The advantages of CER, or, pharmaco-epistemology and the politics of knowledge

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Conflicts of interest

- Neither I nor many of my faculty accept any personal compensation of any kind from any drug or device manufacturer.
- Most of the research in my Division is funded by NIH / AHRQ.
- The Division occasionally accepts unrestricted research grants from industry to conduct specific drug-epi studies.

Where I’m going with this

- What’s “pharmaco-epistemology”?
  - definition: ***How we know what we know*** about drug benefits, risks, side effects, and cost-effectiveness.
- How can drug knowledge have politics?
  - What we study and what we learn about medications is shaped by economic, cultural, and political factors as well as purely scientific ones.

What doctors, payers, patients, and policymakers need to know about a drug

- Its benefits, safety, and value (cost-effectiveness) ***in relation to other reasonable prescribing choices for a given condition.***
- How well the drug actually works in typical populations (effectiveness), not just in randomized controlled trials (efficacy).

What the FDA approval process tells us

- How well a new product works when prescribed by **atypical doctors** treating a **small sample** of **volunteer patients** that **under-represents** several key populations in a **highly protocolized** trial design that is usually **brief**, may compare the new drug only to **placebo**, and may use a **surrogate measure** rather than actual clinical outcomes as its measure of efficacy.

Expanding the scope of FDA pre-approval studies

- These could be far more relevant and useful even within current regulatory structures:
  - use more appropriate populations, endpoints, comparators, durations
- Limits to this approach:
  - legal issues re comparators
  - the arithmetic of rare events
  - long-term followup

Whose job is it to generate the rest of the knowledge we need?

- Historical impotence of FDA's "mandated post-market commitment" requirements
  - FDAAA might help remedy this
- Failure of the marketplace assumption
  - decades of experience that this doesn't produce the data we need
    - Pharma's reservations
    - insurers' reservations
- Re-discovery of the concept of Public Goods
  - like highways, fire departments, clean air, education

Two more missing ingredients

- **Effective communication** of the results of CER to practitioners and policymakers
  - it won't disseminate itself
- **Motivation** for clinicians and systems to take up these findings and use them to transform practice

“Academic detailing”: a good way to get CER into practice

- Origins in 1980s -- learning from industry
- How it works
  - interactive, clinically relevant educational outreach
- Early proof of concept in RCTs
  - Avorn & Soumerai, NEJM 1983; Avorn et al, NEJM 1992
  - evidence of cost-effectiveness
- Growth of programs
  - Europe, Australia, Canada
  - U.S. HMOs

Current status of academic detailing in U.S.

- The “Independent Drug Information Service” (iDiS)
  - impartial, evidence-based review of CER literature
  - production of user-friendly educational materials for MDs, patients
  - runs academic detailing programs in PA, DC, MA
  - trains educators for other programs
- Other state programs in NY, SC, VT, ME, etc.
- Pending federal legislation

Education can take us pretty far… but not all the way

- Most physicians would rather prescribe wisely than poorly.

  …it's just that most of us don't have access to the information we need.

- But this won't work well in combating the perverse incentives of fee-for-service medicine
  - It's hard to educate an entrepreneur to cut his own economic throat.

….which brings us to the politics of CER.

CER and the death panel disinformation strategy

- Generating new knowledge never denied needed care to anyone.
- Most denial of services results from lack of access…
  - …which is largely caused by the unaffordability of care
  - …which is largely the result of inefficient use of available resources.

-- Avorn, NEJM 2009

Implementation issues

- Important points to acknowledge:
  - CER implementation strategies can sometimes be ham-handed, clinically obtuse, and unethical:
    - motivation is sometimes stinginess and profit rather than appropriate care
    - excessively rigid formularies
    - lack of respect for individual patient differences
    - contempt for physician's clinical acumen
    - manipulative and sadistic "prior authorization" requirements

Optimal CER implementation

- Rigorous assessment of the evidence
  - including its nuances
- Clinically helpful, user-friendly presentation of the reasons for recommendations, and the data behind them
  - Not just 1-800-DROP-DEAD phone requirements
- Acknowledgement of the reality of patient differences, even if we haven't discovered the gene yet.
  - ***BUT:*** "individualization of care" should not be used sloppily as an excuse for ignoring the evidence.
- Efficient, respectful provision for exceptions to guidelines when justified

The four crises

- The care many Americans get often does not match the best evidence on what would work best.
- Our inability to maximize the value (cost-effectiveness) of care makes our health care the most over-priced in the world.
- This is a main cause of our failure to provide universal access.
- It is also a central reason that the Medicare budget is driving the U.S. economy over a cliff.

Intelligent development of comparative effectiveness research, and its sensible deployment throughout the health care system, is needed to address all these areas.

For more information….

"Powerful Medicines: the Benefits, Risks, and Costs of Prescription Drugs"

(Knopf, 2005):

www.PowerfulMedicines.org

The BWH Division of Pharmaco-epi and Pharmaco-eco ("DoPE"):

www. DrugEpi.org

Academic detailing program:

www. RxFacts.org