Addressing Cost and Value in Cancer Care: ASCO Initiatives

Therese Mulvey, M.D.
Massachusetts General Hospital/ North
Director Breast Oncology
November 2015
Disclosures

- No financial disclosures.
- ASCO Board of Directors
Why Consider Costs of Cancer Care?

- Cost affects access and outcomes
- Out of pocket costs matter to patients, and affect treatment decisions
- Cost matters to payers
- Cost matters to society
ASC0’s Commitment to Defining Value in Cancer Care: Why?

- **Mission:** …to conquer cancer through research, education, prevention, and delivery of high-quality patient care

- **Vision statement includes the following:**
  - All patients with cancer will have lifelong access to **high-quality, effective, affordable** and **compassionate care**
  - The most **accurate** cancer information will be available so that patients and physicians can make **informed decisions** about cancer prevention and treatment
Nature of the Problem

- Cancer care costs are growing 15% per year.
- High prices of individual drugs are creating a difficult situation for patients and oncologists, who are inadequately prepared for these challenges.
- Cancer patients are unfamiliar with having to make difficult trade-offs between very high out-of-pocket costs and very expensive treatment with measurable but sometimes modest health benefits.
- Oncologists are often conflicted about how the cost of care should affect their behavior.
- Other stakeholders weigh in including payers, health policy experts, government, etc.
US Health Spending at 17.7% of GDP is ~50% Greater than Others (and Still Rising)

Higher Spending Does Not Increase Life Expectancy

Health Care Expenditures and Life Expectancy (2005)

Patients are Bearing More of the Costs

Projected family health insurance premium costs and average household income

Cost of Cancer Care is Rising

$125 billion in 2010

$175 billion in 2020

Figure LCO2: Estimates of national expenditures for cancer care in 2010 (in billions of dollars) by cancer site and phase of care

- Female Breast
- Colorectal
- Lymphoma
- Lung
- Prostate
- Leukemia
- Ovary
- Brain
- Bladder
- Kidney
- Head and Neck
- Uterus
- Melanoma
- Pancreas
- Stomach
- Cervix
- Esophagus
- All Other Sites

Expenditures (billion)

0 5 10 15 20 25

- Initial care
- Continuing care
- Last year of life

Cancer Prevalence and Cost of Care Projections: http://costprojections.cancer.gov/
Cost estimates expressed in 2010 dollars using CMS cost adjusters and adjusted for out-of-pocket expenditures, including co-payments and deductibles. Estimates for the population younger than 85 were developed using ratios of cost in the younger than 85 and older 85 populations from studies conducted in managed care populations.
Mean total cancer-related costs for each of the last 6 months of life for (A) inpatient and hospice and (B) outpatient services.

Chastek B et al. JOP 2012;8:75s-80s

©2012 by American Society of Clinical Oncology
National Health Expenditures, 2010

Total - $2.594 trillion

Conditions Treated by the 55 Highest-Expenditure Medicare Part B Drugs, 2010

<table>
<thead>
<tr>
<th>Conditions treated</th>
<th>Number of drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer, side effects of cancer, and side effects of chemotherapy</td>
<td>23</td>
</tr>
<tr>
<td>Autoimmune disorders and immunodeficiency</td>
<td>13</td>
</tr>
<tr>
<td>Cardiovascular disease testing and treatment</td>
<td>5</td>
</tr>
<tr>
<td>Chronic kidney disease, including ESRD</td>
<td>5</td>
</tr>
<tr>
<td>Asthma and lung diseases</td>
<td>3</td>
</tr>
<tr>
<td>Prevention of organ transplant rejection</td>
<td>3</td>
</tr>
<tr>
<td>Other*</td>
<td>15</td>
</tr>
</tbody>
</table>

Source: GAO analysis of CMS, NIH, and drug manufacturer data.
Eight of Top Ten Most Expensive Drugs Covered by Medicare are Cancer Drugs

### Top Ten Medicare Drugs 2012

<table>
<thead>
<tr>
<th>Drug</th>
<th>Millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranibizumab</td>
<td>$1,220</td>
</tr>
<tr>
<td>Rituximab cancer treatment</td>
<td>$876</td>
</tr>
<tr>
<td>Infliximab injection</td>
<td>$704</td>
</tr>
<tr>
<td>Injection pegfilgrastim 6mg</td>
<td>$642</td>
</tr>
<tr>
<td>Bevacizumab injection</td>
<td>$624</td>
</tr>
<tr>
<td>Aflibercept 1 mg</td>
<td>$384</td>
</tr>
<tr>
<td>Denosumab injection</td>
<td>$347</td>
</tr>
<tr>
<td>Oxaliplatin</td>
<td>$309</td>
</tr>
<tr>
<td>Pemetrexed injection</td>
<td>$292</td>
</tr>
<tr>
<td>Bortezomib injection</td>
<td>$278</td>
</tr>
</tbody>
</table>

Source: Moran Company Analysis of Medicare Physician/Supplier Procedure Summary File, 2012. Includes carrier claims only (physician office and DME). Outpatient Prospective Payment System (OPPS) claims are excluded.
## Challenge: Cost Seldom Considered by Stakeholders

<table>
<thead>
<tr>
<th>STAKEHOLDERS</th>
<th>CONSIDERATION OF COST-EFFECTIVENESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food and Drug Administration</td>
<td>No</td>
</tr>
<tr>
<td>Compendia</td>
<td>No</td>
</tr>
<tr>
<td>Drug product manufacturers</td>
<td>Limited</td>
</tr>
<tr>
<td>Centers for Medicare and Medicaid Services</td>
<td>No</td>
</tr>
<tr>
<td>Private payers</td>
<td>Variable</td>
</tr>
<tr>
<td>Specialty society clinical practice guideline developers</td>
<td>Limited</td>
</tr>
<tr>
<td>Health care/hospital networks</td>
<td>Variable</td>
</tr>
<tr>
<td>Clinicians</td>
<td>Limited</td>
</tr>
<tr>
<td>Patients</td>
<td>No</td>
</tr>
<tr>
<td>Policy makers</td>
<td>Limited</td>
</tr>
</tbody>
</table>
Defining & Increasing Value: Unique Challenges for Oncology

- Sense of urgency as many cancer patients have a poor prognosis and are facing imminent death
- Pressures to use newest technologies/treatments
- Treatments are expensive, making appropriate cancer care a hardship or unaffordable
- Treatments can be highly toxic/life-threatening (secondary expenses)
- Providers, patients & families often reluctant to switch to best supportive care, even at the obvious end of life
- Scientific measures of value requires a rigorous definition

Source: 2009 IOM Report: Assessing and Improving the Value in Cancer Care
ASCO’s Efforts to Lower Costs, Increase Value

- Promoting Adherence to Evidence-Based Medicine: ASCO Guidelines
- Participating in & Promoting “Choosing Wisely”
- Commitment to Quality Improvement: QOPI
- Working with Payers: Integration of Quality Measures into Reimbursement Decision-Making
- Cultivating a Learning Healthcare System: CancerLinQ
- Establishing Clinically Meaningful Outcomes in Cancer Research
- Payment Reform
- The Value in Cancer Care Task Force
What is “Value”? 

“the regard that something is held to deserve; the importance, worth, or usefulness of something.”

Benefit(s)

---------------------------------------------------------------

(Financial Cost + Non-financial Cost)
Value v. Cost

- Cost- measured in dollars to patient, to insurers or to society
- Cost- measured as acute side effects, time away from work or life events or late and long term toxicity.
- Value: changes over time
  benefits are personal
  value proposition is difficult to measure
  value may be receiving therapy or stopping therapy
Seeking an Association Between Clinical Benefit, Toxicity and Cost

Enhanced clinical benefit, tolerable toxicity, affordable cost

Modest benefit, high toxicity, high cost

Relative Value

Needed: valid metrics to distinguish magnitudes of difference for each variable
If a new treatment is to be introduced into clinical practice in the setting of “superiority” to an existing treatment, it is not sufficient to demonstrate that it is “better” than standard therapy. It should be necessary to demonstrate that its benefits outweigh its adverse effects and costs.

Sobrero, CaClinRes, 2015
Clinically Meaningful Outcomes - Sobrero

A “model” of Kaplan–Meier figure showing the four OS-related parameters.

1. HR (Cox model)
2. Gain in median OS (a→b)
3. Absolute increase in OS (c→d) at 2–3 years
4. Proportional increase in OS (ce/de) at 2–3 years
Value as a vocabulary term must be clearly defined if it is to be measured and evaluated in a vigorous scientific manner.

Our goal as health care professionals is to determine the common ground among ourselves and with patients that allows the health care system to provide quality care to all patients.
Value

• Physicians- highest clinical benefit at lowest cost (financial and toxicity) to individual patient

• Patients- a clear and honest discussion with their physician so that the patient can express what they “value”. This may be highest clinical benefit, best quality of life, lowest cost, cultural, spiritual, emotional issues.

• Payers- highest clinical benefit at lowest cost to group of patients

• Policy Makers- ensure broad groups of patients have access to highest quality of care at lowest cost to society
Getting the Doctor to Listen
Each Stakeholder Has a Role

- Providers: trying innovative ways to responsibly control costs while improving quality, through mechanisms such as clinical pathways and adherence to evidence-based medicine

- Payers: looking to assure highest and best use of limited resources through the development of innovative benefit designs and pay for performance mechanisms

- Patients: mobilizing to promote access through initiatives such as uniform patient assistance programs, patient navigation, and education of individuals and families about the cost of care

- Manufacturers: finding ways to innovate in the most cost-effective and efficient way possible

- Pharmacists: finding ways to enhance adherence, coordinate care, manage cost in purchasing.
ASCOb’s Value Initiative

- In spring 2013, ASCO Board of Directors engaged in a strategic discussion on value around the following statement:
  - Increasingly, the desired care for oncology patients will be assessed on the VALUE of that care rather than the COST
  - This is an opportune moment for ASCO to take the lead in defining VALUE and suggesting how VALUE should be integrated into treatment decisions
Established in 2007 as the Cost of Care Task Force to define the challenges related to the cost of cancer care and develop strategies to address these challenges in the context of ASCO’s mission.

Goals:

- Increase physician education and guidance about cost
- Increase patient education and assistance regarding cost
- Promoting high-value medical decision-making
- Assuring value care
Physician Education

• Goal: To develop educational resources to assist oncologists and patients in addressing cost of care.

• Accomplishments to Date:
  – JCO Statement on Individualized Care for Patients with Advanced Cancer (2011)
  – Robust offering of sessions at ASCO meetings
  – ASCO University webinar course
  – JCO Value Framework Statement
Choosing Wisely Campaign: ASCO’s “Top 5” Lists for Oncology

ASCO has issued two “Top Five” lists of interventions that should be questioned— that are frequently practiced but not evidence-based

Examples:

• Cancer directed therapy in patients with low performance status

• Imaging in early-stage prostate cancer with low risk of metastasis

• Use of white cell stimulating factors to prevent febrile neutropenia in patients with < 20% risk
NSCLC patients who get chemotherapy near the end of life (aggressive-approach chemotherapy) do not live any longer than those who stop chemotherapy earlier, but do have delayed or no use of hospice.

Many patients have or develop poor PS.

Then, it is time to re-evaluate plans.

Patient Resources

- **Goal:** To develop decision-making and communication tools to help patients ask questions about cost, understand the realities of the cost involved and interpret cost-benefit.

**Patient Information Booklet**
An easy-to-read booklet to help patients start and guide a conversation with their health care team about coping with costs of cancer care. For distribution to patients in the office setting as well as online.
Standardize Chemo and Oral Drug Order Templates

- Chemotherapy, supportive care meds and hydration
- Reduce mixing time
- Reduce chair time
- Improve patient experience
- Standardize dose rounding
- Limits waste
ASCO’s Value Framework

• The Value in Cancer Care Task Force was tasked with developing a framework for comparing the value of various cancer treatments and interventions

• Three work groups were established, each charged with defining a key Value parameter:
  – Clinical Benefit (OS, PFS, Palliation)
  – Cost (Cost in dollars to deliver a particular mode of therapy)
  – Toxicity (Physical toxicity)

• The work groups initially focused on regimens used to treat advanced/incurable cancers, then expanded to look at the adjuvant setting
Why not just use other established measurements?

- QALY
- ICER
QALY

- Quality Adjusted Life Year
- Evaluate and compare the value of a given treatment by cost for the purposes of allocating resources across a health system.
ICER

- Incremental cost effectiveness ratio
- Difference in cost between two interventions divided by the difference in effectiveness.
- A statistic used in comparative effectiveness research.

\[
\text{ICER} = \frac{C_1 - C_0}{E_1 - E_0}
\]
Neither QALY or ICER meet the criteria of patient centered, shared decision making, transparent discussion between a patient and a provider.
Important Points to Note

- **Importance of High-Quality Evidence**
  - Relies on data available from randomized clinical trials
  - Other endpoints (e.g., quality of life, patient reported outcomes) not adequately collected and reported for inclusion

- **Net Health Benefit = Benefit + Toxicity**
  - Displayed separately from cost
  - Derived from the comparison of 2+ regimens in a trial
  - Does not permit inter-trial comparison

- **Cost**
  - Drugs only; many other facets of cost

- **Physician Judgment**
  - Framework is a tool, not a substitute
  - Helps weigh options, not limit them

www.asco.org/value
ASCO’s Value Framework

• Desired outcome:
  – A transparent, clinically driven, methodologically sound method for defining and assessing relative value of cancer care options
  – Oncology providers will have the skills and tools to assess relative value of therapies and use these in discussing treatment options with their patients.
  – Patients have ready access to information to help them understand the relative value of treatment options that meet their unique needs.
ASCO’s Value Framework

• Designed for doctors to use in conversations with their patients to help inform their individual decisions.

• Intended to support consideration of individual patient circumstances and the best evidence available on a particular treatment’s clinical effectiveness, toxicity and cost
  • The highest ranked regimen may *not* necessarily be the best option for an individual patient

• Begin to work to a uniform definition of “value” that is free of judgement.
Value Framework

- Define
- Assess and measure
- Draft
Framework Overview

• Clinical Benefit
• Toxicity
• Bonus Points
• Net Health Benefit
• Cost
• Summary Assessment

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Calculating Clinical Benefit: Advanced Disease

- Maximum 80 points
- If OS reported:
  - Score (1-5) based on % change in median OS
  - Multiplier: 16
- If no OS reported, PFS:
  - Score (1-5) based on % change in median PFS
  - Multiplier: 11
- If no OS or PFS, Response Rate (RR)
  - Score (1-5)
  - Multiplier: 8

Accounting for the Tail of the Curve in the Advanced Setting:

5 = At double the median survival, there is a 50% improvement in the fraction of patients without progression or death

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Calculating Clinical Benefit: Adjuvant Setting

- Maximum 80 points

- If HR reported:
  - Score (1-5) based on Hazard Ratio for death
  - Multiplier: 16

- If no HR reported, PFS:
  - Score (0-4) based on % change in median PFS
  - Multiplier: 15

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Calculating Toxicity

- **Maximum**: 20 points

- Score (-20 points to +20 points) based on % increase in number Grade 3-5 toxicities

- More Grade 3-5 Toxicities = Lower Score

**Accounting for Late Effects in the Adjuvant Setting:**

If there are unresolved symptomatic treatment-related toxicities at 1 year after completion of treatment, subtract 5 points

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Bonus Points for Quality of Life (Advanced Disease)

- **Maximum:** 30 points
  - Palliation of Symptoms
    - 10 points
  - Treatment-Free Interval
    - 0-20 points, based on % change

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• The added benefit patients may receive from a new cancer drug compared with a standard of care
Calculating Clinical Benefit:
Adjuvant Setting

• Maximum 80 points

• If HR reported:
  • Score (1-5) based on Hazard Ratio for death
  • Multiplier: 16

• If no HR reported, PFS:
  • Score (0-4) based on % change in median PFS
  • Multiplier: 15

www.asco.org/value
## Advanced Disease Example

<table>
<thead>
<tr>
<th>POINTS</th>
<th>Clinical Benefit (Max=80 pts)</th>
<th>OS Score: 25% - 49% = 2</th>
<th>Regimen A: 14 mo. OS</th>
<th>(14 - 10) / 10 = 40%</th>
<th>32</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Regimen B: 10 mo. OS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicty</td>
<td>Regimen A: 20 Gr3-5</td>
<td>(20 – 12) / 12 = 66%</td>
<td>Regimen B: 12 Gr3-5</td>
<td></td>
<td>-10</td>
</tr>
<tr>
<td>(Max = 20 pts)</td>
<td>50-74% more Gr3-5 toxicities = -10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bonus Points (Max = 30 pts)</td>
<td>Palliation?</td>
<td>No</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment-Free Interval?</td>
<td>No</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net Health Benefit (Max = 130 pts)</td>
<td>22</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Cost (monthly)</td>
<td>Drug Acquisition Cost</td>
<td>$12,000.00 (vs. $500)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient Payment</td>
<td>(calculated per patient)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Example: Advanced Disease

- Clinical Benefit:
  - OS 14 mo.
  - OS 10 mo.

- Toxicity:
  - Regimen A: 20
  - Regimen B: 12

- NHB:
  - Regimen A: 22/130

- Cost:
  - Regimen A: $12,000
  - Regimen B: $500

Cost Clinical Benefit NHB

Toxicity

Regimen A Regimen B

Example: Advanced Disease

Massachusetts General Hospital Cancer Center
Example: Adjuvant Setting

45% reduction in risk of recurrence

Regimen A
Regimen B

Clinical Benefit
Toxicity
NHB
Cost

Example: Adjuvant Setting

45% reduction in risk of recurrence

Regimen A
Regimen B

Clinical Benefit
Toxicity
NHB
Cost

Example: Adjuvant Setting

45% reduction in risk of recurrence

Regimen A
Regimen B

Clinical Benefit
Toxicity
NHB
Cost

Example: Adjuvant Setting

45% reduction in risk of recurrence

Regimen A
Regimen B

Clinical Benefit
Toxicity
NHB
Cost
Sample Scenarios

• **Advanced Disease**
  - Non-small cell lung cancer first line therapy
  - Multiple myeloma stage III
  - Castrate resistant prostate cancer

• **Adjuvant Setting**
  - HER-2 amplified breast cancer

• **Examples are:**
  - Relatively common cancers
  - Advanced and adjuvant
  - Solid tumors and blood cancers

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Why Net Health Benefit?

• IOM statement of quality health care delivery:
  – Safety
  – Effectiveness
  – Patient Centeredness
  – Timeliness
  – Efficiency
  – Equity

• NHB encompasses efficacy (clinical benefit), safety (toxicity) and efficiency (cost) to encompass patient centeredness.
Why drug acquisition cost?

- Cost of a drug is not transparent.
- Cost to a patient is difficult to measure due to individual complexity of health plans.
- Cost as DAC is consistent and transparent.
Summary

• Standardized tool for measuring net health benefit
• Transparent information about cost
• Patient-centered – designed to facilitate discussion and shared decision-making
• Highest quality clinical evidence
• Premium on high-value efficacy measures and improvement in side effects

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Summary

• Draft
• Definition of value to assess the relative value of cancer treatment options
• This will be a tool for provider patient discussion once it is in a visually acceptable, easily understood and patient centered format.
• We are not there yet…
Next Steps

Public comment accepted until Aug. 21
Integrate feedback
Develop user-friendly tools

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Change is Coming

• Whether we’re for or against it, pressure is building in U.S. policy circles for the federal government to take action to regulate the cost of drugs and technologies.

• Increasing access is crucial, yet thwarting innovation is a real concern.

• Clinicians can use the value framework to assess “value” of new drugs, procedures or overall therapies.

• Defining “value” allows individual discussion with patients, develop methods for policy makers, payers and society to speak to these issues in a common language.
Everyone wants to give best therapy to the right person at the right time for the lowest cost and toxicity.

- Getting there will be difficult and require input from many stakeholders.
- The end result must be a patient and provider discussion that has the best scientific evidence available and the patients wishes for their health in the context of their lives.
Everyone agrees to help reduce healthcare costs!...

I can't afford that diagnosis. Do you have a cheaper one?
Questions?