

# Comparative Effectiveness Research

Sean R. Tunis MD, MSc.  
Center for Medical Technology Policy  
February 15, 2007

# Max Baucus on CER (2/13/07)

- Controlling costs one of 5 key principles of health care reform
- Investment in CER one approach to costs
- “need to know whether the care we pay for really works”
- “spent less than 1/10 of 1% on “whether we are spending on the right things”
- “funding for HSR is like buying a college education”

# DEFINITION

- 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, diagnostic or procedure

# USES OF CER

- Monitor real world adverse events, outcomes and patterns of care
  - Off-label use / combination therapy
  - Long term clinical and economic outcomes
- Compare benefits/risks of existing tech
- Compare benefits/risks of new technology

# CER METHODS

- Systematic reviews
  - Often called “technology assessment”
- Observational studies
  - administrative data
  - EHR data
- Prospective studies
  - registries
  - trials

# Chronic Wound Therapy

- \$20 billion spent in US on care of chronic wounds
- NPWT in top 20 list for DME spending
- Is it better than standard wound care?
- HTA excludes all observational studies
- 6 RCTs, all low quality, 5 with  $N < 25$
- Same situation with HBO, e-stim, etc.
- Non-cover? CED? Sponsor trial?

# Albuterol / Xopenex

- 6 cents vs 1.09 per dose for asthma / COPD
- DMERCS draft policy – LCA
- Several head to head trials showing modest differences on some outcomes
- CMS decided postpone LCA, open NCD
- Review or retrospective studies not helpful  
- will require large prospective trial

# CT angiography

- MCAC mtg 2006
  - EPC report: 10 small single center studies
  - Committee gives low QOE scores
- ACC did appropriateness guidelines
  - Using RAND methodology
  - Intermediate risk, symptomatic pts
- Aetna, Cigna, United non-cover

# CCTA – Medicare local coverage

- Based on ACC guidelines
- CCTA can “reliably rule out CAD” in low and intermediate risk patients
- CCTA can reliably replace conventional angiography
- Indications will be revised “as higher level evidence-based studies become available”
- No trials ongoing for low/intermediate risk pts

# CMTP CCTA pilot project

- Center for Medical Technology Policy
  - Funded by CHCF, BSCF, Commonwealth
- CCTA Workgroup
  - GE, Phillips, Siemens, ACC, ACR, AHA, Aetna, Kaiser, FDA, AHRQ, ACRIN
- Draft protocol under development for low/intermediate risk pts
- CED funding mechanism probable

# Some Observations

- Increased capacity for CER will be valuable
- Need to understand appropriate use of reviews and observational data
- Must develop faster, cheaper, reliable ways to conduct prospective studies
- Collaboration on design, implementation and funding will be critical
- Still need good policy making mechanisms and aligned incentives for decision makers

# More Information

- [sean.tunis@cmltpnet.org](mailto:sean.tunis@cmltpnet.org)
- [www.cmltpnet.org](http://www.cmltpnet.org)
- 410-963-8876