Evidence in the Coverage Process: An Evolving Paradigm

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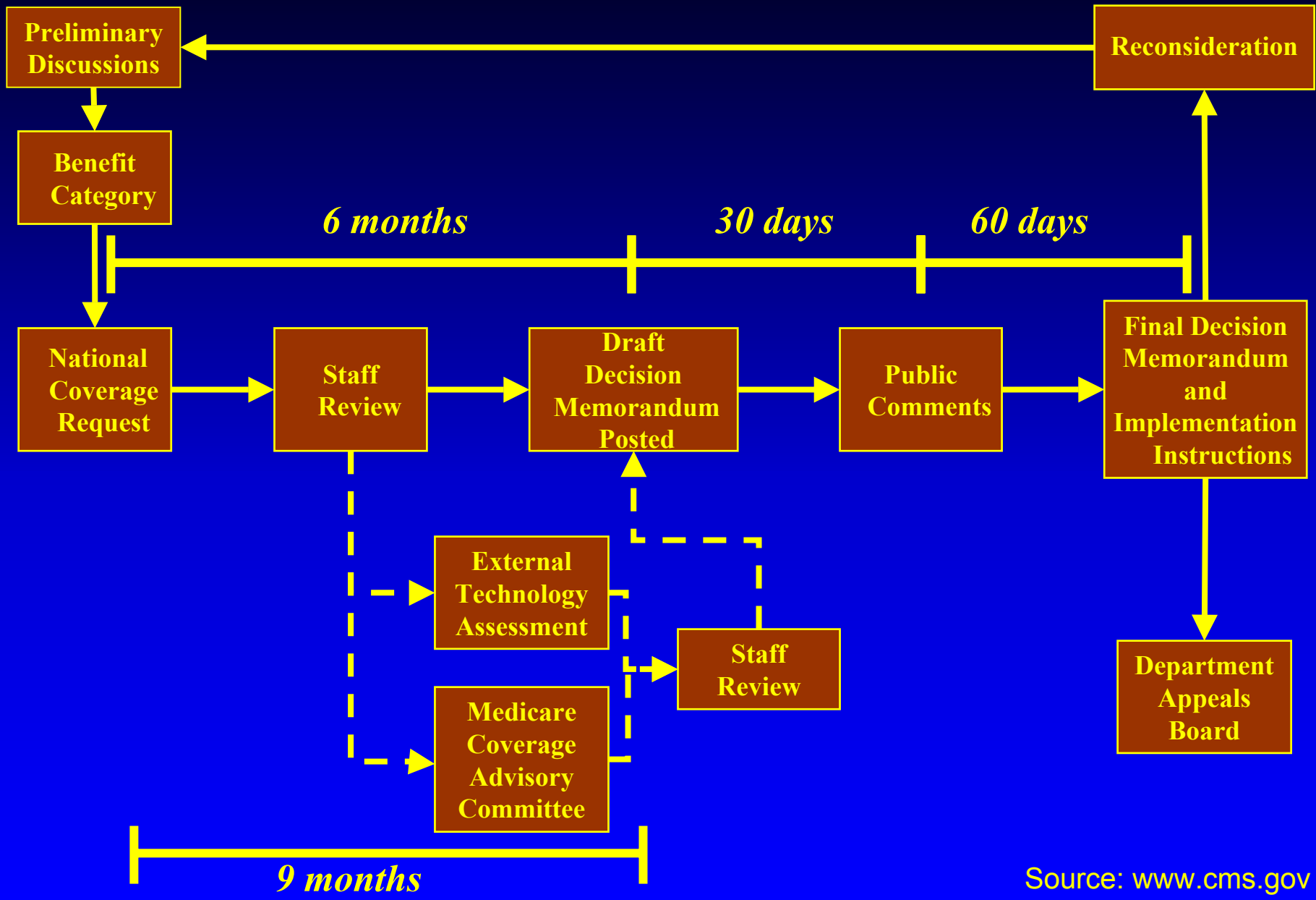
Trends in Medicare FFS

- Adoption of Evidence-Based Medicare Concepts
- Data Development Platform
- Looking Forward: Economic Analysis

National Coverage Process

- Formal mechanism for evidence review
  - Public processes
  - Transparency
- New structures to support decision-making
  - Medicare Coverage and Advisory Committee (MCAC)
  - Evidence-based Practice Centers (EPCs)
  - DEcIDE Network

Medicare National Coverage Process



Source: www.cms.gov

Decision-Making Structures

Medicare Coverage Advisory Committee (MCAC) – 80 voting members, 6 voting members (patient advocates), 6 industry representatives, 6 consumer representatives

Evidence-based Practice Centers (EPC) – 12 centers (1997); 13 centers (2002) – lost 2 of the previous centers and added 3 new centers

Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) **Network** – 13 research centers

Challenges for Evidence-Based Decision Making in Medicare

- Quality of the evidence
  - FDA approval is not a purchase recommendation

"Approval only means it's better than nothing, not that is should be reimbursed".

– Ray Lipicky, former Director of Cardio-Renal Division, FDA

- Variability in risk-benefit tradeoff between review divisions and between drugs and devices
  - Would Cox-2's have been approved by the Cardio-Renal Division of FDA?

Challenges for Evidence-Based Decision Making in Medicare

- Short-term clinical trials for chronic therapies
  - Lack of evidence: long term outcomes
  - Sepsis therapies – 28 day follow-up
- Generalizability to the Medicare population
  - Age and clinical condition of study patients (co-morbidity)
  - Multinational clinical trials – does treatment in Hungary generalize to the US market?

Generalizability to Medicare

	Number	Mean Age	Female Sex (%)	30-day Mortality (%)	1-year Mortality (%)
CCP	132,130	76.8	19.3	21.0	37.0
GUSTO-I	41,021	61.0	34.0	6.3-7.4*	9.1-10.1

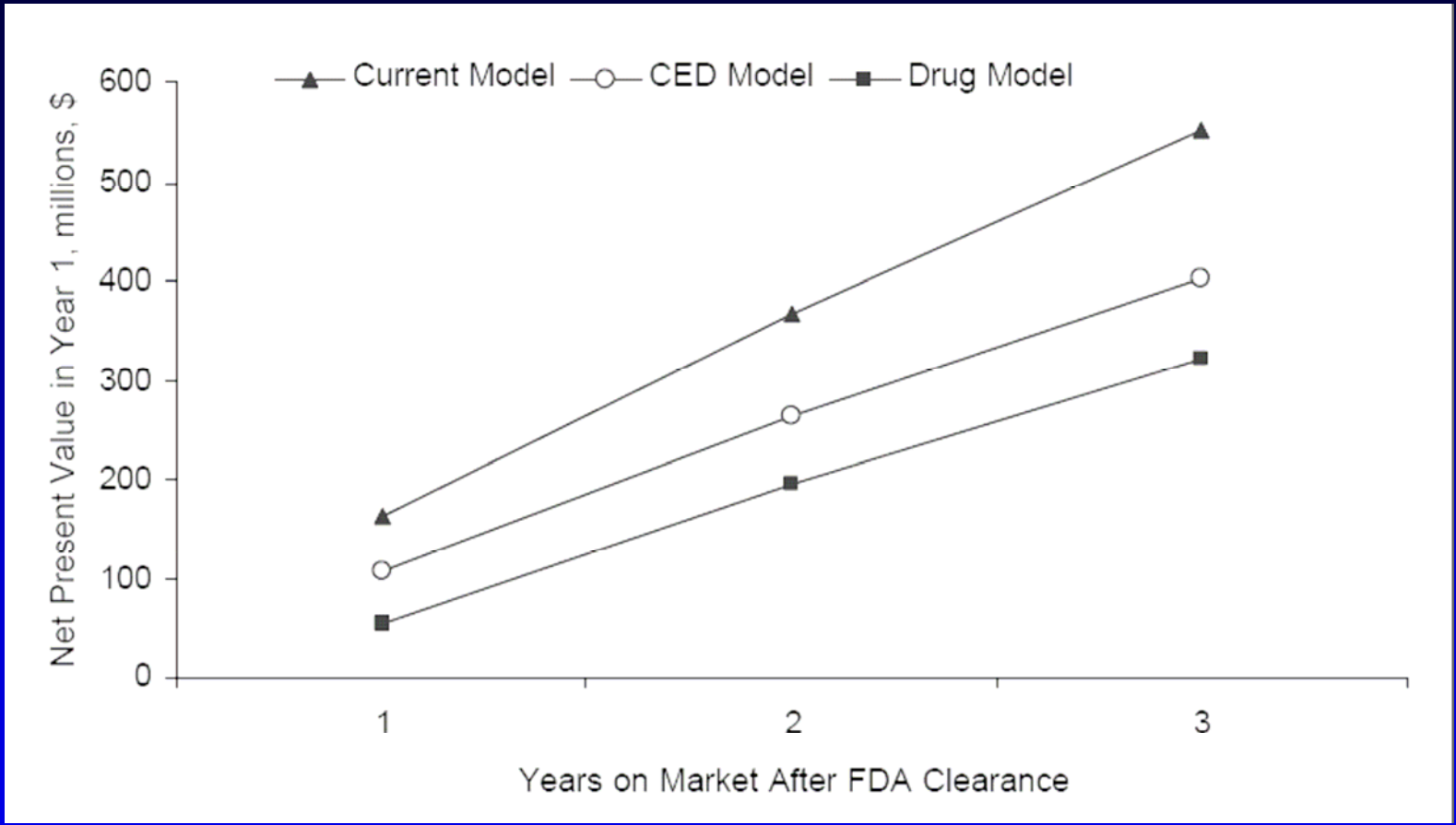
*Patients were groups by 4 treatment arms

Sources: CCP – Rao et al. *Arch Intern Med*. 2004; 164:1128-33.
GUSTO-I – Califf, R. M. et al. *Circulation*. 1996; 94:1233-1238.

Medicare as a Data Development Platform

- Coverage with Evidence Development (CED)
- Trials (lung volume reduction surgery)
- Medicare Part D

CED Impact on Firm Investment



Current Model - represents current regulatory– level of evidence necessary for approval of class III med devices is far less than that required for pharmaceutical products

CED - make coverage contingent on participation in a clinical trial or national registry

Drug Model - approval process for class III medical devices is the same as that currently employed for pharmaceutical products

Source: Reed et al. *Forthcoming*

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A Randomized Trial Comparing Lung-Volume–Reduction Surgery with Medical Therapy for Severe Emphysema

National Emphysema Treatment Trial Research Group*

Table 3. Total Health Care–Related Costs, Quality-Adjusted Life-Years Gained, and Estimated Cost-Effectiveness Ratios at Three Years.*

Variable	Surgery Group		Medical-Therapy Group		P Value	Incremental Cost-Effectiveness Ratio for Surgery ($)
	No. of Patients	Mean (95% CI)	No. of Patients	Mean (95% CI)		
All patients	531		535			190,000
Total costs ($)		98,952 (91,694–106,210)		62,560 (56,572–68,547)	<0.001	
Quality-adjusted life-years gained		1.46 (1.46–1.47)		1.27 (1.27–1.28)	<0.001	
Patients with predominantly upper-lobe emphysema and low exercise capacity	137		148			98,000
Total costs ($)		110,815 (93,404–128,226)		61,804 (50,248–73,359)	<0.001	
Quality-adjusted life-years gained		1.54 (1.53–1.55)		1.04 (1.03–1.05)	<0.001	
Patients with predominantly upper-lobe emphysema and high exercise capacity	204		212			240,000
Total costs ($)		84,331 (73,699–94,962)		55,858 (47,161–64,555)	<0.001	
Quality-adjusted life-years gained		1.54 (1.54–1.55)		1.42 (1.42–1.43)	<0.001	
Patients with non–upper-lobe emphysema and low exercise capacity	82		65			330,000
Total costs ($)		111,986 (93,944–130,027)		65,655 (52,075–79,236)	<0.001	
Quality-adjusted life-years gained		1.25 (1.23–1.26)		1.10 (1.09–1.12)	<0.001	

Source: Ramsey et al. N Engl J Med 2003;348:2092-102.

Medicare Part D: Claims Data Analysis

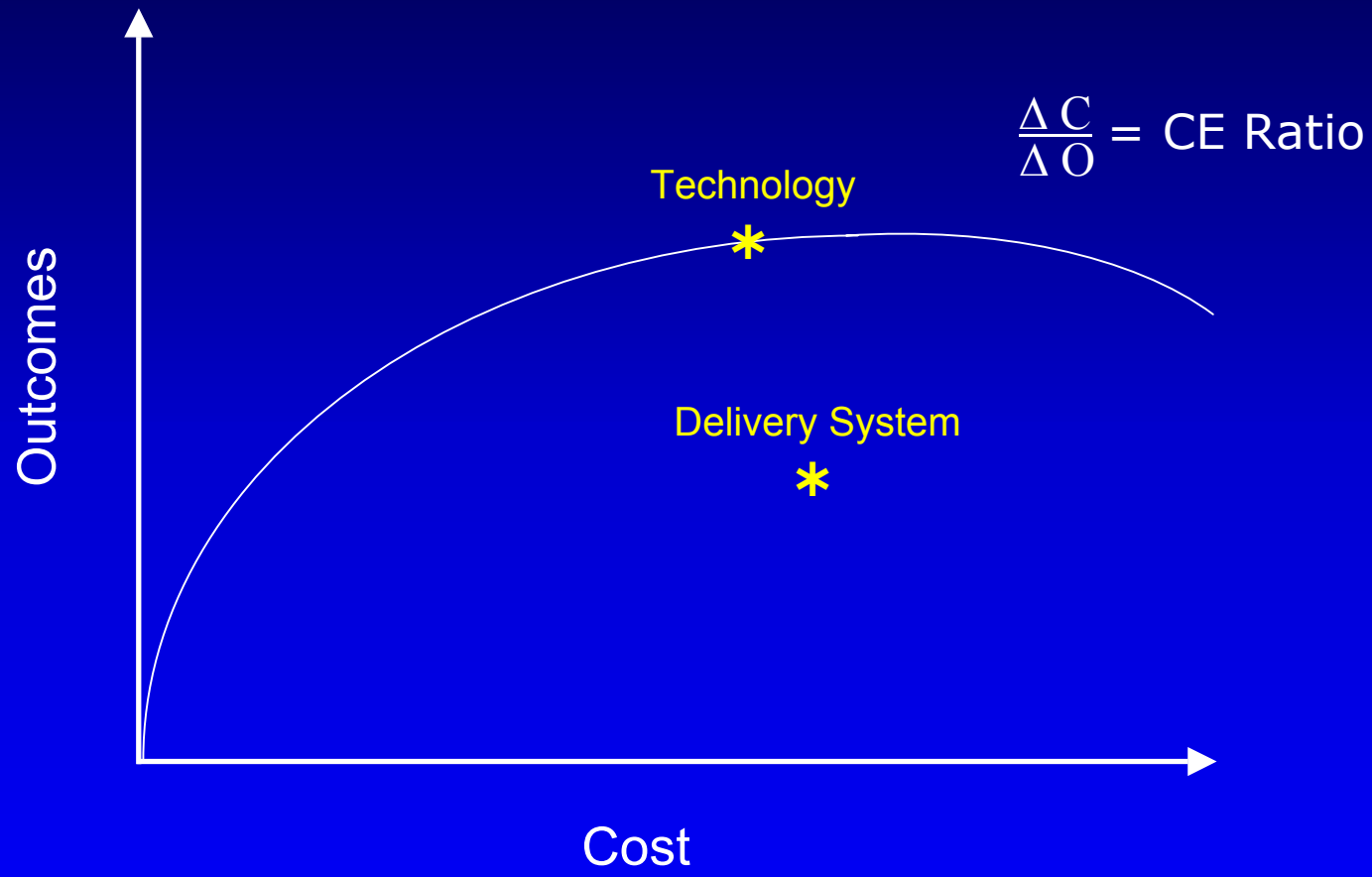
- Lack of clinical data on individuals
  - ICD codes not specific
- Lack of randomization / selection issues
- Timely access to data

Looking Forward: Economic Analysis

- Economics is considered already: the higher the cost the higher the evidence requirement for reasonable and necessary

- Cost-effectiveness as a criterion
  - Data quality
  - Threshold (cost-saving or cost/QALY ratio)
  - Generalizability to the Medicare population

Conclusion


$\frac{\Delta C}{\Delta O}$ = CE Ratio
Technology
Delivery System
Outcomes
Cost