Physicists on the Front Lines of Comparative Effectiveness Research

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Disclosure

- CMTP develops tools and strategies for comparative effectiveness research
- We receive funding from government, foundations, life sciences companies, health plans, and medical professional societies
- Aim is to serve as a neutral convener

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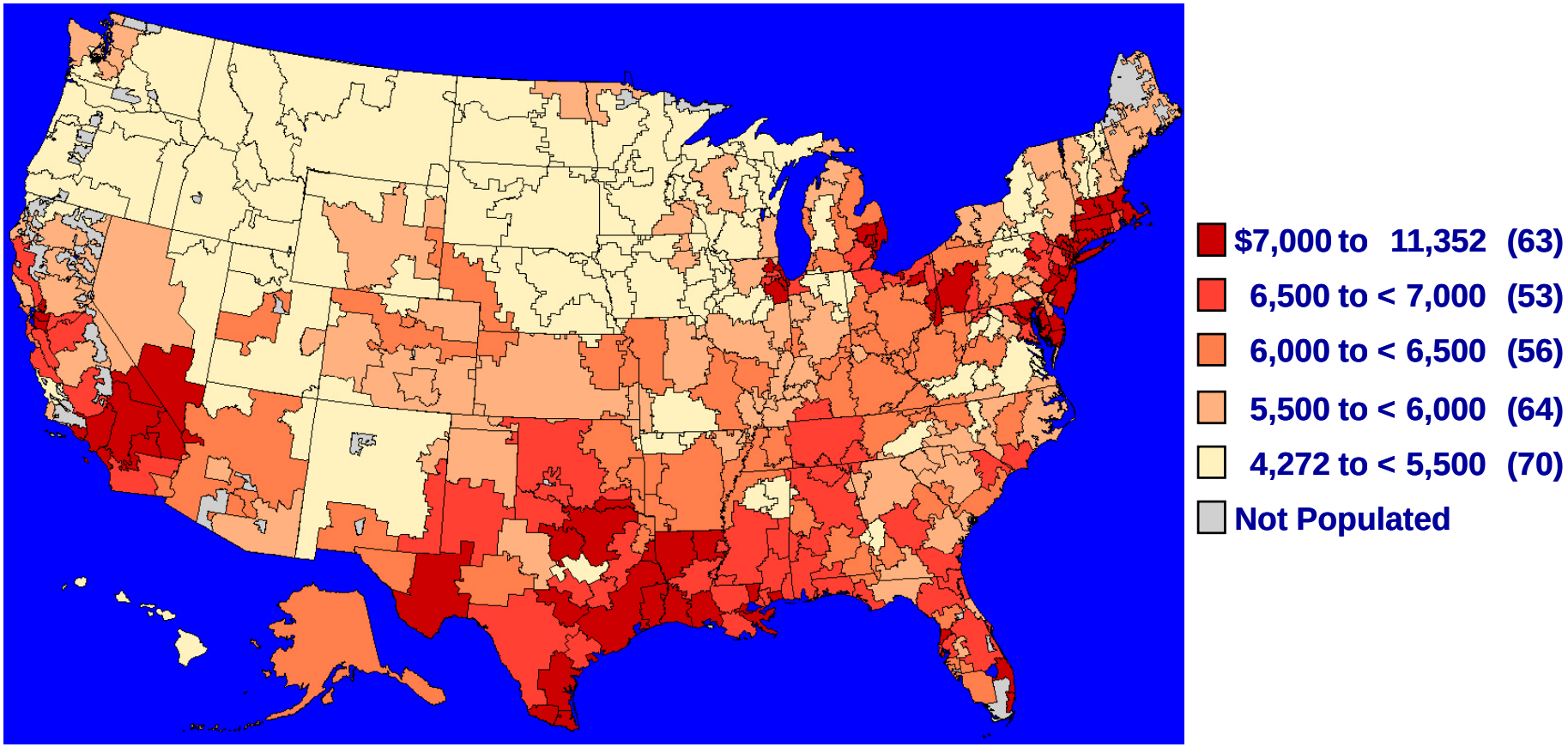
Medicare Spending per Capita in the United States, 2003



Source: www.dartmouthatlas.org.

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Calls for New "Comparative Effectiveness" Entity

- MMA Section 1013 (2003)
- Gail Wilenksy, Health Affairs (11/06)
- AHIP, BCBSA proposals (early 2007)
- MedPAC report, CBO testimony (6/07)
- Obama, Clinton, McCain health plans
- CBO final report (12/07)
- Commonwealth Fund (01/08)
- Baucus-Conrad Senate bill (07/08)

High Expectations

- "Better information about the costs and benefits of different treatment options, combined with new incentive structures reflecting the information….is essential to putting the country on a sounder long-term fiscal path."
    - Peter Orszag, then Director of the Congressional Budget Office, June 2007

Prescient Perspectives 2008

- "None of us agree on what CER actually is, but we all agree it will cost about $5B to do it"
  - Jack Rowe, former CEO, Aetna
- "Whenever you observe unanimous support for a new idea in Washington, it means that the concept has not been adequately defined"
  - Anonymous policy wonk, Washington DC
  - Jeffords variation: "Without ambiguity, there can be no unanimity".

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IOM CER Working Definition

- “The generation and synthesis of evidence that compares the effectiveness of alternative methods to prevent, diagnose, treat, monitor, and improve delivery of care for a clinical condition.
- The purpose of CER is to assist patients, clinicians, purchasers, and policy makers in making informed health decisions.”

American Recovery and Reinvestment Act

CER Funding

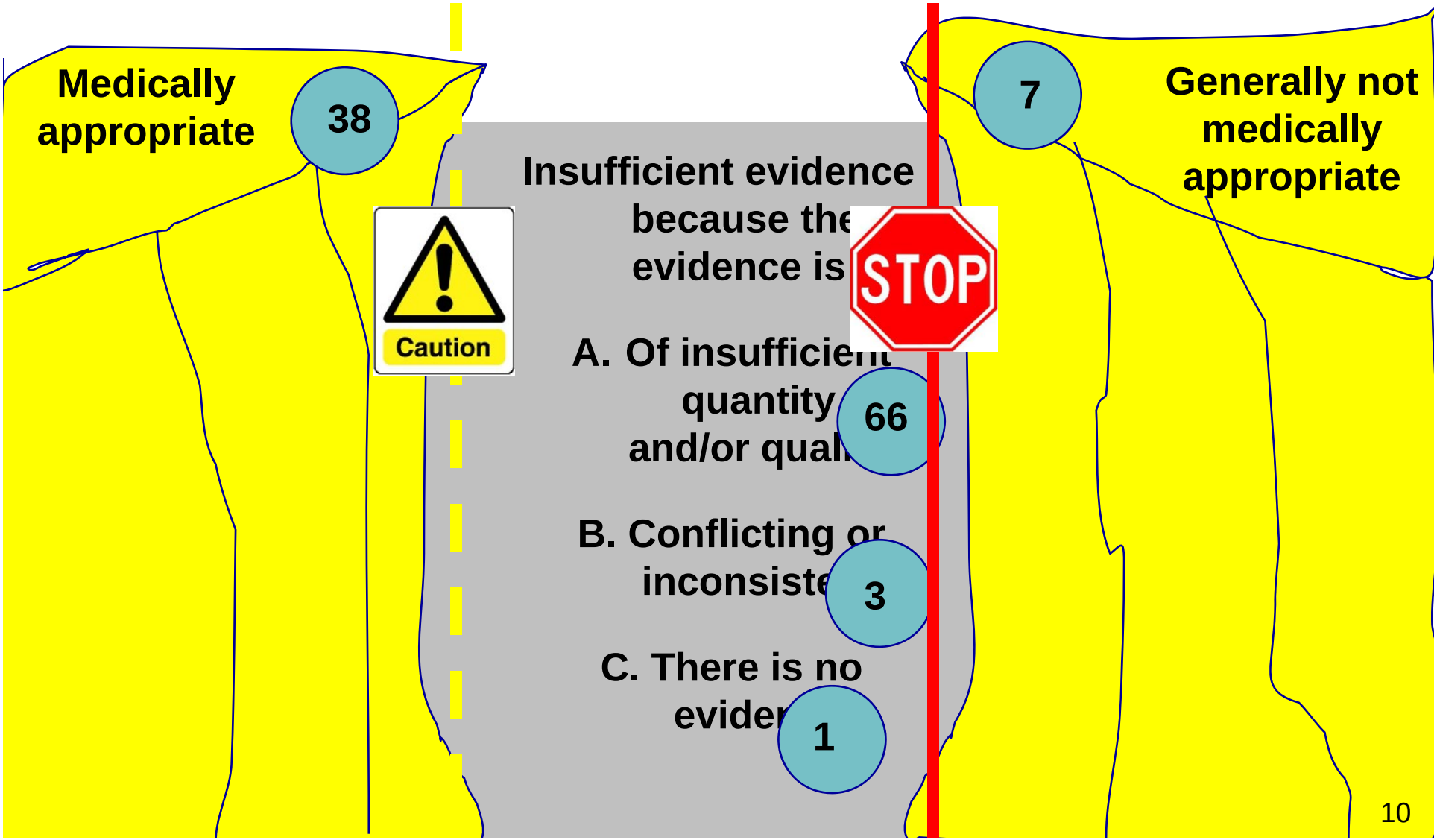
- $300 million to AHRQ
- $400 million to NIH
- $400 million for CER to HHS Secretary
- Vigorous organizing underway
  - IOM to report on national priorities for CER by June 2009
  - Federal Coordinating Council
  - AHRQ, NIH, AHRQ-NIH Councils
  - Blizzard of white papers
  - Battling coalitions

Medicare Review of CCTA

- EPC report from Duke (April 2006)
  - Limited evidence of clinical utility in any population
- MedCAC mtg (May 2006)
  - "Uncertain confidence about existing evidence"
- Broad local coverage of CCTA
- Medicare draft policy in 12/07 proposed CED for CCTA in "adequate" studies
- Final Medicare policy in 3/08 left local coverage in place, despite poor evidence

115 Technologies Reviewed by Kaiser

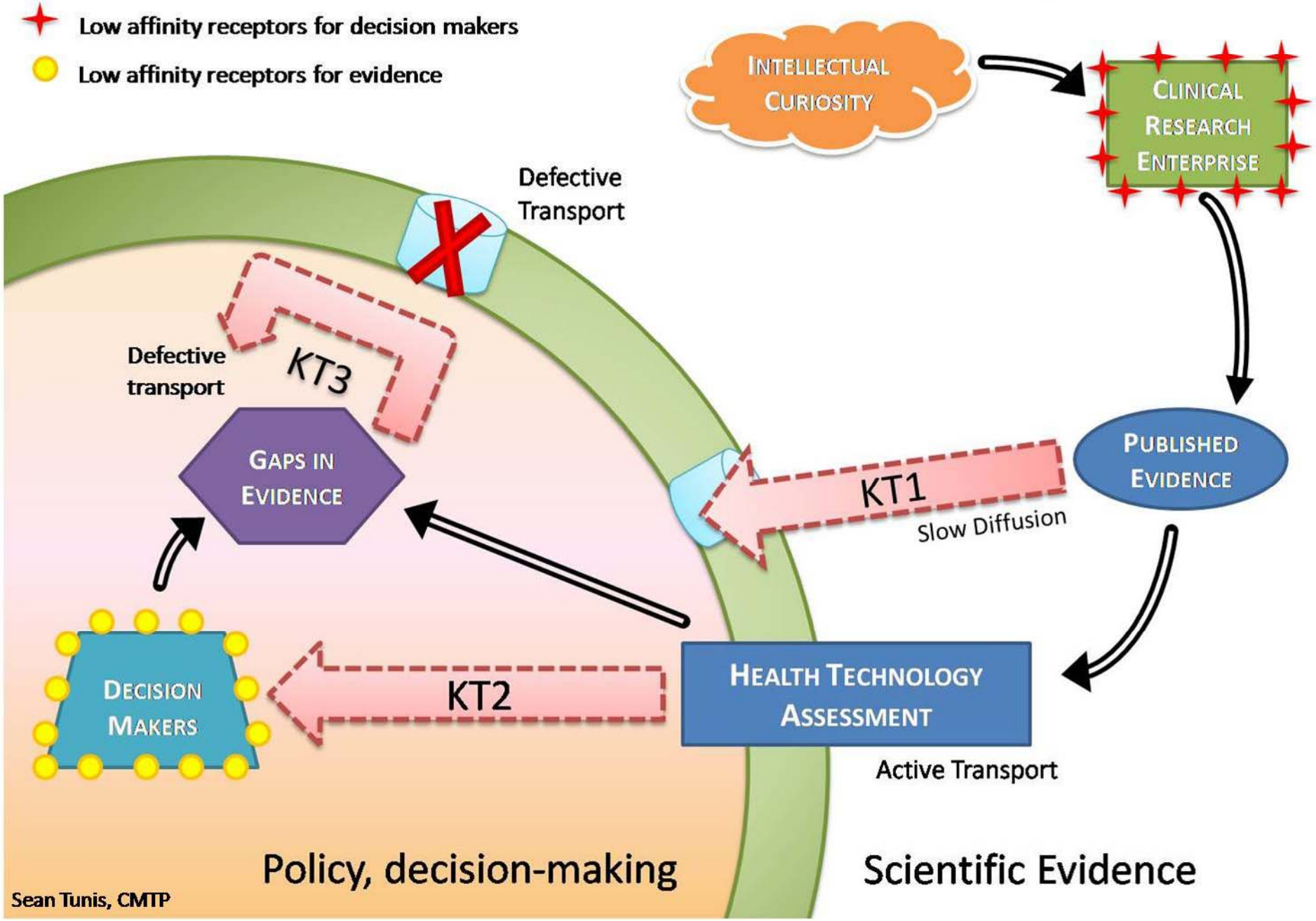
Paul Wallace, Permanente Federation



Critical Knowledge Gaps

- The paradox
  - 18,000 RCTs published each year
  - “Available evidence is limited or poor quality”
- Patients, settings, comparators, outcomes, timing often not aligned with decision makers
  - Patients, clinicians, payers, policy makers
- Decision makers have limited traction
  - “didn’t invite CMS because it’s a scientific mtg”
  - “don’t want patients messing up our protocols”

Molecular Basis of Uncertainty



AHRQ Systematic Review: Tx of Clinically Localized Prostate Cancer

- Limited evidence on relative safety and effectiveness of major treatment options
  - prostatectomy, brachytherapy, radiation, active surveillance
- New technologies rapidly spreading without data
  - robotic surgery, proton beam
- Rigorous trials needed to compare treatment options, especially for side effects

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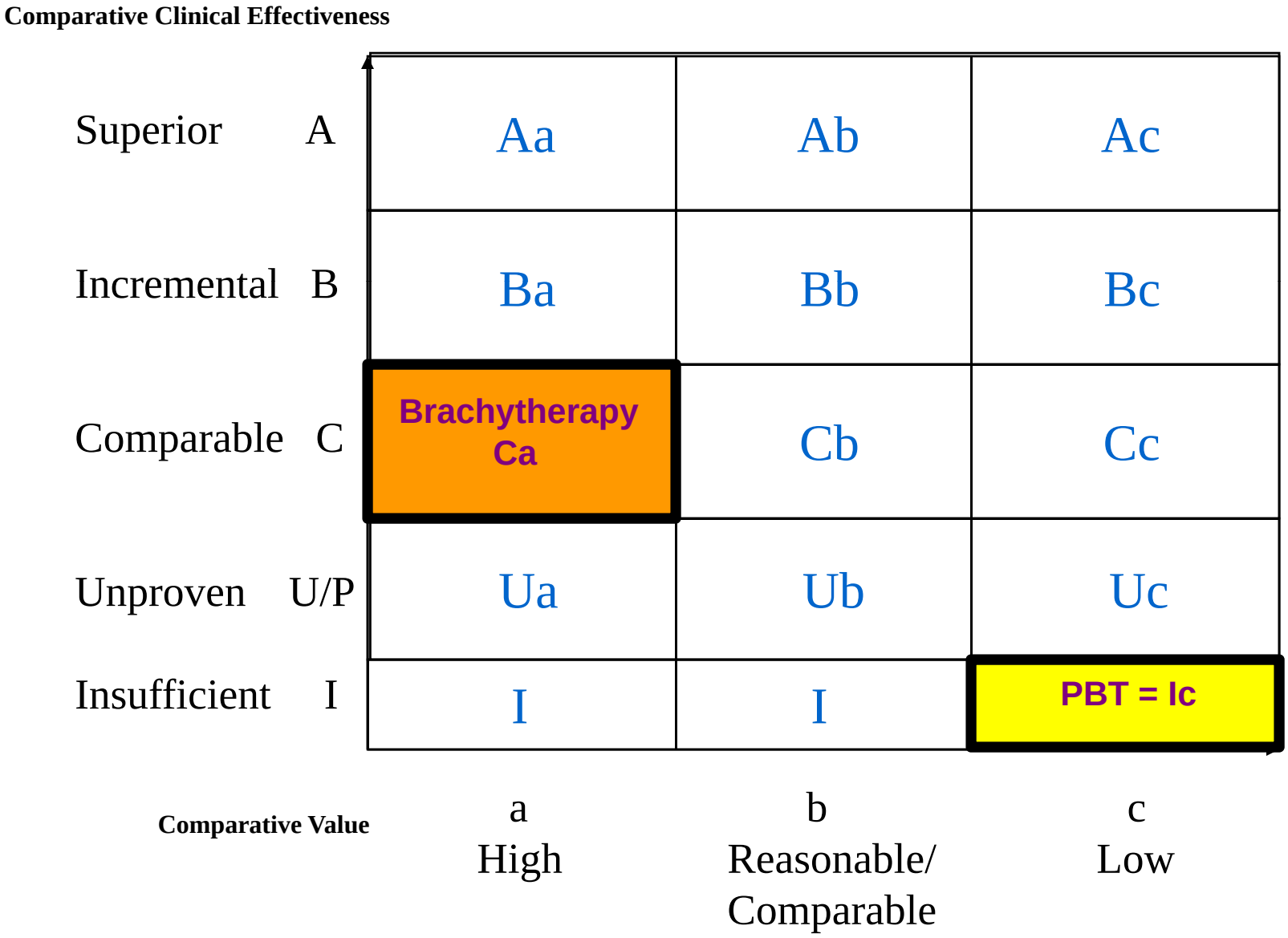
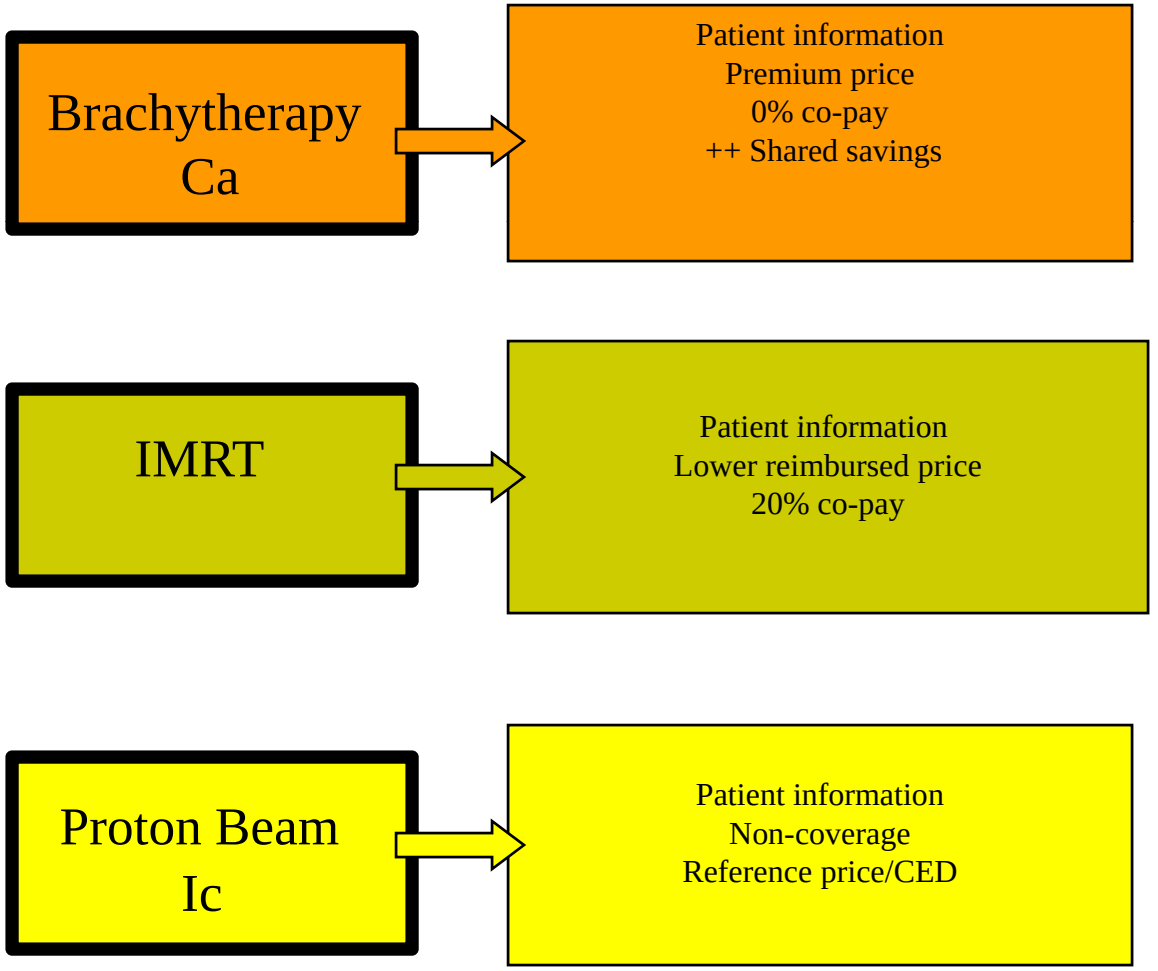
Radiation for prostate cancer Compared to IMRT



From Comparative Effectiveness to Medical Policy



CMTP-AHRQ-ASTRO meeting

- July 2008
  - Purpose was to discuss draft study protocol for comparative study
  - Meeting participants included:

Vendors	Payers	Researchers	Government
IBA Particle therapy	Blue Shield	Fox Chase Cancer Center	CMS
Siemens	Aetna	Radiation Therapy Services	AHRQ
Still River	United Healthcare	University of Michigan	VA
ProCure	CMS	Henry Ford Health Systems	
Varian	WellPoint	RTOG	
Hitachi		Thomas Jefferson University Hospital	
		ACR	
		NIH/NCI	
		CTEP	
		Johns Hopkins	
		University of Pennsylvania	

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Methodological debate

- RCT
- Observational comparison
- Neither necessary
- Both

Key Features of the Proton/IMRT Study

- Multi-site prospective cohort study based on a registry
- Will accrue 1,600 patients (800 per arm)
- Primary outcome measures is patient reported bowel function at 2 years using EPIC
- Will also look at a number of secondary outcomes measures

Proton Beam – IMRT Status

- Study protocol completed, budget prepared
  - Observational, parallel cohort study
- R18 grant submitted in March for 2 year feasibility/pilot
  - CMTP, Outcomes, Zietman, Wallner, Konski
  - Ltrs of support from 2 IMRT and 2 proton centers
  - Ltrs of support from CMS, Aetna, United, Wellpoint
- Exploring potential collaboration for RCT with Penn, MGH, IU

Implications of CER Purpose

- If primary purpose of CER is to inform decisions
- CER requires high level of involvement of decision makers
  - Implies collaborative approach
- Future debate is not about whether outcomes studies will be needed, but about the details of the protocol

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