



Oncology Stewardship: Value, Quality, and Safety

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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

Patient Case

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)

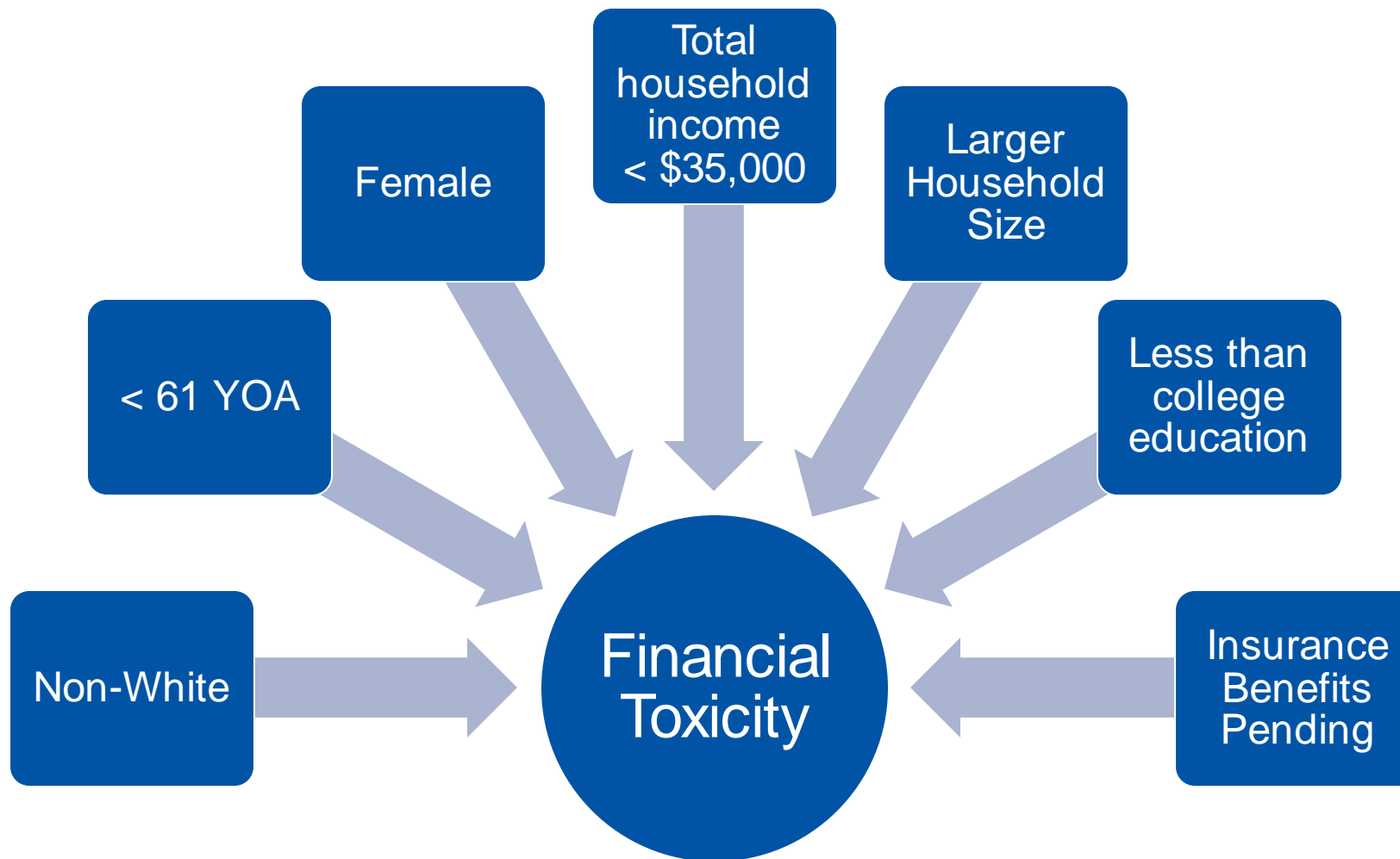


What is Financial Toxicity?

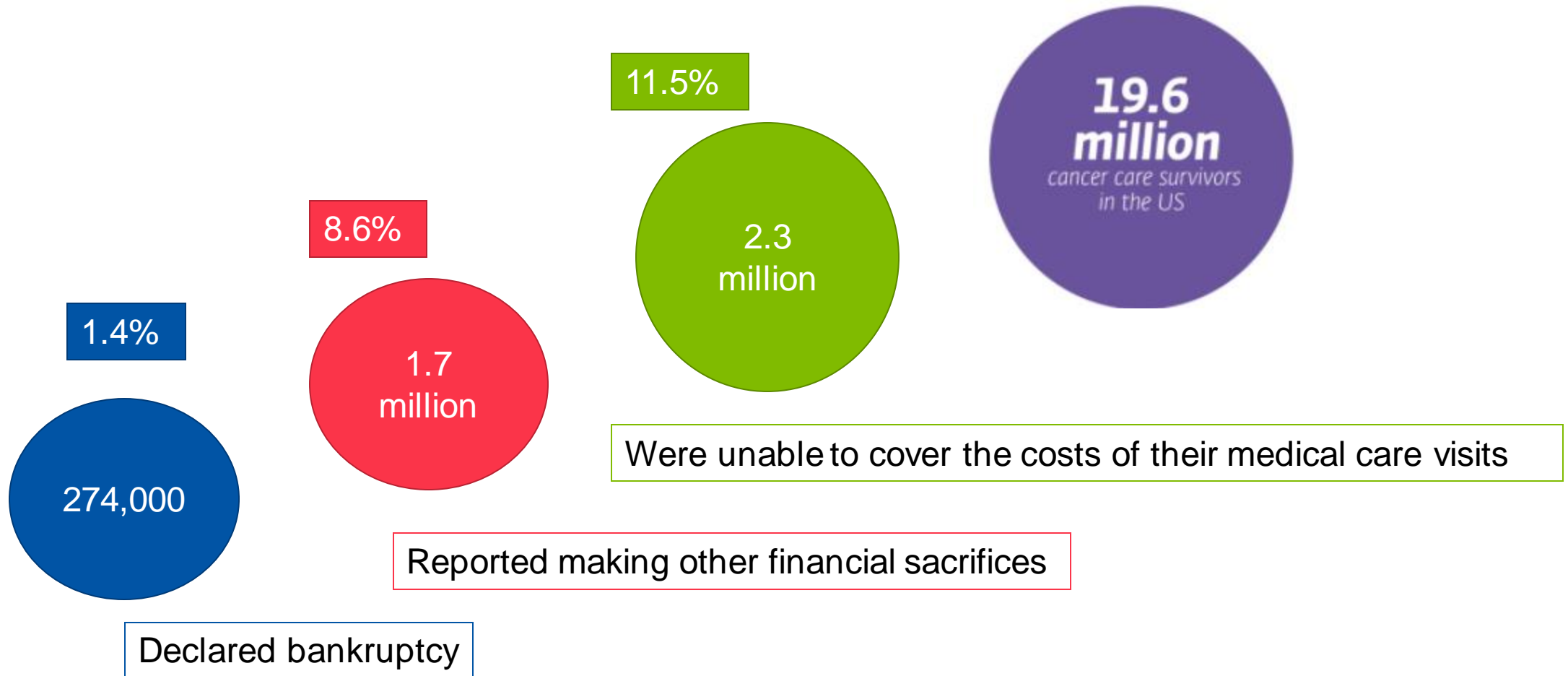


The distress or hardship arising from the financial burden of cancer treatment

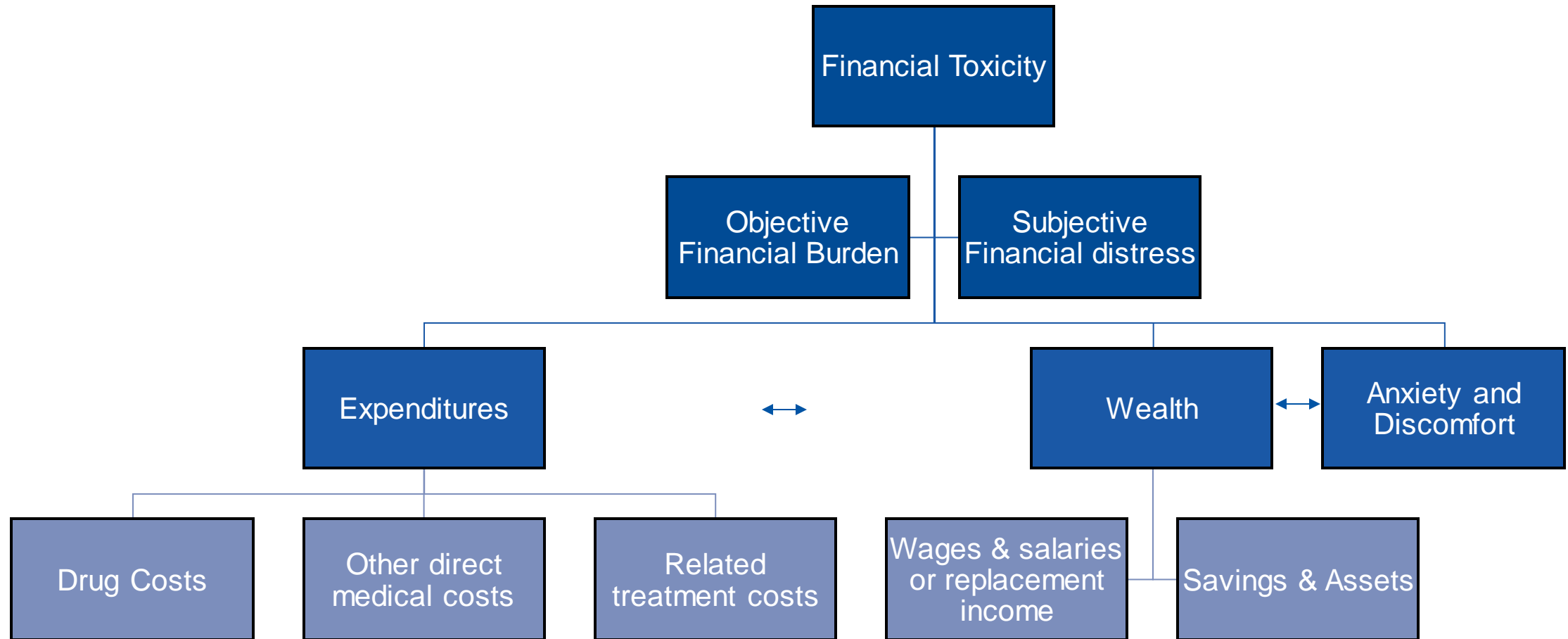
Patient Risk Factors



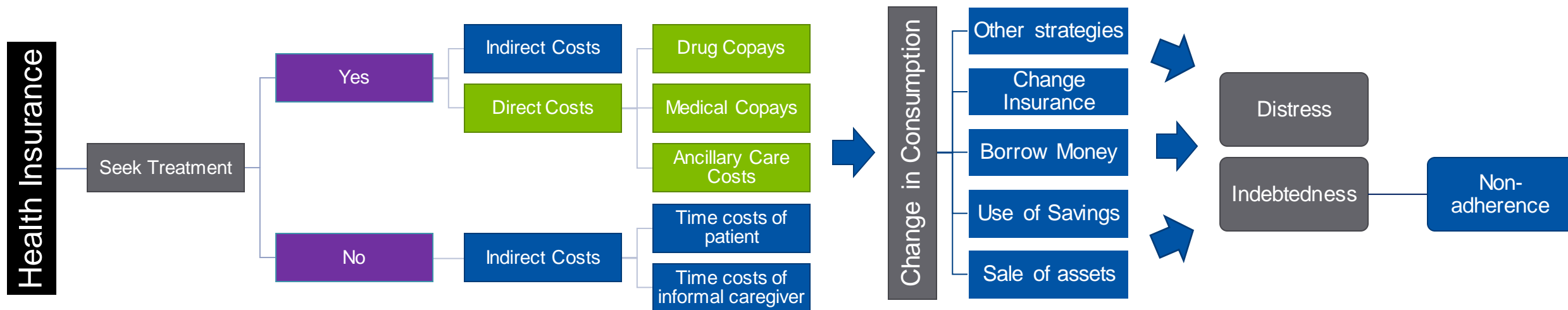
Impact on Cancer Patients



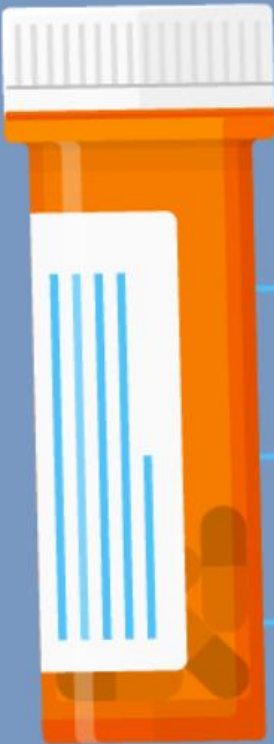
Framework of Financial Toxicity in a Cancer Patient








Economic Consequences of Cancer Treatment

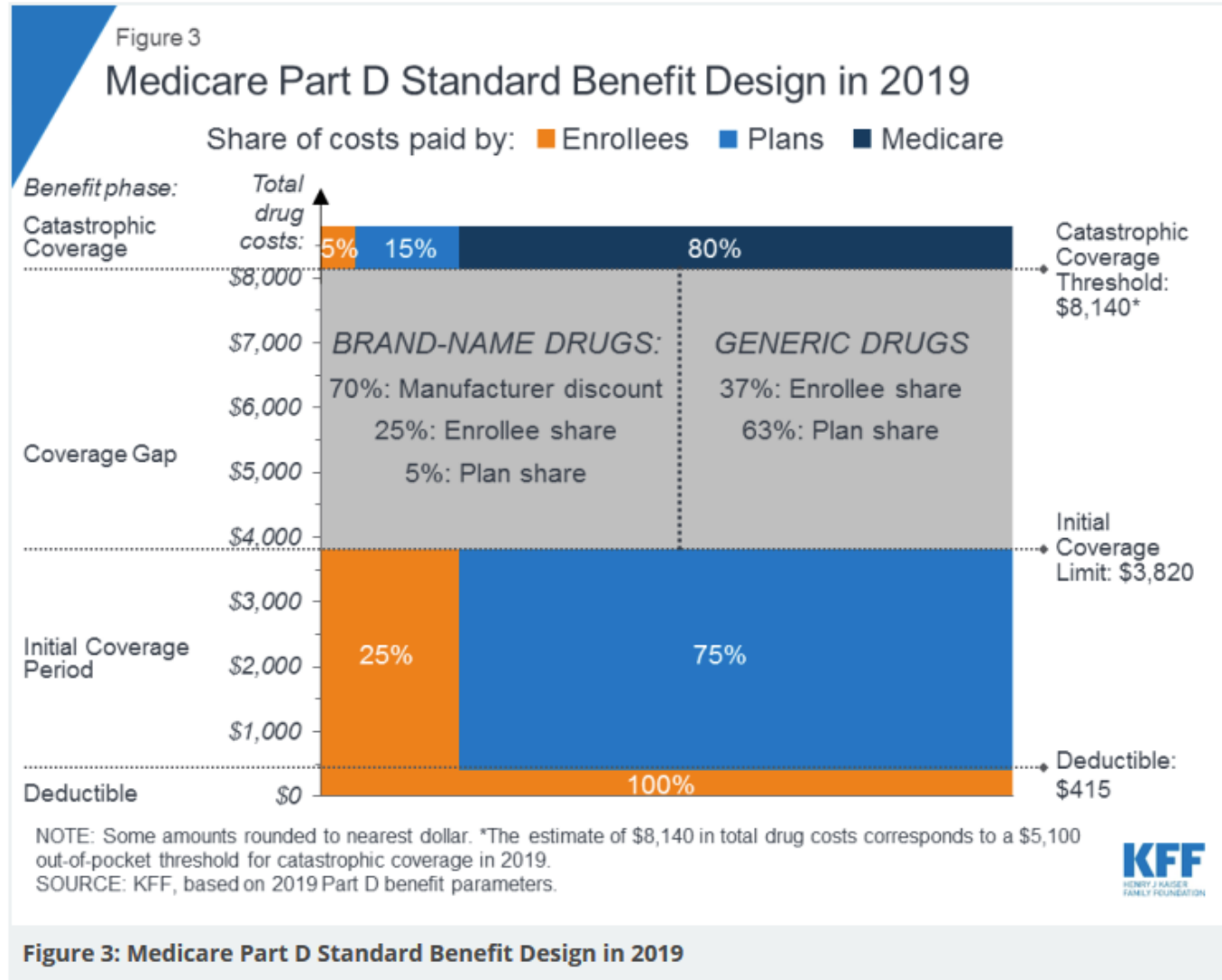


Cost Containment Issues



TIER	DRUG TYPE	COST
1	Preferred Generics 	\$
2	Generics 	\$\$
3	Preferred Brands 	\$\$\$
4	Non-Preferred 	\$\$\$\$
5	Specialty 	\$\$\$\$\$

Impact on Cancer Patients with Medicare



US FDA-Approved Oral Cancer Drugs in 2016 to 2017 and Costs of Treatment

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

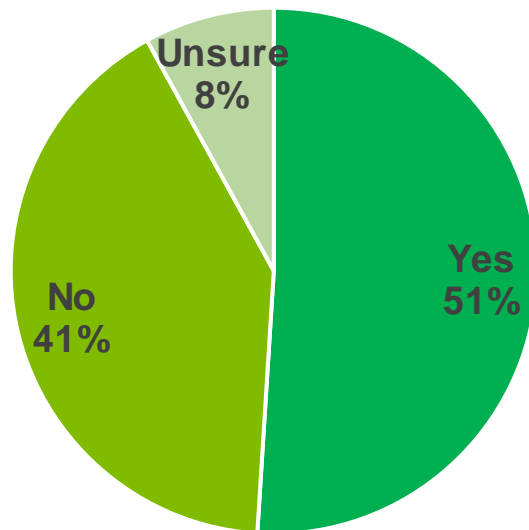
Question for the Audience

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

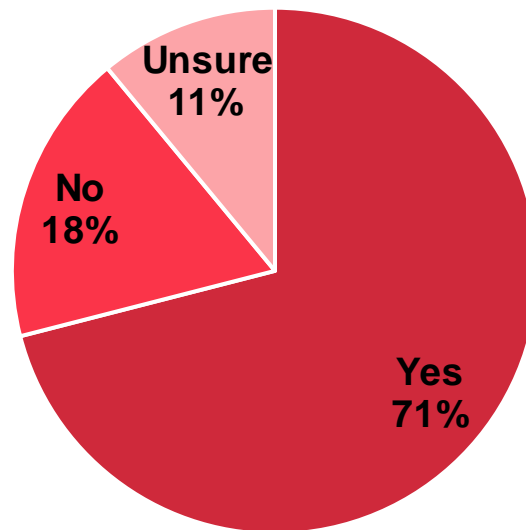
- A. \$0
- B. \$10,000
- C. \$25,000
- D. \$100,000

Willingness to Pay for an Expensive Anti-Cancer Drug

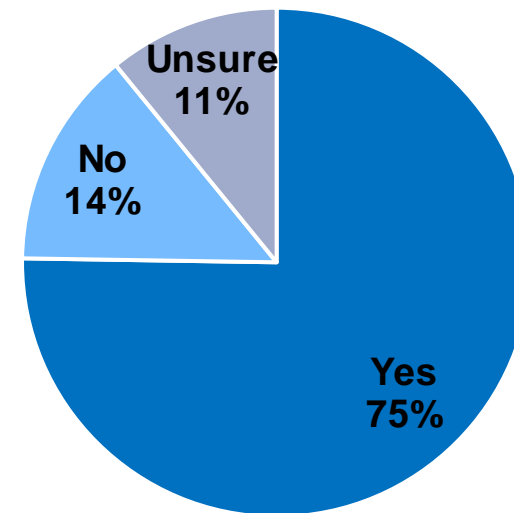
Drug A: Improved Survival



Drug B: Less Toxicity



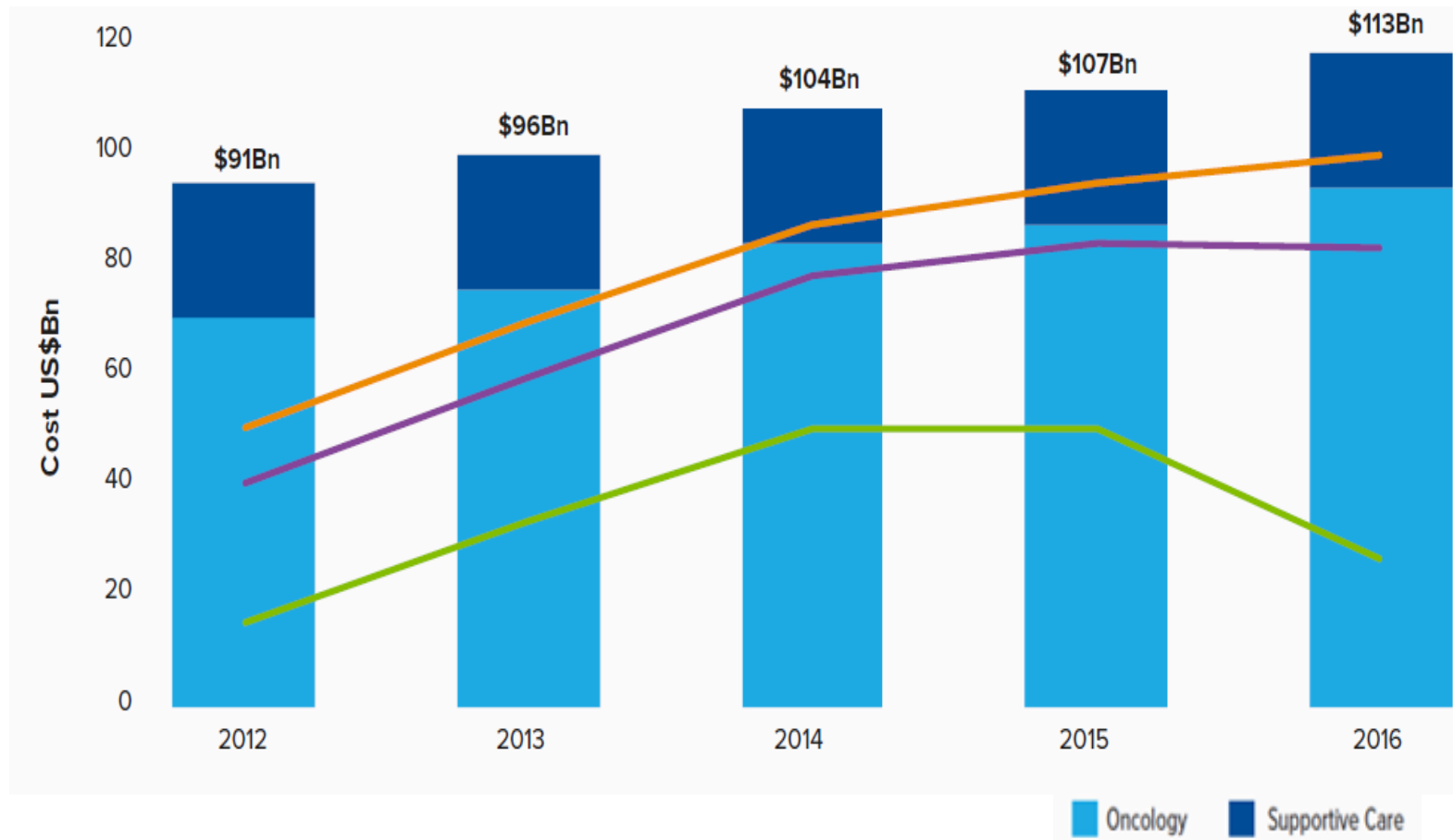
Drug C: 50% response rate



Impact on the US

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



Multilayered Payment Structure

Patients spend not only their own personal resources, but also the pooled resources of others

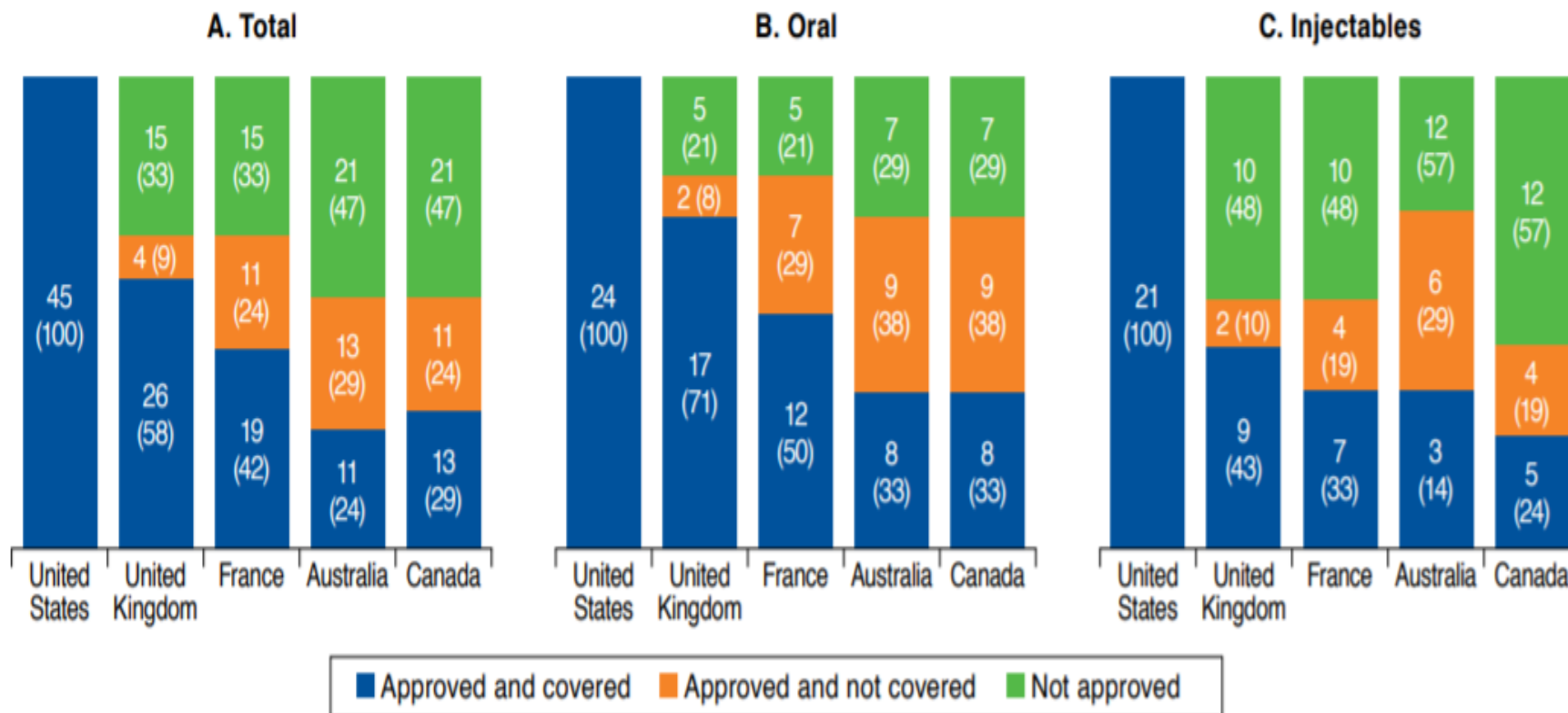
Protects individual consumers from inflated cost

Makes it difficult to judge the relative economic value

Contrasts in US and UK Drug Approval Process

	Cost-Effectiveness Analysis	Transparency of nonpublished drug trials	Time required for approval	Coverage Mandates
United States		X	X	X
United Kingdom	X			

Approval and Coverage Decision Comparison



Question for the Audience

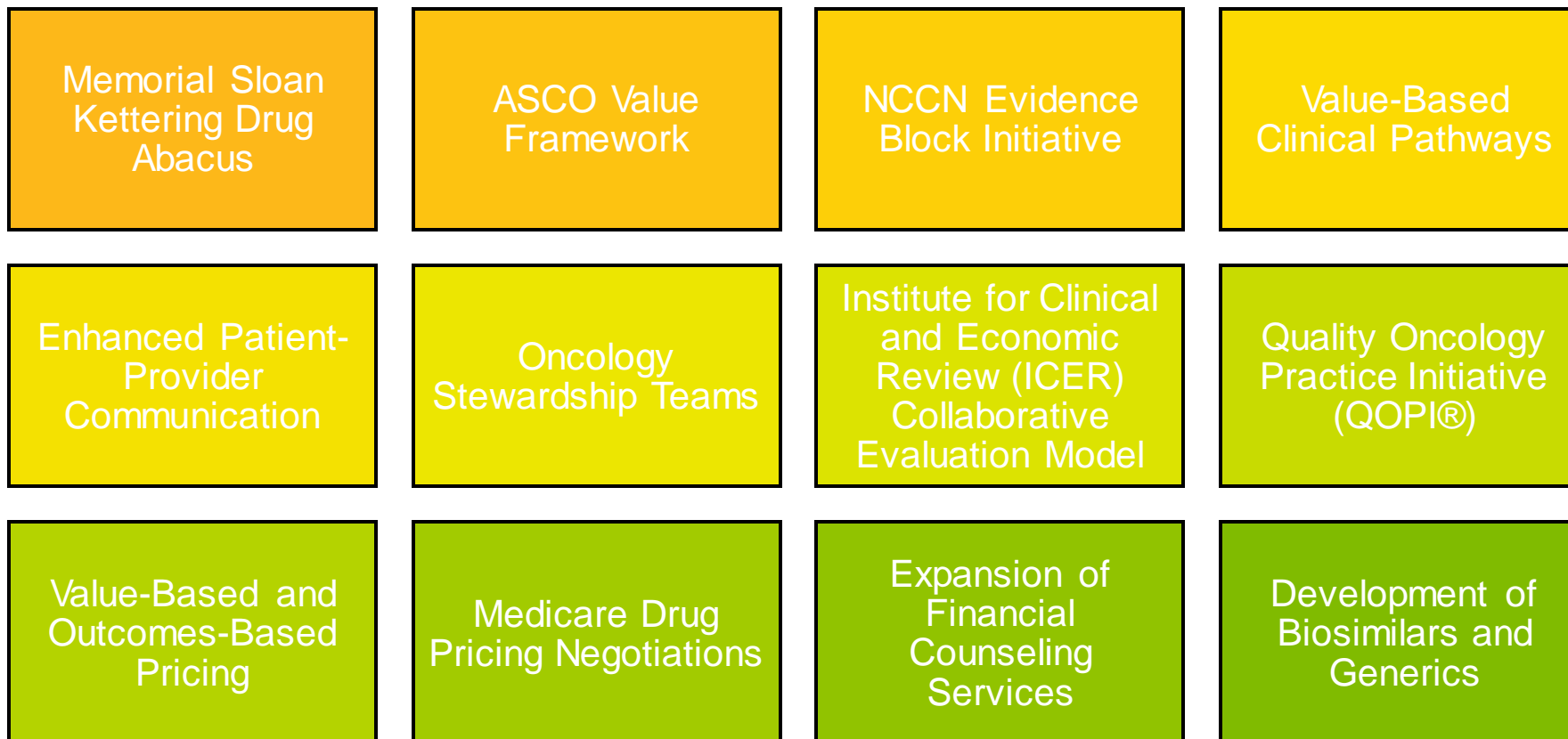
Financial toxicity is an evolving issue in the United States due to which of the following:

- 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

ASCO Position Statement

- 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



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

Memorial Sloan Kettering Drug Abacus

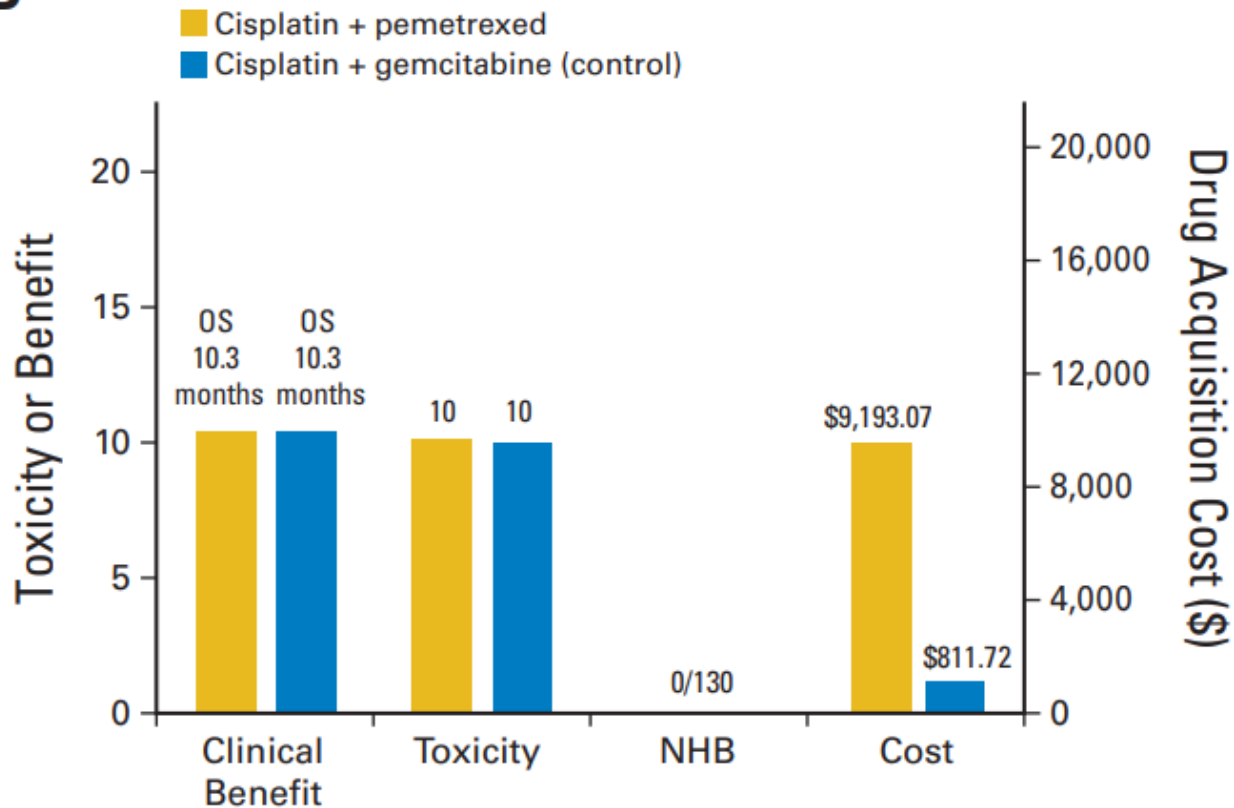
- **Goal:** To allow users to generate a recommended value-based price based, and compare it to the actual list price for a drug
- **How goal is accomplished:**
 - Accounts for factors such as efficacy, toxicity, novelty, cost of development, rarity of cancer, and overall prognosis of disease state to 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

ASCO Value Framework

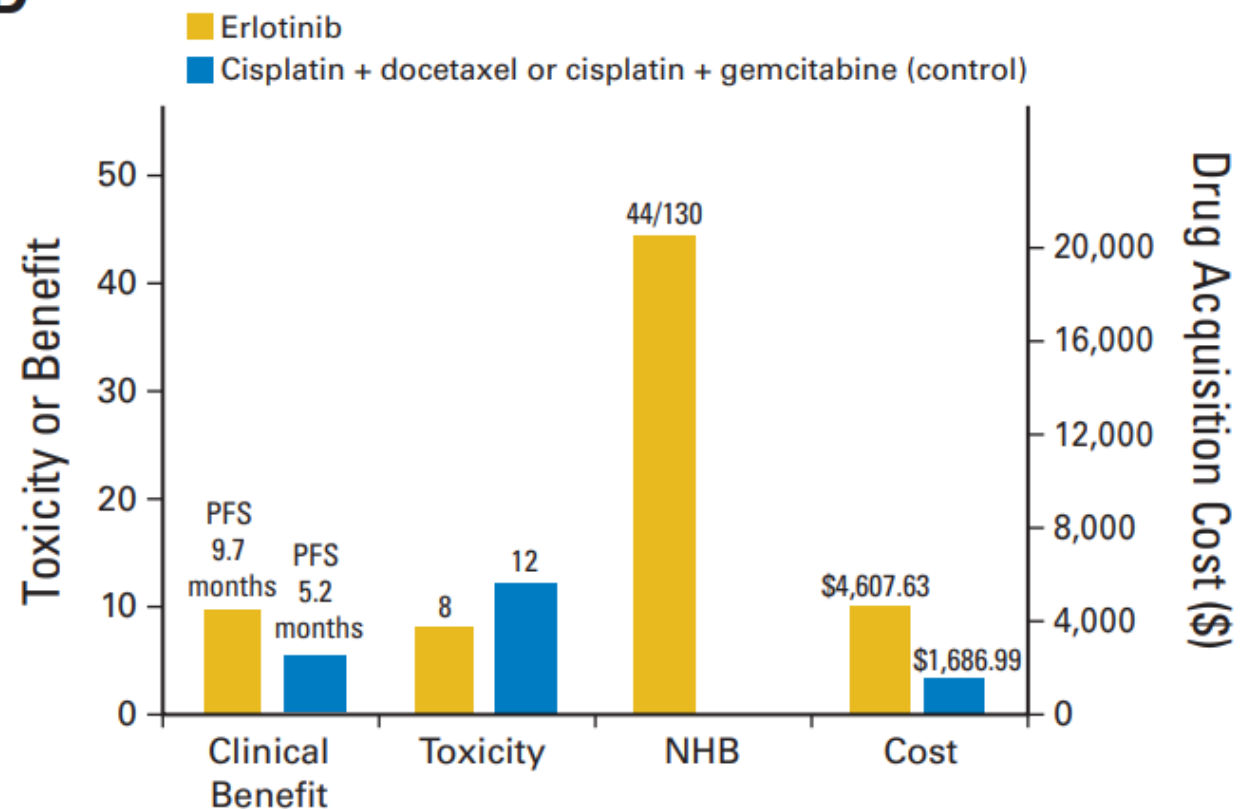
- **Goal:** Guide physicians on the net health benefit between two regimens, and the associated difference in cost, in order to facilitate shared-decision-making
- **How goal is accomplished**
 - Users review prospective clinical trials in which two regimens are compared head-to-head
 - Value worksheet 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

B



D



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

5						E = Efficacy of Regimen/Agent S = Safety of Regimen/Agent Q = Quality of Evidence C = Consistency of Evidence A = Affordability of Regimen/Agent
4						
3						
2						
1						
	E	S	Q	C	A	

NCCN Evidence Blocks: Example

EVIDENCE BLOCKS FOR PREOPERATIVE/ADJUVANT THERAPY FOR HER2-POSITIVE DISEASE













Preferred regimens	Neoadjuvant	Adjuvant
AC followed by T/trastuzumab (doxorubicin/cyclophosphamide followed by paclitaxel/trastuzumab)		
Dose-dense AC followed by T/trastuzumab (doxorubicin/cyclophosphamide followed by paclitaxel/trastuzumab)		
AC followed by T/trastuzumab/pertuzumab (doxorubicin/cyclophosphamide followed by paclitaxel plus trastuzumab/pertuzumab)		
Paclitaxel/trastuzumab		
TCH (docetaxel/carboplatin/trastuzumab)		
TCH (docetaxel/carboplatin/trastuzumab)/pertuzumab		
If residual disease after preoperative therapy:		
Ado-trastuzumab emtansine	—	
If no residual disease after preoperative therapy or no preoperative therapy:		
Trastuzumab to complete 1 year of HER2 targeted therapy	—	
Trastuzumab/pertuzumab to complete 1 year of HER2 targeted therapy	—	
Useful in certain circumstances	Neoadjuvant	Adjuvant
Docetaxel/cyclophosphamide/trastuzumab		
Other recommended regimens	Neoadjuvant	Adjuvant
AC followed by docetaxel/trastuzumab		
AC followed by docetaxel/trastuzumab/pertuzumab		

Question for the Audience

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

EVIDENCE BLOCKS FOR PREOPERATIVE/ADJUVANT THERAPY FOR HER2-POSITIVE DISEASE

Preferred regimens	Neoadjuvant	Adjuvant
AC followed by T/trastuzumab (doxorubicin/cyclophosphamide followed by paclitaxel/trastuzumab)		
Dose-dense AC followed by T/trastuzumab (doxorubicin/cyclophosphamide followed by paclitaxel/trastuzumab)		
AC followed by T/trastuzumab/pertuzumab (doxorubicin/cyclophosphamide followed by paclitaxel plus trastuzumab/pertuzumab)		
Paclitaxel/trastuzumab		
TCH (docetaxel/carboplatin/trastuzumab)		
TCH (docetaxel/carboplatin/trastuzumab)/pertuzumab		

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

How are they developed?

Clinical benefit

Toxicity

Strength of national guideline recommendations

Cost

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)

* 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?

Mount Sinai Oncology Stewardship Team

- **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

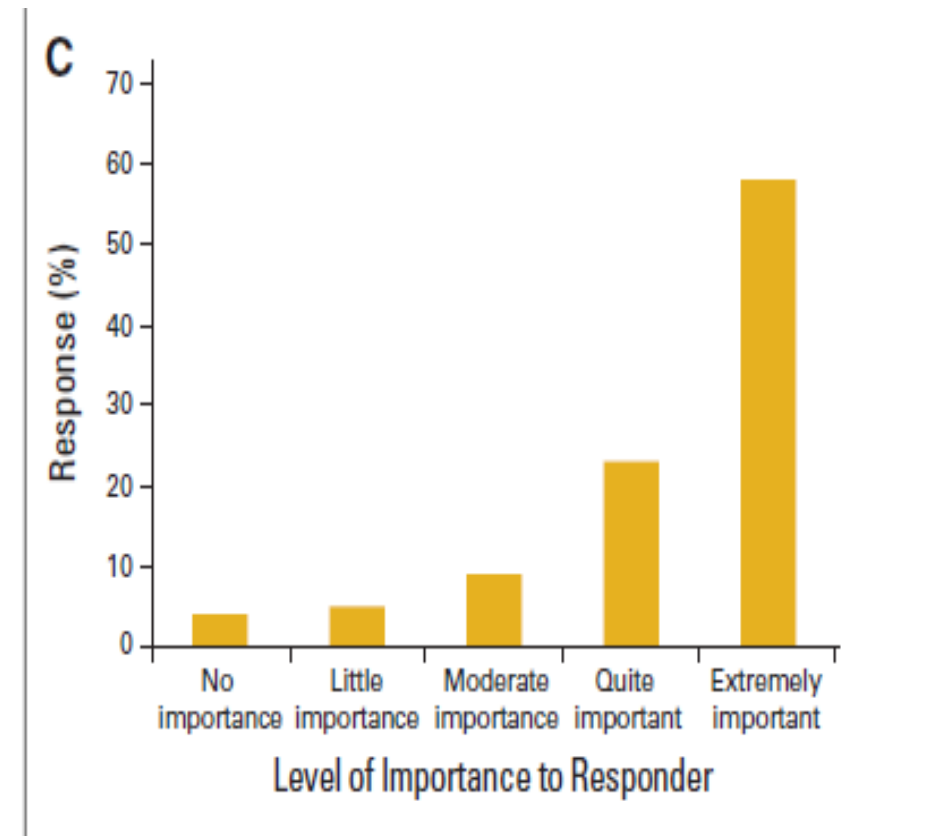


Costs of Cancer Treatment Discussions

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

Integration of Pharmacists into Cost-of-Care Discussions

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

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