The Role of the Agency for Healthcare Research and Quality (AHRQ) in the US Drug Safety System

Scott R. Smith, MSPH, PhD

Center for Outcomes & Evidence
Agency for Healthcare Research & Quality
July 20, 2005
Outline

- Provide a brief overview of AHRQ.
- Outline 10 potential contributions by AHRQ to ensuring drug safety.
- Discuss new AHRQ programs, relevant to pharmaceuticals, starting in Oct 2005.
Mission Statement

To improve the quality, safety, efficiency, and effectiveness of health care for all Americans.

Vision

The vision of the Agency is to improve health care through the production and use of evidence. As a result of AHRQs efforts, American healthcare will provide services of the highest quality, with the best possible outcomes, at the lowest cost.
AHRQ Research Focus: How it Differs

- Patient-centered, not disease-specific.

- Dual Focus -- Services + Delivery Systems effectiveness research focuses on actual daily practice, not ideal situations ("efficacy").
AGENCY FOR HEALTHCARE RESEARCH & QUALITY

Center for Quality Improvement & Patient Safety

Center for Outcomes & Evidence

Center for Primary Care, Prevention, Partnerships

Center for Delivery & Organization & Markets

Center for Financing, Access, & Cost Trends

Extramural Research, Education & Priority Populations

Communication & Knowledge Transfer

Performance Accountability, Resources, & Technology

Director
Carolyn M. Clancy, MD
Ten Focused Portfolios

- Care management.
- Cost, organization, socio-economics.
- Data development.
- Health information technology.
- Long-term care.
- Pharmaceutical outcomes.
- Prevention.
- Quality and safety of patient care.
- System capacity & bio-terrorism.
- Training.
Pharmaceutical Outcomes Portfolio Mission

To improve health outcomes through the safe and effective use of pharmaceuticals.
10 Areas of Potential Contribution by AHRQ to Ensuring Drug Safety
1. Pharmaceutical research.

AHRQ sponsors clinical, laboratory, & epidemiologic research on drugs, biological products, & devices.

- In consultation with the FDA, AHRQ administers the Centers for Education and Research on Therapeutics (CERTs) program.

- 7 research centers, each focuses on a broad theme where limited comparative information exists on the risks, benefits, and interactions of new and older therapeutic agents.
2. Evidence-based reviews.

Systematic review, evaluation, and synthesis of clinical trial and observational data.

- A network of 13 evidence-based practice centers (EPC’s) located at institutions across the US & Canada.

- The EPC program provides unbiased, independent, scientific analysis and research syntheses.

- Use advanced methodologies, such as meta-analysis and meta-regression to conduct rigorous evaluations of available scientific data.
Goals of Evidence-based Practice

- Increase benefit, decrease harm, improve quality, and reduce inappropriate variation.

- Past reports have evaluated pharmaceutical topics
  - epoetin for anemia in oncology.
  - ephedra for weight-loss & athletic performance.
  - pharmacologic treatment of conditions such as dementia, depression, epilepsy, and heart failure.
3. Patient safety research.

Identifying health care risk and hazards.

- AHRQ has awarded approximately $150 million in new grants, contracts, and other activities to reduce medical errors and improve patient safety.

- The goals are to
  - a) improve identification of risks and hazards of patients from the delivery of health care;
  - b) raise awareness for iatrogenic injury and harm; and
  - c) build capacity for research and development.

- Three Centers of Excellence in patient safety research.
4. Analysis of large health care databases.

Intramural & extramural programs providing access to medical and pharmaceutical data.

Intramural

- Analysis of Medicare A,B.
- MEPs: National Survey on Costs & Utilization.
- HCUP: National Discharge Data.
- Private Health Plan Data.
- Media Advertising Data.
4. Analysis of large health care databases.

Extramural

- **IDSRN** - Integrated Delivery System Research Network.
  - A field-base research network of 9 integrated healthcare delivery systems that link scientists with large US health care systems and their electronic databases.
  - A network of over 55 million Americans including the privately insured, Medicare (3 million) and Medicaid (2 million) patients, the uninsured (0.6 million), ethnic and racial minorities (5.8 million), and rural (6.3 million) and inner-city residents.

- **DEcIDE** - Developing Evidence to Inform Decisions about Effectiveness (new in 2005).
5. Access to unique populations.

Access to populations at potential increased risk for adverse effects in “real world” settings.

- **PBRN**: Primary Care Practice-based Research Network.
- A group of ambulatory primary-care practices used to investigate questions related to community practice.
- 19 PBRNs who provide access to over 5,000 primary care providers and almost 7 million patients who are being followed in a variety of settings in 49 States.
- Includes low income; minority; women; children; elderly; and those with disabilities, need chronic care, or need end-of-life health care.
6. Information technology.

Innovative applications of health information technology to improve quality and drug safety.

- Grants to fund IT infrastructure across states and regions to share information on medical care.
- Research into new clinical informatics tools such as decision support systems and electronic prescribing.
  - National Resource Center for Health IT.
  - State Demonstrations on Interoperability.
  - Indian Health Service EHR Collaboration.
  - CMS–AHRQ demonstration collaboration.
  - Development of clinical data standards.
FY ’04 HIT Investment

$60M initiative:

- **$26M**: to implement proven technologies in small and rural communities where HIT penetration has been low.

- **$24M**: targeted for developing, implementing, and evaluating the use of new and innovative technologies to improve patient safety and quality of care in diverse health care settings.

- **$10M**: targeted for clinical data standards and interoperability.
Clinical Data Standards
$10M Investment

- Further standards development work to allow systems to share important health information.

- Focus on gaps in the areas:
  - national standard nomenclature for drugs and biological products
  - standards related to comprehensive clinical terminology and nomenclature
  - research related to accelerating the adoption of interoperable health IT systems.

- Examples include:
  - RxNorm/Daily Med
  - Device Nomenclature
  - ePrescribing
<table>
<thead>
<tr>
<th>Research</th>
<th>Error Prevention</th>
<th>Monitoring</th>
<th>Detection</th>
<th>Intervention</th>
<th>Infrastructure</th>
<th>Technology Adoption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value of drug labeling knowledge for electronic prescribing (Indiana)</td>
<td>Electronic tools to reduce warfarin errors.</td>
<td>Rural Indian Health Service monitoring of medication errors (California)</td>
<td>ADE detection and intervention system (North Carolina)</td>
<td>Patient specific health alerts in a community wide network (North Carolina)</td>
<td>UMLS standards</td>
<td>Community wide health record to improve medication administration</td>
</tr>
<tr>
<td>Missing clinical data for disease emergence and sends to public health officials (Mass, Indiana)</td>
<td>Computerized decision support to reduce ADE’s (Washington)</td>
<td>Monitoring of medical errors &amp; interventions. (Iowa)</td>
<td>ADE alert for pregnant inpatients (Oregon)</td>
<td>Bar coding in pharmacy systems.</td>
<td>FDA labeling</td>
<td>Rural ADE monitoring &amp; reporting. (Michigan)</td>
</tr>
<tr>
<td>ParentLink for pediatric patients in EDs (Massachusetts)</td>
<td>Web-based diabetes education (Connecticut)</td>
<td>Patient safety even database (Indiana)</td>
<td>Real-time outbreak and disease surveillance (Penn)</td>
<td>Implementations of computerized prescriptions order entry. (Georgia)</td>
<td>NCVHS standards recommendation.</td>
<td>Automating MAR process to include automated dispensing. (California)</td>
</tr>
</tbody>
</table>
7. Conducting national health surveys.

Collection and analysis of national data through annual surveys on health care and prescription use.

- National surveys on health care use, including prescription drug use.
- MEPS produces national estimates on the health services that Americans use, including frequency & costs.
- Components
  - (1) household survey;
  - (2) survey of medical providers (including pharmacies) linked to the household survey; and
  - (3) a periodic survey of nursing home residents.
8. Translation & dissemination.

Dissemination of evidence-based information.

- **NGC**: National Guideline Clearinghouse.
- Comprehensive online database of evidence-based clinical practice guidelines and related documents.
- Provides physicians, pharmacists, nurses, and other health professionals with detailed information on clinical practice guidelines and to further their dissemination, implementation and use.
- EG, there are 67 guidelines in the database which are related to the use of cardiovascular agents and 111 guidelines on anti-infective agents.
9. Develop quality measures.

Development and dissemination of quality measurements for monitoring & tracking.

- **NQMC**: National Quality Measures Clearinghouse.
  - public repository for evidence-based quality measures and measure sets.

- **Quality Indicators**: (QIs) are measures of health care quality that make use of readily available hospital inpatient administrative data.
  - Patient Safety Indicators (currently not drug focused).
10. New authorization by MMA.

Authorizes AHRQ to conduct research to improve the quality, effectiveness, and efficiency of Medicare, Medicaid, and (SCHIP).

A. Evidence synthesis
   - Transparent process of systematically reviewing and synthesizing evidence on treatment effectiveness.
   - Identifying relevant knowledge gaps.

B. Evidence generation
   - Development of new scientific knowledge to address knowledge gaps.

C. Evidence communication/translation
   - Communication of scientific information in plain language to policymakers, patients, and providers.
A. Evidence Synthesis

2005 Topics

- Management strategies for GERD.
- Benefits & safety of analgesics for osteoarthritis.
- Epoetin and darbepoetin for managing anemia.
- Off-label use of atypical anti-psychotics.
- Therapies for localized prostate cancer.
- Oral medications for diabetes management.
- Medications for depression management.
- Drug therapies for osteoporosis and osteopenia.
B. Evidence Generation

The main purpose of the DEcIDE network is to expeditiously develop valid scientific evidence about the outcomes, comparative clinical effectiveness, safety, and appropriateness of health care items and services.

The network will be comprised of academic, clinic, and practice-based centers with access to electronic health information databases and the capacity to conduct accelerated research.
What Kind of Databases?

- Electronic medical record data.
- Pharmacy data.
- Public or private health insurance data.
- Long-term care data.
- Specialty databases such as disease, procedure, or medical device registries.
DEcIDE Objectives

- Analyze administrative, survey, and clinical databases.
- Develop and apply new methods, instruments, and methodologies.
- Operate and analyze computerized surveillance and monitoring systems.
- Conduct prospective observational and interventional studies.
<table>
<thead>
<tr>
<th>What Will DEcIDE Do?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform secondary database analysis to compare health outcomes</td>
</tr>
<tr>
<td>Develop algorithms to identify inappropriate drug prescribing patterns</td>
</tr>
<tr>
<td>Conduct clinical economics studies</td>
</tr>
<tr>
<td>Analyze existing disease registries or prescription databases</td>
</tr>
<tr>
<td>Conduct simulations and modeling</td>
</tr>
<tr>
<td>Design &amp; implement prospective studies</td>
</tr>
</tbody>
</table>
new Clinical Decisions & Communications Science Center

- Translate scientific evidence into targeted products for patients, providers, policymakers and the public
- Translation into different mediums
- Medical decision support generally – how to interpret acceptable risk, relative risk, rates, values clarification methods, and guidance or coaching in communicating values and personal preferences etc.
Summary

- Patient safety and drug safety are priorities at AHRQ.

- 10 Potential areas of contribution to drug safety.

- Expertise and resources in data & analysis of pharmaceuticals including utilization, adverse effects, epidemiology, safety, behavior, & informatics.

- Long-standing partnerships with local, State, and regional healthcare organizations facilitating research and education.
Home Page
http://www.AHRQ.gov

Scott R. Smith: ssmith@ahrq.gov
Thank you!