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Cancer Survivor Empowerment Through Patient-Reported Outcomes

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ABSTRACT

Background: Conventional approaches for assessing and managing symptoms in cancer survivors are unlikely to be effective in cancer survivorship care because clinician-driven assessment limits the voice of the cancer survivor while the burden and complexity of cancer care increases. Yet, cancer survivors are not prepared for the shift from clinician-driven assessment and management of symptoms to cancer survivor self-report of symptoms and self-management of their own care. There are gaps in clinician assessment, and no studies describe how patient empowerment may facilitate the cancer survivor's ability to assume the responsibilities of monitoring, reporting, and managing symptoms as the cancer survivor transitions into early survivorship. Patient-reported assessment of symptoms, utilizing patient-reported outcomes (PROs) instruments, may be a mechanism to empower cancer survivors; however, the relationship and associations are not known. Although PROs are not a standard of care, these assessment instruments are included in clinical trials and becoming embedded into the patient electronic health record [EHR]. However, it is unknown if the use of PROs assessments in clinical practice leads to understanding cancer survivor empowerment and if the investment of resources to implement PROs assessment tools is value-added.

Purpose: The purpose of this repeated measures study was to assess if the use of PROs is associated with patient empowerment of adult cancer survivors in early survivorship following primary cancer treatment. The aims were to: (1) describe the relationship between patient empowerment and PROs in breast, colorectal, gynecological, and lung cancer survivors; (2) demonstrate the associations between patient empowerment and PROs in these survivors after

controlling for demographic and clinical characteristics; and (3) explore whether the associations between patient empowerment and PROs change over time, comparing immediately post-treatment and three months post-treatment after controlling demographic and clinical characteristics.

Methods: A convenience sample of 83 adult breast, colorectal, gynecologic, and lung cancer survivors immediately following chemotherapy in any phase of primary cancer treatment were invited to participate. The setting for recruitment is a multi-site community-based cancer center with three hospital-based, outpatient medical oncology clinics in southeastern Wisconsin. Patient clinic schedules were reviewed to identify potential subjects. If eligible, the patient was invited to participate, and informed consent was obtained. The participant chose to complete the questionnaire online or paper format in the clinic and was given a unique passcode. Thirty-three participants, who met eligibility by finishing chemotherapy as the last treatment modality for primary cancer treatment, completed the questionnaire again three months post-treatment for the exploratory aim. *Cancer-related Patient Empowerment Scale, PROMIS® Self-Efficacy Managing Chronic Diseases, and PROMIS®-29 Profile v2.1,* instruments were utilized. Sociodemographic data and clinical characteristics were collected from the participants and their electronic health record. Data analysis used *t*-test, Pearson's correlation coefficient, and hierarchical multiple regression analysis. The statistical analysis was determined at a level of 0.05 level of significance. In addition, analysis of covariance (ANCOVA) for repeated measures was used for the exploratory aim.

Results: Pearson's correlation coefficient found a significant relationship between patient empowerment and self-efficacy, and a significant negative correlation between self-efficacy and symptoms was observed. While patient empowerment and PROs symptom profile total score did

not demonstrate a significant linear relationship, symptom profile subscales were associated with patient empowerment except for sleep disturbances. Managing social role and activities and physical function were positively correlated with patient empowerment whereas a negative correlation was found between patient empowerment and the following symptoms depression, anxiety, fatigue, pain interference and pain rating. Hierarchical multiple regression analysis demonstrated that PROs self-efficacy predicts patient empowerment immediately following chemotherapy treatment; however, this was not observed in the subset of participants when measured again three months post-treatment. PROs symptom profile total score did not add significantly to the model. A decrease in patient empowerment from immediately following the last dose of chemotherapy to three months post-treatment was found using ANCOVA repeated measures, controlling age and highest level of education completed. However, PROs self-efficacy and symptom profile had no statistically significant change observed from immediate post-chemotherapy treatment to three months post-treatment.

Conclusions/Implications: Due to the complex, changing paradigm of cancer care and conventional clinician-driven assessment less sustainable in survivorship care, cancer survivor empowerment must be assessed and supported in clinical practice, engaging survivors in their new responsibilities of self-monitoring, self-reporting, and self-managing symptoms. PROs self-efficacy was a predictor of patient empowerment immediately following the last dose of chemotherapy, but it is seldom assessed in clinical practice. With a decline in patient empowerment and no statistically significant changes in PROs self-efficacy and symptoms from last dose of chemotherapy to three months post-treatment, a qualitative study for conceptual clarification of patient empowerment in cancer survivors is needed, and further studies to investigate what other PROs and/or related concepts describe the decrease in patient

empowerment and what PROs depict patient empowerment at transition points throughout early survivorship are logical next steps for research. A transition to cancer survivor-reported assessment with PROs self-efficacy and symptoms, demonstrating linearity in this study, immediately following last dose of chemotherapy treatment for breast, colorectal, lung, and gynecological cancer survivors, receiving care in a medical oncology clinic, may be a practical starting point; however, generalizability to more diverse populations is limited. Clinicians will need to expand their knowledge of patient empowerment and PROs to prepare themselves to engage cancer survivors to self-monitor, self-report, and self-manage in early survivorship. Oncology nurses are critical for envisioning how to transition from clinician-driven assessment to cancer survivor-reported assessment and implementing research-based interventions that build empowerment in cancer survivors. The investment of resources to train clinicians and survivors to implement PROs assessment tools in a community cancer center is value-added and necessary to empower cancer survivors in early survivorship to achieve optimal outcomes.

Key words: cancer survivor, patient empowerment, patient-reported outcomes, symptoms

CHAPTER I

INTRODUCTION

The number of cancer survivors in the United States, projected to increase by 31% from 15.5 million to 20 million by 2026 (NCI Office of Cancer Survivorship, 2016) amidst a rapidly changing health care system, tightening of financial resources, and increasing focus on value-based care. Conventional approaches for assessing and managing late and long-term symptoms in cancer survivors are unlikely to be effective because the voice of the cancer survivor remains limited while the burden and complexity of cancer care progresses. The burden of cancer, its treatment, and symptoms has been shifting from clinicians to cancer survivors to self-manage their care, and assuming the accountability for monitoring, reporting symptoms to clinicians, and managing them (Foster et al., 2014; McCorkle et al., 2011; Moody & Jackowski, 2010; Roop & Wu, 2014). Many cancer survivors are living longer, changing the view of cancer from an acute to a chronic disease (Bulsara et al., 2006; Loh et al., 2013; McCorkle et al., 2011), necessitating maintenance or periodic treatments, ongoing monitoring for symptoms, and surveillance for recurrence. However, cancer survivors are not prepared for a new paradigm in which they assume primary responsibility to assess, monitor, report, or manage late and long-term effects of their cancer (Phillips & Currow, 2010).

While multiple symptoms occur simultaneously during active treatment (Cleeland et al., 2000; Donovan et al., 2005; Portenoy et al., 1994), approximately, one-third of patients receiving chemotherapy and radiation therapy experience three or more moderate to severe symptoms during and for one year after treatment with less connection to clinicians and cancer care services

(Shi et al., 2011; Wu & Harden, 2015). Symptoms, both expected side effects and adverse toxicities, may lead to a disruption of usual activities, increase physical and functional impairments, heighten emotional distress, and decrease patient adherence, negatively impacting cancer survivor outcomes and quality of life (Esther Kim et al., 2009; Troeschel et al., 2016). Furthermore, the associated symptom burden, severity, and impact of symptoms, affect the cancer survivor's physical function (Cleeland, 2007). Consequently, adult cancer survivors may not be able to fully participate in work and life roles due to restrictions in their mobility and activities of daily living, limiting their independence (Alfano et al., 2019). Additionally, less is known about the symptom experience associated with promising new, novel cancer treatments, such as oral targeted therapies and immunotherapies, and how they may impact long-term effects of physical symptoms, psychosocial distress, physical function, and quality of life among cancer survivors (Atkinson et al., 2017). As such, the chronicity of cancer requires a change in how survivors are empowered and subsequently, engaged in the self-assessment, self-monitoring, and self-management of symptoms.

Problem Statement

Current approaches for assessing and monitoring symptoms in routine cancer care remain clinician-driven, meaning clinician or unlicensed staff elicits response from the patient about symptoms that the clinician identifies as relevant. This symptom assessment approach is oriented toward physical symptoms and to a lesser degree psychosocial distress, physical function, and quality of life. Clinician-rated symptoms emphasize objective, acute toxicities of cancer therapies over patient-rated symptoms (Atkinson et al., 2012; Xiao et al., 2013), and may disregard the assessment of subjective symptoms, such as anxiety, depression, fatigue, and

nausea. As such, symptoms are undetected and underestimated by clinicians in both prevalence and severity (Basch et al., 2011; Fiteni et al., 2019; Fromme, Eilers et al., 2004; Movsas, 2015; Pakhomov et al., 2008; Trautmann et al., 2016).

Contrary to the growing expectation that cancer survivors self-manage the late and long-term effects of their cancer (Hagan & Donovan, 2013), there are multiple gaps in the current conventional, paternalistic approach of clinician's eliciting symptom assessment from cancer survivors, raising a fundamental question about a symptom assessment approach that does not transfer "power" from the clinician to the patient. This approach does not promote patient empowerment in cancer survivors, who may be experiencing complex physical and psychological symptoms, changes in physical function, and quality of life issues. Some of the key symptom assessment gaps include: (a) lack of integration of patient self-reported symptoms (Atkinson et al., 2012; Basch et al., 2011); (b) disconnection between symptom detection and further symptom assessment and intervention (Ester Kim et al, 2009; Reeve et al., 2014; Reilly et al., 2013); (c) episodic symptom assessment rather than continuous monitoring of symptoms over time (Quinten et al., 2011; Trajkovic-Vidakovic et al., 2012); (d) insufficient assessment of late term symptoms or side effects (McCorkle et al, 2011; Shi et al., 2011; Wu & Harden, 2015); and (e) poor capture of real-time symptom data collection in electronic health record [EHR] (Atkinson et al., 2017; Berry et al., 2011; Fiteni, 2019; Howell et al., 2015; Kotronoulas et al., 2014; Luckett et al., 2009).

While there have been advances in the integration of psychosocial distress assessment through standards established by national quality accreditation programs, such as the American College of Surgeons Commission on Cancer (ACoS CoC®) and National Accreditation

Programs for Breast Centers (NAPBC®); there is a lack of consistent, concurrent assessment of physical function with other physical, psychosocial, and quality of life symptoms. Given that physical function has been identified as a predictor of survival outcomes (Basch et al., 2016; Gotay et al., 2008; Carey et al., 2008; Quinten et al., 2011), the lack of a standardized, consistently utilized physical function measure is a gap in oncology practice. The assessment of physical function is limited, occurring on the initial clinic visit and upon clinician-observed deterioration of function. The assessment of physical function may consist of a few screening questions focused on mobility and gait, but this method lacks a more comprehensive assessment of physical function impairments related to type of cancer, its treatment, and co-morbid conditions, impacting daily life of a cancer survivor.

Furthermore, the current assessment approach does not consistently incorporate the patient's voice throughout the continuum of care: diagnosis, active cancer treatment, and post-treatment into survivorship (Atkinson et al., 2017; Basch et al., 2011). As such, this symptom assessment approach may lead to lower empowerment and, subsequently, less engagement and poor self-management. For example, following chemotherapy treatment, a clinician may ask a patient if they have had any fevers or chills and any other signs of infection. After the patient's response, the clinician tells the patient to take their temperature daily and when they feel a chill at home. The clinician may have provided the instruction but did not assess for the patient's ability to perform a task, such as how to take the temperature (knowledge); whether or not the patient has a thermometer (resource); the patient's ability to properly take a temperature (skill); or provided information on frequency, duration, and recognition of parameters and symptoms for when to call the physician. If the patient does not follow the instruction to monitor their

temperature, clinicians may refer to the patient as non-compliant or non-adherent when the expectations of clinicians are unrealistic for the patient's circumstances (Lorig, 2002).

The capacity of patients for self-empowerment may be limited by personal characteristics, illness circumstances, access to social support, and their own personal values (Bravo et al., 2015). Rather than non-adherent or non-compliant, perhaps, it is that the clinician has not assessed if the patient (or cancer survivor) is capable of the responsibilities of self-managing a chronic disease and its symptoms. Some of these responsibilities may include (a) using medications properly; (b) changing health behavior to improve symptoms or decrease progression of disease; (c) coping with the psychological or emotions; (d) adjusting to social or financial burdens; and (e) monitoring and reporting of symptoms to clinicians (Holman & Lorig, 2004).

As patients are capable of self-reporting symptoms (Atkinson et al., 2012; Basch et al., 2007; Basch et al., 2005; Basch et al., 2009; Howell et al., 2015; Lipscomb et al., 2007), a new approach to symptom assessment that is inclusive of patient self-report is needed. Patient self-reported symptoms, referred to as patient-reported outcomes (PROs), have demonstrated an enhanced approach to symptom assessment and improved communication between patients and clinicians (Atkinson, et al., 2017; Basch et al., 2016). PROs are defined as "…any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (United States Food and Drug Administration, 2009). Frequently, PROs are incorrectly referred to as outcome measures (Black, 2013). PROs measure health at different time intervals so that the outcome of the care received by the patient or survivor can be determined (Black, 2013), making them useful in symptom assessment.

There has been a paradigm shift towards the use of PROs for adverse drug reaction reporting in clinical trials (Reilly et al., 2013) with the expectation that PROs will empower patients' decision-making based on their own values (Calvert et al., 2013). However, it is unknown if PROs are associated with patient empowerment as patient empowerment has not been well-defined, conceptualized, or measured in cancer or cancer survivorship literature. Additionally, the transition to the routine use of PROs in community-based cancer practices is still in the early phase of adoption, lessening the patient's voice in their own cancer care (Basch et al., 2014; Basch et al., 2012; Basch et al., 2016). PROs are increasingly becoming more integrated into symptom and functional assessments as EHR systems build PROs into their platforms, improving communication between clinicians and cancer survivors (Atkinson et al., 2017; Basch et al., 2016); however, PROs have only demonstrated a small to moderate effect on symptom reduction and subsequently health outcomes (Black, 2013; Hilarius et al., 2008; Howell et al., 2015; Kotronoulas et al., 2014; Luckett et al., 2009).

A question that has not been asked of cancer survivors in routine cancer care is if the cancer survivor is able to assume responsibility for monitoring, reporting, and managing symptoms in this new paradigm, especially at key transition points, such as the end of primary cancer treatment. Consequently, it remains unknown if PROs assessments empower cancer survivors to become more active in their own care, and subsequently, engage in reporting symptoms or self-management. Clinicians make assumptions about the extent to which cancer survivor is willing and able to engage as their own care without a consistent instrument to measure empowerment or outcomes of empowerment, like self-efficacy, to identify cancer survivors who may need more support during and post-treatment.

The routine use of PRO assessment of self-efficacy combined with physical symptom and functional assessment has recently been recommended for cancer patients as lower levels of self-efficacy among breast and gastrointestinal cancer patients were associated with poorer symptom outcomes and physical function (Kelleher et al., 2016). Because PROs are moving into EHR platforms, there may be value in knowing if PRO measures, like physical function and self-efficacy, empower cancer survivors, especially in early survivorship period at the end of or immediately following primary cancer treatment and up to the first-year post-treatment when symptoms are more prevalent and potentially more problematic (Shi et al., 2011; Wu & Harden, 2015).

In summary, there are limited studies that describe patient empowerment in people with cancer as more focus has been devoted to other chronic diseases. When cancer survivors are not self-reporting physical and psychosocial symptoms, physical function, and quality of life, symptom assessment is not comprehensive at a critical transition point, moving from the end of primary cancer treatment into early survivorship. The current clinician-driven approach does not capture symptoms pertinent to the survivor nor assess the cancer survivor's ability to self-manage them when symptoms are most prevalent. Most cancer care is provided in community-based practice settings closer to home with a unique, heterogeneous cancer population where resources, access, and support systems may be limited, and therefore, further development of resources and programs to support cancer survivors in early survivorship will likely be required. However, until the symptom assessment approach incorporates the patient voice, it is unknown what resources will meet cancer survivors' needs because clinicians do not assess the cancer

survivor's level of patient empowerment to engage and self-manage their cancer and its symptoms as they transition from primary cancer treatment into early survivorship.

Patient empowerment among cancer survivors is a current gap in the literature. The relationship between patient empowerment and PROs warrants further exploration, especially PROs not integrated into current symptom assessment, such as self-efficacy and physical function. The use of PRO self-efficacy instruments has increased in clinical trials as a pertinent assessment alongside other more common PROs (Porter et al., 2002; Kelleher et al., 2016); however, it has not changed assessment of cancer survivors in community-based oncology practices. PRO physical function has demonstrated an impact on survival outcomes (Basch et al., 2016; Carey et al., 2008; Gotay et al., 2008; Quinten et al., 2011); yet there is poor assessment of physical function in the current assessment approach in community-based cancer centers (Alfano et al., 2019; Cheville et al., 2008). Determining if PROs are associated with patient empowerment in cancer survivors may be a necessary and missing assessment component of the current symptom assessment approach to understand how cancer survivors engage in and self-manage multiple, moderate to severe symptoms in early survivorship. Moreover, this study may provide further insights into the conceptual model of patient empowerment and inform future longitudinal studies in cancer survivors.

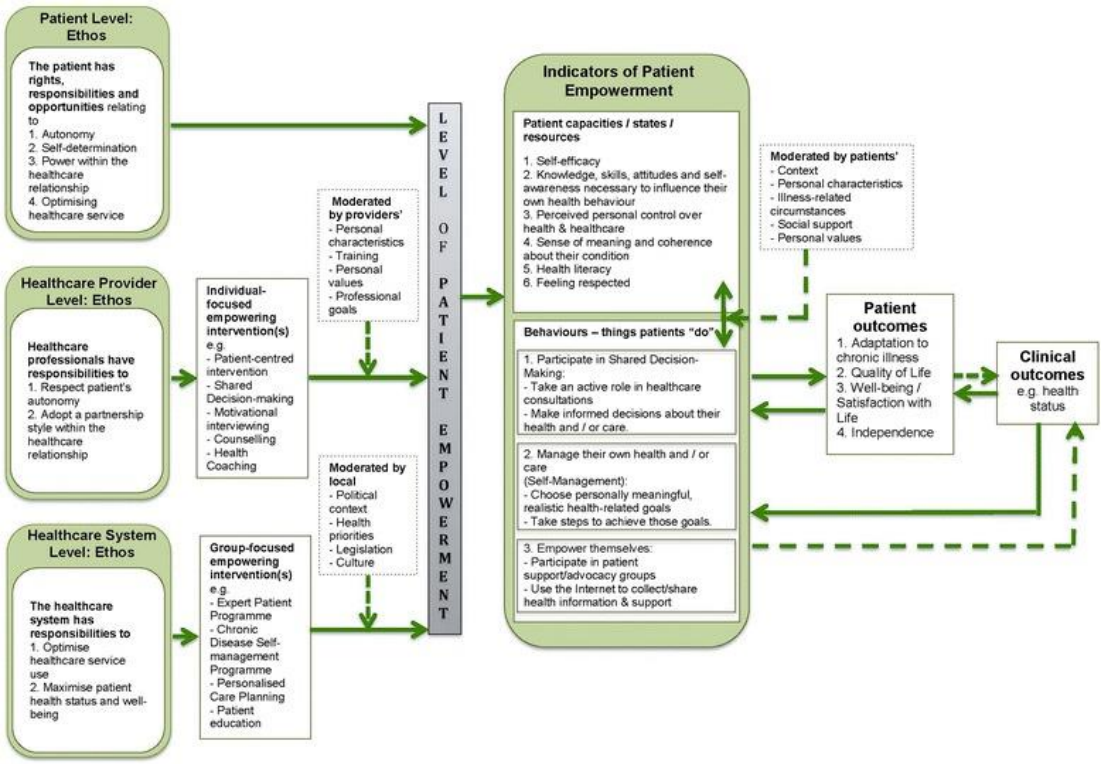
Theoretical Framework

While there are several models of patient empowerment, such as the Health Empowerment Model (Schulz & Nakamoto, 2013); Process Model for Concepts of Patient Empowerment, Patient Participation, and Patient-Centeredness in Health Care (Castro et al., 2016); and Conceptual Model of Empowering Patients in Controlling Cancer Pain (Te Boveldt et

al., 2014), the Bravo et al. (2015) Conceptual Model of Empowerment was utilized because it allows for exploration of PROs of interest in this study.

Bravo et al. (2015) proposed a conceptual model of patient empowerment in primary care of patients with long-term chronic diseases, originated in the United Kingdom that will be utilized as a framework for this study (Figure 1). Developed from a mixed methods study of a scoping review of the literature and qualitative interviews of patients and clinicians, this model describes patient empowerment as a transformative process along a spectrum from high to low levels of patient empowerment, identifying five key components: 1) underpinning of ethos; 2) moderators; 3) indicators; 4) empowering interventions; and 5) outcomes from the patient, clinician, and health care system perspectives.

Figure 1. Conceptual Model for Patient Empowerment



*Note***.** Reprinted from "Conceptualizing patient empowerment: A mixed methods study" (Bravo et al., 2015)

Components of the Conceptual Model. To further describe the components of this model, the *underpinning of ethos* is defined as "principles or values" from the patient, clinician, or health care system level. However, it is the underpinning of ethos from patient level that is pertinent in this study as it seeks knowledge about the cancer survivor's description of patient empowerment. Patient level ethos refers to the patient's "…rights, responsibilities, and opportunities relating to autonomy, self-determination, and power within the healthcare relationship as well as to optimize healthcare service" rather than the clinician or health care system (Bravo et al., 2015, p. 9). *Indicators* of patient empowerment refer to a "state" along a spectrum of high to low levels of empowerment, indicated by patient capacities, beliefs, and resources and *behaviors* to demonstrate an active role in their healthcare and self-management of their chronic disease (Bravo et al., 2015). While patient capacities, beliefs, and resources include: (1) self-efficacy; (2) knowledge and skills; (3) perceived control; (4) sense of meaning; (5) health literacy; and (6) feeling respected, behaviors refer to actions or "things patients do" when they are empowered and subsequently engage in activities, such as (1) shared decision-making; (2) self-management; and (3) empowering themselves. *Moderators* of patient empowerment are variables that influence the patient's ability to assume patient empowerment activities, including (a) patient context; (b) personal characteristics; (c) illness-related circumstances (e.g., duration and severity of disease); (d) social support; and (e) personal values.

Empowering interventions are interventions that may be implemented by clinicians and healthcare systems to promote patient empowerment while *outcomes* refer to improved health status which may be measured by patient outcomes and clinical outcomes (Bravo et al., 2015). Evidence supports that control of the underlying disease is improved when patients are

empowered to manage their own illness (Anderson & Funnell, 2004; Bodenheimer et al., 2002; McCorkle et al., 2011). *Outcomes* of patient empowerment are defined as patient outcomes, such as (a) adaption to their chronic illness; (b) quality of life; (c) well-being; and (d) greater independence from clinicians and health care system; and clinical outcomes, described as health status associated with long-term outcomes.

Assumptions. A premise of the conceptual model of patient empowerment is that patient empowerment is a transformative process for which patients with long-term chronic diseases progress to gain control through behaviors that lead to improved outcomes of their health and healthcare as they adapt to living with a chronic disease as mediated by moderators and demonstrated by behaviors or activities that are empowering (Bravo et al., 2015). The assumptions of the model are: (a) patient empowerment is a commonly held value; (b) patient empowerment is a positive journey towards improved health, well-being, and quality of life; (c) patients with long-term chronic illness progress forward through this model; (d) the level of patient empowerment increases through this process, such as when new knowledge and skills are acquired; and e) clinicians adopt a partnership with patients, living with chronic diseases that supports informed patient decision-making and promotes self-management. The components and sub-components of the model are not fully described. There are limited bidirectional arrows or linkages of concepts to describe what patient empowerment indicators and/or moderators may influence higher or lower levels of patient empowerment.

Furthermore, patient engagement, recognized as a consequence of patient empowerment (Fumagalli et al., 2015), is not specifically addressed in the model, but this concept may be inferred in the behaviors or activities (e.g., shared decision-making, self-management, and

empowering behavior) that an individual engages in to demonstrate patient empowerment. Empowering behaviors may also refer to other concepts related to patient empowerment, such as patient activation, but are not explicitly stated.

Propositions. The conceptual model of patient empowerment is a complex linear model. At the patient level, the concept of patient empowerment has a lateral arrow toward the indicators of patient empowerment with a bidirectional arrow between patient capacities, states, and resources and behaviors, indicating a dual reciprocal relationship, meaning that they are related to each other and share commonalities. For example, if the patient receiving chemotherapy knows how to take the temperature (knowledge), can properly take a temperature (perform a skill or belief in ability to), and has a thermometer at home (resource), the patient monitors his or her temperature at home and calls to report it to the physician according to an established parameter. The knowledge, skill, belief, and/or resources lead to a behavior or action. Alternatively, the action of monitoring the temperature at home may lead to increased confidence in the ability to monitor symptoms.

The indicators of patient empowerment are connected to patient capacities, state, and resources and behaviors by a unidirectional arrow. Patient capacities, states, and resources include self-efficacy, knowledge, skills, attitudes, and self-awareness of health, perceived control over health and healthcare, sense of meaning and coherence, health literacy, and feeling respected. Clinical outcomes have a dashed line to indicate a more distal relationship as these are longer-term outcomes. Bravo et al. (2015) suggested that outcomes may be differentiated into immediate, intermediate, and long-term outcomes as described by de Haes and Benzing (2009) in their work of outcomes of medical communication; and proposed patient outcomes as

immediate and intermediate outcomes and clinical outcomes (i.e., health status) as long-term outcomes.

There are limited bidirectional arrows in this model set between the patient capacities, states, and resources and behaviors. Two arrows are used to connect patient behaviors to patient outcomes; and patient outcomes to clinical outcomes. There are no upward arrows, demonstrating how level of patient empowerment is affected by patient indicators. Other related terms, like patient activation or patient engagement were not indicated in this model, but perhaps, implied by the phrasing related to behavior as "things patients do" and the descriptors of behaviors are shared decision-making; managing their own health or care; and empowering themselves as seeking knowledge through support groups or internet (Figure 1).

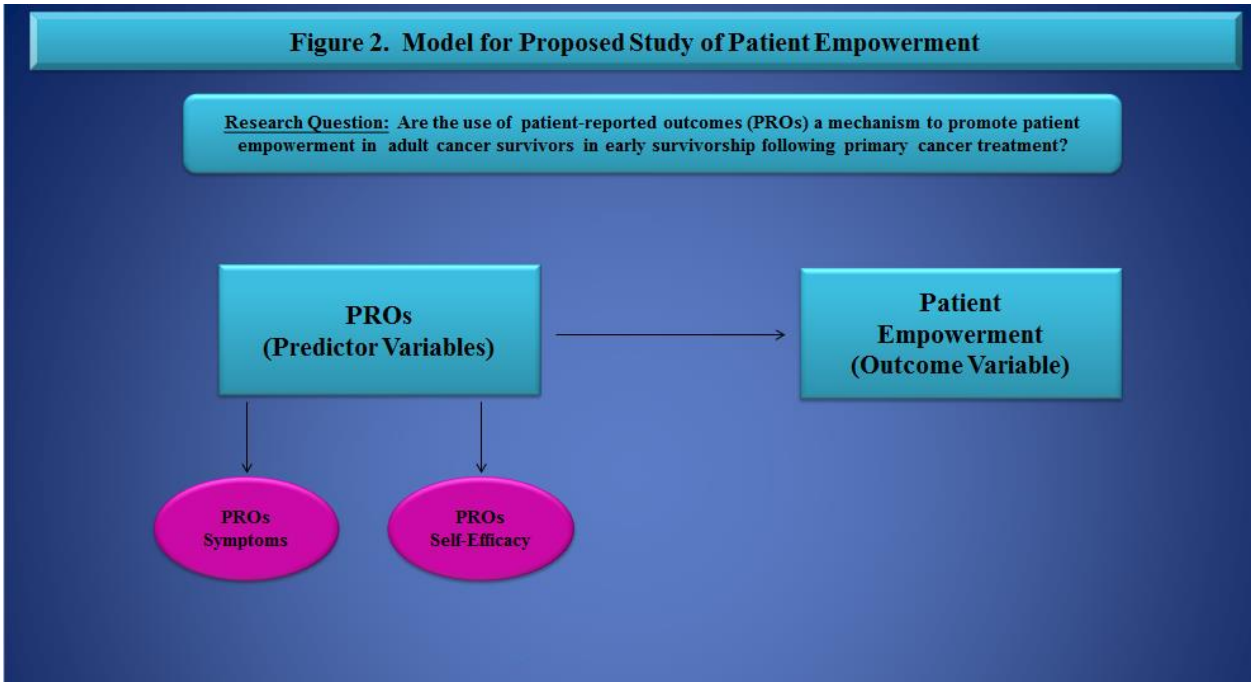
Hypotheses. As described by Bravo et al. (2015), the four hypotheses of the conceptual model of patient empowerment are: (1) empowered patients will report higher levels of patient capacity, states, and resources (e.g., self-efficacy); (2) empowered patients will have better self-reported patient and clinical outcomes; (3) a dual reciprocal relationship exists between patient capacities, beliefs, and resources and behaviors; and (4) dual reciprocal causal relationships exist between patient empowerment indicators and outcomes (i.e. patient and clinical). Based on these hypotheses, patient-reported measures may be utilized to operationalize patient indicators of patient empowerment (Bravo et al., 2015).

Gaps in the Conceptual Model. There are several gaps in the conceptual model of patient empowerment as it is a relatively new model for conceptualizing patient empowerment in patients living with a chronic disease. It has not been used with a cancer population (M. McAllister, personal communication, March 11, 2019). Bravo et al. (2015) recognized

geographic limitation to the United Kingdom as well as the small sample size of key stakeholders (patients and clinicians) who participated in interviews. The mixed stakeholders and predominately one-way progression through the model may not accurately describe patient empowerment at the patient level or what is observed in daily clinical practice, especially among cancer survivors. While patient-reported measures were identified to operationalize patient empowerment and identifies illness circumstances as a moderator, the conceptual model of patient empowerment does not indicate where treatment, symptoms, and physical function fit in the model.

Model for the Proposed Study. For the proposed study, the model focuses two aspects of the conceptual model of patient empowerment by Bravo et al. (2015): 1) patient capabilities, resources, and states, a patient indicator of empowerment; and 2) illness-related circumstances, a moderator of empowerment to describe the relationship between patient empowerment and PROs (Figure 2).

Figure 2. Model for Proposed Study Patient Empowerment and PROs



Patient Capacities, States, and Resources. One of the six patient capacities, states, and resources, identified in the conceptual model of patient empowerment (Bravo et al., 2015), is *self-efficacy*. It is of interest in this study because the relationship between patient empowerment and self-efficacy among cancer survivors at the end of primary cancer treatment in the United States is less known. The relationship between patient empowerment and self-efficacy may influence the cancer survivor's engagement in behaviors or activities, such as self-management, which subsequently influence patient and clinical outcomes. The operational definition for self-efficacy is a patient's belief in his or her ability to master or perform a specific behavior or task (Bandura, 1997). Self-efficacy, whether the cancer survivor feels that he or she is capable of managing cancer and its treatment is not assessed in routine oncology practice with a consistent assessment tool.

Illness-Related Circumstances. One of the moderators of patient empowerment,

identified in the conceptual model of patient empowerment (Bravo et al. 2015), is *illness-related circumstances*, which was briefly described as the circumstances of the individual's chronic disease, including duration and severity. It may be implied that treatment of chronic disease and its related symptoms and physical function impairments are connected to duration and severity of the chronic illness. For the individual living with cancer, the disease itself, treatment, and symptoms may influence their "illness-related circumstances." As such, an expanded definition of illness-related circumstances to include symptoms and physical function may be reasonable in the model for this study.

Cancer survivors living longer with cancer are likely to experience multiple and concurrent physical, functional, psychological, social, and spiritual symptoms (Association of Rehabilitation Nurses, 2011). While physical function has been studied and its assessment has been recognized as important for the early identification of cancer-related impairments, the assessment of physical function has not been adopted into routine symptom assessment in oncology practices (Silver et al., 2013). For this study, the operational definition of symptom is a subjective experience of biophysical, functioning, sensations, and cognitive changes of the individual (Dodd et al., 2001), including physical, psychological, and social symptoms; and physical function is the capability of an individual to perform physical activities (PROMIS® Physical Function, 2018). Thus, illness-related circumstances will be expanded to include symptoms and physical function. This study focused on symptoms and physical function to describe the relationship between patient empowerment and physical function.

Patient Characteristics. Patient demographics and clinical characteristics will be used as control variables in this study. Age, co-morbid conditions, and highest level of education

completed are identified as co-variables for this study as these characteristics have been identified in the literature (Joergensen et al., 2015; McAllister et al., 2012) and may be relevant for exploring patient empowerment in cancer survivors. While age and gender are commonly selected variables, educational level was also selected for this study as it may be a variable of interest in a community-based setting where differences may be observed. There may be other variables associated with sociodemographic and clinical characteristics, such as tumor type and co-morbid illnesses.

These expanded concepts and definitions are of interest in this study as they have not previously been explored in cancer survivors and may serve as an approach to symptom assessment at the critical juncture of end of and immediately after primary treatment for cancer. Therefore, this model is relevant for this study because it was developed for patients with long-term chronic diseases and allows for exploration of patient indicators of patient empowerment to further describe patient empowerment in cancer survivors. As such, arrows have been added, connecting PROs (i.e., self-efficacy, symptoms, and physical function) to patient empowerment to describe the relationship and associations. More research is needed to test the components and relationships in the conceptual model of patient empowerment and its relationships, described by Bravo (2015). With the rising number of cancer survivors, a new symptom assessment approach inclusive of patient self-report of both physical and psychological symptoms, physical function, and self-efficacy may improve patient empowerment so that cancer survivors may engage in their own care and subsequently, self-manage living with cancer.

Research Questions/Aims of the Study

Therefore, the purpose of this study is to assess if the use of PROs (i.e., self-efficacy and

symptoms) is associated with patient empowerment of adult breast and colorectal cancer survivors in early survivorship following primary cancer treatment.

The research question is: *Are the use of PROs (self-efficacy and symptoms) a mechanism to promote patient empowerment among adult cancer survivors in early survivorship following primary cancer treatment?*

Aim 1: Describe the relationship between patient empowerment and PROs (i.e., self-efficacy and symptoms) in breast, colorectal, gynecologic, and lung cancer survivors in early survivorship.

Aim 2: Demonstrate the associations between PROs and patient empowerment in breast, colorectal, gynecologic, and lung cancer survivors in early survivorship, controlling for patient demographics and clinical characteristics.

Aim 3: Explore whether the associations between patient empowerment and PROs in breast, colorectal, gynecologic, and lung cancer survivors change over time, comparing immediately post-treatment and 3 months after treatment and controlling for patient demographics and clinical characteristics.

The research hypotheses will be delineated in Chapter III.

Clinical Significance

Health care systems in the United States have an increased focus on patient-centered, value-based care for improving clinical efficiency and reducing costs (Alfano et al., 2019; Mooney et al., 2017). One example of how the use of PROs has increased was the Institute of Medicine, Stage 3 Meaningful Use requirement for clinicians to collect behavioral and social data in the patient's EHR (Harle et al., 2016). Much of the requested patient data has been disease-specific, such as data collected for accreditation programs to measure quality, ACoS

CoC®, NAPBC®, and Quality Oncology Practice Initiative [QOPI®], drug safety adverse events reporting, such as MedWatch, or patient satisfaction, such as Consumer Assessment of Healthcare Providers and Systems [CAHPS®]. However, patient-generated health data and PROs may be an opportunity to improve how cancer survivors and clinicians manage health and wellness after cancer treatment (Petersen, 2015). The Institute of Medicine (IOM) report, *Crossing the Quality Chasm: A New Health Care System for the 21st Century* (2001), identified key recommendations for patient-centered care as ensuring a patient's physical comfort and providing emotional support. Patient and family engagement supports the Institute of Health Care Improvement (IHI) "triple aim" for improving health outcomes, creating better patient experiences, and reducing costs of health care (Maurer et al., 2015). The Centers for Medicare and Medicaid [CMS] (2018) have developed the Oncology Care Model, a new model for payment and delivery of care, emphasizing high quality and coordinated oncology care at a lower cost through navigation and adherence to national treatment guidelines and evaluating outcomes of care among cancer survivors who have received chemotherapy. One of the core domains of the Oncology Care Model pertains to patient experience, exploring PRO quality measures for pain, functional status, and quality of life in cancer patients, receiving care in medical oncology clinics; however, pain is the only PRO for pain has been initiated.

Furthermore, the Cancer Moonshot Blue Ribbon Panel Report (2016) has issued a call to action to bolster symptom management for people with cancer, who are affected by the disease, its treatment, and managing symptoms long after treatment has ended. As a key component of high-quality cancer care is symptom assessment (Bennett et al., 2012), The Cancer Moonshot Blue Ribbon Panel Report (2016) recommendation related to symptom management includes the

following: (a) utilization of PROs in routine cancer care; (b) enhancement of self-management; and (c) mitigation of symptoms.

Similarly, the Oncology Nursing Society (ONS) Research Agenda supports a focus on integrating symptom assessment and management into systems of care for physical, functional, and psychosocial and quality of life outcomes as well as measuring their effectiveness on mitigating symptoms (Knobf et al., 2015). ONS recognizes the importance of enhancing symptom assessment with PROs tools to promote patient and family engagement (www.ons.org). The use of PROs in routine care of cancer survivors in community practice settings has the potential to strengthen the cancer survivor's self-management skills, optimize their symptom control, physical function, and quality of life, and subsequently, impact the costs of cancer care related to emergency room and urgent care visits, hospitalizations, and unplanned readmissions (Basch et al., 2005; Knobf et al., 2015; Morden et al., 2012; Xiao et al., 2013). Oncology nurses are uniquely positioned to support cancer survivors (Coleman, 2014; Liska et al., 2018) during and post-treatment by assessing and monitoring symptoms, providing education, fostering communication between provider and cancer survivor, and facilitating tailored interventions as the first point of contact along the continuum of cancer care. As such, there may be a role for oncology nurses, using PROs at the end of primary cancer treatment, to initiate prompt, tailored interventions in early survivorship to support patient empowerment and subsequently, self-management.

The purpose of this study is to assess if the use of PROs is associated with patient empowerment among adult cancer survivors in the early survivorship period when these survivors are still experiencing multiple symptoms but are less connected to cancer care services.

The study will focus on PROs (i.e., self-efficacy and symptoms) that have not been well-integrated into routine cancer care to understand their relationships and how they may influence the cancer survivor's empowerment in the early survivorship period. Finally, it will describe how these PROs may provide insights into the conceptual model of patient empowerment.

CHAPTER II

REVIEW OF LITERATURE

Patient empowerment is a dynamic, multidimensional construct for which a consensus has not been reached in its definition and conceptualization among the variety of disciplines (e.g., psychology, sociology, medicine, and nursing) that have explored it (Tengland, 2008). Despite knowledge of the chronicity of cancer, patient empowerment has not been well-studied in cancer or cancer survivorship. Other chronic diseases, like asthma, diabetes, and hypertension, have been studied for patient empowerment and self-management (Anderson et al., 2000; Kuo, Lin, & Tsai, 2014; Tsai, Morton, Mangione, & Keeler, 2005). These studies have demonstrated improvements in health outcomes, such as disease control of chronic illnesses (Bodenheimer et al., 2002; Tsai et al., 2005) and improved symptom monitoring for symptoms of congestive heart failure or depression and glycemic control for diabetic patients (Kuo et al., 2014). Subsequently, improved symptom monitoring has reduced emergency department visits and hospital readmissions (Groen et al., 2015). Among people living with these chronic diseases, patient empowerment has led to engagement in self-management (Groen et al., 2015). As such, it may be valuable to increase our understanding of patient empowerment among cancer survivors to support them in managing symptoms in early survivorship following primary cancer treatment.

Fumgalli et al. (2015) described ability, motivation, and power as commonalities of several definitions of patient empowerment. The connection between patient empowerment and symptom assessment is embedded in cancer survivor's ability, motivation, and power to engage in self-management of their cancer throughout remainder of life which necessitates assessing,

monitoring, reporting, and managing symptoms. The cancer survivor' ability and motivation to assess and manage symptoms is not part of the current symptom assessment approach, meaning clinicians may be asking cancer survivors to perform a task or take an action for which they have no knowledge, skill, or capacity or motivation to successfully complete. The conventional, paternalistic approach to symptom assessment does not transfer power from clinician to cancer survivor, impacting patient empowerment.

Currently, there is no cancer-specific symptom assessment approach embedded in routine clinical practice that includes patient empowerment or its related concepts, like self-efficacy. Patient empowerment may be the missing link in knowledge and understanding of whether or not the cancer survivor is able to engage-in and self-manage their cancer. Perhaps, if a symptom assessment approach inclusive of patient-self reported symptoms were utilized at a critical transition point, such as early survivorship, then cancer survivors, experiencing greater symptom burden (physical, psychosocial) with lesser patient empowerment, self-efficacy, and physical function may be identified earlier and interventions tailored to meet the individual needs of the cancer survivor. In this chapter, the focus is on thorough review of the literature as it pertains to patient empowerment, cancer survivorship, and current knowledge of symptoms and PROs in cancer survivors.

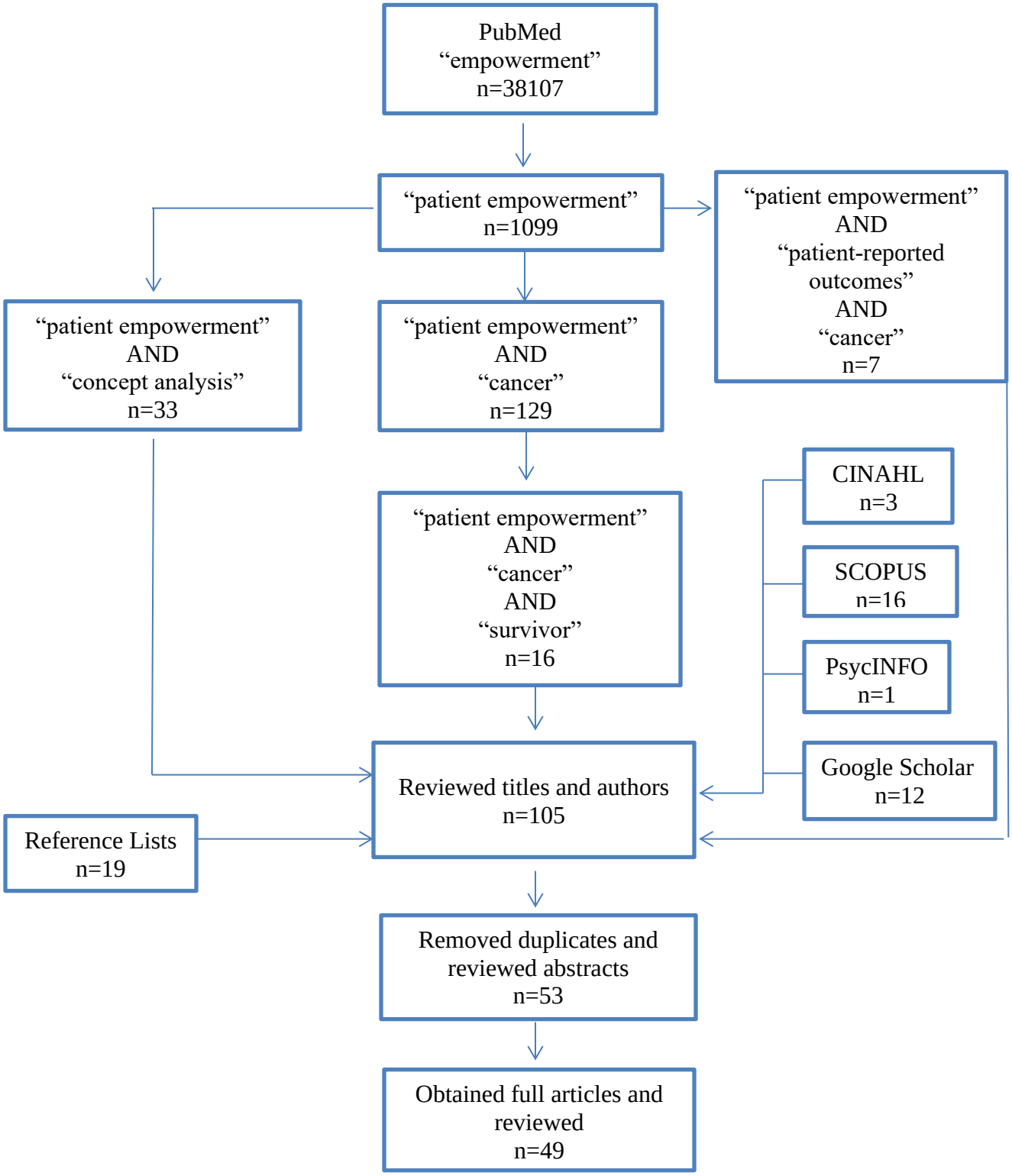
Literature Search

PubMed (16), CINAHL (4), PsycINFO (1), Scopus (18), and Cochrane databases (1) were searched for journal articles from 1994-2018. Key search terms were *patient empowerment, cancer, survivors or patients, and patient-reported symptoms or outcomes*. The limits were set as species (i.e., human), language (i.e., English), and time period. Additional search terms were

added for *chronic diseases, cancer survivorship and clinician-reported symptoms or outcomes.* MESH terms were not used due to the known lack of definition clarity with related or interchangeable terms, such as *patient enablement, patient engagement, patient activation, and patient participation or involvement.* Google Scholar was the search engine utilized for any additional reports and articles; duplicates were removed. Titles and abstracts were screened for the key search terms and excluded if they addressed evaluation of organization/health care system, or community levels as these did not focus on the individual patient or survivor. Full articles were reviewed for the remaining articles. Reference lists provided additional sources, pertaining to patient empowerment concept analyses conducted for other chronic diseases to describe the evolution of the concept. Frequently, patient empowerment was identified as a potential outcome in the introduction or conclusion of the article, but there was no measurement of it in the article. Therefore, these articles were not included in this literature review. A total of 49 sources were retrieved for this literature review (Figure 3).

In addition, sources were separately obtained for patient-and clinician-reporting of symptoms and PROs. The order of this literature review is as follows: (a) evolution of the concept of patient empowerment, describing empowerment and other-related terms, patient empowerment; concept analysis of patient empowerment and cancer survivorship; (b) patient empowerment as a transformative process; (c) patient empowerment facilitators and barriers; (d) patient empowerment and cancer, surgical cancer patients and cancer symptoms (i.e., pain); (e) cancer symptoms and patient-reported outcomes; and (f) patient empowerment and PROs in cancer survivors. This chapter concludes with the current state of practice challenges and gaps in knowledge and contributions of this study to knowledge development.

Figure 3. Literature Search—Patient Empowerment in Cancer Survivors



Evolution of the Concept of Patient Empowerment

Over the past decade, *empowerment*, more specifically *patient empowerment*, has been a growing construct in health care and health-related research, including cancer care (Joergensen et al., 2018); however, it has been difficult to define due to the interchangeability of terms as synonyms for each other and overlapping or closely related terms, such as patient enablement, patient engagement, patient activation, and self-efficacy (Fumagalli et al., 2015), and other related terms, including patient participation or involvement and patient-centered care. Empowerment will be further described as well as similarities and differences between other-related terms and patient empowerment.

Empowerment. Rapport (1987) described empowerment as a positive value of American culture and dynamic, multidimensional construct by which people, organizations, and communities gain mastery over issues of concern to them, such as health and wellness. Later, Zimmerman (1995) defined psychological empowerment, distinguishing empowerment as a process and outcome, at the individual, organizational, and community level. The source of empowerment is the strength or power within a person or group and their ability to harness that power to influence or control over their lives. Some of the positive outcomes associated with patient empowerment have been identified as improved decision-making, managing complications of a chronic disease, and adopting of health-oriented behaviors (Hudon et al., 2011). Zimmerman (1995) described patient empowerment as both a process and an outcome. As a process, patient empowerment has been described as a series of experiences in which opportunities are created or given to patients to control and influence the decisions that affect them, such as choosing a treatment option or how to manage a symptom. As an outcome, patient

empowerment refers to quantitative or qualitative measures to study the effects of interventions, processes, or mechanisms to empower individuals. Furthermore, Zimmerman (1995) described the intrapersonal, interactional, and behavioral components of psychological empowerment as outcomes.

Components of psychosocial empowerment. The intrapersonal component focuses on how an individual thinks about himself or herself, including beliefs about their ability to influence and manage different phases of life, and is considered the foundation for making a change in behavior directed toward a desired outcome (Zimmerman, 1995). It is the individual's perception that provides the "initiative to engage" in behaviors to influence or achieve desired outcomes; therefore, this component "…includes perceived control, self-efficacy, motivation, perceived competence, and mastery (Eskildsen et al., 2017, p. 157). Zimmerman (1995) did not view patient empowerment as a 'static personality trait' instead a more dynamic construct, driven from the context of an individual's life experiences, and therefore, inappropriately conceptualized as a trait, a quality or characteristic of the individual's personality (Oxford Learner's Dictionary, n.d.).

The interactional component of patient empowerment refers to individuals understanding the context and behavioral options while the behavioral component refers to the specific actions taken (Zimmerman, 1995). Consistent with Zimmerman's psychological empowerment at the level of the individual (Joergensen et al., 2018), patient empowerment has been described in the literature as: 1) emergent states, meaning the patient's skills, knowledge or motivation to become engaged; 2) processes, including acquisition of knowledge, skills, attitudes, and self-awareness through cultural, social, and environmental contexts; and 3) behaviors, demonstrating actions

oriented towards self-management and shared decision-making (Fumagalli et al., 2015). Other terms related to empowerment and their relationship to patient empowerment will be further described.

Patient Enablement. Patients become empowered if opportunities to be informed or involved are created by clinicians and the balance of power is accounted for with patients assuming a greater role in managing their own health care. As such, *patient enablement* is considered a component of patient empowerment, described as an antecedent to patient empowerment (Eskildsen et al., 2017; Fumagalli et al., 2015; Hudon et al. 2011). The patient enablement process utilizes clinician interventions to recognize, support, and emphasize the patients' capacities to have control over their own health and life (Hudon et al. 2011). However, enabled patients may be able to participate in their own care, but they may not have the motivation or power to do so (Fumagalli et al., 2015).

Patient Engagement. As a related term, patient engagement, is the "…process of building the capacity of patients, families, [caregivers] as well as health care providers, to facilitate and support the active involvement of patients in their own care, in order to enhance the safety, quality, and people-centeredness of health care delivery" (WHO, 2016, p. 3). Patient engagement describes a relationship of patients and health care providers working together "…in active partnership at various levels across the health care system: direct care, organizational design and governance, and policymaking" (Carman & Workman, 2017, p. 25). It reflects care that is focused on patient preferences, needs, and values, safeguarding that patient values guide clinical decisions (IOM, 2001), fostering and preserving trust between the patient and health care team (WHO, 2016). Graffigna et al. (2015) further defined patient engagement as a

"multidimensional experience resulting from conjoint cognitive (think), emotional (feel), and conative (act) enactment of individuals toward their health condition and management" (p. 2), emphasizing synergy of these domains as necessary for full engagement in one's own healthcare. However, patient engagement has been described as a consequence or cause of patient empowerment (Fumagalli et al., 2015).

Graffigna et al. (2015) recognized patient engagement and empowerment as "…strongly connected in a reciprocal and virtuous relationship" (p. 19). Whereas patient engagement focuses on the relationship, patient empowerment focuses on the individual, promoting recovery of self, following diagnosis and treatment of chronic illness. From this perspective, empowerment is an outcome, mediating patient engagement. While patient engagement is considered a consequence of empowerment, patient activation (behavior) and self-efficacy have been identified as outcomes of patient empowerment (Fumagalli et al., 2015).

Patient Activation. Patient activation and patient empowerment are interdependent concepts (Hibbard et al., 2007) in that they both pertain to increasing skills, motivation, and self-awareness of the cancer survivor's role in managing their own health and health care (Fumagalli et al., 2015). However, patient activation refers to the patient's knowledge, skill, and confidence (Hibbard et al., 2017) and focuses on specific improvement goals related to chronic illnesses, like cancer; whereas patient empowerment is a broader concept for the acquisition of knowledge, skills, and abilities to make decisions about health and well-being across different phases of life (Fumagalli et al., 2015).

Self-Efficacy. Self-efficacy has been identified as patient indicator of patient empowerment in the conceptual model of patient empowerment (Bravo et al., 2015). It has been

described in the literature as necessary for achieving patient empowerment, meaning a patient must have self-efficacy to achieve patient empowerment (Te Boveldt et al., 2014). Often, self-efficacy has been used as an outcome of patient empowerment (Fumagalli et al., 2015; Te Boveldt et al., 2014). As a strongly related concept to patient empowerment, it is a concept of interest for describing patient empowerment in cancer survivors and the relationship between them in this study.

Self-efficacy is defined as a patient's belief in his or her ability to master or perform a specific behavior or task (Bandura, 1997). It is influenced by mastering new skills, modeling, symptom recognition, and communicating effectively through social persuasion (Zwerink et al., 2014). The stronger the individual's self-efficacy the more likely that individual will engage in healthy behaviors and reduce stress, increasing their resiliency (Kobau & DiIorio, 2003). Social cognitive theory proposes that by increasing one's self-efficacy, the individual's self-management skills will be improved (Loh et al., 2013). To determine the individual's confidence in their ability to manage cancer and its treatment, PROs self-efficacy assessments should be routinely collected along with physical function and other physical and psychosocial symptoms (Kelleher, 2016). In turn, strategies to support self-management can be implemented earlier. *Self-management* is defined as "awareness and active participation by the person in their recovery, recuperation, and rehabilitation, to minimize the consequences of treatment, and promote survival, health, and well-being" (Foster et al., 2014, p. 12). Bravo et al. (2015) described patient self-management as "…an activity that is undertaken by empowered patients, by choosing personally meaningful, realistic health related goals, and taking steps to achieve those goals" (p. 12). Self-management focuses on managing treatment-related side effects, monitoring for signs

and symptoms of reoccurrence, re-establishing routines, and social roles, and handling psychosocial distress, minimizing the untoward impact on quality of life and relationships (McCorkle et al., 2011; Mullan, 1985). Thus, patient empowerment is a concept of interest and perhaps a missing component when assessing symptoms and the cancer survivor's ability to self-manage their cancer in early survivorship.

Patient-Centered Care. In the evolution from construct to concept, patient empowerment has been described as emerging from patient-centered care which is a broad term that describes "…a vision of what health care should be: a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patient wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care" (IOM, 2001 as cited by Carman et al., 2013, p. 223).

Patient Participation or Involvement. Within the context of a clinical encounter, patient participation has been described as encompassing three frameworks: 1) empowerment and self-efficacy; 2) therapeutic alliance; and 3) consumerism or satisfaction (Mavis et al., 2008). The patient's experience of participation varies as each patient and nurse has their own perspective on the meaning of patient participation and how to implement it (Sahlsten et al., 2008). Through a concept analysis, Sahlsten et al. (2008) defined patient participation as follows: 1) an established relationship between the nurse and patient; 2) a surrendering of some power or control by the nurse; 3) shared information or knowledge; and 4) active engagement in intellectual and/or physical activities (p. 11).

More recently, a concept analysis compared the three concepts of patient empowerment, patient participation, and patient centeredness and concluded that patient empowerment is the

broader concept, and patient-centeredness facilitates patient empowerment (Castro et al., 2016). The process of patient empowerment occurs within a relationship between clinician and patient with the intention of increasing the patient's capability to assume control of their chronic illness (Fumagalli et al., 2015; Jerofke, 2013). Whereas patient participation or involvement and patient engagement are consequences (cause) of patient empowerment, patient activation and self-efficacy are considered outcomes of patient empowerment (Fumagalli et al., 2015).

Patient Empowerment. Over the past 30 years, patient empowerment has been a commonly used term in the United States with a predominately positive association related to health and health promotion, societal movements, such as the feminist movement, students, teachers, children, single parents, communities, and specific diseases, like auto-immunodeficiency syndrome (AIDS) or breast cancer (Ellis-Stoll & Popkess-Vawter, 1998; Gibson, 1991; Rodwell, 1996; Tengland, 2008). Because of its familiarity or common use and interchangeability with similar or related terms, patient empowerment may have lost some of its meaning, and in some instances, developed a negative connotation overtime associated with perceptions with the above societal movements.

One of the core difficulties in concept development has been the lack of clarity in its definition by the authors and researchers who have attempted to describe or study it (Tengland, 2008). Patient empowerment has different meanings to different people, depending on the social context (Wallerstein & Bernstein, 1988). Bravo et al. (2015) acknowledged that a clear definition of patient empowerment is lacking and identified the most frequently utilized definitions in the literature (Aujoulat et al., 2007; Anderson & Funnell, 2004; Funnell et al., 1991; Lau, 2002; Gibson, 1991). Based on these definitions from the literature review and the qualitative

interviews with key stakeholders, the conceptual model for patient empowerment was developed by Bravo et al. (2015). There are similarities and differences among these definitions of patient empowerment (Table 1).

The most frequently cited definition of patient empowerment in the literature was by Funnell et al. (1991), defining patient empowerment as "an interactive process of cultivating the power in others through sharing of knowledge, expertise, and resources" (p. 41). In that same year, Gibson (1991) defined empowerment as "a social process of recognizing, promoting and enhancing people's abilities to meet their own needs, solve their own problems and mobilize the necessary resources in order to feel in control of their own lives… a process of helping people asset control over the factors which affect their health" (p. 359). With this definition, nurses have a role in facilitating patient empowerment in patients by acting as a resource and mobilizing resources. Patient empowerment has recognized value in nursing practice, education, research, and administration (Gibson, 1991; Rodwell, 1996).

Later, Anderson and Funnell (2010) further defined patient empowerment as a process for self-directed behavior change, and this patient empowerment approach "involves facilitating and supporting patients to reflect on their experience of living with [a chronic disease]. Self-reflection occurring in a relationship characterized by psychological safety, warmth, collaboration, and respect is essential for laying the foundation for self-directed change in behavior, emotions, and/or attitudes" (p. 281). From a health care perspective, Lau (2002) defined patient empowerment as "to promote autonomous self-regulation so that individual's potential for health and wellness is maximized. Patient empowerment begins with information

and education and includes seeking out one's own illness or condition, and actively participating in treatment decisions" (p. 372).

From the perspective of the patient, Aujoulat et al. (2007) defined patient empowerment as "a complex experience of personal change. It is guided by the principle of self-determination and may be facilitated by [clinicians] if they adapt a patient-centered approach of care which acknowledges the patients' experience, priorities, and fears" (p. 18). As people living with a chronic disease become empowered, they develop a greater sense of self-efficacy, and patients are better able self-manage their illness because of their empowerment process (Aujoulat et al., 2007). Later, the definition of patient empowerment was expanded to describe it as a personal transformative process of "holding on" to notion self and roles while "letting go" of control (i.e., power) by accepting it or relinquishing control to integrate what it means to have a chronic illness, like cancer, and limitations set by it to assimilate a new sense of self (Aujoulat, Marcolongo, Bonadiman, & Deccache, 2008). This definition supports complex personal, transformative process of cancer survivors, suggesting that power is created within the individual, allows for facilitation by the clinician. Furthermore, the limitations set by chronic diseases may involve physical and psychological symptoms and changes in physical function that may lead to physical impairment or disability. Patient empowerment reflects how to use power in everyday life, and it is central to the relationship between clinician and patients.

Table 1. Similarities and Differences of Common Definitions of Patient Empowerment

Author/Year	Similarities	Differences
Funnell (1991)	• Patient empowerment is a process. • A relationship between an individual and those who hold the expertise.	• An interactive process to cultivate power within others through sharing of knowledge, skills, expertise, and resources.

Funnell & Anderson (2010)	• Patient empowerment is a process. • Patients actively participate in education and skills to manage their illness. • Patients self-reflect on living with a chronic illness.	• A self-directed behavior change process facilitated by self-reflecting on the chronic disease. • Focused on educational intervention with the chronic illness, diabetes.
Gibson (1991)	• Patient empowerment is a process. • Cultivating power within others by identifying their own abilities. • Individuals seek knowledge about one's own health. • Supported by an exchange or sharing of knowledge and resources.	• A social process (i.e., helping process) to identify, promote, and strengthen one's own abilities, solve problems, mobilize resources to gain control over their own lives. • Facilitated by nurses.
Lau (2002)	• Patient empowerment is a process. • Active participation of individuals, seeking information to optimize health and wellness.	• A social process to maximize one's self-regulation of health and wellness.
Aujoulat et al. (2007)	• Patient empowerment is a process. • Emphasizes internal and external processes. • Focuses on the individual's lived experience with a chronic illness.	• A process of complex, personal change experiences guided by self-determination; facilitated by clinicians, who embody a patient-centered care approach, acknowledging the experiences, fears, and priorities of the person living with a chronic disease. • Facilitated by clinicians rather than one discipline, nursing.
Aujoulat et al. (2008)	• Patient empowerment is a process. • Emphasizes internal and external processes. • Focuses on the individual's lived experience with a chronic illness and what it means.	• Personal, transformative process of 'holding on' and 'letting go' of control (i.e., power) to integrate what it means to have a chronic illness and limitations set by it to assimilate a new sense of self. • Using power in daily life

Operational Definition of Patient Empowerment. For this study, the operational definition for patient empowerment is an outcome of the quantitative or qualitative measures to study the effects of interventions, processes, or mechanisms to empower individuals (Zimmerman, 1995). PROs may be a mechanism to empower cancer survivors.

Concept Analyses of Patient Empowerment

Beyond the work of Rappaport (1987) and Zimmerman (1995), there are several concept analysis papers to describe the evolution of patient empowerment (Ellis-Stoll & Popkess-Vawter, 1998; Finfgeld, 2004; Gibson, 1991; Hawks, 1992; McCarthy & Freeman, 2008; Rodwell, 1996; Ryles, 1999; Tengland, 2008). The shared characteristics or attributes of patient empowerment have been described as: (1) helping process to assert control over what affects our own lives; (2) partnership relationship, transferring power from paternalistic to shared power; (3) mutual goal setting and decision-making; and (4) accepting responsibility for own health and health care (Ellis-Stoll & Popkess-Vawter, 1998; Gibson, 1991; Rodwell, 1996).

There have been five concept analyses on cancer survivorship (de Oliveira et al., 2016; Doyle, 2008; Farmer & Smith, 2002; Peck, 2008; Shepherd & Woodgate, 2008) which have predominately described patient empowerment from the clinician perspective rather than the cancer survivors' perspective. Patient empowerment addresses the complexity of treatment and feelings of uncertainty and vulnerability that cancer survivors experience along the cancer care continuum (Ganz, 2009; Peck, 2008). Patient empowerment facilitates patient engagement and self-management (McCorkle, 2011) as engaged patients are able to better self-manage themselves. When patient concerns, priorities, and resources are included in the plan of care, patients are empowered to manage their chronic illness (Hibbard et al., 2007). However, the level

of patient empowerment is not measured in clinical practice at specific intervals (e.g., initial diagnosis, last day of treatment, survivorship visit). Like to PROs, the level of patient empowerment is not a part of the current symptom assessment approach. This study focused on a specific interval, including cancer survivors at completion of treatment to 3 months after treatment prior to survivorship visit.

Additionally, one concept analysis paper by Jerofke (2013) has addressed both patient empowerment and cancer survivorship, identifying that patient empowerment may have a similar definition to both cancer survivors and nurses as "power-with" is derived from a mutual, trust relationship and respect for autonomy; however, the uses and assumptions differ. Nurses may perceive patient empowerment as a nursing intervention and make assumptions about the extent to which cancer survivors have the desire and ability participate in their care. In contrast, cancer survivors may view their internal resources as a source of patient empowerment and wish to make shared decisions about the extent to which they are willing to participate in their own care, developing shared and mutually agreed upon goals throughout the continuum of cancer care (Jerofke, 2013). Importantly, this concept analysis identifies that there are differences between the nurse and cancer survivor perspectives of cancer survivorship, and a gap exists in both literature and practice which is often devoid of the cancer survivor's voice.

Patient Empowerment as a Transformative Process

One of the earliest qualitative studies of patient empowerment explored its meaning and influencers of patient empowerment among 12 Hong Kong Chinese patients with cancer, describing patient empowerment as a transformative process to not only develop inner strength through connections with other people, including clinicians, but to seek a new perspective on

their cancer through reframing and reinterpretation of their experience of living with cancer (Mok, 2001). Among seven cancer patients with malignant hematologic diseases in Australia, patient empowerment emerges when cancer survivors have determination and regained self-control over their disease (Bulsara et al., 2004). Similar to Mok (2001), Bulsara et al. (2004) found that patient empowerment occurs through cancer survivor's reliance on others (family, friends, and clinicians), adding that the cancer survivor's acknowledgement of cancer, its treatment, and side effects and acceptance is necessary for a cancer survivor's receptivity to developing new ways of coping and managing their cancer.

Additionally, patient empowerment as a "personal" transformative process was reinforced by an exploratory study of 40 chronic disease patients in Belgium and Italy to describe patient empowerment and the illness experience (Aujoulat et al., 2008). According to these researchers, patient empowerment was described by two central processes of regaining control and relinquishing control; however, only two patients interviewed in the study had cancer, multiple myeloma. This study expanded the definition of patient empowerment.

To define patient empowerment from the cancer survivor's perspective, Avery (2018) interviewed 22 head and neck and breast cancer survivors to describe the cancer survivor's experience of patient empowerment in cancer survivorship and rehabilitation for his research dissertation, utilizing social constructivist grounded theory as a method. Similar to Aujoulat et al. (2008), two paradoxical processes of patient empowerment emerged from cancer survivors in this study: 1) establishing control; and 2) relinquishing control. Moreover, Avery (2018) revealed that cancer survivors' experience an "alternative" pathway to patient empowerment by relinquishing control or "letting go" when aspects of cancer, its treatment, and side effects are

beyond their control. This recognition is empowering in and of itself, providing insight into cancer survivors who cannot accept what is perceived as unattainable or for whom it is not feasible, practical to assume responsibility for self-management. Further, this researcher described that it is not that the cancer survivor is a "bad" patient, disengaged, lacks capacity, lives in denial, or subscribes to any other negative stereotypes that clinicians may label cancer survivors. It lends credence to "one size does not fit all" depicted by Jerofke (2013) as levels of patient empowerment fluctuate along the cancer care continuum (Eskildsen et al., 2017; Joergensen et al., 2018; Maunsell et al., 2014). This finding is similarly described by patients in diabetes-related studies (Anderson et al., 2000). Anderson and Funnell (2004) recognized patient empowerment was not a dichotomous variable where an individual is either empowered or not empowered, but a continuous variable as patient empowerment fluctuates along a continuum of high to low levels of empowerment.

In addition, Avery (2018) described flaws in the conceptual model by Bravo et al. (2015) which conceptualized patient empowerment as a process as: (a) accounting for only people who follow a positive path towards patient empowerment can become empowered; and (b) missing how the differences (i.e., age, gender, race, or ethnicity) influence patient empowerment. Bravo's conceptual model of patient empowerment is the model for this study because it is inclusive of PROs and the differences (i.e., age, gender, race, or ethnicity) among cancer survivors will be collected as sociodemographic data. The proposed model for the study patient empowerment does account for a connection from the patient indicators of empowerment, identified as patient capacities, states, and resources, to patient empowerment. This component of patient empowerment was recognized by Barr et al. (2015) as one of four domains for

evaluation of patient empowerment instruments. Patient states, capacities, and resources will be further explored by describing the relationship between patient empowerment and PROs. (Figure 2). Thus, further study of patient empowerment in cancer survivors is necessary to describe how patient empowerment manifests itself in cancer survivors in early survivorship.

Patient Empowerment and Surgical Cancer Patients

Only two quantitative studies of patient empowerment were conducted among cancer patients undergoing major oncologic surgery. First, a prospective study was conducted to explore trajectory associations between nursing care processes and patient empowerment for patient self-management outcomes (Jerofke et al., 2014). Of 113 post-surgical gastrointestinal and lung cancer and cardiac patients, patient perceptions of empowering nurse behaviors were positively associated with patient activation and in turn, positively associated with mental functional health status. Of note, the only significant predictor of physical function health status was length of stay. One study limitation was the sample because it combined two chronic diseases (i.e., cancer and cardiovascular disease) and represented two solid tumor cancers (i.e., gastrointestinal and lung cancers). Another limitation was the focus on the nurse behavior processes that empower cancer patients rather than the cancer survivor's perspective on behaviors that empower them. Furthermore, it underscores a gap in the patient empowerment literature, focusing on processes rather than outcomes of patient empowerment.

Secondly, Schmidt et al. (2015) conducted a randomized, prospective interventional trial of 652 older adult patients with gastrointestinal, genitourinary, and thoracic cancers to investigate the effect of patient empowerment on short-and long-term outcomes in Germany. This study compared a patient empowerment education intervention of a pre-operative informational booklet and diary maintenance to standard of care during hospitalization for major

cancer surgery and for one-year post-discharge with measurement at baseline, 3 months, and 12 months post-discharge. The instrument for this study indirectly measured patient empowerment through the 30-item Eastern European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-30) through the global health-related quality of life score. Patients reported significantly less pain in the intervention arm of the study, compared to usual standard of care, concluding the patient empowerment intervention of the informational booklet and diary improved the quality of care for postoperative pain in older adults. The patient empowerment intervention had no effect on the short-term outcome of post-operative length of stay (LOS) or long-term HRQoL. The study raises questions regarding patient empowerment when the patients may not be cognitively and physically able to utilize the intervention of the booklet and the diary, but it does not add to patient empowerment as a concept. The combination of two interventions may be difficult to determine which had the greater effect on patient empowerment and more likely to meet the individual needs of the patient. While EORTC-QLQ-30 is a recognized reliable and valid tool for measuring quality of life in research, it was an indirect measurement of patient empowerment. A gap remains in how to measure patient empowerment among people with cancer and as an outcome in clinical practice.

Patient Empowerment: Facilitators and Barriers

Joergensen et al. (2018) conducted a qualitative systematic review of literature, yielding 38 articles, to explore the facilitators and barriers of patient empowerment in cancer patients in follow-up care (i.e., the time after first line therapy). Themes identified included: (a) patient empowerment is an ongoing and fluctuating process; (b) knowledge is power; (c) having an active role; (d) communication and interaction between patient and clinician; (e) support from

being in a group; (f) religion and spirituality; and (g) gender. This qualitative systematic review found that cancer survivors did not understand their own patient empowerment and the lack of attention to patient empowerment after primary treatment for cancer were identified as gaps (Joergensen et al., 2018). While patient empowerment has been described as influenced by age, culture, gender, race/ethnicity, and socioeconomic status (McAllister, et al., 2012; Jerofke, 2013), Joergensen et al. (2018) found that these differences and potential "influencers" of patient empowerment have not received sufficient attention in research and practice.

Web-Based Interventions. Additionally, several studies investigated web-based interventions toward improving patient empowerment among cancer survivors by two reviews and one recent qualitative study. Groen et al. (2015) explored the effects of web-based interventions on patient empowerment in cancer survivors through an integrative review of 26 articles to identify attributes of patient empowerment, including (a) education services; (b) possessing knowledge; (c) psychosocial and behavioral skills; (d) perceived support; and (e) perception of self as useful. Perceived support from family, friends, and community; and perception of oneself as useful were coping strategies specific to cancer survivors. Moreover, information technology (IT) services, such as services for education, patient-to-patient connections, electronic PROs, multiple components (a combination of several of these services), and interactive portals, were identified as contributing to patient empowerment through gaining knowledge, skills, and promoting autonomy. Electronic PROs may contribute to patient empowerment through improving communication between clinicians and cancer survivors and utilization of web-based interventions to self-manage manage symptoms and improve overall coping with symptoms of chronic diseases.

Interactive Portals. Kuijpers et al. (2015) identified expectations of breast and lung cancer survivors as well as clinicians of an interactive portal, a web-based tool that allows for the flow of information between the computer and computer user through accessing applications, services, and links and responding to computer user input (Oxford English Dictionary, n.d.). Focus-groups, describing the differences in interests and uses of portal services, have been infrequently utilized in oncology populations (Kuijpers et al., 2015). PROs, described as self-reported data on health status, were one of nine possible features of an interactive portal described to participants in this study. Other components included: survivorship care plans, access to EHR, appointments, E-consultation, online patient community, telemonitoring of physical parameters, online rehabilitation program, and online psychosocial self-management program. Cancer survivors were interested in interactive patient portals for their informational needs, such as survivorship care plan, EHR access; appointments, whereas clinicians named PROs and telemonitoring as useful features. One finding that was shared by cancer survivors and clinicians is that clinicians would likely not take the 'extra' time to review their PROs, underscoring the importance of training cancer survivors and clinicians on how to use PROs. Although the integration of PROs into routine cancer care has been described as the next step toward timely, accurate symptom assessments and subsequently, improve management of symptoms (Gordon & Chen, 2017), PROs have not been integrated as a symptom assessment approach in community-based practices related to several barriers as described in this chapter and a gap in knowledge to determine if the use of PROs is indeed associated with patient empowerment in cancer survivors.

Web-Based Platform. One qualitative study by Renzi (2017) explored the experience of 10 prostate cancer patients, undergoing radiation treatments in a comprehensive cancer center in Italy, to design a web-based platform to promote patient empowerment. Four themes emerged: (a) patient-clinician communication; (b) decision-making; (c) needs; and (d) resources. The researchers concluded that patient empowerment may be promoted when it starts with a personalized approach at the time of diagnosis and supported by technology. These web-based interventions studies seek to improve patient empowerment by making information or knowledge accessible and promoting communication between cancer survivor and clinician; however, patient empowerment an outcome of these IT services has had limited measurement.

More often, patient empowerment is identified as an outcome of educational and IT interventions, but it is not actually measured. Thus, only a few intervention studies have been published, focusing on education and web-based programs (Groen et al., 2015; Kujiers, 2015), many of which do not include a direct measure of patient empowerment. Further studies measuring patient empowerment among cancer survivors are necessary to build on the cancer survivor's strengths and offer tailored interventions.

Patient Empowerment and Cancer Symptom: Pain

One integrated review of 34 articles was conducted on patient empowerment and its related concepts among cancer patients coping with a specific, problematic symptom: cancer pain (Te Boveldt et al., 2014). The purpose of this integrative review was to propose a conceptual model to empower patients in controlling cancer pain from the published qualitative literature. The conceptual model emerged as a two-cycle model, centralizing roles for the patient and clinician with the components of internal and external resources, self-efficacy, shared-

decision making, and active patient participation or coping. Similar to the Conceptual Framework of Patient Empowerment by Bravo et al. (2015), self-efficacy, identified as a patient resource, is a critical component of any model for patient empowerment. The findings emphasized the importance of clinician intervention, patient involvement, and the interaction between clinicians and patients for managing symptoms, like cancer pain (Te Boveldt et al., 2014).

Symptoms and PROs

As previously stated, symptom assessment is a key component of high-quality cancer care and patient self-reported symptoms, PROs, an assessment of the patient's own health condition without interpretation by clinician, allows for active participation by the cancer survivor, capturing information that they know best (Bennett et al., 2012). PROs assessments measure symptoms, including physical symptoms, psychosocial distress, physical function, and quality of life, and these symptoms may be compared at different time periods to determine the outcome of the care received (Black, 2013). While it is unknown if PROs assessments are a mechanism to empower cancer survivors, the current state approach to symptom assessment in cancer survivors has several gaps which will be described further in the next section, including a (a) lack of integration of patient self-reported symptoms (Atkinson et al., 2012; Basch et al., 2011); (b) disconnection between symptom detection and further symptom assessment and intervention (Kim et al, 2009; Reeve et al., 2014; Reilly et al., 2013); (c) episodic symptom assessment rather than continuous monitoring of symptoms over time (Quinten et al., 2011; Trajkovic-Vidakovic et al., 2012); (d) insufficient assessment of late term symptoms or side effects (McCorkle et al, 2011; Shi et al., 2011; Wu & Harden, 2015); and (e) poor capture of

real-time symptom data collection in electronic health record [EHR] (Atkinson et al., 2017; Berry et al., 2011; Fiteni, 2019; Howell et al., 2015; Kotronoulas et al., 2014; Luckett et al., 2009).

Lack of Integration of Patient Self-Reported Symptoms. Several systematic reviews have demonstrated that patients self-report their symptoms earlier, with more frequency and severity than clinicians (Basch et al., 2011; Berry et al., 2011; Loh et al., 2013; Phillips & Currow, 2010; Xiao et al., 2013). However, clinicians focus on clinical outcomes and objective symptom data, pertaining adverse reactions or toxicities of cancer therapies (Atkinson et al., 2012; Xiao et al., 2013) without integration of patient self-reported symptoms. Pakhomov et al. (2008) reported that symptoms are not detected by clinicians half of the time. Physicians reported less severe and lower rates of symptoms, such as fatigue, nausea, and pain, and higher functional status (Basch et al., 2009). Patient-reported symptoms are more specific to daily health status and quality of life (Basch et al., 2005; Xiao et al., 2013).

Several early studies demonstrated that lung cancer and gynecological cancer patients are capable of using PROs to report symptoms experienced with chemotherapy in outpatient clinics (Basch et al., 2007; Basch et al., 2006; Basch, 2005) even in patients with advanced disease or poor performance status (Basch et al., 2011). Additional studies have identified that patients are not only capable of reporting their own symptoms but possess expert knowledge of their own bodies (Basch et al, 2011; Lavalle et al., 2016; Movsas, 2015). As such, the cancer survivor is the source of knowledge about their lived experience of cancer and its symptoms, and they should be asked to report on their symptom experience and its meaning without interpretation or modification by a clinician or caregiver (Lipscomb et al., 2007). The routine use of PROs in

cancer care allows for active participation by the cancer survivor, capturing information that they know best (Bennett et al., 2012).

During ambulatory clinic visits, physicians, nurses, and other clinicians are responsible for obtaining symptom information and documenting it in an EHR without standardized, valid measurement tools or with terminology which is not reflective of the cancer survivor's description (Basch et al., 2011). As such, the cancer survivor's symptom experience is interpreted by the clinician and may be modified in documentation (Atkinson et al., 2012; Basch et al., 2011). If the clinician does not ask about a specific symptom, the cancer survivor may not report it, especially if the symptoms occurred between clinic visits, leading to missed symptoms (Basch et al., 2011). Furthermore, clinicians may be reluctant to ask about subjective symptoms, like fatigue, or symptoms for which effective evidence-based interventions are less known, such as cognitive impairment and peripheral neuropathy (Berry et al., 2011). Despite knowledge of the earlier, more severe symptoms through patient-reported symptoms and the inaccuracies in clinician-driven symptom assessment, PROs have not been integrated into community-based oncology practices as standard of care (Fiteni et al., 2019).

Disconnection Between Symptom Detection and Further Symptom Assessment. While several clinicians (physician, nurse, licensed practical nurse) may screen for multiple symptoms associated with the cancer diagnosis and its treatment, they may not account for the symptoms that the patient values, such as symptoms that impact daily living. A thorough assessment of any identified problematic symptom may not occur during a clinical visit or telephone encounter due to the scope of the clinician's role who obtained the symptom data and workflow issues in the EHR as well as the practice setting. Clinic visits may be viewed as an

episode of care or a single clinical encounter, making it difficult to track symptoms over time.

Multiple symptoms. More complexity is added to symptom assessment when multiple symptoms are present. Kim et al. (2009) conducted a systematic review assessing the occurrence of multiple symptoms in oncology patients undergoing active treatment, describing an association between multiple symptom occurrence and patient outcomes, such as function and quality of life. In this review of 18 studies, 40% of active cancer treatment patients experienced more than one symptom. To determine the prevalence and impact of multiple symptoms in oncology patients receiving active cancer treatments, a systematic review of 21 studies assessing symptoms in homogenous pooled sample of cancer patients (N=4067) revealed that symptoms are prevalent and severe (Reilly et al., 2013). This systematic review demonstrated that a core set of symptoms is common across cancer diseases, especially in patients living with advanced cancer. The core set of symptoms included fatigue, insomnia, dry mouth, anxiety, distress, and depression; however, health-related quality of life symptoms, such as physical function or enjoyment in life, were not evaluated in this study. Later, Reeve et al. (2014) developed a core or common set of 12 symptoms, including fatigue, insomnia, pain, anorexia, dyspnea, cognitive problems, anxiety, nausea, depression, neuropathy, constipation, and diarrhea, for inclusion in clinical trials with adult cancer patients to measure treatment efficacy, identify toxicities, and more easily compare findings with other similar clinical trial studies; however, a core set of symptoms has been incorporated into community-based practice.

Episodic Versus Continuous Monitoring of Symptoms Over Time. Several researchers identified the importance of continuous or ongoing assessment and monitoring symptoms throughout cancer treatment and into survivorship. Trajkovic-Vidakovic et al. (2012) conducted

a systematic review of 44 articles to ascertain the prognostic meaning of symptoms in patients with advanced cancer, receiving palliative care, and concluded that several symptoms were associated with worse survival, functional impairment, and deconditioning, such as confusion, anorexia, drowsiness, dyspnea, and dysphagia in greater than 50% of the studies reviewed. Thus, this study recommended the use of patient-reported instruments for initial and ongoing assessment of symptoms in routine oncology practice.

Quinten et al. (2011) explored the extent to which both clinician- and patient- scoring symptoms at baseline, such as pain, fatigue, vomiting, nausea, diarrhea, and constipation, improves overall survival estimates. Based on a large, heterogeneous dataset of cancer patients (N=2279) from 14 closed European Organization Research and Treatment of Cancer (EORTC) randomized controlled clinical trials from 1990-2002, patient-reported scores did differ from clinician-reported scores for symptoms, like fatigue, providing an important subjective measure of symptom severity. While both patient-and clinician-reported scores contributed to the accuracy of predicting overall survival, some symptoms, like nausea, vomiting, and diarrhea, may be better predictors when scores are obtained with baseline and periodic assessments throughout cancer treatment.

Insufficient Assessment of Late Term Symptoms. Several researchers have identified the complexities of symptoms of cancer and its treatment and insufficient assessment of symptoms, especially in cancer survivors experiencing late term symptoms or side effects. Shi et al. (2011) analyzed population-based data from American Cancer Society's Study of Cancer Survivors-I to identify which survivors experience higher symptom burden in early survivorship, meaning one year after completion of active cancer treatment, and what factors contribute to

more severe symptoms. Of 4512 cancer survivors, one in four survivors were categorized in the high symptom group (i.e. higher symptom severity and lower HRQOL scores), characterized as younger (less than 55 years old), lower socioeconomic status (low education level; low household income; minimal health insurance, and unemployed), lung and/or metastatic cancer, co-morbid conditions, and currently receiving chemotherapy, emphasizing that less is known about sociodemographic factors are associated with patient empowerment (Ackermans et al., 2018). This study underscores the vulnerability of the cancer survivor in early survivorship immediately post-treatment and emphasizes the need for follow-up symptom assessment, monitoring, reporting, and management for one-year post-treatment, supporting closer follow-up of cancer survivors at greater risk for more severe symptoms.

Later, Wu & Harden (2015) conducted a literature review among adult cancer survivors with breast, colorectal, lung, and gynecological cancers and their caregivers on their survivorship experience with symptom burden and quality of life. The literature review showed that one-third of cancer survivors experience symptoms after treatment similar to those experienced during active cancer treatment. While common symptoms were reported as fatigue, depression, mood changes, sleep disturbances, and pain all of which impact quality of life, patient characteristics, such as younger age, lower socioeconomic status, and increased co-morbidities were associated with increased symptom distress. Symptom burden and diminished quality of life are experienced long into survivorship (Bloom, 2002; Hewitt, 2006; McCorkle et al, 2011; Mullan, 1985) with the greatest symptom occurrence during and for the first year after treatment (Wu & Harden, 2015). Similar to Shi et al. (2011), early survivorship immediately following active, primary cancer treatment is emphasized as vulnerable period for cancer survivors as a significant

number of symptoms will still need to be assessed and managed. Thus, the study focused on early survivorship as it is not addressed in current literature on patient empowerment and PROs.

Poor Capture of PROs in the Electronic Health Record (EHR). Basch et al. (2007) proposed paradigm shift from clinician reporting or tracking of objective toxicities to symptoms reported by patients or by both clinicians and patients. The use of patient-reported outcome measures in cancer survivors is gradually increasing, expanding beyond clinical trials and into routine assessment in oncology practices toward standard of care (Atkinson et al., 2017; Howell et al., 2015; Kotronoulas et al., 2014; Luckett et al., 2009) however, in community-based clinical practices where most cancer care is delivered, PROs have been slow to integrate. It is remains unclear if standardization of PROs in oncology practices will lead to actual improvements in patient outcomes, processes of care, and cancer survivors' self-management of symptoms (Howell et al., 2015; Luckett et al., 2009). There are several barriers to implementation to the adoption of PROs, such as the EHR and training on how to use PROs for clinicians and cancer survivors. It is unknown if the use of PROs assessment is associated with patient empowerment and subsequently, cancer survivors to engage in self-management.

While the EHR has facilitated the use of PROs through real time data collection of symptoms and function, tracking and monitoring symptoms over time, earlier identification of interventions, and reporting data for quality metrics to cancer center accreditation bodies (e.g., American College of Surgeons Commission on Cancer [ACoS CoC®]), (Bennett et al., 2012), the EHR has also been an implementation barrier to the uptake of PROs (Basch et al., 2016) as these instruments have only recently begun to be embedded into EHRs. For example, EPIC®, a widely used EHR system began to add some PROs in 2012 (Bennett et al., 2012). PROMIS®

short form questionnaires have been integrated into EPIC® system for symptoms, such as pain, pain interference, sleep disturbances, anxiety, depression, and physical function. However, health care systems may not have been upgraded to the version containing these measures as it is dependent on their planned clinical information upgrade cycles. Other impediments to the adoption of PROs as standard of care are: (a) processes of care; (b) clinician training for interpretation of scores and selection of tailored interventions; and (c) survivor training for self-management of symptoms (Howell et al., 2015; Kotronoulas et al., 2014; Luckett et al., 2009). Whether obtaining PROs from the cancer survivor and sharing PROs between cancer survivor and clinician facilitates the cancer survivor's sense of empowerment in the clinical encounter or improves satisfaction with the processes of care has not been well studied (Ackermans et al., 2018), identifying an area of focus for the study.

PROs and Survival. Basch et al. (2016) conducted a randomized clinical trial of 766 metastatic breast, genitourinary, gynecologic, or lung cancer patients who were starting chemotherapy treatment in outpatient cancer clinics to test web-based data collection of patient-reported symptoms routinely during and post-treatment for a year. The findings demonstrated that the integration of PROs is associated with greater survival among cancer patients over usual care as patients, who self-reported symptoms remained on their chemotherapy regimen two months longer and had an overall median survival of five months. In addition, the results demonstrated improved health care related quality of life (HRQoL) by participants in the intervention arm than usual care (34%, 18% respectively), and reduced cost of care outcomes through decreased emergency department use (34%, 41% respectively) and hospitalization (45%, 49% respectively).

Physical Function and PROs

Decreased physical function has been associated with worsening survival (Kim et al., 2009; Trajkovic-Vidakovic et al., 2012). Physical function has been defined as "the ability to perform the basic actions (i.e., mobility, strength, and endurance) that are essential for maintaining independence and carrying out more complex activities (Painter, Stewart, & Carey, 1999). More simply, physical function refers to the capability of an individual to perform physical activities (PROMIS® Physical Function, 2018); whereas physical impairment may lead to a disability (Silver et al., 2013), limiting a "…person's physical capacity to move, coordinate actions, or perform physical activities" (USLegal™, n.d.). Cancer survivors experience greater physical limitations, such as more difficulty with physical and motor tasks, impacting activities of daily living, than those without a history of cancer as they experience persistent late effects of cancer, its treatment, and symptoms (Zucca et al., 2012).

Several studies have identified the importance of physical function. Ostroff et al. (2008) conducted a cross-sectional study of 359 early-stage lung cancer survivors one to six years following primary surgical resection with curative intent to examine HRQOL, compared to a matched sample of older adults in a lung cancer screening trial. The findings demonstrated that early-stage lung cancer survivors experienced more symptoms, like dyspnea and depression, more co-morbid conditions (e.g., cataracts, another cancer, osteoarthritis, and chronic obstructive pulmonary), and more frequently reported lower physical functioning, compared to the matched sample. The conclusion was that early-stage lung cancer survivors are likely to experience mild impairment in physical functioning, identifying that some of these survivors may benefit from referral to physical therapy and pulmonary rehabilitation (Ostroff et al., 2008).

Lowery et al. (2014) explored the impact of HRQOL and performance status on 183 non-small cell lung cancer patients, who were one to six years post-surgery, focusing on the symptoms of pain, fatigue, dyspnea, depression, and anxiety. Many lung cancer survivors (79.8%) reported some degree of symptom burden. For 49.2% of survivors, who reported two or more symptoms, symptom burden increased as physical HRQOL decreased; however, mental HRQOL only significantly decreased in the lung cancer survivors who had three or more symptoms (Lowery et al., 2014). The most common symptom cluster was pain and dyspnea. This study identified that two or more symptoms adversely affect physical function and quality of life (Lowery et al., 2014), highlighting the importance of measuring not only the symptom, but the functional impact of symptoms. Additionally, this study identified a sub-group of lung cancer survivors may have an increased risk for higher symptom burden due to single status, lower socioeconomic status, and multiple co-morbidities.

In a study of 163 metastatic breast cancer patients, 92% of the patients had at least one cancer-related physical impairment; and these physical impairments, affecting the cardiac, pulmonary, and musculoskeletal system, were poorly assessed in outpatient settings, minimizing its importance in cancer care (Cheville et al., 2008). Similarly, Thorsen et al. (2011) found that 63% of cancer survivors (N=1325) had a need for at least one rehabilitation service, predominately physical therapy (43%). Consequently, physical impairments, frequently a source for emotional distress for cancer survivors, may progress to physical disabilities; however, physical function is not well-assessed or documented by clinicians in in outpatient clinics (Silver et al., 2013). As a consequence, with no or too limited assessment of physical function, physical impairments are not identified and referrals to cancer rehabilitation do not occur. Basic

functional assessments of daily activities are not sufficient to assess physical function because the changes, leading to physical impairment, may be subtle throughout cancer treatment and in some instances, they culminate at the end of treatment (Silver et al., 2013).

Additionally, Stukenborg et al. (2017) conducted longitudinal study, utilizing PROMIS® instruments to measure anxiety, depression, fatigue, pain interference, and/or physical function, with patients with advanced cancer. These PROs instruments identified worsening symptoms, prompting more aggressive symptom management. As such, physical function is proposed as a potential moderator of patient empowerment based on the impact of cancer and its treatment on physical function, supported by the literature. Since the relationship between physical function and patient empowerment is not known, it is of interest in the intended study, describing patient empowerment in cancer survivors. PROs assessments, like physical function and self-efficacy, have not yet been integrated into cancer care in community-based practice, and it remains unknown if PROs are associated with patient empowerment in cancer survivors.

Patient Empowerment and PROs in Cancer Survivors

In the transition from active, primary cancer treatment into early survivorship when multiple moderate to severe symptoms are still present, the current symptom assessment approach does not evaluate the cancer survivor's ability, motivation, or resources to engage in and subsequently, manage their symptoms. A few studies have been published on patient empowerment in cancer survivors outside of the United States.

First, a systematic review summarized the impact of a patient having both cancer and diabetes on PROs (Vissers et al., 2016). Ten studies were evaluated with a heterogeneous population of cancer patients, revealing that patient with both cancer and diabetes experience

higher symptom burden and lower HRQoL and physical function. HRQoL was measured, but a specific patient empowerment measure was not utilized. However, this systematic review recognized the need to explore PROs with inclusion of psychosocial domain, patient empowerment, and self-management in future studies.

Secondly, a qualitative study of cancer patients (N=16) in follow-up care after primary treatment in Denmark, explored the concept of patient empowerment as a key to developing a PRO measure of patient empowerment (Johnsen et al., 2017). Key themes included: (a) perception that it is possible to master treatment and care; (b) possess knowledge and skill for treatment, care, and management of late effects; and (c) ability to leverage own concerns and needs to health care system, specifically clinician. However, a PRO measure was not developed from this study as the participants were less motivated to act on empowered behaviors (moving to a self-care action) and what constitutes appropriate knowledge varied, raising a question about the cancer patient's self-efficacy.

Thirdly, a recently published quality improvement project described the physical and psychosocial needs and feelings of patient empowerment of post-treatment breast (n-70) and colorectal (n=53) cancer survivors in a Canadian academic cancer center, who enrolled in an ambulatory cancer survivorship program at the end of primary cancer treatment, referred by their oncologist, and one year after transitioning to primary care (Liska et al., 2018). For breast cancer survivors, the following concerns were identified at baseline: sleep disturbances, weight changes, and fear of recurrence, and "feeling empowered" scores ranged from 3.06 to 3.75 out of 4.0, on the 15-item Cancer-related Patient Empowerment Scale with a higher score indicating stronger feelings or a higher level of empowerment. There were no statistically significant

changes to the physical or psychosocial needs or “feeling empowered” over time for breast cancer survivors.

In contrast, colorectal cancer survivors reported negligible concerns at baseline and “feeling empowered” scores ranged from 3.00-3.76 out of 4.0 on the same scale. There were no statistically significant changes to “feeling empowered” over time for colorectal cancer survivors. However, the fear of recurrence among colorectal cancer survivors increased, demonstrating the only statistically significant difference in needs from baseline at time of referral to the survivorship program to one year after referral date. Consequently, the researchers stated that they were unable to perform correlational analyses on needs and empowerment because there was no change over time. Given a predominately clinician-driven symptom assessment approach, these physical and psychosocial symptoms of breast and colorectal cancer survivors may be unrecognized or inadequately assessed by clinicians.

While this quality improvement project focused on cancer survivors in cancer survivorship and utilized a direct measure of patient empowerment by utilizing the Cancer-Related Patient Empowerment Scale (Bulsara & Styles, 2006), the time frame is too broad from the end of active cancer treatment and referral for entry into the program, averaging 4.6 years for breast cancer survivors and 1.2 years for colorectal cancer survivors since end of active cancer treatment. Knowing multiple symptoms are more prevalent, bothersome immediately following and up to the first year following primary cancer treatment (Shi et al., 2011; Wu & Harden, 2015), the study focused on a more defined time interval of early survivorship period immediately following primary treatment for cancer when multiple moderate to severe symptoms are likely to be present.

Current State Practice Challenges and Gaps in Knowledge

Patient empowerment is not well-studied or understood in cancer survivors in early survivorship following primary cancer treatment, especially among those receiving chemotherapy or immunotherapy. Several gaps exist in the literature related to the limited studies of patient empowerment and among cancer survivors as: (a) more qualitative than quantitative studies have been published; (b) sample populations have been mixed with both patients with cancer and other chronic diseases; (c) length of time as a cancer survivor of the samples have been either too early (following diagnosis around the time of major oncologic surgery), referring to the survivor as "patient"; or later (one or more years after primary cancer treatment when symptoms are less prevalent); (e) limited attention to other cancer treatment modalities (e.g., chemotherapy, radiation therapy, immunotherapy) and (f) insufficient attention to what differences (e.g., age, gender, race/ethnicity, socioeconomic status) may influence patient empowerment in cancer survivors. Of note, most of these studies occurred outside the United States with different health care delivery systems for cancer care.

No studies describe how to identify the level of patient empowerment as a means to ascertain if the cancer survivor is capable of assuming the responsibilities of managing, monitoring, and reporting of symptoms. A significant gap exists in the assessment symptoms, perpetuating the absence of the cancer survivor's voice in early survivorship. Consequently, cancer survivors may not be optimally engaged in self-management of their cancer at a critical transition point when they are expected by clinicians to increase their responsibilities for self-managing and ongoing monitoring of their cancer and its symptoms. As such, it is important to describe patient empowerment (i.e., outcome variable) in these cancer survivors and assess if the

use of PROs (i.e., predictor variables) is associated with patient empowerment in cancer survivors.

Contribution of Study to Knowledge Development

With growing numbers of cancer survivors living with the chronic disease of cancer, the relationship of patient empowerment to PROs (i.e., self-efficacy and symptoms) needs to be determined. Because patient empowerment in this study is viewed as an outcome rather than a process, this study may add to the knowledge of how to measure patient empowerment as an outcome. The research question lends itself to a quantitative study design which may serve as a basis for future research on how patient empowerment and PROs, not currently or consistently assessed in routine cancer care, may be measured in clinical practice, especially at other transition points along the continuum of cancer survivorship. As such, this proposed study may advance our knowledge of patient empowerment in cancer survivors and identify if PROs measure, like self-efficacy, symptoms, and physical function, are associated with patient empowerment at the end of or immediately following primary cancer treatment.

Atkinson et al. (2017) acknowledged the importance of accurately assessing physical function to promote early identification and restore any physical function losses as cancer survivors' complete primary cancer treatment and transition into early survivorship. Increased physical function (i.e., maintenance of independence in physical abilities) may be associated with patient empowerment; however, the relationship requires further exploration alongside symptoms. This study may serve as a step towards improving our symptom assessment approach in early survivorship immediately after primary cancer treatment; and subsequently, explore how to tailor interventions for cancer survivors in this early survivorship period, identifying resources

necessary to support these cancer survivors and further development of them in community-based cancer centers.

CHAPTER III

RESEARCH DESIGN AND METHODS

The purpose of this study was to assess if the use of PROs (i.e., self-efficacy and symptoms) is associated with patient empowerment of adult breast, colorectal, gynecologic, and lung cancer survivors in early survivorship following primary cancer treatment.

The research question was: *Are the use of PROs (self-efficacy and symptoms) a mechanism to promote patient empowerment among adult cancer survivors in early survivorship following primary cancer treatment?*

Aim 1: Describe the relationship between patient empowerment and PROs (i.e., self-efficacy and symptoms) in breast, colorectal, gynecologic, and lung cancer survivors in early survivorship.

Aim 2: Demonstrate the associations between PROs and patient empowerment in breast, colorectal, gynecologic, and lung cancer survivors in early survivorship, controlling for patient demographics and clinical characteristics.

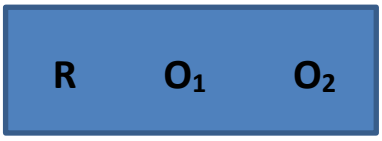
Aim 3: Explore whether the associations between patient empowerment and PROs in breast, colorectal, gynecologic, and lung cancer survivors change over time, comparing immediately post-treatment and 3 months after treatment and controlling for patient demographics and clinical characteristics.

Overview of Research Design

The primary aims for this study capitalized on a descriptive, repeated measures design to describe the relationship between patient empowerment and PROs associated with patient empowerment in early survivorship immediately following primary cancer treatment.

Additionally, data collection at a second time interval was utilized for a within-subject repeated measures analysis 3 months post-treatment to explore if any change in patient empowerment occurs (Figure 4).

Figure 4. Repeated Measures



(R=recruitment; O=Observations)

Sample and Sampling

A convenience sample of adult breast, colorectal, gynecologic, and lung cancer survivors at the end of active, primary cancer treatment with a chemotherapy regimen were invited to participate in the study. Breast and colorectal cancer survivors were selected as these cancers are recognized as two of the most prevalent groups of survivors with a broad range of treatment-related physical and psychological (i.e., emotional) symptoms, impacting quality of life in survivorship (Jefford et al., 2017). Based on tumor registry data from the recruitment site, describing patient volumes by cancer diagnosis and treatment modality, lung and gynecologic cancer survivors were also included. According to American Society of Clinical Oncology (ASCO) and Oncology Nursing Society (ONS) standards, chemotherapy has been broadly defined as antineoplastic agents used to treat cancer, given through oral or parenteral routes, including targeted agents, alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, antitumor antibiotics, monoclonal antibodies, and biologics and related agents; however, hormonal therapies are not included (Neuss et al., 2013).

Previous research on patient empowerment in chronic disease populations indicated sample sizes, ranging from 35-8261 participants (Barr et al., 2015). One study, pertaining to

empowerment in post-surgical cancer and cardiac patients, utilized a medium effect size (f^2=0.15) with alpha 0.05 and power of 0.80 to explore associations between patient perceptions of nurse empowering behaviors during post-surgical hospitalization and six weeks post-discharge self-management outcomes, identified as patient activation and functional health status (Jerofke, et al., 2014). Due to an estimated high attrition rate associated with a six-week interval between data collection periods, the estimated sample size was increased by 30%. In a randomized controlled, prospective interventional study of patient empowerment in older adult cancer patients hospitalized for major oncologic surgery, the effect size was medium (f^2=0.5) with alpha 0.25 and power of 0.80 to explore the effect of patient empowerment on short-and long-term outcomes (Schmidt et al., 2015). In other chronic conditions, like osteoarthritis, a prospective, cohort study to determine if sharing PROs measures with the patient increases empowerment or satisfaction, established a medium effect size as 0.5 with alpha 0.25 and power of 0.80 (Ackermans et al., 2018).

Descriptive analysis was performed, including summary statistics and data visualizations. The statistical tests for this study included: 1) Pearson's correlations for the relationship between patient empowerment (outcome variable) and PROs (predictor variables), such as self-efficacy and symptoms; 2) hierarchical multiple linear regression to determine if a model that contains PROs and other sociodemographic data provides a significant improvement over a model that is limited to the sociodemographic influencers previously described in the literature; and 3) ANCOVA repeated measures to assess changes at three months post-treatment. With Pearson's correlations, a scatterplot was used to assess if the relationship was linear. If the linearity assumption was not met, then a nonparametric approach would be utilized (e.g., Spearman's

correlations). In addition, sociodemographic data included both demographic and clinical characteristics, such as age, co-morbid conditions, and highest level of education completed.

For Aim 1, the estimated sample size was 82 for this study, based on a medium effect size of 0.30, alpha of .05, and power of .80 for Pearson's Coefficient (Figure 5).

Figure 5. G*Power Analysis Calculation for Sample Size-Pearson's Correlation

t tests – Correlation: Point biserial model

Analysis:	A priori: Compute required sample size		
Input:	Tail(s)	=	Two
	Effect size |ρ|	=	0.3
	α err prob	=	0.05
	Power (1−β err prob)	=	0.80
Output:	Noncentrality parameter δ	=	2.8477869
	Critical t	=	1.9900634
	Df	=	80
	Total sample size	=	82
	Actual power	=	0.8033045

For multiple linear regression analysis, the estimated sample size was 81, based on a medium effect size of 0.10, alpha of .05, and power of .80 (Figure 6).

Figure 6. G*Power Analysis Calculation for Sample Size-Linear Multiple Regression Model

t tests – Linear multiple regression: Fixed model, single regression coefficient

Analysis:	A priori: Compute required sample size		
Input:	Tail(s)	=	Two
	Effect size f^2	=	0.10
	α err prob	=	0.05
	Power (1−β err prob)	=	0.8
	Number of predictors	=	5
Output:	Noncentrality parameter δ	=	2.8460499
	Critical t	=	1.9921022
	Df	=	75
	Total sample size	=	81
	Actual power	=	0.8021900

To mitigate attrition, the sample size was increased by 10%. Therefore, the estimated sample size for cancer survivors in this study was 90; an estimated sample size to ensure adequate power for

this study. Aim 3 is exploratory and was not used to estimate sample size but may serve as pilot data to inform future longitudinal studies.

Recruitment

Description of the Setting. The setting for recruitment was a hospital-based outpatient medical oncology clinic of a multi-site community-based cancer center in southeastern Wisconsin, extending from suburban to rural, farm communities with a predominately Caucasian population of individuals of mixed levels of education. One site of the cancer center was free-standing with several services, including diagnostic and interventional radiology, medical and radiation oncology clinics, disease-specific specialty clinics, pharmacy, and cancer rehabilitation. The medical oncology clinic included medical oncologist and Advanced Practice Provider (APP) clinics and a treatment area with 8 private rooms and 4 infusion bays for intravenous chemotherapy treatments and symptom management. Other interdisciplinary team members met with patients and families in private exam rooms in the clinic or private rooms or small patient and family lounges in the treatment area.

Recruitment Process. PI (or designee) identified and screened for potential participants as they near end of treatment visit (last treatment visit) through the patient clinic schedule and schedule for delivery of survivorship care plan. The PI (or designee) approached the potential participant in the clinic setting to introduce the study. The brochure was provided to the patient by the PI (or designee). For patients who were interested in the study, a discussion of informed consent was initiated. Informed consent was obtained prior to completing the questionnaire either in a written hard copy or electronically. For patients requesting more time to review the information, the brochure contained contact information and a tear-off portion for the patient to

request more information about the study and, subsequently, self-select to participate in the study. The tear-off section of the brochure asked potentially interested participants to provide their contact information, including a mail address, telephone number, and e-mail address and select the option for survey completion either electronically or written (Appendix F).

While some patients indicated a preference toward electronic completion of surveys, it was unknown if only one option for survey completion would be a barrier to participation; therefore, both electronic and written options were provided for selection by the participant. In addition, a recruitment flyer and the brochure were developed for distribution at survivorship program events held within the data collection period of the study and planned for placement with survivorship education materials; however, due to pandemic precautions, there were no in-person survivorship programs (Appendix F).

As indicated by the participant's choice, the PI (or designee) identified the option selected and met the participant in clinic or mailed the instructions to complete the questionnaire at home with a hard copy of the questionnaire and self-addressed envelope with postage paid to return completed materials. Informed consent was obtained prior to completing the questionnaire. No materials were posted on the walls, exam rooms, or infusion bay due to environmental regulations of the institution.

Inclusion and Exclusion Criteria

The inclusion criteria were: (a) 18 years of age or older; (b) diagnosis of breast, colorectal, gynecologic, or lung cancer; (c) immediately following last dose of chemotherapy in any phase (neoadjuvant or adjuvant) of primary cancer treatment (may still be receiving maintenance therapy with oral agents, such as hormonal agents, monoclonal antibodies, such as

bevacizumab or rituximab); and (d) able to read and write in English. The exclusion criteria were: (a) had no cancer treatment (i.e., watch and wait); (b) surgery and/or radiation only; (c) non-English speaking; (d) has a limited life expectancy of less than three months; (e) psychological condition or cognitive impairment, limiting the participant's ability to respond to questionnaire; and (f) other important medical or safety considerations at the discretion of the investigator, including non-compliance with the study or other activities.

Rationale for Inclusion and Exclusion Criteria

The inclusion and exclusion criteria facilitated identifying breast, colorectal, gynecologic, and lung cancer survivors for this study who are in the early survivorship period following active, primary cancer treatment with chemotherapy, meaning individuals who completed first line treatment for cancer. Individuals with relapsed or refractory cancers, receiving second line or more chemotherapy treatment regimens, were excluded from this study because these individuals have experienced symptoms associated with more than one chemotherapy regimen which may have influenced their perception of patient empowerment and PROs. Chemotherapy treatment was defined as traditional chemotherapy (antineoplastic agents) as well as targeted agents, monoclonal antibodies, and biologics and was the definition utilized in this study for consistency with the ASCO and ONS definition (Neuss et al., 2013). The rationale was that previous literature has focused on a single cancer treatment modality, like surgery, or multiple cancer treatment modalities, like radiation and chemotherapy.

With its broad definition, chemotherapy is a cancer treatment modality associated with potentially significant symptoms, and it has a definitive end point (i.e., last treatment day) that can be identified in clinic settings. The anticipated number of people with diagnosed with breast,

colorectal, gynecologic, and lung cancer receiving chemotherapy as a primary cancer treatment modality in this community-based cancer center was sufficient to meet the inclusion criteria and estimated sample size. While a potential participant may have been receiving maintenance therapy with oral agents, such as hormonal agents; and monoclonal antibodies, such as bevacizumab or rituximab, they were eligible to participate in this study as long as there was a definitive endpoint for the primary chemotherapy treatment regimen.

The study was limited to an adult population, defined as 18 years of age and older, as the community-based cancer center does not diagnose or treat children and adolescents. The time parameter for inclusion criteria was related to how cancer survivors were identified by visit types (last treatment visit, one month follow-up visit, and survivorship visit), occurring at the end of treatment or on completion of primary chemotherapy treatment for cancer. These visit types were identified in the electronic scheduling system and well-known to the nurses.

In addition, the method for data collection was a self-report questionnaire, composed of instruments which had been utilized in chronic disease populations and clinical trials with the potential for use in a cancer survivor in community-based cancer center. Several options for completion of the questionnaire either online or paper and at home or in clinic were provided to maximize participant's ability to participate in the study. These options included participants, who may not be comfortable with technology or require some assistance related to vision or dexterity due to peripheral neuropathy. Furthermore, glitches in technology were not uncommon and the participant may have experienced frustration with other online surveys, making the option for support in clinic a desired option. The PI (or designee) developed and maintained a

log to keep track of refusals to participate in the study. The threats to internal and external validity of this study design are described later in this chapter.

Recruitment Site

Setting. The recruitment site was ProHealth Care (PHC), a healthcare system in southeastern Wisconsin with a multi-site cancer center in suburban and rural areas of Waukesha County, located between two large metropolitan areas of Madison and Milwaukee. Approximately 1,400 newly diagnosed people with cancer have been seen annually within this community-based cancer center with a significant proportion receiving care in one of the three medical oncology clinics. The largest of the three medical oncology clinics is a free-standing cancer center on the outskirts of downtown Waukesha near a major expressway, increasing accessibility for patients and their families. As a community-based facility, people were diagnosed with solid tumors, like breast, colorectal, gynecologic, lung, prostate, and renal cancers, and hematologic malignancies.

Sample. Of these 1,400 people with new cancer diagnoses, the most commonly diagnosed cancers were breast, colorectal, gynecologic, and lung cancers. Based on tumor registry data, 313 patients received intravenous chemotherapy and 555 patients received immunotherapy, including oral targeted therapies, monoclonal antibodies, and other biologic therapies. In addition, survivorship care plans were developed and delivered to approximately 370 cancer survivors within three months of completing primary cancer treatment, aligning with American College of Surgeons Commission on Cancer (CoC®) and National Accreditation Program for Breast Centers (NAPBC®) standards for survivorship care plans. Consequently, it was anticipated that the number of breast, colorectal, lung, and gynecologic cancer survivors at

the end of primary chemotherapy treatment was sufficient to obtain the sample for this study from this community-based cancer center.

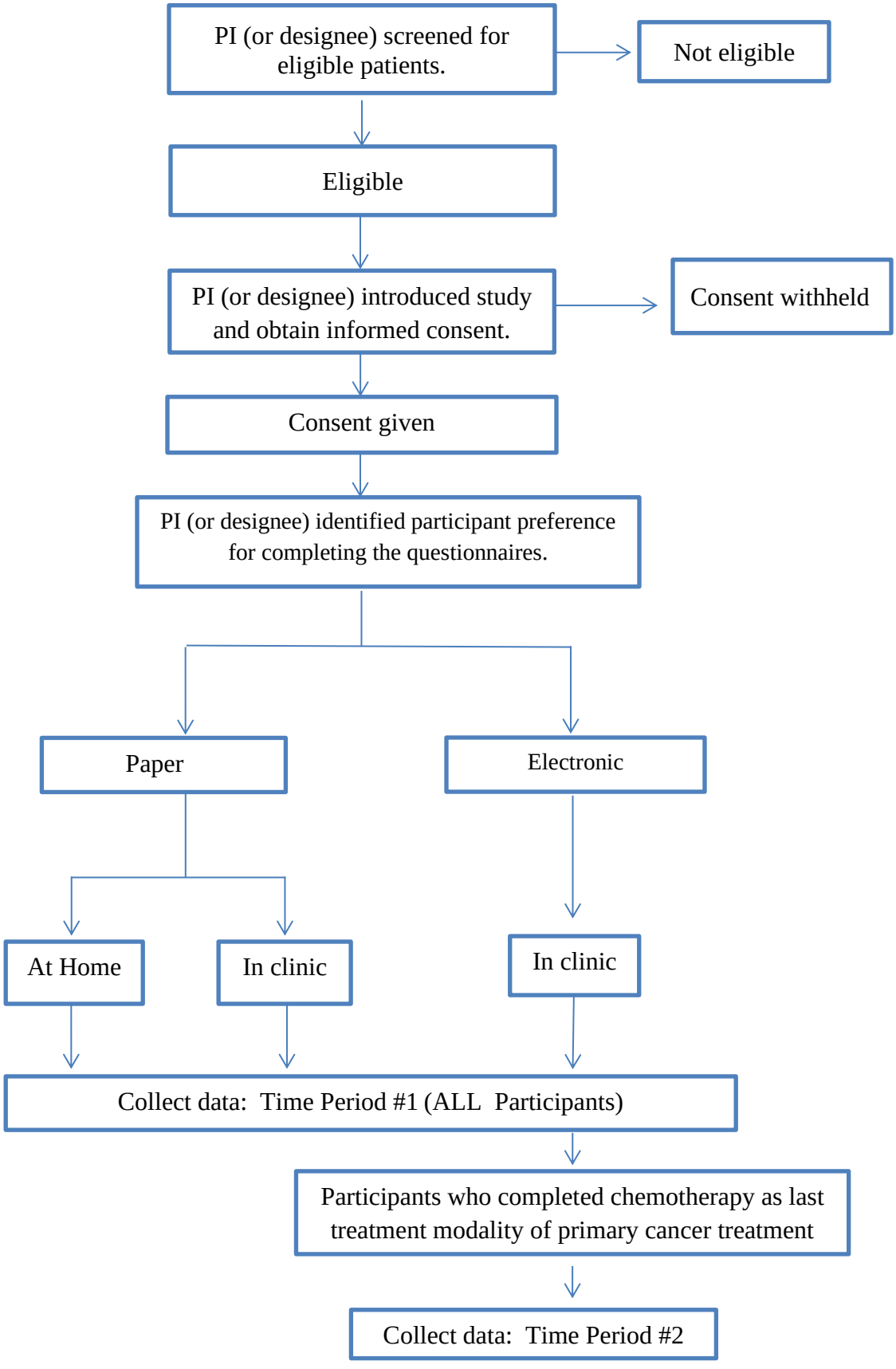
Procedures

Several strategies were employed to recruit cancer survivors for this study (Figure 7). PI educated oncology nurses, nurse navigators, nurse practitioners, and physician assistants about the study prior to initiation. The PI (or designee) conferred with oncology nurses (e.g., RNs, Oncology Nurse Navigators, or Nurse Practitioners) to reduce the risk of missing potentially eligible cancer survivors for this study. PI (or designee) actively reviewed patient clinic visits, and survivorship care plan visit schedules to identify breast, colorectal, lung, and gynecologic cancer survivors nearing the end of treatment visit and screen to determine if eligible for the study. Some cancer survivors were contacted by the PI (or designee) directly through brochures in the clinic or flyer at cancer survivor program events to learn more about the study. The PI (or designee) screened for eligibility.

If eligible, the PI (or designee) introduced the study to the breast or colorectal cancer survivor with the brochure. If he or she was interested in proceeding with the study, the PI (or designee) obtained informed consent and the preferred method for completing the questionnaire will be selected by the participant. For patients who refused participation, they were thanked for their time, and the refusal and reason for refusal, such as time commitment, symptom intensity, fatigue, loss of privacy, method of data collection, fear about sharing information, perceived discomfort with questions, no direct benefit, and previously negative experience with research, was documented. A log was developed and maintained to keep track of refusals to participate in the study in a password protected Excel spreadsheet.

If the participant wished to complete electronically, they were provided with a tablet to complete the questionnaire in clinic. If the participant preferred a paper questionnaire, the option to complete it in clinic or at home was offered. If the participant preferred to complete it at home, an addressed, stamped or postage paid envelope was provided to expedite its return. Participants were provided with a unique code for their questionnaire to use for first and second time periods for data collection. The questionnaire was similarly organized in the electronic or paper version. In the paper version, the questionnaire was presented in as a stapled packet (8½ x11 inches) with questions, item responses, and boxes formatted with the same appearance, such as font, size, and spacing, and color selection (Dillman et al., 2014). Similar order and format applied to the electronic version of the questionnaire. The PI collected data from the participant's EHR after informed consent was obtained to reduce the number of sociodemographic and clinical characteristic questions for the participant to complete. As some of the clinical characteristic questions may have been difficult for the participant to accurately complete, such as diagnosis, stage, cancer treatment, and co-morbid illnesses or conditions, this data were collected and held in an Excel spreadsheet of a passcode protected file. It was held separately from the screening for eligibility log.

Figure 7: Screening and Recruitment Procedures



Electronic or Written Questionnaire in the Clinic. Participants, who chose to complete the questionnaire while in the clinic setting, the PI (or designee), coordinated a convenient time for the participant, such as before or after a clinic visit. Some participants opted to complete it on a date other than the clinic visit. PI (or designee) arranged to meet with cancer survivors at a mutually agreed time and offer a separate, private clinic consultation room or family waiting room with doors to close for privacy and comfort. PI (or designee) showed the participant how to access the survey on the laptop and offered assistance on how get started with the electronic or paper format. If the participant needed more assistance (e.g., difficulty with reading the questions or documenting a response), the PI (or designee) provided it by reading the questions as presented and documenting the participant's response as stated. For participants who completed the first survey (following last treatment) in the clinic setting, the PI (or designee) identified the clinic visit closet to the second data collection period (3 months post-treatment) to connect with the participant to coordinate a time to complete the questionnaire. The PI (or designee) sent a postcard and/or called via telephone with a reminder of the second data collection.

Written Questionnaire at Home. For those participants, who preferred to complete paper questionnaires at home, it was sent to home address with addressed, stamped postage-paid envelope with a thank you reminder sent within one week. If not received two weeks following the date that the questionnaire was sent, the PI (or designee) connected with the participant in the clinic or via telephone to determine if a replacement questionnaire was needed. If they were interested in the replacement questionnaire, it was given or sent with a follow-up with a final notice reminder. If the participant is no longer interested, a reason will be documented in the log

and no further contact about the study will occur. If the first questionnaire (immediately following treatment) was not completed, the second questionnaire (three months post-treatment) was not sent.

For the second time-period data collection, a postcard reminder was sent to thank them for their participation in the study and inform them the questionnaire would arrive in the mail over the next week and followed 3-5 days later by a cover letter and the questionnaire (Dillman et al., 2014). A thank you reminder was sent within one week, emphasizing the importance of completing the survey and expressing appreciation for their response will be sent 10-14 days later. If not received two weeks following the date that the questionnaire was sent, the PI (or designee) sent the participant with a replacement questionnaire and a final reminder notice. These steps of the procedure were tracked in a passcode protected file in an Excel spreadsheet to document when each type of mailing was sent, receipt of completed questionnaire booklet, and when to send or stop additional contacts. Incentives were documented when sent for each completed survey.

Participants received a $15 gift card following completion of one questionnaire and $25 gift card following completion of two questionnaires, distributed by the PI (or designee) at a cost of $1600. The questionnaire has four parts, including: (1) sociodemographic information; (2) Cancer-Related Patient Empowerment Scale; 3) PROMIS® Self-Efficacy for Managing Chronic Illnesses; and (4) PROMIS®-29 Profile v2.1, responding to 67 items, excluding the sociodemographic items, taking approximately 15-20 minutes to complete (Appendix D). The paper and electronic questionnaires were reviewed by ONNs, oncology nurse, educator, and RAs to engage them in the study and piloted with cancer survivors, who participated in the cancer

center's Patient and Family Advisory Committee to identify any issues with procedures, instructions, and length of time to complete (Dillman et al., 2014).

A secure web application, Qualtrics, was utilized for managing online surveys and databases. Consistent with the policies of the PHC IRB, this consent form was filed in a locked cabinet behind a locked door. Only the PI and RAs had access to the locked file drawer.

Data Collection Instruments

Patient empowerment is difficult to measure as it is not directly observable (Bulsara & Styles, 2004). Despite efforts toward the development of a generic measure of patient empowerment in people living with chronic diseases (Small et al., 2013), the lack of consensus around the definition of patient empowerment and inability to identify one single measure for patient empowerment (McAllister et al., 2012) has complicated efforts towards instrument development. Several studies were conducted toward the development of patient empowerment scales: 1) Patient Empowerment Scale (mental health); 2) Health-Related Quality of Life (chronic conditions); 3) Diabetes Patient Empowerment Scale (diabetes); and 4) the Genetic Counseling Outcome Scale (genetics) (Anderson et al., 2000; Barr et al., 2015; Maunsell et al., 2014; McAllister & Dearing, 2015; Rogers, Chamberlin, & Ellison, 1999). Additionally, the Health Education Impact Questionnaire (heiQ) scale, developed for chronic conditions to assess the effects of health education programs on people living with chronic diseases, was utilized in cancer patients (Maunsell et al., 2014) to validate the scale in this population.

One systematic review was conducted to evaluate instruments with PROs, designed to measure patient empowerment in adult cancer survivors, and identified that the Patient Empowerment Scale (PES) and Cyber Info-Decisional Patient Empowerment Scale (CIDES)

were developed specifically for cancer patients, whereas the CEQ and heiQ were validated for cancer patients (Eskildsen et al., 2017). However, only three scales are specialty-specific from the cancer patient or survivor perspective: 1) Patient empowerment Scale (PES); 2) Cancer-related Patient Empowerment Scale; and 3) Cancer Patient empowerment Questionnaire (CEQ) (Bulsura et al., 2006; Bulsara & Style, 2013; van den Berg et al., 2013).

While PES and CEQ were utilized with cancer survivors, they were not selected as the instruments for this study. PES is a 28-item Likert scale self-report questionnaire to measure patient empowerment among cancer patients during treatment (Bulsura et al., 2006). However, PES had not been utilized with cancer survivors' post-treatment, and the length of the tool may prohibit its adoption in busy oncology practices. PES provided a definition of patient empowerment but was unclear about patient empowerment as a process or outcome (Eskildsen et al., 2017). CEQ, a 40-item, Likert scale self-report questionnaire to measure psychological patient empowerment among breast cancer survivors at the end of primary, curative-intent treatment, in the Netherlands (van den Berg et al., 2013), is limited in that it has only been utilized in one study with a small sample size (n=40) with one cancer diagnosis. In addition, it did not assess decision-making and knowledge acquisition (Eskildsen et al., 2017). Both PES and CEQ are limited in their ability to comprehensively measure patient empowerment (Eskildsen et al., 2017).

To measure patient empowerment in this study, the Cancer-related Patient Empowerment Scale will be utilized, a 15-item Likert scale self-report questionnaire to measure the level of patient empowerment in cancer patients which was developed from its precursor, PES. From a systematic review of 19 measures to evaluate patient empowerment, Barr et al. (2015) concluded

that future research should focus on development of a clear definition of patient empowerment, and the need for a definitive measure of patient empowerment has been indicated by other researchers (McAllister et al., 2012). The study may contribute to the definition of patient empowerment among cancer survivors at the transition point of end of primary treatment in the early survivorship period by validating the Cancer-related Patient Empowerment Scale which is not currently present in the literature.

The instrument to measure the level of patient empowerment in this study is the Cancer-related Patient Empowerment Scale (Bulsara & Styles, 2013). PROs self-efficacy and physical function will be measured by PROMIS® Self-Efficacy and PROMIS® Physical Function. Each of the instruments will be further described, emphasizing their origins, composition, reliability, and validity.

Cancer-Related Patient Empowerment Scale. Cancer-related Patient Empowerment Scale originated with its predecessor, the Patient Empowerment Scale (PES), a 28-item, patient self-report questionnaire with Likert, cumulative response scale which was developed from a literature review on empowerment and self-efficacy and interviews with patients living with chronic diseases (Bulsara et al., 2006). PES is a self-report questionnaire to assess the level of patient empowerment among 100 cancer patients during treatment and receiving at least one treatment in a hematology center, medical and radiation oncology clinics of a large academic hospital in Australia. The PES questionnaire defined patient empowerment as coping and self-efficacy, both of which are necessary for patient empowerment. This scale has been described by the researchers as useful in identifying the patient's level of patient empowerment and supporting decision-making to cope with their cancer. However, a limitation to the study is that

many participants in the academic setting had moderate to high levels of patient empowerment, compared to the PES items and they were early in their treatment phase. Similar to studies of patients living with diabetes, cancer survivors may use different coping strategies, based on diagnosis of and treatment for early or advanced, metastatic disease (Livneh & Antonak, 1994).

To examine the psychometric properties for validity and reliability, the Rasch Model, an early, popular psychometric model from Item Response Theory, an alternative to Classical Response Theory, when measuring item difficulty associated with cognitive or affective items, was utilized for analysis of categorical data, derived from questionnaire responses to the items in the PES (DeVellis, 2012; Polit & Beck, 2012). This method was chosen because the *unidimensionality* of this model measures empowerment as a singular construct (Bulsara et al., 2006). The analysis revealed that the data were a good fit with the Rasch Model. The Person Separation Index, a statistic of reliability and equivalent to Cronbach's alpha, indicated a high degree of reliability at .926. Eskildsen et al. (2017) evaluated psychometric tests of these instruments, identifying internal consistency and construct validity for CEQ and content validity, internal consistency, and reliability for PES, the only patient empowerment instrument that tested reliability.

Based on their previous work, Bulsara, and Styles (2013) conducted a study, utilizing PES, to identify elements of patient empowerment among cancer patients, focusing on areas influenced by diagnosis and treatment and strategies for cancer patients to self-manage their illness, to construct a valid, reliable instrument to measure patient empowerment in cancer. The scale was developed in two stages of a pilot study, utilizing 28-item PES. The second study utilized a 15-item modified scale from a different location with a sample size of 101 cancer

patients.

Bulsara and Styles (2013) reduced the 28-item scale to 15-items after determining how cancer patients respond to these items, using the Polytomous Rasch Measurement, similar to the model used in the previous study; however, a trait or ability is measured by one, two, or three parameters, describing the respondent, and items may differ in difficulty, discrimination, and proneness (Waltz et al., 2010). The purpose was to identify different levels of empowerment in cancer patients (n=101) from a Hematology Shared Care Model, a model of survivorship care in which care is shared between an oncology-specialist and a general practitioner, in a metropolitan teaching hospital in Australia. Similar to PES, the Cancer-related Patient Empowerment Scale utilizes a patient self-report questionnaire with a simple, four-point Likert scale with responses ranging from strongly agree to strongly disagree (4=strongly agree; 3=agree; 2=disagree; 1=strongly disagree). Cancer patients respond to each of the items on the scale, and the scores for each response are tallied into a cumulative score with higher scores associated with higher empowerment (Bulsara et al., 2006). The maximum cumulative score is 60. An acceptable degree of reliability was indicated by the Person Separation Index of .783 prior to and .787 after item reduction. There were 13 items removed and two pairs of statements on spirituality and complimentary therapies were decreased to one statement for each topic, selecting the one that fit the model better (Appendix D: Questionnaire Cancer-Related Patient Empowerment Scale and Appendix E: Permission to Use). The PES scale was reduced from 28-to 15-items based on an acceptable degree of reliability as demonstrated by the Person Separation Index of .78. Thus, the decrease in the items did not change reliability of the Cancer-Related Patient Empowerment Scale (Bulsara & Styles, 2013).

The 15-item Cancer-related Patient Empowerment Scale is currently entitled the *Patient Support Strategies Questionnaire* as it was evaluated in academic, outpatient cancer clinics setting for use by clinicians. Yet, there have been no cut scores established for levels of empowerment. The instrument was intended for patient self-report of empowerment in a busy clinic setting and to be used by clinicians (C. Bulsara, personal communication, October 11, 2018). The higher the cumulative score is associated with a more empowered respondent. This 15-item Cancer-related PES empowerment scale was utilized in a Canadian quality improvement project to evaluate the physical and psychosocial needs and feelings of empowerment among cancer survivors, who completed primary cancer treatment, upon entry into a wellness program and one year after discharge to primary care (Liska et al., 2018). While Liska et al. (2018) recognized that reliability and validity had been established by Bulsara et al. (2006); however, the authors did not describe the reliability and validity of the Cancer-related PES tool in their quality improvement study.

PROs Instruments. In 2003, the National Institutes of Health (NIH) Roadmap was launched to establish a multicenter cooperative group with the goal of centralizing the development and collection of PROs, addressing the problematic issues for researchers and clinicians, including: (a) different measures are used in studies about the same concept and therefore, it is not possible to combine studies or compare interventions across studies; (b) lengthy patient questionnaires contain too many measures for patients to complete; (c) physicians, nurses, and other interdisciplinary team members inadequately and inaccurately describe patient's experience in their assessments (Bevans et al., 2014). Recognizing that patients are the best source for describing their symptoms, functioning, and quality of life and

managing the effects of their chronic disease and its treatment, this cooperative group, funded by NIH, developed the Patient Reported Outcomes Measurement Information System (PROMIS®) to provide researchers and clinicians with access to valid, reliable, and standardized common tools for measuring patient self-report of the individual's own mental, physical, and social well-being (Bevans et al., 2014; Cella et al., 2010; HealthMeasures, 2016). These PROs instruments have been used to obtain patient self-report of symptoms, physical and mental function, and perceptions, based on Health Care Related Quality of Life (HCQL) model (Wilson & Cleary, 1995) in adults (ages 18 years or older), developed in English and other languages and targeted a sixth-grade reading level or less. PROMIS® measures may stand alone as a single measure of a concept or may be combined for clinician assessment to improve accuracy of symptom assessment, enhance treatment decisions, improve patient-physician communication, and promote patient autonomy (Bevans et al., 2014).

PROMIS® instruments were developed on Item Response Theory (IRT) is a family of measurement models that place items and people on a continuum from low to high levels of the trait that is being measured. It measures abilities or attitudes. Each item can be modeled as a single measure of the trait. IRT focuses on reliability of items along a continuum for a given person taking the test. Response-centered scaling increases the precision of measurements which leads to fewer items that are more specific to the person based on his or her response to the previous item (Bevans et al., 2014; Fries et al., 2005).

Description of PROMIS® Instruments. PROMIS® Instruments established norms were based on the general population of the U.S. Census and a score of 50 is the mean for this population, referred to as the reference sample, with a standard deviation of 10 (Barsevick et al.,

2013). With a higher PROMIS® score, more of the concept is measured which may be desirable or undesirable, depending on the symptom or domain being measured (PROMIS®, 2019). The item question or statement may be either negatively or positively worded. For example, with a negatively worded concept, like fatigue, a higher PROMIS® score indicates more of that symptom is present and a greater severity while a lower PROMIS® score indicates less fatigue. In contrast, a positively worded concept, like physical function, a higher PROMIS® score indicates better physical function whereas a lower PROMIS® score indicates greater difficulty with physical function (Shaw et al., 2018).

Scoring. Response pattern scoring utilizes each item for each participant. It is a method more accurate than raw (or scale) scores. Each question contains a 5-point Likert scale for responses, ranging from one to five. The total raw score for a fixed-item short form is the sum of the individual raw score responses, making the lowest total raw score is 4 and the highest score is 20. To produce a valid score, questions are presented and answered in the order of the instrument. The total raw score is converted into a standardized T-score for each participant with a mean of 50 and a standard deviation of 10 and reported as the final score for each participant. Of importance, a t-score does not equal percentile. As such, a participant, who has fatigue, a raw score of 10 translates to a T-score of 34.4 with a standard error of 2.1, based on Scoring Tables for PROMIS 29-Profile 1.0 (PROMIS®, 2019), approximately one and one-half standard deviation below the mean of 50, indicating better than average of the United States general population.

PROMIS® measures in a short form are available with the core difference as length of the instrument. Reliability and precision are similar with the short form. The short form tools are

preferred to decrease burden on the participant, increase likelihood that the participant will complete the survey tools, and useful for asking the question of all participants or the same participant over time for comparison (PROMIS®, 2019). In addition, short form instruments are currently being embedded into EHR platforms and more likely to be completed in clinical practice if they are not too lengthy.

Interpretation of Scores. Since inception, interpretation of scores has been a concern for researchers and clinicians as there were no established cut off scores. However, minimally important differences, "a difference in the score that is large enough to have implications for a patient's treatment and care", for six PROMIS® cancer scales (i.e., fatigue [two scales], pain, physical function, anxiety, and depression) were first identified in a study of 101 cancer patients with advanced disease (Yost et al., 2011, p. 508). Jensen et al. (2017) evaluated the responsiveness of eight PROMIS® measures in a large community-based cohort of cancer patients (n=2968), including pain, fatigue, anxiety, depression, and sleep disturbance and cognitive, social, and physical function. The findings indicate that these PROMIS® measures were sensitive to patient perception of worsening and improving symptoms as well as adverse reactions, demonstrating clinically meaningful change with a change of three to five points (Jensen et al., 2017). These findings provide a foundation for interpretation of scores in future research. More recently, default thresholds (i.e., cut points) have been proposed for as (a) a score less than 55 is within normal limits; (b) a score between 50-60 is *mild*; (c) 60-70 is *moderate*; and (d) greater than 70 is *severe* (HealthMeasures, n.d.). However, these are only general guidelines. PROMIS® scores range between 20 to 80. The next section will further describe the PROMIS® instruments for this study.

PROMIS® Self-Efficacy. PROMIS® Self-Efficacy is available in two formats: general and managing chronic conditions. For the self-efficacy measure, the general concept "…is defined as confidence in one's ability to successfully manage or perform a specific tasks or behaviors" (PROMIS® Self-Efficacy, 2017). The item bank for the self-efficacy instruments is for adults with a minimum of one chronic health condition: not disease specific. The self-efficacy instrument selected for this study is: PROMIS® Self-Efficacy Managing Chronic Conditions as it has been used to measure self-efficacy in cancer patients (PROMIS®, 2017) and will be further described in the next section.

PROMIS® Self-Efficacy Managing Chronic Conditions. PROMIS® Self-efficacy Managing Chronic Conditions assesses current level of confidence related to one's own health in the following five sub-scales: (a) managing daily activities [4], (b) emotions [4]; (c) medications or treatments [4], (d) social interactions [4], and (e) symptoms [8]. Each of these subscales is available as either a 4- or 8-item short form; however, the 4-item short forms were selected for all scales except symptoms for which the 8-item short form was selected. As such, the total number of items for the PROMIS® Self-efficacy Managing Chronic Conditions is 24. Most of these selected sub-scales are the 4-item short forms to reduce the burden on the participants completing them and utilize the version of each sub-scale that is in the process of integration into EHR platforms (HealthMeasures, n.d.). The 8-item subscale on symptoms was selected as improving symptom assessment approach is at the heart of this study. A 5-point Likert scale is utilized with ratings from one to five, based on I am not at all confident (1); I am a little bit confident (2); I am somewhat confident (3); I am quite confident (4); and I am very confident (5). The higher total scores the greater the self-efficacy of the respondent. Refer to Appendix D:

Questionnaire PROMIS® Self-Efficacy Managing Chronic Conditions and Appendix E: Permission to Use).

PROMIS®-29 Profile v2.1. PROMIS®-29 Profile v2.1 measures self-report of seven PROMIS® short forms for the following physical and mental health domains: (a) physical function; (b) anxiety; (c) depression; (d) fatigue; (e) sleep disturbance; (f) ability to participate in social roles and activities; and (g) pain interference (PROMIS®, 2019). This version was updated from v2.0 to v2.1 when physical function item bank was updated; only change the profile (PROMIS®, 2019). PROMIS®-29 Profile v2.1 contains four questions for each symptom. Each symptom is referred to as short form 4a. For physical function, the item responses are without any difficulty (1), a little difficulty (2), some difficulty (3), much difficulty (4), and unable to do (5). Item responses for anxiety, depression, and ability to participate in social roles and activities are never (1), rarely (2), sometimes (3), often (4), and always (5). For fatigue, sleep disturbance, and pain interference, the item responses are not at all (1), a little bit (2), somewhat (3), quite a bit (4), and very much (5). In addition, this profile contains pain intensity on a 1-10 numeric rating scale with 0 as no pain and 10 as the worst pain imaginable. Except for physical function with no timeframe provided, all symptoms are assessed over the past 7 days.

PROMIS® Profile 29 v2.0 Reliability and Validity. PROMIS® Profile 29 v2.0 has been utilized to assess physical and mental health domains in adults living with chronic diseases or conditions, such as rheumatoid arthritis (Katz et al., 2017), bone marrow transplantation (Shaw et al., 2018); kidney transplant (Tang et al., 2019), and HIV (Schnall et al., 2017) as well as older adult populations living with multiple chronic diseases (Rose et al., 2018). One study

evaluated the psychometrics of PROMIS® Profile 29 v2.0, demonstrating confirmatory factor analysis supported a physical factor (i.e., physical function, pain interference, pain intensity, ability to participate in social roles and activities) and mental health factor (i.e., anxiety and depression) with high internal consistency reliability for the summary scores of physical health and mental health as (Cronbach's alpha 0.98 and 0.97), respectively (Hays et al., 2018).

Similarly, Tang et al. (2019) reported high internal consistency with Cronbach's alpha > 0.88 and good structural validity through confirmatory factor analysis with 177 kidney transplant patients, comparing PROMIS-29 item short forms to PROMIS-57. Test-retest reliability demonstrated good agreement as indicated by the intraclass correlation coefficient (ICC > 0.6) and convergent validity was assessed with Spearman's Rho. Construct validity was supported by known group comparisons.

In a study of older adults with multiple chronic conditions, physical health scores and mental health scores of PROMIS-29 v2.0 were highly intercorrelated ($r=0.74$, $p < 0.001$) and highly correlated with the Veterans RAND 36 (VR-36) scores, establishing convergent validity (Rose et al., 2018). Additionally, PROMIS-29 Profile v2.1 demonstrated high internal consistency reliability with Cronbach's alpha, ranging 0.87-0.97, and interscale correlations measured convergent and discriminant validity in a study of 209 patients living with human immunodeficiency virus [HIV] (Schnall et al., 2017). Test-retest measures for reproducibility were also reported. ICCs were reported, ranging from 0.40 to 0.75, for the subscales of physical functioning, sleep disturbances, ability to participate in social roles, and pain interference. For other subscales (i.e., anxiety, depression, and fatigue), ICCs were greater than 0.60. Using the

correlation between the total HIV symptom index score and each subscale at two time periods (baseline and follow-up), criterion validity was established by predictive and concurrent validity.

Finally, Shaw et al. (2018) compared PROMIS® 29 Profile v2.1 to 36-Item Short Form Health Survey (SF-36) in 1634 adult hematopoietic cell transplant survivors. Based on Pearson's Correlation Coefficients, similar component and domain scores were strongly correlated for physical function (r=.82). Pearson's correlation coefficients for physical function, pain, and fatigue scores, were .87, -.82, -.82, respectively for allogenic transplant recipients; and .84,-.82, -.81, respectively for autologous transplant recipients. This study concluded that symptoms and function can be adequately assessed with PROMIS-29®.

PROMIS®-29 Profile v2.1 was selected for this study as it has established reliability and validity in chronic diseases. Further use of the instrument is needed with different populations (Hays et al., 2018), like cancer. PROMIS®-29 Profile v2.1 contains symptoms commonly experienced by cancer survivors. It includes the most current version of each of the seven short forms and is consistent with the format embedded into EHR platforms, such as EPIC® with 2017 versions or higher (HealthMeasures, n.d; Appendix D: Questionnaire PROMIS®-29 Profile v2.1 and Appendix E: Permission to Use). Additionally, sociodemographic, and clinical characteristics will include: (a) age; (b) gender; (c) ethnicity; (d) race; (e) level of education completed; (f) type of cancer; and (g) other co-morbid conditions as these factors may influence empowerment (Joergensen et al., 2015; McAllister et al., 2012).

Human Participants

This proposal was prepared, submitted, and reviewed for approval by both the ProHealth Care Institutional Review Board and Loyola University Chicago Institutional Review Board

(Appendix B). Key aspects of informed consent will be reviewed with potential participants as they will be recruited from the medical oncology clinic in which they are currently receiving their cancer care, including (a) voluntary participation; (b) ability to withdraw from the study at any time; and (c) decisions do not affect current or future care, provided by clinicians in the cancer center. In addition, the risks and benefits will be described as the participant may not directly benefit from this study; and there may be some discomfort when completing the questionnaires, identifying some symptoms as an ongoing concern or experience an increase in emotions, like anxiety. If a participant has a symptom of concern identified while completing the questionnaire, they will be encouraged by the PI (or designee) to follow-up with their oncology clinic nurse. Participants will be provided the contact information for the Oncology Counselor for support with any psychosocial concerns that arise from participation in this study, described in the study-related instructions, and provided with questionnaires.

To protect privacy and confidentiality, the participant's names will be de-identified with codes for data entry and data analysis and only minimal identifying data will be collected. Files will be secured with access code(s) limited to PI and potentially one designee for data entry support. The laptop computer, tablet, and application will be secured. The participant will be taught how to use the device and access the survey by the clinical research assistant. Informed consent form(s) will be scanned into the participant's EHR and the original, signed informed consent form and data collection tools that are in a paper format will be secured in a locked cabinet.

Data Analysis Plan

Descriptive statistics will be used to describe patient empowerment in cancer survivors, providing summary statistics and data visualizations. To determine the relationship between patient empowerment (outcome variable) and PROs (predictor variables), Pearson's Correlation will be used for Aim 1. A scatterplot will be used to assess if the relationship is linear. If the linearity assumption is not met, then a nonparametric approach will be utilized (e.g., Spearman's Correlation). Linear multiple regression analysis, Fixed Model, R^2 (partial f test) will be utilized for Aim 2 to determine the relationship of the patient empowerment to PROs measures (self-efficacy and symptoms). For Aim 3, an ANCOVA repeated measures will be utilized to determine if there is a change in the associations between patient empowerment and PROs over two time periods following primary cancer treatment and 3 months post-treatment. SPSS advanced statistical package (Version 29) will be utilized for data analysis. Data files will be secured with passcode. For this study, the null hypotheses are:

H_0: There is no statistically significant relationship between patient empowerment and PROs (self-efficacy and symptoms) in adult breast, colorectal, gynecologic, and lung cancer survivors in early survivorship (Aim 1).

H_0: There is no significant prediction of patient empowerment by PROs (self-efficacy and symptoms), controlling for age, cancer diagnosis, chemotherapy treatment phase, or education in adult breast, colorectal, gynecologic, and lung cancer survivors in early survivorship (Aim 2).

H_0: There is no change in the associations between patient empowerment and PROs in breast,

colorectal, gynecologic, and lung cancer survivors change over time, comparing immediately following primary cancer treatment and 3 months post-treatment and controlling for patient demographics and clinical characteristics (Aim 3).

The research hypotheses are:

H_A: There is a statistically significant relationship between patient empowerment and PROs (self-efficacy and symptoms) in adult breast, colorectal, gynecologic, and lung cancer survivors in early survivorship (Aim 1).

H_A: There is a significant prediction of patient empowerment by PROs (self-efficacy and symptoms), controlling for age, or education in adult breast, colorectal, gynecologic, and lung cancer survivors in early survivorship (Aim 2).

These are two-tailed, non-directional hypotheses as the direction of the relationship between two patient empowerment and the multiple independent variables of PROs (i.e., self-efficacy and symptoms), age, co-morbid conditions, and level of education completed is not known.

Handling Multiple Responses or Missing Data. If the participant completes the instruments electronically, then the program will ensure single responses to each question, eliminating multiple responses and missing data. However, if some participants choose to complete the paper questionnaires, then a process for handling multiple responses and missed data will adopt the HealthMeasures approach described in the scoring manuals of PROMIS® Self-Efficacy Managing Chronic Conditions and Physical Function for all instruments in study, resolving them based on the research participant's response (PROMIS® , 2017; PROMIS®, 2018). If two or more responses are marked by the participant, and these responses are next to one another, then the PI (or designee) entering data will be responsible for randomly selecting

one of them to be entered and will write it down on the form. For two responses next to each other, a flip of a coin will be used (e.g., heads-higher number will be entered, and tails-lower number will be entered); whereas, for three or more responses, a table of random numbers will be used. The participant's response will be considered missing if two or more responses are not next to one another.

Threats to Internal or External Validity

There were several threats to internal and external validity of this study. The threats to interval validity potentially were: (a) selection bias; (b) instrumentation; (c) maturation; (d) mortality or attrition, while threats to external validity limited generalizability of the study results.

Selection Bias. Selection bias threatened the internal validity of this study by the sampling technique and recruitment method. The sample was a convenience sample of cancer survivors at the end of primary cancer treatment. While this sampling method allowed for accessing the population of interest in this study, the sample obtained may not have been typical of the population. Therefore, sociodemographic and clinical characteristics were collected to describe the recruited sample more fully. The potential participants were introduced to the study by the PI (or designee); however, the ONNs and clinic nurses, providing direct care to the cancer survivor may have influenced recruitment. Similar to how nurses decide who is able or not able to self-manage their own care, nurses may have made decisions about who will be able or unable to participate in the study, based on their knowledge of the cancer survivor. Consequently, selection bias may have been inadvertently introduced by these nurses. To reduce this threat, the number of ONNs and clinic nurses were limited to those providing care to the cancer survivor

near the end of treatment visit, and these nurses were trained on the study by the PI, emphasizing recruitment procedures, inclusion and exclusion criteria, and expectations of the nurse's role in avoiding selection bias. Furthermore, the cancer survivor may have felt obligated to participate in the study because of their relationship with the ONN or clinic nurse. As such, their role was limited. Finally, selection bias may have occurred with cancer survivors self-selecting to participate in the study. Cancer survivors, who are experiencing multiple symptoms and may have lower levels of empowerment, may have chosen to participate in the study which may impact the findings of this study. The final study sample will be fully described in Chapter IV.

Instrumentation. For this study, questionnaires were utilized as the instrument for data collection. The benefits of collecting data through a questionnaire were that it is an efficient, low-cost method for obtaining data from participants, offers privacy to the participants, and reduces bias from interviewer or feeling that one must respond based on societal norms (Dillman et al., 2014; Polit & Beck, 2012; Waltz et al., 2010). Despite these recognized benefits, questionnaires presented several disadvantages or challenges to internal validity, such as: (a) questions and responses are structured, narrowing options for choices and eliminating narrative responses; (b) participants must be able to read in the language of the survey; and (c) the participants reading level and comprehension influence their ability to complete the survey (Dillman et al., 2014; Polit & Beck, 2012; Waltz et al., 2010). However, PROMIS® instruments have been extensively studied, reducing the limitation of structured, narrow responses. Cancer-Related Patient Empowerment Scale had been reported in two studies and one quality initiative project. As such, the questionnaire had been previously tested in cancer survivors, the population of interest for this study.

To mitigate internal validity threat of the instrument, several options for completing the questionnaires were available to the participant to identify their preferred method (e.g., online or paper) and setting (home or clinic) to reduce barriers related to technology and physical impairments. PI (or designee) assisted the participant with getting started with the questionnaires. If the participant identified a preference to complete the questionnaire in the clinic, then, the PI (or designee) facilitated the cancer survivor getting started with the questionnaires, especially if they were completing online via a laptop to avoid excluding a potential participant because they were novice with the technology or had a visual or dexterity impairment, making it difficult for them to complete the questionnaires in either the online or paper format.

Maturation. While data collection occurred at two-time intervals approximately 3 months a part for a subset of the participants, maturation was considered an internal validity threat for this study associated with the cancer survivor's condition, including type of cancer, early stage or advanced disease, co-morbid conditions, and other complications of cancer treatment (e.g., febrile neutropenia). By the end of primary cancer treatment, cancer survivors may experience more intense symptoms (e.g., fatigue, nausea, vomiting, and pain), limiting their ability to engage in this study and complete a lengthy questionnaire. To reduce potential internal validity threat, the short form of the instruments (i.e., Cancer-Related Patient Empowerment Scale, PROMIS® Self-Efficacy Managing Chronic Diseases, and PROMIS®-29 Profile v2.1) were selected for this study.

Mortality or Attrition. As this study involves data collection at two-time intervals, separated by approximately three months, mortality and attrition were potentially internal validity threats related to the population of interest in this study. With aggressive primary cancer

treatments and potential complications of treatment, there was a risk of death. To reduce mortality and attrition, life expectancy of fewer than three months had been established as an exclusion criterion. The participant was able to select a time to complete the questionnaire, choosing a time when symptoms were more controlled. To further mitigate attrition, the sample size was increased by 10%.

Generalizability. There were potentially several threats to external validity related to limits on the generalizability of the study results, including (a) convenience sample; (b) heterogeneous cancer diagnoses and subsequently, differences in treatment regimens despite exclusion criteria of surgery alone and radiation therapy; and (c) single, community-based cancer center in the Midwestern United States. To find cancer survivors in the early survivorship period following primary treatment for cancer in a community-based cancer center, a convenience sample is an easy, efficient method to access this population. A heterogeneous cancer survivor population within a broad primary cancer treatment modality (chemotherapy) facilitates an answer to the research question. As described in Chapter II, few studies have been conducted with a focus on early survivorship, in a community-based cancer center, or in the United States.

Study Limitations

As previously described in this chapter, the threats to internal validity included selection bias, instrumentation, maturation, and mortality/attrition. With an oncology population, living with advanced cancer, worsening symptoms, or progressing disease led to participants declining participation rather than leaving the study once enrolled. The threats to internal validity were decreased by planning for increasing sample size by 10% and the exclusion of people with less than three months life expectancy. Other study limitations were the study design related to

selection bias, instrumentation, and single location of one community-based cancer center which threaten external validity, generalizability of the study results. In addition, the design limited the results to early survivorship. Therefore, this study did not assess how patient empowerment impacts long term patient and clinical outcomes. Finally, the skill level of the participant in the use of technology to access an online questionnaire and the challenges of technology, such as proper functioning, potentially presented limitations. The participant's preferred method for survey completion (online or paper) was documented in an Excel spreadsheet.

Summary

This study described patient empowerment in the cancer survivor in early survivorship following primary cancer treatment to address a population, treatment modality, and time frame of early survivorship which has not been well-addressed in the literature. Due to the scope of the clinician's role, obtaining symptom data and workflow issues in the EHR and practice setting, a comprehensive assessment of symptoms does not routinely occur in cancer survivors. Further, the study examined if the use of patient self-report tools were associated with empowerment among cancer survivors which may lead to a transformation in the way clinicians, especially oncology nurses, assess multiple, complex physical and psychological symptoms as well as changes in physical function that impact survivorship. The use of PROs may facilitate increased empowerment of cancer survivors; and subsequently, increase self-management in the early survivorship period when symptoms are still prevalent, impacting health and well-being after cancer.

CHAPTER IV

RESULTS

This chapter describes the results of this study assessing if the use of PROs (e.g., self-efficacy and symptoms) promote patient empowerment of adult breast, colorectal, gynecologic, and lung cancer survivors in early survivorship following primary cancer treatment. The first aim describes the relationship between patient empowerment and PROs. The second aim demonstrates associations between PROs and patient empowerment, controlling for demographics (age, education level) and clinical characteristics (type of cancer, phase of chemotherapy treatment). The third aim explores if the associations between patient empowerment and PROs change over time, comparing immediately post chemotherapy treatment to three months after treatment.

Recruitment Strategies

Two research assistants (RAs), oncology nurses knowledgeable about the clinic workflows, were hired and trained in study procedures. RAs had some knowledge of research from their specialty clinic or treatment roles; however, they were novices in nursing research. Virtual and in-person training was conducted by the principal investigator (PI), including a review of study procedures, Excel spreadsheets for screening and eligibility and monitoring study progress, PI selected YouTube videos, and role playing how to introduce the study and informed consent discussions. Pandemic precautions were also reviewed, emphasizing adherence to clinic procedures, wiping down dedicated laptops for the online survey or providing a single use pen to complete the paper survey. RAs reviewed the study materials, including informed

consent and the paper version of the study instruments and tested the electronic online survey to familiarize themselves with how to access the survey, how it functions, and how to confirm survey results were saved. RAs identified and screened potential participants for eligibility, invited them to participate in the study, obtained informed consent, collected data from electronic health record, entered paper survey data into Qualtrics, and documented steps on the Excel spreadsheets, and other research activities as needed. The PI validated RAs paper survey data entry initially and periodically.

The PI attended virtual clinic meetings to discuss the study and recruitment strategies, posted signs in the clinics, and provided updates via email communication and clinic meetings. Identifying potential participants was difficult via electronic clinic schedules alone. Oncology Nurse Navigators (ONNs) and treatment nurses assisted in identifying who was completing their chemotherapy regimen and expected date of completion. RAs closely communicated with ONNs and treatment RNs and utilized electronic survivorship care plan reports, identifying those who recently completed cancer treatment.

Study Amendments

Two amendments were submitted during data collection. Due to a low number of patients being eligible for the study in the first six months of data collection, the first amendment added another cancer type, gynecologic cancers, for which chemotherapy was one of the prescribed treatment modalities for primary cancer treatment. This decision was based on the cancer center's tumor registry volumes from the previous three years. The second amendment expanded the inclusion criteria as the standard of care had changed for the selected patient populations of this study (i.e., breast, colorectal, lung, and gynecologic cancers). More neoadjuvant

chemotherapy treatments were used to treat breast, colorectal, and lung cancers, making chemotherapy the first treatment modality in the participant's primary cancer treatment regimen rather than the last treatment modality. In addition, the sequencing of chemotherapy in the treatment regimen changed. For gynecologic cancers, women received chemotherapy concurrent with radiation treatment or as spilt cycles of chemotherapy with three prior to and three after radiation. As such, a change in the inclusion criteria was necessary to answer the research question and address Aims 1 and 2 with chemotherapy in different phases of primary cancer treatment. Only the patients receiving chemotherapy as the last treatment modality in the regimen received the second survey at three months post-chemotherapy for Aim 3. Other patients, receiving chemotherapy at a different phase of the treatment regimen, had proceeded onto radiation or surgery within two to four weeks following completion of chemotherapy, managing other symptoms and aspects of recovery. With these two amendments expanding study eligibility, estimated sample size was achieved as there was minimal attrition.

Screening for Eligibility

Of the 118 potential participants screened for eligibility, 83 participants enrolled in this study, conducted between February 2021 to January 2023, indicating a 70% participation rate and meeting the apriori power analysis estimation for Aim 1 (N=82) and Aim 2 (N=81). Of the 35 participants, who were not enrolled in this study, five potential participants were screened and deemed not eligible for the study as two participants had a treatment plan that did not include chemotherapy (immunotherapy only); two participants were beyond the six-week time parameter from completing last dose of chemotherapy to start the first survey; and one participant had moderate cognitive impairment, making the method of data collection too difficult for her. Table

2 lists the reasons that potential participants declined participation in the study.

Table 2. Reasons Potential Participants Declined Participation

Number of Potential Participants	Reasons for Declining Participation in Study
14	Change in condition (e.g., cancer disease progression or new medical condition)
1	Death
1	Living out-of-state during winter months
2	Method of data collection
3	Overwhelmed with emotions
5	Perceived discomfort with the questions
2	No response to communication efforts
2	Too symptomatic with physical symptoms

Of those who completed chemotherapy as the last treatment modality of their primary cancer treatment, 33 of 35 participants completed the survey three months later for a second data collection time point. Two participants declined completing the second survey due to time constraints and length of survey. Most participants chose to complete the survey in clinic (98.8%). More participants completed the survey in the written format (53.0%) than electronically (47.0%). Based on mode of completing the survey, there was one missing item from a participant who completed the survey online (i.e., highest level of education completed). Data collection occurred while pandemic precautions were strict in the recruitment site and community which may have influenced the participant's choice of mode for completing the survey. Otherwise, there was no missing data.

Sociodemographic Data

Overall, participants ranged in age from 28-86 and their mean age was 57.9 (SD 13.7). More females (90.4%) than males (9.6%) participated in the study. The participants were Caucasian (94.0%), college-educated (63.8%), employed (44.5%) and insured (98.8%), limiting generalizability of the study results. The sociodemographic characteristics of the sample are presented in Table 3.

Age. Participants were between 28 and 86 years of age. Participant age, a continuous variable, was collapsed into the following equal groups: less than or equal to 51, 52 to 65, and 66 and older for analysis of covariance.

Gender. More females (90.4%) than males (9.6%) participated in this study as two of the four cancer diagnoses were predominately female cancers (i.e., breast and gynecologic), and these cancers are more commonly treated with neoadjuvant or adjuvant chemotherapy.

Race and Ethnicity. Many participants identified their race as non-Hispanic/Latino American (97.6%) and ethnicity as Caucasian (47.0%). Three participants identified their race as Hispanic/Latino (2.4%). One participant was Indian/Alaskan Native (1.2%), one participant was Asian (1.2%), and three participants selected other (3.6%).

Highest Level of Education Completed. The participants were well-educated with 63.4% receiving a degree: associate (16.9%), bachelor's (36.1%) and master's degree or higher (10.8). The highest level of education , a categorical variable, was collapsed into the following equal groups: 12^{th} grade or GED or less; some college or associate degree; and bachelor's degree or higher for analysis of covariance.

Employment Status. More participants were not employed (55.4%) than employed (44.5%). Of those employed, 32.5% of participants worked a full-time schedule while 12% had a part-time schedule.

Insurance. Given age and employment status, most participants had insurance (98.8%). The types of insurance included private insurance (57.8), Medicare (32.5), and Medicaid (2.3%). A few participants selected "other" (6%) with write-in comments for state insurance plan. Only one person had no insurance.

Table 3. Sociodemographic Data of the Study Sample

Age Grouping	< 51		52-65		66+		Full sample	
Variables	n =28		n = 29		n = 26		n = 83	
	n	(%)	n	(%)	n	(%)	n	(%)
Gender								
Females	26	31.3	28	33.7	21	25.3	75	90.4
Males	2	2.4	1	1.2	5	6.0	8	9.6
Race								
Hispanic	1	1.2	0	0	1	1.2	2	2.4
Non-Hispanic	27	32.5	29	34.9	25	30.1	81	97.6
Ethnicity								
American Indian/Alaskan	1	1.2	0	0	0	0	1	1.2
Caucasian	24	28.9	29	34.9	25	30.1	78	94.0
Asian	1	1.2	0	0	0	0	1	1.2
Other	2	2.4	0	0	1	1.2	3	3.6
Highest Education Level Completed*								
11^{th} grade or less	1	1.2	2	2.4	0	0	3	3.7
12^{th} grade/GED equivalent	2	2.4	6	7.3	8	9.8	16	19.5
Some college, no degree	3	3.7	2	2.4	5	6.1	10	12.2
Associate degree	2	2.4	6	7.3	6	7.3	14	17.1
Bachelor's degree	15	18.3	10	12.2	5	6.1	30	36.6
Master's degree or higher	5	6.1	2	2.4	2	2.4	9	11.0
Employment status								
Not employed	9	10.8	13	15.7	24	28.9	46	55.4
Full-time	15	18.1	10	12.0	2	2.4	27	32.5
Part-time	4	4.8	6	7.2	0	0	10	12.0
Insurance								
No insurance	0	0	1	1.2	0	0	1	1.2

Medicaid	2	2.4	0	0	0	0	2	2.4
Medicare	3	3.6	2	2.4	22	26.5	27	32.5
Private	21	25.3	23	27.7	4	4.8	48	57.8
Other	2	2.4	3	3.6	0	0	5	6.0

Note: Independent t-tests were conducted to determine differences in clinical variables. *Highest education level completed had missing data for one participant.

For the sociodemographic variables, independent t-tests were conducted on the sociodemographic variables and statistically significant differences were found between the younger (≤51 years old) and older (≥66 years old) participants for education level, employment, 884.54, *sd* = 1.32) and employment (*M* =.82, *sd* = .08) were higher for the younger participants than older participants (*M* = 3.54, *sd* = 1.33; *M* = .08, *sd* = .27; respectively). Younger participants were more educated with a bachelor's degree or higher and employed full-time while older participants held an associate degree or less education and were not employed. Whereas the means for insurance (*M* = 1.85, *sd* = .92) was higher for the older participant than younger participants (*M* = 1.46, *sd* = .37), more older adults were insured with Medicare than the younger participants. While race and ethnic diversity are minimal in this overall sample, there was no race or ethnic diversity among participants 52-65 years old. Statistically significant differences in sociodemographic variables are presented in Table 4.

Table 4. Statistically Significant Differences in Sociodemographic Variables

Age Grouping	< 51		66+		
Variables	n	*M*	n	*M*	*p*
Highest Education Level Completed	28	4.54	26	3.54	<.001
11th grade or less [1]	1		0		
12th grade/GED equivalent [2]	2		8		
Some college, no degree [3]	3		5		
Associate degree [4]	2		6		
Bachelor's degree [5]	15		5		
Master's degree or higher [6]	5		2		

Employment status	28	.82	26	.08	<.001
Not employed [0]	9		24		
Full-time [1]	15		2		
Part-time [2]	4		0		
Insurance	28	1.46	26	1.85	.050
No insurance [0]	0		0		
Medicaid [1]	2		0		
Medicare [2]	3		22		
Private [3]	21		4		
Other [4]	2		0		

Note: Independent t-tests were conducted to determine differences in clinical variables. SPSS codes are included within brackets for each variable.

A Chi Square Goodness of Fit Test was performed on two sociodemographic variables: age group 3 [≤ 51, 52-65, 66+] and highest level of education completed [≤12th grade/GED, some college or associate degree, and bachelor's degree or higher] to determine if there were statistically significant differences in these variables. The proportions did not differ for age group 3 and its three groups, χ^2 (2, 83) = .169, p = .919. However, the highest level of education completed between its three groups was not equal and statistically significantly different, χ^2 (2, 82) = 7.93, p = .019.

Clinical Characteristics

RAs abstracted the clinical data from the participant's EHR, and the PI validated 20% of the participants' clinical data entry for accuracy (n=19). The only discrepancy between RA and PI data abstraction was stage of cancer, specifically sub-staging (A-D), which was corrected on the Excel spreadsheet by the PI for five participants. Only the general stage (I-IV) was utilized in this data analysis because cancer diagnosis sub-staging has different levels and descriptors. More participants had a breast cancer diagnosis (47%). Stage III cancer diagnosis (44.6%) and neoadjuvant phase of chemotherapy treatment (48.2%) were more common in this sample. The

participants' treatment plan included one of 18 treatment regimens with many participants receiving two chemotherapy agents (48.2%). In addition, 15.7% of participants received a combination of one or more chemotherapy medications and an immunotherapy medication. Approximately, one-third of the sample had a single comorbid illness (30.1%) with hypertension (37.3%) was the most frequently reported. Clinical characteristics of the sample by age groupings are described in Table 5.

Stage of Cancer. While more participants had Stage III (44.6%), a more advanced stage of cancer, early-stage cancers were diagnosed as Stage I (37.3%) and Stage II (15.7%). Only two participants had cancer diagnosed with metastatic disease at Stage IV (2.4%).

Phase of Chemotherapy Treatment. Neoadjuvant phase (48.2%) was the most common phase of chemotherapy treatment in this sample followed by the adjuvant phase (51.8%). Of the participants completing adjuvant chemotherapy, 33 had chemotherapy as the last treatment modality in their primary cancer treatment, making them eligible for completing the survey again three months later.

Chemotherapy Treatment Regimen. In this sample, there were 18 different chemotherapy treatment regimens, based on the participant's cancer diagnosis and stage. More participants had two chemotherapy agents (48.2%) than three or more chemotherapy agents (24.1%) in their regimen. Single agent chemotherapy treatments (12%) were prescribed as radiosensitizers (e.g., Cisplatin, Paclitaxel). Chemotherapy combined with immunotherapy accounted for 15.7% of the treatments in this sample.

Comorbid Diseases. Comorbid diseases were described in the literature review and included in the clinical data abstracted from the participant's EHR. Besides a cancer diagnosis,

more participants had no comorbid disease (55.4%). Of the participants with a comorbid disease, most participants had a single comorbid disease (30.1%). Several participants had two comorbid diseases (8.4%) and even fewer participants had three comorbid diseases (6.0%) in this sample. Hypertension was the most frequent comorbid disease identified in this sample followed by diabetes (12%); chronic obstructive pulmonary disease (7.2%), autoimmune disorder (6.0%), congestive heart failure (1.2%), and neurologic disorders (1.2%).

Table 5. Clinical Characteristics of the Study Sample

Age grouping	< 51		52-65		66+		Full sample	
Variables	n =28		n = 29		n = 26		n = 83	
	n	(%)	n	(%)	n	(%)	n	(%)
Type of Cancer								
Breast	21	25.3	13	15.7	5	6.0	30	47.0
Colorectal	4	4.8	4	4.8	3	3.6	11	13.3
Gynecologic	3	3.6	9	10.8	8	9.6	20	24.1
Lung	0	0	3	3.6	10	12.0	13	15.7
Stage of Cancer								
I	15	18.1	9	10.8	7	8.4	31	37.3
II	6	7.2	5	6.0	2	2.4	13	15.7
III	7	8.4	15	18.1	15	18.1	37	44.6
IV	0	0	0	0	2	2.4	2	2.4
Phase of Chemotherapy								
Neoadjuvant	17	20.5	14	16.9	9	10.8	40	48.2
Adjuvant	11	13.3	15	18.1	17	20.5	43	51.8
Comorbid Illnesses								
Autoimmune	2	2.4	2	2.4	1	1.2	5	6.0
COPD	0	0	1	1.2	5	6.0	6	7.2
CHF	0	0	1	1.2	0	0	1	1.2
Diabetes	1	1.2	2	2.4	7	8.4	10	12.0
Hypertension	4	4.8	13	15.7	14	16.9	31	37.3
Neurologic disorder	0	0	0	0	1	1.2	1	1.2

Note. COPD = Chronic obstructive pulmonary disease; CHF = Congestive heart failure.

For the clinical variables, statistically significant differences between the younger (≤51 years old) and older (≥66 years old) participants in type of cancer, comorbid disease count, and

type of comorbid disease are presented in Table 6. The means for type of cancer (*M* = 1.88, *sd* = 1.14), comorbid disease count (*M* = 1.11, *sd* = 1.11), and comorbid illnesses of COPD (*M* = .19, *sd* =.40) diabetes (*M* = .27, *sd* =.45), and hypertension (*M* = .54, *sd* = .51) were higher among older participants than younger participants. In addition, there was a statistically significant difference for stage of cancer as older participants (*M* = 2.46, *sd* =.99) had a more advanced stage of cancer (i.e., Stage III) than younger participants (*M* = 1.71, *sd* =.85) with earlier stage of cancer (i.e., Stage I). For types of cancer, younger participants had a breast cancer diagnosis whereas, participants greater than 52 years old had other cancer diagnoses.

Table 6. Statistically Significant Differences in Clinical Characteristics Variables

Age grouping	< 51		66+		
Variables	n	*M*	n	*M*	*p*
Type of Cancer	28	.36	26	1.88	< .001
Breast [0]	21		5		
Colorectal [1]	4		3		
Gynecologic [2]	3		8		
Lung [3]	0		10		
Stage of Cancer	28	1.71	26	2.46	.004
I [1]	15		7		
II [2]	6		2		
III [3]	7		15		
IV [4]	0		2		
Co-morbid Illnesses Count [0=none; 1=one illness; 2=two illnesses; 3 =three illnesses]	28	.25	26	1.11	< .001
COPD*	0	0	5	.19	.022
Diabetes*	1	.04	7	.27	.002
Hypertension*	4	.14	14	.54	.020

Note. Independent t-tests were conducted to determine differences in clinical variables. SPSS codes are included within brackets for each variable except for co-morbid illnesses where SPSS code was *0=no comorbid illnesses; 1=yes, comorbid illness present.

A Chi Square Goodness of Fit Test was performed on one clinical variable: phase of cancer [neoadjuvant, adjuvant] to determine if there were statistically significant differences. The proportions did not differ for phase of cancer by its two groups, χ^2 (1, 83) = .108, p = .742.

Preliminary Data Analysis

Descriptive statistics and correlations for the study variables were performed. Scatterplots were reviewed and met assumptions for normality and homogeneity. According to Bulsara and Styles (2013), the Patient Empowerment Scale has good internal consistency with Person Separated Index, a statistic of reliability and equivalent to Cronbach's alpha, reported as .78. In the current study, Cronbach's alpha was .84, calculated from first survey respondents (n=83). PROMIS® Managing Chronic Conditions Self-Efficacy Scale has good internal consistency with Cronbach's alpha coefficient reported as greater than .90. For this current study, Cronbach's alpha was .93, calculated from the first survey respondents (n=83). Finally, the PROMIS®-29 Profile v2.1 also has good internal consistency with Cronbach's alpha coefficient reported as 0.98 for physical health and 0.97 for mental health factors (Hays, Spritzer, Schalet, & Cella, 2018). The Cronbach's alpha was .78, calculated from first survey respondents (n=83) in this current study. Table 7 depicts the psychometric properties of the study scales, including *M, SD,* Range, and Cronbach's alpha for the current sample. The Cancer-related Patient Empowerment Scale was used to measure patient empowerment on a 15-item, 4-point Likert scale with a higher score indicating a higher level of empowerment. PROMIS® Managing Chronic Conditions Self-Efficacy Scale is a 24-item, 5-point Likert scale with a higher total score indicating higher self-efficacy. PROMIS®-29 Profile v2.1, a 29-item, 5-point Likert scale was used to measure symptoms (symptom profile) with higher score more of the concept is measured which may be desirable or undesirable,

depending on the symptom or domain being measured (PROMIS®, 2019). The item question or statement may be either negatively or positively worded. Negatively worded items (e.g., fatigue, sleep disturbances) and positively worded items (e.g., physical function) were recoded for analysis so that higher symptom scores indicate more symptoms present.

Table 7. Psychometric Properties for Scales

Scale	*M*	*SD*	Range	Cronbach's α
Patient Empowerment	51.8	4.8	40-60	.84
Self-Efficacy Total Score	97.6	13.9	60-120	.93
Symptom Profile Total Score	75.7	12.0	48-94	.78

Subscales. The psychometric properties of the Self-Efficacy subscales and Symptom Profile sub-scales also demonstrated good internal consistency as described in Table 8 which presents the psychometric properties for the five Self-Efficacy subscales followed by Table 9 that describes the seven Symptom Profile subscales, including the *M, SD,* range, and Cronbach's α of each subscale.

Table 8. Psychometric Properties for Self-Efficacy Subscales

Sub-scale	*M*	*SD*	Range	Cronbach's α
Managing Daily Activities	15.35	3.7	5-20	.86
Managing Emotions	14.77	3.3	7-20	.89
Managing Medications and Treatment	18.13	4.1	10-20	.72
Managing Social Interactions	18.48	2.9	13-20	.74
Managing Symptoms	33.02	5.9	10-40	.96

Note. Each subscale had four items except for *Managing Symptoms* which had eight items; items were rated with a 1-4 Likert scale.

Table 9. Psychometric Properties for Symptom Profile Sub-Scales

Sub-scale	*M*	*SD*	Range	Cronbach's α
Physical Function	15.3	4.1	4-20	.89
Anxiety	7.9	3.5	4-19	.90
Depression	6.6	2.9	4-15	.86
Fatigue	11.6	3.7	4-19	.91
Sleep Disturbances	10.7	3.97	4-20	.89
Managing Social Roles	13.4	4.1	4-20	.95
Pain Interference	10.7	5.8	4-20	.96
Pain Intensity	2.8	1.96	1-8	.77

Note. Each subscale had four items rated with a 1-4 Likert scale except for Pain Intensity.

Aim 1

The first aim concerned the relationship between patient empowerment and PROs (i.e., self-efficacy and symptoms) in breast, colorectal, gynecological, and lung cancer survivors in early survivorship. A Pearson correlation coefficient was calculated to examine the relationship between patient empowerment and self-efficacy. A significant positive correlation was found ($r(81) = .592$, $p < .001$), indicating that greater patient empowerment was related to greater self-efficacy. In addition, a significant negative relationship between self-efficacy and symptoms, ($r(81) = -.333$, $p = .002$), was observed indicating greater self-efficacy was related to decreased symptoms. Table 10 summarizes the descriptive statistics and correlations for study variables.

Table 10. Descriptive Statistics and Pearson's Correlations for Study Variables for Patient Empowerment

Variable	*n*	*M*	*SD*	1	2	3	4	5	6
1. Age	83	57.93	4.92	.064					
2. Education Level	82	3.96	13.79	-.331	-.059				
3. Type of Cancer	83	1.08	1.43	.534	-.361	-.92			
4. Phase of Chemo	83	.70	.76	.236	.80	.347	.022		
5. Self-Efficacy	83	72.79	13.19	.058	-.198	.080	.017	.592***	
6. Symptom Profile	83	99.75	10.82	-.317	.166	-.196	-.007	-.333**	-.170

Note. ** $p < .05$, *** $p < .001$.

No significant association was found between patient empowerment and symptom profile (r (81) = -.170, p = .124) which did not indicate a significant linear relationship. Therefore, symptom profile subscales were further explored.

Symptom Profile Subscale

For the symptom profile subscales, Pearson's correlation coefficient analysis was conducted to examine associations between patient empowerment and each of the symptom subscales of the symptom profile. A statistically significant positive correlation was found between patient empowerment and social roles and activities (r (81) = .394, $p < .001$), indicating with greater patient empowerment there is increased participation in social roles and activities. A moderate positive correlation was also found between patient empowerment and physical function (r (81) = .315, p = .004), indicating that with greater patient empowerment, there is an increase physical function. Between patient empowerment and depression, a moderate negative correlation was found (r (81) = -.472, $p < .001$), indicating greater patient empowerment decreases depression. A weak negative correlation was found between patient empowerment and each of the following symptoms: anxiety (r (81) -.243, p = .027); fatigue (r (81) = -280, p =.010); pain interference (r (81) = -.273, p =.013); and pain rating (r (81) = -270, p =.013),

indicating a significant linear relationship. For patient empowerment and sleep disturbances, no significant correlation was found (r (81) = -.158, $p > .05$).

This analysis rejects the null hypothesis as there is a statistically significant linear relationship between patient empowerment and PROs self-efficacy in adult breast, colorectal, gynecologic, and lung cancer survivors in early survivorship. While patient empowerment and PROs symptom profile total score did not demonstrate a significant linear relationship, symptom profile subscales (except sleep disturbances subscale) had an association with patient empowerment. PROs self-efficacy total score and PROs symptom profile total score demonstrated a significant negative relationship. With a decrease in symptoms, there is an increase in self-efficacy.

Aim 2

The second aim examined the associations between patient empowerment and PROs in breast, colorectal, gynecologic, and lung cancer survivors in early survivorship. Hierarchical multiple regression was used to assess the ability of PROs self-efficacy and symptom profile to predict patient empowerment after controlling for age, cancer diagnosis, phase of chemotherapy, and highest level of education completed. In the preliminary analysis, there were no violations of assumptions of normality, linearity, multicollinearity, or homoscedasticity. While patient empowerment and PROs self-efficacy were correlated, there was no collinearity. At Step one, Patient Empowerment Total Score Survey 1 was entered as the dependent variable. Based on the literature, age, highest level of education completed, type of cancer, and phase of chemotherapy were entered in Block 1 of 1 as control variables. At Step two, Self-Efficacy Total Score Survey 1 was added into Block 2 of 2 as independent (predictor) variable followed by Symptom Profile

Total Score Survey 1. Self-efficacy is identified in the literature as a related concept to patient empowerment, therefore, Self-Efficacy Total Score Survey 1 was entered as the first variable in this block. As less is known about patient empowerment and symptoms, Symptom Profile Total Score Survey 1 also an independent (predictor) variable was entered following self-efficacy in Block 2 of 2.

Age, cancer diagnosis, phase of chemotherapy, and highest level of education completed for Model 1, explained 3.1% of the variance in patient empowerment, F (4, 77) = .619, p = .65. For Model 2, the addition of self-efficacy total score (B = .022, $SE\ B$ =.03, β = .60) resulted in a statistically significant increase in the total variance explained by the model was 38.7%, F (5, 76) = 44.183, p < .001. In Model 3, symptom profile total score did not contribute significantly to the Model 2 explaining 38.8%, F (6, 75), = .122, p = .728 of the variance in patient empowerment. In the final model (Model 3), greater self-efficacy was a statistically significant predictor of greater patient empowerment, (B = .023, $SE\ B$ =.36, β = .61, sr = .59, p < .001), whereas PROs symptom profile total score scale was not related to patient empowerment (B = .12, $SE\ B$ =.05, β = .04, sr = .40, p = .728). Table 11 summarizes the hierarchical multiple regression results for patient empowerment.

Table 11. Hierarchical Regression Results for Patient Empowerment

Variable	*B*	*SE B*	*sr*	R^2	ΔR^2
Model 1				.031	.031
Constant	49.99	3.01			
Age	.05	.05	.11		
Education Level	-.37	.76	-.05		
Type of Cancer	-.88	.60	-.16		
Phase of Chemotherapy	.54	1.18	.05		
Model 2				.387***	.356
Constant	26.93	4.23			
Age	.05	.04	.15		
Education Level	.13	.62	.02		
Type of Cancer	-.93	.48	-.22		
Phase of Chemotherapy	.47	.95	.06		
Self-Efficacy Total Score	.22***	.03	.61		
Model 3				.388***	.001
Constant	25.17	6.57			
Age	.05	.04	.16		
Education Level	.11	.62	.02		
Type of Cancer	-.95	.48	-.22		
Phase of Chemotherapy	.44	.96	.06		
Self-Efficacy Total Score	.23***	.36	.59		
Symptom Profile Total Score	.12	.05	.40		

Note. ***$p < .001$.

Based on the hierarchical regression analysis, the null hypothesis that there is a significant prediction of patient empowerment by PROs is rejected, specifically self-efficacy after controlling for age, cancer diagnosis, phase of chemotherapy treatment, and highest level of education completed in adult breast, colorectal, gynecologic and lung cancer survivors in early survivorship. PROs symptom profile total score did not add significantly to the model.

Aim 3

The third aim explored the associations between patient empowerment and PROs in breast, colorectal, gynecologic cancer survivors, comparing immediate post-chemotherapy treatment and three months after treatment. For the thirty-three participants, who completed two

surveys, repeated measures analysis of covariance (ANCOVA) was conducted to examine change in patient empowerment, self-efficacy, and symptom profile to determine the effect across two time periods after controlling for age and highest level of education completed. Preliminary checks were conducted. The assumptions of normality, linearity, homogeneity of variances, and homogeneity of regression slope or reliable measurement of the covariate were met.

Patient Empowerment ANCOVA

An analysis of covariance was conducted to compare the effect of time on patient empowerment after independent variables of age and highest level of education completed were accounted for. The dependent variable was Cancer-Related Patient Empowerment questionnaire scores at the second time point (3 months after chemotherapy treatment ended). Participants' scores on the patient empowerment questionnaire at the first time point (immediately following the last chemotherapy treatment) were entered as the covariate. Table 12 presents descriptive statistics for patient empowerment. There was a significant decline in patient empowerment from the first assessment time (M = 51.57, SD = 5.21) to three months post-treatment (M = 23.06, SD = 3.99), F (1, 29) = 30.12, $p < .001$; η^2 =.509.

Table 12. Descriptive Statistics for Patient Empowerment at Time 1 and Time 2

	Time 1			Time 2			
	N	Mean	SE mean	N	Mean	SE mean	*p*
Age Group 3	33						.936
< 51	9	51.22	3.92	9	24.00	2.39	
52 – 65	12	52.75	5.18	12	22.66	4.25	
66+	12	50.75	6.24	12	23.25	5.01	
Highest Education Level Completed	32						.827
$\leq 12^{th}$ grade or GED equivalent	10	51.70	5.98	10	23.20	4.39	
Some college or associate degree	8	52.62	6.18	8	22.25	4.83	
Bachelor's degree or higher	14	51.36	4.32	14	23.42	3.41	
Patient Empowerment	32	51.78	5.21	32	23.06	3.99	<.001

Age and highest level of education completed did not have a significant effect on the change in patient empowerment scores over time.

Self-Efficacy ANCOVA

Similarly, an ANCOVA was calculated to assess the effect of age on self-efficacy, covarying out the effect of the independent variables of age and highest level of education completed. The dependent variable was PROMIS® Self-Efficacy for Managing Chronic Illnesses (Self-Efficacy) questionnaire scores at the second time point (three months after chemotherapy treatment ended). Participants' scores on the self-efficacy questionnaire at the first time point (immediately following the last chemotherapy treatment) were entered as the covariate. Table 13 the descriptive statistics for self-efficacy at Time 1 and Time 2. Although

self-efficacy means increased from Time 1 (M =102.47, sd = 11.77) to Time 2, (M =107.09, sd = 8.63), there was a not a statistically significant change in self-efficacy over time, F (1, 29) = .009, p = .926; η^2 = .000.

Table 13. Descriptive Statistics for Self-Efficacy at Time 1 and Time 2

	Time 1			Time 2			
	N	Mean	SE mean	N	Mean	SE mean	*p*
Age Group 3	33						.467
< 51	9	98.44	11.58	9	102.44	6.87	
52 – 65	12	107.75	9.19	12	108.92	10.50	
66+	12	98.58	13.51	12	106.75	9.83	
Highest Education Level Completed	32						.833
$\leq$ 12th grade or GED equivalent	10	103.10	15.58	10	109.60	8.61	
Some college or associate degree	8	104.12	11.11	8	107.25	9.30	
Bachelor's degree or higher	14	101.07	9.57	14	105.21	8.43	
Self-Efficacy	32	102.47	11.77	32	107.09	8.63	.926

Neither of the main effects of age: F (1, 29) = .544 , p = .467) or highest level of education completed: F (1, 29) = .045, p = .833) were significant. Age and highest level of education completed did not have a significant effect on self-efficacy.

Symptom Profile ANCOVA

Finally, an ANCOVA was calculated to examine the effect of symptom profile on patient empowerment after accounting for the independent variables of age and highest level of education completed. The dependent variable was PROMIS-29 Profile v2.1 (Symptom Profile) questionnaire scores at the second time point (three months after chemotherapy treatment ended).

Participants' scores on the symptom profile questionnaire at the first time point (immediately following the last chemotherapy treatment). Table 14 presents the descriptive statistics for symptom profile at Time 1 and 2. Although the symptom profile means decreased from Time 1 (M = 70.94, sd = 11.60) to Time 2, (M = 57.31, sd = 14.75), there was not a significant change in symptom profile over time, F (1, 29) = 2.76, p = .108; η^2 = .087.

Table 14. Descriptive Statistics for Symptom Profile Time 1 and Time 2

	Time 1			Time 2			
	N	Mean	SE mean	N	Mean	SE mean	*p*
Age Group 3	33						.501
< 51	9	75.66	12.06	9	62.00	17.23	
52 – 65	12	71.92	10.33	12	55.50	20.24	
66+	12	67.83	12.98	12	59.50	12.62	
Highest Education Level Completed	32						.456
$\leq 12^{th}$ grade or equivalent	10	70.30	11.68	10	57.90	15.66	
Some college or associate degree	8	65.87	14.60	8	58.25	16.00	
Bachelor's degree or higher	14	74.28	9.14	14	56.36	14.47	
Symptom Profile	32	70.94	11.60	32	57.31	14.75	.108

Neither of the main effects of age: F (1, 29) = .464, p = .501 or highest level of education completed: F (1, 29) = .572, p = .456 were significant. Age and highest level of education completed were not significant symptom profile.

In summary, a significant decrease in patient empowerment was observed from the time patients completed their last dose of chemotherapy to three months post treatment. In the subset

of participants, self-efficacy and symptoms did not demonstrate changes in patient empowerment. Findings revealed that neither age nor the highest level of education completed were related to these changes. Age, being younger or older adult cancer survivor, was not related to patient empowerment, self-efficacy, or symptom profile. More or less formal education was not related to patient empowerment, self-efficacy, or symptom profile. These covariates did not account for the differences between the first and second survey scores. The small sample size of the subset of participants, who were eligible to complete the second survey, may not have had sufficient statistical power, limiting ANCOVA repeated measures analysis.

Summary

The results of this study demonstrated a relationship between patient empowerment and PROs (self-efficacy and symptoms). Patient empowerment was associated with self-efficacy and PROs symptom subscales were positively correlated with managing social roles and activities and physical function. A negative linear correlation was found for symptoms of depression, anxiety, fatigue, and pain. Sleep had no association with patient empowerment. After controlling for age, type of cancer, phase of chemotherapy, and highest level of education completed, self-efficacy was a significant predictor of patient empowerment for cancer survivors immediately following the last dose of chemotherapy. However, this was not seen in the subset of participants when measured at three months post-treatment. Patient empowerment decreased from immediately following the last dose of chemotherapy to three months post-treatment after controlling for age and highest level of education completed. Although self-efficacy increased and symptoms decreased during this period, there was not a statistically significant change in self-efficacy or symptoms over time.

CHAPTER V

DISCUSSION

Given the growing number of cancer survivors living with the chronic disease of cancer and the shift of the burden of cancer care management from clinician to cancer survivor, assessing symptoms differently may increase the voice of the cancer survivor and facilitate increased patient empowerment, and subsequently, engagement in self-management. Cancer survivors experience multiple, moderate to severe symptoms and are less frequently seen in cancer clinics in early survivorship, defined as the time from end of primary cancer treatment and up to the first-year post-treatment (Shi et al., 2011; Wu & Harden, 2015). Symptoms, including adverse reactions and treatment complications, negatively affect the cancer survivor's functioning and quality of life (Esther Kim et al.,2009; Mooney et al., 2017). The cancer survivor's ability to fully participate in life and work roles after cancer treatment is significantly affected by the interaction of symptoms and physical function (Alfano et al., 2019; Mooney et al., 2017). Currently, there is a gap in the conventional clinician-driven assessment of symptoms, and no studies describe how patient empowerment may facilitate the cancer survivor's ability to assume the responsibilities of monitoring, reporting, and managing of physical and psychosocial symptoms, physical function, and quality of life as the cancer survivor's transitions into early survivorship.

The primary purpose of this study is to describe the relationship and associations between patient empowerment and PROs (self-efficacy and symptoms) in breast, colorectal, gynecologic and lung cancer survivors immediately following the completion of chemotherapy. For those

survivors, who completed their last dose of chemotherapy as the last treatment modality for their primary treatment of cancer, patient empowerment and PROs were further explored to examine if changes occur over time, using a repeated measure design.

Patient empowerment is an outcome (Funnel, 1991; Zimmerman, 1995) to describe the relationships and associations of PROs (self-efficacy and symptoms) and determine if the use of PROs is a mechanism to empower individuals. Following Zimmerman's previous work on the psychological component of patient empowerment, this study focuses on patient empowerment of cancer survivors at the individual level, the power within a person and their ability to use that power to influence and manage recovery after chemotherapy, supporting patient empowerment as a state, a condition at a specific time rather than a

Patient Empowerment and Relationship with PROs

Overall, study findings demonstrated that there is a statistically significant relationship between patient empowerment and PROs self-efficacy and symptoms immediately following last dose of chemotherapy. Consistent with Bravo et al. (2015) describing self-efficacy as a key indicator of patient empowerment in the conceptual model and Barr et al. (2015) identifying self-efficacy as a 'core construct' of patient empowerment, this study demonstrated a significant positive relationship between patient empowerment and self-efficacy. Additionally, a significant negative relationship between self-efficacy and symptoms was observed. A previous study revealed that lower levels of self-efficacy were associated with increased symptoms and poor physical function among breast and gastrointestinal cancer patients (Kelleher et al., 2016). No significant relationship was found between patient empowerment and symptom profile, PROMIS®-29 Profile v2.1, an instrument with a combined total score of seven symptoms or

domains (e.g., physical function, anxiety, depression, fatigue, sleep disturbances, social roles and activities, pain interference or rating), commonly experienced by cancer survivors in early survivorship. One possible explanation is that the relationship between patient empowerment and symptoms may be better described when examining symptoms individually rather than a combined total score.

Therefore, with further exploration of the symptom profile subscales, a positive linear relationship was found between patient empowerment and participation in social roles and activities and patient empowerment and physical function. Because physical function has been identified as a predictor of survival outcomes (Basch et al., 2016; Gotay et al., 2008; Carey et al., 2008; Quinten et al., 2011), it may be prudent to assess for this symptom or domain in cancer survivors in early survivorship. Physical function was proposed as a potential moderator of patient empowerment (Bravo et al., 2015); however, further exploration as a determinant or predictor of patient empowerment may be warranted.

Furthermore, a negative linear association was found between patient empowerment and each of the following symptoms: depression, anxiety, fatigue, pain interference and pain rating, emphasizing the importance of evaluating symptoms that demonstrate linearity with patient empowerment in cancer survivors and subsequently, optimizing symptom management. There was no association between patient empowerment and sleep. This finding suggests that there are PROs symptoms assessed in cancer survivor clinic visits which may be unnecessary to assess for cancer survivors immediately following completion of chemotherapy treatments. Sleep disturbances may also be correlated with another symptom, like fatigue, but it was not associated with patient empowerment in this study, accentuating the importance of identifying what other

PROs symptoms may impact cancer survivor empowerment in early survivorship. Peripheral neuropathy is one example of the late effect symptoms experienced by cancer survivors, who received chemotherapy, raising the question if there are other PROs more specific to the cancer survivor experience following chemotherapy treatment.

Patient Empowerment and Self-Efficacy

Previous literature identifies self-efficacy as strongly related to patient empowerment (Fumagalli et al., 2015; Te Boveldt et al., 2014) and often, identified self-efficacy as an outcome and way to measure patient empowerment. In the conceptual model for patient empowerment (Bravo et al., 2015), self-efficacy is an indicator as a patient capacity, state, or resource of patient empowerment. Based on hierarchical regression modeling, this study demonstrates a statistically significant prediction of patient empowerment by self-efficacy in adult breast, colorectal, gynecologic and lung cancer survivors in early survivorship immediately following last dose of chemotherapy. As self-efficacy is a predictor of patient empowerment at this transition point, it is value-added to assess and evaluate PROs self-efficacy in cancer survivors so that clinicians tailor interventions supporting empowerment. Yet, cancer survivor-reported self-efficacy is not measured in clinical practice settings.

While this study showed a relationship between symptoms and self-efficacy, PROs symptom profile total score did not add significantly to the hierarchical multiple regression analysis model. One potential rationale for the symptom profile not contributing significantly to the model is that symptom profile may be more closely associated with other patient empowerment related concepts (e.g., patient enablement or patient activation). Another possibility is that there may not be significant changes in symptom burden in early survivorship,

making it difficult to distinguish subtle changes in symptoms and which PROs symptoms subsequently impact patient empowerment. While Bravo's conceptual model of patient empowerment has patient and clinical outcomes aligned with behaviors, the findings from this study suggest that other PROs may be more associated with patient empowerment. Due to the limitations of this study, it is premature to recommend revisions to the comprehensive model by Bravo et al. (2015). Further testing of patient empowerment and other PROs, depicting patient empowerment are necessary.

Patient Empowerment and Time

Addressing the third aim of this study, the associations between patient empowerment and PROs (self-efficacy and symptoms) in breast, colorectal, lung, and gynecologic cancer survivors were explored to determine if a change over time occurred from immediately post-treatment to three months post-treatment after controlling for age and highest level of education completed. A significant decrease in patient empowerment was observed from the time patients completed their last dose of chemotherapy to three months post-treatment; however, there was no significant change in self-efficacy or symptoms, indicating that further investigation of what other PROs or other variables not addressed in this study depict why there was a decrease in patient empowerment three months post-treatment.

Patient empowerment is dynamic and fluctuates over time along a continuum of high to low levels of empowerment (Anderson & Funnel, 2004; Joergensen et al., 2018; Zimmerman, 1995). This study supports previous findings (Eskildsen et al., 2017; Jerofke, 2013; Joergensen et al., 2018; Maunsell et al., 2014) that cancer survivors experience differences in patient empowerment along the cancer care continuum of two transition points (i.e., immediately post-

treatment and three months post-treatment). Patient empowerment is highly personal and experienced differently due to individual factors (e.g., age, gender, race, ethnicity, and other socioeconomics), context (e.g., type of cancer, stage of cancer, and other clinical characteristics), spheres (e.g., family, work or school, and social activities), and at different times (Eskildsen et al., 2017), emphasizing that differences in patient empowerment along the continuum of [cancer] care (Jerofke, 2013) and underscoring the importance of assessing patient empowerment, self-efficacy, and symptoms of cancer survivors, using PROs, at critical transition points in early survivorship.

Furthermore, Aujoulat et al. (2008) described patient empowerment "holding on" and "letting go" of control (i.e., power) by accepting it or relinquishing control. Three months post-treatment, cancer survivors are starting to integrate what it means to have a cancer diagnoses, undergoing cancer treatment with chemotherapy, living with symptoms and limitations begin to develop a new sense of self. Supporting the finding of decreased patient empowerment from last dose of chemotherapy and three months post-treatment, cancer survivors may be experiencing what Avery (2018) described as an "alternative" pathway to patient empowerment by relinquishing control when aspects of cancer, its treatment, and side effects are beyond their control or who perceive self-management as unattainable or not feasible or practical to take on. In this study, cancer survivors did not view themselves as "empowered" three months after chemotherapy treatment. Because patient empowerment has had a longstanding positive trajectory toward improved health outcomes, well-being, and quality of life (Bravo et al., 2015; Jerofke, 2013; Zimmerman, 1995), cancer survivors may not view that a decision not to use power as empowering itself in early survivorship.

More recently, a qualitative study of 22 head and neck and breast cancer survivors, who were three months to five years post-treatment was published describing patient empowerment as a single process that begins every time the survivor perceives their illness as a threat to their sense of self (Avery et al., 2023). When successful with either establishing control or relinquishing control, cancer is no longer viewed as a threat, but their illness is re-interpreted as an empowering experience whereby accepting periods of no control was associated with developing a new empowered sense of self. Acknowledged by Avery et al. (2023), this description of a single process may not be applicable to other cancer diagnoses. In addition, a more defined time-period of survivorship will be needed to determine if patient empowerment is a single process. Furthermore, a decrease in patient empowerment immediately post-chemotherapy and three months post-treatment calls for further qualitative studies to depict what PROs decrease empowerment and what PROs describe patient empowerment at other time intervals (e.g., six months, one year) in early survivorship to understand how patient empowerment may fluctuate and what PROs are associated.

Illness Uncertainty

Within the first three months of post-treatment, symptoms did not significantly change for participants in this study. Cancer survivors experience multiple, moderate symptoms when frequency of clinic visits and connection with physicians, oncology nurses, and other supportive disciplines (e.g., ONN, counselor, dietitian, therapists) have declined. Until three months post-treatment, cancer survivors do not know if their primary cancer treatment regimen met its goal (e.g., cure or control of their cancer), living with uncertainty as they wait to learn the outcome. Uncertainty, defined as the inability to determine meaning of illness-related events and anticipate

health outcomes (Mishel, 1988), is common in people with cancer at diagnosis, initiation of new treatments, and transitions of care (Zhang, 2017), like early survivorship when cancer survivors are required to self-manage potentially threatening experiences. Illness uncertainty is a known psychosocial stressor for cancer survivors as well as family caregivers and has been associated with anxiety, depression, quality of life, and social support (Guan et al., 2023). As such, illness uncertainty may contribute to decreased patient empowerment three months post-treatment when it is unknown if the primary cancer treatment regimen was effective.

Perceived Preparedness

Another possible explanation for the decrease in patient empowerment three months post-treatment is that the cancer survivor may not feel ready to accept their new responsibilities to self-manage, monitor, and report their symptoms. Moving from active treatment into early survivorship, there is an uncertainty that cancer survivors feel unprepared for this next step (Alfano et al., 2019). Cancer survivors are managing these multiple, moderate symptoms (physical and emotional), gradually regaining physical strength (physical function), and lessening fatigue, engaging in social roles, and increasing activities, and planning for or resuming work, school, or other meaningful activities. They may or may not be aware of or prepared for what comes next. According to the American Cancer Society's Cancer Survivor Transition Study, *perceived preparedness* was studied in breast, prostate, and colorectal cancer survivors and revealed that survivors felt only moderately prepared for the transition from end of active treatment to post-treatment care with the lowest levels of preparedness found in survivors with higher depression scores, poor symptom management, and limited discussion about symptoms with clinicians (Leach et al. 2017). In a qualitative study, 11 breast cancer survivors

described their post-treatment experience of empowerment by managing physical symptoms and seeking multiple ways to improve their quality of life which required a belief in good health, capability of self-management, and acquisition of good social support. These survivors were keenly aware of their physical symptoms, reporting more lymphedema and fatigue than pain, adopted health-promoting lifestyle changes, such as nutrition and physical activity, and supported by spouses and family. Similarly, other PROs physical symptoms, like peripheral neuropathy rather than pain, may be a more prevalent symptom for cancer survivors three months post-chemotherapy treatment. In contrast, Luo et al. (2021) suggested that there may be a relationship between level of empowerment and economics, citing a qualitative study of African American breast cancer survivors, who described a lack of knowledge, education, and support about survivorship care and emphasized the importance of spirituality and religion in their survivorship experience (Adams et al., 2017). These findings underscore the importance of measuring PROs other than self-efficacy and symptoms to understand patient empowerment in cancer survivors, especially more diverse populations of cancer survivors as many studies focus on older, Caucasian, female breast cancer survivors.

Transition Readiness

Additionally, a longitudinal study of patient empowerment in young persons with congenital heart disease transitioning to adult care found *transition readiness* had a significant association with patient empowerment (Acuña Mora et al., 2022). The researchers proposed that transition readiness was a determinant or predictor of patient empowerment rather than an indicator of taking an active role and having perceived control as described in the conceptual model on patient empowerment by Bravo et al. (2015). A recent systematic review concluded

with identifying the need for longitudinal studies in to evaluate transition readiness for changes over time in adolescents and young adults (Varty & Popejoy, 2020). Similarly, further research on patient empowerment and transition readiness is needed to increase our understanding of cancer survivors in early survivorship.

The transition from active primary cancer treatment into early survivorship where care has been provided in community-based oncology clinics is analogous to planning for discharge from an inpatient unit in a hospital, like a dedicated oncology unit to home. This suggests that evaluation of patient empowerment and PROs should occur earlier, such as the beginning of primary cancer treatment (chemotherapy) so that tailored interventions are based on the cancer survivor's self-reported symptoms and tailored intervention that build empowerment are planned for, implemented, and evaluated prior to end of treatment and at transitions throughout early survivorship.

As described in previously literature, the early survivorship period extends through the first-year post-treatment (Shi et al., 2011; Wu & Harden, 2015), offering a timeline for consideration of other transition points or critical junctures for assessing, monitoring, and evaluating patient empowerment in early survivorship and beyond. Because the focus has been on the goal(s) of treatment (e.g., cure, control), late or long-term effects of cancer may not be known to the cancer survivor as they complete primary cancer treatment and transition back to their primary care physician. During the first three months post-treatment, it may be unknown to the cancer survivor what cancer-related issues they are at risk for, such as new cancers, late effects of cancer treatment (e.g., bone loss, neuropathy, endocrine, cardiovascular, and musculoskeletal), and the cumulative effect of chronic and late effects on acceleration of normal

aging and comorbid illnesses, presenting at an earlier age (Alfano et al., 2019) and what will be required of them for monitoring, reporting, and managing symptoms. Other PROs may better depict cancer survivor empowerment at three months post-chemotherapy treatment and potentially decreases and increases in empowerment through the first year of early survivorship.

This study explored only a short interval of time from post-treatment to three months post-treatment, raising the question what the best time is to evaluate patient empowerment and PROs given the complexity and advancement in cancer treatments. While this study shows that immediately following end of primary cancer treatment and three-months post-treatment are valuable transition points to evaluate cancer survivor empowerment and PROs. The first follow-up post-treatment clinic visit provides the cancer survivor access to medical oncologist and oncology nurses who can make referrals and offer resources, supporting their transition into survivorship. This study does not identify what other early survivorship transition points are optimal for patient-self report, using PROs, and subsequently, tailoring and implementing interventions to meet the survivor's needs and build cancer survivor empowerment.

Other PROs and Concepts

Despite the lack of conceptual clarity of patient empowerment (Kim et al., 2023; Weisbeck et al., 2023), there are an increasing number of studies reporting on interventions that promote patient empowerment, and other PROs and concepts that may be related to cancer survivor empowerment are emerging through these interventions studies. Intervention studies designed to increase patient empowerment include education, self-management support, social support, decision-making support, survivorship care, and lifestyle modifications (Kim et al., 2023).

Education Interventions

Oncology Nurse-Designed Educational Intervention. An oncology nurse-designed educational intervention evaluated the effect on goal attainment, patient four-module and satisfaction in which 68 adults with pancreatic, ovarian/endometrial, breast, and colorectal cancer participated in the education intervention, developing of one SMART goal (S=specific; M=measurable; A=achievable; R=realistic; T=timely) coached by the nurse for a four-module education program with a telephone call one week later to see if goal was met and make any necessary modifications (Mirabella et al., 2022). Oncology RNs provided 1:1 support to patients for developing and evaluating one meaningful goal for new information presented in each education module. While patient empowerment scores remain high from baseline and throughout, no changes in goal attainment or satisfaction were observed, and a universal approach to health literacy supports adults. Eskildsen et al. (2017) identified health literacy, self-efficacy, shared decision-making, enablement, and communication competence as parts of empowerment. Similarly, Bravo et al. (2015) described health literacy as one of the six indicators of patient empowerment which also included self-efficacy, knowledge and skills, perceived control, sense of meaning, and feeling respected.

Tailored-Based Self-Management Intervention. A multi-center randomized, controlled trial of 94 breast cancer survivors, who had completed primary cancer treatment in South Korea, found that a 7-week partnership-based, needs tailored-based intervention conducted by telephone counseling (10 sessions, 15-20 minutes) compared to a control group increased empowerment and general health perception of women following breast cancer treatment (Kim et al., 2021). The EMPOWER study provided written materials to both groups with self-management

strategies after cancer treatment care in an education book; however, the control group did not receive symptom management skills training in their workbook. The Empowerment Scale for Women with Breast Cancer (Shin & Park, 2015) was used to measure patient empowerment.

Health literacy. Of note, the participants of previous studies (Avery et al., 2023; Mirabella et al., 2022) as well as this current study were predominately female, Caucasian, and college-educated, raising the question re: the needs of individuals who are less educated and if the universal approach for health literacy is effective for them or leads to decreased patient empowerment.

In a cross-sectional survey, exploring oncology nurse communication challenges and patient health literacy, oncology nurses did not identify patient communication behaviors associated with people with low literacy and novice nurses were more comfortable with assessing a patient's health literacy level than experienced nurses (Wittenberg et al., 2018), emphasizing the importance of training on communication skills and health literacy assessment for oncology nurses, who are educating cancer survivors through daily in person or virtual interactions, telephone contacts, electronic patient portals, and more formal education interventions. Other barriers to educational interventions to build empowerment may be encountered, such as travel to facility for an education intervention or follow-up via telephone for modification of goals which may not support learning preferences (e.g., visual).

Social Support

Self-Help Group Participation. The effect of self-help group participation on the relationship between patient empowerment and quality of life (QOL) was analyzed in 264 breast cancer survivors (Shin & Park, 2017). Participation in a self-help group had a significant effect

on the survivor's sense of empowerment that positively influenced their perception of quality of life. While this study focused on cancer survivors, who participated in an in-person group, other web-based self-help resources and symptom management programs are emerging.

Self-Management Program. In a pilot study of an Internet-based self-management program with an emphasis on symptom control, 45 early-stage breast cancer patients had statistically significant improvements in symptoms, such as anxiety, sleep, fatigue, activity level, and pain severity (Henry et al., 2018). Of the 35 breast cancer survivors, who reported fatigue as their primary symptom, greater improvement of multiple symptoms was reported, including increased participation in social activities, through the lifestyle and behavioral management strategies of the self-management program.

Web-Based Self-Management Resources. Additionally, other web-based resources for self-management have been evaluated. Web-based patient portals have been developed to build patient empowerment through symptom monitoring prior to clinic visits, self-help resources, and advice on symptoms (Groen et al., 2015; Kuijpers et al., 2015; Lehmann et al., 2021). A systematic review of ten randomized-controlled trials of patient empowerment and patient portals showed no to a small effect of patient portals on patient empowerment and health-related outcomes for adult patients, including patients with chronic diseases but not cancer (Ammenwerth et al., 2019). This review concluded that future studies should focus on developing taxonomy for patient portal functionalities. In contrast, a study of adult hematology patients, using a patient portal for symptom monitoring with PROs, found that patients were receptive to use of the patient portal, especially prior to clinic visits; however, there was less long-term use of the patient portal for follow-up appointments (Lehmann et al., 2021), providing

support for further exploration of what PROs are associated with patient empowerment and during what time intervals of early cancer survivorship. Given the unique, diverse needs of cancer survivors, the use of patient portals to support self-management and build empowerment requires further evaluation, including cancer survivors with less access or exposure to technology.

Additionally, a systematic review of 12 patient empowerment mobile applications (apps) was conducted to evaluate the content and quality to empower individuals with cancer (Thomas, et al. 2022). The content included: enhancing communication skills, social support, information on cancer and its treatment, and peer-to-peer support and the quality was moderate to high. The apps promoting patient empowerment were minimal and reading level was measured at 10th grade level (above the recommended 8th grade level). Future design and testing of mobile apps should account for the diversity of cancer survivors to ensure usability, benefits, potential barriers, and ability to build empowerment and include these cancer survivors as well as oncology nurses.

Decision-Making Support

Decision-making support has been linked to strategies that build patient empowerment as decision-making styles and communication share "power" between the clinician and cancer survivor. Key facilitators of patient empowerment, identified from a qualitative systematic review, included access to information, feeling respected, positive communication, partnership and learning from experiences of others (Joergensen et al., 2018), making clinician and cancer survivor sharing power essential for patient empowerment. Clinicians who adopt a participatory decision-making support may facilitate empowerment. From survey data of 623 bladder,

colorectal, and leukemia survivors, Arora et al. (2009) identified that physician participatory decision-making style may be associated with a cancer survivor's mental health by two pathways: 1) promoting self-efficacy and subsequently, how the survivor views their own personal control, and 2) enhancing trust, lessening their uncertainty. In addition, shared decision-making models have been evaluated, such as the Agency for Healthcare Research and Quality [AHRQ] (2020) SHARE approach [Seek, Help, Assess, Reach, Evaluate], describing a strategy for oncology nurses and advance practice nurses to utilize in busy oncology clinics because oncology nurses engage cancer survivors (Fairman & Tariman, 2019), building a relationship over time with frequent in-person, telephone, or virtual contacts. Barriers to empowerment are lack of access to information, not feeling well-informed, and feeling rushed in encounters with clinicians (Joergensen et al., 2018), and limited discussions with clinicians have been identified as impediment to optimal symptom control during the first-year post-treatment (Leach et al., 2017). PROs have led to improved communication between cancer survivors and clinicians (Atkinson, et al., 2017; Basch et al., 2016), whereby, cancer survivors identify PROs symptoms of most concern to them, and clinicians further assess those PROs symptoms and other clinically relevant PROs pertinent to the cancer survivor.

Survivorship Care Clinic and Care Plans

Survivorship care and care plans have also been studied. A randomized control trial of nurse-led survivorship care clinic visits for lymphoma survivors demonstrated a model of care that survivors reported less unmet needs, decreased distress, and increased empowerment (Taylor et al., 2019). The intervention group received three visits with the nurse after clinic follow-up visit with physician to discuss their treatment experience and concerns about transitioning into

survivorship care. Any unmet needs were identified, survivorship care plan was completed, and generic and tailored written resources were provided. This model of care illustrates the nurse sharing power with the survivor as they voice their concerns and goals, complete or modify their survivorship care plan, and receive tailored resources to address unmet needs, promoting a more manageable transition into early survivorship.

Care Plans. Electronic Care Plans, generated from PROs, were evaluated to determine if gynecologic and breast cancer patients and providers perceived improvement in care processes through electronic delivery of these plans (Brant et al., 2019). Patient found the electronic PROs (ePROs) generated care plans useful reference guides to manage symptoms and identify self-help resources whereas clinicians indicated improvements in team communication, increased satisfaction with the ability to tailor recommendations, and valued information for symptom management. Moreover, nurses used these care plans as teaching guides, making ePROs monitoring a strategy for survivorship care plans that emphasizes self-management to build empowerment.

In summary, to engage the cancer survivor in their own recovery from primary cancer treatment and facilitate their finding joy in life post-cancer treatment and a return to family, work and activities important to them, clinicians, especially oncology nurses, must update their knowledge of empowerment and research-based interventions that build survivor empowerment (Kim et al., 2023; Luo et al, 2021; Weisbeck et al., 2019), ensuring that educational interventions, self-management programs, social support, decision-making support, survivorship care clinics and care plans, and lifestyle modifications as well as the technology that support these interventions are utilized to improve cancer survivorship care. Accordingly, PROs

depicting patient empowerment are necessary to evaluate the cancer survivors progress toward their optimal outcome at specific intervals of early survivorship. With knowledge, oncology nurses are able to advocate for the use of cancer survivor-reported symptoms and research-based interventions that build empowerment. To change current paradigms, there are implications for clinical practice, nursing education, and future research.

Study Limitations

Although this study contributes insight into patient empowerment in cancer survivors in early survivorship following chemotherapy, there were several study limitations, including generalizability, specifically homogeneity of the sample population, clinic or clinician bias, and instrumentation.

Generalizability

There were several threats to external validity related to limits on the generalizability of the study results, including (a) homogeneity of the study sample; (b) convenience sample; and (c) single, community-based cancer center in the Midwestern United States.

Homogeneity of the Sample Population

Due to homogeneity of the sample, the findings of this study lack generalizability. Most of the sample population was female participants (90.4%). Based on the cancer center's tumor registry report of the highest volume of cancers receiving chemotherapy as part of the primary treatment regimen, two female cancers were identified. Gynecologic cancers were added approximately one year into the data collection, amending inclusion criteria to increase enrollment into the study. In addition, the participants were Caucasian (94.0%), college-educated (63.8%), employed (44.5%) and insured (98.8%) which is consistent with the population served

by this cancer center. Many participants were recruited from the larger, suburban medical oncology clinic of the cancer center, fewer participants were recruited from the two rural clinics of the cancer center.

Clinic or Clinician Bias

The sample was a convenience sample of cancer survivors completing chemotherapy at any phase of their primary cancer treatment. The plan to identify potential participants through electronic clinic schedules was not the primary method for data collection as there were limitations to content of the report and the date of the last dose of chemotherapy was changed due to symptoms (e.g., postponed for one to two weeks due to low blood cell counts or physical symptoms, like mouth sores, peripheral neuropathy). While there were only six ONNs, who facilitated identifying potential participants and date for completion of chemotherapy, they may have excluded potential participants for the study based on their own perceptions of whether the study was appropriate for their patient or the patient appropriate for the study. Furthermore, the cancer survivor may feel obligated to participate in the study because of their relationship with the ONN or clinic nurse. There were no self-referrals to the study as pandemic precautions limited study posters and brochure displays. As such, there may have been a clinic process and/or clinician bias inadvertently introduced into study recruitment procedures.

Instrumentation

For this study, the three instruments and sociodemographic questions were combined into one paper or online survey with 67 questions. Two participants declined completion of the second survey due to the time and length of the survey. Once enrolled in the study, participants, who were eligible to complete the second survey, completed it. While data collection occurred at

two-time intervals approximately three months apart, maturation was not a significant internal validity threat for this study associated with the cancer survivor's condition.

Other Study Limitations

The small sample size for those participants, who were eligible to complete the second survey (N=33), may not have had sufficient statistical power, limiting ANCOVA repeated measures analysis. As an exploratory aim, G* Power Analysis Calculation was not conducted.

Strengths of the Study

The current study has several strengths. First, patient empowerment is an outcome of the quantitative measure to study PROs as a mechanism to empower cancer survivors in early survivorship from end of treatment through first year after treatment when multiple symptoms are present. In addition, this study focused on several gaps in the literature, including lack of studies at the end of primary cancer treatment with chemotherapy as a treatment modality and no studies conducted in community-based cancer centers. Subsequently, this information may be used tailor interventions and outcomes to target at specific transition points in early survivorship. Oncology nurses in a community-based cancer center were engaged in this research, and they are uniquely positioned to transform cancer survivor assessment, using PROs self-efficacy and symptoms and tailoring interventions to build empowerment of cancer survivors.

Implications for Practice

Measuring the cancer survivor's level of patient empowerment and self-efficacy to meet the cancer survivor's needs will be essential to tailoring interventions for delivery of survivorship care. However, the current clinician-driven assessment approach does not support cancer survivor empowerment as "power" is not shared between the clinician and survivor. This

current state assessment model is not sustainable with overburdened clinics and staff and cancer program regulatory and accreditation standards, requiring more symptom screening and assessment (e.g., psychosocial distress, fatigue, sleep) for early identification of symptoms and subsequently, interventions. If clinicians offer cancer survivors the opportunity to become empowered, they are more likely to become empowered (Eskildsen et al., 2017; Tengland, 2008). A strategy that focuses on pre-clinic visit cancer survivor-reported assessment, using PROs instruments, at transition points in early survivorship is a step toward building patient empowerment. In this study, participants demonstrated that they were able to complete the questionnaire in clinic prior to or following the clinic visit with minimal disruption to clinic workflows. With almost half of the cancer survivors completing the online questionnaire, cancer survivors may be receptive to entering patient-reported outcomes electronically and further exploration of cancer survivors entering patient-reported outcomes electronically pre-visit from home should be explored to support a transition from clinician-driven assessment to patient-report so that the clinic visit focuses on cancer survivor symptom experience and their ability to self-manage them. For cancer survivors, at the transition point, immediately following end of primary cancer treatment, a new symptom assessment approach, integrating cancer survivor self-reported physical and psychological symptoms, physical function, and self-efficacy, is likely to build empowerment in survivorship care, identifying the unique needs of each cancer survivor.

As previously stated, self-efficacy tools are not widely used in clinical practice. Self-efficacy, whether the cancer survivor feels that he or she is capable of self-managing cancer and its treatment, is not assessed in community-based oncology practices. Based on the linear relationship found between patient empowerment and self-efficacy, it may be worthwhile to

evaluate self-efficacy in cancer survivors. PROMIS® Self-Efficacy Managing Chronic Diseases is a useful instrument for understanding self-efficacy at transition points in survivorship to know if what clinicians expect is consistent with what cancer survivor's need and builds on empowerment. In addition, measuring PROs symptoms, demonstrating a linear relationship, in cancer survivors may also be advantageous in early survivorship, especially immediately post-chemotherapy treatment. Supported by previous literature (Shi et al., 2011; Wu & Harden, 2015), the cancer survivor's symptom burden remains present in early survivorship. Cancer survivor self-reported symptoms immediately post-treatment may lead to earlier intervention for symptoms that are most important to the survivor at this transition point.

The use of PROs addresses several gaps identified in previous literature (Atkinson et al., 2017; Basch et al., 2011; Berry et al., 2011; Fiteni, 2019; Howell et al., 2015; Kotronoulas et al., 2014; Luckett, Butow, & King, 2009; McCorkle et al, 2011; Shi et al., 2011; Wu & Harden, 2015) and support a transition from clinician-driven assessment to cancer survivor self-reported symptoms in the EHR to integrate patient self-reported symptoms, capture of real-time symptom data collection, and earlier assessment of late and long-term symptoms. Although there are challenges to implementing PROs in the EHR (Basch et al., 2018; Gensheimer et al., 2018; Zhang et al., 2018), Basch et al. (2016) demonstrated that the integration of PROs is associated with greater survival as patients, who self-reported symptoms, remained on their chemotherapy regimen two months longer and had an overall median survival of five months. Further exploration what PROs depict patient empowerment at transition points throughout early survivorship (e.g., three months, six months, one year) will be needed as well as investigating

PROs in cancer survivors, who received new or emerging cancer treatment modalities, such as oral cancer therapies and immunotherapies.

Implications for Nursing Education

Given the conventional approach to symptom assessment embedded in practice and how nurses and other clinicians have been trained in basic and advanced education programs, nursing education will need socialize and train for nurses to two evolving paradigms: patient empowerment and PROs (Weisbeck et al., 2019).

Patient Empowerment

For patient empowerment, the first step is building awareness of current state definitions of patient empowerment. Nurses as well as other clinicians will need to be socialized to a developing a partnership of "working with" patients or cancer survivors rather than the longstanding practice of clinicians "doing to" or "doing for" them (Kim et al., 2023; Weisbeck et al., 2023). In turn, working in partnership with an individual living with a chronic disease, like cancer, facilitates their reflection on the experience of living with that chronic illness. Thus, the shared power between the patient and clinician supports decision-making and developing plans together. Meeting cancer survivors "where they are at", it is more likely that clinicians will recognize the unique, diverse needs of the individual cancer survivor, identifying barriers and research-based interventions, promoting cancer survivor empowerment and subsequently, engagement in self-management (Kim et al., 2023).

Since theoretical or conceptual models of patient empowerment are currently available, nurses need to be trained on how to use them to guide practice and tailor research-based interventions that build patient empowerment, promoting self-management and decision-making

(Kim, Choe, & Kim, 2023). Furthermore, communication skills training and counseling will be necessary for nurses to develop their skills, targeting novice and experienced nurses. A recent pilot study of a one-hour web-based training on shared decision-making demonstrated positive effects on 61 oncology nurses self-reported knowledge, adaptability, and communications skills (Warzyniec et al., 2019) for nurses in current practice. A qualitative study of the decision-making process of gastrointestinal cancer patients showed the importance of physician knowledge of the cancer survivor's values and preferences, especially how they prefer communication, prior to conveying health care information (Haltaufderheide et al., 2019). To promote shared decision-making and build patient empowerment, strategies for clinician conversations with cancer survivors about their values and preferences should be included in training on communication skills, counseling, and shared decision-making. As patient empowerment continues to evolve, clinicians must stay abreast of new, research-based interventions for building empowerment in cancer survivors and advocate for their integration into clinical practice and survivorship care.

PROs

To change the paradigm from clinician-driven assessment to cancer survivor-reported assessment, nurses will need to be trained on the use of PROs in cancer survivors. The first step is building awareness of current state PROs, emphasizing the differences between clinician-driven assessment and cancer survivor self-report of symptoms. Of importance, training programs should emphasize the value of PROs for cancer survivors, including the association with survival (Basch et al., 2016) as well as the value for nurses Any training in clinical practice areas will require how to use PROs assessment tools through written paper forms in clinic or

emerging technology for self-report prior to clinic visits and/or home monitoring (e.g., patient portals, mobile phones, mobile apps). In turn, the nurse will train the cancer survivor to use PROs assessment tools. Nurses will need to understand what PROs measures are best to use in early survivorship and how to interpret the scores. In addition, nurses will need to know what research-based interventions are available for symptom support and build empowerment in cancer survivors. For survivors to effectively use PROs, nurses will need training to develop communication skills and partnerships with physicians, other disciplines, administrative leadership, and support services, like quality and information technology, to create an infrastructure, design and implementation plan, and evaluate PROs in clinical practice.

Implications for Future Research

The presence of patient empowerment in cancer care is increasing in the literature (Alfano et al., 2019; Eskildsen et al., 2017, Kim, Close, & Kim, 2023). A lack of consensus about the definition of patient empowerment persists, however, there is some agreement about patient empowerment as highly personal, dynamic, and ongoing along a continuum of care for people living with a chronic illness, like cancer. More recent literature contributes to the evaluation of current patient empowerment instruments. Pekonen et al. (2020) identified generic instruments for measuring patient empowerment and its related concepts, such as the Health Empowerment Scale [HES] and Patient Activation Management [PAM], suggesting that clinicians and researchers utilize generic instruments to support and evaluate patient empowerment despite the need for further psychometric testing of the instruments. Following a content validation study of the Cancer Patient Empowerment Questionnaire [CPEQ] in follow-up visits with cancer patients, Eskildsen et al. (2020) recommended expanding to a nation-wide study to further evaluate the

instrument and possibly shorten the number of items for clinical practice. No one instrument captures all components of patient empowerment and its related concepts (Alfano et al., 2019; Eskildsen et al., 2020; Pekonen et al., 2020; Acuña Mora et al., 2022); however, utilizing instruments to measure patient empowerment may lead to further clarification of the concept and revisions to the conceptual model, if necessary. As such, a focus for future research is on what other PROs and potentially related concepts, like perceived preparedness or transition readiness, depict patient empowerment in early cancer survivorship (first year post-treatment) and support cancer survivor reported symptoms, monitoring, and management.

While it is important to continue to evaluate patient empowerment instruments for clinical practice as they continue to evolve through research, clarifying its definition and related concepts, this study has shown that there is a relationship between patient empowerment and PROs self-efficacy and symptoms, demonstrated linear relationship between patient empowerment and specific symptoms, found self-efficacy as a predicator of patient empowerment immediately following the last dose of chemotherapy treatment, and identified a decrease in patient empowerment among breast, colorectal, lung, and gynecologic cancer survivors immediately following the last dose of chemotherapy to three months post-treatment. The latter did not appear to be associated with changes in PROs self-efficacy or symptoms.

Based on these results, the recommendations are to: 1) develop a strategy and implement PROs self-efficacy and symptoms, demonstrating linearity with patient empowerment, to transition away from conventional clinician-driven assessment and toward tailored interventions that build empowerment; 2) establish time intervals for cancer survivor-reported symptoms (e.g., last chemotherapy treatment, 3 months post-treatment); 3) utilize technology to support PROs

entry by survivors from home or clinic with integration to EHR; 4) measure PROs self-efficacy and symptoms to advance our understanding of patient empowerment; and 5) investigate other PROs for an association with patient empowerment and which depict decreases in patient empowerment over time.

Based on these study findings, the next step is a qualitative study for conceptual clarification of patient empowerment in cancer survivors, describing more specifically what it is and if modification of the conceptual model is needed. Subsequently, further studies will investigate other PROs or variables not addressed in this study to depict patient empowerment at three months post-treatment. Other qualitative studies should be considered for transition points in early survivorship (e.g., six months, one year) to determine if PROs that depict empowerment similar or different as cancer survivors move further into survivorship. More longitudinal, descriptive and intervention studies are necessary with a more diverse cancer survivor population in other community-based oncology practices. With the advances in cancer treatment modalities, further investigation of patient empowerment and PROs with other emerging cancer therapies, such as oral cancer therapies and immunotherapy, will be needed.

Conclusion

Due to the complex, changing paradigm of cancer care and conventional clinician-driven assessment as less sustainable in survivorship care, cancer survivor empowerment must be assessed and supported in clinical practice, engaging survivors in their new responsibilities of self-monitoring, self-reporting, and self-managing symptoms. There is a relationship between patient empowerment and PROs self-efficacy and symptoms. PROs self-efficacy was a predictor of patient empowerment immediately following the last dose of chemotherapy, but it is seldom

assessed in clinical practice. Patient empowerment decreased from immediately following the last dose of chemotherapy to three months post-treatment, and there was no significant change over time in PROs self-efficacy and symptoms. As such, a qualitative study for conceptual clarification of patient empowerment in cancer survivors is needed, and further studies to investigate what other PROs and/or related concepts describe the decrease in patient empowerment and what PROs depict patient empowerment at transition points throughout early survivorship are logical next steps for research.

A transition to cancer survivor-reported assessment with PROs self-efficacy and symptoms, demonstrating linearity in this study, immediately following last dose of chemotherapy treatment for breast, colorectal, lung, and gynecological cancer survivors, receiving care in a medical oncology clinic, may be a practical starting point. However, the generalizability of these studies findings to more diverse populations is limited. Clinicians will need to expand their knowledge of patient empowerment and PROs to prepare themselves to engage cancer survivors to self-monitor, self-report, and self-manage in early survivorship. Oncology nurses are critical for envisioning how to transition from clinician-driven assessment to cancer survivor-reported assessment and implementing research-based interventions that build empowerment in cancer survivors. The investment of resources to train clinicians and survivors to implement PROs assessment tools in a community cancer center is value-added and necessary to empower cancer survivors in early survivorship to achieve optimal outcomes.

APPENDIX A

IRB APPROVALS AND AMENDMENTS

PROHEALTH CARE

INSTITUTIONAL REVIEW BOARD APPROVAL
Exempt Approval

July 22, 2019

Dear Ms. Johnston,

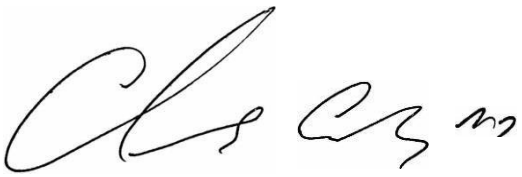
Please be advised that the proposal for the study entitled:

> **IRB # 19-18;** Cancer Survivor Empowerment through Patient-Reported Outcomes: Insights into Recovery after Chemotherapy

was reviewed on 7/19/2019 and determined to meet criteria for exemption from IRB review under 45 CFR 46.104(d)(2 & 4) and thus may be carried out as indicated.

The IRB* will be informed of this decision at the next meeting scheduled for July 24, 2019. Please note that in addition to IRB approval you should ensure you have the approval of appropriate administrators before you conduct the study.

Thank you for bringing your proposal to the attention of the IRB. If the plan or intent of your proposal changes in the future, this information should be brought to the attention of the IRB to determine if IRB review would be required at that time. If you require further assistance, feel free to call 262-928-4773.



Charles Cady, MD
Chairman, Institutional Review Board

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* ***IRB Compliance Statement:*** The Institutional Review Board complies with all applicable laws, guidelines, and regulations that govern its activities and operation. The IRB is duly constituted (fulfilling federal regulatory requirements for diversity), has written procedures for initial and continuing review of clinical trials, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process. In accordance with federal regulations found at 45 CFR 46.107(d) and 21 CFR 56.107(e), the IRB also prohibits any member from participating in the IRB's initial or continuing review of any study in which the member has a conflicting interest, except to provide information requested by the IRB. Pursuant to our policy, a voting member of the IRB must leave the room for final discussion and voting on any protocol in which the member is an investigator or has any conflict of interest.

LOYOLA UNIVERSITY CHICAGO
Health Sciences Division
Institutional Review Board for the Protection of Human Subjects
2160 South First Avenue
Maywood, IL 60153

08/19/2019

NOTICE OF IRB EXEMPTION OF A RESEARCH PROJECT

Investigator **Friend, Patricia**

LU Number **212683**

Title **Cancer Survivor Empowerment through Patient-Reported Outcomes**

Date of Review **08/15/2019**

Reason **45CFR46.102(l) Category Not Research**

Comments **This project consists of activities that do not meet the definition of human subject research according to the 45 CFR 46.102(l). Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.**
1. This is a PhD dissertation project being conducted at ProHealth Care Hospitals and Clinics in Wisconsin and will be implemented as a partial fulfillment of requirements for a PhD at Loyola University Chicago Marcella Niehoff School of Nursing.
2. Should you wish to make modifications that involve changing the type, nature, source (etc.) of the data/materials specified in the current proposal, you MUST request such changes in advance from the Loyola IRB, as this may change the categorization of the proposed research.
3. LUMC is not engaged in this project.

This project has been determined to be EXEMPT from IRB review.
There are no reporting requirements associated with this project.

The Full Board will review this determination on 09/18/2019.
If the Board disagrees with this action, you will be notified by 09/25/2019.

Cynthia C. Tom-Klebba, M.A.
Director, Human Research Protection Program
Loyola University Health Sciences Division

PROHEALTH CARE

Institutional Review Board
FWA#00014941
OHRP IRB Registration# IRB00003210

July 8, 2021

Mary Pat Johnston
UW Health Cancer Center at ProHealth Care

IRB # 19-18, Cancer Survivor Empowerment through Patient-Reported Outcomes: Insights into Recovery after Chemotherapy (EXEMPT)

Dear Ms. Johnston,

Your **Amendment Request for Addition of new study population: gynecological cancers; update to cancer center name** was approved by the IRB using expedited review procedures on **7/8/2021,** pursuant to 45 CFR 46.110(b)(1)(ii) as a minor change. This approval is effective through the current approval period for this study; re-consent is not required. The IRB will be advised of all expedited review actions at the next scheduled meeting on 7/28/2021.

PLEASE NOTE:

- Changes to the protocol or consent document(s) require IRB approval prior to implementation unless the change is necessary to eliminate an apparent immediate hazard to subjects.
- Prompt reporting to the IRB is required for: major protocol deviations, serious adverse events, unanticipated problems involving risk to subjects or others, and serious or continuing noncompliance.
- Other administrative approval(s) may be required for the research and are your responsibility.
- Contact the Human Research Protection Program Specialist with any questions or concerns (262-928-4773).

Charles Cady, MD
Chairman, Institutional Review Board

IRB Compliance Statement

The Institutional Review Board complies with all applicable laws, guidelines, and regulations that govern its activities and operation. The IRB is duly constituted (fulfilling federal regulatory requirements for diversity), has written procedures for initial and continuing review of clinical trials, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process. In accordance with federal regulations found at 45 CFR 46.107(d) and 21 CFR 56.107(e), the IRB also prohibits any member from participating in the IRB's initial or continuing review of any study in which the member has a conflicting interest, except to provide information requested by the IRB. Pursuant to our policy, a voting member of the IRB must leave the room for final *discussion and voting on any protocol in which the member is an investigator or has any conflict of interest.*

PROHEALTH CARE

Institutional Review Board
FWA#00014941
OHRP IRB Registration# IRB00003210

October 14, 2021

Mary Pat Johnston
UW Health Cancer Center at ProHealth Care

IRB # 19-18, Cancer Survivor Empowerment through Patient-Reported Outcomes: Insights into Recovery after Chemotherapy (EXEMPT)

Dear Ms. Johnston,

Your **Amendment Request for Expand inclusion criteria to include all patients receiving chemotherapy for primary cancer treatment** was approved by the IRB using expedited review procedures on **10/14/2021,** pursuant to 45 CFR 46.110(b)(1)(ii) as a minor change. This approval is effective through the current approval period for this study; re-consent is not required. The IRB will be advised of all expedited review actions at the next scheduled meeting on 10/27/2021.

PLEASE NOTE:

- Changes to the protocol or consent document(s) require IRB approval prior to implementation unless the change is necessary to eliminate an apparent immediate hazard to subjects.
- Prompt reporting to the IRB is required for: major protocol deviations, serious adverse events, unanticipated problems involving risk to subjects or others, and serious or continuing noncompliance.
- Other administrative approval(s) may be required for the research and are your responsibility.
- Contact the Human Research Protection Program Specialist with any questions or concerns (262-928-4773).

Charles Cady, MD
Chairman, Institutional Review Board

IRB Compliance Statement

The Institutional Review Board complies with all applicable laws, guidelines, and regulations that govern its activities and operation. The IRB is duly constituted (fulfilling federal regulatory requirements for diversity), has written procedures for initial and continuing review of clinical trials, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process. In accordance with federal regulations found at 45 CFR 46.107(d) and 21 CFR 56.107(e), the IRB also prohibits any member from participating in the IRB's initial or continuing review of any study in which the member has a conflicting interest, except to provide information requested by the IRB. Pursuant to our policy, a voting member of the IRB must leave the room for final discussion and voting on any protocol in which the member is an investigator or has any conflict of interest.

APPENDIX B

INFORMED CONSENT

PHC IRB#: 19-18
Approval date: 10/14/2021
Version: 3

PROHEALTH CARE

STATEMENT OF VOLUNTEER CONSENT FOR CLINICAL RESEARCH STUDY

Study Title: Insights into Recovery after Chemotherapy

Study Investigator: Mary Pat Johnston, MS, RN, AOCN®
UW Health Cancer Center at ProHealth Care
N16 W24131 Riverwood Drive, Pewaukee, WI 53188
262-696-0969

You may be eligible to take part in a research study. Taking part in this study is completely voluntary. If you do not want to take part in this study, it does not change the care that you receive in the cancer center.

In this research study, we are trying to learn more about recovery after chemotherapy. While in this study, we will ask you to answer questions about symptoms and your experiences following chemotherapy treatment. You will be asked to complete the survey as soon as possible following your last chemotherapy treatment. If your chemotherapy is at the end of your primary cancer treatment regimen, you will be asked to complete the survey again at 3 months after treatment. It will take approximately 15-20 minutes to complete the survey. You will have the option to complete the survey in an electronic or paper format in the clinic or in a paper format at home. Your participation in the study will last approximately 1-4 months.

There are risks and benefits to being in a research study. Some risks of this study include an increase in emotions, like anxiety. These risks and others will be discussed in more detail later in the consent form. This study will not provide direct benefits to you, but it will help others as they complete chemotherapy.

If you are interested in learning more about this study, please continue reading the rest of this document. It is important that you understand the information in this consent form before making your decision. If there is anything you do not understand, be sure to ask the study investigator. You may also discuss this study with your family or friends before making a decision.

Why are we asking you about this study?
We are seeking adults with a diagnosis of breast, colorectal, gynecologic, and lung cancer who received chemotherapy treatment to participate in this study. If you decide to be in this study, you will be one of approximately 90 people in this research study.

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Approval date: 10/14/2021
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Do I have to participate in this study?
Your participation in this study is voluntary. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you say yes, you may change your mind at any time and stop being in the study without losing any benefits or medical care to which you are entitled.

Why is this study being done?
The purpose of this study is to describe recovery after chemotherapy, including symptoms and beliefs about the ability to manage them following chemotherapy. We hope to learn how nurses can better support cancer survivors following chemotherapy treatment.

What will happen if I take part in this study?
The study investigator or a designated nurse will ask you to identify your preference of how to complete the survey. If you choose to complete it electronically, then the survey will need to be completed in the clinic. If you choose the paper survey, it can be completed in either the clinic or at home. Once you have selected the method for completing the survey, it will be the same for both time periods of this study. The study investigator or designated nurse will work with you to schedule a convenient time to complete the first survey in the clinic or provide paper survey for completion at home. You will be asked to answer questions about physical symptoms (e.g., fatigue, sleep, pain), psychological or emotional symptoms (e.g., anxiety, depression), physical function, and how you are able to manage symptoms, medications, daily activities, and social activities as you recover from chemotherapy treatment. You will be asked to respond to short questions using a rating scale and a few multiple choice questions about you that will be used to help describe those who participated in the study as a group. It will take approximately 15-20 minutes. If you will be starting radiation and/or having surgery after your chemotherapy, you will complete one survey. If chemotherapy is the last part of your primary cancer treatment regimen, approximately, two months after completion of the first survey, the study investigator or nurse contact you to schedule the completion of the survey again approximately 3 months after your last chemotherapy treatment. The study investigator or nurse will attempt to coordinate completion of surveys around follow-up visits to the clinic.

How long will I be in this study?
If you will be starting radiation and/or having surgery after your chemotherapy, the length of time for the study is less than 1 month because you will only need to complete one survey. If you are finishing your primary cancer treatment regimen with chemotherapy, the total length of time for the study is 4 months from enrollment through completion of the second survey.

What other choices do I have?
You may choose not to participate in the study. You will receive usual care. There is no change to your care based on participation in this study.

Can I **change my mind after I join this study?**
You are free to withdraw from the study at any time. Your decision to withdraw will not affect your ability to receive medical care and you will not lose any benefits you are otherwise entitled to. If you decide to leave, please tell the study investigator.

The study investigator may take you out of this study at any time. This may happen if:

- You are not available to schedule a date and time to complete survey within specified time period after reasonable attempts have been made by the study investigator or designated nurse.

What are the risks?
This research involves no more than minimal risk. There may be some discomfort when completing the surveys:

- identifying some symptoms as new or ongoing concern
- experience an increase in emotions, like anxiety

Will my information be kept confidential?
We will make every effort to keep your information confidential, but it is possible that an unauthorized person might see it.

You will be given a unique passcode for your surveys. Your personal identifying information, like your name, will not be linked to your responses.

It is important for you to know that your doctor, clinic nurse, or other members of your cancer team will not see your responses. If you have new or ongoing symptoms that concern you, please talk to your doctor or clinic nurse about your symptoms. Your Oncology Nurse Navigator can assist you in making a connection with them. In addition, Oncology Counselors are available if you experience an increase in emotions, like anxiety, and are interested in talking about them further.

The results of this research study may be presented in public talks or written articles, but your identity will not be disclosed unless authorized by you or as required by law.

If all personal identification is removed from your study records, the information might be used or released for other research purposes without asking you.

What are the benefits?
This study will not provide direct benefits to you.

Will I be paid?
You will receive a $15 gift card for your participation in the study following completion one survey; or you will receive a $25 gift card for your participation in the study following completion of the second survey approximately 3 months after your last chemotherapy treatment. One gift card per participant.

What costs will there be?
There are no costs incurred by you related to participation in this study.

Who can I contact if I have questions about the study?
You can talk to the study investigator about any questions or concerns you have about this study. Contact the study investigator at 262-696-0969.

For questions about your rights while taking part in this study or to report any problems or complaints, call the ProHealth Care IRB at 262-928-4773.

Will I be given new information about the study?
If we learn any important new information about the study that might change your mind about participating, we will tell you right away. You can then decide if you want to stay in the study.

PERMISSION TO COLLECT AND USE YOUR PROTECTED HEALTH INFORMATION (PHI)
This part of the consent form is asking for your permission to use and share your Protected Health Information (PHI). PHI is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

If you want, we can give you more information about the **Privacy Rule.** Also, if you have any questions about the **Privacy Rule** you can speak to our Privacy Officer at 262-696-5811.

What health information will be used for this study?
To be in this study, the researchers need your permission to access, collect and use your protected health information (PHI). The PHI collected may include data from your medical record or from any surveys or information that is collected during this study.
The health information we will collect and use during this study includes:

- Cancer Diagnosis
- Stage
- Treatment Plan
- Other Illnesses or Conditions

What happens if I do not give permission?

If you say no, you cannot be in this study. The care you get from your doctor will not change and you will not lose any benefits.

PHC IRB#: 19-18
Approval date: 10/14/2021
Version: 3

Why will this information be used and/or given to others?
The researchers need this information to do the research, study the results and make sure the research was done right. We will only use your information for the study as described in this consent form.

Who will see the PHI?
ProHealth Care, Inc. will release protected health information (PHI) to the following researchers, institutions and/or companies who are working on this study:

- ProHealth Care Researchers
- The Institutional Review Board (IRB) overseeing this study
- The United States Food and Drug Administration (FDA) and/or other regulatory agencies that oversee the quality and safety of the research.

Once PHI is released from the institution, there is a risk that your health information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

If this study is related to your medical care, your research related information may be placed in ProHealth Care's electronic medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

You have the right to see and copy the PHI we gather on you for as long as the study investigator or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

When will my permission end?
This authorization expires when the research ends and all required study monitoring is over.

Can I cancel my permission?
You have the right to cancel this authorization at any time by sending a written request to the following: Mary Pat Johnston, UW Health Cancer Center at ProHealth Care, NI 6 W24131 Riverview Drive, Pewaukee,WI 53188. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

PHC IRB#: 19-18
Approval date: 10/14/2021
Version: 3

CONSENT TO PARTICIPATE

I have read (or had read to me) this form. All my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study. I have been told I can stop at any time.

(Signature of Participant)	(Date)
(Signature of Person Conducting Informed Consent Discussion)	(Date)

APPENDIX C

QUESTIONNAIRE

Insights into Recovery after Chemotherapy

PROHEALTH CARE

Insights into Recovery After Chemotherapy

Thank you for volunteering to participate in the study, *Insights into Recovery after Chemotherapy*. You will be asked to respond to short questions using a rating scale and followed by a few multiple choice questions. Please respond to each question or statement. It will take approximately 15-20 minutes to finish the survey. Your name will not be written on the survey or connected to your responses. Instead you will be given a unique, randomly generated 5-digit code for your survey. You will use the same code for both surveys. Your unique code is:

Place Unique Code # Label Here

As a reminder, your doctor, clinic nurse, or other members of your cancer team will not see your responses. If questions on the survey increase your concerns about new or ongoing symptoms, please talk to your doctor or clinic nurse about your symptoms. Your Oncology Nurse Navigator can assist you in making a connection with them. In addition, Oncology Counselors are available if you experience an increase in emotions, like anxiety, and are interested in talking about them further. The study investigator or nurses can provide their contact information to you.

If you have any questions about the survey, please ask the study investigator or another oncology nurse working with the study.

PHC IRB 19-18
Loyola IRB 212683

Start Survey

Patient Support Strategies

Please indicate by marking one box per row whether you strongly agree, agree, disagree, or strongly disagree. Please read the statements carefully and mark (X) your responses to them.

		Strongly Agree	Agree	Disagree	Strongly disagree
1.	I am capable of handling my illness.	☐	☐	☐	☐
2.	I have all the information I need to manage my illness.	☐	☐	☐	☐
3.	I am capable of helping health professionals to reach decisions related to my illness.	☐	☐	☐	☐
4.	My family are very supportive.	☐	☐	☐	☐
5.	I need the support of my family and friends.	☐	☐	☐	☐
6.	My family and friends still rely on me.	☐	☐	☐	☐
7.	I can adapt to the changes in my lifestyle.	☐	☐	☐	☐
8.	Health professionals are happy to include me in decisions related to my illness.	☐	☐	☐	☐
9.	I want my family to continue to rely on me.	☐	☐	☐	☐
10.	My friends are always supportive.	☐	☐	☐	☐
11.	I still feel useful in my daily life.	☐	☐	☐	☐
12.	My spiritual beliefs help me cope with my illness.	☐	☐	☐	☐
13.	I accept that I have to change my lifestyle.	☐	☐	☐	☐
14.	Complimentary therapies help me cope with my illness.	☐	☐	☐	☐
15.	I have a lot of confidence in my doctor (i.e., medical oncologist).	☐	☐	☐	☐

This is the end of the 1st Section.
Please, check that each item has a response.

Turn to Next Page

PROMIS® Self-Efficacy Managing Chronic Conditions

Self-Efficacy for Daily Activities-Short Form 4a

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

CURRENT level of Confidence	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
I can perform my household chores	☐	☐	☐	☐	☐
I can go shopping and run errands	☐	☐	☐	☐	☐
I can walk around inside my house	☐	☐	☐	☐	☐
I can maintain a regular exercise program	☐	☐	☐	☐	☐

Self-Efficacy for Managing Emotions-Short Form 4a

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

CURRENT level of Confidence	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
I can handle negative feelings	☐	☐	☐	☐	☐
I can find ways to manage stress	☐	☐	☐	☐	☐
I can avoid feeling discouraged	☐	☐	☐	☐	☐
I can bounce back from disappointment	☐	☐	☐	☐	☐

Self-Efficacy for Managing Medications and Treatment-Short Form 4a

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

CURRENT level of Confidence	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
I can follow directions when my doctor changes my medications	☐	☐	☐	☐	☐
I can take my medications when there is a change in my usual day (unexpected things happen)	☐	☐	☐	☐	☐
I can manage my medication without help	☐	☐	☐	☐	☐
I can list my medications including the doses and schedule	☐	☐	☐	☐	☐

Turn to Next Page

PROMIS® Self-Efficacy Managing Chronic Conditions

Self-Efficacy for Managing Social Interactions -Short Form 4a

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

CURRENT level of Confidence	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
I can talk about my health problems with someone	☐	☐	☐	☐	☐
If I need help, I can find someone to take me to the doctor's office	☐	☐	☐	☐	☐
I can get emotional support when I need it	☐	☐	☐	☐	☐
I can ask for help when I don't understand something	☐	☐	☐	☐	☐

Self-Efficacy for Managing Symptoms-Short Form 8a

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

CURRENT level of Confidence	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
I can manage my symptoms during daily activities	☐	☐	☐	☐	☐
I can keep my symptoms from interfering with relationships with friends and family	☐	☐	☐	☐	☐
I can manage my symptoms in a public place	☐	☐	☐	☐	☐
I can work with my doctor to manage my symptoms	☐	☐	☐	☐	☐
I can keep my symptoms from interfering with my personal care	☐	☐	☐	☐	☐
I can manage my symptoms when I am at home	☐	☐	☐	☐	☐
I can keep my symptoms from interfering with the work I need to do	☐	☐	☐	☐	☐
I can find the information I need to manage my symptoms	☐	☐	☐	☐	☐

This is the end of the 2nd Section. Please, check that each item has a response.

Turn to Next Page

PROMIS®-29 Profile v2.1

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

Physical Function	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
Are you able to do chores such as vacuuming or yard work?	☐	☐	☐	☐	☐
Are you able to go up and down stairs at a normal pace?	☐	☐	☐	☐	☐
Are you able to go for a walk of at least 15 minutes?	☐	☐	☐	☐	☐
Are you able to run errands and shop?	☐	☐	☐	☐	☐

Anxiety	Never	Rarely	Sometimes	Often	Always
In the past 7 days...					
I felt fearful	☐	☐	☐	☐	☐
I found it hard to focus on anything other than my anxiety	☐	☐	☐	☐	☐
My worries overwhelmed me	☐	☐	☐	☐	☐
I felt uneasy	☐	☐	☐	☐	☐

Depression	Never	Rarely	Sometimes	Often	Always
In the past 7 days...					
I felt worthless	☐	☐	☐	☐	☐
I felt helpless	☐	☐	☐	☐	☐
I felt depressed	☐	☐	☐	☐	☐
I felt hopeless	☐	☐	☐	☐	☐

Fatigue	Not at all	A little bit	Somewhat	Quite a bit	Very much
In the past 7 days...					
I feel fatigued	☐	☐	☐	☐	☐
I have trouble starting things because I am tired	☐	☐	☐	☐	☐
How run-down did you feel on average?	☐	☐	☐	☐	☐
How fatigued were you on average?	☐	☐	☐	☐	☐

Turn to Next Page

Sleep Disturbances	Very poor	Poor	Fair	Good	Very good
In the past 7 days…					
My sleep quality was	☐	☐	☐	☐	☐

	Not at all	A little bit	Somewhat	Quite a bit	Very much
In the past 7 days…					
My sleep was refreshing	☐	☐	☐	☐	☐
I had a problem with my sleep	☐	☐	☐	☐	☐
I had difficulty falling asleep	☐	☐	☐	☐	☐

Ability to Participate in Social Roles and Activities	Never	Rarely	Sometimes	Often	Always
In the past 7 days…					
I have trouble doing all of my regular leisure activities with others	☐	☐	☐	☐	☐
I have trouble doing all of the family activities that I want to do	☐	☐	☐	☐	☐
I have trouble doing all of my usual work (include work at home)	☐	☐	☐	☐	☐
I have trouble doing all of the activities with friends that I want to do	☐	☐	☐	☐	☐

Pain Interference	Not at all	A little bit	Somewhat	Quite a bit	Very much
In the past 7 days…					
How much did pain interfere with your day to day activities?	☐	☐	☐	☐	☐
How much did pain interfere with work around your home?	☐	☐	☐	☐	☐
How much did pain interfere with your ability to participate in social activities?	☐	☐	☐	☐	☐
How much did pain interfere with your household chores?	☐	☐	☐	☐	☐

Pain Intensity
In the past 7 days…
How would you rate your pain on average?

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9	10

This is the end of the 3rd Section. Please, check that each item has a response.

Turn to Next Page

A Few Questions About You

This is the last part of the survey. Your responses to the questions below will be used to describe who participated in this study. Once completed, please, review the survey to see that each question has a response.

Fill-in-the Blank

1. What is your age? ____ Years

Mark your response an "X"; only one response per item.

2. What is your gender?
   - ☐ Male
   - ☐ Female

3. Is your ethnicity Hispanic or Latino?
   - ☐ No (I am not Hispanic or Latino)
   - ☐ Yes (I am Hispanic or Latino)

4. What is your race?
   - ☐ American Indian/Alaskan Native
   - ☐ Asian
   - ☐ Black/African American
   - ☐ Caucasian (White)
   - ☐ Native Hawaiian or Other Pacific Islander
   - ☐ Other Race (those not listed): _____

5. What is your highest degree or level school completed?
   - ☐ 8th grade or less
   - ☐ 9th grade
   - ☐ 10th grade
   - ☐ 11th grade
   - ☐ 12th grade (or GED)
   - ☐ Some college, no degree
   - ☐ Associate degree
   - ☐ Bachelor's degree
   - ☐ Master's degree
   - ☐ Doctorate degree

You are
almost finished.
This is the last section
of the survey!

6. Are you currently employed?
   - ☐ Yes
   - ☐ No

7. If yes to #6, are you employed?
   - ☐ Full-time
   - ☐ Part-time

8. Are you insured?
   - ☐ Yes
   - ☐ No

9. If you responded yes to #8, do you have:
   - ☐ Private insurance
   - ☐ Medicare
   - ☐ Medicaid
   - ☐ Other: _____

If you have any questions about this survey, please, contact the study investigator. Thank you for taking time to complete this questionnaire! Your responses are important to learning more about recovery after chemotherapy treatment.

Place Unique Code # Label Here

ProHealth Care

APPENDIX D

PERMISSIONS TO USE

Permission to Use: Cancer-Related Patient Empowerment Scale

From: Caroline Bulsara <caroline.bulsara@nd.edu.au>
Sent: Thursday, October 11, 2018 9:31 PM
To: Johnston, Mary
Subject: RE: Cancer-Related Patient Empowerment Scale

Dear Mary,

Thank you for your interest in the PES and I am very happy to provide you with the scale for study. The study seems highly appropriate and very relevant to the scale.

Please find attached the patient empowerment scale. The scoring mechanism is very simple. Each item was given a four-point rating scale (strongly agree, agree, disagree, and strongly disagree), scored 4, 3, 2 and 1, respectively. This was because it was intended for busy clinic settings and to be used by clinicians. There have been no cut offs established for levels of empowerment, as yet.
I have also attached the two papers which outline its development. Happy to provide any information that I can help with Mary and all the best with your study.

Best Regards,
Caroline

Assoc Professor Caroline Bulsara
Research coordinator (on campus Mon, Tues, Wed & Friday)
School of Nursing and Midwifery
Room Number: ND37 / 216
T: 9433 0217
Institute for Health Research (Thursday & Friday)
Room Number: ND46 / 306

Email: caroline.bulsara@nd.edu.au | Internet: www.nd.edu.au
The University of Notre Dame Australia
19 Mouat Street (PO Box 1225)
Fremantle, Western Australia 6959

CRICOS Provider Code: 01032F

From: Johnston, Mary [mailto:mjohnston3@luc.edu]
Sent: Friday, 12 October 2018 5:26 AM
To: Caroline Bulsara <caroline.bulsara@nd.edu.au>
Subject: Cancer-Related Patient Empowerment Scale

Dear Dr. Bulsara,

I am a Nursing PhD student at Loyola University Chicago in the United States. I am writing to you to obtain your 15-item Cancer-related Patient Empowerment Scale and permission to use it for my research dissertation. The purpose of my research dissertation is to describe patient empowerment among cancer survivors and determine if the use of patient-reported outcomes (self-efficacy and physical function) promote patient empowerment of adult cancer survivors at the end of primary cancer treatment.

Please, let me know what additional information you may need from me and the next steps if it is possible for me to utilize your scale.

Thank you for your consideration,

Mary Pat Johnston, MS, RN, AOCN

Permission to Use: Conceptual Model of Patient Empowerment

From: Marion McAllister <McAllisterMF@cardiff.ac.uk>
Sent: Monday, March 11, 2019 3:43:49 AM
To: Johnston, Mary
Subject: Re: Conceptual Model of Patient Empowerment

Dear Mary Pat

Yes of course, feel free to use the model. I'm afraid I don't have any further work on it to tell you about. Good luck with your study!

Best wishes,

Marion

Marion McAllister PhD Reader & Programme Director, MSc in Genetic & Genomic Counselling Centre for Medical Education School of Medicine Cardiff University University Hospital of Wales Heath Park, Cardiff, CF14 4XN Phone: +44 (0)29 2251 0811 E-mail: mcallistermf@cardiff.ac.uk GCRB registered -153	Marion McAllister PhD Darllenydd a Chyfarwyddwr Rhaglen, MSc mewn Cwnsela Genetig a Genomig Canolfan Addysg Feddygol Yr Ysgol Meddygaeth Prifysgol Caerdydd Ysbyty Athrofaol Cymru Parc y Mynydd Bychan, Caerdydd CF14 4XN Ffôn : +44 (0)29 2251 0811 E-bost: mcallistermf@cardiff.ac.uk Cofrestredig gyda GCRB –Rhif 153

From: Johnston, Mary <mjohnston3@luc.edu>
Sent: 10 March 2019 16:00
To: Marion McAllister
Subject: Conceptual Model of Patient Empowerment

Dear Dr. McAllister,

I am a Nursing PhD student at Loyola University Chicago in the United States. I am writing to you for permission to use the Conceptual Model of Patient Empowerment described in Bravo et al. (2015). The purpose of my research dissertation is to describe patient empowerment among cancer survivors and determine if the use of patient-reported outcomes promotes patient empowerment of adult cancer survivors at the end of primary cancer treatment. In addition, I am wondering if there is work recently completed or in progress with this model in a cancer.

Thank you,

Mary Pat Johnston, MS, RN, AOCN
Permission to Use: PROMIS-29 v2.1 and PROMIS Self Efficacy Managing Chronic Conditions
Mary Pat Johnston
Subject: Re: Terms of Use/Permission

SEP 25, 2019 | 07:32PM UTC
NIH Toolbox Support replied:

Hello Mary Pat

Thank you for this additional information. You have permission to use the PROMIS measure without fee for this specific purpose you have described . You may find additional information regarding scoring here: http://www.healthmeasures.net/score-and-interpret/calculate-scores. Additionally, please review and adhere to our Terms of Use and Conditions: : http://www.healthmeasures.net/images/PROMIS/Terms_of_Use_HM_approved_1-12-17_-_Updated_Copyright_Notices.pdf

Please let us know if you have additional questions or a need to use PROMIS for other purposes.

Best Regards,

HealthMeasures Support Team

How satisfied were you with the resolution we provided today?

| | |

SEP 24, 2019 | 04:04PM UTC
Mary Pat replied:
The research study is my research dissertation for my PhD in nursing. The purpose of the study is to:

to assess if the use of patient reported outcomes [PROs] is associated with patient empowerment of adult breast, colorectal, and lung cancer survivors in early survivorship following primary cancer treatment.

PROMIS tools that I have been planning to use in my research are: PROMIS-29 v2.1 and PROMIS Self Efficacy Managing Chronic Conditions (Daily Activities, emotions, Medications and Treatments, and Social Interaction Short Forms 4a and Symptoms Short Form 8a). There is another tool to measure empowerment which is not part of PROMIS. Only the English version is needed. It is not a clinical trial. It will be conducted in the medical oncology clinics of a community-based cancer center (one cancer center with 3 medical oncology clinic locations) with an estimated sample size of 90. I am planning to offer the participant the option to complete the survey in paper or electronic format. I was not planning to use the data collection tools available on HealthMeasures. Qualtrics is the tool available to me through school to develop and provide the electronic survey to participants in the clinic setting if that is their choice; and it is compatible with work.

Please, let me know if there are additional questions.

Thank you, I appreciate your help. Mary Pat

SEP 23, 2019 | 03:49PM UTC
NIH Toolbox Support replied:

Hello Mary Pat,

Thank you for your interest in the PROMIS measures. I am happy to provide guidance and have a couple of questions.

1. Are you interested in languages other than English?
2. Can you tell me more about the research study? Is this for a clinical trial? A multi-institution collaboration?
3. Are you interested in any of our data collection tools: http://www.healthmeasures.net/resource-center/data-collection-tools?

Best Regards,

David Ortiz
HealthMeasures Support Team

SEP 23, 2019 | 03:21PM UTC
Odessa Castro replied:

Hello Mary Pat,

Thank you for contacting HealthMeasures Support and your interest in PROMIS measures.

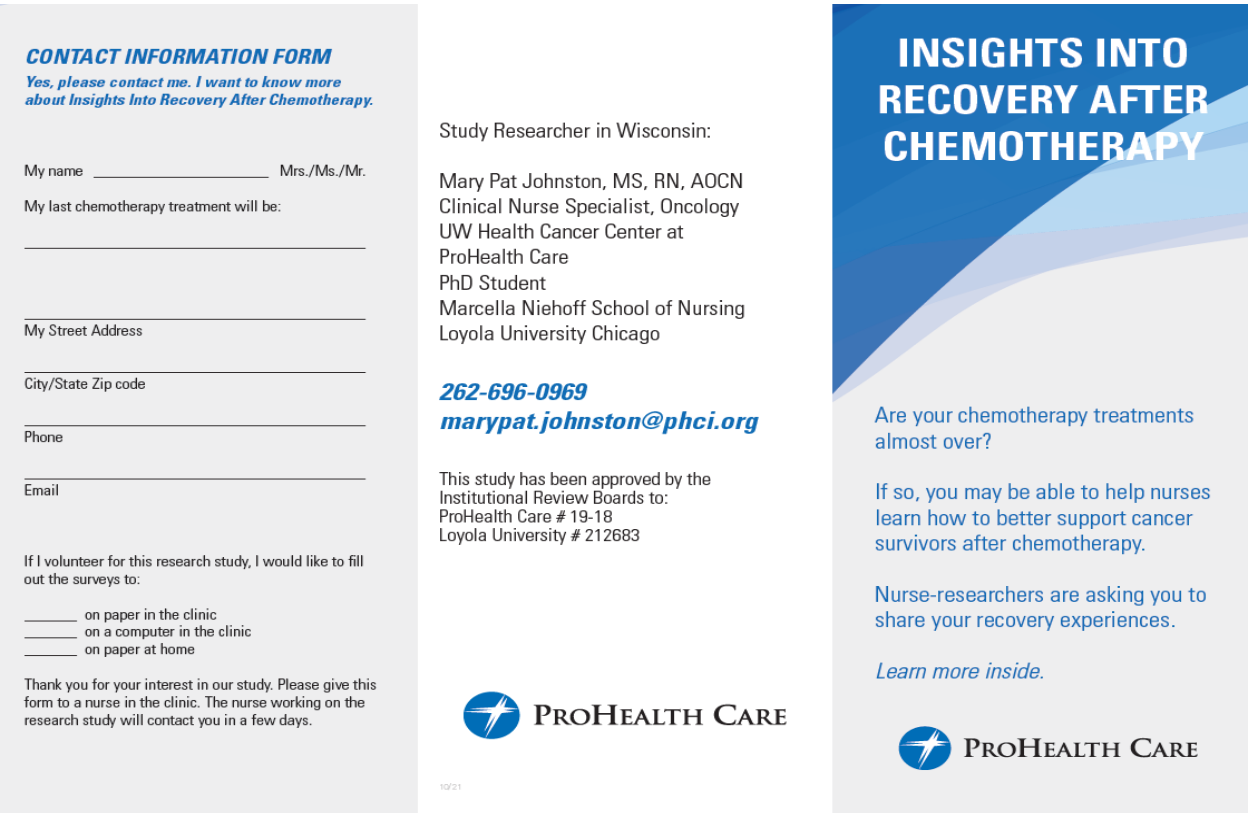
We are forwarding your inquiry to our colleague, David Ortiz, who will follow up with you directly on this case. In the meantime, please see our Terms and Conditions of Use for your reference. http://www.healthmeasures.net/images/PROMIS/Terms_of_Use_HM_approved_1-12-17_-_Updated_Copyright_Notices.pdf

Best Regards,
HealthMeasures Support Team

APPENDIX E

OTHER STUDY MATERIALS

Brochure



CONTACT INFORMATION FORM

Yes, please contact me. I want to know more about Insights Into Recovery After Chemotherapy.

My name _____ Mrs./Ms./Mr.

My last chemotherapy treatment will be:

_____

_____
My Street Address

_____
City/State Zip code

_____
Phone

_____
Email

If I volunteer for this research study, I would like to fill out the surveys to:

_____ on paper in the clinic
_____ on a computer in the clinic
_____ on paper at home

Thank you for your interest in our study. Please give this form to a nurse in the clinic. The nurse working on the research study will contact you in a few days.

Study Researcher in Wisconsin:

Mary Pat Johnston, MS, RN, AOCN
Clinical Nurse Specialist, Oncology
UW Health Cancer Center at
ProHealth Care
PhD Student
Marcella Niehoff School of Nursing
Loyola University Chicago

262-696-0969
marypat.johnston@phci.org

This study has been approved by the Institutional Review Boards to:
ProHealth Care # 19-18
Loyola University # 212683

PROHEALTH CARE

10/21

INSIGHTS INTO RECOVERY AFTER CHEMOTHERAPY

Are your chemotherapy treatments almost over?

If so, you may be able to help nurses learn how to better support cancer survivors after chemotherapy.

Nurse-researchers are asking you to share your recovery experiences.

Learn more inside.

PROHEALTH CARE

Tell me about this research study.

Nurses are conducting this research study because they want to learn how to improve care for cancer survivors. In this study, they ask cancer survivors about their recovery.

Nurses at ProHealth Care are recruiting patients for this study.

Study participants complete one or two surveys, which ask about their experiences during recovery, after their chemotherapy treatment ends.

Can I join this study?

Patients at UW Health Cancer Center at ProHealth Care are eligible to enroll in the Insights Into Recovery After Chemotherapy study if they are…

- At least 18 years old
- Diagnosed with breast, colorectal gynecologic, or lung cancer
- Receiving chemotherapy as part of primary cancer treatment.

If I want to join the study, what happens next?

Please complete the form in this brochure, tear it off, and give the form to a nurse in the clinic. Then a nurse from the study will contact you.

She will explain the study in detail and make sure you are eligible. She will answer any questions you have.

She will give you the consent form, which reviews the details you discussed. Signing the consent form shows that you understand the study and willingly volunteer for it.

What will I do in the study?

Shortly after your last chemotherapy treatment, you will complete the first survey (on paper or computer) in the clinic or at home.

Each survey takes 15 to 20 minutes to finish. If chemotherapy is the last part of your primary cancer treatment regimen, you will complete a second survey three months later.

For your participation in the study, you will receive a $15 gift card for completing one survey or a $25 for completing both surveys.

Will the study help me recover from chemotherapy?

No, this study will not affect your recovery. It only collects and analyzes information about how people experience recovery after chemotherapy. The researchers hope that what they learn from all the study participants will lead to better nursing care for cancer survivors.

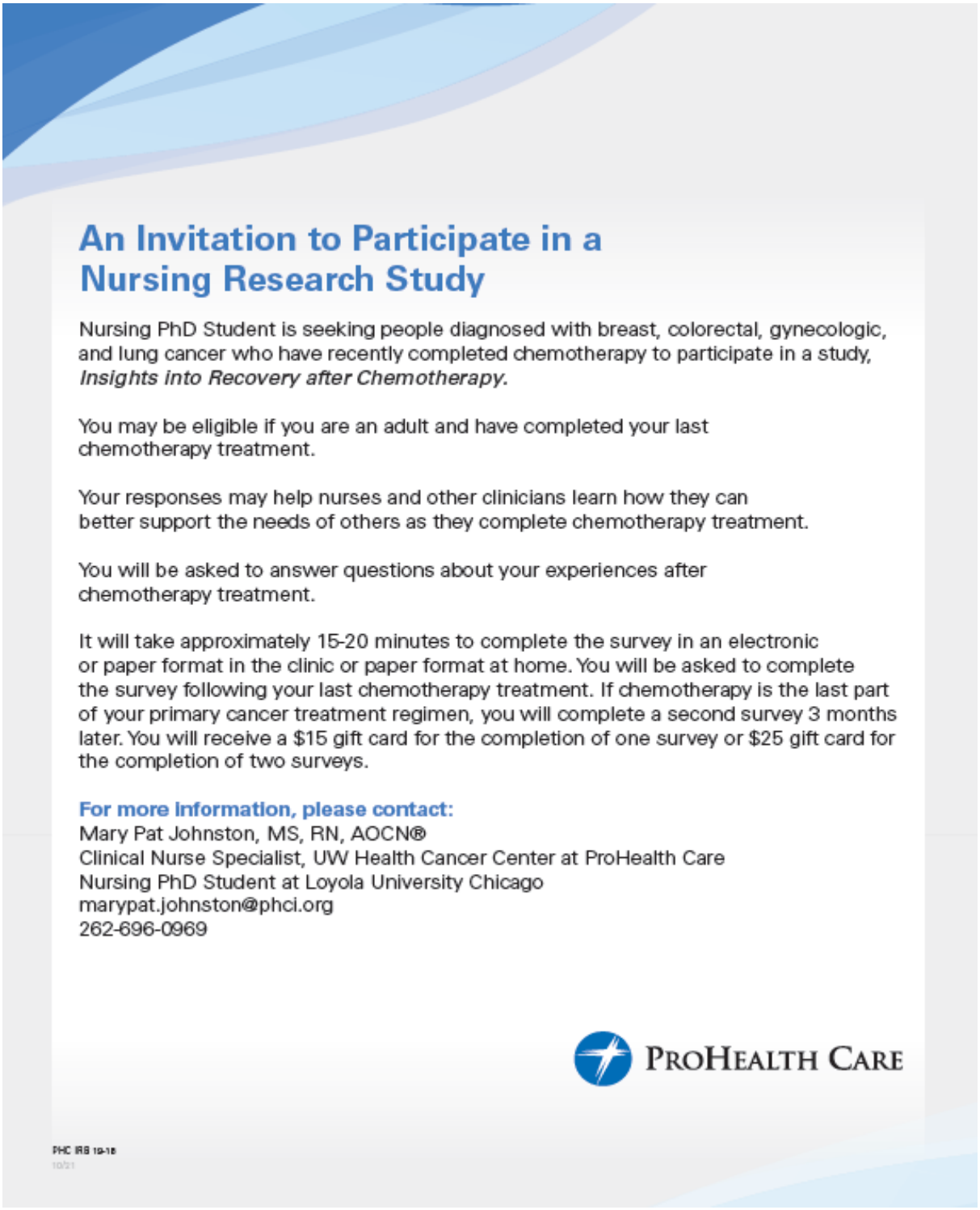
If have more questions, who can tell me more about the Insights Into Recovery After Chemotherapy study?

One of the study researchers will contact you after you fill out the Contact Information Form and give it to a clinic nurse.

You also can call the nurse-researcher, Mary Pat Johnston. Her contact information is on the back of this brochure.

Thank you for considering participation in this study!

Recruitment Flyer



An Invitation to Participate in a Nursing Research Study

Nursing PhD Student is seeking people diagnosed with breast, colorectal, gynecologic, and lung cancer who have recently completed chemotherapy to participate in a study, *Insights into Recovery after Chemotherapy.*

You may be eligible if you are an adult and have completed your last chemotherapy treatment.

Your responses may help nurses and other clinicians learn how they can better support the needs of others as they complete chemotherapy treatment.

You will be asked to answer questions about your experiences after chemotherapy treatment.

It will take approximately 15-20 minutes to complete the survey in an electronic or paper format in the clinic or paper format at home. You will be asked to complete the survey following your last chemotherapy treatment. If chemotherapy is the last part of your primary cancer treatment regimen, you will complete a second survey 3 months later. You will receive a $15 gift card for the completion of one survey or $25 gift card for the completion of two surveys.

For more information, please contact:

Mary Pat Johnston, MS, RN, AOCN®
Clinical Nurse Specialist, UW Health Cancer Center at ProHealth Care
Nursing PhD Student at Loyola University Chicago
marypat.johnston@phci.org
262-696-0969

ProHealth Care

PHC IRB 19-18
10/21

Thank You Note

Date:

Dear ,

Thank you for your participation in the nursing research study, *Insights into Recovery after Chemotherapy*. We appreciate your taking time to participate in this study. Enclosed is your gift card in appreciation. Your participation has provided important information about symptoms and experiences after chemotherapy. Your responses will help nurses learn to better support others as they complete their chemotherapy treatments.

With gratitude and appreciation,

Mary Pat Johnston

Thank You and Reminder Card

REFERENCE LIST

Ackermans, L., Hageman, M. G., Bos, A. H., Haverkamp, D., Scholtes, V. A. B., & Poolman, R. W. (2018). Feedback to patients about patient-reported outcomes does not improve empowerment or satisfaction. *Clinical Orthopaedics and Related Research, 476*(4), 716–722. https://doi.org/10.1007/s11999.0000000000000069

Acuña Mora, M., Sparud-Lundin, C., Fernlund, E., Fadl, S., Kalliopi, K., Rydberg, A., Burström, Å., Hanseus, K., Moons, P., & Bratt, E. L. (2022). The longitudinal association between patient empowerment and patient-reported outcomes: What is the direction of effect? *PloS One*, *17*(11), e0277267.

Adams, N., Gisiger-Camata, S., Hardy, C. M., Thomas, T. F., Jukkala, A., & Meneses, K. (2017). Evaluating survivorship experiences and needs among rural African American breast cancer survivors. *Journal of Cancer Education, 32*, 264-271. https://doi.org/10.1007/s13187-015- 0937-6

Agency for Healthcare Quality Research [AHRQ]. (2020). *The SHARE approach-essential steps for shared decision-making: expanded reference guide with sample conversation starters*. ahrq.gov

Alfano, C. M., Leach, C. R., Smith, T. G., Miller, K. D., Alcaraz, K. I., Cannady, R. S., Wender, R. C., & Brawley, O. W. (2019). Equitably improving outcomes for cancer survivors and supporting caregivers: A blueprint for care delivery, research, education, and policy. *CA: A Cancer Journal for Clinicians*, *69*(1), 35–49. https://doi.org/10.3322/caac.21548

American College of Surgeons (ACoS) Commission on Cancer [CoC®]. (2016). *Cancer center programs: Ensuring patient-centered care.* https://www.facs.org/~/media/files/quality%20programs/cancer/coc/2016%20coc%20standards%20manual_interactive%20pdf.ashx

American Society of Clinical Oncology Quality Oncology Practice Initiative [ASCO QOPI®]. (n.d.). Quality Oncology Practice Initiative [QOPI®]. https://practice.asco.org/quality-improvement/quality-programs/quality-oncology-practice-initiative

Ammenwerth, E., Hoerbst, A., Lannig, S., Mueller, G., Siebert, U., & Schnell-Inderst, P. (2019). Effects of adult patient portals on patient empowerment and health-related outcomes: A systematic review. *Studies in Health Technology and Informatics, 264*, 1106–1110. https://doi.org/10.3233/SHTI19039

Anderson, R. M. & Funnell, M. M. (2010). Patient empowerment: Myths and misconceptions. *Patient Education and Counseling, 79,* 277-82. https://doi: 10/1016/j.pec.2009.07.025

Anderson, R. M., Funnell, M. M., Fitzgerald, J. T., & Marrero, D. G. (2000). The Diabetes Empowerment Scale: A measure of psychosocial self-efficacy. *Diabetes Care*, *23*(6), 739–743. https://doi.org/10.2337/diacare.23.6.739

Arora, N. K., Weaver, K. E., Clayman, M. L., Oakley-Girvan, I., & Potosky, A. L. (2009). Physicians' decision-making style and psychosocial outcomes among cancer survivors. *Patient Education and Counseling*, *77*(3), 404–412. https://doi.org/10.1016/j.pec.2009.10.004

Association of Rehabilitation Nurses. (2008). Standards and scope of rehabilitation nursing practice. (5th ed.). Glenview, IL.

Atkinson, T. M., Stover, A. M., Storfer, D. F., Saracino, R. M., D'Agostino, T. A., Pergolizzi, D., Matsoukas, K., Li, Y., & Basch, E. (2017). Patient-reported physical function measures in cancer clinical trials. *Epidemiologic Reviews*, *39*(1), 59–70. https://doi.org/10.1093/epirev/mxx008

Atkinson, T. M., Li, Y., Coffey, C. W., Sit, L., Shaw, M., Lavene, D., Bennett, A. V., Fruscione, M., Rogak, L., Hay, J., Gönen, M., Schrag, D., & Basch, E. (2012). Reliability of adverse symptom event reporting by clinicians. *Quality of Life Research*, *21*(7), 1159–1164. https://doi.org/10.1007/s11136-011-0031-4

Aujoulat, I., Marcolongo, R., Bonadiman, L., & Deccache, A. (2008). Reconsidering patient empowerment in chronic illness: A critique of models of self-efficacy and bodily control. *Social Science & Medicine (1982)*, *66*(5), 1228–1239. https://doi.org/10.1016/j.socscimed.2007.11.034

Aujoulat, I., d'Hoore, W., & Deccache, A. (2007). Patient empowerment in theory and practice: polysemy or cacophony? *Patient Education and Counseling*, *66*(1), 13–20. https://doi.org/10.1016/j.pec.2006.09.008

Avery, J., Thomas, R., Howell, D., & Dubouloz Wilner, C. J. (2023). Empowering cancer survivors in managing their own health: A paradoxical dynamic process of taking and letting go of control. *Qualitative Health Research*, *33*(5), 412–425. https://doi.org/10.1177/10497323231158629

Avery, J. (2018). A grounded theory of empowerment in cancer survivorship and rehabilitation [Master's thesis, University of Ottawa]. https://ruor-uottawa-ca.archer.luhs.org/bitstream/10393/37859/1/Avery_Jonathan_2018_thesis.pdf

Bandura, A. (1997). *Self-efficacy: The exercise of control*. New York: W. H. Freeman.

Barr, P. J., Scholl, I., Bravo, P., Faber, M. J., Elwyn, G., & McAllister, M. (2015). Assessment of patient empowerment--A systematic review of measures. *PloS One*, *10*(5), e0126553. https://doi.org/10.1371/journal.pone.0126553

Basch, E., Barbera, L., Kerrigan, C. L., & Velikova, G. (2018). Implementation of patient-reported outcomes in routine medical care. *American Society of Clinical Oncology Educational Book. American Society of Clinical Oncology. Annual Meeting*, *38*, 122–134. https://doi.org/10.1200/EDBK_200383

Basch, E., Deal, A. M., Kris, M. G., Scher, H. I., Hudis, C. A., Sabbatini, P., Rogak, L., Bennett, A. V., Dueck, A. C., Atkinson, T. M., Chou, J. F., Dulko, D., Sit, L., Barz, A., Novotny, P., Fruscione, M., Sloan, J. A., & Schrag, D. (2016). Symptom monitoring with patient-reported outcomes during routine cancer treatment: A randomized controlled trial. *Journal of Clinical Oncology*, *34*(6), 557–565. https://doi.org/10.1200/JCO.2015.63.0830

Basch E. (2014). New frontiers in patient-reported outcomes: adverse event reporting, comparative effectiveness, and quality assessment. *Annual Review of Medicine*, *65*, 307–317. https://doi.org/10.1146/annurev-med-010713-141500

Basch, E., Abernethy, A. P., Mullins, C. D., Reeve, B. B., Smith, M. L., Coons, S. J., Sloan, J., Wenzel, K., Chauhan, C., Eppard, W., Frank, E. S., Lipscomb, J., Raymond, S. A., Spencer, M., & Tunis, S. (2012). Recommendations for incorporating patient-reported outcomes into clinical comparative effectiveness research in adult oncology. *Journal of Clinical Oncology*, *30*(34), 4249–4255. https://doi.org/10.1200/JCO.2012.42.5967

Basch, E., Abernethy, A. P., Mullins, C. D., Reeve, B. B., Smith, M. L., Coons, S. J., Sloan, J., Wenzel, K., Chauhan, C., Eppard, W., Frank, E. S., Lipscomb, J., Raymond, S. A., Spencer, M., & Tunis, S. (2012). Recommendations for incorporating patient-reported outcomes into clinical comparative effectiveness research in adult oncology. *Journal of Clinical Oncology*, *30*(34), 4249–4255. https://doi.org/10.1200/JCO.2012.42.5967

Basch, E., Jia, X., Heller, G., Barz, A., Sit, L., Fruscione, M., Appawu, M., Iasonos, A., Atkinson, T., Goldfarb, S., Culkin, A., Kris, M. G., & Schrag, D. (2009). Adverse symptom event reporting by patients vs clinicians: relationships with clinical outcomes. *Journal of the National Cancer Institute, 101*(23), 1624–1632. https://doi.org/10.1093/jnci/djp386

Basch, E., Iasonos, A., Barz, A., Culkin, A., Kris, M. G., Artz, D., Fearn, P., Speakman, J., Farquhar, R., Scher, H. I., McCabe, M., & Schrag, D. (2007). Long- term toxicity monitoring via electronic patient-reported outcomes in patients receiving chemotherapy. *Journal of Clinical Oncology, 25*(34), 5374–5380. https://doi.org/10.1200/JCO.2007.11.2243

Basch, E., Iasonos, A., McDonough, T., Barz, A., Culkin, A., Kris, M. G., Scher, H. I., & Schrag, D. (2006). Patient versus clinician symptom reporting using the National Cancer Institute Common Terminology Criteria for Adverse Events: results of a questionnaire-based study. *The Lancet. Oncology, 7*(11), 903–909. https://doi.org/10.1016/S1470-2045(06)70910-X

Basch, E., Artz, D., Dulko, D., Scher, K., Sabbatini, P., Hensley, M., Mitra, N., Speakman, J., McCabe, M., & Schrag, D. (2005). Patient online self-reporting of toxicity symptoms during chemotherapy. *Journal of Clinical Oncology*, *23*(15), 3552–3561. https://doi.org/10.1200/JCO.2005.04.275

Bennett, A. V., Jensen, R. E., & Basch, E. (2012). Electronic patient-reported outcome systems in oncology clinical practice. *CA: A Cancer Journal for Clinicians, 62*(5), 337–347. https://doi.org/10.3322/caac.21150

Bennett, A. V., Jensen, R. E., & Basch, E. (2012). Electronic patient-reported outcome systems in oncology clinical practice. *CA: A Cancer Journal for Clinicians, 62*(5), 337–347. https://doi.org/10.3322/caac.21150

Bevans, M., Ross, A., & Cella, D. (2014). Patient-Reported Outcomes Measurement Information System (PROMIS): Efficient, standardized tools to measure self-reported health and quality of life. *Nursing Outlook*, *62*(5), 339–345. https://doi.org/10.1016/j.outlook.2014.05.009

Barsevick, A. M., Irwin, M. R., Hinds, P., Miller, A., Berger, A., Jacobsen, P., Ancoli-Israel, S., Reeve, B. B., Mustian, K., O'Mara, A., Lai, J. S., Fisch, M., Cella, D., & National Cancer Institute Clinical Trials Planning Meeting (2013). Recommendations for high-priority research on cancer-related fatigue in children and adults. *Journal of the National Cancer Institute*, *105*(19), 1432–1440. https://doi.org/10.1093/jnci/djt242

Black, N. (2013). Patient reported outcome measures could help transform healthcare. *BMJ (Clinical Research ed.)*, *346*, f167. https://doi.org/10.1136/bmj.f167

Brant, J. M., Hirschman, K. B., Keckler, S. L., Dudley, W. N., & Stricker, C. (2019). Patient and provider use of electronic care plans generated from patient-reported outcomes. *Oncology Nursing Forum*, *46*(6), 715–726. https://doi.org/10.1188/19.ONF.715-726

Bravo, P., Edwards, A., Barr, P. J., Scholl, I., Elwyn, G., McAllister, M., & Cochrane Healthcare Quality Research Group, Cardiff University (2015). Conceptualising patient empowerment: A mixed methods study. *BMC Health Services Research*, *15*, 252. https://doi.org/10.1186/s12913-015-0907-z

Bruner Watkins, D., Hanisch, L. J., Reeve, B. B., Bruner, D. W., Hanisch, L. J., Reeve, B. B., Trotti, A. M., Schrag, D., Sit, L., Mendoza, T. R., Minasian, L., O'Mara, A., Denicoff, A. M., Rowland, J. H., Montello, M., Geoghegan, C., Abernethy, A. P., Clauser, S. B., Castro, K., Mitchell, S. A., Burke, L., Trentacosti, A. M., & Basch, E. M. (2011). Stakeholder perspectives on implementing the National Cancer Institute's patient-reported outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). *Translational Behavioral Medicine*, *1*(1), 110–122. https://doi.org/10.1007/s13142-011-0025-3

Bulsara, C. E. & Styles, I. (2013). Development of a cancer related patient empowerment scale using polytomous Rasch measurement model. *Cancer Clinical Oncology, 2(1),* 87-102. https://doi.org/10.5539/cco.v2n1p87

Bulsara, C., Styles, I., Ward, A. M., & Bulsara, M. (2006). The psychometrics of developing the patient empowerment scale. *Journal of Psychosocial Oncology*, *24*(2), 1–16. https://doi.org/10.1300/J077v24n02_01

Bulsara, C., Ward, A., & Joske, D. (2004). Haematological cancer patients: achieving a sense of empowerment by use of strategies to control illness. *Journal of Clinical Nursing*, *13*(2), 251–258. https://doi.org/10.1046/j.1365-2702.2003.00886.x

Cancer Moonshot Blue Ribbon Panel Report. (2016). *Symptom management research*. www.cancer.gov/brp

Calvert, M., Brundage, M., Jacobsen, P. B., Schunermann, H. J., & Efficace, F. (2013). The CONSORT Patient-Reported Outcome (PRO) extension: Implications for clinical trials and practice. *Health and Quality of Life Outcomes, 11,* 184. https://doi.org/10.1186/1477-7525-11-184

Carey, M. S., Bacon, M., Tu, D., Butler, L., Bezjak, A., & Stuart, G. C. (2008). The prognostic effects of performance status and quality of life scores on progression-free survival and overall survival in advanced ovarian cancer. *Gynecologic Oncology, 108*(1), 100–105. https://doi.org/10.1016/j.ygyno.2007.08.088

Carman, K. L., Dardess, P., Maurer, M., Sofaer, S., Adams, K., Bechtel, C., & Sweeney, J. (2013). Patient and family engagement: A framework for understanding the elements and developing interventions and policies. *Health Affairs (Project Hope), 32*(2), 223–231. https://doi.org/10.1377/hlthaff.2012.1133

Carman, K. L., & Workman, T. A. (2017). Engaging patients and consumers in research evidence: Applying the conceptual model of patient and family engagement. *Patient Education and Counseling*, *100*(1), 25–29. https://doi.org/10.1016/j.pec.2016.07.009

Castro, E. M., Van Regenmortel, T., Vanhaecht, K., Sermeus, W., & Van Hecke, A. (2016). Patient empowerment, patient participation, and patient-centeredness in hospital care: A concept analysis based on a literature review. *Patient Education and Counseling*, *99*(12), 1923–1939. https://doi.org/10.1016/j.pec.2016.07.026

Cella, D., Riley, W., Stone, A., Rothrock, N., Reeve, B., Yount, S., …Weinfurt, K. (2010). Initial adult health item banks and first wave testing of the Patient-reported Outcomes Measurement Information System (™) Network: 2005-2008. *Journal of Clinical Epidemiology, 63,* 1179-1194.

Centers for Medicare and Medicaid Services. (2018). *Oncology care model.* https://innovation.cms.gov/initiatives/Oncology-Care/

Cheville, A. L., Troxel, A. B., Basford, J. R., and Kornblith, A. B. Prevalence and treatment patterns of physical impairments in patients with metastatic breast cancer. *Journal of Clinical Oncology : Official Journal of the American Society of Clinical Oncology, 26*(16), 2621–2629. https://doi.org/10.1200/JCO.2007.12.3075

Cleeland, C. S. (2000). Cancer-related symptoms. *Seminars in Radiation Oncology, 10*(3), 175–190. https://doi.org/10.1053/srao.2000.6590

Consumer Assessment of Healthcare Providers and Systems [CAHPS®]. (2018). *About CAPHS.* https://www.ahrq.gov/cahps/about-cahps/index.html

Coleman, M. (2014). Patient empowerment in the management of chronic myeloid leukemia. *Clinical Journal of Oncology Nursing, 18*(2), E12–E18. https://doi.org/10.1188/14.CJON.E12-E18

Commission on Cancer. (2016). Cancer program standards: Ensuring patient-centered care. https://www.facs.org/~/media/files/quality%20programs/cancer/coc/2016%20coc%20standards%20manual_interactive%20pdf.ashx

de Haes, H. & Bensing, J. (2009). Endpoints in medical communication research, proposing a framework of functions and outcomes. *Patient Education and Counseling, 74*(3), 287–294. https://doi.org/10.1016/j.pec.2008.12.006

de Oliveira, R. A. A., da Conceição, V. M., Araujo, J. S., & Zago, M. M. F. (2018). Concept analysis of cancer survivorship and contributions to oncological nursing. *International Journal of Nursing Practice*, *24*(1), 10.1111/ijn.12608. https://doi.org/10.1111/ijn.12608

DeVellis, R. F. (2012). *Scale development: Theory and applications.* (3rd ed.). Sage.

Dillman, D. A., Smyth, J. D., Christian, L. M. (2014). *Internet, phone, mail, and mixed mode surveys: The tailored design method.* (4th ed.). Wiley.

Dodd, M., Janson, S., Facione, N., Faucett, J., Froelicher, E. S., Humphreys, J., Lee, K., Miaskowski, C., Puntillo, K., Rankin, S., & Taylor, D. & Taylor, D. (2001). Advancing the science of symptom management. *Journal of Advanced Nursing, 33*(5), 668–676. https://doi.org/10.1046/j.1365-2648.2001.01697.x

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. https://doi.org/10.1016/j.ygyno.2005.06.062

Doyle, N. (2008). Cancer survivorship: evolutionary concept analysis. *Journal of Advanced Nursing*, *62*(4), 499–509. https://doi.org/10.1111/j.1365-2648.2008.04617.x

Ellis-Stoll, C. C. & Popkess-Vawter, S. (1998). A concept analysis on the process of empowerment. *ANS. Advances in Nursing Science*, *21*(2), 62–68. https://doi.org/10.1097/00012272-199812000-00007

Eskildsen, N. B., Ross, L., Bulsara, C., Dietz, S. M., Thomsen, T. G., Groenvold, M., Pedersen, S. S., Jørgensen, C. R., & Johnsen, A. T. (2020). Development and content validation of a questionnaire measuring patient empowerment in cancer follow-up. *Quality of Life Research : an International Journal of Quality-Of-Life Aspects of Treatment, Care, and Rehabilitation*, *29*(8), 2253–2274. https://doi.org/10.1007/s11136-020-02483-9

Eskildsen, N. B., Joergensen, C. R., Thomsen, T. G., Ross, L., Dietz, S. M., Groenvold, M., & Johnsen, A. T. (2017). Patient empowerment: a systematic review of questionnaires measuring empowerment in cancer patients. *Acta Oncologica (Stockholm, Sweden)*, *56*(2), 156–165. https://doi.org/10.1080/0284186X.2016.1267402

Esther Kim, J. E., Dodd, M. J., Aouizerat, B. E., Jahan, T., & Miaskowski, C. (2009). A review of the prevalence and impact of multiple symptoms in oncology patients. *Journal of Pain and Symptom Management*, *37*(4), 715–736. https://doi.org/10.1016/j.jpainsymman.2008.04.018

Faiman, B., & Tariman, J. D. (2019). Shared Decision Making: Improving Patient Outcomes by Understanding the Benefits of and Barriers to Effective Communication. *Clinical Journal of Oncology Nursing*, *23*(5), 540–542. https://doi.org/10.1188/19.CJON.540-542

Farmer, B. J., & Smith, E. D. (2002). Breast cancer survivorship: are African American women considered? A concept analysis. *Oncology Nursing Forum*, *29*(5), 779–787. https://doi.org/10.1188/02.ONF.779-787

Finfgeld D. L. (2004). Empowerment of individuals with enduring mental health problems: results from concept analyses and qualitative investigations. *ANS. Advances in Nursing Science*, *27*(1), 44–52. https://doi.org/10.1097/00012272-200401000-00006

Fiteni, F., Cuenant, A., Favier, M., Cousin, C., & Houede, N. (2019). Clinical Relevance of Routine Monitoring of Patient-reported Outcomes *Versus* Clinician-reported Outcomes in Oncology. *In Vivo (Athens, Greece)*, *33*(1), 17–21. https://doi.org/10.21873/invivo.11433

Fromme, E. K., Eilers, K. M., Mori, M., Hsieh, Y. C., & Beer, M. (2004). How accurate is clinician symptom reporting of chemotherapy adverse effects? A comparison with patient- reported symptoms from the Quality-of-Life Questionnaire C30. *Journal of Clinical Oncology*, *22*(17), 3485–3490. https://doi.org/10.1200/JCO.2004.03.025

Foster, C., Breckons, M., Cotterell, P., Barbosa, D., Calman, L., Corner, J., Fenlon, D., Foster, R., Grimmett, C., Richardson, A., & Smith, P. W. (2015). Cancer survivors' self-efficacy to self-manage in the year following primary treatment. *Journal of Cancer Survivorship : Research and Practice*, *9*(1), 11–19. https://doi.org/10.1007/s11764-014-0384-0

Fries, J., Bruce, B., & Cella, D. (2005). The promise of PROMIS: using item response theory to improve assessment of patient-reported outcomes. *Clinical and Experimental Rheumatology*, *23*(5 Suppl 39), S53–S57.

Fumagalli, L. P., Radaelli, G., Lettieri, E., Bertele', P., & Masella, C. (2015). Patient Empowerment and its neighbours: Clarifying the boundaries and their mutual relationships. *Health Policy (Amsterdam, Netherlands)*, *119*(3), 384–394. https://doi.org/10.1016/j.healthpol.2014.10.017

Funnell, M. M. & Anderson, R. M. (2004). Empowerment and self-management of diabetes. *Clinical Diabetes, 22(3),* 123-127.

Funnell, M. M., Anderson, R. M., Arnold, M. S., Barr, P. A., Donnelly, M., Johnson, P. D., Taylor-Moon, D., & White, N. H. (1991). Empowerment: An idea whose time has come in diabetes education. *The Diabetes Educator*, *17*(1), 37–41. https://doi.org/10.1177/014572179101700108

Ganz P. A. (2009). Quality of care and cancer survivorship: the challenge of implementing the institute of medicine recommendations. *Journal of Oncology Practice*, *5*(3), 101–105. https://doi.org/10.1200/JOP.0934402

Gensheimer, S. G., Wu, A. W., Snyder, C. F., PRO-EHR Users' Guide Steering Group, & PRO-EHR Users' Guide Working Group (2018). Oh, the places we'll go: Patient-reported outcomes and electronic health records. *The Patient*, *11*(6), 591–598. https://doi.org/10.1007/s40271-018-0321-9

Gibson C. H. (1991). A concept analysis of empowerment. *Journal of Advanced Nursing*, *16*(3), 354–361. https://doi.org/10.1111/j.1365-2648.1991.tb01660.x

Gotay, C. C., Kawamoto, C. T., Bottomley, A., & Efficace, F. (2008). The prognostic significance of patient-reported outcomes in cancer clinical trials. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*, *26*(8), 1355–1363. https://doi.org/10.1200/JCO.2007.13.3439

Graffigna, G., Barello, S., & Triberti, S. (2015). *Patient engagement: A consumer-centered model to innovate health care.* Berlin: DeGrutyer Open.

Gordon, B. E., & Chen, R. C. (2017). Patient-reported outcomes in cancer survivorship. *Acta Oncologica (Stockholm, Sweden)*, *56*(2), 166–173. https://doi.org/10.1080/0284186X.2016.1268265

Groen, W. G., Kuijpers, W., Oldenburg, H. S., Wouters, M. W., Aaronson, N. K., & van Harten, W. H. (2015). Empowerment of cancer survivors through information technology: An integrative review. *Journal of Medical Internet Research*, *17*(11), e270. https://doi.org/10.2196/jmir.4818

Guan, T., Chapman, M. V., de Saxe Zerden, L., Sharma, A., Chen, D. G., & Song, L. (2023). Correlates of illness uncertainty in cancer survivors and family caregivers: a systematic review and meta-analysis. *Supportive Care in Cancer :Official Journal of the Multinational Association of Supportive Care in Cancer*, *31*(4), 242. https://doi.org/10.1007/s00520-023-07705-7

Haltaufderheide, J., Wäscher, S., Bertlich, B., Vollmann, J., Reinacher-Schick, A., & Schildmann, J. (2019). "I need to know what makes somebody tick …": Challenges and strategies of implementing shared decision-making in individualized oncology. *The Oncologist*, *24*(4), 555–562. https://doi.org/10.1634/theoncologist.2017-0615

Harle, C. A., Listhaus, A., Covarrubias, C. M., Schmidt, S. O., Mackey, S., Carek, P. J., Fillingim, R. B., & Hurley, R. W. (2016). Overcoming barriers to implementing patient-reported outcomes in an electronic health record: a case report. *Journal of the American Medical Informatics Association : JAMIA*, *23*(1), 74–79. https://doi.org/10.1093/jamia/ocv085

Harver, A., & Mahler, D. A. (1990). The symptom of dyspnea. In D. A. Mahler (Ed.). *Dyspnea.* Mount Kisco, NY: Futura.

Hawks J. H. (1992). Empowerment in nursing education: concept analysis and application to philosophy, learning and instruction. *Journal of Advanced Nursing*, *17*(5), 609–618. https://doi.org/10.1111/j.1365-2648.1992.tb02840.x

Hays, R. D., Spritzer, K. L., Schalet, B. D., & Cella, D. (2018). PROMIS®-29 v2.0 profile physical and mental health summary scores. *Quality of Life Research*, *27*(7), 1885–1891. https://doi.org/10.1007/s11136-018-1842-3

HealthMeasures. (2016). Assessing person-centered health care outcomes in cancer patients. *Health Measures.* www.healthmeasures.net.

HealthMeasures. (2013). PROMIS® instrument development and validation scientific standards. Version 2.0. *Health Measures.* http://www.healthmeasures.net/images/PROMIS/PROMISStandards_Vers2.0_Final.pdf

HealthMeasures. (n.d.). PROMIS® Measures in EPIC®. *Health Measures.* http://www.healthmeasures.net/index.php?option=com_content&view=category&layout=blog&id=166&Itemid=1134

Henry, N. L., Kidwell, K. M., Alsamarraie, C., Bridges, C. M., Kwiatkowski, C., Clauw, D. J., Smith, E. M. L., & Williams, D. A. (2018). Pilot study of an internet-based self-management program for symptom control in patients with early—Stage breast cancer. *JCO Clinical Cancer Informatics*, *2*, 1–12. https://doi.org/10.1200/CCI.17.00106

Herbert, R. J., Gagnon, A. J., Rennick, J. E., & O'Loughlin, J. L. (2009). A systematic review of questionnaires measuring health-related empowerment. *Research and Theory for Nursing Practice*, *23*(2), 107–132. https://doi.org/10.1891/1541-6577.23.2.107

Hibbard, J. H., Mahoney, E., & Sonet, E. (2017). Does patient activation level affect the cancer patient journey? *Patient Education and Counseling*, *100*(7), 1276–1279. https://doi.org/10.1016/j.pec.2017.03.019

Hibbard, J. H., Mahoney, E. R., Stock, R., & Tusler, M. (2007). Do increases in patient activation result in improved self-management behaviors? *Health Services Research*, *42*(4), 1443–1463. https://doi.org/10.1111/j.1475-6773.2006.00669.x

Hilarius, D. L., Kloeg, P. H., Gundy, C. M., & Aaronson, N. K. (2008). Use of health-related quality-of-life assessments in daily clinical oncology nursing practice: A community hospital-based intervention study. *Cancer*, *113*(3), 628–637. https://doi.org/10.1002/cncr.23623

Holman, H., & Lorig, K. (2004). Patient self-management: a key to effectiveness and efficiency in care of chronic disease. *Public Health Reports (Washington, D.C. : 1974)*, *119*(3), 239–243. https://doi.org/10.1016/j.phr.2004.04.002

Howell, D., Molloy, S., Wilkinson, K., Green, E., Orchard, K., Wang, K., & Liberty, J. (2015). Patient-reported outcomes in routine cancer clinical practice: a scoping review of use, impact on health outcomes, and implementation factors. *Annals of Oncology*, *26*(9), 1846–1858. https://doi.org/10.1093/annonc/mdv181

Hudon, C., St-Cyr Tribble, D., Bravo, G., & Poitras, M. E. (2011). Enablement in health care context: A concept analysis. *Journal of evaluation in clinical practice*, *17*(1), 143–149. https://doi.org/10.1111/j.1365-2753.2010.01413.x

Institute of Medicine. (2001). *Crossing the quality chasm: A new health care system for the 21st century*. National Academies. www.nap.edu

Jefford, M., Ward, A. C., Lisy, K., Lacey, K., Emery, J. D., Glaser, A. W., Cross, H., Krishnasamy, M., McLachlan, S. A., & Bishop, J. (2017). Patient-reported outcomes in cancer survivors: a population-wide cross-sectional study. *Supportive Care in Cancer*, *25*(10), 3171–3179. https://doi.org/10.1007/s00520-017-3725-5

Jensen, R. E., Moinpour, C. M., Potosky, A. L., Lobo, T., Hahn, E. A., Hays, R. D., Cella, D., Smith, A. W., Wu, X. C., Keegan, T. H., Paddock, L. E., Stroup, A. M., & Eton, D. T. (2017). Responsiveness of 8 Patient-Reported Outcomes Measurement Information System (PROMIS) measures in a large, community-based cancer study cohort. *Cancer*, *123*(2), 327–335. https://doi.org/10.1002/cncr.30354

Jensen, R. E., Potosky, A. L., Reeve, B. B., Hahn, E., Cella, D., Fries, J.,Fries, J., Smith, A. W., Keegan, T. H., Wu, X. C., Paddock, L., & Moinpour, C. M. (2015). Validation of the PROMIS physical function measures in a diverse US population-based cohort of cancer patients. *Quality of Life Research*, *24*(10), 2333–2344. https://doi.org/10.1007/s11136-015-0992-9

Jerofke, T. A. (2013). Concept analysis of empowerment from survivor and nurse perspectives within the context of cancer survivorship. *Research and Theory for Nursing Practice*, *27*(3), 157–172. https://doi.org/10.1891/1541-6577.27.3.157

Jerofke, T., Weiss, M., & Yakusheva, O. (2014). Patient perceptions of patient-empowering nurse behaviours, patient activation, and functional health status in postsurgical patients with life-threatening long-term illnesses. *Journal of Advanced Nursing*, *70*(6), 1310–1322. https://doi.org/10.1111/jan.12286

Johnsen, A. T., Eskildsen, N. B., Thomsen, T. G., Grønvold, M., Ross, L., & Jørgensen, C. R. (2017). Conceptualizing patient empowerment in cancer follow-up by combining theory and qualitative data. *Acta Oncologica (Stockholm, Sweden)*, *56*(2), 232–238. https://doi.org/10.1080/0284186X.2016.1267403

Jørgensen, C. R., Thomsen, T. G., Ross, L., Dietz, S. M., Therkildsen, S., Groenvold, M., Rasmussen, C. L., & Johnsen, A. T. (2018). What facilitates "patient empowerment" in cancer patients during follow-up: A qualitative systematic review of the literature. *Qualitative Health Research*, *28*(2), 292–304. https://doi.org/10.1177/1049732317721477

Katz, P., Pedro, S., & Michaud, K. (2017). Performance of the patient-reported outcomes measurement information system 29-item profile in rheumatoid arthritis, osteoarthritis, fibromyalgia, and systemic lupus erythematosus. *Arthritis Care & Research*, *69*(9), 1312–1321. https://doi.org/10.1002/acr.23183

Kehl, K. L., Landrum, M. B., Arora, N. K., Ganz, P. A., van Ryn, M., Mack, J. W., & Keating, N. L. (2015). Association of actual and preferred decision roles with patient-reported quality of care: Shared decision making in cancer care. *JAMA Oncology*, *1*(1), 50–58. https://doi.org/10.1001/jamaoncol.2014.112

Kelleher, S. A., Somers, T. J., Locklear, T., Crosswell, A. D., & Abernethy, A. P. (2016). Using patient reported outcomes in oncology clinical practice. *Scandinavian Journal of Pain*, *13*, 6–11. https://doi.org/10.1016/j.sjpain.2016.05.035

Kim, S. H., Choe, Y. H., Cho, Y. U., Park, S., & Lee, M. H. (2022). Effects of a partnership-based, needs-tailored self-management support intervention for post-treatment breast cancer survivors: A randomized controlled trial. *Psycho-Oncology*, *31*(3), 460–469. https://doi.org/10.1002/pon.5828

Kim, S. H., Choe, Y. H., & Kim, D. H. (2023). Patient empowerment in cancer care: A scoping review. Patient empowerment in cancer care: A scoping review. *Cancer Nursing*, https://doi.org/10.1097/NCC.0000000000001228. Advance online publication.

Knobf, M. T., Cooley, M. E., Duffy, S., Doorenbos, A., Eaton, L., Given, B., Mayer, D. K., McCorkle, R., Miaskowski, C., Mitchell, S., Sherwood, P., Bender, C., Cataldo, J., Hershey, D., Katapodi, M., Menon, U., Schumacher, K., Sun, V., Von Ah, D. …Mallory, G. (2015). The 2014-2018 oncology nursing society research agenda. *Oncology Nursing Forum*, *42*(5), 450–465. https://doi.org/10.1188/15.ONF.450-465

Kobau, R., & DiIorio, C. (2003). Epilepsy self-management: A comparison of self-efficacy and outcome expectancy for medication adherence and lifestyle behaviors among people with epilepsy. *Epilepsy & Behavior*, *4*(3), 217–225. https://doi.org/10.1016/s1525-5050(03)00057-x

Kotronoulas, G., Kearney, N., Maguire, R., Harrow, A., Di Domenico, D., Croy, S., & MacGillivray, S. (2014). What is the value of the routine use of patient-reported outcome measures toward improvement of patient outcomes, processes of care, and health service outcomes in cancer care? A systematic review of controlled trials. *Journal of Clinical Oncology*, *32*(14), 1480–1501. https://doi.org/10.1200/JCO.2013.53.5948

Kuijpers, W., Groen, W. G., Loos, R., Oldenburg, H. S., Wouters, M. W., Aaronson, N. K., & van Harten, W. H. (2015). An interactive portal to empower cancer survivors: a qualitative study on user expectations. *Supportive Care in Cancer*, *23*(9), 2535–2542. https://doi.org/10.1007/s00520-015-2605-0

Kuo, C. C., Lin, C. C., & Tsai, F. M. (2014). Effectiveness of empowerment-based self-management interventions on patients with chronic metabolic diseases: a systematic review and meta-analysis. *Worldviews on Evidence-Based Nursing*, *11*(5), 301–315. https://doi.org/10.1111/wvn.12066

Lau D. H. (2002). Patient empowerment—A patient-centred approach to improve care. *Hong Kong Medical Journal (Xianggang yi xue za zhi)*, *8*(5), 372–374.

Leach, C. R., Troeschel, A. N., Wiatrek, D., Stanton, A. L., Diefenbach, M., Stein, K. D., Sharpe, K., & Portier, K. (2017). Preparedness and Cancer-Related Symptom Management among Cancer Survivors in the First Year Post-Treatment. *Annals of Behavioral Medicine*, *51*(4), 587–598. https://doi.org/10.1007/s12160-017-9880-6

Lehmann, J., Buhl, P., Giesinger, J. M., Wintner, L. M., Sztankay, M., Neppl, L., Willenbacher, W., Weger, R., Weyrer, W., Rumpold, G., & Holzner, B. (2021). Using the Computer-based Health Evaluation System (CHES) to support self-management of symptoms and functional health: Evaluation of hematological patient use of a web-based patient portal. *Journal of Medical Internet Research*, *23*(6), e26022. https://doi.org/10.2196/26022

Lipscomb, J., Reeve, B. B., Clauser, S. B., Abrams, J. S., Bruner, D. W., Burke, L. B., Denicoff, A. M., Ganz, P. A., Gondek, K., Minasian, L. M., O'Mara, A. M., Revicki, D. A., Rock, E. P., Rowland, J. H., Sgambati, M., & Trimble, E. L. (2007). Patient-reported outcomes assessment in cancer trials: taking stock, moving forward. *Journal of Clinical Oncology*, *25*(32), 5133–5140. https://doi.org/10.1200/JCO.2007.12.4644

Liska, C. M., Morash, R., Paquet, L., & Stacey, D. (2018). Empowering cancer survivors to meet their physical and psychosocial needs: An implementation evaluation. *Canadian Oncology Nursing Journal (Revue canadienne de nursing oncologique)*, *28*(2), 76–81. https://doi.org/10.5737/236880762827681

Livneh, H., Antonak, R. (1994). Psychosocial reactions to disability: A review and critique of the literature. *Critical Review in Physical and Rehabilitative Medicine, 6,* 1-100.

Loh, S. Y., Packer, T., Chinna, K., & Quek, K. F. (2013). Effectiveness of a patient self-management programme for breast cancer as a chronic illness: A non-randomised controlled clinical trial. *Journal of Cancer Survivorship: Research and Practice, 7*(3), 331–342. https://doi.org/10.1007/s11764-013-0274-x

Luckett, T., Butow, P. N., & King, M. T. (2009). Improving patient outcomes through the routine use of patient-reported data in cancer clinics: Future directions. *Psycho-Oncology, 18*(11), 1129–1138. https://doi.org/10.1002/pon.1545

Luo, Z., Chen, C., Xu, W., Wang, P., & Wang, Y. (2021). A qualitative study on the experience of empowerment from the perspectives of breast cancer survivors. *Nursing Open, 8*(5), 2429–2438. https://doi.org/10.1002/nop2.1000

Maunsell, E., Lauzier, S., Brunet, J., Pelletier, S., Osborne, R. H., & Campbell, H. S. (2014). Health-related empowerment in cancer: validity of scales from the Health Education Impact Questionnaire. *Cancer, 120*(20), 3228–3236. https://doi.org/10.1002/cncr.28847

Maurer, M. E., Dardess, P., Frosch, D. L., & Carman, K. L. (2015). Creating change in health care: Developing a shared understanding and roadmap for action. *North Carolina Medical Journal, 76*(3), 161–164. https://doi.org/10.18043/ncm.76.3.161

McAllister, M. & Dearing, A. (2015). Patient reported outcomes and patient empowerment in clinical genetic services. *Clinical Genetics, 88*(2), 114–121. https://doi.org/10.1111/cge.12520

McAllister, M., Dunn, G., Payne, K., Davies, L., & Todd, C. (2012). Patient empowerment: the need to consider it as a measurable patient-reported outcome for chronic conditions. *BMC Health Services Research, 12,* 157. https://doi.org/10.1186/1472-6963-12-157

McCarthy, V. & Freeman, L. (2008). A multidisciplinary concept analysis of empowerment: Implications for nursing. *Journal of Theory Construction and Testing, 12(2),* 68-74. https://doi.org/10.1186/s12913-016-1423-5

McCorkle, R., Ercolano, E., Lazenby, M., Schulman-Green, D., Schilling, L. S., Lorig, K., & Wagner, E. H. (2011). Self-management: Enabling and empowering patients living with cancer as a chronic illness. *CA: A Cancer Journal for Clinicians, 61*(1), 50–62. https://doi.org/10.3322/caac.20093

Mishel, M. H. (1988). Finding meaning: antecedents of uncertainty. *Journal of Nursing Scholarship, 20,* 225-232. https://doi.org/10.111/j.1547-5069.1988.tb0082.x

Mirabella, A., Vrana, A., Bay, R. C., Slater, A., & Brewer, M. A. (2022). SMART oncology nursing: Literacy, goals, coaching, and empowerment. *Oncology Nursing Forum*, *49*(1), 37–45. https://doi.org/10.1188/22.ONF.37-42

Mok E. (2001). Empowerment of cancer patients: From a Chinese perspective. *Nursing Ethics*, *8*(1), 69–76. https://doi.org/10.1177/096973300100800108

Moody, M., & Jackowski, J. (2010). Are patients on oral chemotherapy in your practice setting safe? *Clinical Journal of Oncology Nursing*, *14*(3), 339–346. https://doi.org/10.1188/10.CJON.339-346

Mooney, K., Berry, D. L., Whisenant, M., & Sjoberg, D. (2017). Improving cancer care through the patient experience: How to use patient-reported outcomes in clinical practice. *American Society of Clinical Oncology Educational Book. American Society of Clinical Oncology. Annual Meeting*, *37*, 695–704. https://doi.org/10.1200/EDBK_175418

Morden, N. E., Chang, C. H., Jacobson, J. O., Berke, E. M., Bynum, J. P., Murray, K. M., & Goodman, D. C. (2012). End-of-life care for Medicare beneficiaries with cancer is highly intensive overall and varies widely. *Health Affairs (Project Hope)*, *31*(4), 786–796. https://doi.org/10.1377/hlthaff.2011.0650

Movsas B. (2015). PROceeding with the patient-reported outcomes (PROs) version of the common terminology criteria for adverse events. *JAMA Oncology*, *1*(8), 1059–1060. https://doi.org/10.1001/jamaoncol.2015.2689 9

Mullan F. (1985). Seasons of survival: Reflections of a physician with cancer. *The New England Journal of Medicine*, *313*(4), 270–273. https://doi.org/10.1056/NEJM198507253130421

Náfrádi, L., Nakamoto, K., Csabai, M., Papp-Zipernovszky, O., & Schulz, P. J. (2018). An empirical test of the Health Empowerment Model: Does patient empowerment moderate the effect of health literacy on health status? *Patient Education and Counseling*, *101*(3), 511–517. https://doi.org/10.1016/j.pec.2017.09.004

National Accreditation Program for Breast Centers [NAPBC®]. (2018). NAPBC® Standards manual. https://tinyurl.com/yc6t9z3n

National Cancer Institute (NCI) Dictionary of Cancer Terms. (n.d.). *Survivorship.* https://www.cancer.gov/publications/dictionaries/cancer-terms?search=survivorship.

National Cancer Institute (NCI) Office of Cancer Survivorship (2016). *Definitions, statistics, and graphs.* http://cancercontrol.cancer.gov/ocs/statistics/statistics.html

National Comprehensive Cancer Network. (2017). Distress management. www.nccn.org

Neuss, M. N., Polovich, M., McNiff, K., Esper, P., Gilmore, T. R., LeFebvre, K. B., Schulmeister, L., & Jacobson, J. O. (2013). 2013 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards including standards for the safe administration and management of oral chemotherapy. *Journal of Oncology Practice*, *9*(2 Suppl.), 5s–13s. https://doi.org/10.1200/JOP.2013.000874

Oxford English Dictionary. (n.d.). Portal. In *OxfordDictionaries.com.* Retrieved January 29, 2019 from https://en.oxforddictionaries.com/definition/portal

Oxford Learner's Dictionary. (n.d.). Definitions. In *OxfordLearnersDictionary.com.* Retrieved March 6, 2023 from Retrieved from www.oxfordlearnersdictionary.com

Painter, P., Stewart, A. L., & Carey, S. (1999). Physical functioning: definitions, measurement, and expectations. *Advances in Renal Replacement Therapy*, *6*(2), 110–123. https://doi.org/10.1016/s1073-4449(99)70028-2

Pakhomov, S. V., Jacobsen, S. J., Chute, C. G., & Roger, V. L. (2008). Agreement between patient-reported symptoms and their documentation in the medical record. *The American Journal of Managed Care*, *14*(8), 530–539.

Peck S. (2008). Survivorship: a concept analysis. *Nursing Forum*, *43*(2), 91–102. https://doi.org/10.1111/j.1744-6198.2008.00100.x

Pekonen, A., Eloranta, S., Stolt, M., Virolainen, P., & Leino-Kilpi, H. (2020). Measuring patient empowerment—A systematic review. *Patient Education and Counseling*, *103*(4), 777–787. https://doi.org/10.1016/j.pec.2019.10.019

Petersen C. (2016). Patient-generated health data: a pathway to enhanced long-term cancer survivorship. *Journal of the American Medical Informatics Association*, *23*(3), 456–461. https://doi.org/10.1093/jamia/ocv184

Phillips, J. L., & Currow, D. C. (2010). Cancer as a chronic disease. *Collegian (Royal College of Nursing, Australia)*, *17*(2), 47–50. https://doi.org/10.1016/j.colegn.2010.04.007

Polit, D. F. & Beck, C. T. (2012). *Nursing research: Generating evidence and assessing evidence for nursing practice* (9th edition). W. B. Saunders.

Portenoy, R. K., Kornblith, A. B., Wong, G., Vlamis, V., Lepore, J. M., Loseth, D. B., Hakes, T., Foley, K. M., & Hoskins, W. J. (1994). Pain in ovarian cancer patients. Prevalence, characteristics, and associated symptoms. *Cancer*, *74*(3), 907–915. https://doi.org/10.1002/1097-0142(19940801)74:3<907::aid-cncr2820740318>3.0.co;2-#

Porter, L. S., Keefe, F. J., McBride, C. M., Pollak, K., Fish, L., & Garst, J. (2002). Perceptions of patients' self-efficacy for managing pain and lung cancer symptoms: Correspondence between patients and family caregivers. *Pain*, *98*(1-2), 169–178. https://doi.org/10.1016/s0304-3959(02)00042-8

PROMIS®. (2019). PROMIS® *Adult Profile Instruments.* http://www.healthmeasures.net/administrator/components/com_instruments/uploads/PROMIS%20Adult%20Profile%20Scoring%20Manual.pdf

PROMIS®. (2018). *Physical Function.* http://www.healthmeasures.net/administrator/components/com_instruments/uploads/PROMIS%20Physical%20Function%20Scoring%20Manual.pdf

PROMIS®. (2017). *General Self-Efficacy and Self-Efficacy for Managing Chronic Conditions.* http://www.healthmeasures.net/administrator/components/com_instruments/uploads/PROMIS%20Self%20Efficacy%20Managing%20Chronic%20Conditions%20Scoring%20Manual.pdf

Quinten, C., Maringwa, J., Gotay, C. C., Martinelli, F., Coens, C., Reeve, B. B., Flechtner, H., Greimel, E., King, M., Osoba, D., Cleeland, C., Ringash, J., Schmucker-Von Koch, J., Taphoorn, M. J., Weis, J., & Bottomley, A. (2011). Patient self-reports of symptoms and clinician ratings as predictors of overall cancer survival. *Journal of the National Cancer Institute*, *103*(24), 1851–1858. https://doi.org/10.1093/jnci/djr485

Rappaport, J. (1987). Terms of empowerment/exemplars of prevention: Toward a theory for community psychology. *American Journal of Community Psychology, 15*(2), 121–148. https://doi.org/10.1007/BF00919275

Reilly, C. M., Bruner, D. W., Mitchell, S. A., Minasian, L. M., Basch, E., Dueck, A. C., Cella, D., & Reeve, B. B. (2013). A literature synthesis of symptom prevalence and severity in persons receiving active cancer treatment. *Supportive Care in Cancer*, *21*(6), 1525–1550. https://doi.org/10.1007/s00520-012-1688-0

Renzi, C., Fioretti, C., Oliveri, S., Mazzocco, K., Zerini, D., Alessandro, O., Rojas, D. P., Jereczek-Fossa, B. A., & Pravettoni, G. (2017). A qualitative investigation on patient empowerment in prostate cancer. *Frontiers in Psychology, 8*, 1215. https://doi.org/10.3389/fpsyg.2017.01215

Rodwell C. M. (1996). An analysis of the concept of empowerment. *Journal of Advanced Nursing*, *23*(2), 305–313. https://doi.org/10.1111/j.1365-2648.1996.tb02672.x

Rogers, E. S., Chamberlin, J., Ellison, M. L., & Crean, T. (1997). A consumer-constructed scale to measure empowerment among users of mental health services. *Psychiatric Services (Washington, D.C.), 48*(8), 1042–1047. https://doi.org/10.1176/ps.48.8.1042

Rose, A. J., Bayliss, E., Huang, W., Baseman, L., Butcher, E., García, R. E., & Edelen, M. O. (2018). Evaluating the PROMIS-29 v2.0 for use among older adults with multiple chronic conditions. *Quality of Life Research*, *27*(11), 2935–2944. https://doi.org/10.1007/s11136-018-1958-5

Ryles S. M. (1999). A concept analysis of empowerment: Its relationship to mental health nursing. *Journal of Advanced Nursing*, *29*(3), 600–607. https://doi.org/10.1046/j.1365-2648.1999.00928.x

Schmidt, M., Eckardt, R., Scholtz, K., Neuner, B., von Dossow-Hanfstingl, V., Sehouli, J., Stief, C. G., Wernecke, K. D., Spies, C. D., & PERATECS Group (2015). Patient empowerment improved perioperative quality of care in cancer patients aged ≥ 65 Years—A randomized controlled trial. *PloS One*, *10*(9), e0137824. https://doi.org/10.1371/journal.pone.0137824

Schnall, R., Liu, J., Cho, H., Hirshfield, S., Siegel, K., & Olender, S. (2017). A health-related quality-of-life measure for use in patients with HIV: A validation study. *AIDS Patient Care and STDs*, *31*(2), 43–48. https://doi.org/10.1089/apc.2016.0252

Schulz, P. J., & Nakamoto, K. (2013). Health literacy and patient empowerment in health communication: The importance of separating conjoined twins. *Patient Education and Counseling*, *90*(1), 4–11. https://doi.org/10.1016/j.pec.2012.09.006

Shaw, B. E., Syrjala, K. L., Onstad, L. E., Chow, E. J., Flowers, M. E., Jim, H., Baker, K. S., Buckley, S., Fairclough, D. L., Horowitz, M. M., & Lee, S. J. (2018). PROMIS measures can be used to assess symptoms and function in long-term hematopoietic cell transplantation survivors. *Cancer*, *124*(4), 841–849. https://doi.org/10.1002/cncr.31089

Shepherd, E. J., & Woodgate, R. L. (2010). Cancer survivorship in children and young adults: a concept analysis. *Journal of Pediatric Oncology Nursing*, *27*(2), 109–118. https://doi.org/10.1177/1043454209349807

Shi, Q., Smith, T. G., Michonski, J. D., Stein, K. D., Kaw, C., & Cleeland, C. S. (2011). Symptom burden in cancer survivors 1 year after diagnosis: A report from the American Cancer Society's Studies of Cancer Survivors. *Cancer*, *117*(12), 2779–2790. https://doi.org/10.1002/cncr.26146

Shin, S., & Park, H. (2017). Effect of empowerment on the quality of life of the survivors of breast cancer: The moderating effect of self-help group participation. *Japan Journal of Nursing Science : JJNS*, *14*(4), 311–319. https://doi.org/10.1111/jjns.12161

Small, N., Bower, P., Chew-Graham, C. A., Whalley, D., & Protheroe, J. (2013). Patient empowerment in long-term conditions: development and preliminary testing of a new measure. *BMC Health Services Research*, *13*, 263. https://doi.org/10.1186/1472-6963-13-263

Silver, J. K., Baima, J., & Mayer, R. S. (2013). Impairment-driven cancer rehabilitation: An essential component of quality care and survivorship. *CA: A Journal for Clinicians, 63(5),* 295-317. https://doi.org/10.3322/caac.21186

Stukenborg, G. J., Blackhall, L. J., Harrison, J. H., Dillon, P. M., & Read, P. W. (2016). Longitudinal patterns of cancer patient reported outcomes in end-of-life care predict survival. *Supportive Care in Cancer*, *24*(5), 2217–2224. https://doi.org/10.1007/s00520-015-3024-y

Taylor, K., Chivers, P., Bulsara, C., Joske, D., Bulsara, M., & Monterosso, L. (2019). Care After Lymphoma (CALy) trial: A phase II pilot pragmatic randomised controlled trial of a nurse-led model of survivorship care. *European Journal of Oncology Nursing*, *40*, 53–62. https://doi.org/10.1016/j.ejon.2019.03.005

Tang, E., Ekundayo, O., Peipert, J. D., Edwards, N., Bansal, A., Richardson, C., Bartlett, S. J., Howell, D., Li, M., Cella, D., Novak, M., & Mucsi, I. (2019). Validation of the Patient-Reported Outcomes Measurement Information System (PROMIS)-57 and -29 item short forms among kidney transplant recipients. *Quality of Life Research*, *28*(3), 815–827. https://doi.org/10.1007/s11136-018-2058-2

Te Boveldt, N., Vernooij-Dassen, M., Leppink, I., Samwel, H., Vissers, K., & Engels, Y. (2014). Patient empowerment in cancer pain management: An integrative literature review. *Psycho-Oncology*, *23*(11), 1203–1211. https://doi.org/10.1002/pon.3573

Tengland P. A. (2008). Empowerment: A conceptual discussion. *Health Care Analysis*, *16*(2), 77–96. https://doi.org/10.1007/s10728-007-0067-3

Thomas, T. H., Go, K., Go, K., McKinley, N. J., Dougherty, K. R., You, K. L., & Lee, Y. J. (2022). Empowerment through technology: A systematic evaluation of the content and quality of mobile applications to empower individuals with cancer. *International Journal of Medical Informatics*, *163*, 104782. https://doi.org/10.1016/j.ijmedinf.2022.104782

Thorsen, L., Gjerset, G. M., Loge, J. H., Kiserud, C. E., Skovlund, E., Fløtten, T., & Fosså, S. D. (2011). Cancer patients' needs for rehabilitation services. *Acta oncologica (Stockholm, Sweden)*, *50*(2), 212–222. https://doi.org/10.3109/0284186X.2010.531050

Trautmann, F., Hentschel, L., Hornemann, B., Rentsch, A., Baumann, M., Ehninger, G., Schmitt, J., & Schuler, M. (2016). Electronic real-time assessment of patient-reported outcomes in routine care-first findings and experiences from the implementation in a comprehensive cancer center. *Supportive Care in Cancer*, *24*(7), 3047–3056. https://doi.org/10.1007/s00520-016-3127-0

Trajkovic-Vidakovic, M., deGraff, A., Voest, E. E., & Teunissen, S. (2012). Symptoms tell it all: A systematic review of the value of symptom assessment to predict survival in advanced cancer patients. *Critical Reviews in Oncology/Hematology, 84(1),* 130-148. https://doi.org/10.1016/j.critrevonc.2012.02.011

Troeschel, A., Smith, T., Castro, K., Treiman, K., Lipscomb, J., McCabe, R. M., Clauser, S., Friedman, E. L., Hegedus, P. D., & Portier, K. (2016). The development and acceptability of symptom management quality improvement reports based on patient-reported data: An overview of methods used in PROSSES. *Quality of Life Research*, *25*(11), 2833–2843. https://doi.org/10.1007/s11136-016-1305-7s

Tsai, A. C., Morton, S. C., Mangione, C. M., & Keeler, E. B. (2005). A meta-analysis of interventions to improve care for chronic illnesses. *The American Journal of Managed Care*, *11*(8), 478–488.

United States Food and Drug Administration. (2009). *Patient Reported Outcome (PRO) measures: Use in medical product development to support labeling claims*. https://www.fda.gov/downloads/drugs/guidances/ucm193282.pdf

United States Food and Drug Administration. (2019). *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*. https://www.fda.gov/Safety/MedWatch/default.htm

USLegal™ (n.d.). Physical Impaired Law and Legal Definition. Retrieved March 3, 2019 from https://definitions.uslegal.com/p/physically-impaired/

van den Berg, S. W., van Amstel, F. K., Ottevanger, P. B., Gielissen, M. F., & Prins, J. B. (2013). The cancer empowerment questionnaire: psychological empowerment in breast cancer survivors. *Journal of Psychosocial Oncology*, *31*(5), 565–583. https://doi.org/10.1080/07347332.2013.825361

Varty, M., & Popejoy, L. L. (2020). A systematic review of transition readiness in youth with chronic disease. *Western Journal of Nursing Research, 42*(7), 554–566. https://doi.org/10.1177/0193945919875470

Vissers, P. A., Falzon, L., van de Poll-Franse, L. V., Pouwer, F., & Thong, M. S. (2016). The impact of having both cancer and diabetes on patient-reported outcomes: A systematic review and directions for future research. *Journal of Cancer Survivorship*, *10*(2), 406–415. https://doi.org/10.1007/s11764-015-0486-3

Wallerstein, N., & Bernstein, E. (1988). Empowerment education: Freire's ideas adapted to health education. *Health Education Quarterly*, *15*(4), 379–394. https://doi.org/10.1177/109019818801500402

Waltz, C. F., Strickland, O. L., & Lenz, E. R. (2010). *Measurement in nursing and health research*, (4th ed.). Springer Publishing.

Warzyniec, A., Tariman, J. D., & Simonovich, S. (2019). Shared decision making: Effects of an online education session on knowledge, attitudes, adaptability, and communication skills among nurses. *Clinical Journal of Oncology Nursing*, *23*(6), E93–E99. https://doi.org/10.1188/19.CJON.E93-E99

Weisbeck, S., Lind, C., & Ginn, C. (2019). Patient empowerment: An evolutionary concept analysis. *International Journal of Caring Sciences*, *12*(2), 1148.

Wilson, I. B. & Cleary, P. D. (1995). Linking clinical variables with health-related quality of Life. A conceptual model of patient outcomes. *Journal of the American Medical Association, 273(1),* 59-65.

Wittenberg, E., Ferrell, B., Kanter, E., & Buller, H. (2018). Health literacy: Exploring nursing challenges to providing support and understanding. *Clinical Journal of Oncology Nursing*, *22*(1), 53–61. https://doi.org/10.1188/18.CJON.53-61

World Health Organization. [WHO] (2016). *Patient engagement: Technical series on safer primary care.* https://www.who.int/patientsafety/topics/primary-care/technical_series/en/

Wu, H. S., & Harden, J. K. (2015). Symptom burden and quality of life in survivorship: A review of the literature. *Cancer Nursing*, *38*(1), E29–E54. https://doi.org/10.1097/NCC.0000000000000135

Xiao, C., Polomano, R., & Watkins Bruner, D. (2013). Comparison between patient- reported and clinician-observed symptoms in oncology. *Cancer Nursing*, *36*(6), E1–E16. https://doi.org/10.1097/NCC.0b013e318269040f

Yost, K. J., Eton, D. T., Garcia, S. F., & Cella, D. (2011). Minimally important differences were estimated for six Patient-Reported Outcomes Measurement Information System-Cancer scales in advanced-stage cancer patients. *Journal of Clinical Epidemiology*, *64*(5), 507–516. https://doi.org/10.1016/j.jclinepi.2010.11.018

Zimmerman, M. A. (1995). Psychological empowerment: issues and illustrations. American *Journal of Community Psychology*, *23*(5), 581–599. https://doi.org/10.1007/BF02506983

Zhang, B., Lloyd, W., Jahanzeb, M., & Hassett, M. J. (2018). Use of patient-reported outcome measures in quality oncology practice initiative-registered practices: Results of a national survey. *Journal of Oncology Practice*, *14*(10), e602–e611. https://doi.org/10.1200/JOP.18.00088

Zhang Y. (2017). Uncertainty in Illness: Theory review, application, and extension. *Oncology Nursing Forum*, *44*(6), 645–649. https://doi.org/10.1188/17.ONF.645-649

Zwerick, M., Brusse-Keizer, M., van der Valk, Zielhaus, G. A., Monninkhof, E. M., van derPalen, Frith, & Effing, T. (2014). Self-management for patients with chronic obstructivepulmonary disease: review. *Cochrane Collaboration.* Retrieved fromwww.thecochranelibrary.com

Zucca, A. C., Boyes, A. W., Linden, W., & Girgis, A. (2012). All's well that ends well? Quality of life and physical symptom clusters in long-term cancer survivors across cancer types. *Journal of Pain and Symptom Management*, *43*(4), 720–731. https://doi.org/10.1016/j.jpainsymman.2011.04.023

VITA

Dr. Johnston graduated with a B.S.N. from Marquette University in Milwaukee, WI. Later, she earned her M.S. from the University of Wisconsin-Madison in medical-surgical nursing as a clinical nurse specialist (CNS) with a specialty oncology tract.

Dr. Johnston started her career as a registered nurse in an adult inpatient oncology unit at Evanston Hospital in Evanston, IL. She advanced on the clinical ladder, serving as a preceptor and charge nurse. Before long, she moved to Madison, WI to pursue graduate studies while working at the UW Hospital and Clinics on the solid tumor unit. Following graduation, her first CNS role was for Lakeland Medical Center in St. Joseph, MI where she advanced her knowledge and skills, grew her expertise, and began developing her teaching skills. During this time, Dr. Johnston earned her advanced certification in oncology nursing. She expanded her interests and volunteer commitment in her specialty professional organization, the Oncology Nursing Society (ONS), serving on project teams and as member and subsequently, chair of the ONS Leadership Steering Committee.

Later, Dr. Johnston was elected to the ONS Board of Directors as Director-at-Large and was appointed by that board as ONS Liaison to the Oncology Nursing Certification Corporation (ONCC) Board. Upon completing service to these boards, Dr. Johnston enrolled in the Nursing PhD program at Marcella Niehoff School of Nursing in Chicago, IL. Currently, she is a CNS for the UW Health Cancer Center at ProHealth Care, a multi-site, community-based cancer center with medical, radiation, and specialty clinics, and the Clinical Practice Department for the ProHealth Care (PHC) System in southeastern Wisconsin, ensuring high quality, safe care for

patients and families by advancing policies and nursing practice through education and informatics. She has coordinated and educated nurses on a variety of topics, including chemotherapy and immunotherapy administration, evidence-based practice, symptom management, pain, palliative care, and end-of-life care, and served as a preceptor for graduate nursing students, preparing for advance practice roles.

Finally, Dr. Johnston has participated in various scholarly nursing activities as a presenter and author of journal articles or book chapters in cancer symptom management (e.g., pain, fatigue), patient education, clinical nurse specialist practice, and oncology community health, including survivorship and palliative care. She is the recipient of the PHC Ford and Bobby Titus Extraordinary Care Award and End-of-Life Nursing Education Consortium (ELNEC) Award.