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THE REAL PROMISE OF COMPARATIVE EFFECTIVENESS RESEARCH

9th Annual Marshall Seidman Lecture On Health Policy

October 15, 2009
Harvard Medical School

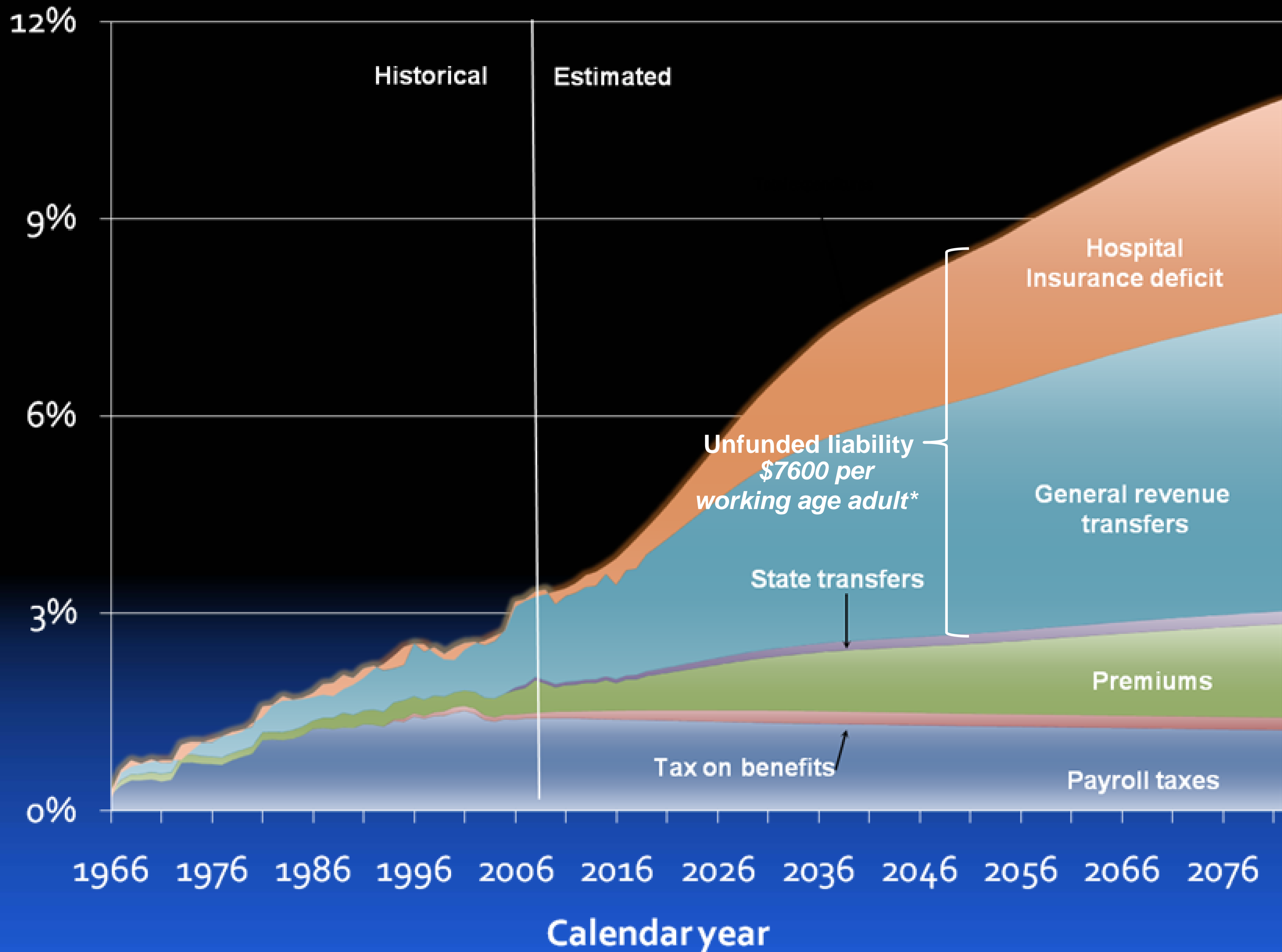
The nation's health care challenges

Uninsured

Federal debt

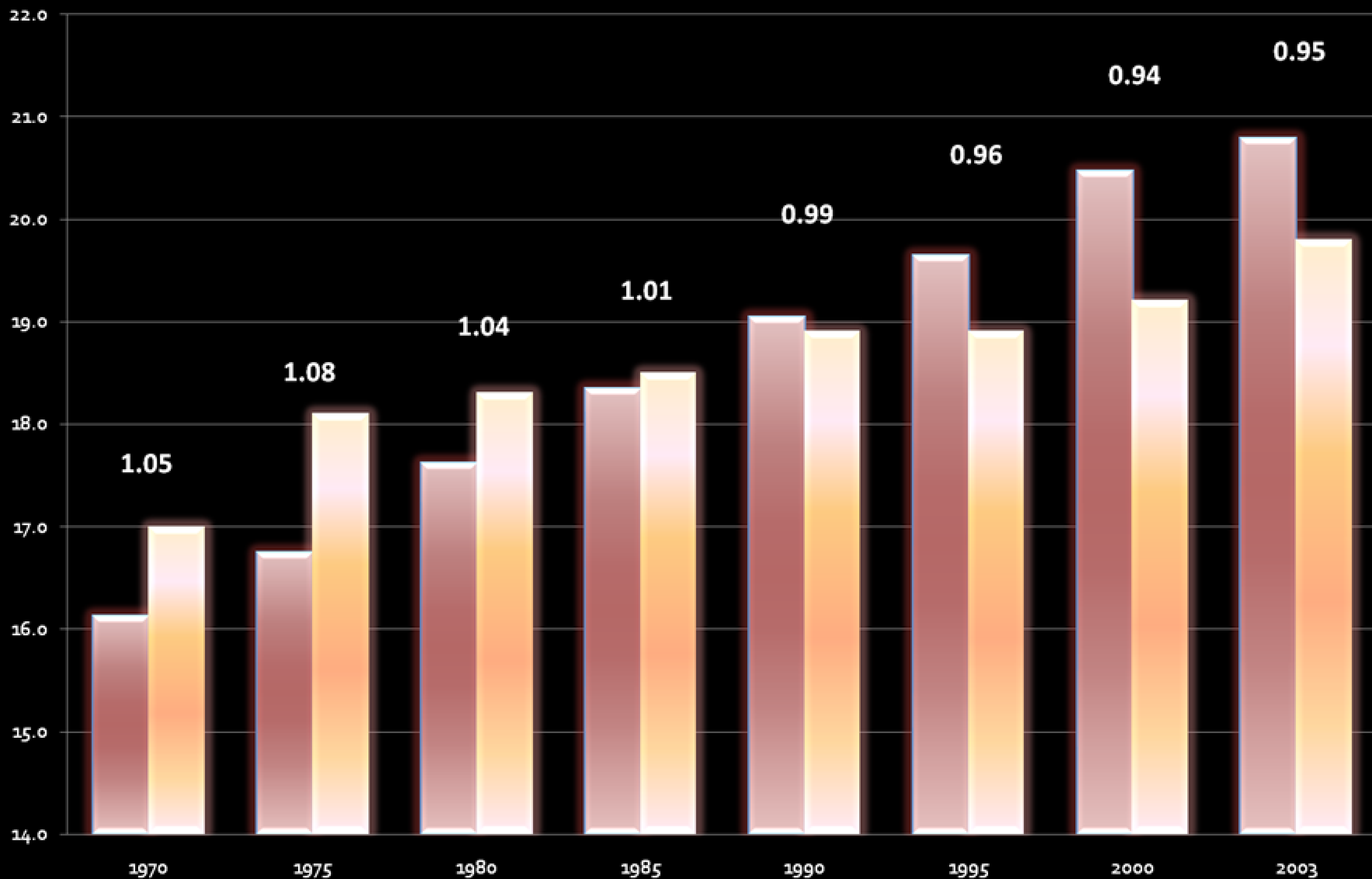
Value

Medicare sources of non-interest income and expenditures as a percentage of Gross Domestic Product

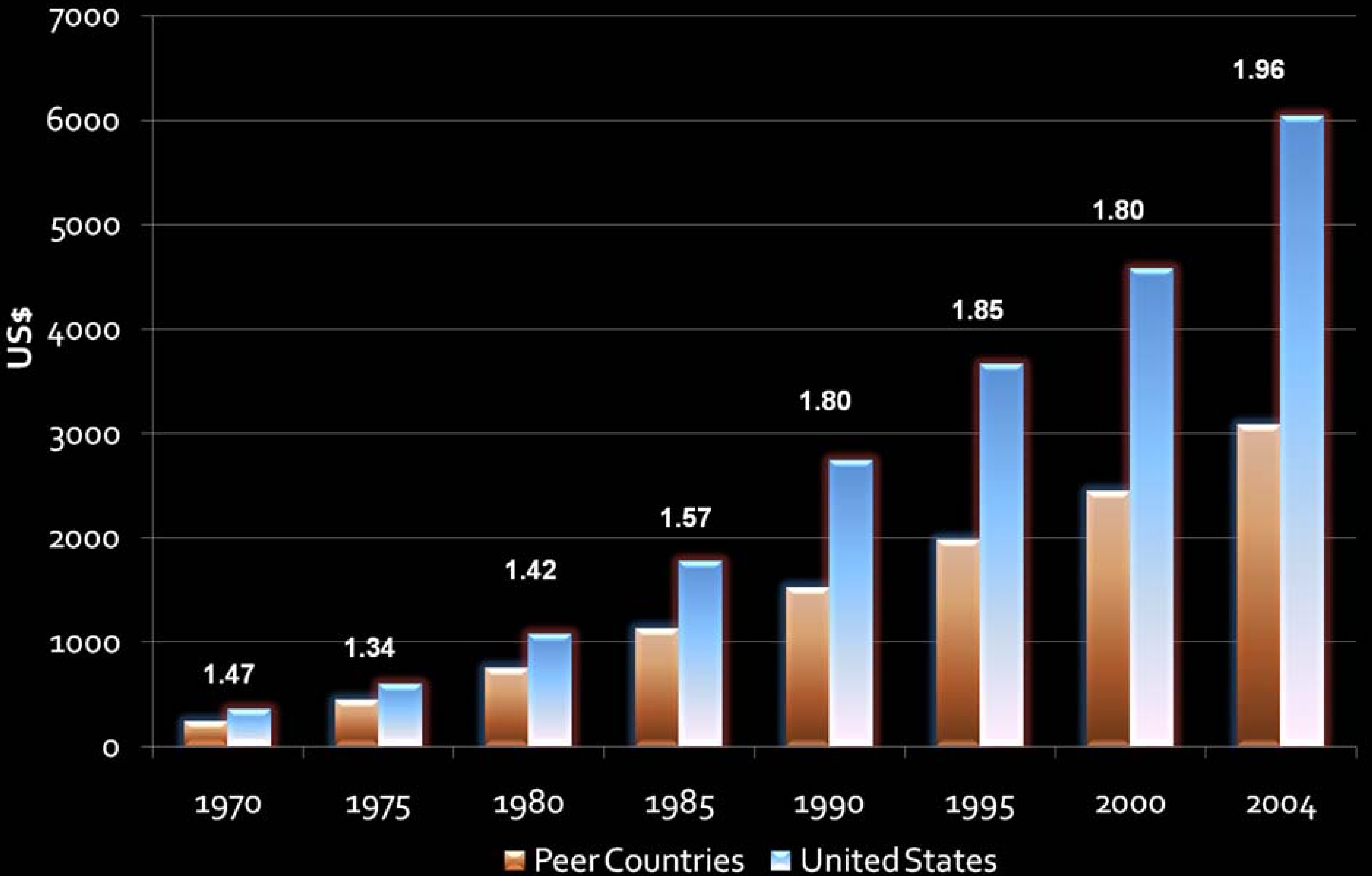


*In constant 2008 dollars

Source: Office of the Actuary, CMS; 2008 Medicare Trustees Report


Female Life Expectancy at 65
Peer Country Average
United States
Peer Countries: Canada, France, Germany, Japan, UK
22.0
21.0
20.0
19.0
18.0
17.0
16.0
15.0
14.0
1.05
1.08
1.04
1.01
0.99
0.96
0.94
0.95
1970
1975
1980
1985
1990
1995
2000
2003

Per Capita Health Care Spending



The promise of comparative effectiveness research

One of the keys to eliminating waste and missed opportunities is to increase our investment in comparative effectiveness reviews and research. Comparative effectiveness studies provide crucial information about which drugs, devices and procedures are the best diagnostic and treatment options for individual patients.

Senator Barack Obama's Plan for a Healthy America

Comparative effectiveness research will inject common sense into our health care system, by improving outcomes for patients and by helping us direct attention and resources to medicines and treatments that work.

Max Baucus, Chair of Senate Finance Committee, Dec. 18, 2007

Health Care?
Lives
Value!
Option!
Under
Socialist
Not everyone is a fan

Giving government exclusive control over electronic health information and reporting is a step toward "comparative effectiveness" research. That in turn will be used to impose price controls and deny some types of medical treatment and drugs. And because government is able to skew the whole health system through Medicare and Medicaid, comparative effectiveness could end up micromanaging the practice of medicine.

Wall Street Journal editorial

[Comparative effectiveness research should p]rovide information on clinical value and patient health outcomes, not cost-effectiveness assessment:

Providing doctors with information about the effectiveness of new tests and treatments can help them make better treatment decisions for their patients. But if the Institute conducts cost-effectiveness research, it will end up putting a dollar value on human life based on average study results that ignore differences between patients. The Institute´s research should not include cost-effectiveness determinations, which would lead to a focus on cetralized [sic] judgments about which healthcare options should be available.

Partnership to Improve Patient Care

http://www.improvepatientcare.org/issue/quality-and-cost

Its time is over before its day has come

21st century science and innovation is moving toward personalized, individual-centered medicine, like genetics, and away from population-based research, like comparative effectiveness. We need to embrace and encourage ways to understand how a specific individual will respond to a specific treatment, not try to determine the lowest common denominator for everyone. This kind of research will give rise to a rational—not rationed—healthcare system.

Newt Gingrich, Oct. 6, 2009

http://www.economist.com/debate/days/view/394

What comparative effectiveness research is

The conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in 'real world' settings

Federal Coordinating Council on Comparative Effectiveness Research

Most versions discussed today exclude or omit mention of cost-effectiveness

Initial CER Priorities from IOM

CAD Compare the effectiveness of treatment strategies for atrial fibrillation including surgery, catheter ablation, and pharmacologic treatment.

DIS Compare the effectiveness of the different treatments (e.g., assistive listening devices, cochlear implants, electric-acoustic devices, habilitation and rehabilitation methods [auditory/oral, sign language, and total communication]) for hearing loss in children and adults, especially individuals with diverse cultural, language, medical, and developmental backgrounds.

ENDO Compare the effectiveness of primary prevention methods, such as exercise and balance training, versus clinical treatments in preventing falls in older adults at varying degrees of risk.

GI Compare the effectiveness of upper endoscopy utilization and frequency for patients with gastroesophageal reflux disease on morbidity, quality of life, and diagnosis of esophageal adenocarcinoma.

HCDS Compare the effectiveness of dissemination and translation techniques to facilitate the use of CER by patients, clinicians, payers, and others.

HCDS Compare the effectiveness of comprehensive care coordination programs, such as the medical home, and usual care in managing children and adults with severe chronic disease, especially in populations with known health disparities.

IMUN Compare the effectiveness of different strategies of introducing biologics into the treatment algorithm for inflammatory diseases, including Crohn’s disease, ulcerative colitis, rheumatoid arthritis, and psoriatic arthritis.

Potential savings from CER

Lewin Group : $18 billion first year, $368 billion over 10 years

CBO: examined HR3162. 10 years to break even, only $1 billion or so annual savings to fed government

assumed that CER would not be used to change coverage or reimbursement policy under Medicare or Medicaid

What it means to apply CER findings

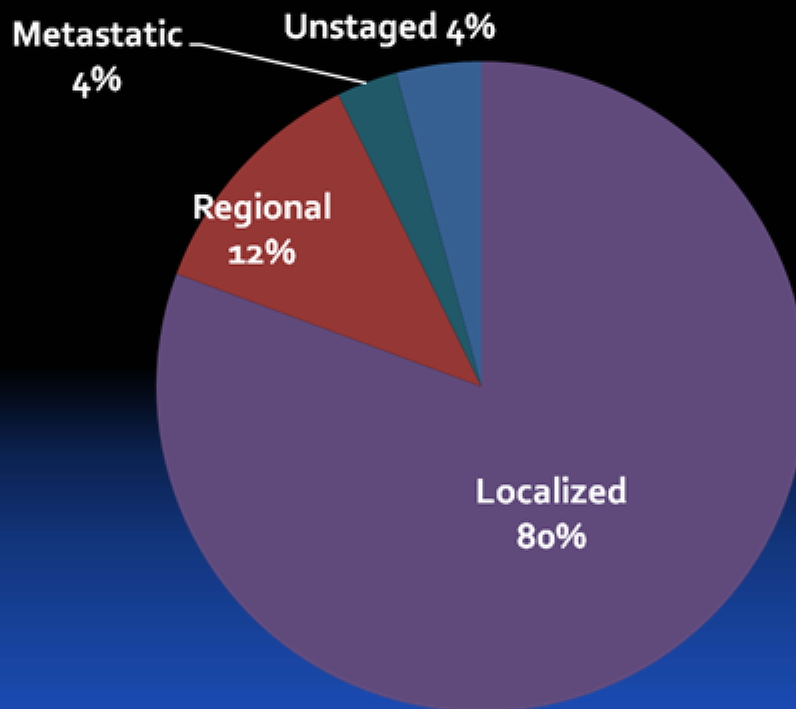
Shift from more to less expensive procedures of comparable effectiveness

What it means to apply cost-effectiveness findings

1. Identify interventions that cost more but are no more effective
2. Select the remaining intervention with the greatest health impact that has an acceptable (incremental) cost-effectiveness ratio

Treatment of localized prostate cancer

Most Prostate Cancer is Localized at Diagnosis



230,110 new cases of prostate cancer in the US 2004

SEER data, American Cancer Society

Treatment Options for Localized Prostate Cancer

Treatment	Description
Active surveillance (watchful waiting)	• Active plan to postpone intervention, usually involving monitoring with digital rectal exam/PSA-test
Radical prostatectomy (RP)	• Complete surgical removal of prostate gland, can be laparoscopic or robotic • Nerve-sparing surgery is latest advance on this technique
Brachytherapy (seed implants)	• Radioactive implants (I^{125} usually) placed using anesthesia, lower dose/permanent seeds usually used
External beam radiation therapy (EBRT)	• Multiple doses of radiation from an external source applied over several weeks • 2 dimensional external beams delivered based on plan • Not used much anymore, replaced by IMRT as standard XRT option
Intensity-modulation radiation therapy (IMRT)	• Next generation 3D conformal radiotherapy where the radiation dose is consistent with the 3-D shape of the tumor by controlling, or modulating, the radiation beam's intensity.

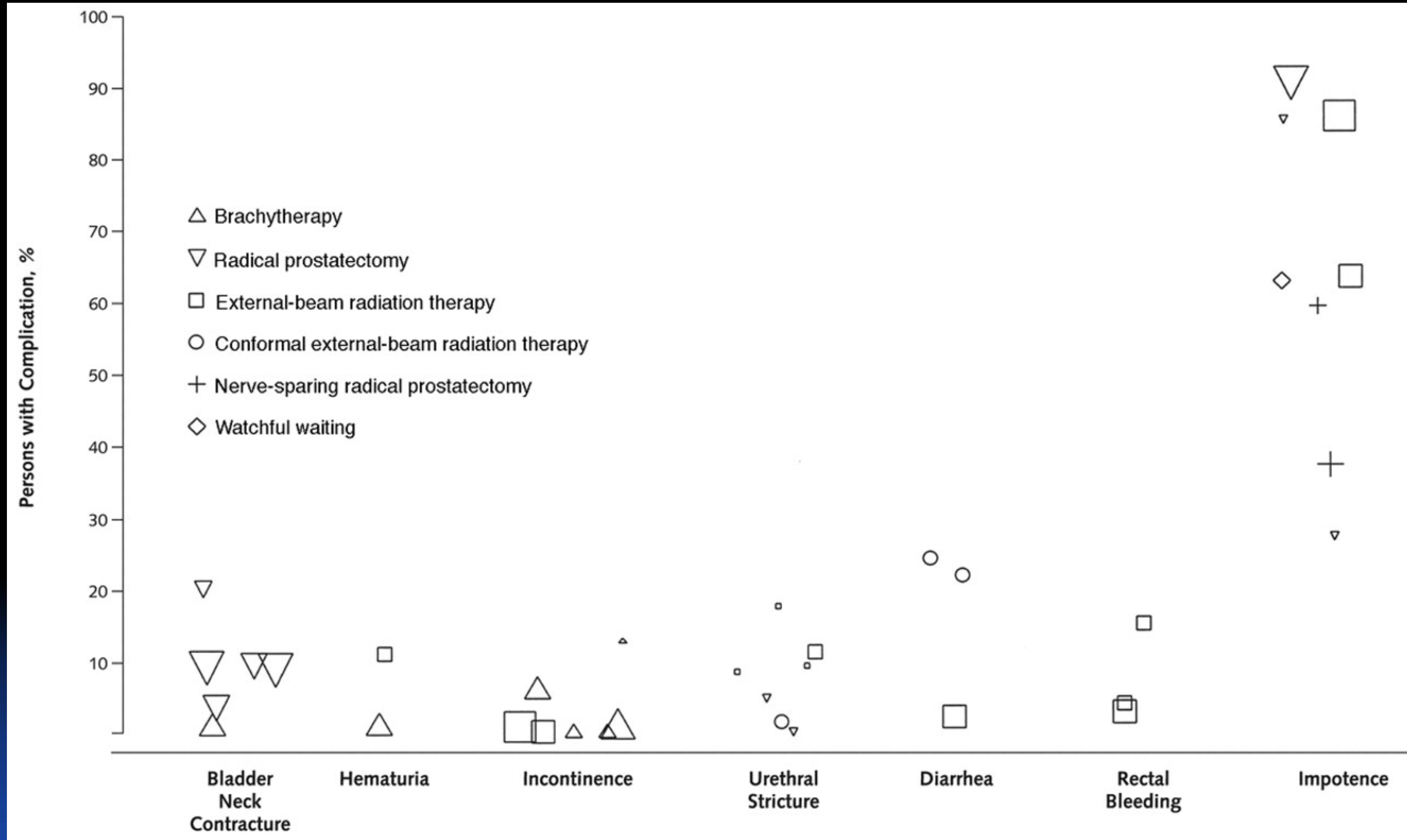
Wilt TJ, et al. Comparative Effectiveness of Therapies for Clinically Localized Prostate Cancer. Comparative Effectiveness Review No. 13. (Prepared by Minnesota Evidence-based Practice Center under Contract No. 290-02-0009.) Rockville, MD: Agency for Healthcare Research and Quality, February 2008.

Newer Treatment Options for Localized Prostate Cancer

Treatment	Description
Proton radiation therapy	• A type of EBRT in which protons rather than photons are used for improved dose distribution • Requires very large proton accelerator (football field size) that costs about $150 million dollars
Cryoablation	• Destruction of cells through rapid freezing and thawing with injected gases
Androgen deprivation	• Oral or injection medications, or surgical removal of testicles (orchiectomy) to lower or block circulating androgens that stimulate tumor growth
High-intensity focused ultrasound therapy (HIFU)	• Tissue ablation with intense heat created from high-intensity ultrasound

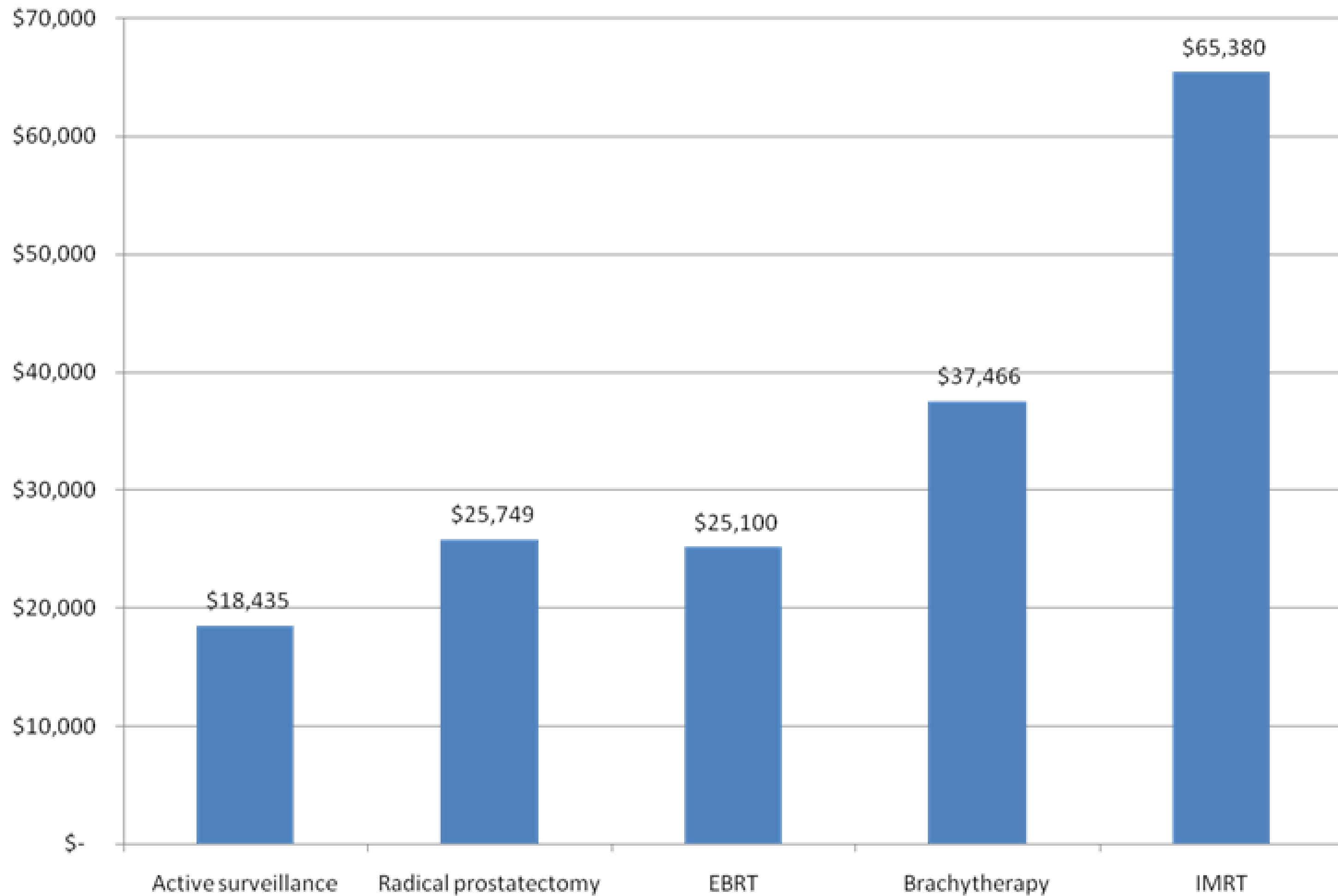
Wilt TJ, et al. Comparative Effectiveness of Therapies for Clinically Localized Prostate Cancer. Comparative Effectiveness Review No. 13. (Prepared by Minnesota Evidence-based Practice Center under Contract No. 290-02-0009.) Rockville, MD: Agency for Healthcare Research and Quality, February 2008.

Complication rates for prostate cancer treatments from nonrandomized studies



Symbol size proportional to number of patients;<50, 50-150, 150-300, >300

Wilt, T. J. et. al. Ann Intern Med 2008;148:435-448



*From analysis of Ingenix claims data, about 2.4 million lives/yr, 3352 localized prostate cancer pts 2004

Health Expenditure Savings Estimates* ($ millions 2009) for Adopting Treatment Strategies Supported by CER for Initial Treatment of Localized Prostate Cancer

Strategy	Unadjusted	Adjusted for average age of 65 years and preceding health expenditures
Shifting patients receiving IMRT to AS	1,250	1,380
Shifting patients receiving IMRT to RP/AS	1,520	1,270
Shifting patients receiving brachy to AS	320	440
Shifting patients receiving brachy to RP/AS	370	390
Shifting patients receiving multiple treatments to single treatments (baseline proportional)	930	1,490
Shifting patients receiving multiple treatments to single EBRT/IMRT/brachy treatments (baseline proportional)	570	1,180

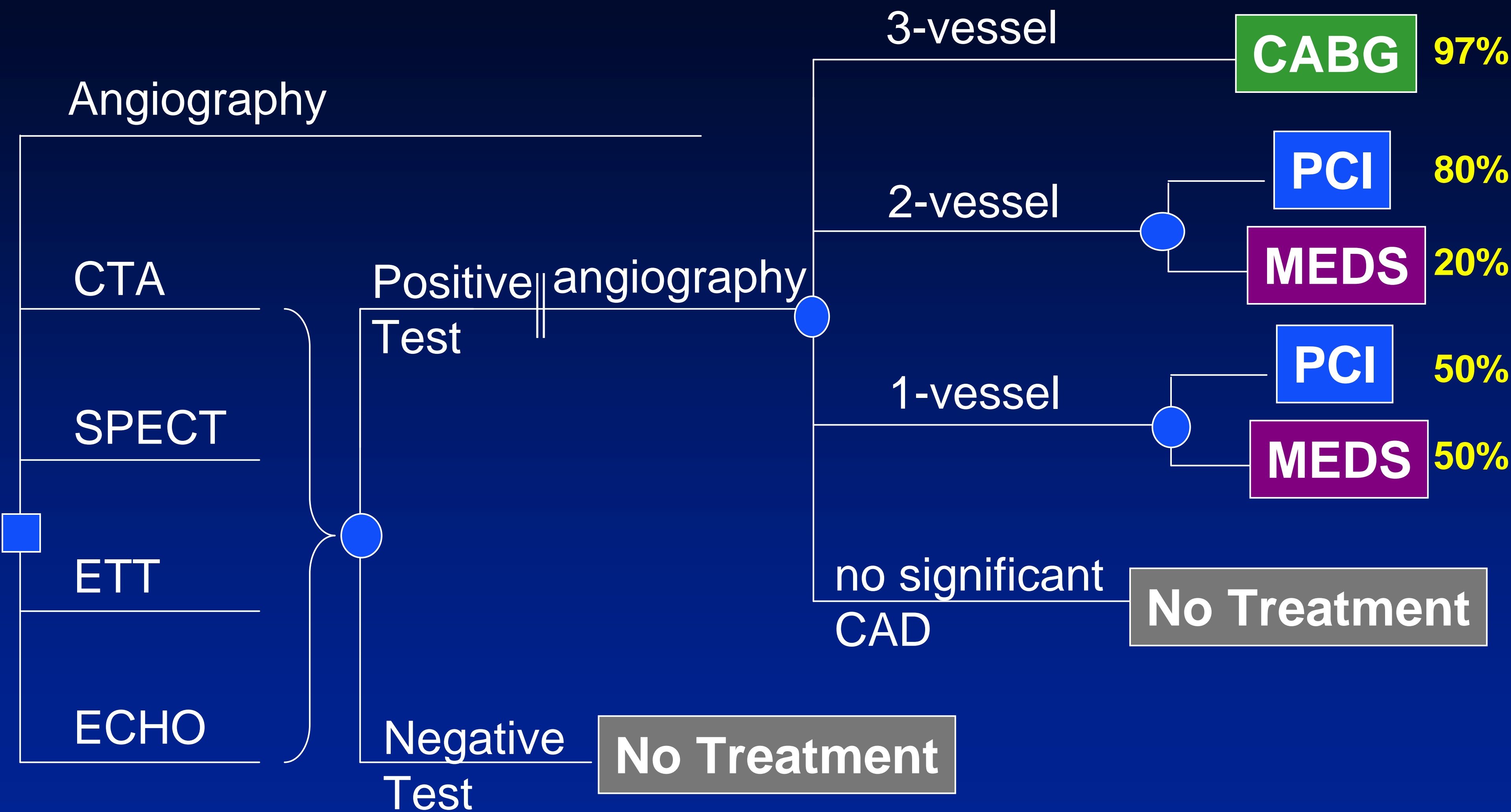
* 2-year estimated savings.
MRT = intensity modulated radiation therapy, RP = radical prostatectomy, AS = active surveillance, EBRT = electron beam radiation therapy, brachy = brachytherapy.

Applying cost-effectiveness analysis: Diagnosing coronary artery disease

Diagnostic tests for coronary disease

- Treadmill (ETT)
- Stress echocardiography (ECHO)
- Myocardial perfusion imaging (SPECT)
- CT angiography (CTA) – multi-slice detector, obtains high resolution images of coronary arteries
- Coronary angiography – invasive “gold standard” test

Testing Strategies



Sensitivity and Specificity of Noninvasive Tests

Test	Sensitivity	Specificity
CTA	97.5	86.7
SPECT	88.9	76.9
ETT	71	78
ECHO	83.3	83

Costs

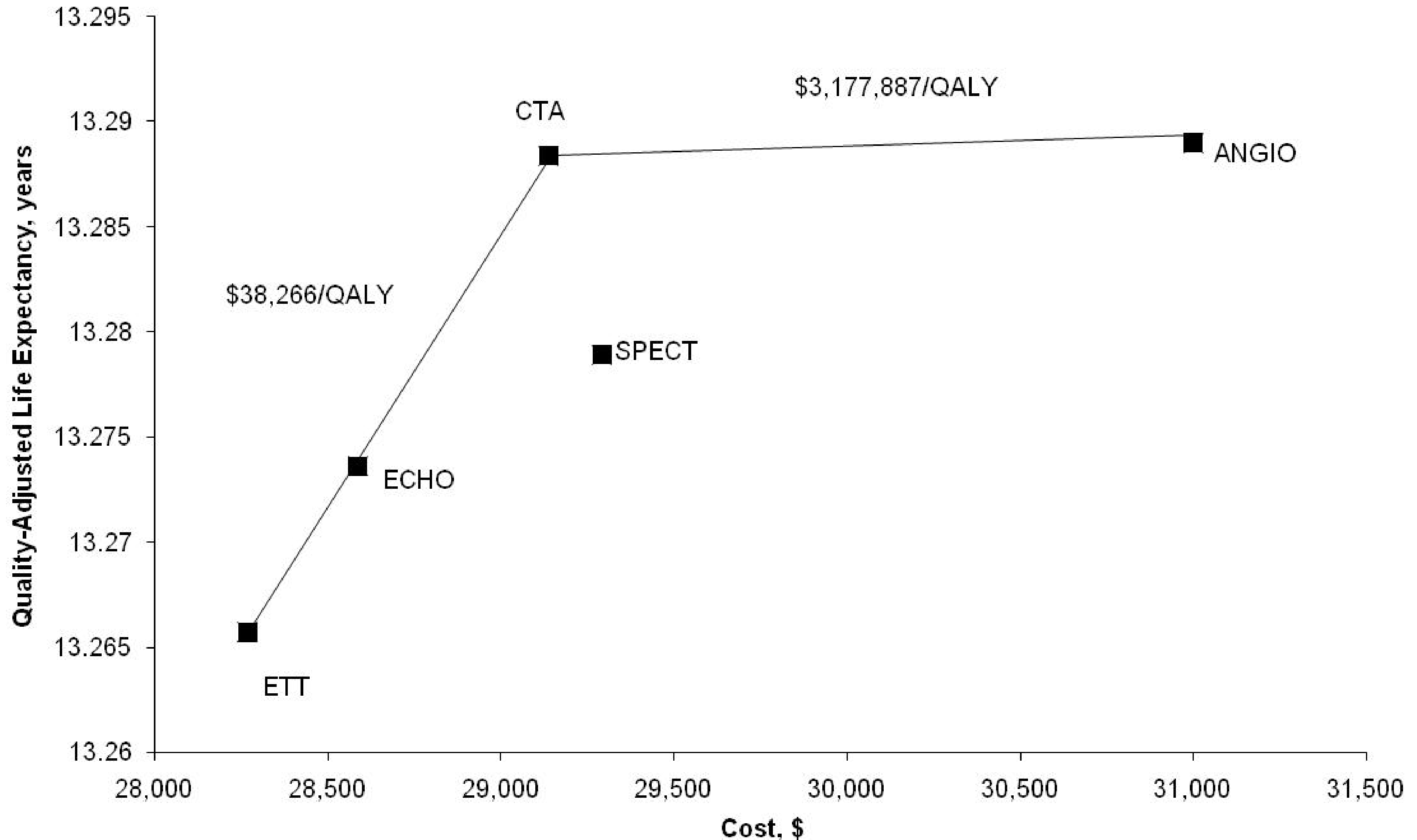
- Evaluated CTA under two reimbursement settings: Medicare and Blue Cross Blue Shield
- Testing

Testing	MEDICARE	BCBS
CTA	$443	$816
SPECT	$853	$463
ETT	$161	$161
ECHO	$389	$419
Angiography	$2,904	$4666

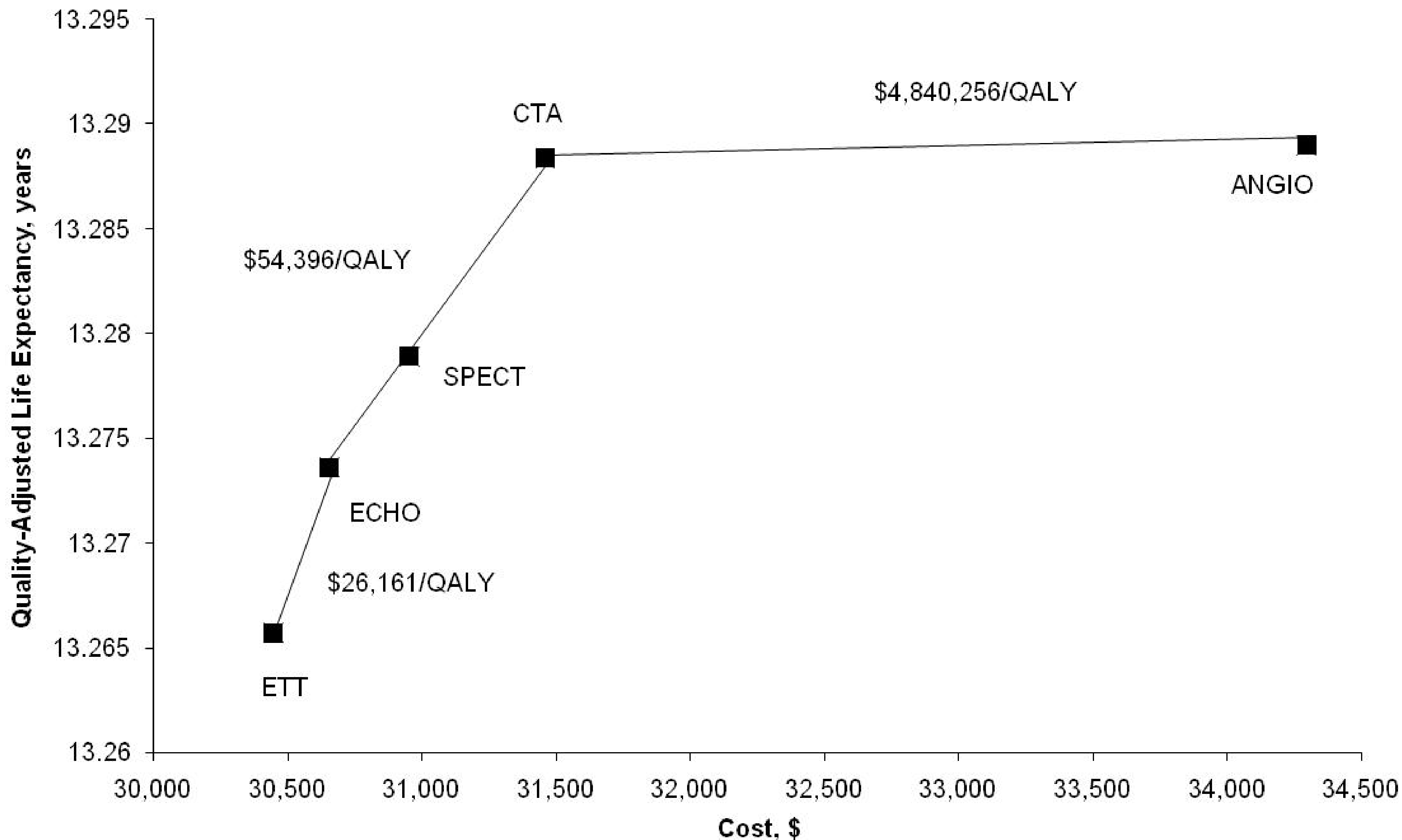
- Treatment

Treatment	MEDICARE
CABG	$30,929
PCI	$11,893

MEDICARE Setting: 55-year old men, 50% prevalence



BCBS Setting:
55-year old men, 50% prevalence



Implementation of findings from CER

I believe that the information from comparative clinical effectiveness needs to be paired with financial incentives to encourage their more appropriate use… What that means is that when there is good clinical evidence… for treating a particular type of cardiac disease or orthopedic disease or whatever, you ought to have the lowest copayments… and higher copayments when the likelihood (of a positive outcome) is very uncertain or very low.

Gail Wilensky, former HCFA Administrator, June 4, 2009

Geisinger Approach

Our cardiology service line reviewed the American Heart Association and the American College of Cardiology guidelines for cardiac surgery and translated these into 40 verifiable best practice steps that we could implement with each patient undergoing this surgery. We hardwired these into our electronic health record so that we would be prompted to meet each identified step – or document the specific reason for any exception.

We then established a package price that included costs of the first physician visit when surgery was deemed necessary, all hospital costs for the surgery, and related care for 90-days after surgery, including cardiac rehabilitation.

Glenn Steele, testimony to Committee on Finance, U.S. Senate, April 21, 2009

Reforming payment

Define optimal mix of services for a group of patients with a defined condition

Cost out the bundle

Pay accordingly

Challenges

- Provider ability to bear financial risk
- Adverse selection
- Defining costs
- What if effectiveness of alternatives is not identical?
- Selecting CE threshold

The real promise of comparative effectiveness research …

…is to protect health as we try to limit health expenditure growth

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