CHARACTERIZING PSYCHOBEHAVIORAL RISKS IN SURVIVORS OF MULTIPLE PRIMARY CANCERS

by

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Background: As the population ages and cancer survival improves, the incidence of multiple primary cancers (MPC) is increasing. Several studies have documented poorer health outcomes among adults with MPC compared to single-cancer survivors. However, there is a paucity of research focused on understanding factors linking MPC to poor health outcomes and identifying individual (e.g., personality, sociodemographic, clinical) factors that increase risk.

Purpose: The purpose of this study was to test a psychobehavioral stress-response model to identify factors associated with MPC health outcomes. We aimed to: 1) test the hypothesized model, examining linear relations among six latent variables: perceived stress, psychological response, behavioral response, financial toxicity, social health, and physical health; 2) explore associations between individual characteristics and upstream latent variables; and 3) describe self-management behaviors of MPC survivors.

Methods: This cross-sectional study included MPC survivors recruited through a regional tumor registry whose first cancers (stages I-III) were diagnosed within 1-10 years. Data were collected via 1) a battery of validated questionnaires to measure latent variables and covariates; 2) tumor registry records; and 3) medical records. Structural equation modeling was performed to fit and modify the measurement model, specify the full SEM, and identify significant covariates. Descriptive statistics were conducted to characterize self-management.

Results: 211 participants completed questionnaires. Data fit a four-factor modified measurement model linking self-management, distress, financial toxicity, and functional health. Overweight BMI, graduate education, less neuroticism, and increased social support predicted better self-management. Poorer self-management, greater neuroticism, and lower social support predicted increased distress. Greater distress predicted financial toxicity. Greater distress and financial toxicity predicted poorer functional health. Scores for positive self-management were generally high; obesity rates were above published norms.

Conclusions: MPC survivors with higher risk BMI, less education, greater neuroticism, and lower social support should be considered at risk for poorer self-management and negative health outcomes. Self-management behaviors and distress are potentially modifiable intervention targets to reduce financial toxicity and improve functional health. Future research should evaluate the model with a focus on developing the science of MPC self-management and financial toxicity and include longitudinal assessments to identify critical times of increased vulnerability during MPC survivorship.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

PREFACE

Thank you to the LAMP Study participants who gave generously of your time to make this dissertation study possible. Your experiences make you shared experts in this research.

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I have been so fortunate throughout my career to have had instructors, mentors, peers, interdisciplinary colleagues, preceptees, students, and patients who have been foundational in challenging me to strive towards excellence and develop as a leader. They have impressed upon me the great privilege it is to touch peoples' lives as a nurse. I would be remiss to not

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1.0 PROPOSAL INTRODUCTION

1.1 SPECIFIC AIMS

As the cancer survivor population ages and cancer survival improves (American Cancer Society, 2017; Bluethmann, Mariotto, & Rowland, 2016; Jemal et al., 2017), the incidence of subsequent primary cancer diagnoses in cancer survivors is increasing. Affecting approximately 3 million Americans, nearly one in five cancers diagnosed in the United States occurs in an individual with a previous cancer diagnosis (Morton, Onel, Curtis, Hungate, & Armstrong, 2014). These multiple primary cancers (MPC), ≥2 histologically distinct primary cancer diagnoses that have been ruled out as being metastatic disease (Begg, 1999), are a leading cause of morbidity and mortality among cancer survivors. Previous large sample studies have established that MPC survivors, compared to single cancer survivors and healthy (no cancer) controls, have increased risk for poor health outcomes including psychological distress, risky health behaviors, and negative physical health outcomes (Andrykowski, 2012; Burris & Andrykowski, 2011; Dowling et al., 2013; Gotay, Ransom, & Pagano, 2007; Thong et al., 2013).

Lazarus and Folkman classically defined perceived stress as the perception that one's demands exceed his or her coping resources (Lazarus & Folkman, 1984). Cancer patients face demands throughout the cancer continuum that may be perceived as exceeding their coping resources (e.g., cancer diagnosis, treatment, and/or persistent symptoms). Resulting perceived stress can produce a cascade of psychological, behavioral, and biologic responses that negatively impact health outcomes (Bode, Hahn, Devellis, & Cella, 2010). The proposed conceptual model for this study (see Figure 1) is informed by biobehavioral frameworks, which have contributed to research identifying pathways linking stress to poor outcomes (Andersen, Kiecolt-Glaser, & Glaser, 1994; Andersen et al., 2008; Bower & Lamkin, 2013; Cohen, Kessler, & Underwood Gordon, 1995; Sherwood et al., 2008). This study will be the first to apply this type of framework to MPC research, providing opportunities to 1) guide early identification of

MPC survivors most vulnerable to persistent stress and 2) identify important pathways (i.e., possible intervention points) that contribute to the cascade of negative health outcomes observed in this patient population (Grady & Gough, 2014; Grey, Knafl, & McCorkle, 2006; Grey, Schulman-Green, Knafl, & Reynolds, 2015).

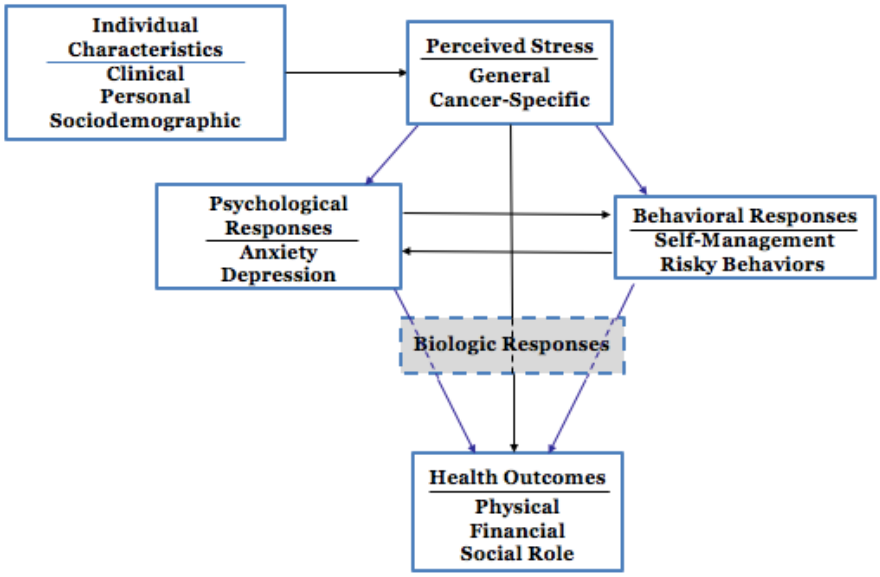

Figure 1. Conceptual model. This figure depicts the cascade of psychological, behavioral, and biologic responses to perceived stress that can negatively impact health outcomes in adults with multiple primary cancers. Biologic responses and pathways will be investigated in future study.

Our preliminary work, building on early MPC literature, has demonstrated that, compared to single cancer survivors, adults with MPC generally experience higher levels of stress (Gotay et al., 2007), report poorer psychological well-being (Andrykowski, 2012; Belcher et al., 2017; Belcher, Hausmann, Cohen, Donovan, & Schlenk, 2016; Burris & Andrykowski, 2011; Gotay et al., 2007; Thong et al., 2013), engage in more negative health behaviors (Burris & Andrykowski, 2011), and are at increased risk for poor health outcomes (Andrykowski, 2012; Belcher et al., 2015; Dowling et al., 2013; Gotay et al., 2007; Thong et al., 2013). Our work also complements previous findings that MPC survivors live with cancer as a chronic illness (Belcher et al., 2017; Gotay et al., 2007; Thong et al., 2013). Importantly, prolonged perceived stress has been shown

to increase susceptibility to negative physical health outcomes (Cohen et al., 1995; Cohen, n.d.; G. E. Miller, Cohen, & Ritchey, 2002; O'Connor et al., 2009). However, little is known about the characteristics that put individual MPC survivors at risk for prolonged perceived stress or the psychological and behavioral pathways that could serve as targets for self-management interventions to improve health outcomes in MPC survivors.

This proposed conceptual model is informed by several biobehavioral frameworks, which have contributed to research identifying pathways linking stress to poor health outcomes (Andersen et al., 1994; Andersen et al., 2008; Bower & Lamkin, 2013; Cohen et al., 1995; Sherwood et al., 2008). However, these models have not yet been applied to MPC research. Important weaknesses in MPC survivorship research to date include: 1) a lack of attention to who among the many survivors of MPC are at increased risk for poor health outcomes; 2) inattention to consistent, valid perceived stress measurement; and 3) an almost exclusive focus on negative behavioral responses without attention to positive behavioral responses (i.e., self-management). Robust self-management literature in chronic illness (Grady & Gough, 2014; Grey et al., 2015; Lorig & Holman, 2003) and general cancer (Chen et al., 2015; Hammer et al., 2015; McCorkle et al., 2011; Miller, Bowen, Croyle, & Rowland, 2009; Risendal et al., 2015) supports the premise that identification of characteristics of MPC survivors most at risk of poor health outcomes and factors that promote positive self-management behavioral responses will advance MPC science toward early risk identification and interruption of negative stress response pathways. It has been demonstrated in the literature that MPC survivors are at increased risk for poor health outcomes compared to their single cancer counterparts. This study will advance the science to begin to elucidate who among MPC survivors is at greatest risk and why.

My **long-term goal** is to develop a program of cancer survivorship research focused on the development of strategic self-management interventions to interrupt biobehavioral stress response pathways in at-risk survivors of MPC. The **overarching purpose** of this dissertation

study, and the first step in my program of research, is to test the proposed conceptual model to better understand the components that impact health outcomes in persons with a history of MPC diagnoses. This study aims to answer the following **research question**: Does the proposed conceptual model explain poor health outcomes in persons with MPC? Our **central hypothesis** is that survivors of MPC are exposed to a wide range of cancer- and treatment-related stressors that are associated with persistent perceived stress and result in a cascade of psychological (e.g., depression, anxiety), behavioral (i.e., lack of positive self-management and risky behaviors), and biologic responses that are associated with poor health outcomes (i.e., physical, financial, and social). The **rationale** underlying the proposed research is that positive self-management behaviors have the potential to interrupt these negative pathways and to reduce negative impact after an MPC diagnosis. By elucidating mechanisms and identifying characteristics of MPC survivors with high risk for poor health outcomes, findings from this study will provide the basis for future studies that will include development of targeted self-management interventions, interventions to trigger appropriate screening in high risk MPC patients, and incorporate important biological pathways known to impact health outcomes.

Specifically, in a cross-sectional sample of n=440 adults with a history of multiple (i.e., two or more) primary cancers, we will pursue the following specific aims:

Aim 1: Determine whether the proposed conceptual model fits data collected from MPC survivors.

Aim 1a: Evaluate whether the proposed overall model adequately explains variation in health outcomes among adults with MPC.

Aim 1b: Evaluate whether post-hoc model modifications based on previous cancer literature and sample data improve model fit and parsimony.

Exploratory Aim 2: Identify additional individual characteristics (i.e., clinical, personal, and sociodemographic) that contribute to improved model fit.

Exploratory Aim 3: Describe the self-management behaviors used by MPC survivors.

1.2 BACKGROUND, SIGNIFICANCE, AND INNOVATION

1.2.1 Background

The National Academy of Medicine, the American Cancer Society, cancer survivorship advocates, clinicians, and scientists have called for an increased focus on addressing the health and psychosocial needs of cancer survivors (American Cancer Society, 2016; Klein et al., 2014; Miller et al., 2016; Mullan, 1985, 2016; National Academy of Sciences, 2006), and survivors of MPC represent a growing, understudied, and at-risk group in critical need of additional research.

The current number of cancer survivors living in the United States, 15.5 million, is projected to increase to 26.1 million by 2040, and the cancer survivor population is aging (American Cancer Society, 2017; Bluethmann et al., 2016; Jemal et al., 2017). With improved survival and increased age, however, comes the risk of developing a wide range of late effects of cancer and cancer treatment including the development of second cancers. As compared to those in the general population without a cancer diagnosis, cancer survivors face a 14% higher risk of developing a new primary cancer (Fraumeni, Curtis, Edwards, & Tucker, 2006). The observed increased risk is likely attributable to complex interactions among risk factors, including factors ranging from age at, and site of, first diagnosis, carcinogenic effects of cancer treatment, and genetic susceptibility (most pronounced in childhood survivors) to cumulative environmental exposures and lifestyle factors (e.g., smoking, alcohol use) in adult survivors (American Cancer Society, 2016; Fraumeni et al., 2006; Morton et al., 2014). Cancers specifically linked to the risk of subsequent cancer diagnoses include Hodgkin's lymphoma, non-Hodgkin's lymphoma, select solid tumors (i.e., prostate, testicular, ovarian, breast, and cervical), and childhood cancers (American Cancer Society, 2012; Meadows et al, 2009). The National Cancer Institute reports that one in five cancers diagnosed in the United States will occur in someone who has a previous cancer diagnosis, and MPCs are a major cause of morbidity and mortality in cancer survivors (De Gonzalez et al., 2011; Morton et al., 2014; National Cancer Institute, n.d.-a).

Diagnoses, disease- and treatment-related effects, and care transition points (e.g., transition to survivorship, recurrence, and end of life) commonly result in varying levels of distress for cancer patients (National Comprehensive Cancer Network, 2015); 20-47% of cancer patients with new and recurrent cancer diagnoses experience significant distress (Holland et al, 2013). Literature from various countries estimates mood disorders are experienced by 30-40% of cancer patients in acute care settings experience (Mitchell, Lancet 2011), and 10.3-14.9% of individuals with cancer experience anxiety and depression, respectively (Holland et al, 2013; Jacobsen & Andrykowski, 2015). These rates are critically important, as distress has been linked to cancer therapy nonadherence, increased difficulty in treatment decision making, poorer quality of life (QOL), poorer adherence to cancer surveillance screening recommendations, and poorer health behaviors (Holland et al, 2013). However, most cancer research related to psychological distress has been conducted irrespective to number of cancer diagnoses.

There is a robust body of literature documenting associations between stress and negative health outcomes (Cohen, Tyrrell, & Smith, 1991; Kiecolt-Glaser, Marucha, Malarkey, Mercado, & Glaser, 1995; Matthews & Gump, 2002; Pace, Hu, & Miller, 2007; Pyykkönen et al., 2010; Sandberg et al., 2000). In cancer specifically, distress is known to be associated with cancer diagnosis, treatment, and persistent symptoms (Holland et al., 2013; Jacobsen & Andrykowski, 2015; Mitchell et al., 2011; National Comprehensive Cancer Network, 2015). We posit that negative psychobehavioral and biologic responses may be more severe in those with MPC, influencing the negative outcomes previously described in the literature. Importantly, findings are indicative of chronic illness in MPC survivors, and prolonged stress has been shown to decrease immune cell sensitivity to cortisol and increase pro-inflammatory cytokines and susceptibility to poor health outcomes (Cohen et al., 1995; Cohen, n.d.; Miller et al., 2002; O'Connor et al., 2009). The importance of biological response pathways is recognized and will be a source of inquiry for future research studies.

Self-management was first described as the work of living with a chronic illness (e.g., medical management, behavioral management, and emotional management) (Corbin & Strauss, 1988). MPC survivors live with cancer as a chronic illness (Belcher et al., 2017; Gotay et al., 2007; Thong et al., 2013). As cancer conceptualization has shifted from acute to chronic disease management, responsibility for day-to-day management has been gradually shifting from providers to individuals (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002; Green McDonald, O'Connell, & Lutgendorf, 2013; Klein et al., 2014; McCorkle et al., 2011). Thus, it is becoming ever more critical to determine trends in self-management, determine associations between self-management and other key variables, and eventually optimize individuals' ability to effectively manage health in the MPC survivor population.

No prior work has examined how MPC survivors self-manage their health. The proposed study directly addresses a National Institute of Nursing Research (NINR) priority to advance self-management science and dissemination of results for clinical translation (Grady & Gough, 2014). By assessing self-management behaviors, incorporating recommended common data elements for self-management research, and evaluating associations between self-management and health outcomes in MPC survivors, the proposed study will address public health and clinical priorities of self-management in chronic disease as identified by the Department of Health and Human Services, the National Academy of Medicine, the NINR, Oncology Nursing Society, and the American Cancer Society (Grady & Gough, 2014; Knobf et al., 2015; National Cancer Survivorship Resource Center, n.d.). Additionally, tailored self-management interventions have been shown to provide positive benefit in varying ethnic, geographic, and age groups, making this research promising in its applicability to diverse populations of MPC survivors (Grady & Gough, 2014).

The proposed research study, the first step in a planned program of research, is critically important to advance the state of the science in the growing population of vulnerable survivors of MPC. The proposed study will contribute to the field of cancer survivorship research by being

the first to identify associations among key pathways that lead to health outcomes and by identifying the behaviors MPC survivors use to manage their health. Findings from this study will assist clinicians and researchers in identifying MPC survivors at greatest risk for poor outcomes and will identify modifiable targets for future intervention development. Timely, targeted self-management interventions guided by the findings from this study could reduce long-term health problems experienced by this population. Future studies will also examine biological pathways to further elucidate mechanisms resulting in poor health outcomes. The long-term research goal is to create an innovative program of research focused on the development of strategic self-management interventions to interrupt stress response pathways and optimize wellness in survivors of MPC.

1.2.2 Significance

The proposed study is significant and timely because it will address gaps in MPC literature and add to the currently limited knowledge regarding risk factors for poor health outcomes in the rapidly expanding MPC survivor population. Additionally, the healthcare system is requiring increasing levels of disease self-management, making the previously undescribed self-management variable key in understanding psychobehavioral mechanisms in the MPC survivor population. Clinically, this research has the potential to guide early identification of MPC survivors most vulnerable to prolonged stress and the associated cascade of negative health outcomes, providing a potential health promotion opportunity early on in a person's illness trajectory. Identified risk and protective factors for MPC survivors can then be used by researchers to as behavioral targets to pave the way for future, targeted intervention work.

1.2.3 Innovation

We argue that both the current conceptualization of cancer survivorship and practices that traditionally do not include the potential impact of MPC (e.g., often excluding MPC survivors from clinical trials), is doing a disservice to MPC survivors and has resulted in a dearth of knowledge that impacts over one million people in the United States.

Previous MPC studies have lacked theoretical underpinnings to guide their research. This study is innovative because it will be the first study to employ a biobehavioral stress response framework and the first to begin to describe mechanisms underlying poor health outcomes in adult MPC survivors. This cross-sectional study will establish the groundwork for future longitudinal studies using this framework to investigate novel 1) biological pathways resulting in poor health outcomes and 2) temporal associations among variables. We will be the first to recruit a sample of MPC survivors to identify clinical, personal, and sociodemographic characteristics associated with perceived stress, paving the way for early identification of at-risk patients and potential targets for future interventions. Assessing self-management behaviors among MPC survivors is novel and provides information on whether interventions to promote self-management could be a potential avenue for optimizing health among MPC survivors.

1.3 PRELIMINARY STUDIES

1.3.1 State of the science (manuscript #1 in 3.1)

The first major step in establishing the state of the science for MPC survivors included a review and synthesis of the literature to determine the relationship between MPC diagnoses and psychological distress in adult cancer survivors (S.M. Belcher et al., 2016). We hypothesized that, compared to single cancer survivors, persons with MPC diagnoses would report higher psychological distress. Effect size (ES) values were calculated using Cohen's *d*. Across the five studies included in this study, we found that MPC survivors, when compared with single cancer survivors, had lower global QOL (*d* = 0.32–0.37), poorer emotional role function and stress (*d* = 0.08–0.20), greater and more frequent distress (*d* = 0.11–0.37), and greater anxiety symptoms (*d* = 0.15). Differences between MPC survivors and single cancer survivors were more variable for depressive symptoms (*d* = 0.01–0.22), and no statistically significant differences between MPC and single cancer groups were identified for sleep or suicidal ideation. Supporting our original hypothesis, effect sizes reflect small but potentially significant higher psychological distress in survivors of MPC compared with survivors of a single cancer.

1.3.2 Expansion of conceptual model

As the proposed conceptual model expanded (Figure 1), subsequent MPC literature searches included the addition of the following key model concepts: perceived stress; behavioral responses, health behaviors, self-management, risk behaviors; physical health outcomes; financial toxicity; social health/social role function. Only one additional article (Dowling et al., 2013) was identified. In this study, MPC was found to be a consistent predictor of disease burden, including physical function limitations and lost productivity.

1.3.2.1 Financial toxicity. We used WRITE Symptoms® data to conduct an exploratory analysis to compare measures of QOL, including well-being, social support, and financial vulnerability, between women with recurrent ovarian cancer with and without more than one additional cancer diagnosis (Belcher et al., 2015).

Methods. Design: A secondary analysis of data from a completed three-arm randomized controlled trial (RCT) of a Web-based symptom management study of women with recurrent ovarian cancer. Sample: Participants (N= 497) were women ≥18 years old with a diagnosis of recurrent ovarian, fallopian tube, or primary peritoneal cancer, experiencing ≥3 symptoms associated with cancer or cancer treatment. Setting: Participants were recruited from 53 GOG sites across the country. Within 28 days of signing informed consent, participants completed baseline questionnaires via the web-based WRITE Symptoms Questionnaire System. Measures: Multiple dimensions of QOL were assessed using the FACT-O (well-being), ISEL-12 (social support), and sociodemographic survey (financial vulnerability, as measured by a single item asking women to rate difficulty paying for basic needs). A single item from the Charlson Comorbidity self-report was used to identify women who had been diagnosed with a second cancer (other than ovarian) within the past 3 years. Analysis: t-tests and chi-square analyses were used to compare QOL between groups.

Results. Sixty-four women (12.9%) reported a cancer diagnosis in addition to ovarian cancer. Well-being subscales and social support did not significantly differ between the two

groups (p=.15-.85 and p=.39, respectively). However, a higher proportion of women diagnosed with a second cancer (51%) reported more difficulty paying for basic needs than did those who had not been diagnosed with a second cancer (36%), p=.02. Additionally, women with second cancers were more likely to report incomes <$60,000 per year (68% vs. 50%, p=.01).

Implications of findings to the proposed dissertation study. This preliminary, exploratory study led to further exploration of financial vulnerability and toxicity in the literature, ultimately resulting in inclusion of measures of financial toxicity in the proposed conceptual model.

1.3.3 Conceptualization of key model concepts (manuscript #2 in Appendix F)

We conducted a study to describe relationships among key model concepts (see Manuscript 1 in Appendix E), specifically evaluating whether survivorship of multiple primary cancers (MPC) is associated with psychological distress, health behaviors, and benefit finding (Belcher et al., 2016).

Methods. Design: Secondary analysis of the 2010 LIVESTRONG cross-sectional survey. Sample: 238 MPC and 3,295 single cancer survivors. Setting: Online survey. Main Research Variables: MPC versus single cancer; psychological distress, health behavior (healthy lifestyle and positive healthcare utilization), and benefit finding scores. Analyses: Chi-square tests of independence and t-tests for comparisons between persons with MPC versus single cancers. Multivariate linear and logistical regression models, adjusted for covariates, were conducted to determine associations between variables.

Results. Survivors of MPC, compared to single cancer survivors, were significantly older (p<.001), less likely to have a spouse/partner (p=.03), further out from original cancer diagnosis (p<.001), less likely to be employed full-time (p<.001), and differed by type of cancer diagnoses (p<.001) and cancer survivorship stage (p<.001). MPC was associated with significantly higher psychological distress (p=.021) and healthcare utilization (p=.003) but not healthy lifestyle (p=.914) or benefit finding (p=.263).

Conclusions. Relative to those with single cancers, MPC survivors in this sample reported higher psychological distress and were more likely to receive recommended cancer screenings. Additional research is needed to understand mechanisms of psychological distress in MPC survivors. Implications for Nursing: Targeted distress screening in MPC survivors may allow for early identification and interventions to ameliorate distress and reduce negative downstream health effects. Knowledge Translation: Nurses should assess for previous cancer histories and recognize that survivorship experiences may differ between MPC and single cancer survivors. MPC survivors have increased psychological distress risk and may have needs related to living with cancer as a chronic illness. Further study of psychological distress mechanisms in MPC survivors is warranted.

Implications of findings to the proposed dissertation study. This descriptive secondary analysis reaffirmed findings of psychological distress for MPC survivors in a large, mixed-cancer survivor population and allowed for clearer conceptualization of the MPC population and key model concepts, including MPC as a chronic illness.

1.3.4 Methodological influences

Additional collaborative analyses have been conducted to inform this study including exploration of the influence of individual characteristics on key model concepts (Belcher, Sereika, Mattos, Hagan, & Donovan, 2017), relationships between psychological responses and physical health (Sherwood et al., 2016), and decision making related to mode of survey administration (Hagan, Belcher, & Donovan, 2017).

1.3.5 MPC science

1.3.5.1 Summary of literature. Across studies, when compared to single cancer survivors, MPC survivors report poorer health outcomes including: higher levels of psychological distress (general and cancer-specific) (Andrykowski, 2012; Belcher et al., 2017; Belcher et al., 2016; Burris & Andrykowski, 2011; Gotay et al., 2007; Thong et al., 2013); more risky health behaviors including physical inactivity, smoking, and alcohol use (Burris & Andrykowski, 2011); increased symptom burden including diarrhea, fatigue, and pain (Thong et al., 2013); poorer physical function (Andrykowski, 2012; Burris & Andrykowski, 2011; Dowling et al., 2013; Gotay et al., 2007; Thong et al., 2013); more financial hardship and lost productivity (Belcher et al., 2015; Dowling et al., 2013); higher numbers of comorbidities (Andrykowski, 2012; Gotay et al., 2007; Thong et al., 2013); and interference with social activities (Thong et al., 2013).

1.3.5.2 Gaps in the science and future directions. While previous studies add to the science by including samples from various geographical regions representing a broad range of cancer diagnoses, this study will address the following critical gaps to advance MPC science:

1. *Atheoretical.* No studies to date have identified theoretical models to guide scientific inquiry in this area, leading to a lack of conceptual clarity for scientific advancement.

2. *Study design.* Previous MPC research has been devoted to comparing groups of cancer survivors based upon the number of cancer diagnoses (e.g., no cancer controls versus 1 primary cancer versus ≥2 primary cancer diagnoses). Differences among groups have now been established, and the time is right to look within MPC survivor groups to identify a) the factors that put particular MPC survivors at risk for poor health outcomes and b) potential mechanisms that link exposure to the chronic stresses of MPC with negative health outcomes.

3. *Negative behavioral responses.* While one previous study evaluated dietary intake and physical activity in this patient population (Burris & Andrykowski, 2011), no studies have formally evaluated positive behavioral responses (self-management) among survivors of MPC. Positive self-management behaviors are important to understand in this population, as they

have potential to interrupt negative pathways and restore optimal wellness in the context of chronic illness, such as occurs with MPC diagnosis.

4. *Inconsistent use of valid and reliable measures.* We will avoid measurement pitfalls and limitations of previous MPC studies by using valid and reliable instruments (Redeker et al., 2015).

5. *Reliable clinical data.* Previous overreliance on self-reported clinical data will be avoided by incorporating cancer registry disease classifications and confirming MPC diagnoses via systematic medical record review using standard definitions of MPC (Begg, 1999; Johnson et al., 2007; Koubkova, Hrstka, Dobes, Vojtesek, & Vyzula, 2014).

6. *Variable inclusion criteria*. Previous study samples differed by inclusion criteria, particularly by age at diagnosis and by cancer type. We will address this gap by removing potential developmental influences on outcomes by including only survivors of cancers diagnosed during adulthood and by excluding noninvasive skin cancer cases, which have been shown to not differ from general noncancer populations in regard to psychosocial issues (Holfeld, Hogan, Eldemire, & Lane, 1990).

7. *Diversity.* Previous studies have largely lacked racial and ethnic diversity. While recognizing the limitations of the planned recruitment frame for diversity of race and ethnicity, processes will be put in place to oversample for minority groups when possible.

1.4 RESEARCH DESIGN AND METHODS

1.4.1 Design

We will implement a cross-sectional design using a self-administered, mixed-mode survey of valid and reliable patient reported outcomes with survivors of two primary cancer diagnoses, or multiple primary cancers. A cross-sectional survey design is feasible and will allow for testing of associations/correlations among variables in the theoretical model (Fowler, 2014; Groves et al., 2009). Identified patterns of association will be tested for temporal ordering in future longitudinal study.

1.4.2 Sample

1.4.2.1 Sampling design. Stratified systematic sampling with oversampling for minorities will be used to select our study sample.

1.4.2.2 Sampling frame and elements. The UPMC Cancer Network Registry (1990 – current) will serve as our sampling frame. The sampling unit will be the registry participant ID number, and MPC survivors will be the sampling elements.

1.4.2.3 Inclusion criteria. 1) history of two or more primary cancers, as defined by Surveillance, Epidemiology, and End Results (SEER) Program coding rules (Johnson et al., 2007), both diagnosed in adulthood [≥18 years old]; 2) first diagnosis is consistent with one of the 7 most prevalent first cancers experienced by male/female MPC survivors (American Cancer Society, 2009), including: breast, prostate, colorectal, urinary bladder, uterine, melanoma, kidney/renal pelvis, lung/bronchus, oral cavity/pharynx, thyroid, and ovary (see Figure 2); 3) stage I-III cancers; 4) between 1 and 10 years following active treatment/no evidence of disease; and 5) able to read and complete questionnaires in English.

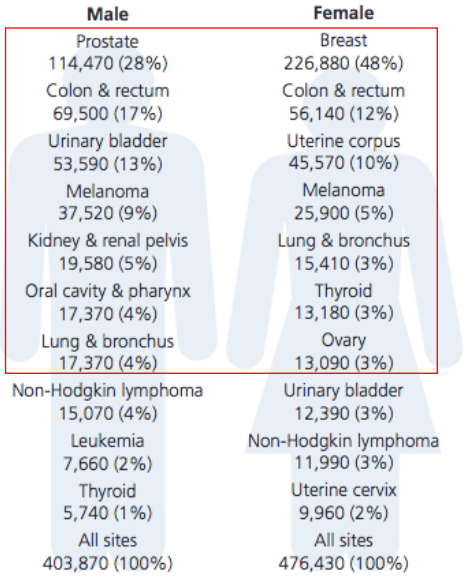

Figure 2. Cancer sites of study inclusion. Estimated survivors who have been diagnosed with more than one cancer, by site of first primary. Diagnoses in red box indicate top 7 cancers for men and women which will be included in this study. Image: (American Cancer Society, 2009).

1.4.2.4 Exclusion criteria. 1) non-melanoma skin cancers; 2) in situ cancers; 3) stage IV cancers; and 4) history of recurrence.

1.4.2.5 Sampling plan. Gotay and colleagues have been the only research team to our knowledge to specifically recruit a sample of adults with MPC from a state tumor registry (Gotay et al., 2007). They reported the following recruitment results: 1) 27.7% were unable to be contacted due to out of date contact information or being deceased, 2) physicians requested that 1.2% of potential participants not be contacted, and 3) 56% of those

contacted via mail returned completed surveys. Balancing cost, feasibility, and analytic power, we plan to send initial invitations to 1,440 MPC survivors (see detailed sampling plan below). Based on conservative estimates from the Gotay study, we expect that we will be able to reach approximately 60% of potential MPC participants, leaving approximately 864 potential responders. Targeting rates of participation similar to those in the Gotay study (approximately 50%), we would have an estimated 432 respondents in this proposed study (rounded up to 440 to allow for equal recruitment attempts among groups of cancer diagnosis sites).

1.4.3 Recruitment and data collection procedures

Cancer Registry personnel will assist in identifying potential study participants from the Cancer or Cancer-like Blood Disorder Registry (UPCI protocol #03-038). Personnel from the UMPC Network Cancer Registry will first match registry participants meeting the study's criteria to the UPCI protocol 03-038 patients. For living patients in common between these data sets, our research team will be provided with the names and mailing addresses for the matching patients in order to conduct the recruitment mailings ourselves. All MPC survivors in the registry meeting inclusion criteria will be considered in the sampling frame. Based on July 2016 Registry data, we expect that all non-white and Hispanic MPC survivors (n=323) will be invited to participate. The remaining 1,117 potential white participants will be randomly sampled from the larger sampling frame. UPMC physician champions who are content experts in the cancers being targeted are being enlisted to introduce the study to prospective participants via a standardized invitation letter facilitated by the study team in collaboration with the Cancer Registry. In response to the invitation, individuals can select their mode of survey delivery (pencil/paper or online) by returning an enclosed postage-paid card, calling the study line, or emailing the PI. Participant follow-up contacts will occur up to four times over a 6-week period based on Dillman’s Tailored Design Method (see study flow chart in Figure 3). Additional participant contact details are provided in the Research Participant Risk and Protection human subjects section of this document.

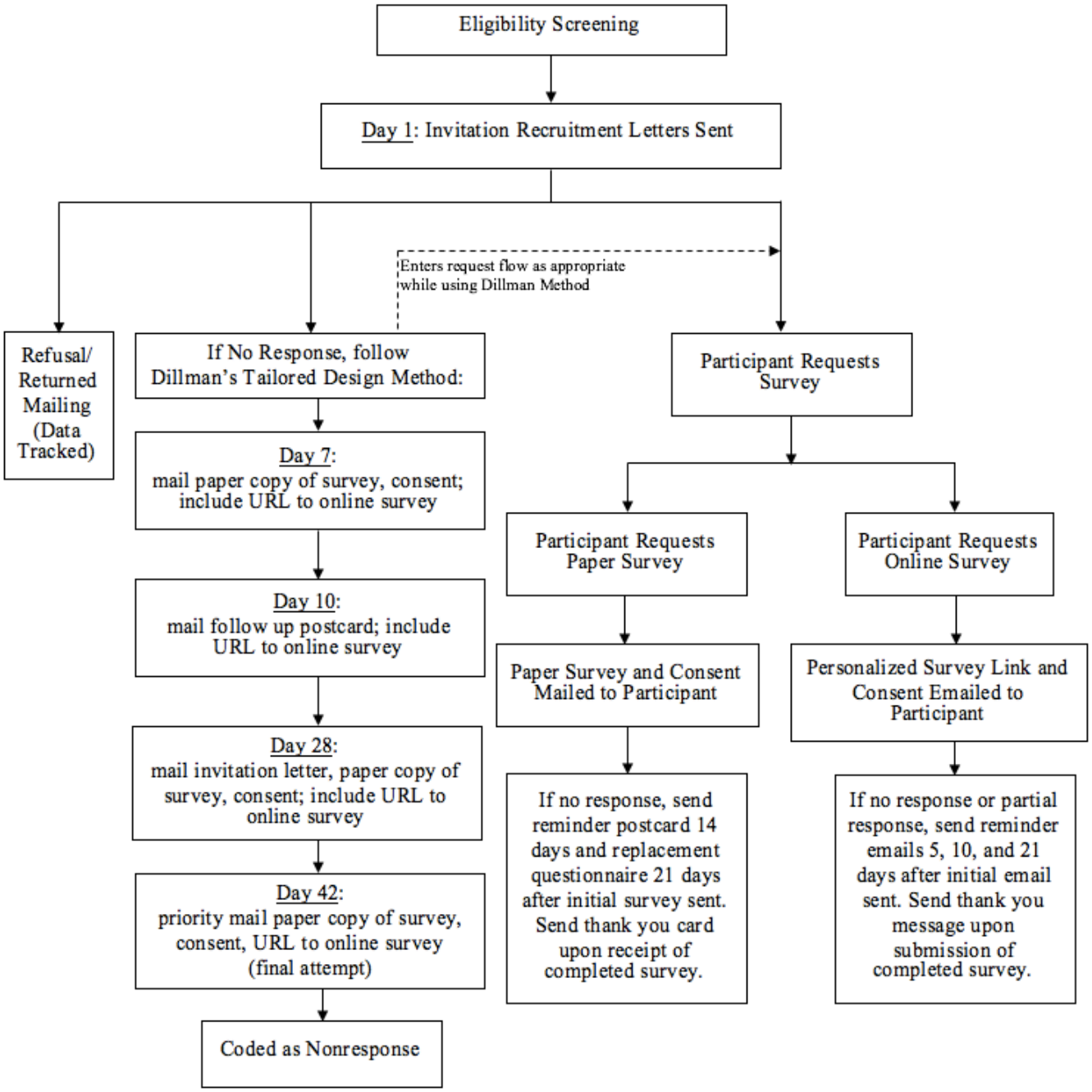

Figure 3. Study flow chart. This figure illustrates the planned study flow. Study protocol allows for +/- 3 days adjustment to timeline to conduct study procedures.

1.4.3.1 Dillman's Tailored Design Method. Dillman's Tailored Design Method (Dillman, Smyth, & Christian, 2014) will be followed to maximize recruitment and response. This method, based on social exchange theory, embeds processes and procedures to increase survey requests and

motivation to complete the survey. This is achieved by establishing trust, increasing perceived benefits of survey completion, and decreasing expected cost of participation. We will establish trust in the following ways: 1) UPMC disease-based specialists will introduce and provide written endorsement of the study; 2) stressing the importance of the knowledge to be gained about MPC survivors in this study; and 3) ensuring participants' privacy. By providing study background in the survey, demonstrating respect for individuals, compensating participants with a $5 gift card in recognition of participants' time and expertise as survivors, and providing social validation of the persistent cancer-related influences experienced by MPC survivors, we will increase participants' perceived benefit of survey completion. Decreasing expected costs to participants will be achieved in the following ways: allowing convenient participation, only including necessary measures and using sort forms when possible, minimizing the amount of private information requested, and avoiding authoritative language.

1.4.3.2 Data collection. Mixed-mode data collection was chosen for the proposed study in order to maximize response rates and data quality (de Leeuw & Berzelak, 2016; Dillman & Edwards, 2016). Surveys will be administered both via Computer Assisted Self-Interviewing via Qualtrics (University of Pittsburgh Computing Services and Systems Development, n.d.) and pencil/paper, based on respondent preference. Participants will complete a one-time battery of patient reported outcomes that will include valid measures of key model concepts (see Table 1). To ensure accuracy (Abraham et al., 2009; Bergmann et al., 1998; Bergmann, Byers, Freedman, & Mokdad, 1998; Inoue et al., 2011; Yoshinaga, Sasaki, & Tsugane, 2001) and to decrease participant burden, clinical data will be extracted from the medical record using a standardized data extraction form. All data collected via pencil/paper mode and medical record extraction will be entered into a separate Qualtrics-based electronic database by the study PI and undergraduate student research assistant personnel via direct data entry, allowing for simple data merging into the final comprehensive dataset. Quality assurance for direct data entry variables (Agency for Healthcare Research and Quality, 2014) will be ensured by using

built in Qualtrics validation features (e.g., limiting characters and ranges allowed for entered variables, such as only allowing 5 characters for zip code variables) and conducting accuracy audits of every 10th paper survey entered into the database; if errors are uncovered, audit frequency will be increased. Additionally, the PI is currently exploring options for collecting and banking biological samples for future analyses.

1.4.4 Measures

A paper copy of the survey battery administered to study participants is included in Appendix A. The online version of the survey was designed to closely mirror the paper copy format. Variables, levels of measurement, measures, and psychometric properties are presented in Table 1.

Table 1.

Dissertation Study Concepts, Measures, Levels of Measurement, and Psychometric Properties

Concept	Level	Self-Report Measures, Description, and Psychometric Properties
		Perceived Stress
Perceived Stress, Global	Highly Ordinal*	The **Perceived Stress Scale** (PSS) is a 10-item measure of globally perceived stress that uses 5-point Likert scale items. Higher scores (0-40) indicate more stress. Extensive reliability and validity (concurrent and predictive) (Cohen, Kamarck, & Mermelstein, 1983) has been demonstrated and confirmed in various populations. Cronbach's α ranges from .86 to .92 in women following breast cancer surgery and demonstrated a two-factor solution of positive versus stress items with stability over 12-month intervals (Golden-Kreutz, Browne, Frierson, & Andersen, 2004).
Perceived Stress, Cancer-Specific	Highly Ordinal*	The **Impact of Event Scale-Revised** (IES-R)(Weiss, 2007; Weiss & Marmar, 1997) is 22-item Likert-scale measure of event-specific post-traumatic stress adapted from Hurowitz and colleagues' earlier Impact of Event Scale. (Weiss & Marmar, 1997) The IES-R includes subscales for intrusion, avoidance, and hyperarousal (verified by factor analyses; correlated with HADS subscales). It has been used specifically to assess how distressed patients have felt in the past 7 days about a range of cancer-related difficulties and demonstrated extensive reliability and validity in various cancer patient populations, including post-treatment survivors (Cronbach's α = .77 - .96; 3-day test-retest reliability *r* = .97) (Salsman, Schalet, Andrykowski, & Cella, 2015; Vodermaier, Linden, & Siu, 2009).
Perceived Stress, Cancer-Worry	Highly Ordinal*	The **Assessment of Survivor Concerns** (ASC) (Gotay & Pagano, 2007; Hershman et al., 2013; Thewes et al., 2012) is a 5-item Likert-scale instrument to measure fears about cancer recurrence and health in mixed population cancer survivors. The item responses range from 1 (not at all) to 4 (very much), with higher scores indicating higher worry. The instrument was developed based on work with previous cancer survivors and has undergone extensive validation work with mixed cancer survivor populations. The 3-item **cancer-specific worry** subscale to be used in this study has demonstrated high internal consistency (Cronbach's α = .93); it measures worry about cancer recurrence, new cancer diagnoses, and future diagnostic testing.
		Psychological Responses
Depressive Symptomatol-ogy	Highly Ordinal*	The **Personal Health Questionnaire Depression Scale** (PHQ-8), (Kroenke, Spitzer, & Williams, 2001; Kroenke et al., 2009; Ory et al., 2013) an adaptation of the valid and reliable PHQ-9 depression scale with omission of the suicidal ideation item, is an 8-item clinically validated measure of depressive symptoms. The PHQ-8 is preferred over PHQ-9 when measures are self-administered. Participants are asked how often over the last 2 weeks they have been bothered by different problems. Higher scores (0-24) indicate more severe depression. Cronbach's α ranges from .80 to .86 in mixed cancer populations and individuals with chronic disorders. To decrease participant burden, individuals who score 0 on the first two items of this measure will be instructed to skip the remaining items in the measures, as the PHQ-2, which taps into depressed mood and anhedonia, has been shown to be an effective screen for depression in validity and sensitivity studies (American Psychlogical Association, 2017; Kurt Kroenke, Spitzer, & Williams, 2003).
Anxiety	Highly Ordinal*	The **Generalized Anxiety Disorder 7-item** scale (GAD-7) (Kroenke, Spitzer, Williams, Monahan, & Lowe, 2007; Löwe et al., 2008; Spitzer, Kroenke, Williams, & Lo, 2006) is a clinically validated measure of generalized anxiety. Participants are asked how often over the last 2 weeks they have been bothered by a list of problems. A cut point of 10 was established to optimize sensitivity and specificity (89% and 82%, respectively), with higher scores indicative of greater anxiety. Confirmatory factor analyses confirmed a 1-factor structure and equitability for gender and age for use in the general population to detect various types of anxiety (Cronbach's α = .89 - .92; intra-class correlation [ICC] = .83 for test-retest reliability). Criterion validity was also established. To decrease participant burden, individuals who score 0 on the first two items of this measure will be instructed to skip the remaining items in the measure, as the GAD-2 is recommended as an "ultra short" diagnostic instrument for generalized anxiety disorder. A positive GAD-2 result is a score ≥3, while a positive GAD-7 result is a score ≥8.

Table 1 (continued).

	Behavioral Responses	
Positive Self-Management	Highly Ordinal*	The **Health Education Impact Questionnaire** (hei-Q) (Deakin University, 2016; Elsworth, Nolte, & Osborne, 2015; Osborne, Batterham, & Livingston, 2011; Osborne, Elsworth, & Whitfield, 2007) is a 40-item scale used internationally to assess 8 domains (factor structure validated) of self-management in chronic illness, including cancer: health directed activities (Cronbach's α = .80); positive and active engagement in life (Cronbach's α = .86); emotional distress (Cronbach's α = .89); self-monitoring and insight (Cronbach's α = .70); constructive attitudes and approaches (Cronbach's α = .81); skill and technique acquisition (Cronbach's α = .81); social integration and support (Cronbach's α = .86); and health service navigation (Cronbach's α = .82). Internal consistency (≥.8) and discriminant validity have been established across sex, age, education, and ethnic background groups.
Risky Behaviors: Alcohol Use	Highly Ordinal*	†The **PROMIS Alcohol Use Short Form 7a** (Gibbons et al., 2016; Patient-Reported Outcomes Measurement Information System, 2014; Pilkonis et al., 2016) assesses drinking patterns, cue-based drinking, cravings to drink, and efforts to control drinking indicative of problematic drinking at the moderate and low severity levels for adults with chronic illness. Participants are first asked if they have consumed any alcohol in the previous 30 days and, if yes, respond to 7 items scored on a 5-point Likert scale, with higher scores indicating more risky alcohol use behavior.
Risky Behaviors: Tobacco Use by Cancer Patients	Highly Ordinal*	The **Cancer Patient Tobacco Use Questionnaire** (C-TUQ),(Land et al., 2016; Land et al., 2016; National Cancer Institute, 2016) developed by joint National Cancer Institute and the American Association for Cancer Research task force, was created to assess tobacco use in cancer patients and survivors. The instrument includes both 4 core constructions and extension items to assess domains of smoking history and current use, use relative to cancer diagnosis and treatment, other tobacco product use, cessation, and second-hand exposure. Expert review panels and iterative cognitive interviews were conducted during instrument development.
Health Outcomes: Global Health, Physical Health, Financial Toxicities, Social Role Function		
	Global Health	
Global Health	Highly Ordinal*	† The **PROMIS SF v1.1 – Global Health**, is a 10-item measure intended to measure general, self-reported health. It includes 10 global health items from the 5 core PROMIS domains and has been tested in broad clinical samples, including adults with cancer. Previous research (Hays et al., 2009) has demonstrated construct validity of items, and found two underlying domains reflected during factor analysis: mental and physical health (Cronbach's α = .81 and .86, respectively). Items are scored on a 5-point Likert scale with higher scores indicating better global health. *This instrument is recommended by NINR as a common data element for self-management research* (Moore et al., 2016) *and will be analyzed for descriptive purposes, not as part of measurement model.*
	Physical Health	
Physical Function	Highly Ordinal*	† The **PROMIS Physical Function Short Form 20a** (Patient-Reported Outcomes Measurement Information System, 2015; Rose et al., 2014; Schalet et al., 2016) measures capability rather than actual performance of physical activities, including dexterity, walking or mobility, neck/back, and instrumental activities of daily living. PROMIS recommends using the 20a short form if variability is expected and various subdomain information is desired, thus the 20a was selected for this study. Higher scores indicate better physical function. Validity over time was established in adults with chronic illness, including cancer. Field testing and criterion testing was consistent, irrespective of health, age, and disease group/number of chronic conditions.
Treatment-Related Symptoms and Interference	Highly Ordinal*	The **MD Anderson Symptom Inventory** (MDASI) (Aktas, Walsh, & Kirkova, 2015; Cleeland et al., 2000; Cleeland, 2016) is a multi-symptom patient-reported outcome measure for clinical and research use. It is used to both assess symptom severity and interference with daily living. The 21-item core bank of symptoms consists of those symptoms that are most frequent and/or severe in cancer patients and yielded 2 symptom factors and interference scales (Cronbach's α = .85 - .87; .82 - .87; and .91 - .94, respectively). The core accounted for 64% of symptom distress variance in principal factor analysis. Sensitivity to disease severity performance status (ECOG) and treatment status was confirmed.

Table 1 (continued).

Comorbidity	Ratio	The **Charlson Comorbidity Index** (CCI) was originally developed in 1987 (Charlson, Pompei, Ales, & MacKenzie, 1987) as a weighted sum measure of chronic disease burden used to predict long term prognosis and outcomes and remains a population instrument for comorbidity risk adjustment. The brief 10-item self-report form selected for this study (short form) has been demonstrated to predict 1-year mortality in racially diverse populations and performed well compared to ICD-9 generated CCI scores (Chaudhry, Jin, & Meltzer, 2005).
		Financial Toxicity
Financial Toxicity	Highly Ordinal*	The 11-item **COmprehensive Score for financial Toxicity** (COST-FACIT, version 1) tool (De Souza et al., 2016; De Souza et al., 2014) was developed using a step-wise approach to provide a patient reported outcome measure of financial toxicity (1-factor latent variable) in patients with cancer. Item responses are scored on a Likert scale of not at all to very much (0-4), with lower scores indicating worse financial toxicity. Internal consistency (Cronbach's α = .92), test-retest reliability (ICC = .80, 95% CI = .57 - .92), convergent validity (POMS Pearson correlation = .26, p<.001; household income Pearson correlation = .28, P<.001), divergent validity (Marlowe-Crowne Social Desirability Scale Pearson correlation = .11, p=.11), and correlation with health-related quality of life (FACT-G Pearson correlation = .42, p<.001; EORTC-QOL Pearson correlation = .33, P<.001) have been validated in samples of adults with advanced cancer.
Economic Hardship	Highly Ordinal*	The **Economic Hardship questionnaire** (Barrera, Caples, & Tein, 2001), a 17-item measure of perceived economic hardship, is based off of four measures of subjective hardship: financial strain (Vinokur, Price, & Caplan, 1996); inability to make ends meet (Conger & Elder Jr., 1994; Pearlin, Menaghan, Lieberman, & Mullan, 1981); not enough money for necessities (Conger & Elder Jr., 1994; Pearlin et al., 1981); and economic adjustments/cutbacks (Conger & Elder Jr., 1994). This scale has demonstrated factor structure, internal structure congruence, and validity in urban families across gender, language (English and Spanish), and ethnicities (African American, European American, and Mexican American), in 4 different domains: financial strain; inability to make ends meet; not enough money for necessities; and economic cutbacks and adjustments (Cronbach's α = .70 - .85). The first 3 domain items are rated on a 5-point Likert-type scale and mean subscale scores are created. Economic Adjustments and Cutbacks are assessed with 9 items, such as added another job, received government assistance, and sold possessions because money was needed. Participants indicate whether these events have occurred in the past month. This subscale score is the total number of events that occurred (0– 9).
		Social Role Function
		Social function, a part of social health with implications for impact on physical health, is broken down into *ability* to and *satisfaction* with participation.(Bode et al., 2010) Both instruments are scored on a never (5) to always (1) Likert scale.
Social Role Function, Ability	Highly Ordinal*	† The **PROMIS - Ability to Participate in Social Roles and Activities Short Form 8a** (Bode et al., 2010; Hahn et al., 2014) is a short form intended to assess perceived *ability* to participate in usual social roles and activities. Higher scores represent better abilities.
Social Role Participation, Satisfaction	Highly Ordinal*	† The **PROMIS – Satisfaction with Participation in Social Roles Short Form 8a** (Bode et al., 2010; Hahn et al., 2014, 2016) is a short form intended to assess perceived *satisfaction with* participation in usual social roles and activities. Responsiveness to change was demonstrated in a sample of adults with chronic illness.
		Personal, Demographic, and Clinical Characteristics
		Personal
Personality: Neuroticism and Conscientious-ness	Highly Ordinal*	The 50-item **International Personality Item Pool** (IPIP)(Goldberg, 1999; Goldberg et al., 2006; Socha, Cooper, & McCord, 2010) includes 10 items each for five personality factors, including extroversion/introversion, agreeableness, conscientiousness, emotional stability-neuroticism, and intellect. The present study is measuring only subscales for Neuroticism (Cronbach's α = .86) and Conscientiousness (Cronbach's α = .85), as they have previously been linked to self-management. Respondents are asked to rate present behaviors on a 1 (very inaccurate) to 5 (very accurate) scale.

Table 1 (continued).

Self-Regulation	Highly Ordinal*	The 9-item **Index of Self-Regulation** (Fleury, 1998; Yeom, Choi, Belyea, & Fleury, 2011) is intended to measure someone's level of self-regulation for physical activity. Psychometric testing has demonstrated Cronbach's α of .81-.96, adequate test-retest reliability (coefficient = .73), and concurrent validity with relevant concepts. *This instrument is recommended by NINR as a common data element for self-management research* (Moore et al., 2016).
Self-Efficacy	Highly Ordinal*	The 6-item **Self-Efficacy for Managing Chronic Disease** instrument asks participants to rate how confident they are in various activities (0-10), with higher scores indicating more confidence. The instrument has demonstrated internal consistency (Cronbach's α = .91) in subjects with chronic disease (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001). *This instrument is recommended by NINR as a common data element for self-management research* (Moore et al., 2016).
		Sociodemographic
Social Support	Highly Ordinal*	The **Interpersonal Support Evaluation List** Short Version (ISEL-12) (Brookings & Bolton, 1988; Cohen, Mermelstein, Karmark, & Hoberman, 1985) is a 12-item questionnaire designed to assesses perceived social support. Respondents are asked to respond to a list of statements on a 1 (definitely false) to 4 (definitely true) Likert scale. Scores are summed. Cronbach's α of .90 has been found in women with breast cancer (Cohen, 2008).
Education, Age, Gender, Marital Status, Income	Ordinal, Ratio, Nominal, Nominal, Ordinal	An adapted, face-valid standardized socio-demographic questionnaire developed in the University of Pittsburgh School of Nursing will be administered to capture demographic characteristics.
		Clinical
Clinical Characteristics	Nominal, Interval, Ordinal	A face-valid standardized medical record review form will be used to extract and record important clinical characteristics such as cancer diagnoses, stages at diagnoses, age at initial and subsequent diagnoses, time since diagnoses and treatments, cancer treatment history, and BMI.
		Exploratory
MPC Experience	Nominal Ordinal Descriptive	The items in this section were generated by the PI, based on the literature, to explore the experience of having multiple primary cancers. Items asks patients to identify their current stage of survivorship (item adapted from the 2010 LIVESTRONG survey), compare challenges/stressors between 1st and 2nd cancer experiences, and enter what they think providers should know about what it's like to have more than on cancer.
Health Care Utilization	Ratio	The Stanford Patient Education Center measure, **Health Care Utilization**, (Lorig et al., 1996; Ritter et al., 2001) is a 4-item questionnaire that asks respondents about their health care utilization in the previous 6 months. Utilization includes physician and emergency department visits and times and nights hospitalized. Test-retest reliability for each item ranged from .76 to .97. in subjects with chronic disease.

Notes. Pretesting pilot work determined that the total survey completion time estimate = 30-45 minutes. Prior team research (Hagan et al., 2017) has demonstrated that participants find the estimated time of survey completion to be acceptable.

*Likert-scaled items from a multi-item scale are ordinal. The mean or sum score of these items will be highly ordinal but approximate an interval scaled variable.

†Patient-Reported Outcomes Measurement Information System (PROMIS) measures were developed as an NIH Roadmap project to provide clinicians and researchers access to efficient, precise, valid, responsive measures of health status. They have undergone rigorous psychometric testing, were designed for universal relevancy, and may be used in the general population and for those who have chronic conditions. Population-based reference values have been estimated for use in cancer by respondent age and disease stage (Cella et al., 2010; Cook et al., 2016; DeWalt, Rothrock, Yount, & Stone, 2007; Jensen et al., 2017; Northwestern University, 2016).

1.4.5 Data analysis plan

As described in Table 1, individual constructs have been theoretically defined and operationalized. The proposed conceptual model (Figure 1) will guide data analyses. Collected data will be exported to a database for analyses.

1.4.5.1 Descriptive statistics. Descriptive and exploratory analyses will first be performed using IBM® SPSS® software, version 25 (IBM Corp., Armonk, NY) to identify any data anomalies (e.g., missing data or outliers that may be a result of data entry error or invalid participant responses) that might invalidate findings of the primary aim analyses to be conducted. To confirm external validity, sample characteristics will be compared to what is currently known in existing MPC literature. For continuous variables, appropriate descriptive statistics including graphical representation will be computed to describe sample characteristics and determine observed variable distributions. For categorical variables, we will examine frequency distributions to ensure adequate category size; categories will be meaningfully collapsed as possible if inadequate category sizes are observed. Pairwise correlations will be calculated to summarize bivariate associations between variables.

For the variables previously described in Table 1, we will report frequency counts and percentages for categorical variables. For the central tendency and dispersion for categorical variables, mode and range will be reported for nominal variables, and median and interquartile range (IQR) will be reported for ordinal variables. For continuous variables, we will describe central tendency as means and dispersion as standard deviations for normally distributed data and medians and IQRs or semi-quartile ranges (SQR) for non-normal data distributions.

1.4.5.2 Data screening procedures. Statistical assumptions for planned analyses will be checked for violations (e.g., independence, normality, homoscedasticity, multivariate normality, and linearity) prior to performing any primary aim analyses. Measured variables will be screened for univariate outliers by z-scores for continuous type variables with absolute values >3.29 and lopsided distributions (i.e., small categories <10%) for categorical variables suggesting

univariate outliers. Univariate and bivariate data exploration with graphical plots will be conducted to determine outliers, potentially influential cases, and linearity of relationships among variables. Mahalanobis distance will be used to assess for multivariate outliers. Correlations (i.e., determinant of the covariance matrix); variance inflation factors (VIF); tolerance; and Belsley, Kuh, and Welch (BKW) diagnostics (Mason, 1987) will be used to assess for multicollinearity.

Data transformations or more statistically robust measures will be used in such instances of assumption violations. Robust maximum likelihood estimation methods are available and will be employed to fit all models if multivariate normality assumptions are questionable. We will also examine correlations between potential covariates/confounders and outcome variables and psychometric properties of multi-item scales. Cronbach's coefficient alpha will be used to estimate internal consistency of multi-item scales. All tests will be two-tailed, with statistical significance criterion set at $p<.05$.

Because our primary multivariate analytic technique, SEM, is based on covariances, parameter estimates and χ^2 tests of fit are sensitive to sample size and require larger samples (Tabachnick & Fidell, 2013). We will assess for representativeness of population due to dropouts/exclusions and amount and patterns of missing data. SEM allows for data missing completely at random (MCAR) and missing at random (MAR) through full information maximum likelihood (FIML) methods (Enders & Bandalos, 2001).

1.4.5.3 Data analysis procedures. SEM, using M*plus*, version 8 (Muthén & Muthén, 2017) will be conducted to analyze structural linear relations between latent constructs and considering the loadings of measured variables and their reliabilities in the proposed multivariate model using results from the primary data collection. The following SEM testing plan is based on standard procedures (Tabachnick & Fidell, 2013).

Aim 1a. The first step will be to fit the full measurement model to identify any issues with measurement. The hypothesized full structural equation model is presented in Figure 4. The

independence model will be conducted first to test whether all variables are uncorrelated (this is anticipated to be easily rejected, allowing us support to move on to the next phase). Next, we will test the hypothesized model using appropriate test statistics and fit indices. Evaluation of model fit has been described as a "gestalt process" (Little, 2013); model fit (Little, 2013) will be evaluated based on theory and 1) statistical rationale using exact, or statistical, fit [χ^2 statistic] and 2) modeling rationale, which incorporate a) absolute fit, or the measured distance between the *hypothesized* model and the perfect fitting model [root mean square error of approximation (RMSEA)] and b) relative fit, or index of the percent improvement from the *null* to the saturated or perfect model (comparative fit indices [CFI] and Tucker Lewis Index [TLI]). Taking statistical rationale into consideration, which are influenced by sample size, the following modeling rationale cutoffs will be considered and interpreted as acceptable when evaluating model fit in this study: 1) RMSEA and associated 90% confidence intervals are ≤.05 and 2) CFI ≥.90 (Little, 2013).

Aim 1b. Post-hoc model modifications will be conducted to attempt to improve model fit and parsimony. Model paths may be added or removed based on χ^2 difference tests and path coefficient significance testing results. The Wald test will be used to determine if there are any parameters that could be deleted from the model without impacting model fit. In a model that fits the data well, we would anticipate that the paths should all be significant and model modification indices should be small. The final model will be presented with significant coefficients in standardized form.

Aim 2. Pending determination of model adequacy, specific aspects of the model will be tested for secondary aims. Paths will be added to explore the relationships among the clinical, personal, and sociodemographic characteristics and the latent variable of perceived stress. Models will be compared using χ^2 difference testing (Tabachnick & Fidell, 2013).

Exploratory Aim 3. Descriptive and exploratory analyses will be conducted to characterize self-management behaviors, as measured by the hei-Q.

1.4.5.4 Sample size justification. Based on cost and feasibility of this dissertation study, we have budgeted for a target sample of 440 MPC survivors returning completed surveys. To fit the full structural equation model, as displayed in Figure 4, will use data from 21 measured variables yielding 21 variances and 210 covariances to estimate and test 57 parameters. As specified, with 172 degrees of freedom and a sample size of 440, we will have > .99 power to fit and test for a close fit based on RMSEA at a significance level of .05.

1.4 STUDY TIMELINE

Table 2

Study timeline

Study activities	7/17	8/17-12/17	1/18-2/18	3/18-4/18	5/18-6/18
IRB submission and approval	X				
Solidify procedures with Research Registry and Physician Champions	X				
Data collection		X			
Data cleaning		X			
Data analysis			X	X	X
Abstract and manuscript dissemination			X	X	X
Dissertation Defense					X

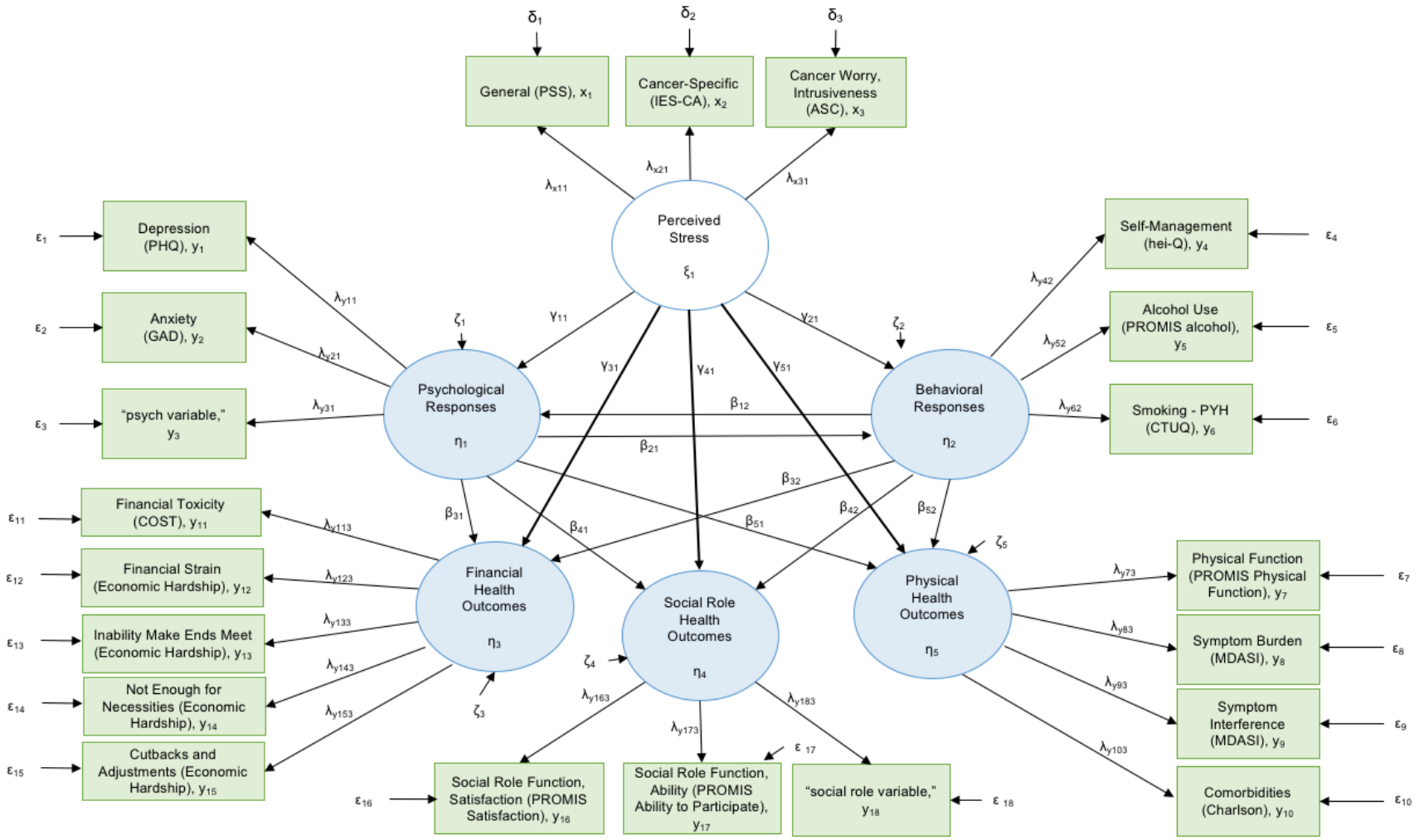

Figure 4. Full hypothesized structural equation modeling model. Blue circles = latent variables; green rectangles = measured variables. Greek letter key: ξ (ksi) = exogenous construct; η (eta) = endogenous construct; β (beta) = estimated regression of one endogenous construct on another endogenous construct; γ (gamma) = estimated regression of one exogenous construct onto an endogenous construct; λ (lambda) = estimated loading of an indicator on a construct; δ (delta) = residual variance of an indicator for an exogenous construct; and ε (epsilon) = residual variance of an indicator for an endogenous construct.

1.6 POTENTIAL LIMITATIONS AND ALTERNATIVE APPROACHES

Limitations and pitfalls are anticipated to be encountered during the course of this research. It is possible that use of the voluntary research registry through the UPMC Network Tumor Registry will not allow us to achieve our sampling goals. If necessary to achieve recruitment goals, our next step would be to utilize the honest broker system within the larger UPMC Network Cancer Registry, facilitating mailings from physician champions under the supervision of the study principal investigator (PI) to introduce the study to prospective participants who fall within our inclusion criteria. Methodologically, it is possible that the data will not lend itself well to SEM analyses. If models will not hold using full SEM, our alternative approach will be to conduct a path analysis or a series of regression models to determine associations among variables in the model. Additionally, it is possible that the sample of MPC survivors in the UPMC registry will not generalize well to the larger MPC population. Previous MPC literature has been largely conducted with non-minority participants with higher socioeconomic statuses. To protect against sampling bias, 1) we are offering participants two modes of survey completion, allowing for people with limited online access to still participate in this research, and 2) we will be oversampling for minority participants. Findings will be compared to existing MPC literature and will be discussed in publications.

1.7 PUBLICATIONS RELEVANT TO THE PROPOSED RESEARCH

Refereed Articles * = Data Based

1. * **Belcher, S. M.**, Low, C. A., Posluszny, D. M., Schear, R., Kramer, R. E., & Donovan, H. S. (2017). Correlates of psychological distress, health behaviors, and benefit finding in survivors of multiple primary cancers: Results from the 2010 Livestrong survey. *Oncology Nursing Forum, 44* (6), 703-711. doi: 10.1188/17.ONF.703-711

2. * Hagan, T. L., **Belcher, S. M.,** & Donovan, H. S. (2017). Mind the mode: Differences in paper vs. web-based survey modes among women with cancer. *Journal of Pain and Symptom Management, 54 (3), 368-375.* doi:10.1016/j.jpainsymman.2017.07.005

3. * **Belcher, S. M.**, Hausmann, E. A., Cohen, S. M., Donovan, H. S., & Schlenk, E. A. (2016). Examining the relationship between multiple primary cancers and psychological distress: A review of current literature. *Psycho-Oncology, 26 (7), 2030-2039*. doi:10.1002/pon.4299

Published Abstracts

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1.8 PROTECTION OF HUMAN SUBJECTS

1.8.1 Human subjects involvement and characteristics

We anticipate that approximately 440 MPC survivors will participate in this research. *Inclusion criteria:* cancers diagnoses in adulthood (≥18 years old); history of two or more primary cancers; first diagnosis consistent with one of the seven most prevalent first cancers experienced by

male/female MPC survivors: female breast, prostate, colorectal, urinary bladder, uterine, melanoma, kidney and renal pelvis, lung/bronchus, oral cavity and pharynx, thyroid, or ovary; stage I-III cancers (both first and second primary cancers); between 1-10 years following active treatment/no evidence of disease; and able to read and complete questionnaires in English. *Exclusion criteria*: non-melanoma skin cancer; in situ cancers; stage IV cancers; and history of recurrence.

Vulnerable participants (i.e., fetuses, pregnant women, children, or institutionalized individualized) are not included in this study. Of note, issues relevant to pediatric survivors of multiple primary cancers are likely to be fundamentally different from adult survivors. MPC survivors who experienced cancer as children warrant additional future study.

1.8.2 Sources of materials

Data will be collected in the form of self-reported questionnaires, either via pencil and paper or online via Qualtrics, based on individual preference. In addition, disease and treatment data will be extracted from participants' medical records. All data will be identified only by code numbers (participant IDs) and will be stored in secure locations, including locked file cabinets and password-protected computers and databases. Participant IDs will be linked to participants' names in a password-protected file that is accessible only to the PI and research team.

1.8.3 Recruitment

We will utilize the Cancer or Cancer-like Blood Disorder Registry (UPCI protocol #03-038) in order to contact individuals with information about the study. Personnel from the UMPC Network Cancer Registry (see Appendix C for letter of support) will first match registry participants meeting the study's criteria to the UPCI protocol 03-038 patients. For living patients in common between these data sets, our research team will be provided with the names and mailing addresses for the matching patients in order to conduct the recruitment mailings ourselves. If necessary to achieve recruitment goals, our next step would be to utilize the honest broker system within the larger UPMC Network Cancer Registry, facilitating mailings from physician

champions under the supervision of the study PI to introduce the study to prospective participants who fall within our inclusion criteria.

Based on Dillman's well established and validated approach, MPC survivors meeting the eligibility criteria according to the UPMC Cancer Registry will receive a series of follow-up contacts (see study flow chart in Figure 3). On Day 1, letters will be sent from physician champions on behalf of the study team to introduce prospective participants to the study and invite participation (see sample letter in Appendix B). Each contact will provide potential participants with an easy email or phone opt-out option, if they wish to be removed from the contact list, and any participant who returns questionnaires will not receive further reminders.

For individuals who choose not to participate in the study, we request that they complete a refusal form, that will include 5 general questions to help us compare our study sample to those who declined participation, helping us understand possible sample bias.

If individuals do want to participate in the study, they can respond accordingly by either returning an enclosed postage-paid card, calling the study line, or emailing the PI. They can choose to complete the survey in one to two ways: 1) paper/pencil or 2) web-based via Qualtrics. Ongoing communication will occur via the mode of participation initiated by and contact information provided by the participant.

For paper/pencil selection, participants will be sent a paper copy of the consent (see Appendix B) and survey (see Appendix A). The consent will state that by completing and returning the completed questionnaire, individuals have agreed to participate in the study, and PI contact information will be provided for questions at any time. If a completed survey is not received back, a reminder postcard will be sent followed by replacement questionnaires. A thank you card and the $5 Amazon.com gift card code will be mailed to participants upon receipt of completed questionnaires.

For online survey selection, participants will be provided with a link to an electronic copy of the consent, which may be viewed within the survey and also downloaded (see Appendix B).

Online consent on Qualtrics is a hard stop before participants can move forward with the link to complete the survey online. Qualtrics is a system for web-based data collection and is approved by the University of Pittsburgh IRB. The consent will state that by completing and submitting the online questionnaire, individuals have agreed to participate in the study. The question will be repeated in the actual survey platform. PI contact information will be provided for questions at any time. If no response or partial response (e.g., participant initiated but did not complete the survey), reminder emails will be sent following the initial email. A thank you email and the $5 Amazon.com gift card code will be sent to participants upon completion of the survey via provided emails.

Surveys are completed at one time point, so retention strategies are not included. Every effort has been made to make paper and online surveys as similar as possible.

1.8.4 Potential risks and adequacy of protection against risks

One potential risk is a breach of confidentiality. To protect participants' privacy, only members of the research team will be aware of individuals' participation in this research study. Participant names will not be included on the paper or electronic questionnaires they complete or the information collected from medical records. All data will be kept in secure, locked file cabinets at the School of Nursing. A username and password will be used to access secured survey data in Qualtrics. All information will be identified only by a study ID number. The information linking ID numbers with identifiable information will be kept separate from the research records; paper data and will be stored under lock and key, and identifiable linkage code data will be stored in a Box cloud folder separate from the deidentified data. The PI will manage access to the identifiable data; access will be provided only to team members who require access for study-related work. All researchers involved in this study have been thoroughly trained and are up to date on online privacy modules. Individual identities will not be revealed in any description or publications of this research, and data will only be presented in aggregate.

Another possible risk of this research study may include stress from having to complete the questionnaires. Participants are advised that, if the questions induce stress or discomfort, they can take a break from completing the questionnaires and do not have to complete all individual questions. If completing the survey online, they are advised that their data will not be lost if they take a break. It is emphasized that survey responses are not sent to their healthcare providers and that they should contact or see their healthcare team if they have any questions or concerns about physical or emotional symptoms, cancer, or medications or if they experience new symptoms or increase in existing symptom severity. It is estimated that survey completion will take approximately 30-45 minutes.

1.8.5 Cost-to-benefit statement

In light of the relatively minor risks associated with the study (e.g., minor distress or physical discomfort, breach of confidentiality), the risk-benefit balance is reasonable. Participants will likely no acquire direct benefit from study participation. The primary benefit of this study lies in the importance of knowledge to be gained.

1.8.5.1 Importance of knowledge to be gained. The number of cancer survivors, specifically the number of individuals with MPC, is growing dramatically in the United States (American Cancer Society, 2014; Bluethmann et al., 2016; DeSantis et al., 2014; Fraumeni et al., 2006; National Cancer Institute, n.d.-c, n.d.-b), increasing the need to identify the characteristics of those diagnosed with MPC and the potentially modifiable self-management behaviors that interrupt negative stress response pathways and have potential to optimize health and well-being. Data from the proposed study will allow investigators to target particular behavioral mechanisms related to prolonged stress in MPC survivors most vulnerable to prolonged stress and the cascade of negative outcomes. The goal is that study data will provide findings that can be used to improve care for future patients and survivors and to inform future intervention studies for this population.

2.0 SUMMARY OF STUDY

2.1 CHANGES TO PROPOSED STUDY

This section is intended as a bridge between the proposed study, as approved by the committee, and the actual study as it was conducted. Reviewed here are the major changes to the originally proposed study related to recruitment and resulting data collection procedures.

2.1.1 Recruitment

The original plan for our study team to directly recruit the majority of our participants through the voluntary Cancer or Cancer-like Blood Disorder Registry (UPCI protocol #03-038) was not possible, as we were notified pre-study launch that the protocol had been permanently closed. Therefore, we used our previously identified alternative approach to recruit participants by partnering with the UPMC Network Cancer Registry's honest broker system (IRB #HB015) to contact prospective participants from the larger cancer registry sampling frame. The UPMC Cancer Registry draws from accredited hospitals who actively follow patients, including: Altoona, East, Horizon, McKeesport, Magee, Northwest, Passavant, Presbyterian Shadyside, and St. Margaret.

2.1.1.1 Additional participation criteria. In addition to our originally planned inclusion and exclusion criteria, additional exclusion criteria were required by the UPMC Registry protocol. Based on requests from physician leaders identified prior to study launch, the UPMC Registry staff compared the list of potentially eligible participants (n=2233) to the corporate "opt out" database maintained by the Medical and Health Sciences Foundation Office and removed 62 (2.8%) of the potentially eligible patients who were common between lists. Per UPMC Registry protocol, each physician champion enlisted as a clinical expert for their respective disease site(s) (see 1.4.3) was also provided with a list of potentially eligible patients from his or her disease specialty. Opportunities were provided for each physician champion to review the list and deem patients not appropriate for contact about this study; 46 (2.1%) potentially eligible

participants were removed based on this review. Lastly, 10 prospective participants who were mailed study letters of invitation were unable to be contacted regarding study participation, as they were either deceased or noted by their families as unable to participate due to dementia; these 10 individuals were subtracted from the number of potentially eligible participants (see Manuscript 3, section 3.3.4.1 for additional details).

2.1.1.2 Dillman's Tailored Design Method. The launch of our initial mailings was delayed due to the previously described changes in the source of recruitment and overlap with major holidays. Consequentially, the timing of reminder mailings to nonrespondents was also delayed until immediately following the start of the new year. See Figure 7 in Manuscript 3 for the revised study flow.

Because we were contacting potential participants using UPMC Registry's honest broker system, we were not provided with an individual's contact information until he or she first contacted us about the study. Thus, our originally planned series of four follow-up contacts with potential participants who did not respond to initial mailings was not possible. Balancing feasibility of UPMC Registry workload and privacy of potential participants being approached through the UPMC Registry, we partnered with the UPMC Registry to send one additional reminder postcard to prospective participants who had not responded to the initial study mailings (IRB approved).

For individuals who requested to complete surveys on paper but had not returned their completed survey by Day 21, our final contact was accomplished via the mode of communication that was used or preferred by each participant. For example, if an individual had called the study telephone number to request a paper survey, our final contact consisted of a reminder telephone call to answer any questions and encourage participation.

2.1.1.3 Nonresponse and return to sender. We provided UPMC Registry personnel with updated lists of individuals who had contacted us about study participation. The UPMC Registry's honest broker system tracked individuals who did not respond to study mailings. They

also identified updated addresses and resent initial letters of invitation for n=114 individuals whose first letter had been returned as undeliverable. UPMC Registry personnel tracked undeliverable letters of invitation and reminder postcards.

2.1.1.4 Measures and scoring. Reviews of the planned set of measures were conducted prior to study launch. Based on a balance of participant burden and desired measurement, the following changes were made pre-survey launch.

2.1.1.4.1 Psychological responses. We utilized the Mental Health subscale of the PROMIS Global Health measure (Hays, Bjorner, Revicki, Spritzer, & Cella, 2009; HealthMeasures, 2017), a scale originally planned for exploratory descriptive purposes, as a measure of the psychological response latent variable. The version of the scale we administered, v1.0, was recently retired. Thus, we followed developer instructions to convert the Global Health data observed in our study to v1.2 format for scoring.

2.1.1.4.2 Physical health outcomes. The 10-item version of the PROMIS Physical Function was administered, rather than the 20-item version, to reduce participant burden.

2.1.1.4.3 Personality. The IPIP mini was administered (Donnellan, Oswald, Baird, & Lucas, 2006), rather than the originally planned 20 item version, to decrease participant burden.

2.1.1.4.4 Exploratory measures. To reduce participant burden and to reduce redundancy among measures, the Index of Self-Regulation and Self-Efficacy for Managing Chronic Disease exploratory measures were not included in our battery of administered instruments.

2.1.1.5 Data sources. In addition to self-reported data and data extracted from the medical record, we incorporated UPMC Cancer Registry clinical and sociodemographic data in our analyses. To maintain consistency with study inclusion criteria based on UPMC Registry queries, first cancer diagnoses are based upon diagnoses recorded in the UPMC Cancer Registry.

Due to feasibility and cost, we were not able to collect and bank biological samples for future analyses.

2.1.2 Data analyses

2.1.2.1 Missing data. Scales were scored per developer instructions. When no information was available regarding number of items required to scale a score, scores were imputed if at least 80% of scale items were completed.

Four participants who consented to online study participation did not complete the full survey and were dropped from analyses.

2.1.2.2 Model fit indices. In additional to comparative fit indices (CFI), Tucker-Lewis Index (TLI), and root mean square error of approximation (RMSEA), we also used standardized root mean square residual (SRMR) to assess model fit. During analyses for determination of good model fit, we adopted more stringent cut points than were originally proposed for practical fit indices: comparative fit index (CFI)$\geq$.95; Tucker-Lewis Index (TLI)$\geq$.95; standardized root mean residual (SRMR)$\leq$.08; root mean square error of approximation (RMSEA)$\leq$.08 (Hu & Bentler, 1999; Kenny, 2015; Little, 2013).

2.1.2.3 Sample size. We had originally set a sample size goal of n=440 to balance cost, feasibility, and analytic power. Ultimately, 215 participants were recruited for this study, and 4 were dropped due to incomplete data (response rate = 15.2%). After 5 additional participants were dropped from analyses due to having multivariate outlier data, a final sample size of 206 participants was included in multivariate analyses.

Despite not achieving our originally desired sample size, the SEM for our primary aim remained adequately powered. With the retained sample size of 206 and 309 degrees of freedom, >.99 power remained for either the test of a close fit (i.e., $RMSEA_0$=.05 vs. $RMSEA_A$=.08) or exact fit (i.e., $RMSEA_0$=0.0 vs. $RMSEA_A$=0.05) at a significance level of .05.

2.1.2.4 Analytic variables for multivariate analyses. Due to sparse cell sizes for race and a large amount of missing data for income, we were unable to retain these planned variables as covariates in analyses. We did, however, include “difficulty making ends meet” as a variable in our multivariate analyses. Clinical variables ultimately examined in Aim 2 included: first cancer

site and years since first cancer diagnosis (obtained from Cancer Registry data); second cancer site, years since second cancer diagnosis, years since most recent treatment, time between first and second cancer diagnoses, presence of three or more cancer diagnoses (*yes* versus *no*), and most recently documented BMI (obtained from medical record review).

2.1.2.5 Aim 3 analyses. To explore individual hei-Q item responses by domain for self-management, responses were collapsed into two categories (*disagree* and *agree*) and explored by domain. Mean domain scores (without score alterations) and individual item responses are reported (see Table 14).

To evaluate potentially modifiable health behaviors, we analyzed heiQ items, alcohol use, tobacco use, and BMI measures in detail (see Tables 14-16).

2.2 CONCLUSIONS, IMPLICATIONS FOR NURSING, FUTURE STUDIES

This dissertation is composed of three complementary studies that demonstrate a clear and focused progression from an evaluation of the state of the science (Manuscript #1), to a secondary analysis to explore associations among select model variables in a national sample of MPC survivors (Manuscript #2), the dissertation study in which we carried out a systematic model evaluation to elucidate key pathways impacting health in MPC survivors (Manuscript #3), and concludes with a characterization of positive and negative self-management behaviors in MPC survivors (Aim 3; section 4.0). Here we briefly summarize the implications of the preliminary studies prior to focusing on the final dissertation study.

In Manuscript 1 (Belcher et al., 2016), we reviewed and synthesized the literature to determine the relationship between experience of MPC diagnoses and psychological distress in adult cancer survivors. This study identified a lack of research focused on and/or including adults with MPC diagnoses. Across the five studies that met criteria for inclusion in the review, calculated effect sizes supported small but potentially significant increases in psychological distress in survivors of MPC compared to single cancer survivors. Findings from this manuscript were combined with literature in other populations to select and refine variables and pathways

for the conceptual model. Additionally, noted gaps including lack of racial and ethnic diversity in MPC samples, self-reported clinical data, inconsistent use of valid and reliable measures, inclusion of non-melanoma skin cancer cases, and lack of focus on characterization of MPC survivors at risk for increased distress were addressed in the design of the subsequent dissertation study.

In Manuscript 2 (Belcher et al., 2017), we conducted a secondary analysis of a national cancer survivorship dataset to compare survivors of single cancer versus MPC diagnoses on psychological distress, self-management behaviors, and benefit finding. Having MPC was associated with psychological distress and positive healthcare utilization (i.e., attending medical appointments, monitoring for second cancer, and being up to date on screenings) but not with healthy lifestyle (i.e., regular physical activity, healthier diet, and attempts to take care of health) or benefit finding. The study reaffirmed findings of psychological distress for MPC survivors in a large, mixed-cancer survivor population and allowed for clearer conceptualization of model concepts, including the introduction of self-management as an important consideration in MPC, where survivors often view cancer as a chronic disease (Belcher et al., 2017).

In Manuscript 3, dissertation aims 1 and 2 (see section 3.3), we used structural equation modeling to evaluate hypothesized relationships linking stress to poor health in an adapted psychobehavioral stress response model. The data fit a modified four-factor measurement model, with latent variables including self-management, distress (combined perceived stress and psychological distress), financial toxicity, and functional health (combined social health and physical health). In the expanded model including possible predictors, overweight BMI, graduate education, less neuroticism, and increased social support predicted better self-management; poorer self-management, greater neuroticism, and lower social support predicted increased distress. The findings provide opportunities for intervention work targeting modifiable pathways and for early identification of individuals at increased risk for negative health outcomes.

To address dissertation aim 3 (see Chapter 4.0), we explored individual positive self-management behaviors and indicators of negative health behaviors (i.e., alcohol use, smoking, and BMI). Self-management item scores were generally high but variable, and rates of obesity were well above population and cancer norms. This exploration of data highlights a need for additional study focused on risk factors associated with positive and negative health behaviors in MPC survivors.

Self-management was the upstream latent variable identified in the final modified model, predicting the other latent variables either directly (i.e., predicting distress) or indirectly (i.e., through distress). In contrast to the common data element instruments recommended by the National Institute of Nursing Research (NINR) (Moore et al., 2016), which are limited to measures ***associated with*** health behaviors (i.e., patient activation, self-regulation, self-efficacy for managing chronic conditions, and global health), the internationally-tested heiQ, selected to measure self-management in this study, was designed specifically to measure outcomes following health education and self-management programs (Elsworth et al., 2015; Osborne et al., 2011, 2007) and directly assess the range of self-management domains recommended to maintain wellness.

In this study, the measures used to capture the hypothesized latent variables of perceived stress and psychological response loaded onto the same factor, which we called *distress*. Future studies should evaluate the validity of combining these measures. It is possible that the high correlations among these sets of variables was a consequence of study design and/or measurement issues. The original conceptualization of the perceived stress latent variable, the perception that one's demands overwhelm one's coping resources (Lazarus & Folkman, 1984), was meant to capture current stressors of general life demands, cancer-specific stress, and cancer worry. Conversely, the psychological response latent variable was mean to capture the longer-term (maladaptive) responses to the chronic stress of cancer (National Comprehensive Cancer Network, 2018a) and included measures of depressive

symptoms, anxiety, and mental health. It is possible that the cross-sectional nature of this study precluded distinguishing between these short- and long-term responses in MPC survivors who had been living with their diagnoses for, in some cases, multiple years. Similarly, social role ability and physical health measures loaded onto a combined factor, which we conceptualized as *functional health*. Ability to participate in social roles and activities does reflect a functional ability, but, again, further research is necessary to evaluate the validity of combining these different measures into a single latent variable. Finally, the PROMIS Global Mental Health measure we attempted to incorporate into this model loaded across many of the latent variables in the model, preventing us from using it in multivariate analyses.

Importantly, these collapsed latent variables demonstrated clear associations among each other in the directions that we had hypothesized. Distress, which was predicted by self-management behaviors, significantly predicted both increased financial toxicity and poorer health outcomes. We hypothesize that increased distress may be impairing an individual's productivity, leading to financial toxicity, and that financial toxicity may be impacting an individual's physical health (e.g., through medication adherence). Further, we hypothesize that distress may be affecting functional health through biological pathways (e.g., triggered glucocorticoid receptor resistance, immune dysregulation, and risk for disease) (Cohen et al., 2012). It is also possible that mechanisms impacting an individual's risk for MPC (e.g., genetic predisposition, previous cancer treatment, negative health behaviors, etc.) may also influence health outcomes in this survivor population. Future studies should identify the individual and interacting influence of these different mechanisms.

Additionally, BMI, education, neuroticism, and social support were significant covariates for this variable. Notably, the rate of obesity in this sample (40.7%) is higher than both that of the general U.S. population (36.5%) and cancer survivors (31.1%) (Centers for Disease Control and Prevention, 2017; National Cancer Institute, 2018b). Also, we recruited a sample of

participants with less education than is typical of previous MPC study samples (38.8% with high school level or less), making this a sample that is more generalizable to the U.S. population.

Not all of the originally hypothesized pathways (see Figures 10 and 11, Section 3.3) were found to be statistically significant. The direct pathway between self-management behaviors and financial toxicity was neither significant nor was it in the direction we had hypothesized; for financial toxicity, distress was a more important direct predictor, while distress mediated the relationship between self-management and financial toxicity. Also, while the coefficient did reflect the hypothesized direction, self-management behaviors also were not a significant direct predictor of functional health. The relationship, again, was mediated by distress.

Additional strengths and limitations are acknowledged in this study. Fortunately, we had adequate power to conduct the planned structural equation modeling despite a lower than expected response rate to study mailings (15.2%). Study participants were similar to participants in previously recruited national MPC samples (e.g., similar age, gender, ethnicity, marital status), despite being recruited from a regional cancer registry. Additionally, study participants did not differ from nonparticipants identified by the Cancer Registry as potentially eligible for participation in this study on key variables including age, gender, race, marital status, primary payer at first diagnosis, years since first cancer diagnosis, and first cancer site (see Table 7 in Section 3.3).

Some differences did exist between our sample and other published reports. First, as a result of our inclusion criteria, this sample of patients was, on average, closer to their first cancer diagnosis (M= 5.8 years, SD=2.9) than other published samples (11-17 years), providing the opportunity to examine a new cohort of MPC survivors not previously included in this body of literature (Belcher, Low, Posluszny, Kramer, & Donovan, 2016; Burris & Andrykowski, 2011; Gotay et al., 2007; Thong et al., 2013). This study also included cancer sites not frequently represented in MPC literature (i.e., lung and thyroid cancer). Additionally, this sample had

higher average BMI and rates of obesity (41%) when compared to other MPC samples (Burris & Andrykowski, 2011; Thong et al., 2013). It is not clear whether this reflects the general increase in BMI across the U.S. or whether it is an emerging and unique problem among MPC survivors. While not successful in recruiting a racially and ethnically diverse sample, we were successful in recruiting a sample of participants with a broad range of educational attainment, which is representative of the broader U.S. population (Ryan & Bauman, 2016). Importantly, educational attainment was identified as an important predictor of self-management in Aim 2 covariate analyses.

The data in this study support healthy self-management behaviors as vitally important to positive health outcomes in MPC survivors. Clinicians caring for MPC survivors should assess persons with high-risk BMI, low educational levels, low social support, and greater neuroticism for poor health behaviors and distress, both of which are modifiable. Assessments should include diet, activity, caloric balance, and brief distress screenings. The National Comprehensive Cancer Network's survivorship and distress clinical practice guidelines (National Comprehensive Cancer Network, 2018b, 2018a) provide direction on ways to assess and intervene in these areas. Clinicians should also increase their awareness of financial toxicity and should engage their patients in care value discussions. As evidenced by the expertise needed to address these key clinical priorities in MPC patients, collaboration among specialists (e.g., nutritionists, behavioral change experts, mental health professionals, financial experts, primary care providers, and oncologists) is key.

As recognized by recent literature documenting increasing rates of MPC in cancer survivors (Davidson, 2017; Murphy, Gerber, & Pruitt, 2017), clinical trial eligibility criteria should be evaluated to ensure representativeness of the U.S. cancer survivor population. Whenever possible, MPC status should not be an explicit exclusion criterion for clinical trial participation. Also, organizations should strive to create systems and policies that allow for continuity of care among providers for these medically complex patients.

Future studies should evaluate this refined model for studying health outcomes in adults with MPC, with a particular focus on self-management and financial toxicity, two newly highlighted areas of importance. Biological pathways also are an untapped line of inquiry in this patient population and could lead to increased understanding of the mechanisms linking distress to poor outcomes in this model. It is also important to understand how risks for poor health outcomes may differ among different subsets of MPC survivors (e.g., childhood versus adulthood diagnoses; MPCs associated with genetic cancer syndromes versus treatment-related MPCs versus MPCs associated with risky behaviors). Future research should move to longitudinal studies to 1) establish temporal relationships among key variables, 2) understand how MPC survivorship risk factors change over time, and 3) identify vulnerable phases in the MPC survivorship trajectory.

Future MPC studies should also focus on novel recruitment methods for this hard to reach patient population, as survivors do not all attend specialty MPC clinics where focused recruitment could occur. Future studies must also focus on conducting studies that are sensitive to the challenges and perspectives of more diverse groups of MPC survivors. With increased demands being placed on people's time and attention, survey response rates have been declining and costs have been rising (National Science Foundation, n.d.), and this type of data collection may be becoming outdated. Attention should also be paid to addressing the reasons for nonparticipation identified in this study (i.e., perception by elderly MPC survivors that their input is not valuable; lack of knowledge/awareness of their MPC cancer status; and concerns about privacy and allowing access to medical records).

3.0 MANUSCRIPTS

This dissertation is comprised of two published manuscripts and one pending submission manuscript draft.

Manuscript 1 (see Appendix E):

Belcher, S. M., Hausmann, E. A., Cohen, S. M., Donovan, H. S., & Schlenk, E. A. (2016). Examining the relationship between multiple primary cancers and psychological distress: A review of current literature. *Psycho-Oncology*, *26*(7), 2030–2039. https://doi.org/10.1002/pon.4299

Manuscript 2 (see Section 3.2 for the manuscript version accepted for publication and Appendix F for link to final publication):

Belcher, S. M., Low, C. A., Posluszny, D. M., Schear, R., Kramer, R. E., & Donovan, H. S. (2017). Psychological distress, health behaviors, and benefit finding in survivors of multiple primary cancers: Results From the 2010 Livestrong survey. *Oncology Nursing Forum*, *44*(6), 703–711. https://doi.org/10.1188/17.ONF.703-711

Manuscript 3 (see Section 3.3):

Belcher, S. M., Donovan, H. S., Bovbjerg, D. H., Sherwood, P. R., Campbell, G. B., & Sereika, S. M. (n.d.). Adapting a psychobehavioral stress-response model to characterize risks in survivors of multiple primary cancers. In preparation.

3.1 DISSERTATION MANUSCRIPT 1: REVIEW OF LITERATURE

The full text of this manuscript was reproduced with permission from *Psycho-Oncology* and can be found in Appendix E.

3.2 DISSERTATION MANUSCRIPT 2: PILOT TESTING ASSOCIATIONS AMONG KEY VARIABLES

Presented here is the full text version of the manuscript accepted for publication, which was subsequently published in *Oncology Nursing Forum*. The final publication may be accessed at: http://store.ons.org/article/find?doi=10.1188/17.ONF.703-711

Psychological Distress, Health Behaviors, and Benefit Finding in Survivors of Multiple Primary Cancers: Results from the 2010 LIVESTRONG Survey

3.2.1 Abstract

Purpose: To evaluate whether survivorship of multiple primary cancers (MPC) is associated with psychological distress, health behaviors, and benefit finding.

Design: Secondary analysis of the 2010 LIVE**STRONG** cross-sectional survey.

Setting: Online survey.

Sample: 238 MPC and 3,295 single cancer survivors.

Methods: Chi-square and t-tests for group comparisons. Multivariate linear regression, adjusted for covariates, for associations between variables.

Main Research Variables: MPC versus single cancer; psychological distress, health behavior (healthy lifestyle and positive healthcare utilization), and benefit finding scores.

Findings: Survivors of MPC, compared to single cancer survivors, were significantly older, less likely to have a spouse/partner, further out from original cancer diagnosis, less likely to be employed full-time, and differed by cancer diagnoses and survivorship stage. MPC was associated with significantly higher psychological distress and healthcare utilization but not healthy lifestyle or benefit finding.

Conclusions: Relative to those with single cancers, MPC survivors are at increased risk for psychological distress and are more likely to receive recommended cancer screenings. Additional research is needed to understand mechanisms surrounding psychological distress in MPC survivors.

Implications for Nursing: Targeted distress screening in MPC survivors may allow for early identification and interventions to ameliorate distress and reduce negative downstream health effects.

Knowledge Translation: Nurses should assess for previous cancer histories and recognize that survivorship experiences may differ between MPC and single cancer survivors. MPC survivors have increased psychological distress risk and may have needs related to living with cancer as a chronic illness. Further study of psychological distress mechanisms in MPC survivors is warranted.

Keywords: multiple primary cancers, cancer survivorship, psychological distress, health behaviors, benefit finding

3.2.2 Background

With improved cancer screenings and treatments, the United States cancer survivor population is predicted to reach 20.3 million people by 2026 and 26.1 million by 2040 (American Cancer Society, 2016; Bluethmann et al., 2016; Jemal et al., 2017). As survival increases following cancer diagnoses and general effects of aging occur, cancer survivors, however, are facing additional serious health issues including subsequent malignant neoplasms. One in five cancers diagnosed in the United States will occur in someone who has a previous cancer diagnosis, and these multiple primary cancers (MPCs) are a major cause of morbidity and mortality in cancer survivors (De Gonzalez et al., 2011; Morton et al., 2014).

A second, or multiple primary, cancer (MPC) is the occurrence of a new cancer that is histologically distinct from the original primary cancer and has been ruled out as metastatic disease of the primary tumor (Begg, 1999). An example of someone who is an MPC survivor is an individual who experiences breast cancer and later presents with a new diagnosis of ovarian cancer. Contrast this with a woman with breast cancer that metastasizes to the bone, which is diagnosed as metastatic spread of the original breast cancer; this would not be considered an MPC. Risk of developing subsequent MPCs varies by site of first primary cancer, age at first cancer diagnosis, environmental and behavioral exposures, genetic susceptibility, and cancer treatment effects (American Cancer Society, 2009, 2012; Morton et al., 2014).

The National Academy of Medicine, professional organizations, cancer survivorship advocates, clinicians, and scientists have called for an increased focus on addressing the health and psychosocial needs of the growing population of cancer survivors (American Cancer Society, 2016; Klein et al., 2014; Knobf et al., 2015; K. D. Miller et al., 2016; Mullan, 1985, 2016; National Academy of Sciences, 2006), and the MPC population represents an understudied and at risk group in critical need of additional research. While having a single cancer has been linked to risks for psychological distress (Holland et al., 2013; Mitchell et al., 2011; National Comprehensive Cancer Network, 2015), poor health behaviors (Mowls, Brame, Martinez, &

Beebe, 2016; Underwood et al., 2012), and poor physical health outcomes (Ness, Wall, Oakes, Robison, & Gurney, 2006; Stein, Syrjala, & Andrykowski, 2008) that can persist throughout cancer survivorship, an initial small body of literature is evolving to suggest that the risk for these poor outcomes appears to be even greater in MPC survivors (Andrykowski, 2012; Belcher, Hausmann, Cohen, Donovan, & Schlenk, 2016; Burris & Andrykowski, 2011; Dowling et al., 2013; Gotay, Ransom, & Pagano, 2007; Thong et al., 2013). Most cancer survivorship literature, however, has been conducted irrespective to number of cancer diagnoses, limiting our ability to understand potentially unique experiences and needs in this survivor subset. Additionally, no studies of MPC cancer survivors to date have analyzed a large national dataset, such as the LIVE**STRONG** survey, that focuses entirely on post-treatment cancer survivorship issues.

Many cancer survivors experience persistent late and/or long-term effects of cancer and cancer treatment (National Comprehensive Cancer Network, 2017). Uncontrolled psychological distress in cancer survivors is known to negatively impact quality of life, adherence to surveillance recommendations, and engagement in health promotion activities (National Comprehensive Cancer Network, 2016). Previous cancer survivorship literature has demonstrated that healthy lifestyle behaviors are associated with decreased chronic illness and improved health and quality of life (Blanchard, Courneya, & Stein, 2008; Davies, Batehup, & Thomas, 2011; Ford et al., 2009). Benefit finding, the perception of positive changes such as renewed appreciation for life following adversity, has been found in single cancer populations and may also be related to positive health behavior change and psychological adjustment (Harper et al., 2007; Hawkins et al., 2010; Kanera et al., 2016; Low et al., 2014). Previous cancer survivorship literature has been conducted without consideration of patients' history of multiple primary cancers, but early literature suggests that this growing population of MCP survivors may be at an increased health risk, highlighting a critical need to build the science to

identify potentially modifiable risk and protective factors contributing to health outcomes in this unique cancer survivor population.

The purpose of this secondary analysis of 2010 LIVE**STRONG** national cancer survivorship survey data is to evaluate whether MPC survivorship is associated with psychological distress, health behaviors, and benefit finding. We report 1) sociodemographic and clinical differences between survivors of single cancers versus MPCs and 2) the contribution of MPC survivorship to psychological distress, health behaviors, and benefit finding after controlling for important covariates. Findings from this study are used to make recommendations to support MPC survivors that are applicable to a wide range of nurses.

3.2.3 Materials and Methods

3.2.3.1 Data. The 2010 LIVE**STRONG** Survey for People Affected by Cancer was a cross-sectional survey fielded online by LIVE**STRONG** between June 2010 and March 2011. Constituents of LIVE**STRONG** were notified about the survey via email, Twitter, and Facebook, and partner organizations, state cancer coalitions, and comprehensive cancer centers shared survey information with their respective constituents and/or patients (Beckjord et al., 2014; Campbell et al., 2011; Shapiro et al., 2009) .

The 2010 LIVE**STRONG** survey was developed in response to the Institute of Medicine Report recommendations (National Academy of Sciences, 2006) that nonprofit organizations increase their support of cancer survivorship research and associated mechanisms and was aimed at examining post-treatment survivorship issues. The LIVE**STRONG** Foundation developed items for the preceding 2006 LIVE**STRONG** survey through a multi-year formative research process, during which experts and cancer survivors were consulted to incorporate challenges faced by cancer survivors. Many of the 2006 LIVE**STRONG** survey items were retained in the 2010 survey following a RAND Corporation analysis that examined survey response patterns and content (Rechis et al., 2011). Main topic areas in the 2010 survey included physical, emotional, and day to day concerns as well as meaning making, information

seeking, and advocacy and engagement. Additional details regarding survey development, participant recruitment, and survey administration have been previously published (Beckjord et al., 2014; Low et al., 2014; Posluszny et al., 2015; Rechis et al., 2011).

3.2.3.2 Sample. The parent study received Institutional Review Board (IRB) approval (Rechis et al., 2011), and this analysis of de-identified 2010 LIVE**STRONG** survey data was approved by the University of Pittsburgh IRB. The initial survey included 4,192 post-treatment adult cancer survivors whose data were considered for this study. Sample selection by single and multiple cancer groups is described below and is presented as a flow chart in Figure 5.

Multiple versus single cancer diagnosis. Survey respondents were asked to report "type of cancer (primary site)" and could choose from an extensive 88-item checklist of cancer types. Respondents were also asked to separately identify any "additional cancer diagnoses or recurrences." As presented in Figure 5, *a priori* decisions were made to exclude nonmelanoma skin cancer cases in both single and MPC groups. Additional exclusion criteria for the MPC group included: second cancer identical to first primary cancer (i.e., recurrence); definite or probable metastatic disease for common sites of cancer metastases (i.e., bone, liver, lung, and brain) (National Cancer Institute, 2013); and/or unclear, missing, "I don't know," or non-cancer "other" diagnoses that were not actual cancer diagnoses (e.g., "stroke").

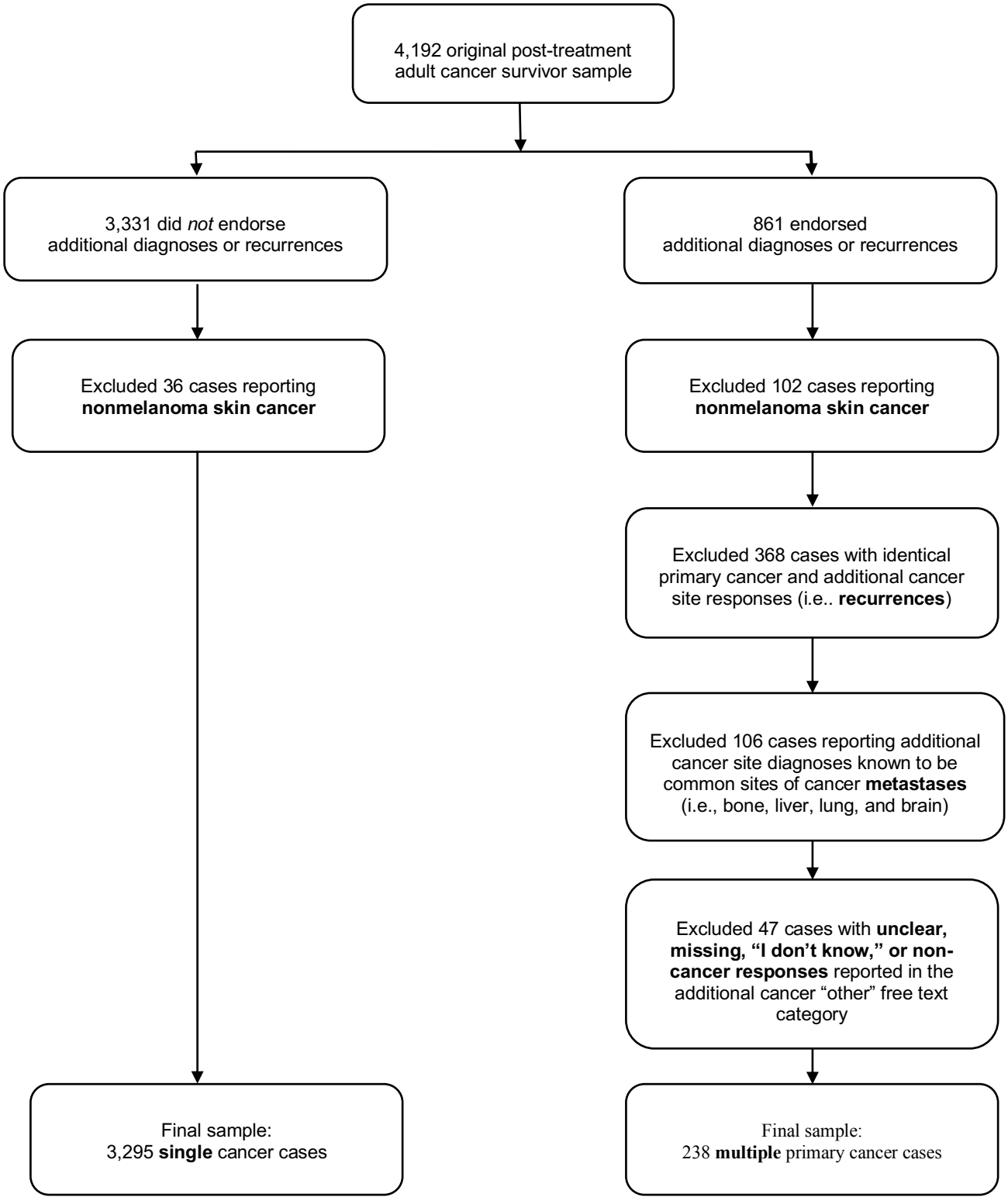

Figure 5. Flow chart of process resulting in (n=3553) post-treatment adult cancer survivor sample

3.2.3.3 Variables of Interest.

Cancer diagnoses. Classification of respondents as either single or MPC survivors is previously described under sample.

The following categories of variables were assessed in the LIVE**STRONG** survey by asking: "Since completing treatment, have any of the following statements been true for you as a result of your experience with cancer?" A series of statements followed, to which respondents could answer "yes," "no," or "I don't know." "I don't know" replies were treated as missing data in this study. Individual survey item endorsements were used to compute sum scores for the four survey outcome categories of interest.

Psychological distress, health behaviors, and benefit finding. **Psychological distress** included 8 items pertaining to anxiety; worry, tension, or stress; preoccupation with cancer; worry about dying from cancer; worry about cancer recurrence; depression; and mood swings. **Health behaviors** were divided into two categories: 1) healthy lifestyle and 2) positive healthcare utilization. Four *healthy lifestyle* behavior items included leading a healthier lifestyle; regular physical activity (2-3 times per week); healthier diet; and attempts to take care of health. *Positive healthcare utilization* included 3 items including attending regular medical appointments; monitoring for second cancer; and being up to date on recommended cancer screenings. Six **benefit finding** items included greater appreciation for life; recognition of what's important in life; renewed spirituality; ability to better deal with stress; better coping; and overall feeling like a better person.

Sociodemographic and clinical variables. Sociodemographic variables included age at survey; gender; race; partner status (i.e., single, divorced/widowed, and married); children under 18 living in the home; educational status; total household income; and employment status. Cancer-related clinical variables included age at initial cancer diagnosis; years since diagnosis; first primary cancer diagnosis (included categories for top 5 most prevalent diagnoses represented by respondents [breast, testicular, colorectal, hematologic, prostate]; remaining

diagnoses were represented by “other”); years since last treatment; stage of survivorship (i.e., currently on treatment, living with cancer as a chronic illness, <1 year post treatment, 1-5 years post treatment, >5 years post treatment, prefer not to answer/unsure); and cancer treatment received (i.e., no chemo, chemo only, chemo plus surgery and/or radiation). The selection of these predictor variables was driven by critical variables identified in the MPC literature (Andrykowski, 2012; Belcher et al., 2015; Belcher et al., 2016; Burris & Andrykowski, 2011; Dowling et al., 2013; Thong et al., 2013).

3.2.3.4 Analyses. Descriptive statistics were used to characterize the sample and key variables of interest. To compare characteristics between SC and MPC groups, we used independent sample *t*-tests for continuous variables and χ^2 for categorical variables. Post-hoc contingency table analyses using Pearson χ^2 testing were conducted for categorical variables reaching statistical significance, and Bonferroni adjusted p-values were calculated to correct for Type I error.

Predictor variables of interest were selected *a priori* based on the literature and were included in the empirically driven multivariate analyses. Multivariate linear regression analysis with listwise deletion was used to develop models for predicting the overall categories of psychological distress, healthy lifestyle behaviors, positive healthcare utilization, and benefit finding, adjusted for both statistically ($p<.05$) and theoretically significant covariates. Variables were included as model covariates if they 1) were related to MPC in bivariate analyses at $p<.05$, or 2) were associated with outcomes in previously published work (i.e., were statistically or theoretically significant). Standardized β and p-values are reported for multivariate linear regression models.

The data were analyzed using IBM SPSS Statistics software, version 22. All tests were 2-tailed, and statistical significance criterion threshold was set at $p<.05$ unless otherwise noted for Bonferroni corrections.

3.2.4 Results

Descriptive statistics are displayed in Table 3 for both single (n=3,295) and MPC (n=238) groups. MPC participants differed significantly from those with single cancer diagnoses in that they were older at the time of survey completion and were further out from their initial diagnosis. Additionally, groups differed statistically by partner status, employment status, type of first primary cancer diagnosis, and stage of survivorship. Specifically, those with MPC were less likely to have had breast cancer and were more likely to have had one of the less common cancers represented in the dataset, "other" as a first primary cancer diagnosis. First primary cancer diagnoses most frequently represented in the other category for MPC survivors included ovarian, uterine, and thyroid cancer. Breast cancer and melanoma were the two most commonly reported second primary cancer diagnoses for MPC survivors. MPC survivors were also more likely than single cancer survivors to endorse living with cancer as a chronic illness when identifying their stage of survivorship. Being divorced or widowed was more common in MPC survivors, but this difference was not significant after Bonferroni adjustment.

Table 3.

Sample Sociodemographic and Clinical Characteristics by Single Cancer and Multiple Primary Cancer Groups (N=3,533)

Variables	Single Cancer n = 3295	Multiple Primary Cancers n = 238	Statistic (df)[a]	95% CI or p-value	p-value for Post-hoc testing[b-d,f]
	Mean (SD)				
Age at Survey, years	48.4 (12.5)	53.3 (11.3)	t (3519) = -5.89	**-6.54, -3.28***	
Age at Initial Diagnosis, years	42.9 (13.8)	41.8 (15.2)	t (3488) = 1.15	-0.76, 2.91	
Time Since First Diagnosis, years	5.1 (6.5)	11.4 (10.3)	t (3372) = -13.53	**-7.21, -5.39***	
	Number (%)				
Gender					
Female (n=2218)	2060 (62.9)	158 (66.7)	χ (1) = 1.37	.24	
Race					
White (n=3074)	2865 (92.4)	209 (91.7)	χ (1) = .16	.69	
Partner Status[b]			χ (2) = 6.93	**.031***	
Single (n=659)	618 (19.0)	41 (17.4)			.535
Divorced/Widowed (n=431)	389 (12.0)	42 (17.8)			.009
Married (n=2397)	2244 (69.0)	153 (64.8)			.180
Children <18 living in the home					
Yes (n=2303)	2142 (65.1)	161 (67.6)	χ (1) = .61	.434	

Table 3 (continued).

Educational Status			$\chi(3) = 1.67$	.643	
No college (n=790)	732 (22.7)	58 (24.8)			
Some college (n=824)	776 (24.1)	48 (20.5)			
College graduate (n=1063)	989 (30.7)	74 (31.6)			
Graduate school (n=778)	724 (22.5)	54 (23.1)			
Total Household Income			$\chi(5) = 9.12$	.105	
$0-39,999 (n=538)	489 (18.7)	49 (27.1)			
$40,000-59,999 (n=462)	432 (16.5)	30 (16.6)			
$60,000-79,999 (n=438)	413 (15.8)	25 (13.8)			
$80,000-99,999 (n=411)	384 (14.7)	27 (14.9)			
$100,000-119,999 (n=319)	301 (11.5)	18 (9.9)			
$120,000 or greater (n=634)	602 (23.0)	32 (17.7)			
Employment Status[c]			$\chi(3) = 18.73$	**<.001***	
Full-time, work or student (n=1852)	1775 (64.1)	97 (49.2)			**<.001***
Part-time (n=350)	317 (11.6)	33 (16.8)			.031
Not employed (n=326)	300 (11.0)	26 (13.2)			.332
Retired (n=407)	366 (13.4)	41 (20.8)			**.004***
First Primary Cancer Diagnosis[d]			$\chi(5) = 28.97$	**<.001***	
Breast (n=1003)	950 (28.9)	43 (18.1)			**<.001***
Testicular (n=306)	296 (9.0)	10 (4.2)			.012
Colorectal (n=207)	185 (5.6)	22 (9.3)			.020
Hematological (n=386)	358 (10.9)	28 (11.8)			.653
Prostate (n=251)	237 (7.2)	14 (5.9)			.453
Other (n=1385)	1265 (38.4)	120 (50.4)[†]			**<.001***
Second Primary Cancer Diagnosis[e]					
Breast		33 (13.9)			
Melanoma		32 (13.4)			
Thyroid		22 (9.2)			
Uterine		16 (6.7)			
Prostate		15 (6.3)			
Cervical		13 (5.5)			
Time Since Last Treatment, years			$\chi(3) = 1.09$	.779	
<1 (n=1041)	974 (31.3)	67 (30.0)			
1-4 (n=1313)	1219 (39.1)	94 (42.2)			
5-9 (n=572)	538 (17.3)	34 (15.2)			
≥10 (n=411)	383 (12.3)	28 (12.6)			
Stage of Survivorship[f]			$\chi(5) = 47.41$	**<.001***	
Prefer not to answer/unsure (n=47)	44 (1.3)	3 (1.3)			.920
Currently on treatment (n=377)	356 (10.8)	21 (8.8)			.337
Living with cancer as a chronic illness (n=169)	136 (4.1)	33 (13.9)			**<.001***
Less than 1 year post-treatment (n=719)	676 (20.5)	43 (18.1)			.358
1-5 years post-treatment (n=1206)	1137 (34.6)	69 (29.0)			.080
Greater than 5 years post-treatment (n=1010)	941 (28.6)	69 (29.0)			.897
Cancer Treatment			$\chi(2) = 1.99$	.369	
No chemotherapy (n=1428)	1340 (40.7)	88 (37.0)			
Chemotherapy only (n=346)	325 (9.9)	21 (8.8)			
Chemotherapy plus surgery and/or radiation (n=1759)	1630 (49.5)	129 (54.2)			

Table 3 (continued).

Notes. Frequencies and percentages represent all available data for given variables; *Statistical significance, p<.05; [a]Reported statistics are Pearson Chi-Square and independent sample t-tests; [b-e]post-hoc contingency table analyses using Pearson Chi-Square to detect within group differences; Bonferroni adjusted *p*-value thresholds to correct for Type I error are as follows: [b]partner status *p*=.008, [c]employment status *p*=.006, [d]first primary cancer diagnosis *p*=.004, and [f]stage of survivorship *p*=.004.
[e]Only second primary cancer diagnoses that represented ≥5% of the MPC sample are reported.
[†]Most frequent first primary cancer diagnoses represented in the other category for MPC survivors included: ovarian 14 (5.9%); uterine 14 (5.9%); and thyroid 10 (4.2%). Remainder of other category diagnoses for MPC survivors not represented here included diagnoses with less than 10 respondents per diagnosis.

Mean scores for primary outcomes by single and MPC groups are displayed in Table 4.

Table 4.

Mean Sum Scores on Outcome Category Scales by Single and Multiple Primary Cancer Groups

Category (number of respondents)	Range	Single Cancer n = 3295	Multiple Primary Cancers n= 238
		Mean Score (SD)	
Psychological Distresses (n=3028)	0-8	3.6 (2.5)	3.9 (2.5)
Health Behaviors:			
Healthy Lifestyle (n=2723)	0-4	3.3 (1.0)	3.3 (1.0)
Positive Healthcare Utilization (n=2739)	0-3	2.4 (0.8)	2.7 (0.6)
Benefit Finding (n=3383)	0-6	4.6 (1.6)	4.6 (1.5)

Multivariate linear regression analysis results are presented in Table 5. The final *psychological distress* model accounted for 8% of the model variance, $F(35, 2670) = 7.51$, $p<.001$. Significant predictors of psychological distress in the final model included age at survey, gender (female), partner status (divorced or widowed and married), first primary cancer diagnosis (colorectal), stage of survivorship (living with cancer as a chronic illness), and survivorship of MPCs. The final *healthy lifestyle behaviors* model accounted for 1% of the model variance, $F(35, 2378) = 1.88$, $p = .001$. Significant predictors of healthy lifestyle in the final model included race (nonwhite), total household income ($80,000-$99,999 and $100,000-$119,999), employment status (not employed), time since last treatment (5-9 years), and stage of survivorship (greater than 5 years post-treatment). The final *positive healthcare utilization behaviors* model accounted for 4% of the variance in healthcare utilization, $F(35, 2392) = 3.80$, $p<.001$. Significant predictors of healthcare utilization in the final model included educational status (college graduate), first primary cancer diagnosis (colorectal and prostate), cancer treatment (chemotherapy plus surgery and/or radiation), and survivorship of MPCs. Lastly, the final *benefit finding* model accounted for 3% of the model variance, $F(35, 2958) = 3.38$, $p<.001$.

Significant predictors of benefit finding in the final model included race (nonwhite), partner status (divorced or widowed and married), having children under 18 living in the home, total household income ($100,000 to $119,999), employment status (not employed), and cancer treatment (chemotherapy only and chemotherapy plus surgery and/or radiation). Survivorship of MPCs, our primary predictor variable of interest, was significantly associated with psychological distress (standardized β = .046, p = .021) and positive healthcare utilization behavior models (standardized β = 2.899, p = .004) but not with healthy lifestyle behaviors (standardized β = -.012, p = .585) or benefit finding (standardized β = .011, p = .562).

Table 5.

Multivariate Linear Regression Models of Psychological Distress, Healthy Lifestyle, Positive Healthcare Utilization, and Benefit Finding "As a Results of Having Cancer"

	Psychological Distress; Model Adjusted R^2 = .08; $F(35, 2640) = 7.51$, $p<.001$*		**Healthy Lifestyle**; Model Adjusted R^2 = .01; $F(35, 2378) = 1.88$, $p = .001$*		**Healthcare Utilization**; Model Adjusted R^2 = .04; $F(35, 2392) = 3.80$, $p<.001$*		**Benefit Finding**; Model Adjusted R^2 = .03; $F(35, 2958) = 3.38$, $p<.001$*	
Sociodemographic or Clinical Variables	**Standardized β**	***p*-value**	**Standardized β**	***p*-value**	**Standardized β**	***p*-value**	**Standardized β**	***p*-value**
Age at Survey, years[a]	-.195	**.012***	.005	.963	.064	.512	-.007	.929
Age at Initial Diagnosis, years	-.017	.838	.048	.651	.079	.447	-.066	.394
Time since First Diagnosis, years[a]	-.069	.105	.055	.381	-.008	. 896	.019	.637
Gender							-.007	.775
Male	reference	-	reference	-	reference	-		
Female	.171	**<.001***	.005	.865	.010	.722		
Race								
White	reference	-	reference	-	reference	-	reference	-
Other	-.004	.816	.057	**.006***	-.006	.749	.053	**.003***
Partner Status								
Single	reference	-	reference	-	reference	-	reference	-
Divorced/Widowed	.075	**.002***	-.016	.554	-.046	.077	-.051	**.030***
Married	.054	**.045***	-.004	.889	.006	.827	-.055	**.033***
Children <18 living in the home								
No	reference	-	reference	-	reference	-	reference	-
Yes	.034	.138	-.016	.551	.010	.669	.114	**<.001***
Educational Status								
No College	reference	-	reference	-	reference	-	reference	-
Some College	-.014	.550	.018	.472	-.010	.690	.013	.559
College Graduate	.009	.707	.029	.274	.068	**.009***	-.034	.142
Graduate School	-.023	.328	.035	.175	.042	.097	-.031	.187
Total Household Income								
$0-39,999	reference	-	reference	-	reference	-	reference	-
$40,000-59,999	<.005	.800	.000	.994	-.041	.065	-.019	.333
$60,000-79,999	-.008	.693	.020	.371	.031	.169	-.037	.066
$80,000-99,999	-.573	.567	.050	**.031***	-.016	.487	-.034	.093
$100,000-119,999	-.025	.226	.060	**.009***	.036	.113	.043	**.035***
$120,000 or greater	-.022	.330	.041	.102	.011	.647	.012	.574
Employment Status								
Full-time	reference	-	reference	-	reference	-	reference	-
Part-time	.006	.848	.003	.885	.020	.337	-.002	.909
Not employed	.032	.772	-.053	**.013***	-.038	.067	-.061	**.001***
Retired	.042	.108	.004	.850	.007	.771	-.004	.859

Table 5 (continued).

First Primary Cancer Diagnosis[a]								
Breast	reference	-	reference	-	reference	-	reference	-
Testicular	.042	.111	-.045	.119	.039	.177	.002	.953
Colorectal	.042	**.045***	.029	.220	.053	**.021***	.009	.658
Hematological	.010	.669	-.006	.823	.011	.680	.013	.572
Prostate	.018	.481	.000	.988	-.065	**.017***	-.013	.589
Other	.034	.194	-.010	.739	.017	.541	-.011	.664
Time since Last Treatment, years				.				
<1	-.020	.482	-.019	.571	-.011	.745	-.035	.213
1-4	reference	-	reference	-	reference	-	reference	-
5-9	-1.311	.190	-.082	**.011***	-.008	.805	-.007	.806
≥10	-1.229	.219	-.997	.319	-.055	.138	.003	.935
Stage of Survivorship[a]								
Prefer not to answer/unsure	-.015	.434	.005	.826	.026	.193	-.021	.256
Currently on treatment	.041	.076	1.076	.282	-.347	.729	.012	.598
Living with cancer as a chronic	.057	**.006***	-.175	.861	-1.373	.170	.007	.722
illness	-.031	.277	-.279	.781	-.017	.606	.040	.159
Less than 1 year post-treatment	reference	-	reference	-	reference	-	reference	-
1-5 years post-treatment	-.015	.686	.086	**.029***	-.011	.772	.046	.194
Greater than 5 years post-treatment								
Cancer Treatment								
No chemotherapy	reference	-	reference	-	reference	**-**	reference	**-**
Chemotherapy only	-.007	.725	.030	.204	-.245	.807	.056	**.007***
Chemotherapy plus surgery and/or radiation	.037	.091	.033	.170	.047	**.046***	.046	**.029***
Survivorship of Multiple Primary Cancers	.046	**.021***	-.012	.585	2.899	**.004***	.011	.562

Notes. [a]Variables with statistically significant differences between single cancer and multiple primary cancer groups in *t*-tests and χ^2. Theoretically-guided variables from the literature were determined *a. priori* and were also included in the multivariate model. *Statistical significance, p<.05.

3.2.5 Discussion

Most striking in this study was the association between MPC and psychological distress, which was consistent with our recent review of literature (Belcher et al., 2016). Consistent with findings in a cohort of MPC survivors 10-20 years older than the MPC survivors in our sample (Gotay et al., 2007; Thong et al., 2013), survivorship of MPC did not predict benefit finding as a result of one's cancer experience. An unexpected finding unique to this study was that MPC survivors were more likely than single cancer survivors to report "living with cancer as a chronic illness" when asked to identify their stage of survivorship. This finding may indicate that MPC survivors face additional survivorship needs related to chronic illness and warrants additional study. Living in a state of chronic illness may be contributing to chronic stress and increasing risk for physical and psychological disease in this population (Corbin & Strauss, 1988; Dowrick, Dixon-Woods, Holman, & Weinman, 2005; Grady & Gough, 2014; Miller et al., 2002).

Consistent with other MPC studies, we found that MPC survivors differed from single cancer survivors, in that they were older (Andrykowski, 2012; Thong et al., 2013) and had experienced more time since their initial cancer diagnosis (Burris & Andrykowski, 2011). However, the MPC survivors represented by this LIVE**STRONG** cancer survivor sample were, on average, approximately 11-18 years younger than those currently represented in previous MPC literature (Andrykowski, 2012; Burris & Andrykowski, 2011; Gotay et al., 2007; Thong et al., 2013). Additionally, MPC and single cancer survivors in this sample also differed by type of initial cancer diagnosis, with MPC survivors being less likely to have had breast cancer as their first diagnosis and more likely to fit into the "other" category (i.e., ovarian, uterine, and thyroid cancer). With differing cancer types come differing treatments and cancer treatment experiences. Thus, additional research is needed to determine the complex implications of differing diagnoses and treatments on health outcomes in MPC survivors.

While this study did not find statistical differences for income between groups, MPC survivors were less likely to be employed full time and more likely to be retired. Other

preliminary work by our team has found that MPC survivors with recurrent ovarian cancer were more likely to endorse lower income and difficulty meeting basic needs than survivors with recurrent ovarian cancer “only” (Belcher et al., 2015). Another study found that MPC survivors experienced greater levels of lost productivity (e.g., employment) as compared to individuals without cancer and to survivors of single cancers (Dowling et al., 2013). With respect to partner status, we found that being divorced or widowed was more common in MPC survivors, though post-hoc testing with Bonferroni adjustments for Type I error did not identify statistical differences. Partner status, both divorced or widowed and married, was predictive of psychological stress. A study from the Netherlands found that MPC survivors report greater cancer impact on life, including body changes and interference with social activities (Thong et al., 2013). When viewed in context with findings from previous studies, results from this study support further examination of the impact of MPC on work and social role function in future MPC studies.

MPC survivors were more likely to report positive healthcare utilization, including engagement in cancer screenings and regular medical appointments. Similarly, Thong and colleagues (Thong et al., 2013) found that MPC presence was associated with greater health awareness. Conversely, MPC status was not associated with healthy lifestyle behaviors such as diet and regular exercise, which was consistent with Burris and Andrykowski’s findings that those with MPC were more likely than single cancer survivors to have unhealthy behaviors (i.e., physical inactivity, smoking, and alcohol use). This may reflect a maladaptive behavioral coping response and warrants additional study in MPC survivors. As day-to-day chronic disease management responsibility shifts from providers to individuals (Barlow et al., 2002; Ryan, 2009), interventions to support survivors in initiating and maintaining healthy behaviors will be increasingly important in limiting exacerbation of existing conditions and preventing new conditions.

Weaknesses in this study are acknowledged. Given the cross-sectional design, causal or temporal relationships between variables cannot be determined. Secondary analysis is limited to questions posed in the dataset, and information about psychological distress severity was not collected. Although we could account for 8% of variance in psychological distress in this large sample of cancer survivors, this suggests that there are other important factors that were not able to be included in this secondary data analysis, such as comorbidities, symptoms, physical function, perceived stress, social support and coping resources, self-management behaviors, financial toxicity, and biological stress responses. Additionally, MPC survivors represented 5.7% of our sample, which is slightly less than the 8% MPC representation that is typically found in the overall cancer survivor population (Mariotto, Rowland, Ries, Scoppa, & Feuer, 2007). By conservatively excluding cases in which survivors reported a common site of metastasis as their second cancer, it is possible that we may have excluded true MPC cases from our analyses. Also, it has previously been reported that LIVE**STRONG** respondents are younger, less diverse, more educated, and wealthier than would be expected, which may be due to the voluntary, online nature of this survey (Low et al., 2014; Rechis et al., 2011) and may lead to decreased generalizability to the general cancer survivor population. However, this study expands what is currently known about MPC survivors by capturing a sample of survivors at an earlier age than has previously been described. Lastly, missing data, mostly in health behavior outcomes, may bias findings. Because rates of missingness were similar for variables between groups, we included as many cases as possible for both groups and presented all available data.

Strengths of this study include the ability to capture a large sample of post-treatment MPC survivors, to provide data on a younger demographic of MPC survivors than has previously been reported, the use of both negative (psychological distress) and positive (benefit-finding and health promotion behaviors) responses as independent outcomes, and models adjusted for a wide range of potential confounding variables.

3.2.6 Implications for Nursing

Nurses are uniquely positioned to support unmet needs in MPC survivors. Nurses should be aware that survivorship needs may differ in cancer survivors based upon number of previous cancer diagnoses, and that the survivorship experience may differ between MPC and single cancer survivors. Additionally, MPC survivors are at an increased risk for psychological distress and may have additional needs related to living with cancer as a chronic illness (e.g., engaging in positive self-management behaviors such as healthy diet and exercise). Targeted and ongoing screening for distress in MPC survivors is warranted in specialty and/or primary care settings and may promote early identification and treatment to reduce potential negative downstream health effects.

Oncology nurse scientists should contribute to building the science in this area to identify, understand, and address the unique needs of MPC survivors. As the number of cancer survivors diagnosed with MPC grows, number of primary cancer diagnoses should be considered in study designs. While an early body of literature has begun to describe the prevalence of health outcomes in MPC survivors, a paucity of research exists surrounding mechanisms and risk factors for late and long-term effects of cancer and their potentially unique needs. Also unclear is whether the potential for care silos and lack of a clinical home influences health outcomes in MPC survivors. Nurses are well suited to study, assess, and address MPC care needs.

3.2.7 Conclusions

Cancer survivors are increasingly being diagnosed with additional subsequent primary cancers. Our findings provide additional evidence that MPC survivors differ from their single cancer counterparts and are at increased risk for psychological distress. Our findings support a need to specifically identify, understand, and address the ongoing, unique needs of MPC survivors. Additional research is needed to identify MPC survivors most at risk for poor outcomes and to

understand the care needs and mechanisms that contribute to poor health outcomes in this growing cancer survivor population.

3.2.8 Acknowledgements

Portions of this study have been presented in poster and abstract forms at the 8th Biennial Cancer Survivorship Research Conference, Washington, D.C, on June 16, 2016

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3.3 DISSERTATION MANUSCRIPT 3: DISSERTATION AIMS 1 AND 2

Adapting a Psychobehavioral Stress-Response Model to Characterize Risks in Survivors of Multiple Primary Cancers

3.3.1 Abstract

Objective: The purpose of this study was to evaluate hypothesized relationships in an adapted psychobehavioral stress-response model among adults with multiple primary cancers (MPC). We aimed to 1) test the hypothesized model to examine associations among measured latent variables: perceived stress, psychological and behavioral responses, financial toxicity, and social role and physical health and 2) explore associations between individual characteristics and latent variables in the model.

Methods: This cross-sectional study of MPC survivors included participants whose first cancers (stages I-III) were diagnosed within 1-10 years. Participants were recruited through a regional tumor registry. Participants completed a battery of valid questionnaires to measure latent variables and covariates; data were extracted from tumor registry and medical record data. Structural equation modeling (SEM) was performed to fit and modify the measurement model, specify the full SEM, and identify significant predictors.

Results: 211 participants completed surveys. Data fit a modified four-factor measurement model with latent variables including self-management, distress, financial toxicity, and functional health. Overweight BMI, graduate level education, less neuroticism, and increased social support predicted better self-management. Poorer self-management, greater neuroticism, and lower social support predicted increased distress. Greater distress predicted financial toxicity. Greater distress and financial toxicity predicted poorer functional health.

Conclusions: Self-management behaviors and distress are modifiable targets with potential to mitigate financial toxicity and improve functional health. MPC survivors with extreme BMIs, less education, greater neuroticism, and lower social support should be considered at risk for poorer self-management and negative downstream health outcomes.

Keywords: multiple primary cancers; subsequent primary cancers; cancer survivorship; biobehavioral oncology; health behaviors; self-management; distress; financial toxicity; health outcomes; conceptual model

3.3.2 Introduction

As the population ages and cancer survival improves, the incidence of subsequent, or multiple, primary cancer (MPC) diagnoses is also increasing. Three million, or one in five, U.S. cancer survivors are diagnosed with an additional cancer in their lifetime (Morton et al., 2014), which increases to one in four for cancer survivors over 65 years old (Murphy et al., 2017). MPCs are histologically distinct cancers that have been ruled out as metastatic disease (Begg, 1999) and are a leading cause of morbidity and mortality among cancer survivors. Risk for psychological distress, risky health behaviors, and poorer physical health is greater in MPC survivors than in single- and no-cancer controls (Andrykowski, 2012; Belcher et al., 2017; Belcher et al., 2016; Burris & Andrykowski, 2011; Dowling et al., 2013; Gotay et al., 2007; Thong et al., 2013). Additionally, there is evidence to suggest that MPC survivors may be at increased risk for financial toxicity and impaired social functioning (Belcher et al., 2015; Dowling et al., 2013; Thong et al., 2013).

An adapted psychobehavioral stress model was used to identify pathways linking stress to poor health outcomes. Perceived stress is the perception that one's demands exceed his or her coping resources (Lazarus & Folkman, 1984), which, if left uninterrupted, can result in a cascade of psychological, behavioral, and biologic responses that negatively impact health outcomes. Links between perceived stress, psychological responses (e.g., depression, anxiety) and behavioral responses (e.g., positive self-management and risky health behaviors), and physical health outcomes (e.g., physical function, symptoms, and comorbidities) have been well established (Andersen et al., 1994; Andersen et al., 2008; Bower & Lamkin, 2013; Cohen et al., 1995; Sherwood et al., 2008).

Additional pathways (see Figure 6) impacting financial and social outcomes are also important in this adapted model. Financial toxicity is increasingly recognized as a potential consequence of cancer and cancer treatment (Zafar & Abernethy, 2013; National Cancer Institute, n.d.-a). and has been linked to poor treatment adherence and mortality (Kent et al.,

2013; National Cancer Institute, 2018c; Park & Look, 2018; Ramsey et al., 2016;). MPC is a known risk factor for financial toxicity (Belcher et al., 2015; Dowling et al., 2013; National Cancer Institute, 2018c). Cancer is also known to impact social function (i.e., involvement in and satisfaction with one's usual social relationships and activities) (Bode et al., 2010; Costa, Mercieca-Bebber, Rutherford, Gabb, & King, 2016; Hahn, Cella, Bode, & Hanrahan, 2010; Syrjala & Yi, 2018). Having MPC has been associated with interference in a range of life and social role activities (e.g., availability to family, not being understood, impact on daily activities) and limitations in ability to do work (Dowling et al., 2013; Thong et al., 2013).

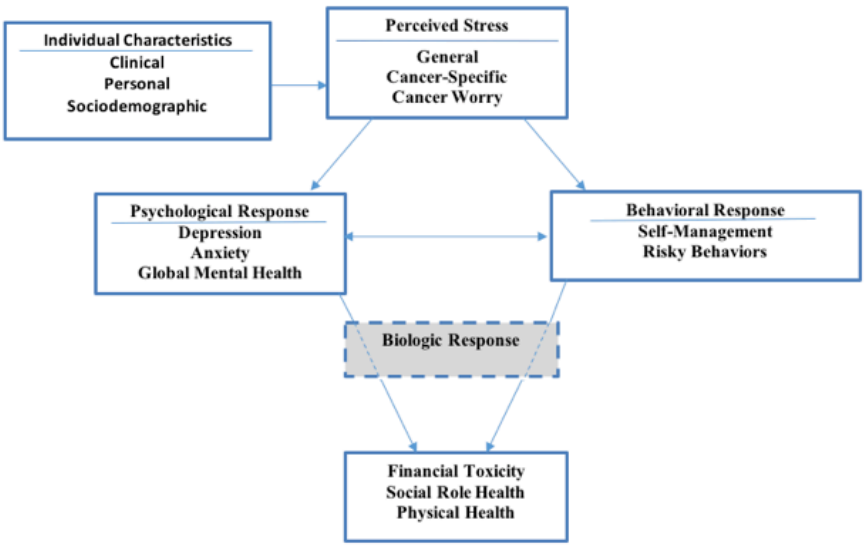

Figure 6. Conceptual model. This figure depicts the cascade of psychological, behavioral, and biologic responses to perceived stress that can negatively impact health outcomes in adults with multiple primary cancers. Biologic responses will be investigated in future studies.

Despite the rising prevalence of MPC and associated poor health outcomes, there is a lack of research examining potential pathways linking MPC to negative outcomes, and research in this patient population has lacked conceptual models to guide inquiry. The purpose of this study, the first to evaluate hypothesized relationships within an adapted psychobehavioral stress-response model in MPC, is to 1) identify important factors associated with negative

health outcomes and 2) guide early identification of MPC survivors at risk for poor health outcomes.

Specifically, the primary aim was to test the hypothesized model using structural equation modeling to examine the linear relations among the measured latent variables of perceived stress, psychological response, behavioral response, financial toxicity, social role function, and functional health. It was hypothesized that:

1. Perceived stress has direct effects on a) psychological response, b) behavioral response, c) financial toxicity, d) social role function, and e) physical health;
2. Behavioral response has direct effects on a) psychological response, b) financial toxicity, c) social role function, and d) physical health; and
3. Psychological response has direct effects on a) financial toxicity, b) social role function, and c) physical health.

The secondary aim was to explore individual, sociodemographic, and clinical characteristics that may directly impact upstream latent variables in the model.

3.3.3 Methods

3.3.3.1 Sample and setting. An honest broker system was used to recruit participants through the UPMC Cancer Network Registry, a member of the National Program of Cancer Registries who report to the larger Pennsylvania Cancer Registry ("Cancer registry requirements," n.d.). Study eligibility criteria included a history of two primary cancers based on Surveillance, Epidemiology, and End Results (SEER) Program coding rules (Johnson et al., 2007), with first cancer sites consistent with most prevalent first diagnoses experienced by adults living after MPC diagnoses: female breast, prostate, colorectal, urinary bladder, uterine, melanoma, kidney and renal pelvis, lung and bronchus, oral cavity and pharynx, thyroid, or ovary (American Cancer Society, 2009). Additional query criteria included first diagnoses 1-10 years ago; stage I-III cancers at time of diagnosis (both first and second primary cancers); and able to read and complete questionnaires in English. Cases of non-melanoma skin cancer; in situ cancer;

advanced staging (i.e., stage IV) at diagnosis, and recurrent cancers were excluded from the query. Additional study exclusion criteria included being listed in the corporate opt-out database and being deemed not appropriate for contact based on physician champion review of cases. Sampling was conducted using stratified systematic sampling by disease type with oversampling of individuals from traditionally underrepresented races and ethnicities.

3.3.3.2 Study procedures. Participants were recruited, and cross-sectional data were collected using a series of contacts based on a modified version of Dillman's Tailored Survey Method (Dillman et al., 2014). The honest broker system was used to identify prospective participants and invite study participation. Letters of invitation were signed by physician champions, and follow up reminder postcards were mailed to individuals who did not respond to initial contact. Participants could either complete the survey online via Qualtrics, an Institutional Review Board (IRB) approved, Web-based survey system (University of Pittsburgh Computing Services and Systems Development, n.d.), or request a postage-paid paper survey via mail, email, or telephone. Informed consent was obtained based on mode of selected survey delivery. Partially completed online surveys prompted reminder emails on Days 5, 10, and 21 following survey invitations. For study packets that had not been returned, reminder postcards were sent on Day 14, and additional follow-up contacts were made via participant-initiated mode of contact on Day 21. Following survey completion, participants were sent a thank you card or email message and compensated with a five-dollar Amazon code. Individuals who did not wish to participate were asked to complete a voluntary, anonymous refusal form, either online or on paper, that included five basic sociodemographic questions. Key clinical variables were obtained from both the Cancer Registry database and medical record review. This study was approved by the University of Pittsburgh IRB.

3.3.3.3 Instruments. A battery of valid and reliable measures was administered to operationalize model latent variables. Short forms and common measures were administered when possible to decrease participant burden and increase generalizability. PROMIS measures

were scored using individual participant response pattern scoring through the online Assessment Center Scoring Service;[SM] for resulting T-scores, 50=average, while T-score=60 is one standard deviation higher, or better, than average (Cella, Gershon, Bass, & Rothrock, 2017). When no information was available regarding number of items required to scale a score, item scores were imputed if at least 80% of scale items were completed.

3.3.3.3.1 Sociodemographic, personal, and clinical predictors.

Sociodemographic. An adapted self-reported instrument (Sereika & Engberg, 2006) was administered to assess sociodemographic variables (e.g., age, gender, race, partner status, education, and employment).

Personality. The neuroticism and conscientiousness domains of the International Personality Item Pool (IPIP), mini, were administered to assess personality (Donnellan et al., 2006; Goldberg, 1999). Each 4-item subscale is scored 1 (*very accurate*) to 5 (*very inaccurate*), with higher sum scores indicating greater neuroticism and conscientiousness.

Social support. The 12-item Interpersonal Support Evaluation List (ISEL-12) was used to measure perceived social support. Items, rated 1 (*definitely* true) to 4 (*definitely* false), are summed, with higher total scores indicating better perceived social support.

Clinical variables. First cancer site and time from first cancer diagnosis was obtained from the Cancer Registry. Second cancer site, time from second cancer diagnosis and treatment, time between cancer diagnoses, more than 2 primary cancer diagnoses, and body mass index (BMI) were extracted from the medical record.

3.3.3.3.2 Latent variables.

Perceived stress. Three measures were used to capture the latent variable of perceived stress. The 10-item Perceived Stress Scale (PSS) captures global perceived stress (Cohen et al., 1983; Golden-Kreutz et al., 2004) on a 0 (*never*) to 4 (*very often*) scale. The PSS total summary score ranges from 0 to 40, where higher scores suggest greater perceived stress. The Revised Impact of Event Scale (IES-R) was used to assess cancer-specific stress (Salsman et

al., 2015; Weiss, 2007; Weiss & Marmar, 1997). The IES-R, with 22 items rated 0 (*not at all*) to 4 (*extremely*), produces a summary total score ranging from 0 to 88, where higher scores indicate greater cancer-specific stress. The 3-item Cancer Worry subscale of the Assessment of Survivor Concerns scale was used to measure cancer survivor stress related to future tests, new diagnoses, and recurrences (Gotay & Pagano, 2007; Thewes et al., 2012). Worry items are rated on a 4-point Likert scale, from 1 (*not at all*) to 4 (*very much*), and are summed to yield a summary score ranging from 3 to 12. Higher cancer worry subscale scores are indicative of greater worry. In the current study, the combined measures of perceived stress demonstrated acceptable internal consistency (standardized Cronbach's α = .75).

Psychological responses. Three measures were used to capture the psychological response latent variable. Two-item Personal Health Questionnaire (PHQ) depression and Generalized Anxiety Disorder (GAD) short form scales were used to measure depression and anxiety, respectively (Kroenke et al., 2003, 2007; Löwe, Kroenke, & Gräfe, 2005; Plummer, Manea, Trepel, & McMillan, 2016; Whooley, Avins, Miranda, & Browner, 1997). Items from each scale, ranked 0 (*not at all*) to 3 (*nearly every day*), produce sum scores ranging from 0 to 6; scores $\geq$3 should prompt further clinical assessment. The 10-item Global Mental Health subscale of the PROMIS Global Health measure (Hays et al., 2009; HealthMeasures, 2017), version 1.0, was used to assess global mental health. Raw scores were converted to v1.2 format and submitted to the Assessment Center Scoring Services website for cancer sample calibrated scoring as T-scores. Internal consistency of the combined psychological response measures in this sample was good (standardized Cronbach's α = .85).

Behavioral responses. Three measures were used to capture the behavioral response latent variable. The 40-item Health Education Impact Questionnaire (hei-Q) (Elsworth et al., 2015; Maunsell et al., 2014; Osborne et al., 2007) assess eight domains of self-management behaviors including health-directed activities (HAD); positive and active engagement in life (PAE); emotional distress (ED); self-monitoring and insight (SMI); constructive attitudes and

approaches (CAA); skill technique and acquisition (STA); social integration and support (SIS); and health service navigation (HSN). Items are ranked 1 (*strongly disagree*) to 4 (*strongly agree*), and are averaged to produce mean subscale scores, with higher scores indicating better self-management (except the emotional distress subscale, which is interpreted inversely). The PROMIS Alcohol Use short form 7a (Patient-Reported Outcomes Measurement Information System, 2014; Pilkonis et al., 2016) was administered to assess alcohol use. Respondents who reported alcohol use were administered six additional items, ranked on a 1 to 5 scale, with higher raw sum scores, calibrated against a chronic illness sample, indicating greater consumption (scale range 5-25; negative screens=0). The Cancer Patient Tobacco Use Questionnaire (CTUQ) was used to assess tobacco use (Land et al., 2016; National Cancer Institute, 2016), yielding data for calculation of pack-year-history. In the current study these combined measures of behavioral response demonstrated questionable internal consistency (standardized Cronbach's α = .67); when alcohol and tobacco use were later dropped from multivariate analyses, acceptable internal consistency was achieved for the set of heiQ subscales (standardized Cronbach's α = .77), leading to renaming the Behavioral Response latent variable as *Self-Management Behaviors*.

Financial toxicity. Two measures were used to capture the latent variable of financial toxicity. The first was the 11-item Comprehensive Score for financial Toxicity (COST), v1 (De Souza et al., 2016; De Souza et al., 2014). Items, ranked on a 5-point scale ranging from 0 (*not at all*) to 4 (*very much*), were summed to produce a total score, ranging from 0 to 44, where higher total scores indicate better financial wellbeing. The second, the Economic Hardship Questionnaire (EHQ) (Barrera et al., 2001), includes four subscales: inability to make ends meet (MEM), not enough money for necessities (MFN), economic cutbacks and adjustments (EA), and anticipation of future financial strain (FS), with higher scores indicating greater hardship. The 2-item MEM and FS subscales include items ranked 1 to 5 and yield mean subscale scores. The first 4-items from the MFN subscale, ranked 1 (*strongly agree*) to 5 (*strongly*

disagree), yield a sum score ranging from 4 to 20. The 9-item EA subscale consists of a checklist of adjustments made due to financial need, with *yes* endorsements summed to produce a 0-9 subscale score. Internal consistency of the combined measures in this sample was excellent (standardized Cronbach's α = .92).

Social role function. Two measures were used to capture the latent variable of social role function. The 8-item PROMIS Ability to Participate in Social Roles and Activities V2.0 and 8-item PROMIS Satisfaction with Participation in Social Roles short forms measure perceived ability to participate in social roles and activities and satisfaction with participation in usual roles and activities, respectively. Items are rated 5 (*never*) to 1 (*always*) and 1 (*not at all*) to 5 (*very much*) on the respective measures. Each measure was calibrated against the default social supplement sample yielding a T-score. Internal consistency in this sample was good (standardized Cronbach's α = .85).

Physical health. Three measures were used to capture the physical health latent variable. The 10-item PROMIS Physical Function 10a short form assesses limitation in physical function (Cook et al., 2016; Patient-Reported Outcomes Measurement Information System, 2015; Rose et al., 2014). Items are ranked 1 to 5 and yield a T-score, calibrated against a cancer sample. The 19-item MD Anderson Symptom Inventory (MDASI) (Aktas et al., 2015; Cleeland et al., 2000; Cleeland, 2016) was used to assess symptom burden, a mean composite of the top five of 13 rated symptoms in the sample (range=0-10, with higher scores indicating greater burden), and symptom distress, the overall mean of the 6 interference items (possible range=0-10, with higher scores indicating greater interference). The brief 10-item self-report comorbidity index was used to assess comorbidities (Charlson et al., 1987; Chaudhry et al., 2005). Weighted items were summed to create an index score, ranging from 0 to 25, with higher scores indicating worse comorbidity. Internal consistency of the combined measures in this sample was good (standardized Cronbach's α = .86).

3.3.3.4 Data analyses. Data for 215 participants were analyzed using IBM® SPSS® software, version 25 (IBM Corp., Armonk, NY) at significance level of .05 for two-sided hypothesis testing. Chi-square test of independence and independent sample t-tests for two-sided hypothesis testing were used to compare characteristics of respondents with nonrespondents. Descriptive statistics, frequency distributions, and exploratory analyses were performed to identify any data anomalies (i.e., normality, univariate and multivariate outliers, multicollinearity, missing data) and characterize the sample. Z-scores and Malahalanobis distance were assessed for univariate and multivariate outliers, respectively. Score alterations were applied to variables with extreme outliers (see Table 6 footnote). Reverse scoring was applied as necessary to achieve consistent direction among sets of measured variables in multivariate analyses. Due to scaling differences across measured variables, measured variables were re-scaled, such that variance of the measured variable was <10 to enhance model convergence. Confirmatory factor analyses were performed for groups of latent variables and the measurement model. Internal consistency of the sets of measured variable for each latent variable was evaluated using the standardized Cronbach's alpha (α) coefficient, where Cronbach's α >.7 is considered acceptable (George & Mallery, 2003).

SEM was performed in two stages. First, the measurement model was fit and modified. All of the measurement models were estimated employing robust maximum likelihood estimation to account for normality violations (Li, 2016). Next, the full SEM was then specified using Mplus, version 8.1 (Muthén & Muthén, Los Angeles, CA). Post-hoc model modifications were made to improve model fit and parsimony based on model test statistics, fit indices, and theory. The model chi-square test was evaluated for model fit. Additional practical fit indices were evaluated for model fit, and cut points were considered acceptable if: comparative fit index (CFI) $\geq$.95; Tucker-Lewis Index (TLI) $\geq$.95; standardized root mean residual (SRMR) $\leq$.08; root mean square error of approximation (RMSEA) $\leq$.06 (Hu & Bentler, 1999; Kenny, 2015; Little, 2013). Significance of standardized path coefficients was evaluated to determine paths to retain

in the final modified model. For the original SEM with a sample size of 206 with 309 degrees of freedom, the analyses had >.99 power for either the test of a close fit (i.e., $RMSEA_0 = .05$ vs $RMSEA_A = .08$) or exact fit (i.e., $RMSEA_0 = 0.0$ vs $RMSEA_A = .05$).

After model adequacy was determined, upstream paths were added to explore possible personal, sociodemographic, and clinical covariates for improved model fit and determination of significantly associated characteristics that may be used to identifying individuals at risk for poor downstream health outcomes.

3.3.4 Results

3.3.4.1 Sample statistics. The Cancer Registry identified 2233 people who were potentially eligible for study participation. Of these people, 62 (2.8%) were on the corporate "do not contact" list, and physicians requested that 46 (2.1%) not be contacted. After sampling, 1443 letters were mailed to the remaining potentially eligible individuals. Thirty-nine letters (2.7%) had undeliverable mailing addresses, 11 (0.8%) were deceased, and 2 (0.1%) had advanced Alzheimer's disease/dementia. This analysis used only complete cases, thus, four were dropped due to partial online survey completion (n=211). Of the remaining 1390 cases, 211 (15.2%) completed surveys (125 [59.2%] on paper; 86 [40.8%] online). See Figure 7 for recruitment flowchart. Five cases were also identified as being multivariate outliers and were also dropped from analysis (final sample size for multivariate analysis, n=206).

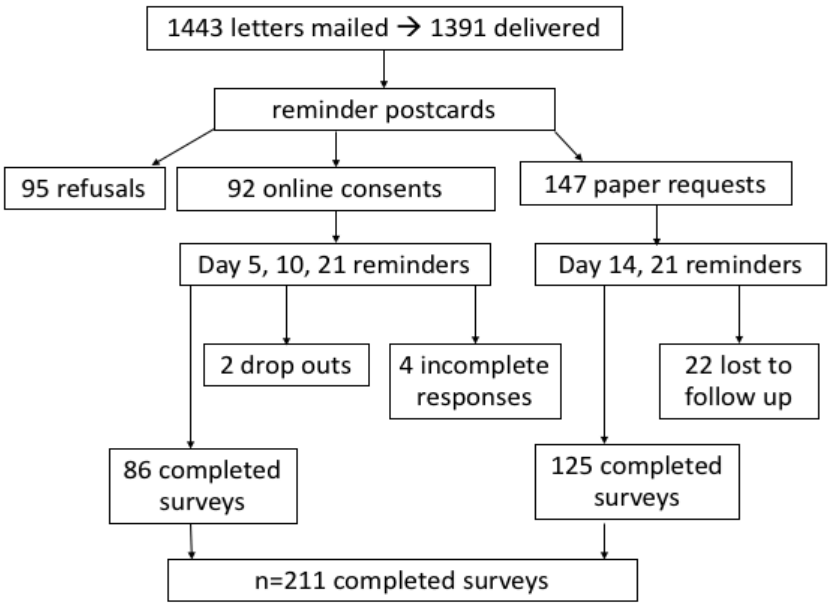

Figure 7. Study flow. This flowchart illustrates study recruitment.

Sociodemographic and clinical characteristics of 211 participants who completed the survey are summarized in Tables 6 and 7 (see also supplementary Tables 9-12). Participants were on average 67 years of age. The majority were female, white, married, retired, and insured. A broad range of educational levels was represented in the sample, with nearly 40% of participants having a high school level education or less. Over 30% of participants reported difficulty paying for basic needs. Neuroticism was in the lower quartile of the scale range, conscientiousness was in the upper quartile of the possible range (10 and 15, respectively), and perceived social support was fairly high (39).

On average, approximately six years had passed since participants' first cancer diagnoses, and the most common sites of first cancer diagnoses included lung, prostate, breast, thyroid, and melanoma. Most commonly identified sites of second cancer diagnoses identified via medical record data included breast, lung, thyroid, kidney, and melanoma. Irrespective of sequence, breast and prostate cancer were the most commonly diagnosed cancers in this sample (n=47 [22.3%] and n=45 [21.3%], respectively), followed by lung cancer (n=42 [19.9%]) (see supplementary Table 10 for complete list). Fifty percent of participants experienced their

first and second cancer diagnoses within a six-month time period. An average of approximately four years had passed since participants' cancer treatment completion, and almost 16% of participants had more than two documented primary cancer diagnoses. The most common combinations of first and second cancer sites diagnosed in this sample were second primaries in the same site: lung/lung (n=29, 9.8%); breast/breast (n=17, 8.3%); thyroid/thyroid (n=12, 5.9%); melanoma/melanoma (n=11, 5.4%) (full list available in supplementary Tables 11 and 12). Over 40% of participants were classified as obese (BMI ≥35), based on most recent records.

Table 6

Self-Reported Sample Characteristics (N=211)

Characteristics	Summary Statistics	
	Mean (SD)	Range
Current Age, years* (n=211)	67.1 (11.4)	29-89
Personality		
Neuroticism (n=211)	9.6 (3.7)	4-20
Conscientiousness* (n=211)	15.1 (3.2)	6-20
Social Support	39.1 (7.6)	15-48
	n	%
Gender (n=211)		
Female	128	60.7
Race/Ethnicity (n=211)		
White or Caucasian	196	93.0
Partner Status (n=211)		
Married/Living with Partner	147	69.7
Educational Attainment (n=209)		
High School/GED or less	81	38.8
Beyond high school through bachelor's degree	81	38.8
Master's Level or beyond	47	22.5
Difficulty Paying for Basic Needs (n=209)		
Not Difficult	142	67.9
Somewhat or Extremely Difficult	67	32.1
Employment Status (n=209)		
Retired, Not Working	109	52.2
Working Full-time (≥35 hours/wk)	39	18.7
Retired, Working Part- or Full-time	18	8.6
Disabled/Unable to Work	18	8.6
Full-time Homemaker	12	5.7
Working Part-time (<35 hours/wk)	10	4.8
Laid Off/Unemployed/Looking for Work	3	1.4
Healthcare Insurance (n=210)	208	99.0

Table 6 (continued).

Notes. SD = standard deviation.

*Values reflect score alterations applied to adjust for extreme values in multivariate analyses.

Table 7.

Sample Clinical Characteristics (N=211)

Characteristics	n (%)
First Cancer Diagnosis Site, (n=211)	
Lung / Bronchus	33 (15.6)
Prostate	30 (14.2)
Breast	26 (12.3)
Thyroid	22 (10.4)
Melanoma	21 (10.0)
Uterine Corpus (includes endometrial)	20 (9.5)
Kidney / Renal Pelvis	17 (8.1)
Colorectal	15 (7.1)
Urinary Bladder	12 (5.7)
Ovarian (includes fallopian tube)	8 (3.8)
Oral Cavity / Pharynx	7 (3.3)
Years from First Cancer Diagnosis, *Mean* (SD) (n=211)	5.8 (2.9); range: 0-11
Most Frequent Second Cancer Diagnosis Sites* (n=205)	
Breast	38 (18.5)
Lung / Bronchus	29 (14.1)
Thyroid	19 (9.3)
Kidney / Renal Pelvis	18 (8.8)
Melanoma	16 (7.8)
Most Frequently Diagnosed Cancer Site Patterns (First Cancer, Second Cancer) * (n=205)	
Lung, Lung	20 (9.8)
Breast, Breast	17 (8.3)
Thyroid, Thyroid	12 (5.9)
Melanoma, Melanoma	11 (5.4)
Bladder, Prostate	10 (4.9)
Years Since Second cancer Diagnosis, *Mean* (SD) (n=197)	4.0 (2.7); range: 0-10
Years Since Most Recent Cancer Treatment, *Mean* (SD) (n=204)	2.7 (2.9); range: 0-10
First and Second Cancers Diagnosed within 6 Month Timeframe (n=206)	102 (49.5)
More than Two Cancer Diagnoses documented in medical record (n=211)	33 (15.6)
Most Recent BMI by Category (n=209)	
≤18.5 (underweight)	5 (2.4)
18.5-24.9 (normal)	62 (24.9)
25.0-29.9 (overweight)	67 (32.1)
≥30 (obese)	85 (40.7)

Note. SD = standard deviation.

*See supplementary online material for complete list of second cancer diagnoses, frequencies of cancer sites diagnosed as either first or second cancer, and patterns of first and second cancer diagnoses.

Ninety-five individuals who did not participate in the study (8.0%) submitted anonymous refusal forms. While 18 of these individuals (18.9%) did not provide a refusal reason, top listed reasons for not participating included perceived ineligibility (e.g., "I've only had one cancer," n=20 [21.1%]), lack of time (n=17 [17.9%]), advanced age (n=12 [12.6%]), concern with accessing medical records (n=10 [10.5%]), and health issues (n=9 [9.5%]). Comparison of de-identified Cancer Registry data using independent sample t-tests and Pearson's chi-square tests of independence indicated that study participants were similar to non-respondents on all variables examined, including age, sex, race, marital status, primary payer at first diagnosis, years since first cancer diagnosis, and first cancer site (see supplementary online material, Table 13).

3.3.4.2 Description of key variables in the measurement model. Table 8 displays scores for all variables considered in the originally hypothesized measurement model.

Table 8.

Scores for Variables in the Originally Hypothesized Measurement Model (N=211)

Measures by Latent Variables	Descriptive Statistics	
	Mean (SD)	Range
Perceived Stress		
Perceived Stress, general (n=206)	13.0 (7.0)	0-31
Cancer-Specific Stress* (n=210)	14.7 (13.0)	0-58
Cancer worry (n=211)	7.5 (2.9)	3-12
Psychological Response		
Depression* (n=211)	1.0 (1.4)	0-5
Anxiety* (n=209)	.9 (1.3)	0-5.1
Global Mental Health (n=210)	48.4 (7.9)	29.0-62.4
Behavioral Response		
Self-Management		
Health Directed Activity (n=208)	2.9 (.7)	1.0-4.0
Positive and Active Engagement in Life (n=208)	3.3 (.6)	1.6-4.0
Emotional Distress (n=208)	3.1 (.6)	1.3-4.0
Self-Monitoring and Insight (n=208)	3.3 (.4)	2.0-4.0
Constructive Attitudes and Approaches* (n=208)	3.4 (.5)	1.7-4.0
Skill and Technique Acquisition* (n=208)	3.2 (.5)	1.7-4.0
Social Integration and Support (n=208)	3.2 (.6)	1.4-4.0
Health Service Navigation* (n=208)	3.4 (.5)	2.1-4.0
Alcohol Use$^{\infty}$ (n=105)	43.7 (5.0)	38-59.4
Tobacco Use: Pack-Year History* (n=205)	15.7 (26.4)	0-150

Table 8 (continued).

Financial Toxicity		
Financial Toxicity (n=205)	28.6 (10.2)	0-44
Economic Hardship		
Financial Strain* (n=209)	1.2 (.4)	1-2.3
Inability to Make Ends Meet (n=208)	2.0 (1.1)	1-5
Not Enough for Necessities (n=208)	1.9 (1.1)	1-5
Cutbacks and Adjustments* (n=209)	.9 (1.7)	0-6.2
Social Role Function		
Social Role Function Ability* (n=209)	52.3 (10.3)	25.9-65.4
Social Role Function Satisfaction* (n=210)	50.7 (10.9)	26.5-65.5
Physical Health		
Physical Function† (n=211)	46.7 (8.3)	29.1-55.2
Symptoms		
Symptom Burden (n=209)	2.2 (2.2)	0-8.6
Symptom Distress* (n=209)	1.5 (2.3)	0-10
Comorbidity Index (n=211)	4.8 (3.4)	0-15

Notes. SD=standard deviation.

*Values reflect score alterations applied to adjust for extreme values in multivariate analyses.

†Mean composite of top five most severely rated symptoms in sample (i.e., fatigue, drowsy, dry mouth, disturbed sleep, and pain).

∞Alcohol use scores can only be calculated for individuals who screen positive for consuming alcohol in the previous 30 days.

3.3.4.3 Measurement model. A confirmatory factor analysis was performed through Mplus. A six-factor model for stress, psychobehavioral responses, and health outcomes was originally hypothesized and is presented in Figure 8, where the factors or latent variables are represented by ovals, and measured variables are represented by rectangles. Absence of a line connecting variables implies no hypothesized direct effect. Indicators of factors for the six latent variables are described with instrument descriptions (see Section 3.3.3.3). All six factors were hypothesized to covary with one another in the measurement model.

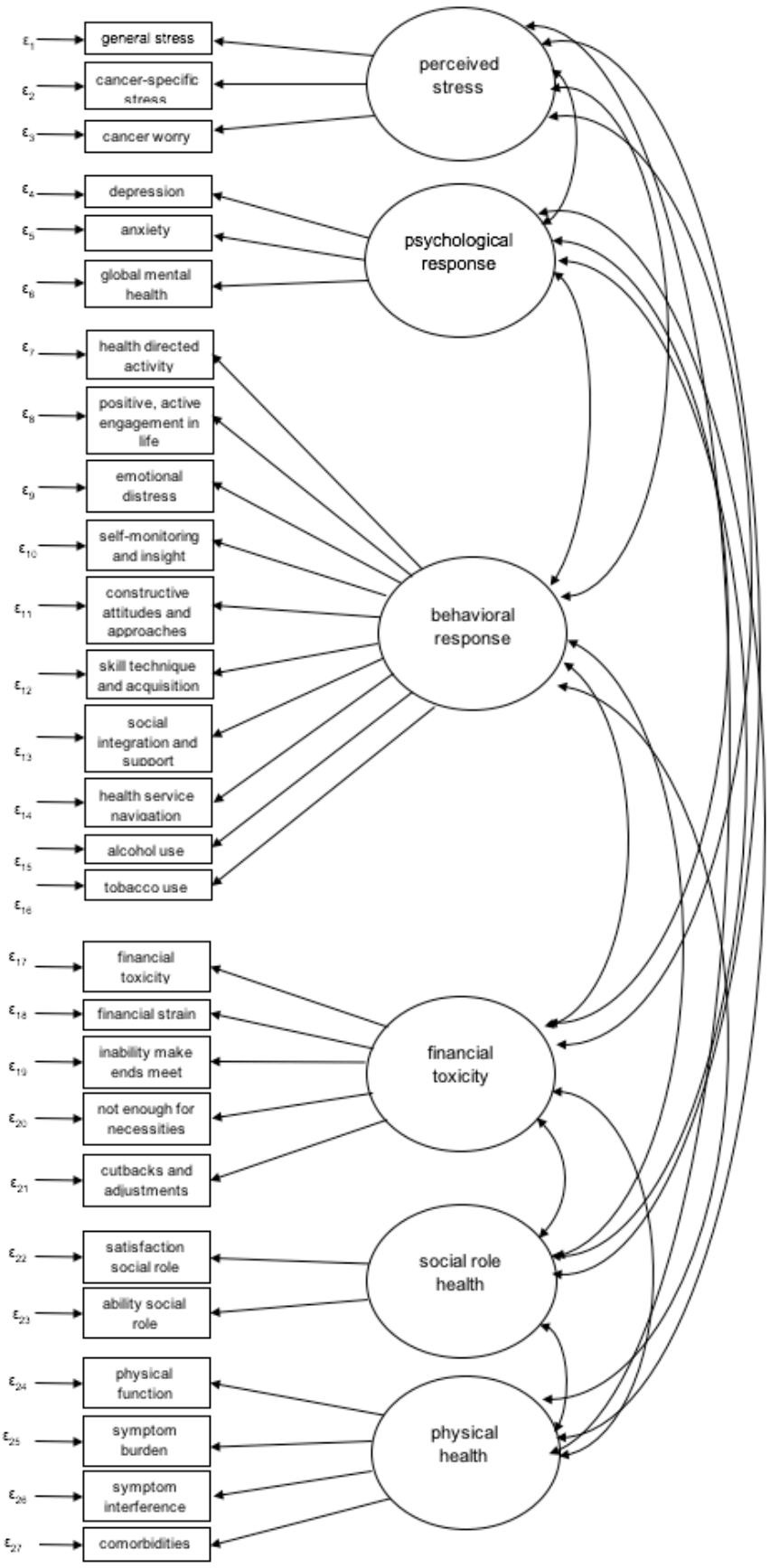

Figure 8. Originally hypothesized six-factor measurement model.

An examination of bivariate correlations and multicollinearity diagnostics suggested possible mild to moderate multicollinearity in the overall model, problematic model correlations, and a four-factor solution to the data. The following modifications, with specific rationales, were made as a result of the measurement model analyses. Measures of the stress and psychological response latent variables were reconceptualized and combined into a new latent variable, conceptualized as *Distress*, due to high correlations among these sets of variables. Measures of the social role function-ability and physical function latent variables were combined into a new latent variable, conceptualized as *Functional Health*, due to high correlations among these variables. The social role function satisfaction measure was dropped due to lack of conceptual congruence with functional health outcomes. The following observed behavioral response variables (the risky behaviors) were also dropped from the hypothesized measurement model: pack-year history and alcohol use (did not correlate well with other measures), heiQ emotional distress (cross-loaded onto many of the stress and behavioral response latent variables). Because of this, the behavioral response latent variable was renamed *Self-Management Behaviors*. Global mental health (cross-loaded onto the behavioral and psychological response latent variables) was also dropped from the measurement model. See modified four-factor measurement model in Figure 9.

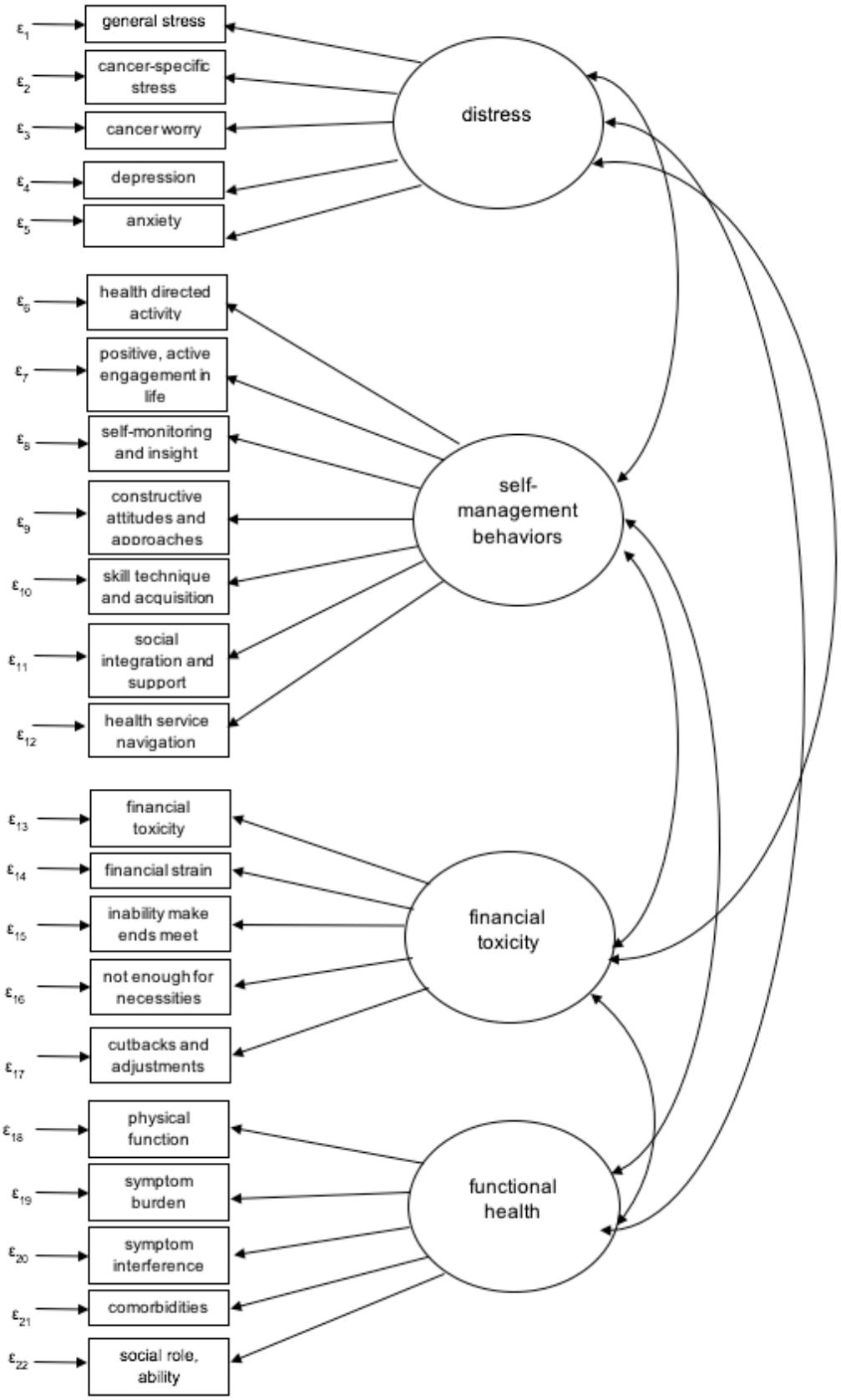

Figure 9. Modified four-factor measurement model.

3.3.4.3.1 Model fit and parameter estimation. Support was found for the modified four-factor measurement model, X^2 (203, *N* = 206) = 455.57, *p*<.01; TLI = .91, CFI = .92, SRMR = .06, RMSEA = .08, 90% confidence interval [CI] for RMSEA = [.07, .09].

To improve model fit, a series of post hoc model modifications were performed, allowing the following pairs of error terms to correlate: cancer-related stress and cancer worry; positive and active engagement in life and health directed activity; physical function and ability to participate in social roles and activities; social integration and support and self-monitoring and insight; and symptom distress and physical function. The final revised measurement model, illustrated in Figure 10, indicated a better fit X^2 (198, *N* = 206) = 331.32, *p* = .135; TLI = .95, CFI = .96, SRMR = .06, RMSEA = .06, 90% CI for RMSEA=[.05, .07].

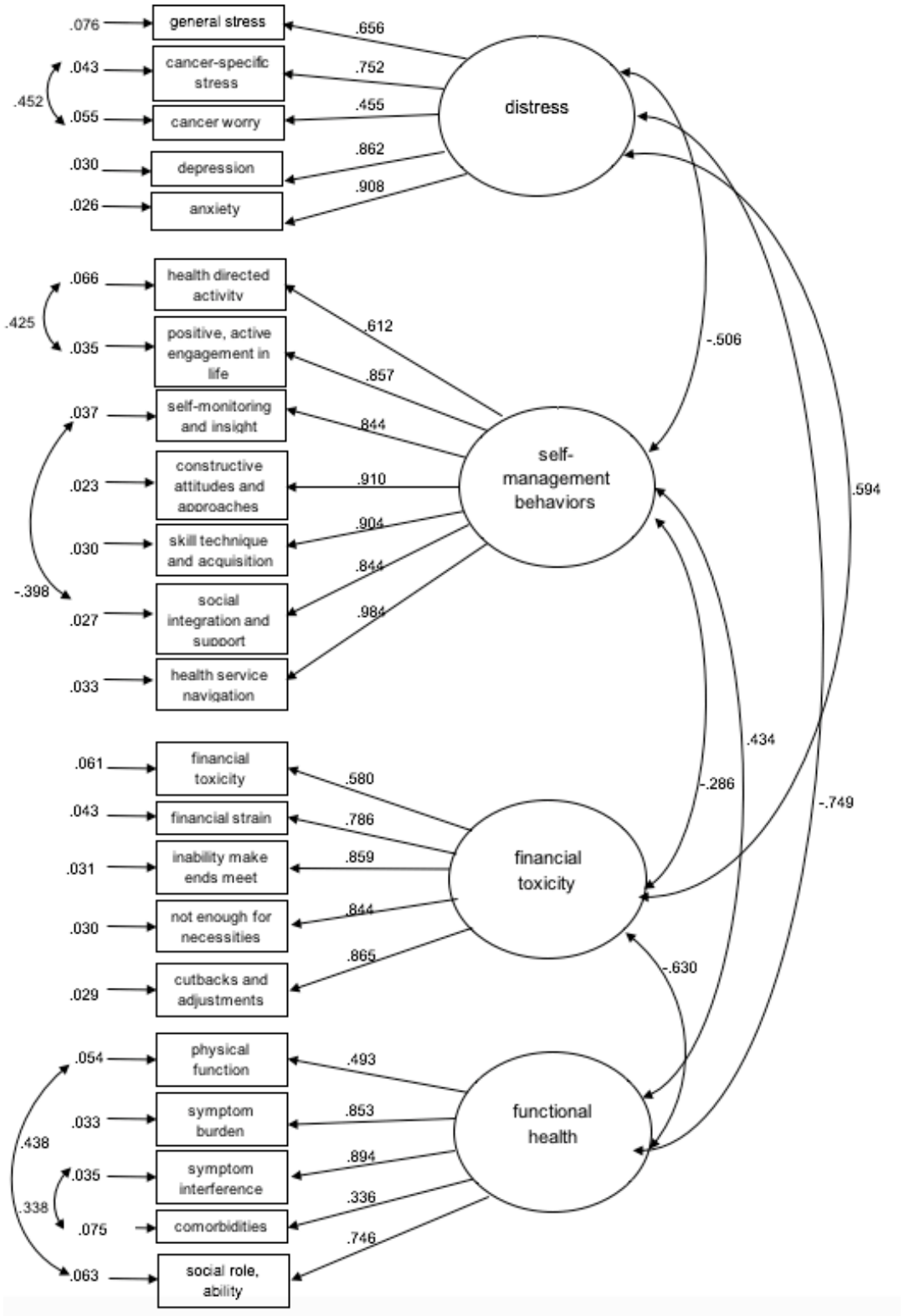

Figure 10. Modified four-factor measurement model. This figure includes factor loadings, error coefficients, and error term correlations.

3.3.4.4 Full structural equation model.

3.3.4.4.1 The hypothesized model. The hypothesized full structural equation model based on the modified four-factor measurement model is presented in Figure 11, where, again, ovals represent latent variables, and rectangles represent measured variables. Absence of a line connecting variables implies no hypothesized direct effect. Curved lines indicate correlated error terms between measured variables.

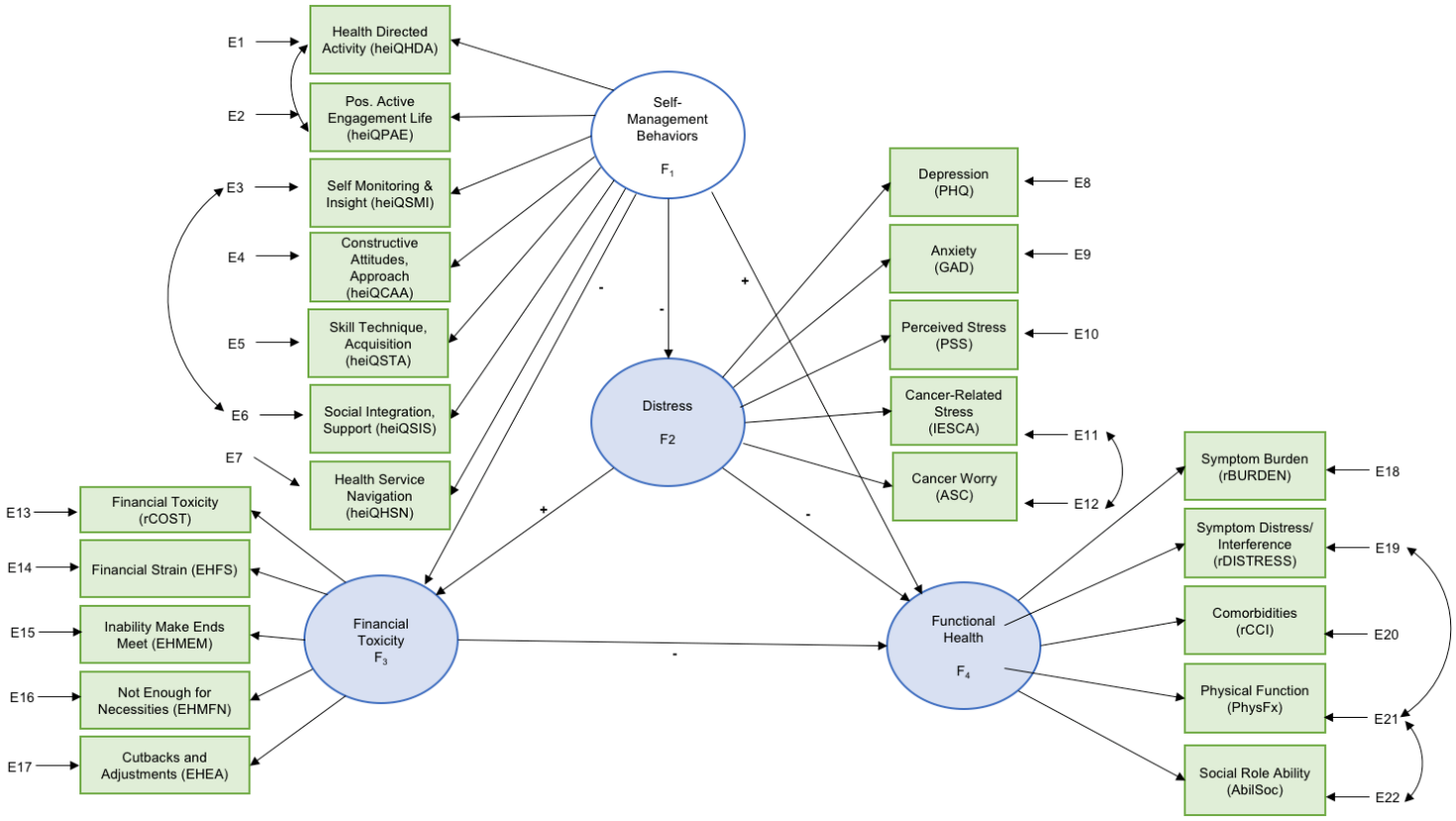

Figure 11. Hypothesized full structural equation model based on modified measurement model.

The hypothesized model examined predictors of financial toxicity and functional health. It was hypothesized that distress and self-management behaviors each directly predicted financial toxicity and functional health. Specifically, increased distress was hypothesized to directly increase financial distress and decrease functional health, and better self-management behaviors were hypothesized to directly decrease financial toxicity and increase functional

health. It was also hypothesized that distress served as an intervening variable between self-management behaviors and both financial toxicity and functional health.

Finally, it was hypothesized that, by adding upstream individual, sociodemographic, and clinical covariates, model fit would be improved. Specifically, the following variables were explored: personality (neuroticism and conscientiousness), age, social support, gender, educational attainment, marital status, difficulty paying for basic needs, years from first cancer diagnosis, years from treatment completion, time between first and second cancer diagnoses, and BMI.

3.3.4.4.2 Model fit and parameter estimation. Even though model fit was good based on study data (model 1), X^2 (198, *N* = 206) = 331.32, *p*<.01; TLI = .95, CFI = .96, SRMR = .06, RMSEA = .06, 90% CI for RMSEA=[.05, .07], there were two hypothesized paths that were not empirically supported: the direct path between self-management behaviors and financial toxicity (standardized coefficient = 0.02, p=.78) and the direct path between self-management behaviors and functional health (standardized coefficient = 0.08, p=.32).

Using model statistics and alignment with theoretical soundness, post hoc model modifications were performed in an attempt to develop a better fitting, more parsimonious model. Similar model fit was found by first removing the non-significant direct path between self-management behaviors and financial toxicity (model 2), X^2 (199, *N* = 206) = 331.46, *p*<.010; TLI = .95, CFI = .96, SRMR = .06, RMSEA = .06, 90% CI for RMSEA=[.05, .07], and then between self-management behaviors and functional health (model 3), X^2 (199, *N* = 206) = 331.93, *p*<.01; TLI = .95, CFI = .96, SRMR = .06, RMSEA = .06, 90% CI for RMSEA=[.05, .07]. Lastly, modest improvement to model fit but increased parsimony was achieved by removing both direct paths between self-management behaviors and financial toxicity and functional health (model 4) X^2 (200, *N* = 206) = 332.06, *p*<.01; TLI = .95, CFI = .96, SRMR = .06, RMSEA = .06, 90% CI for RMSEA=[.05, .07], see Figure 12.

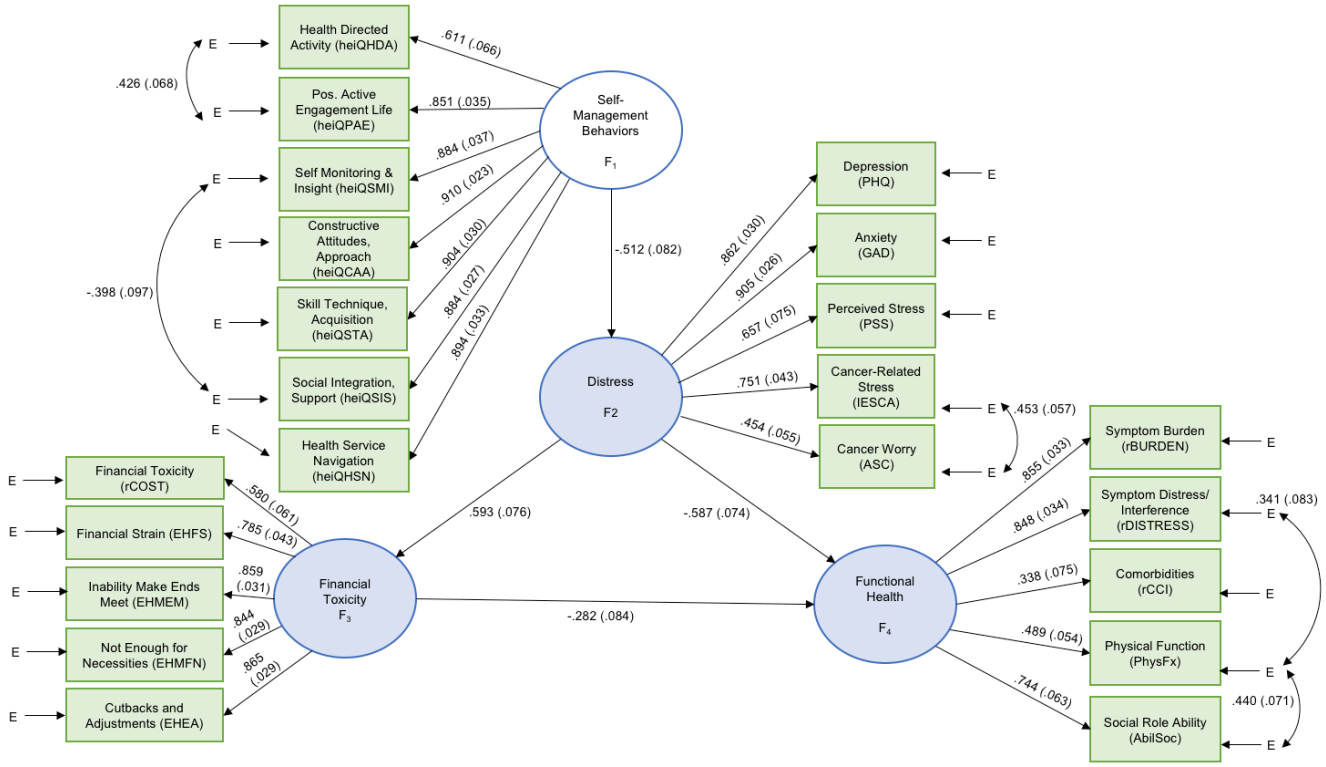

Figure 12. Final modified structural equation model based on modified measurement model. This figure includes standardized and unstandardized path coefficients and error term correlations.

3.3.4.5 Secondary aim. Additional exploratory modification testing was performed on model 4 to explore the impact of covariates as predictors of health behaviors on model fit. First, the model did not converge when all potential covariates were added as predictors of health behaviors. However, a final modified model that included neuroticism, social support, BMI (overweight versus normal and high risk [i.e., underweight plus obese]), and educational attainment (master's or higher versus less than high school and high school through bachelor's) predicting health behaviors and additional paths for neuroticism and social support predicting distress resulted in good model fit, X^2 (282, N = 206) = 511.13, p<.01; TLI = .92, CFI = .93, SRMR = .06, RMSEA = .06, 90% CI for RMSEA=[.05, .07]. Figure 13 shows the final parsimonious model with modifications for the retained statistically significant covariates.

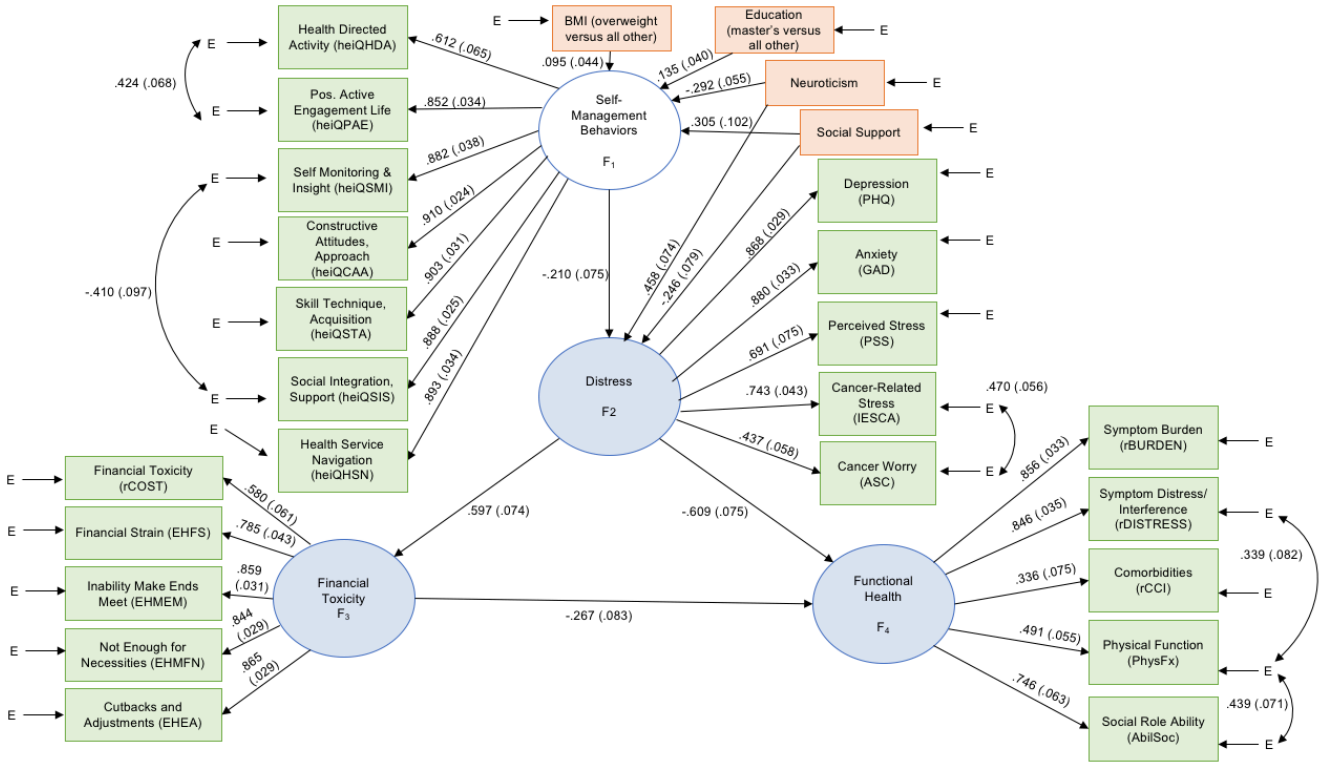

Figure 13. Final parsimonious structural equation model based on modified measurement model with significant covariates retained. This figure includes standardized and unstandardized path coefficients and error term correlations.

3.3.4.5.1 Direct effects. As hypothesized, increased financial toxicity was predicted by greater distress (standardized path coefficient = .60, p<.01) and poorer functional health was predicted by greater distress (standardized path coefficient = -.61, p<.01) and by financial toxicity (standardized path coefficient = -.23, p<.01). Increased distress was predicted by poorer self-management behaviors, greater neuroticism, and lower perceived social support (standardized path coefficients = -.21, .46, and -.25, respectively, p<.01). BMI (overweight), education (master's or greater), decreased neuroticism, and better perceived social support predicted better health behaviors (standardized path coefficients = .10, .14, -.29, .31, respectively, p<.01). Better behavioral responses did not significantly predict financial toxicity or functional health (unstandardized path coefficients = .12 and .04, respectively, $p \geq .05$).

3.3.5 Discussion

Using an adapted psychobehavioral stress-response model, this study was the first to identify pathways and individual risk factors associated with health outcomes in adults with MPC. The data in this study fit a modified four-factor measurement model, with latent variables including self-management, distress (combined perceived stress and psychological distress), financial toxicity, and functional health (combined social health and physical health). Self-management was the upstream latent variable identified in the final modified model; self-management behavior predicted the other latent variables, either directly (i.e., predicting distress) or indirectly (i.e., predicting financial toxicity and functional health through distress). In the expanded model, which included possible predictors (i.e., potential risk factors of poor self-management and increased distress), overweight BMI, graduate education, less neuroticism, and increased social support predicted better self-management; poorer self-management, greater neuroticism, and lower social support predicted increased distress.

Our originally hypothesized six-factor model was not empirically supported by the data in this study. As a result, latent variables, associated measurement variables, and pathway configurations were modified and reconceptualized based on empirical support and congruence with the literature, yielding a four-factor model. The four-factor model, with combined perceived stress/psychological response ("distress") and social role function/physical health ("functional health") variables, highlights important pathways among self-management behaviors, distress, financial toxicity, and functional health. Future studies should evaluate the validity of combining these measures. It is possible that the high correlations among these sets of variables was a consequence of study design and/or measurement issues. The original conceptualization of the perceived stress latent variable, the perception that one's demands overwhelm one's coping resources (Lazarus & Folkman, 1984), was meant to capture current stressors of general life demands, cancer-specific stress, and cancer worry. Conversely, the psychological response latent variable was mean to capture the longer-term (maladaptive) responses to the chronic

stress of cancer (National Comprehensive Cancer Network, 2018a) and included measures of depressive symptoms, anxiety, and mental health. It is possible that the cross-sectional nature of this study precluded distinguishing between these short- and long-term responses in MPC survivors who had been living with their diagnoses for, in some cases, multiple years. Similarly, social role ability and physical health measures loaded onto a combined factor, which we conceptualized as *functional health*. Ability to participate in social roles and activities does reflect a functional ability, but, again, further research is necessary to evaluate the validity of combining these different measures into a single latent variable. Finally, the PROMIS Global Mental Health measure we attempted to incorporate into this model loaded across many of the latent variables in the model, preventing us from using it in multivariate analyses.

Importantly, the four key constructs (self-management, distress, financial toxicity, and functional health outcomes) and their inter-relationships demonstrated in the final model, provide clear direction for future studies. Distress, which was predicted by self-management behaviors, significantly predicted both increased financial toxicity and poorer functional health. We hypothesize that increased distress may be impairing an individual's productivity, leading to financial toxicity, and that financial toxicity may be impacting an individual's functional health (e.g., through medication adherence). Further, we hypothesize that distress may be affecting functional health through biological pathways (e.g., triggered glucocorticoid receptor resistance, immune dysregulation, and risk for disease) (Cohen et al., 2012). It is also possible that mechanisms impacting an individual's risk for MPC (e.g., genetic predisposition, previous cancer treatment, negative health behaviors, etc.) may also influence health outcomes in this survivor population. Future studies should identify the individual and interacting influence of these different potential mechanisms.

Not all of the originally hypothesized pathways were found to be statistically significant. The direct pathway between self-management behaviors and financial toxicity was neither significant nor was it in the direction we had hypothesized; for financial toxicity, distress was a

more important direct predictor, while distress mediated the relationship between self-management and financial toxicity. Also, while the path coefficient did reflect the hypothesized direction, self-management behaviors also were not a significant direct predictor of functional health. The relationship, again, was mediated by distress.

Limitations are acknowledged in this study. Despite adequate power to conduct analyses, the response rate to study mailings (15.2%) was lower than expected and could have introduced bias into study findings. Several findings mitigate this concern. Study participants were similar in age, gender, ethnicity, and marital status to participants in previously recruited national MPC samples, despite being recruited from a regional cancer registry. Perhaps more importantly, study participants did not differ from nonparticipants identified by the Cancer Registry as potentially eligible for participation in this study on key variables including age, sex, race, marital status, primary payer at first diagnosis, years since first cancer diagnosis, and first cancer site. Also, while path analysis can seem to imply temporal or even causal relationships, the cross-sectional design of this study limits interpretation to associations among variables. Longitudinal studies could help to identify the temporal nature of relationships, while experimental studies will be required to understand whether relationships in the proposed model are causal in nature.

Several unique aspects of this sample and contributions to the science are noteworthy. First, as a result of our inclusion criteria, record validated clinical data verified that participants in this sample were closer to their first diagnosis (M= 5.8 years, SD=2.9), as compared to 11-17 years in other studies, providing the opportunity to examine a new cohort of MPC survivors not previously described (Belcher et al., 2016; Burris & Andrykowski, 2011; Gotay et al., 2007; Thong et al., 2013). This study also included cancer sites not frequently represented in MPC literature (i.e., lung and thyroid cancer). Additionally, this sample had higher than average BMI and rates of obesity (40.7%) when compared to the general U.S. population (36.5%), cancer survivors (31.1%) and other published MPC literature (27.4%) (Burris & Andrykowski, 2011;

Centers for Disease Control and Prevention, 2017; National Cancer Institute, 2018b). While not successful broadening racial and ethnic diversity of the literature in this study, we did recruit a sample of participants with a broad range of educational attainment, which is representative of the broader U.S. population (Ryan & Bauman, 2016). Importantly, educational attainment was identified as an important predictor of self-management in Aim 2 covariate analyses.

The data in this study support healthy self-management behaviors as vitally important to positive health outcomes in MPC survivors, and MPC survivors should be evaluated for poor health behaviors and distress, both of which are modifiable. This is particularly important among the subset of MPC patients at increased risk for poor health outcomes (i.e. those with less education, less social support, overweight BMI, and greater neuroticism). The National Cancer Institute recommends that individuals with MPC diagnoses be considered candidates for cancer risk assessment and counseling (i.e., clinical assessment, applicable genetic testing, and recommendations of risk management counseling) to guide screening and risk reduction interventions (National Cancer Institute, 2018a). Additionally, survivorship clinical practice guidelines (National Comprehensive Cancer Network, 2018b, 2018a) recommend clinical assessment of and individualized recommendations for healthy lifestyle and provide direction on ways to assess for and address key topics such as diet, activity, caloric balance, and brief distress screenings. Based on these data, clinicians should also increase their awareness of financial toxicity and engage their patients in care value discussions. As evidenced by the expertise needed to address the identified key clinical priorities in MPC patients, collaboration and communication among specialists (e.g., nutritionists, behavioral change experts, mental health professionals, financial experts, primary care providers, oncologists [potentially including more than one medical or surgical oncology team for cancer disease site specialists], and genetic counselors) is key.

These findings are also relevant to policy discussions. As recognized by recent literature documenting increasing rates of MPC in cancer survivors (Davidson, 2017; Murphy et al.,

2017), clinical trial eligibility criteria should be evaluated to determine representativeness of the U.S. cancer survivor population. Whenever possible, MPC status should not be an explicit exclusion criterion for clinical trial participation. Also, organizations should strive to create systems and policies that allow for continuity of care among providers in medically complex patients.

Future studies should evaluate and expand upon this refined model for studying health outcomes in adults with MPC, with a particular focus on self-management and financial toxicity, two newly highlighted areas of importance, and on identification of the individual and interacting influences of potential mechanisms impacting health outcomes in MPC survivors. Biological pathways also are an untapped line of inquiry in this patient population and could lead to increased understanding of the mechanisms linking distress to poor outcomes in this model. It is also important to move toward understanding how outcomes may differ among different subsets of MPC survivors (e.g., childhood versus adulthood diagnoses; MPCs associated with genetic cancer syndromes versus treatment-related MPCs versus MPCs associated with risky behaviors), as risk factors and health outcomes may vary among groups. It is possible that mechanisms impacting an individual's risk for MPC (e.g., genetic predisposition, previous cancer treatment, negative health behaviors, etc.) may also influence health outcomes in this survivor population and warrants future analysis.

Study design and recruitment are important considerations for the advancement of MPC science. Future research should move to longitudinal studies to 1) establish temporal relationships among key variables; 2) understand how MPC survivorship risk factors change over time; and 3) identify vulnerable phases in the MPC survivorship trajectory. With increased demands being placed on people's time and attention, survey response rates have been declining and costs have been rising (National Science Foundation, n.d.), and this type of data collection may be becoming outdated when attempting to recruit generalizable samples. Future MPC studies should also focus on novel recruitment methods of this hard to reach patient

population, as survivors do not all attend specialty MPIC clinics where targeted recruitment could occur. Attention should also be paid to addressing reasons provided for nonparticipation in this study (i.e., increased age, perceived ineligibility, privacy/accessing medical records). Future research must also focus on conducting studies that are sensitive to the challenges and perspectives of more diverse groups of MPC survivors.

3.3.6 Funding

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3.3.7 Conflict of interest disclosures

The authors have no conflicts of interest to disclose.

3.3.8 Acknowledgements

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3.3.9 Supplementary online material

Table 9

Frequencies of Second Cancer Diagnosis Sites (N=205)

Site	n (%)
Breast	38 (18.5)
Lung / Bronchus	29 (14.1)
Thyroid	19 (9.3)
Kidney / Renal Pelvis	18 (8.8)
Melanoma	16 (7.8)
Prostate	15 (7.3)
Lymphoma	14 (6.8)
Uterine Corpus (Endometrial)	13 (6.3)
Colorectal	9 (4.4)
Urinary Bladder	9 (4.4)
Oral Cavity, Pharynx, Larynx	7 (3.4)
Ovarian	5 (2.4)
Leukemia	2 (1.0)
Multiple Myeloma	2 (1.0)
Neuroendocrine Tumor	2 (1.0)
Cervical	1 (0.5)
Liver	1 (0.5)
Merkel Cell	1 (0.5)
Pancreatic	1 (0.5)
Sarcoma	1 (0.5)
Vulvar	1 (0.5)
Unknown Origin	1 (0.5)

Note. Data were not able to be obtained from medical records for 6 cases.

Table 10

Frequencies of Sample First or Second Cancer Diagnoses Sites (N=211)

Site	n (%)
Breast	47 (22.3)
Prostate	45 (21.3)
Lung / Bronchus	42 (19.9)
Uterine Corpus (Endometrial)	31 (14.7)
Thyroid	29 (13.7)
Kidney / Renal Pelvis	28 (13.3)
Melanoma	26 (12.3)
Colorectal	23 (10.9)
Urinary Bladder	20 (9.5)
Lymphoma	14 (6.6)
Ovarian	13 (6.2)
Oral Cavity, Pharynx, Larynx	11 (5.2)
Leukemia	2 (0.9)
Multiple Myeloma	2 (0.9)
Neuroendocrine Tumor	2 (0.9)

Note. Data were not able to be obtained from medical records for 6 second cancer cases. Additional single cases included cervical, liver, merkel cell, pancreatic, sarcoma, vulvar, and unknown primary sites.

Table 11

Sample Patterns of First and Second Cancer Diagnoses Sites (N=205)

First Cancer Site	Second Cancer Site	n (%)
Lung	Lung	20 (9.8)
Breast	Breast	17 (8.3)
Thyroid	Thyroid	12 (5.9)
Melanoma	Melanoma	11 (5.4)
Bladder	Prostate	10 (4.9)
Renal	Renal	7 (3.4)
Prostate	Bladder	6 (2.9)
Prostate	Lymphoma	6 (2.9)
Uterine	Breast	6 (2.9)
Thyroid	Breast	4 (2.0)
Prostate	Colorectal	4 (2.0)
Prostate	Renal	4 (2.0)
Colorectal	Breast	4 (2.0)
Breast	Uterine	3 (1.5)
Ovarian	Uterine	3 (1.5)
Prostate	Lung	3 (1.5)
Uterine	Ovarian	3 (1.5)
Renal	Prostate	3 (1.5)
Oral Cavity/Pharynx	Oral Cavity/Pharynx	3 (1.5)
Breast	Renal	2 (1.0)
Thyroid	Uterine	2 (1.0)
Ovarian	Breast	2 (1.0)
Prostate	Melanoma	2 (1.0)
Prostate	Oral Cavity/Pharynx	2 (1.0)
Colorectal	Uterine	2 (1.0)
Colorectal	Lung	2 (1.0)
Uterine	Uterine	2 (1.0)
Uterine	Lymphoma	2 (1.0)
Melanoma	Breast	2 (1.0)
Melanoma	Thyroid	2 (1.0)
Renal	Lymphoma	2 (1.0)
Lung	Breast	2 (1.0)
Lung	Renal	2 (1.0)
Breast	Thyroid	1 (0.5)
Breast	Ovarian	1 (0.5)
Breast	Leukemia	1 (0.5)
Thyroid	Prostate	1 (0.5)
Thyroid	Colorectal	1 (0.5)
Thyroid	Melanoma	1 (0.5)
Thyroid	Lung	1 (0.5)
Thyroid	Leukemia	1 (0.5)
Ovarian	Lymphoma	1 (0.5)
Ovarian	Pancreatic	1 (0.5)
Prostate	Multiple Myeloma	1 (0.5)
Prostate	Neuroendocrine Tumor	1 (0.5)
Colorectal	Colorectal	1 (0.5)

Table 11 (continued).

Colorectal	Bladder	1 (0.5)
Colorectal	Renal	1 (0.5)
Colorectal	Laryngeal	1 (0.5)
Colorectal	Lymphoma	1 (0.5)
Colorectal	Liver	1 (0.5)
Bladder	Bladder	1 (0.5)
Bladder	Renal	1 (0.5)
Uterine	Colorectal	1 (0.5)
Uterine	Melanoma	1 (0.5)
Uterine	Renal	1 (0.5)
Uterine	Thyroid	1 (0.5)
Uterine	Cervical	1 (0.5)
Uterine	Neuroendocrine Tumor	1 (0.5)
Uterine	Vulvar	1 (0.5)
Melanoma	Prostate	1 (0.5)
Melanoma	Bladder	1 (0.5)
Melanoma	Lung	1 (0.5)
Melanoma	Lymphoma	1 (0.5)
Melanoma	Merkel Cell	1 (0.5)
Renal	Breast	1 (0.5)
Renal	Lung	1 (0.5)
Renal	Thyroid	1 (0.5)
Renal	Ovarian	1 (0.5)
Oral Cavity/Pharynx	Colorectal	1 (0.5)
Oral Cavity/Pharynx	Lung	1 (0.5)
Oral Cavity/Pharynx	Thyroid	1 (0.5)
Oral Cavity/Pharynx	Multiple Myeloma	1 (0.5)
Lung	Colorectal	1 (0.5)
Lung	Uterine	1 (0.5)
Lung	Melanoma	1 (0.5)
Lung	Oral Cavity/Pharynx	1 (0.5)
Lung	Thyroid	1 (0.5)
Lung	Lymphoma	1 (0.5)
Lung	Sarcoma	1 (0.5)
Lung	Unknown Origin	1 (0.5)

Note. Second cancer data were not able to be obtained from medical records for 6 cases.

Table 12

Most Common Second Cancer Sites within Each First Primary Cancer Site Group (N=205)

First Cancer Site	Second Cancer Site	n (%)
Lung/Bronchus* (n=32)	Lung/Bronchus	20 (62.5)
Prostate* (n=29)	Bladder	6 (20.7)
	Lymphoma	6 (20.7)
Breast* (n=25)	Breast	17 (69.0)
Thyroid (n=22)	Thyroid	12 (54.5)
Melanoma* (n=20)	Melanoma	11 (55.0)
Uterine Corpus (n=20)	Breast	6 (30.0)
Kidney/Renal Pelvis* (n=16)	Kidney/Renal Pelvis	7 (43.8)
Colorectal* (n=14)	Breast	4 (28.6)
Urinary Bladder (n=12)	Prostate	10 (83.3)
Ovarian (n=8)	Uterine	3 (37.5)
Oral Cavity/Pharynx (n=7)	Oral Cavity/Pharynx	3 (42.9)

Note. Data were not able to be obtained from medical records for 6 cases (*one case per each disease site indicated). Percentages were calculated based on number of total cases per first cancer site.

Table 13

Sociodemographic and Clinical Comparisons of Cancer Registry Sociodemographic and Clinical Data: Participants versus Nonparticipants

	Participants *n* = 215		Nonparticipants *n* = 1176		Test Statistic* (df)	p-value
Age *Mean (SD)*	67.2	11.5	67.7	12.1	t (1389) = 0.502	.248
Years Since First Cancer Diagnosis *Mean (SD)*	5.8	2.8	5.6	2.9	t (1384) = -0.916	.176
	n	%	*n*	%		
Sex						
Male	85	39.5	512	43.5	$\chi^2(1) = 1.189$	.276
Female	130	60.5	664	56.5		
Race					$\chi^2(1) = 2.323$	.136
White	200	93.0	1049	89.7		
Other	15	7.0	121	10.3		
Marital Status					$\chi^2(1) = 2.358$	.125
Married/Living with a Partner	147	72.1	739	66.6		
Other	57	27.9	371	33.4		
Primary Payer at First Cancer Diagnosis					$\chi^2(2) = 4.812$	.090
Private Insurance	129	66.5	637	58.5		
Medicare, Tricare, or VA	53	27.3	384	35.3		
Medicaid	12	6.2	67	6.2		
First Cancer Site					$\chi^2(2) = 13.319$	.206
Breast	26	12.6	180	15.3		
Prostate	32	14.9	117	9.9		
Colorectal	15	7.0	121	10.3		
Bladder	12	5.6	86	7.3		
Uterine	20	9.3	109	9.3		
Melanoma	21	9.8	97	8.2		
Kidney/Renal Pelvis	17	7.9	116	9.9		
Oral Cavity/Pharynx	7	3.3	65	5.5		
Lung/Bronchus	33	15.3	139	11.8		
Thyroid	23	10.7	107	9.1		
Ovarian	8	3.7	39	3.3		

Notes. SD = standard deviation

*Reported statistics are Pearson chi-square test of independence and independent samples t-tests.

4.0 DESCRIPTION OF SELF-MANAGEMENT BEHAVIORS (DISSERTATION AIM 3)

4.1 THE IMPORTANCE OF SELF-MANAGEMENT BEHAVIORS

Previous literature has demonstrated poorer health in MPC survivors versus their single cancer counterparts. Cancer diagnosis and the post-treatment survivorship phase can result in both negative and positive influence on health behaviors (Carmack, Basen-Engquist, & Gritz, 2011; Park, Edmondson, Fenster, & Blank, 2008). However, unhealthier behaviors have been documented in MPC survivors (Burris & Andrykowski, 2011), including greater likelihood of physical inactivity, greater alcohol consumption when drinking (though less likely to use alcohol overall), and greater likelihood of cigarette and smokeless tobacco use. Given known health deficits in this population of cancer survivors, positive self-management behaviors represent targets (Risendal et al., 2015), providing opportunities to interrupt negative downstream health outcomes and maintain and/or restore optimal wellness.

Corbin and Strauss first identified the process of self-management by describing the work (e.g., medical management, behavioral management, and emotional management) of living with a chronic illness (Corbin & Strauss, 1988). As this day-to-day work of managing one's health is shifting from providers to survivors (Barlow et al., 2002) and their family members, studies in patients with chronic illness (Grady & Gough, 2014; Grey et al., 2015; Lorig & Holman, 2003) and general cancer (Chen et al., 2015; Hammer et al., 2015; McCorkle et al., 2011; Miller et al., 2009; Risendal et al., 2015) have established that self-management is both a public health and clinical priority. The National Institutes of Health and others (Grady, Daley, & Gough, 2014; Grady & Gough, 2014; Knobf et al., 2015; National Cancer Survivorship Resource Center, n.d.; National Institute of Health, 2017; Rudy & Grady, 2005) have called for biobehavioral research to identify mechanisms underlying self-management behaviors.

No prior work has examined how MPC survivors self-manage their health. It is vital to identify the individual characteristics (i.e., personal, clinical, sociodemographic) that are

associated with self-management in MPC survivors and to understand mechanisms linking self-management to health outcomes to 1) better characterize at risk MPC survivors and 2) better understand mechanisms linking self-management to health outcomes. Targeted and tailored self-management interventions, which have been shown to provide positive benefit in varying ethnic, geographic, and age groups in other patient populations (Grady & Gough, 2014), could reduce long-term health problems experienced by MPC survivors.

In Aim 3 of this dissertation study, we describe potentially modifiable health behaviors by analyzing the heiQ items, alcohol use, tobacco use, and BMI measures in detail.

4.2 RESULTS

4.2.1 Self-management domain scores

Table 14 displays scores for self-management domains, as measured by the heiQ (no score alterations applied). In general, most mean heiQ subscale scores were above 3.0, though ranges demonstrate good variability in the scale scores. Health Directed Behavior, which includes items that reflect incorporation of healthy behaviors (e.g., physical and healthy activity) into one's lifestyle, had the lowest subscale score (Mean=2.9, SD=0.7) and lowest observed minimum scores (1.0).

Table 14

Raw Scores for Self-Management Domains, as Measured by Health Education Impact Questionnaire Measure Subscales (N=208)

	Result	
Domains	Mean (SD)	Range
Health Directed Activity	2.9 (0.7)	1.0-4.0
Positive and Active Engagement in Life	3.3 (0.6)	1.6-4.0
Emotional Distress*	3.1 (0.6)	1.3-4.0
Self-Monitoring and Insight	3.3 (0.4)	2.0-4.0
Constructive Attitudes and Approaches	3.4 (0.5)	1.4-4.0
Skill and Technique Acquisition	3.2 (0.5)	1.5-4.0
Social Integration and Support	3.2 (0.6)	1.4-4.0
Health Service Navigation	3.4 (0.5)	1.8-4.0

Notes. SD=standard deviation.

*Emotional distress is interpreted inversely, with higher scores indicating increased negative impact of health on emotions.

4.2.2 Self-management behavior item scores

Frequencies and percentages of self-management behaviors by individual items are presented in Table 15. Across items, only about 54-78% of individuals agreed that they were engaging in regular health directed activities, with the lowest percentage observed being for the walking for exercise item (53.8%). Approximately 82-95% of individuals agreed that they participated in activities to positively and actively engage in life. Approximately 13-48% of individuals agreed with items in the emotional distress domain, with nearly 50% of participants agreeing that they often worried about their health. Approximately 80-98% agreed with doing things reflective of self-monitoring and insight; the lowest frequency in this domain was knowing what triggers and makes health problems worse (79.8%). Frequency of agreement with items in the constructive attitudes and approaches and skill technique acquisition ranged from high 80's-90's. Social integration and support varied by item (78.4-92.8%); 78.4% of participants felt that family and caregivers understood what they were going through when feeling ill. Lastly, frequencies for health service navigation were approximately 90% or above.

Table 15

Frequencies of participants who agree with performing self-management behaviors, by domain and item (N=208)

	Item Results	
Individual Items by Domain	n	%
Health Directed Activity		
Activity at least 1 day per week to improve health	161	77.4
At least 1 type of physical activity daily for 30 minutes	154	78.0
Set aside time for healthy activities on most days of week	149	71.6
Walk for exercise at least 15 minutes per day most days of week	112	53.8
Positive and Active Engagement in Life		
Do some of things I really enjoy on most days	172	82.7
Try to make most of life	198	95.2
Doing interesting things in my life	171	82.2
Have plans to do enjoyable things for self during next few days	185	88.9
Feel like actively involved in life	182	87.5
Emotional Distress*		
Often worry about health	98	47.1
Health problems make me dissatisfied with life	45	21.6
Often feel angry when think about health	39	18.8
Feel hopeless because of health problems	26	12.5
I get upset when think about my health	41	19.7

Table 15 (continued).

I get depressed if I think about my health	41	19.7
Self-Monitoring and Insight		
As well as seeing doctor, regularly monitor changes in my health	193	92.8
I know what triggers and makes health problems worse	166	79.8
Have very good understanding of when/why I should take my meds	203	97.6
Have clear understanding of what to do to control health problems	193	92.8
Carefully watch health and do what is necessary to keep healthy	176	84.6
Have realistic expectations of what can and cannot do with health in mind	193	92.8
Constructive Attitudes and Approaches		
Try not to let health problems stop from enjoying life	196	94.2
My health problems do not ruin my life	192	92.3
Feel well looked after by friends/family	199	95.7
Do not let health problems control life	196	94.2
If others can cope with problems like mine, I can too	204	98.1
Skill and Technique Acquisition		
Have effective ways to prevent symptoms from limiting what can do	184	88.5
Have very good idea of how to manage health problems	198	95.2
Have skills to help cope when have symptoms	190	91.3
Have clear understanding of equipment that could make life easier	183	88.0
Social Integration and Support		
Have plenty of people can rely on if need help	181	87.0
Have enough friends who help me cope with health problems	181	87.0
Family and carers really understand when I feel ill	163	78.4
Feel well looked after by friends or family	193	92.8
Get enough chances to talk about health problems with people who understand me	176	84.6
Health Service Navigation		
Have very positive relationships with my healthcare professionals	205	98.6
Communicate very confidently with my doctor about my healthcare needs	202	97.1
Confidently give healthcare professionals the information they need to help me	205	98.6
Get needs met from available healthcare resources	201	96.6
I work in a team with doctors and other healthcare professionals	186	89.4

Notes. SD=standard deviation. Scales were scored based on developer guidelines, which required over 50% item completion per subscale for valid response scale scoring.

4.2.3 Indicators of negative health behaviors

Table 16 displays data describing indicators of potentially modifiable negative health behaviors.

Approximately 50% of the sample reported drinking alcoholic beverages within the past 30 days. The sample mean raw score for alcohol use, with negative alcohol screens set equal to zero, was 3.6. For individuals who screened positive for alcohol use, the mean sample T-score was 43.7 (SD=5.0, range 38-59.4). Because T-scores are a standardized score with a mean of

50 and a standard deviation of 10 (Patient-Reported Outcomes Measurement Information System, 2014), participants with negative alcohol consumption screens were not assigned a T-score.

Approximately 53% of participants reported that they had smoked 100 cigarettes in their lifetime. Of those 109 individuals, the mean age at first cigarette was 15.6 years (range 6-30 years). The average pack year history, with nonsmokers equal to zero, was around 16 pack-years (range 0-150). Around 9% of respondents were current or recent (within the past 12 months) smokers, however, 44% (n=91) were past smokers.

The average BMI in this sample was 29.4kg/m^2 (range 16.6-52.9). Because BMI has been shown to be associated with a J-shaped dose response curve for mortality (Aune et al., 2016), categorical data are also presented. Less than 3% of the sample was underweight. Around 25% were normal weight. Over 32% were overweight, and over 40% were obese.

Table 16

Sample Characterization of Modifiable Health Behaviors (N=211)

Concept	Result Mean (SD) or n	% or range
Alcohol Use		
Alcohol Use Raw Score (n=211)	3.6 (4.0)	0-16
Drank Alcoholic Beverages within Past 30 Days (n=211)		
No	106	50.2
Yes	105	49.8
Alcohol Use T-Score for Positive Screens (n=105)	43.7 (5.0)	38-59.4
Tobacco Use		
Smoked 100 Cigarettes in Lifetime (n=208)		
No	95	45.7
Yes	110	52.9
If Yes, Age at First Cigarette (n=109)	15.6 (3.5)	6-30
Pack Year History (n=205)	15.7 (26.4)	0-150
Current Smoking Status (n=207)		
Non-Smoker	95	45.9
Past Smoker	91	44.0
Current or Recent Smoker	18	8.7
Anthropometric Data		
Most Recently Documented BMI (kg/m^2) (n=209)	29.4 (7.0)	16.6-52.9
Most Recent BMI by Category (n=209)		
≤18.5 (Underweight)	5	2.4
18.5-24.9 (Normal)	62	24.9
25.0-29.9 (Overweight)	67	32.1
≥30 (Obese)	85	40.7

Note. SD=standard deviation.

4.3 DISCUSSION

This study describes positive self-management behaviors and indicators of negative health behaviors in a sample of MPC survivors. While self-management behaviors were generally high there was variability among scores. Tobacco use findings were comparable to population norms, but rates of obesity were higher than both cancer and general populations.

Our analyses of self-management results were consistent with previous literature identifying MPC patients as more likely to be physically inactive than single cancer patients (Burris & Andrykowski, 2011). Across items, about half to three quarters of the sample agreed that they were engaging in *health directed activities*, with walking for exercise only agreed upon

by about half of the sample. Our finding that most of the sample agreed with activities reflective of *self-monitoring and insight* was also consistent with previous studies noting greater health awareness and positive healthcare utilization (i.e., attending regular appointments, monitoring for cancer, and current with cancer screenings) in MPC patients versus single cancer patients (Belcher et al., 2016; Thong et al., 2013). Less than 80% of participants felt that family and caregivers understood what they were going through when feeling ill, which is in line with previous literature finding greater interference with social activities in MPC patients than in single cancer patients (Thong et al., 2013), as measured by the Impact of Cancer scale (Costa et al., 2016). As identified in Section 3.0, BMI (overweight vs normal weight and obesity), graduate education, lower neuroticism, and increased social support were identified as characteristics associated with improved self-management and should be used to identify MPC patients at risk for poor self-management.

The National Institute for Nursing Research (NINR) describes the science of self-management as examining strategies to aid understanding and management of one's illness and improve health behaviors (National Institute of Nursing Research, n.d.). The topic of self-management has generated a great deal of interest in oncology over the past five years, with influence from a long history of research in chronic illness. Noted issues within self-management science have included need for greater conceptual clarity, identification of valid measures, and identification of mechanisms (Grady et al., 2014). There is a great deal of debate as to how to best include self-management in oncology research and translate findings into practice. Current recommendations for common data elements (CDE) to use in studies of self-management include measures of activation (Patient Activation Measure®), self-regulation (Index of Self-Regulation), self-efficacy for managing chronic conditions (Self-efficacy for Managing Chronic Illnesses Scale), global health (Patient-Reported Outcomes Measurement Information System [PROMIS] Global Heath short form), and biomarkers based on NINR symptom priorities of fatigue, depression, cognition, pain, and sleep disturbance (cytokines,

HPA axis marker, neuropeptide, and DNA polymorphisms) (Moore et al., 2016; Page et al., 2018).

In contrast to the CDE recommended by NINR, which are limited to measures *associated with* health behaviors, the internationally-tested heiQ, selected to measure self-management behaviors in this study, was designed specifically to measure outcomes following health education and self-management programs (Elsworth et al., 2015; Osborne et al., 2011, 2007) and directly addresses the range of self-management domains recommended to maintain wellness, including: health directed activity; positive and active engagement in life; emotional distress; self-monitoring and insight; constructive attitudes and approaches; skill technique and acquisition; social integration and support; and health service navigation. Future self-management studies and nursing scientists should continue to study the best measures of self-management, with consideration for whether the study intent is to measure the actual self-management behaviors or the variables that are associated with self-management behaviors.

Our findings that approximately half of the sample reported drinking alcoholic beverages within the past 30 days is lower than the national rate (56.0%) (National Institute on Alcohol Abuse and Alcoholism, 2017). Other literature using Behavioral Risk Factor Surveillance System data (Burris & Andrykowski, 2011) has described higher alcohol consumption among MPC survivors who consume alcohol, based on analysis of typical number of drinks consumed in the past month when drinking. However, the effect sizes for these comparisons were small, and, as authors acknowledge, are not likely to be clinically meaningful.

Smoking is the number one preventable cause of death in the U.S. and increases risk for heart disease, stroke, and cancer (Center for Disease Control and Prevention, 2018). Tobacco smoking is a known carcinogen in the general population and has been implicated as a causative factor associated with increased risk for additional cancer development in cancer survivors (Fraumeni Jr et al., 2006); length and duration of exposure are known to impact carcinogenesis (National Cancer Institute, 2015). Only around 9% of our study participants were

current or recent smokers; however, 44% were past smokers. Of these individuals, the mean age at first cigarette was 15.6 (range: 6-30 years), and pack year history ranged from 0-150 (Mean=16). When compared to national and regional data, the rates of current smoking in this sample was lower than the national average, similar to rates in adults 65 years of age and older, and lower than rates in Pennsylvania (9% versus 15.5% and 18.6-21.7%, respectively) (The Centers for Disease Control and Prevention, 2018; Underwood et al., 2012). Both the early age at which some of our participants first smoked (i.e., 6 years old) and the high pack year history (i.e., 150) are notable. Future studies should evaluate triggers for smoking cessation in patients with MPC.

Obesity is a risk factor for many diseases and conditions [e.g., heart disease, osteoarthritis, sleep apnea, depression, anxiety, pain, physical function impairment), including being a risk factor for cancer (i.e., breast [post-menopausal women], endometrial, colon, kidney, gallbladder, and liver) (Centers for Disease Control and Prevention, 2015). Additionally, diet, physical inactivity, and obesity are implicated as potential risk factors for subsequent cancer development among survivors of breast (female), reproductive organs, and upper and lower digestive tract cancers (Fraumeni et al., 2006). The high rates of obesity in this sample (over 40%) is concerning, given the associated known health risks. The American Society of Clinical Oncology and other organizations have published position statements on obesity and cancer offer strategies for healthcare providers to address obesity with their patients (Ligibel et al., 2014).

Previous studies have suggested greater health awareness in MPC versus single cancer patients (Belcher et al., 2017; Thong et al., 2013). However, awareness does not directly translate to behavioral change. A cancer diagnosis or experience has been described as a teachable moment, but studies have pointed out that desire to change varies by individuals and is impacted by many complex factors (Corbett et al., 2018; Demark-Wahnefried, Aziz, Rowland, & Pinto, 2005). Others have suggested that the teachable moment afforded during one's cancer

experience may be halted by subsequent cancer diagnoses (Burris & Andrykowski, 2011). Future research should evaluate how having more than one cancer impacts health behavior changes.

In addition to the poorer health observed in patients with MPC (Andrykowski, 2012; Belcher et al., 2017; Burris & Andrykowski, 2011; Dowling et al., 2013; Gotay et al., 2007; Thong et al., 2013), some MPC patients (16% in this study) will go on to develop more than two primary cancers. In addition to non-modifiable familial cancer syndromes and potential carcinogenetic effects of previous cancer treatments, risk for development of more than one primary cancer diagnosis increases with modifiable causative exposures (e.g., smoking and alcohol); diet, obesity, physical inactivity, and reproductive risk factors have also been implicated in the development of subsequent cancers in patients with breast (female), reproductive, and upper and lower digestive tract cancers (Fraumeni et al., 2006; Schottenfeld & Beebe-Dimmer, 2006). Health optimization and risk reduction remain critical in this subset of cancer survivors; future MPC research should include self-management as a modifiable target through which this may be achieved.

5.0 APPENDICES

APPENDIX A

STUDY RECRUITMENT MATERIALS AND REFUSAL FORM

UPMC LIFE CHANGING MEDICINE

October 11, 2016

Sarah M. Belcher, RN, BSN, OCN
Predoctoral Scholar
Robert Wood Johnson Foundation Future of Nursing Scholars
Health & Community Systems, University of Pittsburgh School of Nursing
3500 Victoria Street
Room 434 Victoria Building
Pittsburgh, PA 15261

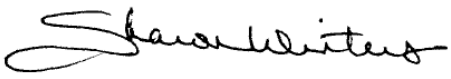
Dear Sarah,

This letter is to formally confirm the number of patients in the UPMC Network Cancer Registry who fit the criteria for the human subjects portion of the American Cancer Society Doctoral Degree Scholarship in Cancer Nursing application that you are submitting entitled "*Characterizing Psychobehavioral Risks in Multiple Primary Cancer Survivors.*"

As you are aware, the UPMC Network Cancer Registry maintains a standardized data system designed for the collection, management, and analysis of patient demographic, grading, staging, treatment and progression data on patients having a diagnosis of cancer who are treated at UPMC hospitals and hospital based clinics of UPMC CancerCenters. Given the criteria you provided *(e.g. Include: adults [18 or older]; all cancer diagnosed during adulthood; history of 2 or more primary cancers; only Stage I-III cancers; all UPMC sites; and all years of registry inclusiveness. Exclude: cases of non-melanoma skin cancer; in situ cancers; Stage IV/M1 cases at presentation; and disease recurrent cases [same as original cancer diagnosis])*, there is expected to be an sufficient pool of potential participants *(5,757 survivors)* to assure that you will be able to attain your target sample size.

Should you have any questions about the data provided by the UPMC Network Cancer Registry and our Registry Information Services, or should you need additional data, please feel free to contact me.

Sincerely,



Sharon Winters, MS, CTR
Director, Registry Information Services, UPMC CancerCenter
Manager, HSTB/RIS/DBMI Collaborative Honest Broker System *(IRB#HB015)*
Adjunct Instructor, University of Pittsburgh
Shadyside Place
First Floor, Suite 110
580 South Aiken Avenue
Pittsburgh, PA 15232Pittsburgh, PA 15232-1304
(412) 647-6390
winterssb@upmc.edu

[Address Block] [Date]

Dear [Title] [Patient Name],

I'm writing to tell you about an exciting new research study called *Shining a light on **L**ife **A**fter **M**ultiple **P**rimary cancers: The LAMP study*. This research study is led by Sarah Belcher, a nurse and graduate student at the University of Pittsburgh School of Nursing.

We want to learn more about patients who have had more than one cancer. You have been identified through UPMC's tumor registry as someone who may be eligible for this research study.

If you choose to participate, you will be asked to provide consent to participate in the research study. You will then fill out a one-time survey (30-40 minutes) online or through the mail. This survey asks about your stress, health behaviors, emotions, and overall health. With your permission, we will then combine your responses with health and cancer treatment information from your medical record. We will use this information to better understand and better support cancer survivors like you. You will receive a $5 Amazon gift card for completing the survey.

You can complete the survey in a couple of different ways:

1. You can easily complete the consent and survey online by typing the following website URL into your browser: http://tinyurl.com/LAMP-PittNursing
2. If you would rather have a paper copy, please complete and return the enclosed Paper Survey Request Form in the pre-paid envelope included with this letter.

If you do not wish to be in the study, you can complete a voluntary refusal form either online at http://tinyurl.com/LAMP-PittNursing or via the enclosed paper Refusal Form.

Please call or email the study lead, Sarah Belcher, with any questions at:

- 412-624-8938 or
- LAMPstudy@pitt.edu

This research study is funded by the American Cancer Society, the Robert Wood Johnson Foundation Future of Nursing Scholars program, the Nightingale Awards of Pennsylvania, and the School of Nursing.

I fully support this study and believe it will help us to better meet the needs of cancer survivors like you. I hope you will take the time to participate in this important research study.

Sincerely,

[Cancer Center Physician Name]

University of Pittsburgh
School of Nursing
Department of Health and Community Systems

Paper Survey Request Form

Thank you for your interest in the LAMP study!

Please fill out the information below, and return this form in the included postage-paid envelope. We will mail you a paper copy of the survey.

I am interested in completing questionnaires **on paper**.

My name is: _____

My mailing address is:_____

_____

_____

_____

My email address is: _____

Thank you for your time! If you have any questions, please contact Sarah Belcher at 412-624-8938 or LAMPstudy@pitt.edu.

ID: _____
(for study use only)

University of Pittsburgh
School of Nursing
Department of Health and Community Systems

Refusal Form

We understand that not everyone is able or interested in completing the survey. We are trying to understand more about the people who do not complete the survey. If you are willing, it would help us if you would answer and return the following 5 general questions about yourself in the included prepaid envelope. These answers are confidential and voluntary.

If you prefer, this information may also be completed online at:

http://tinyurl.com/LAMP-PittNursing

Instructions: Please circle the answers that best describe you.

1. **What is your sex?**
   a. Male
   b. Female

2. **How long has it been since your most recent cancer treatment?**
   a. 0-1 year
   b. 1-5 years
   c. 5-10 years
   d. Over 10 years
   e. I am currently receiving treatment for cancer.

3. **What best describes your race? Select all that apply.**
   a. White or Caucasian
   b. African American
   c. American Indian
   d. Alaska Native
   e. Native Hawaiian or other Pacific Islander
   f. Asian
   g. Unknown
   h. Other _____

4. **What is the highest grade or degree you have completed?**
   a. Less than High School
   b. High school diploma or GED
   c. 2 year/ Associate's Degree
   d. 4 year/Bachelor's Degree
   e. Graduate/Professional Degree (Masters, PhD, MD, JD, etc.)

5. **What age group best describes you:**
   a. 18-29
   b. 30-49
   c. 50-69
   d. 70 and above

Please turn form over for remainder of questions.

Can you briefly share why you don't want to participate in this study? _____

_____

_____

Is there anything else you would like us to know? _____

_____

_____

Thank you for your time!

Please return this form in the postage-paid envelope included with this mailing.

If you have any questions, please contact Sarah Belcher at
412-624-8938 or LAMPstudy@pitt.edu.

ID: _____
(for study use only)

University of Pittsburgh School of Nursing

You may have recently received a letter inviting you to participate in *The LAMP study*, a research study led by a nurse and graduate student at the University of Pittsburgh School of Nursing.

Thank you if you already responded! If you have not yet responded and would like more information about this one-time study, please contact us via the phone or email information listed below. You can also log on to the following website to complete the one-time survey or a refusal form online: http://tinyurl.com/LAMP-PittNursing

Please call or email the study lead, Sarah Belcher,
with any questions or to request a paper survey copy.
412-624-8938 | LAMPstudy@pitt.edu

University of Pittsburgh School of Nursing

You may have recently received a letter inviting you to participate in *The LAMP study*, a research study led by a nurse and graduate student at the University of Pittsburgh School of Nursing.

Thank you if you already responded! If you have not yet responded and would like more information about this one-time study, please contact us via the phone or email information listed below. You can also log on to the following website to complete the one-time survey or a refusal form online: http://tinyurl.com/LAMP-PittNursing

Please call or email the study lead, Sarah Belcher,
with any questions or to request a paper survey copy.
412-624-8938 | LAMPstudy@pitt.edu

University of Pittsburgh School of Nursing

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APPENDIX B

STUDY COVER LETTER AND INSTRUMENTS

University of Pittsburgh

School of Nursing
Department of Health & Community Systems

Thank you so much for your interest in volunteering to participating in the LAMP research study. As you may know, I am an oncology nurse and graduate student at the University of Pittsburgh School of Nursing. I am conducting this study as part of my dissertation work to better understand and support cancer survivors like you who have had **two separate types of cancer**. We call these types of cancers, "**multiple primary cancers**."

First, please review and complete one copy of the Consent Form included with this mailing. The signed consent form must be returned along with your survey responses in order for us to include you in the study. A second copy is provided for you to keep for yourself.

The study consists of two parts:

1. We ask you to complete and return the included paper survey questionnaire packet and return it along with the Consent Form in the included prepaid envelope.

   The questions will ask about your stress, health behaviors, emotions, and overall health. This survey will take you about 30 - 40 minutes to complete. We realize that we are asking you for a significant amount of time to complete the questions. If you need a break, you can pause and come back to the survey later. We truly believe that the experiences of people like you who have had multiple primary cancers have not be adequately been addressed in research and clinical practice. It is our hope that your participation in this study will help us address this critical lack of understanding and help people like you in the future.

2. Next, our research team will review your medical records to find out more about your cancer and health history.

You will receive a $5 Amazon.com gift card code for completing the survey.

Please note that your responses to this survey will not be sent to your healthcare providers. It is important that you contact or see your professional healthcare team if you have any questions or concerns about physical or emotional symptoms, cancer, or medications. If you experience a new symptom or increase in severity of an existing symptom, please report this to your healthcare team or emergency medical services immediately.

Each questionnaire has a unique set of instructions and possible response options. Questions will ask you to think back about different periods of time. Some questions may seem similar, because we are testing different ways of asking about similar ideas. There are no right or wrong answers.

If you have questions at any point, you can contact me, Sarah Belcher, at LAMPstudy@pitt.edu or 412-624-8938.

Sincerely,

Sarah M. Belcher, PhD(c), RN, OCN®

Shining a light on
Life **A**fter **M**ultiple **P**rimary cancers

LAMP Study Questionnaires

Thank you for being a part of this study!

Please return this completed packet and a copy of the signed consent and to Sarah Belcher in the enclosed postage-paid envelope.

ID: _____
(for study use only)

Socio-Demographic Questionnaire – Part 1

Please begin by entering the following basic information about yourself.

SD_1. First Name: _____

SD_2. Middle Initial: _____

SD_3. Last Name: _____

SD_4. Date of birth: _____ / ____ / _____
(month / day / year)

SD_5. Current Age in years: _____ years old

SD_6. What is your sex? • Male • Female

SD_7. Do you consider yourself to be Hispanic or Latino? That is, of Mexican, Puerto Rican, Cuban, Caribbean, or of Latin American descent.

• Yes • No • Do not know

SD_8. Please select the racial and ethnic category or categories with which you most closely identify. *Check all that apply.*

- White or Caucasian
- Black or African American
- American Indian (SD8a. specify tribe _____)
- Alaska Native
- Native Hawaiian or other Pacific Islander
- Asian
- Unknown
- Other (SD8b. specify _____)

(socio-demographics, continued)

SD_9. Email Address: _____

SD_10. Phone Number: (_____)_____-_____

SD_11. Does your current household income meet your basic needs? • Yes • No

Multiple Primary Cancer (MPC) Items – Part 1

In order to provide the best care and support, we need to understand how a second cancer diagnosis may be different than a first cancer diagnosis. Thank you for taking the time to share your experiences with us.

MPC_1. How old were you when you were *first* diagnosed with cancer? _____ years old

MPC_2. What type of cancer were you *first* diagnosed with? _____

MPC_3. How old were you when you were diagnosed with a *second* type of cancer?

_____ years old

MPC_4. What type of cancer was your *second* cancer diagnosis? _____

MPC_5. Were you diagnosed with any additional cancers? *For example, a third or more different type of cancer.*

- No → *Skip to MPC_6 on page 4.*
- Yes

MPC_5a. If YES, please explain: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

(MPC items, continued)

MPC_6. What is your current stage of cancer survivorship? *Please indicate with a check all that apply.*

- I finished treatment less than 1 year ago.
- I finished treatment between 1 and 5 years ago.
- I finished treatment between 5 and 10 years ago.
- I finished treatment 10 or more years ago.
- I am currently receiving treatment for cancer.
- I am living with cancer as a chronic illness.
- I am currently receiving palliative care.
- I am currently receiving hospice care.
- I prefer not to answer, or I am not sure.

(MPC items, continued)

MPC_7. For each of the following common challenges or stressors, please select whether your second cancer diagnosis was more difficult, the same, or less difficult than your first cancer diagnosis. Select N/A if this was not a problem with either cancer diagnosis.

	This was **more difficult** with my second cancer.	This was the **same** for both cancers.	This was **less difficult** with my second cancer.	N/A – This was **not a problem for me with either** cancer diagnosis.
MPC_7a. Managing stress	☐	☐	☐	☐
MPC_7b. Feeling down or blue	☐	☐	☐	☐
MPC_7c. Feeling nervous or anxious	☐	☐	☐	☐
MPC_7d. Managing my overall health	☐	☐	☐	☐
MPC_7e. Finding good ways to cope	☐	☐	☐	☐
MPC_7f. Completing life activities (e.g., bathing/dressing, light housework, walking more than a mile)	☐	☐	☐	☐
MPC_7g. Treatment- and/or cancer-related symptoms	☐	☐	☐	☐
MPC_7h. Financial hardship	☐	☐	☐	☐
MPC_7i. Managing my relationships	☐	☐	☐	☐
MPC_7j. Getting the support that I need	☐	☐	☐	☐
MPC_7k. Communicating with my healthcare team	☐	☐	☐	☐
MPC_7l. Other challenge or stressor? – *please specify*: MPC_7m. _____ _____	☐	☐	☐	☐

(MPC items, continued)

MPC_8n. Would you like to further explain any of the answers you provided in the previous table?

- No → *Skip to PSS_1 on page 7.*
- Yes → MPC_8o. *If YES, please explain in the space below:*

General Stress

The questions in this scale ask you about your feelings and thoughts during the **last month**. In each case, please indicate with a check how often you felt or thought a certain way.

	Never	Almost never	Some-times	Fairly often	Very often
PSS_1. In the last month, how often have you been upset because of something that happened unexpectedly?	☐	☐	☐	☐	☐
PSS_2. In the last month, how often have you felt that you were unable to control the important things in your life?	☐	☐	☐	☐	☐
PSS_3. In the last month, how often have you felt nervous and "stressed"?	☐	☐	☐	☐	☐
PSS_4. In the last month, how often have you felt confident about your ability to handle your personal problems?	☐	☐	☐	☐	☐
PSS_5. In the last month, how often have you felt that things were going your way?	☐	☐	☐	☐	☐
PSS_6. In the last month, how often have you found that you could not cope with all the things that you had to do?	☐	☐	☐	☐	☐
PSS_7. In the last month, how often have you been able to control irritations in your life?	☐	☐	☐	☐	☐
PSS_8. In the last month, how often have you felt that you were on top of things?	☐	☐	☐	☐	☐
PSS_9. In the last month, how often have you been angered because of things that were outside of your control?	☐	☐	☐	☐	☐
PSS_10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	☐	☐	☐	☐	☐

Cancer-Related Stress

Instructions – Below is a list of difficulties people sometimes have after a diagnosis of cancer. Please reach each item, and then indicate how distressing (or how common) each difficulty has been for you **during the past seven days**.

*(check **one** box on each line)*

	Not at all 0	A little bit 1	Moder-ately 2	Quite a bit 3	Extreme-ly 4
IES_1. Any reminder of cancer brought back feelings about it.	☐	☐	☐	☐	☐
IES_2. I had trouble staying asleep.	☐	☐	☐	☐	☐
IES_3. Other things kept making me think about cancer.	☐	☐	☐	☐	☐
IES_4. I felt irritable and angry.	☐	☐	☐	☐	☐
IES_5. I avoided letting myself get upset when I thought about cancer or was reminded of it.	☐	☐	☐	☐	☐
IES_6. I thought about cancer when I didn't mean to.	☐	☐	☐	☐	☐
IES_7. I felt as if it hadn't happened or wasn't real.	☐	☐	☐	☐	☐
IES_8. I stayed away from reminders about cancer.	☐	☐	☐	☐	☐
IES_9. Pictures about being ill with cancer popped into my mind.	☐	☐	☐	☐	☐
IES_10. I was jumpy and easily startled.	☐	☐	☐	☐	☐
IES_11. I tried not to think about cancer.	☐	☐	☐	☐	☐
IES_12. I was aware that I still had a lot of feelings about cancer, but I didn't deal with them.	☐	☐	☐	☐	☐
IES_13. My feelings about cancer were kind of numb.	☐	☐	☐	☐	☐
IES_14. I found myself feeling as though I was back at that time of my bad news.	☐	☐	☐	☐	☐
IES_15. I had trouble falling asleep.	☐	☐	☐	☐	☐
IES_16. I had waves of strong feelings about cancer.	☐	☐	☐	☐	☐
IES_17. I tried to remove cancer from my memory.	☐	☐	☐	☐	☐
IES_18. I had trouble concentrating.	☐	☐	☐	☐	☐

(cancer-related stress, continued)

	Not at all 0	A little bit 1	Moderate-ly 2	Quite a bit 3	Extreme-ly 4
IES_19. Reminders of cancer caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	☐	☐	☐	☐	☐
IES_20. I had dreams about cancer.	☐	☐	☐	☐	☐
IES_21. I felt watchful or on-guard.	☐	☐	☐	☐	☐
IES_22. I tried not to talk about cancer.	☐	☐	☐	☐	☐

Cancer Survivor Concerns

Below is a list of worries people sometimes have after a diagnosis of cancer. Please indicate how much worry you experience with each of the following topics.

I worry about…	**Not at all 1**	**A little bit 2**	**Somewhat 3**	**Very much 4**
ASC_1. Future diagnostic tests	□	□	□	□
ASC_2. Another type of cancer	□	□	□	□
ASC_3. My cancer coming back	□	□	□	□

Emotions, part 1

Over the **last 2 weeks**, how often have you been bothered by any of the following problems?

*(check **one** box on each line)*

How often during the past 2 weeks were you bothered by…	**Not at all 0**	**Several days 1**	**More than half the days 2**	**Nearly every day 3**
PHQ_1. Little interest or pleasure in doing things…….	☐	☐	☐	☐
PHQ_2. Feeling down, depressed, or hopeless…….	☐	☐	☐	☐

If you answered "Not at All" for BOTH PHQ_1 and PHQ_2 above, skip ahead now to page 12 (GAD_1). Otherwise, continue to PHQ_3 below.

PHQ_3. Trouble falling or staying asleep, or sleeping too much……...	☐	☐	☐	☐
PHQ_4. Feeling tired or having little energy……	☐	☐	☐	☐
PHQ_5. Poor appetite or overeating…….…….	☐	☐	☐	☐
PHQ_6. Feeling bad about yourself, or that you are a failure, or have let yourself or your family down……	☐	☐	☐	☐
PHQ_7. Trouble concentrating on things, such as reading the newspaper or watching television……	☐	☐	☐	☐
PHQ_8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual…….	☐	☐	☐	☐

Emotions, part 2

Over the last 2 weeks, how often have you been bothered by the following problems? *(check **one** box on each line)*	**Not at all sure 0**	**Several days 1**	**Over half the days 2**	**Nearly every day 3**
GAD_1. Feeling nervous, anxious, or on edge	☐	☐	☐	☐
GAD_2. Not being able to stop or control worrying	☐	☐	☐	☐
If you answered "Not at All" for BOTH GAD_1 and GAD_2 above, skip ahead now to heiQ 1 on page 13. Otherwise, continue to GAD 3 below.				
GAD_3. Worrying too much about different things	☐	☐	☐	☐
GAD_4. Trouble relaxing	☐	☐	☐	☐
GAD_5. Being so restless that it's hard to sit still	☐	☐	☐	☐
GAD_6. Becoming easily annoyed or irritable	☐	☐	☐	☐
GAD_7. Feeling afraid as if something awful might happen	☐	☐	☐	☐

GAD_8. If you checked off any of the problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all_____

Somewhat difficult_____

Very difficult_____

Extremely difficult_____

Self-Management of Your Health

Instructions

There are no right or wrong answers but please make sure that you answer every question the best you can.

Please indicate how strongly you disagree or agree with the following statements by checking the response which best describes you **now**.

Please answer the following questions:

Check a box by crossing it: ☐ ☐ ☐ ☒

	Right now			
	Strongly disagree	Disagree	Agree	Strongly Agree
heiQ_1. On most days of the week, I do at least one activity to improve my health (e.g., walking, relaxation, exercise).	☐	☐	☐	☐
heiQ_2. Most days I am doing some of the things I really enjoy.	☐	☐	☐	☐
heiQ_3. As well as seeing my doctor, I regularly monitor changes in my health.	☐	☐	☐	☐
heiQ_4. I often worry about my health.	☐	☐	☐	☐
heiQ_5. I try to make the most of my life.	☐	☐	☐	☐
heiQ_6. I know what things can trigger my health problems and make them worse.	☐	☐	☐	☐
heiQ_7. My health problems make me very dissatisfied with my life.	☐	☐	☐	☐
heiQ_8. I am doing interesting things in my life.	☐	☐	☐	☐
heiQ_9. I do at least one type of physical activity every day for at least 30 minutes (e.g., walking, gardening, housework, golf, bowls, dancing, Tai Chi, swimming)	☐	☐	☐	☐

(self-management, continued)

Check a box by crossing it: ☐ ☐ ☐ ☒

Right now

	Strongly disagree	Disagree	Agree	Strongly Agree
heiQ_10. I have plans to do enjoyable things for myself during the next few days.	☐	☐	☐	☐
heiQ_11. I have a very good understanding of when and why I am supposed to take my medication.	☐	☐	☐	☐
heiQ_12. I often feel angry when I think about my health.	☐	☐	☐	☐
heiQ_13. On most days of the week, I set aside time for healthy activities (e.g., walking, relaxation, exercise).	☐	☐	☐	☐
heiQ_14. I feel hopeless because of my health problems.	☐	☐	☐	☐
heiQ_15. I feel like I am actively involved in life.	☐	☐	☐	☐
heiQ_16. When I have health problems, I have a clear understanding of what I need to do to control them.	☐	☐	☐	☐
heiQ_17. I carefully watch my health and do what is necessary to keep as healthy as possible.	☐	☐	☐	☐
heiQ_18. I get upset when I think about my health.	☐	☐	☐	☐
heiQ_19. I walk for exercise, for at least 15 minutes per day, most days of the week.	☐	☐	☐	☐
heiQ_20. With my health in mind, I have realistic expectations of what I can and cannot do.	☐	☐	☐	☐
heiQ_21. If I think about my health, I get depressed.	☐	☐	☐	☐
heiQ_22. If I need help, I have plenty of people I can rely on.	☐	☐	☐	☐

(self-management, continued)

Check a box by crossing it: ☐ ☐ ☐ ☒

Right now

	Strongly disagree	Disagree	Agree	Strongly Agree
heiQ_23. I have effective ways to prevent my symptoms (e.g., discomfort, pain, and stress) from limiting what I can do in my life.	☐	☐	☐	☐
heiQ_24. I have very positive relationships with my healthcare professionals.	☐	☐	☐	☐
heiQ_25. I have a very good idea of how to manage my health problems.	☐	☐	☐	☐
heiQ_26. When I have symptoms, I have skills that help me cope.	☐	☐	☐	☐
heiQ_27. I try not to let my health problems stop me from enjoying life.	☐	☐	☐	☐
heiQ_28. I have enough friends who help me cope with my health problems.	☐	☐	☐	☐
heiQ_29. I communicate very confidently with my doctor about my healthcare needs.	☐	☐	☐	☐
heiQ_30. I have a good understanding of equipment that could make my life easier.	☐	☐	☐	☐
heiQ_31. When I feel ill, my family and carers really understand what I am going through.	☐	☐	☐	☐
heiQ_32. I confidently give healthcare professionals the information they need to help.	☐	☐	☐	☐
heiQ_33. I get my needs met from available healthcare resources (e.g., doctors, hospitals, and community services).	☐	☐	☐	☐
heiQ_34. My health problems do not ruin my life.	☐	☐	☐	☐

(self-management, continued)

Check a box by crossing it: Right now

☐ ☐ ☐ ☒

	Strongly disagree	Disagree	Agree	Strongly Agree
heiQ_35. Overall, I feel well looked after by friends or family.	☐	☐	☐	☐
heiQ_36. I feel I have a very good life even when I have health problems.	☐	☐	☐	☐
heiQ_37. I get enough chances to talk about my health problems with people who understand me.	☐	☐	☐	☐
heiQ_38. I work in a team with my doctors and other healthcare professionals.	☐	☐	☐	☐
heiQ_39. I do not let my health problems control my life.	☐	☐	☐	☐
heiQ_40. If others can cope with problems like mine, I can too.	☐	☐	☐	☐

Alcohol Use

The following questions ask about your alcohol use and behaviors. Please recall that all answers will be kept confidential.

		Yes	No
ETOH_1	In the past 30 days, did you drink any type of alcoholic beverages?	☐	☐

If yes, proceed to items below (ETOH_2).

If no, skip the remaining items on this page and go to ETOH_7 on page 18.

	In the past 30 days..	**1-2 drinks**	**3-4 drinks**	**5-6 drinks**	**7-10 drinks**	**More than 10 drinks**
ETOH_2	On a typical day when I drank alcohol, I had……..	☐	☐	☐	☐	☐
ETOH_3	The largest number of drinks that I had in a single day was…..	☐	☐	☐	☐	☐
		Never	**1-2 times**	**3-5 times**	**6-10 times**	**More than 10 times**
ETOH_4	I became drunk or intoxicated….	☐	☐	☐	☐	☐
		Never	**1 time**	**2 times**	**3 times**	**4 or more times**
ETOH_5	I spent a whole weekend drinking……...	☐	☐	☐	☐	☐
		1-7 drinks	**8-14 drinks**	**15-21 drinks**	**22-28 drinks**	**More than 28 drinks**
ETOH_6	In a typical week I drank…….	☐	☐	☐	☐	☐

Alcohol Use in Relation to Cancer Diagnosis and Treatment

In the following section, you will be asked about when you were first told you had a second cancer. Please answer these questions about **your second cancer diagnosis**.

		Yes	No
ETOH_7	I quit drinking alcohol more than 1 year before I was told I had a second cancer. *Also check "yes" if you never drank alcohol.*	☐	☐

If yes, skip the remaining items on this page and go to CTUQ_1 on page 19.

If no, proceed to items below (ETOH_8).

ETOH_8. During each of the following time frames, please indicate whether you drank alcohol every day, some days, or not at all.

	Drank every day	**Drank some days**	**Didn't drink at all**	**Don't know/ Not sure**
ETOH_8a. The year before you were told you had a second cancer	☐	☐	☐	☐
ETOH_8b. After your second cancer diagnosis, and before treatment for the second cancer started	☐	☐	☐	☐
ETOH_8c. During the course of treatment for your second cancer	☐	☐	☐	☐
ETOH_8d. After treatment ended for your second cancer	☐	☐	☐	☐

Tobacco Use

Section 1. Basic Tobacco Use Information

CTUQ_1. **Have you smoked at least 100 cigarettes (5 packs = 100 cigarettes) in your <u>entire life</u>?**

- ☐ Yes
- ☐ No → **Go to PGLOB_1 (page 22).**
- ☐ Don't know / Not sure → **Go to PGLOB_1 (page 22).**

CTUQ_2. **How old were you when you first smoked a cigarette (even one or two puffs)?**

_____ years old

CTUQ_3. **Have you ever smoked cigarettes <u>regularly</u>?**

- ☐ No. I have never smoked cigarettes regularly.
- ☐ Yes

CTUQ_3a. If YES, how old were you when you first began smoking cigarettes regularly?

_____ years old

CTUQ_4. **How many total years have you smoked (or did you smoke) cigarettes? Do not count any time you may have stayed off cigarettes.**

_____ Years *If you smoked less than one year, write "1."*

CTUQ_5. **On average when you have smoked, about how many cigarettes do you (or did you) smoke a day?**

A pack usually has 20 cigarettes in it.

_____ Number of cigarettes per day

(tobacco use, continued)

CTUQ_6. **How long has it been since you last smoked a cigarette (even one or two puffs)?**

First check which one of the following choices applies to you. Then, if applicable, write a number on the line for how many days, weeks, months, or years it has been since your last cigarette.

- ☐ I smoked a cigarette today (at least one puff).
- ☐ 1-7 days. → CTUQ_6a. Number of days since last cigarette: _____
- ☐ Less than 1 month. → CTUQ_6b. Number of weeks since last cigarette: _____
- ☐ Less than 1 year. → CTUQ_6c. Number of months since last cigarette: _____
- ☐ More than 1 year. → CTUQ_6d. Number of years since last cigarette: _____
- ☐ Don't know / Don't remember

(tobacco use, continued)

INSTRUCTIONS

In the following section, you will be asked about when you were first told you had a second cancer. Please answer these questions about **your second cancer diagnosis**.

Section 2. Tobacco Use in Relation to Cancer Diagnosis and Treatment

---

		Yes	No
CTUQ_7	I quit smoking more than 1 year before I was told I had a second cancer. *Also check "yes" if you never smoked or smoked less than 100 cigarettes in your entire life.*	☐	☐

If yes, skip the remaining items on this page and go to PGLOB_1 on page 22.

If no, proceed to items below (CTUQ_8).

CTUQ_8. During each of the following time frames, please indicate whether you smoked cigarettes every day, some days, or not at all.

	Smoked every day	**Smoked some days**	**Didn't smoke at all**	**Don't know/ Not sure**
CTUQ_8a. **The year before you were told you had a second cancer**	☐	☐	☐	☐
CTUQ_8b. **After your second cancer diagnosis, and before treatment for the second cancer started**	☐	☐	☐	☐
CTUQ_8c. **During the course of treatment for your second cancer**	☐	☐	☐	☐
CTUQ_8d. **After treatment ended for your second cancer**	☐	☐	☐	☐

Overall Health

Please respond to each item by marking one box per row.

		Excellent 5	Very Good 4	Good 3	Fair 2	Poor 1
PGLOB_1	In general, would you say your **health** is: ……	☐	☐	☐	☐	☐
PGLOB_2	In general, would you say your **quality of life** is: ……	☐	☐	☐	☐	☐
PGLOB_3	In general, how would you rate your **physical health**? …	☐	☐	☐	☐	☐
PGLOB_4	In general, how would you rate your **mental health**, including your mood and your ability to think? ……	☐	☐	☐	☐	☐
PGLOB_5	In general, how would you rate your *satisfaction* with your **social activities** and **relationships**? ……	☐	☐	☐	☐	☐
PGLOB_6	In general, please rate *how well you carry out* your usual **social activities** and **roles**. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)…….	☐	☐	☐	☐	☐

(overall health, continued)

		Completely 5	Mostly 4	Moderately 3	A little 2	Not at all 1
PGLOB_7	To what extent are you able to carry out your **everyday physical activities** such as walking, climbing stairs, carrying groceries, or moving a chair?.....	□	□	□	□	□

	In the past 7 days…	Never 1	Rarely 2	Sometimes 3	Often 4	Always 5
PGLOB_8	How often have you been bothered by **emotional problems** such as feeling anxious, depressed or irritable?.....	□	□	□	□	□

		None 1	Mild 2	Moderate 3	Severe 4	Very Severe 5
PGLOB_9	How would you rate your **fatigue** on average?.....	□	□	□	□	□

PGLOB_10	How would you rate your **pain** on average?..... *Please circle a number.*	0 No pain	1	2	3	4	5	6	7	8	9	10 Worst imaginable pain

Physical Function

Please respond to each item by marking one box per row.

		Not at all 5	Very little 4	Somewhat 3	Quite a lot 2	Cannot do 1
PFX_1	Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?.....	☐	☐	☐	☐	☐
PFX_2	Does your health now limit you in walking more than a mile?.....	☐	☐	☐	☐	☐
PFX_3	Does your health now limit you in climbing one flight of stairs?.....	☐	☐	☐	☐	☐
PFX_4	Does your health now limit you in lifting or carrying groceries?.....	☐	☐	☐	☐	☐
PFX_5	Does your health now limit you in bending, kneeling, or stooping?.....	☐	☐	☐	☐	☐

		Without any difficulty 5	With a little difficulty 4	With some difficulty 3	With much difficulty 2	Unable to do 1
PFX_6	Are you able to do chores such as vacuuming or yard work?.....	☐	☐	☐	☐	☐
PFX_7	Are you able to dress yourself, including tying shoelaces and doing buttons?.....	☐	☐	☐	☐	☐
PFX_8	Are you able to shampoo your hair?.....	☐	☐	☐	☐	☐
PFX_9	Are you able to wash and dry your body?.....	☐	☐	☐	☐	☐
PFX_10	Are you able to get on and off the toilet?.....	☐	☐	☐	☐	☐

Symptoms

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please select a number from 0 (symptom has not been present) to 10 (the symptom was as bad as you can imagine it could be) for each item.

Please circle one number per row.	Not Present										As Bad As You Can Imagine
MDASI_1. Your **pain** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_2. Your **fatigue (tiredness)** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_3. Your **nausea** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_4. Your **disturbed sleep** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_5. Your feelings of being **distressed (upset)** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_6. Your **shortness of breath** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_7. Your problem with **remembering things** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_8. Your problem with **lack of appetite** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_9. Your feeling **drowsy (sleepy)** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_10. Your having a **dry mouth** at its WORST?	0	1	2	3	4	5	6	7	8	9	10

(symptoms, continued)

Please circle one number per row.	Not Present										As Bad As You Can Imagine
MDASI_11. Your feeling **sad** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_12. Your **vomiting** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
MDASI_13. Your **numbness or tingling** at its WORST?	0	1	2	3	4	5	6	7	8	9	10

Part II. How have your symptoms **interfered** with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items ***in the last 24 hours?*** Please select a number from 0 (symptoms have not interfered) to 10 (symptoms interfered completely) for each item.

Please circle one number per row.	Did Not Interfere										Interfered Completely
MDASI_14. **General activity?**	0	1	2	3	4	5	6	7	8	9	10
MDASI_15. **Mood?**	0	1	2	3	4	5	6	7	8	9	10
MDASI_16. **Work** (including work around the house)?	0	1	2	3	4	5	6	7	8	9	10
MDASI_17. **Relations** with other people?	0	1	2	3	4	5	6	7	8	9	10
MDASI_18. **Walking?**	0	1	2	3	4	5	6	7	8	9	10
MDASI_19. **Enjoyment** of life?	0	1	2	3	4	5	6	7	8	9	10

Health History

Please use this form to indicate with a check whether you have any of the following **health conditions** you may have experienced or be dealing with presently.

Please check yes or no for each row.	**Yes**	**No**
CCI_1. Asthma, emphysema, or chronic bronchitis	☐	☐
CCI_2. Arthritis or rheumatism	☐	☐
CCI_3. Cancer diagnosed in the **past 3 years**	☐	☐
CCI_4. Diabetes	☐	☐
CCI_5. Digestive problems (such as ulcer, colitis, or gallbladder disease)	☐	☐
CCI_6. Heart trouble (such as angina, congestive heart failure, or coronary artery disease)	☐	☐
CCI_7. HIV illness or AIDS	☐	☐
CCI_8. Kidney disease	☐	☐
CCI_9. Liver problems (such as cirrhosis)	☐	☐
CCI_10. Stroke	☐	☐

Financial Impact of Cancer

People who have experienced cancer may be impacted financially. We are trying to learn the financial impacts of having multiple cancers.

The next set of questions will ask you about **financial problems** you may have experienced. As with the rest of the study, all responses will be kept confidential.

Below is a list of statements that other people with cancer have said are important. Please check one box per line to indicate your response as it applies to the **past 7 days.**

		Not at all 0	A little bit 1	Some-what 2	Quite a bit 3	Very much 4
COST_1	I know that I have enough money in savings, retirement, or assets to cover the costs of my treatment……	☐	☐	☐	☐	☐
COST_2	My out-of-pocket medical expenses are more than I thought they would be……..…..	☐	☐	☐	☐	☐
COST_3	I worry about the financial problems I will have in the future as a result of my illness or treatment…….	☐	☐	☐	☐	☐
COST_4	I feel I have no choice about the amount of money I spend on care……...……...	☐	☐	☐	☐	☐
COST_5	I am frustrated that I cannot work or contribute as much as I usually do……...	☐	☐	☐	☐	☐
COST_6	I am satisfied with my current financial situation…..	☐	☐	☐	☐	☐
COST_7	I am able to meet my monthly expenses……	☐	☐	☐	☐	☐
COST_8	I feel financially stressed……	☐	☐	☐	☐	☐
COST_9	I am concerned about keeping my job and income, including work at home……..	☐	☐	☐	☐	☐
COST_10	My cancer or treatment has reduced my satisfaction with my present financial situation……	☐	☐	☐	☐	☐
COST_11	I feel in control of my financial situation……...	☐	☐	☐	☐	☐

Financial Hardships

Please check one answer per row that best applies to you.

Financial Strain	**Almost never 1**	**Once in a while 2**	**Sometimes 3**	**A lot of the time (frequently) 4**	**Almost always 5**
EH_1. In the next three months, how often do you think that you and your family will experience bad times such as poor housing or not having enough food?	☐	☐	☐	☐	☐
EH_2. In the next three months, how often do you expect that you will have to do without the basic things that your family needs?	☐	☐	☐	☐	☐

Inability to Make Ends Meet	**A great deal of difficulty 1**	**Quite a bit of difficulty 2**	**Some difficulty 3**	**A little difficulty 4**	**No difficulty at all 5**
EH_3. Think back over the past 3 months and tell us how much difficulty you had paying your bills. Would you say you had...	☐	☐	☐	☐	☐
	More than enough money left 1	**Some money left 2**	**Just enough money left 3**	**Somewhat short of money 4**	**Very short of money 5**
EH_4. Think again over the past 3 months. Generally, at the end of each month, did you end up with...	☐	☐	☐	☐	☐

(financial hardships, continued)

Please check one answer per row that best applies to you.

Not Enough Money for Necessities

Please think about how you felt about your family's economic situation over the past 3 months. Indicate how much you would agree or disagree with each statement.	**Strongly agree 1**	**Agree 2**	**Neutral/ Mixed 3**	**Disagree 4**	**Strongly disagree 5**
EH_5. My family had enough money to afford the kind of home we should have.	☐	☐	☐	☐	☐
EH_6. We had enough money to afford the kind of clothing we should have.	☐	☐	☐	☐	☐
EH_7. We had enough money to afford the kind of furniture or household appliances we should have.	☐	☐	☐	☐	☐
EH_8. We had enough money to afford the kind of car we need.	☐	☐	☐	☐	☐
EH_9. We had enough money to afford the kind of food we should have.	☐	☐	☐	☐	☐
EH_10. We had enough money to afford the kind of medical care we should have.	☐	☐	☐	☐	☐
EH_11. My family had enough money to afford leisure and recreational activities.	☐	☐	☐	☐	☐

(financial hardships, continued)

Please check one answer per row that best applies to you.

Economic Adjustments/Cutbacks

In the past 3 months, has your family made any of the following adjustments because of financial need?	**Yes 1**	**No 2**
EH_12. Changed food shopping or eating habits a lot to save money	☐	☐
EH_13. Shut down the heat or air conditioning to save money even though it made the house uncomfortable	☐	☐
EH_14. Didn't go to see the doctor or dentist when you needed to because you had to save money	☐	☐
EH_15. Fell far behind in paying bills	☐	☐
EH_16. Asked relatives or friends for money or food to help you get by	☐	☐
EH_17. Added another job to help make ends meet	☐	☐
EH_18. Received government assistance	☐	☐
EH_19. Sold some possessions because you needed the money (even though you really wanted to keep them)	☐	☐
EH_20. Moved to another house or apartment to save money	☐	☐

Ability to Participate in Social Roles and Activities

Please respond to each item by marking one box per row.

		Never 5	Rarely 4	Some-times 3	Usually 2	Always 1
PABIL_1	I have trouble doing all of my regular leisure activities with others.....	☐	☐	☐	☐	☐
PABIL_2	I have trouble doing all of the family activities that I want to do…….	☐	☐	☐	☐	☐
PABIL_3	I have trouble doing all of my usual work (include work at home)……...	☐	☐	☐	☐	☐
PABIL_4	I have trouble doing all of the activities with friends that I want to do…….	☐	☐	☐	☐	☐
PABIL_5	I have to limit the things I do for fun with others…….	☐	☐	☐	☐	☐
PABIL_6	I have to limit my regular activities with friends……..	☐	☐	☐	☐	☐
PABIL_7	I have to limit my regular family activities……...	☐	☐	☐	☐	☐
PABIL_8	I have trouble doing all of the work that is really important to me (including work at home)…..	☐	☐	☐	☐	☐

<u>Satisfaction</u> with Participation in Social Roles

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	Not at all 5	A little bit 4	Some-what 3	Quite a bit 2	Very much 1
PSAT_1	I am satisfied with how much work I can do (include work at home)……..	☐	☐	☐	☐	☐
PSAT_2	I am satisfied with my ability to work (include work at home)…..	☐	☐	☐	☐	☐
PSAT_3	I am satisfied with my ability to do regular personal and household responsibilities……..	☐	☐	☐	☐	☐
PSAT_4	I am satisfied with my ability to perform my daily routines……..	☐	☐	☐	☐	☐
PSAT_5	I am satisfied with my ability to meet the needs of those who depend on me……..	☐	☐	☐	☐	☐
PSAT_6	I am satisfied with my ability to do household chores/tasks……..	☐	☐	☐	☐	☐
PSAT_7	I am satisfied with my ability to do things for my family……..	☐	☐	☐	☐	☐
PSAT_8	I am satisfied with the amount of time I spend performing my daily routines……..	☐	☐	☐	☐	☐

General Outlook

Please use the rating scale below to indicate how accurately each statement describes you.

How much do you agree with each statement about you as you generally are **now**, not as you wish to be in the future?

In general, I…	**Strongly Disagree 1**	**Somewhat Agree 2**	**Neither Agree nor Disagree 3**	**Somewhat Agree 4**	**Strongly Agree 5**
IPIP_1. Get chores done right away.	☐	☐	☐	☐	☐
IPIP_2. Have frequent mood swings.	☐	☐	☐	☐	☐
IPIP_3. Often forget to put things back in their proper place.	☐	☐	☐	☐	☐
IPIP_4. Am relaxed most of the time.	☐	☐	☐	☐	☐
IPIP_5. Like order.	☐	☐	☐	☐	☐
IPIP_6. Get upset easily.	☐	☐	☐	☐	☐
IPIP_7. Make a mess of things.	☐	☐	☐	☐	☐
IPIP_8. Seldom feel blue.	☐	☐	☐	☐	☐

Social Support

Instructions: This scale is made up of a list of statements each of which may or may not be true about you. For each statement circle "definitely true" if you are sure it is true about you and "probably true" if you think it is true but are not absolutely certain. Similarly, you should circle "definitely false" if you are sure the statement is false and "probably false" if you think it is false but are not absolutely certain.

ISEL_1. **If I wanted to go on a trip for a day (for example, to the country or mountains), I would have a hard time finding someone to go with me.**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL_2. **I feel that there is no one I can share my most private worries and fears with.**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL_3. **If I were sick, I could easily find someone to help me with my daily chores.**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL_4. **There is someone I can turn to for advice about handling problems with my family.**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL_5. **If I decide one afternoon that I would like to go to a movie that evening, I could easily find someone to go with me.**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL_6. **When I need suggestions on how to deal with a personal problem, I know someone I can turn to.**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL_7. **I don't often get invited to do things with others.**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL_8. **If I had to go out of town for a few weeks, it would be difficult to find someone who would look after my house or apartment (the plants, pets, garden, etc.).**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL_9. **If I wanted to have lunch with someone, I could easily find someone to join me.**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL_10. **If I was stranded 10 miles from home, there is someone I could call who could come and get me.**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL11. **If a family crisis arose, it would be difficult to find someone who could give me good advice about how to handle it.**
1. definitely false 2. probably false 3. probably true 4. definitely true

ISEL_12. **If I needed some help in moving to a new house or apartment, I would have a hard time finding someone to help me.**
1. definitely false 2. probably false 3. probably true 4. definitely true

Socio-demographic Questionnaire – Part 2

SD_13. Which of the following best describes your current marital status?

- Never married
- Currently married
- Living with partner / significant other
- Widowed
- Separated
- Divorced
- Other (SD_13a. specify _____)

SD_14. How many years have you been at your current marital status?
Answer "1" if less than one year. _____ years

SD_15. Is English your primary language (the one you speak most often)? • Yes • No

SD_16. What is the zip code where you live most of the time? _____ (5-digit)

SD_17. In what type of area did you live most of your childhood?

- Urban, large city
- Urban, small city
- Suburb of large city
- Suburb of small city
- Rural, farm
- Rural, non-farm
- Other (SD_17a. specify _____)

(socio-demographics, continued)

SD_18. How many total years of formal education do you have? _____

SD_19. What is the ***highest*** grade or degree you have completed?

- Grade school (grades 1-8)
- High school diploma (grades 9-12)
- GED (Graduate Equivalent Degree)
- Vocational/Technical school certificate
- 2-year college (Associate's level)
- 4-year college (Bachelor's level)
- Graduate school (Master's level)
- Professional school (i.e., MD, DVM, JD)
- Graduate school (Doctoral level, i.e., PhD, EdD)
- Unknown

SD_20. What is your *current* employment status?

- Full time (working at least 35 hours a week)
- Part time (working less than 35 hours a week)
- Laid off or unemployed, looking for work
- Laid off or unemployed, not looking for work
- Retired, not working at all
- Retired, but working part or full time
- Disabled/unable to work
- Full time homemaker
- Student
- Other (SD_20a. specify _____)

(socio-demographics, continued)

SD_21. Are you *currently* employed? • Yes • No

If you are NOT currently employed:

SD_21a. What *was* your primary occupation? _____

SD_21b. When was the last year you were employed? _____

If you ARE currently employed:

SD_21c. What *is* your primary occupation? _____

SD_22. Did you make changes at work since your second cancer diagnosis?

• Yes • No *(If no, skip to SD_23 on page 39.)*

SD_22a. If YES, why?

- I changed because of the physical demands of my job.
- I changed because of the mental demands of my job.
- I changed for other reasons.
- No, my change in occupation was not because of my cancer.

SD_22b. If YES, what change(s) did you make at work since your second cancer diagnosis?

Please specify: _____

_____

_____

SD_22c. Did that change affect your insurance coverage? • Yes • No

SD_22d. If YES, please specify how: _____

_____

SD_22e. Did that change affect your retirement benefits? • Yes • No

SD_22f. If YES, please specify how: _____

(socio-demographics, continued)

SD_23. Has your cancer or treatment caused you to take **paid** time off work? • Yes • No

SD_23a. If YES, how many days in the past month? Please specify: _____

SD_24. Has your cancer or treatment caused to take **unpaid** time off work? • Yes • No

SD_24a. If YES, how many days in the past month? Please specify: _____

SD_25. Do you have any children? • Yes • No *(If no, skip to SD_26.)*

SD_25a. If YES, specify number of children: _____

SD_25b. If YES, specify current age(s) of children:
For example, you might write, "2, 7, 21" on the line below, if these are the ages of your children.

_____

SD_26. How many people presently live in your household, *including yourself*?

SD_26a. Adults: _____

SD_26b. Children (under 18 years old): _____

(socio-demographics, continued)

SD_27. How important is religion or spirituality in your life?

- Not at all important
- Somewhat important
- Extremely important

SD_28. Do you have a religious background or preference? • Yes • No *(If no, skip to SD_29 on page 41.)*

SD_28a. If YES, please specify:

- Christianity
- Judaism
- Islam
- Hinduism
- Buddhism
- Other (SD_28b. specify: _____)

SD_28c. To what extent do you follow the customs and practices of your religion?

- Never
- Sometimes
- Frequently
- Always

(socio-demographics, continued)

SD_29. Do you have health care insurance? • Yes • No *(If no, skip to SD_30, page 42.)*

SD_29a. If YES, please specify type:

- Medicare
- Medicaid/Medical Assistance
- SSI
- Veterans Administration
- Workers Compensation
- Private health insurance (SD_29b. specify _____)
- Other (SD_29c. specify _____)

SD_29d. Does your insurance cover the cost of your *medications*?

- Yes, all the cost
- Yes, some of the cost (SD_29e. specify _____)
- No
- Unknown

SD_29f. Does your insurance cover the cost of your *health care*?

- Yes, all the cost
- Yes, some of the cost - for example, it does not cover the cost of co-pays or other expenses
  (SD_29g. specify _____)
- No
- Unknown

(socio-demographics, continued)

SD_30. What are the sources of your **<u>own</u>** total **gross** annual income (all sources of income before taxes)? *Select all that apply:*

- Wages, salaries, commissions, bonus, tips from all jobs
- Self employment income from farm or non-farm business
- Interest, dividend, net rental income, royalties, or from estates or trusts
- Social security or railroad retirement
- Supplemental security income or other public assistance income
- Retirement, survivor, or disability pensions
- Other (SD_30a. please specify _____)

SD_31. What is the total **gross** annual income for your **<u>household</u>** (all sources of income before taxes and donations)?

- Under $10,000
- $10,000 - $14,999
- $15,000 - $19,999
- $20,000 - $29,999
- $30,000 - $39,999
- $40,000 - $49,999
- $50,000 - $59,999
- $60,000 - $69,999
- $70,000 - $79,999
- $80,000 - $99,999
- $100,000 - $150,000
- Over $150,000
- Unknown
- Refuse/Prefer not to answer

SD32. How difficult is it to pay for your basic needs?

- Not at all difficult
- Somewhat difficult
- Extremely difficult

Health Care Use

HCU_1.	**In the past 6 months**, how many times did you visit a physician? *Do **NOT** include visits while in the hospital or the hospital emergency room.*	_____ visits
HCU_2.	**In the past 6 months,** how many times did you go to a **hospital** emergency room? …….....	_____ times
HCU_3.	How many different **times** did you stay in a hospital overnight or longer **in the past 6 months**? …….	_____ times
HCU_4.	How many total **NIGHTS** did you spend in the hospital **in the past 6 months**? …….....	_____ nights

Multiple Primary Cancer (MPC) Items – Part 2

MPC_9. What do you wish every healthcare provider knew about what it's like to be diagnosed with cancer more than once? *Please feel free to attach additional sheets if more space is needed.*

You have completed all questionnaires.

A sincere thank you for being a part of this study!

Please return 1) this packet of questionnaires and 2) one signed copy of the consent form to Sarah Belcher in the enclosed postage-paid envelope. The second consent form copy is for your records.

You will be receiving instructions from our research team for accessing your compensation.

If you have any questions or concerns,
please contact the study's principal investigator,
Sarah Belcher, at 412-624-8938
or LAMPstudy@pitt.edu.

MEDICAL RECORD REVIEW

Medical Record Data Extraction Form

Participant Study ID:	Medical Record Number:
Data Collector Name:	
Data Collection Date (mm/dd/yyyy):	

Participant Socio-Demographics

Insurance: *Record types from up to 1 year prior to 1st cancer diagnosis to present.*

Insurance Type(s):	Date(s) Recorded in Medical Record (mm/dd/yyyy)

Anthropometric Data

Time Point	Height (centimeters)	Weight (kilograms)	BMI (kg/m^2)
At *first* diagnosis Date: _____	_____ cm	_____ kg	_____ (kg/m^2)
At *second* diagnosis Date: _____	_____ cm	_____ kg	_____ (kg/m^2)
Most recently recorded Date: _____	_____ cm	_____ kg	_____ (kg/m^2)

Family Cancer History

Family history of cancer in 1st degree relative (parent, brother, sister, or child)?

☐ Yes ☐ No If yes, list:

Relationship:	Type of Cancer:

Genetic Testing

Did participant receive any type of genetic testing?

☐ Yes ☐ No If yes, describe:

Date:	Type/Findings:

Most Current Medication List (prescription and OTC):

Date Recorded in Medical Record (mm/dd/yyyy): _____

☐ aspirin

☐ atorvastatin (Lipitor)

☐ diphenhydramine hydrochloride (Benadryl)

☐ famotidine (Pepcid)

☐ furosemide (Lasix)

☐ hydrochlorothiazide (Microzide)

☐ hydrocodone/acetaminophen (Vicodin, Norco, Xodol)

☐ levothyroxine (Synthroid, Levoxyl, Unithyroid)

☐ lisinopril (Prinivil, Zestril)

☐ meclizine hydrochloride (Bonine, Verticalm)

☐ metformin hydrochloride (Glucophage)

☐ metoprolol (Lopressor, Toprol XL)

☐ omeprazole (Prilosec)

☐ ondansetron (Zofran)

☐ prednisone (Delasone, Sterapred)

☐ ranitidine (Zantac)

☐ sertraline hydrochloride (Zoloft)

☐ simvastin (Zocor, FloLipid)

☐ zolpidem tartrate (Ambien)

☐ Other *(specify on lines below):*

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Non-Cancer Past Medical/Surgical History (Comorbidities):
Include non-invasive skin cancer (e.g. basal cell carcinoma) here if applicable.

☐ Arthritis

☐ Cardiac Disease *(If yes, describe below:)*

_____

☐ Depression

☐ Diabetes

☐ Dyslipidemia

☐ Hypertension

☐ Hypothyroidism

☐ Menopause

☐ Obesity

☐ Osteoporosis &/or Osteopenia

☐ Other *(specify below):*

_____

_____

_____

_____

_____

_____

_____

_____

_____

Cancer History:

Number of primary cancer diagnoses, excluding non-invasive skin cancers (e.g. basal cell).
Do not count metastases or recurrences!

_____ primary cancer diagnoses

Were primary cancer diagnoses:

☐ Synchronous (at same time)? ☐ Metachronous (at different times)?

Relevant notes: _____

_____

_____

_____

_____

First Primary Cancer Type:

Note: ***Exclude cases of non-invasive skin cancer (list in past medical/surgical history).***

☐ Breast Cancer

☐ Prostate Cancer

☐ Colorectal Cancer

☐ Urinary Bladder Cancer

☐ Uterine Corpus Cancer

☐ Melanoma

☐ Kidney / Renal Pelvis Cancer

☐ Oral Cavity / Pharynx Cancer

☐ Lung / Bronchus Cancer

☐ Thyroid Cancer

☐ Ovarian Cancer

☐ Other (*specify below*):

_____

Date of Diagnosis: _____

Histology: _____

Cancer Stage at *first* cancer diagnosis: _____

Did the first cancer recur?

☐ Yes ☐ No

If yes: List number of *total* recurrences: _____ (*describe in table below*)

Recurrence(s)	Date: (mm/dd/yyyy)	Site(s) of Recurrent/Metastatic Disease:
1st Recurrence		
2nd Recurrence		
3nd Recurrence		
4th Recurrence		

Cancer Treatment Type(s) Received for *First* Cancer:

☐ Surgery, *If yes, describe below* ☐ Targeted Therapy

_____

_____

☐ Radiation Therapy ☐ Hormone Therapy

☐ Chemotherapy ☐ Stem Cell Transplant

☐ Immunotherapy ☐ Other:

_____

Date of Treatment Initiation for ***First*** *Primary Cancer*:

_____

Date of Treatment Completion for ***First*** *Primary Cancer:* (*check here if treatment ongoing:* •)

_____

Note **Frontline** Therapy Received for ***First*** *Primary Cancer* Below:

(e.g. *FOLFOX 32mg/m2, every 6 weeks x 6 cycles; 6 cycles received; last dose held due to grade 4 neuropathy;* Radiation therapy doses of 75.6-79 Gy in conventional 36-41 Gy fractions to the prostate with 3D-CRT/IMRT with daily image-guided radiotherapy (IGRT) or brachytherapy)

Regimen Name(s)	Individual Drug Name(s) and Prescribed Dosages	Time Interval/ Frequency	Dosage Received	Dose Delay? (Y or N)	Dose Reduction? (Y or N)	Additional Notes (include regimen alteration rationale)

Note **Subsequent** Lines of Therapy (e.g. palliative, salvage intent) Received for ***First*** *Primary Cancer* Below:

Regimen Name(s)	Individual Drug Name(s) and Prescribed Dosages	Time Interval/ Frequency	# Cycles Received	Additional Notes (include regimen alteration rationale)

Second Primary Cancer Type:

Note: ***Exclude cases of non-invasive skin cancer (list in past medical/surgical history).***

☐ Breast Cancer

☐ Prostate Cancer

☐ Colorectal Cancer

☐ Urinary Bladder Cancer

☐ Uterine Corpus Cancer

☐ Melanoma

☐ Kidney / Renal Pelvis Cancer

☐ Oral Cavity / Pharynx Cancer

☐ Lung / Bronchus Cancer

☐ Thyroid Cancer

☐ Ovarian Cancer

☐ Other (*specify below*):

_____

Date of Diagnosis: _____

Histology: _____

Cancer Stage at *second* cancer diagnosis: _____

Did the *second* cancer recur?

☐ Yes ☐ No

If yes: List number of *total* recurrences: _____ (*describe in table below*)

Recurrence(s)	Date: (mm/dd/yyyy)	Site(s) of Recurrent/Metastatic Disease:
1st Recurrence		
2nd Recurrence		
3nd Recurrence		
4th Recurrence		

Cancer Treatment Type(s) Received for *Second* Cancer:

☐ Surgery, *If yes, describe below* ☐ Targeted Therapy

_____

_____

☐ Radiation Therapy ☐ Hormone Therapy

☐ Chemotherapy ☐ Stem Cell Transplant

☐ Immunotherapy ☐ Other:

_____

Date of Treatment Initiation for *Second Primary Cancer*:

_____

Date of Treatment Completion for *Second Primary Cancer:* (*check here if treatment ongoing:* •)

_____

Note **Frontline** Therapy Received for *Second Primary Cancer* Below:

(e.g. *FOLFOX 32mg/m2, every 6 weeks x 6 cycles; 6 cycles received; last dose held due to grade 4 neuropathy;* Radiation therapy doses of 75.6-79 Gy in conventional 36-41 Gy fractions to the prostate with 3D-CRT/IMRT with daily image-guided radiotherapy (IGRT) or brachytherapy)

Regimen Name(s)	Individual Drug Name(s) and Prescribed Dosages	Time Interval/ Frequency	Dosage Received	Dose Delay? (Y or N)	Dose Reduction? (Y or N)	Additional Notes (include regimen alteration rationale)

Note **Subsequent** Lines of Therapy (e.g. palliative, salvage intent) Received for *Second Primary Cancer* Below:

Regimen Name(s)	Individual Drug Name(s) and Prescribed Dosages	Time Interval/ Frequency	# Cycles Received	Additional Notes (include regimen alteration rationale)

Third Primary Cancer Type:

Note: ***Exclude cases of non-invasive skin cancer (list in past medical/surgical history).***

☐ Breast Cancer

☐ Prostate Cancer

☐ Colorectal Cancer

☐ Urinary Bladder Cancer

☐ Uterine Corpus Cancer

☐ Melanoma

☐ Kidney / Renal Pelvis Cancer

☐ Oral Cavity / Pharynx Cancer

☐ Lung / Bronchus Cancer

☐ Thyroid Cancer

☐ Ovarian Cancer

☐ Other (*specify below*):

_____

Date of Diagnosis: _____

Histology: _____

Cancer Stage at *third* cancer diagnosis: _____

Did the third cancer recur?

☐ Yes ☐ No

If yes: List number of *total* recurrences: _____ (*describe in table below*)

Recurrence(s)	Date: (mm/dd/yyyy)	Site(s) of Recurrent/Metastatic Disease:
1st Recurrence		
2nd Recurrence		
3nd Recurrence		
4th Recurrence		

Cancer Treatment Type(s) Received for *Third* Cancer:

☐ Surgery, *If yes, describe below* ☐ Targeted Therapy

_____

_____

☐ Radiation Therapy ☐ Hormone Therapy

☐ Chemotherapy ☐ Stem Cell Transplant

☐ Immunotherapy ☐ Other:

_____

Date of Treatment Initiation for *Third Primary Cancer*:

_____

Date of Treatment Completion for *Third Primary Cancer:* (*check here if treatment ongoing:* •)

_____

Note **Frontline** Therapy Received for *Third Primary Cancer* Below:

(e.g. *FOLFOX 32mg/m2, every 6 weeks x 6 cycles; 6 cycles received; last dose held due to grade 4 neuropathy;* Radiation therapy doses of 75.6-79 Gy in conventional 36-41 Gy fractions to the prostate with 3D-CRT/IMRT with daily image-guided radiotherapy (IGRT) or brachytherapy)

Regimen Name(s)	Individual Drug Name(s) and Prescribed Dosages	Time Interval/ Frequency	Dosage Received	Dose Delay? (Y or N)	Dose Reduction? (Y or N)	Additional Notes (include regimen alteration rationale)

Note **Subsequent** Lines of Therapy (e.g. palliative, salvage intent) Received for *Third Primary Cancer* Below:

Regimen Name(s)	Individual Drug Name(s) and Prescribed Dosages	Time Interval/ Frequency	# Cycles Received	Additional Notes (include regimen alteration rationale)

Fourth Primary Cancer Type:

Note: ***Exclude cases of non-invasive skin cancer (list in past medical/surgical history).***

☐ Breast Cancer

☐ Prostate Cancer

☐ Colorectal Cancer

☐ Urinary Bladder Cancer

☐ Uterine Corpus Cancer

☐ Melanoma

☐ Kidney / Renal Pelvis Cancer

☐ Oral Cavity / Pharynx Cancer

☐ Lung / Bronchus Cancer

☐ Thyroid Cancer

☐ Ovarian Cancer

☐ Other (*specify below*):

_____

Date of Diagnosis: _____

Histology: _____

Cancer Stage at *fourth* cancer diagnosis: _____

Did the fourth cancer recur?

☐ Yes ☐ No

If yes: List number of *total* recurrences: _____ (*describe in table below*)

Recurrence(s)	Date: (mm/dd/yyyy)	Site(s) of Recurrent/Metastatic Disease:
1st Recurrence		
2nd Recurrence		
3nd Recurrence		
4th Recurrence		

Cancer Treatment Type(s) Received for *Fourth* Cancer:

☐ Surgery, *If yes, describe below* ☐ Targeted Therapy

_____

_____

☐ Radiation Therapy ☐ Hormone Therapy

☐ Chemotherapy ☐ Stem Cell Transplant

☐ Immunotherapy ☐ Other:

_____

Date of Treatment Initiation for *Fourth Primary Cancer*:

_____

Date of Treatment Completion for *Fourth Primary Cancer:* (*check here if treatment ongoing:* •)

_____

Note **Frontline** Therapy Received for *Fourth Primary Cancer* Below:

(e.g. *FOLFOX 32mg/m2, every 6 weeks x 6 cycles; 6 cycles received; last dose held due to grade 4 neuropathy;* Radiation therapy doses of 75.6-79 Gy in conventional 36-41 Gy fractions to the prostate with 3D-CRT/IMRT with daily image-guided radiotherapy (IGRT) or brachytherapy)

Regimen Name(s)	Individual Drug Name(s) and Prescribed Dosages	Time Interval/ Frequency	Dosage Received	Dose Delay? (Y or N)	Dose Reduction? (Y or N)	Additional Notes (include regimen alteration rationale)

Note **Subsequent** Lines of Therapy (e.g. palliative, salvage intent) Received for *Fourth Primary Cancer* Below:

Regimen Name(s)	Individual Drug Name(s) and Prescribed Dosages	Time Interval/ Frequency	# Cycles Received	Additional Notes (include regimen alteration rationale)

UPMC Cancer Registry Data

Hospital ID:	
Managing Physician of Record (Last, First):	
Surgeon of Record (Last, First):	
Date of Last Contact (mm/dd/yyyy):	

Cancer Registry - Cancer Data:

First Primary Cancer:	
Diagnosis 1	
Date of Diagnosis 1 (mm/dd/yyyy)	
Laterality	
Histology	
Stage at Diagnosis	

Second Primary Cancer:	
Diagnosis 2	
Date of Diagnosis 2 (mm/dd/yyyy)	
Laterality	
Histology	
Stage at Diagnosis	

Third Primary Cancer:	
Diagnosis 3	
Date of Diagnosis 3 (mm/dd/yyyy)	
Laterality	
Histology	
Stage at Diagnosis	

Fourth Primary Cancer:	
Diagnosis 4	
Date of Diagnosis 4 (mm/dd/yyyy)	
Laterality	
Histology	
Stage at Diagnosis	

APPENDIX C

HUMAN SUBJECTS APPROVALS AND CONSENTS (PRO16050542)

Pitt Seal

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

To: Sarah Belcher

From: IRB Office

Date: 10/3/2017

IRB#: PRO16050542

Subject: Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers

---

The University of Pittsburgh Institutional Review Board reviewed and approved the above referenced study by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110. Your research study was approved under:

45 CFR 46.110.(5)
45 CFR 46.110.(7)

The risk level designation is Minimal Risk.

Approval Date: 10/3/2017
Expiration Date: 10/2/2018

For studies being conducted in UPMC facilities, no clinical activities can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of

Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

Pitt Seal

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
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http://www.irb.pitt.edu

Memorandum

To: Sarah Belcher

From: IRB Office

Date: 10/17/2017

IRB#: MOD16050542-01 / PRO16050542

Subject: Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers

---

The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 10/17/2017
Expiration Date: 10/2/2018

For studies being conducted in UPMC facilities, no clinical activities that are impacted by the modifications can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

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http://www.irb.pitt.edu

Memorandum

To: Sarah Belcher

From: IRB Office

Date: 12/7/2017

IRB#: MOD16050542-02 / PRO16050542

Subject: Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers

---

The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 12/7/2017
Expiration Date: 10/2/2018

For studies being conducted in UPMC facilities, no clinical activities that are impacted by the modifications can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

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Memorandum

To: Sarah Belcher

From: IRB Office

Date: 12/20/2017

IRB#: MOD16050542-03 / PRO16050542

Subject: Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers

---

The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 12/20/2017
Expiration Date: 10/2/2018

For studies being conducted in UPMC facilities, no clinical activities that are impacted by the modifications can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

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Memorandum

To: Sarah Belcher

From: IRB Office

Date: 2/8/2018

IRB#: MOD16050542-04 / PRO16050542

Subject: Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers

---

The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 2/8/2018
Expiration Date: 10/2/2018

[see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

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Memorandum

To: Sarah Belcher

From: IRB Office

Date: 3/13/2018

IRB#: MOD16050542-06 / PRO16050542

Subject: Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers

---

The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 3/13/2018
Expiration Date: 10/2/2018

For studies being conducted in UPMC facilities, no clinical activities that are impacted by the modifications can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

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Memorandum

To: Sarah Belcher

From: IRB Office

Date: 3/16/2018

IRB#: MOD16050542-07 / PRO16050542

Subject: Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers

---

The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 3/16/2018
Expiration Date: 10/2/2018

For studies being conducted in UPMC facilities, no clinical activities that are impacted by the modifications can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE OF RESEARCH PROJECT:

Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers: The LAMP Study

PRINCIPAL INVESTIGATOR: Sarah M. Belcher, PhD(c), RN, OCN®
Doctoral Candidate
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415 Victoria Building
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412-624-8938

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UPMC
412-648-6578

SOURCES OF SUPPORT: American Cancer Society Doctoral Degree Scholarship in Cancer Nursing
Robert Wood Johnson Foundation Future of Nursing Scholars
Nightingale Awards of Pennsylvania
University of Pittsburgh School of Nursing

You are being asked to take part in a research study being conducted by the University of Pittsburgh's School of Nursing. We will ask you to complete a one-time set of questionnaires that will take approximately 30-40 minutes to complete.

WHY IS THIS RESEARCH BEING DONE?

We are doing this study to help us understand the experiences of adult cancer survivors like you who have had two separate types of cancer. We call two or more separate types of cancers "multiple primary cancers." We want to learn more about how having multiple primary cancers impacts stress, health behaviors, and emotional and overall health.

WHO IS BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being invited to take part in this research study because you have a history of two separate types of cancer, or multiple primary cancers. We will enroll 450 multiple primary cancer survivors like you in this study.

WHAT PROCEDURES WILL BE PERFORMED FOR RESEARCH PURPOSES?

The study procedures consist of a one-time completion of a set of questionnaires and a medical record review. We will send you either a personalized internet link to complete the questionnaire online or a pencil-paper copy of the questionnaires with a pre-stamped, pre-addressed return envelope.

1. The questionnaire can be completed online, or we can mail you the questionnaire to do on paper.
You will complete a set of questionnaires that include demographic and health information and questions about stress, health behaviors, your experience with cancer, and emotional and overall health.

If done on paper, you will then return the signed consent form (required) along with the completed questionnaires in the return envelope provided to you.

Online responses are automatically recorded.

We estimate that the questionnaire will take **30-40 minutes** to complete.

If we do not receive your questionnaires after we sent you the initial packet in the mail, we will send you a reminder postcard two weeks after the initial letter and a reminder letter and replacement questionnaire three weeks after the initial letter.

2. We will review your medical record to find out about your health.
   We will record information about types of cancer, dates diagnosed, cancer treatments, and any other illnesses you may have had.

3. A refusal form is requested if you do not want to participate in the study.

If you choose not to participate in the study, you will be asked to complete five questions to help us understand why people are not participating in this study. Answering these additional five questions is voluntary.

WHAT ARE THE POSSIBLE RISKS, SIDE EFFECTS, AND DISCOMFORTS OF THIS RESEARCH STUDY?

This is a very low risk study, but you should be aware of risks.

1. One potential risk is a breach of confidentiality, but we will do everything possible to protect your privacy. To protect your privacy, only Ms. Belcher (the principle investigator) and members of the research team will be aware of your participation in this research study. Your name will not be included on the questionnaires we ask you to complete or the information we collect from your medical record. Mailed questionnaires and information collected about you from your medical record will be kept in secure, locked file cabinets at the School of Nursing. All information will be identified only by a study ID number. The information linking these ID numbers with your identify will be kept separate from the research records and will be stored under lock and key. If you complete the questionnaires online, the website where you complete the questionnaire is secure, and your data will be safely stored and can only be accessed by study team members. All researchers involved in this study have been thoroughly trained to maintain your privacy. All information you provide will be kept by the Principle Investigator in a locked file cabinet within a locked office at the School of Nursing. Your identity will not be revealed in any description or publications of this research, and data will only be presented about groups and not individual participants.

2. Another possible risk of this research study may include stress from having to complete the questionnaires. If the questions cause you stress or discomfort, you can take a break from completing the questionnaires. If any individual questions makes you feel distressed (anxious, sad, or nervous), you do not have to answer them.

WHAT ARE POSSIBLE BENEFITS FROM TAKING PART IN THIS STUDY?

You will likely receive no direct benefit from taking part in this research study. The results from this study may benefit survivors like you who experience multiple primary cancer diagnoses in the future but will have no direct benefit to you.

WILL I BE PAID IF I TAKE PART IN THIS RESEARCH STUDY?

Each participant will be provided with a $5 Amazon.com gift card code in recognition of his or her time and expertise after completing and returning the survey to Ms. Belcher.

WHO WILL KNOW ABOUT MY PARTICIPATION IN THIS RESEARCH STUDY?

Any information about you obtained from this research will be kept strictly confidential (private), and any data that includes your identity will be stored in locked files in Research Project Office or in a password protected computer system. All records related to your involvement in this research study will be stored in a locked file cabinet in a locked room at the School of Nursing. Your identity on these records, and in the corresponding data entered into the computerized system, will be indicated by an ID number rather than by your name. The information linking these ID numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research. All records will be retained by us for a minimum of seven years.

It is possible that we may use the information obtained from this study to answer more research questions in other research studies. This information may also be shared with other researchers here, and at other research centers, but those researchers will never be provided with any personal identifiers that would allow them to learn who you are.

Why is my authorization being requested?

We are also requesting your authorization, or permission, to review your medical records to confirm information about your cancer and medical history and treatments. The authorization to access your medical records will be valid for a minimum of 7 years. **We will obtain the following information**: your diagnoses and treatments, age, past medical history, and results of any tissue biopsies or blood tests done as part of your standard evaluation at the Cancer Center. **This identifiable medical record information will be made available to members of the research team for an indefinite period of time**. Your medical information, as well as information obtained during this research study, **may be shared with other groups**, possibly including authorized officials from the University of Pittsburgh Research Conduct and Compliance Office, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and address billing and operational issues.

We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but **cannot guarantee the confidentiality of your research records, including information obtained from your medical records** once your personal information is disclosed to others outside UPMC or the University. Y**ou can always withdraw your authorization to allow the research team to review your medical records** by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

IS MY PARTICIPATION IN THIS STUDY VOLUNTARY?

Your participation in this study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this form. Your decision will not affect your relationship or

current or future care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you are eligible to participate, you will not be removed from this study without your consent.

HOW CAN I GET MORE INFORMATION ABOUT THIS STUDY?

If you have any further questions about this research study, you may contact Ms. Belcher (412-624-8938 or LAMPstudy@pitt.edu) or the investigators listed at the beginning of this consent form. If you have any questions about your rights as a research subject, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office at 866-212-2668.

****

Agreement to Participate

By clicking "Yes, I agree," in the online survey, you are providing your consent to participate in this research study and your agreement with the following information:

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction. A copy of this consent form has been made available to me.

- I understand that I am encouraged to ask questions about any aspect of this research study and that those questions will be answered by the researchers listed on the first page of this form.

- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future relationship with this institution.

- I consent to participate in this research study and provide my authorization to share my medical records with the research team for the purposes described above.

Completion of the following questions in the online survey will serve as verification of electronic consent to participate in this research study and HIPAA authorization for use of medical records for the purposes described above:

- Subject's full name
- Subject's birthdate
- Subject's answer to one of the following verifiable questions:
  1. What is your mother's maiden name?
  2. In what city were you born?
  3. What high school did you attend?

University of Pittsburgh

School of Nursing
Department of Health and Community Systems

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE OF RESEARCH PROJECT:

Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers: The LAMP Study

PRINCIPAL INVESTIGATOR: Sarah M. Belcher, PhD(c), RN, OCN®
Doctoral Candidate
University of Pittsburgh School of Nursing
415 Victoria Building
3500 Victoria Street
Pittsburgh, PA 15261
412-624-8938

CO-INVESTIGATORS:

Leonard Appleman, MD, PhD
Physican, Division of Hematology-Oncology
UPMC
412-648-6507

Dana Bovbjerg, PhD
Director, Biobehavioral Oncology Program
University of Pittsburgh Cancer Institute
412-623-5965

Adam Brufsky, MD, PhD
Associate Chief, Division of Hematology-Oncology
Co-Director, Comprehensive Breast Center
UPMC
412-641-6500

Grace Campbell, PhD, MSW, RN, CRRN
Assistant Professor
School of Nursing
412-417-8804

Edward Chu, MD
Chief, Division of Hematology-Oncology
UPMC
412-648-6589

Heidi Donovan, PhD, RN
Professor and Vice Chair for Research
School of Nursing
412-624-2699

Robert Edwards, MD
Chair, Gynecology & Reproductive Sciences
Magee-Womens Hospital of UPMC
412-641-4212

Jonas Johnson, MD
Chairman, Otolaryngology
UPMC
412-647-2100

John Kirkwood, MD
Director, Melanoma and Skin Cancer Program
UPMC
412-623-7707

Susan Sereika, PhD
Director, Center for Research and Evaluation
School of Nursing
412-624-0799

Paula Sherwood, PhD, RN, CNRN, FAAN
Professor
School of Nursing
412-624-4802

Liza Villaruz, MD
Physician, Division of Hematology-Oncology
UPMC
412-648-6578

SOURCES OF SUPPORT: American Cancer Society Doctoral Degree Scholarship in Cancer Nursing
Robert Wood Johnson Foundation Future of Nursing Scholars
Nightingale Awards of Pennsylvania
University of Pittsburgh School of Nursing

You are being asked to take part in a research study being conducted by the University of Pittsburgh's School of Nursing. We will ask you to complete a one-time set of questionnaires that will take approximately 30-40 minutes to complete.

WHY IS THIS RESEARCH BEING DONE?

We are doing this study to help us understand the experiences of adult cancer survivors like you who have had two separate types of cancer. We call two or more separate types of cancers "multiple primary cancers." We want to learn more about how having multiple primary cancers impacts stress, health behaviors, and emotional and overall health.

WHO IS BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being invited to take part in this research study because you have a history of two separate types of cancer, or multiple primary cancers. We will enroll 450 multiple primary cancer survivors like you in this study.

WHAT PROCEDURES WILL BE PERFORMED FOR RESEARCH PURPOSES?

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Agreement to Participate

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction. A copy of this consent form has been provided to me.
- I understand that I am encouraged to ask questions about any aspect of this research study and that those questions will be answered by the researchers listed on the first page of this form.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future relationship with this institution.
- By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team.

_____
Subject's Printed Name

_____ _____ _____
Subject's Signature Date Time

Certification of Informed Consent

To Be Completed by Research Team

I certify that the above-named individual(s) has been provided with information about the nature and purpose of this research study, and he/she has been informed of the potential benefits and possible risks of study participation. Contact information and encouragement to contact study personnel in case of any questions has been provided. We will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Informed Consent	Role in Research Study

_____	_____	_____
Signature	Date of Consent Receipt	Time

APPENDIX D

HUMAN SUBJECTS TRAINING

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Sarah Belcher (ID: 4013572)
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Email:** smb208@pitt.edu
- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** Biomedical Human Subjects Research
- **Course Learner Group:** Biomedical Course
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

- **Record ID:** 12328541
- **Completion Date:** 09-Feb-2014
- **Expiration Date:** 09-Feb-2018
- **Minimum Passing:** 80
- **Reported Score*:** 98

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
University of Pittsburgh (ID: 14517)	09-Feb-2014	No Quiz
Belmont Report and Its Principles (ID: 1127)	09-Feb-2014	3/3 (100%)
History and Ethics of Human Subjects Research (ID: 498)	09-Feb-2014	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	09-Feb-2014	5/5 (100%)
Informed Consent (ID: 3)	09-Feb-2014	4/4 (100%)
Genetic Research in Human Populations (ID: 6)	09-Feb-2014	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview (ID: 7)	09-Feb-2014	4/4 (100%)
Research Involving Children (ID: 9)	09-Feb-2014	3/3 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	09-Feb-2014	5/5 (100%)
Research Involving Prisoners (ID: 8)	09-Feb-2014	3/4 (75%)
Stem Cell Research Oversight (Part I) (ID: 13882)	09-Feb-2014	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?ka5adbd32-73e2-4a18-96be-b270fdd39ffa-12328541

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Sarah Belcher (ID: 4013572)
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Email:** smb208@pitt.edu
- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** Biomedical Human Subjects Research
- **Course Learner Group:** Biomedical Course
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

- **Record ID:** 12328541
- **Report Date:** 07-Jun-2018
- **Current Score**:** 98

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 498)	09-Feb-2014	7/7 (100%)
University of Pittsburgh (ID: 14517)	09-Feb-2014	No Quiz
Informed Consent (ID: 3)	09-Feb-2014	4/4 (100%)
Belmont Report and Its Principles (ID: 1127)	09-Feb-2014	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	09-Feb-2014	2/2 (100%)
Research Involving Prisoners (ID: 8)	09-Feb-2014	3/4 (75%)
Research Involving Children (ID: 9)	09-Feb-2014	3/3 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	09-Feb-2014	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	09-Feb-2014	5/5 (100%)
Stem Cell Research Oversight (Part I) (ID: 13882)	09-Feb-2014	5/5 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview (ID: 7)	09-Feb-2014	4/4 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Sarah Belcher (ID: 4013572)
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Email:** smb208@pitt.edu
- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** Biomedical Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - RCR
- **Description:** This course is for investigators, staff and students with an interest or focus in **Biomedical Research**. This course contains text, embedded case studies AND quizzes.

- **Record ID:** 12328543
- **Completion Date:** 09-Feb-2014
- **Expiration Date:** 09-Feb-2018
- **Minimum Passing:** 80
- **Reported Score*:** 97

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Introduction to the Responsible Conduct of Research Archived 1248 (ID: 1248)	09-Feb-2014	No Quiz
Research Misconduct (RCR-Biomed) (ID: 1215)	09-Feb-2014	5/5 (100%)
Data Management (RCR-Biomed) (ID: 1308)	09-Feb-2014	5/5 (100%)
Authorship (RCR-Biomed) (ID: 1380)	09-Feb-2014	5/5 (100%)
Mentoring (RCR-Interdisciplinary) (ID: 1250)	09-Feb-2014	5/5 (100%)
Collaborative Research (RCR-Biomed) (ID: 1450)	09-Feb-2014	5/5 (100%)
Responsible Conduct of Research (RCR) Course Conclusion (ID: 1043)	09-Feb-2014	No Quiz
Conflicts of Interest (RCR-Biomed) (ID: 1622)	09-Feb-2014	5/6 (83%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?k72260891-402f-4eda-88f0-789a6e6e5e86-12328543

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Sarah Belcher (ID: 4013572)
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- **Institution Email:** smb208@pitt.edu
- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** Biomedical Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - RCR
- **Description:** This course is for investigators, staff and students with an interest or focus in **Biomedical Research**. This course contains text, embedded case studies AND quizzes.

- **Record ID:** 12328543
- **Report Date:** 07-Jun-2018
- **Current Score**:** 97

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Mentoring (RCR-Interdisciplinary) (ID: 1250)	09-Feb-2014	5/5 (100%)
Data Management (RCR-Biomed) (ID: 1308)	09-Feb-2014	5/5 (100%)
Authorship (RCR-Biomed) (ID: 1380)	09-Feb-2014	5/5 (100%)
Collaborative Research (RCR-Biomed) (ID: 1450)	09-Feb-2014	5/5 (100%)
Conflicts of Interest (RCR-Biomed) (ID: 1622)	09-Feb-2014	5/6 (83%)
Plagiarism (RCR-Basic) (ID: 15156)	02-Mar-2018	5/5 (100%)
Authorship (RCR-Basic) (ID: 16597)	02-Mar-2018	4/5 (80%)
Research Misconduct (RCR-Biomed) (ID: 1215)	09-Feb-2014	5/5 (100%)
Introduction to the Responsible Conduct of Research Archived 1248 (ID: 1248)	09-Feb-2014	No Quiz
Collaborative Research (RCR-Basic) (ID: 16598)	02-Mar-2018	5/5 (100%)
Data Management (RCR-Basic) (ID: 16600)	02-Mar-2018	5/5 (100%)
Mentoring (RCR-Basic) (ID: 16602)	02-Mar-2018	5/5 (100%)
Peer Review (RCR-Basic) (ID: 16603)	02-Mar-2018	5/5 (100%)
Research Misconduct (RCR-Basic) (ID: 16604)	02-Mar-2018	5/5 (100%)
Responsible Conduct of Research (RCR) Course Conclusion (ID: 1043)	09-Feb-2014	No Quiz

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COURSEWORK REQUIREMENTS*

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- **Curriculum Group:** CITI Conflicts of Interest
- **Course Learner Group:** Conflicts of Interest
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 14006386
- **Completion Date:** 11-Sep-2014
- **Expiration Date:** 11-Sep-2018
- **Minimum Passing:** 80
- **Reported Score*:** 80

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
CITI Conflict of Interest Course - Introduction (COI-Basic) (ID: 15177)	11-Sep-2014	No Quiz
Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (COI-Basic) (ID: 15070)	11-Sep-2014	4/5 (80%)
Institutional Responsibilities as They Affect Investigators (COI-Basic) (ID: 15072)	11-Sep-2014	3/5 (60%)
Conflicts of Interest Institution-Specific Policies (ID: 15179)	11-Sep-2014	10/10 (100%)
Conflicts of Commitment and Conscience (COI-Basic) (ID: 15073)	11-Sep-2014	3/5 (60%)

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Sarah Belcher (ID: 4013572)
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Email:** smb208@pitt.edu
- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** CITI Conflicts of Interest
- **Course Learner Group:** Conflicts of Interest
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 14006386
- **Report Date:** 07-Jun-2018
- **Current Score**:** 80

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
CITI Conflict of Interest Course - Introduction (COI-Basic) (ID: 15177)	11-Sep-2014	No Quiz
Conflicts of Interest Institution-Specific Policies (ID: 15179)	11-Sep-2014	10/10 (100%)
Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (COI-Basic) (ID: 15070)	11-Sep-2014	4/5 (80%)
Institutional Responsibilities as They Affect Investigators (COI-Basic) (ID: 15072)	11-Sep-2014	3/5 (60%)
Conflicts of Commitment and Conscience (COI-Basic) (ID: 15073)	11-Sep-2014	3/5 (60%)

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COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Sarah Belcher (ID: 4013572)
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Email:** smb208@pitt.edu
- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** Information Privacy & Security
- **Course Learner Group:** Privacy & Information Security
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 23759774
- **Completion Date:** 03-Jul-2017
- **Expiration Date:** 03-Jul-2021
- **Minimum Passing:** 80
- **Reported Score*:** 95

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Basics of Health Privacy (ID: 1417)	03-Jul-2017	5/5 (100%)
Health Privacy Issues for Researchers (ID: 1419)	03-Jul-2017	5/5 (100%)
Basics of Information Security, Part 1 (ID: 1423)	03-Jul-2017	4/5 (80%)
Basics of Information Security, Part 2 (ID: 1424)	03-Jul-2017	5/5 (100%)

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

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- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** Information Privacy & Security
- **Course Learner Group:** Privacy & Information Security
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 23759774
- **Report Date:** 07-Jun-2018
- **Current Score**:** 95

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Basics of Health Privacy (ID: 1417)	03-Jul-2017	5/5 (100%)
Health Privacy Issues for Researchers (ID: 1419)	03-Jul-2017	5/5 (100%)
Basics of Information Security, Part 1 (ID: 1423)	03-Jul-2017	4/5 (80%)
Basics of Information Security, Part 2 (ID: 1424)	03-Jul-2017	5/5 (100%)

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COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Sarah Belcher (ID: 4013572)
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Email:** smb208@pitt.edu
- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 26362482
- **Completion Date:** 02-Mar-2018
- **Expiration Date:** 01-Mar-2022
- **Minimum Passing:** 80
- **Reported Score*:** 97

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Authorship (RCR-Basic) (ID: 16597)	02-Mar-2018	4/5 (80%)
Collaborative Research (RCR-Basic) (ID: 16598)	02-Mar-2018	5/5 (100%)
Data Management (RCR-Basic) (ID: 16600)	02-Mar-2018	5/5 (100%)
Mentoring (RCR-Basic) (ID: 16602)	02-Mar-2018	5/5 (100%)
Peer Review (RCR-Basic) (ID: 16603)	02-Mar-2018	5/5 (100%)
Research Misconduct (RCR-Basic) (ID: 16604)	02-Mar-2018	5/5 (100%)
Plagiarism (RCR-Basic) (ID: 15156)	02-Mar-2018	5/5 (100%)

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Sarah Belcher (ID: 4013572)
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Email:** smb208@pitt.edu
- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 26362482
- **Report Date:** 07-Jun-2018
- **Current Score**:** 97

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Plagiarism (RCR-Basic) (ID: 15156)	02-Mar-2018	5/5 (100%)
Authorship (RCR-Basic) (ID: 16597)	02-Mar-2018	4/5 (80%)
Collaborative Research (RCR-Basic) (ID: 16598)	02-Mar-2018	5/5 (100%)
Data Management (RCR-Basic) (ID: 16600)	02-Mar-2018	5/5 (100%)
Mentoring (RCR-Basic) (ID: 16602)	02-Mar-2018	5/5 (100%)
Peer Review (RCR-Basic) (ID: 16603)	02-Mar-2018	5/5 (100%)
Research Misconduct (RCR-Basic) (ID: 16604)	02-Mar-2018	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Sarah Belcher (ID: 4013572)
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Email:** smb208@pitt.edu
- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** Social and Behavioral Science Human Subjects
- **Course Learner Group:** Social-Behavioral-Educational Course
- **Stage:** Stage 2 - Refresher Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- **Record ID:** 14006384
- **Completion Date:** 29-Jul-2016
- **Expiration Date:** 29-Jul-2020
- **Minimum Passing:** 80
- **Reported Score*:** 94

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
SBE Refresher 1 – Instructions (ID: 943)	29-Jul-2016	No Quiz
SBE Refresher 1 – History and Ethical Principles (ID: 936)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Federal Regulations for Protecting Research Subjects (ID: 937)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Informed Consent (ID: 938)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Defining Research with Human Subjects (ID: 15029)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Assessing Risk (ID: 15034)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Privacy and Confidentiality (ID: 15035)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – International Research (ID: 15028)	29-Jul-2016	1/2 (50%)
SBE Refresher 1 – Research in Educational Settings (ID: 940)	29-Jul-2016	2/2 (100%)

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

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- **Name:** Sarah Belcher (ID: 4013572)
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
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- **Institution Unit:** School of Nursing
- **Phone:** 412-624-2469

- **Curriculum Group:** Social and Behavioral Science Human Subjects
- **Course Learner Group:** Social-Behavioral-Educational Course
- **Stage:** Stage 2 - Refresher Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- **Record ID:** 14006384
- **Report Date:** 07-Jun-2018
- **Current Score**:** 94

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
SBE Refresher 1 – History and Ethical Principles (ID: 936)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Federal Regulations for Protecting Research Subjects (ID: 937)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Informed Consent (ID: 938)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Research in Educational Settings (ID: 940)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Instructions (ID: 943)	29-Jul-2016	No Quiz
SBE Refresher 1 – International Research (ID: 15028)	29-Jul-2016	1/2 (50%)
SBE Refresher 1 – Defining Research with Human Subjects (ID: 15029)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Assessing Risk (ID: 15034)	29-Jul-2016	2/2 (100%)
SBE Refresher 1 – Privacy and Confidentiality (ID: 15035)	29-Jul-2016	2/2 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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From: **Mike Minjock** mminjock@ons.org
Subject: RE: reproduction agreement with MM requested edit
Date: August 1, 2018 at 8:43 AM
To: Belcher, Sarah Marie SMB208@pitt.edu
Cc: Donovan, Heidi Ann Scharf donovanh@pitt.edu

MM

Dear Sarah,

I agree to the terms stated in your letter.

Thank you,

Mike Minjock
Licensing Manager
Oncology Nursing Society
+1-412-859-6251
mminjock@ons.org
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From: Belcher, Sarah Marie <SMB208@pitt.edu>
Sent: Tuesday, July 31, 2018 4:56 PM
To: Mike Minjock <mminjock@ons.org>
Cc: Donovan, Heidi Ann Scharf <donovanh@pitt.edu>
Subject: reproduction agreement with MM requested edit

Dear Mr. Minjock,

Thank you for working with Dr. Donovan and I to find a solution that works well for both ONS and our research and professional endeavors.

In consultation with the University of Pittsburgh's Office of Scholarly Communication and Publishing, I have drafted the attached document (also copied and pasted at the end of this message) to serve as documentation of our recent communication regarding reproduction of my previous publication in *Oncology Nursing Forum* in my dissertation document.

If the noted arrangements meet your approval, please reply to me via your ONS email with an affirmative, such as "I agree to the terms stated in your letter."

Thank you again for your assistance.

Regards,
Sarah Belcher

Sarah M. Belcher, PhD(c), RN, OCN®
Doctoral Candidate (DSCN-17-077-01-SCN)
Robert Wood Johnson Foundation Future of Nursing Scholar
University of Pittsburgh School of Nursing
415 Victoria Building
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Pittsburgh, PA 15261
smb208@pitt.edu
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@SarahMBelcher

Mike Minjock

Licensing Manager

Oncology Nursing Society

125 Enterprise Drive

Pittsburgh, PA 15275-1214

412-859-6251 (phone)

mminjock@ons.org

July 31, 2018

Dear Mr. Minjock,

This letter is to confirm the recent email exchanges between you, my dissertation chair, Dr. Heidi Donovan, and myself. As discussed, I am completing my doctoral dissertation at the University of Pittsburgh School of Nursing, entitled, "Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers." This correspondence will confirm your permission to reprint excerpts from the following publication in my dissertation:

> Belcher, S. M., Low, C. A., Posluszny, D. M., Schear, R., Kramer, R. E., & Donovan, H. S. (2017). Psychological distress, health behaviors, and benefit finding in survivors of multiple primary cancers: Results From the 2010 Livestrong survey. *Oncology Nursing Forum*, *44*(6), 703–711. https://doi.org/10.1188/17.ONF.703-711

The entire full text article accepted for publication by Dr. Katz on 4/17/17 will be included as an appendix. This article and the work it represents is foundational to my dissertation. Full and clear credit will be given to *Oncology Nursing Forum* as the publisher and copyright owner of the final published article.

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Sincerely,

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July 31, 2018

Dear Mr. Minjock,

This letter is to confirm the recent email exchanges between you, my dissertation chair, Dr. Heidi Donovan, and myself. As discussed, I am completing my doctoral dissertation at the University of Pittsburgh School of Nursing, entitled, "Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers." This correspondence will confirm your permission to reprint excerpts from the following publication in my dissertation:

> Belcher, S. M., Low, C. A., Posluszny, D. M., Schear, R., Kramer, R. E., & Donovan, H. S. (2017). Psychological distress, health behaviors, and benefit finding in survivors of multiple primary cancers: Results From the 2010 Livestrong survey. *Oncology Nursing Forum*, *44*(6), 703–711. https://doi.org/10.1188/17.ONF.703-711

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Sincerely,

Sarah Belcher

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APPENDIX F

DISSERTATION MANUSCRIPT 1:

EXAMINING THE RELATIONSHIP BETWEEN MULTIPLE PRIMARY CANCERS AND PSYCHOLOGICAL DISTRESS: A REVIEW OF CURRENT LITERATURE

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WILEY

REVIEW

Examining the relationship between multiple primary cancers and psychological distress: A review of current literature

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Abstract

Objective The incidence of multiple primary cancers (MPCs) is increasing, but little is known about psychological distress in this population. The purpose of this study is to review and synthesize the literature regarding what is known about psychological distress in adults who have experienced MPC diagnoses.

Methods All potentially eligible studies identified in PubMed and CINAHL were reviewed by 2 independent evaluators, and each relevant article was assessed for methodological quality. Data were extracted, organized, and recorded using a coding log, PRISMA flow diagram, and a standardized table of evidence. Effect size (ES) values were calculated using Cohen's *d*.

Results Five of the 562 potentially relevant articles were selected for final analysis. MPC survivors, when compared with single cancer survivors, had lower global quality of life (d = 0.32–0.37), poorer emotional role function and stress (d = 0.08–0.20), greater and more frequent distress (d = 0.11–0.37), and greater subclinical anxiety (d = 0.15). Depressive symptoms were variable (d = 0.01–0.22), and no differences between MPC and single cancer groups were identified for sleep and suicidal ideation.

Conclusion There is a substantial lack of evidence focused on psychological distress among the growing MPC survivor population. ES noted in the 5 studies reflect small but potentially significant increases in psychological distress in survivors of MPC compared with survivors of a single cancer. Clinicians should be aware of this at-risk population when screening for distress in cancer survivors. Suggestions for future research are provided.

KEYWORDS

cancer survivorship, cancer-related distress, multiple primary cancers, oncology, psychological distress, subsequent malignancies

1 | BACKGROUND

Improved cancer treatments and screening have contributed to a growing and aging cancer survivor population, and, by 2026, the number of Americans living with a history of cancer is predicted to rise to 20.3 million people.[1–3] However, aging and other risk factors contribute to a 14% higher risk for cancer survivors to develop new primary cancers, when compared with the general population. Even greater risk may occur depending on the individual's site of first primary cancer, age at first cancer diagnosis, causative exposures, genetic factors, and carcinogenic effects due to cancer treatment.[3,4] Cancers specifically linked to the development of subsequent malignancies, or multiple primary cancers (MPCs), include Hodgkin disease, non-Hodgkin lymphoma, and certain solid tumor (ie, prostate, testicular, ovarian, breast, and cervical) and childhood cancers.[5,6] Nearly 1 in 5 cancers occurs in an individual with a previous cancer diagnosis, and MPCs are a significant cause of morbidity and mortality among cancer survivors.[7–9]

All of those faced with cancer experience varying levels of distress related to diagnoses, disease- and treatment-related effects, and care transition points,[10] and 20% to 47% of those with newly diagnosed and recurrent cancer experience significant distress.[11] A 2011 meta-

analysis of studies conducted in varying countries estimated that 30% to 40% of cancer patients in hospital settings have some combination of mood disorders.[12] Anxiety and depression are common causes of distress in individuals with cancer with estimated prevalence of 10.3% and 14.9%, respectively, both of which are higher rates than are seen in the general population.[11,13] These patterns are especially concerning, considering that distress is a risk factor for nonadherence to cancer therapy, increased difficulty of treatment decision making, and is associated with poorer quality of life (QOL), poorer adherence with surveillance screening recommendations, and poorer health behaviors, such as inactivity and smoking.[11]

Most research examining psychological distress in cancer patients has been conducted without attention to number of primary cancers. Despite epidemiological data acknowledging the growing number of individuals with MPC, little is known regarding the relationship between MPC and psychological distress and if this distress is similar to individuals with 1 primary cancer. Lack of knowledge about the prevalence and types of psychological distress experienced by this population is an impediment to supporting their potentially unique needs. Clinically, providers need to be able to identify and target MPC survivors most at risk for psychological distress and resulting behavioral and health response sequelae.

The purpose of this study is to review and synthesize the literature regarding what is known about psychological distress in adults who have experienced MPC diagnoses. The research question being examined is: What is the relationship between experience of MPC diagnoses and psychological distress in adult cancer survivors? We hypothesized that adults who had experienced MPC diagnoses would report increased psychological distress as compared with survivors of single cancer diagnoses.

2 | METHODS

2.1 | Selection criteria

Criteria used to select studies for inclusion were established a priori and were as follows: (1) study participants were ≥18 years old at time of the study with any type of initial primary cancer diagnosis, at least 1 additional subsequent type of primary cancer diagnosis, and in any phase of the cancer trajectory; (2) study reported on results evaluating the relationships between the presence of ≥2 primary cancer diagnoses (independent variable) and psychological distress variables (dependent variable); and (3) study was published in English. No study designs were excluded.

2.2 | Search procedures

With expert health science librarian consultation, electronic literature searches were constructed and implemented in PubMed (which also includes Medline)[14] and CINAHL[15] databases, including articles from inception of databases to February 2016. Searches were built to account for variant terminology and indexing variations identified during phases of search term harvesting and testing. Searches included results for both MPC diagnoses and the responses of stress, anxiety, and/or depression. Synonyms and modified versions of terms related to MPC (eg, neoplasm, malignancy, cancer; second, multiple, metachronous; and treatment associated) and psychological distress (eg, depression, anxiety, psychological stress, and trauma) were searched to achieve the largest possible sample (search strings available online as supporting information).

2.3 | Relevant study identification

The resulting searches yielded 562 potentially relevant articles. Articles were reviewed for eligibility prior to analysis. In addition to the first author (S.B.), a second independent reviewer (E.H.) selected and coded articles. If article selection and/or data extraction differed between reviewers, a process of consensus-based decision making was exercised until agreement was met.[16] One hundred five articles were not published in English and were therefore excluded. Initial title and abstract review was conducted on the remaining 457 articles. The 394 articles that did not meet basic selection criteria were excluded. An electronic log was created to record article details of interest and included a coding system to note rationale for each excluded article.

The remaining 63 articles received full text review. During this phase, the 2 primary reasons for exclusion were as follows: (1) MPC was discussed only as a part of post-treatment surveillance and (2) psychological distress was not evaluated separately for the MPC and single cancer diagnosis groups. No studies were identified that examined distress only within those with MPC, and no qualitative or literature synthesis studies were identified. Despite inclusion criteria that were quite broad and employment of strategic search strategies, only 3 of the 63 articles that received full review met criteria for inclusion. Hand searches of reference lists and forward citation searches of the 3 selected articles yielded 2 additional articles for analysis. See Figure 1 for a detailed description of search and article extraction processes and reasons for article exclusion.

2.4 | Data extraction and analyses

The 5 selected articles were reviewed and assessed for methodological quality based on the Newcastle-Ottawa Quality Assessment Scale criteria for assessing nonrandomized studies.[17–19] A standardized table of evidence was created to extract, record, and appraise data from the 5 articles based on criteria relevant to this study. Effect size (ES) and 95% confidence intervals were calculated using Cohen's *d* to measure relationship direction and magnitude between MPC and psychological distress.[20] For the articles that presented results as odds ratios, results were converted to Cohen's *d* to allow for comparison of results between studies [21,22] (Table 1). Study methodologies were compared, and results were synthesized across studies.

3 | RESULTS

Five studies met inclusion criteria for this review. Results of those studies are presented in chronological order to facilitate evaluation of the progression of scientific findings in this area.

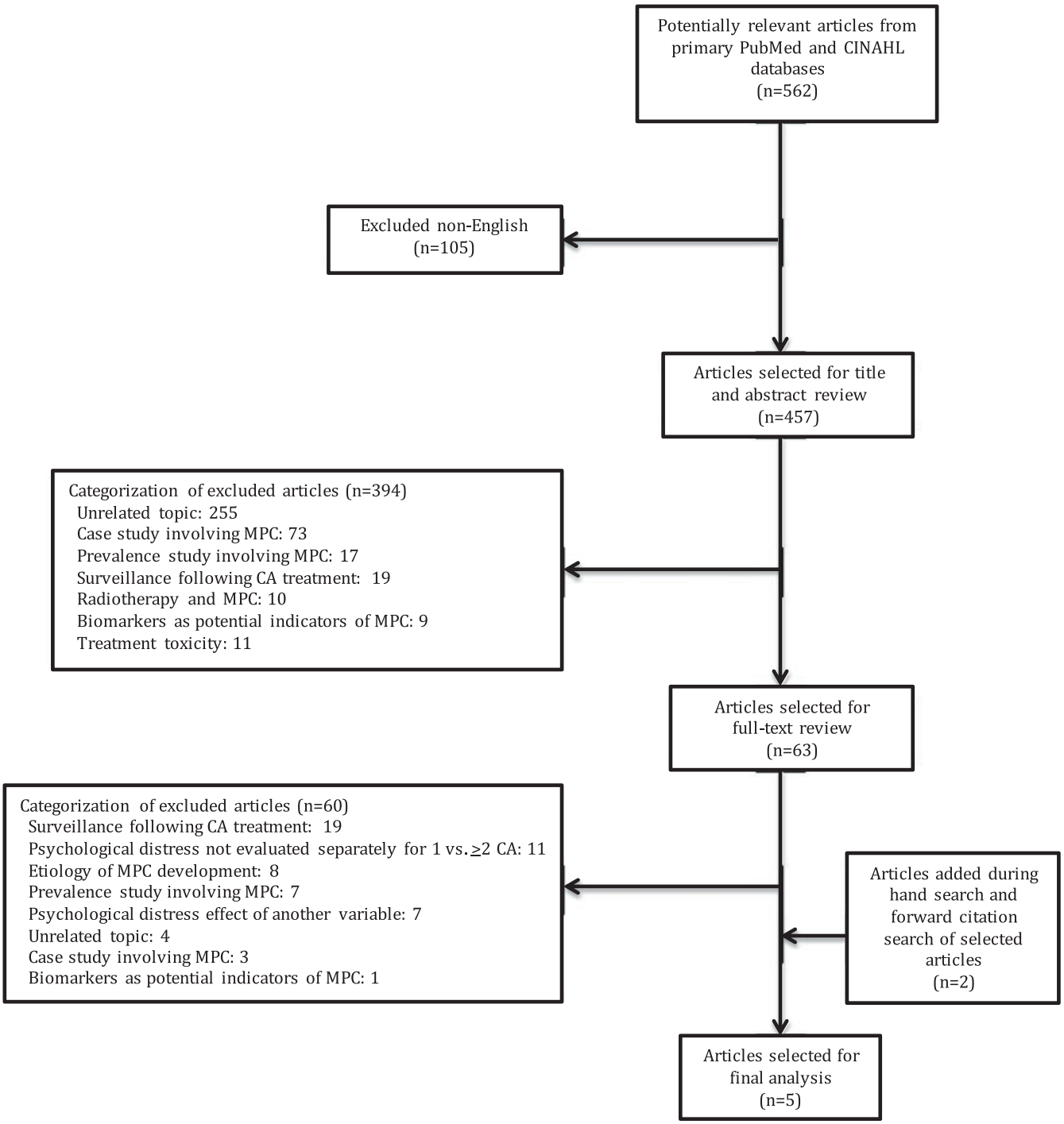

FIGURE 1 Summary of evidence search and selection

3.1 | Gotay et al (2007)

Gotay et al[23] conducted a cross-sectional, correlational study using mailed surveys to evaluate global QOL, depressive symptoms, and cancer-specific stress after a single versus MPC diagnosis. The population-based convenience sample of 1076 subjects was selected from the Hawaii Tumor Registry (HTR), which does not record basal and squamous cell cancers, and included 487 subjects with MPC diagnoses and 589 single cancer controls, matched on initial disease site, age, sex, race/ethnicity, time since initial diagnosis, and disease stage at initial diagnosis. Two-tailed independent sample *t* tests were used to compare groups.

Time since first cancer diagnosis was significantly longer for MPC survivors (13.6 ± 6.1 years) compared with those with a single cancer (9.9 ± 4.0 years; $P < .05$). Despite this difference, when compared with those with single cancers, those with MPC were still found to have significantly lower global QOL ($d = -0.37$) as measured by a single item on the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) and higher total cancer-specific stress ($d = 0.14$) measured by the Revised Impact

TABLE 1 Combined table of results

Reference and geographical location	Study design, method of CA diagnosis obtainment; NOS star ratings	Inclusion/exclusion criteria	MPC sample	Single CA groups	Measures	Cohen's *d* effect sizes and 95% CI	Results
Gotay et al., 2007, Hawaii	Cross-sectional, correlational, population-based with matching Medical Record NOS: Selection: 3 Comparability: 2 Exposure: 2	CA dx recorded in Hawaii Tumor Registry (diagnosed 1964–1999); proficient in English; residents of Hawaii; no basal or squamous cell skin CA included in registry MPC sample: second PC dx made ≥6 mo after initial dx	N = 487 Initial disease sites: breast, GI, GU, GYN Second disease sites: breast, GI, GU, GYN Mean age (SD): 71.3 y (11.8) Mean years since 1st dx (SD): 13.6 (6.1)	N = 589 Disease site: breast, GI, GU, GYN Mean age (SD): 71.4 y (10.7) Mean years since dx (SD): 9.9 (4.0)	Mailed Surveys: •Global QOL: Single item from EORTC QOL-C30 •Depressive Symptomatology: CES-D •CA-specific stress (total): IES-R with subscales for avoidance an intrusiveness	*d* = −0.37 (−0.49, −0.24) *d* = 0.01 (−0.02, 0.13) IES-T: *d* = 0.14 (0.02, 0.26) IES-A: *d* = 0.13 (0.01, 0.25) IES-I: *d* = 0.14 (0.02, 0.26)	MPC with lower global QOL, higher total stress, marginally significant subscales for higher avoidance and intrusiveness No significant differences between groups for depressive symptomatology
Recklitis et al., 2010, United States and Canada	Cross-sectional, correlational, population-based; evaluated MPC as covariate of SI in CA survivors Self-report NOS: Selection: 3 Comparability: 2 Exposure: 1	For childhood CA survivors: adults enrolled onto the multi-site CCSS and diagnosed 1970–1986; treated at CCSS study site; ≤ 21 y old at diagnosis; survival ≥5 y after diagnosis	N = 292 Demographics combined for all survivors: Cancer diagnoses: leukemia, Hodgkin disease, CNS, bone Age (y): 18–24 (39.1%), 25–29 (27.4%), 30–34 (20.4%), ≥35 (13.2%) Years since dx: 6–10 (7.3%), 11–15 (28.9%), 16–20 (35.8%), ≥21 (28.1%)	N = 8834	Mailed surveys: SI = endorsing any SI on item 9 of BSI-18: "thoughts of ending your life"	*d* = <.01 (−0.23, 0.24)	Suicidal ideation not associated with second malignancy
Burris and Andrykowski, 2011, United States, District of Columbia, Puerto Rico, Guam, and Virgin Islands	Cross-sectional, population-based Self-Report NOS: Selection: 2 Comparability: 2 Exposure: 1	CA dx recorded in 1999 BRFSS Survey analysis "Have you ever been told by a doctor, nurse, or other health professional that you had cancer?"	N = 8734 (2 CA N = 7278 + ≥3 CA N = 1456) Most recent CA dx: nonmelanoma skin, female breast, male reproductive, GI, melanoma	N = 47,562 CA dx: nonmelanoma skin, female breast, male reproductive, female reproductive	Computer-assisted telephone survey: •Report no. days in past month when mental health was "not good" (dichotomized into: infrequent = 0–13; frequent = 14–30)	*d* = 0.11 (0.07, 0.14)	Those with MPC were more likely to experience frequent mental distress No significant differences between groups for frequent sleep problems

(Continues)

TABLE 1 (Continued)

Reference and geographical location	Study design, method of CA diagnosis obtainment; NOS star ratings	Inclusion/exclusion criteria	MPC sample	Single CA groups	Measures	Cohen's *d* effect sizes and 95% CI	Results
		"Yes" = CA survivor "How many different types of cancer have you had?" "Only 1," "2," or "3 or more"	Mean age (*SD*): 67.55 y (13.36) Mean years since 1st dx (SD): 16.8 (12.4)	Mean age (SD): 62.41 y (14.87) Mean years since 1st dx (SD): 11.1 (10.2)	•Report no. days in past month when did not get good enough rest or sleep (dichotomized into: infrequent = 0–13; frequent = 14–30)	*d* = <.01 (−0.02, 0.04)	
Andrykowski, 2012, United States	Cross-sectional, population-based, correlational with multistage sampling and oversampling for minorities Self-Report NOS: Selection: 2 Comparability: 1 Exposure: 1	CA dx recorded in 2009 NHIS "Have you ever been told by a physician or other health professional that you had cancer or a malignancy of any kind?" for up to 3 lifetime CA dx Excluded proxy interviews, nonmelanoma skin CA, <1 y since initial dx, and initial CA dx < 18 y old	N = 154 (2CA N = 134 + 3 CA N = 16 + 4 CA N = 4) CA dx represented in group: other, breast, prostate, colon Mean age (SD): 64.9 y (14.6) Mean years since initial dx (SD): 16.1 (11.0)	N = 1427 CA dx represented in group: breast, prostate, other, cervix. Mean age (SD): 63.7 (14.6) Mean years since dx (SD): 11.2 (10.4)	Personal household interview: •Total distress index (six 5-point items summed, 0–24) •Serious psychological distress (score ≥ 13) •Distress symptom interference for those acknowledging ≥1 symptom in past 30 days ("not at all" = 0–"a lot" = 4)	*d* = 0.21 (0.04, 0.38) *d* = 0.37 (0.06, 0.69) *d* = 0.03 (−0.14, 0.19)	Those with MPC reported greater total distress scores and were more likely to meet criteria for serious psychological distress when compared with those with a single CA No difference found for symptom interference
Thong et al.,2013, Southern Netherlands	Secondary data analysis of cross-sectional, correlational, population-based, data Medical Record NOS: Selection: 3 Comparability: 2 Exposure: 2	Registered in Eindhoven CA Registry: all eligible if diagnosed with melanoma, endometrial, or colorectal CA (1998–2007) and lymphoma or multiple myeloma (1999–2008) Included all skin CA except basal cell	N = 560 (2 CAs N = 423 + ≥3 CAs N = 137) Primary CA at time of survey: colon, endometrial, NHL, melanoma Mean age (SD): 69.4 y (10.1) Mean years since last dx (SD): 3.6 (2.4)	N = 3076 Primary CA at time of survey: colon, endometrial, NHL, melanoma Mean age (SD): 63.9 y (12.5) Mean years since last dx (SD): 4.7 (2.5)	Mailed surveys: •Health Status for Melanoma, Endometrial, Colorectal Group: Dutch SF-36 - Emotional role fx - Mental health •CA-Specific Health Status for Lymphoma and Multiple Myeloma Group: EORTC QOL-C30 with 15 subscales - Global QOL - Emotional fx	 *d* = −0.08 (−0.19, 0.02) *d* = −0.08 (−0.18, 0.02) *d* = −0.32 (−0.50, −0.14) *d* = −0.20 (−0.39, −0.02)	No significant ES differences for emotional role fx, mental health, and insomnia MPC with lower global QOL and emotional role function MPC more likely to meet subclinical scores for anxiety and depressive symptoms

(Continues)

TABLE 1 (Continued)

Reference and geographical location	Study design, method of CA diagnosis obtainment; NOS star ratings	Inclusion/exclusion criteria	MPC sample	Single CA groups	Measures	Cohen's *d* effect sizes and 95% CI	Results
					- Insomnia	*d* = 0.02 (–0.02, 0.35)	
					•Mental Health for all CA types except Melanoma: HADS		
					- Anxiety	*d* = 0.10 (– < 0.01, 0.21)	
					- Subclinical anxiety (≥8)	*d* = 0.15 (0.02, 0.29)	
					- Depressive symptoms	*d* = 0.22 (0.11, 0.32)	
					- Subclinical depressive symptoms (≥8)	*d* = 0.25 (0.12, 0.38)	

Top 4 cancer diagnoses are reported when list of diagnoses included in study exceeded 4.

BRFSS indicates Behavioral Risk Factor Surveillance System; BSI-18, Brief Symptom Inventory-18; CA, cancer; CCSS, Childhood Cancer Survivor Study; CES-D, Center for Epidemiological Studies–Depression Scale; CI, confidence interval; CNS, central nervous system; dx, diagnosis; EORTC QOL-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; fx, function; GI, gastro-intestinal; GU, genitourinary; GYN, gynecologic; IES-R, Impact of Event Scale, Revised (T, total; A, avoidance; I, intrusiveness); MPC, multiple primary cancer; NHIS, National Center for Health Statistic; NHL, non-Hodgkin lymphoma; NOS, Newcastle-Ottawa Scale; PC, primary cancer; QOL, quality of life; SD, standard deviation; SI, suicidal ideation.

of Event Scale (IES-R). Although neither stress subscale was determined to be statistically significant ($p \leq .07$), trends toward higher stress subscale scores for both avoidance ($d = 0.13$) and intrusiveness ($d = 0.14$) were noted. No between-group differences were identified for depressive symptomatology ($d = 0.01$) on the Center for Epidemiologic Studies–Depression (CES-D) scale.

Both the use of the HTR to identify and confirm cancer diagnoses and the use of matching for key factors between groups were strengths of this study. Limitations of this study included differences in response rates between MPC (55.8%) and single cancer groups (41.1%). Nonresponders differed from responders, in that responders were younger, more likely to have a partner, and more likely to report Japanese and Chinese ethnicity. In addition, individuals living with active disease were not included in this study, and prognosis was not included as a covariate in the analysis. Both of these factors could be important to understanding the impact of MPC on psychological distress. Although geographical location (Hawaii) and a large percentage of Pacific Islander participants could lead to decreased generalizability to other populations, it is a strength to focus on a relatively understudied population such as this.

3.2 | Recklitis et al (2010)

Recklitis et al[24] published a cross-sectional, correlational study to determine the prevalence of suicidal ideation (SI) and identify correlates of SI in an adult cohort of childhood cancer survivors (n = 9126) compared with their noncancer sibling controls (n = 2986). The population-based convenience sample of 12,112 adult subjects was selected from the Childhood Cancer Survivor Study (CCSS) from participating institutions across the United States and parts of Canada. The self-reported presence of a second malignant neoplasm in 292 cancer survivors was examined as a covariate of SI. Participants who endorsed any SI on a single item on the Brief Symptom Inventory-18 (BSI-18) about thoughts of ending one's life ("not at all" to "extremely") were considered to have SI.

Although the proportion of those endorsing SI was significantly greater in childhood cancer survivors (7.8%), as compared with sibling controls (4.5%; $d = 0.32$), hierarchical logistical regression modeling, adjusted for demographic factors, cancer diagnosis, cancer treatment, and health outcomes, did not find MPC to be a significant predictor of SI in childhood cancer survivors ($d = <.01$).

The inclusion of survivors from 2 countries is a strength of this study as is the focus on childhood cancer survivors, a group known to be at high risk for MPC development.[3,6,25] Statistical regression models predicting SI were also theoretically based. Methodological concerns in this study included reliance on a single item to assess SI and self-reported health data outcomes including health and cancer history. In addition, as MPC is treated as a covariate rather than primary outcome in this study, demographic information for those with MPC is not reported separately.

3.3 | Burris and Andrykowski (2011)

Burris and Andrykowski [26] published a cross-sectional, case-control study aimed at assessing the physical and psychological health status and health behaviors of survivors of MPC. The population-based convenience sample of 404,525 subjects was selected from the 2009

Behavioral Risk Factor Surveillance System survey, which used a computer-assisted, random-digit dialing method and included 8734 subjects with 2 or more primary cancer diagnoses, 47,562 subjects with a single cancer diagnosis, and 348,229 controls with no cancer history. The survey was conducted throughout the continental United States, District of Columbia, Puerto Rico, Guam, and Virgin Islands. Cancer survivors whose first cancer occurred during childhood (<18 years old) were excluded. Participants were asked to report the number of days in the past month when their mental health was "not good" as well as number of days in the past month they did not get enough rest or sleep (both on a 0–30 scale). Responses for unhealthy days and days of sleep problems were also dichotomized into infrequent (0–13) or frequent (14–30). Analyses of covariance (ANCOVA) and binomial logistic regression analyses were used to compare differences among groups on continuous and categorical outcomes, respectively, controlling for significant covariates.

Those with MPC differed from single cancer survivors by age at first cancer diagnosis (50.9 ± 15.9 years vs 52.0 ± 16.0; $P < .001$) and time since original cancer diagnosis (16.9 ± 12.4 vs 11.1 ± 10.2 years; $P < .001$). Analyses of categorical outcomes, adjusted for age, sex, race/ethnicity, marital/partner status, body mass index (BMI), and education, found that those with MPC, compared with those with single cancers, were more likely to experience frequent mental distress ($d = 0.11$) but were no more likely to experience frequent days of sleep problems ($d = <.01$). Result patterns reported for number of days of mental distress and sleep problems were the same when analyzed continuously.

The large international sample, rigorous recruitment strategies (eg, including unlisted numbers), and controlling for significant covariates were strengths of the study. However, cancer diagnoses were obtained via self-report, and no information was provided regarding treatment history and disease staging. Individuals with a pediatric cancer history were excluded despite having similar risks for MPC, limiting generalizability to adult pediatric cancer survivors with MPC. The inclusion of nonmelanoma skin cancers may also bias data, as psychosocial problems in individuals with these types of cancers have not been shown to differ from those in the general population.[27]

3.4 | Andrykowski (2012)

Andrykowski's 2012[28] cross-sectional, population-based correlational study utilized data from the 2009 National Health Information Survey to compare health status of individuals with MPC, single cancers, and no previous cancers. Multistage sampling, including oversampling for minorities, was conducted in the United States via personal household interviews. The number of cancer diagnoses was obtained via self-report. The sample included 154 respondents with 2 or more primary cancer diagnoses, 1427 respondents with a single cancer diagnosis, and 25,004 respondents with no previous cancer history. Exclusion criteria in cancer survivors included data obtained via proxy interview, being less than 1 year since initial cancer diagnosis, and being <18 years old at initial cancer diagnosis. Nonmelanoma skin cancer diagnoses were also excluded from this study. Participants were asked to recall feelings during the previous 30 days (sad, nervous, restless or fidgety, hopeless, everything was an effort, and worthless) and rate the 6 items on a 5-point scale, "none of the time" to "all of the time." The researchers summed the items to create a 0 to 24 total distress score. A cutoff score of ≥13 was selected to indicate serious psychological distress. Participants who endorsed responses of at least "a little of the time" for at least 1 of the 6 items were asked, "How much did these feelings interfere with your life or activities," with choices on a 4-point scale from "not at all" to "a lot." Demographic variables that differed by group were included as covariates in subsequent analyses. ANCOVA and binary logistic regression were used to compare groups, controlling for difference between groups in time since initial cancer diagnosis.

MPC survivors differed from single cancer survivors in age at initial diagnosis (48.8 vs 52.5 years; $P < .01$) and time since initial cancer diagnosis (16.2 vs 11.2 years; $P < .001$). When comparing MPC with single cancers, those with MPC had greater total distress index scores ($d = 0.21$) and were more likely to meet criteria for serious psychological distress ($d = 0.37$). No difference was found for symptom interference of psychological distress between groups ($d = 0.03$).

Sample size, sampling procedures to increase inclusion of minorities, and exclusion of nonmelanoma skin cancers were study strengths. Again, however, cancer diagnosis was obtained via self-report, no information was provided regarding treatment history and disease staging, and individuals with a pediatric cancer history were excluded. In addition, the distress score measure generated for this study limits ability to compare it with other studies.

3.5 | Thong et al (2013)

To evaluate health status and psychosocial well-being of MPC versus single cancer survivors, Thong et al[29] conducted a cross-sectional secondary data analysis of 5 large cancer survivorship studies. Parent studies were conducted through the Patient Reported Outcomes Following Initial treatment and Long-term Evaluation of Survivorship (PROFILES) Eindhoven Cancer Registry in the Netherlands[30] and began mailed survey data collection between 2008 and 2009. The sample for the MPC study included 3637 subjects either diagnosed with melanoma, endometrial, or colorectal cancer between 1998 and 2007 or lymphoma or multiple myeloma between 1999 and 2008. The MPC group was comprised of individuals with other primary cancers (excluding basal cell cancer) that existed in this group of cancer survivors, either before or after the cancer for which they were originally included in parent studies. The final sample included 560 subjects with MPC diagnoses and 3077 controls with a single cancer diagnosis. Chi-square tests were used to compare demographic and clinical characteristics between groups. ANCOVA, controlling for a priori determined confounding variables (age at survey, years since last diagnosis, sex, marital status, comorbidity at survey, last type of received treatment, BMI, and MPC versus single cancer × years since last diagnosis interaction term), was used to compare MPC and single cancer group scores on the Dutch Short Form-36 (SF-36), EORTC QLQ-C30, and Hospital Anxiety and Depression Scale (HADS). Associations between sociodemographic, clinical, and psychological variables on SF-36 and EORTC QLQ-C30 scores were investigated using multivariate linear regression modeling.

There were no statistically significant group differences in percentage of responders, nonresponders, and those with nonverified mailing addresses for presence of MPC at the time of the survey, but those with nonverified addresses were younger, had experienced more years since last diagnosis, and differed by type of last diagnosed primary cancer. In the participant groups, compared with those with 1 cancer, those with MPC were more likely to be older at time of survey (69.4 ± 10.1 years vs 63.9 ± 12.5; $P < .0001$), have had fewer mean years since last cancer diagnosis (3.6 ± 2.4 vs 4.7 ± 2.5; $P < .0001$), be retired or not working (87% vs 75%; $P < .0001$), and report significantly higher rates of heart disease (19% vs 13%; $P = .0001$), diabetes mellitus (14% vs 9%; $P = .0004$), and stomach disease (2% vs 1%; $P = .008$). In the melanoma, endometrial, and colorectal group, mean scores for individuals with MPC did not differ significantly from those with single cancer on the Dutch SF-36 subscales of emotional role function ($d = -0.08$) or mental health ($d = -0.08$). As in the Gotay et al[23] study, individuals with MPC in the lymphoma and multiple myeloma group had lower EORTC QLQ-C30 mean scores for global QOL ($d = -0.32$). Those with MPC also had lower mean scores for emotional function ($d = -0.20$) than those in the single cancer group. Similar to the Burris and Andrykowski study,[26] the groups in this study did not differ in regard to insomnia ($d = 0.02$). The HADS was used to measure anxiety and depression for endometrial and colorectal cancer, Hodgkin and non-Hodgkin lymphoma, and multiple myeloma survivors. MPC and single cancer groups did not differ on mean anxiety scores ($d = 0.10$). Survivors of MPC, compared with single cancer survivors had higher depressive symptom scores ($d = 0.22$), and significantly more survivors of MPC met the established cutoff scores of ≥8 both for anxiety ($d = 0.15$) and subclinical depressive symptoms ($d = 0.25$) compared with those with single cancers, again with small but potentially important ES noted.

High respondent survey response rate (70%) and ability to rely on tumor registry information for disease and treatment variables are major strengths of this study. The use of different instruments to measure health status variables limits interpretation across disease types and potentially allows for underestimation of psychological distress in this study. This study also does not report on whether participants were undergoing active treatment at the time of the survey.

3.6 | Synthesis across studies

In summary, varying measures were used to capture cross-sectional data on 10,227 MPC survivors across the 5 studies. Work by Andrykowski et al[26,28,29] has provided most of the scientific literature evaluating the relationship between MPC and psychological distress, and, aside from one,[23] all of the studies reviewed were conducted using large, preexisting data sets. MPC survivors, when compared with single cancer survivors, had lower global QOL ($d = 0.32–0.37$), poorer emotional role function and stress ($d = 0.08–0.20$), greater and more frequent distress ($d = 0.11–0.37$), and greater subclinical anxiety ($d = 0.15$). Depressive symptoms were variable ($d = 0.01–0.22$), and no differences between MPC and single cancer groups were identified for sleep and suicidal ideation. Using Cohen's conventions for ES,[20,22] the 5 studies reviewed support a small ($d = 0.10$ to 0.37) increase in psychological distress in survivors of MPC, as compared with survivors of a single cancer. Questions remains as to whether this effect goes beyond theoretical interest and has clinical importance for cancer survivors, who within the MPC survivor population is most at risk for psychological distress, how the trajectory may vary over time, and long-term implications of distress in this population.

Strengths of these 5 studies include being large, population-based studies with strong designs and inclusion of a broad range of cancer types with participants residing in various locations. Consistent findings across studies despite the use of different psychological distress measures increase the generalizability of and confidence in these findings.

Limitations in this body of literature are noted. First, the inclusion of a diverse range of cancer diagnoses may make the aggregation of findings across different types of cancer problematic. Studies also differed as to whether they included subjects with histories of childhood and nonmelanoma skin cancers and participants undergoing active treatment. A primary limitation of these studies includes an overemphasis on cross-sectional survey studies, preventing ability to both establish causality of psychological distress and to determine how and under what conditions psychological distress changes. Additional major limitations are (1) a reliance on self-reporting of cancer diagnoses (reliability of self-reported cancer diagnosis has been found to vary by age, race, education, disease types/sites, and culture)[31–34] and (2) lack of racial and ethnic diversity. Given that prevalence of psychological distress and access to support services differs across racial and ethnic groups, the homogeneity of the samples in the majority of studies examined in this review limits generalizability of the findings.[35,36] Aside from the Gotay study conducted in Hawaii,[23] participants of non-White race and ethnicity are not well represented in the MPC literature.

4 | CONCLUSIONS

Although this search yielded too few articles to draw strong conclusions, the identified patterns across studies support the original hypothesis that those with MPC appear to experience greater amounts of psychological distress than those with a single primary cancer. Important too was the critical lack of MPC literature identified. Despite the large sample of MPC survivors represented in this analysis, there remains a striking paucity of research describing psychological distress and the experiences of those in the growing MPC survivor population. Current Commission on Cancer guidelines on psychosocial distress screening[37] are aimed at addressing cancer patients' psychosocial issues and include distress and psychosocial health needs screening as a standard of high-quality cancer care. The current knowledge gap in MPC science prevents clinicians and researchers from being able to adequately identify MPC survivors most at risk for distress and from developing targeted interventions to reduce distress and promote well-being for those most vulnerable to distress and resulting negative health sequelae. However, the use of National Comprehensive Cancer Network guidelines for distress screening, with special attention to previous cancer history, can allow for early identification of distress by clinicians and improvements in medical management.[11,38] Systematic screening for previous primary cancers at time of new primary cancer diagnosis can be an additional cue to monitor for distress.

Researchers can build upon the findings in these preliminary studies to move the science forward to develop more robust, high-quality studies. Future work in this area should include recruitment of diverse samples with particular emphasis on multiple racial and ethnic groups, verification of the number of primary cancer diagnoses via medical record review, use of uniform measurements of psychological distress that have demonstrated validity and reliability in diverse populations,[39,40] exclusion of nonmelanoma skin cancers from primary cancer count, and exploration of differences within the MPC survivor population. Another important gap in the literature is whether MPC survivors who experienced initial cancer during childhood have different psychological risks compared with MPC survivors who experience cancer diagnoses only as adults. Moreover, future work should include longitudinal designs to determine if and under what conditions these findings may change over time. Despite modest ES in the identified studies, MPC survivors appear to represent a group at risk for additional psychological distress associated with MPC development. Next steps to move the science forward should include studies that discern why and under what conditions those with MPC are at increased risk and implications for distress on health outcomes. Being able to identify those within this population who are most vulnerable to negative outcomes will allow for targeted intervention work aimed at improving outcomes.

Strengths of this review include systematic research methodology consisting of a priori hypotheses and inclusion/ exclusion criteria, construction of a robust literature search in reputable databases, hand searches and forward citation searches of selected articles (resulting yield of only 2 additional relevant articles increases confidence that the 5 highly recognized, highly cited articles selected represent the current body of literature in this area), and use of 2 independent reviewers with consensus-based decision making. Systematic record keeping, data extraction, and analysis; inclusion of a PRISMA flow diagram; methodological study quality assessment; and ES calculations to allow for estimates of relationship direction and magnitude also add strength to this study. A potential limitation of this review is exclusion of articles not published in English. This analysis will hopefully spur additional research to understand and address the psychological needs of this growing population of MPC survivors. Further research should address the scientific and clinical need to understand the experiences of the expanding population of individuals with MPC.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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APPENDIX G

DISSERTATION MANUSCRIPT 2:

PSYCHOLOGICAL DISTRESS, HEALTH BEHAVIORS, AND BENEFIT FINDING IN SURVIVORS OF MULTIPLE PRIMARY CANCERS: RESULTS FROM THE 2010 LIVESTRONG SURVEY

Manuscript 2 is unable to be published in this document due to copyright constraints. Please refer to following link to access the full document via the publisher's website: https://onf-ons-org.pitt.idm.oclc.org/onf/44/6/psychological-distress-health-behaviors-and-benefit-finding-survivors-multiple-primary.

APPENDIX H

COVER LETTER FOR UNPUBLISHED MANUSCRIPT 3

Shelley Blozis, PhD
Senior Statistical Editor
Health Psychology
American Psychological Association
750 First St. NE
Washington, DC 20002-4242

August 2018

Dear Dr. Blozis,

As advances are made in early detection and cancer treatment and the cancer survivor population ages, the number of individuals diagnosed with two or more, or multiple, primary cancers is also increasing. While data is known regarding risk for and prevalence of second order or higher cancer diagnoses, little is known regarding the factors linking MPC to poor health outcomes in this population and the sociodemographic and clinical factors that place individuals at risk. Previous studies have also lacked theoretical grounding. By testing a psychobehavioral stress response model, this study, entitled, "Characterizing Psychobehavioral Risks in Survivors of Multiple Primary Cancers," addresses these gaps.

This manuscript addresses a critical cancer survivorship research gap by identifying key pathways associated with health outcomes in a growing yet understudied cancer survivorship population. We also identify individual characteristics associated with these pathways to guide early identification of at risk survivors and provide guidance for advancing the science, clinical care, and policies related to patients with MPC. We believe that this manuscript is a valuable addition to the scientific literature and would fit well within the scope of *Health Psychology.* This manuscript addresses current research gaps, provides data on concepts and challenges for future study, and is applicable to a wide variety of researchers and clinicians alike, providing insight into the unique needs of people in the growing population of multiple primary cancer survivors.

We have followed *Health Psychology*'s Instructions for Authors. All authors have read and approved the manuscript. This manuscript is part of the first author's dissertation research study. It is not under review elsewhere, nor does it contain data that are under review or published elsewhere, aside from the aforementioned dissertation documents. Please feel free to contact me with any questions regarding this submission.

Sincerely,

Sarah Belcher, BSN, RN, OCN®
Doctoral Candidate
Robert Wood Johnson Foundation Future of Nursing Scholar

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