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Comparative Effectiveness Research-CER

_A new current in_ Pharmaceutical Brand Management
Comparative Effectiveness Research CER

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A new current in Pharmaceutical Brand Management

- Description
- Federal Government
- International Landscape
- U.S. Marketplace
- CER Challenges
- Outlook
- Opportunity
- Assessment
- Pilot Program
- Summary
Pharmaceutical Comparative Effectiveness Research (CER) provides insight to:

- Clinical/cost effectiveness of individual medications
- Comparative performance between therapies
- Comparative performance of therapies vs. procedures
CER is an extension of Evidenced-based Medicine and Health Economics Outcomes Research

Consumer-driven health plans (CDHP) are growing, high consumer demand for value

Medical/pharmacy benefit cost issues and national economic concerns increase the interest in healthcare cost-justification

Employers, managed care organizations and other entities are actively assessing CER’s potential

The Federal Government’s interest and investment in CER is substantially growing
The cycle of care and cost evaluation...
Outcomes of a brand’s CER performance may directly impact:

- Commercial, Medicaid and Medicare policies and prescription drug coverage
- Patient/consumer opinion
- Physician prescribing
- Marketplace success
Federal government is largest payer and is seeking ways to better control/reduce healthcare costs

- Over last 30 years, Medicaid/Medicare spending has risen from 1.3% in 1975 to roughly 4% in 2007

- Total healthcare spending was about 8% of the GDP in 1975 and about 16% of GDP in 2007

- Current trend rate is about 20% of GDP by 2016
The Medicare Modernization Act of 2003 allocated over $50 million dollars to evaluate outcomes, comparative effectiveness and healthcare items & services for Medicare and Medicaid enrollees.

In 2007, the Congressional Budget Office (CBO) issued a formal report on CER, “Research on the Comparative Effectiveness of Medical Treatments.”

The National Institute of Health (NIH), CMS/HHS, and Veteran’s Administration (VA) are assertive CER advocates.
$1.1 billion dollars assigned to CER in American Recovery and Reinvestment Act of 2009 (AARA)

- Encompasses drugs, devices and other treatments

Funds will be distributed to:

- Agency for Healthcare Research and Quality (AHRQ)
- Health & Human Services (CMS/HHS)
- National Institute of Health (NIH)
Further discussions will determine which areas of evaluation the CER stimulus money is allocated towards.

Legislators, policy experts and various healthcare advocates are lobbying Federal government to create an “Institute for Comparative Effectiveness Research”.

Concepts include utilization registries, data analysis and specific clinical trials to develop optimum protocols for “average” patients with certain conditions/diseases.
Drug Effectiveness Review Project (DERP) is a public/private effort to conduct CER and other drug therapy research.

AHRQ contracts with 13 evidenced-based practice centers in academic/private sectors to accumulate data and expertise:

- Alberta, BCBS, Duke, ECRI Institute, John Hopkins, OHSU, McMaster, Minnesota, Ottawa, RTI-UNC, Stanford, Tufts-NEMC and USC
CER is a global healthcare management concept

Leading international CER entities include:

- Australia-Pharmaceutical Benefits Advisory Committee
- Canada-Health Policy Research Program
- Germany-Institute for Quality and Efficiency
- Great Britain-National Institute for Health and Clinical Excellence
• BCBS, Kaiser and other health plan entities have CER evaluation initiatives underway

  – Health plans may choose not to divulge their CER findings and decisions to industry counterparts who have not contributed any resources to the research

  – Public sector health (Medicaid/Medicare) which accounts for over 40% of national health spend actively monitors costs but does not have necessary resources to initiate/maintain ongoing CER programs
• National Business Group on Health (NBGH), a coalition of employers, is strongly supportive of federal effort to bolster CER

• The American College of Physicians (ACP) has assertively endorsed CER measures
Primary CER Stakeholders:

- Patients
- Pharmaceutical Manufacturers
- Pharmacy Directors (PBM/MCO)
- Medical Directors (Employer/MCO/PBM)
- Employers/Employee Benefit Consultants
- Federal/State Government Health Agencies
CER Challenges

• There are no CER Federal guidelines or healthcare industry clinical/analytical standards except those recognized as “best practices” by professional researchers and industry.

• Complexity of patient variables/co-morbidities/side-effects may not be accounted for.

• Potential focus on cost savings versus patient benefit.

• CER expense may drive drug/healthcare costs up further and add complexity to care/cost management.
CER Challenges

- Results need to be undeniable, minimize risk to patients
- New therapies would have to be continually benchmarked, lack of data may disadvantage new therapies
- Very difficult to account for therapies effectively prescribed by physicians for off-label uses
- Patients changing medical/pharmacy benefit plans create data/outcome inconsistencies
CER Challenges

- Concerns CER may lead to restrictive selection for patients/physicians
- Flexibility necessary to account for subgroups of patients with special therapeutic needs
- Additional input required from healthcare and government entities to create guidelines/coverage rules for commercial, Medicaid and Medicare plans based on findings
How are evaluative standards applied to:

- Comparative cost of products/course of therapy?
- Long or short term benefits performance?
- Definition of treatment failure/success?
- Duration of therapy/prescribed dosing?
- Patient co-morbidities/demographics?
- Brand vs. Brand, Brand vs. Generic?
- Sample side/sources of data?
- Products sharing indications?
- Sample size/sources of data?
- Products only within class?
- Side effects?
Due to complexities, expense and care concerns, government CER initiatives likely to be highly specialized:

- Applied to those areas offering greatest return based on maximum care with cost-saving results
- Widely prescribed brand product versus generic
- High safety, low side-effect risks
- Result in creation of reinforced guidelines, not mandates
• Largest national/regional MCOs and BCBS plans

  – Follow government CER guidelines/results closely and apply them to their own plans when appropriate

  – Duplicate government CER models, apply them in their own research according to specific categories

  – Contract for medications with high performance ratings at preferred status, allocate lesser performers to 3rd tier and require higher rebates
A strong CER performance by the brand:

- Empowers its market position
- Fortifies it against existing products/upcoming agents
- Helps gain/retain preferred formulary status
- Strengthens its marketing message
- Links clinical/cost justification to physician/patient choice
Throughout the brand’s product development and marketplace lifecycle, it will be beneficial to align its value and fortify its position according to managed care parameters:

- Level of incidence/increase or decrease
- Co-morbidities and associated costs
- Per member per year (PMPY) costs
- Overall treatment cost trends
- Average per treatment cost
A brand may demonstrate overwhelming clinical superiority over competitors in clinical trials and in select clinical studies.

- Is it feasible for the brand to embark on a CER initiative?
- Can the brand deliver solid results by cross-examination of care, clinical and cost attributes and performance?
- Will its performance be duplicated in a large-scale?
• Brand may have subpar care/cost performance compared to competitor's
• Brand may demonstrate less favorable outcomes versus medical procedure conducted to treat the same condition/disease
• Results may be inconclusive, no significant care/cost differences between the brand and competitor's)
Assessment

- Assess latest treatment standards which positively/negatively impact the brand and its competitors
- Review results of competitor’s clinical studies
- Review current/ongoing clinical resources, including:
  - HEOR projects completed or underway
  - Post-launch surveillance data
  - Syndicated reports
• What is the position of the brand and its competitors in managed care circles and formularies?

• Initially consider widest used indications for greatest impact

  – Lesser indications may provide utility in niche applications channeled through managed care PA edits
Assessment

- Survey medical, pharmacy and managed care professionals to learn their:
  - Greatest challenge treating particular conditions/diseases
  - Perceptions/issues of brand’s care/cost performance
  - Preferred approach to drug care/cost evaluation
  - Opinions concerning competitor care/cost performance
  - Requirements to fill knowledge gaps
Based on compiling latest clinical data and industry input:

- Is the brand’s performance robust enough and competitor’s performance vulnerable to the extent a pilot CER initiative would yield positive results?
- What are financial, staff and time resources available?
- How would a pilot CER program be implemented and can it be designed to be scalable if initial results are solid?
Pilot Profile

• Define specific indications(s), competitor(s), patient sample, and care/cost considerations being evaluated

• Is the design/methodology a truly “head to head” evaluation?

• Would a competitor execute the evaluation in the same way?

• Does the pilot meet professional research standards which may be migrated to a full-scale CER initiative?

• Are the expected results promising enough to move to the next level and will there be sufficient funding to do so?
Base evaluation parameters:

- Acute or chronic treatment application
- Approved indication(s)
- Competitive agent(s)
- Co-therapies (therapeutic and/or reduce side effects)
- Duration of therapy
- Medical/pharmacy claims data
- Patient characteristics (age, sex, ethnicity, co-morbidities)
- Pertinent medical/pharmacy benefit plan design features
- Re-treatment/discontinuation of treatment
- Therapy cost and medical treatment cost data
- Timeframe
Sources of data:

- Actuarial firms
- Managed care organizations
- Contract research organizations
- Healthcare data management/reporting companies
- Prescription benefit management companies/PBMs
Leading data source considerations:

- Comprehensive medical/pharmacy files
- Access/ownership/security
- Data Integrity
- Timeframe
- HIPPA
- Cost
Upon completion of the pilot:

– Do results favor the brand enough to proceed to a full-scale CER initiative?

– Did results lead to other areas of research?

– If large scale results were realized, how would they be used to benefit the brand?
CER is a growing healthcare management concept in the United States. Government, managed care and other entities have an active interest in the development of CER. Driven by clinical and cost data, it requires substantial financial, staff and time resources to accomplish.
• CER will play a pivotal but controversial role in select drug and medical management applications

• There is a high risk/reward ratio for a brand to successfully undertake its own CER initiative

• Pharmaceutical manufacturers need to consider care/cost performance earlier in drug development stages to better manage R&D resources and assess pipeline forecasts
Go to:


for ongoing business and clinical healthcare industry resources