

Health Care Reform's Wild Card: The Uncertain Effectiveness of Comparative Effectiveness Research

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Overview

- Comparative effectiveness research (CER) the “wild card” in health care reform
- Better evidence = Better medical practice
- “Why would anyone oppose it?”
- But....

Translation Barriers

- Costly data that may raise more questions than it answers
- Government agenda ill-defined
- Physician “Tune Out”
- Law not helping set right incentives and may be exacerbating the translation challenges
- What to *do* with the info?

What is CER?

- Comparative effectiveness research (CER) vs. traditional effectiveness research
 - *Comparative*, not general efficacy
 - *Real world* clinical conditions with broader # of representative subjects
 - Looks at *existing treatments* as well
- Weak governmental/private CER efforts in the past
- CER vs. cost effectiveness

Shifting Agendas

- “More research on what works, what doesn’t ...could help to reduce costs without harming quality.” (2008)
- CER is “about making sure that your doctor and you have as much information as possible on what is likely to work for you.” (2010)
 - Peter Orszag, Director of the Office of Management and Budget (2010)

2009 Recovery Act

- \$1.1 billion allotment for CER
 - \$400m to HHS Secretary
 - \$400m to NIH
 - \$300m to Agency for Healthcare Research & Quality
- Federal Coordinating Council for CER
- Inst. of Medicine recommendations for national CER priorities

2010 Patient Protection and Affordable Care Act

- Federal CER Council replaced by new private, nonprofit Patient-Centered Outcomes Research Institute (17 board members: at least 3 from drug/device industry and 3 representing private payers)
- Institute will coordinate substantial government support for CER and direct government funds to private entities
- Institute funded approx. \$500M per year by 2014; \$\$ shifted from Medicare Part A and B trust funds/plus new insurer tax

Limitations on Using CER

- Federal payer coverage decisions cannot be based solely on CER
- If CER is used to inform coverage decisions, it must be through “an iterative and transparent process” that includes public comment and considers effect on subpopulations

Limitations on Using CER

- Medicare cannot use CER in a manner that assigns a lesser value to extending the life of elderly, disabled, or terminal patients
- CER not to be construed as mandates for practice guidelines, coverage, payment, or policy recommendations
- Institute cannot use \$/QALY to establish what treatments are cost effective or recommended

Physician Concerns

- CER often relies on “weaker” evidence
- Current plans (IOM Report) suggest CER will not consistently target immediate treatment decisions
- Bias (including role of Partnership to Improve Patient Care)
- Crude cost-cutting
- Clinical autonomy
- MedPAC 2009 physician survey

CER vs. Individualized Medicine

- Some medical practice are altered by condition of individual and “must be adapted to a particular person.”
- A good doctor looks to ongoing research “but then decides what is quality care for the individual patient...what is best sometimes deviates from the norms.”
 - Jerome Groopman, M.D.

Physician Tune-Out/Disregard

- “That’s Not How I Do It”....
 - Example: the randomized bypass on/off pump (ROOBY) trial – NEJM 2009
- No clear reimbursement incentives
- Malpractice liability concerns

MD Practice Patterns

- Information dissemination alone traditionally has weak impact
- Technological imperative hard to overcome
- Many non-evidence factors influence physician decision-making

Conclusions

- Serious missed opportunity
- Possible improvements:
 - 1) reimbursement incentives
 - 2) malpractice incentive links
 - 3) academic detailing (modest efforts so far)
 - 4) more comparative *translation* research