Defining Value in Healthcare: A New Challenge for Medical Research and Publications

ISMPP International Society for Medical Publication Professionals

Speakers

- Clifford Goodman, PhD
  Vice President, The Lewin Group

- John W. Draper
  Senior Vice President, Healthcare Management, Peloton Advantage

- Kim Pepitone
  Director of Credentialing and Professional Development, ISMPP

ISMPP International Society for Medical Publication Professionals

What defines value in healthcare?

- Patient benefit
- Risk benefit
- Cost benefit
- Cost effectiveness
- Comparative effectiveness

ISMPP International Society for Medical Publication Professionals

Comparative effectiveness

- Title VIII of the American Recovery and Reinvestment Act of 2009 authorizes the expenditure of **$1.1 billion** to conduct research comparing “clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions”
- Federal support of “comparative effectiveness” research has been viewed as a cornerstone in controlling runaway health care costs

Wienstein, Skinner. *N Engl J Med* 2010. 362;5

The debate…….

- Can costs be controlled and adequate healthcare still be delivered?
- Does spending dictate outcomes?
- Can we have our cake and eat it too?
- Who decides?
- How does it all affect our profession?

ISMPP International Society for Medical Publication Professionals

ISMPP

Defining Value in Healthcare: A New Challenge for Medical Research and Publications

Implications of Comparative Effectiveness Research

April 20, 2010
Arlington, VA

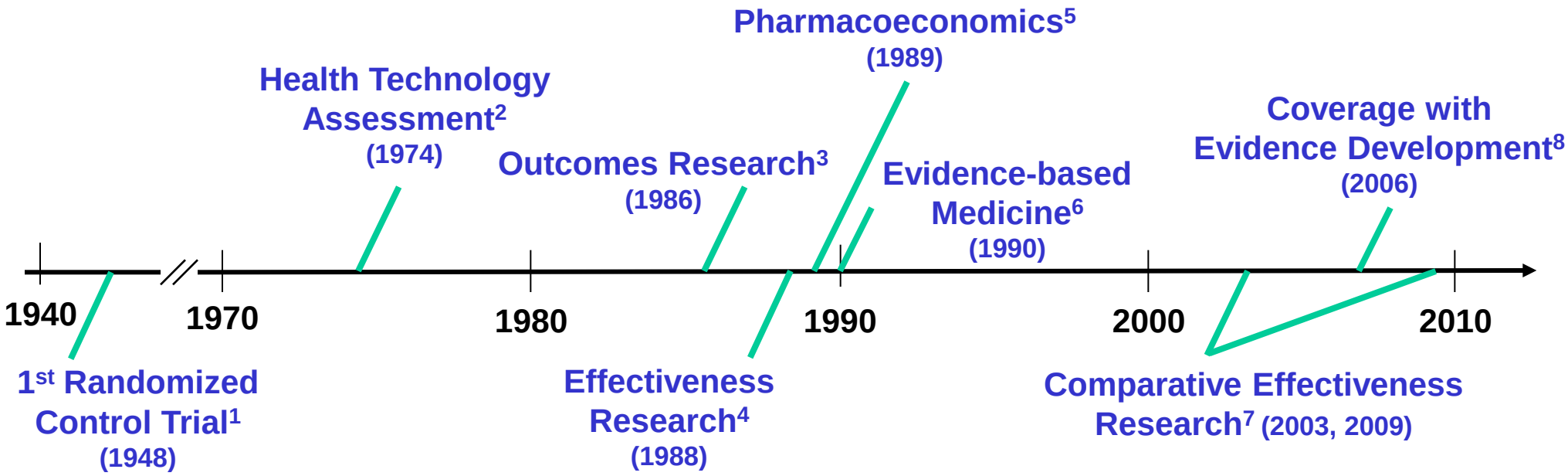
Clifford Goodman, PhD
Vice President
clifford.goodman@lewin.com

The LEWIN GROUP®
Center for Comparative Effectiveness Research

Why CER?

- **Evidence of inappropriate use of health care technologies, including over-use, under-use, and improper use**
- **Evidence of large variations in practice**
- **Evidence for FDA market approval/clearance often not sufficient to support clinical and policy decisions**
- **Inconsistent, insufficiently rigorous evidence for many technologies not regulated by FDA (i.e., many medical and surgical procedures)**
- **Lack of evidence on "head-to-head" comparisons of alternative interventions for particular health problems**
- **Lack of evidence in "real-world" practice (efficacy vs. effectiveness)**
- **Continued rapid increases in health care costs**

Timeline: Getting to CER



[1] RCT of streptomycin for pulmonary tuberculosis, sponsored by Medical Research Council (UK): 1948

[2] Origin of TA (not focused on health) in 1965: US Congressman Daddario; first "experimental" HTA by National Academy of Engineering in 1969 (multiphasic screening); Office of Technology Assessment published first HTA in 1974

[3] Patient Outcomes Assessment Research Program (later, PORTs) initiated by NCHSR (later renamed AHCPR; now AHRQ) in 1986 ("promote research with respect to patient outcomes of selected medical treatments and surgical procedures for the purpose of assessing their appropriateness, necessity and effectiveness ")

[4] HCFA (later renamed CMS) Effectiveness Initiative: 1988

[5] Early published appearance of "pharmacoeconomics": Bootman et al. 1989

[6] "Evidence-based": Eddy 1990; "Evidence-based medicine": Guyatt et al. 1992

[7] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) specifies AHRQ role in "comparative clinical effectiveness"; American Recovery and Reinvestment Act of 2009 (ARRA) authorizes major national investment in CER

[8] CMS draft guidance in 2005; formalized in 2006. Medicare and other payers began linking coverage to clinical research in 1990s

Source: C. Goodman

CER Attributes

Generally common attributes:

- **Direct comparisons of alternative interventions (as opposed to comparison with placebo or indirect comparisons)**
- **Applies to all types of interventions**
  - pharma, biotech, devices/equip't, medical and surgical procedures; organization, delivery, management, financing
- **Effectiveness (in realistic health care settings) rather than efficacy (in ideal circumstances)**
- **Health care outcomes (e.g., morbidity, mortality, QoL, adverse events, and symptoms) rather than surrogates or other intermediate endpoints**
- **No (US) consensus regarding incorporation of cost-effectiveness analysis or other economic analysis**

CER Methods Portfolio (Evolving)

Clinical Trials

- Randomized clinical trials
- Practical (pragmatic) clinical trials
- Other non-randomized controlled trials
- Adaptive clinical trials and other trial designs
- Other, e.g., randomized consent, regression discontinuity, combined single-subject (“n of 1”) trials

Observational Studies (prospective or retrospective)

- Population-based longitudinal cohort studies
- Patient registries
- Claims databases
- Clinical data networks
- Electronic health record data analyses
- Post-marketing surveillance (passive and active)

Syntheses of Existing Evidence

- Systematic reviews (comparative effectiveness reviews)
- Meta-analyses
- Modeling

Recent Major Clinical Trials That Have Attributes of CER: Budgets and Duration

Trial Name	Interventions	Approx. Budget ($M)	Approx. Duration (yrs)	Average/Year ($M)
COURAGE	coronary stents v. drugs	33.5	7	4.2
NETT	lung volume reduction	34.2	7	4.9
CATIE	antipsychotics	42.6	6	7.1
ALLHAT	antihypertensives	83.2	12	6.9
NLST	lung cancer screening	200.0	8	25.0
WHI	hormone replacement, other	725.0	15	48.3

CER Funding Before February 2009 …

- **The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 authorized $50 M for "comparative clinical effectiveness" at the Agency for Healthcare Research and Quality (AHRQ) and "such sums as necessary" for later years.**
- **Actual appropriations were been lower:**
  - 2005-07: $15 M each year
  - 2008: $30 M
  - 2009: $50 M
- **During that time, AHRQ developed CER capacity, especially by funding academic researchers to do CER and develop CER methods. NIH, VA, other agencies did some CER, too.**

Then, major new legislation in February 2009 …

CER in the American Recovery and Reinvestment Act of 2009 (ARRA)

- **Provides $1.1 billion, to be obligated by Sept. 30, 2010**

  $300 M - Agency for Healthcare Research and Quality

  $400 M - National Institutes of Health

  $400 M - Secretary of Health and Human Services
- **Designates two groups to provide recommendations on national CER priorities and other advice by June 30, 2009:**
  - Federal Coordinating Council for CER
  - Institute of Medicine

ARRA Funding for CER: Real $$?

Funding in 2009	$ Billions
AHRQ budget (original)	0.326
CER in ARRA	1.1
- AHRQ	0.300
- NIH	0.400
- HHS Sec'y	0.400
NIH budget	30.395
Pharma/bio R&D	65
Total U.S. health care	2,510

ARRA Mandated Two Reports on CER Priorities

Both reports were released June 30, 2009

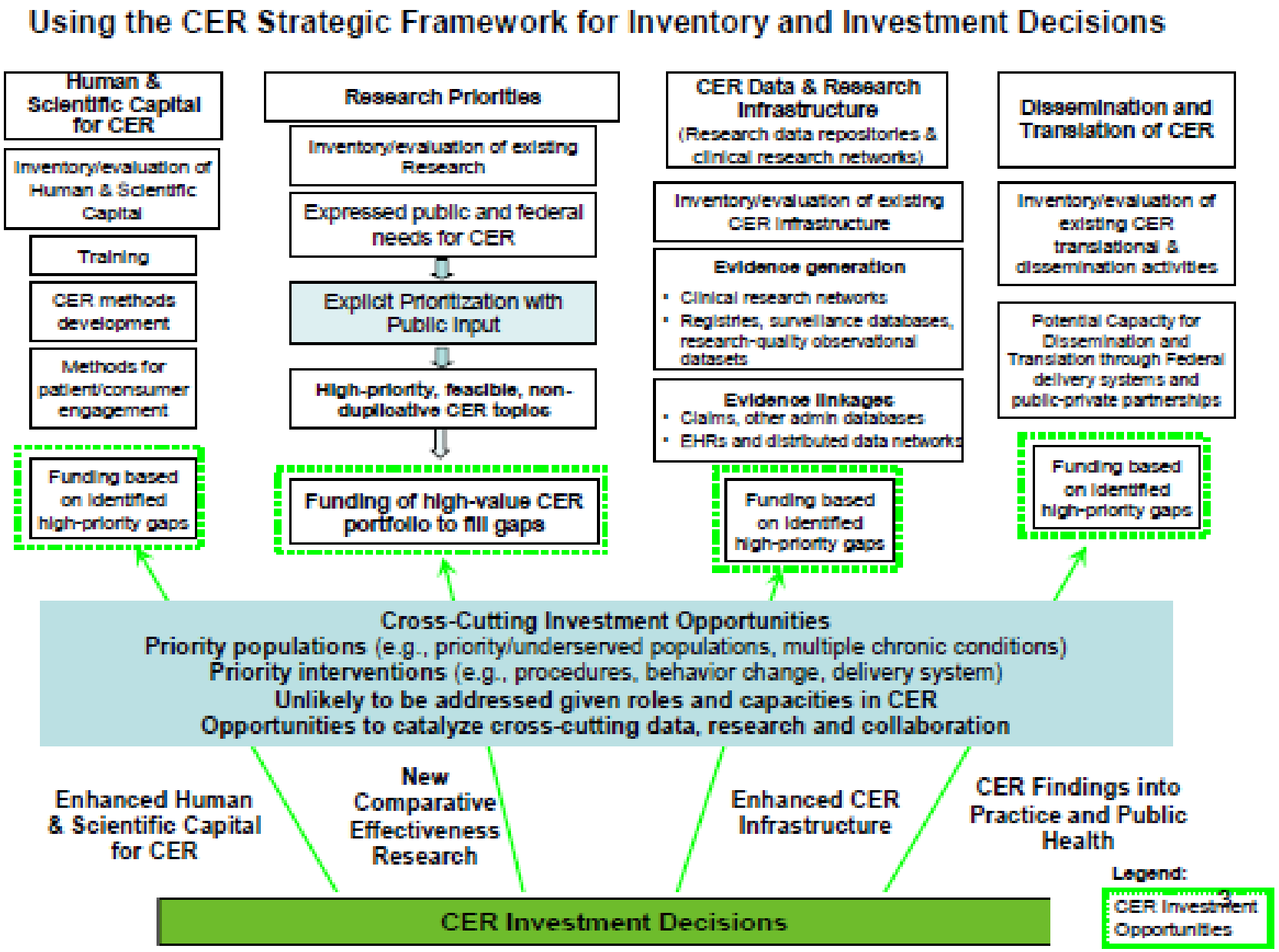
- **Institute of Medicine**
  - 100 priorities (4 tiers X 25) clinical and other health care problems
- **Federal Coordinating Council on CER**
  - Coordination across federal CER assets
  - Research (in comparative effectiveness)
  - Human and scientific capital (training, methods, etc.)
  - CER data infrastructure
  - Dissemination and translation of CER
  - Priority populations and other subgroups
  - In addition to pharma, behavioral, procedures, prevention, and delivery system interventions

Federal Coordinating Council for Comparative Effectiveness Research

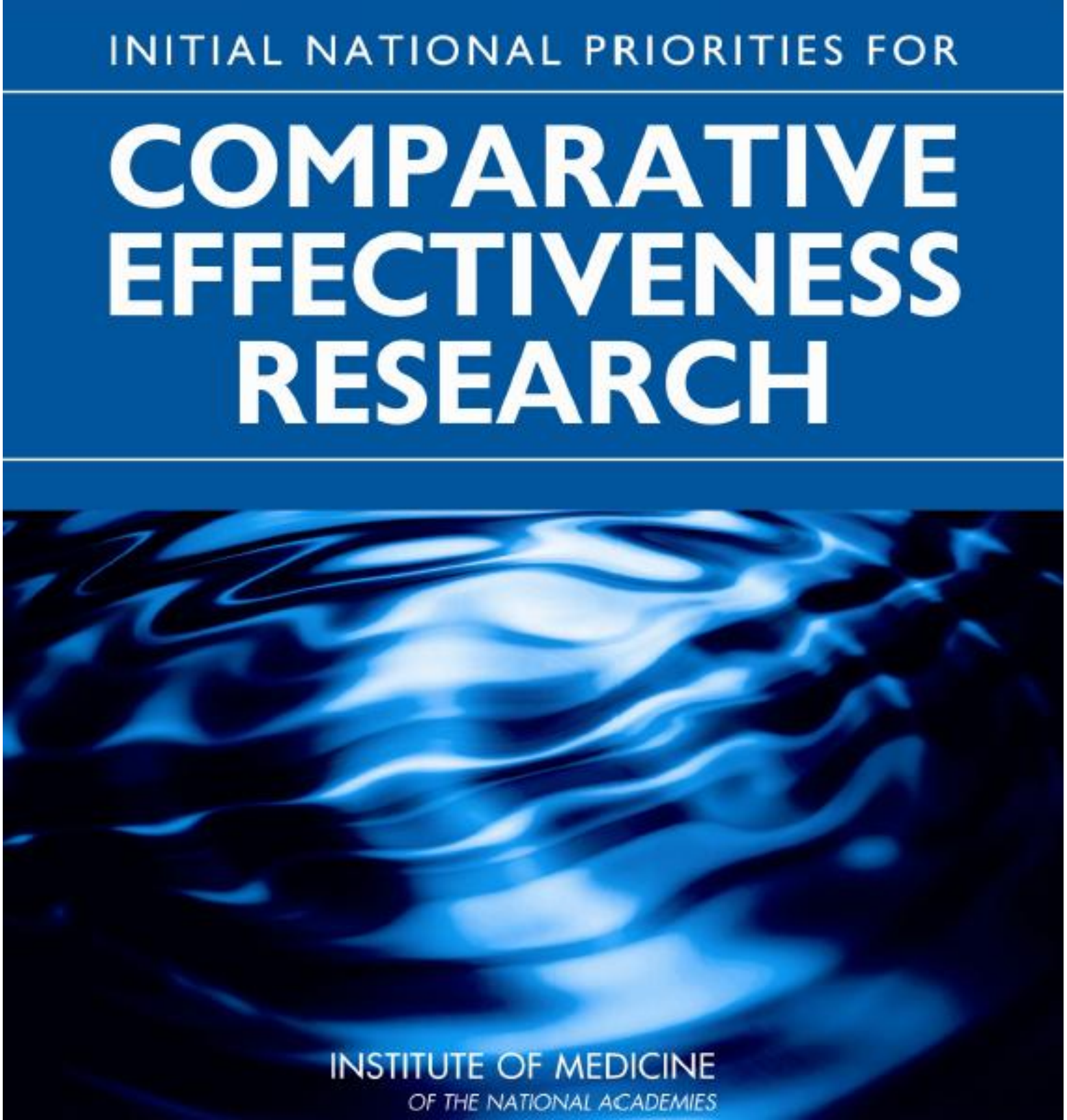
Report to the President and the Congress

June 30, 2009

US Department of Health and Human Services



[14] The following paragraphs draw on information contained in an environmental scan prepared by the Lewin Group for the Federal Coordinating Council on Comparative Effectiveness Research.


INITIAL NATIONAL PRIORITIES FOR
COMPARATIVE EFFECTIVENESS RESEARCH
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

June 2009

LIST OF PRIORITY CER TOPICS

TABLE S-1 Final List of Priority Topics, by Quartile Ratings
**display within quartile does not indicate priority rank—topics are listed alphabetically by primary research area*

First Quartile (listed alphabetically by primary research area)	
CAD	Compare the effectiveness of treatment strategies for atrial fibrillation including surgery, catheter ablation, and pharmacologic treatment.
DIS	Compare the effectiveness of the different treatments (e.g., assistive listening devices, cochlear implants, electric-acoustic devices, habilitation and rehabilitation methods [auditory/oral, sign language, and total communication]) for hearing loss in children and adults, especially individuals with diverse cultural, language, medical, and developmental backgrounds.
ENDO	Compare the effectiveness of primary prevention methods, such as exercise and balance training, versus clinical treatments in preventing falls in older adults at varying degrees of risk.
GI	Compare the effectiveness of upper endoscopy utilization and frequency for patients with gastroesophageal reflux disease on morbidity, quality of life, and diagnosis of esophageal adenocarcinoma.
HCDS	Compare the effectiveness of dissemination and translation techniques to facilitate the use of CER by patients, clinicians, payers, and others.
HCDS	Compare the effectiveness of comprehensive care coordination programs, such as the medical home, and usual care in managing children and adults with severe chronic disease, especially in populations with known health disparities.

AHRQ Spending Plan Through FY 2010

Horizon scanning	**$ 9.5 M**
Evidence synthesis	**25.0**
Evidence gap identification	**25.0**
Evidence generation	**173.0**
Translation & dissemination	**34.5**
Training & career development	**20.0**
Citizen forum	**10.0**
AHRQ CER staff	**3.0**
Total	**$ 300.0 M**

CER Thinking is Apparent in Coverage Determinations

- **For example, the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), which examines available evidence pertaining to current or potential national coverage determinations by CMS for Medicare …**

MEDCAC: Catheter Ablation for the Treatment of Atrial Fibrillation, Oct. 21, 2009

1. **How confident are you that the evidence is adequate to draw conclusions about the health outcomes of interest to patients treated with catheter ablation for atrial fibrillation?**
   - **Recurrence of arrhythmia**
   - **Symptom relief**
   - **Stroke**
   - **Survival**
2. **How confident are you that catheter ablation for the treatment of atrial fibrillation improves health outcomes compared to other therapies or treatments in the following populations:**
   - **As first-line therapy?**
   - **As second-line therapy?**
   - **For first detected atrial fibrillation?**
   - **For long-standing (greater than 1 year) atrial fibrillation?**
   - **For paroxysmal atrial fibrillation?**
   - **For persistent atrial fibrillation?**

MEDCAC: Catheter Ablation for the Treatment of Atrial Fibrillation, Oct. 21, 2009

3. How confident are you that ablation improves long-term (greater than 1 year) health outcomes?
4. How confident are you that the outcomes can be extrapolated to:
   - Patients outside a controlled clinical study?
   - The Medicare beneficiary population (age 65 years and older, 56% female)?
5. How confident are you that additional evidence is needed?

Discussion - Additional evidence, if needed:

- What type of additional evidence is needed to determine health outcomes?
- What study designs are most appropriate to obtain this additional evidence?

Publishing CER: Consensus Recommendations for *Reporting* Various Study Types

- **Systematic reviews and meta-analyses (QUOROM,[1] PRISMA[2])**
- **Randomized trials (CONSORT)[3]**
- **Studies of diagnostic tests (STARD)[4]**
- **Meta-analyses of observational studies (MOOSE)[5]**
- **Observational epidemiological studies (STROBE)[6,7]**

➢ **These are for authors of reports, not for assessing validity of individual research reports**

Consensus Statement Recommendations for *Reporting* Various Study Types

[1]Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF. Improving the quality of reports of meta-analyses of randomized controlled trials: the QUOROM statement. Quality of reporting of meta-analyses. Lancet 1999;354:1896–900.

[2]Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. Int J Surg 2010 Feb 17.

[3]Schulz KF, Altman DG, Moher D; for the CONSORT Group*. CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials. Ann Intern Med 2010 Mar 24.

[4]West S, King V, Carey TS, Lohr KN, McKoy N, Sutton SF, Lux L. Systems to Rate the Strength of Evidence. Evidence Report/Technology Assessment No. 47. 2002. Agency for Healthcare Research and Quality, Rockville, MD. AHRQ Publication No. 02-E016.

[5]Stroup DF, Berlin JA, Morton SC et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA 2000;283:2008–12.

[6]von Elm E, Egger M. The scandal of poor epidemiological research. BMJ 2004;329:868–69.

[7]Altman D, Egger M, Pocock S, Vandenbrouke JP, von Elm E. Strengthening the reporting of observational epidemiological studies. STROBE Statement: Checklist of Essential Items Version 3 (September 2005) http://www.strobe-statement.org/Checkliste.html).

Table. CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial*

Section/Topic	Item Number	Checklist Item
Title and abstract	1a	Identification as a randomized trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts [21, 31])
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial), including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomization		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomization; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results		
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome
	13b	For each group, losses and exclusions after randomization, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance, see CONSORT for harms [28])
Discussion		
Limitations	20	Trial limitations; addressing sources of potential bias; imprecision; and, if relevant, multiplicity of analyses
Generalizability	21	Generalizability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other Information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

Source: Schulz KF, Altman DG, Moher D; for the CONSORT Group*. CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials. Ann Intern Med 2010 Mar 24.

Patient-Centered Outcomes Research Institute

- **Established by Patient Protection and Affordable Care Act, Section 6301**
- **Private, non-profit organization that is not "an agency or establishment of the U.S. Government."**
- **Identify research priorities and establish and implement research agenda**
- **Overseen by 21-member Board of Governors, including the Directors of AHRQ and NIH; 19 members appointed by Comptroller General**
  - Assisted by expert advisory panels and methodology committee
- **Funded through combination of appropriations, transfers from the Medicare Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, and transfers from health insurance and self-insured health plans**
- **Limitations on PCORI's and the Secretary's ability to use PCORI research findings for coverage and reimbursement**
  - Cannot "mandate coverage, reimbursement, or other policies for any public or private payer"
  - Government may use findings in coverage "if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations" and subject to other constraints

Patient-Centered Outcomes Research Institute

Act establishes Patient-Centered Outcomes Research Trust Fund (PCORTF) in U.S. Treasury. Appropriations:

- **FY 2010: $10 million**
- **FY 2011: $50 million**
- **FY 2012: $150 million**

FYs 2013-19: $150 million in appropriations plus transfers from:

- **Medicare Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds**
- **Health insurance and self-insured health plans**
- **Formula: avg. number of enrollees in the plans (Medicare, health insurance policies, and self-insured plans) multiplied by:**
  - $1 for FY 2013
  - $2 for FY 2014
  - $2 increased by annual medical inflation for FYs 2015-19
- **No amounts available for expenditure after September 30, 2019**

CER Impact Beyond the US

- **Funding infusion and other attention to CER in US will have external effects:**
  - Expand the CER evidence base
  - Expand CER data resources
  - Improve CER methods
  - Improve CER expertise
- **CER findings will "move market share" beyond US**
- **CER requirements/expectations (e.g., higher evidence requirements, emphasis on head-to-head studies) will prompt changes in global innovation**

CER: Issues to Monitor …

- **Continued transparency and stakeholder input to CER priority-setting, study design, other processes?**
- **Synergy with personalized medicine?**
- **Use of CER findings for coverage and reimbursement by Medicare and other payers?**
- **Eventual incorporation of economic analyses?**
- **Ability to deliver results: affect health care decisions and patient outcomes?**
- **Impact on health care spending?**
- **Ramp-up and ongoing viability of new Patient-Centered Outcomes Research Institute?**

Implications for Life Sciences Industry (1)

1. **Regulatory, payment, other HTA requirements are being joined by further CER evidence requirements**
2. **Evidence standards are not getting any lower; it is particularly difficult to demonstrate:**
   - **superiority vs. an effective standard of care**
   - **impact of screening and diagnostics (including pharmacogenomics) on health outcomes**
   - **statistically significant treatment effects in subgroups**
3. **Expanded support of U.S. CER/HTA will increase global capacity and rigor for assessing technologies**
4. **Anticipate evidence req'ts throughout technology lifecycle: Who will want what evidence when?**
   - **Are gatekeepers providing clear signals?**

Implications for Life Sciences Industry (2)

5. **CER/HTA redefine value and shift direction of innovation. There will be opportunities; shakeouts**
6. **Consider tradeoffs for pursuing therapies for broad, population-based indications vs. more focused ones**
7. **Get to know (and build relationships where possible with) HTA agencies in your markets**
8. **Track CER/HTA priority setting: Where and how will it involve your technology?**
9. **Monitor and participate in developments pertaining to building U.S. and global CER/HTA capacity**
10. **Need to reorganize? CER/HTA and related trends may suggest need to change processes for innovation, validation, commercialization**

ISMPP

Defining Value in Healthcare: A New Challenge for Medical Research and Publications

Implications of Comparative Effectiveness Research

April 20, 2010
Arlington, VA

Clifford Goodman, PhD
Vice President
clifford.goodman@lewin.com

The LEWIN GROUP®
Center for Comparative Effectiveness Research

Medical Publications: A Critical Role in the New Health Care Landscape

John W. Draper
Senior Vice President
Health Care Management
Peloton Advantage, LLC

April 20, 2010

ISMPP International Society for Medical Publication Professionals

ISMPP International Society for Medical Publication Professionals

"All the News That's Fit to Print"

The New York Times

Late Edition

VOL. CLVII . . No. 54,310 © NEW YORK, WEDNESDAY, DECEMBER 3, 2008 $1.50

BRITISH BALANCE BENEFIT VS. COST OF LATEST DRUGS

SYSTEM SEEN AS MODEL

But Protests Lead Panel to Reconsider Denial in Some Cases

By GARDINER HARRIS

PURSUING U.S. AID, G.M. ACCEPTS NEED FOR DRASTIC CUTS

Automakers Request More in Loans — Industry Reports Big Slide in Sales

By BILL VLASIC and DAVID M. HERSZENHORN

Fewer Vehicles Sold

Gallery Awaits a Reluctant (to Sit) Cuomo

By DANNY HAKIM

Even in Home of Carmakers, Not Everyone Wants a Lifeline

By MONICA DAVEY and SUSAN SAULNY

The New York Times

Wednesday, December 3, 2008

THE EVIDENCE GAP

British Balance Gain Against the Cost of the Latest Drugs

By GARDINER HARRIS

Types of Payers

- United Kingdom vs United States
  - In the UK, budgets are capped
    - Necessary to spread a benefit across the population
    - Access can be denied for all patients
  - In the US, budgets are not capped
    - Rising premiums, co-pays, and co-insurance
    - Access is not denied
    - Uninsured
  - All patients believe they are entitled to treatments
    - Different villains

THE NEW YORKER

Annals of Medicine

THE COST CONUNDRUM

What a Texas town can teach us about health care.

by Atul Gawande

JUNE 1, 2009

It is spring in McAllen, Texas. The morning sun is warm. The streets are lined with palm trees and pickup trucks. McAllen is in Hidalgo County, which has the lowest household income in the country, but it's a border town, and a thriving foreign-trade zone has kept the unemployment rate below ten per cent. McAllen calls itself the Square Dance Capital of the World.

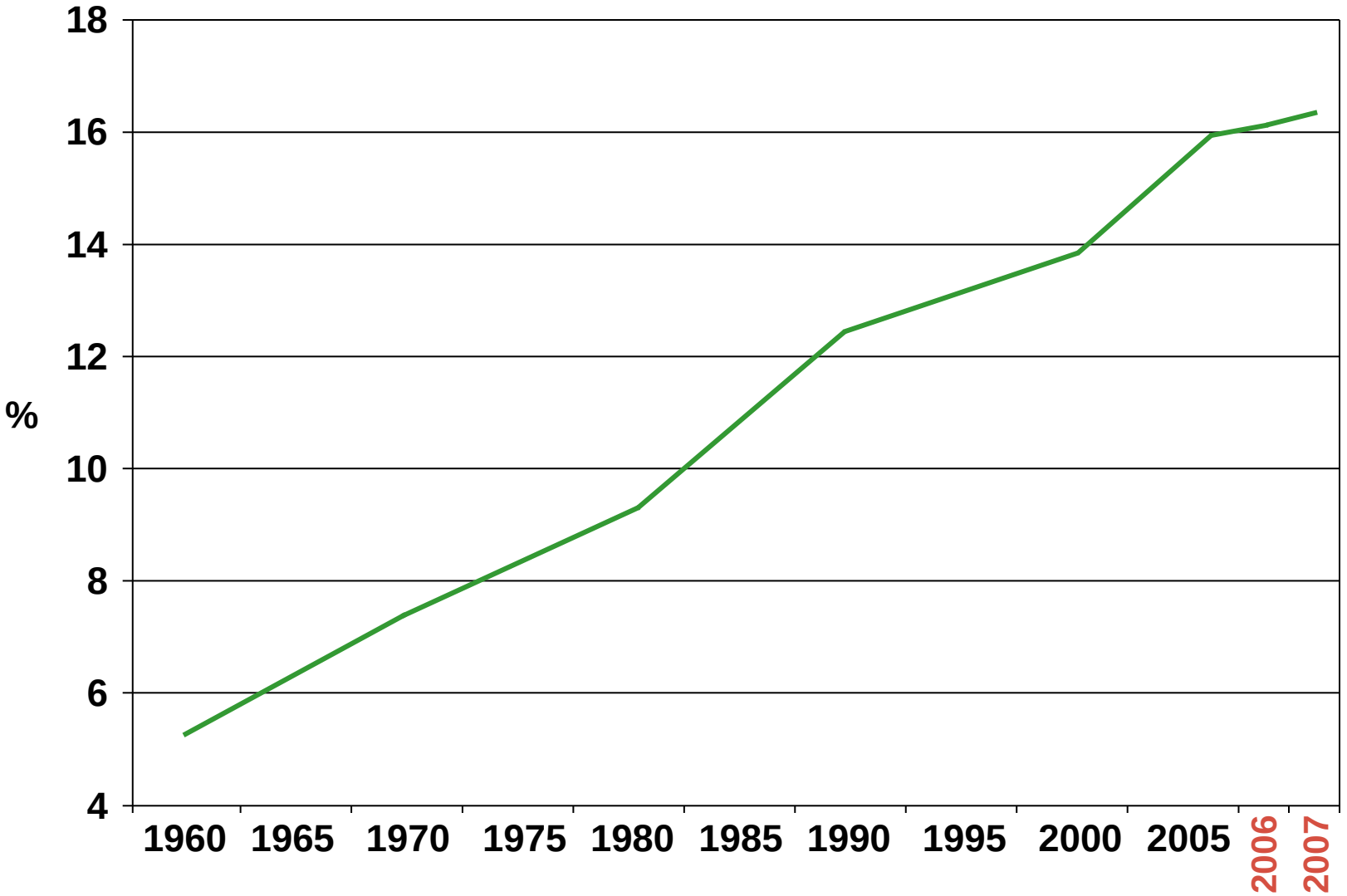
"Lonesome Dove" was set around here.

McAllen has another distinction, too: it is one of the most expensive health-care markets in the country. Only Miami—which has much higher labor and living costs—spends more per person on health care. In 2006, Medicare spent fifteen thousand dollars per enrollee here, almost twice the national average. The income per capita is twelve thousand dollars. In other words, Medicare spends three thousand dollars more per person here than the average person earns.

The explosive trend in American medical costs seems to have occurred here in an especially intense form. Our country's health care is by far the most expensive in the world. In Washington, the aim of health-care reform is not just to extend medical coverage to everybody but also to bring costs under control. Spending on doctors, hospitals, drugs, and the like now consumes more than one of every six dollars we earn. The financial burden has damaged the global competitiveness of American businesses and bankrupted millions of families, even those with insurance. It's also devouring our government. "The greatest threat to America's fiscal health is not Social Security," President Barack Obama said in a March speech at the White House. "It's not the investments that we've made to rescue our economy during this crisis. By a wide margin, the biggest threat to our nation's balance sheet is the skyrocketing cost of health care. It's not even close."

Health Care Expenditures

US Health Expenditures as a Percentage of GDP



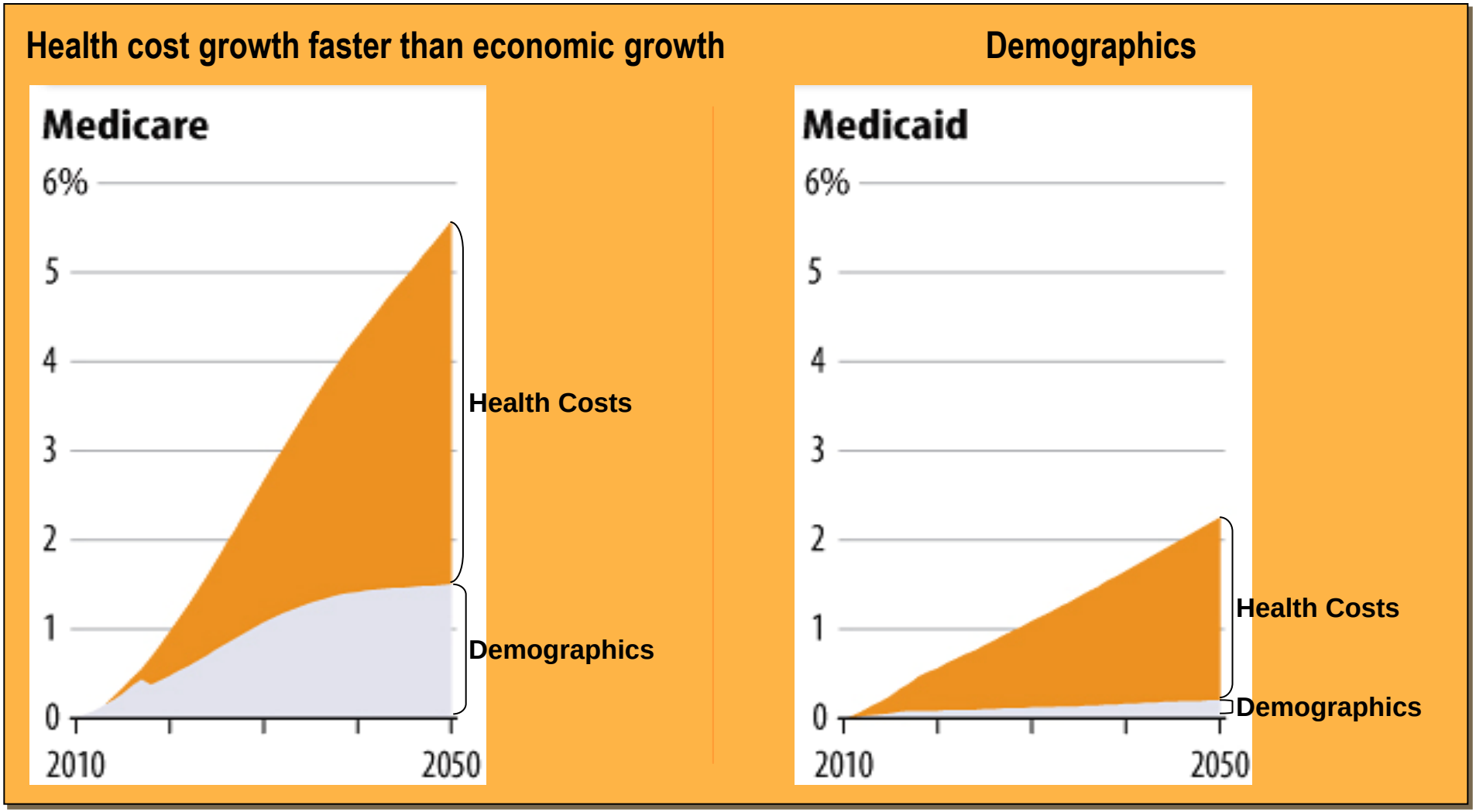
Today +16% of GDP

Sources: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group; US Department of Commerce, Bureau of Economic Analysis; and US Bureau of the Census.

ISMPP International Society for Medical Publication Professionals

Health Care Costs, Not Demographics, Are Main Drivers of Medicare and Medicaid Growth

Sources of Cost Growth as a Share of GDP



Source: CBPP calculations based on CBO data.

ISMPP International Society for Medical Publication Professionals

REUTERS

Health care system wastes up to $800 billion a year

Health care system wastes up to $800 billion a year

Mon Oct 26, 2009 6:10pm EDT

By Maggie Fox, Health and Science Editor

WASHINGTON (Reuters) - The U.S. health care system is just as wasteful as President Barack Obama says it is, and proposed reforms could be paid for by fixing some of the most obvious inefficiencies, preventing mistakes and fighting fraud, according to a Thomson Reuters report released on Monday.

The U.S. health care system wastes between $505 billion and $850 billion every year, the report from Robert Kelley, vice president of healthcare analytics at Thomson Reuters, found.

"America's health care system is indeed hemorrhaging billions of dollars, and the opportunities to slow the fiscal bleeding are substantial," the report reads.

"The bad news is that an estimated $700 billion is wasted annually. That's one-third of the nation's health care bill," Kelley said in a statement.

"The good news is that by attacking waste we can reduce healthcare costs without adversely affecting the quality of care or access to care."

One example—a paper-based system that discourages sharing of medical records accounts for 6 percent of annual overspending.

"It is waste when caregivers duplicate tests because results recorded in a patient's record with one provider are not available to another or when medical staff provides inappropriate treatment because relevant history of previous treatment cannot be accessed," the report reads.

Some other findings in the report from Thomson Reuters, the parent company of Reuters:

- **Unnecessary care** such as the overuse of antibiotics and lab tests to protect against malpractice exposure makes up 37 percent of health care waste, or $200 to $300 billion a year.
- **Fraud** makes up 22 percent of healthcare waste, or up to $200 billion a year in fraudulent Medicare claims, kickbacks for referrals for unnecessary services and other scams.
- **Administrative inefficiency** and redundant paperwork account for 18 percent of healthcare waste.
- **Medical mistakes** account for $50 billion to $100 billion in unnecessary spending each year, or 11 percent of the total.
- **Preventable conditions** such as uncontrolled diabetes cost $30 billion to $50 billion a year.

"

The Search for Value

"A Market in Play"

"Managed Care on Steroids"

"The Thin Edge of the Wedge"

"Reshuffling Stakeholder Economics"

"Peer-Reviewed Publications Identify Value"

ISMPP International Society for Medical Publication Professionals

Value

The NEW ENGLAND JOURNAL of MEDICINE

Slowing the Growth of Health Care Costs — Learning from International Experience
Karen Davis, PhD

- The (U.S.) option currently receiving the most attention is a system for generating more information about the **effectiveness of medical treatments, weighing it against that of other diagnostic or treatment options, and assessing cost relative to benefits to determine whether more expensive therapies warrant their additional cost**.

- **We need to ensure that new technology yields value over and above existing technologies, commensurate with its incremental cost**. Investing in the knowledge needed to improve decision making and incorporating information about relative clinical value and cost-effectiveness into the design of insurance benefits, would yield an estimated 10-year savings of $368 billion for our health care system.

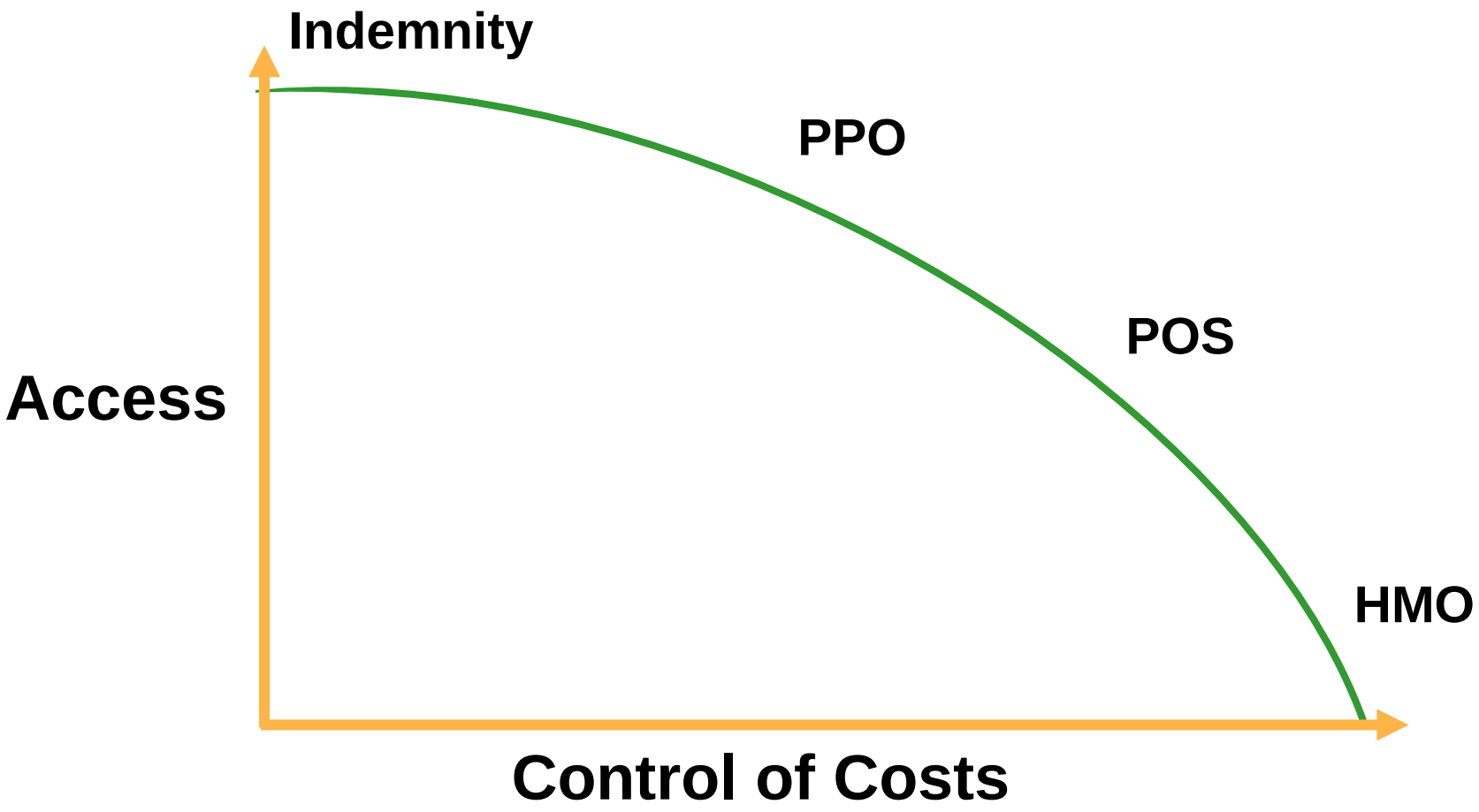
ISMPP International Society for Medical Publication Professionals

Value

The relevant standard should be value, not cost.

But…

Managed Care Curve

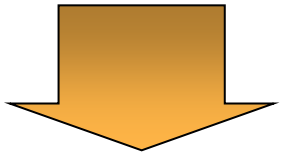
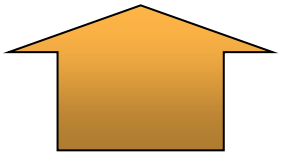
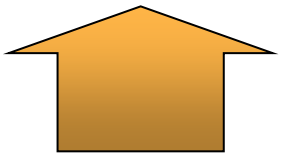
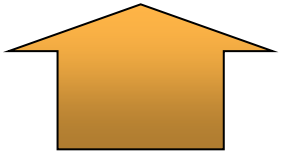
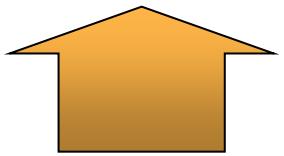
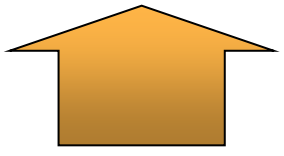


Source: Aetna.

Health Care Buyer's Market

- Growing influence of health care buyers
  - Patient cost-sharing
  - Medicare Modernization Act
  - Deficit Reduction Act
  - FDAAA
  - American Recovery and Reinvestment Act
    - Comparative Effectiveness legislation

Changing Influence of Decision Makers

Decision Makers	Influence
Physicians	
Payers	
Health Technology Assessors	
Patients	
Pharmacists	
NPs, PAs, Retail Clinics	

ISMPP International Society for Medical Publication Professionals

Pharmaceutical Marketing

- Restricted physician access for detail sales force

FierceBiotech
THE BIOTECH INDUSTRY'S DAILY MONITOR
ıttp://www.fiercebiotech.com)

Time to Blow Up the Pharmaceutical Sales Model? New Deloitte Debate

By ejones
Created Nov 20 2009 - 11:18am

Time to Blow Up the Pharmaceutical Sales Model? New Deloitte Debate

What: "New Commercial Model: Science or Swag?"

Who: W. Scott Evangelista, principal, Deloitte Consulting LLP

When: Available immediately

Where: www.deloitte.com/us/debates/scienceorswag

Details: Pharmaceutical companies face a fundamental decision about the best way to sell their products. Even if they could find a way to make the current sales model work, pharma companies still face sky-high commercial costs. So, the question is, should pharma companies stick with their traditional sales approach or blow it up and try something new?

ISMPP International Society for Medical Publication Professionals

Pharmaceutical Marketing

- Restricted physician access for detail sales force
- Direct-to-consumer challenges
- CME financial guidelines
- New contracting and rebate implications
- AMA reviewing impact of sampling
- REMs critical to newly approved products
- Publications and Health Technology Assessment

ISMPP International Society for Medical Publication Professionals

Communication of Value

How do you communicate
a brand's value proposition?

Formulary Process


Pharmacy Benefit Managers


3rd-Party Payers


Employers

Federal and State Government Agencies/CMS

Retail Pharmacy Chains

Pharmacy and Therapeutic Committee Evaluation

Determines Therapeutic Value Based on Published Studies and Data

Pricing, Volume Discount Programs, Rebate Programs

Compliance Programs, Disease Management, Patient/Physician Education

Formulary Policy

Utilization Management Tools


Prior Authorization


Specialist Referral


Therapeutic Switch


Tiered Co-pays

ISMPP International Society for Medical Publication Professionals

Health Care Decision Maker Survey

What sources of information do you look to first when making access, coverage, and reimbursement decisions?

- Pricing and contracting?
- Costs associated with episode of care?
- Physician demand?
- Patient demand?
- Published studies and outcomes data?

ISMPP International Society for Medical Publication Professionals

Health Care Decision Maker Survey (cont'd)

Published studies and outcomes data were identified as the first source of information when making access, coverage, and reimbursement decisions.

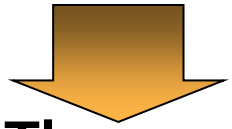
Does documented industry sponsorship impact which articles are reviewed by your P&T committees?

ISMPP International Society for Medical Publication Professionals

Wellpoint Access Criteria

Starts with drug information managers conducting an evidence-based literature review and requests for information from manufacturers

Evidence-Based Monograph



Pharmacy and Therapeutic Committee

1. <u>Physician Clinical Review Committee</u>

- Reviews efficacy, safety, and effectiveness
- Seeks improvement in health outcomes
  - Surrogate markers
  - Cost is not the first consideration

2. <u>Value Assessment Committee</u>

- Market share
- Utilization
- Rebate
- Pharmacoeconomics
- Physician/patient issues with change

ISMPP International Society for Medical Publication Professionals

Kaiser Access Criteria

- Distributes clinical practice guidelines
  - Value assessed in terms of clinical benefits compared with alternative
  - Evaluation first considers health outcomes
  - When therapeutic alternatives are available, then cost-effectiveness is reviewed
- Kaiser wants manufacturers to develop evidence of value before marketing approval
  - Efficacy vs real-world effectiveness

Center for Medicare and Medicaid Services (CMS)

- CMS had 3 choices for Medicare
  1. Price controls
  2. NICE-type access controls
  3. Evidence-based reimbursement
- Move from an insurance model to an evidence-based system
  - "Reasonable and necessary"
  - Real-world effectiveness
  - CER process

What to Do?

- Identify your value proposition
- Build link to a real-world environment
- Identify evidence-based support within an episode of care
- Communicate value and real-world evidence through peer-reviewed publications

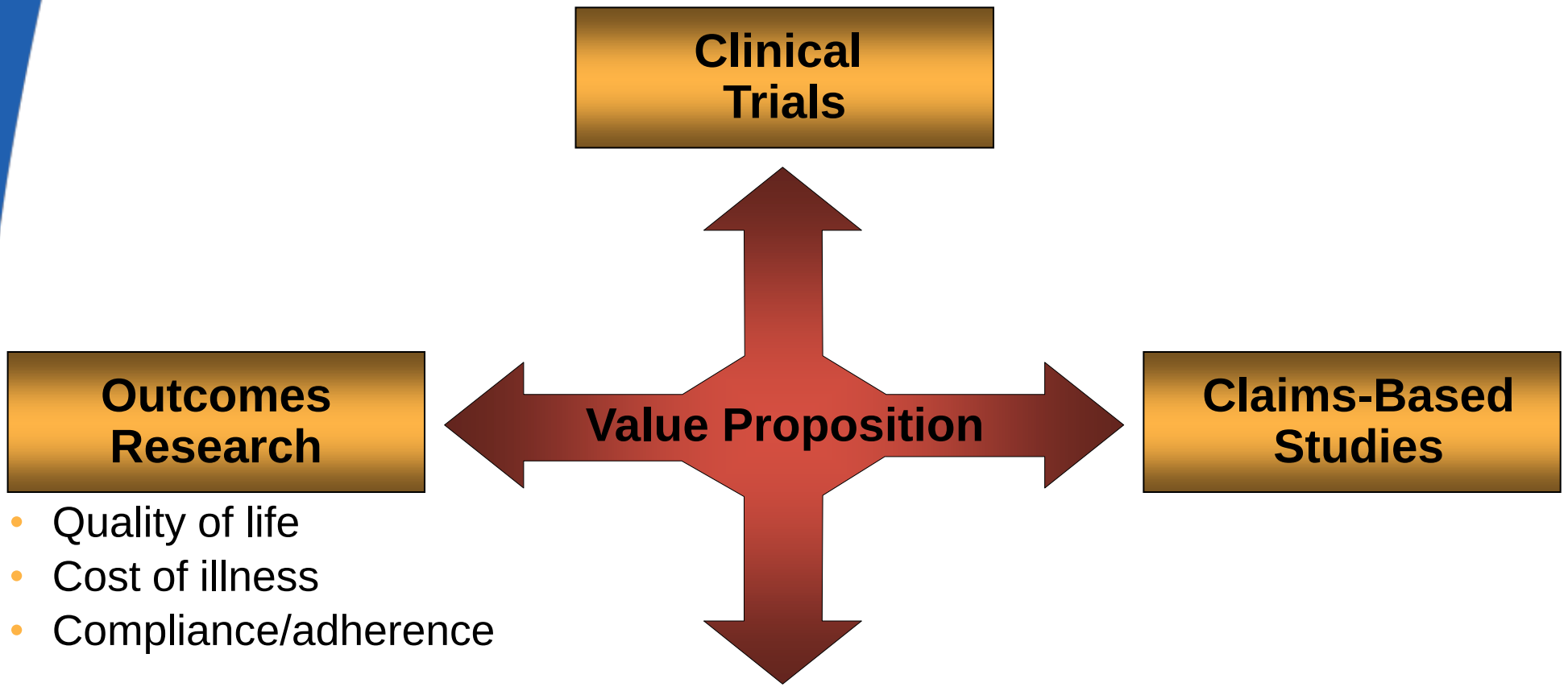
ISMPP International Society for Medical Publication Professionals

The Potential Conflict in an Episode of Care

Medical Costs vs Drug Costs

ISMPP International Society for Medical Publication Professionals

Types of Studies



- Quality of life
- Cost of illness
- Compliance/adherence

- Case control
- Cohort
- Incidence, prevalence, risk

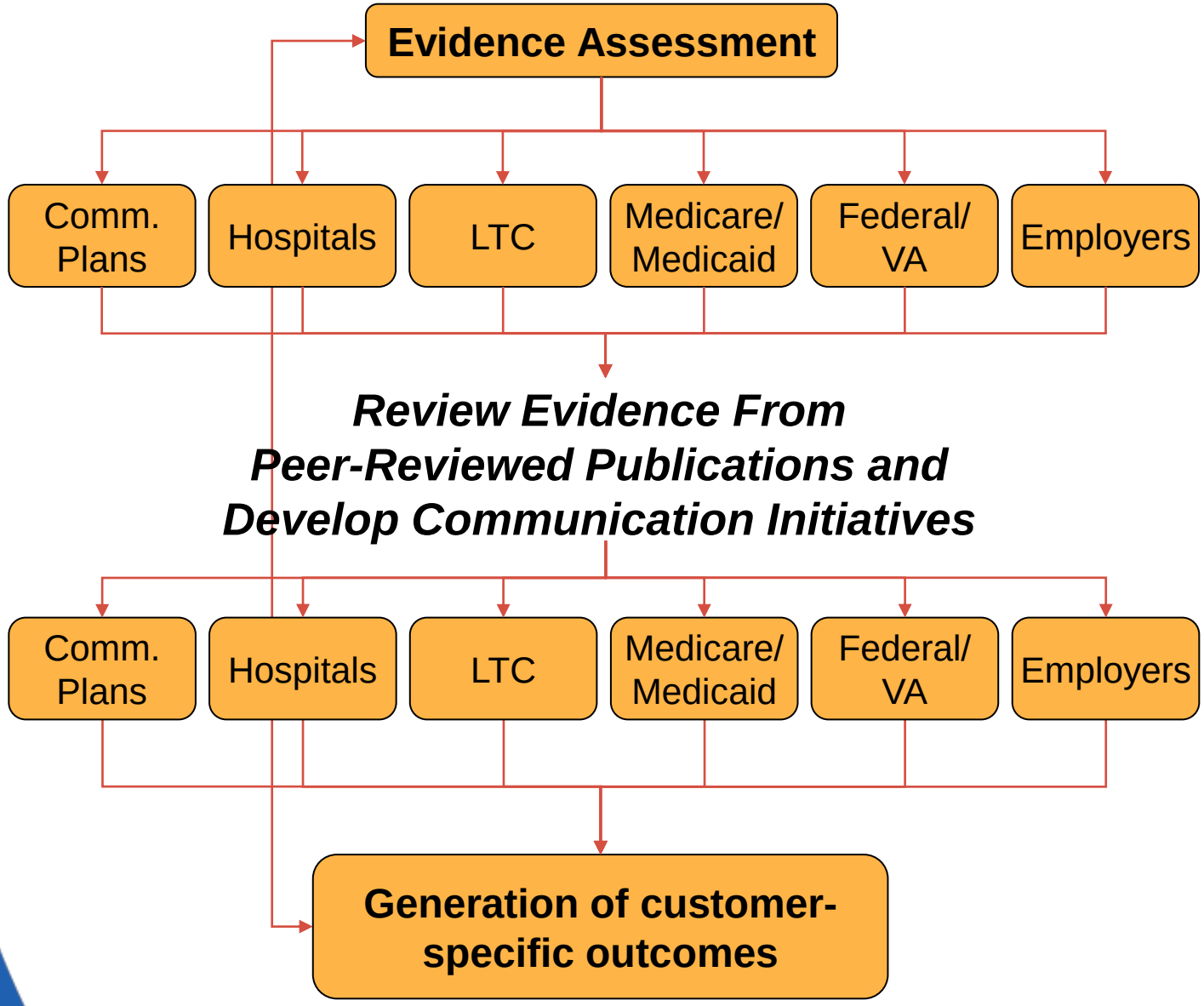
ISMPP International Society for Medical Publication Professionals

Gap Analysis: Value Message

Objectives

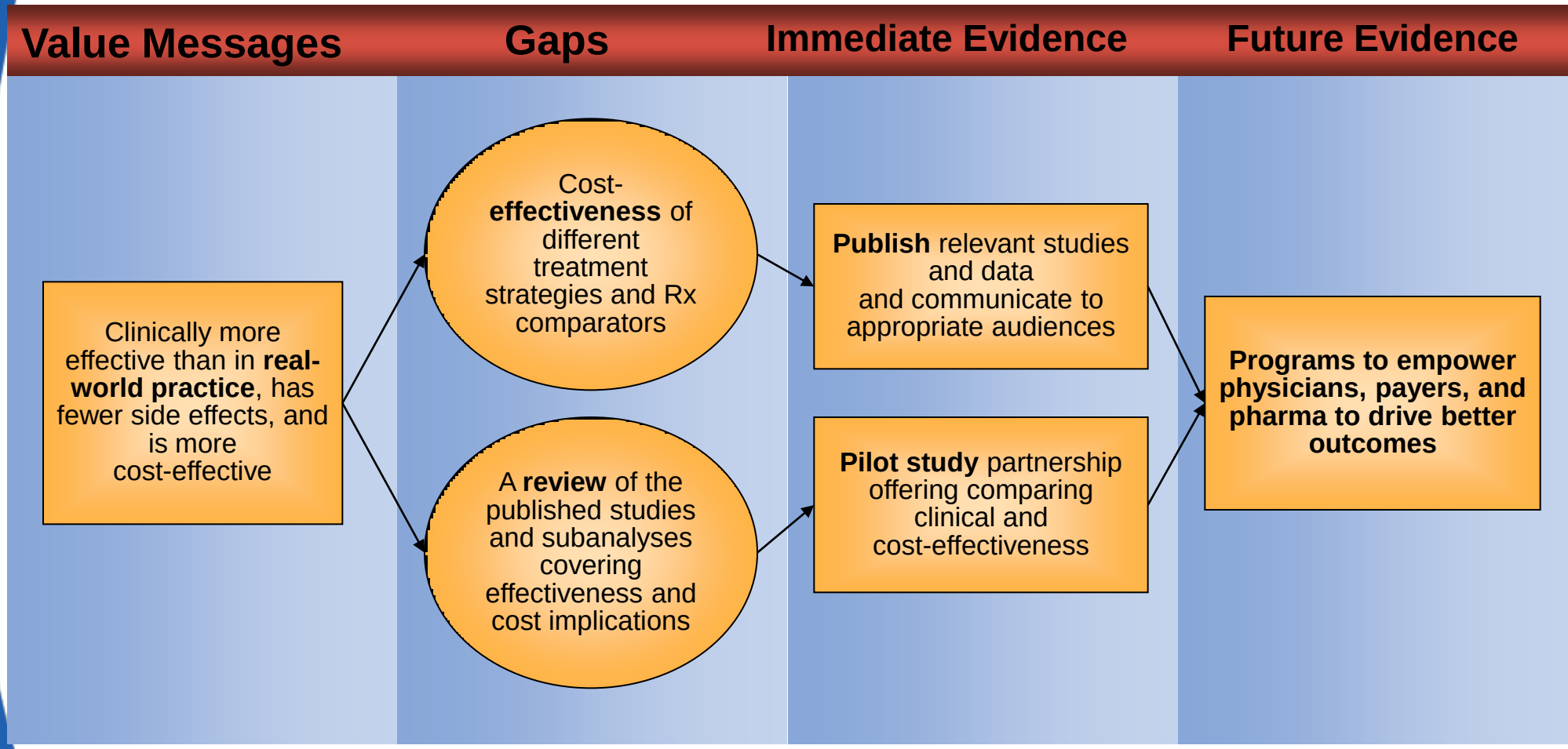
- To identify gaps and opportunities to improve messaging demonstrating value
- To identify existing, ongoing, and new clinical and outcomes evidence necessary to communicate value

Evidence Assessment Process



ISMPP International Society for Medical Publication Professionals

Evidence Analysis



ISMPP International Society for Medical Publication Professionals

Research Study Design and Publication Guidelines

Interventional Studies

Investigator-led comparison of the effects of 2 or more interventions

Study Type	Medical Research Guidelines	Publication Guidelines
Randomized Trials—Comparison of 2 or more interventions, possibly including a control, following random allocation of treatments to participants	• FDA Regulations Relating to Good Clinical Practice and Clinical Trials* • World Medical Association Declaration of Helsinki†	• CONSORT • GPP2 • ICMJE • COPE
Nonrandomized Trials—Quantitative assessment of the effectiveness (harm or benefit) of an intervention without randomization to comparison groups		• GPP2 • ICMJE • COPE

*http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm.
†http://ohsr.od.nih.gov/guidelines/helsinki.html.

ISMPP International Society for Medical Publication Professionals

Research Study Design and Publication Guidelines

Observational Studies

Inferences are drawn about the possible effect of treatment on subjects assigned to a treated group vs a control group outside the control of the investigator

Study Type	Medical Research Guidelines	Publication Guidelines
Case Control—Assessment of risk factors for a condition/disease through comparison with a historical control sample	Good Research Practices for Comparative Effectiveness Research: Defining, Reporting, and Interpreting Nonrandomized Studies of Treatment Effect Using Secondary Data Sources: The ISPOR Research Practices for Retrospective Database Analysis*	• STROBE • GPP2 • ICMJE • COPE
Cohort (prospective and retrospective)—Starts with an exposure and looks forward in time for the occurrence of a specific condition		• STROBE • GPP2 • ICMJE
Individual Case—Objective description of one case		• GPP2 • ICMJE • COPE

*Berger ML, et al. *Value in Health.* 2009;12:1044-1052.

ISMPP International Society for Medical Publication Professionals

Research Study Design and Publication Guidelines

Observational Studies

Inferences are drawn about the possible effect of treatment on subjects assigned to a treated group vs a control group outside the control of the investigator

Study Type	Medical Research Guidelines	Publication Guidelines
***Case Series*—**Objective description of a series of cases, usually with all individuals receiving the same intervention and with no control group	Good Research Practices for Comparative Effectiveness Research: Defining, Reporting, and Interpreting Nonrandomized Studies of Treatment Effect Using Secondary Data Sources: The ISPOR Research Practices for Retrospective Database Analysis	• GPP2 • ICMJE • COPE
***Ecologic or Epidemiologic*—** Observations based on population trends		• STROBE • GPP2 • ICMJE • COPE
***Cross-sectional*—**Comparison of groups at one point in time		• STROBE • GPP2 • ICMJE • COPE

*Berger ML, et al. *Value in Health.* 2009;12(8):1044-1052.

ISMPP International Society for Medical Publication Professionals

Publication Guidelines Resources

- CONSORT 2010 Checklist; CONSORT 2010 Explanation and Elaboration. Available at: www.consort-statement.org.
- Graf C, Battisti WP, Bridges D, et al, for the International Society for Medical Publication Professionals. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ*. 2009;339:1299-1303.
- International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. *Ann Intern Med*. 1997;126:36-47.
- The Committee on Publication Ethics (COPE). Guidelines. Updated: 2009. Available at: http://publicationethics.org/guidelines. Accessed March 1, 2010.
- von Elm E, Altman DG, Egger M, et al, for the STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Ann Intern Med*. 2007;147:573-577.

ISMPP International Society for Medical Publication Professionals

Medical Publications: A Critical Role in the New Health Care Landscape

- Determination of value beyond placebo-controlled trials will flow through publications
- A value proposition will first be defined by the published literature and studies
- Peer-review process will provide credibility and confirm value
- Peer-reviewed publications become the "currency" of pharmaceutical communications in the new health care marketplace

ISMPP International Society for Medical Publication Professionals

A New Marketplace

"A Market in Play"

"Managed Care on Steroids"

"The Thin Edge of the Wedge"

"Reshuffling Stakeholder Economics"

"Peer-Reviewed Publications Identify Value"

ISMPP International Society for Medical Publication Professionals

Thank you!

John W. Draper
Senior Vice President
Health Care Management
Peloton Advantage, LLC
973-582-5728
jdraper@pelotonadvantage.com

ISMPP International Society for Medical Publication Professionals