Genetics Testing

Carolyn M. Clancy, MD
Director
Agency for Healthcare Research and Quality
AHRQ Priorities

Patient Safety
- Health IT
- Patient Safety Organizations
- New Patient Safety Grants

Effective Health Care Program
- Comparative Effectiveness Reviews
- Patient-Centered Outcomes Research
- Clear Findings for Multiple Audiences

Ambulatory Patient Safety
- Safety & Quality Measures, Drug Management and Patient-Centered Care
- Patient Safety Improvement Corps

Medical Expenditure Panel Surveys
- Visit-Level Information on Medical Expenditures
- Annual Quality & Disparities Reports

Other Research & Dissemination Activities
- Quality & Cost-Effectiveness, e.g. Prevention and Pharmaceutical Outcomes
- U.S. Preventive Services Task Force
- MRSA/HAI's
## Efficacy vs. Effectiveness

<table>
<thead>
<tr>
<th>Clinical Trials</th>
<th>Clinical Practice</th>
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<tbody>
<tr>
<td>Efficacy</td>
<td>Effectiveness</td>
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<tr>
<td>Single diagnosis</td>
<td>High-risk patients with co-morbid conditions</td>
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<tr>
<td>Drug vs. placebo</td>
<td>Multiple drug choices and alternatives</td>
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<tr>
<td>Exclusions of user groups e.g.,</td>
<td>Use is generally unlimited</td>
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<tr>
<td>elderly</td>
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<tr>
<td>Clinical endpoints, biomarkers</td>
<td>Death, disability, QoL</td>
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<tr>
<td>Genetics/biology</td>
<td>Sociology/psychology</td>
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<tr>
<td>“Artificial” settings</td>
<td>Real world clinics</td>
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Support for U.S. Preventive Services Task Force (USPSTF)

- Evidence-Based Practice Centers support *The Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force*

- Prepare systematic evidence reviews and evidence summaries for topics under consideration by Task Force
CT Colonography is Replacing Other Methods

- “Two types of studies to assess the sensitivity of colonoscopy – tandem colonoscopy studies, in which the same patient is studied twice, and studies comparing colonoscopy and CT colonography – show that colonoscopy may miss even polyps larger than 10 mm and colorectal cancer.”

- “Recent clinical studies of CT colonography suggest that this screening method may be at least as sensitive as optical colonoscopy at identifying colorectal cancer and large adenomas in the community setting.”

U.S. Preventive Services Task Force
www.uspreventiveservicestaskforce.org
Angelina Jolie’s Decision

- She carries a defective BRCA1 gene that puts her at high risk of developing breast and ovarian cancer
  - Her mother had breast cancer and died of ovarian cancer
  - Her maternal grandmother had ovarian cancer
Challenges in Genomic Medicine

- Clarify benefits and harms of genetic tests
  - Urgent need for electronic infrastructure to support CDS, assess real world penetrance
  - Collaboration with guideline and quality measure developers

- Clarify *value* of adding genomic test(s) to existing diagnostic tests / strategies
  - Assure appropriate use
  - Feedback *from* care delivery to science
$20 million contract to support 15 specialized cancer registries to include genetic information, prognostic biomarkers, etc.

- Colorectal: assessment of uptake and outcomes for KRAS, including survival differences
- Breast: appropriateness of HER testing
- CML: appropriate use of BCR-ABL gene, survival and outcome differences
- Important insights re standard processes**
How AHRQ Can Help

- Leverage expertise and investments in patient-centered outcomes research (PCOR)
  - Methods for analyzing observational data, strong focus on patient registries, dx tests
  - Unique mandate to disseminate PCOR*
  - MEPS as potential platform for public attitudes, understanding
  - Emerging experience with CDC re challenges for incorporating genetic information in cancer registries
Knowledge Transfer Case Study: Anaconda Internal Medicine (Montana)

- **U.S. Preventive Services Task Force/electronic Preventive Services Selector (ePSS)**
  - Incorporated ePSS into curriculum so students in clinical rotations learn to use preventive care recommendations
  - Incorporated USPSTF recommendations into office-based technology system (DocSite)
Multidisciplinary Science: EDM Forum Research Networks

11 Projects Using Electronic Health Research for CER/PCOR and QI, including:

- The Indiana PROSPECT (Prospective Outcomes Systems using Patient-specific Electronic data to Compare Tests and Therapies)
- Builds on the Indiana Network for Patient Care, the nation’s largest HIE
- Enhancement for capturing richer data include incorporating genomic and other higher throughput results

www.edm-forum.org
AHRQ Health Care Innovations Exchange

Web-based repository of cutting-edge service innovations

www.innovations.ahrq.gov
Thank You

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

AHRQ Vision
As a result of AHRQ's efforts, American health care will provide services of the highest quality, with the best possible outcomes, at the lowest cost

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