



The Dbriefs Health Sciences series presents:

Comparative Effectiveness: A Compelling Approach to Cost Control and Quality Improvement

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Discussion areas

Introduction to comparative effectiveness

Perception and policy discussion

Discussion of lessons from abroad

Implications for life science companies

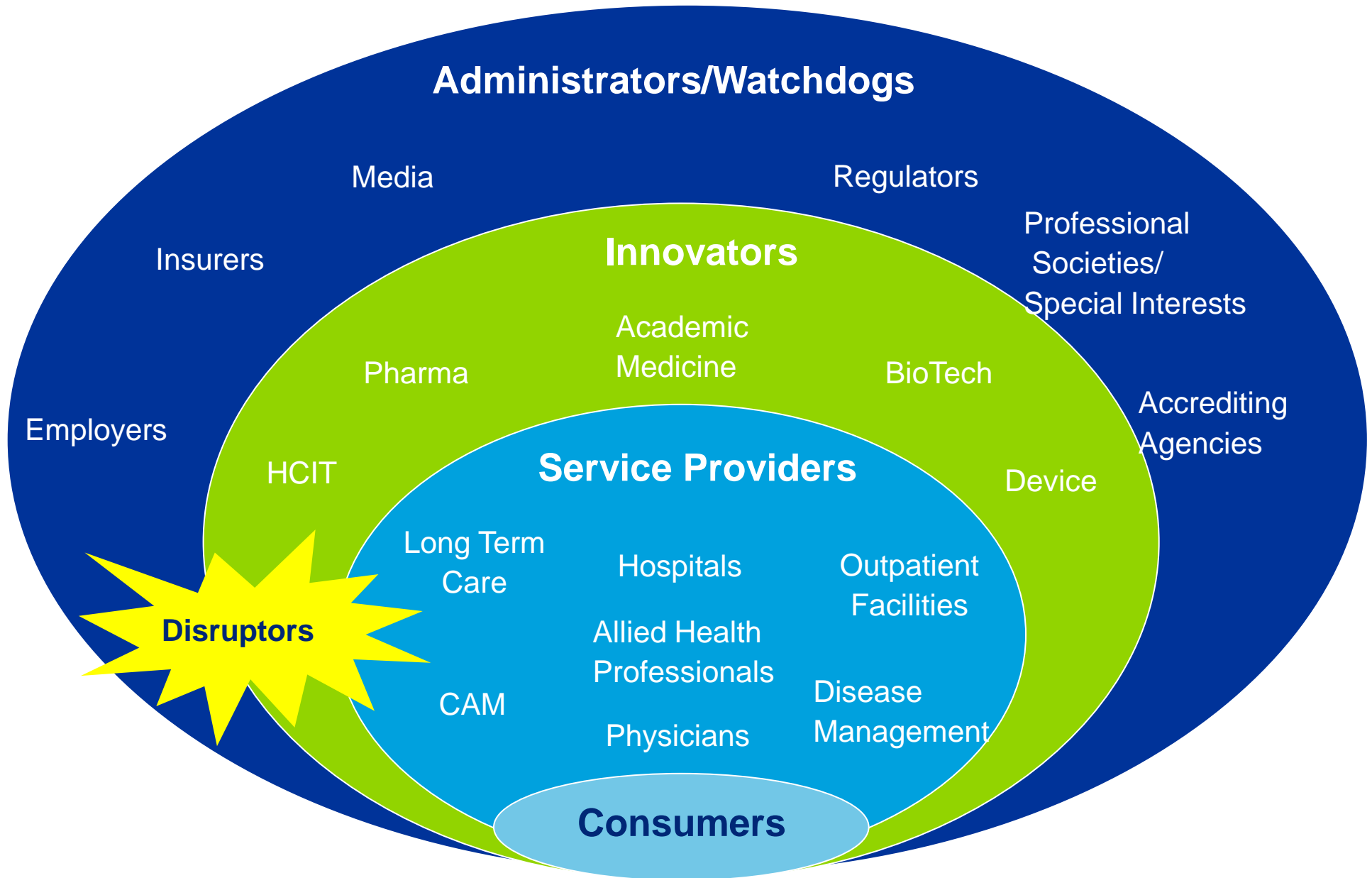
Things to think about now

Polling question 1

What part of the Health Care Ecosystem best represents your area of focus?

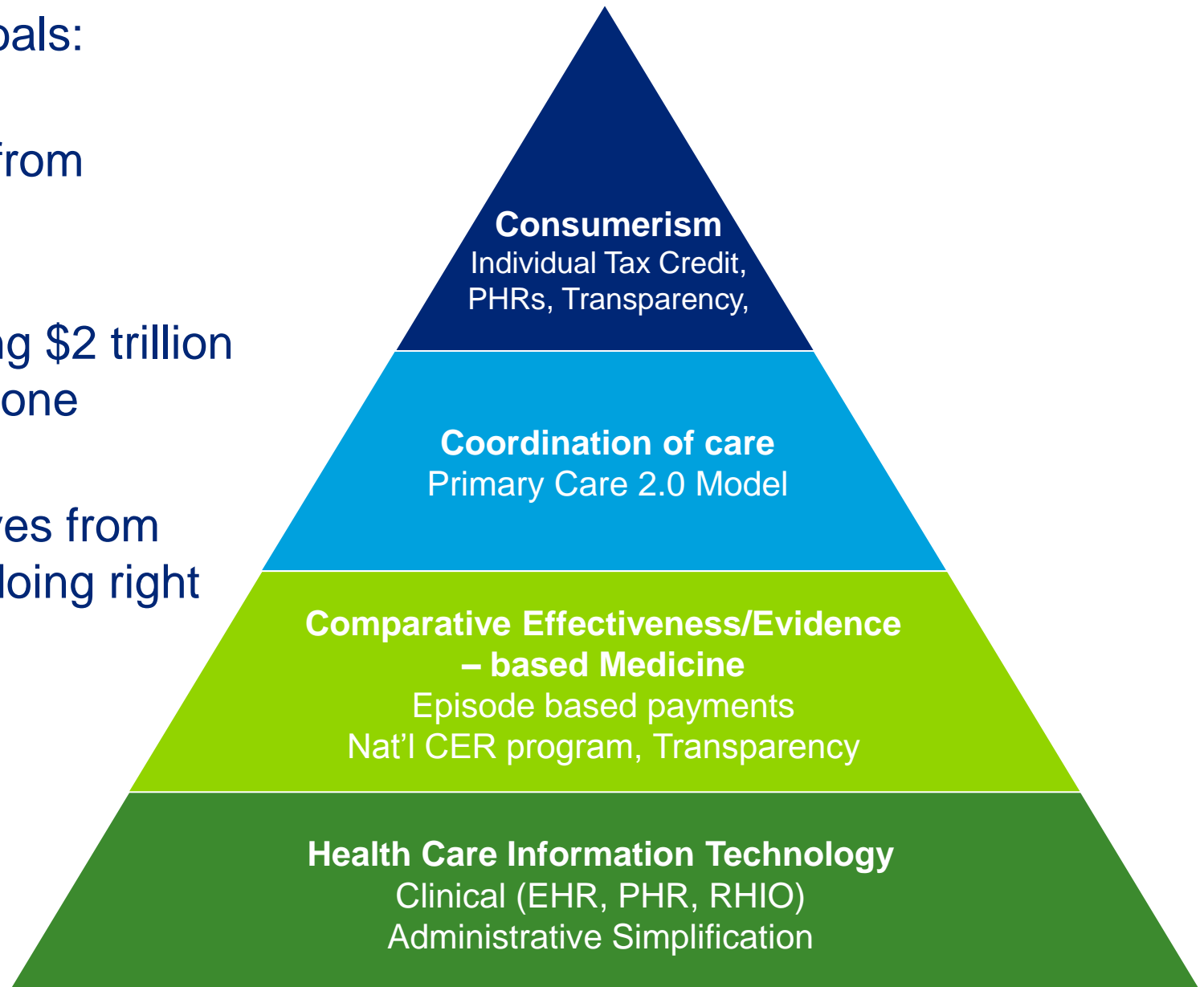
- Drug Company
- Medical Technology/Device Company
- Health Plan
- Health Care Provider
- Government
- Other / Not Applicable

The current system: big, expensive, fragmented



Health reform taking shape: Four major areas

- White House Goals:
- Reduce CAGR from 6.2% to 4.7%
- Reduce spending \$2 trillion and cover everyone
- Change incentives from doing more to doing right things

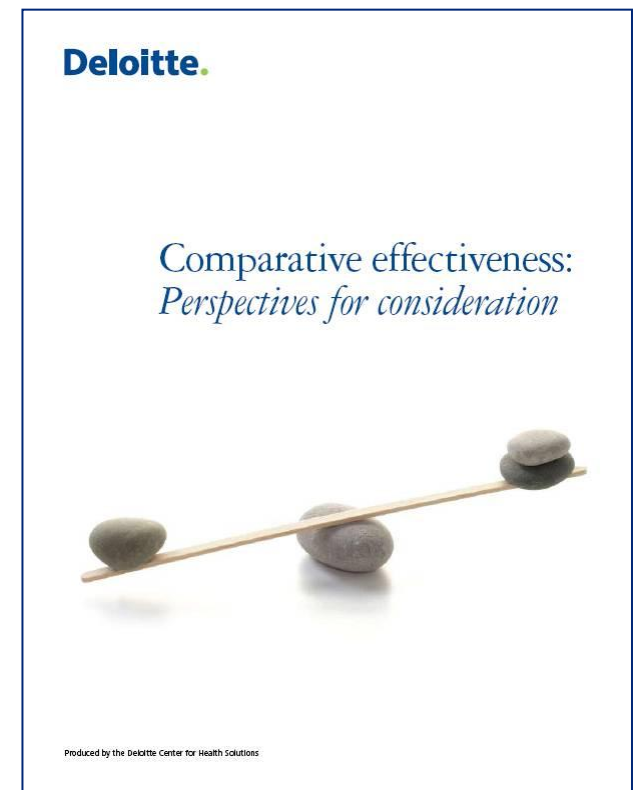


June 9: “Patient Centered Outcomes Research Act of 2009”

- Introduced by Sen. Max Baucus (D-MT) and Sen. Kent Conrad (D-ND) to amend Title XI of Social Security Act and amend IRS Code of 1986
- Creates non-profit organization **Patient Centered Outcomes Research Institute** “to assist **patients, clinicians, purchasers, and policy makers** in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be **prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis** that considers variations in patient sub-populations, and the dissemination of research findings with respect to the relative clinical outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items in subsection (a)(2)(b).

June 30: Federal coordinating council for comparative effectiveness research

- 15 member Council, named in accordance with a Congressionally-mandated timeline, will assist the agencies of the Federal government to coordinate comparative effectiveness and related health services research.
- The Recovery Act authorized funding to support comparative effectiveness research:
 - \$300 million for the Agency for Healthcare Research and Quality
 - \$400 million for the National Institutes of Health,
 - \$400 million for the Secretary of Health and Human Services



June 30: Federal coordinating council for comparative effectiveness research *(continued)*

- “It is critically important to be able to share the results of comparative effectiveness research with doctors and patients and make better investments in how information is disseminated;
- Research should focus on the needs of priority populations such as racial and ethnic minorities, persons with disabilities, persons with multiple chronic conditions, the elderly, and children;
- Research should be in specific high-impact health arenas such as medical and assistive devices, surgical procedures, behavioral interventions and prevention; and
- Investments should be made in data infrastructure such as linking current data sources to enable answering CER questions, development of distributed electronic data networks and partnerships with the private sector.”

Polling question 2:

- Do you believe Congress will pass a health reform bill this fall that includes comparative effectiveness?
- Yes
- No

Key terms and definitions

- **Evidence-Based Medicine:** The application of scientific knowledge to the diagnostic and treatment recommendations that medical professionals make for their patients
- **Clinical Guidelines:** A systematically developed statement for practitioners and patients about appropriate health care for specific clinical circumstances
- **Appropriate and Inappropriate Variation in Clinical Practice:** Appropriate variation would be supported by evidence based practice, e.g. Stage 1 breast cancer patients receiving breast conserving surgery vs. higher Stage breast cancer patients receiving more extensive mastectomy. Inappropriate variation refers to Underuse of Effective Care, Misuse of Preference Sensitive Care, or Overuse of Supply Sensitive Care
- **Evidence Grading:** Evaluation of individual research reports and an assessment of the overall strength of the evidence supporting a particular conclusion or recommendation

What is comparative effectiveness?

There is a lack of a standard definition for Comparative Effectiveness and Comparative Effectiveness Research

Comparative Effectiveness (CE) is “a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients”. “Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy. The analysis may focus only on the relative medical benefits and risks of each option, or it may also weigh both the costs and the benefits of those options.”

- Congressional Budget Office

Research on the Comparative Effectiveness of Medical Treatments, 2007

Comparative Effectiveness Research (CER) involves the conduct, support, or synthesis of research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions. CER studies typically focus on comparing the impact of different options on comprehensive health outcomes, including patient mortality, morbidity, quality of life, and performance of the health system. The overarching goal is to provide better evidence to inform decisions made by patients and clinicians.

- Federal Coordinating Council for Comparative Effectiveness

Source: <http://www.blsmeetings.net/MayFCC/>

CE key points

Although CE is still being defined, several key points emerge:

- Focus is shifting from Efficacy to Effectiveness
- CE compares options within one therapeutic category (e.g., drugs vs. drugs) and between therapeutic categories (e.g., drugs vs. procedures); Comparison expands beyond therapeutics into diagnostics and care delivery
- Whether CE should include cost effectiveness is still controversial, but CE will eventually have an impact on cost

Efficacy vs. Effectiveness

- Efficacy
 - Performance under controlled or ideal conditions
 - Question addressed: Is the intervention better than placebo or doing nothing?
 - Methods: Randomized, controlled clinical trials
- Effectiveness
 - Performance under “real life” practice conditions
 - Question addressed: Does this intervention achieve better health outcome in real-world situation?
 - Methods: “Real-world” clinical trials; observational studies

Comparative Effectiveness shifts the focus for intervention evaluation from efficacy to effectiveness.

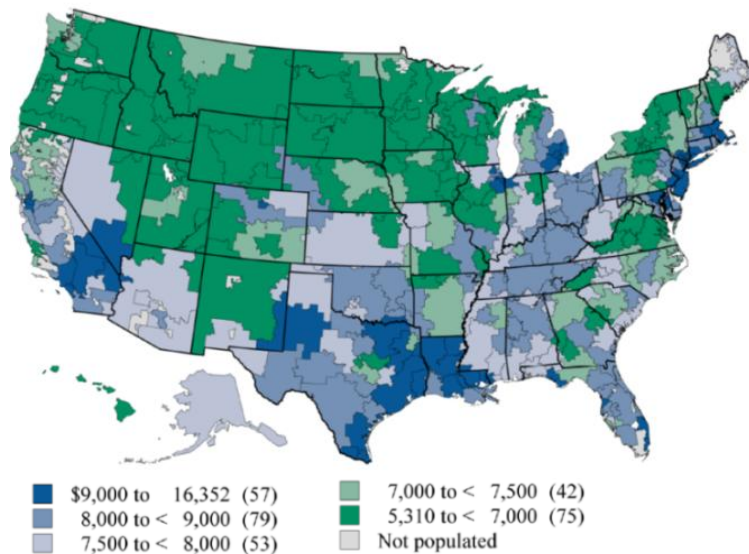
Why Comparative Effectiveness is receiving so much attention?

The increasing variation of medical care and cost and in the U.S. has sparked renewed interest in CE.

High variation of care

- Health care cost and care varies greatly between regions
- High cost does not necessarily correlate with high quality of care; more care doesn't mean better care
- Less than half of all medical care currently provided in the United States is supported by evidence¹

Medicare Spending per Enrolee (2006)²



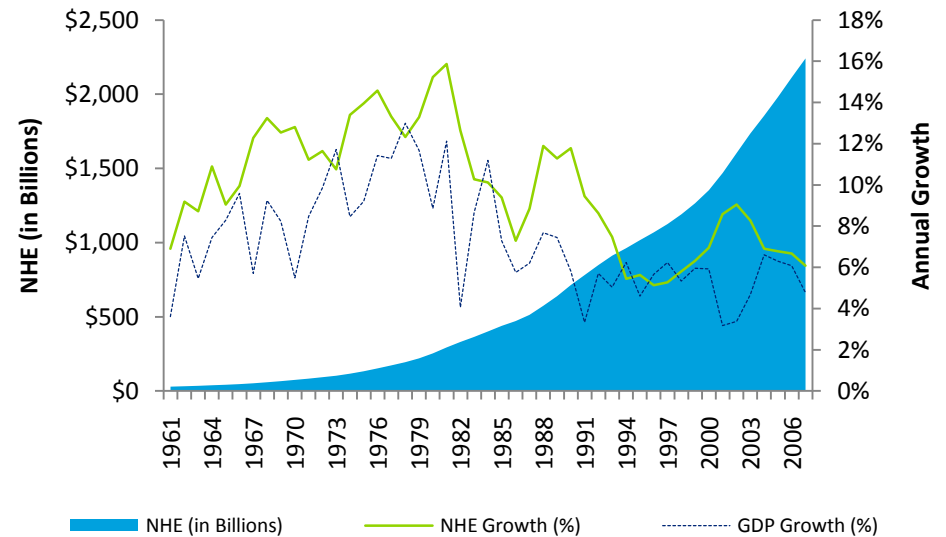
¹ Congressional Budget Office, 2007

² The Dartmouth Atlas of Health Care, 2009

Skyrocketing health care spending

- Health care cost has consistently grown at a rate that is higher than GDP or personal income growth; total health spending as % of GDP grew from 8% in 1975 to 16% in 2007³
- Aging of the population and the coming retirement of the baby boom generation put extra pressure on health care cost

National Health Expenditure: 1961-2007⁴



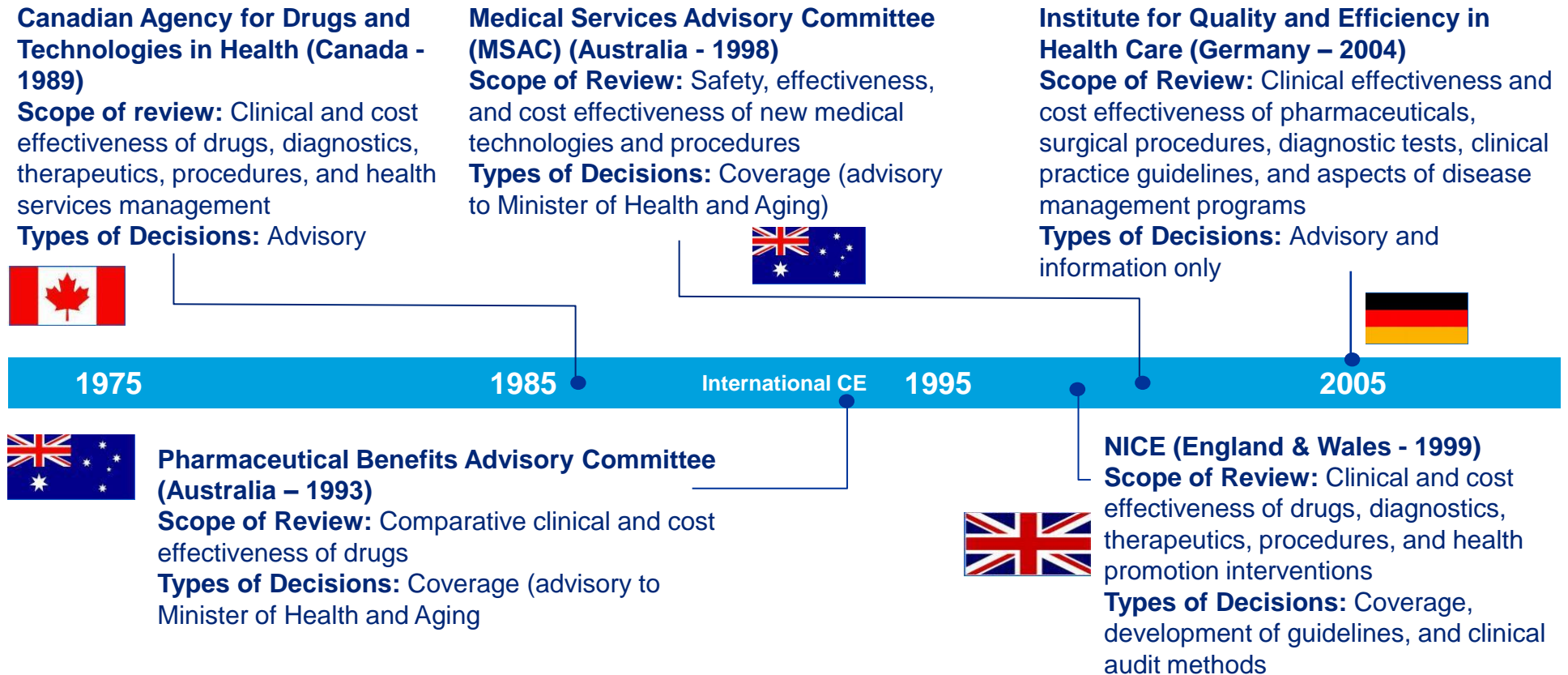
³ Congressional Budget Office, 2007

⁴ CMS

Comparative Effectiveness is a hot topic because it offers the prospect of cutting costs while improving health care quality

CE is used in many developed systems of the world to define “standards of care”

Many developed countries implemented national CE programs prior to the U.S. and use CE findings to shape their health care coverage and payment decisions.

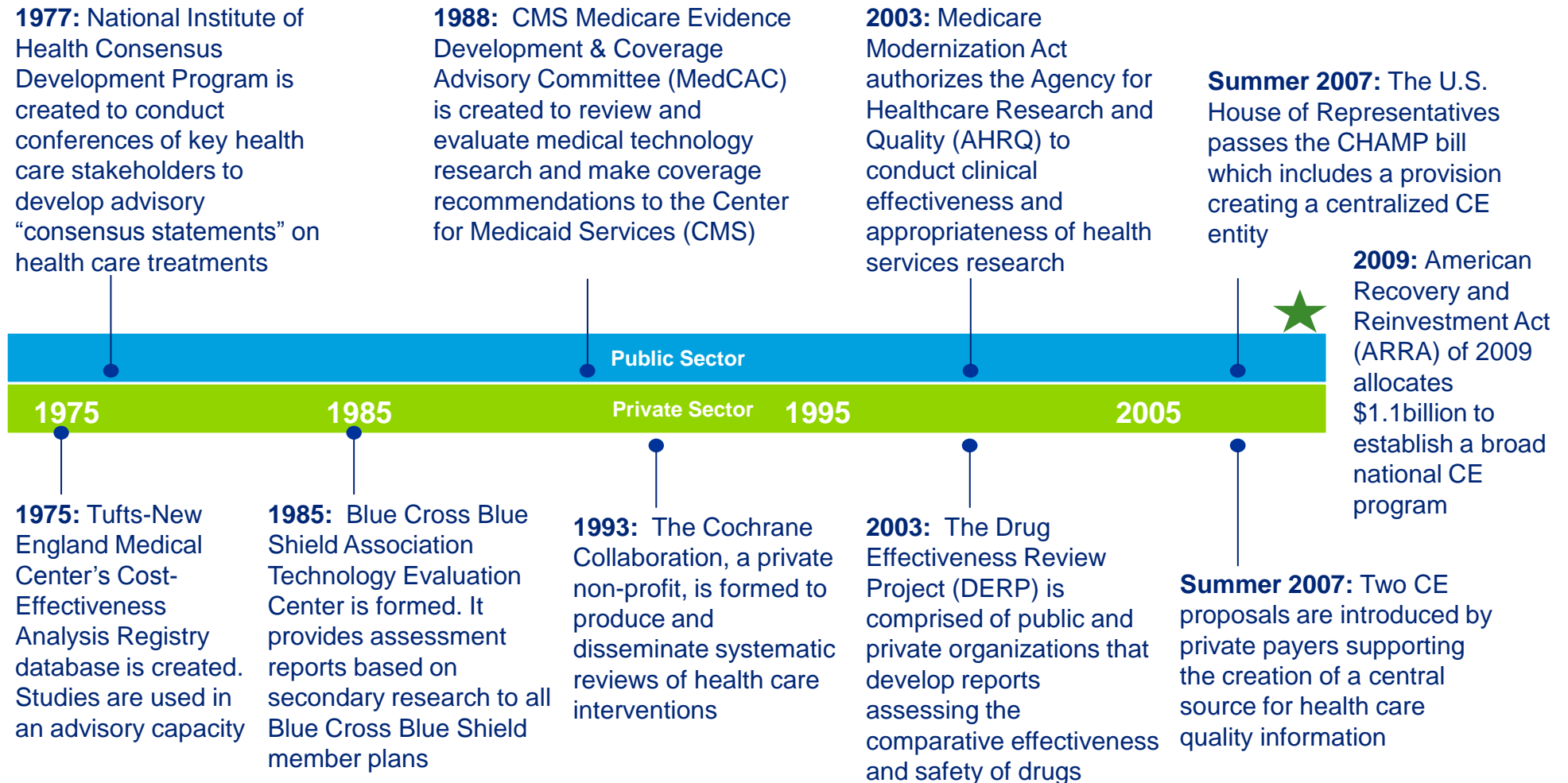


Key Observations

- Countries that have successfully implemented CE have predominantly government-run health care systems
- CE programs in different countries differ in funding, timing, methodology, and conclusions
- The roles of CE agencies range from advisory to coverage decision making, and their decisions are sometimes controversial

CE is a relatively new concept in the US: it is getting attention now in the U.S. because of the funding in the stimulus package

For several decades, fragmented CE programs have been initiated in both the public and private sectors. In recent years, the effort to migrate to a coordinated national CE approach has been a visible agenda item of the federal government.



The CE initiative outlined in ARRA in February, 2009 represents a major step toward a coordinated, national approach to CE in the U.S.

Investment in health system R&D in the US is low compared to others





Although each of the countries described here has different structure and mechanism for health care financing, it is helpful to examine CE investment relative to other metrics.

Metrics	Australia	Canada	Germany	UK	U.S.
Population*	21,007,310	33,212,696	82,369,552	60,943,912	303,824,640
CE Program Funding	NA	\$23.7million	\$19.67million	\$50 million	\$30 million **
Per Capita Expenditure on CE Research Program (US\$)	NA	\$0.71	\$0.23	\$0.82	\$0.10
Per Capita Total Expenditure on Health (US\$)	\$3,181	\$3,419	\$3,628	\$3,064	\$6,350
Per Capita Government Expenditure on Health (% of Total Health Expenditure)	(67.2%)	(70.4%)	(76.6%)	(87.4%)	(45.8%)
Government Health Expenditure as % of Total Government Expenditure	17%	17.5%	17.6%	16.2%	21.8%
Total Health Expenditure % of GDP	8.8%	9.7%	10.7%	8.2%	16.2%
WHO Overall Health System Performance Ranking	32	30	25	18	37

The U.S. health care spending relative to its CE investment is clearly disproportional. To foster success, significant funding for CE is needed.

To better understand how international programs “work” in the real world, we examined examples of CE across four national programs

Four national CE programs evaluated two interventions (the use of statins for treatment of elevated cholesterol and a surgical treatment of benign prostatic hyperplasia (BPH)) for different reasons and came to differing conclusions.

Studies	Canada 	Australia 	UK 	Germany 
Treatment of hypercholesterolemia with statin drugs	<p>Reason: Uncertainty in statin role in CVD risk</p> <p>Result: No evidence that one statin was more effective than another in decreasing CVD risk</p>	<p>Reason: New statin application request (rosuvastatin)</p> <p>Result: Rosuvastatin not worse in therapeutic effect than atorvastatin</p>	<p>Reason: Uncertainty on statin role of prevention of CVD</p> <p>Result: No evidence that one statin was more effective than another in reducing CVD events</p>	<p>Reason: Controversy about superiority claims of one statin</p> <p>Result: There was insufficient evidence to compare the effectiveness of the statins with each other</p>
Surgical methods for treating BPH	<p>Reason: Approval for new laser device (Photoselective vaporization of the prostate, PVP) requested by manufacturer</p> <p>Result: PVP not a substitute for TURP (Transurethral Resection of the Prostate). RCTs and longer-duration studies are required</p>	<p>Reason: Assess safety, effectiveness and cost effectiveness of the Transurethral Needle Ablation (TUNA) procedure</p> <p>Result: Long-term effectiveness of TUNA is not supported by sufficient evidence. TUNA received interim restricted funding</p>	<p>Reason: Make recommendations on safety and efficacy of laparoscopic prostatectomy</p> <p>Result: Laparoscopic prostatectomy should only be used when TURP is contraindicated</p>	<p>Reason: Test assumption that “minimally invasive” procedures are more effective than TURP</p> <p>Result: TURP has the strongest long-term effects on reducing BPH symptoms. Some alternatives may provide better short-term results</p>

Deloitte Center for Health Solutions, 2009

Decisions from each country’s program can reflect the medical treatment practices and norms of that country. Therefore, different conclusions can often be drawn from similar data sets.

Health sciences knowledge and medical evidence is exploding

The health care knowledge pool is comprised of articles, studies, and analyses that vary in the methodology, number of subjects, specificity, and bias of influence. Despite a large pool of knowledge, the U.S. has not determined how to effectively use it.

Hierarchy of evidence



Abundance of Knowledge on-hand

- There are 20,000 biomedical journals
- Greater than 150,000 medical articles are published each month
- Greater than 300,000 randomized controlled have been conducted
- GENBANK contains 25 million DNA sequences, 40+ billion DNA base pairs,

“We are drowning in information, but starved for knowledge”

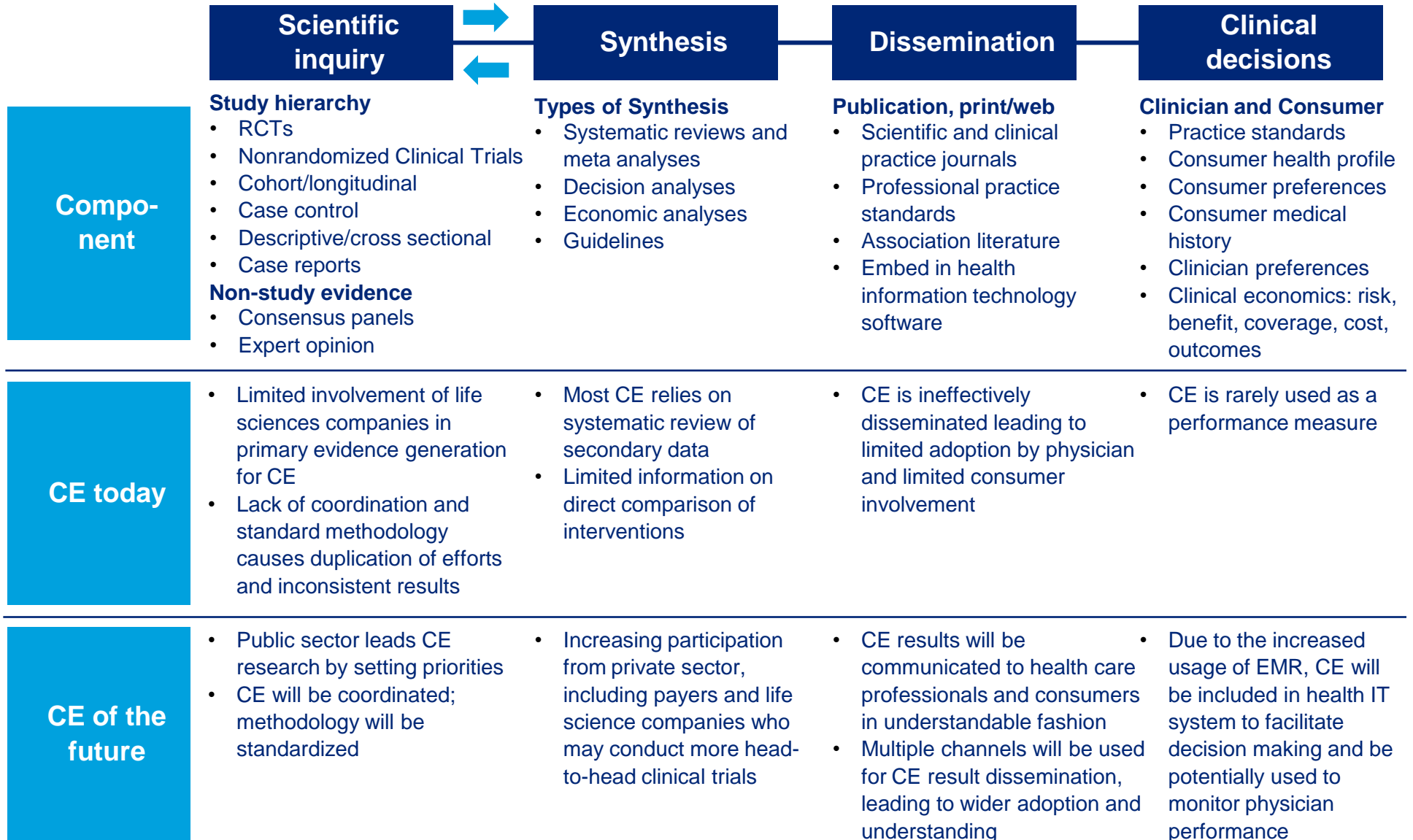
-John Naisbitt, 1982

Author of the Best Seller *Megatrends*

The decision on which types of evidence to focus on for U.S. CE will drive many of the downstream effects and contribute to the controversy surrounding the legislation.

The development, implementation, and management of a US CE program represents a major ongoing investment

The approach developed by the Federal Coordinating Council for Comparative Effectiveness Research and subsequent owners will determine decisions on approach for each major part of the CE process.



Why the fuss?

While the concept of Comparative Effectiveness looks simple on the surface, its implementation raises many questions and fears.

Questions

- Will cost effectiveness be part of CE?
- Who will set the priorities for CE, and how?
- When will a new intervention be subject to CE, prior to market approval or after certain period of clinical application?
- What research methods will be used?
- Who will be responsible for generating CE evidence?
- How will CE results be used?
- How will CE impact personalized medicine?

CE legislation would create “a permanent government rationing board prescribing care instead of doctors and patients.”

-Tom Price (R-GA)

Fears

- CE will be used to deny access to expensive treatments
- U.S. will create a model similar to NICE in the UK to ration health care
- CE will stifle innovation
- CE will not account for variations in subpopulations and create “cook-book medicine”

“I think there’s been some concern that the ultimate outcome could be perceived by someone as a giant thumbs up or giant thumbs down on a particular service. In fact, we find that that’s rarely the case....”; “We think the reports actually...help clinicians and health care organizations refine the process of identifying more rapidly which patients are most likely to benefit from particular services, so that access to effective treatments is actually maximized.”

- Carolyn Clancy (head of ARHQ)

The newly appointed Federal Coordinating Council for Comparative Effectiveness Research will coordinate CE while addressing the controversies along the way

How these questions and fears about CE get addressed will impact the speed and scope of its adoption

If widely adopted, CE will provide the information needed for Evidence-Based Medicine - the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of the individual patient.

Extension of status quo

Evidence-Based Medicine 

Key Driver	Limited CE Adoption	Moderate CE Adoption	Wide CE Adoption
Government Push	Government role limited to conducting CE and does not enforce the application of CE for clinical and payment decisions	Government encourages and incentivizes the application of CE in public health care system	Government mandates the application of CE findings for treatment and coverage decisions in the public health care system
Goal of CE	CE strictly focuses on clinical effectiveness only; cost effectiveness is excluded from study; no clinical guidelines issued	Primarily focus on clinical effectiveness; some cost effectiveness studies conducted; clinical guidelines may be issued, but not as recommendations	CE covers both clinical effectiveness and cost effectiveness; clinical guidelines are issued and recommended by CE agencies
Scope	Focus on product comparison within same treatment option only (e.g., drug vs. drug)	Primarily focus on product comparison within one treatment option; some comparison between different treatment options (e.g., drug vs. surgery)	Compare products within same treatment option AND compare different treatment options; comparison expands beyond treatments to diagnostics and care delivery
Research Method	Exclusively rely on examining existing evidence (e.g., literature review, claims record /EMR data analysis)	Primarily rely on examining existing evidence; new evidence generated in limited cases	Rely on both new and existing evidence. New evidence will be generated (e.g., clinical trial) when existing evidence is insufficient
Technology	Limited implementation of health IT; low adoption of EMR; performance tracking rejected by physicians	HIT gained acceptance, but implementation level varies; EMR data used for CE; physician/provider performance tracking is resisted	Wide adoption of Health IT system; CE module built into HIT; EMR data used for CE; physician/provider performance tracked and disclosed

Polling question 3:

Do you believe the Comparative Effectiveness program implemented in health reform will be designed for

- Limited adoption
- Moderate adoption
- Widespread adoption

CE will impact every major sector

Major Reforms	Providers	Health Plans	Biotech & Pharma	Medical Device	Employers
Comparative Effectiveness	●	●	●	●	●
Episode-based Payments	●	●	●	●	●
Employer Pay or Play Mandate	●	●	●	●	●
Importation of Prescription Drugs	●	●	●	●	●
Individual Mandates	●	●	●	●	●
Insurance Exchange	●	●	●	●	●
Primary Care Expansion (Medical Home)	●	●	●	●	●
Public Plan	●	●	●	●	●
Tax Credit from Employers to Individuals	●	●	●	●	●

● Modest
 ● Moderate impact
 ● Significant impact

The adoption of CE will impact all stakeholders in the health care system

Stakeholder	High-Level Potential Impact
Consumers / Patients	<ul style="list-style-type: none"> • Consumer-friendly CE information on alternative treatments allows more consumers to make informed clinical decisions • Consumers will demand more decision support tools and coaching to better leverage CE information • CE can potentially help consumers reduce out-of-pocket health care spending; however, CE, if used as a tool to ration care, may restrict consumer access to certain care
Life Sciences Companies	<ul style="list-style-type: none"> • The bar for innovation is raised and CE discourages “me-too” products; rewards for truly breakthrough innovations may be greater • CE may encourages innovation beyond therapeutics into diagnostics and preventative interventions • CE will pressure companies to seek truly breakthrough innovations and provide more CE evidence, potentially increasing R&D risk and cost • Increased emphasis on CE increases the hurdle for product adoption and may force companies to adopt new commercialization models • CE will likely lead to increased utilization of generics if branded products can’t be proven to be more effective
Physicians / Hospitals	<ul style="list-style-type: none"> • Accurate, relevant clinical effectiveness information available at the point of care improves quality and efficiency of care and may reduce avoidable errors and spur demand for electronic medical records • If used as rule rather than a tool, CE may penalize deviations from standards of care, potentially discouraging personalized care
Private Health Plans	<ul style="list-style-type: none"> • Timely, comprehensive effectiveness data can be used as basis for coverage and payment decisions to encourage adoption of most valuable treatments • CE information might be available too late to be relevant, and premature adoption of CE may lead to legal backlashes
Employers	<ul style="list-style-type: none"> • A Pay-or-Play mandate will likely include a set of plan choices to which adherence to CE program recommendations will be key • CE efforts will take time to develop and implement; employers will be able to align plan design with provider adherence to evidence based practices
Government Health Plans	<ul style="list-style-type: none"> • Medicare and Medicaid can lead wide adoption of CE into clinical decision making to improve outcomes and reduce cost • CE, if perceived as a tool to ration care, may cause backlash from public plan enrollees

BioPharma Impact Analysis

Function	Potential Impact	Questions to Address
Discovery	<ul style="list-style-type: none"> • The search for breakthrough innovations leads to higher risk and lower throughput • L&A or M&A may be required to bolster innovation in early stage pipelines 	<ul style="list-style-type: none"> • How will the market define “breakthrough innovation”? • How do our research priorities align to national priorities and/or truly unmet needs? • How do we build in “CE-risk” into the discovery portfolio management approach?
Development	<ul style="list-style-type: none"> • CE will pressure companies to generate and provide more comparative effectiveness data • CE is likely to drive demand for increased transparency of clinical data • Burden to produce CE evidence will increase development cost and force companies to be more selective in pipeline decisions • CE expands innovation scope beyond therapeutics into diagnostics and preventative interventions, creating opportunities for BioPharma companies • CE may accelerate the development of personalized medicine 	<ul style="list-style-type: none"> • How to meet the increased demand for CE information and at the same time increase speed to market? • Whether and how to conduct risky and expensive head-to-head trials? • How to evaluate product portfolio and make go/ no-go decisions to properly manage pipeline? • Whether and how to expand business scope beyond therapeutic drugs? • How to collaborate with payers in the development phase to ensure that studies address relevant questions and comparators?
Commercialization	<ul style="list-style-type: none"> • FDA approval alone may be insufficient for market adoption • Product adoption and sales increasingly depend on clinical effectiveness and health outcomes • Payers may use CE data in price negotiation • Truly innovative products command premium pricing and leap frog the competition • CE may encourage usage of generics and biosimilars 	<ul style="list-style-type: none"> • How to conduct post-approval CE, esp. with the increased usage of electronic health record? • How to accelerate the adoption of new commercial models, which rely more on clinical expertise and less on physician detailing? • How to implement value-based contracting? • What is the right generic strategy?

Medical Device / Diagnostic Impact Analysis

Function	Potential Impact	Questions to Address
Research & Development	<ul style="list-style-type: none"> • The search for breakthrough innovations may lead to higher risk and lower throughput • L&A or M&A may be required to bolster pipeline, and will likely emphasize technology platform • CE will pressure companies to generate and provide more comparative effectiveness data • Burden to produce CE evidence will increase development cost and force companies to be more selective in pipeline decisions • CE may accelerate the development of companion diagnostics which may be accelerated as Biopharma develops more targeted therapies • CE likely to drive demand for increased transparency of clinical data 	<ul style="list-style-type: none"> • How to screen R&D or L&A/M&A targets and manage risk? • How to meet the increased demand for CE information and at the same time increase speed to market? • Whether and how to conduct risky and expensive head-to-head trials? • How to evaluate product portfolio and make go/ no-go decisions to properly manage pipeline? • Whether and how to partner with others to accelerate the development of personalized medicine or combination products? • How to collaborate with payers in the development phase to ensure that studies address relevant questions and comparators (“design for reimbursement”)?
Commercialization	<ul style="list-style-type: none"> • FDA approval alone may be insufficient for market adoption • CE may accelerate the shifting of power from “clinical buyer” to “economic buyer” of medical devices • Payers may use CE data in price negotiation • Truly innovative products command premium pricing and leap frog the competition 	<ul style="list-style-type: none"> • How to harvest post market data to meet payer/provider evidence requirements? • How to develop medical affairs function in the context of CE? • How to accelerate the adoption of new commercial models which rely more on economic buyers than clinical buyers? • How will pricing and contracting strategy change?

Life sciences companies should closely monitor the development of CE and approach CE proactively

What to Watch for

- Research priorities for CE released by Institute of Medicine
- FDA policy change regarding approval criteria, esp. head-to-head clinical trials
- Policy change by CMS regarding the usage of CE in coverage, payment decisions, and clinical guidelines
- Government policy regarding allowing government health agencies to directly negotiate drug prices with manufacturers
- Government policy regarding generic and biosimilar drugs

Actions to Consider

- Brutally honest product portfolio assessment to determine impact of CE on the value, competitiveness of the portfolio
- Re-examine appropriate portfolio mix (highly innovative, me-too, generic, etc); weed pipeline and allocate resources to high value targets
- Review pipeline decision making process to enhance opportunity & risk analysis and screen for breakthrough innovations
- Map the influence shift of different stakeholders under CE framework
- Involve relevant stakeholders in modifying clinical study design to meet the demand for more health outcomes and economics information
- Rethink commercialization model, including sales, contracting, pricing, payer strategy etc.

Health care providers should closely monitor the development of CE and prepare for its adoption

What to Watch for

- Research agenda for CE and prioritization of disease conditions to be addressed
- Publication schedule and timeline for results of CE
- Payers, including CMS, incorporating CE into reimbursement policies
- Publication of “scores” of providers based on their compliance of CE guidelines
- Payment policies related to deviations from care guidelines

Actions to Consider

- Implement technology to support providers delivery of care based on latest CE
- Develop a process acceptable to payers for reimbursement for care delivery when it appropriately does not follow CE based guidelines
- Adopt clinical practices based on CE early
- Ensure that proper clinical documentation is in place to justify any deviation from CE
- Participate in CE as a research site

Health plans should closely monitor the development of CE and prepare to capture the potential opportunities it brings

What to Watch for

- Government
 - When and how will cost metrics and considerations be included in CE methodology?
- Plans/PBM
 - Use of CE by payers to reduce or level medical trends
- Patients/Individuals
 - Use of CE to improve decision making and change behavior

Actions to Consider

- Provide education and promotion of CE principles to key stakeholders
- Develop creative and mitigating strategies to reduce IT and administrative cost impact
- Evaluate potential changes and refinements to provider contracts, networks, and relationships
- Analyze potential impact to formulary design, structure and governance
- Educate and discuss with employers potential impact to ERISA rules and benefit programs
- Consider new product suite/platform for a two-tier market place

All stakeholders should carefully watch the moves of the Federal Government...the nexus of CE activity

What to Watch for

- How will the Federal Coordinating Council for Comparative Effectiveness Research disperse funds to Federal Agencies to conduct CE?
- What will the new reporting requirements be for research activities?
- How will studies impact preferred therapeutic approaches for plans, providers, and consumers?
- What will be the Council's approach to grants management and overall coordination of CE?
- Will there be an emergence of a public private partnership as a long-term model for CE in the US?
- What are the relative priorities of research questions?

Actions to Consider

- Enhance grants management capabilities to improve the efficiency of studies
- Improve the dissemination of CE results with consumer communication portals and clinician tools
- Develop coordination approaches and services to help NIH Institutes and Federal Health Agencies collaborate in research
- Support VA, DoD, and IHS leverage their EHRs to make CE more cost effective and expeditious
- Develop a long-term sustainability model for CE
- Identify a suitable future organizational model (e.g., public private partnership) that promotes transparency and consumer trust

Polling question 4:

- In which sector of health care do you believe comparative effectiveness will have the most disruptive impact:
 - Providers (physicians, hospitals)
 - Health plans
 - BioPharma companies
 - Medical Device/Diagnostic companies
 - Federal Health Agencies
 - Consumers

Key takeaways

- Comparative effectiveness (CE) is one of the most disruptive components of health reform
- CE is complex, and it is still being shaped by policy makers
- Despite the controversies about cost effectiveness, CE will certainly have an impact on cost; it's not a matter of whether; it's a matter of when
- Multiple factors will influence the scope and adoption of CE
- CE implementation creates both challenges and opportunities for the health care industry
- CE calls for reexamination of business models for the health care industry; to get ahead, stakeholders should approach CE proactively, rather than defensively

Questions & Answers

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