

Webinar

## Developing and Using Value Frameworks Part II

Laurie Fazio, Michael F. Drummond and Robert W. Dubois

MODERATOR:



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SPEAKERS:



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Executive Vice President & Chief Science Officer National Pharmaceutical  
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## Payer Feedback

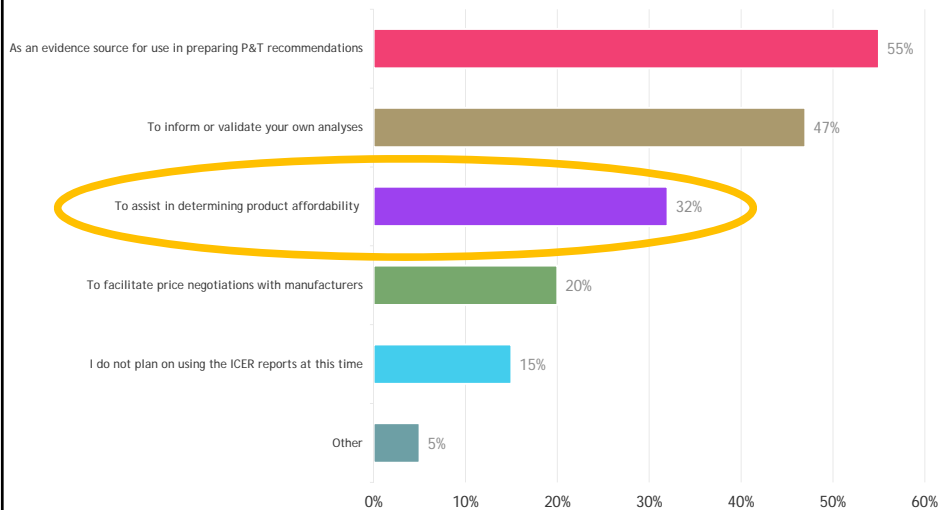


- Web-based platform that connects HCDMs and their evidence requirements
- Review, evaluate and compare products to support informed, evidence-based decisions

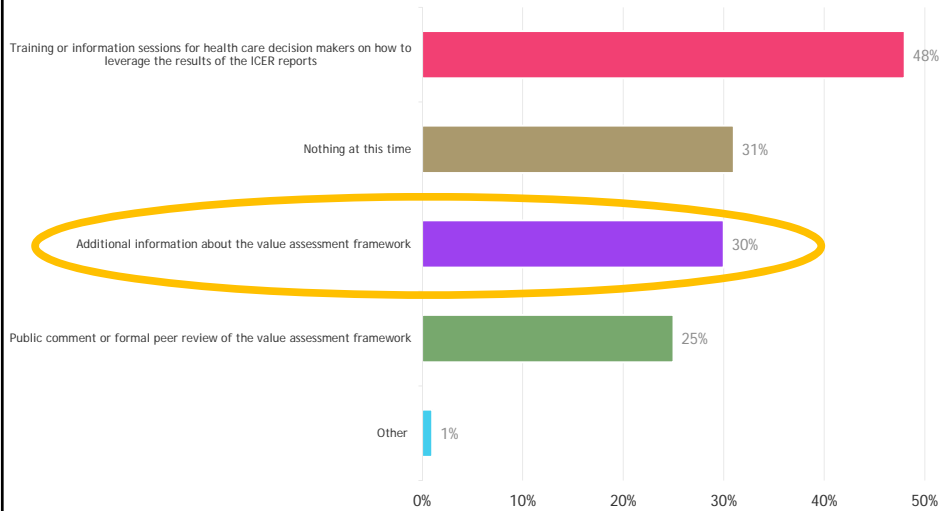


- 1,200+ US Healthcare Decision Makers
- FDA-compliant unsolicited request process
- Partnership with AMCP and supported by life sciences organizations

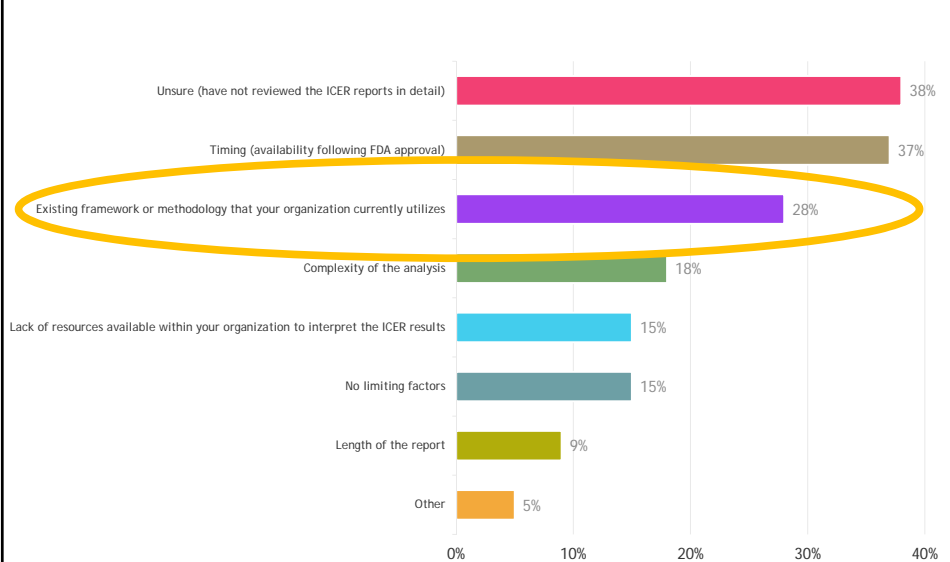
## How do you plan on using the ICER reports in your formulary evaluation process? (select all that apply)



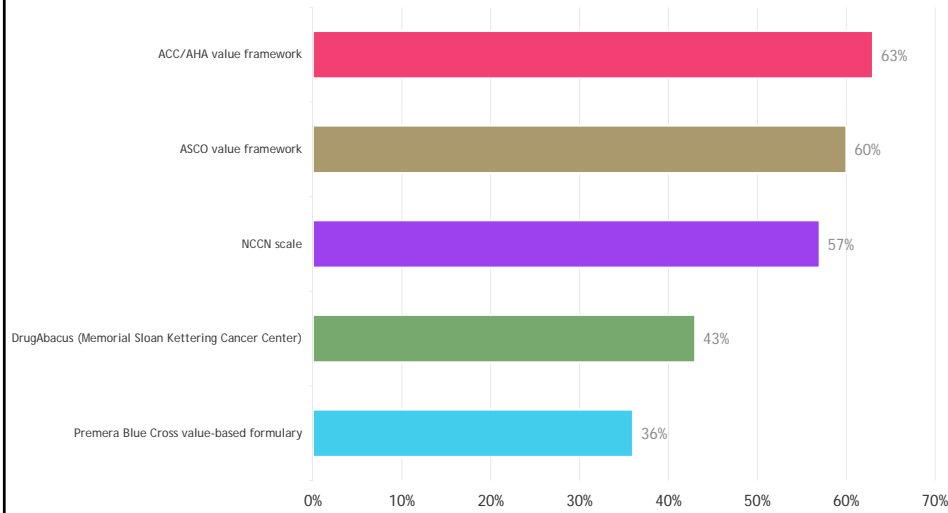
Is there anything else that ICER can do to increase the value of their new drug assessment program? (select all that apply)



Are there factors, if any, that you feel limit the usefulness of the ICER reports? (select all that apply)



A number of other value framework and assessment tools have been developed or will be made available shortly. Which of the following have you or are you considering using? (Very Likely/Somewhat Likely)



**SPEAKER:**  
**Michael F. Drummond, PhD**

Professor of Health Economics,  
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# Developing and Using Value Frameworks for Health Technologies

Michael Drummond  
Centre for Health Economics,  
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THE UNIVERSITY *of York*



## Topics to be Discussed

- Experience with value frameworks outside the US
- Issues in developing and using value frameworks
- Lessons for the US

## Experience with Value Frameworks Outside the US

- Cost per QALY approach (Australia, Canada Sweden, UK, others)
  - calculation of the cost to 'buy' a unit of health (eg a quality-adjusted life-year)
  - technologies judged against a formal or informal 'threshold' (eg £20,000 per QALY in the UK)
- Scoring systems (France, Germany)
  - 'added clinical value' assessed based on a review of the clinical evidence

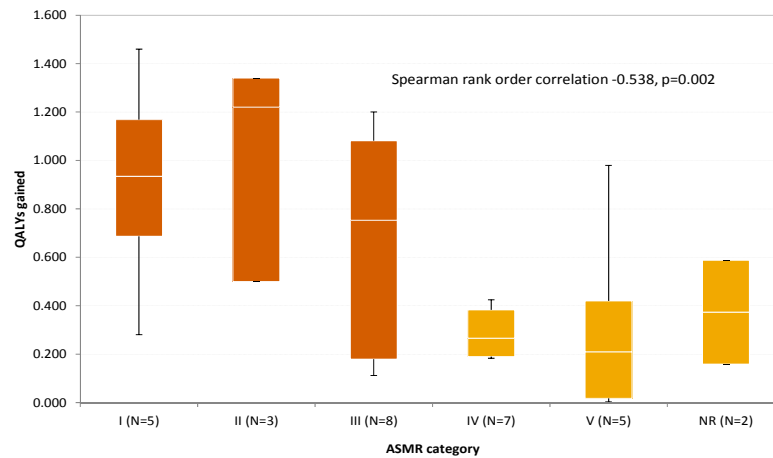
## Scoring Systems in France and Germany

France                      Germany

	ASMR	G-BA/ IQWiG Level of Added Benefit
<b>Innovative</b>	I – Major innovation ("majeure")	Major ("erheblich")
	II – Important improvement ("importante")	Considerable ("beträchtlich")
	III – Moderate improvement ("modérée")	
	IV – Minor improvement ("mineure")	Minor ("gering")
	V – No improvement ("inexistante")	Non-quantifiable ("nicht quantifizierbar")
<b>Non-innovative</b>		No added benefit ("kein Zusatznutzen")
		Lesser benefit ("geringerer Nutzen")

## Comparisons of Value Assessments by NICE (UK) and HAS (France) on 49 Cancer Drugs

(Drummond et al, *Pharmacoeconomics*, 2014)



## Issues in Developing and Using a Value Framework

- Whose perspective?
- What constitutes 'value'?
- How is budgetary impact considered?
- Do other factors matter?
- Is transparency important?
- Which decisions will the framework influence?

## Whose Perspective?

- Outside the US the cost perspective is mainly that of the health care system/payer
- In the US, one would expect the perspective of the enrollee/patient as a payer to receive more attention

## What Constitutes Value?

- In the case of QALYs, the focus is on health gain
- In scoring systems, the focus is on clinical benefit
- Other possibilities include:
  - convenience to the patient/family
  - wider social benefits (eg on productivity)
  - innovation (irrespective of the gains in health)



## How is Budgetary Impact Considered?

- Outside the US, budgetary impact is not always assessed; where it is assessed, it is kept separate from the assessment of value for money
- In the UK, the argument is that it is taken account of through the threshold, but budgetary management decisions are left to the health care system
- In the US it often amounts a commercial decision on whether to increase premiums and/or patient copayments, although disinvestment in other services could also be considered to accommodate new technologies

## Do Other Factors Matter?

- Outside the US, factors that are often discussed include:
  - severity of disease (eg 'end of life')
  - availability of other treatments for the condition
  - likely financial consequences for patients in the absence of coverage

## Does Transparency Matter?

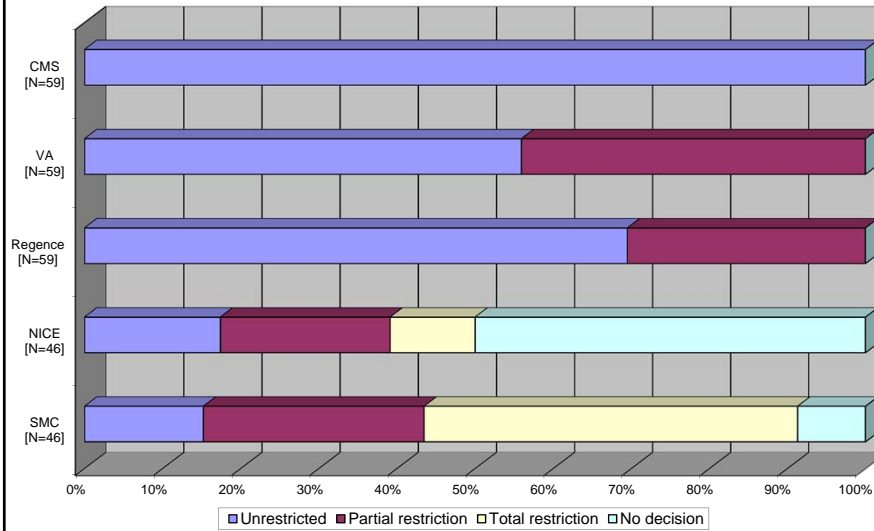
- Outside the US, countries take quite different positions on this
- Some of the scoring systems used (eg in France) lack transparency
- The cost per QALY approach tends to be more transparent, although they may be complexities in the economic models used
- Details of price negotiations tend to be kept confidential

## Which Decisions will the Value Framework Influence?

- In France and Germany the value assessments are mainly used in price negotiations
- In the UK, historically they have influenced coverage decisions (ie approve, reject, restrict to a sub-set of patients), but increasingly price negotiations
- In the US they could also influence insurance design and formulary tiers; restrictions in coverage are currently less common

## Coverage Restrictions for Eligible Anticancer Drugs, FDA Approved 2004-2008 (US versus UK)

Mason et al J. Clinical Oncology 2010; 28: 3234-8



## Concluding Remarks

- Value frameworks have been in use outside the US for many years
- Although the various frameworks differ, 'value' is mostly considered to be related to the health gain or clinical benefit
- Outside the US, budget impact tends to be considered separately from value for money
- Value frameworks have been used for different purposes and this is likely to be one of the biggest issues for the US if value frameworks become widely adopted



SPEAKER:  
**Robert W. Dubois, MD, PhD**

Executive Vice President & Chief Science Officer National  
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# Developing and Using Value Frameworks

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## Developing and Using Value Frameworks

1. Multiple frameworks are used in the US
2. These frameworks have similarities and differences
3. Frameworks raise areas of concern
4. “Principles” can guide framework evolution

HealthAffairsBlog

Rising Cost Of Drugs: Where Do We Go From Here?



**Three State Legislatures Eye Drug Price Limits**



**Obama Administration Seeks to Negotiate Medicare Drug Prices**

# Value Frameworks Proliferate



DrugAbacus



## ACC/AHA Practice Guideline

**ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures**  
 A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines

Value	Cost/QALY
High	<\$50k
Intermediate	\$50k-\$150k
Low	>\$150k



# DrugAbacus Considers Many Factors

(Peter Bach, Memorial Sloan Kettering)

## Modifiable Price Components



## ASCO Value Framework

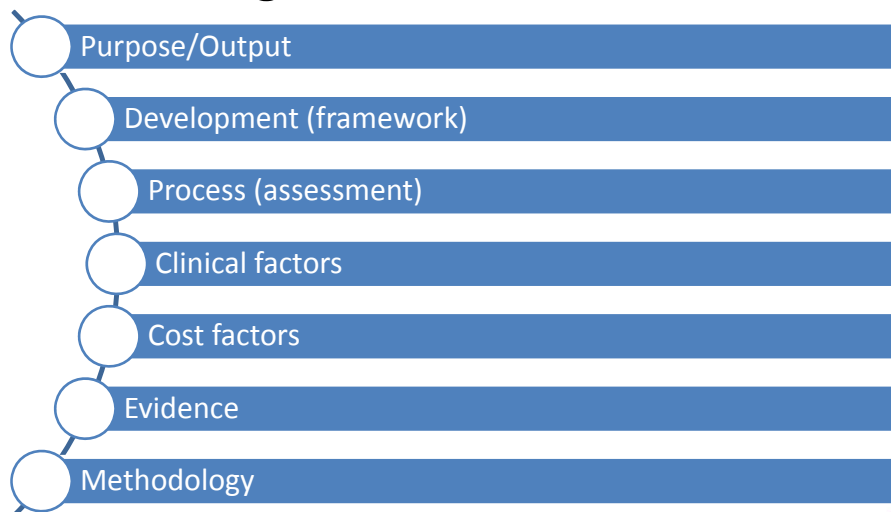
	Clinical Benefit +	Toxicity +	Bonus =	Net Health Benefit*
Advanced Disease	0 to 80 points	-20 to 20 points	0 to 30 points	Max 130 points
Adjuvant Treatment	0 to 80 points	-20 to 20 points		Max 100 points

- \*relative to an RCT comparator
- costs: drug acquisition, patient cost-sharing

## Developing and Using Value Frameworks

1. Multiple frameworks are used in the US
2. These frameworks have similarities and differences

## Categories for Assessment





## Clinical Factors

Clinical Factors	ACC/AHA	ASCO	DrugAbacus	ICER	NCCN
Perspective	patient	patient	patient	patient	patient
Patient-Centric Metrics	No ○	No ○	No ○	Qualitatively ◐	No ○
Indirect Benefits	No ○	No ○	No ○	Qualitatively ◐	No ○
Unmet Need	Qualitatively ◐	No ○	Yes ●	Qualitatively ◐	No ○
Burden of Illness	No ○	No ○	Yes ●	Qualitatively ◐	No ○

### 3. Frameworks Raise Concerns

- Non-transparency creates uncertainty
- Methodologies and thresholds need vetting and testing
- Evidence choices affect the results

## 4. Principles Can Guide Evolution\*

- Examine all aspects of care, not just drugs
- Include relevant stakeholders
- Time frames should encompass full benefits and harms
- Economic models should be readily available
- Transparency at every step
- Include customizable “weights” for key factors

\*6 out of 34 NPC draft principles listed here

Questions?



Let's Keep in Touch



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Stay Tuned



Webinar will be posted on the AMCP website.