilization growth in diagnostic technologies for coronary heart disease, and the drivers of that growth

4. Discuss population health implications of the ACA for cardiovascular disease prevention and testing

# Cardiovascular Disease (CVD) is a Major Public Health Challenge

**Epidemiology**

- 15.4 million adults in the US live with coronary heart disease (CHD) and 795,000 have a stroke each year
- CHD: 6.4% of adults overall; 7.9% of men and 5.1% of women
- CHD affects 20% of persons ≥ 65 years




Picture source: NHLBI

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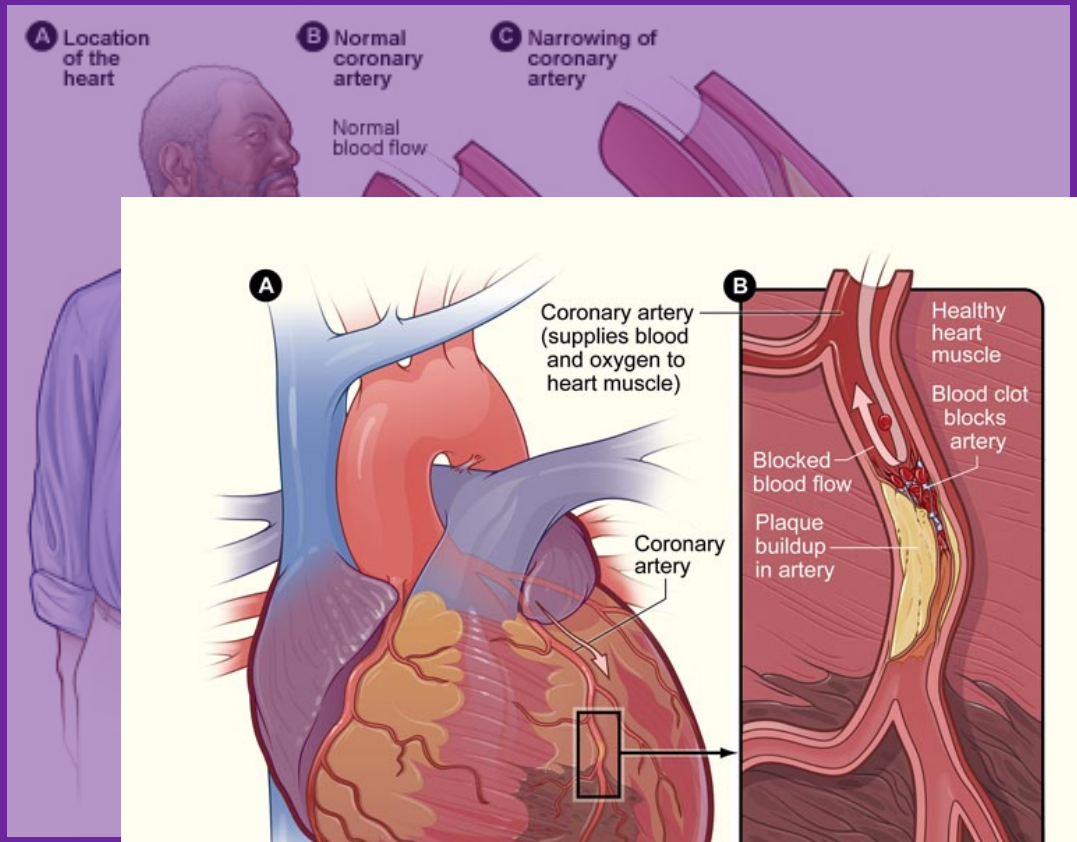


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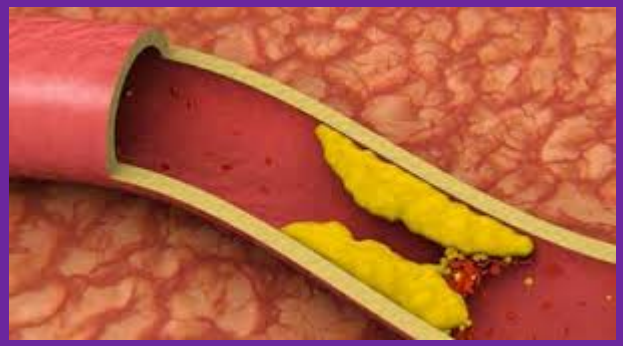
# Risk Factors for Cardiovascular Disease

Diabetes

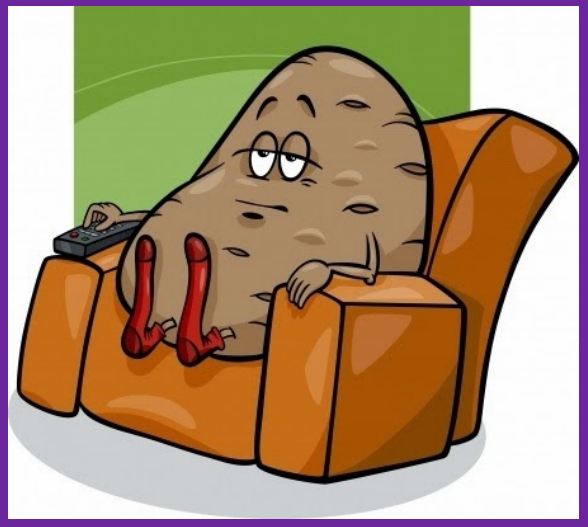
High Cholesterol



High Blood Pressure

Smoking

Physical Inactivity



Obesity

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Picture sources: NIH, Doctor Murray, True Med Cost, Flight Physical, 123 RF, Daily Hiit

# Morbidity and Mortality Attributable to Cardiovascular Disease in the United States

## Morbidity/Quality of Life

- CVD accounts for 18% of total lost disability-adjusted life years (DALYs) in developed countries

## Mortality

- CHD accounts for over 386,000 deaths annually (1 in 6 of all deaths)
- **More than half of sudden cardiac deaths occur in people with no prior history of heart disease**

## Myocardial infarction

- Nearly one million new or recurrent heart attacks each year
- **Early diagnosis is important because treatment & preventive practices significantly reduce morbidity and mortality**

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National Health Interview Survey, 2010; Go, *Circulation* 2013; WHO, Global Burden of Coronary Heart Disease, 2002

# Healthcare Utilization and Costs Attributable to Coronary Heart Disease are Substantial

## Healthcare utilization and costs

- CHD costs $195.2 billion in direct and indirect costs annually (2009)
- In 2006, Medicare spent $11.7 billion on inpatient care for CHD
- By 2030, medical costs for CHD (real 2010$) projected to increase ≈100%

## Ambulatory care

- In 2009, there were over 14 million ambulatory care visits with CHD as the first-listed diagnosis

## Hospital care

- 1.3 million hospital admissions with CHD listed as the first diagnosis
- 954,000 percutaneous coronary interventions (PCIs), 397,000 cardiac bypass surgeries, 1.03 million diagnostic cardiac catheterizations

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National Health Interview Survey, 2010; Go, *Circulation* 2013

# In Men And Women Without A History Of CHD, Noninvasive And Invasive Testing Are Central To Making A Diagnosis

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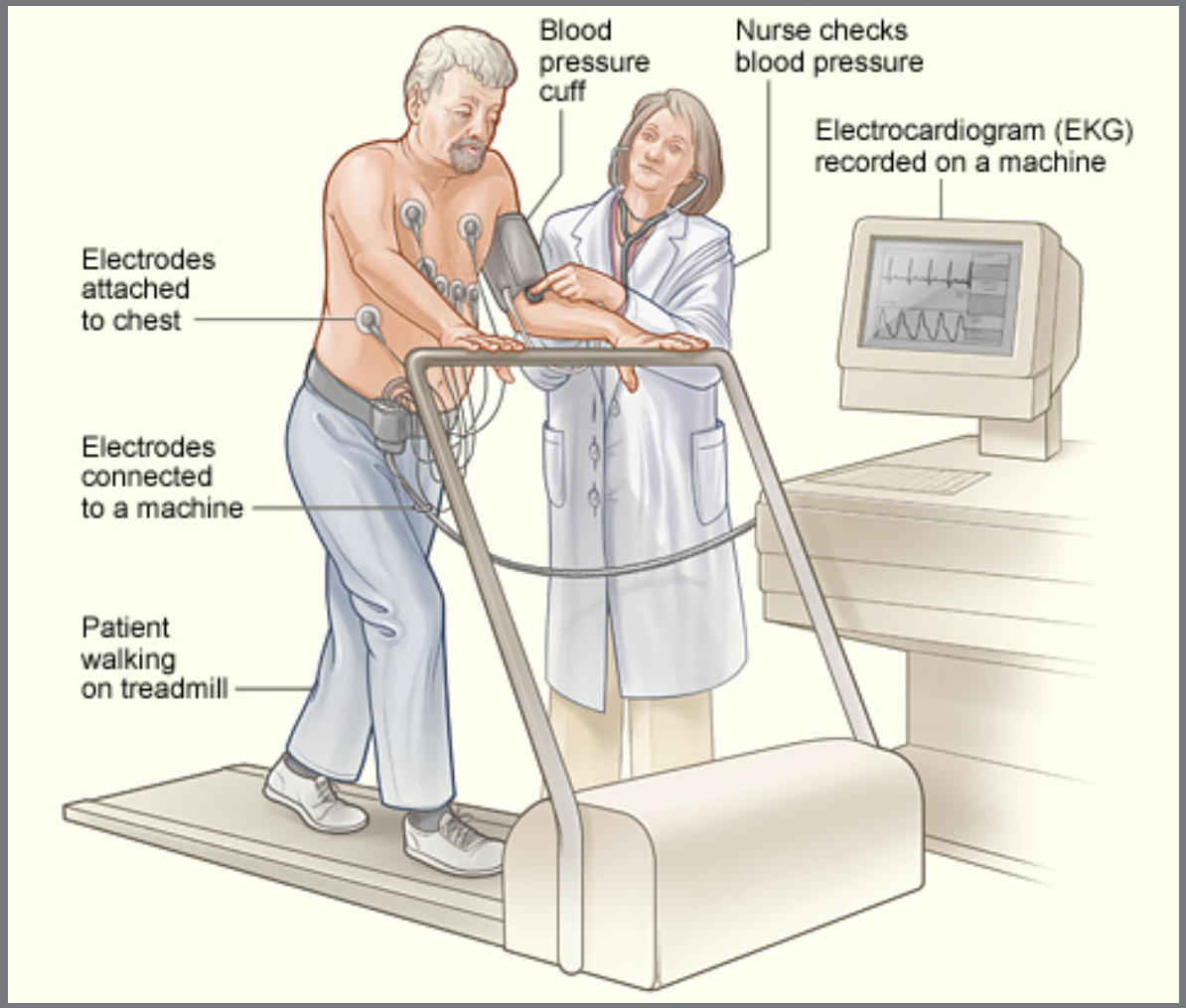
# Cardiac Stress Testing

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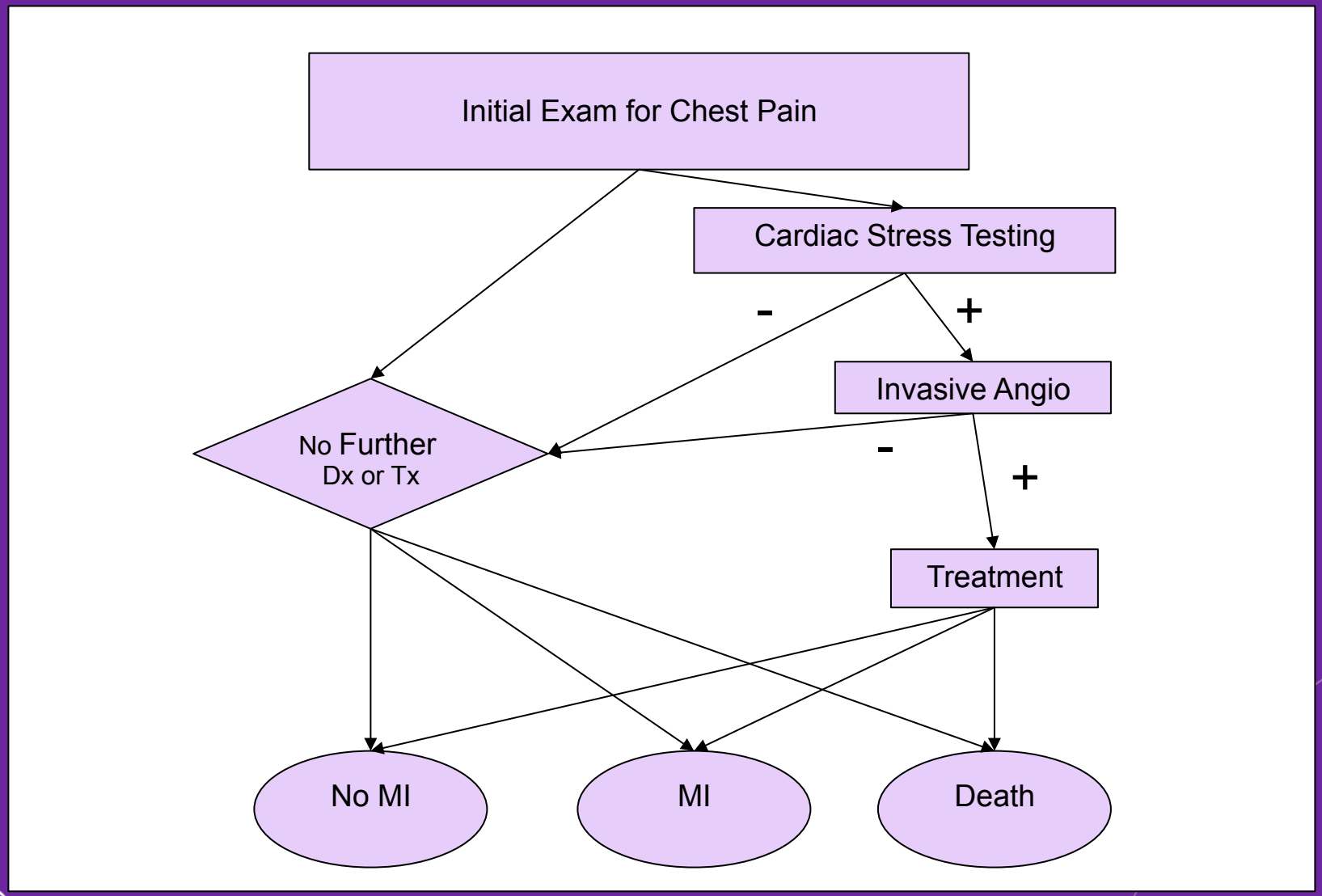
Source of picture: NHLBI

# Clinical Decision Pathway for Patients Evaluated for CHD




Abbreviations - Dx: Diagnosis, Tx: Treatment, MI: Myocardial Infarction

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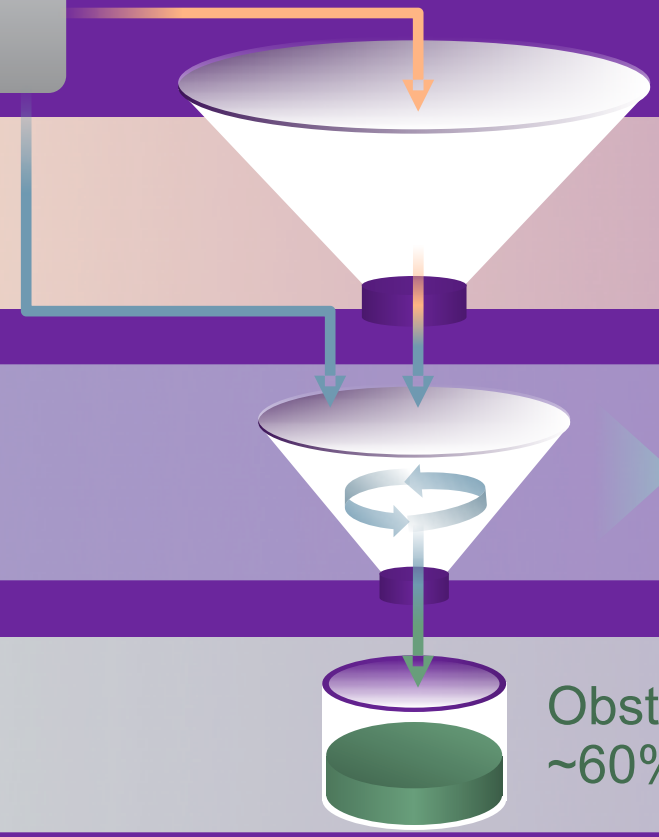
# Primary Care Physicians Routinely Manage Patients With Suspected or Diagnosed CHD

**~4M Stable, Symptomatic Patients Suggestive of Coronary Disease Annually**



Primary Care

Cardiology

Invasive Angiography

Often Repeat Testing

Diagnostic Tools

Clinical Factors

EKG Treadmill

Stress Echo

Nuclear Imaging

CT Angiography

Obstructive CAD is not found in ~60% patients[1]

## ~$4.5B annual expenditures[2]

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[1] Patel et al, *N Engl J Med* 2010;362:886-95; COMPASS study.
[2] IMV Market Reports

# Cost-effectiveness of Diagnostic Tests vs. Public Health Interventions for CHD

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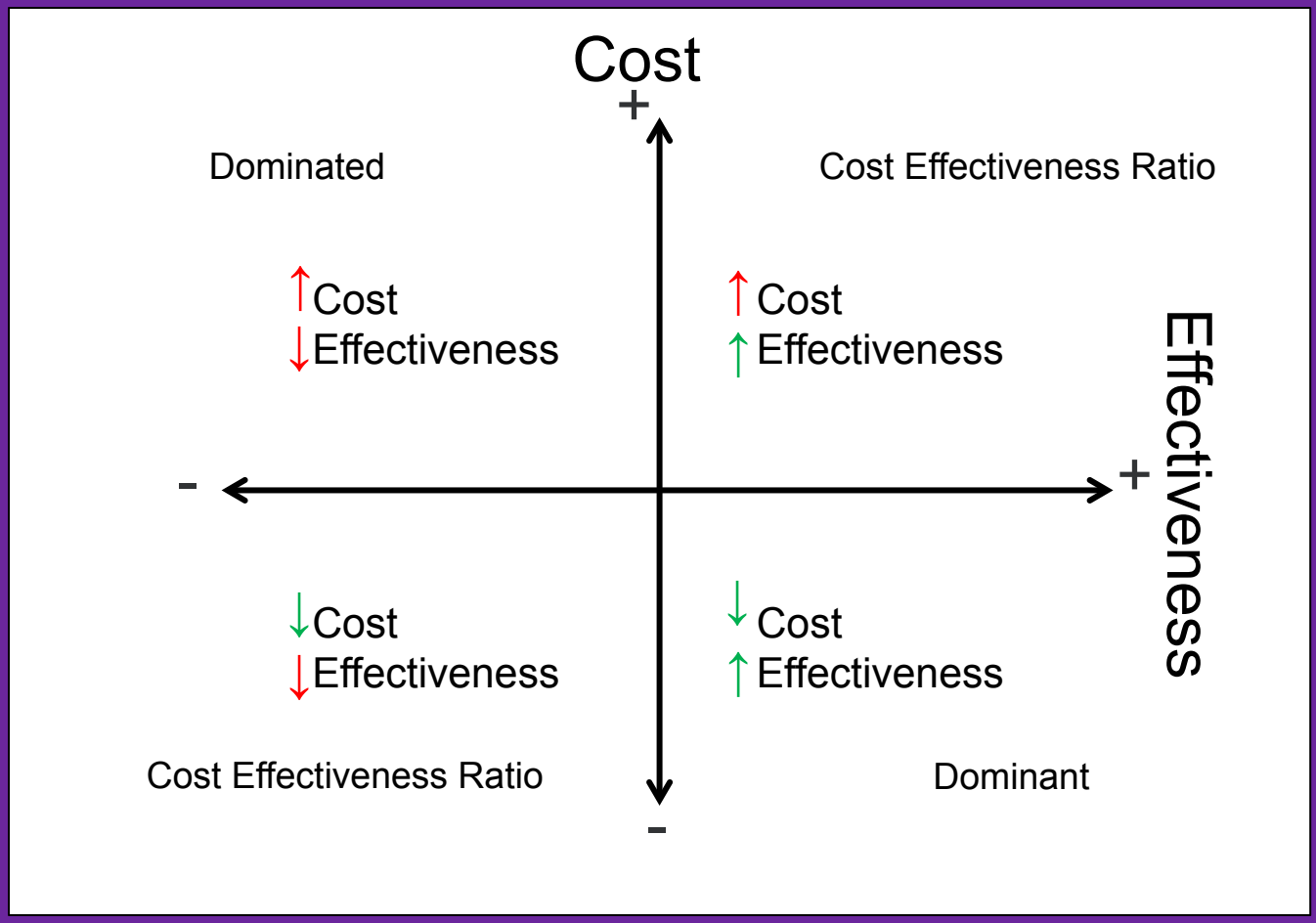
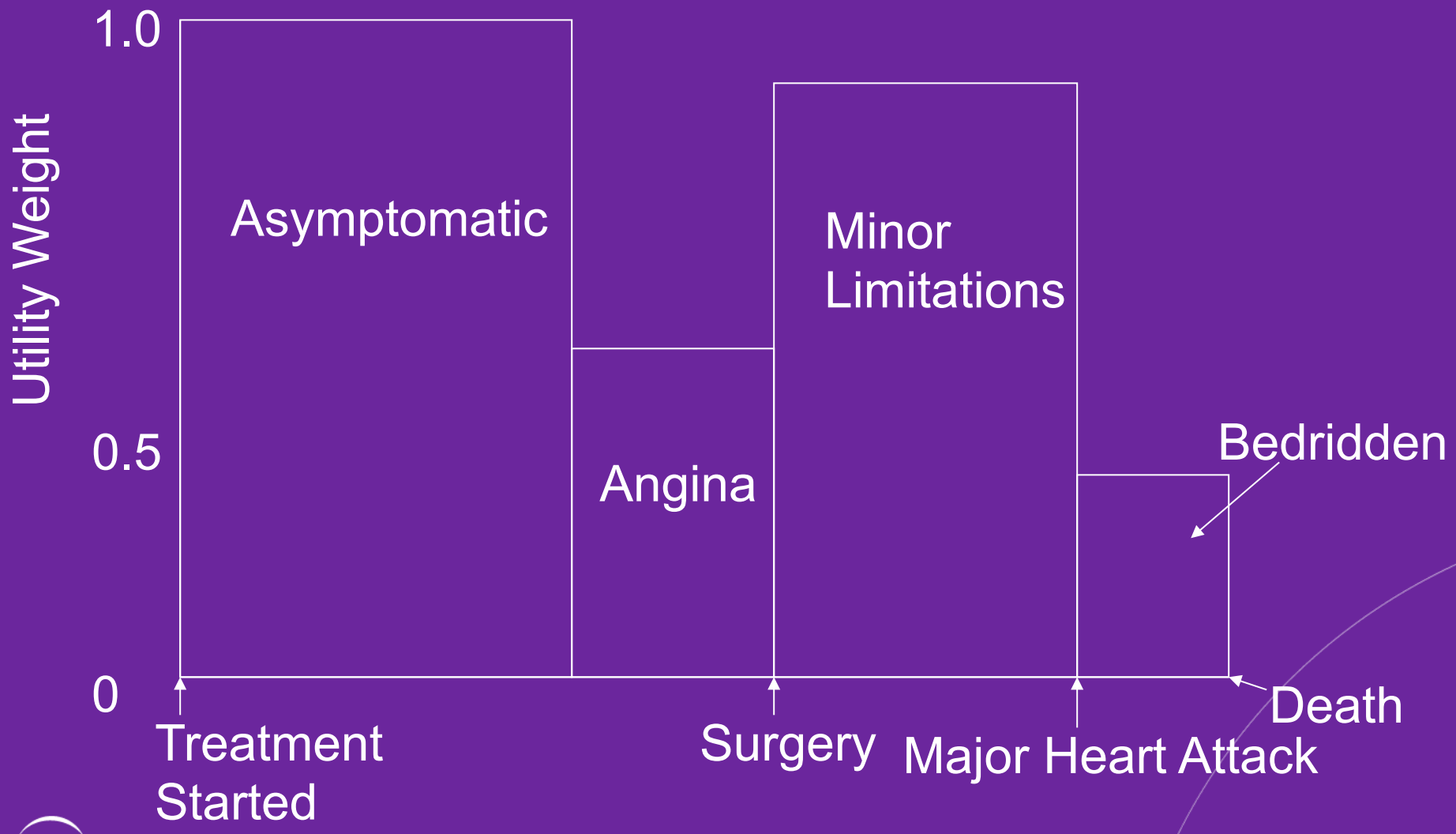

Cost
+
Dominated
Cost Effectiveness Ratio
Cost
Effectiveness
Cost
Effectiveness
-
+
Effectiveness
Cost
Effectiveness
Cost
Effectiveness
Cost Effectiveness Ratio
Dominant
-

# Quality-Adjusted Survival: Heart Attack Example

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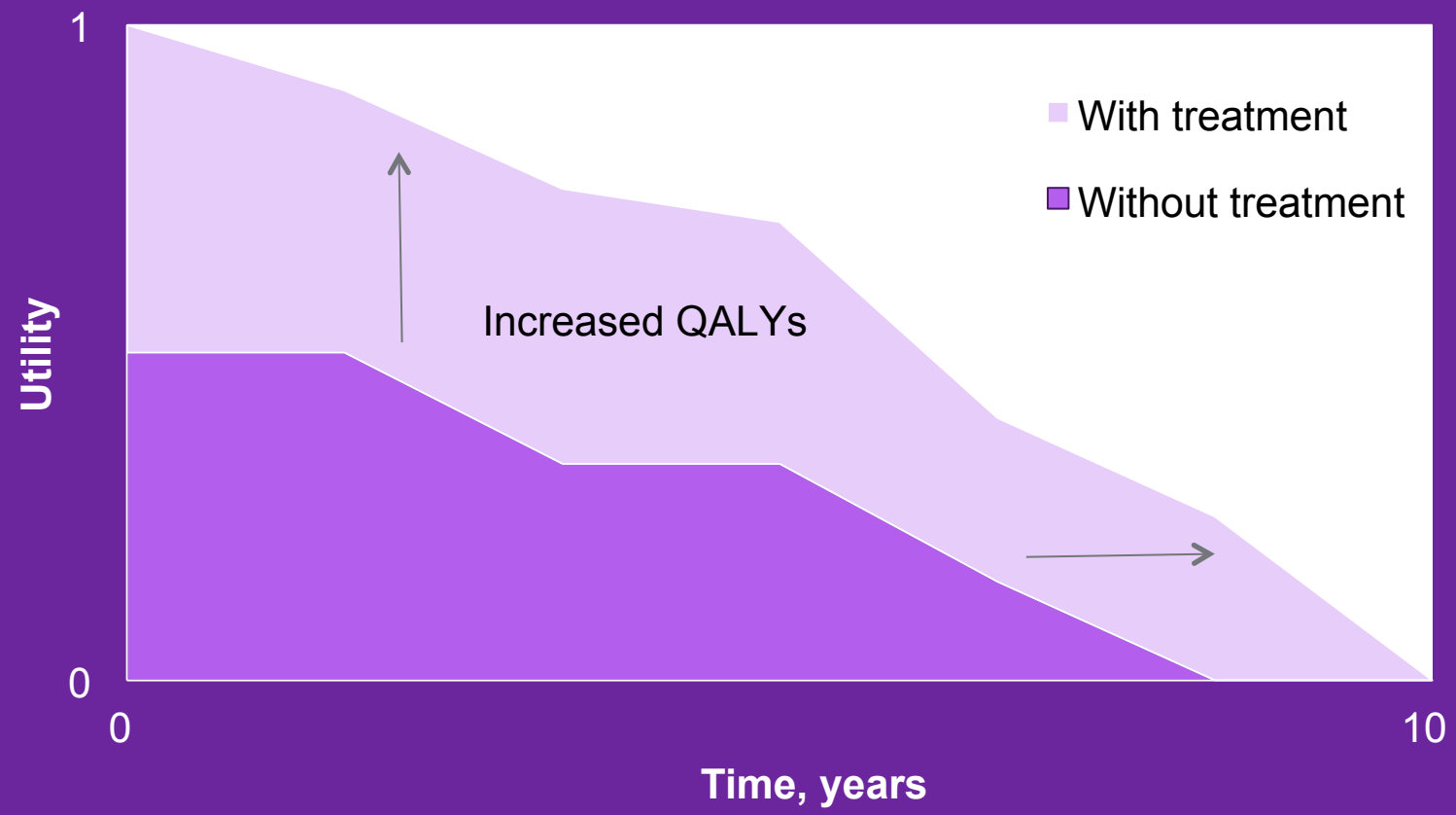
# QALYs

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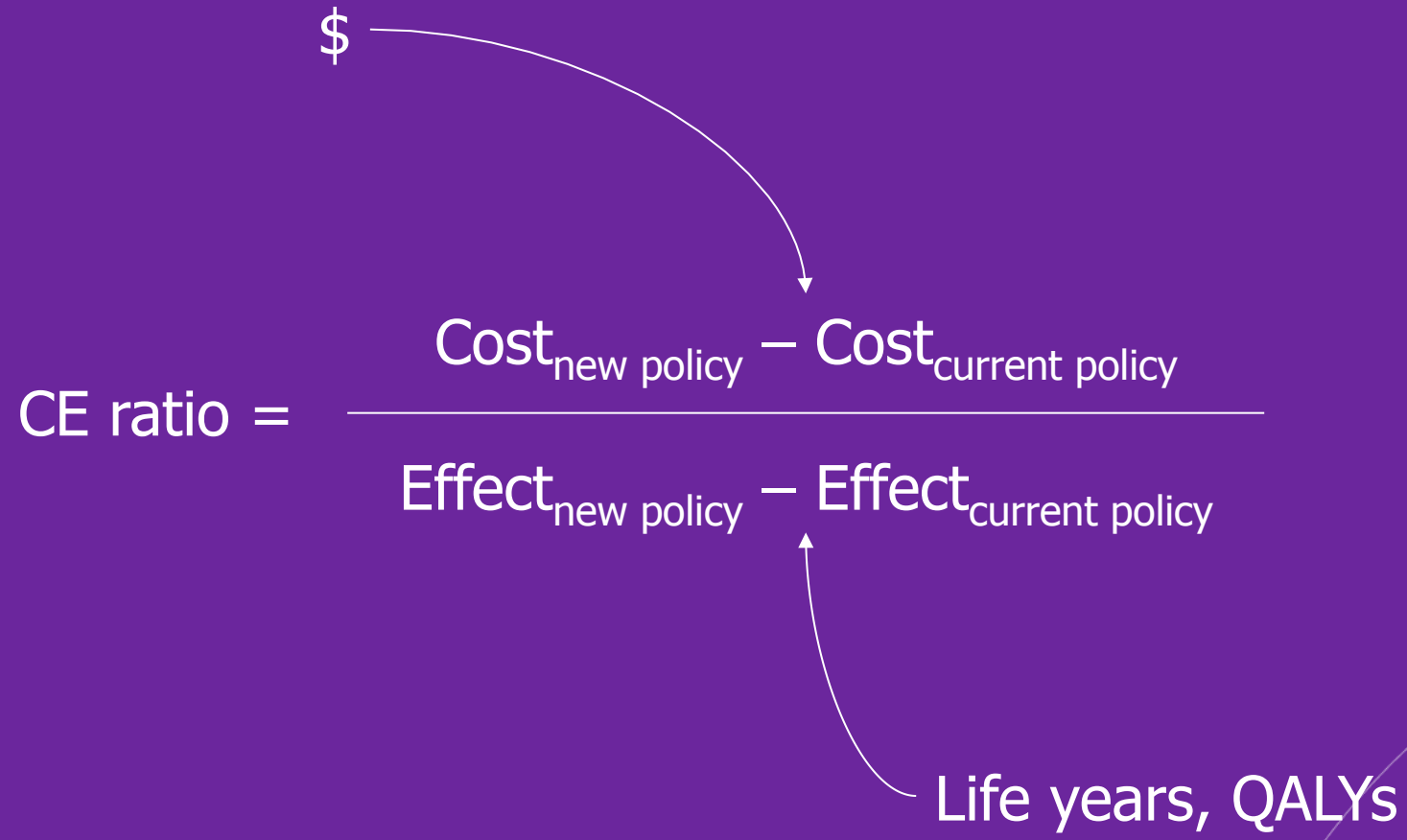
# Cost-effectiveness Ratio

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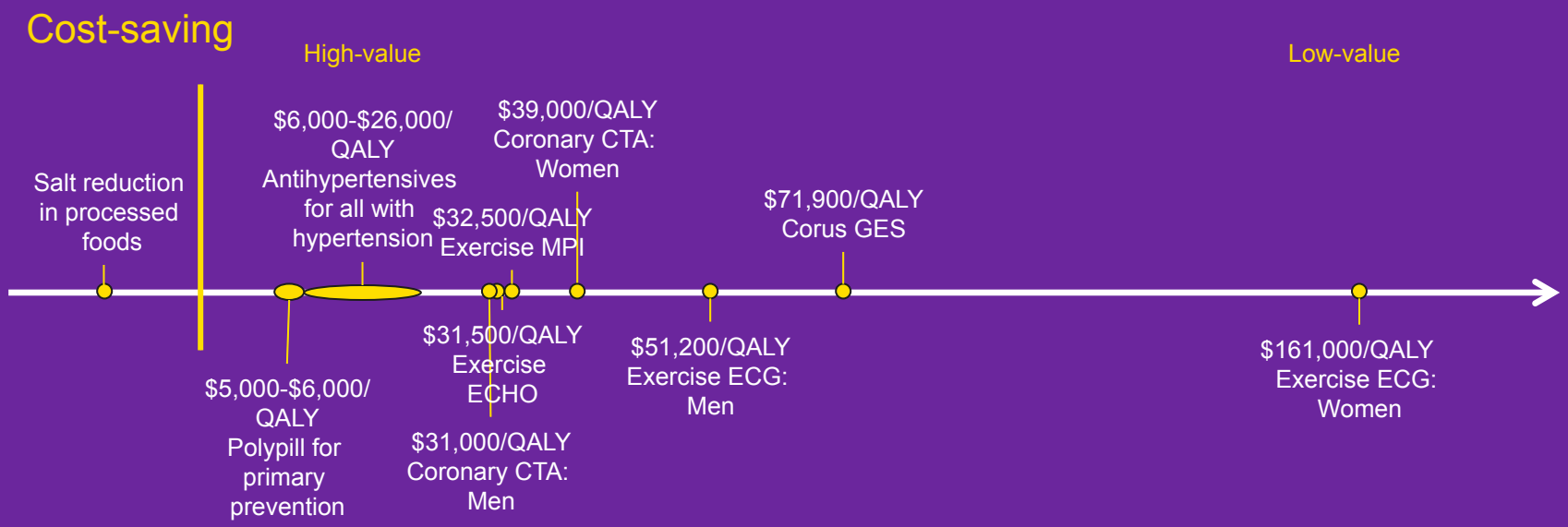
# Cost-effectiveness of Diagnostic Tests vs. Public Health Interventions for CHD




Sources: Ladapo et al, *JACC* 2009; Kuntz et al, *Annals* 1999; Phelps et al, *AHJ* 2014; Bibbins-Domingo, *NEJM* 2010; Weintraub et al, *Circulation* 2011

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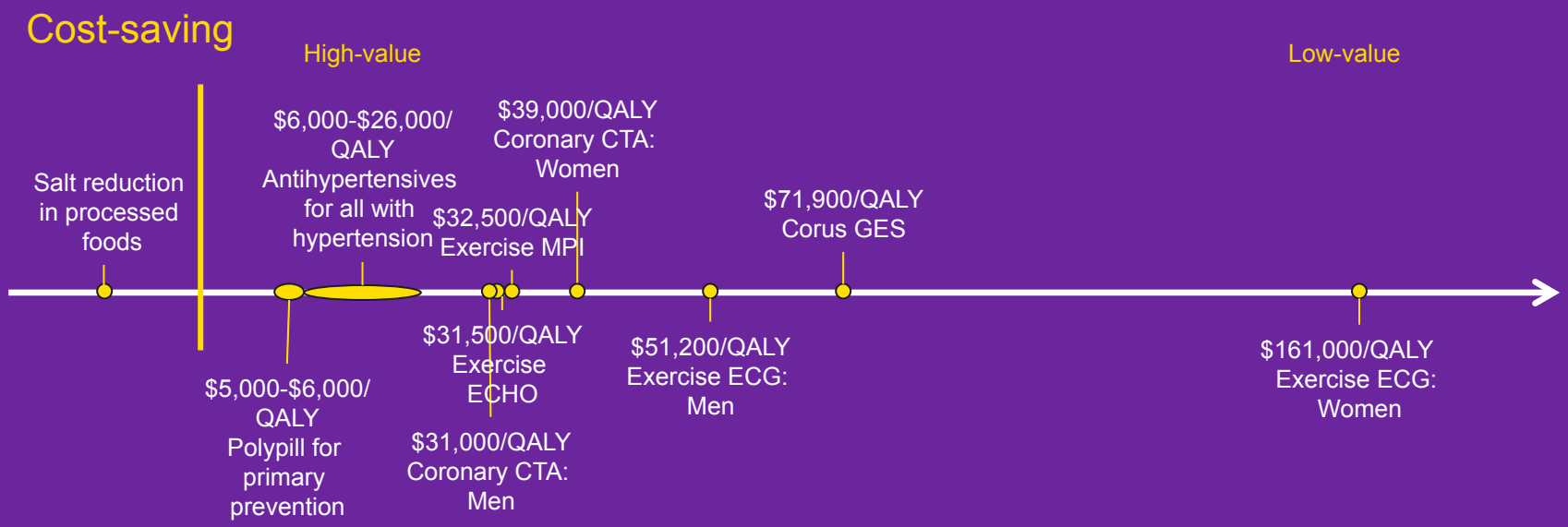
# Cost-effectiveness of Diagnostic Tests vs. Public Health Interventions for CHD




*Public health interventions tend to be more cost-effective but individual patients benefit from diagnostic tests, and diagnosis often cannot be made without them*

Sources: Ladapo et al, *JACC* 2009; Kuntz et al, *Annals* 1999; Phelps et al, *AHJ* 2014; Bibbins-Domingo, *NEJM* 2010; Weintraub et al, *Circulation* 2011

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# Challenges With Cardiac Stress Test Use: Clinical, Payer, and Policy Concerns

- ☑ **1. Too much low-value, high-intensity testing → less cost-effective at population level**
- ☐ 2. Poor diagnostic accuracy → missed diagnoses
- ☐ 3. Unnecessary radiation → radiation-related cancers

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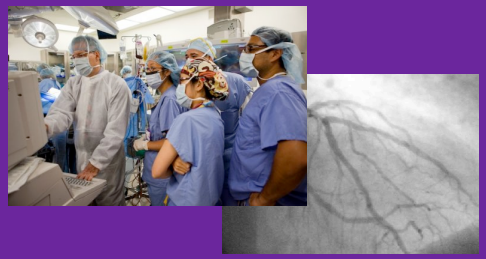
# Trend Toward Use of Increasingly Intensive Technologies in Patients Evaluated for CHD

Then



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Source of pictures: NYU School of Medicine, Bleiglass at the English language Wikipedia

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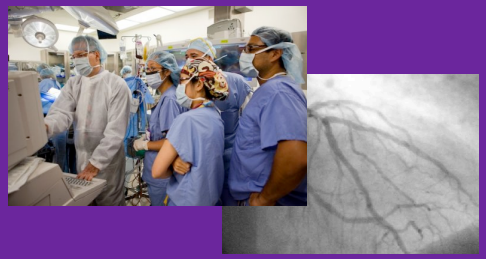

Now


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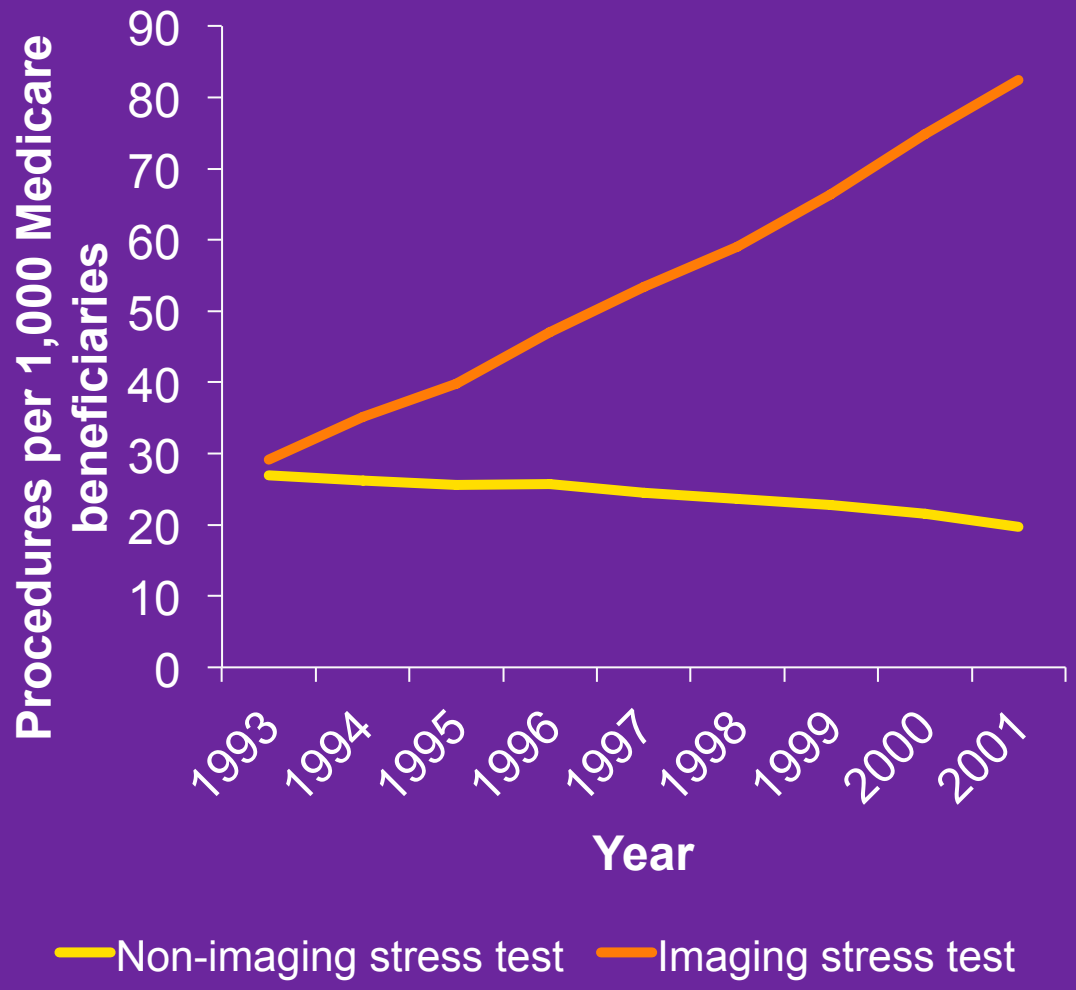
Source of pictures: NYU School of Medicine, Bleiglass at the English language Wikipedia

# Utilization of Cardiac Imaging Stress Tests Has Grown Tremendously




**Medicare population**

- Between 1993 and 2001, nearly 300% increase in use of imaging stress tests (stress echocardiography, ECHO; myocardial perfusion imaging, MPI)
- Rose from 29 to 82 per 1,000 beneficiaries
- Rate of non-imaging stress tests fell modestly
- Rate of PCI doubled from 6 to 12 per 1,000 beneficiaries

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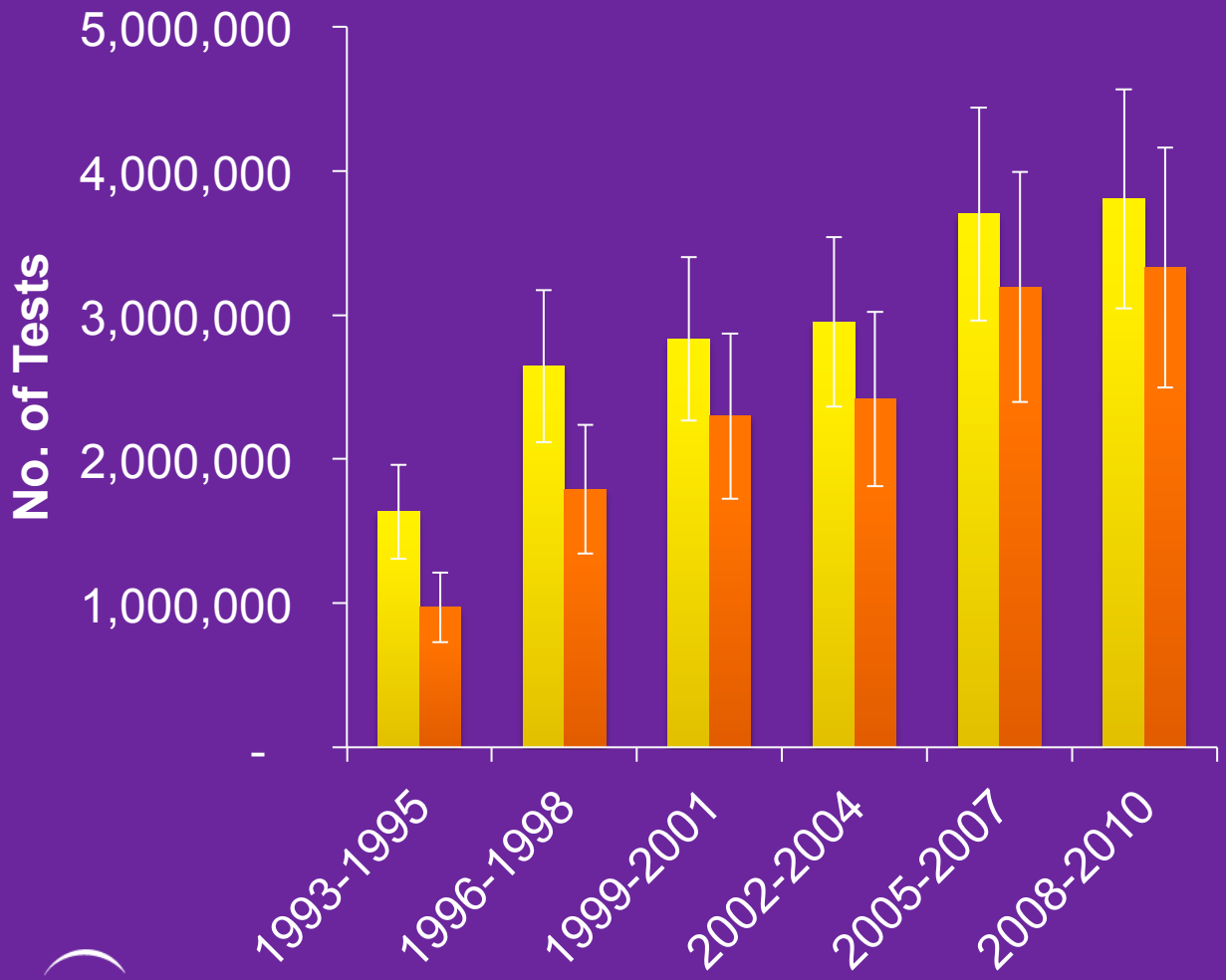
Lucas, *Circulation* 2006

# Ambulatory Care: Cardiac Stress Tests In Patients Without CHD, From 1993 To 2010




| | Avg. annual cost in 1993-1995 | Avg. annual cost in 2008-2010 |
|---|---|---|
| All cardiac stress tests | $820M | $2.0B |
| Stress imaging | $550M | $1.9B |

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Source: Ladapo et al, *Annals of Internal Medicine* 2014 (forthcoming); National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey data (1993-2010)

# Unnecessary Testing is Common

**Our Threshold for Testing Patients May be Falling**

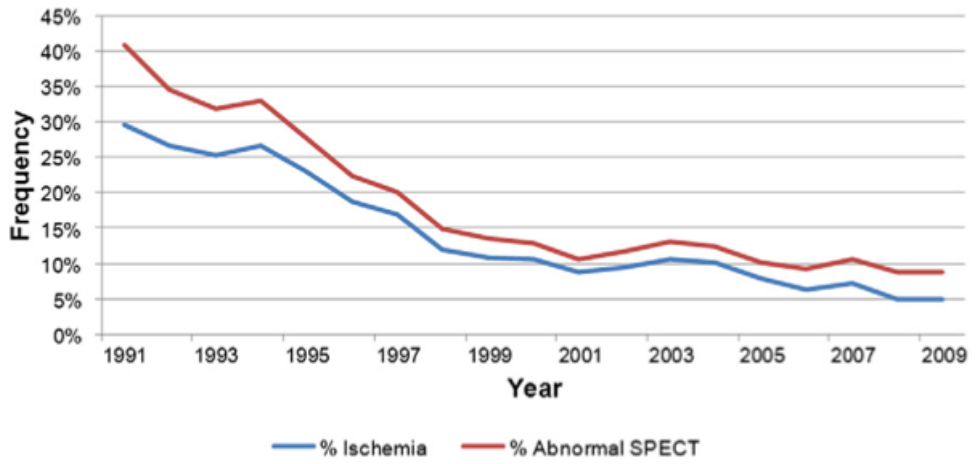
- 39,515 patients undergoing stress MPI between 1991-2009 at Cedars Sinai
- Incidence of abnormal scans **fell** from 41%→9%
- Incidence of ischemic scans **fell** from 30%→5%
- **Only 3%** of patients who did not have typical angina and could exercise had an abnormal scan

Journal of the American College of Cardiology
© 2013 by the American College of Cardiology Foundation
Published by Elsevier Inc.
Vol. 61, No. 10, 2013
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2012.11.056

**Temporal Trends in the Frequency of Inducible Myocardial Ischemia During Cardiac Stress Testing**

1991 to 2009

Alan Rozanski, MD,* Heidi Gransar, MS,†‡ Sean W. Hayes, MD,†‡ James Min, MD,†‡
John D. Friedman, MD,†‡ Louise E. J. Thomson, MBChB,†‡ Daniel S. Berman, MD†‡
*New York, New York; and Los Angeles, California*

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Rozanski, *JACC* 2013

# Challenges With Cardiac Stress Test Use: Clinical, Payer, and Policy Concerns

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- ☑ **2. Poor diagnostic accuracy → missed diagnoses**
- ☐ 3. Unnecessary radiation → radiation-related cancers

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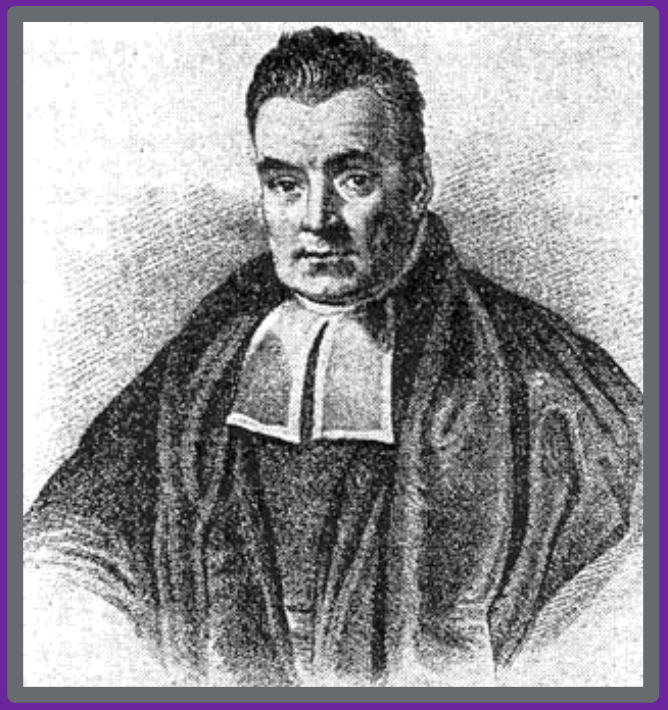
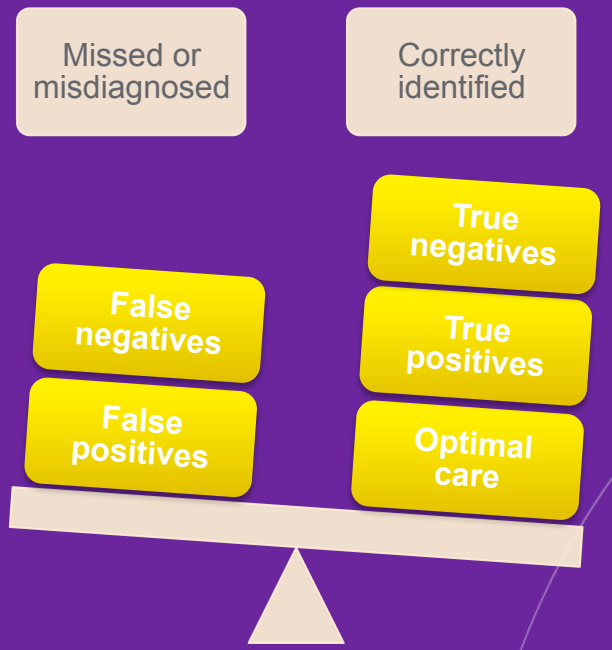
# Uncertainty About How to Interpret Diagnostic Test Results is Common

- Bayes' theorem defines how pretest disease risk and diagnostic test performance can be used to guide interpretation of test results



Reverend Thomas Bayes

$$P(A \mid B) = \frac{P(B \mid A)P(A)}{P(B)}$$

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# Referral Bias Influences Diagnostic Accuracy and Test Interpretation

## Referral bias

- Sometimes called “verification bias” or “workup bias”
- Occurs because higher-risk patients are preferentially referred to cardiac catheterization
- Bayesian methods needed to adjust diagnostic test performance for referral

## Biases clinical decision-making

- Because it biases test performance, it may also bias clinical decision-making

## Most studies do not account for referral

- Studies of stress test performance do not adjust for this phenomenon so estimates of sensitivity and specificity biased

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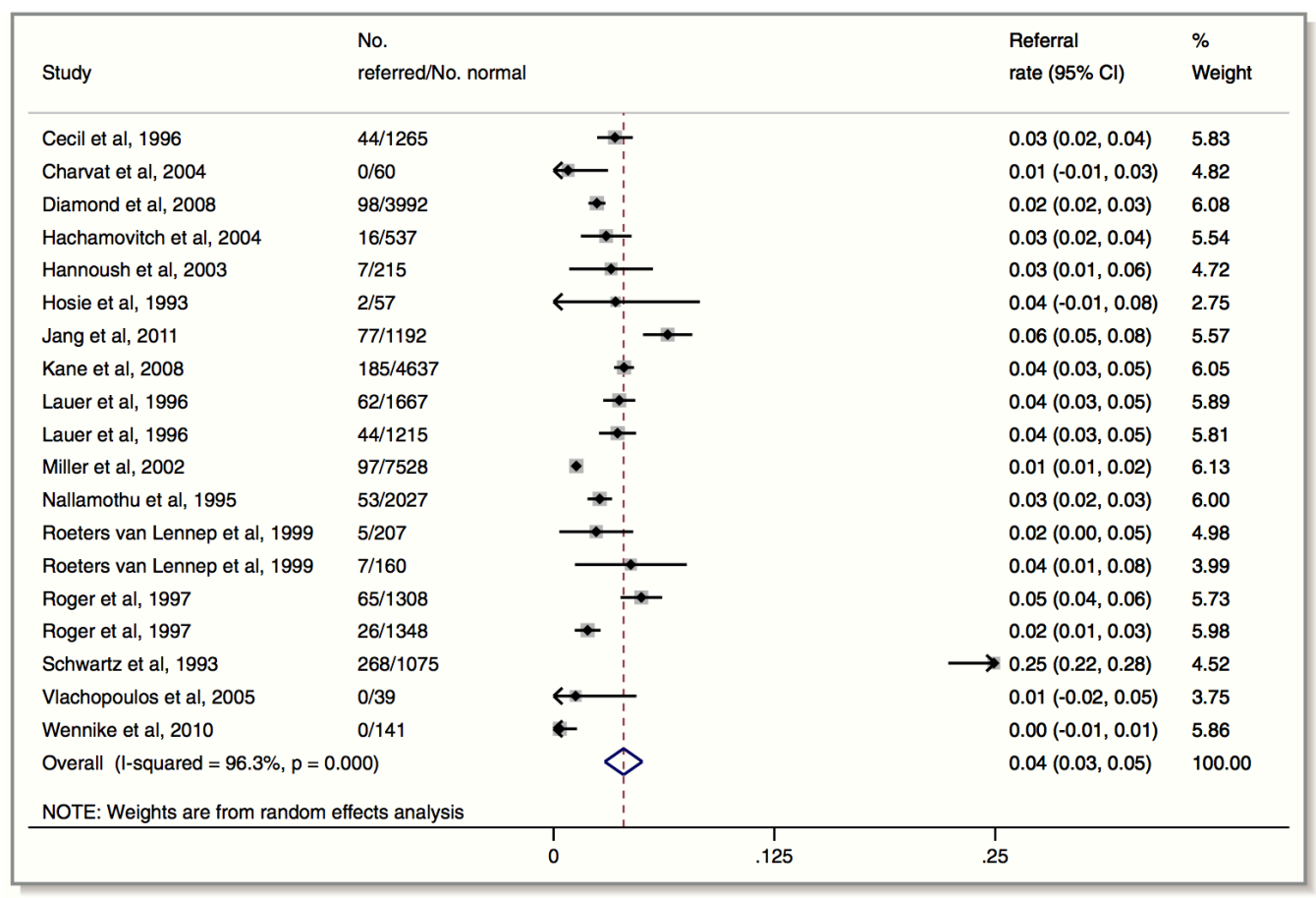
Begg, *Biometrics* 1983

Journal of the American Heart Association
OPEN ACCESS

# Clinical Implications of Referral Bias in the Diagnostic Performance of Exercise Testing for Coronary Artery Disease

Joseph A. Ladapo, Saul Blecker, Michael R. Elashoff, Jerome J. Federspiel, Dorice L. Vieira, Gaurav Sharma, Mark Monane, Steven Rosenberg, Charles E. Phelps and Pamela S. Douglas

# Cardiac Catheterization Referral Rates After **Normal** Exercise ECHO or MPI Results




**Referral rates are low after a normal study**

- Range of ~1% to 5% generally

**Homogenous**

- Geographic location and patient characteristics vary but little variation in referral rates

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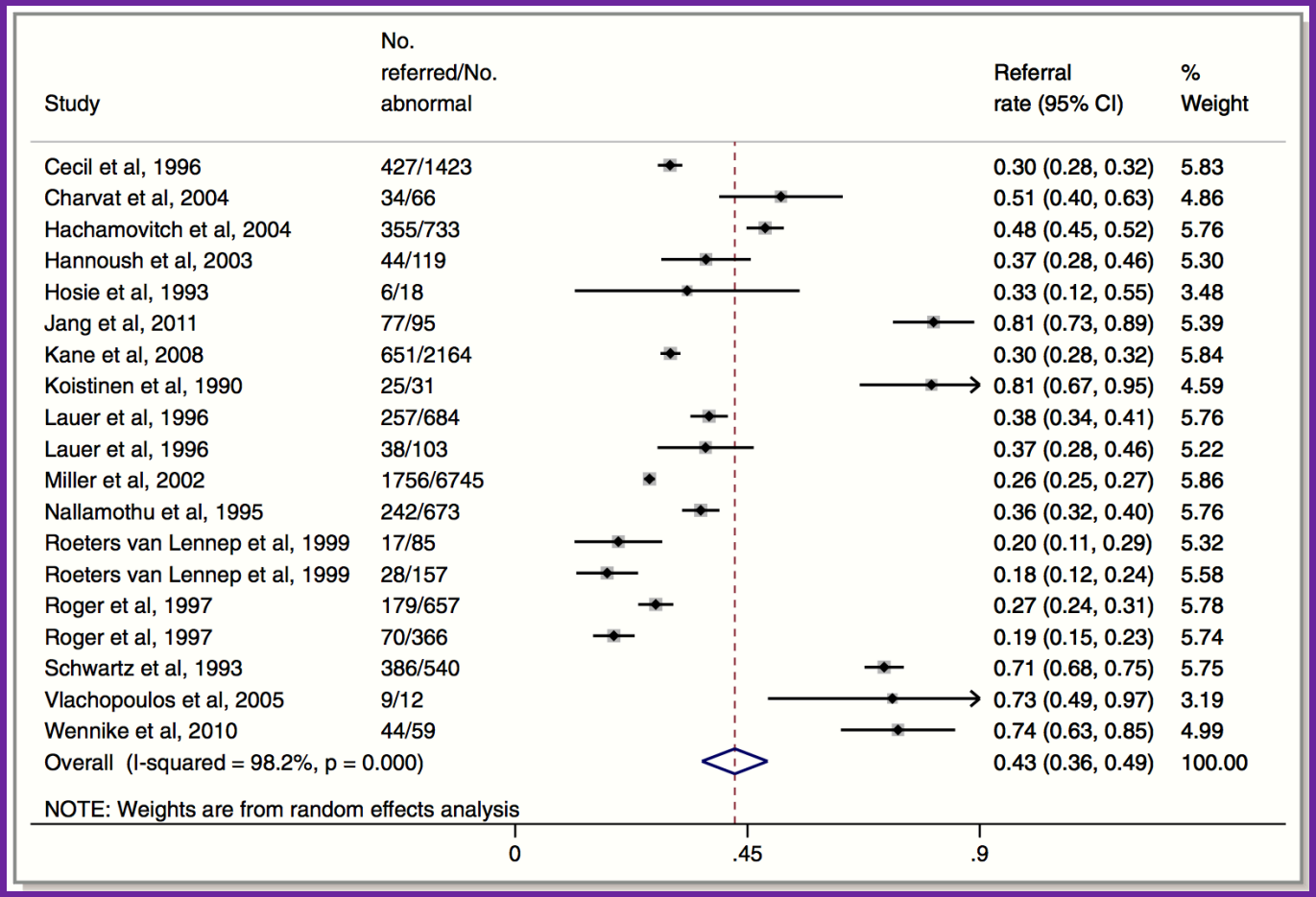
Ladapo et al, *JAHA* 2013

# Cardiac Catheterization Referral Rates After **Abnormal** Exercise ECHO or MPI Results




**Referral rates higher after an abnormal test**

- Range of ~20% to 50% generally

**Heterogeneity**

- Significant variation in referral rates

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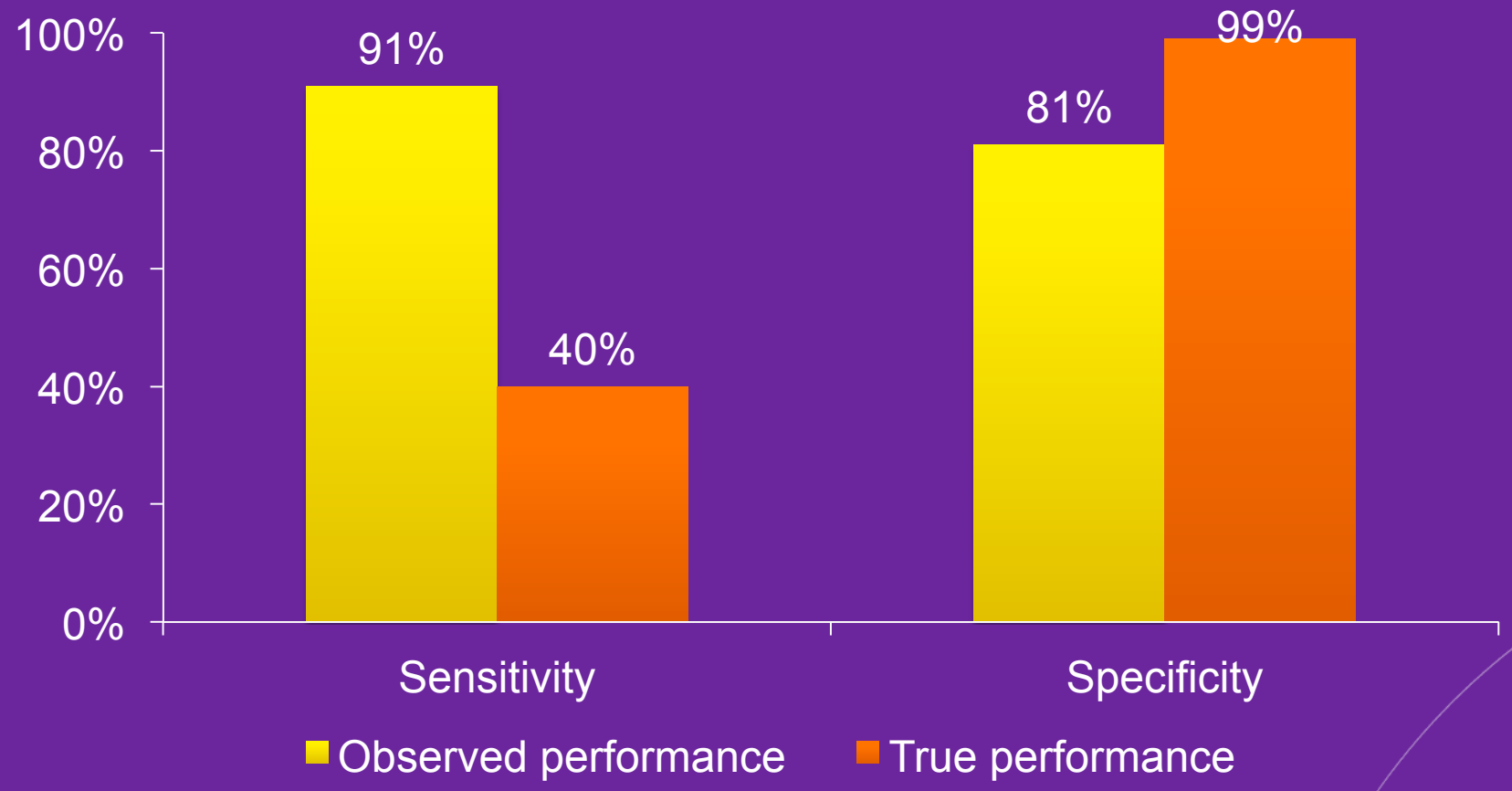
Ladapo et al, *JAHA* 2013

# Observed vs. True Diagnostic Performance of Exercise ECHO

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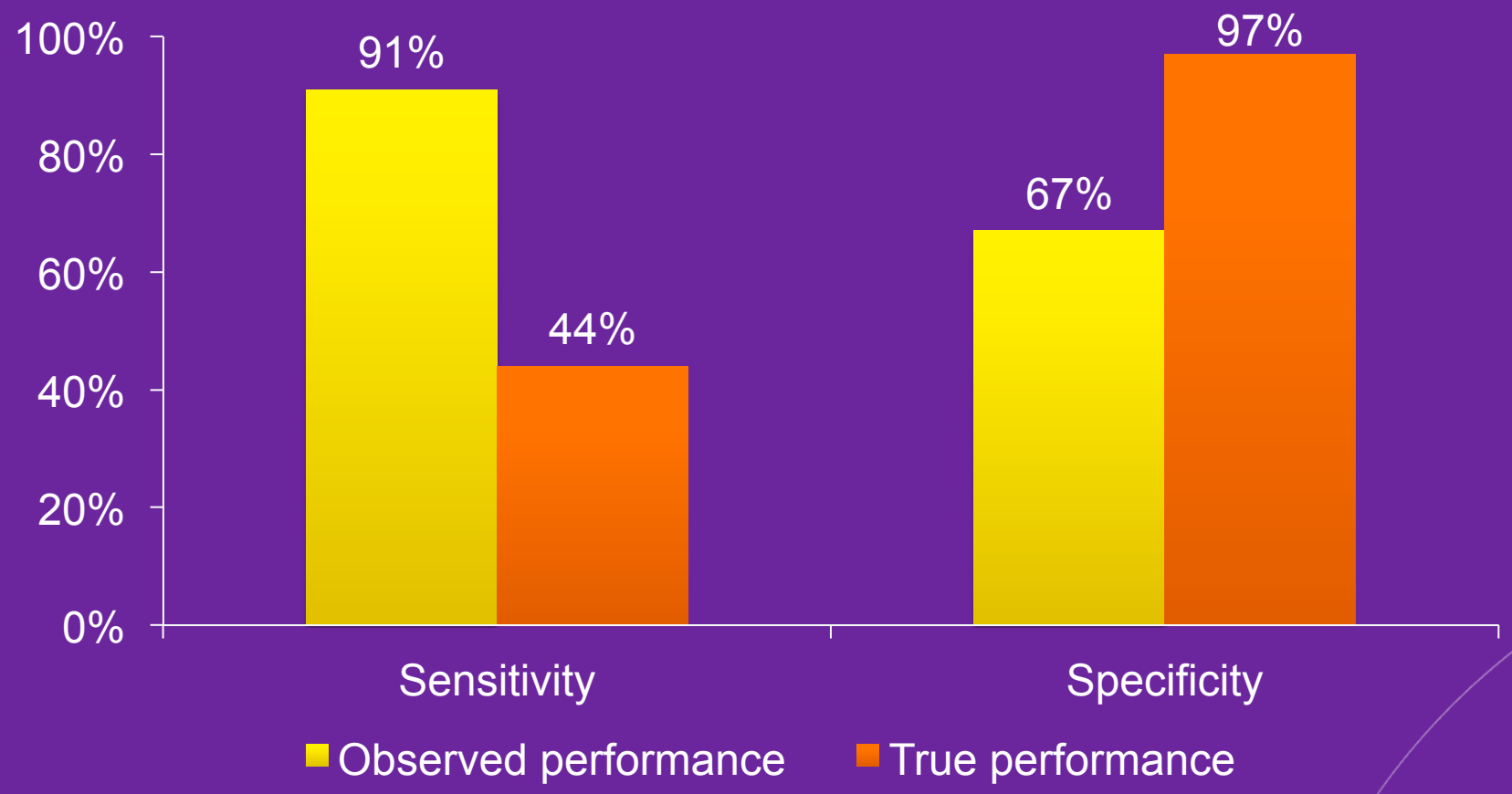
True performance = observed performance **after** adjustment for referral

# Observed vs. True Diagnostic Performance of Exercise MPI

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True performance = observed performance **after** adjustment for referral

# Morbidity and Mortality Attributable to Missed Diagnoses of CHD in the US

4 million patients/yr x 20% CHD prevalence x 60% false negative rate ≈

500,000 missed diagnoses

Approx. 2,200 preventable cardiac events

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Ladapo et al, *under review*

# Challenges With Cardiac Stress Test Use: Clinical, Payer, and Policy Concerns

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- ☑ 2. Poor diagnostic accuracy → missed diagnoses
- ☑ **3. Unnecessary radiation → radiation-related cancers**

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The New York Times

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THE RADIATION BOOM

## X-Rays and Unshielded Infants




**EXPEDITED PUBLICATION**

## Cumulative Exposure to Ionizing Radiation from Diagnostic and Therapeutic Cardiac Imaging P

### A Population-Based Analysis

Jersey Chen, MD, MPH,*§ Andrew J. Einstein, MD,
Harlan M. Krumholz, MD, SM,*†‡§ Yongfei Wang, MS,§ Joseph S. Ross, MD, MHS,#
Henry H. Ting, MD, MBA,** Nilay D. Shah, PHD,†† Khurram Nasir, MD, MPH,‡‡
Brahmajee K. Nallamothu, MD, MPH§§

*New Haven, Connecticut; New York, New York; Atlanta, Georgia; Rochester, Minnesota; Baltimore, Maryland; Boston, Massachusetts; and Ann Arbor, Michigan*

# Radiation Concerns Rise With Patients' Exposure

By ALASTAIR GEE
Published: June 12, 2012

The New York Times

Even in health care systems in they administer, the use of diagnostic imaging like CT and PET scans has soared, as has patients' radiation exposure, a new study has found.

OOK

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 27, 2009 VOL. 361 NO. 9

## Exposure to Low-Dose Ionizing Radiation from Medical Imaging Procedures

Reza Fazel, M.D., M.Sc., H
Jersey Chen, M.D., M.P.H., He
Andrew J. Einst

## Medicare Claims Show Overuse for CT Scanning

The New York Times

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# Unnecessary Radiation Exposure is a Growing Problem

## Potential harms related to radiation exposure are poorly understood

- Stress MPI accounts for 22% of cumulative effective radiation from medical sources
- One MPI ≈ 1,000 chest x-rays ≈ 10-15 mSv
- Persons at risk for repeated radiation exposure, such as healthcare workers and the nuclear industry, typically restricted to max 100 mSv every 5 years

## Columbia University Medical Center

- 1,097 consecutive patients, 8-10 years of follow-up
- Multiple MPIs performed in 424 patients (39%)
- Median cumulative effective dose from MPI was 29 mSv
- Median cumulative effective dose from medical sources was 64 mSv

## Medicare population

- Between 1993-2001, 34% of enrollees underwent repeat testing

## US nonelderly population

- 952,420 adults in 5 US markets (2005-2007)
- Among patients undergoing cardiac imaging, mean cumulative dose 16.4 mSv (1.5-190 mSv)
- MPI accounted for 74% of cumulative dose

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Fazel, *NEJM* 2009; Einstein, *JAMA* 2010; Gerber, *Circulation* 2009; Lucas, *Circulation* 2006; Chen, *JACC* 2010

# Reducing the Population Health Burden of Coronary Heart Disease: Clinical, Professional Society, and Policy Steps

- [x] **1. Reduce unnecessary testing**
- [ ] 2. Improve diagnostic accuracy
- [ ] 3. Promote prevention/Affordable Care Act

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# Improving Quality of Care: Reducing Unnecessary Testing

## Appropriate use criteria

- Growing physician awareness of appropriate use criteria for diagnostic testing in patients suspected of having CAD
- ACC and United Healthcare registry reported that 34% of stress MPIs were inappropriate or of uncertain appropriateness

## Insurer policies and regulation

- Prior authorization by radiology benefits managers
- Reductions in reimbursement
- Medicare released national coverage decision requesting more evidence for coronary CT angiography (CTCA)

## Patient/Professional education

- Informed decision-making

Choosing Wisely®
An initiative of the ABIM Foundation

- Shared decision-making
- Professional society scrutiny

***…Impact on health is unknown and needs to be studied***

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Shaw, *JACC: CV Imaging* 2010; Gibbons, *JACC* 2008

# Reducing the Population Health Burden of Coronary Heart Disease: Clinical, Professional Society, and Policy Steps

- ☑ 1. Reduce unnecessary testing
- ☑ **2. Improve diagnostic accuracy**
- ☐ 3. Promote prevention/Affordable Care Act

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# Improving Quality of Care: Optimizing Diagnostic Accuracy

**Research on diagnostic accuracy of stress testing that accounts for referral patterns to cardiac catheterization is needed**

- Wider dissemination of accurate information about diagnostic performance

**Coronary CT angiography**

- High-resolution visualization of coronary anatomy
- Limitation: Ischemic heart disease occurs in absence of coronary stenosis

**Blood-based gene-expression test for diagnosing obstructive CAD (Corus CAD)**

- First clinically validated gene expression test for CAD
- Nondiabetic patients only

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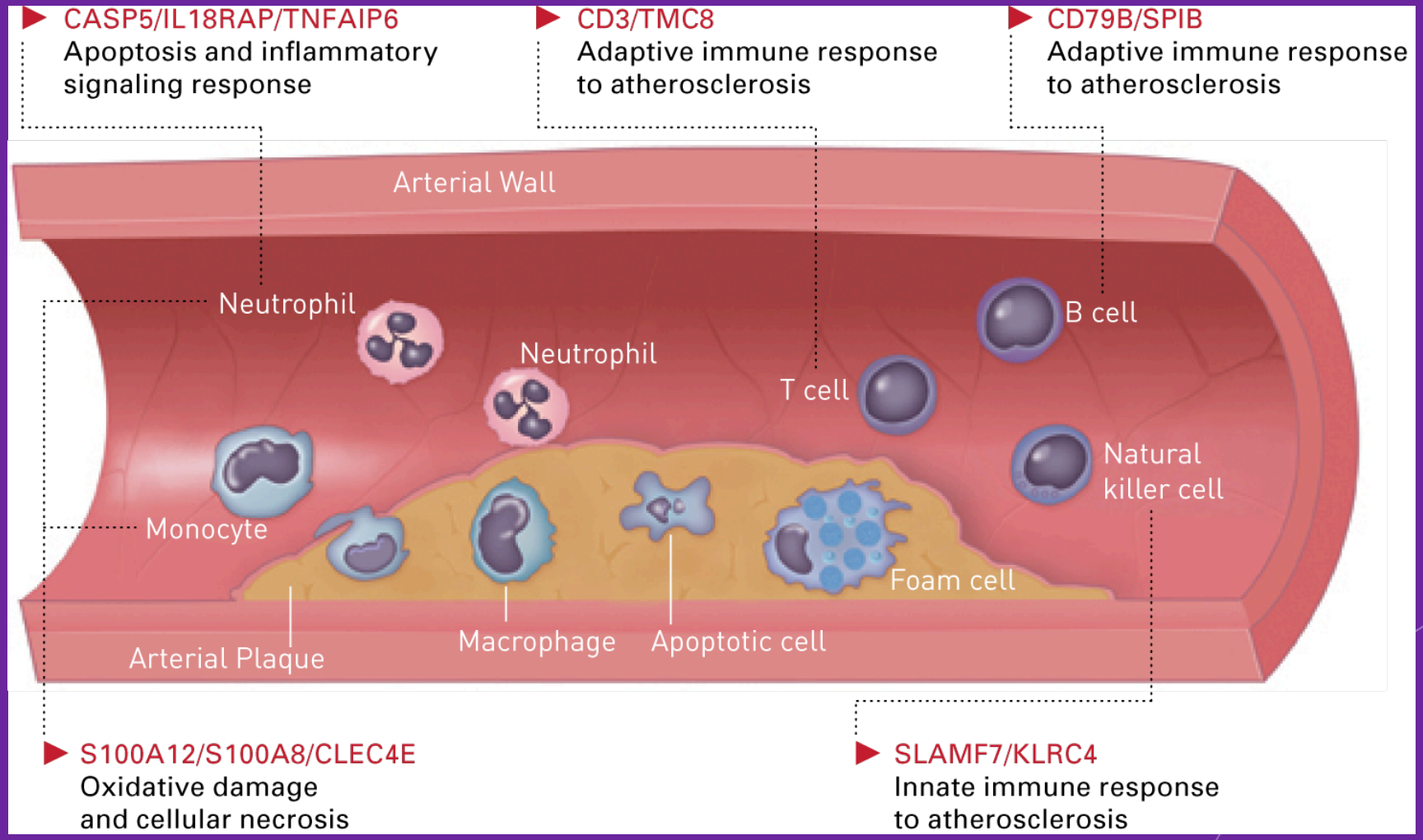
# Blood-based Gene Expression Score (GES) Measures Expression of 23 Genes From Peripheral Blood Cells




Picture source: CardioDx

Circulation
Cardiovascular Genetics
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association
Learn and Live

**A Blood Based Gene Expression Test for Obstructive Coronary Artery Disease Tested in Symptomatic Non-Diabetic Patients Referred for Myocardial Perfusion Imaging: The COMPASS Study**

Gregory S. Thomas, Szilard Voros, John A. McPherson, Alexandra J. Lansky, Mary E. Winn, Timothy M. Bateman, Michael R. Elashoff, Hsiao D. Lieu, Andrea M. Johnson, Susan E. Daniels, Joseph A. Ladapo, Charles E. Phelps, Pamela S. Douglas and Steven Rosenberg

*Circ Cardiovasc Genet* published online February 15, 2013;
DOI: 10.1161/CIRCGENETICS.112.964015
Circulation: Cardiovascular Genetics is published by the American Heart Association. 7272 Greenville Avenue, Dallas, TX 72514
 Print ISSN: 1942-325X. Online ISSN: 1942-3268

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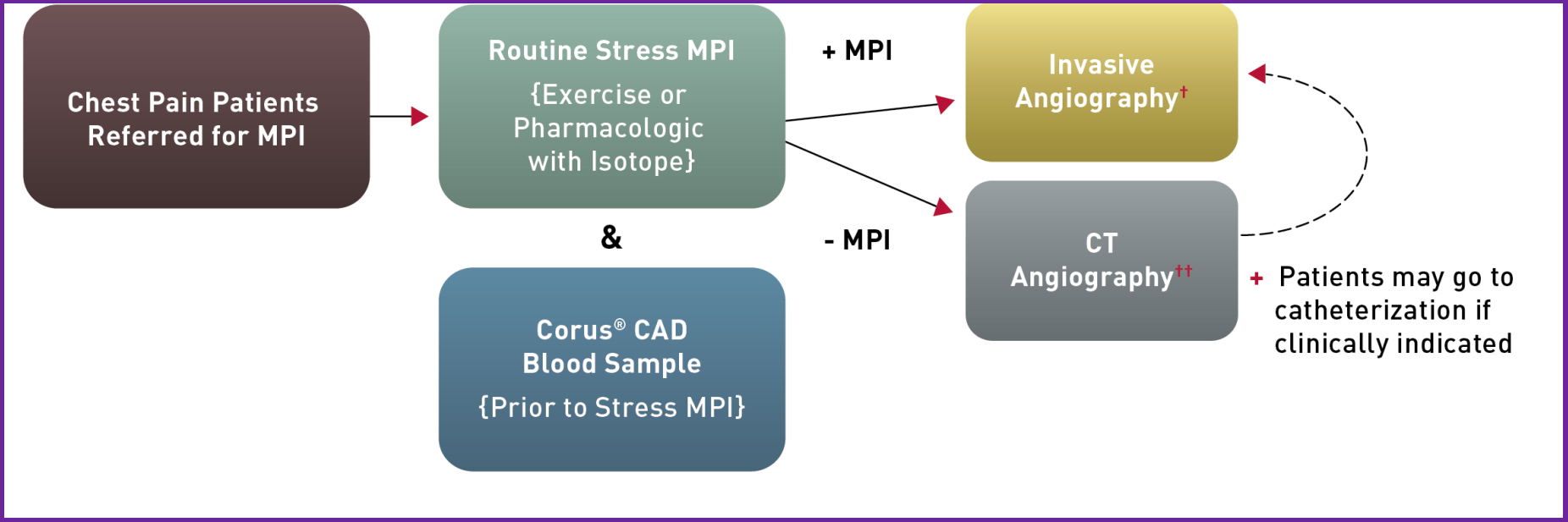
Thomas et al, *Circ Card Genetics* 2013

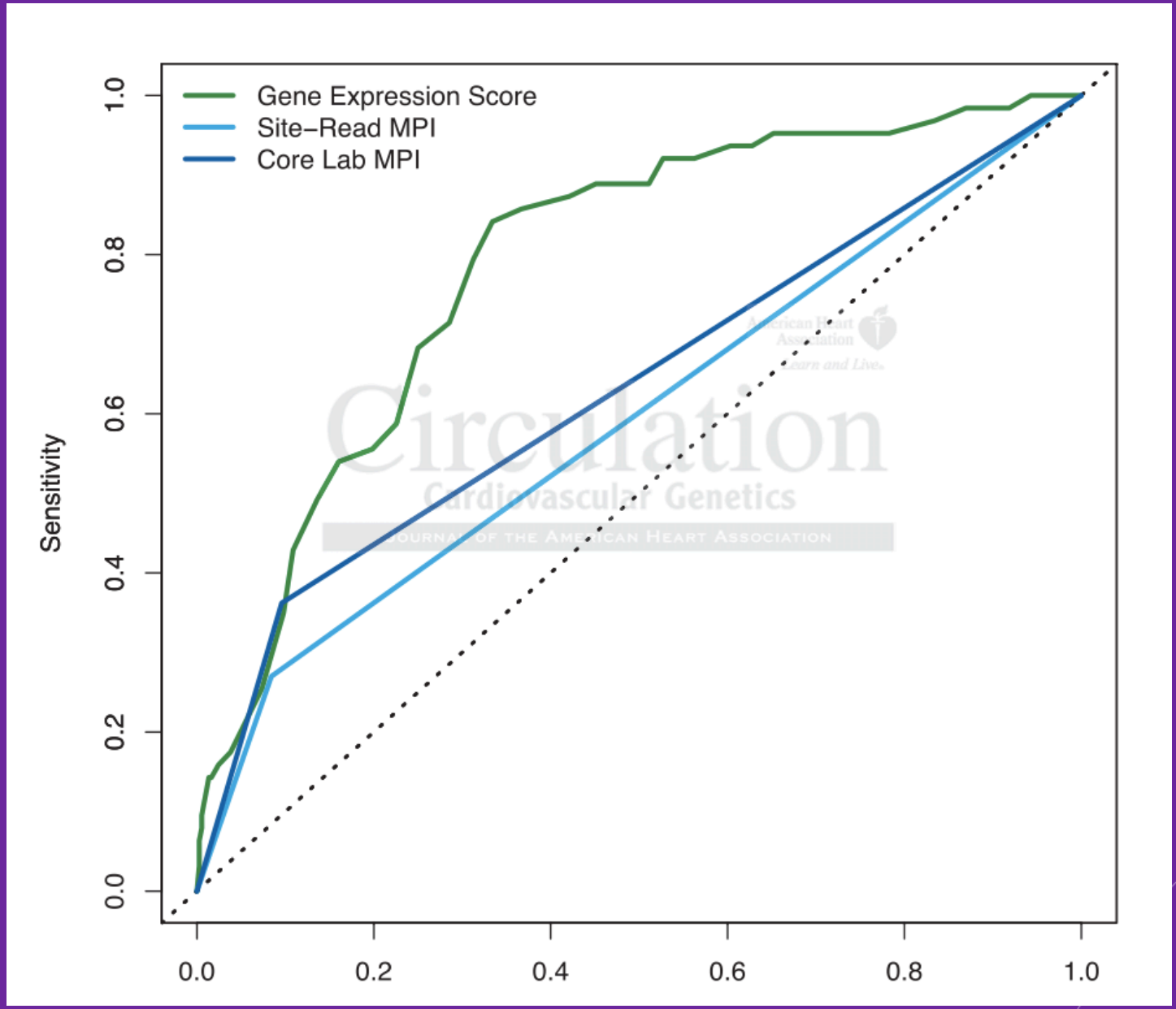
# COMPASS Trial Design

## COMPASS (Coronary Obstruction Detection by Molecular Personalized Gene Expression)




- Primary Endpoint: GES performance by ROC analysis
- Steering Committee: Greg Thomas, MD, MPH, John McPherson, MD, Alexandra Lansky, MD, Szilard Voros, MD
- 19 U.S. sites, 431 patients

† Data analyzed by Quantitative Coronary Angiography (QCA) core lab.
†† Data analyzed by CT Angiography core lab.



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# Reducing the Population Health Burden of Coronary Heart Disease: Clinical, Professional Society, and Policy Steps

- ☑ 1.Reduce unnecessary testing
- ☑ 2. Improve diagnostic accuracy
- ☑ **3. Promote prevention/Affordable Care Act**

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# Implications For Cardiovascular Health: Healthcare Reform and Focus on Prevention

## Affordable Care Act

- No more gender rating → women cannot be charged higher premiums than men
- Expansion of insurance access → more testing
- Elimination of cost-sharing for some preventive care

## ACC/AHA Cholesterol Guidelines

- Lower thresholds for prescribing statins
- New risk equations for predicting CAD events

## Million Hearts®

- Launched by Dept of Health and Human Services in 2011 to prevent 1 million heart attacks and strokes by 2017
- **ABCS** - **A**spirin, **B**lood-pressure control, **C**holesterol management, and **S**moking cessation

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# Conclusions

- Population health burden of cardiovascular disease is substantial, but many public health interventions and diagnostic tests are cost-effective
- Cardiac stress testing, the principal test used to diagnose CHD, may be overused, inaccurate, and expose patients to unnecessary radiation
- Clinical guidelines, new technologies, and recent policy changes may improve the effective use of diagnostic technologies and reduce the population health burden of CHD

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**Thank you!**

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