Establishing a National Comparative Effectiveness Research Capacity: Overview of Key Issues

Murray N. Ross, Ph.D.
Kaiser Permanente Institute for Health Policy

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For discussion

• Why is comparative effectiveness research (CER) on everyone’s agenda?

• What does “establish CER capacity” mean?

• Where is there broad-based agreement?

• What are some of the unresolved legislative issues?

• What issues need to be resolved later?

• Some preliminary thoughts on where to get going
Why is CER on the policy agenda?

• Status quo in health care is not sustainable, not desirable
  • Spending growth exceeds income growth
  • World’s highest spending not reflected in health outcomes
  • Quality of care falls short of knowledge
  • Care patterns exhibit substantial unwarranted variation

• How could comparative effectiveness research help?
  • Inform head-to-head (or head-to-head-to-head) comparisons of treatments—benefits, risks, costs—not now possible
  • Enable clinicians to make better treatment recommendations, patients to make informed decisions
  • Help payers tailor reimbursement and cost sharing to value, avoid “zero-one” decisions
What “establishing CER capacity” means

• Creation/designation of an entity to:
  • Prioritize among health conditions for research
  • Develop evidentiary standards
  • Evaluate research findings
  • Disseminate results/recommendations

• Creation/designation of some entity to undertake (and/or fund) comparative effectiveness research
  • Evidence reviews
  • New trials, registries, and so on

• What “establishing CER capacity” does not mean
  • Entity would not make coverage decisions
  • Entity would not negotiate prices
Areas of agreement

• Clinicians, patients, payers need better information about what works and what does not

• CER should be condition-based and have wide scope: drugs, devices, biologics, and medical procedures

• Priority setting and evaluation should obtain input from stakeholders with diverse perspectives and expertise

• Trust is crucial—need transparent process, credible results

• Funding should be stable and broad-based

• CER should not stifle productive innovation
Legislative issues on the table

- **Scope**: Will research on comparative cost effectiveness be part of the new entity’s mandate?
  - Is addressing unsustainable spending an objective or not?

- **Governance**: How can the process be protected from political meddling and/or undue stakeholder influence?
  - Need accountability for funding, independence of judgments
  - Want expertise, buy-in without impairing integrity or paralysis

- **Funding**: What is the appropriate amount and source?
  - How much research to inform $2+ trillion in health spending?
  - Appropriation or trust fund?
  - How (and when) should private funds be in the mix?
Issues the new entity will need to address

• Accounting for differences across technologies
  • Product life-cycles (evolutionary vs. revolutionary)
  • Amenability to randomized controlled trials or not
  • Sorting out roles of clinicians, technology, patients

• Developing an analytic framework
  • What evidentiary standards will determine “better?”
  • How will benefits and risks be measured?

• Confronting worries about “zero-one” decision-making
  • How will findings and recommendations be characterized?
  • To whom will they be conveyed?

• None of these trivial, none of these a show-stopper
Priority setting

- Address conditions with alternative treatments available
- Address conditions with significant clinical or financial implications
- Choose research areas with a reasonable expectation that results will influence provider and/or patient behavior
- Choose research areas with a reasonable expectation of getting usable results
- Avoid researching conditions for which treatment is self-evidently necessary (see next page)
Avoiding the obvious ...

For further reading: Gordon C S Smith, Jill P Pell, Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials, BMJ 2003; 327:1 459-461