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?

### Health Care Expenditures (%GDP)

- **US**: 16.6%
- **France**: 11.1%
- **Canada**: 10.0%
- **UK**: 9.9%
- **Sweden**: 11.2%
- **Australia**: 9.0%
- **Japan**: 11.4%

### Pharmaceutical Expenditures (%Total)

- **US**: 12.3%
- **France**: 15.0%
- **Canada**: 17.2%
- **UK**: 12.2%
- **Sweden**: 9.6%
- **Australia**: 15.0%
- **Japan**: 18.9%

### Health Care Expenditures (US$)

- **US**: $9,024
- **France**: $4,367
- **Canada**: $4,496
- **UK**: $3,971
- **Sweden**: $5,065
- **Australia**: $4,207
- **Japan**: $4,152

### Pharmaceutical Expenditures (US$)

- **US**: $1,112
- **France**: $656
- **Canada**: $772
- **UK**: $485
- **Sweden**: $489
- **Australia**: $626
- **Japan**: $783

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

Abraham I, McBride A, MacDonald K. Arguing (about) the value of cancer care. JNCCN 2016;14:1487-1489
Oncology value frameworks

Issues:
- Living longer
- Living better
- Efficacy
- Safety
- QALY
- Thresholds
- Cost/price
- Value
- Societal
- Payer

## Value in (cancer) care

<table>
<thead>
<tr>
<th>Health status achieved or retained</th>
<th>Process of recovery</th>
<th>Sustainability of health</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Survival</td>
<td>• Time to ...</td>
<td>• No recurrence or complications</td>
</tr>
<tr>
<td>• Degree of health or recovery</td>
<td>• Disutility of care or treatment process</td>
<td>• Long-term consequences of therapy</td>
</tr>
</tbody>
</table>

**Dynamic risk-adjustment over time for:**

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

Abraham I, McBride A, MacDonald K. Arguing (about) the value of cancer care. JNCCN 2016;14:1487-1489
Not-for-profit est. 2006 - funded by
- non-profit foundations (70%)
- life sciences companies (17%)
- insurers/providers (9%)
- government contracts (4%)

Threshold-driven value
- long-term value – value for money – QALY …
- short-term value – affordability – budget impact

https://icer-review.org
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
# Framework for Value Metrics

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

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
Jennifer Hinkel, MSc
McGivney Global Advisors
Oncology Value Frameworks: Analysis and Strategic Navigation

Greatest Potential Impact to Market Access and Decision-making Autonomy

- NCCN Evidence Blocks
- ICER: Institute for Clinical and Economic Review
- ASCO Value Framework
- MSKCC Drug Abacus

accc-iclio.org
ICER: Organizational Timeline and Background

- **2005**: ICER founded as academic group at Harvard Medical School, funded by Blue Shield of CA Foundation
- **2007**: Pearson at NICE (UK)
- **2009**: Pearson at AHIP (US)
- **2013**: ICER founded as non-profit separate from Harvard
- **2015**: ICER receives $5.3M grant from Arnold Foundation
- **2017**: ICER adopts aggressive publishing schedule of reports on Hepatitis C, cancers and other high-visibility specialty disease areas

Pearson tenure at CMS (US): Technology and Coverage Policy

ICER assessments focus on non-drug interventions such as radiation, surgery, imaging
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.

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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?

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 decision-making 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.
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
Questions?
Thank you for participating in the ICLIO e-Course. Presentation slides and archived recording will be available at accc-icl.io.org