Comparative Effectiveness Research: So Far, So Good …

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CER: Now Part of Health Care Reform

- A “huge win” plus key features are the right ones
- Focus on alternative ways to treat medical conditions
- Includes medical procedures
- Information-generating and dissemination not decision-making
CER: Part of Health Care Reform

But --

- Concept remains controversial
- And with a variety of limitations
- And an uncertain role in decision-making
Several Legislative Attempts Before ARRA/PPACA

♦ HR 2184, “Allen/Emerson”
  -- Introduced 5/07

♦ HR 3162, “CHAMP” Bill
  -- Passed House 8/07

♦ S. 3408, “Baucus/Conrad”
  -- Introduced 8/08; the basis of PCORI
CER – Still Very Fragile

♦ Limits on its (direct) use
♦ Limited funding
  -- $600 mil in FY 2014
♦ Implementation challenges
♦ “Concerns” continue to be raised
Need to Learn From ARRA Experiences

♦ Focus on what happens in “real world”
♦ Role of Federal Coordinating Council
  -- Definition of CER, priority setting
♦ Need for coordinating function
♦ Setting strategic framework
Too Early to Know ARRA Results

Can focus now on *processes; priority setting*

- Use of IOM to help prioritize research
- Public input
- Importance of outreach
- Importance of transparency
Early Results Will Be Important

♦ Mix of studies

♦ Mix of methodologies
  -- IOM top 100: ½ RCT; ½ not

♦ Some results *could be* controversial
  -- Need input from affected parties

♦ Dissemination/explanations are important
Many Short-Term Challenges for PCORI

♦ Appointment of Governing Board
♦ Executive Director/Senior Staff
♦ Developing a priority-setting strategy
♦ Establishing the rules for “credible evidence”
“Credible Evidence” Issues

♦ Methodology committee to be created to assist PCORI
  -- Due to report in 18 months

♦ Need to determine what constitutes “credible evidence”
  -- Impact of usual-care setting requirement
  -- Use of observational/other non-experimental design data

♦ Challenges of past systematic reviews
Ultimate Challenge: Making Use of CER

♦ Primary stated purpose: *improved health outcomes*
♦ “Secondary” purpose: building block to “spending smarter”

-- CER more suited to *reimbursement* decisions
-- *Value-based reimbursement/value-based insurance* principles
Improving Health Outcomes

♦ Difficult to change physician behavior
  -- Need to get “buy-in” to the process
  -- Especially important if challenge “conventional wisdom”

♦ Important to involve patients/advocacy groups
  -- Include patients “like them”, not just “averages”
Using CER to Moderate Spending

A major challenge!

♦ PCORI: *can’t* mandate coverage or reimbursement
♦ Other limitations on PCORI
♦ CMS *can’t* use cost in coverage decision; no authority to use CER in reimbursement
First Steps to Moderating Spending

♦ Encourage private payers to use CER in making reimbursement decisions

♦ Encourage use of value-based insurance by private payers

♦ Promote pilots/demo’s of VBI for Medicare reimbursement

Need to focus on the long run