Coverage with Evidence Development: Some Lessons

UBC Conference on Health Innovation

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February 25, 2009

The Problem

- The health care system fails to get best value from technology due in part to evidence gaps
- Critical evidence gaps are common
  - 18,000 RCTs published each year, but….
  - Most reviews conclude: "…available evidence is limited or of poor quality"
- Limited or uncertain evidence may default to coverage (e.g. Medicare off-label policy)

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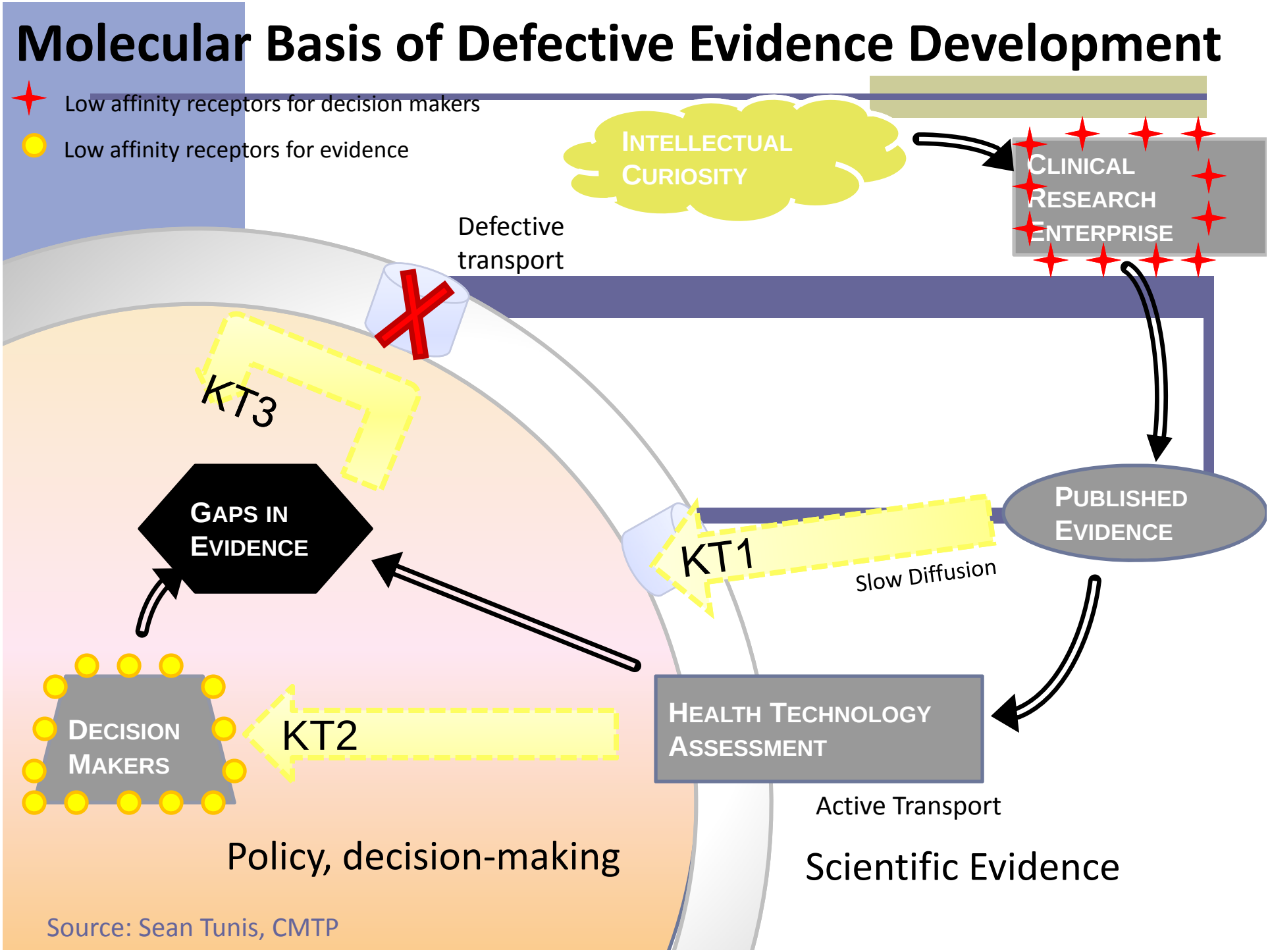
Molecular Basis of Defective Evidence Development



Source: Sean Tunis, CMTP

Baucus-Conrad Senate Bill

- Establishes Health Care Comparative Effectiveness Research Institute
- Purpose: "to improve the health care to individuals…by advancing the quality and thoroughness of evidence"
- Non-profit, non-government corporation, with multi-stakeholder governing board
- Potential for substantial funds in econ stimulus bill, though situation changes daily

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CMS Efforts to Improve Evidence

- Category B IDE regulation (1996)
- Cover routine costs of clinical trials (2000)
- Coverage with evidence development (2003)
- Promote pragmatic clinical trials (2003)
- Priorities for Sec 1013 of MMA (2004)
- MCAC becomes MedCAC (2005)
- Ad hoc efforts to work with NIH

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Coverage with Evidence Development

- **Medicare's attempt to drive CER**
- **Links reimbursement to requirement for prospective data collection**
- **Medicare must approve study design**
- **Lower evidence threshold, but…**
  - **Often end up paying anyway**
  - **Better off with CED evidence than without**

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Examples of Medicare CED

- Lung volume reduction surgery
- FDG-PET for suspected dementia
- Implantable defibrillators
- Off-label use of drugs for colorectal cancer
- FDG-PET for oncology
- Home testing for sleep apnea
- Artificial heart
- Coronary CT angiography (almost)

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Implantable Defibrillator Registry

- Medicare coverage expanded 01/05
- Registry intended for risk stratification
- 250k patients now in registry
- Baseline data interesting
  - Median age 74 (vs 60 in trials); LVEF higher
  - 3.6% complication rate
- No firing info or other outcomes data
  - Low priority for NHLBI, Industry, ACC/HRS
  - AHRQ has recently identified funds
  - Small fraction of $12.5B could have major ROI
  - Next time: get industry/docs commitment first

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Medicare Review of CCTA

- EPC report from Duke (April 2006)
  - Limited evidence of clinical utility
- MedCAC mtg (May 2006)
  - “Uncertain confidence about existing evidence”
  - Consistent with BCBSA review same month
- Medicare (local) and private coverage expand
- Medicare draft policy in 12/07 proposed CED
- Final 3/08 Medicare policy: no CED
- Several major trials now under discussion, but window of opportunity was early 2006

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Proton Beam Study: Too late for CED?

- Prostate Cancer: 186,000 new cases in 2008
- Proton Centers: “new nuclear arms race” (NYT)
  - More than twenty in development at $100m+ each
- Costs of Proton Beam Therapy about $85,000 per episode of treatment, more than 2X IMRT
- Proposed Study under ‘CED’: Proton Beam and IMRT in Treatment of Early Stage Prostate CA
- Multi-stakeholder collaboration including all major stakeholders: ASTRO, AHRQ, NCI, physicists, RTOG, vendors, plans, consumers, AUA
- Too late for true CED. Strategy to move forward despite fact that most plans already cover

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Brief Window for Evaluation

- “It is always too early to evaluate a new medical technology, until it is too late”
  - Doug Altman, quoting ??

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CED Challenges

- Timing: when coverage under review, may be too late for CED
- Methods
  - Difficult to design studies in coverage context
  - Registries provide broader access; ?? validity
  - RCTs viewed as equivalent of non-coverage
    - Large simple trials may help, but no examples
- Payers view as benefit expansion; Vendors opposite
- Unclear how best to fund clinical and research costs
- Private payers contract language
- Lack of neutral, coordinating entity

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Potential Topics for CED

- Devices/procedures for atrial fibrillation
- Biologics for treatment of osteoporosis, arthritis, cancer
- Molecular imaging
- Genetic tests and other molecular diagnostics
- Minimally invasive heart bypass surgery
- Merci Clot Retriever for Acute Ischemic Stroke

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Manufacturers believe CED is going to happen

- How do product manufacturers view the impact of CED on their revenue stream?
  - The believe it will happen and are preparing for it
  - Some modeling predicts only 5% of expected revenue in the first three years of a CED study
  - Probability that product will meet or exceed evidence standards after study is completed is between 50% to 90%
  - Savings from inappropriate dissemination of new products will accrue to payers and be passed on to purchasers

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What is CMTP's role in CED?

- The CMTP multi-stakeholder group, with support from the California HealthCare foundation, has developed a Framework for implementing CED that includes:
  - A model of how different stakeholders would interact
  - Ways to incorporate CED into benefit language …or not
  - Criteria for selecting a research topic for a CED pilot project
  - Pragmatic research design criteria
  - Protections against anti-trust for plan sponsors
  - Transparent and accountable processes
- What's next?
  - Select high priority technology and implement

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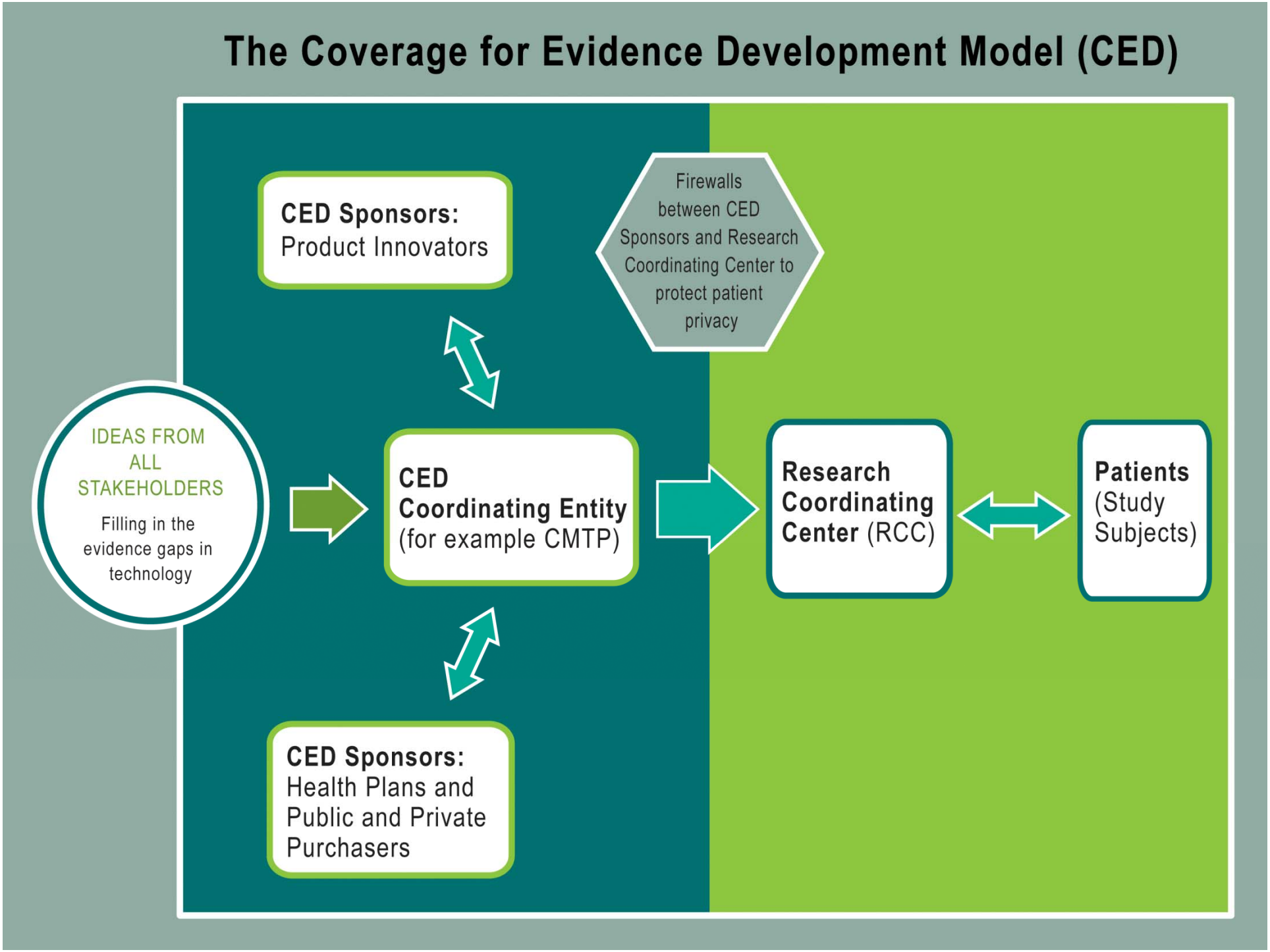
The Coverage for Evidence Development Model (CED)



Effectiveness Guidance Documents

- Analogous to FDA-guidance
- Targeted to product developers, clinical researchers
  - Recommendations for design of clinical studies to generate evidence that is adequate for decision making
  - “reasonable confidence” of improved health outcomes
- Started from insights from systematic reviews
- Multi-stakeholder advisory group, iterative draft and comment process
- Pilot projects
  - Gene expression profiling for breast cancer
  - Treatments for chronic wounds
  - Cardiac imaging

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Pragmatic Clinical Trials Initiative

- Optimize design of phase III, IIIb trials to be maximally useful to post-FDA decision makers
- Clarify patient, clinician payer evidence needs
- Identify potential approach to more “pragmatic” designs
- Identify critical regulatory, methodological financial, operational barriers
- Develop PPCT guidance document
- FDA, CMS, CTTI, NICE others are confirmed

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