



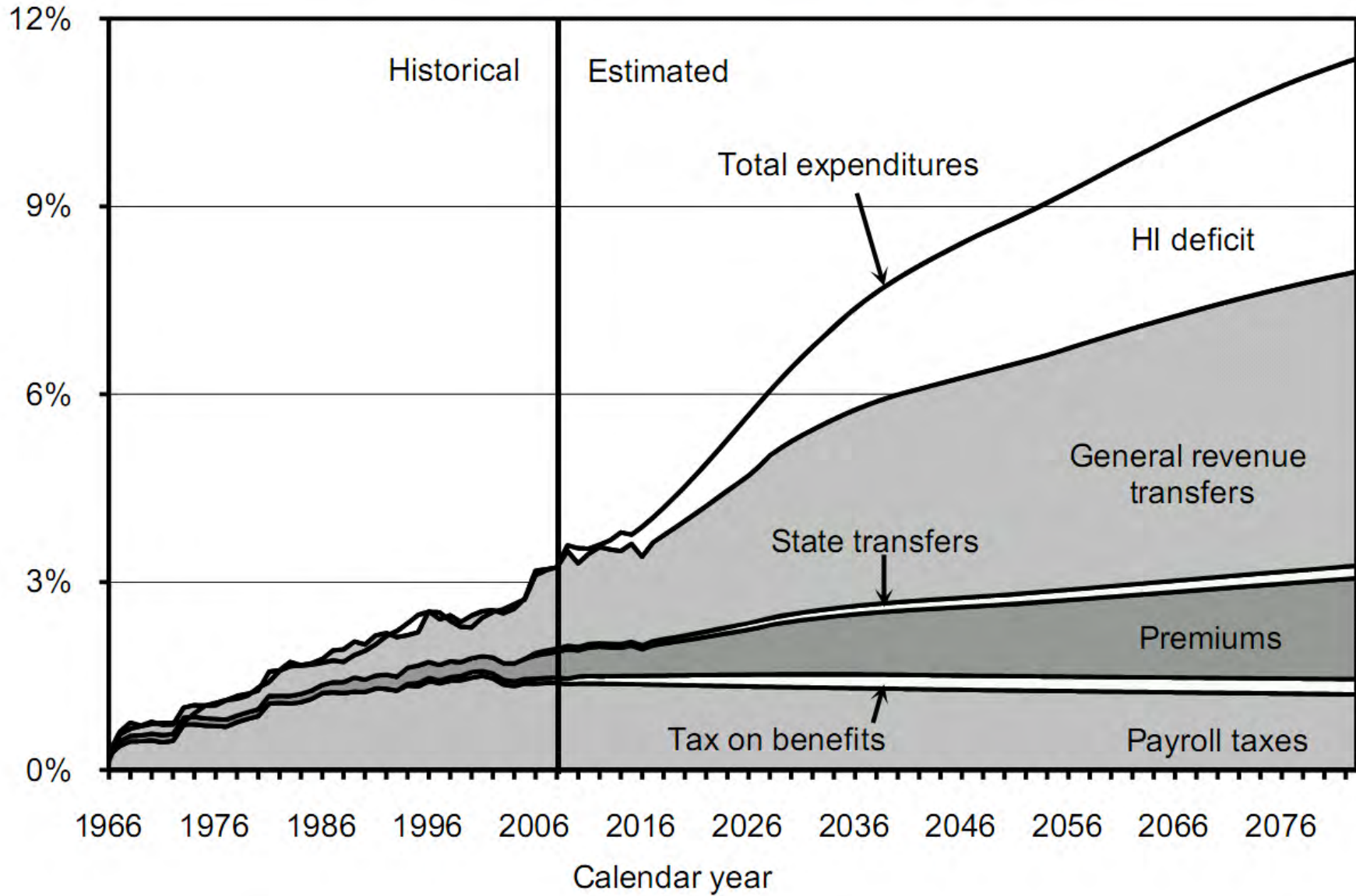
THE CAPSTONE CONFERENCE
Fresh-Thinking on Health Care Reform

**Value-Conscious Biomedical
Innovation**

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Veterans Affairs and
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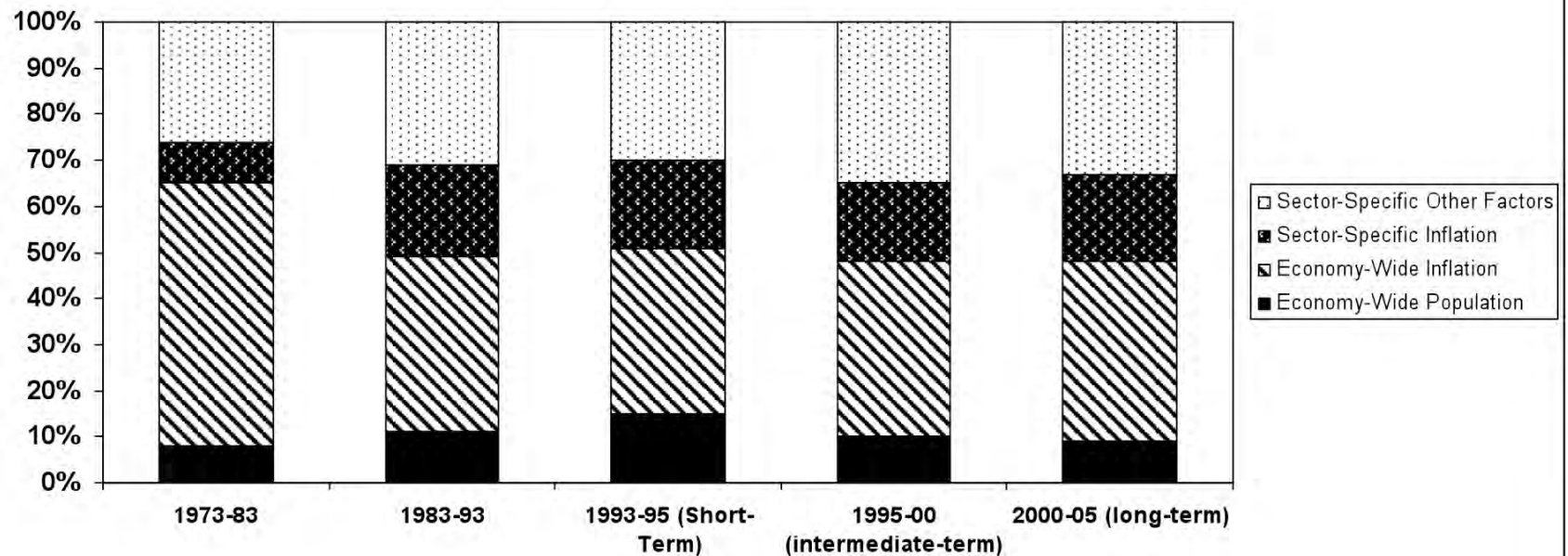
May 14, 2009

Figure II.D2.—Medicare Sources of Non-Interest Income and Expenditures as a Percentage of the Gross Domestic Product

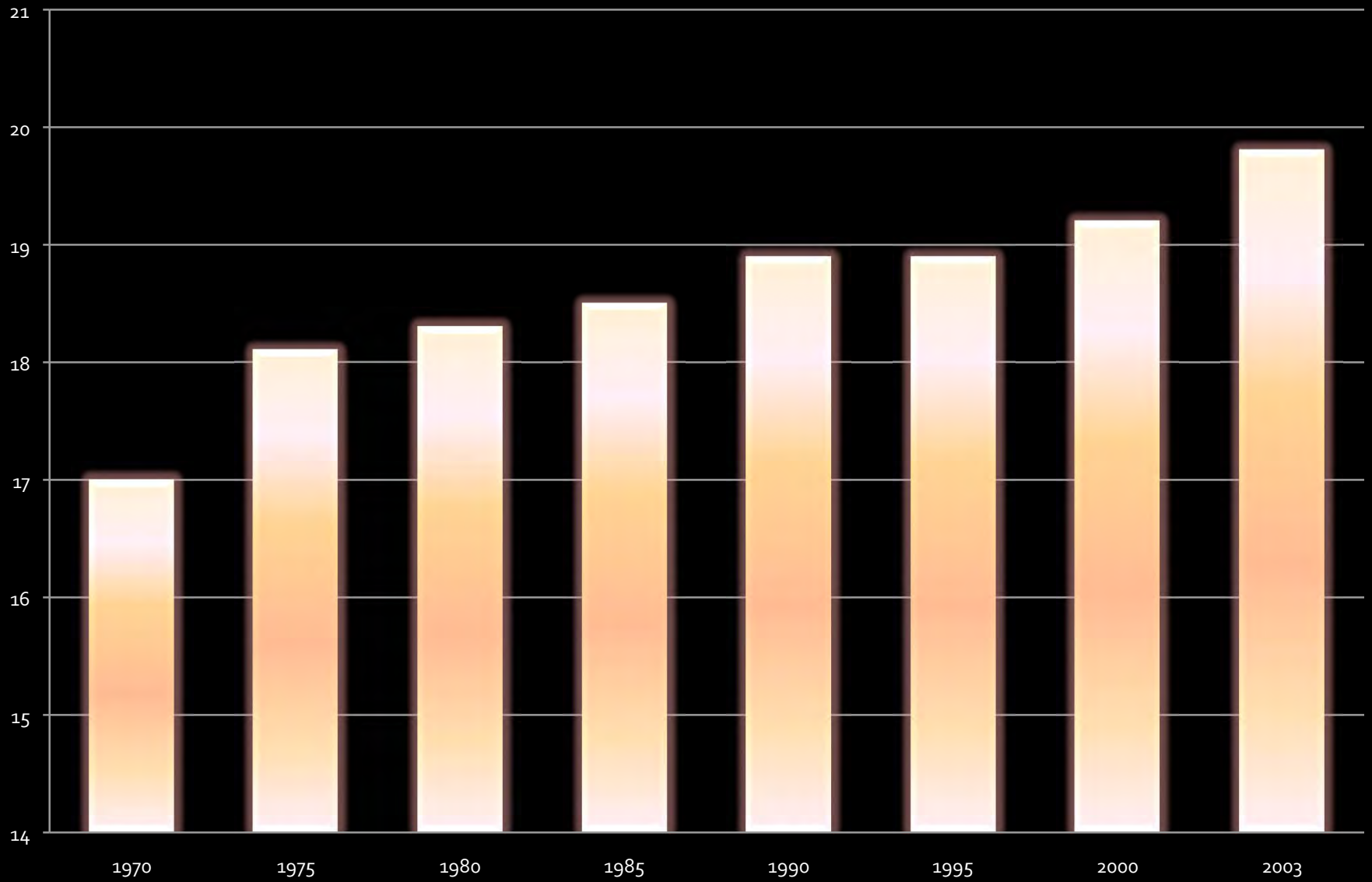


The paradox of biomedical innovation

Relative Contribution of Factors Accounting for Average Annual Growth in National Health Expenditures for Selected Periods: 1973-2005



U.S. Female Life Expectancy at Age 65



How insurers make decisions about medical technologies



Medicare authorizing legislation:

“No payment may be made [by the Medicare program] for any expenses incurred for items and services that ‘are not **reasonable and necessary** for the diagnosis or treatment of illness or injury...’ ”

Title XVIII of the Social Security Act

Commercial Plans: Reimburse for Care that is “Medically Necessary”

- Based upon prevailing practices/community standards in past
- Today explicit processes are usually evidence-based



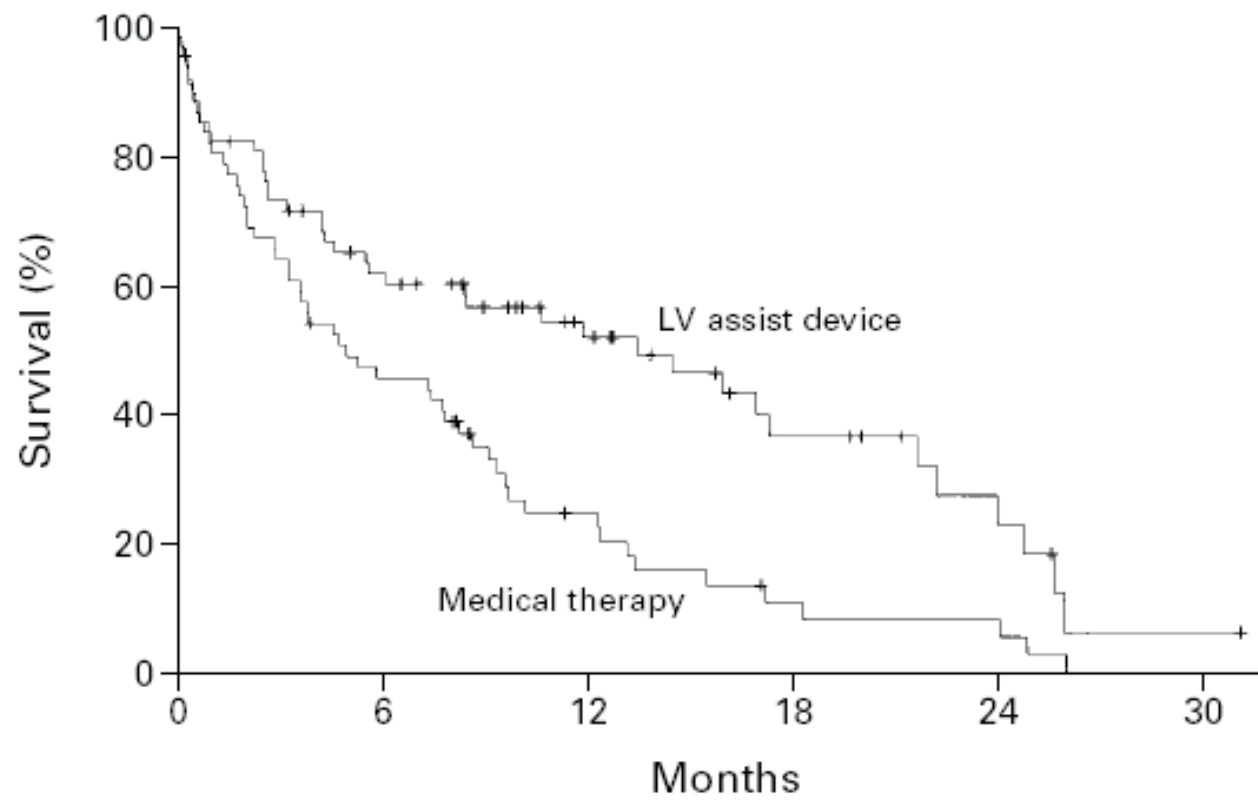
Blue Cross Blue Shield Association's TEC Criteria

- 1) Technology must have final approval from the appropriate government regulatory bodies
- 2) **Scientific evidence must permit conclusions concerning the effect of the technology on health outcomes**
- 3) **Technology must improve the net health outcome**
- 4) **Technology must be as beneficial as any established alternatives**
- 5) Improvement must be available outside the investigational settings



HEARTMATE 2

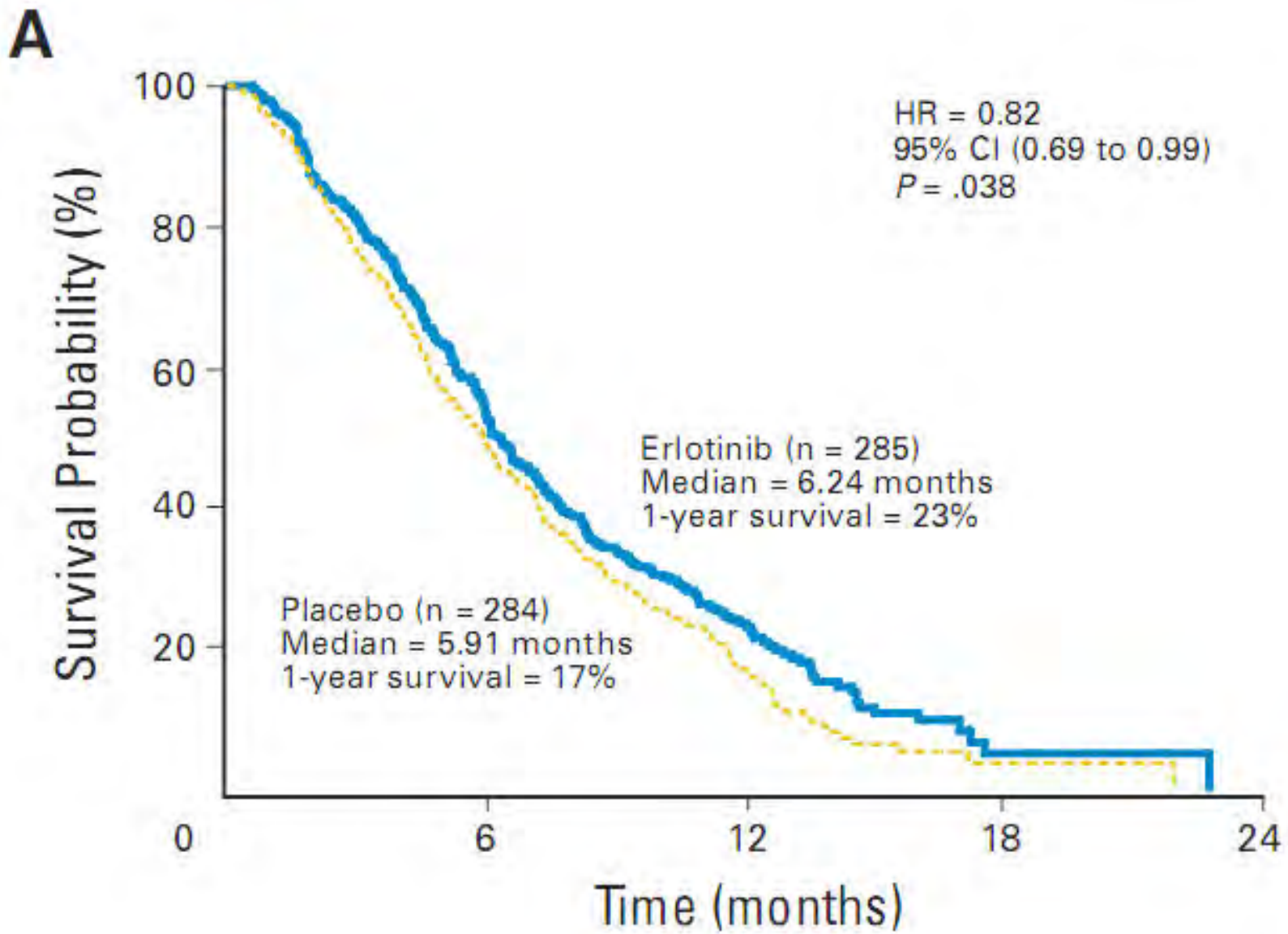




No. AT RISK		0	6	12	18	24	30
LV assist device	68	38	22	11	5	1	
Medical therapy	61	27	11	4	3	0	

Figure 2. Kaplan–Meier Analysis of Survival in the Group That Received Left Ventricular (LV) Assist Devices and the Group That Received Optimal Medical Therapy.

Crosses depict censored patients. Enrollment in the trial was terminated after 92 patients had died; 95 deaths had occurred by the time of the final analysis.



Erlotinib and gemcitabine in pancreatic cancer. Overall survival results.

We found that overall survival in patients with advanced pancreatic cancer was significantly improved with erlotinib and gemcitabine compared with placebo plus gemcitabine; the HR [hazard ratio] of 0.82 represents a 18% reduction in the risk of death, or alternately, an overall 22% improvement in survival. HR is the most appropriate measure of overall and progression-free survival in rapidly progressive diseases such as pancreatic cancer because it encompasses the whole observation period and not just a single point estimate, such as the median.

The improvement in median overall survival with erlotinib and gemcitabine is modest (6.24 v 5.91 months) while the 1-year survival rate with erlotinib and gemcitabine is 23% versus 17% with placebo and gemcitabine. The improvement in progression-free survival with a HR of 0.77 supports the beneficial effects of erlotinib. This benefit was achieved without a difference in response rate between the arms.

Evaluating Technology: Comparative Effectiveness Research

Comparative Effectiveness Research:

“A rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy. The analysis may focus only on the relative medical benefits and risks of each option, or it may also weigh both the costs and the benefits of those options. In some cases, a given treatment may prove to be more effective clinically or more cost-effective for a broad range of patients, but frequently a key issue is determining which specific types of patients would benefit most from it. Related terms include cost-benefit analysis, technology assessment, and evidence-based medicine, although the latter concepts do not ordinarily take costs into account.”

Congressional Budget Office, 2007



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Treatment Options for Localized Prostate Cancer

Treatment	Description
Watchful waiting	<ul style="list-style-type: none">• Active plan to postpone intervention, usually involving monitoring with digital rectal exam/PSA-test
Radical prostatectomy (RP)	<ul style="list-style-type: none">• Complete surgical removal of prostate gland, can be laparoscopic or robotic• Nerve-sparing surgery is latest advance on this technique
Brachytherapy (seed implants)	<ul style="list-style-type: none">• Radioactive implants (^{125}I usually) placed using anesthesia, lower dose/permanent seeds usually used
External beam radiation therapy (EBRT)	<ul style="list-style-type: none">• 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)	<ul style="list-style-type: none">• 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.

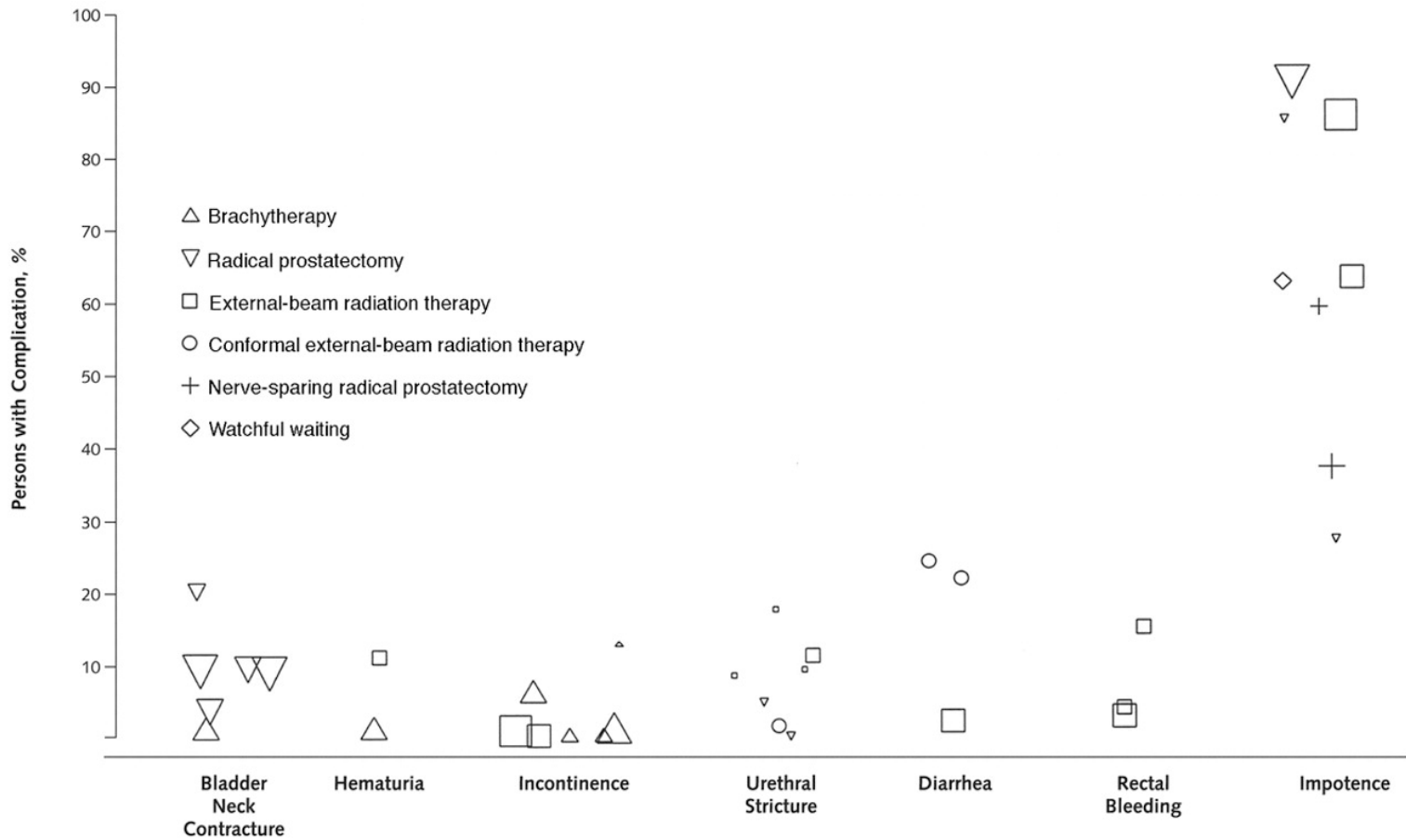
Wilt TJ, et al. Comparative Effectiveness of Therapies for Clinically Localized Prostate Cancer. Comparative Effectiveness Review No. 13. (Prepared by Minnesota Evidence-based Practice Center under Contract No. 290-02-0009.) Rockville, MD: Agency for Healthcare Research and Quality, February 2008.

Treatment Trade-offs

Treatment	Pros	Cons
Watchful waiting	<ul style="list-style-type: none"> • No side effects 	<ul style="list-style-type: none"> • May be anxiety-provoking for some
Radical prostatectomy (RP)	<ul style="list-style-type: none"> • 1 time treatment • Nerve-sparing surgery seems to have decreased sexual, GU side effects • Essentially no GI side effects 	<ul style="list-style-type: none"> • Surgical complications include 0.5% risk of death, 4-10% risk of complications • Generally thought to have more side effects than RT (particularly initially) • Need to be able to tolerate surgery
Brachytherapy (seed implants)	<ul style="list-style-type: none"> • 1 or 2 day treatment • May be superior to RT for large glands in terms of side effect profile 	<ul style="list-style-type: none"> • Must tolerate spinal/general anesthesia • Must have no previous h/o prostate procedure (e.g. TURP) • Gland must be between 20-60
External beam radiation therapy (EBRT)	<ul style="list-style-type: none"> • Not used much anymore, replaced by IMRT as standard RT option 	<ul style="list-style-type: none"> • GI/GU side effects
Intensity-modulation radiation therapy (IMRT)	<ul style="list-style-type: none"> • May have better side effect profile than RP (may not be true for nerve-sparing surgery) • Few exceptions to patient selection 	<ul style="list-style-type: none"> • Requires 7 – 8 weeks of weekday therapy



Complication rates for prostate cancer treatments from nonrandomized studies

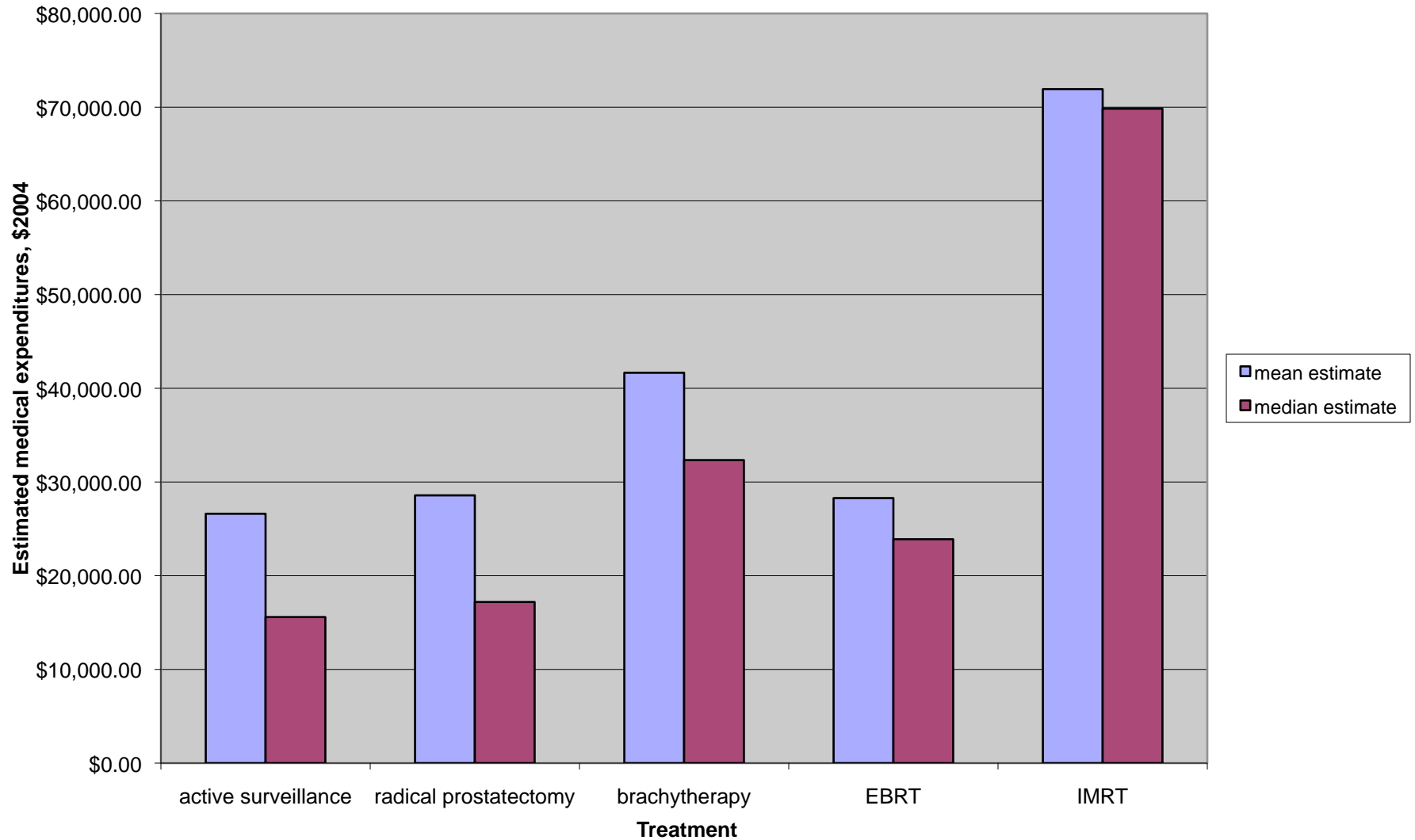


Given that evidence currently suggests all localized prostate cancer treatment options are equally effective, what are the cost differences, and thus potential for savings, obtained by using the lowest cost initial treatment option?



Medical expenditures by treatment for 65 year-olds

One-year expenditures, adjusted for comorbidities



Cost Implications for Alternative Approaches

Assuming that

- 20% of all prostate cancer patients receive radiation therapy (SEER data)
- 75% of that portion are receiving IMRT (Ingenix data, others)
- 12% of all patients are receiving brachytherapy (SEER)
- 207,000 new cases of localized prostate cancer diagnosed annually
- Save \$40,000 per case of IMRT now receiving EBRT, RP (2004 USD)
- Save \$13,000 per case of brachytherapy now receiving EBRT, RP (2004 USD)

Then,

- \$1.4 billion dollars would be saved over 24 months if patients today receiving IMRT instead received EBRT/RP
- \$370 million if patients receiving brachytherapy instead received RP/EBRT



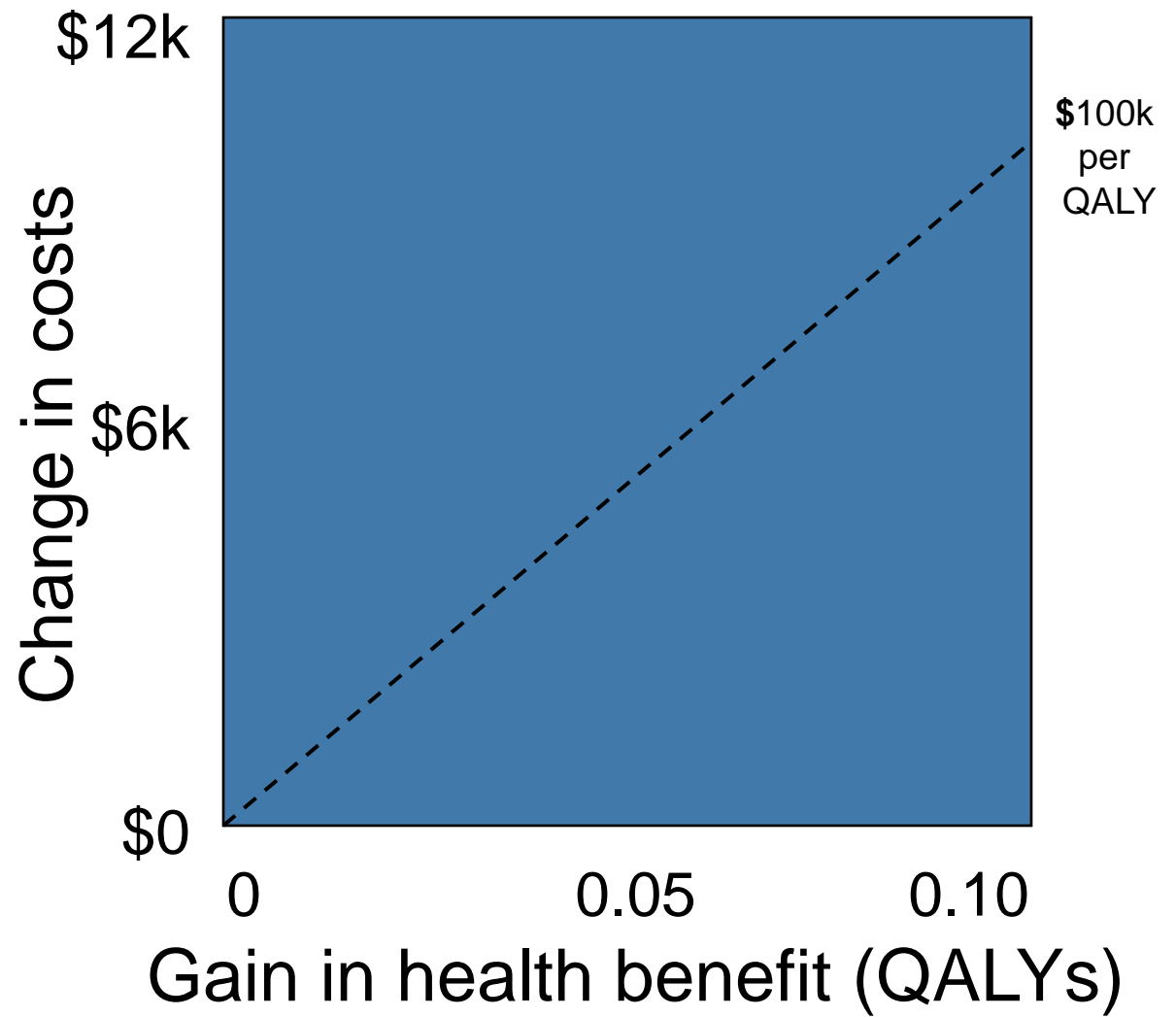
Cost-effectiveness analysis



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COX-2 Inhibitors vs NSAIDS

Comparator:
Naproxen



COX-2 Inhibitors vs NSAIDS

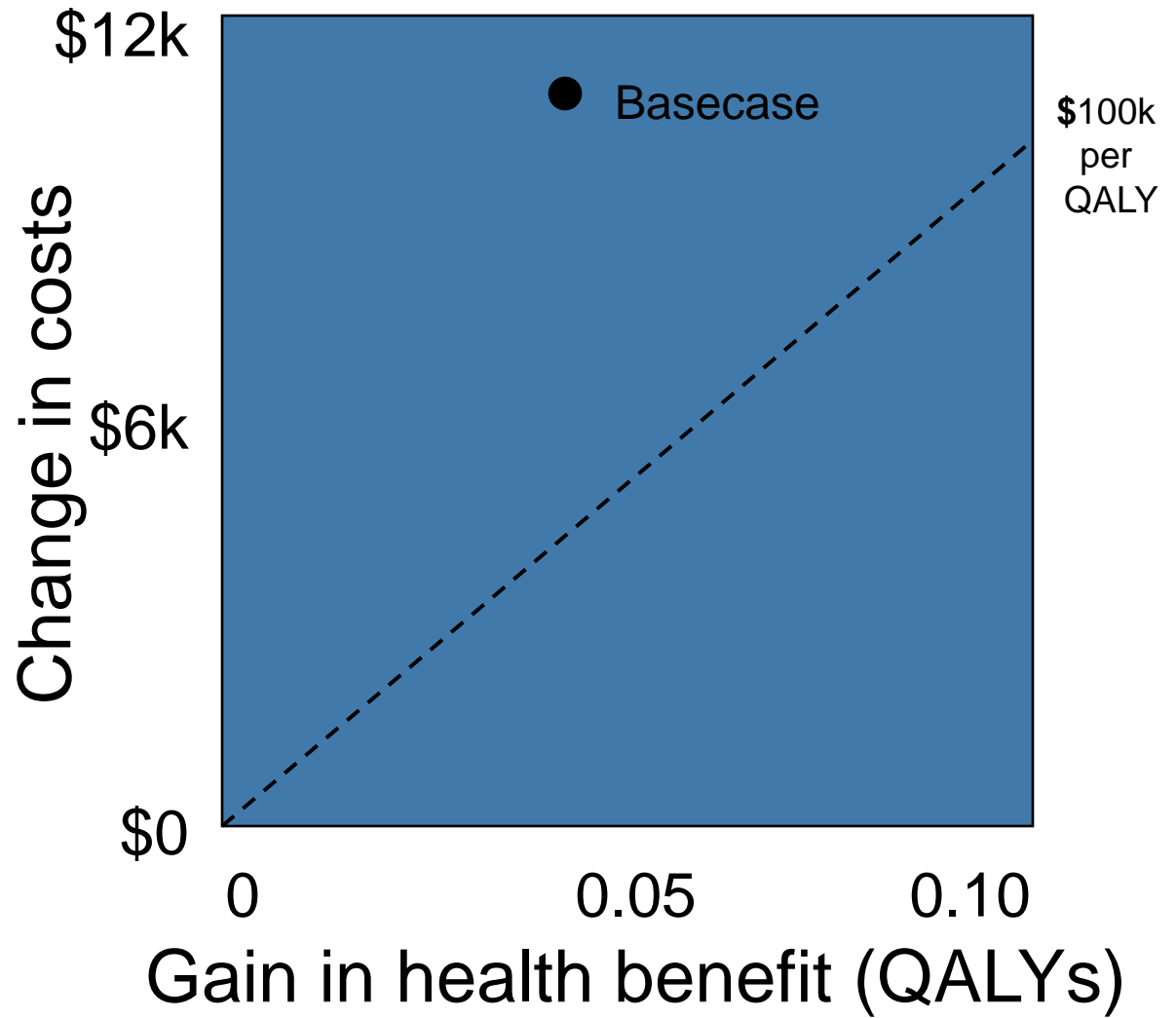
Comparator:
Naproxen

Assumption:
Excludes effects
on heart

Change in cost:
\$11,600

Change in benefit:
0.04 QALYs

Incremental CER:
\$290,000/QALY



COX-2 Inhibitors vs NSAIDS

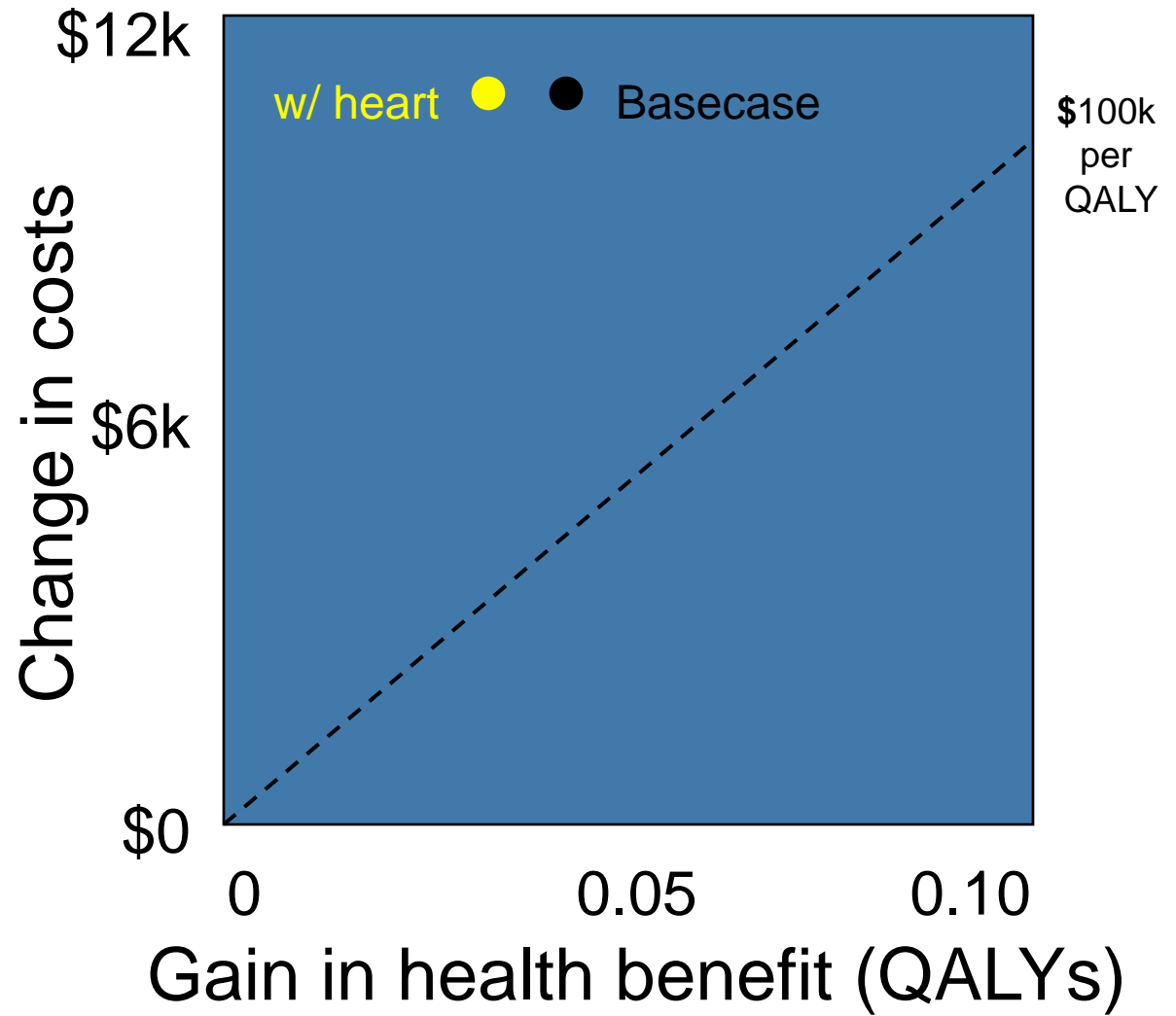
Comparator:
Naproxen

Assumption:
INCLUDES
effects on heart

Change in cost:
\$11,600

Change in benefit:
0.03 QALYs

Incremental CER:
\$395,000/QALY



COX-2 Inhibitors vs NSAIDS

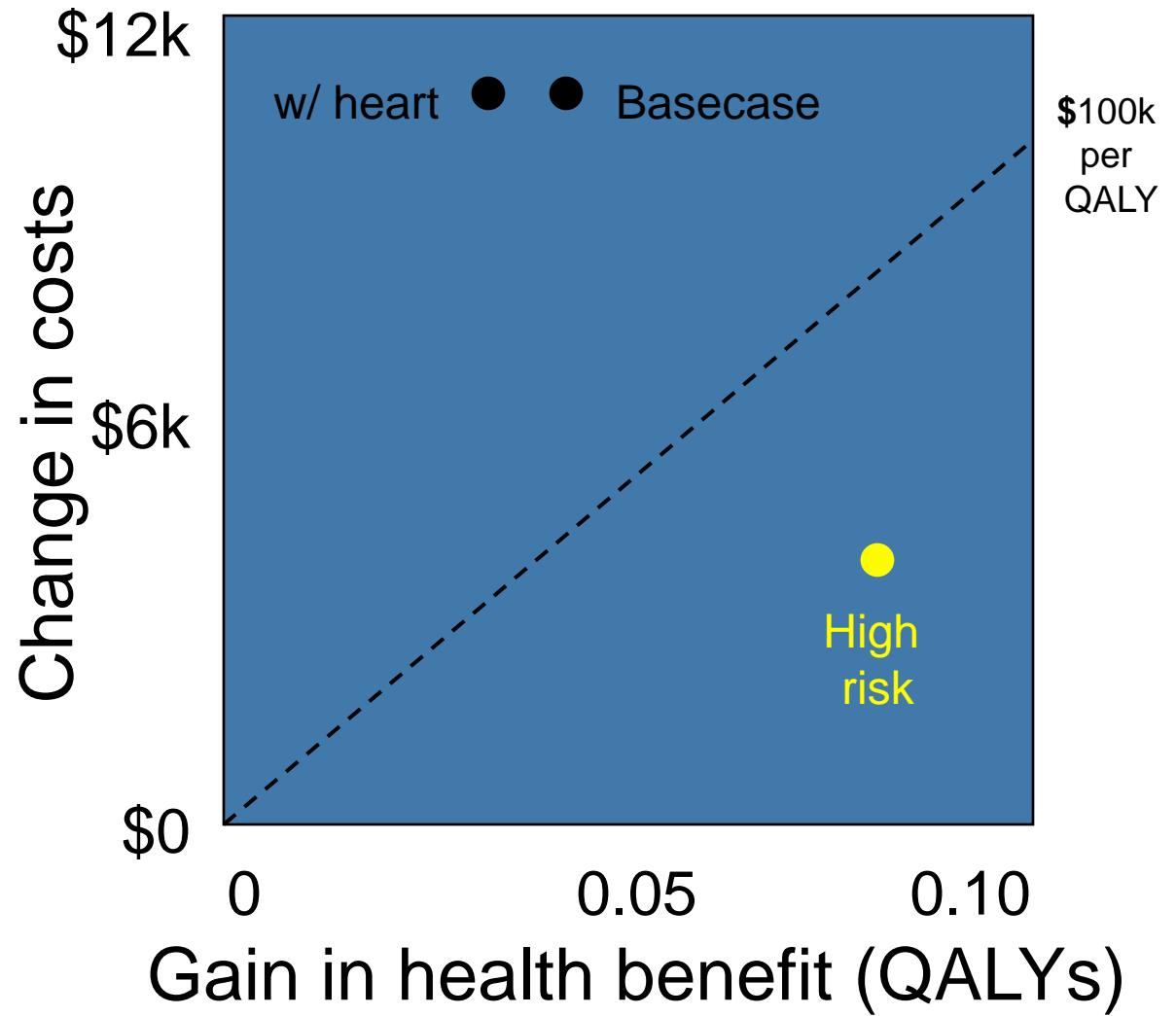
Comparator:
Naproxen

Assumption:
High-risk
patients

Change in cost:
\$4,720

Change in benefit:
0.08 QALYs

Incremental CER:
\$56,000/QALY



Moving to a cost-effectiveness criterion shifts both expenditures and outcomes



Impact Of Selected Medical Technologies On Spending And Life Years, 2015 And 2030

Technology	Annual treatment cost (\$ billions)		Increase in health care spending over status quo (%)		Cost per additional life year (\$)
	2015	2030	2015	2030	
Anti-aging compound (healthy)	48.6	72.8	8.7	13.8	8,790
Cancer vaccines	0.5	0.8	0.1	0.4	18,236
Treatment of acute stroke	3.1	4.4	0.4	0.4	21,905
Anti-aging compound (unhealthy)	48.8	73.3	22.7	70.4	29,785
Telomerase inhibitors	4.4	6.4	0.2	0.5	61,884
Alzheimer's prevention	33.6	49.1	7.4	8.0	80,334
ICDs	14.0	20.7	3.6	3.7	103,095
Diabetes prevention	13.7	20.6	2.6	3.2	147,199
Anti-angiogenesis	38.8	51.9	8.8	8.0	498,809
→ LVADs	10.2	14.2	2.1	2.3	511,962 ←
Pacemaker for atrial fibrillation	10.4	13.6	2.2	2.3	1,403,740

SOURCE: Simulations based on data from the Medicare Current Beneficiary Survey and the National Health Interview Study.

NOTES: All spending is in constant (1999) dollars. The exhibit shows the treatment costs, additional health care spending, and cost per additional life year associated with ten promising medical innovations. Treatment costs refer to the costs of providing the listed breakthrough technology and are based on comparisons with existing technologies as identified by expert panels. The additional health care spending differs from treatment costs because the technologies can lead to changes in disability, morbidity, and mortality, all of which are accounted for in the simulation model. Costs per additional life year do not include improvements in morbidity and disability during a lifetime and hence should be thought of as upper bounds on a cost-effectiveness ratio. ICD is intraventricular cardioverter defibrillator. LVAD is left ventricular assist device.

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Implementation

- Consumers: increased cost-sharing
- Insurers: coverage policy
- Providers: payment policy



Innovation will be rewarded

But it will be rewarded in new ways



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