

Comparative Effectiveness Research: Initial Success Future Challenges

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CER: A Different Focus in the U.S.



- ◆ Alternative ways to treat *medical conditions*
- ◆ Includes medical procedures, not just Rx and devices
- ◆ Information generation and dissemination –
not decision-making

CER: Now Part of Health Care Reform



But --

- ◆ Controversy remains over the concept
- ◆ *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

CER – Still Very Fragile



- ◆ Limits on its (direct) use
- ◆ Limited funding
 - \$600 mil in FY 2014
- ◆ Implementation challenges
- ◆ Continuing “*concerns*” by various groups

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



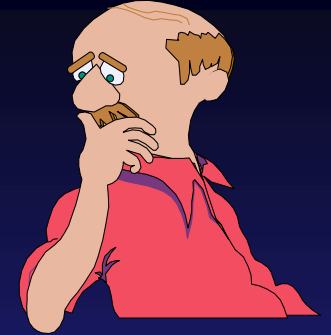
- ◆ Mix of studies
- ◆ Mix of methodologies
 - IOM top 100: 1/2 RCT; 1/2 not
- ◆ Some results *could be* controversial
 - Need input from affected parties
- ◆ Dissemination/explanations are important

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



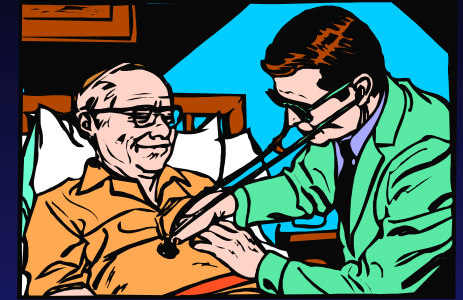
- ◆ Methodology committee to be created to assist PCORI
 - Due to report in 18 months
- ◆ Need to determine what constitutes “credible evidence”
 - Impact of usual-care setting requirement
 - Use of observational/other non-experimental design data
- ◆ Challenges of past systematic reviews

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
 - Included 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

Start using CER for *Private Sector Reimbursement*

Then try to move to Medicare

Shaping Convergent Strategies for Comparative Effectiveness Research

