Reducing the Population Health Burden of Cardiovascular Disease

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Department of Population Health
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
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
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
Risk Factors for Cardiovascular Disease

- Diabetes
- High Cholesterol
- High Blood Pressure
- Smoking
- Physical Inactivity
- Obesity

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

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 \( \approx 100\% \)

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

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
Cardiac Stress Testing

Source of picture: NHLBI
Clinical Decision Pathway for Patients Evaluated for CHD

Initial Exam for Chest Pain

Cardiac Stress Testing

Invasive Angio

No Further Dx or Tx

Treatment

No MI

MI

Death

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

Obstructive CAD is not found in ~60% patients

~$4.5B annual expenditures

Diagnostic Tools

Clinical Factors
EKG Treadmill
Stress Echo
Nuclear Imaging
CT Angiography

2 IMV Market Reports
Cost-effectiveness of Diagnostic Tests vs. Public Health Interventions for CHD
Dominated

Cost Effectiveness Ratio

↑ Cost
↓ Effectiveness

Cost Effectiveness Ratio

↓ Cost
↓ Effectiveness

Dominant

↑ Cost
↑ Effectiveness

↑ Cost
↓ Effectiveness

↑ Cost
↑ Effectiveness
Quality-Adjusted Survival: Heart Attack Example

Utility Weight

Asymptomatic

Minor Limitations

Angina

Bedridden

Death

Treatment Started

Surgery

Major Heart Attack
QALYs

Utility

With treatment

Without treatment

Increased QALYs

Time, years

0

0

10
Cost-effectiveness Ratio

\[ \text{CE ratio} = \frac{\text{Cost}_{\text{new policy}} - \text{Cost}_{\text{current policy}}}{\text{Effect}_{\text{new policy}} - \text{Effect}_{\text{current policy}}} \]

\[ \text{Life years, QALYs} \]
Cost-effectiveness of Diagnostic Tests vs. Public Health Interventions for CHD

Cost-saving

- Salt reduction in processed foods
  - $5,000-$6,000/QALY
- Antihypertensives for all with hypertension
  - $6,000-$26,000/QALY
- Polypill for primary prevention
  - $5,000-$6,000/QALY

High-value

- Antihypertensives for all with hypertension
  - $6,000-$26,000/QALY
- Exercise ECG: Men
  - $32,500/QALY
- Exercise MPI
  - $39,000/QALY
- Coronary CTA: Men
  - $31,000/QALY
- Coronary CTA: Women
  - $31,500/QALY
- Exercise ECHO
  - $51,200/QALY

Low-value

- Antihypertensives for all with hypertension
  - $6,000-$26,000/QALY
- Polypill for primary prevention
  - $5,000-$6,000/QALY
- Coronary CTA: Women
  - $71,900/QALY
- Exercise ECG: Women
  - $161,000/QALY

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.

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

Then

Source of pictures: NYU School of Medicine, Bleiglass at the English language Wikipedia
Trend Toward Use of Increasingly Intensive Technologies in Patients Evaluated for CHD

Then

Now

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

Lucas, Circulation 2006
Ambulatory Care: Cardiac Stress Tests In Patients Without CHD, From 1993 To 2010

<table>
<thead>
<tr>
<th></th>
<th>No. of Tests</th>
<th>Avg. annual cost in 1993-1995</th>
<th>Avg. annual cost in 2008-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any cardiac stress test</td>
<td>2,500,000</td>
<td>$820M</td>
<td>$2.0B</td>
</tr>
<tr>
<td>Stress imaging</td>
<td>2,000,000</td>
<td>$550M</td>
<td>$1.9B</td>
</tr>
</tbody>
</table>

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

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, MBCxT,B,†‡ Daniel S. Berman, MD†‡

New York, New York, and Los Angeles, California

Rozanski, JACC 2013
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
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

\[ P(A \mid B) = \frac{P(B \mid A)P(A)}{P(B)} \]

Reverend Thomas Bayes
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

Begg, *Biometrics* 1983
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
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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<table>
<thead>
<tr>
<th>Study</th>
<th>No. referred/No. normal</th>
<th>Referral rate (95% CI)</th>
<th>% Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cecil et al, 1996</td>
<td>44/1265</td>
<td>0.03 (0.02, 0.04)</td>
<td>5.83</td>
</tr>
<tr>
<td>Charvat et al, 2004</td>
<td>0/60</td>
<td>0.01 (-0.01, 0.03)</td>
<td>4.68</td>
</tr>
<tr>
<td>Diamond et al, 2008</td>
<td>98/39992</td>
<td>0.02 (0.02, 0.03)</td>
<td>6.08</td>
</tr>
<tr>
<td>Hachamovitch et al, 2004</td>
<td>16/537</td>
<td>0.03 (0.02, 0.04)</td>
<td>5.54</td>
</tr>
<tr>
<td>Hannoush et al, 2003</td>
<td>7/215</td>
<td>0.03 (0.01, 0.06)</td>
<td>4.72</td>
</tr>
<tr>
<td>Hosie et al, 1993</td>
<td>2/57</td>
<td>0.04 (-0.01, 0.08)</td>
<td>2.75</td>
</tr>
<tr>
<td>Jang et al, 2011</td>
<td>77/1192</td>
<td>0.06 (0.05, 0.08)</td>
<td>5.57</td>
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<tr>
<td>Kane et al, 2008</td>
<td>185/4637</td>
<td>0.04 (0.03, 0.05)</td>
<td>6.05</td>
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<tr>
<td>Lauer et al, 1996</td>
<td>62/1667</td>
<td>0.04 (0.03, 0.05)</td>
<td>5.89</td>
</tr>
<tr>
<td>Lauer et al, 1996</td>
<td>44/1215</td>
<td>0.04 (0.03, 0.05)</td>
<td>5.81</td>
</tr>
<tr>
<td>Miller et al, 2002</td>
<td>977/528</td>
<td>0.01 (0.01, 0.02)</td>
<td>6.13</td>
</tr>
<tr>
<td>Nallamothu et al, 1995</td>
<td>53/2027</td>
<td>0.03 (0.02, 0.03)</td>
<td>6.00</td>
</tr>
<tr>
<td>Roeters van Lennep et al, 1999</td>
<td>5/207</td>
<td>0.02 (0.00, 0.05)</td>
<td>4.98</td>
</tr>
<tr>
<td>Roeters van Lennep et al, 1999</td>
<td>7/160</td>
<td>0.04 (0.01, 0.08)</td>
<td>3.99</td>
</tr>
<tr>
<td>Roger et al, 1997</td>
<td>65/1308</td>
<td>0.05 (0.04, 0.06)</td>
<td>5.73</td>
</tr>
<tr>
<td>Roger et al, 1997</td>
<td>28/1348</td>
<td>0.02 (0.01, 0.03)</td>
<td>5.98</td>
</tr>
<tr>
<td>Schwartz et al, 1993</td>
<td>268/1075</td>
<td>0.25 (0.22, 0.28)</td>
<td>4.52</td>
</tr>
<tr>
<td>Vlachopoulos et al, 2005</td>
<td>0/39</td>
<td>0.01 (-0.02, 0.05)</td>
<td>3.75</td>
</tr>
<tr>
<td>Wennike et al, 2010</td>
<td>0/141</td>
<td>0.00 (-0.01, 0.01)</td>
<td>5.86</td>
</tr>
<tr>
<td>Overall (I² = 96.3%, p = 0.000)</td>
<td></td>
<td>0.04 (0.03, 0.05)</td>
<td>100.00</td>
</tr>
</tbody>
</table>

NOTE: Weights are from random effects analysis

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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<td>0.30 (0.28, 0.32)</td>
<td>5.83</td>
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<tr>
<td>Charvat et al, 2004</td>
<td>34/66</td>
<td>0.51 (0.40, 0.63)</td>
<td>4.86</td>
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<tr>
<td>Hachamovitch et al, 2004</td>
<td>355/733</td>
<td>0.48 (0.45, 0.52)</td>
<td>5.76</td>
</tr>
<tr>
<td>Hannoush et al, 2003</td>
<td>44/119</td>
<td>0.37 (0.28, 0.46)</td>
<td>5.30</td>
</tr>
<tr>
<td>Hosie et al, 1993</td>
<td>6/18</td>
<td>0.33 (0.12, 0.55)</td>
<td>3.48</td>
</tr>
<tr>
<td>Jang et al, 2011</td>
<td>77/95</td>
<td>0.81 (0.73, 0.89)</td>
<td>5.39</td>
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<tr>
<td>Kane et al, 2008</td>
<td>651/2164</td>
<td>0.30 (0.28, 0.32)</td>
<td>5.84</td>
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<tr>
<td>Koistinen et al, 1990</td>
<td>25/31</td>
<td>0.61 (0.57, 0.95)</td>
<td>4.59</td>
</tr>
<tr>
<td>Lauer et al, 1996</td>
<td>257/684</td>
<td>0.38 (0.34, 0.41)</td>
<td>5.76</td>
</tr>
<tr>
<td>Lauer et al, 1996</td>
<td>38/103</td>
<td>0.37 (0.28, 0.46)</td>
<td>5.22</td>
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<tr>
<td>Miller et al, 2002</td>
<td>1756/6745</td>
<td>0.26 (0.25, 0.27)</td>
<td>5.86</td>
</tr>
<tr>
<td>Nallamothu et al, 1995</td>
<td>242/673</td>
<td>0.36 (0.32, 0.40)</td>
<td>5.76</td>
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<tr>
<td>Roeters van Lennep et al, 1999</td>
<td>17/85</td>
<td>0.20 (0.11, 0.29)</td>
<td>5.32</td>
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<tr>
<td>Roeters van Lennep et al, 1999</td>
<td>28/157</td>
<td>0.18 (0.12, 0.24)</td>
<td>5.58</td>
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<tr>
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<td>179/657</td>
<td>0.27 (0.24, 0.31)</td>
<td>5.78</td>
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<tr>
<td>Roger et al, 1997</td>
<td>70/366</td>
<td>0.19 (0.15, 0.23)</td>
<td>5.74</td>
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<tr>
<td>Schwartz et al, 1993</td>
<td>386/540</td>
<td>0.71 (0.68, 0.75)</td>
<td>5.75</td>
</tr>
<tr>
<td>Vilachopoulos et al, 2005</td>
<td>9/12</td>
<td>0.73 (0.49, 0.97)</td>
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**NOTE:** Weights are from random effects analysis
Observed vs. True Diagnostic Performance of Exercise ECHO

True performance = observed performance after adjustment for referral
Observed vs. True Diagnostic Performance of Exercise MPI

- **Sensitivity**:
  - Observed performance: 91%
  - True performance: 44%

- **Specificity**:
  - Observed performance: 67%
  - True performance: 97%

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

Ladapo et al, under review
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
Radiation Concerns Rise With Patients’ Exposure

By ALASTAIR GEE
Published: June 12, 2012

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.

The NEW ENGLAND JOURNAL OF MEDICINE

Cumulative Exposure to Ionizing Radiation from Diagnostic and Therapeutic Cardiac Imaging Procedures

A Population-Based Analysis

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

Medicare Claims Show Overuse for CT Scanning

The New York Times
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
- Among patients undergoing cardiac imaging, mean cumulative dose 16.4 mSv (1.5-190 mSv)
- MPI accounted for 74% of cumulative dose

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

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

• Shared decision-making

• Professional society scrutiny

...Impact on health is unknown and needs to be studied

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

- **CASP5/IL18RAP/TNFAIP6**: Apoptosis and inflammatory signaling response
- **CD3/TMC8**: Adaptive immune response to atherosclerosis
- **CD79B/SPIB**: Adaptive immune response to atherosclerosis
- **S100A12/S100A8/CLEC4E**: Oxidative damage and cellular necrosis
- **SLAMF7/KLRC4**: Innate immune response to atherosclerosis

Picture source: CardioDx
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

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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

- Patients may go to catheterization if clinically indicated

\[\text{Chest Pain Patients Referred for MPI} \rightarrow \text{Routine Stress MPI} \{\text{Exercise or Pharmacologic with Isotope}\} \rightarrow \begin{cases} \text{Invasive Angiography}\dagger & \text{+ MPI} \\ \text{CT Angiography}^{\ddagger} & \text{- MPI} \end{cases}\]

\(\dagger\) Data analyzed by Quantitative Coronary Angiography (QCA) core lab.
\(\ddagger\) Data analyzed by CT Angiography core lab.
1 - Specificity

- Gene Expression Score
- Site–Read MPI
- Core Lab MPI

Sensitivity vs. 1 - Specificity

[Graph with lines for Gene Expression Score, Site–Read MPI, and Core Lab MPI]
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
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

- Launched by Dept of Health and Human Services in 2011 to prevent 1 million heart attacks and strokes by 2017
- **ABCS** - Aspirin, Blood-pressure control, Cholesterol management, and Smoking cessation
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.
Thank you!

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