Oncology Stewardship: Value, Quality, and Safety
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KENTUCKY HEMATOLOGY/ONCOLOGY
PHARMACY SYMPOSIUM 2020
Disclosures

• The authors have no relevant disclosures
Learning Objectives

• Explain the impact of financial toxicity on the cancer population.
• Discuss the evolution of financial toxicity and how this has developed in the United States.
• Identify the solutions being evaluated to improve access and affordability of drugs.
The Pillars of Oncology Stewardship

• **Value**
  - The use of available resources to maximize returns on investment and produce optimal outcomes

• **Quality**
  - Safe, consistent, and appropriate care to provide optimal patient outcomes

• **Safety**
  - Providing a reasonable, appropriate dose to the correct patient at the correct treatment schedule for an appropriate indication, based on a specific treatment setting
Ms. R is a 59-year-old woman diagnosed with Stage II HER2+ breast cancer

- Lost her job during treatment
- Has started to withdraw money from her retirement account to pay for medical care

**Current treatment:** Docetaxel, carboplatin, trastuzumab, pertuzumab, peg-filgrastim OnPro (TCHP)
What is Financial Toxicity?

The distress or hardship arising from the financial burden of cancer treatment
Patient Risk Factors

- Female
- Total household income < $35,000
- Larger Household Size
- Less than college education
- Non-White
- Insurance Benefits Pending
- < 61 YOA

Financial Toxicity

Impact on Cancer Patients

- Declared bankruptcy: 1.4%
- 1.7 million reported making other financial sacrifices
- 2.3 million were unable to cover the costs of their medical care visits
- 19.6 million cancer care survivors in the US

Based on data collected by Hrishikesh Kale and Norman V. Carroll, Ph.D VCU March 2016.
Objective Financial Burden

- Expenditures
  - Drug Costs
  - Other direct medical costs
  - Related treatment costs

Subjective Financial distress

- Wealth
  - Wages & salaries or replacement income
  - Savings & Assets

Financial Toxicity

Anxiety and Discomfort

Carrera PM. Paper presented at: Multi-national Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) 2017 Annual Meeting; June 22–24, 2017; Washington, DC
Economic Consequences of Cancer Treatment

Health Insurance

Seek Treatment

Yes
- Indirect Costs
- Drug Copays
- Medical Copays
- Ancillary Care Costs
- Time costs of patient
- Time costs of informal caregiver

No
- Indirect Costs

Direct Costs

Change in Consumption

Other strategies
- Change Insurance
- Borrow Money
- Use of Savings
- Sale of assets

Distress

Indebtedness

Non-adherence

Carrera PM. Paper presented at: Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) 2017 Annual Meeting; June 22–24, 2017; Washington, DC
## Cost Containment Issues

<table>
<thead>
<tr>
<th>TIER</th>
<th>DRUG TYPE</th>
<th>COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Preferred Generics</td>
<td>$</td>
</tr>
<tr>
<td>2</td>
<td>Generics</td>
<td>$$</td>
</tr>
<tr>
<td>3</td>
<td>Preferred Brands</td>
<td>$$$</td>
</tr>
<tr>
<td>4</td>
<td>Non-Preferred</td>
<td>$$$$</td>
</tr>
<tr>
<td>5</td>
<td>Specialty</td>
<td>$$$$$</td>
</tr>
</tbody>
</table>

Available at: https://medicarehelp.healthpartners.com/blog/prescription-drug-tiers/
Impact on Cancer Patients with Medicare
# US FDA-Approved Oral Cancer Drugs in 2016 to 2017 and Costs of Treatment

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Cancer Type</th>
<th>Cost Per Month of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brigatinib</td>
<td>Alunbrig</td>
<td>Renal cell carcinoma</td>
<td>$12,868.76</td>
</tr>
<tr>
<td>Cabozantinib</td>
<td>Cabometyx</td>
<td>Renal cell carcinoma</td>
<td>$15,156.59</td>
</tr>
<tr>
<td>Enasidenib</td>
<td>Idhifa</td>
<td>Acute myeloid leukemia</td>
<td>$25,141.67</td>
</tr>
<tr>
<td>Midostaurin</td>
<td>Rydapt</td>
<td>Acute myeloid leukemia</td>
<td>$15,798.72</td>
</tr>
<tr>
<td>Neratinib</td>
<td>Nerlynx</td>
<td>Breast cancer</td>
<td>$10,613.75</td>
</tr>
<tr>
<td>Niraparib</td>
<td>Zejula</td>
<td>Ovarian cancer</td>
<td>$14,430.19</td>
</tr>
<tr>
<td>Ribociclib</td>
<td>Kisqali</td>
<td>Breast cancer</td>
<td>$8,476.31</td>
</tr>
<tr>
<td>Rucaparib</td>
<td>Rubraca</td>
<td>Ovarian cancer</td>
<td>$20,162.74</td>
</tr>
<tr>
<td>Venetoclax</td>
<td>Venclexta</td>
<td>Chronic lymphocytic leukemia</td>
<td>$7,514.41</td>
</tr>
</tbody>
</table>

How much are you willing to pay for an additional 4 – 6 months of life with good quality?

A. $0
B. $10,000
C. $25,000
D. $100,000
Willingness to Pay for an Expensive Anti-Cancer Drug

Drug A: Improved Survival
- Yes: 51%
- No: 41%
- Unsure: 8%

Drug B: Less Toxicity
- Yes: 71%
- No: 18%
- Unsure: 11%

Drug C: 50% response rate
- Yes: 75%
- No: 14%
- Unsure: 11%
Medical expenditures for cancer in the year 2020 are projected to reach at least $158 billion — an increase of 27% over 2010.

Global Oncology and Supportive Care Costs

| Global Oncology Trends 2017. Report by the Quintiles IMS Institute | KENTUCKY HEMATOLOGY/ONCOLOGY PHARMACY SYMPOSIUM 2020 |
Patients spend not only their own personal resources, but also the pooled resources of others.

- Protects individual consumers from inflated cost
- Makes it difficult to judge the relative economic value
## Contrasts in US and UK Drug Approval Process

<table>
<thead>
<tr>
<th>Cost-Effectiveness Analysis</th>
<th>Transparency of nonpublished drug trials</th>
<th>Time required for approval</th>
<th>Coverage Mandates</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Van Norman, G. *Jacc: Basic To Translational Science* Vol. 1, No. 5, August 2016:399 – 412
Financial toxicity is an evolving issue in the United States due to which of the following:

A. The increased medication non-adherence rates
B. The fear of having cost-of-care discussions
C. The lack of cost-effectiveness evaluations in the current FDA drug approval process
D. All of the above
• Focus on value-based solutions that are patient-centered and evidence-driven
• Cost-containment strategies should not limit access to or prescribing of appropriate care
• Cost-containment strategies should incentivize—not hamper—innovation
Solutions Underway

- Memorial Sloan Kettering Drug Abacus
- ASCO Value Framework
- NCCN Evidence Block Initiative
- Value-Based Clinical Pathways
- Enhanced Patient-Provider Communication
- Oncology Stewardship Teams
- Institute for Clinical and Economic Review (ICER) Collaborative Evaluation Model
- Quality Oncology Practice Initiative (QOPI®)
- Value-Based and Outcomes-Based Pricing
- Medicare Drug Pricing Negotiations
- Expansion of Financial Counseling Services
- Development of Biosimilars and Generics

Question for the Audience

Which of the following tools have you referred to in your practice to enhance the delivery of value-based care?

A. Drug Abacus
B. NCCN Evidence Blocks
C. Clinical Pathways
D. None of the above
**Goal:** To allow users to generate a recommended value-based price based, and compare it to the actual list price for a drug.

**How goal is accomplished:**
- Accounts for factors such as efficacy, toxicity, novelty, cost of development, rarity of cancer, and overall prognosis of disease state to calculate the “abacus price”
- The user decides how much each factor matters in determining a drug’s value.

- Abacus has not been updated so the number of drugs included is limited.

- Intended to be a proof-of-principle research tool.

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ASCO Value Framework

• **Goal:** Guide physicians on the net health benefit between two regimens, and the associated difference in cost, in order to facilitate shared-decision-making

• **How goal is accomplished**
  • Users review prospective clinical trials in which two regimens are compared head-to-head
  • Value worksheet takes into account clinical benefit, side effects, and quality of life measures, in the context of cost
    • Separate version for advanced cancer treatment and potentially curative

ASCO Value Framework: Example

NHB = Net Health Benefit

NCCN Evidence Blocks

• **Goal:** Provide patients and providers information to make more informed choices when selecting therapies based on supporting data, cost, and other treatment-related measures

• **How goal is accomplished**
  • Panel members score each measure using a standardized ‘1-5’ scale
  • Experts combine published data with their clinical experience in real-world populations

# NCCN Evidence Blocks: Example

## Evidence Blocks for Preoperative/Adjuvant Therapy for HER2-Positive Disease

<table>
<thead>
<tr>
<th>Preferred regimens</th>
<th>Neoadjuvant</th>
<th>Adjuvant</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC followed by T/trastuzumab (doxorubicin/cyclophosphamide followed by paclitaxel/trastuzumab)</td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td>Dose-dense AC followed by T/trastuzumab (doxorubicin/cyclophosphamide followed by paclitaxel/trastuzumab)</td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td>AC followed by T/trastuzumab/pertuzumab (doxorubicin/cyclophosphamide followed by paclitaxel plus trastuzumab/pertuzumab)</td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td>Paclitaxel/trastuzumab</td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td>TCH (docetaxel/carboplatin/trastuzumab)</td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td>TCH (docetaxel/carboplatin/trastuzumab)/pertuzumab</td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td><strong>If residual disease after preoperative therapy:</strong></td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td>Ado-trastuzumab emtansine</td>
<td>![Icon]</td>
<td></td>
</tr>
<tr>
<td><strong>If no residual disease after preoperative therapy or no preoperative therapy:</strong></td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td>Trastuzumab to complete 1 year of HER2 targeted therapy</td>
<td>![Icon]</td>
<td></td>
</tr>
<tr>
<td>Trastuzumab/pertuzumab to complete 1 year of HER2 targeted therapy</td>
<td>![Icon]</td>
<td></td>
</tr>
<tr>
<td><strong>Useful in certain circumstances</strong></td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td>Docetaxel/cyclophosphamide/trastuzumab</td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td><strong>Other recommended regimens</strong></td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
<tr>
<td>AC followed by docetaxel/trastuzumab</td>
<td>![Icon]</td>
<td>![Icon]</td>
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<tr>
<td>AC followed by docetaxel/trastuzumab/pertuzumab</td>
<td>![Icon]</td>
<td>![Icon]</td>
</tr>
</tbody>
</table>
Based on the NCCN Evidence Blocks for breast cancer, is Ms. R on a preferred treatment regimen for neoadjuvant HER2+ disease (TCH + Pertuzumab)?

A. Yes
B. No
C. Not sure

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<tr>
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<th>Adjuvant</th>
</tr>
</thead>
</table>
| AC followed by T/trastuzumab  
(doxorubicin/cyclophosphamide followed by paclitaxel/trastuzumab) | ![](image) | ![](image) |
| Dose-dense AC followed by T/trastuzumab  
(doxorubicin/cyclophosphamide followed by paclitaxel/trastuzumab) | ![](image) | ![](image) |
| AC followed by T/trastuzumab/pertuzumab  
(doxorubicin/cyclophosphamide followed by paclitaxel plus trastuzumab/pertuzumab) | ![](image) | ![](image) |
| Paclitaxel/trastuzumab | ![](image) | ![](image) |
| TCH (docetaxel/carboplatin/trastuzumab) | ![](image) | ![](image) |
| TCH (docetaxel/carboplatin/trastuzumab)/pertuzumab | ![](image) | ![](image) |
Clinical Pathways

• **Goal**: Increase quality and decrease costs associated with cancer care

• **How goal is accomplished**
  - Provides “preferred regimens” for various disease states
  - Designed to support the implementation of guidelines and protocols
  - Provides financial incentives to institutions based on compliance with pathway recommended care

Clinical Pathways

How are they developed?

- Clinical benefit
- Toxicity
- Strength of national guideline recommendations
- Cost

https://aimproviders.com/medoncology-anthem/about-the-program/cancer-treatment-pathways/
Accessed 8/14/2020.
# Clinical Pathways: Example

## Neoadjuvant and Adjuvant Therapy | HER2 Negative

- **ddAC → weekly T**: dose dense doxorubicin (Adriamycin) and cyclophosphamide followed by weekly paclitaxel
- **TC**: docetaxel (Taxotere) and cyclophosphamide

## Neoadjuvant and Adjuvant Therapy | HER2 Positive

- **AC → TH**: doxorubicin (Adriamycin) and cyclophosphamide followed by paclitaxel and trastuzumab*
- **TCH**: docetaxel (Taxotere), carboplatin, and trastuzumab*

## Neoadjuvant Therapy | HER2 Positive | Hormone Receptor (ER/PR) Negative

- **TCH+P**: docetaxel (Taxotere), carboplatin, trastuzumab, and pertuzumab (Perjeta)

## Adjuvant Therapy | HER2 Positive

- **TH**: paclitaxel and trastuzumab (*Pathway for stage I, HER2 positive breast cancer only)*

## Adjuvant Therapy | HER2 Negative | Hormone Receptor (ER/PR) Negative | Residual Disease following Neoadjuvant Therapy

- **Capecitabine**

## Adjuvant Therapy | HER2 Positive | Residual Disease following Neoadjuvant Therapy

- **Ado-trastuzumab emtansine (Kadcyla)**

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* Administration of trastuzumab is limited to 1 year (maximum 18 cycles)
Clinical Pathways

Pros
• Incentivizes drug companies and providers to reduce cost
• Prior authorizations waived
• Encourages high value therapies
• Helps eliminate usage of “me too” agents

Cons
• Can limit patient choice
• Impedes access to innovative treatments
• Encourages one-size-fits-all oncology care
• Who are making these pathways?
• **Goal:** Promote evidence-based practice and minimize resource overutilization while improving patient outcomes

• **How goal is accomplished**
  
  • “Cancer therapy steward” reviewed all requests for non-formulary or off-label chemotherapy/supportive care medications for a year on their inpatient service line
  
  • 100% of requests were approved…but valuable insights obtained
Key Components of a Successful Oncology Pharmacy Stewardship

- Interprofessional approach
- Accountability
- Leadership commitment and active involvement
- Informatics-based approach
- Implementation of a practice or process that supports stewardship
- Reporting
- Education
- Tracking
Be a Voice of Reason

- Serve as an advocate for your patients for decreased cancer drug costs
- Critically review the data, including degree of clinical benefit weighed against all forms of toxicity
- Example: Ziv-aflibercept
**Costs of Cancer Treatment Discussions**

80% of patients wanted cost information

80% of patients had no negative feelings about hearing cost information

28% of oncologists felt comfortable discussing cost

Importance of understanding what patient will be responsible for paying

Pharmacists can:

• Incorporate cost discussions into the education session
• Fill the void to ensure all patients receive the needed treatment cost discussion
• Be an advocate for reduced cancer pharmaceutical costs
Other Solutions to Achieve High-Value Care

• Site of Care
  • At-home use of SQ dosage forms?
  • At-home IV infusion services?

• Restructuring the drug development process
  • Incorporate QOL and patient-reported outcomes
  • Requiring “clinical meaningful” outcome measures for approval
  • Grading financial toxicity of new therapies

• Increased transparency of drug costs and reimbursement
How Can You Help?

• Be judicious in using new and costly products until there is clearly established value

• Ensure that valued product aligns with that patients unique needs, preferences, and goals

• Make sure patients are aware of the cost, benefit, and personal financial impact of their treatment options and choices
How do we manage financial toxicity?
4 expert perspectives

- Invest resources to identify those most likely to benefit from therapy
- Remove coverage mandates from state and federal insurance laws
- Physician acceptance, practice, and promotion of transparency in price
- Engage in treatment planning to better reflect patient values

Zafar Y et al. 2017 ASCO Educational Book.
Onkology Stewardship: Value, Quality, and Safety
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