

# **Comparative Effectiveness: What, Why, How, Who, Where, When?**

**Technology Assessment Roundtable  
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# Objective

- To help identify areas of agreement, disagreement or confusion on issues related to comparative effectiveness research
- Definitions, assertions, assumptions and conclusions presented here are for purposes of discussion only

# RESOLVED

- A new Center for Comparative Effectiveness Research should be established in the United States
- The Center will provide information on the relative clinical (and cost) effectiveness of alternative health care interventions
- It shall be funded at the level of \$4 to 6 billion dollars annually
- So far, so good (?)

# WHY?

- Help payers make better coverage and spending decisions (Wilensky)
- Help patients and clinicians become informed, cost-conscious decision makers?
- Reduce cost
- Reduce variations in care
- Improve quality and safety
- Sustain innovation
- Improve value

# WHAT?

- Comparative Effectiveness Research compares the benefits, risks (and costs) of health care option A to health care option B (and C, etc).
- Options A and B will usually be a drug, devices, procedure, or diagnostic.
- “Effectiveness” implies preference for “real world” performance

# WHAT ? CMS VIEW

- National Emphysema Treatment Trial
- Pragmatic trial of FDG-PET for suspected dementia
- Head to head trial of drug treatment for macular degeneration
- Daily vs conventional dialysis for ESRD
- Dose comparison studies for CIA

# WHAT? Other Options

- Part D drug class comparisons
- Comparing providers on quality/cost
- Condition-based decision guides
  - Drugs, exercise, observation for severe osteoporosis
- Geographic variations and other HSR

# HOW? (and how much?)

- Prospective clinical studies
- Observational studies with EMR data
- Observational studies with integrated administrative data
- Systematic reviews / HTA
- Health services research



# Chronic Wound Therapy

- \$20 billion spent on care of chronic wounds
- NPWT in top 20 list for CMS spending on DME
- CER question: is NPWT better than standard wound care for treating chronic wounds
- HTA excludes all observational studies
- 6 RCTs, all low quality, 5 with  $N < 25$
- Highlights need for robust capacity for trials

# WHO?

## Existing Capacity / Models

- NIH (NETT, ALLHAT, CATIE, LABS)
- Life Sciences Industry (stents, lipids)
- Veterans Administration
- CMS (various CED projects)
- European / Canadian PCT funders
- AHRQ (Effective Health Care)
- BCBSA, EPCs, DERP, ECRI, Hayes
- NICE, PBAC, other INAHTA
- (ICER, CMTP)

# WHERE?

## Lessons from the past

- National Center for Healthcare Tech
- National Emphysema Treatment Trial
- Office of Technology Assessment
- AHCPR to AHRQ / CPG to EPC
- Technology Advisory Cmte / MCAC

# Plausible Interpretations

- Small is beautiful, but not sturdy
- Creating evidence is safe; making decisions is not
- Hazards of compulsive truth-telling
  - John Eisenberg's allegory
- Lack of transparency, stakeholder input, public accountability, appeals

# A few major wild cards

- Will CMS and private payers widely adopt CED approach?
- What can be learned from massively integrated data
- How and when will broad EMR change approach to clinical research
- What are the implications of personalized medicine on conduct of CER?

# What Next and When?

- IOM roundtable on EBM
- HIF / AHIP / Kaiser / Merck alliance
- Legislative proposals
- Proof of concept approach
  - ICER, CMTP
- More, better ideas by 3PM today

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- Looking forward to further clarity from presentation and discussion to follow

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# Center for Medical Technology Policy (CMTP)

- Non-profit funded by CHCF, BSCF
- Platform to expand role for decision makers in creating better evidence
- Activities:
  - Identify priorities of decision makers
  - Develop faster, cheaper methods
  - Establish standards for effectiveness
  - Select and design pilot projects

# Pilot projects

Criteria: evidence gaps, promising, high demand, major health impact

- CT Angiography
- Oncotype DX test
- IMRT
- Tele-ICU
- Bariatric surgery