ICLIO Webinar: ICLIO eCourse – Real World Introduction to the Institute for Clinical and Economic Review (ICER): Panel Discussion

12.19.16 1:00pm to 2:00pm EST





#### Introductions

**Moderator:** 

Bill McGivney, PhD McGivney Global Advisors

Panelists:

**Ivo Abraham, PhD** *The University of Arizona Cancer Center* 

Ali McBride, PharmD, MS, BCPS The University of Arizona Cancer Center

Jennifer Hinkel, MSc McGivney Global Advisors

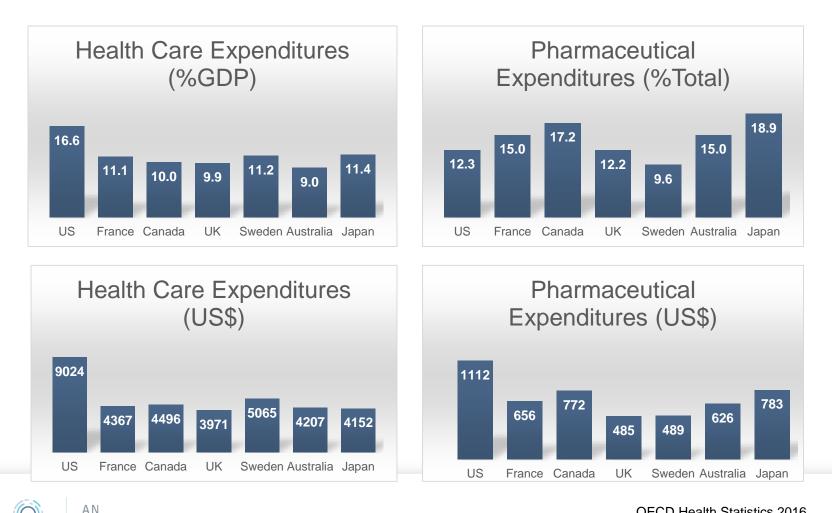


#### "Cost and Value of Cancer Care"

#### Ivo Abraham, PhD The University of Arizona Cancer Center



### Is the US spending too much?



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OECD Health Statistics 2016 (data shown are for 2014)

## **Policy options**

- Cost = payer
  - Price controls by payer
  - Enforced by payer
  - Driven by payer
    - \$ taken in
    - \$ paid out
    - \$ difference
  - Example: UK National Health Service

- Quality partnering
  - Cost x Quality
  - Accountability
    - Performance
    - Financial
  - Quality incentives
    - Coordination
    - Navigation
    - Adherence to guidelines
    - Access to care
  - Example: CMS Oncology
     Care Model



#### Oncology value frameworks

	Primary purpose	Treatment modalities assessed	Scoring/grading	Cost		Issues:
ASCO [10]	Shared decision- making, patients/ MDs	Pharmaceuticals for solid tumors, hematologic malignancies	Net Health Benefit Score (NHB)	Cost/month (advanced disease), cost/ course (adjuvant disease	2)	<ul> <li>Living longer</li> <li>Living better</li> <li>Efficacy</li> </ul>
ESMO [11]	Inform public policy, clinical guidelines, day-to-day clinical situations	Pharmaceuticals for solid tumors	(A,B,C) for adjuvant disease; (5, 4, 3, 2, 1) for advanced disease	N/A		<ul><li>Efficacy</li><li>Safety</li></ul>
NCCN [12]	Providers and patients, as well as other stakeholders involved in the treatment decision-making process	Systemic therapies in all major cancer types, radiation oncology, imaging, surgical interventions	Evidence Block Score (5, 4, 3, 2, 1)	Affordability scale (1–5)		<ul><li>QALY</li><li>Thresholds</li><li>Cost/price</li></ul>
ICER [13]	Inform society; inform policymakers/payers	Drugs, devices, procedures, and delivery system innovations	Evidence rating matrix	Care value (expressed as a QALY) and health system value (judging long-ter value)		<ul><li>Value</li><li>Societal</li></ul>
Drug Abacus [16]	Inform policymakers and physicians	FDA-approved drugs since 2001	Abacus price varies with clinical benefit, toxicity, innovativeness, etc.	Abacus derived "price" based on above variable vs. industry- specified price		Payer
	AN INSTITUTE		accc-icli	to		n: Schnipper LE, Bastian A. New fra cancer care: strengths and limitatior 1:654-658. 6

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### Value in (cancer) care

Health status						
achieved or						
retained						

- Survival
- Degree of health
   or recovery

#### Process of recovery

- Time to ...
- Disutility of care or treatment process

## Sustainability of health

- No recurrence or complications
- Long-term consequences of therapy

Dynamic risk-adjustment over time for: type of cancer – stage of disease – treatment options – prognosis – trial efficacy – real-world effectiveness – treatment-related consequences and complications – patient acceptance

Accommodate changes in: patient preferences – guidelines – clinician decision-making





#### Not-for-profit est. 2006 - funded by

- non-profit foundations (70%)
- life sciences companies (17%)
- insurers/providers (9%)
- government contracts (4%)
- Threshold-driven value
  - Iong-term value value for money QALY …
  - short-term value affordability budget impact



#### Ali McBride, PharmD, MS, BCPS The University of Arizona Cancer Center



#### Value Based Models Cancer

- Costs and treatment innovations continuing to drive the value discussion
  - Innovation
  - Newer Therapies
  - Access to options
- Costs continue to increase
  - Population
  - Medical Resource
  - Drug Pricing
  - End of Life Care

The Oncologist 2016;21:651-653



#### **Framework for Value Metrics**

Source	Primary purpose	Treatment modalities assessed	Data source	Scoring/grading	Cost	Updating
ASCO	Shared decision making, patients/ MDs	Pharmaceuticals for solid tumors, hematologic malignancies	Clinical trial	Net Health Benefit Score (NHB)	Cost/month (advanced disease), cost/ course (adjuvant disease)	Dynamic-value changes as impact of agents change
ESMO	Inform public policy, clinical guidelines,	Pharmaceuticals for solid tumors	Clinical trial	(A,B,C) adjuvant; (5, 4, 3, 2, 1) for advanced	N/A	Not stated
NCCN	Providers and patients, as well as other stakeholders	Systemic therapies in all major cancer types, radiation oncology, imaging, surgical interventions	Clinical trials and expert consensus	Evidence Block Score (5, 4, 3, 2, 1)	Affordability scale (1– 5)	Annually updated, changes as impact of therapies change
ICER	Inform society; inform policymakers/pay ers	Drugs, devices, procedures, and delivery system innovations	Clinical trials, econometri cs	Evidence rating matrix	Care value (expressed as a QALY) and health system value (judging long-term value)	Reports for individual areas commissioned,
Drug Abacus	Inform policymakers and physicians	FDA-approved drugs since 2001	Public data FDA to obtain approval	Abacus price varies with clinical benefit, toxicity, innovativeness, etc.	Abacus derived "price" based on above variables vs. industry specified price	Enhancements planned but not explicitly stated

The Oncologist 2016;21:651-653

#### Value in Cancer Care

- The Institute of Medicine has delineated six elements of value in cancer care: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.
- ASCO selected only three of these for its framework clinical benefit (effectiveness), toxicity (safety), and cost (efficiency)
- Analysts used a clinical-benefit score derived from comparisons of overall survival, progression-free survival, or response rates, as well as comparative toxicities of the two regimens to define a "net health benefit" (NHB).

N Engl J Med 2015; 373:2593-2595



#### **Implications of Value Metrics**

- Provider Based
- Payor Based
- Institution Based
- Genetic Based

# What metrics may be superfluous or hard to identify?



### **Implications of Value Metrics**

**Clinical Practice Implementation** 

- Patients Decision
- Value Based Workflow
  - Evaluation for Treatment Options
    - Outcomes
    - Outcomes+ Symptom Control+ QOL+ Cost of Treatment
      - Clinical Trial Outcomes

#### **Implications for Metrics**





#### Cancer Center Development

- Outcome Measures
- Structure Measures
- Process Measures
- Efficiency Measures
- Cost-Of-Care Measures
- Patients' Perception-Of-Care Measures

Health Aff 2011;30:664-72

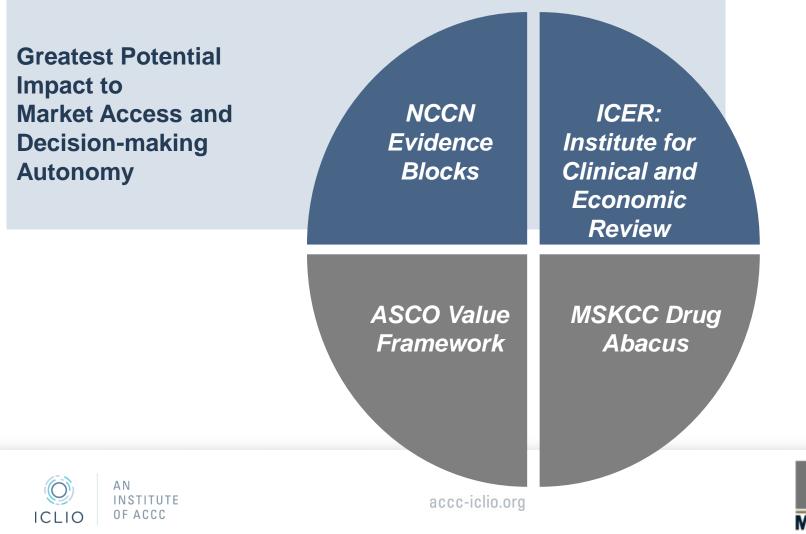


#### Jennifer Hinkel, MSc McGivney Global Advisors



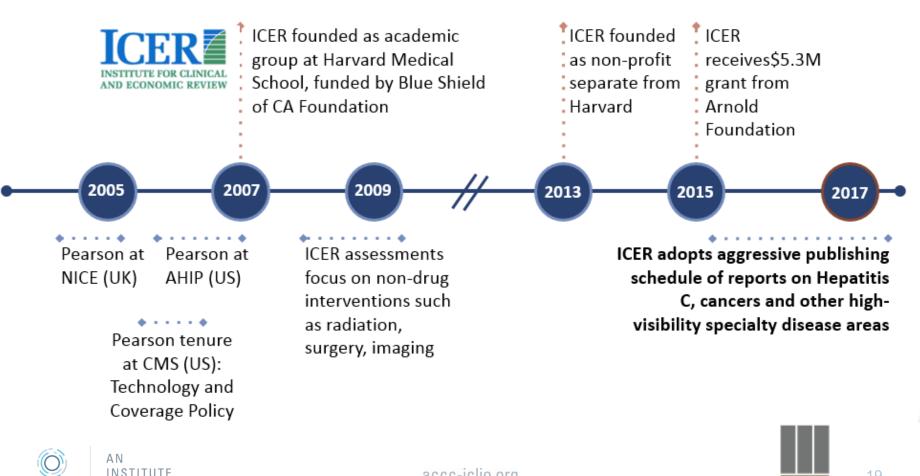


#### Oncology Value Frameworks: Analysis and Strategic Navigation



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#### **ICER:** Organizational Timeline and Background



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# Is ICER equipped to make accurate assessments?

- ICER's report on NSCLC has numerous flaws and gaps, mainly pertaining to ICER's lack of inclusion of all relevant data, apparent biases in its communication of such data and results, and questionable interpretation of available clinical evidence.
- Flaws in ICER's NSCLC report, gaps in methodology, and lack of transparency point to questions regarding ICER's objectives and alignment

Does ICER have the **appropriate expertise** to interpret complex clinical data without disease-specific clinical experts on staff or advisory panels?

Does ICER have processes in place to adequately prevent or limit bias or policy/political aims from creeping into its reports? Is ICER's approach of evaluating products close to approval time (or pre-approval) appropriate, given their methodology of including only RCT data?

Does ICER have the **staff bandwidth** to review and update reports in disparate disease areas and to ensure accuracy? Would ICER's various approaches, meet the standards of peer review in a widely published journal?





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#### **Op-Ed:** Our View on Value Frameworks in Oncology: Proposing Principles for Value Framework Development

By Lee Schwartzberg, MD, David Ettinger, MD, Mohammad Jahanzeb, MD, Gregory Otterson, MD and David Waterhouse, MD

In the past year, Value Frameworks have been introduced as potential tools for policy-setting and decisionmaking in oncology by organizations including ASCO, NCCN, and ICER. We recently reviewed a report issued by ICER, the Institute for Clinical and Economic Review, regarding Non-Small Cell Lung Cancer (NSCLC). This report is the basis for a meeting and voting by ICER's committee that will take place on Thursday, October 20, 2016, in St. Louis, MO.

For us as practicing oncologists and lung cancer researchers, this report has raised serious concerns regarding ICER's ability to interpret clinical evidence and reach conclusions on drug value that are scientific, comprehensive, and unbiased.

> We support these principles and wish to see them widely communicated and adopted as potential best practices in Value Framework development. We also invite our colleagues, our patients, and other stakeholders in cancer care delivery to communicate their perspectives on critical principles for Value Frameworks as we move this field forward.











David Waterhouse, MD, MPH

McGA





#### Principles Proposed for Value Frameworks by Lung Cancer KOLs

**Disease Experts as Evaluators and Authors** 

Patient-Centered Endpoints, Conclusions, and Definitions of Value

Rigorous Methodologies Reflecting Evidence Based Medicine

**Continuous Review and Revision** 

Peer Review and Authorship to Scientific Standards



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# **Questions?**



Thank you for participating in the ICLIO e-Course. Presentation slides and archived recording will be available at accc-iclio.org



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