

**DEVELOPMENT OF A MEASURE OF SELF-ADVOCACY
AMONG FEMALE CANCER SURVIVORS**

by

Teresa Louise Hagan

Bachelor of Arts, University of Notre Dame, 2007

Bachelor of Science of Nursing, University of Pittsburgh, 2010

Submitted to the Graduate Faculty of
the School of Nursing in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy

University of Pittsburgh

2015

UNIVERSITY OF PITTSBURGH
SCHOOL OF NURSING

This dissertation was presented

by

Teresa Louise Hagan

It was defended on

July 22, 2015

and approved by

Susan M. Cohen, Associate Professor, School of Nursing, Department of Health & Community Systems

Margaret Q. Rosenzweig, Associate Professor, School of Nursing, Department of Acute & Tertiary Care

Kristin Zorn, Associate Professor, University of Arkansas for Medical Sciences, Gynecological

Oncology

Clement A. Stone, Professor, School of Education

Dissertation Advisor: Heidi S. Donovan, Professor, School of Nursing,

Department of Health & Community Systems

Copyright © by Teresa Louise Hagan

2015

DEVELOPMENT OF A MEASURE OF SELF-ADVOCACY AMONG FEMALE CANCER SURVIVORS

Teresa Louise Hagan, PhD, RN

University of Pittsburgh, 2015

Background: The Female Self-Advocacy in Cancer Survivorship (FSACS) Scale is a new measurement tool designed to address the increasing need for cancer survivors to participate in and lead their care in face of barriers. Pilot work has demonstrated the FSACS Scale's content validity and reliability.

Purpose: The purpose of this study was to evaluate the construct validity of the FSACS Scale. This instrumentation study evaluates the construct validity of the FSACS Scale as evidenced by: (I) Internal structure consistent with the underlying model of self-advocacy; (II) Sensitivity to differences between known groups; (III) Relationships between self-advocacy and key predictors (openness and conscientiousness; information engagement; social support) and outcomes (symptom distress and healthcare utilization); (IV) Relationships between FSACS subscales and related concepts (patient activation; self-advocacy within the HIV/AIDS population); and (V) Relationships between FSACS scores and criterion measures.

Methods: A mixed-mode (online or mailed) cross-sectional survey design was used. Women with a history of an adult diagnosis of invasive cancer were recruited from two patient registries and seven advocacy organizations. Instrument selection and analyses to evaluate construct validity were based on the American Educational Research Association's instrumentation guidelines. Analyses included an exploratory factor analysis, t-tests, and bivariate correlations.

Results: A total of $N = 315$ adult female cancer survivors completed the survey. Evidence from all five construct validity hypotheses supports the construct validity of the FSACS Scale. The FSACS Scale factor analysis confirmed the three underlying dimensions of self-advocacy resulting in a 20-item measure explaining 45.87% of the variance in responses with subscales' Cronbach's alphas between 0.791 and 0.850. While able to detect differences between women with low and high levels of education, the scale did not differentiate between recent and long-term survivors. Predictor and outcome variables performed as expected. The FSACS subscales were more highly correlated with these outcomes than the measure of self-advocacy for HIV/AIDS.

Conclusion: Results support that the FSACS Scale is a theoretically-grounded measure of self-advocacy that can be used by clinicians and researchers to identify women at-risk for the poor outcomes associated with low self-advocacy.

TABLE OF CONTENTS

| | |
|---|-----------|
| PREFACE..... | XI |
| 1.0 INTRODUCTION..... | 1 |
| 1.1 SPECIFIC AIMS | 1 |
| 1.2 PURPOSE..... | 4 |
| 1.3 BACKGROUND, SIGNIFICANCE & INNOVATION..... | 6 |
| 1.3.1 Background | 6 |
| 1.3.2 Significance..... | 10 |
| 1.3.3 Innovation..... | 11 |
| 1.4 PRELIMINARY STUDIES | 12 |
| 1.4.1 Concept Analysis..... | 12 |
| 1.4.2 Justification of Predictors and Outcomes of Self-Advocacy..... | 13 |
| 1.4.3 Initial Item Creation & Evidence of Validity Based on Instrument Content..... | 16 |
| 1.4.4 Evaluation of Reliability | 18 |
| 1.5 RESEARCH DESIGN & METHODS | 21 |
| 1.5.1 Research Design & Setting..... | 21 |
| 1.5.2 Population & Sample..... | 21 |
| 1.5.2.1 Sample Size Adequacy | 21 |
| 1.5.2.2 Inclusion Criteria | 23 |
| 1.5.2.3 Sampling Procedures. | 24 |
| 1.5.3 Instruments | 26 |
| 1.5.3.1 Predictors | 30 |
| 1.5.3.2 Outcomes..... | 30 |
| 1.5.3.3 Related Concepts..... | 30 |
| 1.5.4 Data Collection Procedures | 30 |
| 1.5.4.1 Web-based..... | 31 |
| 1.5.4.2 Mailed..... | 32 |
| 1.5.4.3 Both Web-based and Mailed..... | 33 |
| 1.5.5 Data Analysis Procedures | 34 |
| 1.5.5.1 Descriptive Statistics | 34 |
| 1.5.5.2 Data Screening Procedures | 35 |
| 1.5.5.3 Data Analysis Procedures..... | 37 |
| 1.6 DISSERTATION TIMELINE..... | 41 |
| 1.7 DATA INTERPRETATION..... | 43 |
| 1.8 STUDY LIMITATIONS | 43 |
| 1.9 POTENTIAL PROBLEMS | 44 |
| 1.9.1 Reducing Survey Error | 44 |

| | | | |
|------|---------|---|-----|
| | 1.9.2 | Achieving Sample Size..... | 45 |
| 1.10 | | ALTERNATIVE APPROACHES | 48 |
| 1.11 | | PROTECTION OF HUMAN SUBJECTS | 49 |
| 1.12 | | INCLUSION OF WOMEN, MINORITIES, AND CHILDREN | 51 |
| 1.13 | | RESEARCH PARTICIPATION RISK & RISK REDUCTION | 54 |
| | 1.13.1 | Involvement..... | 54 |
| | 1.13.2 | Sources of Data | 54 |
| | 1.13.3 | Recruitment and Retention | 54 |
| | 1.13.4 | Potential Risks & Risk Reduction..... | 56 |
| | 1.13.5 | Risk-Benefit Ratio | 57 |
| 2.0 | | SUMMARY OF STUDIES..... | 58 |
| 2.1 | | FINAL SAMPLE | 58 |
| 2.2 | | RECRUITMENT | 58 |
| | 2.2.1 | Registries | 58 |
| | 2.2.2 | Advocacy Organizations | 60 |
| 2.3 | | DATA COLLECTION PROCEDURES | 62 |
| 2.4 | | ASSUMPTIONS FOR DATA ANALYSIS | 62 |
| 2.5 | | ITEM REDUCTION PROCESS..... | 64 |
| 2.6 | | RENAMING FSACS SCALE DIMENSIONS..... | 74 |
| 2.7 | | ADDITIONAL FSACS SCALE DETAILS..... | 75 |
| 3.0 | | MANUSCRIPTS | 76 |
| 3.1 | | CONCEPT ANALYSIS..... | 77 |
| 3.2 | | FOCUS GROUP TESTING..... | 78 |
| 3.3 | | CONTENT VALIDITY AND RELIABILITY TESTING MANUSCRIPT | 79 |
| | 3.3.1 | Abstract | 79 |
| | 3.3.2 | Background & Conceptual Framework | 79 |
| | 3.3.3 | Procedures for Instrument Development | 80 |
| | 3.3.3.1 | Intent | 82 |
| | 3.3.3.2 | Construct Definition | 82 |
| | 3.3.3.3 | Construct..... | 83 |
| | 3.3.3.4 | Challenges | 84 |
| | 3.3.4 | Description, Administration, and Scoring of the Instrument..... | 87 |
| | 3.3.4.1 | Operationalization and Item Development..... | 87 |
| | 3.3.4.2 | Administration & Scoring..... | 87 |
| | 3.3.5 | Content Validity Testing & Results | 88 |
| | 3.3.6 | Reliability Testing & Results | 90 |
| | 3.3.7 | Discussion | 98 |
| 3.4 | | CONSTRUCT VALIDITY TESTING MANUSCRIPT | 101 |
| | 3.4.1 | Abstract | 101 |
| | 3.4.2 | Introduction | 102 |
| | 3.4.3 | Methods | 105 |
| | 3.4.3.1 | Design | 105 |
| | 3.4.3.2 | Procedure | 106 |
| | 3.4.3.3 | Measures | 107 |
| | 3.4.3.4 | Data Analysis..... | 109 |
| | 3.4.4 | Results..... | 111 |

| | | |
|-----|---|-----|
| | 3.4.4.1 Hypothesis 1: Internal structure..... | 120 |
| | 3.4.4.2 Hypothesis 2: Sensitivity to Known Groups..... | 126 |
| | 3.4.4.3 Hypothesis 3: Relationships to Key Predictors and Outcomes..... | 128 |
| | 3.4.4.4 Hypothesis 4: Concurrence with Related Concepts..... | 130 |
| | 3.4.4.5 Hypothesis 5: Criterion Measures..... | 131 |
| | 3.4.5 Discussion | 132 |
| | 3.4.6 Conclusions..... | 136 |
| | 3.4.7 Funding Support..... | 137 |
| | 3.4.8 Conflict of Interest Disclosures | 137 |
| 4.0 | INCIDENTAL FINDINGS..... | 138 |
| 4.1 | DIMENSIONALITY | 138 |
| 4.2 | SUB-GROUP DIFFERENCES IN FSACS SCORES | 139 |
| | 4.2.1 Cancer Type Differences..... | 139 |
| | 4.2.2 Time Since Diagnosis Differences | 140 |
| | 4.2.3 Stage of Cancer Diagnosis Differences | 140 |
| | 4.2.4 Racial Differences | 141 |
| | 4.2.5 Age Differences | 141 |
| | 4.2.6 Educational Differences | 142 |
| | 4.2.7 Income Differences | 143 |
| | 4.2.8 Summary of Differences..... | 144 |
| 5.0 | APPENDICES | 145 |
| | APPENDIX A | 146 |
| | APPENDIX B | 147 |
| | APPENDIX C | 148 |
| | APPENDIX D | 149 |
| | APPENDIX E | 150 |
| | APPENDIX F | 151 |
| | BIBLIOGRAPHY | 152 |

LIST OF TABLES

| | |
|---|-----|
| Table 1. FSACS Scale Subscales..... | 13 |
| Table 2. CVI Statistics of FSACS Scale..... | 17 |
| Table 3. Suggestions for Exploratory Factor Analysis Sample Size | 22 |
| Table 4. Predictors, Outcomes, and Related Measures to Self-Advocacy..... | 28 |
| Table 5. Dissertation Timeline..... | 42 |
| Table 6. Numbers of Potentially Eligible Participants by Recruitment Site..... | 46 |
| Table 7. Demographics of Registries..... | 52 |
| Table 8. Demographics of Advocacy and Cancer Organizations | 53 |
| Table 9. Item Reduction Criteria and Elimination from 57 to 20 Item Scale | 66 |
| Table 10. Expert Panelists for Content Validity | 88 |
| Table 11. Content Validity Statistics | 90 |
| Table 12. Demographic and Health Information for Reliability Study Sample | 93 |
| Table 13. Predictor, Outcome, and Related Measures..... | 108 |
| Table 14. Sample Demographics | 114 |
| Table 15. Descriptive Statistics for All Measures | 119 |
| Table 16. Hypothesis 1: Factor Analysis with Oblique Rotation | 121 |
| Table 17. FSACS Scale Variance Explained..... | 125 |
| Table 18. FSACS Subscale Correlation Matrix..... | 126 |
| Table 19. Hypothesis 2: Group Comparisons | 127 |
| Table 20. Hypotheses 3 and 4 : FSACS Subscale Scores Compared to Predictors, Outcomes, and Related Concepts | 129 |
| Table 21. Hypothesis 4: FSACS and PSAS Subscale Correlations..... | 131 |
| Table 22. Hypothesis 5: FSACS Subscale Scores vs. PSAS Scores on Outcome Measures | 132 |

LIST OF FIGURES

| | |
|---|-----|
| Figure 1. Measurement Model of the Female Self-Advocacy in Cancer Survivorship Scale with Hypotheses for Validity Testing | 15 |
| Figure 2. Derivation of Female Self-Advocacy in Cancer Survivorship Scale's Dimensions Based on Deductive and Inductive Pilot Work..... | 86 |
| Figure 3. Cancer Diagnoses of Reliability Study Sample..... | 94 |
| Figure 4. Initial Female Self-Advocacy in Cancer Survivorship Measurement Model with Results of Content Validity, Reliability, and Cognitive Interview Testing..... | 98 |
| Figure 5. Measurement Model of the Female Self-Advocacy in Cancer Survivorship Scale with Hypotheses for Validity Testing | 105 |
| Figure 6. CONSORT Flowchart of Site Recruitment, Sample Enrollment, and Data Collection | 112 |
| Figure 7. Types of Cancer Diagnoses in Sample..... | 116 |
| Figure 8. Cancer Stage at Time of Diagnosis | 117 |
| Figure 9. Time Since Diagnosis in a Three-group Split | 117 |

PREFACE

Acknowledgements

To all the women who contributed their voices to this study: I promise to try my best to translate your stories, your perseverance, and your desire to help others into tangible ways of addressing the needs of women with cancer.

I would be remiss not to acknowledge the incredible support of my dissertation committee chaired by Heidi Donovan. Susan Cohen, Margaret Rosenzweig, Kristin Zorn, and Clement Stone have provided invaluable perspectives, ideas, and energy without which I would not have been able to ask the questions the matter and hopefully find the answers that can be of use.

My mother, father, three sisters, four brothers, foster siblings, and extended family all provided me with encouragement and determination to complete this dissertation, for which I am eternally grateful. A group of passionate, selfless, independent, and principled women in my life (my mother, my grandmothers, my two sisters, all of my aunts, and my academic and professional mentors) have shown me what female strength looks like, talks like, lives like, and cares like. For these women, I am eternally grateful.

Nomenclature

The term “cancer survivor,” as defined by the National Institute of Cancer is anyone from the time of diagnosis until the end of life.

1.0 INTRODUCTION

1.1 SPECIFIC AIMS

Currently, more than 6.8 million adult women are living with a history of cancer in the U.S. (Jemal, Siegel, Xu, & Ward, 2010). Female survivors face significant barriers to achieving optimal, high-quality, patient-centered cancer treatment and care including disparities in recognition and treatment of symptoms (Cleeland et al. 1994; Donovan, Hartenbach, & Method, 2005; Miaskowski, 2003; Paulson, Wirtalla, Armstrong, & Mahmoud, 2009; Skalla, Bakitas, Furstenberg, Ahles, & Henderson, 2003; Yeom & Heidrich, 2009). Survivors must invest significant personal involvement in order to manage the complexities of treatment decisions, treatment side-effects, and a fragmented healthcare system on top of facing considerable life disruptions, financial burdens, and long-term survivorship issues (Aranda et al., 2005; Ferrell, Koczywas, Borneman, Piper, & Uman, 2010; Ferrell, Smith, Cullinane, & Melancon, 2003; Hewitt & Simone, 1999; Pigott, Pollard, Thomson, & Aranda, 2009; Saatci, Akin, & Akipinar, 2007; Sherwood, Donovan, Rosenzweig, Hamilton, & Bender, 2008; Stovall, Greenfield, & Hewitt, 2005; Wen & Gustofson, 2004). Self-advocacy is a concept uniformly encouraged by healthcare professionals (Clark & Stovall, 1995), cancer advocacy organizations (American Society of Clinical Oncology, 2012; Shapiro et al., 2009), and policy organizations (Institute of Medicine, 2001) as a means of addressing such barriers to quality, patient-centered cancer care.

However, a critical disconnect exists between the expectation and ability of female cancer survivors to self-advocate for their cancer care.

Despite being roundly prescribed as a remedy for achieving quality cancer care and symptom management, the term self-advocacy remains largely unexamined among female cancer survivors. Among the HIV/AIDS, disability, and mental health populations' self-advocacy has been shown to be a modifiable factor associated with positive outcomes such as improved symptom relief, quality of life, and effective use of healthcare resources (Brashers, Neidig, & Goldsmith, 2004; Pickett et al., 2010; Test, Fowler, Brewer, & Wood, 2005).

However, studies also show that women are at particular risk for poor self-advocacy (Mendelson & Poole, 2007; Rosenzweig, Wiehagen, Brufsky, & Arnold, 2009; Sinding, Miller, Hudak, Keller-Olaman, & Sussman, 2012; Wade, 2001; Wiltshire, Cronin, Sarto, & Brown, 2006). Even with a strong basis in other populations, attempts at translating previous conceptualizations of self-advocacy to the cancer population have shown distinct incongruities (Hermansen-Kobulnicky, 2008). The PI's pilot work studying self-advocacy in cancer survivorship (Hagan & Donovan, 2013a) and specifically among female survivors (Hagan & Donovan, 2013b) further demonstrates this population's unique experiences of and barriers to self-advocacy including difficulty asserting needs to others and the additional demands of being a caregiver.

One major barrier to examining self-advocacy is that no valid, reliable measurement tool exists specific to female cancer survivors. This lack of clear conceptualization of the construct of this population's distinct form of self-advocacy and an associated measurement tool prevents the development and testing of evidence-based interventions to improve self-advocacy among female survivors and to improving quality cancer care. The Patient Self-advocacy Scale (PSAS)

(Brashers, Haas, & Neidig, 1999) originally developed in the context of patients with HIV, captures some essential dimensions, however it does not adequately capture the unique characteristics of self-advocacy in cancer survivors in general (Hermansen-Kobulnicky, 2008), and female survivors in particular (e.g. few items focus on females' unique symptom experiences, propensity for social connectivity, and roles as caretakers and mothers) (DeMarco, Miller, Patsdaughter, Chisholm, & Grindel, 1998; Wade, 2001). Notably, the original measure was based on an 89% male sample.

Following a comprehensive literature review and concept analysis of self-advocacy and a focus group study of ovarian cancer survivors, the candidate (Hagan) has developed an initial measure of self-advocacy, the Female Self-Advocacy in Cancer Survivorship (FSACS) Scale. The scale's content validity has been analyzed using an 8-member expert panel of female survivors, clinicians, researchers, and advocates. The scale includes 3 key dimensions specific to cancer survivors and females: 1) the application of information, 2) mindful non-adherence, and 3) connected strength. The FSACS Scale's reliability has been tested among a sample of 40 adult female cancer survivors. Initial evaluations indicate that the test-retest reliability is strong ($r = 0.94, p < .001$). The scale's internal consistency demonstrates a strong degree of common variance among items (Cronbach's $\alpha = 0.92$). Item revision and reduction based on the item and scale reliability findings along with cognitive interviews will be completed prior to the proposed construct validity study. The FSACS Scale's validity has yet to be examined.

1.2 PURPOSE

The purpose of the proposed instrumentation study is to evaluate the construct validity of the FSACS Scale in a diverse sample of adult female cancer survivors ($N = 300$). Validity will be evaluated based on the following hypotheses (illustrated in red in Figure 1):

1. The internal structure of the FSACS Scale should be consistent with the three proposed theoretical dimensions of self-advocacy;
2. FSACS Scale scores should be significantly higher for survivors who have increased time since diagnosis and higher levels of education compared to newly diagnosed women and women with less education, respectively;
3. FSACS Scale scores should be positively associated with survivors who are open to new ideas, conscientious, engaged in health information, have available social support.
FSACS Scale scores should be negatively associated with symptom severity and interference and healthcare utilization;
4. Higher scores on the FSACS Scale should scores be positively associated with scores on a measure of patient activation. Subscale scores between the FSACS Scale and the previous patient advocacy should vary according to the level of similarity between the old and new subscales; and
5. FSACS Scale scores should be more highly correlated with outcome measures of symptom severity and interference and healthcare utilization than the PSAS total score.

The proposed instrument will provide a new means to assess self-advocacy that incorporates female-specific aspects of self-advocacy. This scale will advance the science by providing a means to: 1) identify key components of self-advocacy among female cancer survivors, 2) evaluate the impact of self-advocacy on patient outcomes including symptom

management and healthcare utilization, and 3) identify individuals at risk for poor outcomes associated with low self-advocacy.

This study directly addresses the National Institute of Nursing Research's focus on improving symptom management and patient outcomes through an innovative patient-focused approach. The development and validation of the FSACS Scale represents the critical first step in the candidate's program of research. Data from this study will inform future research to identify at-risk cancer survivors and elements of self-advocacy amenable to intervention in order to improve patient outcomes.

1.3 BACKGROUND, SIGNIFICANCE & INNOVATION

1.3.1 Background

The Institute of Medicine (IOM) asserted that within the new model of healthcare “control should reside with patients” because this has been associated with better outcomes and lower costs (Institute of Medicine, 2001). In cancer, momentum toward greater patient advocacy has resulted in interventions to improve patient self-advocacy from the LIVESTRONG Foundation (Shapiro et al., 2009), American Society of Clinical Oncology (2012), National Coalition for Cancer Survivorship (2015), and international organizations (Errico & Bowden, 2006; McNally, 1996). Yet for all the attention paid to self-advocacy and attempts to promote it, clinicians continue to have difficulty fostering self-advocacy because we lack a validated instrument to measure changes in this concept, especially among female cancer survivors.

Self-advocacy has been studied in other populations and shown to be an important and modifiable characteristic. Self-advocacy, understood at a simplistic level as “standing up for one’s self”, has a strong theoretical and clinical foundation in other patient populations as a modifiable factor important to improving health outcomes. Pickett et al. (2010) demonstrated that an 8-week course in self-advocacy among mental health consumers decreased symptoms, improved coping skills, and increased empowerment. Additional research in self-advocacy among disability and HIV/AIDS populations has demonstrated improved symptom management, quality of life, treatment adherence, and effective use of healthcare resources (Test, Fowler, Brewer, & Wood, 2005; Walsh-Burke & Marcusen, 1999).

There is a lack of research in self-advocacy among cancer survivors: Self-advocacy has been widely adopted by oncology clinicians (Balough et al., 2011; Cartwright & Allotey, 2006; Clark & Stovall, 1996; Haggstrom & Doebbeling, 2011), policy makers (McCabe, Varricchio,

Padberg, & Simpson, 1995; Stovall, Greenfield, & Hewitt, 2005), advocacy organizations (O’Hair et al., 2003) and researchers (Green, Hart-Johnson, & Loeffler, 2011; LaFargue, 2010; Sinding et al., 2010) as a necessary part of being a cancer survivor. Complex treatment decisions and uncertain health outcomes place extraordinarily high demands on survivors. Nevertheless, while an appealing means to overcome these challenges, the implicit transfer of responsibility for self-advocacy to cancer survivors is not without problems. We risk demanding that patients do something we do not yet understand and which may actually lead to adverse outcomes (Sinding, Miller, Hudak, Keller-Olaman, & Sussman, 2012). One study demonstrated that when a measurement scale based on conceptualizations of self-advocacy in other populations was administered to cancer survivors, the scale’s reliability and validity fell and multiple problems existed within and between the scale’s dimensions (Hermansen-Kobulnicky, 2008). To meet IOM goals and growing demand from clinicians, it is imperative that a conceptual definition appropriate for cancer survivors and a corresponding measure of self-advocacy be systematically developed and validated for cancer survivors. Only then can we create interventions to improve self-advocacy and therefore address the needs of survivors at-risk for the poor outcomes associated with low self-advocacy.

Female cancer survivors have unique needs and are at high risk for not being able to self-advocate. Despite advances in cancer survival for both genders, the 6.8 million female cancer survivors in the U.S. (Jemal, Siegel, Xu, & Ward, 2010) continue to encounter challenges in cancer care and symptom management (Cleeland et al. 1994; Paulson, Wirtalla, Armstrong, & Mahmoud, 2009; Seale, Ziebland, & Charteris-Black, 2006). Known gender differences in communication, decision-making, and engagement in healthcare may contribute to women’s difficulties in self-advocating (Anderson et al., 2004; Cimprich et al., 2005; Elderkin-Thompson

& Waitzkin, 1999; Howard, Balneaves, & Bottorff, 2007; Miaskowski, 2003; O'Brien et al., 2008; Skalla, Bakitas, Furstenberg, Ahles, & Henderson, 2003; Sulik, Cameron, & Chamberlin, 2012; Wade, 2001). Specific groups of females, including those of low socio-economic status and minority survivors, are less likely to have the tools to self-advocate, placing them at higher risk for poor outcomes (Deshields, Potter, Olsen, Liu, & Dye, 2011; Jones & Johnson, 2012; Rosenzweig, Wiehagen, Brufsky, Sillaman, & Arnold, 2009). Despite these distinct challenges and needs, no mechanism currently exists to quantify how these needs affect patient outcomes or to create profiles of women at greatest risk for poor outcomes.

Previous measures of self-advocacy (e.g. the Patient Self-Advocacy Scale, PSAS) developed among individuals with HIV/AIDS were based on male conceptualizations of power, coping, and risk assessment (Brashers, Haas, & Neidig, 1999; Brashers, Neidig, & Goldsmith, 2004). Two dimensions of the PSAS (“information-seeking” and “mindful non-adherence”) were reflected in prior work of the candidate (concept analysis, focus groups findings); however, the third dimension (“assertiveness”) was not. This lack of congruence between previous measures such as the PSAS and the experiences of female cancer survivors appears to be caused by two factors: 1) inability to identify gender differences in self-advocacy with a sample comprised of 89% males; and 2) a lack of attention to factors unique to cancer survivorship. A new measure is required that focuses on the distinct phenomenon of self-advocacy among female cancer survivors.

Self-advocacy is required in symptom management: The ability to self-advocate may affect myriad aspects of cancer survivorship including the ability to achieve adequate cancer symptom management. Cancer- and treatment-related symptoms are known to co-occur; change over time; influence multiple domains of patients' lives; and require vigilance and persistence on

the part of the survivors to achieve symptom relief (DeFlorio & Massie, 1995; Donovan, Hartenbach, & Method, 2005; Ferrell, Koczywas, Borneman, Piper, & Uman, 2010). Research demonstrates that achieving effective symptom relief remains challenging for females. Significant patient- and system-level barriers exist including physiological differences in pain sensitivity, analgesic effectiveness, incomplete provider assessment, lack of effective treatments, and poor patient-provider communication (Anderson et al., 2000; Cheung, Le, Gagliese, & Zimmerman, 2011; Cleeland et al. 1994; Duncan, Forbes-Thompson, & Bott, 2008; Donovan, Hartenbach, & Method, 2005; Ferrell, Koczywas, Borneman, Piper, & Uman, 2010; Ferrell, Smith, Cullinane, & Melancon, 2003; Komurcu et al., 2000; Miaskowski, 2004; Shoemaker, Estfan, Induru, & Walsh, 2011; Yeom & Heidrich, 2009). Female subjects in Dr. Donovan's study reported a mean of 14 ± 4.84 concurrent symptoms with 5.6 ± 4.35 of these rated as ≥ 5 (0-10 severity scale). However, women received management recommendations for only 15-33% of these symptoms. These statistics are disheartening given the documented negative impact of symptoms on function and quality of life (Ferrell, Koczywas, Borneman, Piper, & Uman, 2010; National Institute of Nursing Research, 2011; U.S. Public Health Service, 2010; Yeom & Heidrich, 2009). Unrelieved symptoms can also lead to healthcare utilization (Sherwood, Donovan, Rosenszweig, Hamilton, & Bender, 2008). The goal of this study is to provide a theoretically-based measurement tool with the potential to identify these problems and be easily integrated into clinical practice.

In summary, this study addresses a critical disconnect: self-advocacy is widely prescribed as a remedy for achieving quality cancer care and symptom management but the concept remains under-examined and difficult to quantify for female cancer survivors particularly in the area of

symptom management. To date, no valid, reliable scale to measure the ability of female cancer survivors to self-advocate exists.

1.3.2 Significance

A reliable, valid measure of self-advocacy in female cancer survivors (defined as any woman with a history of a cancer diagnosis) is urgently needed. Although self-advocacy is widely endorsed by healthcare providers and cancer advocacy organizations as a means of improving patient outcomes, the vast majority of research in self-advocacy has been completed in men, with an alarming paucity of conceptualization and testing in the female cancer survivor population. Without this information, clinicians, researchers, and advocacy organizations are creating and promoting self-advocacy interventions based on conceptualizations of self-advocacy that have been shown to be non-generalizable to cancer survivors and inconsistent with the experiences of self-advocacy in females, inadvertently creating the possibility of doing harm.

The Female Self-Advocacy in Cancer Survivorship (FSACS) Scale will provide a mechanism for answering the role self-advocacy plays in patient outcomes for female cancer survivors by identifying:

- Female cancer survivors at risk for poor outcomes associated with low self-advocacy; and
- Factors of self-advocacy most amenable to intervention and most capable of reducing the poor symptom management outcomes known to be experienced by female cancer survivors.

This study directly addresses the NINR's goal of improving symptom management (2011), the IOM's call for innovative ways to involve patients in their healthcare, and the Office of Research on Women's Health priority of personalized prevention based on individual differences in behavior (U.S. Public Health Service, 2010).

This study addresses a critical disconnect: self-advocacy is widely prescribed as a remedy for achieving quality cancer care and symptom management but the concept remains under-examined and difficult to quantify for female cancer survivors particularly in the area of symptom management. To date, no valid, reliable scale to measure the ability of female cancer survivors to self-advocate exists.

1.3.3 Innovation

We challenge the idea that self-advocacy is adequately understood among female cancer survivors due to its non-specific definition and origin in dissimilar male patient populations. We caution that practice and advocacy focusing on current conceptualizations of self-advocacy may actually do a disservice to female cancer survivors.

We propose a new scale of self-advocacy born out of a systematic review of the literature and research with female cancer survivors to identify the specific and unique aspects of self-advocacy within this population. This is the first study to conceptualize and test self-advocacy in female cancer survivors and can therefore uncover the characteristics of self-advocacy that are important to women and provide critical information for the development of interventions to improve self-advocacy. The FSACS Scale has the potential to transform the current approach to promoting self-advocacy in clinical practice, advocacy, and research arenas.

1.4 PRELIMINARY STUDIES

In collaboration with her mentoring team and consultation with multiple experts in women's health, cancer survivorship, qualitative research, and instrumentation, the candidate's prior work led to the creation of the FSACS Scale.

1.4.1 Concept Analysis ([Publication #1](#) in Chapter 3.1)

First, the candidate conducted a systematic literature review and concept analysis of self-advocacy to uncover the defining attributes, antecedents, and consequences of self-advocacy and their applicability to cancer survivorship (Hagan & Donovan, 2013a). Secondly, she led and analyzed focus groups to describe self-advocacy as experienced by female cancer survivors (Hagan & Donovan, 2013b). Based on these results, key dimensions of self-advocacy were selected based on conceptual congruency with the concept analysis, essential and distinct factors found in the focus groups, and modifiability of factors for the purposes of future intervention studies.

The construct of self-advocacy among female cancer survivors is defined as a woman's ability to know her body and her needs, and ensuring that both are respected throughout her cancer care journey. This process resulted in 3 key dimensions of the FSACS Scale: "application of information", "mindful non-adherence", and "connected strength" (Table 1). "Application of information" refers to the ability of female cancer survivors to gather trustworthy, personally relevant information and apply it to their personal experiences and problems related to their cancer. "Mindful non-adherence" refers to the survivor's ability to ask questions and adjust provider recommendations to fit her health concerns, needs, and preferences. "Connected strength" refers to the survivor's ability to seek support, give support, balance personal needs

with others' needs, and raise awareness. This dimension incorporates female health psychology and women's experiences expressed during the focus group study (Hagan & Donovan, 2013b). These dimensions are distinct from the PSAS as they focus on the application rather than possession of information and highlight relational strength rather than individual assertiveness. These findings parallel previous literature uncovering the need for gender-specific considerations to the ways in which individuals encounter the healthcare system which may marginalize their needs and prevent them from receiving optimal care (Carr, 2003; Martin, 1988; Szumacher, 2006; Sulik, 2007).

Table 1. FSACS Scale Subscales

| FSACS Subscale | # of Items | Item response options/Level of Measurement | Corresponding PSAS Subscale |
|--------------------------------------|-------------------|---|------------------------------------|
| 1. Application of information | 16 | 6-point Likert-type Ordinal | Illness education |
| 2. Mindful non-adherence | 21 | 6-point Likert-type Ordinal | Mindful non-adherence |
| 3. Connected strength | 20 | 6-point Likert-type Ordinal | Assertiveness |

1.4.2 Justification of Predictors and Outcomes of Self-Advocacy

Key predictors established in the literature include demographic characteristics (e.g. education, income, race/ethnicity) (Hibbard & Cunningham, 2008; McConigley et al., 2011; Wiltshire, Cronin, Sarto, & Brown, 2006), openness & conscientiousness (Hagan & Donovan, 2013b; Osborne, Elsworth, Kissane, Burke, & Hooper, 1999; Test, Fowler, Brewer, & Wood, 2005) engagement in information (Clark & Stovall, 1995; Haggstrom & Doebbeling, 2011; Radina, Ginter, Brandt, Swaney, & Longo, 2011; Vessey & Miola, 1997) and availability of social support (Brashers, Neidig, & Goldsmith, 2004; Hagan & Donovan, 2013b; Lythcott, Green, &

Kramer Brown, 2003; Sulik, 2007). Documented outcomes of self-advocacy in other patient populations that are posited to be relevant to female cancer survivors include improved symptom management (Hagan & Donovan, 2013b; Hibbard, Greene, & Tusler, 2009; Tschopp, Frain, & Bishop, 2008) and decreased healthcare utilization (Hibbard & Cunningham, 2008; Hibbard, Greene, & Tusler, 2009; Mutchler et al., 2011).

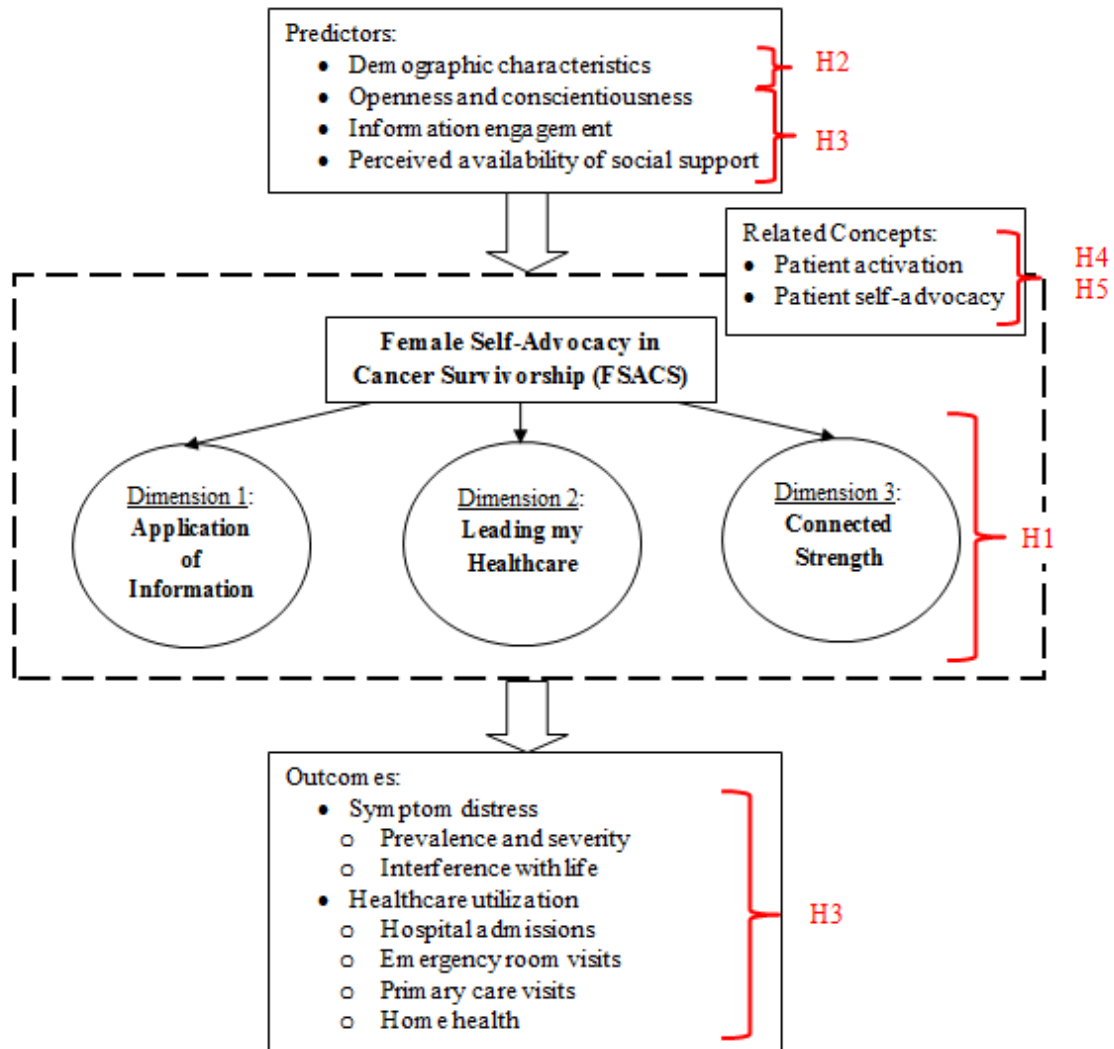


Figure 1. Measurement Model of the Female Self-Advocacy in Cancer Survivorship Scale with Hypotheses for Validity Testing

While other outcomes of self-advocacy are likely to exist, these outcomes were selected because they are proximal, significant, defined, and specific to cancer symptom management. The measurement model of self-advocacy (Figure 1) illustrates how the 3 dimensions are related to key predictors and outcomes from the literature and pilot work.

1.4.3 Initial Item Creation & Evidence of Validity Based on Instrument Content ([Unpublished Manuscript #3](#) in Chapter 3.3)

A large set of items was developed to encompass the breadth and depth of each dimension of self-advocacy using items specific to cancer survivorship (see [Appendix A](#) for all items). Item wording was based on the overall measurement model, content analysis, focus groups, and content validity experts' opinions.

Likert-type scaling was used to form a continuum ranging from 1 (*strongly disagree*), 2 (*disagree*), 3 (*somewhat disagree*), 4 (*somewhat agree*), 5 (*agree*), to 6 (*strongly agree*). Six response options were selected in order to capture variability and discriminate meaningfully between respondents. Negatively worded items and reverse coded items were included. Varying levels of difficulty (or how hard the action or belief described in an item would be for a survivor) were included to differentiate between levels of self-advocacy. An even number of response options was selected to avoid a neutral response option and require directionality of response (agree or disagree).

Content validity of this scale was evaluated using 8 experts including 3 female cancer survivors, 2 clinicians, 2 researchers, and 1 patient advocate. Each expert panelist was sent a copy of the preliminary FSACS Scales and asked to review each item and the scale as a whole. Each item was rated for relevancy and clarity using a 4-point Likert-type scale (1 = *not relevant/clear* to 4 = *very relevant/clear*) and space was given for comments. Lynn's (1986) methodology was used to calculate the Content Validity Index (CVI). The CVI was determined for each scale item and the entire scale. Based on Lynn's criteria, a CVI of 0.78 (or 7 of the 9 panelists) indicates adequate endorsement of an item or the instrument beyond the 0.05 level of significance.

Based on panelist feedback, 22 items had ≥ 3 panelists rate relevancy as a 1 or 2. Interestingly, 5 items from the previous self-advocacy measure (PSAS) received low-rankings from the panelists. Fourteen items were deleted due to low CVI, redundancy of items, and inclusion of items that were determined to be outcomes of self-advocacy rather than behaviors of self-advocacy. Thirteen items were reworded, mainly to soften adversarial language, improve specificity, and include action-orientation. Also of note, 3 items were preserved despite low ratings because of disagreement between researchers and survivors. For example, the item “I don’t know enough to make decisions about my cancer and treatment” (reverse scored) was endorsed by survivors but not researchers.

Table 2 reports the CVI statistics for the revised FSACS Scale. The CVI was calculated in multiple ways to account for the item-level and scale-level variations in expert ratings of the FSACS Scale’s relevancy. The Average Scale-CVI (S-CVI/Ave) was calculated by averaging the proportion of experts rating each individual item as relevant (rating of 3 or 4). In other words, the S-CVI/Ave is equal to the average of each of the individual item CVIs (I-CVI). The Scale-CVI/Universal Agreement (S-CVI/UA) was calculated as the proportion of items rated as relevant (rating of 3 or 4) by all 8 experts (Polit & Beck, 2006). Both the S-CVI/Ave (0.81) and S-CVI/UA (0.83) were above the recommended cut-off level of 0.78.

Table 2. CVI Statistics of FSACS Scale

| Type of CVI | Statistic | Calculation |
|--|-----------|--|
| Average Scale-CVI (S-CVI/Ave) | 0.81 | Average proportion experts rating each item as relevant (rating of 3 or 4). |
| Scale-CVI Universal Agreement (S-CVI/UA) | 0.83 | Proportion of total items judged by all experts as relevant (rating of 3 or 4) |

Pilot testing of the final 57 items was conducted with a group of masters-prepared nurses, research staff, and staff at the University of Pittsburgh School of Nursing as final check for readability, grammar, spelling, and formatting.

1.4.4 Evaluation of Reliability ([Unpublished Manuscript #3 in Chapter 3.3](#))

Reliability testing was performed in order to 1) evaluate internal consistency and test-retest reliability of the FSACS Scale; 2) evaluate the feasibility of assessing self-advocacy and related measures necessary for instrument validation; and 3) produce a parsimonious scale to be validated in the candidate's dissertation.

Design: A repeated measure design with baseline and 2-week measures was used. Time points were chosen to test the scale's consistency (test-retest reliability) within a time period in which little variation is thought to occur (DeVillis, 2012).

Sample: Subjects ($N = 40$) were recruited from three cancer clinics (two at Magee Women's Hospital of UPMC and Passavant Hospital) and members of four advocacy and cancer organizations (Gilda's Club of Western PA, National Ovarian Cancer Coalition of Pittsburgh, Urban League of Greater Pittsburgh, and the African American Women Speaker's Bureau). Two women who were approached at the clinics refused to participate, both due to time constraints while at the clinic.

Inclusion Criteria: 1) female, 2) at least 18 years old, and 3) have a history of a cancer diagnosis at age 18 or older (younger cancer survivors are likely to differ in their responses).

Exclusion Criteria: 1) unable to complete questionnaires in English (only English version) or 2) have a diagnosis of basal cell carcinoma or cervical intraepithelial neoplasia stage

1 (these survivors have inherently different treatment and symptom experiences than other cancer survivors).

Procedures: Directors at clinics and organizations identified potential participants and introduced the study to them. Potential subjects who expressed interest in participating were introduced to the candidate who then carried out screening and informed consent procedures.

On Day 1, the candidate screened potential subjects for eligibility. If the inclusion criteria were met and the potential participant was interested in participating in the study, written consent was obtained. Participants completed all baseline study measures in a private room within the clinic or office. The candidate handed all measures to the participant, instructed the participant to complete the survey independently, asking the candidate for clarifications or assistance as needed. Following completion of the FSACS Scale, the candidate conducted cognitive interviews with the participant to review any problems or issues with the items or survey and to assess the feasibility of completing the survey.

After all surveys were complete, the candidate provided the participant with an envelope containing the follow-up survey, instructions to complete the survey in 2 weeks (14 days), and a pre-addressed, pre-stamped envelope to mail the survey to the candidate. The candidate called each participant 2 days before the follow-up survey was to be completed and sent reminder postcards 3 and 5 days after the due date if the survey was not received. Participants were sent thank you cards with payment after receipt of the follow-up survey.

Measures (See Table 4 for full description of measures):

Baseline: a) Demographic questionnaire; b) FSACS Scale; and c) related measures.

Two-week follow-up: a) FSACS Scale.

Analysis: Internal consistency reliability was measured using Cronbach's alpha for summary scores (total scale and proposed subscales), item-total correlations, and the influence of each item on total scale and relevant subscale reliability. Test-retest reliability was calculated using Pearson's Product-Moment Correlation. Criteria for reliability were based on standards set by Nunnally (1978).

Results: The sample had a mean age of 57.28 years (SD = 13.16, Observed Range = 25-89) and 53.8% were married. Considering racial and ethnic background, 12.8% identified as Black or African American and one woman identified as Hispanic. For education and employment status, 20.5% of women had a high school degree or less and only 35.9% were working full-time. About 20% ($n = 8$) of women had a household gross annual income less than \$30,000.

Most women ($n = 17$, 42.5%) had a diagnosis of ovarian cancer, followed by breast cancer ($n = 15$, 37.5%). The remaining eight women reported a variety of six additional cancer sites. Almost half of the women were within one year of their cancer diagnosis ($n = 19$, 47.5%). The remaining women were either between 1 and 5 years since diagnosis ($n = 11$, 27.5%) or greater than 5 years since diagnosis ($n = 10$, 25%). Most women ($n = 26$, 65%) were receiving treatment at the time of survey completion. Seven (12.5%) women had experienced at least one recurrence.

Preliminary evaluations show that the test-retest reliability is strong ($r = 0.94$), indicating that the scale is stable across time points. The scale's internal consistency demonstrates a strong degree of common variance (internal consistency) among items (Cronbach's alpha = 0.92 for the full scale). The three dimensions had Cronbach's alpha's of 0.88, 0.81, and 0.90, respectively.

Feasibility and acceptability of completing the FSACS Scale was reported to be high by participants.

Transition to Proposed Study: Based on the findings from reliability testing and cognitive interviews, adjustments will be made based on Nunnally's standards of reliability including a reduced number of items. Considerations for item deletion include: 1) low item-to-total score correlations (<0.30), 2) improved Cronbach's alphas if item deleted, 3) poor clarity or ease of understanding from the feasibility data, and 4) large amounts of user-defined missing data (refusal or confusion on how to respond).

1.5 RESEARCH DESIGN & METHODS

1.5.1 Research Design & Setting

A cross-sectional design with a sample will be used to evaluate the validity of the FSACS Scale. The primary sampling strategy is random sampling followed by purposive sampling based on a review of completed questionnaires to ensure adequate representation of important sub-groups.

All data will be collected through web-based or mailed self-report surveys.

1.5.2 Population & Sample

Potential subjects will be identified through 1) cancer and research registries and 2) advocacy organization databases.

1.5.2.1 Sample Size Adequacy No gold standard exists to determine the necessary sample size when conducting an instrument validation study. Rather, sample size determination must

consider the proposed use of data in the study. Major considerations used to determine the ideal sample size for this study include: 1) performing an exploratory factor analysis (Hypothesis 1), 2) comparing groups of survivors by stage of diagnosis and educational achievement (Hypothesis 2), and 3) evaluating relationships between the FSACS Scale/Subscales and related concepts. (Hypotheses 3-5).

Sample Size for Exploratory Factor Analysis Various ideal sample sizes have been suggested for drawing valid conclusions during factor analysis. Table 3 summarizes the most commonly cited sample size justifications.

Table 3. Suggestions for Exploratory Factor Analysis Sample Size

| Author(s) | Sample Size Suggestions |
|--|--|
| Comrey & Lee (1992) | 300 subjects as “good” |
| DeVellis (2012) | 300 for pilot samples |
| Rouquette (2011) | generally need 300; for EFA with 3 constructs and >30 items |
| Tabachnick & Fidell (2001) | 300 subjects as rule of thumb |
| MacCallum, Widaman, Zhang, and Hong (2001) | difficult to estimate sample size a priori; required sample size needs depends in large part to obtained data (i.e. large communalities <0.60 and several items for each factor, can reduce the necessary sample size) |
| Munro (2001) | >5 subjects per variable; minimum required in order to perform a factor analysis |
| Stevens (2002) | 5-20 participants per variable; fewer when component saturation is high |

Based on these suggestions, a sample size of 300 appears adequate given the FSCACS Scale’s 3 subscales and 57 items. Even if communalities (the squared multiple correlation among items) are low, 300 individuals is adequate to provide reliable correlation coefficients in the factor analysis.

Sample Size for Group Comparisons and Relationship to Other Concepts The sample size must be large enough to perform hypothesis testing for Hypotheses 2-5. These hypothesis-driven comparisons will establish construct validity and also be used as pilot data in future studies testing the FSACS Scale. For two-tailed t-tests between groups (Hypothesis 2), desired confidence level of 95% and 80% power, and anticipated Cohen's D effect size of 0.45 (Stevens, 2002) (based on the patient activation literature) a sample size of $N = 158$ and subgroup sample size of $n = 79$ is needed. Because the sample size of each subgroup (time since survival and educational level) will be used in targeted recruitment and checked regularly during recruitment, this sample size will be easily reached with the overall goal of $N = 300$ for the factor analysis. For bivariate correlations between scales and subscales (Hypotheses 3-5) using two-tailed test of significance set at $\alpha = 0.05$, a correlation coefficient with an acceptable absolute error rate of 0.15 (the difference between different scales'/subscales' correlations) a sample size of 223 is needed. A sample size goal of $N = 300$ will be able to tolerate an absolute error rate of 0.13. In conclusion, a sample size of $N = 300$ is large enough to both perform the construct validity testing and group comparisons.

Using a conservative response rate of 30-50% (based on Dillman's estimate of 74% (2002)), an estimated 600 to 1,000 women will be contacted with equal numbers from registries and organizational databases.

1.5.2.2 Inclusion Criteria Identical to the reliability testing study, participants will meet inclusion criteria if they are: 1) female, 2) over the age of 18, and 3) have a history of a cancer diagnosis after the age of 18. This sample is purposefully broad in order to include of a wide variety of cancer sites, survivorship stages, health statuses, ethnicities, socioeconomic status, and current disease status (a key principle of instrument development necessary to ensure potential

generalizability). *Exclusion Criteria:* Participants will be considered ineligible if they are 1) unable to complete questionnaires in English or 2) have a diagnosis of basal cell carcinoma or cervical intraepithelial neoplasia stage 1 because these survivors are expected to have inherently different experiences than other female cancer survivors.

Sampling procedures are designed to limit the risk of coverage error and sampling error. Coverage error (or failure to randomly sample from the population of interest) and sampling error (or obtaining responses from too few people representative of the population) are addressed by recruiting from national and local registries and databases, regular recruitment checks, and minority recruitment plans.

1.5.2.3 Sampling Procedures Emailed or mailed letters of invitation will be sent to approximately 600 to 1,000 women in order to meet the target sample size of 300. If data is available from the registries or organizational databases regarding socio-demographic information of interest (time since diagnosis, cancer type, minority status, and/or educational level), then that information will be used to help target specific groups of potential participants.

Potential participants will be identified through cancer and research registries and advocacy organization databases.

- *Cancer and research registries:* Participants will be recruited from two research registries: 1) a research registry (the Clinical and Translational Research Institute Patient Research Registry and 2) tumor registry (the Pennsylvania Tumor Registry). Participants included in the CTSI Registry have previously participated in research studies and have agreed to be contacted by researchers. A convenience sample of the Patient Research Registry will be obtained by members of the registry responding to an email from the

registry notifying them of their potential eligibility in this study. A random sample of the Pennsylvania Tumor Registry members from specific years between 1985 and 2013 will be created. Letters of introduction will be emailed to participants who may be eligible for the proposed study. If no email address is provided in the registry, letters of introduction will be mailed to the address provided by potential participants.

- *Advocacy organization databases:* Participants will be recruited from the American Cancer Society, National Ovarian Cancer Coalition, the African American Women's Speaker's Bureau, the Urban League of Greater Pittsburgh, and the Cancer Caring Center. The organizations' databases contain names and information about the organization's members. Directors at these organizations have agreed to introduce the candidate and the proposed study to potential participants. A random sample of the organization's members will be selected. If an email address is available, organization directors will email the letter of introduction to potential participants. If no email address is provided in the organization's database, letters of introduction will be mailed by the directors of the organizations to the address provided by potential participants.
- *Both registries and organization databases:* After 150 participants have completed questionnaires, the candidate will review the cumulative proportion of participants with different times since diagnoses, cancer sites, years since education, and racial and ethnic backgrounds. Based on these findings, purposive sampling will be used in both registries and organization databases containing this information to target under-represented sub-groups.

1.5.3 Instruments

[Appendix A](#) includes a paper copy of all survey instruments given to participants. The Qualtrics online survey mirrored the format of these surveys. The construct of self-advocacy among female cancer survivors is defined as a woman's ability to know her body and her needs, and insuring that both are respected throughout her cancer care journey. The FSACS Scale is a 57-item (will be reduced) 6-point Likert-type self-report scale. Likert-type scaling was used to form a continuum ranging from 1 (*strongly disagree*), 2 (*disagree*), 3 (*somewhat disagree*), 4 (*somewhat agree*), 5 (*agree*), to 6 (*strongly agree*). The number of items will be reduced after reliability analysis is complete. Six response options were selected in order to capture variability and discriminate meaningfully between respondents. Negatively worded items and reverse coded items were included. Varying levels of difficulty (or how hard an item would be) were included to differentiate between levels of self-advocacy. An even number of response options was selected to avoid a neutral response option and require directionality of response (agree or disagree). Content validity has demonstrated strong internal consistency (Cronbach's $\alpha = 0.92$) and test-retest reliability ($r = 0.94$) among a sample of 40 women with a history of a cancer diagnosis.

During reliability testing, the average time to complete the 57-item FSACS Scale was 17 minutes, and 49 minutes for the complete set of questionnaires. The Flesch Reading ease score is 69.5 (ideal range for patient information and questionnaires is 60-70 on a 100-point scale). The Flesch-Kincaid reading level is 6.4 (ideal level of 7 or 8, though less to include a broader range of educational backgrounds). Acceptability was high among women in the reliability study. No special requirements, such as looking up health information or performing tasks, are required while completing the measurement.

The 3 key dimensions of the FSACS Scale are “application of information”, “mindful non-adherence”, and “connected strength” (Table 1). “Application of information” refers to the ability of female cancer survivors to gather trustworthy, personally relevant information and apply it to their personal experiences and problems related to their cancer. “Mindful non-adherence” refers to the survivor’s ability to ask questions and adjust provider recommendations to fit their health concerns, needs, and preferences. “Connected strength” refers to survivor’s ability to seek support, give support, balance personal needs with others’ needs, and raise awareness.

Table 4. Predictors, Outcomes, and Related Measures to Self-Advocacy

| Construct | Citation | Measure | # of Items | Item response options | # of Subscales | % Female | Cronbach's α |
|---|---|-----------------------------------|-------------------|------------------------------|-----------------------|-----------------|---------------------------------------|
| <i>Predictors</i> | | | | | | | |
| Demographic Characteristics | (Sereika & Engberg, 2006) | CRCDC Sociodemographic Survey - R | 25 | Variable | n/a | 100 | n/a |
| Disease Characteristics | n/a | Investigator-developed | 7 | Single response | n/a | n/a | n/a |
| Openness and conscientiousness | (Goldberg et al., 1999; Goldberg, 2006) | IPIP | 20 | 5-point Likert-type | 2 | Not reported | .81-.82 |
| Information engagement | (DuBenske et al., 2009) | HIOS | 8 | 5-point Likert-type | 1 | 63.6 | .65 |
| Perceived availability of social support | (Cohen et al., 1985) | ISEL | 12 | 4-point Likert-type | 3 | 74.4 | .31-.81 |
| <i>Outcomes</i> | | | | | | | |
| Symptom severity & interference with life | (Cleeland et al., 2000) | MDASI | 24 | 11-point Likert-type | 2 | 57 | .91-.94 |
| Healthcare utilization | (Given & Given, 2013) | Adapted questionnaire | 4 | Single response | 4 | Not reported | n/a |
| <i>Related Measures</i> | | | | | | | |
| Patient activation | (Hibbard et al., 2004) | PAM | 13 | 5-point Likert-type | 1 | 63 | .91 |
| Patient self-advocacy | (Brashers, Haas, & Neidig, 1999) | PSAS | 12 | 5-point Likert-type | 3 | 9.2 | .60-.82 |

Valid, reliable measures were selected to capture the hypothesized predictors, outcomes, and related concepts in the literature (Table 4). Measures were selected based on their conceptual congruence with the literature and focus groups, number of items to reduce patient burden, the percent of female participants in the original scale development, and reliability. Measures with low reliability (ISEL) were kept based on the strength of other criteria.

1.5.3.1 Predictors Specific socio-demographic characteristics such as age, level of education, and income are measured using the Center for Research in Chronic Disorders (CRCD) Sociodemographic Survey. The personality traits of openness and conscientiousness are measured using the International Personality Inventory Pool (IPIP). Information engagement is measured using the Health Information Orientation Scale (HIOS). Perceived availability of social support is measured by the Interpersonal Support Evaluation List (ISEL).

1.5.3.2 Outcomes Symptom severity and interference, measured by the MD Anderson Symptom Inventory (MDASI), captures the symptoms commonly experienced by individuals with cancer and how symptoms interfere with their daily life. The adapted healthcare utilization questionnaire tracks the number of primary care visits, emergency department visits, hospital admissions, and home health care visits individuals had within past 3 months and whether or not these were related to cancer.

1.5.3.3 Related Concepts Patient activation, measured by the Patient Activation Measure (PAM), assesses the knowledge, confidence, and skills individuals have in managing their health. A previous measure of self-advocacy, the Patient Self-Advocacy Scale (PSAS), measures patient involvement in decision-making and was developed among a mostly male population of individuals with HIV/AIDS.

1.5.4 Data Collection Procedure

The finalized FSACS Scale will be developed into web-based and paper-pencil formats. Both approaches will use Dillman's Tailored Design Method to increase internet and mailed survey response rates through personalized, systematic design and implementation strategies (Dillman, 2002). The Research Electronic Data Capture (REDCap) application will be used for web-based questionnaires, and mailed questionnaire responses will be manually entered into REDCap. The following will occur after receipt of participant information from the registry and organization databases. *A mixed mode data system will be used including both web-based and mailed surveys.*

1.5.4.1 Web-based A) Initial Email and Survey Delivery (Day 0): For web-based questionnaires, emails will be sent to potential participants containing information about 1) the purpose of the research study; 2) amount of time involved; 3) description of voluntariness of participation, minimal risks, and lack of personal benefit involved; 4) candidate's contact information for any questions about the research; and 5) contact information for the IRB regarding questions about rights as a research participant. A link to the study website containing all questionnaires will be included. Potential participants will be given the choice to opt out of further contact in the email. Even if they do not opt out, no potential participant will be contacted more than twice (initial and follow-up invitation).

On the website, all information on informed consent will be included as a required page for reading prior to beginning the web-based survey and that can be printed for their records. A question asking for voluntary consent to participate in the research study will be required. The website will include explicit statements that no identifiable information is being collected in the

surveys, that responses will not be linked to participants' emails (after the data collection phase), and that completion of the surveys implies that participants are consenting to be a part of this research study.

B) *Reminder Emails* (Days 5 and 10): Reminders will be emailed to the participant including a link to the survey if the candidate has not received the returned survey.

C) *Final Reminder Email* (Day 21): A final reminder will be emailed to the participant including a link to the survey if the candidate has not received the returned survey with a note that this is the final notice to participate.

1.5.4.2 Mailed A) Initial Letter and Survey Delivery (Day 0): For mailed questionnaires, an initial letter will be mailed to the participant's address provided by the registry or advocacy organization. It will include the same introduction and consent information as the emailed survey along with a pre-stamped postcard to allow women to opt out of participation.

B) *First Questionnaire Delivery* (Day 7) If no postcard is received by the in 1 week, the candidate will mail a packet of information to the participant including all the information emailed in the web-based questionnaire (see above), a written consent form indicating that completion and return of the questionnaires indicates agreement to participate in the research study, instructions to complete the questionnaires, a copy of the questionnaires, and instructions to return all items in the pre-addressed, pre-stamped envelope to the candidate at the participants' earliest convenience.

C) *Reminder Post-card* (Days 14): A reminder post-card will be mailed if the candidate has not received the returned survey.

D) *Replacement Questionnaire Delivery* (Day 21): If the survey has not be returned, the study will send a replacement questionnaire along with a reminder letter and replacement consent form. A pre-addressed, pre-stamped return envelope will also be included.

1.5.4.3 Both Web-based and Mailed Emailed and mailed questionnaire items and formatting will be identical and use standardized methodology for constructing questionnaires to decrease patient burden and increase response rate (Dillman, 2002). This mixed-mode use of a web-based survey with the option for a paper-and-pencil version with reminders has demonstrated equivalency of scale measurements, has minimal confounding effects, and will compensate for the differences in response rate and data completeness known to exist in each delivery method (Kongsved, Basnov, Holm-Christensen, & Hjollund, 2007). This approach does not exclude those without internet access, decreases need for resources and funds, is appropriate for all age groups (Edwards et al., 2009; van den Berg, et al., 2011).

Participants will be paid \$8 after successfully completing and returning questionnaires. Participants completing web-based questionnaires will receive Amazon.com gift codes in an email from the candidate. Participants completing mailed questionnaires will receive WePay pre-paid credit cards in the mail.

1.5.5 Data Analysis Procedures

This study evaluates the validity of the FSACS Scale in a sample of 300 female cancer survivors. The proposed psychometric testing in this study will focus on reducing total items to the most parsimonious set of items in order to achieve optimal reliability and validity.

1.5.5.1 Descriptive Statistics Descriptive statistics will be collected and analyzed on all scales through a collection of methods. These statistics serve to describe the sample, examine distributions for each variable, and examine relationships among variables before completing the primary analyses.

Frequency distributions will provide numerical comparisons within and between categorical variables. Graphs such as bar graphs and bivariate scatterplots will provide pictorial comparisons between variables and help identify outliers. Variable distributions (along with FSACS Scale item distributions) will be summarized through plots. Box and whisker (percentiles), histograms (number or percent of cases for ranges of values), and stem-and-leaf plots (all data values but group similar data values) will be analyzed for each variable.

Summary statistics will calculate the distribution of observed data values for each variable. For nominally-scaled categorical data, mode and range will be reported for individual items. For all ratio scales and intervally-treated Likert-type scales (due to large number of response options with meaningful variation in responses), the mean, standard deviation, and standard errors will be reported along with appropriate subscale scores. For the FSACS Scale,

mean, standard deviation, standard error, range, and minimum/maximum values will be analyzed as appropriate for the total scale, item means, item variances, and inter-item correlations.

1.5.5.2 Data Screening Procedures Patterns of missing data will be examined to detect the type of missingness for variables and cases. Nonrandom missing data will be explored for patterns between variables. A t-test for variables missing completely at random will be performed to examine differences between sub-groups (select socio-demographic, disease, and site variables). If greater than 5%, missing data will be handled using Expectation Maximization (EM) algorithm because this method uses observed values and current estimates of relationships between variables in order to substitute an expectation for missing data. This iterative method is considered more desirable than mean substitution or last observation carried forward methods. Regression methods and multiple imputation methods will also be considered and compared to EM using a sensitivity analysis to ensure the strongest method incorporating available data is used.

Assumptions of validity testing and factor analysis will be tested prior to analysis. All variables will be examined for violations of normality (histograms, Shapiro-Wilk, and Kolmogorov–Smirnov testing), independence of observations (inherent in design), linear relationships between variables (scatterplots), and homogeneity of variance (boxplots and Levene test). Variables exhibiting significant skewness and/or kurtosis will be adjusted in order to satisfy the assumptions and produce stable results. Violations of assumptions will be reported,

and if egregious, transformations will be performed. Prior to analyses between known groups, these same assumptions will be checked and corrected for each sub-group.

Additional assumptions for conducting an Exploratory Factor Analysis will be tested. Factorability will be tested to ensure an adequate degree of intercorrelation between FSACS Scale items so that coherent factors can be named. This assumption will be tested with the inter-item correlations, anti-image correlation matrix diagonals, and measures of sampling adequacy (Kaiser-Myer-Olkin greater than 0.5 and Bartlett's test in which the sphericity should be statistically significant). Sample size adequacy will be tested to ensure reliable estimates of correlations between items can be made. In addition to the sample size estimates provided in [Section 1.5.2.1](#), this assumption will also be tested *post hoc* by checking sample distribution for each group and estimating sample size as described in [Section 1.5.2.1](#).

Instrument development requires variability in response rates among participants. Item distributions of the FSACS Scale will be examined by reviewing frequency distributions and means/standard deviations for all questionnaire items. Items that are highly skewed and have unbalanced distributions will be identified because these items convey little information. Items reflecting a broad range of distribution will be retained because these items discriminate between individuals and are desirable during factor analysis and psychometric evaluation. Item performance across different sub-groups (cancer site, time since diagnosis, active treatment) will be examined and chi-square statistics of association produced in order to check assumptions prior to analysis. Tukey's test of non-additivity will be performed to test the assumption that there is no evidence of multiplicative interaction among FSACS Scale items.

Categorical data will be examined for univariate and bivariate outliers by examining frequency distributions and cross-tabulations. Continuous data will be examined for univariate and bivariate outliers by creating standardized scores and reviewing cases with z-scores above 3 or below -3, examining box-and-whisker plots, bivariate scatterplots, and Mahalanobis' distances. Any atypical values will be considered for transformation or deletion depending on their influence on hypothesis testing. Winsorizing, or score alteration, will be considered for extreme values.

Data transformations will be conducted for highly skewed or non-normal data distributions. Positively skewed data will be considered for square-root or logarithmic (Log 10) transformations, depending on the extent of the skewness. Negatively skewed data will be considered for square-root or logarithmic (Log 10) transformations following a reflection of the variable, depending on the extent of the skewness.

1.5.5.3 Data Analysis Procedures Validity refers to the extent to which an instrument is capable of producing inferences that actually capture the underlying construct it intends to measure. If valid, the interpretation of a measurement's scores should be able to be used in making inferences about an individual's scores on the measure. Unlike previous decades in which validity was measured as static and discrete forms (i.e. content, criterion, and construct breakdown), validity is now recognized as a unitary quality of a measurement. Validity involves "an overall evaluation of the plausibility of the intended interpretations" (Kane, 1994) of a

measure. Validity evidence requires multiple, diverse types of bodies of evidence and arguments that are substantiated with evidence collected over time.

According to the American Educational Research Association's (AERA) *Standards for Educational and Psychological Testing*, in the absence of a gold standard against which to measure convergent validity, establishing construct validity is a process of gathering evidence on the extent to which a measure performs as expected in relevant situations (1999). To establish construct validity, an investigator must generate a set of propositions that guide interpretation of the measure's performance.

For the FSACS Scale, validity will be based on evaluation of the hypotheses testing validity (in red in Figure 1):

- **H1)** *Internal structure*: the internal structure of the FSACS Scale should be consistent with the three proposed theoretical dimensions of self-advocacy;
- **H2)** *Sensitivity to differences between known groups*: Total and subscale FSACS scores should be significantly higher for: 1) Experienced survivors (≥ 5 years since diagnosis) compared to newly diagnosed women (≤ 6 months); and 2) Women with high levels of education (\geq master's degree) compared to those with low levels of education (\leq a high school education);
- **H3)** *Relationships between self-advocacy and key predictors and outcomes*: FSACS Scale total score and subscale scores should be positively associated with the personal attribute of openness and conscientiousness (IPIP), the learned skill of information

engagement (HIOS), social support (ISEL) and negatively associated with symptom severity and interference (MDASI) and healthcare utilization;

- **H4)** *Concurrence with related concepts (formerly convergent validity)*: Higher scores on the FSACS Scale should be positively associated with scores on the Patient Activation Measures (PAM). Subscale score correlations between the FSACS Scale and the previous patient advocacy measure (PSAS) are expected to vary according to the level of similarity between the old and new subscales: 1) the two “mindful non-adherence” subscales should be strongly positively correlated ($r > 0.70$); 2) the “illness education” (PSAS) and “application of information” (FSACS) subscales are expected to be moderately correlated ($r = 0.30-0.70$); and 3) the “assertiveness” (PSAS) and “connected strength” (FSACS) subscales are expected to be weakly correlated ($r < .30$), and finally;
- **H5)** *Criterion measures (formerly criterion validity)*: The FSACS Scale total score should be more highly correlated with outcome measures of symptom severity and interference and healthcare utilization than the PSAS total score.

Psychometric evaluation of the FSACS Scale will be based on the propositions defined above.

H1: Exploratory Factor Analysis will be performed using maximum likelihood (ML) method with the goal of reducing items and producing a parsimonious scale. Oblique rotation will be used to allow for correlation between factors. A chi-square goodness-of-fit statistic will evaluate the degree of congruence between data and the proposed model. In the event that the assumptions of ML method are not met, Principal Axis Factoring will be used along with an

examination of the residual correlation matrix instead to determine goodness-of-fit. Scree plots and percent of variance explained will be used to help identify how many factors to extract. The pattern matrix will be used to examine the partial standardized regression coefficients and determine if a simple solution has been achieved. Items will be considered for deletion based on item-to-total correlations ≤ 0.35 , inter-item correlations < 0.20 , and factor loadings $< .40$ and $> .90$ in order to ensure items contribute to the total variance explained without being redundant. Items that cross-load onto more than one factor will be individually reviewed in consideration for their congruency with factors and the overall construct and retained if loading higher on the intended factor. Ultimately, a parsimonious scale should be created based on the above criteria that considers the theoretical underpinnings, distinguishability, simplicity, internal consistency, and interpretability of factor scores.

H2: T-tests will be used to compare FSACS Scale scores between experienced and newly diagnosed cancer survivors and survivors with high and low levels of education.

H3: Bivariate correlations and t-tests as appropriate will be conducted between FSACS Scale scores and scores on designated measures of predictors (IPIP, HIOS, and ISEL) and outcomes (MDASI, Healthcare Utilization).

H4: Bivariate correlations will be conducted between the FSACS Scale scores and subscale scores of related concepts from the literature (PAM and PSAS) to evaluate concurrent validity.

H5: Bivariate correlations will be calculated between the PSAS scale scores and outcome variables (MDASI, Healthcare Utilization) and compared with the strength of association

between the FSACS and outcomes to evaluate whether the FSACS performs better among female cancer survivors compared to the PSAS. Pearson correlations between the both the PSAS and FSACS Scale will be respective outcome measures will be compared.

All tests will be conducted at the $\alpha = 0.05$ significance level. Data analysis will be conducted using SPSS (version 21, SPSS, Inc., Chicago, IL).

1.6 DISSERTATION TIMELINE

Table 5 outlines the dissertation timeline originally presented by the candidate during her Comprehensive Exam and Overview in May 2015. As of late June 2015, all anticipated deadlines and times were met except that participants were recruited through March 2015.

Table 5. Dissertation Timeline

| | May - June 2014 | July– Sept. 2014 | Oct.–Dec. 2014 | Jan.– Feb. 2015 | March- May 2015 | June-Aug. 2015 |
|---|-----------------------|------------------------|-------------------|-----------------------|-----------------------|-------------------|
| Dissertation Proposal | X | | | | | |
| Dissertation Approval | X | | | | | |
| Recruitment (minority recruitment strategy implemented at 50% & 75% recruitment) | | X | X | X | | |
| Analysis -Developing syntax Performing planned analyses Consulting research team members | | | X | X | X | |
| Manuscript Preparation | | | | | X | X |
| Dissemination | | | | | | X |
| Post-doctoral Award Preparation | | | | X | X | X |

1.7 DATA INTERPRETATION

Validity of the interpretation of FSACS Scale scores will be evaluated based on the five hypotheses listed in [Section 1.5.5.3](#). Since each hypothesis could be rejected or retained, the argument for validity testing will be based on the extent each hypothesis is or is not retained.

If these hypotheses are substantiated in this study's results, then the interpretation of high FSACS Scale scores will be indicative of an adult woman with cancer with a high ability to self-advocate.

Item reduction of the FSACS Scale will occur by looking at the performance of the new instrument based on scale-, factor-, and item-level statistics. Criteria for exclusion will include 1) low item-item correlations (<0.30), 2) poor fit into the factor structures within the Exploratory Factory Analysis, and 3) large amounts of user-defined missing data (refusal or confusion on how to respond).

1.8 STUDY LIMITATIONS

Survey research inherently includes errors of observation and non-observation. Furthermore, using a self-reported administration method introduces respondent recall and bias error which can impact external validity of score interpretations. Particularly in the current study, bias is introduced because of the social desirability of self-advocacy. Concerns of observation and bias

were addressed by including a large number of items behaviors varying in difficulty that reflect the depth and breadth of self-advocacy as defined in previous work.

Another limitation to this study includes not including more types of validity evidence. Given the lack of an alternate measure of self-advocacy for female cancer survivors, item responses cannot be compared to a gold standard. Responsiveness, or a measurement's sensitivity to detect change, is not measured given the cross-sectional design of the study. Future studies collecting longitudinal data will measure changes in outcomes based on individuals' responses to the FSACS Scale.

1.9 POTENTIAL PROBLEMS

1.9.1 Reducing Survey Error

Survey development research must be concerned with error in estimating the true score of the surveys being administered. In order to produce accurate information about self-advocacy in female cancer survivors, four types of survey error all pose potential problems with this study: coverage error, sampling error, nonresponse error, and measurement error (Dillman, 2002). Each of these types will be systematically addressed:

- Coverage error, or the risk of not all members of the population have a known, nonzero chance of being included in the sample, will be addressed by using broad sample frames

(particularly the Pennsylvania Tumor Registry) and regularly scheduled recruitment checks.

- Sampling error, or error in precision due to not all members of the population being sampled, is addressed by randomly sampling a high enough proportion of the portion based on sample size estimations.
- Nonresponse error, or error due to systematic differences between participants receiving the survey who do and do not return completed surveys, is addressed by sending personalized, tailored instructions intended to motivate all women receiving questionnaires.
- Measurement error, or inaccurate or imprecise survey responses, is addressed through extensive pilot testing of survey questions to ensure clarity of instructions and wording along with survey design and construction.

1.9.2 Achieving Sample Size

One of the major potential problems in this study is not achieving the desired sample of 300 adult female cancer survivors. To address this problem, special attention will be made to include culturally sensitive statements in the recruitment flyers/paperwork, survey paperwork, FSACS scale, and consent forms. Recruitment activities during will include personalized, culturally sensitive language according to Dillman's methods of formatting web-based and paper surveys according to social exchange theory. Minority female survivors were included within the eight-

member expert panel during the creation of the FSACS Scale items and assisted in assuring the FSACS Scale represents minority female cancer survivors' experiences.

Table 6 illustrates the intended recruitment by site and racial status. To ensure inclusion of a wide variety of cancer sites, survivorship stages, health statuses, ethnicities, socioeconomic statuses, and current disease statuses (a key principle of instrument development necessary to ensure potential generalizability), these factors will be evaluated by the research team after accrual is 50% and 75% complete. If necessary, the candidate will increase efforts to recruit a diverse sample including targeted selection of clinics and direct requests to clinical staff. less than a high school education and 20% being non-Caucasian.

Table 6. Numbers of Potentially Eligible Participants by Recruitment Site

| | White (n) | Black (n) | Asian/PI (n) | Other (n) | TOTAL |
|--|----------------------|----------------------|-------------------------|----------------------|--------------|
| PA Cancer Tumor Registry* | 52 | 16 | 3 | 1 | 72 |
| CTSI Participant Research Registry | 70 | 4 | 1 | 3 | 78 |
| TOTAL Registries | 122 | 20 | 4 | 4 | 150 |
| American Cancer Society | 80 | 1 | 0 | 5 | 86 |
| Urban League of Greater Pittsburgh | 0 | 9 | 0 | 0 | 9 |
| National Ovarian Cancer Coalition (Pittsburgh and National) | 30 | 1 | 0 | 4 | 35 |
| African American Women's Speakers' Bureau | 0 | 10 | 0 | 0 | 10 |
| Cancer Caring Center | 10 | 0 | 0 | 0 | 10 |
| TOTAL Cancer and Advocacy Organizations | 120 | 21 | 0 | 9 | 150 |
| TOTAL | 242 | 41 | 4 | 13 | N=300 |
| *These data were provided by the Bureau of Health Statistics and Research, Pennsylvania Department of Health. The Department specifically disclaims responsibility for any analyses, interpretations or conclusions. | | | | | |

Our goal is to ensure diversity in education and race by achieving the pre-set goals of 10% having Based on demographic information from the individual recruitment sites, we believe this enrollment strategy is feasible.

Minority recruitment will be discussed at the weekly research team meetings and monthly meetings. Low minority recruitment at specific clinics and organizations will be addressed through a detailed recruitment plan with Dr. Rosenzweig. These contingency minority recruitment plans are detailed below:

- A panel of minority recruitment experts including Dr. Rosenzweig, the Center for Minority Health (CMH), and the directors of the African American Women's Speakers' Bureau and Urban League of Greater Pittsburgh plan to meet for consultation and formation of a detailed plan including: 1) targeting minority female survivors within cancer clinics and cancer registries, 2) developing culturally-sensitive recruitment flyers and literature, and 3) working directly with clinic and advocacy organization staff to direct efforts at minority women.
- The candidate has registered with an additional cancer advocacy organization, the Army of Women, and will be able to recruit from the women included in this registry who have indicated interest in participating in cancer trials and research projects. The registry currently includes 12,297 Black or African American women, 12,000 Hispanic or Latina women, 3,897 Asian women, 1,665 Native American women, and 19,806 women of other racial and ethnic groups.

1.10 ALTERNATIVE APPROACHES

Alternate methods exist to empirically validate new measurement tools. Different modes of survey delivery could be used including telephone or face-to-face survey delivery modes. Alternatively, a single mode of web-based or mailed questionnaires could be used. However, these alternate survey delivery modes reduce external validity and generalizability for future use of the FSACS Scale in clinical or research settings. Likewise, using a single mode would significantly increase the cost of implementation (mailed) or increase sampling error if not including women without reliable access to the internet (web-based).

Additional alternative approaches include consideration of additional hypotheses to establish validity based on the AERA guidelines. However, the five hypotheses currently included consider both the structural dimensions of the FSACS Scale and external relationships of the FSACS Scale with other measures, both of which are based on previous literature surrounding self-advocacy and female cancer survivorship literature. Content validity has previously been reviewed and found to be adequate. Future research can explore additional hypotheses regarding the interpretation of the FSACS Scale scores with additional measures, samples, and settings.

1.11 PROTECTION OF HUMAN SUBJECTS

Approvals have been achieved to secure the safety of research participants, access to participants, and instrument use:

- Institutional Review Board
 - University of Pittsburgh Institutional Review Board (PRO12110062)
- Access to Participants
 - CTSI Participant Research Registry
 - Pennsylvania Department of Health for the Cancer Registry
 - National Ovarian Cancer Coalition (National)
 - African American Women Speaker's Bureau (Pittsburgh)
 - Cancer Caring Center (Pittsburgh)
 - *American Cancer Society (National) (*currently being developed*)
- Instrument Use for paper- and web-based questionnaires from the owners or creators of each instrument.

Consents will be obtained from all participants. Mailed questionnaires will include a consent form stating “By completing and returning the completed questionnaire you agree to participate in this research study”. Web-based questionnaires will include a typed copy of the consent form and ask participants to indicate their voluntary consent by responding “Yes” to the item “By clicking “YES” you agree to participate in this research study.”

Potential Risks and Risk Reduction: The major risks of 1) subject burden and 2) breach of confidentiality will be systematically addressed.

1) *Subject Burden:* To reduce the risk of subject burden, shortened versions of scales and select subscales of larger measures were used when valid/reliable and appropriate to minimize patient burden. Participants will be given written instructions in their formal introduction to the survey to take time to rest and return to questionnaires at a later time if they begin to experience fatigue and/or distress during questionnaire completion. These instructions will be provided for both web-based and mailed questionnaires.

2) *Breach of Confidentiality:* To reduce the likelihood of a breach of confidentiality, questionnaire data will be assigned a code number and stored in a locked file cabinet separate from the file identifying participants by code number. Internet surveys will be designed to assure confidentiality in responses. Internet surveys will be delivered on a secure website (REDCap) which uses the Secure Sockets Layer (SSL) encryption. The REDCap website ensures that data are maximally secured and in accord with the Health Information Portability and Accountability Act. Data is stored behind the University of Pittsburgh firewall. Unique identification numbers will be assigned to each participant. No identifying information will be collected on the web-based survey. Survey responses will be stored on a secure server at the University of Pittsburgh. The candidate has established plans with clinic and organization directors to assure protection of all participants including confidentiality of all identifiable information, minimization of any risk, use of informed consent materials, and description of risks and benefits.

Data and safety monitoring will be conducted during monthly meetings with Drs. Donovan and Cohen during which data quality, management and any adverse events arising from the study will be reviewed. A summary of these reviews will be provided to the IRB at the time of the yearly renewal. Any unanticipated adverse events will be reported immediately to the IRB.

1.12 INCLUSION OF WOMEN, MINORITIES, AND CHILDREN

This study specifically addresses a research question relevant to female cancer survivors. All adult women with a history of a cancer diagnosis ages ≥ 18 years old are included in this study independent of cancer stage. Women with a previous diagnosis only of basal cell carcinoma or cervical intraepithelial neoplasia stage 1 are excluded because these survivors are expected to have inherently different experiences than other female cancer survivors.

We plan to ensure that 10% of the sample has less than a high school education and 20% be non-Caucasian. Tables 7 and 8 describe the racial and ethnic make-up of the recruitment sites. We anticipate that adult women at various stages of cancer survivorship share experiences and situations in which self-advocacy and symptom management are likely to occur and significantly impact their lives. These statements are supported by the candidate's focus group study in which female survivors' experiences consistently expressed the same central themes of self-advocacy independent of individual disease state, age, number of recurrences, years since diagnosis, racial background, and years of education (Hagan & Donovan, 2013b).

Table 7. Demographics of Registries

| | By Race | | | | | By Ethnicity | | | |
|---|------------|-----------|--------------------|---------------------------|-------------|----------------------|----------------------|----------------------|----------------------|
| | White | Black | Asian/ PI | Undisc losed/ Other | TOTAL | Non- Hispa nic | Hisp anic | Und isclo sed | TOTAL |
| Allegheny County | 81.5% | 13.2% | 2.8% | 2.5% | 100% | 98.4% | 1.6% | n/a | 100% |
| CTSI Participant Research Registry ^A | 6,974 | 74 | 49 | 954 | 8,451 | 7,426 | 9 | 1 | 7,976 |
| | 82.5% | 5.6% | 0.6% | 11.3% | 100% | 93.1% | 0.1% | 6.8% | 100% |
| PA Cancer Tumor Registry ^B | 697,251 | 9,990 | 4,683 | 82,102 | 844,026 | 358,177 | 3,868 ^C | Not avail able | 62,045 |
| | 82.6% | 7.1% | 0.6% | 9.7% | 100% | Not availa ble | Not avail able | Not avail able | Not availabl e |
| TOTAL | 92% | 7% | 0.001 % | 1.6% | 100% | 97% | 3% | n/a | 100% |
| <p>A: Females \geq 18 years old in with history of cancer diagnosis as of February 2014.</p> <p>B: Females \geq 20 years old with previous diagnosis of cancer in registry (1990-2010 data available for statistical review. These data were provided by the Bureau of Health Statistics and Research, Pennsylvania Department of Health. The Department specifically disclaims responsibility for any analyses, interpretations or conclusions.</p> <p>C: Data from 2002-2010. The Pennsylvania Department of Health began tracking ethnic data in 2002.</p> | | | | | | | | | |

Table 8. Demographics of Advocacy and Cancer Organizations

| | Total | % Female | % Minority |
|--|---------------|-----------------|-------------------|
| American Cancer Society | TBD* | TBD* | TBD* |
| Urban League of Greater Pittsburgh | 20,000** | 75%** | 85% |
| National Ovarian Cancer Coalition (Pittsburgh) | 400** | 85%** | Not known |
| National Ovarian Cancer Coalition (National) | 5,000** | 85%** | Not known |
| African American Women's Speakers Bureau | 20*** | 100% | 100% |
| Cancer Caring Center | 7,000*** | 90% | Not known |
| TOTAL Advocacy and Cancer Organizations | 32,420 | 75-100% | |
| <p>*Information from the American Cancer Society will be given to the candidate prior to study implementation.</p> <p>**Estimate from advocacy organization director. Because organizations' records vary, directors estimates of total membership and what proportion is female and minority are described to represent the large sample from which eligible women can be recruited.</p> <p>***The African American Women's Speakers Bureau includes 20 African American women. This organization sponsors regular educational series, health forums, and events that are widely advertised to African American women throughout western Pennsylvania. Dr. Rosenzweig has high success in recruiting minority cancer survivors through this organization.</p> | | | |

1.13 RESEARCH PARTICIPATION RISK & RISK REDUCTION

Human participants will be protected from risks associated with participating in this research study.

1.13.1 Involvement

Three hundred female adult cancer survivors will participate in this study by completing paper- or web-based surveys at one time point. *Inclusion Criteria:* 1) female, 2) at least 18 years old, and 3) have a history of a cancer diagnosis at age 18 or older (younger cancer survivors are likely to differ in their responses). *Exclusion Criteria:* 1) unable to complete questionnaires in English (only English version) or 2) have a diagnosis of basal cell carcinoma or cervical intraepithelial neoplasia stage 1 (these survivors have inherently different treatment and symptom experiences than other cancer survivors).

1.13.2 Sources of Data

All data will be collected in the paper- or web-based surveys completed by participants.

1.13.3 Recruitment and Retention

Recruitment strategies have been developed with each recruitment site to identify email listservs and databases from which the candidate can contact potential participants.

Dillman's Tailored Design Method (2002) will be utilized to maximize recruitment and return of paper- and web-based surveys by reducing the burden of participation. Dillman's survey procedures are based on social exchange theory in which the survey request and motivation to complete the surveys is based on establishing trust and increasing the perceived benefits of completing the survey while decreasing the expected costs of participation.

Trust will be established by 1) providing written endorsement from the leaders of the organizations from which the participants are recruited, 2) stressing the importance of the knowledge to be gained in this study, and 3) ensuring confidentiality of all participant information. Participants' perceived benefits of participation will be highlighted by providing background information about the survey, asking for help and advice, showing respect for individuals, and providing social validation. Participants' expected costs of participation will be decreased by making participation convenient, used abbreviated versions of questionnaires, requesting minimal private information and no sensitive information, and avoiding any subordinating language.

Scheduled recruitment checks will occur after 50% and 75% of the total sample has been recruited. If it low participation among women with low educational status and minority status is discovered, then targeted recruitment strategies will be developed and implemented if with consultation with Dr. Rosenzweig and her research team. Surveys are completed at one time point, so retention strategies are not included.

1.13.4 Potential Risks & Risk Reduction

1) *Subject Burden*: To reduce the risk of subject burden, shortened versions of scales and select subscales of larger measures were used when valid/reliable and appropriate to minimize patient burden. Participants will be given written instructions in their formal introduction to the survey to take time to rest and return to questionnaires at a later time if they begin to experience fatigue and/or distress during questionnaire completion. These instructions will be provided for both web-based and mailed questionnaires.

2) *Breach of Confidentiality*: To reduce the likelihood of a breach of confidentiality, questionnaire data will be assigned a code number and stored in a locked file cabinet separate from the file identifying participants by code number. Internet surveys will be delivered on a secure website (REDCap) which uses the Secure Sockets Layer (SSL) encryption. Data is stored behind the University of Pittsburgh firewall. Surveys are designed to assure confidentiality in responses. Unique identification numbers will be assigned to each participant. No identifying information will be collected on the web-based survey.

Survey responses will be stored on a secure private server with the assistance of Dr. Donovan's research team's web-design experts and information science specialist who will be available to assist the candidate for the duration of the study. The candidate has established plans with clinic and organization directors to assure protection of all participants including confidentiality of all identifiable information, minimization of any risk, use of informed consent materials, and description of risks and benefits.

1.13.5 Risk-Benefit Ratio

This study has minimal risk. The benefit of creating a valid, reliable measure of self-advocacy among female cancer survivors constitutes a significant and innovative research methodology capable of being used in future research to address the needs of female cancer survivors.

2.0 SUMMARY OF STUDIES

2.1 FINAL SAMPLE

We originally planned to compare FSACS Scale scores of women within 6 months of their diagnosis and over 5 years (Hypothesis 2). In order to ensure more equal distribution during planned analyses, participants' times since diagnosed with classified as 0-1 year, 1-5 years, and over 5 five years. Given that most women within 1 year of diagnosis had received or were currently receiving some type of ongoing treatment (e.g. radiation (40.0%), chemotherapy (70.5%), or adjuvant treatment(18.8%)), it is likely that between 6 months and 12 months these women were still acutely impacted by their cancer and its treatment.

2.2 RECRUITMENT

2.2.1 Registries

The Pennsylvania Tumor Registry contained the names, street addresses at time of diagnosis, racial and ethnic categories, date of birth, and ICD-9 codes of all adult females diagnosed with cancer from 1985-2013. Concerns arose with the registry including:

- Outdated addresses caused many initial letters to be returned.
- The registry was not checked against the Social Security Death Index.
- In situ cancers were included with invasive cancers; some ICD-9 coded that were of unclear invasiveness and malignancy. Several women called or mailed the researcher to indicate that they had never received a cancer diagnosis.
- The registry contained more years for women who would be > 5 years since diagnosis (1985 – 2009) than 1 – 5 years (2009 – 2013) or < 1 year (some 2013) although the planned hypotheses of the study required roughly equally numbers from these three groups.

To address these concerns, the candidate used a random number generator to randomly identify women from specific years and checked each randomly selected woman against: (1) a publically available website with addresses (whitepages.com), (2) the Social Security Death Index, (3) online obituary searches particularly for women diagnosed within the past two years, and (4) a list of ICD-9 codes. Years from the original list of registry participants were weighted toward 2009-2013 in order to achieve equal numbers participants from the three groups of times since diagnosis.

Initial letters sent through the Pennsylvania Tumor Registry were not cross-checked against the ICD-9 manual to ensure all potential participants had invasive cancers. Even after cross-checking occurred, some participants still indicated having been diagnosed with an in situ or non-invasive cancer. As a result, 19 participants (6.1%) in the final sample had a non-invasive cancer diagnosis. These participants remain in the analyses because

the treatment and psychological adjustment for this population has been shown to reflect that of individuals diagnosed at later stages.

While the response rate of 17.3% from the Pennsylvania Tumor Registry is low compared with other studies having used this registry, this study randomly selected potential participants from the entire registry. Individuals who are older, non-White, and have more advanced disease are known to have lower response rates when recruited through state tumor registries (Kelly, Frazee, & Hornik, 2010), but it was important to the study design and hypotheses to select a variety of ages, ethnicities, and times since diagnosis.

2.2.2 Advocacy Organizations

Difficulties recruiting occurred at several sites. At the Urban League, personnel changes and problems accessing eligible participants greatly impeded recruitment. To address these barriers to recruitment, the candidate instead attended events sponsored by the Urban League and brought copies of the survey study, consent form, return envelopes with postage, and business cards to recruit potential participants face-to-face at these events.

At the American Cancer Society (ACS), both national and local recruitment strategies were undertaken. Originally, the ACS's online website for their Cancer Support Network posted a study announcement on their website (<http://csn.cancer.org/announcements>). However, given the limited visibility of this advertisement, very few participants were recruited despite bi-monthly updates to put the study at the top of the Announcement webpage. Several suspicious emails were sent to the study's email address requesting to participate

referencing this announcement. While the first few requesters were given access to the survey, a distinct pattern of email addresses, email text, and abnormal survey responses raised concerns which the candidate brought to her Committee and determined that emails fitting this pattern could be ignored in order to preserve the integrity of the data. While the announcement remained on the ACS website, the candidate decided to also recruit from the local ACS Pittsburgh Chapter by speaking at local volunteer meetings.

The African American Women's Speakers Bureau leadership helped recruit participants at events they were organizing or attending. Researchers from this study were not present at those events. Few potential participants elected to participate in the study.

Due to the low recruitment from the Urban League of Greater Pittsburgh and the African American Women's Speakers Bureau (both of which were assumed to help ensure diversity of the sample), the candidate used available racial and ethnic data through the Pennsylvania Tumor Registry to target minority women.

Additional sites were included including the LiveWell Survivorship Program at Hillman Cancer Center (October 2014), cancer support groups at Hillman Cancer Center (November 2014), and Magee Women's Hospital newsletters and clinic flyers (October 2014). All of these sites were able to recruit several eligible to complete online and paper surveys.

2.3 DATA COLLECTION PROCEDURES

Prior to the start date of the study, the decision was made to use Qualtrics rather than REDCap for web-based survey dissemination, data collection and management. Qualtrics' superior survey-building capabilities, export options, and usability drove this decision. Blocks of individual questionnaires were randomly presented to participants in order to prevent order effect.

The Pennsylvania Tumor Registry had guidelines for using their registry that altered the data collection procedures. Prior to any participant research activity, the participant needed to return a signed consent form. Originally, no reminders were sent to participants after sending the questionnaire packet. Later, after clarification with the directors of the registry, replacement questionnaires were sent to participants who had not yet returned the questionnaires.

Participants were given \$10.00 Amazon.com gift cards instead of WePay cards. This was done to avoid collecting participants' Social Security numbers and to make the experience as easy as possible for all participants in accordance with Dillman's Tailored Design Method.

2.4 ASSUMPTIONS FOR DATA ANALYSIS

Prior to any analyses, all data was cleaned, recoded, and assumptions were checked. For the factor analysis, item performance was checked. Item-to-total correlations and inter-item correlations were examined. While some correlations were less than 0.35 and 0.20, respectively,

these items were determined to be poor performers during earlier testing and throughout future factor analysis stages.

Almost all assumptions for the factor analysis (Hypothesis 1) and additional hypotheses (Hypotheses 2 – 4) were met for all scales except for the FSACS Scale and the MDASI. The MDASI symptom severity and symptom interference subscales had significant floor effects. One hundred and ten women did not report any symptoms. The 205 women who did report any symptom being above 0 had a mean symptom severity score of 1.37 (SD = 1.38) and mean symptom interference of 1.16 (SD = 1.83) indicating low overall symptom burden among this sample.

For the final 20-item FSACS Scale, several univariate and multivariate outliers existed and several items demonstrated high skewness and kurtosis. Six participants were univariate and/or multivariate outliers on the FSACS and other scales. The factor analysis and additional analyses were run with and without these 6 participants, and the number of factors and factor loadings did not significantly differ. Eleven of the final 20 items in the FSACS Scale had skewness and/or kurtosis +/- 1.00 mostly due to ceiling effects in which most respondents scored items as a 4, 5, or 6 on the 6-point Likert scale. After collapsing response options 1 and 2 into option 3, the problems of skewness and kurtosis were resolved.

All scales had less than 4.1% missing data save for the FSACS Scale which had 8.0% missing data. Although the pattern of missingness was determined to be random (MCAR: chi-square = 790.754, df = 1317, p = 1.000), the decision was made to use estimation maximization (EM) to input missing data in order to provide the largest sample size for the

factor analysis. After missing data was imputed using EM, factor analyses results were compared to results without the EM imputation, regression, regression with residuals, and multiple imputation techniques for addressing missing data. Factor analysis results did not vary between methods.

The six univariate and multivariate outliers were deleted from analyses for Hypotheses 2-5. Results of hypotheses testing did not change when these outliers were eliminated.

2.5 ITEM REDUCTION PROCESS

The original 57 items used during reliability testing were included in the construct validity testing. Online surveys had random ordering of the 57 items. Paper surveys had the same ordering.

Decisions about what items to keep or delete must incorporate multiple sources of information regarding item performance. While the data analysis plan inferred that results of factor analysis statistics (item-to-total correlations, inter-item correlations, factor loadings, cross-loading items) would be the primary determinants of item deletion while considering theoretical underpinnings, reliability, interpretability, and simplicity.

During the process of determining the final set of items for a theoretically-consistent, psychometrically robust, parsimonious, and clinically useful measurement, we also considered item's previous performance during content validity, cognitive interview, and reliability testing. For example, during content validity testing the experts were asked to rank

the five items they found most important and the five items they found least important to self-advocacy. These items were noted and kept in the analyses despite low communalities and factor loadings in order to increase the face validity of the final measure. Responses of the cancer survivors on the expert panel were given extra weight during this process.

In order to track decisions to delete or retained items in the FSACS Scale, a table was used to track item performance across several psychometric criteria (Table 9). As noted in the table, items were reworded after content validity testing, therefore complicating cross-evaluations with reliability and construct validity testing results. While there was no one formula or rule by which items were deleted or retained, this table provides evidence and/or explanations behind the choices we made in deciding on the final items measure. Future research will investigate items that performed differently than expected based on the original theory or which may be performing poorly due to lack of clarity or poor wording choice.

Table 9. Item Reduction Criteria and Elimination from 57 to 20 Item Scale

| Item | Content Validity: # of experts ranking item as Most and Least Important* | Problems Identified during Cognitive Interviews | Low Content Validity Index Score | Poor Initial Reliability | Low Communalities (<0.30) | Low Factor Loading (<0.40) | Notes** | Delete or Keep |
|---|---|---|--|--------------------------------|---------------------------------|-------------------------------------|---|----------------------|
| BEING AN INFORMED DECISION MAKER (FORMERLY APPLICATION OF INFORMATION) | | | | | | | | |
| 1. I seek out information to help me improve my life as a cancer survivor. | Most: 2 (1 cancer survivor) | | | | | | Poor conceptual clarity with factor; Low variability | Delete |
| 2. I make sure the health information I get is trustworthy. | Most: 1 (cancer survivor) Item confusing to others including survivors | | | | | | Poor conceptual clarity with factor; Low variability | Delete |
| 3. I can tell the difference between health information that does and does not apply to me. | Most: 1 Least: 1 | | | | X | X | | Delete |
| 4. Health information gives me more control as a cancer survivor. | Most: 1 Many experts disagree with concept of "control" | | | | | | Low variability | Delete |
| 5. I ignore questionable health information. | | | | | X | X | | Delete |

Table 10 (continued)

| | | | | | | | | |
|---|---|---|---|---|---|---|--------------------|--------|
| 6. I try new things to improve my life as a cancer survivor. | Most: 1 (cancer survivor) Least: 1 | | | | | | Cross-loading | Delete |
| 7. I don't know enough to help make decisions about my cancer care. | Least: 1 | | X | X | | X | | Delete |
| 8. I use my skills to solve the problems I face as a cancer survivor. | Most: 3 | X | | | | | | Keep |
| 9. I gather information before making decisions about my cancer care. | Most: 1 (cancer survivor) | | | | | | | Keep |
| 10. If I had problems with my job or other responsibilities, I would know where to look for help. | Least: 1 | X | X | | X | X | | Delete |
| 11. I weigh my options carefully before making important decisions about my cancer care. | | | X | | | | | Keep |
| 12. I prepare myself to make decisions about my cancer care. | Most: 1 | | | | | | | Keep |
| 13. When it comes to making decisions about my cancer care, I know what my priorities are. | Most: 2 | | | | | | | Keep |
| 14. Having information helps me to make decisions about my cancer care. | Most: 3 (1 cancer survivor) Confusing item to many; hard to disagree with item | | | | | | Lowest variability | Delete |
| 15. If a health problem doesn't go away, I look for different ways to manage it. | Least: 2 | X | X | X | X | X | | Delete |
| 16. If I had problems covering the costs of my cancer care, I would know where to look for help. | Least: 1 | | X | X | X | X | | Delete |

Table 10 (continued)

| COMMUNICATING WITH MY HEALTH CARE PROVIDERS (FORMERLY LEADING MY HEALTH CARE) | | | | | | | | |
|--|---|---|---|---|----------|----------|---------------------------------------|--------|
| 17. Sometimes I adjust my provider's recommendations to better fit with my life. | Most: 1 Least: 2 (1 cancer survivor) | X | X | | X | X | | Delete |
| 18. If a treatment is not working, I wait for my provider to make a change. | | | | X | X | <u>X</u> | | Delete |
| 19. I ask questions when I don't understand what my provider is telling me. | Most: 5 (1 cancer survivor) | | | X | | | Cross-loading between factors 1 and 3 | Keep |
| 20. My provider knows what is best for me. | Most: 1 | X | | X | X | X | | Delete |
| 21. Sometimes I decide not to follow the advice of my provider. | Most: 1 Least: 1 | | X | X | X | <u>X</u> | | Delete |
| 22. I don't want my provider to think I am a difficult patient. | Least: 1 | | | X | X | X | | Delete |
| 23. If I don't do what my provider asks me to do, I have a good reason. | Least: 1 | | X | X | X | <u>X</u> | | Delete |
| 24. I feel like I can disagree with my provider. | Most: 1 Least: 1 | | | X | <u>X</u> | <u>X</u> | | Delete |
| 25. If a medication is not working, I tell my provider. | Most: 1 (cancer survivor) Confusion if person not taking medication; confusion about chemotherapy vs. medication | | | | <u>X</u> | X | Very low variability | Delete |

Table 10 (continued)

| | | | | | | | | |
|---|------------------------------|---|---|---|---|---|---|--------|
| 26. I question my provider if I don't agree with his or her recommendations. | Most: 1 | | | | X | X | Cross-loading between Factors 1 and 3; Kept in due to Content Expert approval | Keep |
| 27. I don't talk about a health concern with my provider unless I think there is a solution. | | | X | | | | | Keep |
| 28. I rarely tell my provider about the problems I am having. | | | | | | | | Keep |
| 29. I know where to get an answer if my provider can't give me one. | Most: 3 | | X | | X | | Kept in due to Content Expert approval | Keep |
| 30. I ask my provider to explain his or her recommendations. | Most: 4 (2 cancer survivors) | | | | | X | Cross-loading between Factors 1 and 3 | Keep |
| 31. I am not sure where I would go if my provider is not able to answer the questions I have. | Not included | | | | | | Removed due to redundancy with #29 | Delete |
| 32. I am comfortable asking for a second opinion. | Most: 2 | | | | X | X | Kept in due to Content Expert approval | Keep |
| 33. Not following the advice of my provider bothers me. | | X | X | X | X | X | | Delete |
| 34. I know what's best for me medically. | | X | X | X | X | X | | Delete |

Table 10 (continued)

| | | | | | | | | |
|---|---------------------------------------|---|--|---|---|----------|---|--------|
| 35. I seek other help for my needs that are not being met by my provider. | Most: 1 Least: 1 | X | | X | X | X | Initially kept in initially due to Content Expert approval, but ultimately poor fit | Delete |
| 36. I worry that asking for a second opinion would hurt my relationship with my provider. | | | | | | | Duplicate of Item 32 | Delete |
| 37. I have a hard time voicing my preferences to my provider. | Most: 2 (2 cancer survivors) | | | | | | | Keep |
| CONNECTED STRENGTH | | | | | | | | |
| 38. I seek out support from other cancer survivors. | Most: 1 | | | | | | | Keep |
| 39. I seek out support from friends and family. | Most: 1 | X | | X | X | X | | Delete |
| 40. Helping other cancer survivors also helps me. | Most: 1 | | | | | | | Keep |
| 41. I don't like asking my friends and family for help. | Most: 1 Least: 1 (cancer survivor) | | | | X | X | | Delete |
| 42. Many of my decisions are based on what's best for my family. | | | | | X | <u>X</u> | | Delete |
| 43. Being there for other cancer survivors is an important part of being a cancer survivor. | Most: 1 | | | | | | Redundant with #44 | Delete |

Table 10 (continued)

| | | | | | | | | |
|--|---------------------------------------|--|---|---|---|----------|--|--------|
| 44. When I hear someone has cancer, I try to reach out to them. | | | | | | | | Keep |
| 45. It helps me to know that other cancer survivors have gone through what I am going through. | Most: 1 | | X | | | | | Keep |
| 46. My friends and family motivate me to get better. | Most: 1 (cancer survivor) | | | X | X | X | Kept in initially due to Content Expert approval | Delete |
| 47. I can balance my needs with the needs of others who depend on me. | | | X | | X | X | | Delete |
| 48. I am comfortable telling my friends and family what I need. | Most: 1 | | | X | X | X | | Delete |
| 49. I protect my family and friends from my health problems. | Least: 1 | | | | X | <u>X</u> | Cross-loaded onto Factor 3 | Delete |
| 50. Sometimes I have to put myself first. | | | | | X | X | | Delete |
| 51. I feel connected to other cancer survivors. | | | | | | | Poor conceptual clarity with factor | Delete |
| 52. I support other cancer survivors. | | | | | | | Poor conceptual clarity with factor | Delete |
| 53. Telling other people my story makes me feel good. | | | | | | | | Keep |
| 54. I prefer to deal with my cancer on my own. | Most: 1 Least: 1 (cancer survivor) | | X | | | | Cross-loading | Delete |

Table 10 (continued)

| | | | | | | | | |
|---|----------|--|--|--|--|--|-------------------------------------|--------|
| 55. I want to give back by helping other cancer survivors. | Least: 1 | | | | | | Poor conceptual clarity with factor | Delete |
| 56. I try to raise awareness about cancer. | | | | | | | Cross-loaded onto Factor 3 | Keep |
| 57. I am comfortable sharing my cancer experience with others. | Least: 1 | | | | | | | Keep |
| <p>*Many items during content expert review were worded differently from the items in the 57-item scale included in the Reliability and Validity testing.</p> <p>**This category was only considered in the last rounds of item deletion if there was acceptable item performance on all previous measures.</p> <p><u>Underlined</u> X's indicate that poor communalities and/or factor loadings occurred after the first set of items was deleted.</p> | | | | | | | | |

Several items loaded or cross-loaded on unexpected factors. Two items (Item 19: “I ask questions when I don't understand what my provider is telling me.”; Item 26: “I question my provider if I don’t agree with his or her recommendations.”; and Item 30: “I ask my provider to explain his or her recommendations.”) were originally included in the “Leading my Health Care” dimension but cross-loaded slightly more strongly on the “Application of Information” dimension. This was assumed to be because all three questions included aspects of communication (e.g. “I ask...” and “I question...”) and decision-making (e.g. seeking clarification and explanations). Due to the original intent for the items to be in the “Leading my Health Care” dimension, lack of impact on factor correlations, and difference of < 0.25 factor loading between dimensions, the decision was made to keep Items 19 and 30 on the “Leading my Health Care” factor which would later be named “Communicating with My Health Care Providers.”

One item, (Item 32: “I am comfortable asking for a second opinion.”) clearly and solely loaded onto the “Application of Information” factor rather than the “Leading my Health Care” dimension for which it was originally intended. While the intent of the item was intended to tap into patients who fear speaking up to their provider or being rude at the expense of their pursuing more diagnosis and treatment options, the item also includes aspects of seeking out information and going to a new provider to ask for a recommendation. Due to the clear loading and conceptual congruence with patients seeking out information this item was moved to the factor on which it loaded.

2.6 RENAMING FSACS SCALE DIMENSIONS

In accordance with scale development procedures, the FSACS Scale dimensions were renamed after the final item set was determined. First, the three factors from the factor analysis were selected. For each factor, the items were ranked from highest to lowest factor loadings. Items that cross-loaded onto other factors (e.g. Items 19 and 30) were ranked at the bottom. Items were reviewed by three researchers (T. L. H., S. M. C., and H. S. D.) to identify common attributes or themes between a factor's items. A new dimension name was agreed upon by the three researchers that encompassed all items within the factor.

The original dimension "Application of Information" was updated to "Being an Informed Decision Maker" after reviewing factor loadings. Not only was the word "decision" used in 4 of the 6 items, but the terms "prepare," "weigh my options," "asking," and "use my skills," and "gather information" all demonstrate the work necessary to being informed decision makers and participants in their health care. This factor explained the most amount of variance in participant responses.

The original dimension "Connected Strength" remained the same after reviewing the factor loadings. This factor explained the second most variance in participant responses. Items reflect the ways in which female cancer survivors benefit from giving and receiving support..

The original dimension "Mindful Non-adherence" had been updated to "Leading my Health Care" prior to construct validity testing and was finally updated to "Communicating with My Health Care Providers" after reviewing the factor items. Many items within this dimension had significant problems throughout all stages of psychometric testing. The items that remained strong during most or all of the content validity, reliability, and factor analysis testing centered on the ability of participants to communicate their questions, problems,

misunderstandings, and preferences to their healthcare providers. The verbs “tell,” “ask,” “voicing,” “talk,” and “question” were included in these items. Due to this emphasis on communication, the dimension was named to emphasize the ability or inability of some participants to communicate their needs to their providers. This factor explained the least amount of variance in participant responses.

The final 20-item FSACS Scale is reported in [Appendix B](#).

2.7 ADDITIONAL FSACS SCALE DETAILS

After the final FSACS Scale item set was determined, reliability statistics were reanalyzed for the total scale and three dimensions. Internal consistency was measured using Cronbach alpha as a coefficient of consistency for the 20-item set. The Cronbach’s alpha for the total FSACS Scale was $\alpha = 0.880$ and $\alpha = 0.817, 0.791,$ and 0.850 for the “Being an Informed Decision Maker,” “Connected Strength,” and “Communicating with My Health Care Providers” dimensions, respectively.

Test-retest reliability was also calculated for the final FSACS Scale. Using data from the previous reliability study, test-retest reliability for the final 20-item scale was calculated. The Pearson Product Moment Correlation for the total FSACS Scale was $r = 0.926$ ($p \leq 0.001$) and $r = 0.982, 0.980,$ and 0.888 for the “Being an Informed Decision Maker,” “Connected Strength,” and “Communicating with My Health Care Providers” dimensions, respectively, all at a significance level below $p = 0.01$.

3.0 MANUSCRIPTS

The candidate has 2 published, 1 submitted, and 1 submission-pending manuscripts documenting her research team's linear process of creating, testing, and validating the FSACS Scale.

Manuscript 1: First, the candidate conducted a systematic literature review and concept analysis of self-advocacy to uncover the defining attributes, antecedents, and consequences of self-advocacy and their applicability to cancer survivorship. The focus group manuscript is published in the *Journal of Advanced Nursing* in October 2013.

Manuscript 2: The candidate then led and analyzed focus groups to describe self-advocacy as experienced by female cancer survivors. The focus group manuscript is published in the *Oncology Nursing Forum* in March 2013.

Manuscript 3: Next, the candidate tested the content validity and initial reliability of the FSACS Scale in order to endure the face validity and consistency of item response. The content validity and reliability manuscript has been submitted to the *Journal of Nursing Measurement* in June 2015.

Manuscript 4: Finally, the candidate will submit the construct validity manuscript to *Cancer* in August 2015.

3.1 CONCEPT ANALYSIS

See Attachment 1.

3.2 FOCUS GROUP TESTING

See Attachment 2.

3.3 CONTENT VALIDITY AND RELIABILITY TESTING MANUSCRIPT

Theoretical to Tangible: Creating a Measure of Self-Advocacy

3.3.1 Abstract

Background & Purpose: Abstract concepts are difficult to measure. This article reports the process of creating a measurement of self-advocacy among female cancer survivors.

Methods: The development of the Female Self-Advocacy in Cancer Survivorship (FSACS) Scale's theoretical underpinnings and item development led to evaluations of the measure's content validity and reliability.

Results: The construct of self-advocacy contains 3 sub-dimensions with a total of 57 Likert-type self-report items. Content validity results ($S-CVI = 0.81$ and $S-CVI/UA = 0.83$) indicated strong relevancy of items. Reliability results supported the consistency of the FSACS Scale scores, with strong internal consistency (Cronbach's $\alpha = 0.92$) and test-retest reliability (PPMC $r = 0.94$).

Conclusions: Translating constructs like self-advocacy into quantifiable measures takes substantial effort, but is crucial to developing psychometrically strong, relevant measurements.

3.3.2 Background & Conceptual Framework

Self-advocacy has been identified as a critical component of improving health outcomes because it underlies individuals' ability to understand and lead their own care (Clark & Stovall, 1996; Ferrell, McCabe, & Levit, 2013; Walsh-Burke & Marcusen, 1999). A patient's ability to advocate for her health, social, and personal needs not only has the potential to make her a proactive and engaged health care consumer, but also affords her the ability to ensure her health

and care promote her self-worth and identity. Yet a dearth of research leaves researchers and clinicians unable to measure survivors' ability to self-advocate and therefore provide evidence-based interventions (Hermansen-Kobulnicky, 2008). Moreover, differences between and within genders are known to exist in how cancer survivors self-advocate (Sinding *et al.*, 2010; Wiltshire *et al.*, 2006). In order for self-advocacy to be an accurate, effective variable for use in research and practice, a new measurement tool must be created specific to the phenomena of self-advocacy in this population.

The purpose of this study is to report the content validity and reliability of a measurement of self-advocacy among female cancer survivors, the Female Self-Advocacy in Cancer Survivorship (FSACS) Scale. We aim to 1) report the conceptual and empirical steps included in our process and 2) evaluate the initial content validity and reliability of the FSACS Scale. Conceptual challenges and key decisions will be discussed along with their implications for clinical and research use of the final instruments. The process of compiling quantitative (deductive) and qualitative (inductive) sources of information to form the domains of a construct, developing items within each domain, and then testing the content validity and reliability of the instrument will be described.

3.3.3 Procedures for Instrument Development

Concepts and constructs are the basic building blocks of scientific theory and represent our verbal representations of “real world” phenomena (Watt & van den Berg, 1995). Some of these phenomena are directly observable; others are more abstract. Regardless of the level of abstraction, concepts and constructs must be unambiguously defined in order to operationalize the construct into reliable and valid instruments. As Shadish, Cook, & Campbell (2002) caution,

“To the extent that experiments contain construct errors, they risk misleading both theory and practice.” Ensuring that measures of these subjective phenomena accurately and meaningfully detect the presence of these concepts allows inferences to be made regarding the presence of the construct based on the measurement.

The process of creating valid and reliable measures of abstract constructs such as behaviors, attitudes, personal characteristics, and quality of life is a complex, time-consuming, but essential task in behavioral research. Few articles provide practical advice and methodological directions about how to operationalize abstract behavioral concepts into psychometrically sound, parsimonious instruments. Similarly, most manuals and textbooks provide broad guidelines without describing the contextual nuances of item and scale development. This article, which describes the progression from concept to tool can provide an exemplar for researchers endeavoring to develop measures that accurately operationalize abstract constructs.

Establishing the initial FSACS Scale was performed in multiple steps using established methods for psychometric and instrument development (American Educational Research Association, 1999; Food and Drug Administration, 2009): 1) *Developing the initial instrument*: Quantitative and qualitative findings from the literature and qualitative data from focus groups was analyzed and synthesized into a construct definition, three dimensions, and 57 items. 2) *Content validity testing*: The initial instrument was tested for face value approval among a group of professional and lay experts in self-advocacy to evaluate relevancy and clarity. 3) *Reliability testing*: A revised instrument was tested among a pilot sample of 40 adult female cancer survivors for consistency in item responses over a two week time period.

3.3.3.1 Intent The first step in instrument development is defining the intent of the instrument.

We wanted to measure adult female cancer survivor's abilities to advocate for their health, well-being, and self-worth during their cancer journey. Self-advocacy was assumed to be a state, or transient characteristic, rather than a trait, or enduring, characteristic.

3.3.3.2 Construct Definition Constructs link theories to experiments, and therefore how we define constructs is crucial to ensuring that inferences from measurement to theory can be made within and across concepts, theories, and uses (Shadish, Cook & Campbell, 2002). During a two-year period, we collected and analyzed multiple sources of evidence and reduced all of our data into clearly defined, essential attributes of self-advocacy. The goal was to operationalize the concept of self-advocacy using its distinguishing features as revealed by previous research and patient experience. This iterative process included several revisions before deciding on a set of items. Conceptual domains were created using both deductive and inductive methods.

Deductive methods included a concept analysis and literature review of self-advocacy within cancer survivorship (Hagan & Donovan, 2013a). An in-depth review of the literature and patient experiences were absolutely critical to uncovering the full range and breadth of the phenomena. Research was included from oncology, HIV/AIDS, mental health, disability, empowerment, engagement, and female health psychology fields. After reviewing this broad literature, theoretical clarity came through conceptually differentiating the predictors, outcomes, and defining characteristics of self-advocacy within oncology according to Walker and Avant's methodology (2005).

During the literature review, an existing measure of self-advocacy, the Patient Self-Advocacy Scale (PSAS; Brashers, Haas, & Neidig, 1999), was identified. While both the PSAS and the FSACS attempt to capture the construct of "self-advocacy," the populations of interest

are categorically distinct. The PSAS was developed among individuals with HIV and a primarily male population. Because of the significant disease and gender differences and existing evidence for inadequacy of the PSAS when tested among cancer survivors (Hermansen-Kobulnicky, 2008), we chose not to adapt the previous measure but to create a new measure with consideration for the behavioral aspects that may overlap between patient and gender populations.

Inductive methods included a focus group of cancer survivors ($n = 14$) in order to elicit patient perspectives on and experiences of self- advocacy (Hagan & Donovan, 2013b). The results corroborated several of the findings from the concept analysis, but also revealed new attitudes about self-advocacy particular to the female cancer population that had not yet been discussed in the literature.

3.3.3.3 Construct The construct of self-advocacy was ultimately defined as how patients stand up for themselves during their cancer experience. When faced with any of the myriad challenges that cancer diagnosis, treatment, and survivorship presents, how is a woman able to get her needs, priorities, and preferences met? Beyond just being proactive and engaged, self-advocacy defines the ability to face problems that come as a result of the cancer. Many of these problems may concern treatment and working with the medical team, but other problems may concern accessing and utilizing information or maintaining relationships with family members, friends, and other cancer survivors.

While historically advocacy has been used as a means of addressing social inequalities and power hegemony within the medical institution (Brashers, Haas, Neidig, & Rintamaki, 2002), the construct of self-advocacy does not promote adversarial relationships between patients and their health care providers or institutions. Rather, the degree to which a patient is able to

self-advocate is the degree to which she can productively participate as an equal member of her health care team and social support network even in the face of difficult situations.

3.3.3.4 Challenges Conceptual challenges arose while developing the definition of self-advocacy. This has consequences not only for the measurement tool but also in how the tool 1) will be applied to and translated into intervention research and 2) can support broader theory development. As discovered while conducting the concept analysis (deductive method), theories of self-advocacy within cancer are largely immature and non-parsimonious, creating confusion regarding the defining features of self-advocacy and differentiation with its antecedents or consequences. Definitions encompassed both attitudinal and behavioral components; inter- and intrapersonal applications; and situational and policy spheres of action. Different disciplines made different assumptions about the intent of advocacy varying from collective groups changing national or state policies to groups of individual survivors for improving their personal health, well-being, and autonomy. Ultimately, we decided to define self-advocacy in terms most relevant to cancer survivors which had scientific evidence in the literature and would ensure that the application of the tool would be meaningful given the needs of this population.

Difficulties also occurred during the inductive derivation of item content. The focus groups uncovered the real-life behaviors and attitudes of how women define “self-advocacy” in their contextually situated cancer experiences. The initial analysis of the results provided rich descriptive data identifying a multitude of themes and subthemes. However, consistent with traditional focus group analysis, analyses focused on reaching theoretical saturation and not generalizability to other populations. In order for instrument development to encompass the full breadth of the participants’ conversations, a fresh reading of the focus group transcripts was

required to assure all possible behavioral indicators of self-advocacy would be captured in the measurement's items and dimensions.

Combining the results from the use of the deductive and inductive methods was a third challenge, and the most conceptually demanding. Our aim was to have subscales that were similar enough to have a shared relationship with the overall construct yet different enough to provide unique information about the full conceptual breadth of self-advocacy. After consulting with instrumentation experts, it was decided to focus on three dimensions of self-advocacy supported by both deductive and inductive methods which together would be able to define self-advocacy, discriminate between women who do and do not self-advocate, and potentially be the most modifiable characteristics. This meant that some findings from the concept analysis and focus group study were not directly included in the scale's dimensions. These findings were considered outside the scope of the measurement model and scale building because they did not focus on actions but remain significant aspects of self-advocacy to be integrated into future research. Figure 2 illustrates the synthesis and refinement of the focus group and concept analysis results into the dimensions of the FSACS Scale.

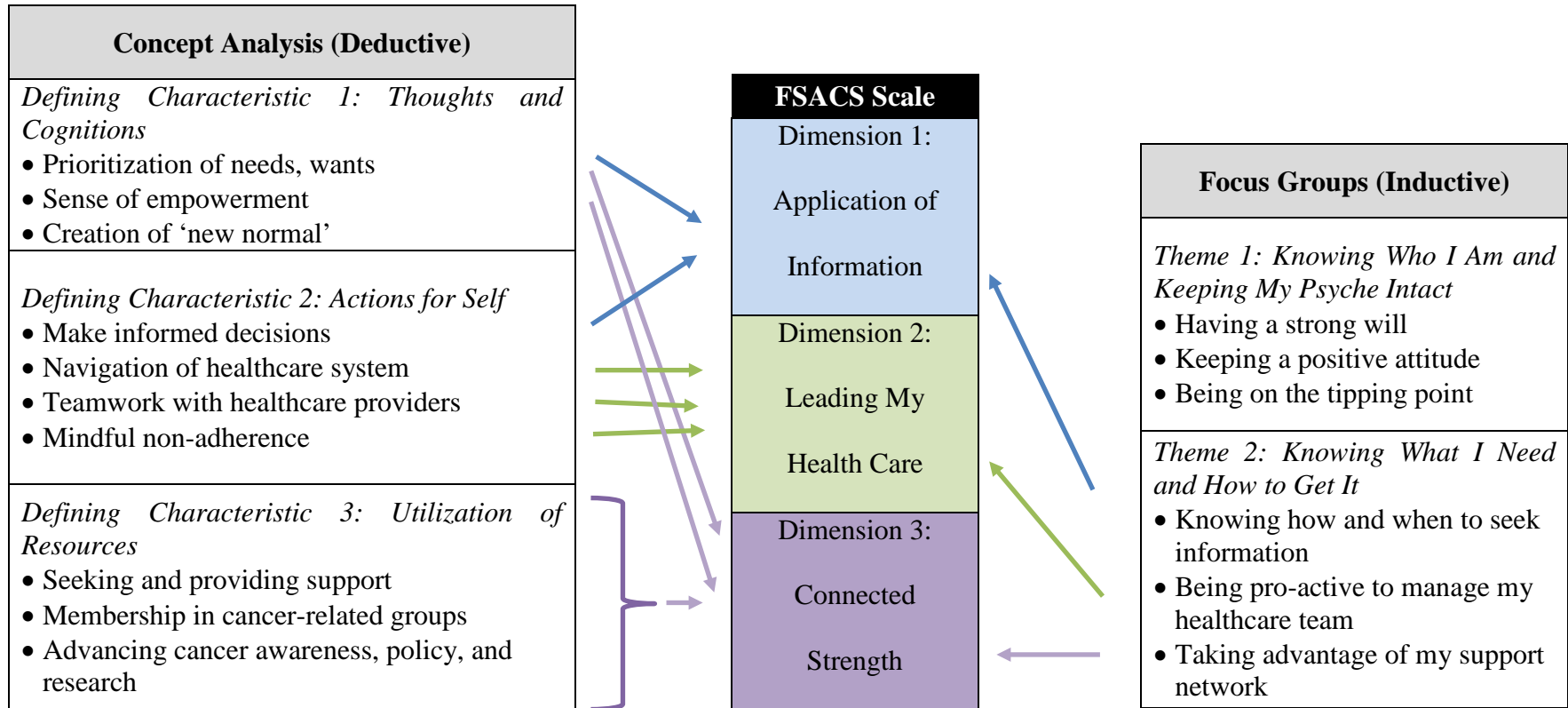


Figure 2. Derivation of Female Self-Advocacy in Cancer Survivorship Scale's Dimensions Based on Deductive and Inductive Pilot Work

3.3.4 Description, Administration, and Scoring of the Instrument

3.3.4.1 Operationalization and Item Development After each of the three dimensions was defined, self-report items were created according to the domain sampling model (DeVellis, 2012). An exhaustive list of items from a hypothetical universe of items relating to the defining characteristics of self-advocacy among female cancer survivors resulting in 20-30 items for each dimension with a total of 71 items. This was considered enough to provide sufficient breadth of items per domain. Redundancy was encouraged at this stage with the goal of capturing the full breadth of the construct.

Response options included a 6-point Likert-type (1 = strongly disagree and 6 = strongly agree) response scale to avoid over-selection of a neutral response option that is often observed in response bipolar scales with a midpoint. Positive and negative stems were included. Varying levels of intensity or difficulty were included to ensure response variance and scale sensitivity to differences in self-advocacy.

Central to our consideration of writing items was ensuring that the items were specific and concrete enough to inform future research to support women who struggle to self-advocate. By selecting reflective indicators of the construct as opposed to unobservable precursors that give rise to self-advocacy, items are more likely to be modifiable and translated into intervention. Items asking for respondents to indicate their beliefs or react to hypothetical situations were therefore avoided and preference given to actions and behaviors.

3.3.4.2 Administration & Scoring The FSACS Scale is intended to be a self-administered measurement tool to be used in both research and practice settings as a means of identifying

female cancer survivors who struggle to advocate for themselves. A total score will be used to measure a woman’s overall ability to self-advocate, while sub-dimension scale scores will provide more specific information about areas in which they may struggle.

3.3.5 Content Validity Testing & Results Content validity is “the degree to which elements of an assessment instrument are relevant to and representative of the targeted construct for a particular assessment purpose” (Haynes, Richard, & Kubany, 1995). Testing content validity assesses the degree to which the content of the instrument reflects the construct of self-advocacy among female cancer survivors. Employing both population and content experts was critical to establishing a valid measure (Vogt, King, & King, 2004). The expert panel, described in Table 10, included 9 representatives (N = 9): 3 females with cancer, 1 nurse practitioner, 1 physician, 2 researchers, 1 social worker, and 1 patient advocate. One of the survivors was an African American female. All professionals on the panel specialized in working with female cancer survivors. Qualifications of experts were evaluated by their professional and personal experience with female cancer survivors and identification by peers as promoting patient self-advocacy (Grant & Davis, 1997).

Table 10. Expert Panelists for Content Validity

| Member | Number | Gender | Years in Role | Cancer Survivor |
|--------------------|--------|--------|------------------|-----------------------------|
| Cancer Survivors | 3 | Female | 9, 10, & 18 | Breast, Ovarian, & Brain |
| Nurse Practitioner | 1 | Female | 18 | No |

Table 10 (continued)

| | | | | |
|------------------|---|--------|-------------|----------|
| Physician | 1 | Male | 30 | No |
| Researcher | 2 | Female | 14, 25, &35 | No |
| Social Worker | 1 | Female | 30 | No |
| Patient Advocate | 1 | Male | 10 | Melanoma |

We personally contacted each panel member to explain the instrument development process, the definition of self-advocacy, and the value of their experiential expertise in self-advocacy to critiquing our instrument. All contacted experts agreed to participate. Each expert panel member was sent the initial FSACS Scale, a written introduction to the concept of self-advocacy, a content validity questionnaire, and a copy of the preliminary FSACS Scale. The experts reviewed each item and the scale as a whole. Each item was rated separately for relevancy and clarity using 4-point Likert-type scales ranging from 1 (not relevant/clear) to 4 (very relevant/clear) and space was given for comments. We also asked questions regarding the overall scale, suggestions for additions and revisions to the measure, and any other comments. Completed packets were returned and analyzed.

Lynn's (1986) methodology was used to calculate the Content Validity Index (CVI) for each scale item and the entire scale. Based on Lynn's criteria, a CVI of 0.78 (or 7 of the 9 panelists) indicates adequate endorsement of an item or the instrument beyond the $\alpha = 0.05$ level of significance.

In total, 14 items were deleted due to low CVI, redundancy of items, or for being outcomes rather than behaviors of self-advocacy. Thirteen items were reworded, mainly to soften any confrontational language, improve specificity, and include action-orientation. Based on

panelist feedback, 22 items had ≥ 3 panelists rating its relevancy as a 1 or 2. Five of the twelve items from the previous self-advocacy measure received low-rankings from the panelists. Of note, 3 items were preserved despite low ratings because of discrepancies between researchers' and survivors' ratings with preference given to survivors' ratings. For example, the item "I don't know enough to make decisions about my cancer and treatment" (reverse scored) was endorsed by survivors but not researchers.

Content validity statistics of the 57-item scale are reported in Table 11. The Average Scale-CVI (S-CVI/Ave) was calculated by averaging the proportion of experts rating each individual item as relevant (rating of 3 or 4). In other words, the S-CVI/Ave is equal to the average of each of the individual item CVIs (I-CVI). The Scale-CVI/Universal Agreement (S-CVI/UA) was calculated as the proportion of items rated as relevant (rating of 3 or 4) by all 8 experts (Polit & Beck, 2006). Both the S-CVI/Ave (0.81) and S-CVI/UA (0.83) were above the recommended cut-off level of 0.78.

Table 11. Content Validity Statistics

| Type of CVI | Statistic | Calculation |
|--|-----------|--|
| Average Scale-CVI (S-CVI/Ave) | 0.81 | Average proportion experts rating each item as relevant (rating of 3 or 4) |
| Scale-CVI Universal Agreement (S-CVI/UA) | 0.83 | Proportion of total items judged by all experts as relevant (rating of 3 or 4) |

3.3.6 Reliability Testing & Results

Reliability testing was performed in order to 1) evaluate internal consistency (the degree of consistency among items in the instrument) and test-retest reliability (the stability of the observed scores over time) of the FSACS Scale; 2) evaluate the feasibility of assessing self-

advocacy and related measures necessary for instrument validation; and 3) produce a parsimonious scale to be validated in a large sample study. Note that prior to reliability testing, pilot testing of the final 57 items was conducted with a group of masters-prepared nurses, research staff, and staff at the University of Pittsburgh School of Nursing as final check for readability, grammar, spelling, and formatting.

Evaluation was completed with a sample of female adult cancer survivors. To estimate test-retest reliability, a repeated measure design with baseline and 2-week measures was used. Time points were chosen to test the scale's consistency within a time period in which little variation is expected (DeVillis, 2012).

Recruitment of $N = 40$ participants was conducted at four cancer and advocacy organizations and three cancer clinics in Pittsburgh, PA. Inclusion criteria included: 1) female, 2) ≥ 18 years old, 3) history of a cancer diagnosis at ≥ 18 years old, and 4) a cancer diagnosis other than basal cell carcinoma or cervical intraepithelial neoplasia stage 1 (these survivors have inherently different treatment and symptom experiences than other cancer survivors). Equal numbers of participants were recruited through clinics and organizations. Directors at clinics and organizations identified potential participants and introduced the study to them. Potential subjects who expressed interest in participating were introduced to the researcher (T. H.) who then carried out screening and informed consent procedures.

On Day 1, the researcher screened potential subjects for eligibility. If the potential participant met the inclusion criteria and was interested in participating in the study, written consent was obtained. Participants completed all baseline study measures in a private room at the clinic or office. Individual measures were randomly ordered to avoid an order effect. The researcher (T. H.) handed all measures to the participant, instructed the participant to complete

the survey independently, asking the candidate for clarifications or assistance as needed.

Following completion of the FSACS Scale, the researcher conducted cognitive interviews with the participant to review any problems or issues with the items or survey and to assess the feasibility of completing the survey.

After all surveys were complete, the researcher provided the participant with an envelope containing the follow-up survey, instructions to complete the survey in 2 weeks (14 days), and a pre-addressed, pre-stamped envelope to mail the survey to the candidate. The researcher called each participant 2 days before the follow-up survey was to be completed and sent reminder postcards 3 and 5 days after the due date if the survey was not received. Participants were sent thank you cards with a \$20 pre-paid debit card after receipt of the follow-up survey.

Sample characteristics and health histories for the reliability study are described in Table 12 and Figure 3. The sample had a mean age of 57.28 years ($SD = 13.16$, Observed Range = 25-89) and 53.8% were married. Women represented a diverse population with 12.8% of participants identifying as Black or African American and one identifying as Hispanic. Twenty-one percent of women had a high school degree or less, and only 35.9% were working full-time. About 20% ($n = 8$) of women had a household gross annual income less than \$30,000. Most women ($n = 17$, 42.5%) had a diagnosis of ovarian cancer, followed by breast cancer ($n = 15$, 37.5%). Almost half of the women were within one year of their cancer diagnosis ($n = 19$, 47.5%). The remaining women were either between 1 and 5 years since diagnosis ($n = 11$, 27.5%) or greater than 5 years since diagnosis ($n = 10$, 25%). Most women ($n = 26$, 65%) were receiving treatment at the time of survey completion. Seven (12.5%) women had experienced at least one recurrence.

Table 12. Demographic and Health Information for Reliability Study Sample

| | n | % | M | SD |
|--|----|------|------|------|
| <i>Demographic Information</i> | | | | |
| Age | | | 57.5 | 13.1 |
| Years of education | | | 14.6 | 4.2 |
| Race and Ethnicity | | | | |
| White | 32 | 84.2 | | |
| African American/Black | 5 | 13.2 | | |
| Other | 1 | 2.6 | | |
| Latina | 1 | 2.6 | | |
| Employment status | | | | |
| Working \geq 35 hours/week | 14 | 35.9 | | |
| Retired | 10 | 25.6 | | |
| Working < 35 hours/week | 9 | 23.1 | | |
| Disabled | 4 | 10.3 | | |
| Laid off/unemployed | 1 | 2.6 | | |
| Relationship status | | | | |
| Currently married | 21 | 53.8 | | |
| Divorced/separated | 7 | 18.0 | | |
| Never married | 4 | 10.3 | | |
| Widowed | 4 | 10.3 | | |
| Living with partner | 3 | 7.7 | | |
| Household annual income | | | | |
| < \$30,000 | 7 | 20.6 | | |
| \$30,000 - \$59,999 | 8 | 23.5 | | |
| \$60,000 - \$99,999 | 9 | 26.5 | | |
| \geq \$100,000 | 9 | 26.5 | | |
| <i>Cancer History</i> | | | | |
| Time since diagnosis | | | | |
| <1 year | 19 | 47.5 | | |
| 1 -5 years | 11 | 27.5 | | |
| > 5 years | 10 | 25.0 | | |
| Cancer recurrence (M and SD if any recurrence) | 7 | 17.5 | 3.4 | 4.4 |
| Multiple cancer diagnoses | 5 | 12.5 | | |
| Currently on treatment | 26 | 65.0 | | |

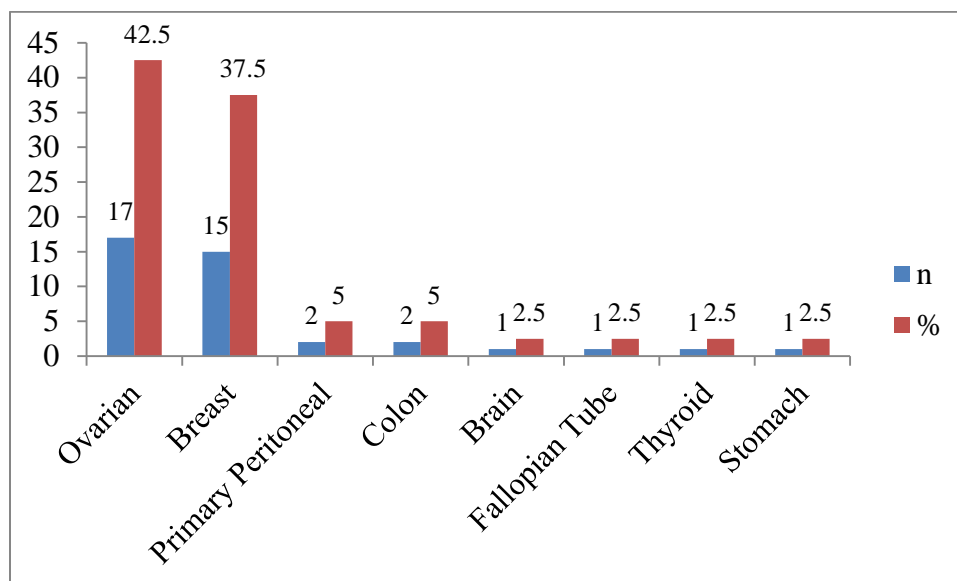


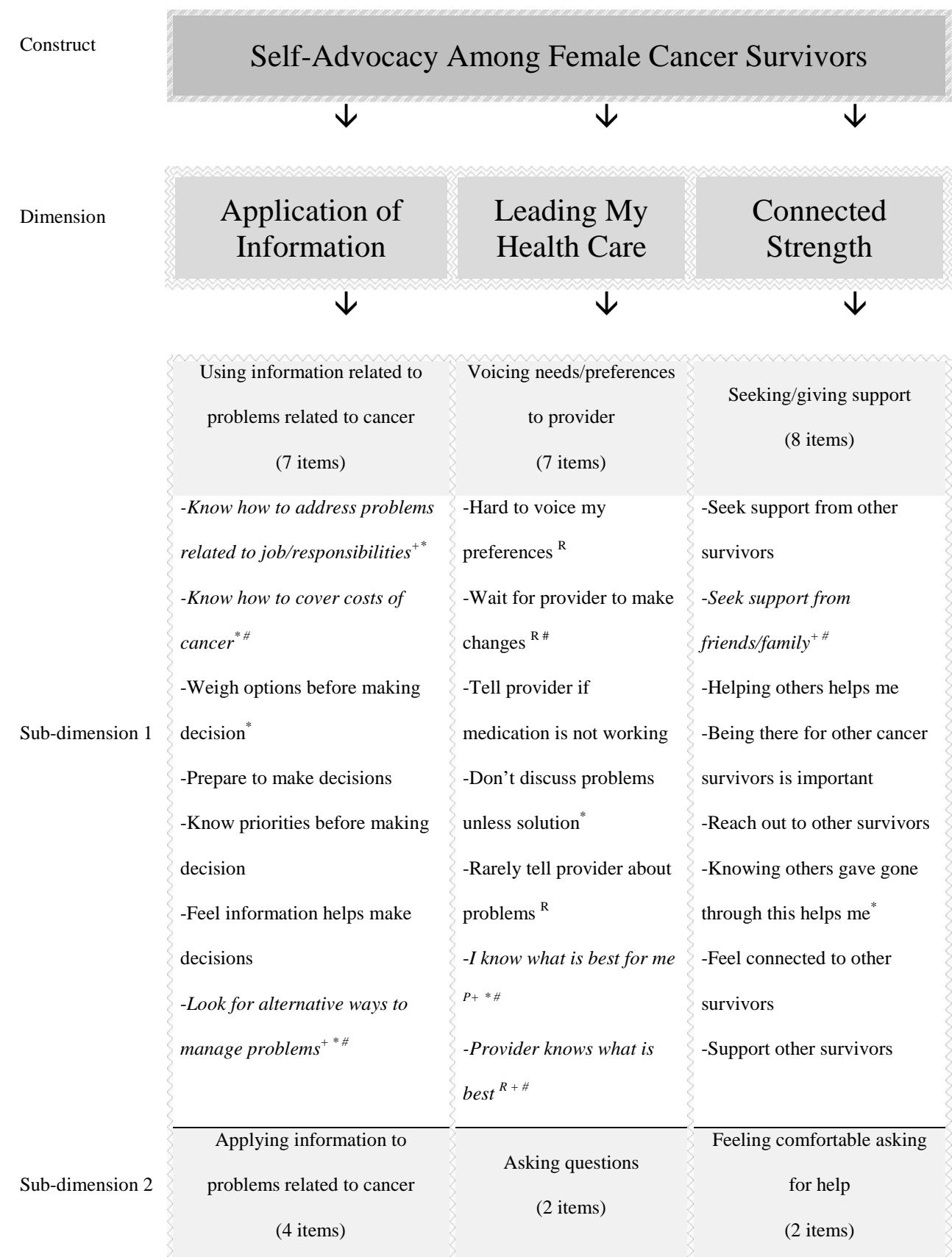
Figure 3. Cancer Diagnoses of Reliability Study Sample

Two measures of reliability were estimated: 1) internal consistency as measured by Cronbach's alphas based on $N = 40$ and 2) test-retest reliability or item response stability as measured by Pearson's Product Moment Correlations based on $n = 39$. Participant feedback was reviewed using content analysis to identify recurring themes. Internal consistency for the FSACS was strong ($\alpha = 0.92$). The three dimensions had Cronbach's alpha's of 0.88, 0.81, and 0.90, respectively.

Preliminary evaluation of test-retest reliability indicates that the scale is highly stable across time points (Pearson Product Moment Correlation of $r = 0.94$). The three dimensions also showed strong test-retest reliability (Application of Information: $r = 0.85$; Leading My Health Care: $r = 0.97$; Connected Strength: $r = 0.88$). Feasibility and acceptability of completing the FSACS Scale was reported to be high by participants though several participants noted that the number of items in the FSACS Scale would need to be greatly reduced to reduce response burden.

Cognitive interviews identified participant concerns about specific questionnaire items. The most common concerns reported by participants included difficulty responding to items that implied that they have control over their cancer, have an adversarial relationship with their provider, or suggested a need to actively reach out to other survivors or tell their story to others. Future iterations of the survey instructions and final item selection will consider these patient concerns.

Figure 4 illustrates the FSACS Scale used during reliability testing. Indications are made to highlight items that performed poorly during content validity testing, reliability testing, and cognitive interviewing. Items listed in this figure do not represent the final FSACS Scale; construct validity testing will further test this measurement model and result in a parsimonious scale with a significantly reduced number of items. Figure 4 is meant to be a useful template for instrument developers who are looking to take a construct and clarify its dimensions, sub-dimensions (if any), and items while ensuring consistency between these varying levels of abstraction.



| | | | |
|-----------------|--|--|--|
| | <ul style="list-style-type: none"> -Try new ways to improve life -Don't know enough to make decisions^{R*#} -Use skills to solve problems⁺ -Gather information prior to making decisions | <ul style="list-style-type: none"> -Ask questions if I don't understand^{P#} -Ask provider to clarify recommendations^P | <ul style="list-style-type: none"> -Comfortable telling friends/family what I need[#] -Don't like asking for help^R |
| | <p>Finding trustworthy, relevant information</p> <p>(5 items)</p> | <p>Seeking additional support beyond that of provider</p> <p>(5 items)</p> | <p>Balancing needs of self with needs of others</p> <p>(6 items)</p> |
| | <ul style="list-style-type: none"> -Seek out information^P -Make sure information is trustworthy -Distinguish if information is applicable or not -Feel control from information -Ignore questionable information | <ul style="list-style-type: none"> -Know other places to get answers to my questions[*] -Don't know where to go if provider can't help me^R -Feel comfortable asking for second opinion -Worry that second opinion would hurt relationship -Seek help for other needs⁺ # | <ul style="list-style-type: none"> -Make decisions based on family -Friends and family motivate me[#] -Balance my needs with others' needs[*] -Able to put self first -Prefer to deal with cancer by myself[*] -Protect friends/family from health problems^R |
| Sub-dimension 4 | | <p>Adjusting providers recommendations</p> <p>(3 items)</p> | <p>Raising awareness and support for cancer causes</p> <p>(4 items)</p> |
| | | <ul style="list-style-type: none"> -Adjust recommendations to fit my life^{P+*} -Decide not to follow recommendations^{P*#} -Have reason for not | <ul style="list-style-type: none"> -Feel good telling my story -Want to give back to survivors -Try to raise awareness -Feel comfortable sharing my |

| | | | |
|-----------------|--|---|------------|
| Sub-dimension 5 | | <i>following</i> | experience |
| | | <i>recommendations</i> ^{* #} | |
| | | Feeling comfortable | |
| | | disagreeing with provider | |
| | | (4 items) | |
| | | -Feel I can disagree with provider [#] | |
| | | -Don't want to be seen as difficult ^{R#} | |
| | | -Question provider if I disagree with him or her ^P | |
| | | <i>-Bothered by not following provider^{+ * #}</i> | |

P = In previous measure of self-advocacy for HIV/AIDS population

R = Reverse-scored item

+ = Cognitive Interviews: Negative verbal feedback from at least 3 participants

* = CVI score: Low score measured by at least 3 content experts rating item a 1 or 2 for relevancy or clarity

= Reliability: Low internal consistency measure by item-total correlations <0.30

Italicized = Considered for deletion in future testing based on ≥ 1 negative reliability and content validity testing

(+, *, or #)

Figure 4. Initial Female Self-Advocacy in Cancer Survivorship Measurement Model with Results of Content Validity, Reliability, and Cognitive Interview Testing

3.3.7 Discussion

Self-advocacy is a process that precedes and promotes many positive healthcare behaviors and attitudes. Only by measuring self-advocacy through scientifically-discovered indicators of the construct can we as researchers and practitioners aim to improve it. The FSACS Scale, which operationalizes the latent variable of self-advocacy, should provide the means by which to

measure self-advocacy. In this study, we moved the construct of “self-advocacy” from a well-appreciated but under-defined part of the cancer lexicon into a concrete, measurable construct. Using both deductive and inductive reasoning in a conjoint, purposeful manner we formed and tested the FSACS Scale for content validity and reliability. By rigorously developing and testing the initial content validity and reliability of the measure, users can have increased confidence in the ability to make inferences about patients’ abilities to self-advocate based on their FSACS Scale scores.

A S-CVI of 0.81 and S-CVI/UA of 0.83 and strong reliability results provide promising evidence that the content is 1) representative of the targeted construct, 2) item responses are stable over time, and 3) items have a high degree of consistency with each other. Cronbach’s alpha is a function of scale length and may be overinflated, so internal consistency will be retested in future construct validity testing with the final set of scale items.

While the methodology of clarifying the dimensions of self-advocacy was time-consuming and required reading multiple sources of literature to understand the historical uses and intentions of self-advocacy, we believe this detailed attention resulted in a clear tool capable of being retested and reapplied in future patient populations. By paying attention to previous research, patient experiences, expert opinion, and thorough analysis of the initial tool, future applications of the tool should be easier to understand and interpret because it reflects the best understanding of the phenomena of self-advocacy among female cancer survivors.

The version of the FSACS Scale discussed in this analysis is not the final scale. Currently, in-depth construct validity testing of the FSACS Scale is underway in a large-sample study. Hypotheses will be tested related to the extent to which the factor structure of the scale is congruent with the conceptual dimensions of self-advocacy and how the FSACS Scale scores

should compare to scores on other measures including, 1) predictors and outcomes of self-advocacy and 2) constructs that are similar but distinct from self-advocacy (e.g. PSAS, patient activation). Our goal is to validate a parsimonious measure of self-advocacy that is specific to self-advocacy in female cancer survivors, sensitive to changes in self-advocacy over time, and specific enough to distinguish between women who struggle to self-advocate and those who do not.

Finally, this study has limitations. Survey research inherently includes errors of observation and non-observation that impact the precision of a measure. Participant responses may not be accurate (observational error), the sample may not represent the population to which the instrument is to be made generalizable (coverage error), and people who are approached do not always complete the study (response error). Self-reported administration methods introduce respondent recall, bias error, and social desirability error which can impact external validity of score interpretations. Concerns of observation and bias were addressed by instructing participants that little is known about the benefits or harms of self-advocacy, including a large number of items, and targeting behaviors varying in level of difficulty. Despite these limitations, the initial FSACS Scale meets most of Lohr et *al.*'s (1996) attributes for high-quality, health outcome measurement tools.

3.4 CONSTRUCT VALIDITY TESTING MANUSCRIPT

3.4.1 Abstract

Background: The Female Self-Advocacy in Cancer Survivorship (FSACS) Scale is a new measurement tool designed to address the increasing need for cancer survivors to participate in and lead their care in face of barriers. Pilot work has demonstrated the FSACS Scale's content validity and reliability.

Purpose: The purpose of this study was to evaluate the construct validity of the FSACS Scale. This instrumentation study evaluates the construct validity of the FSACS Scale as evidenced by: (I) Internal structure consistent with the underlying model of self-advocacy; (II) Sensitivity to differences between known groups; (III) Relationships between self-advocacy and key predictors (openness and conscientiousness; information engagement; social support) and outcomes (symptom distress and healthcare utilization); (IV) Relationships between FSACS subscales and related concepts (patient activation; self-advocacy within the HIV/AIDS population); and (V) Relationships between FSACS scores and criterion measures.

Methods: A mixed-mode (online or mailed) cross-sectional survey design was used. Women with a history of an adult diagnosis of invasive cancer were recruited from two patient registries and seven advocacy organizations. Instrument selection and analyses to evaluate construct validity were based on the American Educational Research Association's instrumentation guidelines. Analyses included an exploratory factor analysis, t-tests, and bivariate correlations.

Results: A total of $N = 315$ adult female cancer survivors completed the survey. Evidence from all five construct validity hypotheses supports the construct validity of the FSACS Scale. The FSACS Scale factor analysis confirmed the three underlying dimensions of

self-advocacy resulting in a 20-item measure explaining 45.87% of the variance in responses with subscales' Cronbach's alphas between 0.791 and 0.850. While able to detect differences between women with low and high levels of education, the scale did not differentiate between recent and long-term survivors. Predictor and outcome variables performed as expected. The FSACS subscales were more highly correlated with these outcomes than the measure of self-advocacy for HIV/AIDS.

Conclusion: Results support that the FSACS Scale is a theoretically-grounded measure of self-advocacy that can be used by clinicians and researchers to identify women at-risk for the poor outcomes associated with low self-advocacy.

3.4.2 Introduction

Individuals with cancer benefit from being engaged, active members in their care. A united group of patients, providers, advocacy organizations, and government agencies (American Society of Clinical Oncology, 2012; Clark & Stovall, 1995; Institute of Medicine, 2001; Shapiro *et al.*, 2009) extols the benefit of cancer patients advocating for their needs, preferences, and desires. Self-advocacy is a concept similar to concepts of self-management and engagement, but distinct in its focus on situations in which a challenge or problem occurs. Despite this call for increased patient involvement, little research has guided providers, patients, or researchers on how to support patient self-advocacy.

Existing theories and measurements of self-advocacy have been shown to inadequately represent the unique needs of individuals with cancer, especially those of women who face different problems of communication, symptom management, and quality of life compared to male cancer survivors (Anderson *et al.*, 2004; Cleeland *et al.* 1994; Cimprich *et al.*, 2005;

Elderkin-Thompson & Waitzkin, 1999; Howard, Balneaves, & Bottorff, 2007; Miaskowski, 2003; O'Brien et al., 2008; Paulson, Wirtalla, Armstrong, & Mahmoud, 2009; Seale, Ziebland, & Charteris-Black, 2006). Over 7.6 million U.S. adult women had a history of a cancer diagnosis in 2013 (American Cancer Society, 2014). Women face physical, psychological, social, and financial challenges during their diagnosis, treatment, and survivorship. From the time of diagnosis through to long term survivorship, survivors must overcome barriers and negotiate to ensure they receive quality care that is concordant with their priorities (Sheppard, Adams, Lamdan, & Taylor, 2011). Gender differences in symptom prevalence and severity, patient care delivery, and communication place female cancer survivors at risk for poor health outcomes such as increased symptom distress and healthcare utilization (Bertakis & Azari, 2011; Bertakis & Azari, 2012; Keogh, 2014; Miaskowski, 2003). The degree to which these challenges can be addressed in a way that supports women's needs, preferences, and priorities is a defining feature of providing patient-centered care.

To fill this gap, a multi-phase instrument development process beginning with a literature review (Hagan & Donovan, 2013a), focus groups (Hagan & Donovan, 2013b), content validity (Hagan, Cohen, Stone & Donovan, 2015), and initial reliability (Hagan, Cohen, Stone & Donovan, 2015) studies resulted in a novel measure of self-advocacy for female cancer survivors that established the face validity and consistency of participant responses. The purpose of the current study is to evaluate the construct validity of the Female Self-Advocacy in Cancer Survivorship (FSACS) Scale in order to test the accuracy with which researchers and clinicians can use the FSACS Scale to make inferences about women's abilities to self-advocate.

The FSACS Scale is intended to measure the ability of female cancer survivors to get their needs, priorities, and desires met in the context of their cancer care. The construct consists

of three conceptual dimensions: (a) Application of Information, (b) Leading my Healthcare, and (c) Connected Strength. Application of information captures a woman's ability to find trustworthy information and apply it to herself. Leading my healthcare exemplifies how a woman can build productive, respectful relationships with her health care team. Connected strength refers to a woman's ability to both give and receive support, balance her needs with the needs of others, and gain strength through relationships.

According to the American Educational Research Association (1999), establishing the construct validity of a measure is a process of developing and testing hypotheses about how the interpretation of a measurement's scores should perform if it truly captures the intended construct. For example, by constructing proposed relationships between the interpreted scores of a new measure and scores of validated measures, a researcher can build an argument that the new measure's scores accurately predict the presence of a latent concept.

In order to test the FSACS Scale's conceptual accuracy, the researchers tested a series of hypotheses including self-advocacy's relationship with theoretical predictors, outcomes, related measures, and known differences between survivors. Predictors (personality traits of being open and conscientious, engaging in health information, and having social support) and outcomes (symptom distress and using healthcare resources) were selected based on findings from the concept analysis and focus group studies. Related measures were selected based on their conceptual similarity to self-advocacy and included patient activation and the previous measure of self-advocacy developed within the HIV/AIDS patient population. Evidence for construct validity will be determined by the failure to reject these five hypotheses. Figure 5 illustrates the measurement model relating all measures and hypotheses for construct validity testing.

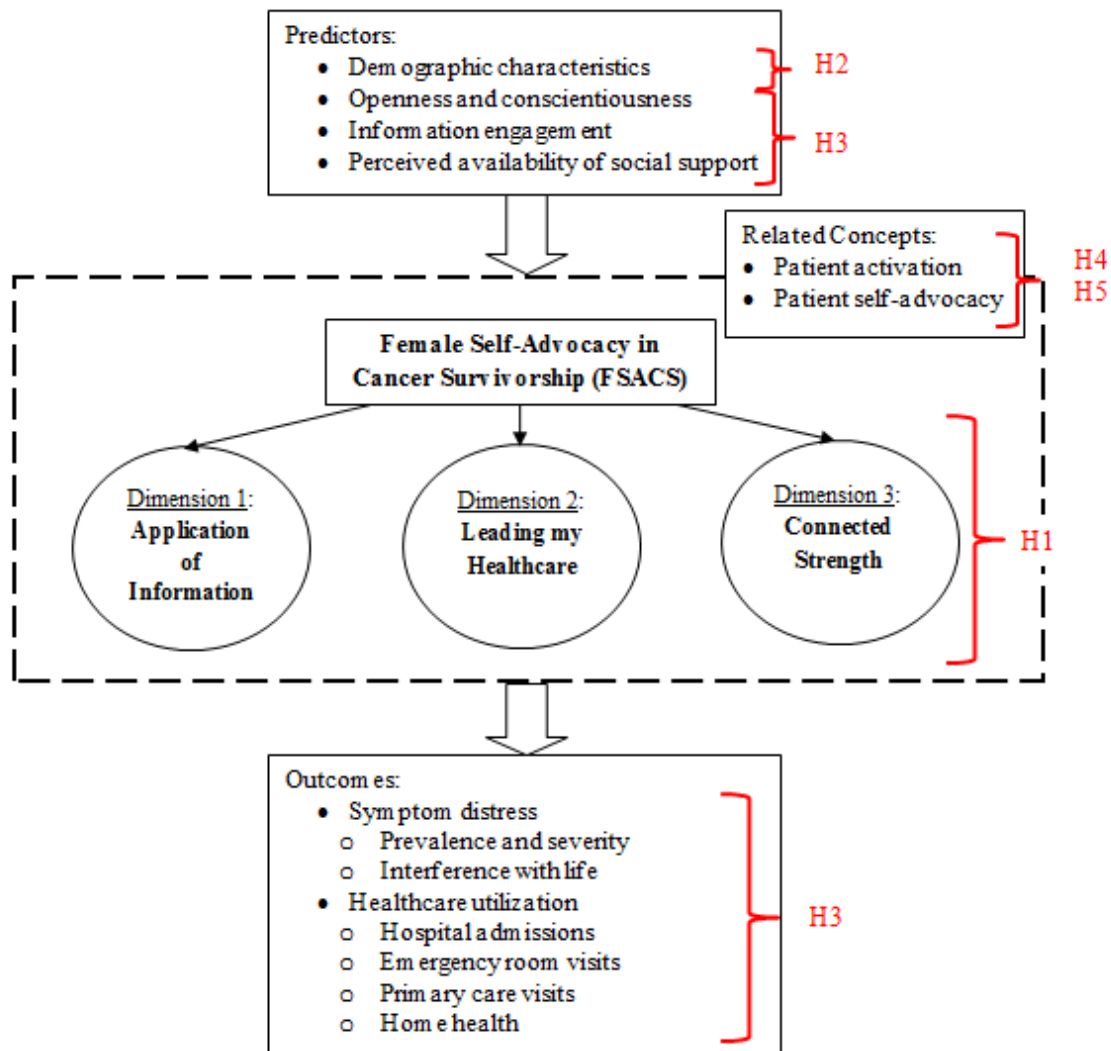


Figure 5. Measurement Model of the Female Self-Advocacy in Cancer Survivorship Scale with Hypotheses for Validity Testing

3.4.3 Methods

3.4.3.1 Design A cross-sectional mixed-mode survey study design with a mixture of random and convenience sampling was used. A sample of 315 adult female cancer survivors was justified based on Tinsely and Tinsley (1987) and Comrey's (1973) recommendations for factor analyses. Inclusion criteria included: 1) female, 2) being diagnosed with cancer after the age of 18, 3)

ability to read and write in English, and 4) a diagnosis of an invasive cancer (e.g. not basal cell carcinoma, squamous cell carcinoma, or cervical intraepithelial neoplasia Stage I).

Women were recruited from 2 patient registries and 7 advocacy organizations. Figure 6 lists each recruitment site and strategy. For the advocacy organizations and cancer clinics, leaders notified their members about the study through email, newsletters, and in-person meetings based on the preferences and feasibility of each site. Interested women contacted the principle investigator who screened the potential participants and mailed online or paper-based questionnaires to all eligible participants based on their preference.

Members of the University of Pittsburgh Clinical and Translational Science Institute (CTSI) Patient Research Registry were alerted about the study, contacted the CTSI, and referred to the principal investigator if they screened as eligible for the study. Members of the Pennsylvania Tumor Registry (34.0% of the total study sample) were randomly selected from a list of women diagnosed with any type of cancer in the state for 15 selected years between 1985 and 2013.

3.4.3.2 Procedure Surveys were completed either on paper through the mail or online according to participant preference between July 2014 and March 2015. Dillman's (2002) Tailored Design Method (e.g. personalization, ease of participation, and building a relationship with the participants) guided the design and delivery of both mailed and online surveys in order to build trust with participants and increase response rates and data quality. To further reduce sources of sample and respondent bias, refusal forms were given in the initial mailing to members of the Pennsylvania Tumor Registry if they did not want to participate.

Paper surveys were mailed with a pre-addressed, pre-stamped return envelope. Online surveys were sent through Qualtrics, a secure web-based data management system. If

questionnaires were not returned, then reminder postcards or emails were sent on 5, 10, and 21 days after the initial survey. Participants received a \$10 gift certificate after returning the survey. The study was approved by the University of Pittsburgh's Institutional Review Board.

3.4.3.3 Measures The previously developed FSACS Scale is a 57-item 6-point Likert-type self-report scale capturing 3 dimensions of how women with a history of cancer advocate (or stand up for) their needs, priorities, and wants in the face of an obstacle. Valid, reliable measures were selected to capture the hypothesized predictors, outcomes, and related concepts in the literature. Shortened versions were selected when available to reduce participant burden. Table 13 describes each construct's selected measure including number of items, response options, percent of female participants in the original study population, and reliability data. Predictors and outcomes were derived from the literature and previous qualitative work. Related measures were selected to compare and contrast the FSACS Scale with patient activation and the previous measure of self-advocacy derived from an HIV/AIDS population of mostly male patients (Brashers, Haas, & Neidig, 1999).

Table 13. Predictor, Outcome, and Related Measures

| Construct | Citation | Measure | # of Items | Item response options | # of Subscales | % Female | Cronbach's α |
|---|---|----------------------------------|-------------------|------------------------------|-----------------------|-----------------|---------------------------------------|
| <i>Predictors</i> | | | | | | | |
| Demographic Characteristics | (Sereika & Engberg, 2006) | CRCD Sociodemographic Survey - R | 25 | Variable | n/a | 100 | n/a |
| Disease Characteristics | n/a | Investigator-developed | 7 | Single response | n/a | n/a | n/a |
| Openness and conscientiousness | (Goldberg et al., 1999; Goldberg, 2006) | IPIP | 20 | 5-point Likert-type | 2 | Not reported | .81-.82 |
| Information engagement | (DuBenske et al., 2009) | HIOS | 8 | 5-point Likert-type | 1 | 63.6 | .65 |
| Perceived availability of social support | (Cohen et al., 1985) | ISEL | 12 | 4-point Likert-type | 3 | 74.4 | .31-.81 |
| <i>Outcomes</i> | | | | | | | |
| Symptom severity & interference with life | (Cleeland et al., 2000) | MDASI | 24 | 11-point Likert-type | 2 | 57 | .91-.94 |
| Healthcare utilization | (Given & Given, 2013) | Adapted questionnaire | 4 | Single response | 4 | Not reported | n/a |
| <i>Related Measures</i> | | | | | | | |
| Patient activation | (Hibbard et al., 2004) | PAM | 13 | 5-point Likert-type | 1 | 63 | .91 |
| Patient self-advocacy | (Brashers, Haas, & Neidig, 1999) | PSAS | 12 | 5-point Likert-type | 3 | 9.2 | .60-.82 |

3.4.3.4 Data Analysis

Hypothesis 1: Internal Structure To test if the internal structure of the FSACS Scale reflected its theoretical underpinnings, an Exploratory Factor Analysis was performed using maximum likelihood (ML) method, oblique rotation, and scree plots. For comparison, Principal Axis Factoring and Principle Components extraction methods, orthogonal rotation, and eigenvalues were used to extract factors, and found to provide weaker explanations of item variance and factor structure. A goodness-of-fit statistic was evaluated the degree of congruence between data and the proposed model.

Hypothesis 2: Sensitivity to Known Groups Comparisons were made between groups of women known to differ in their abilities to self-advocate to assure that the FSACS Scale is sensitive enough to detect differences between these groups. FSACS subscale scores should be significantly higher among (a) women with 5 or more years since their diagnosis compared to women within 1 year of their diagnosis and (b) women with more than a bachelor's degree compared to women with a high school degree or less. Student t-tests were used to make these comparisons.

Hypothesis 3: Relationships to Key Predictors and Outcomes FSACS total and subscale scores should be positively correlated to key predictors: participant's personality traits of being open to new experiences and conscientiousness (IPIP), comfort and engagement in health information (HIOS), and perceived availability of social support (ISEL). Scores should also be negatively correlated to key outcomes: symptom severity and interference (MDASI) and healthcare utilization (HCU). Bi-variate correlations and t-tests as appropriate were conducted between FSACS Scale scores and other scale scores.

Hypothesis 4: Concurrence with Related Concepts Convergent validity was tested by comparing FSACS Scale scores with measures of patient activation and a previous measure of self-advocacy. Higher scores on the FSACS Scale should be positively associated with scores on the Patient Activation Measures (PAM). Subscale score correlations between the FSACS Scale and the previous patient advocacy measure (PSAS) are expected to vary according to the level of similarity between the old and new subscales: 1) the “Mindful Non-adherence” and “Leading My Health Care” subscales should be strongly positively correlated ($r > 0.70$); 2) the “Illness Education” (PSAS) and “Application of Information” (FSACS) subscales are expected to be moderately correlated ($r = 0.30-0.70$); and 3) the “Assertiveness” (PSAS) and “Connected Strength” (FSACS) subscales are expected to be weakly correlated ($r < 0.30$). Bi-variate correlations were conducted between the FSACS Scale scores of related concepts from the literature (PAM and PSAS) to evaluate concurrent validity.

Hypothesis 5: Criterion Measures Criterion validity was tested by comparing FSACS Scale scores and PSAS total scores on outcome measures. FSACS Scale scores should be more highly correlated with outcome measures of symptom severity and interference (MDASI) and healthcare utilization (HCU) than the PSAS total score. Bi-variate correlations were calculated between the PSAS scores and outcome variables and compared with the strength of association between the FSACS Scale and outcomes to evaluate whether the FSACS Scale performs better among female cancer survivors compared to the PSAS. All data analyses were conducted using SPSS (Version 22, SPSS, Inc., Chicago, IL).

3.4.4 Results

A total of $N = 315$ adult female cancer survivors completed the study. Recruitment site information and enrollment are listed in Figure 6. Women who refused to participate were significantly older ($\chi^2 (4, N = 409) = 93.6, p < .001$), further from their time of diagnosis ($\chi^2 (2, N = 403) = 8.3, p = .015$), more racially diverse ($\chi^2 (6, N = 405) = 14.8, p = .022$), and less educated ($\chi^2 (4, N = 400) = 79879.9, p < .001$) than women who did participate in the study.

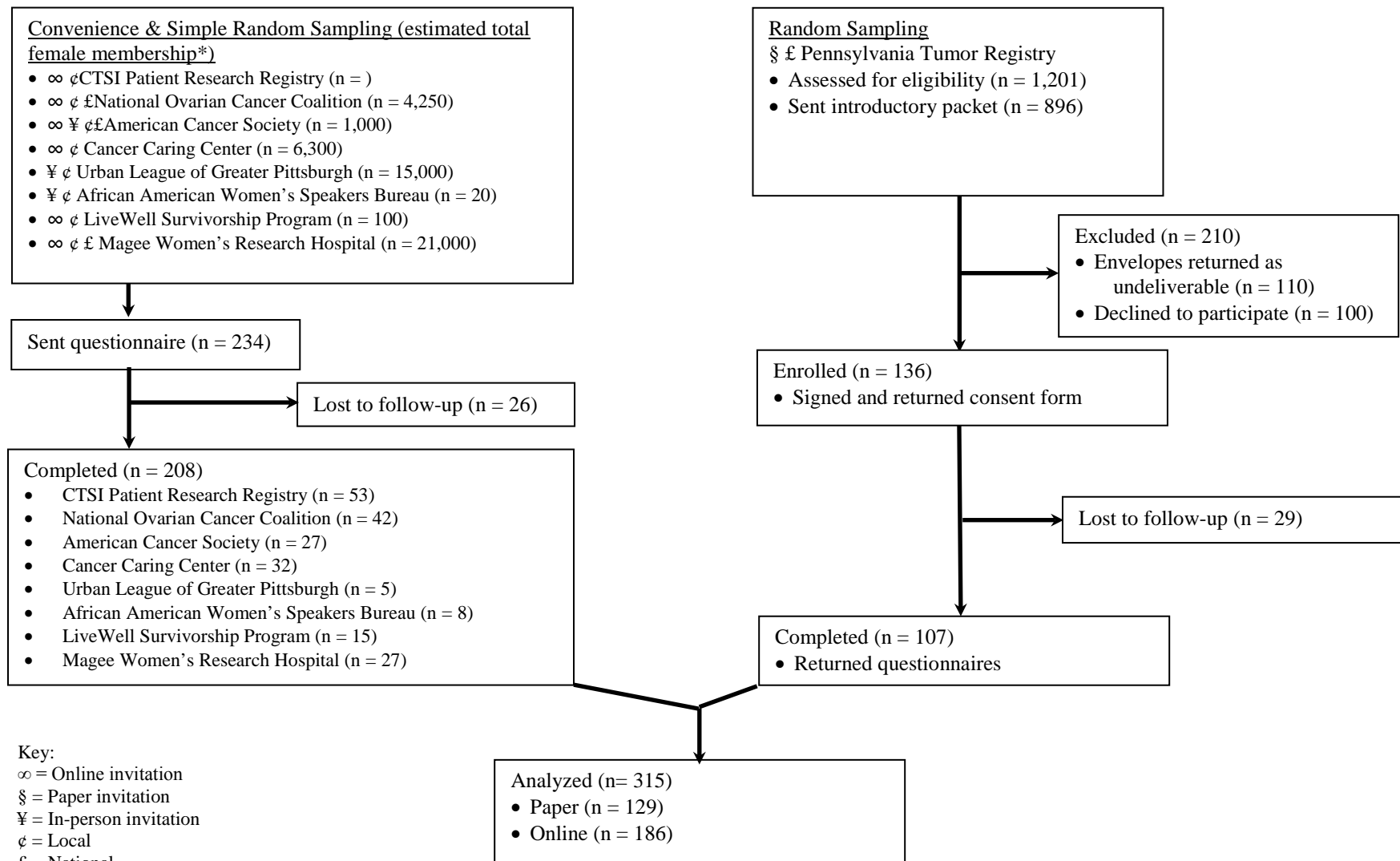


Figure 6. CONSORT Flowchart of Site Recruitment, Sample Enrollment, and Data Collection

Sociodemographic and health information of the sample are reported in Table 14. Among the total sample, participants had a mean age of 58.4 (observed range = 21 – 95). Most women were white ($n = 280$, 89.7%), married ($n = 194$, 62.2%), earned at least a bachelor's degree ($n = 166$, 53.4%), and had a median household income of at least \$50,000 ($n = 164$, 54.7%). Forty-one women (13.0%) reported that their current household income did not meet their basic needs.

Table 14. Sample Demographics

| | n | % |
|---|------|------|
| Age (Mean, Standard deviation) | 58.4 | 13.5 |
| Highest Degree Earned | | |
| <i>Less than high school</i> | 2 | 0.6 |
| <i>High school</i> | 70 | 22.5 |
| <i>Associates</i> | 72 | 23.2 |
| <i>Bachelor's</i> | 83 | 26.7 |
| <i>More than bachelor's</i> | 83 | 26.7 |
| Household Annual Income | | |
| <i>< \$20,000</i> | 33 | 11.0 |
| <i>\$20 – 49,999</i> | 65 | 21.7 |
| <i>\$50 – 79,999</i> | 70 | 23.3 |
| <i>\$80 – 150,000</i> | 74 | 24.7 |
| <i>> \$150,000</i> | 20 | 6.7 |
| <i>Unknown/decline</i> | 53 | 16.8 |
| Marital Status | | |
| <i>Currently married</i> | 194 | 62.2 |
| <i>Separated/Divorced</i> | 41 | 13.1 |
| <i>Never married</i> | 30 | 9.6 |
| <i>Living with partner/ significant other</i> | 22 | 7.1 |

Table 14 (continued)

| | | |
|-------------------------------|-----|------|
| <i>Widowed</i> | 22 | 7.1 |
| <i>Other</i> | 3 | 1.0 |
| Race | | |
| <i>White</i> | 280 | 89.7 |
| <i>African American/Black</i> | 24 | 7.7 |
| <i>American Indian</i> | 1 | 0.3 |
| <i>Alaska Native</i> | 1 | 0.3 |
| <i>Asian</i> | 3 | 1.0 |
| <i>Other</i> | 3 | 1.0 |
| Ethnicity | | |
| <i>Hispanic or Latino</i> | 7 | 2.2 |
| Types of Health Insurance | | |
| <i>Private</i> | 242 | 76.8 |
| <i>Medicare</i> | 121 | 38.4 |
| <i>Medicaid</i> | 25 | 7.9 |
| <i>Disability</i> | 14 | 4.4 |
| <i>Other</i> | 30 | 9.5 |

Figure 7 lists the frequencies and percentages of all cancer diagnoses reported by participants. While most women reported having breast ($n = 148$, 47%) or ovarian ($n = 68$, 21.6%) cancer, women listed over twenty different types of cancer. Figure 8 reports participants' stages at diagnosis. Almost half of the participants were diagnosed at Stage I or II ($n = 153$,

48.7%). Figure 9 illustrates participants' times since diagnosis. The sample included 63 (20.0%) women within one year, 109 (34.6%) women between one and five years, and 140 (44.4%) women over five years since their cancer diagnosis. Fifty-three (16.9%) women had more than one cancer diagnosis, and 73 (23.4%) women reported a recurrence of a cancer. Seventy women (45.5%) had previous illness experiences related to cancer outside of their own diagnosis.

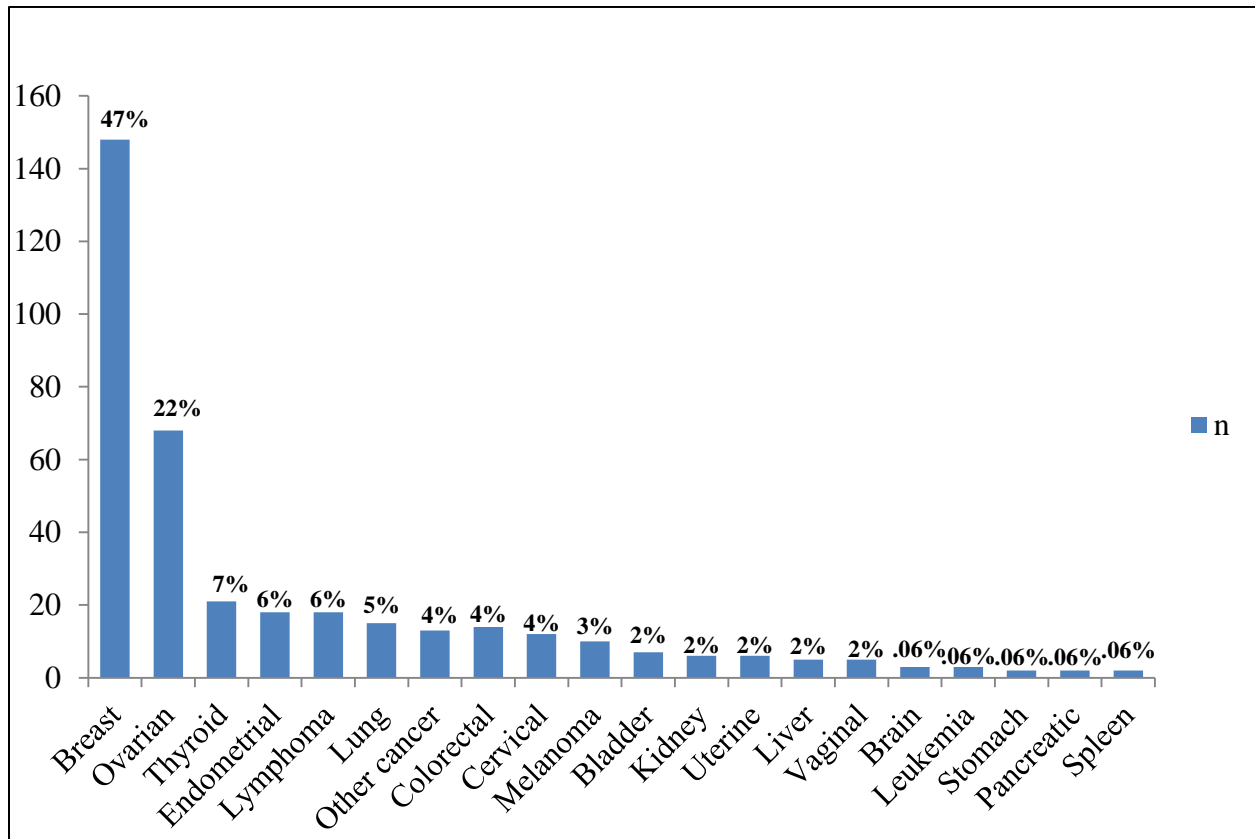


Figure 7. Types of Cancer Diagnoses in Sample

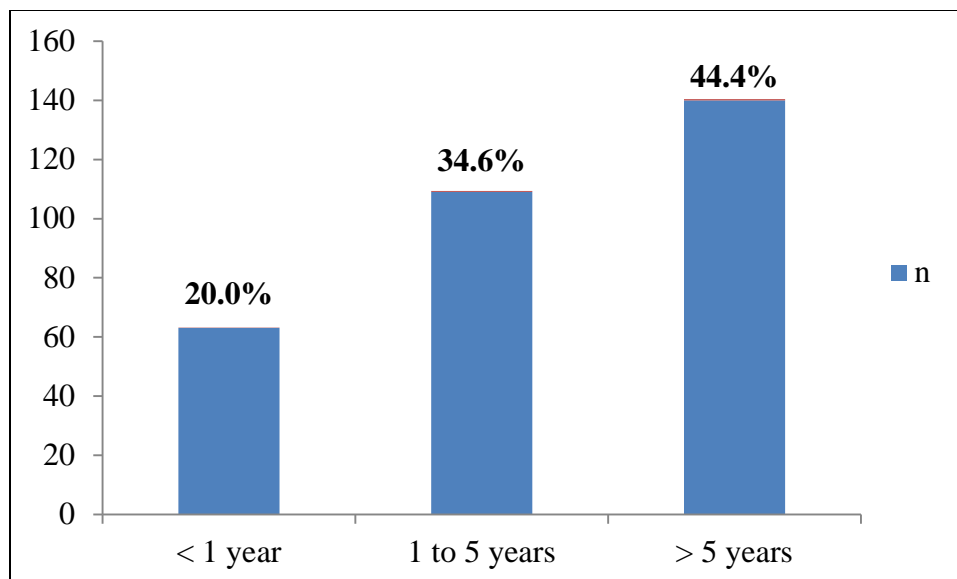


Figure 8. Cancer Stage at Time of Diagnosis

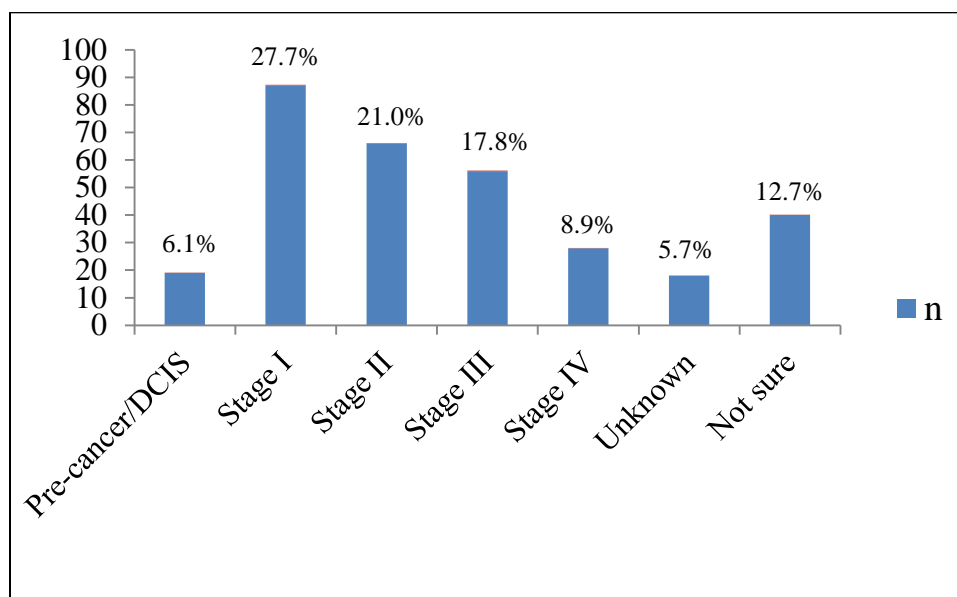


Figure 9. Time Since Diagnosis in a Three-group Split

Assumptions for maximum likelihood factor analysis, sub-group analyses, and planned comparisons were tested prior to data analyses. Estimation maximization was used to address missing data (8.0%) in the FSACS Scale responses; all other measures had <4% missing data. All assumptions for scales and subscales were upheld save for the FSACS Scale, which had skewness and kurtosis concerns which were managed by collapsing item response categories into

4 rather than 6 point scales. Also, both subscales of the MDASI were negatively skewed which was expected for this broad population of all cancer survivors. Descriptive statistics for all measures are reported in Table 15.

Table 15. Descriptive Statistics for All Measures

| | Measure | Mean | SD | SE |
|---|-------------------------------|-------|-------|------|
| <i>FSACS Scales</i> | | | | |
| Being an Informed Decision Maker | FSACS Scale | 34.55 | 4.67 | 0.26 |
| Connected Strength | FSACS Scale | 33.11 | 5.96 | 0.34 |
| Communicating with My Health Care Providers | FSACS Scale | 29.80 | 4.40 | 0.25 |
| <i>Predictors</i> | | | | |
| Openness and Conscientiousness | IPIP | 76.45 | 9.58 | 0.03 |
| Health Information Orientation | HIOS | 23.57 | 4.18 | 0.03 |
| Social Support | ISEL | 43.45 | 5.66 | 0.03 |
| <i>Outcomes</i> | | | | |
| Symptom Burden* | MDASI – Severity | 11.97 | 16.90 | 0.10 |
| | MDASI – Interference | 5.06 | 10.02 | 0.13 |
| Utilization (n, %) in past 3 months | Hospitalized | 39 | 12.5% | |
| | Visited Emergency Department | 36 | 11.5% | |
| | Visited Primary Care Provider | 187 | 59.9% | |
| | Visited by Home Care | 12 | 3.9% | |
| <i>Related Measures</i> | | | | |
| Patient self-advocacy | PSAS | 43.59 | 6.26 | 0.03 |
| Patient activation | PAM | 43.31 | 5.02 | 0.02 |

3.4.4.1 Hypothesis 1: Internal structure The factor analysis of the 57-item FSACS Scale resulted in a 20-item, 3-factor structure consistent with theoretical dimensions of self-advocacy. The three factors were named based on the content and themes of retained items within each dimension: 1) “Application of Information” was changed to “Being an Informed Decision Maker” (6 items); “Leading My Health Care” was changed to “Communicating with My Health Care Providers” (7 items); and “Connected Strength” remained the same (7 items). Reliability testing using Cronbach’s alpha and test-retest reliability data from the previous study (Hagan, Cohen, Stone, & Donovan, Submitted) was performed on the final measure and was strong across the FSACS Scale total and subscale scores (Table 16).

Table 16. Hypothesis 1: Factor Analysis with Oblique Rotation

| | Communal ity | Factor 1 | Factor 2 | Factor 3 |
|--|-------------------------|-----------------|-----------------|-----------------|
| <i>Being an Informed Decision Maker</i> ($\alpha = 0.817$; $r = 0.980^{**}$) | | | | |
| I gather information before making decisions about my cancer care. | 0.569 | 0.822 | -0.036 | -0.131 |
| I weigh my options carefully before making important decisions about my cancer care. | 0.646 | 0.793 | 0.036 | -0.005 |
| I prepare myself to make decisions about my cancer care | 0.575 | 0.768 | -0.058 | 0.017 |
| I use my skills to solve the problems I face as a cancer survivor. | 0.418 | 0.638 | 0.152 | -0.133 |
| When it comes to making decisions about my cancer care, I know what my priorities are. | 0.450 | 0.632 | -0.065 | 0.109 |
| I am comfortable asking for a second opinion. | 0.249 | 0.437 | 0.031 | 0.088 |
| I know where to get an answer if my provider can't give me one. | 0.164 | 0.395 | 0.049 | -0.021 |
| <i>Connected Strength</i> ($\alpha = 0.791$; $r = 0.888^{**}$) | | | | |
| I try to raise awareness about cancer. | 0.561 | -0.050 | 0.758 | 0.020 |

Table 16 (continued)

| | | | | |
|--|-------|--------|--------------|--------------|
| Helping other cancer survivors also helps me. | 0.598 | 0.139 | 0.722 | -0.023 |
| Telling other people my story makes me feel good. | 0.507 | -0.150 | 0.717 | 0.106 |
| I seek out support from other cancer survivors. | 0.449 | 0.161 | 0.655 | -0.197 |
| I am comfortable sharing my cancer experience with others. | 0.492 | -0.173 | 0.641 | 0.253 |
| When I hear that someone has cancer, I try to reach out to them. | 0.403 | 0.027 | 0.633 | -0.024 |
| It helps me to know that other cancer survivors have gone through what I am going through. | 0.342 | 0.101 | 0.574 | -0.097 |
| <i>Communicating with My Health Care Providers</i> ($\alpha = 0.850$; $r = 0.980^{**}$) | | | | |
| I don't talk about a health concern with my provider unless I think there is a solution. (Reverse) | 0.562 | -0.068 | -0.033 | 0.791 |
| I rarely tell my provider about problems I am having related to cancer. (Reverse) | 0.552 | -0.031 | 0.052 | 0.739 |
| I have a hard time voicing my preferences to my provider. (Reverse) | 0.343 | 0.178 | -0.051 | 0.495 |

Table 16 (continued)

| | | | | |
|--|-------|-------|--------|--------------|
| I question my provider if I don't agree with his or her recommendations. | 0.299 | 0.416 | -0.103 | 0.247 |
| I ask my provider to explain his or her recommendations. | 0.518 | 0.404 | 0.089 | 0.381 |
| I ask questions when I don't understand what my provider is telling me. | 0.474 | 0.420 | 0.003 | 0.373 |

Primary factor loadings for each item are indicated in bold text.

Reliability statistics are in parentheses following each dimension's name (Total Internal Consistency: Cronbach's $\alpha = 0.880$; Total Pearson Product Moment Correlation: $r = 0.926^{**}$)

* indicates correlation is significant at a level below $p = 0.01$)

** indicates correlation is significant at a level below $p = 0.001$)

The chi-square goodness of fit test statistic tested the adequacy of the number of extracted factors. At $\chi^2 (133, N = 315) = 272.42, p < 0.01$. To protect against a Type II error of rejecting additional factors due to the conservative p-value of 0.05, additional numbers of factors were tested. The chi-square statistics for the 4-factor solution also resulted in significant chi square statistics. While the 5-factor solution resulted in a non-significant chi square statistic, the pattern matrix did not result in conceptually understandable factors based on the underlying theory.

Thirty-seven items were deleted based on their individual communalities, inter-item correlations, item-to-total correlations, factor loadings, previous input from content validity experts, and conceptual meaningfulness. The alternative extraction methods did not result in significantly different item-total correlations, extracted factors, or explanation of variance in item responses. The Kaiser-Meyer-Olkin measure of sampling adequacy of 0.902 and Bartlett's test of sphericity was significant ($X^2(190) = 2,583, p < 0.001$), indicating adequate sampling size.

Table 16 shows the factor loadings for all three dimensions, which in total explained 45.87% of the variance in participant responses (Table 17). The three factors were significantly correlated with each other but had weak to moderately-high correlations (Table 18). Due to this empirical evidence of distinct subscales, the decision to report FSACS subscale scores rather than total scores was made.

Table 17. FSACS Scale Variance Explained

| Factor | Initial Eigenvalues | | | Extracted Sums of Squared Loadings | | | Rotated Sums of Squared Loadings |
|---|---------------------|---------------|--------------|------------------------------------|---------------|--------------|----------------------------------|
| | Total | % of Variance | Cumulative % | Total | % of Variance | Cumulative % | Total |
| | | | | | | | |
| Being an Informed Decision Maker | 6.32 | 31.61 | 31.61 | 5.80 | 29.00 | 29.00 | 4.87 |
| Connected Strength | 2.78 | 13.88 | 45.49 | 2.25 | 11.27 | 40.27 | 4.03 |
| Communicating with My Health Care Providers | 1.61 | 8.03 | 53.52 | 1.12 | 5.60 | 45.87 | 3.50 |

Table 18. FSACS Subscale Correlation Matrix

| | Being an Informed Decision Maker | Connected Strength | Communicating with My Health Care Providers |
|---|--|-----------------------|---|
| Being an Informed Decision Maker | 1.00 | - | - |
| Connected Strength | 0.452** | 1.00 | - |
| Communicating with My Health Care Providers | 0.628** | 0.279** | 1.00 |

* $p \leq 0.05$

** $p \leq 0.01$

3.4.4.2 Hypothesis 2: Sensitivity to Known Groups Table 19 compares FSACS subscale scores of women with varying educational levels and times since diagnosis. As hypothesized, women with higher levels of education scored significantly higher on all three FSACS total scale and subscale scores compared to women with lower levels of education. However, experienced survivors did not have significantly different scores than women within a year of cancer diagnosis.

Table 19. Hypothesis 2: Group Comparisons

| | Being an Informed Decision Maker | | Connected Strength | | Communicating with My Health Care Providers | |
|---|--|------------------------|-----------------------|-----------------|---|------------------------|
| | M (SD) | t (p- value) | M (SD) | t (p- value) | M (SD) | t (p- value) |
| <i>Time Since Diagnosis</i> | | | | | | |
| Within 1 year (<i>n</i> = 63) | 33.52 (5.21) | -1.82 (0.07) | 32.95 (5.65) | -0.98 (0.33) | 29.43 (5.06) | -0.87 (0.39) |
| Greater than 5 years (<i>n</i> = 140) | 34.76 (4.10) | | 33.78 (5.50) | | 29.99 (3.91) | |
| <i>Highest Level of Education</i> | | | | | | |
| High school or less (<i>n</i> = 72) | 33.34 (4.15) | -4.25 ($<.001$)** | 33.04 (5.58) | -0.18 (0.38) | 28.35 (4.46) | -4.39 ($<.001$)** |
| More than a bachelor's degree (<i>n</i> = 83) | 36.00 (3.62) | | 33.87 (6.16) | | 31.22 (3.67) | |

* $p \leq 0.05$ two-tailed significance

** $p \leq 0.01$ two-tailed significance

3.4.4.3 Hypothesis 3: Relationships to Key Predictors and Outcomes Table 20 shows correlations between FSACS subscale scores and those of predictors and outcomes of self-advocacy. Predictors: FSACS subscale scores were significantly positively correlated with all predictors (openness and conscientiousness, information engagement, and social support). The only predictor that did not perform as expected was information engagement which was significantly positively correlated with “Connected Strength” but significantly negatively correlated with “Communicating with My Health Care Providers.”

Table 20. Hypotheses 3 and 4 : FSACS Subscale Scores Compared to Predictors, Outcomes, and Related Concepts

| | Being an Informed Decision Maker | Connected Strength | Communicating with My Health Care Providers |
|---------------------------------------|--|-----------------------|---|
| <i>Predictor Variable</i> | | | |
| Openness and conscientiousness (IPIP) | 0.460** | 0.245** | 0.438** |
| Information engagement (HIOS) | 0.047 | 0.127* | -0.127* |
| Social support (ISEL) | 0.243** | 0.199** | 0.227** |
| <i>Outcome Variable</i> | | | |
| Symptom severity (MDASI) | -0.076 | 0.032 | -0.130* |
| Symptom interference (MDASI) | -0.167** | -0.044 | -0.260** |
| Hospitalization | 0.210** | 0.030 | 0.130* |
| Emergency Department Visit | 0.153** | -0.058 | 0.117* |
| Primary Care Visit | 0.008 | 0.035 | -0.113 |
| Home Health Visit | -0.146** | -0.150** | -0.097 |
| <i>Related Concepts</i> | | | |
| Patient Activation (PAM) | 0.553** | 0.272** | 0.498** |
| Patient Self-Advocacy (PSAS) | 0.501** | 0.237** | 0.342** |

* $p \leq 0.05$

** $p \leq 0.01$

Outcomes: FSACS subscale scores showed mixed evidence for the hypothesized relationships between FSACS subscale scores and symptom distress and healthcare utilization.

The “Being an Informed Decision Maker” subscale was significantly negatively correlated with symptom interference only. The “Connected Strength” subscale was not related to either symptom distress subscale. The “Communicating with My Health Care Providers” subscale was significantly negatively correlated with both symptom severity and symptom interference.

For healthcare utilization, the “Being an Informed Decision Maker” subscale was significantly negatively correlated with having had a home health visits and significantly positively correlated with being hospitalized and emergency department visits. The “Connected Strength” subscale was significantly negatively correlated only with home health visits. The “Communicating with My Health Care Providers” subscale was significantly positively correlated with both being hospitalized and emergency department visits.

3.4.4.4 Hypothesis 4: Concurrence with Related Concepts Table 21 reports correlations between the FSACS subscale scores and related concepts. As hypothesized, patient activation scores were significantly positively correlated with each of the FSACS subscale scores. Compared to the self-advocacy scale created for individuals with HIV/AIDS, the FSACS subscales demonstrated similarities and differences (Table 22). “Being an Informed Decision Maker” was significantly positively correlated with “Illness Education.” “Connected Strength” was weakly, but significantly positively correlated with “Assertiveness.” However, the “Communicating with My Health Care Providers” was not correlated with “Mindful Non-Adherence.”

Table 21. Hypothesis 4: FSACS and PSAS Subscale Correlations

| PSAS Subscale | FSACS Subscales | | |
|---------------------------|--|-----------------------|---|
| | Being an Informed Decision Maker | Connected Strength | Communicating with My Health Care Providers |
| Illness Education | 0.517** | | |
| Assertiveness | | 0.373** | |
| Mindful Non- Adherence | | | -0.042 |
| * $p \leq 0.05$ | | | |
| ** $p \leq 0.01$ | | | |

3.4.4.5 Hypothesis 5: Criterion Measures The FSACS Subscales were more highly correlated with the outcomes of symptom distress and healthcare utilization than the PSAS total score (Table 22). The PSAS scores were only significantly and positively related to hospitalizations.

Table 22. Hypothesis 5: FSACS Subscale Scores vs. PSAS Scores on Outcome Measures

| | FSACS Scale | | | |
|---------------------------------|---|-----------------------|---|------------|
| | Being an Informed Decision Maker | Connected Strength | Communicating with My Health Care Providers | PSAS Total |
| <i>Symptom Distress</i> | | | | |
| Symptom severity (MDASI) | -0.076 | 0.032 | -0.130* | -0.100 |
| Symptom interference (MDASI) | -0.167** | -0.044 | -0.260** | -0.023 |
| <i>Healthcare Utilization</i> | | | | |
| Hospitalization | 0.210** | 0.030 | 0.130* | 0.155** |
| Emergency Department Visit | 0.153** | -0.058 | 0.117* | -0.010 |
| Primary Care Visit | 0.008 | 0.035 | -0.113 | 0.074 |
| Home Health Visit | -0.146** | -0.150** | -0.097 | 0.042 |

* $p \leq 0.05$ ** $p \leq 0.01$

3.4.5 Discussion

Results of the five *a priori* hypotheses largely supported the accuracy of the FSACS as a measure of self-advocacy. The internal structure of the FSACS Scale is consistent with the theoretical underpinnings of self-advocacy among female cancer survivors and provides a parsimonious set of 20 items tapping into three distinct dimensions of self-advocacy.

In this model of self-advocacy, women's self-advocacy is defined as (a) preparing and making informed decisions consistent with a woman's priorities, (b) finding strength through mutually supporting and being supported by other cancer survivors, friends, and family, and (c) openly and confidently voicing concerns, problems, and confusions with health care providers and working with them to find solutions. The more a woman is able to be an informed decision maker in her health care, communicate her concerns and questions to her health care provider, and both get and give receive support, the more she is able to advocate for herself. Like similar self-care concepts, self-advocacy promotes patient engagement and empowerment (Richard & Shea, 2011), but unlike these other concepts incorporates specific behaviors of how survivors perform when faced with a challenge or problem in their experience.

The FSACS Scale adeptly detected differences between women with high and low levels of education. The lack of difference between women at different times since diagnosis may reflect the long-term survivors' distance from the health-related problems and the paucity of recently diagnosed women in the sample. If women further from diagnosis and treatment experience fewer challenges related to being a cancer survivor, then their need for self-advocacy may naturally decrease over time. The lack of difference may also reflect the current lack of training in self-advocacy skills for cancer survivors, leaving all survivors at risk for poor self-advocacy. Given that both informed decision making and communication are amenable to intervention (Au et al., 2012; Meropol et al., 2013), self-advocacy may also be capable of increasing if directly taught through a targeted intervention.

The FSACS subscale scores largely performed as expected with the predictors of self-advocacy. Openness and conscientiousness (IPIP) were the most strongly correlated with all three self-advocacy subscales as was perceived availability of social support (ISEL). The health

information engagement measure (HIOS) was positively correlated with “Connected Strength” but negatively correlated with “Communicating with My Health Care Providers.” While the association between health information seeking and Connected Strength was expected, the inverse relationship with communication with providers was unexpected. This may reflect a tendency for those who have strong communication with their providers to view providers as their most trusted source of health information and therefore reduce their need to actively seek outside sources of health information.

Several outcomes were associated with “Being an Informed Decision Maker” and “Communicating with My Health Care Provider.” The higher a woman’s score on these self-advocacy subscales, the less likely her symptoms were to interfere with her life. A woman who discusses her symptoms with her health care provider may be more likely to receive effective recommendations on how to treat them. Surprisingly, higher self-advocacy scores on these same two dimensions were positively correlated with hospitalizations and emergency department visits. This unexpected finding could be because a woman (a) is engaged in making health decisions and communicates openly so refers herself or receives a referral from her healthcare providers to go to a hospital or emergency department or (b) has several medical problems that cause her to have hospital admissions and emergency department visits which then necessitate decision-making and communication with her healthcare providers. Unfortunately, there is no way to determine whether the healthcare utilization by women in this study were appropriate. Therefore, it remains unclear whether self-advocacy is associated with women’s ability to seek and obtain medical attention when in need.

Compared to the previous measure of self-advocacy among individuals with HIV/AIDS (PSAS), the FSACS subscale of “Communicating with My Health Care Providers” was not

associated with “Mindful Non-Adherence” as hypothesized. In fact, many of the items derived from the PSAS measure were eliminated during the factor analysis including items about adjusting provider recommendations, deciding not to follow provider’s advice, and acknowledging that health care providers did not know more about the woman’s health than she did. Given this discrepancy along with the weak to moderate correlations among other subscales and mostly insignificant correlations with symptom distress and healthcare utilization, the FSACS subscale seems to be tapping into a type of self-advocacy distinct from that of the PSAS and one that relates to important health outcomes.

The poor correlation between the FSACS communication subscale and the PSAS mindful non-adherence subscale may reflect the significant changes made to this dimension throughout psychometric testing and therefore represent a drift from the original concept. For this reason along with concerns about the three cross-loading items on this subscale, future testing will explore whether these communication items adequately detect a woman’s ability to drive her own care and work with her health care team or if there are additional behaviors needed to more completely represent this concept.

As the first psychometric analysis of a measure of self-advocacy particular to cancer and females, additional testing of the FSACS Scale will continue to refine the model and find targets for intervention. Specifically, research will focus on find predictors of low self-advocacy and identifying sub-groups of female cancer survivors at risk for poor self-advocacy. In this way, self-advocacy interventions can be tailored to fit the distinct needs of women struggling in specific dimensions of self-advocacy.

In accordance with principles of instrument development, the sample in this study was purposefully broad in order to capture the full breadth of self-advocacy among and be

generalizable to all adult female cancer survivors. Future research explicitly will explore variations in self-advocacy among women who are likely to face greater challenges during their cancer experience including women with advanced cancers, recurrences, lower levels of education, financial difficulties, etc. Likewise, more precise measures of healthcare utilization appropriateness will be used.

Limitations to this study are consistent with those of survey studies. Self-reported disease and treatment information were not able to be verified. The cross-sectional design limits statistical testing to associations rather than using self-advocacy as a predictor or outcome as proposed in the measurement model. Low response rates and significant differences between non-responders and responders in the Pennsylvania Tumor Registry along with unknown non-response rates with the advocacy organizations risks bias in the sample and therefore limits the generalizability of data to all adult female cancer survivors.

3.4.6 Conclusions

The FSACS Scale is a psychometrically-sound, parsimonious measure self-advocacy among female cancer survivors. Evidence in support of the tool's construct validity supported the theoretical dimensions of the overall construct, and the final 20-item measure performed mostly as expected compared to proposed predictors, outcomes, and related measures of self-advocacy.

Future work to explore the use of the tool in detecting women with low self-advocacy will assist clinicians and researchers in being able to support women ill-equipped to address their problems, needs, and wants throughout their cancer experience. Partnering with key health care providers and patient navigators in the clinical setting will be critical next steps to ensuring the application of this new tool and theory of self-advocacy in the most appropriate settings.

3.4.7 Funding Support

These data were supplied by the Bureau of Health Statistics & Research, Pennsylvania Department of Health, Harrisburg, Pennsylvania. The Pennsylvania Department of Health specifically disclaims responsibility for any analyses, interpretations or conclusions.

Teresa Hagan, BSN was supported by a Doctoral Degree Scholarship in Cancer Nursing, DSCN-14-077-01-SCN from the American Cancer Society.

3.4.8 Conflict of Interest Disclosures

The authors have no disclosures.

4.0 INCIDENTAL FINDINGS

4.1 DIMENSIONALITY

Surprisingly, many of the items conceptually derived from the Patient Self-Advocacy Scale (PSAS) did not have strong reliability and validity results in the current study. In fact, the FSACS subscale “Communicating with My Health Care Providers” had an extremely weak, non-significant correlation ($r = -0.042$) with the PSAS subscale “Mindful Non-adherence” subscale. The lack of significant association between these two dimensions suggests that they are unique and distinct despite originally being intended to tap into a similar concept. The “Mindful Non-adherence” questions regarding whether or not survivors adjusted their providers’ recommendations did not perform well during cognitive interviews, content validity and reliability testing. Despite being conceptually congruent with the PSAS (2 of the three items were directly derived from the PSAS), these items were below the acceptable cut-off for at least two of these three psychometric evaluations. In short, these large discrepancies in this one subscale along with weak correlations in the other two subscales confirm that the FSACS Scale is tapping into a type of self-advocacy among women with cancer that is conceptually distinct from self-advocacy among individuals with HIV/AIDS.

4.2 SUB-GROUP DIFFERENCES IN FSACS SCORES

Subsets of participants were compared on the FSACS subscales, predictors (IPIP, ISEL, and HIOS), outcomes (symptom severity and interference; healthcare utilization), and related measures (PSAS and PAM) to explore if there were significant differences among women with varying health and sociodemographic backgrounds. While exploratory in nature, these demographic distinctions will be essential in designing future study's sampling procedures and interventions in order to ensure that women who struggle to self-advocate are both being identified and served according to their unique needs.

4.2.1 Cancer Type Differences

The two largest subgroups of cancer types were breast ($n = 122$) and ovarian cancer ($n = 65$).

Comparing women with breast and ovarian cancer diagnoses only the “Connected Strength” subscale significantly varied between groups with women with ovarian cancer reporting higher scores ($M = 35.17$) than women with breast cancer ($M = 32.49$), $t(185) = -3.13$, $p = 0.002$.

Because most ovarian cancer survivors were recruited through the National Ovarian Cancer Coalition (NOCC) which is an advocacy group with no breast cancer advocacy group counterpart, this result may reflect the sampling bias. For example, when FSASCS subscale scores of women recruited from the NOCC were compared to women recruited from the Pennsylvania Tumor Registry (which used a random sampling procedure), “Connected Strength” was the only subscale that significantly differed between groups with women with NOCC members having higher scores) ($t(147) = -2.67$, $p = 0.008$). Conversely, this difference between women with breast vs. ovarian cancer diagnoses may reflect true differences in the extent to which ovarian cancer seek out and support others with their same diagnosis.

4.2.2 Time Since Diagnosis Differences

Compared to women within a year of diagnosis, women with more than 5 years since their cancer diagnosis did not have significantly different scores on any FSACS subscale. However, when compared to women between 1 and 5 years of diagnosis, women within a year of diagnosis had significantly lower scores on the “Being an Informed Decision Maker” subscale ($t(170) = -2.43, p = 0.016$). Although symptom severity did not differ between women who were newly diagnosed compared to long-term survivors, symptom interference was significantly higher among women within a year of diagnosis ($t(196) = 2.15, p = 0.032$). Surprisingly, long-term survivors were more likely to have been admitted to a hospital in the past three months ($t(196) = -4.72, p < 0.001$), less likely to have a PCP ($t(200) = 2.11, p = 0.036$), and have a visiting nurse ($t(199) = -1.99, p = 0.048$) than women who were newly diagnosed. These two groups did not significantly differ in any of the predictor or related measures.

4.2.3 Stage of Cancer Diagnosis Differences

FSACS subscale scores did not significantly differ between women diagnosed at Stage I compared to Stage IV. These groups did not differ on any predictor, outcome, or related measure save for the PAM on which women diagnosed at Stage IV scored higher ($t(110) = -2.30, p = 0.023$). Interestingly, women diagnosed at Stage III reported higher “Connected Strength” subscale scores than women diagnosed at Stage I ($t(141) = -2.28, p = 0.024$). Beyond symptom distress (which women diagnosed at Stage III understandably reported significantly higher scores than women diagnosed at Stage I), no other significantly different scale scores existed between these two groups. No significant differences existed between women diagnosed at Stage III compared to women diagnosed at Stage IV.

4.2.4 Racial Differences

FSACS subscale scores did not significantly differ between white ($n = 280$) and African American ($n = 24$) women, nor did any of the scores of any of the predictors, outcomes, or related measures. Given the uneven sample sizes, this variable will continue to be examined in the future in order to detect if race impacts self-advocacy scores.

4.2.5 Age Differences

In order to compare women based on their age, six groups were created based on the median age and quartile ranges. Only scores on the “Connected Strength” subscale significantly differed between young women (age 25 – 42) and older women (age 76 and above), with younger women reporting higher scores on this subscale ($t(67) = 2.76, p = 0.007$). Furthermore, these two groups had significantly different scores on many of the predictor, outcome, and related measures. Compared to older women, younger women reported significantly higher symptom interference, patient self-advocacy with individuals with HIV/AIDS (PSAS), health information orientation (HIOS), and openness and conscientiousness (IPIP) scores. Healthcare utilization did not significantly differ between the youngest and oldest participants, nor did perceived availability of social support (ISEL) or patient activation (PAM).

Interestingly, when women age 25-42 (youngest) were compared to women age 68-75 (second oldest), the older age group scored significantly higher on the “Being an Informed Decision Maker” ($t(87) = -2.74, p = 0.007$) and “Communicating with my Health Care Providers” ($t(87) = -2.41, p = 0.018$) subscales. Yet, this youngest group of women scored significantly higher than women age 68-75 on the health information orientation (HIOS) measure. These findings may reflect more healthcare experience among older women and a better ability to

prepare and communicate their needs, and younger women's skills at obtaining and gathering health information.

4.2.6 Educational Differences

Comparing women with a high school degree or less with women with at least some graduate school, both the "Being an Informed Decision Maker" ($t(153) = -4.25, p < 0.001$) and "Communicating with My Health Care Providers" ($t(153) = -4.39, p < 0.001$) subscales significantly varied with more educated women having higher FSACS subscale scores. "Connected Strength" subscale scores did not significantly vary between these groups. The same statistically significant differences in FSACS subscale scores existed among women with a vocational degree or 2-year degree compared to women with at least some graduate school, but not between women with a vocation degree or 2-year degree and women with a bachelor's degree.

Symptom severity ($t(149) = 3.63, p < 0.001$) and symptom interference ($t(149) = 1.97, p = 0.05$) were also significantly higher among women with less than a high school education compared to those with at least some graduate school. Women with a vocational degree or 2-year degree also had significantly higher symptom severity and symptom interference than women with a graduate degree.

Women with less than a high school education scored significantly lower on the PSAS, PAM, and IPIP compared to women with at least some graduate school but on no other measures.

4.2.7 Income Differences

Women with a household income less than \$20,000 a year reported strong differences than women with household incomes over \$150,000 a year. Women with higher household incomes had significantly higher scores on the “Being an Informed Decision Maker” ($t(44) = -3.56, p = 0.001$) and “Communicating with My Health Care Providers” ($t(44) = -3.79, p < 0.001$) subscales of the FSACS compared to poorer women, but not the “Connected Strength” subscale. This wealthiest group also reported statistically higher PSAS, PAM, IPIP, and ISEL total scores. There were no group differences in either symptom distress or healthcare utilization. Similar results were found among the subset ($n = 41$) women who responded “No” to the sociodemographic question asking if their current household income met their basic needs.

Women’s reported household income was combined with their total number of adult and children living their house. These household incomes by total household number were compared to the 2015 federal poverty thresholds in order to categorize all participants as either below or above the poverty line. Only 15 women were below the poverty line. While this was not a large enough sample size for comparisons, exploratory analyses were conducted to evaluate whether women below the federal poverty line scored differently on the three FSACS dimensions compared to women above the federal poverty line. Across all three dimensions, women below the poverty line had significantly lower FSACS scores than women above the federal poverty line.

4.2.8 Summary of Differences

Strong differences in FSACS subscales and other measures by age, educational status, and income warrant further investigation. Of note, the 18 women who were over age 80 all had household incomes below \$50,000 a year and 12 (66.7%) had less than a high school education.

Lack of differences between newly diagnosed women and long-term survivors needs to be further investigated. It is not clear if women further from diagnosis are not making decisions regarding their health, interacting with their health care team and not in need of getting/giving support from others and therefore scoring lower. Or, self-advocacy may be behaving more like a trait rather than a state, in which case efforts to build self-advocacy as a skill might be difficult.

5.0 APPENDICES

APPENDIX A

VALIDITY INSTRUMENTS



Self-Advocacy in Cancer Survivorship Questionnaires

Thank you for being a part of this study!

ID: _____



Screening Questionnaire

1. Are you female?

☐ Yes

☐ No

2. Can you read and write in English?

☐ Yes

☐ No

3. Have you been diagnosed with cancer **AFTER** the age of 18?

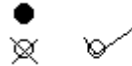
☐ Yes

☐ No

4. Have you been diagnosed with a cancer **OTHER THAN** basal cell carcinoma, squamous cell carcinoma, or cervical intraepithelial neoplasia?

☐ Yes

☐ No



Female Self-Advocacy Measure - Oncology

ID Number:

Administration Date:

 / /

(month)

(day)

(year)

Visit Number:

1

2

☐
☐

Baseline 2 Weeks

(FOR STAFF USE ONLY)

INSTRUCTIONS:

The following statements reflect "self-advocacy" among female cancer survivors. A cancer survivor is anyone who has ever been diagnosed with cancer.

These questions are purposefully redundant. We are trying to find the best statements to reflect "self-advocacy." Your responses will help us figure out which statements are best.

Please read each of the following statements carefully. Think about your experiences having cancer and, if you currently do not have cancer, think about your experiences since you had cancer.

Then, for each statement, fill in the circle that corresponds to the response that best reflects how much you agree or disagree with each statement.

| | Strongly Disagree 1 | Disagree 2 | Somewhat Disagree 3 | Somewhat Agree 4 | Agree 5 | Strongly Agree 6 |
|---|------------------------|-----------------------|------------------------|-----------------------|-----------------------|-----------------------|
| 1. I seek out information to help me improve my life as a cancer survivor. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2. I make sure the health information I get is trustworthy. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3. I can tell the difference between health information that does and does not apply to me. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4. Health information gives me more control as a cancer survivor. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5. I ignore questionable health information. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6. I try new things to improve my life as a cancer survivor. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7. I don't know enough to help make decisions about my cancer care. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8. I use my skills to solve the problems I face as a cancer survivor. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9. I gather information before making decisions about my cancer care. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10. If I had problems with my job or other responsibilities, I would know where to look for help. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Continued on next page . . .

40813



| | Strongly Disagree 1 | Disagree 2 | Somewhat Disagree 3 | Somewhat Agree 4 | Agree 5 | Strongly Agree 6 |
|--|------------------------|-----------------------|------------------------|-----------------------|-----------------------|-----------------------|
| 11. I weigh my options carefully before making important decisions about my cancer care. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 12. I prepare myself to make decisions about my cancer care. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 13. When it comes to making decisions about my cancer care, I know what my priorities are. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 14. Having information helps me to make decisions about my cancer care. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 15. If a health problem doesn't go away, I look for different ways to manage it. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 16. If I had problems covering the costs of my cancer care, I would know where to look for help. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 17. Sometimes I adjust my provider's recommendations to better fit with my life. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 18. If a treatment is not working, I wait for my provider to make a change. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 19. I ask questions when I don't understand what my provider is telling me. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 20. My provider knows what is best for me. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 21. Sometimes I decide not to follow the advice of my provider. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 22. I don't want my provider to think I am a difficult patient. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 23. If I don't do what my provider asks me to do, I have a good reason. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 24. I feel like I can disagree with my provider. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 25. If a medication is not working, I tell my provider. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 26. I question my provider if I don't agree with his or her recommendations. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 27. I don't talk about a health concern with my provider unless I think there is a solution. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 28. I rarely tell my provider about problems I am having related to cancer. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 29. I know where to get an answer if my provider can't give me one. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Continued on next page . . .

40813

| | Strongly Disagree 1 | Disagree 2 | Somewhat Disagree 3 | Somewhat Agree 4 | Agree 5 | Strongly Agree 6 |
|--|------------------------|-----------------------|------------------------|-----------------------|-----------------------|-----------------------|
| 30. I ask my provider to explain his or her recommendations. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 31. I am not sure where I would go if my provider is not able to answer the questions I have. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 32. I am comfortable asking for a second opinion. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 33. Not following the advice of my provider bothers me. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 34. I know what's best for me medically. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 35. I seek other help for my needs that are not being met by my provider. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 36. I worry that asking for a second opinion would hurt my relationship with my provider. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 37. I have a hard time voicing my preferences to my provider. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 38. I seek out support from other cancer survivors. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 39. I seek out support from friends and family. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 40. Helping other cancer survivors also helps me. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 41. I don't like asking my friends and family for help. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 42. Many of my decisions are based on what's best for my family. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 43. Being there for other cancer survivors is an important part of being a cancer survivor. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 44. When I hear that someone has cancer, I try to reach out to them. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 45. It helps me to know that other cancer survivors have gone through what I am going through. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 46. My friends and family motivate me to get better. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 47. I can balance my needs with the needs of others who depend on me. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 48. I am comfortable telling my friends and family what I need. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 49. I protect my family and friends from my health problems. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Continued on next page . . .

| | Strongly Disagree 1 | Disagree 2 | Somewhat Disagree 3 | Somewhat Agree 4 | Agree 5 | Strongly Agree 6 |
|--|-----------------------------------|-----------------------|-----------------------------------|--------------------------------|-----------------------|--------------------------------|
| 50. Sometimes I have to put myself first. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 51. I feel connected to other cancer survivors. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 52. I support other cancer survivors. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 53. Telling other people my story makes me feel good. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 54. I prefer to deal with my cancer on my own. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 55. I want to give back by helping other cancer survivors. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 56. I try to raise awareness about cancer. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 57. I am comfortable sharing my cancer experience with others. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Instrument Number:

1 1 6 0

Shade circles like this: ●

Not like this: ○

Please use **BLACK** Pen Only!

Study ID:

1

8

5

Patient Self-Advocacy Scale (PSAS)

ID Number:

Administration Date:

(month)

(day)

(year)

Visit Number:

1

2

☐☐

Baseline 2 Weeks

(FOR STAFF USE ONLY)

INSTRUCTIONS:

Please read each of the following statements carefully. Think about what you experienced while having cancer and, if you currently do not have cancer, think about your experiences since you had cancer.

Then, for each statement, fill in the circle that corresponds to the response that best reflects how much you agree or disagree with each statement.

| | Strongly Disagree 1 | Disagree 2 | Neutral 3 | Agree 4 | Strongly Agree 5 |
|--|------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 1. I believe it is important for people with cancer to learn as much as they can about their illnesses and treatments. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2. I actively seek out information on my illnesses. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3. I am more educated about my health than most US citizens. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4. I have full knowledge of the health problems of people like myself (people with cancer). | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5. I don't get what I need from my physician because I am not assertive enough. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6. I am more assertive about my health care needs than most U.S. citizens. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7. I frequently make suggestions to my physicians about my health care needs. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8. If my physician prescribes something I don't understand or agree with, I question it. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9. Sometimes there are good reasons not to follow the advice of a physician. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10. Sometimes I think I have a better grasp of what I need medically than my doctor does. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 11. If I am given a treatment by my physician that I don't agree with, I am likely not to take it. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 12. I don't always do what my physician or health care worker has asked me to do. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Brashers, D.E., Haas, S.M., & Neidig, J.L. (1999). The patient self-advocacy scale: Measuring patient involvement in health care decision-making interactions. *Health Communication*, 11(2), 97-121.

21648





Health Information Orientation Scale (HIOS)

ID Number:

| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

Administration Date:

| | |
|--|--|
| | |
|--|--|

(month)

| | |
|--|--|
| | |
|--|--|

(day)

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

(year)

Visit Number:

1

2

☐☐

Baseline 2 Weeks

(FOR STAFF USE ONLY)

INSTRUCTIONS:

Think about the following statements in terms of how you react when you are dealing with health concerns.

Then, for each statement, fill in the circle that corresponds to how true each statement is for you, choosing only ONE response per line.

| | Not at all true 0 | A little bit true 1 | Somewhat true 2 | Quite a bit true 3 | Very much true 4 |
|--|-------------------------|---------------------------|-----------------------|--------------------------|------------------------|
| 1. I like to gather as much information as I can before I make a decision. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2. I have difficulty making sense of information from multiple sources. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3. I fear that I might find out something I don't want to know. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4. I like to review information multiple times before making a decision. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5. I like to make decisions quickly. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6. After I've made a decision, I continue to look for related information. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7. I think it's the doctor's job to deal with information, not mine. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8. I feel overwhelmed by the amount of information available. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

DuBenske, L. L., Burke-Beckjord, E., Hawkins, R. P., & Gustafson, D. H. (2009). Psychometric evaluation of the Health Information Orientation Scale: a brief measure for assessing health information engagement and apprehension. *Journal of Health Psychology, 14*(6), 721-730.

Instrument Number:

1 1 6 2

Shade circles like this: ●

Not like this: ○

Please use **BLACK** Pen Only!

Study ID:

1 8 5

International Personality Inventory Pool (IPIP)

ID Number:

Administration Date:

(month)

(day)

(year)

Visit Number:

1

2

☐☐

Baseline 2 Weeks

(FOR STAFF USE ONLY)

INSTRUCTIONS:

This questionnaire contains phrases that describe people's behaviors. Please use the rating scale below to indicate how accurately each statement describes you. Describe yourself as you generally are now, not as you wish to be in the future.

Describe yourself as you honestly see yourself, in relation to other people you know of the same sex as you, and roughly your same age. So that you can describe yourself in an honest manner, your responses will be kept in absolute confidence.

Please read each statement carefully, and then fill in the circle that corresponds to your response.

| | Very inaccurate 1 | Moderately inaccurate 2 | Neither inaccurate nor accurate 3 | Moderately accurate 4 | Very accurate 5 |
|---|-------------------------|-------------------------------|--|-----------------------------|-----------------------|
| 1. I believe in the importance of art. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2. I am not interested in abstract ideas. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3. I have a vivid imagination. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4. I tend to vote for liberal political candidates. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5. I carry the conversation to a higher level. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6. I avoid philosophical discussions. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7. I enjoy hearing new ideas. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8. I do not like art. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9. I do not enjoy going to art museums. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10. I tend to vote for conservative political candidates. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 11. I am always prepared. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 12. I make plans and stick to them. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 13. I shirk my duties. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 14. I don't see things through. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 15. I pay attention to details. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 16. I get chores done right away. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 17. I carry out my plans. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 18. I waste my time. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 19. I find it difficult to get down to work. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 20. I do just enough work to get by. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Goldberg, L. R. (1999). A broad-bandwidth, public domain, personality inventory measuring the lower-level facets of several five-factor models, *Personality Psychology in Europe*. I. D. Mervielde, I. De Fruyt, F. & Ostendorf, F. Tilburg (Eds.), The Netherlands, Tilburg University Press, 7: 7-28.

22558

Instrument Number:

1 1 6 3

Shade circles like this: ●

Not like this: ○

Please use **BLACK** Pen Only!

Study ID:

1

8

5

M.D. Anderson Symptom Inventory (MDASI)

ID Number:

Administration Date:

(month)

(day)

(year)

Visit Number:

1

2

☐☐

Baseline 2 Weeks

(FOR STAFF USE ONLY)

INSTRUCTIONS:

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.

For each symptom listed below, fill in one circle that corresponds to its severity in the last 24 hours, using a scale from "0" (the symptom was "Not present") to "10" (the symptom was "As bad as you can imagine").

1. How severe are your symptoms in the last 24 hours?

| | Not present | | | | | | | | | | | As bad as you can imagine |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|---------------------------|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
| a. Your pain at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| b. Your fatigue (tiredness) at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| c. Your nausea at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| d. Your disturbed sleep at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| e. Your feelings of being depressed (upset) at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| f. Your shortness of breath at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| g. Your problem with remembering things at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| h. Your problem with lack of appetite at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| i. Your feeling drowsy (sleepy) at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| j. Your having a dry mouth at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| k. Your feeling sad at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| l. Your vomiting at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| m. Your numbness or tingling at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |

22881



INSTRUCTIONS:

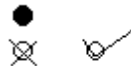
Now, we are asking you to rate how your symptoms possibly interfered with your life in the last 24 hours.

For each symptom listed below, fill in one circle that corresponds to its interference in your life in the last 24 hours, using a scale from "0" (the symptom "Did not interfere") to "10" (the symptom "Interfered completely").

2. How have your symptoms interfered with your life in the last 24 hours?

| | Did not interfere | | | | | | | | | | Interfered completely | |
|---------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|--|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
| a. General activity? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| b. Mood? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| c. Work (including around the house)? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| d. Relations with other people? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| e. Walking? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| f. Enjoyment of life? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |

Cleeland, C. S., T. R. Mendoza, Wang, X. S., Chou, C., Harle, M. T., Morrissey, M., & Engstrom, M. C. (2000). Assessing symptom distress in cancer patients: The M. D. Anderson Symptom Inventory. *Cancer*, 89(7), 1634-1646.

Please use **BLACK** Pen Only!

Healthcare Utilization

ID Number:

| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

Administration Date:

| | | | | | | | | | |
|---------|--|---|-------|--|---|--------|--|--|--|
| | | / | | | / | | | | |
| (month) | | | (day) | | | (year) | | | |

Visit Number:

| | |
|-----------------------|-----------------------|
| 1 | 2 |
| <input type="radio"/> | <input type="radio"/> |

Baseline 2 Weeks

(FOR STAFF USE ONLY)

INSTRUCTIONS:

Please indicate the number of times you have used health care services in the past 3 months.

1. Were you admitted to a hospital in the past 3 months?

☐ 1 Yes ☐ 2 No ----> SKIP to Question 2 on the next page

How many times:

| | |
|--|--|
| | |
|--|--|

a. First time:b. Second time:

If not hospitalized a second time,
fill in this circle: ☐ N/A (-2)

c. Third time:

If not hospitalized a third time,
fill in this circle: ☐ N/A (-2)
then,

SKIP to Question 2 on the next page

1. How many nights did you
spend in the hospital?

| | |
|--|--|
| | |
|--|--|

 (nights)

2. Was the admission related to
your cancer or its treatment?

☐ 1 Yes ☐ 2 No ☐ 3 Not sure

3. Were you admitted to the ICU?

☐ 1 Yes ----> a. For how many
nights:
☐ 2 No

| | |
|--|--|
| | |
|--|--|

 (nights)

4. Name of the hospital:

5. In what city is it located:

1. How many nights did you
spend in the hospital?

| | |
|--|--|
| | |
|--|--|

 (nights)

2. Was the admission related to
your cancer or its treatment?

☐ 1 Yes ☐ 2 No ☐ 3 Not sure

3. Were you admitted to the ICU?

☐ 1 Yes ----> a. For how many
nights:
☐ 2 No

| | |
|--|--|
| | |
|--|--|

 (nights)

4. Name of the hospital:

5. In what city is it located:

1. How many nights did you
spend in the hospital?

| | |
|--|--|
| | |
|--|--|

 (nights)

2. Was the admission related to
your cancer or its treatment?

☐ 1 Yes ☐ 2 No ☐ 3 Not sure

3. Were you admitted to the ICU?

☐ 1 Yes ----> a. For how many
nights:
☐ 2 No

| | |
|--|--|
| | |
|--|--|

 (nights)

4. Name of the hospital:

5. In what city is it located:

FOR
OFFICE
USE
ONLY4.
5.

| | |
|--|--|
| | |
| | |

FOR
OFFICE
USE
ONLY4.
5.

| | |
|--|--|
| | |
| | |

FOR
OFFICE
USE
ONLY4.
5.

| | |
|--|--|
| | |
| | |

2. Have you visited an Emergency Department in the past 3 months?

☐ 1 Yes ☐ 2 No ----> **SKIP to Question 3 on the next page**

How many times:

| | |
|--|--|
| | |
|--|--|

a. First time:

b. Second time:

c. Third time:

If not applicable, fill in this circle: ☐ N/A (-2)

If not applicable, fill in this circle: then, ☐ N/A (-2)

SKIP to Question 3 on the next page

1. What were the approximate dates for the first ER visit?

a.

 /

 /

(month) (day) (year)

through

b.

 /

 /

(month) (day) (year)

2. Was the admission related to your cancer or its treatment?

☐ 1 Yes ☐ 2 No ☐ 3 Not sure

3. Name of the hospital:

4. In what city is it located:

1. What were the approximate dates for the second ER visit?

a.

 /

 /

(month) (day) (year)

through

b.

 /

 /

(month) (day) (year)

2. Was the admission related to your cancer or its treatment?

☐ 1 Yes ☐ 2 No ☐ 3 Not sure

3. Name of the hospital:

4. In what city is it located:

1. What were the approximate dates for the third ER visit?

a.

 /

 /

(month) (day) (year)

through

b.

 /

 /

(month) (day) (year)

2. Was the admission related to your cancer or its treatment?

☐ 1 Yes ☐ 2 No ☐ 3 Not sure

3. Name of the hospital:

4. In what city is it located:

FOR
OFFICE
USE
ONLY

3.
4.

| | |
|--|--|
| | |
| | |

FOR
OFFICE
USE
ONLY

3.
4.

| | |
|--|--|
| | |
| | |

FOR
OFFICE
USE
ONLY

3.
4.

| | |
|--|--|
| | |
| | |

3. Do you have a Primary Care physician?

☐ 1 Yes ☐ 2 No ----> **SKIP to Question 4 below**



a. What is your Primary Care physician's name?

(First Name)

(Last Name)

b. In what city is he/she located: _____

c. Have you visited your Primary Care physician in the past 3 months?

☐ 1 Yes ----> ☐ 2 No

1. How many times?

| | |
|--|--|
| | |
|--|--|

2. Were the visits related to your cancer or its treatment?

☐ 1 Yes -----> ☐ 2 No
☐ 3 Not sure

3. How many of the visits were related to your cancer or its treatment?

| | |
|--|--|
| | |
|--|--|

FOR
OFFICE
USE
ONLY

a.

| | |
|--|--|
| | |
|--|--|

b.

| | |
|--|--|
| | |
|--|--|

4. Has a nurse from a home care service (Visiting Nurse) provided care to you in your home in the past 3 months?

☐ 1 Yes ☐ 2 No



a. How many times:

| | |
|--|--|
| | |
|--|--|

b. Were the visits related to your cancer or its treatment?

☐ 1 Yes -----> ☐ 2 No
☐ 3 Not sure

c. How many of the visits were related to your cancer or its treatment?

| | |
|--|--|
| | |
|--|--|

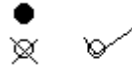


Instrument Number:

1 1 6 5

Shade circles like this: ●

Not like this: ○

Please use **BLACK** Pen Only!

Study ID:

1 8 5

Patient Activation Measure (PAM)

ID Number:

Administration Date:

(month)

(day)

(year)

Visit Number:

1

2

☐
☐

Baseline 2 Weeks

(FOR STAFF USE ONLY)

INSTRUCTIONS:

For each statement, fill in the circle that indicates how much you agree or disagree with the statement.

| | Strongly Disagree 1 | Disagree 2 | Agree 3 | Strongly Agree 4 | Not Applicable (-2) |
|---|---------------------------|-----------------------|-----------------------|------------------------|---------------------------|
| 1. When all is said and done, I am the person who is responsible for taking care of my health. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2. Taking an active role in my own health care is the most important thing that affects my health. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3. I am confident I can help prevent or reduce problems associated with my health. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4. I know what each of my prescribed medications does. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5. I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6. I am confident that I can tell a doctor concerns I have even when he or she does not ask. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7. I am confident that I can follow through on medical treatments I may need to do at home. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8. I understand my health problems and what causes them. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9. I know what treatments are available for my health problems. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 11. I know how to prevent problems with my health. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 12. I am confident I can figure out solutions when new problems arise with my health. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 13. I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Hibbard, J.H., Stockard, J., Mahoney, E.R., & Tusler, M. (2004). Development of the Patient Activation Measure (PAM): Conceptualizing and measuring activation in patients and consumers. *Health Service Research, 39*(4 Pt 1), 1005-1026.

23358



Interpersonal Support Evaluation List

ID Number:

Administration Date:

(month)

(day)

(year)

Visit Number:

1

☐

2

☐

Baseline 2 Weeks

(FOR STAFF USE ONLY)

INSTRUCTIONS:

This scale is made up of a list of statements each of which may or may not be true about you.

If you are absolutely certain a statement is true about you, choose "Definitely True." If you think it is true but you are not absolutely certain, choose "Probably True."

Similarly, if you are absolutely certain a statement is false, choose "Definitely False." If you think it is false but you are not absolutely certain, choose "Probably False."

| | Definitely False 1 | Probably False 2 | Probably True 3 | Definitely True 4 |
|---|-----------------------|-----------------------|-----------------------|-----------------------|
| 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. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2. I feel that there is no one I can share my most private worries and fears with. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3. If I were sick, I could easily find someone to help me with my daily chores. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4. There is someone I can turn to for advice about handling problems with my family. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 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. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6. When I need suggestions on how to deal with a personal problem, I know someone I can turn to. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7. I don't often get invited to do things with others. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 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.). | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9. If I wanted to have lunch with someone, I could easily find someone to join me. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10. If I was stranded 10 miles from home, there is someone I could call who could come and get me. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 11. If a family crisis arose, it would be difficult to find someone who could give me good advice about how to handle it. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 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. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |



0 0 7

1 8 5

SOCIODEMOGRAPHIC QUESTIONNAIRE

(Short Form)

Center for Research and Evaluation
University of Pittsburgh School of Nursing

ID Number:

| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

Administration Date:

| | |
|--|--|
| | |
|--|--|

(month)

| | |
|--|--|
| | |
|--|--|

(day)

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

(year)

(FOR STAFF USE ONLY)

Shade circles like this:

Not like this:Please use **BLACK** Pen Only!

For optimum accuracy, it is recommended that characters be written block style without touching the sides of the blocks, such as in the following example.

Place only one letter or one number in each box as shown . . .

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|

The following information requested is important in helping us understand more about you and your health. The information that you provide will be used for research purposes **ONLY** and will be held in confidence.

Please do not skip any questions. Thank you!

1. What is your sex?

- ☐ 1 Male
☐ 2 Female

2. What is your date of birth?

| | | | | | | | | | |
|---------|--|---|-------|--|---|--------|--|--|--|
| | | / | | | / | | | | |
| (month) | | | (day) | | | (year) | | | |

3. What was your age at your last birthday?

| | | |
|--|--|--|
| | | |
|--|--|--|

 (years)

4. Which one of the following best describes your *current* relationship status?

- ☐ 1 Never married
- ☐ 2 Currently married
- ☐ 3 Living with partner/significant other
- ☐ 4 Widowed
- ☐ 5 Separated
- ☐ 6 Divorced
- ☐ 7 Other; specify ----> _____

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

5. How many years have you been in your *current* relationship:
(If *less* than one year, write in "00")

| | |
|--|--|
| | |
|--|--|

(years)

(-2)

☐

N/A;

***I am not currently
in a relationship***

Given the ever-increasing ethnic diversity of the population in the United States of America, the following questions are being asked to gather information on your racial/ethnic background . . .

6. What is your race:

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

- ☐ 1 Yes
- ☐ 2 No
- ☐ 3 Unknown

b. Please choose the one category that best applies to you . . .

- ☐ 1 White
- ☐ 2 Black or African American
- ☐ 3 American Indian; please specify: _____
- ☐ 4 Alaska Native
- ☐ 5 Native Hawaiian or other Pacific Islander
- ☐ 6 Asian
- ☐ 7 Other; specify: _____
- ☐ 8 Unknown

c. Are you of more than one racial/ethnic background?

- ☐ 1 Yes -----> Please specify all categories that apply to you
- ☐ 2 No
- ☐ 3 Unknown

(1)

- ☐ 1 White
- ☐ 2 Black or African American
- ☐ 3 American Indian
- ☐ 4 Alaska Native
- ☐ 5 Native Hawaiian or other Pacific Islander
- ☐ 6 Asian
- ☐ 7 Other



7. Is English your first language?

☐ 1 Yes

☐ 2 No ----> a. What was your first language:

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

8. We'd like to know where you live. Please enter the 5-digit ZIPCODE of your PRIMARY RESIDENCE: (where you live most of the time)

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

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

- ☐ 1 Urban, large city
☐ 2 Urban, small city
☐ 3 Suburb of large city
☐ 4 Suburb of small city
☐ 5 Rural, farm
☐ 6 Rural, non-farm
☐ 7 Other; specify --> _____

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

11. Select the *highest* diploma or degree you have completed:

- ☐ 1) Grade school [grades 1-8]
☐ 2) High school [grades 9-12]
☐ 3) Earned G.E.D. [Graduate Equivalent Diploma]
☐ 4) Vocational/Technical school certificate
☐ 5) 2-year college [Associate's level]
☐ 6) 4-year college [Bachelor's level]
☐ 7) Graduate school [Master's level]
☐ 8) Professional school [i.e., MD; D.V.M.; JD]
☐ 9) Graduate school [Doctoral level, i.e., PhD; Ed.D.]
☐ 10) Unknown

12. What is your *current* employment status?

- ☐ 1 Full time (working at least 35 hours a week)
☐ 2 Part time (working less than 35 hours a week)
☐ 3 Laid off or unemployed, but looking for work
☐ 4 Laid off or unemployed, but not looking for work
☐ 5 Retired, not working at all
☐ 6 Retired, but working part or full time
☐ 7 Disabled, unable to work
☐ 8 Full time homemaker
☐ 9 Other; specify: _____

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

10. How many years of formal education have you completed?

(For example, if you completed high school in the USA, you would have had 12 years of education.)

| | |
|--|--|
| | |
|--|--|

 (years)

13. Are you *currently* a student?

- ☐ 1 Yes ----> What is your student status?
☐ 2 No
☐ 1 Part time
☐ 2 Full time



14. Have you ever been employed?

- ☐ 1 Yes ---->
☐ 2 No

↓

SKIP
to
Question
15

Are you currently employed?

- ☐ 1 Yes

↓

a. What is your *primary* occupation? (*the one where you work the most hours per week*):

Job title: _____

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

b. Has this been your *primary* occupation for most of your working life?

- ☐ 1 Yes

- ☐ 2 No ---->

c. What was your *primary* occupation?

Job title: _____

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

d. Did you change occupations because of health reasons?

- ☐ 1 Yes ☐ 2 No

↓

Please select all reasons that apply to you

(1)

- ☐ 1. I changed because of the **physical** demands of my job.
- ☐ 2. I changed because of the **mental** demands of my job.
- ☐ 3. Other; specify:

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

- ☐ 2 No

↓

a. When you were employed, what was your *primary* occupation? (*the one where you worked the most hours per week*):

Job title: _____

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

b. When was the last year that you were employed:

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

c. Did you stop working because of health reasons?

- ☐ 1 Yes ☐ 2 No

↓

Please select all reasons that apply to you

(1)

- ☐ 1. I changed because of the **physical** demands of my job.
- ☐ 2. I changed because of the **mental** demands of my job.
- ☐ 3. Other; specify:

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

15. Do you have any children?

- ☐ 1 Yes ---->
- ☐ 2 No

a. How many:

| | |
|--|--|
| | |
|--|--|

16. Including yourself, how many people currently live in your household?

a.

| | |
|--|--|
| | |
|--|--|

(adults)

b.

| | |
|--|--|
| | |
|--|--|

(children under age 18)

If NONE, enter 00.

17 a.) Do you have a religious preference?

- ☐ 1 Yes ---->
- ☐ 2 No

1. Please specify:
(Choose **ONE** response only.)

- ☐ 1 Christianity
- ☐ 2 Judaism
- ☐ 3 Islam
- ☐ 4 Hinduism
- ☐ 5 Buddhism
- ☐ 6 Other; specify: _____

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

- ☐ 1 Never
- ☐ 2 Sometimes
- ☐ 3 Frequently
- ☐ 4 Always

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

b.) How important is religion in your life?

- ☐ 1 Not at all ☐ 2 Somewhat ☐ 3 Extremely

18. Do you have health care insurance?

☐ 1 Yes ----->

☐ 2 No



**SKIP
to
Question
19**

a. What type(s) of insurance do you have?

(Please choose ALL that apply.)

⁽¹⁾

☐ 1 Medicare

☐ 2 Medicaid

☐ 3 Supplemental Security Income (SSI)

☐ 4 Veterans Administration

☐ 5 Disability income

☐ 6 Private health insurance

☐ 7 Other; specify: _____

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

b. Does your insurance cover the cost of medication?

☐ 1 Yes, all

☐ 2 Yes, some of the cost -----> Please specify in what way:

☐ 3 No

☐ 4 Unknown

| |
|-------|
| _____ |
| _____ |
| _____ |

c. Does your insurance cover the cost of health care?

☐ 1 Yes, all

☐ 2 Yes, some of the cost -----> Please specify in what way:

☐ 3 No

☐ 4 Unknown

| |
|-------|
| _____ |
| _____ |
| _____ |

The following questions concern family and individual income. We recognize the sensitive nature of these questions. This information is important in order to understand the economic impact of the chronic illness on the family and individual. Your answers will be held in strict confidence.

19. What are all the sources of your own total gross annual income (before taxes and deductions):

(1)

- ☐ a. Wages, salaries, commissions, bonuses, or tips from all jobs
- ☐ b. Self-employment income from tax or non-farm business
- ☐ c. Interest, dividend, net rental income, royalty income, or income from estates or trusts
- ☐ d. Social security or railroad retirement
- ☐ e. Supplemental Security Income or other public assistance income
- ☐ f. Retirement, survivor, or disability pensions
- ☐ g. Workers Compensation
- ☐ h. Other; specify: _____

(for office use only)

| | | |
|--|--|--|
| | | |
|--|--|--|

20. If you are currently employed, please select your own gross annual income from wages only (before taxes and deductions):

- | | |
|--|---|
| <input type="radio"/> (1) Under \$10,000 | <input type="radio"/> (8) \$60,000 to \$69,999 |
| <input type="radio"/> (2) \$10,000 to \$14,999 | <input type="radio"/> (9) \$70,000 to \$79,999 |
| <input type="radio"/> (3) \$15,000 to \$19,999 | <input type="radio"/> (10) \$80,000 to \$99,999 |
| <input type="radio"/> (4) \$20,000 to \$29,999 | <input type="radio"/> (11) \$100,000 to \$150,000 |
| <input type="radio"/> (5) \$30,000 to \$39,999 | <input type="radio"/> (12) Over \$150,000 |
| <input type="radio"/> (6) \$40,000 to \$49,999 | <input type="radio"/> (13) Unknown |
| <input type="radio"/> (7) \$50,000 to \$59,999 | <input type="radio"/> (14) Refused |

(-2)

☐

N/A

(not employed)

21. What is the total gross annual income for your household from all sources (before taxes and deductions):

- | | |
|--|---|
| <input type="radio"/> (1) Under \$10,000 | <input type="radio"/> (8) \$60,000 to \$69,999 |
| <input type="radio"/> (2) \$10,000 to \$14,999 | <input type="radio"/> (9) \$70,000 to \$79,999 |
| <input type="radio"/> (3) \$15,000 to \$19,999 | <input type="radio"/> (10) \$80,000 to \$99,999 |
| <input type="radio"/> (4) \$20,000 to \$29,999 | <input type="radio"/> (11) \$100,000 to \$150,000 |
| <input type="radio"/> (5) \$30,000 to \$39,999 | <input type="radio"/> (12) Over \$150,000 |
| <input type="radio"/> (6) \$40,000 to \$49,999 | <input type="radio"/> (13) Unknown |
| <input type="radio"/> (7) \$50,000 to \$59,999 | <input type="radio"/> (14) Refused |

22. Does your *current* household income meet your basic needs (such as food, housing, utilities, and health care)?

- ☐ 1 Yes
- ☐ 2 No

36132





Health History Questionnaire

(1) With what type of cancer(s) have you been diagnosed?

If you have had multiple types of cancer, please fill out the remaining questionnaires about your first cancer diagnosis.

(2) What stage was your cancer when it was diagnosed?

- ☐ DCIS or pre-cancer
- ☐ Stage I
- ☐ Stage II
- ☐ Stage III
- ☐ Stage IV
- ☐ Unknown
- ☐ Not sure

(3) When were you diagnosed with cancer? (MM/DD/YYYY)

(4) Have you had any recurrences?

☐ Yes

If YES, how many recurrences have you had?

☐ No

(5) Are you currently receiving treatment?

☐ Yes

☐ No

If **YES**, what kind of treatments are you currently receiving? (Select all that apply.)

- ☐ Chemotherapy
☐ Radiation therapy
☐ Surgery
☐ Adjuvant therapy
☐ Maintenance therapy
☐ Other _____

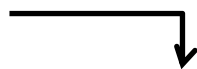
(6) What past treatments have you had for your cancer (if different from what you are currently receiving)?

Select all that apply. Please type in the approximate dates that you received this/these treatment(s).)

- ☐ Chemotherapy Dates (approximate): _____
☐ Radiation therapy Dates (approximate): _____
☐ Surgery Dates (approximate): _____
☐ Adjuvant therapy Dates (approximate): _____
☐ Maintenance therapy Dates (approximate): _____
☐ Other _____ Dates (approximate): _____

(7) Were you diagnosed with more than one type of cancer?

- ☐ Yes
☐ No



If yes, when were you diagnosed with the other types of cancer you have had? What types of treatment did you receive?
(Any details you give us are welcome!)



Some Final Questions...

1. Where did you hear about this study?

- ☐ CTSI Research Participant Registry (University of Pittsburgh)
☐ Pennsylvania Tumor Registry
☐ National Ovarian Cancer Coalition
☐ American Cancer Society (Cancer Survivors Network)
☐ Cancer Caring Center
☐ Urban League of Greater Pittsburgh
☐ African American Women's Speakers Bureau
☐ Our Clubhouse (formerly Gilda's Club of Western Pennsylvania)
☐ Other: (Please describe) _____

2. Would you like to see the results of this study?

- ☐ Yes
☐ No

3. How much experience do you have managing a complex illness (your own or someone else's) in addition to your own cancer? Please describe.

4. Would you be open to being contacted in the future for other research studies regarding self-advocacy and cancer?

- ☐ Yes
☐ No

5. Is there anything else that you would like us to know about yourself or your answers to this survey?

You have completed all questionnaires.

Thank you for your time and thought!

If you have any additional thoughts you want us
to know, please add them here:

If you have any questions or concerns,
please contact the study's principle investigator,
Teresa Hagan at 412-624-4101 or selfadvocacystudy@gmail.com.



APPENDIX B

FINAL FSACS SCALE

Female Self-Advocacy in Cancer Survivorship Scale

Please read each of the following statements carefully. Think about your experiences having cancer and (if you do not currently have cancer) your time since cancer.

Circle the number the best reflects how much you agree or disagree with each statement.

**START
HERE** 

1. I use my skills to solve the problems I face as a cancer survivor.

| | | | | | |
|----------------------|----------|----------------------|-------------------|----------|-------------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

2. I gather information before making decisions about my cancer care.

| | | | | | |
|----------------------|----------|----------------------|-------------------|----------|-------------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

3. I weigh my options carefully before making important decisions about my cancer care.

| | | | | | |
|----------------------|----------|----------------------|-------------------|----------|-------------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

4. I prepare myself to make decisions about my cancer care.

| | | | | | |
|----------------------|----------|----------------------|-------------------|----------|-------------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

5. When it comes to making decisions about my cancer care, I know what my priorities are.

| | | | | | |
|----------------------|----------|----------------------|-------------------|----------|-------------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

6. I am comfortable asking for a second opinion.

| | | | | | |
|----------------------|----------|----------------------|-------------------|----------|-------------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

7. I ask questions when I don't understand what my provider is telling me.

| | | | | | |
|----------------------|----------|----------------------|-------------------|----------|-------------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

8. I question my provider if I don't agree with his or her recommendations.

| | | | | | |
|-------------------|----------|-------------------|----------------|----------|----------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

9. I don't talk about a health concern with my provider unless I think there is a solution.*

| | | | | | |
|-------------------|----------|-------------------|----------------|----------|----------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

10. I rarely tell my provider about the problems I am having.*

| | | | | | |
|-------------------|----------|-------------------|----------------|----------|----------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

11. I know where to get an answer if my provider can't give me one.

| | | | | | |
|-------------------|----------|-------------------|----------------|----------|----------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

12. I ask my provider to explain his or her recommendations.

| | | | | | |
|-------------------|----------|-------------------|----------------|----------|----------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

13. I seek out support from other cancer survivors.

| | | | | | |
|-------------------|----------|-------------------|----------------|----------|----------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

14. I seek out support from friends and family.

| | | | | | |
|-------------------|----------|-------------------|----------------|----------|----------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

15. Helping other cancer survivors also helps me.

| | | | | | |
|-------------------|----------|-------------------|----------------|----------|----------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

16. When I hear someone has cancer, I try to reach out to them.

| | | | | | |
|-------------------|----------|-------------------|----------------|----------|----------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |

FSACS Scale – 20 item

disagree

disagree

agree

agree

17. It helps me to know that other cancer survivors have gone through what I am going through.

1

2

3

4

5

6

Strongly
disagree

Disagree

Somewhat
disagree

Somewhat
agree

Agree

Strongly
agree

18. Telling other people my story makes me feel good.

1

2

3

4

5

6

Strongly
disagree

Disagree

Somewhat
disagree

Somewhat
agree

Agree

Strongly
agree

19. I try to raise awareness about cancer.

1

2

3

4

5

6

Strongly
disagree

Disagree

Somewhat
disagree

Somewhat
agree

Agree

Strongly
agree

20. I am comfortable sharing my cancer experience with others.

1

2

3

4

5

6

Strongly
disagree

Disagree

Somewhat
disagree

Somewhat
agree

Agree

Strongly
agree

*** Reverse=scored item**

APPENDIX C

HUMAN SUBJECTS APPROVALS AND CONSENTS

Informational Script

Title: Content Validity of the Self-Advocacy in Cancer Survivorship (SACS) Scale

PI: Teresa Hagan

The purpose of this research study is to assess the validity of a questionnaire of self-advocacy among women with a history of cancer (the Self-Advocacy in Cancer Survivorship (SACS) Scale). Validity means that this questionnaire is measuring what it is supposed to measure. We are asking 8 individuals who are experts in self-advocacy, oncology, and/or women's health to review our proposed measure of self-advocacy. You are being asked to participate in this study because your expertise fits in these categories and allows you to give expert opinion concerning this measure of self-advocacy. If you chose to participate, we will send you three documents:

1. A brief introduction to the SACS Scale
2. A copy of the SACS Scale
3. A survey about your opinion the SACS Scale

You will review our proposed measure. Then you will complete the survey about the proposed measure. Finally, you will return the survey to Teresa in a pre-stamped, pre-addressed envelope. This study should take a total of approximately **90 minutes**. Reading the introduction will take about 15 minutes. Reading the scale will take about 30 minutes. Responding to the survey will take about 45 minutes. These times may vary depending on how much time you take in reviewing the measure and preparing your response.

There are no risks or benefits to participating in this study. No personal or sensitive information will be collected. Your responses to the survey are confidential and will not be kept in a locked file cabinet at the School of Nursing. To ensure confidentiality, the survey will be completely anonymously. You will not receive any payment for participation. Your participation in this research study is completely voluntary. You may withdraw at any time. This study is being conducted by Teresa Hagan. She can be reached at 412-334-6457 if you have any questions or concerns.



University of Pittsburgh

*School of Nursing
Acute/Tertiary Care Department*

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Establishment of the Reliability of the Self-Advocacy in Cancer Survivorship Scale

PRINCIPAL INVESTIGATOR:

Teresa Hagan, BSN, RN
Graduate Student
University of Pittsburgh School of Nursing
336 Victoria Building, 3500 Victoria Street
Telephone: 412-334-6457

CO-INVESTIGATORS:

Heidi Donovan, PhD, RN
Associate Professor, Department of Acute and Tertiary Care
University of Pittsburgh School of Nursing
336 Victoria Building, 3500 Victoria Street
Telephone: 412-624-2699

Susan Cohen, DSN, APRN, FAAN
Associate Professor, Department of Health Promotion and Development
University of Pittsburgh School of Nursing
440 Victoria Building, 3500 Victoria Street
Telephone: 412-624-5345

CONSULTANTS:

Margaret Rosenzweig, PhD, CRNP-C, AOCN
Associate Professor, Department of Acute and Tertiary Care
University of Pittsburgh School of Nursing
336 Victoria Building, 3500 Victoria Street
Telephone: 412-383-8839

Clement Stone, PhD
Professor, Department of Education
University of Pittsburgh School of Education
5920 Wesley W. Posvar Hall, 230 South Bouquet Street
Telephone: 412-624-9359

SOURCE OF SUPPORT:

NINR F31 NR01466-01A1
Sigma Theta Tau International/Rosemary Crisp Berkel Research Award
Nightingale Awards of Pennsylvania PhD Award

Why is this research being done?

You are being asked to participate in a research study. We are studying a measurement tool to assess self-advocacy among female cancer survivors. Self-advocacy is a term that describes how well someone is able to stand up for their values, priorities, and beliefs. Right now, there is no measurement tool for self-advocacy for female cancer survivors. This study will measure the reliability (or consistency) of a questionnaire that can measure self-



advocacy among female cancer survivors.

Who is being asked to take part in this research study?

You are being invited to take part in this research study because you are a female with a history of cancer.

People invited to participate in this study must be at least 18 years old, female, have a history of cancer (that has been diagnosed after the age of 18), and be able to complete the questionnaires in English. You can not have a diagnosis of basal cell carcinoma or cervical intraepithelial neoplasia stage 1. The study is being performed on a total of 40 individuals in three different medical centers and four cancer and advocacy organizations in Pittsburgh.

What procedures will be performed for research purposes?

If you decide to take part in this research study, you will undergo the following procedures that are not part of your standard medical care:

Screening Procedures:

You have already undergone screening to participate in this research study. You have indicated that you meet the following inclusion and exclusion criteria (listed above in "Who is being asked to take part in this research study" section).

Research Study Procedures:

If you qualify to take part in this research study, you will undergo the procedures listed below. These procedures will take place in a private area in the clinic or organization.

You will be asked to complete a set of questionnaires today and 2 weeks from today.

Questionnaires include a demographic questionnaire, basic health information, and self-advocacy among people with cancer.

- i. **Today:** You will complete the first set of questionnaires the same day as you sign this consent form (today):
 1. After you complete the first set of questionnaires, you will be asked five short questions about how you answered one of the questionnaires and if you had problems completing this questionnaire.
- ii. **Two Weeks from Today:** You will complete the second set of questionnaires 2 weeks from today. It is the same set of questionnaires as before.
 1. After you finish completing the first set of questionnaires today, the Principal Investigator (Ms. Hagan) will provide you a copy of the second questionnaire and instructions of when and how to complete the questionnaires. You will also be given instructions of how to return the completed questionnaires, along with a pre-stamped, pre-addressed envelope.
 2. Ms. Hagan will call you to remind to complete and return the second questionnaires 2 days before the due date.
 3. Ms. Hagan will send reminder postcards to you to complete and return the questionnaires 3 and 5 days after the due date if the questionnaires are not received.

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. The major potential risk is a breach of confidentiality, but we will do everything possible to protect your privacy. To reduce the likelihood of a breach of confidentiality

To protect your privacy, only Ms. Hagan and members of the research team will be aware of your participation in this research study. All information will be identified only by a code or case number. The information linking these case numbers with your identity will be kept separate from the research records. 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.

Although we will do everything in our power to protect your privacy and the confidentiality of your records, just as with the use of your medical information for health care purposes, we cannot guarantee the privacy of your research records. Authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office may review your data for the purpose of monitoring the conduct of this study

2. Another possible risk of this research study may include stress from having to complete the questionnaires. It is expected to take between 40 and 60 minutes total for each set of questionnaires. (The questionnaires will take 30 to 45 minutes to complete. The interview will take between 10 and 15 minutes.) To reduce the stress, you will be allowed to take breaks during this time as often as needed. You may stop participating at any time.

What are possible benefits from taking part in this study?

You will receive no direct benefit from taking part in this research study. The creation and use of this measurement tool may benefit female cancer survivors in the future, but will have no direct benefit to you.

Will I be paid if I take part in this research study?

You will receive a \$20 gift card for your time and effort in taking part in this research study. You will receive this gift card after completing and returning both sets of questionnaires to Ms. Hagan.

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept strictly confidential. 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 will be indicated by a case number rather than by your name, and the information linking these case 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 in other research studies examining the validity of this questionnaire. 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.

Will this research study involve the use or disclosure of my identifiable medical information?

No.



Is my participation in this research study voluntary?

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study. Any information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you decide you no longer wish to participate after you have signed the consent form, you should contact Ms. Hagan (412-334-6457). Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh. If you would like additional information, you may contact the Research Office at 412-692-5551. Questions about your rights as a research participant can be answered by the Human Subject Protection Advocate at the University of Pittsburgh IRB Office- 866-212-2668.

If I agree to take part in this research study, can I be removed from the study without my consent?

You will not be removed from this study without your consent.



VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Participant's Signature

Printed Name of Participant

Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise."

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date





University of Pittsburgh

School of Nursing

Acute/Tertiary Care Department

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Establishment of the Validity of the Female Self-Advocacy in Cancer Survivorship Scale

PRINCIPAL INVESTIGATOR:

Teresa Hagan, BSN, RN
Graduate Student
University of Pittsburgh School of Nursing
336 Victoria Building, 3500 Victoria Street
Telephone: 412-624-4101

CO-INVESTIGATORS:

Heidi Donovan, PhD, RN
Associate Professor, Department of Acute and Tertiary Care
University of Pittsburgh School of Nursing
336 Victoria Building, 3500 Victoria Street
Telephone: 412-624-2699

Susan Cohen, DSN, APRN, FAAN
Associate Professor, Department of Health Promotion and Development
University of Pittsburgh School of Nursing
440 Victoria Building, 3500 Victoria Street
Telephone: 412-624-5345

CONSULTANTS:

Margaret Rosenzweig, PhD, CRNP-C, AOCN
Associate Professor, Department of Acute and Tertiary Care
University of Pittsburgh School of Nursing
336 Victoria Building, 3500 Victoria Street
Telephone: 412-383-8839

Clement Stone, PhD
Professor, Department of Education
University of Pittsburgh School of Education
5920 Wesley W. Posvar Hall, 230 South Bouquet Street
Telephone: 412-624-9359

SOURCE OF SUPPORT:

NINR F31 NR01466-01A1
American Cancer Society Doctoral Scholarship in Cancer Nursing

Why is this research being done?

You are being asked to participate in a research study. We are developing a questionnaire to measure how well female cancer survivors are able to stand up for themselves. We call a person's ability to stand up for her own values and beliefs "self-advocacy". We want to see whether our questionnaire accurately measures self-advocacy among female cancer survivors.

Who is being asked to take part in this research study?

You are being invited to take part in this research study because you are an adult female with a history of cancer diagnosed after age 18.

What procedures will be performed for research purposes?

The study procedures consist of 2 mailed questionnaires. We will send you paper copies of both questionnaires with a pre-stamped, pre-addressed return envelope.

1. The first questionnaire is a screening questionnaire.

You will answer 4 questions to make sure you are eligible to participate. If you are not eligible, you will not complete the second questionnaire. Instead, you will be asked to complete 4 additional questions to help us understand what women are not participating in this study. Answering these 4 additional questions is voluntary.

We estimate that this screening questionnaire will take 1 minute to complete.

2. The second questionnaire will be completed online or by mail.

You will complete a set of questionnaires including demographic information, basic health information, and questions about your health and experience with cancer. You will then return the completed questionnaires in the return envelope provided to you.

We estimate that both questionnaires will take 60 minutes to complete.

If we do not receive these questionnaires, we will send you a reminder postcard 2 weeks after the initial letter and a reminder letter and replacement questionnaire 3 weeks after the initial letter.

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. The major potential risk is a breach of confidentiality, but we will do everything possible to protect your privacy. To protect your privacy, only Ms. Hagan and members of the research team will be aware of your participation in this research study. Mailed questionnaires will be kept in secure, locked file cabinets at the School of Nursing. All information will be identified only by a case number. The information linking these case numbers with your identity will be kept separate from the research records. 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.

Although we will do everything in our power to protect your privacy and the confidentiality of your records, just as with the use of your medical information for health care purposes, we cannot guarantee the privacy of your research records. Authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office may review your data for the purpose of monitoring the conduct of this study.

2. Another possible risk of this research study may include stress from having to complete the questionnaires. In case any questions cause you stress or discomfort, you can take a break from completing the questionnaires.

What are possible benefits from taking part in this study?

You will receive no direct benefit from taking part in this research study. The creation and use of this measurement tool may benefit female cancer survivors in the future, but will have no direct benefit to you.

Will I be paid if I take part in this research study?

Participants will be paid a \$10 Amazon.com gift card after completing and returning the questionnaires to Ms. Hagan.

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept strictly confidential. 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 will be indicated by a case number rather than by your name, and the information linking these case 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 in other research studies examining the validity of this questionnaire. 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.

Will this research study involve the use or disclosure of my identifiable medical information?

No.

Is my participation in this research study voluntary?

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study. Any information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you decide you no longer wish to participate after you have signed the consent form, you should contact Ms. Hagan (412-624-4101). Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh. If you would like additional information, you may contact the Research Office at 412-692-5551. Questions about your rights as a research participant can be answered by the Human Subject Protection Advocate at the University of Pittsburgh IRB Office- 866-212-2668.

If I agree to take part in this research study, can I be removed from the study without my consent?

If you are ineligible to participate, you will be removed from the study. Your screening data may be kept to track who was not participating. If you are eligible to participate, you will not be removed from this study without your consent.

Agreement to Participate

By completing and returning the completed questionnaire you agree to participate in this research study.



University of Pittsburgh

School of Nursing

Acute/Tertiary Care Department

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Establishment of the Validity of the Female Self-Advocacy in Cancer Survivorship Scale

PRINCIPAL INVESTIGATOR:

Teresa Hagan, BSN, RN
Graduate Student
University of Pittsburgh School of Nursing
336 Victoria Building, 3500 Victoria Street
Telephone: 412-624-4101

CO-INVESTIGATORS:

Heidi Donovan, PhD, RN
Associate Professor, Department of Acute and Tertiary Care
University of Pittsburgh School of Nursing
336 Victoria Building, 3500 Victoria Street
Telephone: 412-624-2699

Susan Cohen, DSN, APRN, FAAN
Associate Professor, Department of Health Promotion and Development
University of Pittsburgh School of Nursing
440 Victoria Building, 3500 Victoria Street
Telephone: 412-624-5345

CONSULTANTS:

Margaret Rosenzweig, PhD, CRNP-C, AOCN
Associate Professor, Department of Acute and Tertiary Care
University of Pittsburgh School of Nursing
336 Victoria Building, 3500 Victoria Street
Telephone: 412-383-8839

Clement Stone, PhD
Professor, Department of Education
University of Pittsburgh School of Education
5920 Wesley W. Posvar Hall, 230 South Bouquet Street
Telephone: 412-624-9359

SOURCE OF SUPPORT:

NINR F31 NR01466-01A1
American Cancer Society Doctoral Scholarship in Cancer Nursing

WHY IS THIS RESEARCH BEING DONE?

You are being asked to participate in a research study. We are developing a questionnaire to measure how well female cancer survivors are able to stand up for themselves. We call a person's ability to stand up for her own values and beliefs "self-advocacy". We want to see whether our questionnaire accurately measures self-advocacy among female cancer survivors.

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

You are being invited to take part in this research study because you are an adult female with a history of cancer diagnosed after age 18.

WHAT PROCEDURES WILL BE PERFORMED FOR RESEARCH PURPOSES?

The study procedures consist of 2 questionnaires on a secure website. We will send you the web address of the website.

1) The first questionnaire is a screening questionnaire (you just completed this).

You previously answered 4 questions to make sure you are eligible to participate. If you are not eligible, you will not complete the second questionnaire. Instead, you will be asked to respond to 4 additional questions to help us understand a little more about women who are not participating in the study.

We estimate that this screening questionnaire will take **1 minute** to complete.

2) The second questionnaire will be completed on-line. You will also be asked if you want to be mailed the questionnaires to do on paper.

You will complete a set of questionnaires including demographic information, basic health information, and questions about your health and experience with cancer.

We estimate that the second questionnaire will take **60 minutes** to complete.

If we do not receive your questionnaires, we will send you reminder emails 5, 10, and 21 days after the first email we sent you.

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) The major potential risk is a breach of confidentiality, but we will do everything possible to protect your privacy. To protect your privacy, only Teresa Hagan (the principle investigator) and members of the research team will be aware of your participation in this research study. The website where you complete the questionnaires is secure, and your data will be safely stored and only be accessed by Ms. Hagan. Any records will be kept in secure, locked file cabinets at the School of Nursing. All information will be identified only by a case number. The information linking these case numbers with your identity will be kept separate from the research records. 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.

Although we will do everything in our power to protect your privacy and the confidentiality of your records, just as with the use of your medical information for health care purposes, we cannot guarantee the privacy of your research records. Authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office may review your data for the purpose of monitoring the conduct of this study.

2) Another possible risk of this research study may include stress from having to complete the questionnaires. In case any questions cause you stress or discomfort, you can take a break from completing the questionnaires and return at any time without any of your data being lost.

WHAT ARE POSSIBLE BENEFITS FROM TAKING PART IN THIS STUDY?

You will receive no direct benefit from taking part in this research study. The creation and use of this measurement tool may benefit female cancer survivors in the future, but will have no direct benefit to you.

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

Participants will be given a \$10 Amazon.com gift code after returning the completed on-line survey to Ms. Hagan.

Note: If you want to complete the questionnaires through mail rather than on-line, you will receive a \$10 Amazon.com gift code when you return the completed questionnaires to Ms. Hagan.

WHO WILL KNOW ABOUT MY PARTICIPATION IN THIS RESEARCH STUDY?

Any information about you obtained from this research will be kept strictly confidential. 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 will be indicated by a case number rather than by your name, and the information linking these case 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 in other research studies examining the validity of this questionnaire. 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.

WILL THIS RESEARCH STUDY INVOLVE THE USE OR DISCLOSURE OF MY IDENTIFIABLE MEDICAL INFORMATION?

No.

IS MY PARTICIPATION IN THIS RESEARCH STUDY VOLUNTARY?

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

MAY I WITHDRAW, AT A FUTURE DATE, MY CONSENT FOR PARTICIPATION IN THIS RESEARCH STUDY?

You may withdraw, at any time, your consent for participation in this research study. Any information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you decide you no longer wish to participate after you have signed the consent form, you should contact Teresa Hagan (412-624-4101). Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh. If you would like additional information, you may contact the Research Office at 412-692-5551. Questions about your rights as a research participant can be answered by the Human Subject Protection Advocate at the University of Pittsburgh IRB Office- 866-212-2668.

IF I AGREE TO TAKE PART IN THIS RESEARCH STUDY, CAN I BE REMOVED FROM THE STUDY WITHOUT MY CONSENT?

If you are ineligible to participate, you will be removed from the study. Your screening data may be kept to track who was not participating. If you are eligible to participate, you will not be removed from this study without your consent.

Agreement to Participate

By clicking “yes” to the following question asking if you consent to participate in this research study, you are providing your consent to participate.



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: Teresa Hagan, RN, BSN, BA

From: Sue Beers, PhD, Vice Chair

Date: 9/12/2012

IRB#: [PRO12090171](#)

Subject: Content Validity of the Self-Advocacy in Cancer Survivorship (SACS) Scale

The above-referenced protocol has been reviewed by the University of Pittsburgh Institutional Review Board. Based on the information provided to the IRB, this project includes no involvement of human subjects, according to the federal regulations [§45 CFR 46.102(f)]. That is, the investigator conducting research will not obtain information about research subjects via an interaction with them, nor will the investigator obtain identifiable private information. Should that situation change, the investigator must notify the IRB immediately.

Given this determination, you may now begin your project.

Please note the following information:

- If any modifications are made to this project, use the "**Send Comments to IRB Staff**" process from the project workspace to request a review to ensure it continues to meet the determination.
- Upon completion of your project, be sure to finalize the project by submitting a "**Study Completed**" report from the project workspace.

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



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: Teresa Hagan BSN RN
From: Sue Beers PHD, Vice Chair
Date: 12/12/2012
IRB#: [PRO12100617](#)
Subject: Establishment of the Reliability of the Self-Advocacy in Cancer Survivorship Scale

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.(7)

The risk level designation is Minimal Risk.

Approval Date: 12/12/2012
Expiration Date: 12/11/2013

The following documents were approved by the IRB:

We, the University of Pittsburgh Institutional Review Board, approve the protocol for this research study, "Establishment of the Reliability of the Self-Advocacy in Cancer Survivorship Scale" and the following documents: -Consent form -Survey questionnaires -Cognitive interview questions

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.



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: Teresa Hagan
From: Sue Beers , Vice Chair
Date: 11/8/2013
IRB#: [PRO12110062](#)
Subject: Establishment of the Validity of the Self-Advocacy in Cancer Survivorship Scale

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.(7) characteristics/behaviors

The IRB has approved the waiver for the requirement to obtain a written informed consent.

The risk level designation is Minimal Risk.

Approval Date: 11/7/2013

Expiration Date: 11/6/2014

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.

APPENDIX D

HUMAN SUBJECTS TRAINING

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* 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:** Teresa Hagan (ID: 2765729)
- **Email:** tlh42@pitt.edu
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Unit:** School of Nursing

- **Curriculum Group:** Biomedical Human Subjects Research
- **Course Learner Group:** Biomedical Researchers (includes fellows, residents, and medical students)
- **Stage:** Stage 2 - Refresher Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

- **Report ID:** 14808600
- **Completion Date:** 12/29/2014
- **Expiration Date:** 12/28/2017
- **Minimum Passing:** 80
- **Reported Score*:** 96

| REQUIRED AND ELECTIVE MODULES ONLY | DATE COMPLETED | SCORE |
|--|----------------|------------|
| Biomed Refresher 1 - Instructions (ID:960) | 12/29/14 | No Quiz |
| Biomed Refresher 1 – History and Ethical Principles (ID:975) | 12/29/14 | 2/2 (100%) |
| Biomed Refresher 1 – Informed Consent (ID:980) | 12/29/14 | 2/2 (100%) |
| Biomed Refresher 1 – Regulations and Process (ID:981) | 12/29/14 | 3/3 (100%) |
| Biomed Refresher 1 – SBR Methodologies in Biomedical Research (ID:982) | 12/29/14 | 3/3 (100%) |
| Biomed Refresher 1 – Records-Based Research (ID:983) | 12/29/14 | 2/2 (100%) |
| Biomed Refresher 1 – Genetics Research (ID:984) | 12/29/14 | 2/2 (100%) |
| Biomed Refresher 1 - Populations in Research Requiring Additional Considerations and/or Protections (ID:985) | 12/29/14 | 2/2 (100%) |
| Biomed Refresher 1 – FDA-Regulated Research (ID:987) | 12/29/14 | 3/3 (100%) |
| Biomed Refresher 1 – Vulnerable Subjects - Children (ID:974) | 12/29/14 | 3/4 (75%) |

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.

CITI Program

Email: citisupport@miami.edu

Phone: 305-243-7970

Web: <https://www.citiprogram.org>

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK TRANSCRIPT REPORT**

** 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:** Teresa Hagan (ID: 2765729)
- **Email:** tlh42@pitt.edu
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Unit:** School of Nursing

- **Curriculum Group:** Biomedical Human Subjects Research
- **Course Learner Group:** Biomedical Researchers (includes fellows, residents, and medical students)
- **Stage:** Stage 2 - Refresher Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

- **Report ID:** 14808600
- **Report Date:** 06/23/2015
- **Current Score**:** 96

| REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES | MOST RECENT | SCORE |
|--|-------------|------------|
| Biomed Refresher 1 - Instructions (ID:960) | 12/29/14 | No Quiz |
| Biomed Refresher 1 – History and Ethical Principles (ID:975) | 12/29/14 | 2/2 (100%) |
| Biomed Refresher 1 – Regulations and Process (ID:981) | 12/29/14 | 3/3 (100%) |
| Biomed Refresher 1 – Informed Consent (ID:980) | 12/29/14 | 2/2 (100%) |
| Biomed Refresher 1 – SBR Methodologies in Biomedical Research (ID:982) | 12/29/14 | 3/3 (100%) |
| Biomed Refresher 1 – Records-Based Research (ID:983) | 12/29/14 | 2/2 (100%) |
| Biomed Refresher 1 – Genetics Research (ID:984) | 12/29/14 | 2/2 (100%) |
| Biomed Refresher 1 - Populations in Research Requiring Additional Considerations and/or Protections (ID:985) | 12/29/14 | 2/2 (100%) |
| Biomed Refresher 1 – Vulnerable Subjects - Children (ID:974) | 12/29/14 | 3/4 (75%) |
| Biomed Refresher 1 – FDA-Regulated Research (ID:987) | 12/29/14 | 3/3 (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.

CITI Program

Email: citisupport@miami.edu

Phone: 305-243-7970

Web: <https://www.citiprogram.org>

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* 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:** Teresa Hagan (ID: 2765729)
- **Email:** tlh42@pitt.edu
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Unit:** School of Nursing

- **Curriculum Group:** Biomedical Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 2 - RCR Refresher
- **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.

- **Report ID:** 14813840
- **Completion Date:** 12/29/2014
- **Expiration Date:** 12/28/2017
- **Minimum Passing:** 80
- **Reported Score*:** 100

| REQUIRED AND ELECTIVE MODULES ONLY | DATE COMPLETED | SCORE |
|--|----------------|------------|
| Authorship (RCR-Refresher) (ID:15661) | 12/29/14 | 5/5 (100%) |
| Collaborative Research (RCR-Refresher) (ID:15662) | 12/29/14 | 5/5 (100%) |
| Conflicts of Interest (RCR-Refresher) (ID:15663) | 12/29/14 | 5/5 (100%) |
| Data Management (RCR-Refresher) (ID:15664) | 12/29/14 | 5/5 (100%) |
| Peer Review (RCR-Refresher) (ID:15665) | 12/29/14 | 5/5 (100%) |
| Research Misconduct (RCR-Refresher) (ID:15666) | 12/29/14 | 5/5 (100%) |
| Mentoring (RCR-Refresher) (ID:15667) | 12/29/14 | 5/5 (100%) |
| Research Involving Human Subjects (RCR-Refresher) (ID:15668) | 12/29/14 | 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.

CITI Program

Email: citisupport@miami.edu

Phone: 305-243-7970

Web: <https://www.citiprogram.org>

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK TRANSCRIPT REPORT**

** 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:** Teresa Hagan (ID: 2765729)
- **Email:** tlh42@pitt.edu
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Unit:** School of Nursing

- **Curriculum Group:** Biomedical Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 2 - RCR Refresher
- **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.

- **Report ID:** 14813840
- **Report Date:** 06/23/2015
- **Current Score**:** 100

| REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES | MOST RECENT | SCORE |
|--|-------------|------------|
| Authorship (RCR-Refresher) (ID:15661) | 12/29/14 | 5/5 (100%) |
| Collaborative Research (RCR-Refresher) (ID:15662) | 12/29/14 | 5/5 (100%) |
| Conflicts of Interest (RCR-Refresher) (ID:15663) | 12/29/14 | 5/5 (100%) |
| Data Management (RCR-Refresher) (ID:15664) | 12/29/14 | 5/5 (100%) |
| Peer Review (RCR-Refresher) (ID:15665) | 12/29/14 | 5/5 (100%) |
| Research Misconduct (RCR-Refresher) (ID:15666) | 12/29/14 | 5/5 (100%) |
| Mentoring (RCR-Refresher) (ID:15667) | 12/29/14 | 5/5 (100%) |
| Research Involving Human Subjects (RCR-Refresher) (ID:15668) | 12/29/14 | 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.

CITI Program

Email: citisupport@miami.edu

Phone: 305-243-7970

Web: <https://www.citiprogram.org>

Collaborative Institutional
Training Initiative
at the University of Miami

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* 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:** Teresa Hagan (ID: 2765729)
- **Email:** tlh42@pitt.edu
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Unit:** School of Nursing

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

- **Report ID:** 16200343
- **Completion Date:** 06/03/2015
- **Expiration Date:** 06/02/2018
- **Minimum Passing:** 80
- **Reported Score*:** 92

REQUIRED AND ELECTIVE MODULES ONLY

| | DATE COMPLETED | SCORE |
|--|----------------|------------|
| CITI Conflict of Interest Course - Introduction (ID:15177) | 06/03/15 | No Quiz |
| Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (ID:15070) | 06/03/15 | 5/5 (100%) |
| Institutional Responsibilities as They Affect Investigators (ID:15072) | 06/03/15 | 5/5 (100%) |
| Conflicts of Interest Institution-Specific Policies (ID:15179) | 06/03/15 | 9/10 (90%) |
| Conflicts of Commitment and Conscience (ID:15073) | 06/03/15 | 4/5 (80%) |

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.

CITI Program

Email: citisupport@miami.edu

Phone: 305-243-7970

Web: <https://www.citiprogram.org>

Collaborative Institutional
Training Initiative
at the University of Miami

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK TRANSCRIPT REPORT**

** 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:** Teresa Hagan (ID: 2765729)
- **Email:** tlh42@pitt.edu
- **Institution Affiliation:** University of Pittsburgh (ID: 2074)
- **Institution Unit:** School of Nursing

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

- **Report ID:** 16200343
- **Report Date:** 06/23/2015
- **Current Score**:** 92

| REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES | MOST RECENT | SCORE |
|--|-------------|------------|
| CITI Conflict of Interest Course - Introduction (ID:15177) | 06/03/15 | No Quiz |
| Conflicts of Interest Institution-Specific Policies (ID:15179) | 06/03/15 | 9/10 (90%) |
| Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (ID:15070) | 06/03/15 | 5/5 (100%) |
| Institutional Responsibilities as They Affect Investigators (ID:15072) | 06/03/15 | 5/5 (100%) |
| Conflicts of Commitment and Conscience (ID:15073) | 06/03/15 | 4/5 (80%) |

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.

CITI Program

Email: citisupport@miami.edu

Phone: 305-243-7970

Web: <https://www.citiprogram.org>

Collaborative Institutional
Training Initiative
at the University of Miami

APPENDIX E

PERMISSIONS TO USE PUBLISHED MANUSCRIPTS

JOHN WILEY AND SONS LICENSE
TERMS AND CONDITIONS

May 11, 2015

This Agreement between Teresa L Hagan ("You") and John Wiley and Sons ("John Wiley and Sons") consists of your license details and the terms and conditions provided by John Wiley and Sons and Copyright Clearance Center.


| | |
|-------------------------------------|--|
| License Number | 3625970336506 |
| License date | May 11, 2015 |
| Licensed Content Publisher | John Wiley and Sons |
| Licensed Content Publication | Journal of Advanced Nursing |
| Licensed Content Title | Self-advocacy and cancer: a concept analysis |
| Licensed Content Author | Teresa L. Hagan, Heidi S. Donovan |
| Licensed Content Date | Jan 24, 2013 |
| Pages | 12 |
| Type of use | Dissertation/Thesis |
| Requestor type | Author of this Wiley article |
| Format | Electronic |
| Portion | Full article |
| Will you be translating? | No |
| Title of your thesis / dissertation | Development of a Measure of Self-Advocacy Among Female Cancer Survivors |
| Expected completion date | Aug 2015 |
| Expected size (number of pages) | 60 |
| Requestor Location | Teresa L Hagan 336 Victoria Building 3500 Victoria Street PITTSBURGH, PA 15261 United States Attn: Teresa L Hagan |
| Billing Type | Invoice Teresa L Hagan 336 Victoria Building 3500 Victoria Street |
| Billing Address | PITTSBURGH, PA 15261 United States Attn: Teresa L Hagan |

Total

0.00 USD

Terms and Conditions

TERMS AND CONDITIONS

This copyrighted material is owned by or exclusively licensed to John Wiley & Sons, Inc. or one of its group companies (each a "Wiley Company") or handled on behalf of a society with which a Wiley Company has exclusive publishing rights in relation to a particular work (collectively "WILEY"). By clicking  in connection with completing this licensing transaction, you agree that the following terms and conditions apply to this transaction (along with the billing and payment terms and conditions established by the Copyright Clearance Center Inc., ("CCC's Billing and Payment terms and conditions"), at the time that you opened your Rightslink account (these are available at any time at <http://myaccount.copyright.com>).

Terms and Conditions

- The materials you have requested permission to reproduce or reuse (the "Wiley Materials") are protected by copyright.
- You are hereby granted a personal, non-exclusive, non-sub licensable (on a stand-alone basis), non-transferable, worldwide, limited license to reproduce the Wiley Materials for the purpose specified in the licensing process. This license is for a one-time use only and limited to any maximum distribution number specified in the license. The first instance of republication or reuse granted by this licence must be completed within two years of the date of the grant of this licence (although copies prepared before the end date may be distributed thereafter). The Wiley Materials shall not be used in any other manner or for any other purpose, beyond what is granted in the license. Permission is granted subject to an appropriate acknowledgement given to the author, title of the material/book/journal and the publisher. You shall also duplicate the copyright notice that appears in the Wiley publication in your use of the Wiley Material. Permission is also granted on the understanding that nowhere in the text is a previously published source acknowledged for all or part of this Wiley Material. Any third party content is expressly excluded from this permission.
- With respect to the Wiley Materials, all rights are reserved. Except as expressly granted by the terms of the license, no part of the Wiley Materials may be copied, modified, adapted (except for minor reformatting required by the new Publication), translated, reproduced, transferred or distributed, in any form or by any means, and no derivative works may be made based on the Wiley Materials without the prior permission of the respective copyright owner. You may not alter, remove or suppress in any manner any copyright, trademark or other notices displayed by the Wiley Materials. You may not license, rent, sell, loan, lease, pledge, offer as security, transfer or assign the Wiley Materials on a stand-alone basis, or any of the

rights granted to you hereunder to any other person.

- The Wiley Materials and all of the intellectual property rights therein shall at all times remain the exclusive property of John Wiley & Sons Inc, the Wiley Companies, or their respective licensors, and your interest therein is only that of having possession of and the right to reproduce the Wiley Materials pursuant to Section 2 herein during the continuance of this Agreement. You agree that you own no right, title or interest in or to the Wiley Materials or any of the intellectual property rights therein. You shall have no rights hereunder other than the license as provided for above in Section 2. No right, license or interest to any trademark, trade name, service mark or other branding ("Marks") of WILEY or its licensors is granted hereunder, and you agree that you shall not assert any such right, license or interest with respect thereto.
- NEITHER WILEY NOR ITS LICENSORS MAKES ANY WARRANTY OR REPRESENTATION OF ANY KIND TO YOU OR ANY THIRD PARTY, EXPRESS, IMPLIED OR STATUTORY, WITH RESPECT TO THE MATERIALS OR THE ACCURACY OF ANY INFORMATION CONTAINED IN THE MATERIALS, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY, ACCURACY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE, USABILITY, INTEGRATION OR NON-INFRINGEMENT AND ALL SUCH WARRANTIES ARE HEREBY EXCLUDED BY WILEY AND ITS LICENSORS AND WAIVED BY YOU
- WILEY shall have the right to terminate this Agreement immediately upon breach of this Agreement by you.
- You shall indemnify, defend and hold harmless WILEY, its Licensors and their respective directors, officers, agents and employees, from and against any actual or threatened claims, demands, causes of action or proceedings arising from any breach of this Agreement by you.
- IN NO EVENT SHALL WILEY OR ITS LICENSORS BE LIABLE TO YOU OR ANY OTHER PARTY OR ANY OTHER PERSON OR ENTITY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY OR PUNITIVE DAMAGES, HOWEVER CAUSED, ARISING OUT OF OR IN CONNECTION WITH THE DOWNLOADING, PROVISIONING, VIEWING OR USE OF THE MATERIALS REGARDLESS OF THE FORM OF ACTION, WHETHER FOR BREACH OF CONTRACT, BREACH OF WARRANTY, TORT, NEGLIGENCE, INFRINGEMENT OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, DAMAGES BASED ON LOSS OF PROFITS, DATA, FILES, USE, BUSINESS OPPORTUNITY OR CLAIMS OF THIRD PARTIES), AND WHETHER OR NOT THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THIS LIMITATION SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN.

- Should any provision of this Agreement be held by a court of competent jurisdiction to be illegal, invalid, or unenforceable, that provision shall be deemed amended to achieve as nearly as possible the same economic effect as the original provision, and the legality, validity and enforceability of the remaining provisions of this Agreement shall not be affected or impaired thereby.
- The failure of either party to enforce any term or condition of this Agreement shall not constitute a waiver of either party's right to enforce each and every term and condition of this Agreement. No breach under this agreement shall be deemed waived or excused by either party unless such waiver or consent is in writing signed by the party granting such waiver or consent. The waiver by or consent of a party to a breach of any provision of this Agreement shall not operate or be construed as a waiver of or consent to any other or subsequent breach by such other party.
- This Agreement may not be assigned (including by operation of law or otherwise) by you without WILEY's prior written consent.
- Any fee required for this permission shall be non-refundable after thirty (30) days from receipt by the CCC.
- These terms and conditions together with CCC's Billing and Payment terms and conditions (which are incorporated herein) form the entire agreement between you and WILEY concerning this licensing transaction and (in the absence of fraud) supersedes all prior agreements and representations of the parties, oral or written. This Agreement may not be amended except in writing signed by both parties. This Agreement shall be binding upon and inure to the benefit of the parties' successors, legal representatives, and authorized assigns.
- In the event of any conflict between your obligations established by these terms and conditions and those established by CCC's Billing and Payment terms and conditions, these terms and conditions shall prevail.
- WILEY expressly reserves all rights not specifically granted in the combination of (i) the license details provided by you and accepted in the course of this licensing transaction, (ii) these terms and conditions and (iii) CCC's Billing and Payment terms and conditions.
- This Agreement will be void if the Type of Use, Format, Circulation, or Requestor Type was misrepresented during the licensing process.
- This Agreement shall be governed by and construed in accordance with the laws of the State of New York, USA, without regards to such state's conflict of law rules. Any legal action, suit or proceeding arising out of or relating to these Terms and Conditions or the breach thereof shall be instituted in a court of competent jurisdiction in New York County in the State of New York in the United States of America and each party hereby consents and submits to the personal jurisdiction of such court, waives any objection to venue in such court and consents to service of

process by registered or certified mail, return receipt requested, at the last known address of such party.

WILEY OPEN ACCESS TERMS AND CONDITIONS

Wiley Publishes Open Access Articles in fully Open Access Journals and in Subscription journals offering Online Open. Although most of the fully Open Access journals publish open access articles under the terms of the Creative Commons Attribution (CC BY) License only, the subscription journals and a few of the Open Access Journals offer a choice of Creative Commons Licenses:: Creative Commons Attribution (CC-BY) license [Creative Commons Attribution Non-Commercial \(CC-BY-NC\) license](#) and [Creative Commons Attribution Non-Commercial-NoDerivs \(CC-BY-NC-ND\) License](#). The license type is clearly identified on the article.

Copyright in any research article in a journal published as Open Access under a Creative Commons License is retained by the author(s). Authors grant Wiley a license to publish the article and identify itself as the original publisher. Authors also grant any third party the right to use the article freely as long as its integrity is maintained and its original authors, citation details and publisher are identified as follows: [Title of Article/Author/Journal Title and Volume/Issue. Copyright (c) [year] [copyright owner as specified in the Journal]. Links to the final article on Wiley's website are encouraged where applicable.

The Creative Commons Attribution License

The [Creative Commons Attribution License \(CC-BY\)](#) allows users to copy, distribute and transmit an article, adapt the article and make commercial use of the article. The CC-BY license permits commercial and non-commercial re-use of an open access article, as long as the author is properly attributed.

The Creative Commons Attribution License does not affect the moral rights of authors, including without limitation the right not to have their work subjected to derogatory treatment. It also does not affect any other rights held by authors or third parties in the article, including without limitation the rights of privacy and publicity. Use of the article must not assert or imply, whether implicitly or explicitly, any connection with, endorsement or sponsorship of such use by the author, publisher or any other party associated with the article.

For any reuse or distribution, users must include the copyright notice and make clear to others that the article is made available under a Creative Commons Attribution license, linking to the relevant Creative Commons web page.

To the fullest extent permitted by applicable law, the article is made available as is and without representation or warranties of any kind whether express, implied, statutory or otherwise and including, without limitation, warranties of title, merchantability, fitness for a particular purpose, non-infringement, absence of defects, accuracy, or the presence or

absence of errors.

Creative Commons Attribution Non-Commercial License

The [Creative Commons Attribution Non-Commercial \(CC-BY-NC\) License](#) permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.(see below)

Creative Commons Attribution-Non-Commercial-NoDerivs License

The [Creative Commons Attribution Non-Commercial-NoDerivs License](#) (CC-BY-NC-ND) permits use, distribution and reproduction in any medium, provided the original work is properly cited, is not used for commercial purposes and no modifications or adaptations are made. (see below)

Use by non-commercial users

For non-commercial and non-promotional purposes, individual users may access, download, copy, display and redistribute to colleagues Wiley Open Access articles, as well as adapt, translate, text- and data-mine the content subject to the following conditions:

- The authors' moral rights are not compromised. These rights include the right of "paternity" (also known as "attribution" - the right for the author to be identified as such) and "integrity" (the right for the author not to have the work altered in such a way that the author's reputation or integrity may be impugned).
- Where content in the article is identified as belonging to a third party, it is the obligation of the user to ensure that any reuse complies with the copyright policies of the owner of that content.
- If article content is copied, downloaded or otherwise reused for non-commercial research and education purposes, a link to the appropriate bibliographic citation (authors, journal, article title, volume, issue, page numbers, DOI and the link to the definitive published version on **Wiley Online Library**) should be maintained. Copyright notices and disclaimers must not be deleted.
- Any translations, for which a prior translation agreement with Wiley has not been agreed, must prominently display the statement: "This is an unofficial translation of an article that appeared in a Wiley publication. The publisher has not endorsed this translation."

Use by commercial "for-profit" organisations

Use of Wiley Open Access articles for commercial, promotional, or marketing purposes requires further explicit permission from Wiley and will be subject to a fee. Commercial

purposes include:

- Copying or downloading of articles, or linking to such articles for further redistribution, sale or licensing;
- Copying, downloading or posting by a site or service that incorporates advertising with such content;
- The inclusion or incorporation of article content in other works or services (other than normal quotations with an appropriate citation) that is then available for sale or licensing, for a fee (for example, a compilation produced for marketing purposes, inclusion in a sales pack)
- Use of article content (other than normal quotations with appropriate citation) by for-profit organisations for promotional purposes
- Linking to article content in e-mails redistributed for promotional, marketing or educational purposes;
- Use for the purposes of monetary reward by means of sale, resale, licence, loan, transfer or other form of commercial exploitation such as marketing products
- Print reprints of Wiley Open Access articles can be purchased from:
corporatesales@wiley.com

Further details can be found on Wiley Online Library
<http://olabout.wiley.com/WileyCDA/Section/id-410895.html>

Other Terms and Conditions:

v1.9

Questions? customercare@copyright.com or +1-855-239-3415 (toll free in the US) or +1-978-646-2777.

Gratis licenses (referencing \$0 in the Total field) are free. Please retain this printable license for your reference. No payment is required.

Mike Minjock
Licensing Manager
Oncology Nursing Society
125 Enterprise Drive
Pittsburgh, PA 15275-1214
412-859-6251 (phone)
412-859-6163 (fax)

Dear Mike Minjock:

This letter will confirm our recent telephone e-mail exchange. I am completing a doctoral dissertation at the University of Pittsburgh entitled "The Development of a Measure of Self-Advocacy Among Female Cancer Survivors." I would like your permission to reprint in my dissertation excerpts from the following:

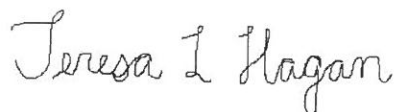
Hagan, T. L., & Donovan, H. S. (2013). Ovarian cancer survivors' experiences of self-advocacy: A focus group study. *Oncology Nursing Forum*, 40(2), 140-147.

The excerpts to be reproduced include the entire article. The full article will be reprinted as an appendix. This article (and the work it represents) is foundational to my dissertation, so rather than retyping it and self-plagiarizing, I want to have the published ONF article included. Full and clear credit will be given to ONF as the publisher and copywriter of the article.

The requested permission extends to any future revisions and editions of my dissertation, including non-exclusive world rights in all languages, to the electronic publication of my dissertation by the University of Pittsburgh, and to the prospective publication of my dissertation by ProQuest. ProQuest may supply copies of my dissertation on demand. These rights will in no way restrict republication of the material in any other form by you or by others authorized by you. Your signing of this letter will also confirm that your company owns the copyright to the above-described material.

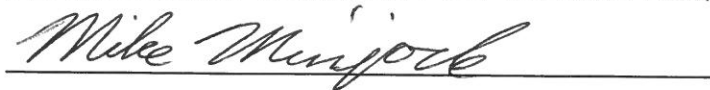
If these arrangements meet with your approval, please sign this letter where indicated below and return it to me in the enclosed return envelope. Thank you very much.

Sincerely,



Teresa L. Hagan

PERMISSION IS GRANTED FOR THE USE REQUESTED ABOVE:



Mike Minjock, Licensing Manager, Oncology Nursing Society

Date: 4/29/2015

APPENDIX F

COVER LETTERS FOR UNPUBLISHED MANUSCRIPTS



University of Pittsburgh

School of Nursing

Victoria Building
3500 Victoria St.
Pittsburgh, PA 15261
Fax: 412-624-2401

Janice L. Hinkle, PhD, RN, CNRN
The Catholic University of America
School of Nursing-Gowan Hall
620 Michigan Avenue NE
Washington, DC 20064

June 15, 2015

Dear Dr. Hinkle,

It is my pleasure to submit the Letter to the Editor: "Theoretical to Tangible: Creating a Measure of Self-Advocacy" to *The Journal of Nursing Measurement*. In this manuscript, we describe in detail the process of taking an abstract yet relevant concept like self-advocacy (or the ability of an individual to stand up for themselves and make their needs known) and operationalize it into a reliable measurement tool.

We believe this manuscript is relevant to your readership because it:

- Addresses the process of moving a concept into a construct using a systematic and rigorous process;
- Reports how focus group and literature review findings about a single concept were synthesized and used to develop sub-dimensions of the construct along with an item list for a measurement tool;
- Reports the content validity and reliability testing results of the initial tool; and
- Describes the challenges faced by the researchers during the measurement process along with the researchers' decisions.

This manuscript has not been submitted elsewhere. All authors have significantly contributed to the design and data analysis of the study as well as the writing of the manuscript. We would appreciate any specific instructions or direction to improve this version of the manuscript.

I look forward to your reply.

Sincerely,

Teresa L Hagan

Teresa Hagan, BSN, RN, BA



University of Pittsburgh

School of Nursing

Fadlo R. Khuri, MD
Cancer Editorial Office
American Cancer Society
250 Williams Street NW
Atlanta, Georgia 30303 USA

August 15, 2015

Dear Dr. Khuri,

It is our pleasure to submit the manuscript "Validating the Female Self-Advocacy in Cancer Survivorship Scale" for your editorial review. This manuscript discusses the development of a novel measure self-advocacy but in a novel population – women with a history of cancer.

We believe that this article addresses the needs of your readership in the following ways:

- Addresses the absence of a theoretically-based, psychometrically strong measure of cancer patients' ability to stand up for herself, or "self-advocate."
- Reports the multi-phase procedures and empirical evidence supporting the reliability and validity of a novel measurement of self-advocacy among female cancer survivors.
- Explores the relationship of self-advocacy with health outcomes (e.g. symptom management and healthcare utilization) and related concepts (e.g. patient activation, health information orientation, social support, etc.).

All authors have read and approved the manuscript. This manuscript is not under consideration elsewhere.

Thank you for your review of this manuscript. We look forward to your response.

Sincerely,
Teresa Hagan
University of Pittsburgh School of Nursing

BIBLIOGRAPHY

- American Cancer Society. (2014). *Cancer Treatment and Survivorship Facts & Figures 2014-2015*. Atlanta: American Cancer Society.
- American Educational Research Association, American Psychological Association, National Council on Measurement in Education, Joint Committee on Standards for Educational, & Psychological Testing (US). (1999). *Standards for educational and psychological testing*. American Educational Research Association.
- American Society of Clinical Oncology. (2012). Self-Advocacy: Participating in Your Cancer Care. Retrived from: <http://www.cancer.net/all-about-cancer/cancernet-feature-articles/cancer-basics/self-advocacy-participating-your-cancer-care>.
- Anderson, K. O., Mendoza, T. R., Valero, V., Richman, S. P., Russell, C., Hurley, J., ... & Cleeland, C. S. (2000). Minority cancer patients and their providers. *Cancer*, 88(8), 1929-1938.
- Anderson, K. O., Mendoza, T. R., Payne, R., Valero, V., Palos, G. R., Nazario, A., ... & Cleeland, C. S. (2004). Pain education for underserved minority cancer patients: a randomized controlled trial. *Journal of Clinical Oncology*, 22(24), 4918-4925.
- Aranda, S., Schofield, P., Weih, L., Yates, P., Milne, D., Faulkner, R., & Voudouris, N. (2005). Mapping the quality of life and unmet needs of urban women with metastatic breast cancer. *European journal of cancer care*, 14(3), 211-222.
- Au, D. H., Udris, E. M., Engelberg, R. A., Diehr, P. H., Bryson, C. L., Reinke, L. F., & Curtis, J. R. (2012). A randomized trial to improve communication about end-of-life care among patients with COPD. *CHEST Journal*, 141(3), 726-735.
- Balogh, E. P., Ganz, P. A., Murphy, S. B., Nass, S. J., Ferrell, B. R., & Stovall, E. (2011). Patient-centered cancer treatment planning: improving the quality of oncology care. Summary of an Institute of Medicine workshop. *The Oncologist*, 16(12), 1800-1805.

- Brashers, D. E., Haas, S. M., & Neidig, J. L. (1999). The Patient Self-Advocacy Scale: Measuring patient involvement in health care decision-making interactions. *Health Communication, 11*(2), 97-121.
- Brashers, D. E., Neidig, J. L., & Goldsmith, D. J. (2004). Social support and the management of uncertainty for people living with HIV or AIDS. *Health Communication, 16*(3), 305-331.
- Bertakis, K. D., & Azari, R. (2011). Patient-centered care is associated with decreased health care utilization. *The Journal of the American Board of Family Medicine, 24*(3), 229-239.
- Bertakis, K. D., & Azari, R. (2012). Patient-centered care: the influence of patient and resident physician gender and gender concordance in primary care. *Journal of Women's Health, 21*(3), 326-333.
- Carr, E. S. (2003). Rethinking empowerment theory using a feminist lens: The importance of process. *Affilia, 18*(1), 8-20.
- Cartwright, E., & Allotey, P. (2006). Women's Health: New Frontiers in Advocacy & Social Justice Research—Introduction. *Women & Health, 43*(4), 1-6.
- Chakamian, S. (2014). The fight is won [Painting]. Retrieved from <http://www.sherisartstudio.com/>
- Cheung, W. Y., Le, L. W., Gagliese, L., & Zimmermann, C. (2011). Age and gender differences in symptom intensity and symptom clusters among patients with metastatic cancer. *Supportive Care in Cancer, 19*(3), 417-423.
- Cimprich, B., Janz, N. K., Northouse, L., Wren, P. A., Given, B., & Given, C. W. (2005). Taking CHARGE: A self-management program for women following breast cancer treatment. *Psycho-Oncology, 14*(9), 704-717.
- Clark, E. J., & Stovall, E. L. (1995). Advocacy: the cornerstone of cancer survivorship. *Cancer Practice, 4*(5), 239-244.

- Cleeland, C. S., Gonin, R., Hatfield, A. K., Edmonson, J. H., Blum, R. H., Stewart, J. A., & Pandya, K. J. (1994). Pain and its treatment in outpatients with metastatic cancer. *New England Journal of Medicine*, 330(9), 592-596.
- Cleeland, C. S., Mendoza, T. R., Wang, X. S., Chou, C., Harle, M. T., & Morrissey, M. (2000). Assessing symptom distress in cancer patients. The MD Anderson symptom inventory. *Cancer*, 89, 1634-1646.
- Cohen, S., Mermelstein, R., Kamarck, T., & Hoberman, H. M. (1985). Measuring the functional components of social support. In *Social support: Theory, research and applications* (pp. 73-94). Springer Netherlands.
- Comrey, A. L., & Lee, H. B. (2013). *A first course in factor analysis*. Psychology Press.
- DeFlorio, M. L., & Massie, M. J. (1995). Review of depression in cancer: Gender differences. *Depression*, 3(1-2), 66-80.
- DeMarco, R. F., Miller, K. H., Patsdaughter, C. A., Chisholm, M., & Grindel, C. G. (1998). From silencing the self to action: Experiences of women living with HIV/AIDS. *Health Care for Women International*, 19(6), 539-552.
- DeVellis, R. F. (2012). *Scale development: theory and applications* (3rd ed.). Washington, DC, SAGE.
- Deshields, T. L., Potter, P., Olsen, S., Liu, J., & Dye, L. (2011). Documenting the symptom experience of cancer patients. *The Journal of Supportive Oncology*, 9(6), 216-223.
- Dillman, D. A. (2002). *Mail and internet surveys: the tailored design method* (2nd ed.). New York, NY, John Wiley & Sons, Inc.
- Donovan, H. S., Hartenbach, E. M., & Method, M. W. (2005). Patient-provider communication and perceived control for women experiencing multiple symptoms associated with ovarian cancer. *Gynecologic Oncology*, 99(2), 404-411.
- DuBenske, L. L., Beckjord, E. B., Hawkins, R. P., & Gustafson, D. H. (2009). Psychometric evaluation of the Health Information Orientation Scale: A brief measure for assessing

- health information engagement and apprehension. *Journal of Health Psychology*, 14(6), 721-730.
- Duncan, J. G., Forbes-Thompson, S., & Bott, M. J. (2008). Unmet symptom management needs of nursing home residents with cancer. *Cancer Nursing*, 31(4), 265-273.
- Edwards, P. J., Roberts, I., Clarke, M. J., Diguiseppi, C., Wentz, R., Kwan, I., ... & Pratap, S. (2009). Methods to increase response to postal and electronic questionnaires (Review). *Cochrane Database System Review*, 3, MR000008.
- Elderkin-Thompson, V., & Waitzkin, H. (1999). Differences in clinical communication by gender. *Journal of General Internal Medicine*, 14(2), 112-121.
- Errico, K. M., & Rowden, D. (2006). Experiences of breast cancer survivor-advocates and advocates in countries with limited resources: A shared journey in breast cancer advocacy. *The Breast Journal*, 12(s1), S111-S116.
- Ferrell, B. R., Koczywas, M., Borneman, T., Piper, B. F., & Uman, G. (2010). Barriers to symptom management in oncology. In *ASCO Annual Meeting Proceedings*, 28(15 Suppl), 9083.
- Ferrell, B., McCabe, M. S., & Levit, L. (2013). The Institute of Medicine report on high-quality cancer care: implications for oncology nursing. *Oncology Nursing Forum*, 40(6), 603–609.
- Ferrell, B., Smith, S., Cullinane, C., & Melancon, C. (2003). Symptom concerns of women with ovarian cancer. *Journal of Pain and Symptom Management*, 25(6), 528-538.
- Food and Drug Administration. (2009). Draft Guidance for Industry: Patient-reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Silver Spring, MD: U.S. Department of Health and Human Services.
- Given, B., & Given, W. (2013). Healthcare utilization questionnaire. Michigan State University School of Nursing.

- Golden Goose. (2010). Everyone is art [Painting]. Retrieved from <http://www.goldengoosepr.com/everyone-is-art/>
- Grant, J. S., & Davis, L. L. (1997). Selection and use of content experts for instrument development. *Research in Nursing & Health*, 20(3), 269–274.
- Green, C. R., Hart-Johnson, T., & Loeffler, D. R. (2011). Cancer-related chronic pain. *Cancer*, 117(9), 1994-2003.
- Greene, J., & Hibbard, J. H. (2012). Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. *Journal of general internal medicine*, 27(5), 520-526.
- Goldberg, L. R. (1999). A broad-bandwidth, public domain, personality inventory measuring the lower-level facets of several five-factor models. *Personality Psychology in Europe*, 7, 7-28.
- Goldberg, L. R., Johnson, J. A., Eber, H. W., Hogan, R., Ashton, M. C., Cloninger, C. R., & Gough, H. G. (2006). The international personality item pool and the future of public-domain personality measures. *Journal of Research in Personality*, 40(1), 84-96.
- Hagan, T. L., & Donovan, H. S. (2013a). Self-advocacy and cancer: A concept analysis. *Journal of Advanced Nursing*, 69(10), 2348-2359.
- Hagan, T. L., & Donovan, H. S. (2013b). Ovarian cancer survivors' experiences of self-advocacy: A focus group study. *Oncology Nursing Forum*, 4(2), 140-147.
- Haggstrom, D. A., & Doebbeling, B. N. (2011). Quality measurement and system change of cancer care delivery. *Medical Care*, 49, S21-S27.
- Haynes, S. N., Richard, D. C. S., & Kubany, E. S. (1995). Content validity in psychological assessment: A functional approach to concepts and methods. *Psychological Assessment*, 7(3), 238-247, p. 238.
- Hermansen-Kobulnicky, C. J. (2008). Measurement of self-advocacy in cancer patients and survivors. *Supportive Care in Cancer*, 16(6), 613-618.

- Hewitt, M., & Simone, J. V. (Eds.). (1999). *Ensuring quality cancer care*. National Academies Press.
- Hibbard, J. H., & Cunningham, P. J. (2008). How engaged are consumers in their health and health care, and why does it matter. *Research Briefs*, 8, 1-9.
- Hibbard, J. H., Greene, J., & Tusler, M. (2009). Improving the outcomes of disease management by tailoring care to the patient's level of activation. *The American Journal of Managed Care*, 15(6), 353-360.
- Hibbard, J. H., Stockard, J., Mahoney, E. R., & Tusler, M. (2004). Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Services Research*, 39(4p1), 1005-1026.
- Hopkins, A. C. (2010). Cancer Cell #4. Retrieved from <http://angelacanadahopkins.com/>
- Howard, A. F., Balneaves, L. G., & Bottorff, J. L. (2007). Ethnocultural women's experiences of breast cancer: a qualitative meta-study. *Cancer Nursing*, 30(4), E27-E35.
- Institute of Medicine (US). Committee on Quality of Health Care in America. (2001). *Crossing the quality chasm: a new health system for the 21st century*. National Academy Press.
- Jemal, A., Siegel, R., Xu, J., & Ward, E. (2010). Cancer statistics, 2010. *CA: A Cancer Journal for Clinicians*, 60(5), 277-300.
- Jones, S. C., & Johnson, K. (2012). Women's awareness of cancer symptoms: a review of the literature. *Women's Health*, 8(5), 579-591.
- Kane, M. T. (1994). Validating interpretive arguments for licensure and certification examinations. *Evaluation & the Health Professions*, 17(2), 133-159.
- Kelly, B. J., Frazee, T. K., & Hornik, R. C. (2010). Response rates to a mailed survey of a representative sample of cancer patients randomly drawn from the Pennsylvania Cancer

- Registry: a randomized trial of incentive and length effects. *BMC Medical Research Methodology*, 10(1), 65.
- Keogh, E. (2014). Gender differences in the nonverbal communication of pain: A new direction for sex, gender, and pain research?. *Pain*, 155(10), 1927-1931.
- Komurcu, S., Nelson, K. A., Walsh, D., Donnelly, S. M., Homsy, J., & Abdullah, O. (2000). Common symptoms in advanced cancer. *Seminars in Oncology*, 27(1), 24-33.
- Kongsved, S. M., Basnov, M., Holm-Christensen, K., & Hjollund, N. H. (2007). Response rate and completeness of questionnaires: a randomized study of Internet versus paper-and-pencil versions. *Journal of Medical Internet Research*, 9(3), e25.
- La Fargue, M. M. (2010). Policy and advocacy in the quest for effective translational breast care research. *The Breast*, 19(4), 303-306.
- Lohr, K. N., Aaronson, N. K., Alonso, J., Burnam, M. A., Patrick, D. L., Perrin, E. B., & Roberts, J. S. (1996). Evaluating quality-of-life and health status instruments: Development of scientific review criteria. *Clinical Therapeutics*, 18(5), 979-992.
- Lynn, M. R. (1986). Determination and quantification of content validity. *Nursing Research*, 35(6), 382-386.
- Lythcott, N., Green, B. L., & Kramer Brown, Z. (2003). The perspective of African-American breast cancer survivor-advocates. *Cancer*, 97(S1), 324-328.
- MacCallum, R. C., Widaman, K. F., Preacher, K. J., & Hong, S. (2001). Sample size in factor analysis: The role of model error. *Multivariate Behavioral Research*, 36(4), 611-637.
- Martin, E. (1988). Medical metaphors of women's bodies: Menstruation and menopause. *International Journal of Health Services*, 18(2), 237-254.
- McCabe, M. S., Varricchio, C. G., Padberg, R., & Simpson, N. (1995). Women's health advocacy: Its growth and development in oncology. *Seminars in Oncology Nursing*, 11(2), 137-142.

- McConigley, R., Holloway, K., Smith, J., Halkett, G., Keyser, J., Aoun, S., & Monterosso, L. (2011). The diagnosis and treatment decisions of cancer patients in rural Western Australia. *Cancer Nursing*, 34(4), E1-E9.
- McNally, S. (1996). Self-advocacy skills workshop: a report. *British Journal of Nursing*, 5(2), 99-103.
- Mendelson, C., & Poole, J. L. (2007). Become your own advocate: advice from women living with scleroderma. *Disability and Rehabilitation*, 29(19), 1492-1501.
- Meropol, N. J., Egleston, B. L., Buzaglo, J. S., Balshem, A., Benson, A. B., Cegala, D. J., ... & Weinfurt, K. P. (2013). A Web-based communication aid for patients with cancer. *Cancer*, 119(7), 1437-1445.
- Miaskowski, C. (2003). Gender differences in pain, fatigue, and depression in patients with cancer. *Journal of the National Cancer Institute. Monographs*, (32), 139-143.
- Moshiri, B. (2014). Halted [Painting]. Retrieved from <https://worldwideartla.com/chat-artist-breast-cancer-survivor-boutia-moshiri/>
- Munro, B. H. (2001). Statistical methods for health care research (4th ed.). Philadelphia Lippincott.
- Mutchler, M. G., Wagner, G., Cowgill, B. O., McKay, T., Risley, B., & Bogart, L. M. (2011). Improving HIV/AIDS care through treatment advocacy: Going beyond client education to empowerment by facilitating client-provider relationships. *AIDS Care*, 23(1), 79-90.
- National Coalition for Cancer Survivorship: Cancer Survival Toolbox: Available at: <http://www.canceradvocacy.org/toolbox/>. Accessibility verified June 20, 2015.
- National Institute of Nursing Research. (2011). Bringing Science to Life: NINR Strategic Plan.
- Nunnally, J. C. (1978). Psychometric theory (2nd ed.). New York, McGraw Hill.

- O'Brien, M. A., Whelan, T. J., Charles, C., Ellis, P. M., Gafni, A., Lovrics, P., ... & Dimitry, S. (2008). Women's perceptions of their treatment decision-making about breast cancer treatment. *Patient Education and Counseling*, 73(3), 431-436.
- O'Hair, D., Villagran, M. M., Wittenberg, E., Brown, K., Ferguson, M., Hall, H. T., & Doty, T. (2003). Cancer survivorship and agency model: Implications for patient choice, decision making, and influence. *Health Communication*, 15(2), 193-202.
- Orjuela, C. A. (2006). Why me? [Painting]. Retrieved from <http://www.yenra.com/cancer/art.html>
- Osborne, R. H., Elsworth, G. R., Kissane, D. W., Burke, S. A., & Hopper, J. L. (1999). The Mental Adjustment to Cancer (MAC) scale: Replication and refinement in 632 breast cancer patients. *Psychological Medicine*, 29(06), 1335-1345.
- Paulson, E. C., Wirtalla, C., Armstrong, K., & Mahmoud, N. N. (2009). Gender influences treatment and survival in colorectal cancer surgery. *Diseases of the Colon & Rectum*, 52(12), 1982-1991.
- Pickett, S. A., Diehl, S., Steigman, P. J., Prater, J. D., Fox, A., & Cook, J. A. (2010). Early outcomes and lessons learned from a study of the Building Recovery of Individual Dreams and Goals through Education and Support (BRIDGES) program in Tennessee. *Psychiatric Rehabilitation Journal*, 34(2), 96.
- Pigott, C., Pollard, A., Thomson, K., & Aranda, S. (2009). Unmet needs in cancer patients: Development of a supportive needs screening tool (SNST). *Supportive Care in Cancer*, 17(1), 33-45.
- Polit, D. F., & Beck, C. T. (2006). The content validity index: Are you sure you know what's being reported? Critique and recommendations. *Research in Nursing & Health*, 29(5), 489-497.
- Radina, M. E., Ginter, A. C., Brandt, J., Swaney, J., & Longo, D. R. (2011). Breast cancer patients' use of health information in decision making and coping. *Cancer Nursing*, 34(5), E1-E12.

- Richard, A. A., & Shea, K. (2011). Delineation of Self-Care and Associated Concepts. *Journal of Nursing Scholarship*, 43(3), 255-264.
- Rosenzweig, M. Q., Wiehagen, T., Brufsky, A., & Arnold, R. (2009). Challenges of illness in metastatic breast cancer: a low-income African American perspective. *Palliative and Supportive Care*, 7(2), 143-152.
- Rosenzweig, M. Q., Wiehagen, T., Brufsky, A., Sillaman, A., & Arnold, R. (2009). The unique perspective of illness among women with metastatic breast cancer according to race and income. *Journal of Hospice & Palliative Nursing*, 11(1), 27-38.
- Rouquette, A., & Falissard, B. (2011). Sample size requirements for the internal validation of psychiatric scales. *International Journal of Methods in Psychiatric Research*, 20(4), 235-249.
- Saatci, E., Akin, S., & Akpinar, E. (2007). Do the unmet needs affect the quality of life in breast cancer patients?. *The West Indian Medical Journal*, 56(3), 253-257.
- Seale, C., Ziebland, S., & Charteris-Black, J. (2006). Gender, cancer experience and internet use: a comparative keyword analysis of interviews and online cancer support groups. *Social Science & Medicine*, 62(10), 2577-2590.
- Sereika, S. M., & Engberg, S. J. (2006). Development of standardized sociodemographic and comorbidity questionnaires. In *Sigma Theta Tau International Honor Society of Nursing 17th International Nursing Research Congress*.
- Shadish, W. R., Cook, T. D., & Campbell, D. T. (2001). *Experimental and quasi-experimental designs for generalized causal inference* (2nd ed.). Florence, KY: Wadsworth Publishing.
- Shapiro, C. L., McCabe, M. S., Syrjala, K. L., Friedman, D., Jacobs, L. A., Ganz, P. A., ... & Marcus, A. C. (2009). The LIVESTRONG survivorship center of excellence network. *Journal of Cancer Survivorship*, 3(1), 4-11.
- Shoemaker, L. K., Estfan, B., Induru, R., & Walsh, T. D. (2011). Symptom management: An important part of cancer care. *Cleveland Clinic Journal of Medicine*, 78(1), 25-34.

- Sinding, C., Hudak, P., Wiernikowski, J., Aronson, J., Miller, P., Gould, J., & Fitzpatrick-Lewis, D. (2010). "I like to be an informed person but..." negotiating responsibility for treatment decisions in cancer care. *Social Science & Medicine*, 71(6), 1094-1101.
- Sinding, C., Miller, P., Hudak, P., Keller-Olaman, S., & Sussman, J. (2012). Of time and troubles: Patient involvement and the production of health care disparities. *Health (London)*, 16(4), 400-417.
- Skalla, K. A., Bakitas, M., Furstenberg, C. T., Ahles, T., & Henderson, J. V. (2003). Patients' need for information about cancer therapy. *Oncology Nursing Forum*, 31(2), 313-319.
- Sheppard, V. B., Adams, I. F., Lamdan, R., & Taylor, K. L. (2011). The role of patient-provider communication for black women making decisions about breast cancer treatment. *Psycho-Oncology*, 20(12), 1309-1316.
- Sherwood, P. R., Donovan, H. S., Rosenzweig, M., Hamilton, R., & Bender, C. M. (2008). A house of cards: The impact of treatment costs on women with breast and ovarian cancer. *Cancer nursing*, 31(6), 470-477.
- Stevens, J. (2002). *Applied Multivariate Statistics for the Social Sciences*. Lawrence Erlbaum,
- Stovall, E., Greenfield, S., & Hewitt, M. (Eds.). (2005). *From cancer patient to cancer survivor: Lost in transition*. National Academies Press.
- Sulik, G. A. (2007). On the receiving end: Women, caring, and breast cancer. *Qualitative Sociology*, 30(3), 297-314.
- Sulik, G. A., Cameron, C., & Chamberlain, R. M. (2012). The future of the cancer prevention workforce: Why health literacy, advocacy, and stakeholder collaborations matter. *Journal of Cancer Education*, 27(2), 165-172.
- Szumacher, E. (2006). The feminist approach in the decision-making process for treatment of women with breast cancer. *Annals – Academy of Medicine Singapore*, 35(9), 655.
- Tabachnick, B., & Fidell, L. (2001). Principal components and factor analysis. *Using Multivariate Statistics* 4th Ed., 582-652.

- Test, D. W., Fowler, C. H., Brewer, D. M., & Wood, W. M. (2005). A content and methodological review of self-advocacy intervention studies. *Exceptional Children*, 72(1), 101-125.
- Tschopp, M. K., Frain, M. P., & Bishop, M. (2008). Empowerment variables for rehabilitation clients on perceived beliefs concerning work quality of life domains. *Work (Reading, Mass.)*, 33(1), 59-65.
- U.S. Public Health Service. (2010). Moving Into the Future with New Dimensions and Strategies: A Vision for 2020 for Women's Health Research. *Bethesda, MD: National Institutes of Health*.
- van den Berg, M. H., Overbeek, A., van der Pal, H. J., Versluys, A. B., Bresters, D., van Leeuwen, F. E., ... & van Dulmen-den Broeder, E. (2011). Using web-based and paper-based questionnaires for collecting data on fertility issues among female childhood cancer survivors: Differences in response characteristics. *Journal of Medical Internet Research*, 13(3), e76.
- Vessey, J. A., & Miola, E. S. (1996). Teaching adolescents self-advocacy skills. *Pediatric Nursing*, 23(1), 53-56.
- Vogt, D. S., King, D. W., & King, L. A. (2004). Focus groups in psychological assessment: Enhancing content validity by consulting members of the target population. *Psychological Assessment*, 16(3), 231-243.
- Wade, M. E. (2001). Women and salary negotiation: The costs of self-advocacy. *Psychology of Women Quarterly*, 25(1), 65-76.
- Walker, L. O., & Avant, K. C. (2005). *Strategies for Theory Construction in Nursing* (4th ed.). Upper Saddle River, NJ: Pearson Prentice Hall.
- Walsh-Burke, K., & Marcusen, C. (1999). Self-advocacy training for cancer survivors. *Cancer Practice*, 7(6), 297-301.

Watt, J. H., & van den Berg, S. (1995). *Research Methods for Communication Science*. Boston, MA: Allyn & Bacon.

Wen, K. Y., & Gustafson, D. H. (2004). Needs assessment for cancer patients and their families. *Health and Quality of Life Outcomes*, 2(1), 11.

Wiltshire, J., Cronin, K., Sarto, G. E., & Brown, R. (2006). Self-advocacy during the medical encounter: Use of health information and racial/ethnic differences. *Medical Care*, 44(2), 100-109.

Yeom, H. E., & Heidrich, S. M. (2009). Effect of perceived barriers to symptom management on quality of life in older breast cancer survivors. *Cancer Nursing*, 32(4), 309.