Societal Implications of CER & Personalized Medicine – Session XI

How Can We Keep the Debate Rational?

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• “. . . [All] improvement is change, and human systems resist change . . . [I]mprovement requires a source of tension, discomfort with the *status quo*, sufficient to overcome this inertia.”
Public Perceptions: A Double-Edged Sword

• Can be an Asset

• Or a Liability
Primary Sources of Resistance

- Those with ideological agendas, &
- Those fearing loss of a financial stake in the *status quo*
Keeping the Debate Rational

1. Re-frame the terminology

1. Emphasize “We’ve been doing it for years”

2. Control the agenda & the momentum
1. Re-frame the Terminology: What’s in a Name?

- **Comparative Effectiveness Research**
  Term itself a lightning rod for controversy?
  – Too easy to confuse w **cost** effectiveness?
  – Too easy to demonize with the R-word?

- **Patient Centered Outcomes Research**
  Puts patient in the center – literally
  – Undercuts allegation of one-size-fits-all, “cookbook medicine”
2. “We’ve Been Doing It for Years”

• Clinical trials of new drugs & devices

“Adequate and well-controlled”

• Amendment to FDCA in 1962 established “adequate and well-controlled studies” as the basis for determining efficacy of new drugs

• 21 CFR 314.126, on active control studies: “Similarity of test drug and active control can mean either that both drugs were effective or that neither was effective.”

• Further detailed in ICH E-9 and E-10
2. “We’ve Been Doing It for Years” (cont.)

• Veterans Administration health services
2. “We’ve Been Doing It for Years” (cont.)

• Practice Guidelines

ACP Clinical Practice Guidelines

National Guideline Clearinghouse www.guideline.gov
3. Control the Agenda & the Momentum

- Take proactive stance re getting value for money
  - Show “what works” (& what doesn’t)
  - Demonstrate cost saving potential
- Emphasize: patient-centered medicine + effectiveness data = better care for individuals