AMCP Webinar

Cost-effectiveness analysis: Balancing value with affordability?

Michael Drummond, Dan Danielson and Steven D. Pearson

MODERATOR:

Michael Drummond, PhD

University of York UK

Cost-Effectiveness Analysis: Balancing Value With Affordability?

Michael Drummond
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CHE
Centre For Health Economics

Use of Cost-Effectiveness Analysis Worldwide

- Cost-effectiveness analysis (CEA) is well-established in the formulary decision-making process in many jurisdictions
- These include around half the countries in the European Union, Canada, Australia and several countries in Asia and Latin America
- Typically, these countries have large public payers with the resources to evaluate manufacturer submissions
- Affordability/budget impact is normally assessed
- However, the role of CEA in the US is uncertain

Dymaxium Surveys of US Payers

- Surveyed the 1,200+ US Healthcare Decision Makers registered on the AMCP eDossier system in October 2014, April 2015 and September 2015
- Between 70 and 100 responses to the three surveys
- Asked questions about attitudes towards cost-effectiveness and industry-produced models
- Also, explored the concerns that decision-makers had about the evidence presented to them and the other sources of evidence they consulted

Payers' Use of Industry Provided Models

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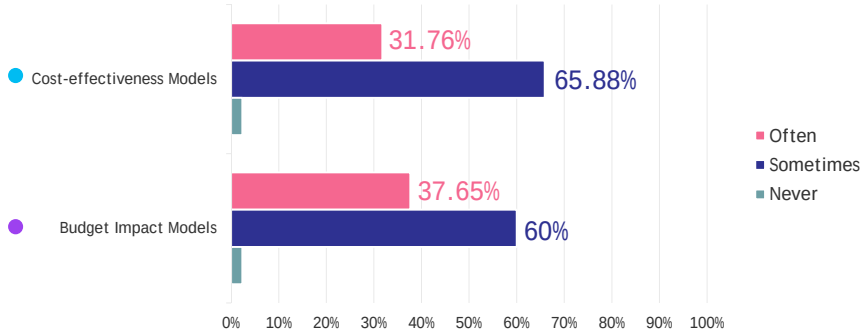
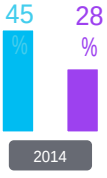
How often do they consult industry models:





2014

Payers' Use of Industry Provided Models

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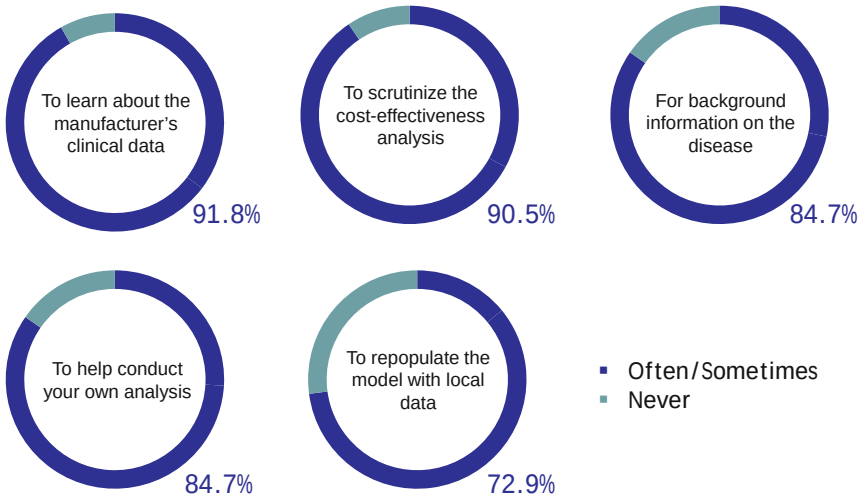
In what ways do they use industry models?



What tools and resources do you currently use to assess product affordability? (multiple responses possible)

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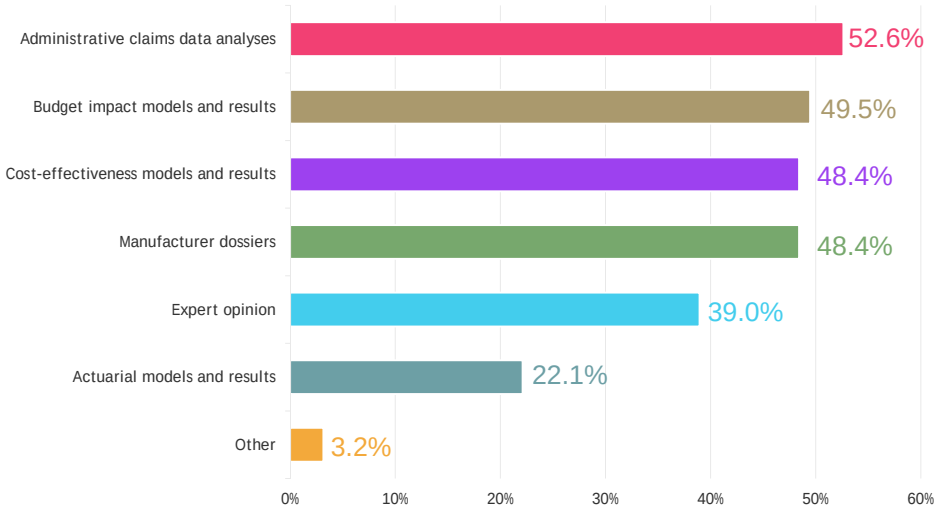

SPEAKER:

Dan Danielson, MS, RPH

Pharmacy Manager, Clinical Services, Premera Blue Cross.

Premera Value Assessment Process

Background

Value-Based Insurance Design (VBID)

Concept:

- Align out-of-pocket costs with the value of health services:
  - Different health services have different levels of value
  - Reduce member cost barriers to high-value treatments
  - Discourage low-value treatments by raising out-of-pocket costs
- Expected Result:
  - Improved health outcomes at any level of health care expenditure.
  - Studies show that when barriers are reduced, significant increases in patient compliance with recommended treatments and potential cost savings result

-Center for Value-Based Insurance Design
-University of Michigan, www.sph.umich.edu/vbidcenter/

Background

VBRx is built using VBID concepts and is unique in the US market

- Guiding Principles
  - Premera's core values
  - Transparent processes
  - Evidence-based
  - Internal and external decision-making committee
  - Leverage input from practicing physicians and other providers
  - Uses clinical and economic data to determine value
- Academy of Managed Care Pharmacy defines value as:
  - *"Value in health care relates to whether a medical intervention… improves health outcomes **enough** to justify additional dollars spent compared to another intervention."*

Committees

Specialized functions; working in tandem not isolation

- Pharmacy & Therapeutics Committee
  - Clinical evaluation: Safety, effectiveness
  - 7 MDs, 3 pharmacists, 1 lay member – no Premera associates
- Value Assessment Committee
  - 1 MD, PhD, Practicing Internist and Health Economist, Fred Hutchinson Cancer Research Center (chair)
  - 3 PhD Pharmacoeconomist (vice chair)
  - 1 PhD, Bioethics, UW
  - 1 each
    - Community-based oncologist
    - Community-based cardiologist
    - Lay member

How is value measured?

Clinical dimension:

- Incremental Clinical Effectiveness
  - Therapeutic effect size versus
    - Placebo
    - Comparator therapy
    - Cure disease/prolong life or survival (progression free or overall)
  - Adverse effect profile
  - Use/avoidance of use of other medical services
    - Office visits
    - Lab tests
    - Medical procedures

How is value measured?

Human dimension :

- Impacts on patient quality of life
  - Activities of Daily Life
  - Social Role function
    - Spouse/Parent
    - Employment
    - Community
  - Psychological function

Clinical and humanistic outcomes drive the quality of life measure- Quality Added Life Years (QALY)

How is value measured?

Economic dimension ($):

- **Incremental Costs** versus comparator therapy
  - Costs associated with
    - Drug/procedure costs
    - Treating adverse effects
    - Office visits
    - Lab tests
    - Medical procedures

How is value measured?

Incremental cost effectiveness ratio (ICER)

$$\frac{Incremental\ [total] cost\ of\ therapy \quad (\$)}{Incremental\ Quality\ Added\ Life\ Years\ (QALY)}$$

- NOT commonly used in USA
- Used EU, Canada and elsewhere
  - Validated surveys of actual target patients (or similar)
  - Some caution using surveys conducted outside of target population/country

More than a calculation

Premera Value Matrix

Category	Factor	Evaluation of Relevant Considerations	
Clinical Benefit	Research Question	Strength of Evidence	
	Safety	B	
	Efficacy	A	
	Effectiveness	B	
Cost-Effectiveness Analysis	Base Case	$20,000-$30,000/QALY	
	High Estimate		
	Low Estimate	<$10,000/QALY	
Societal Values	Ethical Issues	Affordability of the _____'s. While cost effective, the costs of these drugs make widespread coverage impossible within a financially responsible manner. Therefore prioritization of treatment given the very high cost is essential. Prioritization needs to guard against discrimination against patients because others disapprove of the behavior that led to infection (needle sharing, etc.)	
	Rare Disease	☐ No ☐ Yes ___% of the population has_____	
	Unmet Need	☐ No ☐Yes More effective _____	
	Other Societal Considerations	Potential for_____. Potential societal impact of _____ is substantial.	
	Regulatory Issues	None noted.	
Budget Impact Analysis		Pharmacy Budget Impact	Medical Budget Impact
	Base Case	$X PMPM	N/A PMPM
	High Estimate	$Y PMPM	N/A PMPM
	Low Estimate	$Z PMPM	N/A PMPM

Finding economic information

Credible sources

- Center for the Evaluation of Value and Risk in Health (CEVR, Tufts University) CEA Registry
- National Institute for Health and Care Excellence (NICE)
- PubMed.gov
- Institute for Clinical and Economic Review
- Manufacturers Models
- Value Assessment Committee Members

U.S. Payers Should Use Models

- **Cost-effectiveness models**
  - Support value-based benefit (VBID) designs
  - Reduce copay access barriers to high value drugs
  - Provide means to evaluate drug price
  - Identify clinical nuances and inappropriate pricing
- **Budget impact**
  - Complements CEA
  - Supports discussion of affordability
  - Disease-based models total costs of care
- **Most of the models we reject are eliminated on *clinical* grounds, not technical flaws**

What Makes a Good Model?

- **Addresses decision makers' information needs**
  - What decision are they making?
  - What do they need to inform that decision?
  - Which model type best fits the disease state and setting?
- **Has "Real World" clinical relevance**
  - To clinicians and patients in the plan's population
  - Reflects actual clinical practice
  - **Models with faulty clinical assumptions will be rejected**
- **Uses Transparent methodology**
  - Per decision makers' guidance (AMCP/ISPOR)
  - Open, unlocked spreadsheets with good documentation

What's missing?

A measure for health system affordability

Just because a product may have good clinical value does not necessarily mean that it is affordable (budget impact).

Tesla Model S

Nissan Leaf

Drugs don't work in patients who don't take them

-C. Everett Koop

SPEAKER:

Steven D. Pearson, MD, MSc

President and Founder, Institute for Clinical and Economic Review.

Evaluating the Value of New Drugs and Devices

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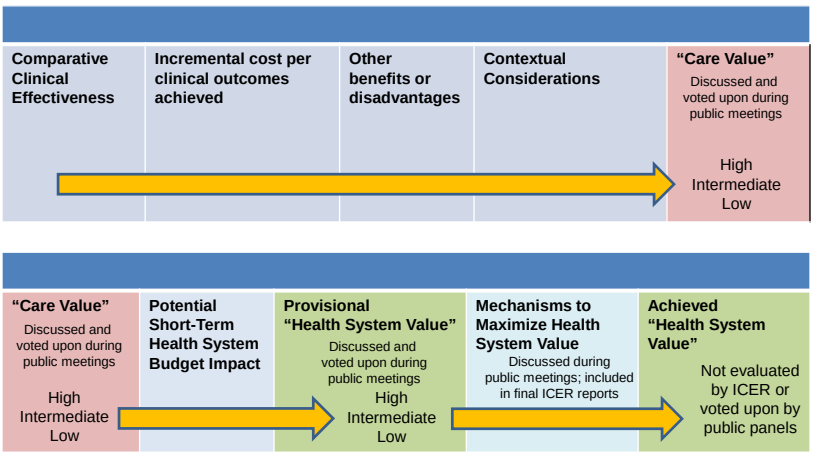
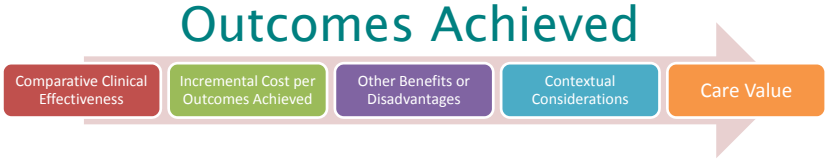
ICER Value Assessment Policy Development Group*

- ***NB: All participants provided input into the development of the value assessment framework but none should be assumed to approve of its approach**
- **Insurers and Pharmacy Benefit Management Companies**
  - Aetna
  - Wellpoint
  - Kaiser Permanente
  - OmedaRx
  - Premera
  - America's Health Insurance Plans (AHIP)
- **Patient Organizations**
  - FamiliesUSA
- **Physician Specialty Societies**
  - ASCO
- **Manufacturers**
  - Merck
  - Covidien
  - Lilly
  - GSK
  - Philips
  - Amgen
  - National Pharmaceutical Council (NPC)
  - Biotechnology Industry Organization (BIO)

ICER Value Framework 3.0

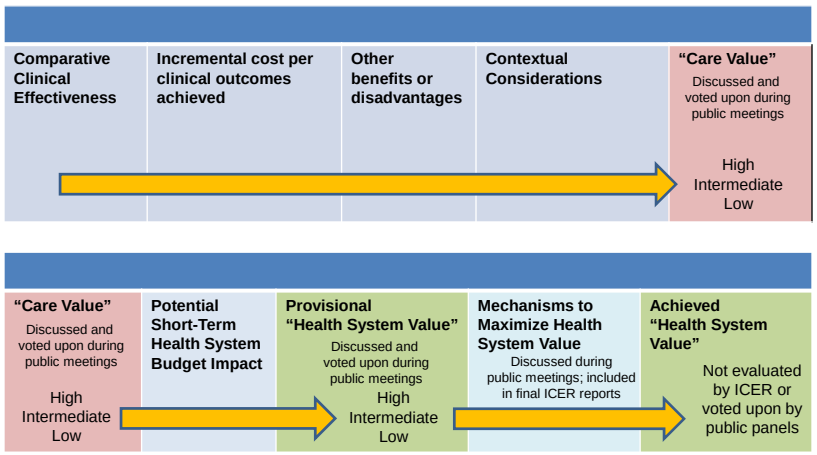


Incremental Cost per Outcomes Achieved



- Incremental Cost per Outcomes Achieved
  - Long-term perspective
  - Cost per quality-adjusted life year (QALY) gained
    - Associated with high care value
      - <$100,000/QALY
    - Associated with intermediate care value
      - $100-150K/QALY
    - Associated with low care value
      - >$150,000/QALY

A Value Assessment Flowchart



Provisional Health System Value

- Integration of long-term care value with consideration of potential short-term budget impact
- Why short-term budget impact as a part of value?
  - A potential budget impact for an individual drug estimated to contribute significantly to cost growth above some threshold should serve as an "alarm bell" for greater scrutiny and for efforts to maximize health system value

Potential Budget Impact Threshold

- How much potential budget impact is "too much"?
- Key assumption based on national and state legislation
  - The United States would like to take measures so that overall health care cost growth does not outstrip growth in the national economy
- Measure
  - The amount of net cost increase per individual new intervention that would contribute to growth in overall health care spending greater than the anticipated growth in national GDP + 1%

Summary of Potential Budget Impact Threshold Calculations

Item	Parameter	Estimate (Drugs)	Estimate (Devices)	Source
1	Growth in US GDP, 2015-2016 (est.) +1%	3.75%	3.75%	World Bank, 2015
2	Total health care spending ($)	$3.08 trillion	$3.08 trillion	CMS NHE, 2014
3	Contribution of drug/device spending to total health care spending (%)	13.3%	6.0%	CMS NHE, Altarum Institute, 2014
4	Contribution of drug spending to total health care spending ($) (Row 2 x Row 3)	$410 billion	$185 billion	Calculation
5	Annual threshold for net health care cost growth for ALL new drugs (Row 1 x Row 4)	$15.4 billion	$6.9 billion	Calculation
6	Average annual number of new molecular entity or device approvals, 2013-2014	34	23	FDA, 2014
7	Annual threshold for average cost growth per individual new molecular entity (Row 5 ÷ Row 6)	$452 million	$301 million	Calculation
8	Annual threshold for estimated potential budget impact for each individual new molecular entity (doubling of Row 7)	**$904 million**	**$603 million**	Calculation

From Value Assessment to "Value-Based Price Benchmarks"

	Care Value Price: $100K/QALY	Care Value Price: $150K/QALY	Max Price at Potential Budget Impact Threshold	Draft Value-Based Price Benchmark
PCSK9 Drugs ***List price $14,350*** ***(n=2,636,179)***	***$5,404***	***$7,735***	***$2,177***	***$2,177***

	Price to Achieve $100K/QALY	Price to Achieve $150K/QALY	Max Price at Potential Budget Impact Threshold	Draft Value-Based Price Benchmark
Entresto ***List price $4,560*** ***(n=1,949,400)***	***$9,480***	***$14,472***	***$3,779***	***$3,779***

ICER Drug Assessment Expansion

- Support from the Laura and John Arnold Foundation (LJAF)
- Ramping up to produce 15-20 reports per year on highest impact new drugs near time of FDA approval
- All reports to be debated in public by independent committees
- Work with patient, manufacturer, payer, provider, and policymaker communities to enhance uptake and application of reports

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Advancing value assessment and pricing for new drugs

- For payers
  - Track and use ICER reports to support value-based coverage decisions and benefit designs
    - Make independent value reports an explicit and transparent part of coverage and price negotiation
    - Apply reports to justify non-coverage, step therapy, or other restrictions if improved comparative clinical effectiveness is not demonstrated
    - If price meets a price benchmark
      - Drug gets first tier and low or no co-pay
      - Drug is “gold carded” with provider groups
    - If price does not meet the benchmark
      - Automatic third tier
      - “Reference price” to value benchmark: Additional costs paid by patients or manufacturers
      - High prior authorization requirements for providers

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Thank you

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Questions?

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Stay Tuned

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Webinar will be posted on the AMCP website.