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Disclosure

"I have received travel expenses from ViewRay."

"I have no conflicts of interest related to this presentation."

Addressing Value for Human Medical Technology

Institute of Medicine

National Cancer Policy Forum Workshop:

Appropriate Use of Advance Technology Technologies for Radiation Therapy and Surgery

July 21, 2015

Addressing Value for Human Medical Technology …..

and emerging payment models for its use

Institute of Medicine

National Cancer Policy Forum Workshop:

Appropriate Use of Advance Technology Technologies for Radiation Therapy and Surgery

July 21, 2015

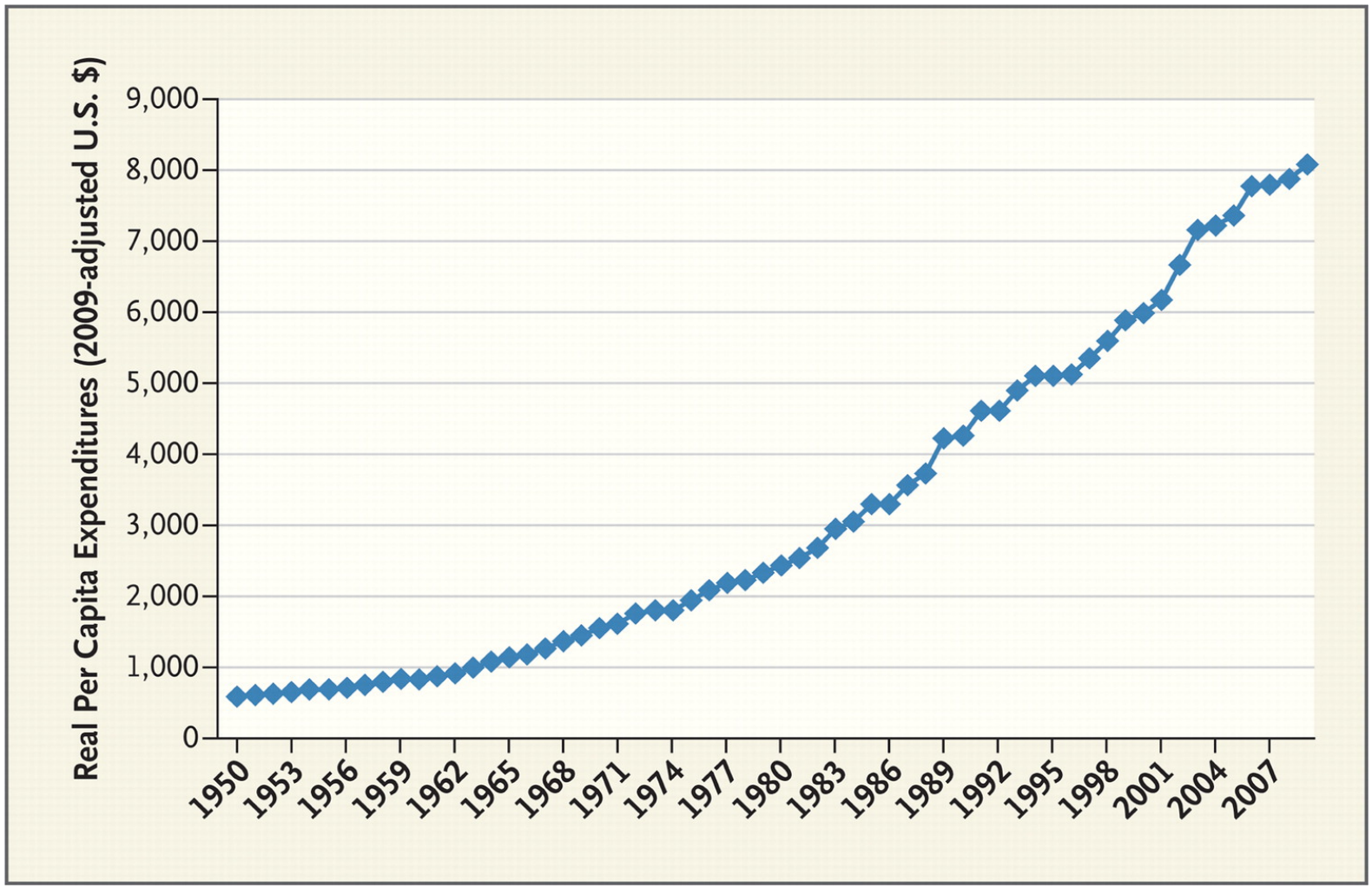
What We Will Cover

- This presentation will address the emerging value proposition in healthcare
- A general overview about metrics to evaluate the value of new technology in cancer care from various perspectives
  - Scientific Community
  - Patients
  - Payers
  - Society
- Emerging payment models

The Subtext: “what I will barely mention”

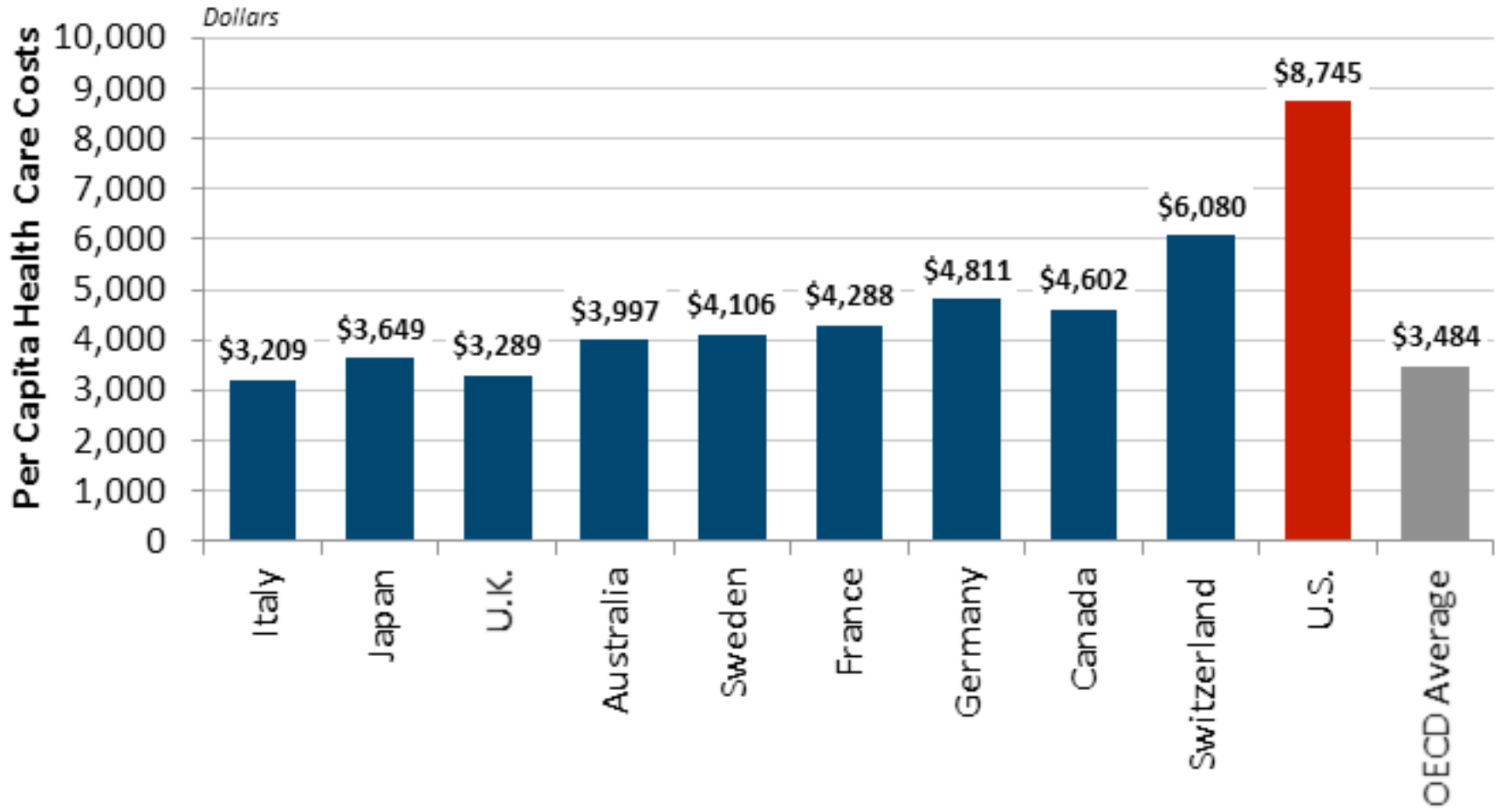
- The process of technology assessment leading to coverage
- The epistemological problem of evidence development for technology
- The societal dilemma of ever rising cost of healthcare, much of which is driven by discovery
- But, I will mention the imperative of multiple stakeholders stepping up to fund evidence development to show value

WHY COST MATTERS ?



Peter G. Peterson Foundation
Our America. Our Future.

Americans spend over twice as much per capita on healthcare as the average developed country does

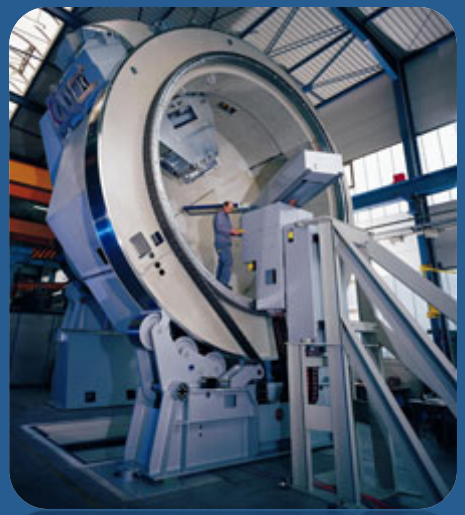


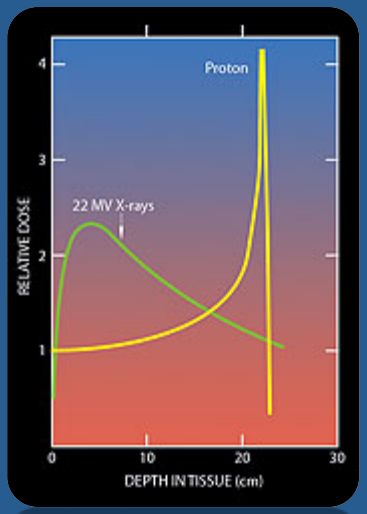
SOURCE: OECD, *OECD Health Statistics 2014*, June 2014. Compiled by PGPF.
NOTE: Per capita health expenditures are for the year 2012, except Australia, for which 2011 data are the latest available. Chart uses purchasing power parities to convert data into dollars.

What Did Our Extra Spending Buy?

- Over a 10 year period:
  - 10% more office visits
  - Same number of overnight hospital stays
  - 80% more MRI scans and
  - Twice the number of CT scans (and associated radiation dose)
  - Doubling in the cost of Specialty Drugs

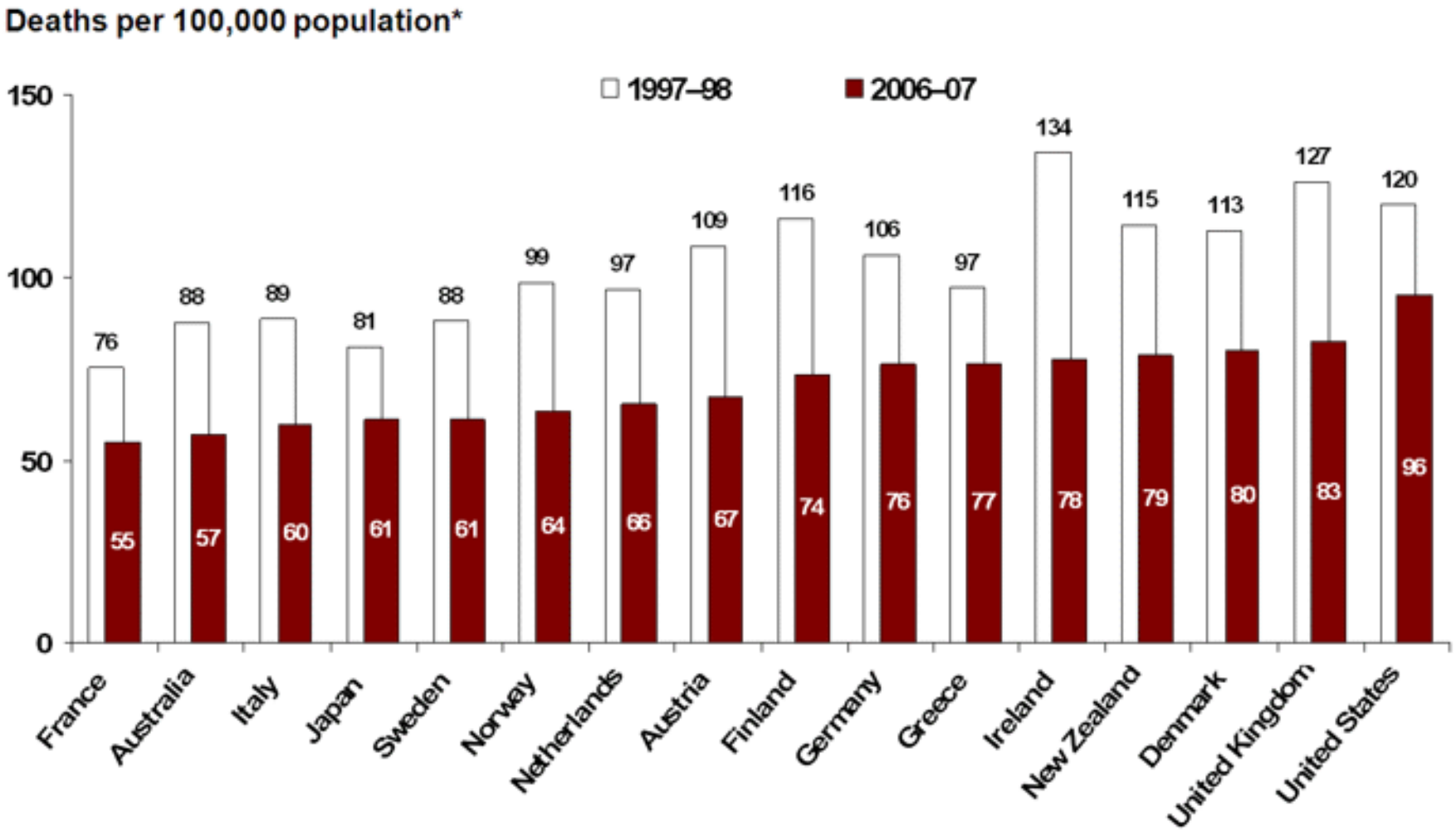
More Proton Facilities





So We Are #1
In Healthcare,
Right ?

U.S. Lags Other Countries: Mortality Amenable to Health Care



* Countries' age-standardized death rates before age 75; including ischemic heart disease, diabetes, stroke, and bacterial infections. Analysis of World Health Organization mortality files and CDC mortality data for U.S.

Source: Adapted from E. Nolte and M. McKee, "Variations in Amenable Mortality—Trends in 16 High-Income Nations," *Health Policy,* published online Sept. 12, 2011.

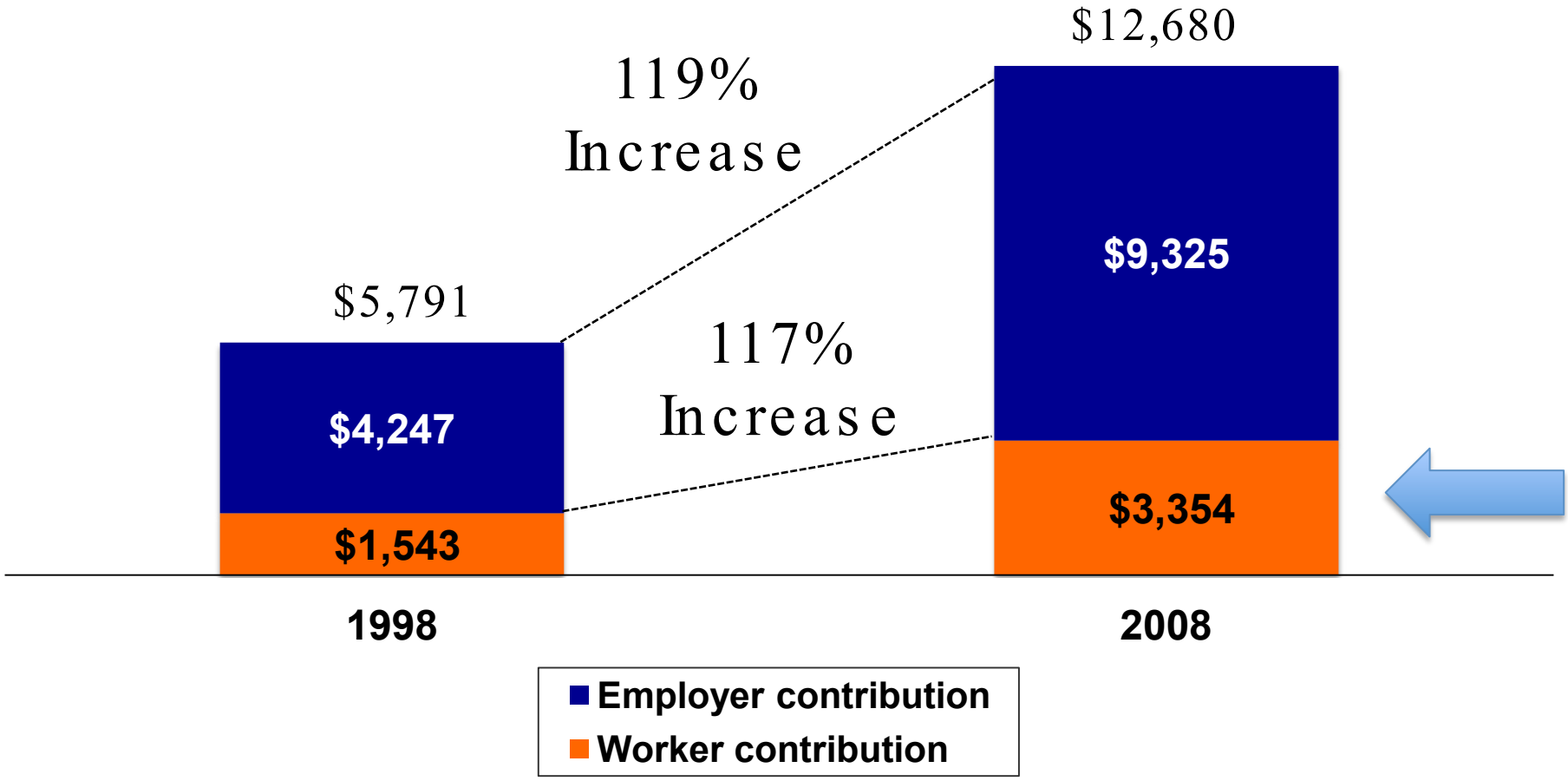
THE COMMONWEALTH FUND

What else happened in the 10 years?

- **Adult life expectancy in the US grew by 1 year – but, roughly half the average gain in life expectancy achieved by other OECD countries (2.2 years)**

- ***….and for a family of 4 ….***

Average Health Insurance Premiums and Worker Contributions for Family Coverage, 1999-2008



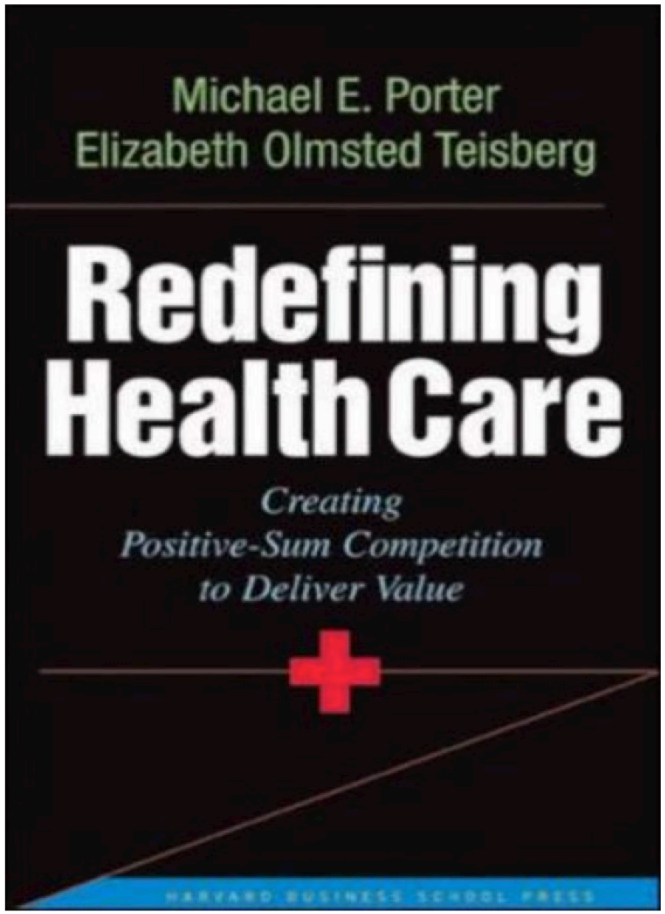
THE HENRY J. KAISER FAMILY FOUNDATION

NOTE: The average worker contribution and the average employer contribution do not add to the average total premium due to rounding.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 1999-2008.

With permission of Art Kellerman

A9750-10 04/2012



"Achieving high value for patients must become the overarching goal of health care delivery."

Porter, ME. *What is Value in Health Care?* NEJM 2010.

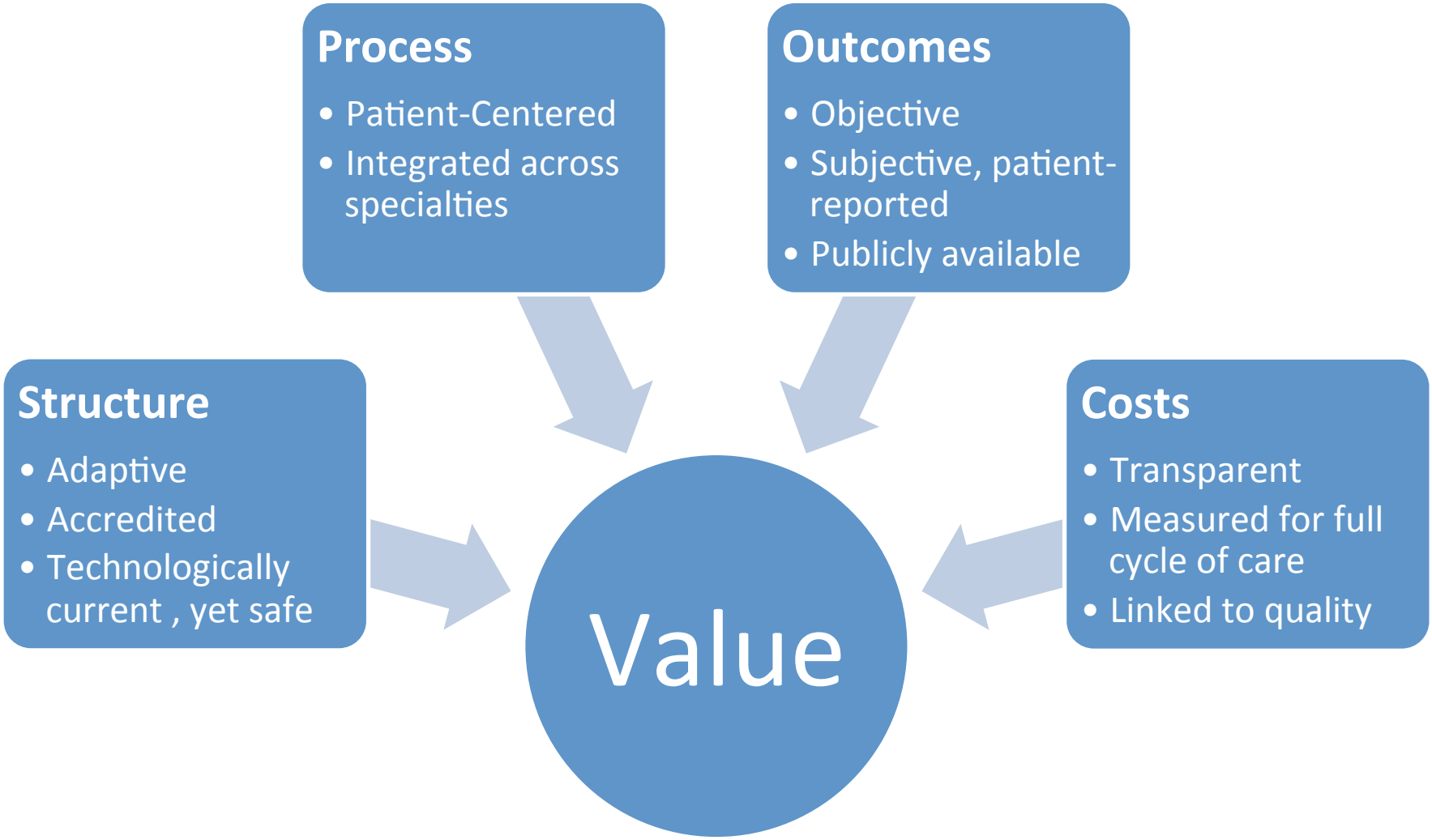
JOURNAL OF CLINICAL ONCOLOGY

REVIEW ARTICLE

Value: A Framework for Radiation Oncology

Sewit Teckie, Susan A. McCloskey, and Michael L. Steinberg

JCO, September 10, 2014 vol. 32 no. 26 2864-2870



JCO September 10, 2014 vol. 32 no. 26 2864-2870

WHAT IS VALUE?

What is value ?

- In the world outside of medicine, a "good value" is a desirable product or service that can be purchased for a fair price
  - Definition varies depending on social identity and social context; varies with the person doing the purchasing (the patient)
  - Desirable product or service very much in the eye of the beholder.

Challenges to Achieving Value in Healthcare

- Information asymmetries
  - The provider and patient often do not possess the same information about any of the components of care, especially cost and quality
  - Precludes patients from being "utility maximizers"
  - Prevents the function of the "invisible hand," and therefore a true free market in healthcare
  - Payers' response to this situation, where information is lacking, is to save by simply grinding on unit price

Challenges to Achieving Value -Economic Self Interest-

- Misaligned financial incentives
  - Supplier-induced demand
    - FFS payments encourage overuse
    - Payer response (cutting reimbursement or limiting coverage) leads to increased utilization via provider based volume effect → total cost spiral
  - Principal-agent problem
    - Patients (principals) assume that providers (agent) act in principal's best interest
    - e.g. Self-referral of urologists to IMRT shops in which they have ownership significantly increases use of IMRT in all age categories

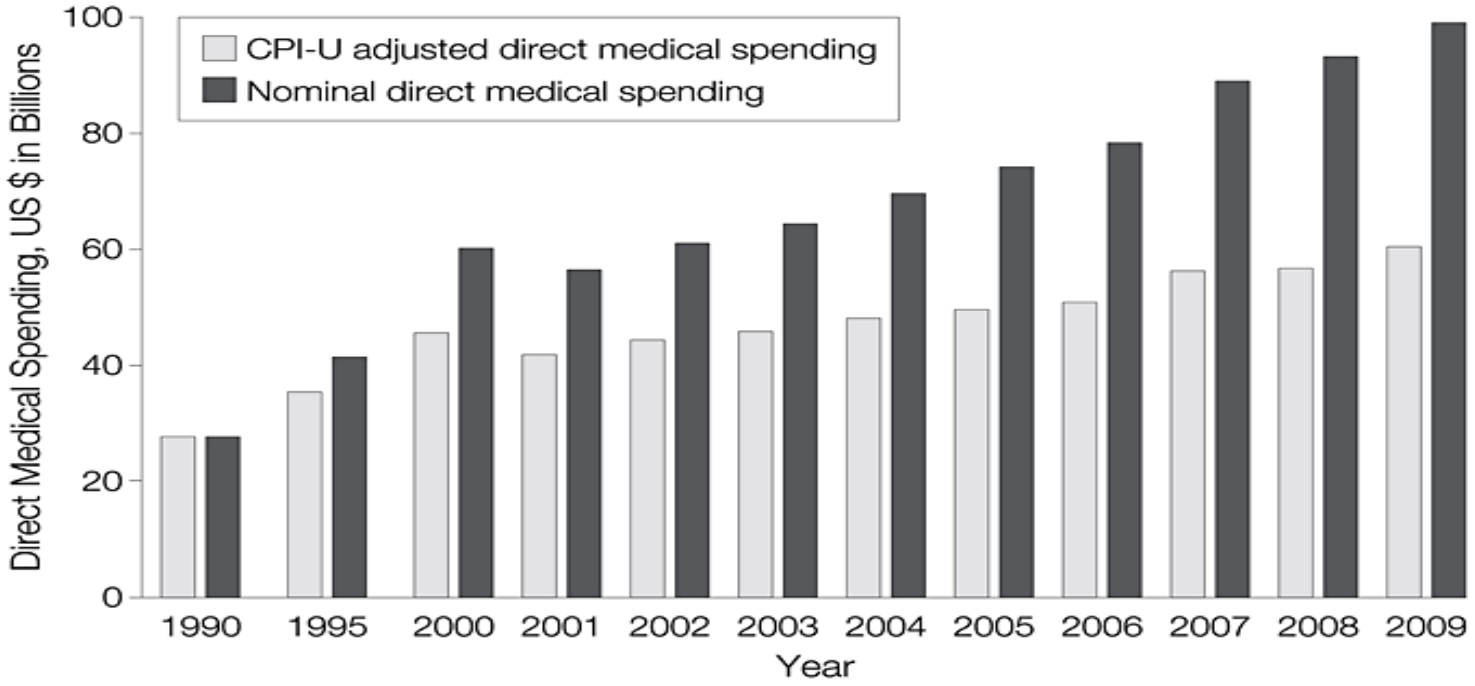
Mitchell, JM. NEJM 2013.

Challenges to Achieving Value

- Cultural attitudes to cancer care
  - Historically Cancer Care was a “sacred cow”
  - Spending in the last 6 months of life is high
  - Not much attention to rising cost until recently,

Challenges to Achieving Value

- Economic trends in cancer care
  - Inflation-adjusted direct medical spending on cancer care exhibited a 50% higher growth rate compared to the rest of healthcare over a 20-year period (Elkin, JAMA, 2010;303:1086-1087)



Challenges to Achieving Value

- Economic trends in cancer care
  - System-wide and out-of-pocket costs for cancer are rising
  - Supply-demand dilemma: patients may demand less medical care as the prices of healthcare as well as complementary and substitute goods rise
- "Financial Toxicity" (Zafar, et al The Oncologist 2013; 18:381–390)
  - 254 patients: 68% cut back on leisure activities, 46% reduced spending on food & clothing, 20% took less than prescribed prescriptions, 24% did not fill prescriptions at all

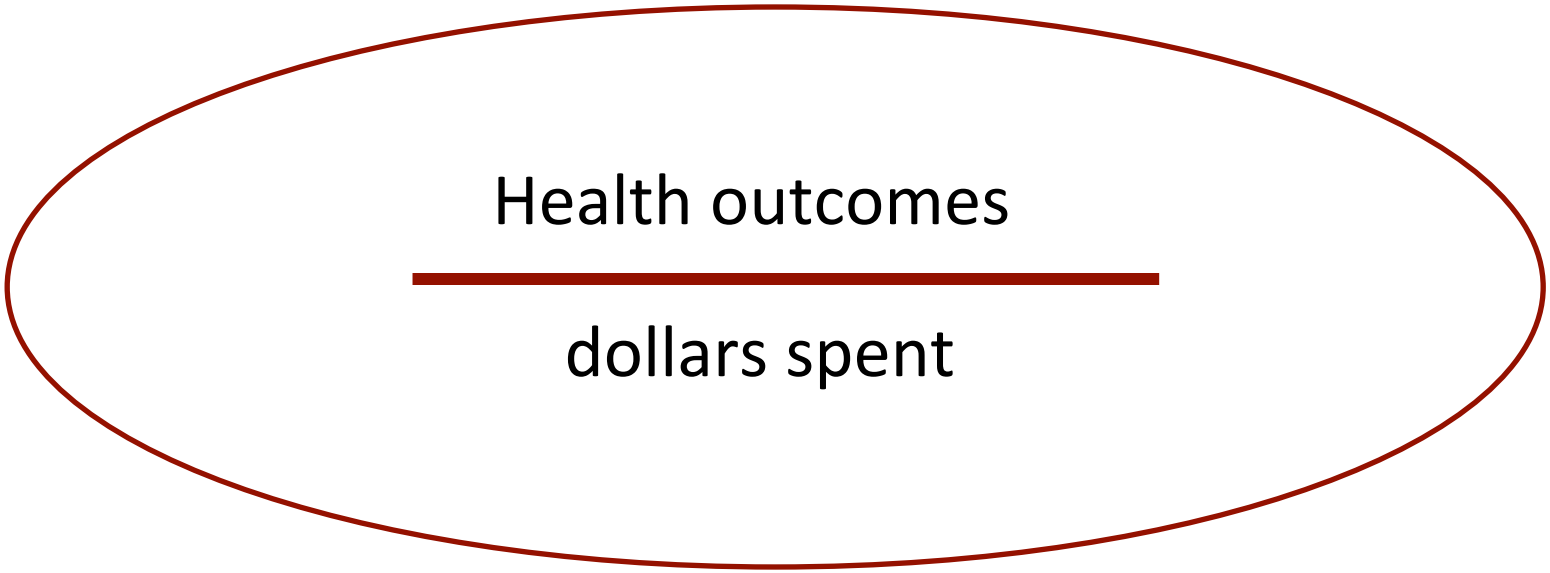
The Cost Conundrum

- Inability to assess cost poses the greatest challenge in determining value in healthcare
- **Charges ≠ Costs**
- Charges for the same procedure or supply can vary wildly between different providers and settings
- In healthcare, we simply do not know our costs

Measuring Costs

- **How it is currently done**: measure costs around departments, specialties, procedure types. Reflects current financing of care.
- **How it should be done**: measure costs around the patient's care cycle.

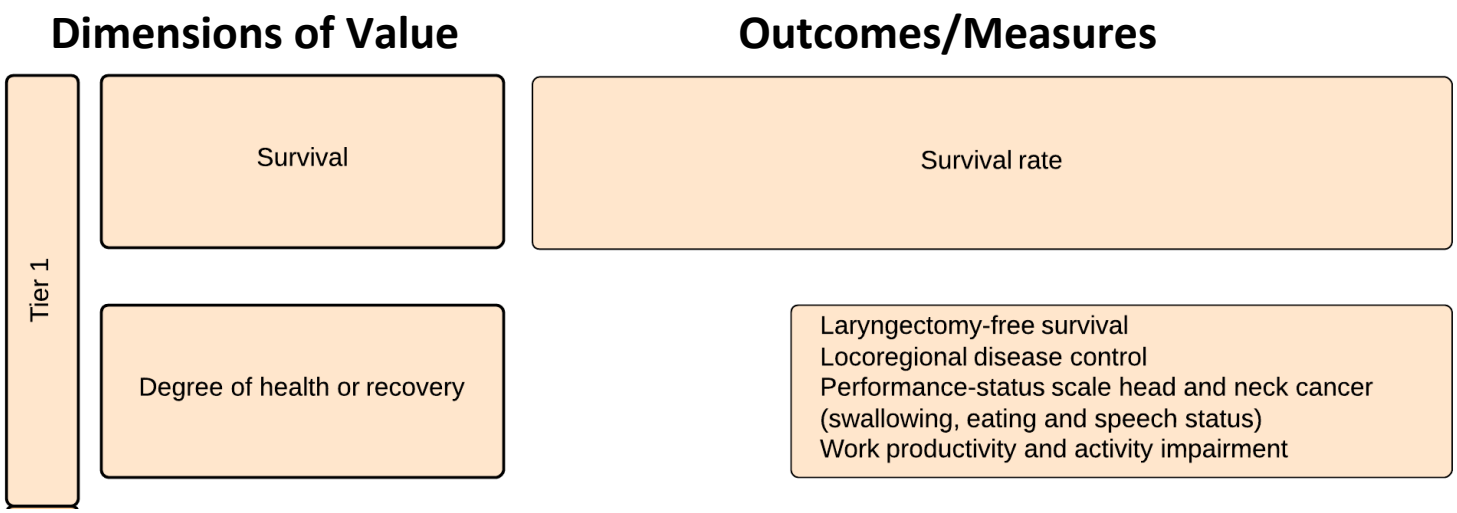
What is Value?



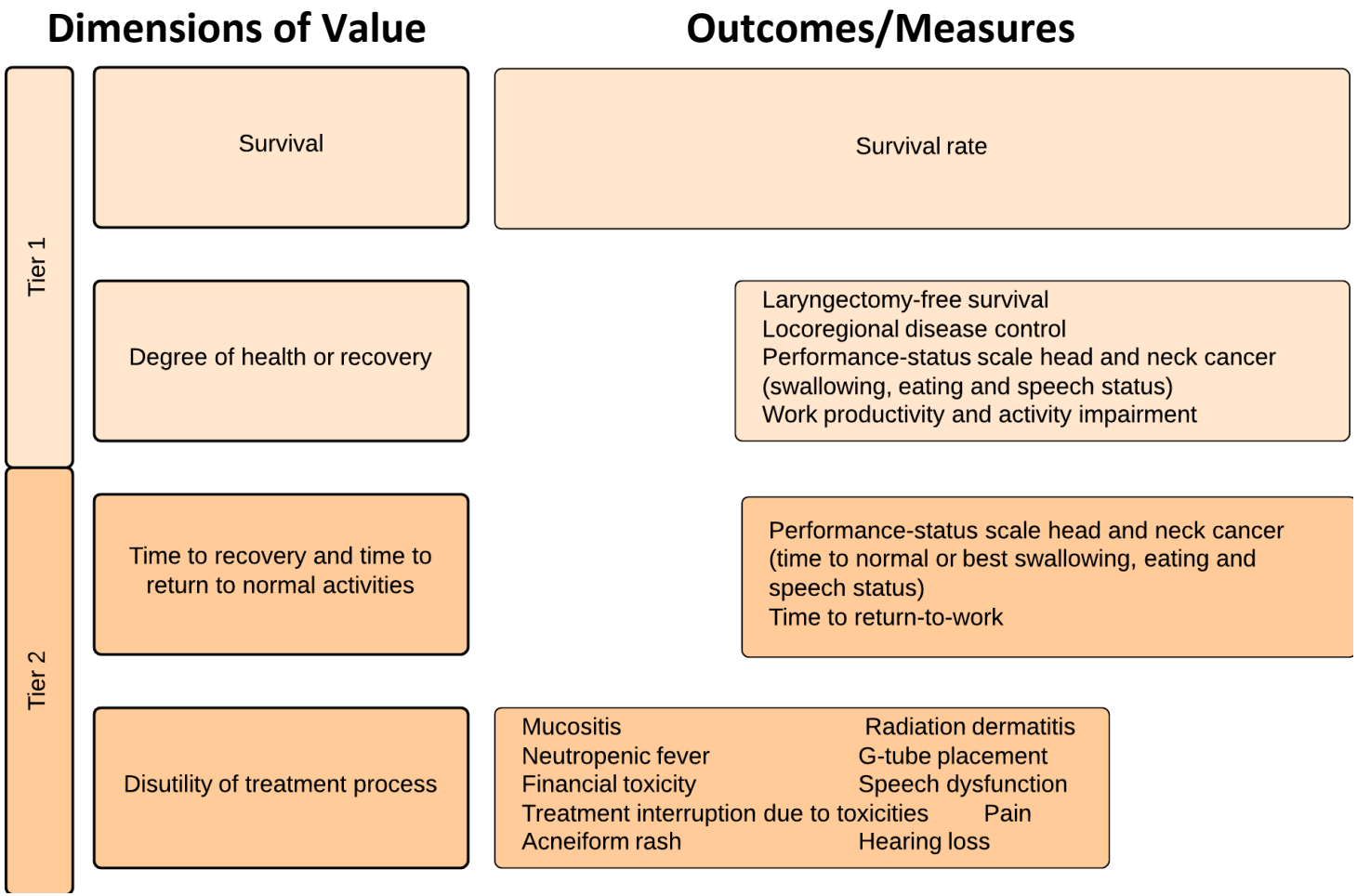
Entire cycle of care

Porter ME. What Is Value in Health Care? *New England Journal of Medicine.* 2010;363(26): 2477-2481.

From Jonas DeSouza



de Souza JA, Seiwert TY: A value framework in head and neck cancer care. Am Soc Clin Oncol Educ Book 34:e304-9, 2014



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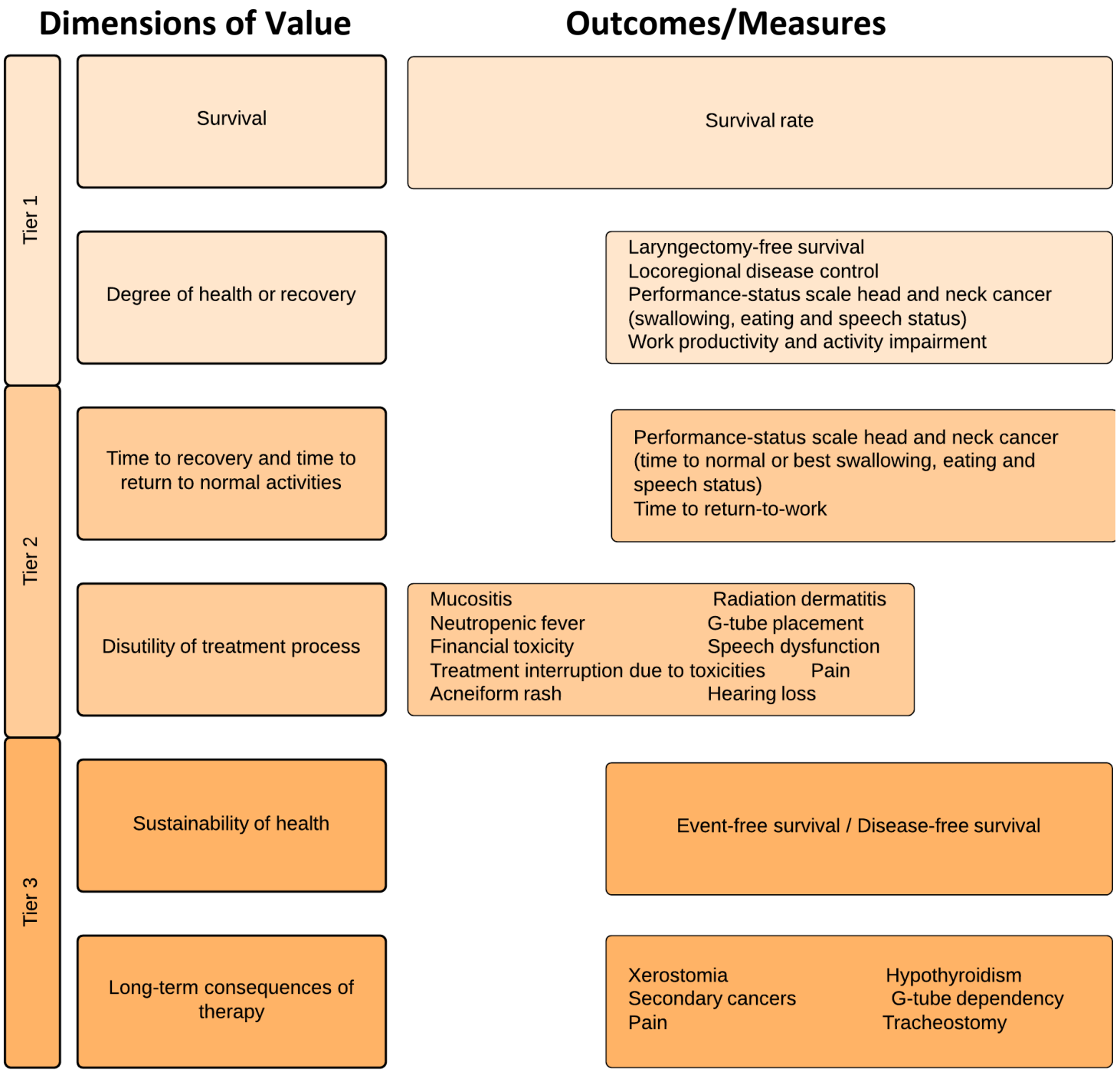

Dimensions of Value
Outcomes/Measures
Tier 1
Tier 2
Tier 3
Survival
Survival rate
Degree of health or recovery
Laryngectomy-free survival
Locoregional disease control
Performance-status scale head and neck cancer (swallowing, eating and speech status)
Work productivity and activity impairment
Time to recovery and time to return to normal activities
Performance-status scale head and neck cancer (time to normal or best swallowing, eating and speech status)
Time to return-to-work
Disutility of treatment process
Mucositis
Neutropenic fever
Financial toxicity
Treatment interruption due to toxicities
Acneiform rash
Radiation dermatitis
G-tube placement
Speech dysfunction
Pain
Hearing loss
Sustainability of health
Event-free survival / Disease-free survival
Long-term consequences of therapy
Xerostomia
Secondary cancers
Pain
Hypothyroidism
G-tube dependency
Tracheostomy

Beyond Survival
Head and Neck Cancer

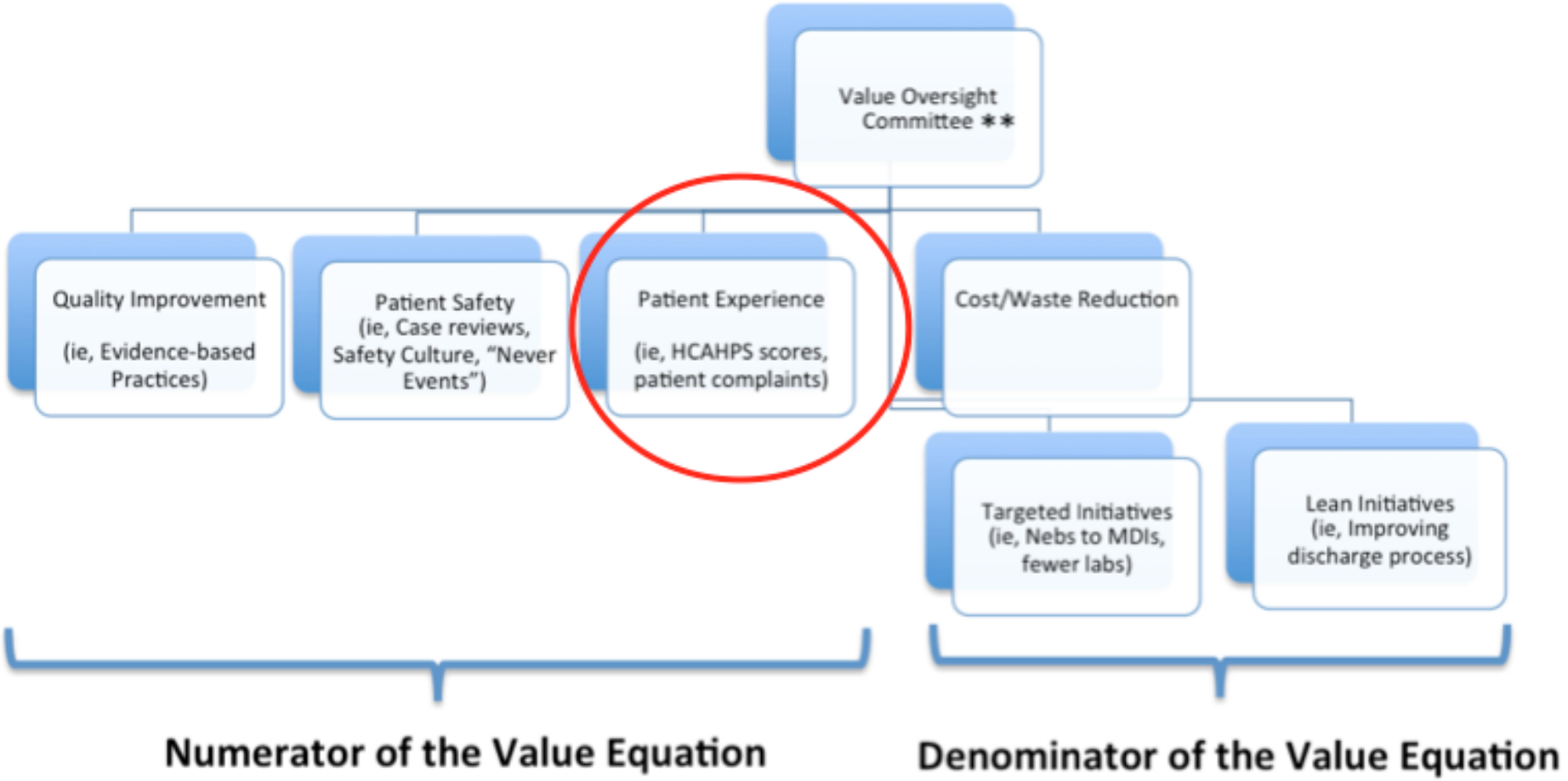
- 33% (n=301) to 52% (n = 384) of patients who were employed at the time of diagnosis were unable to return to work after treatment was completed

- Taylor JC, Terrell JE, Ronis DL, et al. DIsability in patients with head and neck cancer. *Archives of Otolaryngology–Head & Neck Surgery.* 2004;130(6):764-769.
- Vartanian JG, Carvalho AL, Toyota J, Kowalski IS, Kowalski LP. Socioeconomic effects of and risk factors for disability in long-term survivors of head and neck cancer. *Archives of otolaryngology--head & neck surgery.* Jan 2006;132(1):32-35.

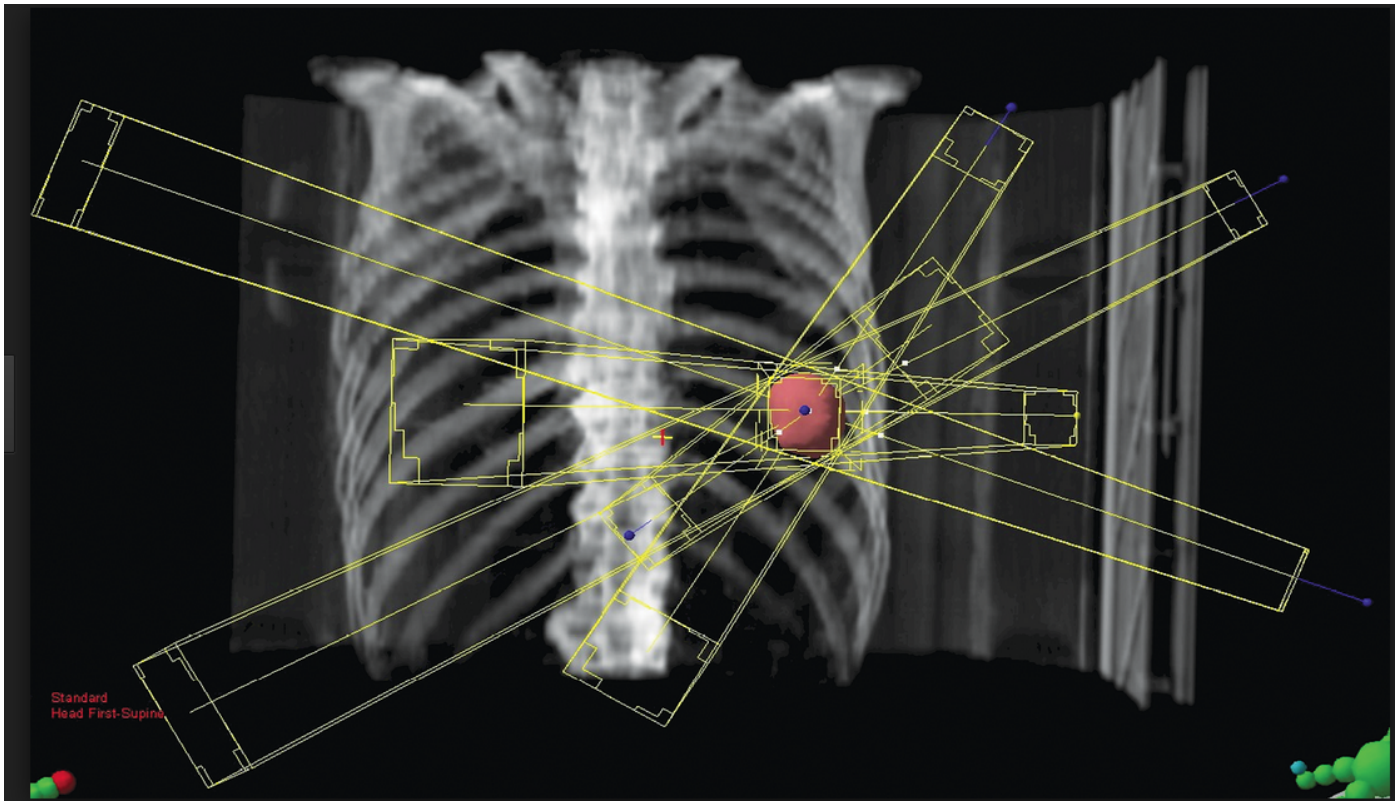
Outcomes

- Subjective measures
  - Traditionally not well-measured or even well accepted
  - Quality of life measurements are not enough
  - Should include:
    - Patient-reported outcomes
    - Psychosocial ramifications of disease or treatment
    - Ability to maintain employment
    - Patient understanding of own medical condition
    - Suffering through the “system” of care

A Model Organizational Chart for a "Value Improvement" Program*

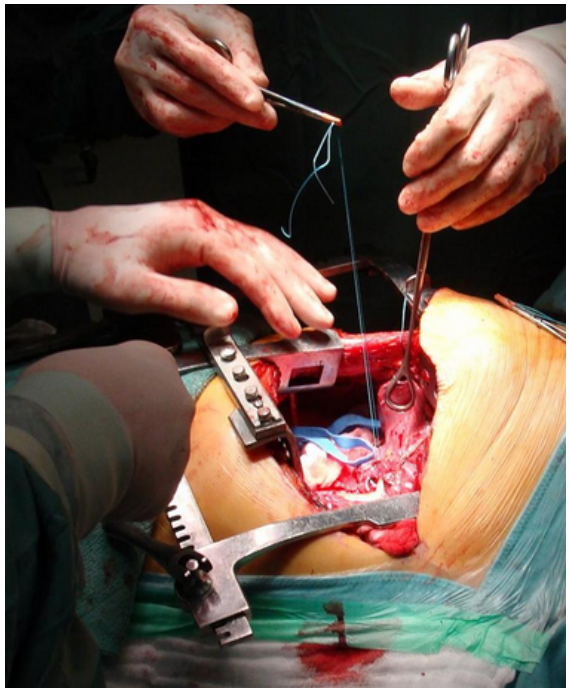


The patient's perspective on stereotactic body radiation therapy (SBRT) for treatment of early stage non small cell lung cancer



Study Questions

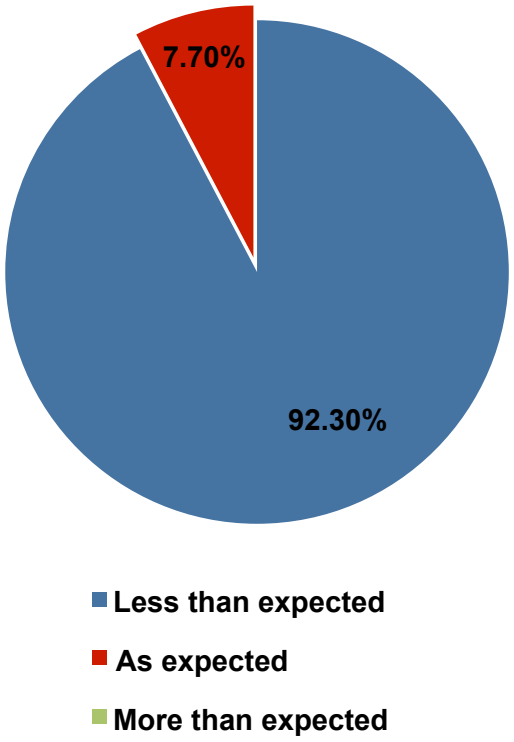
- How did a patient's actual treatment experience compare to original expectations in terms of side effects, convenience, treatment anxiety and caregiver strain?
- For patients that had prior surgical resection for a previously diagnosed Stage I NSCLC, how did their SBRT experience compare to that of their prior surgery?
- 102 patients contacted with 89% participating in the study. 39% of patients had history of lung surgery for prior early stage NSCLC.



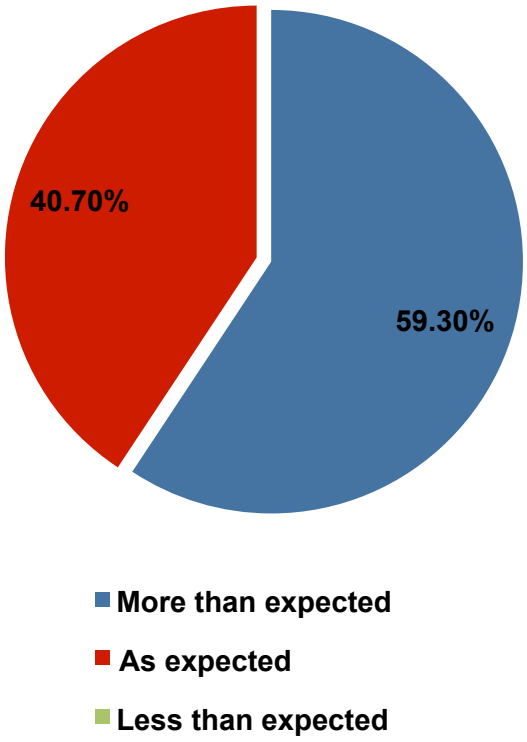
Results:

How was the patient's actual experience compared to original expectations?

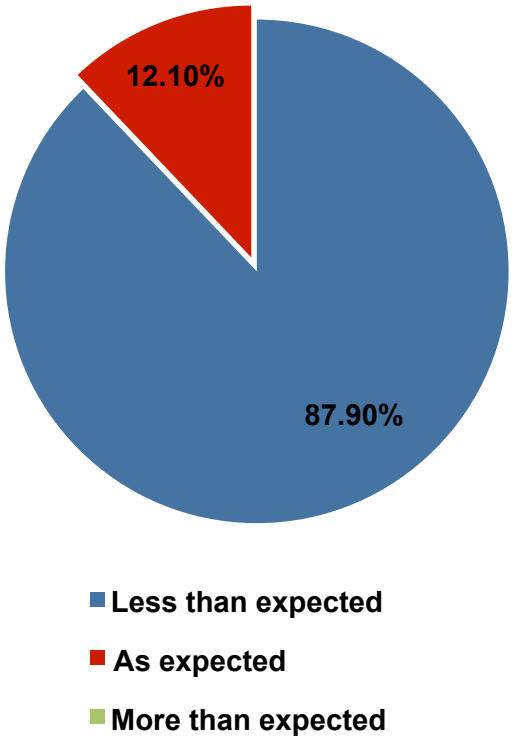
Side effects



Convenience



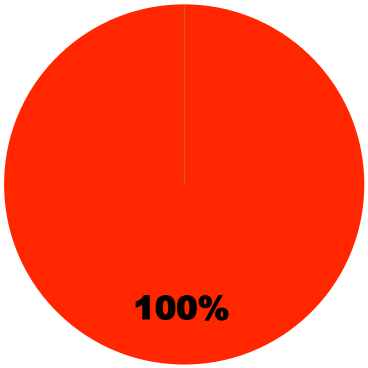
Treatment Anxiety



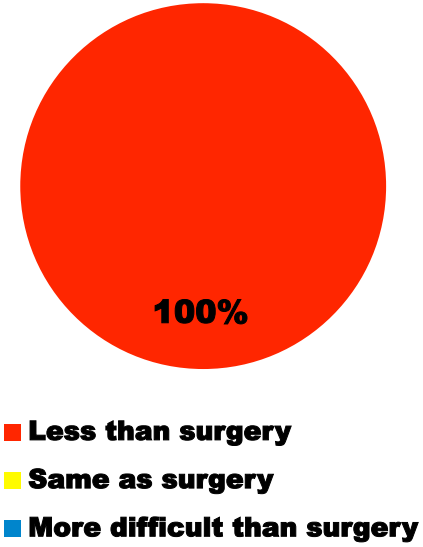
Results:

How did the patient's SBRT experience compare to prior experience with surgery?

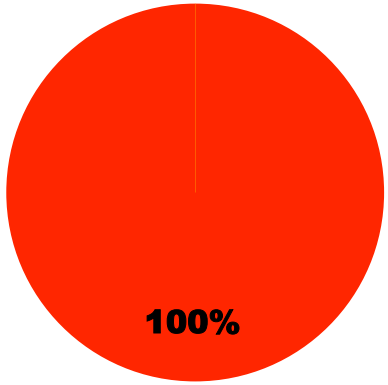
Recovery?



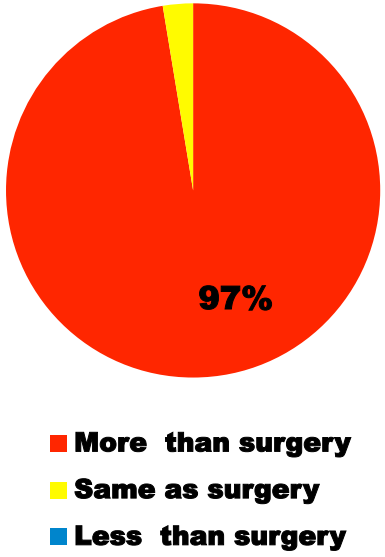
Treatment Anxiety?



Caregiver Strain?

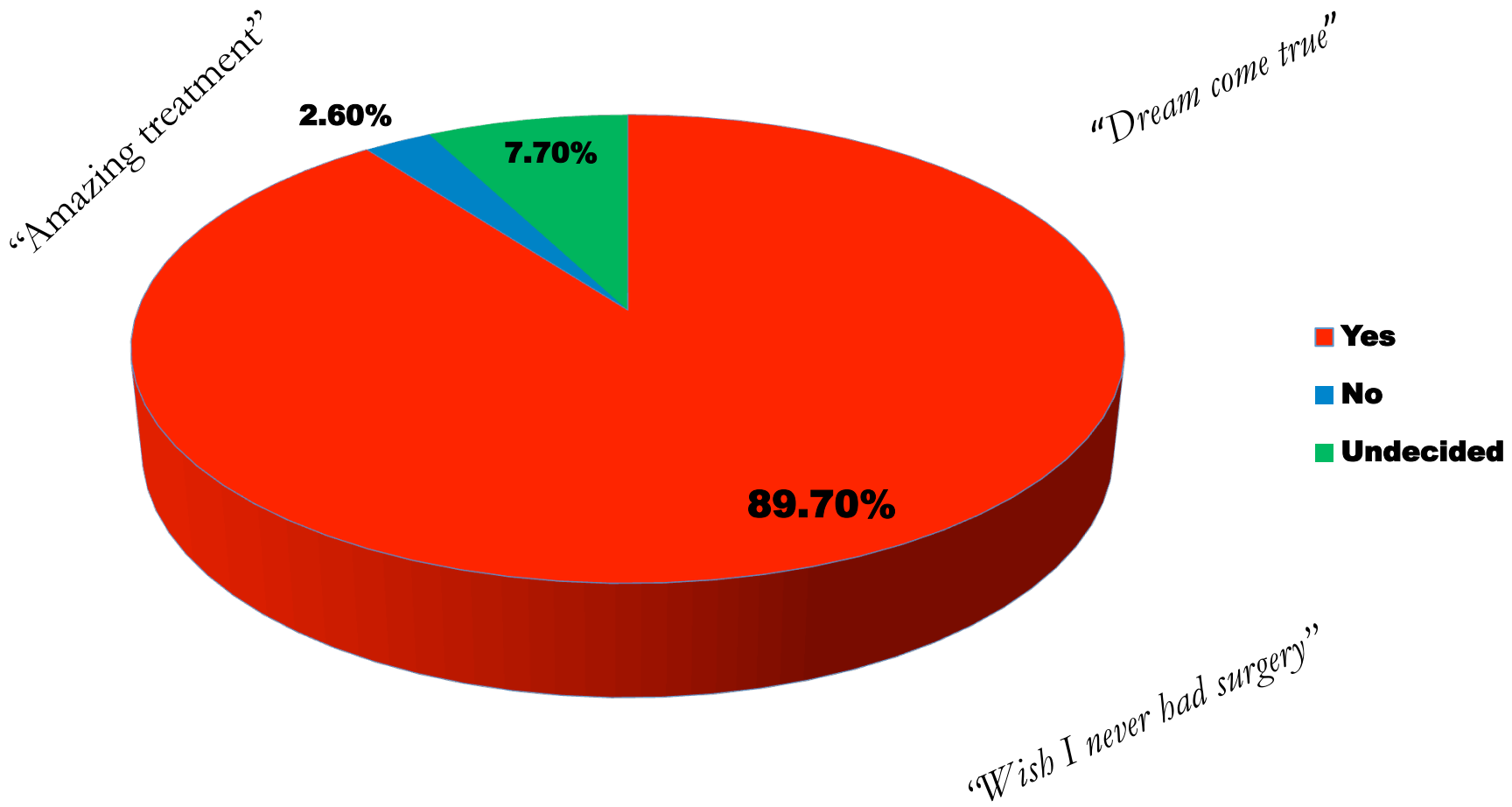


Convenience?



Results:

If you could decide now, and you knew that SBRT was as effective as surgery, would you have rather had SBRT for your prior early stage lung cancer that was operated on?



Can we afford the new wave of "high value" health care?

Who assesses value in the U.S.?

- Medicare
  - "Reasonable and necessary"
- US Preventive Services Task Force
- Private health plans
  - "Medically necessary"
  - Value managed through medical policies but rarely through non-coverage
- Academics
- AHRQ
- Professional specialty societies?
  - Choosing Wisely
  - American College of Cardiology, ASCO, ASTRO
- Patients?
- Technology Assessment Groups

California Technology Assessment Forum (CTAF)

- Independent CTAF Panel of physicians and lay members
- Reviews evidence, including clinical effectiveness assessment and economic modeling
- Votes on comparative effectiveness and value of new procedures, processes and therapies
- Makes recommendations on options for coverage policies and clinical practice
- New: forwards a "value-based price benchmark" for consideration in the policy debate

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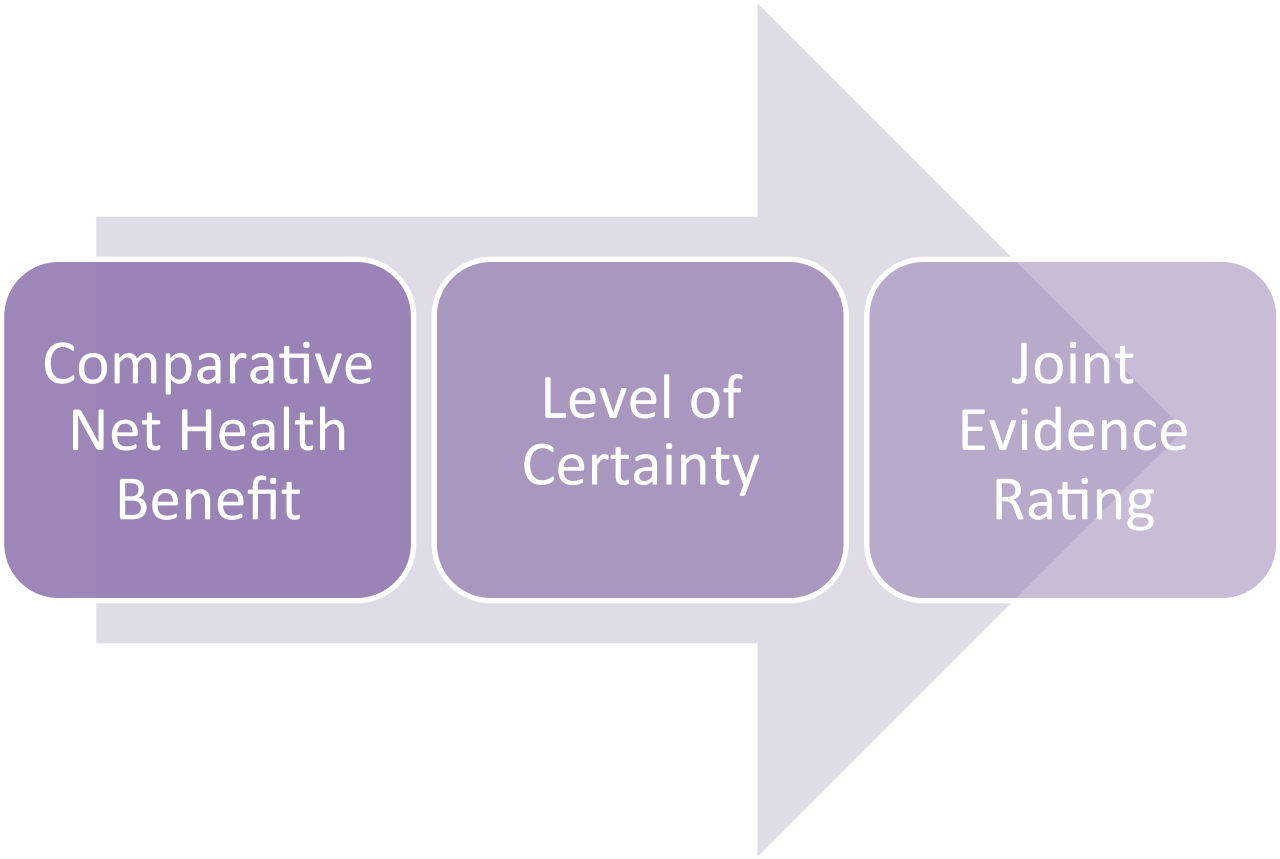
- **New: forwards a "value-based price benchmark" for consideration in the policy debate**

From CTAF

Basic Components

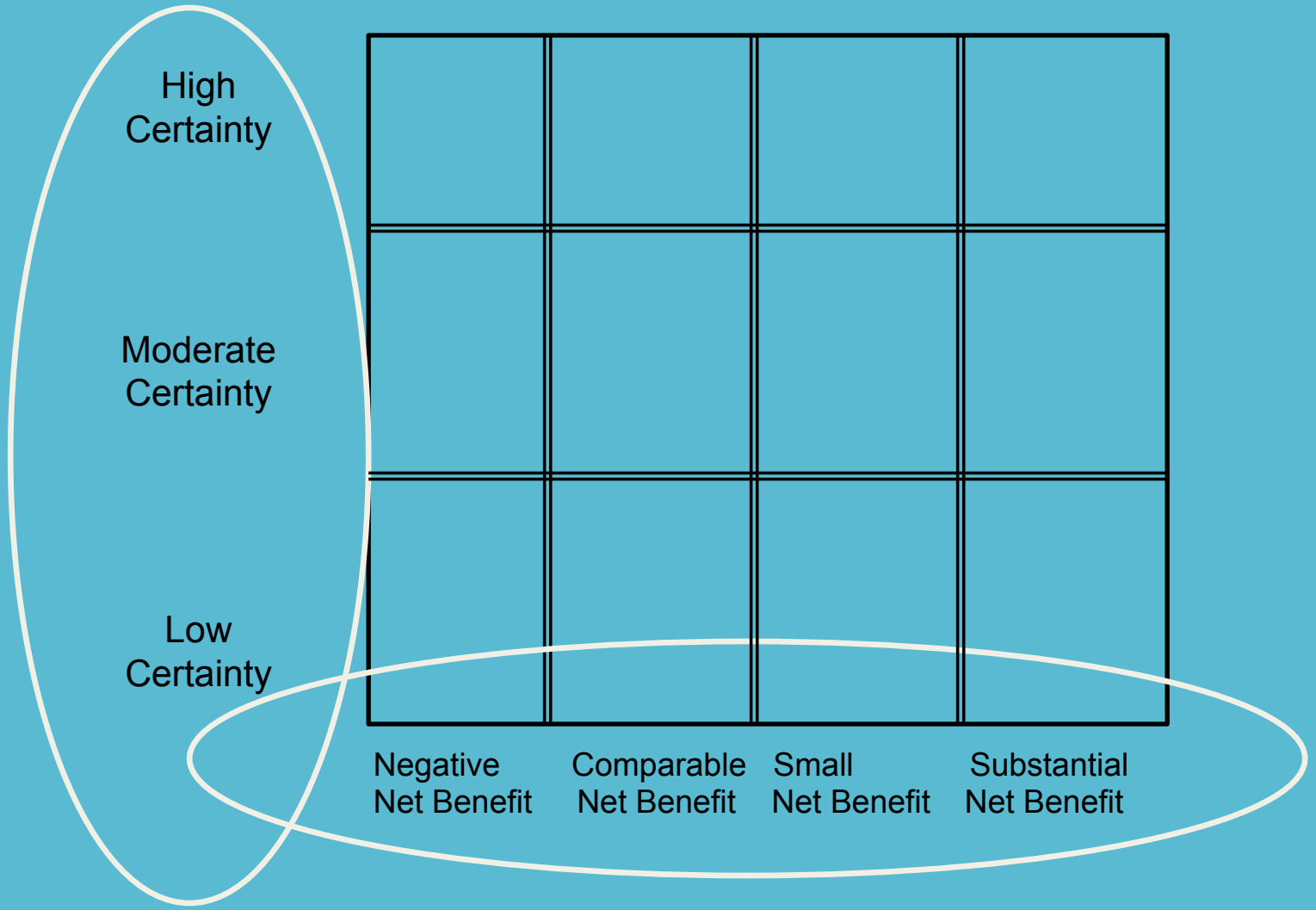
- Systematic evidence review
  - Prospective Trials
  - Observational Data (Registries)
- Decision Analysis
- Cost Effectiveness Analysis

The ICER Evidence Rating Matrix



With permission of ICER

ICER Evidence Rating Matrix



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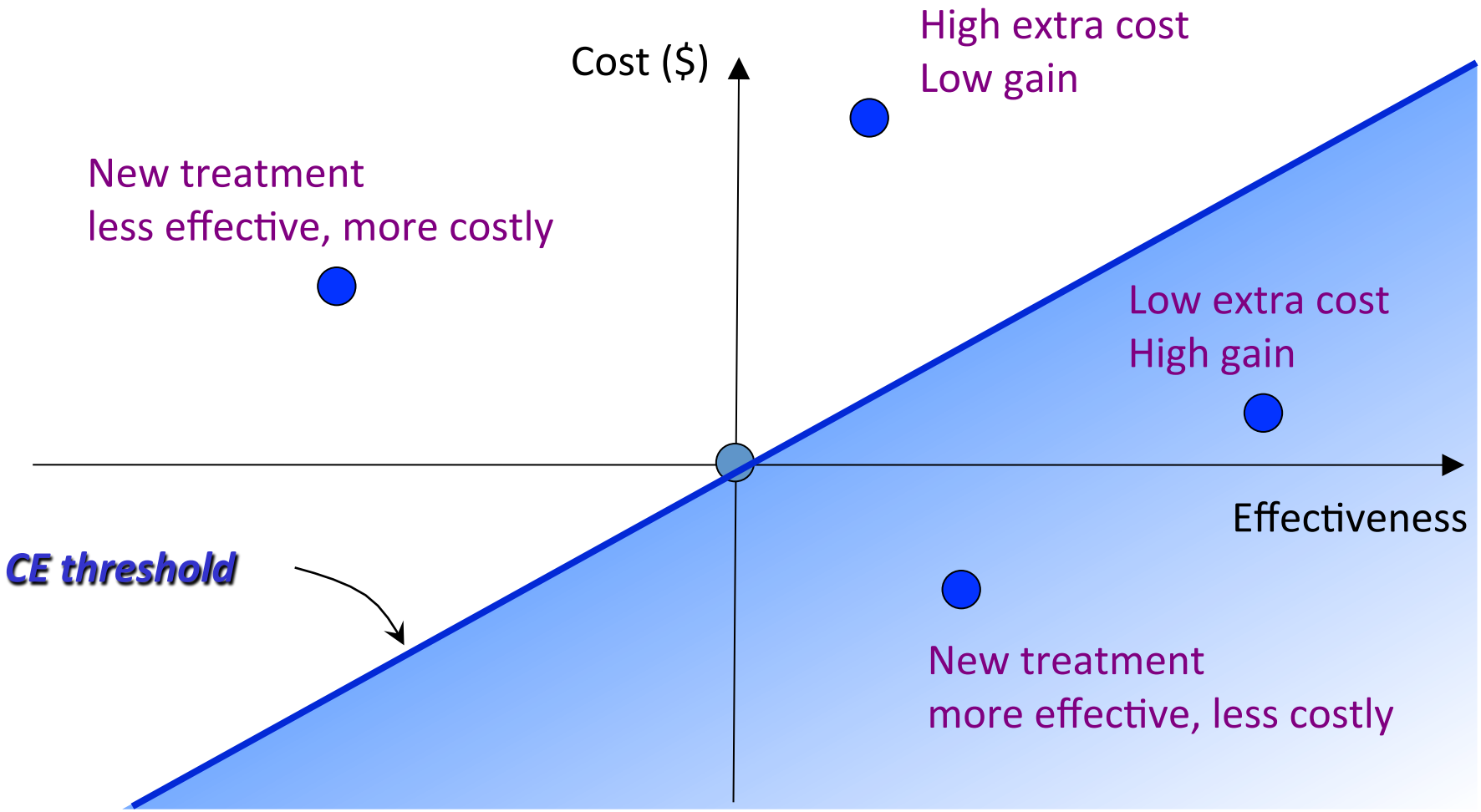
The cost-effectiveness threshold



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Is there more to value than incremental cost-effectiveness?

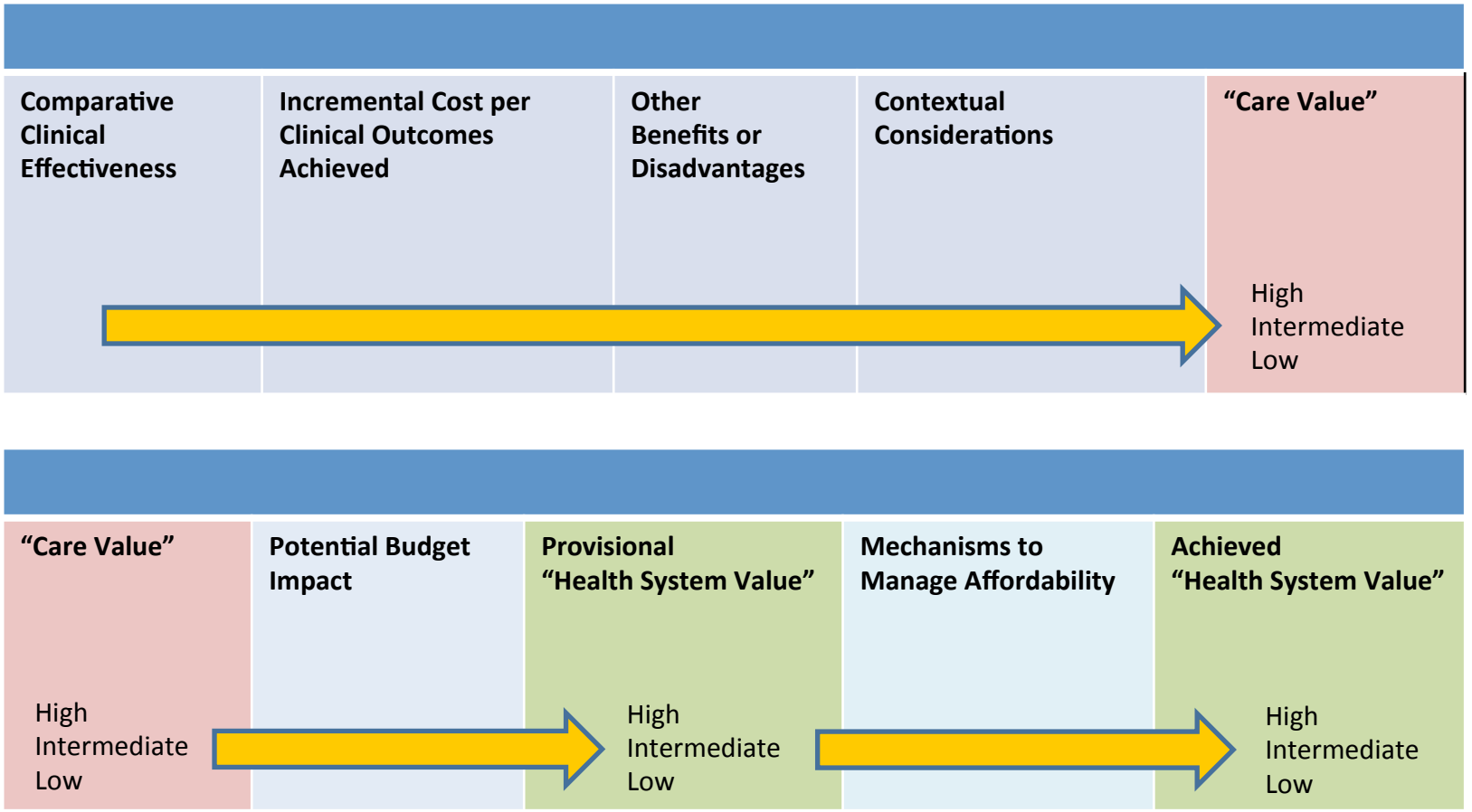
YES!

Assessing Value

A Framework for CTAF Assessments of Health Interventions

J

Value Flowchart



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Incremental Cost per Outcomes Achieved and Care Value

- Incremental Cost per Outcomes Achieved
  - –Cost per aggregated health measure (QALY)
    - Diverse health economic and policy analyst perspectives on mechanisms to set and use cost/QALY thresholds
    - Common practice: WHO recommended thresholds linked to national GDP (1xGDP ~ $50,000 in the United States)

With permission of ICER

Incremental Cost per Outcomes Achieved and Care Value

– ICER will use the following in its reports and in its guidance to CTAF and CEPAC:

- High care value
  - < $50,000/QALY if no "substantial" other benefits and/or contextual considerations
  - $50,000-$100,000 per QALY if "substantial" other benefits and/or contextual considerations
- Intermediate care value
  - $50,000-$100,000/QALY if no "substantial" other benefits and/or contextual considerations
  - $101,000-$150,000/QALY if "substantial" other benefits and/or contextual considerations
- Low care value
  - $101,000-$150,000/QALY if no "substantial" other benefits and/or contextual considerations
  - > $150,000/QALY

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Other Benefits or Disadvantages

- Any substantial benefits or disadvantages offered by the intervention to caregivers, the delivery system, or other patients in the health care system that would not have been captured in the available "clinical" evidence
- Examples include (but are not limited to):
  - **Mechanisms of treatment delivery that require many fewer (or more) visits to the clinician's office**
  - **Treatment outcomes that reduce disparities across various patient groups**
  - New mechanisms of action for treatments of clinical conditions (e.g., mental illness) that have demonstrated low rates of response to currently available treatments
  - Public health benefits (e.g., reducing risk of new infections)

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Contextual Considerations

- Contextual considerations can include ethical, legal, or other issues (but not cost) that influence the relative priority of illnesses and interventions
- Examples include:
  - **Is there a particularly high burden/severity of illness and no acceptable treatments currently exist? (e.g. genetic conditions)**
  - **Does the condition include high-priority populations?**

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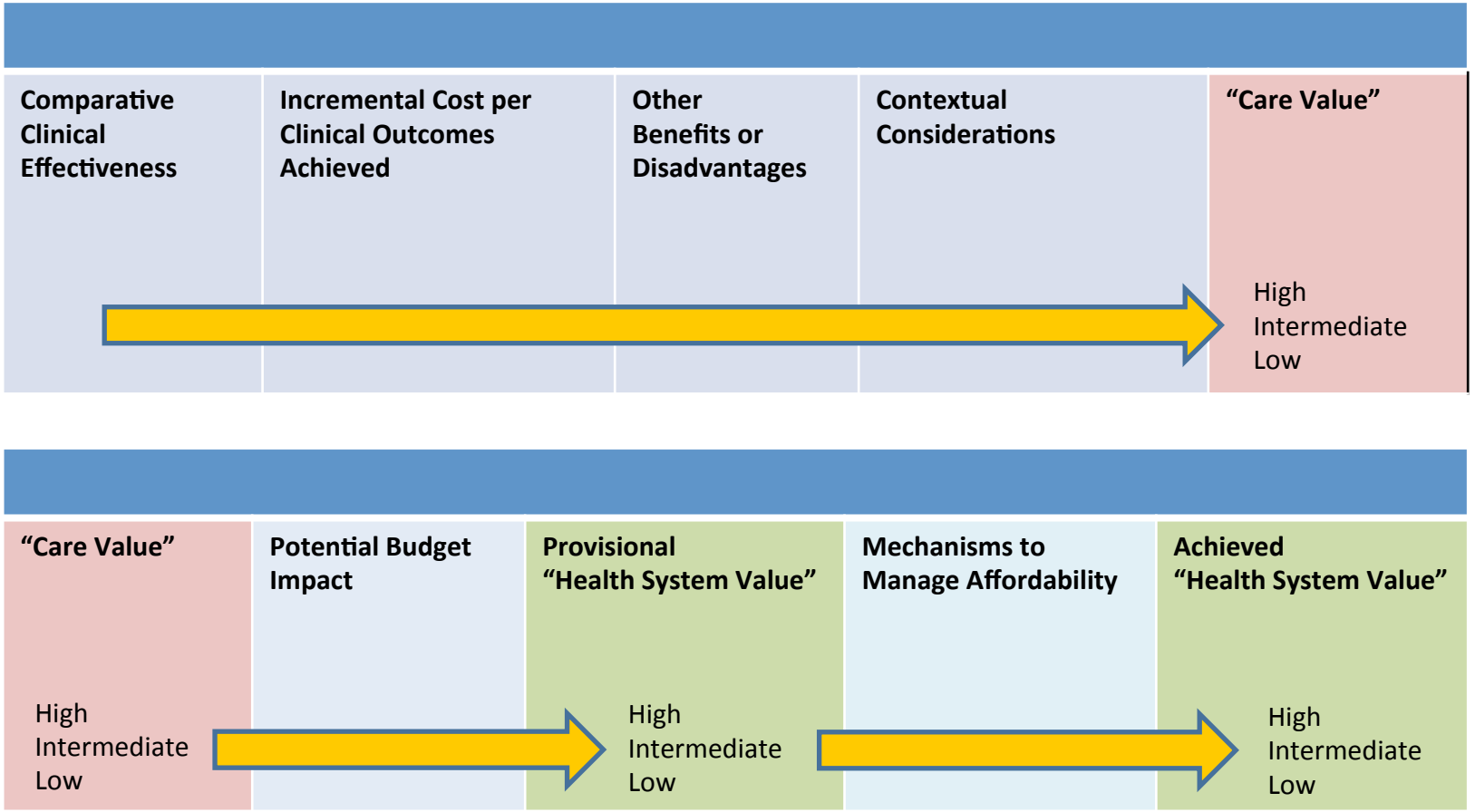
A Value Flowchart



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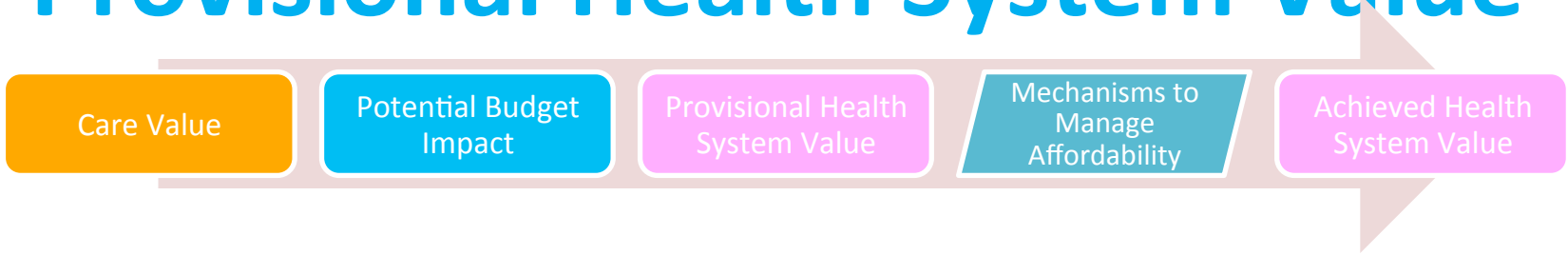
Potential Budget Impact to Provisional Health System Value



- Provisional Health System Value
  - **An early judgment of "provisional" health system value based on the potential budget impact** of a change in care is used as a trigger for determining whether mechanisms need to be considered to help manage the affordability of a new intervention

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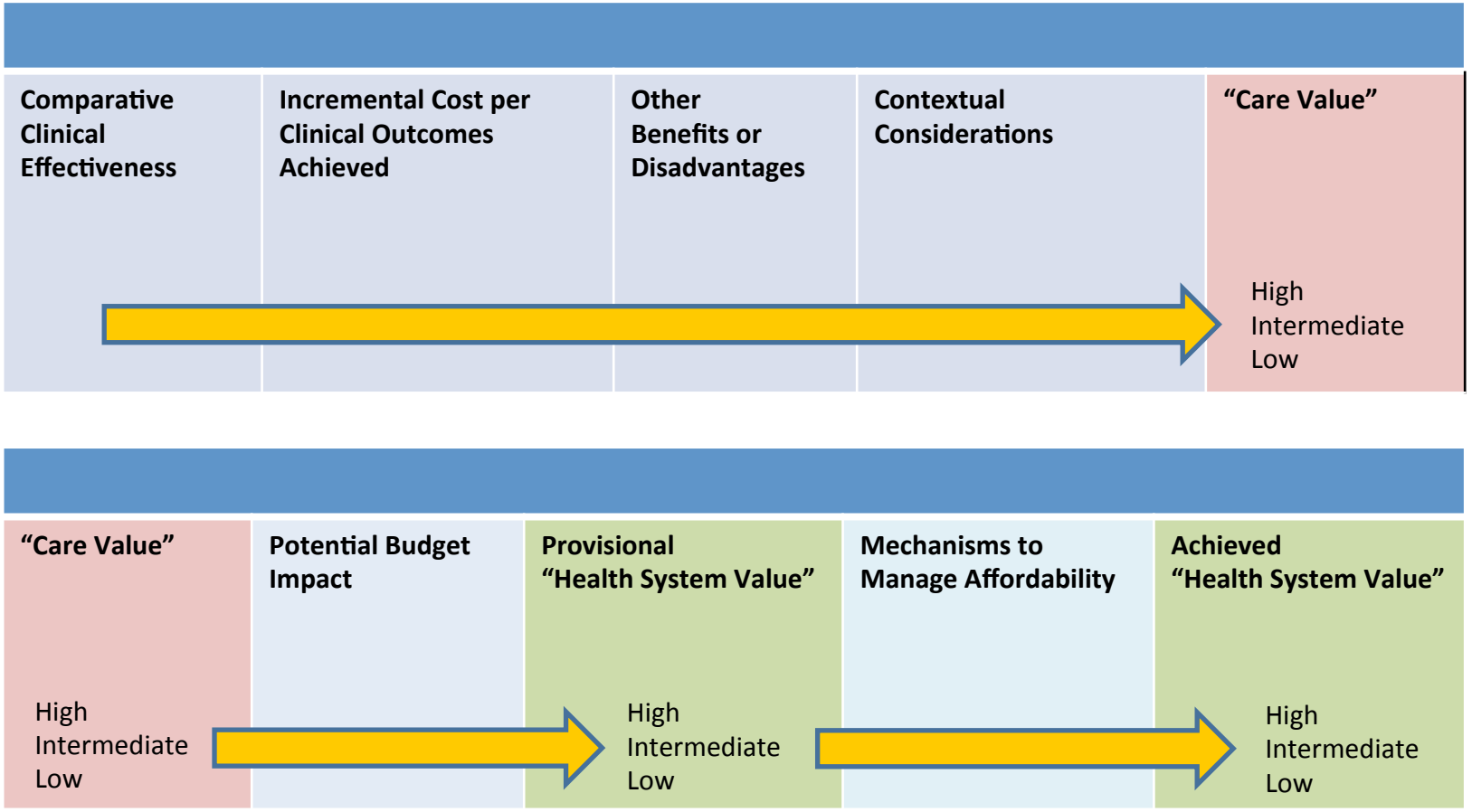
A Value Flowchart



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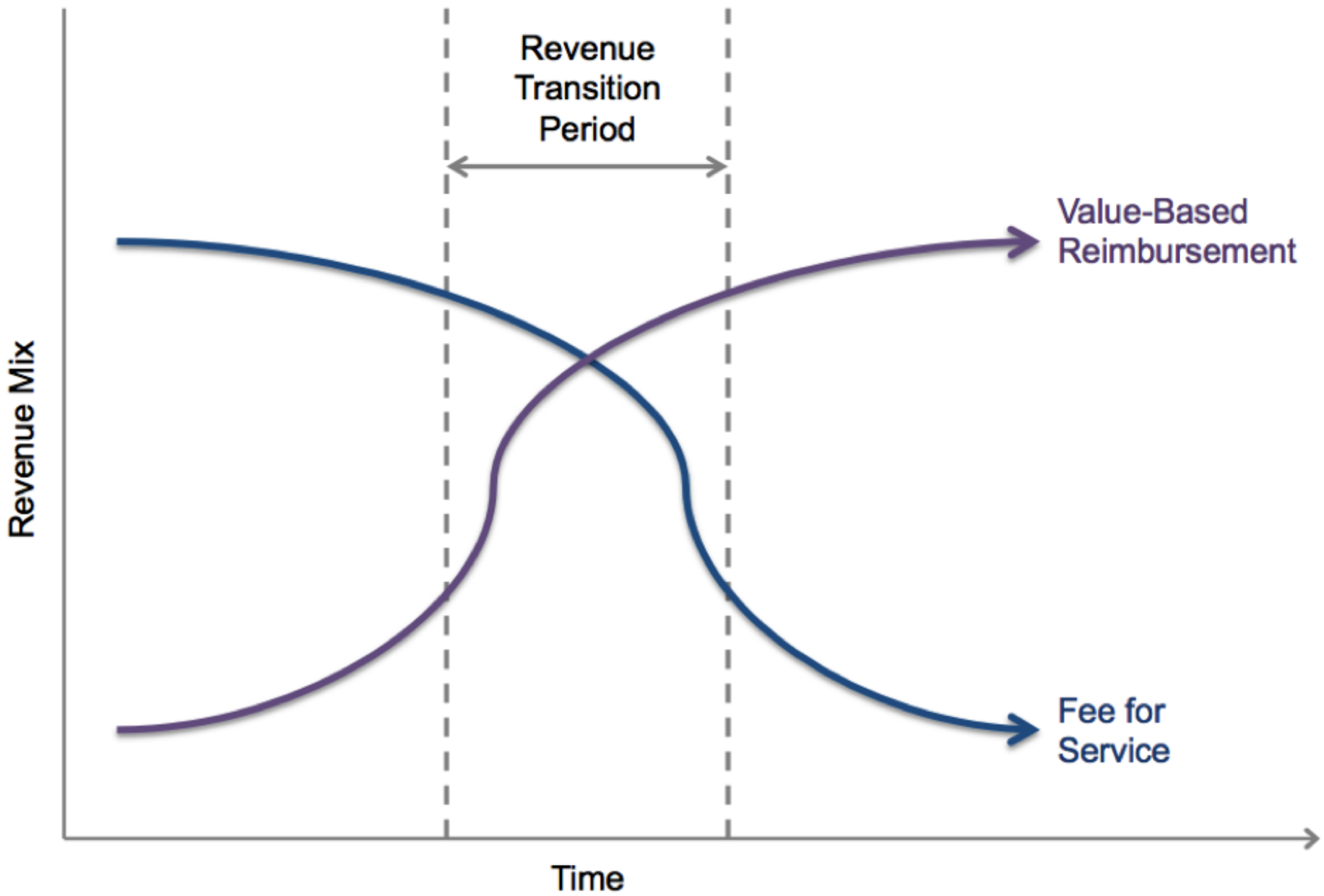
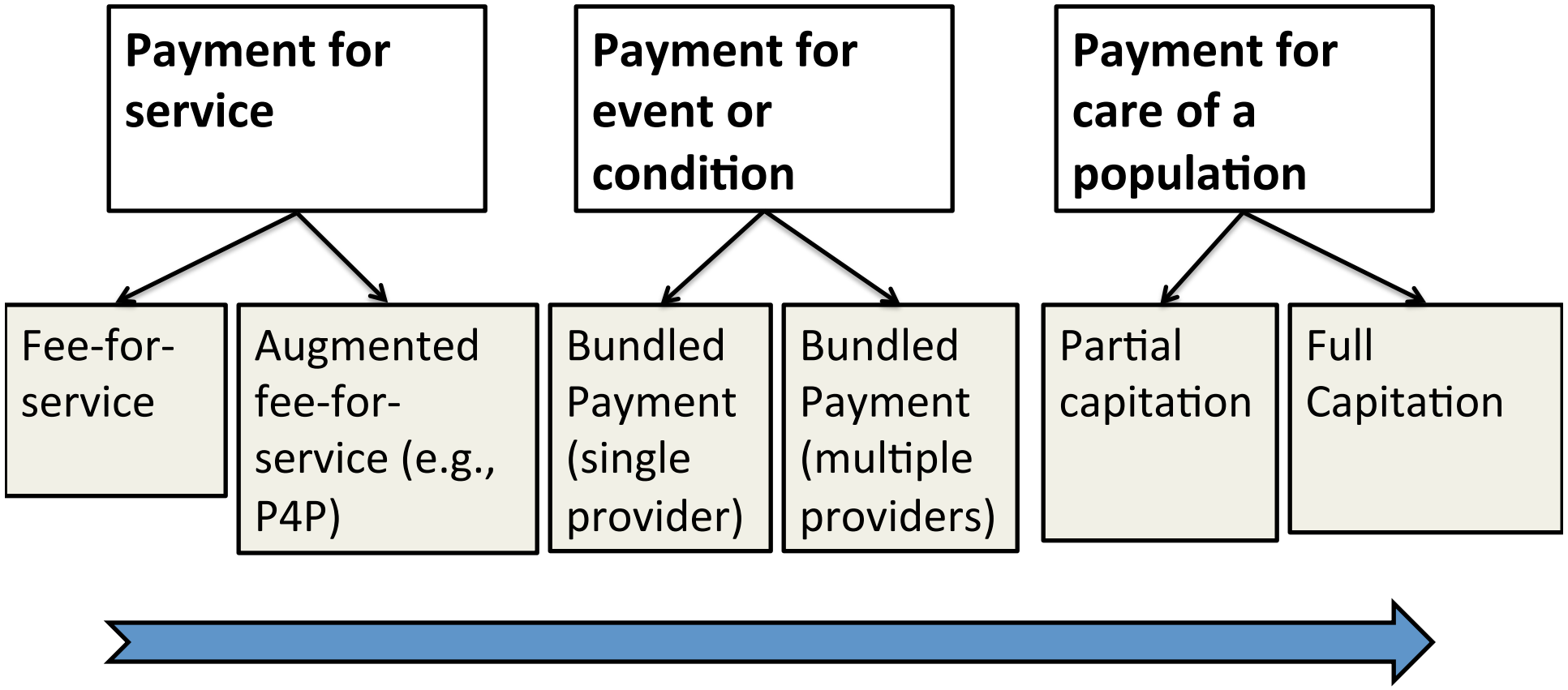
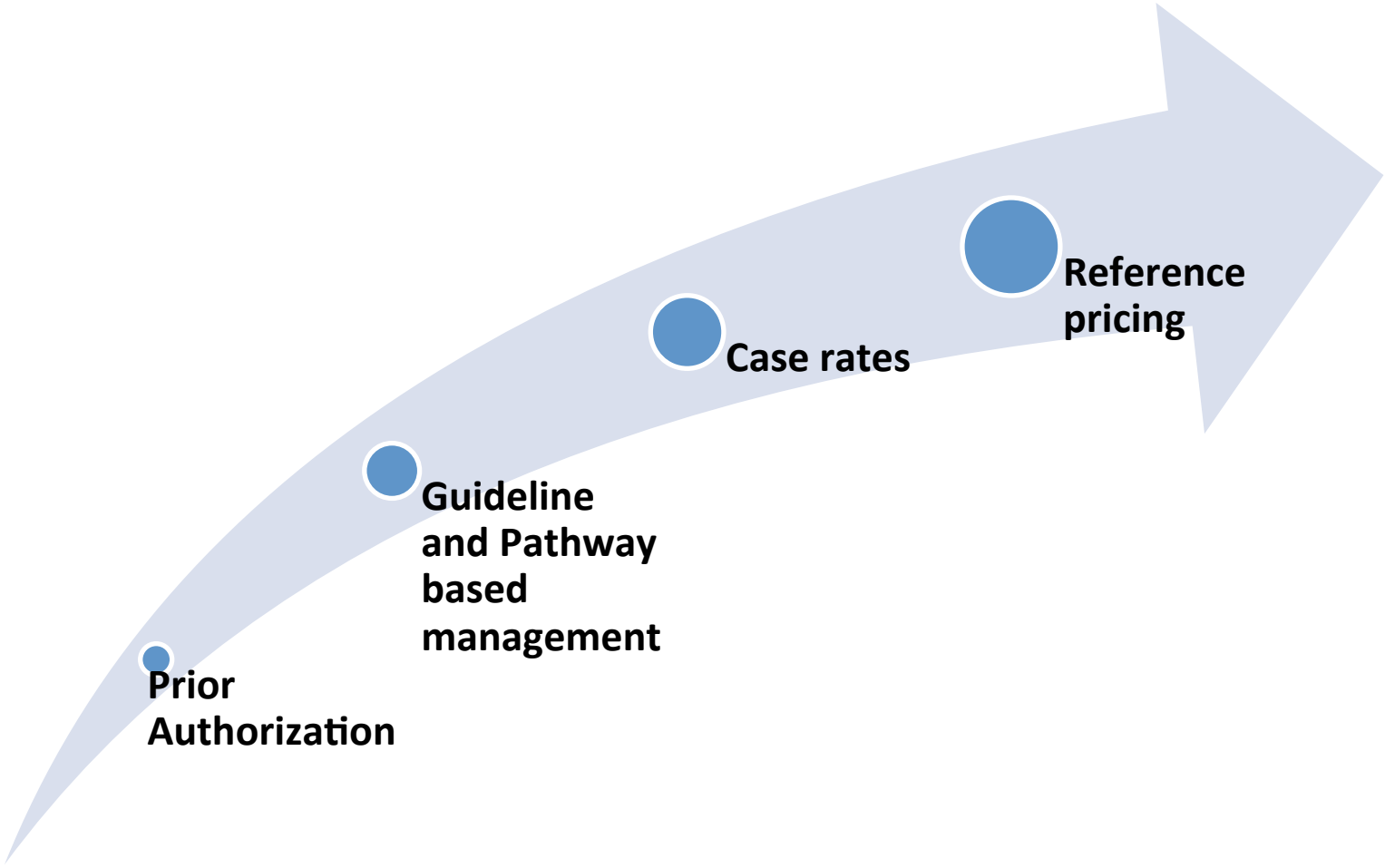
PAYMENT MODELS


Revenue
Transition
Period
Value-Based
Reimbursement
Fee for
Service
Revenue Mix
Time

Payment Reform Models



Payment Models for Medical Technology



“Pathways” are considered part of the solution to rising costs of cancer care

Speak Up!

All Pathways Are Not Created Equal

BY PETER G. ELLIS, MD

State Oncology Groups Advance Clinical Pathways

BY LOLA BUTCHER

PATHWAYS

ONCOLOGY TIMES

The Independent Hem/Onc News Source

Indiana Oncology Society's recent decision to endorse the pathways services of P4 Healthcare marks the third regional oncology organization to take a position on cancer care pathways.

"Increasingly, insurers are mandating that health care providers follow certain quality measures, or pathways, that define what constitutes appropriate services for the majority of our patients," Naveed Chowhan, MD, President of the Indiana society, said in a news release announcing the decision. "IOS is approaching this preemptively to ensure that cancer care providers not only assist in the development of the pathways to be used in Indiana, but are comfortable with them as well.

The Indiana group follows the lead of Oncology Physician Resource (OPR), a physician-owned group purchasing organization in Michigan. OPR worked with the state's biggest insurer to develop

Cancer Care Pathways Catching on with Payers

BY LOLA BUTCHER

Three pathways companies—Innovent Oncology, P4 Healthcare, and Via Oncology—are actively marketing their services to insurers, and others are expected to come on the scene soon. And while it is clear that the use of clinical pathways will change how oncologists are paid, exactly how that will play out is not.

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Strategies for Career Success

JOURNAL OF ONCOLOGY PRACTICE • VOL. 7, ISSUE 1

Strategic Use of Clinical Pathways

By Dean H. Gesme, MD, and Marian Wiseman, MA

Minnesota Oncology, Minneapolis, MN; Wiseman Communications, Washington, DC

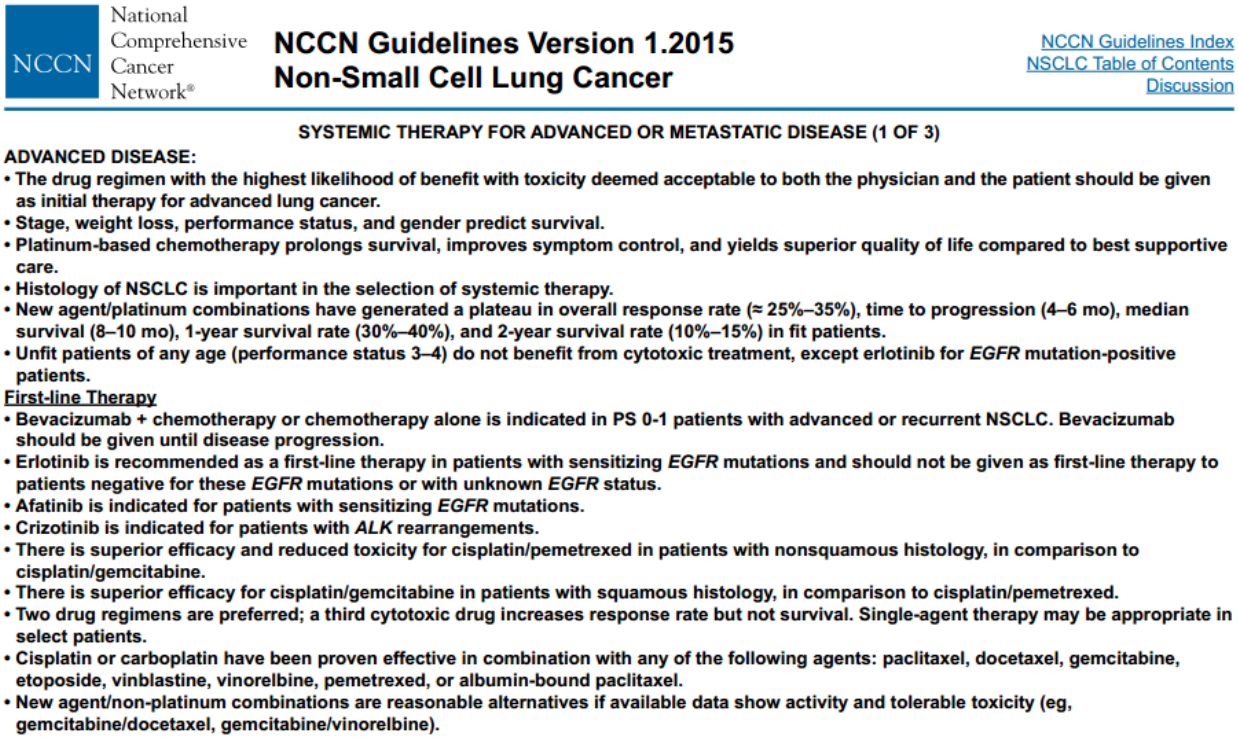
What's involved in using clinical pathways in oncology practice? Who's using them, and why? Are they something your practice should consider?

Some oncologists have embraced pathways, while others have resisted. "Some physicians will say it's too much of a cookie-cutter approach," comments oncologist Bruce A. Feinberg, DO, vice president and chief medical officer of P4 Healthcare, which develops oncology pathway programs and was acquired by Cardinal Health earlier this year. He goes on to say, "I always derived my greatest satisfaction from making the diagnosis,

The scope, granularity, and available options of pathways vary. For example, Via Oncology, a subsidiary of the University of Pittsburgh Medical Center, has pathways that cover 17 types of cancer and include prognostic testing such as KRAS and *Oncotype*DX, chemotherapy and biologic therapy, supportive care, and radiation therapy. Via is adding an end-of-life pathway in early 2011. Via's pathways have a single treatment protocol for each specific patient presentation, including stratification for scenarios such as poor performance or elderly status.

Guidelines Tend To Be Very Broad

NCCN includes 64 platinum-based combinations as guideline-concordant treatment options for first line therapy of non-small cell lung cancer



National Comprehensive Cancer Network®

NCCN Guidelines Version 1.2015
Non-Small Cell Lung Cancer

NCCN Guidelines Index
NSCLC Table of Contents
Discussion

SYSTEMIC THERAPY FOR ADVANCED OR METASTATIC DISEASE (1 OF 3)

ADVANCED DISEASE:

- The drug regimen with the highest likelihood of benefit with toxicity deemed acceptable to both the physician and the patient should be given as initial therapy for advanced lung cancer.
- Stage, weight loss, performance status, and gender predict survival.
- Platinum-based chemotherapy prolongs survival, improves symptom control, and yields superior quality of life compared to best supportive care.
- Histology of NSCLC is important in the selection of systemic therapy.
- New agent/platinum combinations have generated a plateau in overall response rate (≈ 25%–35%), time to progression (4–6 mo), median survival (8–10 mo), 1-year survival rate (30%–40%), and 2-year survival rate (10%–15%) in fit patients.
- Unfit patients of any age (performance status 3–4) do not benefit from cytotoxic treatment, except erlotinib for *EGFR* mutation-positive patients.

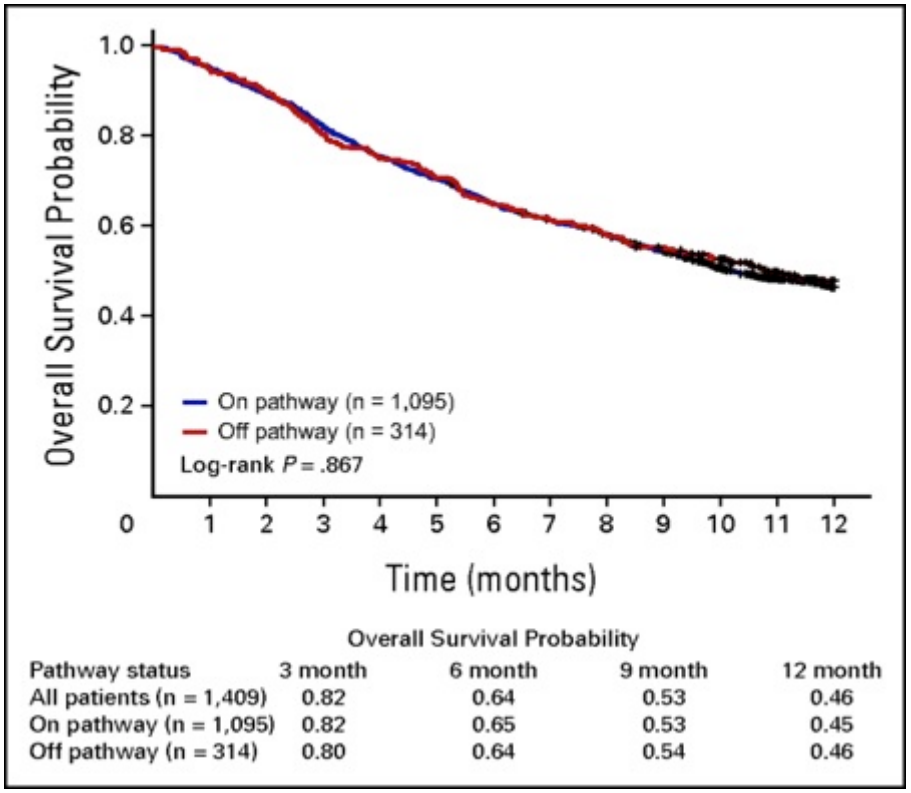
First-line Therapy

- Bevacizumab + chemotherapy or chemotherapy alone is indicated in PS 0-1 patients with advanced or recurrent NSCLC. Bevacizumab should be given until disease progression.
- Erlotinib is recommended as a first-line therapy in patients with sensitizing *EGFR* mutations and should not be given as first-line therapy to patients negative for these *EGFR* mutations or with unknown *EGFR* status.
- Afatinib is indicated for patients with sensitizing *EGFR* mutations.
- Crizotinib is indicated for patients with *ALK* rearrangements.
- There is superior efficacy and reduced toxicity for cisplatin/pemetrexed in patients with nonsquamous histology, in comparison to cisplatin/gemcitabine.
- There is superior efficacy for cisplatin/gemcitabine in patients with squamous histology, in comparison to cisplatin/pemetrexed.
- Two drug regimens are preferred; a third cytotoxic drug increases response rate but not survival. Single-agent therapy may be appropriate in select patients.
- Cisplatin or carboplatin have been proven effective in combination with any of the following agents: paclitaxel, docetaxel, gemcitabine, etoposide, vinblastine, vinorelbine, pemetrexed, or albumin-bound paclitaxel.
- New agent/non-platinum combinations are reasonable alternatives if available data show activity and tolerable toxicity (eg, gemcitabine/docetaxel, gemcitabine/vinorelbine).

US Oncology found pathways associated with same overall survival and 30% lower cost

Outcomes associated with pathways vs. usual care for advanced non-small cell lung cancer

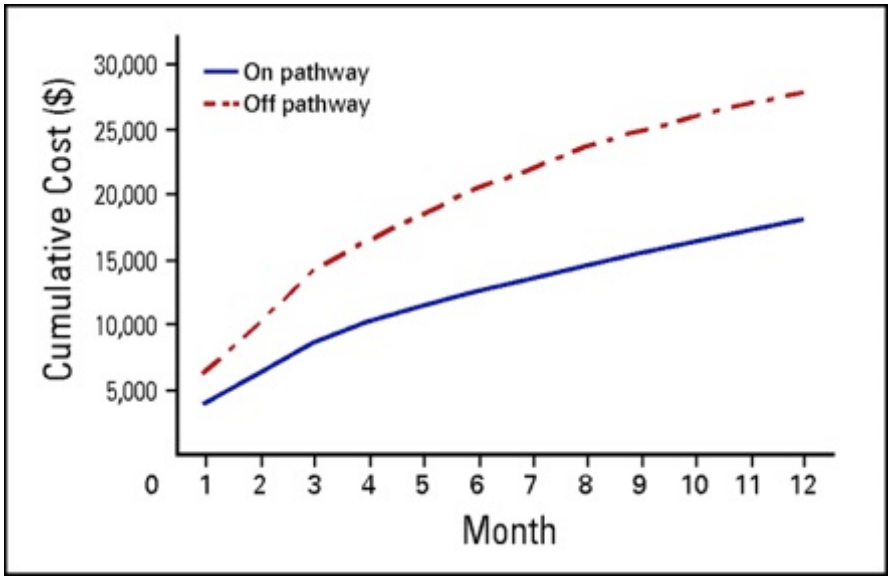
Overall survival by Pathway status



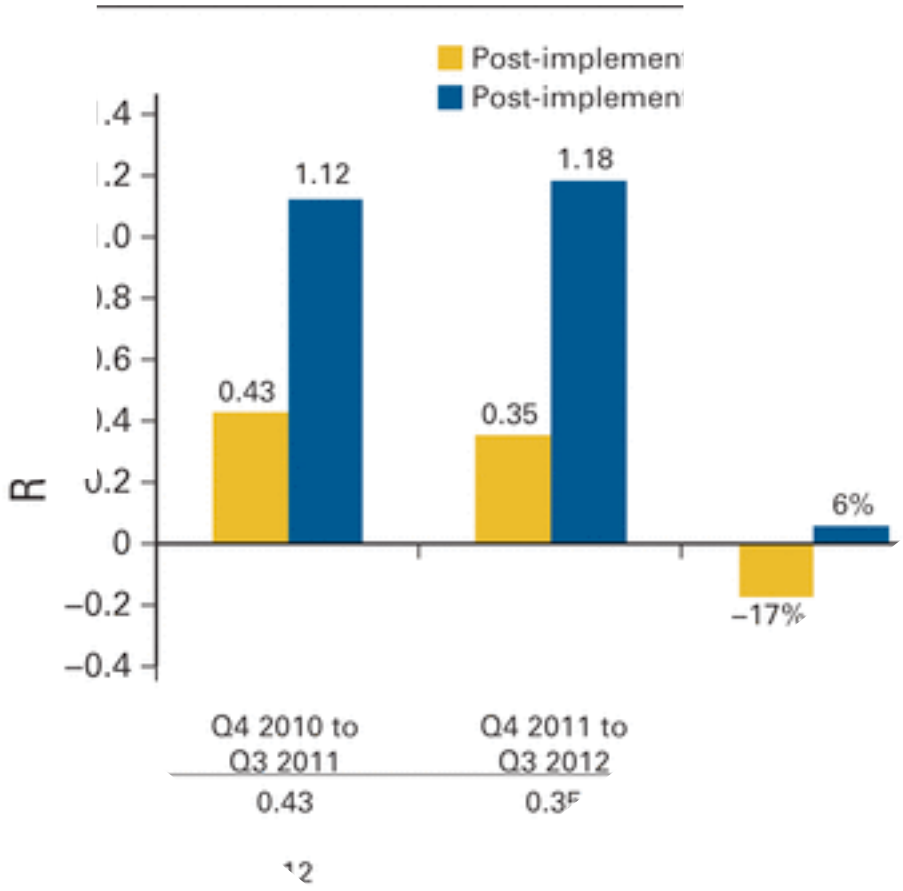
Overall Survival Probability

Pathway status	3 month	6 month	9 month	12 month
All patients (n = 1,409)	0.82	0.64	0.53	0.46
On pathway (n = 1,095)	0.82	0.65	0.53	0.45
Off pathway (n = 314)	0.80	0.64	0.54	0.46

12-month cumulative cost by Pathway status



Neubauer M A et al. JOP 2010;6:12-18



Steingisser, et al, J Oncol Pract. 2014 Sep;10(5):e321-

Targets for Reduced Cost For Cancer Care

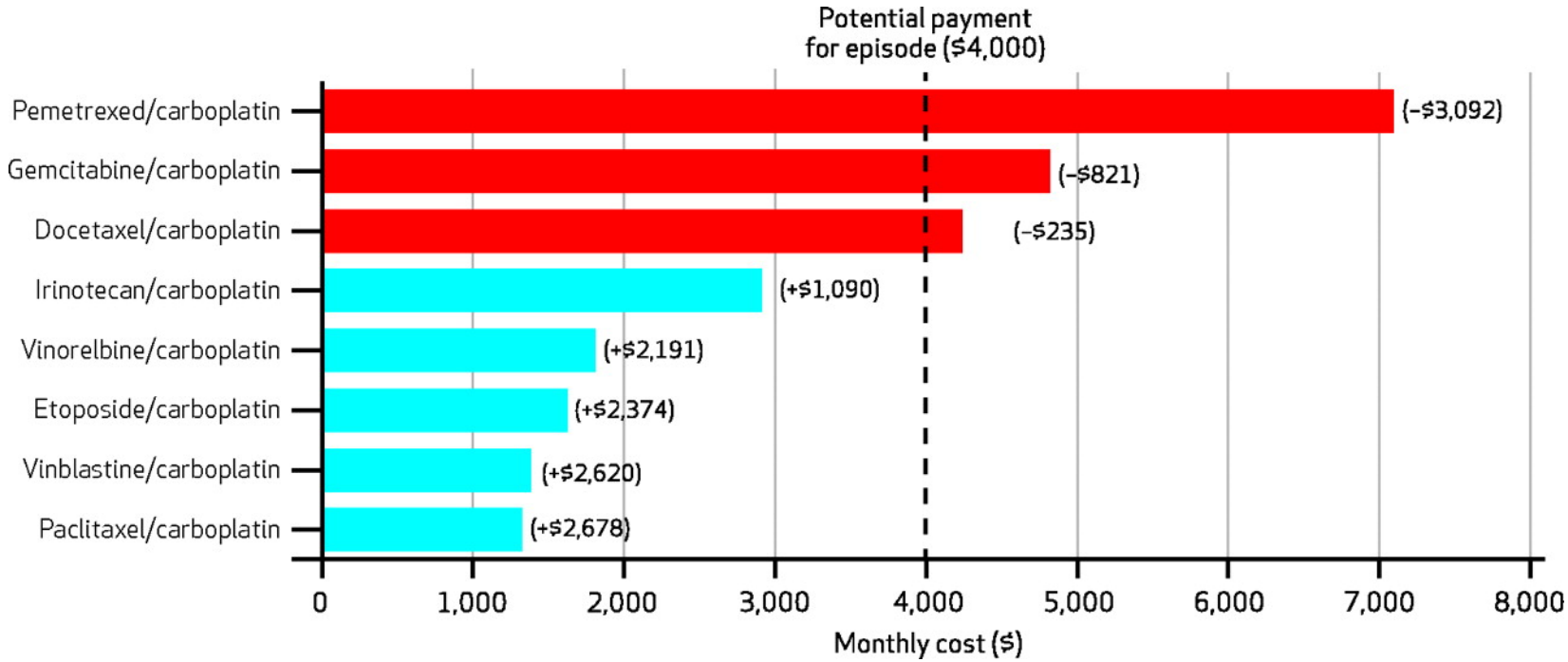
- No benefit
- Marginal benefit
- Unclear benefit
- Not desired by patients
- Duplicative test or service
- **Equally effective cheaper treatment alternative exists**

Where Equally Effective Cheaper Alternatives Exist: "Least Costly Alternative"

- Prostate Cancer
- Breast Cancer
- Lung Cancer
- Palliative Care

"Equally" Effective Cheaper Alternative Payment Tactic ?

- Set reimbursement for an individual episode of care at the average cost of treatment
  - Define the episode of care
  - Establish acceptable treatment options
  - Based on standard fee-for-service claims
  - Average ?
- Or, set cost at "least costly alternative"?
- How will this exercise be perceived?



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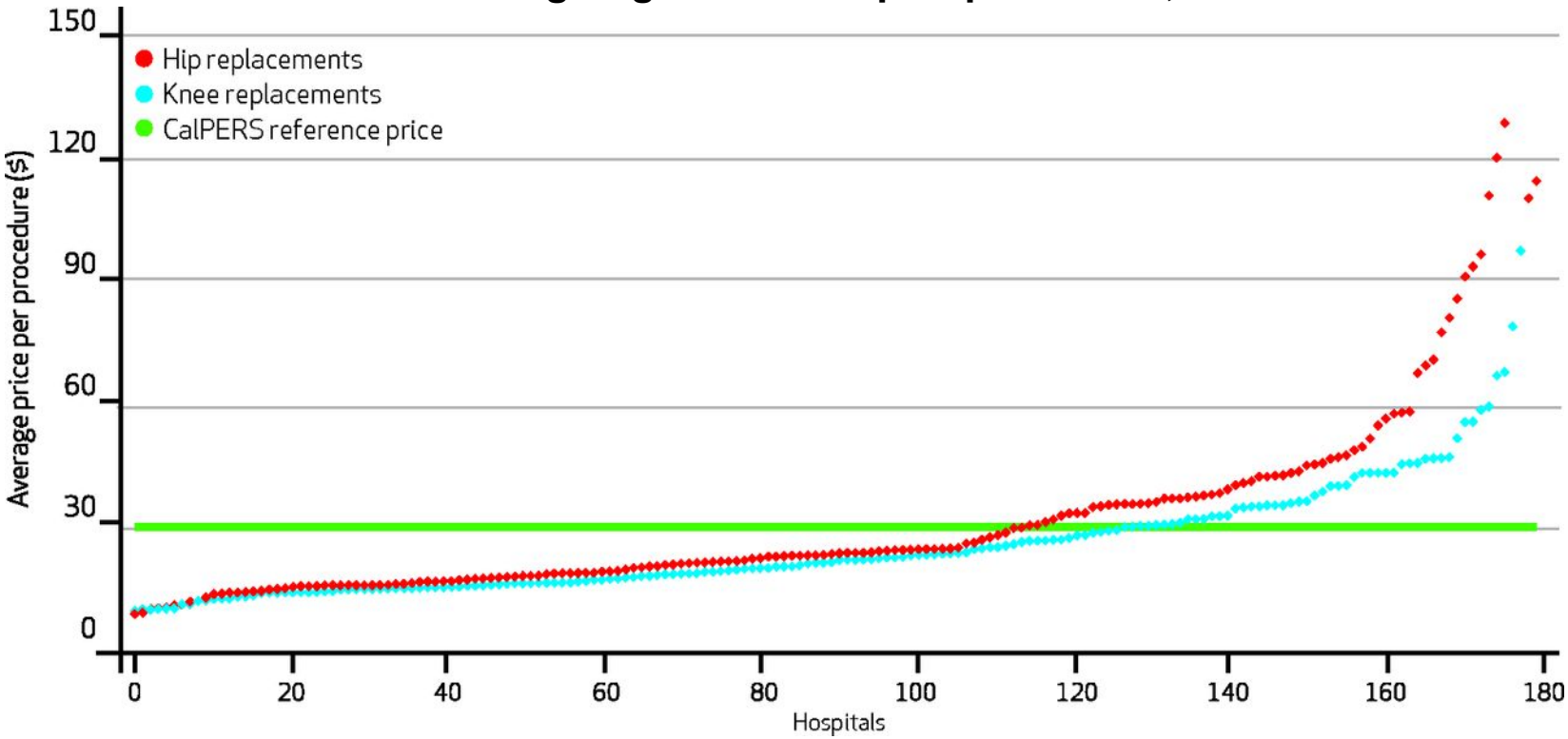
Reference Pricing
CalPERS Joint Replacement Pilot

Range In Average Price Per Procedure Across California Hospitals For California Public Employees' Retirement System (CalPERS) Patients Undergoing Knee Or Hip Replacement, 2009.



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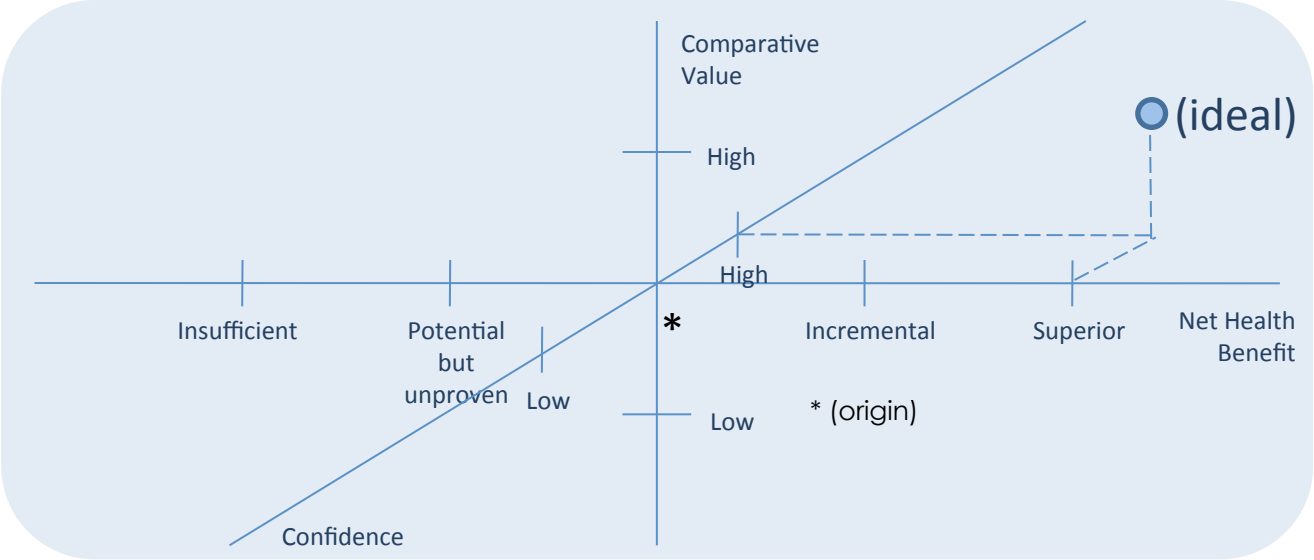
Institute for Clinical and Economic Review (ICER):

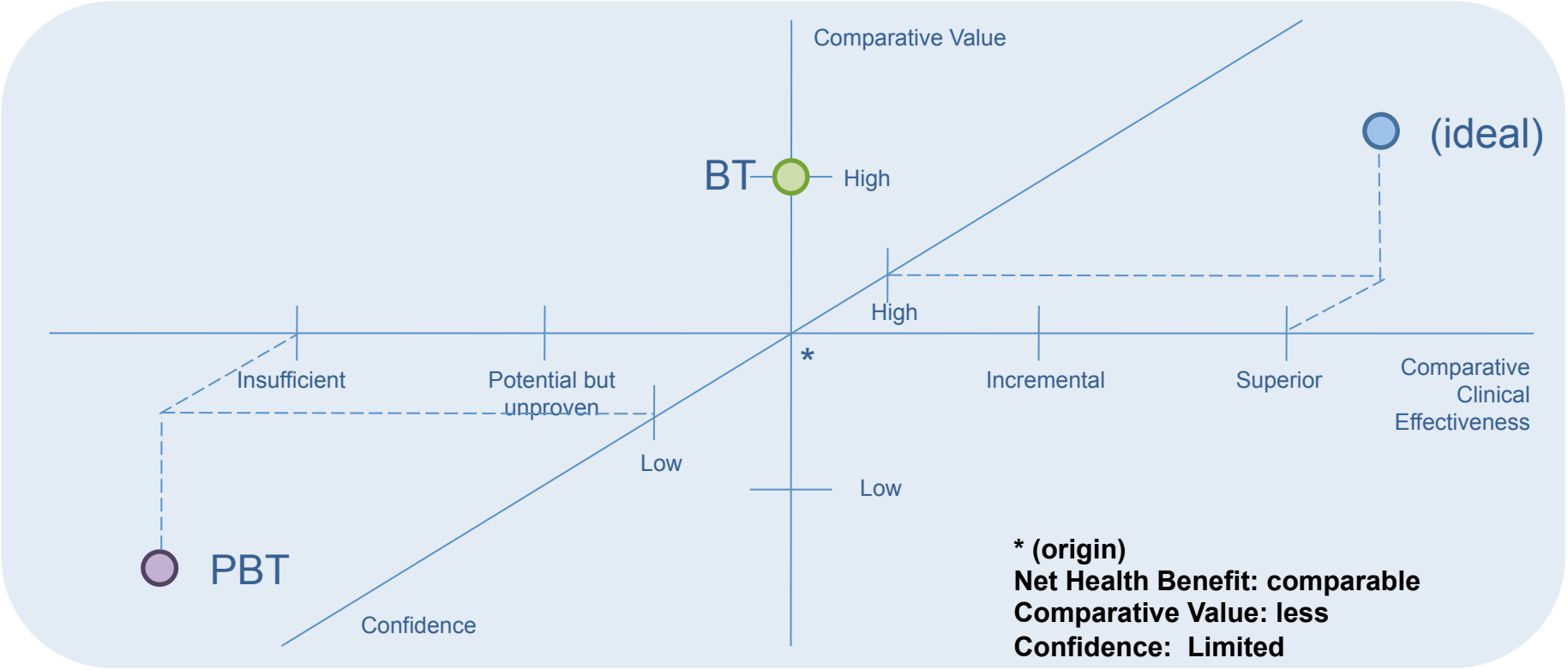
Integrated Evidence Rating



- **Net Health Benefit**
- **Comparative Value**
- **Confidence**

Source: ICER final appraisal document: brachytherapy & proton beam therapy for the treatment of clinically-localized, low-risk prostate cancer. *ICER*, 2008.

Example: BT vs. PBT



Source: ICER final appraisal document: brachytherapy & proton beam therapy for the treatment of clinically-localized, low-risk prostate cancer. *ICER*, 2008.

How might CER be used to address coverage questions?

Prostate Cancer

- Brachytherapy
- IMRT
- Proton

COVERED

CO-PAY

NON-COVERED or REFERENCE PRICING

Pearson, 2010

Final Thoughts

- **The conceptual view of value by payers in the US today is dominated by comparative clinical effectiveness and budget impact.**
- **The conceptual view of value by manufacturers in the US is dominated by (comparative) clinical effectiveness, additional benefits, and the intrinsic value of having multiple treatment options.**
- **The best policy outcome will result if:**
  - **Payers become more transparent and consistent while focusing more on the balance of long-term benefits and costs in their conception of value**
  - **Manufacturers begin to view affordability as a mutual and immediate imperative.**
  - **Payment systems takes into consideration the cost of evidence development(particularly for technology) and support the process of evidence development**

“Nowadays people know the price of everything and the value of nothing.”

—Lord Henry Wotton from *The Picture of Dorian Gray*, Oscar Wilde