



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

Comparative Effectiveness: How Health Plans and Employers Will Translate Evidence to Practice

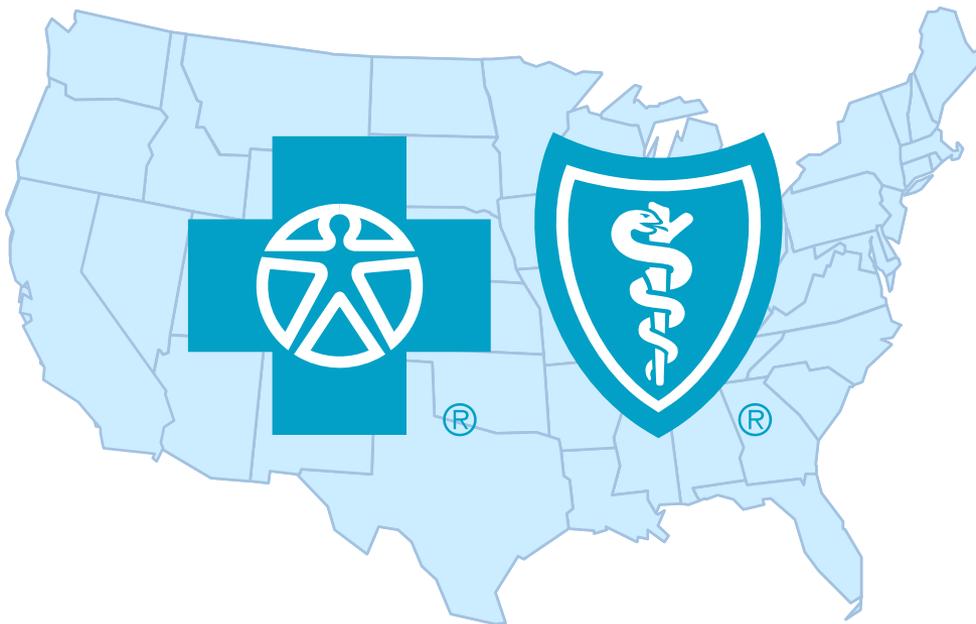
Comparative Effectiveness Summit
Arlington, VA
September 14, 2010

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Technology Evaluation Center

Overview

- BCBSA Technology Evaluation Center (TEC) perspective
- Translating evidence into health plan practice
- Improving the evidence base for decision-making

Blue Plans Cover Every Community in the Nation



- 39 Blue Cross and/or Blue Shield Plans
- 100 million members
- Contract with 90% of hospitals, 80% of doctors
- 5-million member FEP Program – Largest private health insurance product in world
- Largest processor of Medicare claims in the nation
- 1985 Technology Evaluation Center (TEC)

Technology Evaluation Center (TEC)

- Rigorous assessment of clinical evidence, systematic review with quality appraisal: Does this technology improve health?
- Independent, expert Medical Advisory Panel
- TEC Assessments 3-year inventory at (www.bcbs.com/tec)
- Medical Policy Reference Manual (MPRM): a confidential and proprietary inventory of approximately 350 evidence-based policies, updated annually, that is offered to support Blue Plans' operations*
- Dedicated professional staff
- Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (www.ahrq.gov)
- AHRQ CER EPC cancer and infectious disease

*Note: Each Plan, acting independently, may adopt the MPRM, in whole or in part, modify it, or reject it, in making that Plan's own medical policy decisions.

Comparative Effectiveness > A vs. B

Comparative effectiveness addresses strategies to manage a condition, taking into account real world practice and variations in patient populations

IOM national priorities for comparative effectiveness research

(<http://www.hhs.gov/recovery/programs/cer>)

100 priority topics

- Half compare the care delivery system (“*how* or *where* services are provided”)
- One-third address racial and ethnic disparities
- One-fifth address patient’s functional limitations and disabilities

Clinical topic priorities

- Cardiovascular and peripheral vascular disease
- Psychiatric and neurologic disorders
- Cancer

(Iglehart JK. *N Engl J Med* 2009 Jul 23;361(4):325-8)

CER > A vs. B: Strategies to Manage a Condition

- Erythropoiesis-stimulating agents: How to manage anemia related to cancer therapy? Who should be treated? Is a higher hemoglobin level an improvement?
- Accelerated partial breast irradiation after breast conserving surgery: What is critical length of follow-up to compare recurrence? Is it replacing no radiation therapy or best radiation therapy? What about the use of accelerated whole breast irradiation?
- Carotid artery angioplasty and stenting: Safer than endarterectomy for high risk individuals? Or inferior to best medical therapy? Who benefits from intervention?

CER > A vs. B: Care Delivery System

Nearly half of the physician care delivered in U.S. does not adhere to best practices

Percentage of Recommended Adult Care Received

- **64.7%** Hypertension
- **63.9%** Congestive Heart Failure
- **53.9%** Colorectal Cancer
- **53.5%** Asthma
- **45.4%** Diabetes
- **39.0%** Pneumonia
- **22.8%** Hip Fracture

McGlynn EA et al. N Engl J Med 2003; 348(26):2635-45; Mangione-Smith R et al. N Engl J Med 2007; 26(5):644-649

CER: New Questions...New Paradigms

Early palliative care in metastatic non-small-cell lung cancer: a randomized controlled trial

Standard oncologic care alone vs. standard oncologic care plus palliative care early after diagnosis

- Early palliative care improved quality of life, depression, anxiety
- Decreased resource use and aggressive end-of-life care
- Counterintuitive: longer survival (2 months)
- Generalizability?

(Temel, Greer, Muzikansky et al., N Engl J Med 2010; 363: 733-42)

Health Plan Levers for Translating Research into Practice

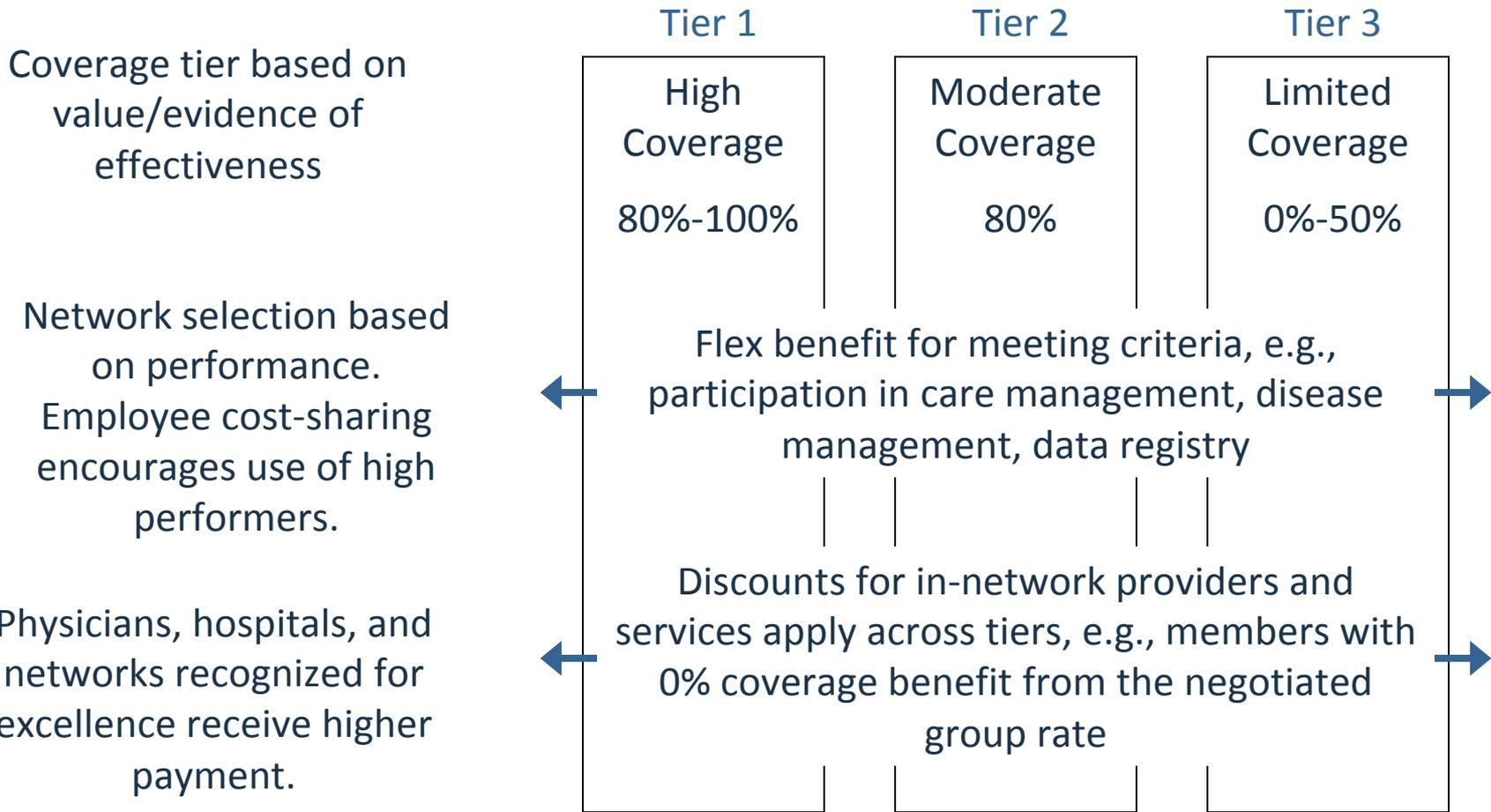
The diagram consists of three horizontal bars stacked vertically. Each bar has a dark blue rounded rectangular section on the left containing white text, and a white rectangular section on the right. The bars are connected by a thin blue line on the left side.

Benefit Design

Purchasing

Consumer
Engagement

National Business Group on Health: National Committee on Evidence-Based Benefit Design



Source: National Business Group on Health

Blue Distinction Centers[®]: Nationwide Access



More than 1,700 designations across 47 states and the District of Columbia provide Blue members with quality choices

529* Blue Distinction Centers
for Knee and Hip
ReplacementSM

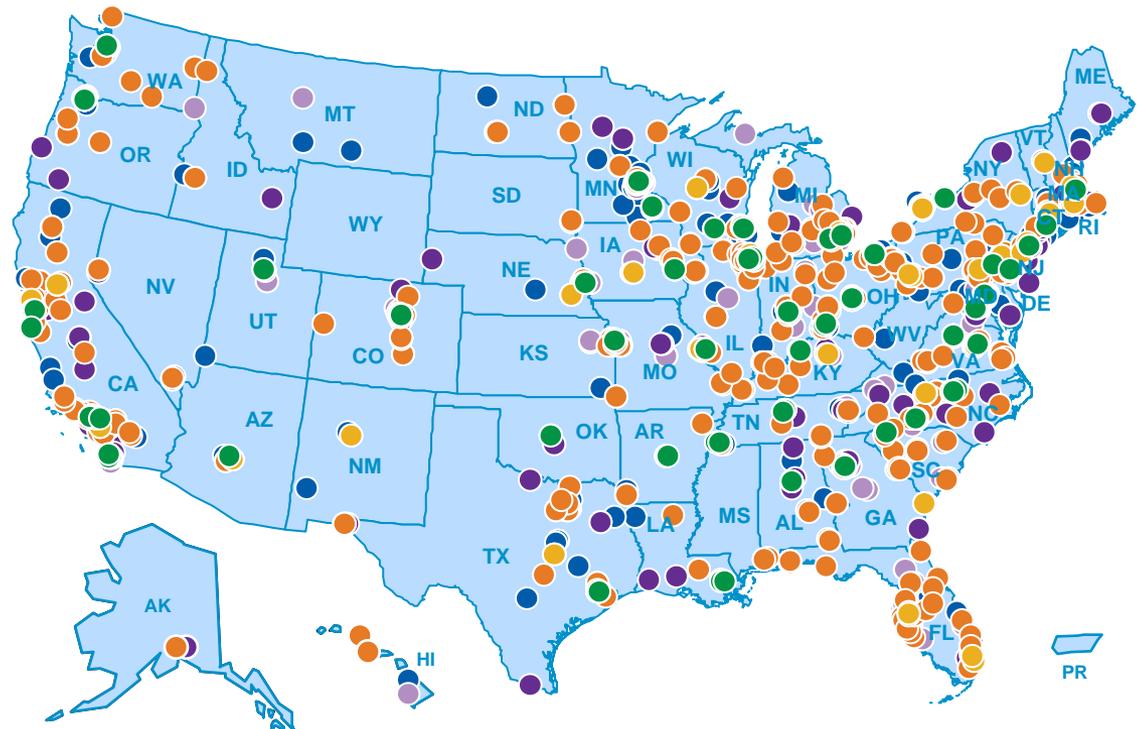
489* Blue Distinction Centers
for Cardiac Care[®]

307* Blue Distinction Centers
for Spine SurgerySM

273* Blue Distinction Centers
for Bariatric Surgery[®]

94* Blue Distinction Centers
for Transplants[®]

90* Blue Distinction Centers
for Complex and Rare
Cancers[®]



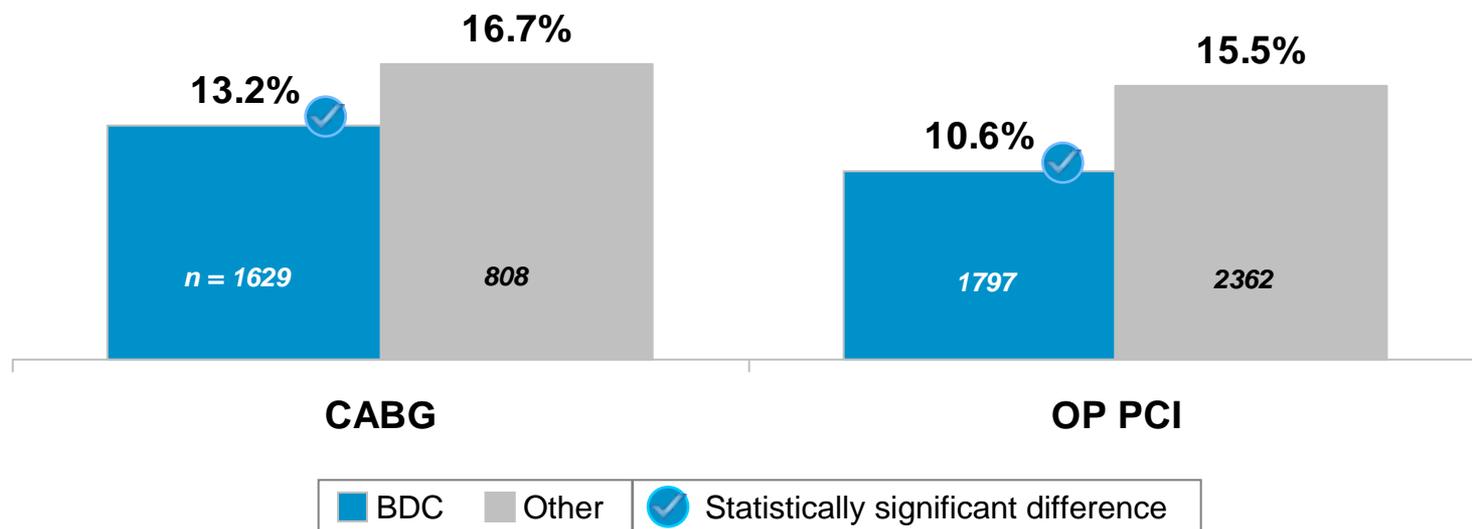
*Number of designated facilities as of August 2010

Note: Designation as Blue Distinction Centers means these facilities' overall experience and aggregate data met objective criteria established in collaboration with expert clinicians' and leading professional organizations' recommendations. Individual outcomes may vary. To find out which services are covered under your policy at any facilities, please call your local Blue Cross and/or Blue Shield Plan.

Quality of Care: Readmission Rate

Readmission rates following cardiac procedures are lower at Blue Distinction Centers for Cardiac Care®

Cardiac-Related Readmission Rate, BDC vs. Other



Note: Results shown are mean values for cumulative 0-90 day readmission rate. Results shown did not require epidemiologic risk adjustment as no significant population differences were identified between BDC and non-BDC groups utilizing the Deyo Charlson Index Risk Score.

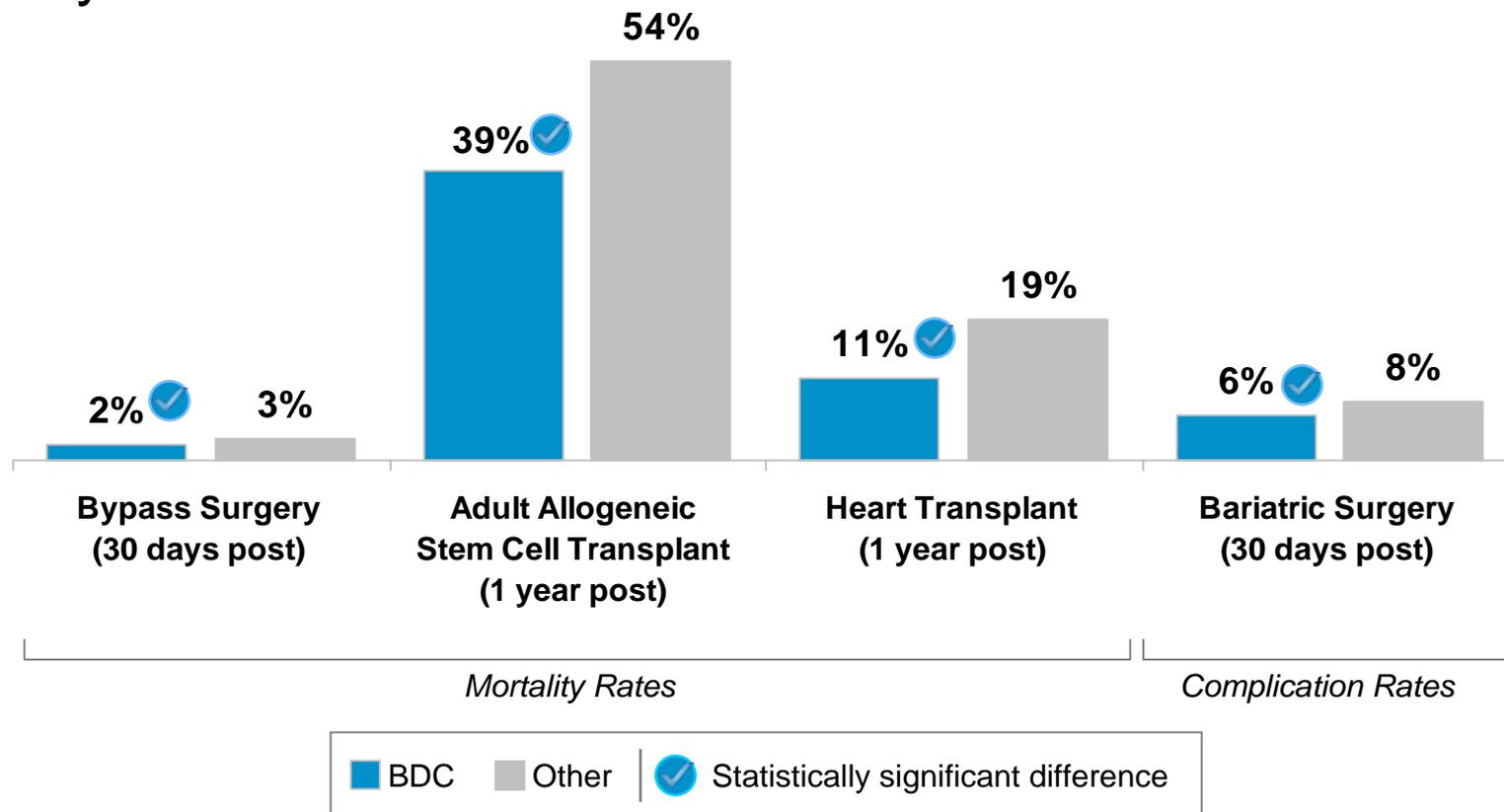
CABG = Coronary Artery Bypass Graft, OP PCI = Outpatient Angioplasty

Source: HealthCore, Inc. Cardiac Multi-Plan Claims Analysis, November 2008

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Quality of Care: Patient Outcomes

Blue Distinction Centers deliver significantly better overall quality outcomes

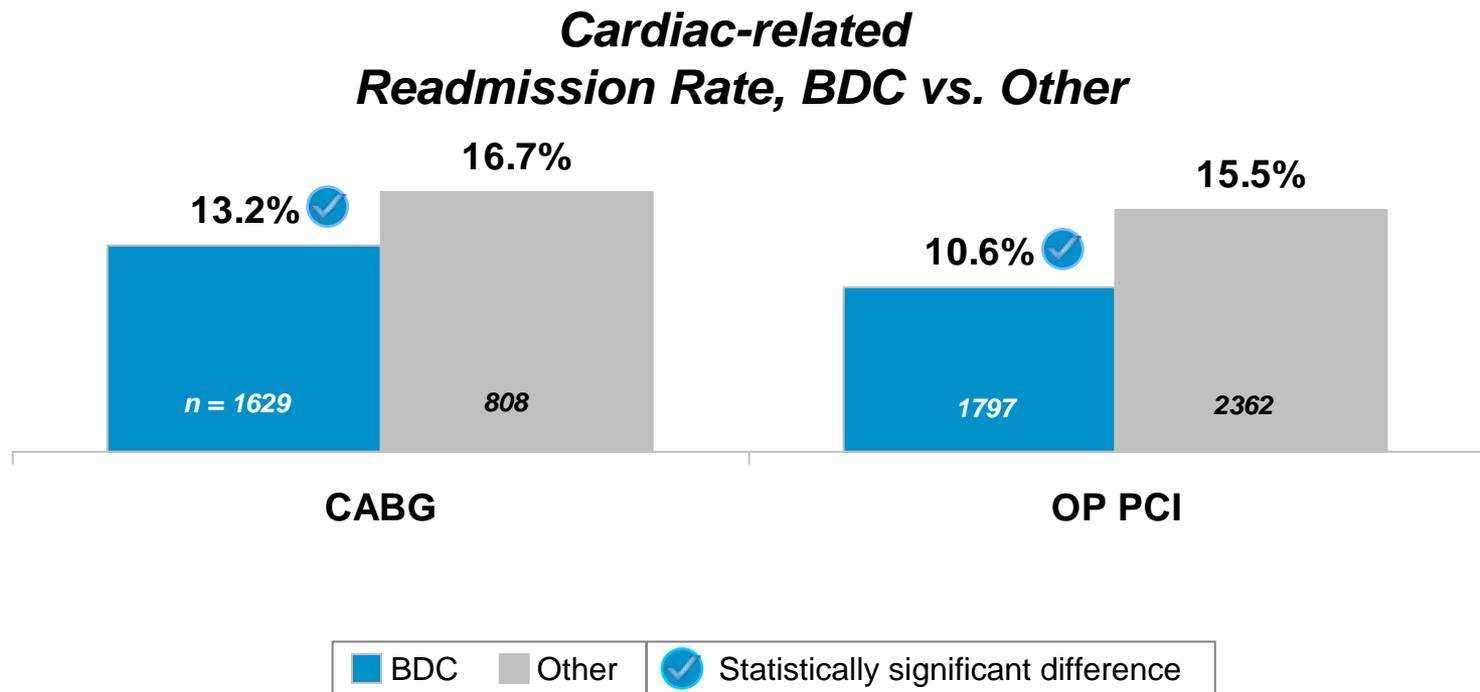


Note: Results shown are mean values. Mortality rates for bypass surgery and heart transplant are risk-adjusted.

Source: BCBSA Analysis of 2005-06 Hospital RFI Data. Bone marrow transplant data based on 2009 actuarial analysis of RFI data. Heart transplant data include facility results abstracted from the Scientific Registry for Transplant Recipients.

Quality of Care Readmission Rate

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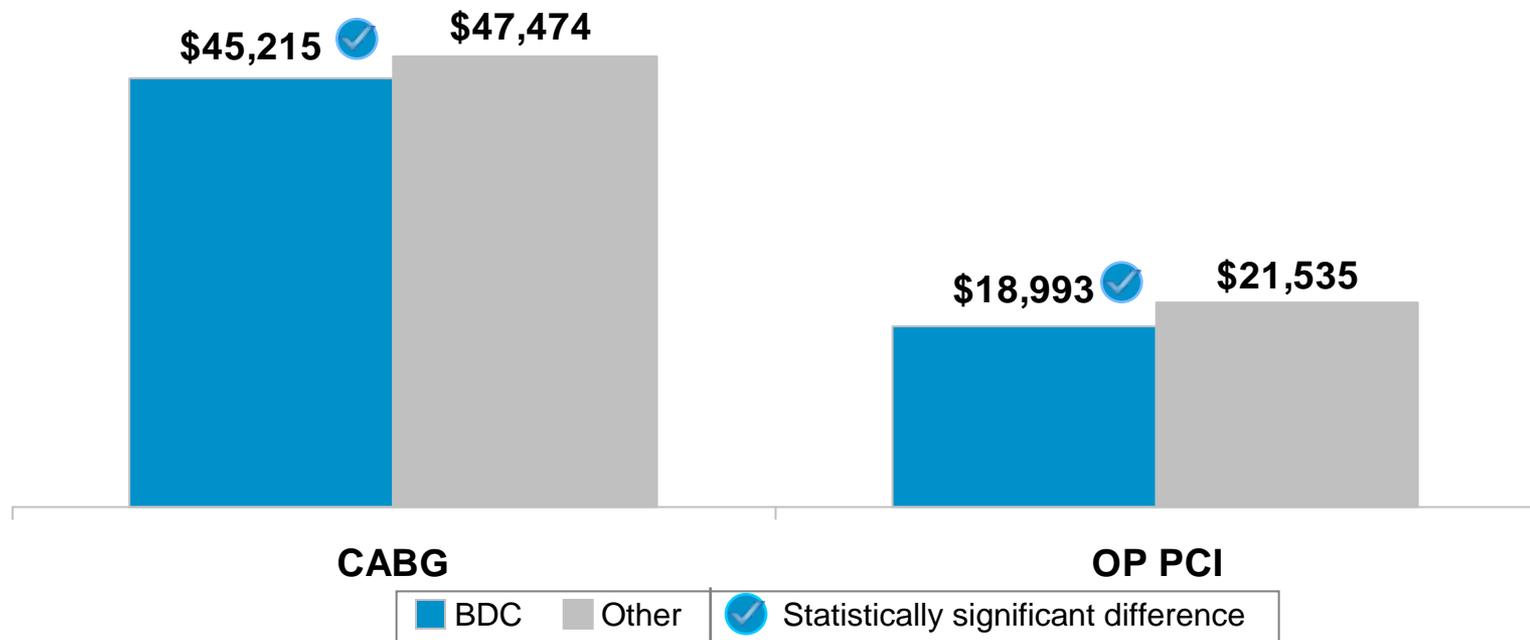
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Source: HealthCore, Inc. Cardiac Multi-Plan Claims Analysis, November 2008

Value of Quality Care

Quality care provided at Blue Distinction Centers for Cardiac Care resulted in lower costs

90-Day Episode Allowed Amount BDC vs. Other



Note: Results shown are median values from the risk-adjusted analysis. All allowable costs for initial admission through 90 days, not including outpatient pharmacy costs. 90-day eligibility required for patient cohort. Allowed amount = total claims from inpatient and outpatient services.

CABG = Coronary Artery Bypass Graft, OP PCI = Outpatient Angioplasty

Source: HealthCore, Inc. Cardiac Multi-Plan Claims Analysis, November 2008

Consumer Engagement Clinically Localized Prostate Cancer

AHRQ 2008

- Primary decision is whether to choose expectant management or active treatment
 - If active treatment is chosen, there is limited comparative evidence to guide the choice
 - All active treatments can cause temporary/permanent side effects
 - Patient preferences are an important factor in determining management strategy
 - Men treated in higher volume hospitals and by higher volume surgeons have fewer complications
- Provide decision-supports on treatment
 - Present risks and side effects to help patients make treatment choices
 - Provide decision-supports on provider selection

Improving the Evidence Base for Decision-making

Comparative effectiveness “stands on the shoulders” of present knowledge. There are significant obstacles to assessing outcomes.

- Outcome measures don't measure health
- Inconsistent reporting of adverse effects
- Noninferiority trials where inappropriate
- Selective reporting and publication bias
- Gap: efficacy vs. effectiveness

Outcome Measures Do Not Measure Health

- Intermediate vs. health outcomes
 - Tumor response vs. survival (autologous bone-marrow transplant for breast cancer)
- Define clinically significant improvement in trial protocol
 - Critical for soft measures (mortality vs. pain)
 - Pain (mean vs. % patients achieving 50% change)
 - TEC Special Report: Measuring and Reporting Pain Outcomes (http://www.bcbs.com/blueresources/tec/vol21/21_11.html)
- Validated scales or consensus outcomes
 - Unpublished scales show larger effect than published, validated scales
- Composite outcome may be driven by least important outcome (transient ischemic attack vs. stroke, restenosis vs. myocardial infarction)

Noninferiority Trials Where Inappropriate

- Noninferiority trials ask whether treatments are “close enough” for clinical purposes (e.g., 15% less efficacy)
- Credible where new treatment has known advantages (i.e., cost, less invasive), comparator outcomes rigorously demonstrated, margin of equivalence appropriate and data driven
- Not informative where comparator lacks rigorous trials
- Noninferiority as an “Orwellian” concept: “un-ungood” if “the worst to be expected of the new treatment is no worse than the worst to be expected of the standard treatment”

(Diamond GA and Kaul S, Am J Cardiol 2007; 99:284-287)

Measuring and Reporting Adverse Effects

- Ioannidis et al.: “Better Reporting of Harms in Randomized Trials: CONSORT Statement” (*Ann Intern Med* 2004; 141(10):781-8)
- Radiation Therapy Oncology Group criteria to grade toxicity severity
- Size and duration of premarket / prediffusion studies do not permit thorough assessment of adverse effects, especially excess common events or rare events

“...journal articles reporting clinical trials tend to dedicate more space to listing the authors’ names than to listing possible side effects associated with the drug.”

(Ledford H. *Nature* 2007; 447(7144):512)

Evidence Gap: Efficacy → Effectiveness

ICD Results in Trial Populations

Study	Population/Subgroup		Follow-up (months)	Hazard Ratio for Mortality	Absolute Mortality Benefit	NNT
	Prior MI	NoPrior MI				
MADIT II	X		20	0.69	5.6%	17.9
DEFINITE		X	29	0.65	5.3%	18.9
SCD-HeFT		X	45.5	0.73	6.5%	15.4
SCD-HeFT	X	X	45.5	0.77	6.8%	13.9

- Expect the unexpected: “Because accurate failure rate data are unavailable for these devices, management decisions are being made according to the perceived rather than the actual risk of catastrophic ICD failure.”

(Hauser RG and Maron BJ, Circulation 2005;112:2040-2042)

- Need to refine predictors of benefit: “Population-based data show that only a small proportion of sudden death victims could have benefited from the current primary prevention ICD guidelines.”

(Groh WJ, J Am Coll Cardiol 2006; 47:1161-6)

Selective Reporting and Publication Bias

- American Medical Association, Council on Scientific Affairs. 2004 Influence of Funding Source on Outcome, Validity and Reliability of Pharmaceutical Research. CSA Report 10-A-04.
- “Salvation by Registration” (ClinicalTrials.gov)
(Drazen JD and Zarin DA, *N Engl J Med* 2007; 356(2):184-5)
- Publication of Clinical Trials in *JAMA*
(Fontanarosa PB and DeAngelis CD, *JAMA* 2008; 299(1):95-6)



Robust Evidence of Effects and Comparative Effectiveness

- High-quality trials
- Long-term follow-up to assess benefits and harms
- Surrogate outcomes may be misleading
- Comparative trials and studies
 - Drug vs. drug
 - Drug vs. surgery vs. radiotherapy
 - Early vs. late
 - Strategies to manage condition
- Promise and pitfalls of observational data



Summary

- Comparative effectiveness addresses strategies to manage a condition, taking into account real world practice and variations in patient populations.
- Comparative effectiveness includes systems of care delivery to improve outcomes.
- New questions can lead to new paradigms. Counterintuitively, early palliative care in metastatic non-small-cell lung cancer resulted in less aggressive end-of-life care and longer survival.
- Health plan levers for translating evidence into practice are benefit design, purchasing, and consumer engagement.
- Blue Distinction Centers show that higher quality can be delivered at lower cost, using evidence-based institutional selection criteria.
- Comparative effectiveness “stands on the shoulders” of present knowledge. There are significant obstacles to assessing outcomes.

Questions?

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