Federal Initiatives in Comparative Effectiveness Research

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Comparative Effectiveness Research, Patient Safety and Quality

- AHRQ: New Resources, Ongoing Priorities
- Comparative Effectiveness: AHRQ’s Role
- IOM’s Priority Topics
- Comparative Effectiveness Research and Medical Devices

AHRQ Priorities

- Effective Health Care Program
- Comparative Effectiveness Reviews
- Comparative Effectiveness Research (new funding)
- Clear Findings for Multiple Audiences
- Quality & Cost-Effectiveness, e.g. Preventive Services
- U.S. Preventive Services Task Force
- Medicare
The American Recovery and Reinvestment Act (AARA) of 2009 includes $1.1 billion for comparative effectiveness research:

- AHRQ: $300 million
- National Institutes of Health (NIH): $400 million (appropriated to AHRQ and transferred to NIH)
- HHS Office of the Secretary: $400 million (allocated at the Secretary’s discretion)

What Is AHRQ’s Role?

- Leader of federal funding
- Engage private sector
- Increase knowledge base to spur high-value care
- Aggregate best evidence to inform learning and implementation challenges

The Myths Live On

- Excludes role of clinical judgment
- Aims to limit health services
- Ignores realities of practice
  - Reimbursement, liability concerns, patient expectations
- Useless when evidence is uncertain
What Comparative Effectiveness Can Do...

- Reduce the chance of getting it wrong
- Help make decisions more consistent, transparent and rational
- Clarify nature of disputes over practice and policy
- Help inform states’ quality improvement efforts
- Persuade skeptical parties

... And What It Cannot

- Solve controversies due to conflicting values, costs, etc.
- Remove barriers due to conflicting incentives, patient factors and system failures
- Ensure appropriate application to policy

Comparative Effectiveness Challenges

- Making sure that comparative effectiveness is “descriptive, not prescriptive”
- Anticipating downstream effects of policy applications
- Creating a level playing field among all stakeholders, including patients and consumers
- Using research to address concerns of patients and clinicians
Where To Start: IOM’s 100 Priority Topics

Initial National Priorities for Comparative Effectiveness Research (June 20, 2009)

Several topics relevant to device industry:

- Treatment strategies for atrial fibrillation, including surgery, catheter ablation and pharmacologic treatment (Topic #1)
- Formulary management practices and usual practices in controlling hospital expenditures for products other than drugs (e.g. medical devices)
- Treatment strategies (artificial cervical discs, spinal fusion, pharmacologic treatment with PT) for cervical disc and neck pain

Report Brief Available At http://www.iom.edu

Comparing Evidence: Medical vs. Semiconductor Research

“When I was doing semiconductor device research, it was expected that I would compare my results with other people’s previously published results and that I would comment on any differences. But it seemed to be different in medicine.

“Medical practitioners primarily tended to publish their own data; they often didn’t compare their data with the data of other practitioners, even in their own field, let alone with the results of other types of treatments for the same condition.”

Intel co-founder and prostate cancer patient Andy Grove, Forbes 5/13/96

Atrial Fibrillation (AF): What’s at stake?

- AF most common sustained arrhythmia seen in clinical practice.
- Prevalence increases with age, from 0.1% in people under 55 years of age to more than 5% in those 80 and older.
- Ablation for AF a potential topic for National Coverage Determination by Centers for Medicare and Medicaid Services. (7/30/08)
- Comments closed on 9/28/08; CMS considering evidence to determine if coverage decision is warranted.
Questions about Radiofrequency Catheter Ablation for AF

- Many different types of catheters
  - First two catheters specifically approved for atrial fibrillation by the FDA in Feb. 2009
  - Many other catheters used "off-label" by physicians
- Many different variations of the procedure
  - Different areas of the heart ablated
  - Different imaging techniques to guide the procedure (fluoroscopy, MRI, CT, electroanatomic navigation)
- Evidence is lacking to determine which of these variations would work best in different patients

Finding Answers in Comparative Effectiveness Reviews

- Full Report
- Concise Executive Summary
- Summary Guides for
  - Clinicians
  - Consumers
  - Policymakers

Radio-Frequency Catheter Ablation for Atrial Fibrillation: What is the Evidence?

- Moderate evidence that patients who received RFA as second-line therapy had higher chance of maintaining sinus rhythm than those treated with medical therapy alone (outcomes measured over one year)
- Low evidence to suggest that RFA improves quality of life more than medical treatment
- Insufficient evidence to compare rates of congestive heart failure between RFA and medical treatment

http://effectivehealthcare.ahrq.gov
September 23, 2009
Consumer Guides Help Guide Patients’ Decisions

- Insufficient evidence to determine whether angioplasty with stenting is a better treatment than aggressive medical therapy alone
- Not enough data to determine whether individual characteristics have an effect on treatment outcomes
- About 1% of people who have angioplasty die within first 30 days; 10-21% who have angioplasty with stent have restenosis within 40 months

What’s Next? Translating Research Results into Practice

IOM’s Challenge:
“Research on these topics will not yield real improvements unless results are adopted by health care providers and … integrated into clinical practice.”

Initial National Priorities for Comparative Effectiveness Research (June 20, 2009)

How AHRQ Research Affects Medical Device Industry

- Rapid Innovative Cycle for Devices
  - Timely completion of CER reviews
  - Analyzing role of innovations, such as robotic therapies for stroke rehab, when usual care varies
  - Evaluating applicability of studies of older versions of devices to new devices
How AHRQ Research Affects Medical Device Industry

- Diagnostics (such as new genetic tests)
- Evaluating devices for which there is no consensus on best outcome measures
  - Intraocular lens implants: Is outcome measure reading chart in doctor’s office or reading the newspaper?
  - Enlarged prostate: Is outcome measure symptom relief or urine flow rate?
  - Evaluating the impact of the tests on improving patient outcomes

Role of Adjunctive Therapies in Device Effectiveness

- AHRQ-funded study comparing the long-term effectiveness of drug-eluting and bare-metal stents
  - 4,666 patients at 6- and 12-month follow-up periods
  - Conclusion: Extended use of clopidogrel may be associated with reduced risk. The appropriate duration for clopidogrel administration should be determined in a randomized clinical trial

Long-Term Outcomes and Costs of Ventricular Assist Devices

- AHRQ-funded study found costs, morbidity and mortality high for patients with mechanical heart pumps
  - Many survivors readmitted within 6 months and costs remain high
  - Improving patient selection is important to improving overall outcomes
Clinician-Consumer Health Advisory Information Network (CHAIN)

- Offers expert perspectives, advice and guidance on drugs, biological products and medical devices.
- Assists in clinical practice and health care decision making in areas where evidence is undergoing significant and rapid changes.

http://www.chainonline.org

AHRQ User’s Guide to Patient Registries

- Patient registries can be used to evaluate outcomes for diverse purposes ranging from the natural history of a disease, to the safety of drugs or devices, to the real-world effectiveness of therapies.
- AHRQ’s guide is the first government-supported handbook for establishing, managing and analyzing patient registries.

http://effectivehealthcare.ahrq.gov

Moving Forward: Issues to Consider

- Comparative effectiveness research is a useful tool in a much larger toolkit – it cannot answer all relevant questions.
- It does not make policy or health care decisions, tell doctors how to practice medicine or decide which treatments insurers will cover.
- It does weigh the evidence and present it in a way that helps consumers and their doctors make the best possible decisions about health care choices.
- It’s also an opportunity to identify what is not known and areas where research is needed.
**What Health Care Decision Makers Need To Know**

- **Can it work?**
- **Will it work?**
  - For this patient?
  - In this setting?
- **Is it worth it?**
  - Do benefits outweigh harms?
  - Do benefits justify costs?
  - Does it offer important advantages over existing alternatives?

**21st Century Health Care**

Improving quality by promoting a culture of safety through Value-Driven Health Care

Information-rich, patient-focused enterprises

Evidence is continuously refined as a by-product of care delivery

21st Century Health Care

Information and evidence transform decision-making: from reactive to proactive (benefits and harms)

Actionable information available – to clinicians AND patients – just in time!

**Where to From Here?**

- **Timing**: Significant support for and interest in comparative effectiveness research
- **The mission**: Address gaps in quality and resolve conflicting or lack of evidence about most effective treatment approaches
- **Words of wisdom**: “In theory, there is no difference between theory and practice. In practice, there is.” – Yogi Berra