

# Comparative Effectiveness Research: So Far, So Good ...

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# CER: Now Part of Health Care Reform

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- ◆ 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

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*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

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- ◆ 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

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- ◆ 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

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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

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- ◆ 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

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- ◆ 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

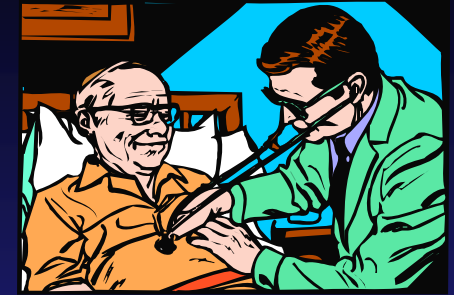
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- ◆ Primary stated purpose: *improved health outcomes*
- ◆ “Secondary” purpose: building block to “*spending smarter*”
  - CER more suited to *reimbursement* decisions
  - *Value-based reimbursement/value-based insurance* principles

# Improving Health Outcomes

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- ◆ 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

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*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

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- ◆ 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*