

Evidence We Can Believe In!

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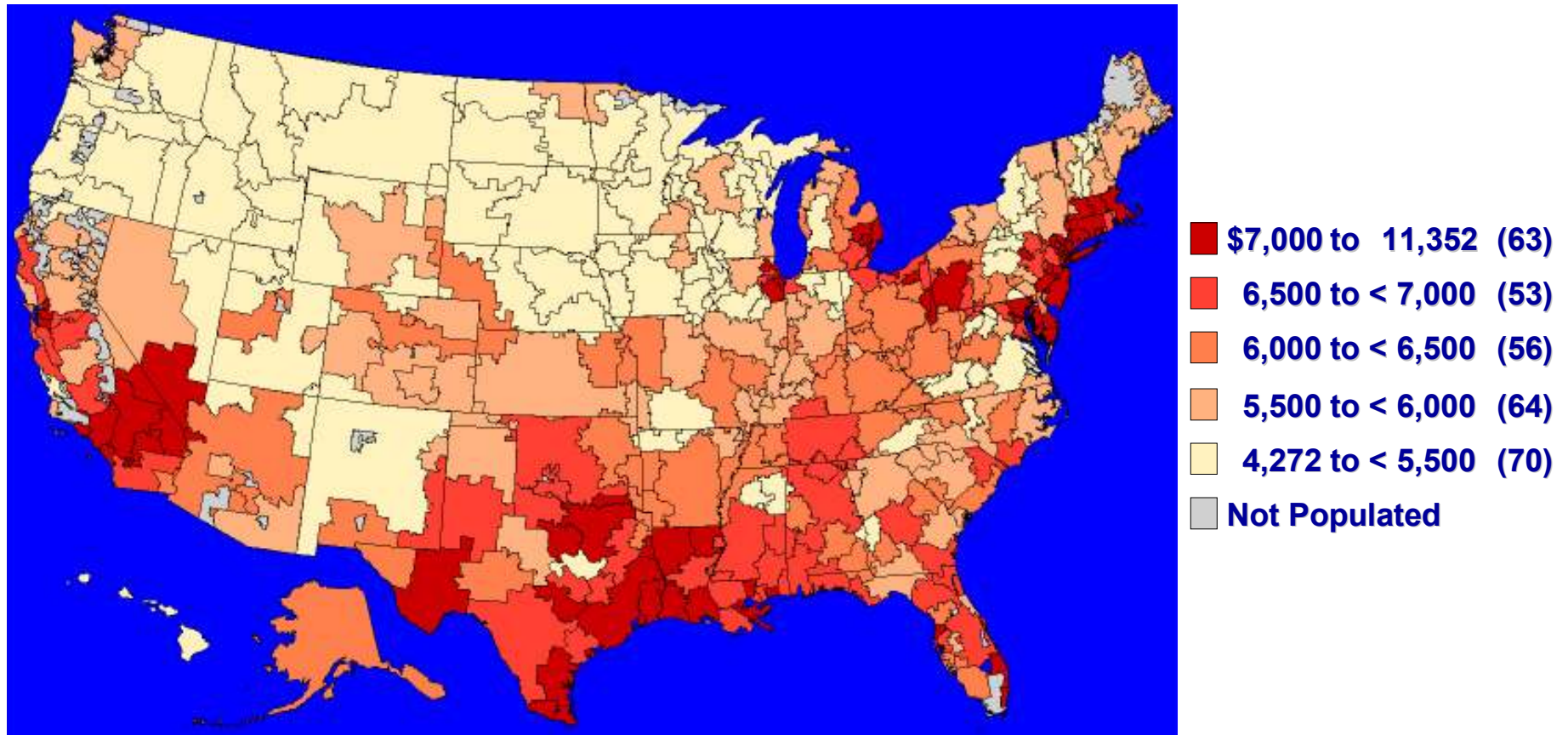
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Overview

- Policy context for comparative effectiveness
- CER Methods
- When is evidence “adequate”?
- Case study – Coronary CTA
- Effectiveness Guidance Documents

Medicare Spending per Capita in the United States, 2003



Source: www.dartmouthatlas.org.

Critical Knowledge Gaps

- “Available evidence is limited or poor quality”
- Evidence producers
 - NIH: discovery and proof of concept
 - Industry: FDA and market focus
 - AHRQ: modest budget, broad portfolio
 - DERP / BCBSA / Cochrane: reviews
- Decision makers have no significant influence in what evidence is created

Calls for New “Comparative Effectiveness” Entity

- MMA Section 1013 (2003)
- Gail Wilensky, Health Affairs (11/06)
- AHIP, BCBSA proposals (early 2007)
- MedPAC report, CBO testimony (6/07)
- Obama, Clinton, Edwards reform plans (mid 2007)
- CBO final report (12/07)

Putting Consensus in Perspective

- “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

Baucus-Conrad Senate Bill

- Establishes Health Care Comparative Effectiveness Research Institute
- Non-profit, non-government corporation
- Multi-stakeholder governing board
- Methodology subcommittee would contract with NAS for report on CEA (within 5 years)
- Approps: \$4M in 2009; 60M in 2011; \$150M in 2013
- Introduced and withdrawn week of 3/3/08
- No CE language in latest Medicare bill

Pop Quiz:

Who made these recommendation?

- “conduct more and more efficient clinical trials that yield valid comparative information on health technologies...”
- “encourage payers to link health insurance coverage for new technologies with structured evaluations”
- Extra credit: In what year?

CER Definition

- “Research evaluating and comparing the implications and outcomes of 2 or more health care strategies to address a particular medical condition”
- Primary focus on drugs, devices, procedures, diagnostics “and any other processes or items used in the treatment or diagnosis of patients”

Methods

- Systematic reviews (traditional HTA)
- Retrospective studies
 - with claims and/or EMR data
- Modeling (+/- cost data)
- Prospective observational or experimental studies
 - Registries
 - Pragmatic trials, Cluster RCTs
 - Bayesian / adaptive methods

Methods and Decisions

- What constitutes “adequate” evidence?
- Which methods are sufficient for which question, and by which decision maker?
- Take home message: CER will succeed only if we orient around decisions
 - Decision-based evidence making
- In other word: give me evidence I can believe in!

Data Mining vs. Trials

- Standard logic for retrospective studies
 - Clinical trials are expensive, lengthy, not generalizable
 - Many unanswered questions
 - Therefore, must rely on observational methods
 - “I lost my keys in the bushes, but its too dark over there”
- First understand what evidence is necessary
 - Improve methods for analysis of routinely collected data
 - Develop cheaper, faster, simpler, broader trials
- The Learning Healthcare System must include both

CT angiography

- Duke EPC report (April 2006)
 - 10 single center studies, all N<100
 - Most evidence in high risk scheduled for angio
- MedCAC mtg (May 2006)
 - Uncertain confidence about existing evidence
- ACCF/ACR/SCCT appropriateness criteria
 - Scores of 5(U) and 7(A) for intermediate risk
 - Used by local Medicare contractors to cover
- CMS opened NCD in June 2007
- Draft NCD in 12/07 proposed CED

CMTP Coronary CTA Project

Workgroup Members and Observers

- Aetna
- Kaiser Permanente
- UnitedHealth
- MN Medicaid
- GE Healthcare
- Siemens Medical
- Philips Medical
- Toshiba
- AHA
- ACC, ACR
- FDA, CMS, AHRQ
- ACRIN
- Clinical researchers
- Patient representative

Adequacy of CCTA Evidence

- Payers want RCT with death/AMI outcome
- Vendors / clinicians find existing evidence adequate
 - dx performance studies in high risk patients
- Medicare final decision
 - No adequately designed studies show improved outcomes
 - “We believe large, well-designed prospective trials needed”
 - Broad coverage by local contractors retained
- If we had the money, what study would we fund?
- First must agree on what constitutes adequate evidence of benefit for cardiac imaging
 - CMTTP planning workshop with ACC, ACR, SCCT, NHLBI, AHRQ, payers, vendors, patients, etc.

Effectiveness Guidance Documents

- Analogous to FDA-guidance
- Foundation is systematic reviews
- Focus on evidence requirements of payers, patients, and clinicians
- Primary audience is product developers
 - Also to those who fund clinical research and HSR
- Multi-stakeholder workgroup and iterative-draft comment process
- Raises question of which methods will provide “adequate” evidence
 - How else can we decide what CER studies to do?
- Gene expression testing, chronic wounds

Review

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