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Advanced Cancer Patients' Medical Decision-Making While Experiencing Financial Toxicity

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Abstract

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MBA, Arizona State University West, 2000

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Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

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Abstract

Financial toxicity (FT) is the impact that out of pocket (OOP) costs of cancer care have on patients' well-being, leading to lower quality of life, less compliance with prescribed therapy, and poorer outcomes, including increased mortality. The purpose of this study was to understand the impact of FT on advanced cancer patients' lives and their health care decision-making. Fuzzy trace theory provided the framework for examining how patients use gist and verbatim when making health care decisions while experiencing FT. Gist refers to main ideas that are often infused with emotional overlays that people use to make risky decisions, while verbatim thinking involves the recall of precise facts and figures to make decisions. The research method was case study that included conducting 13 in-depth interviews, collecting artifacts, and scoring of FT using the Comprehensive Score for Financial Toxicity tool. Findings from two-cycle coding and cross-case analysis indicated that FT and OOP costs have significant impacts on patients' lives and how they make decisions about their cancer care. Participants considered cost as a risk in cancer treatment decisions and encoded this information using verbatim rather than gist, which they used for other dimension of risk in these decisions. Participants reported they would decline care if OOP costs were high and FT was present. When OOP costs were low, participants relied on gist decision-making and generally followed their physicians' recommendations. Findings may assist cancer experts who are investigating FT and its impact on cancer care as well as those who are developing support programs for patients who experience FT.

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Dedication

This is for you: Paul and Katelyn Morel. You have been my greatest supporters and have remained patient as I worked many hours and missed out on time together to complete my doctoral work. Thank you for giving me the freedom and inspiration to pursue this goal and for helping me every step of the way.

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Thank you to my immediate family, Paul Morel and Katelyn Morel for your love and kindness as I pushed toward this big goal for many years. You guys always make each day a joy for me. Thanks to my extended family and my parents for always

encouraging me. Dad, you were an inspiration to set out on this journey for a degree in "piled higher and deeper – PhD". Mum, you were always my cheering section when I was frustrated. Thank you all.

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Chapter 1: Introduction to the Study

Cancer is one of the most impactful diseases in the United States; it is the cause of one in four deaths, with 609,640 expected cancer-related deaths in 2018 (Siegel, Miller, & Jemal, 2018). There are now 14.5 million Americans living with cancer (NCI, 2016a). Since President Nixon declared war on cancer in 1971, the United States invested in prevention, detection, and treatments in an attempt to reduce deaths and morbidity associated with the disease (Drake, 2011). Although billions of dollars were invested in research and treatment, advances in cures have not been forthcoming. Cancer continues to cause mortality with men, women, and children in the United States and globally each year. The impact of this disease is far reaching, with nearly 40% of Americans having a cancer diagnosis at some point in their lives (NCI, 2016b).

Although cancer research produced some advances, the cure that many hoped would come from the 40-year war on cancer has yet to be achieved; cancer has proven to be a strong foe (Drake, 2011). Nevertheless, cancer patients are surviving longer with the disease (NCI, 2016c; Siegel et al., 2018) due to advances in early detection methodologies, surgical options, radiation, chemotherapy, and advanced biologic treatments (Masters et al., 2015). Overall mortality rates have improved 20% compared to the rate in 1991 (Masters et al., 2015). Mass screenings for colon, breast, cervical, and prostate cancer yielded improved survival results (NCI, 2016c). Early detection means that treatment options can include surgery or less invasive options, and newer therapeutic options give some metastatic patients extended survival (Masters et al.,2015; Seiden, 2016). For example, new infused immunotherapy options offer remarkable new survival benefits to metastatic cancer patients where previously few efficacious options existed (Seiden, 2016). Therapeutic options have expanded, but not all patients are equally benefiting from the scientific advances (IOM, 2009; NIH, 2007; Siegel, Ward, Brawley, & Jemal, 2011). These advances in care and technology come at a price; research in cancer and the delivery of cancer care is expensive, and not all access the benefits (Goss, Lopez, Brown, Wollins, Brawley, & Raghavan, 2009). Moreover, cancer patients are increasingly bearing a larger share of costs (Balfe et al., 2016; Chang et al., 2004).

There is a growing body of literature addressing the impact of the costs of care that cancer patients bear for their treatment and the resultant financial distress that it causes. A new term, *financial toxicity* (FT), emerged to describe the financial and emotional distress that the direct *out of pocket* (OOP) costs of cancer care have on patients. Despite this, few researchers have addressed the patient perspective of how FT is impacting patients and their decision-making processes about treatments and cancer. This qualitative case study provided a perspective on how advanced cancer patients experienced FT and making decisions about cancer care.

The findings from this study may contribute to a deeper understanding of how patients seek to incorporate costs and financial responsibilities into their decision-making, and how these costs can become a source of distress and can create access barriers. Health care providers can use this information to be more responsive to signs of FT and to have support resources available to assist patients before FT becomes severe. Researchers may benefit from the current study findings to identify additional ways to incorporate the patient perspective into treatment decisions and decision support tools.

In Chapter 1, I describe the problem of FT and how it may impact decision-making in advanced cancer patients, the purpose of the research, and the research questions addressed in the study. I outline the theoretical basis for the inquiry and describe how the theory may be applied to decision-making in patients experiencing FT. I also provide an overview of the study's scope, methodology, assumptions, and delimitations. Finally, I address the importance of the study to social change and provide a transition to Chapter 2.

Background of the Study

With over 14.5 million Americans living with cancer (NCI, 2016b) and approximately 50% of Medicare beneficiaries spending at least 10% of their income on OOP costs of cancer care (Davidoff et al., 2013), patients' costs of cancer are a growing challenge. Patients' OOP cancer care costs are increasing to the point that it is creating a new side effect of cancer care called FT (Zafar & Abernethy, 2013a). FT is the mental and physical distress that is felt by cancer patients who are coping with both the disease and the impact of the OOP costs of the disease treatment (Zafar & Abernethy, 2013a). This distress is linked to poorer outcomes, poorer quality of life, and greater risk of mortality in cancer patients (Delgado-Guay et al., 2015; Khera, 2014; Ramsey et al., 2016; Ubel, Abernethy, & Zafar, 2013). Researchers are working to characterize, report, and grade this potential side effect of cancer care so that appropriate strategies may be developed to combat it (de Souza et al., 2014; Khera, 2014).

The distress that FT causes is a major source of anxiety and suffering for cancer patients and their families and creates greater disparities in cancer outcomes (Carrera, Kantarjian, & Blinder, 2018); the IOM has called for solutions to this issue (IOM, 2009; Zafar & Abernethy, 2013b). The issue has emerged as a major topic of debate in academic and public health forums, especially with the increased scrutiny that drug costs are receiving (Morrison, 2015; IOM, 2009; Ubel et al., 2013). Although drug and other medical services costs are increasing, there are associated improvements in length of survival for cancer patients. Nevertheless, disparities exist, especially for those who are not accessing these advanced care options (Howard et al., 2016). These increased costs create an anguishing dilemma for some patients who seek to survive their cancer, but find paying for the services to be extremely difficult. In particular, there is a lack of understanding of patients' needs and experiences with FT and how it impacts medical decision-making (Zafar, Ubel, Tulsky, & Pollak, 2015).

As patients progress in cancer care, they are often presented with a bewildering series of treatment choices between options that offer a wide variety of outcomes, risks, and costs (Reyna, Nelson, Han, & Pignone, 2015a). These decisions are typically made with their physician, but must be made without a full understanding of the costs associated with the treatment because medical oncologists and radiation oncologists do not always know what the exact costs will be for a patient. Costs depend on many factors (Peddie et al., 2012; Zafar et al., 2015). Estimating costs for care include factoring in the type of insurance; the probable coverage provided by the insurer for the proposed treatment; the deductible, and a patient's coinsurance or copayment requirement (Reinhardt, 2013; Sinaiko & Rosenthal, 2011). Although costs of care may be discussed, it can be a difficult discussion with many uncertain factors, and satisfaction with decision-making may be eroded when too much uncertainty is introduced into the patient-physician relationship (Politi, Clark, Ombao, Dizon, & Elwyn, 2011).

Most patients remain willing to discuss their treatment options and the costs of their cancer care with their providers so long as the physician is making therapy selections that support their disease treatment plan (Bullock, Hofstatter, Yushak, & Buss, 2012), but many providers are not eager to discuss difficult social or emotional issues (Bestvina et al., 2014). In a recent survey of medical oncologists, 76% either felt it was not their responsibility to discuss costs or rarely did so with patients (Altomare et al., 2016).

Many cancer patients develop deep trusting relationships with their oncologists and have cost discussions with their physicians, particularly when they are experiencing distress associated with FT (Abbott, Curley, Hanseman, & Sohn, 2014; Hillen, de Haes, & Smets, 2011). These physicians work to develop treatment plans for their patients based on the cancer's response to therapy, sometimes working for years with patients to treat and retreat the cancer as it undergoes metastasis and moves throughout the body. Some researchers suggested that improving patient and physician cost-related health literacy is a key strategy to reduce the impact of FT on cancer patients (Zafar et al., 2015). This will involve additional research to better understand the patient perspective on FT.

Problem Statement

Cancer is the second largest killer of Americans, and as the baby boomer generation continues to age, epidemiologists expect even greater incidence and prevalence of the disease in the United States (Masters et al., 2015; NIH, 2016). Through research and prevention strategies, advances in overall survival have improved, but not all people are able to access these benefits (Goss et al., 2009). Although researchers have examined many of the factors related to cancer outcome disparities for race and socioeconomic status (Freedman et al., 2011; Grubbs et al., 2013; Parise & Caggiano, 2013; Walker et al., 2014) and the barriers resulting from FT (de Souza & Wong, 2013; Delgado-Guay et al., 2015; Ramsey et al., 2016; Zafar et al., 2015), there is a gap in knowledge about how patients who are experiencing FT make decisions about their cancer care (Abbott et al., 2014; Bullock et al., 2012; Ó Céilleachair et al., 2012; Zafar, 2016). My study may help to create a better understanding of advanced cancer patients' experiences and medical decision-making while experiencing FT.

Purpose of the Study

The purpose of this qualitative case study was to understand the experiences of advanced cancer patients who are under financial distress and FT to understand how OOP cancer care costs impacted these patients' experiences and decision-making. The study focused on understanding how patients feel and think while experiencing FT and making decisions about their care. Knowledge about how FT impacts patients' experiences and decision-making may be used to develop strategies to address the declines in health outcomes and decreased quality of life for patients with FT.

Research Questions

Several research questions guided this research:

1. What was the experience of advanced cancer patients who experienced financial distress stemming from OOP costs of the disease treatment?
2. How did financial toxicity manifest in patients’ lives, and how did patients use gist and verbatim as they made medical decisions?
3. How, if at all, did financial toxicity factor into treatment decisions in patients with advanced cancer?

Theoretical Framework

I used fuzzy trace theory (FTT), a cognition theory proposed by Reyna and Brainerd (1995), as the theoretical basis for exploring advanced cancer patients’ experiences and decision-making while experiencing FT and financial distress associated with treatment. This theory explains how patients may use mental shortcuts or heuristics and gist, which are core mental conceptual representations of an idea or concept, in making risky medical decisions (Reyna & Brainerd, 2011). The theory also provides an explanation for how the use of cognitive approaches can lead to bias (Reyna & Brainerd, 2011). Reyna et al. (2015) applied FTT to cancer decision-making and underscored how adults develop their reliance on gist-based decision-making. Reyna et al., (2015) use FTT to understand how advanced cancer patients create meaning in challenging, risky, and stressful decisions.

Nature of the Study

The research design was a qualitative case study. A method should fit with the researcher’s proposed research questions and subject of inquiry (see Creswell, 2013). A case study design was an appropriate choice because it was consistent with gathering the patients’ perspectives and gaining an in-depth understanding of their thoughts, underlying considerations in decision-making, and experiences. Case study research creates an deep understanding of a person’s or group’s experiences and lives; the case study includes in-depth observations and understanding of respondents’ perspectives using secondary artifacts and data collection means (see Creswell, 2008). I used in-depth interviews triangulated with secondary data to answer the research questions.

To ensure protection for the research respondents and to gain access to an appropriate sample of individuals, a researcher must identify a recruitment and access strategy and pass the institutional review board (IRB) evaluation and approval process (HHS, n.d.). Researchers use these processes to ensure that the study does not harm the participants and that their privacy is protected (HHS, n.d.). Researchers cannot contact a vulnerable population such as advanced patients without first gaining access to the patients either via their health care provider or some other means. Before contacting patients, researchers must create an informed consent form that details the key reasons for the study, the potential benefits of participation, the potential risks, and the assurances of confidentiality (Patton, 2015).

The size of the sample should be consistent with the method (see Creswell, 2013), and interviews should be conducted and data analyzed until a point of saturation or consistency is met (see Patton, 2015). I determined that 12 in-depth interviews with patients, supplemented with secondary data artifacts, would be a large enough sample to answer my research questions. To access potential participants, I approached a community oncology practice in Colorado. Physicians own these practices, and their consent and support required a second IRB approval process.

Definition of Terms

Advanced cancer: Cancer that has spread from its primary origination site or organ to nearby or distant organ sites; treatments generally focus on controlling the growth of these cancers and are not curative (NCI, 2015).

Biological therapy: A large-molecule therapy that is grown in a living cell line in a biotechnology production center and is infused to treat a disease (Morrow & Felcone, 2004).

Cancer: A collection of associated diseases having unmitigated cellular growth in which the cells invade from a tumor site to nearby tissues or distant organs (NCI, 2015).

Chemotherapy: A form of treatment that may be given as an injection, infusion, or oral treatment to destroy targeted cancer cells (NCI, 2015).

Copayment: A form of cost sharing in a health insurance plan that requires the patient to pay a flat dollar amount to the provider who is rendering a service at the time the service is given (KFF, 2016).

Cost: Resources or dollars spent directly or indirectly to attain a good or service (NIH, 2007).

Deductible: The dollar amount of covered services that a consumer must pay before the insurance will begin to pay for covered services (KFF, 2016).

Direct cost: Resources spent for the prevention or provision of health care services (NIH, 2007).

Disparities: Inequalities that result when one group does not enjoy the equivalent health benefits or health status as another group (NIH, 2007).

Financial toxicity (FT): The financial burden caused by OOP costs and the financial distress that it can cause patients and their families. FT is associated with lower adherence to therapy, poorer quality of life, and potentially worse health outcomes, including lower survival (Zafar & Abernethy, 2013a).

Gist: The mental process of organizing facts and concepts into a simplified and core set of mental representations (Reyna & Brainerd, 1995).

Health literacy: An ability to read, assess, interpret, and understand health-related concepts and constructs so a person can function in a health care environment as a patient (Morris et al., 2013).

Infused therapy: A drug or biologic treatment that is provided to a patient via a venous port or needle, typically delivered slowly over a period of an hour or more and may be administered in an outpatient setting (NCI, 2015).

Medicaid insurance: A state and federal jointly run health insurance program for low-income Americans (Shi & Singh, 2011).

Medicare insurance: A federal governmental insurance program for Americans age 65 and older or those qualifying via disability (Shi & Singh, 2011).

Metastatic cancer: A cancer that has spread from its original site to nearby tissues or distant organs. This can also be referred to as advanced cancer (NCI, 2015).

Out of pocket costs (OOP): Direct costs borne by a patient for the provision of health care services and are not covered by insurance (Gordon, Merollini, Lowe, & Chan, 2016).

Patient Assistance Program (PAP): A program to provide free drug supply to uninsured or underinsured individuals as part of a pharmaceutical company's philanthropic effort to improve access to their products (Fein, 2017; Zafar & Peppercorn, 2017a).

Quality of life: A measure of several dimensions of well-being and health including emotional, psychological, and physical measures (NIH, 2007).

Radiation therapy: A form of treatment in which high energy beams of radiation are targeted and delivered to destroy cancer tumors (NCI, 2015)

Tumor stage: The categorization of the size, extent, and presence or lack of presence of metastasis of the initial cancer tumor at diagnosis. A cancer is staged at initial diagnosis, and even if it worsens or improves, the tumor staging categorization does not change (NCI, 2015).

Assumptions

There were several assumptions that I acknowledged prior to the beginning of this study. First, I assumed that advanced cancer patients who are undergoing treatments for their cancer want to access care that extends their survival while balancing the risks and adverse effects of that care. I also assumed that patients can self-identify the distress that FT causes them and can describe what they consider when making medical decisions. Finally, I considered that patients may be reluctant to participate in the research if they believe that discussing financial concerns, limitations, or FT could make their physician less likely to treat their cancer or impact the care that they receive in any way.

Scope

The scope of this study was advanced cancer patients’ experiences, perceptions, and decision-making about cancer treatments while experiencing FT. The study provided perspective from patients, an area of research where there were little data. Researchers and cancer care providers may be better able to develop strategies and support programs to address the specialized needs that patients with FT have if providers have more understanding of the patient perspective.

Delimitations

I chose to delimit the research with advanced cancer patients from several dimensions. First, I included only adults older than 18 years because children may not have similar experiences with financial responsibility or FT. I explored the patient experiences in decision-making and living with FT and cancer, but I did not seek to demonstrate health outcomes associated with FT or measure the clinical impact of adherence to prescribed therapy. These may be important dimensions for additional research, but this study was not designed to address these outcomes.

An important delimitation was the setting for the study. I recruited and interviewed cancer patients who were receiving care in a community-based ambulatory setting, not those receiving care in a hospital. Although several of the patients were unwell during the interview, they were not critically ill or impaired to the extent that their communication and conversation was impeded. The research was also limited to cancer patients with some form of health insurance who were experiencing FT. This was a subpopulation of people for whom there is a paucity of published research relating to their experiences with FT.

Limitations

There were several limitations that stemmed from the qualitative case study method and from me. First, the research method included in-depth interviews during which I asked patients to describe their thinking, decision-making processes, and experiences after the fact. This may have introduced bias as the patient sought to recall the previous situation and thought processes and articulate them for me. What the patient felt and thought at the time may have been altered by the time that elapsed or by additional experiences that influenced how the patient recalled and described a particular decision or experience (see Patton, 2015).

I was an important part of the research because it was my job to develop trust during the interview with the patient, synthesize the findings, interpret them, and report on them as objectively as possible (see Janesick, 2011). I did not have first-hand experience as a cancer patient, so I may have misinterpreted the participants’ meaning and may have inadvertently added my own bias. To guard against this, I identified my biases as best I could, and during the research and analysis phases I attempted to insulate the work from my biases. Another limitation of the study was that findings are not generalizable to the entire population of advanced cancer patients with FT. The sample size was small and limited to cancer patients who were well enough to have ambulatory care and who had health insurance.

Cancer is a collection of many subforms of the disease, and the treatment experience, costs, side effects, and intensity of care varies widely between the many types of cancer. This study included cancer patients with different forms of the disease such as breast, colon, prostate, or lung, and this variety impacted the patient experiences and costs. Moreover, the variety of cancer types led to a variety of experiences and decision-making criteria that could have complicated interpretation of the data and achieving saturation of data.

Significance

This study focused on understanding patients’ perceptions and decision-making while experiencing FT, a phenomenon that is increasing in scale and scope for cancer patients (Zafar, 2016). FT erodes a patient’s access care and it decreases his or her quality of life (Barber, Bensen, Snavely, Gehrig, & Doll, 2016; Delgado-Guay et al., 2015). To eliminate barriers to care and decrease disparities in cancer outcomes, access to standard services and support of a patient’s psycho-social needs for decision-making must be considered.

Using FTT, I sought to understand how gist and verbatim are intertwined in decision-making for patients with FT, and the ways in which health care providers and health care systems may better support patients and reduce barriers to care and improve quality of life. The knowledge gained from this study may help policymakers and health care administrators understand patient reactions and decisions to improve access to care and to support quality medical decision-making.

Summary

Although tremendous advances in cancer care have extended lives and improved outcomes, FT has emerged as a major challenge to care provision in the United States (Carrera et al., 2018; Head, Harris, Kayser, Martin, & Smith, 2018). There are over 14.5 million cancer patients in the United States (NCI, 2016b), and despite access to insurance through both governmental and private sources, the costs of cancer care to individuals is increasing so substantially that is the leading cause of medical bankruptcy (Ramsey et al., 2013) and increased mortality (Ramsey et al., 2016). A major priority of the IOM and other major professional societies is to reduce the impact of FT and the disparities in outcomes that it produces (IOM, 2009; Meropol, 2009). Research on this challenge and the physician perspective is available, but there is little known about how patients experience FT and make decisions about their care while under duress. I sought to understand the advanced cancer patient perspective and decision-making while experiencing FT.

In Chapter 1, I provided a summary of the challenges in cancer care, including how FT is contributing to access and disparities in care and outcomes. I addressed the theoretical basis for the inquiry and outlined the methodology, constraints, and assumptions of the study in Chapter 1. In Chapter 2, I review the current literature on FT and define the need for the study. Chapter 3 presents a detailed overview of the methodology used to conduct the fieldwork, analyze the data, and support conclusions from the study to answer the research questions. Chapter 4 provides an in-depth discussion of the research findings, and Chapter 5 provides analysis, interpretation, and conclusions from the research. Further, I recommend additional research that may flow from the study conclusions, and provide insights into the implications for social change.

Chapter 2: Literature Review

Metastatic cancer patients have to battle the disease from at least two perspectives. First, they must physically and emotionally fight cancer, and second they must cope with paying for their OOP costs of care created by treatment. Both of these battles create mental distress (Delgado-Guay et al., 2015). Therapeutic approaches and early diagnosis are improving cancer patients' chances of survival, but there are significant costs associated with treatment and care (CDC, 2010). New therapies are extending patients' lives: FT is an unintended consequence of these therapy advances (Meropol et al., 2009; Meropol & Schulman, 2007; Tangka et al., 2010; Zafar & Abernethy, 2013a). FT is a term that researchers define as the strain and distress borne by cancer patients as a result of coping with perceived high OOP costs for therapy and loss of income resulting from reduced participation in the workforce (Ubel et al., 2013; Zafar et al., 2013; Zajacova, Dowd, Schoeni, & Wallace, 2015). The impact of FT is significant and extends beyond the mental health and financial aspects of the disease (Carrera et al., 2018; Chatterjee et al., 2017; Head et al., 2018).

Cancer Costs Can Reduce Access for Patients

The costs of cancer care can be high, and cost sharing for the consumer is significant in many insurance plans, resulting in many patients, both insured and uninsured, being unable to afford the costs for cancer care (Jagsi et al., 2014; Zafar et al., 2015). New infused biologic therapies can cost over $150,000 per year, in addition to the costs of diagnostic testing and imaging, radiation therapy, doctor visits, and hospital care (Newcomer, 2012; Seiden, 2016; Staton, 2014). The costs of drugs and testing have increased, and insurance products have changed to shift more costs on the consumer, with high deductibles and the requirements for patients to pay coinsurance versus flat copays for many medical services (Goldman, Joyce, Lawless, Crown, & Willey, 2006; Lo Sasso, Helmchen, & Kaestner, 2010; Wharam, Ross-Degnan, & Rosenthal, 2013). As these costs increase, cancer patients are bearing a significant portion of the costs, called OOP, which can ultimately reduce their access to services if the patients cannot afford the services and elect not to receive them (Himmelstein, Thorne, & Woolhandler, 2011).

For patients fighting cancer, there are many OOP costs to pay. There is the cost of surgeries and hospitalizations, OOP costs for both medical services and prescription drugs, coinsurance payments for medical imaging, and radiation treatments. Other indirect costs such as loss of income from time away from work, transportation, or child care costs also impact patients (Chang et al., 2004; Tsimicalis et al., 2013). A diagnosis of cancer typically will reduce a patient’s ability to work, further reducing income and the ability to afford the costs of care (Meropol & Schulman, 2007; Zajacova et al., 2015).

Inflation in the cost of health care services has eroded real income gains for most Americans over the last decade, which decreases patients’ ability to afford OOP costs (Auerbach & Kellermann, 2011). Additionally, cancer disproportionately affects older Americans who generally have more limited incomes after retirement and cannot afford extra costs (Davidoff et al., 2013). Although Medicare and Medicare supplemental insurance can afford these patients with more protection from OOP costs, cancer patients are bearing more costs than patients with other diseases. As a result more of these patients are falling into medical debt, which can lead to bankruptcy, loss of homes, and severe distress, all of which can limit the ability to have the social and physical support necessary to fight a difficult disease (Davidoff et al., 2013; Himmelstein et al., 2011; Ramsey et al., 2013).

For many cancer patients, insurance no longer holds the protective effect it had a decade ago; the OOP costs of cancer care are resulting in FT for patients (Zafar & Abernethy, 2013a). FT is the mental and physical distress that is felt by cancer patients who are coping with both the disease and the impact of the OOP costs of the disease treatment. Factors such as race, low socioeconomic status, and the ability to afford care (even with insurance) are linked to poorer outcomes, worse quality of life, and greater risk of mortality in cancer patients (Delgado-Guay et al., 2015; Khera, 2014; Ramsey et al., 2016; Ubel et al., 2013). Researchers are working to characterize, report, and grade the factors that are creating disparities in cancer care so that appropriate strategies may be developed to combat them (de Souza et al., 2014; Khera, 2014). A cancer diagnosis is one of the leading factors in predicting medical bankruptcy (Ramsey et al., 2013). New data published by Ramsey et al. (2016) indicated that cancer patients who experience severe FT resulting in bankruptcy have significantly higher mortality rates than those who are more protected from costs, after controlling for potentially confounding factors such as age, gender, race, severity of disease at diagnosis, and tumor type. FT can worsen a patient’s likelihood to survive cancer.

Sometimes there is help available to patients who have large OOP costs to pay for care and who, despite their insurance coverage, cannot afford care. This assistance comes from foundations that provide financial grants to qualified individuals (Rajurkar, Presant, Bosserman, & McNatt, 2011; Zafar & Peppercorn, 2017a; Zullig, Wolf, Vlastelica, Shankaran, & Zafar, 2017). Patients also may qualify for free drugs or reduced copays via patient assistance programs or copay card programs. Although these programs can be extremely helpful for some patients, not all who need help will qualify, and many programs exclude federally funded Medicare and Medicaid patients due to anti-kickback legislation (Nicolla, Friedman, Manners, & Zafar, 2017; Zafar, Peppercorn, Asabere, & Bastian, 2017; Zafar & Peppercorn, 2017b).

The emotional strain and distress of FT can be severe; Delgado-Guay et al. (2015) found that 30% of advanced cancer patients rated the financial stress resulting from their disease as worse than the physical symptoms, the emotional distress, and the family distress. FT can cause deep emotional anguish for cancer patients and their families. Although researchers are beginning to understand the depth of the problem for patients, little is known about how patients make decisions while under stress from FT.

Use of Decision-Making Theory in Cancer Decisions

Reyna, Nelson, Han, and Pignone (2015) used FTT to explain how cancer patients made decisions involving complex treatment options. This work included important dimensions of regime safety and efficacy and gave a solid perspective on how patients apply gist and other recall mechanisms in this decision-making. Gist is defined as the individual’s ability to distill a complex concept into an essential qualitative conceptual block of information that may be ordered into hierarchical frames of reference for decision-making (Reyna & Brainerd, 1995). No researchers have explored how a third dimension of decision-making, OOP costs and the financial distress that these cause, can influence how patients make decisions.

My study focused on understanding advanced cancer patients’ medical decision-making while experiencing FT. I applied FTT as a theoretical construct. In addition, I examined how cancer treatment impacted patients’ financial stability and the extent to which OOP costs have contributed to distress in their lives. In Chapter 2, I provide a review of the literature on FT and the decision-making theory, FTT.

Purpose of the Research

The purpose of the study was to understand the experiences of advanced cancer patients who are under financial stress and to understand how cancer care costs impacted patients’ experiences and decisions. FT is a growing area of oncology research; however, most of the literature published to date addressed the size and scope of FT (de Souza et al., 2014; de Souza & Wong, 2013; Delgado-Guay et al., 2015; Jagsi et al., 2014; Khera, 2014; Zafar et al., 2013). These researchers used a quantitative methodology to examine patient expenditures and measure associated distress experienced by patients. Few researchers studied patient experiences, decision-making, and thought processes of patients under financial duress in the United States. These experiences and the decisions that patients make during times of stress impact not only the patient’s cancer journey, but also the costs that the family bears.

Literature Search Strategy

The literature on FT and OOP costs in cancer is still emerging. Zafar and Abernethy (2013a) coined the phrase, financial toxicity, and they detailed the complex emotional and physical distress that FT caused. They stated that the distress caused by OOP costs in cancer care was so great that it deserved to be named and managed as aggressively as the other major adverse events or toxicities of cancer treatment (Zafar & Abernethy, 2013a). Other researchers examined the cost borne by patients, including loss of income and total costs of care including ancillary costs, but these researchers did not link these to financial toxicity. Some of these studies included focused subpopulations such as patients with colon cancer, breast cancer, renal cell carcinoma, and other tumors. The search terms that I used for this study focused on the foundational literature on costs of care, total costs, and the economic impact of cancer on patients and families. The search also included the terms *financial distress* and *financial toxicity*. I combined these search terms with *cancer*, *metastatic*, and *oncology*, and I included searches for *medical bankruptcy* and *cancer*. I attempted to limit all searches to articles published in 2010 or later.

I also searched for journal articles that included a qualitative methodology to investigate patient's experiences with costs and cancer care. To identify qualitative methodologies for investigating FT in cancer, I searched the terms *qualitative research* and *cancer costs, case study* and *cancer costs*, *cost* and *case study in cancer*, and a combination of *insurance, cancer,* and *qualitative study*. To identify the relevant literature on FTT, I searched *FTT* and *cancer*, *FTT* and *gist, decision-making in cancer, gist in cancer decisions*, and *heuristics in patient cancer decisions*.

I used the Google Scholar search engine and Walden University's databases. I also searched industry databases including the American Society of Clinical Oncology

(ASCO) publication databases and those of the Kaiser Family Foundation to identify additional sources of evidence. These databases were extensive and returned consistent literature for the key terms searched. To ensure a complete literature review, I examined the reference lists of recently published work and checked key terms that were listed in the online versions of articles to see if I had missed any relevant journal articles.

Theoretical Foundation

I used FTT to support the investigation. FTT helps researchers explain how two decision-making processes (verbatim and gist) work in tandem, and researchers applied it to help explain how people make decisions in medical and health related contexts (Reyna & Brainerd, 1995; Reyna et al., 2015). Verbatim refers to the precise encoding of information such as numbers, risk ratios, or other facts that humans can recall and apply in a logical way to sort through a decision (Reyna & Brainerd, 1995). Verbatim is generally used when a situation calls for factual precision. Gist is a process in which people construct essential concepts and remember these key qualitative features and functions of information to use efficiently and logically in decision-making (Reyna & Brainerd, 1995). FTT includes the approaches from previous decision-making theory. Researchers applied the constructs of why and how people are imperfect decision-makers and how decision-makers apply many shortcuts and have weaknesses in information processing that may yield inconsistent decisions and less than optimal choices, particularly under stress (Reyna et al., 2015). In health care decision-making, researchers found that people use heuristics, make inconsistent estimates of risk, and lack training and application experience when using numbers, statistics, and numerical relationships to make decisions (Peddie et al., 2012; Peters, McCaul, Stefanek, & Nelson, 2006). These factors reduce the effectiveness of decision-making by people (Puts et al., 2015).

FTT and Cancer Decisions

When patients with cancer face decisions about their therapy choices and end-of-life options, these are important decisions that can produce life-changing consequences. For example, a breast cancer patient may need to select between options involving postsurgical drug therapy, and each option has significant potential adverse effects (Zikmund-Fisher, Fagerlin, & Ubel, 2008). These decisions involve trading potential high-risk side effects for higher probability of cure, duration of therapy, or period of remission (Reyna et al., 2015). Reyna et al. (2015) found that patients making therapy choices use gist to recall and process risk information and apply it as a flexible and efficient process to evaluate alternatives. The gist of the risk, not the verbatim numerical representation of the risk, is how cancer patients encode the options available to them and process the information in decision-making. Reyna et al. (2015) also observed other factors that could mediate these decisions. Patients often must apply their morals and judgment in the situation, making choices that are consistent with their values. In these cases, patients’ gist is infused with emotional and moral considerations and is accessed by memory and processed efficiently in decision-making (Reyna et al., 2015). The fuzzy nature of applying conceptual frameworks is the foundation of the FTT.

Researchers found that the recommendations by physicians are some of the most important influencers in patient decision-making in cancer (Puts et al., 2015). The significant influence of physicians in cancer care increases the importance of the patient’s assessment and decision-making based on physician recommendations. Applying FTT to the examination of physician recommendations and patient decision-making, researchers found that patients will listen and encode or remember key conceptual gist representations from their discussions with physicians about treatment options. Rarely are verbatim data recalled by patients; instead, patients hold imprecise gist representations of their options as presented by their physicians and use these as flexible and simple building blocks accessed by their memory and imbued with emotion and moral judgment to make choices (Reyna & Brainerd, 1995; Reyna et al., 2015).

The U.S. Preventive Services Task Force (USPTF) recommendations for breast cancer screening list the need to tailor evidence based recommendations to individual patient's situations (USPSTF, 2016). Helping patients to understand their risk, especially for those patients with low health literacy or lower understanding of comparative risk information, was significant to cancer decision-making and FTT (Reyna et al., 2015). Although decision-making in cancer used data and recommendations from trusted sources, patients with cancer made decisions that were emotionally charged. For those with cancer, there was a high degree of emotion during decision-making. Patients also had to make projections of preferred states of emotional well-being. These two elements form the decision-making process called dual processing (Reyna & Brainerd, 2011). Dual processing decision-making is a way to synthesize the emotional and cognitive aspects of how patients approach a decision. FTT uses these decision-making approaches and the theory includes moral values and mental shortcuts of verbatim and gist. FTT also provides researchers with a way to explain how patients mentally interpret statistics associated with a proposed decision’s risk. Researchers showed that FTT used the two processes of decision-making, but extended cognition and emotion by adding the elements of gist and verbatim (Reyna & Brainerd, 2011).

The concepts of gist and verbatim stemmed from research in psychology and developmental linguistics (Corbin, Reyna, Weldon, & Brainerd, 2015). Verbatim and gist worked together like two ends on a scale. Exact recall, verbatim, is on one end of the scale. Gist, a simple, bottom-line, essential meaning of a concept, is on the other end of the scale. People remember gist and verbatim in context to a person’s entire experience, including culture and emotions. As one develops and gains experience, researchers found that gist was important to making risky medical decisions because gist can help one discern between various states of risk (Reyna & Brainerd, 2011). When applied to complex decision-making such as in selecting between treatment options in cancer, decision-makers used gist to give meaning to the options and distill the most important elements relative to that individual. These processes occurred in a fuzzy, inexact manner as the patient ordered his or her gist representations of the states of risk (Reyna & Brainerd, 1995; Reyna et al., 2015) Retrieval and use of gist is a core process that patients use in cancer decision-making by applying their essential feelings and choices between therapies or actions given their situation. Researcher have also applied FTT to cancer decision-making and risk communication strategies (Brewer, Richman, DeFrank, Reyna, & Carey, 2012). The researchers studied how patients made decisions when presented with complex future risks such as the potential for development of breast cancer for those women who carry genetic mutations. In this evaluation, researchers prepared a series of vignettes describing the risk of developing cancer and surveyed women who had undergone testing to understand their comprehension of risk (Brewer et al., 2012). The study results showed that women rely on gist in applying genetic testing results to the likelihood of developing breast cancer. The researchers found that simpler graphics depicting risk were better accepted by patients and improved decisions by patients (Brewer et al., 2012). This approach fits with the use of fuzzy gist representations. It was shown to assist patients with making sound risk-based decisions because providing incremental verbatim information to patients was less helpful in patients' decision-making.

When selecting therapy options, patients with cancer can become overloaded with verbatim facts and risk ratios, which reduces the efficacy of decision-making, especially when stress and emotions are high (Reyna et al., 2015). When patients use online therapy risk decision tools, such as one for selecting adjuvant therapy in breast cancer, Zikmund-Fisher et al. (2008) found that simplified graphics support use of gist decision-making and improved patients' understanding of the risks. These studies demonstrated the utility of gist in helping patients to make therapy decisions in cancer. The use of FTT was also established in other medical decision-making processes including vaccination decisions and health prevention activities.

Use of Fuzzy-Trace Theory in My Study of Financial Toxicity

The FTT theory fits my study of how FT impacts cancer patients' decision-making when there are risk and efficacy options for consideration. Researchers studied FTT in a several applications of medical decision-making including cancer and found

FTT to be reliable and valid (see Reyna et al., 2015). These studies showed that by including verbatim and gist, researchers may better understand how patients made life-changing decisions. While these researchers have reliable knowledge of the application of FTT to cancer patients' decision-making, none examined how OOP costs and FTT may create gist that are not discussed in risk communications but are important to patients in their decision-making.

I applied FTT to evaluate advanced cancer patients' perspectives with fuzzy gist in medical decision-making and how FT impacted these choices. My study showed how FTT can extend to include verbatim costs and how financial costs can be risks that patients consider in decision-making. The research may extend knowledge to identify how FT may be incorporated into decision support tools. This may help patients who are experiencing financial distress to make better decisions while undergoing cancer treatment.

Literature Review Related to Financial Toxicity

Cancer was a top cause of mortality and a major cause of overall health care spending due to the increases in incidence, prevalence, and costs of care in the United States (Mariotto, Yabroff, Shao, Feuer, & Brown, 2011). Epidemiologists expect the total costs of cancer care to increase by approximately 40%, exceeding $173 billion by 2020. Innovative new drugs have higher costs than older chemotherapy (Howard et al., 2016; Mailankody & Prasad, 2015). Over the last decade, new biotechnology drugs entered the market with higher prices compared to previous periods with the average cancer drug costing about $100,000 per year (Mailankody & Prasad, 2015). At the same time, there were advances in radiation technologies and imaging that increased overall costs of cancer care (Lievens & Grau, 2012; Nguyen et al., 2011; Patel et al., 2016). Community oncology practices began to join the hospitals which increased the cost to deliver the same care in communities around the United States (Association of Community Cancer Centers, 2013). Drug costs increased; radiation and imaging technology improved, but increased costs of radiation treatment and more patients were treated in higher cost hospital outpatient settings. These all increased the total cost of care and the OOP cost to cancer patients.

In response to these and other costs, employers and public insurers made changes to the design of insurance products, which shifted more of the risk to the individual and increased patient cost sharing (Lo Sasso et al., 2010; Samuel, Raleigh, Hower, & Schwartz, 2003; Wharam et al., 2013). Physicians and public health advocates voiced a new concern about the ability of the cancer patients to afford care and the concept of financial distress emerged, particularly in cancer patients (KFF, 2006).

Cancer Disparities Exist

In cancer care, there are health outcome disparities and lack of access to nationally recognized standards of care. People of color, those of lower socioeconomic status and lower health literacy, and those without health insurance consistently have less access to cancer standards-of-care, early detection, and, as a result, have poorer survival (Freedman et al., 2011; IOM, 2009; Parise & Caggiano, 2013; Walker et al., 2014). While cancer is a disease that affects all types of people irrespective of gender, age, race, or socio-economic status, there are distinct disparities in cancer outcomes despite efforts to increase access and reduce barriers to screening (Freeman & Rodriguez, 2011; R. Siegel et al., 2011).

Disparities in cancer outcomes stem from many factors including lack of access to services (Freeman & Rodriguez, 2011). Other barriers to care stem from language, lower health literacy, and cultural barriers to routine health screening services. Those without access to routine prevention and screening are more likely to have cancers diagnosed at later stages of disease when the disease is more advanced and has spread to other parts of the body (Parise & Caggiano, 2013). The treatments for late stage cancer are more intensive, invasive, and can have significant health and financial consequences to the patient (Freedman et al., 2011; Walker et al., 2014). Researchers have identified the complex interplay of factors that increase mortality in cancer; those who more money, more education, better insurance, and are white, generally have more favorable outcomes that those who are not part of those groups (National Academies Press, 2009; R. Siegel et al., 2011; Walker et al., 2014).

In cancer, lower socioeconomic status and lack of insurance are key factors contributing to poorer health outcomes (Bittoni, Wexler, Spees, Clinton, & Taylor, 2015; Bleyer, Ulrich, & Martin, 2012). When controlling for other factors including tumor site, size, and stage, researchers found that those without insurance and with lower incomes, had more mortality and shorter survival. For people who have lower incomes, there is a high correlation to having Medicaid insurance. Medicaid insurance is a notoriously low paying insurance plan for doctors and hospitals and many providers refuse to accept Medicaid (Bittoni et al., 2015; Walker et al., 2014). When few specialists in an area accept the plan, it creates access barriers for patients with Medicaid. Cancer patients with private or Medicare insurance have more financial protection because the insurance insulates them from some of the OOP costs associated with care and does not require a means test to qualify for it (IOM, 2009).

Cost Can Decrease Compliance to Therapy

A deeper understanding of financial distress caused by cancer treatment costs led researchers to investigate the correlation between costs and treatment compliance and outcomes. Researchers began to study the impact of OOP cost on adherence and patient concordance with prescribed regimens, in particular, in patients who were prescribed oral therapy treatments requiring daily medication ingestion at home (Eliasson, Clifford, Barber, & Marin, 2011; Gebbia, Bellavia, Ferraù, & Valerio, 2012; Hede, 2009; Verbrugghe, Verhaeghe, Lauwaert, Beeckman, & Van Hecke, 2013). Investigators found that patients did not comply with oral therapy regimens in cancer care and this effect was more pronounced amongst older patients and those who experienced side effects (Verbrugghe et al., 2013). Hede (2009) found that the costs and complexities of oral cancer therapy decreased compliance in cancer patients. Patient cost was cited as a contributing factor, but Verbrugghe et al. (2013) and Hede (2009) called for more qualitative research to explore why and how patients think about these regimens and their decisions to act in concordance with their physicians' prescriptions for care.

Relationship Between High OOP Costs and Distress

As the evidence mounted on the impact of financial distress, researchers began to focus their work on quantifying and qualifying the costs that were borne by patients, and to the extent possible, identifying compliance challenges and other accommodations or deprivations made by patients and their families. FT can cause severe emotional distress and this can lead to poorer outcomes as patients continue therapy and accrue higher debt. Delgado-Guay et al. (2015) reported that in a cohort of advanced cancer patients, greater than 30% believed that the stress caused by their cancer cost was more severe than other disease-related stress including their family’s reactions and distress, their symptoms, and their personal emotional reaction associated with the disease.

Impact of Insurance, Age, and Race on OOP Costs

There is a correlation between insurance status and the affordability of cancer services in specific cancer types and by insurance type. (Weaver, Rowland, Bellizzi, & Aziz, 2010). Weaver et al. (2010) found that lack of insurance increased the likelihood of patients bearing significantly higher OOP costs. In gastric cancer, for example, patient costs exceeded $40,000 over approximately 50 days for first -line therapy and were similar for subsequent lines of treatment (Hess et al., 2015). In a cohort of racially diverse early stage breast cancer survivors, Jagsi et al. (2014) found that greater than 15% of the cancer patients experienced personal financial costs greater than $5,000 and 12% of survivors were managing debt four years post-diagnosis. Women of color, Latinas and Blacks, were more likely than those who were White to experience a degradation of the ability to pay for essentials of life such as rent or food (Jagsi et al., 2014). Younger patients who are working full-time and are then diagnosed with cancer experience greater distress compared retirees. For younger patients, treatments can interfere significantly with patients’ ability to provide income for their family (Gordon et al., 2016). This leads to significant distress and more privation. In a study of Medicare patients with private supplemental and Medicaid insurance, more patients with private insurance received chemotherapy treatment consistent with national guidelines than those with Medicaid supplemental insurance, a lower paying plan (Warren et al., 2015). Because of these studies and other large reviews of costs of care and impact on cancer outcomes, professional associations formed committees to respond to the challenges that OOP costs were creating for patients (Goss et al., 2009).

In 2009, the ASCO issued a statement focusing on elimination of disparities of care within cancer, including reductions in financial barriers for patients (Goss et al., 2009). The study identified that racial disparities exist that documented poorer outcomes for Blacks and Hispanics, but these are exacerbated when the patient is underinsured or uninsured. In 2015, ASCO issued a list of diagnostic services and interventions that oncologists should avoid to prevent high costs with low clinical utility (Schnipper et al., 2015). This effort to focus on preventing use of low utility services does not address the OOP costs for services that do have utility. Cancer care costs were increasing, patient OOP spending for care was mounting, and patients were experiencing financial, emotional, and health-related distress. Rather than focus on measuring these costs, some health scientists began to study the effect of prolonged exposure to OOP costs and the resultant distress. A new concept in cancer care emerged, FT.

OOP Costs Lead to FT

FT emerged as an important consideration for oncologists in managing cancer patients (Zafar & Abernethy, 2013a). Through the use of quantitative data analysis, industry and professional association studies demonstrated that costs of cancer care are increasing and the patient OOP portion are becoming significant.(Mariotto et al., 2011; Schnipper et al., 2015; Tangka et al., 2010) In addition, researchers correlated cancer costs, FT and decreased mental and physical well-being (de Souza & Wong, 2013; Delgado-Guay et al., 2015; Smith, Nicolla, & Zafar, 2014; Timmons, Gooberman-Hill, & Sharp, 2013; Tsimicalis et al., 2013).

The patient voice began to emerge around the experience of living with FT. Researchers published on OOP cancer costs and the impact on well-being, financial stability and the trade-off between cancer care and essentials of living including home mortgage payments, food, clothing, and children’s education cost. Head et al. (2018) found that cancer survivors applied a series of coping strategies to adapt to the financial consequences of cancer costs. Delgado-Guay et al. (2015) used interviews and self-reported surveys with cancer patients receiving care in a public hospital and a private for-profit hospital to assess both the presence of FT and its associated distress. This mixed method research study identified that patients treated in the public hospital were far more susceptible to the physical and emotional impacts of FT than those who had insurance that enabled them to seek care in a private cancer center. In another study, the 30% of cancer survivors who experienced FT had lower quality of life, higher rates of depression, and the worry of cancer recurrence was worse for these individuals (Kale & Carroll, 2016). While measuring the distress with scales was important, other researchers delved into the qualitative aspects of cancer and FT.

Ó Céilleachair et al. (2012) researched the impact of FT on newly diagnosed colorectal cancer patients in Ireland and found that the emotional impact of the disease to be equally stressful as the financial impact. They found that the stress of the cost of the disease reduced the cancer patients' ability to cope well with the disease. Ó Céilleachair et al. (2012) concluded that the emotional impact of colorectal cancer and the financial impact were intricately intertwined; there is the potential for one to worsen the other. The authors concluded that family relationships and support, and a strong self-caring approach by the patient, can mitigate the exacerbation of these factors (Ó Céilleachair et al., 2012). While this study provided insights into the inter-relationships of financial and emotional health in colorectal cancer patients, it did not focus on decision-making around privations or other considerations.

In 2013, de Souza & Wong (2013)(2013) published a review of the reasons for the emerging financial burdens that cancer patients were experiencing including higher costs for emerging treatments, shifts in insurance products that expose consumers to higher cost sharing, and imaging. They defined the term *financial distress*, *financial toxicity*, and *financial burden* as the terms that the oncology community used to refer to a patient's experiences when treatment costs consume a high proportion of income (de Souza & Wong, 2013). Using other disease states as metrics, de Souza and Wong (2013) estimated that if a patient were to spend greater than 20% of their income on OOP costs, the patient could be termed as experiencing FT. These authors linked FT to poorer health outcomes including skipping drug doses and indicated that a dearth of quantitative metrics of FT hindered better understanding of the implications on patients and outcomes. A year later, (de Souza et al., 2014) began to publish early results from the development of a validated instrument that would help assess the patient outcomes associated with quantitative measures of the costs borne by the patient.

Evaluation of how care givers, health professionals, and patients were coping with FT is important. The amount of OOP dollars and its proportion to total income may be less relevant to those with low income or greater financial responsibilities to children and family since these patients may experience the same amount of financial OOP cost to be far more distressing than others (Timmons et al., 2013). Timmons et al. (2013) used semi-structured interviews with oncology social workers and advanced cancer patients in Ireland to identify the strategies that these patients used to cope with financial distress and to understand how decisions were made about coping with the distress and tradeoffs that the families made to afford care. They uncovered that patients made behavioral changes to reduce spending and cope with lower income and higher costs while trying to protect children from deprivation. The emotional stress and distress reported was a strong indicator that despite a public and private insurance system in Ireland, most cancer patients are experiencing financial distress in addition to coping with disease. Timmons et al. (2013) describe that patients make decisions about reducing costs of care by staying home instead of going to the clinic when experiencing side effects from the medication. Patients reported delaying treatments until insurance is secured and reducing use of beneficial medications due to costs. Each of these causes distress, but patient reported the financial distress stemming from increasing costs were not as important to them as taking these actions. The development of the COST tool by de Souza et al. (2014) was an important milestone since it marked the first cancer specific measure to assess patient-self-reported costs and FT. Researchers published studies linking worsening health outcomes for cancer patients experiencing FT (Delgado-Guay et al., 2015; Kale & Carroll, 2016; Ramsey et al., 2016). Researchers reported that breast cancer patients with high deductible plans could be personally liable for $55,000 of costs and that a Medicare colorectal cancer patient might have an $8,800 OOP cost for a single course of biotech drug therapy (Ubel et al., 2013) Ubel et al. (2013) concluded that physicians should consider the potential costs to be borne by a patient to be as important as potential side effects when making a therapy selection. They recommended that physicians work to intervene early in treatment to mitigate FT to the extent possible.

Communication between patients and oncologists is one way to potentially mitigate some of the impact of FT (Ubel et al., 2013). In 2010, Hofstatter (2010) found that there was little information available about cost communication preferences in cancer patients with their physicians. The only published study was conducted with physicians not patients. Hofstatter (2010) cautioned against using data from other diseases because of the uniqueness of cancer, its acuity, high rates of mortality, and high costs. He acknowledged a gap in the literature regarding patient preference and decision-making in cancer with respect to inclusion of the cost dimension.

Additional research began to emerge on patient preferences on cost communication. In a survey of cancer patients, Bullock, Hofstatter, Yushak, and Buss (2012) found that 68% of patients wanted to understand the cost of care upfront but fewer patients, 59%, wanted their physician to discuss it with them. Also, 55% of patients believed that their physicians should not take cost into consideration of their treatment and this number was statically higher in those patients currently under therapy (Bullock, et al., 2012). The concept of cost communication between physician and patient is posited as one way to mitigate the FT experienced by patients.

Research demonstrated that patients with FT experience changes in decisions about their cancer care and often make choices to skip therapy and make tradeoffs that may affect their activities of daily living. Barber, Bensen, Snavely, Gehrig, and Doll (2016) that women diagnosed with gynecologic cancer experienced significant barriers to accessing health care services as a result of the patient's ability to pay for these services. In this same study, younger women reported forgoing medicines and other services in greater proportion than an older cohort of patients. Cost can impact a patient's daily decisions about remaining consistently compliant to oral chemotherapy or undergoing IV drug therapy.

In a large survey of cancer survivors in the United States, Weaver et al. (2010) asked patients to disclose whether they had elected not to have any medical services or to discontinued services due to cost concerns. The results demonstrated that compared to those without a cancer diagnosis, cancer patients were more likely to not have medical care, not to use a recommended prescription, or to delay care (Weaver et al., 2010). Younger patients were more likely to undertake these actions than those greater than 65 years of age.

While some researchers have published insights into patients' actions and behaviors while experiencing FT, few have explored the decision-making and thinking that patients use while under FT distress. This is an important gap in knowledge because t it is difficult to build strategies and implement support programs without the knowledge. Applying FTT to the complex problem of FT will be helpful. It will improve the understanding of decision-making processes among those most impacted by FT, the cancer patients.

Summary and Conclusions

The study used FTT framework to help guide an analysis and investigation of patient decision-making while experiencing FT. There is a rich body of knowledge about decision-making theory and understanding how patients select between options that include benefits, risks, and elements that are unknown (Reyna et al., 2015). Understanding how people use emotion, gist, and verbatim recall when making choices about their cancer care and including costs as a consideration was important since it may expand understanding of decision-making for patients experiencing FT. These are concepts that are not well studied but are important for those treating and caring for cancer patients.

What is well understood in the literature is that FT is a problem that is becoming more widespread due to increasing costs and shifts of costs to consumers (Ahuja Parikh, Amin, Hall, & Patel, 2017; Chino et al., 2017; Gordon, Merollini, Lowe, & Chan, 2016). FT is well documented to impact the lives of patients with its distress and to decrease access to care. When FT is severe, it can impact outcomes and decrease survival. FT is not a number, but a state of emotional being for cancer patients. It is important to assess the mental processes that patients apply to important decisions that impact their lives and their cancer outcomes.

To study these decisions and understand the patient perspective, my research study utilized qualitative research design. Using case study methods and selecting advanced cancer patients who are living with FT and cancer in community settings helped to provide deeper insights into decision-making and choices. Chapter 3 will discuss the methodology used to evaluate the role of FTT in cancer patient decision-making while experiencing FT associated with cancer care.

Chapter 3: Research Method

The purpose of this qualitative case study was to develop a deeper understanding of how adult advanced cancer patients who are experiencing FT make decisions about their medical care and how they experience FT in their lives. FT has been reported to be one of the most important dimensions of cancer patients' experiences (de Souza et al., 2014; Delgado-Guay et al., 2015) and is causing serious distress (de Souza et al., 2016), yet there is a paucity of literature about how patients experience FT and how they make decisions about their care when FT is present (Zafar & Abernethy, 2013b; Zafar et al., 2015). To address this gap in knowledge, I used FTT to examine the decision-making of advanced cancer patients who are experiencing FT.

There is a body of research that has focused on helping patients make informed choices regarding their cancer care and other chronic illnesses. This literature focused on patient-centered decisions (Barry & Edgman-Levitan, 2012; Joseph-Williams, Elwyn, & Edwards, 2014; Shay & Lafata, 2015) and how to present clinical information about an option that may contain numbers and concepts that are not usually part of a patient's everyday experience. Researchers focused on how to make health and numerical literacy more accessible for cancer patients and patients with chronic illnesses to select appropriate treatment (Chewning et al., 2012; Joseph-Williams et al., 2014; Patkar et al., 2011). Health and numerical literacy can help patients make informed choices and empower them in medical decision-making. None of the studies that I reviewed included extensive cost information, and none of the FT literature focused on patient decision-making while experiencing FT (de Souza et al., 2016; Zafar et al., 2015). My study addressed this gap in the literature to provide the patient’s perspective.

In Chapter 3, I give a detailed description of my research plan to gain access to potential respondents and to analyze the data. I describe how I designed the study and justified the research method. I define the core concepts that I used throughout the study and how the method allowed me to answer the research questions. I address threats to validity and explain how I controlled for bias and how I protected the participants from potential harm. I also provide an overview of the data analysis plan.

Research Design and Rationale

The research questions addressed in the study were the following:

1. What was the experience of advanced cancer patients who experienced financial distress stemming from OOP costs of the disease treatment?
2. How does financial toxicity manifest in patients’ lives, and how did patients use gist and verbatim as they make decisions about therapy?
3. How, if at all, did financial toxicity factor into treatment decisions in patients with advanced cancer?

The study focused on learning more about how advanced cancer patients make decisions about their care when FT is present in their lives. I explored how patients think about options, what information they rely on, and how they process that information as they make choices about their care and their lives while experiencing FT.

I used qualitative methods to learn from patients how they make decisions. According to Patton (2015), researchers use qualitative methods to gather and analyze data to identify themes. Qualitative methods can be used to describe how people act, think, or make decisions, and to explain the contexts and the processes by which people take actions or make decisions (see Maxwell, 2013). Qualitative methods include a deep and rich approach of collecting data that includes not only the answers to the interview questions but also participants’ tone of voice, observations of the setting, and other data artifacts that may add to the description and observation (see Janesick, 2011; Patton, 2015).

For this study, I used a case study method. I conducted in-depth interviews with patients and collected additional documents and artifacts from patients that addressed their FT and cancer experience. I supplemented the interviews and artifacts with field notes and observation memos. This design allowed for thick descriptions and rich contextual observations of patients regarding their decision-making processes (see Maxwell, 2013). Because I did not know how patients would describe their experiences with FT or how they would characterize their decision-making while experiencing FT, the case study design allowed for collection of data that included the context for their responses (see Maxwell, 2013). A case study method was appropriate to answer my research questions because the method can be used to focus on how patients who are experiencing FT think, act, and make decisions. This method allowed me to gain insight into the application of FTT to cancer decision-making in patients with FT (see Yin, 2003). Yin (2003) stated that case studies, with appropriate structure and systemic processes, can enable researchers to explain behaviors, thinking, and actions through a theoretical framework. Case study methods are helpful to researchers who are attempting to study decisions and decision-making under a set of circumstances in a naturalistic setting (Yin, 2003).

Role of the Researcher

In any qualitative inquiry, the researcher is the vital link between the experiences and thinking of the respondents and the analysis and reporting of results and conclusions. The researcher is the instrument or medium through which the data are collected and processed; therefore, understanding the connections, personal goals, potential biases, and previous experience that the researcher brings to a study is essential (see Maxwell, 2013). Prior to beginning the study, it was important to examine my role as a researcher and observer in this study.

I have professional relationships with the community cancer center sites where I conducted the research, and I examined how my relationships and potential biases were managed to limit the power I may exert over participants and site leaders. As a consultant and then later in my career, I led a business that supported patients and physicians to navigate the complex reimbursement framework of health care. I have worked with teams of people focused on improving access to cancer care and novel drugs. For many years, I have had a deep concern for the impact of health care costs, particularly pharmaceutical costs, on patients’ lives and how these costs impact their health and wellness. I have directed my career toward helping patients, providers, and pharmaceutical companies find efficient ways to help underinsured and uninsured patients gain access to breakthrough therapies by working to advocate for coverage with payers and educate the payers about the benefits of providing access to these drugs or novel treatments for clinically appropriate patients. In this role, I was a consultant to the innovators and marketers of the drugs, the pharmaceutical companies. I sought new ways to expand access to the therapy for as many appropriate patients as possible, usually by working to improve the insurance reimbursement environment for the therapy.

That job helped me hone my expertise in how health care services, particularly care provided in the community care setting, is paid and the challenges patients and their families face when insurance denies coverage or the coverage leaves the family with large unaffordable OOP costs. The work sensitized me to the deep and painful challenges that many people face as they try to pay for necessary services and care. I have respect for the difficulties that severe chronic illness and costs of care can cause for patients and their families.

Potential biases may have stemmed from my early career choices in which my work was financed by pharmaceutical companies; however, I focused on helping people to access care. I believed that patients should advocate for themselves, be involved, and be educated regarding their health. I recognized that this is an ideal and not a reality for all, and I understood that others do not share my perspective. I accepted that there are many people who choose not to be involved or who are unable or unprepared to be their own health advocates. I generally do not have negative feelings toward the pharmaceutical industry or other health care providers such as doctors or hospitals. This could have created a bias where I inadvertently discounted the potential distrust, anger, or other emotions that patients may have toward pharmaceutical companies and health care providers. To mitigate this potential bias, I focused on capturing the patient’s perspective in my research. To the extent that personal emotions or thoughts arose in my research, I ensured that I recognized these and prevented them for altering how I recorded the patients' experiences in my notes, analysis, and reporting.

A third bias that I managed was my desire to repair situations for patients and make their lives easier, especially where costs of care are escalating. Prior to starting this study, I had a deep understanding of the reimbursement, billing, and coding environment and recognized how difficult it can be for patients. I knew that it required a fair amount of health literacy and more insurance literacy to be comfortable understanding claims and health care costs. I have years of experience leading teams focused on the mission of helping patients. I recognized that in this study it was my job to understand the patient perspective and it was not my job to be a remedy to all potential challenges for patients or to find ways to bail them out of FT. To do this would be to overstep the researcher-participant relationship. To manage these biases, I used a strategy of having another research participant, such as chair, read a sample of transcripts. I also asked the respondents to read the transcripts and confirm the accuracy of my results.

The data artifacts that patients shared with me provided another check and a means for triangulation (see Patton, 2015). Case study research has three potential ways in which bias or distortion can be managed (Patton, 2015). Patton (2015) stated that one the most important ways to control bias is to ensure that the data are always kept in context and not to yield to the temptation to extrapolate results from the sample or context in which the data are provided. Patton further explained that qualitative researchers must ensure that the data are firmly grounded in the purposeful sample and situations under study, within a time bound period, and that limitations arise from the type of people selected for the study and the types of artifacts observed in the study. To control bias in my study, I ensured that I included field notes and reflective writing to note potential limitations during data collection and encourage myself to remain focused on what was observed in context.

Another concern in research is controlling for power relationships (Patton, 2015). In 2015, I changed my job to work more directly with medical oncologists, radiation oncologists, and surgeons who provide cancer care in the community setting. My organization contracts with groups of cancer care providers to manage all aspects of their cancer center services except for the clinical care delivery. At the time of the study, I was in a leadership position for the team that delivers the services to practices servicing providers across the United States. These practices are customers of my company, and my team manages the employees who work in the practices. I have employees supporting all the services to deliver cancer care. I have relationships with the administrators who lead the business support services for the practice, but I do not have direct access to the patients. These relationships could have created power concerns for me and study participants as I worked to gain access to the potential sites for recruitment of advanced cancer patients. Potential power concerns that might have stemmed from this relationship included staff engaged in helping to identify patients may have feared that to not participate in the study may have jeopardized their pay, their annual review, or their job security. To reduce this concern, I ensured that I was not directly involved in any staff annual reviews or salary discussions for a period of 1 year after the study. Prior to the study, I was not routinely involved in staff reviews at the site because it is the responsibility of the local leadership team. Although this power concern was a perceived issue, it was minimized.

Power relationships can emerge from other sources of blurred lines between researchers and participants in case studies (Creswell, 2013). In a case study and other qualitative research, although the inquiry is structured, the participant is sharing his or her perspective and approach and the researcher must follow the lead of the participant and not attempt to compartmentalize the results into preconceived survey responses (Karnieli-Miller, Strier, & Pessach, 2008). This distributes some power to the participants who construct meaning from their experiences through sharing it with the researcher. A researcher must put aside bias and seek to understand the respondent's intended meaning as closely as possible. It is important for researchers to gather the participants' stories and experiences without coloring them with personal bias (Karnieli-Miller et al., 2008). A researcher must create trust and rapport with the respondent in all phases of the research from the solicitation to participate to the data collection and through the analysis phase (Karnieli-Miller et al., 2008). I conducted my research in the centers where patients come for treatment, but I also visited a respondent at home when that was more convenient and when travel was problematic. In selecting the treatment center, I chose a site where the patients had trusting relationships and where they were being treated for cancer. The site was also likely to be one of the sources of costs to them, and this may have created a concern for patients if they perceived that any of my research would be shared with the center and linked to them personally. The patients may have worried that the sharing of information could have interfered with the provision of care. To ease this concern, I ensured that I would not share individual case stories with the center and that the narratives and examples would not reference the individual’s name.

Participants with advanced cancer patients and FT are considered a vulnerable population (HHS, n.d.).They were afforded incremental protections and care as part of my study. There were costs that the participants incurred to participate in my study including travel costs and time away from family, home, or work. To compensate the participants for their efforts and costs, I reimbursed each study participant with $80 cash or check. This is not an amount that unduly influenced or coerced a respondent to participant in the study, but it did recognize their contribution and repay costs for travel. I asked the participants to acknowledge receipt for the money. This payment to patients was disclosed and approved by the IRBs.

My study sites have researchers who conduct studies for investigational cancer drugs and have a culture of supporting research. The physicians in the centers participate in research and use a centralized IRB and their IRB became IRB of record for my study. I received approval from the center IRB and the Walden University IRB (Walden University IRB Approval 17071).

Methodology

A case study method must have sufficient proposed rigor such that researchers can replicate the research design (Yin, 2003). I selected advanced cancer patients who were experiencing FT as participants and I collected data by using predominantly interviews for my case study. The interviews were supplemented with artifacts shared by the patients and the results of a validated instrument. I used this instrument to assess the severity of the FT and the questions served as a discussion items. Typically, case studies use multiple data sources to form a full rich view of a perspective or line of inquiry (Yin, 2003).

Participant Selection

The target participant selection audience for my inquiry was insured advanced cancer patients who were receiving cancer care in a community setting. These patients were in either active cancer treatments or follow up care. Most participants in community oncology practices receive care that involves a number of therapeutic modalities including surgery, radiation, and chemotherapy or advanced biotechnology therapy (see Ubel et al., 2013). The patients in my study were adults over the age of 18; no children were part of this study. These patients responded to a flier that described asked for participants who were concerned about costs of cancer care. Each participant had some form of health insurance. There is a newly validated tool called the **CO**mprehensive **S**core for financial **T**oxicity (COST) tool that is available to researchers to assist with grading potential FT experienced (de Souza et al., 2016). With permission, I used this COST score to help score the current feelings of FT at the time of the interview within the selected participants. This served as a document used for discussion purposes, not as a quantitative data gathering tool.

I used a purposeful sample of advanced cancer patients who were seeking their care at a community oncology practice in Colorado. Purposeful sampling helps a researcher to achieve several goals that add validity to the study (Maxwell, 2013). First when a small number of participants are expected, purposeful sampling gives the researcher some assurance that the patients in the study are typical of most or average community cancer center patients (Maxwell, 2013). Purposeful sampling can also help a researcher to achieve heterogeneity and to hear opposing views, and to include variance that occurs within the typical population (see Maxwell, 2013). In my study, there was heterogeneity in the sample in age, gender, experience with treatment, types of cancers, employment, and marital status.

To identify and recruit the sample, I introduced myself to the targeted centers' leadership and established a relationship with the physicians and their staff. The IRB approved several recruitment methodologies including allowing patients to pick up the flier at the center. Fliers were available to patients in waiting rooms. The IRB also permitted me to ask center staff to disseminate the flier to invite the patients to participate in the study. Financial counselors and patient benefit representatives disseminated fliers. This sampling strategy supported purposeful sampling. It produced cases with typical experiences and permitted inclusion of participants who could share these experiences. Some use of snowball or chain recruitment was used since some patients shared the fliers at their support groups that take place in the community cancer centers. In this case, a patient referred a fellow patient who was interested and contacted me.

Once the patients contacted me on email, via text, or by phone, I communicated with the patient by email or phone to introduce myself, to describe the study, and to set an interview date. With the participant's permission, I emailed the informed consent form for review prior to the interview. I also introduced the need to bring an item with them to the interview that represented how they think or feel about financial costs of cancer. At the interview, I further described the study, its data collection and analysis processes, and obtained their signature on the informed consent form (Appendix A).

The patient sample size was 13 participants. This was a size that allowed for enough cases to identify homogeneity and heterogeneity in the cases and the context in which people make decisions about their care while experiencing FT (see Maxwell, 2013). With this number of respondents, I gathered rich descriptions of how patients made decisions while experiencing FT in a community cancer setting. According to Patton (2015), qualitative methods rely most on the deep richness of the information generated from the cases to provide the insights and significance from the research. To determine if the sample size was adequate, I transcribed the results and conducted thematic analysis and began coding, and from there, determined that the sample provided saturation. By working with the data from each case, and understanding if new perspectives emerged, I identified that a point of saturation was achieved with 13 patients (see Patton, 2015). Saturation can occur in qualitative case study methods when the cases do not add new insights or additional findings (see Patton, 2015).

Instrumentation

There were three forms of data collection. First, there were in-depth interviews that I conducted, following an interview guide (Appendix B). The interviews were audio recorded and transcribed. These interviews were supplemented by field notes and observations that I made about the interview and the respondent. In addition, I asked the respondent to share any paperwork or artifacts that they believed to be helpful to understand their experience with FT and health care decision-making. These materials were redacted of patient identifier information and were part of the data collection process. I asked the respondents to bring these items to the interview and explain to me why they selected the item; I sought to understand the importance of the artifacts to the respondents. A few questions in the discussion guide were attributed to these artifacts. A third way in which I collected data was asking the respondent to take a survey with a validated instrument called COST that grades the patient’s current level of FT (de Souza et al., 2016). I obtained permission for the use of this tool from the investigator, Dr. de Souza (2016), who developed it (Appendix C). This validated tool is available online to the public and allows one to receive an immediate response with a grading of the degree of severity for FT once the questions are answered. The COST score helped to validate and triangulate the degree of distress that the patient described. The survey questions also generated more extensive exploration of the issues of FT and how patient experienced it as part of the interview process.

Recruitment, Participation, and Data Collection Procedures

Once I received IRB approval, I began the recruitment procedures including working with key informants at the cancer centers. The types of individuals that I worked with were patient social workers, patient navigators, patient benefit representatives, and patient financial counselors. These staff members are responsible for assisting patients with understanding and planning for the costs of their care including their insurance benefits and their OOP costs as well. In addition, these individuals help to enroll patients into specialized programs that can provide cost offsets and financial support if a patient qualifies for the programs. Generally, community practice employees learn about the patients who are struggling with FT and seek to help with assistance programs. For this reason, the social workers were particularly helpful in supplying the flier to patients who were potentially interested in becoming study participants. The protocol for explaining the distribution procedures for the fliers to center staff is in Appendix E. The recruitment flier that was posted and distributed in the center is contained in Appendix B.

Once a patient contacted me, I emailed or called them. During the phone call or email, I screened them for participation. I ensured that the patient was an adult, had advanced cancer, had insurance, and was experiencing FT. Once these criteria were confirmed, I introduced the informed consent form and asked the patient to read it prior to the interview so that he or she might consider participation. I underscored that a patient may change his or her mind about participation at any point and that participation is voluntary. I then set a time and place for the interview. I scheduled each interview for approximately one hour. As I set up the time for the interview with the patient, I explained that the participant could bring any paperwork or artifact that they believed to be helpful in demonstrating the impact of cost of cancer upon them and their lives. I explained that I will copy or photograph the material during the interview and then return the originals to them.

I conducted interviews at the cancer center, by telephone, or at the respondent’s home depending on the availability and convenience of the patient. With permission, each interview was audio recorded. Not all patients permitted audio recording. In that case, I took extensive notes and the patient read the notes immediately following the interview for accuracy. We discussed areas where further description or explanation was needed. This interview and review period was over two hours with the patient's permission because of the extra time it took for her to review the notes and further explain her thoughts. For one interview, I used a transcription service called Transcribe Me to create an initial transcription that I reviewed and edited with the audio source. This transcription service was HIPAA compliant and secure (Transcribe Me, 2017). A copy of the agreement with Transcribe Me that contains the company confidentiality is in Appendix F. I transcribed the remainder of the interviews myself by listening to the recordings.

A COST score tool was discussed using the tool on the website costofcancer.org (Appendix D). This tool gives patients a way to obtain a scoring of the severity of their current FT (de Souza et al., 2016). I followed the research protocol and read the questions to the patient, asking them to score each question. After the interview concluded, I entered responses into the COST webpage and it returned a score. I chose to delay the scoring of the COST tool until after the interview was complete since the result could distract the discussion to details of the tool. Giving a diagnostic grade of FT in the interview could have been emotionally distressing for the patient and may have require follow-up that was not in the scope of the researcher's relationship with the patient. The results of the COST score was used to further triangulate and reference the experience of FT that the patient described in the interview.

After each interview, I thanked the participant and asked if he or she would review my written transcript of the interview to ensure I captured their responses accurately. I asked if I might contact them again if I had follow up questions or needed additional information. At this stage of the interview, I provided them with their honoraria and ask for them to sign for receipt for the honoraria (Appendix H). With thanks, I concluded the interview.

Data Analysis Plan

A researcher should specify a data analysis plan in sufficient detail that others could follow the research and replicate it and demonstrate how each portion of the research connects to the proposed research questions (see Patton, 2015). The data analysis plan provides a guide that describes how the data was categorized and organized for the researcher to identify themes.

Each interview was recorded (if the patient consented) and each was transcribed into a written transcript. I took field notes about the non-verbal elements of the interview as well as the telephone calls that I had to set up the interview. Artifacts were copied or photographed. I recorded the results of the COST tool and stored them electronically. These three forms of data were collected for each patient to the extent possible. Each of these data was stored and loaded into NVivo data analysis software (Version 11). This software assisted me in the coding of the data for each case, and in the cross-case analysis.

I used an open coding method and two coding cycles in the data coding process (see Saldana, 2015). I made my first cycle of coding by reviewing the transcript of the interview and listening to the recording while using descriptive coding. I coded the artifact data using descriptive coding in the first cycle as well. To help guide the interpretation of codes and emerging themes and concepts, I wrote analytic memos. I used a code book within the NVivo data analysis software (Version 11)that included the codes, their definitions, and links to the coded data (see Saldana, 2015). This was shared with my dissertation chair for review as well. Once I had collected all the data and my first cycle coding was complete, I reviewed the data and coding using a second cycle method (see Saldana, 2015). In this cycle, I used pattern coding to help to assemble the data toward the analysis and themes.

For analysis, one method is to fully describe each case and develop themes from a full evaluation of each case, but not compare between cases (see Yin, 2003). Another method is to collect multiple cases and then identify the themes within each case and cross-connect the individual cases to analyze the data in that manner (see Yin, 2003). I used a cross-cases analysis plan. The key to successful data analysis in qualitative research is to fully examine the data and evaluate all evidence that supports and contradicts themes that emerge. All data must be included and rival interpretations or themes should be explored (see Yin, 2003). The data analysis plan for this research included exploration and discussion of potential rival interpretation of conclusions and themes.

Issues of Trustworthiness

Issues of trustworthiness in research are critically important since a lack of trustworthiness can erode the validity and reliability of the results, casting doubt on the conclusions and the research process (see Maxwell, 2013; Patton, 2015; Yin, 2003). The trustworthiness of this study may be evaluated by its ability to meet tests that promote credibility, transferability, dependability, and confirmability (see Yin, 2003).

Credibility

In qualitative inquires, credibility increases the validity of the study by helping to improve the quality of the inferences that emerge when a researcher is unable to directly observe something (see Yin, 2003). In my study, I asked participants to recall and discuss what they did or thought in the past. To improve credibility, a researcher must fully explore potential rational and reasons why an inference could be thought of differently; alternatives should be explored, and either dismissed or discussed as potential future research (see Yin, 2003). To improve the credibility of the study, I used cross-case pattern matching in my data analysis to identify where emerging patterns and inferences may have alternative explanations. I also used reflective journals after the interview to record observations about the interview, the tone and demeanor of the statements by the patient, and any bias I may be self-observing so that I limited the entrance of bias into the analysis.

Transferability

Transferability deals with the extent to which, if at all, the findings and conclusions of the research may be applicable outside of the study (see Yin, 2003). The applicability of the results of the study beyond my cases research depends on whether there is logic in the FTT between the cases to help explain how patients make decisions while under FT, but there are likely to be important limitations. To enhance the transferability, I used thick description. This provided a rich context for the analysis. There was variation in the types of cancer participants and their experience.

Dependability

In case study methods, one seeks to increase the ability of the same case to be replicated later by others and achieve similar results (see Yin, 2003). This means that a researcher must document steps and procedures within the research to provide full descriptions of the operations of the case study such that one could later replicate it. Dependability also is focused on ensuring that the research follows operational procedures to reduce the subjectivity of data collection, especially in case study methods (see Yin, 2003). In my research, I used a protocol for the data collection and a case study database for the collation, storage, and collection of data. I provided a detailed listing of my coding procedure and analysis.

To improve dependability in this research, I used several sources of information including patient interviews, field notes and observations, the validated and published COST tool, and data artifacts supplied by the patients. The use of several types of information provides the researcher with opportunities to increase the convergence of the emerging description of the experience, from the patient’s perspective. Using this, a researcher can triangulate the data. Another means to improve dependability is to ensure that data collection follows a process and that steps are taken to ensure the artifacts are correctly entered into the case database and ascribed to the correct respondent (see Yin, 2003). In my study, the interviews, COST tool discussion notes and scores, and artifact collection followed a protocol (Appendix I) to ensure that the data supplied by each patient was correctly and accurately ascribed to that respondent. Each artifact was labeled belonging to the respondent by number and a photograph or scanned electronic image was loaded into NVivo data analysis software (Version 11) for analysis and coding.

Confirmability

To enhance confirmability, I used reflectivity. I also ask the patients to review their transcripts for their perceptions, comments and accuracy. This helped to ensure that the responses recorded were concordant with the patient's intent. During the data gathering, analysis, and coding I used self-reflection to enhance confirmability. I asked questions of myself such as those suggested by (see Patton, 2015). These questions included thinking and noting how I mentally approached the study's knowledge-base, how patients knew their experiences, and how the study audience will learn of and interpret my findings. The object of reflectivity is to inquire how the researcher and her experiences are interacting with the study itself and to note these interactions (see Patton, 2002).I reduced the four threats of validity, credibility, transferability, dependability and confirmability to my research by consistently applying the approaches I described.

Ethical Procedures

Ethical procedures are critical to protect the health and well-being of those who volunteer to participate in research (Patton, 2015). The IRB is the review process that sets standards that must be followed in order to field any research but beyond the IRB there are ethical standards and safeguards that must be part of the everyday practice of the research process (HHS, n.d.). It is critical to maintain ethical standards for all research with human subjects.

To recruit subjects, I gained access to patients via a relationship I have with a cancer practice in Colorado. I created and obtained signature on a letter of cooperation with the president of the practice. Before I started any research, I obtained IRB approvals from Walden University and the IRB associated with the cancer center. The IRB of the cancer center was the IRB of record.

To recruit patients, I used several methods including asking the center staff to help disseminate fliers to patients about the research. I also disseminated the fliers within the center by posting them in the waiting rooms of the center. These fliers described the research and asked interested patients to email or call me directly. To recruit the subjects, I explained the purpose of the research and the potential benefits of the research. I disclosed that the research may ask them about personal subjects such as making decisions about cancer care, which may conjure up strong emotions or cause patients to relive stress from the past. I disclosed that an honorarium was being offered to compensate the patient for their time and travel costs associated with meeting with me. Once a patient was screened and agreed to participate, I obtained a signed informed consent agreement from the patient. Before starting the interview, I obtained consent to record it. Patients were concerned that I may share their feelings with the clinical staff and I stressed that their individual findings will not be attributed to them and that date will be kept confidential. I explained that I will be seeking to report the cross-case major themes and will not disclose identifiable information.

Keeping the data confidential is a key concern for patients and was maintained by removing identifiable information and referring to patients using numbers. All data entered into my database was stripped of names and other key pieces of information including addresses and phone numbers. A master key was held separately by the researcher and used only for follow-up as needed and permitted by IRB and the patient. The transcription service had a signed confidentiality agreement (Appendix F). To help ensure that there was no impact on the patients’ care or relationship with the treatment center, no individual patient data was shared back with the physicians or the center staff.

Summary

This qualitative inquiry used a case study method to research how advanced cancer patients who are experiencing FT make decisions about their care and how they experience FT within their lives. FTT is a decision-making theory that can be applied to this research; it was the theoretical basis for the study. The methods used included in-depth interviews, collection of artifacts, and a validated measure of FT to gather additional insights into the use of gist and verbatim in decisions by patients with FT. The study recruited patients from in a community cancer center setting and the sites provided me with assistance to identify potential patients to participate.

I took care to conduct the highest quality research and maintain the validity of the study. To improve the trustworthiness of the case study, the research used multiple means to improve and maintain construct validity, credibility, external validity, and dependability. The research was conducted with the approval of the Walden University IRB and the IRB approval from the cancer center.

Chapter 4: Results

This chapter provides a detailed summary of the results of interviews with patients with advanced cancer who are experiencing FT stemming from the cost of cancer care. This study's purpose was to understand the experiences of advanced cancer patients who are under financial stress to understand its impact on decision-making. There is a growing body of quantitative research that has addressed the impact of OOP costs on patients and linked these costs to adverse outcomes (Delgado-Guay et al., 2015; McDermott, 2017; Zafar, Newcomer, Jusfin McCarthy, Nasso, & Saltz, 2017). However, there is little research about how insured advanced cancer patients experience FT and its influence on their medical decision-making. In Chapter 4, I describe my research instrument, the partner organization that helped to facilitate the research, and the setting in which I conducted the study. I also describe the recruitment and data collection processes and my data analysis approach.

I used a qualitative case study method because it provided a means to explore patients' perspectives and gain an in-depth understanding of their thoughts, experiences, and considerations in decision-making (see Creswell, 2013).This method also included the collection of secondary artifacts (see Creswell, 2008). I used in-person and telephone interviews and supplemented these with secondary artifacts that I obtained during the interview process.

I met with 13 patients with advanced cancer from three sites in Colorado during the months of August through December of 2017. I included only those patients who had health insurance. Two of the participants preferred to include their family caregiver in the interview.

Research Tools

Prior to the study, I prepared a research interview guide (Appendix C). The guide had basic information questions about the patients including their living situation, cancer diagnosis and treatment journey, and history of employment. The rest of the interview guide contained questions designed to elicit data to answer my three research questions:

1. What was the experience of advanced cancer patients who experienced financial distress stemming from OOP costs of the disease treatment?
2. How did financial toxicity manifest in patients' lives, and how did patients use gist and verbatim as they made medical decisions?
3. How, if at all, did financial toxicity factor into treatment decisions in patients with advanced cancer?

I partnered with a community cancer practice that offers cancer care in locations in Colorado. The leadership of this cancer practice allowed me to place fliers in treatment waiting rooms in several of their sites and provided private conference room space for my interviews in their medical offices. I met with the president of the community cancer practice, who signed a letter of cooperation that I included in my IRB application. Before I asked to distribute fliers, I made telephone calls and sent emails to each of the administrative and patient care teams to explain the purpose of my study and to solicit their cooperation.

Study Setting

I conducted the research within three sites of a community cancer practice in Colorado After the first month, I expanded the number of sites because of a low number of volunteers.

The three sites where I conducted my research were all part of a larger single community cancer practice. Each site offered comprehensive medical oncology services including laboratory services, infusion services, outpatient pharmacy services, and cancer support services. Two of the sites offered radiation oncology services within the same location as the medical oncology services. Financial counseling services and social work services were available at each of these sites.

Each site had a pleasant entry and waiting room with side tables and chairs where patients and their family members checked in for appointments, filled out necessary paperwork, and waited to be called for their services. This is where I placed recruitment fliers. Behind the entry to the examination rooms, there are small desk areas for scheduling and other administrative paperwork meetings between staff and patients. Beyond these areas are small phlebotomy and laboratory stations where patients' laboratory work is conducted by the staff before treatments. There are interconnected hallways with exam rooms for each physician, nursing stations, and sub-waiting rooms further back. I placed fliers in the sub-waiting rooms. Each site had an infusion room equipped with wide reclining chairs, IV infusion pumps, and a nursing station. There was also an enclosed pharmacy where the pharmacy staff did admixture of drugs and biological agents. In each site, there was a room for patient education and meetings. In these rooms, there were conference room tables and chairs, relevant patient pamphlets and fliers, and boxes of tissues. Each of these rooms had a solid door that could close for privacy.

There was one patient who preferred that I come to his home that was located near the cancer center to conduct the interview because he was having on chemotherapy at home using a portable infusion pump and it was uncomfortable for him to travel. I accommodated his request and we met for approximately one hour in his living room. Sitting for long periods of time was painful for him, and he was more comfortably in his own home.

Data Collection

I recruited patient volunteers who obtained my information from the cancer centers where I left stacks of the fliers in waiting rooms, check-in areas, and sub-waiting rooms. The flier had a few details about my study and asked patients to call, email, or text me if they were interested in participating. Only two patients connected with me via text; all others called or emailed me. I used my mobile phone as the primary number and took the calls when I saw a Colorado number. If the patient connected with me by email, I responded by email within a few hours and, after several exchanges, I would ask if I could call the patient to discuss the study and arrange a convenient time to meet. Because I had to travel from my home in Arizona to Colorado for the interviews, this process allowed me to group the interviews into a short period and accommodate the preferences of the patients. Speaking with the patients in advance let me fully explain the consent process, screen the patients for advanced cancer, and ensure that they had health insurance as these were two important inclusion criteria. I emailed the informed consent form to each patient and caregiver in advance of the interview. I also explained that I was wanting them to share something with me that was representative of their experience with the cost of cancer during the interview.

The process of explaining the study and arranging for consent also enabled me to establish a relationship with the patients. I had only one patient cancel on the day of the interview. This patient was undergoing chemotherapy treatment and was unwell and emailed me to cancel. All others came prepared to meet me and appeared eager for the discussions.

After receiving IRB approval, I arranged to interview several patients via telephone. The change in protocol to include telephone interviews was for several reasons. Patients were interested in participating, but some were recovering from surgery or had limitations for travel and it was more convenient for them to participate by phone. It was also helpful for me as I lived in Arizona, and each trip to Colorado was time consuming. To ensure security, the IRB requested the use of a code word that I provided in advance and arranged to have the patient tell me during the interview as a form of secondary verification.

To ensure each patient had adequate time to consider participation, I emailed or mailed the consent form in advance. If the interview was to be in-person, I asked patients to bring the artifacts that were representative of cancer costs in their lives. I had consent forms ready for them to sign. If the patient preferred a telephone interview, I emailed the form and asked the patient to print, sign, and scan it so I could have an electronic copy of the signature. Otherwise, we used mail to send the materials back and forth. I sent a packet with a return envelope and asked the patient to mail back the signed copy. These processes were successful in obtaining informed consent.

Participant Selection

I applied a purposeful sampling approach to recruit each volunteer participant in the study. The approach yielded a heterogeneous sample of advanced cancer patients with respect to age range, insurance type, severity of FT, employment status, and cancer type. Purposeful sampling helped increase the validity of the study by making sure the patients were representative of typical community cancer center patients (see Maxwell, 2013).

Each participant was an adult over 18 years of age and was receiving care from a community cancer practice in Colorado where they learned about the study from a flier. I screened each participant to ensure that he or she maintained some form of health insurance. The COmprehensive Score for financial Toxicity (COST) tool was administered with each participant during the interview for discussion purposes (see de Souza et al., 2016). With permission, I later scored the patient experience of FT using the COST tool.

Some of the sites had key staff members who handed the fliers out to patients who were known to be struggling with costs of cancer care. These patients’ experience was known to staff, and this process reflected the power of purposeful sampling because these patients represented the experience addressed in the study. Four patients received the flier from a staff member of the clinic. There was limited use of snowball or chain recruitment. Two patients declared that they would suggest participation to their peers in a cancer support group because they had found the interview to be a pleasant and helpful opportunity to verbalize their feelings about cancer costs. Each interview was planned to be an hour in duration although some were shorter with the shortest being 31 minutes and the longest being 1 hour and 22 minutes. Most were concluded within 50 minutes. After each interview, I provided the patient with an $80 honorarium. Several patients did not want to accept the payment stating that the research was so important to them that they did not feel the need to be paid for their contribution.

I recorded every interview using my password-secured iPhone. One participant did not consent to the recording, so I made detailed notes and met with her after the interview to go over the notes I had made. I used field notes and memos after every interview to note the situation, nonverbal signals, and facial expressions. I kept memos during the fieldwork to observe my reactions and note my potential bias.

I used a commercial transcription service for the first interview and transcribed each recording myself thereafter using a Word document that I secured on an encrypted password-protected laptop and cloud backup. I found that the transcription service was accurate, but I preferred the process of re-listening to the interview. In addition, I made memos after the transcription to capture nonverbal cues that I recalled. I uploaded the notes, memos, and transcriptions into NVivo data analysis software (Version 11) for data analysis and coding. The protocol called for a photo of each patient to be taken, but this seemed to make patients uncomfortable, so I did not take pictures.

After the interviews, I copied the recorded responses for the COST tool and ran a report. I copied and uploaded a screen shot of the report into Nvivo data analysis software

(Version 11). The questions and rating scale served as a good source of discussion during the interview, and patients stated that the questions on the COST tool are good ones for consideration. After each interview, I obtained the patient’s email or home mailing address and emailed or mailed a typed copy of the transcript to the member for fact checking and to give the patient the option to comment or correct the record. All but two patients responded to my mailing or email. Several had small changes such as dates that they had trouble recalling during the interview. Most stated that the transcripts were accurate. Several patients stated that they were surprised by how much they shared during the interview and apologized for the volume of typing that I had to do to capture their thoughts. I had proposed to speak with 12 participants in the study, and I found that I reached saturation at that number. I included a 13th volunteer who was eager to participate in the study, so the total was 13 plus two caregivers.

Coding Analysis

To assist with data coding, organization, and storage, I used the 2016 version of Nvivo data analysis software (Version 11). This software was a useful tool in my open coding method. My two-cycle coding process (Saldana, 2015) followed two passes of coding within the data. Pass one used descriptive coding developed by re-reading the transcripts multiple times and reviewing the artifacts’ descriptions. I wrote memos and notes about the key words and concept nodes. I used the Nvivo data analysis software (Version 11) to the create the codes, record my code definitions, and mark portions of each interview that contained data pertaining to each code in this first pass of coding (see Saldana, 2015).

I used a second-cycle method to begin to reassemble the codes into patterns and to link to my three research questions (see Saldana, 2015). This work involved re-reading the linked materials, grouping them until I recognized themes that were tightly linked to the research questions.

Yin (2003) describes a method that I used in my cross-case analysis. I used a two-cycle coding process. I first identified themes that transcended each case and then I compared and cross connected them to each case. Yin (2003) calls this a cross-case analysis method. An important part of this cross-case analysis work was to identify data that was in contradiction to most of the cases and to fully explore this. There were several examples of data where there was a view presented that others in the sample did not share. This analysis will be presented in the next section of this chapter.

Research Findings

After discussing the demographic data, I organized the research findings into themes in this section of Chapter 4. In the first section, I provide an overview of the general background of the study participants including their cancer types, insurance status, employment status, living situation, and self-reported score on the COST tool (de Souza et al., 2016). I report the themes that I found and use them to answer the three research questions.

Demographic Data

To begin each interview and establish rapport, I asked each participant background questions. I asked about their health insurance since this was a screening question and I confirmed their participation eligibility. Thirteen patients with advanced cancer participated and two included their caregivers as active participants in the interview. To denote those who had a caregiver in the interview, I added the initials CG to the patient number in the demographic tables. All except one of the participants were female (see Table 1). Some forms of cancer are extremely rare; I have denoted one patient’s cancer in the more general form to provide her with a higher level of anonymity (see Table 1).

All participants had advanced cancer and had undergone several modalities of treatment including surgery, radiation, chemotherapy, and immunomodulation therapy. By asking about the patient’s cancer journey, I recorded the interval since the initial cancer diagnosis and the interview. The time with cancer for patients ranged from being in their first year of cancer care, to having fought cancer through active treatments, remissions, and recurrences with metastases for over a decade (see Table 1). Participants’ living situations ranged from living alone to living with their spouse, partner, family member (adult child), or with a spouse and children/stepchildren (see Table 1). Most participants were married and living with their spouse or living with a partner (*n* = 10; see Table1). Patients had either commercial insurance, Medicare, or Medicaid coverage. All those with Medicare also purchased secondary coverage called Medicare supplemental that covers the coinsurance OOP costs for outpatient treatments including intravenous infusions (*n* = 5; see Table 1).

During the interviews, I asked about the current employment status and at the time of the patient’s diagnosis (see Table 2). Of those who were working at the time of their diagnosis, eight significantly decreased their level of employment. These changes included retirement, full-time disability, or choosing to leave employment. Two of the participants decided to discontinue working once they were diagnosed with cancer because this was the only way to qualify for Medicaid insurance. Their jobs did not provide insurance.

Each of the participants took the COST assessment during the interview. The tool uses a list of 11 statements for patients to rate their degree of agreement on a Likert scale from one to five. The assessment is scored by entering the results of the questions into an online web-form that returns an level of FT based on the score (see de Souza et al., 2016). I asked the questions and the participants then rated their current state of agreement with the COST statements (see Table 2). During and after the taking the COST assessment, we discussed their thinking and their answers.

I used this assessment to generate discussion with the participants. Several participants commented that this tool was useful to help them think about how costs impacted their lives. The assessment tool asked questions such as the degree to which participants felt in control of their financial situation. It asked about their ability to meet monthly financial obligations, and their feelings of how their present situation affects their future ability to afford costs of living. Several participants indicted that their level of FT has been much higher at several points earlier in their treatment when they were facing high OOP costs and had no ability work to pay for the care.

After the interview concluded, I recorded the score and FT severity grade for each participant. The tool returns one of four degrees of FT; these include no impact on quality of life, mild impact on quality of life, moderate impact, or high impact on quality of life (see Table 2). No impact means that at the time of the assessment, the patient has less FT impact on the quality of their life than 95% of cancer patients, and there is no impact on daily finances (de Souza et al., 2014, 2016). A mild impact is when FT is present and it is impacting quality of life for the patient more than 50% of cancer patients who took the instrument. A moderate impact indicates that the patient has a FT quality of life impact that is moderate and greater than 75% of patients with cancer. A severe rating for a patient indicated that he or she is experiencing a severe degree of FT on quality of life, greater than 95% of patients with cancer (see de Souza et al., 2014, 2016).

Based on the results of the COST tool, most (n=10) of the interviewed patients were experiencing a moderate or mild level of FT on their quality of life at the time of the interview (see Table 2). Five patients had mild impact and five had moderate impact. The patients' results ranged from two participants currently feeling no impact to one who was experiencing a high impact of FT on quality of life.

Table 1

Participant Demographics and Background Data

Participant number	Gender	Cancer type	Time since diagnosis	Living situation	Insurance type
Patient 1 + CG	Female	CMML	1 yr.	Alone	Medicare
Patient 2	Female	Breast	14 yrs.	Partner	Medicaid
Patient 3	Female	Lung	6 mo.	Spouse	Commercial
Patient 4	Female	Lung	4 yrs.	Son	Medicare
Patient 5	Male	Colon	2 yrs.	Spouse	Medicaid
Patient 6	Female	Breast	2 yrs.	Spouse/children	Commercial
Patient 7	Female	Breast	15 yrs.	Spouse	Medicare
Patient 8	Female	Breast	1 yr.	Spouse	Commercial
Patient 9	Female	Breast	8 yrs.	Spouse/children	Commercial
Patient 10	Female	Multiple Myeloma	1.5 yrs.	Alone	Medicare
Patient 11+CG	Female	Lung	2 yrs.	Spouse	Medicare
Patient 12	Female	Breast	4 yrs.	Partner	Medicaid
Patient 13	Female	Sarcoma	1.5 yrs.	Spouse/children	Commercial

Table 2

Employment Status and FT Severity According to the COST Tool

Participant number	Employment status at diagnosis	Current employment status	COST tool severity rating
Patient 1	Retired	Retired	Moderate
Patient 2	Working FT	Disability/unemployed	Moderate
Patient 3	Working FT	Medical disability	Mild
Patient 4	Retired	Retired	Mild
Patient 5	Working FT	Unemployed	Moderate
Patient 6	Working FT	Working FT	Mild
Patient 7	Working FT	Retired	No impact
Patient 8	Working FT	Working PT	No impact
Patient 9	Working FT	Medical disability	High
Patient 10	Retired	Retired	Mild
Patient 11+CG	Retired	Retired	Mild
Patient 12	Working FT	Unemployed	Moderate
Patient 13	Working FT	Unemployed	Moderate

Note. COST tool from: de Souza, J. A., Yap, B. J., Wroblewski, K., Blinder, V., Araújo, F. S., Hlubocky, F. J., Cella, D. (2016). Measuring financial toxicity as a clinically relevant patient-reported outcome: The validation of the COmprehensive Score for financial Toxicity: Measuring financial toxicity. *Cancer*. https://doi.org/10.1002/cncr.30369 and https://costofcancercare.uchicago.edu

Themes

Every interview participant who responded to my flier indicated that her or she was concerned about cancer costs although each had a unique experience and individual perspective. Nevertheless, as I conducted the coding, I noted common themes between the cases. To help limit the potential biases I may bring to the analysis, I worked to ensure that I was capturing the voice of the patient as I coded the interview transcript. By comparing themes that were present between the patients, it helped me to recognize the emerging themes versus bringing in my personal perspective. I examined the commonalities between the cases and looked for any differences between the cases as well or those with a different experience.

In the next section of this chapter, I discuss the way in which patients responded to the interview questions, the themes that I noted as I made cross-case comparisons, and the answers to the three research questions.

Research Questions

In this study, I sought to address three primary research questions. In the interview discussion guide, I asked questions that pertained to each of the three research questions which were:

1. What was the experience of advanced cancer patients who experienced financial distress stemming from OOP costs of the disease treatment?
2. How did financial toxicity manifest in patients’ lives, and how did patients use gist and verbatim as they made medical decisions?

3. How, if at all, did financial toxicity factor into treatment decisions in patients with advanced cancer?

The following section contains the detailed findings for each research question.

Research Question 1

To learn about participants' experiences with OOP costs stemming from their advance cancer care, I asked a series of questions (see Appendix C: IQ1-4). First, I asked about the patient's living situation and employment. I asked about the cancer care treatments that each participant had and asked each to tell me about the OOP of care and how those costs have impacted their lives.

Employment Status

Patients experienced an impact on their ability to work outside the home because of their cancer diagnosis. Nearly all participants were hospitalized and had surgery within a week or two of diagnosis; most followed with chemotherapy. These treatments, combined with the impact of the disease on the patient's overall health reduced most of the patients' ability to work. Nearly all who were working at the time of diagnosis took some form of short-term or long- term medical leave to undergo therapy. Several had additional follow-on surgery as the disease metastasized and worsened, and these patients all discontinued work either by retiring, depleting their medical leave, or quitting their jobs. Two patients had to voluntarily abandon their jobs because they were unable to afford individual health insurance policies and no insurance was offered at work. The income from their jobs made them unable to qualify for Medicaid insurance and so the only option was to quit.

For most who were working at the time of diagnosis, the advanced cancer and treatment led to work discontinuation and that resulted in income reduction. Patients who tried to work found that it was difficult to manage the dual responsibilities of work and demands of active cancer treatment.

> Patient 6: At the very beginning I felt hopeless. The emotional side of it is hard because it's like you are drinking out of a fire hose. You have all this information about your diagnosis coming at you! You are being told, not asked, that you need to go out and get all these appointments. I remember sitting at work, trying to work, and I had 20 missed calls on my phone from people trying to schedule appointments with me. On top of that, you have this big disruption in your life, and you have the cost of all of it.
>
> Patient 1 caregiver: I had to take a leave of absence to care for my mom. Before I took leave, I missed a lot of work taking care of my mom. I had sick time built up to use but I just was not getting my work done.

For some, losing a job, or shifting to medical disability was a major source of stress and loss of identity.

> Patient 13: I don't know how to not work. I have not let go of that yet, I think. My family and friends, who have been very supportive of this diagnosis, don't understand this pain of losing my job. It does not seem to be as big a deal to them that I had to give up my job, but they are concerned about how I am feeling. For me, it's such a huge deal and it seems not to be such a big deal to anybody else. So that makes it hard too.

> Patient 5: I am very much impacted. I cry many days because I cannot work and contribute. When I was going (working) I had eight hats; I could do it! I could do it all! Now, I cannot even take care of myself.
>
> Patient 7: Costs are less of an issue for me because my husband has an income that supports us. My paycheck was not as significant so to lose it was not a large issue from the money side. Quitting my job impacted me in that before even though I was only bringing in a small portion of our income, it was the fact that I was working. I was happy, and I was good at what I did. This is emotional even now for me all these years later. You can imagine how important that was to me.

For some, the loss of income compounds the increased OOP costs. Some patients moved from full-time to part-time work to accommodate their decline in health. As the treatments continue, patients must pay premiums and deductibles for insurance. Two patients found the only solution was to quit their jobs to qualify for Medicaid. With no income, these patients can obtain Medicaid insurance. They must cope with the lack of income as a result.

> Patient 5: I am out of cash totally. I have no income. I used to do well. I mean, I wasn’t rich, but I had my own company and we did alright. Cancer has made me poor.
>
> Patient 5: I’m on Medicaid now. It’s embarrassing. At first, I did not want to take it because I never believed I would be on Medicaid but, I have to do it for my family.

> Patient 12: I had breast cancer four years ago but six months ago it came back. The first time I had cancer I had insurance but recently I had four jobs but no insurance. I had a terrible pain in my back; just terrible. I kept going to the doctor and they said it was a muscle spasm. Then it went to my arm and they still said it was a muscle spasm. I did not have any insurance so they did not go any further. They did not do any xrays or anything like that. I was in the emergency room a couple of times. I was doubled over in pain. I was crying, “I am in terrible pain. I am not here for the pain pills! I want you to find out what’s wrong with me”. So finally, I went down to our community health center and they said you don’t qualify for Medicaid. I did not qualify. If I quit my jobs, I can get Medicaid. I got to the point where I could not walk but I was still trying to work. Finally, one of the doctors did a reflex test and watched me walk and I had zero reflexes. He said something is really wrong. He did blood work and found out the cancer had metastasized on my bones. I quit my job so I could get Medicaid. Now they can do more stuff. All these doctors who told me I had muscle spasms almost let me die because I did not have insurance. They would not do anything. I ended up in the hospital as soon as they found out by blood work I had cancer. I had hypocalcemia. My oncologist said if I had not gotten in there that weekend I would have died. It was so crazy.

Cancer Diagnosis: A Major Life Event that Triggers Downstream Costs

Patients shared that their cancer diagnosis had a major impact on them, their families, and their lives. First, there was the emotional shock that the pain or cough that they had been experiencing was a serious and life-threatening disease. Treatment became the primary focus. At first, costs were not typically discussed but, patients do have them on their minds.

The initial diagnosis was typically followed by a rapid succession of doctor appointments, tests, and scans. All but one patient had surgery. Several had chemotherapy treatments prior to surgery, but most were hospitalized and had surgery first. Patients expressed that they were scared and disoriented during this time. Some patients spoke of their diagnosis using analogies and explained how the diagnosis impacted them.

> Patient 2: My diagnosis was like a bomb going off in my life. It was like a total shock. My ex-husband took my son while I had surgery and chemo. I couldn’t work or take care of him. I had to jump through hoops to see him. He basically stole custody of him from me.
>
> Patient 10: (Leaning of her diagnosis) That was quite a shock! I went into shock. I drove past a Costco and went in, and randomly went around the store putting things in my cart and eventually, I looked out and it was dark. I went home; I called my two children. I had no idea what to do. My heart is pounding just thinking about it now.
>
> Patient 7: It was so serious that they told me over the phone. They said, “I am sorry to tell you, but you have cancer and it’s very serious.” It was so serious that they said I had to come in very quickly. I was diagnosed with breast cancer. I was told on a Friday that I had cancer and that was my last day of work ever because

> from there I immediately went into all the appointments for surgery and for treatment so I never went back to work.

Patients explained that once they began to recover from their initial whirlwind of surgery and treatments, the realities of the disease set in and the bills for treatment began to come in the mail. For some, costs were always a concern, but this was the first time that they felt stable and well enough to really understand the magnitude of the cost. Also, most pointed out that that health care systems failed to tell them how much something was going to cost beforehand. For some patients, the costs were always largely unknown. The only known costs were those that were expected to be paid directly by the patient. The costs began to mount immediately for or a younger breast cancer patient who had fertility treatment to store her eggs for the future prior to treatment.

> Patient 6: The fertility clinic told me that they would work with me and they told me it would cost me $2,000. They said insurance would cover some. I thought I could make that work. But then, after I started hormones, they called me and told me the insurance was not covering it and they needed $5,000 right that day. So, as you can imagine, I completely freaked out. I just could not deal with it; I had just been diagnosed with cancer and the pressure that I may never be able to have a kid was too much. Also, I had concern about my body; I mean I had already started the hormones and I would not be able to get any cancer care, let alone have a fertility procedure. There was a lot of back and forth, and I was able to be put on a payment plan and I gave them the $2,000 they had said it would be.

> Patient 1: I think one of the things that I have seen through all of this,on the financial side, it feels like you’re never told. And I feel like, not purposely, but I feel like we’re so caught up in the diagnosis side of things or the treatment that sometimes the places forget that there’s this other side (cost).
>
> Patient 4: I did not think that much about the cost until after my second surgery and all those bills and receipts for how much they paid started to pour in. I got out my computer and started to add up what it cost. I was astounded. I was astounded at what I have cost. Not that I am not worth it; I am, but to me, it was just horrifying.

OOP Costs Paid by Patients

Patients who have insurance and have lower or no OOP costs for routine care stated that they generally were not aware of what a covered treatment, surgery, radiation therapy, or drug costs. When something has a copay or coinsurance amount associated with it, participants stated that the cancer center staff tried to ensure that the patient was aware prior to treatment or testing. In addition, many patients who had commercial insurance or managed Medicare had to pay a copay for every visit. Sometimes those copays are $50 for each visit and it is common that patients have one or two visits a week. One patient, living on Social Security income, stated that her copays were too much to afford while paying rent and utilities. Patients expressed that these costs add up, especially when there is no income or limited income. Those with Medicare and supplemental insurance reported that OOP costs were more manageable because the insurance paid for nearly everything.

Patient 11: The treatment costs are astronomical but fortunately we have been able to manage it. In the greater scope of things, the costs are going quite well due to insurance. But for me it makes me feel so bad for others who are not as fortunate. It's a shame what things cost for medical care.

Patient 10: I have concerns and worries but at the moment, it's not so bad. I am financially stressed a bit, somewhat because the costs are always there. I don't feel in control of my financial situation. It scares the hell out of me.

Patient 8: When I was diagnosed a year ago, I was very concerned about the costs. It stressed me a lot. I worry about the cancer coming back and future costs I might have. It will always be a concern for me.

Patient 4: I don't pay that much except for over $500 a month in premiums but my absolute terror is when I watch the news and they talk about cutting Medicare. I keep thinking about "what if". What if I lose my health insurance? Then I will be in a lot of trouble.

Patient 3: I don't do anything that does not change the course of the disease. I don't do the extras that may be nice because I have to pay extra.

Financial Assistance and Charity

When insurance does not cover a medical test or treatment, patients explained that the test is offered and the costs are explained. Usually, the test or treatment is declined. For example, one patient's insurance company would cover a CT scan but not a PET scan for her lung cancer. She did not have the PET scan.

> Patient 3: I have finished chemo and I've had two CT scans since I finished chemo. I am in remission. My doctor wants to get a PET scan but my insurance company won't pay for my PET scan that he wants. Everyone would like to see a better picture. But they won't pay.

Several patients stated that they cannot afford the costs that are required to be paid for the recommended care. In these cases, the cancer center staff work to find financial assistance for the patient. There are programs that provide charity funds to patients who qualify. Foundations will cover the OOP costs of care that patients may incur including fees for infused drug therapy and other treatments. The funds are sometimes called foundation grants and these help the patient afford medical OOP costs (see Kaisaeng, Harpe, & Carroll, 2014; Rajurkar et al., 2011). There are also copay card programs that help with pharmacy costs that patients face. These programs are funded by the pharmaceutical company and provide for cost offsets for OOP costs associated with drugs (see Fein, 2017; Zafar & Peppercorn, 2017b). Foundations differ from patient assistance programs (PAPs) and copay programs. In PAPs, the drug company donates supply of the product to patient when the patient applies and meets criteria for not having insurance for the product. In this way, the drug is supplied free of charge for those who are without coverage. In copay programs, the drug is charged to the insurance and the pharmacy uses a copay card to charge the cost of the copay to the pharmaceutical company instead of the patient, thereby, reducing the OOP cost for the patient. Often there is a small remaining copay that the patient must pay. Because of self-referral laws, Medicare patients are largely unable to obtain support from these PAP and copay programs (see Zullig et al., 2017). Instead, charitable foundations can make grants to patients to cover their OOP costs that the insurance company does not (see Zafar & Peppercorn, 2017a).

> Patient 6: While I was on my chemo my doctor recommended getting Neulasta shots to help me prevent infection. Each time, I had to pay like $3,000 a shot or something egregious like that. The insurance did not cover them fully – they were like $14,000 total a shot and I needed six shots. So, I talked to the financial people at the cancer center again but there were no more copay cards available to cover me so I was going to go without it. But fortunately, she (the cancer center financial counselor) called and said that they were able to get me in and that brought my out of pocket cost down to $25. But even with insurance and without that card, I would not have been able to have the Neulasta shots. I could not make that work.

In the interviews, patients expressed both deep gratitude and passionate frustration with these programs. The processes to enroll and receive benefits are not easily understood or transparent for the patient. Patients must complete applications and provide detailed financial information. Sometimes staff at the hospital or cancer clinic assisted the patients with the paperwork but often it was the patient who completed the forms. This caused a great deal of anxiety and stress at a time when the patient was unwell.

> Patient 13: Well, I have had to do a lot of asking for charity. My cancer center and the hospital that I went to have these charity programs where you can apply for financial aid. I did all that, and well, in the case of one hospital – it took five

months! Of course, there were back and forth letters. You can never talk to a human being on the phone. The people who make the decisions sit in some dark back-room somewhere. So, this was constant “give us this piece of information; give us this piece of information; send us your bank records; send us your tax records.” You know, you swear to this and you swear to that and its stressful because you don’t know what is happening. The hospital is sending collection notices from the hospital and all of this was during the time that I was on chemo and some days I could not even get out of bed. So, it was highly stressful to say the least. Every letter the charity sent had a deadline on it that I was supposed to respond to but the letters always seemed to come after the deadline had passed. For some reason, the mail took two weeks and so I would get a letter that was past due to get them information and here I am, lying in bed, puking my brains out. It was a lot more stress than I really needed at that time.

Patient 6: I got a little money from a foundation. So that was helpful, but affording all the copays for my treatment was a huge financial stressor. On top of that, I had to fully pay up-front for tests and stuff that I did until I met my deductible which is $1,500. Some family and friends helped me to piece together the money that I needed until I fully met my deductible.

Patient 1: She (referring to her daughter caregiver) has been working to get some help on these things for us.

Patient 1 caregiver: We did get one grant so far for $5,000. That’ll go on account here, so all these copays will go against that. And we’ve got little grants that

> we've done. Well, let's see. Through the social worker here, I applied to six different places. And some of it's like we got a $100 check. We got a $500 check from one place, a $100 from the other. And so, we're using that to pay for these copays. If I was not helping my mom, there is no way she could do it. I think most people don't do it because it so hard and requires a lot of follow-up.
>
> Patient 4: I feel guilty about getting the money from the foundation because there is these other people who have it so much worse than me. And then I say, why are they better than me? So, I try to dismiss it, but that we have to even make those choices is offensive.

Research Question 2

Research question two focused on how FT manifested in patients' lives, and how patients used gist and verbatim as they made medical decisions. To understand how FT was present in patients lives, I asked participants to tell me about how their cancer costs impacted them. I asked about the experience of having advanced cancer, having treatments, and paying for their care. I also asked the participants to tell me about how the costs of cancer made them feel. Patients discussed the impact of OOP cost in their everyday living, their relationships, and their interactions with their oncologists. They discussed the coping mechanisms that they used when the costs were a strain and how, if at all, it impacted their decisions to undergo cancer treatments and supportive care.

Deprivations

Sometimes the trade-offs and choices that patients made to afford their cancer care were harrowing and caused them distress. Patients recounted how they saved money to live and pay for care. To save money while paying for cancer care, most patients immediately stopped spending money on things that they viewed as discretionary, such as gifts for charities, money to go out to eat, travel, and gifts for family and friends.

> Patient 2: I do everything by hand because it is cheaper. If I want something to eat, I have to make it by hand. I cannot afford to eat out. I am back to cleaning to keep myself. I clean houses.
>
> Patient 4: Before cancer, I traveled. I was not a world traveler, but I went back and forth to Kansas a lot and saw my friends and family that still lives back there. I am guardian for my brother-in-law who is 60 years old and mentally handicapped. So, I would go back to Kansas two to three times a year to check on him, "yuck it up" with my friends, and see my family. And now, I am lucky if I go once a year. Part of the reason is the money, and part has been how I felt because of the drug and the fatigue.

Sometimes it was little things that the patient gave up to save money. For example, one patient mentioned that she used to love to knit and was part of a knitting group. She no longer buys yarn to knit anymore. Another mentioned that she feels guilty forgoing school fund raisers.

> Patient 9: I have worries about money, I do. Like for example, last week I was not going to buy my girls' school pictures because of the price of the pictures and because I worry about my cancer costs. They give us a picture at the end of the year and because I am a teacher I thought maybe I could just take a picture of the picture and enlarge it. I am embarrassed to admit that I was thinking I could "steal

> it”. And I told my husband, “I am not buying the pictures this year; it’s not an expense I can make.” He went ahead and paid. And another example is that last night was the deadline to order things to raise money for the school. The girls were reminding me to order and spend the money and I just did not want to order. I ended up ordering some little mini thing for $22 each. I was aggravated that I had to spend the money on something silly. And then I felt terrible because it was for a good cause. The school needs the money. Without cancer costs, I would not be thinking like that, because all I could think about was those $46 I just spent could go into my cancer care.
>
> Patient 3: I was thinking, “how the hell are we going to do this?” I quit my job and I used to make good money. But we worked it out – by not doing anything. So, I just spend less and am more contentious. It’s more like when we were young and we were broke. It’s kind of disappointing.

Impact on Friendships and Relationships

The costs of cancer impacted patients’ friendships and relationships. In many discussions, patients became teary and wept while recounting the impact of their cancer and cancer costs on their families. Two patients wanted their caregiver to participate in the interview because they felt strongly that their caregiver’s perspective on the cost of cancer was important for me to capture. Patient 1 said that her relationship with her adult daughter caregiver was the reason she is undergoing treatment for her cancer at all. She stated she would not have had the ability to do all the paperwork to get help to afford her care without help. Two other advanced cancer patients said their husbands always handled the money and their cancer care costs. Both were aware that their care costs a lot but neither professed a focus on costs. They have decided to focus on treatment and leave the financials to their spouse. These patients depend on their family for this support.

Patients who lived with a partner found that their family members supported them both emotionally and financially which was extremely reassuring for them. It also created feelings of guilt for the patient. As one patient puts it, she does not want to spend their entire retirement savings only to die and leave her husband without money. This is a concern for some patients. For others, there was less concern on the overall impact of the costs upon their loved ones and more focus on how cancer has changed their relationships.

One patient stated that fighting cancer together with her husband at her side has deepened their relationship. Recently, they had made the decision to stop her treatment and look into hospice care. She was comforted by his support and involvement in her decision. Another patient spoke about her cancer and the blessing that it has been in her life in some ways.

> Patient 9: Actually, the treatment time for my cancer was one of the most beautiful experiences of my life; the whole experience of having cancer in 2009 and 2010. I won’t say that cancer was a gift, but it was the closest I have ever felt to God. I just got on my hands and knees and prayed. I just spent time reading the Bible and praying. I knew I was in His hands; I was taken care of physically and emotionally. So then, I was able to get better.

Another patient reported that she has seen her friends change. Some of her old friends have become uncomfortable around her. She also reflected that she has less interest or empathy for what she deemed to be her friends’ petty complaints about their lives. She believes that she makes them uncomfortable because her advanced cancer reminds them of their fragility.

Distrust of the Health Care System Motives

As patients go through cancer care, some experienced a rapid succession of bewildering series of tests, procedures, surgeries, radiation, and infusion treatments. As these tests and treatments progressed, some patients expressed concern that the health care system was too focused on making money from their cancer care. Patients expressed distrust in the motives of the health care systems and sometimes those of their providers. One patient stated that she overheard her surgeon asking her medical oncologist if the oncologists had convinced her to undergo a full mastectomy versus having a lumpectomy. She related that hearing this conversation made her think that the surgeon must make more money on the bigger and more invasive surgery and she became worried that perhaps her medical needs were not the primary focus. It was too late to change surgeons but she was concerned.

> Patient 2: I had a biopsy and a mastectomy. I was poisoned by chemo, but I suppose everyone needs a paycheck (laughs). I just hope its legitimate. It seems like cancer treatment is a real racket.
>
> Patient 6: Before my surgery, I was really anxious about the surgery – the costs are big concerns. Financial costs impact my every part of my decision-making – I

> mean, I didn’t go to the doctor much before and I am always a little skeptical – am I getting these recommendations because it is what I need and they are the best form of care or because they are such a money maker? It all is a bit disconcerting to me.
>
> Patient 11 caregiver: Maybe this is beyond the intent of the interview, but I feel like the drug companies are in league with the government. It should not cost what it does to treat cancer. I am not angry like, “poor me”, but the excessive costs of care are appalling.

How Cancer Costs Make Patients Feel

The emotional impact of cancer costs changes as patients progress through cancer care. Patients described periods of time in which they felt fear about their ability to afford their care. They spoke about how their emotions changed throughout their cancer care. Some have had a cancer diagnosis for 15 years while others were in their first year of treatment. The most common word that was used was *worry*.

> Patient 1: I worry – I still worry about it a lot. When I worry, I get sick.
>
> Patient 8: Cancer treatment monetary costs are hard to put in monetary terms. The stress from having this disease interfered with my relationships. I worry about being unemployed and having cancer and I could not sleep. I had always been an insomniac but now I could not sleep at all.
>
> Patient 4: Money is the last thing I think about before I fall asleep and the first thing I think of when I wake up. I was never like that before cancer.

> Patient 12: It makes me so angry that it has to cost so much. There is no way to tell me that the bag of chemo costs $5,000. There is no way it costs that much, but that is what they charge.
>
> Patient 3: How you feel about the whole thing is, that it takes your self-esteem. You know? Where if you were strong – you're not strong anymore.
>
> Patient 1: I feel that it is very important to pay my debts and so I worry.
>
> Patient 13: For me, it has never been a question of doing the treatment that needs to be done and I figured I would figure out the money at some point. My mom went through this and she wound up passing away in debt to her oncologist. But it has been very stressful.

Cancer Costs Representation in Their Lives

As part of the interview, patients shared artifacts with me and described what their experience has been with cancer care costs. Some patients shared objects while others shared or described images. One patient described what her life was like before and after cancer and cancer costs. Prior to her cancer diagnosis, this patient felt that her life was like a perfect bubble moving along but once cancer struck the bubble began to take on cracks and was shattered. The snug bubble was gone for this patient, replaced by shattered glass. She feels that reality is harsh.

> Patient 2: This notebook is a reminder of how hard I have to work to keep on top of things. I am really obsessed with my cancer. It can be a lot. I write things in here that I am thinking about or working on. I am thinking about taking the bus to

> save money. If my car goes, I cannot afford to fix it – oh my gosh. I need a miracle. I mean really. I need a miracle.
>
> Patient 9: The image to me of cancer costs is the iceberg. The unknown costs are all those unknown expenses below the waterline. In the rest of my life, if I go on a trip, I can research around and get a comparison of choices. Or if I go to the grocery store, I am going buy organic, so I will pay a little more and I know it. I know the price before I buy. In cancer, you don't know. You never know how much it will be.
>
> Patient 8: My image is of a dead flower with the petals and leaves falling off. It's not a good image. It's losing its leaves. Life is losing its capacity. I pick that because of the process. The leaves fall off one by one and is a slow dying process. Once it was beautiful. Old age and being sick does that to you. It uses it up.
>
> Patient 12: The waves catch you in the ocean. It feels like I was on the shore and waves keep pulling me further and further out. There is nothing I can do. I am drowning. You are downing in debt. Scary!

Some patients shared physical artifacts. One participant showed me a satchel filled with vitamins that he was taking to complement his cancer treatment. He explained that he was following a regime of vitamins and supplements to boost his body's ability to fight the cancer. Even though it was expensive and a large bag of vitamins that he took throughout the day, he wanted to do all he could to beat the disease.

Use of Gist and Verbatim in Health Care Decisions

To better understand decisions that patients made about their health care, I asked about how they made choices about cancer care options. I probed to hear about the information the patients relied on, and what they recalled about these decisions, including the use of gist and verbatim.

The types of decisions that we discussed did vary and some of it was based on the types of tumor the patient had, or the circumstances surrounding the decision. I listened to how patients included costs in their thinking and in their narratives of their decision-making. For example, in women with breast cancer, several mentioned that they worked with their surgeons to decide about whether to elect a lumpectomy or a full mastectomy. Some women indicated that a lumpectomy was not offered as a choice and they only found out about that option after having mastectomy. Others indicated that they struggled with the decision, recognizing that a less invasive surgery might mean a faster recovery which could afford them a chance to start chemotherapy sooner, perhaps offering an advantage to them in survival. Others knew a lumpectomy might mean that they could return to work faster.

Several had pre-surgical chemotherapy, which their oncologists recommended to the patients. In each of these scenarios, the patients did not recall specific verbatim statements or facts that their surgeon or medical oncologist made to them about the efficacy or safety of options. Instead, the patients recalled the emotion of their recent breast cancer diagnosis, the general gist of the written materials that their doctors provided about the surgery, and the feelings of fear of the unknown including the unknown costs. In no case was the cost of the surgery discussed with the patient in advance. The decision was not whether to have surgery; it was a decision about the kind of surgery to have and whether chemotherapy should be started prior.

One patient shared that she wanted to limit the exposure of her body to the toxic effects of chemotherapy and she was concerned about the costs. She wanted to have the least amount of chemotherapy possible and conveyed this to her doctor who had recommended the standard number of cycles of therapy for her tumor and line of treatment. In this case, she recalled the exact verbatim of the discussion and chose to follow her doctor's recommendation.

> Patient 6: For example, when I was asking my doctor, what happens if I take four treatments instead of six? He said, "we did not really study that; we only know that six is the number that works." I was asking for a couple of reasons. I had wanted to have a destination wedding and did not want to get married when I was so weak from chemo and the idea of pumping poison into my body and killing off all the cells was just…a lot. I wanted to see what the least was that I could do. I wanted to see what my body really needed and what would be best for my system. And there was a cost worry to that as well.

In another example, a patient who had been on treatment for her cancer intermittently for 10 years was making a decision about treatment for a recurrence. She reported her recollection of her recent discussion with her doctor. She did not have an OOP cost for her oral medication but was concerned about taking a drug every day and the potential side effects on her body. She remembered a vivid combination of verbatim statements from her doctor about the efficacy of the recommended therapy, and her own emotional gist recollection of feelings of distrust of the side effects of the medication. She also had gist thinking that she had a desire to extend her chances to live but balanced that thinking with a concern of not poisoning her body with chemotherapy.

> Patient 2: I remember feeling very anxious. I was very vulnerable. I don't want to die and my doctor said my cancer was going up – what I mean is my cancer treatment was not working anymore and doctor said I have to do something else. I was trying to understand what the benefits of my latest drugs are to me, so I asked a doctor about it and she said that they are excellent drugs to help women with breast cancer to live longer. She said women who took these live two times longer than those who don't take them. People who don't take them died earlier.

Some patients explained that they followed the recommendations of their physician. Although they received information about their therapy, it was provided to help them manage through the treatment and know what to expect rather than part of a decision-making process. They were satisfied with following the doctor's treatment plan for them.

> Patient 13: My doctor did a fairly good job of explaining the chemo. She explained why I needed it. I was in the hospital post-surgery and it was not a great time and I got a little more detail on the therapy from a chemo class later. I learned about the specific side effects about the drug and what to expect. I got an info sheet and I asked questions. I don't remember any numbers or statistics – just

> that there are five protocols that I could choose from but this one had the best results.
>
> Patient 11: With the immunocancer therapy I am on now, we followed the doctor's advice. We did not have any real questions about it. He is terribly knowledgeable about cancer care. He told us that "it got very good results" so we followed his lead. We did not discuss costs.
>
> Patient 5: I follow my doctor's advice on what therapy to take and when to go to have it. I would very much like to do the additional holistic therapy that my holistic doctor has prescribed but I have not been able to afford it and I cannot ask my children to cover it. We are researching the other therapy to see what it will cost but those are in addition to what my doctor prescribes.
>
> Patient 8: I got information about a chemo – they said this is what the drug is. It will block things and kill cancer cells. So, I said OK. Let's do it. I got a ton of info – a huge folder about my condition and treatments. I went to her2.com – and for my radiation I asked other doctors like my primary care. My doctor was wonderful and he explained. On radiation I just went with my doctor's orders. I went with what he said.

Research Question 3

The final research question was how did FT factor into treatment decisions in patients with advanced cancer? To address this question, I asked patients to talk about how costs that they were responsible for factored into their decisions for cancer care.

Patients spoke openly about the serious nature of their disease and stated that they focused their energy and effort to elect care strategies that put the cancer into remission or cure it. Nevertheless, many patients were pragmatic about treatment choices that might not be curative but may offer a longer life. Patients said that they followed the recommendations of their doctor provided their insurance covered the therapy. Even though the copays may accumulate over time, patients believed that they needed to do these therapies to live.

There were two patients who had what each patient believed to be very expensive OOP costs associated with oral chemotherapy. In each case, the patient wanted to start on the drug that their doctor prescribed but upon learning of their financial responsibility, they refused to take the drug until the cancer center helped to arrange for charitable assistance for the OOP costs.

> Patient 4: I got information from my oncologist who said this drug was very new. He explained what it would do and the risks, and the side effect, and he said it's really expensive. And I said, "well, talk to me about what you mean by really expensive". And he said, "I will let the pharmacist do that – he's better". So, the pharmacist called me and he told me what it would cost me with my insurance and I told him right then and there, "I cannot do that. I cannot. I cannot pay you $5,000 or $6,000 a month. I can't do that". I can't sell my home, and I can't sell my body, you know (laughs). So, he said, "whoa, not to worry, this is what we are going to do. I need to get you into a foundation to help and I just need some info from you and I will call you back". He called me back and said, "it's fine, it's

> covered". And so, I was able to get an extra $5,000. But without that, I wouldn't take it for $5,000 a month. It's never been an option for me that I won't take the drug or do the surgery until it comes to the fact that I will have to live under a bridge to afford it. What's the point?

Another patient had a similar experience and she obtained financial assistance through a foundation but once the grant money was discontinued, she elected to stop taking the drug. This was a decision that was not solely based on cost although cost was a major determinant. In her case, she had been experiencing significant fatigue on the drug and when she combined that feeling with the high OOP cost, she simply did not want to continue the drug and pay for the costs herself.

> Patient 10: I have been pretty good with my Medicare insurance and supplemental until my doctor wanted me to take a maintenance medication. Then, I found out how much the maintenance medication was going to cost – because that is a pill I take every day. I have Part D, but that particular prescription was something I needed to get from the specialty pharmacy and not even the preferred pharmacy. Initially, it was going to be $13,000 a month. So, I would have had to pay some ridiculous amount, thousands of dollars a month as my share. I flipped out! I went to the financial counsellor here and she was rather useless. So, I got the information and made the calls to get my own grant of money because she was too slow. I got a grant of $25,000; it covered the rest of the year. Then, I was taking the pill and not doing too well on it and at the same time, I got a letter in the mail, post-dated mind you, saying "thanks for being one of our grant

> recipients but we are pulling the money". I panicked! I thought they might want money back I had already spent on the drug. I was so afraid and so freaked out. My throat fills up just thinking about it. I called them and the phone people were reading from a script and not helpful. They were wonderful, but it was not their fault. It was weighing on me and weighing on me. And the quality of life on the drug was not good. And what was I going to do next year without a grant? I talked to my friends and family who I knew would understand. I decided to stop taking the drug. I just decided that I would take the risk of having a shorter life than giving one cent of equity in my house to afford my drugs. I was not going to do that! I worked really hard for that. I was not going to use the equity in my house or the tiny bit of savings that I have to keep me alive. That is ridiculous!

OOP can be significant for cancer patients who may also have premiums, deductibles, copays, and drug coinsurance (Dixon, Cole, & Dusetzina, 2017). Patients stated that they must either fund their OOP costs from savings, home equity, debt, or charities. The other option is to forgo the care. For example, patient nine was about to start chemotherapy for a breast cancer recurrence and was very concerned about costs. She wanted to save money and did research and thought an option might be to forgo having a central port inserted. She found that venous access was a possibility and she wanted to avoid the surgical costs of the port. She knew from having a port placement before that there were surgical visit fees, port placement surgery costs, and follow-up visits for post-surgery assessments. With a surgeon consult, the copays were a concern to patient nine. Nevertheless, the cancer center team urged her to have the port placed. She was upset when she learned she had to pay a $50 copay to have a port maintenance learning session with the nurse because she was experienced and knew how to care for her port and did not want to pay for that visit. She did not return to the surgeon to have her port stitches removed because she thought she would have to pay for a visit copay but learned that it was covered as part of the global surgical costs. The patient exclaimed that the costs owed by patients are not clear and trying to manage them can be frustrating and confusing.

> Patient 9: So, I get my port and surgeon left the plastic stitches not the dissolvable ones and I thought, "I am not going to pay $50 to get my stiches out from the surgeon. I will get my nurses at the clinic to do it when I am there for chemo and only pay one copay." But they won't do it. They said that the surgeon does not want them to do it and they tell me it can actually infect and I realize something - I am being stubborn about money and this could actually hurt me. So, I call the surgeon's office and ask how much it costs to get the stiches out and they say it does not cost anything more; it's part of your surgery. That's another thing. How do we know how much things cost and what things costs?

Only one patient said she could afford the massage therapy and physical therapy that was recommended but not covered by insurance. Several patients said that they believed that they would benefit from these therapies but have not elected to do them because of the cost. Another example is that patient one did not followed up on recommended care with a rheumatologist because she cannot afford the copay for the extra specialist visits beyond her cancer care. If the care is not treatment for the cancer itself, it is more likely to be viewed as optional by the patient and not elected. Even with therapy meant to prevent recurrence or maintain remission, patients considered or did forgo the treatment, and cost was a primary driver in the decision.

Evidence of Quality

To be quality research and to make contributions to the study of the impact of FT on advanced cancer patients, a study must demonstrate trustworthiness. It was critical that I followed processes and procedures that increased the validity and reliability of the results or one might question the results (see Maxwell, 2013; Patton, 2015; Yin, 2003). The quality and trustworthiness can be tested by evaluating the credibility, transferability, and dependability, and confirmability (see Yin, 2003).

Process for Credibility

In my study, I was not able to observe patients while they were making health care decisions; I had to ask them to recall their thinking and emotions at the time of the decision (see Yin, 2003). I improved the credibility of the study by asking the patient to explain the full rationale of their thinking in several situations and asked clarifying questions to ensure I understood their explanation. In this study, I looked for cross-case pattern alternative explanations. To improve the credibility of the study, I tried to identify alternative inference when I was examining themes that I saw in my cross-case patterns. I looked for alternative explanations in the data analysis. During the interview phase of the study, I kept journals and notes about the interviews, including the emotional context that the patient displayed. I noted my bias or emotions since I wanted to ensure I was not inserting my bias into study.

Process for Transferability

When a study has transferability, its results may be applicable outside of the study (see Yin, 2003). To increase my transferability, I worked to use rich and thick descriptions which helped provide a deep contextual frame for the study. My descriptions included verbatim text from the patients with advanced cancer, describing their thoughts, feelings, actions, and beliefs.

Process for Dependability

Dependability in case study methods is achieved when a study can be replicated in the future and achieve comparable results (see Yin, 2003). To increase the dependability of my study, I documented my study patient recruitment and interview operations. I followed my detailed steps for data collection and data collection and storage. Moreover, I followed the steps for my coding of the data and data analysis.

This study used four major forms of data. I relied on patient interviews, field notes and observations, the validated and published COST tool, and data artifacts supplied by the patients. Taken together, these helped me to establish triangulation in the patient experiences between the cases. I was careful to increase the dependability by ensuring I kept the results attributed to each individual respondent and followed my processes for data management (Appendix I) All data was loaded, stored, and managed in the software, Nvivo (Version 11).

Process for Confirmability

I helped to enhance the confirmability of my study by using reflectivity. Each participant was asked to review the typed transcript of their interview to give me feedback on whether I appropriately collected their information. I sent these transcripts to them on email and asked for them to either email me back or call with their thoughts and comments. I asked them to check the transcripts for accuracy. Several patients made small adjustments to facts. Most stated that the notes were more detailed that they thought that they would be and appreciated my focus on the accuracy. They were also able to give me feedback if there was any area that they wished for me to elaborate on or that they did not wish to have included, for any reason. Patton (2015) suggests that qualitative researchers use self-reflection to help examine how the researcher interacted with the content of the study, and limit bias. In this manner, I increased the confirmability of the study.

Summary

My study's purpose was to understand the experiences of advanced cancer patients 'decision-making and experiences while experiencing financial distress and FT. I worked to understand how OOP cancer care costs impacted these patients' experiences and decision-making. In Chapter 4, I discussed the study setting, my community partner that helped me to facilitate the research, and how I recruited and secured participants. The study followed a purposeful sampling method and I obtained informed consent prior to the interviews.

I organized the discussion of the research findings by the three research questions. My first question focused on research participants' OOP costs that stem from their cancer care. Some patients discussed reductions in employment and the impact that had on their income and mental health. Patients spoke about the significant impact that a cancer diagnosis had upon their life and most shared that costs for care have been worrisome and a source of stress throughout their care. The OOP costs can become significant for some patients, even with insurance and coverage for procedures, surgeries, and infused drugs. Sometimes financial assistance is a helpful way for patients to manage their financial obligations. Even with insurance, several stated that their care would be unaffordable without charitable care assistance.

Research question two centered on the manifestations of FT in patients' lives, and their use of gist and verbatim in medical decisions. Patients shared the deprivations that they and their families have used to accommodate the extra costs of cancer care. Patients reported the impact of cancer and cancer costs on their relationships with friends and family. In addition, patients shared how the experience of paying for cancer care made them feel and how this increased their distrust of the health care system profit motives. Patients make extensive use of gist in their decisions about health care but often have a clear verbatim recall of when OOP costs are mentioned. Patients shared exact dollar figures about costs that were shared when a therapy was proposed.

To address research question three, I captured how patients explained the impact of FT into treatment decisions. Patients shared that OOP costs can be a major impact in their decisions and how the distress that it caused impacted their decisions.

In the final section of Chapter 4, I discussed the methods and processes that I followed to increase the quality of the study including credibility, transferability, and dependability, and confirmability. To improve credibility, I worked to fully understand patients' explanations, asking clarifying questions. I also applied a process of cross-case pattern analysis to provide for the emergence of alternative interpretations. Finally, I used journaling to decrease my bias. To increase transferability, I employed the use of thick and rich descriptions and direct patient quotes. To improve the dependability of my study, I followed a written process for my research participant recruitment and interview conduct. I used triangulations from several sources of data including interviews, artifacts, and the COST tool. The confirmability of study was maintained by my use of reflectivity and full participant review of interview transcripts.

In Chapter 5, I will provide my insight on the interpretation of my results and the limitations of the study. I will examine the recommendations stemming from the study, the implications for social change, and my experiences as a researcher in this study.

Chapter 5: Discussion, Conclusions, and Recommendations

The purpose of this qualitative case study was to understand the experiences of advanced cancer patients who are under financial stress to understand how OOP cancer care costs impacted these patients' experiences and decision-making. How patients feel and think while experiencing FT and making decisions about their care was central to the study. There is little published literature about advanced patients' experiences and health care decision-making thought processes while experiencing FT. Findings may help those who care for these patients to develop options to mitigate declines in health outcomes and decreased quality of life for patients with FT.

Three questions framed my study:

1. What was the experience of advanced cancer patients who experienced financial distress stemming from OOP costs of the disease costs of the disease treatment?
2. How did financial toxicity manifest in patients' lives, and how did patients use gist and verbatim as they made medical decisions?
3. How, if at all, did financial toxicity factor into treatment decisions in patients with advanced cancer?

I used a case study method to design and implement my qualitative research. I conducted in-depth in-person or telephone interviews with 13 patients with advanced cancer. I recorded all but one of the interviews, and I collected responses on a validated COST tool that was used to score FT. I also gathered artifacts and representations of the cost of cancer in the patients' lives to triangulate the data. I transcribed the interviews and used NVivo data analysis software (Version 11) to assist in data management and analysis. I used a two-cycle coding process and applied a cross-case analysis to identify common and explore infrequent themes.

In Chapter 5, I provide an interpretation of the results using the themes identified in Chapter 4. I also relate these themes to FTT, the theory used in my study. In the next sections of Chapter 5, I discuss limitations of my study and recommendations for further study. The implications for social change are also included, as well as my personal insights from conducting the study.

Interpretation of Findings

Demographic Information

This study included advanced cancer patients who self-identified as being concerned about the costs of cancer and who volunteered for the research. Participants were from three areas of Colorado. I excluded patients without insurance. The time since diagnosis ranged from 6 months to 15 years. Most patients (8) had been under treatment for less than 2 years. Most patients lived with a spouse or family member; only two lived alone. The most common site of tumor was the breast with six of the 13 patients having a primary diagnosis of breast cancer. Of the 13 volunteers, 12 were women. I did not exclude any men. Women have been shown to participate in equal proportion to men in cancer research (Unger et al., 2013). In the United States, the overall incidence of cancer in women is only slightly higher at 50.6% of all cases compared to 49.4% in men (Siegel et al., 2018).

Employment Status and FT COST Scores

Most of the participants experienced a change in their ability or willingness to work after their diagnosis with cancer. No participant increased her or his work hours after diagnosis; only one was still working full time after two years of cancer treatment. The others reduced their work schedule or remained retired. This was consistent with the national experience of cancer patients who reported loss of income and employment (Zajacova et al., 2015).

The self-assessment of FT was another dimension of the demographics of the patient group who participated in the study (de Souza et al., 2016). Each participant took the COST assessment and discussed her or his feelings associated with FT during the interview. At the time of the interview, five participants were feeling moderate levels of FT while five were feeling mild levels. Two participants explained that they were feeling no symptoms of FT at the time of interview. One participant shared that he felt high levels of FT. During the interview, several participants commented that they had resolved some of their anxiety and distress and that their FT score had come down over time.

Certain events triggered greater recollection of FT for participants in the interview including unexpected large OOP costs for a necessary and prescribed therapy, sudden loss of benefits for care including loss of charitable foundation funds, and surprise bills in the mail from hospitals and providers. Participants relayed feelings of loss of control and a need to choose between a therapy important to their ongoing battle against a serious diagnosis of cancer and financial stability. These feeling of stress and anxiety can contribute to poorer outcomes for patients with cancer and maladaptive coping strategies (Chan, Gordon, Zafar, & Miaskowski, 2018; Delgado-Guay et al., 2015).

Research Question 1

Employment Status

Participants described the years of treatment and disabilities they endured resulting from treatment for their advanced cancer. Many had multiple surgeries and hospitalizations. Most had undergone long periods of chemotherapy or immunotherapy. Advanced cancer is a disease that has a high level of mortality, and the treatments for the disease typically involve surgical procedures, radiation therapy, and immune and chemotherapy regimens designed to attack the active cancer cells (Masters et al., 2015). The treatments are resource intensive and costly, and can lead to considerable recovery time for the patient. The impact of the disease and its treatment caused nearly all participants who were employed at the time of their diagnosis to either quit their jobs or take some form of medical leave. This was consistent with the literature on FT and the impact of cancer on patients' incomes (Jagsi et al., 2014; Zajacova et al., 2015).

The loss of financial security, independence, and self-worth derived from employment was an emotional burden to some of the cancer patients in the study. Patients described these dimensions of self-confidence and loss of independence as some of the most painful aspects of the cancer diagnosis. The loss of employment contributed to FT for patients not only from a financial perspective but also from a self-efficacy and mental health perspective.

Cancer Diagnosis: A Major Life Event that Triggers Downstream Costs

Cancer for patients was a tipping point in their lives. The diagnosis meant that they immediately moved to active treatment, with all but one having surgery within a few weeks of the diagnosis or chemotherapy followed by surgery. These events and the diagnostic workup triggered the first wave of costs. Typically, patients described an initial numbness and lack of focus on costs of care. The costs were on their minds but the devastating nature of their diagnosis coupled by the urgent need for intervention to prolong their life outweighed the cost focus.

As patients progressed through care and began to recover from the initial treatments, the costs became more a focus and reality. Patients described opening piles of mail from their health care providers and being astounded at the total costs paid by their insurance. Patents relayed that there were many unknown costs that came to them during this time and that their general reactions were to try to pay them as best as they could because not receiving the care was choosing not to live.

OOP Costs Paid by Patients

Patients’ insurance provided some degree of protection from OOP costs, particularly for those with Medicaid and Medicare supplemental insurance. In those cases, most of the routine care and copayments were covered by insurance, and the OOP costs were for things stemming from cancer care such as supportive care services or transportation. In addition, the cost of the insurance premium was considered a necessary monthly OOP cost. For those with commercial insurance plans, there was a higher likelihood of OOP costs including copayments, coinsurance, and high deductibles. Most of these costs began to hit immediately following initial treatment, and this group of patients reported a higher level of anxiety and distress stemming from these costs. This was consistent with the literature on the impact of OOP costs, particularly on those who are younger and have commercial insurance (Barber et al., 2016; Jagsi et al., 2014). Those with Medicaid also have distress because their costs are largely covered but their income is so low that affording the basics of daily life is an ongoing struggle (Ramsey et al., 2016).

Financial Assistance and Charity

Among all participants except one, access to care associated with high OOP costs was obtained with the assistance from charity and foundation grants. One patient had household income and savings sufficient to afford the costs of care. Hospital and cancer center staff typically introduced these options to patients once therapy program costs were explained and patients expressed a concern for affordability. These programs have become central vehicles to providing bridge coverage of drugs and services that otherwise are not affordable for patients because they are not fully covered by insurance (see Nicolla et al., 2017; Yezefski, Schwemm, Lentz, Hone, & Shankaran, 2017; Zafar & Peppercorn, 2017b).

Research Question 2

Deprivations

Patients and their families make accommodations in their lives to afford cancer care. These coping strategies include changing their spending patterns and reducing spending on items that are no longer deemed essential. Participants also expressed that they stopped planning for future expenses like travel or retirement activities. This caused disappointment and sadness for the participants who felt that they had worked to maintain a lifestyle and future security, which had been eroded by health care costs. These findings were consistent with those from recent studies of patients with FT in cancer and coping mechanisms (see Head et al., 2018).

Impact on Friendships and Relationships

Cancer and its costs impact patients and their families. The costs are often carried not only by the patient but also by the spouse and family. This can add stress and strain to relationships and cause feelings of anxiety and worry for the whole family. Participants described the impact of their family and friends supporting them both financially and emotionally, including how their relationships changed as they progressed through cancer. Several participants credited their family for providing the stability and support to make treatment possible; without them the patients would not have had the resources or expertise to navigate the system, find help, and access care.

These relationships formed a stabilizing force for many cancer patients providing them with both financial and emotional support necessary to endure the challenges of cancer care. This stabilization provided by family and friends became a source of stress when patients felt that they had become a burden to their family or friends who were not able to cope with the changes that cancer created. One participant shared that she had found it more difficult to be around her friends since being diagnosed with cancer. Beyond providing financial protection, supportive friends and family have been identified as a factor for increased resiliency and coping with the stress and distress caused by cancer (see Carrera et al., 2018; Kim, Han, Shaw, McTavish, & Gustafston, 2010).

Distrust of Health Care System Motives

The system for caring for cancer patients can make some feel as if it is set up to profit from their misfortune, and some participants expressed concern that some care may be not necessary but is recommended because of a profit motive by health care providers and pharmaceutical companies. Although patients expressed distrust of the system, nearly all spoke of the deep trust that each had with their individual oncologist. Distrust in financial motives is one of several dimensions of trust and is part of a concept called values distrust (Yang, Matthews, & Hillemeier, 2011). The patient may feel that ethical values, financial motives, and transparency are misaligned. Distrust of the health care system in cancer screening is well documented, particularly by those of color and lower incomes (Armstrong et al., 2013; Yang et al., 2011). Although researchers have documented the erosion of trust in the health care system (Ozawa & Sripad, 2013), there is a gap in the literature in understanding the dimensions of mistrust and its impact on cancer patients who are experiencing FT. This dimension of the patients' mindset may also impact their medical decision-making in terms of choosing therapies, tests, and options and in their compliance with oral therapy regimens.

How Cancer Costs Make Patients Feel

Participants described a range of emotional reactions to how cancer costs made them feel throughout the course of their care. A common theme was a constant nagging worry that plagued participants' everyday lives and thinking. This worry eroded their psychological well-being and was a constant source of stress. The way patients feel about cancer costs and the level of stress changes over time depending on the circumstances. Participants cited examples of how cancer costs impacted their lives including not being able to provide for their child and losing custody as a result, generating large debts, and moving in with others to afford to live. These actions had an emotional strain on participants, and their reactions included deep sadness, worry, anger, and fear. Some cancelled their plans for travel in their retirement, cut all social engagements, ended charitable donations, and lived more simply in the moment, not thinking so much about the future. Several patients mentioned the positive aspects of cancer costs on their relationships because they realized how much their families supported them financially and emotionally.

Cancer Cost Representation in Their Lives

Patients shared images and artifacts that represented their experience of cancer costs in their lives during the interview. These were powerful and complicated discussions, often taking the patient some time to explain why they chose the particular image or artifact and how it made them feel. The themes of these artifacts ranged from harsh images of destruction and debilitation to images of amulets or ammunition and means to keep order in life and fight against the cancer. One patient described cancer costs as the constant pull and pounding of the ocean waves taking a swimmer from the safety of the shore out to deep waters and drowning them. Another spoke of living in a happy snug bubble that is shattered and fractured forever more. An iceberg represents the danger of the unknown potential future costs for one patient. Another patient described the file drawer full of paperwork, remittances, bills, and correspondence that came like an avalanche into her life after cancer costs began. The drawer and the financial maintenance of her care requires her energy and focus to help keep track of all her bills, costs, and foundation support and is a constant reminder of the stress of this dimension of her care.

Use of Gist and Verbatim in Health Care Decisions

There was use of gist and verbatim in decision-making. Decisions were often infused with emotion around the grave risks that cancer posed to the patient as well as the worry and concern about its affordability. The trust in the medical oncologist was an important element in the gist decision-making processes for patients. Patients cited that they recalled that the therapy or the surgery was what the doctor thought was best for them at the time. This gist recollection is aligned with research around patient health care decisions making in situations where risks are high and outcomes uncertain (Reyna et al., 2015). Nevertheless, patients did have specific verbatim recall of costs of care. In these cases, patients recalled the quoted costs that they would be responsible for and the resultant decision. If the costs were considered unaffordable, then the patients opted to not have the recommended therapy. OOP costs of care in cancer produced a high degree of verbatim recall in the patients in this study.

Research Question 3

Patients focused their decision-making on selecting the therapy recommended by their doctor if the OOP costs were reasonably affordable for them. Patients gave many examples of recommended supportive and complementary care including physical therapy, acupuncture, and massage therapy that they believed would benefit them, but they did not access due to costs. Only one patient paid OOP for these therapies. Patients focused on paying for their cost share on services that treat the cancer and extend their life. In three separate patient examples, OOP costs were high for prescribed oral drugs or supportive care drugs. In each situation, the patient elected to forgo the drug until a foundation offset the cost. These findings are fully consistent with literature correlating higher OOP cancer costs and reduced access to therapy (see Dusetzina, Basch, & Keating, 2015; NIH, 2007; Parise & Caggiano, 2013; Puts et al., 2015). Multiple studies have confirmed the reduction in access to care when OOP costs increase for cancer patients, even with the protection of health insurance affords.

Theoretical Framework

I applied FTT as the theoretical framework for this study of decision-making of advanced cancer patients. This theory holds that cancer patients use conceptually encoded blocks of information that they have gathered in the decision-making process to help them in selecting an option (see Reyna et al., 2015). In my study, patients described making important and risky choices between full mastectomy or lumpectomy, accepting an oral chemotherapy regimen, radiation, or undergoing white blood cell growth stimulator therapy as supportive care during high risk chemotherapy treatment. Patients described the gist of their decision-making, including the information that their physician relayed and why they consented to the option. The FTT theory posits that patients use gist as an efficient means to accurately recall and process options and select from alternatives (Reyna et al., 2015). My findings that confirm the use of gist information as a means by which patients recalled and processed information. Reyna, et al. (2015) advanced the theory that patients overlay their emotions, morals, and judgement with makes for the fuzzy nature of gist decision-making (Reyna et al., 2015). My study found that the advanced cancer patients did have emotional and moral overlays in their decision-making processes. In my study, patients use verbatim to recall FT and costs. Patients who had large OPP costs associated with their care had vivid verbatim recall of those costs and these dimensions of the decision-making dominated. Even the patient who had no FT, when she described shopping for hospice centers, she quoted the per day costs and told me that it was an important factor in their decision-making. The hospice cost was not covered by insurance but would need to be paid by the patient. In the study, when the patient was responsible for a significant cost, and was experiencing FT at the time of the decision, the verbatim cost trumped all other decision factors including safety, efficacy, and trust in their physician’s recommendation. The patients’ verbatim recall was of specific costs for which they were to be responsible and were, at the time deemed to be unaffordable by the patient. This produced an immediate decision to either discontinue on a therapy or to not select a therapy that may have been the best opportunity for survival by the patient. The patients describe great emotional anguish in making these decisions but pragmatically describe their rationale.

This is a significant finding that was not part of past research in cancer decision-making within the FTT framework. Patient responsibility for cost of care had not been a part of past evaluations of decision-making. OOP cost is a significant part of advanced cancer patients’ experience and should be considered whenever an evaluation of medical decisions making is applied. Patients in my study commented that their doctor did not mention exact costs of care and support staff to handle these discussions. Once participants understood the cost, patients began to resist accepting the therapy. One patient explained that it does her no good to survive longer with cancer only to become bankrupt and homeless as a result. The verbatim OOP costs are a significant determinant in advance cancer patients' medical decision-making.

Limitations of the Study

This study is limited by several factors that are inherent in its design and scope. The study had a small sample size with patients who had different types of cancer. With only 13 study respondents, and nearly all of them women, the study may not represent the wide variety of experiences and decision-making that thousands of advanced cancer patients have. My study focused on participants from Colorado and one may find that the experiences and patients' views are different in other geographies or more rural communities. Cancer is a diverse and broad disease covering hundreds of diagnoses, each with a different therapy plan. This variance means that by having patients with different diseases, there may be a wide variety of decisions and costs and the range of variance is not adequately covered by this study. The sampling methodology was not random and does not allow one to extrapolate the findings to a larger sample. Patients who responded to the recruitment flier self-identified that they felt concern about the costs of cancer care and were willing to discuss their experiences and beliefs. Others who did not respond may feel differently and therefore, the sample may have inherent selection bias.

Recommendations of the Study

The study was an in-depth review of how FT impacted advanced cancer patients' lives, families, emotional well-being, and medical decision-making. Although it had limitations, it produced an understanding of the impact of OOP cost on insured advanced cancer patients. There are five compelling recommendations stemming from this study. First, cancer care providers need to continue support patient access to foundations, copay programs, and PAPs that help patients afford OOP costs. These foundations and programs need to continue to be funded with simplified enrollment processes. Additional research into the impact that OOP costs and FT have on the use of gist and verbatim in FTT is also be important. A third recommendation is to continue research into the dimensions of advanced cancer patients' trust in the health care system and the extent to which that trust is eroded by FT and mistrust in financial motivations. Finally, identifying ways to increase patient education and health care literacy may improve patient understanding of how insurance works and how to navigate OOP costs. This could lead to better levels of action and processes for patients that may reduce FT stress and improve outcomes.

The study uncovered the difficult decisions that patients must make while having OOP costs and fighting for their lives against a formidable disease. Patients with advanced cancer rely on the support of the cancer care community to guide them through care, therapy selection, charitable assistance access, and decisions about therapy discontinuation and access to hospice care. Advanced cancer patients are particularly vulnerable to increases in OOP benefit designs and rely on insurance to afford life-extending therapy. The charitable foundations and PAP that offer financial support for patients are critical but the processes to access the help can be difficult for cancer center staff and patients (Yezefski et al., 2017; Zafar & Peppercorn, 2017a). These programs, while imperfect, do improve access to necessary care but their funding mechanisms are dependent on pharmaceutical companies and on the government allowing the pharmaceutical companies to continue them. This study underscored the importance of pharmaceutical companies and governmental officials preserving these important bridges to care for underinsured patients. It also highlighted why it is important that community cancer care professionals continue to assist patients to access these programs.

The study confirmed the FTT and that cancer patients make extensive use of gist in decision-making. The research further found that for some patients who are experiencing FT and have high OOP costs for a proposed therapy, use verbatim recall of specific costs. This verbatim recall becomes the dominant decision factor in whether to access the therapy. The identification of the importance of verbatim recall of costs for cancer patients should be further explored to better understand how it is used in cancer treatment decisions by patients. My findings potentially expand FTT to include FT as a prominent issue that may drive greater reliance on verbatim recall over gist when OOP costs are perceived by patients to be high. Given the growing impact of consumer cost in cancer care, it will be important to expand research into FTT and FT in medical decision-making to include how patients factor costs into medical decisions.

A third recommendation is to continue research into the dimensions of advanced cancer patients’ trust in the health care system and the extent to which that trust is eroded by patients experiencing FT and mistrust in financial motivations of their health system. In the study, patients expressed mistrust in the financial motivations of the health care system, particularly when the level of FT was more severe. Therefore, it will be important to understand the implications of these dimensions of trust upon patient decision-making and access to care. Studies of trust have shown that patients with lower levels of trust in the health care system access fewer cancer preventive services and that cancer patients are less likely to remain compliant with therapy (Armstrong et al., 2012; Yang et al., 2011). Further research into the amplifying effect of FT on health care system distrust will be important, especially if effective solutions to help patients with the impact of FT on their lives and cancer care are to be found.

A final recommendation comes from a patient who recommends that the health care system prepare and educate its patients on cancer costs. The patient recommends that cancer centers offer a class on navigating the cancer treatment costs, dealing with insurance companies, finding financial assistance, and planning for costs. Patients could benefit by feeling more empowered to handle the confusing paperwork and reduce their stress and worry if they better understood what the costs were likely to be, how insurance works, and what options are available for help.

Implications for Social Change of the Study

This study provided insight into the experiences of patients with advanced cancer in Colorado with their cancer care, FT, and their experiences of paying for cancer care. Many of the patients expressed their gratitude to me for focusing my research on this topic; they believe more can be done to support patients through these difficult times.

This study can increase knowledge about how patients who are experiencing FT make decisions about cancer care. Because the costs of cancer care are increasing, and patients are exposed to even greater OOP, this study can help inform providers, health systems, pharmaceutical companies, and payers about the need to support patients who are struggling to pay for their OOP cancer costs.

The important role of copay, PAP, and foundation support for patients was a key theme in the research. Insight from my study may help lawmakers and insurance companies to develop fair policies to allow continued access to these programs by qualified cancer patients. This research can help provide the voice of patient to these debates, because often their insights are not part of the discussion. Lawmakers and policy makers need to be briefed on the patient perspective in addition to that of the insurance company or pharmaceutical company. To amplify the impact of this study, I intend to disseminate it and its findings.

I plan to publish the study results and share it with the cooperating sites and patients via presentations, summary reviews, and by speaking at regional and national professional conferences. I will submit the study for published in a peer-reviewed journal. I will seek venues to educate the pharmaceutical and insurance industry on the impact of their policies on cancer patients.

Summary

In this study I examined how patients with advanced cancer think, feel and make health care decisions while experiencing FT. The research examined the experiences of patients with FT and found that there are significant impacts on patients’ lives, work, families, lifestyle, and mental well-being when FT increases.

In research question 2, I reviewed how FT impacted patients and their use of gist and verbatim in medical decision-making. I found that FT had a profound impact on patients, especially at certain periods of their lives. I identified that FT impacted patients’ trust in the health care system. The impact of FT created a constant worry for many advanced cancer patients. I examined how FT could be a key determinant in patients’ decisions about cancer care. Using FTT, I confirmed the use of gist in cancer decision-making and extended my findings to include a strong use of verbatim cost representations in decision-making.

My third research question focused on how FT factored into treatment decisions about their cancer treatments. I found that for nearly all the patients in the study, FT had a significant impact as OOP increased. The patients did believe that they were fighting for their survival and sincerely wanted to access the treatments recommended by their doctor, but the treatments needed to be affordable. When the costs of cancer began to threaten their everyday living budget, patients began to make decisions to not access the care.

FTT was the theoretical framework that I used to help guide and anchor the research. In FTT in cancer, Reyna et al. (2015) found that patients make extensive use of gist representations to make decisions involving risks and reward trade-offs for cancer care. My research found that patients use gist predominantly in cancer decisions except when patients had high OOP and were experiencing FT. In these instances, the patients rely on the verbatim costs associated with the choice and these became the clear determinants for selection of care.

In Chapter 5, I provided a discussion of the recommendation and implications for social change from this study. This research provides guidance for additional research and helps health care providers, payers, pharmaceutical companies, governmental leaders, patients, and families to find ways to cope with the challenges of FT. The study will help providers and the cancer community develop effective and meaningful solutions to support advanced cancer patients during some of the most stressful times of their lives.

References

Abbott, D., Curley, S., Hanseman, D., & Sohn, V. (2014). Patient attitudes about the cost of cancer care: Expectations and realities in the current health care climate. *Clinical Cancer Investigation Journal*, *3*(3), 225. https://doi.org/10.4103/2278-0513.132116

Ahuja Parikh, D., Amin, K., Hall, E. T., & Patel, M. I. (2017). Financial toxicity of cancer treatment at a large academic cancer center. *Journal of Clinical Oncology*, *35*(15_suppl), e18323. https://doi.org/10.1200/JCO.2017.35.15_suppl.e18323

Altomare, I., Irwin, B., Zafar, S. Y., Houck, K., Maloney, B., Greenup, R., …Peppercorn, J. (2016). Recap: Physician experience and attitudes toward addressing the cost of cancer care. *Journal of Oncology Practice*, *12*(3), 247–248. https://doi.org/10.1200/JOP.2015.007401

Armstrong, K., Putt, M., Halbert, C. H., Grande, D., Schwartz, J. S., Liao, K., …Shea, J. (2012). The influence of health care policies and health care system distrust on willingness to undergo genetic testing: *Medical Care*, *50*(5), 381–387. https://doi.org/10.1097/MLR.0b013e31824d748b

Armstrong, K., Putt, M., Halbert, C. H., Grande, D., Schwartz, J. S., Liao, K., …Shea, J. A. (2013). Prior experiences of racial discrimination and racial differences in health care system distrust: *Medical Care*, *51*(2), 144–150. https://doi.org/10.1097/MLR.0b013e31827310a1

Association of Community Cancer Centers. (2013) Association of Community Cancer Centers position paper on the 340B drug discount program. Retrieved from http://www.accc-cancer.org/advocacy/pdf/2013-position-paper-340B.pdf

Auerbach, D. I., & Kellermann, A. L. (2011). A decade of health care cost growth has wiped out real income gains for an average US family. *Health Affairs*, *30*(9), 1630–1636. https://doi.org/10.1377/hlthaff.2011.0585

Balfe, M., Butow, P., O'Sullivan, E., Gooberman-Hill, R., Timmons, A., & Sharp, L. (2016). The financial impact of head and neck cancer caregiving: A qualitative study. *Psycho-Oncology*, n/a-n/a. https://doi.org/10.1002/pon.4079

Barber, E. L., Bensen, J. T., Snavely, A. C., Gehrig, P. A., & Doll, K. M. (2016). Financial toxicity among privately insured gynecologic oncology patients: Silent barriers to care. *Gynecologic Oncology*, *141*, 82–83. https://doi.org/10.1016/j.ygyno.2016.04.232

Barry, M. J., & Edgman-Levitan, S. (2012). Shared decision making — The pinnacle of patient-centered care. *New England Journal of Medicine*, *366*(9), 780–781. https://doi.org/10.1056/nejmp1109283

Bestvina, C. M., Zullig, L. L., Rushing, C., Chino, F., Samsa, G. P., Altomare, I., … Nicolla, J. (2014). Patient-oncologist cost communication, financial distress, and medication adherence. *Journal of Oncology Practice*, *10*(3), 162–167. https://doi.org/10.1200/jop.2014.001406

Bittoni, M. A., Wexler, R., Spees, C. K., Clinton, S. K., & Taylor, C. A. (2015). Lack of private health insurance is associated with higher mortality from cancer and other chronic diseases, poor diet quality, and inflammatory biomarkers in the United States. *Preventive Medicine*, *81*, 420–426. https://doi.org/10.1016/j.ypmed.2015.09.016

Bleyer, A., Ulrich, C., & Martin, S. (2012). Young adults, cancer, health insurance, socioeconomic status, and the Patient Protection and Affordable Care Act: Young adults, cancer, and health insurance. *Cancer*, *118*(24), 6018–6021. https://doi.org/10.1002/cncr.27685

Brewer, N. T., Richman, A. R., DeFrank, J. T., Reyna, V. F., & Carey, L. A. (2012). Improving communication of breast cancer recurrence risk. *Breast Cancer Research and Treatment*, *133*(2), 553–561. https://doi.org/10.1007/s10549-011-1791-9

Brooks, J., Wilson, K., & Amir, Z. (2011). Additional financial costs borne by cancer patients: A narrative review. *European Journal of Oncology Nursing*, *15*(4), 302–310. https://doi.org/10.1016/j.ejon.2010.10.005

Bullock, A. J., Hofstatter, E. W., Yushak, M. L., & Buss, M. K. (2012). Understanding patients’ attitudes toward communication about the cost of cancer care. *Journal of Oncology Practice*, *8*(4), e50–e58. https://doi.org/10.1200/JOP.2011.000418

Carrera, P. M., Kantarjian, H. M., & Blinder, V. S. (2018). The financial burden and distress of patients with cancer: Understanding and stepping-up action on the financial toxicity of cancer treatment, a primer on financial toxicity. *CA: A Cancer Journal for Clinicians*. https://doi.org/10.3322/caac.21443

Center for Disease Control. (2010) United States cancer statistics: 1999–2006 incidence and mortality web-based report. Retrieved from http://198.246.124.29/cancer/npcr/pdf/USCS_FactSheet.pdf

Chan, R. J., Gordon, L., Zafar, S. Y., & Miaskowski, C. (2018). Financial toxicity and symptom burden: What is the big deal? *Supportive Care in Cancer*. https://doi.org/10.1007/s00520-018-4092-6

Chang, S., Long, S. R., Kutikova, L., Bowman, L., Finley, D., Crown, W.H., … Bennett, C.L. (2004). Estimating the cost of cancer: Results on the basis of claims data analyses for cancer patients diagnosed with seven types of cancer during 1999 to 2000. *Journal of Clinical Oncology*, *22*(17), 3524–3530. https://doi.org/10.1200/jco.2004.10.170

Chatterjee, S., Gabor, L., Jones, N. L., Buskwofie, A., Burke, W. M., Hou, J. Y., & Wright, J. D. (2017). Estimating financial toxicity in patients with gynecological malignancies undergoing chemotherapy. *Gynecologic Oncology*, *145*, 175. https://doi.org/10.1016/j.ygyno.2017.03.397

Chewning, B., Bylund, C. L., Shah, B., Arora, N. K., Gueguen, J. A., & Makoul, G. (2012). Patient preferences for shared decisions: A systematic review. *Patient Education and Counseling*, *86*(1), 9–18. https://doi.org/10.1016/j.pec.2011.02.004

Chino, F., Peppercorn, J. M., Rushing, C., Kamal, A. H., Altomare, I., Samsa, G., & Zafar, S. Y. (2017). Out-of-pocket costs, financial distress, and underinsurance in cancer care. *JAMA Oncology*. https://doi.org/10.1001/jamaoncol.2017.2148

Corbin, J. C., Reyna, V. F., Weldon, R. B., & Brainerd, C. J. (2015). How reasoning, judgment, and decision making are colored by gist-based intuition: A fuzzy-trace theory approach. *Journal of Applied Research in Memory and Cognition*, *4*(4), 344–355. https://doi.org/10.1016/j.jarmac.2015.09.001

Creswell, J. W. (2008). *Research design: Qualitative, quantitative, and mixed methods approaches*. Thousand Oaks, CA: Sage Publications, Inc.

Creswell, J. W. (2013). *Qualitative inquiry and research design: Choosing among five approaches* (3rd ed.). Thousand Oaks, CA: Sage Publications, Inc.

Davidoff, A. J., Erten, M., Shaffer, T., Shoemaker, J. S., Zuckerman, I. H., Pandya, N., … Stuart, B. (2013). Out-of-pocket health care expenditure burden for Medicare beneficiaries with cancer. *Cancer*, *119*(6), 1257–1265. https://doi.org/10.1002/cncr.27848

de Souza, J. A., & Wong, Y.-N. (2013). Financial distress in cancer patients. *Journal of Medicine and the Person*, *11*(2), 73–77. https://doi.org/10.1007/s12682-013-0152-3

de Souza, J. A., Yap, B. J., Hlubocky, F. J., Wroblewski, K., Ratain, M. J., Cella, D., & Daugherty, C. K. (2014). The development of a financial toxicity patient-reported outcome in cancer: The COST measure. *Cancer*, *120*(20), 3245–3253. https://doi.org/10.1002/cncr.28814

de Souza, J. A., Yap, B. J., Wroblewski, K., Blinder, V., Araújo, F. S., Hlubocky, F. J., … Cella, D. (2016). Measuring financial toxicity as a clinically relevant patient-reported outcome: The validation of the COmprehensive Score for financial

Toxicity: Measuring financial toxicity. *Cancer*. https://doi.org/10.1002/cncr.30369

Delgado-Guay, M., Ferrer, J., Rieber, A. G., Rhondali, W., Tayjasanant, S., Ochoa, J., … Bruera, E. (2015). Financial distress and its associations with physical and emotional symptoms and quality of life among advanced cancer patients. *The Oncologist*. https://doi.org/10.1634/theoncologist.2015-0026

Dixon, M. S., Cole, A. L., & Dusetzina, S. B. (2017). Out-of-pocket spending under the Affordable Care Act for patients with cancer: *The Cancer Journal*, *23*(3), 175–180. https://doi.org/10.1097/PPO.0000000000000262

Drake, N. (2011). Forty years on from Nixon’s war, cancer research “evolves.” *Nature Medicine*, *17*(7), 757–757. https://doi.org/10.1038/nm0711-757

Dusetzina, S. B., Basch, E., & Keating, N. L. (2015). For uninsured cancer patients, outpatient charges can be costly, putting treatments out of reach. *Health Affairs*, *34*(4), 584–591. https://doi.org/10.1377/hlthaff.2014.0801

Eliasson, L., Clifford, S., Barber, N., & Marin, D. (2011). Exploring chronic myeloid leukemia patients’ reasons for not adhering to the oral anticancer drug imatinib as prescribed. *Leukemia Research*, *35*(5), 626–630. https://doi.org/10.1016/j.leukres.2010.10.017

Fein, A. (2017). Copay accumulators: Costly consequences of a new cost-shifting pharmacy benefit. Retrieved from http://www.drugchannels.net/2018/01/copay-accumulators-costly-consequences.html

Freedman, R. A., Virgo, K. S., He, Y., Pavluck, A. L., Winer, E. P., Ward, E. M., & Keating, N. L. (2011). The association of race/ethnicity, insurance status, and socioeconomic factors with breast cancer care. *Cancer*, *117*(1), 180–189. https://doi.org/10.1002/cncr.25542

Freeman, H. P., & Rodriguez, R. L. (2011). History and principles of patient navigation. *Cancer*, *117*(S15), 3537–3540. https://doi.org/10.1002/cncr.26262

Gebbia, V., Bellavia, G., Ferraù, F., & Valerio, M. R. (2012). Adherence, compliance and persistence to oral antineoplastic therapy: A review focused on chemotherapeutic and biologic agents. *Expert Opinion on Drug Safety*, *11*(S1), S49–S59. https://doi.org/10.1517/14740338.2011.645803

Goldman, D. P., Joyce, G. F., Lawless, G., Crown, W. H., & Willey, V. (2006). Benefit design and specialty drug use. *Health Affairs*, *25*(5), 1319–1331. https://doi.org/10.1377/hlthaff.25.5.1319

Gordon, L. G., Merollini, K. M. D., Lowe, A., & Chan, R. J. (2016). A systematic review of financial toxicity among cancer survivors: We can’t pay the co-pay. *The Patient - Patient-Centered Outcomes Research*. https://doi.org/10.1007/s40271-016-0204-x

Goss, E., Lopez, A. M., Brown, C. L., Wollins, D. S., Brawley, O. W., & Raghavan, D. (2009). American Society of Clinical Oncology policy statement: Disparities in cancer care. *Journal of Clinical Oncology*, *27*(17), 2881–2885. https://doi.org/10.1200/jco.2008.21.1680

Grubbs, S. S., Polite, B. N., Carney, J., Bowser, W., Rogers, J., Katurakes, N., & Paskett, … E.D. (2013). Eliminating racial disparities in colorectal cancer in the real world: It took a village. *Journal of Clinical Oncology*, *31*(16), 1928–1930. https://doi.org/10.1200/JCO.2012.47.8412

Head, B., Harris, L., Kayser, K., Martin, A., & Smith, L. (2018). As if the disease was not enough: Coping with the financial consequences of cancer. *Supportive Care in Cancer*, *26*(3), 975–987. https://doi.org/10.1007/s00520-017-3918-y

Hede, K. (2009). Increase in oral cancer drugs raises thorny issues for oncology practices. *Journal of the National Cancer Institute*, *101*(22), 1534–1536. https://doi.org/10.1093/jnci/djp421

Hess, L. M., Michael, D., Mytelka, D. S., Beyrer, J., Liepa, A.M., & Nicol, S. (2015). Chemotherapy treatment patterns, costs, and outcomes of patients with gastric cancer in the United States: A retrospective analysis of electronic medical record (EMR) and administrative claims data. *Gastric Cancer*, 1–9. https://doi.org/0.1007/s10120-015-0486-z

Hillen, M.A., de Haes, H. C. J. M., & Smets, E. M. (2011). Cancer patients' trust in their physician-A review. *Psycho-Oncology*, *20*(3), 227–241. https://doi.org/10.1002/pon.1745

Himmelstein, D. U., Thorne, D., & Woolhandler, S. (2011). Medical bankruptcy in Massachusetts: Has health reform made a difference? *The American Journal of Medicine*, *124*(3), 224–228. https://doi.org/10.1016/j.amjmed.2010.11.009

Hofstatter, E. W. (2010). Understanding patient perspectives on communication about the cost of cancer care: A review of the literature. *Journal of Oncology Practice*, *6*(4), 188–192. https://doi.org/10.1200/JOP.777002

Howard, D. H., Chernew, M. E., Abdelgawad, T., Smith, G. L., Sollano, J., & Grabowski, D. C. (2016). New anticancer drugs associated with large increases in costs and life expectancy. *Health Affairs*, *35*(9), 1581–1587. https://doi.org/10.1377/hlthaff.2016.0286

Institutes of Medicine. (2009) Americans uninsured crisis. National Academies Press. Washington, DC. Retrieved from https://www.nap.edu/read/12511/chapter/1

Jagsi, R., Pottow, J. A. E., Griffith, K. A., Bradley, C., Hamilton, A. S., Graff, J., … Hawley, S. (2014). Long-term financial burden of breast cancer: Experiences of a diverse cohort of survivors identified through population-based registries. *Journal of Clinical Oncology*, *32*(12), 1269–1276. https://doi.org/10.1200/JCO.2013.53.0956

Janesick, V. J. (2011). *"Stretching" exercises for qualitative researchers* (3rd ed.). Thousand Oaks, CA: Sage Publications Inc. Retrieved from http://informahealthcare.com/doi/pdf/10.1080/01421599880445

Joseph-Williams, N., Elwyn, G., & Edwards, A. (2014). Knowledge is not power for patients: A systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Education and Counseling*, *94*(3), 291–309. https://doi.org/10.1016/j.pec.2013.10.031

Kaisaeng, N., Harpe, S. E., & Carroll, N. V. (2014). Out-of-pocket costs and oral cancer medication discontinuation in the elderly. *Journal of Managed Care Pharmacy, 20*(7), 669–675. https://doi.org/10.18553/jmcp.2014.20.7.669

Kaiser Family Foundation. (2006). The role of consumer copayments for health care: Lessons from the RAND health insurance experiment and beyond. Retrieved from http://kff.org/health-costs/report/the-role-of-consumer-copayments-for-health/

Kaiser Family Foundation. (2016). Understanding Health Insurance. Retrieved from http://kff.org/understanding-health-insurance/

Kale, H., & Carroll, N. V. (2016). Self-reported financial burden of cancer care and its effect on physical and mental health-related quality of life among US cancer survivors: Cancer-related financial burden and HRQOL. *Cancer, 122*(8), 283–289. https://doi.org/10.1002/cncr.29808

Karnieli-Miller, O., Strier, R., & Pessach, L. (2008). Power relations in qualitative research. *Qualitative Health Research*, *19*(2), 279–289. https://doi.org/10.1177/1049732308329306

Khera, N. (2014). Reporting and grading financial toxicity. *Journal of Clinical Oncology*, *32*(29), 3337–3338. https://doi.org/10.1200/JCO.2014.57.8740

Kim, J., Han, J. Y., Shaw, B., McTavish, F., & Gustafston, D. (2010). The roles of social support and coping strategies in predicting breast cancer patients' emotional well-being. *Journal of Health Psychology*, *15*(4), 543–552. https://doi.org/10.1177/1359105309355338

Lievens, Y., & Grau, C. (2012). Health economics in radiation oncology: Introducing the ESTRO HERO project. *Radiotherapy and Oncology, 103*(1), 109–112. https://doi.org/10.1016/j.radonc.2011.12.026

Lo Sasso, A. T., Helmchen, L. A., & Kaestner, R. (2010). The effects of consumer-directed health plans on health care spending. *Journal of Risk and Insurance*, *77*(1), 85–103. https://doi.org/10.1111/j.1539-6975.2009.01346.x

Mailankody, S., & Prasad, V. (2015). Five years of cancer drug approvals: Innovation, efficacy, and costs. *JAMA Oncology*, *1*(4), 539. https://doi.org/10.1001/jamaoncol.2015.0373

Mariotto, A. B., Yabroff, K.R., Shao, Y., Feuer, E. J., & Brown, M. L. (2011). Projections of the cost of cancer care in the United States: 2010–2020. *Journal of the National Cancer Institute*. https://doi.org/10.1093/jnci/djq495

Masters, G. A., Krilov, L., Bailey, H. H., Brose, M. S., Burstein, H., Diller, L. R, … Patel, D. (2015). Clinical cancer advances 2015: Annual report on progress against cancer from the American Society of Clinical Oncology. *Journal of Clinical Oncology*, *33*(7), 786–809. https://doi.org/10.1200/JCO.2014.59.9746

Maxwell, J. A. (2013). *Qualitative research design: An interactive approach*. Thousand Oaks, CA: Sage Publications, Inc.

McDermott, C. (2017). Financial toxicity: A common but rarely discussed treatment side effect. *Annals of the American Thoracic Society*. https://doi.org/10.1513/AnnalsATS.201707-578OR

Meropol, N. J., Schrag, D., Smith, T. J., Mulvey, T. M., Langdon, R. M., Blum, D., ... Schnipper, L.E. (2009). American Society of Clinical Oncology guidance statement: The cost of cancer care. *Journal of Clinical Oncology*, *27*(23), 3868–3874. https://doi.org/10.1200/jco.2009.23.1183

Meropol, N. J., & Schulman, K. A. (2007). Cost of cancer care: Issues and implications. *Journal of Clinical Oncology*, *25*(2), 180–186. https://doi.org/10.1200/jco.2006.09.6081

Morris, N. J., Field, T. S., Wagner, J. L., Cutrona, S. L., Roblin, D. W., Gaglio, B., …Mazor, K. M. (2013). The association between health literacy and cancer-related attitudes, behaviors, and knowledge. *Journal of Health Communication*, *18*(sup1), 223–241. https://doi.org/10.1080/10810730.2013.825667

Morrison, C. (2015). "Financial toxicity" looms as cancer combinations proliferate. *Nature Biotechnology*, *33*(8), 783–784. https://doi.org/10.1038/nbt0815-783

Morrow, T., & Felcone, L. H. (2004). Defining the difference: What makes biologics unique. *Biotechnology Healthcare*, *1*(4), 24–29. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/

National Cancer Institute. (2015). What is cancer. Retrieved from https://www.cancer.gov/about-cancer/understanding/what-is-cancer#when-cancer-spreads

National Cancer Institute. (2016a). PDQ screening and prevention editorial board. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK65793/

National Cancer Institutes. (2016b). Cancer statistics. Retrieved from https://www.cancer.gov/about-cancer/understanding/statistics

National Cancer Institutes. (2016c). Annual report to the nation on the status of cancer, 1975-2014. Retrieved from https://www.cancer.gov/research/progress/annual-report-nation

National Institutes of Health. (2007). *Economic costs of cancer health disparities* (Economic costs of cancer health disparities No. 07–6131). Rockville, MD.

Newcomer, L. N. (2012). Changing physician incentives for cancer care to reward better patient outcomes instead of use of more costly drugs. *Health Affairs*, *31*(4), 780–785.

Nguyen, P. L., Gu, X., Lipsitz, S. R., Choueiri, T. K., Choi, W. W., Lei, Y., & Hu, J. C. (2011). Cost implications of the rapid adoption of newer technologies for treating prostate cancer. *Journal of Clinical Oncology*, *29*(12), 1517–1524. https://doi.org/10.1200/JCO.2010.31.1217

Nicolla, J., Friedman, F., Manners, I., & Zafar, Y. (2017). Empowering patients to self-identify financial assistance programs using an online application. *Journal of Clinical Oncology*, *35*(8_suppl), 4–4. https://doi.org/10.1200/JCO.2017.35.8_suppl.4

NVivo data analysis software (Version 11) [Computer software]. London, England: QSR International.

Ó Céilleachair, A., Costello, L., Finn, C., Timmons, A., Fitzpatrick, P., Kapur, K., … Sharp, L. (2012). Inter-relationships between the economic and emotional consequences of colorectal cancer for patients and their families: A qualitative study. *BMC Gastroenterology, 12*(1), 62. https://doi.org/10.1186/1471-230X-12-62

Ozawa, S., & Sripad, P. (2013). How do you measure trust in the health system? A systematic review of the literature. *Social Science & Medicine*, *91*, 10–14. https://doi.org/10.1016/j.socscimed.2013.05.005

Parise, C. A., & Caggiano, V. (2013). Disparities in race/ethnicity and socioeconomic status: Risk of mortality of breast cancer patients in the California cancer registry, 2000–2010. *BMC Cancer*, *13*(1). https://doi.org/10.1186/1471-2407-13-449

Patel, T., Palmer, J., Eldredge-Hindy, H., Smyles, J., DiNome, J., Babaria, U., & Fisher, S. (2016). Financial toxicity: a side effect of radiation therapy for cancer? *Research Day*. Retrieved from http://digitalcommons.pcom.edu/research_day/research_day_PA_2016/researchPA2016/35

Patkar, V., Acosta, D., Davidson, T., Jones, A., Fox, J., & Keshtgar, M. (2011). Cancer multidisciplinary team meetings: Evidence, challenges, and the role of clinical decision support technology. *International Journal of Breast Cancer*, *2011*. https://doi.org/10.4061/2011/831605

Patton, M. Q. (2015). *Qualitative research and evaluation methods* (4th ed.). Thousand Oaks, CA: Sage Publications, Inc.

Peddie, V., Porter, M., Barbour, R., Culligan, D., MacDonald, G., King, D., & Bhattacharya, S. (2012). Factors affecting decision-making about fertility preservation after cancer diagnosis: a qualitative study: Perceptions of fertility preservation after cancer diagnosis. *BJOG: An International Journal of Obstetrics & Gynaecology*, *119*(9), 1049–1057. https://doi.org/10.1111/j.1471-0528.2012.03368.x

Peters, E., McCaul, K. D., Stefanek, M., & Nelson, W. (2006). A heuristics approach to understanding cancer risk perception: Contributions from judgment and decision-making research. *Annals of Behavioral Medicine*, *31*(1), 45–52. https://doi.org/10.1207/s15324796abm3101_8

Politi, M. C., Clark, M. A., Ombao, H., Dizon, D., & Elwyn, G. (2011). Communicating uncertainty can lead to less decision satisfaction: A necessary cost of involving patients in shared decision making? *Health Expectations*, *14*(1), 84–91. https://doi.org/10.1111/j.1369-7625.2010.00626.x

Puts, M. T. E., Tapscott, B., Fitch, M., Howell, D., Monette, J., Wan-Chow-Wah, D., … Alibhai, S. (2015). A systematic review of factors influencing older adults' decision to accept or decline cancer treatment. *Cancer Treatment Reviews*, *41*(2), 197–215. https://doi.org/10.1016/j.ctrv.2014.12.010

Rajurkar, S. P., Presant, C. A., Bosserman, L. D., & McNatt, W. J. (2011). A copay foundation assistance support program for patients receiving intravenous cancer therapy. *Journal of Oncology Practice*, *7*(2), 100–102.

Ramsey, S., Bansal, A., Fedorenko, C. R., Blough, D. K., Overstreet, K. A., Shankaran, V., & Newcomb, P. (2016). Financial insolvency as a risk factor for early mortality among patients with cancer. *Journal of Clinical Oncology*, *34*(9), 980–986. https://doi.org/10.1200/JCO.2015.64.6620

Ramsey, S., Blough, D., Kirchhoff, A., Kreizenbeck, K., Fedorenko, C., Snell, K., … Overstreet, K. (2013). Washington State cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. *Health Affairs*, *32*(6), 1143–1152. https://doi.org/10.1377/hlthaff.2012.1263

Reinhardt, U. E. (2013). The disruptive innovation of price transparency in health care. *JAMA*, *310*(18), 19–27. https://doi.org/10.1001/jama.2013.281854

Reyna, V. F., & Brainerd, C. J. (1995). Fuzzy-trace theory: An interim synthesis. *Learning and Individual Differences*, *7*(1), 1–75. https://doi.org/10.1016/1041-6080(95)90031-4

Reyna, V. F., & Brainerd, C. J. (2011). Dual processes in decision making and developmental neuroscience: A fuzzy-trace model. *Developmental Review*. https://doi.org/10.1016/j.dr.2011.07.004

Reyna, V. F., Nelson, W. L., Han, P. K., & Pignone, M. P. (2015). Decision making and cancer. *American Psychologist*, *70*(2), 105–118. https://doi.org/10.1037/a0036834

Sahay, T. B., Gray, R. E., & Fitch, M. (2000). A qualitative study of patient perspectives on colorectal cancer. *Cancer Practice*, *8*(1), 38–44. https://doi.org/10.1046/j.1523-5394.2000.81012.x

Saldana, J. (2015). *The coding manual for qualitative researchers*. SAGE Publications, Inc. Thousand Oaks, CA.

Samuel, T. W., Raleigh, S. G., Hower, J. M., & Schwartz, R. W. (2003). The next stage in the health care economy: aligning the interests of patients, providers, and third-party payers through consumer-driven health care plans. *American Journal of Surgery*, *186*(2), 117. https://doi.org/10.1016/s0002-9610(03)00189-2

Schnipper, L. E., Davidson, N. E., Wollins, D. S., Tyne, C., Blayney, D. W., Blum, D. … Langdon, R. (2015). American Society of Clinical Oncology Statement: A conceptual framework to assess the value of cancer treatment options. *Journal of Clinical Oncology*, JCO–2015. https://doi.org/10.1200/jco.2015.61.6706

Seiden, M. (2016). Immuno-oncology 2016 and beyond: The opportunities, challenges, and risks. *American Journal of Managed Care*. Retrieved from http://www.ajmc.com/journals/evidence-based-oncology/2016/february-2016/immuno-oncology-2016-and-beyond-the-opportunities-challenges-and-risks/P-4#sthash.IoI9VLIA.dpuf

Shay, L. A., & Lafata, J. E. (2015). Where is the evidence? A systematic review of shared decision making and patient outcomes. *Medical Decision Making*, *35*(1), 114–131. https://doi.org/10.1177/0272989x14551638

Shi, L., & Singh, D. A. (2011). *Delivering Health Care In America: A Systems Approach* (5th ed.). Jones & Bartlett Learning. Burlington, MA.

Siegel, R. L., Miller, K. D., & Jemal, A. (2018). Cancer statistics, 2018. *CA: A Cancer Journal for Clinicians*, *68*(1), 7–30. https://doi.org/10.3322/caac.21442

Siegel, R., Ward, E., Brawley, O., & Jemal, A. (2011). Cancer statistics, 2011: The impact of eliminating socioeconomic and racial disparities on premature cancer deaths. *CA: A Cancer Journal for Clinicians, 61*(4), 212–236. https://doi.org/10.3322/caac.20121

Sinaiko, A. D., & Rosenthal, M. B. (2011). Increased price transparency in health care — Challenges and potential effects. *New England Journal of Medicine, 364*(10), 891–894. https://doi.org/10.1056/NEJMp1100041

Smith, S. K., Nicolla, J., & Zafar, S. Y. (2014). Bridging the gap between financial distress and available resources for patients with cancer: A qualitative study. *Journal of Oncology Practice,* JOP–2013. https://doi.org/10.1200/JOP.2013.001342

Staton, T. (2014). Amgen slaps record-breaking $178K price on rare leukemia drug Blincyto. Fierce Pharma. Retrieved from http://www.fiercepharmamarketing.com/story/amgen-slaps-record-breaking-178k-price-rare-leukemia-drug-blincyto/2014-12-18

Tangka, F. K., Trogdon, J. G., Richardson, L. C., Howard, D., Sabatino, S. A., & Finkelstein, E. A. (2010). Cancer treatment cost in the United States. *Cancer*, *116*(14), 3477–3484. https://doi.org/10.1093/jnci/djr009

Timmons, A., Gooberman-Hill, R., & Sharp, L. (2013). "It's at a time in your life when you are most vulnerable": A qualitative exploration of the financial impact of a cancer diagnosis and implications for financial protection in health. *PLoS ONE, 8*(11), e77549. https://doi.org/10.1371/journal.pone.0077549

Transcribe Me. (2017). Agreement for transcription services. Retrieved from http://transcribeme.com/

Tsimicalis, A., Stevens, B., Ungar, W. J., McKeever, P., Greenberg, M., Agha, M., … Barr, R. (2013). A mixed method approach to describe the out-of-pocket expenses incurred by families of children with cancer. *Pediatric Blood & Cancer*, *60*(3), 438–445. https://doi.org/10.1002/pbc.24324

Ubel, P. A., Abernethy, A. P., & Zafar, S. Y. (2013). Full disclosure—out-of-pocket costs as side effects. *New England Journal of Medicine*, *369*(16), 1484–1486. https://doi.org/10.1056/nejmp1306826

Unger, J. M., Hershman, D. L., Albain, K. S., Moinpour, C. M., Petersen, J. A., Burg, K., & Crowley, J. J. (2013). Patient income level and cancer clinical trial participation. *Journal of Clinical Oncology*, *31*(5), 536–542. https://doi.org/10.1200/JCO.2012.45.4553

U.S. Department of Health and Human Services. (n.d.). Special protections for children as research subjects. Retrieved from http://www.hhs.gov/ohrp/policy/populations/children.html

U.S. Preventive Services Task Force. (2016). Breast cancer screening. Retrieved from https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening1

Verbrugghe, M., Verhaeghe, S., Lauwaert, K., Beeckman, D., & Van Hecke, A. (2013). Determinants and associated factors influencing medication adherence and persistence to oral anticancer drugs: A systematic review. *Cancer Treatment Reviews*. https://doi.org/10.1016/j.ctrv.2012.12.014

Walker, G. V., Grant, S. R., Guadagnolo, B. A., Hoffman, K. E., Smith, B. D., Koshy, M., … Mahmood, U. (2014). Disparities in stage at diagnosis, treatment, and survival in nonelderly adult patients with cancer according to insurance status. *Journal of Clinical Oncology*, *32*(28), 3118–3125. https://doi.org/10.1200/JCO.2014.55.6258

Warren, J. L., Butler, E. N., Stevens, J., Lathan, C. S., Noone, A. -M, Ward, K. C., & Harlan, L. (2015). Receipt of chemotherapy among Medicare patients with cancer by type of supplemental insurance. *Journal of Clinical Oncology*, *33*(4), 312–318. https://doi.org/10.1200/jco.2014.55.3107

Weaver, K. E., Rowland, J. H., Bellizzi, K. M., & Aziz, N. M. (2010). Forgoing medical care because of cost. *Cancer*, *116*(14), 3493–3504. https://doi.org/10.1002/cncr.25209

Wharam, J. F., Ross-Degnan, D., & Rosenthal, M. B. (2013). The ACA and high-deductible insurance—strategies for sharpening a blunt instrument. *New England Journal of Medicine*, *369*(16), 1481–1484. https://doi.org/10.1056/NEJMp1309490

Yang, T. -C., Matthews, S. A., & Hillemeier, M. M. (2011). Effect of health care system distrust on breast and cervical cancer screening in Philadelphia, Pennsylvania. *American Journal of Public Health*, *101*(7), 1297–1305. https://doi.org/10.2105/AJPH.2010.300061

Yezefski, T., Schwemm, A., Lentz, M., Hone, K., & Shankaran, V. (2017). Patient assistance programs—A valuable, yet imperfect, way to ease the financial toxicity of cancer care. *Seminars in Hematology*. https://doi.org/10.1053/j.seminhematol.2017.07.004

Yin, R. K. (2003). *Case study research: Design and methods* (3rd Ed.). Thousand Oaks, CA: SAGE Publications, Inc. Thousand Oaks, CA.

Zafar, S. Y. (2016). Financial toxicity of cancer care: It's time to intervene. *Journal of the National Cancer Institute*, *108*(5), djv370. https://doi.org/10.1093/jnci/djv370

Zafar, S. Y., & Abernethy, A. P. (2013a). Financial toxicity, Part I: A new name for a growing problem. *Oncology*, *27*(2), 80–1. https://doi.org/10.1200/JCO.2014.57.8740

Zafar, S. Y., & Abernethy, A. P. (2013b). Financial toxicity, Part II: How can we help with the burden of treatment-related costs. *Oncology*, *27*(4), 253–4. Retrieved from http://www.cancernetwork.com/practice-policy/financial-toxicity-part-ii-how-can-we-help-burden-treatment-related-costs

Zafar, S. Y., Newcomer, L. N., Jusfin-McCarthy, J. D., Nasso, S. F., & Saltz, L. B. (2017). How should we intervene on the financial toxicity of cancer care? One shot, four perspectives. In *American Society of Clinical Oncology educational book* (Vol. 37, p. 35). Chicago, IL: ASCO. Retrieved from https://www.researchgate.net/profile/Dirk_Schadendorf/publication/317270400_Advances_in_the_Treatment_of_Advanced_Extracutaneous_Melanomas_and_Nonmelanoma_Skin_Cancers/links/593cff5f458515e398360b91/Advances-in-the-Treatment-of-Advanced-Extracutaneous-Melanomas-and-Nonmelanoma-Skin-Cancers.pdf#page=53

Zafar, S. Y., Peppercorn, J., Abernethy, A., & Bastian, A. (2017). Transparency of industry-sponsored oncology patient financial assistance programs using a patient-centered approach. *Journal of Oncology Practice*, *13*(3), e240–e248. https://doi.org/10.1200/JOP.2016.017509

Zafar, S. Y., & Peppercorn, J. M. (2017a). Patient financial assistance programs: A path to affordability or a barrier to accessible cancer care? *Journal of Clinical Oncology*, *35*(19), 2113–2116. https://doi.org/10.1200/JCO.2016.71.7280

Zafar, S. Y., & Peppercorn, J. M. (2017b). Patient financial assistance programs: A path to affordability or a barrier to accessible cancer care? *Journal of Clinical Oncology*, JCO–2016. https://doi.org/10.1200/JCO.2016.71.7280

Zafar, S. Y., Peppercorn, J. M., Schrag, D., Taylor, D. H., Goetzinger, A. M., Zhong, X., & Abernethy, A. P. (2013). The financial toxicity of cancer treatment: A pilot study assessing out-of-pocket expenses and the insured cancer patient’s experience. *The Oncologist*, *18*(4), 381–390. https://doi.org/10.1634/theoncologist.2012-0279

Zafar, S. Y., Ubel, P. A., Tulsky, J. A., & Pollak, K. I. (2015). Cost-related health literacy: A key component of high-quality cancer care. *Journal of Oncology Practice*, *11*(3), 171–173. https://doi.org/10.1200/JOP.2015.004408

Zajacova, A., Dowd, J. B., Schoeni, R. F., & Wallace, R. B. (2015). Employment and income losses among cancer survivors: Estimates from a national longitudinal survey of American families. *Cancer*. https://doi.org/10.1002/cncr.29510

Zikmund-Fisher, B. J., Fagerlin, A., & Ubel, P. A. (2008). Improving understanding of adjuvant therapy options by using simpler risk graphics. *Cancer*, *113*(12), 3382–3390. https://doi.org/10.1002/cncr.23959

Zullig, L. L., Wolf, S., Vlastelica, L., Shankaran, V., & Zafar, S. Y. (2017). The role of patient financial assistance programs in reducing costs for cancer patients. *Journal of Managed Care & Specialty Pharmacy*, *23*(4), 407–411. https://doi.org/10.18553/jmcp.2017.23.4.407

Appendix A: Informed Consent Form

Study #17071

Protocol Title: Understanding Cancer Patients' Medical Decision-Making While Experiencing Financial Toxicity

Patient Name: ______________________________

DOB: ______________ **OR Medical Record/Account #:** ______________

INFORMED CONSENT PROCESS

NOTE: If any of the pre-study assessments are not part of normal patient care, INFORMED CONSENT must be obtained before proceeding with the assessments.

Informed consent was obtained on (MMDDYY) _______________with version # ________ prior to initiating any study procedures on this protocol. The patient (legal guardian) had the opportunity to review the consent and ask questions, and a signed copy was provided to him/her.

This version of the consent signed by the patient was ☐ initial or ☐ re-consent. If re-consent, does this version replace any versions that have been skipped?

☐ NO ☐ YES If yes, which version? # _________ Please explain why:

____

Additional details regarding the informed consent form process can be documented below. (For example, any researcher/participant date differences, any witnesses present, the use of a legally authorized representative, etc.):

____

NOTE: Include this form with the source documents.

Signature: ______________________________ Date: ______________

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Protocol Title: Understanding Cancer Patients' Medical Decision-Making While Experiencing Financial Toxicity

STUDY RESEARCHER: Heather Morel

RESEARCH PARTICIPANT'S NAME: ____

Introduction:

You are invited to take part in a research study about how costs of cancer care impact cancer patients and their health care decision-making. Patients to be included in the study are adult advanced cancer patients who have insurance. This form is part of a process called "informed consent" to allow you to understand this study before deciding whether to take part.

This study is being conducted by a researcher named Heather Morel. She is a doctoral student (studying to obtain a PhD) at Walden University.

Background Information:

The purpose of this study is to better understand how cancer patients who pay for part of their care believe those costs to impact them in their lives and their health care decision-making.

Number of Participants:

This study is being conducted at one oncology practice and will enroll approximately 12 patients.

Procedures:

If you agree to be in this study, you will be asked to:

- Participate in a one hour face-to-face interview with the researcher. This is a one-time interview. This will complete your participation in the research study.
    - The researcher will also be making observations and taking notes during the interview so the researcher can capture not only what you say, but also how you say it with "body language".
    - The researcher will ask your permission to photograph you. If you agree, this photograph will be used by the researcher only to recall the interview once all personal information that identifies you has been removed from the study data.
- To the extent that you wish to, share examples of things or paperwork that exemplifies your experience with costs of cancer care.

  - Examples that may be helpful include Explanation of Benefit forms from insurance companies, a photograph that represents your experience with cancer costs, or other items you feel to be relevant.
  - Original items will be returned and with your permission, copies or photographs will be made for the research.
- If the session can be audio recorded and transcribed to capture all of your comments.
- You will have the opportunity to review the transcription to assure that your comments are accurately captured.

Here are some sample questions:

- How have the costs of care that you have had to pay for (those costs not covered by your insurance) impacted you? How has it made you feel?
- As you know, I am researching the important topic of the affordability of cancer care for patients like you, who have a serious diagnosis of cancer and are experiencing concern regarding affording their care. Please tell me about your care and the cost associated with care?
- How have the costs of care that you have had to pay for (those costs not covered by your insurance) impacted you? How has it made you feel?
- What other costs related to your cancer diagnosis, besides the bills that you get for your care, are impacting you financially?
- While making a health care decision, to what extent, if at all, have costs of care made you consider not undergoing a treatment, or discontinuing treatment?
- What was the decision that you were making about your care in which cancer costs were a factor?
  - Where did you get information about your choices?
  - Do you recall what you were thinking about in terms of your choice or the thoughts you were having while you were making these decisions?

Voluntary Nature of the Study:
This study is voluntary. You are free to accept or turn down the invitation. No one at your doctor’s office will treat you differently if you decide not to be in the study. If you decide to be in the study now, you can still change your mind later. You may stop at any time.

Risks and Benefits of Being in the Study:
Being in this type of study involves some risk of the minor discomforts that can be encountered in daily life, such as becoming sad or distressed from discussing these topics. Being in this study would not pose risk to your safety or wellbeing.

By participating in this study, you will be helping to provide more information on how patients like you experience costs associated with cancer, and the impact on health care decision-making. This may help develop future programs and ways to help patients in the future.

Payment:
You will receive $80 at the conclusion of the interview to compensate you for your time and travel costs.

Confidentiality:
Agreeing to be in this study gives the researcher your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Reports coming out of this study will not share the identities of individual participants. Details that might identify participants, such as the location of the study, also will not be shared. The study data collected by the researcher does not include your name, address, social security number, phone number or other information that directly identifies you. Instead, upon entry into the study, the **researcher** will assign a code to your study file. Any data submitted will only identify you by this code and may use your initials. The researcher will not use your personal information for any purpose outside of this research project.

Data will be kept secure by using computer security with encryption, password protection, use of codes instead of patient names in the report and database, and locked file cabinets. Data will be kept for a period of at least **2** years.

Your health and personal information will not be disclosed without your written authorization except where permitted by state and federal laws or required by law. If you sign this form, it will provide that authorization. The form is intended to inform you about how your information will be used or disclosed in the study. Your information will only be used in accordance with this authorization and as required or allowed by law. Results of this study may be published, or used in discussions after all identifying data has been removed.

Your information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies without your prior written permission.

Organizations that may review your information for quality assurance and data analysis, as required under the guidelines of the Health Insurance Portability and Accountability Act (HIPAA) are this Institutional Review Board, and regulatory agencies, such as U.S. Food and Drug Administration (FDA). These groups will be permitted to review information contained in your record that includes your name, inspect and/or copy records kept prior to and related to your participation in this study and any of the data generated by the study.

Authorization for the uses and disclosures described in this document does not expire until the conclusion of any regulatory assessments of the study that may be conducted by the United States or any other country. However, California law requires that participants who reside in California be informed that the disclosure of their information has a specific end date; this date has been defined as fifty years after the date of this authorization.

You may cancel this authorization at any time by providing a written notice to the researcher. If you cancel this authorization after you have started in the study, the researcher will take all necessary steps to comply with this revocation and no longer use or disclose your information in connection with this study. However, the researcher will continue to use information which has already been obtained.

If you cancel this authorization, or do not sign this authorization, you will no longer be able to participate in the study. This is because the researcher would not be able to collect the information needed to evaluate how costs of cancer care impact cancer patients and their health care decision-making.

Contacts and Questions:
You may ask any questions you have now. Or if you have questions later, you may contact the researcher via 602-697-9255 or via email heather.morel@gmail.com.

For questions about your rights as a research participant, contact the Institutional Review Board which is a group of people of various backgrounds who review research to protect your rights at 1-800-381-2637 or 281-863-2406 (ask the receptionist for the IRB Coordinator; collect calls will be accepted). The IRB Coordinator will assist you.

The researcher will give you a copy of this form to keep.

Obtaining Your Consent

If you feel you understand the study well enough to make a decision about it, please indicate your consent by signing below.

Printed Name of Participant ________________________________

Date of consent ________________________________

Participant’s Signature ________________________________

Researcher’s Signature ________________________________

Appendix B: Patient Recruitment Flier

FEELING CONCERNED ABOUT CANCER TREATMENT COSTS?

CONSIDER PARTICIPATING IN A PAID RESEARCH STUDY TO UNDERSTAND HOW FEELINGS ABOUT CANCER TREATMENT COST IMPACTS PATIENT DECISIONS

PAID $80 for interview

EMAIL: Heather.Morel@gmail.com

BE PART OF THIS STUDY

SEEKING ADULT PATIENTS WHO:

- Feel distress about cost of cancer care
- Have advanced or metastatic cancer

TO LEARN MORE OR ENROLL

Call, text or email
Heather Morel
(PhD student)

Mobile phone:
602-697-9255

EMAIL
heather.morel@gmail.com

Appendix C: Interview Discussion Guide

Interview opening:

The researcher will introduce herself and the purpose for the interview. She will thank the participant and will review the informed consent document and answer any questions that the participant may have. The researcher will obtain consent to audio record the interview and audio recording will begin. The researcher will begin to conduct the interview.

a. Begin with a series of questions to gather some background data on the patient, their disease, and their life
    i. What is your full name?
    ii. What city do you live in now?
    iii. Do you live alone or with family?
    iv. Are you currently working outside the home?
    v. Has your employment status changed since you were diagnosed with cancer?
    vi. Tell me a bit about your cancer journey? What kind of cancer do you have? How long have you been fighting it?

2. Can you describe the treatments that you've had for your cancer?

3. As you know, I am researching the important topic of the affordability of cancer care for patients like you, who have a serious diagnosis of cancer and how those costs impact your health care decision-making and your life. How have the costs of care that you have had to pay for (those costs not covered by your insurance) impacted you? How has it made you feel?

4. What other costs related to your cancer diagnosis, besides the bills that you get for your care, are impacting you financially?

5. Let’s take this COST tool score together and see how you rate your current feelings related to cancer costs.

   a. To what extent, if at all, does the score surprise you? Why or why not?
   b. Which of those questions in the COST tool seem to fit with your personal experience? Why?

6. I would like to explore how these feeling about paying for cancer care may impact your decisions around your health care choices. Please think back to a recent time when you were faced with a choice about your cancer care, or your doctor was recommending a treatment for you. Alternatively, if you are making a health care decision now, please tell me how, if at all, the concern for paying for your part of care impacted your decisions to proceed?

7. While making a health care decision, to what extent, if at all, have costs of care made you considered not undergoing a treatment, or discontinuing treatment?

8. What was the decision that you were making about your care in which cancer costs were a factor?

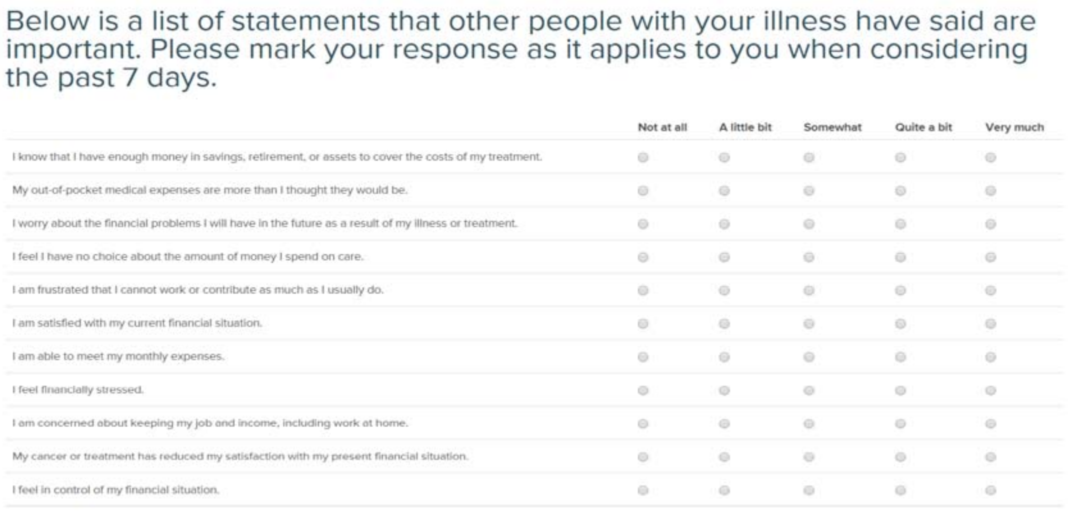
   a. Where did you get information about your choices?
   b. Do you recall what you were thinking about in terms of your choice or the thoughts you were having while you were making these decisions?
   c. Please describe in your own words what were the main concepts or central ideas that were the focus of your decision? Do you recall any specific

thoughts, numbers, or phrases that helped you in making your decision? If so, what were they and why do you think you remember them?

9. You have brought along some documents to share with me. In setting up our interview, I asked you to consider bringing along anything that I might copy and use in my research to help me understand what your experience has been in paying for and experiencing the cost of cancer on you and your family. Please tell me about what you have brought along to share with me.

   a. Why is this significant to you?
   b. What does it represent to you and what should I know about it?

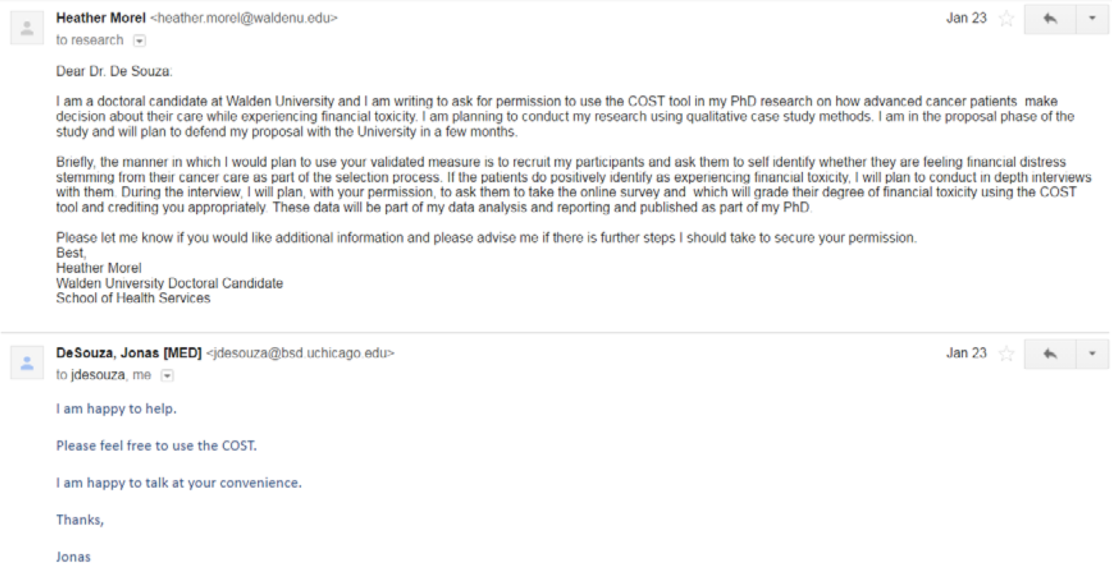
Appendix D: COST Tool and Permission for Use



Below is a list of statements that other people with your illness have said are important. Please mark your response as it applies to you when considering the past 7 days.

	Not at all	A little bit	Somewhat	Quite a bit	Very much
I know that I have enough money in savings, retirement, or assets to cover the costs of my treatment.	○	○	○	○	○
My out-of-pocket medical expenses are more than I thought they would be.	○	○	○	○	○
I worry about the financial problems I will have in the future as a result of my illness or treatment.	○	○	○	○	○
I feel I have no choice about the amount of money I spend on care.	○	○	○	○	○
I am frustrated that I cannot work or contribute as much as I usually do.	○	○	○	○	○
I am satisfied with my current financial situation.	○	○	○	○	○
I am able to meet my monthly expenses.	○	○	○	○	○
I feel financially stressed.	○	○	○	○	○
I am concerned about keeping my job and income, including work at home.	○	○	○	○	○
My cancer or treatment has reduced my satisfaction with my present financial situation.	○	○	○	○	○
I feel in control of my financial situation.	○	○	○	○	○

Email Permission for Use of COST Tool from Dr. de Souza



Heather Morel <heather.morel@waldenu.edu> Jan 23

to research

Dear Dr. De Souza:

I am a doctoral candidate at Walden University and I am writing to ask for permission to use the COST tool in my PhD research on how advanced cancer patients make decision about their care while experiencing financial toxicity. I am planning to conduct my research using qualitative case study methods. I am in the proposal phase of the study and will plan to defend my proposal with the University in a few months.

Briefly, the manner in which I would plan to use your validated measure is to recruit my participants and ask them to self identify whether they are feeling financial distress stemming from their cancer care as part of the selection process. If the patients do positively identify as experiencing financial toxicity, I will plan to conduct in depth interviews with them. During the interview, I will plan, with your permission, to ask them to take the online survey and which will grade their degree of financial toxicity using the COST tool and crediting you appropriately. These data will be part of my data analysis and reporting and published as part of my PhD.

Please let me know if you would like additional information and please advise me if there is further steps I should take to secure your permission.
Best,
Heather Morel
Walden University Doctoral Candidate
School of Health Services

DeSouza, Jonas [MED] <jdesouza@bsd.uchicago.edu> Jan 23

to jdesouza, me

I am happy to help.

Please feel free to use the COST.

I am happy to talk at your convenience.

Thanks,

Jonas

Appendix E: Protocol for Cancer Center Staff to Disseminate Fliers

There is a completely optional research study that is being conducted by a student here in this center. The study involves an interview with the researcher and will gather your experience with paying for cancer care, the impact of the cost of care on your life, and your health care decisions. This research does not involve any drug therapy. This study is completely optional.

To learn more, please contact the researcher with information on this flier. Hand over the flier.

Appendix F: Agreement for Transcription Services: TranscribeMe

IMPORTANT! PLEASE CAREFULLY READ THESE TERMS OF USE AS THEY AFFECT YOUR LEGAL RIGHTS AND OBLIGATIONS.

Please read carefully the following provisions of these Terms of Use (the "Agreement" or "Terms of Use"). This is a legal agreement between you and TranscribeMe, Inc. ("TranscribeMe", "we", or "us) regarding the use of our online and/or mobile services, website, and software provided by us (collectively known as the "TranscribeMe Service"). By accessing or using the TranscribeMe Service, you agree that you have read, understood, and agree to be bound by these Terms of Use, whether or not you are a registered user of the TranscribeMe Service.

We reserve the right to amend this Agreement at any time by notifying you as provided in this Agreement, provided that no notice shall be required or given for non-substantive changes to the Agreement. If we substantively amend This Agreement, we will give you at least seven (7) days notice before the changes take effect, during which period of time you may reject the changes by terminating your account. Your continued use of the TranscribeMe Service after any such change takes effect constitutes your acceptance of the new Terms of Use. If you do not agree to any of these terms or any future Terms of Use, your only remedy shall be to not use or access (or continue to access) the TranscribeMe Service. This Agreement applies to all visitors, users, and others who access the TranscribeMe Service ("Users").

USE OF OUR SERVICE

1. ELIGIBILITY

You may use the TranscribeMe Service only if you can form a binding contract with TranscribeMe, and only in compliance with this Agreement and all applicable local, state, national, and international laws, rules and regulations. If you are under 18, your parent or guardian must enter into this Agreement on your behalf, and will be responsible for your use of and access to the TranscribeMe Service. Any use or access to the TranscribeMe Service by anyone under 13 is prohibited and in violation of this Agreement. If you are under 13, please do not attempt to register for the TranscribeMe Service or send any information about yourself to us, including your name, address, telephone number, or email address. If we learn that we have collected personal information from anyone under age 13 without verification of parental consent, we will delete that information as quickly as possible. TranscribeMe reserves all rights not expressly granted under this Agreement. Any attempt by you to transfer any of the rights, duties or obligations hereunder, except as expressly provided for in this Agreement, is void.

2. TRANSCRIBEME ACCOUNT

You must create an account in order to gain access to the services and functionality that we may establish and maintain from time to time and in our sole discretion. You may never use another User’s account without permission. You are solely responsible for the activity that occurs on your account, and you must keep your account password secure. You must notify TranscribeMe immediately of any breach of security or unauthorized use of your account. TranscribeMe will not be liable for any losses caused by any unauthorized use of your account.

The TranscribeMe Service is available through Facebook’s “Facebook Connect” service, which requires an active Facebook account, and you hereby represent and warrant that you have read and agreed to be bound by all applicable Facebook policies and will act in accordance with those policies, in addition to your obligations under this Agreement. If you access the TranscribeMe Service through Facebook Connect, TranscribeMe may require that your TranscribeMe user ID be the same as your user name for Facebook. If you sign into TranscribeMe through Facebook Connect, you will provide your Facebook account credentials to TranscribeMe, and you are consenting to have the information in that account transmitted into your TranscribeMe account, and you agree that you shall only use Facebook accounts owned by you, and not by any other person or entity.

By providing TranscribeMe your email address, you consent to our using that email address to send you TranscribeMe Service-related notices, including any notices required by law, in lieu of communication by snail mail. We may also use your email address to send you other messages, such as changes to features of the TranscribeMe Service and special offers. If you do not want to receive such email messages, you may opt out by sending us a request at optout@transcribeme.com. Opting out may prevent you from receiving email messages regarding updates, improvements, or offers. Please note that if you do not want to receive legal notices from us, including without limitation a notice that this Agreement has changed, those legal notices will still govern your use of the TranscribeMe Service. We will post legal notices to the TranscribeMe Service, and you are responsible for reviewing such legal notices for changes. Please see our Privacy Policy for more details.

3. SERVICE RULES

You agree not to engage in any of the following prohibited activities in connection with the TranscribeMe Service: (i) copying, distributing, or disclosing any part of the TranscribeMe Service in any medium, including without limitation by any automated or non-automated “scraping”; (ii) using any automated system, including without limitation “robots,” “spiders,” “offline readers,” etc., to access the TranscribeMe Service in a manner that sends more request messages to the TranscribeMe servers than a human can reasonably produce in the same period of time by using a conventional on-line web browser; (iii) transmitting spam, chain letters, or other unsolicited email; (iv) attempting to interfere with, compromise the system integrity or security or decipher any transmissions to or from the servers running the TranscribeMe Service; (v) taking any action that imposes, or may impose at our sole discretion an unreasonable or disproportionately large load on our infrastructure; (vi) uploading invalid data, viruses, worms, or other software agents through the TranscribeMe Service; (vii) collecting or harvesting any personally identifiable information, including account names, from the TranscribeMe Service; (viii) using the TranscribeMe Service for any commercial purposes; (ix) impersonating another person or otherwise misrepresenting your affiliation with a person or entity, conducting fraud, hiding or attempting to hide your identity; (x) interfering with the proper working of the TranscribeMe Service; (xi) accessing any content on the TranscribeMe Service through any technology or means other than those provided or authorized by the TranscribeMe Service; (xii) bypassing the measures we may use to prevent or restrict access to the TranscribeMe Service, including without limitation features that prevent or restrict use or copying of any content or enforce limitations on use of the TranscribeMe Service or the content therein, or (xiii) decompiling, reverse engineering, or otherwise attempting to obtain the source code of the TranscribeMe Service.

You may not access or use the TranscribeMe Service if you work with or for a competitor, except with TranscribeMe’s prior written consent. In addition, you may not use or access the TranscribeMe Service for purposes of monitoring the performance or functionality for a competitor or for any third party, or for any other benchmarking or competitive purposes and you may not share any benchmarking data regarding the TranscribeMe Service usage with any third party without TranscribeMe’s prior written consent.

We may, without prior notice, change the TranscribeMe Service, stop providing the TranscribeMe Service or features of the TranscribeMe Service (to you or generally), or create usage limits for the TranscribeMe Service. You agree that TranscribeMe has no responsibility or liability for the deletion or failure to store any documents, data or other content maintained or uploaded by you to the TranscribeMe Service. We may permanently or temporarily terminate or suspend your access to the TranscribeMe Service without notice or liability to TranscribeMe, for any reason or for no reason, including if in our sole determination you violate any provision of this Agreement. Upon termination of this Agreement or your access to the TranscribeMe Service for any reason or no reason, you will continue to be bound by the terms of this Agreement which, by their nature, should survive termination, including without limitation ownership provisions, warranty disclaimers, indemnity, and limitations of liability.

4. USER CONTENT

You are solely responsible for all audio and other data (“User Content”) that you upload, post, publish or display (hereinafter, “upload”) or email or otherwise use

via the Service.
You agree not to upload User Content that: (i) may create a risk of harm, loss, physical or mental injury, emotional distress, death, disability, disfigurement, or physical or mental illness to you, to any other person; (ii) may create a risk of any other loss or damage to any person or property; (iii) seeks to harm or exploit children by exposing them to inappropriate content, asking for personally identifiable details or otherwise; (iv) may constitute or contribute to a crime or tort; (v) contains any information or content that we deem to be unlawful, harmful, abusive, racially or ethnically offensive, defamatory, infringing, invasive of personal privacy or publicity rights, harassing, humiliating to other people (publicly or otherwise), libelous, threatening, profane, obscene, pornographic, or otherwise objectionable; (vi) contains any information or content that is illegal (including, without limitation, the disclosure of insider information under securities law or of another party's trade secrets); (vii) contains any information or content that you do not have a right to make available under any law or under contractual or fiduciary relationships; or (viii) contains any information or content that you know is not correct and current. You agree that any User Content that you upload does not and will not violate third-party rights of any kind, including without limitation any Intellectual Property Rights (as defined below) or rights of privacy. For the purposes of this Agreement, "Intellectual Property Rights" means all patent rights, copyright rights, mask work rights, moral rights, rights of publicity, trademark, trade dress and service mark rights, goodwill, trade secret rights and other intellectual property rights as may now exist or hereafter come into existence, and all applications therefore and registrations, renewals and extensions thereof, under the laws of any state, country, territory or other jurisdiction.

In connection with your User Content, you affirm, represent and warrant that your User Content and TranscribeMe's use thereof as contemplated by this Agreement and the TranscribeMe Service will not violate any law or infringe any rights of any third party, including but not limited to any Intellectual Property Rights and privacy rights.

TranscribeMe takes no responsibility and assumes no liability for any User Content that you or any other User or third party posts or sends over the TranscribeMe Service. You acknowledge and agree that Transcribme may preserve your User Content and may also disclose content if required to do so by law or in the good faith belief that such preservation or disclosure is reasonably necessary to: (a) comply with legal process, applicable laws or government requests; (b) enforce this Agreement; (c) respond to claims that any content violates the rights of third parties; or (d) protect the rights, property, or personal safety of TranscribeMe, its users and the public. You understand that the technical processing and transmission of the TranscribeMe Service, including your content, may involve (a) transmissions over various networks; and (b) changes to conform and adapt to technical requirements of connecting networks or devices

By uploading any User Content you hereby grant and will grant TranscribeMe and its affiliated companies a nonexclusive, worldwide, royalty free, fully paid up, transferable, sublicenseable, perpetual, irrevocable license to copy, display, upload, perform, distribute, store, modify and otherwise use your User Content in connection with the operation of the TranscribeMe Service, in any form, medium or technology now known or later developed.

5. Digital Millennium Copyright Act

DMCA Notification. We comply with the provisions of the Digital Millennium Copyright Act applicable to Internet service providers (17 U.S.C. §512, as amended). If you have an intellectual property rights-related complaint about material posted on the TranscribeMe Service, you may contact our Designated Agent at the following address:

TranscribeMe, Inc.

ATTN: Copyright Notification

2150 Shattuck Ave, Suite 250

Berkeley CA 94705, USA

Email: copyright@transcribeme.com

Any notice alleging that materials hosted by or distributed through the TranscribeMe Service infringe intellectual property rights must include the following information:

a. an electronic or physical signature of the person authorized to act on behalf of the owner of the copyright or other right being infringed;
b. a description of the copyright-protected work or other intellectual property right that you claim has been infringed;
c. a description of the material that you claim is infringing and where it is located on the TranscribeMe Service;
d. your address, telephone number, and email address;

e. a statement by you that you have a good faith belief that the use of those materials on the TranscribeMe Service is not authorized by the copyright owner, its agent, or the law; and

f. a statement by you that the above information in your notice is accurate and that, under penalty of perjury, you are the copyright or intellectual property owner or authorized to act on the copyright or intellectual property owner's behalf.

Repeat Infringers. TranscribeMe will promptly terminate without notice the accounts of users that are determined by TranscribeMe to be "Repeat Infringers." A Repeat Infringer is a user who has been notified of infringing activity or has had User Content removed from the TranscribeMe Service at least twice.

6. CONFIDENTIALITY

Any materials or data that you provide to TranscribeMe for the purpose of providing the TranscribeMe Service will be your "Confidential Information," except to the extent such documents (a) are known to TranscribeMe prior to receipt from you from a source other than one having an obligation of confidentiality to you; (b) become known (independently of disclosure by you) to TranscribeMe directly or indirectly from a source other than one having an obligation of confidentiality to you; or (c) become publicly known or otherwise cease to be secret or confidential, except through a breach of this Section by TranscribeMe. TranscribeMe will use the Confidential Information solely for the purpose of providing the TranscribeMe Service to you (the "Permitted Purpose"). TranscribeMe will not, without your prior consent, disclose to any third party your Confidential Information, other than furnishing such Confidential Information to our directors, officers, employees, agents, consultants, contractors, representatives or affiliated entities (collectively, "Associated Persons") who need to have access to such Confidential Information in connection with the Permitted Purpose. TranscribeMe will use at least reasonable care to protect the confidentiality of your Confidential Information. In the event that TranscribeMe is required by law to make any disclosure of any of your Confidential Information, by subpoena, judicial or administrative order or otherwise, TranscribeMe will use commercially reasonable efforts to give you notice of such requirement (to the extent legally permissible) and will permit you to intervene in any relevant proceedings to protect your interests in your Confidential Information

7. FEES

To use the TranscribeMe Service, you will be required to make one or more payments and provide us with information regarding your credit card. You represent and warrant to TranscribeMe that such information is true and that you are authorized to use the payment instrument. You will promptly update your account information with any changes (for example, a change in your billing address or credit card expiration date) that may occur. You agree to pay TranscribeMe the amount that is specified by the TranscribeMe Service in accordance with the terms therein and this Agreement. TranscribeMe reserves the right to change our prices. If we change our prices, we will provide notice of the change on the TranscribeMe web site or in email to you, at our option. Your continued use of the TranscribeMe Service after the price change becomes effective constitutes your agreement to pay the changed amount.

If TranscribeMe agrees, in its sole discretion, to invoice you for your receipt of the TranscribeMe Service (rather than requiring you to pay all fees by credit card), you must nevertheless provide TranscribeMe with your credit card information (as reasonably requested by TranscribeMe) and promptly update such information with any changes that may occur. If you fail to pay any invoices within 30 days of the date of the invoice, TranscribeMe will notify you by email of the overdue charge and, if the invoice remains unpaid, TranscribeMe will charge your credit card the full amount owing under the invoice on the 35th day following the date of the invoice. You hereby authorize us to charge any such overdue amounts to your credit card on file and acknowledge that TranscribeMe may suspend its provision to you of the TranscribeMe Service if any amounts remain unpaid. You may be required to pay all subsequent fees by credit card if you fail to pay an invoice within 35 days of the invoice date. TranscribeMe will only remove a credit card on file at your request if your account balance is $0 and there are no TranscribeMe Services pending for you.

END USER LICENSE GRANT

8. TRANSCRIBEME SERVICE

Subject to the terms and conditions of this Agreement, you are hereby granted a non-exclusive, limited, non-transferable, freely revocable license to use the TranscribeMe Service for your personal, non-commercial use, as permitted by the features of the TranscribeMe Service. TranscribeMe reserves all rights not expressly granted herein in the TranscribeMe Service and the TranscribeMe Content (as defined below). TranscribeMe may terminate this license at any time for any reason or no reason.

9. MOBILE SOFTWARE

We may make available software to access the TranscribeMe Service via a mobile device (“Mobile Software”). To use the Mobile Software you must have a mobile device that is compatible with the Mobile TranscribeMe Service. TranscribeMe does not warrant that the Mobile Software will be compatible with your mobile device. TranscribeMe hereby grants you a non-exclusive, non-transferable, revocable license to use a compiled code copy of the Mobile Software for one TranscribeMe account on one mobile device owned or leased solely by you, for your personal, non-commercial use. You may not: (i) modify, disassemble, decompile or reverse engineer the Mobile Software, except to the extent that such restriction is expressly prohibited by law; (ii) rent, lease, loan, resell, sublicense, distribute or otherwise transfer the Mobile Software to any third party or use the Mobile Software to provide time sharing or similar services for any third party; (iii) make any copies of the Mobile Software; (iv) remove, circumvent, disable, damage or otherwise interfere with security-related features of the Mobile Software, features that prevent or restrict use or copying of any content accessible through the Mobile Software, or features that enforce limitations on use of the Mobile Software; or (v) delete the copyright and/or other proprietary rights notices on the Mobile Software. You acknowledge that TranscribeMe may from time to time issue upgraded versions of the Mobile Software, and may automatically electronically upgrade the version of the Mobile Software that you are using on your mobile device. You consent to such automatic upgrading on your mobile device, and agree that the terms and conditions of this Agreement will apply to all such upgrades. Any third-party code that may be incorporated in the Mobile Software is covered by the applicable open source or third-party license EULA, if any, authorizing use of such code. The foregoing license grant is not a sale of the Mobile Software or any copy thereof, and TranscribeMe or its third party partners or suppliers retain all right, title, and interest in the Mobile Software (and any copy thereof).

10. MOBILE SOFTWARE FROM APPLE APP STORE

This paragraph is intended to apply to you if you have downloaded the Mobile Software from the Apple App Store. TranscribeMe and you acknowledge that this Agreement is concluded between TranscribeMe and you only, and not with Apple Inc. (“Apple”), and as between TranscribeMe and Apple, TranscribeMe, not Apple, is solely responsible for the Software and TranscribeMe Services and the content thereof. You acknowledge that Apple, Inc. has no obligation whatsoever to furnish any maintenance and support services with respect to the Mobile Software. You acknowledge that you have reviewed the App Store Terms and Conditions (located online at http://www.apple.com/legal/itunes/us/terms.html#APPS). You represent and warrant that (i) you are not located in a country that is subject to a U.S. Government embargo, or that has been designated by the U.S. Government as a “terrorist supporting” country; and (ii) You are not listed on any U.S. Government “watch list” of prohibited or restricted parties, including the Specially Designated Nationals list published by the Office of Foreign Assets Control of the U.S. Treasury or the Denied Persons List published by the U.S. Department of Commerce.

This Agreement incorporates by reference the Licensed Application End User License Agreement (the “LAEULA”) published by Apple, Inc. (located online at http://www.apple.com/legal/itunes/appstore/dev/stdeula/). For purposes of this Agreement, the “Mobile Software” is considered the “Licensed Application” as defined in the LAEULA and “TranscribeMe” is considered the “Application Provider” as defined in the LAEULA. If any terms of this Agreement conflict with the terms of the LAEULA, the terms of this Agreement shall control.

11. MOBILE SOFTWARE FROM GOOGLE ANDROID MARKET

This paragraph is intended to apply to you if you have downloaded the Mobile Software on a device powered by the Android operating system. TranscribeMe and you, the end-user of the Mobile Software and TranscribeMe Services, acknowledge that the Agreement is entered into by and between TranscribeMe and you. TranscribeMe is solely responsible for the Software and TranscribeMe Services. Should you have downloaded the Software from the Google Android Market located online at https://play.google.com/store. You acknowledge that you have reviewed the Android Market Terms of Service (located online at https://play.google.com/about/play-terms.html) and the Android Market Business and Program Policies (located online at http://play.google.com/about/play-terms.html). You represent and warrant that (i) you are not located in a country that is subject to a U.S. Government embargo, or that has been designated by the U.S. Government as a "terrorist supporting" country; and (ii) you are not listed on any U.S. Government "watch list" of prohibited or restricted parties, including the Specially Designated Nationals list published by the Office of Foreign Assets Control of the U.S. Treasury or the Denied Persons List published by the U.S. Department of Commerce.

12. TRANSCRIBEME PROPRIETARY RIGHTS

Except for your User Content, the TranscribeMe Service and all materials therein or transferred thereby, including, without limitation, software, images, text, graphics, illustrations, logos, patents, trademarks, service marks, copyrights, photographs, audio, videos, music, and User Content (the "TranscribeMe Content"), and all Intellectual Property Rights related thereto, are the exclusive property of TranscribeMe and its licensors. Except as explicitly provided herein, nothing in this Agreement shall be deemed to create a license in or under any such Intellectual Property Rights, and you agree not to sell, license, rent, modify, distribute, copy, reproduce, transmit, publicly display, publicly perform, publish, adapt, edit or create derivative works from any materials or content accessible on the TranscribeMe Service. Use of the TranscribeMe Content or materials on the TranscribeMe Service for any purpose not expressly permitted by this Agreement is strictly prohibited.

13. PREMIUM SERVICES

From time to time, TranscribeMe may provide additional features and/or TranscribeMe Services that you pay for ("Premium TranscribeMe Services"). TranscribeMe may also offer from time to time in its sole discretion, certain Premium TranscribeMe Services for free, whether for a trial period or otherwise. Unless expressly stated otherwise, references in this Agreement to the TranscribeMe Service include the Premium TranscribeMe Services.

14. PRIVACY

For information about how TranscribeMe protects your privacy, please read the TranscribeMe Privacy Policy. This policy explains how TranscribeMe treats your personal information, and protects your privacy, when you use the TranscribeMe Service.

15. DELIVERY TERMS OF SERVICE

TranscribeMe will undertake service delivery to complete the assigned work in the shortest amount of time possible. Where time commitments are explicitly agreed on, the time indicated is confined to business days only in the Pacific Standard Timezone. For example, 24 hour delivery equates to 1 business day, 48 hour delivery equates to 2 business days and so forth. Our standard hours of service are 8am to 6pm Monday-Friday, Pacific Standard time. Additional support hours and after-hour service is available by inquiry. Transcripts will be returned back to the users

16. TRANSCRIPTION OUTPUT STYLE

TranscribeMe provides output in “clean verbatim”, “full verbatim”, and “edited text” transcriptions. The “clean verbatim” is the default style choice, and automatically removes “umms”, “ahhs”, “likes”, “you knows”, and other filler word in addition to stuttering from the final transcript. The “edited text” transcripts go beyond clean verbatim transcripts and improve on grammar to make a transcript more readable. We consider these transcripts as publishable and this option is frequently used by bloggers, podcasters and conference speakers. Full verbatim transcripts capture speech exactly how it sounds, including all filler words and speech errors.

17. SECURITY

TranscribeMe cares about the integrity and security of your personal information. However, we cannot guarantee that unauthorized third parties will never be able to defeat our security measures or use your personal information for improper purposes. You acknowledge that you provide your personal information at your own risk.

18. THIRD PARTY LINKS

The TranscribeMe Service may contain links to third-party websites, advertisers, services, special offers, or other events or activities that are not owned or controlled by TranscribeMe. TranscribeMe does not endorse or assume any responsibility for any such third-party sites, information, materials, products, or services. If you access a third party website from the TranscribeMe Service, such as through Facebook Connect, you do so at your own risk, and you understand that this Agreement and TranscribeMe’s Privacy Policy do not apply to your use of such sites. You expressly relieve TranscribeMe from any and all liability arising from your use of any third-party website, service, or content. Additionally, your dealings with or participation in promotions of advertisers found on the TranscribeMe Service, including payment and delivery of goods, and any other terms (such as warranties) are solely between you and such third parties. You agree that TranscribeMe shall not be responsible for any loss or damage of any sort relating to your dealings with such third parties.

19. INDEMNITY

You agree to defend, indemnify and hold harmless TranscribeMe and its subsidiaries, agents, licensors, managers, and other affiliated companies, and their employees, contractors, agents, officers and directors (collectively, the "TranscribeMe Parties"), from and against any and all claims, damages, obligations, losses, liabilities, costs or debt, and expenses (including but not limited to attorney's fees) arising from: (i) your use of and access to the TranscribeMe Service, including any data or content transmitted or received by you; (ii) your violation of any term of this Agreement, including without limitation your breach of any of the representations and warranties you make in this Agreement; (iii) your violation of any third-party right, including without limitation any right of privacy or Intellectual Property Rights; (iv) your violation of any applicable law, rule or regulation; (v) any claim or damages that arise as a result of any of your User Content or any that is submitted via your account; or (vi) any other party's access and use of the TranscribeMe Service with your username, password or other appropriate security code.

20. NO WARRANTY

THE TRANSCRIBEME SERVICE AND ANY PRODUCT OR SERVICE YOU PURCHASE THROUGH THE TRANSCRIBEME SERVICE ("PRODUCT") ARE PROVIDED ON AN "AS IS" AND "AS AVAILABLE" BASIS. USE OF THE SERVICE IS AT YOUR OWN RISK. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, THE TRANSCRIBEME SERVICE AND THE PRODUCTS ARE PROVIDED WITHOUT WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. WITHOUT LIMITING THE FOREGOING, TRANSCRIBEME, ITS SUBSIDIARIES, AND ITS LICENSORS DO NOT WARRANT THAT THE CONTENT IS ACCURATE, RELIABLE OR CORRECT; THAT THE TRANSCRIBEME SERVICE OR THE PRODUCTS WILL MEET YOUR REQUIREMENTS; THAT THE SERVICE WILL BE AVAILABLE AT ANY PARTICULAR TIME OR LOCATION, UNINTERRUPTED OR SECURE; THAT ANY DEFECTS OR ERRORS WILL BE CORRECTED; OR THAT THE SERVICE IS FREE OF VIRUSES OR OTHER HARMFUL COMPONENTS. ANY CONTENT DOWNLOADED OR OTHERWISE OBTAINED THROUGH THE USE OF THE TRANSCRIBEME SERVICE IS

DOWNLOADED AT YOUR OWN RISK AND YOU WILL BE SOLELY RESPONSIBLE FOR ANY DAMAGE TO YOUR COMPUTER SYSTEM OR LOSS OF DATA THAT RESULTS FROM SUCH DOWNLOAD OR YOUR USE OF THE TRANSCRIBEME SERVICE.

TRANSCRIBEME DOES NOT WARRANT, ENDORSE, GUARANTEE, OR ASSUME RESPONSIBILITY FOR ANY PRODUCT OR SERVICE ADVERTISED OR OFFERED BY A THIRD PARTY THROUGH THE TRANSCRIBEME SERVICE OR ANY HYPERLINKED WEBSITE OR SERVICE, AND TRANSCRIBEME WILL NOT BE A PARTY TO OR IN ANY WAY MONITOR ANY TRANSACTION BETWEEN YOU AND THIRD-PARTY PROVIDERS OF PRODUCTS OR SERVICES.

IF YOU DOWNLOADED THE MOBILE SOFTWARE FROM THE APPLE APP STORE, YOU FURTHER ACKNOWLEDGE THAT APPLE HAS NO RESPONSIBILITY FOR ADDRESSING ANY CLAIMS RELATING TO THE SOFTWARE OR TRANSCRIBEME SERVICES OR YOUR POSSESSION AND/OR USE OF THE SOFTWARE OR TRANSCRIBEME SERVICES, INCLUDING, BUT NOT LIMITED TO: (I) PRODUCT LIABILITY CLAIMS; (II) ANY CLAIM THAT THE SOFTWARE OR TRANSCRIBEME SERVICES FAIL TO CONFORM TO ANY APPLICABLE LEGAL OR REGULATORY REQUIREMENT; AND (III) CLAIMS ARISING UNDER CONSUMER PROTECTION OR SIMILAR LEGISLATION.

21. LIMITATION OF LIABILITY

IN NO EVENT SHALL THE TRANSCRIBEME PARTIES BE LIABLE, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR ANY OTHER LEGAL THEORY, FOR ANY LOSSES, LIABILITIES, CLAIMS OR DAMAGES OF ANY KIND, WHETHER DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE, OR FOR LOSS OF REVENUE OR PROFITS, LOSS OF BUSINESS, OR ANY OTHER DAMAGES, ARISING OUT OF OR IN CONNECTION WITH THE SOFTWARE AND/OR ANY OF THE TRANSCRIBEME SERVICES, THESE TERMS OF USE OR THE PERFORMANCE, SUSPENSION, TERMINATION OR BREACH HEREOF, EVEN IF TRANSCRIBEME OR ANY OTHER TRANSCRIBEME PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF. THE TRANSCRIBEME PARTIES SHALL HAVE NO LIABILITY IN CONNECTION WITH OR ARISING FROM THESE TERMS OF USE OR USE OF THE SOFTWARE OR ANY OF THE TRANSCRIBEME SERVICES. SOME JURISDICTIONS DO NOT ALLOW THE LIMITATION OF LIABILITY FOR PERSONAL INJURY, OR OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THIS LIMITATION MAY NOT APPLY TO YOU. IN NO EVENT SHALL TRANSCRIBEME’S (OR APPLE’S

IF YOU DOWNLOADED THE SOFTWARE FROM THE APPLE APP STORE) TOTAL LIABILITY TO YOU FOR ALL DAMAGES (OTHER THAN AS MAY BE REQUIRED BY APPLICABLE LAW IN CASES INVOLVING PERSONAL INJURY) EXCEED THE AMOUNT YOU HAD PAID TO TRANSCRIBEME OVER THE PRECEDING THREE MONTHS PERIOD.

THE FOREGOING LIMITATIONS WILL APPLY EVEN IF THE ABOVE STATED REMEDY FAILS OF ITS ESSENTIAL PURPOSE. THESE LIMITATIONS OF LIABILITY ALSO APPLY WITH RESPECT TO DAMAGES INCURRED BY YOU BY REASON OF ANY PRODUCTS OR TRANSCRIBEME SERVICES SOLD OR PROVIDED BY THIRD PARTIES OTHER THAN TRANSCRIBEME AND RECEIVED THROUGH OR ADVERTISED ON ANY OF THE TRANSCRIBEME SERVICES. YOU AGREE THAT IN THE EVENT YOU INCUR ANY DAMAGES, LOSSES OR INJURIES THAT ARISE OUT OF TRANSCRIBEME ACTS OR OMISSIONS, THE DAMAGES, IF ANY, CAUSED TO YOU ARE NOT IRREPARABLE OR SUFFICIENT TO ENTITLE YOU TO AN INJUNCTION PREVENTING ANY EXPLOITATION OF ANY WEB SITE, PROPERTY, PRODUCT, SERVICE, OR OTHER MATERIALS OWNED OR CONTROLLED BY THE TRANSCRIBEME PARTIES, AND YOU WILL HAVE NO RIGHTS TO ENJOIN OR RESTRAIN THE DEVELOPMENT, PRODUCTION, DISTRIBUTION, ADVERTISING, EXHIBITION OR EXPLOITATION OF ANY WEB SITE, PROPERTY, PRODUCT, SERVICE, OR OTHER MATERIALS OWNED OR CONTROLLED BY THE TRANSCRIBEME PARTIES.

SOME COUNTRIES DO NOT ALLOW THE LIMITATION OR EXCLUSION OF LIABILITY IN CONTRACTS WITH CONSUMERS AND AS A RESULT THE CONTENTS OF THIS SECTION MAY NOT APPLY TO YOU.

GENERAL

22. GOVERNING LAW AND JURISDICTION

This Agreement shall be governed by and construed under the laws of the State of California, excluding that body of law related to choice of laws, and of the United States of America. If a lawsuit or court proceeding is permitted under these Terms of Use, any such lawsuit or court proceeding shall be brought in the County of Santa Clara, State of California (if under State law) or the Northern District of California (if under Federal law), and each of the parties hereby submits itself to the exclusive jurisdiction and venue of such courts for purposes of any such action, and waives any jurisdictional, venue, or inconvenient forum objections to such courts. If you refuse or otherwise fail to fulfill any of your material obligations pursuant to this Agreement, including, without limitation, any indemnity obligation hereunder, TranscribeMe shall be entitled, in addition to any other rights and remedies available to it hereunder or otherwise at law or in equity, to reimbursement for its costs and expenses (including court costs and reasonable fees for attorneys and expert witnesses) incurred with respect to bringing and maintaining any legal action regarding any such matter; and (iii) any claim or legal action initiated by you must be brought individually and shall not be consolidated as part of a group or class action lawsuit.

23. Dispute Resolution and Arbitration

a. **Generally**. In the interest of resolving disputes between you and TranscribeMe in the most expedient and cost effective manner, you and TranscribeMe agree that every dispute arising in connection with these Terms of Use will be resolved by binding arbitration. Arbitration is less formal than a lawsuit in court. Arbitration uses a neutral arbitrator instead of a judge or jury, may allow for more limited discovery than in court, and can be subject to very limited review by courts. Arbitrators can award the same damages and relief that a court can award. This agreement to arbitrate disputes includes all claims arising out of or relating to any aspect of these Terms of Use, whether based in contract, tort, statute, fraud, misrepresentation, or any other legal theory, and regardless of whether a claim arises during or after the termination of these Terms of Use. YOU UNDERSTAND AND AGREE THAT, BY ENTERING INTO THESE TERMS, YOU AND KABUNI ARE EACH WAIVING THE RIGHT TO A TRIAL BY JURY OR TO PARTICIPATE IN A CLASS ACTION.

b. **Exceptions**. Despite the provisions of Section 23.a., nothing in these Terms of Use will be deemed to waive, preclude, or otherwise limit the right of either party to: (a) bring an individual action in small claims court; (b) pursue an enforcement action through the applicable federal, state, or local agency if that action is available; (c) seek injunctive relief in a court of law; or (d) to file suit in a court of law to address an intellectual property infringement claim.

c. **Arbitrator**. Any arbitration between you and TranscribeMe will be settled under the Federal Arbitration Act, and governed by the Commercial Dispute Resolution Procedures and the Supplementary Procedures for Consumer Related Disputes (collectively, “AAA Rules”) of the American Arbitration Association (“AAA”), as modified by these Terms of Use, and will be administered by the AAA. The AAA Rules and filing forms are available online at www.adr.org, by calling the AAA at 1-800-778-7879, or by contacting TranscribeMe.

d. **Notice; Process**. A party who intends to seek arbitration must first send a written notice of the dispute to the other party by certified U.S. Mail or by Federal Express (signature required) or, only if such other party has not provided a current physical address, then by electronic mail (“Notice”). TranscribeMe’s address for Notice is: TranscribeMe, Inc., 2150 Shattuck Ave, Suite 250, Berkeley CA 94705, USA. The Notice must: (a) describe the nature and basis of the claim or dispute; and (b) set forth the specific relief sought ("Demand"). The parties will make good faith efforts to resolve the claim directly, but if the parties do not reach an agreement to do so within 30 days after the Notice is received, you or TranscribeMe may commence an arbitration proceeding. During the arbitration, the amount of any settlement offer made by you or TranscribeMe must not be disclosed to the arbitrator until after the arbitrator makes a final decision and award, if any. If the dispute is finally resolved through arbitration in your favor, TranscribeMe will pay you the highest of the following: (i) the amount awarded by the arbitrator, if any; (ii) the last written settlement amount offered by TranscribeMe in settlement of the dispute prior to the arbitrator's award; or (iii) $1,000.

e. **Fees**. If you commence arbitration in accordance with these Terms of Use, TranscribeMe will reimburse you for your payment of the filing fee, unless your claim is for more than $10,000, in which case the payment of any fees will be decided by the AAA Rules. Any arbitration hearing will take place at a location to be agreed upon in Newcastle County, Delaware, but if the claim is for $10,000 or less, you may choose whether the arbitration will be conducted: (a) solely on the basis of documents submitted to the arbitrator; (b) through a non-appearance based telephone hearing; or (c) by an in-person hearing as established by the AAA Rules in the county (or parish) of your billing address. If the arbitrator finds that either the substance of your claim or the relief sought in the Demand is frivolous or brought for an improper purpose (as measured by the standards set forth in Federal Rule of Civil Procedure 11(b)), then the payment of all fees will be governed by the AAA Rules. In that case, you agree to reimburse TranscribeMe for all monies previously disbursed by it that are otherwise your obligation to pay under the AAA Rules. Regardless of the manner in which the arbitration is conducted, the arbitrator must issue a reasoned written decision sufficient to explain the essential findings and conclusions on which the decision and award, if any, are based. The arbitrator may make rulings and resolve disputes as to the payment and reimbursement of fees or expenses at any time during the proceeding and upon request from either party made within 14 days of the arbitrator's ruling on the merits.

f. **No Class Actions**. YOU AND TRANSCRIBEME AGREE THAT EACH MAY BRING CLAIMS AGAINST THE OTHER ONLY IN YOUR OR ITS INDIVIDUAL CAPACITY AND NOT AS A PLAINTIFF OR CLASS MEMBER IN ANY PURPORTED CLASS OR REPRESENTATIVE PROCEEDING. Further, unless both you and TranscribeMe agree otherwise, the arbitrator may not consolidate more than one person's claims, and may not otherwise preside over any form of a representative or class proceeding.

g. **Modifications to this Arbitration Provision**. If TranscribeMe makes any future change to this arbitration provision, other than a change to

TranscribeMe's address for Notice, you may reject the change by sending us written notice within 30 days of the change to TranscribeMe's address for Notice, in which case your account with TranscribeMe will be immediately terminated and this arbitration provision, as in effect immediately prior to the changes you rejected will survive.

h. **Enforceability**. If Section 23.f. is found to be unenforceable or if the entirety of this Section 23 is found to be unenforceable, then the entirety of this Section 23 will be null and void and, in that case, the parties agree that the exclusive jurisdiction and venue described in Section 22 will govern any action arising out of or related to these Terms of Use.

24. NOTICE TO CALIFORNIA USERS

Pursuant to California Civil Code Section 1789.3, California users of TranscribeMe Service are entitled to the following specific consumer rights notice: The Complaint Assistance Unit of the Division of Consumer Services of the California Department of Consumer Affairs may be contacted in writing at 1625 North Market Blvd., Suite N 112, Sacramento, CA 95834, or by telephone at (800) 952-5210. TranscribeMe's mailing address and email address can be found in the Contact Us section of this Agreement.

25. ENTIRE AGREEMENT / SEVERABILITY

This Agreement, together with any amendments and any additional agreements you may enter into with TranscribeMe in connection with the TranscribeMe Service, shall constitute the entire agreement between you and TranscribeMe concerning the TranscribeMe Service. If any provision of this Agreement is deemed invalid by a court of competent jurisdiction, the invalidity of such provision shall not affect the validity of the remaining provisions of this Agreement, which shall remain in full force and effect.

26. NO WAIVER

No waiver of any term of this Agreement shall be deemed a further or continuing waiver of such term or any other term, and TranscribeMe's failure to assert any right or provision under this Agreement shall not constitute a waiver of such right or provision.

27. THIRD PARTY BENEFICIARIES AND AGREEMENTS

If you downloaded the Mobile Software from the Apple App Store, you acknowledge and agree that Apple, and Apple's subsidiaries, are third party beneficiaries of this Agreement, and that, upon your acceptance of the terms and conditions of this Agreement, Apple will have the right (and will be deemed to have accepted the right) to enforce this Agreement against you as a third party beneficiary hereof. You agree to comply with, and your license to use the Mobile Software and TranscribeMe Service is conditioned upon your compliance with, all applicable third-party terms of agreement, as may be applicable, when using the Mobile Software and/or TranscribeMe Service.

28. ASSIGNMENT

This Agreement, and any rights and licenses granted hereunder, may not be transferred or assigned by you, but may be assigned by TranscribeMe without restriction or notice.

29. NOTICES

We may provide notices, whether such notices are required by law or are for marketing or other business related purposes, to you via email notice, written or hard copy notice, or through posting of such notice on our website, Apple App Store or Google Android Marketplace, as determined by us in our sole discretion. We reserve the right to determine the form and means of providing notifications to our Users, provided that you may opt out of certain means of notification as described in this Agreement.

30. CONTACT US

Should you wish to contact us with any questions, complaints or claims with respect to the TranscribeMe Service, you should visit the TranscribeMe website at www.transcribeme.com, by mail at 2150 Shattuck Ave, Suite 250, Berkeley CA 94705, USA or email at support@transcribeme.com.

These terms of service were last amended on May 26, 2016.

Appendix G: Honoraria Receipt

I, __________________________ have received an Honoraria of $80.00 for participation in research conducted by Heather Morel, Student at Walden University.

____ Date: __________________________

Appendix H: Interview Protocol

1) Interview Set Up Procedures
    a) Meet with center staff to explain study purpose and methodology, and procedures for flier dissemination – either by email, mail, or in-person dissemination (See Appendix E)
    b) Researcher returns emails and /or calls potential participant, discusses the study and purpose, commitment and answers any questions. Sets up interview if participant is able and willing.
    c) Send consent form to participant by email or mail.
    d) Most interviews will be conducted in a private room at the cancer center although some may be completed in a quiet corner of the infusion room while a patient has therapy, if more convenient.
    e) Researcher explains to patient to bring any artifacts representative of the patient's experience with FT and how they think about its impact on their lives and health care decision-making.
2) On site interview procedures for the procedure
    a) Researcher will arrive early and make observations on the interview setting.
    b) Greet patient, welcome them to the interview and introduce myself.
    c) Describe the process of the interview, how I will safeguard their private and confidential information.
    d) Show them the informed consent and ask them to sign it.

- e) Ask if I can audio record the interview so I can concentrate on the conversation and not trying to write all their words down.
- f) Ask if I may take a photograph of them.
- g) Transition to discussion guide (Appendix A.) questions

3) Interview close down procedures

- a) In a few days, I would like to get your feedback on the transcript that I will make from our interview today. Could I email it to you to read over and if you find that there are things you would like to further explain or that I may not have captured accurately, you can call me or email me we can adjust it?
- b) Thank you very much for taking time with me today. I am providing you an $80 honorarium for your time and travel expenses. Do you mind signing a receipt for the honoraria?