



Advising the Congress on Medicare issues

Enhancing Medicare's flexibility to implement value-based policies

Nancy Ray
March 5, 2010

Overview

- Problem—Medicare lacks flexibility and resources necessary to become a more innovative program and to alter the spending trajectory
- This session focuses on giving Medicare more flexibility to implement:
 - Reference pricing
 - Performance-based pricing strategies
 - Coverage with evidence development

Three value-based strategies for discussion

- Reference pricing strategies
 - Set a service's payment based on the rate of the least costly, clinically comparable service
 - Medicare's legal foundation is unclear
- Performance-based strategies
 - Link payment to a service's effectiveness
 - Medicare cannot implement policy without a change in law
- Coverage with evidence development
 - Link Medicare payment to collection of clinical evidence
 - Medicare's legal foundation is unclear

Expert panel

- Peter Neumann, Director, Center for the Evaluation of Value & Risk in Health, Tufts Medical Center
- Sean Tunis, Founder and Director of the Center for Medical Technology Policy

For discussion

- Medicare does not have clear legal foundation to adopt many policies that encourage efficiency and value
- Pros/cons of increasing Medicare's flexibility to adopt value-based policies
- June report chapter that discusses these policies and enhancing Medicare's research and demonstration capacity



Value-based Policies

Presentation for MedPAC

March 5, 2010

Peter J. Neumann

**Center for the Evaluation of Value and
Risk in Health, Tufts Medical Center**



Objectives

- Describe value-based policies for drugs, devices, and medical services adopted by payers in the U.S. (excluding Medicare) and abroad;
- Discuss issues and challenges that payers have faced in adopting approaches
- Discuss implications for Medicare.



Types of value-based policies

- Outcomes/performance-based agreements
- Value-based insurance design
- Reference pricing

Selected case studies

- Performance-based agreements
 - Beta interferon for MS/(UK)
 - Bortezomib (Velcade®) (UK)
 - Oncotype Dx test/(United Healthcare)
 - Sitagliptin (Januvia)/(Cigna)
 - Risedronate (Actonel)/Health Alliance
- Value-based insurance design
- Reference pricing

Key challenges

- **Reference pricing**

- How to determine therapeutic equivalence?
- Exceptions policies?

- **Value-based insurance design**

- Evidence requirements
- Lack of focus on “low value” services

- **Outcomes/performance-based agreements**

- Implementation costs (and who pays?)
- Measurement issues
- Data systems and infrastructure



Medicare Experience with Coverage with Evidence Development (CED)



Sean Tunis MD, MSc
March 5, 2010

Overview

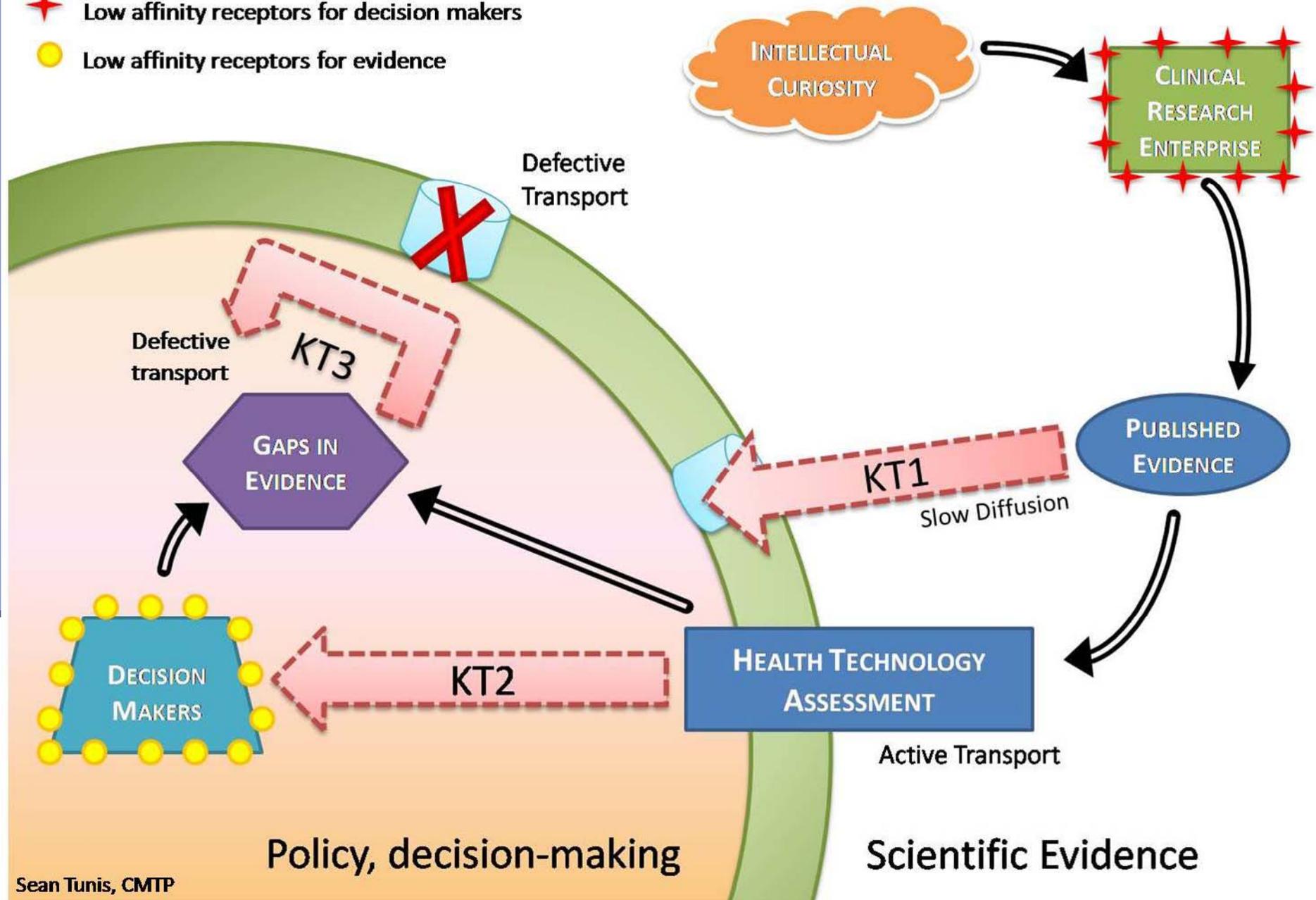
- Definition and purpose of CED
- CED and comparative effectiveness research
- Medicare CED case studies
- Selected lessons learned
 - Statutory authority
 - Priority setting
 - Funding

CED Definition and Purpose

- Coverage contingent on participation in clinical study
- Reconciles tension between desire for CER evidence and rapid access to innovation
 - When evidence limited, payers in relatively poor position to restrict access to technology
 - Evidence is almost always “limited” for new tech
- Allows for CMS views on relevant patients, comparators, outcomes, design

Molecular Basis of Uncertainty

- ★ Low affinity receptors for decision makers
- Low affinity receptors for evidence



Case studies of Medicare CED

- Lung volume reduction surgery (pre-CED)
- FDG-PET for suspected dementia
- Off-label use of drugs for colorectal cancer
- FDG-PET for oncology
- Long-term oxygen treatment
- Artificial heart
- Genetic testing for warfarin sensitivity

Statutory Authority

- Statutory foundation for CED is controversial
 - §1862(a)(1)(A) – reasonable, necessary
 - §1862(a)(1)(E) – AHRQ research authority
 - CAD: coverage with appropriateness determination
 - CSP: coverage with study participation
- Non-specific legal authority for CED impede clear, consistent implementation

Priority Setting

- CED topic selection is reactive
- Each CED project created de novo
 - Guided by what is feasible, not what is desirable; labor intensive
- Time frame and high stakes of coverage process impose difficult constraints
- Horizon-scanning, priority setting criteria and process needed to identify good topics early

Funding for research costs

- Several CED efforts have been impeded by funding challenges
- Design and oversight of studies influenced by entity that provides funding
- Competitive research funding process too slow and has different priorities
- Dedicated resources would be helpful

Final Observations

- Medicare's experience with CED to date has fallen short of original policy objectives
- CED shortcomings not intrinsic to the concept
- Experience to date has highlighted potential strategies to improve implementation
- Growing interest among private payers in CED approach, would likely follow CMS lead
- Coordinated multi-payer CED could contribute significantly to production of CER