OPTIMIZING COST DISCUSSIONS BETWEEN ONCOLOGISTS AND PATIENTS TO REDUCE FINANCIAL TOXICITY: A QUALITATIVE STUDY OF ONCOLOGIST PERSPECTIVES

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ABSTRACT

Dana Swartzberg Wollins: Optimizing Cost Discussions Between Oncologists and Patients to Reduce Financial Toxicity: A Qualitative Study of Oncologist Perspectives
(Under the direction of Stacie B. Dusetzina)

As the cost of cancer care continues to rise and patients shoulder increasing financial burden for their care, there is a growing sentiment within the oncology community that patients be clearly informed of their out-of-pocket (OOP) costs as part of delivering high quality cancer care. The American Society of Clinical Oncology (ASCO), in particular, has dedicated significant time and attention to raising awareness of the rising cost of cancer care, as well as emphasizing the importance of cost discussions between oncologists and their patients. Despite these efforts, cost discussions are not happening frequently, and there are no established models for how this communication should be integrated into oncology practice.

This study used a qualitative methods approach to assess how doctor-patient discussions about cost can be optimized to reduce patient financial toxicity in the cancer setting. Semi-structured telephone interviews were conducted with clinical oncologists (n=24) in a variety of practice settings and disease specialties. Results showed oncologists view communicating with their patients about OOP costs as an important yet challenging aspect of care. The frequency and way in which cost conversations occur between oncologists and their patients vary significantly depending on practice setting and patient population served. The process of obtaining OOP cost information, in addition to the necessary steps required to obtain financial assistance, is a time-intensive, back-and-forth process that can increase patient anxiety and lead to delays in care. Primary barriers to OOP cost communication are lack of education, resources and a systemic process for identifying and mitigating financial toxicity. OOP cost estimator tools and payment models that incentivize OOP cost communication are facilitators for oncologists to have cost-related conversations with their patients. To effectively assist patients in understanding, minimizing and managing their OOP costs, physician and patient education, information-based solutions and a systems-based, whole care team approach are needed.

Based on these findings, an overall strategy to be taken up and used by the oncology stakeholder community is proposed, as well as a set of recommendations for ASCO to implement as part of its efforts to improve cancer care.

This dissertation is dedicated to:

Aaron, for your unconditional love, unwavering support, many sacrifices, patience, and encouragement.

Ethan, for putting up with my busy days and nights, for studying beside me, and for always showing me your support and care.

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“The good physician treats the disease;

the great physician treats the patient who has the disease.”

- Sir William Osler

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LIST OF ABBREVIATIONS

AAIM	Alliance for Academic Internal Medicine
AAR	Ask, Advise, Refer
ABIM	American Board of Internal Medicine
ACCC	Association of Community Cancer Centers
ACP	American College of Physicians
ASCO	American Society of Clinical Oncology
CDS	Clinical Decision Support
CME	Continuing Medical Education
CMS	Center for Medicare & Medicaid Services
COST	Comprehensive Score for Financial Toxicity
CPT	Current Procedural Terminology
EHR	Electronic Health Record
EMR	electronic medical record
ERISA	Employee Retirement Income Security Act
FDA	Food and Drug Administration
HER	human epidermal growth factor receptor
IRB	Institutional Review Board
IV	intravenous
JOP	Journal of Oncology Practice
MIPS	Merit-based Incentive Payment System
MOC	Maintenance of Certification
NAM	National Academies of Medicine
NCCN	National Comprehensive Cancer Network
NCI	National Cancer Institute

NHB	Net Health Benefit
OCM	Oncology Care Model
OOP	Out-of-Pocket
PARP	poly ADP ribose polymerase
PCORI	Patient-Centered Outcomes Research Institute
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROMIS	Patient-Reported Outcomes Measurement Information System
QOPI	Quality Oncology Practice Initiative
QPP	Quality Payment Program
RTBC	real-time benefit check
SES	socioeconomic status

CHAPTER 1: INTRODUCTION

Financial Toxicity of Cancer Care

Over the last decade, U.S. healthcare expenditures, particularly in the area of cancer care, have risen dramatically. Cancer drugs represent the fastest-growing component of rising cancer care costs, with the average price of a novel anticancer drug routinely exceeding $100,000 per year or course of treatment.[1] Increasingly these costs are being passed on to patients in the form of cost sharing (i.e., deductibles, coinsurance, and copayments), which can have catastrophic effects on the financial well-being of patients and their families.[2,3] As a result, a new side effect of treatment has been coined in the oncology community: financial toxicity.[4] Financial toxicity has been shown to impact not only individuals' finances, but also their survival, leading to poor patient compliance with medications, dose adjustments, and skipped appointments.[4]

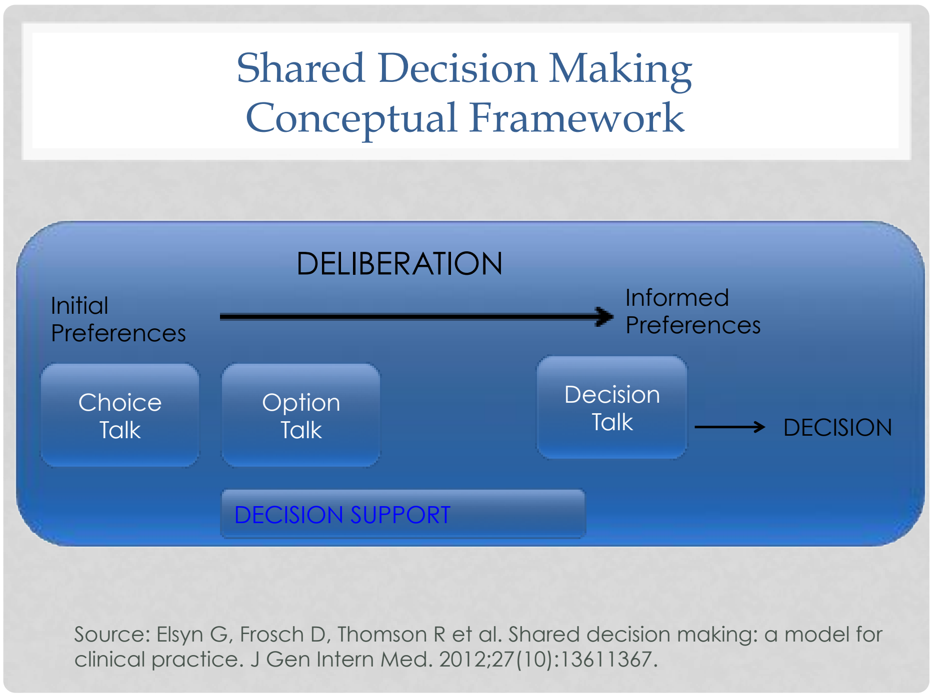
To address this issue, the National Academies of Medicine (NAM), the American Society of Clinical Oncology (ASCO) and others have recommended that patients be clearly informed of costs as part of delivering high quality cancer care.[5,6] Financial navigation services have begun to take root to help patients understand the costs of their care as well as to identify co-pay assistance, "free drug" programs and other resources. These services generally begin after the physician-patient encounter, once the treatment plan is already determined.[7] As cancer patients continue to bear more of the financial burden of their care, however, there is growing sentiment within the oncology community that the cost of a patient's treatment should be discussed as an integral part of shared decision-making with the physician. Doing so allows for the personal financial impact of care to be incorporated into the treatment selection process, in the same way that any other potential toxic effect is considered.[8]

Cost as a Component of Shared Decision-Making

Improving the value of cancer care by reducing cost while maintaining or improving quality has become a shared goal among patients, clinicians, payers and policy makers. The patient perspective, however, is of critical importance in defining value. Because perception of value is so individualized, it is important that discussions with patients include an assessment of patient needs, goals, and preferences. Including cost-benefit discussions as a component of shared decision-making has the potential of both improving outcomes and decreasing costs, thereby increasing the value of care delivered.

Shared decision making is defined by the Informed Medical Decisions Foundation as a collaborative process that allows patients and providers to jointly make healthcare decisions, considering the best clinical evidence available, as well as patients' values and preferences. The goal of shared decision making is to optimize health decisions in order to achieve outcomes that matter most to the patient. Shared decision making is appropriate for any health decision where there is more than one medically reasonable option.[9] Elwyn et al describe a conceptual model for shared decision-making that begins with the elicitation of *initial* preferences, introduces a series of steps for deliberation, and ends with a decision driven by *informed* preferences (see Figure 1).[10] Discussion of options for treatment is central to this model, and to the rationale for including cost as a part of the physician-patient medical decision-making process.

Figure 1. Conceptual Model for Shared Decision-Making



Source: Elsyn G, Frosch D, Thomson R et al. Shared decision making: a model for clinical practice. J Gen Intern Med. 2012;27(10):13611367.

Despite the perceived benefits of discussing cost with their patients, physicians today often do not do so, whether due to lack of training or lack of information on how much the treatments they prescribe actually cost. Among physicians, common barriers reported include insufficient time and a belief that they did not have a solution to offer.[11] Among patients, a wide variety of barriers have been reported including patients' own discomfort, insufficient time, a belief that their physician did not have a viable solution, and concerns about the impact of discussions on quality of care.[12–14]

The Role of Clinical Decision Support

Clinical decision support (CDS) encompasses a variety of tools to enhance decision-making in the clinical workflow, such as computerized alerts and reminders, data reports and summaries, and diagnostic and treatment decision-making support.[15] CDS tools can be used to facilitate shared decision-making by helping patients understand the clinical evidence and identify their preferences, preparing them to make informed, values-based decisions with their healthcare providers. Clinical decision support has been shown to support patient-centered, evidence based clinical decision making across a variety of clinical settings as well as to improve quality and reduce costs by increasing adherence to evidence-based practices.[16] In the cancer setting, clinical decision aids have been developed across the continuum of cancer care to promote shared decision-making. A 2013 systematic review identified 22 risk prognostic tools across several cancer types.[17] Several tools also have been developed to assess the risk of chemotherapy toxicity in older adults.[18,19] However none appears to have been developed to date to facilitate discussions between physicians and patients about the cost of cancer care.

Tools to Improve Cost Communication

A promising effort is underway among organizations in the cancer community to help make the cost of care more transparent to clinicians and patients, and to place cost within the overall context of value.

- The National Comprehensive Cancer Network (NCCN) has established evidence blocks to help inform clinical decision making with a focus on efficacy, safety, quality of supporting evidence, and affordability.[20]
- Memorial Sloan Kettering Cancer Center has developed the DrugAbacus, an interactive tool designed to help determine a more appropriate price for a specific agent, based on what experts consider are possible components of a drug's value.[21]
- ASCO has developed the Value Framework, a conceptual tool to help physicians and patients weigh the potential benefits of treatment with possible side effects and costs.[22]

Each of these tools above was developed for different purposes and, hence, address different aspects of price and cost. ASCO and NCCN’s tools were developed for use by patients and physicians in the context of shared decision-making about treatment options, and both use estimates of drug acquisition costs as a surrogate for patient affordability (meaning they do not actually integrate patient cost). In contrast, the DrugAbacus evaluates therapies at the population level to inform policies and payer coverage decisions. It considers cost from the point of view of price and therefore is not designed to aid in doctor-patient discussions.

The ASCO Value Framework

ASCO developed the Value Framework to facilitate shared decision-making between doctors and patients by helping them assess the relative value of cancer treatment regimens that have been studied head-to-head in clinical trials. The framework defines value as a combination of clinical benefit, side effects, and improvement in patient symptoms or quality of life in the context of cost. Two versions of the framework have been developed: one for treatments used in metastatic cancer and the other for adjuvant drugs used in earlier disease. In both types, a single net health benefit (NHB) score is generated by awarding points for clinical benefit and adding or subtracting them for toxicity. The score can then be contrasted to a drug regimen's cost—both the drug acquisition and the patient-specific cost if used in the clinical setting. The initial version of the Value Framework was released in 2015 for public comment.[23] ASCO published an updated Value Framework in 2016 incorporating feedback that was received.[22]

It is envisioned that the updated ASCO Value Framework could become the basis of an interactive, web-based tool to be used by physicians on a laptop or tablet to engage patients in a conversation about their treatment options. The tool would include complete, curated, and regularly updated information on those treatment regimens that that have been compared in prospective randomized trials and published in the literature for each cancer type and stage. Using the tool, physicians would be able to review treatment alternatives with their patients with respect to clinical benefit, toxicity and cost and generate an NHB score, which could be displayed along with each treatment's overall cost.

To address each patient's needs and preferences, the framework authors envisioned that a tool of this type should allow for patients to change the weight of the included variables, enabling the application to recalculate the NHB and display the new results. For example if, in the advanced disease setting, longevity is less important to a patient than freedom from toxicity, the tool should be able to adjust the clinical benefit and toxicity parameters to reduce the impact of clinical benefit and enhance the impact of toxicity, thereby producing a personalized NHB.

For each regimen in the tool, cost information would be provided using average sales price data for intravenous therapies and wholesaler acquisition cost information for oral drugs. Patient-specific cost information would be entered into the tool manually based on the patient's insurance plan and status, which would need to be obtained separately. Development of the tool would begin with a prototype, which would likely undergo changes based on feedback from physicians and patients.

Ultimately ASCO's goal is to enable development of a tool for use by oncologists in discussing treatment options with their patients. However, in developing the tool, several questions will need to be addressed. First, it is unclear when in the clinical workflow a tool of this type would be most useful, and for which patients. It also is not clear if the tool will be used if it requires additional time on the part of the oncologist. However if adding this step ultimately leads to reduced costs and better care and outcomes for patients, oncologists may be willing to take part. Finally, it is important to note that the ASCO Value Framework, as currently constructed, integrates the drug acquisition and/or patient-specific cost of the cancer drug only, not other costs such as imaging, laboratory testing, hospitalization or indirect costs such as time off work. It remains to be seen how valuable a tool will be to oncologists if it is not able to synthesize information beyond the costs of cancer drugs alone, or to provide patient-specific costs in an automatic way.

Improving Cost Discussions in Cancer Care

As the cost of cancer care continues to rise and patients shoulder an increasing degree of financial burden for their care, there is a growing sentiment within the oncology community that the cost patients will bear as a result of their treatment should be discussed as an integral part of shared decision-making. Doing so can help ensure patients make informed decisions and receive information and assistance on how to reduce such harm.   However these discussions are not happening frequently, and there are no established models for how cost discussions should be integrated into oncology practice. Greater understanding is needed of how these discussions are currently taking place, what barriers and facilitators exist to having these discussions, and the ways in which these discussions can impact patient care.

Research Question and Aims

The goal of this study is to answer the following question: How can doctor-patient discussions about cost be optimized to reduce patient financial toxicity in the cancer setting? Study aims are as follows:

1. Describe the nature of these discussions, the process or tools used, and the perceived impact (key informant interviews)
2. Identify the barriers and facilitators for oncologists to having cost-related conversations with their patients (key informant interviews)
3. Establish an action plan for improving the integration of cost discussions into oncology practice (plan for change)

Significance of Study

For the last several years, in my role as ASCO’s Health Policy Division Director, I have had primary staff oversight of the Value in Cancer Care Task Force, the group responsible for developing the Value Framework. In this role, I have worked alongside the Task Force to conceptualize the framework, share it with multiple stakeholder groups, and revise and refine it to its current state. Through this work, I have developed a strong interest in better understanding how to help oncologists and their patients address the cost of cancer care, and I have identified several gaps in knowledge in this area. For example, when oncologists discuss cost with their patients, what is the nature of these discussions? What processes or tools are used? What are the key barriers and facilitators to having cost-related discussions? Are these discussions helpful to patients and, if so, how? Addressing these knowledge gaps will help inform potential models for integrating doctor-patient cost discussions into the clinical encounter and workflow, as well as identify practice- and system-level changes that may be needed to support these discussions. Ultimately it is hoped this research will not only help guide ASCO's thinking in how to evolve the Value Framework, but also help the larger oncology community design effective interventions to address financial burden in the cancer setting.

CHAPTER 2: LITERATURE REVIEW

Introduction

The purpose of this literature review was to assess the following question: When discussions about cost occur between oncologists and patients, what is their impact? Limited evidence exists as to the extent or nature of cost discussions between oncologists and patients. The incidence and quality of discussions have been assessed in three ways: survey-based studies that query patients and/or providers about their desire to have cost discussions; survey-based studies that ask patients and/or providers to recall whether they have discussed costs with their oncologist; and studies of audio-recorded conversations between patients and providers. These studies show that relatively few physicians or patients initiate cost discussions, suggesting missed opportunities for discussion between clinicians and interested patients.[13,24,25]

Significant variation exists in the degree to which patients report a desire to have cost discussions with their physicians, ranging from approximately 50% to nearly 100% of surveyed patients with cancer.[14,26,27] Similarly, studies based on recall suggest variation in the extent to which patients report discussing their costs with oncologists. Those estimates of cost discussions frequency vary widely, from as low as 14% of patients discussing their healthcare spending with physicians to as high as 44% in a single year.[2,11,26,28] The heterogeneity in estimates may be in part a result of differences in study design, with survey-based studies subject to recall bias. Studies that rely on analyzing recorded conversations between physicians and patients report that 30% of patient-physician interactions include cost conversations.[29]

Oncologists and patients report multiple barriers to having effective cost discussions.

Oncologists may avoid cost discussions because they are unprepared for those discussions.[13] Oncologists often report not knowing how much the treatment they prescribe will cost to any given patient, and few believe they have access to adequate resources to discuss costs.[12] With lack of transparency in health systems' pricing, and with per-patient variation in insurance coverage, tracking costs for patients is challenging if not impossible. Patients also report a wide variety of barriers to having effective cost discussions with their oncologists, including patients' own discomfort, insufficient time, a belief that their physician cannot reduce their costs, and concerns about the impact of cost discussions on quality of care.[26]

While little is known about the incidence of cost discussions, even less is known about whether there is an ideal way in which to have these discussions. An emotionally-charged first visit with an oncologist might not be the most appropriate time to do so. However, it is reasonable to anticipate that if a conversation about cost is helpful, it will likely be most helpful earlier in the course of care. Social workers and financial counselors are better able to provide financial assistance to patients before debt is incurred rather than after.[30] Additionally, it is important that discussions are tailored to individuals' literacy levels and personal circumstances. As well, these discussions should occur throughout the treatment period—particularly at the time of any change in treatment—and throughout the cancer care continuum. Cancer survivors are also at risk for experiencing financial burden, suggesting that assessments for financial burden should continue into survivorship.[31]

Although there have been a number of studies assessing oncologists' and patients' attitudes and perceptions of discussing cost, few studies have investigated the impact of these cost discussions on patient care in general, or on financial toxicity in particular. However some information on this topic can be gleaned from studies conducted in the primary care setting. In a recent study of 1755 recorded patient-physician conversations, Hunter et al found that 22% of cost-reducing strategies discussed involved switching to lower-cost therapies.[32] Twenty-three percent of the time, physicians discussed reducing OOP costs by changing the timing, source, or location of care. Of note, this study was limited in that these strategies were recorded, but there was no follow-up to determine whether the strategies were instituted or whether they reduced costs for patients.

Methods

A systematic literature review was conducted using PubMed, Scopus, and Embase databases. These databases were selected because they represent most comprehensive sources of medical literature with a concentrated focus on North America and Europe. PubMed covers journal articles related to medicine and healthcare, but does not include information about meeting abstracts or conference proceedings. In contrast, Embase includes meeting abstracts and conference proceedings, which is desirable in studying the relatively new field of financial toxicity. Scopus delivers a broad overview of interdisciplinary scientific information, drawing from the physical, health, life and social sciences, making it a valuable resource for this topic as well. This strategy was supplemented with searching by hand and with expert suggestions as well.

In querying the literature, I used the following search terms: “(physician or doctor) and patient and cost and (discussion or conversation) and (cancer or oncology)”. Articles were included that reported on physician-patient cost discussions in the oncology setting, and assessed the effect of these discussions on patients. No language, publication date, or publication status restrictions was imposed. Studies were excluded from the review if the participants were less than 18 years of age or older or did not have cancer, or if the intervention was not an actual physician-patient discussion about cost.

Once all studies were initially identified, eligibility assessment was performed first by removing duplicate records and then by screening the titles and abstracts to determine whether or not each met the eligibility criteria. Those studies that appeared to meet criteria were then reviewed in full-text version to confirm eligibility. Information was extracted from each included study on:

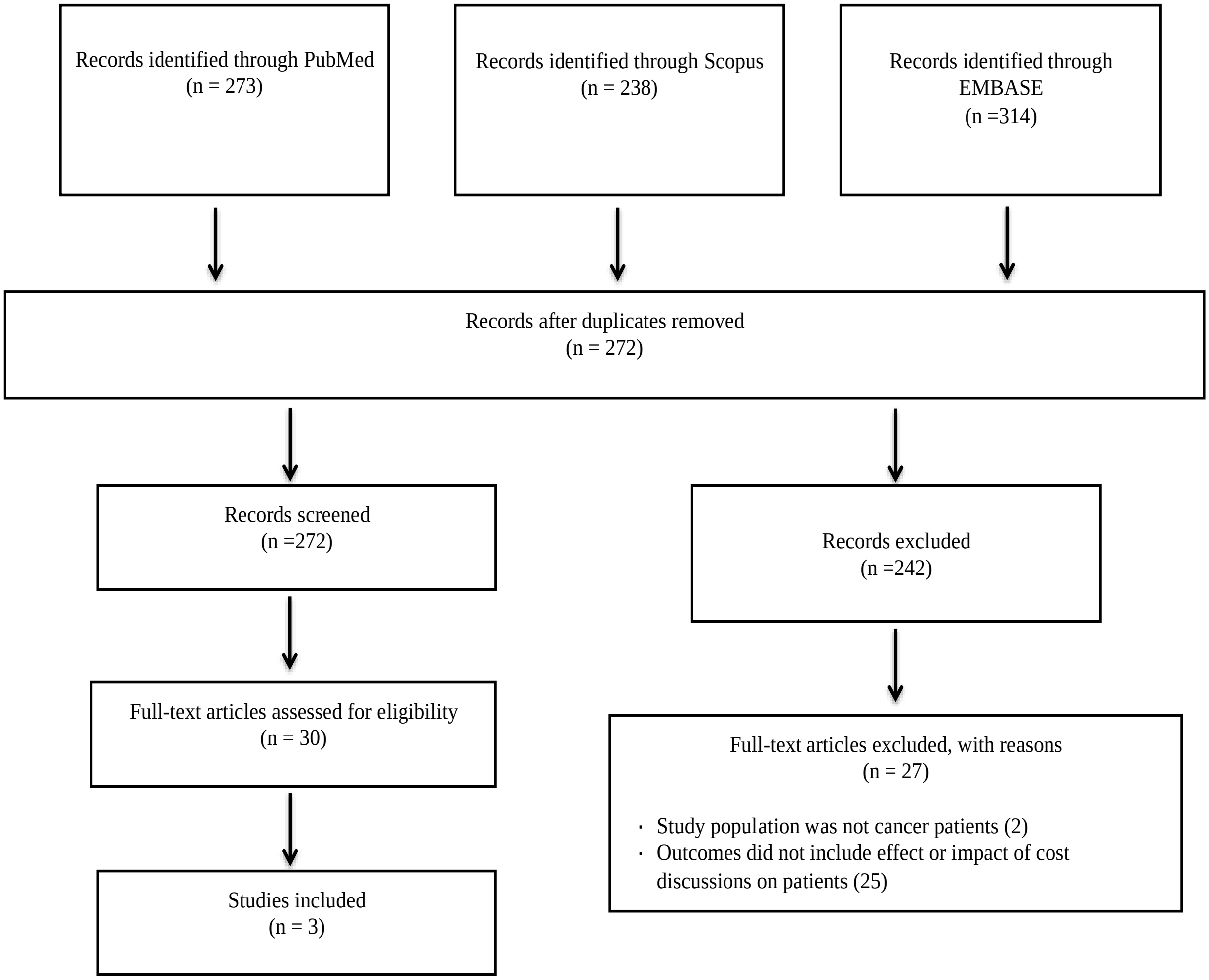
- Characteristics of study participants
- Study's inclusion and exclusion criteria
- Type of intervention
- Type of outcome measure

The potential for bias exists in this review. In addition to publication bias and selection bias within studies, there is a potential for recall bias if patients studied were asked to recall the impact of cost and/or a discussion with their physician at a future date. This bias could be significant for cancer patients, who are under emotional stress at and following the time of diagnosis and may have difficulty with accurate recall. To minimize this bias, studies that assessed financial toxicity and the presence of a physician-patient cost discussion at the time of the clinical encounter were sought in particular, although recall-based studies were not excluded.

Results

The results of the literature search are summarized below in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram (see Figure 2). The search yielded a total of 273 results in PubMed, 238 results in Scopus, and 314 results in EMBASE. After removing duplicates, 272 articles remained. Title and abstract review excluded 242 articles. The remaining 30 articles were examined for full review, and 27 of these were eliminated based on exclusion criteria. Three articles ultimately were included in the literature review. Bibliographies of these three articles also were searched to identify additional relevant studies, however no additional articles were identified that met the inclusion criteria.

Figure 2. PRISMA Diagram



Although there are a growing number of studies assessing physicians' and patients' attitudes and perceptions of discussing cost as a hypothetical construct, there is a dearth of studies that have been published assessing the outcomes of actual discussions between physicians and patients in the cancer setting. Three studies that have recently been published on this topic are as follows:

- A study by Zafar et al examined whether having a patient-oncologist discussion of cancer treatment costs lowered OOP expense for the patient.[14]
- Another study by Bestvina et al assessed the association between having a patient-oncologist discussion of cancer treatment OOP cost and medication adherence, a critical component of quality cancer care.[2]
- Finally, a study Kelly et al study assessed patient satisfaction when the physician consultation included discussion of costs. [33]

Table 1 below provides a summary of key characteristics of the studies reviewed including year of publication, study population, design, size, measure(s) of effect, and major finding(s).

Table 1. Characteristics of Included Studies

Study (year)	Population	Design	Size	Measure(s) of Effect	Major Finding(s)
Zafar (2015)	Insured patients with breast and colorectal cancer at a U.S. academic medical center	Cross-sectional survey study with follow-up	300	Patient desire to discuss cost of treatment with doctors, interest in incorporating cost into treatment decision making, and whether or not patients found cost discussions useful in lowering OOP expense	Patients with cancer receiving treatment varied in their desire to discuss costs with doctors, however most who talked to their doctors about costs believed the conversations helped reduce their costs.
Bestvina (2014)	Insured patients with breast and colorectal cancer at a U.S. academic medical center	Cross-sectional survey study with follow-up	300	Self-reported medication non-adherence	Patient-oncologist cost communication and financial distress were associated with medication non-adherence, suggesting that cost discussions are important for patients forced to make cost-related behavior alterations.
Kelly (2015)	Previously treated metastatic breast, lung, or colorectal cancer who were either on active treatment or surveillance	Cross-sectional survey study	96	Patient attitudes and assessed patient satisfaction when consultations included discussion of costs.	Patients with cancer desired cost-of-treatment discussions, and these conversations did not lead to negative feelings in the majority of patients.

Utility of cost conversations between physicians and patients

The study by Zafar et al examined whether having a patient-oncologist discussion lowered OOP expense for the patient. In this study, the researchers administered a survey to a convenience sample of 300 adult, insured cancer patients at a comprehensive cancer center and three affiliated rural oncology clinics. Patients were approached while waiting in clinic to receive chemotherapy. After obtaining informed consent, trained interviewers surveyed each patient in person at the time of enrollment. Three months after completion of the baseline survey, interviewers surveyed each patient again by phone or in person to determine whether preferences for cost discussions changed over time. To assess the generalizability of their findings, the researchers compared age, disease characteristics, and treatment characteristics of patients who chose to participate to those who declined participation. The researchers summarized descriptive variables including demographics, clinical, and financial characteristics, and they used logistic regression to assess which characteristics were associated with a greater patient desire to discuss costs with doctors.

Results showed that 56% (n = 155) of patients expressed a desire to discuss treatment related OOP costs with their doctor. However, only 19% (n = 56) had actually spoken with their doctor about their OOP costs. Of those, 32 (57%) reported lower OOP costs as a result of the cost discussion. (Note: Statistical significance was not reported.) Methods of cost reduction included physician referral of the patient to a financial assistance program (53%), the physician advocating for the patient or facilitating the insurance approval/coverage process (25%), switching to less expensive prescription medications (19%), changing or decreasing the number of tests (13%), or decreasing the number of physician visits (6%). While based on a small sample, these results suggest that cost discussions might help lower patients' financial burden without, in the majority of cases, changing care.

Association between cost conversations, financial distress, and medical non-adherence

Using the data collected by Zafar and colleagues described above, Bestvina et al conducted a secondary study using multivariable analysis to assess the association between doctor-patient cost discussions, financial distress and medication non-adherence, which is a critical component of quality cancer care. Subjective financial distress was measured using the InCharge Financial Distress/Financial Well-Being Scale. Non-adherence included skipping doses, taking less medication than prescribed, or not filling the prescription because of cost. Fifty-two (17%) reported “high” or “overwhelming” financial distress, and 80 (27%) reported non-adherence to their cancer medications.

Effect of physician-patient cost conversations on the doctor-patient relationship

Kelly et al assessed patient satisfaction after the cost of chemotherapy was introduced into the doctor-patient relationship. Chemotherapy and targeted therapy costs were provided to patients by their oncologist during the consultation using a web-based decision-support platform called eviti Advisor. The study population was composed of 96 cancer patients with previously treated metastatic breast, lung, or colorectal cancer who were either on active treatment or surveillance and receiving their oncology care from an oncologist on faculty at Johns Hopkins University. Researchers identified patients by contacting oncologists weekly over a period of 7 months and asking them to provide a list of eligible patients attending their clinic. A member of the study team approached patients at the time of registration, provided the patient with information about the study and obtained written consent. Before their consultation with their oncologist, patients were asked to complete a baseline questionnaire evaluating their need for cost of treatment information. At the end of the clinical encounter, participating oncologists were asked to discuss with their patients whether they had any financial difficulties with their treatments to date. Physicians were provided with a pre-scripted text to help them introduce cost discussions. They were made aware that patients had been approached to participate before their appointment.

Results showed that more than 80% of patient respondents reported that it is “quite important” or “extremely important” for them to know what they will be personally responsible for paying. Additionally, the majority of patients (81.2%) reported that they felt no negative feelings or conflicts (graded 1-2 on 10-point Likert scale) when they discussed cost of treatments with their oncologist.

Discussion

While a growing body of evidence suggests that patients often struggle with treatment-related financial burden, little work has been done to identify effective ways of introducing cost into physician-patient discussions, or to place this information within the overall context of the value of various treatment options under consideration. Several studies have been published documenting attitudes and perceptions among physicians and patients, as well as assessing the frequency with which these conversations are occurring. However few studies have described the nature of these discussions, the process or tools used to have these studies, and/or their impact on patient care. Compounding the problem is that those studies that have assessed the impact of cost discussions between oncologists and patients vary in the outcomes they assessed, making it difficult to generalize the findings.

This review highlights the paucity of studies documenting the impact of discussions between physicians and patients about cost during treatment decision-making. Given the purpose of having physician-patient discussions about cost is, in part, to assist patients in identifying strategies to lower financial toxicity, it is unfortunate that there appears to be such little research assessing this outcome in the literature. That said, some observations can be made from the studies reviewed about the utility of cost conversations between physicians and patients, and their impact on patients in a variety of ways.

The Zafar et al study represents an important contribution to the literature on barriers to physician-patient communication on cost. Despite the well-described patient- and physician-reported barriers to effective cost discussions, this study reports lower OOP costs can result from cost discussions. However, as noted by the researchers themselves, further study is needed to test the effectiveness of practice-based, cost-related alterations in care.

The study by Bestvina et al also contributes to the literature by reporting, perhaps for the first time, that cost-related communication may be a marker for people who are concerned about the personal cost implications of their health care and are at risk for non-adherence. Because non-adherence can be such a strong indicator of poor outcome, this finding is significant. As the researchers note, instead of waiting for behavioral change (e.g. medication non-adherence) caused by financial distress, broaching the topic of cost earlier in the course of treatment could help patients avoid non-adherence.

The Kelly et al study sheds further light on an important, under-studied questions: Can physicians and patients discuss treatment costs in the clinic, and how will this discussion affect the patient-physician relationship? This study demonstrates that these discussions do not cause patient dissatisfaction and are viewed by both oncologists and patients as important. As the only study that introduced a cost conversation and tested its impact, this study offers a model for future studies of this type.

Of the studies included in this review, several strengths can be noted. All three studies utilized existing, validated survey instruments and established metrics where they exist to assess the impact of cost on patients. As well, all three studies obtained Institutional Review Board (IRB) approval and followed appropriate informed consent procedures. An additional strength of the studies by Zafar et al and Bestvina et al is that they employed a follow-up survey to assess differences in perceptions over time. A strength of the Kelly et al study is that it utilized broad inclusion criteria and had diversity among the patients it enrolled, suggesting these data could represent a real-world oncology clinic (at least within an academic cancer center). Additionally, in the Kelly et al study, a small number of health care professionals conducted all of the surveys using a standard questionnaire and met frequently to ensure consistency across the study team.

Several limitations can be noted among these studies as well. Because all three studies focused on insured cancer patients being treated at a major academic referral center, the results may not be generalizable to that of the overall cancer patient population. Additionally, many of the outcomes relied on patient self-report, which could diminish the reliability of the results. Additional specific weaknesses of these studies are noted below:

- In the Zafar et al study, patients were sampled in a consecutive but nonrandom way and, as stated above, most were treated at a major referral center, diminishing the generalizability of the findings. However, the study had a high response rate and non-responders and responders were quite similar, suggesting the sample was representative of the center itself. Additionally, the desire to discuss costs was not measured via a validated measure (no validated instruments were available to measure this outcome.) Additionally, the follow-up interval of 3 months was short. As well, only a small number of patients reported having cost discussions, and the researchers relied on patient self-report.
- In the Bestvina et al study, the data linking medical non-adherence and cost conversations suggest correlation but not evidence of direction. Additionally, details of the cost discussions between patients and physicians were not recorded. As well, adherence was self-reported, leading to the possibility of recall bias.

- Specific weaknesses of the Kelly et al study include its small sample size as well as the absence of any recordings of the physician-patient discussions. Another weakness is that the researchers did not provide patient-specific costs; rather, average costs were provided and therefore lacked accuracy for the patient receiving the information.

As the cost of cancer care continues to rise and patients shoulder an increasing degree of financial burden for their care, there is a need for systematically designed interventions that assess the impact of physician-patient discussions on patient financial toxicity. In conducting future studies, it will be important to achieve better understanding of what constitutes a physician-patient discussion of cost and what components of the discussion yield optimal results. Additionally, it will be crucial to identify those patients who wish to discuss cost and those who do not, in order to optimize patient-centered care. To do so, tools are needed to assess patient preferences and to identify those patients who are most likely to benefit from a discussion with their physician about cost.

CHAPTER 3: METHODS

For this study, I used a qualitative methods approach to assess how doctor-patient discussions about cost can be optimized to reduce patient financial toxicity in the cancer setting. Semi-structured telephone interviews were conducted with clinical oncologists (n=24) in a variety of practice settings and disease specialties. Participants were identified through several sources, including ASCO practice survey data, snowball sampling, and direct outreach to ASCO members identified through participation in ASCO committee work. The 40-45 minute interviews explored current practices, barriers and facilitators to communicating cost information to cancer patients. The study was approved by the University of North Carolina – Chapel Hill Institutional Review Board (study number 16-2871) in March 2018.

Development of the Interview Guide

To structure the content and flow of each interview, I developed an interview guide (see Appendix 2) composed of a series of open-ended questions designed to gain insight each aim of the study. Questions were divided into five themes: Practice Experience (e.g. years in practice, cancer types treated); Addressing Cost (e.g. how, why and when cost discussions occur, who initiates, resources used), Facilitators (i.e., what enables these conversations to happen, or happen well), Barriers (i.e., what hinders these conversations from happening, or happening well), Impact (i.e., impact to oncologists and patients, potential benefits and harms), and Improving Cost Discussions (e.g. ideas for improving cost discussions and/or making them easier to have). The majority of questions included open-ended probes to encourage clarification and gather more detail about each issue raised.

Selection of Study Participants

Participants were a convenience sample of practicing oncologists located across the United States in a variety of geographic locations and practice settings, identified through purposive sampling. Potential respondents were drawn initially from the ASCO 2016 Trends Survey, which yielded only 3 participants. The remaining 21 participants were identified from current and prior ASCO committee membership rosters, as well as through snowball sampling. In identifying participants, I sought to identify a diverse mix of oncologists representing different areas of specialization, as well as a mix of gender, years in practice, geographic location, practice type and patient mix.

Interview Methods

Prospective participants were recruited by email (see Appendix 1). After participants agreed to be interviewed for the study, appointments were scheduled for the telephone interview, usually within two weeks of the initial contact. I informed each participant that the research was for my dissertation (as part of doctoral studies at the UNC Gillings School of Global Public Health), and that the results would be used to inform my work at ASCO in this area.

Interviews were conducted by telephone with each participant between July 13, 2018 and August 29, 2018. After introductions were made and the purpose of the study explained, I requested verbal informed consent at the start of each interview. The oncologists were informed that their participation in the study was completely voluntary, and that they could stop the interview at any time or opt to not answer any of the questions asked. I then described the provisions for confidentiality and assured participants that their name and their institution's name would not be associated with specific comments or answers, nor would their name or organization name be included in any report or presentation of the findings. Participants were asked for permission to audio record the discussion; all consented to have their interviews recorded. There were no offers of a monetary or nonmonetary incentive to the participants in this study, other than the offer to provide a copy of a completed summary of this research after committee approval. In addition, there were no costs to be borne by subjects, other than their time. All interviews were audio-recorded and professionally transcribed.

Data Analysis

After each interview was recorded and transcribed, the transcripts were reviewed and coded using Nvivo 12 software. After coding the first five interviews, a preliminary coding scheme was developed based on the topics in the interview guide, for review and input by committee member Antonia Bennett, PhD, before proceeding. I then employed a thematic analysis approach to code and analyze the data, revising the coding scheme iteratively based on emerging themes. Relevance of the issue to the overall topic of the study, frequency of mention, and importance of the issue as stated by the participants were three factors in the identification of themes. The code book is provided in Appendix 4.

CHAPTER 4: RESULTS

Interviews with 24 oncologists from a variety of disease specializations and practice settings were included in the study. Participant characteristics are provided in Table 2 below. The majority of oncologists specialized in adults hematology or medical oncology, however the specialties of gynecologic oncology, surgical oncology, radiation oncology, and pediatric oncology also were represented.

Practice settings were identified as physician-owned, hospital/health system-owned, academic or public hospital (non-academic). The majority of oncologists interviewed came from large academic settings (54%) and served primarily Medicare- and private-insured patient populations.

Table 2. Study Participant Characteristics

Characteristic	No.	%
Individual Characteristics		
Gender		
Female	13	54
Male	11	46
Race/Ethnicity		
African-American/Black	2	8
Asian	5	21
Caucasian	13	54
Hispanic/Latino	3	12
Not Available	1	4
Specialty		
Hematology or Medical Oncology	17	71
Gynecologic Oncology	3	13
Surgical Oncology	2	8
Radiation Oncology	1	4
Pediatric Oncology	1	4

Cancers Treated		
Breast Cancer	9	38
Gastrointestinal (i.e., colorectal, pancreatic)	3	13
Gynecologic (i.e., endometrial, cervical, uterine)	3	13
Hematologic (i.e., leukemia, lymphoma)	3	13
Skin and Soft Tissue Sarcomas	1	4
All Cancer Types	4	17
Years in Practice		
Less than 10 y.	5	21
11-20 y.	6	25
21 or more y.	13	54
Practice Characteristics		
Clinical Care Setting[a]		
Physician-Owned	5	21
Hospital/Health System-Owned	2	8
Academic	13	54
Public Hospital (Non-Academic)	4	17
Size[b]		
1-5	5	21
6-12	1	4
13-40	4	17
41-100	4	17
>100	10	42
Region		
Midwest	3	13
Northeast	7	29
Southeast	7	29
Southwest	3	13
West	4	17
Insurance Mix[c]		
Predominantly Medicare and Private Pay	18	75
Predominantly Medicaid, Medicare/Medicaid Dual and Uninsured	6	25

[a] Practice setting categories based on the ASCO Oncology Practice Census, with the addition of the category, Public Hospital (Non-Academic) to distinguish this unique practice setting

[b] Practice size based on the number of practicing hematologist/oncologists in the setting, as defined in the ASCO Oncology Practice Census

[c] Insurance mix self-reported by oncologists. Responses were categorized into two main category types that emerged: Predominantly Medicare and Private Pay and Predominantly Medicaid, Medicare/Medicaid Dual and/or Uninsured

Qualitative analysis of the contents of each interview yielded 43 codes, which I grouped into nine distinct themes. In Table 3, I present a summary of these themes, followed by an in-depth description of each.

Table 3. Study Themes

Theme	Description
1. Why cost comes up	The issue of OOP costs arises primarily due to insurance coverage concerns, high drug costs and patient inability to pay for the ancillary costs of care (e.g. transportation, time off work). For oncologists in private practice, discussing cost is viewed as important not only for patient well-being, but also for the financial health of the practice.
2. When and how cost comes up	The topic of OOP costs can arise in several ways, by either the patient or the oncologist bringing it up before or during treatment. Often the patient initiates discussion with another member of the staff, who brings the issue to the attention of the oncologist.
3. Discussion frequency and initiation	The frequency with which OOP cost discussions take place between oncologists and patients varies widely depending practice setting and population served. Oncologists in private practice are significantly more likely to initiate a discussion of cost and ensure it takes place.
4. Attitude and experience	Oncologists believe not being able to afford one's care has become expected and universal. They view communicating with their patients about OOP costs as important, but most do not feel adequately prepared to do so.
5. Processes and resources used in practice	The process of obtaining OOP cost information, in addition to the necessary steps required to obtain financial assistance, is a time-intensive, back-and-forth process that can increase patient anxiety and lead to delays in care.
6. Strategies to reduce OOP costs	Oncologists are aware of and use a wide range of strategies to help patients predict, plan for, and afford their OOP costs. Oncologists view enrolling a patient in a clinical trial as a way to reduce OOP costs, but say doing so also can increase indirect costs.
7. Barriers to cost communication	Lack of education, resources and a systemic process for identifying and mitigating financial toxicity in practice are barriers to OOP cost communication between oncologists and patients.
8. Facilitators of cost communication	Dedicated staff support, OOP cost estimator tools, and payment models that incent OOP cost communication are facilitators for oncologists to having cost-related conversations with their patients.
9. Improving cost discussions in oncology practice	To effectively assist patients in understanding, minimizing and managing their OOP costs, physician and patient education, information-based solutions and a systems-based, whole care team approach are needed.

1. Why Cost Comes Up

Oncologists identified several reasons why the issue of OOP costs comes up in discussions with their patients, with the most commonly cited reasons being insurance coverage concerns, high drug costs, and patient inability to pay for ancillary costs of care (i.e., transportation, time off work).

Insurance coverage concerns

Oncologists spoke at length about the significantly increased impact OOP costs are having on their patients compared to the past due to patients' poor insurance coverage. Oncologists frequently cited an overall increase over the past several years in patients coming in with high-deductible health plans, or plans that do not cover the cost of prescription drugs. They also identified high co-pays, as well as the accumulation of smaller but collectively significant co-pay expenses for patients who require long durations of therapy. Most oncologists said their patients don't have an uninsured problem; rather, they have an under-insured problem. They may be uninsured briefly/temporarily, but for the most part they can qualify for state emergency Medicaid, which can be done retroactively. The exception is undocumented individuals, who cannot qualify for Medicaid and who will be turned away even by non-profit hospitals in some states (i.e., Florida).

Newer, more expensive drugs

Oncologists discussed how new drugs carry exponentially higher price tags than their older, often generic, counterparts. In particular, targeted therapies—which can offer significantly improved length and quality of life compared to earlier generation treatments—can cost upwards of $10,000 per month.

The oral revolution. Among expensive newer treatments, oncologists pointed to the rise in the availability of orally administered drugs as a reason why cost issues increasingly come up in discussions with patients. Oral drugs, such as poly ADP ribose polymerase (PARP) inhibitors for ovarian cancer, can be more convenient for patients compared to intravenously administered drugs. However oral drugs usually have higher associated patient OOP costs. One breast oncologist from a hospital/health-system-owned setting in California noted,

> I had a patient, she was the perfect candidate for CD46 inhibitor with an [aromatase inhibitor], perfect candidate, and there was not one way I could get it affordable. And she just sat there and said, "You know what? We can't afford this. We accept it and we can't afford it. We are not going to sell our house. We know this isn't curable." And she couldn't get it. And so we had to give [her] chemotherapy, which might be covered because of intravenous (IV) versus oral. Instead of having a three years' survival on pills (average disease free survival), she progressed in eight months. We had to give her more chemo. It was terrible.

Ancillary expenses

Oncologists caring for patients from low socioeconomic (SES) backgrounds often identified ancillary expenses as the main cost concern among their patients. These costs include transportation to and from appointments, lost wages from being out of work, daycare costs, eating food in restaurants instead of cooking at home, and loss of housing. Oncologists working in public hospitals noted there is less concern about the cost of what they are prescribing, because most care is covered from a treatment perspective. Instead conversations tend to focus on ancillary costs that their patients have trouble affording. From a medical oncologist from a public hospital in New York City:

> As far as the drugs are concerned, our patients are actually pretty insulated from drug cost just because of how poor they are. If they're undocumented uninsured, our pharmacy will give drugs to patients for a nominal fee. I'm talking $2 copay for upper-tier chemotherapy medicines—or free, for that matter. There's no instance of a donut hole. There's no intermediate level of suffering that our patients need to pay in order to get access to the drugs. You're either able to pay a little bit or pay none at all.
>
> Where we run into costs are the ancillary costs of treating cancer. For example, a lot of patients have trouble getting from wherever they live to our hospital. Another thing that comes up is the opportunity cost of missing work. A lot of times patients work off the books. When that happens, there's no such thing as workman's comp if you're not working. A lot of times you have some problems eating in order to just be here all the time.

> Sometimes patients who are living in a not secure housing situation who pay month-to-month without a year-long lease, who get themselves admitted for two to three weeks at a time, get discharged to find that their room has been given away, and that they're newly homeless. That causes a crisis on discharge.
>
> Just today we had a patient with multiple myeloma who would be a candidate for an autologous bone marrow transplant, and she elected for a course of treatment that didn't include that because she was worried about cost, and she's worried about not being home for multiple weeks at a time and the ability to hang on to her housing. We ended up picking a substandard level of care. We could offer the standard of care, but she picked the substandard level of care because she couldn't deal with the expense of not living at home. So there's that.

A necessity to preserve practice health

Oncologists in private practice noted they consider discussing cost not only as important for their patients, but also as necessary to ensure the financial health of the practice. They uniformly identified concern about expense to the practice if the patient is unable to cover the cost of care. A private practice oncologist in rural Texas explained:

> We do talk to people about cost because we have to. If we can treat the patient for free and actually break even, we can do that. But if we are going to be losing so much money that we really can't do that, we have to talk to them about that.

Oncologists also made it clear that expenses are increasing for practices due to decreasing reimbursement, which can result in lower profit margin to the practice. They noted that because oncologists purchase their drugs up front, then bill insurance for them when they are used, the financial risk—and burden—is on the oncologist. A gynecologic oncologist in private practice in Texas:

> In gyn/onc, most of our drugs are generic, like carboplatin and taxol. You get very little reimbursement for that. When I first started, I was like, "Okay, I'm going to give chemo to everybody." What I noticed when I first started was that I had some patients that had either Medicaid or one of those Obama type plans that paid very little for the drugs that I give most often, which are generic anyway. So I was actually losing money. I had two patients that wound up dying and their insurance did not pay for their drugs, but at least

> they got one or two cycles. So I actually ended having to pay that out of my pocket, because the company I use expects to be reimbursed whether the insurance pays or not. So I kind of learned from that experience having to pay. And I could not send the family the bill because the patient had just died. So I ate this cost and paid it myself.

2. When and How Cost Comes Up

Oncologists described several scenarios in which the topic of OOP costs comes up between them and their patients, both during and after the initial treatment decision-making period: 1) The patient brings it up in anticipation of high costs prior to treatment; 2) the oncologist knows a treatment tends to be expensive and brings it up prior to treatment; 2) the patient brings it up when having trouble coping with OOP costs during treatment; 4) the oncologist becomes concerned by something their patient says either before or during treatment, leading him/her to think there may be financial concerns going on; and 5) the oncologist is notified by his/her staff that a patient is having financial concerns that cannot be addressed adequately by the office, and needs to discuss alternative treatment options.

Not at the initial visit

Most oncologists said the topic of OOP rarely comes up—and is not appropriate for them to bring up—during the initial consultation or visit. During this time, patients are usually consumed with worry and emotionally distraught over the diagnosis of cancer. As well, there are often more pressing issues to discuss. From a pediatric oncologist from a rural academic cancer center in Alabama:

> A kid comes in, a four-year-old who had been fine until about three weeks ago and then suddenly started becoming more and more tired, started having low-grade fevers. You do all the tests during the day and you are sitting in the evening with a tired, exhausted, frightened family, and you are telling them that their child has cancer.
>
> First of all, for them to absorb all of that… none of the other things are on their mind. The finances, nothing. All they are thinking about is, "Is my child going to die?" So you walk them through all of that, as much as they will absorb. Usually these meetings last

> for about three hours or more. I don't know how much they absorb in those three hours. You tell them everything, you come back the next morning and you tend to then repeat a large part of it again. Then you break it down into bite-sized pieces: Today we will do this, tomorrow we will do this, and the next day we will do this. You give them as much reassurance as you can.
>
> I'm painting this scenario to tell you that within this mix, we have to, at some point, address finances also. We have to address issues such as how many days will the father miss of work, will the employer be okay with them missing work, how long will they be okay, this is going to be a three-year haul, how much of it will they tolerate, what will the siblings do, who will handle the day-care for the siblings, if both of them are working, how will they juggle that. So lost wages bringing the patient, who quite often lives four hours away, back and forth, having the right transportation for that. And then in the mix of things, we have to fit in this conversation about how much it is going to cost. So that is why the cost issue is often neglected in these conversations upfront.

During treatment decision-making

Several oncologists said they have incorporated addressing the topic of finances into their discussions in a general way with their patients, particularly if they know the treatment they are prescribing tends to be expensive. From a gastrointestinal cancer oncologist in an academic medical center in Chicago:

> I'll say to the patient something to the effect of, "we will be running all of this through your insurance company and will let them know if the costs are prohibitive."

From a breast oncologist in a large physician-owned practice in Texas:

> I try to set expectations because I find there's a lot of anxiety in cancer care when expectations aren't met. So I try to set the expectation of cost and so they know they can approach me back and they don't have to feel guilty or shame or concern that I'm not going to care for them if they have financial concerns around treatment decisions.
>
> I don't know, and patients don't know, what their out of pocket costs are for the treatment that we're making decisions about in the room. So after they leave the room, we query what their plan is, what portion of their deductible is in that and where they fall in the donut hole for the rest of their other medications.

From a surgical oncologist in an academic cancer center in New York:

> I will mention to people the very high cost of drugs for our patients with a HER [human epidermal growth factor receptor] 2 positive cancer, for example, but I will tell them, “I don't know your exact insurance, I don't know your exact deductibles, but it will be covered as to the extent of your deductibles." So I have raised that. I don't formally do that with every case, but I will bring that up with individuals. Usually in the tune of, "Don't worry. This is covered by your insurance. These expensive drugs are covered by your insurance, to the extent of your deductibles."

Oncologists often said they look for “red flags” from their patients to gauge if financial issues are a concern. If there are “red flags,” oncologists will often bring in financial services or social workers to help address concerns. From a hematologist-oncologist in an urban public hospital center in New York City:

> I always try to get to know a little more about who they live with, how they support themselves. And if I find anything concerning then I bring it up. If I find that, for example, they're unemployed or if they're supporting other family members, if they're having some issues with housing, for example, then I will bring it up. But otherwise, if I don't see anything that I consider my own red flags, I don't bring it up.

From a surgical oncologist from rural academic cancer center in New Hampshire:

> It is often times tip-toed into, especially because when you come and see me it does involve an operation and sometimes people view that as an opportunity to get into the 'how much work am I going to miss' perspective of things. When people start worrying about missing a couple of days of work, it often times signifies that there is not a lot of give in their savings and in what they can do.

Absent any “red flags,” many oncologists reported not discussing cost issues during the initial treatment decision-making visit, because at that point they do not know how much various treatments are going to cost their patient. Instead, they identify their preferred treatment and then send the patient to another member of the staff—either a billing or practice manager, nurse, or financial counselor, who will research the patient’s insurance coverage and determine if the treatment will be paid for, and to what degree. At that point, the patient is asked if the cost is going to be an issue. If so, most practices help the patient identify financial assistance of some kind. If the search does not yield adequate assistance, then the billing or practice manager will let the oncologist know another treatment should be considered, if possible. Only at that time will the issue of cost come up in the context of treatment decision-making.

At the start of or during treatment

Once a patient has been prescribed treatment and is beginning or in the midst of care, the topic of OOP costs tends to be initiated more often by patients. Several oncologists noted it is often the case that the patients get one to two months down the road, and they get a flurry of bills and are overwhelmed. Commonly, patients will bring it up to another person on the care team, who then brings it to the oncologists' attention.

3. Discussion Frequency & Initiation

When asked about the frequency with which OOP cost issues comes up in their discussions with patients, oncologists provided a wide range of responses, ranging from "rarely" to "every hour." Most qualified their answers noting the issue of cost comes up with nearly every patient, just not necessarily with the oncologist him or herself. Many admitted to not talking about it as much as they should.

Variation by practice setting

The frequency with which oncologists reported engaging in cost communication with their patients varied significantly by practice setting. Compared to academic and hospital/health-system owned practices, oncologists in private (physician-owned) settings said they were much likely to be aware of the costs of care they prescribe, to initiate discussions with their patients about OOP costs, and to have systems in place to ensure patients are informed of costs up front. They attributed this to the fact that if a patient can't pay, it affects the financial health of their practice, as noted earlier. From a breast oncologist who has worked in both a physician-owned and hospital/health-system owned setting:

> In my private practice, cost was so important to patients that every patient had a chemo education visit where they actually sign a consent form after full detailed education. And they had a financial counseling visit. They knew the co-pay and the coverage and the cost of their care. Because as a private practice, we had no slush fund or philanthropy to pay for costs patients couldn't pay for and there were definitely patients over time that said, "I can't afford to pay for this regimen. What is the second choice, the third choice? What would that cost?" And there were patients that had too much money to qualify for patient assistance programs. And we know the cost of things, because it came up with our patients all the time.

Oncologists not in physician-owned practices varied in the degree to which they said they address cost issues with their patients. Oncologists in public hospital settings reported discussing costs with nearly every patient, at every visit. They attributed this to the fact that their patients usually struggle to afford their care and need financial assistance, and their institutions lack the resources to have ancillary staff available to help patients with their financial needs, leaving the task to the oncologists themselves.

4. Attitude & Experience

Oncologists believe OOP costs are a significant problem affecting a growing number of their patients. They view communicating with their patients about OOP costs as an important but challenging aspect of care.

Uncomfortable to discuss, but less so than in the past

Most oncologists agreed that while discussing cost can be uncomfortable for themselves and their patients, doing so seems less uncomfortable than in the past. Respondents attributed this to the fact that not being able to afford one’s care has become expected and universal. As a result, discussing it has become legitimized. That said, oncologists universally agreed it is difficult to discuss cost with patients because the topic is so complex, and they do not feel equipped to help. A few also said they did not believe it is their role to discuss costs with their patients. From a breast oncologist from a rural academic cancer center in Alabama:

> I think that we don't, as a community, feel incredibly comfortable with talking about cost. Many of us, myself included, don't necessarily believe that that is our role. I'd much rather have patients talking with a financial counselor about cost than me. That is not my area of expertise.

Easier if the patient brings it up first

Many oncologists said they feel more comfortable discussing cost if the patient brings it up first, because they are concerned the topic could make the patient uncomfortable and create a challenging dynamic. For this reason, a few oncologists said they try to minimize the focus on cost to the degree that they can. From a hematologist-oncologist at a hospital/health system-owned cancer center in Florida:

> It’s a double-edged sword, right? People already sometimes have a skewed view of us either trying to overcharge, and so if we talk too much about cost, then people have a skewed view. "Hey, this person is talking more about the cost of something than the actual healing." So we try to minimize that to some degree, purposefully. But then when we notice that there are areas of concern—“Hey, we notice that this either might not be covered or there is a high deductible"—or something that is reasonable to discuss, then we discuss it at that point and we explain why we are discussing it.

Positive effects

Many oncologists reported there can be positive effects from bringing up OOP cost issues with their patients. Doing so can come to a relief to patients and can also help patients feel heard and understood by their doctors. Additionally, oncologists noted having the discussion can create a more intimate relationship between doctor and patient. From a hematologist-oncologist at a public hospital in New York city:

> When you have the conversation with the patients, it does, first of all, it helps your doctor-patient relationship a lot. They do realize that you do care about everything that's

> going on in their life, not just their cancer, and you do understand that certain things, there are things which, you know, go above and beyond even their health and you know, they do appreciate that you are trying to help them with that aspect of their treatment as well.

A shared responsibility among the care team

Oncologists expressed they feel it is important to inform patients about what their treatment will cost, and to help them identify ways to make their care as affordable as possible. However, as noted earlier, many said they do not think it is necessary for this information and assistance to come from the oncologist directly—and some said they do not believe it is their role. However oncologists generally agreed they do have a role in addressing cost in the context of clinical decision making, i.e., to know and discuss what clinical options are available for the patient that may be similar clinically but less expensive in cost.

5. Processes and Resources Used within the Oncology Practice

Oncologists described a variety of approaches they use in their practices to help patients understand and address OOP costs. These approaches varied significantly depending on the presence or absence of ancillary staff to assist them in the process. However in every case, oncologists described the process of helping their patients as time- and resource-intensive, noting it can take weeks of work to obtain help for one patient.

Role of staff support

Oncologists in this study reported having different types and levels of staff resources available to assist their patients with OOP costs. Some oncologists interviewed work in settings with several financial counselors. Others work with none. Oncologists in many hospital/health system settings generally have financial counselors, billing managers and/or nursing staff who work directly with the patients to estimate their OOP costs and assist them with finding assistance, if needed. Oncologists working in small (i.e. solo) private practices have little to no ancillary staff to assist. Those in larger, well-resourced physician-owned practices have what appears to be the greatest amount of staff support. Oncologists in academic settings varied in the degree of staff assistance available; however most in areas serving lower-SES patient populations reported needing more help than they have. Those in public hospitals varied significantly in the degree of available staff support, depending on the level of resources available within the system.

In many practice settings, often a nurse, front desk worker, or billing or practice manager serves in a financial counseling role, checking the patient's insurance, checking to see if they need co-pay assistance, and identifying free drug programs or other foundations to help minimize expenses. Many oncologists described this work as occurring "in the background," apart from the doctor-patient interaction. From a breast oncologist in urban cancer center in Seattle:

> Intake nurses identify patients that are likely to have financial challenges and limitations and will notify a financial counseling office. Sometimes there's even communication or discussion with the patient about their financial situation before they see the doctor. However, since often these patients, the urgency of their clinical situation or just their desire to be seen as soon as possible, not infrequently, they'll actually see the oncologist before any financial issues are worked out. After the treatment plan and management plan is worked out, then the financial office will be informed of that, so as they have some idea of what the patient may be facing in terms of financial obligations.

From a breast oncologist in rural cancer center in Alabama:

> There are social workers and financial counselors and pre-op people, all the people that are working in this space are definitely aware of different resources that are available both locally and nationally. I really believe that those groups that are working in the trenches on covering the cost are using multiple different resources to try to find a way to get this covered and/or budget more appropriately or set up a payment plan. Those are all helping to address this issue. Much of that is happening in the background.

The role of the financial counselor is usually to check the patient's insurance, confirm if the patient needs co-pay assistance, and identify free drug programs or other foundations to help minimize expenses, if necessary. The same is true when oral chemotherapy is prescribed, except assistance usually takes place through a specialty pharmacy, as described further below. Oncologists noted that sometimes the patient can receive the drug for little or no co-pay as a result of this work.

Reactive versus proactive financial counseling

In some situations, usually in large physician-owned practices, all patients meet with a financial counselor before starting treatment. From a breast oncologist in a large, urban physician-owned practice in Texas:

> We have several financial counselors. Every patient that receives any kind of chemotherapy in my practice, it's the standard of care that we have them meet with a financial counselor, so they understand what their out of pocket cost is, prior to initiating treatment, for every single patient that initiates therapeutic intervention. We are always completely transparent about what their out of pocket cost is, before they initiate treatment, but frequently that discussion enters in my room with patients, whenever the costs are very high. So an example is the CDK46 inhibitors. And so we help manage that through patient assistance programs, and then some patients don't receive that particular intervention, because the cost is prohibitive.

In the majority of cases, financial counselors meet with patients only when called in by a clinic nurse, social worker, office coordinator or other staff member who “senses a problem” or when an issue arises. For example, if a patient receives a bill or was charged for a service he or she doesn’t understand, then the financial counselor will address the specific problem. It is not often that the counselor meets with the patient to explore what the treatment costs are going to be in advance. Oncologists noted their counselors have not been used in that way and, in fact, are not often prepared to do so. From a medical oncologist in a hospital/health system-owned cancer center in Florida:

> A: If I told [the financial counselor], “Here is a patient and this is what I am going to be treating them with, could you give the patient a general sense about the cost,” they would

> not be able to do that easily. They certainly wouldn’t be able to do it on the spot and it would take a lot of digging on their part to be able to produce those estimates for patients.
>
> Q: What would you, if we could wave a magic wand, would you like them to be able to do that?
>
> A: At least at this point, the general answer is no. Until I am really confident that we can identify exactly what is going to be the patients' out-of-pocket burden versus what the insurance company is going to pick up and do that with any degree of certainty, I think all that process does is create anxiety for patients, because it always ends up being this, "You know you could have to pay as much as $30 000. Now it may be much less than that, it may be $500." So what does that really tell you? I find it working in more of a reactive way. If there is a problem, then we must identify what that problem is and work on it, rather than trying to give patients a sense of the world of possibilities of what this could be depending on how the insurance company views certain things.

Oral drugs and the role of pharmacy

When prescribing oral drug regimens, oncologists noted they often rely on prescription (specialty) drug pharmacies to financially counsel their patients and help them with their drug expenses. They described the process as beginning by the oncologist completing a form and sending it to the pharmacist, who then performs a benefits investigation and shares with the patient what he or she will owe.

Oncologists often noted the cost for a given drug is “all over the map,” with some people owing close to nothing and others needing to pay $10,000 or more before their drug benefits begin. If the costs are high for the patient, the specialty pharmacy will investigate whether there is a foundation (often established by the drug company) to help pay for the drug. From a gastrointestinal cancer oncologist in academic cancer center in Chicago:

> Usually, the specialty pharmacy will actually take the lead. They will call the patient, let them know what they have done and then will help them file for assistance programs or look for other third party assistance. If all that is exhausted, and they are unable to find that, then it will go back to my nurse and ultimately to me with, "Well, this is how much the patient’s out-of-pocket is going to be. What do you want to do?" We have never used financial counselors for that purpose. Financial counselors are used almost exclusively

> for imaging, hospitalization, and those types of co-payments that are very specific to our institution, to either give a sense of what their total burden would be or to help patients that are having issues with their insurance companies through. But we have always used some specialty group to help with drugs.
>
> There has been, between foundations and drug company reimbursement, you have always had these options of dealing with the co-pay problem, and it really required folks who knew that market well. So we always found that, especially pharmacy folks, A, know it well and, B, always had a nice incentive because obviously they were taking it because they hope to fill it. So financially it was in their best interest to do the work and for the small percentage of patients that they couldn't for insurance reasons, it was okay because they got enough of our business otherwise. So it was very nice—it worked for everybody involved and was pretty hassle free.

Some oncologists noted they have a specialty pharmacy within their institution, making it easier to coordinate care. However for most oncologists, there appears to be less of a relationship with the pharmacies where their patients receive their drugs. In these cases, oncologists describe using a “come back and tell me” approach: They prescribe the treatment and ask the patient to let them know, once he/she goes to fill the prescription, if the cost is prohibitive. From a breast oncologist at academic center in New York City:

> We make it pretty clear to patients that if they found out there is going to be a huge co-insurance payment or that their prescription co-pay is really high and not something that they can cover, to let us know before they pay it. Then we try to go to the drug company and see what we can get that way.

From a pediatric oncologist in rural academic cancer center in Alabama:

> I tell my patients, because sometimes they go to the pharmacy and that's where they find out that this is not covered by their insurance and they need to pay out of pocket. I tell them that if this ever happens, they need to call me, and I will make sure that we appeal this, and they get the medication so that they are not paying out-of-pocket for the whole cost of that medicine.
>
> Very often the pharmacists are very helpful that way. So a patient ends up at the pharmacy and they say, "This is the medication that is written. I have a cheaper version available, do you want that?" And the patient will say, "Yes, of course I want that." And they will go with that.

OOP cost estimators

Some oncologists noted their practices have begun using OOP cost estimators as part of their financial counseling for patients. However they noted these tools are incomplete (i.e., they do not include any supportive drugs or indirect costs) and are not patient-specific (i.e., they do not consider a patient's insurance coverage, but rather provide estimates in the aggregate). For this reason, oncologists said these tools don't' provide a very useful metric or estimate, although they can be useful in prompting conversations that would not have occurred otherwise.

Oncologists in private practice described tools available to their practices through large group purchasing organizations such as McKesson and ION, and that their practice managers often use these tools to estimate Medicare payments to the practice. One oncologist in private practice said she would use the tool herself to provide information to her patients. But like with other tools, the information would be for the drugs only—not for the treatment plan as a whole.

Financial screening tools

Many oncologists said their practices use screening tools to identify patients for signs of distress—both emotional and financial. They noted these screenings usually are used with established patients to assess how they are doing in affording their drugs, rather than a priori to assess their financial situation. Moreover, the results of these screens do not necessarily return to the oncologist. Oncologists noted that if they did receive this information, they could have a more complete picture of their patients' issues and quality of life concerns. From a pediatric oncologist in rural medical center in Alabama:

> When I came here, I established a mechanism where I was asking the patient to complete a very brief questionnaire, which was asking them about material hardships. It's a validated questionnaire. It has been used in other settings in pediatrics. And we are now administering it to all our patients and using a triggered approach to get social service to help them. It is given to all diagnosed patients as well as all the survivors that come in.

> For each newly diagnosed patient we would ask, "Over the next month, are you at risk of losing the house you live in or the roof over your head? Over the past month, have you had electricity cut off? Over the past month have you had food not available to you for all three meals of the day?" I will tell you that about 30% of our patients say yes to one of these. So this is at its most severe form, and what we then do is that this triggers a call to our social worker, who then helps us in arranging for either transportation or working towards getting them vouchers or getting them food stamps and food along the lines of where they can have access to all of these three things. The social worker has very good systems in place where they can provide them with access to these things, in the out-patient side as well as the in-patient side.

From a surgical oncologist in rural academic cancer center in New Hampshire:

> We do get a flag if somebody is self-pay, which is basically uninsured. My schedulers let me know, because as a surgeon, a lot of times, it's not the expense of having an office visit. As an oncologist, it's can they actually get chemo or not. From a surgical perspective, it's can you actually schedule them for an operation. They come in and they are self-pay and I see them, and we actually make the determination that they need an operation, not only do they need to get scheduled for the operation, but they need to go back to the financial people and work out how that is going to look for them.

From a breast oncologist in urban academic center in California:

> A: We have, in our clinic in-take process, the PROMIS [Patient-Reported Outcomes Measurement Information System] tool. It is a distress screening tool that gets sent to patients before their first visit and also periodically, at least every three months. If a patient indicates distress on this tool, they then get triaged. And if it is financial distress they are experiencing, they get triaged to either the social worker or the financial counselor. So we have formal streaming in place. We have looked at the compliance with that formal streaming tool and it is about 35%. So 35% of patients go on that.
>
> Q: Do you think this is working to catch the patients who need the help? And catch them at the right time?
>
> A: It's working at the extreme. It's working for patients who have extreme financial difficulty, I think. For the patients who are having mild trouble paying their bills or trading off cancer care versus other necessities of life, I'm not sure it's working well. I mean, I don't know, it might be. Really, I have no way of knowing.

6. Strategies for Reducing Patient Out-of-Pocket Costs

Oncologists described various methods they use to help patients predict, plan for, and afford their OOP costs, including free drug and co-pay assistance programs; changing insurance plans or programs; changing the site of care; selecting generic equivalents; choosing alternative treatments; and financing or absorbing costs within the institution. They noted clinical trials can be a strategy to save OOP costs, however participation also can cost patients more in indirect expenses (i.e., travel). Oncologists generally agreed that employing these strategies is a time-consuming process that does not always lead to satisfactory outcomes for the patient.

Free drug and co-pay assistance programs

Oncologists identified many resources available to help their patients financially, including free drug programs sponsored by pharmaceutical companies, co-pay foundation, and drug coupons. Of note, however, challenges with these options exist. Financial assistance programs are often inadequate or change frequently, making it administratively difficult and resource-intensive for staff. From a hematologist-oncologist from a public hospital in New York City:

> We were pursuing that medication but then with the more expensive one, actually the financial assistance came through and they actually gave us like a, they gave us a few months’ worth of supply, free of cost pretty much. So we said, okay, we'll go with this now that we have it. So it's kind of like, we just kept going back and forth.

From a hematologist-oncologist from public hospital in Atlanta:

> We are in an environment of need. We have expertise on this, so we have a person that is assigned only for patient assistant programs. Any or most of the drugs that I use have a patient assistance program, so we are able to cover their medications through a patient assistance program almost for free and the care of the patient is either absorbed by our program or by the Georgia Cancer State Aid. That being said, the treatment might be delayed, because we have to get all the process of those support systems in order that we can have access t. If there is an urgency, there will not be delay. But if there is not urgency, it can take about two to three weeks. Sometimes a week.

From a medical oncologist from a public hospital in New York City:

> We have limited social work here, so it's a lot of times the physician's job to talk with the patient about what is their level of income, and how many people are supported with your level of income… and to process the copay assistance or free drug program in order to get patients access to a certain medication.

Changing insurance plans or enrolling in government programs

Oncologists also noted they can often help their patients save money by helping them obtain or switch insurance plans, or qualify for other federal- or state-sponsored programs. For example, if uninsured, patients can often qualify for emergency Medicaid, as well assistance for breast and cervical cancer patients through state-based breast and cervical cancer programs. One oncologist who worked in a public hospital in Atlanta said there are times when it is better for the patient to be uninsured. "I tell them, 'Terminate your insurance. Become uninsured and we will cover everything.'"

Changing site of care

Another way oncologists described helping their patients with cost is by selecting a different place for their patients to receive care. One method is to choose a less expensive pharmacy or imaging center. (Oncologists in private practice were more acutely aware of differences in costs among pharmacies than others.) Other oncologists noted a useful strategy is to select a specialty pharmacy they know discusses cost with patients. From a breast oncologist in rural academic cancer center in Alabama:

> Some of these medications, [if I know it is] a high cost medication, is routed through our pharmacy if possible and then if not, passed on to another pharmacy where I know that they are discussing cost. I will sometimes mention that it is expensive again in the same line where I explain to them that they need to let us know if there is a problem.

Oncologists in physician-owned practices noted a common strategy to help their patients afford their care is to send them to a nearby hospital for IV drug treatment rather than provide care in their office. They noted many hospitals are able to obtain discounted 340B pricing, which makes these hospitals more able to absorb the costs if the patient is unable to pay. Oncologists also noted resources are limited, and may be declining, for hospitals caring for indigent patients. Alternatively, oncologists in physician-owned practices said they will send their patients to a county hospital or free clinic where they can receive care—but usually not in a timely way, or with the most preferred options. As well, one oncologist stated, if no other options exist, she will select in-patient rather than out-patient option.

Selecting different mode or schedule of therapy

Many oncologists identified ways they can help their patients with the cost of care by selecting choosing an infusion equivalent instead of an oral therapy; selecting a treatment that requires less frequent visits to clinic; and scheduling surgery on a Friday so patients can recover over a weekend and not miss work.

Selecting generic drug equivalents

One important strategy for reducing OOP drug costs for patients is to choose a generic equivalent versus a brand-name drug. Oncologists uniformly agreed generic drugs generally cost less than brand-name drugs and that they tried to use these when possible. Looking ahead, some oncologists expressed hope that, for new cancer treatments and supportive care, there will lower cost, equivalent options due to the rise of biosimilars. They noted the majority of the drug-pricing rise over the last few years has occurred with biologic therapies (i.e., Herceptin, Rituxan, and Rituximab). They noted these new biologic therapies are, in many cases, seen as game-changers in terms of their dramatic impact on survival in some populations. As well, they expressed that as biosimilars continue to be created as alternatives to these new biologics, patients are expected to pay less.

Choosing an alternative treatment

Oncologists said the degree to which different options may be available that are similar clinically but different in cost varies depending on disease stage and type, with most agreeing there are more options in the metastatic rather than curative setting. Additionally, they felt strongly that initial treatment options should first be considered agnostic to cost.

Variation by cancer type. Oncologists generally agreed that the degree to which there are clinically similar treatment options depends, to a certain extent, on the cancer type. In some circumstances, there are a large number of "me too" drugs, which can then be compared according to which one will be the cheapest for a given patient depending on his/her insurance. But other times, there is only one suitable option from a clinical standpoint, for example when a new targeted therapy is available that is dramatically better than the older models.

Breast cancer oncologists tended to consider it fairly common that there are clinically similar but less costly options available. From a breast oncologist in academic medical center in New York City:

> There are a lot of things we do where there are really good other options that don't cost as much. I mean, the fact that we give Abraxane and it costs 10 times more than some of the other drugs that have the same benefit. Maybe people just aren't aware and maybe that is why.

In contrast, oncologists treating hematologic, gastrointestinal and lung malignancies considered this scenario "not common" or "rare," with many times just one or a couple of options available at most. From a hematologist-oncologist in a public hospital in Atlanta:

> It's because of the degree of potency. For example, thalidomide for myeloma, thalidomide went off the market, it went off patent, and is regular now, and is very cheap.

> But the situation is that Revlimid is a thousand times more potent than thalidomide and it causes less side effects. So you see what I'm saying.
>
> The medications that we have, at least in the field that I am, are from the same family but not the same toxicity profile nor the same efficacy profile. And the same, I mean in lymphomas we are using a regimen that is now close to 20 years old. But there is nothing better than that, so we keep using it.

From a gastrointestinal oncologist in urban academic medical center in Chicago:

> It's a very rare circumstance where I have a clear, much cheaper alternative that I would say we can either do this one or this much cheaper version if this doesn't work out. Usually that would be my distant second choice, so I tend not to think about it. And even, the areas where I know - growth factor is one of those areas - where bio similar, the 3 or 4 days at home versus one time shot in the office, we don’t usually bring up the different options to the patient. We kind of just decide what we think would be best for the patient. And again, if we run into an insurance issue, then we can look at the alternatives.

From a lung cancer oncologist in an academic cancer center in Indiana:

> The problem that we have is that the generics of these drugs are going to take many years. For example, 36 new lung cancer drugs have been approved in the last 2 years. I think it takes about 10 years before we get a generic. All the chemo’s that we have approved for lung cancer were approved in the first years of this millennium. Of course all the drugs are generic now, but all of these drugs - five or six - they only keep the patient alive for one year. So of course, if you ask me which of these drugs to use, yes, all of them are the same. I'd go for the cheaper one. But remember that these are the drugs they use to keep the patient alive for one year. Now with the pills for lung cancer and immunotherapy, patients can take pills and live for years. But all of these pills and immunotherapies have 10 years of patent life and you have to wait 10 years for their generic pills.

Variation by cancer stage. The degree to which there are treatment options also tends to depend on cancer stage, oncologists noted. In early-stage cancers, when systemic (i.e., drug) therapy is used, most agreed there usually aren’t a lot of options. Oncologists noted there are often are a handful of regimens that have been well established in major clinical trials, and they generally have a sense whether there is one that is particularly higher in cost than the others. Moreover in early-stage patients, when one is treating a patient for cure, oncologists said they don’t want to take any chances by selecting a slightly inferior but less costly drug, as doing so could end up compromising a patient's long-term outcomes. In contrast, in the metastatic or advanced disease setting, oncologists noted it is far more common to have clinically similar but disparately priced treatment options. In these cases, there are often multiple therapies (drugs) that can be used that have similar and often, unfortunately, fairly low response rates. They noted in this setting, there is more utility to comparing drugs based on cost, because the benefits are much more circumscribed and similar to one another, yet the cost can vary widely. From a lung cancer oncologist in an academic cancer center in Indiana:

> As we get to second and third line and fourth line, the efficacy differences between a more expensive and a less expensive option become smaller. The efficacy differences become smaller. Our first line trials, if you look at a patient with lung cancer and you give them carboplatin, alimpta plus pembrolizimab, that is an extraordinarily expensive regimen and you are giving it as maintenance therapy. Patients can remain on alimpta, pembrolizimab or both for a couple of years, three years. Extraordinarily expensive regimen.
>
> Having said that, when you compare that to a cheaper cisplatin plus etoposide, a regimen that could have been used in the eighties, the two, three and four year survivals are dramatically higher for the more expensive regimens. So in that case you really are - especially with immunotherapy - while it's extremely expensive, you are getting long term survivors with that approach, so you are getting a lot out of it. But when you get to second and third and fourth line, there are very expensive drug options and there are cheap drug options and the efficacy differences are very small.
>
> A good example of that is recently with prostate cancer, if patients have metastatic hormone sensitive prostate cancer but with high volume disease. They have several options. One option, they can go on Lupron, the second option is they can get Lupron plus taxotere and the third option is to get Lupron plus Zytiga. The cost differential between those is dramatic. Zytiga is an oral medicine so that introduces another issue with insurance.

An opportunity in supportive care. One important area in which oncologists noted dollars can be saved by selecting alternative treatments is in the area of symptom management drugs, such as anti-emetics. For example, one oncologist noted, “palenosetron is better in moderately emetogenic chemotherapy than granisetron, and it helps a little bit more for delayed nausea, however the differences are small. But to pay $10 for one and $500 for another seems ridiculous.” From a pediatric oncologist in rural academic cancer center in Alabama:

> Q: In the pediatric arena, putting aside generic versus brand, would you say there are often/sometimes/never more than one treatment option available between different drug options that could have variable cost and that would be clinically equivalent? Or is that just not the case?
>
> A: Oh, it does. Absolutely. You can look at antibiotics. You can look at antiemetics. You can look at a variety of symptomatic relief medicine such as allergy medicine and all of those. It's very clear that there are certain medicines that cost much more than the others. And most often, we try to choose the ones that are least expensive. The important thing is for the physician to be very responsible in trying to remember that there are expensive options and there are cheaper options, and an expensive option is not necessarily the best option.

Treatment options by specialty. Medical oncologists commented that knowing cost differences among brand-name drugs is difficult, because each patient’s insurance may cover these drugs differently. (The exception was oncologists in physician-owned practices, who tended to have a strong knowledge of how drug costs, in general, compare.) Surgical and radiation oncologists interviewed agreed they are not likely to identify alternative treatment options for their patients that cost them less. One surgical oncologist noted there is not a lot the oncologist can control, because these services are covered under a global payment structure. For example, from a surgical oncologist in rural academic center in New Hampshire:

> Q: So if I decide to use a cheaper instrument in the operating room. So let's say I decide to use the old fashioned one as opposed to the brand new one. The patient doesn't realize any difference. It's what the hospital gets.
>
> A: So it would not change the patient’s out-of-pocket at all?

> Q: No. Not for cancer. I think if the patient was undergoing some kind of cosmetic procedure, a type of plastic surgery or something, and it was like, "You can have this kind of implant or that kind of implant." Then the cost will get passed down to the patient. Because it's totally elective and it is not really something that insurance covers, but a cancer operation? That's like 90% covered by the insurance if you have the insurance. And the insurance would pay the negotiated rate and then it's on the surgeon and the hospital to figure out if they are going to use the really expensive implant or instrument then that is going to come out of the cost. So I can save the hospital money by using the less expensive piece of equipment, but none of that gets passed down to the patient.

From a radiation oncologist in urban academic cancer center in Philadelphia:

> Radiation therapy is a fixed cost. So, that hospital system is paid for linear accelerator, whether it gets used or not. Whereas, when you're putting devices into people, or proteins, or chemo, it's a different type of expenditure.

Financing or absorbing costs within the practice or institution

Another way oncology practices help patients manage OOP costs is through the use of payment plans, which helps to spread the cost to patients over a longer period of time. As well, most oncologists noted their institutions sometimes will absorb the costs internally if their patients are unable to afford their OOP costs. This is particularly true for public hospitals, which will treat patients regardless of ability to pay and absorb the cost of what is not paid for by insurance and/or financial assistance programs.

Cost as a component of treatment decision-making

Most oncologists said they would prefer initially to consider treatment options with their patients agnostic to cost. Then, only after the optimal treatment is identified, do they wish to consider OOP cost with and for their patients. Additionally several oncologists brought up the importance of distinguishing between treatments taking place in the adjuvant versus the metastatic setting. In particular, in the curative setting, several oncologists balked at the notion that discussions about trade-offs would even include the element of cost. For example, from a breast oncologist at an academic medical center in Chicago:

> I don't think people should be making decisions that way, whether or not they can afford the treatment. It's not like they are buying a car. It's one thing when you are talking about one month progression free survival and it costing $2 million. People disproportionately weigh the toxicity against survival if the impact is that they might not be the person that has the recurrence. And we don't want to be going backwards. We don't want more people recurring because they can't afford the right treatment. In the curative setting, I think it is up to us to find every way to find every way possible to let patients have that decision not be financial.
>
> Regardless of whether they are on Medicaid or whether they have this “super-duper expensive care, generally these things are covered. Very few people are refusing curative adjuvant therapy on this basis. People who do actually turn down the adjuvant therapy are small in number.”
>
> In the curative setting, I think it is up to us to find every way to find every way possible to let patients have that decision not be financial. I think we need resources so that people can get it in those settings.

In contrast oncologists generally agreed that a cost discussion can be useful to help guide a discussion about options in the metastatic setting. For example, one breast oncologist in an academic setting in New York city noted:

> I think that we give patients really expensive drugs, especially in the metastatic setting, where the benefits of overall survival are somewhat questionable. That is where these issues become really, really important. What I don’t think people can wrap their head around in terms of the number, is patients in the adjuvant setting, where you are talking about living or dying. Then it is of miniscule value if you are talking about having your cancer come back or not.
>
> As you get into more second, third, fourth line therapy in the metastatic setting, I think [cost] will become more and more of an issue. My personal opinion is that the doctors ought to start bringing it up more and more as you get further and further down the line.

Another oncologist also discussed the importance of discussing cost in the metastatic setting because of the impact it has on the family.

> The stress is not just in the patient. It is on the caregiver, especially in the metastatic setting, because the patient may not live, but it is the partner that is going to end up with the debt.

Role of clinical trials

Most oncologists agreed the ability to place a patient on a clinical trial generally helps—or at least does not hurt—patients financially. They agreed it can help patients with OOP costs, since the pharmaceutical company covers the drug cost itself. Moreover the trials also may offer more support in terms of ancillary costs such as travel (i.e., cab vouchers, hotel stays), which otherwise would have to be borne by the patient if he/she were in conventional treatment. However, oncologists also noted there are a lot of additional “hidden” costs for patients on clinical trials that are not always considered. For example, treatment under a clinical trial often involves more back-and-forth and effort on the patient’s part (i.e., additional scans, office visits) and can require travel from a distance, adding to patient cost. Additionally, oncologists noted enrolling a patient in a clinical trial is not always an option. While insurance usually covers routine costs for large phase 3 trials, this is not necessarily the case with earlier phase trials. As well, trials are becoming more complex, expensive, and difficult to enroll patients in general. As well, enrollment in a trial is not an option for many patients such as older patients with co-morbidities.

7. Barriers to Cost Discussions between Oncologists and Patients

Lack of OOP cost transparency

Oncologists identified lack OOP cost information is a significant barrier to cost discussions between themselves and their patients. This lack of awareness includes both an inability to identify specific treatment costs as well as to have a holistic picture of costs for their patients. They said while it is possible to identify the amount an individual co-pay will be for a drug regimen, information on surgery, radiation, and non-medical (ancillary) expenses are much more difficult to obtain. None of the oncologists interviewed indicated they can provide whole-treatment cost information in a predictive way to their patients. As a result, oncologists are not able to provide their patients with a comprehensive look at their patients' financial as well as clinical situation and options during medical decision-making, nor are they able to know when the treatment they prescribe may cause, or is causing, financial toxicity to their patients. From a radiation oncologist in urban academic medical center in Philadelphia:

> When you go to the dentist and need a tooth removed and an implant or something like that, within a week or so you get a pretty good idea of what it's going to cost. But I think there's so many in the flow diagram of decision-making, I don't think you get clarity. In an extreme example, patients who have lost their loved ones, they keep getting bills way after someone's died. That's pretty common.

Many noted they are reluctant to bring up cost if they are not sure what a patient is going to have to pay—they don't want to use estimates if they're not confident they're going to be good ones for an individual patient. From a gastrointestinal oncologist in an academic medical center in Chicago:

> If you could say with 100% certainty that we know that with this insurance, this is going to be their out-of-pocket and work with the patients upfront on how they are going to deal with that, I would be happy. But we are so far from being able to do that with any certainty that I think we end up creating undue anxiety for patients before it is needed.

However other physicians said they would be comfortable with, and benefit from, having estimated costs to use with their patients, as it would provide them with at least a starting point. From a radiation oncologist at urban academic medical center in Philadelphia:

> It seems no matter where you get your care, it's never clear up front what you're in for and the bills just keep organically growing and changing and there's no real planning

> financially that is cohesive. So you might know for example you might have a financial manager sitting in the medical oncologist's office who might explain to you that your insurance company is going to cover this oral drug or not, fine. But what about when it's multi-modality therapy. You're seeing the surgeons. You're seeing the radiation oncologist. At the end of the day, obviously your focus is on getting well. But is there anybody who's putting those costs together and really sitting with you as a patient, so you understand does the institution provide a holistic view for any patient getting chronic care, and the answer is, "No."

Lack of education and training

Oncologists also identified lack of education and training as a barrier to helping their patients with the cost component of their care, noting a major limitation in oncology training is that cost is not addressed. One oncologist said of the institution at which she trained—a major National Cancer Institute (NCI)-designated cancer center: "It is "a wonderful place, very grateful to have been there. We never once talked about cost of care." Oncologists said education is needed in several areas: Understanding the financial cost of treatment (i.e., how much treatment actually costs), understanding the basic structure of health insurance and how the reimbursement process works for patients; learning ways to help (i.e., what to do, what are the "words that work" or the "things that can be done" to mitigate financial distress); and becoming socialized to the notion that it is acceptable to discuss cost with patients as a physician. From a hematologist-oncologist in a public hospital in New York City:

> The overall education we get on the financial cost of treatment is so poor, and it's just so much learning on the job that I've had to do. I try to make an effort to know more about this, like, I follow people, financial, medical people, that care about financial toxicity to patients on Twitter. I read their articles, I do what it takes. But I just feel so poorly informed most times.

From a gynecologic oncologist in a solo private practice in suburban Texas:

> I had one patient who just died. She had a bladder infection and she was on chemo, so I sent in her prescription just for an over the counter antibiotic. What I didn't know is that she did not take it; she did not get it because she was waiting. I guess she lived with her

> family member. She was an older lady, maybe 70. She was a widow, she didn't have money to get prescription pills and she wound up getting sepsis. Had I known that she didn't get the medicine I would have given her IV? Did she get it? No, we have not picked it up yet because I do not get paid till Friday. Those things I am more aware of now where I was not when I was at an academic center because I probably would have had social work or case manager say "Oh, maybe we have a grant or something to help pay your bills."

Difficulty identifying resources to help appears to be particularly pronounced for oncologists treating patients in less urban areas, as well as those treating less common cancers. From the same gynecologic oncologist in solo private practice in suburban Texas:

> Just in general knowing what resource are available to patients and how to access it. I'm learning as I have been here for two years. I did not know where to go and who to ask. It is not always easy to find.
>
> I used to start with the American Cancer Society. Sometimes they are helpful, not always in my community because the main branch is in Houston. I find that gyn-cancers are under served because you see a lot about breast, there is very much about uterine, ovarian or cervix.
>
> I had a patient who had ovarian cancer. She just would not take IV chemo because she could not afford co-pay and she wouldn't tell her children she was struggling she would say, "No, I'm not going to worry them. They do not have money either," and so she actually declined therapy. I tried to look at Komen see what breast cancer groups could give her help, but we could not find anything. I'm sure there is stuff out there; I just could not find it.

Lack of a systemic process for identifying and mitigating financial distress in the practice

In general, oncologists described a lack of confidence in the process used in their practice to identify individual who may be at risk of—or are currently experiencing—financial distress. While most described having some type of screening in place, several oncologists described screening as triggering assistance only if the patient has issues at "the extreme," such as if they lack health insurance altogether (i.e., is self-pay). As a result, they said there is a real potential for individuals to “slip through the cracks” despite the presence of screening. From a breast oncologist in suburban hospital/health system-owned cancer center in New Jersey:

> If there are those patients that are suffering, I might not know about it. Sometimes the people we might be missing are those people in the middle who are proud and don't mention it and don't ask.

From a surgical oncologist from rural academic cancer center in New Hampshire:

> If you are self-pay, it's an automatic, “you have to go talk to the financial people.” But for the high deductible health plans, there is no automatic, “You have to go see the financial people.” It's definitely not automatic. It probably should be.

Oncologists said another challenge is that that they rarely see the responses their patients provide to the screening questions; as a result, they lack information—either at the time of diagnosis or during treatment—regarding their patients’ financial circumstances or concerns related to their care.

Oncologists also reported often hearing complaints from patients that the responses they provide are not are not taken up and addressed within the practice. Even in well-resourced settings with significant financial counselors, this can be an issue. From a breast oncologist at large academic cancer center in California:

> One of the things, as we roll out this PROMIS screening, one of the things we get from patients is that nobody pays attention to this screening. "I answer these questions, but nobody does anything about it. So why am I filling this out again? The last time I filled this out, nobody did anything."

Other times the issue is that screening triggers the need for assistance that the practice does not have the capability or set-up to provide. From a pediatric oncologist in a rural academic medical center in Alabama:

> What we try to do is to make sure that all the costs are covered by the insurance companies, but they are often charges that are unintended, unwanted that land up in the patient's pile. If the patient is savvy, if they are smart, they will appeal that. However,

> there are some patients who don't have that understanding. A large proportion of patients in Birmingham or in rural Alabama don't have that ability. They just go more and more, deeper and deeper into bankruptcy because of that.

From a medical oncologist in public hospital in New York City:

> A: Every patient gets ... I'm not sure if it's every new patient or every patient on every visit, has a color-coded questionnaire that they have to answer that identifies the hot points for intervention. For example, like do you have trouble paying for food or do you feel unsafe at home?
>
> Q: Do you get to see those responses?
>
> A: Yes, we do. The problem, though, is that the city is permanently in a budget crisis. The question is, pay for the subways or pay for the hospitals. When it comes to staffing, right now we're permanently in an attrition staffing mode, so when our social worker left two years ago, that job hasn't been filled.

Many oncologists noted a significant concern is the potential for patients on oral drugs to "slip through the cracks." From the date the oncologist decides to prescribe the treatment, there are a lot of factors that can get in the way of their patients receiving the drug. Moreover, the oncologist may not know what ultimately happens with the patient. From a breast oncologist in large academic medical center in New York City:

> Patients think somebody is going to call them when they leave the office. The problem is tracking it. There is no good system to track it all so sometimes stuff falls through the cracks. The patient is just sitting there waiting. Nobody knows that the patient didn't get the drugs. You know? There is like a gazillion a thing that can go wrong, that interferes with that pathway. And you are not there. We are so used to a patient coming in, us writing an order for them to get IV chemo, and we know they got it that day. But when it's oral, it's out there. You just don't know.

Lack of ability to identify resources for their patients

Many oncologists, particularly those in small physician-owned practice settings, said a major barrier to having productive cost conversations with their patients is that they lack the ability to adequately help their patients identify resources to help them afford their care. These oncologists reported feeling isolated from a support structure around them to help identify resources for their patients, as well as to help them detect when the patient might be experiencing financial distress. Even oncologists who have staff resources to assist often find the assistance inadequate. One reason is for Medicare patients, co-pay assistance is prohibited. Additionally, they noted that often financial counselors can't solve the problem. One oncologist noted, “They really try with what is available, but it's like a Band-Aid on a much bigger issue, and if somebody happens to be in that 'not poor enough to qualify', it's not there is gobs of resources to help them.”

Time- and resource-intensive process

Oncologists also reported how time consuming and administratively burdensome the process is to help their patients navigate the financial aspects of their care, including addressing insurance issues as well as securing financial assistance.

Oncologists repeatedly initiated discussion during the interviews about the administrative burden associated with helping their patients deal with insurance issues. Oncologists noted every Medicaid, Medicare Manage Care and private plan goes through different sub-specialty pharmacies; some have preferred providers or preferred drug companies, so it is difficult to know at the time the oncologist is prescribing the drug which company has a relationship. One oncologist noted, “You can give them Kisqali, but you can't give them palbociclib. You just can't know until you actually try to get them the drug. So it ends up being trial and error.” They also noted the emotional cost to the patient caused by the delay it can take to get coverage decisions in place with insurance companies, particularly in the area of imaging. From a gastrointestinal oncologist in an academic medical center in Chicago:

> For our patients, I don’t run into as much scrutiny on drugs. So it is very rare that I get the, "This is not something we will cover." It is almost always covered; it's just a question

> of co-pay. Where I run into the pre-certification problem is much more on imaging. Imaging has become a much bigger issue for us in terms of precertification and running through the pathways we have on imaging. Very rarely do I run into it on the drug side, at least in the GI oncology world.
>
> Any time we are running CAT scans now, 20 or 30 percent of the time I am getting a ping back that I have to have a peer-to-peer, either to justify imaging that has been done in the last 3 months that we are repeating or wanting more clinical information about why we are ordering this test. So there is much more scrutiny than there is on the drug side. So it always comes back to me to do the peer-to-peer. It's usually not co-pay. If it gets approved, patients almost never have to pay much on that kind of stuff.
>
> It's not a financial toxicity issue as much as it is a hassle factor issue, getting things approved in a timely manner.

To secure financial assistance, oncologists noted it takes a significant amount of time for the patient to collect information and then get the paperwork processed. In some cases, the patient must be fully approved before therapy can begin; in other cases, if the patient is actively applying, the oncologist can proceed.

8. Facilitators of Cost Discussions between Oncologists and Patients

As noted previously, many oncologists and their care teams have established ways to help address OOP costs with their patients, and to facilitate having informed discussions at different points in the care continuum. These include the use of OOP cost estimator and financial screening tools, in addition to having financial staff/counselors who are dedicated to addressing patient OOP costs and are embedded within the cancer care team. When asked what helps facilitate OOP cost conversations between them and their patients, oncologists emphasized the importance of having dedicated support and also identified other facilitators, including payment models that incent OOP cost conversations, and flexible coverage and formulary policies.

Dedicated staff support

Those oncologists interviewed who have dedicated staff in place to address patient OOP costs describe being better equipped to identify the potential for financial toxicity and help patients prevent or manage it before and during treatment. In particular, oncologists who feel most equipped work in settings that have individuals dedicated to serving in a financial counseling role full time.

Patient screening and OOP cost estimator tools

As noted earlier in this section, oncologists viewed the use of screening tools as helpful to identifying and helping patients at the extreme, but they said they worry that those with moderate financial concerns may not say so and "slip through the cracks." Also, to be optimally used, they noted screening tools need to be more systematically applied and integrated into the workflow so that results actually reach the oncologist.

The few oncologists who have integrated OOP cost estimates into their practices have found, while imperfect, doing so can be useful in prompting a financial conversation—particularly if the information is automatically given to the patient. However they noted an OOP cost estimate must be accompanied by information on a patient's resources in order to assess if the cost is likely to be a burden to that particular patient. From a breast oncologist in an academic medical center in New York:

> I'd like to see built into the EMR [electronic medical record] for patients specifically, what a patient's out of pocket costs are for everything that we order so that when we order it, we can see it. And it's not just what it costs; it's what resources the patient has. It's really based on their wealth. You could have Medicare and have $2 billion in the bank, you know? Those costs are relevant. You could have Medicare and Medicaid and the costs are also irrelevant because the costs are paid for by your supplemental. We need to be able to pull in information that is meaningful on regimen A and regimen B. Information about the patient's preferences and together that can lead to the better decision.

Payment models that incent OOP cost communication with patients

Oncologists whose practices have begun to participate in the Oncology Care Model (OCM) noted they are required to provide patients with an OOP cost estimate. They said this requirement has led to an increased focus on this issue within their practices, sometimes leading to the hiring of one or more financial counselors to help. From a breast oncologist in rural cancer care center in Alabama:

> The other thing that is a little bit different in some ways here is we are doing the Oncology Care Model, and so we are required to tell patients about cost. I will say that that is not necessarily coming at the physician level. It is coming really more with the ancillary staff. Our pharmacy has developed a way to provide that out-of-pocket cost information to patients. We are providing patients with sort of an estimated cost of chemotherapy when they are starting a new treatment. And it's a monthly estimate.
>
> But some of the difficulty is that it is literally just the drug cost. It is on a patient level, but it does not even include drugs like Neulasta or something that might be prescribed sort of as a bundle with that. So I understand that it's not going to incorporate indirect costs, but I still find it useful. I think it has prompted conversations that would not have occurred otherwise, but it is hard to be a really useful metric or estimate.

9. Improving the Integration of Cost Discussions into Oncology Practice

Oncologists noted that, given differences in the way their practices are structured, resources and staffing available, and patients served, improving cost discussions in oncology practice is not going to be a one-size-fits-all solution. Moreover, it will be essential that the issue be addressed from multiple directions, including interventions at the doctor, patient, caregiver, and health system levels. Oncologists suggested several strategies that would help improve their ability to address patient OOP costs with their patients—in a way that is informed, efficient, and patient-specific.

Physician education and training

Oncologists – particularly those working in settings without other staff available to help—stated they need more education on the financial cost of treatment, and how to help their patients navigate the cost of their care. In particular, this education should focus on several areas, including helping oncologists understand there are expensive options and cheaper options, and an expensive option is not necessarily the best option; teaching how the topic of cost should be brought into the "mix" when caring for patients—what are the words to use, and when; and teaching how to consider the non-treatment related costs that patients may not think of (e.g. transportation, opportunity cost for work). Additionally, oncologists identified the need for education on the resources available for patients in their communities, as well as on where drugs are sold more cheaply. Finally, several oncologists said they would benefit from clinical practice guidelines that help identify options that are just as effective but cost less.

Oncologists also noted they need to be taught it is okay to discuss cost—in general, and with patients directly. Many oncologists said there is a need to socialize clinicians to transparency around price. Voicing the sentiments of many interviewed, one oncologist said, "I think we need to socialize clinicians that it's okay to talk about cost. It's okay to talk about costs with patients. We need to familiarize clinicians with this idea of being transparent with our patients. And having reasonable discussions with each other, because it's important and we need to be talking about it."

Several oncologists emphasized the opportunity that exists to educate the next generation of the medical community, who are ready and accepting for this kind of guidance. They emphasized the importance of focusing on this reservoir of people who are not yet "beaten down" and are eager to "do the right thing."

One of the oncologists interviewed who is Hispanic/Latino noted the importance of a diverse oncology workforce in ensuring issues such as cost are discussed, since individuals often feel more comfortable engaging with physicians who share a similar background.

Patient and family education

Oncologists in this study emphasized the importance of education for patients and their families in several key areas. First, patients need information on how to bring up cost with their oncologist and cancer care team, i.e., what to do, or what are the words that work or the things that can be done to mitigate financial distress. Additionally, they said it is important to educate patients and their families about what their insurance plans cover in terms of OOP costs. To understand and anticipate their costs, patients should know their OOP insurance maximums for themselves and their families, and whether the pharmaceutical OOP maximum is "in addition to" their medical OOP maximum. As well, patients need to know what financial assistance resources are available where the patient lives. Making these resources available online, where patients can complete applications for assistance independently, would save office staff time. Finally, oncologists suggested their patients would benefit from information on "what you get for what you pay," both regarding the treatment itself as well as the site of care.

Information-based solutions for clinical decision support

Oncologists identified several points of information that are needed at different times to ensure their patients receive the best treatment at the lowest cost to them.

Up-front OOP cost information before leaving the office. Once the treatment plan is established, oncologists would like patients to know what their financial cost is going to be up front rather than at the tail end, after they have left the doctor's office and are showing up at the pharmacy. That way there can be a more intelligent upfront conversation, and the oncologist can say, "Based off your insurance, this preferred medication is going to be $100 a month. Can you afford that?"

Cost estimates appear to be satisfactory as a start. At the time of initial treatment decision-making, oncologists would like to have information on the patient's insurance plan (i.e., if it is a high deductible plan, or what their drug coverage OOP maximums are). Also for each drug regimen, they would like the name(s) of the manufacturer and the price per tablet size. They acknowledged this information would not be fully accurate, since it would not factor in whether a patient has met his or her deductible or what the cumulative cost of co-pays would be for the other services needed (i.e., bloodwork, imaging). However, many said they believed this information would help them have a beginning discussion with patients about treatment options and how big of a financial cost it will be for them.

Patient-specific, full-treatment OOP cost estimates are ideal. Optimally, oncologists would like a way to show patients what the overall treatment plan will cost them, including the cost for all facets of the treatment and the indirect costs expected. Not only would this help the patient, it also would help them, as physicians, assess if the treatments they are prescribing are leading to additional patient expense without commensurate clinical benefit. From a pediatric oncologist in a rural academic cancer center in Alabama:

> We need to have a very good sense of how much it costs to take care of an adult from newly diagnosed to the time of relapse. These costs of care need to be put out. So even if they are a ballpark, at least they are there. Having these publications out would be absolutely amazing, so that people can use those.

Oncologists expressed skepticism that it will be possible—at least in the near term—to have patient-specific information available. They noted this would require such a deep understanding of the insurance and the institutional contracts involved that it would not be feasible to identify average—or estimated—costs that are close enough to be meaningful to patients. Oncologists thought developing these kinds of informational resources may need to come from individual institutions rather than be developed for use across practice settings. Despite these challenges, most oncologists felt it is important, as an oncology community, for physicians to know the cost implications of what they are ordering for their patents. From a breast oncologist in hospital/health system-owned cancer center in Seattle:

> Clinical care, we need to provide the best clinical care. Even if there's no options, I think it's our obligation to let patients know what may be coming their way in the mail at some point and go from there.

From a breast oncologist in a hospital/health-system owned cancer center in California:

> At some point we are going to have to have a better plan for how to include that cost information with all the decision-making and the choices. Because it is a priority for patients beyond what most of us realize. Each patient may have different insurance, with different ability to apply for and obtain assistance based on their income. In an ideal world what you would want is, within some type of decision support tool - a pathway, your EMR, something in that space - to say not just generically, "This is expensive," but this is what this patient's out-of-pocket costs will be over some unit of time. I envision this being most easily done in the scope of a pathway program, which we do not have. We do not necessarily, at this point, have a decision support tool, which you could easily layer that on top of. Do I think that, ultimately, we will have that? Yes.
>
> Ten years from now, every oncology practice will have some type of a decision support tool, whether it is a pathway or whatever. I think that will someday be the case and that this information will be generated electronically. You will put information in upfront and that piece of information will be and should be one of multiple pieces of information that should help guide the decision making process. Because there are trade-offs. That patient example that I gave you, she was absolutely unwilling to lose her hair, so she might have actually spent the $1,000 to be able to get this capecitabine, which wasn’t going to make her lose her hair. But I think it could have been better if we could have had that conversation. I was able to actually get her some support through the company and she didn't have that terrible co-pay after the beginning. But I think that is sort of the ideal situation, to have it as part of the decision support tool.

From a breast oncologist in a rural academic cancer center in Alabama:

> Today the tools aren't there, and the best person, clinically to know if there are two options is not the back office manager, right? The best person to know if clinically there is more than one option is you.

From a breast oncologist in large academic medical center in New York City:

> Theoretically, you could get information every time you write an order, which would make it easier for people. If every time I wrote a chemo order, it was to give me a clue. Like if you were ordering a certain medication, and if you change x in your regimen, the patient's out-of-pocket costs would go down $200 a month.

Systems approaches to support value-based care delivery

In addition to better information to aid in clinical decision support, oncologists pointed to the need for systems approaches to help oncologists more easily integrate cost discussions into practice.

Setting OOP cost expectations for patients should be standard of care. Several oncologists suggested an important goal is for patients to have transparency around costs and to feel comfortable with getting that information from their clinical team. They suggested setting those OOP cost expectations for patients should be the standard of care. To achieve this, some of the oncologists in larger physician-owned and hospital/health system-owned practices said it is important that every patient meet with a financial counselor before starting treatment. From a breast oncologist in large physician-owned practice in Texas:

> There is a need for practices to have this as part of their process workflow. This is something that we need to do for every patient. I was really happy that the OCM prioritized the importance of meeting with a financial councilor. In my opinion, that's a part of getting people there. Because if you have financial counselors meet with patients, it invites patients to discuss this with their clinical team. And sets clear expectations of patient out-of-pocket costs that allows them to bring that into their discussions.

For practices without strong ancillary staff support, oncologists suggested it would be helpful to implement feedback loops between themselves and the specialty pharmacy office after oral drug regimens are ordered to ensure the prescription was filled, and at what cost to the patient. Doing so would provide the oncologist with important information not only about their patients' care, but also their anticipated financial burden.

Financial screening and mitigation systems for financial distress. Oncologists also suggested systems be put in place that automatically refer certain patients to financial counselors or other staff who can help them with the financial aspect of their care. Before and during treatment, oncologists noted it is important to have screening as well as mitigating systems in place for financial distress, just as many practices now regularly have for emotional distress. Such screening tools should be used to assess the likelihood that a patient will have trouble affording his/her care, as well as throughout the treatment period to detect emerging financial issues. They also noted it is critical that these tools be integrated into the system of care so that a positive screen is followed up on consistently and automatically. Such screens should assess not only if patients feel they need help, but also if they understand how to use their insurance and if they have experience navigating the healthcare system. Validating and promoting the use of these tools in oncology practices is important as well, and this could be achieved by integrating cost communication into quality initiatives, and creating and sharing best practices.

Easier access to financial assistance. Oncologists also pointed to the need to make it easier to help patients obtain financial assistance. Doing so would make the process of addressing cost concerns less time intensive. One example is using a centralized process workflow and prior authorization program system to help with patient assistance. Another example is fax-to-refer forms, which are commonly used to help refer patients to tobacco cessation programs but also could be used to connect patients to financial assistance programs.

Whole team approach

A common theme that emerged is that oncologists do not think clinicians can be depended upon to discuss cost with their patients universally well, given the age distribution of oncologists and the lack of expertise they have on the topic. The majority of oncologists pointed to the important role of the care team in ensuring the financial aspect of a patient's care is addressed up front and throughout the course of therapy.

Oncologists identified the critical role of dedicated staff support to help patients navigate what is often very complex treatment. Patient navigators or counselors can serve an important role in helping their patients understand the financial aspects of their care. They warned, however, that having trained financial counselors is not adequate; rather, counselors also need to be educated about, and embedded in, the oncology practice in order to offer meaningful help to patients. From a breast oncologist in hospital/health system in Seattle:

> Surveys that others we have done showed [cost] may not be something [patients] want to talk about right at the very beginning (they're more concerned about their disease and the best treatment), but that at some point [they want to have] a discussion about what this all means, financially, to them. Because they don't want to leave their family destitute because of the cost of their illness. So, these are really difficult conversations and frankly ones where we try to involve the whole care team.
>
> Patients may have difficulty talking to their oncologist about some of these difficulties, but are far more open with the financial counselors, of course, and even with other support team - the nurses and so forth. They may express their fear or apprehensions or concerns more openly with others than with the oncologists. That's where we really need the team to be coordinated and on the same page when it comes to making sure that the care team is addressing all the patients' needs, both clinical and financial.

Policy change

When asked if there is anything else that would help them address OOP cost with their patients, nearly every oncologist interviewed identified the need to make more care affordable for patients as the primary issue to fix. They pointed to policy solutions such as mandating standardized insurance policies that protect patients from catastrophic OOP medical and drug costs; action to lower drug prices on the part of pharmaceutical companies; and investment in clinical research on older drugs for alternate therapy uses as a way to bring less expensive medications to patients. Additionally, a few oncologists who work, or have worked, in physician-owned practices pointed to changes needed in today's reimbursement system. These oncologists identified challenges with buy-and-bill, which they said can create a perverse incentive to use more, not less, expensive treatments. They noted changing the reimbursement structure in a way that rewards oncologists for the time it takes to care for patients would remove this element from the equation. From a breast oncologist in suburban hospital/health system-owned center in California:

> Let's be really clear, as sad as it is, we don't get paid to take care of patients. The practices run on the drug margin and this is really the way it is. So definitely there is influence. A new drug comes along; somebody claims it is better, better for the patient, better for the practice. And it's adopted immediately because everybody is a winner. Taxotere is the best example. The institution was claiming it is better, and it had a big margin on it and so we gave a lot of it and pretty soon the FDA [Food and Drug Administration] said, "You have to stop saying that. It is not better than taxol. And then we were back to using generic taxol. So much less money for patients. But these are the really difficult conflicts.

ASCO's role

Several oncologists identified ways ASCO can help improve cost discussions between oncologists and patients. They suggested ASCO has a role in helping across the spectrum, including supporting the education of oncologist about cost and cost communications; making patient resources more easily available to oncologists and patients/families; creating and promoting quality of care initiatives focused on this topic; working with insurance companies and employers to devise a tool available to oncologists that calculates reasonable estimates of

OOP costs; and taking on the larger policy issues related to defining how much treatments should actually cost (or are worth), promoting innovative payment and other healthcare delivery models that incent the provision of financial counseling, and leading other interventions to help oncologists integrate effective strategies to address OOP cost into practice.

CHAPTER 5: DISCUSSION

Rising cancer care costs, combined with an increased shift of medical care costs from insurers to patients, have led an increasing number of individuals in the United States to experience financial toxicity, or the harmful personal financial burden faced by patients receiving cancer treatment. Discussing OOP costs can enable patients to choose lower-cost treatments when there are viable alternatives, make trade-offs between medical benefit and financial cost if they wish to do so, and seek financial assistance resources earlier rather than later in their care to avoid financial distress. Addressing financial toxicity through enhanced shared decision-making between oncologists and patients has been identified as an important part of high quality care, however little research exists to inform how this communication should occur in the clinical care setting. This study sought to expand the evidence regarding how oncologists and patients communicate about costs, and how these discussions can be optimized to reduce patient financial toxicity.

Findings show oncologists view OOP costs as a significant problem affecting a growing number of their patients. Oncologists reported being aware of, and shared first-hand, the impact OOP costs are having on their patients' health and overall well-being. For this reason, they view communicating with patients about OOP costs as an important part of care, if doing so can lead to reduced costs and ultimately better outcomes for their patients. That said, most oncologists in this study agreed discussing cost with patients is difficult because the topic is so complex, and they do not feel equipped to help. Except for some of the newer, targeted therapies that are known to carry high price tags, oncologists said they generally are not aware of the costs of various treatment options, nor are they aware of their patient's expected OOP costs and whether or not they are affordable to the patient. In addition, oncologists pointed to a lack of education on effective ways to discuss cost with their patients, as well as a lack of resources to help their patients avoid or lessen the financial impact of their care. Many noted the time-intensive nature of obtaining financial assistance, and reported a lack of staff support to help them identify and address patients' financial concerns.

Results of this study identify important differences in how oncologists think about, and engage in, cost discussions depending on their practice setting and patient population served. The study also provides greater understanding of the barriers and facilitators to cost communication between oncologists and patients, and points to several changes that are needed to improve the integration of cost communication in oncology practice in the future. Some of the more salient themes that emerged, as well as the study's limitations, are discussed below.

Cost Discussions between Oncologists and Patients: Current State

In this study, insurance coverage concerns in general, and the affordability of cancer drugs in particular, were the main reasons why OOP costs come up in conversations between oncologists and their patients. In another study, health insurance and anti-neoplastic therapy also came up most frequently in cost conversations.[29] This not surprising, given health insurers in the United States have increasingly shifted medical care costs to patients through higher premiums, deductibles, and coinsurance, resulting in high OOP costs for patients. Moreover, patients with cancer are receiving increasingly expensive anticancer therapy, both alone and in combination, as well as expensive supportive care drugs.

Managing the cost of orally administered drugs for patients presents a particular challenge in the cancer setting. Oral cancer drugs are increasingly common, and they are often viewed as more convenient for patients compared to intravenously administered agents, because they can be taken at home. However orally administered drugs usually have higher associated OOP cost, because they are frequently covered under patients' pharmacy benefit specialty tier, for which higher co-insurance rates apply. Affordability of oral chemotherapy can be particularly challenging for Medicare beneficiaries, for whom OOP costs have been shown to be higher than for patients enrolled in private insurance.[34] The majority of states have passed "oral parity" laws designed to ensure patients with some types of private insurance pay no more for oral cancer medications than those administered by infusion, and federal legislation is currently pending. While intended to improve financial protection for many patients, there is growing research demonstrating these laws are insufficient to ensure that patients are protected from high OOP medication costs.[35] Notably, these state laws do not extend protections to patients on Medicare or to approximately half of patients on private insurance plans who are exempt from state insurance mandates due to the Employee Retirement Income Security Act (ERISA), meaning those in self-funded insurance plans.

Oncologists in this study expressed concern that the patients for whom they prescribe oral drugs are at risk of "falling through the cracks," noting that if the OOP cost of the oral drug they prescribe is high and the patient does not fill it because he/she is not able to afford it, the oncologist may not know. Indeed, risk of non-adherence to oral drugs has been well documented.[36,37] For this reason, greater attention is needed to identify individuals on oral therapies who may be experiencing financial burden and creating feedback loops with the patient to ensure prescriptions are being filled and taken. Efforts are needed to improve coordination between the prescribing oncologist and the specialty pharmacy.

One potentially promising model is the establishment of in-office pharmacies that directly embed the dispensing pharmacy within the oncology practice. Establishing in-office pharmacies would be challenging for smaller practices; however given the high level of consolidation that has occurred in oncology, it may be possible for smaller practices to connect to larger hospital systems to take advantage of the existing infrastructure that may already be in place. Standards to guide in-office pharmacy dispensing practices and ensure coordination between members of the care team have been established.[38] Improving the uptake and promotion of these standards is important, as well as evaluating the impact of in-office dispensing on oral chemotherapy adherence.

Additionally, oncologists said best practices for more medically integrated pharmacy prescribing should not be limited to in-office dispensing; rather, they can be replicated for use by stand-alone specialty pharmacies as well.   Improving the integration of pharmacy and oncology is not without its challenges, however. Pharmacist services are rarely reimbursed directly; rather they are paid for by drug margins, which are increasingly being rolled back through 340B drug discount program reform and the Administration's efforts to remove oncologists from these financial transactions for Part B drugs, at least.

Consistent with the literature, oncologists in this study—even those who practice in low-resource environments—said the most significant issue at hand is under-insurance, not un-insurance, among the patients they serve. Patients may be uninsured at the time they are diagnosed, but in most states, they can qualify for state emergency Medicaid. The exception is patients without legal immigration status (commonly named undocumented immigrants), for whom care presents a special challenge. [39]   It also is important to note that, among oncologists in the study who care for low-income, primarily Medicaid patients, OOP cost concerns have much more to do with a patient's ability to afford the ancillary (or in-direct) costs of care rather than issues with insurance coverage. Concerns affording the ancillary cost of care have been well documented.[40] and include costs such as travel or transportation (i.e., gas, parking), cost of childcare (for when patient is accessing care), as well as patient and/or family work productivity or lost wages. This finding underscores the importance of considering the specific needs of patients and the socioeconomic context from which they come when designing interventions to address financial burden.

This study found that the frequency and way in which cost conversations occur between oncologists and their patients vary depending on practice setting and patient population served. Compared to academic- and hospital/health-system-owned practices, oncologists in private practice were much more likely to be aware of the costs of care they prescribe, to initiate discussions with their patients about OOP costs, and to have systems in place to ensure patients are informed of costs up front. A similar result was found in an ASCO member survey by Altomare et al, which showed practitioners in academic settings were significantly less likely than physicians in community or private practice to discuss costs with their patients, and they felt less prepared for such discussions.[12]

It is important to note that while private-practice oncologists in this study reported being more focused on giving their patients up-front cost information, they did not necessarily have greater ability to help their patients afford their care. This shows that motivation to inform and engage patients about OOP costs does not necessarily translate into greater capacity to make patient care more affordable. This finding also points to reimbursement issues in oncology that, while beyond the scope of this study, have important implications for how we consider the impact of payment reform and healthcare economics on physician behavior, in general, and on cost communication, in particular. Oncologists from physician-owned practices in this study pointed out themselves that discussing cost with their patients is necessary not only because it is important to their patients, but also because it is required to avoid bad debt and keep their practices financially viable.

As the cost of cancer care has escalated, so has the complexity of care delivery. As a result, oncologists in physician-owned practices have argued providing services beyond the physician's time is infeasible, and providing care for patients without insurance or the ability to pay for treatment may threaten the sustainability of the entire practice.[39] Studies have shown oncology practices are experiencing increased competitive pressure, with many struggling to attract patients and skilled providers in a competitive market, and some being targeted for purchase by other organizations.[41] Hospital-physician consolidation, or vertical integration, has been increasing substantially over the last decade, and has been shown to be more prevalent in medical oncology than in other high-volume specialties and to be increasing at a faster rate.[42,43]

Additionally in this study, striking differences were found in the level and type of support oncologists have in their practices to identify and help mitigate financial toxicity, with oncologists in small private practices as well as oncologists in public (non-academic) settings serving low-SES patients having much less help from ancillary staff than others. As a result, these oncologists tend to take on a much greater role compared to oncologists in larger, more well-resourced practices in helping their patients understand their OOP costs and secure financial assistance when it is needed. This finding has implications for how we consider the role of the oncologist in addressing OOP costs with their patients, as well as what we define as the key components of information and resources oncologists need to fulfill this role. These findings suggest that the role of the oncologist in addressing OOP costs with patients should be defined in a flexible way, allowing for differences not only in patient need, but also in practice resources. As well, it suggests the need for a variety of models to be designed and implemented for addressing financial toxicity in clinical oncology practice, depending on practice setting and population served.

Another important finding of this study is that although oncologists often feel challenged knowing how to discuss OOP costs with their patients, they actually are aware of, and employ, a wide range of strategies to help make their patients' care more affordable, including helping them obtain free drugs or co-pay assistance, enroll in a different insurance plan or government assistance program; change the location/site of care; select a different mode (i.e., oral versus IV) or schedule of therapy; select generic drug equivalents; or select an alternative drug regimen. Other studies show similar findings, suggesting cost discussions can be important in helping lower patients' financial burden without, in the majority of cases, changing care.[44] However it is clear not all oncologists feel equally prepared with resources or knowledge to address their patients' cost concerns, suggesting an opportunity to assemble the knowledge and practical wisdom of the group more broadly.

This study provides collective insight from clinical oncologists on the degree to which, and instances where, there are multiple clinically appropriate drugs or other treatment options available to discuss with patients. Oncologists in this study were mixed on this point, noting the answer depends on disease stage and type. Yet most agreed there is greater opportunity for considering costs in treatment decision-making in the metastatic rather than curative setting, given the incremental benefits of continuing later-line therapies can be so low compared to the cost of care. Researchers have suggested there are not many instances in which there are multiple options from which to choose in the cancer setting, and that options may be less numerous going forward as more regimens become targeted to narrower groups of patients.[45] However analyses using ASCO's Value Framework have demonstrated the availability of more than one clinically appropriate treatment option across a variety of cancer types and stages, suggesting at least at the present time, the opportunity exists to select among multiple treatments based on cost if desired.[22] Increasingly, ASCO is beginning to provide cost information in its clinical practice guidelines. While not patient specific (typically guidelines have included Medicare reimbursement for a single course of treatment), the information provides a benchmark from which to compare and frequently lists multiple treatment options that differ based on cost. That said, the availability of multiple options for a given patient is dependent on his or her insurance plan covering multiple treatment options in an equally affordable way.

Although oncologists consider selecting an alternative treatment option as a strategy that can be used to reduce OOP costs, it is important to note that oncologists in this study, and elsewhere, have expressed they have an obligation to identify the clinically most appropriate treatment option for their patients, agnostic to cost. [13,25,46] Additionally, authors have pointed out that the desire to discuss treatment costs should not be assumed to represent a simultaneous desire to integrate cost considerations into clinical decision making.[27] As well, studies show patients want their oncologists to discuss OOP costs with them even if they are unlikely to be affordable or play a role in their individual decision making process.[27,47] Given these findings, oncologists may be most likely to meet their patients' needs if they initiate a discussion about cost with all patients, even if there is no interest on their patient's part to factor cost into the decision making process.

The published literature on cost discussions between oncologists and patients highlights how challenging the topic can be for both parties. Oncologists tend to avoid cost discussions with their patients, in part because they are unprepared for those discussions. They often report not knowing how much the treatment they prescribe will cost to any given patient, and few believe they have access to adequate resources to discuss costs.[12] A recent combined review of the literature showed 70% of oncologists consider it their responsibility to discuss out-of-pocket cost with patients, however less than 30% felt comfortable with such communication.[48] Meanwhile, patients are often reluctant to bring up a discussion of cost with their physicians out of concern that bringing up costs is inappropriate, or because they do not want to use the limited time they have during their visit.[12,48,49]

While oncologists in this study agreed discussing cost can be uncomfortable for themselves as well as their patients, they suggested this discomfort has lessened over time. Additionally, oncologists in this study noted there are positive effects to discussing OOP costs with their patients, including that doing so can increase intimacy in the doctor-patient relationship as well as help patients feel heard and understood by their doctors. This effect also has been published elsewhere.[50,51] It is possible that the increased level of attention and research that has occurred over the last several years on financial toxicity has helped to normalize the topic; alternatively, as was suggested by an oncologist in the study, trouble affording one’s cancer care has become so commonplace today, discussing it has become legitimized.

While it is clear cost discussions between oncologists and their patients are considered an important component of high quality cancer care, it is less clear what comprises a cost conversation, and which members of the care team are best positioned to address different various components of the conversation. These are important questions to address given the time constraints that already exist for oncologists. Cost-of-care conversations can be defined as discussions regarding all the costs patients and their families might face, including indirect costs (e.g., transportation, child care, lost wages) for a health care option.[52] In a retrospective analysis of cost discussions analyzing 1,755 outpatient encounters between physicians and patients, Hunter and colleagues identified three basic types of cost conversations: a) discussion of a patient's OOP costs for a healthcare service; (b) discussion of a patient's OOP costs or insurance coverage; and (c) discussion of financial costs or insurance coverage related to health or health care. No distinction was made, however, regarding the purpose or desired outcome of these discussions. In another study, Henrikson identified three types of cost-of-care conversations based on varying patient needs: The patient has an acute financial need, the patient has a planning and budgeting need, and the patient needs to engage in clinical decision-making.[53] In this model, clinicians have a role in each conversation type but play the primary role when the patient's needs relate to clinical decision-making.

Oncologists in the present study demonstrated a similar view that their role should be to help patients discuss cost in the context of treatment decision-making. However to do this well, oncologists expressed the need for better OOP cost information, available at the time of clinical decision making, to advise their patients on the relative benefits, risks and financial impact of treatment options.   As described in the Introduction, several tools and frameworks have been developed to assist in the comparison of expected cancer care costs, outcomes and toxicities. However, none of these resources to date provides cost information from the perspective of the patient (i.e., OOP costs).

Improving the Integration of Cost Discussions into Oncology Practice

This study adds to a growing body of literature demonstrating the need for changes at multiple levels to improve cost communication in the clinical cancer setting. Given differences in the way oncology care is structured, resources and staffing available, and patients served, improving cost discussions in oncology practice is not going to be a one-size-fits-all solution. To effectively assist patients in understanding, minimizing and managing patient OOP costs, strategies are needed at the physician level, the patient and family level, the health system level, and the policy level. Physician, patient and family education; clinical decision support through information-based solutions, and a systems-based, whole care team approach are needed.

Physician education and training

To improve cost communication with their patients, oncologists need better education and training on effective ways to discuss cost with their patients, as well as on how to help their patients avoid or lessen the impact of financial toxicity when it is identified.[54] During training, physicians have traditionally learned very little about health policy, economics, or the cost of the treatments they prescribe, nor have they received training in how to engage patients on the sensitive topic of treatment expense. Authors have noted this problem is analogous to palliative care, for which training has historically been lacking to help oncologists incorporate discussions about prognosis and goals of care.[55] This has resulted in a lack of conversations and inadequate end-of-life-care for patients. Oncotalk, an NCI-funded program, has successfully educated palliative medicine and oncology physicians-in-training on how to discuss transitions to palliative care, and could serve as a good model for improving discussions on the cost of care.[56]

Given increased attention to rising costs, inefficiencies, and waste in health care, the importance of training physicians in this area has become increasingly clear. Cost consciousness is now included as a competency of medical training, however most residency programs currently lack curricula to fulfill this requirement. Programs for physicians-in-training have begun to be developed such as a case-based curriculum for residents at the University of California, San Francisco.[57] In 2012, the Alliance for Academic Internal Medicine (AAIM) and the American College of Physicians (ACP) collaborated on a curriculum that introduces a framework for the delivery of high-value care. The AAIM/ACP curriculum engages residents and faculty in small-group activities involving real-life clinical scenarios that require careful analysis of the benefits, harms, and costs of a test or intervention as well as use of evidence-based, shared decision making.[58] The curriculum is available online along with additional resources for clinicians and medical educators, clinical guidelines, best practice advice, case studies and patient resources on a wide variety of related topics. Currently oncology fellowship programs vary in the level and type of training they offer oncologists-in-training to assess the value of therapy and to develop skill and comfort in discussing financial issues with patients. The AAIM-ACP curriculum could serve as a useful model for the creation of oncology-specific training materials for use by fellows as well as practicing physicians.

Some cost communication models have been developed to train physicians on how to structure cost conversations to meet patients' needs. In 2007, Smith et al. developed SPIKE$, a six-step protocol for discussing medical care costs with patients.[59] Earlier this year, researchers at the University of Alabama at Birmingham developed a framework that recommends clinicians consider three elements to structure their cost conversations: reassurance, action, and resources.[60] Similarly, other authors have recommended following the tobacco cessation counseling model of Ask, Advise, Refer (AAR), recommended by the U.S. Department of Health and Human Services.[61] This three-step approach should start with an open dialogue between patients and their cancer care team, asking about the potential financial impact of cancer to the patient. Next, treatment decision should be made by advising patients of the treatment considered to be most valuable to patients given the evidence, patient's goals and values, prognosis, and financial standing. Lastly, if the treatment of choice could place patients at high risk for financial toxicity, it should trigger an automatic referring mechanism to direct patients to patient financial assistance programs. Having easily accessible resources with understandable estimates of OOP cost for patients is a critical step toward system readiness for the cancer care delivery system to implement the AAR approach to tackle financial toxicity.

Better OOP cost information to promote high-value care

There is increasing interest among medical professional organizations, patient advocacy groups, and other stakeholders in the cancer community to improve clinician and patient access to OOP costs for use in the clinical setting.[8,62] Inconsistent definitions of OOP costs, coupled with difficulty predicting their magnitude, are two of the most frequently cited reasons why cost communication is so challenging. [63] While some researchers focus on the proportion of financial responsibility a patient is required to pay for a specific drug or other treatment, others include the additional costs of services that may be needed to prevent treatment complications or to improve quality of life. Still others focus on not only the direct costs of treatment, but also indirect costs such as travel, time off work, etc.

Another complicating issue is that OOP costs vary widely depending on insurance plan, with significant differences existing between and among different Medicare and private insurance plans. Coupled with this, where a patient is in meeting his or her deductibles and OOP maximums (and whether a service is subject to OOP maximums) is a moving target, and not easily available to patients or their providers. An additional challenge is that the complex and multidisciplinary nature of cancer care makes predicting OOP costs for a given patient particularly difficult. Patients with cancer often undergo a combination of treatments that may include surgery, chemotherapy, radiation therapy, as well as supportive care. The particular combination and duration of treatments depend on many factors, such as cancer diagnosis, stage, and comorbidity. Moreover, treatment plans often need to be modified as a patient progresses through therapy based on their response and sometimes their ability to pay.[61]

Over the last several years, efforts have been made to improve cost transparency as a way not only to improve informed decision making among providers and patients, but also to help drive down overall healthcare costs by promoting increased competition among healthcare providers. Increased cost transparency can improve shared decision-making as well as help to identify patients most likely to benefit from financial assistance services. As well, having OOP cost information can help patients budget for OOP treatment expenses, which may be desirable even for people with the ability to pay.[62] Price transparency laws have been passed in the majority of states mandating that healthcare providers make price information available to all consumers, either upon request or posted online.[64,65] However these laws vary considerably and, in many states, do not require the level of price transparency that consumers need. For example, many states have laws requiring healthcare providers to publicly disclose their chargemaster prices for common procedures. While this information could be useful to uninsured consumers, they are not useful to insured consumers, whose financial responsibility is based on their insurance company's negotiated prices. Moreover these mandates often apply only to hospital facilities and not to physician services, making them incomplete. And perhaps most importantly, this information is typically not available in formats that are easily understood or user-friendly.[66]

Additionally, several companies have developed public-facing websites such as GoodRx and BlinkHealth, which provide the average cash-pay price healthcare providers charge across an array of services by geographic area. Some prices are available for a bundle of services, which can be developed using existing data on care paths, episodes of care and relevant Current Procedural Terminology (CPT) codes. Approximately 42% of patients with high-deductible health plans are estimated to have used or tried one of these platforms when deciding where to purchase their medication.[67] However, these tools are significantly limited by the fact that the cost estimates provided do not account for provider-related variables that can influence patients' costs (i.e., different providers charge different amounts for the same service) or health plan-related variables (i.e., deductible requirements or out-of-network reimbursement formula variations). Some companies have begun to partner with insurers and employers to make this information available, including price and quality information that is specific to patients' plan design.[68] However these tools vary significantly in the information they provide and how they present it to consumers. Moreover these tools are viewed as not very helpful in the cancer setting, because they only provide information on commonly used procedures and "shoppable" services, and oncology services are considered neither common nor "shoppable."[68]

Catalyst for Payment Reform, a national not-for-profit working on behalf of employers and other health care purchasers, has developed a set of key attributes for price transparency tools, with the goal of helping employers and other purchasers select tools and solutions most helpful for their populations.[69] These attributes are summarized in Table 4 below.

Table 4. Desired Attributes for Price Transparency Tools

- Be easy to use
- Allow consumers to understand their share of cost, the total cost, and their spending and utilization to date
- Show quality measures that matter to consumers
- Allow consumers to compare price and quality, easily and side-by-side
- Help consumers identify and understand value
- Contain information on pharmacy and ancillary services, as well as other information designed in particular to assist the elderly and the chronically-ill
- Help consumers avoid unneeded care and find less expensive care options
- Encourage consumers to use the tool
- Be easily customized, while integrating smoothly with other platforms and products
- Give employers reports on utilization and savings, and involves them in continuous quality improvement activities

An important aspect of the cost transparency movement is the evolution of real-time benefit check (RTBC) technology. RTBC provides prescription benefit details including OOP cost information, drug alternatives and prior authorization information to clinicians at the point of prescribing, when they can have conversations with their patients about the most clinically appropriate and affordable treatment options. By providing true price and coverage transparency, patients are less likely to be surprised at the pharmacy and more likely to remain adherent. RTBC holds significant promise in the context of oncology care, where more drugs are being prescribed orally and, as identified in this study, there is a risk of communication gaps that can lead to prescriptions going unfilled. Payers, providers, pharmacies, electronic health record (EHR) systems and pharmaceutical manufacturers all play a role in bringing RTBC technology to the point of prescribing. To be effective, RTBC must provide accurate patient pay amounts prior to prescription submission, which providers say does not exist within the current formulary and benefit model. Additionally, providers must be willing to adopt the solution, which means factoring in another technology into their workflow. Therefore RTBC will need to provide the elements oncologists and their patients say are important such as cash price, patient assistance programs, prior authorization requirements and medication alternatives. RTBC standards are currently in development, led by the National Council for Prescription Drug Programs. Currently these standards do not account for some functionality providers indicate they value most in an RTBC solution, including cash price and availability of patient assistance programs.[67] It is important that oncology provider and patient groups provide input into these evolving standards to ensure they meet their needs.

A promising step recently was taken by the Center for Medicare & Medicaid Services (CMS) with a proposed rule released in November 2018 that would require Medicare Part D plan sponsors to implement an electronic real-time benefit tool capable of integrating with prescribers' e-prescribing and electronic medical record systems, providing prescribers who service its beneficiaries with complete, accurate, timely and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements) by January 1, 2020. In issuing the proposed rule, CMS noted it is interested in fostering the use of these real-time solutions in the Part D program given their potential to lower prescription drug and beneficiary OOP, which could also yields benefits in patients' medication adherence.[70]

Ultimately, it is important that, at a minimum, oncology practices are able to provide price estimates to patients on request. Longer term, health systems and insurers should partner to make plan-specific negotiated payments available at the point of care, such as through EHRs. To achieve this, an aggregated data resource is needed that provides RTBC information for not only Medicare Part D beneficiaries, but for all health insurance types and plans—Medicare and other public payers, as well as private insurers. Creating this type of resource is complicated by the fact that different insurance companies structure their data differently, making it necessary to have not only current data, but also network design information. Real-time feeds would be required with respect to which clinicians are in-network or out-of-network, as well as where a patient is in meeting his/her deductible. Participation would be required from the insurers themselves as well as the states, who have access to the claims data needed to report at a granular level.[71] Realizing this goal may require a public/private partnership with endorsements and commitment from not only insurers, but also from healthcare providers, hospitals, consumers, employers, and the organizations that represent them.

While having OOP cost estimators that work in the cancer setting will go a long way toward giving patients and providers information they can understand and act upon, this information is meaningless without accompanying guidance from the clinician on how the potential benefits and harms of treatment options compare to their financial costs for patients. For this reason, OOP cost information will be insufficient without corresponding information on quality or outcomes—whether related to a specific treatment option or to the provider delivering it. Several oncologists in this study said they would benefit greatly from clinical practice guidelines that help oncologists identify options that are just as effective but cost less. ASCO's Value Framework aims to address this challenge by providing NHB scores to different drug regimens, allowing oncologists to compare the clinical benefits and toxicities of various treatment options against their OOP costs. If realized, a tool of this type would help to provide the comprehensive picture needed to support informed decision-making.

Patient and family education

Feedback from patients with cancer has supported the development of a financial literacy course that addresses barriers to discussing cost concerns, employment changes during cancer, and available resources for financial assistance.[72] ASCO, the American Cancer Society and other organizations have developed and disseminated patient educational materials to help patients ask questions about cost, understand the realities of the cost involved and interpret cost-benefit. However studies show patients need additional help initiating a discussion about cost with their oncologist, as well as to better understand their OOP costs and healthcare coverage.[26,27,73] Greater efforts to disseminate education to patients and their families (e.g., posters in the waiting room or exam room, buttons for healthcare providers to wear) could be useful. Additionally, evaluation of patient education efforts that have taken place to date also would be helpful to ensure they are meeting patient needs.

Improved access to financial assistance resources

Both oncologists and patients have identified the need for better access to up-to-date, patient-specific financial assistance resources and ways to secure them in an efficient manner. Several challenges in obtaining financial assistance for patients have been documented, including stringent eligibility criteria among financial assistance programs, inadequate patient education on treatment costs and financial resources, and insufficient resources to screen and identify available financial assistance.[30,74] To enhance the delivery of resources to patients, authors suggest using financial distress screening and educating patients about insurance issues early in treatment, as well as improving coordination of financial services in practice by developing a shared database of available resources, assigning responsibility for conducting needs assessments, holding regular meetings across social work and financial counseling teams, and educating physicians on the cost of treatment.[30]

Online tools have been created to help identify sources of financial support for patients. Vivor’s PayRx Navigator (vivor.com) is an online tool that identifies foundations from which patients may be eligible to receive assistance. Tailor Med (tailormed.com) and Assist Point (assistpoint.com) are other online tools that can help financial navigators identify sources of financial support for their patients. Some of these tools also alert staff when an organization begins accepting new assistance applications, removing the need for staff to continuously monitor the program's status.[75]

Comprehensive financial navigation support

Oncologists in this study identified strong staff support as a facilitator for cost communication between them and their patients, noting it improves their ability to obtain OOP cost information and identify financial assistance resources for their patients when it is needed. One challenge they described, however, is that financial counseling and assistance tends to be focused on patients with no insurance, making it likely that individuals with high deductibles and other insurance challenges are missed. As well, the financial assistance process is usually reactive rather than proactive, meaning patients are contacted only when staff "senses a problem" or there is a problem paying a bill. Published reports describing the nature of financial assistance in oncology practices today paint a similar picture: The majority of programs offer some type of financial counseling or assistance, however these services are usually limited in scope and population served (with many focusing solely on the uninsured), and fragmented (with responsibility for various aspects of the process divided among registration staff, social workers, business office staff and clinicians). Also current financial models begin after a treatment plan is developed, removing the opportunity for the counselor to be a partner in providing information and support to the clinician and patient to assess treatment options as they relate not only to clinical benefit, but also to cost.[75]

To address these challenges, several health systems and cancer programs have begun to implement comprehensive financial navigation programs.[7,76,77] Unlike more limited financial counseling or assistance services, comprehensive navigation programs are set up to proactively reach out to all patients to assess their needs for services and work closely with the patient, clinical staff and administrative staff to establish and carry out a plan to help alleviate patients' financial burden associated with their care. Some institutions employ a six-step process for maximizing collections and minimizing patient burden. The steps can be grouped into three broad categories: identifying patients with need; educating patients about their OOP expenses, preferably by providing them with a customized estimate of their financial obligation; and, finally, working with patients to make it as easy as possible for them to pay their bills, either through a payment plan or outside assistance.[78] Studying the effectiveness of these programs, harnessing lessons learned, and using this knowledge to build and scale models for different practice settings is a natural next step.

Due to the complexity of cancer care, oncologists in this study noted financial counselors operate best when they are adequately trained in oncology issues and embedded in the cancer care team, rather than working in a centralized area serving all disease types. Experts in the field have identified the need for better training among financial counselors, who often have only high school degrees.[7] This study's findings suggest training needs to be more robust in general and also more oncology-specific. The Association of Community Cancer Centers (ACCC) has established a Financial Advocacy Network, which offers online resources to support individuals and programs in offering comprehensive financial navigation services to patients.[79] A 2017 white paper by the Michigan Cancer Consortium describes the purpose and benefits of a comprehensive financial navigation program, and the role of a financial navigator in the cancer setting, as summarized in Table 5 below.[75]

Table 5. Role of a Financial Navigator

- Seeking out patients to work with and assist, instead of exclusively working with uninsured patients or those who directly ask for assistance. This includes educating other cancer program staff and accounts receivable about financial navigation services, so they may refer patients they identify as needing financial support.
- Reviewing and verifying all new patients' insurance status. This may need to happen on a regular basis, as insurance status may change over the course of treatment due to changes in employment status or other circumstances.
- Communicating with patients about their insurance status, benefit coverage (as it relates to their expected treatment plan), and expected cost of the planned treatment.
- Using tools to assess a patient's risk of financial toxicity or financial stress, such as the COmprehensive Score for financial toxicity survey[80] or the NCCN distress management tool.[81]
- Completing insurance optimization to identify the best insurance for each patient's needs.
- Assisting patients in accessing financial resources to cover the cost of their treatment, if needed. These may include copay assistance programs, foundation support, drug replacement programs, or the cancer program, the hospital's charity, or financial assistance options.
- Completing paperwork for patients to apply for additional insurance, payment assistance, or drug replacement programs.
- Connecting patients to other available social or financial supports, such as counseling resources or assistance in covering basic living expenses, especially if they had to stop working or have a reduced income because of treatment.
- Creating payment plans with patients, based on their financial situation and expected treatment plan, to ensure they can pay for their portion of medical care.
- Sharing the payment plan with cancer program staff, such as clinic check-in staff, who may be responsible for collecting copays at the time of the visit.
- Monitoring for potential new patients by noting changes in insurance and working with accounts receivable to identify patients with missed payments or unpaid balances.

Financial screening tools and resources

Some oncologists have begun to incorporate universal screening of all patients regardless of insurance status or other factors, a practice that has begun to take root in the financial toxicity research community as a suggested standard of care for cancer patients.[82] Financial navigation experts advise screening should be used not only at the beginning of treatment to assess for financial toxicity risk, but also throughout the cancer care continuum, as OOP expenditures are not always evident until later in the course of care.[7] Additionally, patients may have changes in their ability to work as treatment progresses, affecting their income. Screening for financial toxicity is important after treatment ends as well, as financial toxicity has been shown to persist even after treatment is completed.[31] Several screening instruments have been developed to help oncology practices predict, identify, and discuss financial burden, including single screening question as well as brief patient reported outcome instruments such as the Comprehensive Score for Financial Toxicity (COST), a validated measure that can be incorporated into the intake process by nurses, care coordinators, or financial counselors.[83] Researchers at Duke University have developed a web-based mobile app for patients that can screen for financial toxicity risk and alert providers about the results. The app also will connect patients with financial resources, coach patients about how to discuss costs and educate them on the variables of drug prices.[84] These types of tools are likely to be applicable to all oncologists and their patients, but may be most helpful for those working in settings with few ancillary staff support to help.

A concern raised by oncologists in this study is a lack of follow-up in their practices when a screening test is administered. For financial screening tools to work, they must be integrated into the practice workflow with solid feedback loops to the oncologist and/or other staff in order to ensure the patient’s concerns are addressed. Efforts to embed financial distress screening into oncology practice are underway but early in their maturity. The field is ripe for testing these interventions and scaling them in a way that can be implemented across a variety of patient and practice settings.

Cost communication as a quality of care metric

Improving cost discussions between oncologists and patients will also require practice-level changes to ensure a whole-team focus and process is in place to help prevent, identify, and mitigate financial toxicity for cancer patients. To achieve this, an important strategy is to integrate a focus on reducing patient financial toxicity into oncology quality assessment and improvement initiatives. Measures of clinical quality are foundational to today's approach in healthcare delivery and evolving payment systems. The shift by Medicare and other payers to value based payment has promoted the increased development of quality measures, including (but not limited to) measures of clinical and patient-reported outcomes, team-based care/care coordination and cost/resource use. Commercial payers and other stakeholders are also adding new quality reporting requirements for many practices.

Quality measures serve multiple functions including providing practice insight into clinical performance; compliance with required public and private quality reporting; and development of quality scores, which determine payment and provide an outward signal of value in competitive markets. Cancer quality measures have been developed by several organizations, including ASCO , the American College of Surgeons' Commission on Cancer, RAND Corporation, the National Committee on Quality Assurance, the College of American Pathologists, the American Society of Breast Surgeons, the American Society for Gastrointestinal Endoscopy, and the Physician Consortium for Performance Improvement. ASCO's quality measures form the basis of a growing number of quality assessment and improvement programs it offers to its members. Many of its measures are based on ASCO's clinical practice guidelines, which help set the standard for cancer care. A summary of ASCO's quality of care initiatives is provided in Appendix 4.

Policy changes to support cost communication

As noted earlier in this section, technology solutions are needed to allow for the diffusion of real-time data on the costs and benefits of treatment options for cancer patients. Armed with these data, oncologists could refer patients to reliable sources of cost information, as well as more easily have the information they need to consider alternative treatment options based on cost, if appropriate. Efforts like the Medicare Part D proposed rule to require RTBC technology for benefit carriers is a good example of how policy can be used to facilitate cost communication. Legislative and/or regulatory change should continue to be explored as a tactic for improving cost communication between clinicians and patients.

Payment policy and other health policy change also can play an important role in incenting physician- and practice-level behavior change. Oncologists in this study identified participation in the OCM as helping to transform their practices in a way that places greater emphasis on improving cost communication. Developed by CMS, the OCM is an innovative payment and delivery program designed to improve the effectiveness and efficiency of care.[85] The program includes case management requirements from diagnosis through survivorship, which have led participating oncology practices to use financial counselors and provide OOP cost estimators often for the first time. Historically, physician reimbursement for the time it takes to talk with patients is undervalued relative to reimbursement for procedure-related services. Cost communication between oncologists and patients could be facilitated by improving reimbursement for the time it takes to discuss cost of care with patients, engage in shared decision making, and provide patient financial education and navigation. Promoting payment models like the OCM could help improve the focus on financial toxicity among oncology practices.

Research needs

Developing and testing ways to help patients and oncologists communicate about the financial burden of cancer treatment is increasingly important.[73] Several research priorities have been identified in the literature to improve cost communication between oncologists and reduce patient financial toxicity in the cancer setting. Some of the more salient research priorities are identified below.

First, research is needed to better understand the impact of financial toxicity—materially, psychologically and behaviorally—in order to ensure the appropriate targets are identified for intervention.[73,86] For example, depending on a patient's circumstances, it may be important to address the lack of financial resources to cover the direct and indirect costs of cancer care, the psychological distress that is caused by a lack of financial resources to cover these costs, and/or the coping behaviors that families adopt to manage the financial burden of cancer care, which too often leads to financial ruin of the household.[31,40]

Research also is needed to determine which care components induce financial distress and for which patients. Much emphasis recently has been placed on financial toxicity associated with new anti-cancer drugs. Understanding risk for financial distress based on patient socioeconomic characteristics as well as cancer type, stage and line of therapy, is important, because components of care may differ across types of cancer. Moreover, existing insurance benefits can shield patients from financial distress associated with specific care components but not others.[87]

It also is important to study patients' experiences of financial distress in association with the healthcare environment in which they receive care. For example, hospital out-patient chemotherapy has been shown to be more expensive than that administered in the community.[87]

Understanding not only where care is less expensive, but also where it offers maximal benefit in terms of quality and outcomes is key to helping patients identify the most high-value care options available to them.

Additionally, healthcare delivery research is needed to define best models for addressing financial toxicity in oncology practice and the roles of multidisciplinary clinical and support team members. This research is needed to help answer the question of when financial toxicity should be assessed, and who among the team members should do the assessing.[86]

Another important research need is to improve our understanding of what types of charitable aid is already being provided to patients with cancer, and what may be missing. Surveying national samples of patients with cancer may be required, since many types of assistance are offered by families, friends, patient advocacy groups and local faith-based charities that are not recorded in patient medical records, EHRs, or claims data.[87] Finally, it is important to assess the impact of policy efforts taken to date to address financial toxicity, such as cost transparency laws requiring that patients have cost information of the same procedures at multiple locations, as well as Affordable Care Act requirement for (nonprofit) hospitals to have financial assistance policies in place that are readily available to patients.[31] Such research is necessary in order to determine which types of policy efforts are likely to have maximum effect and should be pursued in the future.

Study Limitations

This study is subject to several limitations, which are summarized below along with information on steps I took to help reduce each limitation, where possible.

1. **Interviewer bias.** As an ASCO employee conducting the interviews, my role as the interviewer could have influenced participants' responses. To help avoid this issue, I ensured

the interview questions and tone were neutral, and I limited positive or negative reinforcement to respondent feedback. To reduce confirmation bias that may extend into analysis of the research findings, I sought to reevaluate impressions of respondents and challenge preexisting assumptions and hypotheses. Additional best practices were employed to reduce bias including asking questions that were general before specific, unaided before aided, and positive before negative.

2. **Sampling and selection bias.** Because the majority of oncologists interviewed were known to me, the results could be subject to a lack of objectivity in my interpretation of the interview findings. To help reduce this risk, I checked for—and was largely able to rule out—alternative explanations when interpreting the data, helping to ensure my interpretations were robust.

3. **Stakeholder perspective.** Another limitation of this study is the relatively few number of radiation oncologists and surgical oncologists represented compared to medical oncologists. As a result, the opinions, experiences, and examples provided were mainly focused on medical oncology treatment, namely anti-cancer drug regimens. It would have been preferable to include adequate numbers of medical, radiation and surgical oncologists in order to obtain more information about experiences from each treatment modality. Additional research is needed to better define the attitudes of physicians in these fields regarding cost discussions with patients. Additionally this study was limited to understanding oncologists' perspectives; therefore the results related to patients' beliefs, attitudes and behaviors may not reflect how patients actually experience cost discussions

with their oncologists. Nevertheless, these data shed light on how oncologists perceive the patient experience in relation to cost communication, providing additional insight and contributing to our understanding of the issue.

Despite these limitations, this study provides some of the richer data collected in the literature on this topic from the point of view of oncologists. The study included a diverse array of oncologists practicing in different geographic locations and settings, serving different patient populations. The findings provide important information on the nature of discussions between oncologists and patients, and identify several areas for interventions and research to improve the integration of cost discussions into oncology practice with the ultimate goal of reducing patient financial toxicity in the cancer setting.

CHAPTER 6: PLAN FOR CHANGE

The final component of this study is a plan for change, which presents a set of recommendations and strategies for integrating cost discussions between oncologists and patients into oncology practice. This plan for change is divided into three sections. The first section provides an overall strategy to be used by the larger oncology stakeholder community based on findings from the literature and this original research. The second section lays out a proposed set of recommendations that ASCO is uniquely positioned to advance to improve the integration of cost communication into oncology practice. The final section presents a plan for how ASCO could implement the recommendations as part of its overall strategy to improve cancer care.

Overall Strategy for Integrating Cost Communication in the Cancer Setting

Given differences in the way oncology practices are structured, resources and staffing available, and patients served, improving cost discussions in oncology practice is not going to be a one-size-fits-all solution. Several strategies are needed to ensure oncologists are able to address patient OOP costs in a way that is informed, efficient, and patient-centered. To effectively assist patients in understanding, minimizing and managing their OOP costs, interventions are needed at the patient, oncologist, health system, policy, and research levels, as shown in Figure 3 below.

Figure 3. Strategic Goals

Oncologist-Level	Oncologists have the education, tools and resources needed to effectively integrate cost considerations into the process of shared decision-making, and to assist their patients in preventing and/or reducing the financial burden of the care they prescribe.
Patient-Level	Patients and families are equipped with the information, tools and resources they need to initiate a discussion of cost with their oncologist, understand the benefits and limitations of their health insurance coverage, and identify where they can obtain financial assistance when they need it.
Practice-Level	Assessing for patient financial toxicity and having mitigating steps in place to address it is an established part of oncology practice and integrated into the oncology workflow.
Policy-Level	Integration of cost discussions in oncology practice is supported through payment reform and other health policy changes.
Research-Level	Research is prioritized and supported to improve the integration of cost communication into oncology practice.

To advance these goals, a proposed strategy—including a summary of needs, desired outcomes, and key recommendations— to be taken up and used by the oncology community is presented in Table 6 below.

Table 6. Strategy for Integrating Cost Communication in the Oncology Setting

<table>
<tr><td colspan="3">Oncologist-Level Goal: Oncologists have the education, tools and resources needed to effectively integrate cost considerations into the process of shared decision-making, and to assist their patients in preventing and/or reducing the financial burden of the care they prescribe.</td></tr>
<tr><th>Need</th><th>Desired Outcome</th><th>Recommendation(s)</th></tr>
<tr><td>Oncologist engagement and buy-in regarding the importance of cost discussions with patients and why they are an important part of their responsibility as a clinician</td><td>Oncologists are comfortable with, and recognize the importance of, considering the impact cost may have on the care they prescribe their patients, in addition to other potential side effects of treatment.</td><td>Increase education about cost and value early in oncology training curricula and continuing education programs</td></tr>
<tr><td>Improved skills in the areas of doctor-patient communication, shared decision making, and how to integrate the topic of cost into doctor-patient discussions.</td><td>Oncologists possess the knowledge and skills to initiate a discussion of cost with their patients and assess whether their patients are having trouble affording their care.</td><td>Enhance training for oncologists regarding how to have effective cost conversations, in ways that are sensitive to patient differences and needs</td></tr>
<tr><td>Greater knowledge among oncologists about the costs of treatment and lower-cost options</td><td>Oncologists are aware of OOP costs of treatment (both direct and indirect), and the availabilty of lower-cost treatment options.</td><td>Disseminate information to the oncology community on the relative costs and benefits of treatment options</td></tr>
<tr><td>Tools and resources to support cost conversations</td><td>Oncologists have the tools and resources they need to identify the highest-value treatment options in accordance with their patients’ preferences and goals of care.</td><td>Publicly disseminate information on the cost of treatment regimens and how they compare as a benchmark for oncologists to begin to be educated
Create treatment plan cost estimates—regionalized or by institution—that can be used at the time of treatment decision making
Develop patient-specific cost tools for use at the provider level</td></tr>
<tr><td>More easily accessible financial assistance resources</td><td>Oncologists have access to up-to-date resources on how to secure financial assistance for</td><td>Create and make available an online universal patient assistance portal</td></tr>
</table>

	their patients, including available resources in their local communities.	

Patient-Level Goal: Patients and families are equipped with the information, tools and resources they need to initiate a discussion of cost with their oncologist, understand the benefits and limitations of their health insurance coverage, and identify where they can obtain financial assistance when they need it.

Need	**Desired Outcome**	**Recommendation(s)**
Patient information on how to bring up cost with the oncologist and cancer care team, i.e., what questions to ask.	Patients and their families are comfortable initiating a discussion of cost with their oncologists and know the questions to ask to help or prevent financial toxicity as a result of their cancer care.	Create and disseminate patient education materials with question prompts on what to ask the oncologist (e.g., posters in the waiting room or exam room, buttons to wear)
Increased cost health literacy	Patients understand the benefits and limitations of their health insurance coverage, including OOP insurance maximum for themselves and their families	Create and disseminate educational materials designed to improve cost health literacy among patients and their families
Easily accessible information for patients on “what you get for what you pay”	Patients and their families are educated consumers when it comes to their health care, armed with knowledge of what treatment options exist and how they compare—both at the individual treatment level (i.e., treatment options) and about site of care (i.e., what treatment will cost if you go to one place versus another).	Create and disseminate culturally competent, low-health literacy patient education and decision support tools to share information on clinical benefits, risks and costs
Accessible, up-to-date information on available financial assistance resources, and a mechanism for patients and their families to easily identify and apply for these resources.	Patients and their families have access to up-to-date, national and local financial assistance resources and programs, as well as a mechanism to easily apply for them.	Improve accessibility of up-to-date, patient-specific financial assistance: create and make available a patient-facing version of an online universal patient assistance portal as well as resources for clinicians to make available in their clinics, waiting areas, and online patient portals

Practice-Level Goal: Assessing for patient financial toxicity and having mitigating steps in place to address it is an established part of oncology practice and integrated into the oncology workflow.

Need	Desired Outcome	Recommendation(s)
Increased availability of trained financial counseling support	Financial counselors have the education and skills necessary to effectively address cancer-specific financial toxicity issues with their patients.	Standardize financial counseling core competencies Establish cancer financial counseling training programs and accreditation Expand training opportunities to nurses and other oncology care team members
Whole-team approach to addressing financial toxicity	The cancer care team is engaged in and equipped with knowledge, tools and resources to help their patients understand and cope with the financial aspects of their care, both up front and throughout the course of treatment.	Create education programs for oncology practices to raise awareness of financial toxicity and encourage each member of the care team to have a role in ensuring a patient’s financial aspect of care is addressed
Models for patient financial navigation that work for different practice types and settings	All practices, regardless of size, structure or available resources, can identify and implement a process to address financial toxicity in their setting.	Build, test and scale models for integrating cost communication into the oncology workflow Share best practices to facilitate learning from groups who are similar to one another
Screening tools to assist oncology practices in assessing for, identifying, and mitigating financial distress in a way that ensures a positive screen is followed up on consistently and automatically.	Oncology practices have access to, and take up the use of, screening tools that help them assess for and mitigate patient financial toxicity.	Establish financial toxicity screening and assistance as a quality metric and integrate it into the quality measurement and improvement agenda Validate and promote the use of financial screening tools
Institutional investment and commitment to reducing patient financial toxicity in the cancer setting.	Oncologists have the commitment and resources from their institutions to offer robust financial navigation services to their patients.	Encourage oncologists to partner with their hospital or other institutional staff to invest in financial counseling services as a way to reduce patient financial toxicity

Policy-Level Goal: Promote the integration of cost discussions in oncology practice through payment reform and other health policy changes.		
Need	**Desired Outcome**	**Recommendation(s)**
OOP cost transparency	Policy change enables cost discussions by making cost information more accessible.	Support passage of medical cost transparency laws Support regulation requiring payers and electronic health vendors to provide RTBC in a way that can be aggregated with other data systems (i.e., multi-payer RTBC feasibility)
Increased reimbursement for the time it takes to have shared decision-making conversations about costs and benefit of treatment options	Oncology providers are adequately reimbursed for the time it takes to adequately address the OOP cost of their patients' care.	Promote payment models that integrate a focus on financial counseling (e.g. OCM)
Research-Level Goal: Increase research to improve the integration of cost communication into oncology practice		
Need	**Desired Outcome**	**Recommendation(s)**
Oncologist and Patient Level		
Research to better define, assess and characterize the impact of financial toxicity—materially, psychologically and behaviorally	Greater understanding and better measurement of the material, psychological, and behavioral aspects of the financial toxicity of cancer care, which can help identify potential modifiable factors to reduce the financial impact of cancer care patients and their families.	Investigate the tradeoffs families make as they navigate cancer care
Research about which care components induce financial distress and for which patients	To identify and target interventions for individuals at greatest risk for financial toxicity, it is understood which components of care induce financial toxicity and for which patients.	Collect standardized measures of key social and behavioral determinants in EHRs and make available to appropriate professionals
Better understanding of how to help patients and oncologists communicate about the financial burden of cancer treatment	Evidence-based strategies exist for oncologists to use in communicating with their patients about cost in a way that optimizes their ability to reduce financial toxicity.	Determine which patients want to discuss cost and with whom on the team, to ensure preference-sensitive care Identify which components of the discussions lead reduced

		financial toxicity, and in what way Assess the impact of efforts to integrate OOP cost discussions into oncology practice on patient financial toxicity Create a model that integrates cost discussions into the clinical encounter in a way that will be accepted and taken up by physicians, patients and other stakeholders in the oncology community
Practice Level		
Screening tools that are integrated into the practice work flow	Oncology practices have the tools they need to assess for, identify, and mitigate financial distress in a way that ensures a positive screen is followed up on consistently and automatically.	Test the inclusion of financial distress screening tools as a part of standard practice
Health care delivery research to identify optimal models for addressing financial toxicity in oncology practice	Effective models exist that delineate the role of cancer care team members in ensuring cost discussions are part of treatment and survivorship care plans.	Test, validate and scale models
Systematic understanding of what types of charitable aid is already being provided to patients with cancer and what types of aid is missing	An understanding of the current availability, and gaps, in charitable aid exists in order to inform interventions to improve the adequacy of aid for those who need it.	Survey national samples of patients with cancer to measure the aid that is currently available
Policy Level		
Greater understanding of the impact of policy efforts taken to date to address financial toxicity	We understand the impact of policy efforts taken to date to address financial toxicity, in order to inform the design and implementation of future policy efforts.	Conduct policy analyses to assess the impact of prior policy efforts, e.g. the Affordable Care Act requirement for (nonprofit) hospitals to have financial assistance policies in place that are readily available to

		patients, and cost transparency laws that provide patients with the costs of the same procedures at multiple locations

Recommendations for ASCO

ASCO is the world's leading professional society of multidisciplinary professionals who treat people with cancer. For more than 50 years, ASCO has been a leading advocate for quality treatment and services for cancer patients and an authoritative source for evidence-based information on cancer care issues. ASCO has nearly 45,000 professional members worldwide, including clinical oncologists representing all oncology disciplines and subspecialties; physicians and other healthcare professionals participating in approved oncology training programs; oncology nurses; and other healthcare practitioners with a predominant interest in oncology. ASCO is governed by an elected Board of volunteer members, which includes domestic and international representatives from community oncology and academia. ASCO conducts much of its work through a staff of nearly 500 employees, in addition to numerous volunteer committees and task forces composed of more than 1,000 members and non-member experts who dedicate their time and effort to the Society's programs.

ASCO has launched a number of programs designed to address the rising cost of cancer care, beginning in 2009 with an ASCO Guidance Statement on the Cost of Cancer Care and continuing with efforts including participation in the Choosing Wisely campaign and, most recently, ASCO's Value Framework, which aims to help oncologists and patients assess treatment options in a way that addresses their cost. However, controlling cost is only one component of a comprehensive strategy ASCO is pursuing to assure every patient has access to high quality care at a cost that is sustainable—both for individual patients and the overall healthcare system. This strategy requires a set of mutually reinforcing elements that are the hallmarks of a continuously learning health care system.

A continuously learning healthcare system is defined by the NAM as a system in which "science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."[88] This description is illustrated in Figure 4 below.

Figure 4. NAM Schematic of the Continuously Learning Healthcare System

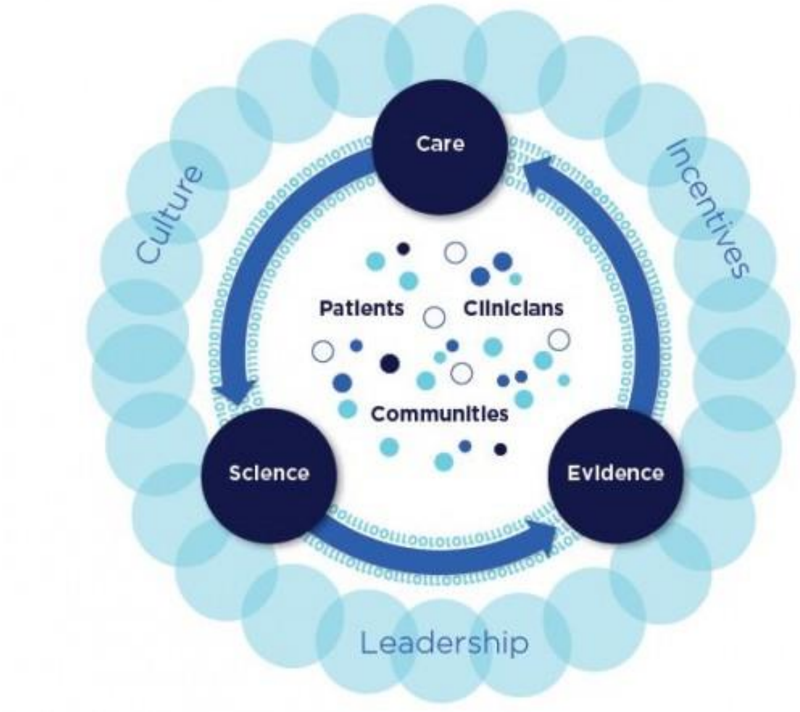


FIGURE S-3 Schematic of the continuously learning health care system.

Reproduced with Permission. The original citation is as follows: Institute of Medicine. 2013. *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*. Washington, DC: The National Academies Press. https://doi.org/10.17226/13444.

In this system, science and evidence (i.e., research) form a continuous cycle along with care, encircling patients, clinicians and communities. Research both relies on and informs the provision of care, requiring partnerships to measure and share data. Leadership (including healthcare providers and the organizations that represent them), culture (including patients as well as providers), and incentives (such as payment and other healthcare policies) enclose the entire system.

In its 2013 report, the NAM noted that by convening their constituent professionals and providing a forum for action, professional societies have important roles in achieving the vision of a learning healthcare system. Through guidelines, performance measures, quality improvement initiatives, and data infrastructures for assessing performance with respect to specific procedures or conditions, these societies can take a leadership role in improving quality, safety, and efficiency.[5]

ASCO's Framework for Patient-Centered, High-Value Cancer Care

ASCO believes four elements are required to achieve and sustain delivery of high value, patient centered cancer care: a strong evidence base and education to identify/disseminate recommended care; payment that supports delivery of that care; a robust quality monitoring system to assure care is consistent with recommended standards; and the means to learn quickly about, and act on, performance gaps or new clinical insights. ASCO has developed programs in all four areas, summarized below.

Evidence-Based Medicine. ASCO has a wide range of science and care delivery content offered through a variety of mechanisms, designed to assure every oncology professional has access to the latest information about recommended care. ASCO has the world's largest portfolio of physician education programs and scientific meetings in oncology, and publishes several peer-reviewed journals on clinical science and care delivery issues. ASCO also offers expert clinical guidance, mentorship, and targeted tools and assistance to practices. ASCO's

Conquer Cancer Foundation invests millions of dollars each year in support of promising research, including a heavy emphasis on young investigators. As well, ASCO's Center for Research and Analytics harnesses ASCO's growing data assets to conduct research on clinical cancer care.

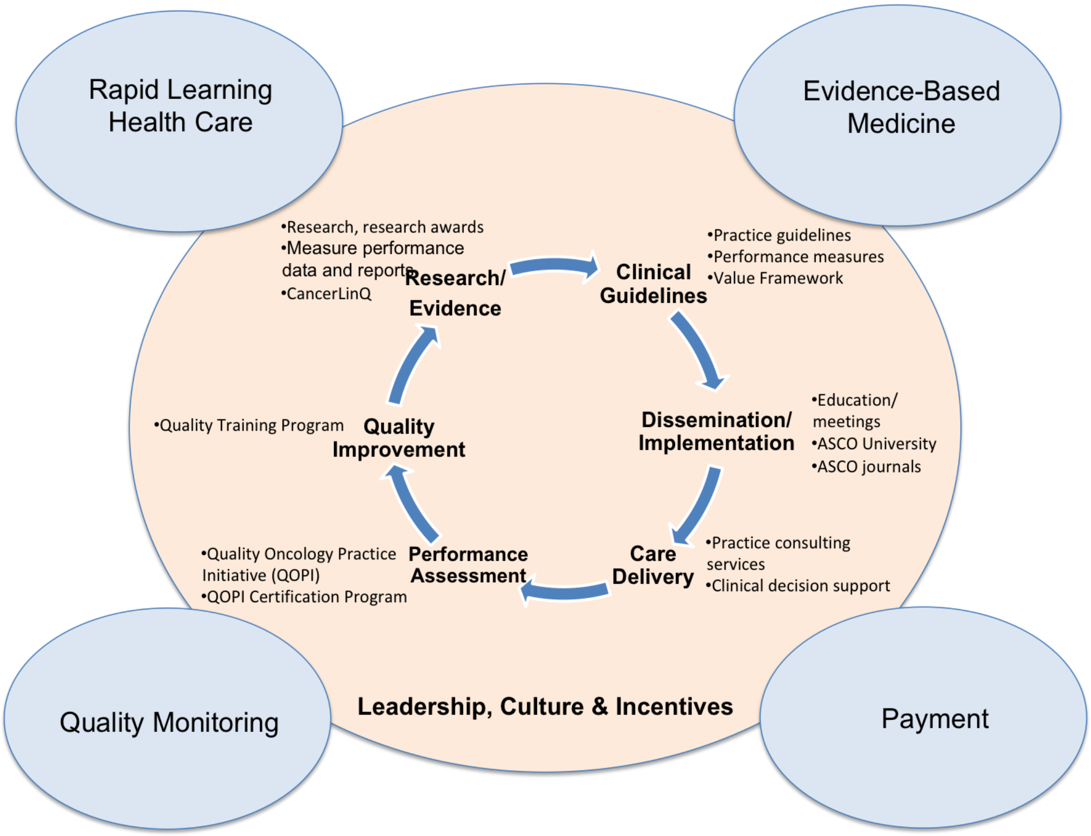
Payment to Support High-Value Care. ASCO has a strong record of advocating for adequate coverage and reimbursement as a requisite to ensuring patient access to high quality care. ASCO created the Patient Centered Oncology Payment model, which allows practice flexibility in how care delivery is organized, holds practices accountable for both cost and quality, and supports the services critical to improved care management and coordination. These areas, which are not reimbursed or incentivized in today's payment systems, are critical to achieving the best patient outcomes at the lowest cost.

Quality Monitoring. Oncology providers, patients, and payers all require knowledge about the quality of cancer care being delivered. Oncology providers need to know how they are doing relative to peers/national standards; payers need a way to identify and reward high quality providers; and patients need to be confident they are receiving evidence-based care. ASCO has established a wide range of programs designed to meet these needs, including the Quality Oncology Practice Initiative (QOPI), which measures clinical quality; Practice.Net, which measures practice financial performance; and the QOPI Certification Program, which provides a public signal for practices that have achieved desired quality of care benchmarks. These programs depend on valid and reliable measures in areas such as clinical quality, patient care experience, care coordination, and resource use. ASCO has a well-established mechanism and expertise for developing these measures, and currently maintains a library of more than 180 measures for use in these and other quality reporting programs.

Rapid-Learning Health Care. ASCO is developing a rapid-learning system for cancer care through CancerLinQ, a technology platform that will allow cancer care providers to improve the quality and value of care by analyzing millions of cancer patient medical records, identifying patterns and trends, and measuring their care against their peers and recommended guidelines. CancerLinQ is the only effort of its kind being driven by a non-profit, physician organization. To date, CancerLinQ has ingested more than one million patient records from 70 institutions with a broad range of geographic distribution and care settings representing more than 1,500 oncologists.

These four elements form the foundation of ASCO's framework for patient-centered, high-value cancer care, depicted in Figure 5 below. Within this cycle, clinical standards are set using the best available research and evidence; dissemination and implementation of those standards occur through education and care delivery resources such as clinical decision support; assessment of performance identifies opportunities for quality improvement; and research and real-world learning from every-day patient care fuels the promulgation of more evidence, which form the basis of new and improved clinical standards. All of this must occur within an environment that supports the provision of high-quality, high-value care, requiring leadership from groups like ASCO, incentives such as reimbursement models, insurance benefit design that supports high value care; and a culture of continuous self-improvement and value among providers, patients and the healthcare system at large.

Figure 5. ASCO's Framework for Patient-Centered, High-Value Cancer Care

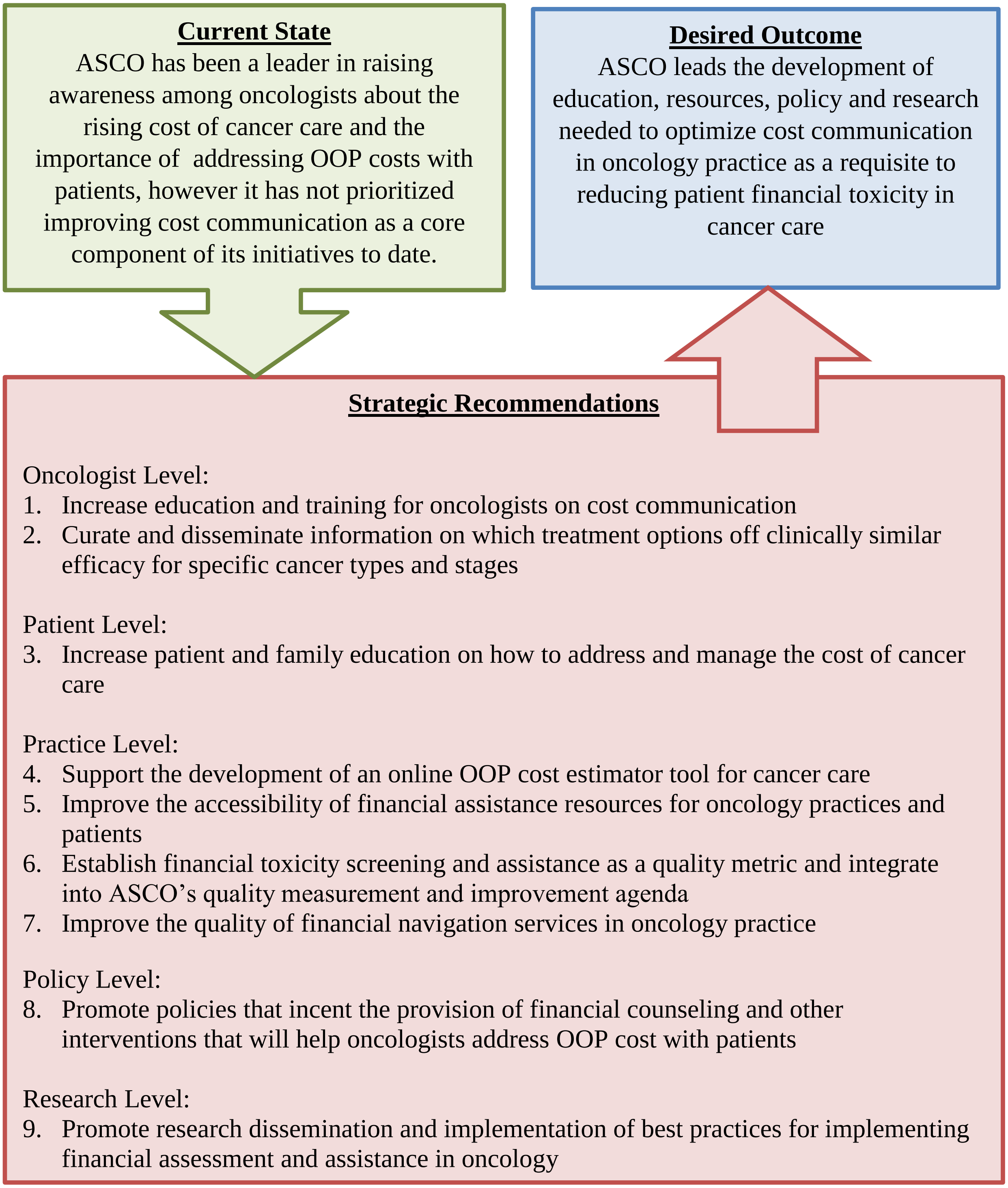


Harnessing ASCO's Framework to Improve Cost Communication in Oncology

ASCO has been a leader in helping to educate oncologists on the rising cost of cancer care, and on the importance in discussing OOP costs with patients. As a result of its efforts to date, oncologists appear to recognize their role in addressing cost with their patients, however they lack the education, tools, and resources to do so. They also work within systems that have not developed the supporting structures necessary to promote cost communication between oncologists and patients. ASCO must update its approach to meet oncologists' needs and the patients they serve as a requisite to improving quality of care in this area of oncology.

ASCO should expand its efforts to incorporate a greater focus on cost communication between oncologists and patients. A successful initiative will address goals at each level of the strategy presented in Section One, but will focus on those programs and policies ASCO is well positioned to support. To this end, the following ASCO recommendations are proposed in Figure 6 below.

Figure 6. Strategic Recommendations



Current State

ASCO has been a leader in raising awareness among oncologists about the rising cost of cancer care and the importance of addressing OOP costs with patients, however it has not prioritized improving cost communication as a core component of its initiatives to date.

Desired Outcome

ASCO leads the development of education, resources, policy and research needed to optimize cost communication in oncology practice as a requisite to reducing patient financial toxicity in cancer care

Strategic Recommendations

Oncologist Level:

1. Increase education and training for oncologists on cost communication
2. Curate and disseminate information on which treatment options off clinically similar efficacy for specific cancer types and stages

Patient Level:

3. Increase patient and family education on how to address and manage the cost of cancer care

Practice Level:

4. Support the development of an online OOP cost estimator tool for cancer care
5. Improve the accessibility of financial assistance resources for oncology practices and patients
6. Establish financial toxicity screening and assistance as a quality metric and integrate into ASCO's quality measurement and improvement agenda
7. Improve the quality of financial navigation services in oncology practice

Policy Level:

8. Promote policies that incent the provision of financial counseling and other interventions that will help oncologists address OOP cost with patients

Research Level:

9. Promote research dissemination and implementation of best practices for implementing financial assessment and assistance in oncology

To pursue these recommendations, several tactics are presented in Table 7 below, organized into the following domains: Oncologist Education & Training, Patient Education &

Awareness, Clinical Guidance, Practice Tools & Resources, Quality Assessment & Improvement, Policy and Research. These domains are interrelated, working together to help achieve the goal of improving the integration of cost communication into oncology practice.

Table 7. Cost Communication Initiative Domains, Recommendations & Tactics

Domain	Recommendation(s)	Tactics
ONCOLOGIST LEVEL		
Oncologist Education & Training	Recommendation #1: Increase education and training for oncologists on cost communication	1. Develop a set of core competencies for oncologists on assessing and managing financial toxicity 2. Create and disseminate a cost of care curriculum for oncologists based on core competencies 3. Enhance education about cost and insurance coverage at ASCO meetings and journals
Clinical Guidance	Recommendation #2: Curate and disseminate information on which treatment options offer clinically similar efficacy for specific cancer types and stages	1. Begin publishing NHB scores for commonly used drug regimens in ASCO guidelines 2. Continue to refine the NHB methodology to address current limitations, including the ability to conduct cross-trial comparisons 3. Publish recommendations for what data elements should be routinely collected in clinical trials in the future, in order to populate the NHB with more a comprehensive set of variables patients want
PATIENT LEVEL		
Patient Education & Awareness	Recommendation #3: Increase patient and family education on how to address and manage the cost of cancer care	1. Create decision-making guides and communication tools to help patients ask questions about cost, understand the realities of the costs involved and interpret cost versus benefit 2. Disseminate materials to oncologists for use in the clinic 3. Create a social marketing campaign for patients on this issue, similar to AARP's "check up on your prescriptions" campaign
PRACTICE LEVEL		
Practice Tools & Resources	Recommendation #4: Support the development of an online OOP cost estimator tool for cancer care	1. Develop an ASCO Blueprint for Cost Transparency in Cancer Care, laying out the core requirements and steps needed in order for oncology providers to have patient-

		specific, real-time OOP cost information available for their patients at the point of care 2. Partner with a CMS to create an OOP cost estimator prototype for cancer care, using RTBC functionality to estimate OOP costs for Medicare beneficiaries first before moving to private payers
	Recommendation #5: Improve the accessibility of financial assistance resources	1. Create and disseminate resources for clinicians to make available in their clinics, waiting areas, and online portals as part of comprehensive patient education 2. Encourage state and regional ASCO affiliate organizations to develop and keep up-to-date databases of regional and local financial assistance resources
Quality Assessment & Improvement	Recommendation #6: Establish financial toxicity screening and assistance as a quality metric and integrate it into ASCO's quality measurement and improvement agenda	1. Create a performance measure set for financial toxicity screening and assistance that assesses the degree to which oncology practices 1) screen their patients for financial toxicity (using the COST metric or another validated screening tool); 2) provide OOP cost estimates to their patients; and 3) refer their patients to financial assistance resources when necessary 2. Launch quality training programs including virtual learning networks and quality coaching services for the implementation of financial toxicity assessment and mitigation into oncology practice
	Recommendation #7: Improve the quality of financial navigation services in oncology practices	1. Create a microsite on cost of care that includes links to ASCO's resources for the whole care team on cost communication 2. Establish oncology financial counseling core competencies, training programs and possibly accreditation
POLICY LEVEL		
Policy	Recommendation #8: Promote policies that incent the provision of financial counseling and other interventions that will help oncologists address OOP cost with patients	1. Publish an ASCO policy statement advocating for specific policy changes needed to facilitate cost communication in cancer care 2. Support passage of medical cost transparency legislation 3. Support regulation requiring payers and electronic health vendors to provide RTBC in a way that can be aggregated with other data systems (i.e., multi-payer RTBC feasibility)

		4. Promote payment models that integrate a focus on financial counseling (e.g. OCM)
RESEARCH LEVEL		
Research	Recommendation #9: Promote research dissemination and implementation of best practices for implementing financial assessment and assistance in practice	1. Publish an ASCO statement articulating the need for increased research and identifying specific questions to be addressed by researchers in this area 2. Encourage submission of financial toxicity research at ASCO scientific meetings and in ASCO journals 3. Establish research awards through Conquer Cancer Foundation for investigators in the area of financial toxicity and cost communication 4. Partner with others in the research community to engage directly in research about ASCO members, patients and other stakeholders in the community

Oncologist Education & Training

Recommendation #1: Increase education and training for oncologists on cost communication

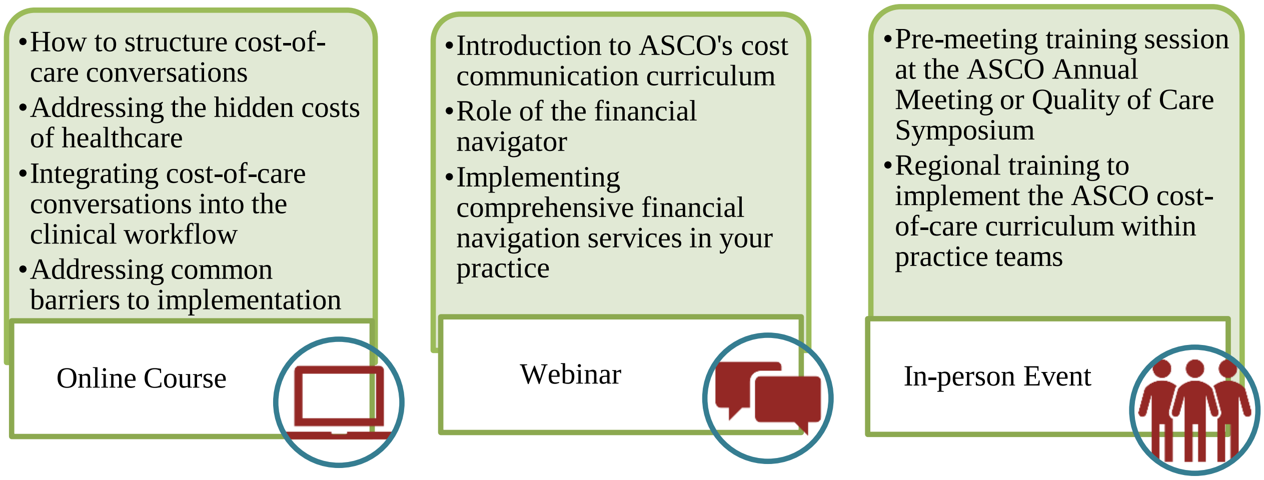
For the last several years, ASCO has offered an increasing number of educational sessions at the ASCO Annual Meeting and Quality of Care Symposium focused on cost of care issues, however there has been little formal education on the practical aspects of holding cost conversations with patients, and how to integrate such conversations into the overall workflow. Developing a formal set of core competencies on this topic, and building a curriculum to address these competencies, will enable ASCO to create a foundation of content that can be reformatted and used in a variety of venues to educate oncologists about this issue.

Education and training on cost and value in health care has been hindered by not having adequate expertise within medical schools to teach the content. ASCO can draw on its deep contacts in health policy and health economics (i.e., CMS and private payers, health economists from ASCO's Value Task Force, and others) to develop expert-delivered content during fellowship and as continuing education for practicing oncologists throughout their career trajectory. Specific tactics are as follows:

- Tactic 1: Develop a set of core competencies for oncologists on assessing and managing financial toxicity in practice, and encourage their uptake in oncology training curricula and testing.
    - Include competencies on how to obtain information and assess treatment options according to their relative benefit versus cost; how to engage patients in discussions about OOP costs; and how to obtain assistance for their patients when needed.
    - Also include competencies on understanding of the financial and regulatory aspects of medical care, such as the basics of health insurance, value-based payment, the Affordable Care Act, and Medicare/Medicaid.
    - Build competencies on a shared decision making model and include education on how to help patients move through the stages of decision-making as outlined by Elwyn et al.[10]
    - Work with the American Board of Internal Medicine (ABIM) to include questions on the oncology fellowship certification exam addressing these core competencies.
- Tactic 2: Create and disseminate a cost of care curriculum for oncologists based on core competencies (see Curriculum example in Figure 7 below).
    - Pursue funding for content development through an unrestricted educational grant aimed at educating physicians on the cost of cancer care.
    - Make curriculum available online through ASCO University for Continuing Medical Education (CME) and Maintenance of Certification (MOC) credit.
    - Work with oncology fellowship training directors to integrate curriculum content in fellowship training.

- Use a “train the trainer” model to teach practicing oncologists the curriculum and have them hold seminars and trainings at their home institutions.

Figure 7. Example of a Multi-Modal ASCO Cost Communication Curriculum



- How to structure cost-of-care conversations
- Addressing the hidden costs of healthcare
- Integrating cost-of-care conversations into the clinical workflow
- Addressing common barriers to implementation

Online Course

- Introduction to ASCO's cost communication curriculum
- Role of the financial navigator
- Implementing comprehensive financial navigation services in your practice

Webinar

- Pre-meeting training session at the ASCO Annual Meeting or Quality of Care Symposium
- Regional training to implement the ASCO cost-of-care curriculum within practice teams

In-person Event

- Tactic 3: Enhance education about cost and healthcare coverage at ASCO meetings and journals.
  - Work with ASCO journal editors to create a special series on addressing the cost of cancer care in oncology practice, and invite researchers to submit articles.
  - Publish a series of practice briefs in *Journal of Oncology Practice* (JOP) that offer practical advice and resources.
  - Engage patients and patient advocates in developing and participating in meeting and journal content (i.e., education sessions, articles and other venues) to allow for oncologists to hear first-hand from individuals who have dealt with financial issues directly.
  - Hold workshops on cost communication in conjunction with the ASCO Annual Meeting and Quality of Care Symposium, to include a patient simulation component and other hands-on learning opportunities to help oncologists gain familiarity with the

communication skills, tools and resources needed to effectively engage their patients on this topic.

- Interview oncologists who are creating innovative ways to address OOP costs with their patients, and share via podcasts and written feature articles in the ASCO Post and other media.

Clinical Guidance

Recommendation #2: Curate and disseminate information on which treatment options offer clinically similar efficacy for specific cancer types and stages

Through the creation of the Value Framework, ASCO has envisioned a system in which information about the clinical benefits, risks and financial costs of cancer treatment options is readily available to patients and providers at the point of care. Two components of work are required to realize this vision: 1) calculation of a treatment's NHB and 2) OOP cost information that is patient specific. Even without the availability of patient-specific OOP costs, however, oncologists have indicated having more general information about the costs of treatment options (i.e., using Medicare prices as a benchmark) would be beneficial in providing a starting point for discussion with patients. ASCO should create guidance that helps oncologists identify options that are just as effective but may cost less. Specific tactics are below:

- Tactic 1: For every ASCO guideline and guideline update, include a table of current regimen-specific costs, using average sales price data from Medicare as a benchmark, and begin publishing NHB scores for commonly used drug regimens to help inform discussions between clinicians and patients.
- Tactic 2: Continue to refine the NHB methodology to address current limitations, including the ability to conduct cross-trial comparisons.

- Tactic 3: Publish a blueprint for what data elements should be routinely collected in clinical trials in the future, in order to populate the NHB with more a comprehensive set of variables patients want.

Patient and family education

Recommendation #3: Increase patient and family education on how to address and manage the cost of cancer care

ASCO can play an important role in increasing education for patients and their families about how to communicate with their oncologists about the cost of their care, as well as to better understand their healthcare coverage and OOP costs. ASCO's patient education and information website, Cancer.Net, currently contains limited information to help patients manage the cost of their care. ASCO's Value in Cancer Care Task Force can work with the Cancer.Net Editorial Board to significantly expand the amount and type of content offered on Cancer.Net. This content can serve as the foundation for patient and family resources, tools and education on managing the cost of cancer care. Specific tactics are below:

- Tactic 1: Create a set of decision-making guides and communication tools to help patients ask questions about cost, understand the realities of the costs involved and interpret cost versus benefit to the patient.
    - Draw on the NAM report, *Cancer Care for the Whole Patient: Meeting Psychosocial Needs* to develop the content.
    - Utilize the Cancer.Net Editorial Board to oversee and guide development of the content.
    - Conduct focus groups with patients to determine content and messaging of materials, and to test prototypes before content is finalized.

- Tactic 2: Disseminate materials to oncologists for use in the clinic (e.g. posters in the waiting room or exam room, flags on the chart, buttons to wear, pamphlets on where to obtain financial assistance).
- Tactic 3: Create a social marketing campaign for patients on this issue, similar to AARP's "check up on your prescriptions" campaign.
    - Partner with patient advocacy groups to develop and execute the campaign.

Practice tools and resources

Recommendation #4: Support the development of an online OOP cost estimator tool for cancer care

An important criticism of ASCO's value framework has been that, while it is the only one of its kind that acknowledges the importance of using OOP costs, it does not identify how providing these costs to patients would be achieved.[68] A natural next step in the evolution of the Value Framework is to create a path for how the inclusion of OOP costs could be integrated. To this end, ASCO should use its influence and stature in the oncology community to publicly advocate for, and initiate the development of, a technology solution that allow patients and their providers to have meaningful, comprehensive OOP cost estimates available at the time of medical decision-making. ASCO should articulate a vision and strategy for making OOP cost information available at the point of care through the development of this technology solution. ASCO should begin by recommending all oncology practices provide OOP cost estimates to patients on request, as part of the treatment plan summary. Longer term, ASCO can recommend that health systems and insurers partner to make plan-specific negotiated payments available at the point of care, such as through electronic health records. Specific tactics are below:

- Tactic 1: Develop an ASCO Blueprint for Improving Cost Transparency in Cancer Care, laying out the core requirements and steps needed in order for oncology providers to have patient-specific, real-time OOP cost information available for their patients at the point of care. The statement should:

- Lay out the elements to be included in defining OOP costs for patients. For example, it should call for the inclusion not only of drug or other treatment, but also of the additional costs of services that may be needed to prevent treatment complications (e.g. growth factors or anti-emetics), and/or improve quality of life (e.g. home care or physical therapy). Information on a patient's expected indirect costs also should be included (e.g. number of days off of work).
- Indicate what information is needed from a patient's insurance company, for example where a patient is in meeting his/her deductible, how the cost of a particular treatment compares to other treatments available for that indication.
- Call for health systems, insurers, and others—including ASCO—to work together to create OOP cost estimates for total episodes of care, with future costs modeled based on disease morbidity and mortality data and modifiers based on site of care and patient risk factors. One way to accomplish this is through the use of pathways-based treatment plans based on cancer diagnosis, stage and co-morbidities, with OOP costs estimated for each node in the pathway, as well as estimates for adverse events using CancerLinQ and other real world evidence. Because this level of information may be overwhelming for patients and subject to change once therapy is underway, however, the statement also should call for research to determine the degree and circumstances in which this information is meaningful and even desirable for patients at the point of care.
- Call for a public/private partnership to develop an aggregated data resource that provides RTBC information for all health insurance types and plans. Specific stakeholders

should be identified for this partnership, to include insurance companies, employers, patients, oncology providers, practice administrators, and the organizations that represent them.

- Tactic 2: To jump-start this work, ASCO should partner with CMS to create an OOP cost estimator prototype for cancer care, using RTBC functionality to estimate OOP costs for Medicare beneficiaries first before moving to private payers.
    - The goal would be to create patient-specific OOP cost estimates for treatment options that can be compared against one another. The project could start with one cancer type and stage, providing estimates for the commonly used drug regimens for that indication. Over time additional costs could be added to create episode-based OOP cost estimates.
    - Existing care pathways could be used based on commercially available programs such as NCCN or Via Oncology. Alternatively, episodes of care could be drawn from the existing OCM episodes, or from bundles already created by private payers such as UnitedHealth.
    - The prototype should be tested with oncologists.
    - Once proof of concept is achieved, ASCO could approach private payers to replicate the model.

Recommendation #5: Improve the accessibility of financial assistance resources

ASCO should work with other stakeholders to promote the availability of up-to-date information on available financial assistance resources, as well as to ensure a mechanism is in place for patients and their families to easily identify and apply for these resources. Specific tactics are below:

- Tactic 1: Create and disseminate resources for clinicians to make available in their clinics, waiting areas, and online portals as part of comprehensive patient education.

- Tactic 2: Encourage state and regional ASCO affiliate organizations to develop and keep up to date databases of regional and local financial assistance resources.

Quality measurement and improvement

Recommendation #6: Establish financial toxicity screening and assistance as a quality metric and integrate it into ASCO's quality measurement and improvement agenda

To promote cost communication in the clinical cancer setting, an important next step is to develop, test and implement measures to ensure oncology practices are screening for financial distress, as well as providing information and financial support services to patients receiving high cost therapies. ASCO should harness its growing suite of quality assessment and improvement programs to improve practice-level competency in financial toxicity assessment and mitigation for patients. To do so, ASCO should create and promote quality of care initiatives focused on this topic, including establishing a quality metric for financial assessment and assistance that includes the use of a patient-reported outcome of financial distress. These measures can draw from existing tools such as NCCN distress screening and the COST metric to assess for financial toxicity. Once developed, these measures should be implemented broadly in a variety of quality assessment and improvement programs, such as ASCO's Quality Training Program and QOPI Certification, as well as in Merit-based Incentive Payment System (MIPS), a quality measurement track under the CMS' Quality Payment Program (QPP).

As a first step, ASCO could create measures to assess the provision of financial screening and assistance, as these represent the behaviors and practices that oncology providers themselves can control. However, it also will be important to assess the impact of financial assessment and assistance on patient financial toxicity. Establishing this type of outcome measure will be more complicated, as it would need to be risk adjusted for SES/patient mix in order to ensure such measures would not disadvantage oncologists caring for low-SES patients. Specific tactics are as follows:

- Tactic 1: Create a performance measure set for financial toxicity screening and assistance that assesses the degree to which oncology practices 1) screen their patients for financial toxicity risk (using the COST metric or another validated screening tool); 2) provide OOP cost estimates to their patients; and 3) refer their patients to financial assistance resources when necessary.
    - Include the measure set in QOPI.
    - Submit the measure set for inclusion in MIPS.
- Tactic 2: Launch quality training programs including virtual learning networks and quality coaching services for the implementation of financial toxicity assessment and mitigation into oncology practice.
    - Launch a cost communication track in ASCO's Quality Training Program, inviting practices who are implementing innovative ways to improve cost communication to serve as practice mentors.
    - Apply for MIPS quality improvement points for participating in these programs.

Recommendation #7: Improve the quality of financial navigation services in oncology practices

ASCO should take a leadership role in addressing current gaps in financial navigation services, including helping raise the competency level of financial counselors and helping practices to implement comprehensive financial navigation programs. The ACCC has developed financial navigation resources for oncology practices. ASCO can build on these resources by creating competency standards and formal quality training programs. Once established, ASCO can help by studying the effectiveness of these programs, harnessing lessons learned and using this knowledge to build and scale models for different practice settings. Specific tactics are as follows:

- Tactic 1: Create a microsite on cost of care that includes links to ASCO's resources for the whole care team on cost of care communication.
  - Materials to be included are educational links for providers, patient resources available through Practice.Net, and additional tools and resources for practices (i.e., a directory of patient assistance resources available by zip code, information on where to find a financial counselor, and information on how to set up a financial navigation program in one's practice setting).
  - Include guides and other materials for oncology practices to raise awareness of financial toxicity and encourage each member of the care team to have a role in helping patients understand and cope with the financial aspects of their care, both up front and throughout the course of treatment.
  - Create how-to guides for oncology practices to use in setting up financial counseling services as a way to reduce patient financial toxicity.
  - The microsite can be modeled after ASCO's Cancer Survivorship Compendium website, which contains information and practice tools for how to set up and build a suite of survivorship care services in oncology practice.[89]
- Tactic 2: Explore the development of oncology financial counseling core competencies, training programs and potentially an accreditation program for financial navigators.
  - Develop financial counseling training opportunities for nurses and other oncology care team members.

  - Conduct research to assess the market for an oncology financial navigator certification program, modeled after ASCO's QOPI Certification Program.
  - Explore potential partnerships with ACCC and/or the Academy of Oncology Nurse and Patient Navigators for these efforts.

Policy

Recommendation #8: Promote policies that incent the provision of financial counseling and other interventions that will help oncologists address OOP cost with patients

Legislative and/or regulatory change should be advanced as a tactic for improving cost communication between clinicians and patients. ASCO can play an important role in tackling the larger policy issues that are helping and/or hindering effective cost communication. Specifically, ASCO should play a more active role in supporting OOP cost transparency regulation, payment reform models, and reimbursement and coverage policies that facilitate cost communication in oncology practice. Specific tactics are as follows:

- Tactic 1: Publish an ASCO policy statement advocating for specific policy changes needed to facilitate cost communication in cancer care.
- Tactic 2: Support passage of medical cost transparency legislation.
  - Partner with other stakeholders, including the American Medical Association's price transparency coalition, to advance regulations requiring health insurers and health systems to provide meaningful OOP cost information in a way that can be useful at the point of care.
- Tactic 3: Support regulation requiring payers and electronic health vendors to provide RTBC in a way that can be aggregated with other data systems (i.e., multi-payer RTBC feasibility).
- Tactic 4: Promote payment models that integrate a focus on financial counseling (e.g. OCM).

Research

Recommendation #9: Promote research dissemination and implementation of best practices for implementing financial assessment and assistance in practice

ASCO should play a stronger role in promoting research needed to advance our understanding of, and ability to effectively address, OOP cost as a part of cancer care communication. ASCO can do this either by directly funding the research of its members or by advocating for increased research funding dedicated to these issues by others. Once additional research is gathered, ASCO could help to further test, disseminate and implement the findings throughout its membership broadly. Specific tactics are below:

- Tactic 1: Publish an ASCO statement articulating the need for increased research and identifying specific questions to be addressed by researchers in this area.
    - Advocate for Patient-Centered Outcomes Research Institute (PCORI), NCI and other publicly funded research entities to prioritize research in the area of patient financial toxicity.
- Tactic 2: Encourage submission of financial toxicity research at ASCO scientific meetings and in ASCO journals.
- Tactic 3: Establish research awards through Conquer Cancer Foundation for investigators in the area of financial toxicity and cost communication.
- Tactic 4: Partner with others in the research community to engage directly in research about ASCO members, patients and other stakeholders in the community.
    - Harness ASCO’s growing practice-level data assets—including CancerLinQ, ASCO’s rapid-learning healthcare system-- to help define and measure financial toxicity of care by identifying correlations between patient socioeconomic and other factors and care received.

    - Design performance improvement “report cards” that track financial toxicity metrics over time and connect to opportunities for improvement. Make available to ASCO members for improvement activities.
    - Develop regional and national reports on patient demographics, financial toxicity metrics, and quality of care; make available to external stakeholders, such as payers, policy makers and other researchers.
    - Participate in CancerLinQ efforts to capture core data elements important to assessing financial toxicity through participating electronic health record vendors.

ASCO’s Cost of Care Task Force previously identified the following research objectives for prioritization by the larger research community. These topics, summarized in Table 8 below, should be considered high-priority for ASCO.

Table 8. Priority Research Objectives for ASCO

Need	**Research Objectives**
Physician-Patient Communication	• Evaluate roles of physicians versus other clinicians versus administrative staff in facilitating communication about costs of cancer care. • Characterize the significance of other participants in patient decisions regarding cost (e.g. children, spouse) that require communication strategies • Identify, implement, and assess potential methods of patient empowerment that help patients to actively participate in shared decision-making regarding costs and benefits of cancer treatments • Identify a range of practice-level physician interventions (e.g. routine screen for financial burden) that may be useful complements to patient or provider education • Test the impact of different ways of framing information about costs, benefits, and risks of interventions • Develop/identify outcome measures that will help evaluate and compare various practices • Test the impact of social marketing campaigns conducted by ASCO and other professional organizations on physicians' attitudes and self-reported practices regarding communication regarding costs of cancer care
Decision-Making	• Delineate trade-offs relevant to specific decisions that are commonly faced • Assess standard decision outcomes (satisfaction with decision, decision conflict, adherence, anxiety, time costs of such communication) • Characterize patient characteristics (e.g. demographics, related preferences, insurance characteristics) that bear on trade-off decisions • Develop decision aids to promote informed decision-making
Defining Value in Cancer Care	• Gather information on economic consequences of cancer interventions (i.e., financial consequences for patients, financial consequences for third-party payers, consequences for industry and for development of new interventions) • Evaluate cost-effectiveness of new interventions compared with their older counterparts (i.e., marginal cost effectiveness)

New initiatives are underway to better understand how healthcare cost discussions and use of tools can be integrated into the clinical encounter and practice workflow. Of particular note is the Cost Conversation project, which launched in 2016 by Robert Wood Johnson

Foundation, in partnership with Avalere Health. This initiative, detailed further in Table 9 below, could serve as a model for ASCO's research dissemination and implementation efforts.

Table 9. Robert Wood Johnson Foundation Case Study

Funded by the Robert Wood Johnson Foundation (RWJF), the Cost Conversation project is a $4 million initiative to support research and the development of resources to encourage conversations about costs of care between patients and their care teams. Research by Avalere Health identified six broad priorities for improving patient-clinician cost-of-care conversations: education and engagement, tools and resources, clinical workflow, training, measurement, and scaling. Eight Cost of Conversation projects were funded to explore ways patients and providers (e.g., clinicians, staff, and practice administrators) can improve the value and frequency of cost-of-care conversations. Early findings demonstrate both providers and care staff are interested in discussing cost, and these conversations can become a normal, valued part of health care. As well, results show increased training is needed for providers on how to conduct these conversations as well as tools to make conversations easier.

From these findings, Avalere Health and project researchers developed a set of practice briefs and are working with several organizations including the National Patient Advocate Foundation, ACP, and America's Essential Hospitals to disseminate lessons from this research, with the goal of improving the frequency and quality of cost conversations in the clinical setting. Through a site at America's Essential Hospitals, clinicians and health system leaders have access to an online repository of resources to help them implement changes in their own practices. Patients and their families, as well as advocates, can participate in upcoming cost-of-care webinars and stay up to date on cost issues that are important to patients. Additionally, the National Patient Advocate Foundation will produce tools for case managers, while the ACP will develop tools for physicians, and incorporate project findings into their High Value Care Curricula and cases, as well as other ACP venues.

In just two short years, this initiative has proven successful in mobilizing a large group of diverse stakeholders to make significant progress toward its goals of improving cost of care communication among patients and clinicians. Moving the needle in this area requires increased knowledge but also a change in culture and behavior, which is usually fraught with challenges. By drawing on the skills, resources and perspectives of a variety of stakeholder groups to develop, test and scale solutions, RWJF has established a model that could be replicated and expanded to optimize cost communication in cancer care.

Source: Costs of Care: Getting the Patient-Provider Conversation Right. Accessed at: https://www.rwjf.org/en/blog/2016/06/costs_of_care_getti.html

A summary of these tactics is provided in Table 10 below.

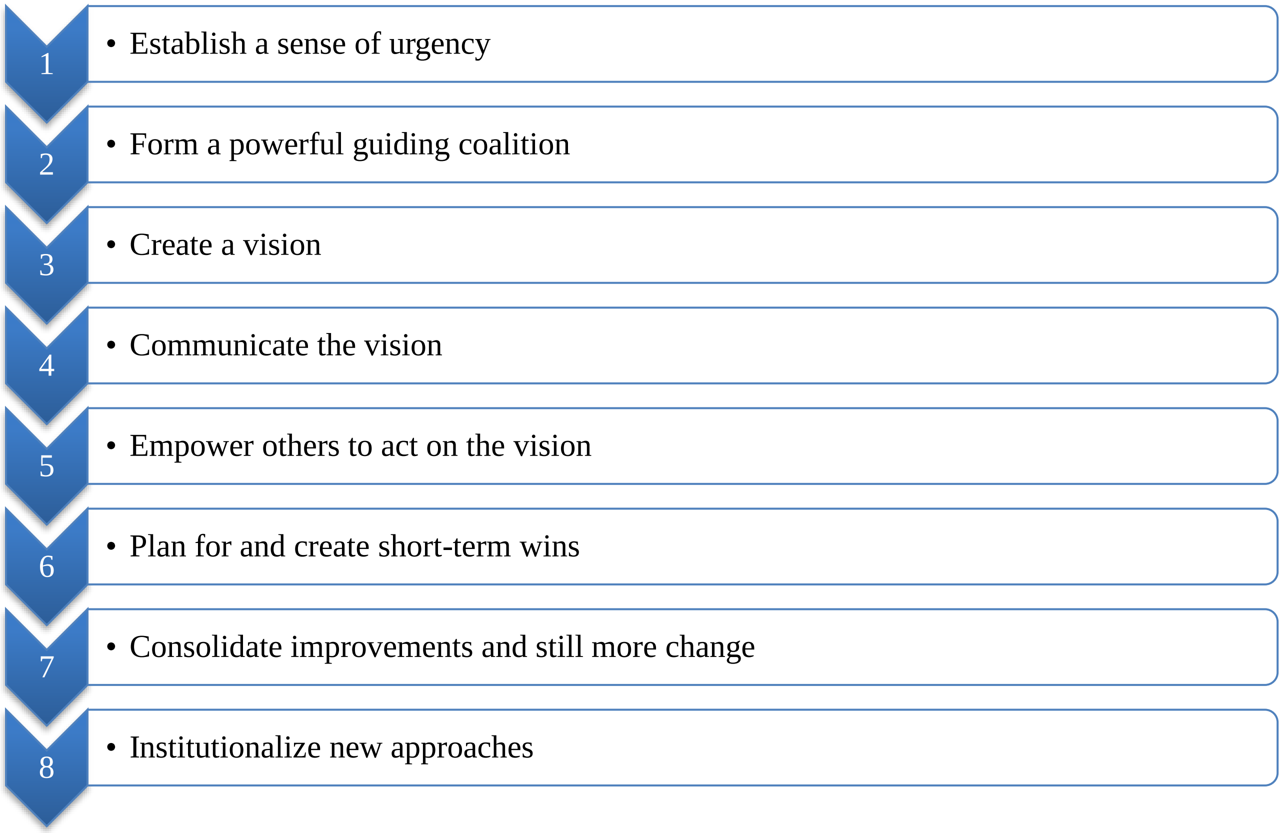
Table 10. Cost Communication Initiative Tactics

Domain	Oncologist Education & Training	Clinical Guidance	Patient Education & Awareness	Practice Tools & Resources	Quality Assessment & Improvement	Policy	Research
Tactics	Core competencies	NHB score dissemination	Communication and decision-making tools	Blueprint for cost transparency statement	Microsite of resources and tools for the care team	Policy statement on cost communication	Statement on research needs in cost communication
	Curriculum	NHB refinement	Patient information materials for the clinic	OOP cost estimator prototype	Financial counseling core competencies, training, and accreditation	Advocacy for medical transparency legislation	Promote research at ASCO meetings and in journals
	Meetings & journals	Recommendations for data collection elements	Social marketing campaign	Patient assistance resources for the clinic	Performance measure development	Advocacy for RTBC technology requirements for payers	Research awards through Conquer Cancer Foundation
				Promote regional databases to state affiliates	Quality training programs, coaching, and learning networks	Advocacy for payment models that support cost communication	Research using ASCO and other data resources

ASCO Implementation Strategy

To implement this strategy, I have selected Kotter's "8 Stages of Change" (Figure 8), given its strong credibility in the management literature and its straightforward, step-wise framework.[90] I have aligned each of the stages with the broad recommendations derived from this study.

Figure 8. Kotter's Eight Stages of Change



The following is a proposed implementation plan that follows this eight-step framework:

Steps 1 & 2

The first two steps comprise the foundational work needed to initiate the program and set its overall direction. I will be responsible for all of the components of step 1 (create a sense of urgency), which includes producing a summary of study findings and circulating to those study participants who requested it during the interview process; presenting my study findings and recommendations to the ASCO Value in Cancer Care Task Force; apprising ASCO leadership and the Board Executive Committee of the study findings; and obtaining the necessary approvals to move forward.

Step 2 (forming a powerful guiding coalition) involves establishing a Cost Communication Steering Group under the Value in Cancer Care Task Force and forming several tactically focused work groups. I will be responsible for creating a Steering Group charter delineating the charge of the group, scope of work, and membership roster, working in concert with the Value in Cancer Care Task Force chair. Next, I will work with my staff to identify ASCO members to be invited to participate in the Steering Group through the ASCO Volunteer Corp, an online database containing the names and expertise of ASCO volunteers. I will personally reach out to stakeholders from the patient advocacy and payer communities to participate as well. As well, I will work with my colleagues on staff to identify representatives to participate from ASCO's Education Council, Clinical Practice Guidelines Committee, Quality of Care Council, Measures Steering Group, Cancer.Net Editorial Board, Government Relations Committee, and Cancer Research Committee. I also will identify appropriate individuals on my team to coordinate the work of the Steering Group, to include the program lead of the Value in Cancer Care Task Force and one to two Health Policy Division staff. Working with my team and the Task Force Steering Group, we will establish working groups of ASCO volunteer members and staff in the core strategy domains (Provider Education, Clinical Guidance, Tools & Resources, Quality Assessment & Improvement, Patient Education, Policy and Research). Each group will be chaired and/or co-chaired by liaisons from those committees and councils listed above and supported by the relevant ASCO staff. I will oversee the staff in planning and holding an initial Steering Group call to review and provide feedback on the overall work plan, as well as individual work group calls to review the goals and work plan. These steps are summarized in Table 11 below.

Table 11. Implementation Plan- Steps 1 & 2

• Produce a summary of study findings and circulate to study participants. • Present study findings and recommendations to the ASCO Value in Cancer Care Task Force team in person. • Apprise ASCO leadership and Board Executive Committee of the study findings and obtain approval to plan a vision and roadmap for the next phase of ASCO's cost communication initiative.	• Establish a Cost Communication Steering Group under the Value in Cancer Care Task Force and create a Steering Group charter delineating the charge of the group, scope of work, and membership criteria. • Invite ASCO members to participate in the Steering Group through the ASCO Volunteer Corps, and engage other stakeholders from the patient advocacy and payer community to participate as well. Include representatives from ASCO's Education Council, Clinical Practice Guidelines Committee, Quality of Care Council, Measures Steering Group, Cancer.Net Editorial Board, Government Relations Committee and Cancer Research Committee. • Identify ASCO staff who will be responsible for coordinating the Steering Group, including the program lead of the Value in Cancer Care Task Force and 1-2 Health Policy Division staff. • Establish individual working groups in the core strategy domains (Provider Education, Clinical Guidance, Tools & Resources, Quality Assessment & Improvement, Patient Education, Policy and Research), to be chaired and/or co-chaired by the committee and council liaisons listed above and supported by relevant ASCO departmental staff. • Hold Steering Group call to review and provide feedback on overall work plan. • Hold individual work group calls to review goals/ work plan.

Steps 3-8

The remaining steps 3-8 will be accomplished by the relevant work groups and ASCO staff. My role will be to provide overall strategic guidance and oversight of these steps, meeting regularly with the staff team to discuss and trouble-shoot as each project progresses. I will participate in all Steering Group calls to report on, and discuss, the status of each project and identify areas where further input and discussion is needed. I will facilitate discussions with ASCO leadership to ensure clarity in scope and outcomes, and initiate discussion with external stakeholders to ensure there is robust communication with all parties throughout the initiative. Specific contributions I plan to make as part of my role are as follows:

- I will work with the ASCO leadership to identify and secure needed resources, and to develop and maintain a sound budget.
- I will work with my staff to make sure each project is based on a robust needs assessment; a clearly articulated target audience, goals, objectives and tactics; and measurable outcomes. I will make sure, in particular, we identify the most culturally appropriate ways to reach individuals and communities, developing patient educational materials in culturally and linguistically appropriate ways, for example.
- I will contribute substantively to the development of ASCO policy positions and strategy related to this initiative, reviewing and analyzing proposed legislative and regulatory opportunities and working with my staff to form ASCO policy positions on them. I will review draft comments and briefs, as well as oversee the development of clinical policy work including quality measures and standards for best practice.
- I will partner with our quality measurement and improvement staff to provide input into the practice support related components of our initiative, applying quality measurement and

improvement principles and identifying technical experts to ensure our performance measures are well constructed and validated.

- I will work with our marketing and communications staff to ensure there is strong awareness of, and participation in, the programmatic offerings that comprise this initiative, helping identify ways to increase awareness and encourage buy-in among key partners and participants.

Steps 3-8 for each tactic are summarized in Tables 12-18 below.

Table 12. Oncologist Education & Training

	Step 3: Create a Vision	Step 4: Communicate the Vision	Step 5: Empower Others to Act on the Vision	Step 6: Plan for and Create Short-Term Wins	Step 7: Consolidate Improvements and Still More Change	Step 8: Institutionalize New Approaches
Core competencies	Establish a consensus expert panel to develop a set of core competencies for oncologists in the area of cost communication using a modified Delphi approach	Invite panel members with relevant expertise and representation from key stakeholder groups (i.e., nurse navigators, social work, shared decision making experts, training program directors)	Publish core competencies in ASCO journals and disseminate broadly through ASCO communication channels	Present core competencies to oncology training program directors at ASCO Training Directors' Retreat to increase awareness of this initiative	Create test questions for inclusion in ABIM certification exams	Work with the ABIM to include questions on the oncology fellowship certification exam addressing these core competencies
Curriculum	Establish a curriculum development timeline and budget	Identify outside funding to develop curriculum, potentially from healthcare company and/or foundation support	Share plans for curriculum with other stakeholders, and invite representatives from other organizations to serve as curriculum development faculty	Using the core competencies as the basis, create a modular curriculum content outline	Develop the curriculum, to include learning objectives, teaching slides and key articles and other references available for each module	Launch curriculum, making available online through ASCO University for CME and MOC credit Work with oncology fellowship training directors to integrate curriculum

						content in training
Meetings & journals	Create a list of key topics to be included in call for submissions for a JOP or JCO special series on cost of care, with special emphasis on cost communication research	Approach JCO and JOP editors with special series concept, sharing proposed list of topics Engage patients and patient advocates in developing and participating in meeting and journal content	Launch call for submissions Develop a series of practice briefs to be included in special series offering practice advice and resources	Publish special series, to include ASCO briefs plus articles from peer-reviewed submissions	Interview oncologists who are creating innovative ways to address OOP costs with patients, and share via podcasts and feature articles in the ASCO Post and other media	Hold cost communication workshop at Annual Meeting based on curriculum content Use “train the trainer” model to teach oncologists

Table 13. Clinical Guidance

	Step 3: Create a Vision	Step 4: Communicate the Vision	Step 5: Empower Others to Act on the Vision	Step 6: Plan for and Create Short-Term Wins	Step 7: Consolidate Improvements and Still More Change	Step 8: Institutionalize New Approaches
Cost and NHB information in ASCO guidelines	Work with Clinical Practice Guidelines Committee to begin including a table of current regimen-specific prices, using Medicare prices as a standard, as well as NHB scores when feasible	Launch member communications to let oncologists know the information is going to become available	Invite ASCO members to identify drug regimens for which they would like cost and NHB information provided in addition to those in ASCO guidelines	Begin to publish cost and NHB information	Evaluate inclusion of cost and NHB information in guidelines through ASCO member survey Begin to develop cost and NHB information for drug regimens oncologists have identified as commonly used and/or high priority	Modify ASCO guideline approach, if needed, based on survey findings Begin to disseminate cost and NHB information online in response to ASCO member need
NHB score refinement	With Value in Cancer Care Task Force leadership, identify list of priority areas	Share intent to continue refinement of NHB score methodology with external	Working with key stakeholders, develop proposed NHB	Survey clinicians to determine if new NHB scoring methodology is	Test new NHB methodology with a series of drug regimen	Publish new version of the NHB methodology and begin using it to score regimens

	for updating the NHB scoring methodology	stakeholders, including patient advocacy organizations, drug manufacturers, and payers; obtain feedback on priority areas for change	changes and ask for feedback	clinical assessments	calculations to ensure validity	
Recommendations for data collection elements	Conduct environmental scan to identify data elements identified by patient groups and other stakeholders as desired for inclusion in future frameworks	Identify patient groups and other stakeholders to participate in a consensus project to identify data elements that should be routinely collected to inform more robust NHB scores	Using modified Delphi process, come to an agreement on a core set of data elements	Distribute proposed data elements for public comment	Revise data elements based on public feedback	Publish consensus recommendations in ASCO journal Share findings with FDA and CancerLinQ for real-world evidence data collection improvements

Table 14. Patient Education & Awareness

	Step 3: Create a Vision	Step 4: Communicate the Vision	Step 5: Empower Others to Act on the Vision	Step 6: Plan for and Create Short-Term Wins	Step 7: Consolidate Improvements and Still More Change	Step 8: Institutionalize New Approaches
Communication and decision-making tools	Invite the Cancer.Net Editorial Board to oversee and guide development of an online compendium of patient and family resources	Approach patient assistance organizations, financial navigators, and other organizations to obtain existing resources for inclusion in the curriculum and to invite their participation in developing new resources	Post existing resources online and print hard copies for dissemination to oncology practices	Conduct user testing via patient focus groups to advise on content and messaging of new materials, and to test prototypes before content is finalized	Finalize new materials based on patient user testing	Survey patients to assess awareness, uptake and satisfaction with resources
Patient information materials for the clinic	Invite a focus group of ASCO members include oncologists, nurses, and practice administrators to identify patient	Present vision for patient information materials at state affiliate meetings to engage local and regional oncology practices in the effort and obtain their feedback	Alert members to the availability of patient resources for the clinic and how to order them from ASCO's Bookstore in	Utilize ASCO's consulting services to further disseminate patient resources by bringing sample materials with them when visiting practices around the U.S.	Learn from consulting representatives about which tools are most popular and which may need revising and/or enhancing	Revise and redistribute patient tools based on practice feedback

	information needs and to suggest strategies for educating patients in the clinic		hard copy, if desired			
Social marketing campaign	Develop social marketing campaign goals, objectives and proposed tactics in conjunction with Communications staff	Identify patient, provider and other stakeholder partners to participate in social marketing campaign to encourage patient awareness and engagement in OOP cost education and communication	Launch campaign in concert with the availability of resources, with a strong media component to increase exposure to the public	Post podcasts with patients and oncologists discussing the importance of OOP cost communication and sharing campaign goals Track media coverage and share results with ASCO leadership	Work with communications staff to hone messages based on initial feedback from patients	Continue campaign with revised tactics

Table 15. Practice Tools & Resources

	Step 3: Create a Vision	Step 4: Communicate the Vision	Step 5: Empower Others to Act on the Vision	Step 6: Plan for and Create Short-Term Wins	Step 7: Consolidate Improvements and Still More Change	Step 8: Institutionalize New Approaches
Blueprint for cost transparency statement	Develop a project timeline, budget and list of stakeholders to help create a step-wise strategy/ blueprint for improving OOP cost transparency in cancer care	Share intent to develop blueprint with external stakeholders, including patient advocacy organizations, drug manufacturers, and payers, and invite their participation	Working with key stakeholder representatives, develop proposed blueprint and ask for feedback from their relevant organizations	Share proposed blueprint with CMS, private payers and employers for targeted feedback and to obtain early buy-in	Revise blueprint based on payer and employer feedback	Publish blueprint and disseminate widely through ASCO member and media communication challenges
OOP cost estimator prototype	Develop a proposed timeline, budget and list of partners to help create patient-specific OOP cost estimator tool	Approach CMS with project goals and design Develop and publicize a call for proposals for a vendor to help develop the prototype	Establish a steering group composed of oncologists, patients, EHR vendors, and CMS representatives to guide the conceptual development of the tool	Demonstrate prototype of tool at the ASCO Quality Symposium	Conduct user testing and modify prototype based on results Approach private payer to replicate model	Advocate for CMS to make tool available to local and regional carriers

Patient assistance resources for the clinic Promote regional databases to state affiliates	Ask the Cancer.Net Editorial Board to review and provide input on the types of patient assistance programs to be included in an ASCO inventory	Approach patient assistance organizations, financial navigators, and other organizations to build inventory of existing programs	Develop and publicize a call for information on existing resources	Post existing resources online and print hard copies for dissemination to oncology practices	Attend state/regional affiliate meetings and discuss the need for local financial assistance resources for oncology members in their area Develop a template of the types of resources to be collected; share with affiliates	For affiliates who are interested, identify potential partners (i.e., American Cancer Society) with local and regional presence to work with them

Table 16. Quality Assessment & Improvement

	Step 3: Create a Vision	Step 4: Communicate the Vision	Step 5: Empower Others to Act on the Vision	Step 6: Plan for and Create Short-Term Wins	Step 7: Consolidate Improvements and Still More Change	Step 8: Institutionalize New Approaches
Performance measure development	Utilize the ASCO Measures Steering Group to oversee the development and implementation of quality measures focused on financial toxicity assessment and mitigation	Engage the Measures Steering Group in the vision, and establish a measure development panel composed of Measures Steering Group members and other experts to develop the measure concepts	Develop measure specifications and implement in subset of QOPI practices to collect feasibility data	Publish article in ASCO Connection about the test measures and ASCO's plans to begin to incorporate them into its overall quality agenda	Modify measures based on QOPI experience and test more with more practices for measure reliability and validity	Launch measures for use by all QOPI practices Submit measures for use in CMS' MIPS program
Quality training programs, coaching, and learning networks	Work with the Quality of Care Council to create a timeline and plan for the development of a practice-level quality training	Advertise quality training program opportunity to ASCO members in ASCO journals, online and through other channels, targeting oncologists as	Identify practices interested in implementing cost communication quality improvement	Enroll five practices in the program; establish virtual learning network for sharing of best practices Create measurable	Conduct program evaluation assessing progress against measurable outcomes	Present training program findings and lessons learned at Quality Symposium as an education session or abstract presentation

	program opportunity in the area of cost communication	well as nurses and practice administrators	Identify experts in quality improvement as well as patient financial navigation to serve as faculty	outcomes for program participants	Identify changes to the program based on evaluation findings	Launch program to more practices, with changes made based on evaluation
Microsite of resources and tools for the care team	Bring together a group of advance practice providers from ASCO’s Clinical Practice Committee to advise on the contents to be included in the microsite	Approach organizations such as ACCC to partner in the development of the microsite and serve as advisory group members	Identify tools and resources for inclusion in the microsite	Release beta version of microsite for user testing and feedback	Modify/enhance microsite based on user feedback	Launch microsite and advertise to ASCO members broadly Hold live webinars to demonstrate the site to ASCO members; utilize ASCO’s consulting services to conduct in-person demonstrations

Financial counseling core competencies, training, and accreditation	Present proposal to ASCO’s Quality and Education committees to develop oncology financial counseling core competencies, training programs and potentially an accreditation program for financial navigators; obtain buy-in	Meet with representatives from ACCC to discuss needs in financial counseling education and training and present vision for education and training	Identify tools and resources already available through ACCC and offer to disseminate more broadly to ASCO members; incorporate on ASCO microsite	Develop set of core competencies for financial navigation in oncology in partnership with ACCC and others	Publish core competencies Conduct market research to assess interest and feasibility for oncology financial navigation certification program	Pursue certification program if positive signals from market research are received

Table 17. Policy

	Step 3: Create a Vision	Step 4: Communicate the Vision	Step 5: Empower Others to Act on the Vision	Step 6: Plan for and Create Short-Term Wins	Step 7: Consolidate Improvements and Still More Change	Step 8: Institutionalize New Approaches
Policy statement on cost communication	Assemble writing group to develop ASCO policy statement on transparency legislation, RTBC technology, and payment models that support cost communication.	Approach key experts and stakeholders from the oncology, payer, and patient advocacy communities to participate in the writing group	Develop statement draft.	Circulate statement to key ASCO committees (Government Relations, Quality, Clinical Practice) for feedback	Revise statement based on feedback	Obtain Board approval Publish statement; develop podcast of lead authors discussing the recommendation
Advocacy for cost transparency legislation, RTBC technology regulation, and alternative payment models and designs	Present policy statement recommendations to ASCO Government Relations Committee members and staff and agree on long/short term goals	Dialogue with stakeholders to identify common ground Talk to opponents to discuss areas of compromise	Mobilize supporters using the media; communicate with policymakers; present at local/regional and national ASCO meetings	For legislation, identify sponsors and committee(s) for referral, create communication strategy to reach policy makers and other allies (individual lobbying, letter	Mobilize others through grassroots efforts (i.e., ASCO Action Network); public speaking at organizational meetings,	Continue to execute advocacy plan until new regulatory policies and optimal outcomes through rulemaking are achieved

	Research the law and relevant issues to understand key opportunities and challenges Identify stakeholders and their influence (supporters and opponents)	Develop and distribute fact sheets, testimony talking points to describe problem and needed action	and other venues Distribute issue briefs to other advocacy groups for use with their constituents	writing campaign) Develop strategy for regulatory objectives; prepare allies to write comments in support of the changes	advertising, letter writing or petition campaigns, action alerts,	

Table 18. Research

	Step 3: Create a Vision	Step 4: Communicate the Vision	Step 5: Empower Others to Act on the Vision	Step 6: Plan for and Create Short-Term Wins	Step 7: Consolidate Improvements and Still More Change	Step 8: Institutionalize New Approaches
Statement on research needs in cost communication	Present policy statement proposal to Research Committee and invite representatives to develop section on research needs in cost communication.	Invite Research Committee representatives to join policy statement writing group	Begin to develop section for policy statement on research needs in cost communication	Complete section and send to writing group for incorporation in overall statement	Revise section based on feedback Develop an internal strategy document identifying key priorities, partners and opportunities to promote research recommendations	Publish statement Present research needs and strategy to ASCO and to external research groups (i.e., PCORI, NCI)
Promote research at ASCO meetings and in journals	Contribute to the development of key topic list for JOP or JCO special series call for submissions	Highlight cost communication as an area for research submissions at the ASCO Annual Meeting	Launch call for submissions to ASCO Annual Meeting	Publish special series, to include ASCO briefs and articles from peer-reviewed submissions	Identify cost communication abstracts for a Clinical Science Symposium at the Annual Meeting	Hold Clinical Science Symposium at the Annual Meeting

Research awards through Conquer Cancer Foundation	Develop proposal documenting lack of research on cost communication and laying out award structure(s)	Present proposal to the Conquer Cancer Foundation; gain approval	Publicly announce research award opportunity along with other Foundation awards	Once award recipients are selected, announce broadly to increase awareness	Invite award recipients to present their findings at ASCO meetings and in journals	Integrate research findings into ASCO education and quality training programs
Research using ASCO data resources	With CancerLinQ staff, identify opportunities to begin capturing data to help define and measure financial toxicity	Present proposed data elements to be collected to CancerLinQ Board of Directors	Communicate to CancerLinQ practices the additional data capture that will be available, and the importance of collecting these data	Develop and provide to ASCO members “report cards” that track financial toxicity metrics over time and connect to opportunities for improvement	Participate in CancerLinQ efforts to capture core data elements for assessing financial toxicity through participating EHR vendors	Develop regional and national reports on patient demographics and financial toxicity metrics, make available to payers, policy makers and others

Illustrative timelines for each domain of the implementation plan is presented below (see Tables 19-25), followed by a preliminary operational and financial model (Table 26).

Table 19. Oncologist Education & Training Timeline

	Q3/2019	Q4/2019	Q1/2020	Q2/2020	Q3/2020
Oncologist Education & Training	Develop core competencies		Publish core competencies in ASCO journal		
			Create curriculum content	Launch curriculum publicly	Hold cost communication workshop at Annual Meeting
		Call for submissions for special series in JOP on cost communication			Publish special series articles

Table 20. Clinical Guidance Timeline

	Q3/2019	Q4/2019	Q1/2020	Q2/2020	Q3/2020
Clinical Guidance	Work with Clinical Practice Guidelines Committee to identify an initial set of drug regimens to be scored using the NHB construct		Calculate scores and begin to publish online Launch member communications to let oncologists know the scores are available and how to access them		
	Continue work on NHB methodology to allow for cross-trial comparisons		Test new NHB methodology with a series of drug regimen calculations to ensure validity		Publish new version of the NHB methodology and begin using it to score regimens
		Identify patient groups and other stakeholders to participate in a consensus project to identify data elements that should be routinely collected to inform more robust NHB scores	Using modified Delphi process, come to an agreement on a core set of data elements		Publish consensus group recommendations in ASCO journal; share findings with FDA and also with CancerLinQ for real-world evidence data collection improvements

Table 21. Patient Education & Awareness Timeline

	Q3/2019	Q4/2019	Q1/2020	Q2/2020	Q3/2020
Patient Education & Awareness	Conduct telephone interviews with patient assistance foundations to identify needs and available resources	Create a compendium of available resources; begin to create new resources		Post resources online and print hard copies for dissemination to oncology practices	
		Identify partners for a social marketing campaign on cost communication	Work with communications staff to hone messages	Launch campaign in concert with the availability of new patient resources	

Table 22. Practice Tools & Resources Timeline

	Q3/2019	Q4/2019	Q1/2020	Q2/2020	Q3/2020
Practice Tools & Resources	Convene a multi-stakeholder work group to create a step-wise strategy/ blueprint for creating OOP cost transparency for cancer care			Publish blueprint for OOP cost transparency in cancer care	
				Identify payer interested in developing an OOP cost estimator prototype using the blueprint as a guide	
	Develop a directory of patient assistance resources and distribute to practices				
	Attend state/regional affiliate meetings and discuss the need for local financial assistance resources for oncology members in their area				
	For affiliates who are interested, identify potential partners (i.e., American Cancer Society) with local and regional presence to work with them				
	Develop a template of the types of resources to be collected; share with affiliates				

Table 23. Quality Assessment & Improvement Timeline

	Q3/2019	Q4/2019	Q1/2020	Q2/2020	Q3/2020
Quality Assessment & Improvement	Identify and collect tools and resources in use by practices	Create new templates and resources		Launch microsite of resources and tools for the care team	
	Partner with patient navigation groups and ACC to develop core competencies for oncology financial navigation			Publish core competencies; assess market interest for navigation certification program	
	Develop financial toxicity assessment and mitigation measure concepts	Develop measure specifications	Test measures with QOPI practices for reliability and validity		Launch measures for use by QOPI practices
	Advertise cost communication quality training program opportunity	Identify practices interested in implementing cost communication quality improvement	Enroll five practices in the program; establish virtual learning network for sharing of best practices		Present training program findings and lessons learned at Quality Symposium as an education session or abstract presentation

Table 24. Policy Timeline

	Q3/2019	Q4/2019	Q1/2020	Q2/2020	Q3/2020
Policy	Assemble writing group to develop ASCO policy statement on cost communication	Dialogue with other stakeholders to gain perspective on current issues and areas of synergy Develop statement draft		Obtain Board approval	Publish statement; develop podcast of lead authors discussing the statement recommendations
	Research the law and relevant issues to understand key opportunities and challenges	Dialogue with stakeholders to identify common ground; talk to opponents to discuss areas of compromise		Develop and distribute fact sheets, testimony talking points to describe problem and needed action	Communication strategy to reach policy makers and other allies (individual lobbying, letter writing campaign)
	Identify stakeholders and their influence (supporters and opponents)				

Table 25. Research Timeline

	Q3/2019	Q4/2019	Q1/2020	Q2/2020	Q3/2020
Research	Issue call for research for a special series on cost communication in ASCO journal	Begin to develop section for policy statement on research needs in cost communication	Complete section and send to writing group for incorporation in overall statement		
	Approach Conquer Cancer Foundation about creating one or more researcher awards on cost communication	Highlight cost communication as an area for research submissions at the ASCO Annual Meeting		Identify cost communication research abstracts and collate into a Clinical Science Symposium at the Annual Meeting	Hold Clinical Science Symposium at the Annual Meeting
			Publicly announce research award opportunity along with other Foundation awards		

Table 26. Operational & Financial Model

Domain	Operational Investment (marginal costs)	Sources of Revenue
Oncologist Education & Training	Staff support to develop course, plan events, and market activities	ASCO University courses Registration for live events Event sponsorship Certification fees (future)
Patient Education & Awareness	Staff support to develop education materials Printing and design costs	ASCO Bookstore sales of bulk patient materials Foundation or other organizational grant support to develop and disseminate resources
Clinical Guidance	Staff and/or consultant support to calculate NHB scores	---
Practice Tools & Resources	Staff support to develop blueprint for cost transparency statement IT consultant support to develop OOP cost estimator prototype Staff support to assemble patient assistance resources for the clinic; printing and design costs to produce resources in hard copy Staff support to meet with state affiliates and promote the development of regional databases to state affiliates	Foundation or other organizational grant support to develop and disseminate resources
Quality Assessment & Improvement	Staff support to develop performance measures; consultant support to test measures for validity and reliability Staff support to design, build, and market quality training and recognition program, reports	Performance improvement reports fees Practice consultant support fees
Policy	Staff and outside policy counsel support to advocate for policy initiatives, including developing issue briefs, grassroots advocacy and other efforts	---
Research	Staff and consultant support to design research protocol and assemble data from CancerLinQ or other resources	Outside sponsorship for Conquer Cancer Foundation researcher awards

CHAPTER 7: CONCLUSION

Despite a growing consensus in the oncology community that cost discussions between oncologists and patients is an important component of high quality cancer care, these conversations do not appear to be occurring frequently. Moreover, little work has been done to identify effective ways of introducing cost into physician-patient discussions, or to place this information within the overall context of the value of various treatment options under consideration. This study helps further our understanding of the degree and way in which oncologists are integrating a focus on cost into their discussions with patients; the barriers and facilitators to cost discussions between oncologists and their patients; and the ways in which communication with patients about cost can be optimized to reduce patient financial toxicity in the cancer setting.

The findings of this study underscore the significant challenges oncologists face in addressing OOP cost with their patients. The steps required to prescribe therapy and to obtain financial assistance when it is needed is a time-intensive, back-and-forth process that can increase patient anxiety and lead to delays in care. Like prior research on this topic, this study found oncologists generally are not aware of the costs of the various treatment options they prescribe, nor are they aware of how affordable they will be for their patients. Additional barriers identified were lack of education and training on effective ways to discuss cost with their patients, and inadequate resources and/or systems in place within the practice address patient financial toxicity.

Despite these barriers, this study shows oncologists are finding ways to effectively engage with patients about OOP costs and to help them reduce their financial burden, whether through obtaining financial assistance or by modifying the treatment to reduce direct or indirect costs to the patient. The study also highlights several factors that appear to serve as facilitators to effective cost communication, including the presence of dedicated staff support, OOP cost estimator tools, and payment models that incent OOP cost communication such as the OCM.

An important finding of this study is that the frequency and way in which cost conversations occur between oncologists and their patients varies depending on practice setting and patient population served. Additionally striking differences were observed in the level and type of support oncologists have in their practices to identify and help mitigate financial toxicity. These findings suggest the role of the oncologist in addressing OOP costs with patients should be defined in a flexible way, allowing for differences not only in patient need, but also in practice resources. As well, it suggests the need for a variety of models to be designed and implemented for addressing financial toxicity in clinical oncology practice depending on practice setting and population served.

This study also provides new insight from oncologists on the degree, and instances, in which there are perceived to be multiple clinically appropriate treatment options available to discuss with a given patient. It appears from this study there may be greater opportunity for considering costs in treatment decision making in the metastatic rather than curative setting, given the incremental benefits of continuing later-line therapies can be low compared to the cost of care. However in all cases, oncologists expressed a strong conviction they wish to consider the cost of therapy only after identifying the clinically best option for the patient. This suggests cost information is important for oncologists to have, but that it will be used in a specific way and sequence during the decision-making process with patients.

Given differences in the way oncology practices are structured, resources and staffing available, and patients served, improving cost discussions in oncology practice is not going to be a one-size-fits-all solution. To effectively assist patients in understanding, minimizing and managing their OOP costs, interventions are needed at the physician level, the patient level, the health system level, and the policy level. ASCO has a role in helping across the spectrum, including supporting the education of oncologists; making patient resources more easily available to oncologists and patients and families; creating and promoting quality of care initiatives focused on financial toxicity; working with public and private health insurance plans to devise a tool available to oncologists that calculates reasonable estimates of OOP costs; taking on the larger policy issues to incent the integration of financial screening and assistance into oncology practice; and addressing outstanding research needs.

Limitations of this study included selection bias as well as interviewer bias, which I sought to minimize by following interviewing best practices to ensure my interpretations were robust. Another limitation was the relatively few number of radiation oncologist and surgical oncologists represented compared to medical oncologists. As well, this study was limited to understanding oncologists' perspectives; therefore results related to patients' beliefs, attitudes and behaviors may not represent an accurate portrayal of how patients actually experience cost discussions with their oncologists.

Despite these limitations, this study contributes to the literature by offering the perspectives of oncologists from a diverse set of practice settings, providing valuable insight that can help to guide research efforts in the future. Ultimately it is hoped this study will not only help guide ASCO’s work, but also help the larger oncology community design interventions to better address patient financial burden in the cancer setting.

APPENDIX 1: EMAIL SOLICIATION

Email Recruitment

IRB Study # 16-2871

Dear _____________,

My name is Dana Wollins, and I am a student from the University of North Carolina at Chapel Hill conducting a series of key informant interviews (research) about doctor-patient discussions of cost in the cancer setting. I'm writing to ask if you would be willing to be interviewed for this study. Participating in this survey is voluntary and you do not have to participate if you don't want to.

During the interview, you will be asked a series of open-ended questions about your experience and opinions related to discussing cost-of-care issues with cancer patients. Your answers will be completely confidential, and your name will not be used in connection with any of the information you provide. The interview will take about 30-40 minutes and can be conducted by phone at a time that is convenient for you. It will be recorded and transcribed for the sake of accuracy and review, but only for research purposes. You have the option to opt out of having this interview recorded and still be able to participate.

Please let me know at your earliest convenience if you have any questions, and if would be willing to serve in this role.

Sincerely,
Dana Wollins
Tel: 202-255-9804

APPENDIX 2: INTERVIEW GUIDE

Practice Experience

- Please tell me a bit about your work as an oncologist.
- How long have you been in practice since completing training?
- How long have you been at your current practice/institution?
- What is the breadth of cancer diagnoses you treat?

Addressing Cost

Initiation

- How frequently does the issue of cost (to the patient, meaning patient out-of-pocket cost/expenses) come up in your discussions with patients?
- When it comes up, who tends to bring it up (you or the patient)?
- Why does the topic of cost come up?
- With which patients does the topic tend to come up?
    - *Probe: For example, with patients with specific cancer, insurance, demographics, or other characteristics? Treatment type (oral versus IV)?*
- At what point (i.e., at an initial consultation, later in the process) does it typically come up?

Content

- In thinking about the nature of these discussions, what issues tend to be asked or raised, and by whom?
- When cost is identified as a concern for the patient, what do you say, do, or offer? Do you discuss less expensive options? Do you identify patient assistance resources?
- What is it like for you to talk about cost issues with your patients? Does it create any discomfort? Is it a difficult subject to broach?
- Same question, but from the side of the patient: What do you think it's like for your patients when cost is discussed? Does it create any discomfort? Is it a difficult subject to broach?

Resources

- When patients have questions for you about the cost of their care, how do you address these questions? What information, tools and/or resources—if any—do you use? Do you have information about patient-specific cost at the time you're discussing treatment options with patients, or does this information become available later? What is the sequencing of information patients in your office receive in this respect?
- How do patient financial questions or concerns get handled in your office?
    - *Probe: For example, do you have a financial counselor or navigator involved?*

Facilitators

- What do you think enables these conversations to happen, or happen well?

    - *Probe: For example, patient and/or provider education and training?*

Barriers

- What hinders these conversations from happening, or happening well, from the physician/oncologist side?
    - *Probe: For example, access to electronic or other data? Lack of price transparency, fear of being viewed as money-hungry?*
- What hinders these conversations from happening, or happening well, from the patient side?
    - *Probe: Fear of getting lesser care?*

Impact

- What do you perceive is the impact to physicians/oncologists of having these discussions?
    - *Probe: Does it change the treatment regimen that is prescribed?*
    - *Probe: Does it change the dynamic between you and the patient?*
- What do you perceive is the impact to patients of having these discussions?
    - *Probe: Does it change what kind of treatment or financial assistance the patient receives?*
- What do you believe are the potential benefits of discussing cost with your patients?
- What do you believe are potential harms of discussing cost with your patients?

Improving Cost Discussions

- What tools or resources would be helpful for you to make sure patients' cost concerns are addressed when they exist?
- At what point in the care process are these resources needed? For example, would it be helpful to obtain information before the clinic visit, during the clinical encounter, and/or as part of the after-visit summary?
- Risks as well as costs to patients? To society?
- How helpful would a tool be that presents information on the clinical benefits versus cost to patients, versus cost to society? Cost to you as a provider?
- Relative value of clinical treatment options, i.e., their clinical benefits versus risks as well as financial costs? How would this information be used?

Closing

- Are there any other suggestions you would like to make to those who are trying to help oncologists and their patients address cost issues?
- Do you have any additional thoughts you would like to share?
- Do you have any recommendations for other oncologists oriented toward discussing cost issues with their patients who might be willing to be interviewed for this study?

APPENDIX 3: TELEPHONE CONSENT FOR KEY INFORMANT INTERVIEWS

Hello, my name is Dana Wollins. I am a student from the University of North Carolina at Chapel Hill conducting a series of key informant interviews (research) about doctor-patient discussions of cost in the cancer setting. Your participation in this research is completely voluntary. You do not have to participate if you don't want to.

An estimated 25 oncologists will be interviewed for this study. During the interview, you will be asked a series of open-ended questions. There are no right or wrong answers, and you may answer in any way. Your answers are completely confidential. Your name will not be used in connection with any of the information you tell me. You do not have to answer any questions that you do not want to answer, and you may end the interview at any time if you want to. Your answers to these questions will help to better understand oncologists' views on how to improve doctor-patient discussions about cost. The interview will take about 30-40 minutes. It will be recorded and transcribed for the sake of accuracy and review, but only for research purposes. You have the option to opt out of having this interview recorded and still be able to participate.

All the information I receive from you by phone, including your name and any other identifying information will be strictly confidential and will be kept under lock and key. I will not identify you or use any information that would make it possible for anyone to identify you in any presentation or written reports about this study. If it is okay with you, I might want to use direct quotes from you, but these would only be quoted as coming from "a person" or a person of a certain label or title, like "one woman said." When I finish with all the interviews from everyone who has agreed to participate, I will group all the answers together in any report or presentation.

The only risk to you might be if your identity were ever revealed. But I will not record your name with your responses, so this will not occur. There are no other expected risks to you for helping me with this study. There are also no expected benefits for you, either. There is no compensation for participating in this study. Additionally, it will not cost you anything to participate.

Do you have any questions at this time? (*Answer the participant's questions about the interview before proceeding to the next question.)*

May I have your permission to record this interview? (*If yes, proceed to turn on the recorder and begin the interview questions.)*

APPENDIX 4: CODE BOOK

Name	Description	Files	References
1-Why Cost Comes Up	The reasons why cost comes up, for which patients, which concerns		
a. Insurance coverage concerns		19	48
b. Newer, more expensive drugs		7	16
c. Orals		5	10
d. Ancillary expenses		6	7
e. A necessity to preserve practice health		4	6
2-When and How it Comes Up	Who initiates the discussion about cost and at what point in the care trajectory		
a. Not at the initial visit		6	6
b. During initial treatment decision-making period		4	5
c. At start of or during treatment		4	4
3-Discussion Frequency and Initiation	How often the issue of patient out-of-pocket cost/expenses comes up in oncologists' discussions with patients, and who brings it up		
a. Frequency			
i. Not often		4	4
ii. Often		5	5
iii. Rarely		4	4
iv. Very often		6	7
b. Who initiates		0	0
i. Both		1	1
ii. Patient		5	6
iii. Physician		9	18
4-Attitude and Experience	How do oncologists view cost discussions and what is their experience like to communicate with patients about costs		

Name	Description	Files	References
a. Lack of OOP cost information		14	28
b. Uncomfortable to discuss, but less so than in the past		5	5
c. Easier if patient initiates		1	1
d. Positive effects		3	3
e. A shared responsibility among the care team		2	2
5-Process and Resources Used	What are the processes and resources used to address OOP cost with your patients		
a. Back-and-forth, time-intensive process		8	19
b. Role of staff support		7	15
i. Financial counselors		1	1
ii. Nurse		3	3
iii. Practice or Billing Manager		3	4
iv. Social Worker		2	2
c. Reactive vs. proactive		2	2
d. Oral drugs and role of pharmacy		5	9
e. OOP cost estimators		2	4
f. Financial screening		7	10
6-Strategies to Reduce OOP Costs	What information is provided or steps taken		
a. Free drug and co-pay assistance programs		16	32
b. Changing insurance plans or enrolling in government aid programs		5	7
c. Changing site of care		8	17
d. Choosing an alternative treatment		21	45
e. Selecting different mode or schedule of therapy		6	7

Name	Description	Files	References
f. Financing or absorbing costs within the practice or institution		5	7
g. Role of clinical trials		7	8
7-Barriers to Cost Communication	What hinders your ability to address cost with your patients		
a. Lack of OOP cost transparency		16	29
b. Lack of education and training		4	5
c. Lack of ability to identify resources for patients		7	11
d. Lack of a systemic process for identifying and mitigating financial toxicity in the practice		10	14
e. Time- and resource-intensive process		5	9
8-Facilitators	What helps you address cost with your patients		
a. Dedicated, trained staff support		9	11
b. OOP cost estimator tools		2	2
c. Payment models that incent OOP cost communication with patients		3	4
9-Improving Discussions	What tools, resources, other would be helpful to make sure patients' cost concerns are addressed?		
a. Physician education and training		7	16
i. How to discuss cost		2	3
ii. Knowing what resources are available in my community		2	9

Name	Description	Files	References
iii. Published cost information		6	13
iv. Resource-stratified guidelines		3	3
b. Patient and family education		7	14
c. Information-based solutions		9	18
d. Systems to support value-based care delivery		4	13
i. Feedback Loop with Patient		3	3
ii. Info. to Patient Up Front		1	1
iii. Institutional Influence		12	43
iv. Patient navigation		3	3
v. Quality of care standard		3	3
vi. Screening tool or automatic trigger		5	12
e. Whole Team Approach		4	4
f. Policy change		22	52
i. Growth in Medicare Advantage enrollment		2	2
ii. Standardized coverage policies		1	4
g. ASCO's role		9	17
i. ASCO as a trusted expert		1	1
ii. ASCO Value Framework		7	13
iii. Education		1	2

APPENDIX 5: SUMMARY OF STUDY FINDINGS

Domain	Theme	*Sub-Theme*
Why cost comes up	The issue of OOP costs arises primarily due insurance coverage concerns, high drug costs and patient inability to pay for the ancillary costs of care (e.g. transportation, time off work).	***Insurance coverage concerns.*** Oncologists spoke at length about the significantly increased impact OOP costs are having on their patients compared to the past due to poor insurance coverage. Oncologists frequently cited an overall increase in patients coming in with high-deductible health plans and plans that do not cover the cost of prescription drugs. They also identified high co-pays, as well as the accumulation of smaller but collectively significant co-pay expenses for patients who require long durations of therapy. Most said they don't have an uninsured problem; rather, they have an under-insured problem. They may be uninsured briefly/temporarily, but for the most part they can qualify for state emergency Medicaid, which can be done retroactively. The exception is undocumented individuals who cannot qualify for Medicaid and who will be turned away even by non-profit hospitals in some states. ***Newer, more expensive drugs.*** Oncologists explained how new drugs carry exponentially higher price tags than their older, often generic, counterparts. In particular, targeted therapies – which can offer significantly improved length and quality of life compared to earlier generation treatments—can cost upwards of $10,000 per month. ***The oral revolution.*** Among expensive newer treatments, oncologists pointed to the rise in the availability of orally administered drugs as a reason why cost issues arise in discussions with patients. Oral drugs, such as PARP inhibitors for ovarian cancer, can be more convenient for patients than intravenously administered drugs, however compared to drugs administered intravenously, orally administered usually have higher associated patient OOP costs, because of the pharmacy benefit options in part D. ***Ancillary expenses***. Oncologists caring for patients from low-SES backgrounds often identified

		ancillary expenses as the main issue for their patients. These include transportation to and from appointments, lost wages from being out of work, daycare costs, eating food in restaurants instead of cooking at home, and losing their housing. Those working in public hospitals noted the direct cost of care (i.e., the drug regimen or other therapy) is usually not the issue for the patients they serve; instead, ancillary expenses are the main issues of concern for their patients. ***A necessity to preserve practice health***. Oncologists in private practice consider discussing cost with their patients not only as important for their patients, but also as necessary to ensure the financial health of the practice.
When and how cost comes up	Oncologists described several scenarios in which the topic of OOP costs comes up between them and their patients, both during and after the initial treatment decision-making period.	***Not at the initial visit.*** Most oncologists said the topic of OOP rarely comes up-- and is not appropriate for them to bring up-- during the initial consultation or visit. During this time, patients are usually consumed with worry and emotionally distraught over the diagnosis of cancer. As well, there are often more pressing issues to discuss. ***During the initial treatment decision-making period.*** Several oncologists said they have incorporated addressing the topic of finances into their discussions in a general way with their patients, particularly if they know the treatment they are prescribing tends to be expensive. Other oncologists said they look for "flags" from their patients to gauge if financial issues are a concern**.** If there are "red flags," oncologists will often bring in financial services or social workers to help address concerns. Absent any "red flags," many oncologists said they do not bring up the issue of cost. ***At the start of or during treatment.*** Once a patient has been prescribed treatment and is beginning or in the midst of care, the topic of OOP cost tends to be initiated more often by patients. Several oncologists noted it is often the case that the patients get one to two months down the road, receive a flurry of bills, and are overwhelmed. Often patients will bring up cost concerns to

		another person on the care team, who then brings it to the oncologists' attention.
Discussion frequency and initiation	The frequency with which OOP cost discussions take place between oncologists and patients varies widely depending practice setting and population served.	***Variation by practice setting.*** Oncologists varied widely in how frequently they say OOP cost discussions come up between themselves and their patients, with those in private practice significantly more likely to initiate a discussion of cost and ensure it takes place compared to those in academic and hospital/health-system owned practices. The exception is oncologists in public hospital (non-academic) settings serving low-SES patients, who also reported discussing costs frequently.
Attitude and experience	Oncologists believe OOP cost is a significant problem affecting a growing number of their patients, and they view communicating with their patients about OOP costs as an important aspect of patient care. That said, most oncologists do not feel comfortable discussing OOP costs with their patients because the topic is so complex, and they do not feel adequately equipped to help.	***Lack of OOP cost information makes cost communication a challenge.*** Except for some of the newer, targeted therapies that are known to carry high price tags, oncologists generally are not aware of the costs of various treatment options, and they do not have information on what the patient in front of them is going to play due to how complex and opaque patients' health insurance coverage is. ***Uncomfortable to discuss, but less so than in the past.*** Most oncologists agreed discussing cost can be uncomfortable for oncologists as well as patients, however it seems less so than in the past. Respondents attributed this to the fact that not being able to afford one's care has become expected and universal. As a result, discussing it has become legitimized. ***Easier if the patient brings it up first.*** Many oncologists said they feel more comfortable discussing cost if the patient brings it up first, because they are concerned the topic could make the patient uncomfortable and create a challenging dynamic. ***Positive effects.*** Many oncologists reported positive effects of bringing up OOP cost issues with their patients. Doing so can come to a relief to patients and can also help patients feel heard and understood by their doctors. Additionally, oncologists noted having the discussion creates a more intimate relationship between doctor and patient.

		A shared responsibility among the care team. Oncologists think it is important to inform patients about what their treatment will cost, and to help them identify ways to make their care as affordable as possible. However, they do not think it is necessary that this information and assistance comes from the oncologist directly. Oncologists believe they have a role to play in addressing cost in the context of clinical decision making, i.e., to know and discuss what clinical options are available for the patient that may be similar clinically but less expensive in cost.
Processes and resources used	Oncologists are aware of, and use, a variety of approaches in their practices to help patients understand and reduce their OOP costs. The level and type of support they have varies considerably depending on practice setting. However in all cases, the process of obtaining OOP cost information, in addition to the necessary steps required to obtain financial assistance, is a time-intensive, back-and-forth process that can increase patient anxiety and lead to delays in care.	***Back-and-forth, time-intensive process.*** Because OOP cost information is difficult to obtain, and often requires several intermediary steps to obtain insurance approval, treatment decision-making can require a back-and-forth pattern between the oncologist, patient, insurance company, and other practice staff: Initial preferences are discussed, then other office staff or a pharmacist determines what the desired treatment will cost the patient; then the practice seeks to find help to cover the costs if they are significant to the patient; and then—if adequate assistance isn't available—the patient returns to the doctor to discuss alternative options. ***Role of staff support.*** A variety of types of oncology practice staff participate in the task of helping patients understand and cope with their OOP costs. In smaller office settings, the front desk and/or billing manager takes on the majority of work, where other settings employ dedicated financial navigators or counselors to serve in this role. Oncologists in large private practices or hospital/health system settings are generally well staffed to help their patients understand their OOP costs and assist with finding financial assistance, whereas oncologists in small private practices have little to no staff to assist. Oncologists in academic medical centers and public hospitals vary in the degree of staff assistance available, with oncologists in areas serving low-SES patient

		populations universally needing more help than they have. ***Reactive versus proactive.*** In some situations, usually large physician-owned practices, all patients meet with a financial counselor before starting treatment. However in the majority of cases, financial counselors meet with patients only when called in by a clinic nurse, social worker, office coordinator or other staff member when they "sense a problem" or an issue arises. ***Oral drugs and the role of pharmacy.*** When prescribing oral drug regimens, oncologists noted they often rely on prescription (specialty) drug pharmacies to financially counsel their patients and help them with their drug expenses. ***OOP cost estimators.*** Some oncologists have integrated OOP cost estimator tools into their practices and have found, while imperfect, they can be useful in prompting a financial conversation. Oncologists in private practice identified more sophisticated tools used by their practice managers, and sometimes themselves, to help estimate costs directly. ***Financial screening.*** Screening tools are used during the course of treatment to identify signs of patient financial distress, however oncologists are not confident the results of these screening tests are always followed up upon, and they do not usually return to the oncologist, making it difficult for them to know if their patients are experiencing financial concerns.
Strategies to reduce OOP costs	Oncologists are aware of and use a wide range of strategies to help patients afford their care.	***Free drug and co-pay assistance programs.*** Free drug programs, co-pay assistance, and drug coupons can help make care more affordable for patients, but are often inadequate and unpredictable, making it administratively difficult and resource-intensive for staff. ***Changing insurance plans or enrolling in government aid programs.*** Oncologists are often able to help their patients save money by helping

		them obtain or switch insurance plans, or to qualify for other federally- or state-sponsored programs. ***Changing site of care.*** Selecting a different site of care can help their patients save money. **Selecting different mode or schedule of therapy.** Many oncologists identified ways they can help their patients with the cost of care by choosing an infusion equivalent instead of an oral therapy, or selecting a treatment based on when and how often a patient must travel to the clinic. ***Selecting generic drug equivalents.*** An important strategy for reducing OOP drug costs is to choose a generic equivalent versus a brand-name drug. ***Choosing an alternative treatment.*** Oncologists said the degree to which different options may be available that are similar clinically but different in cost varies depending on disease stage and type, with most agreeing there are more options in the metastatic rather than curative setting. Additionally, they felt strongly that initial treatment options should first be considered agnostic to cost. ***Financing or absorbing costs within the practice or institution.*** Other ways oncology practices help patients manage OOP costs is through the use of payment plans or by absorbing the costs internally. ***Role of clinical trials.*** Most oncologists view enrolling a patient on a clinical trial as helping, or at least not hurting, patients financially, however they warned against the hidden, indirect costs involved.
Barriers to Cost Communication	Several barriers exist that make it challenging for oncologists and their patients to address cost of care issues as part of treatment decision-making	***Lack of OOP cost transparency.*** Lack OOP cost information is a significant barrier to cost discussions between oncologists and patients. The notion of using cost estimates that are not specific to the patient was met with mixed reviews. ***Lack of education and training.*** Oncologists also identified a lack of education and training as a barrier to helping their patients address the cost

	as well as during the course of care. Except for some of the newer, targeted therapies that are known to carry high price tags, oncologists generally are not aware of the costs of the various treatment options they prescribe, nor are they aware of how affordable they will be for their patients. Additionally, oncologists also lack education and training on effective ways to discuss cost with their patients, as well as how to help their patients avoid or lessen the impact of financial toxicity when it is identified. Finally, many oncologists lack having systems in place and/or the assistance of staff support to help them identify and address patient financial toxicity in their practices. The steps required to prescribe	component of their care, noting a major limitation in oncology training is that cost is not addressed. ***Lack of ability to identify resources for patients.*** Many oncologists, particularly those in small physician-owned practice settings, said they lack the ability to adequately help their patients identify resources to help them afford their care. ***Lack of a systemic process for identifying and mitigating financial toxicity in the practice.*** Oncologists lack information—either at the time of diagnosis or during treatment—regarding their patients' financial circumstances or concerns related to their care, even in practices that practice routine financial screening for financial distress. Many noted particular concern for patients on oral drugs, who have a high risk of "slipping through the cracks." ***Time- and resource-intensive process.*** Oncologists also reported how time consuming and administratively burdensome the process is to help their patients navigate the financial aspects of their care, including addressing insurance issues as well as securing financial assistance.

	therapy and try to obtain financial assistance when it is needed is a time-intensive, back-and-forth process that can increase patient anxiety and lead to delays in care.	
Facilitators of Cost Communication	Oncologists emphasized the importance of dedicated staff support in facilitating cost communication between themselves and their patients. They also identified OOP cost estimator tools and payment models that incent OOP cost communication as important facilitators to ensuring a focus on cost is addressed with their patients.	***Dedicated, trained staff support.*** Those oncologists interviewed who have a staff support system to address patient OOP costs describe being better equipped to identify the potential for financial toxicity and to help prevent or manage it before and during a patient's treatment. Financial counselors can offer significant assistance to oncologists and their patients; however they work best when are adequately trained and when they are embedded as part of the cancer care team rather than in a centralized area serving all disease areas. ***OOP cost estimator tools.*** The few oncologists who have integrated an OOP cost estimator tool into their practices have found, while imperfect, they can be useful in prompting a financial conversation—particularly if the information is automatically given to the patient. ***Payment models that incent OOP cost communication with patients.*** Participating in the OCM has helped transform oncology practices to place a greater emphasis on improving the ability to inform patients about their OOP costs.
Improving Cost Discussions in Oncology Practice	To effectively assist patients in understanding, minimizing and managing their OOP costs, interventions are needed at the physician level, the patient level, the caregiver level, the health	***Physician education and training.*** Oncologists – particularly those working in settings without other staff available to help—stated they need more education on the financial cost of treatment, and how to help their patients navigate the cost of their care. ***Patient and family education.*** Oncologists emphasized the importance of education for patients and their families to help them initiate a conversation with their doctors about cost, as well as to help them better understand their health

	system level, and the policy level. Physician, patient and family education; clinical decision support through information-based solutions; a systems-based, whole care team approach; and policy change are needed. Given differences in the way oncology practices are structured, resources and staffing available, and patients served, improving cost discussions in oncology practice is not going to be a one-size-fits-all solution. ASCO has a role in helping across the spectrum, including supporting the education of oncologists; making patient resources more easily available to oncologists and patients/families; creating and promoting quality of care initiatives focused on financial toxicity; working with	insurance coverage and be better able to distinguish the value different care options. ***Information-based solutions for clinical decision support.*** Oncologist pointed to the need for better information to aid in clinical decision support as a key way to help them address OOP costs with their patients. ***Systems approaches to support value-based care delivery.*** Oncologists identified to the need to integrate processes that facilitate cost communicate with patients into the oncology practice workflow ***Whole team approach.*** Oncologists identified the critical role of dedicated staff support to help patients navigate through what is often a very complex treatment, and they called for additional professionals trained to effectively address patient financial toxicity in the oncology setting. ***Policy change.*** Oncologists called for policy solutions to address rising OOP costs for cancer patients, including health insurance reform as well as action to reduce drug prices on the part of pharmaceutical companies. ***ASCO's role.*** ASCO has a role in helping across the spectrum, including supporting the education of oncologists; making patient resources more easily available to oncologists and patients/families; creating and promoting quality of care initiatives focused on this topic; working with the payer community to devise a tool available to oncologists that calculates reasonable estimates of OOP costs; and taking on the larger policy issues related to defining how much treatments should actually cost (or are worth), as well as promoting innovative payment and other healthcare delivery models that incent the provision of financial counseling and other interventions to help oncologists address OOP cost into practice.

	public and private health insurance plans to devise a tool available to oncologists that calculates reasonable estimates of OOP costs; and taking on the larger policy issues including promoting innovative payment and other healthcare delivery models that incent the integration of financial screening and assistance into oncology practice.	

APPENDIX 6: ASCO'S QUALITY OF CARE INITIATIVES

Promoting the highest quality care for patients with cancer is a core component of ASCO's mission, and it is achieved through the dedicated professionals at oncology practices who implement the necessary standards and procedures. Below is a summary of ASCO's initiatives designed to assess and improve the quality of cancer care.

Clinical Practice Guidelines: ASCO develops and maintains a robust set of clinical practice guidelines and practice standards, which provide evidence-based recommendations that serve as a guide for clinicians and outline appropriate methods of treatment and care. ASCO guidelines and standards can address specific clinical situations (disease-oriented) or use of approved medical products, procedures, or tests (modality- oriented). Multidisciplinary panels of experts, including patient advocates, develop ASCO's clinical practice guidelines.

Quality Measures: ASCO began developing measures more than a decade ago in the context of its National Initiative on Cancer Care Quality, a study to assess clinical quality of breast and colon cancer care in five U.S. cities. Measures were then developed and deployed as part of ASCO's Quality Oncology Practice Initiative (QOPI) beginning in 2006. Since that time, ASCO has invested significantly in its portfolio of quality measures for use in oncology practice. Currently ASCO's measures library contains more than 190 measures that are used in ASCO's growing suite of quality assessment programs including QOPI and QOPI Certification. The latter confers a 3-year certification to practices that meet specified clinical and safety standards. Several ASCO measures have been adopted by CMS for use in the QPP.

Quality Oncology Practice Initiative (QOPI): QOPI is an oncologist-led, practice-based quality assessment program designed to promote excellence in cancer care by helping practices create a culture of self-examination and improvement. QOPI provides a standard methodology, a robust library of quality metrics for oncology, and a collection tool to reliably and routinely assess care, inform quality improvement activities, and demonstrate quality to patients and external stakeholders. Early adopters of QOPI® are well-positioned to meet external reporting requirements for payers and the government and participate in new payment models focused on quality.

QOPI Certification Program: The QOPI Certification Program provides a three-year certification for outpatient hematology-oncology practices. The program validates processes that demonstrate a practice's commitment to quality to patients, payors, and the medical community. The primary mission of the QOPI Certification process is practice improvement. Benchmarking performance against performance thresholds can assist practitioners in achieving specific improvement goals. The process of preparing for and completing the Site Assessment stimulates internal discussion regarding opportunities for practice improvement, team collaboration, and implementation of improved systems.

CancerLinQ: CancerLinQ is a big data initiative to rapidly improve the quality of care for people with cancer. CancerLinQ will allow cancer care providers to improve the quality and value of care by analyzing millions of cancer patient medical records, uncovering patterns and trends, and measuring their care against that of their peers and recommended guidelines. The

CancerLinQ platform is the only effort of its kind being driven by a non-profit, physician organization. To date, CancerLinQ has ingested over one million records in the data lake, and 70 institutions with a broad range of geographic distribution and care settings representing more than 1,500 oncologists are in the process of contributing data. Participants who have signed on become users of the CancerLinQ platform, the "CancerLinQ Vanguard Practices," range from small private practices to some of the nation's leading cancer centers. CancerLinQ's development is well under way. Once complete, CancerLinQ will aggregate and analyze a massive web of real-world cancer care data in order to:

- **Provide real-time quality feedback to providers.** CancerLinQ will enable oncology practices to measure how their care compares against guidelines and compares to their peers based on aggregated reports of quality, offering instant feedback and guidance for improvement.

- **Feed personalized insights to doctors.** CancerLinQ's real-time clinical decision support will help physicians choose the right therapy at the right time for each patient, based on clinical guidelines and the experiences of many similar patients.

- **Uncover patterns that can improve care.** Powerful analytic tools will reveal new, previously unseen patterns in patient characteristics, treatments and outcomes that can lead to improvements in care.

ASCO Quality Training Program: The ASCO Quality Training Program is designed to train oncology health care providers to investigate and implement data-driven quality improvement and manage clinical and administrative processes and outcomes. The comprehensive 6-month program brings oncology teams of together to create and facilitate an improvement project. Each team selects a project that will solve a problem in its own clinical setting, so the learning experience is simultaneously fostering a solution or best practice. The program includes five days of in-person learning across three sessions, as well as hands-on learning at the participants' practices. To ensure a well-rounded experience, sessions include seminars, case examples, and small group exercises.

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