



REIMBURSEMENT &
HEALTHCARE ECONOMICS
enabling patient access to care



ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Pursuit of Value for Medical Devices: Strategies for Collaboration

Comparative Effectiveness & Evaluation for Medical Devices

May 22, 2008
IHA Conference

Comparative effectiveness

- Comparative effectiveness research is gaining popularity as a potentially significant cost saving tool.
- Many question linger regarding how this information should be gathered and used.
 - What should a comparative effectiveness entity look like- government agency, private entity, or a public-private partnership
 - How to ensure independence from political and industry pressure
 - Should these studies look only at clinical efficacy or also consider the monetary cost of various treatments
 - How would and should this research effect coverage determinations
 - How would research priorities be established
 - Where would the funding for this research come from- should it be entirely government funded or should there be user fees.

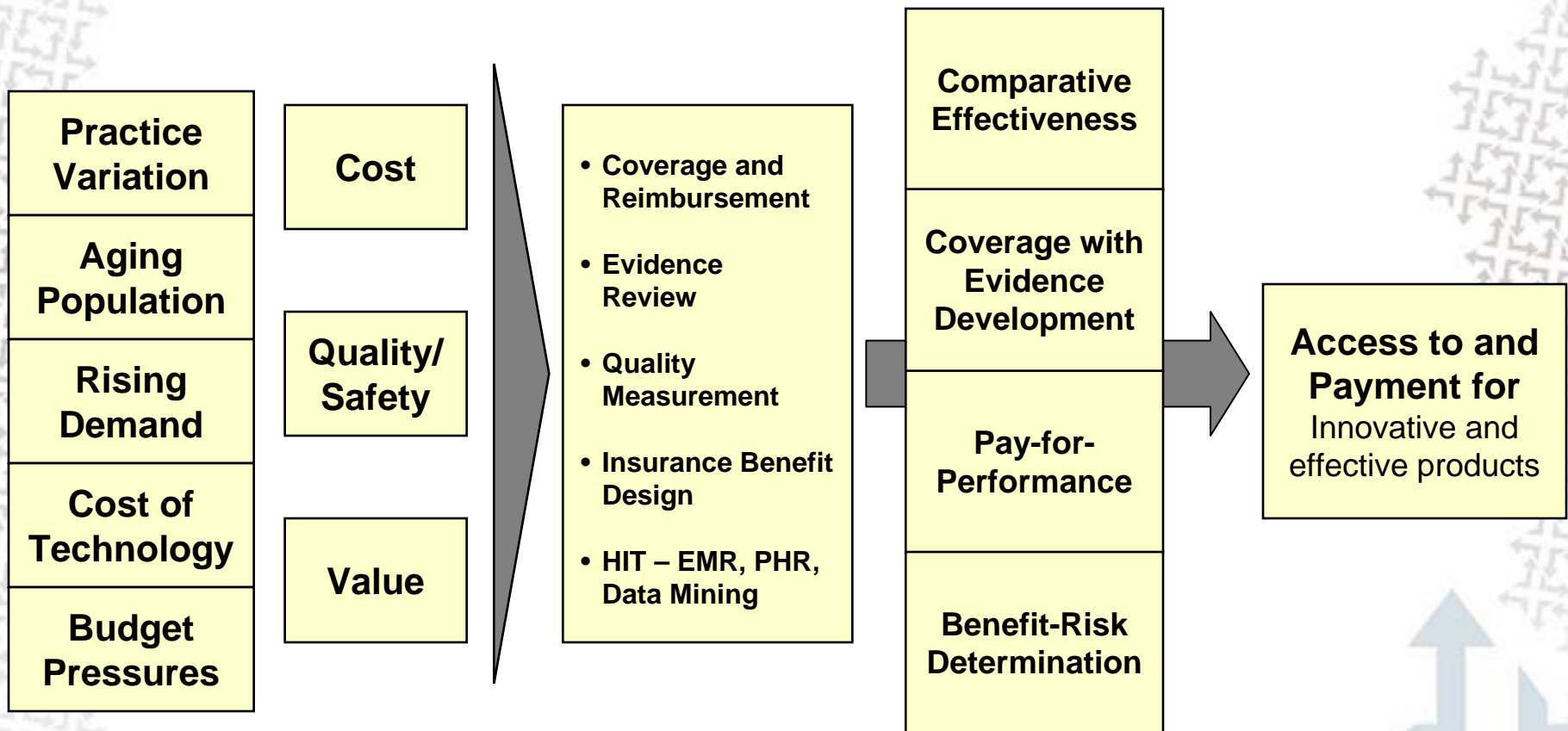
Evolving Environment

Challenges

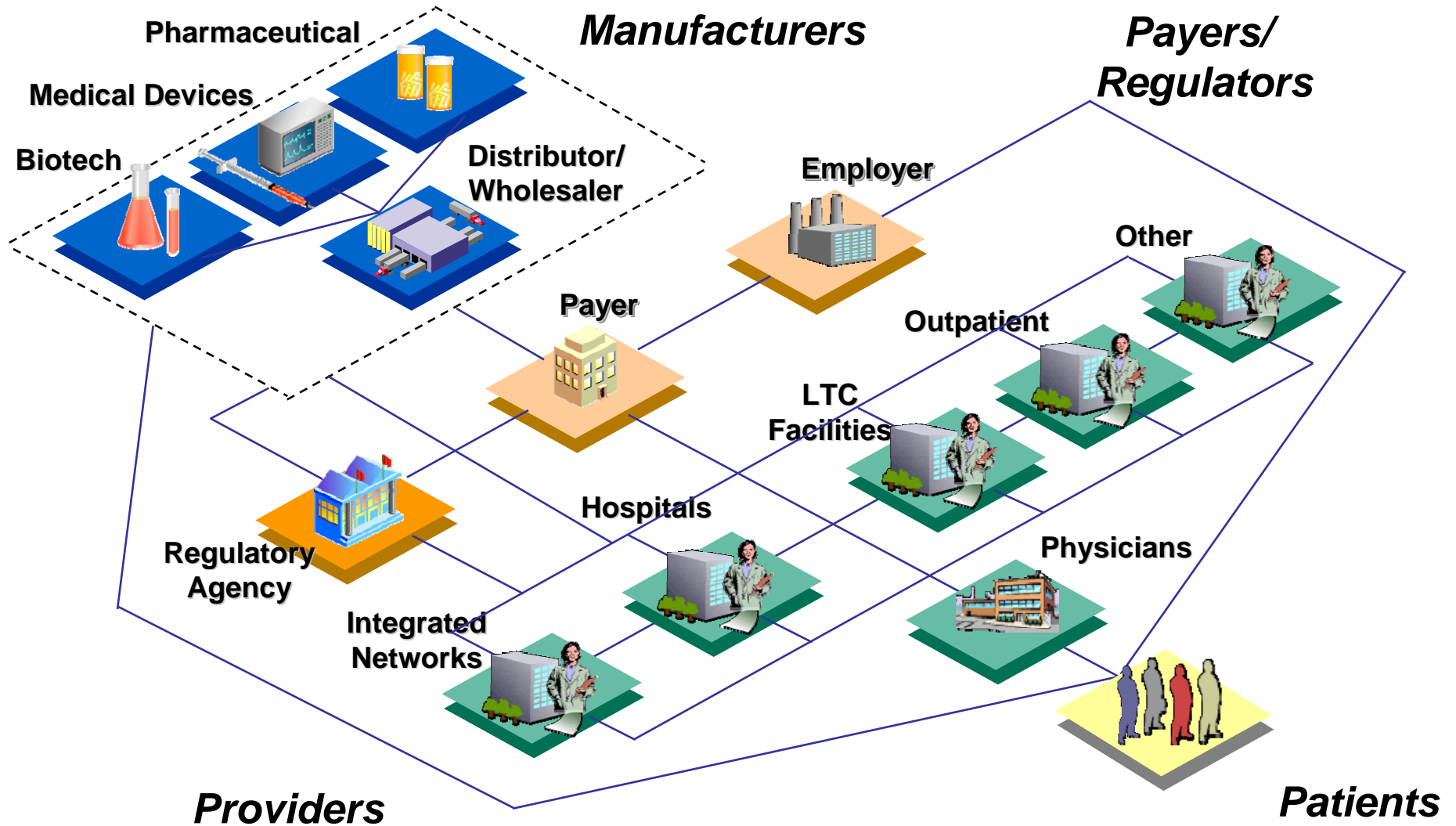
Drivers

Activities

Policies

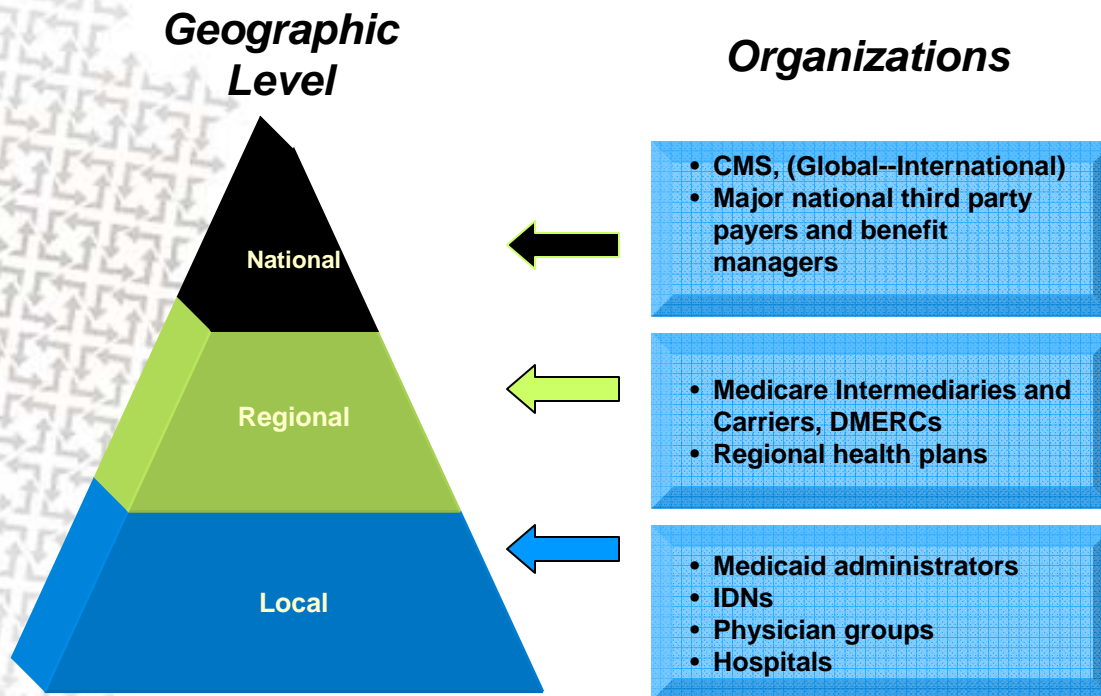


Healthcare Stakeholders



Evidence Demands

Decision-Making Occurs at Multiple Levels



- 8,000 private payers in the US
 - Contracts negotiated with “Providers”
 - Providers negotiate with doctors, hospitals, suppliers, pharmacies, hospitals that own doctors, etc.
- So, where do you target to show the value of your technology? Value to whom? Primary audience?

Comparative Effectiveness

- MedPAC
 - June 2007 Report to Congress – recommended that Congress charge an independent entity to sponsor credible research on comparative effectiveness of health care services and disseminate this information to patients, providers, and public and private payers
 - March 2008 Meeting – identified three possible models for a comparative effectiveness entity
 - June 2008 Report to Congress – will focus on the structure of a potential comparative effectiveness entity

Legislative Proposals

2007: House passed “CHAMP” bill contained provisions creating funding for comparative effectiveness research

2008: Senate Finance Committee “draft” introduced and pulled back comparative effectiveness research legislation

Comparative Effectiveness

- Congress
 - Senators Max Baucus (D-MT) and Kent Conrad (D-ND) introduced a bill on March 4, only to withdraw it with intentions to revise the proposal
 - The proposal would:
 - Require the U.S. Comptroller General to submit a report to Congress on Medicare's coverage determination process
 - Establish a Comparative Effectiveness Research Institute
 - report to Congress every February
 - provide policy recommendations after 5 years
 - draft research priorities

House “CHAMP” vs. Senate Draft

	HOUSE “CHAMP”	SENATE DRAFT
Comparative Clinical Effectiveness?	YES	YES
Cost Effective?	“Value”	Cost effectiveness methods report
Restrictions on Use of Findings?	None	No coverage decisions, policy recommendations, clinical guidelines
Manufacturers as Stakeholders?	No	Yes

Key Questions about Products

- Does it work? Is it safe?
 - Regulatory Approval
 - Relevant for covered population (i.e. Medicare over 65y)
- When should it be used? Who will most benefit?
 - Appropriateness guidelines
 - Patient selection criteria
- How does it compare? Is it definitively better?
 - Earlier generation of technology
 - Within same class of technology
 - Rigor of comparative reviews
- What is the value? Can the value be captured?
 - Capturing costs over time?
 - Is there an ROI? When? To Whom?

Evidence Challenges

- Availability of evidence
 - Needs for evidence are increasing
 - Large gaps in the existing literature
 - Limited generalizability of trials data to real-world practice
 - Unique challenges of devices
 - Distinguishing operator vs. product effects
 - Short product life-cycles
 - Feasibility of RCTs
 - Transactional data-bases (claims data)
- Conclusions from the evidence
 - Reconciling “average” population effects with individual effects
 - “Shelf-life” of evidence
- Practical use of evidence
 - Application of evidence to real-world medical decisions
 - Provider “accountability” for using evidence

Comparative Effectiveness

- What is J&J's position on comparative effectiveness?
 - Help establish the value of treatments
 - Promote a more quality-focused cost-effective health system
 - Help physicians and patients make better decisions
 - Be a way for manufacturers to differentiate innovative products
 - However, it is not the “silver bullet” as it will not automatically solve our cost and quality challenges
- How should information from CE research be used?
 - Should inform medical decisions, not replace medical judgment with treatment formulas
 - Will need to reconcile “average” population effects and with impacts on individuals that reflect differences in side effects, intolerance, noncompliance, and quality of life

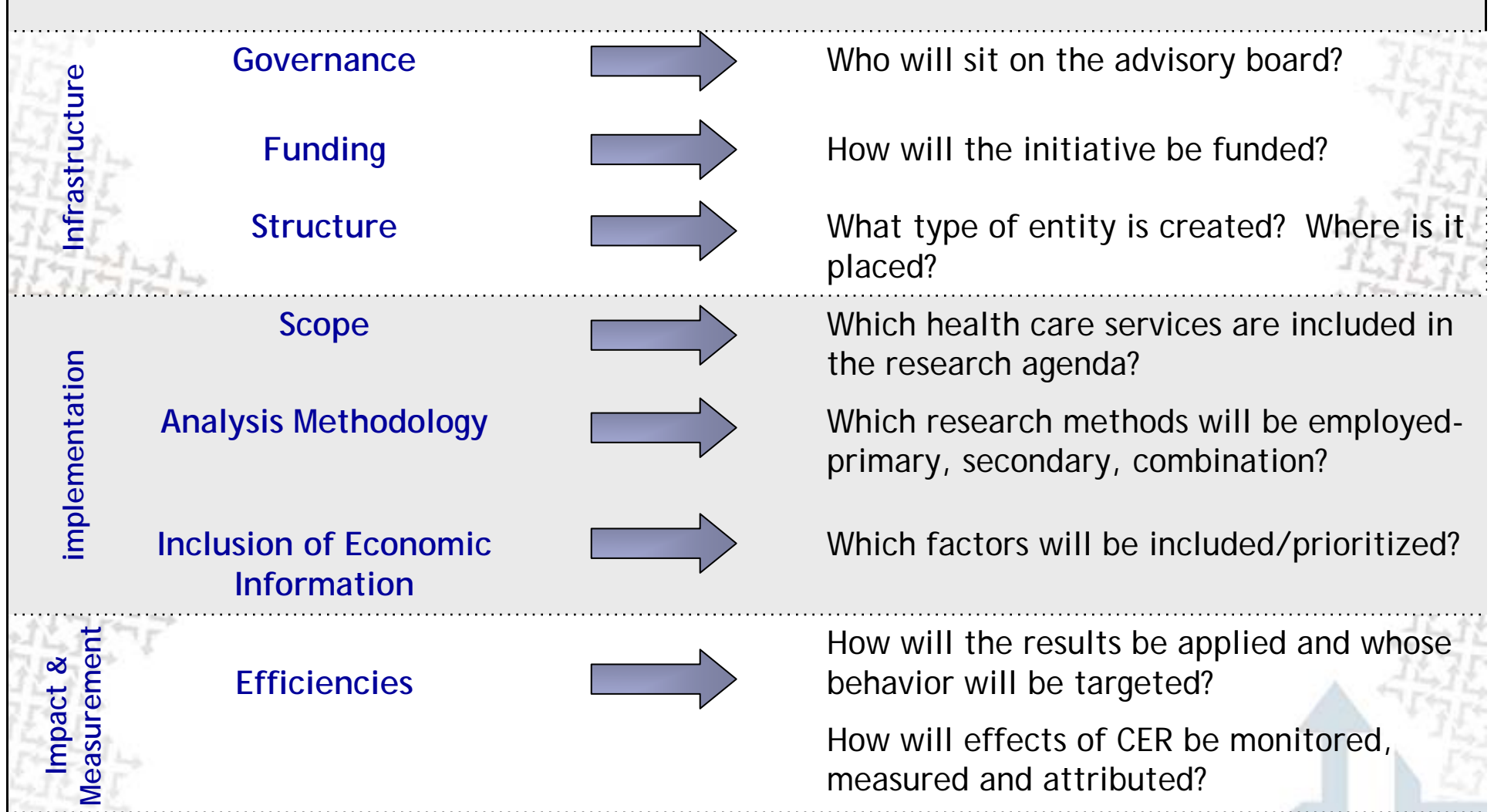
Comparative Effectiveness

- How should it be linked to coverage decisions by payers?
 - Should not serve the cost containment concerns of payers
 - Might be most useful in informing treatment options and assigning appropriate reimbursement premiums
- How should this information be communicated?
 - Share widely with all stakeholders, particularly providers and patients
 - Consider the dangers of incomplete understanding of results, particularly when communicated in an overly simplistic manner
 - Acknowledge that CE information can be incomplete, misleading, or misinterpreted
- How should stakeholders be involved?
 - Participate in framing the methods that will be used and prioritizing the key therapeutic areas
 - Promote transparency about the processes, findings, limitations, and appropriate uses of the information

A Few Suggestions

- Definitions
 - Comparison of “what to what”
 - Treatment options / gold standard / defined by whom?
 - What will success look like – information availability vs. impact on care delivery
- Scope
 - Clinical decision dilemmas vs. population economics
 - Synthesis of current evidence vs. initiating new comparative research
- Funding
 - Commitment to conduct adequately powered studies
 - Distance from payment authorities
- Stakeholders
 - Genuine involvement with priority setting, methods review and communication approaches

Design Characteristics Drive Impact of CEDR Proposals



Device and Drug Distinctions

<u>Characteristics</u>	<u>Drug</u>	<u>Device</u>
<i>Separating efficacy of procedure from efficacy of device</i>	Not relevant	High influence
<i>Influence of MD technique on outcomes</i>	Low influence	High influence
<i>Product life cycles</i>	Long development, long patent life	Short development, rapid obsolescence
<i>Placebo controlled trials</i>	High influence	Difficult, very challenging
<i>Recruitment for trials</i>	Large potential pool	Usually limited numbers
<i>Comparative evidence</i>	Widely available	Limited comparator data
<i>End user</i>	Patient	Physician

Opportunities and Challenges

- Opportunities:
 - Transition from “evidence-based decision-making” to a “learning healthcare system”, where evidence continuously refreshes and informs
 - Real world data on how the product is used in clinical practice
 - Support informed decision-making by providers and patients
 - Demonstrate the value proposition to payers
 - Identify quality, safety and utilization issues
- Challenges:
 - Limitations of observational data
 - Costs of supporting high-quality data collection and analysis
 - Inconsistent technical standards for the use of post-approval data
 - Addressing heterogeneity of effects
 - Unique device considerations

Example

- Bariatric Surgery
 - Clinical data demonstrating value
 - Dixon, John B and Paul O'Brien, Adjustable Gastric Banding & Conventional Therapy for T2D, JAMA. 2008; 29 (3): 316-323
 - Adams TD and others, Long-Term Mortality after Gastric Bypass Surgery, NEJM 2007, 357 (8): 753-61-820;
- Minimally invasive surgery vs. Open
 - Roumm AR, Pizzi LP, Goldfarb NI, et al. Minimally Invasive Minimally Reimbursed? An Examination of Six Laparoscopic Procedures. Surg Innov 2005 Sep; 12(3):261-87.
 - : Brill, Andrew MD, Brossette, Stephen MD, Ph.D. et. al. (2008) Effects of Laparoscopic Cholecystectomy, Hysterectomy and Appendectomy on Nosocomial Infection Risks, *Surg. Endoscop.* DOI 10.10071-5 00464-008-9815-1

Direct cost:

- Shorter LOS and reduced hospital resources
- Less post procedure pain = less Rx. and physical therapy
- Indirect costs:
 - Quicker return to normal activities
 - reduced absenteeism

MIP Adoption

Procedure	Current Adoption
Appendectomy	56%
Breast Biopsy	65%
Cholecystectomy	97%
Hysterectomy (LAV & V)	47%
Reflux Surgery	67%
Gastric Bypass	85%
PPH	15%
Ventral Hernia	24%

Many of these procedures have the opportunity for a much higher adoption rate