Comparative Effectiveness Research:
Opportunities and Challenges for Transforming Health Care

March 18, 2011
Learning Objectives

➔ Understand the critical role of comparative effectiveness research (CER) to provide information on the costs and benefits of different treatment options as a guide to fiscal policy

➔ Identify some of the key data issues in comparative effectiveness research

➔ Learn about the funding sources and agencies involved in comparative effectiveness research
Outline

→ AcademyHealth – An Overview
→ Forces driving CER
→ Definitions and funding priorities
→ Summary of recent funding
→ PCORI & lessons learned internationally
→ CTSA Key Function Committee on CER
As the professional society for health services researchers and health policy analysts, our mission is three-fold:

1. Support the development of health services research
2. Facilitate the use of the best available research and information
3. Assist health policy and practice leaders in addressing major health challenges

We work to both “push” the production of research and promote the “pull” by decision makers.
Programs Support the Mission

Methods seminars  
EDM Forum  
NLM HSRProj  
RWJF PHSSR Fellowship  
Improving the field

RWJF’s HCFO  
Annual Research Meeting  
Health Policy Orientation  
Using the best available research and information

SCI  
AHRQ Medicaid Medical Director’s Learning Network  
State Quality Improvement Institute  
Assisting health policy and practice leaders
Leveraging >4,000 Diverse, Expert Members

- Regular Members
- Student Members
- Fellow Members
- Senior Members
- International Members
Organizational Affiliates Add Reach

- Health Plan
- Pharmaceutical
- Consulting Firms
- State and Federal Government
- Health Provider
- Foundations
- Associations
- University-based research/policy centers
- Other Research/Policy Centers
- Other
Interest Groups Add Value

- Behavioral Health Services Research
- Child Health Services Research
- Disability Research
- Disparities
- Gender and Health
- Health Economics
- Health Information Technology
- Health Policy Communications
- Health Workforce
- Interdisciplinary Research Group on Nursing Issues
- Long-Term Care
- Public Health Systems Research
- Quality
- Research Translation
- State Health Research and Policy
Stable Foundation & Broad Reach

$10 million budget
50 staff
Reach:
- Database of >80,000 research & policy experts
- >4000 members
- >2,000 at Annual Research Meeting
- >800 at annual National Health Policy Conference
Growth in last 2 years:
- 10% per year in membership
2011 Priorities: Grow the Field, Expand Reach and Translation

Growing the Field
→ Students
→ Diversity
→ HIT
→ CER

Expanding Users
→ Strategic Partners
→ Delivery Systems

Translating Research into Action
→ States
→ Delivery Systems
At the Forefront of CER

- Electronic Data Methods Forum
- Multi-payer Claims Databases
- CER Inventory (Lewin)
- CER Institute (CMTP)
- CER at the ARM
EDM Forum: Aims

- Advance methods related to developing the infrastructure and methodology for collecting and analyzing prospective electronic clinical data for CER
- Serve as the learning forum and sustainable foundation for CER using prospective electronic clinical data
- Focus on a specific set of issues related to implementing CER with electronic clinical data in the following domains:
  - Scientific
  - Clinical
  - Technical
  - Organizational
  - Data Governance
CER Research Projects

- Prospective Outcome Systems using Patient-specific Electronic data to Compare Tests and therapies (PROSPECT) studies (n=6)
- Enhanced Registries for Quality Improvement and CER (n=2)
- Scalable Distributed Research Networks for CER grant programs (n=3)
Leadership: Sub-Committees

→ Analytic methods for CER
→ Clinical informatics
→ Data governance (data stewardship & privacy, including HIPAA, IRB’s, etc.)
Stakeholder Symposium: April 8th

→ Designed to engage in dialogue with key CER stakeholders (both users and producers of CER).

→ Key objectives:
  – Update the community on the work of the EDM Forum and the participating research projects (PROSPECT Studies, Enhanced Registries, and Scalable Distributed Research Networks).
  – Provide stakeholders with the opportunity to:
    • share innovative ideas and/or provide updates on projects they are involved in that have relevance for the EDM Forum; and
    • provide input on priority topics and activities the EDM Forum should undertake.
  – Encourage participant engagement with the EDM Forum online to provide feedback and share information.
Related Websites

→ Research Portal (March 2011)
  – Secure online space to collaborate within and across research teams

→ Stakeholder Public Website (April 2011)
  – Channel for promoting and disseminating EDM Forum products
  – Will allow stakeholders to submit commentary on commissioned papers and issue briefs
Research Team Site Visits

➤ Bay Area, CA: March 10-11
  – Comet (Kushida); SUPREME-DM (Selby)

➤ New York, NY: April 29
  – WICER (Wilcox)

➤ Cincinnati, OH: May 6
  – PEDSNet (Hutton)

➤ Seattle, WA: June 10
  – SCOAP (Flum)

➤ Denver, CO: June 28-29
  – SPAN (Steiner); SAFTINet (Schilling)
Emerging Topics: Analytic Methods

- Policy brief on major CER study designs and challenges presented by each
- Policy brief on the Best practices for incorporating patient-reported data into EHRs
- A two-paper series on assessing data (both data availability/missing data and data quality) across health systems
  - Paper 1: Describe the issues and different ways to assure quality when drawing data from various systems, outlining the lessons learned, and enumerating potential problems
  - Paper 2: Technical focus on approaches to assessing and handling missing data
- Methodological issues related to identifying cohorts (especially across systems and types of data – e.g. EMR and claims)
  - Two case examples will be used based on the diabetes and asthma teams (Selby and Lieu)
Emerging Topics: Clinical Informatics

- Policy brief on data warehousing v. distributed data approaches: understanding of the landscape and potential issues related to conducting CER. Those in the clinical informatics sub-committee have recommended writing the following two briefs or papers instead

- Paper on cloud computing and the risks of hosting technologies, including privacy and proprietary/data ownership issues
  - Ideally this paper would provide guidance for IRBs faced with making a security and privacy determination about the use of these technologies.

- A two-paper series on clinical informatics platforms:
  - Information platforms for comparative effectiveness research (e.g. i2b2, HMORN, OMOP, and homegrown systems such as RedX).
  - Criteria for selecting information platforms (see examples above).
Emerging Topics: Data Governance

- Policy brief that will provide a thorough review of state laws that are applicable to data sharing and re-use
- Technical brief on multi-site IRB approval for CER, with an overview of key issues “pathways to success” for seeking IRB approval
- Technical brief that includes a review of DUAs and ‘Round Robin’ approaches to multi-site approval
- A technical paper on de-identification that gets deeper into the range of technical issues/options for de-identifying data
Outline

→ AcademyHealth

→ Forces driving CER
Interest in comparative information is not new…

→ In US, used for payment/coverage and cost containment and grows whenever interest in competition
→ Many health plans have “in house” capabilities
→ Internationally, long standing efforts
  • UK
  • Australia
  • Canada
  • Germany
→ Focus on pharmaceuticals
Great Expectations for CER

“Better information about the costs and benefits of different treatment options, combined with new incentive structures reflecting the information….is essential to putting the country on a sounder long-term fiscal path.”

– Peter Orszag testimony, June 2007
Patient Centered Outcomes Research Institute (PCORI)

- Non-profit organization to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions
- carrying out research projects that provide quality, relevant evidence on how diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed.
- 19 member Board appointed by GAO & AHRQ and NIH Directors
- GAO to appoint 15 members to a Methodology Committee of PCORI
Outline

➤ AcademyHealth – An Overview
➤ Forces driving CER
➤ Definitions and funding priorities
IOM Committee’s Definition of CER

The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.
Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings.

The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.
ACA Definitions

→ CER:
  – “research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items.”

→ “medical treatments, services, and items”:
  – defined as “health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.”
CER Defining Characteristics

→ Objective of directly informing clinical or health policy decision
→ Compares at least 2 alternatives
→ Results at population and subgroup level
→ Measures outcomes important to patients
→ Methods and data sources appropriate for the decision of interest
→ Conducted in real world settings

Sean Tunis, 2009
Categories of CER Methods

- Systematic reviews of existing research
- Decision modeling, with or without cost information
- Retrospective analysis of existing clinical or administrative data
  - Significant new investments in data infrastructure
- Prospective non-experimental studies, including registries
- Experimental studies, including randomized clinical trials (RCTs)

Sean Tunis, 2009
All methods have a role

- Inevitable tradeoff between internal validity and feasibility, generalizability, cost, time
- The nature of the research question, and the decision maker will influence best practices
- Experimental studies will have a crucial role in CER, and there is need for improving design and implementation
- Non-experimental methods hold great promise, particularly as methods are refined and data infrastructure is improved

Sean Tunis, 2009
CER Methods

→ June 2010 supplement to *Medical Care* on CER Methods
→ 22 original articles, special focus on:
  - Ways to enhance the inclusion of clinically heterogeneous populations in clinical and comparative effectiveness studies
  - Methods for implementing longitudinal investigations that capture longer term health outcomes, including patient
→ Printed copies available free of charge through the AHRQ Publications Clearinghouse
Unique Dimensions

- Four “Ds”
  - Development
  - Differential epidemiology
  - Dependency
  - Demographics
IOM Priorities:
Distribution of the recommended research priorities by primary & secondary research areas

Top 5:
- Health Delivery
- Disparities
- Disabilities
- Cardiovascular
- Geriatrics
FCC Report: Strategic Framework for CER

Priority Populations

Priority Conditions

Types of Interventions

Investments can be made in a single category and/or be cross-cutting in one of the themes
Outline

→ Forces driving CER
→ Definitions and funding priorities
→ Summary of recent funding
Allocations for the $1.1 billion in comparative effectiveness research funding in the American Recovery and Reinvestment Act of 2009:

- Research: $681M (62%)
- Data Infrastructure: $268M (24%)
- Dissemination and Adoption: $132M (12%)
- Administrative support, inventory, evaluation: $19M (2%)
### FCC and IOM Recommendations Guide ARRA Funding

#### FCC-CER
- Data infrastructure
- Dissemination and translation
- Human and scientific capital
- Real-world settings for subpopulations, priority conditions and interventions

#### IOM
- 100 top priority CER topics
  - 50% focus on health care delivery systems
  - Only three of the topics are narrowly focused on drug vs. drug

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#### Select examples of AHRQ funding
- Enhanced State Data for Analysis and Tracking of Comparative Effectiveness Impact: Improved Clinical Content and Race-Ethnicity Data
- Registry of Patient Registries

#### Select examples of OS funding
- Electronic Data Methods (EDM) Forum for Comparative Effectiveness Research
- Enhanced Registries for Quality Improvement and Comparative Effectiveness Research
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<th>Category</th>
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<td>Medicaid Claims</td>
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<td>Clinically Enhanced State Data</td>
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<td>Design and Implementation</td>
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<td>Distributed Networks</td>
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<td>HRSA</td>
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<td>Data and Research: Chronic Conditions</td>
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<td>Pediatric Care Networks</td>
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NIH Challenge Grants

- 8416 Challenge Grants funded under ARRA.
  - 116 projects focus on CER topics
    - 76 of which can be classified as HSR.
- This represents 9% of the ARRA Challenge Grants
- In total, NIH ARRA funding for Challenge Grants focused on HSR-related CER represents more than $35.4 million in new investment in the field.
<table>
<thead>
<tr>
<th>NIH Center/Institute</th>
<th>Number of Challenge Grants with Keywords “Comparative Effectiveness”</th>
<th>Number of HSR CER Challenge Grants</th>
<th>Funding ($)</th>
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<td>National Library of Medicine (NLM)</td>
<td>2</td>
<td>2</td>
<td>$897,606</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>116</strong></td>
<td><strong>76</strong></td>
<td><strong>$35,439,123</strong></td>
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Source: National Institutes of Health Research Online Portfolio Tool Expenditures and Report (RePORTER). Data shown are from records retrieved from RePORTER on November 13, 2009.
NIH Dissemination

Figure 2. Distribution of Challenge Grant Funding for HSR Projects Across Performing Organizations

- College/University: 64%
- Hospital/Medical Center: 18%
- Research Center/Institute: 18%
AHRQ CER Investments

Includes Recovery Act Investments

- Stakeholder Input & Involvement: 3%
- Horizon Scanning: 3%
- Evidence Synthesis: 13%
- Evidence Need Identification: 6%
- Evidence Generation: 57%
- Dissemination & Translation: 12%
- Career Development: 6%
RFI for CER Inventory

- Sources for CER
- Encouraging participation/submission
- Categorization
- Data elements
- Features
- Sustainability
- Additional considerations
Outline

- Forces driving CER
- Definitions and funding priorities
- Summary of recent funding
- PCORI & lessons learned internationally
PCORI Funding

→ Patient-Centered Outcomes Research Trust Fund (PCORTF)

→ For FYs 2010-2012, appropriations:
  – $10M, $50M, $150 M

→ For FYs 2013-2019,
  – $150 million in appropriations **PLUS**
  – Transfers = the average # of individuals enrolled in the Medicare, health insurance policies, and self-insured plans x:
    • $1 for FY 2013;
    • $2 for FY 2014;
    • $2 for FYs 2015 through 2019 (w/inflation).
PCORI – International Lessons

- Independence from government is important
- Independent oversight boards are common
- Some CE entities set standards while others only identify and recommend standards
- Most CE entities are relatively small & operate with a modest budget
PCORI – International Lessons

- Prioritization process critical
- Acceptance depends on methodological rigor
- Applicability to different populations essential
- Different types of data used for recommendations
- Increasing use of conditional coverage & costs are considered

- Crucial elements:
  - Transparency
  - Timeliness
  - Appeal process
Future Challenges

- Concerns about role of CER in dampening innovation
- Desire to repeal ACA’s "most egregious provisions" including:
  - Eliminating AHRQ
  - “AHRQ could be eliminated and no one would notice, except the academics and consultants who both set AHRQ's research agenda and get paid for the research.”
- Eliminate:
  - Center for Medicare and Medicaid Innovation (CMS) ($10 billion through 2019)
  - Patient-Centered Outcomes Research Institute (avoiding taxes on health plans of about $500 million a year)
  - Funding for Shared Decisionmaking and Quality Measurement Development ($75 million)
  - The new NIH National Institute on Minority Health and Health Disparities (NIMHD) ($220 million)
Outline

- Forces driving CER
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- CTSA Key Function Committee on CER
CTSA Consortium Executive Committee
Priority Objective for SGC #4, vMarch 1, 2011

Develop a CTSA Consortium-wide framework for community-engaged and comparative effectiveness research that will support improvement in healthcare access, quality, efficiency, and patient-centered outcomes and will improve the health of diverse communities and the public.
SGC4 Objective 1 ("CE"): Linking and facilitating collaboration among community based research networks to implement research best practices.

SGC4 Objective 2 ("CER"): Develop capacity and methods for the translation of research results into practice across the healthcare system, including but not limited to: health services and health policy research, comparative effectiveness research, and research into the generation and implementation of evidence-based medicine.
Updated SGC4 Structure Merged from 4A and 4B
(Merged Winter/Spring 2010)

Strategic Goal Committee 4

Community Engagement
KFC

Comparative Effectiveness Research
KFC

Operations

Publications Committee

Operations

Workgroups (WG)
1. Education, Scholar., and Engagement
2. Outcomes
4. Partners Integration
5. Networking

Taskforces (TF)
1. Admin Supplement
2. Translation White Paper
3. Principles Booklet
4. Best Practices

Workgroups (WG)
1. Collaboration
2. Information Dissemination
3. Methods
4. Capacity and Needs Assessment
5. Education, Training, and Workforce Development

Taskforces (TF)
1. CER Forum, Stakeholder Meetings, and Effort Task Force
2. CER Health Information Technology/Informatics Taskforce
Structure of Comparative Effectiveness Research KFC (CER KFC)

Co-Chairs: Jodi Segal and Tom Concannon
CER KFC PI Liaison of the SGC & CCSC, Harry Selker
CMG Liaison, Nick Gaich
NIH Coordinator, Rosemarie Filart

Collaboration Workgroup
- Acting Lead: Tom Concannon
- KFC Chair: Tom Concannon

Information Dissemination
- Lead: Paul Meissner
- KFC Chair: Tom Concannon

(SGC4B WG Moved) CER Methods Workgroup
- Lead: Mark Helfand; Chris Schmid; Sean Tunis
- KFC Chair: Tom Concannon

(SGC4B WG Moved) Capacity and Needs Assessment
- Lead: Dan Ford and Harold Pincus
- KFC Chair: Jodi Segal

(NEW) CER HIT/Informatics Taskforce
- Co-Leads: Joel Saltz and Bill Hersh

Operations Group:
- Co-Chairs, PI and CMG Liaisons, WG/TF
- Leads, NIH Coordinator and BAH PM

Sunsetted: CER Forum/Stakeholder Meetings and Effort: co-Leads, Tom Concannon and Harry Selker

All Members invited to participate in any group
**Mission Statement**

The Comparative Effectiveness Research (CER) Key Function Committee builds the field of comparative effectiveness research (CER) and patient-centered outcomes research by creating a learning community across CTSA institutions, spurring the development of methods, expanding training and education, promoting community and public engagement, applying CER findings and sharing successes and lessons learned.

**Vision Statement**

Through collaborative work products, the Comparative Effectiveness Research (CER) Key Function Committee facilitates the generation and synthesis of evidence about alternative interventions that results in actionable findings for policymakers, clinicians, patients, and purchasers to use in improving the quality and outcomes of patient-centered health care.
Education/Training/Workforce Development Workgroup

Mission Statement:
To promote and facilitate incorporation of comparative effectiveness research skills into the training activities of early investigators at CTSA consortium institutions, and to promote activities that allow established investigators to develop skills of comparative effectiveness research and thereby broaden the available workforce.

Vision Statement:
To advance comparative effectiveness research by expanding the workforce nationwide that has the requisite skills for conducting and using comparative effectiveness research.
Collaboration Workgroup

Mission/Vision Statement:
Support development of connections & collaborations to develop, execute, and apply CER at multiple levels:
- Within individual CTSA institutions
- Across CTSA CER investigators
- Between CTSA CER investigators and other investigators and stakeholders (e.g. AHRQ EPC institutions, DeCIDE network, CERTS, etc)
Methods Workgroup

Mission Statement:
To identify high priority methodological issues that would benefit from careful analysis and discussion within the CTSA program, with the objective of ensuring that the future CER work of the CTSAs is consistently aligned with the nature and purpose of CER.

Vision Statement:
To improve public health by improving the methods used in comparative effectiveness research conducted by CTSA institutions.
Capacity and Needs Assessment Workgroup

Mission Statement
Through periodic assessments, provide data to academic institutions and funding organizations and other stakeholders about current capacities to conduct comparative effectiveness research and how the CTSA program supports CER.

Vision Statement
Academic organizations will organize their resources so that the CER research capacity, including training, will incorporate the priorities for CER as expressed by national groups such as IOM, federal agencies, professional societies, and consumer organizations as well as local stakeholders, providers and patients, health plans and purchasers.
Mission Statement
To collect and disseminate CER information among interested CTSA Stakeholders in order to facilitate high impact CER outcomes and activities through the CTSAs.

Vision Statement
• Identify information dissemination and implementation science theories and principles that are being applied in CER within and among the CTSAs
• Identify best practices and methods in information dissemination and implementation science as related to CER within and among the CTSAs
• Foster, facilitate and enable information dissemination, communications, and collaboration in the CTSA Consortium regarding CER
New

CER Health Information Technology/Informatics Task Force

Task: Address Action Items of Dec. 1st CER Forum

Co-Leads: Joel Saltz and Bill Hersh
## Cross Communication with Liaison Members

<table>
<thead>
<tr>
<th>Committee</th>
<th>Liaison</th>
<th>CTSA</th>
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<tbody>
<tr>
<td>Biostatistics / Epidemiology / Research Design (BERD) KFC</td>
<td>Frank Harrell, Chang Yu</td>
<td>Vanderbilt University, Vanderbilt University</td>
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<tr>
<td>CTSA Consortium Child Health Oversight Committee (CC-CHOC)</td>
<td>Jill Herndon, Daphne Hsu</td>
<td>University of Florida, Albert Einstein</td>
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<tr>
<td>AHRQ DARTnet (Distributed Ambulatory Research in Therapeutics Network)</td>
<td>Jeanne-Marie Guise, Doug Landsittel</td>
<td>OHSU, UPMC</td>
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<td>Clinical Research Management (CRM) KFC</td>
<td>Jeffrey Silverstein</td>
<td>Mount Sinai</td>
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<td>Education/Training KFC</td>
<td>Wishwa Kapoor, Pam Mitchell</td>
<td>UPMC, University of Washington</td>
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<td>Community Engagement KFC – White Paper WG, Networking WG, etc..</td>
<td>Lucy Savitz, Tom Concannon</td>
<td>Utah University, Tufts University</td>
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<td>Mary Anne McDonald</td>
<td>Duke University</td>
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<td>University of North Carolina</td>
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<td>Informatics KFC</td>
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<td>IOM</td>
<td>Harry Selker, Lucy Savitz, Rosemarie Filart</td>
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Conclusion

- CER is growing in scope and funding
- CTSA family is engaging
- Opportunities for additional research & impact
Questions?

Lisa Simpson, MB, BCh, MPH, FAAP
President and CEO